Dokumentvorlage, Version vom 16.12.2021

Dossier zur Nutzenbewertung gemäß § 35a SGB V

Enfortumab Vedotin (PADCEV™)

Astellas Pharma GmbH

Modul 4A – Anhang 4G

Erstlinientherapie bei erwachsenen Patienten mit nicht resezierbarem oder metastasiertem Urothelkarzinom, die für eine platinhaltige Chemotherapie infrage kommen.

Medizinischer Nutzen und
medizinischer Zusatznutzen,
Patientengruppen mit therapeutisch
bedeutsamem Zusatznutzen

Stand: 20.09.2024

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Table 302.1.1000.1.1: Summary of Baseline Demographics - Analysis Set mITT 1

Parameter and Category/Statistic	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Age (years)			
n	240	242	482
Mean (SD)	65.35 (8.91)	64.65 (9.48)	65.00 (9.19)
Median	66.0	65.0	66.0
Range	37.0 - 85.0	22.0 - 85.0	22.0 - 85.0
Age Group (years)			
< 65 years	105 (43.8%)	106 (43.8%)	211 (43.8%)
>= 65 years	135 (56.3%)	136 (56.2%)	271 (56.2%)
Sex			
Female	42 (17.5%)	57 (23.6%)	99 (20.5%)
Male	198 (82.5%)	185 (76.4%)	383 (79.5%)
Ethnicity			
Hispanic or Latino	26 (10.8%)	25 (10.3%)	51 (10.6%)
Not Hispanic or Latino	192 (80.0%)	186 (76.9%)	378 (78.4%)
Not reportable	14 (5.8%)	22 (9.1%)	36 (7.5%)
Unknown	8 (3.3%)	9 (3.7%)	17 (3.5%)
Race			
Non-White	74 (30.8%)	93 (38.4%)	167 (34.6%)
White	166 (69.2%)	149 (61.6%)	315 (65.4%)
Region			
Europe	98 (40.8%)	102 (42.1%)	200 (41.5%)
North America	57 (23.8%)	51 (21.1%)	108 (22.4%)
Rest of World	85 (35.4%)	89 (36.8%)	174 (36.1%)

Abbreviations: BMI=body mass index; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.1.1: Summary of Baseline Demographics - Analysis Set mITT 1

Parameter and Category/Statistic	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Baseline ECOG Status			
0	136 (56.7%)	128 (53.1%)	264 (54.9%)
1	100 (41.7%)	111 (46.1%)	211 (43.9%)
2	4 (1.7%)	2 (0.8%)	6 (1.2%)
Missing	0	1	1
Smoking Status			
Current	43 (17.9%)	39 (16.1%)	82 (17.0%)
Former	122 (50.8%)	118 (48.8%)	240 (49.8%)
Never	68 (28.3%)	74 (30.6%)	142 (29.5%)
Unknown	7 (2.9%)	11 (4.5%)	18 (3.7%)
Height (cm)			
n	240	241	481
Mean (SD)	170.62 (9.83)	169.90 (9.19)	170.26 (9.51)
Median	171.0	170.0	170.0
Range	143.0 - 198.0	147.3 - 199.2	143.0 - 199.2
Weight (kg)			
n	240	242	482
Mean (SD)	77.76 (16.07)	78.21 (18.68)	77.99 (17.41)
Median	76.6	76.3	76.5
Range	36.5 - 136.0	39.0 - 157.9	36.5 - 157.9

Abbreviations: BMI=body mass index; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.1.1: Summary of Baseline Demographics - Analysis Set mITT 1

Parameter and Category/Statistic	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Weight group (kg)			
<=100	221 (92.1%)	215 (88.8%)	436 (90.5%)
>100	19 (7.9%)	27 (11.2%)	46 (9.5%)
BMI (kg/m2)			
n	240	241	481
Mean (SD)	26.61 (4.55)	26.92 (5.34)	26.76 (4.96)
Median	26.0	26.4	26.2
Range	16.1 - 42.3	15.6 - 46.0	15.6 - 46.0
BMI (kg/m2)			
<18.5	5 (2.1%)	8 (3.3%)	13 (2.7%)
>=18.5 to <25	95 (39.6%)	91 (37.8%)	186 (38.7%)
>=25 to <30	85 (35.4%)	85 (35.3%)	170 (35.3%)
>=30	55 (22.9%)	57 (23.7%)	112 (23.3%)
Missing	0	1	1
BSA (m2)			
n	240	241	481
Mean (SD)	1.91 (0.23)	1.91 (0.26)	1.91 (0.25)
Median	1.9	1.9	1.9
Range	1.2 - 2.7	1.3 - 2.9	1.2 - 2.9
Renal Function			
Mild	116 (48.3%)	122 (50.4%)	238 (49.4%)
Moderate	46 (19.2%)	38 (15.7%)	84 (17.4%)
Normal	78 (32.5%)	82 (33.9%)	160 (33.2%)

Abbreviations: BMI=body mass index; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.1.1: Summary of Baseline Demographics - Analysis Set mITT 1

Parameter and Category/Statistic	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Hepatic function			
Mild	20 (8.3%)	23 (9.5%)	43 (8.9%)
Moderate	3 (1.3%)	0	3 (0.6%)
Normal	217 (90.4%)	217 (89.7%)	434 (90.0%)
Unknown	0	2 (0.8%)	2 (0.4%)
HbA1c (%)			
n	221	216	437
Mean (SD)	5.40 (1.07)	5.35 (1.15)	5.37 (1.11)
Median	5.6	5.6	5.6
Range	2.5 - 7.9	0.5 - 7.9	0.5 - 7.9
HbA1c group (%)			
<5.7	113 (51.1%)	117 (54.2%)	230 (52.6%)
>=5.7 and <6.5	85 (38.5%)	73 (33.8%)	158 (36.2%)
>=6.5	23 (10.4%)	26 (12.0%)	49 (11.2%)
Missing	19	26	45
Hemoglobin (g/dL)			
< 10	14 (5.8%)	27 (11.2%)	41 (8.5%)
>= 10	226 (94.2%)	215 (88.8%)	441 (91.5%)
Bajorin risk factors			
0	105 (43.8%)	112 (46.5%)	217 (45.1%)
1	135 (56.3%)	129 (53.5%)	264 (54.9%)
Missing	0	1	1

Abbreviations: BMI=body mass index; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.1.1: Summary of Baseline Demographics - Analysis Set mITT 1

Parameter and Category/Statistic	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
PD-L1 expression			
High (CPS >= 10)	139 (57.9%)	140 (57.9%)	279 (57.9%)
Low (CPS < 10)	101 (42.1%)	102 (42.1%)	203 (42.1%)
H-score of Nectin-4 expression			
n	211	222	433
Mean (SD)	252.12 (68.74)	239.68 (77.46)	245.74 (73.52)
Median	284.0	270.0	280.0
Range	0.0 - 300.0	0.0 - 300.0	0.0 - 300.0
H-score			
0	2 (0.9%)	4 (1.8%)	6 (1.4%)
> 0	209 (99.1%)	218 (98.2%)	427 (98.6%)
Missing	29	20	49
Metastases at Baseline			
Lymph Node only	60 (25.0%)	67 (27.7%)	127 (26.3%)
Not applicable	10 (4.2%)	14 (5.8%)	24 (5.0%)
Visceral Metastases	170 (70.8%)	161 (66.5%)	331 (68.7%)
Liver Metastases			
Absent	192 (80.0%)	194 (80.2%)	386 (80.1%)
Present	48 (20.0%)	48 (19.8%)	96 (19.9%)
Primary Disease Site of Origin			
Lower Tract	177 (73.8%)	193 (79.8%)	370 (76.8%)
Unknown	2 (0.8%)	0	2 (0.4%)
Upper Tract	61 (25.4%)	49 (20.2%)	110 (22.8%)

Abbreviations: BMI=body mass index; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.1.2: Summary of Baseline Demographics - Analysis Set mITT 2

Parameter and Category/Statistic	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Age (years)			
n	202	202	404
Mean (SD)	70.92 (8.45)	71.95 (7.50)	71.43 (8.00)
Median	71.0	73.0	72.0
Range	40.0 - 87.0	47.0 - 91.0	40.0 - 91.0
Age Group (years)			
< 65 years	39 (19.3%)	29 (14.4%)	68 (16.8%)
>= 65 years	163 (80.7%)	173 (85.6%)	336 (83.2%)
Sex			
Female	56 (27.7%)	51 (25.2%)	107 (26.5%)
Male	146 (72.3%)	151 (74.8%)	297 (73.5%)
Ethnicity			
Hispanic or Latino	26 (12.9%)	27 (13.4%)	53 (13.1%)
Not Hispanic or Latino	167 (82.7%)	157 (77.7%)	324 (80.2%)
Not reportable	8 (4.0%)	15 (7.4%)	23 (5.7%)
Unknown	1 (0.5%)	3 (1.5%)	4 (1.0%)
Race			
Non-White	60 (29.7%)	61 (30.2%)	121 (30.0%)
White	142 (70.3%)	141 (69.8%)	283 (70.0%)
Region			
Europe	74 (36.6%)	95 (47.0%)	169 (41.8%)
North America	46 (22.8%)	34 (16.8%)	80 (19.8%)
Rest of World	82 (40.6%)	73 (36.1%)	155 (38.4%)

Abbreviations: BMI=body mass index; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.1.2: Summary of Baseline Demographics - Analysis Set mITT 2

Parameter and Category/Statistic	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Baseline ECOG Status			
0	87 (43.1%)	87 (43.3%)	174 (43.2%)
1	104 (51.5%)	105 (52.2%)	209 (51.9%)
2	11 (5.4%)	9 (4.5%)	20 (5.0%)
Missing	0	1	1
Smoking Status			
Current	25 (12.4%)	26 (12.9%)	51 (12.6%)
Former	111 (55.0%)	96 (47.5%)	207 (51.2%)
Never	60 (29.7%)	70 (34.7%)	130 (32.2%)
Unknown	6 (3.0%)	10 (5.0%)	16 (4.0%)
Height (cm)			
n	200	200	400
Mean (SD)	167.97 (10.39)	167.15 (10.14)	167.56 (10.26)
Median	168.0	166.6	167.6
Range	139.0 - 195.6	135.0 - 193.0	135.0 - 195.6
Weight (kg)			
n	201	201	402
Mean (SD)	72.58 (18.29)	74.19 (17.78)	73.38 (18.03)
Median	70.8	73.0	72.0
Range	30.4 - 132.9	35.0 - 150.8	30.4 - 150.8

Abbreviations: BMI=body mass index; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.1.2: Summary of Baseline Demographics - Analysis Set mITT 2

Parameter and Category/Statistic	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Weight group (kg)			
<=100	189 (94.0%)	188 (93.5%)	377 (93.8%)
>100	12 (6.0%)	13 (6.5%)	25 (6.2%)
Missing	1	1	2
BMI (kg/m2)			
n	199	200	399
Mean (SD)	25.43 (4.86)	26.36 (5.03)	25.90 (4.96)
Median	24.7	25.9	25.3
Range	15.1 - 40.4	16.1 - 49.3	15.1 - 49.3
BMI (kg/m2)			
<18.5	12 (6.0%)	5 (2.5%)	17 (4.3%)
>=18.5 to <25	94 (47.2%)	81 (40.5%)	175 (43.9%)
>=25 to <30	59 (29.6%)	70 (35.0%)	129 (32.3%)
>=30	34 (17.1%)	44 (22.0%)	78 (19.5%)
Missing	3	2	5
BSA (m2)			
n	199	200	399
Mean (SD)	1.83 (0.28)	1.85 (0.25)	1.84 (0.26)
Median	1.8	1.8	1.8
Range	1.1 - 2.7	1.2 - 2.8	1.1 - 2.8
Renal Function			
Mild	49 (24.3%)	40 (19.8%)	89 (22.0%)
Moderate	140 (69.3%)	141 (69.8%)	281 (69.6%)
Normal	6 (3.0%)	13 (6.4%)	19 (4.7%)
Severe	7 (3.5%)	8 (4.0%)	15 (3.7%)

Abbreviations: BMI=body mass index; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.1.2: Summary of Baseline Demographics - Analysis Set mITT 2

Parameter and Category/Statistic	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Hepatic function			
Mild	24 (11.9%)	25 (12.4%)	49 (12.1%)
Normal	177 (87.6%)	175 (86.6%)	352 (87.1%)
Unknown	1 (0.5%)	2 (1.0%)	3 (0.7%)
HbA1c (%)			
n	180	176	356
Mean (SD)	5.41 (1.10)	5.33 (1.08)	5.37 (1.09)
Median	5.6	5.6	5.6
Range	2.8 - 9.7	2.7 - 7.6	2.7 - 9.7
HbA1c group (%)			
<5.7	92 (51.1%)	91 (51.7%)	183 (51.4%)
>=5.7 and <6.5	70 (38.9%)	67 (38.1%)	137 (38.5%)
>=6.5	18 (10.0%)	18 (10.2%)	36 (10.1%)
Missing	22	26	48
Hemoglobin (g/dL)			
< 10	37 (18.3%)	26 (12.9%)	63 (15.6%)
>= 10	165 (81.7%)	176 (87.1%)	341 (84.4%)
Bajorin risk factors			
0	74 (36.6%)	71 (35.3%)	145 (36.0%)
1	128 (63.4%)	130 (64.7%)	258 (64.0%)
Missing	0	1	1

Abbreviations: BMI=body mass index; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.1.2: Summary of Baseline Demographics - Analysis Set mITT 2

Parameter and Category/Statistic	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
PD-L1 expression			
High (CPS >= 10)	117 (57.9%)	115 (56.9%)	232 (57.4%)
Low (CPS < 10)	85 (42.1%)	87 (43.1%)	172 (42.6%)
H-score of Nectin-4 expression			
n	183	184	367
Mean (SD)	246.73 (72.12)	242.67 (72.81)	244.69 (72.40)
Median	275.0	270.0	275.0
Range	0.0 - 300.0	0.0 - 300.0	0.0 - 300.0
H-score			
0	1 (0.5%)	2 (1.1%)	3 (0.8%)
> 0	182 (99.5%)	182 (98.9%)	364 (99.2%)
Missing	19	18	37
Metastases at Baseline			
Lymph Node only	43 (21.3%)	37 (18.3%)	80 (19.8%)
Not applicable	11 (5.4%)	8 (4.0%)	19 (4.7%)
Visceral Metastases	148 (73.3%)	157 (77.7%)	305 (75.5%)
Liver Metastases			
Absent	152 (75.2%)	152 (75.2%)	304 (75.2%)
Present	50 (24.8%)	50 (24.8%)	100 (24.8%)
Primary Disease Site of Origin			
Lower Tract	128 (63.4%)	146 (72.3%)	274 (67.8%)
Unknown	0	1 (0.5%)	1 (0.2%)
Upper Tract	74 (36.6%)	55 (27.2%)	129 (31.9%)

Abbreviations: BMI=body mass index; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.1: Summary of Medical History by SOC/PT - Analysis Set mITT 1

MedDRA SOC and PT	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Overall	232 (96.7%)	236 (97.5%)	468 (97.1%)
Blood and lymphatic system disorders	35 (14.6%)	40 (16.5%)	75 (15.6%)
Anaemia	33 (13.8%)	30 (12.4%)	63 (13.1%)
Leukocytosis	2 (0.8%)	0	2 (0.4%)
Microcytic anaemia	1 (0.4%)	0	1 (0.2%)
Thrombocytosis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Anaemia megaloblastic	0	1 (0.4%)	1 (0.2%)
Anaemia vitamin B12 deficiency	0	1 (0.4%)	1 (0.2%)
Bone marrow oedema	0	1 (0.4%)	1 (0.2%)
Haemorrhagic diathesis	0	1 (0.4%)	1 (0.2%)
Heparin-induced thrombocytopenia	0	1 (0.4%)	1 (0.2%)
Hypochromic anaemia	0	1 (0.4%)	1 (0.2%)
Increased tendency to bruise	0	1 (0.4%)	1 (0.2%)
Iron deficiency anaemia	0	4 (1.7%)	4 (0.8%)
Pernicious anaemia	0	1 (0.4%)	1 (0.2%)
Secondary thrombocytosis	0	1 (0.4%)	1 (0.2%)
Splenic cyst	0	1 (0.4%)	1 (0.2%)
Cardiac disorders	52 (21.7%)	54 (22.3%)	106 (22.0%)
Atrial fibrillation	10 (4.2%)	12 (5.0%)	22 (4.6%)
Myocardial ischaemia	8 (3.3%)	11 (4.5%)	19 (3.9%)
Cardiac failure chronic	7 (2.9%)	9 (3.7%)	16 (3.3%)
Bundle branch block right	4 (1.7%)	1 (0.4%)	5 (1.0%)
Coronary artery disease	4 (1.7%)	11 (4.5%)	15 (3.1%)
Myocardial infarction	4 (1.7%)	6 (2.5%)	10 (2.1%)
Mitral valve incompetence	3 (1.3%)	0	3 (0.6%)
Angina pectoris	2 (0.8%)	0	2 (0.4%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.1: Summary of Medical History by SOC/PT - Analysis Set mITT 1

MedDRA SOC and PT	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Arteriosclerosis coronary artery	2 (0.8%)	2 (0.8%)	4 (0.8%)
Extrasystoles	2 (0.8%)	0	2 (0.4%)
Hypertensive heart disease	2 (0.8%)	2 (0.8%)	4 (0.8%)
Ventricular extrasystoles	2 (0.8%)	0	2 (0.4%)
Acute myocardial infarction	1 (0.4%)	2 (0.8%)	3 (0.6%)
Arrhythmia	1 (0.4%)	0	1 (0.2%)
Atrial flutter	1 (0.4%)	0	1 (0.2%)
Atrioventricular block first degree	1 (0.4%)	0	1 (0.2%)
Bundle branch block left	1 (0.4%)	0	1 (0.2%)
Cardiac failure	1 (0.4%)	3 (1.2%)	4 (0.8%)
Cardiac valve sclerosis	1 (0.4%)	0	1 (0.2%)
Cardiomegaly	1 (0.4%)	0	1 (0.2%)
Coronary artery occlusion	1 (0.4%)	1 (0.4%)	2 (0.4%)
Dilated cardiomyopathy	1 (0.4%)	0	1 (0.2%)
Myocardial fibrosis	1 (0.4%)	4 (1.7%)	5 (1.0%)
Restrictive cardiomyopathy	1 (0.4%)	0	1 (0.2%)
Sinus bradycardia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Sinus tachycardia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Tricuspid valve incompetence	1 (0.4%)	0	1 (0.2%)
Acute coronary syndrome	0	1 (0.4%)	1 (0.2%)
Aortic valve stenosis	0	1 (0.4%)	1 (0.2%)
Bradycardia	0	1 (0.4%)	1 (0.2%)
Cardiac failure congestive	0	1 (0.4%)	1 (0.2%)
Cardiomyopathy	0	1 (0.4%)	1 (0.2%)
Coronary artery dilatation	0	1 (0.4%)	1 (0.2%)
Coronary artery stenosis	0	1 (0.4%)	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.1: Summary of Medical History by SOC/PT - Analysis Set mITT 1

MedDRA SOC and PT	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Diastolic dysfunction	0	1 (0.4%)	1 (0.2%)
Dilatation atrial	0	1 (0.4%)	1 (0.2%)
Left ventricular dysfunction	0	1 (0.4%)	1 (0.2%)
Left ventricular hypertrophy	0	1 (0.4%)	1 (0.2%)
Palpitations	0	1 (0.4%)	1 (0.2%)
Pericardial effusion	0	1 (0.4%)	1 (0.2%)
Supraventricular extrasystoles	0	2 (0.8%)	2 (0.4%)
Supraventricular tachycardia	0	1 (0.4%)	1 (0.2%)
Tachycardia	0	1 (0.4%)	1 (0.2%)
Ventricular hypertrophy	0	1 (0.4%)	1 (0.2%)
Wolff-Parkinson-White syndrome	0	1 (0.4%)	1 (0.2%)
Congenital, familial and genetic disorders	6 (2.5%)	14 (5.8%)	20 (4.1%)
Corneal dystrophy	1 (0.4%)	1 (0.4%)	2 (0.4%)
Delta-beta thalassaemia	1 (0.4%)	0	1 (0.2%)
Gilbert's syndrome	1 (0.4%)	0	1 (0.2%)
Klinefelter's syndrome	1 (0.4%)	0	1 (0.2%)
Thalassaemia	1 (0.4%)	0	1 (0.2%)
Type V hyperlipidaemia	1 (0.4%)	0	1 (0.2%)
Bicuspid aortic valve	0	1 (0.4%)	1 (0.2%)
Coarctation of the aorta	0	1 (0.4%)	1 (0.2%)
Congenital cardiovascular anomaly	0	1 (0.4%)	1 (0.2%)
Hereditary non-polyposis colorectal cancer syndrome	0	2 (0.8%)	2 (0.4%)
Hydrocele	0	3 (1.2%)	3 (0.6%)
Kidney duplex	0	1 (0.4%)	1 (0.2%)
Macular dystrophy congenital	0	1 (0.4%)	1 (0.2%)
Optic disc pit	0	1 (0.4%)	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.1: Summary of Medical History by SOC/PT - Analysis Set mITT 1

MedDRA SOC and PT	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Retinal anomaly congenital	0	1 (0.4%)	1 (0.2%)
Spleen malformation	0	1 (0.4%)	1 (0.2%)
Type IIb hyperlipidaemia	0	1 (0.4%)	1 (0.2%)
Ear and labyrinth disorders	14 (5.8%)	18 (7.4%)	32 (6.6%)
Hypoacusis	7 (2.9%)	3 (1.2%)	10 (2.1%)
Tinnitus	4 (1.7%)	6 (2.5%)	10 (2.1%)
Deafness	1 (0.4%)	4 (1.7%)	5 (1.0%)
Deafness bilateral	1 (0.4%)	0	1 (0.2%)
Deafness neurosensory	1 (0.4%)	2 (0.8%)	3 (0.6%)
Ear pain	1 (0.4%)	0	1 (0.2%)
Allergic otitis media	0	1 (0.4%)	1 (0.2%)
Eustachian tube dysfunction	0	1 (0.4%)	1 (0.2%)
Presbyacusis	0	1 (0.4%)	1 (0.2%)
Vertigo	0	1 (0.4%)	1 (0.2%)
Vertigo positional	0	1 (0.4%)	1 (0.2%)
Endocrine disorders	14 (5.8%)	17 (7.0%)	31 (6.4%)
Hypothyroidism	11 (4.6%)	9 (3.7%)	20 (4.1%)
Autoimmune thyroiditis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Hyperthyroidism	1 (0.4%)	2 (0.8%)	3 (0.6%)
Hypogonadism	1 (0.4%)	1 (0.4%)	2 (0.4%)
Goitre	0	2 (0.8%)	2 (0.4%)
Hyperplasia adrenal	0	2 (0.8%)	2 (0.4%)
Thyroid mass	0	2 (0.8%)	2 (0.4%)
Eye disorders	145 (60.4%)	149 (61.6%)	294 (61.0%)
Cataract	87 (36.3%)	90 (37.2%)	177 (36.7%)
Dry eye	19 (7.9%)	14 (5.8%)	33 (6.8%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.1: Summary of Medical History by SOC/PT - Analysis Set mITT 1

MedDRA SOC and PT	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Cataract nuclear	10 (4.2%)	10 (4.1%)	20 (4.1%)
Glaucoma	7 (2.9%)	10 (4.1%)	17 (3.5%)
Hypermetropia	5 (2.1%)	8 (3.3%)	13 (2.7%)
Amblyopia	4 (1.7%)	1 (0.4%)	5 (1.0%)
Dry age-related macular degeneration	4 (1.7%)	2 (0.8%)	6 (1.2%)
Epiretinal membrane	4 (1.7%)	6 (2.5%)	10 (2.1%)
Myopia	4 (1.7%)	2 (0.8%)	6 (1.2%)
Age-related macular degeneration	3 (1.3%)	1 (0.4%)	4 (0.8%)
Astigmatism	3 (1.3%)	2 (0.8%)	5 (1.0%)
Blepharitis	3 (1.3%)	0	3 (0.6%)
Macular degeneration	3 (1.3%)	3 (1.2%)	6 (1.2%)
Maculopathy	3 (1.3%)	1 (0.4%)	4 (0.8%)
Pterygium	3 (1.3%)	1 (0.4%)	4 (0.8%)
Corneal disorder	2 (0.8%)	2 (0.8%)	4 (0.8%)
Corneal opacity	2 (0.8%)	0	2 (0.4%)
Diabetic retinopathy	2 (0.8%)	0	2 (0.4%)
Diplopia	2 (0.8%)	0	2 (0.4%)
Presbyopia	2 (0.8%)	8 (3.3%)	10 (2.1%)
Punctate keratitis	2 (0.8%)	2 (0.8%)	4 (0.8%)
Retinal tear	2 (0.8%)	0	2 (0.4%)
Vitreous degeneration	2 (0.8%)	2 (0.8%)	4 (0.8%)
Vitreous floaters	2 (0.8%)	1 (0.4%)	3 (0.6%)
Arcus lipoides	1 (0.4%)	0	1 (0.2%)
Cataract cortical	1 (0.4%)	0	1 (0.2%)
Conjunctival oedema	1 (0.4%)	0	1 (0.2%)
Conjunctivitis allergic	1 (0.4%)	0	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.1: Summary of Medical History by SOC/PT - Analysis Set mITT 1

MedDRA SOC and PT	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Corneal deposits	1 (0.4%)	0	1 (0.2%)
Corneal scar	1 (0.4%)	0	1 (0.2%)
Diabetic retinal oedema	1 (0.4%)	0	1 (0.2%)
Exfoliation syndrome	1 (0.4%)	0	1 (0.2%)
Eye opacity	1 (0.4%)	0	1 (0.2%)
Hyalosis asteroid	1 (0.4%)	0	1 (0.2%)
Lacrimation decreased	1 (0.4%)	0	1 (0.2%)
Lens disorder	1 (0.4%)	0	1 (0.2%)
Meibomian gland dysfunction	1 (0.4%)	1 (0.4%)	2 (0.4%)
Neovascular age-related macular degeneration	1 (0.4%)	1 (0.4%)	2 (0.4%)
Optic atrophy	1 (0.4%)	1 (0.4%)	2 (0.4%)
Pigment dispersion syndrome	1 (0.4%)	0	1 (0.2%)
Pseudophakia	1 (0.4%)	5 (2.1%)	6 (1.2%)
Retinal degeneration	1 (0.4%)	1 (0.4%)	2 (0.4%)
Retinal drusen	1 (0.4%)	2 (0.8%)	3 (0.6%)
Retinal haemorrhage	1 (0.4%)	1 (0.4%)	2 (0.4%)
Retinal pigment epitheliopathy	1 (0.4%)	0	1 (0.2%)
Retinal vascular disorder	1 (0.4%)	2 (0.8%)	3 (0.6%)
Retinopathy	1 (0.4%)	1 (0.4%)	2 (0.4%)
Retinopathy hypertensive	1 (0.4%)	3 (1.2%)	4 (0.8%)
Strabismus	1 (0.4%)	0	1 (0.2%)
Uveitis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Vitreous detachment	1 (0.4%)	3 (1.2%)	4 (0.8%)
Acquired hypertrophy of the retinal pigment epithelium	0	1 (0.4%)	1 (0.2%)
Amaurosis	0	1 (0.4%)	1 (0.2%)
Angle closure glaucoma	0	1 (0.4%)	1 (0.2%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.1: Summary of Medical History by SOC/PT - Analysis Set mITT 1

MedDRA SOC and PT	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Anisocoria	0	1 (0.4%)	1 (0.2%)
Arteriosclerotic retinopathy	0	1 (0.4%)	1 (0.2%)
Blepharospasm	0	1 (0.4%)	1 (0.2%)
Cataract subcapsular	0	2 (0.8%)	2 (0.4%)
Choroidal neovascularisation	0	1 (0.4%)	1 (0.2%)
Cornea verticillata	0	1 (0.4%)	1 (0.2%)
Corneal erosion	0	1 (0.4%)	1 (0.2%)
Corneal leukoma	0	2 (0.8%)	2 (0.4%)
Entropion	0	1 (0.4%)	1 (0.2%)
Exophthalmos	0	1 (0.4%)	1 (0.2%)
Eye disorder	0	1 (0.4%)	1 (0.2%)
Eyelid ptosis	0	2 (0.8%)	2 (0.4%)
Keratitis	0	1 (0.4%)	1 (0.2%)
Keratopathy	0	1 (0.4%)	1 (0.2%)
Lenticular opacities	0	1 (0.4%)	1 (0.2%)
Macular pigmentation	0	1 (0.4%)	1 (0.2%)
Macular scar	0	1 (0.4%)	1 (0.2%)
Ocular hypertension	0	2 (0.8%)	2 (0.4%)
Open angle glaucoma	0	2 (0.8%)	2 (0.4%)
Optic nerve cupping	0	1 (0.4%)	1 (0.2%)
Pinguecula	0	1 (0.4%)	1 (0.2%)
Posterior capsule opacification	0	1 (0.4%)	1 (0.2%)
Retinal artery occlusion	0	1 (0.4%)	1 (0.2%)
Retinal detachment	0	1 (0.4%)	1 (0.2%)
Retinal vein occlusion	0	2 (0.8%)	2 (0.4%)
Ulcerative keratitis	0	1 (0.4%)	1 (0.2%)

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Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.1: Summary of Medical History by SOC/PT - Analysis Set mITT 1

MedDRA SOC and PT	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Vision blurred	0	1 (0.4%)	1 (0.2%)
Vitreoretinal traction syndrome	0	1 (0.4%)	1 (0.2%)
Vitreous opacities	0	1 (0.4%)	1 (0.2%)
Gastrointestinal disorders	106 (44.2%)	118 (48.8%)	224 (46.5%)
Constipation	43 (17.9%)	47 (19.4%)	90 (18.7%)
Gastrooesophageal reflux disease	28 (11.7%)	19 (7.9%)	47 (9.8%)
Abdominal pain	17 (7.1%)	6 (2.5%)	23 (4.8%)
Nausea	13 (5.4%)	11 (4.5%)	24 (5.0%)
Chronic gastritis	6 (2.5%)	13 (5.4%)	19 (3.9%)
Inguinal hernia	6 (2.5%)	3 (1.2%)	9 (1.9%)
Diarrhoea	5 (2.1%)	2 (0.8%)	7 (1.5%)
Hiatus hernia	5 (2.1%)	6 (2.5%)	11 (2.3%)
Abdominal hernia	4 (1.7%)	2 (0.8%)	6 (1.2%)
Gastritis	4 (1.7%)	2 (0.8%)	6 (1.2%)
Haemorrhoids	4 (1.7%)	9 (3.7%)	13 (2.7%)
Gastric ulcer	3 (1.3%)	3 (1.2%)	6 (1.2%)
Irritable bowel syndrome	3 (1.3%)	1 (0.4%)	4 (0.8%)
Rectal haemorrhage	3 (1.3%)	0	3 (0.6%)
Abdominal pain lower	2 (0.8%)	5 (2.1%)	7 (1.5%)
Abdominal pain upper	2 (0.8%)	4 (1.7%)	6 (1.2%)
Diverticulum	2 (0.8%)	3 (1.2%)	5 (1.0%)
Diverticulum intestinal	2 (0.8%)	5 (2.1%)	7 (1.5%)
Flatulence	2 (0.8%)	1 (0.4%)	3 (0.6%)
Large intestine polyp	2 (0.8%)	3 (1.2%)	5 (1.0%)
Pancreatitis chronic	2 (0.8%)	2 (0.8%)	4 (0.8%)
Abdominal compartment syndrome	1 (0.4%)	0	1 (0.2%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.1: Summary of Medical History by SOC/PT - Analysis Set mITT 1

MedDRA SOC and PT	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Abdominal discomfort	1 (0.4%)	3 (1.2%)	4 (0.8%)
Abdominal distension	1 (0.4%)	2 (0.8%)	3 (0.6%)
Abdominal wall cyst	1 (0.4%)	0	1 (0.2%)
Barrett's oesophagus	1 (0.4%)	2 (0.8%)	3 (0.6%)
Colitis	1 (0.4%)	0	1 (0.2%)
Colonic fistula	1 (0.4%)	0	1 (0.2%)
Duodenal ulcer	1 (0.4%)	2 (0.8%)	3 (0.6%)
Dysphagia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Erosive oesophagitis	1 (0.4%)	0	1 (0.2%)
Gastric polyps	1 (0.4%)	0	1 (0.2%)
Gastrointestinal haemorrhage	1 (0.4%)	0	1 (0.2%)
Intestinal metaplasia	1 (0.4%)	0	1 (0.2%)
Lower gastrointestinal haemorrhage	1 (0.4%)	0	1 (0.2%)
Mechanical ileus	1 (0.4%)	0	1 (0.2%)
Pancreatic cyst	1 (0.4%)	0	1 (0.2%)
Pancreatitis	1 (0.4%)	0	1 (0.2%)
Pelvic floor dysfunction	1 (0.4%)	0	1 (0.2%)
Peptic ulcer perforation	1 (0.4%)	0	1 (0.2%)
Proctalgia	1 (0.4%)	0	1 (0.2%)
Umbilical hernia	1 (0.4%)	4 (1.7%)	5 (1.0%)
Colitis ulcerative	0	1 (0.4%)	1 (0.2%)
Dental caries	0	1 (0.4%)	1 (0.2%)
Diaphragmatic hernia	0	1 (0.4%)	1 (0.2%)
Duodenal obstruction	0	1 (0.4%)	1 (0.2%)
Duodenitis	0	1 (0.4%)	1 (0.2%)
Duodenogastric reflux	0	1 (0.4%)	1 (0.2%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.1: Summary of Medical History by SOC/PT - Analysis Set mITT 1

MedDRA SOC and PT	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Dyspepsia	0	7 (2.9%)	7 (1.5%)
Gastrointestinal angiodysplasia	0	1 (0.4%)	1 (0.2%)
Ileus	0	1 (0.4%)	1 (0.2%)
Intestinal obstruction	0	1 (0.4%)	1 (0.2%)
Oesophagitis	0	2 (0.8%)	2 (0.4%)
Periodontal disease	0	1 (0.4%)	1 (0.2%)
Proctitis ulcerative	0	1 (0.4%)	1 (0.2%)
Rectal tenesmus	0	1 (0.4%)	1 (0.2%)
Vomiting	0	3 (1.2%)	3 (0.6%)
General disorders and administration site conditions	46 (19.2%)	47 (19.4%)	93 (19.3%)
Fatigue	30 (12.5%)	23 (9.5%)	53 (11.0%)
Oedema peripheral	7 (2.9%)	13 (5.4%)	20 (4.1%)
Asthenia	3 (1.3%)	5 (2.1%)	8 (1.7%)
Pain	3 (1.3%)	6 (2.5%)	9 (1.9%)
Hernia	2 (0.8%)	0	2 (0.4%)
Chest pain	1 (0.4%)	0	1 (0.2%)
Chills	1 (0.4%)	1 (0.4%)	2 (0.4%)
Drug intolerance	1 (0.4%)	0	1 (0.2%)
Pyrexia	1 (0.4%)	3 (1.2%)	4 (0.8%)
Swelling	1 (0.4%)	0	1 (0.2%)
Chest discomfort	0	1 (0.4%)	1 (0.2%)
Gait disturbance	0	1 (0.4%)	1 (0.2%)
Localised oedema	0	1 (0.4%)	1 (0.2%)
Non-cardiac chest pain	0	3 (1.2%)	3 (0.6%)
Peripheral swelling	0	1 (0.4%)	1 (0.2%)
Suprapubic pain	0	2 (0.8%)	2 (0.4%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.1: Summary of Medical History by SOC/PT - Analysis Set mITT 1

MedDRA SOC and PT	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Hepatobiliary disorders	16 (6.7%)	19 (7.9%)	35 (7.3%)
Hepatic cyst	7 (2.9%)	6 (2.5%)	13 (2.7%)
Hepatic steatosis	4 (1.7%)	5 (2.1%)	9 (1.9%)
Cholelithiasis	3 (1.3%)	2 (0.8%)	5 (1.0%)
Cholecystitis chronic	1 (0.4%)	1 (0.4%)	2 (0.4%)
Gallbladder volvulus	1 (0.4%)	0	1 (0.2%)
Hepatic cytolysis	1 (0.4%)	0	1 (0.2%)
Hepatic pain	1 (0.4%)	1 (0.4%)	2 (0.4%)
Porcelain gallbladder	1 (0.4%)	0	1 (0.2%)
Bile duct stone	0	1 (0.4%)	1 (0.2%)
Biliary colic	0	1 (0.4%)	1 (0.2%)
Cholecystitis	0	1 (0.4%)	1 (0.2%)
Hepatic function abnormal	0	1 (0.4%)	1 (0.2%)
Hepatitis	0	1 (0.4%)	1 (0.2%)
Hepatomegaly	0	1 (0.4%)	1 (0.2%)
Hyperbilirubinaemia	0	1 (0.4%)	1 (0.2%)
Liver disorder	0	1 (0.4%)	1 (0.2%)
Immune system disorders	21 (8.8%)	19 (7.9%)	40 (8.3%)
Drug hypersensitivity	15 (6.3%)	12 (5.0%)	27 (5.6%)
Rubber sensitivity	2 (0.8%)	0	2 (0.4%)
Seasonal allergy	2 (0.8%)	6 (2.5%)	8 (1.7%)
Allergy to plants	1 (0.4%)	0	1 (0.2%)
Anaphylactic reaction	1 (0.4%)	0	1 (0.2%)
Contrast media reaction	1 (0.4%)	0	1 (0.2%)
Dust allergy	1 (0.4%)	0	1 (0.2%)
Food allergy	1 (0.4%)	0	1 (0.2%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.1: Summary of Medical History by SOC/PT - Analysis Set mITT 1

MedDRA SOC and PT	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Iodine allergy	1 (0.4%)	1 (0.4%)	2 (0.4%)
Mite allergy	1 (0.4%)	1 (0.4%)	2 (0.4%)
Perfume sensitivity	1 (0.4%)	0	1 (0.2%)
Contrast media allergy	0	3 (1.2%)	3 (0.6%)
Infections and infestations	37 (15.4%)	47 (19.4%)	84 (17.4%)
Urinary tract infection	13 (5.4%)	17 (7.0%)	30 (6.2%)
COVID-19	6 (2.5%)	1 (0.4%)	7 (1.5%)
Cystitis	3 (1.3%)	3 (1.2%)	6 (1.2%)
Diverticulitis	3 (1.3%)	1 (0.4%)	4 (0.8%)
Herpes zoster	3 (1.3%)	0	3 (0.6%)
Hepatitis C	2 (0.8%)	1 (0.4%)	3 (0.6%)
Cellulitis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Diphtheria	1 (0.4%)	0	1 (0.2%)
Ear infection	1 (0.4%)	0	1 (0.2%)
Genital herpes	1 (0.4%)	0	1 (0.2%)
Meningitis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Oral candidiasis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Otitis media chronic	1 (0.4%)	0	1 (0.2%)
Pyelonephritis chronic	1 (0.4%)	4 (1.7%)	5 (1.0%)
Renal abscess	1 (0.4%)	0	1 (0.2%)
Tinea pedis	1 (0.4%)	0	1 (0.2%)
Viral pericarditis	1 (0.4%)	0	1 (0.2%)
Appendicitis	0	1 (0.4%)	1 (0.2%)
Bacteraemia	0	1 (0.4%)	1 (0.2%)
Biliary sepsis	0	1 (0.4%)	1 (0.2%)
Bronchitis	0	1 (0.4%)	1 (0.2%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.1: Summary of Medical History by SOC/PT - Analysis Set mITT 1

MedDRA SOC and PT	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Endocarditis bacterial	0	1 (0.4%)	1 (0.2%)
Epididymitis	0	2 (0.8%)	2 (0.4%)
Erysipelas	0	1 (0.4%)	1 (0.2%)
Fungal foot infection	0	1 (0.4%)	1 (0.2%)
H1N1 influenza	0	1 (0.4%)	1 (0.2%)
Herpes simplex	0	1 (0.4%)	1 (0.2%)
Laryngitis	0	1 (0.4%)	1 (0.2%)
Meningitis pneumococcal	0	1 (0.4%)	1 (0.2%)
Orchitis	0	1 (0.4%)	1 (0.2%)
Osteomyelitis	0	1 (0.4%)	1 (0.2%)
Paronychia	0	1 (0.4%)	1 (0.2%)
Periodontitis	0	1 (0.4%)	1 (0.2%)
Pertussis	0	1 (0.4%)	1 (0.2%)
Pneumonia legionella	0	1 (0.4%)	1 (0.2%)
Pulmonary tuberculosis	0	2 (0.8%)	2 (0.4%)
Sepsis	0	1 (0.4%)	1 (0.2%)
Tinea infection	0	1 (0.4%)	1 (0.2%)
Tooth abscess	0	1 (0.4%)	1 (0.2%)
Urinary tract infection enterococcal	0	1 (0.4%)	1 (0.2%)
Urosepsis	0	2 (0.8%)	2 (0.4%)
Injury, poisoning and procedural complications	19 (7.9%)	19 (7.9%)	38 (7.9%)
Procedural pain	2 (0.8%)	0	2 (0.4%)
Rib fracture	2 (0.8%)	0	2 (0.4%)
Tendon rupture	2 (0.8%)	0	2 (0.4%)
Abdominal injury	1 (0.4%)	0	1 (0.2%)
Ankle fracture	1 (0.4%)	0	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.1: Summary of Medical History by SOC/PT - Analysis Set mITT 1

MedDRA SOC and PT	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Clavicle fracture	1 (0.4%)	0	1 (0.2%)
Closed globe injury	1 (0.4%)	0	1 (0.2%)
Exposure to chemical pollution	1 (0.4%)	0	1 (0.2%)
Femoral nerve injury	1 (0.4%)	0	1 (0.2%)
Fibula fracture	1 (0.4%)	1 (0.4%)	2 (0.4%)
Foot fracture	1 (0.4%)	1 (0.4%)	2 (0.4%)
Foreign body in skin or subcutaneous tissue	1 (0.4%)	0	1 (0.2%)
Incisional hernia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Limb crushing injury	1 (0.4%)	0	1 (0.2%)
Limb injury	1 (0.4%)	0	1 (0.2%)
Lower limb fracture	1 (0.4%)	0	1 (0.2%)
Lumbar vertebral fracture	1 (0.4%)	0	1 (0.2%)
Procedural pneumothorax	1 (0.4%)	0	1 (0.2%)
Radiation injury	1 (0.4%)	0	1 (0.2%)
Radius fracture	1 (0.4%)	0	1 (0.2%)
Road traffic accident	1 (0.4%)	1 (0.4%)	2 (0.4%)
Skin laceration	1 (0.4%)	0	1 (0.2%)
Skull fractured base	1 (0.4%)	0	1 (0.2%)
Spondylolysis	1 (0.4%)	0	1 (0.2%)
Fall	0	1 (0.4%)	1 (0.2%)
Femur fracture	0	2 (0.8%)	2 (0.4%)
Head injury	0	1 (0.4%)	1 (0.2%)
Humerus fracture	0	1 (0.4%)	1 (0.2%)
Ligament rupture	0	1 (0.4%)	1 (0.2%)
Limb traumatic amputation	0	1 (0.4%)	1 (0.2%)
Muscle rupture	0	1 (0.4%)	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.1: Summary of Medical History by SOC/PT - Analysis Set mITT 1

MedDRA SOC and PT	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Skin abrasion	0	1 (0.4%)	1 (0.2%)
Spinal cord injury cervical	0	1 (0.4%)	1 (0.2%)
Stoma site discomfort	0	2 (0.8%)	2 (0.4%)
Tibia fracture	0	1 (0.4%)	1 (0.2%)
Traumatic coma	0	1 (0.4%)	1 (0.2%)
Urinary tract stoma complication	0	1 (0.4%)	1 (0.2%)
Wrist fracture	0	1 (0.4%)	1 (0.2%)
Investigations	30 (12.5%)	29 (12.0%)	59 (12.2%)
Blood alkaline phosphatase increased	6 (2.5%)	6 (2.5%)	12 (2.5%)
Weight decreased	6 (2.5%)	6 (2.5%)	12 (2.5%)
Blood creatinine increased	4 (1.7%)	3 (1.2%)	7 (1.5%)
Amylase increased	3 (1.3%)	4 (1.7%)	7 (1.5%)
Blood lactate dehydrogenase increased	3 (1.3%)	1 (0.4%)	4 (0.8%)
Gamma-glutamyltransferase increased	3 (1.3%)	0	3 (0.6%)
Lymphocyte count decreased	3 (1.3%)	1 (0.4%)	4 (0.8%)
Alanine aminotransferase increased	2 (0.8%)	1 (0.4%)	3 (0.6%)
Aspartate aminotransferase increased	2 (0.8%)	2 (0.8%)	4 (0.8%)
Blood cholesterol increased	2 (0.8%)	0	2 (0.4%)
Biopsy liver	1 (0.4%)	0	1 (0.2%)
Blood albumin decreased	1 (0.4%)	0	1 (0.2%)
Blood testosterone decreased	1 (0.4%)	0	1 (0.2%)
Blood thyroid stimulating hormone decreased	1 (0.4%)	0	1 (0.2%)
C-reactive protein increased	1 (0.4%)	0	1 (0.2%)
Hepatitis B virus test positive	1 (0.4%)	0	1 (0.2%)
Intraocular pressure increased	1 (0.4%)	1 (0.4%)	2 (0.4%)
Lipase increased	1 (0.4%)	0	1 (0.2%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.1: Summary of Medical History by SOC/PT - Analysis Set mITT 1

MedDRA SOC and PT	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Optic nerve cup/disc ratio increased	1 (0.4%)	0	1 (0.2%)
Prostatic specific antigen increased	1 (0.4%)	0	1 (0.2%)
Bacterial test positive	0	1 (0.4%)	1 (0.2%)
Blood creatine increased	0	1 (0.4%)	1 (0.2%)
Blood creatine phosphokinase increased	0	1 (0.4%)	1 (0.2%)
Hepatitis C test negative	0	1 (0.4%)	1 (0.2%)
Immunoglobulins increased	0	1 (0.4%)	1 (0.2%)
Nitrite urine present	0	1 (0.4%)	1 (0.2%)
Troponin T increased	0	1 (0.4%)	1 (0.2%)
Metabolism and nutrition disorders	107 (44.6%)	113 (46.7%)	220 (45.6%)
Hyperlipidaemia	26 (10.8%)	26 (10.7%)	52 (10.8%)
Hypercholesterolaemia	25 (10.4%)	19 (7.9%)	44 (9.1%)
Decreased appetite	18 (7.5%)	13 (5.4%)	31 (6.4%)
Diabetes mellitus	18 (7.5%)	14 (5.8%)	32 (6.6%)
Dyslipidaemia	17 (7.1%)	22 (9.1%)	39 (8.1%)
Type 2 diabetes mellitus	16 (6.7%)	20 (8.3%)	36 (7.5%)
Obesity	10 (4.2%)	7 (2.9%)	17 (3.5%)
Hyperuricaemia	6 (2.5%)	4 (1.7%)	10 (2.1%)
Gout	4 (1.7%)	6 (2.5%)	10 (2.1%)
Hypoalbuminaemia	4 (1.7%)	2 (0.8%)	6 (1.2%)
Hypertriglyceridaemia	2 (0.8%)	3 (1.2%)	5 (1.0%)
Glucose tolerance impaired	1 (0.4%)	8 (3.3%)	9 (1.9%)
Hypercalcaemia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Hyperglycaemia	1 (0.4%)	3 (1.2%)	4 (0.8%)
Hyperlipasaemia	1 (0.4%)	0	1 (0.2%)
Hypomagnesaemia	1 (0.4%)	1 (0.4%)	2 (0.4%)

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Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.1: Summary of Medical History by SOC/PT - Analysis Set mITT 1

MedDRA SOC and PT	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Hyponatraemia	1 (0.4%)	4 (1.7%)	5 (1.0%)
Hypophosphataemia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Impaired fasting glucose	1 (0.4%)	1 (0.4%)	2 (0.4%)
Abnormal loss of weight	0	1 (0.4%)	1 (0.2%)
Body fat disorder	0	1 (0.4%)	1 (0.2%)
Cachexia	0	1 (0.4%)	1 (0.2%)
Haemochromatosis	0	1 (0.4%)	1 (0.2%)
Hypocalcaemia	0	2 (0.8%)	2 (0.4%)
Hypokalaemia	0	3 (1.2%)	3 (0.6%)
Iron deficiency	0	3 (1.2%)	3 (0.6%)
Lipid metabolism disorder	0	1 (0.4%)	1 (0.2%)
Overweight	0	1 (0.4%)	1 (0.2%)
Vitamin D deficiency	0	3 (1.2%)	3 (0.6%)
Musculoskeletal and connective tissue disorders	87 (36.3%)	85 (35.1%)	172 (35.7%)
Back pain	33 (13.8%)	34 (14.0%)	67 (13.9%)
Arthralgia	18 (7.5%)	12 (5.0%)	30 (6.2%)
Flank pain	14 (5.8%)	9 (3.7%)	23 (4.8%)
Osteoarthritis	9 (3.8%)	11 (4.5%)	20 (4.1%)
Arthritis	6 (2.5%)	7 (2.9%)	13 (2.7%)
Pain in extremity	5 (2.1%)	11 (4.5%)	16 (3.3%)
Myalgia	4 (1.7%)	2 (0.8%)	6 (1.2%)
Muscular weakness	3 (1.3%)	4 (1.7%)	7 (1.5%)
Spinal osteoarthritis	3 (1.3%)	7 (2.9%)	10 (2.1%)
Bone pain	2 (0.8%)	5 (2.1%)	7 (1.5%)
Intervertebral disc protrusion	2 (0.8%)	3 (1.2%)	5 (1.0%)
Musculoskeletal chest pain	2 (0.8%)	2 (0.8%)	4 (0.8%)

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Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.1: Summary of Medical History by SOC/PT - Analysis Set mITT 1

MedDRA SOC and PT	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Musculoskeletal pain	2 (0.8%)	1 (0.4%)	3 (0.6%)
Spinal pain	2 (0.8%)	1 (0.4%)	3 (0.6%)
Bone lesion	1 (0.4%)	0	1 (0.2%)
Bursitis	1 (0.4%)	0	1 (0.2%)
Cervical spinal stenosis	1 (0.4%)	0	1 (0.2%)
Fibromyalgia	1 (0.4%)	0	1 (0.2%)
Groin pain	1 (0.4%)	2 (0.8%)	3 (0.6%)
Intervertebral disc disorder	1 (0.4%)	0	1 (0.2%)
Joint range of motion decreased	1 (0.4%)	0	1 (0.2%)
Musculoskeletal discomfort	1 (0.4%)	1 (0.4%)	2 (0.4%)
Osteochondrosis	1 (0.4%)	0	1 (0.2%)
Osteopenia	1 (0.4%)	0	1 (0.2%)
Osteoporosis	1 (0.4%)	2 (0.8%)	3 (0.6%)
Pathological fracture	1 (0.4%)	0	1 (0.2%)
Scoliosis	1 (0.4%)	0	1 (0.2%)
Spondylolisthesis	1 (0.4%)	0	1 (0.2%)
Tendonitis	1 (0.4%)	0	1 (0.2%)
Chest wall mass	0	1 (0.4%)	1 (0.2%)
Chondrodynia	0	1 (0.4%)	1 (0.2%)
Enthesopathy	0	1 (0.4%)	1 (0.2%)
Foot deformity	0	1 (0.4%)	1 (0.2%)
Intervertebral disc degeneration	0	4 (1.7%)	4 (0.8%)
Lumbar spinal stenosis	0	2 (0.8%)	2 (0.4%)
Muscle spasms	0	1 (0.4%)	1 (0.2%)
Neck pain	0	5 (2.1%)	5 (1.0%)
Rotator cuff syndrome	0	1 (0.4%)	1 (0.2%)

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Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.1: Summary of Medical History by SOC/PT - Analysis Set mITT 1

MedDRA SOC and PT	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Sacral pain	0	2 (0.8%)	2 (0.4%)
Sacroiliitis	0	1 (0.4%)	1 (0.2%)
Spinal stenosis	0	2 (0.8%)	2 (0.4%)
Spondylitis	0	1 (0.4%)	1 (0.2%)
Synovial cyst	0	1 (0.4%)	1 (0.2%)
Vertebral osteophyte	0	1 (0.4%)	1 (0.2%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	48 (20.0%)	49 (20.2%)	97 (20.1%)
Cancer pain	9 (3.8%)	8 (3.3%)	17 (3.5%)
Prostate cancer	7 (2.9%)	8 (3.3%)	15 (3.1%)
Haemangioma of liver	3 (1.3%)	1 (0.4%)	4 (0.8%)
Tumour pain	3 (1.3%)	4 (1.7%)	7 (1.5%)
Basal cell carcinoma	2 (0.8%)	5 (2.1%)	7 (1.5%)
Breast cancer	2 (0.8%)	1 (0.4%)	3 (0.6%)
Colorectal adenoma	2 (0.8%)	0	2 (0.4%)
Lung neoplasm malignant	2 (0.8%)	0	2 (0.4%)
Acrochordon	1 (0.4%)	0	1 (0.2%)
Adenocarcinoma of colon	1 (0.4%)	0	1 (0.2%)
Adrenal adenoma	1 (0.4%)	3 (1.2%)	4 (0.8%)
Adrenal neoplasm	1 (0.4%)	0	1 (0.2%)
Bladder cancer	1 (0.4%)	1 (0.4%)	2 (0.4%)
Bladder cancer stage 0, with cancer in situ	1 (0.4%)	0	1 (0.2%)
Chronic lymphocytic leukaemia	1 (0.4%)	0	1 (0.2%)
Endometrial cancer	1 (0.4%)	0	1 (0.2%)
Fibrous histiocytoma	1 (0.4%)	0	1 (0.2%)
Follicular thyroid cancer	1 (0.4%)	0	1 (0.2%)
Haemangioma of bone	1 (0.4%)	0	1 (0.2%)

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Table 302.1.1000.2.1: Summary of Medical History by SOC/PT - Analysis Set mITT 1

MedDRA SOC and PT	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Hodgkin's disease	1 (0.4%)	0	1 (0.2%)
Hormone receptor positive breast cancer	1 (0.4%)	0	1 (0.2%)
Intraductal proliferative breast lesion	1 (0.4%)	0	1 (0.2%)
Laryngeal cancer	1 (0.4%)	0	1 (0.2%)
Liposarcoma	1 (0.4%)	0	1 (0.2%)
Lung adenocarcinoma stage I	1 (0.4%)	0	1 (0.2%)
Malignant melanoma	1 (0.4%)	0	1 (0.2%)
Papillary tumour of renal pelvis	1 (0.4%)	0	1 (0.2%)
Prostate cancer stage IV	1 (0.4%)	1 (0.4%)	2 (0.4%)
Pyogenic granuloma	1 (0.4%)	0	1 (0.2%)
Renal hamartoma	1 (0.4%)	0	1 (0.2%)
Seborrhoeic keratosis	1 (0.4%)	0	1 (0.2%)
Transitional cell cancer of the renal pelvis and ureter	1 (0.4%)	0	1 (0.2%)
Tumour thrombosis	1 (0.4%)	0	1 (0.2%)
Angiolipoma	0	1 (0.4%)	1 (0.2%)
Anogenital warts	0	1 (0.4%)	1 (0.2%)
Benign hepatic neoplasm	0	1 (0.4%)	1 (0.2%)
Benign mediastinal neoplasm	0	1 (0.4%)	1 (0.2%)
Benign neoplasm of adrenal gland	0	1 (0.4%)	1 (0.2%)
Benign soft tissue neoplasm	0	1 (0.4%)	1 (0.2%)
Blepharal papilloma	0	1 (0.4%)	1 (0.2%)
Brain neoplasm benign	0	1 (0.4%)	1 (0.2%)
Cardiac myxoma	0	1 (0.4%)	1 (0.2%)
Cervix carcinoma	0	2 (0.8%)	2 (0.4%)
Colon cancer	0	1 (0.4%)	1 (0.2%)
Colon cancer stage I	0	1 (0.4%)	1 (0.2%)

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Table 302.1.1000.2.1: Summary of Medical History by SOC/PT - Analysis Set mITT 1

MedDRA SOC and PT	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Endometrial adenocarcinoma	0	1 (0.4%)	1 (0.2%)
Eye naevus	0	1 (0.4%)	1 (0.2%)
Fibroadenoma of breast	0	1 (0.4%)	1 (0.2%)
Gastric cancer	0	1 (0.4%)	1 (0.2%)
Malignant melanoma in situ	0	2 (0.8%)	2 (0.4%)
Melanocytic naevus	0	1 (0.4%)	1 (0.2%)
Oropharyngeal cancer	0	1 (0.4%)	1 (0.2%)
Renal cancer stage II	0	1 (0.4%)	1 (0.2%)
Seminoma	0	1 (0.4%)	1 (0.2%)
Soft tissue sarcoma	0	1 (0.4%)	1 (0.2%)
Squamous cell carcinoma of skin	0	2 (0.8%)	2 (0.4%)
Ureteric cancer	0	1 (0.4%)	1 (0.2%)
Uterine leiomyoma	0	3 (1.2%)	3 (0.6%)
Nervous system disorders	46 (19.2%)	43 (17.8%)	89 (18.5%)
Peripheral sensory neuropathy	9 (3.8%)	7 (2.9%)	16 (3.3%)
Paraesthesia	6 (2.5%)	0	6 (1.2%)
Headache	5 (2.1%)	5 (2.1%)	10 (2.1%)
Dizziness	4 (1.7%)	3 (1.2%)	7 (1.5%)
Carpal tunnel syndrome	3 (1.3%)	0	3 (0.6%)
Cerebrovascular accident	3 (1.3%)	1 (0.4%)	4 (0.8%)
Migraine	3 (1.3%)	1 (0.4%)	4 (0.8%)
Post herpetic neuralgia	3 (1.3%)	0	3 (0.6%)
Peripheral motor neuropathy	2 (0.8%)	0	2 (0.4%)
Sciatica	2 (0.8%)	4 (1.7%)	6 (1.2%)
Transient ischaemic attack	2 (0.8%)	1 (0.4%)	3 (0.6%)
Vascular encephalopathy	2 (0.8%)	4 (1.7%)	6 (1.2%)

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Table 302.1.1000.2.1: Summary of Medical History by SOC/PT - Analysis Set mITT 1

MedDRA SOC and PT	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Carotid arteriosclerosis	1 (0.4%)	2 (0.8%)	3 (0.6%)
Carotid artery stenosis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Cognitive disorder	1 (0.4%)	1 (0.4%)	2 (0.4%)
Cranial nerve palsies multiple	1 (0.4%)	0	1 (0.2%)
Disturbance in attention	1 (0.4%)	1 (0.4%)	2 (0.4%)
Encephalopathy	1 (0.4%)	0	1 (0.2%)
Essential tremor	1 (0.4%)	0	1 (0.2%)
Hypoaesthesia	1 (0.4%)	0	1 (0.2%)
IVth nerve paralysis	1 (0.4%)	0	1 (0.2%)
Nerve compression	1 (0.4%)	0	1 (0.2%)
Optic neuritis	1 (0.4%)	0	1 (0.2%)
Phantom limb syndrome	1 (0.4%)	0	1 (0.2%)
Seizure	1 (0.4%)	1 (0.4%)	2 (0.4%)
Somnolence	1 (0.4%)	0	1 (0.2%)
Ulnar nerve palsy	1 (0.4%)	0	1 (0.2%)
Amnesia	0	1 (0.4%)	1 (0.2%)
Cerebral arteriosclerosis	0	1 (0.4%)	1 (0.2%)
Cerebral infarction	0	1 (0.4%)	1 (0.2%)
Cerebral ischaemia	0	1 (0.4%)	1 (0.2%)
Cerebrovascular disorder	0	2 (0.8%)	2 (0.4%)
Dysgeusia	0	1 (0.4%)	1 (0.2%)
Epilepsy	0	1 (0.4%)	1 (0.2%)
Intracranial aneurysm	0	1 (0.4%)	1 (0.2%)
Ischaemic stroke	0	1 (0.4%)	1 (0.2%)
Lethargy	0	1 (0.4%)	1 (0.2%)
Lumbar radiculopathy	0	2 (0.8%)	2 (0.4%)

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Table 302.1.1000.2.1: Summary of Medical History by SOC/PT - Analysis Set mITT 1

MedDRA SOC and PT	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Meningeal disorder	0	1 (0.4%)	1 (0.2%)
Neuralgia	0	1 (0.4%)	1 (0.2%)
Peroneal nerve palsy	0	1 (0.4%)	1 (0.2%)
Quadriplegia	0	1 (0.4%)	1 (0.2%)
Restless legs syndrome	0	1 (0.4%)	1 (0.2%)
Tremor	0	1 (0.4%)	1 (0.2%)
Psychiatric disorders	58 (24.2%)	42 (17.4%)	100 (20.7%)
Insomnia	33 (13.8%)	20 (8.3%)	53 (11.0%)
Anxiety	20 (8.3%)	10 (4.1%)	30 (6.2%)
Depression	13 (5.4%)	12 (5.0%)	25 (5.2%)
Alcohol abuse	2 (0.8%)	1 (0.4%)	3 (0.6%)
Rapid eye movement sleep behaviour disorder	2 (0.8%)	0	2 (0.4%)
Affective disorder	1 (0.4%)	0	1 (0.2%)
Alcoholism	1 (0.4%)	0	1 (0.2%)
Anxiety disorder	1 (0.4%)	1 (0.4%)	2 (0.4%)
Bipolar disorder	1 (0.4%)	0	1 (0.2%)
Claustrophobia	1 (0.4%)	0	1 (0.2%)
Drug abuse	1 (0.4%)	0	1 (0.2%)
Panic attack	1 (0.4%)	1 (0.4%)	2 (0.4%)
Parasomnia	1 (0.4%)	0	1 (0.2%)
Psychotic disorder	1 (0.4%)	0	1 (0.2%)
Bipolar I disorder	0	1 (0.4%)	1 (0.2%)
Depressed mood	0	1 (0.4%)	1 (0.2%)
Generalised anxiety disorder	0	1 (0.4%)	1 (0.2%)
Mood swings	0	1 (0.4%)	1 (0.2%)
Schizophrenia	0	1 (0.4%)	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.1: Summary of Medical History by SOC/PT - Analysis Set mITT 1

MedDRA SOC and PT	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Renal and urinary disorders	106 (44.2%)	98 (40.5%)	204 (42.3%)
Haematuria	41 (17.1%)	32 (13.2%)	73 (15.1%)
Pollakiuria	15 (6.3%)	7 (2.9%)	22 (4.6%)
Hydronephrosis	13 (5.4%)	11 (4.5%)	24 (5.0%)
Dysuria	12 (5.0%)	12 (5.0%)	24 (5.0%)
Chronic kidney disease	10 (4.2%)	10 (4.1%)	20 (4.1%)
Nephrolithiasis	10 (4.2%)	11 (4.5%)	21 (4.4%)
Renal cyst	8 (3.3%)	9 (3.7%)	17 (3.5%)
Proteinuria	6 (2.5%)	8 (3.3%)	14 (2.9%)
Nocturia	5 (2.1%)	4 (1.7%)	9 (1.9%)
Calculus urinary	3 (1.3%)	1 (0.4%)	4 (0.8%)
Micturition urgency	3 (1.3%)	5 (2.1%)	8 (1.7%)
Renal failure	3 (1.3%)	6 (2.5%)	9 (1.9%)
Urinary incontinence	3 (1.3%)	8 (3.3%)	11 (2.3%)
Urinary retention	3 (1.3%)	4 (1.7%)	7 (1.5%)
Acute kidney injury	2 (0.8%)	0	2 (0.4%)
Leukocyturia	2 (0.8%)	0	2 (0.4%)
Urinary hesitation	2 (0.8%)	0	2 (0.4%)
Urinary tract pain	2 (0.8%)	1 (0.4%)	3 (0.6%)
Urine flow decreased	2 (0.8%)	0	2 (0.4%)
Bladder diverticulum	1 (0.4%)	3 (1.2%)	4 (0.8%)
Bladder pain	1 (0.4%)	1 (0.4%)	2 (0.4%)
Bladder spasm	1 (0.4%)	5 (2.1%)	6 (1.2%)
Calculus bladder	1 (0.4%)	3 (1.2%)	4 (0.8%)
Glomerulonephritis chronic	1 (0.4%)	0	1 (0.2%)
Haemoglobinuria	1 (0.4%)	5 (2.1%)	6 (1.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.1: Summary of Medical History by SOC/PT - Analysis Set mITT 1

MedDRA SOC and PT	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Hydroureter	1 (0.4%)	0	1 (0.2%)
Hypertonic bladder	1 (0.4%)	0	1 (0.2%)
Lower urinary tract symptoms	1 (0.4%)	0	1 (0.2%)
Nephrotic syndrome	1 (0.4%)	0	1 (0.2%)
Pelvi-ureteric obstruction	1 (0.4%)	0	1 (0.2%)
Postrenal failure	1 (0.4%)	0	1 (0.2%)
Renal impairment	1 (0.4%)	1 (0.4%)	2 (0.4%)
Single functional kidney	1 (0.4%)	0	1 (0.2%)
Stress urinary incontinence	1 (0.4%)	0	1 (0.2%)
Ureterolithiasis	1 (0.4%)	0	1 (0.2%)
Urethral stenosis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Bladder metaplasia	0	1 (0.4%)	1 (0.2%)
Cystitis noninfective	0	1 (0.4%)	1 (0.2%)
Microalbuminuria	0	1 (0.4%)	1 (0.2%)
Pyelocaliectasis	0	1 (0.4%)	1 (0.2%)
Renal artery arteriosclerosis	0	1 (0.4%)	1 (0.2%)
Tubulointerstitial nephritis	0	1 (0.4%)	1 (0.2%)
Ureteric stenosis	0	1 (0.4%)	1 (0.2%)
Urethral meatus stenosis	0	1 (0.4%)	1 (0.2%)
Urge incontinence	0	1 (0.4%)	1 (0.2%)
Urinoma	0	1 (0.4%)	1 (0.2%)
Vesical fistula	0	1 (0.4%)	1 (0.2%)
Reproductive system and breast disorders	62 (25.8%)	55 (22.7%)	117 (24.3%)
Benign prostatic hyperplasia	38 (15.8%)	32 (13.2%)	70 (14.5%)
Erectile dysfunction	9 (3.8%)	7 (2.9%)	16 (3.3%)
Pelvic pain	7 (2.9%)	3 (1.2%)	10 (2.1%)

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Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.1: Summary of Medical History by SOC/PT - Analysis Set mITT 1

MedDRA SOC and PT	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Prostatitis	3 (1.3%)	5 (2.1%)	8 (1.7%)
Gynaecomastia	2 (0.8%)	0	2 (0.4%)
Penile pain	2 (0.8%)	1 (0.4%)	3 (0.6%)
Breast hyperplasia	1 (0.4%)	0	1 (0.2%)
Pelvic discomfort	1 (0.4%)	0	1 (0.2%)
Pelvic organ prolapse	1 (0.4%)	0	1 (0.2%)
Perineal pain	1 (0.4%)	1 (0.4%)	2 (0.4%)
Prostatic obstruction	1 (0.4%)	0	1 (0.2%)
Testicular pain	1 (0.4%)	3 (1.2%)	4 (0.8%)
Vaginal ulceration	1 (0.4%)	0	1 (0.2%)
Vulvovaginal pain	1 (0.4%)	0	1 (0.2%)
Calculus prostatic	0	1 (0.4%)	1 (0.2%)
Endometrial thickening	0	1 (0.4%)	1 (0.2%)
Haematospermia	0	1 (0.4%)	1 (0.2%)
Postmenopausal haemorrhage	0	1 (0.4%)	1 (0.2%)
Priapism	0	1 (0.4%)	1 (0.2%)
Prostatomegaly	0	2 (0.8%)	2 (0.4%)
Scrotal oedema	0	1 (0.4%)	1 (0.2%)
Seminal vesiculitis	0	1 (0.4%)	1 (0.2%)
Testicular cyst	0	1 (0.4%)	1 (0.2%)
Uterine polyp	0	1 (0.4%)	1 (0.2%)
Vaginal dysplasia	0	1 (0.4%)	1 (0.2%)
Vaginal prolapse	0	1 (0.4%)	1 (0.2%)
Varicocele	0	1 (0.4%)	1 (0.2%)
Respiratory, thoracic and mediastinal disorders	67 (27.9%)	64 (26.4%)	131 (27.2%)
Chronic obstructive pulmonary disease	18 (7.5%)	13 (5.4%)	31 (6.4%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
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Table 302.1.1000.2.1: Summary of Medical History by SOC/PT - Analysis Set mITT 1

MedDRA SOC and PT	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Cough	11 (4.6%)	9 (3.7%)	20 (4.1%)
Dyspnoea	8 (3.3%)	5 (2.1%)	13 (2.7%)
Pulmonary embolism	6 (2.5%)	9 (3.7%)	15 (3.1%)
Emphysema	5 (2.1%)	4 (1.7%)	9 (1.9%)
Obstructive sleep apnoea syndrome	5 (2.1%)	3 (1.2%)	8 (1.7%)
Asthma	4 (1.7%)	6 (2.5%)	10 (2.1%)
Rhinitis allergic	4 (1.7%)	6 (2.5%)	10 (2.1%)
Sleep apnoea syndrome	4 (1.7%)	8 (3.3%)	12 (2.5%)
Bronchitis chronic	2 (0.8%)	4 (1.7%)	6 (1.2%)
Hypoxia	2 (0.8%)	0	2 (0.4%)
Productive cough	2 (0.8%)	1 (0.4%)	3 (0.6%)
Dysphonia	1 (0.4%)	0	1 (0.2%)
Dyspnoea exertional	1 (0.4%)	0	1 (0.2%)
Haemoptysis	1 (0.4%)	0	1 (0.2%)
Interstitial lung disease	1 (0.4%)	0	1 (0.2%)
Laryngeal polyp	1 (0.4%)	0	1 (0.2%)
Lung disorder	1 (0.4%)	0	1 (0.2%)
Nasal polyps	1 (0.4%)	0	1 (0.2%)
Nasal septum deviation	1 (0.4%)	0	1 (0.2%)
Nasal turbinate hypertrophy	1 (0.4%)	0	1 (0.2%)
Nasopharyngeal reflux	1 (0.4%)	0	1 (0.2%)
Pharyngeal dyskinesia	1 (0.4%)	0	1 (0.2%)
Pleurisy	1 (0.4%)	0	1 (0.2%)
Pulmonary fibrosis	1 (0.4%)	2 (0.8%)	3 (0.6%)
Pulmonary mass	1 (0.4%)	0	1 (0.2%)
Respiratory failure	1 (0.4%)	0	1 (0.2%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.1: Summary of Medical History by SOC/PT - Analysis Set mITT 1

MedDRA SOC and PT	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Sinus polyp	1 (0.4%)	0	1 (0.2%)
Vasomotor rhinitis	1 (0.4%)	0	1 (0.2%)
Bronchiectasis	0	1 (0.4%)	1 (0.2%)
Laryngeal inflammation	0	1 (0.4%)	1 (0.2%)
Lung opacity	0	1 (0.4%)	1 (0.2%)
Nasal congestion	0	2 (0.8%)	2 (0.4%)
Oropharyngeal pain	0	3 (1.2%)	3 (0.6%)
Pleural effusion	0	1 (0.4%)	1 (0.2%)
Pneumothorax spontaneous	0	1 (0.4%)	1 (0.2%)
Pulmonary hypertension	0	1 (0.4%)	1 (0.2%)
Respiratory distress	0	1 (0.4%)	1 (0.2%)
Tachypnoea	0	1 (0.4%)	1 (0.2%)
Upper-airway cough syndrome	0	2 (0.8%)	2 (0.4%)
Vocal cord leukoplakia	0	1 (0.4%)	1 (0.2%)
Vocal cord polyp	0	1 (0.4%)	1 (0.2%)
Skin and subcutaneous tissue disorders	20 (8.3%)	9 (3.7%)	29 (6.0%)
Night sweats	3 (1.3%)	1 (0.4%)	4 (0.8%)
Dry skin	2 (0.8%)	0	2 (0.4%)
Eczema	2 (0.8%)	0	2 (0.4%)
Pruritus	2 (0.8%)	1 (0.4%)	3 (0.6%)
Rash maculo-papular	2 (0.8%)	1 (0.4%)	3 (0.6%)
Seborrhoeic dermatitis	2 (0.8%)	0	2 (0.4%)
Actinic keratosis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Dermal cyst	1 (0.4%)	1 (0.4%)	2 (0.4%)
Dermatitis	1 (0.4%)	0	1 (0.2%)
Dermatitis contact	1 (0.4%)	0	1 (0.2%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.1: Summary of Medical History by SOC/PT - Analysis Set mITT 1

MedDRA SOC and PT	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Dyshidrotic eczema	1 (0.4%)	0	1 (0.2%)
Miliaria	1 (0.4%)	0	1 (0.2%)
Nail dystrophy	1 (0.4%)	0	1 (0.2%)
Psoriasis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Rash macular	1 (0.4%)	0	1 (0.2%)
Rosacea	1 (0.4%)	0	1 (0.2%)
Skin hypopigmentation	1 (0.4%)	0	1 (0.2%)
Urticaria	1 (0.4%)	1 (0.4%)	2 (0.4%)
Alopecia	0	1 (0.4%)	1 (0.2%)
Erythema multiforme	0	1 (0.4%)	1 (0.2%)
Telangiectasia	0	1 (0.4%)	1 (0.2%)
Social circumstances	6 (2.5%)	2 (0.8%)	8 (1.7%)
Alcohol use	2 (0.8%)	1 (0.4%)	3 (0.6%)
Eye prosthesis user	2 (0.8%)	0	2 (0.4%)
Corrective lens user	1 (0.4%)	0	1 (0.2%)
Postmenopause	1 (0.4%)	0	1 (0.2%)
Tobacco user	1 (0.4%)	1 (0.4%)	2 (0.4%)
Surgical and medical procedures	53 (22.1%)	50 (20.7%)	103 (21.4%)
Appendicectomy	5 (2.1%)	9 (3.7%)	14 (2.9%)
Nephrostomy	4 (1.7%)	7 (2.9%)	11 (2.3%)
Cataract operation	3 (1.3%)	4 (1.7%)	7 (1.5%)
Cholecystectomy	3 (1.3%)	3 (1.2%)	6 (1.2%)
Inguinal hernia repair	3 (1.3%)	3 (1.2%)	6 (1.2%)
Knee arthroplasty	3 (1.3%)	1 (0.4%)	4 (0.8%)
Tonsillectomy	3 (1.3%)	5 (2.1%)	8 (1.7%)
Vasectomy	3 (1.3%)	2 (0.8%)	5 (1.0%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.1: Summary of Medical History by SOC/PT - Analysis Set mITT 1

MedDRA SOC and PT	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Caesarean section	2 (0.8%)	0	2 (0.4%)
Central venous catheterisation	2 (0.8%)	1 (0.4%)	3 (0.6%)
Female sterilisation	2 (0.8%)	0	2 (0.4%)
Haemorrhoid operation	2 (0.8%)	3 (1.2%)	5 (1.0%)
Hernia repair	2 (0.8%)	1 (0.4%)	3 (0.6%)
Hysterectomy	2 (0.8%)	2 (0.8%)	4 (0.8%)
Intraocular lens implant	2 (0.8%)	1 (0.4%)	3 (0.6%)
Meningioma surgery	2 (0.8%)	0	2 (0.4%)
Nephrectomy	2 (0.8%)	1 (0.4%)	3 (0.6%)
Nephroureterectomy	2 (0.8%)	1 (0.4%)	3 (0.6%)
Prostatectomy	2 (0.8%)	0	2 (0.4%)
Thyroidectomy	2 (0.8%)	1 (0.4%)	3 (0.6%)
Ureteral stent insertion	2 (0.8%)	2 (0.8%)	4 (0.8%)
Abdominoplasty	1 (0.4%)	0	1 (0.2%)
Amygdalotomy	1 (0.4%)	1 (0.4%)	2 (0.4%)
Arm amputation	1 (0.4%)	0	1 (0.2%)
Bladder calculus removal	1 (0.4%)	1 (0.4%)	2 (0.4%)
Bladder catheterisation	1 (0.4%)	1 (0.4%)	2 (0.4%)
Bladder operation	1 (0.4%)	0	1 (0.2%)
Cardiac ablation	1 (0.4%)	1 (0.4%)	2 (0.4%)
Cardiac pacemaker insertion	1 (0.4%)	1 (0.4%)	2 (0.4%)
Colectomy	1 (0.4%)	0	1 (0.2%)
Colporrhaphy	1 (0.4%)	0	1 (0.2%)
Corneal suture	1 (0.4%)	0	1 (0.2%)
Cystostomy	1 (0.4%)	0	1 (0.2%)
Elbow operation	1 (0.4%)	0	1 (0.2%)

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Table 302.1.1000.2.1: Summary of Medical History by SOC/PT - Analysis Set mITT 1

MedDRA SOC and PT	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Eye prosthesis insertion	1 (0.4%)	0	1 (0.2%)
Finger amputation	1 (0.4%)	1 (0.4%)	2 (0.4%)
Fracture treatment	1 (0.4%)	1 (0.4%)	2 (0.4%)
Gallbladder operation	1 (0.4%)	0	1 (0.2%)
Hip arthroplasty	1 (0.4%)	3 (1.2%)	4 (0.8%)
Hysterosalpingo-oophorectomy	1 (0.4%)	0	1 (0.2%)
Intervertebral disc operation	1 (0.4%)	0	1 (0.2%)
Iridotomy	1 (0.4%)	1 (0.4%)	2 (0.4%)
Keratomileusis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Knee operation	1 (0.4%)	0	1 (0.2%)
Large intestinal polypectomy	1 (0.4%)	1 (0.4%)	2 (0.4%)
Lens extraction	1 (0.4%)	0	1 (0.2%)
Lung lobectomy	1 (0.4%)	0	1 (0.2%)
Meniscus operation	1 (0.4%)	0	1 (0.2%)
Mitral valve repair	1 (0.4%)	0	1 (0.2%)
Nasal septal operation	1 (0.4%)	2 (0.8%)	3 (0.6%)
Neck surgery	1 (0.4%)	0	1 (0.2%)
Oesophagogastric fundoplasty	1 (0.4%)	0	1 (0.2%)
Osteomyelitis drainage	1 (0.4%)	0	1 (0.2%)
Parathyroidectomy	1 (0.4%)	0	1 (0.2%)
Parotidectomy	1 (0.4%)	0	1 (0.2%)
Percutaneous coronary intervention	1 (0.4%)	2 (0.8%)	3 (0.6%)
Pulmonary resection	1 (0.4%)	0	1 (0.2%)
Radiotherapy to prostate	1 (0.4%)	0	1 (0.2%)
Renal stone removal	1 (0.4%)	1 (0.4%)	2 (0.4%)
Salivary gland resection	1 (0.4%)	0	1 (0.2%)

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Table 302.1.1000.2.1: Summary of Medical History by SOC/PT - Analysis Set mITT 1

MedDRA SOC and PT	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Skin graft	1 (0.4%)	0	1 (0.2%)
Spinal laminectomy	1 (0.4%)	0	1 (0.2%)
Suprapubic prostatectomy	1 (0.4%)	0	1 (0.2%)
Tenoplasty	1 (0.4%)	2 (0.8%)	3 (0.6%)
Transurethral prostatectomy	1 (0.4%)	0	1 (0.2%)
Ureteral stent removal	1 (0.4%)	0	1 (0.2%)
Ureteric operation	1 (0.4%)	0	1 (0.2%)
Urethral meatotomy	1 (0.4%)	0	1 (0.2%)
Urostomy	1 (0.4%)	1 (0.4%)	2 (0.4%)
Varicose vein operation	1 (0.4%)	1 (0.4%)	2 (0.4%)
Venous operation	1 (0.4%)	0	1 (0.2%)
Wrist surgery	1 (0.4%)	0	1 (0.2%)
Adenotonsillectomy	0	1 (0.4%)	1 (0.2%)
Ankle operation	0	1 (0.4%)	1 (0.2%)
Brachytherapy to skin	0	1 (0.4%)	1 (0.2%)
Bunion operation	0	1 (0.4%)	1 (0.2%)
Bursa removal	0	1 (0.4%)	1 (0.2%)
Carpal tunnel decompression	0	1 (0.4%)	1 (0.2%)
Coronary angioplasty	0	1 (0.4%)	1 (0.2%)
Coronary arterial stent insertion	0	1 (0.4%)	1 (0.2%)
Coronary artery bypass	0	4 (1.7%)	4 (0.8%)
Gastric bypass	0	1 (0.4%)	1 (0.2%)
Leg amputation	0	1 (0.4%)	1 (0.2%)
Ligament operation	0	1 (0.4%)	1 (0.2%)
Meniscus removal	0	1 (0.4%)	1 (0.2%)
Micrographic skin surgery	0	1 (0.4%)	1 (0.2%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.1: Summary of Medical History by SOC/PT - Analysis Set mITT 1

MedDRA SOC and PT	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Mitral valve replacement	0	1 (0.4%)	1 (0.2%)
Oophorectomy	0	1 (0.4%)	1 (0.2%)
Open reduction of fracture	0	1 (0.4%)	1 (0.2%)
Pelvic exploration	0	1 (0.4%)	1 (0.2%)
Peripheral artery stent insertion	0	1 (0.4%)	1 (0.2%)
Phacocystectomy	0	1 (0.4%)	1 (0.2%)
Radical prostatectomy	0	1 (0.4%)	1 (0.2%)
Removal of foreign body from eye	0	2 (0.8%)	2 (0.4%)
Retained placenta operation	0	1 (0.4%)	1 (0.2%)
Salpingo-oophorectomy unilateral	0	1 (0.4%)	1 (0.2%)
Shoulder arthroplasty	0	1 (0.4%)	1 (0.2%)
Shoulder operation	0	1 (0.4%)	1 (0.2%)
Spinal operation	0	1 (0.4%)	1 (0.2%)
Splenectomy	0	1 (0.4%)	1 (0.2%)
Thrombectomy	0	1 (0.4%)	1 (0.2%)
Tracheostomy	0	1 (0.4%)	1 (0.2%)
Transfusion	0	1 (0.4%)	1 (0.2%)
Urethrotomy	0	2 (0.8%)	2 (0.4%)
Urinary cystectomy	0	1 (0.4%)	1 (0.2%)
Uterine operation	0	1 (0.4%)	1 (0.2%)
Vascular disorders	118 (49.2%)	134 (55.4%)	252 (52.3%)
Hypertension	116 (48.3%)	121 (50.0%)	237 (49.2%)
Aortic arteriosclerosis	5 (2.1%)	3 (1.2%)	8 (1.7%)
Deep vein thrombosis	3 (1.3%)	5 (2.1%)	8 (1.7%)
Peripheral arterial occlusive disease	3 (1.3%)	3 (1.2%)	6 (1.2%)
Arteriosclerosis	2 (0.8%)	2 (0.8%)	4 (0.8%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.1: Summary of Medical History by SOC/PT - Analysis Set mITT 1

MedDRA SOC and PT	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Varicose vein	2 (0.8%)	3 (1.2%)	5 (1.0%)
Arterial insufficiency	1 (0.4%)	0	1 (0.2%)
Hypertensive angiopathy	1 (0.4%)	0	1 (0.2%)
Pelvic venous thrombosis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Peripheral venous disease	1 (0.4%)	1 (0.4%)	2 (0.4%)
Superficial vein thrombosis	1 (0.4%)	0	1 (0.2%)
Venous thrombosis limb	1 (0.4%)	0	1 (0.2%)
Aortic aneurysm	0	3 (1.2%)	3 (0.6%)
Aortic stenosis	0	1 (0.4%)	1 (0.2%)
Arterial thrombosis	0	1 (0.4%)	1 (0.2%)
Essential hypertension	0	2 (0.8%)	2 (0.4%)
Intermittent claudication	0	2 (0.8%)	2 (0.4%)
Lymphostasis	0	1 (0.4%)	1 (0.2%)
Peripheral vascular disorder	0	1 (0.4%)	1 (0.2%)
Thrombosis	0	1 (0.4%)	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.2: Summary of Medical History by SOC/PT - Analysis Set mITT 2

MedDRA SOC and PT	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Overall	202 (100.0%)	201 (99.5%)	403 (99.8%)
Blood and lymphatic system disorders	50 (24.8%)	52 (25.7%)	102 (25.2%)
Anaemia	41 (20.3%)	47 (23.3%)	88 (21.8%)
Iron deficiency anaemia	4 (2.0%)	1 (0.5%)	5 (1.2%)
Anaemia megaloblastic	1 (0.5%)	0	1 (0.2%)
Anaemia of malignant disease	1 (0.5%)	0	1 (0.2%)
Blood loss anaemia	1 (0.5%)	0	1 (0.2%)
Deficiency anaemia	1 (0.5%)	0	1 (0.2%)
Eosinophilia	1 (0.5%)	0	1 (0.2%)
Lymph node pain	1 (0.5%)	0	1 (0.2%)
Microcytic anaemia	1 (0.5%)	0	1 (0.2%)
Thrombocytopenia	1 (0.5%)	1 (0.5%)	2 (0.5%)
Leukocytosis	0	1 (0.5%)	1 (0.2%)
Leukopenia	0	1 (0.5%)	1 (0.2%)
Neutrophilia	0	1 (0.5%)	1 (0.2%)
Normochromic normocytic anaemia	0	1 (0.5%)	1 (0.2%)
Polycythaemia	0	1 (0.5%)	1 (0.2%)
Splenic calcification	0	1 (0.5%)	1 (0.2%)
Thrombocytosis	0	1 (0.5%)	1 (0.2%)
Cardiac disorders	52 (25.7%)	66 (32.7%)	118 (29.2%)
Atrial fibrillation	15 (7.4%)	18 (8.9%)	33 (8.2%)
Myocardial ischaemia	9 (4.5%)	10 (5.0%)	19 (4.7%)
Cardiac failure chronic	8 (4.0%)	7 (3.5%)	15 (3.7%)
Angina pectoris	6 (3.0%)	2 (1.0%)	8 (2.0%)
Coronary artery disease	6 (3.0%)	8 (4.0%)	14 (3.5%)
Acute myocardial infarction	3 (1.5%)	3 (1.5%)	6 (1.5%)

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Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.2: Summary of Medical History by SOC/PT - Analysis Set mITT 2

MedDRA SOC and PT	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Hypertensive heart disease	3 (1.5%)	0	3 (0.7%)
Mitral valve incompetence	3 (1.5%)	1 (0.5%)	4 (1.0%)
Myocardial fibrosis	3 (1.5%)	2 (1.0%)	5 (1.2%)
Arrhythmia	2 (1.0%)	2 (1.0%)	4 (1.0%)
Arteriosclerosis coronary artery	2 (1.0%)	3 (1.5%)	5 (1.2%)
Atrial flutter	2 (1.0%)	0	2 (0.5%)
Cardiac failure congestive	2 (1.0%)	1 (0.5%)	3 (0.7%)
Myocardial infarction	2 (1.0%)	3 (1.5%)	5 (1.2%)
Sinus tachycardia	2 (1.0%)	0	2 (0.5%)
Tricuspid valve incompetence	2 (1.0%)	0	2 (0.5%)
Angina unstable	1 (0.5%)	0	1 (0.2%)
Aortic valve incompetence	1 (0.5%)	0	1 (0.2%)
Arrhythmia supraventricular	1 (0.5%)	0	1 (0.2%)
Cardiac amyloidosis	1 (0.5%)	0	1 (0.2%)
Cardiac aneurysm	1 (0.5%)	1 (0.5%)	2 (0.5%)
Cardiac arrest	1 (0.5%)	0	1 (0.2%)
Cardiac dysfunction	1 (0.5%)	0	1 (0.2%)
Cardiac failure	1 (0.5%)	2 (1.0%)	3 (0.7%)
Cardiomyopathy	1 (0.5%)	1 (0.5%)	2 (0.5%)
Degenerative aortic valve disease	1 (0.5%)	0	1 (0.2%)
Ischaemic cardiomyopathy	1 (0.5%)	1 (0.5%)	2 (0.5%)
Left ventricular dysfunction	1 (0.5%)	0	1 (0.2%)
Left ventricular hypertrophy	1 (0.5%)	0	1 (0.2%)
Palpitations	1 (0.5%)	2 (1.0%)	3 (0.7%)
Pericarditis	1 (0.5%)	0	1 (0.2%)
Subendocardial ischaemia	1 (0.5%)	0	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.2: Summary of Medical History by SOC/PT - Analysis Set mITT 2

MedDRA SOC and PT	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Supraventricular tachycardia	1 (0.5%)	0	1 (0.2%)
Tachycardia	1 (0.5%)	0	1 (0.2%)
Ventricular arrhythmia	1 (0.5%)	0	1 (0.2%)
Ventricular extrasystoles	1 (0.5%)	1 (0.5%)	2 (0.5%)
Wolff-Parkinson-White syndrome	1 (0.5%)	0	1 (0.2%)
Aortic valve sclerosis	0	1 (0.5%)	1 (0.2%)
Atrioventricular block	0	1 (0.5%)	1 (0.2%)
Atrioventricular block first degree	0	3 (1.5%)	3 (0.7%)
Bifascicular block	0	1 (0.5%)	1 (0.2%)
Bundle branch block left	0	1 (0.5%)	1 (0.2%)
Bundle branch block right	0	1 (0.5%)	1 (0.2%)
Dilated cardiomyopathy	0	2 (1.0%)	2 (0.5%)
Hypertensive cardiomyopathy	0	1 (0.5%)	1 (0.2%)
Left ventricular failure	0	1 (0.5%)	1 (0.2%)
Rheumatic heart disease	0	1 (0.5%)	1 (0.2%)
Systolic dysfunction	0	1 (0.5%)	1 (0.2%)
Ventricular tachycardia	0	2 (1.0%)	2 (0.5%)
Congenital, familial and genetic disorders	10 (5.0%)	9 (4.5%)	19 (4.7%)
Corneal dystrophy	2 (1.0%)	3 (1.5%)	5 (1.2%)
Renal fusion anomaly	2 (1.0%)	0	2 (0.5%)
Accessory renal artery	1 (0.5%)	0	1 (0.2%)
Alkaptonuria	1 (0.5%)	0	1 (0.2%)
Cerebral cavernous malformation	1 (0.5%)	0	1 (0.2%)
Congenital cystic kidney disease	1 (0.5%)	0	1 (0.2%)
Ectopic kidney	1 (0.5%)	0	1 (0.2%)
Phimosis	1 (0.5%)	0	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.2: Summary of Medical History by SOC/PT - Analysis Set mITT 2

MedDRA SOC and PT	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Congenital bladder diverticulum	0	1 (0.5%)	1 (0.2%)
Gilbert's syndrome	0	1 (0.5%)	1 (0.2%)
Hypertrophic cardiomyopathy	0	1 (0.5%)	1 (0.2%)
Talipes	0	1 (0.5%)	1 (0.2%)
Thalassaemia	0	1 (0.5%)	1 (0.2%)
Type V hyperlipidaemia	0	1 (0.5%)	1 (0.2%)
Vitello-intestinal duct remnant	0	1 (0.5%)	1 (0.2%)
Ear and labyrinth disorders	38 (18.8%)	33 (16.3%)	71 (17.6%)
Deafness	18 (8.9%)	10 (5.0%)	28 (6.9%)
Hypoacusis	8 (4.0%)	15 (7.4%)	23 (5.7%)
Deafness neurosensory	5 (2.5%)	2 (1.0%)	7 (1.7%)
Tinnitus	4 (2.0%)	3 (1.5%)	7 (1.7%)
Deafness bilateral	2 (1.0%)	0	2 (0.5%)
Deafness unilateral	1 (0.5%)	2 (1.0%)	3 (0.7%)
Presbyacusis	1 (0.5%)	2 (1.0%)	3 (0.7%)
Vertigo	1 (0.5%)	0	1 (0.2%)
Vertigo positional	0	1 (0.5%)	1 (0.2%)
Vestibular disorder	0	1 (0.5%)	1 (0.2%)
Endocrine disorders	18 (8.9%)	22 (10.9%)	40 (9.9%)
Hypothyroidism	11 (5.4%)	17 (8.4%)	28 (6.9%)
Adrenal insufficiency	2 (1.0%)	0	2 (0.5%)
Cushing's syndrome	1 (0.5%)	0	1 (0.2%)
Hyperplasia adrenal	1 (0.5%)	0	1 (0.2%)
Hyperthyroidism	1 (0.5%)	1 (0.5%)	2 (0.5%)
Hypogonadism	1 (0.5%)	1 (0.5%)	2 (0.5%)
Hypothyroidic goitre	1 (0.5%)	0	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.2: Summary of Medical History by SOC/PT - Analysis Set mITT 2

MedDRA SOC and PT	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Autoimmune thyroiditis	0	1 (0.5%)	1 (0.2%)
Goitre	0	3 (1.5%)	3 (0.7%)
Hyperparathyroidism	0	1 (0.5%)	1 (0.2%)
Eye disorders	132 (65.3%)	141 (69.8%)	273 (67.6%)
Cataract	87 (43.1%)	89 (44.1%)	176 (43.6%)
Dry eye	10 (5.0%)	6 (3.0%)	16 (4.0%)
Glaucoma	8 (4.0%)	5 (2.5%)	13 (3.2%)
Cataract nuclear	7 (3.5%)	11 (5.4%)	18 (4.5%)
Hypermetropia	6 (3.0%)	7 (3.5%)	13 (3.2%)
Astigmatism	5 (2.5%)	5 (2.5%)	10 (2.5%)
Presbyopia	5 (2.5%)	6 (3.0%)	11 (2.7%)
Retinal degeneration	5 (2.5%)	4 (2.0%)	9 (2.2%)
Vitreous detachment	5 (2.5%)	3 (1.5%)	8 (2.0%)
Macular degeneration	4 (2.0%)	12 (5.9%)	16 (4.0%)
Myopia	3 (1.5%)	2 (1.0%)	5 (1.2%)
Pseudophakia	3 (1.5%)	4 (2.0%)	7 (1.7%)
Retinal detachment	3 (1.5%)	2 (1.0%)	5 (1.2%)
Vitreous degeneration	3 (1.5%)	1 (0.5%)	4 (1.0%)
Age-related macular degeneration	2 (1.0%)	1 (0.5%)	3 (0.7%)
Cataract cortical	2 (1.0%)	0	2 (0.5%)
Corneal opacity	2 (1.0%)	1 (0.5%)	3 (0.7%)
Diabetic retinopathy	2 (1.0%)	1 (0.5%)	3 (0.7%)
Eyelid ptosis	2 (1.0%)	0	2 (0.5%)
Pinguecula	2 (1.0%)	1 (0.5%)	3 (0.7%)
Retinal haemorrhage	2 (1.0%)	0	2 (0.5%)
Amblyopia	1 (0.5%)	0	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.2: Summary of Medical History by SOC/PT - Analysis Set mITT 2

MedDRA SOC and PT	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Anterior capsule contraction	1 (0.5%)	0	1 (0.2%)
Blepharitis	1 (0.5%)	1 (0.5%)	2 (0.5%)
Blindness unilateral	1 (0.5%)	1 (0.5%)	2 (0.5%)
Conjunctival haemorrhage	1 (0.5%)	0	1 (0.2%)
Corneal disorder	1 (0.5%)	0	1 (0.2%)
Dermatochalasis	1 (0.5%)	0	1 (0.2%)
Diabetic retinal oedema	1 (0.5%)	0	1 (0.2%)
Epiretinal membrane	1 (0.5%)	5 (2.5%)	6 (1.5%)
Iridocyclitis	1 (0.5%)	1 (0.5%)	2 (0.5%)
Macular oedema	1 (0.5%)	0	1 (0.2%)
Meibomian gland dysfunction	1 (0.5%)	1 (0.5%)	2 (0.5%)
Meibomianitis	1 (0.5%)	0	1 (0.2%)
Myopic chorioretinal degeneration	1 (0.5%)	0	1 (0.2%)
Ocular hypertension	1 (0.5%)	0	1 (0.2%)
Ophthalmic vein thrombosis	1 (0.5%)	0	1 (0.2%)
Optic nerve cupping	1 (0.5%)	1 (0.5%)	2 (0.5%)
Pterygium	1 (0.5%)	1 (0.5%)	2 (0.5%)
Punctate keratitis	1 (0.5%)	3 (1.5%)	4 (1.0%)
Retinal artery embolism	1 (0.5%)	0	1 (0.2%)
Retinal depigmentation	1 (0.5%)	2 (1.0%)	3 (0.7%)
Retinal drusen	1 (0.5%)	0	1 (0.2%)
Retinal dystrophy	1 (0.5%)	0	1 (0.2%)
Retinal vascular disorder	1 (0.5%)	0	1 (0.2%)
Retinal vein occlusion	1 (0.5%)	2 (1.0%)	3 (0.7%)
Retinopathy hypertensive	1 (0.5%)	1 (0.5%)	2 (0.5%)
Vision blurred	1 (0.5%)	0	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.2: Summary of Medical History by SOC/PT - Analysis Set mITT 2

MedDRA SOC and PT	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Visual impairment	1 (0.5%)	0	1 (0.2%)
Vitreoretinal traction syndrome	1 (0.5%)	0	1 (0.2%)
Vitreous floaters	1 (0.5%)	3 (1.5%)	4 (1.0%)
Arcus lipoides	0	2 (1.0%)	2 (0.5%)
Arteriosclerotic retinopathy	0	1 (0.5%)	1 (0.2%)
Chorioretinal scar	0	2 (1.0%)	2 (0.5%)
Conjunctival cyst	0	1 (0.5%)	1 (0.2%)
Corneal degeneration	0	1 (0.5%)	1 (0.2%)
Corneal erosion	0	1 (0.5%)	1 (0.2%)
Corneal leukoma	0	2 (1.0%)	2 (0.5%)
Corneal pigmentation	0	1 (0.5%)	1 (0.2%)
Corneal scar	0	4 (2.0%)	4 (1.0%)
Corneal thinning	0	1 (0.5%)	1 (0.2%)
Cystoid macular oedema	0	3 (1.5%)	3 (0.7%)
Detachment of retinal pigment epithelium	0	1 (0.5%)	1 (0.2%)
Diplopia	0	1 (0.5%)	1 (0.2%)
Dry age-related macular degeneration	0	2 (1.0%)	2 (0.5%)
Entropion	0	1 (0.5%)	1 (0.2%)
Exfoliation glaucoma	0	1 (0.5%)	1 (0.2%)
Eye haemorrhage	0	1 (0.5%)	1 (0.2%)
Hyalosis asteroid	0	1 (0.5%)	1 (0.2%)
Iridocele	0	1 (0.5%)	1 (0.2%)
Macular pigmentation	0	2 (1.0%)	2 (0.5%)
Mydriasis	0	1 (0.5%)	1 (0.2%)
Neovascular age-related macular degeneration	0	1 (0.5%)	1 (0.2%)
Open angle glaucoma	0	2 (1.0%)	2 (0.5%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.2: Summary of Medical History by SOC/PT - Analysis Set mITT 2

MedDRA SOC and PT	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Optic atrophy	0	1 (0.5%)	1 (0.2%)
Optic disc haemorrhage	0	1 (0.5%)	1 (0.2%)
Papilloedema	0	1 (0.5%)	1 (0.2%)
Pigment dispersion syndrome	0	1 (0.5%)	1 (0.2%)
Posterior capsule opacification	0	1 (0.5%)	1 (0.2%)
Retinal fibrosis	0	1 (0.5%)	1 (0.2%)
Retinal pigmentation	0	1 (0.5%)	1 (0.2%)
Retinal scar	0	1 (0.5%)	1 (0.2%)
Retinal tear	0	1 (0.5%)	1 (0.2%)
Retinopathy	0	1 (0.5%)	1 (0.2%)
Vitreous adhesions	0	1 (0.5%)	1 (0.2%)
Gastrointestinal disorders	94 (46.5%)	83 (41.1%)	177 (43.8%)
Constipation	42 (20.8%)	40 (19.8%)	82 (20.3%)
Gastrooesophageal reflux disease	22 (10.9%)	13 (6.4%)	35 (8.7%)
Abdominal pain	18 (8.9%)	10 (5.0%)	28 (6.9%)
Nausea	12 (5.9%)	10 (5.0%)	22 (5.4%)
Abdominal pain lower	6 (3.0%)	4 (2.0%)	10 (2.5%)
Diarrhoea	6 (3.0%)	3 (1.5%)	9 (2.2%)
Gastric ulcer	6 (3.0%)	3 (1.5%)	9 (2.2%)
Chronic gastritis	5 (2.5%)	5 (2.5%)	10 (2.5%)
Gastritis	4 (2.0%)	1 (0.5%)	5 (1.2%)
Proctalgia	4 (2.0%)	3 (1.5%)	7 (1.7%)
Diverticulum intestinal	3 (1.5%)	2 (1.0%)	5 (1.2%)
Hiatus hernia	3 (1.5%)	4 (2.0%)	7 (1.7%)
Abdominal pain upper	2 (1.0%)	1 (0.5%)	3 (0.7%)
Dyspepsia	2 (1.0%)	2 (1.0%)	4 (1.0%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.2: Summary of Medical History by SOC/PT - Analysis Set mITT 2

MedDRA SOC and PT	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Haemorrhoids	2 (1.0%)	7 (3.5%)	9 (2.2%)
Inguinal hernia	2 (1.0%)	4 (2.0%)	6 (1.5%)
Large intestine polyp	2 (1.0%)	0	2 (0.5%)
Pancreatic steatosis	2 (1.0%)	0	2 (0.5%)
Pancreatitis chronic	2 (1.0%)	1 (0.5%)	3 (0.7%)
Vomiting	2 (1.0%)	1 (0.5%)	3 (0.7%)
Abdominal distension	1 (0.5%)	1 (0.5%)	2 (0.5%)
Abdominal hernia	1 (0.5%)	2 (1.0%)	3 (0.7%)
Barrett's oesophagus	1 (0.5%)	0	1 (0.2%)
Coeliac disease	1 (0.5%)	0	1 (0.2%)
Crohn's disease	1 (0.5%)	1 (0.5%)	2 (0.5%)
Dry mouth	1 (0.5%)	0	1 (0.2%)
Dysphagia	1 (0.5%)	0	1 (0.2%)
Epigastric discomfort	1 (0.5%)	0	1 (0.2%)
Gastric polyps	1 (0.5%)	0	1 (0.2%)
Gastroduodenal ulcer	1 (0.5%)	1 (0.5%)	2 (0.5%)
Gastrointestinal haemorrhage	1 (0.5%)	2 (1.0%)	3 (0.7%)
Intestinal obstruction	1 (0.5%)	0	1 (0.2%)
Lower gastrointestinal haemorrhage	1 (0.5%)	0	1 (0.2%)
Mallory-Weiss syndrome	1 (0.5%)	0	1 (0.2%)
Obstructive pancreatitis	1 (0.5%)	1 (0.5%)	2 (0.5%)
Oesophagitis	1 (0.5%)	2 (1.0%)	3 (0.7%)
Pancreatitis	1 (0.5%)	1 (0.5%)	2 (0.5%)
Peptic ulcer	1 (0.5%)	0	1 (0.2%)
Rectal haemorrhage	1 (0.5%)	0	1 (0.2%)
Umbilical hernia	1 (0.5%)	1 (0.5%)	2 (0.5%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.2: Summary of Medical History by SOC/PT - Analysis Set mITT 2

MedDRA SOC and PT	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Anal fistula	0	1 (0.5%)	1 (0.2%)
Dental caries	0	1 (0.5%)	1 (0.2%)
Diverticulum	0	2 (1.0%)	2 (0.5%)
Duodenal bulb deformity	0	1 (0.5%)	1 (0.2%)
Duodenitis	0	1 (0.5%)	1 (0.2%)
Flatulence	0	1 (0.5%)	1 (0.2%)
Gastrointestinal necrosis	0	1 (0.5%)	1 (0.2%)
Hernial eventration	0	1 (0.5%)	1 (0.2%)
Oesophageal atony	0	1 (0.5%)	1 (0.2%)
Oesophageal obstruction	0	1 (0.5%)	1 (0.2%)
Oesophageal spasm	0	1 (0.5%)	1 (0.2%)
Pancreatic disorder	0	1 (0.5%)	1 (0.2%)
Periodontal disease	0	3 (1.5%)	3 (0.7%)
Retroperitoneal haematoma	0	1 (0.5%)	1 (0.2%)
General disorders and administration site conditions	51 (25.2%)	51 (25.2%)	102 (25.2%)
Fatigue	26 (12.9%)	34 (16.8%)	60 (14.9%)
Oedema peripheral	10 (5.0%)	8 (4.0%)	18 (4.5%)
Asthenia	7 (3.5%)	7 (3.5%)	14 (3.5%)
Pain	3 (1.5%)	1 (0.5%)	4 (1.0%)
Non-cardiac chest pain	2 (1.0%)	2 (1.0%)	4 (1.0%)
Pyrexia	2 (1.0%)	1 (0.5%)	3 (0.7%)
Chest pain	1 (0.5%)	0	1 (0.2%)
Drug intolerance	1 (0.5%)	2 (1.0%)	3 (0.7%)
Malaise	1 (0.5%)	0	1 (0.2%)
Peripheral swelling	1 (0.5%)	0	1 (0.2%)
Suprapubic pain	1 (0.5%)	0	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.2: Summary of Medical History by SOC/PT - Analysis Set mITT 2

MedDRA SOC and PT	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Temperature intolerance	1 (0.5%)	0	1 (0.2%)
Generalised oedema	0	1 (0.5%)	1 (0.2%)
Hepatobiliary disorders	12 (5.9%)	11 (5.4%)	23 (5.7%)
Hepatic cyst	5 (2.5%)	3 (1.5%)	8 (2.0%)
Cholelithiasis	3 (1.5%)	1 (0.5%)	4 (1.0%)
Hepatic steatosis	3 (1.5%)	1 (0.5%)	4 (1.0%)
Gallbladder enlargement	1 (0.5%)	0	1 (0.2%)
Hepatic cirrhosis	1 (0.5%)	0	1 (0.2%)
Hepatomegaly	1 (0.5%)	0	1 (0.2%)
Alcoholic liver disease	0	1 (0.5%)	1 (0.2%)
Cholangitis acute	0	1 (0.5%)	1 (0.2%)
Cholecystitis chronic	0	1 (0.5%)	1 (0.2%)
Hepatic calcification	0	1 (0.5%)	1 (0.2%)
Hepatic function abnormal	0	1 (0.5%)	1 (0.2%)
Hepatitis	0	2 (1.0%)	2 (0.5%)
Liver disorder	0	2 (1.0%)	2 (0.5%)
Immune system disorders	11 (5.4%)	19 (9.4%)	30 (7.4%)
Drug hypersensitivity	10 (5.0%)	16 (7.9%)	26 (6.4%)
Seasonal allergy	3 (1.5%)	4 (2.0%)	7 (1.7%)
Contrast media allergy	0	1 (0.5%)	1 (0.2%)
Infections and infestations	35 (17.3%)	33 (16.3%)	68 (16.8%)
Urinary tract infection	7 (3.5%)	10 (5.0%)	17 (4.2%)
Pyelonephritis chronic	5 (2.5%)	3 (1.5%)	8 (2.0%)
COVID-19	3 (1.5%)	3 (1.5%)	6 (1.5%)
Cystitis	3 (1.5%)	1 (0.5%)	4 (1.0%)
Pneumonia	3 (1.5%)	2 (1.0%)	5 (1.2%)

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Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.2: Summary of Medical History by SOC/PT - Analysis Set mITT 2

MedDRA SOC and PT	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Asymptomatic bacteriuria	2 (1.0%)	0	2 (0.5%)
Sepsis	2 (1.0%)	0	2 (0.5%)
Abdominal sepsis	1 (0.5%)	0	1 (0.2%)
Appendicitis	1 (0.5%)	0	1 (0.2%)
COVID-19 pneumonia	1 (0.5%)	1 (0.5%)	2 (0.5%)
Clostridium difficile colitis	1 (0.5%)	0	1 (0.2%)
Conjunctivitis	1 (0.5%)	0	1 (0.2%)
Diverticulitis	1 (0.5%)	1 (0.5%)	2 (0.5%)
Encephalitis	1 (0.5%)	0	1 (0.2%)
Escherichia urinary tract infection	1 (0.5%)	0	1 (0.2%)
Hepatitis A	1 (0.5%)	1 (0.5%)	2 (0.5%)
Hepatitis B	1 (0.5%)	3 (1.5%)	4 (1.0%)
Herpes zoster	1 (0.5%)	1 (0.5%)	2 (0.5%)
Metapneumovirus pneumonia	1 (0.5%)	0	1 (0.2%)
Onychomycosis	1 (0.5%)	0	1 (0.2%)
Otitis media chronic	1 (0.5%)	0	1 (0.2%)
Pyelonephritis	1 (0.5%)	3 (1.5%)	4 (1.0%)
Pyuria	1 (0.5%)	0	1 (0.2%)
Respiratory tract infection	1 (0.5%)	0	1 (0.2%)
Rhinitis	1 (0.5%)	0	1 (0.2%)
Septic shock	1 (0.5%)	0	1 (0.2%)
Sinusitis	1 (0.5%)	0	1 (0.2%)
Bacterial prostatitis	0	1 (0.5%)	1 (0.2%)
Encephalitis viral	0	1 (0.5%)	1 (0.2%)
Escherichia sepsis	0	1 (0.5%)	1 (0.2%)
Fungal foot infection	0	1 (0.5%)	1 (0.2%)

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Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.2: Summary of Medical History by SOC/PT - Analysis Set mITT 2

MedDRA SOC and PT	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Helicobacter infection	0	1 (0.5%)	1 (0.2%)
Kidney infection	0	1 (0.5%)	1 (0.2%)
Laryngitis	0	1 (0.5%)	1 (0.2%)
Latent tuberculosis	0	1 (0.5%)	1 (0.2%)
Lymphangitis	0	1 (0.5%)	1 (0.2%)
Oral candidiasis	0	1 (0.5%)	1 (0.2%)
Paronychia	0	1 (0.5%)	1 (0.2%)
Pharyngitis	0	1 (0.5%)	1 (0.2%)
Poliomyelitis	0	1 (0.5%)	1 (0.2%)
Viral pericarditis	0	1 (0.5%)	1 (0.2%)
Injury, poisoning and procedural complications	15 (7.4%)	11 (5.4%)	26 (6.4%)
Spinal compression fracture	3 (1.5%)	0	3 (0.7%)
Limb injury	2 (1.0%)	0	2 (0.5%)
Anal injury	1 (0.5%)	0	1 (0.2%)
Conjunctival laceration	1 (0.5%)	0	1 (0.2%)
Contusion	1 (0.5%)	1 (0.5%)	2 (0.5%)
Fall	1 (0.5%)	0	1 (0.2%)
Incisional hernia	1 (0.5%)	0	1 (0.2%)
Joint dislocation	1 (0.5%)	0	1 (0.2%)
Lower limb fracture	1 (0.5%)	0	1 (0.2%)
Neck injury	1 (0.5%)	0	1 (0.2%)
Procedural pain	1 (0.5%)	1 (0.5%)	2 (0.5%)
Rib fracture	1 (0.5%)	0	1 (0.2%)
Shunt thrombosis	1 (0.5%)	0	1 (0.2%)
Subdural haematoma	1 (0.5%)	0	1 (0.2%)
Urinary tract stoma complication	1 (0.5%)	0	1 (0.2%)

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Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.2: Summary of Medical History by SOC/PT - Analysis Set mITT 2

MedDRA SOC and PT	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Ankle fracture	0	1 (0.5%)	1 (0.2%)
Femur fracture	0	1 (0.5%)	1 (0.2%)
Fibula fracture	0	1 (0.5%)	1 (0.2%)
Humerus fracture	0	1 (0.5%)	1 (0.2%)
Meniscus injury	0	1 (0.5%)	1 (0.2%)
Patella fracture	0	3 (1.5%)	3 (0.7%)
Radius fracture	0	1 (0.5%)	1 (0.2%)
Tendon rupture	0	1 (0.5%)	1 (0.2%)
Tibia fracture	0	1 (0.5%)	1 (0.2%)
Upper limb fracture	0	1 (0.5%)	1 (0.2%)
Urostomy complication	0	1 (0.5%)	1 (0.2%)
Investigations	32 (15.8%)	31 (15.3%)	63 (15.6%)
Blood creatinine increased	11 (5.4%)	14 (6.9%)	25 (6.2%)
Amylase increased	4 (2.0%)	1 (0.5%)	5 (1.2%)
Blood alkaline phosphatase increased	4 (2.0%)	5 (2.5%)	9 (2.2%)
Weight decreased	4 (2.0%)	1 (0.5%)	5 (1.2%)
Aspartate aminotransferase increased	3 (1.5%)	2 (1.0%)	5 (1.2%)
Blood lactate dehydrogenase increased	3 (1.5%)	1 (0.5%)	4 (1.0%)
Alanine aminotransferase increased	2 (1.0%)	1 (0.5%)	3 (0.7%)
Blood bilirubin increased	2 (1.0%)	0	2 (0.5%)
Blood urine present	2 (1.0%)	0	2 (0.5%)
Lipase increased	2 (1.0%)	1 (0.5%)	3 (0.7%)
Lymphocyte count decreased	2 (1.0%)	1 (0.5%)	3 (0.7%)
Activated partial thromboplastin time prolonged	1 (0.5%)	0	1 (0.2%)
Apolipoprotein B increased	1 (0.5%)	0	1 (0.2%)
Biopsy skin	1 (0.5%)	0	1 (0.2%)

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Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
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Table 302.1.1000.2.2: Summary of Medical History by SOC/PT - Analysis Set mITT 2

MedDRA SOC and PT	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Blood bicarbonate decreased	1 (0.5%)	0	1 (0.2%)
Blood fibrinogen increased	1 (0.5%)	0	1 (0.2%)
Blood pressure increased	1 (0.5%)	0	1 (0.2%)
Blood triglycerides increased	1 (0.5%)	0	1 (0.2%)
Blood urea increased	1 (0.5%)	0	1 (0.2%)
Catheterisation cardiac	1 (0.5%)	1 (0.5%)	2 (0.5%)
Colonoscopy	1 (0.5%)	0	1 (0.2%)
Creatinine renal clearance decreased	1 (0.5%)	2 (1.0%)	3 (0.7%)
Ejection fraction	1 (0.5%)	0	1 (0.2%)
Ejection fraction decreased	1 (0.5%)	0	1 (0.2%)
Gamma-glutamyltransferase increased	1 (0.5%)	1 (0.5%)	2 (0.5%)
Ureteroscopy	1 (0.5%)	0	1 (0.2%)
Biopsy liver	0	1 (0.5%)	1 (0.2%)
Biopsy prostate	0	1 (0.5%)	1 (0.2%)
Echocardiogram abnormal	0	1 (0.5%)	1 (0.2%)
Glomerular filtration rate decreased	0	1 (0.5%)	1 (0.2%)
Optic nerve cup/disc ratio increased	0	1 (0.5%)	1 (0.2%)
Platelet count increased	0	1 (0.5%)	1 (0.2%)
White blood cell count decreased	0	1 (0.5%)	1 (0.2%)
Metabolism and nutrition disorders	109 (54.0%)	123 (60.9%)	232 (57.4%)
Decreased appetite	25 (12.4%)	17 (8.4%)	42 (10.4%)
Hypercholesterolaemia	25 (12.4%)	21 (10.4%)	46 (11.4%)
Dyslipidaemia	22 (10.9%)	29 (14.4%)	51 (12.6%)
Hyperlipidaemia	21 (10.4%)	22 (10.9%)	43 (10.6%)
Diabetes mellitus	18 (8.9%)	20 (9.9%)	38 (9.4%)
Type 2 diabetes mellitus	14 (6.9%)	16 (7.9%)	30 (7.4%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.2: Summary of Medical History by SOC/PT - Analysis Set mITT 2

MedDRA SOC and PT	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Gout	6 (3.0%)	8 (4.0%)	14 (3.5%)
Hyponatraemia	6 (3.0%)	4 (2.0%)	10 (2.5%)
Obesity	4 (2.0%)	5 (2.5%)	9 (2.2%)
Dehydration	3 (1.5%)	0	3 (0.7%)
Hyperuricaemia	3 (1.5%)	13 (6.4%)	16 (4.0%)
Hypoalbuminaemia	3 (1.5%)	3 (1.5%)	6 (1.5%)
Vitamin B12 deficiency	3 (1.5%)	0	3 (0.7%)
Glucose tolerance impaired	2 (1.0%)	2 (1.0%)	4 (1.0%)
Hyperglycaemia	2 (1.0%)	2 (1.0%)	4 (1.0%)
Hypertriglyceridaemia	2 (1.0%)	0	2 (0.5%)
Hypocalcaemia	2 (1.0%)	1 (0.5%)	3 (0.7%)
Hypomagnesaemia	2 (1.0%)	1 (0.5%)	3 (0.7%)
Abnormal loss of weight	1 (0.5%)	0	1 (0.2%)
Carbohydrate intolerance	1 (0.5%)	1 (0.5%)	2 (0.5%)
Folate deficiency	1 (0.5%)	0	1 (0.2%)
Hypercreatininaemia	1 (0.5%)	0	1 (0.2%)
Hyperkalaemia	1 (0.5%)	3 (1.5%)	4 (1.0%)
Hypokalaemia	1 (0.5%)	0	1 (0.2%)
Lipid metabolism disorder	1 (0.5%)	0	1 (0.2%)
Vitamin D deficiency	1 (0.5%)	1 (0.5%)	2 (0.5%)
Cachexia	0	1 (0.5%)	1 (0.2%)
Hypercalcaemia	0	3 (1.5%)	3 (0.7%)
Hypophosphataemia	0	1 (0.5%)	1 (0.2%)
Metabolic syndrome	0	1 (0.5%)	1 (0.2%)
Overweight	0	1 (0.5%)	1 (0.2%)
Musculoskeletal and connective tissue disorders	73 (36.1%)	68 (33.7%)	141 (34.9%)

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Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.2: Summary of Medical History by SOC/PT - Analysis Set mITT 2

MedDRA SOC and PT	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Back pain	28 (13.9%)	19 (9.4%)	47 (11.6%)
Osteoarthritis	15 (7.4%)	13 (6.4%)	28 (6.9%)
Arthralgia	8 (4.0%)	12 (5.9%)	20 (5.0%)
Arthritis	7 (3.5%)	3 (1.5%)	10 (2.5%)
Flank pain	5 (2.5%)	5 (2.5%)	10 (2.5%)
Osteoporosis	5 (2.5%)	6 (3.0%)	11 (2.7%)
Spinal osteoarthritis	4 (2.0%)	4 (2.0%)	8 (2.0%)
Bone pain	3 (1.5%)	0	3 (0.7%)
Pain in extremity	3 (1.5%)	1 (0.5%)	4 (1.0%)
Intervertebral disc degeneration	2 (1.0%)	0	2 (0.5%)
Muscle spasms	2 (1.0%)	0	2 (0.5%)
Muscular weakness	2 (1.0%)	1 (0.5%)	3 (0.7%)
Myalgia	2 (1.0%)	1 (0.5%)	3 (0.7%)
Spinal stenosis	2 (1.0%)	0	2 (0.5%)
Chest wall haematoma	1 (0.5%)	0	1 (0.2%)
Degenerative bone disease	1 (0.5%)	0	1 (0.2%)
Groin pain	1 (0.5%)	3 (1.5%)	4 (1.0%)
Intervertebral disc disorder	1 (0.5%)	0	1 (0.2%)
Lumbar spinal stenosis	1 (0.5%)	1 (0.5%)	2 (0.5%)
Neck pain	1 (0.5%)	0	1 (0.2%)
Osteonecrosis	1 (0.5%)	0	1 (0.2%)
Osteopenia	1 (0.5%)	1 (0.5%)	2 (0.5%)
Polyarthritis	1 (0.5%)	0	1 (0.2%)
Polymyalgia rheumatica	1 (0.5%)	1 (0.5%)	2 (0.5%)
Pubic pain	1 (0.5%)	1 (0.5%)	2 (0.5%)
Rheumatoid arthritis	1 (0.5%)	0	1 (0.2%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.2: Summary of Medical History by SOC/PT - Analysis Set mITT 2

MedDRA SOC and PT	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Spinal pain	1 (0.5%)	0	1 (0.2%)
Coccydynia	0	1 (0.5%)	1 (0.2%)
Intervertebral disc protrusion	0	3 (1.5%)	3 (0.7%)
Joint range of motion decreased	0	1 (0.5%)	1 (0.2%)
Kyphosis	0	1 (0.5%)	1 (0.2%)
Musculoskeletal pain	0	1 (0.5%)	1 (0.2%)
Neck mass	0	1 (0.5%)	1 (0.2%)
Nodal osteoarthritis	0	1 (0.5%)	1 (0.2%)
Osteochondrosis	0	1 (0.5%)	1 (0.2%)
Pathological fracture	0	1 (0.5%)	1 (0.2%)
Psoriatic arthropathy	0	1 (0.5%)	1 (0.2%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	50 (24.8%)	46 (22.8%)	96 (23.8%)
Cancer pain	15 (7.4%)	10 (5.0%)	25 (6.2%)
Prostate cancer	7 (3.5%)	11 (5.4%)	18 (4.5%)
Breast cancer	3 (1.5%)	3 (1.5%)	6 (1.5%)
Haemangioma of liver	3 (1.5%)	0	3 (0.7%)
Tumour pain	3 (1.5%)	3 (1.5%)	6 (1.5%)
Basal cell carcinoma	2 (1.0%)	3 (1.5%)	5 (1.2%)
Blepharal papilloma	2 (1.0%)	0	2 (0.5%)
Uterine leiomyoma	2 (1.0%)	0	2 (0.5%)
Benign renal neoplasm	1 (0.5%)	0	1 (0.2%)
Bladder cancer	1 (0.5%)	1 (0.5%)	2 (0.5%)
Bladder cancer stage II	1 (0.5%)	0	1 (0.2%)
Breast cancer stage I	1 (0.5%)	0	1 (0.2%)
Cervix carcinoma	1 (0.5%)	0	1 (0.2%)
Endometrial cancer stage I	1 (0.5%)	0	1 (0.2%)

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Table 302.1.1000.2.2: Summary of Medical History by SOC/PT - Analysis Set mITT 2

MedDRA SOC and PT	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Intracranial meningioma malignant	1 (0.5%)	0	1 (0.2%)
Lip and/or oral cavity cancer stage IV	1 (0.5%)	0	1 (0.2%)
Lung adenocarcinoma	1 (0.5%)	1 (0.5%)	2 (0.5%)
Lung carcinoma cell type unspecified stage I	1 (0.5%)	0	1 (0.2%)
Malignant melanoma	1 (0.5%)	1 (0.5%)	2 (0.5%)
Osteosarcoma	1 (0.5%)	0	1 (0.2%)
Seborrhoeic keratosis	1 (0.5%)	0	1 (0.2%)
Seminoma	1 (0.5%)	0	1 (0.2%)
Squamous cell carcinoma of lung	1 (0.5%)	0	1 (0.2%)
Transitional cell cancer of the renal pelvis and ureter	1 (0.5%)	0	1 (0.2%)
Acinar cell carcinoma of pancreas	0	1 (0.5%)	1 (0.2%)
Adenocarcinoma of colon	0	1 (0.5%)	1 (0.2%)
Adrenal adenoma	0	3 (1.5%)	3 (0.7%)
Benign neoplasm of adrenal gland	0	1 (0.5%)	1 (0.2%)
Breast cancer stage II	0	1 (0.5%)	1 (0.2%)
Ear neoplasm malignant	0	1 (0.5%)	1 (0.2%)
Endometrial cancer stage II	0	1 (0.5%)	1 (0.2%)
Eye naevus	0	3 (1.5%)	3 (0.7%)
Hepatocellular carcinoma	0	1 (0.5%)	1 (0.2%)
Lip squamous cell carcinoma	0	1 (0.5%)	1 (0.2%)
Meningioma benign	0	2 (1.0%)	2 (0.5%)
Metastases to liver	0	1 (0.5%)	1 (0.2%)
Metastases to lung	0	1 (0.5%)	1 (0.2%)
Myeloproliferative neoplasm	0	1 (0.5%)	1 (0.2%)
Neurilemmoma benign	0	1 (0.5%)	1 (0.2%)
Non-secretory adenoma of pituitary	0	1 (0.5%)	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.2: Summary of Medical History by SOC/PT - Analysis Set mITT 2

MedDRA SOC and PT	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Prostatic adenoma	0	1 (0.5%)	1 (0.2%)
Schwannoma	0	1 (0.5%)	1 (0.2%)
Squamous cell carcinoma of skin	0	1 (0.5%)	1 (0.2%)
Triple negative breast cancer	0	1 (0.5%)	1 (0.2%)
Tumour compression	0	1 (0.5%)	1 (0.2%)
Nervous system disorders	38 (18.8%)	47 (23.3%)	85 (21.0%)
Peripheral sensory neuropathy	10 (5.0%)	6 (3.0%)	16 (4.0%)
Migraine	4 (2.0%)	1 (0.5%)	5 (1.2%)
Cerebrovascular accident	3 (1.5%)	5 (2.5%)	8 (2.0%)
Dizziness	3 (1.5%)	3 (1.5%)	6 (1.5%)
Carotid artery stenosis	2 (1.0%)	2 (1.0%)	4 (1.0%)
Epilepsy	2 (1.0%)	1 (0.5%)	3 (0.7%)
Headache	2 (1.0%)	2 (1.0%)	4 (1.0%)
Tremor	2 (1.0%)	2 (1.0%)	4 (1.0%)
Vascular encephalopathy	2 (1.0%)	1 (0.5%)	3 (0.7%)
Arachnoid cyst	1 (0.5%)	1 (0.5%)	2 (0.5%)
Carotid artery occlusion	1 (0.5%)	1 (0.5%)	2 (0.5%)
Carpal tunnel syndrome	1 (0.5%)	0	1 (0.2%)
Cerebellar stroke	1 (0.5%)	0	1 (0.2%)
Cerebral infarction	1 (0.5%)	0	1 (0.2%)
Cerebrovascular disorder	1 (0.5%)	0	1 (0.2%)
Dementia Alzheimer's type	1 (0.5%)	0	1 (0.2%)
Disturbance in attention	1 (0.5%)	0	1 (0.2%)
Dizziness postural	1 (0.5%)	0	1 (0.2%)
Dysaesthesia	1 (0.5%)	0	1 (0.2%)
Dysgeusia	1 (0.5%)	2 (1.0%)	3 (0.7%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.2: Summary of Medical History by SOC/PT - Analysis Set mITT 2

MedDRA SOC and PT	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
IVth nerve paralysis	1 (0.5%)	0	1 (0.2%)
Neuralgia	1 (0.5%)	0	1 (0.2%)
Osmotic demyelination syndrome	1 (0.5%)	0	1 (0.2%)
Paraesthesia	1 (0.5%)	2 (1.0%)	3 (0.7%)
Spinal meningeal cyst	1 (0.5%)	0	1 (0.2%)
Transient ischaemic attack	1 (0.5%)	1 (0.5%)	2 (0.5%)
Vertebral artery arteriosclerosis	1 (0.5%)	0	1 (0.2%)
Vertebrobasilar stroke	1 (0.5%)	0	1 (0.2%)
Acute motor-sensory axonal neuropathy	0	1 (0.5%)	1 (0.2%)
Anosmia	0	1 (0.5%)	1 (0.2%)
Autonomic nervous system imbalance	0	1 (0.5%)	1 (0.2%)
Balance disorder	0	1 (0.5%)	1 (0.2%)
Cerebral cyst	0	1 (0.5%)	1 (0.2%)
Cerebral vascular occlusion	0	1 (0.5%)	1 (0.2%)
Diabetic neuropathy	0	4 (2.0%)	4 (1.0%)
Facial paresis	0	1 (0.5%)	1 (0.2%)
Hypoaesthesia	0	1 (0.5%)	1 (0.2%)
Ischaemic cerebral infarction	0	1 (0.5%)	1 (0.2%)
Ischaemic stroke	0	3 (1.5%)	3 (0.7%)
Notalgia paraesthetica	0	1 (0.5%)	1 (0.2%)
Ophthalmic migraine	0	1 (0.5%)	1 (0.2%)
Parkinson's disease	0	2 (1.0%)	2 (0.5%)
Peripheral motor neuropathy	0	1 (0.5%)	1 (0.2%)
Radiculopathy	0	2 (1.0%)	2 (0.5%)
Restless legs syndrome	0	1 (0.5%)	1 (0.2%)
Sciatica	0	2 (1.0%)	2 (0.5%)

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Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
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Table 302.1.1000.2.2: Summary of Medical History by SOC/PT - Analysis Set mITT 2

MedDRA SOC and PT	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Syncope	0	1 (0.5%)	1 (0.2%)
Psychiatric disorders	46 (22.8%)	40 (19.8%)	86 (21.3%)
Insomnia	26 (12.9%)	20 (9.9%)	46 (11.4%)
Anxiety	15 (7.4%)	16 (7.9%)	31 (7.7%)
Depression	13 (6.4%)	12 (5.9%)	25 (6.2%)
Attention deficit hyperactivity disorder	2 (1.0%)	0	2 (0.5%)
Alcohol abuse	1 (0.5%)	0	1 (0.2%)
Drug abuse	1 (0.5%)	0	1 (0.2%)
Dysphoria	1 (0.5%)	0	1 (0.2%)
Dyssomnia	1 (0.5%)	0	1 (0.2%)
Mixed anxiety and depressive disorder	1 (0.5%)	2 (1.0%)	3 (0.7%)
Post-traumatic stress disorder	1 (0.5%)	0	1 (0.2%)
Pseudodementia	1 (0.5%)	0	1 (0.2%)
Sleep disorder	1 (0.5%)	0	1 (0.2%)
Aggression	0	1 (0.5%)	1 (0.2%)
Anxiety disorder	0	1 (0.5%)	1 (0.2%)
Confusional state	0	1 (0.5%)	1 (0.2%)
Depressed mood	0	1 (0.5%)	1 (0.2%)
Major depression	0	1 (0.5%)	1 (0.2%)
Persistent depressive disorder	0	1 (0.5%)	1 (0.2%)
Renal and urinary disorders	140 (69.3%)	130 (64.4%)	270 (66.8%)
Chronic kidney disease	49 (24.3%)	42 (20.8%)	91 (22.5%)
Renal impairment	41 (20.3%)	36 (17.8%)	77 (19.1%)
Haematuria	30 (14.9%)	23 (11.4%)	53 (13.1%)
Hydronephrosis	17 (8.4%)	16 (7.9%)	33 (8.2%)
Dysuria	9 (4.5%)	5 (2.5%)	14 (3.5%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.2: Summary of Medical History by SOC/PT - Analysis Set mITT 2

MedDRA SOC and PT	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Nephrolithiasis	9 (4.5%)	5 (2.5%)	14 (3.5%)
Pollakiuria	9 (4.5%)	8 (4.0%)	17 (4.2%)
Urinary incontinence	8 (4.0%)	3 (1.5%)	11 (2.7%)
Renal failure	7 (3.5%)	14 (6.9%)	21 (5.2%)
Renal cyst	6 (3.0%)	4 (2.0%)	10 (2.5%)
Nocturia	5 (2.5%)	1 (0.5%)	6 (1.5%)
Urinary retention	4 (2.0%)	2 (1.0%)	6 (1.5%)
Acute kidney injury	3 (1.5%)	7 (3.5%)	10 (2.5%)
Bladder spasm	2 (1.0%)	1 (0.5%)	3 (0.7%)
Haemoglobinuria	2 (1.0%)	1 (0.5%)	3 (0.7%)
Leukocyturia	2 (1.0%)	0	2 (0.5%)
Micturition urgency	2 (1.0%)	4 (2.0%)	6 (1.5%)
Proteinuria	2 (1.0%)	3 (1.5%)	5 (1.2%)
Renal atrophy	2 (1.0%)	0	2 (0.5%)
Urinary tract obstruction	2 (1.0%)	2 (1.0%)	4 (1.0%)
Albuminuria	1 (0.5%)	0	1 (0.2%)
Bladder diverticulum	1 (0.5%)	1 (0.5%)	2 (0.5%)
Bladder neck obstruction	1 (0.5%)	0	1 (0.2%)
Calculus urinary	1 (0.5%)	1 (0.5%)	2 (0.5%)
Micturition frequency decreased	1 (0.5%)	0	1 (0.2%)
Nephrosclerosis	1 (0.5%)	0	1 (0.2%)
Pyelocaliectasis	1 (0.5%)	0	1 (0.2%)
Renal injury	1 (0.5%)	0	1 (0.2%)
Single functional kidney	1 (0.5%)	0	1 (0.2%)
Ureteric obstruction	1 (0.5%)	0	1 (0.2%)
Urinary tract pain	1 (0.5%)	0	1 (0.2%)

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Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.2: Summary of Medical History by SOC/PT - Analysis Set mITT 2

MedDRA SOC and PT	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Urine flow decreased	1 (0.5%)	0	1 (0.2%)
Calculus bladder	0	1 (0.5%)	1 (0.2%)
Diabetic nephropathy	0	1 (0.5%)	1 (0.2%)
Renal colic	0	1 (0.5%)	1 (0.2%)
Ureteric stenosis	0	1 (0.5%)	1 (0.2%)
Urinary tract discomfort	0	1 (0.5%)	1 (0.2%)
Reproductive system and breast disorders	44 (21.8%)	52 (25.7%)	96 (23.8%)
Benign prostatic hyperplasia	29 (14.4%)	37 (18.3%)	66 (16.3%)
Erectile dysfunction	5 (2.5%)	2 (1.0%)	7 (1.7%)
Prostatomegaly	3 (1.5%)	2 (1.0%)	5 (1.2%)
Vaginal prolapse	3 (1.5%)	0	3 (0.7%)
Pelvic pain	2 (1.0%)	4 (2.0%)	6 (1.5%)
Prostatitis	2 (1.0%)	6 (3.0%)	8 (2.0%)
Vaginal haemorrhage	2 (1.0%)	0	2 (0.5%)
Calculus prostatic	1 (0.5%)	0	1 (0.2%)
Gynaecomastia	1 (0.5%)	0	1 (0.2%)
Perineal pain	1 (0.5%)	2 (1.0%)	3 (0.7%)
Prostatic calcification	1 (0.5%)	0	1 (0.2%)
Scrotal oedema	1 (0.5%)	0	1 (0.2%)
Uterine prolapse	1 (0.5%)	0	1 (0.2%)
Colpocele	0	1 (0.5%)	1 (0.2%)
Pelvic cyst	0	1 (0.5%)	1 (0.2%)
Prostatic disorder	0	1 (0.5%)	1 (0.2%)
Prostatic obstruction	0	1 (0.5%)	1 (0.2%)
Seminal vesiculitis	0	1 (0.5%)	1 (0.2%)
Vulvovaginal dryness	0	1 (0.5%)	1 (0.2%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.2: Summary of Medical History by SOC/PT - Analysis Set mITT 2

MedDRA SOC and PT	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Vulvovaginal swelling	0	1 (0.5%)	1 (0.2%)
Respiratory, thoracic and mediastinal disorders	59 (29.2%)	52 (25.7%)	111 (27.5%)
Chronic obstructive pulmonary disease	19 (9.4%)	21 (10.4%)	40 (9.9%)
Dyspnoea	11 (5.4%)	7 (3.5%)	18 (4.5%)
Asthma	9 (4.5%)	10 (5.0%)	19 (4.7%)
Pulmonary embolism	7 (3.5%)	7 (3.5%)	14 (3.5%)
Bronchitis chronic	6 (3.0%)	2 (1.0%)	8 (2.0%)
Cough	6 (3.0%)	4 (2.0%)	10 (2.5%)
Sleep apnoea syndrome	6 (3.0%)	5 (2.5%)	11 (2.7%)
Emphysema	3 (1.5%)	1 (0.5%)	4 (1.0%)
Pneumothorax	2 (1.0%)	0	2 (0.5%)
Pulmonary hypertension	2 (1.0%)	1 (0.5%)	3 (0.7%)
Rhinitis allergic	2 (1.0%)	1 (0.5%)	3 (0.7%)
Chronic respiratory failure	1 (0.5%)	0	1 (0.2%)
Dysphonia	1 (0.5%)	0	1 (0.2%)
Dyspnoea exertional	1 (0.5%)	0	1 (0.2%)
Pulmonary calcification	1 (0.5%)	0	1 (0.2%)
Pulmonary fibrosis	1 (0.5%)	0	1 (0.2%)
Rhinorrhoea	1 (0.5%)	0	1 (0.2%)
Sinus congestion	1 (0.5%)	0	1 (0.2%)
Bronchospasm	0	1 (0.5%)	1 (0.2%)
Epistaxis	0	1 (0.5%)	1 (0.2%)
Laryngeal oedema	0	1 (0.5%)	1 (0.2%)
Obstructive sleep apnoea syndrome	0	4 (2.0%)	4 (1.0%)
Pleural effusion	0	1 (0.5%)	1 (0.2%)
Productive cough	0	2 (1.0%)	2 (0.5%)

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Table 302.1.1000.2.2: Summary of Medical History by SOC/PT - Analysis Set mITT 2

MedDRA SOC and PT	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Pulmonary mass	0	1 (0.5%)	1 (0.2%)
Respiratory failure	0	2 (1.0%)	2 (0.5%)
Snoring	0	1 (0.5%)	1 (0.2%)
Skin and subcutaneous tissue disorders	21 (10.4%)	13 (6.4%)	34 (8.4%)
Eczema	5 (2.5%)	2 (1.0%)	7 (1.7%)
Dry skin	3 (1.5%)	0	3 (0.7%)
Pruritus	2 (1.0%)	1 (0.5%)	3 (0.7%)
Psoriasis	2 (1.0%)	2 (1.0%)	4 (1.0%)
Acquired porokeratosis	1 (0.5%)	0	1 (0.2%)
Decubitus ulcer	1 (0.5%)	1 (0.5%)	2 (0.5%)
Dermatitis allergic	1 (0.5%)	0	1 (0.2%)
Hyperhidrosis	1 (0.5%)	0	1 (0.2%)
Lichen planus	1 (0.5%)	0	1 (0.2%)
Nail ridging	1 (0.5%)	0	1 (0.2%)
Night sweats	1 (0.5%)	1 (0.5%)	2 (0.5%)
Rash	1 (0.5%)	1 (0.5%)	2 (0.5%)
Seborrhoeic dermatitis	1 (0.5%)	0	1 (0.2%)
Skin ulcer	1 (0.5%)	1 (0.5%)	2 (0.5%)
Urticaria	1 (0.5%)	1 (0.5%)	2 (0.5%)
Urticaria chronic	1 (0.5%)	0	1 (0.2%)
Dyshidrotic eczema	0	1 (0.5%)	1 (0.2%)
Lichen sclerosus	0	1 (0.5%)	1 (0.2%)
Rash maculo-papular	0	1 (0.5%)	1 (0.2%)
Rosacea	0	1 (0.5%)	1 (0.2%)
Social circumstances	3 (1.5%)	1 (0.5%)	4 (1.0%)
Alcoholic	1 (0.5%)	0	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
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Table 302.1.1000.2.2: Summary of Medical History by SOC/PT - Analysis Set mITT 2

MedDRA SOC and PT	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Postmenopause	1 (0.5%)	1 (0.5%)	2 (0.5%)
Tobacco user	1 (0.5%)	0	1 (0.2%)
Surgical and medical procedures	55 (27.2%)	53 (26.2%)	108 (26.7%)
Cataract operation	7 (3.5%)	9 (4.5%)	16 (4.0%)
Hysterectomy	7 (3.5%)	5 (2.5%)	12 (3.0%)
Nephrostomy	6 (3.0%)	9 (4.5%)	15 (3.7%)
Appendicectomy	5 (2.5%)	7 (3.5%)	12 (3.0%)
Cholecystectomy	5 (2.5%)	8 (4.0%)	13 (3.2%)
Urostomy	4 (2.0%)	1 (0.5%)	5 (1.2%)
Aortic valve replacement	3 (1.5%)	2 (1.0%)	5 (1.2%)
Central venous catheterisation	3 (1.5%)	0	3 (0.7%)
Coronary arterial stent insertion	3 (1.5%)	0	3 (0.7%)
Knee arthroplasty	3 (1.5%)	0	3 (0.7%)
Carpal tunnel decompression	2 (1.0%)	0	2 (0.5%)
Coronary artery bypass	2 (1.0%)	5 (2.5%)	7 (1.7%)
Fracture treatment	2 (1.0%)	0	2 (0.5%)
Hernia repair	2 (1.0%)	1 (0.5%)	3 (0.7%)
Hip arthroplasty	2 (1.0%)	0	2 (0.5%)
Inguinal hernia repair	2 (1.0%)	4 (2.0%)	6 (1.5%)
Shoulder arthroplasty	2 (1.0%)	0	2 (0.5%)
Tonsillectomy	2 (1.0%)	8 (4.0%)	10 (2.5%)
Ureteral stent insertion	2 (1.0%)	0	2 (0.5%)
Bladder catheterisation	1 (0.5%)	1 (0.5%)	2 (0.5%)
Bladder repair	1 (0.5%)	0	1 (0.2%)
Bunion operation	1 (0.5%)	0	1 (0.2%)
Cardiac pacemaker insertion	1 (0.5%)	2 (1.0%)	3 (0.7%)

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Table 302.1.1000.2.2: Summary of Medical History by SOC/PT - Analysis Set mITT 2

MedDRA SOC and PT	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Colectomy	1 (0.5%)	1 (0.5%)	2 (0.5%)
Drain placement	1 (0.5%)	0	1 (0.2%)
Eye laser surgery	1 (0.5%)	0	1 (0.2%)
Gallbladder operation	1 (0.5%)	0	1 (0.2%)
Gastric banding	1 (0.5%)	0	1 (0.2%)
Hysterosalpingo-oophorectomy	1 (0.5%)	1 (0.5%)	2 (0.5%)
Intraocular lens implant	1 (0.5%)	4 (2.0%)	5 (1.2%)
Knee operation	1 (0.5%)	2 (1.0%)	3 (0.7%)
Leg amputation	1 (0.5%)	0	1 (0.2%)
Lymphadenectomy	1 (0.5%)	0	1 (0.2%)
Mammary ductectomy	1 (0.5%)	0	1 (0.2%)
Meniscus operation	1 (0.5%)	1 (0.5%)	2 (0.5%)
Micrographic skin surgery	1 (0.5%)	0	1 (0.2%)
Mitral valve repair	1 (0.5%)	0	1 (0.2%)
Nasal operation	1 (0.5%)	1 (0.5%)	2 (0.5%)
Neck surgery	1 (0.5%)	0	1 (0.2%)
Nephrectomy	1 (0.5%)	1 (0.5%)	2 (0.5%)
Nephroureterectomy	1 (0.5%)	1 (0.5%)	2 (0.5%)
Orchidopexy	1 (0.5%)	0	1 (0.2%)
Pelvic exenteration	1 (0.5%)	0	1 (0.2%)
Peripheral artery angioplasty	1 (0.5%)	0	1 (0.2%)
Peripheral artery bypass	1 (0.5%)	0	1 (0.2%)
Peripheral nerve decompression	1 (0.5%)	0	1 (0.2%)
Pterygium operation	1 (0.5%)	0	1 (0.2%)
Rotator cuff repair	1 (0.5%)	0	1 (0.2%)
Shoulder operation	1 (0.5%)	0	1 (0.2%)

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MedDRA SOC and PT	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Skin lesion removal	1 (0.5%)	0	1 (0.2%)
Spinal laminectomy	1 (0.5%)	0	1 (0.2%)
Spinal operation	1 (0.5%)	1 (0.5%)	2 (0.5%)
Thrombectomy	1 (0.5%)	0	1 (0.2%)
Thyroidectomy	1 (0.5%)	0	1 (0.2%)
Transfusion	1 (0.5%)	0	1 (0.2%)
Transurethral prostatectomy	1 (0.5%)	2 (1.0%)	3 (0.7%)
Umbilical hernia repair	1 (0.5%)	1 (0.5%)	2 (0.5%)
Urethrotomy	1 (0.5%)	0	1 (0.2%)
Urinary cystectomy	1 (0.5%)	0	1 (0.2%)
Vasectomy	1 (0.5%)	3 (1.5%)	4 (1.0%)
Abdominal hernia repair	0	1 (0.5%)	1 (0.2%)
Aneurysm repair	0	1 (0.5%)	1 (0.2%)
Breast conserving surgery	0	1 (0.5%)	1 (0.2%)
Caesarean section	0	1 (0.5%)	1 (0.2%)
Carotid endarterectomy	0	2 (1.0%)	2 (0.5%)
Colostomy	0	1 (0.5%)	1 (0.2%)
Cystostomy	0	1 (0.5%)	1 (0.2%)
Duodenal ulcer repair	0	1 (0.5%)	1 (0.2%)
Ear operation	0	1 (0.5%)	1 (0.2%)
Endarterectomy	0	1 (0.5%)	1 (0.2%)
Epididymectomy	0	1 (0.5%)	1 (0.2%)
Gastric bypass	0	1 (0.5%)	1 (0.2%)
Hepatectomy	0	1 (0.5%)	1 (0.2%)
Ileectomy	0	1 (0.5%)	1 (0.2%)
Implantable defibrillator insertion	0	1 (0.5%)	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.2: Summary of Medical History by SOC/PT - Analysis Set mITT 2

MedDRA SOC and PT	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Implantable defibrillator replacement	0	1 (0.5%)	1 (0.2%)
Internal fixation of fracture	0	1 (0.5%)	1 (0.2%)
Lens extraction	0	1 (0.5%)	1 (0.2%)
Ligament operation	0	1 (0.5%)	1 (0.2%)
Limb operation	0	1 (0.5%)	1 (0.2%)
Nasal septal operation	0	1 (0.5%)	1 (0.2%)
Percutaneous coronary intervention	0	1 (0.5%)	1 (0.2%)
Phlebectomy	0	1 (0.5%)	1 (0.2%)
Proctocolectomy	0	1 (0.5%)	1 (0.2%)
Prostatectomy	0	2 (1.0%)	2 (0.5%)
Pulmonary resection	0	1 (0.5%)	1 (0.2%)
Radical prostatectomy	0	1 (0.5%)	1 (0.2%)
Rectocele repair	0	1 (0.5%)	1 (0.2%)
Skin neoplasm excision	0	1 (0.5%)	1 (0.2%)
Spinal fusion surgery	0	1 (0.5%)	1 (0.2%)
Transcatheter aortic valve implantation	0	1 (0.5%)	1 (0.2%)
Transurethral bladder resection	0	1 (0.5%)	1 (0.2%)
Vaginal prolapse repair	0	1 (0.5%)	1 (0.2%)
Varicose vein operation	0	2 (1.0%)	2 (0.5%)
Vascular disorders	125 (61.9%)	133 (65.8%)	258 (63.9%)
Hypertension	112 (55.4%)	122 (60.4%)	234 (57.9%)
Varicose vein	6 (3.0%)	2 (1.0%)	8 (2.0%)
Aortic aneurysm	4 (2.0%)	2 (1.0%)	6 (1.5%)
Aortic arteriosclerosis	3 (1.5%)	2 (1.0%)	5 (1.2%)
Peripheral arterial occlusive disease	3 (1.5%)	2 (1.0%)	5 (1.2%)
Deep vein thrombosis	2 (1.0%)	5 (2.5%)	7 (1.7%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.2.2: Summary of Medical History by SOC/PT - Analysis Set mITT 2

MedDRA SOC and PT	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Essential hypertension	2 (1.0%)	0	2 (0.5%)
Vena cava thrombosis	2 (1.0%)	0	2 (0.5%)
Aortic dilatation	1 (0.5%)	0	1 (0.2%)
Embolism venous	1 (0.5%)	0	1 (0.2%)
Hypertensive angiopathy	1 (0.5%)	0	1 (0.2%)
Hypotension	1 (0.5%)	1 (0.5%)	2 (0.5%)
Lymphoedema	1 (0.5%)	1 (0.5%)	2 (0.5%)
Pelvic venous thrombosis	1 (0.5%)	1 (0.5%)	2 (0.5%)
Peripheral artery aneurysm	1 (0.5%)	0	1 (0.2%)
Peripheral embolism	1 (0.5%)	1 (0.5%)	2 (0.5%)
Peripheral ischaemia	1 (0.5%)	0	1 (0.2%)
Peripheral vascular disorder	1 (0.5%)	2 (1.0%)	3 (0.7%)
Peripheral venous disease	1 (0.5%)	1 (0.5%)	2 (0.5%)
Thrombosed varicose vein	1 (0.5%)	0	1 (0.2%)
Aortic stenosis	0	1 (0.5%)	1 (0.2%)
Arteriosclerosis	0	2 (1.0%)	2 (0.5%)
Diabetic macroangiopathy	0	1 (0.5%)	1 (0.2%)
Embolism	0	1 (0.5%)	1 (0.2%)
Giant cell arteritis	0	1 (0.5%)	1 (0.2%)
Peripheral artery occlusion	0	1 (0.5%)	1 (0.2%)
Peripheral artery thrombosis	0	1 (0.5%)	1 (0.2%)
Venoocclusive disease	0	1 (0.5%)	1 (0.2%)
Venous thrombosis limb	0	3 (1.5%)	3 (0.7%)
White coat hypertension	0	1 (0.5%)	1 (0.2%)

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Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted in alphabetic by System Organ Class and descending by the number of subjects in the investigational arm by Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.3.1: Summary of Previous Therapies - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Prior systemic therapy in neoadyuvant or adjuvant setting	24 (10.0%)	22 (9.1%)	46 (9.5%)
Platinum-based therapy	24 (10.0%)	19 (7.9%)	43 (8.9%)
Cisplatin-based regimen	21 (8.8%)	17 (7.0%)	38 (7.9%)
Carboplatin-based regimen	3 (1.3%)	2 (0.8%)	5 (1.0%)
Non-platinum-based therapy	1 (0.4%)	4 (1.7%)	5 (1.0%)
Prior surgery (a)	80 (33.3%)	81 (33.5%)	161 (33.4%)
Cystectomy (b)	47 (19.6%)	54 (22.3%)	101 (21.0%)
Nephrectomy/ureterectomy (c)	38 (15.8%)	29 (12.0%)	67 (13.9%)
Metastasectomy (d)	6 (2.5%)	9 (3.7%)	15 (3.1%)
Prior radiation therapy	17 (7.1%)	17 (7.0%)	34 (7.1%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: (a) Prior cystectomy, nephrectomy/ureterectomy, metastasectomy without including transurethral resection of the bladder tumor or biopsy. A subject may be counted in more than one category; (b) Includes partial and total cystectomy/cystoprostatectomy; (c) Includes partial and total nephrectomy/nephroureterectomy/ureterectomy; (d) Includes surgical resection of one or more distant metastasis.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.3.2: Summary of Previous Therapies - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Prior systemic therapy in neoadyuvant or adjuvant setting	16 (7.9%)	17 (8.4%)	33 (8.2%)
Platinum-based therapy	16 (7.9%)	17 (8.4%)	33 (8.2%)
Cisplatin-based regimen	14 (6.9%)	16 (7.9%)	30 (7.4%)
Carboplatin-based regimen	2 (1.0%)	1 (0.5%)	3 (0.7%)
Non-platinum-based therapy	0	0	0
Prior surgery (a)	85 (42.1%)	82 (40.6%)	167 (41.3%)
Cystectomy (b)	45 (22.3%)	52 (25.7%)	97 (24.0%)
Nephrectomy/ureterectomy (c)	47 (23.3%)	39 (19.3%)	86 (21.3%)
Metastasectomy (d)	2 (1.0%)	5 (2.5%)	7 (1.7%)
Prior radiation therapy	16 (7.9%)	22 (10.9%)	38 (9.4%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: (a) Prior cystectomy, nephrectomy/ureterectomy, metastasectomy without including transurethral resection of the bladder tumor or biopsy. A subject may be counted in more than one category; (b) Includes partial and total cystectomy/cystoprostatectomy; (c) Includes partial and total nephrectomy/nephroureterectomy/ureterectomy; (d) Includes surgical resection of one or more distant metastasis.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Overall	238 (99.2%)	233 (96.3%)	471 (97.7%)
Agents Acting On The Renin-Angiotensin System	85 (35.4%)	78 (32.2%)	163 (33.8%)
Ace Inhibitors And Calcium Channel Blockers	2 (0.8%)	3 (1.2%)	5 (1.0%)
Amlodipine;benazepril	1 (0.4%)	0	1 (0.2%)
Trandolapril;verapamil Hydrochloride	1 (0.4%)	0	1 (0.2%)
Amlodipine Besilate;perindopril Arginine	0	2 (0.8%)	2 (0.4%)
Enalapril Maleate;lercanidipine Hydrochloride	0	1 (0.4%)	1 (0.2%)
Ace Inhibitors And Diuretics	2 (0.8%)	3 (1.2%)	5 (1.0%)
Delapril;indapamide	1 (0.4%)	0	1 (0.2%)
Indapamide;perindopril Arginine	1 (0.4%)	0	1 (0.2%)
Hydrochlorothiazide;lisinopril	0	2 (0.8%)	2 (0.4%)
Indapamide;perindopril Erbumine	0	1 (0.4%)	1 (0.2%)
Ace Inhibitors, Other Combinations	1 (0.4%)	1 (0.4%)	2 (0.4%)
Amlodipine Besilate;indapamide;perindopril Arginine	1 (0.4%)	0	1 (0.2%)
Amlodipine;indapamide;perindopril	0	1 (0.4%)	1 (0.2%)
Ace Inhibitors, Plain	34 (14.2%)	36 (14.9%)	70 (14.5%)
Enalapril	10 (4.2%)	4 (1.7%)	14 (2.9%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Ramipril	9 (3.8%)	15 (6.2%)	24 (5.0%)
Lisinopril	5 (2.1%)	8 (3.3%)	13 (2.7%)
Enalapril Maleate	3 (1.3%)	1 (0.4%)	4 (0.8%)
Perindopril	3 (1.3%)	3 (1.2%)	6 (1.2%)
Captopril	2 (0.8%)	2 (0.8%)	4 (0.8%)
Fosinopril	1 (0.4%)	0	1 (0.2%)
Perindopril Erbumine	1 (0.4%)	0	1 (0.2%)
Benazepril Hydrochloride	0	1 (0.4%)	1 (0.2%)
Perindopril Arginine	0	2 (0.8%)	2 (0.4%)
Angiotensin Ii Receptor Blockers (Arbs) And Calcium Channel Blockers	9 (3.8%)	3 (1.2%)	12 (2.5%)
Amlodipine Besilate;olmesartan Medoxomil	3 (1.3%)	1 (0.4%)	4 (0.8%)
Amlodipine Besilate;valsartan	3 (1.3%)	1 (0.4%)	4 (0.8%)
Amlodipine Besilate;irbesartan	2 (0.8%)	0	2 (0.4%)
Amlodipine;valsartan	1 (0.4%)	0	1 (0.2%)
Amlodipine Besilate;telmisartan	0	1 (0.4%)	1 (0.2%)
Angiotensin Ii Receptor Blockers (Arbs) And Diuretics	5 (2.1%)	3 (1.2%)	8 (1.7%)
Hydrochlorothiazide;valsartan	4 (1.7%)	0	4 (0.8%)
Hydrochlorothiazide;olmesartan	1 (0.4%)	0	1 (0.2%)
Candesartan Cilexetil;hydrochlorothiazide	0	1 (0.4%)	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Hydrochlorothiazide;losartan	0	2 (0.8%)	2 (0.4%)
Angiotensin Ii Receptor Blockers (Arbs), Other Combinations	2 (0.8%)	0	2 (0.4%)
Sacubitril;valsartan	2 (0.8%)	0	2 (0.4%)
Angiotensin Ii Receptor Blockers (Arbs), Plain	35 (14.6%)	32 (13.2%)	67 (13.9%)
Losartan	7 (2.9%)	10 (4.1%)	17 (3.5%)
Telmisartan	6 (2.5%)	3 (1.2%)	9 (1.9%)
Valsartan	5 (2.1%)	8 (3.3%)	13 (2.7%)
Candesartan	4 (1.7%)	0	4 (0.8%)
Losartan Potassium	4 (1.7%)	5 (2.1%)	9 (1.9%)
Candesartan Cilexetil	3 (1.3%)	1 (0.4%)	4 (0.8%)
Irbesartan	2 (0.8%)	3 (1.2%)	5 (1.0%)
Azilsartan Kamedoxomil	1 (0.4%)	0	1 (0.2%)
Azilsartan Medoxomil	1 (0.4%)	0	1 (0.2%)
Fimasartan	1 (0.4%)	0	1 (0.2%)
Fimasartan Potassium Trihydrate	1 (0.4%)	1 (0.4%)	2 (0.4%)
Olmesartan	1 (0.4%)	2 (0.8%)	3 (0.6%)
Azilsartan	0	1 (0.4%)	1 (0.2%)
Olmesartan Medoxomil	0	1 (0.4%)	1 (0.2%)
All Other Therapeutic Products	16 (6.7%)	9 (3.7%)	25 (5.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Antidotes	7 (2.9%)	4 (1.7%)	11 (2.3%)
Acetylcysteine	3 (1.3%)	1 (0.4%)	4 (0.8%)
Naloxone	1 (0.4%)	1 (0.4%)	2 (0.4%)
Naloxone Hydrochloride	1 (0.4%)	2 (0.8%)	3 (0.6%)
Protamine Sulfate	1 (0.4%)	0	1 (0.2%)
Sugammadex Sodium	1 (0.4%)	0	1 (0.2%)
Detoxifying Agents For Antineoplastic Treatment	1 (0.4%)	0	1 (0.2%)
Calcium Folinate	1 (0.4%)	0	1 (0.2%)
Drugs For Treatment Of Hyperkalemia And Hyperphosphatemia	3 (1.3%)	6 (2.5%)	9 (1.9%)
Sodium Polystyrene Sulfonate	2 (0.8%)	4 (1.7%)	6 (1.2%)
Calcium Polystyrene Sulfonate	1 (0.4%)	2 (0.8%)	3 (0.6%)
Medical Gases	4 (1.7%)	0	4 (0.8%)
Oxygen	4 (1.7%)	0	4 (0.8%)
Other Therapeutic Products	1 (0.4%)	0	1 (0.2%)
Lactobacillus Rhamnosus	1 (0.4%)	0	1 (0.2%)
Analgesics	164 (68.3%)	146 (60.3%)	310 (64.3%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Anilides	111 (46.3%)	91 (37.6%)	202 (41.9%)
Paracetamol	110 (45.8%)	90 (37.2%)	200 (41.5%)
Propacetamol Hydrochloride	2 (0.8%)	1 (0.4%)	3 (0.6%)
Caffeine;paracetamol;promethazine;salicylamide	1 (0.4%)	0	1 (0.2%)
Chlorphenamine Maleate;dextromethorphan Hydrobromide;paracetamol;phenylephrine Hydrochloride	1 (0.4%)	0	1 (0.2%)
Ibuprofen;paracetamol	1 (0.4%)	0	1 (0.2%)
Paracetamol;pseudoephedrine	1 (0.4%)	0	1 (0.2%)
Propacetamol	1 (0.4%)	1 (0.4%)	2 (0.4%)
Diphenylpropylamine Derivatives	0	1 (0.4%)	1 (0.2%)
Methadone	0	1 (0.4%)	1 (0.2%)
Gabapentinoids	35 (14.6%)	20 (8.3%)	55 (11.4%)
Gabapentin	19 (7.9%)	10 (4.1%)	29 (6.0%)
Pregabalin	18 (7.5%)	9 (3.7%)	27 (5.6%)
Mirogabalin Besilate	1 (0.4%)	1 (0.4%)	2 (0.4%)
Natural Opium Alkaloids	53 (22.1%)	59 (24.4%)	112 (23.2%)
Morphine	14 (5.8%)	13 (5.4%)	27 (5.6%)
Oxycodone	14 (5.8%)	20 (8.3%)	34 (7.1%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Oxycodone Hydrochloride	13 (5.4%)	11 (4.5%)	24 (5.0%)
Morphine Sulfate	10 (4.2%)	12 (5.0%)	22 (4.6%)
Hydromorphone	6 (2.5%)	1 (0.4%)	7 (1.5%)
Naloxone Hydrochloride;oxycodone Hydrochloride	6 (2.5%)	9 (3.7%)	15 (3.1%)
Hydromorphone Hydrochloride	5 (2.1%)	3 (1.2%)	8 (1.7%)
Morphine Hydrochloride	3 (1.3%)	1 (0.4%)	4 (0.8%)
Codeine	2 (0.8%)	3 (1.2%)	5 (1.0%)
Codeine Phosphate	1 (0.4%)	0	1 (0.2%)
Dihydrocodeine	0	1 (0.4%)	1 (0.2%)
Hydrocodone	0	1 (0.4%)	1 (0.2%)
Morphine Sulfate Pentahydrate	0	3 (1.2%)	3 (0.6%)
Naloxone;oxycodone	0	1 (0.4%)	1 (0.2%)
Papaver Somniferum	0	2 (0.8%)	2 (0.4%)
Opioids In Combination With Non-Opioid Analgesics	41 (17.1%)	28 (11.6%)	69 (14.3%)
Paracetamol;tramadol Hydrochloride	22 (9.2%)	13 (5.4%)	35 (7.3%)
Hydrocodone;paracetamol	5 (2.1%)	1 (0.4%)	6 (1.2%)
Codeine Phosphate;paracetamol	4 (1.7%)	7 (2.9%)	11 (2.3%)
Oxycodone Hydrochloride;paracetamol	4 (1.7%)	2 (0.8%)	6 (1.2%)
Codeine Phosphate;ibuprofen;paracetamol	2 (0.8%)	0	2 (0.4%)
Paracetamol;tramadol	2 (0.8%)	0	2 (0.4%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Caffeine;codeine;paracetamol	1 (0.4%)	0	1 (0.2%)
Dexketoprofen Trometamol;tramadol Hydrochloride	1 (0.4%)	0	1 (0.2%)
Hydrocodone Bitartrate;paracetamol	1 (0.4%)	3 (1.2%)	4 (0.8%)
Codeine;paracetamol	0	2 (0.8%)	2 (0.4%)
Oripavine Derivatives	1 (0.4%)	0	1 (0.2%)
Buprenorphine Hydrochloride	1 (0.4%)	0	1 (0.2%)
Other Analgesics And Antipyretics	7 (2.9%)	9 (3.7%)	16 (3.3%)
Duloxetine Hydrochloride	3 (1.3%)	1 (0.4%)	4 (0.8%)
Amitriptyline	2 (0.8%)	2 (0.8%)	4 (0.8%)
Amitriptyline Hydrochloride	1 (0.4%)	1 (0.4%)	2 (0.4%)
Duloxetine	1 (0.4%)	1 (0.4%)	2 (0.4%)
Cannabis Sativa	0	2 (0.8%)	2 (0.4%)
Carbamazepine	0	1 (0.4%)	1 (0.2%)
Nefopam Hydrochloride	0	1 (0.4%)	1 (0.2%)
Other Antimigraine Preparations	0	1 (0.4%)	1 (0.2%)
Metoprolol	0	1 (0.4%)	1 (0.2%)
Other Opioids	31 (12.9%)	27 (11.2%)	58 (12.0%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Tramadol	19 (7.9%)	21 (8.7%)	40 (8.3%)
Tramadol Hydrochloride	9 (3.8%)	4 (1.7%)	13 (2.7%)
Tapentadol	2 (0.8%)	0	2 (0.4%)
Naloxone Hydrochloride;tilidine Hydrochloride	1 (0.4%)	0	1 (0.2%)
Tapentadol Hydrochloride	1 (0.4%)	2 (0.8%)	3 (0.6%)
Phenylpiperidine Derivatives	20 (8.3%)	15 (6.2%)	35 (7.3%)
Fentanyl	19 (7.9%)	13 (5.4%)	32 (6.6%)
Fentanyl Citrate	1 (0.4%)	3 (1.2%)	4 (0.8%)
Pyrazolones	24 (10.0%)	16 (6.6%)	40 (8.3%)
Metamizole	17 (7.1%)	4 (1.7%)	21 (4.4%)
Metamizole Sodium	6 (2.5%)	9 (3.7%)	15 (3.1%)
Metamizole Magnesium	2 (0.8%)	3 (1.2%)	5 (1.0%)
Fenpiverinium Bromide;metamizole Sodium;pitofenone Hydrochloride	1 (0.4%)	0	1 (0.2%)
Salicylic Acid And Derivatives	6 (2.5%)	6 (2.5%)	12 (2.5%)
Acetylsalicylic Acid	6 (2.5%)	5 (2.1%)	11 (2.3%)
Salicylamide	0	1 (0.4%)	1 (0.2%)
Selective Serotonin (5ht1) Agonists	0	1 (0.4%)	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Sumatriptan Succinate	0	1 (0.4%)	1 (0.2%)
Anesthetics	34 (14.2%)	16 (6.6%)	50 (10.4%)
Amides	26 (10.8%)	13 (5.4%)	39 (8.1%)
Lidocaine	13 (5.4%)	5 (2.1%)	18 (3.7%)
Lidocaine;prilocaine	7 (2.9%)	5 (2.1%)	12 (2.5%)
Lidocaine Hydrochloride	6 (2.5%)	1 (0.4%)	7 (1.5%)
Chlorhexidine Gluconate;lidocaine Hydrochloride	1 (0.4%)	0	1 (0.2%)
Epinephrine;lidocaine	1 (0.4%)	0	1 (0.2%)
Levobupivacaine	1 (0.4%)	0	1 (0.2%)
Lidocaine Hydrochloride Monohydrate	1 (0.4%)	0	1 (0.2%)
Ropivacaine	1 (0.4%)	0	1 (0.2%)
Lidocaine;sodium Bicarbonate	0	2 (0.8%)	2 (0.4%)
Prilocaine	0	3 (1.2%)	3 (0.6%)
Halogenated Hydrocarbons	1 (0.4%)	0	1 (0.2%)
Sevoflurane	1 (0.4%)	0	1 (0.2%)
Opioid Anesthetics	11 (4.6%)	3 (1.2%)	14 (2.9%)
Fentanyl	9 (3.8%)	3 (1.2%)	12 (2.5%)
Fentanyl Citrate	2 (0.8%)	0	2 (0.4%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Remifentanil Hydrochloride	1 (0.4%)	0	1 (0.2%)
Other General Anesthetics	7 (2.9%)	1 (0.4%)	8 (1.7%)
Propofol	7 (2.9%)	0	7 (1.5%)
Ketamine	1 (0.4%)	0	1 (0.2%)
Etomidate	0	1 (0.4%)	1 (0.2%)
Other Local Anesthetics	1 (0.4%)	0	1 (0.2%)
Capsaicin	1 (0.4%)	0	1 (0.2%)
Anti-Acne Preparations	3 (1.3%)	0	3 (0.6%)
Antiinfectives For Treatment Of Acne	2 (0.8%)	0	2 (0.4%)
Clindamycin	2 (0.8%)	0	2 (0.4%)
Retinoids For Topical Use In Acne	1 (0.4%)	0	1 (0.2%)
Adapalene;clindamycin	1 (0.4%)	0	1 (0.2%)
Anti-Parkinson Drugs	1 (0.4%)	0	1 (0.2%)
Tertiary Amines	1 (0.4%)	0	1 (0.2%)
Biperiden Hydrochloride	1 (0.4%)	0	1 (0.2%)
Antianemic Preparations	33 (13.8%)	43 (17.8%)	76 (15.8%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Folic Acid And Derivatives	4 (1.7%)	10 (4.1%)	14 (2.9%)
Folic Acid	4 (1.7%)	10 (4.1%)	14 (2.9%)
Iron Bivalent, Oral Preparations	14 (5.8%)	12 (5.0%)	26 (5.4%)
Ferrous Sulfate	8 (3.3%)	7 (2.9%)	15 (3.1%)
Ferrous Gluconate	2 (0.8%)	2 (0.8%)	4 (0.8%)
Ferrous Bisglycinate	1 (0.4%)	0	1 (0.2%)
Ferrous Fumarate	1 (0.4%)	2 (0.8%)	3 (0.6%)
Ferrous Sodium Citrate	1 (0.4%)	1 (0.4%)	2 (0.4%)
Ferrous Sulfate Exsiccated	1 (0.4%)	0	1 (0.2%)
Ferrous Glycine Sulfate	0	1 (0.4%)	1 (0.2%)
Iron In Combination With Folic Acid	0	1 (0.4%)	1 (0.2%)
Calcium Folinate;iron Succinyl-Protein Complex	0	1 (0.4%)	1 (0.2%)
Iron In Other Combinations	1 (0.4%)	6 (2.5%)	7 (1.5%)
Copper Gluconate;ferrous Gluconate;manganese Gluconate	1 (0.4%)	2 (0.8%)	3 (0.6%)
Ascorbic Acid;cyanocobalamin;ferrous Fumarate;folic Acid	0	1 (0.4%)	1 (0.2%)
Ascorbic Acid;ferrous Sulfate	0	3 (1.2%)	3 (0.6%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Iron Trivalent, Oral Preparations	2 (0.8%)	6 (2.5%)	8 (1.7%)
Ferric Hydroxide Polymaltose Complex	1 (0.4%)	3 (1.2%)	4 (0.8%)
Ferric Sodium Gluconate Complex	1 (0.4%)	0	1 (0.2%)
Ascorbic Acid;ferric Pyrophosphate	0	1 (0.4%)	1 (0.2%)
Dextriferron	0	1 (0.4%)	1 (0.2%)
Iron Polysaccharide Complex	0	1 (0.4%)	1 (0.2%)
Iron, Parenteral Preparations	4 (1.7%)	9 (3.7%)	13 (2.7%)
Ferric Carboxymaltose	3 (1.3%)	3 (1.2%)	6 (1.2%)
Ferric Hydroxide Polymaltose Complex	1 (0.4%)	1 (0.4%)	2 (0.4%)
Iron	0	4 (1.7%)	4 (0.8%)
Saccharated Iron Oxide	0	2 (0.8%)	2 (0.4%)
Not Applicable	4 (1.7%)	4 (1.7%)	8 (1.7%)
Iron	4 (1.7%)	3 (1.2%)	7 (1.5%)
Ferumoxytol	0	1 (0.4%)	1 (0.2%)
Other Antianemic Preparations	5 (2.1%)	9 (3.7%)	14 (2.9%)
Epoetin Alfa	2 (0.8%)	5 (2.1%)	7 (1.5%)
Erythropoietin	2 (0.8%)	0	2 (0.4%)
Darbepoetin Alfa	1 (0.4%)	4 (1.7%)	5 (1.0%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Vitamin B12 (Cyanocobalamin And Analogues)	9 (3.8%)	2 (0.8%)	11 (2.3%)
Vitamin B12 Nos	8 (3.3%)	2 (0.8%)	10 (2.1%)
Cyanocobalamin	1 (0.4%)	0	1 (0.2%)
Antibacterials For Systemic Use	133 (55.4%)	90 (37.2%)	223 (46.3%)
Beta-Lactamase Inhibitors	8 (3.3%)	3 (1.2%)	11 (2.3%)
Clavulanic Acid	6 (2.5%)	2 (0.8%)	8 (1.7%)
Tazobactam	3 (1.3%)	2 (0.8%)	5 (1.0%)
Beta-Lactamase Resistant Penicillins	2 (0.8%)	3 (1.2%)	5 (1.0%)
Dicloxacillin Sodium Monohydrate	1 (0.4%)	0	1 (0.2%)
Flucloxacillin	1 (0.4%)	1 (0.4%)	2 (0.4%)
Cloxacillin	0	1 (0.4%)	1 (0.2%)
Nafcillin	0	1 (0.4%)	1 (0.2%)
Carbapenems	6 (2.5%)	12 (5.0%)	18 (3.7%)
Meropenem	3 (1.3%)	4 (1.7%)	7 (1.5%)
Meropenem Trihydrate	2 (0.8%)	2 (0.8%)	4 (0.8%)
Ertapenem	1 (0.4%)	6 (2.5%)	7 (1.5%)
Cilastatin Sodium;imipenem	0	1 (0.4%)	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Ertapenem Sodium	0	1 (0.4%)	1 (0.2%)
Imipenem	0	1 (0.4%)	1 (0.2%)
Combinations Of Antibacterials	0	1 (0.4%)	1 (0.2%)
Ciprofloxacin;tinidazole	0	1 (0.4%)	1 (0.2%)
Combinations Of Penicillins, Incl. Beta-Lactamase Inhibitors	45 (18.8%)	34 (14.0%)	79 (16.4%)
Amoxicillin Sodium;clavulanate Potassium	10 (4.2%)	7 (2.9%)	17 (3.5%)
Amoxicillin Trihydrate;clavulanate Potassium	10 (4.2%)	9 (3.7%)	19 (3.9%)
Amoxicillin;clavulanic Acid	9 (3.8%)	6 (2.5%)	15 (3.1%)
Piperacillin;tazobactam	9 (3.8%)	6 (2.5%)	15 (3.1%)
Piperacillin Sodium;tazobactam Sodium	7 (2.9%)	5 (2.1%)	12 (2.5%)
Ampicillin Sodium;sulbactam Sodium	4 (1.7%)	1 (0.4%)	5 (1.0%)
Amoxicillin;clavulanate Potassium	2 (0.8%)	1 (0.4%)	3 (0.6%)
Amoxicillin Sodium;flucloxacillin Sodium	1 (0.4%)	0	1 (0.2%)
Ampicillin;sulbactam	1 (0.4%)	1 (0.4%)	2 (0.4%)
Combinations Of Sulfonamides And Trimethoprim, Incl. Derivatives	29 (12.1%)	9 (3.7%)	38 (7.9%)
Sulfamethoxazole;trimethoprim	29 (12.1%)	9 (3.7%)	38 (7.9%)
First-Generation Cephalosporins	24 (10.0%)	11 (4.5%)	35 (7.3%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Cefalexin	12 (5.0%)	6 (2.5%)	18 (3.7%)
Cefazolin	7 (2.9%)	2 (0.8%)	9 (1.9%)
Cefazolin Sodium	5 (2.1%)	0	5 (1.0%)
Cefadroxil	3 (1.3%)	2 (0.8%)	5 (1.0%)
Cefalexin Monohydrate	0	1 (0.4%)	1 (0.2%)
Fluoroquinolones	57 (23.8%)	39 (16.1%)	96 (19.9%)
Ciprofloxacin	29 (12.1%)	24 (9.9%)	53 (11.0%)
Levofloxacin	20 (8.3%)	13 (5.4%)	33 (6.8%)
Ciprofloxacin Hydrochloride	8 (3.3%)	3 (1.2%)	11 (2.3%)
Moxifloxacin	4 (1.7%)	1 (0.4%)	5 (1.0%)
Gemifloxacin Mesilate	1 (0.4%)	0	1 (0.2%)
Levofloxacin Hemihydrate	1 (0.4%)	0	1 (0.2%)
Moxifloxacin Hydrochloride	1 (0.4%)	0	1 (0.2%)
Lascufloxacin Hydrochloride	0	1 (0.4%)	1 (0.2%)
Ofloxacin	0	1 (0.4%)	1 (0.2%)
Fourth-Generation Cephalosporins	5 (2.1%)	5 (2.1%)	10 (2.1%)
Cefepime	5 (2.1%)	4 (1.7%)	9 (1.9%)
Cefepime Hydrochloride	0	1 (0.4%)	1 (0.2%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Glycopeptide Antibacterials	6 (2.5%)	6 (2.5%)	12 (2.5%)
Vancomycin	4 (1.7%)	5 (2.1%)	9 (1.9%)
Teicoplanin	1 (0.4%)	1 (0.4%)	2 (0.4%)
Vancomycin Hydrochloride	1 (0.4%)	0	1 (0.2%)
Herbal Antibacterials For Systemic Use	1 (0.4%)	0	1 (0.2%)
Taraxacum Spp. Whole Plant	1 (0.4%)	0	1 (0.2%)
Herbal Urinary Antiseptics And Antiinfectives	1 (0.4%)	2 (0.8%)	3 (0.6%)
Vaccinium Macrocarpon	1 (0.4%)	1 (0.4%)	2 (0.4%)
Copaifera Officinalis	0	1 (0.4%)	1 (0.2%)
Imidazole Derivatives	4 (1.7%)	1 (0.4%)	5 (1.0%)
Metronidazole	4 (1.7%)	1 (0.4%)	5 (1.0%)
Ornidazole	1 (0.4%)	0	1 (0.2%)
Intermediate-Acting Sulfonamides	1 (0.4%)	2 (0.8%)	3 (0.6%)
Sulfamethoxazole	1 (0.4%)	2 (0.8%)	3 (0.6%)
Lincosamides	6 (2.5%)	2 (0.8%)	8 (1.7%)
Clindamycin	5 (2.1%)	2 (0.8%)	7 (1.5%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Clindamycin Phosphate	1 (0.4%)	0	1 (0.2%)
Macrolides	13 (5.4%)	3 (1.2%)	16 (3.3%)
Azithromycin	9 (3.8%)	3 (1.2%)	12 (2.5%)
Clarithromycin	4 (1.7%)	0	4 (0.8%)
Nitrofuran Derivatives	7 (2.9%)	4 (1.7%)	11 (2.3%)
Nitrofurantoin	7 (2.9%)	4 (1.7%)	11 (2.3%)
Not Applicable	1 (0.4%)	0	1 (0.2%)
Penicillin Nos	1 (0.4%)	0	1 (0.2%)
Other Aminoglycosides	4 (1.7%)	4 (1.7%)	8 (1.7%)
Amikacin	3 (1.3%)	3 (1.2%)	6 (1.2%)
Amikacin Sulfate	1 (0.4%)	1 (0.4%)	2 (0.4%)
Gentamicin	0	1 (0.4%)	1 (0.2%)
Other Antibacterials	9 (3.8%)	10 (4.1%)	19 (3.9%)
Linezolid	4 (1.7%)	3 (1.2%)	7 (1.5%)
Fosfomycin	3 (1.3%)	2 (0.8%)	5 (1.0%)
Daptomycin	1 (0.4%)	3 (1.2%)	4 (0.8%)

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Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Fosfomycin Trometamol	1 (0.4%)	2 (0.8%)	3 (0.6%)
Methenamine Hippurate	1 (0.4%)	1 (0.4%)	2 (0.4%)
Penicillins With Extended Spectrum	17 (7.1%)	12 (5.0%)	29 (6.0%)
Amoxicillin	11 (4.6%)	9 (3.7%)	20 (4.1%)
Piperacillin	3 (1.3%)	2 (0.8%)	5 (1.0%)
Amoxicillin Trihydrate	2 (0.8%)	2 (0.8%)	4 (0.8%)
Ampicillin	1 (0.4%)	1 (0.4%)	2 (0.4%)
Piperacillin Sodium	1 (0.4%)	0	1 (0.2%)
Pivmecillinam Hydrochloride	1 (0.4%)	0	1 (0.2%)
Second-Generation Cephalosporins	12 (5.0%)	7 (2.9%)	19 (3.9%)
Cefuroxime	5 (2.1%)	6 (2.5%)	11 (2.3%)
Cefaclor	3 (1.3%)	1 (0.4%)	4 (0.8%)
Cefuroxime Axetil	2 (0.8%)	0	2 (0.4%)
Cefmetazole Sodium	1 (0.4%)	0	1 (0.2%)
Cefoxitin	1 (0.4%)	0	1 (0.2%)
Flomoxef	1 (0.4%)	0	1 (0.2%)
Steroid Antibacterials	1 (0.4%)	0	1 (0.2%)
Fusidic Acid	1 (0.4%)	0	1 (0.2%)

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Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Tetracyclines	12 (5.0%)	3 (1.2%)	15 (3.1%)
Doxycycline	9 (3.8%)	1 (0.4%)	10 (2.1%)
Doxycycline Hyclate	1 (0.4%)	1 (0.4%)	2 (0.4%)
Doxycycline Monohydrate	1 (0.4%)	0	1 (0.2%)
Minocycline Hydrochloride	1 (0.4%)	1 (0.4%)	2 (0.4%)
Third-Generation Cephalosporins	27 (11.3%)	28 (11.6%)	55 (11.4%)
Ceftriaxone	11 (4.6%)	12 (5.0%)	23 (4.8%)
Cefixime	6 (2.5%)	6 (2.5%)	12 (2.5%)
Ceftriaxone Sodium	4 (1.7%)	6 (2.5%)	10 (2.1%)
Ceftriaxone Sodium Sesquaterhydrate	2 (0.8%)	1 (0.4%)	3 (0.6%)
Cefcapene Pivoxil Hydrochloride Hydrate	1 (0.4%)	2 (0.8%)	3 (0.6%)
Cefdinir	1 (0.4%)	0	1 (0.2%)
Cefotaxime Sodium	1 (0.4%)	0	1 (0.2%)
Cefpodoxime	1 (0.4%)	1 (0.4%)	2 (0.4%)
Cefpodoxime Proxetil	1 (0.4%)	1 (0.4%)	2 (0.4%)
Ceftazidime	1 (0.4%)	1 (0.4%)	2 (0.4%)
Ceftibuten	1 (0.4%)	0	1 (0.2%)
Cefcapene Pivoxil Hydrochloride	0	1 (0.4%)	1 (0.2%)
Cefditoren Pivoxil	0	2 (0.8%)	2 (0.4%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Trimethoprim And Derivatives	1 (0.4%)	2 (0.8%)	3 (0.6%)
Trimethoprim	1 (0.4%)	2 (0.8%)	3 (0.6%)
Antibiotics And Chemotherapeutics For Dermatological Use	36 (15.0%)	6 (2.5%)	42 (8.7%)
Antivirals	4 (1.7%)	1 (0.4%)	5 (1.0%)
Aciclovir	3 (1.3%)	1 (0.4%)	4 (0.8%)
Vidarabine	1 (0.4%)	0	1 (0.2%)
Other Antibiotics For Topical Use	31 (12.9%)	5 (2.1%)	36 (7.5%)
Mupirocin	11 (4.6%)	4 (1.7%)	15 (3.1%)
Bacitracin;neomycin Sulfate;polymyxin B Sulfate	4 (1.7%)	1 (0.4%)	5 (1.0%)
Gentamicin	4 (1.7%)	0	4 (0.8%)
Fusidic Acid	3 (1.3%)	0	3 (0.6%)
Gentamicin Sulfate	3 (1.3%)	0	3 (0.6%)
Neomycin;tyrothricin	3 (1.3%)	0	3 (0.6%)
Bacitracin Zinc;neomycin Sulfate;polymyxin B Sulfate	2 (0.8%)	0	2 (0.4%)
Bacitracin Zinc;polymyxin B Sulfate	2 (0.8%)	0	2 (0.4%)
Fusidate Sodium	2 (0.8%)	0	2 (0.4%)
Bacitracin	1 (0.4%)	0	1 (0.2%)
Bacitracin;neomycin Sulfate	1 (0.4%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Chloramphenicol	1 (0.4%)	0	1 (0.2%)
Nadifloxacin	1 (0.4%)	0	1 (0.2%)
Neomycin Sulfate	1 (0.4%)	0	1 (0.2%)
Ofloxacin	1 (0.4%)	0	1 (0.2%)
Other Chemotherapeutics	1 (0.4%)	0	1 (0.2%)
Metronidazole	1 (0.4%)	0	1 (0.2%)
Sulfonamides	3 (1.3%)	0	3 (0.6%)
Sulfadiazine Silver	2 (0.8%)	0	2 (0.4%)
Sulfathiazole Silver	1 (0.4%)	0	1 (0.2%)
Tetracycline And Derivatives	4 (1.7%)	0	4 (0.8%)
Tetracycline	3 (1.3%)	0	3 (0.6%)
Tetracycline Hydrochloride	1 (0.4%)	0	1 (0.2%)
Antidiarrheals, Intestinal Antiinflammatory/Antiinfective Agents	49 (20.4%)	20 (8.3%)	69 (14.3%)
Aminosalicylic Acid And Similar Agents	1 (0.4%)	0	1 (0.2%)
Mesalazine	1 (0.4%)	0	1 (0.2%)
Antibiotics	2 (0.8%)	2 (0.8%)	4 (0.8%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Rifaximin	1 (0.4%)	1 (0.4%)	2 (0.4%)
Vancomycin	1 (0.4%)	1 (0.4%)	2 (0.4%)
Antidiarrheal Microorganisms	9 (3.8%)	7 (2.9%)	16 (3.3%)
Saccharomyces Boulardii	3 (1.3%)	0	3 (0.6%)
Enterococcus Faecalis;escherichia Coli;lactobacillus Acidophilus;lactobacillus Helveticus	2 (0.8%)	0	2 (0.4%)
Lactobacillus Helveticus;lactobacillus Rhamnosus	2 (0.8%)	1 (0.4%)	3 (0.6%)
Bifidobacterium Bifidum;bifidobacterium Breve;bifidobacterium Longum;fructooligosaccharides;lactiplantibacillus Plantarum;lactobacillus Acidophilus;lactobacillus Casei;lactobacillus Rhamnosus; Streptococcus Lactis;streptococcus Thermophilus	1 (0.4%)	0	1 (0.2%)
Bifidobacterium Longum;enterococcus Faecium	1 (0.4%)	0	1 (0.2%)
Lactobacillus Acidophilus;lactobacillus Bulgaricus	1 (0.4%)	0	1 (0.2%)
Probiotics Nos	1 (0.4%)	1 (0.4%)	2 (0.4%)
Bacillus Clausii	0	1 (0.4%)	1 (0.2%)
Bacillus Lichenformis	0	1 (0.4%)	1 (0.2%)
Bacillus Nos	0	1 (0.4%)	1 (0.2%)
Bacillus Subtilis;enterococcus Faecium	0	1 (0.4%)	1 (0.2%)
Bifidobacterium Nos;lactobacillus Nos	0	1 (0.4%)	1 (0.2%)
Lactobacillus Nos	0	1 (0.4%)	1 (0.2%)
Antipropulsives	36 (15.0%)	8 (3.3%)	44 (9.1%)
Loperamide	19 (7.9%)	5 (2.1%)	24 (5.0%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Loperamide Hydrochloride	18 (7.5%)	3 (1.2%)	21 (4.4%)
Atropine Sulfate;diphenoxylate Hydrochloride	1 (0.4%)	0	1 (0.2%)
Atropine;diphenoxylate	1 (0.4%)	0	1 (0.2%)
Corticosteroids Acting Locally	15 (6.3%)	1 (0.4%)	16 (3.3%)
Prednisone	11 (4.6%)	0	11 (2.3%)
Prednisolone	5 (2.1%)	0	5 (1.0%)
Beclometasone Dipropionate	0	1 (0.4%)	1 (0.2%)
Imidazole Derivatives	1 (0.4%)	0	1 (0.2%)
Ciprofloxacin Hydrochloride;tinidazole	1 (0.4%)	0	1 (0.2%)
Not Applicable	0	1 (0.4%)	1 (0.2%)
Lactomin	0	1 (0.4%)	1 (0.2%)
Oral Rehydration Salt Formulations	1 (0.4%)	1 (0.4%)	2 (0.4%)
Oral Rehydration Salt Formulations	1 (0.4%)	1 (0.4%)	2 (0.4%)
Other Antidiarrheals	2 (0.8%)	0	2 (0.4%)
Colestyramine	1 (0.4%)	0	1 (0.2%)
Racecadotril	1 (0.4%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Other Intestinal Adsorbents	5 (2.1%)	2 (0.8%)	7 (1.5%)
Diosmectite	5 (2.1%)	2 (0.8%)	7 (1.5%)
Antiemetics And Antinauseants	85 (35.4%)	187 (77.3%)	272 (56.4%)
Herbal Antiemetics Containing Cannabinoids	0	1 (0.4%)	1 (0.2%)
Cannabis Sativa	0	1 (0.4%)	1 (0.2%)
Not Applicable	37 (15.4%)	81 (33.5%)	118 (24.5%)
Metoclopramide	27 (11.3%)	60 (24.8%)	87 (18.0%)
Metoclopramide Hydrochloride	12 (5.0%)	23 (9.5%)	35 (7.3%)
Alizapride	0	1 (0.4%)	1 (0.2%)
Alizapride Hydrochloride	0	2 (0.8%)	2 (0.4%)
Other Antiemetics	24 (10.0%)	106 (43.8%)	130 (27.0%)
Prochlorperazine	13 (5.4%)	18 (7.4%)	31 (6.4%)
Prochlorperazine Maleate	6 (2.5%)	10 (4.1%)	16 (3.3%)
Dimenhydrinate	2 (0.8%)	1 (0.4%)	3 (0.6%)
Butylscopolamine	1 (0.4%)	0	1 (0.2%)
Domperidone	1 (0.4%)	0	1 (0.2%)
Doxylamine Succinate;folic Acid;pyridoxine Hydrochloride	1 (0.4%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Rolapitant	1 (0.4%)	1 (0.4%)	2 (0.4%)
Trimethobenzamide Hydrochloride	1 (0.4%)	0	1 (0.2%)
Aprepitant	0	66 (27.3%)	66 (13.7%)
Chlorpromazine	0	2 (0.8%)	2 (0.4%)
Chlorpromazine Hydrochloride	0	1 (0.4%)	1 (0.2%)
Cyclizine	0	2 (0.8%)	2 (0.4%)
Difenidol Hydrochloride	0	1 (0.4%)	1 (0.2%)
Diphenhydramine	0	1 (0.4%)	1 (0.2%)
Diphenhydramine Hydrochloride	0	1 (0.4%)	1 (0.2%)
Fosaprepitant	0	6 (2.5%)	6 (1.2%)
Fosaprepitant Meglumine	0	5 (2.1%)	5 (1.0%)
Levosulpiride	0	2 (0.8%)	2 (0.4%)
Netupitant	0	5 (2.1%)	5 (1.0%)
Serotonin (5ht3) Antagonists	45 (18.8%)	174 (71.9%)	219 (45.4%)
Ondansetron	29 (12.1%)	91 (37.6%)	120 (24.9%)
Ondansetron Hydrochloride	13 (5.4%)	26 (10.7%)	39 (8.1%)
Granisetron	2 (0.8%)	19 (7.9%)	21 (4.4%)
Granisetron Hydrochloride	1 (0.4%)	8 (3.3%)	9 (1.9%)
Ramosetron Hydrochloride	1 (0.4%)	0	1 (0.2%)
Netupitant;palonosetron	0	8 (3.3%)	8 (1.7%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Netupitant;palonosetron Hydrochloride	0	23 (9.5%)	23 (4.8%)
Palonosetron	0	23 (9.5%)	23 (4.8%)
Palonosetron Hydrochloride	0	15 (6.2%)	15 (3.1%)
Antiepileptics	3 (1.3%)	4 (1.7%)	7 (1.5%)
Benzodiazepine Derivatives	1 (0.4%)	0	1 (0.2%)
Clonazepam	1 (0.4%)	0	1 (0.2%)
Other Antiepileptics	3 (1.3%)	4 (1.7%)	7 (1.5%)
Levetiracetam	2 (0.8%)	3 (1.2%)	5 (1.0%)
Perampanel	1 (0.4%)	0	1 (0.2%)
Pregabalin	0	1 (0.4%)	1 (0.2%)
Antifungals For Dermatological Use	17 (7.1%)	7 (2.9%)	24 (5.0%)
Antibiotics	2 (0.8%)	1 (0.4%)	3 (0.6%)
Nystatin	1 (0.4%)	1 (0.4%)	2 (0.4%)
Nystatin;triamcinolone Acetonide	1 (0.4%)	0	1 (0.2%)
Antifungals For Systemic Use	1 (0.4%)	1 (0.4%)	2 (0.4%)
Terbinafine	1 (0.4%)	0	1 (0.2%)
Terbinafine Hydrochloride	0	1 (0.4%)	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Imidazole And Triazole Derivatives	10 (4.2%)	5 (2.1%)	15 (3.1%)
Ketoconazole	2 (0.8%)	0	2 (0.4%)
Sertaconazole Nitrate	2 (0.8%)	0	2 (0.4%)
Betamethasone Dipropionate;clotrimazole	1 (0.4%)	0	1 (0.2%)
Betamethasone;clotrimazole	1 (0.4%)	0	1 (0.2%)
Clotrimazole	1 (0.4%)	1 (0.4%)	2 (0.4%)
Econazole Nitrate	1 (0.4%)	0	1 (0.2%)
Miconazole	1 (0.4%)	2 (0.8%)	3 (0.6%)
Sertaconazole	1 (0.4%)	1 (0.4%)	2 (0.4%)
Econazole	0	1 (0.4%)	1 (0.2%)
Efinaconazole	0	1 (0.4%)	1 (0.2%)
Other Antifungals For Topical Use	5 (2.1%)	1 (0.4%)	6 (1.2%)
Butenafine Hydrochloride	2 (0.8%)	0	2 (0.4%)
Terbinafine	1 (0.4%)	0	1 (0.2%)
Terbinafine Hydrochloride	1 (0.4%)	1 (0.4%)	2 (0.4%)
Urea	1 (0.4%)	0	1 (0.2%)
Antigout Preparations	16 (6.7%)	7 (2.9%)	23 (4.8%)
Preparations Inhibiting Uric Acid Production	14 (5.8%)	7 (2.9%)	21 (4.4%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Allopurinol	10 (4.2%)	5 (2.1%)	15 (3.1%)
Febuxostat	4 (1.7%)	2 (0.8%)	6 (1.2%)
Topiroxostat	1 (0.4%)	0	1 (0.2%)
Preparations With No Effect On Uric Acid Metabolism	4 (1.7%)	2 (0.8%)	6 (1.2%)
Colchicine	4 (1.7%)	2 (0.8%)	6 (1.2%)
Antihemorrhagics	8 (3.3%)	7 (2.9%)	15 (3.1%)
Amino Acids	5 (2.1%)	3 (1.2%)	8 (1.7%)
Tranexamic Acid	5 (2.1%)	3 (1.2%)	8 (1.7%)
Other Systemic Hemostatics	1 (0.4%)	5 (2.1%)	6 (1.2%)
Etamsilate	1 (0.4%)	3 (1.2%)	4 (0.8%)
Carbazochrome Sodium Sulfonate Trihydrate	0	2 (0.8%)	2 (0.4%)
Proteinase Inhibitors	1 (0.4%)	0	1 (0.2%)
Camostat Mesilate	1 (0.4%)	0	1 (0.2%)
Vitamin K	1 (0.4%)	0	1 (0.2%)
Vitamin K Nos	1 (0.4%)	0	1 (0.2%)
Antihistamines For Systemic Use	130 (54.2%)	42 (17.4%)	172 (35.7%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Aminoalkyl Ethers	22 (9.2%)	8 (3.3%)	30 (6.2%)
Diphenhydramine Hydrochloride	14 (5.8%)	1 (0.4%)	15 (3.1%)
Diphenhydramine	7 (2.9%)	7 (2.9%)	14 (2.9%)
Piprinhydrinate	1 (0.4%)	0	1 (0.2%)
Other Antihistamines For Systemic Use	82 (34.2%)	16 (6.6%)	98 (20.3%)
Loratadine	21 (8.8%)	6 (2.5%)	27 (5.6%)
Fexofenadine Hydrochloride	17 (7.1%)	4 (1.7%)	21 (4.4%)
Desloratadine	13 (5.4%)	1 (0.4%)	14 (2.9%)
Ebastine	11 (4.6%)	1 (0.4%)	12 (2.5%)
Bilastine	10 (4.2%)	1 (0.4%)	11 (2.3%)
Fexofenadine	9 (3.8%)	1 (0.4%)	10 (2.1%)
Bepotastine Besilate	5 (2.1%)	0	5 (1.0%)
Olopatadine Hydrochloride	5 (2.1%)	0	5 (1.0%)
Cyproheptadine Hydrochloride	3 (1.3%)	0	3 (0.6%)
Cyproheptadine	2 (0.8%)	0	2 (0.4%)
Epinastine Hydrochloride	2 (0.8%)	1 (0.4%)	3 (0.6%)
Rupatadine Fumarate	2 (0.8%)	1 (0.4%)	3 (0.6%)
Bepotastine	1 (0.4%)	0	1 (0.2%)
Ketotifen	1 (0.4%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Olopatadine	0	1 (0.4%)	1 (0.2%)
Phenothiazine Derivatives	4 (1.7%)	1 (0.4%)	5 (1.0%)
Mequitazine	2 (0.8%)	0	2 (0.4%)
Promethazine Hydrochloride	1 (0.4%)	0	1 (0.2%)
Thiethylperazine Maleate	1 (0.4%)	0	1 (0.2%)
Promethazine Methylene Disalicylate	0	1 (0.4%)	1 (0.2%)
Piperazine Derivatives	64 (26.7%)	14 (5.8%)	78 (16.2%)
Levocetirizine Dihydrochloride	16 (6.7%)	1 (0.4%)	17 (3.5%)
Cetirizine	14 (5.8%)	5 (2.1%)	19 (3.9%)
Hydroxyzine	13 (5.4%)	1 (0.4%)	14 (2.9%)
Levocetirizine	13 (5.4%)	3 (1.2%)	16 (3.3%)
Cetirizine Hydrochloride	10 (4.2%)	3 (1.2%)	13 (2.7%)
Hydroxyzine Hydrochloride	10 (4.2%)	1 (0.4%)	11 (2.3%)
Buclizine Hydrochloride	2 (0.8%)	0	2 (0.4%)
Substituted Alkylamines	29 (12.1%)	13 (5.4%)	42 (8.7%)
Chlorphenamine Maleate	10 (4.2%)	6 (2.5%)	16 (3.3%)
Chlorphenamine	9 (3.8%)	2 (0.8%)	11 (2.3%)
Dexchlorpheniramine Maleate	6 (2.5%)	1 (0.4%)	7 (1.5%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Dexchlorpheniramine	4 (1.7%)	1 (0.4%)	5 (1.0%)
Dimetindene Maleate	2 (0.8%)	0	2 (0.4%)
Pheniramine	0	1 (0.4%)	1 (0.2%)
Pheniramine Maleate	0	2 (0.8%)	2 (0.4%)
Substituted Ethylene Diamines	5 (2.1%)	1 (0.4%)	6 (1.2%)
Chloropyramine	4 (1.7%)	0	4 (0.8%)
Chloropyramine Hydrochloride	1 (0.4%)	1 (0.4%)	2 (0.4%)
Antihypertensives	7 (2.9%)	6 (2.5%)	13 (2.7%)
Alpha-Adrenoreceptor Antagonists	5 (2.1%)	3 (1.2%)	8 (1.7%)
Doxazosin	3 (1.3%)	1 (0.4%)	4 (0.8%)
Prazosin	1 (0.4%)	0	1 (0.2%)
Terazosin Hydrochloride	1 (0.4%)	0	1 (0.2%)
Doxazosin Mesilate	0	2 (0.8%)	2 (0.4%)
Hydrazinophthalazine Derivatives	2 (0.8%)	1 (0.4%)	3 (0.6%)
Hydralazine	2 (0.8%)	1 (0.4%)	3 (0.6%)
Imidazoline Receptor Agonists	0	2 (0.8%)	2 (0.4%)
Clonidine Hydrochloride	0	1 (0.4%)	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Rilmenidine Phosphate	0	1 (0.4%)	1 (0.2%)
Antiinflammatory And Antirheumatic Products	75 (31.3%)	43 (17.8%)	118 (24.5%)
Acetic Acid Derivatives And Related Substances	18 (7.5%)	7 (2.9%)	25 (5.2%)
Diclofenac	4 (1.7%)	2 (0.8%)	6 (1.2%)
Diclofenac Sodium	4 (1.7%)	2 (0.8%)	6 (1.2%)
Ketorolac	4 (1.7%)	1 (0.4%)	5 (1.0%)
Aceclofenac	3 (1.3%)	0	3 (0.6%)
Ketorolac Tromethamine	2 (0.8%)	1 (0.4%)	3 (0.6%)
Acemetacin	1 (0.4%)	1 (0.4%)	2 (0.4%)
Diclofenac Potassium	0	1 (0.4%)	1 (0.2%)
Coxibs	7 (2.9%)	4 (1.7%)	11 (2.3%)
Celecoxib	4 (1.7%)	2 (0.8%)	6 (1.2%)
Etoricoxib	3 (1.3%)	2 (0.8%)	5 (1.0%)
Fenamates	1 (0.4%)	0	1 (0.2%)
Mefenamic Acid	1 (0.4%)	0	1 (0.2%)
Herbal Antiinflammatory And Antirheumatic Remedies	3 (1.3%)	2 (0.8%)	5 (1.0%)
Angelica Sinensis Root;atractylodes Macrocephala Rhizome;calcium Sulfate Dihydrate;ephedra Spp. Herb;forsythia Suspensa Fruit;gardenia Jasminoides;glycyrrhiza Spp. Root With Rhizome;ligusticum	1 (0.4%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Chuanxiong Rhizome;mentha Canadensis Herb;mirabilite;nepeta Tenuifolia Spike;paeonia Lactiflora Root;platycodon Grandiflorus Root;rheum Spp. Root With Rhizome;saposhnikovia Divaricata Root; Scutellaria Baicalensis Root;talc			
Arnica Montana	1 (0.4%)	0	1 (0.2%)
Linum Usitatissimum Seed Oil	1 (0.4%)	0	1 (0.2%)
Glycyrrhiza Spp. Root;paeonia Lactiflora Root	0	2 (0.8%)	2 (0.4%)
Other Antiinflammatory And Antirheumatic Agents, Non-Steroids	4 (1.7%)	3 (1.2%)	7 (1.5%)
Ademetionine	1 (0.4%)	0	1 (0.2%)
Chondroitin Sulfate Sodium	1 (0.4%)	0	1 (0.2%)
Chondroitin;glucosamine	1 (0.4%)	0	1 (0.2%)
Glucosamine	1 (0.4%)	1 (0.4%)	2 (0.4%)
Nimesulide	0	2 (0.8%)	2 (0.4%)
Other Antiinflammatory/Antirheumatic Agents In Combination With Other Drugs	1 (0.4%)	0	1 (0.2%)
Fenpiverinium Bromide;ibuprofen;pitofenone Hydrochloride	1 (0.4%)	0	1 (0.2%)
Oxicams	3 (1.3%)	0	3 (0.6%)
Meloxicam	3 (1.3%)	0	3 (0.6%)
Propionic Acid Derivatives	47 (19.6%)	32 (13.2%)	79 (16.4%)
Ibuprofen	25 (10.4%)	16 (6.6%)	41 (8.5%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Dexketoprofen	6 (2.5%)	4 (1.7%)	10 (2.1%)
Dexketoprofen Trometamol	5 (2.1%)	1 (0.4%)	6 (1.2%)
Naproxen	5 (2.1%)	7 (2.9%)	12 (2.5%)
Loxoprofen Sodium Dihydrate	3 (1.3%)	2 (0.8%)	5 (1.0%)
Ketoprofen	2 (0.8%)	1 (0.4%)	3 (0.6%)
Esomeprazole Magnesium;naproxen	1 (0.4%)	1 (0.4%)	2 (0.4%)
Flurbiprofen	1 (0.4%)	0	1 (0.2%)
Flurbiprofen Axetil	1 (0.4%)	0	1 (0.2%)
Ibuprofen;pseudoephedrine Hydrochloride	1 (0.4%)	0	1 (0.2%)
Loxoprofen Sodium	1 (0.4%)	1 (0.4%)	2 (0.4%)
Naproxen Sodium	1 (0.4%)	0	1 (0.2%)
Zaltoprofen	1 (0.4%)	0	1 (0.2%)
Loxoprofen	0	1 (0.4%)	1 (0.2%)
Antimycobacterials	0	1 (0.4%)	1 (0.2%)
Hydrazides	0	1 (0.4%)	1 (0.2%)
Isoniazid	0	1 (0.4%)	1 (0.2%)
Antimycotics For Systemic Use	11 (4.6%)	7 (2.9%)	18 (3.7%)
Antibiotics	2 (0.8%)	3 (1.2%)	5 (1.0%)
Nystatin	2 (0.8%)	3 (1.2%)	5 (1.0%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Imidazole Derivatives	1 (0.4%)	0	1 (0.2%)
Miconazole	1 (0.4%)	0	1 (0.2%)
Other Antimycotics For Systemic Use	1 (0.4%)	0	1 (0.2%)
Micafungin	1 (0.4%)	0	1 (0.2%)
Triazole And Tetrazole Derivatives	9 (3.8%)	6 (2.5%)	15 (3.1%)
Fluconazole	9 (3.8%)	6 (2.5%)	15 (3.1%)
Voriconazole	1 (0.4%)	0	1 (0.2%)
Antiprotozoals	4 (1.7%)	0	4 (0.8%)
Nitroimidazole Derivatives	1 (0.4%)	0	1 (0.2%)
Clotrimazole	1 (0.4%)	0	1 (0.2%)
Other Agents Against Amoebiasis And Other Protozoal Diseases	3 (1.3%)	0	3 (0.6%)
Atovaquone	3 (1.3%)	0	3 (0.6%)
Antipruritics, Incl. Antihistamines, Anesthetics, Etc.	29 (12.1%)	2 (0.8%)	31 (6.4%)
Anesthetics For Topical Use	4 (1.7%)	1 (0.4%)	5 (1.0%)
Cinchocaine Hydrochloride;diphenhydramine;zinc Oxide	3 (1.3%)	0	3 (0.6%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Benzocaine;chlorphenamine Maleate	2 (0.8%)	0	2 (0.4%)
Chlorhexidine;lidocaine	1 (0.4%)	0	1 (0.2%)
Dexpanthenol;lidocaine Hydrochloride;mepyramine Maleate	0	1 (0.4%)	1 (0.2%)
Antihistamines For Topical Use	12 (5.0%)	1 (0.4%)	13 (2.7%)
Dimetindene Maleate	4 (1.7%)	0	4 (0.8%)
Diphenhydramine	3 (1.3%)	0	3 (0.6%)
Diphenhydramine Hydrochloride	2 (0.8%)	1 (0.4%)	3 (0.6%)
Dimetindene	1 (0.4%)	0	1 (0.2%)
Hydroxyzine	1 (0.4%)	0	1 (0.2%)
Pheniramine Maleate	1 (0.4%)	0	1 (0.2%)
Herbal Antipruritics	1 (0.4%)	0	1 (0.2%)
Sophora Flavescens	1 (0.4%)	0	1 (0.2%)
Not Applicable	4 (1.7%)	0	4 (0.8%)
Antipruritics, Incl. Antihistamines, Anesthetics, Etc.	2 (0.8%)	0	2 (0.4%)
Camphor;chlorphenamine Maleate;lidocaine Hydrochloride;menthol;methyl Salicylate	1 (0.4%)	0	1 (0.2%)
Cetirizine	1 (0.4%)	0	1 (0.2%)
Other Antipruritics	10 (4.2%)	0	10 (2.1%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Calamine	3 (1.3%)	0	3 (0.6%)
Camphor;menthol	3 (1.3%)	0	3 (0.6%)
Doxepin	2 (0.8%)	0	2 (0.4%)
Calamine;zinc Oxide	1 (0.4%)	0	1 (0.2%)
Crotamiton	1 (0.4%)	0	1 (0.2%)
Doxepin Hydrochloride	1 (0.4%)	0	1 (0.2%)
Antipsoriatics	2 (0.8%)	0	2 (0.4%)
Other Antipsoriatics For Topical Use	1 (0.4%)	0	1 (0.2%)
Betamethasone;calcipotriol	1 (0.4%)	0	1 (0.2%)
Tars	1 (0.4%)	0	1 (0.2%)
Coal Tar	1 (0.4%)	0	1 (0.2%)
Antiseptics And Disinfectants	4 (1.7%)	7 (2.9%)	11 (2.3%)
Biguanides And Amidines	3 (1.3%)	0	3 (0.6%)
Chlorhexidine	2 (0.8%)	0	2 (0.4%)
Chlorhexidine Gluconate	1 (0.4%)	0	1 (0.2%)
Iodine Products	2 (0.8%)	5 (2.1%)	7 (1.5%)
Povidone-Iodine	2 (0.8%)	5 (2.1%)	7 (1.5%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Not Applicable	0	1 (0.4%)	1 (0.2%)
Calcium Chloride Dihydrate;polihexanide;potassium Chloride;sodium Chloride	0	1 (0.4%)	1 (0.2%)
Other Antiseptics And Disinfectants	0	1 (0.4%)	1 (0.2%)
Hypochlorous Acid	0	1 (0.4%)	1 (0.2%)
Antithrombotic Agents	89 (37.1%)	99 (40.9%)	188 (39.0%)
Direct Factor Xa Inhibitors	20 (8.3%)	36 (14.9%)	56 (11.6%)
Apixaban	15 (6.3%)	21 (8.7%)	36 (7.5%)
Rivaroxaban	3 (1.3%)	16 (6.6%)	19 (3.9%)
Edoxaban	1 (0.4%)	2 (0.8%)	3 (0.6%)
Edoxaban Tosilate	1 (0.4%)	1 (0.4%)	2 (0.4%)
Enzymes	2 (0.8%)	1 (0.4%)	3 (0.6%)
Lumbrokinase	1 (0.4%)	0	1 (0.2%)
Urokinase	1 (0.4%)	0	1 (0.2%)
Alteplase	0	1 (0.4%)	1 (0.2%)
Heparin Group	40 (16.7%)	43 (17.8%)	83 (17.2%)
Enoxaparin	11 (4.6%)	16 (6.6%)	27 (5.6%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Enoxaparin Sodium	9 (3.8%)	13 (5.4%)	22 (4.6%)
Heparin	7 (2.9%)	5 (2.1%)	12 (2.5%)
Bemiparin Sodium	4 (1.7%)	1 (0.4%)	5 (1.0%)
Heparin Sodium	4 (1.7%)	1 (0.4%)	5 (1.0%)
Tinzaparin	3 (1.3%)	2 (0.8%)	5 (1.0%)
Tinzaparin Sodium	3 (1.3%)	2 (0.8%)	5 (1.0%)
Bemiparin	2 (0.8%)	1 (0.4%)	3 (0.6%)
Dalteparin Sodium	2 (0.8%)	4 (1.7%)	6 (1.2%)
Dalteparin	1 (0.4%)	2 (0.8%)	3 (0.6%)
Heparin Porcine	1 (0.4%)	1 (0.4%)	2 (0.4%)
Nadroparin	1 (0.4%)	0	1 (0.2%)
Certoparin Sodium	0	1 (0.4%)	1 (0.2%)
Heparin Sodium Porcine	0	1 (0.4%)	1 (0.2%)
Other Antithrombotic Agents	0	1 (0.4%)	1 (0.2%)
Fondaparinux Sodium	0	1 (0.4%)	1 (0.2%)
Platelet Aggregation Inhibitors Excl. Heparin	43 (17.9%)	40 (16.5%)	83 (17.2%)
Acetylsalicylic Acid	33 (13.8%)	38 (15.7%)	71 (14.7%)
Clopidogrel	8 (3.3%)	3 (1.2%)	11 (2.3%)
Acetylsalicylic Acid;magnesium Hydroxide	2 (0.8%)	1 (0.4%)	3 (0.6%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Acetylsalicylate Lysine	1 (0.4%)	0	1 (0.2%)
Clopidogrel Bisulfate	1 (0.4%)	0	1 (0.2%)
Dipyridamole	1 (0.4%)	0	1 (0.2%)
Limaprost	1 (0.4%)	0	1 (0.2%)
Prasugrel Hydrochloride	0	1 (0.4%)	1 (0.2%)
Vitamin K Antagonists	2 (0.8%)	1 (0.4%)	3 (0.6%)
Acenocoumarol	1 (0.4%)	0	1 (0.2%)
Warfarin Sodium	1 (0.4%)	0	1 (0.2%)
Warfarin Potassium	0	1 (0.4%)	1 (0.2%)
Antivirals For Systemic Use	20 (8.3%)	13 (5.4%)	33 (6.8%)
Neuraminidase Inhibitors	1 (0.4%)	0	1 (0.2%)
Oseltamivir	1 (0.4%)	0	1 (0.2%)
Nucleoside And Nucleotide Reverse Transcriptase Inhibitors	1 (0.4%)	0	1 (0.2%)
Tenofovir Alafenamide Fumarate	1 (0.4%)	0	1 (0.2%)
Nucleosides And Nucleotides Excl. Reverse Transcriptase Inhibitors	15 (6.3%)	9 (3.7%)	24 (5.0%)
Molnupiravir	3 (1.3%)	2 (0.8%)	5 (1.0%)
Remdesivir	3 (1.3%)	2 (0.8%)	5 (1.0%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Valaciclovir	3 (1.3%)	1 (0.4%)	4 (0.8%)
Aciclovir	2 (0.8%)	1 (0.4%)	3 (0.6%)
Famciclovir	2 (0.8%)	0	2 (0.4%)
Valaciclovir Hydrochloride	2 (0.8%)	3 (1.2%)	5 (1.0%)
Other Antivirals	2 (0.8%)	1 (0.4%)	3 (0.6%)
Lysozyme	1 (0.4%)	0	1 (0.2%)
Umifenovir	1 (0.4%)	0	1 (0.2%)
Favipiravir	0	1 (0.4%)	1 (0.2%)
Protease Inhibitors	2 (0.8%)	3 (1.2%)	5 (1.0%)
Nirmatrelvir;ritonavir	2 (0.8%)	2 (0.8%)	4 (0.8%)
Nirmatrelvir	0	1 (0.4%)	1 (0.2%)
Ritonavir	0	1 (0.4%)	1 (0.2%)
Appetite Stimulants	18 (7.5%)	14 (5.8%)	32 (6.6%)
Herbal Appetite Stimulants	1 (0.4%)	0	1 (0.2%)
Cannabis Sativa	1 (0.4%)	0	1 (0.2%)
Not Applicable	17 (7.1%)	14 (5.8%)	31 (6.4%)
Megestrol Acetate	13 (5.4%)	8 (3.3%)	21 (4.4%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Megestrol	3 (1.3%)	4 (1.7%)	7 (1.5%)
Carnitine Hydrochloride;cyanocobalamin;cyproheptadine Orotate;lysine Hydrochloride	1 (0.4%)	0	1 (0.2%)
Dronabinol	1 (0.4%)	2 (0.8%)	3 (0.6%)
Beta Blocking Agents	40 (16.7%)	45 (18.6%)	85 (17.6%)
Alpha And Beta Blocking Agents	5 (2.1%)	4 (1.7%)	9 (1.9%)
Carvedilol	4 (1.7%)	3 (1.2%)	7 (1.5%)
Arotinolol	1 (0.4%)	0	1 (0.2%)
Labetalol	0	1 (0.4%)	1 (0.2%)
Beta Blocking Agents, Non-Selective	2 (0.8%)	2 (0.8%)	4 (0.8%)
Propranolol	1 (0.4%)	1 (0.4%)	2 (0.4%)
Sotalol	1 (0.4%)	1 (0.4%)	2 (0.4%)
Beta Blocking Agents, Selective	34 (14.2%)	40 (16.5%)	74 (15.4%)
Bisoprolol	14 (5.8%)	14 (5.8%)	28 (5.8%)
Atenolol	4 (1.7%)	2 (0.8%)	6 (1.2%)
Bisoprolol Fumarate	4 (1.7%)	9 (3.7%)	13 (2.7%)
Metoprolol Succinate	4 (1.7%)	5 (2.1%)	9 (1.9%)
Metoprolol Tartrate	3 (1.3%)	3 (1.2%)	6 (1.2%)
Nebivolol	3 (1.3%)	3 (1.2%)	6 (1.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Metoprolol	2 (0.8%)	5 (2.1%)	7 (1.5%)
Nebivolol Hydrochloride	2 (0.8%)	2 (0.8%)	4 (0.8%)
Betaxolol Hydrochloride	1 (0.4%)	0	1 (0.2%)
Beta Blocking Agents, Selective, And Other Diuretics	0	1 (0.4%)	1 (0.2%)
Atenolol;chlortalidone	0	1 (0.4%)	1 (0.2%)
Bile And Liver Therapy	14 (5.8%)	1 (0.4%)	15 (3.1%)
Bile Acids And Derivatives	8 (3.3%)	0	8 (1.7%)
Ursodeoxycholic Acid	8 (3.3%)	0	8 (1.7%)
Liver Therapy	8 (3.3%)	0	8 (1.7%)
Allium Sativum Oil;dimethyl 4,4'-Biphenyldicarboxylate	3 (1.3%)	0	3 (0.6%)
Silybum Marianum	3 (1.3%)	0	3 (0.6%)
Ornithine Aspartate	2 (0.8%)	0	2 (0.4%)
Adenine Hydrochloride;bifendate;carnitine Orotate;cyanocobalamin;liver;pyridoxine Hydrochloride;riboflavin	1 (0.4%)	0	1 (0.2%)
Adenine Hydrochloride;carnitine Orotate;cyanocobalamin;liver;pyridoxine Hydrochloride;riboflavin	1 (0.4%)	0	1 (0.2%)
Glycyrrhizic Acid;phospholipids	1 (0.4%)	0	1 (0.2%)
Phospholipids Soybean	1 (0.4%)	0	1 (0.2%)
Not Applicable	0	1 (0.4%)	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Bicyclol	0	1 (0.4%)	1 (0.2%)
Other Drugs For Bile Therapy	1 (0.4%)	0	1 (0.2%)
Drotaverine	1 (0.4%)	0	1 (0.2%)
Blood Substitutes And Perfusion Solutions	53 (22.1%)	77 (31.8%)	130 (27.0%)
Amino Acids	1 (0.4%)	0	1 (0.2%)
Alanyl Glutamine	1 (0.4%)	0	1 (0.2%)
Blood Substitutes And Plasma Protein Fractions	3 (1.3%)	0	3 (0.6%)
Albumin Human	3 (1.3%)	0	3 (0.6%)
Electrolyte Solutions	8 (3.3%)	6 (2.5%)	14 (2.9%)
Calcium Gluconate	4 (1.7%)	2 (0.8%)	6 (1.2%)
Magnesium Sulfate;potassium Chloride;sodium Chloride	1 (0.4%)	3 (1.2%)	4 (0.8%)
Sodium Phosphate Dibasic	1 (0.4%)	0	1 (0.2%)
Sodium Phosphate Dibasic;sodium Phosphate Monobasic	1 (0.4%)	1 (0.4%)	2 (0.4%)
Sodium Phosphate Dibasic;sodium Phosphate Monobasic (Anhydrous)	1 (0.4%)	0	1 (0.2%)
Calcium Chloride	0	1 (0.4%)	1 (0.2%)
Not Applicable	2 (0.8%)	2 (0.8%)	4 (0.8%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Carbohydrates Nos;potassium Chloride;sodium Chloride;sodium Lactate	2 (0.8%)	2 (0.8%)	4 (0.8%)
Other Irrigating Solutions	0	2 (0.8%)	2 (0.4%)
Sorbitol	0	2 (0.8%)	2 (0.4%)
Salt Solutions	2 (0.8%)	0	2 (0.4%)
Glucose;sodium Bicarbonate	1 (0.4%)	0	1 (0.2%)
Sodium Chloride	1 (0.4%)	0	1 (0.2%)
Solutions Affecting The Electrolyte Balance	46 (19.2%)	64 (26.4%)	110 (22.8%)
Sodium Chloride	34 (14.2%)	39 (16.1%)	73 (15.1%)
Calcium Chloride Dihydrate;potassium Chloride;sodium Chloride;sodium Lactate	9 (3.8%)	2 (0.8%)	11 (2.3%)
Magnesium Sulfate	9 (3.8%)	24 (9.9%)	33 (6.8%)
Potassium Chloride	9 (3.8%)	11 (4.5%)	20 (4.1%)
Calcium Chloride Dihydrate;glucose;potassium Chloride;sodium Chloride;sodium Lactate	3 (1.3%)	0	3 (0.6%)
Gluconate Sodium;magnesium Chloride;potassium Chloride;sodium Acetate Trihydrate;sodium Chloride	2 (0.8%)	0	2 (0.4%)
Glucose;sodium Chloride	2 (0.8%)	1 (0.4%)	3 (0.6%)
Sodium Bicarbonate	2 (0.8%)	1 (0.4%)	3 (0.6%)
Calcium Acetate;magnesium Acetate Tetrahydrate;potassium Acetate;sodium Acetate Trihydrate;sodium Chloride	1 (0.4%)	1 (0.4%)	2 (0.4%)
Calcium Chloride Dihydrate;maltose Monohydrate;potassium Chloride;sodium Chloride;sodium Lactate	1 (0.4%)	1 (0.4%)	2 (0.4%)
Calcium Chloride Dihydrate;potassium Chloride;sodium Acetate Trihydrate;sodium Chloride	1 (0.4%)	4 (1.7%)	5 (1.0%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Calcium Chloride;potassium Chloride;sodium Chloride	1 (0.4%)	1 (0.4%)	2 (0.4%)
Calcium Chloride;potassium Chloride;sodium Chloride;sodium Lactate	1 (0.4%)	0	1 (0.2%)
Calcium Chloride;potassium Chloride;sodium Chloride;sodium Lactate;sorbitol	1 (0.4%)	0	1 (0.2%)
Calcium Gluconate Monohydrate;glucose;magnesium Chloride Hexahydrate;potassium Chloride;sodium Acetate;sodium Chloride;sodium Citrate Dihydrate	1 (0.4%)	0	1 (0.2%)
Gluconate Sodium;magnesium Chloride Hexahydrate;potassium Chloride;sodium Acetate Trihydrate;sodium Chloride	1 (0.4%)	2 (0.8%)	3 (0.6%)
Gluconate Sodium;magnesium Chloride;potassium Chloride;sodium Acetate;sodium Chloride	1 (0.4%)	1 (0.4%)	2 (0.4%)
Glucose Monohydrate;sodium Chloride	1 (0.4%)	1 (0.4%)	2 (0.4%)
Potassium Acetate	1 (0.4%)	0	1 (0.2%)
Potassium Chloride;sodium Chloride	1 (0.4%)	3 (1.2%)	4 (0.8%)
Potassium Phosphate Dibasic;potassium Phosphate Monobasic	1 (0.4%)	2 (0.8%)	3 (0.6%)
Potassium;sodium Chloride	1 (0.4%)	1 (0.4%)	2 (0.4%)
Calcium Chloride Dihydrate;glucose;potassium Chloride;sodium Acetate;sodium Chloride	0	1 (0.4%)	1 (0.2%)
Calcium Chloride Dihydrate;glucose;potassium Chloride;sodium Lactate	0	1 (0.4%)	1 (0.2%)
Calcium Chloride Dihydrate;magnesium Chloride Hexahydrate;potassium Chloride;sodium Chloride;sodium Lactate	0	2 (0.8%)	2 (0.4%)
Calcium Chloride;potassium Chloride;sodium Acetate	0	1 (0.4%)	1 (0.2%)
Calcium Chloride;potassium Chloride;sodium Lactate	0	2 (0.8%)	2 (0.4%)
Electrolytes Nos	0	1 (0.4%)	1 (0.2%)
Glucose;magnesium Chloride Hexahydrate;potassium Acetate;potassium Phosphate Monobasic;sodium Acetate;sodium Chloride	0	1 (0.4%)	1 (0.2%)
Glucose;potassium Chloride;sodium Chloride;sodium Lactate	0	1 (0.4%)	1 (0.2%)
Magnesium Chloride;maltose;potassium Chloride;potassium Phosphate Monobasic;sodium Acetate;sodium Chloride	0	1 (0.4%)	1 (0.2%)
Potassium	0	1 (0.4%)	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Sodium L-Lactate	0	1 (0.4%)	1 (0.2%)
Solutions Affecting The Electrolyte Balance	0	3 (1.2%)	3 (0.6%)
Solutions For Parenteral Nutrition	13 (5.4%)	8 (3.3%)	21 (4.4%)
Glucose	5 (2.1%)	6 (2.5%)	11 (2.3%)
Amino Acids Nos;carbohydrates Nos;electrolytes Nos	3 (1.3%)	0	3 (0.6%)
Alanine;arginine Glutamate;aspartic Acid;calcium Chloride Dihydrate;glucose Monohydrate;glutamic Acid;glycine;histidine Hydrochloride;isoleucine;leucine;lysine Hydrochloride;magnesium Acetate Tetrahydrate;methionine;phenylalanine;potassium Hydroxide;potassium Phosphate Monobasic;proline;serine;sodium Acetate Trihydrate;sodium Chloride;sodium Hydroxide;threonine;tryptophan;valine	1 (0.4%)	0	1 (0.2%)
Alanine;arginine Hydrochloride;cysteine Hydrochloride;glycine;histidine Hydrochloride;isoleucine;leucine;lysine Acetate;methionine;phenylalanine;proline;serine;threonine;tryptophan;valine	1 (0.4%)	0	1 (0.2%)
Alanine;arginine;calcium Chloride Dihydrate;fish Oil;glucose Monohydrate;glycine;glycine Max Oil;histidine;isoleucine;leucine;lysine Hydrochloride;magnesium Sulfate Heptahydrate;medium-Chain Triglycerides;methionine;olea Europaea Oil;phenylalanine;potassium Chloride;proline;serine;sodium Acetate Trihydrate;sodium Glycerophosphate;threonine;tryptophan;tyrosine;valine;zinc Sulfate Heptahydrate	1 (0.4%)	1 (0.4%)	2 (0.4%)
Amino Acids Nos;electrolytes Nos;glucose;thiamine Hydrochloride	1 (0.4%)	0	1 (0.2%)
Histidine;isoleucine;leucine;lysine Acetate;methionine;phenylalanine;threonine;tryptophan;valine	1 (0.4%)	0	1 (0.2%)
Solutions For Parenteral Nutrition	1 (0.4%)	0	1 (0.2%)
Alanine;arginine;aspartic Acid;calcium Chloride Dihydrate;glucose;glutamic Acid;glycine;glycine Max Oil;histidine;isoleucine;leucine;lysine Acetate;magnesium Chloride Hexahydrate;methionine;olea Europaea Oil;phenylalanine;potassium Chloride;proline;serine;sodium Acetate Trihydrate;sodium Glycerophosphate;threonine;tryptophan;tyrosine;valine	0	1 (0.4%)	1 (0.2%)
Alanine;arginine;calcium Chloride;fish Oil;glucose Monohydrate;glycine;glycine Max Seed Oil;histidine;isoleucine;leucine;lysine Acetate;magnesium Sulfate;medium-Chain Triglycerides;methionine;olea Europaea Oil;phenylalanine;potassium Chloride;proline;serine;sodium Acetate;sodium Glycerophosphate;taurine;threonine;tryptophan;tyrosine;valine;zinc Sulfate	0	1 (0.4%)	1 (0.2%)
Fish Oil;glycine Max Seed Oil;olea Europaea Oil;triglycerides	0	1 (0.4%)	1 (0.2%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Solutions Producing Osmotic Diuresis	0	26 (10.7%)	26 (5.4%)
Mannitol	0	26 (10.7%)	26 (5.4%)
Vitamins	1 (0.4%)	1 (0.4%)	2 (0.4%)
Ascorbic Acid;biotin;cocarboxylase Tetrahydrate;colecalciferol;cyanocobalamin;dexpanthenol;dl-Alpha Tocopherol;folic Acid;nicotinamide;pyridoxine Hydrochloride;retinol Palmitate;riboflavin Sodium Phosphate	1 (0.4%)	0	1 (0.2%)
Vitamins Nos	0	1 (0.4%)	1 (0.2%)
Calcium Channel Blockers	41 (17.1%)	43 (17.8%)	84 (17.4%)
Benzothiazepine Derivatives	2 (0.8%)	5 (2.1%)	7 (1.5%)
Diltiazem	1 (0.4%)	4 (1.7%)	5 (1.0%)
Diltiazem Hydrochloride	1 (0.4%)	1 (0.4%)	2 (0.4%)
Dihydropyridine Derivatives	37 (15.4%)	40 (16.5%)	77 (16.0%)
Amlodipine	15 (6.3%)	29 (12.0%)	44 (9.1%)
Amlodipine Besilate	12 (5.0%)	8 (3.3%)	20 (4.1%)
Nifedipine	4 (1.7%)	1 (0.4%)	5 (1.0%)
Amlodipine Maleate	1 (0.4%)	0	1 (0.2%)
Benidipine Hydrochloride	1 (0.4%)	0	1 (0.2%)
Lercanidipine	1 (0.4%)	0	1 (0.2%)
Lercanidipine Hydrochloride	1 (0.4%)	0	1 (0.2%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Manidipine	1 (0.4%)	1 (0.4%)	2 (0.4%)
Nitrendipine	1 (0.4%)	0	1 (0.2%)
Nicardipine	0	2 (0.8%)	2 (0.4%)
Phenylalkylamine Derivatives	2 (0.8%)	0	2 (0.4%)
Verapamil	2 (0.8%)	0	2 (0.4%)
Calcium Homeostasis	1 (0.4%)	0	1 (0.2%)
Other Anti-Parathyroid Agents	1 (0.4%)	0	1 (0.2%)
Calcifediol	1 (0.4%)	0	1 (0.2%)
Cardiac Therapy	14 (5.8%)	20 (8.3%)	34 (7.1%)
Adrenergic And Dopaminergic Agents	4 (1.7%)	5 (2.1%)	9 (1.9%)
Epinephrine	2 (0.8%)	0	2 (0.4%)
Norepinephrine	2 (0.8%)	1 (0.4%)	3 (0.6%)
Phenylephrine	2 (0.8%)	0	2 (0.4%)
Dopamine	1 (0.4%)	1 (0.4%)	2 (0.4%)
Ephedrine	1 (0.4%)	0	1 (0.2%)
Norepinephrine Bitartrate	1 (0.4%)	1 (0.4%)	2 (0.4%)
Midodrine	0	2 (0.8%)	2 (0.4%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Antiarrhythmics, Class Ib	0	2 (0.8%)	2 (0.4%)
Lidocaine	0	1 (0.4%)	1 (0.2%)
Lidocaine Hydrochloride Monohydrate	0	1 (0.4%)	1 (0.2%)
Antiarrhythmics, Class Ic	1 (0.4%)	1 (0.4%)	2 (0.4%)
Flecainide	1 (0.4%)	0	1 (0.2%)
Flecainide Acetate	0	1 (0.4%)	1 (0.2%)
Antiarrhythmics, Class Iii	2 (0.8%)	7 (2.9%)	9 (1.9%)
Amiodarone	2 (0.8%)	6 (2.5%)	8 (1.7%)
Amiodarone Hydrochloride	0	1 (0.4%)	1 (0.2%)
Digitalis Glycosides	3 (1.3%)	1 (0.4%)	4 (0.8%)
Digoxin	2 (0.8%)	1 (0.4%)	3 (0.6%)
Digitoxin	1 (0.4%)	0	1 (0.2%)
Organic Nitrates	2 (0.8%)	7 (2.9%)	9 (1.9%)
Glyceryl Trinitrate	2 (0.8%)	5 (2.1%)	7 (1.5%)
Isosorbide Dinitrate	1 (0.4%)	2 (0.8%)	3 (0.6%)
Isosorbide Mononitrate	0	1 (0.4%)	1 (0.2%)

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Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Other Cardiac Combination Products	0	1 (0.4%)	1 (0.2%)
Magnesium Aspartate;potassium Aspartate	0	1 (0.4%)	1 (0.2%)
Other Cardiac Preparations	4 (1.7%)	2 (0.8%)	6 (1.2%)
Adenosine	1 (0.4%)	0	1 (0.2%)
Annona Muricata	1 (0.4%)	0	1 (0.2%)
Ivabradine	1 (0.4%)	0	1 (0.2%)
Ivabradine Hydrochloride	1 (0.4%)	0	1 (0.2%)
Adenosine Triphosphate Disodium Trihydrate	0	1 (0.4%)	1 (0.2%)
Ranolazine	0	1 (0.4%)	1 (0.2%)
Other Cardiac Stimulants	1 (0.4%)	0	1 (0.2%)
Atropine	1 (0.4%)	0	1 (0.2%)
Other Vasodilators Used In Cardiac Diseases	0	1 (0.4%)	1 (0.2%)
Nicorandil	0	1 (0.4%)	1 (0.2%)
Contrast Media	4 (1.7%)	4 (1.7%)	8 (1.7%)
Ultrasound Contrast Media	0	1 (0.4%)	1 (0.2%)
Sulfur Hexafluoride	0	1 (0.4%)	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Watersoluble, Nephrotropic, Low Osmolar X-Ray Contrast Media	4 (1.7%)	4 (1.7%)	8 (1.7%)
Iopamidol	3 (1.3%)	1 (0.4%)	4 (0.8%)
Iohexol	2 (0.8%)	2 (0.8%)	4 (0.8%)
Iodixanol	1 (0.4%)	0	1 (0.2%)
Iobitridol	0	1 (0.4%)	1 (0.2%)
Corticosteroids For Systemic Use	131 (54.6%)	175 (72.3%)	306 (63.5%)
Corticosteroids For Systemic Use, Combinations	1 (0.4%)	0	1 (0.2%)
Chlorphenamine;triamcinolone	1 (0.4%)	0	1 (0.2%)
Glucocorticoids	130 (54.2%)	175 (72.3%)	305 (63.3%)
Prednisone	53 (22.1%)	6 (2.5%)	59 (12.2%)
Prednisolone	38 (15.8%)	9 (3.7%)	47 (9.8%)
Methylprednisolone	37 (15.4%)	17 (7.0%)	54 (11.2%)
Dexamethasone	27 (11.3%)	151 (62.4%)	178 (36.9%)
Methylprednisolone Sodium Succinate	20 (8.3%)	5 (2.1%)	25 (5.2%)
Hydrocortisone	9 (3.8%)	4 (1.7%)	13 (2.7%)
Deflazacort	3 (1.3%)	2 (0.8%)	5 (1.0%)
Dexamethasone Sodium Phosphate	3 (1.3%)	13 (5.4%)	16 (3.3%)
Prednisolone Sodium Succinate	2 (0.8%)	0	2 (0.4%)
Triamcinolone Acetonide	2 (0.8%)	0	2 (0.4%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Betamethasone Dipropionate;betamethasone Sodium Phosphate	1 (0.4%)	0	1 (0.2%)
Cortisone	1 (0.4%)	0	1 (0.2%)
Dexamethasone Phosphate	1 (0.4%)	2 (0.8%)	3 (0.6%)
Hydrocortisone Sodium Succinate	1 (0.4%)	2 (0.8%)	3 (0.6%)
Methylprednisolone Acetate	1 (0.4%)	0	1 (0.2%)
Prednisolone Acetate	1 (0.4%)	0	1 (0.2%)
Prednisone Acetate	1 (0.4%)	0	1 (0.2%)
Triamcinolone	1 (0.4%)	0	1 (0.2%)
Betamethasone Sodium Phosphate	0	2 (0.8%)	2 (0.4%)
Not Applicable	1 (0.4%)	0	1 (0.2%)
Corticosteroid Nos	1 (0.4%)	0	1 (0.2%)
Corticosteroids, Dermatological Preparations	142 (59.2%)	15 (6.2%)	157 (32.6%)
Corticosteroids, Moderately Potent (Group Ii)	34 (14.2%)	4 (1.7%)	38 (7.9%)
Triamcinolone	13 (5.4%)	1 (0.4%)	14 (2.9%)
Triamcinolone Acetonide	10 (4.2%)	1 (0.4%)	11 (2.3%)
Clobetasone Butyrate	4 (1.7%)	0	4 (0.8%)
Desonide	3 (1.3%)	1 (0.4%)	4 (0.8%)
Hydrocortisone Butyrate	2 (0.8%)	1 (0.4%)	3 (0.6%)
Alclometasone Dipropionate	1 (0.4%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Clobetasone	1 (0.4%)	0	1 (0.2%)
Dexamethasone Valerate	1 (0.4%)	0	1 (0.2%)
Fluprednidene Acetate	1 (0.4%)	0	1 (0.2%)
Corticosteroids, Moderately Potent, Combinations With Antibiotics	3 (1.3%)	0	3 (0.6%)
Gentamicin Sulfate;nystatin;triamcinolone Acetonide	1 (0.4%)	0	1 (0.2%)
Gramicidin;neomycin;nystatin;triamcinolone Acetonide	1 (0.4%)	0	1 (0.2%)
Neomycin Sulfate;nystatin;triamcinolone Acetonide	1 (0.4%)	0	1 (0.2%)
Corticosteroids, Potent (Group Iii)	77 (32.1%)	9 (3.7%)	86 (17.8%)
Betamethasone Valerate	20 (8.3%)	1 (0.4%)	21 (4.4%)
Betamethasone	14 (5.8%)	1 (0.4%)	15 (3.1%)
Mometasone Furoate	13 (5.4%)	2 (0.8%)	15 (3.1%)
Methylprednisolone Aceponate	12 (5.0%)	3 (1.2%)	15 (3.1%)
Fluocinonide	10 (4.2%)	0	10 (2.1%)
Betamethasone Butyrate Propionate	6 (2.5%)	0	6 (1.2%)
Prednicarbate	6 (2.5%)	2 (0.8%)	8 (1.7%)
Betamethasone Dipropionate	5 (2.1%)	1 (0.4%)	6 (1.2%)
Difluprednate	4 (1.7%)	0	4 (0.8%)
Desoximetasone	3 (1.3%)	0	3 (0.6%)
Diflucortolone	3 (1.3%)	0	3 (0.6%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Diflucortolone Valerate	2 (0.8%)	0	2 (0.4%)
Fluticasone	2 (0.8%)	0	2 (0.4%)
Diflorasone Diacetate	1 (0.4%)	0	1 (0.2%)
Fludroxycortide	1 (0.4%)	0	1 (0.2%)
Fluocinolone Acetonide	1 (0.4%)	0	1 (0.2%)
Halometasone	1 (0.4%)	0	1 (0.2%)
Mometasone	1 (0.4%)	0	1 (0.2%)
Corticosteroids, Potent, Combinations With Antibiotics	12 (5.0%)	0	12 (2.5%)
Betamethasone Dipropionate;clotrimazole;gentamicin Sulfate	3 (1.3%)	0	3 (0.6%)
Betamethasone Dipropionate;gentamicin Sulfate	3 (1.3%)	0	3 (0.6%)
Betamethasone;gentamicin	3 (1.3%)	0	3 (0.6%)
Betamethasone Valerate;gentamicin Sulfate	1 (0.4%)	0	1 (0.2%)
Betamethasone;fusidic Acid	1 (0.4%)	0	1 (0.2%)
Fluocinolone Acetonide;neomycin	1 (0.4%)	0	1 (0.2%)
Corticosteroids, Very Potent (Group Iv)	46 (19.2%)	1 (0.4%)	47 (9.8%)
Clobetasol Propionate	30 (12.5%)	0	30 (6.2%)
Clobetasol	19 (7.9%)	1 (0.4%)	20 (4.1%)
Halcinonide	1 (0.4%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Corticosteroids, Weak (Group I)	42 (17.5%)	4 (1.7%)	46 (9.5%)
Hydrocortisone	34 (14.2%)	3 (1.2%)	37 (7.7%)
Methylprednisolone	6 (2.5%)	1 (0.4%)	7 (1.5%)
Hydrocortisone Acetate	2 (0.8%)	0	2 (0.4%)
Prednisolone Valeroacetate	1 (0.4%)	0	1 (0.2%)
Corticosteroids, Weak, Combinations With Antibiotics	2 (0.8%)	0	2 (0.4%)
Diphenhydramine Hydrochloride;hydrocortisone Acetate;neomycin Sulfate	1 (0.4%)	0	1 (0.2%)
Methylprednisolone;neomycin Sulfate	1 (0.4%)	0	1 (0.2%)
Cough And Cold Preparations	33 (13.8%)	15 (6.2%)	48 (10.0%)
Expectorants	2 (0.8%)	2 (0.8%)	4 (0.8%)
Guaifenesin	2 (0.8%)	2 (0.8%)	4 (0.8%)
Herbal Expectorants And Emollients	1 (0.4%)	0	1 (0.2%)
Coptis Spp. Rhizome;hedera Helix Leaf	1 (0.4%)	0	1 (0.2%)
Mucolytics	20 (8.3%)	10 (4.1%)	30 (6.2%)
Acetylcysteine	14 (5.8%)	7 (2.9%)	21 (4.4%)
Ambroxol Hydrochloride	3 (1.3%)	0	3 (0.6%)
Erdosteine	2 (0.8%)	0	2 (0.4%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
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Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Ambroxol	1 (0.4%)	1 (0.4%)	2 (0.4%)
Carbocisteine	1 (0.4%)	1 (0.4%)	2 (0.4%)
Acetylcysteine;ascorbic Acid	0	1 (0.4%)	1 (0.2%)
Not Applicable	3 (1.3%)	1 (0.4%)	4 (0.8%)
Cough And Cold Preparations	3 (1.3%)	1 (0.4%)	4 (0.8%)
Opium Alkaloids And Derivatives	7 (2.9%)	5 (2.1%)	12 (2.5%)
Dextromethorphan	4 (1.7%)	1 (0.4%)	5 (1.0%)
Codeine	2 (0.8%)	1 (0.4%)	3 (0.6%)
Dextromethorphan Hydrobromide;lysozyme Hydrochloride;potassium Cresolsulfonate	1 (0.4%)	0	1 (0.2%)
Dextromethorphan Hydrobromide	0	1 (0.4%)	1 (0.2%)
Dihydrocodeine Bitartrate	0	1 (0.4%)	1 (0.2%)
Dihydrocodeine Thiocyanate	0	1 (0.4%)	1 (0.2%)
Opium Derivatives And Expectorants	4 (1.7%)	0	4 (0.8%)
Dextromethorphan Hydrobromide;guaifenesin	2 (0.8%)	0	2 (0.4%)
Ammonium Chloride;chlorphenamine Maleate;dihydrocodeine Bitartrate;methylephedrine Hydrochloride-Dl;pelargonium Sidoides	1 (0.4%)	0	1 (0.2%)
Chlorphenamine Maleate;dihydrocodeine Bitartrate;guaifenesin;methylephedrine Hydrochloride-Dl	1 (0.4%)	0	1 (0.2%)
Other Cough Suppressants	6 (2.5%)	2 (0.8%)	8 (1.7%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Benzonatate	5 (2.1%)	1 (0.4%)	6 (1.2%)
Levodropropizine	1 (0.4%)	0	1 (0.2%)
Cloperastine Hydrochloride	0	1 (0.4%)	1 (0.2%)
Diagnostic Agents	1 (0.4%)	0	1 (0.2%)
Tests For Thyreoidea Function	1 (0.4%)	0	1 (0.2%)
Protirelin Tartrate Monohydrate	1 (0.4%)	0	1 (0.2%)
Digestives, Incl. Enzymes	7 (2.9%)	4 (1.7%)	11 (2.3%)
Enzyme Preparations	6 (2.5%)	4 (1.7%)	10 (2.1%)
Pancreatin	5 (2.1%)	1 (0.4%)	6 (1.2%)
Aspergillus Oryzae Enzyme;pancreatin	1 (0.4%)	0	1 (0.2%)
Alpha-D-Galactosidase;amylase;bromelains;cellulase;lipase;protease Nos;tilactase	0	1 (0.4%)	1 (0.2%)
Pancrelipase	0	2 (0.8%)	2 (0.4%)
Herbal Digestives, Amara	1 (0.4%)	0	1 (0.2%)
Achillea Millefolium Herb;artemisia Absinthium Herb;centaurium Erythraea Herb;cichorium Intybus;gentiana Lutea Root;juniperus Communis;peucedanum Ostruthium Rhizome;salvia Officinalis Leaf;taraxacum Officinale	1 (0.4%)	0	1 (0.2%)
Diuretics	33 (13.8%)	62 (25.6%)	95 (19.7%)
Aldosterone Antagonists	5 (2.1%)	5 (2.1%)	10 (2.1%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Spironolactone	4 (1.7%)	4 (1.7%)	8 (1.7%)
Eplerenone	1 (0.4%)	1 (0.4%)	2 (0.4%)
Herbal Diuretics, Other	0	1 (0.4%)	1 (0.2%)
Lespedeza Bicolor	0	1 (0.4%)	1 (0.2%)
Low-Ceiling Diuretics And Potassium-Sparing Agents	1 (0.4%)	0	1 (0.2%)
Hydrochlorothiazide;triamterene	1 (0.4%)	0	1 (0.2%)
Sulfonamides, Plain	24 (10.0%)	56 (23.1%)	80 (16.6%)
Furosemide	14 (5.8%)	53 (21.9%)	67 (13.9%)
Torasemide	7 (2.9%)	0	7 (1.5%)
Bumetanide	2 (0.8%)	0	2 (0.4%)
Indapamide	2 (0.8%)	3 (1.2%)	5 (1.0%)
Chlortalidone	1 (0.4%)	0	1 (0.2%)
Furosemide Sodium	0	1 (0.4%)	1 (0.2%)
Thiazides, Plain	9 (3.8%)	4 (1.7%)	13 (2.7%)
Hydrochlorothiazide	8 (3.3%)	3 (1.2%)	11 (2.3%)
Trichlormethiazide	1 (0.4%)	0	1 (0.2%)
Bendroflumethiazide	0	1 (0.4%)	1 (0.2%)

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Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Drugs For Acid Related Disorders	135 (56.3%)	112 (46.3%)	247 (51.2%)
Aluminium Compounds	1 (0.4%)	0	1 (0.2%)
Aldioxa;aluminium Magnesium Silicate	1 (0.4%)	0	1 (0.2%)
Antacids With Antispasmodics	1 (0.4%)	1 (0.4%)	2 (0.4%)
Aluminium Magnesium Silicate;essential Oils Nos;mamytase;scopolia Carniolica Extract;sodium Bicarbonate;thiamine Mononitrate	1 (0.4%)	1 (0.4%)	2 (0.4%)
Antacids With Sodium Bicarbonate	3 (1.3%)	3 (1.2%)	6 (1.2%)
Sodium Bicarbonate	2 (0.8%)	1 (0.4%)	3 (0.6%)
Sodium Alginate;sodium Bicarbonate	1 (0.4%)	0	1 (0.2%)
Alginic Acid;aluminium Hydroxide;magnesium Trisilicate;sodium Bicarbonate	0	1 (0.4%)	1 (0.2%)
Magnesium Carbonate;magnesium Trisilicate;sodium Bicarbonate	0	1 (0.4%)	1 (0.2%)
Calcium Compounds	3 (1.3%)	1 (0.4%)	4 (0.8%)
Calcium Carbonate	3 (1.3%)	1 (0.4%)	4 (0.8%)
Combinations And Complexes Of Aluminium, Calcium And Magnesium Compounds	9 (3.8%)	8 (3.3%)	17 (3.5%)
Aluminium Hydroxide;calcium Carbonate;magnesium Carbonate;oxetacaine	3 (1.3%)	6 (2.5%)	9 (1.9%)
Almagate	2 (0.8%)	0	2 (0.4%)
Aluminium Magnesium Hydroxide	1 (0.4%)	0	1 (0.2%)

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Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Aluminium;magnesium	1 (0.4%)	1 (0.4%)	2 (0.4%)
Calcium Carbonate;magnesium Carbonate	1 (0.4%)	0	1 (0.2%)
Magaldrate	1 (0.4%)	1 (0.4%)	2 (0.4%)
H2-Receptor Antagonists	30 (12.5%)	16 (6.6%)	46 (9.5%)
Famotidine	21 (8.8%)	15 (6.2%)	36 (7.5%)
Lafutidine	5 (2.1%)	0	5 (1.0%)
Cimetidine	2 (0.8%)	1 (0.4%)	3 (0.6%)
Nizatidine	1 (0.4%)	0	1 (0.2%)
Ranitidine	1 (0.4%)	1 (0.4%)	2 (0.4%)
Ranitidine Hydrochloride	1 (0.4%)	0	1 (0.2%)
Herbal Remedies For Treatment Of Peptic Ulcer, Other	1 (0.4%)	1 (0.4%)	2 (0.4%)
Artemisia Argyi Leaf	1 (0.4%)	0	1 (0.2%)
Artemisia Argyi	0	1 (0.4%)	1 (0.2%)
Not Applicable	0	1 (0.4%)	1 (0.2%)
Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (Gord)	0	1 (0.4%)	1 (0.2%)
Other Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (Gord)	9 (3.8%)	8 (3.3%)	17 (3.5%)
Rebamipide	5 (2.1%)	3 (1.2%)	8 (1.7%)

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Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Sucralfate	2 (0.8%)	0	2 (0.4%)
Oxetacaine	1 (0.4%)	0	1 (0.2%)
Sodium Alginate	1 (0.4%)	1 (0.4%)	2 (0.4%)
Algeldrate;sodium Alginate	0	1 (0.4%)	1 (0.2%)
Bismuth Subsalicylate	0	1 (0.4%)	1 (0.2%)
Calcium Carbonate;sodium Alginate;sodium Bicarbonate	0	1 (0.4%)	1 (0.2%)
Sodium Bicarbonate;sodium Gualenate Hydrate	0	1 (0.4%)	1 (0.2%)
Proton Pump Inhibitors	114 (47.5%)	101 (41.7%)	215 (44.6%)
Omeprazole	40 (16.7%)	32 (13.2%)	72 (14.9%)
Pantoprazole	34 (14.2%)	26 (10.7%)	60 (12.4%)
Pantoprazole Sodium Sesquihydrate	16 (6.7%)	18 (7.4%)	34 (7.1%)
Lansoprazole	12 (5.0%)	10 (4.1%)	22 (4.6%)
Esomeprazole	9 (3.8%)	12 (5.0%)	21 (4.4%)
Esomeprazole Magnesium	7 (2.9%)	8 (3.3%)	15 (3.1%)
Dexlansoprazole	3 (1.3%)	1 (0.4%)	4 (0.8%)
Rabeprazole Sodium	3 (1.3%)	0	3 (0.6%)
Vonoprazan Fumarate	3 (1.3%)	1 (0.4%)	4 (0.8%)
Omeprazole Magnesium	2 (0.8%)	4 (1.7%)	6 (1.2%)
Pantoprazole Magnesium	2 (0.8%)	0	2 (0.4%)
Esomeprazole Magnesium Trihydrate	1 (0.4%)	0	1 (0.2%)

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Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Esomeprazole Magnesium;sodium Bicarbonate	1 (0.4%)	1 (0.4%)	2 (0.4%)
Esomeprazole Strontium	1 (0.4%)	0	1 (0.2%)
Omeprazole Sodium	1 (0.4%)	0	1 (0.2%)
Rabeprazole	1 (0.4%)	0	1 (0.2%)
Tegoprazan	1 (0.4%)	1 (0.4%)	2 (0.4%)
Esomeprazole Magnesium Trihydrate;sodium Bicarbonate	0	1 (0.4%)	1 (0.2%)
Drugs For Constipation	96 (40.0%)	106 (43.8%)	202 (41.9%)
Bulk-Forming Laxatives	4 (1.7%)	0	4 (0.8%)
Fibre, Dietary	2 (0.8%)	0	2 (0.4%)
Bulk-Forming Laxatives	1 (0.4%)	0	1 (0.2%)
Plantago Ovata	1 (0.4%)	0	1 (0.2%)
Contact Laxatives	47 (19.6%)	49 (20.2%)	96 (19.9%)
Sennoside A+b	24 (10.0%)	32 (13.2%)	56 (11.6%)
Bisacodyl	15 (6.3%)	5 (2.1%)	20 (4.1%)
Sennoside A+b Calcium	7 (2.9%)	3 (1.2%)	10 (2.1%)
Bisacodyl;docusate Sodium;sennoside A+b	2 (0.8%)	0	2 (0.4%)
Bisacodyl;sennoside B	2 (0.8%)	0	2 (0.4%)
Docusate Sodium;sennoside A+b	2 (0.8%)	5 (2.1%)	7 (1.5%)
Aloe Vera	1 (0.4%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Phenolphthalein	1 (0.4%)	0	1 (0.2%)
Ricinus Communis Oil	1 (0.4%)	0	1 (0.2%)
Sodium Picosulfate	1 (0.4%)	4 (1.7%)	5 (1.0%)
Docusate;sennoside A+b	0	1 (0.4%)	1 (0.2%)
Sodium Picosulfate Monohydrate	0	1 (0.4%)	1 (0.2%)
Enemas	9 (3.8%)	5 (2.1%)	14 (2.9%)
Sodium Phosphate;sodium Phosphate Dibasic	4 (1.7%)	0	4 (0.8%)
Sodium Phosphate Dibasic;sodium Phosphate Monobasic	3 (1.3%)	1 (0.4%)	4 (0.8%)
Glycerol	1 (0.4%)	0	1 (0.2%)
Sodium Bicarbonate;sodium Phosphate	1 (0.4%)	1 (0.4%)	2 (0.4%)
Docusate Sodium;sorbitol	0	1 (0.4%)	1 (0.2%)
Enemas	0	1 (0.4%)	1 (0.2%)
Phosphoric Acid Sodium;sodium Phosphate Dibasic	0	1 (0.4%)	1 (0.2%)
Not Applicable	3 (1.3%)	1 (0.4%)	4 (0.8%)
Docusate Sodium;sennoside B	1 (0.4%)	0	1 (0.2%)
Drugs For Constipation	1 (0.4%)	0	1 (0.2%)
Frangula Alnus;sterculia Urens	1 (0.4%)	1 (0.4%)	2 (0.4%)
Osmotically Acting Laxatives	66 (27.5%)	79 (32.6%)	145 (30.1%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Lactulose	19 (7.9%)	18 (7.4%)	37 (7.7%)
Magnesium Oxide	15 (6.3%)	17 (7.0%)	32 (6.6%)
Macrogol 3350	14 (5.8%)	15 (6.2%)	29 (6.0%)
Macrogol	12 (5.0%)	16 (6.6%)	28 (5.8%)
Macrogol 3350;potassium Chloride;sodium Bicarbonate;sodium Chloride	7 (2.9%)	11 (4.5%)	18 (3.7%)
Magnesium Hydroxide	7 (2.9%)	5 (2.1%)	12 (2.5%)
Lactitol	1 (0.4%)	2 (0.8%)	3 (0.6%)
Macrogol;potassium Chloride;sodium Bicarbonate;sodium Chloride	1 (0.4%)	1 (0.4%)	2 (0.4%)
Magnesium Citrate	1 (0.4%)	1 (0.4%)	2 (0.4%)
Electrolytes Nos;macrogol	0	2 (0.8%)	2 (0.4%)
Macrogol 3350;potassium Chloride;sodium Bicarbonate;sodium Chloride;sodium Sulfate Anhydrous	0	1 (0.4%)	1 (0.2%)
Macrogol 4000	0	1 (0.4%)	1 (0.2%)
Magnesium Sulfate	0	6 (2.5%)	6 (1.2%)
Sodium Phosphate Monobasic (Anhydrous)	0	1 (0.4%)	1 (0.2%)
Other Drugs For Constipation	10 (4.2%)	5 (2.1%)	15 (3.1%)
Prucalopride Succinate	3 (1.3%)	0	3 (0.6%)
Elobixibat	2 (0.8%)	1 (0.4%)	3 (0.6%)
Angelica Sinensis Root;cannabis Sativa Fruit;notopterygium Spp. Root With Rhizome;prunus Spp. Seed;rheum Spp. Root With Rhizome	1 (0.4%)	0	1 (0.2%)
Glycerol	1 (0.4%)	2 (0.8%)	3 (0.6%)
Linaclotide	1 (0.4%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Lubiprostone	1 (0.4%)	2 (0.8%)	3 (0.6%)
Phyllanthus Emblica	1 (0.4%)	0	1 (0.2%)
Sodium Bicarbonate;sodium Phosphate Monobasic (Anhydrous)	0	2 (0.8%)	2 (0.4%)
Peripheral Opioid Receptor Antagonists	2 (0.8%)	0	2 (0.4%)
Methylnaltrexone	1 (0.4%)	0	1 (0.2%)
Naldemedine Tosilate	1 (0.4%)	0	1 (0.2%)
Softeners, Emollients	15 (6.3%)	16 (6.6%)	31 (6.4%)
Docusate Sodium	15 (6.3%)	13 (5.4%)	28 (5.8%)
Docusate	1 (0.4%)	1 (0.4%)	2 (0.4%)
Paraffin	0	1 (0.4%)	1 (0.2%)
Paraffin, Liquid	0	1 (0.4%)	1 (0.2%)
Drugs For Functional Gastrointestinal Disorders	36 (15.0%)	21 (8.7%)	57 (11.8%)
Belladonna Alkaloids, Semisynthetic, Quaternary Ammonium Compounds	10 (4.2%)	3 (1.2%)	13 (2.7%)
Hyoscine Butylbromide	8 (3.3%)	3 (1.2%)	11 (2.3%)
Butylscopolamine	2 (0.8%)	0	2 (0.4%)
Herbal Antispasmodic Agents, Other	1 (0.4%)	1 (0.4%)	2 (0.4%)
Corydalis Yanhusuo Tuber;ipomoea Nil Seed	1 (0.4%)	1 (0.4%)	2 (0.4%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Herbal Carminatives	1 (0.4%)	0	1 (0.2%)
Herbal Carminatives	1 (0.4%)	0	1 (0.2%)
Other Drugs For Functional Gastrointestinal Disorders	7 (2.9%)	2 (0.8%)	9 (1.9%)
Simeticone	5 (2.1%)	1 (0.4%)	6 (1.2%)
Dimeticone	1 (0.4%)	1 (0.4%)	2 (0.4%)
Pinaverium Bromide	1 (0.4%)	0	1 (0.2%)
Papaverine And Derivatives	1 (0.4%)	1 (0.4%)	2 (0.4%)
Drotaverine Hydrochloride	1 (0.4%)	1 (0.4%)	2 (0.4%)
Propulsives	17 (7.1%)	14 (5.8%)	31 (6.4%)
Metoclopramide	7 (2.9%)	3 (1.2%)	10 (2.1%)
Mosapride Citrate	4 (1.7%)	1 (0.4%)	5 (1.0%)
Metoclopramide Hydrochloride	3 (1.3%)	0	3 (0.6%)
Domperidone	2 (0.8%)	7 (2.9%)	9 (1.9%)
Alizapride Hydrochloride	1 (0.4%)	0	1 (0.2%)
Domperidone Maleate	1 (0.4%)	0	1 (0.2%)
Itopride	1 (0.4%)	0	1 (0.2%)
Cinitapride Tartrate	0	1 (0.4%)	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Itopride Hydrochloride	0	1 (0.4%)	1 (0.2%)
Mosapride	0	1 (0.4%)	1 (0.2%)
Synthetic Anticholinergic Agents In Combination With Analgesics	1 (0.4%)	0	1 (0.2%)
Fenpiverinium Bromide;metamizole Sodium;pitofenone Hydrochloride	1 (0.4%)	0	1 (0.2%)
Synthetic Anticholinergics, Esters With Tertiary Amino Group	2 (0.8%)	2 (0.8%)	4 (0.8%)
Dicycloverine Hydrochloride	1 (0.4%)	1 (0.4%)	2 (0.4%)
Trimebutine Maleate	1 (0.4%)	1 (0.4%)	2 (0.4%)
Synthetic Anticholinergics, Quaternary Ammonium Compounds	4 (1.7%)	0	4 (0.8%)
Otilonium Bromide	3 (1.3%)	0	3 (0.6%)
Glycopyrronium Bromide	1 (0.4%)	0	1 (0.2%)
Synthetic Antispasmodics, Amides With Tertiary Amines	0	1 (0.4%)	1 (0.2%)
Tiropramide Hydrochloride	0	1 (0.4%)	1 (0.2%)
Drugs For Obstructive Airway Diseases	33 (13.8%)	17 (7.0%)	50 (10.4%)
Adrenergics In Combination With Anticholinergics Incl. Triple Combinations With Corticosteroids	9 (3.8%)	3 (1.2%)	12 (2.5%)
Ipratropium Bromide;salbutamol Sulfate	3 (1.3%)	0	3 (0.6%)
Ipratropium;salbutamol	3 (1.3%)	0	3 (0.6%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Fluticasone Furoate;umeclidinium Bromide;vilanterol Trifenatate	2 (0.8%)	2 (0.8%)	4 (0.8%)
Budesonide;formoterol Fumarate;glycopyrronium Bromide	1 (0.4%)	0	1 (0.2%)
Glycopyrronium Bromide;indacaterol Maleate	1 (0.4%)	0	1 (0.2%)
Ipratropium Bromide;levosalbutamol Sulfate	1 (0.4%)	0	1 (0.2%)
Olodaterol;tiotropium	1 (0.4%)	0	1 (0.2%)
Umeclidinium Bromide;vilanterol	0	1 (0.4%)	1 (0.2%)
Adrenergics In Combination With Corticosteroids Or Other Drugs, Excl. Anticholinergics	9 (3.8%)	6 (2.5%)	15 (3.1%)
Budesonide;formoterol Fumarate	3 (1.3%)	1 (0.4%)	4 (0.8%)
Fluticasone;salmeterol	3 (1.3%)	0	3 (0.6%)
Beclometasone Dipropionate;formoterol Fumarate	2 (0.8%)	2 (0.8%)	4 (0.8%)
Beclometasone;formoterol	1 (0.4%)	1 (0.4%)	2 (0.4%)
Fluticasone Propionate;vilanterol Trifenatate	1 (0.4%)	1 (0.4%)	2 (0.4%)
Fluticasone Furoate;vilanterol Trifenatate	0	1 (0.4%)	1 (0.2%)
Formoterol Fumarate;mometasone Furoate	0	1 (0.4%)	1 (0.2%)
Anticholinergics	9 (3.8%)	4 (1.7%)	13 (2.7%)
Ipratropium Bromide	6 (2.5%)	2 (0.8%)	8 (1.7%)
Ipratropium	1 (0.4%)	0	1 (0.2%)
Tiotropium Bromide Monohydrate	1 (0.4%)	1 (0.4%)	2 (0.4%)
Umeclidinium	1 (0.4%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Umeclidinium Bromide	0	1 (0.4%)	1 (0.2%)
Glucocorticoids	9 (3.8%)	0	9 (1.9%)
Budesonide	5 (2.1%)	0	5 (1.0%)
Fluticasone Propionate	2 (0.8%)	0	2 (0.4%)
Beclometasone	1 (0.4%)	0	1 (0.2%)
Beclometasone Dipropionate	1 (0.4%)	0	1 (0.2%)
Leukotriene Receptor Antagonists	2 (0.8%)	0	2 (0.4%)
Levocetirizine Dihydrochloride;montelukast Sodium	1 (0.4%)	0	1 (0.2%)
Montelukast	1 (0.4%)	0	1 (0.2%)
Selective Beta-2-Adrenoreceptor Agonists	18 (7.5%)	9 (3.7%)	27 (5.6%)
Salbutamol	9 (3.8%)	5 (2.1%)	14 (2.9%)
Salbutamol Sulfate	6 (2.5%)	4 (1.7%)	10 (2.1%)
Terbutaline Sulfate	2 (0.8%)	0	2 (0.4%)
Formoterol	1 (0.4%)	0	1 (0.2%)
Procaterol Hydrochloride Hemihydrate	1 (0.4%)	0	1 (0.2%)
Terbutaline	1 (0.4%)	0	1 (0.2%)
Xanthines	3 (1.3%)	1 (0.4%)	4 (0.8%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Aminophylline	1 (0.4%)	0	1 (0.2%)
Doxofylline	1 (0.4%)	0	1 (0.2%)
Theophylline	1 (0.4%)	1 (0.4%)	2 (0.4%)
Drugs For Treatment Of Bone Diseases	13 (5.4%)	8 (3.3%)	21 (4.4%)
Bisphosphonates	8 (3.3%)	6 (2.5%)	14 (2.9%)
Zoledronic Acid	3 (1.3%)	2 (0.8%)	5 (1.0%)
Alendronate Sodium	2 (0.8%)	1 (0.4%)	3 (0.6%)
Pamidronate Disodium	2 (0.8%)	0	2 (0.4%)
Alendronic Acid	1 (0.4%)	1 (0.4%)	2 (0.4%)
Ibandronate Sodium	1 (0.4%)	0	1 (0.2%)
Zoledronic Acid Monohydrate	1 (0.4%)	2 (0.8%)	3 (0.6%)
Other Drugs Affecting Bone Structure And Mineralization	5 (2.1%)	2 (0.8%)	7 (1.5%)
Denosumab	5 (2.1%)	2 (0.8%)	7 (1.5%)
Drugs Used In Diabetes	54 (22.5%)	41 (16.9%)	95 (19.7%)
Alpha Glucosidase Inhibitors	2 (0.8%)	0	2 (0.4%)
Acarbose	1 (0.4%)	0	1 (0.2%)
Voglibose	1 (0.4%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Biguanides	28 (11.7%)	26 (10.7%)	54 (11.2%)
Metformin	18 (7.5%)	21 (8.7%)	39 (8.1%)
Metformin Hydrochloride	10 (4.2%)	5 (2.1%)	15 (3.1%)
Combinations Of Oral Blood Glucose Lowering Drugs	8 (3.3%)	2 (0.8%)	10 (2.1%)
Gemigliptin Tartrate;metformin Hydrochloride	2 (0.8%)	0	2 (0.4%)
Metformin Hydrochloride;sitagliptin Phosphate Monohydrate	2 (0.8%)	0	2 (0.4%)
Linagliptin;metformin Hydrochloride	1 (0.4%)	0	1 (0.2%)
Metformin Hydrochloride;sitagliptin	1 (0.4%)	0	1 (0.2%)
Metformin Hydrochloride;vildagliptin	1 (0.4%)	0	1 (0.2%)
Mitiglinide Calcium;voglibose	1 (0.4%)	0	1 (0.2%)
Dapagliflozin;metformin Hydrochloride	0	1 (0.4%)	1 (0.2%)
Metformin;sitagliptin	0	1 (0.4%)	1 (0.2%)
Dipeptidyl Peptidase 4 (Dpp-4) Inhibitors	8 (3.3%)	9 (3.7%)	17 (3.5%)
Linagliptin	2 (0.8%)	2 (0.8%)	4 (0.8%)
Sitagliptin	2 (0.8%)	3 (1.2%)	5 (1.0%)
Gemigliptin	1 (0.4%)	0	1 (0.2%)
Gemigliptin Tartrate	1 (0.4%)	0	1 (0.2%)
Sitagliptin Phosphate Monohydrate	1 (0.4%)	3 (1.2%)	4 (0.8%)
Vildagliptin	1 (0.4%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Sitagliptin Phosphate	0	1 (0.4%)	1 (0.2%)
Glucagon-Like Peptide-1 (Glp-1) Analogues	5 (2.1%)	4 (1.7%)	9 (1.9%)
Semaglutide	3 (1.3%)	1 (0.4%)	4 (0.8%)
Dulaglutide	2 (0.8%)	2 (0.8%)	4 (0.8%)
Liraglutide	0	1 (0.4%)	1 (0.2%)
Insulins And Analogues For Injection, Fast-Acting	25 (10.4%)	10 (4.1%)	35 (7.3%)
Insulin Human	10 (4.2%)	2 (0.8%)	12 (2.5%)
Insulin	9 (3.8%)	2 (0.8%)	11 (2.3%)
Insulin Lispro	6 (2.5%)	1 (0.4%)	7 (1.5%)
Insulin Aspart	2 (0.8%)	4 (1.7%)	6 (1.2%)
Insulin Glulisine	2 (0.8%)	0	2 (0.4%)
Insulin Porcine	1 (0.4%)	1 (0.4%)	2 (0.4%)
Insulins And Analogues For Injection, Intermediate- Or Long-Acting Combined With Fast-Acting	2 (0.8%)	0	2 (0.4%)
Insulin Aspart;insulin Aspart Protamine (Crystalline)	1 (0.4%)	0	1 (0.2%)
Insulin Aspart;insulin Degludec	1 (0.4%)	0	1 (0.2%)
Insulins And Analogues For Injection, Intermediate-Acting	0	2 (0.8%)	2 (0.4%)
Insulin Human Injection, Isophane	0	1 (0.4%)	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Insulin Isophane Porcine	0	1 (0.4%)	1 (0.2%)
Insulins And Analogues For Injection, Long-Acting	12 (5.0%)	4 (1.7%)	16 (3.3%)
Insulin Glargine	7 (2.9%)	3 (1.2%)	10 (2.1%)
Insulin Degludec	3 (1.3%)	1 (0.4%)	4 (0.8%)
Insulin Degludec;liraglutide	1 (0.4%)	0	1 (0.2%)
Insulin Glargine;lixisenatide	1 (0.4%)	0	1 (0.2%)
Insulin Glargine Yfgn	0	1 (0.4%)	1 (0.2%)
Other Blood Glucose Lowering Drugs, Excl. Insulins	3 (1.3%)	3 (1.2%)	6 (1.2%)
Mitiglinide Calcium	2 (0.8%)	1 (0.4%)	3 (0.6%)
Cyamopsis Tetragonoloba Gum	1 (0.4%)	0	1 (0.2%)
Imeglimin Hydrochloride	1 (0.4%)	0	1 (0.2%)
Repaglinide	0	2 (0.8%)	2 (0.4%)
Sodium-Glucose Co-Transporter 2 (Sglt2) Inhibitors	12 (5.0%)	2 (0.8%)	14 (2.9%)
Empagliflozin	5 (2.1%)	2 (0.8%)	7 (1.5%)
Dapagliflozin	3 (1.3%)	0	3 (0.6%)
Dapagliflozin Propanediol Monohydrate	3 (1.3%)	0	3 (0.6%)
Canagliflozin Hemihydrate	1 (0.4%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Sulfonylureas	10 (4.2%)	5 (2.1%)	15 (3.1%)
Gliclazide	4 (1.7%)	3 (1.2%)	7 (1.5%)
Glimepiride	3 (1.3%)	2 (0.8%)	5 (1.0%)
Glipizide	3 (1.3%)	0	3 (0.6%)
Thiazolidinediones	0	1 (0.4%)	1 (0.2%)
Pioglitazone	0	1 (0.4%)	1 (0.2%)
Emollients And Protectives	41 (17.1%)	8 (3.3%)	49 (10.2%)
Carbamide Products	13 (5.4%)	1 (0.4%)	14 (2.9%)
Urea	12 (5.0%)	1 (0.4%)	13 (2.7%)
Lauromacrogol 400;urea	2 (0.8%)	0	2 (0.4%)
Not Applicable	3 (1.3%)	1 (0.4%)	4 (0.8%)
Ceramide;copper;madecassoside;panthenol;zinc	1 (0.4%)	0	1 (0.2%)
Cetomacrogol	1 (0.4%)	1 (0.4%)	2 (0.4%)
Emollients And Protectives	1 (0.4%)	0	1 (0.2%)
Retinol;tocopherol	1 (0.4%)	0	1 (0.2%)
Other Emollients And Protectives	19 (7.9%)	3 (1.2%)	22 (4.6%)
Heparinoid	7 (2.9%)	1 (0.4%)	8 (1.7%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Aquaphilus Dolomiae;elaeis Guineensis Oil;glycerol;oenothera Biennis Oil;paraffin, Liquid;tocopherol	4 (1.7%)	0	4 (0.8%)
Benzalkonium Chloride;chlorhexidine Hydrochloride;isopropyl Myristate;paraffin, Liquid	2 (0.8%)	0	2 (0.4%)
Cetomacrogol;paraffin, Liquid;propylene Glycol;white Soft Paraffin	2 (0.8%)	1 (0.4%)	3 (0.6%)
Allantoin;diethylene Glycol Monostearate;dimeticone;isopropyl Myristate;lanolin Oil;paraffin, Liquid;propylene Glycol;stearic Acid;tocopheryl Acetate;trolamine	1 (0.4%)	0	1 (0.2%)
Aloe Vera Juice;citrus Aurantium Oil;docosahexaenoic Acid;hyaluronic Acid;melaleuca Alternifolia Oil;olea Europaea Oil;persea Americana Oil;sesamum Indicum Seed Oil;vitis Vinifera Oil	1 (0.4%)	0	1 (0.2%)
Dimethiconol;dimeticone;glycerol;glyceryl Monostearate;nicotinamide;paraffin, Liquid;vitellaria Paradoxa Subsp. Paradoxa	1 (0.4%)	0	1 (0.2%)
Glycerol	1 (0.4%)	0	1 (0.2%)
Glycerol;paraffin, Liquid;white Soft Paraffin	1 (0.4%)	0	1 (0.2%)
Mucopolysaccharide Polysulfuric Acid Ester	0	1 (0.4%)	1 (0.2%)
Protectives Against Uv-Radiation For Topical Use	1 (0.4%)	0	1 (0.2%)
Protectives Against Uv-Radiation For Topical Use	1 (0.4%)	0	1 (0.2%)
Salicylic Acid Preparations	2 (0.8%)	0	2 (0.4%)
Salicylic Acid	2 (0.8%)	0	2 (0.4%)
Silicone Products	0	1 (0.4%)	1 (0.2%)
Dimeticone	0	1 (0.4%)	1 (0.2%)
Soft Paraffin And Fat Products	9 (3.8%)	1 (0.4%)	10 (2.1%)
White Soft Paraffin	4 (1.7%)	0	4 (0.8%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Paraffin	3 (1.3%)	0	3 (0.6%)
Paraffin, Liquid	2 (0.8%)	0	2 (0.4%)
Emulsifying Wax;paraffin, Liquid;white Soft Paraffin	1 (0.4%)	0	1 (0.2%)
Light Liquid Paraffin;white Soft Paraffin	1 (0.4%)	0	1 (0.2%)
Paraffin, Liquid;white Soft Paraffin;wool Fat	1 (0.4%)	1 (0.4%)	2 (0.4%)
Zinc Products	6 (2.5%)	1 (0.4%)	7 (1.5%)
Zinc Oxide	5 (2.1%)	1 (0.4%)	6 (1.2%)
Avena Sativa;copper Sulfate;zinc Oxide;zinc Sulfate	1 (0.4%)	0	1 (0.2%)
Endocrine Therapy	1 (0.4%)	1 (0.4%)	2 (0.4%)
Anti-Estrogens	1 (0.4%)	0	1 (0.2%)
Tamoxifen	1 (0.4%)	0	1 (0.2%)
Gonadotropin Releasing Hormone Analogues	0	1 (0.4%)	1 (0.2%)
Leuprorelin	0	1 (0.4%)	1 (0.2%)
General Nutrients	17 (7.1%)	7 (2.9%)	24 (5.0%)
Fat/Carbohydrates/Proteins/Minerals/Vitamins, Combinations	4 (1.7%)	3 (1.2%)	7 (1.5%)
Ascorbic Acid;biotin;calcium;carbohydrates Nos;chlorine;choline;chromium;copper;fats Nos;folic Acid;fructooligosaccharides;iron;levocarnitine;magnesium;manganese;molybdenum;nicotinic Acid; Pantothenic Acid;phosphorus;potassium;proteins Nos;pyridoxine Hydrochloride;retinol;riboflavin;selenium;sodium;taurine;vitamin B1 Nos;vitamin B12 Nos;vitamin D Nos;vitamin E Nos;vitamin K Nos;zinc	2 (0.8%)	0	2 (0.4%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Ascorbic Acid;biotin;calcium;carbohydrates Nos;chloride;colecalciferol;copper;cyanocobalamin;fats Nos;folic Acid;iron;magnesium;manganese;nicotinamide;pantothenic Acid;phosphorus;potassium;proteins Nos;pyridoxine;retinol;riboflavin;sodium;thiamine;tocopherol;zinc	1 (0.4%)	2 (0.8%)	3 (0.6%)
Fibre Soluble;nutrients Nos	1 (0.4%)	0	1 (0.2%)
Carbohydrates Nos;fats Nos;minerals Nos;proteins Nos;vitamins Nos	0	1 (0.4%)	1 (0.2%)
Not Applicable	9 (3.8%)	3 (1.2%)	12 (2.5%)
Nutrients Nos	6 (2.5%)	1 (0.4%)	7 (1.5%)
Other Nutrients	2 (0.8%)	0	2 (0.4%)
General Nutrients	1 (0.4%)	0	1 (0.2%)
Protein Supplements	1 (0.4%)	0	1 (0.2%)
Carbohydrates Nos;lipids Nos;minerals Nos;proteins Nos	0	1 (0.4%)	1 (0.2%)
Omega-3 Fatty Acids	0	2 (0.8%)	2 (0.4%)
Other Combinations Of Nutrients	4 (1.7%)	2 (0.8%)	6 (1.2%)
Fish Oil	3 (1.3%)	1 (0.4%)	4 (0.8%)
Amino Acids Nos;carbohydrates Nos;electrolytes Nos;lipids Nos	1 (0.4%)	0	1 (0.2%)
Other Combinations Of Nutrients	0	1 (0.4%)	1 (0.2%)
Gynecological Antiinfectives And Antiseptics	1 (0.4%)	0	1 (0.2%)
Imidazole Derivatives	1 (0.4%)	0	1 (0.2%)
Clotrimazole	1 (0.4%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Immunostimulants	8 (3.3%)	70 (28.9%)	78 (16.2%)
Colony Stimulating Factors	6 (2.5%)	70 (28.9%)	76 (15.8%)
Filgrastim	4 (1.7%)	51 (21.1%)	55 (11.4%)
Lenograstim	1 (0.4%)	1 (0.4%)	2 (0.4%)
Lipegfilgrastim	1 (0.4%)	1 (0.4%)	2 (0.4%)
Filgrastim Sndz	0	2 (0.8%)	2 (0.4%)
Granulocyte Colony Stimulating Factor	0	1 (0.4%)	1 (0.2%)
Pegfilgrastim	0	14 (5.8%)	14 (2.9%)
Pegfilgrastim Cbqv	0	1 (0.4%)	1 (0.2%)
Herbal Immunomodulators	1 (0.4%)	0	1 (0.2%)
Angelica Acutiloba Root;astragalus Spp. Root;atractylodes Spp. Rhizome;cinnamomum Cassia Bark;citrus Aurantium Peel;glycyrrhiza Spp. Root;paeonia Lactiflora Root;panax Ginseng Root;polygala Tenuifolia Root;poria Cocos Sclerotium;rehmannia Glutinosa Root;schisandra Chinensis Fruit	1 (0.4%)	0	1 (0.2%)
Other Immunostimulants	1 (0.4%)	1 (0.4%)	2 (0.4%)
Leucogen	1 (0.4%)	0	1 (0.2%)
Colostrum	0	1 (0.4%)	1 (0.2%)
Immunosuppressants	9 (3.8%)	0	9 (1.9%)
Other Immunosuppressants	3 (1.3%)	0	3 (0.6%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Azathioprine	1 (0.4%)	0	1 (0.2%)
Colchicine	1 (0.4%)	0	1 (0.2%)
Hydroxychloroquine	1 (0.4%)	0	1 (0.2%)
Selective Immunosuppressants	5 (2.1%)	0	5 (1.0%)
Mycophenolate Mofetil	4 (1.7%)	0	4 (0.8%)
Vedolizumab	1 (0.4%)	0	1 (0.2%)
Tumor Necrosis Factor Alpha (Tnf-) Inhibitors	2 (0.8%)	0	2 (0.4%)
Infliximab	2 (0.8%)	0	2 (0.4%)
Lipid Modifying Agents	72 (30.0%)	73 (30.2%)	145 (30.1%)
Bile Acid Sequestrants	1 (0.4%)	0	1 (0.2%)
Colestyramine	1 (0.4%)	0	1 (0.2%)
Combinations Of Various Lipid Modifying Agents	3 (1.3%)	3 (1.2%)	6 (1.2%)
Ezetimibe;rosuvastatin	1 (0.4%)	0	1 (0.2%)
Ezetimibe;rosuvastatin Calcium	1 (0.4%)	1 (0.4%)	2 (0.4%)
Ezetimibe;simvastatin	1 (0.4%)	1 (0.4%)	2 (0.4%)
Atorvastatin Calcium;ezetimibe	0	1 (0.4%)	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Fibrates	6 (2.5%)	3 (1.2%)	9 (1.9%)
Fenofibrate	4 (1.7%)	2 (0.8%)	6 (1.2%)
Gemfibrozil	2 (0.8%)	0	2 (0.4%)
Bezafibrate	0	1 (0.4%)	1 (0.2%)
Herbal Cholesterol And Triglyceride Reducers	1 (0.4%)	0	1 (0.2%)
Monascus Purpureus	1 (0.4%)	0	1 (0.2%)
Hmg Coa Reductase Inhibitors	64 (26.7%)	64 (26.4%)	128 (26.6%)
Atorvastatin	24 (10.0%)	26 (10.7%)	50 (10.4%)
Atorvastatin Calcium	11 (4.6%)	8 (3.3%)	19 (3.9%)
Simvastatin	10 (4.2%)	12 (5.0%)	22 (4.6%)
Rosuvastatin	7 (2.9%)	8 (3.3%)	15 (3.1%)
Rosuvastatin Calcium	7 (2.9%)	4 (1.7%)	11 (2.3%)
Pitavastatin Calcium	3 (1.3%)	0	3 (0.6%)
Lovastatin	1 (0.4%)	1 (0.4%)	2 (0.4%)
Pitavastatin	1 (0.4%)	0	1 (0.2%)
Pitavastatin Calcium Pentahydrate	1 (0.4%)	0	1 (0.2%)
Atorvastatin Strontium	0	1 (0.4%)	1 (0.2%)
Pravastatin	0	5 (2.1%)	5 (1.0%)
Pravastatin Sodium	0	1 (0.4%)	1 (0.2%)

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Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Lipid Modifying Agents In Combination With Other Drugs	1 (0.4%)	1 (0.4%)	2 (0.4%)
Atorvastatin;fimasartan	1 (0.4%)	0	1 (0.2%)
Atorvastatin Calcium;irbesartan	0	1 (0.4%)	1 (0.2%)
Other Lipid Modifying Agents	5 (2.1%)	10 (4.1%)	15 (3.1%)
Ezetimibe	2 (0.8%)	7 (2.9%)	9 (1.9%)
Colecalciferol;docosahexaenoic Acid;eicosapentaenoic Acid	1 (0.4%)	0	1 (0.2%)
Docosahexaenoic Acid;eicosapentaenoic Acid;omega-3 Fatty Acids;ubidecarenone;vitamin E Nos	1 (0.4%)	0	1 (0.2%)
Omega-3-Acid Ethyl Ester	1 (0.4%)	1 (0.4%)	2 (0.4%)
Evolocumab	0	1 (0.4%)	1 (0.2%)
Omega-3 Fatty Acids	0	1 (0.4%)	1 (0.2%)
Mineral Supplements	48 (20.0%)	48 (19.8%)	96 (19.9%)
Calcium	7 (2.9%)	9 (3.7%)	16 (3.3%)
Calcium	4 (1.7%)	5 (2.1%)	9 (1.9%)
Calcium Carbonate	2 (0.8%)	4 (1.7%)	6 (1.2%)
Calcium Gluconate	1 (0.4%)	0	1 (0.2%)
Calcium, Combinations With Vitamin D And/Or Other Drugs	11 (4.6%)	6 (2.5%)	17 (3.5%)
Calcium Carbonate;colecalciferol	5 (2.1%)	3 (1.2%)	8 (1.7%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Calcium;vitamin D Nos	3 (1.3%)	0	3 (0.6%)
Calcium Carbonate;calcium Lactate;colecalciferol	1 (0.4%)	0	1 (0.2%)
Calcium Carbonate;vitamin D Nos	1 (0.4%)	1 (0.4%)	2 (0.4%)
Calcium Citrate;vitamin D Nos	1 (0.4%)	0	1 (0.2%)
Calcium, Combinations With Vitamin D And/Or Other Drugs	1 (0.4%)	0	1 (0.2%)
Calcium Citrate;colecalciferol;magnesium;zinc	0	1 (0.4%)	1 (0.2%)
Calcium;magnesium;vitamin D Nos	0	1 (0.4%)	1 (0.2%)
Magnesium	13 (5.4%)	18 (7.4%)	31 (6.4%)
Magnesium	5 (2.1%)	9 (3.7%)	14 (2.9%)
Magnesium Oxide	4 (1.7%)	5 (2.1%)	9 (1.9%)
Magnesium Bromide;magnesium Fluoride;magnesium Hydroxide	1 (0.4%)	0	1 (0.2%)
Magnesium Citrate	1 (0.4%)	0	1 (0.2%)
Magnesium Glycinate	1 (0.4%)	0	1 (0.2%)
Magnesium Lactate;pyridoxine Hydrochloride	1 (0.4%)	0	1 (0.2%)
Magnesium Sulfate	1 (0.4%)	0	1 (0.2%)
Magnesium Aspartate	0	1 (0.4%)	1 (0.2%)
Magnesium Chloride	0	1 (0.4%)	1 (0.2%)
Magnesium Gluconate	0	1 (0.4%)	1 (0.2%)
Magnesium;magnesium Carbonate;magnesium Citrate;magnesium Phosphate	0	1 (0.4%)	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Other Mineral Products	4 (1.7%)	4 (1.7%)	8 (1.7%)
Potassium Phosphate Monobasic;sodium Phosphate Dibasic	2 (0.8%)	0	2 (0.4%)
Potassium Bicarbonate;sodium Bicarbonate;sodium Phosphate Dibasic	1 (0.4%)	0	1 (0.2%)
Sodium Phosphate	1 (0.4%)	0	1 (0.2%)
Phosphoric Acid Sodium;sodium Phosphate Dibasic	0	1 (0.4%)	1 (0.2%)
Potassium Phosphate Dibasic;potassium Phosphate Monobasic;sodium Phosphate Dibasic;sodium Phosphate Monobasic	0	1 (0.4%)	1 (0.2%)
Potassium Phosphate Monobasic;sodium Phosphate Dibasic;sodium Phosphate Monobasic (Anhydrous)	0	1 (0.4%)	1 (0.2%)
Sodium Phosphate Dibasic;sodium Phosphate Monobasic	0	1 (0.4%)	1 (0.2%)
Potassium	22 (9.2%)	20 (8.3%)	42 (8.7%)
Potassium Chloride	14 (5.8%)	14 (5.8%)	28 (5.8%)
Potassium	2 (0.8%)	1 (0.4%)	3 (0.6%)
Potassium Gluconate	2 (0.8%)	2 (0.8%)	4 (0.8%)
Ascorbic Acid;potassium Bicarbonate	1 (0.4%)	0	1 (0.2%)
Magnesium Aspartate;potassium Aspartate	1 (0.4%)	0	1 (0.2%)
Potassium Aspartate	1 (0.4%)	0	1 (0.2%)
Potassium Phosphate Dibasic;potassium Phosphate Monobasic	1 (0.4%)	0	1 (0.2%)
Aspartic Acid;potassium Ascorbate	0	3 (1.2%)	3 (0.6%)
Potassium Bicarbonate	0	1 (0.4%)	1 (0.2%)
Sodium	2 (0.8%)	3 (1.2%)	5 (1.0%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Sodium Chloride	2 (0.8%)	3 (1.2%)	5 (1.0%)
Zinc	5 (2.1%)	0	5 (1.0%)
Zinc Gluconate	3 (1.3%)	0	3 (0.6%)
Zinc	1 (0.4%)	0	1 (0.2%)
Zinc Glycinate	1 (0.4%)	0	1 (0.2%)
Muscle Relaxants	12 (5.0%)	13 (5.4%)	25 (5.2%)
Ethers, Chemically Close To Antihistamines	0	2 (0.8%)	2 (0.4%)
Orphenadrine Citrate;paracetamol	0	2 (0.8%)	2 (0.4%)
Other Centrally Acting Agents	7 (2.9%)	10 (4.1%)	17 (3.5%)
Tizanidine	3 (1.3%)	1 (0.4%)	4 (0.8%)
Baclofen	2 (0.8%)	7 (2.9%)	9 (1.9%)
Eperisone Hydrochloride	2 (0.8%)	0	2 (0.4%)
Capsaicin;cyclobenzaprine Hydrochloride;menthol	1 (0.4%)	0	1 (0.2%)
Cyclobenzaprine Hydrochloride	1 (0.4%)	0	1 (0.2%)
Diazepam	1 (0.4%)	1 (0.4%)	2 (0.4%)
Cyclobenzaprine	0	1 (0.4%)	1 (0.2%)
Other Quaternary Ammonium Compounds	3 (1.3%)	0	3 (0.6%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Cisatracurium	2 (0.8%)	0	2 (0.4%)
Rocuronium	1 (0.4%)	0	1 (0.2%)
Rocuronium Bromide	1 (0.4%)	0	1 (0.2%)
Oxazol, Thiazine, And Triazine Derivatives	2 (0.8%)	1 (0.4%)	3 (0.6%)
Chlorzoxazone	2 (0.8%)	1 (0.4%)	3 (0.6%)
Nasal Preparations	12 (5.0%)	6 (2.5%)	18 (3.7%)
Corticosteroids	6 (2.5%)	4 (1.7%)	10 (2.1%)
Fluticasone Propionate	3 (1.3%)	2 (0.8%)	5 (1.0%)
Mometasone Furoate	2 (0.8%)	0	2 (0.4%)
Betamethasone Dipropionate	1 (0.4%)	0	1 (0.2%)
Beclometasone Dipropionate	0	1 (0.4%)	1 (0.2%)
Fluticasone Furoate	0	1 (0.4%)	1 (0.2%)
Other Nasal Preparations	3 (1.3%)	1 (0.4%)	4 (0.8%)
Dexpanthenol	1 (0.4%)	0	1 (0.2%)
Mupirocin	1 (0.4%)	0	1 (0.2%)
Sodium Chloride;xylitol	1 (0.4%)	0	1 (0.2%)
Sodium Chloride	0	1 (0.4%)	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Sympathomimetics	2 (0.8%)	1 (0.4%)	3 (0.6%)
Cetirizine Hydrochloride;pseudoephedrine Hydrochloride	1 (0.4%)	0	1 (0.2%)
Fexofenadine;pseudoephedrine Hydrochloride	1 (0.4%)	0	1 (0.2%)
Ebastine;pseudoephedrine Hydrochloride	0	1 (0.4%)	1 (0.2%)
Sympathomimetics, Plain	1 (0.4%)	0	1 (0.2%)
Oxymetazoline Hydrochloride	1 (0.4%)	0	1 (0.2%)
Ophthalmologicals	61 (25.4%)	17 (7.0%)	78 (16.2%)
Antibiotics	4 (1.7%)	0	4 (0.8%)
Tobramycin	3 (1.3%)	0	3 (0.6%)
Erythromycin	1 (0.4%)	0	1 (0.2%)
Anticholinergics	2 (0.8%)	0	2 (0.4%)
Phenylephrine Hydrochloride;tropicamide	2 (0.8%)	0	2 (0.4%)
Antiinflammatory Agents, Non-Steroids	4 (1.7%)	0	4 (0.8%)
Diclofenac Sodium	2 (0.8%)	0	2 (0.4%)
Diclofenac	1 (0.4%)	0	1 (0.2%)
Indometacin	1 (0.4%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Antineovascularisation Agents	1 (0.4%)	0	1 (0.2%)
Aflibercept	1 (0.4%)	0	1 (0.2%)
Beta Blocking Agents	2 (0.8%)	2 (0.8%)	4 (0.8%)
Brinzolamide;timolol Maleate	1 (0.4%)	0	1 (0.2%)
Timolol Maleate	1 (0.4%)	0	1 (0.2%)
Dorzolamide Hydrochloride;timolol Maleate	0	1 (0.4%)	1 (0.2%)
Dorzolamide;timolol	0	1 (0.4%)	1 (0.2%)
Carbonic Anhydrase Inhibitors	2 (0.8%)	0	2 (0.4%)
Acetazolamide	2 (0.8%)	0	2 (0.4%)
Corticosteroids And Antiinfectives In Combination	5 (2.1%)	0	5 (1.0%)
Dexamethasone;neomycin Sulfate;polymyxin B Sulfate	3 (1.3%)	0	3 (0.6%)
Dexamethasone Sodium Phosphate;gentamicin Sulfate;tetryzoline Hydrochloride	2 (0.8%)	0	2 (0.4%)
Dexamethasone;gentamicin Sulfate	1 (0.4%)	0	1 (0.2%)
Corticosteroids, Plain	12 (5.0%)	0	12 (2.5%)
Fluorometholone	5 (2.1%)	0	5 (1.0%)
Dexamethasone	3 (1.3%)	0	3 (0.6%)
Prednisolone	3 (1.3%)	0	3 (0.6%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Betamethasone	1 (0.4%)	0	1 (0.2%)
Dexamethasone Phosphate	1 (0.4%)	0	1 (0.2%)
Fluocinolone Acetonide	1 (0.4%)	0	1 (0.2%)
Fluorometholone Acetate	1 (0.4%)	0	1 (0.2%)
Hydrocortisone Sodium Phosphate	1 (0.4%)	0	1 (0.2%)
Prednisolone Acetate	1 (0.4%)	0	1 (0.2%)
Triamcinolone	1 (0.4%)	0	1 (0.2%)
Fluoroquinolones	5 (2.1%)	0	5 (1.0%)
Levofloxacin	3 (1.3%)	0	3 (0.6%)
Ofloxacin	3 (1.3%)	0	3 (0.6%)
Herbal Ophthalmologicals, Other	1 (0.4%)	0	1 (0.2%)
Echinacea Purpurea;rosa Canina Oil	1 (0.4%)	0	1 (0.2%)
Local Anesthetics	1 (0.4%)	0	1 (0.2%)
Proxymetacaine Hydrochloride	1 (0.4%)	0	1 (0.2%)
Not Applicable	1 (0.4%)	0	1 (0.2%)
Ophthalmologicals	1 (0.4%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Other Antiallergics	5 (2.1%)	2 (0.8%)	7 (1.5%)
Olopatadine Hydrochloride	2 (0.8%)	0	2 (0.4%)
Azelastine	1 (0.4%)	0	1 (0.2%)
Azelastine Hydrochloride	1 (0.4%)	0	1 (0.2%)
Emedastine	1 (0.4%)	0	1 (0.2%)
Tranilast	1 (0.4%)	0	1 (0.2%)
Emedastine Fumarate	0	1 (0.4%)	1 (0.2%)
Ketotifen	0	1 (0.4%)	1 (0.2%)
Other Ophthalmologicals	44 (18.3%)	8 (3.3%)	52 (10.8%)
Hyaluronate Sodium	11 (4.6%)	2 (0.8%)	13 (2.7%)
Hypromellose	8 (3.3%)	0	8 (1.7%)
Dextran 70;hypromellose	6 (2.5%)	0	6 (1.2%)
Macrogol 400;propylene Glycol	4 (1.7%)	0	4 (0.8%)
Artificial Tears [umbrella Term]	3 (1.3%)	0	3 (0.6%)
Hyaluronate Sodium;trehalose	3 (1.3%)	0	3 (0.6%)
Macrogol	2 (0.8%)	0	2 (0.4%)
Ascorbic Acid;betacarotene;cupric Oxide;sodium Selenate;tocopheryl Acetate;zinc Oxide	1 (0.4%)	0	1 (0.2%)
Ascorbic Acid;tocopheryl Acetate;xantofyl;zeaxanthin;zinc	1 (0.4%)	0	1 (0.2%)
Carbomer	1 (0.4%)	1 (0.4%)	2 (0.4%)
Carbomer;hyaluronate Sodium	1 (0.4%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Carmellose	1 (0.4%)	0	1 (0.2%)
Carmellose Sodium	1 (0.4%)	1 (0.4%)	2 (0.4%)
Carmellose Sodium;glycerol	1 (0.4%)	1 (0.4%)	2 (0.4%)
Ciclosporin	1 (0.4%)	2 (0.8%)	3 (0.6%)
Dexpanthenol	1 (0.4%)	0	1 (0.2%)
Dexpanthenol;hyaluronate Sodium	1 (0.4%)	0	1 (0.2%)
Dextran;hypromellose	1 (0.4%)	0	1 (0.2%)
Diquafosol Tetrasodium	1 (0.4%)	0	1 (0.2%)
Ectoine	1 (0.4%)	0	1 (0.2%)
Glycerol;propylene Glycol	1 (0.4%)	0	1 (0.2%)
Paraffin	1 (0.4%)	0	1 (0.2%)
Paraffin, Liquid	1 (0.4%)	0	1 (0.2%)
Paraffin;paraffin, Liquid;retinol Palmitate;white Soft Paraffin;wool Fat	1 (0.4%)	0	1 (0.2%)
Pirenoxine	1 (0.4%)	0	1 (0.2%)
Retinol Palmitate	1 (0.4%)	0	1 (0.2%)
Trehalose	1 (0.4%)	0	1 (0.2%)
Methylcellulose	0	1 (0.4%)	1 (0.2%)
Other Surgical Aids	1 (0.4%)	0	1 (0.2%)
Hyaluronidase	1 (0.4%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Parasympathomimetics	1 (0.4%)	0	1 (0.2%)
Neostigmine Metilsulfate	1 (0.4%)	0	1 (0.2%)
Prostaglandin Analogues	2 (0.8%)	6 (2.5%)	8 (1.7%)
Bimatoprost	1 (0.4%)	2 (0.8%)	3 (0.6%)
Latanoprost	1 (0.4%)	4 (1.7%)	5 (1.0%)
Sympathomimetics In Glaucoma Therapy	1 (0.4%)	0	1 (0.2%)
Benzododecinium Bromide;berberine Hydrochloride;oxedrine Tartrate	1 (0.4%)	0	1 (0.2%)
Sympathomimetics Used As Decongestants	1 (0.4%)	1 (0.4%)	2 (0.4%)
Naphazoline Hydrochloride	1 (0.4%)	0	1 (0.2%)
Brimonidine	0	1 (0.4%)	1 (0.2%)
Other Alimentary Tract And Metabolism Products	18 (7.5%)	6 (2.5%)	24 (5.0%)
Amino Acids And Derivatives	7 (2.9%)	1 (0.4%)	8 (1.7%)
Acetylcysteine	3 (1.3%)	1 (0.4%)	4 (0.8%)
Ademetionine	3 (1.3%)	0	3 (0.6%)
Levocarnitine Hydrochloride	1 (0.4%)	0	1 (0.2%)
Not Applicable	2 (0.8%)	0	2 (0.4%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Clostridium Butyricum	2 (0.8%)	0	2 (0.4%)
Various Alimentary Tract And Metabolism Products	9 (3.8%)	5 (2.1%)	14 (2.9%)
Sodium Bicarbonate	4 (1.7%)	3 (1.2%)	7 (1.5%)
Phosphorus	3 (1.3%)	1 (0.4%)	4 (0.8%)
Ubidecarenone	2 (0.8%)	1 (0.4%)	3 (0.6%)
Various Alimentary Tract And Metabolism Products	1 (0.4%)	0	1 (0.2%)
Polaprezinc	0	1 (0.4%)	1 (0.2%)
Other Dermatological Preparations	8 (3.3%)	0	8 (1.7%)
Agents For Dermatitis, Excluding Corticosteroids	2 (0.8%)	0	2 (0.4%)
Tacrolimus	2 (0.8%)	0	2 (0.4%)
Not Applicable	2 (0.8%)	0	2 (0.4%)
Other Dermatological Preparations	2 (0.8%)	0	2 (0.4%)
Other Dermatologicals	4 (1.7%)	0	4 (0.8%)
Guaiazulene	1 (0.4%)	0	1 (0.2%)
Minoxidil	1 (0.4%)	0	1 (0.2%)
Omega-3 Fatty Acids;omega-6 Fatty Acids;taurine;vitamin E Nos	1 (0.4%)	0	1 (0.2%)
Pyrithione Zinc	1 (0.4%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Wart And Anti-Corn Preparations	1 (0.4%)	0	1 (0.2%)
Salicylic Acid	1 (0.4%)	0	1 (0.2%)
Other Drugs For Disorders Of The Musculo-Skeletal System	1 (0.4%)	0	1 (0.2%)
Other Drugs For Disorders Of The Musculo-Skeletal System	1 (0.4%)	0	1 (0.2%)
Hyaluronate Sodium	1 (0.4%)	0	1 (0.2%)
Other Hematological Agents	4 (1.7%)	0	4 (0.8%)
Enzymes	4 (1.7%)	0	4 (0.8%)
Bromelains;cysteine	2 (0.8%)	0	2 (0.4%)
Hyaluronidase	1 (0.4%)	0	1 (0.2%)
Streptodornase;streptokinase	1 (0.4%)	0	1 (0.2%)
Other Nervous System Drugs	16 (6.7%)	7 (2.9%)	23 (4.8%)
Antivertigo Preparations	2 (0.8%)	0	2 (0.4%)
Acetylleucine	1 (0.4%)	0	1 (0.2%)
Betahistine	1 (0.4%)	0	1 (0.2%)
Choline Esters	1 (0.4%)	1 (0.4%)	2 (0.4%)
Bethanechol Chloride	1 (0.4%)	1 (0.4%)	2 (0.4%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Drugs Used In Nicotine Dependence	2 (0.8%)	2 (0.8%)	4 (0.8%)
Nicotine	1 (0.4%)	2 (0.8%)	3 (0.6%)
Nicotine Polacrilex	1 (0.4%)	1 (0.4%)	2 (0.4%)
Drugs Used In Opioid Dependence	0	1 (0.4%)	1 (0.2%)
Buprenorphine	0	1 (0.4%)	1 (0.2%)
Herbal Antivertigo Preparations	1 (0.4%)	0	1 (0.2%)
Ginkgo Biloba Extract	1 (0.4%)	0	1 (0.2%)
Other Nervous System Drugs	9 (3.8%)	2 (0.8%)	11 (2.3%)
Mecobalamin	3 (1.3%)	1 (0.4%)	4 (0.8%)
Thioctic Acid	3 (1.3%)	0	3 (0.6%)
Cyanocobalamin	1 (0.4%)	0	1 (0.2%)
Cyanocobalamin;pyridoxine Hydrochloride;thiamine Hydrochloride	1 (0.4%)	0	1 (0.2%)
Cytidine Phosphate Sodium;uridine	1 (0.4%)	0	1 (0.2%)
Methylethylpiridinol Succinate	1 (0.4%)	0	1 (0.2%)
Vitamin B12 Nos	1 (0.4%)	0	1 (0.2%)
Gabapentin	0	1 (0.4%)	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Other Parasympathomimetics	2 (0.8%)	1 (0.4%)	3 (0.6%)
Choline Alfoscerate	1 (0.4%)	1 (0.4%)	2 (0.4%)
Pilocarpine	1 (0.4%)	0	1 (0.2%)
Other Respiratory System Products	1 (0.4%)	2 (0.8%)	3 (0.6%)
Other Respiratory System Products	1 (0.4%)	0	1 (0.2%)
Ambroxol	1 (0.4%)	0	1 (0.2%)
Respiratory Stimulants	0	2 (0.8%)	2 (0.4%)
Caffeine	0	1 (0.4%)	1 (0.2%)
Caffeine Citrate	0	1 (0.4%)	1 (0.2%)
Otologicals	1 (0.4%)	0	1 (0.2%)
Corticosteroids	1 (0.4%)	0	1 (0.2%)
Dexamethasone	1 (0.4%)	0	1 (0.2%)
Pancreatic Hormones	1 (0.4%)	0	1 (0.2%)
Glycogenolytic Hormones	1 (0.4%)	0	1 (0.2%)
Glucagon	1 (0.4%)	0	1 (0.2%)
Peripheral Vasodilators	3 (1.3%)	0	3 (0.6%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Ginkgo Remedies	1 (0.4%)	0	1 (0.2%)
Ginkgo Biloba	1 (0.4%)	0	1 (0.2%)
Nicotinic Acid And Derivatives	1 (0.4%)	0	1 (0.2%)
Nicametate Dihydrogen Citrate	1 (0.4%)	0	1 (0.2%)
Purine Derivatives	1 (0.4%)	0	1 (0.2%)
Xantinol Nicotinate	1 (0.4%)	0	1 (0.2%)
Pituitary And Hypothalamic Hormones And Analogues	3 (1.3%)	2 (0.8%)	5 (1.0%)
Acth	1 (0.4%)	2 (0.8%)	3 (0.6%)
Tetracosactide	1 (0.4%)	0	1 (0.2%)
Tetracosactide Acetate	0	2 (0.8%)	2 (0.4%)
Somatostatin And Analogues	1 (0.4%)	0	1 (0.2%)
Octreotide	1 (0.4%)	0	1 (0.2%)
Vasopressin And Analogues	2 (0.8%)	0	2 (0.4%)
Vasopressin	2 (0.8%)	0	2 (0.4%)
Preparations For Treatment Of Wounds And Ulcers	5 (2.1%)	0	5 (1.0%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Herbal Preparations For Treatment Of Wounds And Ulcers Containing Asiaticosid	1 (0.4%)	0	1 (0.2%)
Centella Asiatica Extract	1 (0.4%)	0	1 (0.2%)
Herbal Preparations For Treatment Of Wounds And Ulcers, Other	1 (0.4%)	0	1 (0.2%)
Myroxylon Balsamum	1 (0.4%)	0	1 (0.2%)
Not Applicable	1 (0.4%)	0	1 (0.2%)
Benzethonium Chloride;lauromacrogol 400;urea	1 (0.4%)	0	1 (0.2%)
Other Cicatrizants	3 (1.3%)	0	3 (0.6%)
Alprostadil Alfadex	1 (0.4%)	0	1 (0.2%)
Dexpanthenol	1 (0.4%)	0	1 (0.2%)
Panthenol	1 (0.4%)	0	1 (0.2%)
Proteolytic Enzymes	1 (0.4%)	0	1 (0.2%)
Collagenase	1 (0.4%)	0	1 (0.2%)
Psychoanaleptics	36 (15.0%)	20 (8.3%)	56 (11.6%)
Anticholinesterases	2 (0.8%)	0	2 (0.4%)
Ipidacrine	2 (0.8%)	0	2 (0.4%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Centrally Acting Sympathomimetics	2 (0.8%)	1 (0.4%)	3 (0.6%)
Methylphenidate	1 (0.4%)	1 (0.4%)	2 (0.4%)
Methylphenidate Hydrochloride	1 (0.4%)	0	1 (0.2%)
Non-Selective Monoamine Reuptake Inhibitors	1 (0.4%)	0	1 (0.2%)
Opipramol Hydrochloride	1 (0.4%)	0	1 (0.2%)
Other Antidepressants	22 (9.2%)	10 (4.1%)	32 (6.6%)
Trazodone	7 (2.9%)	3 (1.2%)	10 (2.1%)
Mirtazapine	6 (2.5%)	3 (1.2%)	9 (1.9%)
Trazodone Hydrochloride	4 (1.7%)	0	4 (0.8%)
Venlafaxine	2 (0.8%)	1 (0.4%)	3 (0.6%)
Venlafaxine Hydrochloride	2 (0.8%)	0	2 (0.4%)
Bupropion	1 (0.4%)	0	1 (0.2%)
Bupropion Hydrochloride	1 (0.4%)	2 (0.8%)	3 (0.6%)
Duloxetine	1 (0.4%)	0	1 (0.2%)
Lamotrigine	1 (0.4%)	1 (0.4%)	2 (0.4%)
Other Psychostimulants And Nootropics	2 (0.8%)	1 (0.4%)	3 (0.6%)
Citicoline	1 (0.4%)	1 (0.4%)	2 (0.4%)
Idebenone	1 (0.4%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Selective Serotonin Reuptake Inhibitors	9 (3.8%)	10 (4.1%)	19 (3.9%)
Citalopram	3 (1.3%)	3 (1.2%)	6 (1.2%)
Escitalopram	2 (0.8%)	2 (0.8%)	4 (0.8%)
Citalopram Hydrobromide	1 (0.4%)	0	1 (0.2%)
Escitalopram Oxalate	1 (0.4%)	2 (0.8%)	3 (0.6%)
Paroxetine	1 (0.4%)	1 (0.4%)	2 (0.4%)
Sertraline	1 (0.4%)	1 (0.4%)	2 (0.4%)
Fluoxetine	0	1 (0.4%)	1 (0.2%)
Psycholeptics	86 (35.8%)	79 (32.6%)	165 (34.2%)
Benzamides	0	1 (0.4%)	1 (0.2%)
Sulpiride	0	1 (0.4%)	1 (0.2%)
Benzodiazepine Derivatives	51 (21.3%)	40 (16.5%)	91 (18.9%)
Lorazepam	22 (9.2%)	21 (8.7%)	43 (8.9%)
Alprazolam	10 (4.2%)	9 (3.7%)	19 (3.9%)
Diazepam	5 (2.1%)	2 (0.8%)	7 (1.5%)
Clonazepam	4 (1.7%)	2 (0.8%)	6 (1.2%)
Midazolam	4 (1.7%)	3 (1.2%)	7 (1.5%)
Midazolam Hydrochloride	4 (1.7%)	1 (0.4%)	5 (1.0%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Oxazepam	4 (1.7%)	1 (0.4%)	5 (1.0%)
Bromazepam	3 (1.3%)	1 (0.4%)	4 (0.8%)
Estazolam	2 (0.8%)	1 (0.4%)	3 (0.6%)
Lormetazepam	2 (0.8%)	1 (0.4%)	3 (0.6%)
Brotizolam	1 (0.4%)	0	1 (0.2%)
Etizolam	1 (0.4%)	0	1 (0.2%)
Flunitrazepam	1 (0.4%)	0	1 (0.2%)
Temazepam	1 (0.4%)	1 (0.4%)	2 (0.4%)
Clorazepate Dipotassium	0	1 (0.4%)	1 (0.2%)
Delorazepam	0	1 (0.4%)	1 (0.2%)
Fludiazepam	0	1 (0.4%)	1 (0.2%)
Benzodiazepine Related Drugs	22 (9.2%)	9 (3.7%)	31 (6.4%)
Zolpidem	9 (3.8%)	2 (0.8%)	11 (2.3%)
Zopiclone	7 (2.9%)	2 (0.8%)	9 (1.9%)
Zolpidem Tartrate	6 (2.5%)	4 (1.7%)	10 (2.1%)
Eszopiclone	0	1 (0.4%)	1 (0.2%)
Butyrophenone Derivatives	6 (2.5%)	2 (0.8%)	8 (1.7%)
Haloperidol	5 (2.1%)	2 (0.8%)	7 (1.5%)
Haloperidol Lactate	1 (0.4%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Diazepines, Oxazepines, Thiazepines And Oxepines	10 (4.2%)	39 (16.1%)	49 (10.2%)
Quetiapine	5 (2.1%)	2 (0.8%)	7 (1.5%)
Olanzapine	4 (1.7%)	35 (14.5%)	39 (8.1%)
Quetiapine Fumarate	2 (0.8%)	1 (0.4%)	3 (0.6%)
Clozapine	0	1 (0.4%)	1 (0.2%)
Diphenylmethane Derivatives	2 (0.8%)	0	2 (0.4%)
Hydroxyzine	1 (0.4%)	0	1 (0.2%)
Hydroxyzine Hydrochloride	1 (0.4%)	0	1 (0.2%)
Hypnotics And Sedatives In Combination, Excl. Barbiturates	3 (1.3%)	0	3 (0.6%)
Diphenhydramine Hydrochloride;paracetamol	2 (0.8%)	0	2 (0.4%)
Diphenhydramine Citrate;ibuprofen	1 (0.4%)	0	1 (0.2%)
Melatonin Receptor Agonists	7 (2.9%)	5 (2.1%)	12 (2.5%)
Melatonin	7 (2.9%)	5 (2.1%)	12 (2.5%)
Ramelteon	1 (0.4%)	0	1 (0.2%)
Not Applicable	3 (1.3%)	0	3 (0.6%)
Blonanserin	1 (0.4%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Cannabidiol	1 (0.4%)	0	1 (0.2%)
Cannabis Sativa	1 (0.4%)	0	1 (0.2%)
Other Antipsychotics	3 (1.3%)	2 (0.8%)	5 (1.0%)
Risperidone	2 (0.8%)	0	2 (0.4%)
Perospirone Hydrochloride Dihydrate	1 (0.4%)	0	1 (0.2%)
Prothipendyl	1 (0.4%)	0	1 (0.2%)
Valproate Sodium	1 (0.4%)	0	1 (0.2%)
Valproic Acid	1 (0.4%)	0	1 (0.2%)
Aripiprazole	0	1 (0.4%)	1 (0.2%)
Paliperidone	0	1 (0.4%)	1 (0.2%)
Other Anxiolytics	5 (2.1%)	7 (2.9%)	12 (2.5%)
Amitriptyline	1 (0.4%)	0	1 (0.2%)
Amitriptyline Hydrochloride	1 (0.4%)	0	1 (0.2%)
Duloxetine Hydrochloride	1 (0.4%)	0	1 (0.2%)
Escitalopram Oxalate	1 (0.4%)	3 (1.2%)	4 (0.8%)
Sertraline	1 (0.4%)	0	1 (0.2%)
Duloxetine	0	1 (0.4%)	1 (0.2%)
Pregabalin	0	1 (0.4%)	1 (0.2%)
Venlafaxine	0	1 (0.4%)	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Venlafaxine Hydrochloride	0	1 (0.4%)	1 (0.2%)
Other Hypnotics And Sedatives	9 (3.8%)	1 (0.4%)	10 (2.1%)
Lemborexant	3 (1.3%)	1 (0.4%)	4 (0.8%)
Dexmedetomidine	1 (0.4%)	0	1 (0.2%)
Dexmedetomidine Hydrochloride	1 (0.4%)	0	1 (0.2%)
Diphenhydramine	1 (0.4%)	0	1 (0.2%)
Diphenhydramine Hydrochloride	1 (0.4%)	0	1 (0.2%)
Doxepin Hydrochloride	1 (0.4%)	0	1 (0.2%)
Doxylamine Succinate	1 (0.4%)	0	1 (0.2%)
Suvorexant	1 (0.4%)	0	1 (0.2%)
Phenothiazines With Aliphatic Side-Chain	4 (1.7%)	3 (1.2%)	7 (1.5%)
Chlorpromazine Hydrochloride	2 (0.8%)	3 (1.2%)	5 (1.0%)
Chlorpromazine	1 (0.4%)	0	1 (0.2%)
Cyamemazine	1 (0.4%)	0	1 (0.2%)
Phenothiazines With Piperazine Structure	0	1 (0.4%)	1 (0.2%)
Prochlorperazine Maleate	0	1 (0.4%)	1 (0.2%)
Sex Hormones And Modulators Of The Genital System	1 (0.4%)	2 (0.8%)	3 (0.6%)

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Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
3-Oxoandrosten (4) Derivatives	1 (0.4%)	1 (0.4%)	2 (0.4%)
Testosterone	1 (0.4%)	0	1 (0.2%)
Testosterone Cipionate	0	1 (0.4%)	1 (0.2%)
Selective Estrogen Receptor Modulators	0	1 (0.4%)	1 (0.2%)
Raloxifene Hydrochloride	0	1 (0.4%)	1 (0.2%)
Stomatological Preparations	32 (13.3%)	18 (7.4%)	50 (10.4%)
Antiinfectives And Antiseptics For Local Oral Treatment	18 (7.5%)	7 (2.9%)	25 (5.2%)
Nystatin	8 (3.3%)	4 (1.7%)	12 (2.5%)
Chlorhexidine	5 (2.1%)	1 (0.4%)	6 (1.2%)
Chlorhexidine Gluconate	3 (1.3%)	2 (0.8%)	5 (1.0%)
Amphotericin B	2 (0.8%)	1 (0.4%)	3 (0.6%)
Miconazole	1 (0.4%)	0	1 (0.2%)
Povidone-Iodine	1 (0.4%)	0	1 (0.2%)
Corticosteroids For Local Oral Treatment	4 (1.7%)	0	4 (0.8%)
Triamcinolone Acetonide	3 (1.3%)	0	3 (0.6%)
Benzalkonium Chloride;dexamethasone;resorcinol;tetracaine Hydrochloride	1 (0.4%)	0	1 (0.2%)
Not Applicable	5 (2.1%)	7 (2.9%)	12 (2.5%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Sodium Bicarbonate	5 (2.1%)	6 (2.5%)	11 (2.3%)
Benzalkonium Chloride;chlorhexidine Hydrochloride;diphenhydramine Salicylate;hydrocortisone Acetate	0	1 (0.4%)	1 (0.2%)
Other Agents For Local Oral Treatment	11 (4.6%)	5 (2.1%)	16 (3.3%)
Benzydamine Hydrochloride	2 (0.8%)	3 (1.2%)	5 (1.0%)
Lidocaine	2 (0.8%)	0	2 (0.4%)
Lidocaine Hydrochloride;matricaria Chamomilla Flower	2 (0.8%)	0	2 (0.4%)
Other Agents For Local Oral Treatment	2 (0.8%)	0	2 (0.4%)
Benzydamine	1 (0.4%)	0	1 (0.2%)
Glycerol;hyetellose;methylparaben;poloxamer 407;propylene Glycol;propylparaben;sodium Benzoate;sodium Phosphate;sodium Phosphate Dibasic;sorbitol;xylitol	1 (0.4%)	0	1 (0.2%)
Hyaluronate Sodium	1 (0.4%)	0	1 (0.2%)
Magic Mouthwash	1 (0.4%)	0	1 (0.2%)
Sodium Gualenate Hydrate	1 (0.4%)	1 (0.4%)	2 (0.4%)
Sucralfate	0	1 (0.4%)	1 (0.2%)
Throat Preparations	7 (2.9%)	1 (0.4%)	8 (1.7%)
Anesthetics, Local	2 (0.8%)	0	2 (0.4%)
Lidocaine Hydrochloride	2 (0.8%)	0	2 (0.4%)
Antiseptics	3 (1.3%)	0	3 (0.6%)
Dequalinium Chloride	1 (0.4%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
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Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Herbal Extract Nos;phenyl Salicylate	1 (0.4%)	0	1 (0.2%)
Phenol	1 (0.4%)	0	1 (0.2%)
Other Throat Preparations	2 (0.8%)	1 (0.4%)	3 (0.6%)
Benzydamine Hydrochloride	2 (0.8%)	1 (0.4%)	3 (0.6%)
Thyroid Therapy	37 (15.4%)	12 (5.0%)	49 (10.2%)
Other Antithyroid Preparations	3 (1.3%)	0	3 (0.6%)
Propranolol	2 (0.8%)	0	2 (0.4%)
Propranolol Hydrochloride	1 (0.4%)	0	1 (0.2%)
Perchlorates	1 (0.4%)	0	1 (0.2%)
Sodium Perchlorate	1 (0.4%)	0	1 (0.2%)
Sulfur-Containing Imidazole Derivatives	3 (1.3%)	1 (0.4%)	4 (0.8%)
Thiamazole	2 (0.8%)	0	2 (0.4%)
Carbimazole	1 (0.4%)	1 (0.4%)	2 (0.4%)
Thyroid Hormones	35 (14.6%)	11 (4.5%)	46 (9.5%)
Levothyroxine Sodium	24 (10.0%)	5 (2.1%)	29 (6.0%)
Levothyroxine	11 (4.6%)	7 (2.9%)	18 (3.7%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Tonics	2 (0.8%)	5 (2.1%)	7 (1.5%)
Not Applicable	2 (0.8%)	5 (2.1%)	7 (1.5%)
Ammonium Molybdate;boric Acid;cobalt Chloride;copper Sulfate;ferrous Sulfate;magnesium Sulfate;manganese Sulfate;nickel Sulfate;sodium Fluoride;vanadium Ammonium;zinc Sulfate	1 (0.4%)	0	1 (0.2%)
Curcuma Longa	1 (0.4%)	3 (1.2%)	4 (0.8%)
Curcumin	0	1 (0.4%)	1 (0.2%)
Tonics	0	1 (0.4%)	1 (0.2%)
Topical Products For Joint And Muscular Pain	5 (2.1%)	10 (4.1%)	15 (3.1%)
Antiinflammatory Preparations, Non-Steroids For Topical Use	5 (2.1%)	9 (3.7%)	14 (2.9%)
Diclofenac Sodium	2 (0.8%)	2 (0.8%)	4 (0.8%)
Diclofenac Diethylamine	1 (0.4%)	0	1 (0.2%)
Diclofenac Epolamine	1 (0.4%)	0	1 (0.2%)
Esflurbiprofen;mentha Spp. Oil	1 (0.4%)	0	1 (0.2%)
Flurbiprofen	1 (0.4%)	0	1 (0.2%)
Diclofenac	0	1 (0.4%)	1 (0.2%)
Felbinac	0	1 (0.4%)	1 (0.2%)
Ketoprofen	0	3 (1.2%)	3 (0.6%)
Loxoprofen Sodium	0	1 (0.4%)	1 (0.2%)
Loxoprofen Sodium Dihydrate	0	1 (0.4%)	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Preparations With Salicylic Acid Derivatives	0	1 (0.4%)	1 (0.2%)
Camphor;eucalyptus Globulus Oil;menthol;methyl Salicylate	0	1 (0.4%)	1 (0.2%)
Uncoded	1 (0.4%)	0	1 (0.2%)
Uncoded	1 (0.4%)	0	1 (0.2%)
Dermatologicals	1 (0.4%)	0	1 (0.2%)
Unspecified Herbal And Traditional Medicine	1 (0.4%)	1 (0.4%)	2 (0.4%)
Not Applicable	1 (0.4%)	1 (0.4%)	2 (0.4%)
Arctium Lappa Fruit	1 (0.4%)	0	1 (0.2%)
Bassia Scoparia Fruit	1 (0.4%)	0	1 (0.2%)
Imperata Cylindrica Rhizome	1 (0.4%)	0	1 (0.2%)
Paeonia Spp. Root	1 (0.4%)	0	1 (0.2%)
Smilax Glabra Rhizome	1 (0.4%)	0	1 (0.2%)
Arctium Lappa Root;rheum Officinale Root;rumex Acetosella Leaf;ulmus Rubra Bark	0	1 (0.4%)	1 (0.2%)
Urologicals	71 (29.6%)	46 (19.0%)	117 (24.3%)
Alpha-Adrenoreceptor Antagonists	53 (22.1%)	26 (10.7%)	79 (16.4%)
Tamsulosin	28 (11.7%)	12 (5.0%)	40 (8.3%)
Tamsulosin Hydrochloride	18 (7.5%)	9 (3.7%)	27 (5.6%)
Dutasteride;tamsulosin Hydrochloride	5 (2.1%)	2 (0.8%)	7 (1.5%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Silodosin	3 (1.3%)	1 (0.4%)	4 (0.8%)
Dutasteride;tamsulosin	2 (0.8%)	0	2 (0.4%)
Naftopidil	1 (0.4%)	0	1 (0.2%)
Terazosin	1 (0.4%)	0	1 (0.2%)
Alfuzosin	0	2 (0.8%)	2 (0.4%)
Doxazosin	0	1 (0.4%)	1 (0.2%)
Drugs For Urinary Frequency And Incontinence	23 (9.6%)	16 (6.6%)	39 (8.1%)
Mirabegron	8 (3.3%)	7 (2.9%)	15 (3.1%)
Oxybutynin	7 (2.9%)	1 (0.4%)	8 (1.7%)
Solifenacin	4 (1.7%)	2 (0.8%)	6 (1.2%)
Oxybutynin Hydrochloride	3 (1.3%)	1 (0.4%)	4 (0.8%)
Solifenacin Succinate	2 (0.8%)	1 (0.4%)	3 (0.6%)
Vibegron	2 (0.8%)	0	2 (0.4%)
Fesoterodine Fumarate	1 (0.4%)	0	1 (0.2%)
Imipramine	1 (0.4%)	0	1 (0.2%)
Propiverine Hydrochloride	1 (0.4%)	0	1 (0.2%)
Tolterodine L-Tartrate	1 (0.4%)	1 (0.4%)	2 (0.4%)
Drotaverine Hydrochloride	0	1 (0.4%)	1 (0.2%)
Fesoterodine	0	1 (0.4%)	1 (0.2%)
Trospium Chloride	0	1 (0.4%)	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Drugs Used In Erectile Dysfunction	6 (2.5%)	2 (0.8%)	8 (1.7%)
Tadalafil	4 (1.7%)	0	4 (0.8%)
Sildenafil	2 (0.8%)	1 (0.4%)	3 (0.6%)
Alprostadil	0	1 (0.4%)	1 (0.2%)
Herbal Drugs Used In Benign Prostatic Hypertrophy	1 (0.4%)	1 (0.4%)	2 (0.4%)
Curcuma Longa;phytosterols Nos;prunus Africana;secale Cereale;serenoa Repens;solanum Lycopersicum;urtica Dioica	1 (0.4%)	0	1 (0.2%)
Serenoa Repens Extract	0	1 (0.4%)	1 (0.2%)
Not Applicable	0	1 (0.4%)	1 (0.2%)
Centaurium Erythraea;levisticum Officinale;salvia Rosmarinus	0	1 (0.4%)	1 (0.2%)
Other Drugs Used In Benign Prostatic Hypertrophy	0	1 (0.4%)	1 (0.2%)
Tadalafil	0	1 (0.4%)	1 (0.2%)
Other Urologicals	9 (3.8%)	7 (2.9%)	16 (3.3%)
Phenazopyridine Hydrochloride	4 (1.7%)	3 (1.2%)	7 (1.5%)
Phenazopyridine	2 (0.8%)	3 (1.2%)	5 (1.0%)
Escherichia Coli	1 (0.4%)	0	1 (0.2%)
Methylthioninium Chloride	1 (0.4%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Pentosan Polysulfate Sodium	1 (0.4%)	0	1 (0.2%)
Citric Acid;sodium Bicarbonate;sodium Citrate;tartaric Acid	0	1 (0.4%)	1 (0.2%)
Testosterone-5-Alpha Reductase Inhibitors	6 (2.5%)	3 (1.2%)	9 (1.9%)
Finasteride	4 (1.7%)	2 (0.8%)	6 (1.2%)
Dutasteride	2 (0.8%)	1 (0.4%)	3 (0.6%)
Vaccines	37 (15.4%)	15 (6.2%)	52 (10.8%)
Covid-19 Vaccines	34 (14.2%)	14 (5.8%)	48 (10.0%)
Tozinameran	20 (8.3%)	3 (1.2%)	23 (4.8%)
Elasomeran	15 (6.3%)	7 (2.9%)	22 (4.6%)
Covid-19 Vaccine	1 (0.4%)	1 (0.4%)	2 (0.4%)
Covid-19 Vaccine Nrvv Ad (Chadox1 Ncov-19)	1 (0.4%)	1 (0.4%)	2 (0.4%)
Covid-19 Vaccine Nrvv Ad26 (Jnj 78436735)	1 (0.4%)	1 (0.4%)	2 (0.4%)
Covid-19 Vaccine Mrna	0	1 (0.4%)	1 (0.2%)
Influenza Vaccines	7 (2.9%)	4 (1.7%)	11 (2.3%)
Influenza Vaccine	4 (1.7%)	2 (0.8%)	6 (1.2%)
Influenza Vaccine Inact Split 4v	3 (1.3%)	2 (0.8%)	5 (1.0%)
Pneumococcal Vaccines	1 (0.4%)	1 (0.4%)	2 (0.4%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Pneumococcal Vaccine Conj 20v (Crm197)	1 (0.4%)	0	1 (0.2%)
Pneumococcal Vaccine Polysacch 23v	0	1 (0.4%)	1 (0.2%)
Vasoprotectives	8 (3.3%)	6 (2.5%)	14 (2.9%)
Bioflavonoids	2 (0.8%)	0	2 (0.4%)
Diosmin;hesperidin	2 (0.8%)	0	2 (0.4%)
Corticosteroids	2 (0.8%)	5 (2.1%)	7 (1.5%)
Betamethasone	1 (0.4%)	0	1 (0.2%)
Betamethasone Valerate;lidocaine Hydrochloride;phenylephrine Hydrochloride	1 (0.4%)	1 (0.4%)	2 (0.4%)
Betamethasone;lidocaine;phenylephrine	1 (0.4%)	0	1 (0.2%)
Bismuth Subgallate;fluocinolone Acetonide;lidocaine Hydrochloride;menthol	0	1 (0.4%)	1 (0.2%)
Hydrocortisone	0	2 (0.8%)	2 (0.4%)
Lidocaine Hydrochloride;triamcinolone Acetonide	0	1 (0.4%)	1 (0.2%)
Heparins Or Heparinoids For Topical Use	1 (0.4%)	0	1 (0.2%)
Benzocaine;benzyl Nicotinate;heparin Sodium	1 (0.4%)	0	1 (0.2%)
Herbal Capillary Stabilizing Remedies	1 (0.4%)	0	1 (0.2%)
Paeonia X Suffruticosa	1 (0.4%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Local Anesthetics	3 (1.3%)	0	3 (0.6%)
Cinchocaine;policresulen	1 (0.4%)	0	1 (0.2%)
Lidocaine	1 (0.4%)	0	1 (0.2%)
Lidocaine Hydrochloride;tribenoside	1 (0.4%)	0	1 (0.2%)
Not Applicable	1 (0.4%)	0	1 (0.2%)
Agents For Treatment Of Hemorrhoids And Anal Fissures For Topical Use	1 (0.4%)	0	1 (0.2%)
Other Agents For Treatment Of Hemorrhoids And Anal Fissures For Topical Use	1 (0.4%)	1 (0.4%)	2 (0.4%)
Ruscogenin;trimebutine Maleate	1 (0.4%)	0	1 (0.2%)
Zinc Sulfate	0	1 (0.4%)	1 (0.2%)
Vitamins	53 (22.1%)	35 (14.5%)	88 (18.3%)
Ascorbic Acid (Vitamin C), Plain	9 (3.8%)	5 (2.1%)	14 (2.9%)
Ascorbic Acid	8 (3.3%)	5 (2.1%)	13 (2.7%)
Calcium Ascorbate	1 (0.4%)	0	1 (0.2%)
Combinations Of Vitamins	2 (0.8%)	0	2 (0.4%)
Bisbentiamine;cyanocobalamin;pyridoxine Hydrochloride;riboflavin	1 (0.4%)	0	1 (0.2%)
Folic Acid;pyridoxine Hydrochloride;vitamin B12 Nos	1 (0.4%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Multivitamins With Minerals	3 (1.3%)	0	3 (0.6%)
Ascorbic Acid;calcium;minerals Nos;retinol;tocopheryl Acetate;vitamin B Nos;vitamins Nos;zinc	2 (0.8%)	0	2 (0.4%)
Minerals Nos;vitamins Nos	1 (0.4%)	0	1 (0.2%)
Multivitamins, Other Combinations	1 (0.4%)	0	1 (0.2%)
Ascorbic Acid;betacarotene;biotin;calcium;chloride;chromium;copper;folic Acid;iodine;lycopene;magnesium;manganese;molybdenum;nickel;nicotinic Acid;pantothenic Acid;phosphorus;potassium;pyridoxine Hydrochloride;riboflavin;selenium;silicon;thiamine;vanadium;vitamin B12 Nos;vitamin D Nos;vitamin E Nos;vitamin K Nos;xantofyl;zinc	1 (0.4%)	0	1 (0.2%)
Multivitamins, Plain	7 (2.9%)	7 (2.9%)	14 (2.9%)
Multivitamins, Plain	6 (2.5%)	6 (2.5%)	12 (2.5%)
Ascorbic Acid;betacarotene;cyanocobalamin;dl-Alpha Tocopheryl Acetate;ergocalciferol;folic Acid;nicotinic Acid;pantothenic Acid;pyridoxine Hydrochloride;riboflavin;thiamine Hydrochloride	1 (0.4%)	1 (0.4%)	2 (0.4%)
Other Plain Vitamin Preparations	7 (2.9%)	3 (1.2%)	10 (2.1%)
Pyridoxine Hydrochloride	3 (1.3%)	0	3 (0.6%)
Dexpanthenol	1 (0.4%)	0	1 (0.2%)
Pyridoxine	1 (0.4%)	2 (0.8%)	3 (0.6%)
Tocopheryl Acetate	1 (0.4%)	0	1 (0.2%)
Vitamin E Nos	1 (0.4%)	1 (0.4%)	2 (0.4%)
Vitamin A, Plain	2 (0.8%)	0	2 (0.4%)
Betacarotene	1 (0.4%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Retinol Palmitate	1 (0.4%)	0	1 (0.2%)
Vitamin B-Complex With Vitamin C	2 (0.8%)	2 (0.8%)	4 (0.8%)
Ascorbic Acid;vitamin B Complex	2 (0.8%)	1 (0.4%)	3 (0.6%)
Ascorbic Acid;calcium Pantothenate;cyanocobalamin;nicotinamide;pyridoxine Hydrochloride;riboflavin;thiamine Hydrochloride	0	1 (0.4%)	1 (0.2%)
Vitamin B-Complex, Plain	10 (4.2%)	1 (0.4%)	11 (2.3%)
Vitamin B Complex	10 (4.2%)	1 (0.4%)	11 (2.3%)
Vitamin B1 In Combination With Vitamin B6 And/Or Vitamin B12	7 (2.9%)	2 (0.8%)	9 (1.9%)
Cyanocobalamin;pyridoxine Hydrochloride;riboflavin;thiamine Mononitrate	2 (0.8%)	1 (0.4%)	3 (0.6%)
Benfotiamine;cyanocobalamin;pyridoxine	1 (0.4%)	0	1 (0.2%)
Benfotiamine;cyanocobalamin;pyridoxine Hydrochloride	1 (0.4%)	0	1 (0.2%)
Benfotiamine;pyridoxine	1 (0.4%)	0	1 (0.2%)
Cyanocobalamin;pyridoxine Hydrochloride;thiamine Disulfide	1 (0.4%)	0	1 (0.2%)
Cyanocobalamin;pyridoxine Hydrochloride;thiamine Hydrochloride	1 (0.4%)	0	1 (0.2%)
Vitamin B1 In Combination With Vitamin B6 And/Or Vitamin B12	1 (0.4%)	0	1 (0.2%)
Cyanocobalamin;pyridoxine Hydrochloride;riboflavin;thiamine Disulfide	0	1 (0.4%)	1 (0.2%)
Vitamin B1, Plain	5 (2.1%)	3 (1.2%)	8 (1.7%)
Thiamine	3 (1.3%)	2 (0.8%)	5 (1.0%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.1: Summary of Concomitant Therapies - Analysis Set mITT 1

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Fursultiamine	1 (0.4%)	0	1 (0.2%)
Fursultiamine Hydrochloride	1 (0.4%)	0	1 (0.2%)
Thiamine Hydrochloride	1 (0.4%)	1 (0.4%)	2 (0.4%)
Vitamin D And Analogues	24 (10.0%)	25 (10.3%)	49 (10.2%)
Colecalciferol	13 (5.4%)	15 (6.2%)	28 (5.8%)
Vitamin D Nos	7 (2.9%)	8 (3.3%)	15 (3.1%)
Calcifediol	2 (0.8%)	1 (0.4%)	3 (0.6%)
Ergocalciferol	2 (0.8%)	2 (0.8%)	4 (0.8%)
Vitamins, Other Combinations	1 (0.4%)	0	1 (0.2%)
Calcium Levomefolate;cyanocobalamin;magnesium;magnesium Glycerophosphate;pyridoxine Hydrochloride;taurine	1 (0.4%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Overall	197 (97.5%)	194 (96.0%)	391 (96.8%)
Agents Acting On The Renin-Angiotensin System	79 (39.1%)	71 (35.1%)	150 (37.1%)
Ace Inhibitors And Calcium Channel Blockers	3 (1.5%)	1 (0.5%)	4 (1.0%)
Amlodipine Besilate;perindopril Arginine	3 (1.5%)	1 (0.5%)	4 (1.0%)
Ace Inhibitors And Diuretics	1 (0.5%)	5 (2.5%)	6 (1.5%)
Hydrochlorothiazide;ramipril	1 (0.5%)	0	1 (0.2%)
Enalapril Maleate;hydrochlorothiazide	0	1 (0.5%)	1 (0.2%)
Hydrochlorothiazide;lisinopril	0	1 (0.5%)	1 (0.2%)
Indapamide;perindopril	0	1 (0.5%)	1 (0.2%)
Indapamide;perindopril Arginine	0	1 (0.5%)	1 (0.2%)
Indapamide;perindopril Erbumine	0	1 (0.5%)	1 (0.2%)
Ace Inhibitors, Plain	29 (14.4%)	26 (12.9%)	55 (13.6%)
Enalapril	12 (5.9%)	11 (5.4%)	23 (5.7%)
Ramipril	8 (4.0%)	6 (3.0%)	14 (3.5%)
Lisinopril	5 (2.5%)	3 (1.5%)	8 (2.0%)
Perindopril	4 (2.0%)	3 (1.5%)	7 (1.7%)
Captopril	1 (0.5%)	0	1 (0.2%)
Enalapril Maleate	1 (0.5%)	1 (0.5%)	2 (0.5%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Perindopril Arginine	1 (0.5%)	1 (0.5%)	2 (0.5%)
Zofenopril	0	1 (0.5%)	1 (0.2%)
Angiotensin Ii Receptor Blockers (Arbs) And Calcium Channel Blockers	8 (4.0%)	3 (1.5%)	11 (2.7%)
Amlodipine Besilate;olmesartan Medoxomil	3 (1.5%)	1 (0.5%)	4 (1.0%)
Amlodipine Besilate;telmisartan	1 (0.5%)	1 (0.5%)	2 (0.5%)
Amlodipine Besilate;valsartan	1 (0.5%)	1 (0.5%)	2 (0.5%)
Amlodipine;olmesartan	1 (0.5%)	0	1 (0.2%)
Amlodipine;telmisartan	1 (0.5%)	0	1 (0.2%)
Amlodipine;valsartan	1 (0.5%)	0	1 (0.2%)
Angiotensin Ii Receptor Blockers (Arbs) And Diuretics	6 (3.0%)	8 (4.0%)	14 (3.5%)
Hydrochlorothiazide;irbesartan	2 (1.0%)	0	2 (0.5%)
Hydrochlorothiazide;losartan	2 (1.0%)	1 (0.5%)	3 (0.7%)
Hydrochlorothiazide;losartan Potassium	1 (0.5%)	2 (1.0%)	3 (0.7%)
Hydrochlorothiazide;olmesartan	1 (0.5%)	0	1 (0.2%)
Azilsartan Medoxomil;chlortalidone	0	1 (0.5%)	1 (0.2%)
Candesartan Cilexetil;hydrochlorothiazide	0	2 (1.0%)	2 (0.5%)
Hydrochlorothiazide;olmesartan Medoxomil	0	1 (0.5%)	1 (0.2%)
Hydrochlorothiazide;valsartan	0	2 (1.0%)	2 (0.5%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Angiotensin Ii Receptor Blockers (Arbs), Other Combinations	1 (0.5%)	1 (0.5%)	2 (0.5%)
Sacubitril;valsartan	1 (0.5%)	1 (0.5%)	2 (0.5%)
Angiotensin Ii Receptor Blockers (Arbs), Plain	36 (17.8%)	30 (14.9%)	66 (16.3%)
Losartan	11 (5.4%)	6 (3.0%)	17 (4.2%)
Valsartan	6 (3.0%)	2 (1.0%)	8 (2.0%)
Candesartan	5 (2.5%)	5 (2.5%)	10 (2.5%)
Telmisartan	4 (2.0%)	3 (1.5%)	7 (1.7%)
Candesartan Cilexetil	2 (1.0%)	0	2 (0.5%)
Irbesartan	2 (1.0%)	5 (2.5%)	7 (1.7%)
Losartan Potassium	2 (1.0%)	4 (2.0%)	6 (1.5%)
Olmesartan	2 (1.0%)	1 (0.5%)	3 (0.7%)
Olmesartan Medoxomil	2 (1.0%)	2 (1.0%)	4 (1.0%)
Azilsartan	1 (0.5%)	1 (0.5%)	2 (0.5%)
Fimasartan Potassium Trihydrate	1 (0.5%)	1 (0.5%)	2 (0.5%)
Renin-Inhibitors	0	1 (0.5%)	1 (0.2%)
Aliskiren Fumarate	0	1 (0.5%)	1 (0.2%)
All Other Therapeutic Products	9 (4.5%)	13 (6.4%)	22 (5.4%)
Antidotes	4 (2.0%)	3 (1.5%)	7 (1.7%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Flumazenil	2 (1.0%)	0	2 (0.5%)
Acetylcysteine	1 (0.5%)	1 (0.5%)	2 (0.5%)
Naloxone	1 (0.5%)	1 (0.5%)	2 (0.5%)
Naloxone Hydrochloride	1 (0.5%)	0	1 (0.2%)
Glutathione	0	1 (0.5%)	1 (0.2%)
Sugammadex Sodium	0	1 (0.5%)	1 (0.2%)
Detoxifying Agents For Antineoplastic Treatment	0	1 (0.5%)	1 (0.2%)
Calcium Folinate	0	1 (0.5%)	1 (0.2%)
Drugs For Treatment Of Hyperkalemia And Hyperphosphatemia	3 (1.5%)	7 (3.5%)	10 (2.5%)
Calcium Polystyrene Sulfonate	2 (1.0%)	3 (1.5%)	5 (1.2%)
Sodium Zirconium Cyclosilicate	1 (0.5%)	0	1 (0.2%)
Glucose;insulin	0	1 (0.5%)	1 (0.2%)
Sodium Polystyrene Sulfonate	0	3 (1.5%)	3 (0.7%)
Medical Gases	3 (1.5%)	3 (1.5%)	6 (1.5%)
Oxygen	3 (1.5%)	3 (1.5%)	6 (1.5%)
Other Therapeutic Products	0	1 (0.5%)	1 (0.2%)
Water	0	1 (0.5%)	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Analgesics	139 (68.8%)	115 (56.9%)	254 (62.9%)
Anilides	91 (45.0%)	85 (42.1%)	176 (43.6%)
Paracetamol	90 (44.6%)	84 (41.6%)	174 (43.1%)
Acetylsalicylic Acid;caffeine;paracetamol	1 (0.5%)	0	1 (0.2%)
Caffeine;drotaverine;naproxen;paracetamol;pheniramine	1 (0.5%)	0	1 (0.2%)
Fursultiamine;paracetamol	1 (0.5%)	0	1 (0.2%)
Propacetamol	1 (0.5%)	0	1 (0.2%)
Propacetamol Hydrochloride	0	1 (0.5%)	1 (0.2%)
Benzomorphan Derivatives	0	1 (0.5%)	1 (0.2%)
Pentazocine	0	1 (0.5%)	1 (0.2%)
Diphenylpropylamine Derivatives	1 (0.5%)	1 (0.5%)	2 (0.5%)
Methadone	1 (0.5%)	1 (0.5%)	2 (0.5%)
Gabapentinoids	35 (17.3%)	16 (7.9%)	51 (12.6%)
Gabapentin	21 (10.4%)	11 (5.4%)	32 (7.9%)
Pregabalin	20 (9.9%)	5 (2.5%)	25 (6.2%)
Natural Opium Alkaloids	48 (23.8%)	50 (24.8%)	98 (24.3%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Oxycodone	17 (8.4%)	10 (5.0%)	27 (6.7%)
Oxycodone Hydrochloride	11 (5.4%)	10 (5.0%)	21 (5.2%)
Morphine	8 (4.0%)	16 (7.9%)	24 (5.9%)
Morphine Sulfate	8 (4.0%)	7 (3.5%)	15 (3.7%)
Naloxone Hydrochloride;oxycodone Hydrochloride	8 (4.0%)	7 (3.5%)	15 (3.7%)
Hydromorphone	2 (1.0%)	4 (2.0%)	6 (1.5%)
Hydromorphone Hydrochloride	2 (1.0%)	4 (2.0%)	6 (1.5%)
Morphine Hydrochloride	2 (1.0%)	1 (0.5%)	3 (0.7%)
Oxycodone Hydrochloride Trihydrate	2 (1.0%)	2 (1.0%)	4 (1.0%)
Codeine	1 (0.5%)	2 (1.0%)	3 (0.7%)
Morphine Sulfate Pentahydrate	1 (0.5%)	0	1 (0.2%)
Naloxone;oxycodone	1 (0.5%)	0	1 (0.2%)
Codeine Phosphate	0	1 (0.5%)	1 (0.2%)
Hydrocodone Bitartrate	0	1 (0.5%)	1 (0.2%)
Opioids In Combination With Non-Opioid Analgesics	31 (15.3%)	19 (9.4%)	50 (12.4%)
Paracetamol;tramadol Hydrochloride	19 (9.4%)	10 (5.0%)	29 (7.2%)
Codeine Phosphate;ibuprofen;paracetamol	3 (1.5%)	2 (1.0%)	5 (1.2%)
Codeine Phosphate;paracetamol	2 (1.0%)	2 (1.0%)	4 (1.0%)
Codeine;paracetamol	2 (1.0%)	0	2 (0.5%)
Hydrocodone;paracetamol	2 (1.0%)	4 (2.0%)	6 (1.5%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Caffeine;codeine Phosphate;paracetamol	1 (0.5%)	0	1 (0.2%)
Codeine Phosphate Hemihydrate;paracetamol	1 (0.5%)	0	1 (0.2%)
Hydrocodone Bitartrate;paracetamol	1 (0.5%)	1 (0.5%)	2 (0.5%)
Oxycodone;paracetamol	1 (0.5%)	0	1 (0.2%)
Paracetamol;tramadol	1 (0.5%)	1 (0.5%)	2 (0.5%)
Oripavine Derivatives	3 (1.5%)	0	3 (0.7%)
Buprenorphine	3 (1.5%)	0	3 (0.7%)
Other Analgesics And Antipyretics	11 (5.4%)	3 (1.5%)	14 (3.5%)
Duloxetine Hydrochloride	6 (3.0%)	0	6 (1.5%)
Amitriptyline Hydrochloride	2 (1.0%)	1 (0.5%)	3 (0.7%)
Amitriptyline	1 (0.5%)	2 (1.0%)	3 (0.7%)
Cannabis Sativa	1 (0.5%)	0	1 (0.2%)
Tetrahydrocannabinols Nos	1 (0.5%)	0	1 (0.2%)
Carbamazepine	0	1 (0.5%)	1 (0.2%)
Other Antimigraine Preparations	2 (1.0%)	1 (0.5%)	3 (0.7%)
Propranolol	1 (0.5%)	0	1 (0.2%)
Topiramate	1 (0.5%)	0	1 (0.2%)
Valproate Sodium	1 (0.5%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Metoprolol	0	1 (0.5%)	1 (0.2%)
Other Opioids	28 (13.9%)	21 (10.4%)	49 (12.1%)
Tramadol	16 (7.9%)	13 (6.4%)	29 (7.2%)
Tramadol Hydrochloride	10 (5.0%)	9 (4.5%)	19 (4.7%)
Tapentadol Hydrochloride	2 (1.0%)	2 (1.0%)	4 (1.0%)
Tapentadol	1 (0.5%)	0	1 (0.2%)
Phenylpiperidine Derivatives	16 (7.9%)	15 (7.4%)	31 (7.7%)
Fentanyl	14 (6.9%)	12 (5.9%)	26 (6.4%)
Fentanyl Citrate	1 (0.5%)	3 (1.5%)	4 (1.0%)
Pethidine	1 (0.5%)	0	1 (0.2%)
Pethidine Hydrochloride	1 (0.5%)	1 (0.5%)	2 (0.5%)
Pyrazolones	12 (5.9%)	20 (9.9%)	32 (7.9%)
Metamizole	7 (3.5%)	12 (5.9%)	19 (4.7%)
Metamizole Sodium	4 (2.0%)	4 (2.0%)	8 (2.0%)
Metamizole Magnesium	2 (1.0%)	5 (2.5%)	7 (1.7%)
Metamizole Sodium;triacetonamine Tosilate	1 (0.5%)	0	1 (0.2%)
Salicylic Acid And Derivatives	5 (2.5%)	1 (0.5%)	6 (1.5%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Acetylsalicylic Acid	2 (1.0%)	1 (0.5%)	3 (0.7%)
Acetylsalicylic Acid;citric Acid;sodium Bicarbonate	2 (1.0%)	0	2 (0.5%)
Acetylsalicylate Lysine	1 (0.5%)	0	1 (0.2%)
Acetylsalicylic Acid;calcium Carbonate	1 (0.5%)	0	1 (0.2%)
Anesthetics	28 (13.9%)	17 (8.4%)	45 (11.1%)
Amides	15 (7.4%)	13 (6.4%)	28 (6.9%)
Lidocaine	10 (5.0%)	6 (3.0%)	16 (4.0%)
Lidocaine Hydrochloride	3 (1.5%)	3 (1.5%)	6 (1.5%)
Lidocaine;prilocaine	3 (1.5%)	5 (2.5%)	8 (2.0%)
Lidocaine Hydrochloride Monohydrate	1 (0.5%)	1 (0.5%)	2 (0.5%)
Prilocaine	0	1 (0.5%)	1 (0.2%)
Esters Of Aminobenzoic Acid	1 (0.5%)	0	1 (0.2%)
Tetracaine Hydrochloride	1 (0.5%)	0	1 (0.2%)
Opioid Anesthetics	13 (6.4%)	8 (4.0%)	21 (5.2%)
Fentanyl	11 (5.4%)	8 (4.0%)	19 (4.7%)
Fentanyl Citrate	2 (1.0%)	0	2 (0.5%)
Remifentanil Hydrochloride	0	1 (0.5%)	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Other General Anesthetics	3 (1.5%)	1 (0.5%)	4 (1.0%)
Propofol	3 (1.5%)	1 (0.5%)	4 (1.0%)
Anthelmintics	1 (0.5%)	0	1 (0.2%)
Avermectines	1 (0.5%)	0	1 (0.2%)
Ivermectin	1 (0.5%)	0	1 (0.2%)
Anti-Acne Preparations	1 (0.5%)	0	1 (0.2%)
Antiinfectives For Treatment Of Acne	1 (0.5%)	0	1 (0.2%)
Clindamycin Phosphate	1 (0.5%)	0	1 (0.2%)
Anti-Parkinson Drugs	0	3 (1.5%)	3 (0.7%)
Dopa And Dopa Derivatives	0	2 (1.0%)	2 (0.5%)
Carbidopa Monohydrate;levodopa	0	1 (0.5%)	1 (0.2%)
Carbidopa;levodopa	0	1 (0.5%)	1 (0.2%)
Dopamine Agonists	0	1 (0.5%)	1 (0.2%)
Pramipexole Dihydrochloride	0	1 (0.5%)	1 (0.2%)
Tertiary Amines	0	1 (0.5%)	1 (0.2%)
Trihexyphenidyl	0	1 (0.5%)	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Antianemic Preparations	45 (22.3%)	53 (26.2%)	98 (24.3%)
Folic Acid And Derivatives	14 (6.9%)	12 (5.9%)	26 (6.4%)
Folic Acid	14 (6.9%)	12 (5.9%)	26 (6.4%)
Iron Bivalent, Oral Preparations	22 (10.9%)	11 (5.4%)	33 (8.2%)
Ferrous Sulfate	9 (4.5%)	4 (2.0%)	13 (3.2%)
Ferrous Fumarate	6 (3.0%)	4 (2.0%)	10 (2.5%)
Ferrous Sulfate Exsiccated	3 (1.5%)	0	3 (0.7%)
Ferrous Sodium Citrate	2 (1.0%)	0	2 (0.5%)
Ferrous Glycine Sulfate	1 (0.5%)	0	1 (0.2%)
Iron Polysaccharide Complex	1 (0.5%)	0	1 (0.2%)
Ferrous Gluconate	0	3 (1.5%)	3 (0.7%)
Iron In Combination With Folic Acid	0	1 (0.5%)	1 (0.2%)
Ferric Hydroxide Polymaltose Complex;folic Acid	0	1 (0.5%)	1 (0.2%)
Iron In Other Combinations	6 (3.0%)	6 (3.0%)	12 (3.0%)
Copper Gluconate;ferrous Gluconate;manganese Gluconate	3 (1.5%)	3 (1.5%)	6 (1.5%)
Iron In Other Combinations	2 (1.0%)	1 (0.5%)	3 (0.7%)
Ascorbic Acid;ferric Pyrophosphate;vitamin B12 Nos	1 (0.5%)	0	1 (0.2%)

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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Ascorbic Acid;ferrous Gluconate;thiamine	1 (0.5%)	0	1 (0.2%)
Ascorbic Acid;ferrous Sulfate	1 (0.5%)	1 (0.5%)	2 (0.5%)
Ascorbic Acid;ferric Pyrophosphate	0	1 (0.5%)	1 (0.2%)
Ferrous Fumarate;folic Acid;pyridoxine Hydrochloride	0	1 (0.5%)	1 (0.2%)
Iron Trivalent, Oral Preparations	2 (1.0%)	2 (1.0%)	4 (1.0%)
Dextriferron	1 (0.5%)	0	1 (0.2%)
Iron Succinyl-Protein Complex	1 (0.5%)	0	1 (0.2%)
Ferric Hydroxide Polymaltose	0	2 (1.0%)	2 (0.5%)
Iron, Parenteral Preparations	2 (1.0%)	13 (6.4%)	15 (3.7%)
Ferric Carboxymaltose	1 (0.5%)	4 (2.0%)	5 (1.2%)
Saccharated Iron Oxide	1 (0.5%)	6 (3.0%)	7 (1.7%)
Ferric Hydroxide Polymaltose Complex	0	2 (1.0%)	2 (0.5%)
Iron	0	1 (0.5%)	1 (0.2%)
Not Applicable	3 (1.5%)	4 (2.0%)	7 (1.7%)
Iron	3 (1.5%)	4 (2.0%)	7 (1.7%)
Other Antianemic Preparations	7 (3.5%)	15 (7.4%)	22 (5.4%)
Erythropoietin	4 (2.0%)	3 (1.5%)	7 (1.7%)

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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Darbepoetin Alfa	2 (1.0%)	5 (2.5%)	7 (1.7%)
Epoetin Alfa	1 (0.5%)	5 (2.5%)	6 (1.5%)
Epoetin Alfa Epbx	0	1 (0.5%)	1 (0.2%)
Epoetin Beta	0	1 (0.5%)	1 (0.2%)
Vitamin B12 (Cyanocobalamin And Analogues)	10 (5.0%)	6 (3.0%)	16 (4.0%)
Vitamin B12 Nos	5 (2.5%)	3 (1.5%)	8 (2.0%)
Cyanocobalamin	4 (2.0%)	0	4 (1.0%)
Hydroxocobalamin	1 (0.5%)	0	1 (0.2%)
Cyanocobalamin;folic Acid;pyridoxine Hydrochloride	0	1 (0.5%)	1 (0.2%)
Mecobalamin	0	2 (1.0%)	2 (0.5%)
Antibacterials For Systemic Use	117 (57.9%)	97 (48.0%)	214 (53.0%)
Beta-Lactamase Inhibitors	2 (1.0%)	7 (3.5%)	9 (2.2%)
Clavulanate Potassium	1 (0.5%)	0	1 (0.2%)
Clavulanic Acid	1 (0.5%)	3 (1.5%)	4 (1.0%)
Sulbactam Sodium	0	1 (0.5%)	1 (0.2%)
Tazobactam	0	6 (3.0%)	6 (1.5%)
Beta-Lactamase Resistant Penicillins	3 (1.5%)	1 (0.5%)	4 (1.0%)
Flucloxacillin	2 (1.0%)	0	2 (0.5%)

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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Cloxacillin	1 (0.5%)	1 (0.5%)	2 (0.5%)
Beta-Lactamase Sensitive Penicillins	0	1 (0.5%)	1 (0.2%)
Phenoxymethylpenicillin Potassium	0	1 (0.5%)	1 (0.2%)
Carbapenems	7 (3.5%)	17 (8.4%)	24 (5.9%)
Cilastatin;imipenem	2 (1.0%)	0	2 (0.5%)
Meropenem	2 (1.0%)	11 (5.4%)	13 (3.2%)
Meropenem Trihydrate	2 (1.0%)	3 (1.5%)	5 (1.2%)
Ertapenem Sodium	1 (0.5%)	1 (0.5%)	2 (0.5%)
Ertapenem	0	4 (2.0%)	4 (1.0%)
Combinations Of Penicillins, Incl. Beta-Lactamase Inhibitors	47 (23.3%)	34 (16.8%)	81 (20.0%)
Amoxicillin;clavulanic Acid	16 (7.9%)	4 (2.0%)	20 (5.0%)
Piperacillin Sodium;tazobactam Sodium	12 (5.9%)	10 (5.0%)	22 (5.4%)
Piperacillin;tazobactam	12 (5.9%)	9 (4.5%)	21 (5.2%)
Amoxicillin Sodium;clavulanate Potassium	6 (3.0%)	9 (4.5%)	15 (3.7%)
Amoxicillin Trihydrate;clavulanate Potassium	4 (2.0%)	9 (4.5%)	13 (3.2%)
Amoxicillin;clavulanate Potassium	2 (1.0%)	3 (1.5%)	5 (1.2%)
Ampicillin;sulbactam	1 (0.5%)	0	1 (0.2%)
Ampicillin Sodium;sulbactam Sodium	0	1 (0.5%)	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Sultamicillin Tosilate	0	1 (0.5%)	1 (0.2%)
Combinations Of Sulfonamides And Trimethoprim, Incl. Derivatives	22 (10.9%)	10 (5.0%)	32 (7.9%)
Sulfamethoxazole;trimethoprim	22 (10.9%)	10 (5.0%)	32 (7.9%)
First-Generation Cephalosporins	18 (8.9%)	3 (1.5%)	21 (5.2%)
Cefazolin	6 (3.0%)	0	6 (1.5%)
Cefadroxil	4 (2.0%)	1 (0.5%)	5 (1.2%)
Cefalexin	3 (1.5%)	0	3 (0.7%)
Cefazolin Sodium	3 (1.5%)	2 (1.0%)	5 (1.2%)
Cefadroxil Monohydrate	1 (0.5%)	0	1 (0.2%)
Cefradine	1 (0.5%)	0	1 (0.2%)
Fluoroquinolones	50 (24.8%)	45 (22.3%)	95 (23.5%)
Ciprofloxacin	29 (14.4%)	26 (12.9%)	55 (13.6%)
Levofloxacin	18 (8.9%)	14 (6.9%)	32 (7.9%)
Moxifloxacin	3 (1.5%)	1 (0.5%)	4 (1.0%)
Ciprofloxacin Hydrochloride	2 (1.0%)	2 (1.0%)	4 (1.0%)
Moxifloxacin Hydrochloride	2 (1.0%)	0	2 (0.5%)
Ciprofloxacin Hydrochloride Monohydrate	1 (0.5%)	1 (0.5%)	2 (0.5%)
Levofloxacin Hemihydrate	0	1 (0.5%)	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Ofloxacin	0	2 (1.0%)	2 (0.5%)
Prulifloxacin	0	1 (0.5%)	1 (0.2%)
Fourth-Generation Cephalosporins	5 (2.5%)	6 (3.0%)	11 (2.7%)
Cefepime	4 (2.0%)	5 (2.5%)	9 (2.2%)
Cefepime Hydrochloride	1 (0.5%)	1 (0.5%)	2 (0.5%)
Glycopeptide Antibacterials	6 (3.0%)	4 (2.0%)	10 (2.5%)
Vancomycin	3 (1.5%)	2 (1.0%)	5 (1.2%)
Teicoplanin	2 (1.0%)	1 (0.5%)	3 (0.7%)
Vancomycin Hydrochloride	1 (0.5%)	1 (0.5%)	2 (0.5%)
Herbal Urinary Antiseptics And Antiinfectives	1 (0.5%)	1 (0.5%)	2 (0.5%)
Vaccinium Macrocarpon	1 (0.5%)	1 (0.5%)	2 (0.5%)
Imidazole Derivatives	8 (4.0%)	1 (0.5%)	9 (2.2%)
Metronidazole	8 (4.0%)	1 (0.5%)	9 (2.2%)
Intermediate-Acting Sulfonamides	1 (0.5%)	0	1 (0.2%)
Sulfamethoxazole	1 (0.5%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Lincosamides	4 (2.0%)	4 (2.0%)	8 (2.0%)
Clindamycin	3 (1.5%)	4 (2.0%)	7 (1.7%)
Clindamycin Phosphate	1 (0.5%)	0	1 (0.2%)
Macrolides	9 (4.5%)	4 (2.0%)	13 (3.2%)
Azithromycin	7 (3.5%)	4 (2.0%)	11 (2.7%)
Clarithromycin	1 (0.5%)	0	1 (0.2%)
Roxithromycin	1 (0.5%)	0	1 (0.2%)
Nitrofuran Derivatives	3 (1.5%)	6 (3.0%)	9 (2.2%)
Nitrofurantoin	3 (1.5%)	6 (3.0%)	9 (2.2%)
Not Applicable	0	1 (0.5%)	1 (0.2%)
Antibiotics	0	1 (0.5%)	1 (0.2%)
Other Aminoglycosides	0	5 (2.5%)	5 (1.2%)
Amikacin	0	5 (2.5%)	5 (1.2%)
Other Antibacterials	11 (5.4%)	6 (3.0%)	17 (4.2%)
Fosfomycin	4 (2.0%)	4 (2.0%)	8 (2.0%)
Linezolid	3 (1.5%)	1 (0.5%)	4 (1.0%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Daptomycin	2 (1.0%)	0	2 (0.5%)
Fosfomycin Trometamol	2 (1.0%)	1 (0.5%)	3 (0.7%)
Fosfomycin Sodium	1 (0.5%)	0	1 (0.2%)
Penicillins With Extended Spectrum	8 (4.0%)	13 (6.4%)	21 (5.2%)
Amoxicillin	5 (2.5%)	7 (3.5%)	12 (3.0%)
Piperacillin	1 (0.5%)	4 (2.0%)	5 (1.2%)
Piperacillin Monohydrate	1 (0.5%)	2 (1.0%)	3 (0.7%)
Pivmecillinam	1 (0.5%)	0	1 (0.2%)
Amoxicillin Trihydrate	0	1 (0.5%)	1 (0.2%)
Ampicillin	0	1 (0.5%)	1 (0.2%)
Ampicillin Sodium	0	1 (0.5%)	1 (0.2%)
Polymyxins	0	1 (0.5%)	1 (0.2%)
Colistimethate Sodium	0	1 (0.5%)	1 (0.2%)
Second-Generation Cephalosporins	11 (5.4%)	10 (5.0%)	21 (5.2%)
Cefuroxime	3 (1.5%)	6 (3.0%)	9 (2.2%)
Cefuroxime Axetil	3 (1.5%)	1 (0.5%)	4 (1.0%)
Cefprozil Monohydrate	2 (1.0%)	0	2 (0.5%)
Cefuroxime Sodium	2 (1.0%)	0	2 (0.5%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Cefaclor	1 (0.5%)	1 (0.5%)	2 (0.5%)
Cefaclor Monohydrate	0	1 (0.5%)	1 (0.2%)
Flomoxef	0	1 (0.5%)	1 (0.2%)
Tetracyclines	7 (3.5%)	0	7 (1.7%)
Doxycycline	5 (2.5%)	0	5 (1.2%)
Doxycycline Hydrochloride	1 (0.5%)	0	1 (0.2%)
Minocycline Hydrochloride	1 (0.5%)	0	1 (0.2%)
Third-Generation Cephalosporins	31 (15.3%)	31 (15.3%)	62 (15.3%)
Ceftriaxone	16 (7.9%)	10 (5.0%)	26 (6.4%)
Ceftazidime	5 (2.5%)	2 (1.0%)	7 (1.7%)
Ceftriaxone Sodium	5 (2.5%)	6 (3.0%)	11 (2.7%)
Cefixime	4 (2.0%)	7 (3.5%)	11 (2.7%)
Cefpodoxime Proxetil	2 (1.0%)	0	2 (0.5%)
Cefcapene Pivoxil Hydrochloride Hydrate	1 (0.5%)	0	1 (0.2%)
Cefdinir	1 (0.5%)	2 (1.0%)	3 (0.7%)
Cefoperazone Sodium;sulbactam Sodium	1 (0.5%)	0	1 (0.2%)
Cefotaxime Sodium	1 (0.5%)	0	1 (0.2%)
Cefpodoxime	1 (0.5%)	1 (0.5%)	2 (0.5%)
Cefditoren Pivoxil	0	1 (0.5%)	1 (0.2%)

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Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Cefoperazone Sodium	0	1 (0.5%)	1 (0.2%)
Ceftriaxone Sodium Sesquaterhydrate	0	4 (2.0%)	4 (1.0%)
Trimethoprim And Derivatives	0	1 (0.5%)	1 (0.2%)
Trimethoprim	0	1 (0.5%)	1 (0.2%)
Antibiotics And Chemotherapeutics For Dermatological Use	22 (10.9%)	3 (1.5%)	25 (6.2%)
Antivirals	1 (0.5%)	0	1 (0.2%)
Aciclovir	1 (0.5%)	0	1 (0.2%)
Other Antibiotics For Topical Use	21 (10.4%)	3 (1.5%)	24 (5.9%)
Mupirocin	6 (3.0%)	1 (0.5%)	7 (1.7%)
Fusidic Acid	5 (2.5%)	1 (0.5%)	6 (1.5%)
Bacitracin Zinc;neomycin Sulfate;polymyxin B Sulfate	2 (1.0%)	0	2 (0.5%)
Bacitracin;neomycin Sulfate;polymyxin B Sulfate	2 (1.0%)	0	2 (0.5%)
Gentamicin Sulfate	2 (1.0%)	1 (0.5%)	3 (0.7%)
Neomycin;tyrothricin	2 (1.0%)	0	2 (0.5%)
Bacitracin Zinc;polymyxin B Sulfate	1 (0.5%)	0	1 (0.2%)
Chloramphenicol	1 (0.5%)	0	1 (0.2%)
Gentamicin	1 (0.5%)	0	1 (0.2%)
Neomycin	1 (0.5%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Other Antibiotics For Topical Use	1 (0.5%)	0	1 (0.2%)
Other Chemotherapeutics	1 (0.5%)	0	1 (0.2%)
Metronidazole	1 (0.5%)	0	1 (0.2%)
Tetracycline And Derivatives	1 (0.5%)	0	1 (0.2%)
Tetracycline Hydrochloride	1 (0.5%)	0	1 (0.2%)
Antidiarrheals, Intestinal Antiinflammatory/Antiinfective Agents	42 (20.8%)	12 (5.9%)	54 (13.4%)
Aminosalicylic Acid And Similar Agents	2 (1.0%)	0	2 (0.5%)
Mesalazine	2 (1.0%)	0	2 (0.5%)
Antibiotics	5 (2.5%)	2 (1.0%)	7 (1.7%)
Vancomycin	5 (2.5%)	0	5 (1.2%)
Fidaxomicin	0	1 (0.5%)	1 (0.2%)
Rifaximin	0	1 (0.5%)	1 (0.2%)
Antidiarrheal Microorganisms	6 (3.0%)	4 (2.0%)	10 (2.5%)
Bacillus Subtilis;enterococcus Faecium	2 (1.0%)	0	2 (0.5%)
Lactobacillus Acidophilus	1 (0.5%)	1 (0.5%)	2 (0.5%)
Lactobacillus Nos	1 (0.5%)	0	1 (0.2%)

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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Probiotics Nos	1 (0.5%)	0	1 (0.2%)
Saccharomyces Boulardii	1 (0.5%)	0	1 (0.2%)
Bacillus Mesentericus;clostridium Butyricum;enterococcus Faecalis	0	1 (0.5%)	1 (0.2%)
Bifidobacterium Bifidum;bifidobacterium Breve;bifidobacterium Longum;fructooligosaccharides;lactiplantibacillus Plantarum;lactobacillus Casei;lactobacillus Helveticus;lactobacillus Rhamnosus; Streptococcus Lactis;streptococcus Thermophilus	0	1 (0.5%)	1 (0.2%)
Bifidobacterium Lactis;fructooligosaccharides;inulin;lactobacillus Acidophilus	0	1 (0.5%)	1 (0.2%)
Antipropulsives	31 (15.3%)	4 (2.0%)	35 (8.7%)
Loperamide	16 (7.9%)	1 (0.5%)	17 (4.2%)
Loperamide Hydrochloride	15 (7.4%)	3 (1.5%)	18 (4.5%)
Atropine Sulfate;diphenoxylate Hydrochloride	1 (0.5%)	0	1 (0.2%)
Corticosteroids Acting Locally	3 (1.5%)	0	3 (0.7%)
Beclometasone Dipropionate	1 (0.5%)	0	1 (0.2%)
Budesonide	1 (0.5%)	0	1 (0.2%)
Prednisone	1 (0.5%)	0	1 (0.2%)
Oral Rehydration Salt Formulations	0	2 (1.0%)	2 (0.5%)
Glucose;sodium Chloride	0	1 (0.5%)	1 (0.2%)
Oral Rehydration Salt Formulations	0	1 (0.5%)	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Other Antidiarrheals	2 (1.0%)	0	2 (0.5%)
Colestyramine	1 (0.5%)	0	1 (0.2%)
Racecadotril	1 (0.5%)	0	1 (0.2%)
Other Intestinal Adsorbents	4 (2.0%)	0	4 (1.0%)
Diosmectite	4 (2.0%)	0	4 (1.0%)
Other Intestinal Antiinfectives	1 (0.5%)	0	1 (0.2%)
Berberine Chloride Hydrate	1 (0.5%)	0	1 (0.2%)
Antiemetics And Antinauseants	68 (33.7%)	138 (68.3%)	206 (51.0%)
Not Applicable	38 (18.8%)	49 (24.3%)	87 (21.5%)
Metoclopramide	22 (10.9%)	28 (13.9%)	50 (12.4%)
Metoclopramide Hydrochloride	15 (7.4%)	17 (8.4%)	32 (7.9%)
Alizapride Hydrochloride	3 (1.5%)	4 (2.0%)	7 (1.7%)
Metoclopramide Hydrochloride Monohydrate	0	1 (0.5%)	1 (0.2%)
Other Antiemetics	19 (9.4%)	41 (20.3%)	60 (14.9%)
Prochlorperazine Maleate	9 (4.5%)	6 (3.0%)	15 (3.7%)
Prochlorperazine	6 (3.0%)	3 (1.5%)	9 (2.2%)
Dimenhydrinate	3 (1.5%)	0	3 (0.7%)

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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Difenidol Hydrochloride	2 (1.0%)	1 (0.5%)	3 (0.7%)
Aprepitant	1 (0.5%)	20 (9.9%)	21 (5.2%)
Dronabinol	1 (0.5%)	0	1 (0.2%)
Trimethobenzamide Hydrochloride	1 (0.5%)	0	1 (0.2%)
Diphenhydramine	0	1 (0.5%)	1 (0.2%)
Doxylamine Succinate;folic Acid;pyridoxine Hydrochloride	0	1 (0.5%)	1 (0.2%)
Fosaprepitant	0	4 (2.0%)	4 (1.0%)
Fosaprepitant Meglumine	0	3 (1.5%)	3 (0.7%)
Fosnetupitant Chloride Hydrochloride	0	1 (0.5%)	1 (0.2%)
Hydroxyzine	0	1 (0.5%)	1 (0.2%)
Hyoscine	0	2 (1.0%)	2 (0.5%)
Metopimazine	0	1 (0.5%)	1 (0.2%)
Netupitant	0	1 (0.5%)	1 (0.2%)
Prochlorperazine Mesilate	0	1 (0.5%)	1 (0.2%)
Promethazine	0	1 (0.5%)	1 (0.2%)
Serotonin (5ht3) Antagonists	42 (20.8%)	128 (63.4%)	170 (42.1%)
Ondansetron	24 (11.9%)	53 (26.2%)	77 (19.1%)
Ondansetron Hydrochloride	12 (5.9%)	15 (7.4%)	27 (6.7%)
Granisetron	5 (2.5%)	22 (10.9%)	27 (6.7%)
Netupitant;palonosetron	1 (0.5%)	3 (1.5%)	4 (1.0%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Netupitant;palonosetron Hydrochloride	1 (0.5%)	11 (5.4%)	12 (3.0%)
Palonosetron Hydrochloride	1 (0.5%)	14 (6.9%)	15 (3.7%)
Granisetron Hydrochloride	0	20 (9.9%)	20 (5.0%)
Palonosetron	0	9 (4.5%)	9 (2.2%)
Ramosetron Hydrochloride	0	1 (0.5%)	1 (0.2%)
Antiepileptics	5 (2.5%)	4 (2.0%)	9 (2.2%)
Barbiturates And Derivatives	1 (0.5%)	0	1 (0.2%)
Phenobarbital	1 (0.5%)	0	1 (0.2%)
Benzodiazepine Derivatives	2 (1.0%)	0	2 (0.5%)
Lorazepam	1 (0.5%)	0	1 (0.2%)
Midazolam	1 (0.5%)	0	1 (0.2%)
Fatty Acid Derivatives	1 (0.5%)	0	1 (0.2%)
Valproic Acid	1 (0.5%)	0	1 (0.2%)
Hydantoin Derivatives	0	1 (0.5%)	1 (0.2%)
Phenytoin Sodium	0	1 (0.5%)	1 (0.2%)
Other Antiepileptics	2 (1.0%)	3 (1.5%)	5 (1.2%)

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Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Gabapentin	1 (0.5%)	0	1 (0.2%)
Pregabalin	1 (0.5%)	0	1 (0.2%)
Levetiracetam	0	3 (1.5%)	3 (0.7%)
Antifungals For Dermatological Use	12 (5.9%)	3 (1.5%)	15 (3.7%)
Antifungals For Systemic Use	1 (0.5%)	0	1 (0.2%)
Terbinafine	1 (0.5%)	0	1 (0.2%)
Imidazole And Triazole Derivatives	8 (4.0%)	2 (1.0%)	10 (2.5%)
Clotrimazole	2 (1.0%)	0	2 (0.5%)
Ketoconazole	2 (1.0%)	0	2 (0.5%)
Diflucortolone Valerate;isoconazole Nitrate	1 (0.5%)	0	1 (0.2%)
Isoconazole Nitrate	1 (0.5%)	0	1 (0.2%)
Miconazole	1 (0.5%)	2 (1.0%)	3 (0.7%)
Oxiconazole	1 (0.5%)	0	1 (0.2%)
Sertaconazole	1 (0.5%)	0	1 (0.2%)
Sertaconazole Nitrate	1 (0.5%)	0	1 (0.2%)
Other Antifungals For Topical Use	5 (2.5%)	1 (0.5%)	6 (1.5%)
Terbinafine Hydrochloride	2 (1.0%)	0	2 (0.5%)
Amorolfine Hydrochloride	1 (0.5%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Ciclopirox Olamine	1 (0.5%)	1 (0.5%)	2 (0.5%)
Naftifine Hydrochloride	1 (0.5%)	0	1 (0.2%)
Antigout Preparations	13 (6.4%)	20 (9.9%)	33 (8.2%)
Preparations Increasing Uric Acid Excretion	0	1 (0.5%)	1 (0.2%)
Sulfinpyrazone	0	1 (0.5%)	1 (0.2%)
Preparations Inhibiting Uric Acid Production	12 (5.9%)	18 (8.9%)	30 (7.4%)
Allopurinol	12 (5.9%)	15 (7.4%)	27 (6.7%)
Febuxostat	1 (0.5%)	3 (1.5%)	4 (1.0%)
Preparations With No Effect On Uric Acid Metabolism	2 (1.0%)	2 (1.0%)	4 (1.0%)
Colchicine	2 (1.0%)	2 (1.0%)	4 (1.0%)
Antihemorrhagics	9 (4.5%)	7 (3.5%)	16 (4.0%)
Amino Acids	3 (1.5%)	2 (1.0%)	5 (1.2%)
Tranexamic Acid	3 (1.5%)	2 (1.0%)	5 (1.2%)
Local Hemostatics	1 (0.5%)	0	1 (0.2%)
Epinephrine	1 (0.5%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Other Systemic Hemostatics	2 (1.0%)	3 (1.5%)	5 (1.2%)
Eltrombopag	1 (0.5%)	0	1 (0.2%)
Etamsilate	1 (0.5%)	2 (1.0%)	3 (0.7%)
Carbazochrome Sodium Sulfonate Trihydrate	0	1 (0.5%)	1 (0.2%)
Proteinase Inhibitors	0	1 (0.5%)	1 (0.2%)
Camostat Mesilate	0	1 (0.5%)	1 (0.2%)
Nafamostat Mesilate	0	1 (0.5%)	1 (0.2%)
Vitamin K	3 (1.5%)	2 (1.0%)	5 (1.2%)
Vitamin K Nos	2 (1.0%)	0	2 (0.5%)
Phytomenadione	1 (0.5%)	2 (1.0%)	3 (0.7%)
Antihistamines For Systemic Use	101 (50.0%)	49 (24.3%)	150 (37.1%)
Aminoalkyl Ethers	24 (11.9%)	11 (5.4%)	35 (8.7%)
Diphenhydramine Hydrochloride	19 (9.4%)	4 (2.0%)	23 (5.7%)
Diphenhydramine	5 (2.5%)	6 (3.0%)	11 (2.7%)
Clemastine	1 (0.5%)	1 (0.5%)	2 (0.5%)
Other Antihistamines For Systemic Use	55 (27.2%)	11 (5.4%)	66 (16.3%)
Loratadine	16 (7.9%)	4 (2.0%)	20 (5.0%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Desloratadine	13 (6.4%)	4 (2.0%)	17 (4.2%)
Fexofenadine Hydrochloride	11 (5.4%)	3 (1.5%)	14 (3.5%)
Bilastine	6 (3.0%)	0	6 (1.5%)
Cyproheptadine Hydrochloride	5 (2.5%)	0	5 (1.2%)
Fexofenadine	5 (2.5%)	0	5 (1.2%)
Bepotastine Besilate	4 (2.0%)	0	4 (1.0%)
Azelastine	3 (1.5%)	0	3 (0.7%)
Ebastine	3 (1.5%)	0	3 (0.7%)
Azelastine Hydrochloride	2 (1.0%)	0	2 (0.5%)
Ketotifen Fumarate	2 (1.0%)	0	2 (0.5%)
Olopatadine Hydrochloride	2 (1.0%)	0	2 (0.5%)
Bepotastine	1 (0.5%)	0	1 (0.2%)
Rupatadine Fumarate	1 (0.5%)	0	1 (0.2%)
Epinastine Hydrochloride	0	1 (0.5%)	1 (0.2%)
Phenothiazine Derivatives	1 (0.5%)	2 (1.0%)	3 (0.7%)
Mequitazine	1 (0.5%)	0	1 (0.2%)
Promethazine	0	2 (1.0%)	2 (0.5%)
Piperazine Derivatives	62 (30.7%)	13 (6.4%)	75 (18.6%)
Levocetirizine Dihydrochloride	23 (11.4%)	4 (2.0%)	27 (6.7%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Hydroxyzine Hydrochloride	20 (9.9%)	1 (0.5%)	21 (5.2%)
Cetirizine	18 (8.9%)	3 (1.5%)	21 (5.2%)
Hydroxyzine	9 (4.5%)	3 (1.5%)	12 (3.0%)
Levocetirizine	9 (4.5%)	1 (0.5%)	10 (2.5%)
Cetirizine Hydrochloride	7 (3.5%)	1 (0.5%)	8 (2.0%)
Hydroxyzine Embonate	1 (0.5%)	0	1 (0.2%)
Oxatomide	1 (0.5%)	0	1 (0.2%)
Substituted Alkylamines	27 (13.4%)	22 (10.9%)	49 (12.1%)
Chlorphenamine Maleate	10 (5.0%)	2 (1.0%)	12 (3.0%)
Chlorphenamine	8 (4.0%)	9 (4.5%)	17 (4.2%)
Dexchlorpheniramine	8 (4.0%)	4 (2.0%)	12 (3.0%)
Dexchlorpheniramine Maleate	3 (1.5%)	4 (2.0%)	7 (1.7%)
Pheniramine	0	1 (0.5%)	1 (0.2%)
Pheniramine Maleate	0	4 (2.0%)	4 (1.0%)
Substituted Ethylene Diamines	4 (2.0%)	0	4 (1.0%)
Chloropyramine Hydrochloride	3 (1.5%)	0	3 (0.7%)
Chloropyramine	1 (0.5%)	0	1 (0.2%)
Antihypertensives	9 (4.5%)	8 (4.0%)	17 (4.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Alpha-Adrenoreceptor Antagonists	2 (1.0%)	4 (2.0%)	6 (1.5%)
Doxazosin	1 (0.5%)	3 (1.5%)	4 (1.0%)
Doxazosin Mesilate	1 (0.5%)	2 (1.0%)	3 (0.7%)
Hydrazinophthalazine Derivatives	4 (2.0%)	2 (1.0%)	6 (1.5%)
Hydralazine	3 (1.5%)	2 (1.0%)	5 (1.2%)
Hydralazine Hydrochloride	1 (0.5%)	0	1 (0.2%)
Imidazoline Receptor Agonists	3 (1.5%)	1 (0.5%)	4 (1.0%)
Clonidine	1 (0.5%)	0	1 (0.2%)
Clonidine Hydrochloride	1 (0.5%)	0	1 (0.2%)
Moxonidine	1 (0.5%)	1 (0.5%)	2 (0.5%)
Not Applicable	0	1 (0.5%)	1 (0.2%)
Combinations Of Antihypertensives In Atc-Gr. C02	0	1 (0.5%)	1 (0.2%)
Antiinflammatory And Antirheumatic Products	34 (16.8%)	27 (13.4%)	61 (15.1%)
Acetic Acid Derivatives And Related Substances	4 (2.0%)	4 (2.0%)	8 (2.0%)
Diclofenac	2 (1.0%)	0	2 (0.5%)
Ketorolac	2 (1.0%)	1 (0.5%)	3 (0.7%)
Diclofenac Potassium	1 (0.5%)	1 (0.5%)	2 (0.5%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Aceclofenac	0	1 (0.5%)	1 (0.2%)
Indometacin	0	1 (0.5%)	1 (0.2%)
Coxibs	6 (3.0%)	0	6 (1.5%)
Etoricoxib	4 (2.0%)	0	4 (1.0%)
Celecoxib	2 (1.0%)	0	2 (0.5%)
Other Antiinflammatory And Antirheumatic Agents, Non-Steroids	3 (1.5%)	3 (1.5%)	6 (1.5%)
Krill Oil	1 (0.5%)	0	1 (0.2%)
Nimesulide	1 (0.5%)	0	1 (0.2%)
Shark Cartilage	1 (0.5%)	0	1 (0.2%)
Chondroitin	0	1 (0.5%)	1 (0.2%)
Chondroitin;glucosamine	0	1 (0.5%)	1 (0.2%)
Glucosamine	0	2 (1.0%)	2 (0.5%)
Oxicams	1 (0.5%)	1 (0.5%)	2 (0.5%)
Meloxicam	1 (0.5%)	0	1 (0.2%)
Lornoxicam	0	1 (0.5%)	1 (0.2%)
Propionic Acid Derivatives	24 (11.9%)	19 (9.4%)	43 (10.6%)
Ibuprofen	10 (5.0%)	5 (2.5%)	15 (3.7%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Esomeprazole Magnesium;naproxen	3 (1.5%)	2 (1.0%)	5 (1.2%)
Loxoprofen Sodium Dihydrate	3 (1.5%)	4 (2.0%)	7 (1.7%)
Naproxen	3 (1.5%)	4 (2.0%)	7 (1.7%)
Dexketoprofen	2 (1.0%)	2 (1.0%)	4 (1.0%)
Ketoprofen	2 (1.0%)	1 (0.5%)	3 (0.7%)
Dexibuprofen	1 (0.5%)	0	1 (0.2%)
Loxoprofen	1 (0.5%)	0	1 (0.2%)
Naproxen Sodium	1 (0.5%)	1 (0.5%)	2 (0.5%)
Dexketoprofen Trometamol	0	1 (0.5%)	1 (0.2%)
Flurbiprofen Axetil	0	1 (0.5%)	1 (0.2%)
Loxoprofen Sodium	0	1 (0.5%)	1 (0.2%)
Antimycobacterials	0	1 (0.5%)	1 (0.2%)
Hydrazides	0	1 (0.5%)	1 (0.2%)
Isoniazid	0	1 (0.5%)	1 (0.2%)
Antimycotics For Systemic Use	9 (4.5%)	4 (2.0%)	13 (3.2%)
Antibiotics	1 (0.5%)	0	1 (0.2%)
Nystatin	1 (0.5%)	0	1 (0.2%)
Other Antimycotics For Systemic Use	2 (1.0%)	0	2 (0.5%)

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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Micafungin Sodium	1 (0.5%)	0	1 (0.2%)
Pentamidine	1 (0.5%)	0	1 (0.2%)
Triazole And Tetrazole Derivatives	7 (3.5%)	4 (2.0%)	11 (2.7%)
Fluconazole	6 (3.0%)	4 (2.0%)	10 (2.5%)
Isavuconazole	1 (0.5%)	0	1 (0.2%)
Itraconazole	1 (0.5%)	0	1 (0.2%)
Antineoplastic Agents	1 (0.5%)	0	1 (0.2%)
Herbal Anticancer Remedies	1 (0.5%)	0	1 (0.2%)
Viscum Album Extract	1 (0.5%)	0	1 (0.2%)
Antiprotozoals	1 (0.5%)	0	1 (0.2%)
Aminoquinolines	1 (0.5%)	0	1 (0.2%)
Primaquine Phosphate	1 (0.5%)	0	1 (0.2%)
Antipruritics, Incl. Antihistamines, Anesthetics, Etc.	25 (12.4%)	4 (2.0%)	29 (7.2%)
Anesthetics For Topical Use	3 (1.5%)	0	3 (0.7%)
Benzocaine;chlorphenamine Maleate	1 (0.5%)	0	1 (0.2%)
Pramocaine Hydrochloride	1 (0.5%)	0	1 (0.2%)
Pramocaine;zinc Acetate	1 (0.5%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Antihistamines For Topical Use	13 (6.4%)	3 (1.5%)	16 (4.0%)
Diphenhydramine	4 (2.0%)	2 (1.0%)	6 (1.5%)
Diphenhydramine Hydrochloride	3 (1.5%)	0	3 (0.7%)
Dimetindene	2 (1.0%)	0	2 (0.5%)
Calamine;diphenhydramine Hydrochloride	1 (0.5%)	0	1 (0.2%)
Dimetindene Maleate	1 (0.5%)	0	1 (0.2%)
Diphenhydramine Hydrochloride;zinc Acetate	1 (0.5%)	0	1 (0.2%)
Pheniramine Maleate	1 (0.5%)	1 (0.5%)	2 (0.5%)
Not Applicable	1 (0.5%)	0	1 (0.2%)
Levocetirizine Dihydrochloride	1 (0.5%)	0	1 (0.2%)
Other Antipruritics	11 (5.4%)	1 (0.5%)	12 (3.0%)
Doxepin Hydrochloride	4 (2.0%)	0	4 (1.0%)
Calamine	3 (1.5%)	0	3 (0.7%)
Crotamiton	2 (1.0%)	1 (0.5%)	3 (0.7%)
Doxepin	2 (1.0%)	0	2 (0.5%)
Calamine;pramocaine Hydrochloride	1 (0.5%)	0	1 (0.2%)
Antipsoriatics	3 (1.5%)	3 (1.5%)	6 (1.5%)

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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Other Antipsoriatics For Topical Use	2 (1.0%)	3 (1.5%)	5 (1.2%)
Betamethasone Dipropionate;calcipotriol	1 (0.5%)	0	1 (0.2%)
Calcipotriol	1 (0.5%)	2 (1.0%)	3 (0.7%)
Calcipotriol Monohydrate	0	1 (0.5%)	1 (0.2%)
Retinoids For Treatment Of Psoriasis	1 (0.5%)	0	1 (0.2%)
Acitretin	1 (0.5%)	0	1 (0.2%)
Antiseptics And Disinfectants	0	5 (2.5%)	5 (1.2%)
Aluminium Agents	0	1 (0.5%)	1 (0.2%)
Aluminium Acetate	0	1 (0.5%)	1 (0.2%)
Biguanides And Amidines	0	3 (1.5%)	3 (0.7%)
Chlorhexidine Gluconate	0	2 (1.0%)	2 (0.5%)
Hexamidine Isetionate	0	1 (0.5%)	1 (0.2%)
Iodine Products	0	1 (0.5%)	1 (0.2%)
Povidone-Iodine	0	1 (0.5%)	1 (0.2%)
Antithrombotic Agents	80 (39.6%)	90 (44.6%)	170 (42.1%)
Direct Factor Xa Inhibitors	27 (13.4%)	23 (11.4%)	50 (12.4%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Apixaban	15 (7.4%)	16 (7.9%)	31 (7.7%)
Rivaroxaban	8 (4.0%)	6 (3.0%)	14 (3.5%)
Edoxaban Tosilate	2 (1.0%)	2 (1.0%)	4 (1.0%)
Edoxaban Tosilate Monohydrate	2 (1.0%)	0	2 (0.5%)
Edoxaban	1 (0.5%)	0	1 (0.2%)
Enzymes	2 (1.0%)	0	2 (0.5%)
Alteplase	2 (1.0%)	0	2 (0.5%)
Heparin Group	31 (15.3%)	43 (21.3%)	74 (18.3%)
Enoxaparin Sodium	9 (4.5%)	11 (5.4%)	20 (5.0%)
Enoxaparin	8 (4.0%)	12 (5.9%)	20 (5.0%)
Heparin	5 (2.5%)	6 (3.0%)	11 (2.7%)
Bemiparin Sodium	4 (2.0%)	1 (0.5%)	5 (1.2%)
Tinzaparin Sodium	4 (2.0%)	4 (2.0%)	8 (2.0%)
Heparin Sodium	3 (1.5%)	3 (1.5%)	6 (1.5%)
Dalteparin Sodium	1 (0.5%)	3 (1.5%)	4 (1.0%)
Tinzaparin	1 (0.5%)	2 (1.0%)	3 (0.7%)
Dalteparin	0	2 (1.0%)	2 (0.5%)
Low Molecular Weight Heparin	0	1 (0.5%)	1 (0.2%)
Nadroparin Calcium	0	1 (0.5%)	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Other Antithrombotic Agents	1 (0.5%)	1 (0.5%)	2 (0.5%)
Fondaparinux	1 (0.5%)	0	1 (0.2%)
Fondaparinux Sodium	0	1 (0.5%)	1 (0.2%)
Platelet Aggregation Inhibitors Excl. Heparin	32 (15.8%)	44 (21.8%)	76 (18.8%)
Acetylsalicylic Acid	23 (11.4%)	37 (18.3%)	60 (14.9%)
Clopidogrel	7 (3.5%)	6 (3.0%)	13 (3.2%)
Clopidogrel Bisulfate	3 (1.5%)	1 (0.5%)	4 (1.0%)
Acetylsalicylic Acid;lansoprazole	1 (0.5%)	0	1 (0.2%)
Acetylsalicylic Acid;magnesium Hydroxide	1 (0.5%)	0	1 (0.2%)
Cilostazol	1 (0.5%)	1 (0.5%)	2 (0.5%)
Acetylsalicylate Lysine	0	1 (0.5%)	1 (0.2%)
Sarpogrelate Hydrochloride	0	1 (0.5%)	1 (0.2%)
Vitamin K Antagonists	2 (1.0%)	5 (2.5%)	7 (1.7%)
Warfarin	2 (1.0%)	2 (1.0%)	4 (1.0%)
Acenocoumarol	0	3 (1.5%)	3 (0.7%)
Antivirals For Systemic Use	11 (5.4%)	5 (2.5%)	16 (4.0%)
Nucleoside And Nucleotide Reverse Transcriptase Inhibitors	0	1 (0.5%)	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Entecavir	0	1 (0.5%)	1 (0.2%)
Nucleosides And Nucleotides Excl. Reverse Transcriptase Inhibitors	8 (4.0%)	1 (0.5%)	9 (2.2%)
Remdesivir	3 (1.5%)	1 (0.5%)	4 (1.0%)
Ganciclovir	2 (1.0%)	0	2 (0.5%)
Famciclovir	1 (0.5%)	0	1 (0.2%)
Molnupiravir	1 (0.5%)	0	1 (0.2%)
Valaciclovir	1 (0.5%)	1 (0.5%)	2 (0.5%)
Valganciclovir Hydrochloride	1 (0.5%)	0	1 (0.2%)
Other Antivirals	3 (1.5%)	1 (0.5%)	4 (1.0%)
Favipiravir	3 (1.5%)	1 (0.5%)	4 (1.0%)
Protease Inhibitors	0	2 (1.0%)	2 (0.5%)
Nirmatrelvir;ritonavir	0	2 (1.0%)	2 (0.5%)
Appetite Stimulants	19 (9.4%)	9 (4.5%)	28 (6.9%)
Herbal Appetite Stimulants	0	1 (0.5%)	1 (0.2%)
Atractylodes Spp. Rhizome;citrus Aurantium Peel;glycyrrhiza Spp. Root;panax Ginseng Root;pinellia Ternata Tuber;poria Cocos Sclerotium;zingiber Officinale Rhizome;ziziphus Jujuba Fruit	0	1 (0.5%)	1 (0.2%)
Not Applicable	19 (9.4%)	8 (4.0%)	27 (6.7%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Megestrol Acetate	15 (7.4%)	5 (2.5%)	20 (5.0%)
Megestrol	2 (1.0%)	2 (1.0%)	4 (1.0%)
Arginine Aspartate;cyproheptadine Alphaketoglutarate	1 (0.5%)	0	1 (0.2%)
Cyproheptadine	1 (0.5%)	1 (0.5%)	2 (0.5%)
Dronabinol	1 (0.5%)	0	1 (0.2%)
Beta Blocking Agents	52 (25.7%)	45 (22.3%)	97 (24.0%)
Alpha And Beta Blocking Agents	4 (2.0%)	4 (2.0%)	8 (2.0%)
Carvedilol	4 (2.0%)	4 (2.0%)	8 (2.0%)
Beta Blocking Agents, Non-Selective	2 (1.0%)	1 (0.5%)	3 (0.7%)
Propranolol	1 (0.5%)	0	1 (0.2%)
Propranolol Hydrochloride	1 (0.5%)	1 (0.5%)	2 (0.5%)
Beta Blocking Agents, Selective	46 (22.8%)	40 (19.8%)	86 (21.3%)
Bisoprolol	18 (8.9%)	16 (7.9%)	34 (8.4%)
Metoprolol	7 (3.5%)	5 (2.5%)	12 (3.0%)
Atenolol	6 (3.0%)	5 (2.5%)	11 (2.7%)
Bisoprolol Fumarate	6 (3.0%)	4 (2.0%)	10 (2.5%)
Metoprolol Succinate	5 (2.5%)	6 (3.0%)	11 (2.7%)
Metoprolol Tartrate	4 (2.0%)	3 (1.5%)	7 (1.7%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Nebivolol Hydrochloride	2 (1.0%)	3 (1.5%)	5 (1.2%)
Nebivolol	1 (0.5%)	0	1 (0.2%)
Esmolol	0	1 (0.5%)	1 (0.2%)
Beta Blocking Agents, Selective, And Other Diuretics	0	1 (0.5%)	1 (0.2%)
Atenolol;chlortalidone	0	1 (0.5%)	1 (0.2%)
Bile And Liver Therapy	16 (7.9%)	9 (4.5%)	25 (6.2%)
Bile Acids And Derivatives	13 (6.4%)	5 (2.5%)	18 (4.5%)
Ursodeoxycholic Acid	13 (6.4%)	5 (2.5%)	18 (4.5%)
Liver Therapy	7 (3.5%)	7 (3.5%)	14 (3.5%)
Adenine Hydrochloride;carnitine Orotate;cyanocobalamin;liver;pyridoxine Hydrochloride;riboflavin	3 (1.5%)	2 (1.0%)	5 (1.2%)
Silybum Marianum	2 (1.0%)	3 (1.5%)	5 (1.2%)
Acetylcysteine	1 (0.5%)	1 (0.5%)	2 (0.5%)
Adenine Hydrochloride;bifendate;carnitine Orotate;cyanocobalamin;liver;pyridoxine Hydrochloride;riboflavin	1 (0.5%)	0	1 (0.2%)
Cysteine;pyridoxine Hydrochloride	1 (0.5%)	0	1 (0.2%)
Ornithine Aspartate	1 (0.5%)	0	1 (0.2%)
Glycyrrhizic Acid, Ammonium Salt	0	1 (0.5%)	1 (0.2%)
Not Applicable	3 (1.5%)	0	3 (0.7%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Bifendate;ursodeoxycholic Acid	2 (1.0%)	0	2 (0.5%)
Bicyclol	1 (0.5%)	0	1 (0.2%)
Blood Substitutes And Perfusion Solutions	51 (25.2%)	46 (22.8%)	97 (24.0%)
Antiinfectives	0	1 (0.5%)	1 (0.2%)
Chlorhexidine Gluconate	0	1 (0.5%)	1 (0.2%)
Blood Substitutes And Plasma Protein Fractions	1 (0.5%)	2 (1.0%)	3 (0.7%)
Albumin Human	1 (0.5%)	2 (1.0%)	3 (0.7%)
Electrolyte Solutions	5 (2.5%)	4 (2.0%)	9 (2.2%)
Calcium Gluconate	3 (1.5%)	3 (1.5%)	6 (1.5%)
Chromic Chloride;copper Sulfate;manganese Sulfate;zinc Sulfate	1 (0.5%)	0	1 (0.2%)
Sodium Phosphate	1 (0.5%)	0	1 (0.2%)
Sodium Phosphate Dibasic;sodium Phosphate Monobasic	0	1 (0.5%)	1 (0.2%)
Not Applicable	1 (0.5%)	2 (1.0%)	3 (0.7%)
Blood, Calf, Deprot., Lmw Portion	1 (0.5%)	0	1 (0.2%)
Carbohydrates Nos;potassium Chloride;sodium Chloride;sodium Lactate	0	2 (1.0%)	2 (0.5%)
Salt Solutions	1 (0.5%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Sodium Chloride	1 (0.5%)	0	1 (0.2%)
Solutions Affecting The Electrolyte Balance	44 (21.8%)	37 (18.3%)	81 (20.0%)
Sodium Chloride	30 (14.9%)	24 (11.9%)	54 (13.4%)
Magnesium Sulfate	8 (4.0%)	2 (1.0%)	10 (2.5%)
Calcium Chloride Dihydrate;potassium Chloride;sodium Chloride;sodium Lactate	5 (2.5%)	5 (2.5%)	10 (2.5%)
Potassium Chloride	5 (2.5%)	4 (2.0%)	9 (2.2%)
Potassium Phosphate Dibasic;potassium Phosphate Monobasic	3 (1.5%)	1 (0.5%)	4 (1.0%)
Calcium Chloride Dihydrate;glucose;potassium Chloride;sodium Chloride;sodium Lactate	2 (1.0%)	0	2 (0.5%)
Potassium Phosphate Monobasic	2 (1.0%)	1 (0.5%)	3 (0.7%)
Amino Acids Nos;electrolytes Nos;glucose	1 (0.5%)	0	1 (0.2%)
Calcium Chloride Dihydrate;magnesium Chloride Hexahydrate;potassium Chloride;sodium Chloride;sodium Lactate	1 (0.5%)	0	1 (0.2%)
Calcium Chloride;potassium Chloride;sodium Chloride	1 (0.5%)	0	1 (0.2%)
Calcium Chloride;potassium Chloride;sodium Chloride;sodium Lactate	1 (0.5%)	0	1 (0.2%)
Gluconate Sodium;magnesium Chloride;potassium Chloride;sodium Acetate;sodium Chloride	1 (0.5%)	0	1 (0.2%)
Glucose Monohydrate;lactic Acid;magnesium Chloride Hexahydrate;potassium Chloride;potassium Phosphate Dibasic;sodium Chloride;sodium Lactate	1 (0.5%)	0	1 (0.2%)
Glucose;magnesium Chloride Hexahydrate;potassium Acetate;potassium Phosphate Monobasic;sodium Acetate;sodium Chloride	1 (0.5%)	0	1 (0.2%)
Glucose;potassium Chloride;sodium Chloride;sodium Lactate	1 (0.5%)	1 (0.5%)	2 (0.5%)
Glucose;sodium Chloride	1 (0.5%)	0	1 (0.2%)
Glucose;sodium Chloride;sodium Lactate	1 (0.5%)	2 (1.0%)	3 (0.7%)
Magnesium Chloride Hexahydrate;potassium Chloride;sodium Acetate Trihydrate;sodium Chloride	1 (0.5%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Potassium	1 (0.5%)	0	1 (0.2%)
Potassium Chloride;sodium Chloride	1 (0.5%)	0	1 (0.2%)
Potassium;sodium Chloride	1 (0.5%)	0	1 (0.2%)
Sodium Bicarbonate	1 (0.5%)	1 (0.5%)	2 (0.5%)
Solutions Affecting The Electrolyte Balance	1 (0.5%)	1 (0.5%)	2 (0.5%)
Calcium Chloride Dihydrate;glucose;potassium Chloride;sodium Acetate;sodium Chloride	0	1 (0.5%)	1 (0.2%)
Calcium Chloride Dihydrate;glucose;potassium Chloride;sodium Lactate	0	1 (0.5%)	1 (0.2%)
Calcium Chloride Dihydrate;magnesium Chloride Hexahydrate;malic Acid;potassium Chloride;sodium Acetate Trihydrate;sodium Chloride	0	1 (0.5%)	1 (0.2%)
Calcium Chloride Dihydrate;potassium Chloride;sodium Acetate Trihydrate;sodium Chloride	0	2 (1.0%)	2 (0.5%)
Calcium Chloride;potassium Chloride;sodium Acetate	0	2 (1.0%)	2 (0.5%)
Calcium Chloride;potassium Chloride;sodium Chloride;sodium Lactate;sorbitol	0	1 (0.5%)	1 (0.2%)
Calcium Chloride;potassium Chloride;sodium Lactate	0	1 (0.5%)	1 (0.2%)
Electrolytes Nos	0	1 (0.5%)	1 (0.2%)
Magnesium Chloride;maltose;potassium Chloride;potassium Phosphate Monobasic;sodium Acetate;sodium Chloride	0	1 (0.5%)	1 (0.2%)
Sodium L-Lactate	0	2 (1.0%)	2 (0.5%)
Solutions For Parenteral Nutrition	8 (4.0%)	7 (3.5%)	15 (3.7%)
Alanine;arginine;calcium Chloride Dihydrate;fish Oil;glucose Monohydrate;glycine;glycine Max Oil;histidine;isoleucine;leucine;lysine Hydrochloride;magnesium Sulfate Heptahydrate;medium-Chain Triglycerides;methionine;olea Europaea Oil;phenylalanine;potassium Chloride;proline;serine;sodium Acetate Trihydrate;sodium Glycerophosphate;threonine;tryptophan;tyrosine;valine;zinc Sulfate Heptahydrate	2 (1.0%)	0	2 (0.5%)
Alanine;arginine;aspartic Acid;glucose;glutamic Acid;glycine;glycine Max Oil;histidine;isoleucine;leucine;lysine Acetate;methionine;olea Europaea Oil;phenylalanine;proline;serine;threonine;tryptophan;	1 (0.5%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Tyrosine;valine			
Alanine;arginine;calcium Chloride;cysteine Hydrochloride;glucose;glycine;histidine;isoleucine;leucine;lysine Acetate;magnesium Chloride;methionine;phenylalanine;potassium Chloride;potassium Phosphate Monobasic;proline;serine;sodium Acetate;sodium Chloride;threonine;tryptophan;valine	1 (0.5%)	0	1 (0.2%)
Amino Acids Nos	1 (0.5%)	0	1 (0.2%)
Amino Acids Nos;calcium Chloride Dihydrate;electrolytes Nos;glucose;lipids Nos	1 (0.5%)	0	1 (0.2%)
Chromium;copper;fluorine;iodine;iron;manganese;zinc	1 (0.5%)	0	1 (0.2%)
Glucose	1 (0.5%)	5 (2.5%)	6 (1.5%)
Solutions For Parenteral Nutrition	1 (0.5%)	0	1 (0.2%)
Amino Acids Nos;electrolytes Nos;glucose;thiamine Hydrochloride	0	3 (1.5%)	3 (0.7%)
Solutions Producing Osmotic Diuresis	1 (0.5%)	3 (1.5%)	4 (1.0%)
Urea	1 (0.5%)	0	1 (0.2%)
Mannitol	0	3 (1.5%)	3 (0.7%)
Vitamins	3 (1.5%)	2 (1.0%)	5 (1.2%)
Vitamins Nos	2 (1.0%)	0	2 (0.5%)
Ascorbic Acid;biotin;cocarboxylase Tetrahydrate;colecalciferol;cyanocobalamin;dexpanthenol;dl-Alpha Tocopherol;folic Acid;nicotinamide;pyridoxine Hydrochloride;retinol Palmitate;riboflavin Sodium Phosphate	1 (0.5%)	2 (1.0%)	3 (0.7%)
Calcium Channel Blockers	47 (23.3%)	54 (26.7%)	101 (25.0%)
Benzothiazepine Derivatives	3 (1.5%)	2 (1.0%)	5 (1.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Diltiazem Hydrochloride	2 (1.0%)	2 (1.0%)	4 (1.0%)
Diltiazem	1 (0.5%)	0	1 (0.2%)
Dihydropyridine Derivatives	44 (21.8%)	51 (25.2%)	95 (23.5%)
Amlodipine	26 (12.9%)	26 (12.9%)	52 (12.9%)
Amlodipine Besilate	11 (5.4%)	12 (5.9%)	23 (5.7%)
Benidipine Hydrochloride	2 (1.0%)	1 (0.5%)	3 (0.7%)
Amlodipine Maleate	1 (0.5%)	1 (0.5%)	2 (0.5%)
Azelnidipine	1 (0.5%)	0	1 (0.2%)
Lercanidipine	1 (0.5%)	2 (1.0%)	3 (0.7%)
Lercanidipine Hydrochloride	1 (0.5%)	2 (1.0%)	3 (0.7%)
Manidipine	1 (0.5%)	1 (0.5%)	2 (0.5%)
Nifedipine	1 (0.5%)	3 (1.5%)	4 (1.0%)
Cilnidipine	0	1 (0.5%)	1 (0.2%)
Felodipine	0	1 (0.5%)	1 (0.2%)
Manidipine Hydrochloride	0	2 (1.0%)	2 (0.5%)
Phenylalkylamine Derivatives	2 (1.0%)	1 (0.5%)	3 (0.7%)
Verapamil	2 (1.0%)	1 (0.5%)	3 (0.7%)
Calcium Homeostasis	1 (0.5%)	1 (0.5%)	2 (0.5%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Not Applicable	0	1 (0.5%)	1 (0.2%)
Parathyroid Hormones And Analogues	0	1 (0.5%)	1 (0.2%)
Other Anti-Parathyroid Agents	1 (0.5%)	0	1 (0.2%)
Paricalcitol	1 (0.5%)	0	1 (0.2%)
Cardiac Therapy	16 (7.9%)	14 (6.9%)	30 (7.4%)
Adrenergic And Dopaminergic Agents	3 (1.5%)	3 (1.5%)	6 (1.5%)
Epinephrine	1 (0.5%)	1 (0.5%)	2 (0.5%)
Norepinephrine	1 (0.5%)	1 (0.5%)	2 (0.5%)
Norepinephrine Bitartrate	1 (0.5%)	0	1 (0.2%)
Dopamine	0	1 (0.5%)	1 (0.2%)
Ephedrine Hydrochloride	0	1 (0.5%)	1 (0.2%)
Antiarrhythmics, Class Ib	0	1 (0.5%)	1 (0.2%)
Lidocaine	0	1 (0.5%)	1 (0.2%)
Antiarrhythmics, Class Ic	0	1 (0.5%)	1 (0.2%)
Propafenone	0	1 (0.5%)	1 (0.2%)
Antiarrhythmics, Class Iii	3 (1.5%)	5 (2.5%)	8 (2.0%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Amiodarone Hydrochloride	2 (1.0%)	2 (1.0%)	4 (1.0%)
Amiodarone	1 (0.5%)	3 (1.5%)	4 (1.0%)
Digitalis Glycosides	1 (0.5%)	4 (2.0%)	5 (1.2%)
Digoxin	1 (0.5%)	4 (2.0%)	5 (1.2%)
Not Applicable	1 (0.5%)	1 (0.5%)	2 (0.5%)
Sodium Alginate	1 (0.5%)	0	1 (0.2%)
Lappaconitine Hydrobromide	0	1 (0.5%)	1 (0.2%)
Organic Nitrates	8 (4.0%)	3 (1.5%)	11 (2.7%)
Glyceryl Trinitrate	6 (3.0%)	3 (1.5%)	9 (2.2%)
Isosorbide Dinitrate	2 (1.0%)	0	2 (0.5%)
Isosorbide Mononitrate	2 (1.0%)	1 (0.5%)	3 (0.7%)
Caffeine Citrate;glyceryl Trinitrate	1 (0.5%)	1 (0.5%)	2 (0.5%)
Other Cardiac Combination Products	2 (1.0%)	0	2 (0.5%)
Magnesium Aspartate;potassium Aspartate	2 (1.0%)	0	2 (0.5%)
Other Cardiac Preparations	2 (1.0%)	0	2 (0.5%)
Ranolazine	1 (0.5%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Trimetazidine Hydrochloride	1 (0.5%)	0	1 (0.2%)
Ubidecarenone	1 (0.5%)	0	1 (0.2%)
Other Cardiac Stimulants	1 (0.5%)	0	1 (0.2%)
Angiotensin Ii	1 (0.5%)	0	1 (0.2%)
Other Vasodilators Used In Cardiac Diseases	0	1 (0.5%)	1 (0.2%)
Nicorandil	0	1 (0.5%)	1 (0.2%)
Contrast Media	1 (0.5%)	1 (0.5%)	2 (0.5%)
Watersoluble, Nephrotropic, High Osmolar X-Ray Contrast Media	0	1 (0.5%)	1 (0.2%)
Ioxitalamate Meglumine	0	1 (0.5%)	1 (0.2%)
Watersoluble, Nephrotropic, Low Osmolar X-Ray Contrast Media	1 (0.5%)	0	1 (0.2%)
Iomeprol	1 (0.5%)	0	1 (0.2%)
Corticosteroids For Systemic Use	100 (49.5%)	138 (68.3%)	238 (58.9%)
Glucocorticoids	100 (49.5%)	138 (68.3%)	238 (58.9%)
Prednisone	41 (20.3%)	7 (3.5%)	48 (11.9%)
Prednisolone	31 (15.3%)	10 (5.0%)	41 (10.1%)
Methylprednisolone	28 (13.9%)	13 (6.4%)	41 (10.1%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Dexamethasone	26 (12.9%)	109 (54.0%)	135 (33.4%)
Methylprednisolone Sodium Succinate	6 (3.0%)	6 (3.0%)	12 (3.0%)
Hydrocortisone	5 (2.5%)	5 (2.5%)	10 (2.5%)
Dexamethasone Sodium Phosphate	4 (2.0%)	14 (6.9%)	18 (4.5%)
Hydrocortisone Sodium Succinate	2 (1.0%)	1 (0.5%)	3 (0.7%)
Cortisone	1 (0.5%)	0	1 (0.2%)
Deflazacort	1 (0.5%)	5 (2.5%)	6 (1.5%)
Methylprednisolone Acetate	1 (0.5%)	0	1 (0.2%)
Prednisone Acetate	1 (0.5%)	0	1 (0.2%)
Triamcinolone Acetonide	1 (0.5%)	0	1 (0.2%)
Betamethasone Acetate	0	1 (0.5%)	1 (0.2%)
Betamethasone Sodium Phosphate	0	2 (1.0%)	2 (0.5%)
Cortisone Acetate	0	1 (0.5%)	1 (0.2%)
Dexamethasone Phosphate	0	1 (0.5%)	1 (0.2%)
Mineralocorticoids	0	1 (0.5%)	1 (0.2%)
Fludrocortisone	0	1 (0.5%)	1 (0.2%)
Corticosteroids, Dermatological Preparations	105 (52.0%)	21 (10.4%)	126 (31.2%)
Corticosteroids, Moderately Potent (Group Ii)	31 (15.3%)	3 (1.5%)	34 (8.4%)
Triamcinolone	18 (8.9%)	0	18 (4.5%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Triamcinolone Acetonide	9 (4.5%)	1 (0.5%)	10 (2.5%)
Clobetasone Butyrate	3 (1.5%)	0	3 (0.7%)
Desonide	3 (1.5%)	1 (0.5%)	4 (1.0%)
Hydrocortisone Butyrate	1 (0.5%)	0	1 (0.2%)
Dexamethasone	0	1 (0.5%)	1 (0.2%)
Corticosteroids, Moderately Potent, Combinations With Antibiotics	2 (1.0%)	0	2 (0.5%)
Gramicidin;neomycin;nystatin;triamcinolone Acetonide	2 (1.0%)	0	2 (0.5%)
Corticosteroids, Moderately Potent, Other Combinations	1 (0.5%)	0	1 (0.2%)
Triamcinolone;urea	1 (0.5%)	0	1 (0.2%)
Corticosteroids, Potent (Group Iii)	55 (27.2%)	10 (5.0%)	65 (16.1%)
Mometasone Furoate	13 (6.4%)	3 (1.5%)	16 (4.0%)
Betamethasone Valerate	10 (5.0%)	2 (1.0%)	12 (3.0%)
Methylprednisolone Aceponate	9 (4.5%)	0	9 (2.2%)
Betamethasone	8 (4.0%)	3 (1.5%)	11 (2.7%)
Betamethasone Dipropionate	8 (4.0%)	1 (0.5%)	9 (2.2%)
Prednicarbate	8 (4.0%)	0	8 (2.0%)
Diflucortolone	4 (2.0%)	0	4 (1.0%)
Fluocinonide	4 (2.0%)	0	4 (1.0%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Mometasone	4 (2.0%)	0	4 (1.0%)
Desoximetasone	3 (1.5%)	0	3 (0.7%)
Diflucortolone Valerate	2 (1.0%)	0	2 (0.5%)
Difluprednate	2 (1.0%)	1 (0.5%)	3 (0.7%)
Betamethasone Butyrate Propionate	1 (0.5%)	1 (0.5%)	2 (0.5%)
Fluticasone	1 (0.5%)	0	1 (0.2%)
Ulobetasol Propionate	1 (0.5%)	0	1 (0.2%)
Fluticasone Propionate	0	1 (0.5%)	1 (0.2%)
Corticosteroids, Potent, Combinations With Antibiotics	6 (3.0%)	2 (1.0%)	8 (2.0%)
Fluocinolone Acetonide;neomycin	3 (1.5%)	0	3 (0.7%)
Betamethasone;gentamicin	2 (1.0%)	0	2 (0.5%)
Betamethasone Valerate;fusidic Acid	1 (0.5%)	0	1 (0.2%)
Betamethasone Valerate;gentamicin Sulfate	1 (0.5%)	2 (1.0%)	3 (0.7%)
Betamethasone;fusidic Acid	1 (0.5%)	0	1 (0.2%)
Corticosteroids, Very Potent (Group Iv)	30 (14.9%)	2 (1.0%)	32 (7.9%)
Clobetasol Propionate	21 (10.4%)	1 (0.5%)	22 (5.4%)
Clobetasol	11 (5.4%)	1 (0.5%)	12 (3.0%)
Corticosteroids, Weak (Group I)	30 (14.9%)	4 (2.0%)	34 (8.4%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Hydrocortisone	27 (13.4%)	3 (1.5%)	30 (7.4%)
Methylprednisolone	2 (1.0%)	0	2 (0.5%)
Hydrocortisone Acetate	1 (0.5%)	0	1 (0.2%)
Hydrocortisone Valerate	0	1 (0.5%)	1 (0.2%)
Corticosteroids, Weak, Combinations With Antibiotics	3 (1.5%)	0	3 (0.7%)
Corticosteroids, Weak, Combinations With Antibiotics	1 (0.5%)	0	1 (0.2%)
Diphenhydramine Hydrochloride;hydrocortisone Acetate;neomycin Sulfate	1 (0.5%)	0	1 (0.2%)
Hydrocortisone;oxytetracycline Hydrochloride	1 (0.5%)	0	1 (0.2%)
Corticosteroids, Weak, Other Combinations	1 (0.5%)	0	1 (0.2%)
Crotamiton;hydrocortisone	1 (0.5%)	0	1 (0.2%)
Not Applicable	0	1 (0.5%)	1 (0.2%)
Corticosteroids, Topical	0	1 (0.5%)	1 (0.2%)
Cough And Cold Preparations	30 (14.9%)	14 (6.9%)	44 (10.9%)
Expectorants	0	1 (0.5%)	1 (0.2%)
Guaifenesin	0	1 (0.5%)	1 (0.2%)
Herbal Diaphoretics And Other Herbal Cough And Cold Remedies	1 (0.5%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Glycyrrhiza Spp. Root With Rhizome;platycodon Grandiflorus Root;polygala Senega;prunus Spp. Seed	1 (0.5%)	0	1 (0.2%)
Herbal Expectorants And Emollients	1 (0.5%)	0	1 (0.2%)
Cinnamomum Cassia Bark;ephedra Spp. Herb;glycyrrhiza Spp. Root;paeonia Lactiflora Root;pueraria Montana Var. Lobata Root;zingiber Officinale Rhizome;ziziphus Jujuba Fruit	1 (0.5%)	0	1 (0.2%)
Mucolytics	22 (10.9%)	5 (2.5%)	27 (6.7%)
Acetylcysteine	17 (8.4%)	3 (1.5%)	20 (5.0%)
Ambroxol Hydrochloride	2 (1.0%)	1 (0.5%)	3 (0.7%)
Bromhexine Hydrochloride	2 (1.0%)	0	2 (0.5%)
Erdosteine	2 (1.0%)	0	2 (0.5%)
Ambroxol	1 (0.5%)	1 (0.5%)	2 (0.5%)
Bromhexine	1 (0.5%)	0	1 (0.2%)
Carbocisteine	1 (0.5%)	0	1 (0.2%)
L-Carbocisteine	1 (0.5%)	0	1 (0.2%)
Not Applicable	1 (0.5%)	1 (0.5%)	2 (0.5%)
Glycyrrhiza Glabra;papaver Somniferum	1 (0.5%)	0	1 (0.2%)
Menthol	0	1 (0.5%)	1 (0.2%)
Opium Alkaloids And Derivatives	6 (3.0%)	4 (2.0%)	10 (2.5%)
Dextromethorphan	3 (1.5%)	0	3 (0.7%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Codeine	1 (0.5%)	1 (0.5%)	2 (0.5%)
Codeine;ethylmorphine Hydrochloride	1 (0.5%)	0	1 (0.2%)
Dextromethorphan Hydrobromide;lysozyme Hydrochloride;potassium Cresolsulfonate	1 (0.5%)	0	1 (0.2%)
Dihydrocodeine Bitartrate	1 (0.5%)	0	1 (0.2%)
Codeine Phosphate	0	2 (1.0%)	2 (0.5%)
Dextromethorphan Hydrobromide	0	1 (0.5%)	1 (0.2%)
Opium Derivatives And Expectorants	5 (2.5%)	2 (1.0%)	7 (1.7%)
Ammonium Chloride;chlorphenamine Maleate;dihydrocodeine Bitartrate;methylephedrine Hydrochloride-Dl	3 (1.5%)	1 (0.5%)	4 (1.0%)
Antimony Potassium Tartrate;glycyrrhiza Spp.;papaver Somniferum Tincture	1 (0.5%)	0	1 (0.2%)
Codeine Phosphate;guaifenesin	1 (0.5%)	0	1 (0.2%)
Dextromethorphan Hydrobromide;guaifenesin	0	1 (0.5%)	1 (0.2%)
Other Cough Suppressants	6 (3.0%)	3 (1.5%)	9 (2.2%)
Benzonatate	4 (2.0%)	2 (1.0%)	6 (1.5%)
Butamirate Citrate	1 (0.5%)	1 (0.5%)	2 (0.5%)
Levodropropizine	1 (0.5%)	0	1 (0.2%)
Other Cough Suppressants And Expectorants	1 (0.5%)	0	1 (0.2%)
Chlorphenamine Maleate;dextromethorphan Hydrobromide Monohydrate;methylephedrine Hydrochloride-Dl;noscapine Hydrochloride;sulfogaiacol	1 (0.5%)	0	1 (0.2%)
Diagnostic Agents	1 (0.5%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Not Applicable	1 (0.5%)	0	1 (0.2%)
Pralmorelin Dihydrochloride	1 (0.5%)	0	1 (0.2%)
Tests For Fertility Disturbances	1 (0.5%)	0	1 (0.2%)
Gonadorelin Diacetate	1 (0.5%)	0	1 (0.2%)
Tests For Pituitary Function	1 (0.5%)	0	1 (0.2%)
Corticorelin (Human)	1 (0.5%)	0	1 (0.2%)
Tests For Thyreoidea Function	1 (0.5%)	0	1 (0.2%)
Protirelin Tartrate	1 (0.5%)	0	1 (0.2%)
Digestives, Incl. Enzymes	7 (3.5%)	1 (0.5%)	8 (2.0%)
Acid Preparations	0	1 (0.5%)	1 (0.2%)
Glutamic Acid	0	1 (0.5%)	1 (0.2%)
Enzyme Preparations	6 (3.0%)	0	6 (1.5%)
Pancreatin;simeticone;ursodeoxycholic Acid	2 (1.0%)	0	2 (0.5%)
Bromelains;dimeticone;pancreatin	1 (0.5%)	0	1 (0.2%)
Dimeticone;hemicellulase;ox Bile;pancreatin	1 (0.5%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Lactoferrin	1 (0.5%)	0	1 (0.2%)
Pancreatin;simeticone	1 (0.5%)	0	1 (0.2%)
Herbal Digestives, Amara	1 (0.5%)	0	1 (0.2%)
Achillea Millefolium Herb;artemisia Absinthium Herb;centaurium Erythraea Herb;cichorium Intybus;gentiana Lutea Root;juniperus Communis;peucedanum Ostruthium Rhizome;salvia Officinalis Leaf;taraxacum Officinale	1 (0.5%)	0	1 (0.2%)
Diuretics	30 (14.9%)	53 (26.2%)	83 (20.5%)
Aldosterone Antagonists	7 (3.5%)	3 (1.5%)	10 (2.5%)
Spironolactone	6 (3.0%)	2 (1.0%)	8 (2.0%)
Eplerenone	1 (0.5%)	1 (0.5%)	2 (0.5%)
Herbal Diuretics, Other	0	2 (1.0%)	2 (0.5%)
Herbal Diuretics, Other	0	1 (0.5%)	1 (0.2%)
Lespedeza Bicolor	0	1 (0.5%)	1 (0.2%)
Low-Ceiling Diuretics And Potassium-Sparing Agents	1 (0.5%)	0	1 (0.2%)
Hydrochlorothiazide;triamterene	1 (0.5%)	0	1 (0.2%)
Other Potassium-Sparing Agents	0	1 (0.5%)	1 (0.2%)
Amiloride	0	1 (0.5%)	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Sulfonamides, Plain	21 (10.4%)	41 (20.3%)	62 (15.3%)
Furosemide	18 (8.9%)	36 (17.8%)	54 (13.4%)
Torasemide	3 (1.5%)	5 (2.5%)	8 (2.0%)
Bumetanide	1 (0.5%)	1 (0.5%)	2 (0.5%)
Indapamide	0	1 (0.5%)	1 (0.2%)
Thiazides And Potassium In Combination	0	1 (0.5%)	1 (0.2%)
Bendroflumethiazide;potassium Chloride	0	1 (0.5%)	1 (0.2%)
Thiazides, Plain	5 (2.5%)	9 (4.5%)	14 (3.5%)
Hydrochlorothiazide	5 (2.5%)	8 (4.0%)	13 (3.2%)
Bendroflumethiazide	0	1 (0.5%)	1 (0.2%)
Vasopressin Antagonists	2 (1.0%)	1 (0.5%)	3 (0.7%)
Tolvaptan	2 (1.0%)	1 (0.5%)	3 (0.7%)
Drugs For Acid Related Disorders	111 (55.0%)	100 (49.5%)	211 (52.2%)
Antacids With Antiflatulents	1 (0.5%)	1 (0.5%)	2 (0.5%)
Aluminium Hydroxide;magnesium Hydroxide;simeticone	1 (0.5%)	1 (0.5%)	2 (0.5%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Antacids With Sodium Bicarbonate	1 (0.5%)	3 (1.5%)	4 (1.0%)
Sodium Bicarbonate	1 (0.5%)	3 (1.5%)	4 (1.0%)
Antacids, Other Combinations	1 (0.5%)	0	1 (0.2%)
Diastase;magnesium Carbonate;scopolia Carniolica Extract;sodium Bicarbonate	1 (0.5%)	0	1 (0.2%)
Calcium Compounds	2 (1.0%)	0	2 (0.5%)
Calcium Carbonate	2 (1.0%)	0	2 (0.5%)
Combinations And Complexes Of Aluminium, Calcium And Magnesium Compounds	10 (5.0%)	2 (1.0%)	12 (3.0%)
Aluminium Hydroxide;calcium Carbonate;magnesium Carbonate;oxetacaine	3 (1.5%)	0	3 (0.7%)
Almagate	2 (1.0%)	1 (0.5%)	3 (0.7%)
Aluminium Hydroxide;magnesium Hydroxide	2 (1.0%)	0	2 (0.5%)
Magaldrate	2 (1.0%)	1 (0.5%)	3 (0.7%)
Hydrotalcite	1 (0.5%)	0	1 (0.2%)
H2-Receptor Antagonists	20 (9.9%)	21 (10.4%)	41 (10.1%)
Famotidine	17 (8.4%)	13 (6.4%)	30 (7.4%)
Nizatidine	2 (1.0%)	0	2 (0.5%)
Lafutidine	1 (0.5%)	1 (0.5%)	2 (0.5%)
Cimetidine	0	4 (2.0%)	4 (1.0%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Ranitidine	0	5 (2.5%)	5 (1.2%)
Ranitidine Hydrochloride	0	2 (1.0%)	2 (0.5%)
Herbal Remedies For Treatment Of Peptic Ulcer, Other	2 (1.0%)	0	2 (0.5%)
Artemisia Argyi Leaf	1 (0.5%)	0	1 (0.2%)
Coptis Spp. Rhizome;glycyrrhiza Spp. Root;panax Ginseng Root;pinellia Ternata Tuber;scutellaria Baicalensis Root;zingiber Officinale Processed Rhizome;ziziphus Jujuba Fruit	1 (0.5%)	0	1 (0.2%)
Not Applicable	1 (0.5%)	0	1 (0.2%)
Antacids	1 (0.5%)	0	1 (0.2%)
Other Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (Gord)	16 (7.9%)	3 (1.5%)	19 (4.7%)
Rebamipide	9 (4.5%)	0	9 (2.2%)
Sucralfate	3 (1.5%)	1 (0.5%)	4 (1.0%)
Alginic Acid;aluminium Hydroxide;magnesium Carbonate;silicon Dioxide	1 (0.5%)	0	1 (0.2%)
Aluminium Hydroxide;magnesium Carbonate;sodium Alginate	1 (0.5%)	0	1 (0.2%)
Calcium Carbonate;sodium Alginate;sodium Bicarbonate	1 (0.5%)	1 (0.5%)	2 (0.5%)
Polaprezinc	1 (0.5%)	0	1 (0.2%)
Teprenone	0	1 (0.5%)	1 (0.2%)
Proton Pump Inhibitors	99 (49.0%)	85 (42.1%)	184 (45.5%)
Omeprazole	31 (15.3%)	35 (17.3%)	66 (16.3%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Pantoprazole	28 (13.9%)	24 (11.9%)	52 (12.9%)
Pantoprazole Sodium Sesquihydrate	16 (7.9%)	14 (6.9%)	30 (7.4%)
Esomeprazole	9 (4.5%)	3 (1.5%)	12 (3.0%)
Esomeprazole Magnesium	9 (4.5%)	6 (3.0%)	15 (3.7%)
Lansoprazole	9 (4.5%)	4 (2.0%)	13 (3.2%)
Dexlansoprazole	4 (2.0%)	3 (1.5%)	7 (1.7%)
Omeprazole Magnesium	3 (1.5%)	3 (1.5%)	6 (1.5%)
Vonoprazan Fumarate	2 (1.0%)	0	2 (0.5%)
Omeprazole Sodium	1 (0.5%)	0	1 (0.2%)
Rabeprazole	1 (0.5%)	0	1 (0.2%)
Rabeprazole Sodium	1 (0.5%)	1 (0.5%)	2 (0.5%)
Esomeprazole Magnesium Dihydrate	0	1 (0.5%)	1 (0.2%)
Drugs For Constipation	84 (41.6%)	85 (42.1%)	169 (41.8%)
Bulk-Forming Laxatives	3 (1.5%)	0	3 (0.7%)
Psyllium Hydrophilic Mucilloid	2 (1.0%)	0	2 (0.5%)
Plantago Ovata	1 (0.5%)	0	1 (0.2%)
Polycarbophil Calcium	1 (0.5%)	0	1 (0.2%)
Contact Laxatives	42 (20.8%)	38 (18.8%)	80 (19.8%)
Sennoside A+b	24 (11.9%)	21 (10.4%)	45 (11.1%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Bisacodyl	8 (4.0%)	5 (2.5%)	13 (3.2%)
Sennoside A+b Calcium	4 (2.0%)	6 (3.0%)	10 (2.5%)
Docusate;sennoside A+b	3 (1.5%)	2 (1.0%)	5 (1.2%)
Sodium Picosulfate Monohydrate	2 (1.0%)	1 (0.5%)	3 (0.7%)
Bisacodyl;casanthranol;docusate Sodium;ursodeoxycholic Acid	1 (0.5%)	0	1 (0.2%)
Bisacodyl;docusate Sodium	1 (0.5%)	0	1 (0.2%)
Docusate Sodium;sennoside A+b	1 (0.5%)	4 (2.0%)	5 (1.2%)
Senna Alexandrina	1 (0.5%)	0	1 (0.2%)
Sodium Picosulfate	1 (0.5%)	6 (3.0%)	7 (1.7%)
Enemas	4 (2.0%)	8 (4.0%)	12 (3.0%)
Bisacodyl	1 (0.5%)	0	1 (0.2%)
Glycerol	1 (0.5%)	0	1 (0.2%)
Glycerol;sodium Citrate Dihydrate;sorbitol	1 (0.5%)	0	1 (0.2%)
Paraffin, Liquid	1 (0.5%)	0	1 (0.2%)
Enemas	0	2 (1.0%)	2 (0.5%)
Sodium Phosphate Dibasic;sodium Phosphate Monobasic	0	3 (1.5%)	3 (0.7%)
Sodium Phosphate;sodium Phosphate Dibasic	0	3 (1.5%)	3 (0.7%)
Osmotically Acting Laxatives	71 (35.1%)	73 (36.1%)	144 (35.6%)
Macrogol 3350	18 (8.9%)	11 (5.4%)	29 (7.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Lactulose	17 (8.4%)	24 (11.9%)	41 (10.1%)
Magnesium Oxide	15 (7.4%)	7 (3.5%)	22 (5.4%)
Macrogol 3350;potassium Chloride;sodium Bicarbonate;sodium Chloride	14 (6.9%)	20 (9.9%)	34 (8.4%)
Macrogol	10 (5.0%)	10 (5.0%)	20 (5.0%)
Magnesium Hydroxide	4 (2.0%)	6 (3.0%)	10 (2.5%)
Macrogol 4000	3 (1.5%)	3 (1.5%)	6 (1.5%)
Magnesium Citrate	3 (1.5%)	0	3 (0.7%)
Sorbitol	2 (1.0%)	0	2 (0.5%)
Macrogol;potassium Chloride;sodium Bicarbonate;sodium Chloride;sodium Sulfate Anhydrous	1 (0.5%)	0	1 (0.2%)
Macrogol 3350;potassium Chloride;sodium Bicarbonate;sodium Chloride;sodium Sulfate Anhydrous	0	1 (0.5%)	1 (0.2%)
Macrogol 400	0	1 (0.5%)	1 (0.2%)
Macrogol;potassium Chloride;sodium Bicarbonate;sodium Chloride	0	1 (0.5%)	1 (0.2%)
Magnesium Oxide Heavy	0	1 (0.5%)	1 (0.2%)
Other Drugs For Constipation	3 (1.5%)	2 (1.0%)	5 (1.2%)
Glycerol	2 (1.0%)	2 (1.0%)	4 (1.0%)
Elobixibat	1 (0.5%)	0	1 (0.2%)
Linaclotide	1 (0.5%)	1 (0.5%)	2 (0.5%)
Lubiprostone	1 (0.5%)	0	1 (0.2%)
Sodium Bicarbonate;sodium Phosphate Monobasic (Anhydrous)	1 (0.5%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Peripheral Opioid Receptor Antagonists	2 (1.0%)	0	2 (0.5%)
Naldemedine Tosilate	1 (0.5%)	0	1 (0.2%)
Naloxegol Oxalate	1 (0.5%)	0	1 (0.2%)
Softeners, Emollients	12 (5.9%)	8 (4.0%)	20 (5.0%)
Docusate Sodium	11 (5.4%)	5 (2.5%)	16 (4.0%)
Paraffin, Liquid	1 (0.5%)	2 (1.0%)	3 (0.7%)
Paraffin	0	1 (0.5%)	1 (0.2%)
Drugs For Functional Gastrointestinal Disorders	32 (15.8%)	25 (12.4%)	57 (14.1%)
Belladonna Alkaloids, Semisynthetic, Quaternary Ammonium Compounds	9 (4.5%)	5 (2.5%)	14 (3.5%)
Hyoscine Butylbromide	8 (4.0%)	4 (2.0%)	12 (3.0%)
Butylscopolamine	1 (0.5%)	3 (1.5%)	4 (1.0%)
Belladonna Alkaloids, Tertiary Amines	0	1 (0.5%)	1 (0.2%)
Hyoscyamine	0	1 (0.5%)	1 (0.2%)
Herbal Antispasmodic Agents, Other	1 (0.5%)	0	1 (0.2%)
Corydalis Yanhusuo Tuber;ipomoea Nil Seed	1 (0.5%)	0	1 (0.2%)
Not Applicable	1 (0.5%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Atropa Bella-Donna Extract;papaver Somniferum Powder	1 (0.5%)	0	1 (0.2%)
Other Drugs For Functional Gastrointestinal Disorders	8 (4.0%)	5 (2.5%)	13 (3.2%)
Simeticone	6 (3.0%)	3 (1.5%)	9 (2.2%)
Alverine Citrate;simeticone	1 (0.5%)	0	1 (0.2%)
Dimeticone	1 (0.5%)	2 (1.0%)	3 (0.7%)
Propulsives	20 (9.9%)	16 (7.9%)	36 (8.9%)
Domperidone	9 (4.5%)	9 (4.5%)	18 (4.5%)
Mosapride Citrate	5 (2.5%)	4 (2.0%)	9 (2.2%)
Metoclopramide	3 (1.5%)	1 (0.5%)	4 (1.0%)
Metoclopramide Hydrochloride	3 (1.5%)	2 (1.0%)	5 (1.2%)
Itopride Hydrochloride	2 (1.0%)	0	2 (0.5%)
Clebopride	1 (0.5%)	0	1 (0.2%)
Itopride	1 (0.5%)	0	1 (0.2%)
Mosapride	1 (0.5%)	0	1 (0.2%)
Alizapride Hydrochloride	0	1 (0.5%)	1 (0.2%)
Synthetic Anticholinergics, Esters With Tertiary Amino Group	2 (1.0%)	1 (0.5%)	3 (0.7%)
Trimebutine	2 (1.0%)	0	2 (0.5%)
Trimebutine Maleate	0	1 (0.5%)	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Synthetic Anticholinergics, Quaternary Ammonium Compounds	1 (0.5%)	0	1 (0.2%)
Otilonium Bromide	1 (0.5%)	0	1 (0.2%)
Drugs For Obstructive Airway Diseases	27 (13.4%)	21 (10.4%)	48 (11.9%)
Adrenergics In Combination With Anticholinergics Incl. Triple Combinations With Corticosteroids	3 (1.5%)	7 (3.5%)	10 (2.5%)
Fenoterol Hydrobromide;ipratropium Bromide	1 (0.5%)	0	1 (0.2%)
Glycopyrronium Bromide;indacaterol	1 (0.5%)	0	1 (0.2%)
Umeclidinium Bromide;vilanterol Trifenatate	1 (0.5%)	2 (1.0%)	3 (0.7%)
Fluticasone Furoate;umeclidinium Bromide;vilanterol Trifenatate	0	2 (1.0%)	2 (0.5%)
Glycopyrronium Bromide;indacaterol Maleate	0	1 (0.5%)	1 (0.2%)
Olodaterol Hydrochloride;tiotropium Bromide Monohydrate	0	2 (1.0%)	2 (0.5%)
Adrenergics In Combination With Corticosteroids Or Other Drugs, Excl. Anticholinergics	10 (5.0%)	6 (3.0%)	16 (4.0%)
Budesonide;formoterol Fumarate	5 (2.5%)	3 (1.5%)	8 (2.0%)
Beclometasone Dipropionate;formoterol Fumarate	2 (1.0%)	1 (0.5%)	3 (0.7%)
Beclometasone;formoterol	2 (1.0%)	1 (0.5%)	3 (0.7%)
Fluticasone Propionate;vilanterol Trifenatate	1 (0.5%)	0	1 (0.2%)
Fluticasone;salmeterol	1 (0.5%)	0	1 (0.2%)
Fluticasone;vilanterol	1 (0.5%)	0	1 (0.2%)
Budesonide;formoterol	0	1 (0.5%)	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Fluticasone Propionate;salmeterol Xinafoate	0	1 (0.5%)	1 (0.2%)
Anticholinergics	10 (5.0%)	11 (5.4%)	21 (5.2%)
Ipratropium Bromide	4 (2.0%)	4 (2.0%)	8 (2.0%)
Tiotropium Bromide Monohydrate	3 (1.5%)	2 (1.0%)	5 (1.2%)
Tiotropium	2 (1.0%)	3 (1.5%)	5 (1.2%)
Aclidinium Bromide	1 (0.5%)	0	1 (0.2%)
Tiotropium Bromide	1 (0.5%)	3 (1.5%)	4 (1.0%)
Glycopyrronium	0	1 (0.5%)	1 (0.2%)
Ipratropium	0	1 (0.5%)	1 (0.2%)
Glucocorticoids	6 (3.0%)	5 (2.5%)	11 (2.7%)
Budesonide	4 (2.0%)	4 (2.0%)	8 (2.0%)
Fluticasone Propionate	2 (1.0%)	1 (0.5%)	3 (0.7%)
Leukotriene Receptor Antagonists	2 (1.0%)	0	2 (0.5%)
Montelukast	1 (0.5%)	0	1 (0.2%)
Montelukast Sodium	1 (0.5%)	0	1 (0.2%)
Selective Beta-2-Adrenoreceptor Agonists	13 (6.4%)	13 (6.4%)	26 (6.4%)
Salbutamol	5 (2.5%)	11 (5.4%)	16 (4.0%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Salbutamol Sulfate	5 (2.5%)	0	5 (1.2%)
Fenoterol	2 (1.0%)	0	2 (0.5%)
Formoterol	1 (0.5%)	1 (0.5%)	2 (0.5%)
Salmeterol	1 (0.5%)	1 (0.5%)	2 (0.5%)
Indacaterol	0	1 (0.5%)	1 (0.2%)
Terbutaline	0	1 (0.5%)	1 (0.2%)
Terbutaline Sulfate	0	1 (0.5%)	1 (0.2%)
Xanthines	2 (1.0%)	1 (0.5%)	3 (0.7%)
Theophylline	2 (1.0%)	1 (0.5%)	3 (0.7%)
Drugs For Treatment Of Bone Diseases	14 (6.9%)	10 (5.0%)	24 (5.9%)
Bisphosphonates	12 (5.9%)	7 (3.5%)	19 (4.7%)
Zoledronic Acid	6 (3.0%)	0	6 (1.5%)
Alendronate Sodium	2 (1.0%)	2 (1.0%)	4 (1.0%)
Pamidronate Disodium	2 (1.0%)	2 (1.0%)	4 (1.0%)
Zoledronic Acid Monohydrate	2 (1.0%)	2 (1.0%)	4 (1.0%)
Alendronic Acid	0	1 (0.5%)	1 (0.2%)
Bisphosphonates, Combinations	1 (0.5%)	0	1 (0.2%)
Colecalciferol;risedronate Sodium	1 (0.5%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Other Drugs Affecting Bone Structure And Mineralization	2 (1.0%)	3 (1.5%)	5 (1.2%)
Denosumab	2 (1.0%)	3 (1.5%)	5 (1.2%)
Drugs Used In Diabetes	43 (21.3%)	40 (19.8%)	83 (20.5%)
Biguanides	28 (13.9%)	19 (9.4%)	47 (11.6%)
Metformin	24 (11.9%)	15 (7.4%)	39 (9.7%)
Metformin Hydrochloride	5 (2.5%)	4 (2.0%)	9 (2.2%)
Combinations Of Oral Blood Glucose Lowering Drugs	5 (2.5%)	6 (3.0%)	11 (2.7%)
Evogliptin Tartrate;metformin Hydrochloride	1 (0.5%)	0	1 (0.2%)
Glimepiride;metformin Hydrochloride	1 (0.5%)	0	1 (0.2%)
Metformin Hydrochloride;sitagliptin Phosphate Monohydrate	1 (0.5%)	1 (0.5%)	2 (0.5%)
Metformin;sitagliptin	1 (0.5%)	0	1 (0.2%)
Metformin;vildagliptin	1 (0.5%)	0	1 (0.2%)
Empagliflozin;metformin Hydrochloride	0	1 (0.5%)	1 (0.2%)
Gemigliptin Tartrate;metformin Hydrochloride	0	2 (1.0%)	2 (0.5%)
Metformin Hydrochloride;sitagliptin	0	1 (0.5%)	1 (0.2%)
Metformin Hydrochloride;teneligliptin Hydrobromide	0	1 (0.5%)	1 (0.2%)
Dipeptidyl Peptidase 4 (Dpp-4) Inhibitors	12 (5.9%)	9 (4.5%)	21 (5.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Linagliptin	6 (3.0%)	4 (2.0%)	10 (2.5%)
Sitagliptin	2 (1.0%)	2 (1.0%)	4 (1.0%)
Evogliptin Tartrate	1 (0.5%)	0	1 (0.2%)
Gemigliptin Tartrate	1 (0.5%)	0	1 (0.2%)
Sitagliptin Phosphate	1 (0.5%)	2 (1.0%)	3 (0.7%)
Vildagliptin	1 (0.5%)	0	1 (0.2%)
Sitagliptin Phosphate Monohydrate	0	1 (0.5%)	1 (0.2%)
Glucagon-Like Peptide-1 (Glp-1) Analogues	2 (1.0%)	2 (1.0%)	4 (1.0%)
Dulaglutide	1 (0.5%)	2 (1.0%)	3 (0.7%)
Semaglutide	1 (0.5%)	0	1 (0.2%)
Insulins And Analogues For Injection, Fast-Acting	12 (5.9%)	10 (5.0%)	22 (5.4%)
Insulin Human	4 (2.0%)	0	4 (1.0%)
Insulin	3 (1.5%)	3 (1.5%)	6 (1.5%)
Insulin Lispro	3 (1.5%)	1 (0.5%)	4 (1.0%)
Insulin Glulisine	2 (1.0%)	1 (0.5%)	3 (0.7%)
Insulin Aspart	1 (0.5%)	5 (2.5%)	6 (1.5%)
Insulins And Analogues For Injection, Intermediate- Or Long-Acting Combined With Fast-Acting	2 (1.0%)	1 (0.5%)	3 (0.7%)
Insulin Aspart;insulin Aspart Protamine (Crystalline)	1 (0.5%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Insulin Lispro;insulin Lispro Protamine Suspension	1 (0.5%)	1 (0.5%)	2 (0.5%)
Insulins And Analogues For Injection, Long-Acting	10 (5.0%)	8 (4.0%)	18 (4.5%)
Insulin Glargine	8 (4.0%)	5 (2.5%)	13 (3.2%)
Insulin Degludec	2 (1.0%)	1 (0.5%)	3 (0.7%)
Insulin Detemir	0	2 (1.0%)	2 (0.5%)
Other Blood Glucose Lowering Drugs, Excl. Insulins	1 (0.5%)	1 (0.5%)	2 (0.5%)
Repaglinide	1 (0.5%)	1 (0.5%)	2 (0.5%)
Sodium-Glucose Co-Transporter 2 (Sglt2) Inhibitors	2 (1.0%)	4 (2.0%)	6 (1.5%)
Dapagliflozin Propanediol Monohydrate	1 (0.5%)	1 (0.5%)	2 (0.5%)
Empagliflozin	1 (0.5%)	3 (1.5%)	4 (1.0%)
Sulfonylureas	13 (6.4%)	6 (3.0%)	19 (4.7%)
Gliclazide	5 (2.5%)	5 (2.5%)	10 (2.5%)
Glimepiride	5 (2.5%)	1 (0.5%)	6 (1.5%)
Glibenclamide	1 (0.5%)	0	1 (0.2%)
Glipizide	1 (0.5%)	0	1 (0.2%)
Gliquidone	1 (0.5%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Thiazolidinediones	1 (0.5%)	2 (1.0%)	3 (0.7%)
Pioglitazone Hydrochloride	1 (0.5%)	2 (1.0%)	3 (0.7%)
Emollients And Protectives	34 (16.8%)	8 (4.0%)	42 (10.4%)
Carbamide Products	9 (4.5%)	1 (0.5%)	10 (2.5%)
Urea	9 (4.5%)	1 (0.5%)	10 (2.5%)
Herbal Emollients And Protectives Containing Or Constituting Oil	2 (1.0%)	0	2 (0.5%)
Olea Europaea Oil	1 (0.5%)	0	1 (0.2%)
Prunus Amygdalus Oil	1 (0.5%)	0	1 (0.2%)
Not Applicable	5 (2.5%)	0	5 (1.2%)
Cetomacrogol	3 (1.5%)	0	3 (0.7%)
Ceramide;copper;madecassoside;panthenol;zinc	1 (0.5%)	0	1 (0.2%)
Emollients And Protectives	1 (0.5%)	0	1 (0.2%)
Other Emollients And Protectives	18 (8.9%)	2 (1.0%)	20 (5.0%)
Heparinoid	6 (3.0%)	2 (1.0%)	8 (2.0%)
Dimethiconol;dimeticone;glycerol;glyceryl Monostearate;nicotinamide;paraffin, Liquid;vitellaria Paradoxa Subsp. Paradoxa	5 (2.5%)	0	5 (1.2%)
Glycerol;paraffin, Liquid;white Soft Paraffin	3 (1.5%)	0	3 (0.7%)
Benzalkonium Chloride;chlorhexidine Hydrochloride;isopropyl Myristate;paraffin, Liquid	1 (0.5%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Cetyl Alcohol;propylene Glycol;sodium Lauryl Sulfate;stearyl Alcohol	1 (0.5%)	0	1 (0.2%)
Mucopolysaccharide Polysulfuric Acid Ester	1 (0.5%)	0	1 (0.2%)
Other Emollients And Protectives	1 (0.5%)	0	1 (0.2%)
Soft Paraffin And Fat Products	10 (5.0%)	4 (2.0%)	14 (3.5%)
Cetomacrogol;cetostearyl Alcohol;paraffin, Liquid;white Soft Paraffin	2 (1.0%)	0	2 (0.5%)
White Soft Paraffin	2 (1.0%)	2 (1.0%)	4 (1.0%)
Cetyl Alcohol;stearyl Alcohol	1 (0.5%)	0	1 (0.2%)
Paraffin	1 (0.5%)	0	1 (0.2%)
Paraffin Soft;paraffin, Liquid;wool Fat	1 (0.5%)	0	1 (0.2%)
Paraffin, Liquid	1 (0.5%)	0	1 (0.2%)
Paraffin, Liquid;white Soft Paraffin	1 (0.5%)	1 (0.5%)	2 (0.5%)
Wool Fat	1 (0.5%)	0	1 (0.2%)
Bisabolol;ceresin;paraffin Soft;paraffin, Liquid;wool Alcohols	0	1 (0.5%)	1 (0.2%)
Zinc Products	2 (1.0%)	1 (0.5%)	3 (0.7%)
Zinc Oxide	2 (1.0%)	0	2 (0.5%)
Sterculia Spp.;zinc Oxide	0	1 (0.5%)	1 (0.2%)
Endocrine Therapy	0	1 (0.5%)	1 (0.2%)
Progestogens	0	1 (0.5%)	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Medroxyprogesterone Acetate	0	1 (0.5%)	1 (0.2%)
General Nutrients	15 (7.4%)	11 (5.4%)	26 (6.4%)
Amino Acids, Incl. Combinations With Polypeptides	1 (0.5%)	1 (0.5%)	2 (0.5%)
Gelatine Hydrolysate	1 (0.5%)	0	1 (0.2%)
Tyrosine	0	1 (0.5%)	1 (0.2%)
Amino Acids/Carbohydrates/Minerals/Vitamins, Combinations	0	1 (0.5%)	1 (0.2%)
Amino Acids Nos;carbohydrates Nos;fats Nos;minerals Nos;vitamins Nos	0	1 (0.5%)	1 (0.2%)
Carbohydrates	1 (0.5%)	0	1 (0.2%)
Glucose	1 (0.5%)	0	1 (0.2%)
Carbohydrates/Proteins/Minerals/Vitamins, Combinations	0	1 (0.5%)	1 (0.2%)
Ascorbic Acid;ergocalciferol;ferric Sodium Pyrophosphate;milk, Fat Free;nicotinamide;retinol Palmitate;riboflavin;thiamine Hydrochloride	0	1 (0.5%)	1 (0.2%)
Fat/Carbohydrates/Proteins/Minerals/Vitamins, Combinations	9 (4.5%)	1 (0.5%)	10 (2.5%)
Carbohydrates Nos;fatty Acids Nos;minerals Nos;proteins Nos;vitamins Nos	3 (1.5%)	0	3 (0.7%)
Ascorbic Acid;biotin;calcium;carbohydrates Nos;chloride;colecalciferol;copper;cyanocobalamin;fats Nos;folic Acid;iron;magnesium;manganese;nicotinamide;pantothenic Acid;phosphorus;potassium;proteins Nos;pyridoxine;retinol;riboflavin;sodium;thiamine;tocopherol;zinc	2 (1.0%)	0	2 (0.5%)
Biotin;calcium Hydroxide;calcium Pantothenate;calcium Phosphate;carotenoids Nos;choline Chloride;chromic Chloride;colecalciferol;copper Gluconate;cyanocobalamin;dl-Alpha Tocopheryl Acetate;folic Acid;	1 (0.5%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Herbal Oil Nos;iron;magnesium Chloride;magnesium Hydroxide;maltodextrin;manganese Sulfate;nicotinamide;phytomenadione;potassium Citrate;potassium Hydroxide;potassium Iodide;proteins Nos;pyridoxine Hydrochloride;retinol Acetate;riboflavin;sodium Ascorbate;sodium Fluoride;sodium Molybdate;sodium Selenite;sucrose;thiamine Hydrochloride;zinc Sulfate			
Carbohydrates Nos;choline;fats Nos;fibre, Dietary;minerals Nos;proteins Nos;vitamins Nos	1 (0.5%)	0	1 (0.2%)
Carbohydrates Nos;choline;fats Nos;minerals Nos;proteins Nos;vitamins Nos	1 (0.5%)	1 (0.5%)	2 (0.5%)
Carbohydrates Nos;fats Nos;minerals Nos;proteins Nos;vitamins Nos	1 (0.5%)	0	1 (0.2%)
Not Applicable	3 (1.5%)	3 (1.5%)	6 (1.5%)
Nutrients Nos	2 (1.0%)	2 (1.0%)	4 (1.0%)
Omega-3 Fatty Acids	1 (0.5%)	0	1 (0.2%)
Protein Supplements	1 (0.5%)	1 (0.5%)	2 (0.5%)
Other Combinations Of Nutrients	3 (1.5%)	4 (2.0%)	7 (1.7%)
Carbohydrates Nos;fats Nos;minerals Nos;proteins Nos;vitamins Nos	1 (0.5%)	0	1 (0.2%)
Carbohydrates Nos;fatty Acids Nos;fibre Soluble;minerals Nos;proteins Nos	1 (0.5%)	1 (0.5%)	2 (0.5%)
Fish Oil	1 (0.5%)	3 (1.5%)	4 (1.0%)
Immune Sera And Immunoglobulins	3 (1.5%)	1 (0.5%)	4 (1.0%)
Antiviral Monoclonal Antibodies	1 (0.5%)	1 (0.5%)	2 (0.5%)
Sotrovimab	1 (0.5%)	1 (0.5%)	2 (0.5%)
Immunoglobulins, Normal Human	1 (0.5%)	0	1 (0.2%)

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Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Immunoglobulin G Human	1 (0.5%)	0	1 (0.2%)
Not Applicable	1 (0.5%)	0	1 (0.2%)
Immunoglobulins Nos	1 (0.5%)	0	1 (0.2%)
Immunostimulants	5 (2.5%)	67 (33.2%)	72 (17.8%)
Colony Stimulating Factors	5 (2.5%)	67 (33.2%)	72 (17.8%)
Filgrastim	5 (2.5%)	39 (19.3%)	44 (10.9%)
Colony Stimulating Factors	0	1 (0.5%)	1 (0.2%)
Filgrastim Sndz	0	5 (2.5%)	5 (1.2%)
Granulocyte Colony Stimulating Factor	0	3 (1.5%)	3 (0.7%)
Lenograstim	0	4 (2.0%)	4 (1.0%)
Lipegfilgrastim	0	4 (2.0%)	4 (1.0%)
Pegfilgrastim	0	15 (7.4%)	15 (3.7%)
Immunosuppressants	2 (1.0%)	0	2 (0.5%)
Other Immunosuppressants	1 (0.5%)	0	1 (0.2%)
Azathioprine	1 (0.5%)	0	1 (0.2%)
Selective Immunosuppressants	1 (0.5%)	0	1 (0.2%)
Mycophenolate Mofetil	1 (0.5%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Lipid Modifying Agents	78 (38.6%)	73 (36.1%)	151 (37.4%)
Bile Acid Sequestrants	3 (1.5%)	0	3 (0.7%)
Colestyramine	3 (1.5%)	0	3 (0.7%)
Combinations Of Various Lipid Modifying Agents	1 (0.5%)	5 (2.5%)	6 (1.5%)
Fenofibrate;pitavastatin Calcium	1 (0.5%)	0	1 (0.2%)
Atorvastatin Calcium;ezetimibe	0	2 (1.0%)	2 (0.5%)
Ezetimibe;simvastatin	0	3 (1.5%)	3 (0.7%)
Fibrates	4 (2.0%)	1 (0.5%)	5 (1.2%)
Gemfibrozil	2 (1.0%)	1 (0.5%)	3 (0.7%)
Bezafibrate	1 (0.5%)	0	1 (0.2%)
Fenofibrate	1 (0.5%)	0	1 (0.2%)
Hmg Coa Reductase Inhibitors	71 (35.1%)	67 (33.2%)	138 (34.2%)
Atorvastatin	30 (14.9%)	25 (12.4%)	55 (13.6%)
Simvastatin	13 (6.4%)	18 (8.9%)	31 (7.7%)
Rosuvastatin	12 (5.9%)	8 (4.0%)	20 (5.0%)
Atorvastatin Calcium	6 (3.0%)	6 (3.0%)	12 (3.0%)
Rosuvastatin Calcium	6 (3.0%)	6 (3.0%)	12 (3.0%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Atorvastatin Calcium Trihydrate	2 (1.0%)	2 (1.0%)	4 (1.0%)
Pitavastatin Calcium Pentahydrate	2 (1.0%)	0	2 (0.5%)
Pitavastatin Calcium	1 (0.5%)	1 (0.5%)	2 (0.5%)
Pravastatin	1 (0.5%)	5 (2.5%)	6 (1.5%)
Pravastatin Sodium	1 (0.5%)	0	1 (0.2%)
Lovastatin	0	1 (0.5%)	1 (0.2%)
Other Lipid Modifying Agents	4 (2.0%)	7 (3.5%)	11 (2.7%)
Omega-3-Acid Ethyl Ester	2 (1.0%)	0	2 (0.5%)
Colestilan	1 (0.5%)	0	1 (0.2%)
Evolocumab	1 (0.5%)	0	1 (0.2%)
Ezetimibe	1 (0.5%)	6 (3.0%)	7 (1.7%)
Docosahexaenoic Acid	0	1 (0.5%)	1 (0.2%)
Mineral Supplements	50 (24.8%)	34 (16.8%)	84 (20.8%)
Calcium	12 (5.9%)	6 (3.0%)	18 (4.5%)
Calcium Carbonate	6 (3.0%)	3 (1.5%)	9 (2.2%)
Calcium	4 (2.0%)	3 (1.5%)	7 (1.7%)
Calcium Citrate	2 (1.0%)	0	2 (0.5%)
Calcium, Combinations With Vitamin D And/Or Other Drugs	10 (5.0%)	2 (1.0%)	12 (3.0%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Calcium Carbonate;colecalciferol	6 (3.0%)	2 (1.0%)	8 (2.0%)
Calcium;vitamin D Nos	2 (1.0%)	0	2 (0.5%)
Calcium Carbonate;calcium Gluconate;calcium Lactate;ergocalciferol	1 (0.5%)	0	1 (0.2%)
Calcium;magnesium;vitamin D Nos	1 (0.5%)	0	1 (0.2%)
Magnesium	16 (7.9%)	9 (4.5%)	25 (6.2%)
Magnesium	8 (4.0%)	5 (2.5%)	13 (3.2%)
Magnesium Chloride	3 (1.5%)	0	3 (0.7%)
Magnesium Oxide	2 (1.0%)	2 (1.0%)	4 (1.0%)
Magnesium Aspartate;magnesium Chloride;magnesium Glutamate;magnesium Glycerophosphate;magnesium Orotate	1 (0.5%)	0	1 (0.2%)
Magnesium Bromide;magnesium Fluoride;magnesium Hydroxide	1 (0.5%)	0	1 (0.2%)
Magnesium Gluconate	1 (0.5%)	0	1 (0.2%)
Magnesium Sulfate	1 (0.5%)	0	1 (0.2%)
Magnesium Aspartate	0	1 (0.5%)	1 (0.2%)
Magnesium Citrate	0	1 (0.5%)	1 (0.2%)
Other Mineral Products	13 (6.4%)	5 (2.5%)	18 (4.5%)
Potassium Phosphate Dibasic;potassium Phosphate Monobasic;sodium Phosphate Dibasic;sodium Phosphate Monobasic	2 (1.0%)	2 (1.0%)	4 (1.0%)
Potassium Phosphate Monobasic;sodium Phosphate Dibasic;sodium Phosphate Monobasic (Monohydrate)	2 (1.0%)	0	2 (0.5%)
Sodium Phosphate Monobasic (Anhydrous)	2 (1.0%)	0	2 (0.5%)
Magnesium Aspartate;potassium Aspartate	1 (0.5%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Phosphorus;potassium;sodium	1 (0.5%)	0	1 (0.2%)
Potassium Bicarbonate;sodium Bicarbonate;sodium Phosphate Monobasic (Anhydrous)	1 (0.5%)	0	1 (0.2%)
Potassium Phosphate Dibasic;potassium Phosphate Monobasic;sodium Phosphate Dibasic;sodium Phosphate Monobasic (Anhydrous)	1 (0.5%)	0	1 (0.2%)
Potassium Phosphate Monobasic;sodium Phosphate Dibasic;sodium Phosphate Monobasic (Anhydrous)	1 (0.5%)	0	1 (0.2%)
Sodium Phosphate	1 (0.5%)	3 (1.5%)	4 (1.0%)
Sodium Phosphate Dibasic Dodecahydrate;sodium Phosphate Monobasic (Dihydrate)	1 (0.5%)	0	1 (0.2%)
Potassium	14 (6.9%)	16 (7.9%)	30 (7.4%)
Potassium Chloride	11 (5.4%)	14 (6.9%)	25 (6.2%)
Potassium	4 (2.0%)	1 (0.5%)	5 (1.2%)
Ascorbic Acid;potassium Bicarbonate	1 (0.5%)	0	1 (0.2%)
Potassium Citrate	1 (0.5%)	0	1 (0.2%)
Potassium Gluconate	1 (0.5%)	0	1 (0.2%)
Potassium Phosphate Monobasic	1 (0.5%)	1 (0.5%)	2 (0.5%)
Ascorbic Acid;aspartic Acid;potassium Bicarbonate	0	1 (0.5%)	1 (0.2%)
Sodium	6 (3.0%)	3 (1.5%)	9 (2.2%)
Sodium Chloride	5 (2.5%)	3 (1.5%)	8 (2.0%)
Sodium	1 (0.5%)	0	1 (0.2%)
Zinc	2 (1.0%)	1 (0.5%)	3 (0.7%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Zinc Sulfate	2 (1.0%)	0	2 (0.5%)
Zinc	0	1 (0.5%)	1 (0.2%)
Muscle Relaxants	11 (5.4%)	9 (4.5%)	20 (5.0%)
Carbamic Acid Esters	2 (1.0%)	0	2 (0.5%)
Acetylsalicylic Acid;methocarbamol	1 (0.5%)	0	1 (0.2%)
Methocarbamol	1 (0.5%)	0	1 (0.2%)
Other Centrally Acting Agents	8 (4.0%)	8 (4.0%)	16 (4.0%)
Diazepam	3 (1.5%)	0	3 (0.7%)
Baclofen	2 (1.0%)	4 (2.0%)	6 (1.5%)
Cyclobenzaprine	1 (0.5%)	0	1 (0.2%)
Eperisone Hydrochloride	1 (0.5%)	0	1 (0.2%)
Tolperisone Hydrochloride	1 (0.5%)	1 (0.5%)	2 (0.5%)
Afloqualone	0	1 (0.5%)	1 (0.2%)
Tizanidine	0	1 (0.5%)	1 (0.2%)
Tizanidine Hydrochloride	0	1 (0.5%)	1 (0.2%)
Other Quaternary Ammonium Compounds	1 (0.5%)	1 (0.5%)	2 (0.5%)
Cisatracurium	1 (0.5%)	0	1 (0.2%)
Rocuronium Bromide	0	1 (0.5%)	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Oxazol, Thiazine, And Triazine Derivatives	1 (0.5%)	0	1 (0.2%)
Chlorzoxazone	1 (0.5%)	0	1 (0.2%)
Nasal Preparations	11 (5.4%)	4 (2.0%)	15 (3.7%)
Antiallergic Agents, Excl. Corticosteroids	0	1 (0.5%)	1 (0.2%)
Olopatadine	0	1 (0.5%)	1 (0.2%)
Corticosteroids	2 (1.0%)	3 (1.5%)	5 (1.2%)
Mometasone	2 (1.0%)	1 (0.5%)	3 (0.7%)
Fluticasone	0	1 (0.5%)	1 (0.2%)
Triamcinolone Acetonide	0	1 (0.5%)	1 (0.2%)
Other Nasal Preparations	4 (2.0%)	0	4 (1.0%)
Hypromellose	1 (0.5%)	0	1 (0.2%)
Ipratropium Bromide	1 (0.5%)	0	1 (0.2%)
Mupirocin	1 (0.5%)	0	1 (0.2%)
Sea Water	1 (0.5%)	0	1 (0.2%)
Sympathomimetics	5 (2.5%)	0	5 (1.2%)
Pseudoephedrine Hydrochloride;triprolidine Hydrochloride	2 (1.0%)	0	2 (0.5%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Ebastine;pseudoephedrine Hydrochloride	1 (0.5%)	0	1 (0.2%)
Loratadine;pseudoephedrine	1 (0.5%)	0	1 (0.2%)
Naproxen Sodium;pseudoephedrine Hydrochloride	1 (0.5%)	0	1 (0.2%)
Ophthalmologicals	48 (23.8%)	12 (5.9%)	60 (14.9%)
Antibiotics	8 (4.0%)	1 (0.5%)	9 (2.2%)
Gentamicin	3 (1.5%)	0	3 (0.7%)
Chloramphenicol	2 (1.0%)	0	2 (0.5%)
Azithromycin	1 (0.5%)	0	1 (0.2%)
Bacitracin Zinc;polymyxin B Sulfate	1 (0.5%)	0	1 (0.2%)
Tobramycin	1 (0.5%)	1 (0.5%)	2 (0.5%)
Anticholinergics	2 (1.0%)	0	2 (0.5%)
Phenylephrine Hydrochloride;tropicamide	2 (1.0%)	0	2 (0.5%)
Antiinflammatory Agents, Non-Steroids	3 (1.5%)	0	3 (0.7%)
Bromfenac	1 (0.5%)	0	1 (0.2%)
Ketorolac	1 (0.5%)	0	1 (0.2%)
Ketorolac Tromethamine	1 (0.5%)	0	1 (0.2%)
Antineovascularisation Agents	2 (1.0%)	1 (0.5%)	3 (0.7%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Aflibercept	2 (1.0%)	0	2 (0.5%)
Bevacizumab	1 (0.5%)	0	1 (0.2%)
Ranibizumab	0	1 (0.5%)	1 (0.2%)
Antivirals	1 (0.5%)	0	1 (0.2%)
Aciclovir	1 (0.5%)	0	1 (0.2%)
Beta Blocking Agents	4 (2.0%)	2 (1.0%)	6 (1.5%)
Dorzolamide Hydrochloride;timolol Maleate	1 (0.5%)	0	1 (0.2%)
Dorzolamide;timolol Maleate	1 (0.5%)	0	1 (0.2%)
Timolol	1 (0.5%)	1 (0.5%)	2 (0.5%)
Timolol Maleate;travoprost	1 (0.5%)	0	1 (0.2%)
Dorzolamide;timolol	0	1 (0.5%)	1 (0.2%)
Carbonic Anhydrase Inhibitors	4 (2.0%)	1 (0.5%)	5 (1.2%)
Dorzolamide	2 (1.0%)	0	2 (0.5%)
Acetazolamide	1 (0.5%)	0	1 (0.2%)
Brinzolamide	1 (0.5%)	0	1 (0.2%)
Brimonidine Tartrate;brinzolamide	0	1 (0.5%)	1 (0.2%)
Colouring Agents	1 (0.5%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Fluorescein	1 (0.5%)	0	1 (0.2%)
Corticosteroids And Antiinfectives In Combination	2 (1.0%)	0	2 (0.5%)
Dexamethasone;moxifloxacin	1 (0.5%)	0	1 (0.2%)
Dexamethasone;neomycin Sulfate;polymyxin B Sulfate	1 (0.5%)	0	1 (0.2%)
Corticosteroids, Plain	14 (6.9%)	2 (1.0%)	16 (4.0%)
Fluorometholone	5 (2.5%)	0	5 (1.2%)
Prednisolone Acetate	3 (1.5%)	1 (0.5%)	4 (1.0%)
Dexamethasone	2 (1.0%)	1 (0.5%)	3 (0.7%)
Fluorometholone Acetate	2 (1.0%)	0	2 (0.5%)
Loteprednol Etabonate	2 (1.0%)	0	2 (0.5%)
Dexamethasone Sodium Phosphate	1 (0.5%)	0	1 (0.2%)
Prednisone	1 (0.5%)	0	1 (0.2%)
Fluoroquinolones	5 (2.5%)	0	5 (1.2%)
Levofloxacin	2 (1.0%)	0	2 (0.5%)
Moxifloxacin Hydrochloride	2 (1.0%)	0	2 (0.5%)
Ofloxacin	1 (0.5%)	0	1 (0.2%)
Other Antiallergics	2 (1.0%)	0	2 (0.5%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Azelastine	1 (0.5%)	0	1 (0.2%)
Olopatadine Hydrochloride	1 (0.5%)	0	1 (0.2%)
Other Ophthalmologicals	24 (11.9%)	7 (3.5%)	31 (7.7%)
Hyaluronate Sodium	6 (3.0%)	2 (1.0%)	8 (2.0%)
Carmellose Sodium	3 (1.5%)	0	3 (0.7%)
Artificial Tears [umbrella Term]	2 (1.0%)	0	2 (0.5%)
Ciclosporin	2 (1.0%)	0	2 (0.5%)
Dextran	2 (1.0%)	0	2 (0.5%)
Macrogol 400;propylene Glycol	2 (1.0%)	0	2 (0.5%)
Calcium Chloride Dihydrate;magnesium Chloride;potassium Chloride;sodium Acetate;sodium Citrate Acid	1 (0.5%)	0	1 (0.2%)
Capryloyl Glycine;centella Asiatica;hyaluronate Sodium;iris X Germanica;macrogol;poloxamer;polysorbate 20;potassium Phosphate Dibasic;propylene Glycol;sodium Hydroxide	1 (0.5%)	0	1 (0.2%)
Carbomer	1 (0.5%)	0	1 (0.2%)
Chlorphenamine Maleate;neostigmine Metilsulfate;taurine;tocopheryl Acetate	1 (0.5%)	0	1 (0.2%)
Dexpanthenol;hyaluronate Sodium	1 (0.5%)	0	1 (0.2%)
Dextran;hypromellose	1 (0.5%)	0	1 (0.2%)
Glycerol;propylene Glycol	1 (0.5%)	0	1 (0.2%)
Hypromellose	1 (0.5%)	0	1 (0.2%)
Paraffin, Liquid;white Soft Paraffin;wool Fat	1 (0.5%)	0	1 (0.2%)
Pirenoxine Sodium	1 (0.5%)	0	1 (0.2%)
Polyvinyl Alcohol	1 (0.5%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Polyvinyl Alcohol;povidone	1 (0.5%)	0	1 (0.2%)
Retinol Palmitate	1 (0.5%)	0	1 (0.2%)
Ascorbic Acid;copper;tocopheryl Acetate;xantofyl;zeaxanthin;zinc Oxide	0	1 (0.5%)	1 (0.2%)
Hyaluronic Acid	0	1 (0.5%)	1 (0.2%)
Pirenoxine	0	1 (0.5%)	1 (0.2%)
Povidone	0	1 (0.5%)	1 (0.2%)
Xantofyl	0	1 (0.5%)	1 (0.2%)
Prostaglandin Analogues	8 (4.0%)	1 (0.5%)	9 (2.2%)
Latanoprost	7 (3.5%)	0	7 (1.7%)
Tafluprost	1 (0.5%)	0	1 (0.2%)
Travoprost	0	1 (0.5%)	1 (0.2%)
Sympathomimetics In Glaucoma Therapy	1 (0.5%)	1 (0.5%)	2 (0.5%)
Brimonidine	1 (0.5%)	1 (0.5%)	2 (0.5%)
Sympathomimetics Used As Decongestants	1 (0.5%)	0	1 (0.2%)
Brimonidine Tartrate	1 (0.5%)	0	1 (0.2%)
Viscoelastic Substances	1 (0.5%)	0	1 (0.2%)
Hyaluronate Sodium	1 (0.5%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Other Alimentary Tract And Metabolism Products	26 (12.9%)	15 (7.4%)	41 (10.1%)
Amino Acids And Derivatives	4 (2.0%)	3 (1.5%)	7 (1.7%)
Acetylcysteine	2 (1.0%)	0	2 (0.5%)
Ademetionine	1 (0.5%)	1 (0.5%)	2 (0.5%)
Levoglutamide	1 (0.5%)	0	1 (0.2%)
Carnitine	0	1 (0.5%)	1 (0.2%)
Cysteine Hydrochloride	0	1 (0.5%)	1 (0.2%)
Glycine	0	1 (0.5%)	1 (0.2%)
Not Applicable	4 (2.0%)	0	4 (1.0%)
Clostridium Butyricum	4 (2.0%)	0	4 (1.0%)
Various Alimentary Tract And Metabolism Products	20 (9.9%)	13 (6.4%)	33 (8.2%)
Sodium Bicarbonate	8 (4.0%)	9 (4.5%)	17 (4.2%)
Phosphorus	3 (1.5%)	2 (1.0%)	5 (1.2%)
Polaprezinc	3 (1.5%)	0	3 (0.7%)
Zinc Acetate Dihydrate	3 (1.5%)	0	3 (0.7%)
Ubidecarenone	2 (1.0%)	0	2 (0.5%)
Biotin;cyanocobalamin;folic Acid;fructooligosaccharides;inulin;nicotinamide;potassium Chloride;prebiotics Nos;probiotics Nos;pyridoxine Hydrochloride;riboflavin Sodium Phosphate;thiamine Hydrochloride	1 (0.5%)	0	1 (0.2%)
Probiotics Nos	1 (0.5%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Citric Acid;sodium Citrate	0	1 (0.5%)	1 (0.2%)
Ulinastatin	0	1 (0.5%)	1 (0.2%)
Various Alimentary Tract And Metabolism Products	0	1 (0.5%)	1 (0.2%)
Other Dermatological Preparations	11 (5.4%)	1 (0.5%)	12 (3.0%)
Agents For Dermatitis, Excluding Corticosteroids	3 (1.5%)	0	3 (0.7%)
Tacrolimus	2 (1.0%)	0	2 (0.5%)
Pimecrolimus	1 (0.5%)	0	1 (0.2%)
Not Applicable	4 (2.0%)	1 (0.5%)	5 (1.2%)
Other Dermatological Preparations	4 (2.0%)	1 (0.5%)	5 (1.2%)
Other Dermatologicals	4 (2.0%)	0	4 (1.0%)
Oenothera Biennis Oil	3 (1.5%)	0	3 (0.7%)
Dexpanthenol	1 (0.5%)	0	1 (0.2%)
Other Drugs For Disorders Of The Musculo-Skeletal System	0	1 (0.5%)	1 (0.2%)
Quinine And Derivatives	0	1 (0.5%)	1 (0.2%)
Quinine Sulfate	0	1 (0.5%)	1 (0.2%)
Other Nervous System Drugs	24 (11.9%)	5 (2.5%)	29 (7.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Antivertigo Preparations	2 (1.0%)	2 (1.0%)	4 (1.0%)
Betahistine Hydrochloride	1 (0.5%)	0	1 (0.2%)
Cinnarizine	1 (0.5%)	0	1 (0.2%)
Betahistine	0	1 (0.5%)	1 (0.2%)
Betahistine Mesilate	0	1 (0.5%)	1 (0.2%)
Choline Esters	0	1 (0.5%)	1 (0.2%)
Bethanechol Chloride	0	1 (0.5%)	1 (0.2%)
Other Nervous System Drugs	21 (10.4%)	2 (1.0%)	23 (5.7%)
Thioctic Acid	8 (4.0%)	1 (0.5%)	9 (2.2%)
Gabapentin	5 (2.5%)	1 (0.5%)	6 (1.5%)
Mecobalamin	4 (2.0%)	0	4 (1.0%)
Cyanocobalamin;pyridoxine Hydrochloride;thiamine Hydrochloride	1 (0.5%)	0	1 (0.2%)
Enzymes Nos;nervonic Acid	1 (0.5%)	0	1 (0.2%)
Fluoxetine Hydrochloride	1 (0.5%)	0	1 (0.2%)
Meldonium	1 (0.5%)	0	1 (0.2%)
Vitamin B12 Nos	1 (0.5%)	0	1 (0.2%)
Naloxone Hydrochloride;oxycodone Hydrochloride	0	1 (0.5%)	1 (0.2%)
Other Parasympathomimetics	1 (0.5%)	0	1 (0.2%)

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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Pilocarpine Hydrochloride	1 (0.5%)	0	1 (0.2%)
Pancreatic Hormones	1 (0.5%)	0	1 (0.2%)
Glycogenolytic Hormones	1 (0.5%)	0	1 (0.2%)
Glucagon	1 (0.5%)	0	1 (0.2%)
Peripheral Vasodilators	3 (1.5%)	3 (1.5%)	6 (1.5%)
Nicotinic Acid And Derivatives	0	1 (0.5%)	1 (0.2%)
Nicametate	0	1 (0.5%)	1 (0.2%)
Other Peripheral Vasodilators	1 (0.5%)	0	1 (0.2%)
Achyranthes Bidentata Root;aconitum Spp. Processed Root;alisma Plantago-Aquatica Subsp. Orientale Tuber;cinnamomum Cassia Bark;cornus Officinalis Fruit;dioscorea Spp. Rhizome;paeonia X Suffruticosa Root Bark;plantago Asiatica Seed;poria Cocos Sclerotium;rehmannia Glutinosa Root	1 (0.5%)	0	1 (0.2%)
Purine Derivatives	2 (1.0%)	3 (1.5%)	5 (1.2%)
Pentoxifylline	2 (1.0%)	2 (1.0%)	4 (1.0%)
Methylethylpiridinol Succinate	0	1 (0.5%)	1 (0.2%)
Pituitary And Hypothalamic Hormones And Analogues	4 (2.0%)	2 (1.0%)	6 (1.5%)
Acth	2 (1.0%)	1 (0.5%)	3 (0.7%)
Tetracosactide Acetate	2 (1.0%)	0	2 (0.5%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Tetracosactide	0	1 (0.5%)	1 (0.2%)
Somatostatin And Analogues	1 (0.5%)	0	1 (0.2%)
Octreotide Acetate	1 (0.5%)	0	1 (0.2%)
Vasopressin And Analogues	1 (0.5%)	1 (0.5%)	2 (0.5%)
Desmopressin	1 (0.5%)	1 (0.5%)	2 (0.5%)
Preparations For Treatment Of Wounds And Ulcers	4 (2.0%)	1 (0.5%)	5 (1.2%)
Not Applicable	1 (0.5%)	0	1 (0.2%)
Nepidermin	1 (0.5%)	0	1 (0.2%)
Other Cicatrizants	2 (1.0%)	1 (0.5%)	3 (0.7%)
Copper Gluconate;hyaluronate Sodium;madecassoside;manganese Gluconate;zinc Gluconate	1 (0.5%)	0	1 (0.2%)
Phenoxyethanol;triticum Aestivum	1 (0.5%)	0	1 (0.2%)
Carmellose Sodium	0	1 (0.5%)	1 (0.2%)
Proteolytic Enzymes	1 (0.5%)	0	1 (0.2%)
Alginic Acid;glucose;glucose Oxidase;guaiacol;lactoperoxidase;macrogol	1 (0.5%)	0	1 (0.2%)
Psychoanaleptics	36 (17.8%)	23 (11.4%)	59 (14.6%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Anticholinesterases	4 (2.0%)	0	4 (1.0%)
Ipidacrine	4 (2.0%)	0	4 (1.0%)
Centrally Acting Sympathomimetics	1 (0.5%)	0	1 (0.2%)
Amfetamine Aspartate;amfetamine Sulfate;dexamfetamine Saccharate;dexamfetamine Sulfate	1 (0.5%)	0	1 (0.2%)
Non-Selective Monoamine Reuptake Inhibitors	2 (1.0%)	2 (1.0%)	4 (1.0%)
Amitriptyline	1 (0.5%)	2 (1.0%)	3 (0.7%)
Amitriptyline Hydrochloride	1 (0.5%)	0	1 (0.2%)
Other Antidepressants	26 (12.9%)	13 (6.4%)	39 (9.7%)
Mirtazapine	11 (5.4%)	7 (3.5%)	18 (4.5%)
Trazodone	7 (3.5%)	2 (1.0%)	9 (2.2%)
Trazodone Hydrochloride	4 (2.0%)	2 (1.0%)	6 (1.5%)
Duloxetine Hydrochloride	2 (1.0%)	0	2 (0.5%)
Bupropion	1 (0.5%)	1 (0.5%)	2 (0.5%)
Desvenlafaxine	1 (0.5%)	0	1 (0.2%)
Duloxetine	1 (0.5%)	0	1 (0.2%)
Venlafaxine Hydrochloride	1 (0.5%)	2 (1.0%)	3 (0.7%)
Venlafaxine	0	1 (0.5%)	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Other Psychostimulants And Nootropics	4 (2.0%)	0	4 (1.0%)
Idebenone	3 (1.5%)	0	3 (0.7%)
Piracetam	1 (0.5%)	0	1 (0.2%)
Selective Serotonin Reuptake Inhibitors	7 (3.5%)	9 (4.5%)	16 (4.0%)
Fluoxetine	2 (1.0%)	0	2 (0.5%)
Sertraline	2 (1.0%)	1 (0.5%)	3 (0.7%)
Citalopram	1 (0.5%)	2 (1.0%)	3 (0.7%)
Escitalopram	1 (0.5%)	2 (1.0%)	3 (0.7%)
Escitalopram Oxalate	1 (0.5%)	0	1 (0.2%)
Fluoxetine Hydrochloride	0	1 (0.5%)	1 (0.2%)
Paroxetine	0	2 (1.0%)	2 (0.5%)
Paroxetine Hydrochloride	0	1 (0.5%)	1 (0.2%)
Psycholeptics	71 (35.1%)	59 (29.2%)	130 (32.2%)
Azaspirodecanedione Derivatives	2 (1.0%)	1 (0.5%)	3 (0.7%)
Buspirone	1 (0.5%)	1 (0.5%)	2 (0.5%)
Buspirone Hydrochloride	1 (0.5%)	0	1 (0.2%)
Benzamides	1 (0.5%)	1 (0.5%)	2 (0.5%)
Levosulpiride	1 (0.5%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Sulpiride	0	1 (0.5%)	1 (0.2%)
Benzodiazepine Derivatives	50 (24.8%)	47 (23.3%)	97 (24.0%)
Lorazepam	27 (13.4%)	19 (9.4%)	46 (11.4%)
Alprazolam	9 (4.5%)	10 (5.0%)	19 (4.7%)
Midazolam	8 (4.0%)	6 (3.0%)	14 (3.5%)
Clonazepam	4 (2.0%)	2 (1.0%)	6 (1.5%)
Diazepam	2 (1.0%)	4 (2.0%)	6 (1.5%)
Estazolam	2 (1.0%)	1 (0.5%)	3 (0.7%)
Midazolam Hydrochloride	2 (1.0%)	1 (0.5%)	3 (0.7%)
Oxazepam	2 (1.0%)	1 (0.5%)	3 (0.7%)
Bromazepam	1 (0.5%)	3 (1.5%)	4 (1.0%)
Delorazepam	1 (0.5%)	1 (0.5%)	2 (0.5%)
Lormetazepam	1 (0.5%)	2 (1.0%)	3 (0.7%)
Rilmazafone	1 (0.5%)	0	1 (0.2%)
Temazepam	1 (0.5%)	3 (1.5%)	4 (1.0%)
Triazolam	1 (0.5%)	0	1 (0.2%)
Benzodiazepine Related Drugs	16 (7.9%)	5 (2.5%)	21 (5.2%)
Zopiclone	8 (4.0%)	2 (1.0%)	10 (2.5%)
Zolpidem Tartrate	4 (2.0%)	1 (0.5%)	5 (1.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Zolpidem	3 (1.5%)	2 (1.0%)	5 (1.2%)
Eszopiclone	1 (0.5%)	0	1 (0.2%)
Butyrophenone Derivatives	5 (2.5%)	5 (2.5%)	10 (2.5%)
Haloperidol	5 (2.5%)	5 (2.5%)	10 (2.5%)
Diazepines, Oxazepines, Thiazepines And Oxepines	10 (5.0%)	10 (5.0%)	20 (5.0%)
Olanzapine	7 (3.5%)	6 (3.0%)	13 (3.2%)
Quetiapine	2 (1.0%)	3 (1.5%)	5 (1.2%)
Quetiapine Fumarate	2 (1.0%)	1 (0.5%)	3 (0.7%)
Diphenylmethane Derivatives	1 (0.5%)	2 (1.0%)	3 (0.7%)
Hydroxyzine Hydrochloride	1 (0.5%)	1 (0.5%)	2 (0.5%)
Hydroxyzine Embonate	0	1 (0.5%)	1 (0.2%)
Lithium	0	1 (0.5%)	1 (0.2%)
Lithium	0	1 (0.5%)	1 (0.2%)
Melatonin Receptor Agonists	5 (2.5%)	1 (0.5%)	6 (1.5%)
Melatonin	5 (2.5%)	1 (0.5%)	6 (1.5%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Not Applicable	1 (0.5%)	1 (0.5%)	2 (0.5%)
Cannabidiol	1 (0.5%)	1 (0.5%)	2 (0.5%)
Other Antipsychotics	1 (0.5%)	2 (1.0%)	3 (0.7%)
Aripiprazole	1 (0.5%)	1 (0.5%)	2 (0.5%)
Risperidone	0	1 (0.5%)	1 (0.2%)
Other Anxiolytics	8 (4.0%)	8 (4.0%)	16 (4.0%)
Amitriptyline	3 (1.5%)	1 (0.5%)	4 (1.0%)
Paroxetine	2 (1.0%)	0	2 (0.5%)
Propranolol	1 (0.5%)	0	1 (0.2%)
Propranolol Hydrochloride	1 (0.5%)	0	1 (0.2%)
Venlafaxine	1 (0.5%)	0	1 (0.2%)
Amitriptyline Hydrochloride	0	1 (0.5%)	1 (0.2%)
Escitalopram	0	1 (0.5%)	1 (0.2%)
Escitalopram Oxalate	0	1 (0.5%)	1 (0.2%)
Pregabalin	0	2 (1.0%)	2 (0.5%)
Sertraline Hydrochloride	0	2 (1.0%)	2 (0.5%)
Other Hypnotics And Sedatives	6 (3.0%)	3 (1.5%)	9 (2.2%)
Diphenhydramine Hydrochloride	2 (1.0%)	0	2 (0.5%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Doxepin Hydrochloride	2 (1.0%)	0	2 (0.5%)
Dexmedetomidine	1 (0.5%)	0	1 (0.2%)
Dexmedetomidine Hydrochloride	1 (0.5%)	0	1 (0.2%)
Diphenhydramine	1 (0.5%)	0	1 (0.2%)
Clomethiazole	0	1 (0.5%)	1 (0.2%)
Lemborexant	0	1 (0.5%)	1 (0.2%)
Valeriana Officinalis Root Dry Extract	0	1 (0.5%)	1 (0.2%)
Phenothiazines With Aliphatic Side-Chain	2 (1.0%)	3 (1.5%)	5 (1.2%)
Chlorpromazine Hydrochloride	1 (0.5%)	2 (1.0%)	3 (0.7%)
Levomepromazine Hydrochloride	1 (0.5%)	0	1 (0.2%)
Chlorpromazine	0	1 (0.5%)	1 (0.2%)
Sex Hormones And Modulators Of The Genital System	3 (1.5%)	5 (2.5%)	8 (2.0%)
3-Oxoandrosten (4) Derivatives	1 (0.5%)	0	1 (0.2%)
Testosterone	1 (0.5%)	0	1 (0.2%)
Natural And Semisynthetic Estrogens, Plain	2 (1.0%)	3 (1.5%)	5 (1.2%)
Estradiol	2 (1.0%)	3 (1.5%)	5 (1.2%)
Estrogens Conjugated	1 (0.5%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Selective Estrogen Receptor Modulators	0	2 (1.0%)	2 (0.5%)
Raloxifene	0	1 (0.5%)	1 (0.2%)
Raloxifene Hydrochloride	0	1 (0.5%)	1 (0.2%)
Stomatological Preparations	30 (14.9%)	19 (9.4%)	49 (12.1%)
Antiinfectives And Antiseptics For Local Oral Treatment	18 (8.9%)	13 (6.4%)	31 (7.7%)
Nystatin	14 (6.9%)	4 (2.0%)	18 (4.5%)
Chlorhexidine Gluconate	2 (1.0%)	3 (1.5%)	5 (1.2%)
Benzethonium Chloride	1 (0.5%)	0	1 (0.2%)
Chlorhexidine	1 (0.5%)	4 (2.0%)	5 (1.2%)
Miconazole	1 (0.5%)	0	1 (0.2%)
Domiphen Bromide	0	1 (0.5%)	1 (0.2%)
Metronidazole	0	1 (0.5%)	1 (0.2%)
Corticosteroids For Local Oral Treatment	8 (4.0%)	0	8 (2.0%)
Triamcinolone Acetonide	5 (2.5%)	0	5 (1.2%)
Prednisolone	2 (1.0%)	0	2 (0.5%)
Dexamethasone	1 (0.5%)	0	1 (0.2%)
Triamcinolone	1 (0.5%)	0	1 (0.2%)
Not Applicable	1 (0.5%)	3 (1.5%)	4 (1.0%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Sodium Bicarbonate	1 (0.5%)	3 (1.5%)	4 (1.0%)
Other Agents For Local Oral Treatment	11 (5.4%)	3 (1.5%)	14 (3.5%)
Benzydamine Hydrochloride	3 (1.5%)	0	3 (0.7%)
Glycerol;hyetellose;methylparaben;poloxamer 407;propylene Glycol;propylparaben;sodium Benzoate;sodium Phosphate;sodium Phosphate Dibasic;sorbitol;xylitol	2 (1.0%)	0	2 (0.5%)
Benzydamine Hydrochloride;chlorhexidine Gluconate	1 (0.5%)	0	1 (0.2%)
Calcium Chloride;sodium Chloride;sodium Phosphate Dibasic;sodium Phosphate Monobasic	1 (0.5%)	0	1 (0.2%)
Glucose Oxidase;lactoferrin;lactoperoxidase;lysozyme	1 (0.5%)	0	1 (0.2%)
Hyaluronate Sodium	1 (0.5%)	0	1 (0.2%)
Lidocaine	1 (0.5%)	0	1 (0.2%)
Lidocaine Hydrochloride;matricaria Chamomilla Flower	1 (0.5%)	0	1 (0.2%)
Magic Mouthwash	1 (0.5%)	0	1 (0.2%)
Zinc	1 (0.5%)	0	1 (0.2%)
Other Agents For Local Oral Treatment	0	1 (0.5%)	1 (0.2%)
Sodium Gualenate Hydrate	0	2 (1.0%)	2 (0.5%)
Throat Preparations	3 (1.5%)	2 (1.0%)	5 (1.2%)
Anesthetics, Local	1 (0.5%)	0	1 (0.2%)
Lidocaine	1 (0.5%)	0	1 (0.2%)
Antiseptics	1 (0.5%)	2 (1.0%)	3 (0.7%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Chlorhexidine	1 (0.5%)	0	1 (0.2%)
Dequalinium Chloride	0	1 (0.5%)	1 (0.2%)
Sodium Gualenate Hydrate	0	1 (0.5%)	1 (0.2%)
Other Throat Preparations	1 (0.5%)	0	1 (0.2%)
Benzydamine Hydrochloride	1 (0.5%)	0	1 (0.2%)
Thyroid Therapy	34 (16.8%)	13 (6.4%)	47 (11.6%)
Other Antithyroid Preparations	3 (1.5%)	0	3 (0.7%)
Propranolol Hydrochloride	2 (1.0%)	0	2 (0.5%)
Propranolol	1 (0.5%)	0	1 (0.2%)
Perchlorates	1 (0.5%)	0	1 (0.2%)
Sodium Perchlorate	1 (0.5%)	0	1 (0.2%)
Sulfur-Containing Imidazole Derivatives	2 (1.0%)	1 (0.5%)	3 (0.7%)
Thiamazole	2 (1.0%)	1 (0.5%)	3 (0.7%)
Thyroid Hormones	31 (15.3%)	12 (5.9%)	43 (10.6%)
Levothyroxine Sodium	17 (8.4%)	6 (3.0%)	23 (5.7%)
Levothyroxine	15 (7.4%)	5 (2.5%)	20 (5.0%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Thyroid	0	1 (0.5%)	1 (0.2%)
Topical Products For Joint And Muscular Pain	12 (5.9%)	8 (4.0%)	20 (5.0%)
Antiinflammatory Preparations, Non-Steroids For Topical Use	11 (5.4%)	8 (4.0%)	19 (4.7%)
Diclofenac	3 (1.5%)	2 (1.0%)	5 (1.2%)
Diclofenac Diethylamine	2 (1.0%)	0	2 (0.5%)
Flurbiprofen	2 (1.0%)	0	2 (0.5%)
Loxoprofen Sodium Dihydrate	2 (1.0%)	2 (1.0%)	4 (1.0%)
Etofenamate	1 (0.5%)	0	1 (0.2%)
Ketoprofen	1 (0.5%)	3 (1.5%)	4 (1.0%)
Loxoprofen	1 (0.5%)	0	1 (0.2%)
Indometacin	0	1 (0.5%)	1 (0.2%)
Preparations With Salicylic Acid Derivatives	1 (0.5%)	0	1 (0.2%)
Eugenol;menthol;methyl Salicylate	1 (0.5%)	0	1 (0.2%)
Unspecified Herbal And Traditional Medicine	2 (1.0%)	1 (0.5%)	3 (0.7%)
Not Applicable	2 (1.0%)	1 (0.5%)	3 (0.7%)
Herbal Preparation	1 (0.5%)	0	1 (0.2%)
Platycodon Grandiflorus Root Fluid Extract	1 (0.5%)	0	1 (0.2%)
Artemisia Spp. Herb Extract	0	1 (0.5%)	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Urologicals	57 (28.2%)	42 (20.8%)	99 (24.5%)
Alpha-Adrenoreceptor Antagonists	44 (21.8%)	29 (14.4%)	73 (18.1%)
Tamsulosin	17 (8.4%)	11 (5.4%)	28 (6.9%)
Tamsulosin Hydrochloride	17 (8.4%)	14 (6.9%)	31 (7.7%)
Silodosin	7 (3.5%)	1 (0.5%)	8 (2.0%)
Dutasteride;tamsulosin Hydrochloride	3 (1.5%)	1 (0.5%)	4 (1.0%)
Doxazosin Mesilate	1 (0.5%)	0	1 (0.2%)
Solifenacin Succinate;tamsulosin Hydrochloride	1 (0.5%)	0	1 (0.2%)
Alfuzosin Hydrochloride	0	1 (0.5%)	1 (0.2%)
Doxazosin	0	1 (0.5%)	1 (0.2%)
Terazosin	0	1 (0.5%)	1 (0.2%)
Drugs For Urinary Frequency And Incontinence	17 (8.4%)	11 (5.4%)	28 (6.9%)
Mirabegron	6 (3.0%)	4 (2.0%)	10 (2.5%)
Solifenacin	4 (2.0%)	0	4 (1.0%)
Solifenacin Succinate	3 (1.5%)	3 (1.5%)	6 (1.5%)
Oxybutynin Hydrochloride	2 (1.0%)	0	2 (0.5%)
Duloxetine Hydrochloride	1 (0.5%)	0	1 (0.2%)
Oxybutynin	1 (0.5%)	2 (1.0%)	3 (0.7%)
Tolterodine	1 (0.5%)	2 (1.0%)	3 (0.7%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Fesoterodine	0	1 (0.5%)	1 (0.2%)
Fesoterodine Fumarate	0	1 (0.5%)	1 (0.2%)
Drugs Used In Erectile Dysfunction	5 (2.5%)	0	5 (1.2%)
Sildenafil	2 (1.0%)	0	2 (0.5%)
Tadalafil	2 (1.0%)	0	2 (0.5%)
Avanafil	1 (0.5%)	0	1 (0.2%)
Sildenafil Citrate	1 (0.5%)	0	1 (0.2%)
Udenafil	1 (0.5%)	0	1 (0.2%)
Herbal Drugs Used In Benign Prostatic Hypertrophy	0	1 (0.5%)	1 (0.2%)
Serenoa Repens Extract	0	1 (0.5%)	1 (0.2%)
Not Applicable	2 (1.0%)	0	2 (0.5%)
Centaurium Erythraea;levisticum Officinale;salvia Rosmarinus	2 (1.0%)	0	2 (0.5%)
Other Urologicals	2 (1.0%)	1 (0.5%)	3 (0.7%)
Escherichia Coli	1 (0.5%)	0	1 (0.2%)
Phenazopyridine Hydrochloride	1 (0.5%)	0	1 (0.2%)
Lidocaine	0	1 (0.5%)	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Testosterone-5-Alpha Reductase Inhibitors	10 (5.0%)	8 (4.0%)	18 (4.5%)
Finasteride	6 (3.0%)	4 (2.0%)	10 (2.5%)
Dutasteride	4 (2.0%)	4 (2.0%)	8 (2.0%)
Vaccines	31 (15.3%)	13 (6.4%)	44 (10.9%)
Covid-19 Vaccines	27 (13.4%)	12 (5.9%)	39 (9.7%)
Tozinameran	18 (8.9%)	8 (4.0%)	26 (6.4%)
Elasomeran	11 (5.4%)	5 (2.5%)	16 (4.0%)
Covid-19 Vaccine	2 (1.0%)	0	2 (0.5%)
Influenza Vaccines	7 (3.5%)	4 (2.0%)	11 (2.7%)
Influenza Vaccine	6 (3.0%)	2 (1.0%)	8 (2.0%)
Influenza Vaccine Inact Split 4v	1 (0.5%)	2 (1.0%)	3 (0.7%)
Pneumococcal Vaccines	2 (1.0%)	0	2 (0.5%)
Pneumococcal Vaccine	1 (0.5%)	0	1 (0.2%)
Pneumococcal Vaccine Conj 13v (Crm197)	1 (0.5%)	0	1 (0.2%)
Vasoprotectives	10 (5.0%)	3 (1.5%)	13 (3.2%)
Bioflavonoids	2 (1.0%)	1 (0.5%)	3 (0.7%)
Bioflavonoids Nos	1 (0.5%)	1 (0.5%)	2 (0.5%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Diosmin;hesperidin	1 (0.5%)	0	1 (0.2%)
Corticosteroids	1 (0.5%)	1 (0.5%)	2 (0.5%)
Hydrocortisone Acetate	1 (0.5%)	0	1 (0.2%)
Hydrocortisone Acetate;zinc Sulfate	1 (0.5%)	1 (0.5%)	2 (0.5%)
Heparins Or Heparinoids For Topical Use	1 (0.5%)	1 (0.5%)	2 (0.5%)
Benzocaine;benzyl Nicotinate;heparin Sodium	1 (0.5%)	0	1 (0.2%)
Heparin	0	1 (0.5%)	1 (0.2%)
Herbal Antivaricose Remedies	1 (0.5%)	0	1 (0.2%)
Vitis Vinifera Seed Extract	1 (0.5%)	0	1 (0.2%)
Local Anesthetics	2 (1.0%)	0	2 (0.5%)
Benzocaine;bismuth Subgallate;diphenhydramine Hydrochloride;zinc Oxide	1 (0.5%)	0	1 (0.2%)
Benzocaine;bismuth Subnitrate;chlorhexidine Diacetate;enoxolone;lidocaine;phenylephrine Hydrochloride	1 (0.5%)	0	1 (0.2%)
Pramocaine Hydrochloride	1 (0.5%)	0	1 (0.2%)
Muscle Relaxants	1 (0.5%)	0	1 (0.2%)
Diltiazem	1 (0.5%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Other Agents For Treatment Of Hemorrhoids And Anal Fissures For Topical Use	2 (1.0%)	0	2 (0.5%)
Live Yeast Cell Extract;shark-Liver Oil	1 (0.5%)	0	1 (0.2%)
Ruscogenin;trimebutine	1 (0.5%)	0	1 (0.2%)
Other Capillary Stabilizing Agents	1 (0.5%)	0	1 (0.2%)
Naftazone	1 (0.5%)	0	1 (0.2%)
Other Sclerosing Agents	1 (0.5%)	0	1 (0.2%)
Calcium Dobesilate	1 (0.5%)	0	1 (0.2%)
Sclerosing Agents For Local Injection	1 (0.5%)	0	1 (0.2%)
Lauromacrogol 400	1 (0.5%)	0	1 (0.2%)
Vitamins	52 (25.7%)	36 (17.8%)	88 (21.8%)
Ascorbic Acid (Vitamin C), Plain	5 (2.5%)	2 (1.0%)	7 (1.7%)
Ascorbic Acid	5 (2.5%)	2 (1.0%)	7 (1.7%)
Multivitamins With Minerals	5 (2.5%)	2 (1.0%)	7 (1.7%)
Ascorbic Acid;calcium;minerals Nos;retinol;tocopheryl Acetate;vitamin B Nos;vitamins Nos;zinc	2 (1.0%)	0	2 (0.5%)
Minerals Nos;vitamins Nos	2 (1.0%)	2 (1.0%)	4 (1.0%)
Iron;minerals Nos;vitamins Nos	1 (0.5%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Multivitamins, Plain	5 (2.5%)	8 (4.0%)	13 (3.2%)
Multivitamins, Plain	4 (2.0%)	8 (4.0%)	12 (3.0%)
Ascorbic Acid;dexpanthenol;ergocalciferol;nicotinamide;pyridoxine Hydrochloride;retinol;riboflavin Sodium Phosphate;thiamine Hydrochloride;tocopherol	1 (0.5%)	0	1 (0.2%)
Other Plain Vitamin Preparations	7 (3.5%)	2 (1.0%)	9 (2.2%)
Pyridoxine Hydrochloride	4 (2.0%)	0	4 (1.0%)
Biotin	1 (0.5%)	1 (0.5%)	2 (0.5%)
Tocopherol	1 (0.5%)	1 (0.5%)	2 (0.5%)
Vitamin E Nos	1 (0.5%)	0	1 (0.2%)
Vitamin B-Complex With Vitamin C	0	2 (1.0%)	2 (0.5%)
Ascorbic Acid;biotin;calcium Pantothenate;cyanocobalamin;folic Acid;nicotinamide;pyridoxine Hydrochloride;riboflavin;thiamine Hydrochloride	0	1 (0.5%)	1 (0.2%)
Ascorbic Acid;biotin;calcium Pantothenate;cyanocobalamin;folic Acid;nicotinamide;pyridoxine Hydrochloride;riboflavin;thiamine Mononitrate	0	1 (0.5%)	1 (0.2%)
Vitamin B-Complex, Plain	5 (2.5%)	5 (2.5%)	10 (2.5%)
Vitamin B Complex	4 (2.0%)	5 (2.5%)	9 (2.2%)
Calcium Pantothenate;cyanocobalamin;nicotinamide;pyridoxine Hydrochloride;riboflavin;thiamine Hydrochloride	1 (0.5%)	0	1 (0.2%)
Vitamin B1 In Combination With Vitamin B6 And/Or Vitamin B12	6 (3.0%)	0	6 (1.5%)
Cyanocobalamin;pyridoxine Hydrochloride;riboflavin;thiamine Mononitrate	3 (1.5%)	0	3 (0.7%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Benfotiamine;cyanocobalamin;pyridoxine Hydrochloride	1 (0.5%)	0	1 (0.2%)
Cyanocobalamin;riboflavin;thiamine Hydrochloride	1 (0.5%)	0	1 (0.2%)
Pyridoxine Hydrochloride;vitamin B1 Nos;vitamin B12 Nos	1 (0.5%)	0	1 (0.2%)
Vitamin B1, Plain	4 (2.0%)	1 (0.5%)	5 (1.2%)
Thiamine	2 (1.0%)	0	2 (0.5%)
Thiamine Hydrochloride	2 (1.0%)	1 (0.5%)	3 (0.7%)
Vitamin D And Analogues	26 (12.9%)	25 (12.4%)	51 (12.6%)
Colecalciferol	14 (6.9%)	15 (7.4%)	29 (7.2%)
Vitamin D Nos	10 (5.0%)	4 (2.0%)	14 (3.5%)
Ergocalciferol	2 (1.0%)	1 (0.5%)	3 (0.7%)
Calcifediol	1 (0.5%)	3 (1.5%)	4 (1.0%)
Alfacalcidol	0	1 (0.5%)	1 (0.2%)
Calcitriol	0	2 (1.0%)	2 (0.5%)
Vitamins With Minerals	0	2 (1.0%)	2 (0.5%)
Ascorbic Acid;betacarotene;biotin;calcium;copper;folic Acid;iodine;iron;magnesium;manganese;nicotinamide;pantothenic Acid;pyridoxine Hydrochloride;riboflavin;selenium;vitamin B1 Nos;vitamin B12 Nos; Vitamin D Nos;zinc	0	1 (0.5%)	1 (0.2%)
Ascorbic Acid;cupric Oxide;tocopheryl Acid Succinate;zinc Oxide	0	1 (0.5%)	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
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Table 302.1.1000.4.2: Summary of Concomitant Therapies - Analysis Set mITT 2

Therapeutic Subgroup (ATC 2nd Level) Chemical Subgroup (ATC 4th Level) Preferred WHO Name	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Vitamins, Other Combinations	3 (1.5%)	0	3 (0.7%)
Cyanocobalamin;lidocaine Hydrochloride;pyridoxine Hydrochloride;thiamine Hydrochloride	2 (1.0%)	0	2 (0.5%)
Ascorbic Acid;calcium Pantothenate;cysteine	1 (0.5%)	0	1 (0.2%)

Abbreviations: ATC=anatomical therapeutic chemical; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; WHO=world health organization.
Note: Concomitant medication is defined as any medication that is ongoing during study treatment or with an end date after the first dose of study treatment and the start date is no later than last dose date plus 30 days.
Data are sorted by ascending alphabetical order of WHO Drug Class and then descending frequency of preferred term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.5.1: Summary of Subsequent Therapies - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Subjects discontinued treatment or never received any study treatment	158 (65.8%)	242 (100.0%)	400 (83.0%)
Subjects received subsequent cancer-related therapies	84 (35.0%)	174 (71.9%)	258 (53.5%)
Palliative radiotherapy	22 (9.2%)	25 (10.3%)	47 (9.8%)
Non-palliative radiotherapy	4 (1.7%)	5 (2.1%)	9 (1.9%)
Systemic therapy	81 (33.8%)	164 (67.8%)	245 (50.8%)
For progressive disease	70 (29.2%)	104 (43.0%)	174 (36.1%)
Maintenance	7 (2.9%)	91 (37.6%)	98 (20.3%)
Avelumab	7 (2.9%)	86 (35.5%)	93 (19.3%)
Atezolizumab	0	0	0
Pembrolizumab	0	5 (2.1%)	5 (1.0%)
Other	0	2 (0.8%)	2 (0.4%)
For secondary malignancy	1 (0.4%)	0	1 (0.2%)
Other (a)	12 (5.0%)	4 (1.7%)	16 (3.3%)
Surgical procedure	5 (2.1%)	11 (4.5%)	16 (3.3%)
Surgical resection	3 (1.3%)	7 (2.9%)	10 (2.1%)
Transurethral resection of the bladder tumor	2 (0.8%)	4 (1.7%)	6 (1.2%)
Other	1 (0.4%)	0	1 (0.2%)
Number of lines of subsequent systemic therapies			
1	55 (22.9%)	109 (45.0%)	164 (34.0%)
2	15 (6.3%)	41 (16.9%)	56 (11.6%)
>=3	11 (4.6%)	14 (5.8%)	25 (5.2%)
First subsequent systemic therapy			
Platinum-based therapy (b)	71 (29.6%)	9 (3.7%)	80 (16.6%)
Cisplatin-based regimen	44 (18.3%)	5 (2.1%)	49 (10.2%)
Carboplatin-based regimen	27 (11.3%)	4 (1.7%)	31 (6.4%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation; TURBT=transurethral resection of the bladder tumor.
Note: (a) Includes systemic therapies other than for progressive disease, maintenance, or secondary malignancy, that were received after discontinuation of study treatment; (b) When platinum-based therapy and a PD-1/L1 agent were given in the same line of therapy, the therapy was categorized under Platinum-based therapy.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.5.1: Summary of Subsequent Therapies - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Other	0	0	0
Maintenance PD-1/L1 inhibitor-containing therapy	0	88 (36.4%)	88 (18.3%)
Atezolizumab	0	0	0
Avelumab	0	84 (34.7%)	84 (17.4%)
Ipilimumab	0	0	0
M 6223	0	1 (0.4%)	1 (0.2%)
Nivolumab	0	0	0
Nktr 255	0	0	0
Pembrolizumab	0	5 (2.1%)	5 (1.0%)
Other PD-1/L1 inhibitor-containing therapy	3 (1.3%)	62 (25.6%)	65 (13.5%)
Atezolizumab	0	19 (7.9%)	19 (3.9%)
Avelumab	0	2 (0.8%)	2 (0.4%)
Bintrafusp alfa	0	0	0
Enfortumab vedotin	0	1 (0.4%)	1 (0.2%)
Nivolumab	0	2 (0.8%)	2 (0.4%)
Pembrolizumab	3 (1.3%)	39 (16.1%)	42 (8.7%)
Other	7 (2.9%)	5 (2.1%)	12 (2.5%)
Cyclophosphamide	1 (0.4%)	1 (0.4%)	2 (0.4%)
Df 1001	0	0	0
Disitamab vedotin	0	0	0
Docetaxel	0	2 (0.8%)	2 (0.4%)
Doxorubicin	1 (0.4%)	0	1 (0.2%)
Enfortumab vedotin	2 (0.8%)	1 (0.4%)	3 (0.6%)
Erdafitinib	1 (0.4%)	0	1 (0.2%)
Gemcitabine	1 (0.4%)	0	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation; TURBT=transurethral resection of the bladder tumor.

Note: (a) Includes systemic therapies other than for progressive disease, maintenance, or secondary malignancy, that were received after discontinuation of study treatment; (b) When platinum-based therapy and a PD-1/L1 agent were given in the same line of therapy, the therapy was categorized under Platinum-based therapy.

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Table 302.1.1000.5.1: Summary of Subsequent Therapies - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Methotrexate	0	1 (0.4%)	1 (0.2%)
Paclitaxel	0	1 (0.4%)	1 (0.2%)
Prednisone	0	0	0
Rituximab	1 (0.4%)	0	1 (0.2%)
Sacituzumab govitecan	1 (0.4%)	0	1 (0.2%)
Samarium (153 sm) lexidronam	1 (0.4%)	0	1 (0.2%)
Vincristine	1 (0.4%)	0	1 (0.2%)
Vinflunine	0	0	0
Second and beyond subsequent systemic therapy			
Platinum-based therapy (b)	5 (2.1%)	7 (2.9%)	12 (2.5%)
Cisplatin-based regimen	4 (1.7%)	4 (1.7%)	8 (1.7%)
Carboplatin-based regimen	1 (0.4%)	4 (1.7%)	5 (1.0%)
Maintenance PD-1/L1 inhibitor-containing therapy	6 (2.5%)	3 (1.2%)	9 (1.9%)
Avelumab	6 (2.5%)	2 (0.8%)	8 (1.7%)
M 6223	0	0	0
Nivolumab	0	1 (0.4%)	1 (0.2%)
Pembrolizumab	0	0	0
Other PD-1/L1 inhibitor-containing therapy	7 (2.9%)	7 (2.9%)	14 (2.9%)
Abbv 151	1 (0.4%)	0	1 (0.2%)
Atezolizumab	0	1 (0.4%)	1 (0.2%)
Avelumab	0	1 (0.4%)	1 (0.2%)
Budigalimab	1 (0.4%)	0	1 (0.2%)
Enfortumab vedotin	0	1 (0.4%)	1 (0.2%)
Nivolumab	2 (0.8%)	1 (0.4%)	3 (0.6%)
Other monoclonal antibodies and antibody drug conjugates	1 (0.4%)	0	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation; TURBT=transurethral resection of the bladder tumor.
Note: (a) Includes systemic therapies other than for progressive disease, maintenance, or secondary malignancy, that were received after discontinuation of study treatment; (b) When platinum-based therapy and a PD-1/L1 agent were given in the same line of therapy, the therapy was categorized under Platinum-based therapy.
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Table 302.1.1000.5.1: Summary of Subsequent Therapies - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
Pembrolizumab	4 (1.7%)	4 (1.7%)	8 (1.7%)
Sitravatinib	0	1 (0.4%)	1 (0.2%)
Other	20 (8.3%)	46 (19.0%)	66 (13.7%)
Bt 8009	0	0	0
Disitamab vedotin	0	1 (0.4%)	1 (0.2%)
Docetaxel	2 (0.8%)	2 (0.8%)	4 (0.8%)
Enfortumab vedotin	0	31 (12.8%)	31 (6.4%)
Erdafitinib	7 (2.9%)	3 (1.2%)	10 (2.1%)
Gemcitabine	0	1 (0.4%)	1 (0.2%)
Ifosfamide	0	0	0
Investigational drug	0	2 (0.8%)	2 (0.4%)
Paclitaxel	8 (3.3%)	9 (3.7%)	17 (3.5%)
Sacituzumab govitecan	5 (2.1%)	8 (3.3%)	13 (2.7%)
Sacituzumab govitecan hziy	1 (0.4%)	0	1 (0.2%)
Tremelimumab	0	1 (0.4%)	1 (0.2%)
Time from last dose of study treatment to first subsequent systemic therapy			
n	70	104	174
Mean (SD)	1.74 (1.72)	4.24 (3.78)	3.23 (3.34)
Median	1.1	3.2	2.1
Q1 - Q3	0.66 - 2.10	1.43 - 5.57	0.99 - 4.47
Range	0.2 - 9.8	0.3 - 23.0	0.2 - 23.0
Site / location of radiation therapy	27 (11.3%)	29 (12.0%)	56 (11.6%)
Bladder tumor / bed	5 (2.1%)	4 (1.7%)	9 (1.9%)
Bone - Other	1 (0.4%)	7 (2.9%)	8 (1.7%)
Bone - Spine	6 (2.5%)	4 (1.7%)	10 (2.1%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation; TURBT=transurethral resection of the bladder tumor.
Note: (a) Includes systemic therapies other than for progressive disease, maintenance, or secondary malignancy, that were received after discontinuation of study treatment; (b) When platinum-based therapy and a PD-1/L1 agent were given in the same line of therapy, the therapy was categorized under Platinum-based therapy.
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Table 302.1.1000.5.1: Summary of Subsequent Therapies - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)	Total (N=482)
CNS - localized	3 (1.3%)	1 (0.4%)	4 (0.8%)
CNS - whole brain	0	3 (1.2%)	3 (0.6%)
Liver	1 (0.4%)	1 (0.4%)	2 (0.4%)
Lung	1 (0.4%)	2 (0.8%)	3 (0.6%)
Mediastinum	0	0	0
Pelvis	2 (0.8%)	4 (1.7%)	6 (1.2%)
Renal pelvis / ureter tumor / bed or ureteral stump	0	0	0
Other	11 (4.6%)	6 (2.5%)	17 (3.5%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation; TURBT=transurethral resection of the bladder tumor.
Note: (a) Includes systemic therapies other than for progressive disease, maintenance, or secondary malignancy, that were received after discontinuation of study treatment; (b) When platinum-based therapy and a PD-1/L1 agent were given in the same line of therapy, the therapy was categorized under Platinum-based therapy.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.5.2: Summary of Subsequent Therapies - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Subjects discontinued treatment or never received any study treatment	140 (69.3%)	202 (100.0%)	342 (84.7%)
Subjects received subsequent cancer-related therapies	56 (27.7%)	139 (68.8%)	195 (48.3%)
Palliative radiotherapy	10 (5.0%)	17 (8.4%)	27 (6.7%)
Non-palliative radiotherapy	2 (1.0%)	1 (0.5%)	3 (0.7%)
Systemic therapy	47 (23.3%)	130 (64.4%)	177 (43.8%)
For progressive disease	43 (21.3%)	89 (44.1%)	132 (32.7%)
Maintenance	2 (1.0%)	57 (28.2%)	59 (14.6%)
Avelumab	2 (1.0%)	52 (25.7%)	54 (13.4%)
Atezolizumab	0	1 (0.5%)	1 (0.2%)
Pembrolizumab	0	4 (2.0%)	4 (1.0%)
Other	0	4 (2.0%)	4 (1.0%)
For secondary malignancy	1 (0.5%)	0	1 (0.2%)
Other (a)	4 (2.0%)	10 (5.0%)	14 (3.5%)
Surgical procedure	3 (1.5%)	3 (1.5%)	6 (1.5%)
Surgical resection	2 (1.0%)	2 (1.0%)	4 (1.0%)
Transurethral resection of the bladder tumor	1 (0.5%)	1 (0.5%)	2 (0.5%)
Other	0	0	0
Number of lines of subsequent systemic therapies			
1	39 (19.3%)	87 (43.1%)	126 (31.2%)
2	7 (3.5%)	34 (16.8%)	41 (10.1%)
>=3	1 (0.5%)	9 (4.5%)	10 (2.5%)
First subsequent systemic therapy			
Platinum-based therapy (b)	39 (19.3%)	8 (4.0%)	47 (11.6%)
Cisplatin-based regimen	9 (4.5%)	3 (1.5%)	12 (3.0%)
Carboplatin-based regimen	29 (14.4%)	4 (2.0%)	33 (8.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation; TURBT=transurethral resection of the bladder tumor.
Note: (a) Includes systemic therapies other than for progressive disease, maintenance, or secondary malignancy, that were received after discontinuation of study treatment; (b) When platinum-based therapy and a PD-1/L1 agent were given in the same line of therapy, the therapy was categorized under Platinum-based therapy.
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Table 302.1.1000.5.2: Summary of Subsequent Therapies - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Other	1 (0.5%)	1 (0.5%)	2 (0.5%)
Maintenance PD-1/L1 inhibitor-containing therapy	0	55 (27.2%)	55 (13.6%)
Atezolizumab	0	1 (0.5%)	1 (0.2%)
Avelumab	0	51 (25.2%)	51 (12.6%)
Ipilimumab	0	1 (0.5%)	1 (0.2%)
M 6223	0	0	0
Nivolumab	0	1 (0.5%)	1 (0.2%)
Nktr 255	0	1 (0.5%)	1 (0.2%)
Pembrolizumab	0	2 (1.0%)	2 (0.5%)
Other PD-1/L1 inhibitor-containing therapy	4 (2.0%)	55 (27.2%)	59 (14.6%)
Atezolizumab	0	23 (11.4%)	23 (5.7%)
Avelumab	0	0	0
Bintrafusp alfa	0	1 (0.5%)	1 (0.2%)
Enfortumab vedotin	0	0	0
Nivolumab	0	0	0
Pembrolizumab	4 (2.0%)	31 (15.3%)	35 (8.7%)
Other	4 (2.0%)	12 (5.9%)	16 (4.0%)
Cyclophosphamide	0	0	0
Df 1001	1 (0.5%)	0	1 (0.2%)
Disitamab vedotin	0	1 (0.5%)	1 (0.2%)
Docetaxel	0	1 (0.5%)	1 (0.2%)
Doxorubicin	0	0	0
Enfortumab vedotin	1 (0.5%)	2 (1.0%)	3 (0.7%)
Erdafitinib	0	2 (1.0%)	2 (0.5%)
Gemcitabine	1 (0.5%)	2 (1.0%)	3 (0.7%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation; TURBT=transurethral resection of the bladder tumor.
Note: (a) Includes systemic therapies other than for progressive disease, maintenance, or secondary malignancy, that were received after discontinuation of study treatment; (b) When platinum-based therapy and a PD-1/L1 agent were given in the same line of therapy, the therapy was categorized under Platinum-based therapy.
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Table 302.1.1000.5.2: Summary of Subsequent Therapies - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Methotrexate	0	0	0
Paclitaxel	0	3 (1.5%)	3 (0.7%)
Prednisone	1 (0.5%)	0	1 (0.2%)
Rituximab	0	0	0
Sacituzumab govitecan	0	0	0
Samarium (153 sm) lexidronam	0	0	0
Vincristine	0	0	0
Vinflunine	0	1 (0.5%)	1 (0.2%)
Second and beyond subsequent systemic therapy			
Platinum-based therapy (b)	3 (1.5%)	3 (1.5%)	6 (1.5%)
Cisplatin-based regimen	1 (0.5%)	1 (0.5%)	2 (0.5%)
Carboplatin-based regimen	2 (1.0%)	2 (1.0%)	4 (1.0%)
Maintenance PD-1/L1 inhibitor-containing therapy	2 (1.0%)	4 (2.0%)	6 (1.5%)
Avelumab	2 (1.0%)	1 (0.5%)	3 (0.7%)
M 6223	0	1 (0.5%)	1 (0.2%)
Nivolumab	0	0	0
Pembrolizumab	0	2 (1.0%)	2 (0.5%)
Other PD-1/L1 inhibitor-containing therapy	0	5 (2.5%)	5 (1.2%)
Abbv 151	0	0	0
Atezolizumab	0	1 (0.5%)	1 (0.2%)
Avelumab	0	0	0
Budigalimab	0	0	0
Enfortumab vedotin	0	1 (0.5%)	1 (0.2%)
Nivolumab	0	0	0
Other monoclonal antibodies and antibody drug conjugates	0	0	0

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation; TURBT=transurethral resection of the bladder tumor.
Note: (a) Includes systemic therapies other than for progressive disease, maintenance, or secondary malignancy, that were received after discontinuation of study treatment; (b) When platinum-based therapy and a PD-1/L1 agent were given in the same line of therapy, the therapy was categorized under Platinum-based therapy.
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Table 302.1.1000.5.2: Summary of Subsequent Therapies - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Pembrolizumab	0	4 (2.0%)	4 (1.0%)
Sitravatinib	0	1 (0.5%)	1 (0.2%)
Other	4 (2.0%)	36 (17.8%)	40 (9.9%)
Bt 8009	0	1 (0.5%)	1 (0.2%)
Disitamab vedotin	0	0	0
Docetaxel	1 (0.5%)	1 (0.5%)	2 (0.5%)
Enfortumab vedotin	0	23 (11.4%)	23 (5.7%)
Erdafitinib	0	2 (1.0%)	2 (0.5%)
Gemcitabine	0	1 (0.5%)	1 (0.2%)
Ifosfamide	1 (0.5%)	0	1 (0.2%)
Investigational drug	0	0	0
Paclitaxel	2 (1.0%)	10 (5.0%)	12 (3.0%)
Sacituzumab govitecan	1 (0.5%)	3 (1.5%)	4 (1.0%)
Sacituzumab govitecan hziy	0	0	0
Tremelimumab	0	0	0
Time from last dose of study treatment to first subsequent systemic therapy			
n	43	89	132
Mean (SD)	2.18 (3.06)	3.78 (3.85)	3.26 (3.68)
Median	1.0	2.8	1.7
Q1 - Q3	0.76 - 2.10	1.08 - 5.16	0.95 - 4.29
Range	0.4 - 17.7	0.5 - 23.5	0.4 - 23.5
Site / location of radiation therapy	12 (5.9%)	18 (8.9%)	30 (7.4%)
Bladder tumor / bed	3 (1.5%)	4 (2.0%)	7 (1.7%)
Bone - Other	3 (1.5%)	4 (2.0%)	7 (1.7%)
Bone - Spine	2 (1.0%)	0	2 (0.5%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation; TURBT=transurethral resection of the bladder tumor.
Note: (a) Includes systemic therapies other than for progressive disease, maintenance, or secondary malignancy, that were received after discontinuation of study treatment; (b) When platinum-based therapy and a PD-1/L1 agent were given in the same line of therapy, the therapy was categorized under Platinum-based therapy.
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Table 302.1.1000.5.2: Summary of Subsequent Therapies - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
CNS - localized	0	2 (1.0%)	2 (0.5%)
CNS - whole brain	0	1 (0.5%)	1 (0.2%)
Liver	0	0	0
Lung	0	2 (1.0%)	2 (0.5%)
Mediastinum	0	0	0
Pelvis	1 (0.5%)	1 (0.5%)	2 (0.5%)
Renal pelvis / ureter tumor / bed or ureteral stump	0	0	0
Other	3 (1.5%)	4 (2.0%)	7 (1.7%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation; TURBT=transurethral resection of the bladder tumor.
Note: (a) Includes systemic therapies other than for progressive disease, maintenance, or secondary malignancy, that were received after discontinuation of study treatment; (b) When platinum-based therapy and a PD-1/L1 agent were given in the same line of therapy, the therapy was categorized under Platinum-based therapy.
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Table 302.1.1000.6: Reasons for Cisplatin Ineligibility - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)	Total (N=404)
Subjects who are cisplatin ineligible at randomization (a)	202	202	404
Subjects following at least one of the following criteria (b)	194 / 202 (96.0%)	197 / 202 (97.5%)	391 / 404 (96.8%)
GFR <60 mL/min	164 / 202 (81.2%)	163 / 202 (80.7%)	327 / 404 (80.9%)
> Grade 2 hearing loss	29 / 202 (14.4%)	29 / 202 (14.4%)	58 / 404 (14.4%)
ECOG PS of 2	9 / 202 (4.5%)	8 / 202 (4.0%)	17 / 404 (4.2%)
NYHA Class III heart failure	4 / 202 (2.0%)	7 / 202 (3.5%)	11 / 404 (2.7%)
Subjects meeting more than one criteria	12 / 202 (5.9%)	10 / 202 (5.0%)	22 / 404 (5.4%)

Abbreviations: ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; GFR=glomerular filtration rate; mITT=modified intent-to-treat; N=number of patients; NYHA=New York Heart Association; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PS=performance status.
Note: (a) As collected in RTSM (Randomization and Trial Supply Management); (b) A subject may be counted in more than one category.
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Table 302.1.1000.7.1: Treatment Duration - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)
Duration of treatment (months) (a)		
n	240	242
Mean (SD)	10.28 (6.84)	3.64 (1.23)
Median	9.63	4.14
Q1 - Q3	4.83 - 14.51	3.22 - 4.37
Range	0.0 - 28.5	0.0 - 6.0
> 0 month	239 (99.6%)	236 (97.5%)
>= 1 month	228 (95.0%)	226 (93.4%)
>= 3 months	202 (84.2%)	188 (77.7%)
>= 6 months	160 (66.7%)	0
>= 12 months	83 (34.6%)	0
Number of cycles (b)		
n	240	242
Mean (SD)	13.87 (9.44)	4.95 (1.64)
Median	12.00	6.00
Q1 - Q3	6.00 - 20.00	4.00 - 6.00
Range	0.0 - 37.0	0.0 - 6.0

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Note: (a) Duration of treatment is the time from the first dose of study drug to the earliest of the following: Day 21 of the last treatment cycle, start of subsequent anticancer therapy, date of death, end of study or analysis data cutoff date if the subject is still on treatment at the time of the analysis; (b) Cycle with any amount (> 0) of study drug received.
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Table 302.1.1000.7.2: Treatment Duration - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)
Duration of treatment (months) (a)		
n	202	202
Mean (SD)	10.03 (6.84)	3.38 (1.45)
Median	9.18	4.11
Q1 - Q3	4.34 - 14.72	2.60 - 4.40
Range	0.0 - 31.9	0.0 - 7.7
> 0 month	201 (99.5%)	197 (97.5%)
>= 1 month	184 (91.1%)	180 (89.1%)
>= 3 months	167 (82.7%)	128 (63.4%)
>= 6 months	137 (67.8%)	1 (0.5%)
>= 12 months	73 (36.1%)	0
Number of cycles (b)		
n	202	202
Mean (SD)	13.29 (9.29)	4.50 (1.82)
Median	12.00	5.00
Q1 - Q3	6.00 - 19.00	3.00 - 6.00
Range	0.0 - 46.0	0.0 - 6.0

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Note: (a) Duration of treatment is the time from the first dose of study drug to the earliest of the following: Day 21 of the last treatment cycle, start of subsequent anticancer therapy, date of death, end of study or analysis data cutoff date if the subject is still on treatment at the time of the analysis; (b) Cycle with any amount (> 0) of study drug received.
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Table 302.1.1000.8.1.1: Summary of Duration of Observation Time for Overall Survival - Analysis Set mITT 1

	EV+Pembro (N=240)	**Plat+Gem (N=242)**
Duration of observation period (months)		
n	240	242
Mean (SD)	15.2 (6.77)	13.1 (7.38)
Median	14.4	12.2
Q1 - Q3	10.3 - 20.1	7.9 - 17.7
Range	1 - 37	0 - 36

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Note: Observation period for overall survival will include the time from randomisation until the last date endpoint data are collected for overall survival.
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Table 302.1.1000.8.1.2: Summary of Duration of Observation Time for Overall Survival - Analysis Set mITT 2

	EV+Pembro (N=202)	**Plat+Gem (N=202)**
Duration of observation period (months)		
n	202	202
Mean (SD)	14.0 (6.96)	11.3 (6.29)
Median	13.7	10.7
Q1 - Q3	9.4 - 19.4	6.6 - 15.3
Range	0 - 32	0 - 32

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Note: Observation period for overall survival will include the time from randomisation until the last date endpoint data are collected for overall survival.
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Table 302.1.1000.8.2.1: Summary of Duration of Observation Time for Overall Survival - Analysis Set mITT 1 - Sensitivity Analysis 1

	EV+Pembro (N=240)	**Plat+Gem (N=242)**
Duration of observation period (months)		
n	240	242
Mean (SD)	15.2 (6.77)	13.1 (7.38)
Median	14.4	12.2
Q1 - Q3	10.3 - 20.1	7.9 - 17.7
Range	1 - 37	0 - 36

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Note: Observation period for overall survival in sensitivity analysis 1 will include the time from randomisation until the last date endpoint data are collected for overall survival.
Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease at end of treatment (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.
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Table 302.1.1000.8.2.2: Summary of Duration of Observation Time for Overall Survival - Analysis Set mITT 2 - Sensitivity Analysis 1

	EV+Pembro (N=202)	**Plat+Gem (N=202)**
Duration of observation period (months)		
n	202	202
Mean (SD)	14.0 (6.96)	11.3 (6.29)
Median	13.7	10.7
Q1 - Q3	9.4 - 19.4	6.6 - 15.3
Range	0 - 32	0 - 32

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Note: Observation period for overall survival in sensitivity analysis 1 will include the time from randomisation until the last date endpoint data are collected for overall survival.
Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease at end of treatment (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.
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Table 302.1.1000.8.3.1: Summary of Duration of Observation Time for Overall Survival - Analysis Set mITT 1 - Sensitivity Analysis 2

	EV+Pembro (N=240)	**Plat+Gem (N=242)**
Duration of observation period (months)		
n	240	242
Mean (SD)	15.2 (6.77)	14.0 (8.11)
Median	14.4	13.1
Q1 - Q3	10.3 - 20.1	8.0 - 19.2
Range	1 - 37	0 - 38

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Note: Observation period for overall survival in sensitivity analysis 2 will include the time from randomisation until the last date endpoint data are collected or imputed for overall survival.
Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease at end of treatment (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.
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Table 302.1.1000.8.3.2: Summary of Duration of Observation Time for Overall Survival - Analysis Set mITT 2 - Sensitivity Analysis 2

	EV+Pembro (N=202)	**Plat+Gem (N=202)**
Duration of observation period (months)		
n	202	202
Mean (SD)	14.0 (6.96)	12.2 (7.07)
Median	13.7	11.4
Q1 - Q3	9.4 - 19.4	6.7 - 17.1
Range	0 - 32	0 - 32

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Note: Observation period for overall survival in sensitivity analysis 2 will include the time from randomisation until the last date endpoint data are collected or imputed for overall survival.
Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease at end of treatment (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.
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Table 302.1.1000.8.4.1: Summary of Duration of Observation Time for Overall Survival - Analysis Set mITT 1 - Sensitivity Analysis 3

	EV+Pembro (N=240)	**Plat+Gem (N=242)**
Duration of observation period (months)		
n	240	242
Mean (SD)	15.2 (6.77)	13.7 (7.77)
Median	14.4	13.1
Q1 - Q3	10.3 - 20.1	8.0 - 19.0
Range	1 - 37	0 - 38

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Note: Observation period for overall survival in sensitivity analysis 2 will include the time from randomisation until the last date endpoint data are collected or imputed for overall survival.
Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease at end of treatment (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab overall survival advantage (8.8 months) or censored at data cutoff date if data cutoff date < date of death + avelumab overall survival advantage.
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Table 302.1.1000.8.4.2: Summary of Duration of Observation Time for Overall Survival - Analysis Set mITT 2 - Sensitivity Analysis 3

	EV+Pembro (N=202)	**Plat+Gem (N=202)**
Duration of observation period (months)		
n	202	202
Mean (SD)	14.0 (6.96)	11.8 (6.60)
Median	13.7	11.4
Q1 - Q3	9.4 - 19.4	6.7 - 16.4
Range	0 - 32	0 - 32

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Note: Observation period for overall survival in sensitivity analysis 2 will include the time from randomisation until the last date endpoint data are collected or imputed for overall survival.
Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease at end of treatment (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab overall survival advantage (7.0 months) or censored at data cutoff date if data cutoff date < date of death + avelumab overall survival advantage.
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Table 302.1.1000.8.5.1: Summary of Duration of Observation Time for Progression-Free Survival (BICR) - Analysis Set mITT 1

	EV+Pembro (N=240)	**Plat+Gem (N=242)**
Duration of observation period (months)		
n	240	242
Mean (SD)	10.5 (6.91)	6.9 (5.38)
Median	8.9	6.1
Q1 - Q3	4.3 - 16.0	3.4 - 8.7
Range	0 - 28	0 - 33

Abbreviations: BICR=blinded independent central review; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Note: Observation period for progression-free survival will include the time from randomisation until the last date endpoint data are collected for progression-free survival.
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Table 302.1.1000.8.5.2: Summary of Duration of Observation Time for Progression-Free Survival (BICR) - Analysis Set mITT 2

	EV+Pembro (N=202)	**Plat+Gem (N=202)**
Duration of observation period (months)		
n	202	202
Mean (SD)	9.8 (6.89)	5.7 (4.52)
Median	8.3	4.7
Q1 - Q3	4.2 - 14.6	2.2 - 7.3
Range	0 - 30	0 - 24

Abbreviations: BICR=blinded independent central review; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Note: Observation period for progression-free survival will include the time from randomisation until the last date endpoint data are collected for progression-free survival.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.8.6.1: Summary of Duration of Observation Time for Objective Response (BICR) - Analysis Set mITT 1

	EV+Pembro (N=240)	**Plat+Gem (N=242)**
Duration of observation period (months)		
n	240	242
Mean (SD)	4.7 (5.55)	5.7 (5.85)
Median	2.1	2.3
Q1 - Q3	2.0 - 4.2	2.1 - 7.9
Range	0 - 38	0 - 37

Abbreviations: BICR=blinded independent central review; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Note: Observation period for objective response will include the time from randomisation until the last date endpoint data are collected for objective response.
Objective response was defined as complete or partial response that was subsequently confirmed.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.8.6.2: Summary of Duration of Observation Time for Objective Response (BICR) - Analysis Set mITT 2

	EV+Pembro (N=202)	**Plat+Gem (N=202)**
Duration of observation period (months)		
n	202	202
Mean (SD)	4.9 (5.53)	6.6 (5.58)
Median	2.2	4.6
Q1 - Q3	2.0 - 4.7	2.1 - 10.3
Range	0 - 26	0 - 29

Abbreviations: BICR=blinded independent central review; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Note: Observation period for objective response will include the time from randomisation until the last date endpoint data are collected for objective response.
Objective response was defined as complete or partial response that was subsequently confirmed.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.8.7.1: Summary of Duration of Observation Time for Duration of Response (BICR) - Analysis Set mITT 1

	EV+Pembro (N=240)	**Plat+Gem (N=242)**
Duration of observation period (months)		
n	240	242
Mean (SD)	7.9 (7.16)	4.1 (5.50)
Median	6.4	2.2
Q1 - Q3	0.0 - 13.6	0.0 - 6.1
Range	0 - 27	0 - 31

Abbreviations: BICR=blinded independent central review; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Note: Observation period for duration of response will include the time from first objective response until the last date endpoint data are collected for duration of response.
Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.8.7.2: Summary of Duration of Observation Time for Duration of Response (BICR) - Analysis Set mITT 2

	EV+Pembro (N=202)	**Plat+Gem (N=202)**
Duration of observation period (months)		
n	202	202
Mean (SD)	6.9 (7.22)	2.6 (4.52)
Median	4.3	0.0
Q1 - Q3	0.0 - 12.5	0.0 - 4.2
Range	0 - 28	0 - 22

Abbreviations: BICR=blinded independent central review; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Note: Observation period for duration of response will include the time from first objective response until the last date endpoint data are collected for duration of response.
Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.8.8.1: Summary of Duration of Observation Time for Disease Control (BICR) - Analysis Set mITT 1

	EV+Pembro (N=240)	**Plat+Gem (N=242)**
Duration of observation period (months)		
n	240	242
Mean (SD)	2.7 (2.39)	2.7 (2.37)
Median	2.1	2.1
Q1 - Q3	2.0 - 2.2	2.0 - 2.3
Range	0 - 22	0 - 21

Abbreviations: BICR=blinded independent central review; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Note: Observation period for disease control will include the time from randomisation until the last date endpoint data are collected for disease control.
Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.8.8.2: Summary of Duration of Observation Time for Disease Control (BICR) - Analysis Set mITT 2

	EV+Pembro (N=202)	**Plat+Gem (N=202)**
Duration of observation period (months)		
n	202	202
Mean (SD)	2.5 (2.67)	3.2 (3.12)
Median	2.1	2.1
Q1 - Q3	2.0 - 2.2	2.0 - 2.6
Range	0 - 22	0 - 20

Abbreviations: BICR=blinded independent central review; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Note: Observation period for disease control will include the time from randomisation until the last date endpoint data are collected for disease control.
Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.8.9.1: Summary of Duration of Observation Time for Complete Response (BICR) - Analysis Set mITT 1

	EV+Pembro (N=240)	**Plat+Gem (N=242)**
Duration of observation period (months)		
n	240	242
Mean (SD)	11.2 (7.34)	11.3 (7.52)
Median	10.4	10.2
Q1 - Q3	4.4 - 15.9	5.2 - 15.4
Range	0 - 38	0 - 37

Abbreviations: BICR=blinded independent central review; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Note: Observation period for complete response will include the time from randomisation until the last date endpoint data are collected for complete response.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1000.8.9.2: Summary of Duration of Observation Time for Complete Response (BICR) - Analysis Set mITT 2

	EV+Pembro (N=202)	**Plat+Gem (N=202)**
Duration of observation period (months)		
n	202	202
Mean (SD)	10.7 (7.05)	9.9 (6.12)
Median	10.2	9.7
Q1 - Q3	4.2 - 15.2	4.7 - 13.3
Range	0 - 29	0 - 29

Abbreviations: BICR=blinded independent central review; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Note: Observation period for complete response will include the time from randomisation until the last date endpoint data are collected for complete response.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1001.1: Breakdown of Appropriate Comparator Therapy and Survival Status at Data Cut Off Date

		Cis+Gem (N=242)	Carb+Gem (N=202)	Total (N=444)
	Randomized to platinum-based CHT in combination with gemcitabine	242 (100.0%)	202 (100.0%)	444 (100.0%)
1	Received at least one dose of platinum-based CHT in combination with gemcitabine Of these:	236 (97.5%)	197 (97.5%)	433 (97.5%)
2	Avelumab maintenance therapy not possible	83 (34.3%)	101 (50.0%)	184 (41.4%)
2.1	Progressive disease or death...	69 (28.5%)	78 (38.6%)	147 (33.1%)
2.1.1	... during CHT (until EOT)	60 (24.8%)	63 (31.2%)	123 (27.7%)
2.1.2	...within 10 weeks after last dose of CHT [1]	9 (3.7%)	15 (7.4%)	24 (5.4%)
2.2	Less than 4 cycles CHT	13 (5.4%)	22 (10.9%)	35 (7.9%)
2.3	Lost to follow-up or discontinuation (until EOT)	1 (0.4%)	1 (0.5%)	2 (0.5%)
2.4	Other reason	0	0	0
3	Avelumab maintenance possible [2]	153 (63.2%)	96 (47.5%)	249 (56.1%)
3.1	Received avelumab maintenance	84 (34.7%)	48 (23.8%)	132 (29.7%)
3.2	Received no maintenance and still alive at data cutoff date	48 (19.8%)	30 (14.9%)	78 (17.6%)
Summary	Correct implementation of Appropriate Comparator Therapy or still alive at data cut off date (2+3.1+3.2) [3]	215 (88.8%)	179 (88.6%)	394 (88.7%)
3.3	Received no maintenance and progressed or died later than 10 weeks after last dose and died later than 10 weeks after last dose of CHT	21 (8.7%)	18 (8.9%)	39 (8.8%)

Abbreviations: Carb=carboplatin; CHT=chemotherapy; Cis=cisplatin; EOT=end of treatment visit; Gem=gemcitabine; N=number of patients.
[1] Patients completed >=4 cycles CHT, had no progressive disease and were alive at the end of CHT. Latency period of 10 weeks as per JAVELIN 100 Bladder.
[2] Eligability criteria as per JAVELIN 100 Bladder: >= 4 cycles of CHT, no progressive disease at EOT Visit.
[3] Subjects included in 3.2 are assumed to have had an identical or better outcome compared to a scenario where they had received avelumab maintenance.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.1.1.1: Summary of Overall Survival - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)	EV+Pembro vs. Plat+Gem
Number of patients at risk	240 (100.0%)	242 (100.0%)	
Number of patients with events	69 (28.8%)	110 (45.5%)	
Number of patients censored	171 (71.3%)	132 (54.5%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	97.9 [95.1, 99.1]	94.9 [91.2, 97.1]	
Month 6	92.9 [88.8, 95.5]	85.1 [79.9, 89.1]	
Month 9	87.4 [82.4, 91.0]	73.1 [67.0, 78.3]	
Month 12	80.7 [74.9, 85.3]	67.3 [60.8, 73.0]	
Month 18	70.2 [63.0, 76.3]	50.7 [43.1, 57.8]	
Month 24	62.5 [53.0, 70.6]	42.2 [33.9, 50.3]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	31.5 [25.4, NC]	18.4 [15.6, 27.5]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.535 [0.395, 0.725]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.1.1.2: Type of Events and Censoring of Overall Survival - Analysis Set mITT 1

	EV+Pembro (N=240)	**Plat+Gem (N=242)**
Number of patients at risk	240 (100.0%)	242 (100.0%)
Number of patients with events	69 (28.8%)	110 (45.5%)
Death	69 (28.8%)	110 (45.5%)
Number of patients censored	171 (71.3%)	132 (54.5%)
Alive	171 (71.3%)	132 (54.5%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.1.1.3: Summary of Overall Survival by Subgroups - Analysis Set mITT 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
PD-L1 Expression									
High (CPS>=10)	139	41 (29.5)	31.5 [25.4, NC]	140	61 (43.6)	18.4 [15.3, NC]	0.587 [0.393, 0.875]	0.0082	0.4665
Low (CPS<10)	101	28 (27.7)	NC [22.3, NC]	102	49 (48.0)	16.6 [15.1, 27.5]	0.474 [0.297, 0.756]	0.0013	
Liver Metastases									
Present	48	20 (41.7)	25.6 [13.8, 31.5]	48	28 (58.3)	15.1 [10.4, 21.1]	0.611 [0.338, 1.101]	0.0979	0.6179
Absent	192	49 (25.5)	NC [25.4, NC]	194	82 (42.3)	18.4 [16.6, NC]	0.511 [0.359, 0.728]	0.0002	
Age									
< 65 years	105	28 (26.7)	NC [22.8, NC]	106	41 (38.7)	31.4 [17.0, NC]	0.561 [0.342, 0.919]	0.0199	0.7093
>= 65 years	135	41 (30.4)	31.5 [25.4, NC]	136	69 (50.7)	16.6 [13.6, 18.4]	0.510 [0.345, 0.754]	0.0006	
Region									
Europe	98	31 (31.6)	NC [20.7, NC]	102	55 (53.9)	13.9 [11.4, 18.4]	0.428 [0.270, 0.679]	0.0002	0.0373
North America	57	22 (38.6)	25.6 [21.2, NC]	51	21 (41.2)	27.5 [18.4, NC]	0.949 [0.506, 1.780]	0.8698	
Rest of World	85	16 (18.8)	NC [NC, NC]	89	34 (38.2)	19.3 [15.3, NC]	0.398 [0.218, 0.727]	0.0019	
Sex									
Male	198	54 (27.3)	31.5 [26.1, 31.5]	185	83 (44.9)	18.4 [16.6, NC]	0.536 [0.379, 0.758]	0.0003	0.9088
Female	42	15 (35.7)	22.8 [19.2, NC]	57	27 (47.4)	15.1 [11.6, 27.5]	0.602 [0.314, 1.157]	0.1245	
Race									
White	166	53 (31.9)	31.5 [22.8, NC]	149	75 (50.3)	16.7 [15.1, 19.7]	0.500 [0.350, 0.714]	0.0001	0.8209
Non-white	74	16 (21.6)	NC [NC, NC]	93	35 (37.6)	27.5 [15.1, NC]	0.577 [0.317, 1.052]	0.0695	

Abbreviations: CI=confidence interval; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.1.1.3: Summary of Overall Survival by Subgroups - Analysis Set mITT 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
ECOG Status at Baseline									
0	136	28 (20.6)	NC [NC, NC]	128	50 (39.1)	22.1 [16.6, NC]	0.469 [0.295, 0.747]	0.0011	0.4444
1-2	104	41 (39.4)	25.6 [21.2, 31.5]	113	60 (53.1)	16.4 [12.3, 18.4]	0.585 [0.390, 0.879]	0.0091	
Metastases at Baseline									
Visceral metastases	170	53 (31.2)	31.5 [25.4, NC]	161	81 (50.3)	16.7 [15.1, 19.3]	0.540 [0.380, 0.768]	0.0005	0.7559
Lymph node only	60	13 (21.7)	NC [21.2, NC]	67	25 (37.3)	27.5 [13.7, NC]	0.462 [0.236, 0.906]	0.0211	
Primary Disease Site of Origin									
Upper tract	61	18 (29.5)	NC [22.8, NC]	49	17 (34.7)	21.1 [15.1, 31.4]	0.770 [0.386, 1.539]	0.4588	0.4076
Lower tract	177	50 (28.2)	31.5 [25.4, NC]	193	93 (48.2)	17.7 [15.1, 22.1]	0.491 [0.347, 0.695]	<.0001	
Renal Function									
Normal	78	22 (28.2)	26.1 [22.3, NC]	82	37 (45.1)	18.4 [13.1, NC]	0.509 [0.296, 0.876]	0.0131	0.9386
Mild	116	31 (26.7)	NC [25.4, NC]	122	56 (45.9)	18.4 [15.1, 27.5]	0.550 [0.352, 0.858]	0.0075	
Moderate	46	16 (34.8)	31.5 [14.5, 31.5]	38	17 (44.7)	16.7 [11.6, NC]	0.579 [0.283, 1.186]	0.1309	

Abbreviations: CI=confidence interval; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.1.2.1: Summary of Overall Survival - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)	EV+Pembro vs. Plat+Gem
Number of patients at risk	202 (100.0%)	202 (100.0%)	
Number of patients with events	64 (31.7%)	116 (57.4%)	
Number of patients censored	138 (68.3%)	86 (42.6%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	93.6 [89.2, 96.2]	92.5 [87.9, 95.4]	
Month 6	87.0 [81.5, 91.0]	78.1 [71.7, 83.2]	
Month 9	81.4 [75.3, 86.2]	66.0 [58.9, 72.1]	
Month 12	75.2 [68.4, 80.7]	54.5 [47.1, 61.3]	
Month 18	68.7 [61.0, 75.2]	37.5 [29.6, 45.4]	
Month 24	56.7 [45.8, 66.1]	24.3 [15.1, 34.7]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [22.9, NC]	12.9 [11.4, 15.9]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.407 [0.297, 0.558]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.1.2.2: Type of Events and Censoring of Overall Survival - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)
Number of patients at risk	202 (100.0%)	202 (100.0%)
Number of patients with events	64 (31.7%)	116 (57.4%)
Death	64 (31.7%)	116 (57.4%)
Number of patients censored	138 (68.3%)	86 (42.6%)
Alive	138 (68.3%)	86 (42.6%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.1.2.3: Summary of Overall Survival by Subgroups - Analysis Set mITT 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
PD-L1 Expression									
High (CPS>=10)	117	38 (32.5)	NC [20.2, NC]	115	65 (56.5)	12.5 [11.3, 17.1]	0.402 [0.264, 0.613]	<.0001	0.8051
Low (CPS<10)	85	26 (30.6)	NC [19.9, NC]	87	51 (58.6)	13.3 [8.3, 16.1]	0.413 [0.256, 0.664]	0.0002	
Liver Metastases									
Present	50	23 (46.0)	17.7 [13.6, NC]	50	38 (76.0)	7.3 [5.8, 10.1]	0.377 [0.215, 0.661]	0.0004	0.8347
Absent	152	41 (27.0)	NC [22.9, NC]	152	78 (51.3)	15.0 [12.7, 18.9]	0.421 [0.288, 0.617]	<.0001	
Age									
< 65 years	39	11 (28.2)	NC [19.1, NC]	29	17 (58.6)	12.2 [9.6, 22.0]	0.265 [0.111, 0.633]	0.0015	0.3309
>= 65 years	163	53 (32.5)	NC [20.2, NC]	173	99 (57.2)	13.3 [10.7, 16.1]	0.466 [0.332, 0.654]	<.0001	
Region									
Europe	74	25 (33.8)	NC [19.1, NC]	95	55 (57.9)	14.6 [10.3, 17.1]	0.359 [0.213, 0.603]	<.0001	0.4815
North America	46	18 (39.1)	19.9 [18.4, NC]	34	21 (61.8)	13.0 [7.4, 22.0]	0.500 [0.253, 0.988]	0.0431	
Rest of World	82	21 (25.6)	NC [NC, NC]	73	40 (54.8)	12.7 [9.6, 18.8]	0.413 [0.239, 0.712]	0.0011	
Sex									
Male	146	47 (32.2)	NC [20.4, NC]	151	89 (58.9)	12.7 [10.7, 16.6]	0.404 [0.280, 0.583]	<.0001	0.9781
Female	56	17 (30.4)	NC [19.9, NC]	51	27 (52.9)	13.6 [10.3, NC]	0.432 [0.228, 0.818]	0.0083	
Race									
White	142	51 (35.9)	NC [19.9, NC]	141	87 (61.7)	12.9 [10.7, 15.5]	0.434 [0.304, 0.619]	<.0001	0.4034
Non-white	60	13 (21.7)	NC [NC, NC]	61	29 (47.5)	15.0 [10.0, NC]	0.349 [0.176, 0.691]	0.0016	

Abbreviations: CI=confidence interval; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.1.2.3: Summary of Overall Survival by Subgroups - Analysis Set mITT 2

Subgroup	EV+Pembro N	EV+Pembro n (%)	EV+Pembro KME [95% CI](a)	Plat+Gem N	Plat+Gem n (%)	Plat+Gem KME [95% CI](a)	EV+Pembro vs. Plat+Gem HR [95% CI](b)	Log-rank p-value(c)	Test for Interaction p-value(d)
ECOG Status at Baseline									
0	87	16 (18.4)	NC [22.9, NC]	87	44 (50.6)	15.5 [12.1, NC]	0.248 [0.135, 0.455]	<.0001	0.1054
1-2	115	48 (41.7)	19.9 [17.7, NC]	114	71 (62.3)	11.4 [7.7, 14.7]	0.512 [0.351, 0.747]	0.0004	
Metastases at Baseline									
Visceral metastases	148	55 (37.2)	22.9 [18.7, NC]	157	101 (64.3)	10.7 [8.9, 12.5]	0.414 [0.294, 0.582]	<.0001	0.8398
Lymph node only	43	9 (20.9)	NC [NC, NC]	37	14 (37.8)	18.3 [13.3, NC]	0.461 [0.198, 1.071]	0.0651	
Primary Disease Site of Origin									
Upper tract	74	20 (27.0)	NC [NC, NC]	55	28 (50.9)	14.3 [9.5, NC]	0.409 [0.226, 0.740]	0.0023	0.7372
Lower tract	128	44 (34.4)	NC [19.1, NC]	146	87 (59.6)	12.7 [10.7, 15.9]	0.425 [0.292, 0.618]	<.0001	
Renal Function									
Normal	6	2 (33.3)	NC [0.7, NC]	13	7 (53.8)	13.0 [3.7, NC]	0.485 [0.046, 5.135]	0.5430	0.7718
Mild	49	11 (22.4)	NC [22.9, NC]	40	22 (55.0)	12.9 [10.3, 18.9]	0.229 [0.103, 0.509]	<.0001	
Moderate	140	48 (34.3)	NC [19.9, NC]	141	82 (58.2)	12.7 [10.4, 16.6]	0.486 [0.338, 0.700]	<.0001	
Severe	7	3 (42.9)	13.8 [0.6, NC]	8	5 (62.5)	5.8 [0.8, NC]	0.521 [0.086, 3.164]	0.4713	

Abbreviations: CI=confidence interval; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.2.1.1: Summary of Overall Survival - Analysis Set mITT 1 - Sensitivity Analysis 1

	EV+Pembro (N=240)	Plat+Gem (N=242)	EV+Pembro vs. Plat+Gem
Number of patients at risk	240 (100.0%)	242 (100.0%)	
Number of patients with events	69 (28.8%)	89 (36.8%)	
Number of patients censored	171 (71.3%)	153 (63.2%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	97.9 [95.1, 99.1]	94.9 [91.2, 97.1]	
Month 6	92.9 [88.8, 95.5]	85.1 [79.9, 89.1]	
Month 9	87.4 [82.4, 91.0]	74.0 [67.8, 79.1]	
Month 12	80.7 [74.9, 85.3]	70.1 [63.8, 75.6]	
Month 18	70.2 [63.0, 76.3]	59.1 [51.4, 66.1]	
Month 24	62.5 [53.0, 70.6]	53.1 [44.4, 61.1]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	31.5 [25.4, NC]	27.5 [18.4, NC]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.661 [0.481, 0.906]
Log-rank test			
Two-sided stratified log-rank p-value			0.0097

Abbreviations: CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent).
Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease at end of treatment (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.2.1.2: Type of Events and Censoring of Overall Survival - Analysis Set mITT 1 - Sensitivity Analysis 1

	EV+Pembro (N=240)	**Plat+Gem (N=242)**
Number of patients at risk	240 (100.0%)	242 (100.0%)
Number of patients with events	69 (28.8%)	89 (36.8%)
Death	69 (28.8%)	89 (36.8%)
Number of patients censored	171 (71.3%)	153 (63.2%)
Alive	171 (71.3%)	132 (54.5%)
Censored due to restrictions of sensitivity analysis 1 (a)	0	21 (8.7%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: (a) Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease at end of treatment (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.2.1.3: Summary of Overall Survival by Subgroups - Analysis Set mITT 1 - Sensitivity Analysis 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
PD-L1 Expression									
High (CPS>=10)	139	41 (29.5)	31.5 [25.4, NC]	140	52 (37.1)	NC [17.9, NC]	0.690 [0.456, 1.043]	0.0769	0.7318
Low (CPS<10)	101	28 (27.7)	NC [22.3, NC]	102	37 (36.3)	27.5 [16.6, NC]	0.621 [0.380, 1.016]	0.0555	
Liver Metastases									
Present	48	20 (41.7)	25.6 [13.8, 31.5]	48	21 (43.8)	21.1 [10.4, NC]	0.787 [0.422, 1.469]	0.4513	0.4531
Absent	192	49 (25.5)	NC [25.4, NC]	194	68 (35.1)	27.5 [18.4, NC]	0.622 [0.431, 0.899]	0.0107	
Age									
< 65 years	105	28 (26.7)	NC [22.8, NC]	106	32 (30.2)	NC [21.1, NC]	0.721 [0.430, 1.210]	0.2129	0.5912
>= 65 years	135	41 (30.4)	31.5 [25.4, NC]	136	57 (41.9)	18.4 [15.3, NC]	0.619 [0.412, 0.929]	0.0194	
Region									
Europe	98	31 (31.6)	NC [20.7, NC]	102	47 (46.1)	16.6 [13.9, NC]	0.510 [0.317, 0.819]	0.0046	0.0459
North America	57	22 (38.6)	25.6 [21.2, NC]	51	16 (31.4)	NC [21.1, NC]	1.168 [0.599, 2.278]	0.6476	
Rest of World	85	16 (18.8)	NC [NC, NC]	89	26 (29.2)	NC [NC, NC]	0.511 [0.273, 0.957]	0.0329	
Sex									
Male	198	54 (27.3)	31.5 [26.1, 31.5]	185	67 (36.2)	NC [18.4, NC]	0.658 [0.458, 0.945]	0.0224	0.8796
Female	42	15 (35.7)	22.8 [19.2, NC]	57	22 (38.6)	21.1 [11.6, 27.5]	0.743 [0.375, 1.471]	0.3921	
Race									
White	166	53 (31.9)	31.5 [22.8, NC]	149	64 (43.0)	18.4 [16.6, NC]	0.588 [0.407, 0.849]	0.0042	0.4984
Non-white	74	16 (21.6)	NC [NC, NC]	93	25 (26.9)	NC [27.5, NC]	0.789 [0.418, 1.490]	0.4643	

Abbreviations: CI=confidence interval; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; INV=investigator; KME=Kaplan-Meier Estimate (median) of time to event (months); mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; OS=overall survival; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.2.1.3: Summary of Overall Survival by Subgroups - Analysis Set mITT 1 - Sensitivity Analysis 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
ECOG Status at Baseline									
0	136	28 (20.6)	NC [NC, NC]	128	40 (31.3)	27.5 [21.1, NC]	0.587 [0.361, 0.955]	0.0298	0.4947
1-2	104	41 (39.4)	25.6 [21.2, 31.5]	113	49 (43.4)	18.4 [16.4, NC]	0.712 [0.467, 1.087]	0.1144	
Metastases at Baseline									
Visceral metastases	170	53 (31.2)	31.5 [25.4, NC]	161	64 (39.8)	19.7 [17.0, NC]	0.678 [0.469, 0.979]	0.0372	0.6604
Lymph node only	60	13 (21.7)	NC [21.2, NC]	67	21 (31.3)	27.5 [18.4, NC]	0.554 [0.276, 1.110]	0.0900	
Primary Disease Site of Origin									
Upper tract	61	18 (29.5)	NC [22.8, NC]	49	10 (20.4)	NC [18.4, NC]	1.240 [0.561, 2.740]	0.5948	0.1201
Lower tract	177	50 (28.2)	31.5 [25.4, NC]	193	79 (40.9)	27.5 [17.0, NC]	0.583 [0.408, 0.834]	0.0028	
Renal Function									
Normal	78	22 (28.2)	26.1 [22.3, NC]	82	33 (40.2)	19.7 [16.6, NC]	0.558 [0.322, 0.969]	0.0356	0.8286
Mild	116	31 (26.7)	NC [25.4, NC]	122	43 (35.2)	27.5 [18.4, NC]	0.705 [0.442, 1.125]	0.1405	
Moderate	46	16 (34.8)	31.5 [14.5, 31.5]	38	13 (34.2)	17.7 [13.9, NC]	0.752 [0.350, 1.617]	0.4643	

Abbreviations: CI=confidence interval; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; INV=investigator; KME=Kaplan-Meier Estimate (median) of time to event (months); mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; OS=overall survival; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.2.2.1: Summary of Overall Survival - Analysis Set mITT 2 - Sensitivity Analysis 1

	EV+Pembro (N=202)	Plat+Gem (N=202)	EV+Pembro vs. Plat+Gem
Number of patients at risk	202 (100.0%)	202 (100.0%)	
Number of patients with events	64 (31.7%)	98 (48.5%)	
Number of patients censored	138 (68.3%)	104 (51.5%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	93.6 [89.2, 96.2]	92.5 [87.9, 95.4]	
Month 6	87.0 [81.5, 91.0]	78.1 [71.7, 83.2]	
Month 9	81.4 [75.3, 86.2]	68.3 [61.4, 74.3]	
Month 12	75.2 [68.4, 80.7]	59.3 [51.8, 65.9]	
Month 18	68.7 [61.0, 75.2]	46.7 [38.3, 54.6]	
Month 24	56.7 [45.8, 66.1]	32.4 [20.9, 44.4]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [22.9, NC]	15.9 [12.2, 20.6]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.488 [0.353, 0.676]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent).
Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease at end of treatment (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.2.2.2: Type of Events and Censoring of Overall Survival - Analysis Set mITT 2 - Sensitivity Analysis 1

	EV+Pembro (N=202)	Plat+Gem (N=202)
Number of patients at risk	202 (100.0%)	202 (100.0%)
Number of patients with events	64 (31.7%)	98 (48.5%)
Death	64 (31.7%)	98 (48.5%)
Number of patients censored	138 (68.3%)	104 (51.5%)
Alive	138 (68.3%)	86 (42.6%)
Censored due to restrictions of sensitivity analysis 1 (a)	0	18 (8.9%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: (a) Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease at end of treatment (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.2.2.3: Summary of Overall Survival by Subgroups - Analysis Set mITT 2 - Sensitivity Analysis 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
PD-L1 Expression									
High (CPS>=10)	117	38 (32.5)	NC [20.2, NC]	115	55 (47.8)	15.0 [12.0, 22.0]	0.480 [0.311, 0.740]	0.0007	0.8071
Low (CPS<10)	85	26 (30.6)	NC [19.9, NC]	87	43 (49.4)	15.9 [10.1, 21.2]	0.499 [0.306, 0.816]	0.0047	
Liver Metastases									
Present	50	23 (46.0)	17.7 [13.6, NC]	50	33 (66.0)	7.4 [5.8, 11.8]	0.448 [0.252, 0.797]	0.0051	0.8127
Absent	152	41 (27.0)	NC [22.9, NC]	152	65 (42.8)	18.9 [14.7, NC]	0.508 [0.343, 0.754]	0.0006	
Age									
< 65 years	39	11 (28.2)	NC [19.1, NC]	29	15 (51.7)	12.7 [9.6, 22.0]	0.297 [0.122, 0.725]	0.0051	0.3086
>= 65 years	163	53 (32.5)	NC [20.2, NC]	173	83 (48.0)	16.1 [12.1, 20.6]	0.560 [0.395, 0.795]	0.0010	
Region									
Europe	74	25 (33.8)	NC [19.1, NC]	95	44 (46.3)	16.1 [12.1, NC]	0.464 [0.271, 0.795]	0.0044	0.6183
North America	46	18 (39.1)	19.9 [18.4, NC]	34	20 (58.8)	13.0 [7.4, 22.0]	0.538 [0.270, 1.073]	0.0750	
Rest of World	82	21 (25.6)	NC [NC, NC]	73	34 (46.6)	13.6 [10.1, NC]	0.506 [0.287, 0.890]	0.0164	
Sex									
Male	146	47 (32.2)	NC [20.4, NC]	151	75 (49.7)	16.1 [12.1, 20.6]	0.485 [0.332, 0.708]	0.0001	0.9534
Female	56	17 (30.4)	NC [19.9, NC]	51	23 (45.1)	15.9 [10.4, NC]	0.503 [0.260, 0.973]	0.0380	
Race									
White	142	51 (35.9)	NC [19.9, NC]	141	70 (49.6)	15.9 [12.0, 20.6]	0.548 [0.378, 0.795]	0.0013	0.1952
Non-white	60	13 (21.7)	NC [NC, NC]	61	28 (45.9)	15.0 [10.1, NC]	0.360 [0.181, 0.716]	0.0024	

Abbreviations: CI=confidence interval; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; INV=investigator; KME=Kaplan-Meier Estimate (median) of time to event (months); mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; OS=overall survival; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.2.2.3: Summary of Overall Survival by Subgroups - Analysis Set mITT 2 - Sensitivity Analysis 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
ECOG Status at Baseline									
0	87	16 (18.4)	NC [22.9, NC]	87	37 (42.5)	18.8 [12.5, NC]	0.297 [0.160, 0.555]	<.0001	0.1158
1-2	115	48 (41.7)	19.9 [17.7, NC]	114	60 (52.6)	13.1 [9.6, 20.6]	0.604 [0.409, 0.893]	0.0107	
Metastases at Baseline									
Visceral metastases	148	55 (37.2)	22.9 [18.7, NC]	157	87 (55.4)	12.1 [10.0, 16.1]	0.486 [0.343, 0.690]	<.0001	0.5844
Lymph node only	43	9 (20.9)	NC [NC, NC]	37	10 (27.0)	NC [15.0, NC]	0.670 [0.271, 1.660]	0.3844	
Primary Disease Site of Origin									
Upper tract	74	20 (27.0)	NC [NC, NC]	55	25 (45.5)	15.0 [11.8, NC]	0.461 [0.251, 0.846]	0.0106	0.5912
Lower tract	128	44 (34.4)	NC [19.1, NC]	146	72 (49.3)	15.9 [12.0, 20.6]	0.514 [0.349, 0.758]	0.0006	
Renal Function									
Normal	6	2 (33.3)	NC [0.7, NC]	13	6 (46.2)	13.0 [3.7, NC]	0.485 [0.046, 5.135]	0.5430	0.9727
Mild	49	11 (22.4)	NC [22.9, NC]	40	15 (37.5)	18.9 [12.2, NC]	0.331 [0.140, 0.781]	0.0085	
Moderate	140	48 (34.3)	NC [19.9, NC]	141	72 (51.1)	15.9 [12.0, 20.6]	0.559 [0.385, 0.812]	0.0020	
Severe	7	3 (42.9)	13.8 [0.6, NC]	8	5 (62.5)	5.8 [0.8, NC]	0.521 [0.086, 3.164]	0.4713	

Abbreviations: CI=confidence interval; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; INV=investigator; KME=Kaplan-Meier Estimate (median) of time to event (months); mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; OS=overall survival; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.3.1.1: Summary of Overall Survival - Analysis Set mITT 1 - Sensitivity Analysis 2

	EV+Pembro (N=240)	Plat+Gem (N=242)	EV+Pembro vs. Plat+Gem
Number of patients at risk	240 (100.0%)	242 (100.0%)	
Number of patients with events	69 (28.8%)	89 (36.8%)	
Number of patients censored	171 (71.3%)	153 (63.2%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	97.9 [95.1, 99.1]	94.9 [91.2, 97.1]	
Month 6	92.9 [88.8, 95.5]	85.1 [79.9, 89.1]	
Month 9	87.4 [82.4, 91.0]	74.0 [67.9, 79.1]	
Month 12	80.7 [74.9, 85.3]	70.2 [63.9, 75.7]	
Month 18	70.2 [63.0, 76.3]	60.8 [53.5, 67.3]	
Month 24	62.5 [53.0, 70.6]	55.9 [48.0, 63.1]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	31.5 [25.4, NC]	NC [19.7, NC]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.701 [0.511, 0.961]
Log-rank test			
Two-sided stratified log-rank p-value			0.0266

Abbreviations: CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent).
Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease at end of treatment (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.3.1.2: Type of Events and Censoring of Overall Survival - Analysis Set mITT 1 - Sensitivity Analysis 2

	EV+Pembro (N=240)	Plat+Gem (N=242)
Number of patients at risk	240 (100.0%)	242 (100.0%)
Number of patients with events	69 (28.8%)	89 (36.8%)
Death	69 (28.8%)	89 (36.8%)
Number of patients censored	171 (71.3%)	153 (63.2%)
Alive	171 (71.3%)	132 (54.5%)
Censored due to restrictions of sensitivity analysis 2 (a)	0	21 (8.7%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: (a) Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease at end of treatment (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.3.1.3: Summary of Overall Survival by Subgroups - Analysis Set mITT 1 - Sensitivity Analysis 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
PD-L1 Expression									
High (CPS>=10)	139	41 (29.5)	31.5 [25.4, NC]	140	52 (37.1)	NC [18.4, NC]	0.718 [0.475, 1.085]	0.1143	0.8196
Low (CPS<10)	101	28 (27.7)	NC [22.3, NC]	102	37 (36.3)	NC [17.7, NC]	0.677 [0.414, 1.107]	0.1172	
Liver Metastases									
Present	48	20 (41.7)	25.6 [13.8, 31.5]	48	21 (43.8)	NC [10.4, NC]	0.850 [0.456, 1.584]	0.6088	0.3647
Absent	192	49 (25.5)	NC [25.4, NC]	194	68 (35.1)	NC [19.7, NC]	0.655 [0.454, 0.947]	0.0233	
Age									
< 65 years	105	28 (26.7)	NC [22.8, NC]	106	32 (30.2)	NC [21.1, NC]	0.751 [0.448, 1.259]	0.2754	0.6426
>= 65 years	135	41 (30.4)	31.5 [25.4, NC]	136	57 (41.9)	27.5 [15.3, NC]	0.655 [0.437, 0.984]	0.0398	
Region									
Europe	98	31 (31.6)	NC [20.7, NC]	102	47 (46.1)	18.4 [13.9, NC]	0.590 [0.373, 0.932]	0.0223	0.0554
North America	57	22 (38.6)	25.6 [21.2, NC]	51	16 (31.4)	NC [21.1, NC]	1.228 [0.628, 2.401]	0.5476	
Rest of World	85	16 (18.8)	NC [NC, NC]	89	26 (29.2)	NC [NC, NC]	0.518 [0.276, 0.971]	0.0369	
Sex									
Male	198	54 (27.3)	31.5 [26.1, 31.5]	185	67 (36.2)	NC [18.4, NC]	0.695 [0.485, 0.998]	0.0474	0.8755
Female	42	15 (35.7)	22.8 [19.2, NC]	57	22 (38.6)	27.5 [11.6, NC]	0.792 [0.399, 1.571]	0.5039	
Race									
White	166	53 (31.9)	31.5 [22.8, NC]	149	64 (43.0)	21.1 [16.7, NC]	0.636 [0.440, 0.917]	0.0146	0.5546
Non-white	74	16 (21.6)	NC [NC, NC]	93	25 (26.9)	NC [27.5, NC]	0.815 [0.433, 1.537]	0.5276	

Abbreviations: CI=confidence interval; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; INV=investigator; KME=Kaplan-Meier Estimate (median) of time to event (months); mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; OS=overall survival; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.3.1.3: Summary of Overall Survival by Subgroups - Analysis Set mITT 1 - Sensitivity Analysis 2

Subgroup	EV+Pembro N	EV+Pembro n (%)	EV+Pembro KME [95% CI](a)	Plat+Gem N	Plat+Gem n (%)	Plat+Gem KME [95% CI](a)	EV+Pembro vs. Plat+Gem HR [95% CI](b)	Log-rank p-value(c)	Test for Interaction p-value(d)
ECOG Status at Baseline									
0	136	28 (20.6)	NC [NC, NC]	128	40 (31.3)	NC [27.5, NC]	0.614 [0.378, 0.999]	0.0475	0.4449
1-2	104	41 (39.4)	25.6 [21.2, 31.5]	113	49 (43.4)	19.7 [16.4, NC]	0.756 [0.496, 1.152]	0.1920	
Metastases at Baseline									
Visceral metastases	170	53 (31.2)	31.5 [25.4, NC]	161	64 (39.8)	NC [17.7, NC]	0.722 [0.499, 1.042]	0.0810	0.5941
Lymph node only	60	13 (21.7)	NC [21.2, NC]	67	21 (31.3)	27.5 [27.5, NC]	0.584 [0.292, 1.168]	0.1226	
Primary Disease Site of Origin									
Upper tract	61	18 (29.5)	NC [22.8, NC]	49	10 (20.4)	NC [21.1, NC]	1.325 [0.598, 2.933]	0.4866	0.0946
Lower tract	177	50 (28.2)	31.5 [25.4, NC]	193	79 (40.9)	27.5 [17.7, NC]	0.614 [0.430, 0.878]	0.0068	
Renal Function									
Normal	78	22 (28.2)	26.1 [22.3, NC]	82	33 (40.2)	NC [16.6, NC]	0.579 [0.334, 1.005]	0.0494	0.7640
Mild	116	31 (26.7)	NC [25.4, NC]	122	43 (35.2)	NC [21.1, NC]	0.740 [0.464, 1.182]	0.2059	
Moderate	46	16 (34.8)	31.5 [14.5, 31.5]	38	13 (34.2)	NC [16.7, NC]	0.818 [0.381, 1.754]	0.6044	

Abbreviations: CI=confidence interval; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; INV=investigator; KME=Kaplan-Meier Estimate (median) of time to event (months); mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; OS=overall survival; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.3.2.1: Summary of Overall Survival - Analysis Set mITT 2 - Sensitivity Analysis 2

	EV+Pembro (N=202)	Plat+Gem (N=202)	EV+Pembro vs. Plat+Gem
Number of patients at risk	202 (100.0%)	202 (100.0%)	
Number of patients with events	64 (31.7%)	98 (48.5%)	
Number of patients censored	138 (68.3%)	104 (51.5%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	93.6 [89.2, 96.2]	92.5 [87.9, 95.4]	
Month 6	87.0 [81.5, 91.0]	78.1 [71.7, 83.2]	
Month 9	81.4 [75.3, 86.2]	68.5 [61.6, 74.4]	
Month 12	75.2 [68.4, 80.7]	60.0 [52.6, 66.5]	
Month 18	68.7 [61.0, 75.2]	49.2 [41.3, 56.6]	
Month 24	56.7 [45.8, 66.1]	40.4 [31.1, 49.4]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [22.9, NC]	17.4 [12.5, 22.0]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.540 [0.393, 0.743]
Log-rank test			
Two-sided stratified log-rank p-value			0.0001

Abbreviations: CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent).
Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease at end of treatment (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.3.2.2: Type of Events and Censoring of Overall Survival - Analysis Set mITT 2 - Sensitivity Analysis 2

	EV+Pembro (N=202)	**Plat+Gem (N=202)**
Number of patients at risk	202 (100.0%)	202 (100.0%)
Number of patients with events	64 (31.7%)	98 (48.5%)
Death	64 (31.7%)	98 (48.5%)
Number of patients censored	138 (68.3%)	104 (51.5%)
Alive	138 (68.3%)	86 (42.6%)
Censored due to restrictions of sensitivity analysis 2 (a)	0	18 (8.9%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: (a) Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease at end of treatment (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.3.2.3: Summary of Overall Survival by Subgroups - Analysis Set mITT 2 - Sensitivity Analysis 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
PD-L1 Expression									
High (CPS>=10)	117	38 (32.5)	NC [20.2, NC]	115	55 (47.8)	18.3 [12.1, NC]	0.548 [0.360, 0.835]	0.0045	0.7405
Low (CPS<10)	85	26 (30.6)	NC [19.9, NC]	87	43 (49.4)	16.1 [10.1, NC]	0.529 [0.325, 0.863]	0.0095	
Liver Metastases									
Present	50	23 (46.0)	17.7 [13.6, NC]	50	33 (66.0)	7.9 [5.8, 11.8]	0.514 [0.297, 0.888]	0.0154	0.8737
Absent	152	41 (27.0)	NC [22.9, NC]	152	65 (42.8)	20.6 [15.0, NC]	0.554 [0.375, 0.820]	0.0028	
Age									
< 65 years	39	11 (28.2)	NC [19.1, NC]	29	15 (51.7)	12.7 [9.6, NC]	0.319 [0.132, 0.773]	0.0081	0.3157
>= 65 years	163	53 (32.5)	NC [20.2, NC]	173	83 (48.0)	17.4 [13.0, NC]	0.609 [0.431, 0.861]	0.0046	
Region									
Europe	74	25 (33.8)	NC [19.1, NC]	95	44 (46.3)	18.3 [12.1, NC]	0.558 [0.334, 0.932]	0.0240	0.6446
North America	46	18 (39.1)	19.9 [18.4, NC]	34	20 (58.8)	13.0 [7.4, NC]	0.538 [0.270, 1.073]	0.0750	
Rest of World	82	21 (25.6)	NC [NC, NC]	73	34 (46.6)	18.8 [10.4, NC]	0.545 [0.312, 0.954]	0.0315	
Sex									
Male	146	47 (32.2)	NC [20.4, NC]	151	75 (49.7)	17.4 [12.1, 22.0]	0.541 [0.374, 0.783]	0.0010	0.9598
Female	56	17 (30.4)	NC [19.9, NC]	51	23 (45.1)	15.9 [11.8, NC]	0.529 [0.274, 1.021]	0.0541	
Race									
White	142	51 (35.9)	NC [19.9, NC]	141	70 (49.6)	17.4 [12.1, NC]	0.624 [0.434, 0.899]	0.0105	0.1279
Non-white	60	13 (21.7)	NC [NC, NC]	61	28 (45.9)	15.0 [10.1, NC]	0.360 [0.181, 0.716]	0.0024	

Abbreviations: CI=confidence interval; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; INV=investigator; KME=Kaplan-Meier Estimate (median) of time to event (months); mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; OS=overall survival; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.3.2.3: Summary of Overall Survival by Subgroups - Analysis Set mITT 2 - Sensitivity Analysis 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
ECOG Status at Baseline									
0	87	16 (18.4)	NC [22.9, NC]	87	37 (42.5)	NC [12.5, NC]	0.323 [0.174, 0.601]	0.0002	0.0993
1-2	115	48 (41.7)	19.9 [17.7, NC]	114	60 (52.6)	13.6 [10.3, 21.2]	0.676 [0.461, 0.991]	0.0439	
Metastases at Baseline									
Visceral metastases	148	55 (37.2)	22.9 [18.7, NC]	157	87 (55.4)	12.2 [10.1, 18.9]	0.546 [0.388, 0.769]	0.0004	0.6242
Lymph node only	43	9 (20.9)	NC [NC, NC]	37	10 (27.0)	NC [15.0, NC]	0.704 [0.285, 1.738]	0.4448	
Primary Disease Site of Origin									
Upper tract	74	20 (27.0)	NC [NC, NC]	55	25 (45.5)	22.0 [11.8, NC]	0.514 [0.283, 0.933]	0.0260	0.5368
Lower tract	128	44 (34.4)	NC [19.1, NC]	146	72 (49.3)	17.4 [12.1, NC]	0.557 [0.378, 0.820]	0.0027	
Renal Function									
Normal	6	2 (33.3)	NC [0.7, NC]	13	6 (46.2)	13.0 [3.7, NC]	0.485 [0.046, 5.135]	0.5430	0.9813
Mild	49	11 (22.4)	NC [22.9, NC]	40	15 (37.5)	NC [12.7, NC]	0.498 [0.226, 1.100]	0.0793	
Moderate	140	48 (34.3)	NC [19.9, NC]	141	72 (51.1)	15.9 [12.0, 21.2]	0.591 [0.408, 0.858]	0.0051	
Severe	7	3 (42.9)	13.8 [0.6, NC]	8	5 (62.5)	5.8 [0.8, NC]	0.521 [0.086, 3.164]	0.4713	

Abbreviations: CI=confidence interval; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; INV=investigator; KME=Kaplan-Meier Estimate (median) of time to event (months); mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; OS=overall survival; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.4.1.1: Summary of Overall Survival - Analysis Set mITT 1 - Sensitivity Analysis 3

	EV+Pembro (N=240)	Plat+Gem (N=242)	EV+Pembro vs. Plat+Gem
Number of patients at risk	240 (100.0%)	242 (100.0%)	
Number of patients with events	69 (28.8%)	100 (41.3%)	
Number of patients censored	171 (71.3%)	142 (58.7%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	97.9 [95.1, 99.1]	94.9 [91.2, 97.1]	
Month 6	92.9 [88.8, 95.5]	85.1 [79.9, 89.1]	
Month 9	87.4 [82.4, 91.0]	74.0 [67.9, 79.1]	
Month 12	80.7 [74.9, 85.3]	70.2 [63.9, 75.7]	
Month 18	70.2 [63.0, 76.3]	59.3 [51.9, 66.0]	
Month 24	62.5 [53.0, 70.6]	44.6 [35.1, 53.7]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	31.5 [25.4, NC]	21.3 [18.4, 27.5]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.620 [0.456, 0.845]
Log-rank test			
Two-sided stratified log-rank p-value			0.0022

Abbreviations: CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent).
Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease at end of treatment (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (8.8 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.4.1.2: Type of Events and Censoring of Overall Survival - Analysis Set mITT 1 - Sensitivity Analysis 3

	EV+Pembro (N=240)	**Plat+Gem (N=242)**
Number of patients at risk	240 (100.0%)	242 (100.0%)
Number of patients with events	69 (28.8%)	100 (41.3%)
Death	69 (28.8%)	89 (36.8%)
Events considering restrictions of sensitivity analysis 3 (a)	0	11 (4.5%)
Number of patients censored	171 (71.3%)	142 (58.7%)
Alive	171 (71.3%)	132 (54.5%)
Censored due to restrictions of sensitivity analysis 3 (a)	0	10 (4.1%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: (a) Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease at end of treatment (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (8.8 months) or censored at data cutoff date if cata cutoff date < date of death + avelumab OS advantage.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.4.1.3: Summary of Overall Survival by Subgroups - Analysis Set mITT 1 - Sensitivity Analysis 3

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
PD-L1 Expression									
High (CPS>=10)	139	41 (29.5)	31.5 [25.4, NC]	140	56 (40.0)	21.1 [17.9, NC]	0.661 [0.440, 0.992]	0.0443	0.6140
Low (CPS<10)	101	28 (27.7)	NC [22.3, NC]	102	44 (43.1)	21.3 [16.6, 27.5]	0.570 [0.354, 0.917]	0.0189	
Liver Metastases									
Present	48	20 (41.7)	25.6 [13.8, 31.5]	48	25 (52.1)	20.4 [10.4, 27.2]	0.715 [0.392, 1.303]	0.2709	0.4646
Absent	192	49 (25.5)	NC [25.4, NC]	194	75 (38.7)	23.9 [18.4, NC]	0.590 [0.412, 0.846]	0.0037	
Age									
< 65 years	105	28 (26.7)	NC [22.8, NC]	106	35 (33.0)	NC [20.2, NC]	0.684 [0.412, 1.135]	0.1383	0.5038
>= 65 years	135	41 (30.4)	31.5 [25.4, NC]	136	65 (47.8)	18.4 [15.3, 23.9]	0.582 [0.392, 0.866]	0.0068	
Region									
Europe	98	31 (31.6)	NC [20.7, NC]	102	53 (52.0)	17.0 [13.9, 20.2]	0.469 [0.297, 0.740]	0.0009	0.0652
North America	57	22 (38.6)	25.6 [21.2, NC]	51	20 (39.2)	27.5 [21.1, NC]	1.066 [0.562, 2.023]	0.8446	
Rest of World	85	16 (18.8)	NC [NC, NC]	89	27 (30.3)	NC [NC, NC]	0.497 [0.267, 0.928]	0.0253	
Sex									
Male	198	54 (27.3)	31.5 [26.1, 31.5]	185	77 (41.6)	21.1 [18.4, NC]	0.609 [0.429, 0.867]	0.0054	0.7571
Female	42	15 (35.7)	22.8 [19.2, NC]	57	23 (40.4)	23.9 [11.6, 27.5]	0.792 [0.399, 1.571]	0.5039	
Race									
White	166	53 (31.9)	31.5 [22.8, NC]	149	72 (48.3)	19.2 [16.6, 23.9]	0.552 [0.386, 0.790]	0.0010	0.4098
Non-white	74	16 (21.6)	NC [NC, NC]	93	28 (30.1)	27.5 [23.9, NC]	0.815 [0.433, 1.537]	0.5276	

Abbreviations: CI=confidence interval; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; INV=investigator; KME=Kaplan-Meier Estimate (median) of time to event (months); mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; OS=overall survival; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (8.8 months) or censored at Data Cutoff Date if data cutoff date < date of death + avelumab OS advantage.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.4.1.3: Summary of Overall Survival by Subgroups - Analysis Set mITT 1 - Sensitivity Analysis 3

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
ECOG Status at Baseline									
0	136	28 (20.6)	NC [NC, NC]	128	46 (35.9)	27.2 [20.2, 30.9]	0.537 [0.335, 0.861]	0.0088	0.4063
1-2	104	41 (39.4)	25.6 [21.2, 31.5]	113	54 (47.8)	18.4 [16.1, 23.9]	0.666 [0.441, 1.007]	0.0524	
Metastases at Baseline									
Visceral metastases	170	53 (31.2)	31.5 [25.4, NC]	161	73 (45.3)	20.2 [17.1, 23.9]	0.634 [0.443, 0.908]	0.0120	0.6977
Lymph node only	60	13 (21.7)	NC [21.2, NC]	67	23 (34.3)	27.5 [18.4, NC]	0.523 [0.264, 1.035]	0.0574	
Primary Disease Site of Origin									
Upper tract	61	18 (29.5)	NC [22.8, NC]	49	13 (26.5)	23.9 [21.1, NC]	1.025 [0.492, 2.135]	0.9464	0.1811
Lower tract	177	50 (28.2)	31.5 [25.4, NC]	193	87 (45.1)	20.2 [17.1, 27.5]	0.554 [0.390, 0.788]	0.0008	
Renal Function									
Normal	78	22 (28.2)	26.1 [22.3, NC]	82	35 (42.7)	19.7 [16.6, NC]	0.536 [0.311, 0.924]	0.0227	0.8748
Mild	116	31 (26.7)	NC [25.4, NC]	122	50 (41.0)	23.9 [19.2, 30.9]	0.656 [0.417, 1.033]	0.0670	
Moderate	46	16 (34.8)	31.5 [14.5, 31.5]	38	15 (39.5)	17.7 [16.1, NC]	0.665 [0.317, 1.394]	0.2773	

Abbreviations: CI=confidence interval; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; INV=investigator; KME=Kaplan-Meier Estimate (median) of time to event (months); mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; OS=overall survival; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (8.8 months) or censored at Data Cutoff Date if data cutoff date < date of death + avelumab OS advantage.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.4.2.1: Summary of Overall Survival - Analysis Set mITT 2 - Sensitivity Analysis 3

	EV+Pembro (N=202)	Plat+Gem (N=202)	EV+Pembro vs. Plat+Gem
Number of patients at risk	202 (100.0%)	202 (100.0%)	
Number of patients with events	64 (31.7%)	111 (55.0%)	
Number of patients censored	138 (68.3%)	91 (45.0%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	93.6 [89.2, 96.2]	92.5 [87.9, 95.4]	
Month 6	87.0 [81.5, 91.0]	78.1 [71.7, 83.2]	
Month 9	81.4 [75.3, 86.2]	68.5 [61.6, 74.4]	
Month 12	75.2 [68.4, 80.7]	60.0 [52.6, 66.5]	
Month 18	68.7 [61.0, 75.2]	43.9 [35.8, 51.7]	
Month 24	56.7 [45.8, 66.1]	22.1 [13.0, 32.7]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [22.9, NC]	15.7 [12.5, 18.4]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.446 [0.324, 0.612]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent).
Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease at end of treatment (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (7.0 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.4.2.2: Type of Events and Censoring of Overall Survival - Analysis Set mITT 2 - Sensitivity Analysis 3

	EV+Pembro (N=202)	**Plat+Gem (N=202)**
Number of patients at risk	202 (100.0%)	202 (100.0%)
Number of patients with events	64 (31.7%)	111 (55.0%)
Death	64 (31.7%)	98 (48.5%)
Events considering restrictions of sensitivity analysis 3 (a)	0	13 (6.4%)
Number of patients censored	138 (68.3%)	91 (45.0%)
Alive	138 (68.3%)	86 (42.6%)
Censored due to restrictions of sensitivity analysis 3 (a)	0	5 (2.5%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: (a) Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease at end of treatment (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (7.0 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.4.2.3: Summary of Overall Survival by Subgroups - Analysis Set mITT 2 - Sensitivity Analysis 3

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
PD-L1 Expression									
High (CPS>=10)	117	38 (32.5)	NC [20.2, NC]	115	64 (55.7)	15.0 [12.1, 18.8]	0.421 [0.276, 0.641]	<.0001	0.9696
Low (CPS<10)	85	26 (30.6)	NC [19.9, NC]	87	47 (54.0)	15.9 [10.1, 20.3]	0.481 [0.297, 0.780]	0.0024	
Liver Metastases									
Present	50	23 (46.0)	17.7 [13.6, NC]	50	36 (72.0)	7.9 [5.8, 11.8]	0.426 [0.242, 0.752]	0.0025	0.9562
Absent	152	41 (27.0)	NC [22.9, NC]	152	75 (49.3)	18.3 [14.7, 20.6]	0.455 [0.310, 0.667]	<.0001	
Age									
< 65 years	39	11 (28.2)	NC [19.1, NC]	29	16 (55.2)	12.7 [9.6, 22.0]	0.279 [0.116, 0.671]	0.0026	0.2961
>= 65 years	163	53 (32.5)	NC [20.2, NC]	173	95 (54.9)	15.9 [13.0, 18.4]	0.516 [0.367, 0.725]	0.0001	
Region									
Europe	74	25 (33.8)	NC [19.1, NC]	95	52 (54.7)	16.1 [12.1, 19.9]	0.399 [0.237, 0.671]	0.0004	0.5914
North America	46	18 (39.1)	19.9 [18.4, NC]	34	21 (61.8)	13.0 [7.4, 22.5]	0.538 [0.270, 1.073]	0.0750	
Rest of World	82	21 (25.6)	NC [NC, NC]	73	38 (52.1)	13.6 [10.4, 18.9]	0.447 [0.258, 0.776]	0.0034	
Sex									
Male	146	47 (32.2)	NC [20.4, NC]	151	84 (55.6)	15.7 [12.1, 18.8]	0.447 [0.309, 0.648]	<.0001	0.8546
Female	56	17 (30.4)	NC [19.9, NC]	51	27 (52.9)	15.0 [11.8, 21.6]	0.452 [0.238, 0.860]	0.0133	
Race									
White	142	51 (35.9)	NC [19.9, NC]	141	83 (58.9)	15.7 [12.1, 18.4]	0.490 [0.342, 0.702]	<.0001	0.2948
Non-white	60	13 (21.7)	NC [NC, NC]	61	28 (45.9)	15.0 [10.1, NC]	0.360 [0.181, 0.716]	0.0024	

Abbreviations: CI=confidence interval; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; INV=investigator; KME=Kaplan-Meier Estimate (median) of time to event (months); mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; OS=overall survival; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (7.0 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.4.2.3: Summary of Overall Survival by Subgroups - Analysis Set mITT 2 - Sensitivity Analysis 3

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
ECOG Status at Baseline									
0	87	16 (18.4)	NC [22.9, NC]	87	42 (48.3)	18.8 [12.5, 22.5]	0.273 [0.148, 0.504]	<.0001	0.0919
1-2	115	48 (41.7)	19.9 [17.7, NC]	114	68 (59.6)	13.2 [10.3, 17.7]	0.546 [0.373, 0.798]	0.0015	
Metastases at Baseline									
Visceral metastases	148	55 (37.2)	22.9 [18.7, NC]	157	97 (61.8)	12.2 [10.1, 15.9]	0.450 [0.319, 0.634]	<.0001	0.8091
Lymph node only	43	9 (20.9)	NC [NC, NC]	37	13 (35.1)	21.6 [15.0, NC]	0.518 [0.220, 1.216]	0.1242	
Primary Disease Site of Origin									
Upper tract	74	20 (27.0)	NC [NC, NC]	55	27 (49.1)	16.5 [11.8, NC]	0.436 [0.240, 0.793]	0.0052	0.6474
Lower tract	128	44 (34.4)	NC [19.1, NC]	146	83 (56.8)	15.7 [12.1, 18.8]	0.471 [0.323, 0.689]	<.0001	
Renal Function									
Normal	6	2 (33.3)	NC [0.7, NC]	13	6 (46.2)	13.0 [3.7, NC]	0.485 [0.046, 5.135]	0.5430	0.7772
Mild	49	11 (22.4)	NC [22.9, NC]	40	22 (55.0)	16.5 [12.7, 21.6]	0.291 [0.134, 0.634]	0.0011	
Moderate	140	48 (34.3)	NC [19.9, NC]	141	78 (55.3)	15.9 [12.0, 18.4]	0.532 [0.368, 0.767]	0.0006	
Severe	7	3 (42.9)	13.8 [0.6, NC]	8	5 (62.5)	5.8 [0.8, NC]	0.521 [0.086, 3.164]	0.4713	

Abbreviations: CI=confidence interval; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; INV=investigator; KME=Kaplan-Meier Estimate (median) of time to event (months); mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; OS=overall survival; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (7.0 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.5.1.1: Summary of Progression-Free Survival (BICR) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)	EV+Pembro vs. Plat+Gem
Number of patients at risk	240 (100.0%)	242 (100.0%)	
Number of patients with events	115 (47.9%)	157 (64.9%)	
Number of patients censored	125 (52.1%)	85 (35.1%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	88.5 [83.6, 91.9]	84.2 [78.8, 88.4]	
Month 6	74.5 [68.4, 79.7]	65.1 [58.2, 71.1]	
Month 9	59.9 [53.2, 66.0]	35.0 [28.3, 41.9]	
Month 12	53.6 [46.7, 60.0]	25.9 [19.6, 32.7]	
Month 18	46.2 [38.9, 53.2]	15.4 [9.9, 22.1]	
Month 24	40.8 [30.9, 50.5]	11.4 [5.8, 19.0]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	12.8 [10.4, NC]	6.5 [6.3, 7.7]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.480 [0.375, 0.614]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

Abbreviations: BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.5.1.2: Type of Events and Censoring of Progression-Free Survival (BICR) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)
Number of patients at risk	240 (100.0%)	242 (100.0%)
Number of patients with events	115 (47.9%)	157 (64.9%)
Death	10 (4.2%)	16 (6.6%)
Radiological Progression	105 (43.8%)	141 (58.3%)
Number of patients censored	125 (52.1%)	85 (35.1%)
New Anti-Cancer Therapy	13 (5.4%)	25 (10.3%)
No Documented Pd Or Death	108 (45.0%)	48 (19.8%)
No Radiological Assessment Post-Baseline	2 (0.8%)	5 (2.1%)
Pd Or Death After >= 2 Missed Assessments	2 (0.8%)	7 (2.9%)

Abbreviations: BICR=blinded independent central review; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.5.1.3: Summary of Progression-Free Survival (BICR) by Subgroups - Analysis Set mITT 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
PD-L1 Expression									
High (CPS>=10)	139	60 (43.2)	22.5 [10.4, NC]	140	91 (65.0)	6.5 [6.1, 8.2]	0.464 [0.333, 0.647]	<.0001	0.5523
Low (CPS<10)	101	55 (54.5)	12.3 [8.3, 16.6]	102	66 (64.7)	6.5 [6.2, 8.1]	0.500 [0.346, 0.723]	0.0002	
Liver Metastases									
Present	48	31 (64.6)	10.5 [4.7, 15.0]	48	36 (75.0)	6.3 [5.1, 6.9]	0.583 [0.351, 0.967]	0.0360	0.2960
Absent	192	84 (43.8)	NC [10.4, NC]	194	121 (62.4)	7.4 [6.3, 8.2]	0.452 [0.341, 0.599]	<.0001	
Age									
< 65 years	105	52 (49.5)	12.7 [9.2, NC]	106	67 (63.2)	6.3 [6.1, 8.3]	0.455 [0.311, 0.668]	<.0001	0.9312
>= 65 years	135	63 (46.7)	15.0 [8.4, NC]	136	90 (66.2)	6.8 [6.3, 8.1]	0.479 [0.345, 0.665]	<.0001	
Region									
Europe	98	49 (50.0)	10.5 [8.4, NC]	102	71 (69.6)	6.5 [6.2, 8.1]	0.482 [0.331, 0.701]	0.0001	0.0578
North America	57	35 (61.4)	10.3 [6.3, 16.4]	51	32 (62.7)	6.4 [6.1, 9.4]	0.708 [0.433, 1.159]	0.1701	
Rest of World	85	31 (36.5)	NC [12.5, NC]	89	54 (60.7)	6.5 [6.1, 8.3]	0.324 [0.203, 0.516]	<.0001	
Sex									
Male	198	91 (46.0)	16.8 [10.4, NC]	185	121 (65.4)	6.7 [6.3, 8.1]	0.455 [0.344, 0.602]	<.0001	0.2883
Female	42	24 (57.1)	10.5 [6.3, 16.4]	57	36 (63.2)	6.4 [4.4, 7.6]	0.649 [0.378, 1.115]	0.1156	
Race									
White	166	86 (51.8)	12.6 [9.2, 20.4]	149	99 (66.4)	6.3 [6.1, 7.4]	0.505 [0.376, 0.680]	<.0001	0.5006
Non-white	74	29 (39.2)	NC [9.7, NC]	93	58 (62.4)	7.7 [6.3, 8.4]	0.447 [0.283, 0.705]	0.0004	

Abbreviations: BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.5.1.3: Summary of Progression-Free Survival (BICR) by Subgroups - Analysis Set mITT 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
ECOG Status at Baseline									
0	136	50 (36.8)	NC [16.4, NC]	128	83 (64.8)	7.6 [6.4, 8.5]	0.342 [0.238, 0.493]	<.0001	0.0270
1-2	104	65 (62.5)	8.3 [6.3, 12.3]	113	74 (65.5)	6.2 [5.1, 7.4]	0.646 [0.459, 0.910]	0.0119	
Metastases at Baseline									
Visceral metastases	170	90 (52.9)	10.6 [8.3, 16.8]	161	114 (70.8)	6.3 [6.1, 6.9]	0.482 [0.362, 0.640]	<.0001	0.7000
Lymph node only	60	21 (35.0)	NC [12.8, NC]	67	35 (52.2)	8.5 [6.4, 14.4]	0.453 [0.261, 0.787]	0.0039	
Primary Disease Site of Origin									
Upper tract	61	31 (50.8)	12.7 [6.3, NC]	49	31 (63.3)	6.8 [6.2, 8.3]	0.592 [0.352, 0.995]	0.0466	0.6564
Lower tract	177	82 (46.3)	16.6 [10.4, NC]	193	126 (65.3)	6.4 [6.3, 8.1]	0.451 [0.339, 0.599]	<.0001	
Renal Function									
Normal	78	36 (46.2)	16.6 [9.7, NC]	82	53 (64.6)	7.3 [6.2, 10.4]	0.479 [0.308, 0.746]	0.0010	0.7040
Mild	116	57 (49.1)	12.5 [8.3, NC]	122	85 (69.7)	6.3 [5.3, 7.4]	0.490 [0.347, 0.691]	<.0001	
Moderate	46	22 (47.8)	12.8 [8.1, NC]	38	19 (50.0)	8.1 [6.2, 14.4]	0.584 [0.307, 1.114]	0.0986	

Abbreviations: BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.5.2.1: Summary of Progression-Free Survival (BICR) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)	EV+Pembro vs. Plat+Gem
Number of patients at risk	202 (100.0%)	202 (100.0%)	
Number of patients with events	108 (53.5%)	150 (74.3%)	
Number of patients censored	94 (46.5%)	52 (25.7%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	87.5 [82.0, 91.3]	77.1 [70.3, 82.5]	
Month 6	70.8 [63.9, 76.6]	55.4 [47.8, 62.4]	
Month 9	54.4 [47.1, 61.2]	22.0 [15.9, 28.8]	
Month 12	47.3 [39.8, 54.4]	16.3 [10.9, 22.6]	
Month 18	41.1 [33.3, 48.7]	7.3 [3.4, 13.2]	
Month 24	35.4 [26.2, 44.6]	7.3 [3.4, 13.2]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	10.6 [8.3, 15.3]	6.1 [5.8, 6.2]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.421 [0.326, 0.543]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

Abbreviations: BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.5.2.2: Type of Events and Censoring of Progression-Free Survival (BICR) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)
Number of patients at risk	202 (100.0%)	202 (100.0%)
Number of patients with events	108 (53.5%)	150 (74.3%)
Death	23 (11.4%)	18 (8.9%)
Radiological Progression	85 (42.1%)	132 (65.3%)
Number of patients censored	94 (46.5%)	52 (25.7%)
New Anti-Cancer Therapy	7 (3.5%)	21 (10.4%)
No Documented Pd Or Death	80 (39.6%)	26 (12.9%)
No Radiological Assessment Post-Baseline	2 (1.0%)	3 (1.5%)
Pd Or Death After >= 2 Missed Assessments	5 (2.5%)	2 (1.0%)

Abbreviations: BICR=blinded independent central review; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.5.2.3: Summary of Progression-Free Survival (BICR) by Subgroups - Analysis Set mITT 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
PD-L1 Expression									
High (CPS>=10)	117	56 (47.9)	15.3 [8.5, NC]	115	86 (74.8)	6.2 [5.9, 6.2]	0.361 [0.254, 0.512]	<.0001	0.1471
Low (CPS<10)	85	52 (61.2)	8.4 [6.2, 12.0]	87	64 (73.6)	6.0 [4.2, 6.7]	0.505 [0.347, 0.734]	0.0003	
Liver Metastases									
Present	50	34 (68.0)	6.3 [4.6, 12.0]	50	41 (82.0)	4.2 [3.1, 6.0]	0.472 [0.294, 0.760]	0.0015	0.5937
Absent	152	74 (48.7)	14.4 [10.3, NC]	152	109 (71.7)	6.2 [6.0, 6.7]	0.402 [0.296, 0.544]	<.0001	
Age									
< 65 years	39	23 (59.0)	11.2 [6.2, NC]	29	21 (72.4)	6.4 [4.0, 7.0]	0.422 [0.221, 0.805]	0.0073	0.9770
>= 65 years	163	85 (52.1)	10.6 [8.2, 16.6]	173	129 (74.6)	6.1 [4.9, 6.2]	0.431 [0.325, 0.571]	<.0001	
Region									
Europe	74	45 (60.8)	8.3 [6.2, 14.6]	95	73 (76.8)	6.1 [4.7, 6.9]	0.524 [0.355, 0.774]	0.0009	0.2360
North America	46	23 (50.0)	12.0 [6.1, NC]	34	23 (67.6)	6.2 [3.8, 6.8]	0.373 [0.199, 0.701]	0.0015	
Rest of World	82	40 (48.8)	14.4 [8.5, NC]	73	54 (74.0)	6.0 [4.3, 6.3]	0.376 [0.244, 0.579]	<.0001	
Sex									
Male	146	77 (52.7)	12.0 [8.2, 18.7]	151	112 (74.2)	6.2 [5.9, 6.5]	0.428 [0.316, 0.580]	<.0001	0.7594
Female	56	31 (55.4)	10.4 [6.2, 14.5]	51	38 (74.5)	6.0 [3.9, 6.2]	0.383 [0.229, 0.641]	0.0002	
Race									
White	142	82 (57.7)	8.5 [6.3, 11.2]	141	108 (76.6)	6.1 [5.8, 6.2]	0.459 [0.339, 0.622]	<.0001	0.1986
Non-white	60	26 (43.3)	18.7 [14.4, NC]	61	42 (68.9)	6.2 [3.9, 7.0]	0.324 [0.192, 0.546]	<.0001	

Abbreviations: BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.5.2.3: Summary of Progression-Free Survival (BICR) by Subgroups - Analysis Set mITT 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
ECOG Status at Baseline									
0	87	43 (49.4)	14.4 [7.1, NC]	87	63 (72.4)	6.3 [6.0, 7.3]	0.389 [0.260, 0.583]	<.0001	0.9460
1-2	115	65 (56.5)	10.4 [6.3, 15.3]	114	87 (76.3)	5.9 [4.3, 6.2]	0.446 [0.319, 0.623]	<.0001	
Metastases at Baseline									
Visceral metastases	148	86 (58.1)	8.4 [6.3, 12.0]	157	124 (79.0)	6.0 [4.3, 6.2]	0.424 [0.318, 0.563]	<.0001	0.8271
Lymph node only	43	17 (39.5)	NC [11.2, NC]	37	20 (54.1)	7.0 [6.0, 10.3]	0.326 [0.159, 0.667]	0.0014	
Primary Disease Site of Origin									
Upper tract	74	38 (51.4)	10.6 [6.3, NC]	55	39 (70.9)	6.1 [4.3, 6.8]	0.430 [0.268, 0.691]	0.0003	0.7253
Lower tract	128	70 (54.7)	10.6 [8.3, 16.6]	146	110 (75.3)	6.2 [5.1, 6.3]	0.421 [0.309, 0.574]	<.0001	
Renal Function									
Normal	6	2 (33.3)	18.7 [0.7, NC]	13	8 (61.5)	6.2 [1.9, 7.0]	0.220 [0.025, 1.902]	0.1377	0.4925
Mild	49	22 (44.9)	14.6 [6.3, NC]	40	29 (72.5)	6.3 [6.0, 6.9]	0.394 [0.220, 0.708]	0.0013	
Moderate	140	82 (58.6)	8.8 [6.4, 14.4]	141	108 (76.6)	6.0 [4.6, 6.2]	0.457 [0.339, 0.617]	<.0001	
Severe	7	2 (28.6)	NC [0.6, NC]	8	5 (62.5)	3.7 [0.8, NC]	0.841 [0.118, 6.017]	0.8629	

Abbreviations: BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.6.1.1: Summary of Objective Response (BICR) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)	EV+Pembro vs. Plat+Gem
Number of patients at risk	240 (100.0%)	242 (100.0%)	
Number of patients with events	169 (70.4%)	125 (51.7%)	
Number of patients censored	71 (29.6%)	117 (48.3%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	31.9 [26.0, 37.9]	50.7 [44.1, 57.0]	
Month 6	27.1 [21.5, 33.0]	46.2 [39.5, 52.5]	
Month 9	26.6 [21.0, 32.5]	44.4 [37.7, 50.8]	
Month 12	26.6 [21.0, 32.5]	44.4 [37.7, 50.8]	
Month 18	26.6 [21.0, 32.5]	44.4 [37.7, 50.8]	
Month 24	26.6 [21.0, 32.5]	44.4 [37.7, 50.8]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	2.1 [2.1, 2.2]	3.9 [2.3, NC]	
Cox proportional hazards model			
Stratified HR [95% CI]			1.706 [1.351, 2.154]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

Abbreviations: BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent).
Objective response was defined as complete or partial response that was subsequently confirmed.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.6.1.2: Type of Events and Censoring of Objective Response (BICR) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)
Number of patients at risk	240 (100.0%)	242 (100.0%)
Number of patients with events	169 (70.4%)	125 (51.7%)
Objective Response	169 (70.4%)	125 (51.7%)
Number of patients censored	71 (29.6%)	117 (48.3%)
Censored due to missing measurable disease per RECIST v1.1 at baseline (a)	1 (0.4%)	2 (0.8%)
Censored due to missing post-baseline response (b)	70 (29.2%)	115 (47.5%)

Abbreviations: BICR=blinded independent central review; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; RECIST=Response Evaluation Criteria in Solid Tumors.
Note: Objective response was defined as complete or partial response that was subsequently confirmed.
(a) Patients without measurable disease per RECIST v1.1 at baseline were censored at date of randomization; (b) Patients without response (confirmed complete or partial response) measured per RECIST v1.1 were censored at minimum date of end of study, death or data cut-off.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.6.1.3: Summary of Objective Response (BICR) by Subgroups - Analysis Set mITT 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
PD-L1 Expression									
High (CPS>=10)	139	102 (73.4)	2.1 [2.1, 2.2]	140	75 (53.6)	2.7 [2.2, NC]	1.751 [1.295, 2.368]	0.0002	0.8363
Low (CPS<10)	101	67 (66.3)	2.2 [2.1, 2.3]	102	50 (49.0)	4.1 [2.3, NC]	1.642 [1.138, 2.369]	0.0072	
Liver Metastases									
Present	48	29 (60.4)	2.3 [2.1, 4.0]	48	28 (58.3)	2.3 [2.1, NC]	1.006 [0.595, 1.700]	0.9613	0.0471
Absent	192	140 (72.9)	2.1 [2.1, 2.2]	194	97 (50.0)	4.2 [2.3, NC]	1.934 [1.491, 2.509]	<.0001	
Age									
< 65 years	105	74 (70.5)	2.1 [2.1, 2.2]	106	59 (55.7)	2.3 [2.1, NC]	1.485 [1.048, 2.104]	0.0239	0.2876
>= 65 years	135	95 (70.4)	2.2 [2.1, 2.2]	136	66 (48.5)	4.4 [2.4, NC]	1.922 [1.400, 2.637]	<.0001	
Region									
Europe	98	66 (67.3)	2.1 [2.1, 2.2]	102	53 (52.0)	4.1 [2.2, NC]	1.689 [1.174, 2.431]	0.0043	0.7119
North America	57	38 (66.7)	2.2 [2.1, 3.9]	51	29 (56.9)	2.7 [2.1, NC]	1.456 [0.886, 2.393]	0.1334	
Rest of World	85	65 (76.5)	2.1 [2.1, 2.2]	89	43 (48.3)	2.4 [2.2, NC]	1.908 [1.288, 2.825]	0.0010	
Sex									
Male	198	141 (71.2)	2.2 [2.1, 2.2]	185	98 (53.0)	2.7 [2.2, NC]	1.638 [1.263, 2.123]	0.0001	0.6860
Female	42	28 (66.7)	2.1 [2.1, 2.3]	57	27 (47.4)	6.3 [2.2, NC]	1.879 [1.098, 3.215]	0.0200	
Race									
White	166	118 (71.1)	2.1 [2.1, 2.2]	149	77 (51.7)	3.9 [2.2, NC]	1.724 [1.289, 2.307]	0.0002	0.8012
Non-white	74	51 (68.9)	2.2 [2.1, 2.3]	93	48 (51.6)	3.4 [2.2, NC]	1.621 [1.090, 2.411]	0.0170	

Abbreviations: BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Objective response was defined as complete or PRpartial response that was subsequently confirmed.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

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Table 302.1.1002.6.1.3: Summary of Objective Response (BICR) by Subgroups - Analysis Set mITT 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
ECOG Status at Baseline									
0	136	102 (75.0)	2.1 [2.1, 2.2]	128	74 (57.8)	2.3 [2.2, 4.4]	1.665 [1.229, 2.256]	0.0008	0.5996
1-2	104	67 (64.4)	2.2 [2.1, 2.3]	113	50 (44.2)	NC [2.3, NC]	1.836 [1.265, 2.665]	0.0010	
Metastases at Baseline									
Visceral metastases	170	115 (67.6)	2.2 [2.1, 2.2]	161	76 (47.2)	6.3 [2.3, NC]	1.801 [1.343, 2.414]	<.0001	0.4915
Lymph node only	60	45 (75.0)	2.1 [2.1, 2.3]	67	39 (58.2)	2.3 [2.1, 4.2]	1.510 [0.976, 2.336]	0.0694	
Primary Disease Site of Origin									
Upper tract	61	43 (70.5)	2.1 [2.1, 2.2]	49	25 (51.0)	2.3 [2.1, NC]	1.527 [0.930, 2.507]	0.0895	0.5367
Lower tract	177	125 (70.6)	2.2 [2.1, 2.2]	193	100 (51.8)	3.9 [2.3, NC]	1.739 [1.333, 2.269]	<.0001	
Renal Function									
Normal	78	53 (67.9)	2.2 [2.1, 2.3]	82	50 (61.0)	2.3 [2.1, 6.2]	1.276 [0.865, 1.881]	0.1971	0.2977
Mild	116	81 (69.8)	2.1 [2.1, 2.2]	122	56 (45.9)	NC [2.3, NC]	1.946 [1.381, 2.744]	0.0001	
Moderate	46	35 (76.1)	2.2 [2.1, 2.3]	38	19 (50.0)	3.9 [2.2, NC]	2.609 [1.360, 5.006]	0.0030	

Abbreviations: BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Objective response was defined as complete or PRpartial response that was subsequently confirmed.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

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Table 302.1.1002.6.2.1: Summary of Objective Response (BICR) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)	EV+Pembro vs. Plat+Gem
Number of patients at risk	202 (100.0%)	202 (100.0%)	
Number of patients with events	127 (62.9%)	71 (35.1%)	
Number of patients censored	75 (37.1%)	131 (64.9%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	38.1 [31.1, 45.1]	67.3 [60.2, 73.5]	
Month 6	31.4 [24.7, 38.3]	63.8 [56.4, 70.2]	
Month 9	31.4 [24.7, 38.3]	61.1 [53.4, 67.9]	
Month 12	31.4 [24.7, 38.3]	61.1 [53.4, 67.9]	
Month 18	30.0 [23.2, 37.1]	61.1 [53.4, 67.9]	
Month 24	30.0 [23.2, 37.1]	61.1 [53.4, 67.9]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	2.2 [2.1, 2.3]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR [95% CI]			2.369 [1.769, 3.173]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

Abbreviations: BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent).
Objective response was defined as complete or partial response that was subsequently confirmed.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
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Table 302.1.1002.6.2.2: Type of Events and Censoring of Objective Response (BICR) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)
Number of patients at risk	202 (100.0%)	202 (100.0%)
Number of patients with events	127 (62.9%)	71 (35.1%)
Objective Response	127 (62.9%)	71 (35.1%)
Number of patients censored	75 (37.1%)	131 (64.9%)
Censored due to missing measurable disease per RECIST v1.1 at baseline (a)	4 (2.0%)	1 (0.5%)
Censored due to missing post-baseline response (b)	71 (35.1%)	130 (64.4%)

Abbreviations: BICR=blinded independent central review; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; RECIST=Response Evaluation Criteria in Solid Tumors.
Note: Objective response was defined as complete or partial response that was subsequently confirmed.
(a) Patients without measurable disease per RECIST v1.1 at baseline were censored at date of randomization; (b) Patients without response (confirmed complete or partial response) measured per RECIST v1.1 were censored at minimum date of end of study, death or data cut-off.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.6.2.3: Summary of Objective Response (BICR) by Subgroups - Analysis Set mITT 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
PD-L1 Expression									
High (CPS>=10)	117	80 (68.4)	2.2 [2.1, 2.3]	115	44 (38.3)	NC [8.3, NC]	2.423 [1.674, 3.509]	<.0001	0.9388
Low (CPS<10)	85	47 (55.3)	2.1 [2.1, 4.2]	87	27 (31.0)	NC [NC, NC]	2.282 [1.418, 3.671]	0.0005	
Liver Metastases									
Present	50	29 (58.0)	2.2 [2.1, 3.9]	50	14 (28.0)	NC [7.7, NC]	2.996 [1.578, 5.687]	0.0004	0.3188
Absent	152	98 (64.5)	2.2 [2.1, 2.3]	152	57 (37.5)	NC [NC, NC]	2.221 [1.600, 3.085]	<.0001	
Age									
< 65 years	39	24 (61.5)	2.2 [2.1, 4.1]	29	11 (37.9)	NC [2.6, NC]	2.550 [1.191, 5.460]	0.0132	0.7588
>= 65 years	163	103 (63.2)	2.2 [2.1, 2.3]	173	60 (34.7)	NC [NC, NC]	2.372 [1.722, 3.267]	<.0001	
Region									
Europe	74	46 (62.2)	2.2 [2.1, 4.0]	95	38 (40.0)	NC [3.5, NC]	1.840 [1.184, 2.859]	0.0062	0.1896
North America	46	28 (60.9)	2.2 [2.1, 4.1]	34	13 (38.2)	NC [2.1, NC]	2.055 [1.050, 4.019]	0.0322	
Rest of World	82	53 (64.6)	2.2 [2.1, 2.3]	73	20 (27.4)	NC [NC, NC]	3.487 [2.065, 5.885]	<.0001	
Sex									
Male	146	91 (62.3)	2.2 [2.1, 2.3]	151	54 (35.8)	NC [NC, NC]	2.380 [1.696, 3.342]	<.0001	0.8667
Female	56	36 (64.3)	2.2 [2.1, 4.1]	51	17 (33.3)	NC [7.7, NC]	2.426 [1.339, 4.394]	0.0025	
Race									
White	142	86 (60.6)	2.2 [2.2, 3.9]	141	53 (37.6)	NC [NC, NC]	1.933 [1.370, 2.726]	0.0001	0.0441
Non-white	60	41 (68.3)	2.1 [2.0, 2.2]	61	18 (29.5)	NC [8.3, NC]	4.168 [2.315, 7.505]	<.0001	

Abbreviations: BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Objective response was defined as complete or PRpartial response that was subsequently confirmed.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

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Table 302.1.1002.6.2.3: Summary of Objective Response (BICR) by Subgroups - Analysis Set mITT 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
ECOG Status at Baseline									
0	87	59 (67.8)	2.2 [2.1, 2.3]	87	32 (36.8)	NC [NC, NC]	2.581 [1.671, 3.985]	<.0001	0.5792
1-2	115	68 (59.1)	2.2 [2.1, 3.0]	114	39 (34.2)	NC [7.7, NC]	2.171 [1.458, 3.232]	<.0001	
Metastases at Baseline									
Visceral metastases	148	87 (58.8)	2.2 [2.1, 2.6]	157	50 (31.8)	NC [NC, NC]	2.450 [1.727, 3.475]	<.0001	0.7660
Lymph node only	43	34 (79.1)	2.2 [2.1, 2.3]	37	16 (43.2)	NC [2.2, NC]	2.440 [1.333, 4.466]	0.0026	
Primary Disease Site of Origin									
Upper tract	74	47 (63.5)	2.2 [2.1, 2.3]	55	17 (30.9)	NC [NC, NC]	2.891 [1.652, 5.061]	0.0001	0.4412
Lower tract	128	80 (62.5)	2.2 [2.1, 2.5]	146	54 (37.0)	NC [8.3, NC]	2.202 [1.556, 3.116]	<.0001	
Renal Function									
Normal	6	5 (83.3)	2.0 [2.0, 2.1]	13	3 (23.1)	NC [2.3, NC]	12.635 [1.269, 125.83]	0.0125	0.0985
Mild	49	30 (61.2)	2.2 [2.1, 3.9]	40	16 (40.0)	NC [2.3, NC]	2.309 [1.232, 4.328]	0.0076	
Moderate	140	88 (62.9)	2.2 [2.1, 2.3]	141	49 (34.8)	NC [NC, NC]	2.318 [1.630, 3.296]	<.0001	
Severe	7	4 (57.1)	2.2 [2.0, NC]	8	3 (37.5)	NC [1.7, NC]	0.707 [0.140, 3.561]	0.6729	

Abbreviations: BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Objective response was defined as complete or PRpartial response that was subsequently confirmed.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

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Table 302.1.1002.7.1.1: Summary of Duration of Response (BICR) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)	EV+Pembro vs. Plat+Gem
Number of patients at risk	240 (100.0%)	242 (100.0%)	
Number of patients with events	55 (22.9%)	70 (28.9%)	
Number of patients censored	185 (77.1%)	172 (71.1%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	99.4 [95.8, 99.9]	98.2 [93.2, 99.6]	
Month 6	87.1 [80.9, 91.4]	61.3 [51.4, 69.8]	
Month 9	72.0 [64.1, 78.5]	46.5 [36.3, 56.1]	
Month 12	66.9 [58.5, 74.0]	41.2 [31.0, 51.0]	
Month 18	62.0 [52.9, 69.9]	19.8 [10.0, 32.0]	
Month 24	55.0 [41.9, 66.3]	19.8 [10.0, 32.0]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [18.2, NC]	8.3 [6.2, 12.1]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.368 [0.256, 0.530]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

Abbreviations: BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent).
Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.7.1.2: Type of Events and Censoring of Duration of Response (BICR) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)
Number of patients at risk	240 (100.0%)	242 (100.0%)
Number of patients with events	55 (22.9%)	70 (28.9%)
Death	5 (2.1%)	3 (1.2%)
Radiological Progression	50 (20.8%)	67 (27.7%)
Number of patients censored	185 (77.1%)	172 (71.1%)
Censored due to missing measurable disease per RECIST v1.1 at baseline (a)	1 (0.4%)	2 (0.8%)
Censored due to missing post-baseline response (b)	70 (29.2%)	115 (47.5%)
New Anti-Cancer Therapy	9 (3.8%)	8 (3.3%)
No Documented Pd Or Death	104 (43.3%)	44 (18.2%)
Pd Or Death After >= 2 Missed Assessments	1 (0.4%)	3 (1.2%)

Abbreviations: BICR=blinded independent central review; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; RECIST=Response Evaluation Criteria in Solid Tumors.
Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.
(a) Patients without measurable disease per RECIST v1.1 at baseline were censored at date of randomization; (b) Patients without response (confirmed complete or partial response) measured per RECIST v1.1 were censored at date of randomization.
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Table 302.1.1002.7.1.3: Summary of Duration of Response (BICR) by Subgroups - Analysis Set mITT 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
PD-L1 Expression									
High (CPS>=10)	139	29 (20.9)	NC [20.2, NC]	140	40 (28.6)	8.9 [5.5, 14.7]	0.396 [0.242, 0.648]	0.0001	0.9075
Low (CPS<10)	101	26 (25.7)	NC [10.6, NC]	102	30 (29.4)	8.3 [5.5, 10.4]	0.339 [0.199, 0.578]	<.0001	
Liver Metastases									
Present	48	15 (31.3)	14.7 [8.4, 20.2]	48	19 (39.6)	5.0 [4.3, 12.6]	0.346 [0.166, 0.721]	0.0034	0.9504
Absent	192	40 (20.8)	NC [NC, NC]	194	51 (26.3)	8.9 [6.8, 12.5]	0.376 [0.248, 0.571]	<.0001	
Age									
< 65 years	105	24 (22.9)	NC [14.7, NC]	106	33 (31.1)	8.3 [5.8, 12.5]	0.277 [0.155, 0.494]	<.0001	0.5532
>= 65 years	135	31 (23.0)	NC [14.6, NC]	136	37 (27.2)	8.3 [5.5, 12.5]	0.426 [0.262, 0.693]	0.0004	
Region									
Europe	98	21 (21.4)	NC [14.5, NC]	102	30 (29.4)	8.3 [5.5, 12.5]	0.331 [0.184, 0.595]	0.0001	0.3610
North America	57	18 (31.6)	14.6 [8.4, NC]	51	19 (37.3)	6.8 [4.4, 14.0]	0.533 [0.272, 1.045]	0.0626	
Rest of World	85	16 (18.8)	NC [NC, NC]	89	21 (23.6)	10.4 [6.0, 17.1]	0.267 [0.132, 0.538]	<.0001	
Sex									
Male	198	43 (21.7)	NC [20.2, NC]	185	57 (30.8)	8.3 [6.0, 10.9]	0.327 [0.216, 0.493]	<.0001	0.1088
Female	42	12 (28.6)	10.6 [8.3, NC]	57	13 (22.8)	14.7 [5.0, 17.4]	0.784 [0.333, 1.845]	0.5758	
Race									
White	166	43 (25.9)	NC [14.6, NC]	149	46 (30.9)	8.3 [5.5, 12.1]	0.412 [0.268, 0.634]	<.0001	0.4377
Non-white	74	12 (16.2)	NC [NC, NC]	93	24 (25.8)	8.3 [5.8, 14.0]	0.297 [0.147, 0.601]	0.0004	

Abbreviations: BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Duration of response is defined as the time from the first objective response (complete or partial that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

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Table 302.1.1002.7.1.3: Summary of Duration of Response (BICR) by Subgroups - Analysis Set mITT 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
ECOG Status at Baseline									
0	136	22 (16.2)	NC [NC, NC]	128	45 (35.2)	8.3 [6.0, 10.9]	0.189 [0.110, 0.324]	<.0001	0.0012
1-2	104	33 (31.7)	10.6 [8.3, NC]	113	25 (22.1)	8.3 [5.1, 17.4]	0.714 [0.418, 1.219]	0.2126	
Metastases at Baseline									
Visceral metastases	170	43 (25.3)	20.2 [12.9, NC]	161	50 (31.1)	6.5 [5.4, 8.9]	0.366 [0.240, 0.559]	<.0001	0.9133
Lymph node only	60	9 (15.0)	NC [NC, NC]	67	15 (22.4)	12.5 [8.3, NC]	0.344 [0.148, 0.796]	0.0092	
Primary Disease Site of Origin									
Upper tract	61	16 (26.2)	NC [10.6, NC]	49	13 (26.5)	9.0 [4.4, NC]	0.520 [0.238, 1.133]	0.0953	0.6260
Lower tract	177	38 (21.5)	NC [18.2, NC]	193	57 (29.5)	8.3 [6.5, 12.4]	0.334 [0.219, 0.510]	<.0001	
Renal Function									
Normal	78	15 (19.2)	NC [18.2, NC]	82	29 (35.4)	8.3 [5.4, 12.6]	0.233 [0.117, 0.461]	<.0001	0.3490
Mild	116	27 (23.3)	NC [14.6, NC]	122	32 (26.2)	8.3 [5.5, 10.3]	0.453 [0.267, 0.768]	0.0027	
Moderate	46	13 (28.3)	20.2 [8.4, NC]	38	9 (23.7)	12.4 [5.1, NC]	0.533 [0.214, 1.326]	0.1696	

Abbreviations: BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Duration of response is defined as the time from the first objective response (complete or partial that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.7.2.1: Summary of Duration of Response (BICR) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)	EV+Pembro vs. Plat+Gem
Number of patients at risk	202 (100.0%)	202 (100.0%)	
Number of patients with events	44 (21.8%)	49 (24.3%)	
Number of patients censored	158 (78.2%)	153 (75.7%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	100.0 [100.0, 100.0]	100.0 [100.0, 100.0]	
Month 6	84.3 [76.5, 89.7]	59.3 [46.2, 70.2]	
Month 9	70.1 [60.6, 77.7]	37.9 [25.9, 49.7]	
Month 12	68.0 [58.4, 75.8]	25.7 [15.1, 37.7]	
Month 18	56.3 [44.7, 66.3]	16.5 [7.2, 29.2]	
Month 24	51.6 [37.6, 63.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [14.6, NC]	6.4 [5.4, 8.6]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.314 [0.205, 0.480]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

Abbreviations: BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent).
Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.7.2.2: Type of Events and Censoring of Duration of Response (BICR) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)
Number of patients at risk	202 (100.0%)	202 (100.0%)
Number of patients with events	44 (21.8%)	49 (24.3%)
Death	10 (5.0%)	2 (1.0%)
Radiological Progression	34 (16.8%)	47 (23.3%)
Number of patients censored	158 (78.2%)	153 (75.7%)
Censored due to missing measurable disease per RECIST v1.1 at baseline (a)	4 (2.0%)	1 (0.5%)
Censored due to missing post-baseline response (b)	71 (35.1%)	130 (64.4%)
New Anti-Cancer Therapy	6 (3.0%)	2 (1.0%)
No Documented Pd Or Death	75 (37.1%)	20 (9.9%)
Pd Or Death After >= 2 Missed Assessments	2 (1.0%)	0

Abbreviations: BICR=blinded independent central review; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; RECIST=Response Evaluation Criteria in Solid Tumors.
Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.
(a) Patients without measurable disease per RECIST v1.1 at baseline were censored at date of randomization; (b) Patients without response (confirmed complete or partial response) measured per RECIST v1.1 were censored at date of randomization.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.7.2.3: Summary of Duration of Response (BICR) by Subgroups - Analysis Set mITT 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
PD-L1 Expression									
High (CPS>=10)	117	25 (21.4)	NC [16.3, NC]	115	32 (27.8)	6.4 [4.2, 10.2]	0.264 [0.152, 0.456]	<.0001	0.1501
Low (CPS<10)	85	19 (22.4)	12.6 [8.6, NC]	87	17 (19.5)	6.6 [5.0, 14.6]	0.412 [0.208, 0.815]	0.0087	
Liver Metastases									
Present	50	13 (26.0)	16.6 [6.2, 20.3]	50	11 (22.0)	5.1 [4.1, 10.2]	0.346 [0.145, 0.825]	0.0128	0.7166
Absent	152	31 (20.4)	NC [16.3, NC]	152	38 (25.0)	6.7 [5.6, 10.3]	0.304 [0.187, 0.496]	<.0001	
Age									
< 65 years	39	9 (23.1)	20.3 [12.6, NC]	29	7 (24.1)	4.9 [3.9, NC]	0.191 [0.054, 0.679]	0.0063	0.2750
>= 65 years	163	35 (21.5)	NC [14.6, NC]	173	42 (24.3)	6.7 [5.6, 10.2]	0.361 [0.228, 0.572]	<.0001	
Region									
Europe	74	21 (28.4)	20.3 [8.3, NC]	95	27 (28.4)	6.5 [5.0, 10.2]	0.424 [0.232, 0.774]	0.0040	0.2488
North America	46	7 (15.2)	NC [14.6, NC]	34	10 (29.4)	4.5 [4.0, 10.2]	0.128 [0.038, 0.428]	0.0002	
Rest of World	82	16 (19.5)	NC [12.5, NC]	73	12 (16.4)	6.7 [4.4, 14.5]	0.313 [0.135, 0.727]	0.0047	
Sex									
Male	146	30 (20.5)	NC [16.3, NC]	151	37 (24.5)	6.5 [5.5, 8.6]	0.285 [0.171, 0.474]	<.0001	0.4233
Female	56	14 (25.0)	NC [8.1, NC]	51	12 (23.5)	7.6 [4.2, 12.5]	0.496 [0.219, 1.126]	0.0952	
Race									
White	142	33 (23.2)	NC [9.8, NC]	141	41 (29.1)	6.1 [4.2, 6.6]	0.291 [0.176, 0.482]	<.0001	0.3725
Non-white	60	11 (18.3)	20.3 [16.3, NC]	61	8 (13.1)	10.6 [7.0, NC]	0.400 [0.150, 1.065]	0.0588	

Abbreviations: BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Duration of response is defined as the time from the first objective response (complete or partial that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.7.2.3: Summary of Duration of Response (BICR) by Subgroups - Analysis Set mITT 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
ECOG Status at Baseline									
0	87	19 (21.8)	20.3 [12.6, NC]	87	23 (26.4)	6.2 [4.3, 10.2]	0.280 [0.146, 0.537]	<.0001	0.5407
1-2	115	25 (21.7)	NC [13.1, NC]	114	26 (22.8)	6.5 [4.9, 10.3]	0.341 [0.189, 0.613]	0.0002	
Metastases at Baseline									
Visceral metastases	148	35 (23.6)	16.6 [10.2, NC]	157	38 (24.2)	6.1 [4.2, 6.6]	0.319 [0.197, 0.518]	<.0001	0.9103
Lymph node only	43	9 (20.9)	NC [16.3, NC]	37	8 (21.6)	12.5 [6.2, 22.1]	0.212 [0.072, 0.623]	0.0026	
Primary Disease Site of Origin									
Upper tract	74	13 (17.6)	NC [12.5, NC]	55	12 (21.8)	5.0 [4.1, 10.4]	0.251 [0.101, 0.622]	0.0016	0.5321
Lower tract	128	31 (24.2)	20.3 [13.1, NC]	146	37 (25.3)	6.6 [5.6, 10.2]	0.334 [0.203, 0.549]	<.0001	
Renal Function									
Normal	6	1 (16.7)	NC [16.6, NC]	13	2 (15.4)	5.0 [3.9, NC]	0.000 [0.000, NC]	0.1336	0.1219
Mild	49	7 (14.3)	NC [12.6, NC]	40	12 (30.0)	5.1 [4.2, 6.6]	0.162 [0.055, 0.479]	0.0003	
Moderate	140	35 (25.0)	20.3 [12.5, NC]	141	33 (23.4)	7.0 [6.1, 10.4]	0.416 [0.251, 0.689]	0.0005	
Severe	7	1 (14.3)	NC [3.7, NC]	8	2 (25.0)	4.1 [3.4, NC]	0.816 [0.050, 13.241]	0.8864	

Abbreviations: BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Duration of response is defined as the time from the first objective response (complete or partial that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.8.1.1: Summary of Disease Control (BICR) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)	EV+Pembro vs. Plat+Gem
Number of patients at risk	240 (100.0%)	242 (100.0%)	
Number of patients with events	207 (86.3%)	199 (82.2%)	
Number of patients censored	33 (13.8%)	43 (17.8%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	10.8 [7.2, 15.2]	14.0 [9.9, 18.9]	
Month 6	10.8 [7.2, 15.2]	12.9 [8.9, 17.7]	
Month 9	10.8 [7.2, 15.2]	12.9 [8.9, 17.7]	
Month 12	10.8 [7.2, 15.2]	12.9 [8.9, 17.7]	
Month 18	10.8 [7.2, 15.2]	12.9 [8.9, 17.7]	
Month 24	NC [NC, NC]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	2.1 [NC, NC]	2.1 [2.1, 2.1]	
Cox proportional hazards model			
Stratified HR [95% CI]			1.225 [1.006, 1.491]
Log-rank test			
Two-sided stratified log-rank p-value			0.0489

Abbreviations: BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent).
Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.8.1.2: Type of Events and Censoring of Disease Control (BICR) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)
Number of patients at risk	240 (100.0%)	242 (100.0%)
Number of patients with events	207 (86.3%)	199 (82.2%)
Disease control	207 (86.3%)	199 (82.2%)
Number of patients censored	33 (13.8%)	43 (17.8%)
Censored due to missing measurable disease per RECIST v1.1 at baseline (a)	1 (0.4%)	2 (0.8%)
Censored due to missing post-baseline response (b)	32 (13.3%)	41 (16.9%)

Abbreviations: BICR=blinded independent central review; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; RECIST=Response Evaluation Criteria in Solid Tumors.
Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.
(a) Patients without measurable disease per RECIST v1.1 at baseline were censored at date of randomization; (b) Patients without response (confirmed CR or PR) measured per RECIST v1.1 were censored at minimum date of end of study, death or data cut-off.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.8.1.3: Summary of Disease Control (BICR) by Subgroups - Analysis Set mITT 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
PD-L1 Expression									
High (CPS>=10)	139	120 (86.3)	2.1 [2.1, 2.1]	140	114 (81.4)	2.1 [2.1, 2.1]	1.207 [0.931, 1.566]	0.1708	0.8835
Low (CPS<10)	101	87 (86.1)	2.1 [2.0, 2.1]	102	85 (83.3)	2.1 [2.1, 2.1]	1.249 [0.925, 1.687]	0.1536	
Liver Metastases									
Present	48	35 (72.9)	2.2 [2.1, 2.3]	48	40 (83.3)	2.1 [2.0, 2.1]	0.728 [0.459, 1.154]	0.1910	0.0190
Absent	192	172 (89.6)	2.1 [2.1, 2.1]	194	159 (82.0)	2.1 [2.1, 2.1]	1.374 [1.106, 1.707]	0.0048	
Age									
< 65 years	105	91 (86.7)	2.1 [2.1, 2.1]	106	88 (83.0)	2.1 [2.1, 2.1]	1.137 [0.845, 1.528]	0.4041	0.6282
>= 65 years	135	116 (85.9)	2.1 [2.1, 2.1]	136	111 (81.6)	2.1 [2.1, 2.2]	1.330 [1.019, 1.735]	0.0415	
Region									
Europe	98	82 (83.7)	2.1 [2.1, 2.1]	102	84 (82.4)	2.1 [2.1, 2.2]	1.273 [0.934, 1.734]	0.1285	0.6343
North America	57	49 (86.0)	2.1 [2.0, 2.1]	51	45 (88.2)	2.1 [2.1, 2.2]	1.451 [0.948, 2.223]	0.0800	
Rest of World	85	76 (89.4)	2.1 [2.1, 2.1]	89	70 (78.7)	2.1 [2.1, 2.1]	1.145 [0.819, 1.600]	0.4693	
Sex									
Male	198	170 (85.9)	2.1 [NC, NC]	185	152 (82.2)	2.1 [2.1, 2.1]	1.238 [0.992, 1.544]	0.0634	0.8937
Female	42	37 (88.1)	2.1 [2.1, 2.1]	57	47 (82.5)	2.1 [2.1, 2.2]	1.238 [0.791, 1.936]	0.3852	
Race									
White	166	142 (85.5)	2.1 [2.1, 2.1]	149	122 (81.9)	2.1 [2.1, 2.2]	1.280 [1.002, 1.635]	0.0486	0.6121
Non-white	74	65 (87.8)	2.1 [2.0, 2.1]	93	77 (82.8)	2.1 [2.0, 2.1]	1.146 [0.821, 1.599]	0.4648	

Abbreviations: BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.8.1.3: Summary of Disease Control (BICR) by Subgroups - Analysis Set mITT 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
ECOG Status at Baseline									
0	136	124 (91.2)	2.1 [2.1, 2.1]	128	110 (85.9)	2.1 [2.1, 2.1]	1.320 [1.018, 1.712]	0.0424	0.5752
1-2	104	83 (79.8)	2.1 [2.1, 2.1]	113	88 (77.9)	2.1 [2.1, 2.2]	1.152 [0.850, 1.562]	0.3592	
Metastases at Baseline									
Visceral metastases	170	142 (83.5)	2.1 [2.1, 2.1]	161	130 (80.7)	2.1 [2.1, 2.1]	1.211 [0.951, 1.543]	0.1219	0.4774
Lymph node only	60	55 (91.7)	2.1 [2.0, 2.1]	67	58 (86.6)	2.1 [2.0, 2.1]	1.009 [0.690, 1.475]	0.9657	
Primary Disease Site of Origin									
Upper tract	61	51 (83.6)	2.1 [2.0, 2.1]	49	36 (73.5)	2.1 [2.1, 2.1]	1.180 [0.766, 1.817]	0.4544	0.6435
Lower tract	177	155 (87.6)	2.1 [NC, NC]	193	163 (84.5)	2.1 [2.1, 2.1]	1.276 [1.021, 1.594]	0.0348	
Renal Function									
Normal	78	69 (88.5)	2.1 [2.0, 2.1]	82	71 (86.6)	2.1 [2.1, 2.2]	1.288 [0.919, 1.805]	0.1311	0.3511
Mild	116	97 (83.6)	2.1 [2.1, 2.1]	122	96 (78.7)	2.1 [2.1, 2.2]	1.300 [0.975, 1.733]	0.0913	
Moderate	46	41 (89.1)	2.1 [2.1, 2.2]	38	32 (84.2)	2.1 [2.0, 2.1]	0.855 [0.522, 1.401]	0.4948	

Abbreviations: BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.8.2.1: Summary of Disease Control (BICR) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)	EV+Pembro vs. Plat+Gem
Number of patients at risk	202 (100.0%)	202 (100.0%)	
Number of patients with events	171 (84.7%)	146 (72.3%)	
Number of patients censored	31 (15.3%)	56 (27.7%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	8.5 [5.0, 13.1]	23.3 [17.5, 29.6]	
Month 6	7.8 [4.4, 12.3]	22.6 [16.9, 28.9]	
Month 9	7.8 [4.4, 12.3]	22.6 [16.9, 28.9]	
Month 12	7.8 [4.4, 12.3]	22.6 [16.9, 28.9]	
Month 18	7.8 [4.4, 12.3]	22.6 [16.9, 28.9]	
Month 24	NC [NC, NC]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	2.1 [2.1, 2.1]	2.1 [2.1, 2.1]	
Cox proportional hazards model			
Stratified HR [95% CI]			1.399 [1.119, 1.749]
Log-rank test			
Two-sided stratified log-rank p-value			0.0027

Abbreviations: BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent).
Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.8.2.2: Type of Events and Censoring of Disease Control (BICR) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)
Number of patients at risk	202 (100.0%)	202 (100.0%)
Number of patients with events	171 (84.7%)	146 (72.3%)
Disease control	171 (84.7%)	146 (72.3%)
Number of patients censored	31 (15.3%)	56 (27.7%)
Censored due to missing measurable disease per RECIST v1.1 at baseline (a)	4 (2.0%)	1 (0.5%)
Censored due to missing post-baseline response (b)	27 (13.4%)	55 (27.2%)

Abbreviations: BICR=blinded independent central review; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; RECIST=Response Evaluation Criteria in Solid Tumors.
Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.
(a) Patients without measurable disease per RECIST v1.1 at baseline were censored at date of randomization; (b) Patients without response (confirmed CR or PR) measured per RECIST v1.1 were censored at minimum date of end of study, death or data cut-off.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.8.2.3: Summary of Disease Control (BICR) by Subgroups - Analysis Set mITT 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
PD-L1 Expression									
High (CPS>=10)	117	102 (87.2)	2.1 [2.1, 2.1]	115	88 (76.5)	2.1 [2.1, 2.1]	1.306 [0.980, 1.742]	0.0643	0.4533
Low (CPS<10)	85	69 (81.2)	2.1 [2.0, 2.1]	87	58 (66.7)	2.1 [2.1, 2.2]	1.550 [1.090, 2.205]	0.0132	
Liver Metastases									
Present	50	38 (76.0)	2.1 [2.0, 2.1]	50	30 (60.0)	2.2 [2.1, NC]	1.984 [1.224, 3.217]	0.0042	0.0536
Absent	152	133 (87.5)	2.1 [2.1, 2.1]	152	116 (76.3)	2.1 [2.1, 2.1]	1.272 [0.990, 1.634]	0.0579	
Age									
< 65 years	39	33 (84.6)	2.1 [2.0, 2.1]	29	20 (69.0)	2.1 [2.1, 2.6]	1.540 [0.860, 2.758]	0.1252	0.5137
>= 65 years	163	138 (84.7)	2.1 [2.1, 2.1]	173	126 (72.8)	2.1 [2.1, 2.1]	1.326 [1.039, 1.693]	0.0188	
Region									
Europe	74	65 (87.8)	2.1 [2.1, 2.2]	95	75 (78.9)	2.1 [2.1, 2.1]	1.099 [0.784, 1.539]	0.5521	0.0985
North America	46	36 (78.3)	2.1 [2.0, 2.1]	34	23 (67.6)	2.1 [2.0, 2.3]	1.233 [0.726, 2.096]	0.4318	
Rest of World	82	70 (85.4)	2.1 [2.1, 2.1]	73	48 (65.8)	2.2 [2.1, 2.4]	1.867 [1.272, 2.740]	0.0011	
Sex									
Male	146	121 (82.9)	2.1 [2.1, 2.1]	151	111 (73.5)	2.1 [2.1, 2.1]	1.418 [1.093, 1.841]	0.0079	0.9835
Female	56	50 (89.3)	2.1 [2.1, 2.1]	51	35 (68.6)	2.1 [2.0, 2.2]	1.445 [0.921, 2.265]	0.0975	
Race									
White	142	120 (84.5)	2.1 [2.1, 2.1]	141	105 (74.5)	2.1 [2.1, 2.1]	1.232 [0.945, 1.608]	0.1122	0.0704
Non-white	60	51 (85.0)	2.1 [2.0, 2.1]	61	41 (67.2)	2.1 [2.1, 2.3]	2.051 [1.315, 3.201]	0.0012	

Abbreviations: BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.8.2.3: Summary of Disease Control (BICR) by Subgroups - Analysis Set mITT 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
ECOG Status at Baseline									
0	87	80 (92.0)	2.1 [2.0, 2.1]	87	67 (77.0)	2.1 [2.1, 2.2]	1.506 [1.078, 2.103]	0.0150	0.3848
1-2	115	91 (79.1)	2.1 [2.1, 2.1]	114	79 (69.3)	2.1 [2.1, 2.1]	1.296 [0.956, 1.757]	0.0833	
Metastases at Baseline									
Visceral metastases	148	121 (81.8)	2.1 [2.1, 2.1]	157	105 (66.9)	2.1 [2.1, 2.2]	1.547 [1.188, 2.015]	0.0011	0.0434
Lymph node only	43	40 (93.0)	2.1 [2.1, 2.2]	37	34 (91.9)	2.1 [2.1, 2.2]	0.915 [0.576, 1.453]	0.7324	
Primary Disease Site of Origin									
Upper tract	74	65 (87.8)	2.1 [2.1, 2.1]	55	40 (72.7)	2.1 [2.1, 2.1]	1.525 [1.016, 2.288]	0.0442	0.6204
Lower tract	128	106 (82.8)	2.1 [2.1, 2.1]	146	106 (72.6)	2.1 [2.1, 2.2]	1.324 [1.009, 1.736]	0.0390	
Renal Function									
Normal	6	5 (83.3)	2.0 [2.0, 2.1]	13	8 (61.5)	2.3 [1.9, NC]	3.943 [0.847, 18.354]	0.0668	0.1604
Mild	49	40 (81.6)	2.1 [2.1, 2.1]	40	34 (85.0)	2.1 [2.1, 2.2]	1.031 [0.648, 1.641]	0.9138	
Moderate	140	121 (86.4)	2.1 [2.1, 2.1]	141	101 (71.6)	2.1 [2.1, 2.1]	1.392 [1.065, 1.820]	0.0127	
Severe	7	5 (71.4)	2.1 [2.0, NC]	8	3 (37.5)	NC [1.7, NC]	0.707 [0.140, 3.561]	0.6729	

Abbreviations: BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

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Table 302.1.1002.9.1.1: Summary of Complete Response (BICR) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)	EV+Pembro vs. Plat+Gem
Number of patients at risk	240 (100.0%)	242 (100.0%)	
Number of patients with events	77 (32.1%)	36 (14.9%)	
Number of patients censored	163 (67.9%)	206 (85.1%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	88.8 [84.0, 92.2]	95.2 [91.5, 97.3]	
Month 6	79.4 [73.5, 84.1]	88.6 [83.6, 92.2]	
Month 9	71.8 [65.3, 77.2]	84.1 [78.3, 88.5]	
Month 12	68.3 [61.6, 74.1]	83.3 [77.4, 87.9]	
Month 18	61.6 [53.9, 68.4]	81.5 [74.9, 86.4]	
Month 24	61.6 [53.9, 68.4]	81.5 [74.9, 86.4]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR [95% CI]			2.209 [1.486, 3.283]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

Abbreviations: BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent).
Complete response was defined as first confirmed complete response.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.9.1.2: Type of Events and Censoring of Complete Response (BICR) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)
Number of patients at risk	240 (100.0%)	242 (100.0%)
Number of patients with events	77 (32.1%)	36 (14.9%)
Complete Response	77 (32.1%)	36 (14.9%)
Number of patients censored	163 (67.9%)	206 (85.1%)
Censored due to missing measurable disease per RECIST v1.1 at baseline (a)	1 (0.4%)	2 (0.8%)
Censored due to best response other than CR	162 (67.5%)	204 (84.3%)

Abbreviations: BICR=blinded independent central review; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; RECIST=Response Evaluation Criteria in Solid Tumors.
Note: Complete response was defined as first confirmed complete response.
(a) Patients without measurable disease per RECIST v1.1 at baseline were censored at date of randomization.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.9.1.3: Summary of Complete Response (BICR) by Subgroups - Analysis Set mITT 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
PD-L1 Expression									
High (CPS>=10)	139	51 (36.7)	NC [13.3, NC]	140	21 (15.0)	NC [NC, NC]	2.638 [1.586, 4.387]	0.0001	0.2629
Low (CPS<10)	101	26 (25.7)	NC [NC, NC]	102	15 (14.7)	NC [NC, NC]	1.636 [0.866, 3.089]	0.1241	
Liver Metastases									
Present	48	11 (22.9)	NC [17.6, NC]	48	3 (6.3)	NC [NC, NC]	4.304 [1.195, 15.494]	0.0150	0.3242
Absent	192	66 (34.4)	NC [NC, NC]	194	33 (17.0)	NC [NC, NC]	2.029 [1.335, 3.082]	0.0007	
Age									
< 65 years	105	30 (28.6)	NC [NC, NC]	106	16 (15.1)	NC [NC, NC]	1.989 [1.078, 3.670]	0.0248	0.4648
>= 65 years	135	47 (34.8)	NC [17.6, NC]	136	20 (14.7)	NC [NC, NC]	2.479 [1.468, 4.188]	0.0004	
Region									
Europe	98	34 (34.7)	NC [12.5, NC]	102	12 (11.8)	NC [NC, NC]	3.222 [1.659, 6.257]	0.0003	0.3871
North America	57	16 (28.1)	NC [17.6, NC]	51	10 (19.6)	NC [NC, NC]	1.499 [0.677, 3.317]	0.3155	
Rest of World	85	27 (31.8)	NC [14.6, NC]	89	14 (15.7)	NC [NC, NC]	1.905 [0.998, 3.636]	0.0449	
Sex									
Male	198	62 (31.3)	NC [NC, NC]	185	28 (15.1)	NC [NC, NC]	2.074 [1.325, 3.246]	0.0011	0.6497
Female	42	15 (35.7)	NC [8.0, NC]	57	8 (14.0)	NC [NC, NC]	2.988 [1.261, 7.083]	0.0092	
Race									
White	166	49 (29.5)	NC [NC, NC]	149	22 (14.8)	NC [NC, NC]	1.984 [1.199, 3.284]	0.0065	0.4190
Non-white	74	28 (37.8)	NC [10.4, NC]	93	14 (15.1)	NC [NC, NC]	2.717 [1.426, 5.174]	0.0015	

Abbreviations: BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Complete response was defined as first confirmed complete response.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.9.1.3: Summary of Complete Response (BICR) by Subgroups - Analysis Set mITT 1

Subgroup	EV+Pembro N	EV+Pembro n (%)	EV+Pembro KME [95% CI](a)	Plat+Gem N	Plat+Gem n (%)	Plat+Gem KME [95% CI](a)	EV+Pembro vs. Plat+Gem HR [95% CI](b)	Log-rank p-value(c)	Test for Interaction p-value(d)
ECOG Status at Baseline									
0	136	57 (41.9)	NC [10.4, NC]	128	21 (16.4)	NC [NC, NC]	2.880 [1.743, 4.759]	<.0001	0.1571
1-2	104	20 (19.2)	NC [NC, NC]	113	14 (12.4)	NC [NC, NC]	1.425 [0.718, 2.829]	0.3074	
Metastases at Baseline									
Visceral metastases	170	44 (25.9)	NC [NC, NC]	161	15 (9.3)	NC [NC, NC]	2.805 [1.558, 5.051]	0.0003	0.2467
Lymph node only	60	28 (46.7)	14.6 [6.3, NC]	67	18 (26.9)	NC [NC, NC]	1.675 [0.916, 3.061]	0.0922	
Primary Disease Site of Origin									
Upper tract	61	15 (24.6)	NC [NC, NC]	49	5 (10.2)	NC [NC, NC]	2.154 [0.781, 5.943]	0.1292	0.9548
Lower tract	177	61 (34.5)	NC [NC, NC]	193	31 (16.1)	NC [NC, NC]	2.211 [1.434, 3.409]	0.0002	
Renal Function									
Normal	78	32 (41.0)	NC [12.1, NC]	82	16 (19.5)	NC [NC, NC]	2.194 [1.203, 4.002]	0.0086	0.5708
Mild	116	29 (25.0)	NC [NC, NC]	122	16 (13.1)	NC [NC, NC]	1.730 [0.937, 3.192]	0.0751	
Moderate	46	16 (34.8)	NC [10.4, NC]	38	4 (10.5)	NC [NC, NC]	3.701 [1.224, 11.196]	0.0133	

Abbreviations: BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Complete response was defined as first confirmed complete response.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.9.2.1: Summary of Complete Response (BICR) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)	EV+Pembro vs. Plat+Gem
Number of patients at risk	202 (100.0%)	202 (100.0%)	
Number of patients with events	50 (24.8%)	19 (9.4%)	
Number of patients censored	152 (75.2%)	183 (90.6%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	90.9 [85.7, 94.2]	93.7 [89.1, 96.4]	
Month 6	82.9 [76.6, 87.7]	92.0 [87.0, 95.1]	
Month 9	77.3 [70.3, 82.8]	88.9 [83.1, 92.8]	
Month 12	76.5 [69.5, 82.2]	88.9 [83.1, 92.8]	
Month 18	67.3 [58.3, 74.8]	88.9 [83.1, 92.8]	
Month 24	65.0 [55.0, 73.3]	88.9 [83.1, 92.8]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR [95% CI]			2.572 [1.515, 4.367]
Log-rank test			
Two-sided stratified log-rank p-value			0.0003

Abbreviations: BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent).
Complete response was defined as first confirmed complete response.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.9.2.2: Type of Events and Censoring of Complete Response (BICR) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)
Number of patients at risk	202 (100.0%)	202 (100.0%)
Number of patients with events	50 (24.8%)	19 (9.4%)
Complete Response	50 (24.8%)	19 (9.4%)
Number of patients censored	152 (75.2%)	183 (90.6%)
Censored due to missing measurable disease per RECIST v1.1 at baseline (a)	4 (2.0%)	1 (0.5%)
Censored due to best response other than CR	148 (73.3%)	182 (90.1%)

Abbreviations: BICR=blinded independent central review; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; RECIST=Response Evaluation Criteria in Solid Tumors.
Note: Complete response was defined as first confirmed complete response.
(a) Patients without measurable disease per RECIST v1.1 at baseline were censored at date of randomization.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.1002.9.2.3: Summary of Complete Response (BICR) by Subgroups - Analysis Set mITT 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
PD-L1 Expression									
High (CPS>=10)	117	35 (29.9)	NC [NC, NC]	115	11 (9.6)	NC [NC, NC]	3.159 [1.603, 6.222]	0.0004	0.3526
Low (CPS<10)	85	15 (17.6)	NC [NC, NC]	87	8 (9.2)	NC [NC, NC]	1.770 [0.747, 4.197]	0.1884	
Liver Metastases									
Present	50	5 (10.0)	NC [NC, NC]	50	1 (2.0)	NC [NC, NC]	3.690 [0.427, 31.869]	0.2038	0.6124
Absent	152	45 (29.6)	NC [19.4, NC]	152	18 (11.8)	NC [NC, NC]	2.506 [1.450, 4.331]	0.0007	
Age									
< 65 years	39	12 (30.8)	NC [10.2, NC]	29	3 (10.3)	NC [NC, NC]	3.090 [0.857, 11.148]	0.0703	0.8800
>= 65 years	163	38 (23.3)	NC [NC, NC]	173	16 (9.2)	NC [NC, NC]	2.427 [1.352, 4.357]	0.0022	
Region									
Europe	74	16 (21.6)	NC [NC, NC]	95	9 (9.5)	NC [NC, NC]	2.157 [0.941, 4.946]	0.0633	0.4838
North America	46	9 (19.6)	NC [19.4, NC]	34	4 (11.8)	NC [NC, NC]	1.752 [0.531, 5.781]	0.3494	
Rest of World	82	25 (30.5)	NC [12.5, NC]	73	6 (8.2)	NC [NC, NC]	3.282 [1.346, 8.006]	0.0057	
Sex									
Male	146	38 (26.0)	NC [NC, NC]	151	12 (7.9)	NC [NC, NC]	3.475 [1.810, 6.672]	<.0001	0.1020
Female	56	12 (21.4)	NC [19.4, NC]	51	7 (13.7)	NC [NC, NC]	1.368 [0.532, 3.521]	0.5107	
Race									
White	142	29 (20.4)	NC [NC, NC]	141	10 (7.1)	NC [NC, NC]	2.819 [1.371, 5.798]	0.0032	0.7802
Non-white	60	21 (35.0)	NC [12.2, NC]	61	9 (14.8)	NC [NC, NC]	2.276 [1.033, 5.012]	0.0362	

Abbreviations: BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Complete response was defined as first confirmed complete response.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

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Table 302.1.1002.9.2.3: Summary of Complete Response (BICR) by Subgroups - Analysis Set mITT 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
ECOG Status at Baseline									
0	87	23 (26.4)	NC [NC, NC]	87	13 (14.9)	NC [NC, NC]	1.744 [0.879, 3.459]	0.1067	0.1052
1-2	115	27 (23.5)	NC [15.4, NC]	114	6 (5.3)	NC [NC, NC]	4.414 [1.814, 10.743]	0.0004	
Metastases at Baseline									
Visceral metastases	148	24 (16.2)	NC [NC, NC]	157	10 (6.4)	NC [NC, NC]	2.231 [1.063, 4.681]	0.0294	0.5989
Lymph node only	43	24 (55.8)	6.4 [4.2, NC]	37	8 (21.6)	NC [NC, NC]	3.090 [1.385, 6.893]	0.0035	
Primary Disease Site of Origin									
Upper tract	74	21 (28.4)	NC [14.8, NC]	55	4 (7.3)	NC [NC, NC]	4.076 [1.396, 11.904]	0.0053	0.3010
Lower tract	128	29 (22.7)	NC [NC, NC]	146	15 (10.3)	NC [NC, NC]	2.154 [1.152, 4.026]	0.0138	
Renal Function									
Normal	6	1 (16.7)	NC [2.0, NC]	13	1 (7.7)	NC [NC, NC]	5.64E8 [0.000, NC]	0.1573	0.6308
Mild	49	16 (32.7)	NC [14.9, NC]	40	3 (7.5)	NC [NC, NC]	4.958 [1.429, 17.203]	0.0054	
Moderate	140	31 (22.1)	NC [NC, NC]	141	15 (10.6)	NC [NC, NC]	1.864 [1.005, 3.459]	0.0443	
Severe	7	2 (28.6)	14.8 [2.1, 14.8]	8	0 (0.0)	NC [NC, NC]	2.19E8 [0.000, NC]	0.1573	

Abbreviations: BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]) and liver metastases (present or absent). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Complete response was defined as first confirmed complete response.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

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Table 302.1.3000.1.1: BPI-SF - Summary of Duration of Observation Time - Analysis Set mITT 1

	EV+Pembro (N=240)	**Plat+Gem (N=242)**
Duration of observation period (months)		
n	240	242
Mean (SD)	11.1 (7.18)	7.5 (6.42)
Median	10.1	5.9
Q1 - Q3	5.9 - 15.6	2.8 - 11.4
Range	0 - 31	0 - 35

Abbreviations: BP-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Note: Observation period for BP-SF questionnaire includes the time from randomisation until the last date data were collected for BP-SF questionnaire.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3000.1.2: BPI-SF - Summary of Duration of Observation Time - Analysis Set mITT 2

	EV+Pembro (N=202)	**Plat+Gem (N=202)**
Duration of observation period (months)		
n	202	202
Mean (SD)	10.2 (7.55)	6.6 (5.85)
Median	9.4	4.6
Q1 - Q3	3.2 - 15.6	2.2 - 10.1
Range	0 - 31	0 - 29

Abbreviations: BP-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Note: Observation period for BP-SF questionnaire includes the time from randomisation until the last date data were collected for BP-SF questionnaire.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3000.2.1: EORTC QLQ-C30 - Summary of Duration of Observation Time - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)
Duration of observation period (months)		
n	240	242
Mean (SD)	11.1 (7.18)	7.5 (6.42)
Median	10.1	5.9
Q1 - Q3	5.9 - 15.6	2.7 - 11.4
Range	0 - 31	0 - 35

Abbreviations: EORTC QLQ-C30=European Organization for Research and Treatment of Cancer Quality of Life Questionnaire - Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Note: Observation period for EORTC QLQ-C30 questionnaire includes the time from randomisation until the last date data were collected for EORTC QLQ-C30 questionnaire.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3000.2.2: EORTC QLQ-C30 - Summary of Duration of Observation Time - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)
Duration of observation period (months)		
n	202	202
Mean (SD)	10.2 (7.56)	6.6 (5.85)
Median	9.4	4.6
Q1 - Q3	3.2 - 15.6	2.2 - 10.1
Range	0 - 31	0 - 29

Abbreviations: EORTC QLQ-C30=European Organization for Research and Treatment of Cancer Quality of Life Questionnaire - Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Note: Observation period for EORTC QLQ-C30 questionnaire includes the time from randomisation until the last date data were collected for EORTC QLQ-C30 questionnaire.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3000.3.1: EQ-5D-5L - Summary of Duration of Observation Time - Analysis Set mITT 1

	EV+Pembro (N=240)	**Plat+Gem (N=242)**
Duration of observation period (months)		
n	240	242
Mean (SD)	11.1 (7.16)	7.6 (6.40)
Median	10.1	5.9
Q1 - Q3	5.9 - 15.6	3.1 - 11.4
Range	0 - 31	0 - 35

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 levels; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Note: Observation period for EQ-5D-5L questionnaire includes the time from randomisation until the last date data were collected for EQ-5D-5L questionnaire.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3000.3.2: EQ-5D-5L - Summary of Duration of Observation Time - Analysis Set mITT 2

	EV+Pembro (N=202)	**Plat+Gem (N=202)**
Duration of observation period (months)		
n	202	202
Mean (SD)	10.2 (7.54)	6.6 (5.85)
Median	9.4	4.6
Q1 - Q3	3.2 - 15.6	2.2 - 10.1
Range	0 - 31	0 - 29

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 levels; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Note: Observation period for EQ-5D-5L questionnaire includes the time from randomisation until the last date data were collected for EQ-5D-5L questionnaire.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3001.1.1: BPI-SF - Return Rates - Analysis Set mITT 1

Analysis Visit	EV+Pembro (N=240)			Plat+Gem (N=242)		
	Compliance rate (a)	Modified completion rate (b)	Completion rate (c)	Compliance rate (a)	Modified completion rate (b)	Completion rate (c)
BASELINE	209 / 240 (87.1%)	209 / 240 (87.1%)	209 / 240 (87.1%)	190 / 242 (78.5%)	190 / 242 (78.5%)	190 / 242 (78.5%)
Week 1	190 / 239 (79.5%)	190 / 240 (79.2%)	190 / 240 (79.2%)	179 / 235 (76.2%)	179 / 240 (74.6%)	179 / 242 (74.0%)
Week 2	204 / 239 (85.4%)	204 / 240 (85.0%)	204 / 240 (85.0%)	173 / 235 (73.6%)	173 / 240 (72.1%)	173 / 242 (71.5%)
Week 3	199 / 239 (83.3%)	199 / 240 (82.9%)	199 / 240 (82.9%)	185 / 235 (78.7%)	185 / 240 (77.1%)	185 / 242 (76.4%)
Week 4	195 / 239 (81.6%)	195 / 240 (81.3%)	195 / 240 (81.3%)	183 / 235 (77.9%)	183 / 240 (76.3%)	183 / 242 (75.6%)
Week 5	193 / 238 (81.1%)	193 / 239 (80.8%)	193 / 240 (80.4%)	187 / 233 (80.3%)	187 / 238 (78.6%)	187 / 242 (77.3%)
Week 6	189 / 238 (79.4%)	189 / 239 (79.1%)	189 / 240 (78.8%)	174 / 233 (74.7%)	174 / 238 (73.1%)	174 / 242 (71.9%)
Week 7	196 / 236 (83.1%)	196 / 238 (82.4%)	196 / 240 (81.7%)	187 / 233 (80.3%)	187 / 238 (78.6%)	187 / 242 (77.3%)
Week 8	192 / 235 (81.7%)	192 / 237 (81.0%)	192 / 240 (80.0%)	167 / 230 (72.6%)	167 / 236 (70.8%)	167 / 242 (69.0%)
Week 9	198 / 234 (84.6%)	198 / 236 (83.9%)	198 / 240 (82.5%)	177 / 230 (77.0%)	177 / 236 (75.0%)	177 / 242 (73.1%)
Week 10	191 / 234 (81.6%)	191 / 236 (80.9%)	191 / 240 (79.6%)	166 / 228 (72.8%)	166 / 234 (70.9%)	166 / 242 (68.6%)
Week 11	196 / 233 (84.1%)	196 / 236 (83.1%)	196 / 240 (81.7%)	168 / 226 (74.3%)	168 / 232 (72.4%)	168 / 242 (69.4%)
Week 12	186 / 233 (79.8%)	186 / 236 (78.8%)	186 / 240 (77.5%)	159 / 223 (71.3%)	159 / 229 (69.4%)	159 / 242 (65.7%)
Week 14	185 / 231 (80.1%)	185 / 234 (79.1%)	185 / 240 (77.1%)	153 / 221 (69.2%)	153 / 227 (67.4%)	153 / 242 (63.2%)
Week 17	178 / 227 (78.4%)	178 / 230 (77.4%)	178 / 240 (74.2%)	156 / 217 (71.9%)	156 / 224 (69.6%)	156 / 242 (64.5%)
Week 20	167 / 226 (73.9%)	167 / 229 (72.9%)	167 / 240 (69.6%)	126 / 211 (59.7%)	126 / 218 (57.8%)	126 / 242 (52.1%)
Week 23	162 / 223 (72.6%)	162 / 226 (71.7%)	162 / 240 (67.5%)	115 / 206 (55.8%)	115 / 213 (54.0%)	115 / 242 (47.5%)
Week 26	156 / 220 (70.9%)	156 / 223 (70.0%)	156 / 240 (65.0%)	108 / 200 (54.0%)	108 / 207 (52.2%)	108 / 242 (44.6%)
Week 29	157 / 215 (73.0%)	157 / 219 (71.7%)	157 / 240 (65.4%)	100 / 198 (50.5%)	100 / 205 (48.8%)	100 / 242 (41.3%)
Week 32	135 / 214 (63.1%)	135 / 218 (61.9%)	135 / 240 (56.3%)	83 / 187 (44.4%)	83 / 195 (42.6%)	83 / 242 (34.3%)
Week 35	132 / 211 (62.6%)	132 / 215 (61.4%)	132 / 240 (55.0%)	76 / 180 (42.2%)	76 / 188 (40.4%)	76 / 242 (31.4%)
Week 38	132 / 208 (63.5%)	132 / 212 (62.3%)	132 / 240 (55.0%)	74 / 174 (42.5%)	74 / 183 (40.4%)	74 / 242 (30.6%)
Week 41	129 / 202 (63.9%)	129 / 209 (61.7%)	129 / 240 (53.8%)	65 / 164 (39.6%)	65 / 177 (36.7%)	65 / 242 (26.9%)
Week 44	108 / 190 (56.8%)	108 / 206 (52.4%)	108 / 240 (45.0%)	60 / 148 (40.5%)	60 / 174 (34.5%)	60 / 242 (24.8%)
Week 47	100 / 172 (58.1%)	100 / 200 (50.0%)	100 / 240 (41.7%)	56 / 142 (39.4%)	56 / 171 (32.7%)	56 / 242 (23.1%)

Abbreviations: BP-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: (a) Compliance rate is defined as the proportion of subjects who completed the instrument among those who were expected to complete at a given visit; (b) Modified completion rate is defined as the proportion of subjects who completed the instrument among the mITT analysis sets while accounting for deaths; (c) Completion rate is defined as the proportion of subjects who completed the instrument among the mITT analysis sets.
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Table 302.1.3001.1.1: BPI-SF - Return Rates - Analysis Set mITT 1

Analysis Visit	EV+Pembro (N=240)			Plat+Gem (N=242)		
	Compliance rate (a)	Modified completion rate (b)	Completion rate (c)	Compliance rate (a)	Modified completion rate (b)	Completion rate (c)
Week 50	89 / 162 (54.9%)	89 / 198 (44.9%)	89 / 240 (37.1%)	51 / 132 (38.6%)	51 / 169 (30.2%)	51 / 242 (21.1%)
Week 53	79 / 149 (53.0%)	79 / 195 (40.5%)	79 / 240 (32.9%)	46 / 122 (37.7%)	46 / 165 (27.9%)	46 / 242 (19.0%)
Week 56	81 / 140 (57.9%)	81 / 191 (42.4%)	81 / 240 (33.8%)	39 / 117 (33.3%)	39 / 163 (23.9%)	39 / 242 (16.1%)
Week 59	72 / 132 (54.5%)	72 / 190 (37.9%)	72 / 240 (30.0%)	37 / 107 (34.6%)	37 / 160 (23.1%)	37 / 242 (15.3%)
Week 62	65 / 127 (51.2%)	65 / 189 (34.4%)	65 / 240 (27.1%)	32 / 100 (32.0%)	32 / 156 (20.5%)	32 / 242 (13.2%)
Week 65	58 / 112 (51.8%)	58 / 186 (31.2%)	58 / 240 (24.2%)	30 / 92 (32.6%)	30 / 155 (19.4%)	30 / 242 (12.4%)
Week 68	53 / 105 (50.5%)	53 / 184 (28.8%)	53 / 240 (22.1%)	25 / 83 (30.1%)	25 / 150 (16.7%)	25 / 242 (10.3%)
Week 71	51 / 98 (52.0%)	51 / 183 (27.9%)	51 / 240 (21.3%)	22 / 79 (27.8%)	22 / 150 (14.7%)	22 / 242 (9.1%)
Week 74	47 / 92 (51.1%)	47 / 182 (25.8%)	47 / 240 (19.6%)	21 / 66 (31.8%)	21 / 144 (14.6%)	21 / 242 (8.7%)
Week 77	44 / 82 (53.7%)	44 / 181 (24.3%)	44 / 240 (18.3%)	18 / 62 (29.0%)	18 / 144 (12.5%)	18 / 242 (7.4%)
Week 80	40 / 73 (54.8%)	40 / 180 (22.2%)	40 / 240 (16.7%)	14 / 55 (25.5%)	14 / 139 (10.1%)	14 / 242 (5.8%)
Week 83	37 / 70 (52.9%)	37 / 180 (20.6%)	37 / 240 (15.4%)	13 / 49 (26.5%)	13 / 138 (9.4%)	13 / 242 (5.4%)
Week 86	34 / 63 (54.0%)	34 / 179 (19.0%)	34 / 240 (14.2%)	12 / 40 (30.0%)	12 / 136 (8.8%)	12 / 242 (5.0%)
Week 89	33 / 57 (57.9%)	33 / 179 (18.4%)	33 / 240 (13.8%)	11 / 38 (28.9%)	11 / 136 (8.1%)	11 / 242 (4.5%)
Week 92	27 / 49 (55.1%)	27 / 178 (15.2%)	27 / 240 (11.3%)	8 / 33 (24.2%)	8 / 135 (5.9%)	8 / 242 (3.3%)
Week 95	22 / 41 (53.7%)	22 / 177 (12.4%)	22 / 240 (9.2%)	9 / 30 (30.0%)	9 / 135 (6.7%)	9 / 242 (3.7%)
Week 98	18 / 35 (51.4%)	18 / 176 (10.2%)	18 / 240 (7.5%)	6 / 27 (22.2%)	6 / 134 (4.5%)	6 / 242 (2.5%)
Week 101	14 / 30 (46.7%)	14 / 175 (8.0%)	14 / 240 (5.8%)	5 / 25 (20.0%)	5 / 134 (3.7%)	5 / 242 (2.1%)
Week 104	10 / 26 (38.5%)	10 / 175 (5.7%)	10 / 240 (4.2%)	4 / 20 (20.0%)	4 / 134 (3.0%)	4 / 242 (1.7%)
Week 107	8 / 24 (33.3%)	8 / 175 (4.6%)	8 / 240 (3.3%)	3 / 16 (18.8%)	3 / 134 (2.2%)	3 / 242 (1.2%)
Week 110	6 / 21 (28.6%)	6 / 175 (3.4%)	6 / 240 (2.5%)	3 / 15 (20.0%)	3 / 134 (2.2%)	3 / 242 (1.2%)
Week 113	8 / 18 (44.4%)	8 / 173 (4.6%)	8 / 240 (3.3%)	2 / 15 (13.3%)	2 / 134 (1.5%)	2 / 242 (0.8%)
Week 116	5 / 15 (33.3%)	5 / 172 (2.9%)	5 / 240 (2.1%)	3 / 14 (21.4%)	3 / 134 (2.2%)	3 / 242 (1.2%)
Week 119	5 / 11 (45.5%)	5 / 172 (2.9%)	5 / 240 (2.1%)	1 / 12 (8.3%)	1 / 134 (0.7%)	1 / 242 (0.4%)
Week 122	4 / 9 (44.4%)	4 / 172 (2.3%)	4 / 240 (1.7%)	3 / 9 (33.3%)	3 / 133 (2.3%)	3 / 242 (1.2%)

Abbreviations: BP-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: (a) Compliance rate is defined as the proportion of subjects who completed the instrument among those who were expected to complete at a given visit; (b) Modified completion rate is defined as the proportion of subjects who completed the instrument among the mITT analysis sets while accounting for deaths; (c) Completion rate is defined as the proportion of subjects who completed the instrument among the mITT analysis sets.
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Table 302.1.3001.1.1: BPI-SF - Return Rates - Analysis Set mITT 1

Analysis Visit	EV+Pembro (N=240)			Plat+Gem (N=242)		
	Compliance rate (a)	Modified completion rate (b)	Completion rate (c)	Compliance rate (a)	Modified completion rate (b)	Completion rate (c)
Week 125	3 / 8 (37.5%)	3 / 172 (1.7%)	3 / 240 (1.3%)	2 / 6 (33.3%)	2 / 133 (1.5%)	2 / 242 (0.8%)
Week 128	1 / 6 (16.7%)	1 / 172 (0.6%)	1 / 240 (0.4%)	3 / 6 (50.0%)	3 / 133 (2.3%)	3 / 242 (1.2%)
Week 131	1 / 4 (25.0%)	1 / 172 (0.6%)	1 / 240 (0.4%)	2 / 6 (33.3%)	2 / 133 (1.5%)	2 / 242 (0.8%)
Week 134	1 / 4 (25.0%)	1 / 172 (0.6%)	1 / 240 (0.4%)	2 / 6 (33.3%)	2 / 133 (1.5%)	2 / 242 (0.8%)
Week 137	1 / 2 (50.0%)	1 / 171 (0.6%)	1 / 240 (0.4%)	2 / 5 (40.0%)	2 / 132 (1.5%)	2 / 242 (0.8%)
Week 140	0 / 1 (0.0%)	0 / 171 (0.0%)	0 / 240 (0.0%)	1 / 3 (33.3%)	1 / 132 (0.8%)	1 / 242 (0.4%)
Week 143	0 / 1 (0.0%)	0 / 171 (0.0%)	0 / 240 (0.0%)	1 / 3 (33.3%)	1 / 132 (0.8%)	1 / 242 (0.4%)
Week 146	0 / 1 (0.0%)	0 / 171 (0.0%)	0 / 240 (0.0%)	1 / 2 (50.0%)	1 / 132 (0.8%)	1 / 242 (0.4%)
Week 149	0 / 1 (0.0%)	0 / 171 (0.0%)	0 / 240 (0.0%)	1 / 2 (50.0%)	1 / 132 (0.8%)	1 / 242 (0.4%)
Week 152	0 / 1 (0.0%)	0 / 171 (0.0%)	0 / 240 (0.0%)	1 / 2 (50.0%)	1 / 132 (0.8%)	1 / 242 (0.4%)

Abbreviations: BP-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: (a) Compliance rate is defined as the proportion of subjects who completed the instrument among those who were expected to complete at a given visit; (b) Modified completion rate is defined as the proportion of subjects who completed the instrument among the mITT analysis sets while accounting for deaths; (c) Completion rate is defined as the proportion of subjects who completed the instrument among the mITT analysis sets.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3001.1.2: BPI-SF - Return Rates - Analysis Set mITT 2

Analysis Visit	EV+Pembro (N=202)			Plat+Gem (N=202)		
	Compliance rate (a)	Modified completion rate (b)	Completion rate (c)	Compliance rate (a)	Modified completion rate (b)	Completion rate (c)
BASELINE	166 / 202 (82.2%)	166 / 202 (82.2%)	166 / 202 (82.2%)	168 / 202 (83.2%)	168 / 202 (83.2%)	168 / 202 (83.2%)
Week 1	142 / 201 (70.6%)	142 / 202 (70.3%)	142 / 202 (70.3%)	146 / 197 (74.1%)	146 / 200 (73.0%)	146 / 202 (72.3%)
Week 2	154 / 198 (77.8%)	154 / 199 (77.4%)	154 / 202 (76.2%)	151 / 194 (77.8%)	151 / 197 (76.6%)	151 / 202 (74.8%)
Week 3	139 / 196 (70.9%)	139 / 197 (70.6%)	139 / 202 (68.8%)	149 / 193 (77.2%)	149 / 196 (76.0%)	149 / 202 (73.8%)
Week 4	147 / 193 (76.2%)	147 / 194 (75.8%)	147 / 202 (72.8%)	151 / 190 (79.5%)	151 / 193 (78.2%)	151 / 202 (74.8%)
Week 5	139 / 193 (72.0%)	139 / 194 (71.6%)	139 / 202 (68.8%)	155 / 190 (81.6%)	155 / 193 (80.3%)	155 / 202 (76.7%)
Week 6	147 / 191 (77.0%)	147 / 192 (76.6%)	147 / 202 (72.8%)	145 / 190 (76.3%)	145 / 193 (75.1%)	145 / 202 (71.8%)
Week 7	150 / 191 (78.5%)	150 / 192 (78.1%)	150 / 202 (74.3%)	149 / 190 (78.4%)	149 / 193 (77.2%)	149 / 202 (73.8%)
Week 8	150 / 191 (78.5%)	150 / 192 (78.1%)	150 / 202 (74.3%)	146 / 189 (77.2%)	146 / 192 (76.0%)	146 / 202 (72.3%)
Week 9	142 / 190 (74.7%)	142 / 192 (74.0%)	142 / 202 (70.3%)	141 / 188 (75.0%)	141 / 191 (73.8%)	141 / 202 (69.8%)
Week 10	139 / 188 (73.9%)	139 / 190 (73.2%)	139 / 202 (68.8%)	142 / 187 (75.9%)	142 / 190 (74.7%)	142 / 202 (70.3%)
Week 11	138 / 186 (74.2%)	138 / 189 (73.0%)	138 / 202 (68.3%)	126 / 186 (67.7%)	126 / 189 (66.7%)	126 / 202 (62.4%)
Week 12	143 / 186 (76.9%)	143 / 189 (75.7%)	143 / 202 (70.8%)	130 / 185 (70.3%)	130 / 188 (69.1%)	130 / 202 (64.4%)
Week 14	140 / 185 (75.7%)	140 / 188 (74.5%)	140 / 202 (69.3%)	125 / 180 (69.4%)	125 / 183 (68.3%)	125 / 202 (61.9%)
Week 17	132 / 181 (72.9%)	132 / 184 (71.7%)	132 / 202 (65.3%)	120 / 174 (69.0%)	120 / 177 (67.8%)	120 / 202 (59.4%)
Week 20	120 / 180 (66.7%)	120 / 184 (65.2%)	120 / 202 (59.4%)	104 / 169 (61.5%)	104 / 172 (60.5%)	104 / 202 (51.5%)
Week 23	117 / 177 (66.1%)	117 / 181 (64.6%)	117 / 202 (57.9%)	88 / 159 (55.3%)	88 / 163 (54.0%)	88 / 202 (43.6%)
Week 26	114 / 173 (65.9%)	114 / 177 (64.4%)	114 / 202 (56.4%)	81 / 154 (52.6%)	81 / 158 (51.3%)	81 / 202 (40.1%)
Week 29	107 / 170 (62.9%)	107 / 174 (61.5%)	107 / 202 (53.0%)	77 / 150 (51.3%)	77 / 154 (50.0%)	77 / 202 (38.1%)
Week 32	102 / 165 (61.8%)	102 / 171 (59.6%)	102 / 202 (50.5%)	64 / 142 (45.1%)	64 / 147 (43.5%)	64 / 202 (31.7%)
Week 35	98 / 163 (60.1%)	98 / 170 (57.6%)	98 / 202 (48.5%)	62 / 135 (45.9%)	62 / 140 (44.3%)	62 / 202 (30.7%)
Week 38	97 / 157 (61.8%)	97 / 165 (58.8%)	97 / 202 (48.0%)	56 / 129 (43.4%)	56 / 135 (41.5%)	56 / 202 (27.7%)
Week 41	95 / 153 (62.1%)	95 / 163 (58.3%)	95 / 202 (47.0%)	52 / 122 (42.6%)	52 / 131 (39.7%)	52 / 202 (25.7%)
Week 44	86 / 141 (61.0%)	86 / 160 (53.8%)	86 / 202 (42.6%)	49 / 108 (45.4%)	49 / 125 (39.2%)	49 / 202 (24.3%)
Week 47	79 / 131 (60.3%)	79 / 157 (50.3%)	79 / 202 (39.1%)	43 / 98 (43.9%)	43 / 121 (35.5%)	43 / 202 (21.3%)

Abbreviations: BP-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: (a) Compliance rate is defined as the proportion of subjects who completed the instrument among those who were expected to complete at a given visit; (b) Modified completion rate is defined as the proportion of subjects who completed the instrument among the mITT analysis sets while accounting for deaths; (c) Completion rate is defined as the proportion of subjects who completed the instrument among the mITT analysis sets.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3001.1.2: BPI-SF - Return Rates - Analysis Set mITT 2

Analysis Visit	EV+Pembro (N=202)			Plat+Gem (N=202)		
	Compliance rate (a)	Modified completion rate (b)	Completion rate (c)	Compliance rate (a)	Modified completion rate (b)	Completion rate (c)
Week 50	75 / 126 (59.5%)	75 / 157 (47.8%)	75 / 202 (37.1%)	36 / 92 (39.1%)	36 / 118 (30.5%)	36 / 202 (17.8%)
Week 53	76 / 120 (63.3%)	76 / 154 (49.4%)	76 / 202 (37.6%)	31 / 80 (38.8%)	31 / 112 (27.7%)	31 / 202 (15.3%)
Week 56	72 / 112 (64.3%)	72 / 154 (46.8%)	72 / 202 (35.6%)	30 / 73 (41.1%)	30 / 108 (27.8%)	30 / 202 (14.9%)
Week 59	69 / 106 (65.1%)	69 / 152 (45.4%)	69 / 202 (34.2%)	23 / 64 (35.9%)	23 / 104 (22.1%)	23 / 202 (11.4%)
Week 62	62 / 94 (66.0%)	62 / 149 (41.6%)	62 / 202 (30.7%)	20 / 60 (33.3%)	20 / 102 (19.6%)	20 / 202 (9.9%)
Week 65	43 / 88 (48.9%)	43 / 149 (28.9%)	43 / 202 (21.3%)	17 / 52 (32.7%)	17 / 100 (17.0%)	17 / 202 (8.4%)
Week 68	46 / 83 (55.4%)	46 / 148 (31.1%)	46 / 202 (22.8%)	13 / 48 (27.1%)	13 / 98 (13.3%)	13 / 202 (6.4%)
Week 71	42 / 79 (53.2%)	42 / 148 (28.4%)	42 / 202 (20.8%)	13 / 42 (31.0%)	13 / 96 (13.5%)	13 / 202 (6.4%)
Week 74	38 / 71 (53.5%)	38 / 147 (25.9%)	38 / 202 (18.8%)	11 / 38 (28.9%)	11 / 95 (11.6%)	11 / 202 (5.4%)
Week 77	37 / 64 (57.8%)	37 / 147 (25.2%)	37 / 202 (18.3%)	11 / 33 (33.3%)	11 / 93 (11.8%)	11 / 202 (5.4%)
Week 80	36 / 60 (60.0%)	36 / 145 (24.8%)	36 / 202 (17.8%)	8 / 30 (26.7%)	8 / 92 (8.7%)	8 / 202 (4.0%)
Week 83	30 / 56 (53.6%)	30 / 143 (21.0%)	30 / 202 (14.9%)	9 / 26 (34.6%)	9 / 90 (10.0%)	9 / 202 (4.5%)
Week 86	26 / 49 (53.1%)	26 / 142 (18.3%)	26 / 202 (12.9%)	6 / 20 (30.0%)	6 / 90 (6.7%)	6 / 202 (3.0%)
Week 89	20 / 43 (46.5%)	20 / 140 (14.3%)	20 / 202 (9.9%)	7 / 17 (41.2%)	7 / 90 (7.8%)	7 / 202 (3.5%)
Week 92	19 / 36 (52.8%)	19 / 139 (13.7%)	19 / 202 (9.4%)	6 / 14 (42.9%)	6 / 88 (6.8%)	6 / 202 (3.0%)
Week 95	14 / 29 (48.3%)	14 / 139 (10.1%)	14 / 202 (6.9%)	4 / 11 (36.4%)	4 / 87 (4.6%)	4 / 202 (2.0%)
Week 98	10 / 23 (43.5%)	10 / 139 (7.2%)	10 / 202 (5.0%)	3 / 8 (37.5%)	3 / 86 (3.5%)	3 / 202 (1.5%)
Week 101	7 / 17 (41.2%)	7 / 138 (5.1%)	7 / 202 (3.5%)	3 / 8 (37.5%)	3 / 86 (3.5%)	3 / 202 (1.5%)
Week 104	7 / 13 (53.8%)	7 / 138 (5.1%)	7 / 202 (3.5%)	3 / 8 (37.5%)	3 / 86 (3.5%)	3 / 202 (1.5%)
Week 107	7 / 12 (58.3%)	7 / 138 (5.1%)	7 / 202 (3.5%)	2 / 7 (28.6%)	2 / 86 (2.3%)	2 / 202 (1.0%)
Week 110	3 / 9 (33.3%)	3 / 138 (2.2%)	3 / 202 (1.5%)	2 / 5 (40.0%)	2 / 86 (2.3%)	2 / 202 (1.0%)
Week 113	4 / 5 (80.0%)	4 / 138 (2.9%)	4 / 202 (2.0%)	1 / 3 (33.3%)	1 / 86 (1.2%)	1 / 202 (0.5%)
Week 116	3 / 4 (75.0%)	3 / 138 (2.2%)	3 / 202 (1.5%)	1 / 3 (33.3%)	1 / 86 (1.2%)	1 / 202 (0.5%)
Week 119	2 / 4 (50.0%)	2 / 138 (1.4%)	2 / 202 (1.0%)	1 / 3 (33.3%)	1 / 86 (1.2%)	1 / 202 (0.5%)
Week 122	2 / 4 (50.0%)	2 / 138 (1.4%)	2 / 202 (1.0%)	1 / 3 (33.3%)	1 / 86 (1.2%)	1 / 202 (0.5%)

Abbreviations: BP-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: (a) Compliance rate is defined as the proportion of subjects who completed the instrument among those who were expected to complete at a given visit; (b) Modified completion rate is defined as the proportion of subjects who completed the instrument among the mITT analysis sets while accounting for deaths; (c) Completion rate is defined as the proportion of subjects who completed the instrument among the mITT analysis sets.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3001.1.2: BPI-SF - Return Rates - Analysis Set mITT 2

Analysis Visit	EV+Pembro (N=202)			Plat+Gem (N=202)		
	Compliance rate (a)	Modified completion rate (b)	Completion rate (c)	Compliance rate (a)	Modified completion rate (b)	Completion rate (c)
Week 125	2 / 3 (66.7%)	2 / 138 (1.4%)	2 / 202 (1.0%)	1 / 2 (50.0%)	1 / 86 (1.2%)	1 / 202 (0.5%)
Week 128	1 / 3 (33.3%)	1 / 138 (0.7%)	1 / 202 (0.5%)	1 / 2 (50.0%)	1 / 86 (1.2%)	1 / 202 (0.5%)
Week 131	1 / 3 (33.3%)	1 / 138 (0.7%)	1 / 202 (0.5%)	0 / 1 (0.0%)	0 / 86 (0.0%)	0 / 202 (0.0%)
Week 134	1 / 1 (100.0%)	1 / 138 (0.7%)	1 / 202 (0.5%)	0 / 1 (0.0%)	0 / 86 (0.0%)	0 / 202 (0.0%)
Week 137	1 / 1 (100.0%)	1 / 138 (0.7%)	1 / 202 (0.5%)	0 / 1 (0.0%)	0 / 86 (0.0%)	0 / 202 (0.0%)

Abbreviations: BP-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: (a) Compliance rate is defined as the proportion of subjects who completed the instrument among those who were expected to complete at a given visit; (b) Modified completion rate is defined as the proportion of subjects who completed the instrument among the mITT analysis sets while accounting for deaths; (c) Completion rate is defined as the proportion of subjects who completed the instrument among the mITT analysis sets.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3001.2.1: EORTC QLQ-C30 - Return Rates - Analysis Set mITT 1

Analysis Visit	EV+Pembro (N=240)			Plat+Gem (N=242)		
	Compliance rate (a)	Modified completion rate (b)	Completion rate (c)	Compliance rate (a)	Modified completion rate (b)	Completion rate (c)
BASELINE	206 / 240 (85.8%)	206 / 240 (85.8%)	206 / 240 (85.8%)	188 / 242 (77.7%)	188 / 242 (77.7%)	188 / 242 (77.7%)
Week 1	190 / 239 (79.5%)	190 / 240 (79.2%)	190 / 240 (79.2%)	173 / 235 (73.6%)	173 / 240 (72.1%)	173 / 242 (71.5%)
Week 2	203 / 239 (84.9%)	203 / 240 (84.6%)	203 / 240 (84.6%)	171 / 235 (72.8%)	171 / 240 (71.3%)	171 / 242 (70.7%)
Week 3	198 / 239 (82.8%)	198 / 240 (82.5%)	198 / 240 (82.5%)	184 / 235 (78.3%)	184 / 240 (76.7%)	184 / 242 (76.0%)
Week 4	194 / 239 (81.2%)	194 / 240 (80.8%)	194 / 240 (80.8%)	183 / 235 (77.9%)	183 / 240 (76.3%)	183 / 242 (75.6%)
Week 5	190 / 238 (79.8%)	190 / 239 (79.5%)	190 / 240 (79.2%)	187 / 233 (80.3%)	187 / 238 (78.6%)	187 / 242 (77.3%)
Week 6	188 / 238 (79.0%)	188 / 239 (78.7%)	188 / 240 (78.3%)	174 / 233 (74.7%)	174 / 238 (73.1%)	174 / 242 (71.9%)
Week 7	195 / 236 (82.6%)	195 / 238 (81.9%)	195 / 240 (81.3%)	186 / 233 (79.8%)	186 / 238 (78.2%)	186 / 242 (76.9%)
Week 8	191 / 235 (81.3%)	191 / 237 (80.6%)	191 / 240 (79.6%)	167 / 230 (72.6%)	167 / 236 (70.8%)	167 / 242 (69.0%)
Week 9	197 / 234 (84.2%)	197 / 236 (83.5%)	197 / 240 (82.1%)	177 / 230 (77.0%)	177 / 236 (75.0%)	177 / 242 (73.1%)
Week 10	191 / 234 (81.6%)	191 / 236 (80.9%)	191 / 240 (79.6%)	166 / 228 (72.8%)	166 / 234 (70.9%)	166 / 242 (68.6%)
Week 11	194 / 233 (83.3%)	194 / 236 (82.2%)	194 / 240 (80.8%)	168 / 226 (74.3%)	168 / 232 (72.4%)	168 / 242 (69.4%)
Week 12	186 / 233 (79.8%)	186 / 236 (78.8%)	186 / 240 (77.5%)	159 / 223 (71.3%)	159 / 229 (69.4%)	159 / 242 (65.7%)
Week 14	185 / 231 (80.1%)	185 / 234 (79.1%)	185 / 240 (77.1%)	153 / 221 (69.2%)	153 / 227 (67.4%)	153 / 242 (63.2%)
Week 17	178 / 227 (78.4%)	178 / 230 (77.4%)	178 / 240 (74.2%)	155 / 217 (71.4%)	155 / 224 (69.2%)	155 / 242 (64.0%)
Week 20	167 / 226 (73.9%)	167 / 229 (72.9%)	167 / 240 (69.6%)	126 / 211 (59.7%)	126 / 218 (57.8%)	126 / 242 (52.1%)
Week 23	162 / 223 (72.6%)	162 / 226 (71.7%)	162 / 240 (67.5%)	115 / 206 (55.8%)	115 / 213 (54.0%)	115 / 242 (47.5%)
Week 26	156 / 220 (70.9%)	156 / 223 (70.0%)	156 / 240 (65.0%)	108 / 200 (54.0%)	108 / 207 (52.2%)	108 / 242 (44.6%)
Week 29	157 / 215 (73.0%)	157 / 219 (71.7%)	157 / 240 (65.4%)	100 / 198 (50.5%)	100 / 205 (48.8%)	100 / 242 (41.3%)
Week 32	135 / 214 (63.1%)	135 / 218 (61.9%)	135 / 240 (56.3%)	83 / 187 (44.4%)	83 / 195 (42.6%)	83 / 242 (34.3%)
Week 35	132 / 211 (62.6%)	132 / 215 (61.4%)	132 / 240 (55.0%)	76 / 180 (42.2%)	76 / 188 (40.4%)	76 / 242 (31.4%)
Week 38	132 / 208 (63.5%)	132 / 212 (62.3%)	132 / 240 (55.0%)	74 / 174 (42.5%)	74 / 183 (40.4%)	74 / 242 (30.6%)
Week 41	129 / 202 (63.9%)	129 / 209 (61.7%)	129 / 240 (53.8%)	65 / 164 (39.6%)	65 / 177 (36.7%)	65 / 242 (26.9%)
Week 44	108 / 190 (56.8%)	108 / 206 (52.4%)	108 / 240 (45.0%)	60 / 148 (40.5%)	60 / 174 (34.5%)	60 / 242 (24.8%)
Week 47	100 / 172 (58.1%)	100 / 200 (50.0%)	100 / 240 (41.7%)	56 / 142 (39.4%)	56 / 171 (32.7%)	56 / 242 (23.1%)

Abbreviations: EORTC QLQ-C30=European Organization for Research and Treatment of Cancer Quality of Life Questionnaire - Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: (a) Compliance rate is defined as the proportion of subjects who completed the instrument among those who were expected to complete at a given visit; (b) Modified completion rate is defined as the proportion of subjects who completed the instrument among the mITT analysis sets while accounting for deaths; (c) Completion rate is defined as the proportion of subjects who completed the instrument among the mITT analysis sets.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3001.2.1: EORTC QLQ-C30 - Return Rates - Analysis Set mITT 1

Analysis Visit	EV+Pembro (N=240)			Plat+Gem (N=242)		
	Compliance rate (a)	Modified completion rate (b)	Completion rate (c)	Compliance rate (a)	Modified completion rate (b)	Completion rate (c)
Week 50	89 / 162 (54.9%)	89 / 198 (44.9%)	89 / 240 (37.1%)	51 / 132 (38.6%)	51 / 169 (30.2%)	51 / 242 (21.1%)
Week 53	79 / 149 (53.0%)	79 / 195 (40.5%)	79 / 240 (32.9%)	46 / 122 (37.7%)	46 / 165 (27.9%)	46 / 242 (19.0%)
Week 56	81 / 140 (57.9%)	81 / 191 (42.4%)	81 / 240 (33.8%)	39 / 117 (33.3%)	39 / 163 (23.9%)	39 / 242 (16.1%)
Week 59	72 / 132 (54.5%)	72 / 190 (37.9%)	72 / 240 (30.0%)	37 / 107 (34.6%)	37 / 160 (23.1%)	37 / 242 (15.3%)
Week 62	65 / 127 (51.2%)	65 / 189 (34.4%)	65 / 240 (27.1%)	32 / 100 (32.0%)	32 / 156 (20.5%)	32 / 242 (13.2%)
Week 65	58 / 112 (51.8%)	58 / 186 (31.2%)	58 / 240 (24.2%)	30 / 92 (32.6%)	30 / 155 (19.4%)	30 / 242 (12.4%)
Week 68	53 / 105 (50.5%)	53 / 184 (28.8%)	53 / 240 (22.1%)	25 / 83 (30.1%)	25 / 150 (16.7%)	25 / 242 (10.3%)
Week 71	51 / 98 (52.0%)	51 / 183 (27.9%)	51 / 240 (21.3%)	22 / 79 (27.8%)	22 / 150 (14.7%)	22 / 242 (9.1%)
Week 74	47 / 92 (51.1%)	47 / 182 (25.8%)	47 / 240 (19.6%)	21 / 66 (31.8%)	21 / 144 (14.6%)	21 / 242 (8.7%)
Week 77	44 / 82 (53.7%)	44 / 181 (24.3%)	44 / 240 (18.3%)	18 / 62 (29.0%)	18 / 144 (12.5%)	18 / 242 (7.4%)
Week 80	40 / 73 (54.8%)	40 / 180 (22.2%)	40 / 240 (16.7%)	14 / 55 (25.5%)	14 / 139 (10.1%)	14 / 242 (5.8%)
Week 83	37 / 70 (52.9%)	37 / 180 (20.6%)	37 / 240 (15.4%)	13 / 49 (26.5%)	13 / 138 (9.4%)	13 / 242 (5.4%)
Week 86	34 / 63 (54.0%)	34 / 179 (19.0%)	34 / 240 (14.2%)	12 / 40 (30.0%)	12 / 136 (8.8%)	12 / 242 (5.0%)
Week 89	33 / 57 (57.9%)	33 / 179 (18.4%)	33 / 240 (13.8%)	11 / 38 (28.9%)	11 / 136 (8.1%)	11 / 242 (4.5%)
Week 92	27 / 49 (55.1%)	27 / 178 (15.2%)	27 / 240 (11.3%)	8 / 33 (24.2%)	8 / 135 (5.9%)	8 / 242 (3.3%)
Week 95	22 / 41 (53.7%)	22 / 177 (12.4%)	22 / 240 (9.2%)	9 / 30 (30.0%)	9 / 135 (6.7%)	9 / 242 (3.7%)
Week 98	18 / 35 (51.4%)	18 / 176 (10.2%)	18 / 240 (7.5%)	6 / 27 (22.2%)	6 / 134 (4.5%)	6 / 242 (2.5%)
Week 101	14 / 30 (46.7%)	14 / 175 (8.0%)	14 / 240 (5.8%)	5 / 25 (20.0%)	5 / 134 (3.7%)	5 / 242 (2.1%)
Week 104	10 / 26 (38.5%)	10 / 175 (5.7%)	10 / 240 (4.2%)	4 / 20 (20.0%)	4 / 134 (3.0%)	4 / 242 (1.7%)
Week 107	8 / 24 (33.3%)	8 / 175 (4.6%)	8 / 240 (3.3%)	3 / 16 (18.8%)	3 / 134 (2.2%)	3 / 242 (1.2%)
Week 110	6 / 21 (28.6%)	6 / 175 (3.4%)	6 / 240 (2.5%)	3 / 15 (20.0%)	3 / 134 (2.2%)	3 / 242 (1.2%)
Week 113	8 / 18 (44.4%)	8 / 173 (4.6%)	8 / 240 (3.3%)	2 / 15 (13.3%)	2 / 134 (1.5%)	2 / 242 (0.8%)
Week 116	5 / 15 (33.3%)	5 / 172 (2.9%)	5 / 240 (2.1%)	3 / 14 (21.4%)	3 / 134 (2.2%)	3 / 242 (1.2%)
Week 119	5 / 11 (45.5%)	5 / 172 (2.9%)	5 / 240 (2.1%)	1 / 12 (8.3%)	1 / 134 (0.7%)	1 / 242 (0.4%)
Week 122	4 / 9 (44.4%)	4 / 172 (2.3%)	4 / 240 (1.7%)	3 / 9 (33.3%)	3 / 133 (2.3%)	3 / 242 (1.2%)

Abbreviations: EORTC QLQ-C30=European Organization for Research and Treatment of Cancer Quality of Life Questionnaire - Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: (a) Compliance rate is defined as the proportion of subjects who completed the instrument among those who were expected to complete at a given visit; (b) Modified completion rate is defined as the proportion of subjects who completed the instrument among the mITT analysis sets while accounting for deaths; (c) Completion rate is defined as the proportion of subjects who completed the instrument among the mITT analysis sets.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3001.2.1: EORTC QLQ-C30 - Return Rates - Analysis Set mITT 1

Analysis Visit	EV+Pembro (N=240)			Plat+Gem (N=242)		
	Compliance rate (a)	Modified completion rate (b)	Completion rate (c)	Compliance rate (a)	Modified completion rate (b)	Completion rate (c)
Week 125	3 / 8 (37.5%)	3 / 172 (1.7%)	3 / 240 (1.3%)	2 / 6 (33.3%)	2 / 133 (1.5%)	2 / 242 (0.8%)
Week 128	1 / 6 (16.7%)	1 / 172 (0.6%)	1 / 240 (0.4%)	3 / 6 (50.0%)	3 / 133 (2.3%)	3 / 242 (1.2%)
Week 131	1 / 4 (25.0%)	1 / 172 (0.6%)	1 / 240 (0.4%)	2 / 6 (33.3%)	2 / 133 (1.5%)	2 / 242 (0.8%)
Week 134	1 / 4 (25.0%)	1 / 172 (0.6%)	1 / 240 (0.4%)	2 / 6 (33.3%)	2 / 133 (1.5%)	2 / 242 (0.8%)
Week 137	1 / 2 (50.0%)	1 / 171 (0.6%)	1 / 240 (0.4%)	2 / 5 (40.0%)	2 / 132 (1.5%)	2 / 242 (0.8%)
Week 140	0 / 1 (0.0%)	0 / 171 (0.0%)	0 / 240 (0.0%)	1 / 3 (33.3%)	1 / 132 (0.8%)	1 / 242 (0.4%)
Week 143	0 / 1 (0.0%)	0 / 171 (0.0%)	0 / 240 (0.0%)	1 / 3 (33.3%)	1 / 132 (0.8%)	1 / 242 (0.4%)
Week 146	0 / 1 (0.0%)	0 / 171 (0.0%)	0 / 240 (0.0%)	1 / 2 (50.0%)	1 / 132 (0.8%)	1 / 242 (0.4%)
Week 149	0 / 1 (0.0%)	0 / 171 (0.0%)	0 / 240 (0.0%)	1 / 2 (50.0%)	1 / 132 (0.8%)	1 / 242 (0.4%)
Week 152	0 / 1 (0.0%)	0 / 171 (0.0%)	0 / 240 (0.0%)	1 / 2 (50.0%)	1 / 132 (0.8%)	1 / 242 (0.4%)

Abbreviations: EORTC QLQ-C30=European Organization for Research and Treatment of Cancer Quality of Life Questionnaire - Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: (a) Compliance rate is defined as the proportion of subjects who completed the instrument among those who were expected to complete at a given visit; (b) Modified completion rate is defined as the proportion of subjects who completed the instrument among the mITT analysis sets while accounting for deaths; (c) Completion rate is defined as the proportion of subjects who completed the instrument among the mITT analysis sets.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3001.2.2: EORTC QLQ-C30 - Return Rates - Analysis Set mITT 2

Analysis Visit	EV+Pembro (N=202)			Plat+Gem (N=202)		
	Compliance rate (a)	Modified completion rate (b)	Completion rate (c)	Compliance rate (a)	Modified completion rate (b)	Completion rate (c)
BASELINE	160 / 202 (79.2%)	160 / 202 (79.2%)	160 / 202 (79.2%)	165 / 202 (81.7%)	165 / 202 (81.7%)	165 / 202 (81.7%)
Week 1	141 / 201 (70.1%)	141 / 202 (69.8%)	141 / 202 (69.8%)	144 / 197 (73.1%)	144 / 200 (72.0%)	144 / 202 (71.3%)
Week 2	150 / 198 (75.8%)	150 / 199 (75.4%)	150 / 202 (74.3%)	147 / 194 (75.8%)	147 / 197 (74.6%)	147 / 202 (72.8%)
Week 3	139 / 196 (70.9%)	139 / 197 (70.6%)	139 / 202 (68.8%)	149 / 193 (77.2%)	149 / 196 (76.0%)	149 / 202 (73.8%)
Week 4	145 / 193 (75.1%)	145 / 194 (74.7%)	145 / 202 (71.8%)	150 / 190 (78.9%)	150 / 193 (77.7%)	150 / 202 (74.3%)
Week 5	137 / 193 (71.0%)	137 / 194 (70.6%)	137 / 202 (67.8%)	153 / 190 (80.5%)	153 / 193 (79.3%)	153 / 202 (75.7%)
Week 6	146 / 191 (76.4%)	146 / 192 (76.0%)	146 / 202 (72.3%)	145 / 190 (76.3%)	145 / 193 (75.1%)	145 / 202 (71.8%)
Week 7	147 / 191 (77.0%)	147 / 192 (76.6%)	147 / 202 (72.8%)	148 / 190 (77.9%)	148 / 193 (76.7%)	148 / 202 (73.3%)
Week 8	147 / 191 (77.0%)	147 / 192 (76.6%)	147 / 202 (72.8%)	145 / 189 (76.7%)	145 / 192 (75.5%)	145 / 202 (71.8%)
Week 9	142 / 190 (74.7%)	142 / 192 (74.0%)	142 / 202 (70.3%)	141 / 188 (75.0%)	141 / 191 (73.8%)	141 / 202 (69.8%)
Week 10	139 / 188 (73.9%)	139 / 190 (73.2%)	139 / 202 (68.8%)	142 / 187 (75.9%)	142 / 190 (74.7%)	142 / 202 (70.3%)
Week 11	137 / 186 (73.7%)	137 / 189 (72.5%)	137 / 202 (67.8%)	126 / 186 (67.7%)	126 / 189 (66.7%)	126 / 202 (62.4%)
Week 12	142 / 186 (76.3%)	142 / 189 (75.1%)	142 / 202 (70.3%)	130 / 185 (70.3%)	130 / 188 (69.1%)	130 / 202 (64.4%)
Week 14	139 / 185 (75.1%)	139 / 188 (73.9%)	139 / 202 (68.8%)	125 / 180 (69.4%)	125 / 183 (68.3%)	125 / 202 (61.9%)
Week 17	132 / 181 (72.9%)	132 / 184 (71.7%)	132 / 202 (65.3%)	120 / 174 (69.0%)	120 / 177 (67.8%)	120 / 202 (59.4%)
Week 20	120 / 180 (66.7%)	120 / 184 (65.2%)	120 / 202 (59.4%)	104 / 169 (61.5%)	104 / 172 (60.5%)	104 / 202 (51.5%)
Week 23	117 / 177 (66.1%)	117 / 181 (64.6%)	117 / 202 (57.9%)	88 / 159 (55.3%)	88 / 163 (54.0%)	88 / 202 (43.6%)
Week 26	112 / 173 (64.7%)	112 / 177 (63.3%)	112 / 202 (55.4%)	81 / 154 (52.6%)	81 / 158 (51.3%)	81 / 202 (40.1%)
Week 29	107 / 170 (62.9%)	107 / 174 (61.5%)	107 / 202 (53.0%)	77 / 150 (51.3%)	77 / 154 (50.0%)	77 / 202 (38.1%)
Week 32	102 / 165 (61.8%)	102 / 171 (59.6%)	102 / 202 (50.5%)	63 / 142 (44.4%)	63 / 147 (42.9%)	63 / 202 (31.2%)
Week 35	98 / 163 (60.1%)	98 / 170 (57.6%)	98 / 202 (48.5%)	62 / 135 (45.9%)	62 / 140 (44.3%)	62 / 202 (30.7%)
Week 38	97 / 157 (61.8%)	97 / 165 (58.8%)	97 / 202 (48.0%)	56 / 129 (43.4%)	56 / 135 (41.5%)	56 / 202 (27.7%)
Week 41	95 / 153 (62.1%)	95 / 163 (58.3%)	95 / 202 (47.0%)	52 / 122 (42.6%)	52 / 131 (39.7%)	52 / 202 (25.7%)
Week 44	86 / 141 (61.0%)	86 / 160 (53.8%)	86 / 202 (42.6%)	49 / 108 (45.4%)	49 / 125 (39.2%)	49 / 202 (24.3%)
Week 47	79 / 131 (60.3%)	79 / 157 (50.3%)	79 / 202 (39.1%)	43 / 98 (43.9%)	43 / 121 (35.5%)	43 / 202 (21.3%)

Abbreviations: EORTC QLQ-C30=European Organization for Research and Treatment of Cancer Quality of Life Questionnaire - Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: (a) Compliance rate is defined as the proportion of subjects who completed the instrument among those who were expected to complete at a given visit; (b) Modified completion rate is defined as the proportion of subjects who completed the instrument among the mITT analysis sets while accounting for deaths; (c) Completion rate is defined as the proportion of subjects who completed the instrument among the mITT analysis sets.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3001.2.2: EORTC QLQ-C30 - Return Rates - Analysis Set mITT 2

Analysis Visit	EV+Pembro (N=202)			Plat+Gem (N=202)		
	Compliance rate (a)	Modified completion rate (b)	Completion rate (c)	Compliance rate (a)	Modified completion rate (b)	Completion rate (c)
Week 50	74 / 126 (58.7%)	74 / 157 (47.1%)	74 / 202 (36.6%)	36 / 92 (39.1%)	36 / 118 (30.5%)	36 / 202 (17.8%)
Week 53	74 / 120 (61.7%)	74 / 154 (48.1%)	74 / 202 (36.6%)	31 / 80 (38.8%)	31 / 112 (27.7%)	31 / 202 (15.3%)
Week 56	72 / 112 (64.3%)	72 / 154 (46.8%)	72 / 202 (35.6%)	30 / 73 (41.1%)	30 / 108 (27.8%)	30 / 202 (14.9%)
Week 59	69 / 106 (65.1%)	69 / 152 (45.4%)	69 / 202 (34.2%)	23 / 64 (35.9%)	23 / 104 (22.1%)	23 / 202 (11.4%)
Week 62	62 / 94 (66.0%)	62 / 149 (41.6%)	62 / 202 (30.7%)	20 / 60 (33.3%)	20 / 102 (19.6%)	20 / 202 (9.9%)
Week 65	43 / 88 (48.9%)	43 / 149 (28.9%)	43 / 202 (21.3%)	17 / 52 (32.7%)	17 / 100 (17.0%)	17 / 202 (8.4%)
Week 68	46 / 83 (55.4%)	46 / 148 (31.1%)	46 / 202 (22.8%)	13 / 48 (27.1%)	13 / 98 (13.3%)	13 / 202 (6.4%)
Week 71	42 / 79 (53.2%)	42 / 148 (28.4%)	42 / 202 (20.8%)	13 / 42 (31.0%)	13 / 96 (13.5%)	13 / 202 (6.4%)
Week 74	38 / 71 (53.5%)	38 / 147 (25.9%)	38 / 202 (18.8%)	11 / 38 (28.9%)	11 / 95 (11.6%)	11 / 202 (5.4%)
Week 77	37 / 64 (57.8%)	37 / 147 (25.2%)	37 / 202 (18.3%)	11 / 33 (33.3%)	11 / 93 (11.8%)	11 / 202 (5.4%)
Week 80	36 / 60 (60.0%)	36 / 145 (24.8%)	36 / 202 (17.8%)	8 / 30 (26.7%)	8 / 92 (8.7%)	8 / 202 (4.0%)
Week 83	30 / 56 (53.6%)	30 / 143 (21.0%)	30 / 202 (14.9%)	9 / 26 (34.6%)	9 / 90 (10.0%)	9 / 202 (4.5%)
Week 86	26 / 49 (53.1%)	26 / 142 (18.3%)	26 / 202 (12.9%)	6 / 20 (30.0%)	6 / 90 (6.7%)	6 / 202 (3.0%)
Week 89	20 / 43 (46.5%)	20 / 140 (14.3%)	20 / 202 (9.9%)	7 / 17 (41.2%)	7 / 90 (7.8%)	7 / 202 (3.5%)
Week 92	19 / 36 (52.8%)	19 / 139 (13.7%)	19 / 202 (9.4%)	6 / 14 (42.9%)	6 / 88 (6.8%)	6 / 202 (3.0%)
Week 95	14 / 29 (48.3%)	14 / 139 (10.1%)	14 / 202 (6.9%)	4 / 11 (36.4%)	4 / 87 (4.6%)	4 / 202 (2.0%)
Week 98	10 / 23 (43.5%)	10 / 139 (7.2%)	10 / 202 (5.0%)	3 / 8 (37.5%)	3 / 86 (3.5%)	3 / 202 (1.5%)
Week 101	7 / 17 (41.2%)	7 / 138 (5.1%)	7 / 202 (3.5%)	3 / 8 (37.5%)	3 / 86 (3.5%)	3 / 202 (1.5%)
Week 104	7 / 13 (53.8%)	7 / 138 (5.1%)	7 / 202 (3.5%)	3 / 8 (37.5%)	3 / 86 (3.5%)	3 / 202 (1.5%)
Week 107	7 / 12 (58.3%)	7 / 138 (5.1%)	7 / 202 (3.5%)	2 / 7 (28.6%)	2 / 86 (2.3%)	2 / 202 (1.0%)
Week 110	3 / 9 (33.3%)	3 / 138 (2.2%)	3 / 202 (1.5%)	2 / 5 (40.0%)	2 / 86 (2.3%)	2 / 202 (1.0%)
Week 113	4 / 5 (80.0%)	4 / 138 (2.9%)	4 / 202 (2.0%)	1 / 3 (33.3%)	1 / 86 (1.2%)	1 / 202 (0.5%)
Week 116	3 / 4 (75.0%)	3 / 138 (2.2%)	3 / 202 (1.5%)	1 / 3 (33.3%)	1 / 86 (1.2%)	1 / 202 (0.5%)
Week 119	2 / 4 (50.0%)	2 / 138 (1.4%)	2 / 202 (1.0%)	1 / 3 (33.3%)	1 / 86 (1.2%)	1 / 202 (0.5%)
Week 122	2 / 4 (50.0%)	2 / 138 (1.4%)	2 / 202 (1.0%)	1 / 3 (33.3%)	1 / 86 (1.2%)	1 / 202 (0.5%)

Abbreviations: EORTC QLQ-C30=European Organization for Research and Treatment of Cancer Quality of Life Questionnaire - Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: (a) Compliance rate is defined as the proportion of subjects who completed the instrument among those who were expected to complete at a given visit; (b) Modified completion rate is defined as the proportion of subjects who completed the instrument among the mITT analysis sets while accounting for deaths; (c) Completion rate is defined as the proportion of subjects who completed the instrument among the mITT analysis sets.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3001.2.2: EORTC QLQ-C30 - Return Rates - Analysis Set mITT 2

Analysis Visit	EV+Pembro (N=202)			Plat+Gem (N=202)		
	Compliance rate (a)	Modified completion rate (b)	Completion rate (c)	Compliance rate (a)	Modified completion rate (b)	Completion rate (c)
Week 125	2 / 3 (66.7%)	2 / 138 (1.4%)	2 / 202 (1.0%)	1 / 2 (50.0%)	1 / 86 (1.2%)	1 / 202 (0.5%)
Week 128	1 / 3 (33.3%)	1 / 138 (0.7%)	1 / 202 (0.5%)	1 / 2 (50.0%)	1 / 86 (1.2%)	1 / 202 (0.5%)
Week 131	1 / 3 (33.3%)	1 / 138 (0.7%)	1 / 202 (0.5%)	0 / 1 (0.0%)	0 / 86 (0.0%)	0 / 202 (0.0%)
Week 134	1 / 1 (100.0%)	1 / 138 (0.7%)	1 / 202 (0.5%)	0 / 1 (0.0%)	0 / 86 (0.0%)	0 / 202 (0.0%)
Week 137	1 / 1 (100.0%)	1 / 138 (0.7%)	1 / 202 (0.5%)	0 / 1 (0.0%)	0 / 86 (0.0%)	0 / 202 (0.0%)

Abbreviations: EORTC QLQ-C30=European Organization for Research and Treatment of Cancer Quality of Life Questionnaire - Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: (a) Compliance rate is defined as the proportion of subjects who completed the instrument among those who were expected to complete at a given visit; (b) Modified completion rate is defined as the proportion of subjects who completed the instrument among the mITT analysis sets while accounting for deaths; (c) Completion rate is defined as the proportion of subjects who completed the instrument among the mITT analysis sets.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3001.3.1: EQ-5D-5L - Return Rates - Analysis Set mITT 1

Analysis Visit	EV+Pembro (N=240)			Plat+Gem (N=242)		
	Compliance rate (a)	Modified completion rate (b)	Completion rate (c)	Compliance rate (a)	Modified completion rate (b)	Completion rate (c)
BASELINE	211 / 240 (87.9%)	211 / 240 (87.9%)	211 / 240 (87.9%)	190 / 242 (78.5%)	190 / 242 (78.5%)	190 / 242 (78.5%)
Week 1	190 / 239 (79.5%)	190 / 240 (79.2%)	190 / 240 (79.2%)	179 / 235 (76.2%)	179 / 240 (74.6%)	179 / 242 (74.0%)
Week 2	204 / 239 (85.4%)	204 / 240 (85.0%)	204 / 240 (85.0%)	174 / 235 (74.0%)	174 / 240 (72.5%)	174 / 242 (71.9%)
Week 3	199 / 239 (83.3%)	199 / 240 (82.9%)	199 / 240 (82.9%)	186 / 235 (79.1%)	186 / 240 (77.5%)	186 / 242 (76.9%)
Week 4	195 / 239 (81.6%)	195 / 240 (81.3%)	195 / 240 (81.3%)	184 / 235 (78.3%)	184 / 240 (76.7%)	184 / 242 (76.0%)
Week 5	193 / 238 (81.1%)	193 / 239 (80.8%)	193 / 240 (80.4%)	188 / 233 (80.7%)	188 / 238 (79.0%)	188 / 242 (77.7%)
Week 6	191 / 238 (80.3%)	191 / 239 (79.9%)	191 / 240 (79.6%)	174 / 233 (74.7%)	174 / 238 (73.1%)	174 / 242 (71.9%)
Week 7	196 / 236 (83.1%)	196 / 238 (82.4%)	196 / 240 (81.7%)	188 / 233 (80.7%)	188 / 238 (79.0%)	188 / 242 (77.7%)
Week 8	193 / 235 (82.1%)	193 / 237 (81.4%)	193 / 240 (80.4%)	168 / 230 (73.0%)	168 / 236 (71.2%)	168 / 242 (69.4%)
Week 9	198 / 234 (84.6%)	198 / 236 (83.9%)	198 / 240 (82.5%)	178 / 230 (77.4%)	178 / 236 (75.4%)	178 / 242 (73.6%)
Week 10	191 / 234 (81.6%)	191 / 236 (80.9%)	191 / 240 (79.6%)	166 / 228 (72.8%)	166 / 234 (70.9%)	166 / 242 (68.6%)
Week 11	196 / 233 (84.1%)	196 / 236 (83.1%)	196 / 240 (81.7%)	168 / 226 (74.3%)	168 / 232 (72.4%)	168 / 242 (69.4%)
Week 12	186 / 233 (79.8%)	186 / 236 (78.8%)	186 / 240 (77.5%)	160 / 223 (71.7%)	160 / 229 (69.9%)	160 / 242 (66.1%)
Week 14	186 / 231 (80.5%)	186 / 234 (79.5%)	186 / 240 (77.5%)	154 / 221 (69.7%)	154 / 227 (67.8%)	154 / 242 (63.6%)
Week 17	178 / 227 (78.4%)	178 / 230 (77.4%)	178 / 240 (74.2%)	156 / 217 (71.9%)	156 / 224 (69.6%)	156 / 242 (64.5%)
Week 20	168 / 226 (74.3%)	168 / 229 (73.4%)	168 / 240 (70.0%)	127 / 211 (60.2%)	127 / 218 (58.3%)	127 / 242 (52.5%)
Week 23	162 / 223 (72.6%)	162 / 226 (71.7%)	162 / 240 (67.5%)	117 / 206 (56.8%)	117 / 213 (54.9%)	117 / 242 (48.3%)
Week 26	157 / 220 (71.4%)	157 / 223 (70.4%)	157 / 240 (65.4%)	108 / 200 (54.0%)	108 / 207 (52.2%)	108 / 242 (44.6%)
Week 29	157 / 215 (73.0%)	157 / 219 (71.7%)	157 / 240 (65.4%)	100 / 198 (50.5%)	100 / 205 (48.8%)	100 / 242 (41.3%)
Week 32	135 / 214 (63.1%)	135 / 218 (61.9%)	135 / 240 (56.3%)	83 / 187 (44.4%)	83 / 195 (42.6%)	83 / 242 (34.3%)
Week 35	133 / 211 (63.0%)	133 / 215 (61.9%)	133 / 240 (55.4%)	76 / 180 (42.2%)	76 / 188 (40.4%)	76 / 242 (31.4%)
Week 38	133 / 208 (63.9%)	133 / 212 (62.7%)	133 / 240 (55.4%)	74 / 174 (42.5%)	74 / 183 (40.4%)	74 / 242 (30.6%)
Week 41	129 / 202 (63.9%)	129 / 209 (61.7%)	129 / 240 (53.8%)	65 / 164 (39.6%)	65 / 177 (36.7%)	65 / 242 (26.9%)
Week 44	108 / 190 (56.8%)	108 / 206 (52.4%)	108 / 240 (45.0%)	60 / 148 (40.5%)	60 / 174 (34.5%)	60 / 242 (24.8%)
Week 47	100 / 172 (58.1%)	100 / 200 (50.0%)	100 / 240 (41.7%)	57 / 142 (40.1%)	57 / 171 (33.3%)	57 / 242 (23.6%)

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 levels; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: (a) Compliance rate is defined as the proportion of subjects who completed the instrument among those who were expected to complete at a given visit; (b) Modified completion rate is defined as the proportion of subjects who completed the instrument among the mITT analysis sets while accounting for deaths; (c) Completion rate is defined as the proportion of subjects who completed the instrument among the mITT analysis sets.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3001.3.1: EQ-5D-5L - Return Rates - Analysis Set mITT 1

Analysis Visit	EV+Pembro (N=240)			Plat+Gem (N=242)		
	Compliance rate (a)	Modified completion rate (b)	Completion rate (c)	Compliance rate (a)	Modified completion rate (b)	Completion rate (c)
Week 50	89 / 162 (54.9%)	89 / 198 (44.9%)	89 / 240 (37.1%)	51 / 132 (38.6%)	51 / 169 (30.2%)	51 / 242 (21.1%)
Week 53	79 / 149 (53.0%)	79 / 195 (40.5%)	79 / 240 (32.9%)	46 / 122 (37.7%)	46 / 165 (27.9%)	46 / 242 (19.0%)
Week 56	81 / 140 (57.9%)	81 / 191 (42.4%)	81 / 240 (33.8%)	39 / 117 (33.3%)	39 / 163 (23.9%)	39 / 242 (16.1%)
Week 59	72 / 132 (54.5%)	72 / 190 (37.9%)	72 / 240 (30.0%)	37 / 107 (34.6%)	37 / 160 (23.1%)	37 / 242 (15.3%)
Week 62	65 / 127 (51.2%)	65 / 189 (34.4%)	65 / 240 (27.1%)	32 / 100 (32.0%)	32 / 156 (20.5%)	32 / 242 (13.2%)
Week 65	58 / 112 (51.8%)	58 / 186 (31.2%)	58 / 240 (24.2%)	30 / 92 (32.6%)	30 / 155 (19.4%)	30 / 242 (12.4%)
Week 68	53 / 105 (50.5%)	53 / 184 (28.8%)	53 / 240 (22.1%)	25 / 83 (30.1%)	25 / 150 (16.7%)	25 / 242 (10.3%)
Week 71	51 / 98 (52.0%)	51 / 183 (27.9%)	51 / 240 (21.3%)	22 / 79 (27.8%)	22 / 150 (14.7%)	22 / 242 (9.1%)
Week 74	47 / 92 (51.1%)	47 / 182 (25.8%)	47 / 240 (19.6%)	21 / 66 (31.8%)	21 / 144 (14.6%)	21 / 242 (8.7%)
Week 77	45 / 82 (54.9%)	45 / 181 (24.9%)	45 / 240 (18.8%)	18 / 62 (29.0%)	18 / 144 (12.5%)	18 / 242 (7.4%)
Week 80	40 / 73 (54.8%)	40 / 180 (22.2%)	40 / 240 (16.7%)	14 / 55 (25.5%)	14 / 139 (10.1%)	14 / 242 (5.8%)
Week 83	37 / 70 (52.9%)	37 / 180 (20.6%)	37 / 240 (15.4%)	13 / 49 (26.5%)	13 / 138 (9.4%)	13 / 242 (5.4%)
Week 86	34 / 63 (54.0%)	34 / 179 (19.0%)	34 / 240 (14.2%)	12 / 40 (30.0%)	12 / 136 (8.8%)	12 / 242 (5.0%)
Week 89	33 / 57 (57.9%)	33 / 179 (18.4%)	33 / 240 (13.8%)	11 / 38 (28.9%)	11 / 136 (8.1%)	11 / 242 (4.5%)
Week 92	27 / 49 (55.1%)	27 / 178 (15.2%)	27 / 240 (11.3%)	8 / 33 (24.2%)	8 / 135 (5.9%)	8 / 242 (3.3%)
Week 95	22 / 41 (53.7%)	22 / 177 (12.4%)	22 / 240 (9.2%)	9 / 30 (30.0%)	9 / 135 (6.7%)	9 / 242 (3.7%)
Week 98	18 / 35 (51.4%)	18 / 176 (10.2%)	18 / 240 (7.5%)	6 / 27 (22.2%)	6 / 134 (4.5%)	6 / 242 (2.5%)
Week 101	14 / 30 (46.7%)	14 / 175 (8.0%)	14 / 240 (5.8%)	5 / 25 (20.0%)	5 / 134 (3.7%)	5 / 242 (2.1%)
Week 104	10 / 26 (38.5%)	10 / 175 (5.7%)	10 / 240 (4.2%)	4 / 20 (20.0%)	4 / 134 (3.0%)	4 / 242 (1.7%)
Week 107	8 / 24 (33.3%)	8 / 175 (4.6%)	8 / 240 (3.3%)	3 / 16 (18.8%)	3 / 134 (2.2%)	3 / 242 (1.2%)
Week 110	6 / 21 (28.6%)	6 / 175 (3.4%)	6 / 240 (2.5%)	3 / 15 (20.0%)	3 / 134 (2.2%)	3 / 242 (1.2%)
Week 113	8 / 18 (44.4%)	8 / 173 (4.6%)	8 / 240 (3.3%)	2 / 15 (13.3%)	2 / 134 (1.5%)	2 / 242 (0.8%)
Week 116	5 / 15 (33.3%)	5 / 172 (2.9%)	5 / 240 (2.1%)	3 / 14 (21.4%)	3 / 134 (2.2%)	3 / 242 (1.2%)
Week 119	5 / 11 (45.5%)	5 / 172 (2.9%)	5 / 240 (2.1%)	1 / 12 (8.3%)	1 / 134 (0.7%)	1 / 242 (0.4%)
Week 122	4 / 9 (44.4%)	4 / 172 (2.3%)	4 / 240 (1.7%)	3 / 9 (33.3%)	3 / 133 (2.3%)	3 / 242 (1.2%)

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 levels; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: (a) Compliance rate is defined as the proportion of subjects who completed the instrument among those who were expected to complete at a given visit; (b) Modified completion rate is defined as the proportion of subjects who completed the instrument among the mITT analysis sets while accounting for deaths; (c) Completion rate is defined as the proportion of subjects who completed the instrument among the mITT analysis sets.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3001.3.1: EQ-5D-5L - Return Rates - Analysis Set mITT 1

Analysis Visit	EV+Pembro (N=240)			Plat+Gem (N=242)		
	Compliance rate (a)	Modified completion rate (b)	Completion rate (c)	Compliance rate (a)	Modified completion rate (b)	Completion rate (c)
Week 125	3 / 8 (37.5%)	3 / 172 (1.7%)	3 / 240 (1.3%)	2 / 6 (33.3%)	2 / 133 (1.5%)	2 / 242 (0.8%)
Week 128	1 / 6 (16.7%)	1 / 172 (0.6%)	1 / 240 (0.4%)	3 / 6 (50.0%)	3 / 133 (2.3%)	3 / 242 (1.2%)
Week 131	1 / 4 (25.0%)	1 / 172 (0.6%)	1 / 240 (0.4%)	2 / 6 (33.3%)	2 / 133 (1.5%)	2 / 242 (0.8%)
Week 134	1 / 4 (25.0%)	1 / 172 (0.6%)	1 / 240 (0.4%)	2 / 6 (33.3%)	2 / 133 (1.5%)	2 / 242 (0.8%)
Week 137	1 / 2 (50.0%)	1 / 171 (0.6%)	1 / 240 (0.4%)	2 / 5 (40.0%)	2 / 132 (1.5%)	2 / 242 (0.8%)
Week 140	0 / 1 (0.0%)	0 / 171 (0.0%)	0 / 240 (0.0%)	1 / 3 (33.3%)	1 / 132 (0.8%)	1 / 242 (0.4%)
Week 143	0 / 1 (0.0%)	0 / 171 (0.0%)	0 / 240 (0.0%)	1 / 3 (33.3%)	1 / 132 (0.8%)	1 / 242 (0.4%)
Week 146	0 / 1 (0.0%)	0 / 171 (0.0%)	0 / 240 (0.0%)	1 / 2 (50.0%)	1 / 132 (0.8%)	1 / 242 (0.4%)
Week 149	0 / 1 (0.0%)	0 / 171 (0.0%)	0 / 240 (0.0%)	1 / 2 (50.0%)	1 / 132 (0.8%)	1 / 242 (0.4%)
Week 152	0 / 1 (0.0%)	0 / 171 (0.0%)	0 / 240 (0.0%)	1 / 2 (50.0%)	1 / 132 (0.8%)	1 / 242 (0.4%)

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 levels; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: (a) Compliance rate is defined as the proportion of subjects who completed the instrument among those who were expected to complete at a given visit; (b) Modified completion rate is defined as the proportion of subjects who completed the instrument among the mITT analysis sets while accounting for deaths; (c) Completion rate is defined as the proportion of subjects who completed the instrument among the mITT analysis sets.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3001.3.2: EQ-5D-5L - Return Rates - Analysis Set mITT 2

Analysis Visit	EV+Pembro (N=202)			Plat+Gem (N=202)		
	Compliance rate (a)	Modified completion rate (b)	Completion rate (c)	Compliance rate (a)	Modified completion rate (b)	Completion rate (c)
BASELINE	166 / 202 (82.2%)	166 / 202 (82.2%)	166 / 202 (82.2%)	168 / 202 (83.2%)	168 / 202 (83.2%)	168 / 202 (83.2%)
Week 1	143 / 201 (71.1%)	143 / 202 (70.8%)	143 / 202 (70.8%)	146 / 197 (74.1%)	146 / 200 (73.0%)	146 / 202 (72.3%)
Week 2	156 / 198 (78.8%)	156 / 199 (78.4%)	156 / 202 (77.2%)	153 / 194 (78.9%)	153 / 197 (77.7%)	153 / 202 (75.7%)
Week 3	141 / 196 (71.9%)	141 / 197 (71.6%)	141 / 202 (69.8%)	150 / 193 (77.7%)	150 / 196 (76.5%)	150 / 202 (74.3%)
Week 4	147 / 193 (76.2%)	147 / 194 (75.8%)	147 / 202 (72.8%)	152 / 190 (80.0%)	152 / 193 (78.8%)	152 / 202 (75.2%)
Week 5	139 / 193 (72.0%)	139 / 194 (71.6%)	139 / 202 (68.8%)	157 / 190 (82.6%)	157 / 193 (81.3%)	157 / 202 (77.7%)
Week 6	150 / 191 (78.5%)	150 / 192 (78.1%)	150 / 202 (74.3%)	146 / 190 (76.8%)	146 / 193 (75.6%)	146 / 202 (72.3%)
Week 7	152 / 191 (79.6%)	152 / 192 (79.2%)	152 / 202 (75.2%)	150 / 190 (78.9%)	150 / 193 (77.7%)	150 / 202 (74.3%)
Week 8	152 / 191 (79.6%)	152 / 192 (79.2%)	152 / 202 (75.2%)	147 / 189 (77.8%)	147 / 192 (76.6%)	147 / 202 (72.8%)
Week 9	144 / 190 (75.8%)	144 / 192 (75.0%)	144 / 202 (71.3%)	142 / 188 (75.5%)	142 / 191 (74.3%)	142 / 202 (70.3%)
Week 10	139 / 188 (73.9%)	139 / 190 (73.2%)	139 / 202 (68.8%)	143 / 187 (76.5%)	143 / 190 (75.3%)	143 / 202 (70.8%)
Week 11	138 / 186 (74.2%)	138 / 189 (73.0%)	138 / 202 (68.3%)	127 / 186 (68.3%)	127 / 189 (67.2%)	127 / 202 (62.9%)
Week 12	143 / 186 (76.9%)	143 / 189 (75.7%)	143 / 202 (70.8%)	130 / 185 (70.3%)	130 / 188 (69.1%)	130 / 202 (64.4%)
Week 14	141 / 185 (76.2%)	141 / 188 (75.0%)	141 / 202 (69.8%)	125 / 180 (69.4%)	125 / 183 (68.3%)	125 / 202 (61.9%)
Week 17	133 / 181 (73.5%)	133 / 184 (72.3%)	133 / 202 (65.8%)	120 / 174 (69.0%)	120 / 177 (67.8%)	120 / 202 (59.4%)
Week 20	120 / 180 (66.7%)	120 / 184 (65.2%)	120 / 202 (59.4%)	104 / 169 (61.5%)	104 / 172 (60.5%)	104 / 202 (51.5%)
Week 23	117 / 177 (66.1%)	117 / 181 (64.6%)	117 / 202 (57.9%)	89 / 159 (56.0%)	89 / 163 (54.6%)	89 / 202 (44.1%)
Week 26	114 / 173 (65.9%)	114 / 177 (64.4%)	114 / 202 (56.4%)	81 / 154 (52.6%)	81 / 158 (51.3%)	81 / 202 (40.1%)
Week 29	108 / 170 (63.5%)	108 / 174 (62.1%)	108 / 202 (53.5%)	77 / 150 (51.3%)	77 / 154 (50.0%)	77 / 202 (38.1%)
Week 32	104 / 165 (63.0%)	104 / 171 (60.8%)	104 / 202 (51.5%)	64 / 142 (45.1%)	64 / 147 (43.5%)	64 / 202 (31.7%)
Week 35	98 / 163 (60.1%)	98 / 170 (57.6%)	98 / 202 (48.5%)	62 / 135 (45.9%)	62 / 140 (44.3%)	62 / 202 (30.7%)
Week 38	97 / 157 (61.8%)	97 / 165 (58.8%)	97 / 202 (48.0%)	56 / 129 (43.4%)	56 / 135 (41.5%)	56 / 202 (27.7%)
Week 41	96 / 153 (62.7%)	96 / 163 (58.9%)	96 / 202 (47.5%)	52 / 122 (42.6%)	52 / 131 (39.7%)	52 / 202 (25.7%)
Week 44	86 / 141 (61.0%)	86 / 160 (53.8%)	86 / 202 (42.6%)	49 / 108 (45.4%)	49 / 125 (39.2%)	49 / 202 (24.3%)
Week 47	79 / 131 (60.3%)	79 / 157 (50.3%)	79 / 202 (39.1%)	43 / 98 (43.9%)	43 / 121 (35.5%)	43 / 202 (21.3%)

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 levels; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: (a) Compliance rate is defined as the proportion of subjects who completed the instrument among those who were expected to complete at a given visit; (b) Modified completion rate is defined as the proportion of subjects who completed the instrument among the mITT analysis sets while accounting for deaths; (c) Completion rate is defined as the proportion of subjects who completed the instrument among the mITT analysis sets.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3001.3.2: EQ-5D-5L - Return Rates - Analysis Set mITT 2

Analysis Visit	EV+Pembro (N=202)			Plat+Gem (N=202)		
	Compliance rate (a)	Modified completion rate (b)	Completion rate (c)	Compliance rate (a)	Modified completion rate (b)	Completion rate (c)
Week 50	75 / 126 (59.5%)	75 / 157 (47.8%)	75 / 202 (37.1%)	36 / 92 (39.1%)	36 / 118 (30.5%)	36 / 202 (17.8%)
Week 53	76 / 120 (63.3%)	76 / 154 (49.4%)	76 / 202 (37.6%)	31 / 80 (38.8%)	31 / 112 (27.7%)	31 / 202 (15.3%)
Week 56	73 / 112 (65.2%)	73 / 154 (47.4%)	73 / 202 (36.1%)	30 / 73 (41.1%)	30 / 108 (27.8%)	30 / 202 (14.9%)
Week 59	69 / 106 (65.1%)	69 / 152 (45.4%)	69 / 202 (34.2%)	23 / 64 (35.9%)	23 / 104 (22.1%)	23 / 202 (11.4%)
Week 62	62 / 94 (66.0%)	62 / 149 (41.6%)	62 / 202 (30.7%)	20 / 60 (33.3%)	20 / 102 (19.6%)	20 / 202 (9.9%)
Week 65	43 / 88 (48.9%)	43 / 149 (28.9%)	43 / 202 (21.3%)	17 / 52 (32.7%)	17 / 100 (17.0%)	17 / 202 (8.4%)
Week 68	46 / 83 (55.4%)	46 / 148 (31.1%)	46 / 202 (22.8%)	13 / 48 (27.1%)	13 / 98 (13.3%)	13 / 202 (6.4%)
Week 71	43 / 79 (54.4%)	43 / 148 (29.1%)	43 / 202 (21.3%)	13 / 42 (31.0%)	13 / 96 (13.5%)	13 / 202 (6.4%)
Week 74	38 / 71 (53.5%)	38 / 147 (25.9%)	38 / 202 (18.8%)	11 / 38 (28.9%)	11 / 95 (11.6%)	11 / 202 (5.4%)
Week 77	37 / 64 (57.8%)	37 / 147 (25.2%)	37 / 202 (18.3%)	11 / 33 (33.3%)	11 / 93 (11.8%)	11 / 202 (5.4%)
Week 80	36 / 60 (60.0%)	36 / 145 (24.8%)	36 / 202 (17.8%)	8 / 30 (26.7%)	8 / 92 (8.7%)	8 / 202 (4.0%)
Week 83	30 / 56 (53.6%)	30 / 143 (21.0%)	30 / 202 (14.9%)	9 / 26 (34.6%)	9 / 90 (10.0%)	9 / 202 (4.5%)
Week 86	26 / 49 (53.1%)	26 / 142 (18.3%)	26 / 202 (12.9%)	6 / 20 (30.0%)	6 / 90 (6.7%)	6 / 202 (3.0%)
Week 89	20 / 43 (46.5%)	20 / 140 (14.3%)	20 / 202 (9.9%)	7 / 17 (41.2%)	7 / 90 (7.8%)	7 / 202 (3.5%)
Week 92	19 / 36 (52.8%)	19 / 139 (13.7%)	19 / 202 (9.4%)	6 / 14 (42.9%)	6 / 88 (6.8%)	6 / 202 (3.0%)
Week 95	14 / 29 (48.3%)	14 / 139 (10.1%)	14 / 202 (6.9%)	4 / 11 (36.4%)	4 / 87 (4.6%)	4 / 202 (2.0%)
Week 98	10 / 23 (43.5%)	10 / 139 (7.2%)	10 / 202 (5.0%)	3 / 8 (37.5%)	3 / 86 (3.5%)	3 / 202 (1.5%)
Week 101	7 / 17 (41.2%)	7 / 138 (5.1%)	7 / 202 (3.5%)	3 / 8 (37.5%)	3 / 86 (3.5%)	3 / 202 (1.5%)
Week 104	7 / 13 (53.8%)	7 / 138 (5.1%)	7 / 202 (3.5%)	3 / 8 (37.5%)	3 / 86 (3.5%)	3 / 202 (1.5%)
Week 107	7 / 12 (58.3%)	7 / 138 (5.1%)	7 / 202 (3.5%)	2 / 7 (28.6%)	2 / 86 (2.3%)	2 / 202 (1.0%)
Week 110	3 / 9 (33.3%)	3 / 138 (2.2%)	3 / 202 (1.5%)	2 / 5 (40.0%)	2 / 86 (2.3%)	2 / 202 (1.0%)
Week 113	4 / 5 (80.0%)	4 / 138 (2.9%)	4 / 202 (2.0%)	1 / 3 (33.3%)	1 / 86 (1.2%)	1 / 202 (0.5%)
Week 116	3 / 4 (75.0%)	3 / 138 (2.2%)	3 / 202 (1.5%)	1 / 3 (33.3%)	1 / 86 (1.2%)	1 / 202 (0.5%)
Week 119	2 / 4 (50.0%)	2 / 138 (1.4%)	2 / 202 (1.0%)	1 / 3 (33.3%)	1 / 86 (1.2%)	1 / 202 (0.5%)
Week 122	2 / 4 (50.0%)	2 / 138 (1.4%)	2 / 202 (1.0%)	1 / 3 (33.3%)	1 / 86 (1.2%)	1 / 202 (0.5%)

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 levels; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: (a) Compliance rate is defined as the proportion of subjects who completed the instrument among those who were expected to complete at a given visit; (b) Modified completion rate is defined as the proportion of subjects who completed the instrument among the mITT analysis sets while accounting for deaths; (c) Completion rate is defined as the proportion of subjects who completed the instrument among the mITT analysis sets.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3001.3.2: EQ-5D-5L - Return Rates - Analysis Set mITT 2

Analysis Visit	EV+Pembro (N=202)			Plat+Gem (N=202)		
	Compliance rate (a)	Modified completion rate (b)	Completion rate (c)	Compliance rate (a)	Modified completion rate (b)	Completion rate (c)
Week 125	2 / 3 (66.7%)	2 / 138 (1.4%)	2 / 202 (1.0%)	1 / 2 (50.0%)	1 / 86 (1.2%)	1 / 202 (0.5%)
Week 128	1 / 3 (33.3%)	1 / 138 (0.7%)	1 / 202 (0.5%)	1 / 2 (50.0%)	1 / 86 (1.2%)	1 / 202 (0.5%)
Week 131	1 / 3 (33.3%)	1 / 138 (0.7%)	1 / 202 (0.5%)	0 / 1 (0.0%)	0 / 86 (0.0%)	0 / 202 (0.0%)
Week 134	1 / 1 (100.0%)	1 / 138 (0.7%)	1 / 202 (0.5%)	0 / 1 (0.0%)	0 / 86 (0.0%)	0 / 202 (0.0%)
Week 137	1 / 1 (100.0%)	1 / 138 (0.7%)	1 / 202 (0.5%)	0 / 1 (0.0%)	0 / 86 (0.0%)	0 / 202 (0.0%)

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 levels; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: (a) Compliance rate is defined as the proportion of subjects who completed the instrument among those who were expected to complete at a given visit; (b) Modified completion rate is defined as the proportion of subjects who completed the instrument among the mITT analysis sets while accounting for deaths; (c) Completion rate is defined as the proportion of subjects who completed the instrument among the mITT analysis sets.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.1: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
EV+Pembro (N=240)												
BASELINE	209	2.99	2.80	0.0	3.00	10.0						
Week 1	190	3.17	2.82	0.0	3.00	10.0	187	0.20	2.24	-8.0	0.00	8.0
Week 2	204	3.22	2.70	0.0	3.00	10.0	192	0.39	2.29	-5.0	0.00	9.0
Week 3	199	3.16	2.48	0.0	3.00	9.0	185	0.10	2.59	-10.0	0.00	8.0
Week 4	195	2.39	2.48	0.0	2.00	10.0	181	-0.54	2.65	-10.0	0.00	7.0
Week 5	193	2.28	2.34	0.0	2.00	8.0	177	-0.53	2.63	-8.0	0.00	8.0
Week 6	189	2.43	2.48	0.0	2.00	8.0	172	-0.34	2.69	-8.0	0.00	8.0
Week 7	196	2.28	2.49	0.0	1.00	10.0	178	-0.67	2.85	-8.0	0.00	10.0
Week 8	192	2.18	2.40	0.0	1.00	10.0	173	-0.76	2.85	-10.0	0.00	8.0
Week 9	198	2.49	2.57	0.0	2.00	10.0	182	-0.43	2.90	-8.0	0.00	10.0
Week 10	191	2.22	2.37	0.0	2.00	9.0	176	-0.68	2.83	-9.0	0.00	8.0
Week 11	196	2.06	2.29	0.0	1.00	10.0	178	-0.88	2.68	-8.0	0.00	6.0
Week 12	186	2.20	2.44	0.0	1.00	10.0	172	-0.73	3.10	-10.0	0.00	8.0
Week 14	185	2.28	2.49	0.0	1.00	9.0	168	-0.54	2.76	-8.0	0.00	9.0
Week 17	178	2.13	2.31	0.0	2.00	9.0	163	-0.69	3.01	-8.0	0.00	9.0
Week 20	167	2.25	2.50	0.0	1.00	10.0	155	-0.52	2.97	-8.0	0.00	7.0
Week 23	162	2.25	2.51	0.0	1.00	9.0	151	-0.44	3.18	-10.0	0.00	7.0
Week 26	156	2.28	2.54	0.0	1.00	9.0	145	-0.51	3.16	-8.0	0.00	7.0
Week 29	157	2.25	2.41	0.0	1.00	9.0	146	-0.32	2.79	-8.0	0.00	7.0
Week 32	135	2.54	2.65	0.0	2.00	8.0	125	0.00	3.05	-8.0	0.00	8.0
Week 35	132	2.50	2.50	0.0	2.00	9.0	122	-0.09	3.00	-8.0	0.00	8.0
Week 38	132	2.29	2.56	0.0	1.00	9.0	124	-0.40	3.26	-10.0	0.00	9.0
Week 41	129	2.35	2.49	0.0	2.00	9.0	119	0.00	3.13	-8.0	0.00	8.0
Week 44	108	2.32	2.53	0.0	1.00	10.0	100	0.09	3.02	-8.0	0.00	10.0
Week 47	100	2.11	2.34	0.0	1.00	7.0	94	-0.22	2.97	-8.0	0.00	7.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.1: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	89	2.22	2.24	0.0	2.00	8.0	84	0.11	2.58	-7.0	0.00	6.0
Week 53	79	2.10	2.45	0.0	1.00	9.0	74	0.08	3.28	-8.0	0.00	9.0
Week 56	81	2.15	2.71	0.0	1.00	10.0	76	-0.01	3.35	-8.0	0.00	9.0
Week 59	72	2.14	2.64	0.0	1.00	9.0	68	0.04	3.25	-8.0	0.00	8.0
Week 62	65	2.25	2.69	0.0	1.00	9.0	63	0.35	3.08	-7.0	0.00	8.0
Week 65	58	2.16	2.36	0.0	1.00	8.0	54	-0.33	3.22	-8.0	0.00	7.0
Week 68	53	1.87	2.39	0.0	1.00	8.0	52	-0.33	3.28	-8.0	0.00	7.0
Week 71	51	1.92	2.23	0.0	1.00	8.0	49	-0.24	3.41	-8.0	0.00	8.0
Week 74	47	1.91	1.99	0.0	2.00	6.0	46	-0.07	2.82	-8.0	0.00	5.0
Week 77	44	2.50	2.49	0.0	2.00	8.0	42	0.10	3.25	-7.0	0.00	7.0
Week 80	40	2.20	2.42	0.0	1.00	8.0	37	-0.43	3.00	-7.0	0.00	7.0
Week 83	37	2.24	2.48	0.0	1.00	8.0	35	-0.43	3.03	-7.0	0.00	7.0
Week 86	34	2.26	2.50	0.0	1.00	8.0	31	-0.13	2.96	-7.0	0.00	8.0
Week 89	33	2.64	2.77	0.0	2.00	8.0	31	0.32	3.47	-7.0	0.00	8.0
Week 92	27	2.48	2.42	0.0	2.00	8.0	25	0.36	2.83	-5.0	0.00	6.0
Week 95	22	2.77	2.74	0.0	3.00	8.0	21	0.48	3.22	-5.0	0.00	6.0
Week 98	18	2.17	2.77	0.0	0.50	8.0	17	0.24	3.42	-5.0	0.00	7.0
Week 101	14	1.86	2.35	0.0	0.50	6.0	14	0.64	2.87	-5.0	0.00	5.0
Week 104	10	2.40	3.06	0.0	0.50	8.0	10	1.40	3.92	-4.0	0.00	8.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.1: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Plat+Gem (N=242)												
BASELINE	190	3.28	2.88	0.0	3.00	10.0						
Week 1	179	3.12	2.60	0.0	3.00	10.0	164	0.02	2.50	-6.0	0.00	10.0
Week 2	173	3.02	2.59	0.0	3.00	10.0	153	0.03	2.55	-6.0	0.00	10.0
Week 3	185	2.99	2.76	0.0	3.00	10.0	163	-0.10	2.66	-8.0	0.00	9.0
Week 4	183	2.77	2.55	0.0	2.00	9.0	157	-0.41	2.50	-7.0	0.00	9.0
Week 5	187	2.99	2.67	0.0	3.00	10.0	157	0.06	2.79	-6.0	0.00	9.0
Week 6	174	2.91	2.71	0.0	2.50	10.0	151	-0.30	2.99	-9.0	0.00	10.0
Week 7	187	2.46	2.42	0.0	2.00	10.0	160	-0.51	2.71	-9.0	0.00	7.0
Week 8	167	2.82	2.66	0.0	2.00	10.0	146	-0.23	3.01	-9.0	0.00	8.0
Week 9	177	2.67	2.63	0.0	2.00	10.0	152	-0.34	3.18	-9.0	0.00	9.0
Week 10	166	2.64	2.66	0.0	2.00	9.0	141	-0.38	3.01	-9.0	0.00	8.0
Week 11	168	2.29	2.51	0.0	1.00	10.0	145	-0.75	2.67	-9.0	0.00	7.0
Week 12	159	2.50	2.57	0.0	2.00	9.0	140	-0.47	2.67	-9.0	0.00	8.0
Week 14	153	2.69	2.47	0.0	2.00	9.0	129	-0.37	2.99	-9.0	0.00	7.0
Week 17	156	2.60	2.67	0.0	2.00	9.0	133	-0.36	3.22	-9.0	0.00	8.0
Week 20	126	2.36	2.58	0.0	2.00	10.0	111	-0.55	3.04	-8.0	0.00	10.0
Week 23	115	2.73	2.84	0.0	2.00	10.0	98	-0.17	3.13	-7.0	0.00	7.0
Week 26	108	2.55	2.86	0.0	1.00	10.0	96	-0.23	2.96	-7.0	0.00	8.0
Week 29	100	2.51	2.37	0.0	2.00	8.0	87	-0.07	2.34	-6.0	0.00	8.0
Week 32	83	2.42	2.63	0.0	1.00	9.0	77	-0.05	2.76	-6.0	0.00	9.0
Week 35	76	2.71	2.68	0.0	2.00	10.0	70	0.30	2.95	-6.0	0.00	9.0
Week 38	74	2.28	2.68	0.0	1.00	8.0	66	-0.05	2.86	-6.0	0.00	8.0
Week 41	65	2.38	2.57	0.0	1.00	8.0	57	0.02	2.69	-5.0	0.00	8.0
Week 44	60	2.93	2.72	0.0	2.50	8.0	54	0.30	2.88	-6.0	0.00	8.0
Week 47	56	2.61	2.63	0.0	2.00	9.0	50	0.02	2.72	-6.0	0.00	6.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.1: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	51	3.06	2.94	0.0	2.00	9.0	47	0.23	2.75	-6.0	0.00	6.0
Week 53	46	2.28	2.44	0.0	1.50	7.0	42	-0.24	2.42	-6.0	0.00	5.0
Week 56	39	3.03	2.86	0.0	3.00	8.0	34	0.21	2.84	-6.0	0.50	6.0
Week 59	37	2.35	2.49	0.0	2.00	8.0	33	-0.24	2.87	-6.0	0.00	7.0
Week 62	32	2.03	2.24	0.0	1.50	7.0	29	-0.66	2.42	-6.0	0.00	6.0
Week 65	30	1.80	2.31	0.0	0.50	8.0	26	-0.88	2.42	-8.0	0.00	4.0
Week 68	25	2.52	2.80	0.0	1.00	8.0	21	-0.43	2.23	-6.0	0.00	4.0
Week 71	22	2.77	3.04	0.0	2.00	9.0	19	0.16	2.83	-6.0	0.00	9.0
Week 74	21	2.67	3.01	0.0	2.00	9.0	18	-0.67	2.09	-6.0	0.00	3.0
Week 77	18	3.50	3.59	0.0	1.50	10.0	15	0.13	3.85	-6.0	0.00	9.0
Week 80	14	2.07	2.16	0.0	2.00	7.0	13	-0.85	1.91	-4.0	0.00	3.0
Week 83	13	3.15	3.05	0.0	2.00	8.0	12	-0.50	3.03	-6.0	0.00	6.0
Week 86	12	1.33	2.27	0.0	0.50	7.0	11	-1.73	2.37	-6.0	-1.00	1.0
Week 89	11	1.91	2.74	0.0	1.00	8.0	10	-1.30	2.54	-6.0	-1.00	2.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.1.1: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Present	EV+Pembro (N= 48)												
	BASELINE	39	3.87	3.16	0.0	4.00	10.0						
	Week 1	32	3.72	3.03	0.0	3.00	10.0	32	-0.19	3.06	-7.0	0.00	7.0
	Week 2	38	4.03	3.16	0.0	4.00	10.0	34	0.53	2.74	-3.0	0.00	9.0
	Week 3	35	3.89	2.51	0.0	4.00	8.0	30	-0.40	3.11	-10.0	0.00	6.0
	Week 4	36	3.22	2.89	0.0	3.00	10.0	31	-0.81	3.35	-10.0	0.00	5.0
	Week 5	31	3.29	2.55	0.0	3.00	8.0	25	-0.68	3.72	-8.0	0.00	8.0
	Week 6	31	3.55	2.71	0.0	4.00	8.0	25	-0.24	2.96	-7.0	0.00	5.0
	Week 7	35	2.94	2.87	0.0	2.00	10.0	29	-0.97	3.57	-8.0	-1.00	10.0
	Week 8	36	3.11	2.68	0.0	3.00	10.0	31	-1.16	3.12	-10.0	-1.00	4.0
	Week 9	35	3.34	2.96	0.0	3.00	10.0	31	-0.48	3.22	-6.0	0.00	10.0
	Week 10	34	2.88	2.77	0.0	2.50	9.0	30	-1.10	3.35	-9.0	-0.50	8.0
	Week 11	35	3.03	2.74	0.0	3.00	10.0	30	-0.90	3.11	-8.0	0.00	5.0
	Week 12	33	2.67	2.85	0.0	2.00	10.0	29	-1.10	3.81	-10.0	0.00	8.0
	Week 14	31	2.68	2.70	0.0	2.00	9.0	26	-1.15	3.43	-8.0	-0.50	9.0
	Week 17	31	2.77	2.43	0.0	2.00	7.0	25	-1.44	3.63	-8.0	-2.00	5.0
	Week 20	27	2.89	2.39	0.0	3.00	8.0	24	-0.88	3.14	-7.0	-0.50	7.0
	Week 23	26	2.85	2.34	0.0	3.00	7.0	23	-1.00	3.38	-8.0	0.00	7.0
	Week 26	25	2.24	2.26	0.0	2.00	7.0	22	-1.45	3.13	-8.0	0.00	3.0
	Week 29	23	2.30	2.48	0.0	1.00	9.0	22	-0.64	2.90	-8.0	0.00	4.0
	Week 32	21	3.29	2.59	0.0	4.00	7.0	19	0.16	3.20	-8.0	1.00	7.0
	Week 35	19	2.84	2.57	0.0	2.00	7.0	17	-0.18	2.65	-8.0	0.00	2.0
	Week 38	18	3.44	3.13	0.0	3.50	9.0	17	-0.29	3.50	-8.0	0.00	3.0
	Week 41	20	2.95	2.61	0.0	2.00	8.0	19	0.16	3.45	-8.0	0.00	8.0
	Week 44	17	2.53	2.00	0.0	3.00	7.0	15	0.13	3.07	-8.0	0.00	4.0
	Week 47	18	2.39	2.30	0.0	2.50	6.0	16	-0.25	3.34	-8.0	0.00	5.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.1.1: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	12	2.17	2.21	0.0	2.00	7.0	11	0.91	2.21	-3.0	0.00	6.0
	Week 53	12	2.33	2.81	0.0	1.50	8.0	11	0.36	3.78	-8.0	0.00	7.0
	Week 56	13	2.54	3.53	0.0	0.00	10.0	12	0.25	4.05	-8.0	0.00	9.0
	Week 59	12	2.08	3.18	0.0	0.00	9.0	11	-0.27	3.93	-8.0	0.00	8.0
	Week 62	10	1.90	2.88	0.0	0.50	9.0	9	0.11	3.55	-5.0	0.00	8.0
	Week 65	10	2.90	2.88	0.0	2.00	8.0	9	0.11	3.82	-7.0	0.00	7.0
	Plat+Gem (N= 48)												
	BASELINE	34	3.79	2.97	0.0	4.50	9.0						
	Week 1	32	3.56	2.80	0.0	3.00	10.0	29	0.07	2.81	-6.0	0.00	10.0
	Week 2	29	3.10	2.19	0.0	3.00	7.0	24	-0.67	2.71	-6.0	0.00	6.0
	Week 3	32	2.56	2.37	0.0	2.50	8.0	27	-1.15	2.70	-6.0	0.00	5.0
	Week 4	32	2.91	2.45	0.0	3.00	8.0	24	-1.04	2.46	-6.0	0.00	4.0
	Week 5	36	2.58	2.61	0.0	2.00	8.0	28	-0.96	2.87	-6.0	0.00	5.0
	Week 6	35	3.06	2.92	0.0	3.00	10.0	28	-1.36	3.58	-9.0	0.00	7.0
	Week 7	38	2.29	2.55	0.0	1.00	8.0	30	-1.73	3.13	-9.0	0.00	5.0
	Week 8	31	2.35	2.56	0.0	2.00	9.0	26	-1.27	3.17	-9.0	0.00	4.0
	Week 9	32	2.66	2.62	0.0	2.00	7.0	26	-1.31	2.85	-9.0	0.00	2.0
	Week 10	34	2.38	2.45	0.0	2.00	7.0	27	-1.81	3.40	-9.0	-2.00	5.0
	Week 11	30	1.57	2.05	0.0	0.50	7.0	25	-2.44	3.06	-9.0	-2.00	3.0
	Week 12	28	2.14	2.65	0.0	1.00	9.0	24	-2.21	3.30	-9.0	-1.50	2.0
	Week 14	26	2.88	2.73	0.0	2.50	9.0	21	-0.95	3.67	-8.0	-1.00	7.0
	Week 17	30	2.17	2.74	0.0	0.50	8.0	26	-1.92	3.50	-9.0	-2.00	8.0
	Week 20	23	1.74	2.18	0.0	0.00	7.0	21	-1.90	3.85	-8.0	-2.00	7.0
	Week 23	22	2.50	2.61	0.0	2.00	8.0	19	-1.21	3.71	-7.0	0.00	7.0
	Week 26	19	1.58	2.36	0.0	0.00	8.0	18	-2.00	3.16	-7.0	-1.50	4.0
	Week 29	16	2.94	2.29	0.0	3.00	7.0	14	-0.57	2.59	-6.0	0.00	4.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.1.1: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 32	11	2.91	2.70	0.0	3.00	6.0	11	-0.55	2.84	-6.0	0.00	3.0
	Week 35	10	4.10	3.11	0.0	4.00	10.0	9	0.33	3.50	-6.0	0.00	5.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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Table 302.1.3002.4.1.1: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Absent	EV+Pembro (N=192)												
	BASELINE	170	2.79	2.68	0.0	2.00	10.0						
	Week 1	158	3.06	2.78	0.0	2.50	9.0	155	0.28	2.03	-8.0	0.00	8.0
	Week 2	166	3.03	2.56	0.0	3.00	9.0	158	0.36	2.20	-5.0	0.00	8.0
	Week 3	164	3.01	2.45	0.0	3.00	9.0	155	0.20	2.48	-7.0	0.00	8.0
	Week 4	159	2.21	2.35	0.0	2.00	8.0	150	-0.48	2.49	-7.0	0.00	7.0
	Week 5	162	2.09	2.26	0.0	1.00	8.0	152	-0.51	2.42	-7.0	0.00	8.0
	Week 6	158	2.22	2.38	0.0	1.00	8.0	147	-0.35	2.66	-8.0	0.00	8.0
	Week 7	161	2.14	2.38	0.0	1.00	9.0	149	-0.61	2.70	-8.0	0.00	8.0
	Week 8	156	1.96	2.29	0.0	1.00	9.0	142	-0.67	2.80	-8.0	0.00	8.0
	Week 9	163	2.31	2.45	0.0	2.00	9.0	151	-0.42	2.85	-8.0	0.00	9.0
	Week 10	157	2.08	2.26	0.0	1.00	9.0	146	-0.59	2.72	-7.0	0.00	7.0
	Week 11	161	1.84	2.13	0.0	1.00	8.0	148	-0.88	2.59	-8.0	0.00	6.0
	Week 12	153	2.10	2.34	0.0	1.00	8.0	143	-0.65	2.94	-8.0	0.00	7.0
	Week 14	154	2.20	2.44	0.0	1.00	9.0	142	-0.43	2.61	-8.0	0.00	7.0
	Week 17	147	2.00	2.26	0.0	1.00	9.0	138	-0.55	2.88	-8.0	0.00	9.0
	Week 20	140	2.13	2.52	0.0	1.00	10.0	131	-0.45	2.95	-8.0	0.00	7.0
	Week 23	136	2.13	2.54	0.0	1.00	9.0	128	-0.34	3.14	-10.0	0.00	7.0
	Week 26	131	2.28	2.60	0.0	1.00	9.0	123	-0.34	3.15	-8.0	0.00	7.0
	Week 29	134	2.24	2.40	0.0	1.00	9.0	124	-0.26	2.77	-8.0	0.00	7.0
	Week 32	114	2.40	2.65	0.0	1.00	8.0	106	-0.03	3.04	-7.0	0.00	8.0
	Week 35	113	2.44	2.49	0.0	2.00	9.0	105	-0.08	3.06	-7.0	0.00	8.0
	Week 38	114	2.11	2.43	0.0	1.00	9.0	107	-0.41	3.23	-10.0	0.00	9.0
	Week 41	109	2.24	2.46	0.0	1.00	9.0	100	-0.03	3.08	-8.0	0.00	8.0
	Week 44	91	2.29	2.62	0.0	1.00	10.0	85	0.08	3.03	-7.0	0.00	10.0
	Week 47	82	2.05	2.35	0.0	1.00	7.0	78	-0.22	2.92	-8.0	0.00	7.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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Table 302.1.3002.4.1.1: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	77	2.23	2.26	0.0	2.00	8.0	73	-0.01	2.62	-7.0	0.00	6.0
	Week 53	67	2.06	2.41	0.0	1.00	9.0	63	0.03	3.22	-8.0	0.00	9.0
	Week 56	68	2.07	2.55	0.0	1.00	8.0	64	-0.06	3.24	-8.0	0.00	7.0
	Week 59	60	2.15	2.55	0.0	1.00	8.0	57	0.11	3.14	-7.0	0.00	8.0
	Week 62	55	2.31	2.68	0.0	1.00	8.0	54	0.39	3.03	-7.0	0.00	7.0
	Week 65	48	2.00	2.24	0.0	1.00	7.0	45	-0.42	3.13	-8.0	0.00	7.0
	Week 68	46	1.80	2.36	0.0	1.00	8.0	45	-0.33	3.13	-8.0	0.00	7.0
	Week 71	44	1.86	2.17	0.0	1.00	8.0	42	-0.24	3.35	-8.0	0.00	8.0
	Week 74	40	1.90	1.92	0.0	2.00	6.0	39	0.03	2.58	-6.0	0.00	5.0
	Week 77	38	2.42	2.45	0.0	2.00	8.0	36	0.17	3.14	-6.0	0.00	7.0
	Week 80	35	2.09	2.44	0.0	1.00	8.0	32	-0.44	2.88	-6.0	0.00	7.0
	Week 83	32	2.13	2.51	0.0	1.00	8.0	30	-0.43	2.94	-6.0	0.00	7.0
	Week 86	29	2.24	2.60	0.0	1.00	8.0	26	-0.04	2.81	-5.0	0.00	8.0
	Week 89	29	2.62	2.83	0.0	2.00	8.0	27	0.41	3.34	-5.0	0.00	8.0
	Week 92	24	2.50	2.47	0.0	2.00	8.0	22	0.27	2.90	-5.0	0.00	6.0
	Week 95	20	2.45	2.67	0.0	2.00	8.0	19	0.21	3.21	-5.0	0.00	6.0
	Week 98	18	2.17	2.77	0.0	0.50	8.0	17	0.24	3.42	-5.0	0.00	7.0
	Week 101	13	1.54	2.11	0.0	0.00	6.0	13	0.31	2.69	-5.0	0.00	5.0
	Plat+Gem (N=194)												
	BASELINE	156	3.17	2.86	0.0	3.00	10.0						
	Week 1	147	3.03	2.55	0.0	3.00	10.0	135	0.01	2.44	-6.0	0.00	8.0
	Week 2	144	3.01	2.67	0.0	3.00	10.0	129	0.16	2.51	-6.0	0.00	10.0
	Week 3	153	3.08	2.83	0.0	3.00	10.0	136	0.10	2.61	-8.0	0.00	9.0
	Week 4	151	2.74	2.57	0.0	2.00	9.0	133	-0.30	2.50	-7.0	0.00	9.0
	Week 5	151	3.09	2.68	0.0	3.00	10.0	129	0.28	2.73	-6.0	0.00	9.0
	Week 6	139	2.87	2.66	0.0	2.00	10.0	123	-0.06	2.79	-7.0	0.00	10.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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Table 302.1.3002.4.1.1: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 7	149	2.50	2.39	0.0	2.00	10.0	130	-0.22	2.53	-8.0	0.00	7.0
	Week 8	136	2.93	2.67	0.0	2.00	10.0	120	-0.01	2.93	-8.0	0.00	8.0
	Week 9	145	2.68	2.63	0.0	2.00	10.0	126	-0.13	3.21	-8.0	0.00	9.0
	Week 10	132	2.71	2.72	0.0	2.00	9.0	114	-0.04	2.82	-8.0	0.00	8.0
	Week 11	138	2.45	2.57	0.0	2.00	10.0	120	-0.40	2.45	-8.0	0.00	7.0
	Week 12	131	2.58	2.55	0.0	2.00	9.0	116	-0.11	2.38	-8.0	0.00	8.0
	Week 14	127	2.65	2.42	0.0	2.00	9.0	108	-0.26	2.85	-9.0	0.00	7.0
	Week 17	126	2.70	2.65	0.0	2.00	9.0	107	0.02	3.05	-7.0	0.00	7.0
	Week 20	103	2.50	2.65	0.0	2.00	10.0	90	-0.23	2.75	-6.0	0.00	10.0
	Week 23	93	2.78	2.90	0.0	2.00	10.0	79	0.08	2.95	-6.0	0.00	7.0
	Week 26	89	2.75	2.92	0.0	2.00	10.0	78	0.18	2.78	-5.0	0.00	8.0
	Week 29	84	2.43	2.39	0.0	2.00	8.0	73	0.03	2.29	-5.0	0.00	8.0
	Week 32	72	2.35	2.63	0.0	1.00	9.0	66	0.03	2.76	-6.0	0.00	9.0
	Week 35	66	2.50	2.57	0.0	2.00	9.0	61	0.30	2.89	-5.0	0.00	9.0
	Week 38	66	2.26	2.72	0.0	1.00	8.0	58	-0.09	2.97	-6.0	0.00	8.0
	Week 41	62	2.34	2.57	0.0	1.00	8.0	54	0.00	2.72	-5.0	0.00	8.0
	Week 44	55	2.85	2.74	0.0	2.00	8.0	49	0.27	2.68	-5.0	0.00	8.0
	Week 47	51	2.55	2.69	0.0	2.00	9.0	45	0.11	2.43	-5.0	0.00	6.0
	Week 50	48	3.17	2.96	0.0	2.50	9.0	44	0.57	2.46	-4.0	0.00	6.0
	Week 53	41	2.34	2.53	0.0	2.00	7.0	37	0.00	2.26	-4.0	0.00	5.0
	Week 56	34	2.76	2.75	0.0	3.00	8.0	29	0.28	2.48	-5.0	0.00	5.0
	Week 59	32	2.34	2.52	0.0	1.50	8.0	28	-0.04	2.50	-5.0	0.00	7.0
	Week 62	27	1.74	1.91	0.0	1.00	7.0	24	-0.75	1.98	-6.0	0.00	3.0
	Week 65	25	1.76	2.26	0.0	1.00	8.0	21	-0.67	2.42	-8.0	0.00	4.0
	Week 68	23	2.74	2.82	0.0	2.00	8.0	19	-0.16	1.92	-3.0	0.00	4.0
	Week 71	21	2.81	3.11	0.0	2.00	9.0	18	0.06	2.88	-6.0	0.00	9.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.1.1: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 74	20	2.80	3.02	0.0	2.00	9.0	17	-0.35	1.66	-5.0	0.00	3.0
	Week 77	16	3.94	3.57	0.0	3.50	10.0	13	1.08	3.17	-2.0	0.00	9.0
	Week 80	12	2.00	2.34	0.0	1.50	7.0	11	-0.36	1.63	-3.0	0.00	3.0
	Week 83	11	3.18	3.06	0.0	2.00	8.0	10	0.00	2.75	-3.0	0.00	6.0
	Week 86	10	1.60	2.41	0.0	1.00	7.0	9	-0.78	1.20	-3.0	-1.00	1.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.1.2: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
< 65 years	EV+Pembro (N=105)												
	BASELINE	94	3.19	2.72	0.0	3.00	9.0						
	Week 1	88	3.16	2.75	0.0	3.00	9.0	87	0.10	2.28	-7.0	0.00	8.0
	Week 2	92	3.16	2.56	0.0	3.00	9.0	88	0.17	2.07	-5.0	0.00	6.0
	Week 3	93	2.94	2.38	0.0	3.00	8.0	86	-0.33	2.51	-7.0	0.00	8.0
	Week 4	90	2.18	2.34	0.0	2.00	9.0	83	-1.02	2.74	-8.0	-1.00	7.0
	Week 5	90	2.08	2.20	0.0	1.50	8.0	82	-0.90	2.61	-8.0	0.00	8.0
	Week 6	90	2.36	2.45	0.0	1.00	8.0	82	-0.91	2.74	-7.0	0.00	8.0
	Week 7	85	2.04	2.33	0.0	1.00	9.0	78	-1.21	2.75	-8.0	-1.00	8.0
	Week 8	90	1.97	2.15	0.0	1.00	10.0	82	-1.20	2.66	-8.0	-0.50	7.0
	Week 9	93	2.38	2.31	0.0	2.00	8.0	86	-0.79	2.76	-7.0	0.00	5.0
	Week 10	88	2.24	2.29	0.0	2.00	9.0	82	-1.05	3.00	-8.0	-1.00	7.0
	Week 11	93	1.96	2.10	0.0	1.00	8.0	85	-1.35	2.86	-8.0	-1.00	4.0
	Week 12	86	2.21	2.31	0.0	2.00	8.0	80	-1.10	3.27	-8.0	-0.50	6.0
	Week 14	84	2.36	2.52	0.0	1.00	9.0	77	-0.77	2.98	-8.0	0.00	7.0
	Week 17	83	2.27	2.39	0.0	2.00	9.0	78	-0.87	3.20	-8.0	0.00	9.0
	Week 20	79	2.29	2.50	0.0	1.00	10.0	74	-0.92	3.14	-8.0	0.00	7.0
	Week 23	78	2.28	2.63	0.0	1.00	9.0	73	-0.79	3.29	-8.0	0.00	6.0
	Week 26	78	2.06	2.37	0.0	1.00	9.0	73	-1.05	3.22	-8.0	0.00	6.0
	Week 29	74	2.23	2.25	0.0	1.50	9.0	68	-0.65	2.81	-8.0	0.00	7.0
	Week 32	64	2.33	2.57	0.0	1.00	8.0	59	-0.47	3.05	-8.0	0.00	8.0
	Week 35	62	2.19	2.37	0.0	1.00	9.0	58	-0.52	2.95	-8.0	0.00	8.0
	Week 38	62	2.24	2.57	0.0	1.00	9.0	59	-0.66	3.17	-8.0	0.00	9.0
	Week 41	64	2.14	2.38	0.0	1.00	8.0	59	-0.53	2.90	-8.0	0.00	7.0
	Week 44	50	2.02	2.39	0.0	1.00	8.0	48	-0.58	2.90	-8.0	0.00	8.0
	Week 47	47	1.98	2.20	0.0	1.00	7.0	46	-0.30	3.07	-8.0	0.00	6.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.1.2: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	44	2.16	2.00	0.0	2.00	7.0	41	0.05	2.77	-7.0	0.00	6.0
	Week 53	40	2.18	2.68	0.0	1.00	9.0	37	0.03	3.73	-8.0	0.00	9.0
	Week 56	44	1.89	2.48	0.0	0.50	10.0	41	-0.37	3.36	-8.0	0.00	9.0
	Week 59	42	2.00	2.49	0.0	1.00	9.0	39	-0.10	3.52	-8.0	0.00	8.0
	Week 62	37	2.27	2.67	0.0	1.00	9.0	36	0.22	3.32	-7.0	0.00	8.0
	Week 65	34	2.18	2.29	0.0	1.50	8.0	31	-0.39	3.67	-7.0	0.00	7.0
	Week 68	34	1.94	2.44	0.0	1.00	7.0	33	-0.42	3.55	-8.0	0.00	7.0
	Week 71	32	2.09	2.28	0.0	1.00	8.0	30	-0.33	3.85	-7.0	0.00	8.0
	Week 74	29	2.34	2.04	0.0	2.00	6.0	28	0.07	3.14	-8.0	0.00	5.0
	Week 77	25	2.80	2.58	0.0	3.00	7.0	24	0.00	3.81	-7.0	0.00	7.0
	Week 80	24	2.71	2.51	0.0	2.00	8.0	22	-0.27	3.45	-7.0	0.00	7.0
	Week 83	23	2.87	2.70	0.0	3.00	8.0	22	-0.09	3.50	-7.0	0.00	7.0
	Week 86	20	3.20	2.73	0.0	3.00	8.0	18	0.39	3.48	-7.0	1.00	8.0
	Week 89	19	3.26	2.75	0.0	3.00	8.0	17	0.59	4.09	-7.0	0.00	8.0
	Week 92	14	3.36	2.17	0.0	3.50	8.0	12	1.00	2.80	-4.0	1.00	4.0
	Week 95	12	3.75	2.70	0.0	3.50	8.0	11	1.18	3.57	-5.0	1.00	6.0
	Plat+Gem (N=106)												
	BASELINE	84	3.71	2.75	0.0	3.50	10.0						
	Week 1	78	3.40	2.40	0.0	3.00	8.0	73	-0.08	2.38	-6.0	0.00	8.0
	Week 2	77	3.23	2.61	0.0	3.00	10.0	69	-0.42	2.65	-6.0	0.00	10.0
	Week 3	80	3.58	2.75	0.0	3.00	9.0	73	-0.16	2.87	-6.0	0.00	9.0
	Week 4	79	3.04	2.50	0.0	3.00	9.0	68	-0.65	2.44	-7.0	0.00	9.0
	Week 5	80	2.95	2.51	0.0	2.50	9.0	68	-0.62	2.98	-6.0	0.00	9.0
	Week 6	76	3.20	2.87	0.0	3.00	10.0	68	-0.53	3.16	-7.0	0.00	10.0
	Week 7	81	2.59	2.42	0.0	2.00	8.0	72	-0.94	2.84	-7.0	0.00	7.0
	Week 8	72	2.75	2.56	0.0	2.50	9.0	65	-0.74	2.85	-7.0	0.00	8.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.1.2: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	78	2.45	2.38	0.0	2.00	8.0	70	-0.97	3.00	-7.0	0.00	7.0
	Week 10	78	2.81	2.59	0.0	2.00	8.0	69	-0.75	2.94	-8.0	0.00	8.0
	Week 11	75	2.21	2.24	0.0	2.00	9.0	67	-1.45	2.64	-7.0	-1.00	6.0
	Week 12	74	2.65	2.49	0.0	2.00	9.0	67	-0.99	2.63	-7.0	0.00	8.0
	Week 14	68	2.44	2.38	0.0	2.00	9.0	59	-1.39	2.72	-8.0	-1.00	5.0
	Week 17	68	2.63	2.57	0.0	2.00	8.0	59	-1.19	3.13	-8.0	0.00	6.0
	Week 20	60	2.13	2.32	0.0	1.50	9.0	53	-1.51	2.59	-8.0	-1.00	3.0
	Week 23	51	2.31	2.47	0.0	2.00	8.0	45	-1.38	2.74	-7.0	-1.00	5.0
	Week 26	47	2.55	2.68	0.0	1.00	9.0	43	-1.37	2.76	-7.0	-1.00	5.0
	Week 29	42	2.43	2.06	0.0	2.00	7.0	38	-0.92	1.88	-6.0	0.00	3.0
	Week 32	37	2.43	2.53	0.0	1.00	7.0	35	-0.86	2.10	-6.0	0.00	3.0
	Week 35	34	2.50	2.69	0.0	1.00	10.0	32	-0.56	2.34	-6.0	0.00	5.0
	Week 38	33	2.33	2.92	0.0	1.00	8.0	29	-0.66	2.78	-6.0	-1.00	8.0
	Week 41	27	2.19	2.27	0.0	1.00	7.0	23	-0.61	2.04	-4.0	-1.00	5.0
	Week 44	28	2.61	2.48	0.0	2.50	8.0	25	-0.68	2.67	-6.0	-1.00	8.0
	Week 47	24	2.92	2.86	0.0	2.00	9.0	22	-0.36	2.48	-6.0	0.00	5.0
	Week 50	26	2.69	2.74	0.0	2.50	8.0	24	-0.96	2.46	-6.0	-1.00	4.0
	Week 53	19	2.47	2.50	0.0	2.00	7.0	17	-0.65	2.47	-6.0	0.00	5.0
	Week 56	13	3.00	3.27	0.0	1.00	8.0	11	-0.36	2.42	-6.0	0.00	2.0
	Week 59	14	1.79	2.52	0.0	0.50	7.0	12	-1.33	1.97	-6.0	-0.50	1.0
	Week 62	13	2.00	2.48	0.0	1.00	7.0	12	-1.08	2.02	-6.0	-0.50	2.0
	Week 65	13	1.69	2.72	0.0	0.00	8.0	11	-1.45	1.86	-6.0	-1.00	0.0
	Week 68	10	2.40	3.06	0.0	0.50	8.0	8	-1.25	2.05	-6.0	-0.50	0.0
	Week 77	10	3.40	4.17	0.0	1.00	10.0	8	-0.63	4.66	-6.0	-0.50	9.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.1.2: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>= 65 years	EV+Pembro (N=135)												
	BASELINE	115	2.83	2.87	0.0	2.00	10.0						
	Week 1	102	3.18	2.90	0.0	2.50	10.0	100	0.29	2.21	-8.0	0.00	8.0
	Week 2	112	3.26	2.82	0.0	3.00	10.0	104	0.58	2.46	-5.0	0.00	9.0
	Week 3	106	3.36	2.55	0.0	3.00	9.0	99	0.47	2.62	-10.0	0.00	7.0
	Week 4	105	2.58	2.59	0.0	2.00	10.0	98	-0.12	2.50	-10.0	0.00	7.0
	Week 5	103	2.47	2.46	0.0	2.00	8.0	95	-0.21	2.62	-7.0	0.00	8.0
	Week 6	99	2.51	2.52	0.0	2.00	8.0	90	0.19	2.56	-8.0	0.00	7.0
	Week 7	111	2.47	2.59	0.0	2.00	10.0	100	-0.25	2.88	-8.0	0.00	10.0
	Week 8	102	2.36	2.60	0.0	1.50	9.0	91	-0.36	2.98	-10.0	0.00	8.0
	Week 9	105	2.60	2.78	0.0	1.00	10.0	96	-0.10	3.00	-8.0	0.00	10.0
	Week 10	103	2.20	2.44	0.0	2.00	9.0	94	-0.35	2.65	-9.0	0.00	8.0
	Week 11	103	2.15	2.46	0.0	1.00	10.0	93	-0.45	2.44	-8.0	0.00	6.0
	Week 12	100	2.19	2.55	0.0	1.00	10.0	92	-0.40	2.92	-10.0	0.00	8.0
	Week 14	101	2.22	2.47	0.0	2.00	9.0	91	-0.35	2.55	-8.0	0.00	9.0
	Week 17	95	2.02	2.24	0.0	2.00	9.0	85	-0.52	2.84	-8.0	0.00	7.0
	Week 20	88	2.22	2.53	0.0	1.00	9.0	81	-0.15	2.78	-8.0	0.00	7.0
	Week 23	84	2.21	2.41	0.0	1.00	8.0	78	-0.10	3.05	-10.0	0.00	7.0
	Week 26	78	2.49	2.71	0.0	1.00	9.0	72	0.04	3.03	-8.0	0.00	7.0
	Week 29	83	2.27	2.55	0.0	1.00	9.0	78	-0.03	2.75	-8.0	0.00	7.0
	Week 32	71	2.73	2.73	0.0	2.00	8.0	66	0.42	3.02	-5.0	0.00	7.0
	Week 35	70	2.77	2.59	0.0	2.00	9.0	64	0.30	3.02	-6.0	0.00	7.0
	Week 38	70	2.33	2.57	0.0	1.00	8.0	65	-0.15	3.34	-10.0	0.00	7.0
	Week 41	65	2.55	2.59	0.0	2.00	9.0	60	0.52	3.29	-8.0	0.00	8.0
	Week 44	58	2.59	2.63	0.0	2.00	10.0	52	0.71	3.02	-5.0	0.00	10.0
	Week 47	53	2.23	2.46	0.0	2.00	7.0	48	-0.15	2.91	-8.0	0.00	7.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.1.2: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	45	2.29	2.48	0.0	2.00	8.0	43	0.16	2.41	-5.0	0.00	6.0
	Week 53	39	2.03	2.23	0.0	2.00	7.0	37	0.14	2.81	-8.0	0.00	6.0
	Week 56	37	2.46	2.96	0.0	1.00	8.0	35	0.40	3.34	-8.0	0.00	7.0
	Week 59	30	2.33	2.87	0.0	1.00	8.0	29	0.24	2.90	-5.0	0.00	8.0
	Week 62	28	2.21	2.77	0.0	0.50	8.0	27	0.52	2.78	-5.0	0.00	7.0
	Week 65	24	2.13	2.51	0.0	0.50	7.0	23	-0.26	2.58	-8.0	0.00	5.0
	Week 68	19	1.74	2.38	0.0	0.00	8.0	19	-0.16	2.81	-8.0	0.00	4.0
	Week 71	19	1.63	2.17	0.0	1.00	8.0	19	-0.11	2.66	-8.0	0.00	4.0
	Week 74	18	1.22	1.73	0.0	0.00	5.0	18	-0.28	2.30	-5.0	0.00	5.0
	Week 77	19	2.11	2.38	0.0	2.00	8.0	18	0.22	2.41	-5.0	0.00	5.0
	Week 80	16	1.44	2.13	0.0	0.00	5.0	15	-0.67	2.26	-5.0	0.00	5.0
	Week 83	14	1.21	1.67	0.0	0.00	5.0	13	-1.00	2.00	-5.0	0.00	3.0
	Week 86	14	0.93	1.33	0.0	0.00	4.0	13	-0.85	1.95	-5.0	0.00	2.0
	Week 89	14	1.79	2.67	0.0	0.50	8.0	14	0.00	2.63	-5.0	0.00	5.0
	Week 92	13	1.54	2.40	0.0	0.00	7.0	13	-0.23	2.83	-5.0	0.00	6.0
	Week 95	10	1.60	2.41	0.0	0.00	6.0	10	-0.30	2.75	-5.0	0.00	5.0
	Week 98	10	1.80	3.01	0.0	0.00	8.0	10	0.10	3.38	-5.0	0.00	5.0
	Plat+Gem (N=136)												
	BASELINE	106	2.93	2.94	0.0	2.50	10.0						
	Week 1	101	2.91	2.73	0.0	2.00	10.0	91	0.10	2.60	-6.0	0.00	10.0
	Week 2	96	2.85	2.57	0.0	3.00	10.0	84	0.39	2.43	-6.0	0.00	8.0
	Week 3	105	2.55	2.69	0.0	2.00	10.0	90	-0.06	2.49	-8.0	0.00	7.0
	Week 4	104	2.57	2.57	0.0	2.00	9.0	89	-0.24	2.55	-7.0	0.00	8.0
	Week 5	107	3.02	2.79	0.0	3.00	10.0	89	0.57	2.53	-6.0	0.00	8.0
	Week 6	98	2.68	2.57	0.0	2.00	10.0	83	-0.11	2.85	-9.0	0.00	8.0
	Week 7	106	2.36	2.42	0.0	2.00	10.0	88	-0.15	2.55	-9.0	0.00	6.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.1.2: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 8	95	2.87	2.74	0.0	2.00	10.0	81	0.17	3.08	-9.0	0.00	8.0
	Week 9	99	2.85	2.80	0.0	2.00	10.0	82	0.21	3.24	-9.0	0.00	9.0
	Week 10	88	2.50	2.73	0.0	1.00	9.0	72	-0.03	3.04	-9.0	0.00	8.0
	Week 11	93	2.35	2.71	0.0	1.00	10.0	78	-0.15	2.56	-9.0	0.00	7.0
	Week 12	85	2.38	2.64	0.0	2.00	9.0	73	0.00	2.64	-9.0	0.00	7.0
	Week 14	85	2.88	2.53	0.0	3.00	9.0	70	0.49	2.96	-9.0	0.00	7.0
	Week 17	88	2.57	2.75	0.0	1.00	9.0	74	0.30	3.17	-9.0	0.00	8.0
	Week 20	66	2.56	2.80	0.0	2.00	10.0	58	0.33	3.18	-6.0	0.00	10.0
	Week 23	64	3.06	3.09	0.0	2.00	10.0	53	0.85	3.10	-6.0	0.00	7.0
	Week 26	61	2.54	3.01	0.0	1.00	10.0	53	0.70	2.81	-5.0	0.00	8.0
	Week 29	58	2.57	2.58	0.0	2.00	8.0	49	0.59	2.46	-5.0	0.00	8.0
	Week 32	46	2.41	2.73	0.0	1.50	9.0	42	0.62	3.07	-5.0	0.00	9.0
	Week 35	42	2.88	2.69	0.0	3.00	9.0	38	1.03	3.23	-5.0	0.00	9.0
	Week 38	41	2.24	2.50	0.0	2.00	8.0	37	0.43	2.86	-5.0	0.00	7.0
	Week 41	38	2.53	2.79	0.0	1.50	8.0	34	0.44	3.01	-5.0	0.00	8.0
	Week 44	32	3.22	2.92	0.0	2.50	8.0	29	1.14	2.82	-5.0	0.00	8.0
	Week 47	32	2.38	2.46	0.0	1.50	7.0	28	0.32	2.91	-5.0	0.00	6.0
	Week 50	25	3.44	3.14	0.0	2.00	9.0	23	1.48	2.52	-3.0	1.00	6.0
	Week 53	27	2.15	2.43	0.0	1.00	7.0	25	0.04	2.39	-4.0	0.00	5.0
	Week 56	26	3.04	2.71	0.0	3.00	8.0	23	0.48	3.03	-5.0	1.00	6.0
	Week 59	23	2.70	2.46	0.0	3.00	8.0	21	0.38	3.15	-5.0	0.00	7.0
	Week 62	19	2.05	2.12	0.0	2.00	7.0	17	-0.35	2.69	-6.0	0.00	6.0
	Week 65	17	1.88	2.03	0.0	1.00	6.0	15	-0.47	2.75	-8.0	0.00	4.0
	Week 68	15	2.60	2.72	0.0	2.00	7.0	13	0.08	2.25	-3.0	0.00	4.0
	Week 71	15	3.07	3.20	0.0	2.00	9.0	13	0.31	3.45	-6.0	0.00	9.0
	Week 74	12	2.67	2.77	0.0	2.00	9.0	11	-0.45	2.07	-5.0	0.00	3.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.1.3: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Europe	EV+Pembro (N= 98)												
	BASELINE	81	3.15	2.92	0.0	3.00	10.0						
	Week 1	74	3.38	2.76	0.0	3.00	9.0	73	0.29	2.29	-4.0	0.00	8.0
	Week 2	80	3.23	2.67	0.0	3.00	9.0	74	0.28	2.28	-5.0	0.00	7.0
	Week 3	79	3.28	2.53	0.0	3.00	8.0	72	0.18	3.03	-10.0	0.00	7.0
	Week 4	78	2.47	2.45	0.0	2.00	8.0	71	-0.30	2.90	-10.0	0.00	7.0
	Week 5	72	2.46	2.21	0.0	2.00	8.0	65	-0.28	2.73	-7.0	0.00	8.0
	Week 6	71	2.39	2.38	0.0	2.00	8.0	63	-0.32	2.45	-7.0	0.00	7.0
	Week 7	79	2.32	2.19	0.0	2.00	8.0	70	-0.66	2.76	-7.0	0.00	8.0
	Week 8	72	2.06	2.17	0.0	1.00	8.0	62	-0.58	2.99	-10.0	0.00	8.0
	Week 9	80	2.41	2.47	0.0	1.50	9.0	71	-0.45	2.91	-7.0	0.00	9.0
	Week 10	71	2.15	2.24	0.0	2.00	7.0	63	-0.57	2.65	-7.0	0.00	7.0
	Week 11	78	1.94	2.20	0.0	1.00	8.0	69	-1.04	2.33	-7.0	-1.00	3.0
	Week 12	73	2.07	2.16	0.0	1.00	9.0	66	-0.95	2.79	-10.0	-1.00	7.0
	Week 14	74	2.31	2.35	0.0	2.00	8.0	65	-0.58	2.56	-7.0	0.00	6.0
	Week 17	70	2.41	2.29	0.0	2.00	8.0	63	-0.54	2.90	-7.0	0.00	7.0
	Week 20	70	2.20	2.43	0.0	1.00	9.0	64	-0.56	2.65	-7.0	0.00	5.0
	Week 23	61	2.08	2.39	0.0	1.00	9.0	57	-0.93	3.22	-10.0	0.00	6.0
	Week 26	62	2.06	2.39	0.0	1.00	8.0	56	-0.66	2.64	-7.0	0.00	6.0
	Week 29	63	2.27	2.44	0.0	1.00	9.0	58	-0.38	2.63	-7.0	0.00	7.0
	Week 32	51	2.69	2.64	0.0	2.00	8.0	47	-0.26	3.15	-7.0	0.00	7.0
	Week 35	56	2.64	2.69	0.0	2.00	9.0	52	-0.04	3.18	-7.0	0.00	8.0
	Week 38	51	2.47	2.84	0.0	1.00	9.0	48	-0.48	3.51	-10.0	0.00	9.0
	Week 41	52	2.63	2.60	0.0	2.00	8.0	48	0.02	3.23	-7.0	0.00	8.0
	Week 44	43	2.58	2.80	0.0	2.00	10.0	39	0.26	3.12	-7.0	0.00	10.0
	Week 47	39	2.49	2.55	0.0	2.00	7.0	36	0.06	2.90	-7.0	0.00	7.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.1.3: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	37	2.38	2.59	0.0	2.00	8.0	36	-0.08	2.95	-7.0	0.00	6.0
	Week 53	28	2.07	2.61	0.0	1.00	8.0	27	-0.48	3.23	-7.0	0.00	7.0
	Week 56	30	2.57	3.15	0.0	0.50	10.0	29	0.24	3.62	-7.0	0.00	9.0
	Week 59	27	2.19	2.80	0.0	0.00	9.0	27	0.04	3.50	-7.0	0.00	8.0
	Week 62	23	2.26	2.97	0.0	0.00	9.0	23	0.17	3.64	-7.0	0.00	8.0
	Week 65	23	2.43	2.74	0.0	2.00	8.0	23	-0.39	3.33	-7.0	0.00	7.0
	Week 68	21	1.43	2.38	0.0	0.00	8.0	21	-1.19	3.06	-7.0	-1.00	6.0
	Week 71	19	2.00	2.62	0.0	1.00	8.0	19	-0.79	3.49	-7.0	0.00	6.0
	Week 74	15	1.93	2.31	0.0	0.00	6.0	15	-0.27	2.94	-6.0	0.00	5.0
	Week 77	19	2.16	2.65	0.0	1.00	8.0	19	-0.37	2.97	-6.0	0.00	5.0
	Week 80	17	1.59	1.97	0.0	0.00	5.0	17	-0.94	2.49	-6.0	0.00	4.0
	Week 83	16	1.75	2.29	0.0	0.00	6.0	16	-0.88	2.58	-6.0	0.00	3.0
	Week 86	14	1.86	2.28	0.0	0.50	6.0	14	-0.14	2.28	-4.0	0.00	4.0
	Week 89	14	2.64	2.71	0.0	2.00	7.0	14	0.71	3.12	-4.0	0.00	7.0
	Week 92	11	2.00	2.00	0.0	1.00	5.0	11	0.36	2.34	-4.0	0.00	4.0
	Week 95	10	2.60	2.46	0.0	3.00	6.0	10	0.60	2.63	-5.0	0.50	5.0
	Plat+Gem (N=102)												
	BASELINE	73	3.52	3.15	0.0	3.00	10.0						
	Week 1	73	3.51	2.82	0.0	3.00	10.0	64	0.22	3.21	-6.0	0.00	10.0
	Week 2	68	3.34	2.68	0.0	3.00	10.0	57	0.18	3.03	-6.0	0.00	10.0
	Week 3	68	3.32	2.88	0.0	3.00	10.0	56	-0.05	3.23	-8.0	0.00	9.0
	Week 4	75	2.83	2.62	0.0	2.00	9.0	60	-0.45	2.82	-7.0	0.00	9.0
	Week 5	77	3.17	2.76	0.0	3.00	10.0	61	0.28	2.86	-6.0	0.00	9.0
	Week 6	70	3.06	2.82	0.0	3.00	10.0	58	-0.28	3.39	-9.0	0.00	10.0
	Week 7	73	2.40	2.36	0.0	2.00	8.0	58	-0.48	3.06	-9.0	0.00	7.0
	Week 8	65	3.17	2.70	0.0	3.00	10.0	55	0.05	3.19	-9.0	0.00	8.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.1.3: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	70	2.79	2.66	0.0	2.00	10.0	57	-0.40	3.50	-9.0	0.00	9.0
	Week 10	60	3.12	2.89	0.0	3.00	9.0	48	0.13	3.83	-9.0	0.00	8.0
	Week 11	64	2.75	2.96	0.0	2.00	10.0	52	-0.38	2.88	-9.0	0.00	7.0
	Week 12	60	2.75	2.72	0.0	2.00	9.0	50	-0.36	3.00	-9.0	0.00	8.0
	Week 14	56	3.14	2.66	0.0	3.00	9.0	43	0.05	3.32	-8.0	0.00	7.0
	Week 17	59	2.63	2.72	0.0	2.00	9.0	47	-0.51	3.44	-9.0	0.00	8.0
	Week 20	47	2.74	2.60	0.0	2.00	9.0	38	-0.18	2.88	-6.0	0.00	7.0
	Week 23	44	2.84	3.00	0.0	2.00	9.0	33	0.39	2.90	-6.0	0.00	7.0
	Week 26	39	2.59	3.02	0.0	1.00	9.0	31	0.13	3.02	-6.0	0.00	7.0
	Week 29	34	2.44	2.41	0.0	2.00	7.0	26	-0.23	2.18	-6.0	0.00	4.0
	Week 32	33	2.76	2.76	0.0	2.00	9.0	28	0.29	3.04	-6.0	0.00	9.0
	Week 35	30	3.27	2.99	0.0	3.00	9.0	25	1.08	3.62	-6.0	0.00	9.0
	Week 38	26	3.04	2.89	0.0	2.50	8.0	22	1.27	3.17	-3.0	0.00	8.0
	Week 41	22	2.68	2.53	0.0	2.50	8.0	18	0.44	2.73	-5.0	0.00	5.0
	Week 44	20	3.70	2.64	0.0	4.00	7.0	17	0.82	2.94	-6.0	0.00	5.0
	Week 47	16	2.75	2.41	0.0	3.00	7.0	13	-0.15	2.94	-6.0	0.00	5.0
	Week 50	11	3.55	2.81	0.0	4.00	9.0	10	0.60	3.84	-6.0	0.50	6.0
	Week 53	11	3.18	2.48	0.0	3.00	7.0	10	-0.10	3.75	-6.0	0.00	5.0
	Week 56	10	3.50	2.72	0.0	3.00	8.0	8	-0.38	3.70	-6.0	0.50	5.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.1.3: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
North America	EV+Pembro (N= 57)												
	BASELINE	48	3.65	2.82	0.0	3.50	9.0						
	Week 1	39	3.10	2.93	0.0	2.00	8.0	38	-0.61	1.98	-7.0	0.00	4.0
	Week 2	44	3.45	2.77	0.0	3.50	8.0	42	0.12	1.89	-4.0	0.00	5.0
	Week 3	44	3.39	2.63	0.0	3.00	9.0	40	-0.43	2.18	-6.0	0.00	3.0
	Week 4	45	2.62	2.72	0.0	2.00	9.0	42	-1.10	2.51	-8.0	0.00	7.0
	Week 5	48	2.40	2.64	0.0	1.50	8.0	42	-1.12	2.65	-8.0	-1.00	5.0
	Week 6	44	2.45	2.49	0.0	2.00	7.0	39	-1.33	2.38	-7.0	-1.00	3.0
	Week 7	46	2.37	2.84	0.0	1.00	9.0	42	-1.19	2.61	-8.0	-1.00	4.0
	Week 8	48	2.42	2.73	0.0	1.50	10.0	43	-1.30	2.89	-8.0	-1.00	5.0
	Week 9	46	2.80	2.77	0.0	2.00	8.0	42	-0.95	2.60	-5.0	-1.00	4.0
	Week 10	47	2.19	2.52	0.0	1.00	9.0	44	-1.48	2.74	-8.0	-1.00	3.0
	Week 11	47	2.34	2.64	0.0	1.00	8.0	42	-1.36	2.94	-8.0	-1.00	3.0
	Week 12	44	2.23	2.65	0.0	1.00	8.0	40	-1.58	3.13	-8.0	-1.00	5.0
	Week 14	43	2.28	2.81	0.0	1.00	9.0	39	-1.18	2.95	-8.0	-1.00	5.0
	Week 17	40	2.30	2.78	0.0	1.50	9.0	37	-1.24	3.10	-8.0	-1.00	4.0
	Week 20	38	2.21	2.82	0.0	1.00	10.0	35	-1.20	3.17	-8.0	-1.00	6.0
	Week 23	38	2.03	2.61	0.0	1.00	9.0	35	-0.94	2.54	-7.0	0.00	4.0
	Week 26	35	2.34	2.92	0.0	1.00	9.0	32	-1.13	3.83	-8.0	-0.50	6.0
	Week 29	38	2.00	2.43	0.0	1.00	9.0	34	-1.09	2.80	-8.0	-0.50	4.0
	Week 32	32	2.22	2.90	0.0	1.00	8.0	29	-0.52	2.90	-6.0	0.00	6.0
	Week 35	33	2.06	2.59	0.0	1.00	9.0	30	-0.73	2.91	-7.0	0.00	5.0
	Week 38	32	1.75	2.36	0.0	1.00	9.0	29	-1.28	3.05	-8.0	-1.00	4.0
	Week 41	28	1.25	1.69	0.0	1.00	6.0	24	-1.21	2.60	-6.0	-1.00	5.0
	Week 44	21	1.38	1.77	0.0	1.00	5.0	20	-1.15	2.54	-5.0	-1.00	4.0
	Week 47	24	1.46	1.96	0.0	0.00	6.0	23	-1.00	2.91	-8.0	0.00	5.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.1.3: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	23	1.91	1.95	0.0	2.00	7.0	20	-0.50	1.99	-4.0	0.00	4.0
	Week 53	17	2.00	2.52	0.0	1.00	9.0	14	0.64	3.34	-3.0	0.00	9.0
	Week 56	20	1.75	2.40	0.0	0.50	8.0	17	-0.59	2.76	-5.0	-1.00	6.0
	Week 59	17	1.65	2.50	0.0	0.00	7.0	14	-0.36	2.82	-5.0	0.00	5.0
	Week 62	14	1.93	2.70	0.0	0.50	8.0	13	0.08	2.72	-5.0	0.00	6.0
	Week 65	12	1.25	1.66	0.0	0.50	5.0	9	-0.89	1.69	-3.0	0.00	1.0
	Week 68	10	1.80	1.99	0.0	1.00	6.0	9	0.11	1.90	-3.0	0.00	4.0
	Week 71	10	1.50	1.18	0.0	1.50	4.0	8	0.13	2.10	-3.0	0.00	4.0
	Week 74	10	1.80	2.15	0.0	1.50	6.0	9	-0.44	3.09	-5.0	-1.00	5.0
	Plat+Gem (N= 51)												
	BASELINE	42	3.02	2.72	0.0	2.00	9.0						
	Week 1	42	3.02	2.65	0.0	2.00	10.0	36	-0.11	1.60	-5.0	0.00	4.0
	Week 2	39	3.08	2.37	0.0	3.00	8.0	34	0.15	2.23	-4.0	0.00	6.0
	Week 3	41	3.07	2.86	0.0	3.00	9.0	36	0.17	2.70	-5.0	0.00	7.0
	Week 4	35	2.71	2.58	0.0	2.00	9.0	29	-0.52	1.99	-4.0	0.00	5.0
	Week 5	39	2.77	2.45	0.0	2.00	8.0	32	-0.41	2.63	-6.0	0.00	6.0
	Week 6	34	2.76	2.36	0.0	3.00	8.0	30	-0.67	2.12	-5.0	0.00	4.0
	Week 7	42	2.19	2.32	0.0	1.00	8.0	37	-0.92	2.50	-7.0	0.00	4.0
	Week 8	39	2.56	2.52	0.0	2.00	9.0	33	-0.73	2.88	-8.0	0.00	6.0
	Week 9	39	2.33	2.43	0.0	2.00	8.0	33	-0.88	3.25	-8.0	0.00	6.0
	Week 10	39	2.23	2.38	0.0	1.00	7.0	32	-0.97	2.47	-6.0	0.00	5.0
	Week 11	39	1.74	2.04	0.0	1.00	7.0	33	-1.67	2.76	-8.0	-1.00	5.0
	Week 12	36	2.39	2.31	0.0	2.00	9.0	32	-0.69	2.21	-7.0	0.00	4.0
	Week 14	34	2.06	2.19	0.0	1.00	9.0	29	-1.38	3.09	-9.0	0.00	3.0
	Week 17	37	2.62	2.54	0.0	2.00	8.0	31	-0.32	3.49	-7.0	0.00	6.0
	Week 20	27	1.89	2.06	0.0	1.00	7.0	23	-1.22	2.75	-8.0	-1.00	3.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.1.3: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 23	27	2.52	2.36	0.0	2.00	7.0	23	-1.04	3.38	-7.0	-1.00	6.0
	Week 26	28	2.82	2.55	0.0	2.50	7.0	25	-0.52	2.93	-7.0	0.00	4.0
	Week 29	29	2.83	2.19	0.0	3.00	7.0	25	0.12	1.96	-4.0	0.00	4.0
	Week 32	17	2.53	2.43	0.0	2.00	7.0	17	0.06	1.85	-3.0	0.00	3.0
	Week 35	16	2.31	2.21	0.0	2.00	8.0	15	0.07	1.53	-2.0	0.00	3.0
	Week 38	16	2.75	2.96	0.0	2.00	8.0	13	-0.23	1.24	-2.0	0.00	3.0
	Week 41	16	3.00	2.66	0.0	3.00	7.0	13	0.23	2.28	-4.0	0.00	4.0
	Week 44	13	3.08	2.84	0.0	2.00	7.0	11	0.27	2.24	-3.0	0.00	4.0
	Week 47	11	3.27	2.69	0.0	2.00	8.0	9	0.78	1.09	0.0	0.00	3.0
	Week 50	17	3.00	2.72	0.0	2.00	7.0	15	-0.33	2.66	-6.0	0.00	4.0
	Week 53	13	2.46	2.63	0.0	1.00	7.0	11	0.00	1.79	-3.0	0.00	3.0
	Week 56	11	4.00	2.86	0.0	4.00	8.0	9	1.44	2.19	-2.0	2.00	6.0
	Week 59	11	3.00	2.45	0.0	3.00	7.0	9	1.00	2.12	-2.0	1.00	6.0
	Week 62	11	2.45	2.46	0.0	2.00	7.0	9	0.56	2.30	-2.0	0.00	6.0
	Week 65	10	2.10	2.73	0.0	1.00	8.0	8	-0.38	1.41	-3.0	0.00	1.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.1.3: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Rest of World	EV+Pembro (N= 85)												
	BASELINE	80	2.44	2.58	0.0	2.00	9.0						
	Week 1	77	3.00	2.86	0.0	2.00	10.0	76	0.53	2.24	-8.0	0.00	8.0
	Week 2	80	3.08	2.71	0.0	3.00	10.0	76	0.64	2.50	-5.0	0.00	9.0
	Week 3	76	2.91	2.34	0.0	3.00	8.0	73	0.32	2.31	-6.0	0.00	8.0
	Week 4	72	2.17	2.37	0.0	2.00	10.0	68	-0.44	2.44	-7.0	0.00	6.0
	Week 5	73	2.04	2.28	0.0	1.00	8.0	70	-0.41	2.50	-7.0	0.00	8.0
	Week 6	74	2.46	2.60	0.0	2.00	8.0	70	0.20	2.93	-8.0	0.00	8.0
	Week 7	71	2.18	2.59	0.0	1.00	10.0	66	-0.35	3.08	-8.0	0.00	10.0
	Week 8	72	2.14	2.40	0.0	1.00	9.0	68	-0.57	2.70	-8.0	0.00	7.0
	Week 9	72	2.39	2.55	0.0	2.00	10.0	69	-0.09	3.06	-8.0	0.00	10.0
	Week 10	73	2.30	2.42	0.0	2.00	9.0	69	-0.26	2.98	-9.0	0.00	8.0
	Week 11	71	2.00	2.15	0.0	2.00	10.0	67	-0.42	2.81	-8.0	0.00	6.0
	Week 12	69	2.32	2.60	0.0	2.00	10.0	66	0.02	3.24	-8.0	0.00	8.0
	Week 14	68	2.25	2.45	0.0	1.50	9.0	64	-0.11	2.78	-8.0	0.00	9.0
	Week 17	68	1.75	1.98	0.0	1.00	9.0	63	-0.51	3.07	-8.0	0.00	9.0
	Week 20	59	2.34	2.42	0.0	2.00	7.0	56	-0.04	3.15	-8.0	0.00	7.0
	Week 23	63	2.54	2.58	0.0	1.00	8.0	59	0.34	3.36	-8.0	0.00	7.0
	Week 26	59	2.46	2.49	0.0	2.00	9.0	57	-0.02	3.21	-8.0	0.00	7.0
	Week 29	56	2.39	2.38	0.0	2.00	9.0	54	0.24	2.87	-8.0	0.00	7.0
	Week 32	52	2.60	2.53	0.0	2.00	8.0	49	0.55	3.02	-8.0	0.00	8.0
	Week 35	43	2.65	2.17	0.0	3.00	7.0	40	0.33	2.80	-8.0	0.00	7.0
	Week 38	49	2.45	2.38	0.0	3.00	8.0	47	0.23	3.04	-8.0	0.00	6.0
	Week 41	49	2.67	2.61	0.0	2.00	9.0	47	0.60	3.16	-8.0	0.00	8.0
	Week 44	44	2.52	2.50	0.0	2.00	8.0	41	0.54	3.05	-8.0	0.00	8.0
	Week 47	37	2.14	2.29	0.0	2.00	7.0	35	0.00	3.09	-8.0	0.00	6.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.1.3: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	29	2.28	2.03	0.0	2.00	6.0	28	0.79	2.36	-3.0	0.00	6.0
	Week 53	34	2.18	2.35	0.0	2.00	7.0	33	0.30	3.33	-8.0	0.00	7.0
	Week 56	31	2.00	2.45	0.0	1.00	7.0	30	0.07	3.45	-8.0	0.00	7.0
	Week 59	28	2.39	2.62	0.0	1.50	8.0	27	0.26	3.30	-8.0	0.00	8.0
	Week 62	28	2.39	2.53	0.0	1.50	8.0	27	0.63	2.80	-5.0	0.00	7.0
	Week 65	23	2.35	2.23	0.0	2.00	7.0	22	-0.05	3.64	-8.0	0.00	7.0
	Week 68	22	2.32	2.59	0.0	1.50	7.0	22	0.32	3.81	-8.0	0.50	7.0
	Week 71	22	2.05	2.28	0.0	1.00	8.0	22	0.09	3.78	-8.0	0.00	8.0
	Week 74	22	1.95	1.76	0.0	2.00	5.0	22	0.23	2.72	-8.0	0.00	5.0
	Week 77	18	3.11	2.37	0.0	3.00	7.0	17	1.18	3.43	-7.0	0.00	7.0
	Week 80	16	2.94	2.54	0.0	2.50	7.0	15	0.67	3.44	-7.0	0.00	7.0
	Week 83	16	2.88	2.33	0.0	3.00	7.0	15	0.67	3.35	-7.0	0.00	7.0
	Week 86	13	3.00	2.55	0.0	3.00	8.0	12	0.83	3.61	-7.0	1.00	8.0
	Week 89	12	2.58	2.50	0.0	2.50	8.0	12	0.50	3.80	-7.0	0.00	8.0
	Plat+Gem (N= 89)												
	BASELINE	75	3.19	2.70	0.0	3.00	10.0						
	Week 1	64	2.75	2.25	0.0	3.00	8.0	64	-0.11	2.09	-6.0	0.00	7.0
	Week 2	66	2.67	2.61	0.0	2.50	8.0	62	-0.18	2.25	-6.0	0.00	6.0
	Week 3	76	2.66	2.59	0.0	2.00	9.0	71	-0.28	2.11	-6.0	0.00	5.0
	Week 4	73	2.74	2.48	0.0	3.00	8.0	68	-0.34	2.43	-6.0	0.00	7.0
	Week 5	71	2.92	2.69	0.0	3.00	8.0	64	0.08	2.81	-6.0	0.00	8.0
	Week 6	70	2.83	2.77	0.0	2.00	8.0	63	-0.14	2.97	-7.0	0.00	8.0
	Week 7	72	2.68	2.54	0.0	2.00	10.0	65	-0.29	2.49	-7.0	0.00	7.0
	Week 8	63	2.62	2.70	0.0	2.00	8.0	58	-0.22	2.91	-7.0	0.00	8.0
	Week 9	68	2.75	2.72	0.0	2.00	8.0	62	0.02	2.81	-7.0	0.00	7.0
	Week 10	67	2.46	2.58	0.0	1.00	8.0	61	-0.48	2.46	-8.0	0.00	5.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.1.3: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	65	2.17	2.21	0.0	2.00	7.0	60	-0.57	2.33	-7.0	0.00	5.0
	Week 12	63	2.33	2.57	0.0	1.00	8.0	58	-0.45	2.64	-7.0	0.00	6.0
	Week 14	63	2.62	2.39	0.0	2.00	8.0	57	-0.18	2.59	-8.0	0.00	6.0
	Week 17	60	2.55	2.73	0.0	1.50	8.0	55	-0.25	2.93	-8.0	0.00	7.0
	Week 20	52	2.25	2.79	0.0	1.00	10.0	50	-0.52	3.28	-8.0	0.00	10.0
	Week 23	44	2.75	3.00	0.0	1.50	10.0	42	-0.14	3.14	-6.0	0.00	7.0
	Week 26	41	2.32	2.95	0.0	1.00	10.0	40	-0.33	2.98	-5.0	0.00	8.0
	Week 29	37	2.32	2.50	0.0	2.00	8.0	36	-0.08	2.71	-5.0	0.00	8.0
	Week 32	33	2.03	2.62	0.0	1.00	9.0	32	-0.41	2.93	-6.0	0.00	8.0
	Week 35	30	2.37	2.55	0.0	1.50	10.0	30	-0.23	2.81	-5.0	0.00	6.0
	Week 38	32	1.44	2.14	0.0	0.00	8.0	31	-0.90	2.83	-6.0	-1.00	6.0
	Week 41	27	1.78	2.52	0.0	0.00	8.0	26	-0.38	2.89	-5.0	0.00	8.0
	Week 44	27	2.30	2.66	0.0	1.00	8.0	26	-0.04	3.12	-5.0	0.00	8.0
	Week 47	29	2.28	2.75	0.0	1.00	9.0	28	-0.14	3.00	-5.0	0.00	6.0
	Week 50	23	2.87	3.24	0.0	2.00	8.0	22	0.45	2.28	-3.0	0.00	4.0
	Week 53	22	1.73	2.25	0.0	0.00	6.0	21	-0.43	1.99	-3.0	0.00	4.0
	Week 56	18	2.17	2.83	0.0	0.00	7.0	17	-0.18	2.65	-5.0	0.00	5.0
	Week 59	17	1.53	2.07	0.0	1.00	7.0	16	-0.69	2.52	-5.0	-0.50	5.0
	Week 62	16	1.63	1.93	0.0	1.00	5.0	15	-1.20	2.18	-6.0	-1.00	3.0
	Week 65	15	1.20	1.66	0.0	0.00	4.0	14	-0.79	2.81	-8.0	0.00	4.0
	Week 68	12	1.83	2.48	0.0	0.50	6.0	11	-0.18	1.89	-3.0	0.00	3.0
	Week 71	13	2.46	3.18	0.0	2.00	9.0	12	0.50	2.97	-3.0	0.00	9.0
	Week 74	10	1.80	2.74	0.0	1.00	9.0	10	-0.20	1.48	-2.0	0.00	3.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.1.4: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	EV+Pembro (N=198)												
	BASELINE	173	3.05	2.90	0.0	3.00	10.0						
	Week 1	157	3.24	2.86	0.0	3.00	10.0	155	0.17	2.26	-8.0	0.00	8.0
	Week 2	168	3.29	2.73	0.0	3.00	10.0	158	0.42	2.37	-5.0	0.00	9.0
	Week 3	162	3.20	2.55	0.0	3.00	9.0	150	0.11	2.72	-10.0	0.00	8.0
	Week 4	159	2.49	2.52	0.0	2.00	10.0	147	-0.49	2.76	-10.0	0.00	7.0
	Week 5	157	2.34	2.35	0.0	2.00	8.0	144	-0.51	2.55	-8.0	0.00	8.0
	Week 6	154	2.47	2.48	0.0	2.00	8.0	140	-0.34	2.77	-8.0	0.00	8.0
	Week 7	160	2.35	2.55	0.0	1.00	10.0	144	-0.66	2.94	-8.0	0.00	10.0
	Week 8	155	2.21	2.41	0.0	1.00	10.0	137	-0.80	2.90	-10.0	0.00	8.0
	Week 9	163	2.64	2.60	0.0	2.00	10.0	148	-0.37	2.97	-8.0	0.00	10.0
	Week 10	159	2.34	2.40	0.0	2.00	9.0	145	-0.60	2.84	-8.0	0.00	8.0
	Week 11	162	2.19	2.38	0.0	1.00	10.0	145	-0.83	2.67	-8.0	0.00	5.0
	Week 12	154	2.29	2.48	0.0	1.00	10.0	141	-0.72	3.14	-10.0	0.00	8.0
	Week 14	154	2.34	2.55	0.0	2.00	9.0	138	-0.57	2.84	-8.0	0.00	9.0
	Week 17	145	2.17	2.36	0.0	2.00	9.0	131	-0.72	3.07	-8.0	0.00	9.0
	Week 20	139	2.27	2.54	0.0	1.00	10.0	127	-0.54	3.06	-8.0	0.00	7.0
	Week 23	133	2.32	2.56	0.0	1.00	9.0	122	-0.41	3.29	-10.0	0.00	7.0
	Week 26	129	2.22	2.49	0.0	1.00	9.0	119	-0.54	3.23	-8.0	0.00	7.0
	Week 29	131	2.25	2.42	0.0	1.00	9.0	121	-0.36	2.81	-8.0	0.00	7.0
	Week 32	111	2.50	2.67	0.0	1.00	8.0	102	-0.18	3.01	-8.0	0.00	8.0
	Week 35	109	2.42	2.51	0.0	2.00	9.0	100	-0.25	2.90	-8.0	0.00	8.0
	Week 38	107	2.28	2.61	0.0	1.00	9.0	100	-0.48	3.39	-10.0	0.00	9.0
	Week 41	103	2.27	2.46	0.0	1.00	9.0	94	-0.12	3.15	-8.0	0.00	8.0
	Week 44	88	2.26	2.62	0.0	1.00	10.0	81	0.01	3.14	-8.0	0.00	10.0
	Week 47	80	2.05	2.31	0.0	1.00	7.0	75	-0.29	3.14	-8.0	0.00	7.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.1.4: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	73	2.21	2.23	0.0	2.00	7.0	68	0.01	2.52	-7.0	0.00	6.0
	Week 53	64	1.98	2.45	0.0	1.00	9.0	59	0.02	3.30	-8.0	0.00	9.0
	Week 56	66	2.05	2.69	0.0	0.00	10.0	61	-0.13	3.31	-8.0	0.00	9.0
	Week 59	58	2.09	2.57	0.0	1.00	9.0	54	0.04	3.20	-8.0	0.00	8.0
	Week 62	54	2.35	2.70	0.0	1.00	9.0	52	0.50	3.07	-7.0	0.00	8.0
	Week 65	51	2.06	2.34	0.0	1.00	8.0	47	-0.32	3.32	-8.0	0.00	7.0
	Week 68	49	1.78	2.36	0.0	1.00	8.0	48	-0.35	3.29	-8.0	0.00	7.0
	Week 71	47	1.91	2.25	0.0	1.00	8.0	45	-0.11	3.43	-8.0	0.00	8.0
	Week 74	42	1.88	1.99	0.0	1.50	6.0	41	0.07	2.82	-8.0	0.00	5.0
	Week 77	38	2.42	2.55	0.0	1.50	8.0	36	0.17	3.38	-7.0	0.00	7.0
	Week 80	35	2.09	2.36	0.0	1.00	8.0	32	-0.44	3.09	-7.0	0.00	7.0
	Week 83	32	2.19	2.47	0.0	1.00	8.0	30	-0.37	3.13	-7.0	0.00	7.0
	Week 86	30	2.17	2.45	0.0	1.00	8.0	27	-0.07	3.01	-7.0	0.00	8.0
	Week 89	28	2.50	2.73	0.0	1.50	8.0	26	0.27	3.50	-7.0	0.00	8.0
	Week 92	24	2.25	2.21	0.0	1.50	8.0	22	0.18	2.36	-4.0	0.00	4.0
	Week 95	21	2.90	2.74	0.0	3.00	8.0	20	0.75	3.04	-5.0	0.00	6.0
	Week 98	16	1.94	2.46	0.0	0.50	7.0	15	0.27	3.13	-4.0	0.00	7.0
	Week 101	12	1.67	2.15	0.0	0.50	6.0	12	0.92	2.50	-3.0	0.00	5.0
	Week 104	10	2.40	3.06	0.0	0.50	8.0	10	1.40	3.92	-4.0	0.00	8.0
	Plat+Gem (N=185)												
	BASELINE	148	3.24	2.86	0.0	3.00	10.0						
	Week 1	137	3.01	2.63	0.0	3.00	10.0	126	0.06	2.44	-6.0	0.00	10.0
	Week 2	129	3.09	2.60	0.0	3.00	10.0	116	0.17	2.47	-6.0	0.00	10.0
	Week 3	142	2.96	2.73	0.0	3.00	10.0	127	-0.04	2.59	-6.0	0.00	9.0
	Week 4	139	2.81	2.57	0.0	2.00	9.0	120	-0.36	2.38	-7.0	0.00	9.0
	Week 5	143	2.95	2.61	0.0	3.00	10.0	121	0.03	2.85	-6.0	0.00	9.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.1.4: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 6	133	2.92	2.73	0.0	2.00	10.0	116	-0.31	3.07	-9.0	0.00	10.0
	Week 7	142	2.31	2.28	0.0	2.00	8.0	122	-0.71	2.70	-9.0	0.00	7.0
	Week 8	125	2.77	2.62	0.0	2.00	10.0	111	-0.19	2.85	-9.0	0.00	8.0
	Week 9	135	2.51	2.52	0.0	2.00	10.0	117	-0.32	2.99	-9.0	0.00	9.0
	Week 10	131	2.55	2.65	0.0	2.00	9.0	113	-0.55	2.86	-9.0	0.00	8.0
	Week 11	128	2.10	2.39	0.0	1.00	10.0	111	-0.85	2.59	-9.0	0.00	7.0
	Week 12	124	2.43	2.53	0.0	2.00	9.0	110	-0.50	2.53	-9.0	0.00	8.0
	Week 14	121	2.52	2.40	0.0	2.00	9.0	102	-0.51	2.79	-8.0	0.00	7.0
	Week 17	122	2.53	2.67	0.0	1.50	9.0	104	-0.38	3.30	-9.0	0.00	8.0
	Week 20	98	2.31	2.60	0.0	1.50	10.0	87	-0.49	2.98	-8.0	0.00	10.0
	Week 23	93	2.53	2.75	0.0	2.00	9.0	79	-0.38	3.06	-7.0	0.00	7.0
	Week 26	86	2.40	2.77	0.0	1.00	9.0	76	-0.22	2.91	-7.0	0.00	8.0
	Week 29	76	2.34	2.32	0.0	2.00	8.0	66	-0.02	2.38	-6.0	0.00	8.0
	Week 32	62	1.89	2.29	0.0	1.00	8.0	57	-0.37	2.63	-6.0	0.00	8.0
	Week 35	58	2.29	2.41	0.0	2.00	9.0	53	-0.06	2.82	-6.0	0.00	7.0
	Week 38	60	2.13	2.55	0.0	1.00	8.0	53	-0.25	2.75	-6.0	0.00	8.0
	Week 41	52	2.13	2.57	0.0	1.00	8.0	45	-0.04	2.80	-5.0	0.00	8.0
	Week 44	46	2.67	2.69	0.0	2.00	8.0	41	0.34	3.02	-6.0	0.00	8.0
	Week 47	44	2.18	2.41	0.0	1.50	9.0	39	-0.13	2.64	-6.0	0.00	6.0
	Week 50	42	2.79	2.88	0.0	2.00	9.0	38	0.11	2.86	-6.0	0.00	6.0
	Week 53	38	1.89	2.29	0.0	1.00	7.0	34	-0.44	2.31	-6.0	0.00	5.0
	Week 56	32	2.72	2.88	0.0	2.00	8.0	28	0.25	2.81	-6.0	0.50	6.0
	Week 59	31	2.19	2.59	0.0	1.00	8.0	27	-0.15	2.78	-6.0	0.00	7.0
	Week 62	29	2.03	2.34	0.0	1.00	7.0	26	-0.38	2.30	-6.0	0.00	6.0
	Week 65	25	1.76	2.42	0.0	0.00	8.0	21	-0.86	1.82	-6.0	0.00	3.0
	Week 68	20	2.10	2.77	0.0	0.50	8.0	16	-0.44	2.16	-6.0	0.00	3.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.1.4: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 71	17	2.12	2.45	0.0	2.00	8.0	14	-0.07	1.44	-3.0	0.00	2.0
	Week 74	17	2.29	2.80	0.0	2.00	9.0	14	-0.57	1.99	-6.0	0.00	3.0
	Week 77	16	3.63	3.69	0.0	1.50	10.0	13	0.15	4.16	-6.0	0.00	9.0
	Week 80	13	1.85	2.08	0.0	2.00	7.0	12	-0.92	1.98	-4.0	0.00	3.0
	Week 83	11	2.82	3.22	0.0	1.00	8.0	10	-0.30	3.23	-6.0	0.00	6.0
	Week 86	12	1.33	2.27	0.0	0.50	7.0	11	-1.73	2.37	-6.0	-1.00	1.0
	Week 89	11	1.91	2.74	0.0	1.00	8.0	10	-1.30	2.54	-6.0	-1.00	2.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.1.4: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	EV+Pembro (N= 42)												
	BASELINE	36	2.69	2.30	0.0	3.00	9.0						
	Week 1	33	2.82	2.65	0.0	2.00	9.0	32	0.34	2.19	-3.0	0.00	8.0
	Week 2	36	2.89	2.54	0.0	3.00	10.0	34	0.24	1.94	-3.0	0.00	6.0
	Week 3	37	3.00	2.13	0.0	3.00	8.0	35	0.09	2.02	-4.0	0.00	6.0
	Week 4	36	1.97	2.31	0.0	1.50	8.0	34	-0.74	2.14	-6.0	0.00	4.0
	Week 5	36	2.06	2.33	0.0	1.50	8.0	33	-0.64	2.99	-7.0	0.00	8.0
	Week 6	35	2.29	2.52	0.0	2.00	8.0	32	-0.31	2.39	-6.0	0.00	4.0
	Week 7	36	1.97	2.18	0.0	1.50	8.0	34	-0.71	2.48	-6.0	-0.50	4.0
	Week 8	37	2.05	2.37	0.0	1.00	8.0	36	-0.58	2.69	-6.0	0.00	5.0
	Week 9	35	1.83	2.31	0.0	1.00	9.0	34	-0.68	2.63	-6.0	0.00	5.0
	Week 10	32	1.63	2.17	0.0	1.00	9.0	31	-1.03	2.82	-9.0	0.00	5.0
	Week 11	34	1.44	1.71	0.0	1.00	6.0	33	-1.12	2.74	-6.0	-1.00	6.0
	Week 12	32	1.78	2.20	0.0	1.00	7.0	31	-0.74	2.95	-6.0	0.00	7.0
	Week 14	31	1.97	2.17	0.0	1.00	8.0	30	-0.43	2.34	-4.0	0.00	5.0
	Week 17	33	1.97	2.07	0.0	2.00	6.0	32	-0.56	2.78	-7.0	0.00	6.0
	Week 20	28	2.14	2.34	0.0	1.50	7.0	28	-0.39	2.57	-5.0	0.00	6.0
	Week 23	29	1.93	2.30	0.0	1.00	8.0	29	-0.55	2.68	-6.0	0.00	4.0
	Week 26	27	2.56	2.81	0.0	2.00	8.0	26	-0.38	2.90	-5.0	0.00	6.0
	Week 29	26	2.23	2.39	0.0	1.50	7.0	25	-0.12	2.71	-5.0	0.00	6.0
	Week 32	24	2.71	2.60	0.0	2.50	8.0	23	0.78	3.19	-5.0	0.00	7.0
	Week 35	23	2.87	2.44	0.0	2.00	7.0	22	0.64	3.37	-6.0	1.00	6.0
	Week 38	25	2.32	2.41	0.0	1.00	7.0	24	-0.04	2.65	-6.0	0.00	5.0
	Week 41	26	2.65	2.62	0.0	2.00	8.0	25	0.44	3.06	-5.0	0.00	8.0
	Week 44	20	2.60	2.09	0.0	2.50	6.0	19	0.42	2.52	-5.0	0.00	6.0
	Week 47	20	2.35	2.50	0.0	2.50	7.0	19	0.05	2.27	-5.0	0.00	5.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.1.4: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	16	2.31	2.39	0.0	2.00	8.0	16	0.50	2.88	-6.0	0.00	6.0
	Week 53	15	2.60	2.47	0.0	2.00	7.0	15	0.33	3.29	-6.0	0.00	6.0
	Week 56	15	2.60	2.85	0.0	1.00	8.0	15	0.47	3.58	-5.0	0.00	7.0
	Week 59	14	2.36	3.00	0.0	0.50	8.0	14	0.07	3.58	-5.0	0.00	8.0
	Week 62	11	1.73	2.72	0.0	0.00	8.0	11	-0.36	3.17	-5.0	0.00	6.0
	Plat+Gem (N= 57)												
	BASELINE	42	3.43	2.98	0.0	3.00	10.0						
	Week 1	42	3.48	2.50	0.0	3.50	7.0	38	-0.13	2.72	-6.0	0.00	7.0
	Week 2	44	2.84	2.58	0.0	2.50	8.0	37	-0.43	2.79	-6.0	0.00	6.0
	Week 3	43	3.12	2.87	0.0	3.00	9.0	36	-0.33	2.91	-8.0	0.00	7.0
	Week 4	44	2.64	2.51	0.0	2.50	8.0	37	-0.59	2.90	-7.0	0.00	7.0
	Week 5	44	3.11	2.86	0.0	3.00	9.0	36	0.14	2.59	-5.0	0.00	8.0
	Week 6	41	2.85	2.67	0.0	3.00	8.0	35	-0.26	2.75	-5.0	0.00	8.0
	Week 7	45	2.93	2.79	0.0	3.00	10.0	38	0.16	2.65	-8.0	0.00	5.0
	Week 8	42	2.98	2.78	0.0	3.00	8.0	35	-0.37	3.51	-8.0	0.00	8.0
	Week 9	42	3.19	2.92	0.0	3.00	8.0	35	-0.37	3.77	-8.0	0.00	7.0
	Week 10	35	3.00	2.73	0.0	3.00	8.0	28	0.29	3.53	-8.0	0.00	8.0
	Week 11	40	2.90	2.78	0.0	2.50	9.0	34	-0.44	2.93	-8.0	0.00	5.0
	Week 12	35	2.77	2.72	0.0	2.00	8.0	30	-0.37	3.19	-8.0	0.00	6.0
	Week 14	32	3.31	2.67	0.0	3.00	8.0	27	0.15	3.66	-9.0	0.00	6.0
	Week 17	34	2.82	2.68	0.0	2.00	8.0	29	-0.31	2.99	-7.0	0.00	5.0
	Week 20	28	2.54	2.55	0.0	2.00	7.0	24	-0.75	3.33	-7.0	0.00	7.0
	Week 23	22	3.59	3.13	0.0	3.00	10.0	19	0.68	3.37	-6.0	0.00	7.0
	Week 26	22	3.14	3.18	0.0	3.00	10.0	20	-0.25	3.23	-6.0	0.00	5.0
	Week 29	24	3.04	2.48	0.0	3.00	8.0	21	-0.24	2.23	-4.0	0.00	4.0
	Week 32	21	4.00	2.97	0.0	5.00	9.0	20	0.85	2.98	-5.0	0.00	9.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.1.4: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 35	18	4.06	3.11	0.0	4.00	10.0	17	1.41	3.16	-4.0	1.00	9.0
	Week 38	14	2.93	3.17	0.0	2.50	8.0	13	0.77	3.24	-5.0	0.00	7.0
	Week 41	13	3.38	2.43	0.0	4.00	7.0	12	0.25	2.34	-4.0	0.00	4.0
	Week 44	14	3.79	2.72	0.0	4.50	7.0	13	0.15	2.48	-5.0	0.00	4.0
	Week 47	12	4.17	2.89	0.0	4.50	8.0	11	0.55	3.08	-5.0	0.00	5.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.1.5: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Visceral metastases	EV+Pembro (N=170)												
	BASELINE	149	3.07	2.88	0.0	3.00	10.0						
	Week 1	135	3.21	2.85	0.0	3.00	10.0	134	0.13	2.29	-8.0	0.00	8.0
	Week 2	146	3.27	2.69	0.0	3.00	10.0	137	0.40	2.21	-5.0	0.00	9.0
	Week 3	142	3.21	2.54	0.0	3.00	9.0	132	0.06	2.61	-10.0	0.00	8.0
	Week 4	136	2.55	2.55	0.0	2.00	10.0	126	-0.51	2.82	-10.0	0.00	7.0
	Week 5	133	2.29	2.32	0.0	2.00	8.0	121	-0.62	2.67	-8.0	0.00	8.0
	Week 6	128	2.51	2.54	0.0	2.00	8.0	115	-0.36	2.76	-8.0	0.00	8.0
	Week 7	136	2.31	2.59	0.0	1.00	10.0	123	-0.80	2.94	-8.0	0.00	10.0
	Week 8	132	2.28	2.52	0.0	1.00	10.0	120	-0.84	2.97	-10.0	0.00	8.0
	Week 9	137	2.55	2.63	0.0	2.00	10.0	126	-0.44	2.95	-8.0	0.00	10.0
	Week 10	135	2.21	2.35	0.0	2.00	9.0	125	-0.80	2.83	-9.0	0.00	8.0
	Week 11	136	2.06	2.35	0.0	1.00	10.0	124	-0.98	2.76	-8.0	0.00	5.0
	Week 12	131	2.09	2.40	0.0	1.00	10.0	121	-0.89	3.15	-10.0	0.00	8.0
	Week 14	130	2.22	2.45	0.0	1.00	9.0	118	-0.72	2.83	-8.0	0.00	9.0
	Week 17	124	2.08	2.37	0.0	1.00	9.0	112	-0.82	3.16	-8.0	0.00	9.0
	Week 20	115	2.25	2.49	0.0	1.00	9.0	106	-0.62	3.06	-8.0	0.00	7.0
	Week 23	111	2.21	2.54	0.0	1.00	9.0	103	-0.55	3.03	-8.0	0.00	7.0
	Week 26	106	2.10	2.50	0.0	1.00	9.0	98	-0.83	3.17	-8.0	0.00	7.0
	Week 29	106	1.92	2.25	0.0	1.00	9.0	99	-0.61	2.76	-8.0	0.00	7.0
	Week 32	92	2.46	2.74	0.0	1.00	8.0	85	-0.21	3.06	-8.0	0.00	8.0
	Week 35	86	2.36	2.52	0.0	1.50	9.0	79	-0.29	3.03	-8.0	0.00	8.0
	Week 38	90	2.19	2.60	0.0	1.00	9.0	84	-0.56	3.20	-8.0	0.00	9.0
	Week 41	87	2.26	2.52	0.0	1.00	9.0	81	-0.30	3.28	-8.0	0.00	8.0
	Week 44	73	2.19	2.53	0.0	1.00	10.0	68	-0.29	3.02	-8.0	0.00	10.0
	Week 47	68	1.88	2.18	0.0	1.00	7.0	63	-0.65	2.85	-8.0	0.00	6.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.1.5: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	61	2.11	2.19	0.0	2.00	7.0	57	-0.09	2.21	-7.0	0.00	6.0
	Week 53	54	2.20	2.61	0.0	1.00	9.0	50	0.12	3.41	-8.0	0.00	9.0
	Week 56	58	1.97	2.81	0.0	0.00	10.0	54	-0.31	3.56	-8.0	0.00	9.0
	Week 59	50	2.06	2.74	0.0	0.00	9.0	47	-0.17	3.49	-8.0	0.00	8.0
	Week 62	45	2.09	2.75	0.0	0.00	9.0	43	0.00	3.30	-7.0	0.00	8.0
	Week 65	37	1.95	2.38	0.0	1.00	8.0	34	-0.65	3.52	-8.0	0.00	7.0
	Week 68	35	1.83	2.41	0.0	1.00	8.0	34	-0.68	3.45	-8.0	0.00	6.0
	Week 71	31	1.81	2.40	0.0	1.00	8.0	30	-0.73	3.71	-8.0	0.00	8.0
	Week 74	29	1.66	2.13	0.0	0.00	6.0	28	-0.61	3.13	-8.0	0.00	5.0
	Week 77	26	2.35	2.70	0.0	1.00	8.0	25	-0.36	3.56	-7.0	0.00	7.0
	Week 80	22	2.05	2.57	0.0	1.00	8.0	21	-0.95	3.12	-7.0	0.00	4.0
	Week 83	23	1.83	2.37	0.0	1.00	8.0	22	-1.05	3.02	-7.0	0.00	5.0
	Week 86	21	2.05	2.46	0.0	1.00	8.0	20	-0.80	2.89	-7.0	0.00	4.0
	Week 89	21	2.62	2.82	0.0	1.00	8.0	20	-0.05	3.56	-7.0	0.00	7.0
	Week 92	18	2.83	2.68	0.0	2.50	8.0	17	0.53	3.26	-5.0	0.00	6.0
	Week 95	13	2.62	3.15	0.0	1.00	8.0	12	0.25	3.84	-5.0	0.00	6.0
	Week 98	11	1.82	2.96	0.0	0.00	8.0	11	0.09	3.78	-5.0	0.00	7.0
	Week 101	11	2.09	2.51	0.0	1.00	6.0	11	0.64	3.14	-5.0	0.00	5.0
	Plat+Gem (N=161)												
	BASELINE	131	3.76	2.84	0.0	3.00	10.0						
	Week 1	117	3.21	2.55	0.0	3.00	10.0	110	-0.26	2.38	-6.0	0.00	10.0
	Week 2	110	3.17	2.58	0.0	3.00	10.0	100	-0.38	2.33	-6.0	0.00	8.0
	Week 3	121	3.09	2.74	0.0	3.00	9.0	109	-0.44	2.70	-8.0	0.00	9.0
	Week 4	116	2.93	2.49	0.0	3.00	9.0	102	-0.77	2.32	-6.0	0.00	8.0
	Week 5	121	2.95	2.64	0.0	3.00	10.0	105	-0.50	2.47	-6.0	0.00	8.0
	Week 6	118	3.02	2.68	0.0	3.00	10.0	104	-0.63	2.99	-9.0	0.00	10.0

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Table 302.1.3002.4.1.5: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 7	122	2.52	2.40	0.0	2.00	10.0	107	-0.95	2.62	-9.0	0.00	5.0
	Week 8	108	2.65	2.49	0.0	2.00	9.0	98	-0.80	2.86	-9.0	0.00	8.0
	Week 9	114	2.67	2.58	0.0	2.00	10.0	101	-0.87	2.97	-9.0	0.00	8.0
	Week 10	109	2.70	2.58	0.0	2.00	9.0	96	-0.90	3.00	-9.0	-0.50	8.0
	Week 11	109	2.26	2.44	0.0	1.00	10.0	97	-1.24	2.70	-9.0	0.00	7.0
	Week 12	103	2.70	2.54	0.0	2.00	9.0	93	-0.78	2.72	-9.0	0.00	7.0
	Week 14	98	2.85	2.51	0.0	3.00	9.0	86	-0.65	3.01	-9.0	0.00	7.0
	Week 17	103	2.75	2.74	0.0	2.00	8.0	91	-0.74	3.26	-9.0	0.00	8.0
	Week 20	82	2.48	2.67	0.0	2.00	9.0	76	-1.03	3.02	-8.0	0.00	7.0
	Week 23	77	2.87	2.89	0.0	2.00	10.0	69	-0.55	3.27	-7.0	0.00	7.0
	Week 26	71	2.55	2.81	0.0	1.00	10.0	66	-0.74	3.01	-7.0	0.00	7.0
	Week 29	65	2.68	2.26	0.0	2.00	8.0	60	-0.33	2.26	-6.0	0.00	4.0
	Week 32	52	2.60	2.62	0.0	2.00	9.0	50	-0.48	2.67	-6.0	0.00	4.0
	Week 35	47	2.77	2.62	0.0	3.00	10.0	45	-0.22	2.86	-6.0	0.00	6.0
	Week 38	42	2.31	2.69	0.0	1.50	8.0	40	-0.45	2.93	-6.0	0.00	8.0
	Week 41	35	2.23	2.45	0.0	1.00	8.0	33	-0.55	2.73	-5.0	-1.00	5.0
	Week 44	36	2.78	2.44	0.0	2.50	7.0	34	-0.21	2.83	-6.0	0.00	5.0
	Week 47	32	2.50	2.38	0.0	2.50	8.0	31	-0.68	2.82	-6.0	0.00	5.0
	Week 50	30	3.13	3.12	0.0	2.00	9.0	29	-0.24	2.98	-6.0	0.00	6.0
	Week 53	25	2.12	2.39	0.0	1.00	7.0	24	-0.58	2.45	-6.0	0.00	5.0
	Week 56	22	3.18	2.79	0.0	3.50	8.0	21	0.19	3.39	-6.0	1.00	6.0
	Week 59	22	2.45	2.34	0.0	2.50	8.0	21	-0.19	3.49	-6.0	0.00	7.0
	Week 62	19	2.37	2.17	0.0	2.00	7.0	18	-0.78	3.02	-6.0	-0.50	6.0
	Week 65	19	1.47	1.93	0.0	0.00	6.0	18	-1.33	2.79	-8.0	-1.50	4.0
	Week 68	13	1.69	2.32	0.0	0.00	6.0	12	-0.83	2.48	-6.0	-0.50	3.0
	Week 71	13	2.92	3.09	0.0	2.00	9.0	12	0.58	3.03	-3.0	0.00	9.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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Table 302.1.3002.4.1.5: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 74	11	2.36	2.66	0.0	2.00	9.0	11	-0.64	2.25	-6.0	0.00	3.0
	Week 77	10	1.60	2.17	0.0	1.00	6.0	10	-1.50	2.64	-6.0	-0.50	2.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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Table 302.1.3002.4.1.5: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Lymph node only	EV+Pembro (N= 60)												
	BASELINE	53	2.89	2.61	0.0	3.00	10.0						
	Week 1	49	3.04	2.76	0.0	2.00	9.0	47	0.26	2.05	-4.0	0.00	8.0
	Week 2	50	3.30	2.76	0.0	3.00	8.0	48	0.46	2.49	-5.0	0.00	8.0
	Week 3	50	3.02	2.33	0.0	3.00	9.0	47	0.02	2.43	-6.0	0.00	6.0
	Week 4	51	2.06	2.34	0.0	1.00	8.0	48	-0.67	1.97	-5.0	0.00	6.0
	Week 5	54	2.26	2.42	0.0	1.00	8.0	50	-0.48	2.41	-6.0	-0.50	7.0
	Week 6	53	2.38	2.30	0.0	2.00	8.0	50	-0.30	2.26	-5.0	0.00	7.0
	Week 7	52	2.12	2.00	0.0	2.00	8.0	48	-0.58	2.26	-5.0	-1.00	5.0
	Week 8	52	1.92	2.02	0.0	1.00	7.0	47	-0.72	2.20	-6.0	-1.00	5.0
	Week 9	53	2.34	2.34	0.0	2.00	9.0	49	-0.57	2.41	-6.0	0.00	5.0
	Week 10	48	2.15	2.33	0.0	1.00	9.0	44	-0.61	2.43	-6.0	-0.50	5.0
	Week 11	53	2.13	2.22	0.0	2.00	8.0	48	-0.63	2.37	-6.0	-0.50	6.0
	Week 12	48	2.60	2.54	0.0	2.00	9.0	45	-0.27	2.80	-6.0	0.00	7.0
	Week 14	48	2.40	2.43	0.0	2.00	9.0	44	-0.39	2.43	-4.0	0.00	5.0
	Week 17	46	2.20	1.94	0.0	2.00	7.0	44	-0.59	2.37	-5.0	-0.50	6.0
	Week 20	44	2.20	2.42	0.0	2.00	8.0	42	-0.45	2.60	-6.0	0.00	5.0
	Week 23	43	2.05	2.17	0.0	1.00	8.0	41	-0.61	3.17	-10.0	0.00	6.0
	Week 26	42	2.48	2.54	0.0	2.00	9.0	40	-0.15	2.77	-6.0	0.00	6.0
	Week 29	45	2.93	2.63	0.0	2.00	9.0	42	0.12	2.62	-5.0	0.00	6.0
	Week 32	38	2.71	2.32	0.0	2.50	7.0	36	0.17	2.87	-5.0	0.00	7.0
	Week 35	42	2.60	2.38	0.0	2.00	9.0	40	-0.10	2.65	-6.0	0.00	7.0
	Week 38	38	2.34	2.42	0.0	1.50	8.0	36	-0.44	3.23	-10.0	0.00	6.0
	Week 41	37	2.46	2.43	0.0	2.00	7.0	34	0.32	2.60	-4.0	0.00	6.0
	Week 44	31	2.45	2.54	0.0	2.00	8.0	29	0.55	2.77	-5.0	0.00	6.0
	Week 47	28	2.25	2.53	0.0	1.50	7.0	27	0.07	2.76	-5.0	0.00	6.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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Table 302.1.3002.4.1.5: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	25	2.32	2.39	0.0	2.00	8.0	24	0.21	3.26	-6.0	0.00	6.0
	Week 53	23	1.48	1.65	0.0	1.00	6.0	22	-0.50	2.61	-6.0	0.00	6.0
	Week 56	21	2.24	2.19	0.0	2.00	7.0	20	0.25	2.29	-4.0	0.00	5.0
	Week 59	20	1.85	2.03	0.0	1.00	6.0	19	-0.05	2.01	-4.0	0.00	5.0
	Week 62	19	2.37	2.45	0.0	2.00	8.0	19	0.79	2.07	-3.0	0.00	5.0
	Week 65	20	2.30	2.15	0.0	2.00	6.0	19	-0.16	2.17	-4.0	0.00	5.0
	Week 68	17	1.65	2.15	0.0	1.00	7.0	17	-0.06	2.44	-4.0	0.00	4.0
	Week 71	19	1.84	1.64	0.0	1.00	5.0	18	0.17	2.38	-5.0	0.00	4.0
	Week 74	17	2.24	1.71	0.0	2.00	5.0	17	0.59	1.94	-3.0	0.00	5.0
	Week 77	17	2.47	2.00	0.0	3.00	6.0	16	0.38	2.25	-4.0	0.00	5.0
	Week 80	17	2.12	2.03	0.0	2.00	5.0	15	-0.20	2.18	-4.0	0.00	5.0
	Week 83	13	2.62	2.40	0.0	3.00	7.0	12	0.08	2.23	-4.0	0.00	3.0
	Week 86	12	2.17	2.17	0.0	1.50	6.0	10	0.40	1.71	-3.0	0.50	2.0
	Week 89	11	2.18	2.36	0.0	2.00	7.0	10	0.30	2.54	-4.0	0.00	5.0
	Plat+Gem (N= 67)												
	BASELINE	49	2.35	2.62	0.0	2.00	8.0						
	Week 1	52	2.90	2.64	0.0	2.50	8.0	45	0.38	2.69	-6.0	0.00	8.0
	Week 2	53	2.89	2.64	0.0	2.00	10.0	44	0.64	2.85	-6.0	0.00	10.0
	Week 3	54	3.04	2.93	0.0	3.00	10.0	45	0.49	2.63	-8.0	0.00	7.0
	Week 4	58	2.62	2.68	0.0	2.00	9.0	47	0.11	2.84	-7.0	0.00	9.0
	Week 5	56	3.02	2.74	0.0	3.00	10.0	44	0.84	2.92	-5.0	0.50	9.0
	Week 6	48	2.75	2.82	0.0	2.00	9.0	40	0.18	2.91	-7.0	0.00	9.0
	Week 7	56	2.36	2.47	0.0	2.00	8.0	46	0.11	2.61	-8.0	0.00	7.0
	Week 8	52	3.31	2.98	0.0	3.00	10.0	42	0.90	3.15	-8.0	0.00	8.0
	Week 9	53	2.74	2.78	0.0	2.00	9.0	42	0.52	3.46	-8.0	0.00	9.0
	Week 10	47	2.68	2.91	0.0	2.00	9.0	36	0.53	2.86	-8.0	0.00	8.0

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Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	51	2.43	2.73	0.0	1.00	9.0	41	0.10	2.45	-7.0	0.00	6.0
	Week 12	47	2.26	2.59	0.0	1.00	8.0	39	0.00	2.51	-8.0	0.00	8.0
	Week 14	47	2.43	2.47	0.0	2.00	8.0	36	-0.08	2.98	-8.0	0.00	6.0
	Week 17	46	2.33	2.58	0.0	1.00	9.0	36	0.28	3.18	-7.0	0.00	6.0
	Week 20	38	1.95	2.10	0.0	1.00	7.0	30	0.07	2.46	-5.0	0.00	7.0
	Week 23	32	2.44	2.80	0.0	1.50	8.0	25	0.60	2.74	-5.0	0.00	7.0
	Week 26	30	2.43	3.00	0.0	1.00	9.0	24	0.71	2.31	-3.0	0.00	6.0
	Week 29	28	2.00	2.42	0.0	1.00	7.0	21	0.00	1.97	-3.0	0.00	6.0
	Week 32	26	2.12	2.72	0.0	1.00	9.0	22	0.68	2.98	-3.0	0.00	9.0
	Week 35	23	2.91	2.94	0.0	2.00	9.0	19	1.47	3.27	-3.0	0.00	9.0
	Week 38	26	2.31	2.85	0.0	0.00	8.0	20	0.45	2.95	-5.0	0.00	7.0
	Week 41	24	2.83	2.87	0.0	2.50	8.0	18	0.89	2.81	-4.0	0.00	8.0
	Week 44	18	3.67	3.18	0.0	4.00	8.0	14	1.36	3.15	-3.0	0.00	8.0
	Week 47	18	2.94	3.00	0.0	2.00	9.0	13	1.15	2.19	-3.0	1.00	6.0
	Week 50	16	3.25	2.98	0.0	3.00	8.0	13	0.92	2.56	-4.0	1.00	4.0
	Week 53	15	2.33	2.61	0.0	2.00	7.0	12	-0.58	2.07	-4.0	0.00	3.0
	Week 56	15	2.93	3.13	0.0	3.00	8.0	11	0.09	1.81	-3.0	0.00	3.0
	Week 59	12	2.42	3.00	0.0	0.50	7.0	9	-0.44	1.51	-3.0	0.00	1.0
	Week 62	10	1.70	2.63	0.0	0.00	7.0	8	-0.50	1.07	-3.0	0.00	0.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.2: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
EV+Pembro (N=202)												
BASELINE	166	3.31	2.88	0.0	3.00	10.0						
Week 1	142	3.58	3.04	0.0	3.00	10.0	134	0.19	2.09	-5.0	0.00	10.0
Week 2	154	3.53	2.85	0.0	3.00	9.0	141	0.20	2.39	-6.0	0.00	8.0
Week 3	139	3.16	2.77	0.0	3.00	10.0	126	-0.25	2.55	-7.0	0.00	8.0
Week 4	147	2.46	2.52	0.0	2.00	8.0	134	-0.68	2.42	-6.0	0.00	6.0
Week 5	139	2.42	2.49	0.0	2.00	8.0	126	-0.64	2.75	-7.0	0.00	8.0
Week 6	147	2.42	2.52	0.0	2.00	10.0	128	-0.81	2.83	-8.0	0.00	8.0
Week 7	150	2.23	2.48	0.0	1.50	8.0	129	-0.90	2.78	-7.0	0.00	8.0
Week 8	150	2.31	2.48	0.0	2.00	10.0	129	-0.96	3.08	-10.0	0.00	10.0
Week 9	142	2.45	2.60	0.0	2.00	9.0	125	-0.51	3.10	-9.0	0.00	9.0
Week 10	139	2.12	2.38	0.0	1.00	9.0	122	-0.84	2.93	-10.0	0.00	7.0
Week 11	138	1.81	2.28	0.0	1.00	10.0	119	-1.15	2.64	-8.0	0.00	7.0
Week 12	143	1.99	2.34	0.0	1.00	8.0	123	-1.03	2.92	-10.0	0.00	7.0
Week 14	140	2.14	2.50	0.0	1.00	9.0	120	-0.93	3.11	-8.0	0.00	7.0
Week 17	132	2.08	2.36	0.0	1.00	9.0	114	-0.94	3.18	-8.0	0.00	8.0
Week 20	120	2.01	2.37	0.0	1.00	10.0	106	-0.86	2.93	-10.0	0.00	6.0
Week 23	117	1.68	2.16	0.0	1.00	8.0	100	-1.06	3.15	-10.0	0.00	7.0
Week 26	114	2.09	2.42	0.0	1.00	8.0	97	-0.74	3.18	-10.0	0.00	8.0
Week 29	107	2.01	2.46	0.0	1.00	8.0	95	-0.71	3.43	-8.0	0.00	8.0
Week 32	102	1.65	2.07	0.0	1.00	7.0	90	-1.26	3.39	-10.0	0.00	7.0
Week 35	98	2.20	2.28	0.0	2.00	8.0	88	-0.67	3.11	-10.0	0.00	8.0
Week 38	97	2.24	2.44	0.0	1.00	10.0	88	-0.85	3.00	-9.0	0.00	7.0
Week 41	95	2.16	2.39	0.0	1.00	7.0	87	-0.79	2.95	-8.0	0.00	7.0
Week 44	86	2.45	2.63	0.0	2.00	8.0	77	-0.43	3.19	-8.0	0.00	8.0
Week 47	79	2.34	2.56	0.0	2.00	8.0	72	-0.64	3.10	-8.0	0.00	7.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.2: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	75	2.41	2.69	0.0	2.00	9.0	66	-0.61	3.13	-8.0	0.00	7.0
Week 53	76	2.67	2.87	0.0	2.00	9.0	66	-0.55	3.25	-8.0	0.00	7.0
Week 56	72	2.57	2.51	0.0	2.00	8.0	63	-1.03	3.07	-8.0	0.00	6.0
Week 59	69	2.80	2.79	0.0	2.00	9.0	59	-0.71	3.30	-8.0	0.00	8.0
Week 62	62	2.50	2.58	0.0	2.00	8.0	54	-0.70	3.02	-8.0	0.00	6.0
Week 65	43	2.49	2.53	0.0	2.00	8.0	41	-0.51	3.46	-8.0	0.00	7.0
Week 68	46	2.57	2.71	0.0	2.00	8.0	43	-0.26	3.06	-8.0	0.00	6.0
Week 71	42	2.45	2.62	0.0	1.50	7.0	39	-0.77	3.34	-8.0	0.00	6.0
Week 74	38	2.16	2.40	0.0	1.50	7.0	36	-0.58	3.38	-8.0	0.00	7.0
Week 77	37	2.03	2.46	0.0	1.00	7.0	34	-0.74	3.07	-8.0	0.00	5.0
Week 80	36	2.69	2.79	0.0	2.00	8.0	35	0.00	3.17	-8.0	0.00	7.0
Week 83	30	2.60	2.71	0.0	1.50	8.0	30	-0.03	3.45	-8.0	0.00	7.0
Week 86	26	2.31	2.84	0.0	1.00	9.0	26	0.08	3.51	-8.0	0.00	8.0
Week 89	20	1.70	2.49	0.0	0.00	8.0	20	-0.15	3.34	-6.0	0.00	7.0
Week 92	19	2.32	2.71	0.0	1.00	8.0	19	0.32	3.33	-7.0	0.00	7.0
Week 95	14	0.93	1.27	0.0	0.00	3.0	14	-1.00	2.57	-7.0	0.00	3.0
Week 98	10	1.40	1.90	0.0	0.50	5.0	10	-1.00	3.23	-6.0	-0.50	5.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.2: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Plat+Gem (N=202)												
BASELINE	168	3.28	3.03	0.0	3.00	10.0						
Week 1	146	3.65	3.10	0.0	3.00	10.0	142	0.29	3.04	-9.0	0.00	10.0
Week 2	151	3.47	2.86	0.0	3.00	10.0	140	0.12	2.70	-7.0	0.00	8.0
Week 3	149	3.09	2.81	0.0	3.00	9.0	138	-0.17	2.83	-8.0	0.00	8.0
Week 4	151	3.17	2.77	0.0	3.00	9.0	137	-0.23	3.12	-9.0	0.00	8.0
Week 5	155	3.08	2.86	0.0	2.00	10.0	141	0.00	3.05	-9.0	0.00	10.0
Week 6	145	2.90	2.98	0.0	2.00	10.0	131	-0.24	3.30	-7.0	0.00	9.0
Week 7	149	2.95	2.70	0.0	3.00	10.0	136	-0.18	2.77	-7.0	0.00	7.0
Week 8	146	3.05	2.78	0.0	2.00	10.0	133	-0.05	3.09	-9.0	0.00	8.0
Week 9	141	2.83	2.69	0.0	2.00	10.0	126	-0.34	3.12	-9.0	0.00	8.0
Week 10	142	2.93	2.85	0.0	2.00	10.0	130	-0.21	3.03	-9.0	0.00	9.0
Week 11	126	2.92	2.82	0.0	2.00	10.0	115	-0.23	3.24	-9.0	0.00	8.0
Week 12	130	2.72	2.77	0.0	2.00	10.0	116	-0.22	3.04	-9.0	0.00	8.0
Week 14	125	3.03	2.76	0.0	3.00	10.0	110	-0.10	3.12	-9.0	0.00	8.0
Week 17	120	2.76	2.88	0.0	2.00	9.0	108	-0.34	3.31	-9.0	0.00	8.0
Week 20	104	2.37	2.61	0.0	1.00	9.0	93	-0.62	3.11	-9.0	0.00	9.0
Week 23	88	2.15	2.53	0.0	1.00	8.0	81	-0.90	3.10	-9.0	0.00	7.0
Week 26	81	2.65	2.78	0.0	2.00	9.0	76	-0.57	3.40	-9.0	0.00	9.0
Week 29	77	3.01	3.10	0.0	2.00	10.0	71	0.15	3.39	-7.0	0.00	9.0
Week 32	64	2.97	2.97	0.0	2.00	9.0	59	-0.08	3.67	-9.0	0.00	9.0
Week 35	62	2.63	2.91	0.0	1.00	9.0	57	-0.53	3.38	-9.0	0.00	9.0
Week 38	56	2.89	3.14	0.0	2.00	9.0	50	0.24	3.22	-7.0	0.00	9.0
Week 41	52	3.00	3.14	0.0	2.00	9.0	47	0.28	2.92	-7.0	0.00	9.0
Week 44	49	3.14	3.12	0.0	2.00	9.0	44	0.18	3.19	-7.0	0.00	9.0
Week 47	43	2.77	2.97	0.0	2.00	9.0	39	-0.18	3.84	-9.0	0.00	8.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.2: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	36	2.86	3.01	0.0	2.00	9.0	31	0.06	3.68	-9.0	0.00	9.0
Week 53	31	2.68	3.26	0.0	1.00	10.0	28	0.00	4.06	-9.0	0.00	8.0
Week 56	30	2.80	3.13	0.0	1.00	9.0	29	0.31	3.29	-7.0	0.00	9.0
Week 59	23	2.52	3.07	0.0	1.00	9.0	21	-0.52	3.46	-7.0	0.00	8.0
Week 62	20	3.30	2.99	0.0	3.00	8.0	20	0.15	3.70	-7.0	0.00	8.0
Week 65	17	3.59	3.55	0.0	3.00	10.0	16	0.69	4.36	-7.0	0.00	10.0
Week 68	13	1.85	3.21	0.0	0.00	8.0	13	-1.00	3.89	-7.0	0.00	8.0
Week 71	13	2.38	3.15	0.0	0.00	8.0	13	-0.69	3.45	-7.0	0.00	6.0
Week 74	11	1.45	2.30	0.0	0.00	7.0	11	-1.73	2.41	-7.0	-2.00	1.0
Week 77	11	1.45	2.46	0.0	1.00	8.0	11	-0.91	2.34	-6.0	0.00	2.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.2.1: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Present	EV+Pembro (N= 50)												
	BASELINE	41	4.29	2.98	0.0	5.00	10.0						
	Week 1	38	4.21	3.01	0.0	4.00	10.0	35	0.03	1.92	-5.0	0.00	4.0
	Week 2	36	3.97	2.81	0.0	4.00	9.0	34	0.06	1.81	-3.0	0.00	4.0
	Week 3	32	3.34	2.89	0.0	3.00	10.0	30	-0.33	2.34	-4.0	0.00	7.0
	Week 4	35	2.43	2.37	0.0	2.00	7.0	31	-1.06	1.95	-5.0	0.00	3.0
	Week 5	32	2.59	2.56	0.0	2.00	8.0	28	-0.71	2.16	-5.0	0.00	3.0
	Week 6	35	2.09	2.24	0.0	2.00	7.0	30	-1.90	2.38	-7.0	-1.00	1.0
	Week 7	35	2.14	2.53	0.0	1.00	8.0	29	-1.45	2.44	-7.0	0.00	2.0
	Week 8	38	2.26	2.27	0.0	1.50	7.0	31	-1.58	2.43	-7.0	-2.00	3.0
	Week 9	33	2.21	2.37	0.0	1.00	8.0	29	-1.28	2.63	-6.0	0.00	4.0
	Week 10	30	1.80	2.07	0.0	1.00	6.0	25	-1.72	2.62	-6.0	-1.00	3.0
	Week 11	31	1.77	2.53	0.0	1.00	10.0	27	-1.67	2.72	-8.0	0.00	3.0
	Week 12	32	1.78	2.09	0.0	1.00	8.0	28	-1.64	2.87	-8.0	-0.50	2.0
	Week 14	36	1.83	2.31	0.0	1.00	8.0	31	-2.00	3.06	-8.0	-2.00	6.0
	Week 17	33	1.88	2.34	0.0	1.00	8.0	27	-2.07	2.81	-8.0	-1.00	3.0
	Week 20	28	2.21	2.75	0.0	1.00	10.0	25	-1.24	2.93	-8.0	0.00	3.0
	Week 23	28	1.57	2.22	0.0	0.50	7.0	24	-1.71	3.00	-8.0	-1.00	4.0
	Week 26	28	2.18	2.61	0.0	1.00	7.0	24	-1.33	3.28	-8.0	-0.50	6.0
	Week 29	27	2.19	2.65	0.0	1.00	8.0	25	-1.36	3.08	-6.0	-1.00	4.0
	Week 32	25	1.40	2.18	0.0	0.00	7.0	23	-1.91	2.68	-8.0	-1.00	2.0
	Week 35	26	2.31	2.46	0.0	1.50	7.0	24	-1.33	2.87	-6.0	-1.00	4.0
	Week 38	26	2.27	2.22	0.0	1.50	5.0	24	-1.46	2.87	-8.0	0.00	3.0
	Week 41	25	1.88	2.20	0.0	1.00	7.0	23	-1.52	2.84	-6.0	-1.00	4.0
	Week 44	22	2.45	2.56	0.0	2.00	7.0	20	-1.20	2.67	-6.0	0.00	3.0
	Week 47	14	2.57	3.11	0.0	1.00	8.0	13	-1.23	3.54	-6.0	-2.00	4.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.2.1: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	2.55	3.03	0.0	2.00	9.0	17	-1.00	3.48	-6.0	-1.00	7.0
	Week 53	21	2.62	3.07	0.0	2.00	9.0	18	-1.11	3.58	-6.0	-0.50	7.0
	Week 56	18	3.22	2.51	0.0	2.50	8.0	15	-1.07	3.26	-6.0	-1.00	5.0
	Week 59	18	2.94	2.58	0.0	3.00	8.0	15	-1.40	2.56	-5.0	0.00	2.0
	Week 62	13	2.38	2.53	0.0	2.00	8.0	11	-1.55	2.58	-5.0	-2.00	3.0
	Week 68	12	2.17	2.25	0.0	2.00	7.0	11	-1.45	2.88	-5.0	-2.00	4.0
	Plat+Gem (N= 50)												
	BASELINE	41	4.34	2.87	0.0	4.00	10.0						
	Week 1	35	4.34	2.96	0.0	5.00	10.0	34	0.09	3.07	-9.0	0.00	7.0
	Week 2	34	3.76	2.47	0.0	3.50	8.0	31	-0.45	2.34	-6.0	0.00	4.0
	Week 3	33	3.09	2.61	0.0	3.00	8.0	30	-0.70	2.32	-6.0	0.00	4.0
	Week 4	36	3.06	2.44	0.0	3.00	8.0	33	-1.18	2.34	-6.0	-1.00	5.0
	Week 5	36	2.81	2.79	0.0	2.00	9.0	33	-1.12	3.25	-9.0	-1.00	6.0
	Week 6	32	2.81	2.76	0.0	3.00	9.0	29	-1.28	3.40	-7.0	-2.00	9.0
	Week 7	35	3.06	2.73	0.0	3.00	10.0	32	-1.28	2.84	-7.0	-1.00	5.0
	Week 8	36	2.94	2.85	0.0	2.00	9.0	32	-1.16	3.15	-9.0	-1.00	6.0
	Week 9	34	2.88	2.35	0.0	2.50	7.0	30	-1.27	3.25	-7.0	-1.00	5.0
	Week 10	33	3.00	2.78	0.0	3.00	8.0	30	-1.43	2.78	-9.0	-1.00	5.0
	Week 11	30	2.77	2.40	0.0	2.00	8.0	26	-1.58	3.23	-9.0	-2.00	6.0
	Week 12	32	2.94	2.71	0.0	2.00	8.0	28	-1.11	3.21	-9.0	0.00	5.0
	Week 14	27	3.30	2.22	0.0	3.00	7.0	23	-0.74	2.83	-6.0	-1.00	6.0
	Week 17	28	2.64	2.25	0.0	2.00	7.0	24	-1.08	3.17	-9.0	-1.00	4.0
	Week 20	20	2.60	2.64	0.0	2.50	8.0	17	-1.18	3.38	-9.0	0.00	5.0
	Week 23	15	2.60	2.56	0.0	2.00	7.0	14	-1.43	3.27	-9.0	0.00	2.0
	Week 26	15	2.13	2.56	0.0	1.00	8.0	14	-2.14	3.84	-9.0	-1.00	3.0
	Week 29	13	3.31	3.90	0.0	1.00	10.0	12	0.25	4.20	-6.0	0.00	9.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.2.1: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Absent	EV+Pembro (N=152)												
	BASELINE	125	2.99	2.79	0.0	3.00	10.0						
	Week 1	104	3.36	3.04	0.0	3.00	10.0	99	0.25	2.16	-5.0	0.00	10.0
	Week 2	118	3.40	2.86	0.0	3.00	9.0	107	0.24	2.55	-6.0	0.00	8.0
	Week 3	107	3.10	2.75	0.0	3.00	9.0	96	-0.22	2.63	-7.0	0.00	8.0
	Week 4	112	2.47	2.58	0.0	2.00	8.0	103	-0.56	2.55	-6.0	0.00	6.0
	Week 5	107	2.37	2.47	0.0	2.00	8.0	98	-0.62	2.91	-7.0	0.00	8.0
	Week 6	112	2.53	2.60	0.0	2.00	10.0	98	-0.48	2.88	-8.0	0.00	8.0
	Week 7	115	2.26	2.47	0.0	2.00	8.0	100	-0.74	2.87	-7.0	0.00	8.0
	Week 8	112	2.32	2.56	0.0	2.00	10.0	98	-0.77	3.24	-10.0	0.00	10.0
	Week 9	109	2.52	2.68	0.0	2.00	9.0	96	-0.28	3.20	-9.0	0.00	9.0
	Week 10	109	2.21	2.45	0.0	2.00	9.0	97	-0.62	2.98	-10.0	0.00	7.0
	Week 11	107	1.82	2.22	0.0	1.00	8.0	92	-1.00	2.61	-8.0	0.00	7.0
	Week 12	111	2.05	2.41	0.0	1.00	8.0	95	-0.85	2.93	-10.0	0.00	7.0
	Week 14	104	2.24	2.56	0.0	1.00	9.0	89	-0.55	3.05	-8.0	0.00	7.0
	Week 17	99	2.14	2.37	0.0	2.00	9.0	87	-0.59	3.22	-8.0	0.00	8.0
	Week 20	92	1.95	2.25	0.0	1.00	8.0	81	-0.74	2.93	-10.0	0.00	6.0
	Week 23	89	1.72	2.16	0.0	1.00	8.0	76	-0.86	3.19	-10.0	0.00	7.0
	Week 26	86	2.06	2.37	0.0	1.00	8.0	73	-0.55	3.14	-10.0	0.00	8.0
	Week 29	80	1.95	2.41	0.0	0.50	8.0	70	-0.47	3.54	-8.0	0.00	8.0
	Week 32	77	1.73	2.04	0.0	1.00	7.0	67	-1.03	3.60	-10.0	0.00	7.0
	Week 35	72	2.17	2.23	0.0	2.00	8.0	64	-0.42	3.18	-10.0	0.00	8.0
	Week 38	71	2.23	2.53	0.0	1.00	10.0	64	-0.63	3.04	-9.0	0.00	7.0
	Week 41	70	2.26	2.46	0.0	1.00	7.0	64	-0.53	2.96	-8.0	0.00	7.0
	Week 44	64	2.45	2.67	0.0	2.00	8.0	57	-0.16	3.34	-8.0	0.00	8.0
	Week 47	65	2.29	2.45	0.0	2.00	7.0	59	-0.51	3.01	-8.0	0.00	7.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.2.1: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	55	2.36	2.58	0.0	2.00	9.0	49	-0.47	3.03	-8.0	0.00	6.0
	Week 53	55	2.69	2.82	0.0	2.00	8.0	48	-0.33	3.13	-8.0	0.00	7.0
	Week 56	54	2.35	2.50	0.0	2.00	7.0	48	-1.02	3.04	-8.0	0.00	6.0
	Week 59	51	2.75	2.89	0.0	2.00	9.0	44	-0.48	3.51	-8.0	0.00	8.0
	Week 62	49	2.53	2.62	0.0	2.00	7.0	43	-0.49	3.11	-8.0	0.00	6.0
	Week 65	36	2.67	2.59	0.0	2.00	8.0	34	-0.26	3.52	-8.0	0.00	7.0
	Week 68	34	2.71	2.88	0.0	2.00	8.0	32	0.16	3.06	-8.0	0.00	6.0
	Week 71	33	2.64	2.68	0.0	2.00	7.0	31	-0.35	3.33	-8.0	0.00	6.0
	Week 74	33	2.33	2.48	0.0	2.00	7.0	31	-0.16	3.41	-8.0	0.00	7.0
	Week 77	31	2.03	2.48	0.0	1.00	7.0	28	-0.36	3.12	-8.0	0.00	5.0
	Week 80	31	2.68	2.81	0.0	2.00	8.0	30	0.27	3.25	-8.0	0.00	7.0
	Week 83	25	2.68	2.61	0.0	2.00	8.0	25	0.44	3.40	-8.0	0.00	7.0
	Week 86	23	2.30	2.77	0.0	1.00	9.0	23	0.30	3.52	-8.0	0.00	8.0
	Week 89	18	1.89	2.56	0.0	0.50	8.0	18	0.22	3.28	-6.0	0.00	7.0
	Week 92	16	2.25	2.44	0.0	2.00	7.0	16	0.69	3.28	-7.0	0.00	7.0
	Week 95	12	1.08	1.31	0.0	0.50	3.0	12	-0.58	2.47	-7.0	0.00	3.0
	Plat+Gem (N=152)												
	BASELINE	127	2.94	3.02	0.0	2.00	10.0						
	Week 1	111	3.43	3.12	0.0	3.00	10.0	108	0.35	3.05	-7.0	0.00	10.0
	Week 2	117	3.38	2.97	0.0	3.00	10.0	109	0.28	2.79	-7.0	0.00	8.0
	Week 3	116	3.09	2.88	0.0	2.50	9.0	108	-0.02	2.95	-8.0	0.00	8.0
	Week 4	115	3.20	2.88	0.0	3.00	9.0	104	0.08	3.28	-9.0	0.00	8.0
	Week 5	119	3.16	2.89	0.0	3.00	10.0	108	0.34	2.92	-7.0	0.00	10.0
	Week 6	113	2.92	3.05	0.0	2.00	10.0	102	0.05	3.22	-7.0	0.00	8.0
	Week 7	114	2.91	2.70	0.0	2.00	10.0	104	0.15	2.67	-7.0	0.00	7.0
	Week 8	110	3.08	2.77	0.0	2.50	10.0	101	0.31	3.00	-7.0	0.00	8.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.2.1: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	107	2.81	2.80	0.0	2.00	10.0	96	-0.05	3.04	-9.0	0.00	8.0
	Week 10	109	2.91	2.88	0.0	2.00	10.0	100	0.16	3.02	-7.0	0.00	9.0
	Week 11	96	2.97	2.95	0.0	2.00	10.0	89	0.16	3.16	-7.0	0.00	8.0
	Week 12	98	2.65	2.80	0.0	2.00	10.0	88	0.07	2.94	-7.0	0.00	8.0
	Week 14	98	2.96	2.90	0.0	2.00	10.0	87	0.07	3.19	-9.0	0.00	8.0
	Week 17	92	2.79	3.05	0.0	1.00	9.0	84	-0.13	3.34	-7.0	0.00	8.0
	Week 20	84	2.31	2.61	0.0	1.00	9.0	76	-0.50	3.06	-8.0	0.00	9.0
	Week 23	73	2.05	2.53	0.0	1.00	8.0	67	-0.79	3.08	-7.0	0.00	7.0
	Week 26	66	2.77	2.84	0.0	2.00	9.0	62	-0.21	3.22	-9.0	0.00	9.0
	Week 29	64	2.95	2.95	0.0	2.00	9.0	59	0.14	3.24	-7.0	0.00	8.0
	Week 32	55	3.02	2.92	0.0	2.00	9.0	50	0.08	3.30	-7.0	0.00	8.0
	Week 35	54	2.78	2.92	0.0	2.00	9.0	49	-0.20	3.18	-7.0	0.00	9.0
	Week 38	47	2.81	3.15	0.0	2.00	9.0	42	0.33	3.32	-7.0	0.00	9.0
	Week 41	45	3.11	3.19	0.0	2.00	9.0	40	0.48	2.91	-7.0	0.00	9.0
	Week 44	41	2.88	3.00	0.0	2.00	9.0	36	0.14	3.15	-7.0	0.00	9.0
	Week 47	35	3.14	3.11	0.0	2.00	9.0	31	0.55	3.58	-7.0	0.00	8.0
	Week 50	29	3.07	2.98	0.0	3.00	9.0	24	0.63	3.44	-7.0	0.00	9.0
	Week 53	25	2.44	2.93	0.0	1.00	8.0	22	0.23	3.58	-7.0	0.00	8.0
	Week 56	26	2.77	3.10	0.0	1.00	9.0	25	0.32	3.45	-7.0	0.00	9.0
	Week 59	20	2.55	3.03	0.0	1.50	9.0	18	-0.72	3.44	-7.0	0.00	8.0
	Week 62	17	3.29	2.91	0.0	3.00	8.0	17	-0.12	3.74	-7.0	0.00	8.0
	Week 65	15	4.00	3.59	0.0	3.00	10.0	14	0.93	4.62	-7.0	0.50	10.0
	Week 68	11	2.18	3.40	0.0	0.00	8.0	11	-0.91	4.21	-7.0	0.00	8.0
	Week 71	12	2.58	3.20	0.0	1.00	8.0	12	-0.50	3.53	-7.0	0.00	6.0
	Week 74	10	1.60	2.37	0.0	0.50	7.0	10	-1.60	2.50	-7.0	-1.00	1.0
	Week 77	10	1.50	2.59	0.0	0.50	8.0	10	-0.80	2.44	-6.0	0.00	2.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.2.2: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
< 65 years	EV+Pembro (N= 39)												
	BASELINE	33	3.52	2.94	0.0	4.00	10.0						
	Week 1	27	3.44	2.67	0.0	3.00	8.0	26	0.04	1.68	-4.0	0.00	3.0
	Week 2	31	3.16	2.99	0.0	2.00	9.0	30	0.03	2.25	-6.0	0.00	6.0
	Week 3	31	2.74	2.65	0.0	2.00	8.0	30	-0.63	2.30	-4.0	-1.00	5.0
	Week 4	30	1.70	1.90	0.0	1.00	6.0	28	-1.50	2.06	-6.0	-1.00	2.0
	Week 5	28	1.50	2.01	0.0	1.00	7.0	27	-1.74	2.14	-7.0	-1.00	2.0
	Week 6	29	1.97	2.49	0.0	1.00	8.0	27	-1.33	2.95	-7.0	-1.00	5.0
	Week 7	30	1.80	2.47	0.0	1.00	8.0	27	-1.33	2.30	-7.0	-1.00	4.0
	Week 8	30	1.77	2.47	0.0	0.50	9.0	27	-1.26	2.58	-5.0	-1.00	6.0
	Week 9	28	2.36	2.67	0.0	1.00	8.0	28	-0.82	3.09	-7.0	0.00	7.0
	Week 10	26	1.92	2.59	0.0	0.50	8.0	24	-0.96	2.71	-7.0	0.00	5.0
	Week 11	28	1.61	2.22	0.0	1.00	7.0	26	-1.27	2.60	-7.0	-0.50	6.0
	Week 12	28	1.54	2.22	0.0	1.00	8.0	26	-1.46	2.63	-8.0	0.00	2.0
	Week 14	26	1.38	2.08	0.0	0.00	7.0	24	-1.63	3.49	-8.0	-1.50	6.0
	Week 17	28	1.96	2.46	0.0	1.00	9.0	25	-0.96	3.85	-7.0	-1.00	8.0
	Week 20	27	1.78	2.38	0.0	1.00	8.0	25	-1.08	2.98	-7.0	-1.00	6.0
	Week 23	26	0.92	1.47	0.0	0.00	6.0	24	-1.79	2.65	-8.0	-1.00	1.0
	Week 26	24	1.42	2.19	0.0	0.00	8.0	22	-1.23	3.78	-8.0	-0.50	8.0
	Week 29	25	1.64	2.31	0.0	0.00	7.0	23	-1.26	3.67	-7.0	-1.00	6.0
	Week 32	25	1.60	1.91	0.0	1.00	6.0	23	-1.43	3.01	-7.0	-1.00	5.0
	Week 35	24	1.92	2.17	0.0	1.00	6.0	22	-1.09	3.22	-7.0	-0.50	6.0
	Week 38	23	1.78	2.32	0.0	1.00	8.0	22	-1.41	2.67	-7.0	0.00	2.0
	Week 41	25	2.12	2.60	0.0	1.00	7.0	24	-0.83	3.43	-7.0	-0.50	7.0
	Week 44	22	2.23	2.84	0.0	0.00	7.0	21	-0.67	3.86	-7.0	-1.00	7.0
	Week 47	20	1.95	2.63	0.0	1.00	8.0	19	-0.84	3.34	-6.0	-1.00	7.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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Table 302.1.3002.4.2.2: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	19	1.74	2.60	0.0	1.00	9.0	18	-0.94	3.39	-7.0	-1.00	5.0
	Week 53	20	1.20	1.94	0.0	0.00	7.0	19	-1.58	2.95	-7.0	-1.00	5.0
	Week 56	17	1.88	2.15	0.0	1.00	7.0	16	-1.50	2.50	-7.0	-1.00	3.0
	Week 59	17	2.24	2.97	0.0	1.00	8.0	16	-1.31	3.46	-7.0	-0.50	6.0
	Week 62	15	2.33	2.53	0.0	2.00	7.0	15	-0.27	3.24	-7.0	0.00	6.0
	Week 65	14	1.50	2.03	0.0	0.50	7.0	14	-1.79	2.64	-7.0	-2.00	3.0
	Week 68	11	2.00	2.41	0.0	2.00	8.0	11	-0.73	2.33	-4.0	-1.00	4.0
	Week 71	13	2.31	2.59	0.0	2.00	7.0	13	-1.08	3.64	-7.0	-1.00	6.0
	Week 74	14	2.29	2.61	0.0	1.50	7.0	14	-0.50	3.46	-7.0	-1.00	7.0
	Week 77	14	2.57	2.65	0.0	2.50	7.0	14	-0.14	2.88	-5.0	0.00	5.0
	Week 80	14	3.36	3.10	0.0	3.50	7.0	14	1.00	3.19	-4.0	0.00	7.0
	Week 83	12	3.08	3.03	0.0	2.50	8.0	12	0.50	3.23	-5.0	0.00	6.0
	Plat+Gem (N= 29)												
	BASELINE	22	3.86	2.98	0.0	4.00	9.0						
	Week 1	21	3.33	3.28	0.0	3.00	10.0	20	-0.55	1.85	-6.0	0.00	2.0
	Week 2	24	3.25	3.18	0.0	2.00	8.0	20	-0.35	2.06	-6.0	0.00	3.0
	Week 3	23	2.91	2.71	0.0	3.00	9.0	20	-0.70	2.00	-6.0	0.00	2.0
	Week 4	23	3.26	3.17	0.0	3.00	9.0	19	-0.79	2.27	-6.0	-1.00	3.0
	Week 5	25	2.80	3.12	0.0	1.00	9.0	20	-1.05	2.65	-9.0	-0.50	2.0
	Week 6	22	2.09	2.41	0.0	1.00	8.0	18	-1.44	2.33	-7.0	-1.00	3.0
	Week 7	24	2.63	2.83	0.0	2.00	10.0	21	-1.24	2.23	-7.0	-1.00	2.0
	Week 8	21	2.38	3.01	0.0	1.00	10.0	19	-1.16	2.91	-9.0	-1.00	4.0
	Week 9	20	2.80	2.48	0.0	2.50	8.0	17	-0.88	2.47	-7.0	0.00	2.0
	Week 10	21	2.19	2.48	0.0	1.00	8.0	18	-1.44	2.38	-9.0	-1.00	1.0
	Week 11	20	2.30	2.49	0.0	2.00	7.0	17	-1.24	3.05	-9.0	-1.00	3.0
	Week 12	21	2.33	2.73	0.0	2.00	8.0	17	-1.29	2.80	-9.0	-1.00	3.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.2.2: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 14	22	3.41	2.84	0.0	3.00	8.0	18	-0.28	2.82	-6.0	0.00	6.0
	Week 17	20	2.45	3.03	0.0	1.00	9.0	17	-1.24	3.46	-9.0	-1.00	7.0
	Week 20	18	3.28	3.34	0.0	2.00	8.0	15	-0.60	3.04	-9.0	0.00	4.0
	Week 23	18	2.33	2.77	0.0	1.00	8.0	16	-1.00	3.22	-9.0	0.00	4.0
	Week 26	16	2.81	3.19	0.0	2.00	9.0	14	-1.00	3.62	-9.0	0.00	4.0
	Week 29	15	3.40	3.22	0.0	3.00	9.0	13	-0.31	2.78	-6.0	0.00	5.0
	Week 32	15	3.00	3.55	0.0	2.00	9.0	13	-0.92	3.86	-9.0	0.00	5.0
	Week 35	15	2.60	3.07	0.0	2.00	9.0	13	-1.08	3.33	-9.0	0.00	4.0
	Week 38	14	3.29	2.97	0.0	2.50	8.0	12	-0.17	3.07	-6.0	0.00	3.0
	Week 41	11	4.18	3.22	0.0	4.00	8.0	9	1.00	2.60	-2.0	0.00	6.0
	Week 44	11	3.55	3.24	0.0	3.00	9.0	9	0.33	2.78	-2.0	0.00	7.0
	Week 47	11	3.27	3.41	0.0	3.00	8.0	9	-0.22	5.14	-9.0	0.00	8.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.2.2: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>= 65 years	EV+Pembro (N=163)												
	BASELINE	133	3.26	2.88	0.0	3.00	10.0						
	Week 1	115	3.62	3.14	0.0	3.00	10.0	108	0.23	2.19	-5.0	0.00	10.0
	Week 2	123	3.63	2.82	0.0	4.00	9.0	111	0.24	2.43	-6.0	0.00	8.0
	Week 3	108	3.28	2.81	0.0	3.00	10.0	96	-0.13	2.63	-7.0	0.00	8.0
	Week 4	117	2.66	2.63	0.0	2.00	8.0	106	-0.46	2.47	-6.0	0.00	6.0
	Week 5	111	2.66	2.55	0.0	2.00	8.0	99	-0.34	2.83	-6.0	0.00	8.0
	Week 6	118	2.53	2.53	0.0	2.00	10.0	101	-0.67	2.80	-8.0	0.00	8.0
	Week 7	120	2.34	2.48	0.0	2.00	8.0	102	-0.78	2.90	-7.0	0.00	8.0
	Week 8	120	2.44	2.48	0.0	2.00	10.0	102	-0.88	3.20	-10.0	0.00	10.0
	Week 9	114	2.47	2.60	0.0	2.00	9.0	97	-0.42	3.11	-9.0	0.00	9.0
	Week 10	113	2.17	2.33	0.0	2.00	9.0	98	-0.82	3.00	-10.0	0.00	7.0
	Week 11	110	1.86	2.30	0.0	1.00	10.0	93	-1.12	2.67	-8.0	0.00	7.0
	Week 12	115	2.10	2.36	0.0	1.00	8.0	97	-0.92	3.00	-10.0	0.00	7.0
	Week 14	114	2.31	2.56	0.0	1.50	9.0	96	-0.75	3.00	-8.0	0.00	7.0
	Week 17	104	2.11	2.34	0.0	2.00	8.0	89	-0.93	3.00	-8.0	0.00	7.0
	Week 20	93	2.08	2.37	0.0	1.00	10.0	81	-0.79	2.92	-10.0	0.00	5.0
	Week 23	91	1.90	2.29	0.0	1.00	8.0	76	-0.83	3.27	-10.0	0.00	7.0
	Week 26	90	2.27	2.46	0.0	1.50	8.0	75	-0.60	3.00	-10.0	0.00	6.0
	Week 29	82	2.12	2.51	0.0	1.00	8.0	72	-0.53	3.36	-8.0	0.00	8.0
	Week 32	77	1.66	2.13	0.0	0.00	7.0	67	-1.19	3.53	-10.0	0.00	7.0
	Week 35	74	2.30	2.33	0.0	2.00	8.0	66	-0.53	3.08	-10.0	0.00	8.0
	Week 38	74	2.38	2.48	0.0	2.00	10.0	66	-0.67	3.10	-9.0	0.00	7.0
	Week 41	70	2.17	2.33	0.0	1.00	7.0	63	-0.78	2.77	-8.0	0.00	6.0
	Week 44	64	2.53	2.57	0.0	2.00	8.0	56	-0.34	2.94	-8.0	0.00	8.0
	Week 47	59	2.47	2.55	0.0	2.00	8.0	53	-0.57	3.04	-8.0	0.00	6.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.2.2: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	56	2.64	2.71	0.0	2.00	9.0	48	-0.48	3.06	-8.0	0.00	7.0
	Week 53	56	3.20	2.98	0.0	3.00	9.0	47	-0.13	3.30	-8.0	0.00	7.0
	Week 56	55	2.78	2.59	0.0	2.00	8.0	47	-0.87	3.25	-8.0	0.00	6.0
	Week 59	52	2.98	2.74	0.0	2.50	9.0	43	-0.49	3.25	-8.0	0.00	8.0
	Week 62	47	2.55	2.63	0.0	2.00	8.0	39	-0.87	2.96	-8.0	0.00	6.0
	Week 65	29	2.97	2.64	0.0	4.00	8.0	27	0.15	3.70	-8.0	0.00	7.0
	Week 68	35	2.74	2.81	0.0	2.00	8.0	32	-0.09	3.30	-8.0	0.00	6.0
	Week 71	29	2.52	2.67	0.0	1.00	7.0	26	-0.62	3.25	-8.0	0.00	6.0
	Week 74	24	2.08	2.32	0.0	1.50	6.0	22	-0.64	3.42	-8.0	0.00	6.0
	Week 77	23	1.70	2.32	0.0	0.00	7.0	20	-1.15	3.20	-8.0	0.00	5.0
	Week 80	22	2.27	2.55	0.0	1.50	8.0	21	-0.67	3.06	-8.0	0.00	6.0
	Week 83	18	2.28	2.52	0.0	1.00	8.0	18	-0.39	3.63	-8.0	0.00	7.0
	Week 86	18	2.50	2.94	0.0	1.50	9.0	18	0.17	3.54	-8.0	0.00	8.0
	Week 89	12	2.17	2.69	0.0	1.00	8.0	12	0.33	3.42	-6.0	0.00	7.0
	Week 92	10	2.00	2.26	0.0	1.50	6.0	10	0.40	3.31	-7.0	0.00	6.0
	Plat+Gem (N=173)												
	BASELINE	146	3.19	3.04	0.0	3.00	10.0						
	Week 1	125	3.70	3.07	0.0	3.00	10.0	122	0.43	3.18	-9.0	0.00	10.0
	Week 2	127	3.51	2.81	0.0	3.00	10.0	120	0.20	2.79	-7.0	0.00	8.0
	Week 3	126	3.13	2.84	0.0	3.00	9.0	118	-0.08	2.95	-8.0	0.00	8.0
	Week 4	128	3.15	2.71	0.0	3.00	9.0	118	-0.14	3.23	-9.0	0.00	8.0
	Week 5	130	3.13	2.82	0.0	3.00	10.0	121	0.17	3.09	-7.0	0.00	10.0
	Week 6	123	3.04	3.06	0.0	2.00	10.0	113	-0.05	3.39	-7.0	0.00	9.0
	Week 7	125	3.01	2.68	0.0	3.00	10.0	115	0.01	2.82	-7.0	0.00	7.0
	Week 8	125	3.16	2.74	0.0	3.00	9.0	114	0.14	3.09	-7.0	0.00	8.0
	Week 9	121	2.83	2.73	0.0	2.00	10.0	109	-0.26	3.21	-9.0	0.00	8.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.2.2: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	121	3.06	2.90	0.0	2.00	10.0	112	-0.01	3.08	-7.0	0.00	9.0
	Week 11	106	3.04	2.87	0.0	2.00	10.0	98	-0.06	3.26	-7.0	0.00	8.0
	Week 12	109	2.80	2.78	0.0	2.00	10.0	99	-0.03	3.05	-7.0	0.00	8.0
	Week 14	103	2.95	2.75	0.0	2.00	10.0	92	-0.07	3.19	-9.0	0.00	8.0
	Week 17	100	2.82	2.86	0.0	2.00	9.0	91	-0.18	3.27	-7.0	0.00	8.0
	Week 20	86	2.17	2.41	0.0	1.00	9.0	78	-0.63	3.15	-8.0	0.00	9.0
	Week 23	70	2.10	2.48	0.0	1.00	8.0	65	-0.88	3.10	-7.0	0.00	7.0
	Week 26	65	2.62	2.70	0.0	2.00	9.0	62	-0.47	3.38	-9.0	0.00	9.0
	Week 29	62	2.92	3.09	0.0	1.50	10.0	58	0.26	3.52	-7.0	0.00	9.0
	Week 32	49	2.96	2.81	0.0	3.00	9.0	46	0.15	3.63	-7.0	0.00	9.0
	Week 35	47	2.64	2.89	0.0	1.00	9.0	44	-0.36	3.42	-7.0	0.00	9.0
	Week 38	42	2.76	3.22	0.0	1.00	9.0	38	0.37	3.30	-7.0	0.00	9.0
	Week 41	41	2.68	3.08	0.0	1.00	9.0	38	0.11	3.00	-7.0	0.00	9.0
	Week 44	38	3.03	3.12	0.0	2.00	9.0	35	0.14	3.33	-7.0	0.00	9.0
	Week 47	32	2.59	2.85	0.0	1.50	9.0	30	-0.17	3.46	-7.0	0.00	8.0
	Week 50	29	2.66	3.03	0.0	1.00	9.0	26	0.27	3.54	-7.0	0.00	9.0
	Week 53	25	2.48	3.24	0.0	1.00	10.0	24	0.38	3.87	-7.0	0.00	8.0
	Week 56	26	2.96	3.29	0.0	1.00	9.0	26	0.42	3.44	-7.0	0.00	9.0
	Week 59	20	2.30	3.18	0.0	0.00	9.0	20	-0.45	3.53	-7.0	0.00	8.0
	Week 62	19	3.26	3.07	0.0	3.00	8.0	19	0.16	3.80	-7.0	0.00	8.0
	Week 65	16	3.38	3.56	0.0	2.50	10.0	16	0.69	4.36	-7.0	0.00	10.0
	Week 68	13	1.85	3.21	0.0	0.00	8.0	13	-1.00	3.89	-7.0	0.00	8.0
	Week 71	13	2.38	3.15	0.0	0.00	8.0	13	-0.69	3.45	-7.0	0.00	6.0
	Week 74	11	1.45	2.30	0.0	0.00	7.0	11	-1.73	2.41	-7.0	-2.00	1.0
	Week 77	10	1.50	2.59	0.0	0.50	8.0	10	-0.70	2.36	-6.0	0.00	2.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.2.3: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Europe	EV+Pembro (N= 74)												
	BASELINE	57	3.61	2.64	0.0	4.00	10.0						
	Week 1	48	3.58	3.00	0.0	3.00	10.0	45	0.22	2.36	-5.0	0.00	10.0
	Week 2	54	3.31	2.75	0.0	3.00	9.0	48	-0.10	2.36	-6.0	0.00	6.0
	Week 3	50	3.36	2.87	0.0	3.00	10.0	43	-0.51	2.56	-6.0	0.00	7.0
	Week 4	52	2.33	2.39	0.0	2.00	8.0	46	-0.89	2.71	-6.0	0.00	6.0
	Week 5	47	2.57	2.53	0.0	2.00	8.0	43	-0.53	2.98	-7.0	0.00	7.0
	Week 6	51	2.31	2.35	0.0	2.00	8.0	41	-0.90	3.09	-7.0	0.00	6.0
	Week 7	51	2.08	2.37	0.0	1.00	7.0	41	-0.88	2.79	-7.0	0.00	7.0
	Week 8	52	2.37	2.28	0.0	2.00	8.0	43	-1.07	2.48	-7.0	0.00	4.0
	Week 9	47	2.26	2.29	0.0	2.00	8.0	39	-1.21	2.93	-7.0	0.00	4.0
	Week 10	45	2.00	2.17	0.0	2.00	7.0	36	-1.14	2.68	-7.0	0.00	3.0
	Week 11	49	1.59	1.89	0.0	1.00	7.0	39	-1.15	2.33	-7.0	0.00	3.0
	Week 12	52	1.94	2.27	0.0	1.00	8.0	41	-1.10	2.53	-7.0	0.00	3.0
	Week 14	51	1.71	2.28	0.0	0.00	8.0	40	-1.35	2.87	-7.0	-1.50	6.0
	Week 17	43	1.63	2.20	0.0	0.00	7.0	34	-1.53	2.94	-7.0	-1.00	4.0
	Week 20	41	1.80	2.44	0.0	1.00	8.0	34	-1.53	2.67	-7.0	-1.00	3.0
	Week 23	41	1.51	2.04	0.0	1.00	7.0	31	-1.65	3.09	-7.0	-2.00	7.0
	Week 26	38	1.87	2.24	0.0	1.00	7.0	29	-1.41	2.83	-7.0	-1.00	6.0
	Week 29	37	1.35	2.10	0.0	0.00	7.0	30	-1.70	2.89	-7.0	0.00	4.0
	Week 32	34	1.15	1.79	0.0	0.00	6.0	27	-2.11	3.02	-7.0	-2.00	6.0
	Week 35	31	2.16	2.18	0.0	2.00	7.0	26	-0.88	3.04	-7.0	0.00	5.0
	Week 38	31	1.87	2.13	0.0	1.00	6.0	27	-1.63	2.59	-7.0	-1.00	3.0
	Week 41	28	2.00	2.29	0.0	1.00	7.0	24	-1.42	2.90	-7.0	0.00	4.0
	Week 44	27	1.63	2.20	0.0	0.00	7.0	23	-1.52	2.74	-7.0	0.00	3.0
	Week 47	25	1.88	2.42	0.0	1.00	7.0	21	-1.24	3.00	-6.0	-1.00	6.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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Table 302.1.3002.4.2.3: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	27	1.96	2.70	0.0	1.00	9.0	23	-1.13	3.35	-7.0	-1.00	7.0
	Week 53	28	2.32	3.06	0.0	0.50	9.0	23	-1.00	3.86	-7.0	0.00	7.0
	Week 56	25	3.04	2.59	0.0	3.00	8.0	21	-0.95	3.41	-7.0	0.00	5.0
	Week 59	23	2.35	2.81	0.0	1.00	9.0	18	-1.78	3.06	-7.0	-2.00	4.0
	Week 62	20	2.45	2.44	0.0	2.00	7.0	17	-1.24	2.80	-7.0	0.00	3.0
	Week 65	13	2.00	2.00	0.0	2.00	5.0	13	-1.00	3.56	-7.0	-2.00	4.0
	Week 68	15	2.67	2.53	0.0	2.00	8.0	15	-0.40	2.56	-4.0	0.00	4.0
	Week 71	13	2.00	2.52	0.0	1.00	7.0	13	-1.46	2.85	-7.0	-1.00	4.0
	Week 74	10	2.00	2.49	0.0	1.00	6.0	9	-0.89	4.01	-7.0	-1.00	6.0
	Plat+Gem (N= 95)												
	BASELINE	76	3.20	3.21	0.0	3.00	10.0						
	Week 1	72	3.69	2.98	0.0	3.50	10.0	70	0.39	2.68	-9.0	0.00	6.0
	Week 2	71	3.66	2.65	0.0	4.00	8.0	63	0.27	2.60	-6.0	0.00	6.0
	Week 3	72	3.04	2.84	0.0	2.00	9.0	65	-0.14	2.80	-8.0	0.00	7.0
	Week 4	69	3.20	2.81	0.0	3.00	9.0	62	-0.13	3.17	-9.0	0.00	8.0
	Week 5	72	3.11	2.95	0.0	2.50	10.0	64	0.02	3.41	-9.0	0.00	10.0
	Week 6	69	2.86	2.85	0.0	2.00	9.0	61	-0.15	3.50	-7.0	0.00	9.0
	Week 7	69	2.90	2.60	0.0	3.00	10.0	62	-0.08	2.77	-7.0	0.00	6.0
	Week 8	68	3.03	2.56	0.0	3.00	8.0	60	-0.08	3.18	-9.0	0.00	8.0
	Week 9	66	2.85	2.74	0.0	2.00	10.0	57	-0.21	3.25	-9.0	0.00	8.0
	Week 10	70	2.89	2.84	0.0	2.00	9.0	63	-0.14	3.07	-9.0	0.00	9.0
	Week 11	63	2.92	2.64	0.0	2.00	8.0	56	-0.07	3.26	-9.0	0.00	8.0
	Week 12	66	2.77	2.59	0.0	2.00	9.0	56	-0.27	3.21	-9.0	0.00	8.0
	Week 14	66	3.30	2.77	0.0	3.00	9.0	56	0.04	3.28	-9.0	0.00	8.0
	Week 17	61	2.84	2.92	0.0	2.00	9.0	53	-0.25	3.40	-9.0	0.00	8.0
	Week 20	54	2.56	2.64	0.0	1.50	9.0	48	-0.52	3.36	-9.0	0.00	9.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.2.3: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 23	44	2.50	2.59	0.0	2.00	8.0	40	-0.58	3.27	-9.0	0.00	7.0
	Week 26	42	3.14	2.88	0.0	2.00	9.0	39	-0.03	3.84	-9.0	0.00	9.0
	Week 29	39	3.41	3.04	0.0	3.00	9.0	36	0.33	2.95	-6.0	0.00	8.0
	Week 32	33	3.64	3.20	0.0	3.00	9.0	31	0.32	4.11	-9.0	0.00	9.0
	Week 35	32	3.03	3.07	0.0	2.00	9.0	30	-0.10	3.56	-9.0	0.00	9.0
	Week 38	28	2.64	3.11	0.0	2.00	9.0	26	0.08	3.54	-7.0	0.00	9.0
	Week 41	25	3.28	3.40	0.0	2.00	9.0	23	0.35	3.34	-6.0	0.00	9.0
	Week 44	24	4.00	3.45	0.0	3.50	9.0	22	0.55	3.67	-7.0	0.00	9.0
	Week 47	22	3.36	3.24	0.0	2.00	9.0	20	0.00	4.69	-9.0	0.00	8.0
	Week 50	17	3.29	3.33	0.0	2.00	9.0	15	0.13	4.67	-9.0	0.00	9.0
	Week 53	15	3.20	3.55	0.0	2.00	10.0	14	-0.07	4.73	-9.0	0.00	8.0
	Week 56	15	3.87	3.36	0.0	3.00	9.0	14	1.50	3.82	-4.0	1.00	9.0
	Week 59	11	2.64	2.87	0.0	2.00	8.0	10	0.00	3.89	-6.0	0.00	8.0
	Week 62	11	3.64	3.20	0.0	3.00	8.0	11	1.00	3.44	-3.0	0.00	8.0
	Week 65	10	3.70	3.09	0.0	3.00	8.0	10	1.40	3.31	-3.0	1.00	6.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.2.3: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
North America	EV+Pembro (N= 46)												
	BASELINE	35	3.80	3.16	0.0	5.00	10.0						
	Week 1	31	4.45	3.16	0.0	6.00	10.0	29	0.17	2.66	-5.0	0.00	7.0
	Week 2	31	3.81	2.97	0.0	4.00	9.0	29	-0.24	2.52	-6.0	0.00	7.0
	Week 3	25	2.80	2.57	0.0	3.00	8.0	23	-0.65	2.64	-7.0	0.00	5.0
	Week 4	30	3.03	2.62	0.0	3.00	8.0	26	-0.85	2.05	-6.0	0.00	2.0
	Week 5	30	2.40	2.34	0.0	2.00	7.0	24	-1.50	2.21	-6.0	-0.50	2.0
	Week 6	31	2.94	2.79	0.0	2.00	10.0	25	-0.52	2.86	-6.0	0.00	5.0
	Week 7	33	2.24	2.45	0.0	2.00	8.0	25	-1.72	2.75	-7.0	-1.00	4.0
	Week 8	29	1.97	2.49	0.0	1.00	8.0	22	-2.14	3.14	-10.0	-2.00	3.0
	Week 9	27	1.85	2.38	0.0	1.00	8.0	23	-1.17	2.98	-9.0	0.00	5.0
	Week 10	29	1.48	1.74	0.0	1.00	6.0	25	-2.32	2.79	-10.0	-2.00	1.0
	Week 11	28	1.82	2.68	0.0	1.00	10.0	23	-1.87	2.65	-8.0	0.00	2.0
	Week 12	29	1.38	1.63	0.0	1.00	5.0	24	-2.29	3.16	-10.0	-2.50	4.0
	Week 14	28	1.61	2.11	0.0	1.00	8.0	23	-1.87	2.56	-8.0	-1.00	3.0
	Week 17	29	2.07	2.58	0.0	2.00	9.0	25	-1.72	3.52	-8.0	-1.00	8.0
	Week 20	23	1.96	2.60	0.0	1.00	10.0	20	-1.60	3.05	-10.0	-1.00	2.0
	Week 23	22	0.95	1.36	0.0	0.00	4.0	19	-2.00	2.92	-10.0	-1.00	1.0
	Week 26	21	1.67	2.18	0.0	1.00	7.0	17	-1.76	2.84	-10.0	-1.00	1.0
	Week 29	20	1.55	1.88	0.0	1.00	5.0	18	-1.72	2.89	-7.0	-2.50	4.0
	Week 32	21	1.05	1.43	0.0	0.00	5.0	19	-2.74	3.21	-10.0	-2.00	1.0
	Week 35	22	1.50	1.90	0.0	0.50	6.0	20	-2.05	2.84	-10.0	-1.00	1.0
	Week 38	20	1.65	2.16	0.0	1.00	6.0	18	-1.89	3.38	-9.0	0.00	1.0
	Week 41	21	1.43	1.83	0.0	1.00	7.0	19	-1.68	2.38	-6.0	-1.00	1.0
	Week 44	16	2.13	2.63	0.0	1.00	8.0	14	-1.29	2.55	-7.0	0.00	1.0
	Week 47	16	2.38	2.90	0.0	1.50	8.0	15	-1.40	2.97	-7.0	0.00	4.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.2.3: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	16	2.00	2.48	0.0	1.50	8.0	13	-1.69	2.25	-6.0	-1.00	1.0
	Week 53	15	3.00	2.83	0.0	3.00	8.0	12	-1.00	2.13	-5.0	-0.50	2.0
	Week 56	17	2.00	2.32	0.0	1.00	7.0	14	-2.36	2.13	-6.0	-2.00	1.0
	Week 59	17	2.24	2.22	0.0	1.00	6.0	14	-1.79	2.08	-5.0	-1.00	0.0
	Week 62	14	2.14	2.82	0.0	0.50	8.0	11	-1.36	3.20	-6.0	-1.00	6.0
	Week 68	11	1.55	2.77	0.0	0.00	7.0	9	-1.78	2.77	-7.0	-1.00	1.0
	Week 71	11	2.18	2.60	0.0	1.00	7.0	9	-1.56	2.92	-6.0	0.00	1.0
	Plat+Gem (N= 34)												
	BASELINE	28	3.64	3.07	0.0	3.00	10.0						
	Week 1	20	3.00	2.90	0.0	3.00	8.0	18	-0.78	2.67	-7.0	0.00	3.0
	Week 2	22	2.50	2.91	0.0	1.50	8.0	21	-1.05	2.99	-7.0	0.00	3.0
	Week 3	20	2.75	2.61	0.0	3.00	9.0	18	-1.39	3.16	-7.0	-1.00	4.0
	Week 4	24	2.29	2.49	0.0	2.00	8.0	20	-1.40	3.65	-7.0	-0.50	4.0
	Week 5	26	2.58	2.84	0.0	2.00	8.0	23	-0.39	3.07	-6.0	0.00	8.0
	Week 6	20	2.20	2.98	0.0	0.50	9.0	17	-1.41	3.61	-7.0	0.00	6.0
	Week 7	24	2.42	2.90	0.0	1.50	8.0	21	-1.10	2.93	-7.0	0.00	4.0
	Week 8	24	3.46	3.11	0.0	3.50	10.0	22	0.18	2.89	-6.0	0.00	6.0
	Week 9	23	2.43	2.73	0.0	2.00	9.0	20	-1.15	3.27	-7.0	0.00	5.0
	Week 10	20	2.85	2.87	0.0	2.50	8.0	18	-0.67	3.45	-7.0	0.00	5.0
	Week 11	18	2.39	2.91	0.0	1.50	9.0	17	-1.41	3.47	-7.0	0.00	3.0
	Week 12	17	2.24	2.28	0.0	2.00	6.0	16	-1.25	2.62	-6.0	-0.50	4.0
	Week 14	16	2.25	2.84	0.0	1.00	8.0	14	-1.36	2.98	-7.0	0.00	2.0
	Week 17	19	2.11	2.96	0.0	0.00	8.0	18	-1.56	3.85	-7.0	-1.00	7.0
	Week 20	16	1.63	1.89	0.0	1.00	6.0	14	-1.86	3.46	-7.0	-2.50	4.0
	Week 23	15	1.40	2.03	0.0	0.00	6.0	14	-2.57	2.79	-7.0	-2.50	1.0
	Week 26	13	1.69	2.21	0.0	0.00	7.0	13	-2.23	2.65	-7.0	-2.00	1.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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Table 302.1.3002.4.2.3: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 29	14	2.29	3.10	0.0	0.50	9.0	13	-0.85	4.54	-7.0	-1.00	7.0
	Week 32	11	1.27	2.00	0.0	0.00	6.0	10	-2.00	3.33	-7.0	-2.50	4.0
	Week 35	13	1.85	2.51	0.0	1.00	8.0	12	-2.08	3.06	-7.0	-1.50	1.0
	Week 38	10	2.80	3.12	0.0	2.50	8.0	9	0.00	2.60	-4.0	0.00	4.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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Table 302.1.3002.4.2.3: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Rest of World	EV+Pembro (N= 82)												
	BASELINE	74	2.85	2.89	0.0	2.50	8.0						
	Week 1	63	3.16	2.98	0.0	2.00	9.0	60	0.18	1.53	-3.0	0.00	5.0
	Week 2	69	3.58	2.90	0.0	3.00	9.0	64	0.63	2.31	-4.0	0.00	8.0
	Week 3	64	3.14	2.80	0.0	3.50	9.0	60	0.10	2.52	-6.0	0.00	8.0
	Week 4	65	2.31	2.58	0.0	1.00	8.0	62	-0.45	2.36	-6.0	0.00	5.0
	Week 5	62	2.32	2.56	0.0	2.00	8.0	59	-0.37	2.75	-6.0	0.00	8.0
	Week 6	65	2.26	2.52	0.0	2.00	8.0	62	-0.87	2.68	-8.0	0.00	8.0
	Week 7	66	2.35	2.60	0.0	2.00	8.0	63	-0.59	2.77	-6.0	0.00	8.0
	Week 8	69	2.41	2.65	0.0	2.00	10.0	64	-0.48	3.33	-7.0	0.00	10.0
	Week 9	68	2.82	2.85	0.0	2.00	9.0	63	0.16	3.14	-7.0	0.00	9.0
	Week 10	65	2.49	2.69	0.0	2.00	9.0	61	-0.07	2.90	-6.0	0.00	7.0
	Week 11	61	1.98	2.39	0.0	1.00	8.0	57	-0.86	2.82	-8.0	0.00	7.0
	Week 12	62	2.32	2.62	0.0	1.00	8.0	58	-0.47	2.96	-8.0	0.00	7.0
	Week 14	61	2.74	2.73	0.0	2.00	9.0	57	-0.25	3.35	-8.0	0.00	7.0
	Week 17	60	2.40	2.34	0.0	2.00	7.0	55	-0.22	3.07	-8.0	0.00	7.0
	Week 20	56	2.18	2.24	0.0	1.50	8.0	52	-0.13	2.92	-8.0	0.00	6.0
	Week 23	54	2.11	2.44	0.0	1.00	8.0	50	-0.34	3.15	-8.0	0.00	7.0
	Week 26	55	2.40	2.61	0.0	2.00	8.0	51	-0.02	3.34	-8.0	0.00	8.0
	Week 29	50	2.68	2.77	0.0	2.00	8.0	47	0.32	3.69	-8.0	0.00	8.0
	Week 32	47	2.28	2.34	0.0	2.00	7.0	44	-0.09	3.35	-8.0	0.00	7.0
	Week 35	45	2.58	2.48	0.0	2.00	8.0	42	0.12	3.09	-8.0	0.00	8.0
	Week 38	46	2.74	2.69	0.0	2.00	10.0	43	0.07	2.86	-8.0	0.00	7.0
	Week 41	46	2.59	2.61	0.0	2.00	7.0	44	-0.07	3.06	-8.0	0.00	7.0
	Week 44	43	3.09	2.76	0.0	4.00	8.0	40	0.50	3.40	-8.0	0.00	8.0
	Week 47	38	2.63	2.53	0.0	2.00	8.0	36	0.03	3.14	-8.0	0.00	7.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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Table 302.1.3002.4.2.3: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	32	3.00	2.76	0.0	2.50	9.0	30	0.27	3.14	-8.0	0.00	6.0
	Week 53	33	2.82	2.79	0.0	2.00	8.0	31	-0.03	3.12	-8.0	0.00	7.0
	Week 56	30	2.50	2.56	0.0	2.00	7.0	28	-0.43	3.08	-8.0	0.00	6.0
	Week 59	29	3.48	3.02	0.0	4.00	8.0	27	0.56	3.60	-8.0	1.00	8.0
	Week 62	28	2.71	2.64	0.0	2.50	7.0	26	-0.08	3.07	-8.0	0.00	6.0
	Week 65	22	3.00	2.67	0.0	3.00	8.0	21	0.43	3.52	-8.0	0.00	7.0
	Week 68	20	3.05	2.80	0.0	3.00	8.0	19	0.58	3.39	-8.0	0.00	6.0
	Week 71	18	2.94	2.75	0.0	3.00	7.0	17	0.18	3.81	-8.0	0.00	6.0
	Week 74	19	2.63	2.50	0.0	3.00	7.0	19	0.32	3.18	-8.0	0.00	7.0
	Week 77	19	2.53	2.61	0.0	2.00	7.0	18	0.17	3.33	-8.0	0.00	5.0
	Week 80	19	3.05	2.97	0.0	3.00	7.0	18	0.78	3.73	-8.0	0.00	7.0
	Week 83	17	3.00	2.67	0.0	3.00	8.0	17	0.76	3.54	-8.0	0.00	7.0
	Week 86	14	2.71	3.20	0.0	1.50	9.0	14	0.64	3.86	-8.0	0.00	8.0
	Week 89	11	1.82	2.86	0.0	0.00	8.0	11	0.73	3.17	-4.0	0.00	7.0
	Plat+Gem (N= 73)												
	BASELINE	64	3.22	2.83	0.0	3.00	9.0						
	Week 1	54	3.83	3.34	0.0	3.00	10.0	54	0.52	3.55	-6.0	0.00	10.0
	Week 2	58	3.60	3.06	0.0	3.00	10.0	56	0.39	2.63	-5.0	0.00	8.0
	Week 3	57	3.28	2.88	0.0	3.00	9.0	55	0.20	2.70	-7.0	0.00	8.0
	Week 4	58	3.48	2.82	0.0	3.50	9.0	55	0.09	2.80	-7.0	0.00	8.0
	Week 5	57	3.26	2.77	0.0	3.00	9.0	54	0.15	2.60	-6.0	0.00	8.0
	Week 6	56	3.20	3.15	0.0	3.00	10.0	53	0.02	2.91	-7.0	0.00	6.0
	Week 7	56	3.23	2.75	0.0	3.00	10.0	53	0.06	2.68	-7.0	0.00	7.0
	Week 8	54	2.89	2.94	0.0	2.00	9.0	51	-0.10	3.12	-7.0	0.00	7.0
	Week 9	52	2.98	2.64	0.0	3.00	9.0	49	-0.16	2.92	-7.0	0.00	7.0
	Week 10	52	3.02	2.91	0.0	2.50	10.0	49	-0.12	2.86	-7.0	0.00	8.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.2.3: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	45	3.13	3.06	0.0	2.00	10.0	42	0.02	3.10	-7.0	0.00	8.0
	Week 12	47	2.83	3.18	0.0	2.00	10.0	44	0.23	2.92	-7.0	0.00	6.0
	Week 14	43	2.91	2.71	0.0	3.00	10.0	40	0.15	2.91	-7.0	0.00	7.0
	Week 17	40	2.95	2.81	0.0	2.00	9.0	37	0.11	2.81	-6.0	0.00	6.0
	Week 20	34	2.41	2.84	0.0	1.00	8.0	31	-0.23	2.43	-7.0	0.00	5.0
	Week 23	29	2.00	2.63	0.0	1.00	8.0	27	-0.52	2.82	-7.0	0.00	5.0
	Week 26	26	2.35	2.81	0.0	1.00	9.0	24	-0.54	2.77	-7.0	0.00	4.0
	Week 29	24	2.79	3.23	0.0	1.50	10.0	22	0.45	3.35	-7.0	0.00	9.0
	Week 32	20	2.80	2.73	0.0	3.00	9.0	18	0.28	2.78	-7.0	0.00	5.0
	Week 35	17	2.47	2.90	0.0	1.00	9.0	15	-0.13	3.09	-7.0	0.00	7.0
	Week 38	18	3.33	3.34	0.0	2.00	8.0	15	0.67	3.13	-7.0	0.00	8.0
	Week 41	18	2.39	2.70	0.0	1.50	7.0	16	0.13	2.70	-7.0	0.00	4.0
	Week 44	16	2.19	2.48	0.0	1.50	8.0	14	-0.21	2.33	-7.0	0.00	3.0
	Week 47	12	2.42	2.87	0.0	1.00	8.0	11	0.45	2.98	-7.0	1.00	5.0
	Week 50	11	2.91	3.08	0.0	1.00	8.0	9	0.00	2.78	-7.0	1.00	3.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.2.4: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	EV+Pembro (N=146)												
	BASELINE	123	3.26	2.95	0.0	3.00	10.0						
	Week 1	103	3.52	3.00	0.0	3.00	10.0	101	0.31	2.15	-5.0	0.00	10.0
	Week 2	109	3.58	2.87	0.0	3.00	9.0	103	0.36	2.52	-6.0	0.00	8.0
	Week 3	94	3.05	2.71	0.0	3.00	10.0	90	-0.09	2.68	-7.0	0.00	8.0
	Week 4	103	2.43	2.40	0.0	2.00	8.0	96	-0.58	2.40	-6.0	0.00	6.0
	Week 5	98	2.33	2.39	0.0	2.00	8.0	92	-0.57	2.75	-7.0	0.00	8.0
	Week 6	106	2.27	2.43	0.0	2.00	10.0	95	-0.78	2.75	-7.0	0.00	8.0
	Week 7	105	2.06	2.43	0.0	1.00	8.0	92	-0.87	2.76	-7.0	0.00	8.0
	Week 8	104	2.13	2.47	0.0	1.00	10.0	94	-1.00	3.16	-10.0	0.00	10.0
	Week 9	100	2.30	2.51	0.0	2.00	9.0	91	-0.56	3.13	-9.0	0.00	9.0
	Week 10	99	2.06	2.39	0.0	1.00	9.0	89	-0.84	3.08	-10.0	0.00	7.0
	Week 11	96	1.69	2.24	0.0	1.00	10.0	86	-1.08	2.53	-8.0	0.00	7.0
	Week 12	99	1.91	2.38	0.0	1.00	8.0	89	-0.92	3.03	-10.0	0.00	7.0
	Week 14	96	2.00	2.40	0.0	1.00	9.0	86	-0.91	3.00	-8.0	0.00	6.0
	Week 17	97	1.96	2.23	0.0	1.00	8.0	86	-1.00	3.01	-8.0	0.00	6.0
	Week 20	90	1.99	2.39	0.0	1.00	10.0	81	-0.78	2.99	-10.0	0.00	6.0
	Week 23	86	1.53	2.04	0.0	1.00	7.0	76	-1.00	3.15	-10.0	0.00	7.0
	Week 26	85	1.94	2.34	0.0	1.00	8.0	75	-0.71	3.15	-10.0	0.00	8.0
	Week 29	80	1.94	2.48	0.0	1.00	8.0	73	-0.73	3.40	-7.0	0.00	8.0
	Week 32	74	1.42	1.91	0.0	0.00	7.0	68	-1.38	3.40	-10.0	0.00	7.0
	Week 35	73	2.11	2.27	0.0	2.00	8.0	68	-0.72	3.18	-10.0	0.00	8.0
	Week 38	75	1.96	2.16	0.0	1.00	8.0	69	-1.04	2.85	-9.0	0.00	5.0
	Week 41	71	1.94	2.20	0.0	1.00	7.0	66	-0.97	2.86	-7.0	0.00	5.0
	Week 44	64	2.27	2.48	0.0	2.00	8.0	58	-0.47	3.14	-7.0	0.00	8.0
	Week 47	56	2.18	2.45	0.0	2.00	8.0	51	-0.76	3.02	-7.0	0.00	6.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.2.4: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	55	2.35	2.70	0.0	2.00	9.0	49	-0.65	3.11	-7.0	0.00	7.0
	Week 53	57	2.53	2.87	0.0	2.00	9.0	50	-0.62	3.15	-7.0	0.00	7.0
	Week 56	53	2.74	2.54	0.0	2.00	8.0	47	-0.96	3.05	-7.0	0.00	5.0
	Week 59	51	2.65	2.64	0.0	2.00	9.0	44	-1.16	2.81	-7.0	0.00	5.0
	Week 62	42	2.48	2.49	0.0	2.00	8.0	37	-0.78	2.92	-7.0	0.00	6.0
	Week 65	31	2.39	2.22	0.0	2.00	7.0	30	-0.60	3.12	-7.0	0.00	4.0
	Week 68	31	2.61	2.65	0.0	2.00	8.0	29	-0.14	2.92	-7.0	0.00	6.0
	Week 71	30	2.73	2.60	0.0	2.00	7.0	28	-0.46	3.45	-7.0	0.00	6.0
	Week 74	29	2.34	2.33	0.0	2.00	7.0	27	-0.48	3.20	-7.0	0.00	6.0
	Week 77	26	2.31	2.46	0.0	1.50	7.0	24	-0.33	3.09	-7.0	0.00	5.0
	Week 80	26	3.00	2.83	0.0	2.50	8.0	26	0.27	2.95	-5.0	0.00	6.0
	Week 83	21	3.00	2.79	0.0	3.00	8.0	21	0.29	3.20	-6.0	0.00	7.0
	Week 86	17	2.88	3.02	0.0	3.00	9.0	17	0.76	3.23	-6.0	1.00	8.0
	Week 89	11	2.00	2.86	0.0	0.00	8.0	11	0.18	3.76	-6.0	0.00	7.0
	Week 92	13	2.85	2.58	0.0	3.00	8.0	13	0.38	3.23	-7.0	1.00	6.0
	Plat+Gem (N=151)												
	BASELINE	126	2.94	2.98	0.0	3.00	10.0						
	Week 1	109	3.25	2.99	0.0	3.00	10.0	106	0.16	3.08	-9.0	0.00	10.0
	Week 2	118	3.22	2.78	0.0	3.00	10.0	108	0.14	2.58	-7.0	0.00	8.0
	Week 3	114	2.98	2.70	0.0	3.00	9.0	105	0.01	2.78	-7.0	0.00	8.0
	Week 4	116	3.01	2.64	0.0	3.00	9.0	105	-0.06	2.84	-7.0	0.00	8.0
	Week 5	121	2.97	2.81	0.0	2.00	10.0	109	0.24	2.89	-6.0	0.00	10.0
	Week 6	109	2.76	2.88	0.0	2.00	9.0	98	0.03	3.06	-7.0	0.00	9.0
	Week 7	115	2.87	2.72	0.0	2.00	10.0	106	0.11	2.54	-7.0	0.00	7.0
	Week 8	112	2.78	2.67	0.0	2.00	10.0	103	0.03	2.99	-7.0	0.00	8.0
	Week 9	107	2.78	2.57	0.0	2.00	10.0	96	-0.06	2.83	-7.0	0.00	8.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.2.4: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	107	2.70	2.76	0.0	2.00	9.0	98	-0.05	2.73	-7.0	0.00	9.0
	Week 11	97	2.69	2.69	0.0	2.00	9.0	88	-0.09	3.09	-7.0	0.00	8.0
	Week 12	100	2.57	2.65	0.0	2.00	9.0	89	-0.01	2.92	-7.0	0.00	8.0
	Week 14	99	2.97	2.65	0.0	2.00	8.0	87	0.17	2.83	-7.0	0.00	8.0
	Week 17	94	2.51	2.70	0.0	2.00	9.0	84	-0.12	3.18	-7.0	0.00	8.0
	Week 20	84	2.39	2.62	0.0	1.00	9.0	74	-0.26	3.00	-8.0	0.00	9.0
	Week 23	70	2.13	2.52	0.0	1.00	8.0	63	-0.57	2.88	-7.0	0.00	7.0
	Week 26	61	2.74	2.71	0.0	2.00	9.0	56	-0.07	2.88	-7.0	0.00	9.0
	Week 29	59	2.68	2.92	0.0	1.00	10.0	53	0.06	3.35	-7.0	0.00	9.0
	Week 32	51	2.96	3.07	0.0	2.00	9.0	46	0.13	3.56	-7.0	0.00	9.0
	Week 35	50	2.60	2.94	0.0	1.00	9.0	45	-0.31	3.16	-7.0	0.00	9.0
	Week 38	46	2.78	3.09	0.0	2.00	9.0	40	0.25	3.39	-7.0	0.00	9.0
	Week 41	42	2.88	3.15	0.0	1.50	9.0	37	0.16	3.15	-7.0	0.00	9.0
	Week 44	39	2.64	3.00	0.0	2.00	9.0	34	0.03	3.48	-7.0	0.00	9.0
	Week 47	33	2.73	3.08	0.0	1.00	9.0	29	0.03	3.67	-7.0	0.00	8.0
	Week 50	27	2.44	2.81	0.0	1.00	9.0	22	-0.18	3.35	-7.0	0.00	9.0
	Week 53	23	2.52	3.09	0.0	1.00	9.0	20	0.00	3.76	-7.0	0.00	8.0
	Week 56	20	1.75	2.40	0.0	1.00	9.0	19	-0.37	3.27	-7.0	0.00	9.0
	Week 59	17	2.00	2.76	0.0	0.00	8.0	15	-0.80	3.82	-7.0	0.00	8.0
	Week 62	14	3.14	3.16	0.0	2.50	8.0	14	0.57	4.16	-7.0	0.00	8.0
	Week 65	13	3.31	3.61	0.0	2.00	10.0	12	0.58	4.74	-7.0	0.00	10.0
	Week 68	10	1.60	2.95	0.0	0.00	8.0	10	-1.30	4.03	-7.0	-1.50	8.0
	Week 71	10	1.70	2.67	0.0	0.00	7.0	10	-1.20	3.61	-7.0	-1.50	6.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.2.4: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	EV+Pembro (N= 56)												
	BASELINE	43	3.47	2.69	0.0	4.00	8.0						
	Week 1	39	3.74	3.20	0.0	3.00	10.0	33	-0.15	1.89	-5.0	0.00	4.0
	Week 2	45	3.42	2.82	0.0	3.00	9.0	38	-0.24	1.97	-5.0	0.00	4.0
	Week 3	45	3.38	2.92	0.0	4.00	9.0	36	-0.64	2.19	-6.0	0.00	5.0
	Week 4	44	2.55	2.82	0.0	2.00	8.0	38	-0.92	2.51	-6.0	0.00	3.0
	Week 5	41	2.66	2.72	0.0	2.00	8.0	34	-0.85	2.79	-6.0	0.00	6.0
	Week 6	41	2.80	2.74	0.0	2.00	8.0	33	-0.91	3.10	-8.0	0.00	5.0
	Week 7	45	2.64	2.56	0.0	2.00	8.0	37	-0.97	2.87	-6.0	0.00	6.0
	Week 8	46	2.70	2.49	0.0	2.50	8.0	35	-0.86	2.87	-7.0	0.00	6.0
	Week 9	42	2.81	2.80	0.0	2.00	8.0	34	-0.38	3.06	-7.0	0.00	7.0
	Week 10	40	2.28	2.36	0.0	1.50	7.0	33	-0.85	2.54	-6.0	0.00	5.0
	Week 11	42	2.10	2.39	0.0	1.00	7.0	33	-1.33	2.94	-8.0	0.00	6.0
	Week 12	44	2.18	2.24	0.0	1.00	7.0	34	-1.32	2.63	-7.0	-1.00	4.0
	Week 14	44	2.43	2.71	0.0	1.50	8.0	34	-0.97	3.42	-8.0	0.00	7.0
	Week 17	35	2.40	2.69	0.0	2.00	9.0	28	-0.75	3.73	-8.0	-0.50	8.0
	Week 20	30	2.07	2.35	0.0	1.00	8.0	25	-1.12	2.76	-8.0	0.00	3.0
	Week 23	31	2.10	2.47	0.0	1.00	8.0	24	-1.25	3.19	-8.0	-0.50	7.0
	Week 26	29	2.52	2.64	0.0	2.00	8.0	22	-0.86	3.34	-8.0	0.00	5.0
	Week 29	27	2.22	2.45	0.0	1.00	7.0	22	-0.64	3.61	-8.0	0.00	7.0
	Week 32	28	2.25	2.38	0.0	1.50	7.0	22	-0.86	3.43	-8.0	-0.50	7.0
	Week 35	25	2.48	2.35	0.0	2.00	6.0	20	-0.50	2.93	-8.0	0.00	6.0
	Week 38	22	3.18	3.10	0.0	3.50	10.0	19	-0.16	3.48	-8.0	0.00	7.0
	Week 41	24	2.79	2.83	0.0	2.50	7.0	21	-0.24	3.22	-8.0	0.00	7.0
	Week 44	22	3.00	3.01	0.0	2.50	7.0	19	-0.32	3.45	-8.0	0.00	7.0
	Week 47	23	2.74	2.83	0.0	2.00	7.0	21	-0.33	3.32	-8.0	0.00	7.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.2.4: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	2.60	2.74	0.0	2.00	8.0	17	-0.47	3.28	-8.0	0.00	6.0
	Week 53	19	3.11	2.92	0.0	3.00	8.0	16	-0.31	3.65	-8.0	-0.50	7.0
	Week 56	19	2.11	2.45	0.0	2.00	7.0	16	-1.25	3.21	-8.0	-1.00	6.0
	Week 59	18	3.22	3.23	0.0	2.50	8.0	15	0.60	4.29	-8.0	0.00	8.0
	Week 62	20	2.55	2.84	0.0	1.50	7.0	17	-0.53	3.32	-8.0	0.00	6.0
	Week 65	12	2.75	3.31	0.0	0.50	8.0	11	-0.27	4.43	-8.0	0.00	7.0
	Week 68	15	2.47	2.92	0.0	2.00	7.0	14	-0.50	3.44	-8.0	0.00	6.0
	Week 71	12	1.75	2.63	0.0	0.50	7.0	11	-1.55	3.08	-8.0	-1.00	3.0
	Week 77	11	1.36	2.42	0.0	0.00	7.0	10	-1.70	2.95	-8.0	-0.50	2.0
	Week 80	10	1.90	2.64	0.0	0.50	7.0	9	-0.78	3.83	-8.0	-1.00	7.0
	Plat+Gem (N= 51)												
	BASELINE	42	4.29	3.01	0.0	5.00	9.0						
	Week 1	37	4.84	3.15	0.0	6.00	10.0	36	0.67	2.95	-6.0	1.00	7.0
	Week 2	33	4.36	3.02	0.0	5.00	9.0	32	0.06	3.13	-6.0	0.00	8.0
	Week 3	35	3.46	3.17	0.0	4.00	9.0	33	-0.73	2.98	-8.0	0.00	5.0
	Week 4	35	3.69	3.16	0.0	3.00	9.0	32	-0.78	3.88	-9.0	0.00	8.0
	Week 5	34	3.47	3.05	0.0	3.00	9.0	32	-0.81	3.47	-9.0	-0.50	8.0
	Week 6	36	3.31	3.28	0.0	2.00	10.0	33	-1.06	3.84	-7.0	-1.00	7.0
	Week 7	34	3.21	2.65	0.0	3.00	8.0	30	-1.23	3.30	-7.0	-0.50	4.0
	Week 8	34	3.94	2.98	0.0	5.00	9.0	30	-0.30	3.47	-9.0	0.00	5.0
	Week 9	34	3.00	3.06	0.0	2.50	9.0	30	-1.23	3.83	-9.0	-0.50	5.0
	Week 10	35	3.63	3.05	0.0	4.00	10.0	32	-0.69	3.81	-9.0	-0.50	6.0
	Week 11	29	3.69	3.13	0.0	4.00	10.0	27	-0.70	3.73	-9.0	0.00	8.0
	Week 12	30	3.23	3.11	0.0	3.00	10.0	27	-0.89	3.38	-9.0	0.00	6.0
	Week 14	26	3.27	3.19	0.0	3.00	10.0	23	-1.13	3.95	-9.0	-2.00	7.0
	Week 17	26	3.65	3.35	0.0	3.50	9.0	24	-1.13	3.69	-9.0	-1.00	5.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.2.4: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 20	20	2.25	2.61	0.0	0.50	7.0	19	-2.05	3.21	-9.0	-2.00	5.0
	Week 23	18	2.22	2.60	0.0	1.00	7.0	18	-2.06	3.65	-9.0	-1.50	7.0
	Week 26	20	2.40	3.05	0.0	0.50	9.0	20	-1.95	4.36	-9.0	-1.50	6.0
	Week 29	18	4.11	3.50	0.0	5.00	9.0	18	0.44	3.57	-7.0	0.00	7.0
	Week 32	13	3.00	2.68	0.0	4.00	7.0	13	-0.85	4.10	-9.0	0.00	7.0
	Week 35	12	2.75	2.90	0.0	2.50	8.0	12	-1.33	4.16	-9.0	0.00	5.0
	Week 38	10	3.40	3.50	0.0	3.00	8.0	10	0.20	2.62	-6.0	0.00	4.0
	Week 41	10	3.50	3.21	0.0	3.50	8.0	10	0.70	1.95	-2.0	0.00	5.0
	Week 44	10	5.10	2.96	0.0	5.50	9.0	10	0.70	2.00	-2.0	0.00	5.0
	Week 47	10	2.90	2.73	0.0	3.50	7.0	10	-0.80	4.44	-9.0	0.00	7.0
	Week 56	10	4.90	3.48	0.0	6.00	8.0	10	1.60	3.06	-4.0	1.00	6.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.2.5: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Visceral metastases	EV+Pembro (N=148)												
	BASELINE	121	3.47	2.97	0.0	3.00	10.0						
	Week 1	106	3.77	3.11	0.0	3.00	10.0	102	0.29	2.22	-5.0	0.00	10.0
	Week 2	110	3.87	2.82	0.0	4.00	9.0	103	0.35	2.36	-5.0	0.00	8.0
	Week 3	98	3.22	2.80	0.0	3.00	10.0	89	-0.24	2.71	-7.0	0.00	8.0
	Week 4	105	2.67	2.59	0.0	2.00	8.0	95	-0.54	2.49	-6.0	0.00	6.0
	Week 5	101	2.64	2.52	0.0	2.00	8.0	91	-0.49	2.86	-6.0	0.00	8.0
	Week 6	106	2.49	2.63	0.0	2.00	10.0	91	-0.89	2.88	-8.0	0.00	8.0
	Week 7	110	2.33	2.47	0.0	2.00	8.0	92	-0.87	2.78	-7.0	0.00	7.0
	Week 8	108	2.28	2.36	0.0	2.00	9.0	91	-1.00	3.03	-10.0	0.00	8.0
	Week 9	105	2.42	2.49	0.0	2.00	8.0	92	-0.62	2.90	-9.0	0.00	7.0
	Week 10	101	2.14	2.35	0.0	1.00	8.0	87	-0.99	2.94	-10.0	0.00	7.0
	Week 11	98	1.94	2.40	0.0	1.00	10.0	84	-1.04	2.77	-8.0	0.00	7.0
	Week 12	101	2.09	2.29	0.0	1.00	8.0	86	-0.98	2.95	-10.0	0.00	4.0
	Week 14	103	2.17	2.45	0.0	1.00	8.0	88	-0.84	3.15	-8.0	0.00	7.0
	Week 17	96	2.07	2.27	0.0	2.00	8.0	81	-0.99	3.11	-8.0	0.00	7.0
	Week 20	87	2.11	2.36	0.0	1.00	10.0	76	-0.71	3.03	-10.0	0.00	5.0
	Week 23	85	1.78	2.20	0.0	1.00	7.0	71	-0.87	3.35	-10.0	0.00	7.0
	Week 26	81	2.01	2.34	0.0	1.00	8.0	67	-0.70	3.38	-10.0	0.00	8.0
	Week 29	72	2.04	2.45	0.0	1.00	8.0	64	-0.63	3.44	-8.0	0.00	8.0
	Week 32	71	1.69	2.06	0.0	1.00	7.0	62	-1.16	3.40	-10.0	0.00	7.0
	Week 35	70	2.10	2.25	0.0	2.00	7.0	63	-0.75	3.12	-10.0	0.00	6.0
	Week 38	70	2.26	2.51	0.0	1.00	10.0	63	-0.79	3.16	-9.0	0.00	7.0
	Week 41	66	2.24	2.48	0.0	1.00	7.0	60	-0.53	3.04	-8.0	0.00	7.0
	Week 44	59	2.61	2.65	0.0	2.00	8.0	53	-0.42	3.07	-8.0	0.00	7.0
	Week 47	52	2.50	2.72	0.0	2.00	8.0	48	-0.52	3.24	-8.0	0.00	7.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.2.5: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	49	2.73	2.89	0.0	2.00	9.0	43	-0.47	3.24	-8.0	0.00	7.0
	Week 53	50	2.88	2.95	0.0	2.00	9.0	44	-0.57	3.43	-8.0	0.00	7.0
	Week 56	45	2.89	2.56	0.0	2.00	8.0	39	-0.79	3.18	-8.0	0.00	6.0
	Week 59	44	3.05	2.73	0.0	2.50	8.0	38	-0.47	3.40	-8.0	0.00	8.0
	Week 62	38	2.53	2.63	0.0	2.00	8.0	33	-0.39	2.95	-8.0	0.00	6.0
	Week 65	25	2.56	2.65	0.0	2.00	7.0	24	-0.38	3.62	-8.0	0.00	7.0
	Week 68	31	2.55	2.66	0.0	2.00	8.0	29	-0.17	3.28	-8.0	0.00	6.0
	Week 71	27	2.44	2.61	0.0	2.00	7.0	25	-0.72	3.46	-8.0	0.00	6.0
	Week 74	23	2.17	2.48	0.0	1.00	7.0	22	-0.50	3.45	-8.0	0.00	7.0
	Week 77	24	2.08	2.50	0.0	0.50	7.0	23	-0.91	3.07	-8.0	0.00	5.0
	Week 80	22	3.18	3.08	0.0	3.00	8.0	22	0.18	3.53	-8.0	0.00	7.0
	Week 83	19	3.00	3.09	0.0	3.00	8.0	19	0.16	3.89	-8.0	0.00	7.0
	Week 86	14	3.00	3.49	0.0	1.50	9.0	14	0.64	4.34	-8.0	1.00	8.0
	Week 89	10	1.60	2.95	0.0	0.00	8.0	10	0.10	3.81	-5.0	0.00	7.0
	Week 92	11	2.73	3.20	0.0	1.00	8.0	11	0.82	3.60	-5.0	0.00	7.0
	Plat+Gem (N=157)												
	BASELINE	130	3.47	3.01	0.0	3.00	10.0						
	Week 1	112	3.78	3.15	0.0	3.00	10.0	109	0.25	3.07	-9.0	0.00	10.0
	Week 2	112	3.29	2.89	0.0	3.00	10.0	105	-0.16	2.55	-6.0	0.00	8.0
	Week 3	112	3.13	2.89	0.0	3.00	9.0	105	-0.20	2.67	-7.0	0.00	8.0
	Week 4	113	3.17	2.84	0.0	3.00	9.0	104	-0.34	2.87	-8.0	0.00	8.0
	Week 5	115	3.04	2.99	0.0	2.00	10.0	106	-0.18	3.11	-9.0	0.00	10.0
	Week 6	107	2.84	3.05	0.0	1.00	10.0	98	-0.39	3.14	-7.0	0.00	9.0
	Week 7	109	2.88	2.70	0.0	3.00	10.0	101	-0.36	2.66	-7.0	0.00	7.0
	Week 8	107	2.83	2.83	0.0	2.00	10.0	99	-0.39	2.99	-9.0	0.00	8.0
	Week 9	105	2.74	2.70	0.0	2.00	10.0	95	-0.56	2.88	-7.0	0.00	8.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.2.5: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	104	2.87	2.87	0.0	2.00	10.0	96	-0.44	2.85	-9.0	0.00	9.0
	Week 11	91	2.81	2.80	0.0	2.00	10.0	84	-0.54	3.06	-9.0	0.00	8.0
	Week 12	94	2.52	2.75	0.0	2.00	10.0	85	-0.58	2.80	-9.0	0.00	8.0
	Week 14	90	2.94	2.72	0.0	2.50	10.0	80	-0.31	2.70	-6.0	0.00	6.0
	Week 17	90	2.61	2.80	0.0	2.00	9.0	82	-0.52	3.12	-9.0	0.00	7.0
	Week 20	74	2.31	2.57	0.0	1.00	8.0	66	-0.89	2.91	-9.0	0.00	5.0
	Week 23	63	2.19	2.62	0.0	1.00	8.0	59	-0.98	2.99	-9.0	0.00	7.0
	Week 26	55	2.60	2.71	0.0	2.00	9.0	53	-0.75	2.89	-9.0	0.00	5.0
	Week 29	53	3.04	3.19	0.0	1.00	10.0	50	0.08	3.06	-6.0	0.00	9.0
	Week 32	43	2.88	3.03	0.0	2.00	9.0	41	-0.32	3.55	-9.0	0.00	9.0
	Week 35	39	2.54	2.95	0.0	1.00	9.0	37	-0.92	2.79	-9.0	0.00	5.0
	Week 38	37	3.16	3.36	0.0	2.00	9.0	34	0.24	3.00	-7.0	0.00	8.0
	Week 41	33	2.85	3.07	0.0	2.00	9.0	31	-0.03	2.68	-6.0	0.00	6.0
	Week 44	32	3.19	3.24	0.0	2.00	9.0	30	-0.07	2.88	-7.0	0.00	7.0
	Week 47	28	2.50	3.09	0.0	1.00	9.0	26	-0.92	3.58	-9.0	0.00	8.0
	Week 50	22	2.45	2.86	0.0	1.50	9.0	20	-0.65	3.13	-9.0	0.00	5.0
	Week 53	19	2.79	3.39	0.0	1.00	10.0	17	-0.41	3.94	-9.0	0.00	7.0
	Week 56	18	2.56	2.94	0.0	1.50	8.0	17	-0.47	2.00	-4.0	0.00	2.0
	Week 59	13	2.69	3.22	0.0	2.00	9.0	12	-0.92	2.94	-6.0	-0.50	5.0
	Week 62	11	3.64	2.87	0.0	4.00	8.0	11	-0.18	2.89	-3.0	0.00	6.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.2.5: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Lymph node only	EV+Pembro (N= 43)												
	BASELINE	36	2.53	2.48	0.0	2.00	7.0						
	Week 1	30	2.90	2.83	0.0	2.00	9.0	26	-0.23	1.73	-4.0	0.00	4.0
	Week 2	37	2.51	2.64	0.0	2.00	8.0	32	-0.41	2.53	-6.0	0.00	6.0
	Week 3	35	2.83	2.62	0.0	3.00	8.0	31	-0.45	2.20	-6.0	0.00	5.0
	Week 4	36	1.72	2.17	0.0	1.00	8.0	33	-1.21	2.36	-6.0	0.00	3.0
	Week 5	34	1.74	2.23	0.0	0.50	7.0	31	-1.19	2.51	-7.0	-1.00	4.0
	Week 6	34	2.06	2.20	0.0	1.50	8.0	31	-0.65	2.94	-6.0	0.00	5.0
	Week 7	34	1.71	2.33	0.0	1.00	8.0	31	-1.19	2.94	-7.0	-1.00	8.0
	Week 8	35	2.40	2.90	0.0	2.00	10.0	32	-0.66	3.16	-7.0	0.00	10.0
	Week 9	30	2.30	2.89	0.0	1.00	9.0	27	-0.33	3.78	-7.0	0.00	9.0
	Week 10	31	1.65	1.99	0.0	1.00	6.0	29	-0.79	3.02	-7.0	0.00	6.0
	Week 11	34	1.32	1.79	0.0	1.00	7.0	30	-1.57	2.39	-7.0	-0.50	2.0
	Week 12	35	1.26	1.95	0.0	0.00	7.0	31	-1.58	2.88	-7.0	-1.00	7.0
	Week 14	30	1.50	2.30	0.0	0.00	8.0	26	-1.46	2.96	-7.0	-1.00	6.0
	Week 17	30	1.70	2.47	0.0	0.00	9.0	27	-0.89	3.58	-7.0	0.00	8.0
	Week 20	27	1.52	2.29	0.0	1.00	7.0	24	-1.38	2.87	-7.0	-1.00	6.0
	Week 23	27	1.26	2.05	0.0	0.00	8.0	24	-1.79	2.72	-7.0	-0.50	3.0
	Week 26	27	2.07	2.64	0.0	0.00	8.0	24	-1.00	2.96	-7.0	0.00	4.0
	Week 29	28	1.75	2.47	0.0	0.00	8.0	25	-1.04	3.81	-7.0	0.00	8.0
	Week 32	24	1.50	2.15	0.0	0.00	7.0	22	-1.50	3.60	-7.0	-1.00	7.0
	Week 35	22	2.41	2.42	0.0	2.00	8.0	20	-0.65	3.42	-7.0	0.00	8.0
	Week 38	21	1.86	2.10	0.0	1.00	6.0	19	-1.32	2.83	-7.0	0.00	2.0
	Week 41	22	1.64	2.08	0.0	1.00	6.0	20	-1.55	2.78	-7.0	-0.50	2.0
	Week 44	22	1.91	2.58	0.0	0.50	8.0	19	-0.68	3.87	-7.0	0.00	8.0
	Week 47	21	1.57	1.80	0.0	1.00	6.0	18	-1.28	3.12	-7.0	-1.00	5.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.2.5: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	1.55	2.14	0.0	0.50	6.0	18	-1.17	3.28	-7.0	-0.50	6.0
	Week 53	20	1.95	2.68	0.0	0.00	8.0	17	-0.65	3.33	-7.0	0.00	6.0
	Week 56	21	1.67	2.13	0.0	1.00	7.0	19	-1.79	3.17	-7.0	-2.00	3.0
	Week 59	21	2.24	2.93	0.0	1.00	9.0	18	-1.39	3.35	-7.0	-1.50	5.0
	Week 62	19	2.16	2.52	0.0	1.00	7.0	17	-1.41	3.47	-7.0	0.00	6.0
	Week 65	16	2.13	2.45	0.0	1.00	8.0	15	-0.73	3.51	-7.0	0.00	4.0
	Week 68	13	2.08	2.66	0.0	1.00	7.0	12	-0.42	2.81	-7.0	0.00	4.0
	Week 71	13	1.92	2.47	0.0	1.00	7.0	12	-0.92	3.53	-7.0	0.00	6.0
	Week 74	13	1.69	2.18	0.0	0.00	6.0	12	-0.58	3.68	-7.0	0.00	6.0
	Week 77	13	1.92	2.47	0.0	1.00	7.0	11	-0.36	3.17	-7.0	0.00	5.0
	Week 80	13	2.08	2.14	0.0	2.00	6.0	12	-0.33	2.67	-5.0	-0.50	6.0
	Week 83	11	1.91	1.81	0.0	1.00	5.0	11	-0.36	2.66	-6.0	0.00	4.0
	Week 86	11	1.64	1.63	0.0	1.00	4.0	11	-0.64	2.29	-6.0	0.00	3.0
	Plat+Gem (N= 37)												
	BASELINE	30	2.77	3.11	0.0	1.50	9.0						
	Week 1	26	3.50	2.87	0.0	3.50	9.0	25	0.48	2.77	-7.0	1.00	5.0
	Week 2	31	4.13	2.57	0.0	4.00	8.0	27	0.89	2.95	-7.0	1.00	6.0
	Week 3	30	3.07	2.60	0.0	3.50	9.0	26	-0.15	3.07	-8.0	0.00	5.0
	Week 4	32	3.34	2.61	0.0	3.00	8.0	27	0.30	3.88	-9.0	0.00	8.0
	Week 5	33	3.09	2.42	0.0	3.00	9.0	28	0.39	2.94	-7.0	0.00	5.0
	Week 6	32	3.13	2.92	0.0	2.50	9.0	27	0.04	3.60	-7.0	0.00	7.0
	Week 7	32	3.34	2.78	0.0	2.50	8.0	27	0.37	2.92	-7.0	1.00	6.0
	Week 8	32	3.88	2.61	0.0	4.00	9.0	27	1.19	3.25	-7.0	1.00	7.0
	Week 9	30	3.33	2.75	0.0	3.00	9.0	25	0.40	3.93	-9.0	1.00	7.0
	Week 10	30	3.43	2.92	0.0	3.00	8.0	26	0.65	3.49	-7.0	0.50	7.0
	Week 11	29	3.31	2.85	0.0	3.00	9.0	25	0.52	3.57	-7.0	0.00	6.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.4.2.5: BPI-SF - Observed Means and Change from Baseline of Worst Pain in the last 24 hours by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 12	28	3.07	2.77	0.0	2.00	10.0	23	0.43	3.47	-7.0	0.00	6.0
	Week 14	28	3.29	3.00	0.0	2.50	9.0	23	0.39	4.08	-9.0	0.00	8.0
	Week 17	25	3.64	3.20	0.0	2.00	9.0	21	0.57	3.85	-7.0	0.00	8.0
	Week 20	23	2.74	2.83	0.0	2.00	9.0	20	0.30	3.54	-7.0	0.50	9.0
	Week 23	20	2.40	2.39	0.0	2.00	7.0	17	-0.41	3.39	-7.0	0.00	7.0
	Week 26	21	3.14	3.14	0.0	2.00	9.0	18	0.11	4.50	-9.0	0.00	9.0
	Week 29	19	3.37	3.04	0.0	3.00	9.0	16	0.69	4.17	-7.0	0.50	8.0
	Week 32	18	3.22	3.15	0.0	3.00	8.0	15	0.27	4.30	-7.0	0.00	8.0
	Week 35	19	2.89	2.88	0.0	2.00	9.0	16	0.38	4.00	-7.0	0.50	9.0
	Week 38	15	2.53	2.85	0.0	2.00	9.0	12	0.08	4.23	-7.0	0.00	9.0
	Week 41	15	3.67	3.52	0.0	2.00	9.0	12	0.92	3.75	-7.0	1.00	9.0
	Week 44	14	3.21	3.19	0.0	2.00	9.0	11	0.64	4.32	-7.0	1.00	9.0
	Week 47	12	3.17	2.82	0.0	2.50	8.0	10	1.00	4.37	-7.0	0.50	8.0
	Week 50	11	4.00	3.26	0.0	4.00	9.0	8	1.75	5.15	-7.0	1.00	9.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.1: BPI-SF - Observed Means and Change from Baseline of Pain Severity - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
EV+Pembro (N=240)												
BASELINE	209	2.20	2.08	0.0	2.00	9.3						
Week 1	190	2.54	2.32	0.0	2.00	10.0	159	-0.06	1.61	-7.9	0.00	6.1
Week 2	204	2.51	2.19	0.0	2.25	10.0	166	0.13	1.66	-7.0	0.00	6.4
Week 3	199	2.51	2.11	0.0	2.25	8.8	150	-0.10	1.90	-8.0	0.00	6.3
Week 4	195	1.89	2.10	0.0	1.00	10.0	158	-0.34	2.04	-8.6	0.00	5.1
Week 5	193	1.81	1.85	0.0	1.25	7.8	158	-0.39	2.09	-8.6	0.00	6.3
Week 6	189	1.96	2.08	0.0	1.00	8.0	150	-0.37	2.23	-8.0	0.00	6.6
Week 7	196	1.78	2.02	0.0	1.00	10.0	154	-0.53	2.54	-8.6	0.00	7.3
Week 8	192	1.75	1.94	0.0	1.00	8.0	147	-0.76	2.50	-8.4	0.00	8.1
Week 9	198	1.99	2.13	0.0	1.00	9.3	149	-0.49	2.16	-8.1	0.00	5.3
Week 10	191	1.74	1.92	0.0	1.00	7.5	149	-0.45	2.22	-8.6	0.00	6.4
Week 11	196	1.65	1.87	0.0	1.00	7.8	154	-0.61	2.28	-8.6	0.00	5.4
Week 12	186	1.73	1.99	0.0	1.00	8.3	147	-0.65	2.38	-8.6	0.00	5.9
Week 14	185	1.85	2.10	0.0	1.00	9.0	146	-0.52	2.34	-8.6	0.00	5.4
Week 17	178	1.74	1.97	0.0	1.13	8.3	136	-0.64	2.61	-8.6	0.00	5.9
Week 20	167	1.84	2.09	0.0	1.00	8.8	130	-0.35	2.33	-8.1	0.00	6.4
Week 23	162	1.83	2.04	0.0	1.00	7.5	127	-0.33	2.37	-8.1	0.00	6.1
Week 26	156	1.88	2.11	0.0	1.00	8.3	115	-0.81	2.59	-8.6	0.00	7.0
Week 29	157	1.76	1.94	0.0	1.00	8.5	123	-0.32	2.33	-8.6	0.00	5.7
Week 32	135	2.18	2.31	0.0	1.25	8.0	103	-0.06	2.61	-8.0	0.00	8.3
Week 35	132	2.04	2.07	0.0	1.25	7.3	100	-0.29	2.16	-8.0	0.00	6.3
Week 38	132	1.89	2.12	0.0	1.00	7.3	102	-0.76	2.60	-8.6	0.00	5.1
Week 41	129	1.93	2.10	0.0	1.00	8.3	100	-0.15	2.34	-8.1	0.00	6.4
Week 44	108	1.94	2.03	0.0	1.13	7.5	87	-0.06	2.73	-8.0	0.00	6.7
Week 47	100	1.76	1.92	0.0	1.13	7.0	81	-0.43	2.66	-8.6	0.00	6.1

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.1: BPI-SF - Observed Means and Change from Baseline of Pain Severity - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	89	1.83	1.86	0.0	1.75	7.0	72	-0.10	2.17	-7.7	0.00	6.3
Week 53	79	1.74	2.06	0.0	1.00	7.0	61	-0.74	2.58	-8.3	0.00	5.7
Week 56	81	1.76	2.32	0.0	0.75	9.5	66	-0.55	2.80	-8.3	0.00	8.0
Week 59	72	1.76	2.23	0.0	0.75	8.0	57	-0.62	2.33	-8.3	0.00	4.4
Week 62	65	1.83	2.26	0.0	1.00	8.0	54	-0.46	2.37	-8.3	0.00	7.4
Week 65	58	1.76	1.98	0.0	1.00	7.0	47	-0.72	2.66	-8.1	0.00	4.1
Week 68	53	1.51	1.85	0.0	1.00	7.0	45	-0.76	2.69	-8.1	0.00	5.1
Week 71	51	1.53	1.78	0.0	1.00	7.0	41	-0.64	2.52	-8.1	0.00	4.7
Week 74	47	1.53	1.68	0.0	0.75	5.3	39	-0.07	1.89	-7.6	0.00	4.9
Week 77	44	1.91	1.93	0.0	1.88	7.0	33	-0.40	2.17	-6.7	0.00	3.6
Week 80	40	1.73	1.94	0.0	1.00	7.0	31	-1.11	1.99	-7.1	-0.43	1.3
Week 83	37	1.66	1.80	0.0	1.00	7.0	28	-1.15	2.36	-7.4	-0.43	2.6
Week 86	34	1.80	2.07	0.0	1.00	8.0	27	-1.03	2.05	-7.1	-0.43	1.7
Week 89	33	2.02	2.27	0.0	1.75	8.0	23	-1.33	2.24	-7.3	-0.43	3.0
Week 92	27	1.96	1.89	0.0	1.50	5.8	22	-0.07	1.82	-3.1	0.00	6.0
Week 95	22	2.16	2.15	0.0	2.00	6.3	15	-0.57	1.64	-4.6	0.00	1.9
Week 98	18	1.68	2.37	0.0	0.50	7.8	13	-1.24	1.49	-3.9	-0.57	0.1
Week 101	14	1.63	2.24	0.0	0.38	5.8	12	-0.33	0.94	-3.0	0.00	0.7
Week 104	10	1.98	2.63	0.0	0.50	7.5	7	-0.02	2.38	-3.3	-0.43	4.7

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.1: BPI-SF - Observed Means and Change from Baseline of Pain Severity - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Plat+Gem (N=242)												
BASELINE	190	2.66	2.34	0.0	2.13	9.8						
Week 1	179	2.60	2.14	0.0	2.25	9.5	139	-0.01	1.64	-7.7	0.00	5.4
Week 2	173	2.55	2.23	0.0	2.25	9.3	135	0.11	1.80	-7.7	0.00	6.6
Week 3	185	2.46	2.32	0.0	2.00	9.0	139	-0.31	1.86	-7.7	0.00	8.6
Week 4	183	2.24	2.14	0.0	1.75	9.3	146	-0.32	1.66	-7.7	0.00	5.1
Week 5	187	2.49	2.20	0.0	2.00	9.0	130	-0.36	1.98	-7.7	0.00	6.1
Week 6	174	2.32	2.22	0.0	2.00	9.0	132	-0.59	2.08	-7.9	0.00	6.3
Week 7	187	2.02	1.97	0.0	1.75	7.8	141	-0.51	1.95	-7.9	0.00	5.4
Week 8	167	2.32	2.17	0.0	2.00	10.0	129	-0.54	2.19	-8.0	0.00	9.3
Week 9	177	2.20	2.14	0.0	1.75	8.8	128	-0.55	2.03	-8.3	0.00	9.3
Week 10	166	2.18	2.18	0.0	1.50	8.0	124	-0.56	1.89	-7.9	0.00	5.6
Week 11	168	1.97	2.15	0.0	1.25	10.0	133	-0.63	1.98	-8.1	0.00	4.6
Week 12	159	2.03	2.13	0.0	1.50	8.0	127	-0.36	1.82	-7.9	0.00	4.6
Week 14	153	2.16	1.99	0.0	1.75	7.3	111	-0.46	2.02	-8.3	0.00	5.0
Week 17	156	2.18	2.20	0.0	1.63	8.3	113	-0.50	1.87	-7.9	0.00	5.0
Week 20	126	1.85	2.07	0.0	1.00	9.3	101	-0.66	1.77	-7.7	0.00	6.6
Week 23	115	2.33	2.39	0.0	1.50	7.3	81	-0.56	1.33	-4.7	0.00	2.9
Week 26	108	2.10	2.31	0.0	1.00	9.0	82	-0.50	1.54	-6.3	0.00	4.3
Week 29	100	2.00	1.82	0.0	1.63	6.5	71	-0.15	1.47	-3.7	0.00	5.7
Week 32	83	2.05	2.27	0.0	1.25	8.0	65	-0.23	1.58	-5.0	0.00	5.0
Week 35	76	2.19	2.14	0.0	1.63	8.0	58	-0.15	1.44	-4.9	0.00	2.7
Week 38	74	2.00	2.37	0.0	1.00	7.8	55	-0.42	1.43	-4.7	0.00	1.6
Week 41	65	2.01	2.21	0.0	1.00	7.3	48	-0.13	1.89	-5.0	0.00	6.6
Week 44	60	2.54	2.48	0.0	1.63	8.5	47	-0.12	1.72	-4.9	0.00	5.0
Week 47	56	2.13	2.19	0.0	1.50	7.8	43	-0.12	2.05	-4.7	0.00	4.3

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.1: BPI-SF - Observed Means and Change from Baseline of Pain Severity - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	51	2.63	2.52	0.0	2.00	9.0	40	-0.09	1.96	-5.4	0.00	4.7
Week 53	46	1.92	2.02	0.0	1.50	6.8	38	0.13	1.62	-4.1	0.00	6.0
Week 56	39	2.53	2.46	0.0	2.50	8.0	27	0.06	2.03	-3.7	0.00	6.3
Week 59	37	1.89	1.97	0.0	1.75	7.0	29	-0.10	1.74	-4.3	0.00	3.0
Week 62	32	1.62	1.83	0.0	1.38	6.5	26	-0.21	1.76	-4.0	0.00	3.1
Week 65	30	1.64	2.15	0.0	0.38	7.3	22	-0.37	1.93	-7.0	0.00	2.3
Week 68	25	2.36	2.61	0.0	1.00	7.5	19	0.23	1.11	-2.3	0.00	3.0
Week 71	22	2.49	2.72	0.0	2.00	8.5	16	0.29	0.54	-0.7	0.00	1.4
Week 74	21	2.50	2.83	0.0	1.00	8.8	18	0.21	1.51	-3.0	0.00	3.0
Week 77	18	3.22	3.40	0.0	1.50	10.0	13	-0.37	1.91	-5.7	0.00	2.6
Week 80	14	1.95	1.99	0.0	1.50	6.8	11	0.14	1.61	-3.4	0.00	3.0
Week 83	13	2.85	2.74	0.0	1.00	6.8	11	-0.21	0.91	-2.3	0.00	1.0
Week 86	12	1.15	2.00	0.0	0.38	6.3	11	-0.45	1.94	-5.6	0.00	1.0
Week 89	11	1.57	2.10	0.0	1.00	6.3	10	-0.69	2.32	-6.6	0.00	2.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.1.1: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Present	EV+Pembro (N= 48)												
	BASELINE	39	2.72	2.37	0.0	2.50	9.3						
	Week 1	32	2.94	2.50	0.0	2.25	10.0	24	0.32	1.96	-3.6	0.00	6.1
	Week 2	38	3.30	2.58	0.0	2.88	10.0	26	-0.05	2.36	-7.0	0.00	3.6
	Week 3	35	3.10	2.11	0.0	3.00	7.0	24	-0.51	3.19	-8.0	0.00	6.3
	Week 4	36	2.69	2.52	0.0	2.25	10.0	26	-0.38	3.23	-8.6	0.00	5.1
	Week 5	31	2.59	2.11	0.0	2.00	7.8	21	-0.71	2.94	-8.6	0.00	4.1
	Week 6	31	2.98	2.53	0.0	2.25	8.0	19	-0.50	2.78	-7.0	0.00	6.3
	Week 7	35	2.45	2.47	0.0	1.50	10.0	26	-1.34	3.36	-8.6	0.00	4.7
	Week 8	36	2.45	2.14	0.0	2.38	7.3	24	-1.32	3.40	-8.4	-0.07	6.4
	Week 9	35	2.68	2.51	0.0	2.25	9.3	23	-0.81	2.90	-8.0	0.00	5.3
	Week 10	34	2.35	2.25	0.0	2.13	7.5	24	-0.48	3.18	-8.6	0.00	6.4
	Week 11	35	2.51	2.25	0.0	2.50	7.8	25	-0.58	3.22	-8.6	0.00	5.4
	Week 12	33	2.20	2.40	0.0	1.50	8.3	26	-0.99	3.11	-8.6	0.00	5.4
	Week 14	31	2.22	2.43	0.0	1.50	9.0	23	-1.17	3.17	-8.6	0.00	5.0
	Week 17	31	2.35	2.23	0.0	1.50	6.5	21	-1.20	3.48	-8.6	0.00	5.7
	Week 20	27	2.40	2.04	0.0	2.50	7.0	20	-0.41	2.28	-5.9	0.00	5.0
	Week 23	26	2.38	1.91	0.0	2.25	5.8	20	0.01	2.80	-7.4	0.00	6.0
	Week 26	25	1.93	1.89	0.0	1.75	5.8	20	-1.41	3.44	-8.6	0.00	5.1
	Week 29	23	2.05	2.17	0.0	1.00	7.3	18	-0.71	3.52	-8.6	0.00	4.7
	Week 32	21	3.04	2.45	0.0	3.75	7.0	17	-0.18	3.33	-8.0	0.00	4.9
	Week 35	19	2.51	2.31	0.0	2.00	6.8	13	-0.40	3.59	-8.0	0.00	4.0
	Week 38	18	3.08	2.76	0.0	3.25	7.3	13	-0.89	4.05	-8.6	0.00	4.9
	Week 41	20	2.59	2.60	0.0	1.75	8.0	15	-0.27	2.76	-7.6	0.00	5.6
	Week 44	17	2.43	1.87	0.0	3.00	5.8	14	-0.06	3.89	-8.0	0.00	6.7
	Week 47	18	2.00	1.81	0.0	2.00	5.3	14	-0.09	3.88	-8.6	0.00	6.1

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.1.1: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	12	1.85	1.88	0.0	1.88	5.8	10	0.47	1.12	-0.4	0.00	3.0
	Week 53	12	2.00	2.41	0.0	1.13	7.0	10	-0.39	2.75	-7.6	0.00	3.0
	Week 56	13	2.25	3.15	0.0	0.00	9.5	11	-0.47	2.61	-7.6	0.00	2.9
	Week 59	12	1.60	2.37	0.0	0.00	6.0	11	-0.94	2.48	-7.6	0.00	1.0
	Week 62	10	1.60	2.49	0.0	0.75	8.0	9	-0.65	2.30	-6.4	-0.14	1.6
	Week 65	10	2.28	2.32	0.0	1.63	6.5	7	-1.14	2.84	-7.6	0.00	0.1
	Plat+Gem (N= 48)												
	BASELINE	34	3.18	2.50	0.0	3.75	8.0						
	Week 1	32	2.82	2.24	0.0	2.63	7.0	25	-0.30	1.90	-7.7	0.00	3.1
	Week 2	29	2.73	1.90	0.0	2.75	6.0	21	0.01	2.39	-7.7	0.00	5.3
	Week 3	32	2.16	2.00	0.0	2.00	6.3	23	-0.94	2.33	-7.7	0.00	4.3
	Week 4	32	2.46	2.23	0.0	2.88	7.0	21	-0.82	2.08	-7.7	-0.43	2.9
	Week 5	36	2.10	2.18	0.0	1.63	6.8	23	-1.06	2.28	-7.7	0.00	3.0
	Week 6	35	2.24	2.30	0.0	1.75	8.3	23	-1.33	2.82	-7.9	0.00	3.7
	Week 7	38	1.76	1.95	0.0	1.00	7.3	28	-1.35	2.66	-7.9	-0.43	3.7
	Week 8	31	1.82	1.74	0.0	2.00	5.5	23	-1.04	2.34	-7.9	0.00	2.1
	Week 9	32	2.08	2.12	0.0	1.50	6.5	22	-0.79	2.28	-7.9	0.00	3.0
	Week 10	34	1.91	1.92	0.0	1.63	5.3	22	-1.79	2.67	-7.9	-0.79	1.3
	Week 11	30	1.34	1.67	0.0	0.50	5.8	23	-1.96	2.63	-7.9	-1.00	0.6
	Week 12	28	1.68	2.20	0.0	0.63	8.0	22	-1.75	2.77	-7.9	-0.29	1.0
	Week 14	26	2.32	2.14	0.0	2.00	6.5	17	-0.93	2.10	-6.3	0.00	1.7
	Week 17	30	1.83	2.32	0.0	0.50	7.0	23	-1.31	2.45	-7.9	0.00	2.0
	Week 20	23	1.32	1.75	0.0	0.00	6.5	19	-1.79	2.18	-7.7	-1.43	1.1
	Week 23	22	2.07	2.14	0.0	1.88	6.3	14	-1.42	1.63	-4.7	-0.93	0.0
	Week 26	19	1.25	1.85	0.0	0.25	6.5	16	-1.20	1.81	-6.3	-0.64	0.9
	Week 29	16	2.14	1.75	0.0	2.00	5.8	11	-0.73	1.17	-2.7	0.00	1.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.1.1: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 32	11	2.64	2.52	0.0	2.50	6.5	9	0.14	2.13	-2.3	0.00	5.0
	Week 35	10	2.98	1.94	0.0	3.00	5.8	8	0.09	1.55	-2.3	0.21	2.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.1.1: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Absent	EV+Pembro (N=192)												
	BASELINE	170	2.08	2.00	0.0	1.75	7.0						
	Week 1	158	2.46	2.28	0.0	2.00	8.0	135	-0.12	1.54	-7.9	0.00	5.7
	Week 2	166	2.33	2.05	0.0	2.00	7.5	140	0.17	1.51	-5.7	0.00	6.4
	Week 3	164	2.39	2.10	0.0	2.00	8.8	126	-0.02	1.54	-7.7	0.00	4.1
	Week 4	159	1.71	1.95	0.0	1.00	7.8	132	-0.33	1.73	-7.7	0.00	4.1
	Week 5	162	1.67	1.76	0.0	1.00	7.0	137	-0.34	1.94	-8.0	0.00	6.3
	Week 6	158	1.76	1.93	0.0	1.00	6.8	131	-0.35	2.15	-8.0	0.00	6.6
	Week 7	161	1.64	1.89	0.0	1.00	8.0	128	-0.37	2.32	-8.1	0.00	7.3
	Week 8	156	1.59	1.86	0.0	1.00	8.0	123	-0.65	2.28	-8.1	0.00	8.1
	Week 9	163	1.84	2.01	0.0	1.00	8.3	126	-0.43	2.01	-8.1	0.00	5.0
	Week 10	157	1.61	1.82	0.0	1.00	7.3	125	-0.44	2.00	-8.0	0.00	5.4
	Week 11	161	1.46	1.72	0.0	1.00	7.5	129	-0.62	2.07	-8.1	0.00	3.0
	Week 12	153	1.63	1.88	0.0	1.00	8.0	121	-0.58	2.19	-8.1	0.00	5.9
	Week 14	154	1.78	2.03	0.0	1.00	8.0	123	-0.39	2.15	-8.1	0.00	5.4
	Week 17	147	1.61	1.89	0.0	1.00	8.3	115	-0.54	2.43	-8.1	0.00	5.9
	Week 20	140	1.73	2.09	0.0	1.00	8.8	110	-0.35	2.35	-8.1	0.00	6.4
	Week 23	136	1.72	2.06	0.0	1.00	7.5	107	-0.40	2.29	-8.1	0.00	6.1
	Week 26	131	1.87	2.15	0.0	1.00	8.3	95	-0.69	2.38	-8.1	0.00	7.0
	Week 29	134	1.71	1.90	0.0	1.00	8.5	105	-0.26	2.07	-8.1	0.00	5.7
	Week 32	114	2.02	2.26	0.0	1.00	8.0	86	-0.04	2.46	-8.0	0.00	8.3
	Week 35	113	1.96	2.03	0.0	1.25	7.3	87	-0.28	1.89	-7.7	0.00	6.3
	Week 38	114	1.71	1.94	0.0	1.00	7.3	89	-0.75	2.35	-8.1	0.00	5.1
	Week 41	109	1.81	1.99	0.0	1.00	8.3	85	-0.13	2.28	-8.1	0.00	6.4
	Week 44	91	1.85	2.05	0.0	1.00	7.5	73	-0.06	2.48	-7.9	0.00	6.0
	Week 47	82	1.71	1.95	0.0	1.00	7.0	67	-0.49	2.36	-8.1	0.00	5.1

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.1.1: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	77	1.82	1.87	0.0	1.50	7.0	62	-0.19	2.29	-7.7	0.00	6.3
	Week 53	67	1.70	2.01	0.0	1.00	7.0	51	-0.81	2.57	-8.3	0.00	5.7
	Week 56	68	1.67	2.14	0.0	0.88	7.3	55	-0.57	2.85	-8.3	0.00	8.0
	Week 59	60	1.79	2.22	0.0	0.75	8.0	46	-0.54	2.32	-8.3	0.00	4.4
	Week 62	55	1.87	2.24	0.0	1.00	7.8	45	-0.43	2.40	-8.3	0.00	7.4
	Week 65	48	1.66	1.92	0.0	1.00	7.0	40	-0.64	2.66	-8.1	0.00	4.1
	Week 68	46	1.43	1.81	0.0	0.88	7.0	39	-0.68	2.66	-8.1	0.00	5.1
	Week 71	44	1.48	1.69	0.0	1.13	7.0	34	-0.57	2.47	-8.1	0.00	4.7
	Week 74	40	1.51	1.60	0.0	0.88	4.5	32	0.14	1.57	-3.0	0.00	4.9
	Week 77	38	1.84	1.88	0.0	1.88	7.0	27	-0.26	2.00	-5.7	0.00	3.6
	Week 80	35	1.61	1.91	0.0	1.00	7.0	27	-0.97	1.75	-5.7	-0.43	1.3
	Week 83	32	1.53	1.78	0.0	1.00	7.0	24	-1.02	2.24	-7.4	-0.43	2.6
	Week 86	29	1.76	2.10	0.0	1.00	8.0	22	-0.93	1.77	-6.1	-0.43	1.7
	Week 89	29	1.98	2.30	0.0	1.75	8.0	19	-1.23	1.96	-5.7	-0.57	3.0
	Week 92	24	1.96	1.89	0.0	1.50	5.8	19	-0.08	1.96	-3.1	0.00	6.0
	Week 95	20	1.85	2.00	0.0	1.38	6.3	14	-0.61	1.69	-4.6	0.00	1.9
	Week 98	18	1.68	2.37	0.0	0.50	7.8	13	-1.24	1.49	-3.9	-0.57	0.1
	Week 101	13	1.31	1.97	0.0	0.00	5.8	11	-0.36	0.98	-3.0	0.00	0.7
	Plat+Gem (N=194)												
	BASELINE	156	2.54	2.30	0.0	2.00	9.8						
	Week 1	147	2.56	2.12	0.0	2.25	9.5	114	0.05	1.58	-7.6	0.00	5.4
	Week 2	144	2.51	2.30	0.0	2.00	9.3	114	0.13	1.68	-7.0	0.00	6.6
	Week 3	153	2.52	2.38	0.0	2.00	9.0	116	-0.18	1.74	-4.6	0.00	8.6
	Week 4	151	2.20	2.13	0.0	1.75	9.3	125	-0.24	1.57	-5.9	0.00	5.1
	Week 5	151	2.59	2.20	0.0	2.25	9.0	107	-0.21	1.89	-5.6	0.00	6.1
	Week 6	139	2.35	2.21	0.0	2.00	9.0	109	-0.43	1.87	-7.0	0.00	6.3

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.1.1: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 7	149	2.09	1.98	0.0	2.00	7.8	113	-0.30	1.69	-6.1	0.00	5.4
	Week 8	136	2.44	2.25	0.0	2.00	10.0	106	-0.44	2.15	-8.0	0.00	9.3
	Week 9	145	2.23	2.15	0.0	1.75	8.8	106	-0.51	1.98	-8.3	0.00	9.3
	Week 10	132	2.25	2.24	0.0	1.50	8.0	102	-0.30	1.58	-4.6	0.00	5.6
	Week 11	138	2.11	2.22	0.0	1.50	10.0	110	-0.35	1.71	-8.1	0.00	4.6
	Week 12	131	2.11	2.12	0.0	1.50	8.0	105	-0.07	1.40	-4.6	0.00	4.6
	Week 14	127	2.13	1.97	0.0	1.75	7.3	94	-0.38	2.00	-8.3	0.00	5.0
	Week 17	126	2.26	2.18	0.0	1.75	8.3	90	-0.30	1.64	-5.6	0.00	5.0
	Week 20	103	1.97	2.13	0.0	1.25	9.3	82	-0.40	1.57	-6.1	0.00	6.6
	Week 23	93	2.39	2.45	0.0	1.00	7.3	67	-0.38	1.19	-4.6	0.00	2.9
	Week 26	89	2.28	2.37	0.0	1.50	9.0	66	-0.33	1.43	-4.9	0.00	4.3
	Week 29	84	1.98	1.85	0.0	1.50	6.5	60	-0.05	1.50	-3.7	0.00	5.7
	Week 32	72	1.96	2.24	0.0	1.00	8.0	56	-0.29	1.49	-5.0	0.00	2.4
	Week 35	66	2.07	2.16	0.0	1.25	8.0	50	-0.19	1.43	-4.9	0.00	2.7
	Week 38	66	1.98	2.41	0.0	1.00	7.8	49	-0.51	1.48	-4.7	0.00	1.6
	Week 41	62	1.99	2.23	0.0	1.00	7.3	46	-0.09	1.91	-5.0	0.00	6.6
	Week 44	55	2.45	2.46	0.0	1.50	8.5	43	-0.12	1.74	-4.9	0.00	5.0
	Week 47	51	2.10	2.25	0.0	1.25	7.8	39	-0.27	1.92	-4.7	0.00	4.0
	Week 50	48	2.74	2.54	0.0	2.25	9.0	37	0.15	1.77	-4.3	0.00	4.7
	Week 53	41	1.98	2.10	0.0	2.00	6.8	33	0.09	1.61	-4.1	0.00	6.0
	Week 56	34	2.37	2.42	0.0	2.13	8.0	23	0.16	2.12	-3.7	0.00	6.3
	Week 59	32	1.93	2.04	0.0	1.63	7.0	25	-0.14	1.73	-4.3	0.00	3.0
	Week 62	27	1.50	1.72	0.0	1.00	6.5	23	-0.14	1.82	-4.0	0.00	3.1
	Week 65	25	1.64	2.13	0.0	0.75	7.3	18	-0.33	2.09	-7.0	0.00	2.3
	Week 68	23	2.57	2.62	0.0	1.75	7.5	17	0.39	0.98	-0.9	0.00	3.0
	Week 71	21	2.55	2.77	0.0	2.00	8.5	16	0.29	0.54	-0.7	0.00	1.4

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.1.1: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 74	20	2.63	2.84	0.0	1.50	8.8	17	0.35	1.42	-3.0	0.00	3.0
	Week 77	16	3.58	3.44	0.0	3.13	10.0	11	0.29	0.82	-0.7	0.00	2.6
	Week 80	12	1.90	2.15	0.0	1.38	6.8	10	0.50	1.14	-0.7	0.00	3.0
	Week 83	11	2.82	2.69	0.0	1.00	6.8	9	0.11	0.56	-0.7	0.00	1.0
	Week 86	10	1.38	2.13	0.0	0.50	6.3	9	0.32	0.59	-0.7	0.29	1.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.1.2: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
< 65 years	EV+Pembro (N=105)												
	BASELINE	94	2.39	2.18	0.0	2.25	9.3						
	Week 1	88	2.55	2.26	0.0	2.00	7.0	71	0.03	1.60	-6.9	0.00	6.1
	Week 2	92	2.38	2.04	0.0	2.13	7.5	77	-0.16	1.91	-7.0	0.00	6.4
	Week 3	93	2.30	1.90	0.0	2.25	6.3	70	-0.16	2.16	-7.7	0.00	4.1
	Week 4	90	1.76	1.97	0.0	1.00	7.8	70	-0.85	2.19	-8.6	0.00	5.0
	Week 5	90	1.74	1.80	0.0	1.13	6.3	72	-0.71	2.62	-8.6	0.00	4.1
	Week 6	90	1.90	2.04	0.0	1.00	6.8	72	-0.65	2.53	-8.0	0.00	6.3
	Week 7	85	1.59	1.87	0.0	0.75	7.5	68	-1.09	2.98	-8.6	0.00	7.3
	Week 8	90	1.59	1.74	0.0	1.00	6.0	69	-1.09	3.09	-8.4	0.00	8.1
	Week 9	93	1.85	1.89	0.0	1.00	8.0	68	-0.81	2.68	-8.0	0.00	5.3
	Week 10	88	1.68	1.76	0.0	1.00	6.3	68	-0.95	2.82	-8.6	0.00	6.4
	Week 11	93	1.56	1.62	0.0	1.00	5.5	73	-1.10	2.80	-8.6	0.00	5.4
	Week 12	86	1.74	1.93	0.0	1.00	8.0	67	-1.05	2.86	-8.6	0.00	5.4
	Week 14	84	1.89	2.05	0.0	1.00	8.0	67	-0.86	2.75	-8.6	0.00	5.0
	Week 17	83	1.80	1.97	0.0	1.25	8.0	62	-1.21	2.92	-8.6	0.00	5.9
	Week 20	79	1.75	1.91	0.0	1.00	7.3	63	-0.60	2.52	-8.0	0.00	5.7
	Week 23	78	1.86	2.10	0.0	1.00	7.5	60	-0.64	2.67	-8.0	0.00	6.0
	Week 26	78	1.66	1.91	0.0	1.00	8.3	58	-1.47	2.92	-8.6	0.00	5.1
	Week 29	74	1.68	1.66	0.0	1.00	5.3	58	-0.70	2.66	-8.6	0.00	4.7
	Week 32	64	1.95	2.14	0.0	1.00	7.5	50	-0.21	3.35	-8.0	0.00	8.3
	Week 35	62	1.76	1.92	0.0	1.00	6.8	50	-0.46	2.52	-8.0	0.00	4.0
	Week 38	62	1.78	2.01	0.0	1.00	7.0	51	-1.08	2.89	-8.6	0.00	4.9
	Week 41	64	1.75	2.02	0.0	1.00	8.0	53	-0.42	2.34	-7.9	0.00	5.6
	Week 44	50	1.65	1.89	0.0	1.00	6.0	45	-0.57	3.07	-8.0	0.00	4.7
	Week 47	47	1.64	1.80	0.0	1.00	6.3	41	-0.66	3.17	-8.6	0.00	6.1

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.1.2: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	44	1.74	1.59	0.0	1.75	5.8	34	-0.37	2.39	-7.7	0.00	3.7
	Week 53	40	1.83	2.28	0.0	1.13	7.0	30	-1.18	2.61	-8.3	0.00	1.6
	Week 56	44	1.53	2.10	0.0	0.50	9.5	37	-0.85	2.45	-8.3	0.00	1.7
	Week 59	42	1.58	2.00	0.0	0.88	7.0	33	-0.94	2.84	-8.3	0.00	4.4
	Week 62	37	1.82	2.19	0.0	1.00	8.0	31	-0.95	2.52	-8.3	0.00	2.1
	Week 65	34	1.82	2.03	0.0	1.25	7.0	27	-0.71	2.91	-7.7	0.00	4.1
	Week 68	34	1.63	1.87	0.0	1.00	7.0	29	-1.09	2.76	-7.7	0.00	1.9
	Week 71	32	1.72	1.88	0.0	1.25	7.0	25	-0.66	2.77	-7.7	0.00	4.7
	Week 74	29	1.85	1.70	0.0	1.25	5.3	24	0.02	2.23	-7.6	0.00	4.9
	Week 77	25	2.15	2.03	0.0	2.00	7.0	19	-0.73	2.58	-6.7	0.00	3.6
	Week 80	24	2.18	2.06	0.0	2.00	7.0	18	-1.44	2.46	-7.1	-0.29	1.3
	Week 83	23	2.10	1.94	0.0	2.00	7.0	18	-1.40	2.84	-7.4	-0.57	2.6
	Week 86	20	2.55	2.21	0.0	2.25	8.0	14	-1.62	2.44	-7.1	-0.79	1.0
	Week 89	19	2.43	2.32	0.0	2.00	8.0	12	-1.64	2.92	-7.3	-0.29	3.0
	Week 92	14	2.59	1.57	0.0	2.75	5.3	9	-0.21	1.40	-3.1	0.00	1.3
	Week 95	12	2.94	2.15	0.0	2.88	6.3	8	-0.63	1.80	-4.6	0.00	1.4
	Plat+Gem (N=106)												
	BASELINE	84	3.02	2.31	0.0	3.25	9.8						
	Week 1	78	2.86	2.08	0.0	3.00	8.0	60	0.03	1.75	-7.6	0.00	4.6
	Week 2	77	2.69	2.28	0.0	2.25	9.3	61	0.00	1.96	-7.0	0.00	6.6
	Week 3	80	2.81	2.30	0.0	2.75	9.0	61	-0.34	2.20	-5.6	0.00	8.6
	Week 4	79	2.36	2.10	0.0	2.00	9.3	64	-0.52	1.57	-4.4	0.00	4.4
	Week 5	80	2.45	2.16	0.0	2.00	9.0	57	-0.75	1.99	-5.6	0.00	3.1
	Week 6	76	2.54	2.41	0.0	2.00	9.0	59	-0.78	1.90	-5.6	0.00	4.1
	Week 7	81	2.21	1.99	0.0	2.00	7.3	62	-0.67	1.96	-6.6	0.00	4.3
	Week 8	72	2.25	2.07	0.0	2.00	7.3	63	-0.44	2.31	-5.3	0.00	9.3

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.1.2: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	78	1.97	1.97	0.0	1.25	7.0	64	-0.68	2.30	-5.6	0.00	9.3
	Week 10	78	2.29	2.15	0.0	2.13	8.0	62	-0.65	1.98	-6.3	0.00	5.6
	Week 11	75	1.83	1.88	0.0	1.25	7.0	64	-0.90	1.95	-6.1	0.00	4.3
	Week 12	74	2.08	2.04	0.0	1.63	7.5	61	-0.50	1.73	-6.1	0.00	4.4
	Week 14	68	1.94	1.97	0.0	1.25	7.3	54	-0.73	2.26	-6.4	0.00	5.0
	Week 17	68	2.16	2.17	0.0	1.38	7.0	51	-0.76	2.07	-6.6	0.00	2.6
	Week 20	60	1.67	1.92	0.0	1.00	9.0	51	-1.11	1.95	-7.7	-0.29	2.1
	Week 23	51	1.92	2.13	0.0	1.00	7.0	38	-0.72	1.58	-4.7	0.00	2.9
	Week 26	47	1.99	2.14	0.0	1.00	6.8	37	-0.99	1.66	-6.3	-0.29	2.4
	Week 29	42	1.93	1.59	0.0	1.63	6.5	32	-0.53	1.47	-3.7	-0.14	3.0
	Week 32	37	1.98	2.13	0.0	1.00	6.5	30	-0.44	1.86	-4.7	0.00	5.0
	Week 35	34	1.90	2.05	0.0	1.13	7.5	27	-0.41	1.47	-4.7	0.00	2.6
	Week 38	33	1.94	2.51	0.0	1.00	7.8	23	-0.92	1.57	-4.7	0.00	1.0
	Week 41	27	1.94	2.08	0.0	1.00	7.0	20	-0.25	2.25	-4.7	0.00	6.6
	Week 44	28	2.30	2.43	0.0	1.63	8.5	23	-0.64	1.53	-4.7	0.00	1.4
	Week 47	24	2.34	2.39	0.0	1.63	7.8	18	-0.56	1.74	-4.7	0.00	1.7
	Week 50	26	2.29	2.35	0.0	2.13	6.5	20	-0.74	1.80	-5.4	0.00	1.7
	Week 53	19	1.96	2.08	0.0	2.00	6.8	15	-0.78	1.41	-4.1	0.00	0.3
	Week 56	13	2.44	2.84	0.0	0.75	7.8	9	-1.06	1.66	-3.7	0.00	0.6
	Week 59	14	1.48	2.32	0.0	0.13	7.0	12	-0.96	1.74	-4.3	0.00	1.0
	Week 62	13	1.58	2.20	0.0	0.25	6.5	12	-0.55	1.89	-4.0	0.00	2.0
	Week 65	13	1.63	2.60	0.0	0.00	7.3	10	-0.44	1.45	-3.7	0.00	1.0
	Week 68	10	2.35	2.98	0.0	0.50	7.5	7	-0.31	1.04	-2.3	0.00	1.0
	Week 77	10	3.35	4.12	0.0	0.88	10.0	7	-1.00	2.28	-5.7	0.00	0.6

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.1.2: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>= 65 years	EV+Pembro (N=135)												
	BASELINE	115	2.05	2.00	0.0	1.75	7.0						
	Week 1	102	2.53	2.38	0.0	2.00	10.0	88	-0.13	1.63	-7.9	0.00	5.7
	Week 2	112	2.61	2.31	0.0	2.25	10.0	89	0.39	1.37	-3.0	0.00	4.4
	Week 3	106	2.70	2.27	0.0	2.50	8.8	80	-0.04	1.65	-8.0	0.00	6.3
	Week 4	105	2.01	2.20	0.0	1.25	10.0	88	0.06	1.82	-8.0	0.00	5.1
	Week 5	103	1.88	1.89	0.0	1.25	7.8	86	-0.12	1.48	-4.0	0.00	6.3
	Week 6	99	2.01	2.13	0.0	1.25	8.0	78	-0.12	1.89	-7.6	0.00	6.6
	Week 7	111	1.93	2.12	0.0	1.25	10.0	86	-0.09	2.04	-8.1	0.00	6.0
	Week 8	102	1.89	2.10	0.0	1.13	8.0	78	-0.47	1.79	-8.1	0.00	4.4
	Week 9	105	2.11	2.32	0.0	1.00	9.3	81	-0.21	1.56	-8.1	0.00	5.0
	Week 10	103	1.80	2.05	0.0	1.25	7.5	81	-0.03	1.44	-3.3	0.00	5.4
	Week 11	103	1.73	2.07	0.0	1.00	7.8	81	-0.17	1.57	-8.1	0.00	5.4
	Week 12	100	1.72	2.05	0.0	1.00	8.3	80	-0.32	1.83	-8.1	0.00	5.9
	Week 14	101	1.83	2.15	0.0	1.00	9.0	79	-0.22	1.91	-8.1	0.00	5.4
	Week 17	95	1.68	1.97	0.0	1.00	8.3	74	-0.17	2.24	-8.1	0.00	5.7
	Week 20	88	1.92	2.25	0.0	1.00	8.8	67	-0.12	2.12	-8.1	0.00	6.4
	Week 23	84	1.79	2.00	0.0	1.00	7.0	67	-0.06	2.05	-8.1	0.00	6.1
	Week 26	78	2.09	2.28	0.0	1.00	8.3	57	-0.15	2.03	-8.1	0.00	7.0
	Week 29	83	1.84	2.16	0.0	1.00	8.5	65	0.01	1.95	-8.1	0.00	5.7
	Week 32	71	2.39	2.44	0.0	1.50	8.0	53	0.08	1.65	-3.0	0.00	4.9
	Week 35	70	2.29	2.17	0.0	1.88	7.3	50	-0.12	1.74	-4.0	0.00	6.3
	Week 38	70	1.99	2.21	0.0	1.00	7.3	51	-0.45	2.26	-8.1	0.00	5.1
	Week 41	65	2.11	2.18	0.0	1.50	8.3	47	0.16	2.33	-8.1	0.00	6.4
	Week 44	58	2.19	2.13	0.0	1.75	7.5	42	0.50	2.21	-3.0	0.00	6.7
	Week 47	53	1.87	2.03	0.0	1.25	7.0	40	-0.19	2.04	-8.1	0.00	5.1

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.1.2: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	45	1.92	2.10	0.0	1.25	7.0	38	0.14	1.95	-3.0	-0.07	6.3
	Week 53	39	1.66	1.84	0.0	1.00	5.3	31	-0.31	2.53	-8.1	0.00	5.7
	Week 56	37	2.04	2.55	0.0	0.75	7.3	29	-0.17	3.19	-8.1	-0.29	8.0
	Week 59	30	2.00	2.53	0.0	0.75	8.0	24	-0.18	1.30	-3.0	-0.07	3.6
	Week 62	28	1.85	2.39	0.0	0.50	7.8	23	0.20	2.00	-3.0	0.00	7.4
	Week 65	24	1.69	1.96	0.0	0.63	5.3	20	-0.73	2.36	-8.1	-0.07	2.7
	Week 68	19	1.30	1.86	0.0	0.00	6.0	16	-0.16	2.52	-8.1	0.00	5.1
	Week 71	19	1.22	1.58	0.0	1.00	5.3	16	-0.63	2.14	-8.1	0.00	1.0
	Week 74	18	1.01	1.54	0.0	0.00	4.5	15	-0.23	1.19	-3.0	0.00	2.3
	Week 77	19	1.59	1.80	0.0	1.50	6.0	14	0.05	1.44	-2.9	0.00	2.7
	Week 80	16	1.06	1.58	0.0	0.00	4.3	13	-0.64	0.96	-3.0	-0.43	0.3
	Week 83	14	0.93	1.28	0.0	0.00	3.8	10	-0.70	1.01	-3.0	-0.43	0.0
	Week 86	14	0.73	1.26	0.0	0.00	4.0	13	-0.38	1.34	-3.0	0.00	1.7
	Week 89	14	1.46	2.17	0.0	0.13	6.3	11	-0.99	1.18	-3.0	-0.43	0.0
	Week 92	13	1.29	2.02	0.0	0.00	5.8	13	0.02	2.11	-3.0	0.00	6.0
	Week 95	10	1.23	1.85	0.0	0.00	5.0	7	-0.51	1.57	-3.0	0.00	1.9
	Week 98	10	1.35	2.55	0.0	0.00	7.8	8	-1.27	1.52	-3.9	-0.71	0.1
	Plat+Gem (N=136)												
	BASELINE	106	2.36	2.34	0.0	2.00	8.8						
	Week 1	101	2.40	2.17	0.0	2.00	9.5	79	-0.05	1.56	-7.7	0.00	5.4
	Week 2	96	2.43	2.20	0.0	2.13	9.3	74	0.20	1.66	-7.7	0.00	5.3
	Week 3	105	2.19	2.31	0.0	1.50	8.3	78	-0.28	1.56	-7.7	0.00	5.0
	Week 4	104	2.15	2.17	0.0	1.75	8.0	82	-0.16	1.72	-7.7	0.00	5.1
	Week 5	107	2.53	2.24	0.0	2.25	8.0	73	-0.06	1.93	-7.7	0.00	6.1
	Week 6	98	2.16	2.07	0.0	1.88	8.0	73	-0.43	2.21	-7.9	0.00	6.3
	Week 7	106	1.87	1.96	0.0	1.38	7.8	79	-0.39	1.95	-7.9	0.00	5.4

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.1.2: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 8	95	2.37	2.25	0.0	2.00	10.0	66	-0.64	2.08	-8.0	0.00	2.9
	Week 9	99	2.39	2.26	0.0	2.00	8.8	64	-0.43	1.72	-8.3	0.00	2.0
	Week 10	88	2.09	2.21	0.0	1.25	8.0	62	-0.48	1.82	-7.9	0.00	4.3
	Week 11	93	2.08	2.35	0.0	1.50	10.0	69	-0.37	1.99	-8.1	0.00	4.6
	Week 12	85	1.99	2.22	0.0	1.25	8.0	66	-0.22	1.89	-7.9	0.00	4.6
	Week 14	85	2.33	2.01	0.0	2.00	7.3	57	-0.21	1.73	-8.3	0.00	5.0
	Week 17	88	2.19	2.24	0.0	1.63	8.3	62	-0.29	1.67	-7.9	0.00	5.0
	Week 20	66	2.02	2.20	0.0	1.13	9.3	50	-0.21	1.45	-3.0	0.00	6.6
	Week 23	64	2.65	2.54	0.0	1.88	7.3	43	-0.42	1.06	-4.6	0.00	1.0
	Week 26	61	2.18	2.45	0.0	1.00	9.0	45	-0.10	1.32	-4.9	0.00	4.3
	Week 29	58	2.05	1.99	0.0	1.38	5.8	39	0.16	1.42	-2.7	0.00	5.7
	Week 32	46	2.11	2.40	0.0	1.25	8.0	35	-0.06	1.30	-5.0	0.00	2.4
	Week 35	42	2.42	2.21	0.0	2.13	8.0	31	0.07	1.39	-4.9	0.00	2.7
	Week 38	41	2.05	2.28	0.0	1.00	7.3	32	-0.07	1.21	-4.7	0.00	1.6
	Week 41	38	2.06	2.32	0.0	1.38	7.3	28	-0.05	1.63	-5.0	0.00	3.0
	Week 44	32	2.74	2.54	0.0	1.75	7.0	24	0.38	1.77	-4.9	0.00	5.0
	Week 47	32	1.98	2.05	0.0	1.38	7.0	25	0.19	2.23	-4.7	0.00	4.3
	Week 50	25	2.98	2.69	0.0	2.00	9.0	20	0.56	1.94	-4.1	0.00	4.7
	Week 53	27	1.89	2.01	0.0	1.00	6.0	23	0.72	1.50	-1.6	0.00	6.0
	Week 56	26	2.57	2.31	0.0	2.75	8.0	18	0.62	2.01	-2.7	0.00	6.3
	Week 59	23	2.14	1.73	0.0	2.25	5.3	17	0.50	1.52	-2.4	0.00	3.0
	Week 62	19	1.64	1.59	0.0	2.00	6.0	14	0.08	1.65	-3.9	0.00	3.1
	Week 65	17	1.65	1.82	0.0	1.00	5.8	12	-0.31	2.32	-7.0	0.00	2.3
	Week 68	15	2.37	2.44	0.0	1.75	6.5	12	0.54	1.07	-0.7	0.00	3.0
	Week 71	15	2.65	2.68	0.0	2.00	8.5	11	0.18	0.52	-0.7	0.00	1.1
	Week 74	12	2.50	2.50	0.0	2.00	8.8	11	0.65	1.67	-3.0	0.00	3.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.1.3: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Europe	EV+Pembro (N= 98)												
	BASELINE	81	2.27	2.16	0.0	2.00	7.0						
	Week 1	74	2.76	2.34	0.0	2.50	7.0	62	0.15	1.54	-4.0	0.00	6.1
	Week 2	80	2.56	2.19	0.0	2.25	7.0	67	0.05	1.51	-5.7	0.00	3.9
	Week 3	79	2.66	2.18	0.0	2.50	7.3	55	-0.16	2.35	-8.0	0.00	6.3
	Week 4	78	1.99	2.14	0.0	1.13	7.8	58	-0.31	2.30	-8.0	0.00	5.1
	Week 5	72	2.08	1.90	0.0	1.63	7.0	56	-0.34	2.30	-7.7	0.00	6.3
	Week 6	71	2.02	2.11	0.0	1.25	8.0	53	-0.54	2.32	-7.7	0.00	6.3
	Week 7	79	1.90	1.84	0.0	1.25	8.0	59	-0.41	2.25	-7.7	0.00	7.3
	Week 8	72	1.72	1.92	0.0	1.00	8.0	48	-0.86	2.91	-8.0	0.00	8.1
	Week 9	80	2.05	2.16	0.0	1.00	8.3	58	-0.28	1.99	-7.7	0.00	5.3
	Week 10	71	1.76	1.94	0.0	1.00	7.0	52	-0.70	2.24	-7.7	0.00	5.6
	Week 11	78	1.56	1.76	0.0	1.00	7.0	59	-0.66	2.16	-7.7	0.00	5.4
	Week 12	73	1.63	1.80	0.0	1.00	7.8	56	-0.72	2.17	-7.7	0.00	5.4
	Week 14	74	1.93	2.00	0.0	1.38	7.0	55	-0.45	2.28	-7.7	0.00	5.4
	Week 17	70	1.97	1.98	0.0	1.38	6.8	54	-0.68	2.35	-7.7	0.00	5.7
	Week 20	70	1.80	2.02	0.0	1.00	7.3	53	-0.41	2.14	-7.7	0.00	5.0
	Week 23	61	1.76	1.95	0.0	1.00	7.5	49	-0.34	2.45	-7.7	0.00	6.1
	Week 26	62	1.78	2.02	0.0	1.00	6.0	47	-0.52	2.12	-7.7	0.00	5.1
	Week 29	63	1.80	1.99	0.0	1.00	7.3	50	-0.09	2.01	-7.7	0.00	5.7
	Week 32	51	2.47	2.44	0.0	2.00	7.3	39	0.46	2.81	-7.7	0.00	8.3
	Week 35	56	2.22	2.26	0.0	1.25	7.3	42	-0.11	2.29	-7.7	0.00	6.3
	Week 38	51	2.09	2.31	0.0	1.25	7.3	40	-0.51	2.51	-7.7	0.00	5.1
	Week 41	52	2.22	2.30	0.0	1.75	8.0	39	0.08	2.05	-4.4	0.00	6.4
	Week 44	43	2.15	2.29	0.0	1.75	7.5	34	-0.07	2.84	-7.7	0.00	6.0
	Week 47	39	2.10	2.07	0.0	1.75	7.0	30	-0.26	2.64	-7.7	0.00	6.1

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.1.3: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	37	2.03	2.08	0.0	1.50	7.0	29	-0.55	2.45	-7.7	0.00	3.4
	Week 53	28	1.72	2.12	0.0	0.75	7.0	23	-0.99	2.71	-8.3	0.00	3.6
	Week 56	30	2.14	2.64	0.0	0.63	9.5	23	-0.95	2.62	-8.3	0.00	1.7
	Week 59	27	1.81	2.22	0.0	0.50	6.3	21	-0.93	2.93	-8.3	0.00	4.4
	Week 62	23	1.96	2.57	0.0	0.50	8.0	20	-0.63	3.13	-8.3	0.00	7.4
	Week 65	23	1.99	2.20	0.0	1.50	6.5	19	-0.65	2.60	-7.7	0.00	4.1
	Week 68	21	1.26	1.76	0.0	0.50	5.8	20	-1.29	2.65	-7.7	0.00	1.1
	Week 71	19	1.70	2.08	0.0	1.00	5.8	16	-0.90	2.09	-7.7	-0.21	1.0
	Week 74	15	1.70	2.01	0.0	0.75	5.3	13	-0.27	0.98	-2.4	-0.43	2.0
	Week 77	19	1.82	2.12	0.0	1.00	6.0	16	-0.61	1.97	-5.7	-0.21	2.1
	Week 80	17	1.37	1.70	0.0	0.00	4.8	15	-1.21	2.02	-5.7	-0.43	0.7
	Week 83	16	1.41	1.77	0.0	0.00	4.0	14	-1.50	2.45	-7.4	-0.57	1.3
	Week 86	14	1.59	1.91	0.0	0.38	4.8	13	-0.92	1.96	-6.1	-0.43	1.0
	Week 89	14	2.21	2.45	0.0	1.63	7.0	10	-0.89	2.47	-5.7	0.00	3.0
	Week 92	11	1.77	1.76	0.0	1.00	4.5	10	-0.14	1.25	-3.1	0.00	1.3
	Week 95	10	2.20	2.13	0.0	2.50	5.5	7	-0.45	1.89	-4.6	0.00	1.4
	Plat+Gem (N=102)												
	BASELINE	73	2.82	2.49	0.0	2.75	8.8						
	Week 1	73	3.01	2.28	0.0	2.75	8.3	51	-0.04	1.75	-7.6	0.00	5.4
	Week 2	68	2.75	2.25	0.0	2.25	9.3	47	0.07	2.13	-7.0	0.00	5.3
	Week 3	68	2.65	2.33	0.0	2.25	8.3	45	-0.26	1.65	-4.6	0.00	5.0
	Week 4	75	2.29	2.19	0.0	2.00	9.3	54	-0.15	1.85	-5.9	0.00	4.4
	Week 5	77	2.63	2.20	0.0	2.50	9.0	47	-0.24	1.95	-5.6	0.00	4.9
	Week 6	70	2.41	2.29	0.0	2.00	9.0	49	-0.56	2.37	-7.9	0.00	6.3
	Week 7	73	1.99	1.97	0.0	1.75	7.0	50	-0.51	2.25	-7.9	0.00	5.4
	Week 8	65	2.51	2.29	0.0	2.00	10.0	45	-0.69	2.39	-7.9	0.00	4.7

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.1.3: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	70	2.26	2.22	0.0	1.75	8.8	46	-0.75	2.09	-7.9	0.00	2.9
	Week 10	60	2.50	2.40	0.0	2.00	8.0	39	-0.47	2.11	-7.9	0.00	4.3
	Week 11	64	2.27	2.48	0.0	1.75	10.0	46	-0.45	1.97	-7.9	0.00	4.6
	Week 12	60	2.21	2.32	0.0	1.75	8.0	44	-0.44	1.96	-7.9	0.00	4.4
	Week 14	56	2.46	2.08	0.0	2.38	7.3	35	-0.23	2.27	-6.4	0.00	5.0
	Week 17	59	2.25	2.34	0.0	1.00	8.3	40	-0.36	1.97	-7.9	0.00	3.9
	Week 20	47	2.03	2.04	0.0	1.50	9.0	34	-0.58	1.11	-4.1	0.00	2.1
	Week 23	44	2.19	2.25	0.0	1.63	6.3	27	-0.23	0.93	-2.3	0.00	1.4
	Week 26	39	2.15	2.49	0.0	1.00	9.0	28	-0.38	1.38	-4.1	0.00	4.3
	Week 29	34	1.88	1.77	0.0	1.00	5.8	23	-0.25	1.53	-3.4	0.00	4.0
	Week 32	33	2.23	2.27	0.0	1.75	8.0	23	-0.12	1.23	-2.3	0.00	2.4
	Week 35	30	2.63	2.35	0.0	2.50	8.0	19	-0.20	1.14	-2.3	0.00	2.6
	Week 38	26	2.73	2.64	0.0	2.50	7.8	14	-0.01	0.82	-1.3	0.00	1.6
	Week 41	22	2.20	2.05	0.0	2.38	7.3	14	0.41	2.04	-2.0	0.00	6.6
	Week 44	20	3.20	2.39	0.0	3.38	7.0	15	0.28	1.70	-2.3	0.00	5.0
	Week 47	16	2.19	1.70	0.0	3.00	4.3	12	0.73	1.78	-2.3	0.43	4.3
	Week 50	11	3.41	2.82	0.0	3.00	9.0	9	0.37	1.25	-2.3	0.86	1.7
	Week 53	11	2.30	1.67	0.0	2.50	4.8	8	0.16	1.78	-2.3	0.14	2.9
	Week 56	10	2.73	2.11	0.0	2.63	6.0	6	0.83	1.99	-2.3	0.71	3.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.1.3: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
North America	EV+Pembro (N= 57)												
	BASELINE	48	2.86	2.39	0.0	2.50	9.3						
	Week 1	39	2.38	2.26	0.0	2.00	6.8	35	-0.20	0.99	-3.3	0.00	2.0
	Week 2	44	2.67	2.21	0.0	2.50	7.5	36	-0.14	1.54	-7.0	0.00	3.3
	Week 3	44	2.78	2.35	0.0	2.50	8.8	36	-0.02	1.62	-7.0	0.00	3.3
	Week 4	45	1.93	2.23	0.0	1.00	7.8	38	-0.84	1.99	-8.6	-0.07	2.4
	Week 5	48	1.79	1.94	0.0	1.13	6.3	40	-0.55	2.11	-8.6	0.00	3.3
	Week 6	44	1.87	2.07	0.0	1.00	6.8	34	-0.43	1.78	-7.0	0.00	5.0
	Week 7	46	1.83	2.35	0.0	0.75	7.8	38	-0.87	2.60	-8.6	0.00	6.0
	Week 8	48	1.94	2.13	0.0	1.00	7.8	38	-1.00	2.14	-8.4	-0.36	1.6
	Week 9	46	2.14	2.21	0.0	1.13	8.0	36	-0.58	1.91	-8.0	-0.14	5.0
	Week 10	47	1.64	1.98	0.0	1.00	7.3	39	-0.22	2.23	-8.6	0.00	6.4
	Week 11	47	1.85	2.08	0.0	1.00	7.5	37	-0.61	2.04	-8.6	0.00	3.1
	Week 12	44	1.78	2.08	0.0	1.00	6.3	35	-0.79	2.06	-8.6	-0.43	3.9
	Week 14	43	1.80	2.25	0.0	0.75	8.0	35	-0.85	2.07	-8.6	-0.43	4.6
	Week 17	40	1.85	2.23	0.0	1.13	8.3	30	-0.58	2.44	-8.6	-0.29	5.1
	Week 20	38	1.86	2.47	0.0	0.88	8.8	30	-0.44	1.58	-4.4	0.00	3.6
	Week 23	38	1.60	2.04	0.0	0.88	7.0	31	-0.70	1.86	-5.3	-0.14	3.4
	Week 26	35	1.81	2.29	0.0	1.00	8.3	27	-1.57	2.36	-8.6	-1.00	2.4
	Week 29	38	1.57	1.94	0.0	1.00	8.5	32	-0.94	2.32	-8.6	-0.50	3.0
	Week 32	32	1.78	2.27	0.0	0.75	8.0	25	-0.93	2.14	-8.0	0.00	2.4
	Week 35	33	1.64	2.11	0.0	1.00	6.5	26	-1.01	2.02	-8.0	-0.43	1.3
	Week 38	32	1.46	1.96	0.0	0.88	6.5	26	-1.27	2.64	-8.6	-0.57	4.4
	Week 41	28	1.13	1.46	0.0	0.75	5.0	23	-0.75	1.55	-4.6	-0.43	2.1
	Week 44	21	1.38	1.74	0.0	1.00	5.3	18	-0.42	2.74	-8.0	-0.21	6.7
	Week 47	24	1.29	1.82	0.0	0.13	6.8	22	-0.45	2.56	-8.6	-0.21	4.3

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.1.3: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	23	1.63	1.75	0.0	1.00	6.5	19	0.37	2.13	-2.0	-0.43	6.3
	Week 53	17	1.60	2.00	0.0	1.00	7.0	11	-0.69	1.91	-5.1	-0.43	3.0
	Week 56	20	1.36	1.99	0.0	0.50	7.3	16	-0.53	2.85	-5.1	-0.50	8.0
	Week 59	17	1.37	2.03	0.0	0.75	6.8	12	-0.25	1.33	-3.0	-0.29	1.9
	Week 62	14	1.52	2.35	0.0	0.25	7.8	11	-0.81	1.69	-4.4	-0.43	1.7
	Week 65	12	0.85	1.03	0.0	0.50	2.8	9	-0.57	2.05	-5.1	-0.14	2.1
	Week 68	10	1.35	1.43	0.0	1.00	4.3	8	0.21	0.49	-0.4	0.07	1.0
	Week 71	10	1.15	0.96	0.0	1.13	3.5	6	-0.17	1.10	-2.0	-0.07	1.4
	Week 74	10	1.28	1.65	0.0	0.88	4.3	7	-0.63	1.36	-3.0	-0.14	0.9
	Plat+Gem (N= 51)												
	BASELINE	42	2.41	2.17	0.0	1.75	7.0						
	Week 1	42	2.57	2.34	0.0	2.00	9.5	31	0.46	1.39	-3.0	0.00	4.6
	Week 2	39	2.58	2.13	0.0	2.50	8.0	31	0.46	1.60	-2.0	0.00	6.6
	Week 3	41	2.54	2.42	0.0	2.50	9.0	31	0.16	2.41	-5.6	0.00	8.6
	Week 4	35	2.19	2.12	0.0	1.75	7.0	27	-0.51	1.21	-3.0	0.00	2.0
	Week 5	39	2.33	2.03	0.0	2.00	6.5	26	-0.88	2.16	-5.4	0.00	4.0
	Week 6	34	2.17	1.87	0.0	2.00	6.5	27	-0.49	2.15	-6.3	0.00	4.1
	Week 7	42	1.77	1.72	0.0	1.25	5.5	31	-0.52	2.12	-6.6	0.00	4.3
	Week 8	39	2.17	2.06	0.0	1.75	7.3	31	-1.02	2.32	-8.0	0.00	3.0
	Week 9	39	2.01	1.98	0.0	1.50	6.8	27	-1.02	2.15	-8.3	0.00	1.1
	Week 10	39	1.92	2.06	0.0	1.00	6.3	29	-0.82	1.81	-6.3	0.00	1.4
	Week 11	39	1.58	1.88	0.0	1.00	6.5	31	-1.30	2.19	-8.1	0.00	0.7
	Week 12	36	1.96	1.85	0.0	1.50	6.8	28	-0.36	1.72	-6.1	0.00	1.9
	Week 14	34	1.65	1.82	0.0	1.00	6.3	26	-0.88	2.66	-8.3	0.00	2.6
	Week 17	37	2.18	2.02	0.0	2.00	7.0	24	-0.96	2.10	-6.6	0.00	1.0
	Week 20	27	1.48	1.77	0.0	0.75	5.8	23	-0.87	2.44	-7.7	0.00	3.3

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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Table 302.1.3002.5.1.3: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 23	27	2.36	2.42	0.0	1.50	7.3	19	-0.70	1.49	-4.7	0.00	0.6
	Week 26	28	2.24	2.10	0.0	1.63	7.0	19	-0.28	1.89	-6.3	0.00	2.4
	Week 29	29	2.27	1.78	0.0	2.00	6.5	17	0.31	0.97	-1.0	0.00	3.0
	Week 32	17	2.24	2.23	0.0	1.50	6.5	13	0.25	1.69	-2.6	0.00	5.0
	Week 35	16	1.89	2.11	0.0	1.13	7.5	13	0.15	1.02	-2.6	0.00	1.9
	Week 38	16	2.36	2.49	0.0	1.63	7.0	13	0.01	0.62	-1.0	0.00	1.4
	Week 41	16	2.56	2.44	0.0	2.50	7.0	12	0.30	1.28	-2.6	0.00	2.9
	Week 44	13	2.62	2.61	0.0	1.50	6.5	10	0.16	1.54	-2.7	0.00	2.7
	Week 47	11	2.75	2.47	0.0	1.75	7.5	7	0.12	0.91	-1.0	0.00	2.0
	Week 50	17	2.72	2.57	0.0	2.00	7.8	13	0.00	2.64	-5.4	0.00	4.7
	Week 53	13	2.23	2.30	0.0	1.00	6.8	10	0.00	1.26	-3.1	0.00	1.7
	Week 56	11	3.64	2.82	0.0	3.75	8.0	6	-0.31	1.94	-3.4	0.00	2.6
	Week 59	11	2.30	1.96	0.0	2.25	6.0	7	-0.02	1.67	-3.1	0.00	2.6
	Week 62	11	1.66	1.92	0.0	1.75	6.5	8	0.18	1.86	-3.7	0.14	2.6
	Week 65	10	1.75	2.38	0.0	1.00	7.3	7	-0.16	1.79	-3.7	0.00	2.3

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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Table 302.1.3002.5.1.3: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Rest of World	EV+Pembro (N= 85)												
	BASELINE	80	1.73	1.68	0.0	1.50	7.0						
	Week 1	77	2.41	2.35	0.0	2.00	10.0	62	-0.18	1.94	-7.9	0.00	5.7
	Week 2	80	2.37	2.19	0.0	1.75	10.0	63	0.38	1.86	-6.4	0.00	6.4
	Week 3	76	2.21	1.87	0.0	1.75	7.0	59	-0.09	1.58	-5.4	0.00	3.6
	Week 4	72	1.76	1.99	0.0	1.38	10.0	62	-0.06	1.77	-7.0	0.00	4.1
	Week 5	73	1.57	1.71	0.0	1.00	7.8	62	-0.33	1.91	-8.0	0.00	3.4
	Week 6	74	1.95	2.09	0.0	1.13	8.0	63	-0.20	2.39	-8.0	0.00	6.6
	Week 7	71	1.62	2.00	0.0	1.00	10.0	57	-0.44	2.80	-8.1	0.00	5.3
	Week 8	72	1.65	1.84	0.0	1.00	7.3	61	-0.53	2.37	-8.1	0.00	4.4
	Week 9	72	1.82	2.06	0.0	1.13	9.3	55	-0.64	2.48	-8.1	0.00	4.0
	Week 10	73	1.79	1.88	0.0	1.25	7.5	58	-0.38	2.21	-8.0	0.00	5.4
	Week 11	71	1.61	1.86	0.0	1.00	7.8	58	-0.56	2.56	-8.1	0.00	5.4
	Week 12	69	1.80	2.14	0.0	1.00	8.3	56	-0.50	2.76	-8.1	0.00	5.9
	Week 14	68	1.81	2.15	0.0	1.00	9.0	56	-0.37	2.58	-8.1	0.00	4.9
	Week 17	68	1.43	1.76	0.0	1.00	8.0	52	-0.64	2.99	-8.1	0.00	5.9
	Week 20	59	1.87	1.95	0.0	1.00	7.0	47	-0.23	2.90	-8.1	0.00	6.4
	Week 23	63	2.02	2.15	0.0	1.00	7.5	47	-0.08	2.59	-8.1	0.00	5.4
	Week 26	59	2.03	2.11	0.0	1.25	8.3	41	-0.64	3.13	-8.1	0.00	7.0
	Week 29	56	1.86	1.90	0.0	1.00	6.0	41	-0.13	2.65	-8.1	0.00	5.6
	Week 32	52	2.14	2.20	0.0	1.75	7.5	39	-0.04	2.58	-8.0	0.00	5.7
	Week 35	43	2.12	1.76	0.0	2.00	6.3	32	0.06	2.01	-7.6	0.00	3.6
	Week 38	49	1.97	2.00	0.0	1.75	7.3	36	-0.68	2.70	-8.1	0.00	3.1
	Week 41	49	2.08	2.13	0.0	1.50	8.3	38	-0.02	2.94	-8.1	0.00	5.6
	Week 44	44	2.00	1.87	0.0	1.75	6.0	35	0.14	2.68	-7.9	0.00	5.1
	Week 47	37	1.71	1.79	0.0	1.25	6.0	29	-0.58	2.84	-8.1	0.00	5.1

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.1.3: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	29	1.72	1.66	0.0	1.75	5.0	24	0.07	1.79	-3.4	0.00	5.9
	Week 53	34	1.83	2.11	0.0	1.25	7.0	27	-0.54	2.77	-8.1	0.00	5.7
	Week 56	31	1.65	2.19	0.0	0.75	7.0	27	-0.23	2.97	-8.1	0.00	8.0
	Week 59	28	1.95	2.40	0.0	0.88	8.0	24	-0.54	2.18	-7.6	0.00	3.6
	Week 62	28	1.88	2.00	0.0	1.50	7.0	23	-0.16	1.89	-6.4	0.00	3.7
	Week 65	23	2.01	2.06	0.0	2.00	7.0	19	-0.86	3.07	-8.1	0.00	3.0
	Week 68	22	1.83	2.12	0.0	1.38	7.0	17	-0.60	3.26	-8.1	0.00	5.1
	Week 71	22	1.57	1.82	0.0	1.13	7.0	19	-0.58	3.16	-8.1	0.00	4.7
	Week 74	22	1.53	1.49	0.0	0.88	4.3	19	0.27	2.45	-7.6	0.00	4.9
	Week 77	18	2.19	1.86	0.0	2.00	7.0	12	-0.07	2.67	-6.7	0.00	3.6
	Week 80	16	2.33	2.27	0.0	2.00	7.0	11	-0.90	2.34	-7.1	0.00	1.3
	Week 83	16	2.14	1.84	0.0	1.88	7.0	10	-0.63	2.59	-6.7	0.00	2.6
	Week 86	13	2.38	2.39	0.0	2.00	8.0	9	-1.13	2.64	-7.1	0.00	1.7
	Week 89	12	1.96	2.27	0.0	2.00	8.0	8	-1.91	2.52	-7.3	-1.14	0.0
	Plat+Gem (N= 89)												
	BASELINE	75	2.64	2.31	0.0	2.25	9.8						
	Week 1	64	2.16	1.74	0.0	2.13	6.8	57	-0.25	1.64	-7.7	0.00	3.1
	Week 2	66	2.31	2.29	0.0	1.75	7.8	57	-0.05	1.60	-7.7	0.00	5.0
	Week 3	76	2.25	2.27	0.0	1.63	7.5	63	-0.57	1.67	-7.7	0.00	3.3
	Week 4	73	2.22	2.12	0.0	1.75	7.3	65	-0.39	1.66	-7.7	0.00	5.1
	Week 5	71	2.43	2.30	0.0	2.00	8.0	57	-0.22	1.91	-7.7	0.00	6.1
	Week 6	70	2.31	2.34	0.0	1.75	8.3	56	-0.66	1.79	-7.7	0.00	2.7
	Week 7	72	2.20	2.12	0.0	1.88	7.8	60	-0.51	1.60	-7.7	0.00	2.7
	Week 8	63	2.22	2.12	0.0	2.00	7.0	53	-0.14	1.89	-4.9	0.00	9.3
	Week 9	68	2.26	2.17	0.0	1.38	7.0	55	-0.16	1.87	-4.7	0.00	9.3
	Week 10	67	2.05	2.03	0.0	1.75	7.0	56	-0.50	1.80	-7.7	0.00	5.6

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.1.3: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	65	1.90	1.94	0.0	1.50	6.0	56	-0.40	1.82	-7.7	0.00	3.7
	Week 12	63	1.90	2.11	0.0	1.00	7.3	55	-0.29	1.78	-7.7	0.00	4.6
	Week 14	63	2.16	1.98	0.0	2.00	7.3	50	-0.41	1.35	-5.4	0.00	2.3
	Week 17	60	2.10	2.21	0.0	1.63	7.0	49	-0.40	1.65	-5.3	0.00	5.0
	Week 20	52	1.88	2.25	0.0	1.00	9.3	44	-0.61	1.82	-5.3	0.00	6.6
	Week 23	44	2.44	2.54	0.0	1.00	7.3	35	-0.74	1.48	-4.6	0.00	2.9
	Week 26	41	1.95	2.33	0.0	0.75	7.5	35	-0.72	1.47	-4.9	0.00	2.0
	Week 29	37	1.91	1.92	0.0	1.50	5.8	31	-0.34	1.63	-3.7	0.00	5.7
	Week 32	33	1.77	2.33	0.0	1.00	7.8	29	-0.54	1.75	-5.0	0.00	1.6
	Week 35	30	1.91	1.92	0.0	1.25	6.5	26	-0.26	1.80	-4.9	0.00	2.7
	Week 38	32	1.23	1.87	0.0	0.00	7.8	28	-0.83	1.79	-4.7	0.00	1.0
	Week 41	27	1.52	2.17	0.0	0.00	6.8	22	-0.71	1.98	-5.0	0.00	3.0
	Week 44	27	2.01	2.44	0.0	1.00	8.5	22	-0.51	1.79	-4.9	0.00	2.0
	Week 47	29	1.87	2.33	0.0	1.00	7.8	24	-0.61	2.31	-4.7	0.00	4.0
	Week 50	23	2.18	2.35	0.0	2.00	6.5	18	-0.39	1.72	-4.3	0.00	2.3
	Week 53	22	1.55	2.02	0.0	0.00	6.0	20	0.18	1.79	-4.1	0.00	6.0
	Week 56	18	1.74	2.25	0.0	0.13	6.0	15	-0.10	2.14	-3.7	0.00	6.3
	Week 59	17	1.29	1.73	0.0	0.75	5.3	15	-0.34	1.50	-4.3	0.00	2.1
	Week 62	16	1.41	1.63	0.0	1.00	5.3	14	-0.48	1.63	-4.0	0.00	1.4
	Week 65	15	1.03	1.42	0.0	0.00	4.0	13	-0.36	2.14	-7.0	0.00	1.6
	Week 68	12	1.83	2.48	0.0	0.50	6.3	10	0.46	1.03	-0.7	0.00	3.0
	Week 71	13	2.19	2.80	0.0	2.00	8.5	11	0.18	0.48	-0.7	0.00	1.1
	Week 74	10	1.68	2.67	0.0	0.88	8.8	10	0.11	1.37	-3.0	0.00	2.6

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.1.4: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	EV+Pembro (N=198)												
	BASELINE	173	2.27	2.17	0.0	2.00	9.3						
	Week 1	157	2.60	2.35	0.0	2.00	10.0	134	-0.10	1.58	-7.9	0.00	6.1
	Week 2	168	2.55	2.24	0.0	2.13	10.0	135	0.07	1.58	-7.0	0.00	6.4
	Week 3	162	2.57	2.22	0.0	2.25	8.8	120	-0.21	1.77	-8.0	0.00	4.1
	Week 4	159	1.98	2.15	0.0	1.50	10.0	125	-0.46	2.09	-8.6	0.00	5.0
	Week 5	157	1.89	1.92	0.0	1.50	7.8	127	-0.46	2.08	-8.6	0.00	6.3
	Week 6	154	2.01	2.14	0.0	1.00	8.0	121	-0.43	2.30	-8.0	0.00	6.6
	Week 7	160	1.85	2.11	0.0	1.00	10.0	126	-0.56	2.60	-8.6	0.00	7.3
	Week 8	155	1.79	1.98	0.0	1.00	8.0	117	-0.80	2.47	-8.4	0.00	8.1
	Week 9	163	2.15	2.23	0.0	1.25	9.3	121	-0.47	2.15	-8.1	0.00	5.3
	Week 10	159	1.81	1.96	0.0	1.00	7.5	120	-0.46	2.22	-8.6	0.00	6.4
	Week 11	162	1.75	1.95	0.0	1.00	7.8	124	-0.62	2.26	-8.6	0.00	5.4
	Week 12	154	1.80	2.05	0.0	1.00	8.3	120	-0.75	2.26	-8.6	0.00	5.4
	Week 14	154	1.93	2.17	0.0	1.13	9.0	121	-0.57	2.30	-8.6	0.00	5.4
	Week 17	145	1.76	1.99	0.0	1.25	8.3	111	-0.73	2.57	-8.6	0.00	5.9
	Week 20	139	1.86	2.11	0.0	1.00	8.8	108	-0.38	2.37	-8.1	0.00	6.4
	Week 23	133	1.90	2.09	0.0	1.00	7.5	101	-0.48	2.41	-8.1	0.00	6.1
	Week 26	129	1.87	2.13	0.0	1.00	8.3	96	-0.95	2.57	-8.6	0.00	7.0
	Week 29	131	1.77	1.98	0.0	1.00	8.5	103	-0.37	2.40	-8.6	0.00	5.7
	Week 32	111	2.14	2.30	0.0	1.00	7.5	85	-0.18	2.65	-8.0	0.00	8.3
	Week 35	109	1.99	2.07	0.0	1.00	7.3	84	-0.35	2.19	-8.0	0.00	6.3
	Week 38	107	1.85	2.13	0.0	1.00	7.3	84	-0.90	2.74	-8.6	0.00	5.1
	Week 41	103	1.87	2.06	0.0	1.00	8.3	79	-0.25	2.37	-8.1	0.00	6.4
	Week 44	88	1.88	2.09	0.0	1.00	7.5	71	-0.23	2.80	-8.0	0.00	6.7
	Week 47	80	1.71	1.90	0.0	1.00	7.0	64	-0.57	2.85	-8.6	0.00	6.1

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.1.4: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	73	1.78	1.88	0.0	1.50	7.0	59	-0.32	1.98	-7.7	0.00	3.4
	Week 53	64	1.61	2.04	0.0	0.88	7.0	48	-0.94	2.62	-8.3	0.00	3.6
	Week 56	66	1.67	2.26	0.0	0.13	9.5	52	-0.94	2.40	-8.3	0.00	2.9
	Week 59	58	1.62	2.02	0.0	0.75	7.0	45	-0.87	2.34	-8.3	0.00	2.6
	Week 62	54	1.87	2.21	0.0	1.00	8.0	44	-0.49	2.49	-8.3	0.00	7.4
	Week 65	51	1.65	1.93	0.0	1.00	7.0	40	-0.90	2.58	-8.1	0.00	3.0
	Week 68	49	1.42	1.76	0.0	1.00	7.0	41	-0.92	2.65	-8.1	0.00	1.9
	Week 71	47	1.49	1.77	0.0	1.00	7.0	37	-0.70	2.64	-8.1	0.00	4.7
	Week 74	42	1.49	1.67	0.0	0.75	5.3	35	-0.09	1.88	-7.6	0.00	4.9
	Week 77	38	1.84	1.97	0.0	1.38	7.0	28	-0.45	2.23	-6.7	0.00	3.6
	Week 80	35	1.61	1.82	0.0	1.00	7.0	26	-1.09	2.14	-7.1	0.00	1.3
	Week 83	32	1.60	1.79	0.0	1.00	7.0	24	-1.14	2.51	-7.4	-0.43	2.6
	Week 86	30	1.71	2.04	0.0	0.88	8.0	23	-1.03	2.15	-7.1	-0.14	1.7
	Week 89	28	1.94	2.27	0.0	1.38	8.0	19	-1.40	2.40	-7.3	-0.43	3.0
	Week 92	24	1.76	1.67	0.0	1.25	5.3	19	-0.19	1.13	-3.1	0.00	1.3
	Week 95	21	2.26	2.15	0.0	2.25	6.3	14	-0.40	1.55	-4.6	0.00	1.9
	Week 98	16	1.41	1.90	0.0	0.50	6.3	11	-1.10	1.53	-3.9	-0.43	0.1
	Week 101	12	1.42	2.02	0.0	0.38	5.8	10	0.00	0.35	-0.6	0.00	0.7
	Week 104	10	1.98	2.63	0.0	0.50	7.5	7	-0.02	2.38	-3.3	-0.43	4.7
	Plat+Gem (N=185)												
	BASELINE	148	2.66	2.36	0.0	2.00	9.8						
	Week 1	137	2.52	2.19	0.0	2.25	9.5	107	-0.01	1.38	-7.7	0.00	4.3
	Week 2	129	2.60	2.25	0.0	2.50	9.3	102	0.16	1.69	-7.7	0.00	5.3
	Week 3	142	2.41	2.29	0.0	2.00	8.3	110	-0.31	1.76	-7.7	0.00	7.0
	Week 4	139	2.28	2.14	0.0	1.75	9.3	111	-0.35	1.60	-7.7	0.00	4.4
	Week 5	143	2.49	2.21	0.0	2.25	9.0	99	-0.28	1.89	-7.7	0.00	6.1

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.1.4: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 6	133	2.31	2.20	0.0	2.00	9.0	99	-0.61	2.08	-7.9	0.00	6.3
	Week 7	142	1.90	1.87	0.0	1.63	7.3	107	-0.54	1.90	-7.9	0.00	5.4
	Week 8	125	2.26	2.15	0.0	2.00	10.0	99	-0.35	2.14	-7.9	0.00	9.3
	Week 9	135	2.05	2.02	0.0	1.50	8.8	98	-0.43	1.91	-7.9	0.00	9.3
	Week 10	131	2.09	2.17	0.0	1.25	8.0	101	-0.58	2.00	-7.9	0.00	5.6
	Week 11	128	1.80	2.04	0.0	1.25	10.0	102	-0.55	1.99	-7.9	0.00	4.6
	Week 12	124	1.90	2.03	0.0	1.25	8.0	101	-0.30	1.83	-7.9	0.00	4.6
	Week 14	121	2.02	1.96	0.0	1.25	7.3	89	-0.50	1.90	-6.4	0.00	5.0
	Week 17	122	2.08	2.20	0.0	1.00	8.3	87	-0.55	1.95	-7.9	0.00	5.0
	Week 20	98	1.83	2.15	0.0	1.00	9.3	79	-0.70	1.64	-7.7	0.00	3.3
	Week 23	93	2.16	2.34	0.0	1.00	7.3	66	-0.58	1.35	-4.7	0.00	2.9
	Week 26	86	1.99	2.32	0.0	1.00	9.0	65	-0.37	1.56	-6.3	0.00	4.3
	Week 29	76	1.87	1.81	0.0	1.25	6.5	53	-0.18	1.37	-3.7	0.00	4.0
	Week 32	62	1.67	2.07	0.0	1.00	7.3	49	-0.37	1.73	-5.0	0.00	5.0
	Week 35	58	1.98	2.12	0.0	1.25	8.0	44	-0.36	1.45	-4.9	0.00	1.9
	Week 38	60	1.89	2.23	0.0	1.00	7.3	46	-0.53	1.52	-4.7	0.00	1.6
	Week 41	52	1.85	2.27	0.0	1.00	7.3	38	-0.39	1.92	-5.0	0.00	6.6
	Week 44	46	2.33	2.55	0.0	1.13	8.5	37	-0.30	1.63	-4.9	0.00	2.7
	Week 47	44	1.78	1.95	0.0	1.00	7.5	35	-0.40	2.04	-4.7	0.00	4.3
	Week 50	42	2.40	2.51	0.0	2.00	9.0	33	-0.24	2.09	-5.4	0.00	4.7
	Week 53	38	1.57	1.86	0.0	0.75	6.8	31	-0.15	1.36	-4.1	0.00	2.9
	Week 56	32	2.24	2.48	0.0	1.50	8.0	23	-0.36	1.59	-3.7	0.00	2.9
	Week 59	31	1.75	2.02	0.0	1.00	7.0	25	-0.13	1.66	-4.3	0.00	2.9
	Week 62	29	1.60	1.89	0.0	1.00	6.5	23	-0.20	1.87	-4.0	0.00	3.1
	Week 65	25	1.55	2.19	0.0	0.00	7.3	20	-0.10	1.29	-3.7	0.00	2.3
	Week 68	20	2.08	2.69	0.0	0.75	7.5	15	0.26	1.21	-2.3	0.00	3.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.1.4: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 71	17	1.82	2.09	0.0	1.25	7.0	13	0.23	0.55	-0.7	0.00	1.4
	Week 74	17	2.10	2.57	0.0	1.00	8.0	14	0.06	1.51	-3.0	0.00	2.6
	Week 77	16	3.31	3.49	0.0	1.50	10.0	12	-0.43	1.98	-5.7	0.00	2.6
	Week 80	13	1.73	1.90	0.0	1.50	6.8	10	0.13	1.69	-3.4	0.00	3.0
	Week 83	11	2.45	2.82	0.0	1.00	6.8	9	-0.33	0.92	-2.3	0.00	1.0
	Week 86	12	1.15	2.00	0.0	0.38	6.3	11	-0.45	1.94	-5.6	0.00	1.0
	Week 89	11	1.57	2.10	0.0	1.00	6.3	10	-0.69	2.32	-6.6	0.00	2.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.1.4: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	EV+Pembro (N= 42)												
	BASELINE	36	1.85	1.54	0.0	2.00	6.0						
	Week 1	33	2.28	2.21	0.0	2.00	8.0	25	0.18	1.78	-4.0	0.00	5.4
	Week 2	36	2.32	1.92	0.0	2.25	7.0	31	0.40	2.00	-6.4	0.00	3.7
	Week 3	37	2.28	1.55	0.0	2.25	6.3	30	0.36	2.32	-5.4	0.00	6.3
	Week 4	36	1.49	1.81	0.0	1.00	6.8	33	0.13	1.78	-4.1	0.00	5.1
	Week 5	36	1.47	1.46	0.0	1.13	4.5	31	-0.10	2.14	-5.6	0.00	3.4
	Week 6	35	1.74	1.83	0.0	1.25	6.0	29	-0.13	1.94	-5.6	0.00	4.4
	Week 7	36	1.46	1.52	0.0	1.13	6.0	28	-0.43	2.27	-7.4	0.00	3.1
	Week 8	37	1.59	1.79	0.0	1.00	6.5	30	-0.59	2.63	-7.4	0.00	4.4
	Week 9	35	1.22	1.34	0.0	1.00	5.0	28	-0.54	2.22	-7.4	0.00	4.0
	Week 10	32	1.38	1.66	0.0	0.75	5.8	29	-0.40	2.25	-7.4	0.00	5.4
	Week 11	34	1.15	1.29	0.0	0.75	3.8	30	-0.57	2.39	-7.4	0.00	3.0
	Week 12	32	1.39	1.67	0.0	1.00	6.0	27	-0.22	2.85	-7.4	0.00	5.9
	Week 14	31	1.50	1.69	0.0	1.00	5.3	25	-0.23	2.56	-7.4	0.00	4.9
	Week 17	33	1.67	1.90	0.0	1.00	6.5	25	-0.26	2.82	-7.4	0.00	5.7
	Week 20	28	1.71	2.00	0.0	0.75	6.5	22	-0.21	2.16	-4.4	0.00	5.7
	Week 23	29	1.49	1.82	0.0	1.00	6.8	26	0.23	2.18	-3.0	0.00	6.0
	Week 26	27	1.92	2.06	0.0	1.00	5.5	19	-0.11	2.63	-7.4	0.00	5.0
	Week 29	26	1.71	1.74	0.0	1.00	6.0	20	-0.06	1.97	-4.0	0.00	5.6
	Week 32	24	2.38	2.37	0.0	2.00	8.0	18	0.51	2.36	-3.0	0.00	5.7
	Week 35	23	2.30	2.08	0.0	2.00	6.8	16	0.01	2.02	-4.0	0.00	3.6
	Week 38	25	2.09	2.08	0.0	1.50	7.0	18	-0.15	1.72	-4.0	0.00	3.1
	Week 41	26	2.17	2.29	0.0	1.63	8.0	21	0.22	2.27	-4.0	0.00	5.6
	Week 44	20	2.19	1.76	0.0	2.00	6.0	16	0.69	2.33	-3.0	0.00	5.1
	Week 47	20	1.98	2.04	0.0	2.00	6.3	17	0.13	1.73	-3.0	0.00	5.1

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.1.4: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	16	2.03	1.79	0.0	1.88	5.8	13	0.88	2.76	-3.0	0.00	6.3
	Week 53	15	2.30	2.16	0.0	2.00	6.0	13	0.02	2.37	-5.1	0.00	5.7
	Week 56	15	2.17	2.59	0.0	1.00	7.3	14	0.87	3.69	-5.1	0.00	8.0
	Week 59	14	2.34	2.96	0.0	0.50	8.0	12	0.31	2.13	-3.0	0.00	4.4
	Week 62	11	1.64	2.61	0.0	0.00	7.8	10	-0.33	1.80	-3.0	-0.50	3.7
	Plat+Gem (N= 57)												
	BASELINE	42	2.63	2.32	0.0	2.63	8.0						
	Week 1	42	2.86	1.96	0.0	2.88	6.3	32	-0.04	2.35	-7.6	0.00	5.4
	Week 2	44	2.38	2.19	0.0	2.00	8.0	33	-0.03	2.11	-7.0	0.00	6.6
	Week 3	43	2.63	2.44	0.0	2.25	9.0	29	-0.30	2.23	-4.6	0.00	8.6
	Week 4	44	2.12	2.16	0.0	1.63	8.0	35	-0.22	1.86	-4.1	0.00	5.1
	Week 5	44	2.50	2.17	0.0	2.00	8.0	31	-0.61	2.25	-5.3	0.00	5.6
	Week 6	41	2.38	2.32	0.0	2.00	8.0	33	-0.52	2.10	-6.3	0.00	4.1
	Week 7	45	2.38	2.24	0.0	2.00	7.8	34	-0.44	2.15	-6.1	0.00	4.3
	Week 8	42	2.51	2.25	0.0	2.13	7.3	30	-1.20	2.26	-8.0	-0.21	2.4
	Week 9	42	2.70	2.43	0.0	2.00	8.0	30	-0.97	2.36	-8.3	0.00	3.0
	Week 10	35	2.53	2.19	0.0	2.00	6.8	23	-0.48	1.37	-4.6	0.00	1.0
	Week 11	40	2.51	2.43	0.0	2.00	8.0	31	-0.88	1.99	-8.1	0.00	2.4
	Week 12	35	2.50	2.42	0.0	2.50	8.0	26	-0.57	1.80	-4.6	0.00	2.3
	Week 14	32	2.68	2.08	0.0	2.63	7.3	22	-0.32	2.48	-8.3	0.00	5.0
	Week 17	34	2.54	2.19	0.0	2.00	7.0	26	-0.35	1.57	-4.1	0.00	2.6
	Week 20	28	1.94	1.80	0.0	1.25	5.0	22	-0.53	2.21	-4.3	-0.07	6.6
	Week 23	22	3.03	2.52	0.0	3.25	7.3	15	-0.50	1.25	-4.3	0.00	1.0
	Week 26	22	2.52	2.29	0.0	3.13	7.5	17	-0.99	1.41	-4.1	-0.43	1.0
	Week 29	24	2.44	1.83	0.0	2.63	5.5	18	-0.07	1.79	-3.4	0.00	5.7
	Week 32	21	3.18	2.52	0.0	3.75	8.0	16	0.19	0.89	-1.7	0.00	1.9

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.1.4: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 35	18	2.85	2.13	0.0	2.88	6.5	14	0.50	1.24	-1.7	0.00	2.7
	Week 38	14	2.50	2.95	0.0	1.13	7.8	9	0.13	0.53	-0.4	0.00	1.0
	Week 41	13	2.65	1.86	0.0	3.00	5.8	10	0.84	1.49	-1.6	0.14	3.0
	Week 44	14	3.23	2.16	0.0	4.00	6.0	10	0.56	1.92	-2.0	0.00	5.0
	Week 47	12	3.44	2.57	0.0	3.88	7.8	8	1.13	1.68	0.0	0.07	4.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.1.5: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Visceral metastases	EV+Pembro (N=170)												
	BASELINE	149	2.31	2.19	0.0	2.00	9.3						
	Week 1	135	2.59	2.37	0.0	2.00	10.0	113	-0.04	1.54	-7.9	0.00	6.1
	Week 2	146	2.57	2.22	0.0	2.25	10.0	118	0.26	1.78	-7.0	0.00	6.4
	Week 3	142	2.56	2.14	0.0	2.50	8.5	106	-0.01	2.04	-8.0	0.00	6.3
	Week 4	136	2.07	2.19	0.0	1.50	10.0	108	-0.17	2.17	-8.6	0.00	5.1
	Week 5	133	1.75	1.80	0.0	1.25	7.8	107	-0.44	2.15	-8.6	0.00	4.1
	Week 6	128	2.01	2.13	0.0	1.25	8.0	98	-0.38	2.39	-8.0	0.00	6.6
	Week 7	136	1.82	2.07	0.0	1.00	10.0	109	-0.52	2.78	-8.6	0.00	7.3
	Week 8	132	1.85	2.01	0.0	1.00	8.0	100	-0.81	2.68	-8.4	0.00	8.1
	Week 9	137	2.03	2.18	0.0	1.00	9.3	103	-0.59	2.36	-8.1	0.00	5.3
	Week 10	135	1.75	1.89	0.0	1.25	7.5	107	-0.45	2.33	-8.6	0.00	6.4
	Week 11	136	1.67	1.92	0.0	1.00	7.8	110	-0.64	2.46	-8.6	0.00	5.4
	Week 12	131	1.67	1.97	0.0	1.00	8.3	107	-0.72	2.56	-8.6	0.00	5.9
	Week 14	130	1.79	2.04	0.0	1.00	9.0	103	-0.69	2.48	-8.6	0.00	5.0
	Week 17	124	1.73	2.07	0.0	1.00	8.3	93	-0.76	2.74	-8.6	0.00	5.9
	Week 20	115	1.83	2.06	0.0	1.00	8.8	92	-0.44	2.34	-8.1	0.00	6.4
	Week 23	111	1.77	2.02	0.0	1.00	7.5	90	-0.45	2.44	-8.1	0.00	6.0
	Week 26	106	1.71	2.03	0.0	1.00	8.3	84	-0.99	2.77	-8.6	0.00	7.0
	Week 29	106	1.54	1.89	0.0	0.88	8.5	85	-0.62	2.44	-8.6	0.00	4.7
	Week 32	92	2.09	2.33	0.0	1.00	8.0	73	-0.22	2.84	-8.0	0.00	8.3
	Week 35	86	1.95	2.09	0.0	1.00	7.3	65	-0.50	2.17	-8.0	0.00	4.0
	Week 38	90	1.78	2.14	0.0	1.00	7.3	73	-0.90	2.76	-8.6	0.00	5.1
	Week 41	87	1.89	2.20	0.0	1.00	8.3	71	-0.28	2.37	-8.1	0.00	5.6
	Week 44	73	1.84	2.04	0.0	1.00	7.5	63	-0.31	2.80	-8.0	0.00	6.7
	Week 47	68	1.55	1.77	0.0	1.00	6.8	59	-0.59	2.88	-8.6	0.00	6.1

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.1.5: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	61	1.79	1.89	0.0	1.75	7.0	52	-0.01	2.18	-7.7	0.00	6.3
	Week 53	54	1.83	2.16	0.0	1.00	7.0	42	-1.09	2.68	-8.3	0.00	3.6
	Week 56	58	1.65	2.42	0.0	0.00	9.5	49	-0.75	3.05	-8.3	0.00	8.0
	Week 59	50	1.70	2.29	0.0	0.50	8.0	42	-0.71	2.39	-8.3	0.00	3.6
	Week 62	45	1.68	2.31	0.0	0.50	8.0	40	-0.58	2.72	-8.3	0.00	7.4
	Week 65	37	1.64	2.02	0.0	0.75	6.5	31	-1.04	2.76	-8.1	-0.14	2.9
	Week 68	35	1.40	1.72	0.0	1.00	6.0	31	-1.00	3.00	-8.1	0.00	5.1
	Week 71	31	1.40	1.79	0.0	1.00	5.8	28	-1.02	2.80	-8.1	-0.07	4.7
	Week 74	29	1.34	1.69	0.0	0.50	5.3	25	-0.53	1.97	-7.6	0.00	2.7
	Week 77	26	1.75	2.00	0.0	1.00	6.0	22	-0.55	2.23	-6.7	0.00	3.6
	Week 80	22	1.58	1.96	0.0	0.75	6.8	20	-1.51	1.97	-7.1	-0.79	0.1
	Week 83	23	1.33	1.57	0.0	0.75	4.0	20	-1.45	2.37	-7.4	-0.64	2.6
	Week 86	21	1.55	1.79	0.0	1.00	5.3	19	-1.44	2.23	-7.1	-0.57	1.0
	Week 89	21	1.92	2.15	0.0	1.00	7.0	17	-1.15	2.27	-7.3	-0.43	3.0
	Week 92	18	2.26	2.08	0.0	1.75	5.8	15	-0.21	2.11	-3.1	0.00	6.0
	Week 95	13	2.06	2.46	0.0	0.75	6.3	10	-1.01	1.63	-4.6	-0.07	0.0
	Week 98	11	1.64	2.75	0.0	0.00	7.8	9	-1.17	1.41	-3.7	-0.57	0.1
	Week 101	11	1.93	2.42	0.0	0.75	5.8	9	-0.52	1.01	-3.0	0.00	0.3
	Plat+Gem (N=161)												
	BASELINE	131	2.94	2.30	0.0	3.00	9.8						
	Week 1	117	2.61	2.07	0.0	2.50	9.5	94	-0.16	1.82	-7.7	0.00	5.4
	Week 2	110	2.67	2.20	0.0	2.50	9.3	90	-0.06	1.88	-7.7	0.00	6.6
	Week 3	121	2.50	2.22	0.0	2.25	9.0	95	-0.38	1.98	-7.7	0.00	8.6
	Week 4	116	2.32	2.05	0.0	1.75	8.0	95	-0.54	1.77	-7.7	0.00	5.1
	Week 5	121	2.35	2.09	0.0	2.00	8.0	88	-0.72	1.91	-7.7	0.00	5.6
	Week 6	118	2.38	2.19	0.0	2.00	8.3	92	-0.80	2.16	-7.9	0.00	4.1

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.1.5: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 7	122	1.97	1.86	0.0	1.75	7.8	97	-0.80	2.04	-7.9	-0.14	4.3
	Week 8	108	2.12	1.93	0.0	1.75	6.5	89	-0.85	2.26	-8.0	0.00	4.7
	Week 9	114	2.13	2.00	0.0	1.75	7.0	87	-0.77	1.94	-8.3	0.00	3.0
	Week 10	109	2.13	2.02	0.0	1.75	7.0	85	-0.86	1.95	-7.9	-0.29	4.3
	Week 11	109	1.92	2.09	0.0	1.25	10.0	90	-0.84	2.24	-8.1	0.00	4.6
	Week 12	103	2.06	2.00	0.0	1.50	8.0	85	-0.49	2.06	-7.9	0.00	4.6
	Week 14	98	2.25	1.98	0.0	2.00	7.3	76	-0.58	2.15	-8.3	0.00	5.0
	Week 17	103	2.20	2.17	0.0	1.75	7.0	79	-0.68	2.09	-7.9	0.00	5.0
	Week 20	82	1.88	2.08	0.0	1.38	9.0	70	-0.94	1.92	-7.7	-0.21	6.6
	Week 23	77	2.37	2.34	0.0	2.00	7.3	57	-0.76	1.41	-4.7	0.00	2.9
	Week 26	71	2.02	2.17	0.0	1.00	7.5	56	-0.78	1.57	-6.3	-0.14	2.4
	Week 29	65	2.07	1.66	0.0	2.00	5.8	50	-0.30	1.59	-3.7	0.00	5.7
	Week 32	52	2.14	2.20	0.0	1.50	7.8	43	-0.34	1.75	-5.0	0.00	5.0
	Week 35	47	2.22	1.99	0.0	2.00	8.0	39	-0.28	1.69	-4.9	0.00	2.7
	Week 38	42	2.02	2.42	0.0	1.13	7.8	35	-0.47	1.49	-4.7	0.00	1.6
	Week 41	35	1.85	2.01	0.0	1.00	7.3	28	-0.38	2.17	-5.0	0.00	6.6
	Week 44	36	2.40	2.25	0.0	1.63	7.0	29	-0.47	1.64	-4.9	0.00	2.3
	Week 47	32	1.98	1.97	0.0	1.88	7.8	28	-0.28	2.24	-4.7	0.00	4.3
	Week 50	30	2.53	2.59	0.0	2.00	9.0	26	-0.42	1.83	-5.4	0.00	2.3
	Week 53	25	1.63	1.78	0.0	1.00	5.0	23	0.00	1.36	-3.1	0.00	2.9
	Week 56	22	2.52	2.32	0.0	3.00	7.8	16	0.12	2.37	-3.4	0.00	6.3
	Week 59	22	1.88	1.69	0.0	2.00	5.3	18	-0.17	1.82	-3.1	0.00	2.9
	Week 62	19	1.78	1.58	0.0	2.00	6.0	15	-0.30	2.04	-3.9	0.00	3.1
	Week 65	19	1.41	1.87	0.0	0.00	5.8	15	-0.65	2.30	-7.0	0.00	2.3
	Week 68	13	1.65	2.30	0.0	0.00	6.3	12	0.19	1.37	-2.3	0.00	3.0
	Week 71	13	2.60	2.88	0.0	2.00	8.5	9	0.32	0.66	-0.7	0.00	1.4

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.1.5: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 74	11	2.14	2.66	0.0	1.00	8.8	11	-0.05	1.70	-3.0	0.00	2.6
	Week 77	10	1.40	1.87	0.0	0.63	5.0	9	-0.56	2.31	-5.7	0.00	2.6

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.1.5: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Lymph node only	EV+Pembro (N= 60)												
	BASELINE	53	1.90	1.62	0.0	1.75	7.0						
	Week 1	49	2.34	2.09	0.0	1.75	8.0	41	-0.24	1.79	-4.0	0.00	5.7
	Week 2	50	2.51	2.10	0.0	2.25	7.0	42	-0.15	1.32	-3.1	0.00	3.1
	Week 3	50	2.37	2.00	0.0	2.00	8.8	40	-0.34	1.58	-5.0	0.00	2.9
	Week 4	51	1.45	1.76	0.0	1.00	7.8	45	-0.58	1.57	-5.4	0.00	2.7
	Week 5	54	1.93	1.91	0.0	1.13	7.0	46	-0.48	1.81	-5.6	0.00	3.1
	Week 6	53	1.87	1.91	0.0	1.25	8.0	46	-0.48	1.71	-5.6	0.00	3.1
	Week 7	52	1.56	1.57	0.0	1.00	6.3	41	-0.52	1.78	-5.4	0.00	2.9
	Week 8	52	1.49	1.60	0.0	1.00	5.8	43	-0.59	2.01	-6.0	0.00	4.4
	Week 9	53	1.85	1.88	0.0	1.00	6.8	42	-0.14	1.44	-5.1	0.00	4.0
	Week 10	48	1.66	1.91	0.0	1.00	7.0	38	-0.34	1.86	-5.4	0.00	5.4
	Week 11	53	1.68	1.78	0.0	1.00	7.0	40	-0.46	1.67	-5.6	0.00	3.0
	Week 12	48	2.00	2.08	0.0	1.38	8.0	36	-0.36	1.65	-5.7	0.00	4.6
	Week 14	48	1.96	2.15	0.0	1.25	8.0	38	-0.25	1.84	-4.9	0.00	4.9
	Week 17	46	1.74	1.68	0.0	1.25	6.0	38	-0.39	2.17	-5.7	0.00	5.7
	Week 20	44	1.87	2.19	0.0	1.00	8.0	33	-0.23	2.07	-4.4	0.00	5.7
	Week 23	43	1.73	1.93	0.0	1.00	7.5	33	-0.22	2.06	-5.3	0.00	5.4
	Week 26	42	2.10	2.20	0.0	1.00	8.3	28	-0.16	1.81	-4.7	0.00	5.0
	Week 29	45	2.16	1.96	0.0	1.75	7.3	35	0.22	1.77	-4.0	0.00	5.6
	Week 32	38	2.36	2.16	0.0	1.88	7.0	28	0.24	1.92	-3.0	0.00	5.7
	Week 35	42	2.04	1.88	0.0	1.38	6.5	33	-0.17	1.82	-5.7	0.00	3.6
	Week 38	38	1.91	1.96	0.0	1.25	6.5	29	-0.42	2.16	-5.7	0.00	3.1
	Week 41	37	1.90	1.81	0.0	1.75	5.8	27	-0.05	2.02	-4.4	0.00	5.6
	Week 44	31	1.95	1.90	0.0	1.75	6.0	23	0.36	2.24	-4.6	0.00	5.1
	Week 47	28	1.82	1.93	0.0	1.38	5.3	22	0.01	1.94	-4.0	0.00	5.1

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.1.5: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	25	1.77	1.78	0.0	1.50	5.8	20	-0.34	2.18	-5.3	0.00	5.9
	Week 53	23	1.20	1.40	0.0	1.00	5.3	19	0.03	2.23	-5.1	0.00	5.7
	Week 56	21	1.74	1.79	0.0	1.75	5.5	17	0.01	1.85	-5.3	0.00	4.4
	Week 59	20	1.50	1.78	0.0	0.88	6.0	15	-0.37	2.22	-5.6	0.00	4.4
	Week 62	19	1.91	1.88	0.0	2.00	5.3	14	-0.13	0.69	-2.0	0.00	1.0
	Week 65	20	1.74	1.61	0.0	1.75	5.3	16	-0.09	2.41	-5.6	0.00	4.1
	Week 68	17	1.43	1.72	0.0	0.75	4.5	14	-0.23	1.81	-5.7	0.00	1.3
	Week 71	19	1.46	1.32	0.0	1.25	4.0	13	0.15	1.59	-3.4	0.00	3.9
	Week 74	17	1.72	1.61	0.0	1.00	4.5	14	0.73	1.46	-0.6	0.07	4.9
	Week 77	17	1.85	1.45	0.0	2.25	4.5	11	-0.09	2.12	-5.7	0.00	2.1
	Week 80	17	1.62	1.55	0.0	1.25	4.3	11	-0.38	1.90	-5.7	0.00	1.3
	Week 83	13	1.83	1.59	0.0	1.75	4.3	8	-0.41	2.31	-5.7	0.00	2.0
	Week 86	12	1.73	1.84	0.0	0.88	4.5	8	-0.04	1.13	-2.0	0.00	1.7
	Week 89	11	1.68	1.89	0.0	1.75	6.3	6	-1.83	2.26	-5.7	-1.14	0.0
	Plat+Gem (N= 67)												
	BASELINE	49	2.07	2.27	0.0	1.25	8.0						
	Week 1	52	2.45	2.18	0.0	2.00	8.0	37	0.28	1.25	-3.4	0.00	3.0
	Week 2	53	2.43	2.32	0.0	2.00	9.3	37	0.39	1.56	-3.0	0.00	4.4
	Week 3	54	2.53	2.62	0.0	1.88	8.3	37	-0.23	1.70	-4.6	0.00	5.0
	Week 4	58	2.19	2.32	0.0	1.63	9.3	43	0.01	1.41	-4.4	0.00	4.4
	Week 5	56	2.70	2.34	0.0	2.50	9.0	36	0.17	1.81	-5.6	0.00	4.9
	Week 6	48	2.26	2.35	0.0	1.63	9.0	35	-0.20	1.88	-5.6	0.00	6.3
	Week 7	56	2.12	2.17	0.0	1.63	7.0	38	0.02	1.68	-5.6	0.00	5.4
	Week 8	52	2.81	2.57	0.0	2.38	10.0	34	0.12	2.03	-4.6	0.00	9.3
	Week 9	53	2.35	2.39	0.0	1.50	8.8	34	-0.17	2.35	-5.6	0.00	9.3
	Week 10	47	2.35	2.51	0.0	1.25	8.0	31	-0.14	1.46	-4.6	0.00	4.3

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.1.5: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	51	2.11	2.30	0.0	1.50	8.0	36	-0.28	1.25	-3.9	0.00	1.6
	Week 12	47	2.05	2.40	0.0	1.00	8.0	34	-0.21	1.22	-4.6	0.00	1.9
	Week 14	47	2.00	2.08	0.0	1.25	7.3	29	-0.34	1.80	-6.4	0.00	2.6
	Week 17	46	2.13	2.28	0.0	1.00	8.3	28	-0.16	1.22	-5.6	0.00	1.6
	Week 20	38	1.56	1.68	0.0	1.00	5.5	27	-0.08	1.25	-4.0	0.00	3.3
	Week 23	32	2.20	2.49	0.0	1.00	7.0	20	-0.11	1.04	-4.0	0.00	1.4
	Week 26	30	2.19	2.67	0.0	1.00	9.0	21	0.12	1.45	-4.1	0.00	4.3
	Week 29	28	1.68	2.00	0.0	0.75	6.5	17	0.18	1.18	-1.7	0.00	4.0
	Week 32	26	1.89	2.49	0.0	0.75	8.0	17	-0.15	1.32	-4.3	0.00	2.4
	Week 35	23	2.30	2.51	0.0	1.25	7.5	14	0.00	0.63	-1.7	0.00	1.0
	Week 38	26	2.00	2.43	0.0	0.38	7.0	15	-0.53	1.44	-4.3	0.00	0.7
	Week 41	24	2.36	2.55	0.0	1.88	7.0	14	0.09	1.49	-4.3	0.00	2.9
	Week 44	18	3.15	2.89	0.0	3.50	8.5	12	0.51	2.07	-4.0	0.07	5.0
	Week 47	18	2.40	2.35	0.0	1.63	7.5	9	-0.16	1.65	-4.3	0.00	1.7
	Week 50	16	3.00	2.70	0.0	3.50	7.8	10	0.53	2.43	-4.3	0.00	4.7
	Week 53	15	2.22	2.32	0.0	2.00	6.8	11	-0.10	1.46	-4.1	0.00	2.0
	Week 56	15	2.60	2.78	0.0	2.25	8.0	9	-0.03	1.69	-3.7	0.00	3.0
	Week 59	12	2.13	2.60	0.0	0.88	7.0	8	-0.16	1.97	-4.3	0.00	3.0
	Week 62	10	1.50	2.47	0.0	0.13	6.5	8	-0.29	1.58	-4.0	0.00	1.4

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.2: BPI-SF - Observed Means and Change from Baseline of Pain Severity - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
EV+Pembro (N=202)												
BASELINE	166	2.53	2.28	0.0	2.25	9.5						
Week 1	142	2.94	2.45	0.0	2.50	9.8	116	0.12	1.46	-4.7	0.00	6.0
Week 2	154	2.76	2.22	0.0	2.75	8.5	115	-0.08	1.51	-4.6	0.00	4.0
Week 3	139	2.62	2.37	0.0	2.00	8.5	104	-0.15	1.75	-6.6	0.00	5.6
Week 4	147	2.05	2.13	0.0	1.50	8.0	117	-0.56	2.06	-8.0	0.00	5.9
Week 5	139	1.93	2.00	0.0	1.50	7.8	101	-0.79	2.19	-8.0	0.00	4.4
Week 6	147	1.95	2.11	0.0	1.25	8.0	110	-0.57	2.69	-9.1	0.00	6.9
Week 7	150	1.81	2.00	0.0	1.00	7.0	109	-0.77	2.46	-8.0	0.00	7.1
Week 8	150	1.80	1.97	0.0	1.25	10.0	106	-0.91	2.53	-8.0	0.00	5.6
Week 9	142	1.92	2.12	0.0	1.25	9.0	104	-0.63	2.42	-8.0	0.00	4.1
Week 10	139	1.68	1.92	0.0	1.00	8.0	101	-0.98	2.57	-8.0	0.00	5.3
Week 11	138	1.39	1.76	0.0	0.75	8.0	103	-0.97	2.41	-7.9	0.00	5.1
Week 12	143	1.61	1.97	0.0	0.75	8.0	104	-0.94	2.59	-8.0	0.00	4.1
Week 14	140	1.73	2.05	0.0	1.00	8.0	102	-1.05	2.68	-9.1	0.00	6.3
Week 17	132	1.67	1.97	0.0	1.00	7.5	96	-0.93	2.68	-9.1	0.00	6.7
Week 20	120	1.50	1.90	0.0	1.00	8.3	88	-0.81	2.65	-8.0	0.00	5.7
Week 23	117	1.33	1.77	0.0	0.75	6.8	85	-1.05	2.62	-9.1	0.00	5.7
Week 26	114	1.70	2.04	0.0	1.00	7.8	83	-0.75	2.72	-9.1	0.00	5.6
Week 29	107	1.61	2.02	0.0	0.75	6.8	76	-1.09	2.60	-9.1	0.00	5.6
Week 32	102	1.37	1.74	0.0	0.63	6.8	74	-1.04	2.68	-9.1	0.00	5.9
Week 35	98	1.76	1.90	0.0	1.13	8.0	71	-0.94	2.52	-9.1	0.00	4.6
Week 38	97	1.70	1.87	0.0	1.00	6.0	77	-0.75	2.70	-9.1	0.00	6.0
Week 41	95	1.72	1.99	0.0	1.00	7.0	70	-0.92	2.29	-9.1	0.00	3.1
Week 44	86	1.86	2.09	0.0	1.00	6.8	63	-0.68	2.52	-9.1	0.00	6.0
Week 47	79	1.76	1.98	0.0	1.00	7.0	59	-0.57	2.80	-9.1	0.00	6.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.2: BPI-SF - Observed Means and Change from Baseline of Pain Severity - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	75	1.86	2.11	0.0	1.00	8.8	54	-0.71	2.73	-9.1	0.00	4.7
Week 53	76	2.13	2.32	0.0	1.50	8.3	54	-0.54	2.56	-9.1	0.00	4.3
Week 56	72	2.04	2.04	0.0	1.75	7.0	53	-0.93	2.59	-9.1	0.00	4.0
Week 59	69	2.18	2.30	0.0	1.00	7.0	49	-1.02	2.73	-9.1	0.00	4.0
Week 62	62	1.99	2.12	0.0	1.38	8.0	46	-0.49	2.68	-9.1	0.00	5.1
Week 65	43	1.88	1.98	0.0	2.00	7.0	31	-1.13	2.55	-9.1	-0.29	3.3
Week 68	46	2.10	2.29	0.0	1.50	7.5	35	-0.51	2.55	-9.1	0.00	2.7
Week 71	42	1.95	2.27	0.0	1.00	7.3	33	-1.15	2.60	-9.1	-0.29	3.0
Week 74	38	1.70	1.93	0.0	0.88	6.3	30	-0.73	3.10	-9.1	-0.07	5.4
Week 77	37	1.69	2.04	0.0	0.50	6.0	28	-1.07	2.50	-9.1	-0.07	2.0
Week 80	36	2.17	2.46	0.0	1.00	7.3	27	-1.02	2.44	-9.1	0.00	2.1
Week 83	30	1.97	2.12	0.0	1.13	7.5	24	-0.93	2.98	-9.1	-0.29	4.7
Week 86	26	1.87	2.51	0.0	0.63	7.8	20	-0.70	2.63	-9.1	0.00	3.3
Week 89	20	1.34	2.22	0.0	0.00	7.8	17	-0.61	2.05	-5.3	-0.14	3.0
Week 92	19	1.91	2.38	0.0	1.00	7.3	15	-0.18	1.96	-3.9	0.00	3.0
Week 95	14	0.66	0.80	0.0	0.13	2.0	14	-0.27	1.64	-3.9	0.00	2.7
Week 98	10	1.03	1.32	0.0	0.63	4.0	10	-0.27	2.03	-3.9	-0.21	3.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.2: BPI-SF - Observed Means and Change from Baseline of Pain Severity - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Plat+Gem (N=202)												
BASELINE	168	2.55	2.39	0.0	2.13	9.8						
Week 1	146	3.01	2.60	0.0	2.75	9.0	122	0.30	1.98	-5.3	0.00	10.0
Week 2	151	2.89	2.43	0.0	2.50	9.0	120	0.26	1.54	-3.6	0.00	6.3
Week 3	149	2.50	2.39	0.0	2.00	9.0	123	0.19	1.75	-6.3	0.00	5.4
Week 4	151	2.57	2.31	0.0	2.00	9.0	120	-0.09	2.24	-8.4	0.00	8.0
Week 5	155	2.46	2.33	0.0	2.00	8.5	124	0.04	1.99	-8.6	0.00	5.9
Week 6	145	2.40	2.50	0.0	1.75	10.0	114	-0.07	2.43	-8.6	0.00	9.0
Week 7	149	2.35	2.17	0.0	2.00	9.0	114	-0.11	2.54	-10.0	0.00	8.0
Week 8	146	2.49	2.23	0.0	2.00	9.3	112	0.09	2.52	-9.6	0.00	8.0
Week 9	141	2.30	2.25	0.0	2.00	9.5	103	-0.23	2.83	-8.4	0.00	7.7
Week 10	142	2.27	2.28	0.0	2.00	10.0	113	-0.20	2.32	-9.4	0.00	6.4
Week 11	126	2.37	2.33	0.0	1.88	10.0	98	0.19	2.65	-7.6	0.00	7.3
Week 12	130	2.27	2.35	0.0	1.75	10.0	100	-0.14	1.77	-8.0	0.00	6.0
Week 14	125	2.49	2.39	0.0	2.00	10.0	93	0.09	1.95	-8.1	0.00	4.9
Week 17	120	2.24	2.25	0.0	1.50	7.8	91	-0.28	2.26	-6.9	0.00	6.0
Week 20	104	2.00	2.21	0.0	1.00	8.3	83	-0.37	2.52	-8.4	0.00	5.7
Week 23	88	1.75	2.02	0.0	1.00	8.0	76	-0.40	2.50	-8.6	0.00	6.9
Week 26	81	2.06	2.22	0.0	1.25	8.5	65	-0.35	2.13	-6.7	0.00	4.0
Week 29	77	2.27	2.37	0.0	1.50	8.3	62	-0.16	2.21	-7.9	0.00	6.0
Week 32	64	2.33	2.36	0.0	1.63	8.8	49	-0.28	2.55	-8.3	0.00	5.6
Week 35	62	2.14	2.33	0.0	1.13	8.3	51	-0.34	1.98	-6.6	0.00	3.1
Week 38	56	2.40	2.76	0.0	1.38	9.3	42	0.04	1.13	-4.3	0.00	3.0
Week 41	52	2.21	2.60	0.0	1.00	9.0	42	0.18	1.51	-3.7	0.00	3.6
Week 44	49	2.39	2.52	0.0	1.50	8.3	40	0.21	1.63	-3.7	0.00	5.1
Week 47	43	2.05	2.26	0.0	1.25	9.0	33	-0.22	1.39	-4.1	0.00	2.9

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.2: BPI-SF - Observed Means and Change from Baseline of Pain Severity - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	36	2.22	2.31	0.0	1.13	7.8	27	0.28	2.18	-5.7	0.00	6.0
Week 53	31	2.06	2.56	0.0	1.00	7.8	24	0.03	2.15	-4.6	0.00	5.9
Week 56	30	2.23	2.65	0.0	1.00	7.8	24	0.54	2.32	-5.7	0.00	6.1
Week 59	23	1.91	2.10	0.0	1.00	7.0	18	0.33	2.24	-5.7	0.00	4.1
Week 62	20	2.70	2.44	0.0	2.25	7.0	17	0.02	2.61	-6.7	0.00	5.1
Week 65	17	2.88	2.88	0.0	2.00	8.0	13	0.99	2.94	-4.4	0.14	8.1
Week 68	13	1.88	2.90	0.0	0.50	7.3	12	0.35	2.03	-4.4	0.00	3.1
Week 71	13	2.21	2.73	0.0	1.00	7.0	12	0.15	2.39	-4.4	0.00	5.7
Week 74	11	1.36	2.13	0.0	0.75	7.0	11	0.17	1.83	-4.0	0.00	2.7
Week 77	11	1.32	1.82	0.0	0.75	5.3	10	1.06	2.41	-1.3	0.00	5.1

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.2.1: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Present	EV+Pembro (N= 50)												
	BASELINE	41	3.38	2.53	0.0	3.50	9.5						
	Week 1	38	3.41	2.46	0.0	3.63	9.3	30	0.22	1.19	-2.1	0.00	3.4
	Week 2	36	2.99	2.16	0.0	2.75	7.0	30	0.06	1.59	-4.0	0.00	3.7
	Week 3	32	2.63	2.43	0.0	2.00	8.5	26	-0.03	1.80	-3.9	0.00	5.0
	Week 4	35	1.94	1.92	0.0	1.50	5.8	29	-0.44	1.67	-4.1	0.00	3.1
	Week 5	32	2.00	2.07	0.0	1.50	7.8	25	-0.66	2.12	-7.1	0.00	2.9
	Week 6	35	1.61	1.87	0.0	1.00	6.5	28	-0.65	2.85	-7.3	0.00	6.9
	Week 7	35	1.74	2.04	0.0	1.00	7.0	24	-0.59	2.81	-7.3	0.00	4.0
	Week 8	38	1.76	1.80	0.0	1.00	6.0	26	-0.82	2.47	-7.3	0.00	3.9
	Week 9	33	1.65	1.88	0.0	1.00	6.8	26	-1.25	2.30	-6.7	-0.07	1.7
	Week 10	30	1.50	1.71	0.0	0.75	4.8	22	-1.82	2.76	-7.3	-0.64	2.0
	Week 11	31	1.18	1.64	0.0	0.50	6.3	24	-0.91	2.86	-7.3	-0.21	5.1
	Week 12	32	1.51	1.90	0.0	0.75	6.5	26	-1.01	2.83	-7.3	0.00	4.1
	Week 14	36	1.56	2.05	0.0	0.88	7.0	29	-1.10	3.33	-7.3	-0.43	6.3
	Week 17	33	1.42	1.88	0.0	0.50	7.5	26	-1.03	2.99	-7.3	0.00	6.7
	Week 20	28	1.51	1.80	0.0	1.00	6.8	22	-0.53	2.98	-6.4	-0.14	5.7
	Week 23	28	1.35	1.89	0.0	0.25	6.0	22	-0.79	2.74	-6.3	-0.07	5.7
	Week 26	28	1.64	1.98	0.0	0.88	6.5	23	-0.65	2.61	-5.9	0.00	4.6
	Week 29	27	1.68	1.96	0.0	1.00	6.5	23	-0.83	2.79	-7.0	0.00	5.6
	Week 32	25	1.19	1.77	0.0	0.00	5.5	22	-1.06	2.87	-7.6	-0.14	5.9
	Week 35	26	1.87	2.13	0.0	1.00	7.0	22	-1.07	2.69	-7.6	-0.14	4.3
	Week 38	26	1.72	1.83	0.0	1.00	5.0	22	-0.80	3.27	-7.3	0.00	6.0
	Week 41	25	1.51	1.88	0.0	0.50	6.3	21	-1.03	2.49	-7.6	0.00	3.1
	Week 44	22	1.88	2.09	0.0	1.50	6.8	18	-0.64	3.14	-7.6	-0.14	6.0
	Week 47	14	2.05	2.43	0.0	1.00	6.5	11	-0.70	3.93	-7.6	-0.29	6.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.2.1: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	2.16	2.64	0.0	1.38	8.8	15	-0.47	3.29	-7.6	0.00	4.7
	Week 53	21	2.14	2.47	0.0	1.75	8.3	15	-1.10	2.73	-7.6	-0.29	2.4
	Week 56	18	2.68	2.01	0.0	2.13	6.5	14	-0.37	3.24	-7.6	0.00	4.0
	Week 59	18	2.39	2.14	0.0	2.13	6.8	15	-0.78	3.05	-7.6	-0.43	4.0
	Week 62	13	2.17	2.36	0.0	1.50	8.0	10	-0.47	3.04	-7.6	0.00	3.1
	Week 68	12	2.02	2.21	0.0	1.63	7.3	10	-0.49	3.14	-7.6	0.00	2.7
	Plat+Gem (N= 50)												
	BASELINE	41	3.52	2.48	0.0	3.00	9.8						
	Week 1	35	3.71	2.71	0.0	3.75	9.0	30	0.52	1.46	-2.0	0.00	4.9
	Week 2	34	3.17	2.15	0.0	3.00	8.3	27	0.25	1.57	-2.0	0.00	5.3
	Week 3	33	2.69	2.23	0.0	3.00	7.0	26	0.55	1.68	-2.0	0.14	5.1
	Week 4	36	2.53	1.90	0.0	2.13	6.3	29	-0.52	2.19	-8.4	0.00	5.6
	Week 5	36	2.18	2.05	0.0	2.13	6.8	30	-0.32	2.73	-8.6	0.00	5.9
	Week 6	32	2.48	2.50	0.0	2.25	9.0	25	-0.42	3.48	-8.6	0.00	9.0
	Week 7	35	2.35	2.13	0.0	2.25	7.3	25	-0.93	2.36	-5.4	-0.29	5.4
	Week 8	36	2.49	2.09	0.0	2.00	6.0	25	-0.35	2.76	-5.6	-0.43	5.4
	Week 9	34	2.40	1.82	0.0	2.38	6.8	24	-0.29	3.07	-7.1	-0.50	5.9
	Week 10	33	2.24	2.06	0.0	2.25	8.0	26	-0.35	2.37	-4.7	0.00	6.4
	Week 11	30	2.22	1.76	0.0	2.13	6.3	22	-0.12	2.90	-5.1	-0.29	6.9
	Week 12	32	2.45	2.17	0.0	2.00	7.0	25	-0.53	1.72	-3.7	0.00	2.9
	Week 14	27	2.71	1.85	0.0	2.75	6.3	19	-0.19	1.25	-3.9	0.00	2.3
	Week 17	28	2.29	1.85	0.0	2.00	6.0	21	-0.41	2.23	-4.9	0.00	3.9
	Week 20	20	2.31	2.60	0.0	1.38	8.3	14	-1.47	2.53	-8.4	-0.64	1.4
	Week 23	15	2.08	2.25	0.0	1.00	6.3	13	-0.82	1.97	-5.0	-0.57	2.4
	Week 26	15	1.97	2.38	0.0	1.25	7.0	12	-1.01	1.91	-4.6	-0.29	1.6
	Week 29	13	2.23	2.39	0.0	1.25	6.8	9	-0.75	1.44	-3.9	-0.29	1.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.2.1: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Absent	EV+Pembro (N=152)												
	BASELINE	125	2.25	2.13	0.0	2.00	7.8						
	Week 1	104	2.77	2.43	0.0	2.13	9.8	86	0.08	1.54	-4.7	0.00	6.0
	Week 2	118	2.70	2.24	0.0	2.63	8.5	85	-0.13	1.49	-4.6	0.00	4.0
	Week 3	107	2.61	2.36	0.0	2.50	8.0	78	-0.19	1.74	-6.6	0.00	5.6
	Week 4	112	2.08	2.20	0.0	1.38	8.0	88	-0.60	2.17	-8.0	0.00	5.9
	Week 5	107	1.91	1.99	0.0	1.50	7.5	76	-0.83	2.22	-8.0	0.00	4.4
	Week 6	112	2.05	2.18	0.0	1.25	8.0	82	-0.55	2.65	-9.1	0.00	6.6
	Week 7	115	1.83	2.00	0.0	1.25	7.0	85	-0.83	2.37	-8.0	0.00	7.1
	Week 8	112	1.81	2.04	0.0	1.25	10.0	80	-0.93	2.57	-8.0	0.00	5.6
	Week 9	109	2.00	2.19	0.0	1.25	9.0	78	-0.42	2.43	-8.0	0.00	4.1
	Week 10	109	1.73	1.98	0.0	1.00	8.0	79	-0.75	2.48	-8.0	0.00	5.3
	Week 11	107	1.45	1.80	0.0	0.75	8.0	79	-0.99	2.28	-7.9	0.00	3.7
	Week 12	111	1.64	2.00	0.0	0.75	8.0	78	-0.92	2.52	-8.0	0.00	3.6
	Week 14	104	1.78	2.05	0.0	1.00	8.0	73	-1.02	2.41	-9.1	0.00	3.0
	Week 17	99	1.75	2.00	0.0	1.00	7.0	70	-0.89	2.57	-9.1	0.00	6.7
	Week 20	92	1.50	1.94	0.0	0.88	8.3	66	-0.90	2.55	-8.0	0.00	4.7
	Week 23	89	1.33	1.74	0.0	0.75	6.8	63	-1.15	2.59	-9.1	0.00	3.7
	Week 26	86	1.72	2.07	0.0	1.00	7.8	60	-0.79	2.78	-9.1	0.00	5.6
	Week 29	80	1.59	2.05	0.0	0.38	6.8	53	-1.21	2.54	-9.1	0.00	4.4
	Week 32	77	1.43	1.74	0.0	1.00	6.8	52	-1.03	2.63	-9.1	0.00	5.0
	Week 35	72	1.72	1.83	0.0	1.25	8.0	49	-0.88	2.47	-9.1	0.00	4.6
	Week 38	71	1.69	1.90	0.0	1.00	6.0	55	-0.72	2.47	-9.1	0.00	3.9
	Week 41	70	1.80	2.04	0.0	1.00	7.0	49	-0.88	2.23	-9.1	0.00	1.3
	Week 44	64	1.86	2.11	0.0	0.88	6.8	45	-0.70	2.27	-9.1	0.00	3.7
	Week 47	65	1.69	1.88	0.0	1.00	7.0	48	-0.54	2.53	-9.1	0.00	4.4

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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Table 302.1.3002.5.2.1: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	55	1.75	1.90	0.0	1.00	6.0	39	-0.81	2.53	-9.1	0.00	4.6
	Week 53	55	2.13	2.28	0.0	1.50	7.0	39	-0.33	2.50	-9.1	0.00	4.3
	Week 56	54	1.82	2.02	0.0	1.13	7.0	39	-1.14	2.33	-9.1	-0.14	3.3
	Week 59	51	2.10	2.37	0.0	1.00	7.0	34	-1.12	2.62	-9.1	0.00	3.3
	Week 62	49	1.94	2.07	0.0	1.25	7.0	36	-0.50	2.62	-9.1	0.00	5.1
	Week 65	36	2.00	2.02	0.0	2.00	7.0	24	-1.15	2.29	-9.1	-0.14	2.0
	Week 68	34	2.13	2.35	0.0	1.38	7.5	25	-0.52	2.34	-9.1	0.00	2.6
	Week 71	33	2.02	2.29	0.0	1.00	7.3	26	-0.80	2.34	-9.1	0.00	2.3
	Week 74	33	1.80	2.00	0.0	1.00	6.3	25	-0.58	2.95	-9.1	0.00	5.4
	Week 77	31	1.63	1.98	0.0	0.50	5.3	23	-0.82	2.32	-9.1	0.00	2.0
	Week 80	31	2.08	2.42	0.0	1.00	7.3	23	-0.85	2.23	-9.1	0.00	2.1
	Week 83	25	1.94	1.90	0.0	1.25	6.0	19	-0.64	2.89	-9.1	-0.29	4.7
	Week 86	23	1.80	2.37	0.0	0.75	7.8	17	-0.62	2.80	-9.1	0.00	3.3
	Week 89	18	1.49	2.30	0.0	0.38	7.8	15	-0.47	2.09	-5.3	0.00	3.0
	Week 92	16	1.81	2.10	0.0	1.38	6.0	12	-0.02	2.00	-3.9	0.00	3.0
	Week 95	12	0.77	0.82	0.0	0.63	2.0	12	-0.02	1.55	-3.9	0.00	2.7
	Plat+Gem (N=152)												
	BASELINE	127	2.23	2.28	0.0	1.50	9.0						
	Week 1	111	2.80	2.54	0.0	2.25	9.0	92	0.23	2.12	-5.3	0.00	10.0
	Week 2	117	2.81	2.51	0.0	2.00	9.0	93	0.27	1.53	-3.6	0.00	6.3
	Week 3	116	2.45	2.43	0.0	2.00	9.0	97	0.10	1.76	-6.3	0.00	5.4
	Week 4	115	2.58	2.43	0.0	2.00	9.0	91	0.04	2.25	-8.0	0.00	8.0
	Week 5	119	2.54	2.41	0.0	2.00	8.5	94	0.16	1.69	-6.3	0.00	5.3
	Week 6	113	2.38	2.52	0.0	1.75	10.0	89	0.03	2.06	-7.1	0.00	6.4
	Week 7	114	2.35	2.19	0.0	2.00	9.0	89	0.13	2.55	-10.0	0.00	8.0
	Week 8	110	2.49	2.28	0.0	2.00	9.3	87	0.21	2.45	-9.6	0.00	8.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.2.1: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	107	2.27	2.38	0.0	1.75	9.5	79	-0.21	2.77	-8.4	0.00	7.7
	Week 10	109	2.28	2.35	0.0	1.75	10.0	87	-0.16	2.32	-9.4	0.00	5.7
	Week 11	96	2.42	2.49	0.0	1.75	10.0	76	0.28	2.59	-7.6	0.00	7.3
	Week 12	98	2.21	2.41	0.0	1.63	10.0	75	-0.01	1.77	-8.0	0.00	6.0
	Week 14	98	2.42	2.52	0.0	1.88	10.0	74	0.16	2.10	-8.1	0.00	4.9
	Week 17	92	2.22	2.37	0.0	1.00	7.8	70	-0.24	2.28	-6.9	0.00	6.0
	Week 20	84	1.93	2.11	0.0	1.00	7.3	69	-0.15	2.48	-8.1	0.00	5.7
	Week 23	73	1.68	1.98	0.0	1.00	8.0	63	-0.31	2.60	-8.6	0.00	6.9
	Week 26	66	2.09	2.21	0.0	1.50	8.5	53	-0.19	2.17	-6.7	0.00	4.0
	Week 29	64	2.28	2.39	0.0	1.50	8.3	53	-0.06	2.31	-7.9	0.00	6.0
	Week 32	55	2.32	2.27	0.0	1.75	8.3	41	-0.25	2.54	-8.3	0.00	5.6
	Week 35	54	2.24	2.42	0.0	1.25	8.3	44	-0.18	1.99	-6.6	0.00	3.1
	Week 38	47	2.24	2.65	0.0	1.25	9.3	34	0.03	1.07	-4.3	0.00	2.0
	Week 41	45	2.32	2.69	0.0	1.00	9.0	35	0.36	1.49	-3.7	0.00	3.6
	Week 44	41	2.31	2.56	0.0	1.50	8.3	33	0.25	1.59	-3.7	0.00	5.1
	Week 47	35	2.24	2.30	0.0	2.00	9.0	26	-0.02	1.21	-4.1	0.00	2.9
	Week 50	29	2.38	2.39	0.0	2.00	7.8	20	0.65	2.23	-5.7	0.00	6.0
	Week 53	25	1.95	2.42	0.0	1.00	7.8	19	0.50	2.03	-4.6	0.00	5.9
	Week 56	26	2.23	2.72	0.0	1.00	7.8	21	0.71	2.41	-5.7	0.00	6.1
	Week 59	20	1.98	2.09	0.0	1.00	7.0	16	0.39	2.37	-5.7	0.00	4.1
	Week 62	17	2.82	2.52	0.0	2.50	7.0	15	-0.01	2.78	-6.7	0.00	5.1
	Week 65	15	3.20	2.92	0.0	2.50	8.0	11	1.16	3.19	-4.4	0.14	8.1
	Week 68	11	2.23	3.05	0.0	0.50	7.3	10	0.44	2.23	-4.4	0.00	3.1
	Week 71	12	2.40	2.77	0.0	1.25	7.0	11	0.21	2.50	-4.4	0.00	5.7
	Week 74	10	1.50	2.19	0.0	0.88	7.0	10	0.21	1.93	-4.0	0.00	2.7
	Week 77	10	1.38	1.91	0.0	0.75	5.3	9	1.21	2.51	-1.3	0.00	5.1

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.2.2: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
< 65 years	EV+Pembro (N= 39)												
	BASELINE	33	2.69	2.36	0.0	2.75	9.5						
	Week 1	27	2.81	2.13	0.0	2.50	7.3	21	0.11	1.50	-3.0	0.00	3.6
	Week 2	31	2.36	2.19	0.0	1.75	7.0	24	-0.18	1.46	-4.0	0.00	2.9
	Week 3	31	2.15	2.18	0.0	2.00	7.0	26	-0.16	2.09	-6.6	0.00	5.6
	Week 4	30	1.24	1.41	0.0	1.00	5.0	25	-1.21	1.81	-6.7	-0.29	1.3
	Week 5	28	1.25	1.67	0.0	0.63	6.8	22	-1.38	1.75	-4.9	-1.07	1.4
	Week 6	29	1.61	2.02	0.0	0.50	5.8	22	-1.47	1.94	-6.9	-0.64	0.6
	Week 7	30	1.40	1.92	0.0	0.50	7.0	23	-1.06	2.16	-4.9	-0.43	4.1
	Week 8	30	1.40	1.83	0.0	0.88	5.8	22	-1.28	1.96	-5.7	-0.57	1.7
	Week 9	28	1.89	2.27	0.0	0.75	7.0	22	-1.65	2.39	-6.7	-1.21	3.0
	Week 10	26	1.42	1.85	0.0	0.50	5.0	20	-1.54	1.93	-4.9	-0.86	1.4
	Week 11	28	1.12	1.44	0.0	0.75	4.8	21	-1.26	1.47	-4.7	-1.00	0.6
	Week 12	28	1.37	1.84	0.0	0.75	6.5	23	-1.02	2.27	-7.0	0.00	2.7
	Week 14	26	1.07	1.39	0.0	0.50	4.5	20	-1.96	2.00	-7.0	-1.71	0.3
	Week 17	28	1.47	1.82	0.0	0.63	6.0	20	-1.09	3.41	-7.0	-1.36	6.7
	Week 20	27	1.24	1.58	0.0	0.75	5.8	22	-1.01	2.68	-6.9	-1.07	5.7
	Week 23	26	0.63	0.90	0.0	0.00	3.5	20	-1.37	1.99	-5.7	-0.43	0.7
	Week 26	24	1.08	1.82	0.0	0.38	7.8	17	-1.64	2.14	-6.9	-0.86	0.6
	Week 29	25	1.47	2.10	0.0	0.25	6.0	19	-1.62	2.17	-6.9	-1.57	1.7
	Week 32	25	1.27	1.61	0.0	0.75	5.3	18	-1.63	1.72	-4.9	-1.21	0.1
	Week 35	24	1.43	1.59	0.0	1.00	4.8	17	-1.51	2.37	-6.9	-1.14	2.0
	Week 38	23	1.34	1.81	0.0	0.50	5.8	18	-1.41	2.20	-6.1	-0.43	2.0
	Week 41	25	1.70	2.08	0.0	0.75	5.8	17	-1.66	2.38	-7.0	-0.71	1.3
	Week 44	22	1.75	2.31	0.0	0.00	6.3	15	-1.40	2.00	-5.4	-0.71	1.6
	Week 47	20	1.50	1.92	0.0	0.75	6.5	15	-0.99	2.72	-6.7	-0.43	4.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.2.2: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	19	1.20	1.63	0.0	0.50	4.8	15	-1.47	2.07	-6.6	-0.29	1.1
	Week 53	20	0.98	1.62	0.0	0.00	5.5	16	-1.11	2.44	-5.9	-0.14	3.9
	Week 56	17	1.47	1.64	0.0	1.00	4.8	14	-0.94	1.57	-3.7	-0.07	1.3
	Week 59	17	1.81	2.38	0.0	1.00	6.5	13	-0.68	2.57	-4.4	-0.43	3.4
	Week 62	15	1.70	1.78	0.0	1.25	4.8	12	-0.38	1.97	-3.9	-0.21	3.6
	Week 65	14	1.18	1.42	0.0	0.38	4.3	12	-1.10	1.44	-4.1	-0.93	1.1
	Week 68	11	1.61	1.79	0.0	1.25	5.5	9	-0.75	2.00	-5.6	0.00	1.3
	Week 71	13	1.90	2.06	0.0	1.50	5.8	10	-1.23	1.82	-4.0	-0.93	1.9
	Week 74	14	1.91	2.01	0.0	1.13	5.3	11	0.05	2.60	-3.1	-0.14	3.9
	Week 77	14	2.27	2.29	0.0	2.00	6.0	10	-0.63	1.40	-3.0	-0.14	1.4
	Week 80	14	2.75	2.81	0.0	2.13	7.0	9	-0.49	1.45	-3.9	0.00	1.4
	Week 83	12	2.50	2.44	0.0	2.38	7.5	9	-0.03	2.79	-3.9	0.00	4.7
	Plat+Gem (N= 29)												
	BASELINE	22	2.88	2.21	0.0	3.13	6.8						
	Week 1	21	2.69	2.81	0.0	2.00	8.0	19	-0.13	0.71	-2.0	0.00	1.0
	Week 2	24	2.51	2.56	0.0	2.00	7.8	19	-0.15	0.65	-1.7	0.00	1.0
	Week 3	23	2.28	2.23	0.0	2.25	8.3	18	-0.15	0.95	-2.4	0.00	2.0
	Week 4	23	2.62	2.74	0.0	2.00	9.0	17	-0.11	0.73	-1.9	0.00	1.0
	Week 5	25	2.12	2.52	0.0	1.00	8.5	18	-0.15	0.91	-2.6	0.00	1.3
	Week 6	22	1.52	1.62	0.0	1.00	5.8	17	-0.18	0.65	-1.6	0.00	0.9
	Week 7	24	2.01	2.30	0.0	1.13	9.0	20	-0.48	1.46	-5.6	0.00	1.1
	Week 8	21	1.64	2.29	0.0	0.75	9.3	17	-0.29	0.90	-2.4	0.00	1.0
	Week 9	20	2.01	2.03	0.0	2.00	8.0	15	0.16	0.86	-1.1	0.00	2.1
	Week 10	21	1.68	1.82	0.0	1.00	5.3	17	0.21	1.23	-2.4	0.00	3.7
	Week 11	20	1.63	2.03	0.0	1.00	7.5	15	-0.36	1.80	-5.7	0.00	2.0
	Week 12	21	1.83	2.15	0.0	0.75	6.0	15	-0.14	1.14	-2.6	0.00	2.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.2.2: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 14	22	2.43	2.38	0.0	2.13	8.0	15	0.29	0.96	-1.0	0.00	3.0
	Week 17	20	1.74	2.25	0.0	0.88	7.8	15	-0.51	1.89	-6.1	0.00	1.1
	Week 20	18	2.56	2.48	0.0	1.88	6.3	13	-0.51	1.95	-6.1	0.00	1.0
	Week 23	18	1.67	2.02	0.0	0.50	5.5	16	-0.74	1.66	-6.1	0.00	0.1
	Week 26	16	1.81	1.88	0.0	1.50	4.5	13	-0.21	2.34	-6.1	0.00	4.0
	Week 29	15	2.08	1.92	0.0	2.00	5.0	12	-0.02	0.76	-1.1	0.00	2.0
	Week 32	15	2.00	2.16	0.0	1.25	6.8	12	-0.45	2.61	-6.1	0.00	4.3
	Week 35	15	1.80	1.89	0.0	1.25	6.0	13	-0.19	2.27	-6.1	0.00	3.1
	Week 38	14	2.68	2.76	0.0	2.13	8.8	10	0.10	0.74	-1.0	0.00	2.0
	Week 41	11	3.02	2.76	0.0	2.25	7.5	8	0.38	1.06	-1.0	0.00	2.0
	Week 44	11	2.45	2.40	0.0	1.75	7.5	8	-0.23	1.19	-3.0	0.00	1.1
	Week 47	11	2.11	2.31	0.0	2.00	6.5	8	-0.61	0.98	-2.7	0.00	0.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.2.2: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>= 65 years	EV+Pembro (N=163)												
	BASELINE	133	2.49	2.27	0.0	2.00	8.8						
	Week 1	115	2.97	2.52	0.0	2.50	9.8	95	0.12	1.45	-4.7	0.00	6.0
	Week 2	123	2.87	2.23	0.0	2.75	8.5	91	-0.06	1.53	-4.6	0.00	4.0
	Week 3	108	2.75	2.41	0.0	2.38	8.5	78	-0.15	1.64	-5.9	0.00	5.0
	Week 4	117	2.25	2.24	0.0	1.75	8.0	92	-0.39	2.09	-8.0	0.00	5.9
	Week 5	111	2.10	2.04	0.0	1.50	7.8	79	-0.63	2.28	-8.0	0.00	4.4
	Week 6	118	2.03	2.13	0.0	1.38	8.0	88	-0.35	2.81	-9.1	0.00	6.9
	Week 7	120	1.91	2.02	0.0	1.25	7.0	86	-0.70	2.54	-8.0	0.00	7.1
	Week 8	120	1.89	2.00	0.0	1.25	10.0	84	-0.81	2.66	-8.0	0.00	5.6
	Week 9	114	1.92	2.10	0.0	1.25	9.0	82	-0.36	2.36	-8.0	0.00	4.1
	Week 10	113	1.74	1.94	0.0	1.00	8.0	81	-0.84	2.70	-8.0	0.00	5.3
	Week 11	110	1.46	1.83	0.0	0.75	8.0	82	-0.90	2.60	-7.9	0.00	5.1
	Week 12	115	1.67	2.00	0.0	0.75	8.0	81	-0.92	2.68	-8.0	0.00	4.1
	Week 14	114	1.88	2.15	0.0	1.00	8.0	82	-0.82	2.79	-9.1	0.00	6.3
	Week 17	104	1.72	2.01	0.0	1.00	7.5	76	-0.88	2.47	-9.1	0.00	3.1
	Week 20	93	1.58	1.99	0.0	1.00	8.3	66	-0.74	2.66	-8.0	0.00	5.0
	Week 23	91	1.53	1.91	0.0	0.75	6.8	65	-0.95	2.79	-9.1	0.00	5.7
	Week 26	90	1.86	2.08	0.0	1.00	7.0	66	-0.53	2.82	-9.1	0.00	5.6
	Week 29	82	1.65	2.00	0.0	1.00	6.8	57	-0.92	2.72	-9.1	0.00	5.6
	Week 32	77	1.40	1.79	0.0	0.50	6.8	56	-0.85	2.92	-9.1	0.00	5.9
	Week 35	74	1.86	1.99	0.0	1.25	8.0	54	-0.76	2.56	-9.1	0.00	4.6
	Week 38	74	1.81	1.89	0.0	1.00	6.0	59	-0.54	2.82	-9.1	0.00	6.0
	Week 41	70	1.73	1.98	0.0	1.00	7.0	53	-0.69	2.23	-9.1	0.00	3.1
	Week 44	64	1.90	2.03	0.0	1.25	6.8	48	-0.46	2.65	-9.1	0.00	6.0
	Week 47	59	1.84	2.00	0.0	1.25	7.0	44	-0.43	2.85	-9.1	0.00	6.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.2.2: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	56	2.08	2.22	0.0	1.50	8.8	39	-0.42	2.92	-9.1	0.00	4.7
	Week 53	56	2.54	2.40	0.0	2.13	8.3	38	-0.30	2.61	-9.1	0.00	4.3
	Week 56	55	2.21	2.12	0.0	1.75	7.0	39	-0.93	2.89	-9.1	0.00	4.0
	Week 59	52	2.30	2.29	0.0	2.00	7.0	36	-1.14	2.82	-9.1	0.00	4.0
	Week 62	47	2.09	2.22	0.0	1.50	8.0	34	-0.53	2.92	-9.1	0.00	5.1
	Week 65	29	2.22	2.15	0.0	2.00	7.0	19	-1.16	3.09	-9.1	0.00	3.3
	Week 68	35	2.25	2.43	0.0	1.50	7.5	26	-0.43	2.74	-9.1	0.00	2.7
	Week 71	29	1.97	2.40	0.0	1.00	7.3	23	-1.12	2.91	-9.1	0.00	3.0
	Week 74	24	1.57	1.92	0.0	0.63	6.3	19	-1.19	3.34	-9.1	0.00	5.4
	Week 77	23	1.34	1.84	0.0	0.00	5.3	18	-1.31	2.95	-9.1	-0.07	2.0
	Week 80	22	1.80	2.19	0.0	1.00	7.3	18	-1.29	2.81	-9.1	-0.14	2.1
	Week 83	18	1.61	1.87	0.0	1.00	6.0	15	-1.48	3.06	-9.1	-0.29	2.0
	Week 86	18	1.89	2.54	0.0	0.88	7.8	14	-0.72	2.78	-9.1	0.00	3.0
	Week 89	12	1.73	2.48	0.0	0.75	7.8	10	-0.51	2.06	-5.3	-0.07	3.0
	Week 92	10	1.50	1.91	0.0	0.88	5.8	8	-0.30	1.23	-3.1	0.00	1.0
	Plat+Gem (N=173)												
	BASELINE	146	2.50	2.42	0.0	2.00	9.8						
	Week 1	125	3.07	2.57	0.0	2.75	9.0	103	0.38	2.12	-5.3	0.00	10.0
	Week 2	127	2.96	2.41	0.0	2.50	9.0	101	0.34	1.64	-3.6	0.00	6.3
	Week 3	126	2.54	2.42	0.0	2.00	9.0	105	0.25	1.85	-6.3	0.00	5.4
	Week 4	128	2.56	2.24	0.0	2.00	9.0	103	-0.09	2.41	-8.4	0.00	8.0
	Week 5	130	2.52	2.29	0.0	2.25	8.3	106	0.08	2.12	-8.6	0.00	5.9
	Week 6	123	2.56	2.61	0.0	2.00	10.0	97	-0.05	2.63	-8.6	0.00	9.0
	Week 7	125	2.42	2.15	0.0	2.00	8.0	94	-0.03	2.71	-10.0	0.00	8.0
	Week 8	125	2.63	2.20	0.0	2.00	9.0	95	0.15	2.71	-9.6	0.00	8.0
	Week 9	121	2.35	2.29	0.0	2.00	9.5	88	-0.29	3.04	-8.4	0.00	7.7

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.2.2: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	121	2.37	2.34	0.0	2.00	10.0	96	-0.28	2.46	-9.4	0.00	6.4
	Week 11	106	2.51	2.37	0.0	2.00	10.0	83	0.29	2.78	-7.6	0.00	7.3
	Week 12	109	2.35	2.39	0.0	1.75	10.0	85	-0.14	1.86	-8.0	0.00	6.0
	Week 14	103	2.50	2.40	0.0	2.00	10.0	78	0.05	2.09	-8.1	0.00	4.9
	Week 17	100	2.34	2.25	0.0	1.88	7.5	76	-0.23	2.33	-6.9	0.00	6.0
	Week 20	86	1.88	2.14	0.0	1.00	8.3	70	-0.35	2.62	-8.4	0.00	5.7
	Week 23	70	1.77	2.04	0.0	1.00	8.0	60	-0.31	2.68	-8.6	0.00	6.9
	Week 26	65	2.13	2.31	0.0	1.25	8.5	52	-0.38	2.10	-6.7	0.00	4.0
	Week 29	62	2.32	2.48	0.0	1.38	8.3	50	-0.19	2.44	-7.9	0.00	6.0
	Week 32	49	2.43	2.43	0.0	2.00	8.8	37	-0.22	2.57	-8.3	0.00	5.6
	Week 35	47	2.24	2.46	0.0	1.00	8.3	38	-0.39	1.90	-6.6	0.00	3.0
	Week 38	42	2.31	2.78	0.0	1.00	9.3	32	0.02	1.24	-4.3	0.00	3.0
	Week 41	41	1.99	2.55	0.0	0.75	9.0	34	0.13	1.61	-3.7	0.00	3.6
	Week 44	38	2.37	2.58	0.0	1.25	8.3	32	0.33	1.72	-3.7	0.00	5.1
	Week 47	32	2.02	2.28	0.0	1.25	9.0	25	-0.09	1.49	-4.1	0.00	2.9
	Week 50	29	2.11	2.36	0.0	1.00	7.8	22	0.32	2.25	-5.7	0.00	6.0
	Week 53	25	1.94	2.62	0.0	1.00	7.8	20	0.12	2.22	-4.6	0.00	5.9
	Week 56	26	2.45	2.78	0.0	1.00	7.8	21	0.52	2.40	-5.7	0.00	6.1
	Week 59	20	1.86	2.18	0.0	0.88	7.0	17	0.40	2.28	-5.7	0.00	4.1
	Week 62	19	2.71	2.51	0.0	2.00	7.0	16	0.08	2.68	-6.7	0.00	5.1
	Week 65	16	2.72	2.89	0.0	1.75	8.0	13	0.99	2.94	-4.4	0.14	8.1
	Week 68	13	1.88	2.90	0.0	0.50	7.3	12	0.35	2.03	-4.4	0.00	3.1
	Week 71	13	2.21	2.73	0.0	1.00	7.0	12	0.15	2.39	-4.4	0.00	5.7
	Week 74	11	1.36	2.13	0.0	0.75	7.0	11	0.17	1.83	-4.0	0.00	2.7
	Week 77	10	1.40	1.90	0.0	0.88	5.3	9	1.29	2.44	-1.3	0.00	5.1

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.2.3: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Europe	EV+Pembro (N= 74)												
	BASELINE	57	2.68	2.13	0.0	2.75	9.5						
	Week 1	48	3.02	2.49	0.0	2.50	9.8	38	0.08	1.11	-2.1	0.00	3.6
	Week 2	54	2.62	2.19	0.0	2.00	7.3	42	0.06	1.45	-2.9	0.00	3.7
	Week 3	50	2.68	2.45	0.0	2.00	8.5	38	0.00	1.55	-3.9	0.00	3.9
	Week 4	52	1.93	2.07	0.0	1.50	8.0	41	-0.20	1.96	-3.6	0.00	5.9
	Week 5	47	2.01	2.04	0.0	1.50	7.8	34	-0.61	1.77	-4.1	0.00	3.0
	Week 6	51	1.81	1.95	0.0	1.25	6.8	35	0.06	2.27	-4.1	0.00	6.6
	Week 7	51	1.66	1.86	0.0	0.75	6.5	34	-0.29	1.89	-4.9	0.00	4.0
	Week 8	52	1.78	1.83	0.0	1.25	6.3	34	-0.43	1.81	-3.9	0.00	3.9
	Week 9	47	1.68	1.77	0.0	1.00	6.8	33	-0.17	2.01	-6.7	0.00	3.0
	Week 10	45	1.62	1.88	0.0	1.00	7.0	30	-0.76	2.13	-7.7	0.00	2.0
	Week 11	49	1.16	1.53	0.0	0.75	6.8	35	-0.35	1.82	-3.9	0.00	5.1
	Week 12	52	1.74	2.12	0.0	0.88	8.0	37	-0.10	1.83	-4.0	0.00	4.1
	Week 14	51	1.45	2.01	0.0	0.75	7.0	35	-0.61	2.33	-4.7	-0.14	5.6
	Week 17	43	1.35	2.08	0.0	0.00	7.5	29	-0.98	2.03	-5.0	-0.29	3.1
	Week 20	41	1.40	2.17	0.0	0.50	8.3	29	-0.59	2.28	-4.4	-0.29	5.0
	Week 23	41	1.28	1.86	0.0	0.75	6.0	25	-0.81	2.40	-5.4	-0.71	5.7
	Week 26	38	1.59	2.06	0.0	1.00	6.8	26	-0.25	2.03	-5.4	0.00	4.6
	Week 29	37	1.04	1.64	0.0	0.00	6.5	27	-0.78	2.27	-5.1	-0.29	5.6
	Week 32	34	0.86	1.28	0.0	0.00	4.8	25	-0.44	2.36	-4.9	-0.14	5.9
	Week 35	31	1.57	1.80	0.0	1.00	7.0	23	-0.42	2.20	-5.4	0.00	4.6
	Week 38	31	1.38	1.69	0.0	0.50	5.3	25	-0.46	1.83	-4.4	0.00	3.4
	Week 41	28	1.56	1.94	0.0	0.63	7.0	19	-0.65	1.93	-4.3	0.00	3.1
	Week 44	27	1.06	1.43	0.0	0.00	4.5	20	-0.71	2.01	-5.4	-0.43	3.6
	Week 47	25	1.35	1.89	0.0	0.25	7.0	17	-0.39	2.40	-4.1	-0.29	4.4

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.2.3: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	27	1.61	2.19	0.0	1.00	8.8	18	-0.15	2.39	-3.9	0.00	4.7
	Week 53	28	2.00	2.53	0.0	0.88	8.3	19	-0.48	1.96	-4.9	0.00	4.3
	Week 56	25	2.49	2.21	0.0	2.00	7.0	16	-0.45	1.96	-3.6	-0.36	3.7
	Week 59	23	1.71	2.02	0.0	1.00	6.5	16	-1.05	1.60	-3.3	-1.14	2.4
	Week 62	20	1.89	1.98	0.0	1.38	7.0	17	0.14	2.21	-3.4	0.00	5.1
	Week 65	13	1.48	1.59	0.0	1.00	4.8	10	-0.63	1.72	-3.0	-0.64	3.3
	Week 68	15	2.43	2.46	0.0	1.75	7.5	13	0.47	1.47	-2.0	0.00	2.7
	Week 71	13	1.73	2.44	0.0	1.00	7.0	13	-0.44	1.85	-3.4	-0.43	3.0
	Week 74	10	1.63	2.28	0.0	0.38	6.3	8	-0.41	2.74	-3.6	-0.29	5.4
	Plat+Gem (N= 95)												
	BASELINE	76	2.44	2.47	0.0	1.75	9.0						
	Week 1	72	3.04	2.52	0.0	2.88	8.3	60	0.07	1.62	-5.3	0.00	4.9
	Week 2	71	2.97	2.31	0.0	2.50	8.3	50	0.36	1.58	-3.1	0.00	6.3
	Week 3	72	2.44	2.37	0.0	1.88	8.3	57	0.23	1.38	-2.9	0.00	5.0
	Week 4	69	2.64	2.38	0.0	2.00	9.0	54	0.25	2.47	-8.0	0.00	8.0
	Week 5	72	2.42	2.39	0.0	1.75	8.5	54	0.13	1.76	-6.3	0.00	5.3
	Week 6	69	2.34	2.41	0.0	1.75	9.0	54	0.22	2.45	-7.1	0.00	9.0
	Week 7	69	2.38	2.22	0.0	2.00	9.0	54	0.08	1.88	-5.1	0.00	7.0
	Week 8	68	2.38	1.98	0.0	2.00	7.8	48	-0.05	1.90	-7.1	0.00	5.3
	Week 9	66	2.28	2.23	0.0	2.00	9.5	47	0.12	2.56	-8.0	0.00	7.7
	Week 10	70	2.19	2.18	0.0	1.88	9.0	55	-0.14	1.95	-7.1	0.00	4.7
	Week 11	63	2.28	2.03	0.0	1.75	8.0	46	0.13	2.54	-6.4	0.00	7.3
	Week 12	66	2.33	2.20	0.0	1.75	9.0	46	-0.07	1.40	-3.7	0.00	3.6
	Week 14	66	2.66	2.30	0.0	2.13	8.0	46	0.19	1.87	-8.0	0.00	4.9
	Week 17	61	2.30	2.25	0.0	1.75	7.8	46	-0.38	2.01	-6.9	0.00	4.6
	Week 20	54	2.01	2.05	0.0	1.38	7.3	43	-0.18	2.15	-8.1	0.00	3.6

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.2.3: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 23	44	2.10	2.22	0.0	1.13	8.0	36	-0.12	2.18	-6.9	0.00	3.9
	Week 26	42	2.40	2.27	0.0	1.88	8.0	32	-0.44	2.19	-6.7	0.00	4.0
	Week 29	39	2.59	2.42	0.0	1.75	8.3	31	0.00	1.82	-6.3	0.00	3.4
	Week 32	33	2.85	2.66	0.0	2.00	8.8	24	0.19	2.45	-5.3	0.00	5.6
	Week 35	32	2.60	2.59	0.0	1.75	8.3	26	-0.12	1.64	-4.3	0.00	3.1
	Week 38	28	2.19	2.46	0.0	1.63	8.0	21	-0.01	0.87	-2.0	0.00	2.0
	Week 41	25	2.44	2.89	0.0	1.00	9.0	21	0.11	1.47	-3.0	0.00	3.6
	Week 44	24	3.01	2.91	0.0	2.13	8.3	20	0.35	1.82	-3.1	0.00	5.1
	Week 47	22	2.57	2.52	0.0	1.75	9.0	16	-0.34	1.45	-4.0	0.00	1.4
	Week 50	17	2.71	2.64	0.0	1.25	7.8	13	0.36	2.38	-2.9	0.00	6.0
	Week 53	15	2.67	3.05	0.0	1.00	7.8	12	0.14	2.66	-4.0	0.00	5.9
	Week 56	15	2.95	2.74	0.0	2.50	7.8	12	0.90	2.16	-2.0	0.00	6.1
	Week 59	11	1.95	2.20	0.0	1.00	7.0	8	0.70	1.49	-1.0	0.00	3.4
	Week 62	11	3.07	2.78	0.0	2.00	7.0	9	0.44	1.25	-1.0	0.00	3.4
	Week 65	10	3.18	2.83	0.0	2.25	8.0	7	0.71	1.59	-1.0	0.00	3.4

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.2.3: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
North America	EV+Pembro (N= 46)												
	BASELINE	35	3.00	2.62	0.0	3.00	8.8						
	Week 1	31	3.54	2.51	0.0	3.75	7.5	25	-0.08	1.67	-3.0	0.00	4.9
	Week 2	31	2.76	2.25	0.0	2.75	7.0	26	-0.60	1.35	-4.0	0.00	1.0
	Week 3	25	2.22	2.05	0.0	2.50	6.3	20	-0.64	1.17	-3.0	-0.29	1.7
	Week 4	30	2.59	2.25	0.0	2.00	6.8	24	-0.32	1.46	-3.0	0.00	3.6
	Week 5	30	2.03	1.78	0.0	1.63	5.3	24	-1.13	2.63	-7.4	0.00	3.0
	Week 6	31	2.34	2.28	0.0	1.50	7.5	24	-0.69	2.58	-7.3	0.00	4.4
	Week 7	33	1.78	1.94	0.0	1.25	5.3	23	-1.05	2.40	-7.3	-0.57	4.1
	Week 8	29	1.43	1.73	0.0	0.75	5.8	22	-1.62	2.57	-8.0	-0.43	1.4
	Week 9	27	1.25	1.58	0.0	0.75	5.3	22	-1.40	2.21	-7.3	-0.57	1.0
	Week 10	29	1.18	1.31	0.0	0.75	4.5	25	-1.67	2.56	-7.3	-0.57	1.4
	Week 11	28	1.33	1.77	0.0	0.75	6.3	21	-1.52	2.51	-7.3	-0.57	2.6
	Week 12	29	1.04	1.37	0.0	0.25	4.0	23	-1.94	2.64	-8.0	-1.00	0.6
	Week 14	28	1.22	1.52	0.0	0.75	5.3	22	-1.68	2.38	-7.3	-0.50	0.9
	Week 17	29	1.48	1.67	0.0	1.25	5.3	24	-0.95	3.02	-7.3	0.00	6.7
	Week 20	23	1.27	1.64	0.0	0.50	5.0	19	-1.44	3.36	-8.0	-0.29	5.7
	Week 23	22	0.80	1.07	0.0	0.25	3.3	19	-1.43	3.02	-8.0	0.00	3.7
	Week 26	21	1.36	1.80	0.0	0.75	7.0	17	-1.78	3.07	-8.0	-0.43	2.9
	Week 29	20	1.28	1.53	0.0	0.75	5.0	16	-1.48	2.72	-7.3	-0.43	1.4
	Week 32	21	0.89	1.25	0.0	0.00	4.8	19	-1.80	2.86	-8.0	-0.57	1.3
	Week 35	22	1.33	1.59	0.0	0.75	5.0	20	-1.44	2.71	-8.0	-0.36	0.9
	Week 38	20	1.41	1.97	0.0	0.50	6.0	17	-1.97	3.10	-7.3	-0.57	1.7
	Week 41	21	1.24	1.73	0.0	0.75	7.0	18	-1.13	2.28	-7.6	0.00	1.0
	Week 44	16	1.50	2.00	0.0	0.38	5.5	13	-1.68	2.66	-7.6	-0.57	0.6
	Week 47	16	1.80	2.23	0.0	1.00	6.5	14	-1.29	2.63	-7.6	0.00	1.1

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.2.3: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	16	1.58	2.02	0.0	0.75	5.5	13	-1.54	2.52	-7.6	-0.57	1.1
	Week 53	15	2.35	2.20	0.0	1.75	5.8	11	-0.96	2.49	-7.6	0.00	1.0
	Week 56	17	1.60	1.86	0.0	1.00	6.3	14	-1.74	2.47	-7.6	-0.64	0.1
	Week 59	17	1.94	2.16	0.0	1.00	6.5	14	-1.52	3.20	-7.6	-0.07	3.4
	Week 62	14	1.75	2.32	0.0	1.00	8.0	9	-1.70	3.18	-7.6	-0.43	1.7
	Week 68	11	1.20	2.18	0.0	0.00	6.0	9	-1.33	2.47	-7.6	-0.14	0.0
	Week 71	11	1.70	2.01	0.0	1.00	5.3	8	-1.18	2.71	-7.6	-0.14	0.9
	Plat+Gem (N= 34)												
	BASELINE	28	3.03	2.68	0.0	2.25	9.8						
	Week 1	20	2.65	2.56	0.0	2.38	8.0	17	-0.15	1.22	-3.7	0.00	1.7
	Week 2	22	2.27	2.47	0.0	1.50	7.8	20	-0.28	0.84	-2.0	0.00	1.0
	Week 3	20	2.24	2.45	0.0	1.75	8.8	16	-0.45	1.88	-6.3	0.00	2.0
	Week 4	24	1.93	2.12	0.0	1.00	6.5	19	-0.92	2.56	-8.4	-0.29	1.6
	Week 5	26	2.24	2.45	0.0	1.63	8.0	22	0.08	2.53	-8.6	0.07	3.9
	Week 6	20	1.88	2.55	0.0	1.25	9.0	15	-1.57	2.70	-8.6	-0.57	1.0
	Week 7	24	2.07	2.44	0.0	1.25	8.0	19	-0.74	2.93	-6.6	0.00	3.6
	Week 8	24	2.79	2.58	0.0	2.63	9.3	20	-0.34	2.24	-5.6	0.00	4.1
	Week 9	23	2.02	2.34	0.0	1.75	8.0	18	-0.70	2.87	-7.1	0.00	5.7
	Week 10	20	2.14	2.15	0.0	1.88	6.5	18	-0.06	2.27	-6.6	0.14	2.9
	Week 11	18	2.24	2.73	0.0	1.25	8.8	16	0.01	2.19	-5.7	0.00	3.0
	Week 12	17	1.82	1.81	0.0	1.75	5.0	14	-0.62	1.56	-4.4	0.00	2.0
	Week 14	16	1.86	2.50	0.0	1.38	8.0	14	0.17	1.84	-4.1	0.00	3.0
	Week 17	19	1.87	2.63	0.0	0.25	7.0	15	-0.89	2.61	-6.6	-0.57	3.3
	Week 20	16	1.42	1.93	0.0	0.50	6.3	13	-1.21	3.77	-8.4	0.00	3.9
	Week 23	15	1.15	1.72	0.0	0.00	5.5	14	-1.22	2.84	-6.6	0.00	2.4
	Week 26	13	1.27	1.75	0.0	0.00	5.3	12	-0.88	2.67	-6.6	0.00	1.6

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.2.3: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 29	14	1.91	2.65	0.0	0.25	8.3	11	-0.19	2.88	-6.6	0.00	6.0
	Week 32	11	1.16	1.67	0.0	0.50	4.5	8	-1.38	2.19	-6.1	-0.43	0.1
	Week 35	13	1.48	1.86	0.0	0.75	5.3	11	-1.12	2.69	-6.6	0.00	1.6
	Week 38	10	2.53	3.24	0.0	1.38	8.8	8	0.38	1.19	-1.0	0.00	3.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.2.3: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Rest of World	EV+Pembro (N= 82)												
	BASELINE	74	2.19	2.21	0.0	1.75	7.8						
	Week 1	63	2.59	2.36	0.0	2.00	7.3	53	0.24	1.57	-4.7	0.00	6.0
	Week 2	69	2.88	2.26	0.0	3.00	8.5	47	0.08	1.62	-4.6	0.00	4.0
	Week 3	64	2.73	2.44	0.0	2.75	8.0	46	-0.07	2.08	-6.6	0.00	5.6
	Week 4	65	1.89	2.12	0.0	1.00	7.3	52	-0.96	2.31	-8.0	0.00	3.3
	Week 5	62	1.83	2.09	0.0	1.38	7.5	43	-0.75	2.25	-8.0	0.00	4.4
	Week 6	65	1.87	2.16	0.0	1.00	8.0	51	-0.95	2.97	-9.1	0.00	6.9
	Week 7	66	1.94	2.15	0.0	1.25	7.0	52	-0.97	2.79	-8.0	0.00	7.1
	Week 8	69	1.96	2.17	0.0	1.25	10.0	50	-0.91	2.88	-8.0	0.00	5.6
	Week 9	68	2.35	2.44	0.0	1.75	9.0	49	-0.59	2.70	-8.0	0.00	4.1
	Week 10	65	1.94	2.14	0.0	1.00	8.0	46	-0.75	2.81	-8.0	0.00	5.3
	Week 11	61	1.60	1.93	0.0	1.00	8.0	47	-1.19	2.69	-7.9	0.00	3.7
	Week 12	62	1.77	2.05	0.0	1.00	7.8	44	-1.12	2.91	-8.0	0.00	3.6
	Week 14	61	2.19	2.22	0.0	1.75	8.0	45	-1.08	3.05	-9.1	0.00	6.3
	Week 17	60	1.98	2.00	0.0	1.63	7.0	43	-0.88	2.91	-9.1	0.00	6.7
	Week 20	56	1.67	1.81	0.0	1.00	6.8	40	-0.68	2.54	-7.7	0.00	4.7
	Week 23	54	1.59	1.90	0.0	1.00	6.8	41	-1.03	2.59	-9.1	0.00	3.3
	Week 26	55	1.90	2.12	0.0	1.25	7.8	40	-0.64	2.90	-9.1	0.00	5.6
	Week 29	50	2.17	2.30	0.0	1.25	6.8	33	-1.16	2.84	-9.1	0.00	4.4
	Week 32	47	1.95	2.04	0.0	1.50	6.8	30	-1.05	2.78	-9.1	0.00	3.1
	Week 35	45	2.09	2.08	0.0	1.50	8.0	28	-1.00	2.64	-9.1	0.00	1.9
	Week 38	46	2.04	1.93	0.0	1.50	5.8	35	-0.36	2.90	-9.1	0.00	6.0
	Week 41	46	2.04	2.12	0.0	1.13	6.3	33	-0.97	2.53	-9.1	0.00	2.0
	Week 44	43	2.49	2.30	0.0	2.50	6.8	30	-0.23	2.72	-9.1	0.00	6.0
	Week 47	38	2.01	1.93	0.0	2.00	6.0	28	-0.33	3.13	-9.1	0.00	6.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.2.3: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	32	2.21	2.10	0.0	1.75	6.5	23	-0.68	3.07	-9.1	0.00	4.0
	Week 53	33	2.14	2.25	0.0	1.25	6.8	24	-0.39	3.06	-9.1	0.00	4.1
	Week 56	30	1.91	1.98	0.0	1.38	5.8	23	-0.78	3.01	-9.1	0.00	4.0
	Week 59	29	2.69	2.55	0.0	2.00	7.0	19	-0.62	3.17	-9.1	0.00	4.0
	Week 62	28	2.19	2.16	0.0	1.88	6.8	20	-0.49	2.77	-9.1	0.00	3.6
	Week 65	22	2.27	2.13	0.0	2.25	7.0	14	-1.18	3.02	-9.1	0.00	2.0
	Week 68	20	2.34	2.21	0.0	1.88	6.0	13	-0.92	3.23	-9.1	0.00	2.6
	Week 71	18	2.26	2.39	0.0	1.75	7.3	12	-1.90	3.16	-9.1	-0.29	1.9
	Week 74	19	2.04	1.86	0.0	2.25	5.3	14	-0.72	3.46	-9.1	0.00	3.9
	Week 77	19	1.99	2.06	0.0	2.00	5.0	13	-1.22	2.78	-9.1	0.00	1.4
	Week 80	19	2.38	2.55	0.0	2.00	6.8	12	-1.13	2.81	-9.1	0.00	1.4
	Week 83	17	2.24	1.95	0.0	2.00	6.0	12	-0.79	3.44	-9.1	-0.29	4.7
	Week 86	14	2.36	2.96	0.0	0.75	7.8	10	-1.06	3.29	-9.1	0.00	3.3
	Week 89	11	1.41	2.59	0.0	0.00	7.8	9	-0.75	2.40	-5.3	0.00	2.9
	Plat+Gem (N= 73)												
	BASELINE	64	2.46	2.17	0.0	2.13	8.0						
	Week 1	54	3.11	2.76	0.0	2.88	9.0	45	0.79	2.51	-4.6	0.00	10.0
	Week 2	58	3.02	2.56	0.0	2.88	9.0	50	0.38	1.68	-3.6	0.00	5.3
	Week 3	57	2.66	2.41	0.0	2.75	9.0	50	0.35	2.05	-5.1	0.00	5.4
	Week 4	58	2.75	2.29	0.0	2.38	9.0	47	-0.16	1.73	-4.0	0.00	5.6
	Week 5	57	2.60	2.23	0.0	2.25	8.3	48	-0.07	2.00	-5.9	0.00	5.9
	Week 6	56	2.66	2.61	0.0	2.25	10.0	45	0.09	2.19	-6.4	0.00	6.4
	Week 7	56	2.43	2.02	0.0	2.25	7.3	41	-0.06	3.07	-10.0	0.00	8.0
	Week 8	54	2.49	2.39	0.0	1.75	9.0	44	0.43	3.16	-9.6	0.00	8.0
	Week 9	52	2.44	2.27	0.0	2.25	9.0	38	-0.44	3.14	-8.4	0.00	6.9
	Week 10	52	2.42	2.48	0.0	2.00	10.0	40	-0.36	2.81	-9.4	0.00	6.4

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.2.3: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	45	2.54	2.59	0.0	2.00	10.0	36	0.35	3.02	-7.6	0.00	6.9
	Week 12	47	2.35	2.73	0.0	1.25	10.0	40	-0.05	2.18	-8.0	0.00	6.0
	Week 14	43	2.45	2.49	0.0	2.00	10.0	33	-0.10	2.15	-8.1	0.00	4.9
	Week 17	40	2.32	2.10	0.0	1.75	7.0	30	0.18	2.42	-6.9	0.00	6.0
	Week 20	34	2.26	2.56	0.0	1.00	8.3	27	-0.28	2.37	-7.9	0.00	5.7
	Week 23	29	1.53	1.80	0.0	0.75	4.8	26	-0.34	2.72	-8.6	0.00	6.9
	Week 26	26	1.92	2.31	0.0	1.00	8.5	21	0.11	1.68	-5.1	0.00	4.0
	Week 29	24	1.97	2.14	0.0	1.50	7.0	20	-0.37	2.46	-7.9	0.00	4.0
	Week 32	20	2.11	1.94	0.0	2.25	6.8	17	-0.43	2.80	-8.3	0.00	4.3
	Week 35	17	1.76	2.04	0.0	1.25	6.0	14	-0.15	1.92	-4.3	0.00	2.4
	Week 38	18	2.67	3.04	0.0	1.50	9.3	13	-0.10	1.48	-4.3	0.00	2.0
	Week 41	18	1.76	2.09	0.0	1.13	6.3	14	-0.03	1.71	-3.7	0.00	2.3
	Week 44	16	1.88	2.05	0.0	1.25	6.0	13	-0.30	1.43	-3.7	0.00	1.0
	Week 47	12	1.65	2.07	0.0	0.75	6.5	10	-0.21	1.44	-4.1	0.00	1.0
	Week 50	11	2.02	2.21	0.0	1.00	6.3	8	-0.11	2.50	-5.7	0.07	3.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.2.4: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	EV+Pembro (N=146)												
	BASELINE	123	2.51	2.35	0.0	2.25	9.5						
	Week 1	103	2.93	2.45	0.0	2.50	9.8	87	0.07	1.56	-4.7	0.00	6.0
	Week 2	109	2.73	2.18	0.0	2.50	8.5	85	0.01	1.50	-4.0	0.00	4.0
	Week 3	94	2.46	2.23	0.0	2.00	8.5	74	-0.22	1.59	-6.6	0.00	5.0
	Week 4	103	2.01	2.01	0.0	1.50	7.0	86	-0.51	1.94	-7.0	0.00	5.9
	Week 5	98	1.82	1.88	0.0	1.50	7.5	76	-0.84	2.04	-7.4	0.00	3.7
	Week 6	106	1.81	1.99	0.0	1.25	8.0	83	-0.46	2.56	-7.3	0.00	6.9
	Week 7	105	1.70	1.96	0.0	1.00	7.0	80	-0.68	2.34	-7.3	0.00	7.1
	Week 8	104	1.65	1.94	0.0	1.00	10.0	81	-0.93	2.36	-8.0	-0.14	4.0
	Week 9	100	1.81	2.03	0.0	1.25	9.0	78	-0.67	2.25	-7.3	0.00	4.1
	Week 10	99	1.61	1.93	0.0	1.00	8.0	75	-1.19	2.51	-7.7	-0.29	4.6
	Week 11	96	1.31	1.72	0.0	0.75	8.0	75	-0.86	2.21	-7.3	0.00	5.1
	Week 12	99	1.55	1.96	0.0	0.75	8.0	78	-0.90	2.54	-8.0	0.00	4.1
	Week 14	96	1.59	1.96	0.0	1.00	8.0	75	-0.98	2.50	-7.3	0.00	6.3
	Week 17	97	1.53	1.82	0.0	1.00	7.0	74	-0.86	2.48	-7.3	0.00	6.7
	Week 20	90	1.44	1.81	0.0	0.75	7.0	68	-0.91	2.53	-8.0	-0.07	5.7
	Week 23	86	1.16	1.56	0.0	0.50	5.5	66	-0.96	2.41	-8.0	0.00	5.7
	Week 26	85	1.61	1.98	0.0	1.00	7.8	67	-0.62	2.50	-8.0	0.00	5.6
	Week 29	80	1.52	1.98	0.0	0.50	6.5	59	-0.93	2.45	-7.3	0.00	5.6
	Week 32	74	1.18	1.54	0.0	0.50	6.5	59	-0.82	2.56	-8.0	0.00	5.9
	Week 35	73	1.73	1.90	0.0	1.00	8.0	58	-1.00	2.43	-8.0	0.00	4.6
	Week 38	75	1.53	1.75	0.0	1.00	6.0	64	-0.77	2.68	-7.3	0.00	6.0
	Week 41	71	1.57	1.87	0.0	1.00	7.0	57	-1.02	2.15	-7.6	0.00	2.0
	Week 44	64	1.73	2.03	0.0	0.88	6.8	50	-0.69	2.44	-7.6	0.00	6.0
	Week 47	56	1.63	1.86	0.0	1.13	7.0	44	-0.68	2.69	-7.6	0.00	6.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.2.4: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	55	1.76	2.07	0.0	1.00	8.8	41	-0.75	2.60	-7.6	0.00	4.7
	Week 53	57	2.02	2.31	0.0	1.50	8.3	43	-0.46	2.46	-7.6	0.00	4.3
	Week 56	53	2.15	2.08	0.0	1.75	7.0	40	-0.90	2.51	-7.6	-0.21	4.0
	Week 59	51	2.09	2.22	0.0	1.00	6.8	39	-0.94	2.71	-7.6	-0.14	4.0
	Week 62	42	2.08	2.16	0.0	1.50	8.0	33	-0.39	2.60	-7.6	0.00	5.1
	Week 65	31	1.74	1.67	0.0	2.00	4.8	23	-0.86	2.33	-7.6	-0.29	3.3
	Week 68	31	2.19	2.31	0.0	1.50	7.5	24	-0.47	2.37	-7.6	0.00	2.7
	Week 71	30	2.24	2.30	0.0	1.75	7.3	23	-0.91	2.22	-7.6	-0.29	3.0
	Week 74	29	1.91	1.96	0.0	1.00	6.3	22	-0.23	2.87	-7.6	-0.14	5.4
	Week 77	26	1.99	2.10	0.0	1.88	6.0	18	-0.75	2.18	-7.6	-0.14	2.0
	Week 80	26	2.46	2.58	0.0	1.50	7.3	20	-0.88	2.10	-7.6	-0.14	2.1
	Week 83	21	2.33	2.18	0.0	2.00	7.5	17	-0.44	2.80	-7.6	-0.29	4.7
	Week 86	17	2.35	2.73	0.0	1.50	7.8	13	-0.01	1.96	-3.7	0.00	3.3
	Week 89	11	1.70	2.63	0.0	0.00	7.8	9	0.06	2.02	-3.9	-0.14	3.0
	Week 92	13	2.33	2.33	0.0	2.25	7.3	10	-0.27	1.99	-3.9	0.00	3.0
	Plat+Gem (N=151)												
	BASELINE	126	2.34	2.36	0.0	1.88	9.8						
	Week 1	109	2.76	2.58	0.0	2.50	9.0	91	0.54	2.04	-5.3	0.00	10.0
	Week 2	118	2.64	2.33	0.0	2.13	8.8	91	0.39	1.43	-3.1	0.00	5.3
	Week 3	114	2.40	2.25	0.0	2.00	8.8	91	0.40	1.65	-5.1	0.00	5.4
	Week 4	116	2.43	2.20	0.0	2.00	9.0	90	0.07	1.99	-8.4	0.00	5.9
	Week 5	121	2.37	2.29	0.0	2.00	8.5	95	0.30	1.93	-8.6	0.00	5.9
	Week 6	109	2.25	2.35	0.0	1.75	9.0	85	0.15	2.36	-8.6	0.00	9.0
	Week 7	115	2.28	2.20	0.0	2.00	9.0	88	0.17	2.41	-10.0	0.00	8.0
	Week 8	112	2.23	2.08	0.0	2.00	9.3	85	0.11	2.35	-9.6	0.00	8.0
	Week 9	107	2.21	2.12	0.0	2.00	9.5	76	0.16	2.49	-8.4	0.00	7.7

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.2.4: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	107	2.04	2.11	0.0	1.75	9.0	85	0.06	2.14	-9.4	0.00	6.4
	Week 11	97	2.20	2.18	0.0	1.75	8.8	73	0.19	2.60	-7.6	0.00	7.3
	Week 12	100	2.13	2.17	0.0	1.75	9.0	75	0.04	1.72	-8.0	0.00	6.0
	Week 14	99	2.40	2.26	0.0	2.00	8.0	73	0.30	1.74	-8.1	0.00	4.9
	Week 17	94	2.06	2.19	0.0	1.25	7.8	69	-0.06	2.17	-6.9	0.00	6.0
	Week 20	84	2.00	2.20	0.0	1.00	8.3	65	-0.13	2.33	-8.4	0.00	5.7
	Week 23	70	1.75	2.07	0.0	1.00	8.0	58	-0.21	2.47	-8.6	0.00	6.9
	Week 26	61	2.11	2.11	0.0	1.75	8.0	48	-0.06	2.09	-6.7	0.00	4.0
	Week 29	59	1.99	2.22	0.0	1.25	8.3	44	-0.11	2.09	-7.9	0.00	4.0
	Week 32	51	2.24	2.39	0.0	1.25	8.8	39	-0.03	2.62	-8.3	0.00	5.6
	Week 35	50	2.09	2.39	0.0	1.00	8.3	39	-0.11	1.88	-6.1	0.00	3.1
	Week 38	46	2.27	2.68	0.0	1.25	9.3	32	0.13	1.19	-4.3	0.00	3.0
	Week 41	42	2.19	2.73	0.0	1.00	9.0	32	0.13	1.61	-3.7	0.00	3.6
	Week 44	39	2.10	2.53	0.0	1.00	8.3	30	0.08	1.77	-3.7	0.00	5.1
	Week 47	33	2.05	2.35	0.0	1.25	9.0	24	-0.27	1.45	-4.1	0.00	2.9
	Week 50	27	1.89	2.22	0.0	1.00	7.8	19	0.22	2.31	-5.7	0.00	6.0
	Week 53	23	1.85	2.29	0.0	1.00	7.0	17	0.24	2.41	-4.6	0.00	5.9
	Week 56	20	1.43	2.13	0.0	0.75	7.8	16	0.43	2.44	-5.7	0.00	6.1
	Week 59	17	1.87	2.23	0.0	1.00	7.0	13	0.05	2.35	-5.7	0.00	4.1
	Week 62	14	2.54	2.57	0.0	1.75	7.0	11	0.26	2.38	-4.1	0.00	5.1
	Week 65	13	2.71	2.91	0.0	1.50	8.0	10	0.93	3.27	-4.4	0.07	8.1
	Week 68	10	1.70	2.70	0.0	0.50	6.8	9	0.06	2.24	-4.4	0.00	3.1
	Week 71	10	1.73	2.46	0.0	0.75	7.0	9	0.29	2.78	-4.4	0.00	5.7

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.2.4: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	EV+Pembro (N= 56)												
	BASELINE	43	2.57	2.11	0.0	2.75	7.8						
	Week 1	39	2.98	2.46	0.0	2.50	7.3	29	0.25	1.10	-2.4	0.00	3.6
	Week 2	45	2.84	2.35	0.0	3.00	6.8	30	-0.34	1.53	-4.6	0.00	2.6
	Week 3	45	2.95	2.63	0.0	3.00	8.0	30	0.01	2.11	-5.9	0.00	5.6
	Week 4	44	2.13	2.42	0.0	1.13	8.0	31	-0.70	2.37	-8.0	0.00	3.6
	Week 5	41	2.20	2.26	0.0	1.50	7.8	25	-0.63	2.64	-8.0	0.00	4.4
	Week 6	41	2.30	2.39	0.0	2.00	7.5	27	-0.92	3.08	-9.1	0.00	4.4
	Week 7	45	2.07	2.09	0.0	1.75	7.0	29	-1.04	2.79	-8.0	0.00	4.1
	Week 8	46	2.12	2.03	0.0	1.63	6.3	25	-0.82	3.09	-8.0	0.00	5.6
	Week 9	42	2.18	2.33	0.0	1.13	7.5	26	-0.51	2.90	-8.0	0.00	4.0
	Week 10	40	1.84	1.93	0.0	1.25	7.0	26	-0.39	2.69	-8.0	0.00	5.3
	Week 11	42	1.57	1.86	0.0	0.88	6.3	28	-1.26	2.91	-7.9	0.00	3.3
	Week 12	44	1.77	2.01	0.0	0.75	7.3	26	-1.05	2.77	-8.0	0.00	3.0
	Week 14	44	2.02	2.22	0.0	0.88	6.8	27	-1.23	3.19	-9.1	0.00	4.1
	Week 17	35	2.05	2.33	0.0	1.25	7.5	22	-1.13	3.31	-9.1	0.00	3.1
	Week 20	30	1.70	2.17	0.0	1.00	8.3	20	-0.47	3.08	-7.7	0.00	4.7
	Week 23	31	1.81	2.22	0.0	1.00	6.8	19	-1.38	3.30	-9.1	0.00	4.0
	Week 26	29	1.96	2.23	0.0	1.00	6.5	16	-1.30	3.55	-9.1	0.00	4.6
	Week 29	27	1.87	2.15	0.0	1.00	6.8	17	-1.66	3.09	-9.1	0.00	2.4
	Week 32	28	1.88	2.13	0.0	1.13	6.8	15	-1.90	3.09	-9.1	0.00	2.0
	Week 35	25	1.84	1.95	0.0	1.25	5.0	13	-0.64	2.99	-9.1	0.00	4.3
	Week 38	22	2.28	2.17	0.0	2.38	5.8	13	-0.64	2.92	-9.1	0.00	3.0
	Week 41	24	2.17	2.30	0.0	1.63	7.0	13	-0.52	2.91	-9.1	0.00	3.1
	Week 44	22	2.23	2.28	0.0	1.63	5.5	13	-0.68	2.91	-9.1	0.00	3.6
	Week 47	23	2.07	2.25	0.0	0.75	5.8	15	-0.26	3.19	-9.1	0.00	4.4

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.2.4: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	2.13	2.25	0.0	1.50	6.0	13	-0.59	3.24	-9.1	0.00	4.6
	Week 53	19	2.47	2.39	0.0	2.25	6.8	11	-0.87	3.03	-9.1	0.00	2.4
	Week 56	19	1.72	1.92	0.0	1.25	5.8	13	-1.02	2.95	-9.1	0.00	3.7
	Week 59	18	2.42	2.59	0.0	1.50	7.0	10	-1.33	2.96	-9.1	0.00	0.7
	Week 62	20	1.80	2.06	0.0	0.75	5.8	13	-0.74	2.99	-9.1	0.00	3.1
	Week 65	12	2.23	2.69	0.0	0.75	7.0	8	-1.91	3.15	-9.1	-0.43	0.0
	Week 68	15	1.92	2.32	0.0	1.25	6.0	11	-0.60	3.02	-9.1	0.00	2.4
	Week 71	12	1.23	2.12	0.0	0.25	6.0	10	-1.71	3.38	-9.1	-0.29	2.3
	Week 77	11	0.98	1.78	0.0	0.00	5.0	10	-1.63	3.02	-9.1	-0.07	0.3
	Week 80	10	1.40	2.02	0.0	0.38	5.5	7	-1.43	3.41	-9.1	0.00	0.1
	Plat+Gem (N= 51)												
	BASELINE	42	3.18	2.39	0.0	3.00	7.0						
	Week 1	37	3.76	2.55	0.0	3.75	9.0	31	-0.40	1.62	-4.6	0.00	3.4
	Week 2	33	3.77	2.60	0.0	4.25	9.0	29	-0.13	1.81	-3.6	0.00	6.3
	Week 3	35	2.83	2.81	0.0	2.00	9.0	32	-0.39	1.91	-6.3	0.00	5.0
	Week 4	35	3.04	2.62	0.0	3.00	9.0	30	-0.60	2.85	-8.0	0.00	8.0
	Week 5	34	2.76	2.46	0.0	2.63	8.3	29	-0.80	1.99	-6.3	-0.14	4.0
	Week 6	36	2.84	2.91	0.0	1.88	10.0	29	-0.72	2.58	-7.1	-0.14	4.9
	Week 7	34	2.60	2.09	0.0	2.38	7.0	26	-1.05	2.76	-8.0	0.00	3.4
	Week 8	34	3.33	2.52	0.0	4.00	9.0	27	0.00	3.04	-7.1	0.00	5.3
	Week 9	34	2.57	2.62	0.0	2.13	9.0	27	-1.33	3.45	-8.0	0.00	6.0
	Week 10	35	2.97	2.66	0.0	2.75	10.0	28	-0.99	2.68	-7.7	0.00	1.9
	Week 11	29	2.92	2.75	0.0	3.00	10.0	25	0.19	2.86	-6.4	0.00	6.4
	Week 12	30	2.75	2.87	0.0	2.25	10.0	25	-0.67	1.84	-4.9	0.00	4.0
	Week 14	26	2.82	2.84	0.0	3.00	10.0	20	-0.68	2.48	-8.0	0.00	4.3
	Week 17	26	2.88	2.41	0.0	3.00	7.5	22	-0.97	2.45	-6.9	0.00	2.1

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.2.4: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 20	20	2.00	2.31	0.0	0.63	7.0	18	-1.26	3.01	-8.1	-0.29	3.4
	Week 23	18	1.75	1.90	0.0	1.00	4.5	18	-1.02	2.55	-6.9	-0.29	2.9
	Week 26	20	1.91	2.60	0.0	0.50	8.5	17	-1.16	2.10	-6.6	-0.29	1.1
	Week 29	18	3.21	2.68	0.0	4.13	8.3	18	-0.26	2.55	-6.6	0.00	6.0
	Week 32	13	2.69	2.30	0.0	2.25	7.0	10	-1.24	2.12	-5.3	-0.57	2.0
	Week 35	12	2.35	2.17	0.0	1.63	5.8	12	-1.08	2.20	-6.6	-0.21	1.9
	Week 38	10	3.00	3.16	0.0	2.13	8.8	10	-0.27	0.91	-2.0	0.00	0.7
	Week 41	10	2.28	2.14	0.0	2.00	5.5	10	0.36	1.21	-2.0	0.43	2.0
	Week 44	10	3.53	2.21	0.0	3.25	7.0	10	0.61	1.07	-1.0	0.36	2.9
	Week 47	10	2.05	2.05	0.0	2.00	5.3	9	-0.08	1.26	-2.7	0.00	1.4
	Week 56	10	3.83	2.97	0.0	4.38	7.8	8	0.75	2.21	-2.0	0.00	5.1

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.2.5: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Visceral metastases	EV+Pembro (N=148)												
	BASELINE	121	2.67	2.33	0.0	2.50	9.5						
	Week 1	106	3.11	2.52	0.0	2.88	9.8	87	0.16	1.51	-4.7	0.00	6.0
	Week 2	110	3.00	2.20	0.0	3.00	8.5	83	0.00	1.47	-4.6	0.00	3.7
	Week 3	98	2.65	2.39	0.0	2.00	8.5	73	-0.19	1.87	-6.6	0.00	5.6
	Week 4	105	2.25	2.22	0.0	1.75	8.0	83	-0.42	2.27	-8.0	0.00	5.9
	Week 5	101	2.09	2.06	0.0	1.50	7.8	72	-0.79	2.35	-8.0	0.00	4.4
	Week 6	106	2.03	2.19	0.0	1.38	8.0	82	-0.64	2.74	-9.1	0.00	5.6
	Week 7	110	1.90	2.04	0.0	1.25	7.0	76	-0.92	2.48	-8.0	0.00	4.0
	Week 8	108	1.76	1.86	0.0	1.13	6.8	75	-1.04	2.82	-8.0	0.00	5.6
	Week 9	105	1.87	1.97	0.0	1.25	7.5	77	-0.68	2.55	-8.0	0.00	4.0
	Week 10	101	1.68	1.90	0.0	1.00	8.0	73	-1.11	2.89	-8.0	0.00	5.3
	Week 11	98	1.48	1.82	0.0	0.75	8.0	70	-0.91	2.62	-7.9	0.00	5.1
	Week 12	101	1.71	1.98	0.0	0.75	7.8	72	-1.03	2.90	-8.0	0.00	4.1
	Week 14	103	1.79	2.06	0.0	1.00	8.0	74	-1.13	2.81	-9.1	0.00	5.6
	Week 17	96	1.67	1.92	0.0	1.13	7.5	69	-0.91	2.94	-9.1	0.00	6.7
	Week 20	87	1.50	1.77	0.0	1.00	8.3	64	-0.73	2.87	-8.0	0.00	5.7
	Week 23	85	1.42	1.78	0.0	0.75	6.5	61	-1.20	2.75	-9.1	0.00	5.7
	Week 26	81	1.62	1.92	0.0	1.00	7.8	58	-0.89	2.75	-9.1	0.00	4.6
	Week 29	72	1.63	1.95	0.0	1.00	6.5	52	-1.04	2.81	-9.1	0.00	5.6
	Week 32	71	1.39	1.66	0.0	1.00	6.8	53	-1.18	2.96	-9.1	0.00	5.9
	Week 35	70	1.69	1.84	0.0	1.00	7.0	52	-0.96	2.75	-9.1	0.00	4.6
	Week 38	70	1.73	1.88	0.0	1.00	6.0	57	-0.75	2.96	-9.1	0.00	6.0
	Week 41	66	1.81	2.07	0.0	1.00	7.0	49	-0.96	2.47	-9.1	0.00	3.1
	Week 44	59	2.00	2.06	0.0	1.50	6.8	44	-0.59	2.70	-9.1	0.00	6.0
	Week 47	52	1.85	2.01	0.0	1.50	6.5	38	-0.61	3.08	-9.1	0.00	6.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.2.5: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	49	2.11	2.27	0.0	1.25	8.8	35	-0.64	3.03	-9.1	0.00	4.7
	Week 53	50	2.29	2.39	0.0	1.63	8.3	34	-0.82	2.89	-9.1	0.00	4.3
	Week 56	45	2.28	1.98	0.0	2.00	6.5	32	-0.63	2.89	-9.1	0.00	4.0
	Week 59	44	2.45	2.36	0.0	2.00	7.0	30	-1.10	2.95	-9.1	0.00	4.0
	Week 62	38	2.09	2.20	0.0	1.38	8.0	27	-0.34	2.92	-9.1	0.00	5.1
	Week 65	25	1.98	2.12	0.0	2.00	7.0	18	-1.40	3.05	-9.1	-0.64	3.3
	Week 68	31	2.07	2.19	0.0	1.50	7.3	23	-0.70	3.09	-9.1	0.00	2.7
	Week 71	27	1.94	2.21	0.0	1.25	7.3	20	-1.48	3.06	-9.1	-0.50	3.0
	Week 74	23	1.77	1.96	0.0	1.00	5.3	17	-0.94	3.62	-9.1	-0.14	5.4
	Week 77	24	1.78	2.13	0.0	0.25	6.0	18	-1.32	2.86	-9.1	-0.14	2.0
	Week 80	22	2.63	2.72	0.0	2.00	7.3	16	-1.44	2.95	-9.1	0.00	1.4
	Week 83	19	2.34	2.44	0.0	1.25	7.5	14	-1.42	3.56	-9.1	-0.29	4.7
	Week 86	14	2.68	3.12	0.0	1.13	7.8	10	-1.10	3.48	-9.1	0.00	3.3
	Week 89	10	1.38	2.73	0.0	0.00	7.8	8	-0.66	2.05	-3.9	-0.21	2.9
	Week 92	11	2.45	2.88	0.0	1.00	7.3	8	-0.41	2.16	-3.9	0.00	3.0
	Plat+Gem (N=157)												
	BASELINE	130	2.73	2.42	0.0	2.63	9.8						
	Week 1	112	3.15	2.62	0.0	3.00	9.0	94	0.33	1.81	-5.3	0.00	7.6
	Week 2	112	2.76	2.47	0.0	2.00	9.0	92	0.24	1.41	-3.1	0.00	5.3
	Week 3	112	2.56	2.47	0.0	2.00	9.0	94	0.33	1.69	-5.1	0.00	5.4
	Week 4	113	2.62	2.38	0.0	2.00	9.0	91	-0.08	2.06	-8.4	0.00	8.0
	Week 5	115	2.45	2.44	0.0	2.00	8.5	95	0.02	2.17	-8.6	0.00	5.9
	Week 6	107	2.38	2.62	0.0	1.75	10.0	87	-0.04	2.53	-8.6	0.00	9.0
	Week 7	109	2.28	2.13	0.0	2.00	9.0	84	-0.16	2.68	-10.0	0.00	8.0
	Week 8	107	2.34	2.30	0.0	2.00	9.3	85	-0.04	2.47	-9.6	0.00	8.0
	Week 9	105	2.20	2.24	0.0	2.00	9.5	81	-0.14	2.78	-8.4	0.00	7.7

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.2.5: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	104	2.20	2.31	0.0	1.75	10.0	85	-0.30	2.33	-9.4	0.00	6.4
	Week 11	91	2.30	2.38	0.0	1.75	10.0	72	0.19	2.65	-7.6	0.00	7.3
	Week 12	94	2.06	2.31	0.0	1.25	10.0	76	-0.23	1.63	-8.0	0.00	6.0
	Week 14	90	2.39	2.35	0.0	2.00	10.0	69	0.01	1.58	-8.1	0.00	4.9
	Week 17	90	2.11	2.20	0.0	1.38	7.8	69	-0.47	2.16	-6.9	0.00	6.0
	Week 20	74	1.91	2.21	0.0	1.00	8.3	60	-0.45	2.57	-8.4	0.00	5.7
	Week 23	63	1.74	2.12	0.0	1.00	8.0	56	-0.33	2.49	-8.6	0.00	6.9
	Week 26	55	2.04	2.12	0.0	1.25	8.0	47	-0.14	1.78	-6.1	0.00	4.0
	Week 29	53	2.24	2.38	0.0	1.50	8.3	43	-0.13	1.93	-7.9	0.00	4.0
	Week 32	43	2.20	2.36	0.0	1.25	8.8	37	-0.18	2.71	-8.3	0.00	5.6
	Week 35	39	2.10	2.40	0.0	1.00	8.0	34	-0.25	1.93	-6.1	0.00	3.1
	Week 38	37	2.62	3.06	0.0	1.25	9.3	29	0.07	1.06	-2.0	0.00	3.0
	Week 41	33	1.95	2.48	0.0	1.00	9.0	28	-0.03	1.45	-3.7	0.00	3.0
	Week 44	32	2.24	2.50	0.0	1.13	8.3	28	0.03	1.39	-3.1	0.00	3.1
	Week 47	28	1.88	2.47	0.0	0.63	9.0	23	-0.43	1.14	-4.0	0.00	1.4
	Week 50	22	1.77	2.07	0.0	1.00	6.3	19	-0.08	1.40	-2.9	0.00	3.0
	Week 53	19	1.93	2.50	0.0	1.00	7.8	15	-0.45	1.47	-4.0	0.00	2.0
	Week 56	18	1.93	2.38	0.0	0.88	7.8	16	0.10	1.16	-2.0	0.00	3.0
	Week 59	13	1.98	2.02	0.0	1.00	5.0	11	0.14	1.63	-1.9	0.00	4.1
	Week 62	11	2.82	2.31	0.0	2.50	7.0	10	-0.31	2.84	-6.7	0.00	5.1

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.2.5: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Lymph node only	EV+Pembro (N= 43)												
	BASELINE	36	1.85	2.00	0.0	1.25	7.0						
	Week 1	30	2.38	2.20	0.0	2.00	7.3	24	-0.21	1.24	-3.0	0.00	3.6
	Week 2	37	2.04	2.08	0.0	1.50	7.3	27	-0.52	1.58	-4.0	0.00	4.0
	Week 3	35	2.38	2.29	0.0	2.50	8.0	26	-0.30	1.17	-3.4	0.00	3.0
	Week 4	36	1.38	1.72	0.0	1.00	7.3	29	-1.08	1.38	-4.0	-0.43	1.0
	Week 5	34	1.41	1.71	0.0	1.00	6.3	26	-0.88	1.83	-5.4	-0.21	3.7
	Week 6	34	1.56	1.88	0.0	1.00	7.0	23	-0.86	2.26	-4.1	-0.43	6.6
	Week 7	34	1.38	1.87	0.0	0.63	6.8	28	-0.67	2.48	-5.6	-0.14	7.1
	Week 8	35	1.87	2.34	0.0	1.25	10.0	26	-0.63	1.68	-3.3	0.00	4.0
	Week 9	30	1.87	2.56	0.0	0.63	9.0	22	-0.92	1.86	-5.0	-0.36	3.3
	Week 10	31	1.28	1.59	0.0	0.75	6.0	23	-0.78	1.41	-3.7	-0.43	1.7
	Week 11	34	1.01	1.38	0.0	0.75	6.3	28	-1.34	1.95	-5.6	-0.36	1.3
	Week 12	35	0.94	1.39	0.0	0.25	6.3	27	-0.87	1.81	-5.0	0.00	3.6
	Week 14	30	1.08	1.75	0.0	0.00	6.5	23	-1.29	2.06	-6.4	-0.43	1.0
	Week 17	30	1.33	1.95	0.0	0.00	6.0	22	-1.19	2.02	-7.3	-0.36	1.9
	Week 20	27	1.32	2.13	0.0	0.25	6.0	19	-1.39	2.06	-7.3	-0.29	0.6
	Week 23	27	0.97	1.75	0.0	0.00	6.8	20	-0.84	2.44	-7.3	0.00	3.7
	Week 26	27	1.69	2.27	0.0	0.00	7.0	19	-0.95	2.81	-7.3	0.00	5.6
	Week 29	28	1.40	2.09	0.0	0.00	6.8	19	-1.61	2.20	-7.3	-0.57	1.0
	Week 32	24	1.28	1.97	0.0	0.00	6.5	16	-1.07	1.88	-6.9	-0.50	0.9
	Week 35	22	1.89	2.11	0.0	1.50	8.0	15	-1.23	1.86	-6.3	-0.71	1.0
	Week 38	21	1.30	1.55	0.0	0.75	5.0	15	-0.96	2.07	-6.3	-0.29	2.0
	Week 41	22	1.24	1.62	0.0	0.88	5.3	15	-1.12	2.16	-5.6	0.00	1.3
	Week 44	22	1.39	2.14	0.0	0.25	6.8	15	-1.25	2.23	-6.6	0.00	1.3
	Week 47	21	1.13	1.37	0.0	0.75	5.0	16	-0.72	2.59	-6.0	-0.14	3.6

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.2.5: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	1.19	1.60	0.0	0.50	5.0	15	-1.24	2.18	-5.1	-0.29	2.0
	Week 53	20	1.54	2.03	0.0	0.13	5.8	15	-0.30	1.96	-5.0	0.00	3.9
	Week 56	21	1.37	1.85	0.0	0.75	7.0	16	-1.84	2.15	-6.1	-1.86	1.9
	Week 59	21	1.52	2.02	0.0	0.75	6.5	16	-1.19	2.53	-6.7	-0.93	3.3
	Week 62	19	1.49	1.69	0.0	0.75	5.3	15	-1.06	2.49	-6.6	0.00	3.6
	Week 65	16	1.55	1.84	0.0	0.88	6.0	11	-0.90	1.81	-5.0	-0.29	2.0
	Week 68	13	1.62	2.19	0.0	0.25	6.0	10	-0.19	0.91	-1.7	0.00	1.3
	Week 71	13	1.48	2.12	0.0	0.25	6.0	11	-0.77	1.77	-5.7	-0.29	1.0
	Week 74	13	1.08	1.44	0.0	0.25	4.3	11	-0.79	2.36	-5.3	-0.29	3.9
	Week 77	13	1.52	1.94	0.0	0.50	5.0	10	-0.61	1.69	-4.0	-0.07	1.4
	Week 80	13	1.56	1.85	0.0	1.00	6.0	10	-0.46	1.38	-3.3	-0.36	2.1
	Week 83	11	1.32	1.26	0.0	1.00	3.5	10	-0.26	1.88	-3.6	-0.43	3.3
	Week 86	11	1.00	0.97	0.0	0.75	2.5	9	-0.33	1.55	-2.7	-0.29	3.0
	Plat+Gem (N= 37)												
	BASELINE	30	1.98	2.10	0.0	1.38	6.8						
	Week 1	26	2.82	2.59	0.0	2.13	8.8	21	-0.09	1.40	-4.6	0.00	2.1
	Week 2	31	3.38	2.20	0.0	3.25	8.0	21	0.14	2.03	-3.6	0.14	6.3
	Week 3	30	2.38	2.23	0.0	2.00	8.8	23	-0.32	1.38	-2.9	0.00	2.1
	Week 4	32	2.55	2.15	0.0	2.50	7.0	23	-0.12	2.73	-8.0	0.00	5.9
	Week 5	33	2.40	1.99	0.0	2.00	7.5	23	0.00	1.36	-5.0	0.00	2.6
	Week 6	32	2.44	2.20	0.0	2.00	7.5	23	-0.21	1.61	-5.0	0.00	2.1
	Week 7	32	2.73	2.37	0.0	2.00	8.0	24	0.15	1.83	-5.0	0.21	3.4
	Week 8	32	3.06	2.04	0.0	2.88	6.8	20	0.33	2.31	-7.1	0.36	4.1
	Week 9	30	2.83	2.36	0.0	2.75	8.3	17	-0.82	2.61	-8.0	0.00	1.7
	Week 10	30	2.69	2.35	0.0	2.38	7.8	22	0.22	2.10	-5.9	0.00	4.7
	Week 11	29	2.63	2.28	0.0	3.00	8.8	21	-0.18	2.66	-6.4	0.00	5.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.5.2.5: BPI-SF - Observed Means and Change from Baseline of Pain Severity by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 12	28	2.71	2.46	0.0	2.00	9.5	17	-0.13	1.85	-4.9	0.00	2.0
	Week 14	28	2.81	2.69	0.0	2.00	8.0	18	0.12	2.70	-8.0	0.00	4.9
	Week 17	25	2.84	2.54	0.0	2.00	7.5	17	0.14	1.75	-6.1	0.57	1.9
	Week 20	23	2.41	2.34	0.0	1.50	7.3	17	-0.05	2.27	-5.3	0.00	3.4
	Week 23	20	1.98	1.82	0.0	2.00	4.8	16	-0.46	2.34	-6.4	0.00	2.9
	Week 26	21	2.39	2.60	0.0	1.75	8.5	14	-0.92	2.51	-6.7	0.00	1.1
	Week 29	19	2.66	2.53	0.0	2.00	8.3	15	0.00	2.59	-6.3	0.00	6.0
	Week 32	18	2.63	2.58	0.0	1.63	7.0	10	-0.80	2.21	-5.3	0.00	1.0
	Week 35	19	2.38	2.33	0.0	1.50	8.3	14	-0.27	1.57	-4.3	0.00	1.9
	Week 38	15	2.10	2.11	0.0	2.00	6.8	10	-0.11	1.51	-4.3	0.14	1.0
	Week 41	15	3.00	2.99	0.0	2.00	9.0	11	0.35	1.54	-3.6	0.00	2.0
	Week 44	14	2.77	2.78	0.0	1.75	8.3	10	0.16	1.68	-3.7	0.00	2.9
	Week 47	12	2.35	1.88	0.0	2.00	6.3	8	0.21	2.02	-4.1	0.50	2.9
	Week 50	11	3.41	2.55	0.0	3.00	7.8	5	0.40	3.63	-5.7	1.86	3.3

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.1: BPI-SF - Observed Means and Change from Baseline of Pain Interference - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
EV+Pembro (N=240)												
BASELINE	209	2.22	2.60	0.0	1.00	9.6						
Week 1	190	2.44	2.50	0.0	1.71	9.6	187	0.25	2.00	-7.9	0.00	7.7
Week 2	204	2.55	2.47	0.0	1.86	10.0	192	0.48	2.29	-6.9	0.14	10.0
Week 3	199	2.45	2.36	0.0	1.86	9.3	185	0.23	2.40	-8.0	0.00	8.0
Week 4	195	1.95	2.19	0.0	1.14	8.3	181	-0.21	2.35	-8.6	0.00	6.6
Week 5	193	1.91	2.25	0.0	1.00	8.4	177	-0.17	2.39	-8.6	0.00	7.7
Week 6	189	1.83	2.16	0.0	1.00	9.6	172	-0.30	2.52	-8.0	0.00	7.4
Week 7	196	1.86	2.29	0.0	1.00	10.0	178	-0.31	2.82	-8.6	0.00	10.0
Week 8	192	1.81	2.34	0.0	0.71	10.0	173	-0.41	2.83	-8.4	0.00	8.1
Week 9	198	2.03	2.35	0.0	1.00	9.7	182	-0.17	2.72	-8.1	0.00	9.7
Week 10	191	1.75	2.20	0.0	1.00	8.4	176	-0.36	2.68	-8.6	0.00	8.4
Week 11	196	1.66	2.10	0.0	0.93	9.7	178	-0.59	2.54	-8.6	0.00	5.7
Week 12	186	1.81	2.26	0.0	0.71	10.0	172	-0.40	2.72	-8.6	0.00	9.1
Week 14	185	1.94	2.31	0.0	1.00	9.3	168	-0.23	2.62	-8.6	0.00	9.0
Week 17	178	1.88	2.26	0.0	0.93	9.4	163	-0.32	2.79	-8.6	0.00	6.1
Week 20	167	2.02	2.51	0.0	1.00	10.0	155	-0.04	2.80	-8.1	0.00	8.9
Week 23	162	1.96	2.28	0.0	1.00	9.4	151	-0.10	2.67	-8.1	0.00	7.0
Week 26	156	2.01	2.36	0.0	1.00	9.3	145	-0.14	2.95	-8.6	0.00	7.0
Week 29	157	1.97	2.25	0.0	1.00	9.7	146	-0.02	2.51	-8.6	0.00	6.3
Week 32	135	2.33	2.44	0.0	1.71	8.9	125	0.44	2.73	-8.0	0.00	8.3
Week 35	132	2.12	2.25	0.0	1.36	9.3	122	0.23	2.61	-7.7	0.00	7.0
Week 38	132	1.99	2.30	0.0	1.00	9.7	124	-0.05	2.97	-8.6	0.00	7.1
Week 41	129	2.26	2.44	0.0	1.43	10.0	119	0.35	2.74	-8.1	0.00	7.0
Week 44	108	2.09	2.23	0.0	1.21	8.4	100	0.33	3.02	-7.9	0.00	7.0
Week 47	100	2.08	2.28	0.0	1.71	9.4	94	0.15	3.06	-8.6	0.00	7.4

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.1: BPI-SF - Observed Means and Change from Baseline of Pain Interference - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	89	2.02	2.16	0.0	1.29	7.3	84	0.45	2.49	-7.7	0.00	6.6
Week 53	79	1.84	2.12	0.0	1.14	8.0	74	0.11	3.18	-8.3	0.00	8.0
Week 56	81	1.92	2.44	0.0	0.71	9.9	76	0.11	3.28	-8.3	0.00	9.7
Week 59	72	1.85	2.24	0.0	0.86	9.1	68	0.05	3.03	-8.3	0.00	9.0
Week 62	65	1.78	2.28	0.0	0.57	8.9	63	0.25	3.00	-8.3	0.00	8.7
Week 65	58	2.09	2.43	0.0	1.00	7.9	54	-0.06	3.00	-8.1	0.00	6.7
Week 68	53	1.78	2.16	0.0	0.86	7.4	52	-0.05	3.08	-8.1	0.00	6.4
Week 71	51	1.76	2.03	0.0	1.00	7.0	49	0.03	2.95	-8.1	0.00	6.9
Week 74	47	1.90	1.98	0.0	1.14	6.1	46	0.39	2.31	-7.6	0.07	6.0
Week 77	44	2.44	2.43	0.0	2.50	8.6	42	0.56	2.75	-6.7	0.50	5.4
Week 80	40	2.16	2.50	0.0	1.07	7.9	37	0.05	2.76	-7.1	0.00	5.1
Week 83	37	2.13	2.15	0.0	2.00	7.7	35	-0.13	2.76	-7.4	0.00	4.3
Week 86	34	2.09	2.23	0.0	1.21	7.7	31	0.08	2.86	-7.1	0.00	5.4
Week 89	33	2.10	2.19	0.0	2.29	7.7	31	-0.18	2.68	-7.3	0.00	4.9
Week 92	27	2.68	2.70	0.0	2.14	9.4	25	0.79	2.49	-3.1	0.00	6.0
Week 95	22	2.75	2.69	0.0	3.07	7.0	21	0.56	2.86	-4.6	0.00	5.9
Week 98	18	1.98	2.61	0.0	0.43	8.4	17	-0.37	2.19	-3.9	0.00	3.3
Week 101	14	2.10	2.78	0.0	0.43	7.4	14	0.48	2.08	-3.0	0.00	6.1
Week 104	10	2.37	3.16	0.0	0.71	9.1	10	0.64	2.28	-3.3	0.00	4.7

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.1: BPI-SF - Observed Means and Change from Baseline of Pain Interference - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Plat+Gem (N=242)												
BASELINE	190	2.64	2.77	0.0	1.57	10.0						
Week 1	179	2.72	2.57	0.0	2.43	10.0	164	0.23	2.24	-7.7	0.00	9.7
Week 2	173	2.66	2.57	0.0	2.14	10.0	153	0.22	2.38	-7.7	0.00	7.9
Week 3	185	2.50	2.59	0.0	1.57	9.0	163	0.03	2.36	-7.7	0.00	8.6
Week 4	183	2.29	2.35	0.0	1.71	9.1	157	-0.20	2.30	-7.9	0.00	7.6
Week 5	187	2.41	2.36	0.0	1.86	9.3	157	0.07	2.53	-7.7	0.00	8.7
Week 6	174	2.23	2.46	0.0	1.43	9.3	151	-0.30	2.47	-7.9	0.00	7.6
Week 7	187	2.12	2.30	0.0	1.29	8.9	160	-0.29	2.45	-7.9	0.00	8.1
Week 8	167	2.29	2.48	0.0	1.43	10.0	146	-0.17	2.83	-8.0	0.00	10.0
Week 9	177	2.35	2.45	0.0	1.57	9.4	152	-0.13	2.71	-8.3	0.00	9.3
Week 10	166	2.15	2.34	0.0	1.29	8.9	141	-0.28	2.56	-7.9	0.00	8.3
Week 11	168	1.98	2.31	0.0	1.07	9.0	145	-0.49	2.32	-8.1	0.00	6.1
Week 12	159	2.08	2.24	0.0	1.29	9.4	140	-0.16	2.32	-7.9	0.00	6.6
Week 14	153	2.10	2.13	0.0	1.29	8.0	129	-0.27	2.42	-8.3	0.00	6.0
Week 17	156	2.27	2.38	0.0	1.43	8.7	133	0.02	2.64	-7.9	0.00	6.9
Week 20	126	1.80	2.25	0.0	1.00	10.0	111	-0.46	2.59	-7.7	0.00	8.3
Week 23	115	2.28	2.59	0.0	1.43	9.0	98	0.16	2.53	-5.7	0.00	8.0
Week 26	108	2.03	2.31	0.0	1.00	9.0	96	-0.04	2.44	-6.3	0.00	6.0
Week 29	100	1.88	1.93	0.0	1.36	7.0	87	-0.01	2.08	-4.6	0.00	5.7
Week 32	83	1.93	2.33	0.0	1.00	8.4	77	0.11	2.45	-5.9	0.00	8.0
Week 35	76	2.04	2.24	0.0	1.14	9.4	70	0.26	2.39	-5.6	0.00	6.7
Week 38	74	1.76	2.25	0.0	0.93	8.1	66	0.06	2.55	-5.7	0.00	7.4
Week 41	65	1.84	2.18	0.0	1.00	8.0	57	0.13	2.39	-6.0	0.00	8.0
Week 44	60	2.25	2.28	0.0	1.64	7.3	54	0.37	2.48	-4.9	0.00	7.0
Week 47	56	2.13	2.17	0.0	1.21	7.6	50	0.32	2.61	-5.0	0.07	6.1

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.1: BPI-SF - Observed Means and Change from Baseline of Pain Interference - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	51	2.68	2.50	0.0	2.29	8.1	47	0.42	2.41	-5.4	0.00	5.6
Week 53	46	1.76	1.96	0.0	0.93	7.0	42	0.01	1.70	-4.1	0.00	3.7
Week 56	39	2.44	2.68	0.0	1.71	9.7	34	0.26	2.57	-3.7	0.00	7.3
Week 59	37	1.85	2.17	0.0	1.29	8.0	33	0.09	2.63	-4.3	0.00	8.0
Week 62	32	1.58	1.76	0.0	1.00	6.0	29	-0.11	2.44	-5.6	0.00	4.6
Week 65	30	1.47	1.94	0.0	0.57	6.6	26	-0.01	2.30	-7.0	0.00	4.3
Week 68	25	2.37	2.81	0.0	1.00	8.0	21	0.64	2.16	-3.3	0.00	6.1
Week 71	22	2.29	2.81	0.0	1.43	8.9	19	0.53	1.81	-3.1	0.43	6.4
Week 74	21	1.91	2.37	0.0	1.00	8.6	18	-0.01	1.68	-3.9	0.00	2.6
Week 77	18	2.33	2.71	0.0	0.86	9.0	15	0.16	2.45	-5.7	0.00	5.3
Week 80	14	2.10	2.38	0.0	1.79	6.7	13	0.20	2.41	-3.4	0.00	6.7
Week 83	13	2.24	2.29	0.0	1.57	6.0	12	0.12	1.59	-2.3	0.00	3.9
Week 86	12	0.96	1.23	0.0	0.79	4.1	11	-0.44	1.94	-5.6	0.14	1.0
Week 89	11	0.61	0.93	0.0	0.00	2.4	10	-0.96	2.23	-6.6	0.00	1.1

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.1.1: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Present	EV+Pembro (N= 48)												
	BASELINE	39	2.94	2.99	0.0	1.71	8.6						
	Week 1	32	3.46	2.79	0.0	3.93	9.0	32	0.64	2.31	-4.0	0.43	6.1
	Week 2	38	3.58	2.86	0.0	3.50	10.0	34	1.00	2.82	-6.4	0.43	10.0
	Week 3	35	3.20	2.61	0.0	2.86	8.4	30	-0.12	2.96	-8.0	0.00	6.3
	Week 4	36	2.95	2.75	0.0	2.64	8.3	31	0.07	3.11	-8.6	0.00	5.1
	Week 5	31	2.48	2.32	0.0	1.86	7.9	25	-0.56	2.55	-8.6	-0.14	4.1
	Week 6	31	2.33	2.55	0.0	1.14	9.6	25	-0.66	2.76	-7.4	0.00	6.3
	Week 7	35	2.39	2.85	0.0	1.29	10.0	29	-0.72	3.57	-8.6	-0.14	10.0
	Week 8	36	2.72	2.96	0.0	1.86	10.0	31	-0.55	3.54	-8.4	-0.14	7.1
	Week 9	35	3.01	3.07	0.0	2.14	9.7	31	0.09	3.28	-7.4	0.00	9.7
	Week 10	34	2.60	2.78	0.0	1.64	8.4	30	-0.29	3.49	-8.6	-0.07	8.4
	Week 11	35	2.57	2.94	0.0	1.57	9.7	30	-0.61	3.50	-8.6	0.00	5.4
	Week 12	33	2.50	3.05	0.0	1.29	10.0	29	-0.62	3.71	-8.6	0.00	9.1
	Week 14	31	2.40	2.71	0.0	2.00	9.0	26	-0.82	3.81	-8.6	-0.14	9.0
	Week 17	31	2.75	2.63	0.0	2.14	7.1	25	-0.81	3.81	-8.6	-0.14	6.1
	Week 20	27	2.94	2.78	0.0	2.00	9.4	24	-0.04	3.13	-5.9	0.00	8.9
	Week 23	26	2.53	2.36	0.0	1.79	6.7	23	-0.45	3.04	-7.4	0.00	5.1
	Week 26	25	2.05	2.36	0.0	1.00	6.9	22	-1.16	3.43	-8.6	0.00	5.1
	Week 29	23	2.07	2.57	0.0	0.86	9.7	22	-0.20	3.09	-8.6	0.00	4.7
	Week 32	21	3.10	2.45	0.0	4.43	6.6	19	0.46	2.76	-7.1	0.00	4.9
	Week 35	19	2.64	2.53	0.0	3.14	9.3	17	0.34	2.82	-7.6	0.43	4.0
	Week 38	18	3.35	3.23	0.0	3.36	9.7	17	0.29	3.86	-8.6	0.57	4.9
	Week 41	20	2.35	2.35	0.0	1.71	7.1	19	-0.02	3.29	-7.6	0.00	6.6
	Week 44	17	2.63	2.01	0.0	3.57	6.7	15	0.62	3.62	-7.6	0.57	6.7
	Week 47	18	2.87	2.85	0.0	2.36	9.4	16	0.42	3.76	-8.6	0.57	6.1

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.1.1: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	12	2.13	2.33	0.0	1.43	6.7	11	1.22	2.08	-0.4	0.57	6.6
	Week 53	12	2.27	2.75	0.0	0.86	7.3	11	0.88	3.67	-7.6	0.00	7.1
	Week 56	13	2.80	3.54	0.0	2.00	9.9	12	0.74	3.91	-7.6	0.00	9.7
	Week 59	12	1.75	3.02	0.0	0.00	9.1	11	-0.01	3.92	-7.6	0.00	9.0
	Week 62	10	1.71	2.88	0.0	0.50	8.9	9	0.65	3.89	-6.4	0.00	8.7
	Week 65	10	2.66	3.19	0.0	1.00	7.9	9	0.29	3.66	-7.6	0.14	6.7
	Plat+Gem (N= 48)												
	BASELINE	34	2.92	2.81	0.0	1.93	7.9						
	Week 1	32	3.30	3.02	0.0	2.64	9.7	29	0.70	3.08	-7.7	0.14	9.7
	Week 2	29	2.91	2.72	0.0	2.29	8.4	24	0.05	2.66	-7.7	-0.21	5.3
	Week 3	32	2.21	2.39	0.0	1.29	7.9	27	-0.58	2.37	-7.7	0.00	4.3
	Week 4	32	2.24	2.48	0.0	1.14	8.4	24	-0.59	2.10	-7.7	-0.36	3.4
	Week 5	36	1.98	2.28	0.0	1.07	7.1	28	-0.63	2.55	-7.7	-0.14	5.4
	Week 6	35	2.26	2.80	0.0	0.43	9.1	28	-1.01	2.80	-7.9	0.00	3.7
	Week 7	38	1.83	2.30	0.0	0.64	8.9	30	-1.40	2.63	-7.9	-0.64	3.7
	Week 8	31	1.53	1.78	0.0	1.14	5.9	26	-0.95	2.56	-7.9	-0.21	3.6
	Week 9	32	2.04	2.40	0.0	1.29	8.4	26	-1.29	2.25	-7.9	-0.71	2.0
	Week 10	34	1.67	1.96	0.0	0.79	6.4	27	-1.93	2.74	-7.9	-1.43	2.9
	Week 11	30	1.09	1.70	0.0	0.00	6.6	25	-2.22	2.55	-7.9	-2.00	0.6
	Week 12	28	1.48	2.03	0.0	0.71	7.6	24	-1.88	2.67	-7.9	-1.07	1.6
	Week 14	26	1.94	1.81	0.0	1.36	6.0	21	-1.31	2.30	-6.3	-0.43	2.3
	Week 17	30	1.90	2.44	0.0	0.86	7.3	26	-1.22	2.69	-7.9	-0.29	5.3
	Week 20	23	1.16	1.46	0.0	0.00	3.9	21	-1.81	2.51	-7.7	-1.57	3.6
	Week 23	22	2.23	2.72	0.0	0.93	7.9	19	-0.49	2.59	-4.9	0.00	4.1
	Week 26	19	1.37	2.05	0.0	0.29	6.9	18	-1.06	2.23	-6.3	-0.71	3.9
	Week 29	16	2.23	2.65	0.0	1.00	7.0	14	-0.27	2.38	-3.1	-0.29	5.4

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.1.1: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 32	11	2.30	2.44	0.0	1.29	7.3	11	-0.03	1.41	-2.6	0.00	2.1
	Week 35	10	2.86	3.23	0.0	1.79	9.4	9	0.27	2.77	-2.3	0.00	6.7

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.1.1: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Absent	EV+Pembro (N=192)												
	BASELINE	170	2.05	2.48	0.0	1.00	9.6						
	Week 1	158	2.23	2.39	0.0	1.57	9.6	155	0.17	1.92	-7.9	0.00	7.7
	Week 2	166	2.32	2.31	0.0	1.64	9.4	158	0.37	2.16	-6.9	0.00	7.7
	Week 3	164	2.29	2.28	0.0	1.64	9.3	155	0.29	2.28	-7.9	0.00	8.0
	Week 4	159	1.72	1.98	0.0	1.00	7.9	150	-0.27	2.16	-7.7	0.00	6.6
	Week 5	162	1.81	2.23	0.0	0.71	8.4	152	-0.11	2.36	-8.0	0.00	7.7
	Week 6	158	1.73	2.07	0.0	0.93	8.9	147	-0.23	2.48	-8.0	0.00	7.4
	Week 7	161	1.75	2.14	0.0	0.86	8.6	149	-0.23	2.66	-8.1	0.00	7.6
	Week 8	156	1.60	2.13	0.0	0.57	8.7	142	-0.38	2.66	-8.1	0.00	8.1
	Week 9	163	1.81	2.12	0.0	1.00	8.3	151	-0.22	2.60	-8.1	0.00	8.3
	Week 10	157	1.56	2.01	0.0	0.86	8.1	146	-0.38	2.50	-8.0	0.00	6.7
	Week 11	161	1.46	1.82	0.0	0.86	8.1	148	-0.59	2.31	-8.1	0.00	5.7
	Week 12	153	1.66	2.04	0.0	0.71	9.1	143	-0.35	2.49	-8.1	0.00	5.9
	Week 14	154	1.85	2.23	0.0	0.86	9.3	142	-0.12	2.35	-8.1	0.00	5.4
	Week 17	147	1.70	2.14	0.0	0.71	9.4	138	-0.23	2.58	-8.1	0.00	6.0
	Week 20	140	1.84	2.43	0.0	0.50	10.0	131	-0.04	2.74	-8.1	0.00	7.6
	Week 23	136	1.85	2.25	0.0	1.00	9.4	128	-0.04	2.60	-8.1	0.00	7.0
	Week 26	131	2.00	2.37	0.0	1.00	9.3	123	0.05	2.84	-8.1	0.00	7.0
	Week 29	134	1.96	2.20	0.0	1.00	9.3	124	0.01	2.41	-8.1	0.00	6.3
	Week 32	114	2.19	2.42	0.0	1.43	8.9	106	0.44	2.74	-8.0	0.00	8.3
	Week 35	113	2.03	2.20	0.0	1.29	8.6	105	0.21	2.59	-7.7	0.00	7.0
	Week 38	114	1.78	2.05	0.0	1.00	7.4	107	-0.11	2.83	-8.1	0.00	7.1
	Week 41	109	2.25	2.47	0.0	1.43	10.0	100	0.42	2.63	-8.1	0.00	7.0
	Week 44	91	1.99	2.27	0.0	1.00	8.4	85	0.28	2.92	-7.9	0.00	7.0
	Week 47	82	1.91	2.12	0.0	1.36	7.4	78	0.10	2.92	-8.1	0.00	7.4

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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Table 302.1.3002.6.1.1: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	77	2.00	2.14	0.0	1.29	7.3	73	0.33	2.54	-7.7	0.00	6.3
	Week 53	67	1.76	2.00	0.0	1.14	8.0	63	-0.03	3.10	-8.3	0.00	8.0
	Week 56	68	1.76	2.16	0.0	0.64	8.0	64	-0.01	3.17	-8.3	0.00	8.0
	Week 59	60	1.87	2.08	0.0	1.00	7.0	57	0.06	2.88	-8.3	0.00	6.3
	Week 62	55	1.80	2.19	0.0	0.57	7.4	54	0.18	2.86	-8.3	0.00	7.4
	Week 65	48	1.97	2.26	0.0	1.00	7.3	45	-0.13	2.90	-8.1	0.00	6.1
	Week 68	46	1.80	2.15	0.0	0.93	7.4	45	-0.07	2.97	-8.1	0.00	6.4
	Week 71	44	1.74	1.89	0.0	1.36	7.0	42	-0.02	2.73	-8.1	0.00	4.7
	Week 74	40	1.95	1.90	0.0	1.43	5.4	39	0.45	1.93	-3.4	0.14	4.9
	Week 77	38	2.31	2.24	0.0	2.50	7.6	36	0.59	2.55	-5.7	0.50	4.9
	Week 80	35	1.98	2.37	0.0	0.86	7.7	32	0.04	2.50	-5.7	0.00	5.1
	Week 83	32	1.93	1.97	0.0	1.64	6.6	30	-0.16	2.57	-7.4	0.00	3.4
	Week 86	29	2.12	2.23	0.0	1.43	7.7	26	0.13	2.59	-6.1	0.00	5.4
	Week 89	29	2.07	2.19	0.0	2.29	7.7	27	-0.16	2.30	-5.7	0.00	3.7
	Week 92	24	2.80	2.71	0.0	2.64	9.4	22	0.68	2.48	-3.1	0.07	6.0
	Week 95	20	2.40	2.56	0.0	1.86	7.0	19	0.31	2.79	-4.6	0.00	5.9
	Week 98	18	1.98	2.61	0.0	0.43	8.4	17	-0.37	2.19	-3.9	0.00	3.3
	Week 101	13	1.78	2.61	0.0	0.00	7.4	13	0.04	1.35	-3.0	0.00	3.0
	Plat+Gem (N=194)												
	BASELINE	156	2.58	2.76	0.0	1.57	10.0						
	Week 1	147	2.59	2.46	0.0	2.14	10.0	135	0.12	2.01	-7.6	0.00	7.4
	Week 2	144	2.62	2.55	0.0	2.07	10.0	129	0.25	2.34	-7.0	0.00	7.9
	Week 3	153	2.56	2.63	0.0	1.57	9.0	136	0.15	2.35	-4.7	0.00	8.6
	Week 4	151	2.30	2.33	0.0	1.86	9.1	133	-0.13	2.33	-7.9	0.00	7.6
	Week 5	151	2.51	2.38	0.0	2.00	9.3	129	0.22	2.51	-5.6	0.00	8.7
	Week 6	139	2.22	2.37	0.0	1.57	9.3	123	-0.14	2.37	-7.0	0.00	7.6

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.1.1: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 7	149	2.19	2.31	0.0	1.29	8.3	130	-0.03	2.34	-6.1	0.00	8.1
	Week 8	136	2.46	2.59	0.0	1.43	10.0	120	0.00	2.87	-8.0	0.00	10.0
	Week 9	145	2.42	2.47	0.0	1.71	9.4	126	0.10	2.74	-8.3	0.00	9.3
	Week 10	132	2.27	2.42	0.0	1.43	8.9	114	0.12	2.37	-4.9	0.00	8.3
	Week 11	138	2.18	2.38	0.0	1.21	9.0	120	-0.14	2.11	-8.1	0.00	6.1
	Week 12	131	2.21	2.27	0.0	1.43	9.4	116	0.20	2.08	-5.0	0.00	6.6
	Week 14	127	2.13	2.20	0.0	1.29	8.0	108	-0.07	2.40	-8.3	0.00	6.0
	Week 17	126	2.35	2.37	0.0	1.57	8.7	107	0.32	2.55	-5.6	0.00	6.9
	Week 20	103	1.95	2.37	0.0	1.00	10.0	90	-0.15	2.52	-6.1	0.00	8.3
	Week 23	93	2.29	2.57	0.0	1.43	9.0	79	0.31	2.51	-5.7	0.00	8.0
	Week 26	89	2.17	2.35	0.0	1.29	9.0	78	0.20	2.44	-5.0	0.00	6.0
	Week 29	84	1.81	1.78	0.0	1.43	5.7	73	0.04	2.03	-4.6	0.00	5.7
	Week 32	72	1.88	2.33	0.0	0.93	8.4	66	0.13	2.60	-5.9	0.00	8.0
	Week 35	66	1.92	2.05	0.0	1.14	8.0	61	0.25	2.35	-5.6	0.00	6.6
	Week 38	66	1.82	2.33	0.0	0.93	8.1	58	0.05	2.68	-5.7	0.00	7.4
	Week 41	62	1.80	2.18	0.0	0.93	8.0	54	0.14	2.41	-6.0	0.00	8.0
	Week 44	55	2.19	2.25	0.0	1.57	7.1	49	0.31	2.39	-4.9	0.00	7.0
	Week 47	51	2.04	2.18	0.0	1.14	7.6	45	0.22	2.54	-5.0	0.00	6.1
	Week 50	48	2.76	2.53	0.0	2.36	8.1	44	0.66	2.26	-4.3	0.07	5.6
	Week 53	41	1.79	2.02	0.0	0.86	7.0	37	0.00	1.68	-4.1	0.00	3.7
	Week 56	34	2.28	2.61	0.0	1.43	9.7	29	0.17	2.34	-3.7	0.00	6.3
	Week 59	32	1.73	1.99	0.0	1.14	8.0	28	-0.11	2.26	-4.3	0.00	5.0
	Week 62	27	1.46	1.66	0.0	1.00	6.0	24	-0.30	2.22	-5.6	0.00	3.1
	Week 65	25	1.52	1.99	0.0	0.86	6.6	21	0.03	2.30	-7.0	0.00	4.3
	Week 68	23	2.58	2.83	0.0	1.29	8.0	19	0.83	2.15	-3.3	0.29	6.1
	Week 71	21	2.33	2.87	0.0	1.43	8.9	18	0.48	1.85	-3.1	0.29	6.4

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.1.1: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 74	20	2.01	2.39	0.0	1.00	8.6	17	0.13	1.63	-3.9	0.00	2.6
	Week 77	16	2.57	2.78	0.0	1.79	9.0	13	0.80	1.79	-1.1	0.14	5.3
	Week 80	12	2.19	2.49	0.0	1.79	6.7	11	0.75	2.17	-1.4	0.00	6.7
	Week 83	11	2.18	2.22	0.0	1.57	6.0	10	0.51	1.42	-1.1	0.00	3.9
	Week 86	10	1.06	1.32	0.0	0.79	4.1	9	0.33	0.58	-0.7	0.29	1.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.1.2: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
< 65 years	EV+Pembro (N=105)												
	BASELINE	94	2.60	2.88	0.0	1.57	9.3						
	Week 1	88	2.53	2.53	0.0	1.71	9.1	87	0.07	2.03	-6.9	0.00	6.1
	Week 2	92	2.53	2.32	0.0	2.14	8.9	88	0.11	2.48	-6.9	0.00	6.4
	Week 3	93	2.49	2.28	0.0	1.86	8.4	86	-0.18	2.51	-7.9	0.00	6.0
	Week 4	90	1.84	2.10	0.0	1.00	7.7	83	-0.73	2.43	-8.6	-0.14	5.0
	Week 5	90	1.94	2.26	0.0	1.00	8.0	82	-0.50	2.83	-8.6	0.00	7.7
	Week 6	90	1.75	1.93	0.0	1.00	7.9	82	-0.89	2.74	-8.0	0.00	6.3
	Week 7	85	1.60	2.02	0.0	1.00	8.6	78	-1.11	2.82	-8.6	-0.14	7.3
	Week 8	90	1.55	2.11	0.0	0.50	8.7	82	-0.99	3.13	-8.4	-0.21	8.1
	Week 9	93	1.76	1.93	0.0	1.00	7.1	86	-0.71	2.79	-8.0	0.00	5.9
	Week 10	88	1.57	1.92	0.0	0.93	7.0	82	-1.05	2.90	-8.6	0.00	6.4
	Week 11	93	1.53	1.68	0.0	1.00	5.9	85	-1.15	2.86	-8.6	0.00	5.4
	Week 12	86	1.74	1.96	0.0	0.93	8.1	80	-0.90	3.05	-8.6	0.00	5.4
	Week 14	84	2.05	2.26	0.0	1.29	9.3	77	-0.60	3.03	-8.6	0.00	5.0
	Week 17	83	1.78	2.13	0.0	0.71	7.9	78	-0.83	3.15	-8.6	0.00	6.1
	Week 20	79	2.03	2.36	0.0	1.14	10.0	74	-0.44	2.99	-8.0	0.00	5.7
	Week 23	78	2.02	2.32	0.0	1.14	8.9	73	-0.44	2.83	-8.0	0.00	5.4
	Week 26	78	1.83	2.19	0.0	1.00	8.0	73	-0.80	3.20	-8.6	0.00	5.6
	Week 29	74	1.89	2.03	0.0	1.07	9.0	68	-0.43	2.75	-8.6	0.00	4.7
	Week 32	64	2.37	2.51	0.0	1.64	8.9	59	0.15	3.07	-8.0	0.00	8.3
	Week 35	62	1.89	2.08	0.0	1.21	8.6	58	-0.21	2.69	-7.7	0.00	5.4
	Week 38	62	1.94	2.09	0.0	1.29	8.0	59	-0.47	3.17	-8.6	0.00	6.3
	Week 41	64	2.06	2.36	0.0	1.29	10.0	59	-0.33	2.55	-7.9	0.00	5.6
	Week 44	50	1.90	2.17	0.0	1.00	8.4	48	-0.49	3.08	-7.9	0.00	4.7
	Week 47	47	2.10	2.13	0.0	1.86	7.1	46	-0.29	3.36	-8.6	0.00	6.7

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.1.2: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	44	1.90	1.82	0.0	1.43	6.7	41	0.11	2.78	-7.7	0.29	6.6
	Week 53	40	1.69	1.93	0.0	1.00	7.3	37	-0.32	3.28	-8.3	0.00	7.1
	Week 56	44	1.60	2.02	0.0	0.79	9.9	41	-0.34	3.16	-8.3	0.00	9.7
	Week 59	42	1.75	2.13	0.0	0.93	9.1	39	-0.12	3.39	-8.3	0.00	9.0
	Week 62	37	1.85	2.30	0.0	1.00	8.9	36	0.07	3.36	-8.3	0.00	8.7
	Week 65	34	2.10	2.26	0.0	1.21	7.3	31	-0.09	3.36	-7.7	0.00	6.7
	Week 68	34	1.88	2.12	0.0	1.00	7.4	33	-0.20	3.36	-7.7	0.14	6.4
	Week 71	32	1.96	1.99	0.0	1.64	7.0	30	0.04	3.26	-7.7	0.00	6.9
	Week 74	29	2.23	2.12	0.0	1.71	6.1	28	0.47	2.68	-7.6	0.29	6.0
	Week 77	25	2.52	2.13	0.0	2.57	6.1	24	0.36	3.26	-6.7	0.86	5.4
	Week 80	24	2.43	2.24	0.0	2.07	7.3	22	0.10	3.40	-7.1	0.43	5.1
	Week 83	23	2.42	2.02	0.0	2.57	6.6	22	0.03	3.40	-7.4	1.29	4.3
	Week 86	20	2.81	2.34	0.0	2.64	7.7	18	0.29	3.63	-7.1	0.79	5.4
	Week 89	19	2.47	2.12	0.0	2.57	6.7	17	-0.20	3.42	-7.3	0.00	4.9
	Week 92	14	3.23	2.24	0.0	3.21	7.4	12	1.19	2.64	-3.1	0.79	5.6
	Week 95	12	3.15	2.34	0.0	3.64	6.9	11	0.82	3.54	-4.6	0.29	5.9
	Plat+Gem (N=106)												
	BASELINE	84	3.00	2.61	0.0	3.00	9.3						
	Week 1	78	2.91	2.33	0.0	2.64	9.6	73	0.16	2.05	-7.6	0.00	7.4
	Week 2	77	2.94	2.54	0.0	2.71	8.9	69	0.04	2.31	-7.0	0.00	7.3
	Week 3	80	2.82	2.69	0.0	1.86	9.0	73	-0.09	2.46	-5.6	0.00	8.6
	Week 4	79	2.52	2.34	0.0	2.14	8.0	68	-0.42	1.90	-4.4	-0.29	4.7
	Week 5	80	2.47	2.27	0.0	2.00	8.4	68	-0.34	2.37	-5.6	0.00	6.0
	Week 6	76	2.44	2.52	0.0	1.93	9.3	68	-0.51	2.29	-5.6	0.00	4.9
	Week 7	81	2.38	2.34	0.0	2.00	8.9	72	-0.52	2.31	-6.6	-0.21	5.9
	Week 8	72	2.21	2.21	0.0	1.50	9.3	65	-0.57	2.46	-5.3	-0.14	9.3

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.1.2: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	78	2.24	2.19	0.0	1.57	9.3	70	-0.57	2.58	-5.6	0.00	9.3
	Week 10	78	2.27	2.21	0.0	1.57	8.9	69	-0.63	2.36	-6.3	0.00	5.6
	Week 11	75	1.98	2.03	0.0	1.43	7.4	67	-1.03	2.11	-6.1	-0.43	4.3
	Week 12	74	2.02	1.84	0.0	1.64	7.1	67	-0.62	2.00	-6.1	-0.14	4.4
	Week 14	68	1.95	2.01	0.0	1.21	7.1	59	-0.93	2.40	-6.4	-0.43	5.0
	Week 17	68	2.34	2.39	0.0	1.50	7.9	59	-0.54	2.30	-6.6	0.00	4.1
	Week 20	60	1.60	2.05	0.0	1.00	10.0	53	-1.29	2.30	-7.7	-0.57	3.7
	Week 23	51	2.25	2.60	0.0	1.43	7.9	45	-0.43	2.54	-4.9	-0.14	7.3
	Week 26	47	2.01	2.11	0.0	1.43	8.1	43	-0.93	2.14	-6.3	-0.71	3.7
	Week 29	42	1.81	1.71	0.0	1.57	6.3	38	-0.69	1.61	-4.0	-0.21	2.0
	Week 32	37	2.08	2.35	0.0	1.00	7.3	35	-0.25	2.24	-5.7	0.00	6.1
	Week 35	34	1.99	2.21	0.0	1.14	9.4	32	-0.15	2.19	-4.7	0.00	6.7
	Week 38	33	1.69	2.27	0.0	0.86	7.4	29	-0.53	2.37	-4.7	-0.14	7.4
	Week 41	27	1.92	2.33	0.0	0.86	6.6	23	-0.24	2.12	-4.7	0.00	6.6
	Week 44	28	2.18	2.15	0.0	1.36	6.0	25	-0.39	1.93	-4.7	0.00	4.6
	Week 47	24	2.23	2.19	0.0	1.43	6.3	22	-0.18	1.82	-4.7	0.07	1.7
	Week 50	26	2.39	2.48	0.0	1.57	8.1	24	-0.59	1.89	-5.4	-0.21	3.0
	Week 53	19	2.11	2.39	0.0	0.71	7.0	17	-0.44	1.72	-4.1	0.00	3.0
	Week 56	13	2.19	2.47	0.0	0.57	6.6	11	-1.00	1.69	-3.7	0.00	1.0
	Week 59	14	1.46	2.24	0.0	0.50	8.0	12	-1.05	1.89	-4.3	0.00	1.4
	Week 62	13	1.55	2.10	0.0	0.29	6.0	12	-0.74	2.01	-4.0	0.00	2.3
	Week 65	13	1.49	2.39	0.0	0.14	6.6	11	-0.61	1.53	-3.7	0.00	1.0
	Week 68	10	2.54	3.11	0.0	0.64	8.0	8	-0.16	1.05	-2.3	0.00	1.0
	Week 77	10	2.00	3.03	0.0	0.57	9.0	8	-1.02	2.12	-5.7	0.00	0.6

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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Table 302.1.3002.6.1.2: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>= 65 years	EV+Pembro (N=135)												
	BASELINE	115	1.90	2.31	0.0	0.86	9.6						
	Week 1	102	2.36	2.48	0.0	1.71	9.6	100	0.41	1.97	-7.9	0.14	7.7
	Week 2	112	2.57	2.59	0.0	1.86	10.0	104	0.80	2.08	-5.0	0.29	10.0
	Week 3	106	2.42	2.43	0.0	1.71	9.3	99	0.57	2.25	-8.0	0.43	8.0
	Week 4	105	2.04	2.26	0.0	1.29	8.3	98	0.22	2.18	-8.0	0.00	6.6
	Week 5	103	1.89	2.26	0.0	1.00	8.4	95	0.11	1.90	-5.6	0.00	7.0
	Week 6	99	1.89	2.36	0.0	1.00	9.6	90	0.24	2.19	-7.6	0.00	7.4
	Week 7	111	2.06	2.46	0.0	1.00	10.0	100	0.30	2.67	-8.1	0.00	10.0
	Week 8	102	2.04	2.52	0.0	0.86	10.0	91	0.12	2.42	-8.1	0.00	7.7
	Week 9	105	2.26	2.66	0.0	1.00	9.7	96	0.32	2.57	-8.1	0.00	9.7
	Week 10	103	1.90	2.41	0.0	1.00	8.4	94	0.24	2.33	-7.0	0.00	8.4
	Week 11	103	1.78	2.42	0.0	0.86	9.7	93	-0.09	2.10	-8.1	0.00	5.7
	Week 12	100	1.87	2.50	0.0	0.64	10.0	92	0.04	2.33	-8.1	0.00	9.1
	Week 14	101	1.85	2.37	0.0	0.57	9.0	91	0.08	2.19	-8.1	0.00	9.0
	Week 17	95	1.97	2.38	0.0	1.00	9.4	85	0.15	2.34	-8.1	0.00	6.0
	Week 20	88	2.01	2.65	0.0	0.71	9.4	81	0.33	2.57	-8.1	0.00	8.9
	Week 23	84	1.89	2.25	0.0	1.00	9.4	78	0.22	2.47	-8.1	0.00	7.0
	Week 26	78	2.19	2.51	0.0	1.29	9.3	72	0.53	2.53	-8.1	0.00	7.0
	Week 29	83	2.04	2.43	0.0	1.00	9.7	78	0.33	2.24	-8.1	0.00	6.3
	Week 32	71	2.30	2.39	0.0	1.86	7.4	66	0.69	2.38	-4.6	0.00	7.0
	Week 35	70	2.32	2.38	0.0	1.64	9.3	64	0.62	2.50	-4.4	0.00	7.0
	Week 38	70	2.04	2.49	0.0	0.93	9.7	65	0.32	2.76	-8.1	0.00	7.1
	Week 41	65	2.47	2.52	0.0	1.86	7.1	60	1.01	2.77	-8.1	0.00	7.0
	Week 44	58	2.26	2.29	0.0	1.64	7.9	52	1.10	2.78	-6.4	0.43	7.0
	Week 47	53	2.06	2.43	0.0	1.00	9.4	48	0.57	2.72	-8.1	0.00	7.4

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.1.2: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	45	2.13	2.45	0.0	1.14	7.3	43	0.77	2.15	-2.3	0.00	6.3
	Week 53	39	2.00	2.31	0.0	1.29	8.0	37	0.53	3.06	-8.1	0.00	8.0
	Week 56	37	2.31	2.83	0.0	0.71	9.0	35	0.62	3.38	-8.1	0.00	8.0
	Week 59	30	1.99	2.40	0.0	0.79	7.0	29	0.28	2.52	-6.4	0.00	6.3
	Week 62	28	1.70	2.30	0.0	0.00	7.4	27	0.48	2.48	-6.9	0.00	7.4
	Week 65	24	2.07	2.70	0.0	0.07	7.9	23	-0.02	2.51	-8.1	0.00	3.9
	Week 68	19	1.61	2.28	0.0	0.14	6.4	19	0.22	2.60	-8.1	0.00	5.1
	Week 71	19	1.41	2.09	0.0	0.00	7.0	19	0.02	2.46	-8.1	0.00	4.0
	Week 74	18	1.37	1.65	0.0	0.29	4.1	18	0.27	1.63	-3.0	0.00	4.1
	Week 77	19	2.34	2.82	0.0	0.43	8.6	18	0.84	1.93	-2.9	0.29	4.6
	Week 80	16	1.76	2.88	0.0	0.00	7.9	15	-0.03	1.51	-3.0	0.00	2.9
	Week 83	14	1.65	2.36	0.0	0.00	7.7	13	-0.42	1.10	-3.0	-0.43	1.3
	Week 86	14	1.07	1.64	0.0	0.00	4.3	13	-0.20	1.26	-3.0	0.00	1.7
	Week 89	14	1.59	2.27	0.0	0.14	7.7	14	-0.14	1.49	-3.0	0.00	2.6
	Week 92	13	2.09	3.10	0.0	0.00	9.4	13	0.43	2.39	-3.0	0.00	6.0
	Week 95	10	2.26	3.12	0.0	0.00	7.0	10	0.27	2.04	-3.0	0.00	4.4
	Week 98	10	1.70	2.94	0.0	0.00	8.4	10	-0.16	2.31	-3.9	0.00	3.3
	Plat+Gem (N=136)												
	BASELINE	106	2.35	2.86	0.0	1.36	10.0						
	Week 1	101	2.57	2.75	0.0	1.71	10.0	91	0.28	2.39	-7.7	0.00	9.7
	Week 2	96	2.45	2.59	0.0	1.57	10.0	84	0.36	2.44	-7.7	0.00	7.9
	Week 3	105	2.25	2.50	0.0	1.00	9.0	90	0.13	2.28	-7.7	0.00	6.9
	Week 4	104	2.11	2.36	0.0	1.43	9.1	89	-0.04	2.56	-7.9	0.00	7.6
	Week 5	107	2.37	2.43	0.0	1.86	9.3	89	0.38	2.62	-7.7	0.00	8.7
	Week 6	98	2.06	2.40	0.0	1.14	7.9	83	-0.12	2.61	-7.9	0.00	7.6
	Week 7	106	1.92	2.27	0.0	1.00	8.3	88	-0.09	2.55	-7.9	0.00	8.1

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.1.2: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 8	95	2.35	2.68	0.0	1.29	10.0	81	0.15	3.07	-8.0	0.00	10.0
	Week 9	99	2.44	2.65	0.0	1.57	9.4	82	0.24	2.77	-8.3	0.00	8.9
	Week 10	88	2.04	2.46	0.0	1.00	8.4	72	0.07	2.71	-7.9	0.00	8.3
	Week 11	93	1.99	2.53	0.0	0.71	9.0	78	-0.04	2.41	-8.1	0.00	6.1
	Week 12	85	2.13	2.54	0.0	1.00	9.4	73	0.27	2.52	-7.9	0.00	6.6
	Week 14	85	2.21	2.22	0.0	2.00	8.0	70	0.28	2.31	-8.3	0.00	6.0
	Week 17	88	2.21	2.39	0.0	1.43	8.7	74	0.46	2.81	-7.9	0.00	6.9
	Week 20	66	2.00	2.41	0.0	0.79	8.4	58	0.29	2.63	-5.6	0.00	8.3
	Week 23	64	2.30	2.60	0.0	1.43	9.0	53	0.65	2.43	-5.7	0.00	8.0
	Week 26	61	2.05	2.47	0.0	1.00	9.0	53	0.69	2.45	-4.9	0.00	6.0
	Week 29	58	1.93	2.09	0.0	0.86	7.0	49	0.51	2.26	-4.6	0.00	5.7
	Week 32	46	1.81	2.33	0.0	0.86	8.4	42	0.41	2.61	-5.9	0.00	8.0
	Week 35	42	2.09	2.29	0.0	1.07	8.0	38	0.60	2.53	-5.6	0.36	6.6
	Week 38	41	1.82	2.27	0.0	1.00	8.1	37	0.52	2.63	-5.7	0.00	6.7
	Week 41	38	1.78	2.10	0.0	1.00	8.0	34	0.38	2.56	-6.0	0.00	8.0
	Week 44	32	2.30	2.41	0.0	1.79	7.3	29	1.02	2.74	-4.9	0.29	7.0
	Week 47	32	2.06	2.18	0.0	1.14	7.6	28	0.71	3.08	-5.0	0.07	6.1
	Week 50	25	2.98	2.53	0.0	2.43	8.0	23	1.47	2.47	-4.1	1.57	5.6
	Week 53	27	1.51	1.59	0.0	1.00	4.3	25	0.32	1.65	-3.7	0.00	3.7
	Week 56	26	2.56	2.81	0.0	1.71	9.7	23	0.86	2.73	-3.3	0.14	7.3
	Week 59	23	2.09	2.15	0.0	1.86	8.0	21	0.74	2.81	-3.3	0.00	8.0
	Week 62	19	1.60	1.55	0.0	1.43	4.7	17	0.33	2.67	-5.6	0.00	4.6
	Week 65	17	1.45	1.60	0.0	1.00	4.3	15	0.43	2.70	-7.0	0.00	4.3
	Week 68	15	2.26	2.69	0.0	1.29	7.6	13	1.13	2.53	-3.3	0.43	6.1
	Week 71	15	2.10	2.42	0.0	1.43	8.0	13	0.51	2.19	-3.1	0.14	6.4
	Week 74	12	2.01	2.52	0.0	1.00	8.6	11	0.12	2.03	-3.9	0.00	2.6

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.1.3: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Europe	EV+Pembro (N= 98)												
	BASELINE	81	2.30	2.68	0.0	1.00	9.3						
	Week 1	74	2.47	2.54	0.0	1.71	9.1	73	0.30	2.10	-4.3	0.00	7.7
	Week 2	80	2.32	2.30	0.0	1.64	8.9	74	0.24	2.27	-5.7	0.00	5.4
	Week 3	79	2.55	2.37	0.0	1.86	8.1	72	0.43	2.90	-8.0	0.29	8.0
	Week 4	78	1.90	2.12	0.0	1.21	7.9	71	-0.01	2.66	-8.0	0.00	6.6
	Week 5	72	2.04	2.36	0.0	1.07	8.0	65	0.06	2.50	-7.7	0.00	7.7
	Week 6	71	1.82	2.25	0.0	0.86	9.6	63	-0.32	2.70	-7.7	0.00	7.4
	Week 7	79	1.93	2.19	0.0	1.14	7.9	70	-0.13	2.84	-7.7	0.00	7.6
	Week 8	72	1.74	2.42	0.0	0.57	8.7	62	-0.34	3.16	-8.0	0.00	8.1
	Week 9	80	2.07	2.35	0.0	1.00	9.4	71	0.01	2.81	-7.7	0.00	8.3
	Week 10	71	1.67	2.10	0.0	0.86	7.0	63	-0.32	2.73	-7.7	0.00	6.6
	Week 11	78	1.67	2.09	0.0	0.93	9.7	69	-0.57	2.61	-7.7	0.00	5.7
	Week 12	73	1.72	2.11	0.0	0.57	10.0	66	-0.47	2.62	-7.7	0.00	5.4
	Week 14	74	1.89	2.11	0.0	0.93	7.3	65	-0.20	2.55	-7.7	0.00	5.4
	Week 17	70	1.86	2.06	0.0	0.93	6.3	63	-0.39	2.85	-7.7	0.00	6.1
	Week 20	70	1.88	2.27	0.0	1.00	9.4	64	-0.17	2.69	-7.7	0.00	7.6
	Week 23	61	1.70	1.96	0.0	0.86	7.0	57	-0.42	2.74	-7.7	0.00	7.0
	Week 26	62	1.80	2.17	0.0	0.86	7.0	56	-0.16	2.52	-7.7	0.00	6.6
	Week 29	63	2.08	2.29	0.0	1.14	9.7	58	0.11	2.25	-7.7	0.00	5.7
	Week 32	51	2.77	2.85	0.0	1.57	8.9	47	0.82	3.02	-7.7	0.00	8.3
	Week 35	56	2.31	2.45	0.0	1.57	9.3	52	0.45	2.61	-7.7	0.00	7.0
	Week 38	51	2.18	2.50	0.0	1.14	9.7	48	0.12	3.04	-7.7	0.00	6.4
	Week 41	52	2.62	2.64	0.0	1.71	10.0	48	0.69	2.61	-4.4	0.00	6.6
	Week 44	43	2.18	2.42	0.0	1.14	8.4	39	0.52	3.01	-7.7	0.00	6.1
	Week 47	39	2.43	2.49	0.0	1.86	9.4	36	0.56	3.29	-7.7	0.14	7.4

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.1.3: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	37	2.03	2.27	0.0	1.00	7.1	36	0.31	2.87	-7.7	0.07	6.6
	Week 53	28	1.99	2.51	0.0	0.57	8.0	27	-0.08	3.63	-8.3	0.00	8.0
	Week 56	30	2.35	2.87	0.0	0.86	9.9	29	0.44	3.70	-8.3	0.00	9.7
	Week 59	27	1.88	2.51	0.0	0.14	9.1	27	0.15	3.58	-8.3	0.00	9.0
	Week 62	23	1.99	2.74	0.0	0.00	8.9	23	0.36	3.71	-8.3	0.00	8.7
	Week 65	23	2.47	2.77	0.0	1.43	7.9	23	0.07	2.99	-7.7	0.00	6.7
	Week 68	21	1.50	2.09	0.0	0.29	6.3	21	-0.71	3.20	-7.7	0.00	6.0
	Week 71	19	1.97	2.51	0.0	0.14	7.0	19	-0.15	3.00	-7.7	0.00	6.9
	Week 74	15	1.96	2.30	0.0	0.43	6.1	15	0.19	2.19	-3.4	-0.43	6.0
	Week 77	19	2.38	2.92	0.0	0.29	8.6	19	0.17	2.83	-5.7	0.00	5.4
	Week 80	17	1.87	2.35	0.0	0.57	7.9	17	-0.57	2.52	-5.7	0.00	5.1
	Week 83	16	1.92	2.46	0.0	0.43	7.7	16	-0.67	2.93	-7.4	-0.21	4.3
	Week 86	14	2.06	2.43	0.0	1.21	7.7	14	-0.06	2.59	-6.1	0.00	4.9
	Week 89	14	2.03	2.31	0.0	0.79	6.7	14	-0.17	2.62	-5.7	0.00	4.9
	Week 92	11	2.16	2.46	0.0	1.57	7.4	11	0.25	1.98	-3.1	0.00	5.0
	Week 95	10	2.39	2.56	0.0	1.86	7.0	10	-0.01	2.84	-4.6	0.14	5.3
	Plat+Gem (N=102)												
	BASELINE	73	2.81	2.94	0.0	1.57	10.0						
	Week 1	73	2.98	2.76	0.0	2.43	10.0	64	0.37	2.57	-7.6	0.00	9.7
	Week 2	68	3.02	2.82	0.0	2.36	10.0	57	0.43	2.85	-7.0	0.00	7.9
	Week 3	68	2.87	2.65	0.0	2.36	9.0	56	0.20	2.25	-4.6	0.00	6.6
	Week 4	75	2.49	2.52	0.0	1.71	9.1	60	0.02	2.30	-5.9	0.00	7.6
	Week 5	77	2.45	2.41	0.0	1.86	9.3	61	0.24	2.45	-5.6	0.00	8.7
	Week 6	70	2.34	2.59	0.0	1.57	9.3	58	-0.18	2.57	-7.9	0.00	6.3
	Week 7	73	2.17	2.46	0.0	1.29	8.3	58	-0.16	2.59	-7.9	0.00	8.1
	Week 8	65	2.56	2.72	0.0	1.57	10.0	55	0.05	3.08	-7.9	0.00	10.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.1.3: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	70	2.66	2.63	0.0	2.00	9.4	57	0.03	2.79	-7.9	0.00	8.9
	Week 10	60	2.54	2.62	0.0	1.71	8.9	48	0.20	2.87	-7.9	0.00	8.3
	Week 11	64	2.35	2.72	0.0	1.00	9.0	52	-0.27	2.20	-7.9	0.00	4.6
	Week 12	60	2.26	2.48	0.0	1.57	9.4	50	-0.11	2.24	-7.9	0.00	5.3
	Week 14	56	2.55	2.36	0.0	2.36	8.0	43	0.05	2.54	-6.4	0.00	5.0
	Week 17	59	2.54	2.64	0.0	1.43	8.7	47	0.17	2.81	-7.9	0.00	6.4
	Week 20	47	1.79	2.19	0.0	1.14	10.0	38	-0.43	1.94	-4.1	-0.14	4.3
	Week 23	44	2.29	2.71	0.0	1.14	9.0	33	0.63	1.89	-2.3	0.00	7.3
	Week 26	39	2.17	2.53	0.0	1.00	9.0	31	0.41	2.30	-4.1	0.00	5.6
	Week 29	34	1.82	1.87	0.0	1.50	7.0	26	-0.16	1.69	-3.4	0.00	4.0
	Week 32	33	2.03	2.21	0.0	2.00	8.4	28	0.29	1.91	-2.6	0.00	7.0
	Week 35	30	2.37	2.34	0.0	2.07	8.0	25	0.70	2.37	-2.6	0.00	6.6
	Week 38	26	2.57	2.67	0.0	1.71	8.1	22	1.30	2.65	-1.3	0.00	7.4
	Week 41	22	2.40	2.30	0.0	1.79	6.6	18	0.74	2.32	-2.4	0.07	6.6
	Week 44	20	2.88	2.45	0.0	2.71	7.3	17	1.03	2.64	-2.3	0.00	6.0
	Week 47	16	2.79	2.41	0.0	3.43	7.6	13	1.25	2.23	-2.3	0.86	6.1
	Week 50	11	3.52	2.91	0.0	4.29	8.1	10	1.21	2.24	-2.3	0.93	5.6
	Week 53	11	2.79	2.51	0.0	2.57	7.0	10	0.50	1.80	-2.3	0.57	3.0
	Week 56	10	2.74	3.08	0.0	1.71	9.7	8	-0.20	1.84	-2.9	0.07	2.9

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.1.3: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
North America	EV+Pembro (N= 57)												
	BASELINE	48	2.57	2.65	0.0	1.64	9.6						
	Week 1	39	2.82	2.68	0.0	1.71	9.6	38	0.19	1.43	-4.0	0.14	3.6
	Week 2	44	3.00	2.77	0.0	2.43	9.4	42	0.62	1.76	-2.4	0.00	5.0
	Week 3	44	2.86	2.81	0.0	1.93	9.3	40	0.10	1.72	-3.7	0.00	4.6
	Week 4	45	2.18	2.42	0.0	1.57	7.7	42	-0.61	2.08	-8.6	-0.36	5.9
	Week 5	48	2.04	2.40	0.0	0.79	7.3	42	-0.44	2.15	-8.6	0.00	3.9
	Week 6	44	1.80	2.28	0.0	0.71	8.9	39	-0.97	1.97	-7.4	-0.43	2.7
	Week 7	46	1.77	2.37	0.0	0.71	8.6	42	-0.79	2.19	-8.6	-0.43	2.9
	Week 8	48	1.88	2.33	0.0	0.71	8.1	43	-0.65	2.45	-8.4	-0.43	7.1
	Week 9	46	2.12	2.49	0.0	0.93	8.0	42	-0.52	2.11	-4.9	-0.29	5.9
	Week 10	47	1.70	2.35	0.0	0.43	8.1	44	-0.72	2.29	-8.6	-0.29	6.4
	Week 11	47	1.78	2.22	0.0	0.86	8.1	42	-0.80	2.22	-8.6	-0.57	3.1
	Week 12	44	2.02	2.44	0.0	0.57	9.1	40	-0.71	2.49	-8.6	-0.43	4.0
	Week 14	43	2.06	2.68	0.0	0.43	9.3	39	-0.65	2.32	-8.6	-0.43	4.6
	Week 17	40	2.25	2.81	0.0	0.79	9.4	37	-0.37	2.51	-8.6	-0.14	5.1
	Week 20	38	1.96	2.93	0.0	0.36	10.0	35	-0.42	2.34	-6.0	-0.57	5.6
	Week 23	38	1.83	2.55	0.0	0.71	9.4	35	-0.39	2.09	-5.3	-0.14	3.4
	Week 26	35	1.59	2.55	0.0	0.14	9.3	32	-0.96	2.84	-8.6	-0.43	5.7
	Week 29	38	1.20	1.98	0.0	0.14	9.3	34	-1.07	2.12	-8.6	-0.57	3.0
	Week 32	32	1.61	2.10	0.0	0.29	6.3	29	-0.21	2.10	-5.9	0.00	5.0
	Week 35	33	1.49	2.24	0.0	0.57	8.6	30	-0.28	2.20	-5.9	-0.43	6.6
	Week 38	32	1.33	2.08	0.0	0.21	8.0	29	-0.81	2.54	-8.6	-0.43	4.4
	Week 41	28	1.03	1.54	0.0	0.14	4.9	24	-0.61	1.85	-4.6	-0.36	4.1
	Week 44	21	1.56	2.34	0.0	0.29	7.9	20	0.11	2.75	-3.6	-0.21	6.7
	Week 47	24	1.51	2.09	0.0	0.14	7.1	23	-0.12	2.72	-8.6	0.00	4.3

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.1.3: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	23	2.05	2.45	0.0	1.29	7.3	20	0.61	2.52	-4.7	-0.07	6.3
	Week 53	17	1.08	1.65	0.0	0.00	5.7	14	0.10	2.48	-5.1	-0.29	5.7
	Week 56	20	1.30	1.97	0.0	0.50	8.0	17	-0.43	2.98	-5.1	-0.43	8.0
	Week 59	17	1.82	2.39	0.0	0.86	7.0	14	0.42	2.32	-3.0	-0.07	6.3
	Week 62	14	0.77	1.16	0.0	0.00	3.9	13	-0.30	2.05	-4.4	-0.14	3.9
	Week 65	12	0.82	1.25	0.0	0.07	3.6	9	-0.57	2.05	-5.1	-0.14	2.1
	Week 68	10	1.14	1.43	0.0	0.86	3.9	9	0.52	1.38	-0.9	0.14	3.9
	Week 71	10	0.87	1.15	0.0	0.36	3.4	8	0.46	1.60	-2.0	0.07	3.4
	Week 74	10	0.96	1.38	0.0	0.43	4.1	9	0.10	2.01	-3.0	0.14	4.1
	Plat+Gem (N= 51)												
	BASELINE	42	2.23	2.59	0.0	0.86	8.3						
	Week 1	42	2.79	2.76	0.0	1.86	10.0	36	0.59	1.73	-3.0	0.00	5.3
	Week 2	39	2.67	2.42	0.0	2.43	8.4	34	0.52	2.07	-2.9	0.00	6.6
	Week 3	41	2.05	2.36	0.0	1.00	8.6	36	0.09	2.71	-5.6	0.00	8.6
	Week 4	35	1.94	2.16	0.0	0.86	7.0	29	-0.22	2.01	-3.9	0.00	6.9
	Week 5	39	2.30	2.29	0.0	1.57	6.9	32	-0.08	2.62	-5.4	0.00	6.7
	Week 6	34	1.93	2.11	0.0	1.14	7.9	30	-0.40	2.20	-6.3	0.00	4.1
	Week 7	42	1.73	1.96	0.0	0.93	6.4	37	-0.39	2.37	-6.6	0.00	6.1
	Week 8	39	1.89	2.31	0.0	1.14	8.0	33	-0.61	2.76	-8.0	0.00	7.9
	Week 9	39	1.85	2.17	0.0	1.00	7.7	33	-0.46	2.92	-8.3	0.00	6.3
	Week 10	39	1.59	1.94	0.0	0.86	6.9	32	-0.84	2.45	-6.3	0.00	6.7
	Week 11	39	1.42	1.94	0.0	0.43	6.7	33	-1.10	2.66	-8.1	-0.14	6.1
	Week 12	36	1.71	1.73	0.0	1.07	6.1	32	-0.32	2.08	-6.1	0.00	5.1
	Week 14	34	1.26	1.40	0.0	0.93	5.0	29	-0.95	2.71	-8.3	0.00	2.6
	Week 17	37	1.98	1.96	0.0	1.29	6.9	31	0.04	2.67	-6.6	0.29	5.0
	Week 20	27	1.39	1.81	0.0	0.71	6.0	23	-1.16	2.70	-7.7	0.00	3.3

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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Table 302.1.3002.6.1.3: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 23	27	2.19	2.22	0.0	1.57	7.4	23	-0.37	3.03	-4.9	-0.29	6.4
	Week 26	28	2.04	1.75	0.0	1.43	5.0	25	-0.34	2.43	-6.3	0.00	4.4
	Week 29	29	2.20	1.83	0.0	1.86	6.3	25	0.15	2.27	-4.6	0.29	5.4
	Week 32	17	2.38	2.58	0.0	1.29	7.3	17	0.57	2.60	-5.7	0.71	6.1
	Week 35	16	1.73	1.87	0.0	1.14	5.6	15	0.18	1.75	-4.0	0.00	3.7
	Week 38	16	1.75	1.90	0.0	1.29	5.1	13	-0.11	1.39	-4.1	0.00	1.4
	Week 41	16	1.97	1.89	0.0	1.43	5.1	13	0.35	1.46	-2.6	0.14	2.9
	Week 44	13	2.34	2.21	0.0	1.86	7.1	11	0.44	1.58	-2.7	0.00	2.7
	Week 47	11	2.45	2.02	0.0	2.14	5.3	9	1.24	1.69	-0.3	1.14	5.1
	Week 50	17	2.73	2.29	0.0	3.14	8.0	15	0.30	2.88	-5.4	0.00	5.0
	Week 53	13	1.60	1.64	0.0	1.14	4.3	11	0.32	1.78	-3.1	0.29	3.7
	Week 56	11	3.31	2.77	0.0	2.71	7.3	9	1.60	3.26	-3.4	0.71	7.3
	Week 59	11	2.49	2.42	0.0	2.71	8.0	9	1.38	3.07	-3.1	0.43	8.0
	Week 62	11	1.61	1.60	0.0	1.43	4.6	9	0.70	2.30	-3.7	0.29	4.6
	Week 65	10	1.29	1.41	0.0	0.79	3.3	8	0.25	2.03	-3.7	0.00	3.1

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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Table 302.1.3002.6.1.3: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Rest of World	EV+Pembro (N= 85)												
	BASELINE	80	1.93	2.48	0.0	0.43	8.1						
	Week 1	77	2.21	2.36	0.0	1.57	9.0	76	0.24	2.15	-7.9	0.00	6.1
	Week 2	80	2.54	2.45	0.0	1.79	10.0	76	0.64	2.57	-6.9	0.29	10.0
	Week 3	76	2.11	2.02	0.0	1.79	8.1	73	0.10	2.17	-7.9	0.00	6.7
	Week 4	72	1.86	2.13	0.0	1.14	8.3	68	-0.18	2.15	-7.0	0.00	4.1
	Week 5	73	1.71	2.05	0.0	1.00	8.4	70	-0.23	2.43	-8.0	0.00	7.0
	Week 6	74	1.85	2.03	0.0	1.00	8.0	70	0.10	2.58	-8.0	0.00	6.6
	Week 7	71	1.85	2.37	0.0	1.00	10.0	66	-0.21	3.14	-8.1	0.00	10.0
	Week 8	72	1.83	2.31	0.0	1.00	10.0	68	-0.32	2.76	-8.1	0.00	6.6
	Week 9	72	1.92	2.30	0.0	1.00	9.7	69	-0.14	2.95	-8.1	0.00	9.7
	Week 10	73	1.86	2.21	0.0	1.14	8.4	69	-0.16	2.88	-8.0	0.00	8.4
	Week 11	71	1.56	2.04	0.0	1.00	9.3	67	-0.49	2.68	-8.1	0.00	5.4
	Week 12	69	1.78	2.32	0.0	1.00	9.3	66	-0.14	2.96	-8.1	0.00	9.1
	Week 14	68	1.93	2.31	0.0	1.29	9.0	64	-0.01	2.87	-8.1	0.00	9.0
	Week 17	68	1.69	2.10	0.0	1.00	7.9	63	-0.22	2.93	-8.1	0.00	5.9
	Week 20	59	2.22	2.52	0.0	1.71	8.9	56	0.35	3.15	-8.1	0.00	8.9
	Week 23	63	2.28	2.38	0.0	1.43	8.9	59	0.39	2.86	-8.1	0.00	5.9
	Week 26	59	2.47	2.39	0.0	2.00	8.0	57	0.34	3.33	-8.1	0.43	7.0
	Week 29	56	2.38	2.27	0.0	2.07	9.0	54	0.49	2.83	-8.1	0.36	6.3
	Week 32	52	2.35	2.11	0.0	2.00	7.0	49	0.46	2.75	-8.0	0.14	7.0
	Week 35	43	2.35	1.92	0.0	2.00	6.9	40	0.32	2.90	-7.6	0.29	6.9
	Week 38	49	2.23	2.17	0.0	1.86	9.3	47	0.23	3.13	-8.1	0.00	7.1
	Week 41	49	2.59	2.46	0.0	2.00	7.1	47	0.49	3.15	-8.1	0.57	7.0
	Week 44	44	2.25	1.99	0.0	2.21	7.0	41	0.27	3.21	-7.9	0.14	7.0
	Week 47	37	2.08	2.15	0.0	1.86	7.1	35	-0.09	3.07	-8.1	0.00	7.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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Table 302.1.3002.6.1.3: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	29	1.98	1.80	0.0	1.86	5.9	28	0.52	1.95	-3.4	0.00	5.9
	Week 53	34	2.09	1.93	0.0	1.50	6.3	33	0.26	3.13	-8.1	0.00	5.7
	Week 56	31	1.92	2.23	0.0	1.29	8.0	30	0.09	3.06	-8.1	0.00	8.0
	Week 59	28	1.84	1.92	0.0	1.43	6.1	27	-0.24	2.83	-7.6	0.00	4.0
	Week 62	28	2.13	2.21	0.0	1.36	6.7	27	0.41	2.77	-6.9	0.29	5.1
	Week 65	23	2.37	2.39	0.0	2.29	7.1	22	0.00	3.41	-8.1	0.07	6.1
	Week 68	22	2.34	2.43	0.0	1.86	7.4	22	0.35	3.45	-8.1	0.57	6.4
	Week 71	22	1.97	1.83	0.0	1.86	4.7	22	0.03	3.35	-8.1	0.00	4.7
	Week 74	22	2.29	1.92	0.0	2.50	5.4	22	0.65	2.55	-7.6	0.71	4.9
	Week 77	18	2.65	2.03	0.0	2.93	6.1	17	1.13	2.82	-6.7	1.86	4.9
	Week 80	16	2.63	2.58	0.0	2.29	7.3	15	0.94	3.09	-7.1	1.43	5.1
	Week 83	16	2.73	1.89	0.0	2.93	6.6	15	0.73	2.70	-6.7	1.29	3.4
	Week 86	13	2.70	2.21	0.0	2.57	6.4	12	0.75	3.54	-7.1	1.36	5.4
	Week 89	12	2.01	1.59	0.0	2.36	4.7	12	-0.01	3.12	-7.3	0.00	3.7
	Plat+Gem (N= 89)												
	BASELINE	75	2.70	2.70	0.0	2.71	10.0						
	Week 1	64	2.37	2.19	0.0	2.29	7.4	64	-0.13	2.12	-7.7	0.00	7.4
	Week 2	66	2.29	2.37	0.0	1.57	8.9	62	-0.15	2.04	-7.7	0.00	5.6
	Week 3	76	2.41	2.64	0.0	1.50	9.0	71	-0.13	2.27	-7.7	0.00	5.7
	Week 4	73	2.25	2.26	0.0	2.00	8.0	68	-0.39	2.42	-7.9	0.00	5.1
	Week 5	71	2.43	2.37	0.0	2.00	8.4	64	-0.02	2.59	-7.7	0.00	8.3
	Week 6	70	2.26	2.50	0.0	1.50	9.1	63	-0.35	2.52	-7.7	0.00	7.6
	Week 7	72	2.29	2.34	0.0	1.71	8.9	65	-0.34	2.39	-7.7	0.00	6.0
	Week 8	63	2.26	2.33	0.0	1.43	9.3	58	-0.13	2.63	-4.9	0.00	9.3
	Week 9	68	2.32	2.41	0.0	1.43	9.3	62	-0.11	2.53	-5.0	0.00	9.3
	Week 10	67	2.13	2.26	0.0	1.29	8.1	61	-0.35	2.33	-7.7	0.00	5.6

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Table 302.1.3002.6.1.3: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	65	1.96	2.01	0.0	1.43	6.9	60	-0.35	2.20	-7.7	0.00	4.7
	Week 12	63	2.12	2.26	0.0	1.29	8.1	58	-0.11	2.54	-7.7	0.00	6.6
	Week 14	63	2.14	2.14	0.0	1.29	7.1	57	-0.17	2.14	-5.4	0.00	6.0
	Week 17	60	2.18	2.37	0.0	1.36	7.6	55	-0.13	2.50	-5.3	0.00	6.9
	Week 20	52	2.04	2.50	0.0	0.71	8.4	50	-0.17	2.94	-5.6	0.00	8.3
	Week 23	44	2.33	2.72	0.0	1.07	8.0	42	0.07	2.66	-5.7	0.00	8.0
	Week 26	41	1.90	2.47	0.0	0.86	8.9	40	-0.19	2.56	-4.9	0.00	6.0
	Week 29	37	1.68	2.09	0.0	0.43	5.7	36	-0.02	2.24	-3.7	0.00	5.7
	Week 32	33	1.60	2.34	0.0	0.57	8.0	32	-0.29	2.79	-5.9	0.00	8.0
	Week 35	30	1.89	2.34	0.0	1.00	9.4	30	-0.08	2.68	-5.6	0.00	6.7
	Week 38	32	1.12	1.87	0.0	0.36	7.1	31	-0.76	2.57	-5.7	0.00	6.0
	Week 41	27	1.31	2.19	0.0	0.00	8.0	26	-0.40	2.74	-6.0	0.00	8.0
	Week 44	27	1.74	2.13	0.0	0.86	7.0	26	-0.09	2.66	-4.9	0.00	7.0
	Week 47	29	1.65	2.04	0.0	1.00	6.3	28	-0.41	2.85	-5.0	0.00	6.0
	Week 50	23	2.24	2.44	0.0	1.57	7.6	22	0.14	2.15	-4.3	0.00	4.0
	Week 53	22	1.33	1.71	0.0	0.21	4.9	21	-0.38	1.60	-4.1	0.00	3.0
	Week 56	18	1.73	2.33	0.0	0.43	6.3	17	-0.24	2.33	-3.7	0.00	6.3
	Week 59	17	1.13	1.58	0.0	0.29	5.0	16	-0.54	2.27	-4.3	0.00	5.0
	Week 62	16	1.23	1.58	0.0	1.00	6.0	15	-0.91	2.28	-5.6	0.00	2.7
	Week 65	15	0.92	1.27	0.0	0.29	4.3	14	-0.30	2.51	-7.0	0.00	4.3
	Week 68	12	2.11	2.92	0.0	0.64	7.6	11	1.04	1.74	-0.7	0.57	5.4
	Week 71	13	1.74	2.58	0.0	0.57	8.0	12	0.65	1.96	-1.6	0.21	6.4
	Week 74	10	1.39	2.65	0.0	0.36	8.6	10	0.21	1.46	-3.0	0.00	2.6

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.1.4: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	EV+Pembro (N=198)												
	BASELINE	173	2.33	2.66	0.0	1.14	9.6						
	Week 1	157	2.41	2.42	0.0	1.71	9.6	155	0.10	1.96	-7.9	0.00	7.7
	Week 2	168	2.60	2.54	0.0	1.71	10.0	158	0.42	2.33	-6.9	0.00	10.0
	Week 3	162	2.46	2.38	0.0	1.71	9.3	150	0.14	2.44	-8.0	0.00	8.0
	Week 4	159	1.95	2.19	0.0	1.14	8.3	147	-0.34	2.45	-8.6	0.00	6.6
	Week 5	157	1.95	2.32	0.0	1.00	8.4	144	-0.28	2.39	-8.6	0.00	7.7
	Week 6	154	1.92	2.26	0.0	1.00	9.6	140	-0.38	2.62	-8.0	0.00	7.4
	Week 7	160	1.98	2.41	0.0	1.00	10.0	144	-0.36	2.89	-8.6	0.00	10.0
	Week 8	155	1.86	2.42	0.0	0.71	10.0	137	-0.51	2.87	-8.4	0.00	8.1
	Week 9	163	2.18	2.43	0.0	1.00	9.7	148	-0.17	2.81	-8.1	0.00	9.7
	Week 10	159	1.91	2.30	0.0	1.00	8.4	145	-0.31	2.73	-8.6	0.00	8.4
	Week 11	162	1.80	2.22	0.0	1.00	9.7	145	-0.60	2.57	-8.6	0.00	5.7
	Week 12	154	1.86	2.32	0.0	0.71	10.0	141	-0.50	2.72	-8.6	0.00	9.1
	Week 14	154	2.00	2.35	0.0	1.14	9.3	138	-0.31	2.67	-8.6	0.00	9.0
	Week 17	145	1.92	2.35	0.0	0.86	9.4	131	-0.41	2.79	-8.6	0.00	6.1
	Week 20	139	2.03	2.58	0.0	1.00	10.0	127	-0.15	2.88	-8.1	0.00	8.9
	Week 23	133	2.01	2.34	0.0	1.14	9.4	122	-0.18	2.78	-8.1	0.00	7.0
	Week 26	129	1.96	2.37	0.0	1.00	9.3	119	-0.30	2.98	-8.6	0.00	7.0
	Week 29	131	2.01	2.34	0.0	0.86	9.7	121	-0.06	2.59	-8.6	0.00	6.3
	Week 32	111	2.35	2.49	0.0	1.57	8.9	102	0.22	2.78	-8.0	0.00	8.3
	Week 35	109	2.14	2.33	0.0	1.29	9.3	100	0.06	2.64	-7.7	0.00	7.0
	Week 38	107	1.98	2.36	0.0	1.00	9.7	100	-0.26	3.08	-8.6	0.00	7.1
	Week 41	103	2.24	2.52	0.0	1.29	10.0	94	0.23	2.73	-8.1	0.00	7.0
	Week 44	88	2.00	2.26	0.0	1.00	8.4	81	0.11	3.04	-7.9	0.00	7.0
	Week 47	80	1.98	2.18	0.0	1.64	9.4	75	0.00	3.20	-8.6	0.00	7.4

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.1.4: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	73	1.86	2.04	0.0	1.29	7.1	68	0.16	2.45	-7.7	0.00	6.6
	Week 53	64	1.81	2.14	0.0	1.14	8.0	59	0.04	3.27	-8.3	0.00	8.0
	Week 56	66	1.86	2.37	0.0	0.64	9.9	61	-0.11	3.20	-8.3	0.00	9.7
	Week 59	58	1.72	2.11	0.0	0.86	9.1	54	-0.22	3.09	-8.3	0.00	9.0
	Week 62	54	1.91	2.35	0.0	0.86	8.9	52	0.28	3.20	-8.3	0.00	8.7
	Week 65	51	2.06	2.49	0.0	0.57	7.9	47	-0.15	3.01	-8.1	0.00	6.7
	Week 68	49	1.70	2.10	0.0	0.86	7.4	48	-0.15	3.11	-8.1	0.00	6.4
	Week 71	47	1.72	2.04	0.0	0.86	7.0	45	-0.02	3.06	-8.1	0.00	6.9
	Week 74	42	1.76	1.95	0.0	0.86	6.1	41	0.29	2.30	-7.6	0.00	6.0
	Week 77	38	2.25	2.42	0.0	1.29	8.6	36	0.45	2.83	-6.7	0.21	5.4
	Week 80	35	1.94	2.26	0.0	0.86	7.9	32	-0.12	2.75	-7.1	0.00	5.1
	Week 83	32	2.11	2.16	0.0	1.64	7.7	30	-0.22	2.87	-7.4	0.00	4.3
	Week 86	30	1.99	2.16	0.0	1.21	7.7	27	-0.04	2.88	-7.1	0.00	5.4
	Week 89	28	1.97	2.02	0.0	1.79	6.7	26	-0.28	2.80	-7.3	0.00	4.9
	Week 92	24	2.38	2.32	0.0	1.93	7.4	22	0.57	2.11	-3.1	0.00	5.6
	Week 95	21	2.88	2.69	0.0	3.29	7.0	20	0.74	2.82	-4.6	0.14	5.9
	Week 98	16	1.70	2.14	0.0	0.43	6.4	15	-0.44	2.01	-3.9	0.00	3.1
	Week 101	12	1.90	2.62	0.0	0.43	7.4	12	0.69	1.97	-0.9	0.00	6.1
	Week 104	10	2.37	3.16	0.0	0.71	9.1	10	0.64	2.28	-3.3	0.00	4.7
	Plat+Gem (N=185)												
	BASELINE	148	2.63	2.76	0.0	1.57	10.0						
	Week 1	137	2.63	2.65	0.0	2.00	10.0	126	0.22	2.02	-7.7	0.00	9.7
	Week 2	129	2.76	2.63	0.0	2.43	10.0	116	0.36	2.34	-7.7	0.00	7.9
	Week 3	142	2.45	2.61	0.0	1.43	9.0	127	0.00	2.24	-7.7	0.00	7.0
	Week 4	139	2.30	2.44	0.0	1.57	9.1	120	-0.21	2.18	-7.9	0.00	7.6
	Week 5	143	2.35	2.35	0.0	1.86	9.3	121	0.06	2.41	-7.7	0.00	8.7

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.1.4: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 6	133	2.25	2.49	0.0	1.43	9.3	116	-0.29	2.43	-7.9	0.00	6.3
	Week 7	142	1.98	2.23	0.0	1.21	8.9	122	-0.51	2.27	-7.9	0.00	6.0
	Week 8	125	2.17	2.41	0.0	1.43	10.0	111	-0.18	2.66	-7.9	0.00	10.0
	Week 9	135	2.24	2.39	0.0	1.43	9.4	117	-0.08	2.62	-7.9	0.00	9.3
	Week 10	131	2.03	2.30	0.0	1.29	8.9	113	-0.48	2.43	-7.9	0.00	8.3
	Week 11	128	1.85	2.18	0.0	1.07	9.0	111	-0.60	2.19	-7.9	0.00	4.6
	Week 12	124	1.97	2.17	0.0	1.21	8.6	110	-0.28	2.25	-7.9	0.00	6.6
	Week 14	121	1.99	2.05	0.0	1.29	7.7	102	-0.41	2.29	-6.4	0.00	5.0
	Week 17	122	2.24	2.40	0.0	1.36	8.7	104	-0.02	2.71	-7.9	0.00	6.9
	Week 20	98	1.76	2.29	0.0	0.79	10.0	87	-0.50	2.60	-7.7	0.00	8.3
	Week 23	93	2.18	2.64	0.0	0.57	9.0	79	0.07	2.61	-5.7	0.00	8.0
	Week 26	86	1.94	2.24	0.0	1.00	9.0	76	-0.02	2.41	-6.3	0.00	6.0
	Week 29	76	1.81	1.94	0.0	1.29	7.0	66	0.12	2.01	-4.0	0.00	5.4
	Week 32	62	1.54	2.05	0.0	0.64	8.0	57	-0.14	2.30	-5.7	0.00	8.0
	Week 35	58	1.75	1.98	0.0	1.00	7.0	53	0.02	2.13	-4.9	0.00	6.0
	Week 38	60	1.68	2.08	0.0	0.93	7.4	53	0.00	2.54	-4.7	0.00	7.4
	Week 41	52	1.69	2.18	0.0	0.71	8.0	45	0.14	2.45	-5.0	0.00	8.0
	Week 44	46	2.06	2.35	0.0	1.00	7.3	41	0.36	2.60	-4.9	0.00	7.0
	Week 47	44	1.74	2.07	0.0	1.00	7.6	39	0.14	2.58	-4.7	0.00	6.1
	Week 50	42	2.53	2.58	0.0	1.79	8.1	38	0.36	2.49	-5.4	0.00	5.6
	Week 53	38	1.49	1.91	0.0	0.43	7.0	34	-0.03	1.52	-4.1	0.00	3.0
	Week 56	32	2.06	2.44	0.0	0.93	7.3	28	0.27	2.41	-3.7	0.00	7.3
	Week 59	31	1.67	2.23	0.0	0.71	8.0	27	0.16	2.44	-4.3	0.00	8.0
	Week 62	29	1.50	1.70	0.0	1.00	6.0	26	0.12	2.32	-4.0	0.00	4.6
	Week 65	25	1.17	1.68	0.0	0.14	6.6	21	-0.09	1.65	-3.7	0.00	3.9
	Week 68	20	1.92	2.59	0.0	0.50	8.0	16	0.66	1.73	-2.3	0.00	5.4

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.1.4: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 71	17	1.58	2.24	0.0	1.14	8.9	14	0.31	0.86	-1.6	0.07	1.4
	Week 74	17	1.45	1.73	0.0	1.00	5.0	14	0.16	1.51	-3.0	0.00	2.6
	Week 77	16	2.29	2.74	0.0	0.86	9.0	13	0.25	2.62	-5.7	0.00	5.3
	Week 80	13	1.76	2.09	0.0	1.29	6.7	12	0.19	2.52	-3.4	0.00	6.7
	Week 83	11	1.79	2.12	0.0	1.00	5.1	10	0.29	1.69	-2.3	0.00	3.9
	Week 86	12	0.96	1.23	0.0	0.79	4.1	11	-0.44	1.94	-5.6	0.14	1.0
	Week 89	11	0.61	0.93	0.0	0.00	2.4	10	-0.96	2.23	-6.6	0.00	1.1

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.1.4: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	EV+Pembro (N= 42)												
	BASELINE	36	1.68	2.25	0.0	0.93	8.9						
	Week 1	33	2.58	2.87	0.0	1.57	9.0	32	0.98	2.03	-3.9	0.29	6.1
	Week 2	36	2.35	2.11	0.0	2.64	8.9	34	0.78	2.14	-6.4	0.43	4.7
	Week 3	37	2.43	2.26	0.0	2.00	8.4	35	0.58	2.19	-5.4	0.43	6.3
	Week 4	36	1.97	2.20	0.0	1.07	7.3	34	0.34	1.77	-4.1	0.00	5.1
	Week 5	36	1.78	1.97	0.0	0.86	6.1	33	0.27	2.37	-5.6	0.00	4.1
	Week 6	35	1.42	1.61	0.0	1.00	6.3	32	0.08	2.03	-5.6	0.07	4.4
	Week 7	36	1.35	1.58	0.0	0.86	6.7	34	-0.11	2.50	-7.4	0.00	4.7
	Week 8	37	1.61	1.98	0.0	0.57	6.6	36	-0.02	2.64	-7.4	0.00	4.6
	Week 9	35	1.31	1.81	0.0	0.57	7.1	34	-0.16	2.29	-7.4	0.00	4.0
	Week 10	32	0.96	1.33	0.0	0.29	5.4	31	-0.61	2.46	-7.4	0.00	5.4
	Week 11	34	1.00	1.21	0.0	0.29	3.3	33	-0.56	2.44	-7.4	0.00	3.3
	Week 12	32	1.59	2.00	0.0	0.79	7.1	31	0.07	2.73	-7.4	0.00	5.9
	Week 14	31	1.63	2.15	0.0	0.43	7.6	30	0.12	2.42	-7.4	0.00	4.9
	Week 17	33	1.70	1.85	0.0	1.00	5.7	32	0.06	2.83	-7.4	0.00	5.7
	Week 20	28	1.96	2.18	0.0	1.21	7.4	28	0.47	2.37	-4.4	0.36	5.7
	Week 23	29	1.70	1.95	0.0	1.00	6.7	29	0.24	2.15	-5.0	0.00	5.1
	Week 26	27	2.21	2.35	0.0	2.00	7.1	26	0.59	2.75	-7.4	0.43	5.6
	Week 29	26	1.81	1.69	0.0	1.57	5.6	25	0.17	2.11	-3.9	0.00	5.6
	Week 32	24	2.26	2.23	0.0	1.93	6.3	23	1.42	2.28	-3.0	1.00	5.7
	Week 35	23	2.02	1.85	0.0	1.71	6.6	22	0.97	2.38	-3.0	0.50	6.6
	Week 38	25	2.06	2.08	0.0	2.00	7.0	24	0.81	2.36	-4.3	0.21	4.7
	Week 41	26	2.35	2.14	0.0	1.86	6.6	25	0.79	2.77	-4.6	0.57	6.6
	Week 44	20	2.51	2.13	0.0	2.50	7.9	19	1.29	2.80	-5.4	1.57	6.4
	Week 47	20	2.51	2.68	0.0	2.00	7.1	19	0.75	2.45	-3.4	0.00	6.7

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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Table 302.1.3002.6.1.4: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	16	2.76	2.57	0.0	2.07	7.3	16	1.69	2.31	-1.0	0.79	6.3
	Week 53	15	1.96	2.08	0.0	1.43	5.7	15	0.36	2.87	-5.1	0.00	5.7
	Week 56	15	2.20	2.79	0.0	1.00	8.0	15	0.99	3.56	-5.1	0.00	8.0
	Week 59	14	2.38	2.71	0.0	0.93	7.0	14	1.08	2.65	-3.0	0.43	6.3
	Week 62	11	1.16	1.86	0.0	0.00	5.0	11	0.08	1.86	-3.0	0.00	3.7
	Plat+Gem (N= 57)												
	BASELINE	42	2.69	2.80	0.0	1.50	9.3						
	Week 1	42	2.99	2.31	0.0	3.14	7.0	38	0.25	2.88	-7.6	0.00	6.9
	Week 2	44	2.38	2.40	0.0	1.93	8.0	37	-0.23	2.48	-7.0	0.00	6.6
	Week 3	43	2.65	2.55	0.0	2.00	8.6	36	0.15	2.78	-4.6	0.00	8.6
	Week 4	44	2.25	2.08	0.0	2.50	7.0	37	-0.18	2.68	-6.9	0.00	6.9
	Week 5	44	2.62	2.42	0.0	2.14	8.3	36	0.10	2.94	-5.3	0.00	8.3
	Week 6	41	2.14	2.36	0.0	1.57	7.9	35	-0.31	2.61	-6.3	0.00	7.6
	Week 7	45	2.57	2.50	0.0	2.14	8.3	38	0.43	2.85	-6.1	0.00	8.1
	Week 8	42	2.62	2.71	0.0	1.57	8.0	35	-0.12	3.35	-8.0	0.00	7.9
	Week 9	42	2.71	2.64	0.0	1.86	9.3	35	-0.33	3.02	-8.3	0.00	6.3
	Week 10	35	2.57	2.49	0.0	1.86	7.6	28	0.56	2.92	-4.6	0.00	7.6
	Week 11	40	2.43	2.65	0.0	1.07	8.9	34	-0.16	2.70	-8.1	0.00	6.1
	Week 12	35	2.46	2.46	0.0	1.71	9.4	30	0.30	2.54	-4.6	0.00	5.1
	Week 14	32	2.49	2.40	0.0	2.00	8.0	27	0.23	2.86	-8.3	0.00	6.0
	Week 17	34	2.37	2.36	0.0	1.71	8.0	29	0.16	2.40	-4.1	0.00	5.6
	Week 20	28	1.96	2.10	0.0	1.64	6.6	24	-0.32	2.60	-4.3	-0.21	6.6
	Week 23	22	2.73	2.33	0.0	2.93	7.0	19	0.53	2.16	-4.3	0.00	4.3
	Week 26	22	2.40	2.60	0.0	2.00	8.9	20	-0.08	2.59	-4.1	-0.21	4.9
	Week 29	24	2.10	1.94	0.0	1.64	5.7	21	-0.44	2.30	-4.6	-0.14	5.7
	Week 32	21	3.10	2.76	0.0	2.43	8.4	20	0.83	2.79	-5.9	0.43	7.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.1.4: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 35	18	2.99	2.78	0.0	2.43	9.4	17	0.99	3.02	-5.6	0.86	6.7
	Week 38	14	2.10	2.96	0.0	0.79	8.1	13	0.29	2.69	-5.7	0.00	6.7
	Week 41	13	2.45	2.13	0.0	2.14	6.4	12	0.11	2.25	-6.0	0.14	2.9
	Week 44	14	2.86	1.97	0.0	2.71	6.0	13	0.41	2.18	-4.4	0.29	3.9
	Week 47	12	3.55	2.00	0.0	3.57	6.3	11	0.96	2.75	-5.0	0.29	5.1

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.1.5: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Visceral metastases	EV+Pembro (N=170)												
	BASELINE	149	2.23	2.68	0.0	0.86	9.6						
	Week 1	135	2.64	2.62	0.0	1.71	9.6	134	0.38	1.97	-7.9	0.14	7.7
	Week 2	146	2.61	2.51	0.0	1.93	10.0	137	0.55	2.31	-6.9	0.29	10.0
	Week 3	142	2.60	2.49	0.0	2.00	9.3	132	0.33	2.49	-8.0	0.29	8.0
	Week 4	136	2.13	2.23	0.0	1.57	8.3	126	-0.08	2.47	-8.6	0.00	5.9
	Week 5	133	1.92	2.25	0.0	1.00	8.4	121	-0.19	2.43	-8.6	0.00	7.7
	Week 6	128	1.91	2.18	0.0	1.00	8.9	115	-0.21	2.69	-8.0	0.00	7.4
	Week 7	136	1.99	2.37	0.0	1.14	10.0	123	-0.28	3.04	-8.6	0.00	10.0
	Week 8	132	1.89	2.38	0.0	0.79	10.0	120	-0.40	2.98	-8.4	0.00	8.1
	Week 9	137	2.05	2.40	0.0	1.00	9.7	126	-0.12	2.83	-8.1	0.00	9.7
	Week 10	135	1.82	2.26	0.0	1.00	8.4	125	-0.31	2.78	-8.6	0.00	8.4
	Week 11	136	1.65	2.12	0.0	0.86	9.3	124	-0.60	2.69	-8.6	0.00	5.7
	Week 12	131	1.75	2.24	0.0	0.57	9.3	121	-0.49	2.88	-8.6	0.00	9.1
	Week 14	130	1.87	2.24	0.0	1.00	9.0	118	-0.39	2.82	-8.6	0.00	9.0
	Week 17	124	1.80	2.28	0.0	0.71	9.4	112	-0.45	2.99	-8.6	0.00	6.1
	Week 20	115	1.88	2.35	0.0	1.00	9.0	106	-0.24	2.84	-8.1	0.00	8.9
	Week 23	111	1.76	2.13	0.0	1.00	9.4	103	-0.39	2.73	-8.1	0.00	7.0
	Week 26	106	1.80	2.34	0.0	0.79	9.3	98	-0.50	3.08	-8.6	0.00	6.6
	Week 29	106	1.59	2.05	0.0	0.64	9.3	99	-0.39	2.60	-8.6	0.00	6.3
	Week 32	92	2.22	2.50	0.0	1.29	8.9	85	0.17	2.87	-8.0	0.00	8.3
	Week 35	86	1.90	2.10	0.0	1.00	7.1	79	-0.01	2.67	-7.7	0.00	7.0
	Week 38	90	1.81	2.23	0.0	0.71	9.3	84	-0.35	2.96	-8.6	0.00	6.0
	Week 41	87	2.07	2.39	0.0	1.29	10.0	81	-0.01	2.80	-8.1	0.00	6.6
	Week 44	73	1.92	2.20	0.0	1.00	8.4	68	-0.08	3.16	-7.9	0.00	6.7
	Week 47	68	1.77	2.06	0.0	1.00	7.1	63	-0.30	3.08	-8.6	0.00	7.1

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.1.5: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	61	2.02	2.29	0.0	1.00	7.3	57	0.45	2.56	-7.7	0.00	6.6
	Week 53	54	1.69	2.20	0.0	0.43	8.0	50	-0.08	3.43	-8.3	0.00	8.0
	Week 56	58	1.79	2.50	0.0	0.50	9.9	54	-0.01	3.65	-8.3	0.00	9.7
	Week 59	50	1.78	2.38	0.0	0.71	9.1	47	0.01	3.33	-8.3	0.00	9.0
	Week 62	45	1.48	2.22	0.0	0.00	8.9	43	-0.11	3.37	-8.3	0.00	8.7
	Week 65	37	1.84	2.45	0.0	0.43	7.3	34	-0.34	3.32	-8.1	0.00	6.7
	Week 68	35	1.53	2.15	0.0	0.86	7.4	34	-0.34	3.46	-8.1	0.00	6.4
	Week 71	31	1.59	2.22	0.0	0.14	7.0	30	-0.41	3.41	-8.1	-0.07	6.9
	Week 74	29	1.51	1.96	0.0	0.14	6.1	28	0.02	2.57	-7.6	0.00	6.0
	Week 77	26	2.26	2.43	0.0	1.29	7.6	25	0.31	3.06	-6.7	0.43	5.4
	Week 80	22	2.13	2.60	0.0	0.64	7.7	21	-0.25	3.23	-7.1	0.00	5.1
	Week 83	23	1.58	1.78	0.0	0.86	5.3	22	-0.53	2.99	-7.4	-0.21	4.3
	Week 86	21	1.71	2.10	0.0	0.57	6.4	20	-0.45	3.15	-7.1	-0.29	4.9
	Week 89	21	2.06	2.50	0.0	0.57	7.7	20	-0.33	2.79	-7.3	0.00	4.9
	Week 92	18	2.87	3.07	0.0	1.64	9.4	17	0.89	2.90	-3.1	0.00	6.0
	Week 95	13	2.10	2.66	0.0	0.43	6.9	12	0.05	3.44	-4.6	-0.07	5.9
	Week 98	11	1.79	2.97	0.0	0.00	8.4	11	-0.45	2.22	-3.7	-0.43	3.3
	Week 101	11	2.38	2.99	0.0	0.86	7.4	11	0.55	2.36	-3.0	0.00	6.1
	Plat+Gem (N=161)												
	BASELINE	131	3.04	2.78	0.0	2.71	10.0						
	Week 1	117	2.84	2.60	0.0	2.43	10.0	110	0.06	2.34	-7.7	0.00	9.7
	Week 2	110	2.90	2.68	0.0	2.71	10.0	100	-0.03	2.33	-7.7	0.00	7.6
	Week 3	121	2.67	2.61	0.0	2.00	9.0	109	-0.18	2.33	-7.7	0.00	8.6
	Week 4	116	2.39	2.36	0.0	2.00	8.9	102	-0.52	2.20	-7.7	-0.43	5.1
	Week 5	121	2.37	2.35	0.0	1.86	8.7	105	-0.35	2.29	-7.7	0.00	5.6
	Week 6	118	2.31	2.47	0.0	1.57	9.3	104	-0.59	2.45	-7.9	0.00	4.9

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.1.5: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 7	122	2.07	2.18	0.0	1.29	8.9	107	-0.74	2.32	-7.9	-0.43	8.1
	Week 8	108	2.05	2.13	0.0	1.29	8.7	98	-0.74	2.53	-8.0	-0.29	6.4
	Week 9	114	2.24	2.31	0.0	1.50	9.4	101	-0.69	2.37	-8.3	-0.43	5.9
	Week 10	109	2.19	2.31	0.0	1.29	8.9	96	-0.76	2.46	-7.9	-0.50	7.6
	Week 11	109	1.92	2.27	0.0	0.86	9.0	97	-0.88	2.46	-8.1	-0.29	4.6
	Week 12	103	2.26	2.29	0.0	1.43	8.6	93	-0.40	2.53	-7.9	-0.14	6.6
	Week 14	98	2.37	2.14	0.0	2.21	7.7	86	-0.42	2.57	-8.3	-0.07	5.0
	Week 17	103	2.39	2.43	0.0	1.57	7.9	91	-0.32	2.75	-7.9	0.00	6.9
	Week 20	82	2.00	2.40	0.0	1.14	10.0	76	-0.81	2.64	-7.7	-0.36	6.6
	Week 23	77	2.45	2.61	0.0	2.00	9.0	69	-0.14	2.57	-5.7	0.00	7.3
	Week 26	71	2.01	2.18	0.0	1.14	8.9	66	-0.46	2.39	-6.3	-0.36	5.1
	Week 29	65	2.00	1.95	0.0	1.71	7.0	60	-0.29	2.12	-4.6	-0.07	5.7
	Week 32	52	1.99	2.23	0.0	1.21	8.0	50	-0.25	2.41	-5.9	0.00	6.1
	Week 35	47	2.15	2.17	0.0	1.43	9.4	45	-0.14	2.48	-5.6	0.00	6.7
	Week 38	42	1.70	2.15	0.0	1.00	7.4	40	-0.36	2.48	-5.7	0.00	7.4
	Week 41	35	1.84	2.14	0.0	1.00	6.6	33	-0.26	2.40	-6.0	0.00	6.6
	Week 44	36	2.39	2.22	0.0	1.71	7.3	34	0.16	2.69	-4.9	0.00	6.0
	Week 47	32	2.18	2.16	0.0	1.36	7.6	31	-0.13	2.75	-5.0	0.00	6.1
	Week 50	30	2.69	2.32	0.0	2.50	6.7	29	-0.07	2.38	-5.4	0.00	5.6
	Week 53	25	1.69	1.87	0.0	1.00	5.9	24	-0.18	1.61	-3.7	0.00	2.9
	Week 56	22	2.72	2.63	0.0	2.07	7.3	21	0.56	3.07	-3.4	0.00	7.3
	Week 59	22	2.00	2.07	0.0	1.79	8.0	21	0.29	3.00	-3.3	0.00	8.0
	Week 62	19	1.87	1.72	0.0	1.86	5.3	18	-0.13	2.94	-5.6	-0.36	4.6
	Week 65	19	1.38	1.91	0.0	0.29	6.6	18	-0.28	2.66	-7.0	0.00	4.3
	Week 68	13	2.04	2.84	0.0	0.29	7.6	12	0.69	2.03	-2.3	0.14	5.4
	Week 71	13	2.48	2.81	0.0	1.43	8.0	12	0.92	1.95	-1.6	0.71	6.4

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.1.5: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 74	11	2.10	2.69	0.0	1.00	8.6	11	0.22	1.77	-3.0	0.57	2.6
	Week 77	10	1.41	1.87	0.0	0.57	5.1	10	-0.61	2.19	-5.7	0.00	2.6

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.1.5: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Lymph node only	EV+Pembro (N= 60)												
	BASELINE	53	2.21	2.36	0.0	1.86	8.0						
	Week 1	49	1.84	2.04	0.0	1.29	7.1	47	-0.21	2.09	-4.1	0.00	6.1
	Week 2	50	2.50	2.38	0.0	1.86	7.9	48	0.36	2.32	-4.6	0.00	7.7
	Week 3	50	2.03	1.88	0.0	1.50	8.1	47	-0.15	2.02	-5.0	0.00	4.9
	Week 4	51	1.50	1.98	0.0	0.71	7.9	48	-0.57	1.73	-5.4	0.00	3.7
	Week 5	54	1.87	2.18	0.0	1.00	7.1	50	-0.21	2.08	-5.6	0.00	3.9
	Week 6	53	1.64	2.12	0.0	1.00	9.6	50	-0.52	1.95	-5.6	0.00	3.1
	Week 7	52	1.43	1.74	0.0	0.71	6.7	48	-0.55	1.94	-5.4	0.00	4.7
	Week 8	52	1.65	2.22	0.0	0.86	8.7	47	-0.53	2.18	-6.0	0.00	4.6
	Week 9	53	1.98	2.17	0.0	1.00	9.4	49	-0.31	2.12	-5.4	0.00	4.0
	Week 10	48	1.43	1.88	0.0	0.64	6.7	44	-0.65	2.21	-5.4	0.00	5.4
	Week 11	53	1.79	2.11	0.0	1.14	9.7	48	-0.46	2.17	-5.6	0.00	3.7
	Week 12	48	2.11	2.39	0.0	1.00	10.0	45	-0.01	2.23	-5.7	0.00	5.4
	Week 14	48	2.07	2.41	0.0	1.00	9.3	44	-0.01	2.02	-4.9	0.00	4.9
	Week 17	46	2.05	2.13	0.0	1.50	7.9	44	-0.08	2.19	-5.7	0.00	5.7
	Week 20	44	2.23	2.76	0.0	1.07	9.4	42	0.30	2.51	-6.0	0.00	5.7
	Week 23	43	2.13	2.33	0.0	1.43	8.9	41	0.26	2.40	-5.3	0.00	5.9
	Week 26	42	2.24	2.24	0.0	1.93	8.0	40	0.42	2.24	-4.7	0.00	7.0
	Week 29	45	2.70	2.45	0.0	2.57	9.7	42	0.60	2.06	-4.0	0.14	5.6
	Week 32	38	2.53	2.27	0.0	2.14	7.4	36	0.84	2.26	-3.0	0.29	7.0
	Week 35	42	2.48	2.48	0.0	1.64	9.3	40	0.49	2.38	-5.7	0.07	6.9
	Week 38	38	2.04	2.27	0.0	1.43	9.7	36	0.11	2.64	-5.7	0.00	7.1
	Week 41	37	2.63	2.52	0.0	1.57	7.0	34	0.92	2.38	-4.4	0.36	7.0
	Week 44	31	2.36	2.29	0.0	2.00	7.0	29	1.01	2.45	-4.6	0.14	7.0
	Week 47	28	2.40	2.50	0.0	2.07	9.4	27	0.60	2.49	-4.0	0.00	7.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.1.5: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	25	1.85	1.88	0.0	1.43	5.9	24	0.24	2.36	-5.3	0.00	5.9
	Week 53	23	2.04	1.94	0.0	1.43	5.7	22	0.36	2.66	-5.1	0.00	5.7
	Week 56	21	2.16	2.36	0.0	1.71	9.0	20	0.26	2.11	-5.3	0.00	4.4
	Week 59	20	1.84	1.91	0.0	1.43	5.6	19	-0.06	2.27	-5.6	0.00	4.4
	Week 62	19	2.42	2.38	0.0	2.43	6.7	19	0.89	1.77	-2.4	0.57	5.0
	Week 65	20	2.50	2.44	0.0	2.93	7.9	19	0.26	2.34	-5.6	0.00	4.1
	Week 68	17	2.18	2.17	0.0	2.71	6.4	17	0.29	2.06	-5.7	0.14	3.9
	Week 71	19	1.93	1.72	0.0	1.86	4.7	18	0.57	1.84	-3.4	0.29	3.9
	Week 74	17	2.55	1.96	0.0	2.71	5.0	17	0.89	1.76	-2.1	0.43	4.9
	Week 77	17	2.66	2.54	0.0	3.43	8.6	16	0.78	2.23	-5.7	1.00	4.0
	Week 80	17	2.16	2.51	0.0	1.71	7.9	15	0.27	1.97	-5.7	0.29	2.9
	Week 83	13	3.00	2.56	0.0	3.43	7.7	12	0.30	2.20	-5.7	0.64	2.4
	Week 86	12	2.48	2.32	0.0	2.29	7.7	10	0.61	1.44	-2.7	0.71	2.0
	Week 89	11	2.01	1.62	0.0	2.57	3.9	10	-0.26	2.41	-5.7	0.00	2.6
	Plat+Gem (N= 67)												
	BASELINE	49	1.87	2.48	0.0	0.57	10.0						
	Week 1	52	2.46	2.37	0.0	1.86	7.1	45	0.38	1.85	-4.1	0.14	5.6
	Week 2	53	2.33	2.31	0.0	1.57	8.4	44	0.50	2.33	-4.4	0.00	7.9
	Week 3	54	2.35	2.67	0.0	1.21	8.1	45	0.36	2.52	-4.6	0.00	6.9
	Week 4	58	2.29	2.42	0.0	1.50	9.1	47	0.31	2.53	-7.9	0.00	7.6
	Week 5	56	2.52	2.42	0.0	1.86	9.3	44	0.65	2.79	-5.6	0.14	8.7
	Week 6	48	2.21	2.54	0.0	1.43	7.9	40	0.18	2.51	-5.6	0.00	7.6
	Week 7	56	2.27	2.62	0.0	1.29	8.3	46	0.44	2.47	-5.6	0.00	6.1
	Week 8	52	2.94	3.11	0.0	1.64	10.0	42	1.04	3.25	-4.6	0.00	10.0
	Week 9	53	2.65	2.81	0.0	2.00	9.3	42	0.85	3.17	-5.6	0.14	9.3
	Week 10	47	2.14	2.47	0.0	1.43	8.3	36	0.56	2.49	-4.6	0.00	8.3

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.1.5: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	51	2.15	2.41	0.0	1.43	8.9	41	0.23	1.87	-3.9	0.00	6.1
	Week 12	47	1.87	2.19	0.0	1.00	9.4	39	0.20	1.79	-4.6	0.00	5.1
	Week 14	47	1.69	2.13	0.0	1.00	8.0	36	-0.13	2.20	-6.4	0.00	6.0
	Week 17	46	2.14	2.34	0.0	1.36	8.7	36	0.71	2.37	-5.6	0.07	6.4
	Week 20	38	1.31	1.63	0.0	0.50	5.7	30	-0.02	2.02	-4.1	0.00	4.3
	Week 23	32	1.92	2.62	0.0	0.57	8.0	25	0.81	2.43	-4.0	0.00	8.0
	Week 26	30	2.10	2.62	0.0	0.71	9.0	24	0.77	2.33	-4.1	0.00	6.0
	Week 29	28	1.67	1.97	0.0	0.57	5.4	21	0.49	1.96	-3.0	0.00	5.3
	Week 32	26	1.97	2.69	0.0	0.71	8.4	22	0.82	2.70	-4.3	0.00	8.0
	Week 35	23	2.12	2.57	0.0	0.57	8.0	19	1.14	2.36	-1.7	0.00	6.6
	Week 38	26	1.96	2.60	0.0	0.29	8.1	20	0.64	2.93	-4.3	0.00	6.7
	Week 41	24	2.10	2.36	0.0	1.21	8.0	18	0.76	2.68	-4.3	0.14	8.0
	Week 44	18	2.27	2.51	0.0	1.36	7.1	14	0.68	2.35	-4.0	0.07	7.0
	Week 47	18	2.18	2.27	0.0	1.29	6.3	13	0.97	2.53	-4.3	0.14	6.0
	Week 50	16	3.00	3.04	0.0	2.57	8.1	13	1.25	2.68	-4.3	0.00	5.0
	Week 53	15	1.86	2.27	0.0	0.29	7.0	12	-0.25	1.83	-4.1	0.00	3.7
	Week 56	15	2.12	2.90	0.0	0.57	9.7	11	-0.34	1.54	-3.7	0.00	1.4
	Week 59	12	1.71	2.59	0.0	0.00	8.0	9	-0.49	2.15	-4.3	0.00	3.1
	Week 62	10	1.11	1.97	0.0	0.14	6.0	8	-0.29	1.58	-4.0	0.00	1.4

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.2: BPI-SF - Observed Means and Change from Baseline of Pain Interference - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
EV+Pembro (N=202)												
BASELINE	166	2.65	2.80	0.0	1.79	9.7						
Week 1	142	2.90	2.61	0.0	2.71	10.0	134	0.33	2.05	-5.0	0.00	7.7
Week 2	154	3.15	2.74	0.0	2.93	9.7	141	0.52	2.30	-4.6	0.00	7.0
Week 3	139	2.74	2.69	0.0	2.14	9.7	126	0.01	2.46	-7.0	0.00	6.7
Week 4	147	2.15	2.37	0.0	1.14	8.0	134	-0.40	2.49	-8.0	0.00	5.9
Week 5	139	2.03	2.31	0.0	1.14	8.1	126	-0.46	2.73	-8.0	0.00	6.7
Week 6	147	2.27	2.55	0.0	1.29	9.4	128	-0.43	3.20	-9.1	0.00	8.1
Week 7	150	1.95	2.27	0.0	1.14	8.4	129	-0.59	3.02	-8.0	0.00	8.4
Week 8	150	1.92	2.28	0.0	0.93	10.0	129	-0.68	3.12	-8.0	0.00	8.7
Week 9	142	2.08	2.49	0.0	1.14	10.0	125	-0.42	3.12	-8.0	0.00	8.4
Week 10	139	1.88	2.29	0.0	1.00	9.1	122	-0.60	3.10	-8.0	0.00	7.0
Week 11	138	1.57	2.14	0.0	0.57	9.3	119	-0.87	2.66	-7.9	0.00	5.3
Week 12	143	1.76	2.34	0.0	0.57	9.3	123	-0.66	3.01	-8.0	0.00	7.7
Week 14	140	1.88	2.49	0.0	0.79	9.9	120	-0.52	3.15	-9.1	0.00	7.6
Week 17	132	1.78	2.30	0.0	0.93	10.0	114	-0.71	3.09	-9.1	0.00	8.0
Week 20	120	1.75	2.12	0.0	0.86	9.0	106	-0.58	2.76	-8.0	0.00	5.7
Week 23	117	1.54	2.14	0.0	0.29	8.0	100	-0.61	2.90	-9.1	0.00	7.0
Week 26	114	1.88	2.27	0.0	1.00	8.3	97	-0.42	3.00	-9.1	0.00	6.3
Week 29	107	1.77	2.22	0.0	0.57	8.9	95	-0.38	3.08	-9.1	0.00	8.6
Week 32	102	1.76	2.22	0.0	0.57	9.4	90	-0.55	3.15	-9.1	0.00	9.1
Week 35	98	1.94	2.21	0.0	1.07	10.0	88	-0.28	3.09	-9.1	0.00	9.7
Week 38	97	1.80	1.99	0.0	1.00	8.1	88	-0.57	2.77	-9.1	0.00	4.0
Week 41	95	1.81	2.15	0.0	1.00	7.7	87	-0.50	2.92	-9.1	0.00	7.1
Week 44	86	2.12	2.49	0.0	1.00	9.4	77	-0.10	2.98	-9.1	0.00	9.1
Week 47	79	2.17	2.42	0.0	1.29	10.0	72	-0.23	3.19	-9.1	0.00	6.7

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.2: BPI-SF - Observed Means and Change from Baseline of Pain Interference - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	75	2.10	2.41	0.0	1.29	9.9	66	-0.16	3.10	-9.1	0.00	7.9
Week 53	76	2.40	2.53	0.0	1.86	8.3	66	-0.03	3.13	-9.1	0.00	6.3
Week 56	72	2.17	2.09	0.0	1.57	7.1	63	-0.52	2.91	-9.1	0.00	5.6
Week 59	69	2.25	2.28	0.0	1.29	8.7	59	-0.54	3.16	-9.1	0.00	6.7
Week 62	62	2.26	2.31	0.0	1.64	7.9	54	-0.12	3.08	-9.1	0.00	6.0
Week 65	43	2.18	2.36	0.0	1.14	7.7	41	-0.07	3.32	-9.1	0.00	7.7
Week 68	46	2.34	2.31	0.0	1.71	8.1	43	0.29	3.06	-9.1	0.00	5.7
Week 71	42	2.01	2.30	0.0	1.00	7.0	39	-0.43	3.15	-9.1	-0.29	6.3
Week 74	38	2.05	2.47	0.0	0.64	7.6	36	-0.11	3.49	-9.1	0.00	7.6
Week 77	37	1.87	2.26	0.0	0.86	7.6	34	-0.45	3.14	-9.1	-0.07	7.6
Week 80	36	2.33	2.63	0.0	1.00	7.9	35	0.01	3.52	-9.1	0.00	7.9
Week 83	30	2.18	2.33	0.0	1.50	8.1	30	-0.15	3.58	-9.1	-0.29	8.1
Week 86	26	2.05	2.59	0.0	0.86	7.9	26	0.12	3.48	-9.1	0.00	7.9
Week 89	20	1.58	2.58	0.0	0.00	8.0	20	0.32	3.06	-5.3	0.00	8.0
Week 92	19	2.20	2.56	0.0	1.00	7.0	19	0.52	2.81	-3.9	0.00	7.0
Week 95	14	0.84	1.05	0.0	0.21	2.7	14	-0.26	1.64	-3.9	0.00	2.7
Week 98	10	0.79	0.97	0.0	0.29	2.4	10	-0.66	1.68	-3.9	-0.43	2.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.2: BPI-SF - Observed Means and Change from Baseline of Pain Interference - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Plat+Gem (N=202)												
BASELINE	168	2.59	2.93	0.0	1.14	10.0						
Week 1	146	3.11	2.83	0.0	2.86	10.0	142	0.61	2.62	-8.3	0.00	10.0
Week 2	151	3.12	2.79	0.0	2.57	9.9	140	0.62	2.21	-5.6	0.00	7.3
Week 3	149	2.65	2.67	0.0	1.86	10.0	138	0.25	2.32	-6.6	0.00	7.6
Week 4	151	2.52	2.48	0.0	1.86	10.0	137	-0.01	2.37	-8.4	0.00	6.0
Week 5	155	2.62	2.51	0.0	2.00	9.3	141	0.25	2.61	-8.6	0.00	7.6
Week 6	145	2.59	2.63	0.0	2.00	10.0	131	0.17	2.86	-8.6	0.00	9.0
Week 7	149	2.61	2.52	0.0	2.00	9.0	136	0.24	2.94	-10.0	0.00	8.0
Week 8	146	2.93	2.66	0.0	2.29	10.0	133	0.53	3.11	-9.6	0.00	8.7
Week 9	141	2.61	2.59	0.0	1.86	10.0	126	0.17	3.17	-8.4	0.07	8.0
Week 10	142	2.58	2.58	0.0	1.86	10.0	130	0.13	2.91	-9.4	0.00	7.1
Week 11	126	2.67	2.57	0.0	2.00	10.0	115	0.28	2.82	-7.6	0.00	7.3
Week 12	130	2.44	2.37	0.0	2.00	10.0	116	-0.02	2.60	-8.0	0.00	6.3
Week 14	125	2.75	2.59	0.0	2.00	10.0	110	0.28	2.89	-8.1	0.00	8.1
Week 17	120	2.66	2.67	0.0	1.86	9.3	108	0.31	3.02	-6.9	0.00	8.6
Week 20	104	2.31	2.64	0.0	1.14	9.4	93	0.14	2.88	-8.4	0.00	7.7
Week 23	88	1.89	2.06	0.0	1.07	6.9	81	-0.17	2.68	-8.6	0.00	6.9
Week 26	81	2.25	2.35	0.0	1.29	8.1	76	0.01	2.66	-6.7	0.00	6.3
Week 29	77	2.52	2.63	0.0	2.00	10.0	71	0.71	3.09	-7.9	0.29	9.7
Week 32	64	2.24	2.47	0.0	1.21	8.6	59	0.31	2.81	-8.3	0.00	5.6
Week 35	62	2.11	2.38	0.0	1.07	8.9	57	0.08	2.60	-6.6	0.00	6.4
Week 38	56	2.27	2.65	0.0	1.07	9.0	50	0.53	2.16	-6.1	0.00	6.4
Week 41	52	2.47	2.57	0.0	1.71	7.9	47	0.79	1.96	-3.7	0.29	5.4
Week 44	49	2.70	2.68	0.0	2.14	8.4	44	1.15	2.70	-3.7	0.14	8.0
Week 47	43	2.25	2.61	0.0	1.29	8.6	39	0.52	2.60	-5.9	0.00	6.7

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.2: BPI-SF - Observed Means and Change from Baseline of Pain Interference - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	36	2.62	2.69	0.0	1.93	8.3	31	0.72	2.79	-5.7	0.14	6.3
Week 53	31	2.40	2.85	0.0	1.14	8.7	28	0.63	2.95	-6.0	0.07	6.6
Week 56	30	2.90	2.77	0.0	2.29	7.7	29	0.97	2.90	-5.7	0.00	7.4
Week 59	23	2.49	2.45	0.0	2.00	7.1	21	0.50	3.08	-6.0	0.00	6.4
Week 62	20	2.78	2.35	0.0	2.64	7.9	20	0.81	3.53	-6.7	0.21	7.9
Week 65	17	3.29	2.68	0.0	3.00	8.4	16	1.71	3.02	-4.4	1.14	8.1
Week 68	13	2.36	2.22	0.0	2.43	6.7	13	0.84	2.65	-4.4	0.00	6.7
Week 71	13	2.52	2.71	0.0	1.29	7.3	13	0.40	2.60	-4.4	0.00	5.7
Week 74	11	1.56	1.54	0.0	1.14	4.3	11	0.12	1.84	-4.0	0.00	2.7
Week 77	11	1.88	2.37	0.0	0.14	6.7	11	0.77	3.21	-6.1	0.00	5.1

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.2.1: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Present	EV+Pembro (N= 50)												
	BASELINE	41	3.31	2.97	0.0	2.86	8.9						
	Week 1	38	3.56	2.87	0.0	3.57	10.0	35	0.57	2.10	-3.3	0.00	7.1
	Week 2	36	3.54	2.68	0.0	3.21	9.7	34	0.53	2.38	-2.9	0.00	6.9
	Week 3	32	2.67	2.59	0.0	2.07	7.7	30	0.04	2.39	-4.0	0.00	6.7
	Week 4	35	2.14	2.36	0.0	1.00	8.0	31	-0.57	1.82	-4.1	-0.29	3.4
	Week 5	32	2.13	2.33	0.0	1.14	7.1	28	-0.46	2.51	-7.1	0.00	5.3
	Week 6	35	2.12	2.50	0.0	1.71	8.6	30	-1.20	3.02	-7.3	-0.14	6.9
	Week 7	35	2.08	2.41	0.0	0.71	7.0	29	-0.60	3.13	-7.3	0.00	4.3
	Week 8	38	1.98	2.07	0.0	1.50	6.4	31	-0.86	2.80	-7.3	0.00	4.0
	Week 9	33	1.85	2.16	0.0	1.00	7.1	29	-1.08	2.62	-6.7	-0.43	4.7
	Week 10	30	1.71	2.01	0.0	0.93	6.1	25	-1.60	2.78	-7.3	-0.43	2.1
	Week 11	31	1.49	2.29	0.0	0.29	9.3	27	-1.13	2.82	-7.3	-0.29	5.1
	Week 12	32	1.54	2.19	0.0	0.50	7.7	28	-1.26	2.80	-7.3	-0.07	4.1
	Week 14	36	2.14	2.68	0.0	0.93	7.7	31	-0.98	3.44	-7.3	-0.43	6.3
	Week 17	33	1.83	2.56	0.0	0.57	10.0	27	-1.09	3.09	-7.3	-0.14	6.7
	Week 20	28	2.03	2.38	0.0	0.93	9.0	25	-0.52	2.88	-6.4	-0.29	5.7
	Week 23	28	1.81	2.28	0.0	0.50	7.4	24	-0.57	2.81	-6.3	-0.21	5.7
	Week 26	28	2.11	2.25	0.0	1.86	7.4	24	-0.61	2.97	-5.9	-0.07	6.3
	Week 29	27	1.99	2.27	0.0	0.57	6.6	25	-0.69	2.79	-7.0	-0.29	5.6
	Week 32	25	1.61	2.09	0.0	0.57	6.1	23	-1.11	2.69	-7.6	-0.43	5.9
	Week 35	26	1.84	2.01	0.0	1.21	5.9	24	-0.76	2.82	-7.6	-0.43	4.3
	Week 38	26	1.95	1.86	0.0	1.43	5.4	24	-0.64	3.08	-7.3	-0.14	3.4
	Week 41	25	1.56	2.00	0.0	0.71	6.4	23	-0.63	2.69	-7.6	0.00	3.6
	Week 44	22	2.18	2.40	0.0	1.29	6.9	20	-0.38	2.82	-7.6	-0.14	3.7
	Week 47	14	2.38	2.98	0.0	1.21	10.0	13	-0.67	3.80	-7.6	-0.43	6.7

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.2.1: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	2.20	2.91	0.0	1.14	9.9	17	-0.24	3.58	-7.6	0.00	7.9
	Week 53	21	2.44	2.65	0.0	2.00	8.3	18	-0.17	3.47	-7.6	-0.14	6.3
	Week 56	18	2.71	1.92	0.0	3.00	5.9	15	-0.28	2.98	-7.6	-0.14	3.9
	Week 59	18	3.02	2.68	0.0	2.71	8.7	15	-0.70	3.03	-7.6	-0.71	4.1
	Week 62	13	2.55	2.65	0.0	2.00	7.9	11	-0.35	3.24	-7.6	0.00	3.1
	Week 68	12	2.14	1.90	0.0	2.14	5.7	11	-0.25	3.61	-7.6	0.00	5.7
	Plat+Gem (N= 50)												
	BASELINE	41	3.43	3.04	0.0	2.71	10.0						
	Week 1	35	3.59	2.66	0.0	3.14	8.7	34	0.47	2.41	-8.3	0.57	5.3
	Week 2	34	3.46	2.74	0.0	2.93	8.7	31	0.65	2.10	-2.0	0.00	5.3
	Week 3	33	3.06	2.72	0.0	2.71	8.7	30	0.39	1.72	-2.9	0.14	5.1
	Week 4	36	2.66	2.46	0.0	2.43	7.6	33	-0.36	2.63	-8.4	0.00	5.6
	Week 5	36	2.75	2.62	0.0	2.07	7.6	33	-0.06	3.17	-8.6	-0.14	7.6
	Week 6	32	2.64	2.70	0.0	2.21	9.0	29	-0.17	3.69	-8.6	0.00	9.0
	Week 7	35	2.87	2.53	0.0	2.57	7.9	32	-0.34	2.94	-5.4	-0.50	5.6
	Week 8	36	3.58	2.58	0.0	3.71	8.9	32	0.52	3.46	-5.6	-0.14	7.4
	Week 9	34	3.22	2.40	0.0	3.14	8.1	30	0.10	3.63	-7.1	-0.64	6.7
	Week 10	33	2.94	2.44	0.0	2.43	8.3	30	-0.43	2.96	-5.1	-0.29	6.4
	Week 11	30	2.96	2.43	0.0	2.36	8.7	26	-0.03	2.98	-5.1	-0.29	6.9
	Week 12	32	2.82	2.17	0.0	2.64	7.4	28	-0.29	2.63	-6.0	0.00	5.4
	Week 14	27	3.04	2.61	0.0	2.29	8.1	23	0.15	3.56	-7.0	0.00	8.1
	Week 17	28	2.64	2.25	0.0	2.36	7.9	24	-0.04	3.37	-6.4	0.00	6.1
	Week 20	20	2.34	2.70	0.0	1.21	9.4	17	-0.67	3.19	-8.4	-0.14	7.0
	Week 23	15	2.18	2.10	0.0	2.43	6.0	14	-0.81	1.93	-5.0	-0.29	2.4
	Week 26	15	2.01	2.52	0.0	0.71	8.1	14	-0.91	2.32	-4.9	-0.29	1.7
	Week 29	13	2.75	3.25	0.0	2.57	10.0	12	1.06	3.39	-3.9	0.14	9.7

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.2.1: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Absent	EV+Pembro (N=152)												
	BASELINE	125	2.44	2.72	0.0	1.43	9.7						
	Week 1	104	2.65	2.49	0.0	2.64	8.1	99	0.24	2.04	-5.0	0.14	7.7
	Week 2	118	3.03	2.75	0.0	2.71	9.7	107	0.52	2.29	-4.6	0.00	7.0
	Week 3	107	2.77	2.73	0.0	2.14	9.7	96	0.00	2.50	-7.0	0.00	6.6
	Week 4	112	2.15	2.38	0.0	1.21	8.0	103	-0.34	2.67	-8.0	0.00	5.9
	Week 5	107	2.00	2.31	0.0	1.14	8.1	98	-0.46	2.80	-8.0	0.00	6.7
	Week 6	112	2.31	2.58	0.0	1.21	9.4	98	-0.19	3.23	-9.1	0.00	8.1
	Week 7	115	1.91	2.24	0.0	1.14	8.4	100	-0.58	3.00	-8.0	0.00	8.4
	Week 8	112	1.90	2.36	0.0	0.71	10.0	98	-0.63	3.23	-8.0	-0.07	8.7
	Week 9	109	2.16	2.58	0.0	1.14	10.0	96	-0.22	3.24	-8.0	0.00	8.4
	Week 10	109	1.93	2.37	0.0	1.00	9.1	97	-0.34	3.14	-8.0	0.00	7.0
	Week 11	107	1.59	2.10	0.0	0.57	8.7	92	-0.79	2.63	-7.9	0.00	5.3
	Week 12	111	1.83	2.39	0.0	0.57	9.3	95	-0.49	3.07	-8.0	0.00	7.7
	Week 14	104	1.79	2.42	0.0	0.71	9.9	89	-0.36	3.04	-9.1	0.00	7.6
	Week 17	99	1.77	2.22	0.0	1.00	8.6	87	-0.59	3.09	-9.1	0.00	8.0
	Week 20	92	1.67	2.05	0.0	0.86	8.3	81	-0.60	2.74	-8.0	0.00	5.0
	Week 23	89	1.46	2.09	0.0	0.29	8.0	76	-0.62	2.95	-9.1	0.00	7.0
	Week 26	86	1.81	2.29	0.0	0.86	8.3	73	-0.36	3.03	-9.1	0.00	6.1
	Week 29	80	1.69	2.21	0.0	0.64	8.9	70	-0.28	3.19	-9.1	0.00	8.6
	Week 32	77	1.82	2.27	0.0	1.00	9.4	67	-0.36	3.29	-9.1	0.00	9.1
	Week 35	72	1.98	2.28	0.0	1.00	10.0	64	-0.10	3.19	-9.1	0.00	9.7
	Week 38	71	1.74	2.05	0.0	1.00	8.1	64	-0.55	2.66	-9.1	0.00	4.0
	Week 41	70	1.89	2.21	0.0	1.00	7.7	64	-0.45	3.01	-9.1	0.00	7.1
	Week 44	64	2.10	2.54	0.0	0.86	9.4	57	-0.01	3.05	-9.1	0.00	9.1
	Week 47	65	2.12	2.31	0.0	1.29	8.4	59	-0.13	3.06	-9.1	0.00	6.6

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.2.1: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	55	2.06	2.24	0.0	1.29	7.4	49	-0.14	2.96	-9.1	0.00	6.4
	Week 53	55	2.39	2.51	0.0	1.29	8.1	48	0.02	3.03	-9.1	0.00	6.1
	Week 56	54	2.00	2.13	0.0	1.21	7.1	48	-0.60	2.92	-9.1	0.00	5.6
	Week 59	51	1.97	2.09	0.0	1.29	7.1	44	-0.49	3.24	-9.1	0.00	6.7
	Week 62	49	2.18	2.23	0.0	1.43	7.4	43	-0.06	3.07	-9.1	0.00	6.0
	Week 65	36	2.32	2.44	0.0	1.36	7.7	34	0.13	3.29	-9.1	0.00	7.7
	Week 68	34	2.41	2.46	0.0	1.50	8.1	32	0.47	2.88	-9.1	0.14	5.4
	Week 71	33	2.05	2.31	0.0	1.00	7.0	31	-0.15	2.86	-9.1	0.00	6.3
	Week 74	33	2.10	2.44	0.0	0.71	7.6	31	0.22	3.36	-9.1	0.00	7.6
	Week 77	31	1.87	2.26	0.0	0.86	7.6	28	-0.07	3.01	-9.1	0.00	7.6
	Week 80	31	2.29	2.69	0.0	1.00	7.9	30	0.30	3.50	-9.1	0.00	7.9
	Week 83	25	2.24	2.33	0.0	2.00	8.1	25	0.31	3.55	-9.1	0.00	8.1
	Week 86	23	2.01	2.46	0.0	1.14	7.9	23	0.19	3.62	-9.1	0.00	7.9
	Week 89	18	1.75	2.67	0.0	0.21	8.0	18	0.55	3.12	-5.3	0.00	8.0
	Week 92	16	2.20	2.44	0.0	1.57	7.0	16	0.76	2.91	-3.9	0.00	7.0
	Week 95	12	0.98	1.07	0.0	0.71	2.7	12	-0.01	1.55	-3.9	0.00	2.7
	Plat+Gem (N=152)												
	BASELINE	127	2.32	2.86	0.0	0.86	10.0						
	Week 1	111	2.96	2.87	0.0	2.57	10.0	108	0.65	2.70	-5.3	0.00	10.0
	Week 2	117	3.02	2.81	0.0	2.43	9.9	109	0.61	2.25	-5.6	0.14	7.3
	Week 3	116	2.53	2.65	0.0	1.86	10.0	108	0.21	2.46	-6.6	0.00	7.6
	Week 4	115	2.47	2.50	0.0	1.71	10.0	104	0.11	2.28	-8.0	0.14	6.0
	Week 5	119	2.58	2.49	0.0	2.00	9.3	108	0.35	2.42	-6.3	0.14	7.0
	Week 6	113	2.58	2.63	0.0	1.71	10.0	102	0.26	2.59	-7.1	0.00	7.1
	Week 7	114	2.53	2.52	0.0	1.86	9.0	104	0.42	2.93	-10.0	0.14	8.0
	Week 8	110	2.72	2.66	0.0	1.86	10.0	101	0.53	3.01	-9.6	0.14	8.7

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.2.1: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	107	2.42	2.63	0.0	1.57	10.0	96	0.19	3.04	-8.4	0.14	8.0
	Week 10	109	2.47	2.63	0.0	1.29	10.0	100	0.30	2.89	-9.4	0.21	7.1
	Week 11	96	2.58	2.62	0.0	1.93	10.0	89	0.37	2.79	-7.6	0.00	7.3
	Week 12	98	2.32	2.42	0.0	1.64	10.0	88	0.07	2.60	-8.0	0.00	6.3
	Week 14	98	2.67	2.59	0.0	1.86	10.0	87	0.32	2.71	-8.1	0.00	7.6
	Week 17	92	2.66	2.80	0.0	1.57	9.3	84	0.41	2.93	-6.9	0.07	8.6
	Week 20	84	2.31	2.64	0.0	1.14	9.3	76	0.33	2.80	-8.1	0.36	7.7
	Week 23	73	1.83	2.07	0.0	1.00	6.9	67	-0.03	2.81	-8.6	0.00	6.9
	Week 26	66	2.30	2.33	0.0	1.43	7.1	62	0.21	2.71	-6.7	0.07	6.3
	Week 29	64	2.47	2.51	0.0	1.86	9.3	59	0.64	3.05	-7.9	0.43	6.6
	Week 32	55	2.27	2.51	0.0	1.29	8.6	50	0.32	2.81	-8.3	0.14	5.6
	Week 35	54	2.23	2.46	0.0	1.14	8.9	49	0.20	2.67	-6.6	0.00	6.4
	Week 38	47	2.21	2.62	0.0	1.14	9.0	42	0.43	2.08	-6.1	0.00	5.4
	Week 41	45	2.57	2.63	0.0	2.14	7.9	40	0.94	2.02	-3.7	0.29	5.4
	Week 44	41	2.65	2.69	0.0	2.00	8.4	36	1.18	2.69	-3.7	0.00	8.0
	Week 47	35	2.41	2.66	0.0	1.29	8.6	31	0.77	2.67	-5.9	0.00	6.7
	Week 50	29	2.80	2.70	0.0	2.00	8.3	24	0.99	2.97	-5.7	0.50	6.3
	Week 53	25	2.25	2.67	0.0	1.14	8.4	22	0.65	2.74	-6.0	0.21	5.9
	Week 56	26	2.79	2.62	0.0	2.29	7.7	25	0.77	2.82	-5.7	0.00	6.1
	Week 59	20	2.54	2.34	0.0	2.29	7.1	18	0.25	2.99	-6.0	0.00	5.0
	Week 62	17	2.76	2.06	0.0	3.29	6.7	17	0.46	3.40	-6.7	0.00	6.7
	Week 65	15	3.69	2.59	0.0	3.29	8.4	14	1.95	3.17	-4.4	2.07	8.1
	Week 68	11	2.78	2.17	0.0	3.14	6.7	11	1.01	2.86	-4.4	0.86	6.7
	Week 71	12	2.73	2.71	0.0	2.14	7.3	12	0.46	2.70	-4.4	0.00	5.7
	Week 74	10	1.70	1.55	0.0	1.43	4.3	10	0.16	1.94	-4.0	0.00	2.7
	Week 77	10	2.06	2.42	0.0	1.29	6.7	10	0.87	3.36	-6.1	0.00	5.1

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.2.2: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
< 65 years	EV+Pembro (N= 39)												
	BASELINE	33	2.83	2.70	0.0	2.86	8.9						
	Week 1	27	2.91	2.22	0.0	3.14	6.7	26	0.16	1.30	-3.0	0.00	3.6
	Week 2	31	2.83	2.57	0.0	2.86	7.4	30	0.13	1.80	-4.0	0.00	5.3
	Week 3	31	2.17	2.31	0.0	1.00	7.3	30	-0.43	2.17	-6.6	-0.21	5.6
	Week 4	30	1.45	1.93	0.0	0.64	7.0	28	-1.10	1.82	-6.7	-0.21	1.9
	Week 5	28	1.28	2.10	0.0	0.07	7.1	27	-1.41	1.72	-4.9	-0.86	1.4
	Week 6	29	1.67	2.34	0.0	0.29	7.0	27	-1.03	2.85	-6.9	-0.43	6.6
	Week 7	30	1.67	2.35	0.0	0.43	7.0	27	-0.93	2.36	-4.9	-0.43	4.1
	Week 8	30	1.30	1.89	0.0	0.64	6.3	27	-1.08	2.26	-5.7	-0.71	5.0
	Week 9	28	1.68	2.25	0.0	0.43	6.4	28	-0.94	2.96	-6.7	-0.57	6.1
	Week 10	26	1.38	2.07	0.0	0.36	6.1	24	-0.95	2.49	-4.9	-0.64	4.9
	Week 11	28	1.14	1.65	0.0	0.21	5.3	26	-1.07	1.91	-4.9	-0.93	3.9
	Week 12	28	1.23	1.86	0.0	0.29	6.1	26	-1.12	2.27	-7.0	-0.14	2.7
	Week 14	26	1.10	1.74	0.0	0.36	6.6	24	-1.20	2.62	-7.0	-0.93	4.9
	Week 17	28	1.78	2.56	0.0	0.57	10.0	25	-0.71	3.37	-7.0	-0.86	6.7
	Week 20	27	1.54	2.08	0.0	0.86	9.0	25	-0.83	2.58	-6.9	-0.71	5.7
	Week 23	26	0.95	1.48	0.0	0.29	4.9	24	-1.19	1.98	-5.7	-0.43	1.6
	Week 26	24	1.14	1.79	0.0	0.21	5.3	22	-0.95	2.61	-6.9	-0.43	5.1
	Week 29	25	1.50	1.91	0.0	1.00	5.6	23	-0.84	2.68	-6.9	-0.29	5.3
	Week 32	25	1.63	2.15	0.0	0.43	6.1	23	-0.79	2.36	-4.9	-0.71	5.1
	Week 35	24	1.85	1.94	0.0	1.00	5.9	22	-0.71	2.86	-6.9	-0.71	5.0
	Week 38	23	1.47	1.84	0.0	1.00	6.1	22	-0.97	2.30	-6.1	0.00	2.1
	Week 41	25	1.84	2.32	0.0	0.71	6.4	24	-0.52	3.05	-7.0	0.00	6.3
	Week 44	22	2.08	2.53	0.0	0.50	6.9	21	-0.16	2.74	-5.4	-0.14	5.6
	Week 47	20	2.10	2.68	0.0	1.29	10.0	19	-0.01	3.41	-6.7	0.00	6.7

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.2.2: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	19	1.24	1.72	0.0	0.57	5.9	18	-0.74	2.62	-6.6	-0.29	5.1
	Week 53	20	1.36	1.91	0.0	0.57	6.3	19	-0.68	2.68	-5.9	0.00	4.7
	Week 56	17	1.71	1.90	0.0	1.14	6.0	16	-0.66	1.78	-3.7	-0.14	2.9
	Week 59	17	2.54	2.90	0.0	1.00	7.1	16	-0.13	2.97	-4.4	-0.21	6.7
	Week 62	15	2.16	2.54	0.0	1.29	7.4	15	0.30	2.43	-3.9	0.00	5.9
	Week 65	14	1.77	2.12	0.0	0.93	6.0	14	-0.63	1.79	-4.1	-0.64	2.7
	Week 68	11	1.77	2.12	0.0	1.29	6.4	11	-0.39	2.51	-5.6	0.00	4.1
	Week 71	13	2.12	2.55	0.0	0.86	7.0	13	-0.45	2.48	-4.0	-0.57	5.1
	Week 74	14	2.68	2.75	0.0	2.07	7.6	14	0.68	3.11	-3.1	-0.07	7.6
	Week 77	14	2.44	2.43	0.0	1.71	6.3	14	0.16	2.44	-3.0	-0.14	4.7
	Week 80	14	2.90	2.77	0.0	2.64	7.4	14	0.84	2.77	-3.9	0.00	7.4
	Week 83	12	2.68	2.30	0.0	3.43	6.0	12	0.37	3.27	-3.9	-0.21	6.0
	Plat+Gem (N= 29)												
	BASELINE	22	2.52	2.46	0.0	2.14	7.3						
	Week 1	21	2.30	2.27	0.0	2.14	6.7	20	-0.05	1.28	-2.9	0.00	2.6
	Week 2	24	2.49	2.94	0.0	1.00	9.4	20	-0.03	1.75	-5.6	0.00	3.4
	Week 3	23	1.84	2.27	0.0	1.43	8.9	20	-0.81	1.57	-4.7	-0.43	2.4
	Week 4	23	2.43	2.80	0.0	2.00	9.4	19	-0.27	1.23	-3.3	0.00	1.7
	Week 5	25	2.44	2.85	0.0	1.29	9.3	20	-0.59	1.73	-5.1	-0.07	1.6
	Week 6	22	1.98	2.41	0.0	0.93	7.7	18	-0.71	1.43	-4.3	-0.29	1.6
	Week 7	24	2.08	2.43	0.0	1.07	7.7	21	-0.75	1.80	-5.6	0.00	2.9
	Week 8	21	1.81	2.45	0.0	0.86	8.7	19	-0.47	2.00	-4.4	0.00	4.6
	Week 9	20	2.41	2.74	0.0	1.43	9.6	17	-0.24	2.11	-4.4	0.00	2.3
	Week 10	21	2.05	2.61	0.0	1.00	8.7	18	-0.40	1.91	-4.4	0.00	3.7
	Week 11	20	1.74	2.29	0.0	0.64	7.3	17	-0.90	2.01	-5.7	0.00	2.0
	Week 12	21	2.19	2.82	0.0	0.86	8.1	17	-0.77	2.02	-5.3	0.00	2.1

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.2.2: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 14	22	3.01	3.09	0.0	1.79	8.4	18	0.25	2.84	-4.7	0.00	7.6
	Week 17	20	2.31	3.10	0.0	0.50	9.3	17	-0.33	2.74	-6.1	0.00	5.6
	Week 20	18	2.94	3.16	0.0	1.93	9.3	15	-0.04	2.42	-6.1	0.00	3.4
	Week 23	18	1.68	2.10	0.0	0.07	5.6	16	-0.73	1.76	-6.1	0.00	1.7
	Week 26	16	2.16	2.55	0.0	0.64	6.9	14	-0.13	2.20	-6.1	0.00	2.7
	Week 29	15	2.32	2.57	0.0	1.71	6.9	13	-0.10	2.19	-6.1	0.00	3.6
	Week 32	15	2.35	3.07	0.0	0.71	8.0	13	-0.12	2.81	-6.1	0.00	4.4
	Week 35	15	2.39	3.02	0.0	0.57	8.9	13	-0.04	2.63	-6.1	0.00	4.9
	Week 38	14	2.85	3.05	0.0	1.29	7.6	12	0.44	2.96	-6.1	0.14	6.4
	Week 41	11	4.16	3.24	0.0	5.71	7.9	9	1.81	1.60	0.0	2.57	3.9
	Week 44	11	2.74	3.00	0.0	2.29	8.4	9	1.10	2.98	-3.0	0.00	5.6
	Week 47	11	2.97	3.51	0.0	0.29	8.6	9	0.41	4.00	-5.9	0.00	6.7

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.2.2: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>= 65 years	EV+Pembro (N=163)												
	BASELINE	133	2.61	2.83	0.0	1.71	9.7						
	Week 1	115	2.89	2.71	0.0	2.57	10.0	108	0.37	2.20	-5.0	0.00	7.7
	Week 2	123	3.23	2.78	0.0	3.00	9.7	111	0.62	2.42	-4.6	0.00	7.0
	Week 3	108	2.91	2.78	0.0	2.36	9.7	96	0.14	2.54	-7.0	0.00	6.7
	Week 4	117	2.32	2.44	0.0	1.43	8.0	106	-0.21	2.62	-8.0	0.00	5.9
	Week 5	111	2.22	2.33	0.0	1.43	8.1	99	-0.20	2.90	-8.0	0.00	6.7
	Week 6	118	2.41	2.59	0.0	1.71	9.4	101	-0.27	3.28	-9.1	0.00	8.1
	Week 7	120	2.02	2.26	0.0	1.29	8.4	102	-0.50	3.17	-8.0	0.00	8.4
	Week 8	120	2.08	2.35	0.0	1.14	10.0	102	-0.58	3.31	-8.0	0.00	8.7
	Week 9	114	2.18	2.54	0.0	1.36	10.0	97	-0.27	3.16	-8.0	0.00	8.4
	Week 10	113	1.99	2.34	0.0	1.14	9.1	98	-0.51	3.24	-8.0	0.00	7.0
	Week 11	110	1.68	2.24	0.0	0.57	9.3	93	-0.81	2.84	-7.9	0.00	5.3
	Week 12	115	1.89	2.43	0.0	0.71	9.3	97	-0.54	3.18	-8.0	0.00	7.7
	Week 14	114	2.06	2.60	0.0	0.86	9.9	96	-0.36	3.25	-9.1	0.00	7.6
	Week 17	104	1.78	2.24	0.0	1.00	8.6	89	-0.71	3.02	-9.1	0.00	8.0
	Week 20	93	1.82	2.15	0.0	0.86	8.3	81	-0.51	2.82	-8.0	0.00	5.0
	Week 23	91	1.71	2.27	0.0	0.43	8.0	76	-0.43	3.12	-9.1	0.00	7.0
	Week 26	90	2.08	2.35	0.0	1.14	8.3	75	-0.27	3.10	-9.1	0.00	6.3
	Week 29	82	1.85	2.31	0.0	0.57	8.9	72	-0.24	3.20	-9.1	0.00	8.6
	Week 32	77	1.81	2.26	0.0	1.00	9.4	67	-0.47	3.39	-9.1	0.00	9.1
	Week 35	74	1.97	2.30	0.0	1.29	10.0	66	-0.14	3.17	-9.1	0.00	9.7
	Week 38	74	1.90	2.03	0.0	1.00	8.1	66	-0.44	2.91	-9.1	0.00	4.0
	Week 41	70	1.79	2.11	0.0	1.00	7.7	63	-0.49	2.89	-9.1	0.00	7.1
	Week 44	64	2.14	2.50	0.0	1.14	9.4	56	-0.08	3.09	-9.1	0.00	9.1
	Week 47	59	2.19	2.35	0.0	1.14	8.4	53	-0.31	3.13	-9.1	0.00	6.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.2.2: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	56	2.39	2.56	0.0	1.86	9.9	48	0.05	3.26	-9.1	0.00	7.9
	Week 53	56	2.78	2.64	0.0	2.43	8.3	47	0.23	3.29	-9.1	0.00	6.3
	Week 56	55	2.32	2.14	0.0	2.00	7.1	47	-0.47	3.22	-9.1	0.00	5.6
	Week 59	52	2.15	2.07	0.0	1.57	8.7	43	-0.70	3.25	-9.1	0.00	5.1
	Week 62	47	2.29	2.25	0.0	2.00	7.9	39	-0.28	3.31	-9.1	0.00	6.0
	Week 65	29	2.38	2.48	0.0	1.86	7.7	27	0.22	3.88	-9.1	0.00	7.7
	Week 68	35	2.52	2.37	0.0	1.86	8.1	32	0.52	3.22	-9.1	0.43	5.7
	Week 71	29	1.96	2.22	0.0	1.00	6.3	26	-0.42	3.48	-9.1	0.00	6.3
	Week 74	24	1.68	2.26	0.0	0.36	6.7	22	-0.61	3.69	-9.1	0.00	5.9
	Week 77	23	1.52	2.13	0.0	0.29	7.6	20	-0.89	3.55	-9.1	-0.07	7.6
	Week 80	22	1.97	2.54	0.0	0.79	7.9	21	-0.54	3.92	-9.1	-0.29	7.9
	Week 83	18	1.84	2.35	0.0	0.64	8.1	18	-0.49	3.82	-9.1	-0.29	8.1
	Week 86	18	2.12	2.70	0.0	1.00	7.9	18	0.23	3.55	-9.1	0.00	7.9
	Week 89	12	1.83	2.93	0.0	0.21	8.0	12	0.50	3.19	-5.3	0.00	8.0
	Week 92	10	1.57	2.25	0.0	0.50	7.0	10	0.54	2.64	-3.1	0.00	7.0
	Plat+Gem (N=173)												
	BASELINE	146	2.60	3.01	0.0	1.14	10.0						
	Week 1	125	3.25	2.89	0.0	3.00	10.0	122	0.71	2.77	-8.3	0.14	10.0
	Week 2	127	3.24	2.75	0.0	2.86	9.9	120	0.72	2.27	-4.6	0.07	7.3
	Week 3	126	2.80	2.72	0.0	2.00	10.0	118	0.43	2.38	-6.6	0.00	7.6
	Week 4	128	2.53	2.43	0.0	1.86	10.0	118	0.04	2.50	-8.4	0.00	6.0
	Week 5	130	2.66	2.45	0.0	2.07	8.6	121	0.39	2.71	-8.6	0.14	7.6
	Week 6	123	2.70	2.67	0.0	2.14	10.0	113	0.31	3.01	-8.6	0.00	9.0
	Week 7	125	2.71	2.53	0.0	2.29	9.0	115	0.42	3.07	-10.0	0.00	8.0
	Week 8	125	3.12	2.66	0.0	3.00	10.0	114	0.70	3.23	-9.6	0.14	8.7
	Week 9	121	2.65	2.58	0.0	2.00	10.0	109	0.23	3.31	-8.4	0.14	8.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.2.2: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	121	2.67	2.58	0.0	2.00	10.0	112	0.22	3.04	-9.4	0.29	7.1
	Week 11	106	2.85	2.60	0.0	2.36	10.0	98	0.48	2.90	-7.6	0.14	7.3
	Week 12	109	2.49	2.28	0.0	2.00	10.0	99	0.11	2.68	-8.0	0.00	6.3
	Week 14	103	2.70	2.48	0.0	2.00	10.0	92	0.29	2.91	-8.1	0.00	8.1
	Week 17	100	2.73	2.59	0.0	2.14	8.6	91	0.43	3.07	-6.9	0.29	8.6
	Week 20	86	2.18	2.51	0.0	1.14	9.4	78	0.18	2.98	-8.4	0.14	7.7
	Week 23	70	1.94	2.07	0.0	1.14	6.9	65	-0.03	2.86	-8.6	0.00	6.9
	Week 26	65	2.27	2.32	0.0	1.57	8.1	62	0.04	2.77	-6.7	0.07	6.3
	Week 29	62	2.56	2.66	0.0	2.07	10.0	58	0.89	3.25	-7.9	0.43	9.7
	Week 32	49	2.20	2.30	0.0	1.43	8.6	46	0.43	2.83	-8.3	0.14	5.6
	Week 35	47	2.02	2.17	0.0	1.14	8.1	44	0.12	2.62	-6.6	0.00	6.4
	Week 38	42	2.07	2.51	0.0	1.00	9.0	38	0.56	1.89	-4.3	0.00	5.4
	Week 41	41	2.02	2.20	0.0	1.14	7.0	38	0.55	1.97	-3.7	0.14	5.4
	Week 44	38	2.69	2.63	0.0	2.07	8.0	35	1.16	2.67	-3.7	0.29	8.0
	Week 47	32	2.00	2.24	0.0	1.29	8.0	30	0.56	2.11	-4.1	0.00	5.6
	Week 50	29	2.30	2.38	0.0	1.86	7.1	26	0.95	2.55	-5.7	0.36	6.3
	Week 53	25	2.19	2.67	0.0	1.14	8.7	24	1.02	2.75	-4.6	0.21	6.6
	Week 56	26	2.92	2.74	0.0	2.29	7.7	26	1.32	2.71	-5.7	0.64	7.4
	Week 59	20	2.24	2.25	0.0	1.86	6.4	20	0.82	2.77	-5.7	0.00	6.4
	Week 62	19	2.82	2.41	0.0	3.29	7.9	19	1.07	3.43	-6.7	0.43	7.9
	Week 65	16	3.05	2.58	0.0	3.00	8.4	16	1.71	3.02	-4.4	1.14	8.1
	Week 68	13	2.36	2.22	0.0	2.43	6.7	13	0.84	2.65	-4.4	0.00	6.7
	Week 71	13	2.52	2.71	0.0	1.29	7.3	13	0.40	2.60	-4.4	0.00	5.7
	Week 74	11	1.56	1.54	0.0	1.14	4.3	11	0.12	1.84	-4.0	0.00	2.7
	Week 77	10	2.07	2.41	0.0	1.36	6.7	10	1.46	2.37	-1.3	0.00	5.1

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.2.3: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Europe	EV+Pembro (N= 74)												
	BASELINE	57	2.36	2.40	0.0	1.86	9.7						
	Week 1	48	3.04	2.78	0.0	2.71	10.0	45	0.94	2.22	-2.1	0.29	7.7
	Week 2	54	2.85	2.60	0.0	2.21	9.7	48	0.76	2.38	-2.9	0.00	6.9
	Week 3	50	2.86	2.74	0.0	2.29	9.7	43	0.33	2.58	-7.0	0.00	5.6
	Week 4	52	1.90	1.98	0.0	1.07	6.6	46	-0.12	2.52	-7.3	-0.07	5.9
	Week 5	47	2.08	2.28	0.0	1.29	7.7	43	0.17	2.70	-4.1	-0.14	6.3
	Week 6	51	2.43	2.67	0.0	1.43	9.3	41	0.39	3.07	-5.7	0.00	6.6
	Week 7	51	1.84	2.10	0.0	1.14	8.4	41	0.15	2.75	-4.9	0.00	8.4
	Week 8	52	2.04	2.09	0.0	1.50	8.0	43	0.12	2.28	-3.9	0.00	5.1
	Week 9	47	2.04	2.29	0.0	1.29	9.1	39	-0.02	2.48	-6.7	0.00	5.3
	Week 10	45	1.69	2.07	0.0	0.86	8.1	36	-0.26	2.59	-7.7	0.00	5.6
	Week 11	49	1.37	1.82	0.0	0.57	6.9	39	-0.18	2.05	-3.9	0.00	5.3
	Week 12	52	1.68	2.08	0.0	0.86	7.6	41	-0.01	2.14	-4.0	0.00	5.6
	Week 14	51	1.57	2.27	0.0	0.43	7.4	40	-0.16	2.75	-4.7	-0.21	6.0
	Week 17	43	1.47	1.99	0.0	0.43	7.7	34	-0.67	2.24	-5.0	-0.36	4.6
	Week 20	41	1.50	2.02	0.0	0.29	6.7	34	-0.46	2.35	-4.4	-0.14	5.0
	Week 23	41	1.45	2.09	0.0	0.29	7.4	31	-0.33	2.78	-5.4	-0.71	6.9
	Week 26	38	1.57	2.04	0.0	0.79	7.6	29	-0.16	2.42	-5.4	0.00	6.3
	Week 29	37	1.27	2.07	0.0	0.14	7.4	30	-0.48	2.50	-5.1	-0.29	5.6
	Week 32	34	1.32	1.95	0.0	0.36	6.0	27	-0.50	2.27	-4.9	-0.43	5.9
	Week 35	31	1.48	1.54	0.0	1.14	4.6	26	-0.12	2.31	-5.4	0.00	4.6
	Week 38	31	1.63	1.89	0.0	0.86	6.3	27	-0.15	2.05	-4.4	0.00	3.4
	Week 41	28	1.55	1.91	0.0	0.71	7.4	24	-0.29	2.19	-4.3	0.00	3.6
	Week 44	27	1.16	1.67	0.0	0.29	5.7	23	-0.37	2.20	-5.4	-0.14	3.7
	Week 47	25	1.81	2.24	0.0	0.71	6.7	21	0.16	2.61	-4.1	0.00	6.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.2.3: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	27	2.11	2.72	0.0	0.86	9.9	23	0.60	2.90	-3.9	0.00	7.9
	Week 53	28	2.44	2.90	0.0	0.93	8.3	23	0.74	2.93	-4.9	0.00	6.3
	Week 56	25	2.47	2.25	0.0	2.14	7.1	21	0.35	2.33	-3.6	0.00	3.9
	Week 59	23	1.91	1.93	0.0	1.29	6.0	18	-0.32	2.41	-3.3	-0.86	4.6
	Week 62	20	2.13	2.14	0.0	1.64	7.3	17	0.24	2.41	-3.4	0.00	5.1
	Week 65	13	1.63	1.88	0.0	1.00	4.7	13	-0.13	2.36	-3.1	-0.43	4.7
	Week 68	15	2.56	2.41	0.0	1.86	8.1	15	0.91	2.63	-3.0	1.29	5.7
	Week 71	13	1.76	2.27	0.0	1.00	6.3	13	-0.19	2.43	-3.4	-0.43	6.0
	Week 74	10	1.63	2.52	0.0	0.29	6.7	9	0.06	2.81	-3.6	-0.14	5.4
	Plat+Gem (N= 95)												
	BASELINE	76	2.38	2.78	0.0	1.00	8.4						
	Week 1	72	2.96	2.68	0.0	2.50	8.1	70	0.55	2.41	-8.3	0.07	7.3
	Week 2	71	3.20	2.59	0.0	3.14	9.4	63	0.77	2.14	-3.1	0.14	7.3
	Week 3	72	2.80	2.65	0.0	2.07	8.9	65	0.56	2.26	-6.6	0.00	7.6
	Week 4	69	2.61	2.39	0.0	2.00	9.4	62	0.21	2.28	-8.0	0.14	5.9
	Week 5	72	2.80	2.55	0.0	2.21	9.3	64	0.46	2.34	-6.3	0.00	7.0
	Week 6	69	2.65	2.65	0.0	2.00	9.0	61	0.35	2.96	-7.1	0.00	9.0
	Week 7	69	2.63	2.40	0.0	2.29	7.9	62	0.35	2.37	-6.4	0.00	6.9
	Week 8	68	2.59	2.14	0.0	2.29	6.9	60	0.30	2.53	-7.1	0.00	6.6
	Week 9	66	2.61	2.37	0.0	2.21	9.6	57	0.32	2.70	-8.0	0.14	7.7
	Week 10	70	2.47	2.27	0.0	2.00	8.7	63	0.16	2.49	-7.1	0.00	6.0
	Week 11	63	2.59	2.34	0.0	2.00	7.7	56	0.33	2.49	-6.4	0.00	7.3
	Week 12	66	2.67	2.39	0.0	2.36	8.1	56	0.24	2.60	-7.0	0.00	6.3
	Week 14	66	2.82	2.54	0.0	2.14	8.4	56	0.45	2.74	-8.0	0.14	7.6
	Week 17	61	2.63	2.62	0.0	1.86	9.3	53	0.40	2.77	-6.9	0.14	8.6
	Week 20	54	2.32	2.59	0.0	1.29	9.3	48	0.29	2.60	-8.1	0.14	7.7

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.2.3: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 23	44	2.16	2.03	0.0	1.57	6.0	40	0.14	2.52	-6.9	0.00	5.0
	Week 26	42	2.66	2.35	0.0	2.43	6.9	39	0.43	2.71	-6.7	0.29	6.3
	Week 29	39	2.81	2.55	0.0	2.86	8.4	36	0.81	2.55	-6.3	0.43	6.6
	Week 32	33	2.73	2.70	0.0	2.00	8.6	31	0.57	2.57	-5.3	0.71	5.6
	Week 35	32	2.47	2.59	0.0	1.64	8.9	30	0.40	2.42	-4.3	0.00	6.4
	Week 38	28	2.15	2.48	0.0	1.14	7.0	26	0.60	1.90	-2.4	0.07	5.4
	Week 41	25	2.59	2.57	0.0	2.57	7.7	23	0.59	1.78	-3.0	0.00	5.1
	Week 44	24	3.39	2.88	0.0	3.36	8.4	22	1.36	2.78	-3.1	0.64	8.0
	Week 47	22	2.79	2.66	0.0	2.00	8.0	20	0.64	2.49	-4.0	0.14	6.4
	Week 50	17	3.05	2.65	0.0	2.57	8.3	15	0.77	2.36	-2.9	0.57	6.0
	Week 53	15	3.26	3.25	0.0	2.86	8.7	14	1.08	3.04	-4.0	0.07	5.9
	Week 56	15	3.82	2.46	0.0	4.14	7.3	14	1.74	2.27	-1.7	1.50	6.1
	Week 59	11	2.57	2.34	0.0	2.00	7.1	10	0.87	2.19	-2.3	0.36	5.0
	Week 62	11	2.99	2.27	0.0	3.43	6.7	11	1.38	2.39	-0.6	0.43	6.7
	Week 65	10	3.31	2.14	0.0	3.14	7.0	10	1.96	2.31	-1.0	2.07	5.9

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.2.3: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
North America	EV+Pembro (N= 46)												
	BASELINE	35	2.87	2.90	0.0	2.71	8.0						
	Week 1	31	3.25	2.84	0.0	2.86	10.0	29	0.24	2.02	-4.0	0.14	4.9
	Week 2	31	3.05	2.59	0.0	2.86	7.3	29	0.08	2.23	-3.6	0.00	6.0
	Week 3	25	1.74	1.75	0.0	1.57	6.0	23	-0.66	1.69	-4.6	0.00	1.7
	Week 4	30	2.71	2.42	0.0	1.79	8.0	26	-0.45	2.03	-6.6	-0.07	3.6
	Week 5	30	1.96	2.04	0.0	1.36	6.6	24	-1.03	2.54	-7.4	0.00	3.0
	Week 6	31	2.36	2.51	0.0	1.29	8.6	25	-0.51	3.12	-7.3	0.00	6.6
	Week 7	33	1.84	2.28	0.0	1.00	6.9	25	-1.10	3.09	-7.3	-0.57	6.0
	Week 8	29	1.37	1.81	0.0	0.29	6.1	22	-2.16	2.76	-8.0	-1.43	1.4
	Week 9	27	1.42	1.81	0.0	0.71	6.3	23	-1.41	2.59	-7.3	-0.57	4.3
	Week 10	29	1.24	1.51	0.0	0.71	5.7	25	-1.96	2.65	-7.3	-1.14	1.4
	Week 11	28	1.64	2.23	0.0	0.79	9.3	23	-1.48	2.58	-7.3	-0.57	2.6
	Week 12	29	1.31	1.95	0.0	0.43	7.7	24	-1.74	2.96	-8.0	-0.93	3.9
	Week 14	28	1.41	1.78	0.0	0.79	5.4	23	-1.37	2.57	-7.3	-0.43	2.1
	Week 17	29	1.73	2.38	0.0	1.00	10.0	25	-1.20	3.44	-7.3	0.00	6.7
	Week 20	23	1.73	2.28	0.0	0.86	9.0	20	-1.31	3.29	-8.0	-0.14	5.7
	Week 23	22	0.84	1.78	0.0	0.00	7.7	19	-1.40	3.05	-8.0	0.00	3.7
	Week 26	21	1.61	2.19	0.0	0.86	7.4	17	-1.69	3.11	-8.0	-0.43	2.9
	Week 29	20	1.31	1.71	0.0	0.57	6.6	18	-1.27	2.62	-7.3	-0.21	1.4
	Week 32	21	1.01	1.11	0.0	0.43	3.4	19	-2.11	2.90	-8.0	-0.57	1.3
	Week 35	22	1.18	1.43	0.0	0.64	5.0	20	-1.67	2.70	-8.0	-0.43	0.9
	Week 38	20	1.26	1.54	0.0	0.79	5.4	18	-1.62	3.13	-7.3	-0.57	2.1
	Week 41	21	1.16	1.75	0.0	0.14	6.4	19	-1.32	2.93	-7.6	0.00	3.1
	Week 44	16	1.26	1.75	0.0	0.36	5.3	14	-1.50	2.74	-7.6	-0.36	1.7
	Week 47	16	2.02	3.00	0.0	1.07	10.0	15	-1.02	3.48	-7.6	0.00	6.7

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.2.3: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	16	1.72	2.39	0.0	0.43	7.4	13	-1.34	2.45	-7.6	-0.57	1.1
	Week 53	15	2.10	2.21	0.0	1.86	6.7	12	-1.23	2.58	-7.6	-0.36	1.1
	Week 56	17	1.62	1.92	0.0	0.57	4.9	14	-2.07	2.55	-7.6	-0.86	0.1
	Week 59	17	2.11	2.56	0.0	0.86	8.7	14	-1.77	3.23	-7.6	-0.79	3.4
	Week 62	14	2.38	2.82	0.0	1.00	7.9	11	-0.71	3.72	-7.6	0.00	5.9
	Week 68	11	1.43	2.29	0.0	0.14	6.7	9	-1.22	2.47	-7.6	-0.14	0.3
	Week 71	11	1.77	2.17	0.0	0.14	5.4	9	-0.84	3.04	-7.6	0.00	2.1
	Plat+Gem (N= 34)												
	BASELINE	28	2.95	3.21	0.0	1.36	10.0						
	Week 1	20	2.35	2.45	0.0	1.50	7.4	18	0.03	1.49	-3.7	0.07	2.1
	Week 2	22	1.90	2.48	0.0	0.71	8.1	21	-0.52	1.46	-5.6	-0.29	1.3
	Week 3	20	1.93	2.64	0.0	1.07	8.7	18	-0.60	2.16	-6.3	0.00	2.1
	Week 4	24	1.61	2.21	0.0	0.71	6.7	20	-0.74	2.64	-8.4	-0.29	2.4
	Week 5	26	1.65	1.84	0.0	1.14	6.9	23	-0.52	2.99	-8.6	0.00	3.9
	Week 6	20	1.14	1.85	0.0	0.36	7.6	17	-1.24	2.72	-8.6	0.00	2.3
	Week 7	24	2.27	2.83	0.0	0.86	9.0	21	-0.01	3.44	-6.6	0.00	7.1
	Week 8	24	2.89	3.05	0.0	1.29	8.7	22	0.41	3.26	-5.6	0.14	5.7
	Week 9	23	1.62	2.21	0.0	1.14	8.6	20	-0.90	3.05	-7.1	-0.14	5.7
	Week 10	20	2.11	2.61	0.0	1.00	8.3	18	-0.07	2.67	-6.6	0.21	5.0
	Week 11	18	1.71	2.26	0.0	0.64	8.6	17	-0.24	2.65	-5.7	0.00	3.0
	Week 12	17	1.48	1.52	0.0	0.86	4.1	16	-0.84	2.71	-6.0	0.00	3.0
	Week 14	16	1.83	2.32	0.0	1.36	7.4	14	-0.77	2.91	-7.0	-0.29	3.0
	Week 17	19	1.99	2.89	0.0	0.00	8.0	18	-0.22	3.66	-6.6	0.00	7.4
	Week 20	16	1.35	2.07	0.0	0.14	6.1	14	-0.77	3.93	-8.4	0.00	4.0
	Week 23	15	1.07	1.56	0.0	0.00	4.1	14	-1.22	2.84	-6.6	0.00	2.4
	Week 26	13	1.35	1.93	0.0	0.00	5.4	13	-0.52	2.78	-6.6	0.00	2.4

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.2.3: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 29	14	1.84	2.83	0.0	0.07	9.3	13	0.15	3.69	-6.6	0.00	6.0
	Week 32	11	0.77	1.50	0.0	0.00	4.6	10	-0.54	2.74	-6.1	0.00	4.6
	Week 35	13	1.24	1.91	0.0	0.29	5.7	12	-0.64	2.89	-6.6	0.00	2.7
	Week 38	10	2.03	2.80	0.0	0.79	7.6	9	0.89	3.34	-6.1	1.00	6.4

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.2.3: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Rest of World	EV+Pembro (N= 82)												
	BASELINE	74	2.77	3.05	0.0	1.64	9.1						
	Week 1	63	2.61	2.37	0.0	2.57	7.4	60	-0.09	1.84	-5.0	0.00	3.6
	Week 2	69	3.42	2.91	0.0	3.14	9.7	64	0.53	2.28	-4.6	0.00	7.0
	Week 3	64	3.04	2.89	0.0	2.57	9.3	60	0.03	2.61	-6.6	0.00	6.7
	Week 4	65	2.08	2.61	0.0	0.86	8.0	62	-0.58	2.67	-8.0	0.00	5.9
	Week 5	62	2.03	2.48	0.0	0.93	8.1	59	-0.69	2.78	-8.0	0.00	6.7
	Week 6	65	2.09	2.50	0.0	1.14	9.4	62	-0.94	3.25	-9.1	0.00	8.1
	Week 7	66	2.08	2.42	0.0	1.29	7.9	63	-0.86	3.11	-8.0	0.00	7.1
	Week 8	69	2.06	2.58	0.0	0.71	10.0	64	-0.71	3.55	-8.0	-0.07	8.7
	Week 9	68	2.38	2.81	0.0	1.43	10.0	63	-0.31	3.57	-8.0	0.00	8.4
	Week 10	65	2.30	2.65	0.0	1.29	9.1	61	-0.24	3.42	-8.0	0.00	7.0
	Week 11	61	1.70	2.34	0.0	0.29	8.7	57	-1.08	2.99	-7.9	0.00	4.9
	Week 12	62	2.05	2.68	0.0	0.57	9.3	58	-0.68	3.45	-8.0	0.00	7.7
	Week 14	61	2.36	2.86	0.0	1.00	9.9	57	-0.44	3.57	-9.1	0.00	7.6
	Week 17	60	2.04	2.47	0.0	1.00	8.6	55	-0.51	3.38	-9.1	0.00	8.0
	Week 20	56	1.95	2.15	0.0	1.14	8.3	52	-0.38	2.79	-7.7	0.00	5.0
	Week 23	54	1.90	2.26	0.0	1.00	8.0	50	-0.48	2.92	-9.1	0.00	7.0
	Week 26	55	2.21	2.44	0.0	1.00	8.3	51	-0.15	3.20	-9.1	0.00	6.1
	Week 29	50	2.33	2.41	0.0	1.50	8.9	47	0.02	3.53	-9.1	0.00	8.6
	Week 32	47	2.42	2.60	0.0	2.14	9.4	44	0.09	3.52	-9.1	0.00	9.1
	Week 35	45	2.63	2.68	0.0	1.57	10.0	42	0.28	3.51	-9.1	0.00	9.7
	Week 38	46	2.15	2.19	0.0	1.71	8.1	43	-0.40	2.95	-9.1	0.00	4.0
	Week 41	46	2.26	2.38	0.0	1.29	7.7	44	-0.26	3.24	-9.1	0.00	7.1
	Week 44	43	3.04	2.83	0.0	2.86	9.4	40	0.54	3.30	-9.1	0.00	9.1
	Week 47	38	2.47	2.29	0.0	2.07	8.0	36	-0.12	3.39	-9.1	0.00	6.6

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.2.3: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	32	2.29	2.20	0.0	1.93	6.6	30	-0.24	3.41	-9.1	0.00	6.4
	Week 53	33	2.51	2.40	0.0	2.00	8.1	31	-0.14	3.39	-9.1	0.00	6.1
	Week 56	30	2.24	2.04	0.0	2.07	6.0	28	-0.39	3.23	-9.1	0.00	5.6
	Week 59	29	2.59	2.40	0.0	3.14	7.1	27	-0.06	3.50	-9.1	0.00	6.7
	Week 62	28	2.30	2.22	0.0	1.93	7.4	26	-0.10	3.25	-9.1	0.00	6.0
	Week 65	22	3.00	2.63	0.0	2.64	7.7	21	0.71	3.74	-9.1	1.14	7.7
	Week 68	20	2.68	2.23	0.0	2.36	6.4	19	0.50	3.49	-9.1	0.86	5.4
	Week 71	18	2.33	2.47	0.0	1.43	7.0	17	-0.40	3.79	-9.1	0.00	6.3
	Week 74	19	2.54	2.43	0.0	2.43	7.6	19	0.26	3.94	-9.1	0.00	7.6
	Week 77	19	2.44	2.45	0.0	1.71	7.6	18	-0.04	3.72	-9.1	0.00	7.6
	Week 80	19	2.55	2.80	0.0	1.43	7.9	18	0.11	4.07	-9.1	0.00	7.9
	Week 83	17	2.97	2.48	0.0	3.43	8.1	17	0.51	4.10	-9.1	0.00	8.1
	Week 86	14	2.60	2.93	0.0	1.64	7.9	14	0.05	4.22	-9.1	0.00	7.9
	Week 89	11	1.88	2.73	0.0	0.43	8.0	11	0.64	3.79	-5.3	0.00	8.0
	Plat+Gem (N= 73)												
	BASELINE	64	2.68	3.02	0.0	1.21	10.0						
	Week 1	54	3.59	3.10	0.0	3.29	10.0	54	0.87	3.13	-4.6	0.00	10.0
	Week 2	58	3.49	3.04	0.0	2.57	9.9	56	0.87	2.42	-4.6	0.36	5.6
	Week 3	57	2.71	2.71	0.0	2.29	10.0	55	0.16	2.40	-5.1	0.00	5.9
	Week 4	58	2.79	2.65	0.0	1.93	10.0	55	0.02	2.35	-4.6	0.00	6.0
	Week 5	57	2.85	2.66	0.0	2.29	8.6	54	0.34	2.74	-5.9	0.29	7.6
	Week 6	56	3.03	2.71	0.0	2.79	10.0	53	0.41	2.72	-6.4	0.00	6.6
	Week 7	56	2.74	2.56	0.0	1.93	8.0	53	0.22	3.34	-10.0	0.00	8.0
	Week 8	54	3.38	3.03	0.0	3.14	10.0	51	0.85	3.65	-9.6	0.00	8.7
	Week 9	52	3.06	2.92	0.0	2.21	10.0	49	0.42	3.67	-8.4	0.14	8.0
	Week 10	52	2.90	2.95	0.0	1.86	10.0	49	0.18	3.49	-9.4	0.00	7.1

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.2.3: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	45	3.17	2.91	0.0	2.43	10.0	42	0.41	3.32	-7.6	0.00	6.9
	Week 12	47	2.47	2.53	0.0	2.00	10.0	44	-0.04	2.57	-8.0	0.00	6.0
	Week 14	43	2.98	2.74	0.0	2.43	10.0	40	0.42	3.08	-8.1	0.00	8.1
	Week 17	40	3.02	2.65	0.0	2.57	7.9	37	0.44	3.10	-6.9	0.00	6.1
	Week 20	34	2.75	2.88	0.0	1.71	9.4	31	0.34	2.78	-7.9	0.00	7.0
	Week 23	29	1.92	2.28	0.0	1.14	6.9	27	-0.07	2.80	-8.6	0.00	6.9
	Week 26	26	2.03	2.47	0.0	0.86	8.1	24	-0.40	2.50	-6.0	0.00	4.1
	Week 29	24	2.45	2.67	0.0	1.86	10.0	22	0.88	3.60	-7.9	0.36	9.7
	Week 32	20	2.24	2.26	0.0	1.50	6.9	18	0.35	3.28	-8.3	0.07	4.4
	Week 35	17	2.10	2.23	0.0	1.43	7.3	15	0.02	2.75	-4.3	0.00	4.9
	Week 38	18	2.58	2.95	0.0	1.00	9.0	15	0.19	1.82	-4.3	0.00	4.1
	Week 41	18	2.26	2.56	0.0	1.07	6.7	16	0.53	2.15	-3.7	0.07	4.3
	Week 44	16	2.26	2.47	0.0	1.50	7.4	14	0.66	2.96	-3.7	0.00	6.1
	Week 47	12	2.26	2.99	0.0	0.71	8.6	11	0.82	2.85	-4.1	0.00	6.7
	Week 50	11	2.68	2.99	0.0	1.00	7.1	9	0.59	3.13	-5.7	0.14	5.1

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.2.4: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	EV+Pembro (N=146)												
	BASELINE	123	2.56	2.73	0.0	1.71	9.7						
	Week 1	103	2.75	2.53	0.0	2.71	10.0	101	0.33	2.01	-4.7	0.00	7.7
	Week 2	109	3.19	2.75	0.0	3.00	9.7	103	0.68	2.26	-4.0	0.00	7.0
	Week 3	94	2.53	2.50	0.0	1.93	7.9	90	0.01	2.51	-7.0	0.00	6.7
	Week 4	103	2.13	2.35	0.0	1.14	8.0	96	-0.35	2.45	-7.3	0.00	5.9
	Week 5	98	1.97	2.31	0.0	1.07	8.1	92	-0.40	2.66	-7.4	0.00	6.7
	Week 6	106	2.15	2.44	0.0	1.21	9.4	95	-0.33	2.97	-7.3	0.00	8.1
	Week 7	105	1.85	2.29	0.0	1.00	8.4	92	-0.55	2.80	-7.3	0.00	8.4
	Week 8	104	1.82	2.23	0.0	0.71	8.7	94	-0.68	2.83	-8.0	-0.14	8.7
	Week 9	100	2.00	2.41	0.0	1.07	9.4	91	-0.42	2.90	-7.3	0.00	8.4
	Week 10	99	1.84	2.29	0.0	0.86	9.1	89	-0.62	3.04	-7.7	0.00	7.0
	Week 11	96	1.50	2.19	0.0	0.36	9.3	86	-0.77	2.32	-7.3	0.00	5.1
	Week 12	99	1.76	2.46	0.0	0.57	9.3	89	-0.49	2.97	-8.0	0.00	7.7
	Week 14	96	1.85	2.49	0.0	0.79	9.9	86	-0.44	2.84	-7.3	0.00	6.6
	Week 17	97	1.77	2.31	0.0	1.00	10.0	86	-0.66	2.86	-7.3	0.00	6.7
	Week 20	90	1.75	2.15	0.0	0.86	9.0	81	-0.50	2.62	-8.0	0.00	5.7
	Week 23	86	1.45	2.06	0.0	0.29	8.0	76	-0.52	2.70	-8.0	0.00	6.9
	Week 26	85	1.92	2.35	0.0	1.00	8.3	75	-0.25	2.82	-8.0	0.00	6.3
	Week 29	80	1.80	2.29	0.0	0.57	8.9	73	-0.27	2.85	-7.3	0.00	8.6
	Week 32	74	1.76	2.18	0.0	0.79	9.4	68	-0.43	2.92	-8.0	0.00	9.1
	Week 35	73	1.88	2.24	0.0	1.00	10.0	68	-0.28	3.08	-8.0	0.00	9.7
	Week 38	75	1.79	2.01	0.0	1.00	8.1	69	-0.51	2.69	-7.3	0.00	3.9
	Week 41	71	1.73	2.17	0.0	0.86	7.7	66	-0.50	2.77	-7.6	0.00	7.1
	Week 44	64	2.05	2.50	0.0	0.86	9.4	58	-0.05	2.83	-7.6	0.00	9.1
	Week 47	56	2.04	2.46	0.0	1.14	10.0	51	-0.34	3.00	-7.6	0.00	6.7

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.2.4: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	55	1.95	2.43	0.0	1.14	9.9	49	-0.26	2.86	-7.6	0.00	7.9
	Week 53	57	2.31	2.46	0.0	1.86	8.3	50	0.04	3.00	-7.6	0.00	6.3
	Week 56	53	2.27	2.08	0.0	1.71	7.1	47	-0.46	2.78	-7.6	-0.14	4.3
	Week 59	51	2.35	2.33	0.0	1.29	8.7	44	-0.59	2.92	-7.6	-0.07	5.1
	Week 62	42	2.36	2.37	0.0	1.64	7.9	37	-0.05	2.82	-7.6	0.00	5.1
	Week 65	31	2.25	2.19	0.0	1.57	6.6	30	0.10	3.06	-7.6	0.00	6.6
	Week 68	31	2.55	2.35	0.0	1.71	8.1	29	0.46	3.00	-7.6	0.29	5.7
	Week 71	30	2.31	2.36	0.0	1.93	7.0	28	-0.07	3.04	-7.6	-0.29	6.3
	Week 74	29	2.37	2.42	0.0	2.00	6.9	27	0.21	3.08	-7.6	0.00	5.9
	Week 77	26	2.28	2.40	0.0	1.57	7.6	24	0.04	3.12	-7.6	-0.14	7.6
	Week 80	26	2.65	2.65	0.0	1.79	7.9	26	0.31	3.19	-7.6	-0.14	7.9
	Week 83	21	2.41	2.33	0.0	2.29	8.1	21	0.05	3.37	-7.6	-0.29	8.1
	Week 86	17	2.48	2.66	0.0	1.71	7.9	17	0.71	3.11	-3.7	0.00	7.9
	Week 89	11	2.27	2.94	0.0	1.00	8.0	11	1.06	3.07	-3.9	0.00	8.0
	Week 92	13	2.52	2.62	0.0	2.14	7.0	13	0.30	2.77	-3.9	0.00	7.0
	Plat+Gem (N=151)												
	BASELINE	126	2.25	2.80	0.0	0.86	10.0						
	Week 1	109	2.94	2.81	0.0	2.14	10.0	106	0.78	2.69	-8.3	0.00	10.0
	Week 2	118	2.91	2.78	0.0	2.29	9.4	108	0.72	2.17	-5.6	0.14	7.3
	Week 3	114	2.53	2.53	0.0	1.79	8.9	105	0.47	2.29	-5.1	0.00	7.6
	Week 4	116	2.39	2.34	0.0	1.79	9.4	105	0.23	2.27	-8.4	0.00	6.0
	Week 5	121	2.64	2.52	0.0	2.00	9.3	109	0.58	2.58	-8.6	0.29	7.6
	Week 6	109	2.48	2.50	0.0	2.00	9.0	98	0.45	2.87	-8.6	0.00	9.0
	Week 7	115	2.51	2.46	0.0	1.86	9.0	106	0.47	2.92	-10.0	0.00	8.0
	Week 8	112	2.70	2.55	0.0	2.00	10.0	103	0.66	3.07	-9.6	0.14	8.7
	Week 9	107	2.56	2.48	0.0	1.86	9.6	96	0.43	2.95	-8.4	0.14	8.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.2.4: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	107	2.36	2.40	0.0	1.57	8.7	98	0.27	2.78	-9.4	0.14	7.1
	Week 11	97	2.55	2.49	0.0	2.00	8.7	88	0.55	2.78	-7.6	0.07	7.3
	Week 12	100	2.39	2.32	0.0	1.93	8.1	89	0.24	2.65	-8.0	0.00	6.3
	Week 14	99	2.65	2.47	0.0	1.86	8.4	87	0.54	2.85	-8.1	0.14	8.1
	Week 17	94	2.52	2.63	0.0	1.71	9.3	84	0.56	3.07	-6.9	0.00	8.6
	Week 20	84	2.27	2.58	0.0	1.21	9.4	74	0.44	2.76	-8.4	0.29	7.7
	Week 23	70	1.89	2.03	0.0	1.14	6.9	63	0.09	2.69	-8.6	0.00	6.9
	Week 26	61	2.28	2.26	0.0	1.57	8.1	56	0.41	2.51	-6.7	0.36	6.3
	Week 29	59	2.35	2.44	0.0	1.71	10.0	53	0.78	3.14	-7.9	0.14	9.7
	Week 32	51	2.19	2.51	0.0	1.14	8.6	46	0.42	2.89	-8.3	0.07	5.6
	Week 35	50	2.26	2.48	0.0	1.14	8.9	45	0.45	2.56	-6.1	0.00	6.4
	Week 38	46	2.22	2.59	0.0	1.14	9.0	40	0.54	2.15	-6.1	0.00	5.4
	Week 41	42	2.54	2.70	0.0	1.71	7.9	37	0.83	2.17	-3.7	0.14	5.4
	Week 44	39	2.56	2.76	0.0	2.00	8.4	34	1.29	2.91	-3.7	0.00	8.0
	Week 47	33	2.28	2.70	0.0	1.14	8.6	29	0.57	2.79	-5.9	0.00	6.7
	Week 50	27	2.41	2.67	0.0	1.86	8.3	22	0.44	3.04	-5.7	0.00	6.3
	Week 53	23	2.32	2.58	0.0	1.14	8.4	20	0.46	3.15	-6.0	0.00	6.6
	Week 56	20	2.11	2.53	0.0	0.79	7.4	19	0.56	3.27	-5.7	0.00	7.4
	Week 59	17	2.20	2.55	0.0	1.57	7.1	15	0.30	3.51	-6.0	0.00	6.4
	Week 62	14	2.76	2.59	0.0	2.64	7.9	14	1.32	3.66	-4.1	0.00	7.9
	Week 65	13	2.99	2.69	0.0	3.00	8.4	12	1.46	3.34	-4.4	0.36	8.1
	Week 68	10	2.07	2.19	0.0	2.21	6.7	10	0.64	3.01	-4.4	-0.14	6.7
	Week 71	10	1.89	2.06	0.0	1.29	5.7	10	0.46	2.96	-4.4	0.00	5.7

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.2.4: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	EV+Pembro (N= 56)												
	BASELINE	43	2.90	3.02	0.0	2.43	9.1						
	Week 1	39	3.30	2.81	0.0	2.71	10.0	33	0.33	2.21	-5.0	0.14	5.3
	Week 2	45	3.04	2.73	0.0	2.86	9.7	38	0.09	2.38	-4.6	0.00	5.7
	Week 3	45	3.19	3.03	0.0	3.00	9.7	36	0.00	2.37	-5.9	0.00	5.6
	Week 4	44	2.19	2.43	0.0	1.57	7.0	38	-0.50	2.62	-8.0	-0.07	5.4
	Week 5	41	2.19	2.34	0.0	1.57	6.7	34	-0.63	2.95	-8.0	-0.29	6.3
	Week 6	41	2.55	2.83	0.0	1.71	9.3	33	-0.71	3.82	-9.1	0.00	6.6
	Week 7	45	2.17	2.24	0.0	1.57	7.9	37	-0.69	3.53	-8.0	-0.57	6.3
	Week 8	46	2.15	2.41	0.0	1.50	10.0	35	-0.69	3.83	-8.0	0.00	8.4
	Week 9	42	2.29	2.68	0.0	1.43	10.0	34	-0.42	3.68	-8.0	0.00	8.4
	Week 10	40	1.97	2.33	0.0	1.00	8.1	33	-0.54	3.30	-8.0	0.00	5.6
	Week 11	42	1.72	2.01	0.0	1.00	6.6	33	-1.13	3.43	-7.9	0.00	5.3
	Week 12	44	1.77	2.08	0.0	1.14	7.4	34	-1.11	3.12	-8.0	-0.14	5.6
	Week 14	44	1.95	2.50	0.0	0.79	7.7	34	-0.74	3.85	-9.1	0.00	7.6
	Week 17	35	1.82	2.29	0.0	0.86	8.0	28	-0.86	3.76	-9.1	0.00	8.0
	Week 20	30	1.78	2.07	0.0	0.93	6.7	25	-0.86	3.23	-7.7	0.00	4.7
	Week 23	31	1.79	2.34	0.0	0.71	7.4	24	-0.90	3.51	-9.1	0.00	7.0
	Week 26	29	1.77	2.04	0.0	1.00	6.4	22	-1.02	3.54	-9.1	-0.36	5.1
	Week 29	27	1.68	2.05	0.0	0.71	6.3	22	-0.76	3.79	-9.1	0.00	6.3
	Week 32	28	1.78	2.36	0.0	0.43	7.9	22	-0.95	3.83	-9.1	-0.57	7.9
	Week 35	25	2.10	2.13	0.0	1.43	6.9	20	-0.31	3.20	-9.1	0.00	4.6
	Week 38	22	1.82	1.96	0.0	1.36	5.3	19	-0.80	3.09	-9.1	0.00	4.0
	Week 41	24	2.04	2.13	0.0	1.57	6.3	21	-0.50	3.42	-9.1	0.00	6.3
	Week 44	22	2.34	2.51	0.0	1.43	7.1	19	-0.27	3.49	-9.1	0.00	5.7
	Week 47	23	2.47	2.36	0.0	2.29	6.6	21	0.05	3.67	-9.1	0.00	6.6

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.2.4: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	2.52	2.38	0.0	2.64	6.4	17	0.12	3.80	-9.1	0.00	6.4
	Week 53	19	2.67	2.79	0.0	2.57	8.1	16	-0.25	3.62	-9.1	0.00	6.1
	Week 56	19	1.90	2.15	0.0	1.43	5.9	16	-0.69	3.34	-9.1	0.00	5.6
	Week 59	18	1.94	2.16	0.0	1.07	6.7	15	-0.42	3.91	-9.1	0.00	6.7
	Week 62	20	2.06	2.20	0.0	1.79	6.0	17	-0.26	3.67	-9.1	0.00	6.0
	Week 65	12	2.00	2.87	0.0	0.00	7.7	11	-0.53	4.07	-9.1	0.00	7.7
	Week 68	15	1.91	2.23	0.0	0.86	6.3	14	-0.08	3.24	-9.1	0.00	5.1
	Week 71	12	1.25	2.01	0.0	0.21	5.6	11	-1.36	3.38	-9.1	0.00	2.3
	Week 77	11	0.90	1.60	0.0	0.00	5.1	10	-1.63	3.02	-9.1	-0.07	0.3
	Week 80	10	1.49	2.53	0.0	0.29	7.4	9	-0.86	4.46	-9.1	0.00	7.4
	Plat+Gem (N= 51)												
	BASELINE	42	3.61	3.12	0.0	3.50	9.4						
	Week 1	37	3.61	2.86	0.0	3.43	9.6	36	0.10	2.36	-4.6	0.00	6.9
	Week 2	33	3.89	2.72	0.0	4.57	9.9	32	0.25	2.35	-3.6	0.00	6.3
	Week 3	35	3.05	3.08	0.0	2.29	10.0	33	-0.47	2.30	-6.6	0.00	5.0
	Week 4	35	2.94	2.90	0.0	2.00	10.0	32	-0.79	2.55	-8.0	-0.14	3.1
	Week 5	34	2.56	2.51	0.0	1.93	8.6	32	-0.84	2.45	-6.3	-0.29	6.3
	Week 6	36	2.94	3.03	0.0	2.43	10.0	33	-0.67	2.71	-7.1	-0.43	4.9
	Week 7	34	2.96	2.71	0.0	3.07	8.3	30	-0.56	2.88	-8.0	0.00	3.9
	Week 8	34	3.68	2.92	0.0	4.36	10.0	30	0.08	3.26	-7.1	0.00	7.4
	Week 9	34	2.77	2.95	0.0	1.79	10.0	30	-0.67	3.75	-8.0	0.00	6.7
	Week 10	35	3.23	3.03	0.0	2.14	10.0	32	-0.29	3.30	-7.7	0.00	6.9
	Week 11	29	3.08	2.86	0.0	3.71	10.0	27	-0.59	2.83	-6.4	-0.29	6.4
	Week 12	30	2.62	2.55	0.0	2.86	10.0	27	-0.85	2.30	-6.1	-0.29	4.0
	Week 14	26	3.14	3.01	0.0	3.21	10.0	23	-0.66	2.89	-8.0	-0.29	4.3
	Week 17	26	3.16	2.83	0.0	3.21	8.6	24	-0.56	2.71	-6.9	0.00	4.9

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.2.4: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 20	20	2.48	2.91	0.0	0.71	8.0	19	-1.00	3.13	-8.1	-0.57	3.4
	Week 23	18	1.89	2.24	0.0	0.43	5.7	18	-1.06	2.54	-6.9	-0.21	2.9
	Week 26	20	2.14	2.67	0.0	0.36	7.1	20	-1.12	2.81	-6.6	-0.43	3.0
	Week 29	18	3.07	3.19	0.0	2.50	9.3	18	0.50	3.01	-6.6	0.43	6.1
	Week 32	13	2.42	2.40	0.0	2.14	6.1	13	-0.05	2.60	-5.3	0.00	4.1
	Week 35	12	1.50	1.90	0.0	0.43	4.7	12	-1.29	2.33	-6.6	-0.43	1.9
	Week 38	10	2.49	3.06	0.0	0.64	7.6	10	0.49	2.32	-2.4	0.14	6.4
	Week 41	10	2.16	2.02	0.0	1.71	5.9	10	0.66	0.79	-0.6	0.79	2.0
	Week 44	10	3.24	2.39	0.0	2.93	7.9	10	0.67	1.88	-2.7	0.93	2.9
	Week 47	10	2.16	2.41	0.0	1.43	6.6	10	0.39	2.08	-2.7	0.00	5.0
	Week 56	10	4.46	2.65	0.0	5.00	7.7	10	1.74	1.95	-0.3	1.50	5.1

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.2.5: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Visceral metastases	EV+Pembro (N=148)												
	BASELINE	121	2.90	3.01	0.0	1.86	9.7						
	Week 1	106	3.17	2.72	0.0	3.07	10.0	102	0.38	2.19	-5.0	0.07	7.7
	Week 2	110	3.51	2.73	0.0	3.14	9.7	103	0.64	2.31	-4.6	0.00	7.0
	Week 3	98	2.87	2.76	0.0	2.21	9.7	89	-0.09	2.53	-7.0	0.00	5.6
	Week 4	105	2.45	2.50	0.0	1.71	8.0	95	-0.27	2.73	-8.0	0.00	5.9
	Week 5	101	2.28	2.45	0.0	1.43	8.1	91	-0.39	2.95	-8.0	0.00	6.7
	Week 6	106	2.32	2.55	0.0	1.50	9.4	91	-0.69	3.22	-9.1	0.00	8.1
	Week 7	110	2.09	2.34	0.0	1.21	8.4	92	-0.63	3.23	-8.0	0.00	8.4
	Week 8	108	2.01	2.31	0.0	1.36	10.0	91	-0.78	3.32	-8.0	0.00	8.4
	Week 9	105	2.16	2.51	0.0	1.14	10.0	92	-0.64	3.13	-8.0	0.00	8.4
	Week 10	101	1.97	2.33	0.0	1.00	8.1	87	-0.79	3.20	-8.0	0.00	5.7
	Week 11	98	1.80	2.26	0.0	0.86	9.3	84	-0.79	2.93	-7.9	0.00	5.3
	Week 12	101	1.83	2.35	0.0	0.71	9.3	86	-0.77	3.16	-8.0	0.00	6.0
	Week 14	103	2.02	2.51	0.0	0.86	9.9	88	-0.52	3.28	-9.1	0.00	7.6
	Week 17	96	1.93	2.44	0.0	1.00	10.0	81	-0.74	3.37	-9.1	0.00	8.0
	Week 20	87	1.90	2.19	0.0	1.00	9.0	76	-0.49	2.99	-8.0	0.00	5.7
	Week 23	85	1.60	2.14	0.0	0.57	8.0	71	-0.65	3.13	-9.1	0.00	7.0
	Week 26	81	1.83	2.20	0.0	1.00	8.3	67	-0.51	3.10	-9.1	0.00	6.3
	Week 29	72	1.88	2.18	0.0	1.00	7.1	64	-0.36	3.20	-9.1	0.00	6.3
	Week 32	71	1.75	2.16	0.0	0.57	8.1	62	-0.72	3.28	-9.1	-0.14	7.9
	Week 35	70	1.85	2.04	0.0	1.00	8.1	63	-0.46	3.14	-9.1	0.00	4.9
	Week 38	70	1.80	1.95	0.0	1.07	8.1	63	-0.65	3.03	-9.1	0.00	4.0
	Week 41	66	1.89	2.26	0.0	1.00	7.7	60	-0.48	3.23	-9.1	0.00	7.1
	Week 44	59	2.40	2.51	0.0	1.57	7.9	53	-0.06	2.98	-9.1	0.00	5.7
	Week 47	52	2.36	2.58	0.0	1.29	10.0	48	-0.27	3.55	-9.1	0.00	6.7

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.2.5: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	49	2.40	2.60	0.0	1.57	9.9	43	-0.09	3.44	-9.1	0.00	7.9
	Week 53	50	2.57	2.51	0.0	2.00	8.3	44	-0.13	3.59	-9.1	0.00	6.3
	Week 56	45	2.45	2.02	0.0	2.29	6.0	39	-0.39	3.16	-9.1	-0.14	5.6
	Week 59	44	2.59	2.47	0.0	2.00	8.7	38	-0.45	3.49	-9.1	0.00	6.7
	Week 62	38	2.29	2.34	0.0	1.93	7.9	33	0.02	3.29	-9.1	0.00	6.0
	Week 65	25	2.34	2.39	0.0	1.86	7.7	24	-0.13	3.91	-9.1	0.00	7.7
	Week 68	31	2.30	2.17	0.0	1.86	6.7	29	0.24	3.54	-9.1	0.29	5.7
	Week 71	27	2.04	2.32	0.0	1.00	7.0	25	-0.63	3.57	-9.1	-0.29	6.3
	Week 74	23	2.40	2.67	0.0	1.71	7.6	22	-0.08	4.07	-9.1	-0.07	7.6
	Week 77	24	2.07	2.48	0.0	1.00	7.6	23	-0.60	3.53	-9.1	-0.29	7.6
	Week 80	22	3.01	2.97	0.0	2.21	7.9	22	0.27	4.13	-9.1	0.00	7.9
	Week 83	19	2.62	2.62	0.0	3.43	8.1	19	-0.08	4.33	-9.1	-0.29	8.1
	Week 86	14	2.91	3.10	0.0	2.21	7.9	14	0.65	4.60	-9.1	0.00	7.9
	Week 89	10	1.76	2.89	0.0	0.00	8.0	10	0.84	3.69	-3.9	0.00	8.0
	Week 92	11	2.73	3.13	0.0	1.00	7.0	11	0.77	3.39	-3.9	0.00	7.0
	Plat+Gem (N=157)												
	BASELINE	130	2.70	2.93	0.0	1.36	10.0						
	Week 1	112	3.15	2.81	0.0	3.14	9.6	109	0.63	2.56	-8.3	0.00	8.6
	Week 2	112	3.08	2.86	0.0	2.36	9.9	105	0.63	2.25	-5.6	0.00	7.3
	Week 3	112	2.76	2.80	0.0	1.86	10.0	105	0.34	2.38	-6.6	0.00	7.6
	Week 4	113	2.60	2.60	0.0	1.71	10.0	104	0.05	2.26	-8.4	0.00	6.0
	Week 5	115	2.68	2.63	0.0	1.71	9.3	106	0.29	2.75	-8.6	0.00	7.6
	Week 6	107	2.67	2.75	0.0	2.00	10.0	98	0.23	2.93	-8.6	0.00	9.0
	Week 7	109	2.58	2.54	0.0	1.86	8.3	101	0.14	2.94	-10.0	0.00	8.0
	Week 8	107	2.93	2.76	0.0	2.29	10.0	99	0.49	3.13	-9.6	0.00	8.7
	Week 9	105	2.59	2.61	0.0	1.71	10.0	95	0.11	3.17	-8.4	0.00	8.0

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.2.5: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	104	2.48	2.61	0.0	1.64	10.0	96	-0.04	2.85	-9.4	0.00	7.1
	Week 11	91	2.65	2.65	0.0	2.00	10.0	84	0.16	2.71	-7.6	0.00	7.3
	Week 12	94	2.37	2.46	0.0	1.57	10.0	85	-0.17	2.42	-8.0	0.00	6.3
	Week 14	90	2.68	2.65	0.0	1.86	10.0	80	0.19	2.81	-8.1	0.00	8.1
	Week 17	90	2.50	2.61	0.0	1.79	9.3	82	0.15	3.01	-6.9	0.00	7.4
	Week 20	74	2.26	2.60	0.0	1.07	9.4	66	-0.01	2.84	-8.4	0.00	7.0
	Week 23	63	1.88	2.10	0.0	1.00	6.9	59	-0.17	2.67	-8.6	0.00	6.9
	Week 26	55	2.25	2.41	0.0	1.57	8.1	53	0.05	2.24	-6.1	0.00	6.0
	Week 29	53	2.61	2.66	0.0	2.43	10.0	50	0.80	3.05	-7.9	0.14	9.7
	Week 32	43	2.27	2.64	0.0	0.71	8.6	41	0.29	2.84	-8.3	0.00	5.6
	Week 35	39	2.17	2.52	0.0	0.86	8.9	37	0.06	2.33	-6.1	0.00	4.9
	Week 38	37	2.45	2.92	0.0	1.00	9.0	34	0.47	2.24	-6.1	0.00	6.4
	Week 41	33	2.41	2.68	0.0	1.00	7.9	31	0.52	1.84	-3.7	0.14	5.1
	Week 44	32	2.59	2.76	0.0	1.71	7.9	30	0.88	2.63	-3.1	0.00	6.1
	Week 47	28	2.15	2.88	0.0	0.29	8.6	26	0.10	2.57	-5.9	0.00	6.7
	Week 50	22	2.32	2.85	0.0	0.57	8.3	20	0.19	2.56	-5.6	0.00	6.3
	Week 53	19	2.17	3.01	0.0	0.43	8.7	17	-0.01	2.78	-6.0	0.00	6.6
	Week 56	18	2.56	2.93	0.0	1.50	7.7	17	0.17	2.49	-5.7	0.00	7.4
	Week 59	13	2.55	2.83	0.0	1.71	7.1	12	-0.07	3.10	-6.0	-0.14	6.4
	Week 62	11	2.51	2.49	0.0	2.00	7.9	11	0.09	3.89	-6.7	0.00	7.9

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.2.5: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Lymph node only	EV+Pembro (N= 43)												
	BASELINE	36	1.89	2.04	0.0	0.79	7.3						
	Week 1	30	1.99	2.13	0.0	1.36	7.4	26	-0.15	1.47	-4.0	0.00	3.6
	Week 2	37	2.06	2.41	0.0	0.57	7.9	32	-0.27	1.97	-4.0	0.00	4.9
	Week 3	35	2.29	2.33	0.0	1.57	6.9	31	-0.17	1.95	-4.3	0.00	6.6
	Week 4	36	1.32	1.80	0.0	0.50	7.0	33	-0.96	1.78	-4.0	-0.71	4.7
	Week 5	34	1.31	1.73	0.0	0.36	6.1	31	-0.84	2.11	-5.4	-0.43	3.9
	Week 6	34	1.89	2.53	0.0	0.64	8.4	31	-0.15	3.08	-4.1	-0.14	6.6
	Week 7	34	1.44	2.10	0.0	0.57	7.9	31	-0.81	2.51	-5.6	-0.43	7.1
	Week 8	35	1.68	2.29	0.0	0.71	8.7	32	-0.54	2.73	-5.0	-0.36	8.7
	Week 9	30	1.63	2.32	0.0	0.71	8.4	27	-0.24	3.08	-5.0	-0.29	8.4
	Week 10	31	1.29	1.78	0.0	0.43	7.0	29	-0.49	2.66	-5.7	-0.43	7.0
	Week 11	34	0.82	1.39	0.0	0.14	6.6	30	-1.31	1.92	-5.6	-0.36	1.3
	Week 12	35	1.19	1.93	0.0	0.29	8.0	31	-0.88	2.50	-5.3	-0.29	7.7
	Week 14	30	0.87	1.69	0.0	0.00	6.0	26	-1.30	2.13	-6.4	-0.50	1.7
	Week 17	30	1.00	1.45	0.0	0.14	5.3	27	-1.09	2.23	-7.3	-0.29	2.3
	Week 20	27	1.09	1.72	0.0	0.29	5.4	24	-1.20	2.14	-7.3	-0.14	2.6
	Week 23	27	1.35	2.25	0.0	0.00	7.7	24	-0.71	2.44	-7.3	0.00	3.7
	Week 26	27	1.76	2.35	0.0	0.86	6.9	24	-0.60	2.98	-7.3	-0.29	6.1
	Week 29	28	1.30	2.15	0.0	0.29	8.9	25	-0.77	3.05	-7.3	-0.29	8.6
	Week 32	24	1.61	2.35	0.0	0.36	9.4	22	-0.51	3.08	-6.9	-0.50	9.1
	Week 35	22	2.20	2.79	0.0	1.21	10.0	20	-0.02	3.26	-6.3	-0.29	9.7
	Week 38	21	1.47	1.88	0.0	0.86	5.3	19	-0.83	1.95	-6.3	-0.57	2.0
	Week 41	22	1.42	1.80	0.0	0.64	6.0	20	-0.89	2.25	-5.6	-0.14	2.7
	Week 44	22	1.39	2.43	0.0	0.21	9.4	19	-0.50	3.30	-6.6	0.00	9.1
	Week 47	21	1.41	1.71	0.0	0.71	5.4	18	-0.61	2.46	-6.0	0.00	3.6

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.2.5: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	1.21	1.72	0.0	0.00	4.9	18	-0.71	2.48	-5.1	-0.14	4.3
	Week 53	20	1.71	2.47	0.0	0.29	8.1	17	-0.10	2.10	-5.0	0.00	3.9
	Week 56	21	1.39	1.90	0.0	0.57	5.6	19	-1.16	2.57	-6.1	-0.57	3.4
	Week 59	21	1.49	1.74	0.0	0.86	5.6	18	-1.09	2.48	-6.7	-0.93	3.3
	Week 62	19	1.76	2.04	0.0	0.71	5.9	17	-0.77	2.89	-6.6	-0.29	5.9
	Week 65	16	1.54	2.17	0.0	0.29	6.1	15	-0.46	2.08	-5.0	0.00	2.7
	Week 68	13	1.87	2.22	0.0	1.00	6.3	12	0.04	1.68	-2.4	0.00	4.1
	Week 71	13	1.49	2.09	0.0	0.14	5.6	12	-0.30	2.40	-5.7	-0.29	5.1
	Week 74	13	0.92	1.36	0.0	0.43	3.9	12	-0.49	2.49	-5.3	-0.14	3.9
	Week 77	13	1.49	1.81	0.0	0.86	5.1	11	-0.14	2.24	-4.0	0.00	4.6
	Week 80	13	1.35	1.58	0.0	0.86	4.6	12	-0.46	2.34	-5.1	-0.36	4.1
	Week 83	11	1.42	1.54	0.0	0.71	4.4	11	-0.27	1.83	-3.6	-0.57	3.3
	Week 86	11	1.14	1.39	0.0	0.57	4.1	11	-0.55	1.34	-2.7	-0.57	2.6
	Plat+Gem (N= 37)												
	BASELINE	30	2.45	3.04	0.0	0.86	9.4						
	Week 1	26	2.90	2.75	0.0	2.36	8.1	25	0.10	1.97	-4.6	0.00	5.3
	Week 2	31	3.43	2.66	0.0	3.43	7.7	27	0.39	2.11	-3.6	0.43	6.3
	Week 3	30	2.52	2.38	0.0	2.29	8.7	26	-0.05	1.79	-2.9	0.00	5.1
	Week 4	32	2.47	2.20	0.0	2.21	6.7	27	-0.08	2.63	-8.0	0.00	5.9
	Week 5	33	2.55	2.21	0.0	2.43	8.6	28	0.06	1.83	-5.0	0.00	5.1
	Week 6	32	2.35	2.41	0.0	1.71	8.1	27	-0.34	2.28	-7.0	0.00	4.1
	Week 7	32	2.90	2.63	0.0	2.21	9.0	27	0.53	2.89	-6.4	0.57	7.1
	Week 8	32	3.06	2.45	0.0	2.64	7.6	27	0.59	2.99	-7.1	0.43	5.9
	Week 9	30	2.76	2.61	0.0	2.07	9.6	25	0.16	2.95	-8.0	0.43	3.7
	Week 10	30	3.02	2.60	0.0	2.29	8.3	26	0.55	2.86	-5.9	0.71	6.0
	Week 11	29	2.74	2.36	0.0	2.00	8.6	25	0.36	2.78	-6.4	0.00	5.6

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.6.2.5: BPI-SF - Observed Means and Change from Baseline of Pain Interference by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 12	28	2.72	2.28	0.0	2.14	7.4	23	0.24	3.18	-7.0	1.00	5.1
	Week 14	28	3.02	2.61	0.0	2.79	7.9	23	0.39	3.14	-8.0	0.14	7.4
	Week 17	25	3.27	3.01	0.0	1.86	8.6	21	0.78	2.79	-6.1	0.71	8.6
	Week 20	23	2.77	3.02	0.0	1.29	8.6	20	0.75	2.99	-5.3	0.50	7.7
	Week 23	20	2.09	2.12	0.0	1.21	5.7	17	-0.17	2.52	-6.4	0.00	3.1
	Week 26	21	2.39	2.29	0.0	1.29	6.7	18	-0.17	3.37	-6.7	0.43	6.3
	Week 29	19	2.56	2.77	0.0	1.71	9.3	16	0.63	3.10	-6.3	0.50	6.6
	Week 32	18	2.16	2.29	0.0	1.29	6.9	15	0.03	2.94	-5.3	0.71	4.4
	Week 35	19	2.11	2.24	0.0	1.14	7.3	16	0.21	2.78	-4.3	0.00	6.4
	Week 38	15	2.09	2.13	0.0	1.43	5.6	12	0.48	2.11	-4.3	0.36	5.4
	Week 41	15	2.66	2.59	0.0	2.14	7.7	12	1.04	2.15	-3.6	1.00	5.4
	Week 44	14	2.69	2.78	0.0	2.07	8.4	11	1.17	2.92	-3.7	0.71	8.0
	Week 47	12	2.27	2.01	0.0	1.57	6.0	10	0.89	2.47	-4.1	1.00	5.6
	Week 50	11	2.95	2.37	0.0	2.57	7.1	8	0.98	2.92	-5.7	1.79	3.3

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
EV+Pembro (N=240)												
BASELINE	206	63.67	22.79	0.0	66.67	100.0						
Week 1	190	61.45	23.13	0.0	66.67	100.0	184	-2.54	16.22	-66.7	0.00	33.3
Week 2	203	60.06	22.04	0.0	66.67	100.0	189	-4.81	19.99	-66.7	0.00	50.0
Week 3	198	57.07	23.25	0.0	58.33	100.0	182	-6.18	21.12	-66.7	0.00	41.7
Week 4	194	63.70	22.04	0.0	66.67	100.0	179	-1.21	21.89	-66.7	0.00	66.7
Week 5	190	65.26	21.21	0.0	66.67	100.0	173	0.58	21.46	-66.7	0.00	50.0
Week 6	188	66.09	20.81	0.0	66.67	100.0	170	1.08	21.44	-50.0	0.00	66.7
Week 7	195	65.56	22.21	0.0	66.67	100.0	176	1.09	22.47	-58.3	0.00	58.3
Week 8	191	65.88	21.80	0.0	66.67	100.0	171	2.34	23.92	-66.7	0.00	66.7
Week 9	197	64.09	21.76	16.7	66.67	100.0	180	0.28	22.33	-75.0	0.00	66.7
Week 10	191	65.97	21.31	0.0	66.67	100.0	175	2.43	23.16	-66.7	0.00	66.7
Week 11	194	66.15	21.59	0.0	66.67	100.0	175	2.90	23.80	-66.7	0.00	66.7
Week 12	186	65.23	23.54	0.0	66.67	100.0	171	1.51	25.72	-100.0	0.00	75.0
Week 14	185	64.14	22.70	0.0	66.67	100.0	167	-0.10	24.63	-66.7	0.00	83.3
Week 17	178	66.43	20.67	0.0	66.67	100.0	162	2.26	22.58	-58.3	0.00	83.3
Week 20	167	65.77	22.16	0.0	66.67	100.0	154	0.49	24.05	-66.7	0.00	66.7
Week 23	162	64.30	23.28	8.3	66.67	100.0	151	-1.21	26.25	-66.7	0.00	66.7
Week 26	156	65.49	22.45	0.0	66.67	100.0	144	1.16	24.07	-83.3	0.00	66.7
Week 29	157	65.71	21.35	0.0	66.67	100.0	145	-0.92	23.18	-83.3	0.00	66.7
Week 32	135	64.32	21.71	16.7	66.67	100.0	125	-1.13	22.95	-66.7	0.00	50.0
Week 35	132	65.72	20.94	0.0	66.67	100.0	122	-0.82	22.43	-66.7	0.00	50.0
Week 38	132	65.21	21.36	0.0	66.67	100.0	124	0.07	22.18	-50.0	0.00	75.0
Week 41	129	62.86	21.73	16.7	66.67	100.0	119	-1.26	22.70	-58.3	0.00	58.3
Week 44	108	65.66	21.28	0.0	66.67	100.0	100	-0.92	23.42	-91.7	0.00	50.0
Week 47	100	63.17	22.88	0.0	66.67	100.0	94	-3.46	25.73	-83.3	0.00	58.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	89	65.82	20.49	16.7	66.67	100.0	84	-0.99	20.26	-50.0	0.00	50.0
Week 53	79	66.24	21.39	16.7	66.67	100.0	74	-2.14	21.77	-66.7	0.00	50.0
Week 56	81	66.46	21.53	0.0	66.67	100.0	76	0.22	23.17	-83.3	0.00	50.0
Week 59	72	66.09	21.82	0.0	66.67	100.0	68	-0.49	23.91	-83.3	0.00	50.0
Week 62	65	67.05	22.26	16.7	66.67	100.0	63	-1.98	22.63	-66.7	0.00	41.7
Week 65	58	66.81	22.70	16.7	66.67	100.0	54	-0.77	22.15	-66.7	0.00	41.7
Week 68	53	65.88	21.14	16.7	66.67	100.0	52	-4.01	20.31	-50.0	0.00	41.7
Week 71	51	66.34	22.30	16.7	66.67	100.0	49	-3.74	21.99	-58.3	-8.33	41.7
Week 74	47	68.09	20.14	25.0	66.67	100.0	46	-1.99	21.60	-41.7	0.00	41.7
Week 77	44	64.01	23.49	16.7	66.67	100.0	42	-3.77	24.01	-50.0	0.00	41.7
Week 80	40	64.17	23.05	0.0	66.67	100.0	37	-2.48	19.82	-41.7	0.00	41.7
Week 83	37	64.19	24.36	8.3	66.67	100.0	35	-1.67	23.03	-58.3	0.00	41.7
Week 86	34	66.67	23.21	16.7	66.67	100.0	31	-2.15	22.15	-58.3	0.00	41.7
Week 89	33	62.63	22.06	16.7	66.67	100.0	31	-4.84	23.94	-58.3	-8.33	50.0
Week 92	27	67.28	22.87	0.0	66.67	100.0	25	-1.67	19.54	-41.7	0.00	33.3
Week 95	22	67.42	23.84	16.7	66.67	100.0	21	-1.98	20.05	-33.3	0.00	33.3
Week 98	18	64.81	24.84	16.7	66.67	100.0	17	-0.98	20.81	-33.3	0.00	33.3
Week 101	14	69.05	24.11	16.7	75.00	100.0	14	-5.95	21.79	-50.0	-4.17	33.3
Week 104	10	70.00	25.52	33.3	79.17	100.0	10	-5.00	25.52	-50.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Plat+Gem (N=242)												
BASELINE	188	59.84	25.26	0.0	66.67	100.0						
Week 1	173	56.74	23.00	0.0	58.33	100.0	158	-4.06	16.92	-66.7	0.00	41.7
Week 2	171	55.07	22.68	0.0	50.00	100.0	151	-5.19	21.70	-83.3	0.00	58.3
Week 3	184	61.68	21.71	0.0	66.67	100.0	162	0.57	21.12	-50.0	0.00	83.3
Week 4	183	59.79	20.95	0.0	66.67	100.0	156	-1.82	20.15	-66.7	0.00	66.7
Week 5	187	56.82	20.63	0.0	58.33	100.0	156	-5.93	21.52	-58.3	-8.33	66.7
Week 6	174	58.91	20.68	0.0	58.33	100.0	149	-2.01	23.52	-58.3	0.00	83.3
Week 7	186	58.38	20.89	0.0	58.33	100.0	157	-4.25	21.88	-58.3	-8.33	66.7
Week 8	167	57.43	21.55	0.0	58.33	100.0	144	-5.50	25.36	-75.0	0.00	50.0
Week 9	177	58.52	20.33	0.0	58.33	100.0	150	-2.83	22.88	-50.0	0.00	58.3
Week 10	166	56.68	20.42	0.0	58.33	100.0	139	-4.68	25.22	-66.7	0.00	50.0
Week 11	168	58.98	19.77	0.0	58.33	100.0	143	-3.55	23.79	-58.3	0.00	75.0
Week 12	159	60.22	19.28	0.0	66.67	100.0	138	-2.17	23.62	-66.7	0.00	75.0
Week 14	153	56.37	21.41	0.0	50.00	100.0	128	-6.71	25.70	-66.7	-8.33	50.0
Week 17	155	58.60	21.14	0.0	58.33	100.0	130	-4.49	23.62	-58.3	0.00	50.0
Week 20	126	63.16	21.38	0.0	66.67	100.0	110	0.08	24.56	-66.7	0.00	66.7
Week 23	115	65.14	21.98	0.0	66.67	100.0	97	1.03	23.94	-58.3	0.00	41.7
Week 26	108	66.51	21.13	0.0	66.67	100.0	95	0.53	21.74	-58.3	0.00	50.0
Week 29	100	64.25	23.10	0.0	66.67	100.0	86	-2.52	26.63	-83.3	0.00	41.7
Week 32	83	65.86	21.84	8.3	66.67	100.0	76	0.11	24.29	-58.3	0.00	58.3
Week 35	76	63.82	21.15	0.0	66.67	100.0	69	-2.17	25.03	-75.0	0.00	66.7
Week 38	74	64.30	22.31	16.7	66.67	100.0	65	0.13	23.96	-58.3	0.00	66.7
Week 41	65	64.10	22.63	0.0	66.67	100.0	56	-0.15	25.05	-58.3	0.00	66.7
Week 44	60	66.94	19.59	33.3	66.67	100.0	53	-0.16	21.65	-41.7	0.00	83.3
Week 47	56	65.18	19.92	0.0	66.67	100.0	49	-3.74	23.63	-75.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	51	64.71	23.66	0.0	66.67	100.0	47	-0.71	24.81	-75.0	0.00	50.0
Week 53	46	67.39	17.90	33.3	66.67	100.0	42	-3.37	22.09	-58.3	0.00	50.0
Week 56	39	62.61	25.43	0.0	66.67	100.0	34	-7.60	25.73	-66.7	-4.17	33.3
Week 59	37	70.50	21.03	16.7	66.67	100.0	33	-0.76	28.06	-66.7	0.00	50.0
Week 62	32	69.79	21.03	16.7	66.67	100.0	29	-0.57	28.43	-66.7	0.00	66.7
Week 65	30	66.39	22.79	0.0	66.67	100.0	26	-2.24	30.69	-83.3	0.00	66.7
Week 68	25	63.00	24.89	0.0	66.67	100.0	21	-1.59	31.58	-83.3	0.00	66.7
Week 71	22	58.71	30.48	0.0	66.67	100.0	19	-3.95	31.96	-83.3	0.00	50.0
Week 74	21	66.67	22.05	8.3	66.67	100.0	18	5.56	24.92	-33.3	0.00	66.7
Week 77	18	67.13	24.67	0.0	75.00	100.0	15	10.00	26.01	-50.0	8.34	66.7
Week 80	14	66.07	17.74	33.3	66.67	100.0	13	1.28	21.74	-50.0	16.66	25.0
Week 83	13	68.59	18.05	33.3	66.67	100.0	12	6.94	27.25	-33.3	4.17	66.7
Week 86	12	70.14	18.62	33.3	70.84	100.0	11	8.33	25.00	-25.0	0.00	66.7
Week 89	11	70.46	17.23	50.0	66.67	100.0	10	9.17	27.34	-33.3	4.17	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Present	EV+Pembro (N= 48)												
	BASELINE	39	53.42	25.41	0.0	50.00	100.0						
	Week 1	32	53.13	26.33	0.0	50.00	100.0	32	-0.78	19.21	-50.0	0.00	33.3
	Week 2	37	50.90	24.04	0.0	50.00	100.0	33	-6.56	23.18	-50.0	0.00	33.3
	Week 3	34	45.59	25.56	0.0	45.84	100.0	29	-4.88	23.73	-58.3	0.00	33.3
	Week 4	36	52.31	24.93	0.0	54.17	100.0	31	-2.69	31.06	-66.7	0.00	66.7
	Week 5	30	53.61	19.04	25.0	50.00	100.0	24	2.43	25.00	-41.7	4.17	50.0
	Week 6	31	59.14	22.09	0.0	58.33	100.0	25	7.67	30.80	-50.0	8.33	66.7
	Week 7	34	59.07	22.69	0.0	58.33	100.0	28	9.52	25.02	-58.3	8.33	58.3
	Week 8	35	57.14	23.58	8.3	58.33	100.0	30	6.39	31.08	-66.7	4.17	66.7
	Week 9	34	57.60	23.60	16.7	50.00	100.0	30	3.33	29.25	-75.0	0.00	66.7
	Week 10	34	60.54	22.22	16.7	66.67	91.7	30	7.22	28.26	-50.0	4.17	66.7
	Week 11	33	56.57	24.98	0.0	50.00	100.0	28	7.14	33.54	-66.7	0.00	66.7
	Week 12	33	60.35	28.11	0.0	66.67	100.0	29	10.63	33.25	-50.0	8.33	75.0
	Week 14	31	61.02	25.22	0.0	66.67	100.0	26	10.58	31.41	-58.3	0.00	83.3
	Week 17	31	62.63	23.36	16.7	66.67	100.0	25	13.67	31.99	-33.3	0.00	83.3
	Week 20	27	64.51	19.28	25.0	66.67	100.0	24	11.81	25.41	-33.3	8.33	66.7
	Week 23	26	60.58	22.43	8.3	66.67	100.0	23	8.33	30.46	-50.0	8.33	66.7
	Week 26	25	67.00	18.40	33.3	66.67	100.0	22	13.64	24.47	-25.0	8.33	66.7
	Week 29	23	65.22	23.52	16.7	66.67	100.0	22	7.20	26.89	-33.3	0.00	66.7
	Week 32	21	61.90	23.65	16.7	66.67	100.0	19	5.70	22.06	-33.3	0.00	50.0
	Week 35	19	67.54	20.01	33.3	75.00	100.0	17	9.80	19.37	-33.3	8.33	41.7
	Week 38	18	52.31	24.89	0.0	50.00	91.7	17	0.00	29.90	-50.0	-8.33	75.0
	Week 41	20	62.92	20.32	33.3	66.67	100.0	19	7.89	25.07	-33.3	0.00	58.3
	Week 44	17	61.27	21.03	33.3	66.67	100.0	15	2.22	22.37	-33.3	0.00	50.0
	Week 47	18	59.26	26.18	0.0	62.50	100.0	16	0.00	30.88	-83.3	0.00	58.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	12	65.28	21.27	33.3	66.67	91.7	11	-0.76	13.67	-33.3	0.00	16.7
	Week 53	12	63.19	25.49	16.7	75.00	91.7	11	-6.06	26.11	-66.7	-8.33	41.7
	Week 56	13	62.82	27.56	0.0	66.67	100.0	12	0.00	31.38	-83.3	0.00	41.7
	Week 59	12	69.44	28.05	0.0	83.33	91.7	11	0.00	33.75	-83.3	0.00	50.0
	Week 62	10	64.17	26.37	16.7	79.17	91.7	9	-9.26	29.00	-66.7	-8.33	41.7
	Week 65	10	66.67	24.53	16.7	75.00	91.7	9	-2.78	29.75	-66.7	0.00	41.7
	Plat+Gem (N= 48)												
	BASELINE	33	57.32	28.39	0.0	66.67	100.0						
	Week 1	31	50.27	28.83	0.0	50.00	100.0	27	-7.41	10.92	-33.3	-8.33	8.3
	Week 2	29	51.15	20.50	16.7	50.00	91.7	24	-3.47	24.44	-50.0	-4.17	50.0
	Week 3	32	65.37	23.68	0.0	66.67	100.0	27	6.79	28.12	-33.3	0.00	83.3
	Week 4	32	63.54	20.27	16.7	66.67	100.0	24	5.21	23.16	-25.0	0.00	66.7
	Week 5	36	59.72	21.04	16.7	66.67	100.0	28	1.19	26.13	-58.3	0.00	66.7
	Week 6	35	60.71	21.63	16.7	66.67	100.0	27	8.33	25.00	-25.0	0.00	83.3
	Week 7	38	59.43	21.76	16.7	62.50	100.0	29	7.76	25.39	-50.0	8.34	66.7
	Week 8	31	63.44	16.76	33.3	66.67	83.3	25	1.00	22.35	-33.3	0.00	50.0
	Week 9	32	57.55	20.99	8.3	50.00	100.0	25	4.33	22.58	-33.3	0.00	41.7
	Week 10	34	57.60	23.60	0.0	58.33	100.0	26	7.69	24.94	-33.3	4.17	50.0
	Week 11	30	62.50	20.03	16.7	66.67	100.0	24	10.07	22.25	-41.7	8.34	50.0
	Week 12	28	64.58	16.92	33.3	66.67	100.0	23	11.59	26.91	-33.3	8.34	75.0
	Week 14	26	59.94	18.71	33.3	62.50	100.0	21	3.57	28.94	-50.0	0.00	50.0
	Week 17	30	59.17	19.74	16.7	66.67	100.0	25	3.67	23.70	-50.0	8.33	50.0
	Week 20	23	67.39	19.29	33.3	66.67	100.0	21	10.32	26.07	-41.7	8.34	66.7
	Week 23	22	68.56	24.79	16.7	75.00	100.0	19	7.46	23.39	-33.3	8.34	41.7
	Week 26	19	75.44	18.10	41.7	75.00	100.0	18	9.26	19.78	-25.0	4.17	41.7
	Week 29	16	64.58	29.74	0.0	70.84	100.0	14	-0.60	35.27	-83.3	4.17	41.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 32	11	71.21	19.49	50.0	66.67	100.0	11	9.09	24.28	-16.7	0.00	58.3
	Week 35	10	69.17	22.24	33.3	75.00	100.0	9	4.63	27.36	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Absent	EV+Pembro (N=192)												
	BASELINE	167	66.07	21.52	0.0	66.67	100.0						
	Week 1	158	63.13	22.14	0.0	66.67	100.0	152	-2.91	15.56	-66.7	0.00	33.3
	Week 2	166	62.10	21.11	8.3	66.67	100.0	156	-4.43	19.32	-66.7	0.00	50.0
	Week 3	164	59.45	22.09	0.0	66.67	100.0	153	-6.43	20.67	-66.7	0.00	41.7
	Week 4	158	66.30	20.55	8.3	66.67	100.0	148	-0.90	19.56	-50.0	0.00	50.0
	Week 5	160	67.45	20.94	0.0	66.67	100.0	149	0.28	20.92	-66.7	0.00	50.0
	Week 6	157	67.46	20.34	16.7	66.67	100.0	145	-0.06	19.31	-50.0	0.00	50.0
	Week 7	161	66.93	21.94	16.7	66.67	100.0	148	-0.51	21.67	-58.3	0.00	50.0
	Week 8	156	67.84	20.96	0.0	66.67	100.0	141	1.48	22.14	-66.7	0.00	66.7
	Week 9	163	65.44	21.18	16.7	66.67	100.0	150	-0.33	20.75	-66.7	0.00	50.0
	Week 10	157	67.14	21.00	0.0	66.67	100.0	145	1.44	21.95	-66.7	0.00	66.7
	Week 11	161	68.12	20.36	0.0	66.67	100.0	147	2.10	21.52	-58.3	0.00	50.0
	Week 12	153	66.29	22.40	0.0	66.67	100.0	142	-0.35	23.61	-100.0	0.00	58.3
	Week 14	154	64.77	22.19	0.0	66.67	100.0	141	-2.07	22.76	-66.7	0.00	50.0
	Week 17	147	67.23	20.05	0.0	66.67	100.0	137	0.18	19.87	-58.3	0.00	50.0
	Week 20	140	66.01	22.73	0.0	66.67	100.0	130	-1.60	23.30	-66.7	0.00	50.0
	Week 23	136	65.01	23.46	8.3	66.67	100.0	128	-2.93	25.18	-66.7	0.00	50.0
	Week 26	131	65.20	23.19	0.0	66.67	100.0	122	-1.09	23.40	-83.3	0.00	50.0
	Week 29	134	65.80	21.05	0.0	66.67	100.0	123	-2.37	22.27	-83.3	0.00	50.0
	Week 32	114	64.77	21.41	16.7	66.67	100.0	106	-2.36	23.00	-66.7	0.00	50.0
	Week 35	113	65.41	21.16	0.0	66.67	100.0	105	-2.54	22.50	-66.7	0.00	50.0
	Week 38	114	67.25	20.13	16.7	66.67	100.0	107	0.08	20.87	-50.0	0.00	50.0
	Week 41	109	62.84	22.06	16.7	66.67	100.0	100	-3.00	21.92	-58.3	0.00	50.0
	Week 44	91	66.48	21.34	0.0	66.67	100.0	85	-1.47	23.68	-91.7	0.00	50.0
	Week 47	82	64.02	22.18	16.7	66.67	100.0	78	-4.17	24.72	-66.7	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	77	65.91	20.51	16.7	66.67	100.0	73	-1.03	21.15	-50.0	0.00	50.0
	Week 53	67	66.79	20.74	16.7	66.67	100.0	63	-1.45	21.09	-50.0	0.00	50.0
	Week 56	68	67.16	20.36	16.7	66.67	100.0	64	0.26	21.62	-50.0	0.00	50.0
	Week 59	60	65.42	20.57	16.7	66.67	100.0	57	-0.58	21.93	-66.7	0.00	41.7
	Week 62	55	67.58	21.68	16.7	66.67	100.0	54	-0.77	21.49	-58.3	0.00	41.7
	Week 65	48	66.84	22.58	16.7	66.67	100.0	45	-0.37	20.72	-50.0	0.00	41.7
	Week 68	46	65.04	21.20	16.7	66.67	100.0	45	-4.82	20.22	-50.0	-8.33	33.3
	Week 71	44	67.80	21.38	16.7	66.67	100.0	42	-2.78	20.55	-58.3	-8.33	41.7
	Week 74	40	67.92	19.66	25.0	66.67	100.0	39	-2.78	21.74	-41.7	0.00	41.7
	Week 77	38	63.82	23.75	16.7	66.67	100.0	36	-4.86	24.18	-50.0	-8.34	41.7
	Week 80	35	64.52	23.51	0.0	66.67	100.0	32	-3.65	19.28	-41.7	0.00	41.7
	Week 83	32	64.84	24.93	8.3	66.67	100.0	30	-2.50	22.76	-58.3	0.00	41.7
	Week 86	29	66.95	23.93	16.7	66.67	100.0	26	-2.56	21.95	-58.3	0.00	33.3
	Week 89	29	62.64	22.12	16.7	66.67	100.0	27	-5.86	23.32	-58.3	-8.33	50.0
	Week 92	24	67.01	24.01	0.0	66.67	100.0	22	0.00	19.92	-41.7	0.00	33.3
	Week 95	20	68.33	24.72	16.7	66.67	100.0	19	-1.76	20.71	-33.3	0.00	33.3
	Week 98	18	64.81	24.84	16.7	66.67	100.0	17	-0.98	20.81	-33.3	0.00	33.3
	Week 101	13	70.51	24.44	16.7	75.00	100.0	13	-3.85	21.14	-50.0	0.00	33.3
	Plat+Gem (N=194)												
	BASELINE	155	60.38	24.61	0.0	66.67	100.0						
	Week 1	142	58.16	21.39	0.0	58.33	100.0	131	-3.37	17.87	-66.7	0.00	41.7
	Week 2	142	55.87	23.08	0.0	58.33	100.0	127	-5.51	21.24	-83.3	0.00	58.3
	Week 3	152	60.91	21.28	0.0	66.67	100.0	135	-0.68	19.32	-50.0	0.00	50.0
	Week 4	151	59.00	21.07	0.0	58.33	100.0	132	-3.09	19.38	-66.7	0.00	41.7
	Week 5	151	56.13	20.54	0.0	50.00	100.0	128	-7.49	20.17	-50.0	-8.33	50.0
	Week 6	139	58.45	20.49	0.0	58.33	100.0	122	-4.30	22.66	-58.3	-8.33	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 7	148	58.11	20.73	0.0	58.33	100.0	128	-6.97	20.14	-58.3	-8.33	50.0
	Week 8	136	56.07	22.33	0.0	50.00	100.0	119	-6.86	25.83	-75.0	0.00	50.0
	Week 9	145	58.74	20.25	0.0	58.33	100.0	125	-4.27	22.76	-50.0	0.00	58.3
	Week 10	132	56.44	19.61	0.0	58.33	100.0	113	-7.52	24.52	-66.7	-8.33	50.0
	Week 11	138	58.21	19.70	0.0	58.33	100.0	119	-6.30	23.22	-58.3	0.00	75.0
	Week 12	131	59.29	19.68	0.0	58.33	100.0	115	-4.93	22.02	-66.7	0.00	50.0
	Week 14	127	55.64	21.92	0.0	50.00	100.0	107	-8.72	24.67	-66.7	-8.33	50.0
	Week 17	125	58.47	21.53	0.0	58.33	100.0	105	-6.43	23.29	-58.3	-8.33	50.0
	Week 20	103	62.22	21.79	0.0	66.67	100.0	89	-2.34	23.70	-66.7	0.00	50.0
	Week 23	93	64.34	21.33	0.0	66.67	100.0	78	-0.53	23.96	-58.3	0.00	41.7
	Week 26	89	64.61	21.33	0.0	66.67	100.0	77	-1.51	21.79	-58.3	0.00	50.0
	Week 29	84	64.19	21.83	0.0	66.67	100.0	72	-2.89	24.91	-83.3	0.00	41.7
	Week 32	72	65.05	22.19	8.3	66.67	100.0	65	-1.41	24.14	-58.3	0.00	50.0
	Week 35	66	63.01	21.04	0.0	66.67	100.0	60	-3.19	24.74	-75.0	0.00	50.0
	Week 38	66	63.00	22.17	16.7	66.67	100.0	57	0.58	25.29	-58.3	0.00	66.7
	Week 41	62	64.25	22.90	0.0	66.67	100.0	53	-0.47	24.59	-58.3	0.00	66.7
	Week 44	55	67.58	19.42	33.3	66.67	100.0	48	1.22	22.21	-41.7	0.00	83.3
	Week 47	51	65.36	20.51	0.0	66.67	100.0	44	-1.89	23.90	-75.0	0.00	66.7
	Week 50	48	64.24	24.00	0.0	66.67	100.0	44	-1.14	25.01	-75.0	0.00	50.0
	Week 53	41	67.28	18.39	33.3	66.67	100.0	37	-1.58	22.55	-58.3	0.00	50.0
	Week 56	34	64.46	25.15	0.0	70.84	100.0	29	-4.31	24.76	-66.7	0.00	33.3
	Week 59	32	71.88	19.60	16.7	70.84	100.0	28	3.27	26.58	-50.0	0.00	50.0
	Week 62	27	70.37	19.38	33.3	66.67	100.0	24	3.13	27.01	-50.0	0.00	66.7
	Week 65	25	69.33	19.94	25.0	66.67	100.0	21	5.16	25.75	-33.3	8.34	66.7
	Week 68	23	66.30	21.83	16.7	66.67	100.0	19	3.51	26.40	-33.3	0.00	66.7
	Week 71	21	60.71	29.71	0.0	66.67	100.0	18	-0.46	28.93	-83.3	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 74	20	66.67	22.62	8.3	66.67	100.0	17	5.88	25.64	-33.3	0.00	66.7
	Week 77	16	65.62	25.44	0.0	75.00	100.0	13	8.33	26.35	-50.0	8.34	66.7
	Week 80	12	66.67	18.46	33.3	66.67	100.0	11	0.76	21.88	-50.0	16.66	16.7
	Week 83	11	70.45	18.77	33.3	66.67	100.0	10	8.33	28.86	-33.3	4.17	66.7
	Week 86	10	70.83	20.51	33.3	79.17	100.0	9	8.33	27.64	-25.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
< 65 years	EV+Pembro (N=105)												
	BASELINE	92	61.96	24.50	0.0	66.67	100.0						
	Week 1	88	61.08	23.12	0.0	66.67	100.0	85	-2.16	14.56	-41.7	0.00	33.3
	Week 2	92	60.51	20.92	16.7	66.67	100.0	86	-2.81	20.71	-66.7	0.00	50.0
	Week 3	93	60.48	22.69	8.3	66.67	100.0	84	-1.09	20.89	-66.7	0.00	41.7
	Week 4	90	66.57	22.50	16.7	66.67	100.0	82	4.27	22.65	-66.7	0.00	66.7
	Week 5	90	69.17	20.77	25.0	75.00	100.0	81	6.89	20.74	-50.0	8.33	50.0
	Week 6	90	69.63	19.84	16.7	66.67	100.0	81	7.51	20.65	-50.0	0.00	66.7
	Week 7	85	69.22	20.57	16.7	75.00	100.0	77	7.36	18.78	-33.3	0.00	50.0
	Week 8	89	70.04	21.57	16.7	75.00	100.0	80	9.06	24.20	-66.7	8.33	66.7
	Week 9	93	66.94	22.13	16.7	66.67	100.0	85	4.31	22.59	-75.0	0.00	66.7
	Week 10	88	69.79	20.70	16.7	75.00	100.0	81	8.13	23.79	-66.7	0.00	66.7
	Week 11	93	69.09	21.20	0.0	66.67	100.0	84	8.33	24.61	-66.7	4.17	66.7
	Week 12	86	69.19	22.25	8.3	66.67	100.0	79	7.59	26.96	-66.7	0.00	75.0
	Week 14	84	65.67	23.51	0.0	66.67	100.0	76	4.72	26.33	-66.7	0.00	83.3
	Week 17	83	68.57	21.79	0.0	66.67	100.0	77	7.58	25.51	-58.3	0.00	83.3
	Week 20	79	68.99	21.72	0.0	66.67	100.0	73	5.82	24.36	-66.7	8.33	66.7
	Week 23	78	66.67	24.14	8.3	66.67	100.0	73	3.65	26.13	-58.3	0.00	66.7
	Week 26	78	67.31	21.27	0.0	66.67	100.0	72	5.67	23.89	-66.7	0.00	66.7
	Week 29	74	67.68	20.50	25.0	66.67	100.0	67	3.36	22.52	-41.7	0.00	66.7
	Week 32	64	66.28	21.23	25.0	66.67	100.0	59	2.68	22.61	-58.3	0.00	50.0
	Week 35	62	66.67	21.02	8.3	66.67	100.0	58	1.15	22.16	-66.7	0.00	41.7
	Week 38	62	66.80	19.99	16.7	66.67	100.0	59	3.96	23.13	-50.0	0.00	75.0
	Week 41	64	65.50	21.10	16.7	66.67	100.0	59	4.38	20.37	-33.3	0.00	58.3
	Week 44	50	69.00	20.42	33.3	66.67	100.0	48	4.34	21.19	-41.7	0.00	50.0
	Week 47	47	62.94	24.07	0.0	58.33	100.0	46	-2.72	28.06	-83.3	0.00	58.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	44	64.58	20.10	16.7	66.67	100.0	41	-1.01	19.47	-41.7	0.00	33.3
	Week 53	40	67.29	20.53	16.7	66.67	100.0	37	0.00	24.37	-66.7	0.00	50.0
	Week 56	44	67.80	22.70	0.0	66.67	100.0	41	1.63	23.88	-83.3	0.00	41.7
	Week 59	42	65.87	22.38	0.0	66.67	100.0	39	-0.21	27.20	-83.3	0.00	50.0
	Week 62	37	67.79	22.75	16.7	66.67	100.0	36	0.23	24.52	-66.7	0.00	41.7
	Week 65	34	66.91	23.16	16.7	66.67	100.0	31	0.00	25.09	-66.7	0.00	41.7
	Week 68	34	66.18	21.61	25.0	66.67	100.0	33	-2.53	23.61	-50.0	0.00	41.7
	Week 71	32	66.93	23.43	16.7	66.67	100.0	30	-1.67	24.89	-58.3	-4.17	41.7
	Week 74	29	67.24	20.65	33.3	66.67	100.0	28	-0.89	23.39	-41.7	0.00	41.7
	Week 77	25	62.67	24.07	16.7	66.67	100.0	24	-3.82	26.80	-50.0	0.00	41.7
	Week 80	24	61.81	23.69	0.0	66.67	100.0	22	-3.79	23.53	-41.7	0.00	41.7
	Week 83	23	64.13	22.81	16.7	58.33	100.0	22	0.00	26.23	-58.3	0.00	41.7
	Week 86	20	63.33	23.16	16.7	66.67	100.0	18	-0.46	26.73	-58.3	0.00	41.7
	Week 89	19	64.03	21.53	16.7	66.67	100.0	17	-0.49	27.87	-58.3	0.00	50.0
	Week 92	14	69.05	19.18	33.3	66.67	100.0	12	2.78	21.42	-33.3	0.00	33.3
	Week 95	12	68.06	20.36	33.3	66.67	100.0	11	0.76	21.23	-33.3	0.00	33.3
	Plat+Gem (N=106)												
	BASELINE	83	61.24	23.37	0.0	66.67	100.0						
	Week 1	75	58.00	21.33	0.0	58.33	100.0	71	-4.11	17.64	-66.7	0.00	41.7
	Week 2	76	55.04	21.78	8.3	50.00	100.0	68	-6.01	22.98	-83.3	-8.33	41.7
	Week 3	80	63.65	20.12	0.0	66.67	100.0	73	1.37	20.13	-41.7	0.00	50.0
	Week 4	79	60.23	17.75	16.7	66.67	100.0	67	-1.87	17.76	-58.3	0.00	33.3
	Week 5	80	58.44	18.91	16.7	58.33	100.0	67	-5.72	20.63	-50.0	-8.33	41.7
	Week 6	76	61.95	19.16	0.0	66.67	100.0	67	-0.75	21.80	-58.3	0.00	41.7
	Week 7	81	59.16	19.92	0.0	58.33	100.0	71	-4.34	20.65	-58.3	-8.33	50.0
	Week 8	72	58.91	18.52	8.3	50.00	100.0	64	-3.78	23.43	-75.0	0.00	41.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	78	60.47	17.06	25.0	66.67	91.7	69	-0.24	20.16	-50.0	0.00	50.0
	Week 10	78	56.09	20.27	0.0	50.00	100.0	68	-5.02	24.69	-66.7	0.00	50.0
	Week 11	75	60.44	17.50	0.0	66.67	100.0	66	-2.40	22.96	-58.3	0.00	41.7
	Week 12	74	61.37	16.70	16.7	66.67	100.0	66	-1.14	22.07	-66.7	0.00	50.0
	Week 14	68	57.97	20.64	16.7	50.00	100.0	58	-5.03	25.12	-58.3	-4.17	50.0
	Week 17	68	59.19	21.27	16.7	66.67	100.0	58	-3.30	22.29	-58.3	-8.33	50.0
	Week 20	60	64.17	21.05	0.0	66.67	100.0	52	1.12	25.41	-66.7	0.00	58.3
	Week 23	51	67.48	19.95	16.7	66.67	100.0	44	5.11	23.59	-58.3	8.34	41.7
	Week 26	47	66.13	19.69	8.3	66.67	100.0	42	3.37	20.75	-58.3	0.00	50.0
	Week 29	42	65.48	19.79	16.7	66.67	100.0	37	1.35	22.95	-66.7	0.00	41.7
	Week 32	37	65.32	20.37	25.0	66.67	100.0	34	1.23	22.39	-50.0	0.00	41.7
	Week 35	34	63.97	19.86	33.3	66.67	100.0	31	-0.54	23.66	-50.0	0.00	50.0
	Week 38	33	63.89	22.41	16.7	66.67	100.0	28	5.65	25.26	-50.0	0.00	66.7
	Week 41	27	65.43	20.76	33.3	66.67	100.0	22	5.68	23.20	-33.3	0.00	66.7
	Week 44	28	67.86	18.52	33.3	66.67	100.0	24	5.21	23.29	-33.3	0.00	83.3
	Week 47	24	65.97	17.71	33.3	62.50	100.0	21	1.19	22.56	-50.0	0.00	66.7
	Week 50	26	64.74	23.01	25.0	50.00	100.0	24	3.47	20.69	-33.3	0.00	50.0
	Week 53	19	68.42	19.16	33.3	66.67	100.0	17	2.45	16.87	-16.7	0.00	50.0
	Week 56	13	71.15	22.21	33.3	83.33	100.0	11	1.51	12.26	-16.7	0.00	25.0
	Week 59	14	75.00	22.17	16.7	83.33	100.0	12	6.95	18.41	-16.7	0.00	50.0
	Week 62	13	80.77	16.45	50.0	83.33	100.0	12	9.72	20.97	-16.7	0.00	66.7
	Week 65	13	73.72	21.74	25.0	75.00	100.0	11	6.06	24.74	-16.7	0.00	66.7
	Week 68	10	66.67	25.15	16.7	70.84	100.0	8	10.42	25.49	-16.7	4.17	66.7
	Week 77	10	69.17	29.67	0.0	79.17	100.0	8	15.63	25.76	-8.3	4.17	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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Table 302.1.3002.9.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>= 65 years	EV+Pembro (N=135)												
	BASELINE	114	65.06	21.32	0.0	66.67	100.0						
	Week 1	102	61.76	23.26	0.0	66.67	100.0	99	-2.86	17.58	-66.7	0.00	33.3
	Week 2	111	59.68	23.02	0.0	66.67	100.0	103	-6.47	19.31	-66.7	0.00	50.0
	Week 3	105	54.05	23.43	0.0	50.00	100.0	98	-10.54	20.43	-66.7	-8.34	33.3
	Week 4	104	61.22	21.44	0.0	66.67	100.0	97	-5.84	20.20	-50.0	0.00	41.7
	Week 5	100	61.75	21.09	0.0	66.67	100.0	92	-4.98	20.64	-66.7	0.00	50.0
	Week 6	98	62.84	21.24	0.0	66.67	100.0	89	-4.78	20.56	-50.0	0.00	41.7
	Week 7	110	62.73	23.10	0.0	66.67	100.0	99	-3.79	23.94	-58.3	0.00	58.3
	Week 8	102	62.25	21.45	0.0	66.67	100.0	91	-3.57	22.16	-66.7	0.00	50.0
	Week 9	104	61.54	21.20	16.7	66.67	100.0	95	-3.33	21.59	-66.7	0.00	50.0
	Week 10	103	62.70	21.38	0.0	66.67	100.0	94	-2.48	21.55	-66.7	0.00	50.0
	Week 11	101	63.45	21.70	0.0	66.67	100.0	91	-2.11	22.00	-50.0	0.00	50.0
	Week 12	100	61.83	24.19	0.0	66.67	100.0	92	-3.71	23.52	-100.0	0.00	50.0
	Week 14	101	62.87	22.03	0.0	66.67	100.0	91	-4.12	22.48	-66.7	0.00	50.0
	Week 17	95	64.56	19.56	8.3	66.67	100.0	85	-2.55	18.41	-50.0	0.00	50.0
	Week 20	88	62.88	22.28	0.0	66.67	100.0	81	-4.32	22.86	-58.3	0.00	50.0
	Week 23	84	62.10	22.38	8.3	66.67	100.0	78	-5.77	25.70	-66.7	0.00	50.0
	Week 26	78	63.68	23.57	0.0	66.67	100.0	72	-3.36	23.56	-83.3	0.00	50.0
	Week 29	83	63.96	22.05	0.0	66.67	100.0	78	-4.59	23.25	-83.3	0.00	50.0
	Week 32	71	62.56	22.13	16.7	66.67	100.0	66	-4.54	22.89	-66.7	0.00	50.0
	Week 35	70	64.88	20.99	0.0	66.67	100.0	64	-2.60	22.71	-66.7	0.00	50.0
	Week 38	70	63.81	22.56	0.0	66.67	100.0	65	-3.46	20.83	-50.0	0.00	50.0
	Week 41	65	60.26	22.18	16.7	66.67	100.0	60	-6.81	23.64	-58.3	-8.33	50.0
	Week 44	58	62.79	21.75	0.0	66.67	100.0	52	-5.77	24.51	-91.7	-4.17	50.0
	Week 47	53	63.36	22.01	16.7	66.67	100.0	48	-4.17	23.57	-66.7	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
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Table 302.1.3002.9.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	45	67.04	21.02	16.7	66.67	100.0	43	-0.97	21.22	-50.0	0.00	50.0
	Week 53	39	65.17	22.45	16.7	66.67	100.0	37	-4.28	18.90	-50.0	-8.33	33.3
	Week 56	37	64.86	20.23	16.7	66.67	100.0	35	-1.43	22.55	-50.0	0.00	50.0
	Week 59	30	66.39	21.38	16.7	66.67	100.0	29	-0.86	19.07	-41.7	0.00	41.7
	Week 62	28	66.07	21.98	25.0	66.67	100.0	27	-4.94	19.92	-50.0	-8.33	33.3
	Week 65	24	66.67	22.52	16.7	70.84	100.0	23	-1.81	17.94	-41.7	0.00	33.3
	Week 68	19	65.35	20.83	16.7	66.67	100.0	19	-6.58	12.90	-33.3	-8.33	16.7
	Week 71	19	65.35	20.83	16.7	66.67	100.0	19	-7.02	16.49	-41.7	-8.33	25.0
	Week 74	18	69.44	19.80	25.0	66.67	100.0	18	-3.70	19.01	-41.7	0.00	33.3
	Week 77	19	65.79	23.22	25.0	66.67	100.0	18	-3.71	20.46	-33.3	-4.17	33.3
	Week 80	16	67.71	22.33	16.7	75.00	100.0	15	-0.56	13.16	-25.0	0.00	16.7
	Week 83	14	64.29	27.63	8.3	70.84	100.0	13	-4.49	16.88	-33.3	0.00	25.0
	Week 86	14	71.43	23.28	16.7	70.84	100.0	13	-4.49	14.28	-25.0	-8.33	25.0
	Week 89	14	60.71	23.44	16.7	66.67	100.0	14	-10.12	17.66	-33.3	-12.50	16.7
	Week 92	13	65.38	26.97	0.0	66.67	100.0	13	-5.77	17.48	-41.7	0.00	16.7
	Week 95	10	66.67	28.60	16.7	70.84	100.0	10	-5.00	19.32	-33.3	0.00	16.7
	Week 98	10	60.00	25.09	16.7	66.67	83.3	10	-10.84	16.22	-33.3	-8.34	16.7
	Plat+Gem (N=136)												
	BASELINE	105	58.73	26.71	0.0	66.67	100.0						
	Week 1	98	55.78	24.27	0.0	58.33	100.0	87	-4.02	16.42	-50.0	0.00	41.7
	Week 2	95	55.09	23.49	0.0	50.00	100.0	83	-4.52	20.71	-66.7	0.00	58.3
	Week 3	104	60.18	22.84	0.0	62.50	100.0	89	-0.09	21.99	-50.0	0.00	83.3
	Week 4	104	59.46	23.17	0.0	62.50	100.0	89	-1.78	21.89	-66.7	0.00	66.7
	Week 5	107	55.61	21.83	0.0	50.00	100.0	89	-6.09	22.29	-58.3	-8.33	66.7
	Week 6	98	56.55	21.58	0.0	54.17	100.0	82	-3.05	24.93	-50.0	-8.33	83.3
	Week 7	105	57.78	21.69	0.0	58.33	100.0	86	-4.17	22.96	-58.3	-8.33	66.7

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Table 302.1.3002.9.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 8	95	56.32	23.62	0.0	66.67	100.0	80	-6.87	26.87	-66.7	-8.33	50.0
	Week 9	99	56.99	22.55	0.0	58.33	100.0	81	-5.04	24.88	-50.0	0.00	58.3
	Week 10	88	57.20	20.65	16.7	58.33	100.0	71	-4.34	25.89	-50.0	-8.33	50.0
	Week 11	93	57.80	21.45	0.0	50.00	100.0	77	-4.55	24.58	-50.0	-8.33	75.0
	Week 12	85	59.22	21.32	0.0	58.33	100.0	72	-3.12	25.08	-58.3	0.00	75.0
	Week 14	85	55.10	22.05	0.0	50.00	100.0	70	-8.10	26.27	-66.7	-8.33	50.0
	Week 17	87	58.14	21.15	0.0	58.33	100.0	72	-5.44	24.75	-50.0	0.00	50.0
	Week 20	66	62.25	21.79	0.0	66.67	100.0	58	-0.86	23.96	-58.3	0.00	66.7
	Week 23	64	63.28	23.46	0.0	66.67	100.0	53	-2.36	23.93	-58.3	0.00	33.3
	Week 26	61	66.80	22.33	0.0	66.67	100.0	53	-1.73	22.43	-58.3	0.00	41.7
	Week 29	58	63.36	25.36	0.0	66.67	100.0	49	-5.44	28.99	-83.3	0.00	41.7
	Week 32	46	66.30	23.17	8.3	66.67	100.0	42	-0.79	25.95	-58.3	0.00	58.3
	Week 35	42	63.69	22.38	0.0	66.67	100.0	38	-3.51	26.33	-75.0	0.00	66.7
	Week 38	41	64.63	22.50	16.7	66.67	100.0	37	-4.05	22.36	-58.3	0.00	33.3
	Week 41	38	63.16	24.09	0.0	66.67	100.0	34	-3.92	25.81	-58.3	-12.50	50.0
	Week 44	32	66.15	20.73	33.3	66.67	100.0	29	-4.60	19.49	-41.7	0.00	41.7
	Week 47	32	64.58	21.69	0.0	66.67	100.0	28	-7.44	24.15	-75.0	-16.66	41.7
	Week 50	25	64.67	24.80	0.0	66.67	100.0	23	-5.07	28.29	-75.0	-8.34	50.0
	Week 53	27	66.67	17.30	33.3	66.67	100.0	25	-7.33	24.57	-58.3	-16.66	33.3
	Week 56	26	58.33	26.25	0.0	66.67	83.3	23	-11.96	29.39	-66.7	-16.66	33.3
	Week 59	23	67.75	20.30	16.7	66.67	100.0	21	-5.16	31.89	-66.7	0.00	50.0
	Week 62	19	62.28	20.85	16.7	66.67	91.7	17	-7.84	31.24	-66.7	-8.33	33.3
	Week 65	17	60.78	22.59	0.0	66.67	91.7	15	-8.33	33.92	-83.3	0.00	41.7
	Week 68	15	60.56	25.29	0.0	66.67	100.0	13	-8.97	33.58	-83.3	0.00	50.0
	Week 71	15	56.11	30.12	0.0	58.33	100.0	13	-9.61	34.83	-83.3	0.00	50.0
	Week 74	12	67.36	17.21	25.0	66.67	83.3	11	3.03	24.52	-33.3	8.33	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Europe	EV+Pembro (N= 98)												
	BASELINE	79	66.14	22.89	0.0	66.67	100.0						
	Week 1	74	65.65	23.37	0.0	66.67	100.0	71	-1.99	15.27	-41.7	0.00	33.3
	Week 2	79	63.29	20.52	16.7	66.67	100.0	71	-4.69	19.66	-66.7	0.00	50.0
	Week 3	78	61.32	21.94	0.0	66.67	100.0	69	-4.11	20.64	-50.0	0.00	41.7
	Week 4	78	67.63	20.05	16.7	66.67	100.0	70	-2.26	23.05	-66.7	0.00	41.7
	Week 5	70	69.05	18.94	33.3	66.67	100.0	62	1.21	21.17	-50.0	0.00	50.0
	Week 6	70	70.71	19.85	0.0	70.84	100.0	61	2.46	22.84	-50.0	0.00	66.7
	Week 7	78	68.27	20.94	16.7	70.84	100.0	68	1.96	21.65	-50.0	0.00	50.0
	Week 8	72	69.91	20.82	16.7	75.00	100.0	61	4.23	24.51	-66.7	0.00	66.7
	Week 9	80	67.29	21.08	16.7	66.67	100.0	70	0.36	22.72	-66.7	0.00	66.7
	Week 10	71	69.25	22.16	0.0	75.00	100.0	62	4.03	23.46	-58.3	0.00	66.7
	Week 11	76	69.08	21.85	0.0	70.84	100.0	66	3.66	23.35	-50.0	0.00	66.7
	Week 12	73	70.55	22.23	0.0	75.00	100.0	65	4.36	25.39	-100.0	0.00	66.7
	Week 14	74	69.26	20.55	0.0	66.67	100.0	64	0.91	21.52	-41.7	0.00	66.7
	Week 17	70	69.41	19.95	16.7	66.67	100.0	62	2.02	23.75	-58.3	0.00	66.7
	Week 20	70	70.60	18.04	25.0	66.67	100.0	63	3.97	25.30	-58.3	0.00	66.7
	Week 23	61	68.72	21.17	16.7	66.67	100.0	57	0.88	27.58	-66.7	0.00	66.7
	Week 26	62	70.83	19.89	8.3	70.84	100.0	55	4.55	20.53	-66.7	0.00	50.0
	Week 29	63	68.39	21.28	16.7	66.67	100.0	57	-0.88	22.80	-50.0	0.00	58.3
	Week 32	51	66.18	20.37	16.7	66.67	100.0	47	0.36	21.56	-50.0	0.00	50.0
	Week 35	56	68.30	18.01	33.3	66.67	100.0	52	0.16	20.38	-41.7	0.00	41.7
	Week 38	51	68.95	19.30	16.7	66.67	100.0	48	0.87	19.16	-50.0	0.00	33.3
	Week 41	52	67.79	18.38	33.3	66.67	100.0	48	0.52	20.80	-33.3	0.00	58.3
	Week 44	43	70.16	20.10	16.7	66.67	100.0	39	0.43	19.58	-41.7	0.00	33.3
	Week 47	39	65.17	23.25	0.0	66.67	100.0	36	-3.24	25.76	-83.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	37	71.17	18.70	33.3	66.67	100.0	36	0.69	17.97	-33.3	0.00	33.3
	Week 53	28	70.83	22.51	16.7	70.84	100.0	27	1.23	21.77	-66.7	0.00	33.3
	Week 56	30	65.83	24.01	0.0	66.67	100.0	29	-3.16	23.82	-83.3	0.00	33.3
	Week 59	27	69.75	22.90	0.0	66.67	100.0	27	-0.93	22.21	-83.3	0.00	33.3
	Week 62	23	68.84	23.86	16.7	66.67	100.0	23	-2.90	24.18	-66.7	0.00	33.3
	Week 65	23	71.38	24.34	16.7	75.00	100.0	23	0.72	23.82	-66.7	0.00	41.7
	Week 68	21	73.41	20.52	33.3	75.00	100.0	21	1.98	15.57	-33.3	0.00	33.3
	Week 71	19	75.00	22.57	33.3	83.33	100.0	19	1.75	21.08	-50.0	0.00	41.7
	Week 74	15	76.11	21.10	33.3	83.33	100.0	15	1.67	21.64	-33.3	0.00	41.7
	Week 77	19	71.49	22.96	25.0	66.67	100.0	19	0.44	21.06	-33.3	0.00	41.7
	Week 80	17	73.53	20.88	33.3	75.00	100.0	17	2.94	17.42	-25.0	0.00	41.7
	Week 83	16	75.52	20.74	33.3	79.17	100.0	16	6.25	18.13	-33.3	0.00	41.7
	Week 86	14	77.38	18.90	33.3	83.33	100.0	14	2.97	16.21	-25.0	0.00	33.3
	Week 89	14	69.64	19.78	33.3	66.67	100.0	14	-3.57	18.69	-33.3	-8.33	33.3
	Week 92	11	81.06	13.48	58.3	83.33	100.0	11	3.79	15.97	-25.0	0.00	33.3
	Week 95	10	77.50	20.05	50.0	75.00	100.0	10	2.50	18.02	-33.3	4.17	33.3
	Plat+Gem (N=102)												
	BASELINE	71	58.10	27.42	0.0	66.67	100.0						
	Week 1	71	53.05	25.60	0.0	50.00	100.0	61	-4.37	16.50	-50.0	0.00	41.7
	Week 2	67	50.75	24.95	0.0	50.00	100.0	56	-6.70	23.91	-83.3	-8.33	58.3
	Week 3	68	57.23	24.98	0.0	58.33	100.0	56	-1.04	21.73	-41.7	0.00	66.7
	Week 4	75	57.33	21.92	0.0	58.33	100.0	59	-3.95	21.13	-66.7	0.00	66.7
	Week 5	77	54.11	22.81	8.3	50.00	100.0	60	-8.19	22.26	-50.0	-8.33	41.7
	Week 6	70	56.07	22.61	0.0	58.33	100.0	56	-4.46	25.52	-58.3	-8.33	58.3
	Week 7	72	54.75	22.93	0.0	50.00	100.0	55	-7.12	21.60	-58.3	-16.66	50.0
	Week 8	65	51.92	23.42	0.0	50.00	100.0	53	-9.12	25.70	-66.7	-8.33	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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Table 302.1.3002.9.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	70	54.29	22.51	0.0	50.00	100.0	55	-5.45	23.36	-50.0	0.00	41.7
	Week 10	60	53.61	21.45	0.0	50.00	100.0	46	-7.43	24.98	-58.3	-12.51	50.0
	Week 11	64	54.04	21.72	0.0	50.00	100.0	50	-6.67	26.19	-58.3	-8.33	75.0
	Week 12	60	57.22	20.03	0.0	54.17	100.0	48	-3.82	24.25	-66.7	0.00	50.0
	Week 14	56	49.85	21.70	0.0	50.00	100.0	42	-14.29	27.38	-66.7	-16.67	50.0
	Week 17	58	55.75	21.36	0.0	50.00	100.0	44	-6.06	25.06	-50.0	-8.33	50.0
	Week 20	47	60.99	19.82	0.0	58.33	100.0	37	-2.25	26.91	-66.7	0.00	66.7
	Week 23	44	64.20	21.68	16.7	66.67	100.0	32	0.26	25.00	-58.3	0.00	33.3
	Week 26	39	63.46	22.59	0.0	66.67	100.0	30	-0.56	23.36	-58.3	0.00	41.7
	Week 29	34	63.97	23.46	0.0	66.67	100.0	25	1.00	32.21	-83.3	0.00	41.7
	Week 32	33	61.11	23.17	8.3	66.67	100.0	27	-2.16	27.60	-58.3	0.00	58.3
	Week 35	30	58.05	23.42	0.0	58.33	100.0	24	-5.21	30.38	-75.0	0.00	66.7
	Week 38	26	57.37	24.98	16.7	54.17	100.0	21	-5.16	25.48	-58.3	0.00	41.7
	Week 41	22	56.44	19.74	8.3	50.00	83.3	17	-7.35	29.30	-58.3	-16.67	50.0
	Week 44	20	60.00	19.23	33.3	62.50	100.0	16	-5.21	20.61	-33.3	0.00	33.3
	Week 47	16	56.77	20.91	0.0	50.00	100.0	12	-14.58	25.41	-75.0	-8.34	25.0
	Week 50	11	53.79	27.73	0.0	50.00	100.0	10	-10.84	32.64	-75.0	-8.34	50.0
	Week 53	11	57.58	17.26	33.3	50.00	83.3	10	-16.67	20.79	-58.3	-16.67	16.7
	Week 56	10	58.33	22.22	8.3	58.34	83.3	8	-14.58	23.04	-50.0	-16.67	25.0

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
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Table 302.1.3002.9.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
North America	EV+Pembro (N= 57)												
	BASELINE	47	61.88	26.28	0.0	66.67	100.0						
	Week 1	39	59.83	24.02	25.0	58.33	100.0	37	0.45	16.07	-41.7	0.00	33.3
	Week 2	44	59.28	24.46	8.3	58.33	100.0	42	-3.17	15.72	-33.3	0.00	33.3
	Week 3	44	53.22	23.99	8.3	58.33	91.7	40	-6.67	19.08	-66.7	0.00	25.0
	Week 4	44	59.66	22.37	8.3	62.50	91.7	41	0.20	23.53	-58.3	0.00	66.7
	Week 5	47	63.65	23.28	0.0	66.67	100.0	41	1.02	23.29	-50.0	0.00	50.0
	Week 6	44	62.88	22.34	16.7	66.67	100.0	39	2.14	23.24	-50.0	0.00	66.7
	Week 7	46	65.94	22.35	16.7	66.67	100.0	42	3.57	20.09	-58.3	0.00	33.3
	Week 8	47	64.89	20.18	25.0	66.67	100.0	42	3.17	21.06	-33.3	0.00	66.7
	Week 9	46	60.51	22.80	16.7	66.67	100.0	42	-1.39	23.20	-75.0	0.00	33.3
	Week 10	47	66.84	20.45	16.7	66.67	100.0	44	3.41	23.11	-66.7	0.00	66.7
	Week 11	47	63.30	21.75	0.0	66.67	91.7	42	1.98	26.66	-66.7	4.17	66.7
	Week 12	44	62.31	24.28	0.0	66.67	100.0	40	3.13	29.09	-66.7	4.17	75.0
	Week 14	43	61.82	23.80	0.0	66.67	91.7	39	2.99	27.80	-66.7	0.00	83.3
	Week 17	40	65.00	20.25	8.3	66.67	100.0	37	5.63	22.74	-33.3	0.00	83.3
	Week 20	38	65.79	26.05	0.0	70.84	100.0	35	2.38	22.01	-50.0	0.00	58.3
	Week 23	38	67.10	24.81	8.3	75.00	100.0	35	1.67	23.38	-58.3	0.00	50.0
	Week 26	35	69.05	21.82	16.7	75.00	100.0	32	8.33	22.30	-33.3	0.00	66.7
	Week 29	38	69.30	21.50	16.7	66.67	100.0	34	3.92	21.15	-33.3	0.00	66.7
	Week 32	32	67.71	21.03	25.0	70.84	91.7	29	0.86	17.73	-33.3	0.00	41.7
	Week 35	33	69.19	22.68	8.3	66.67	100.0	30	1.39	23.48	-66.7	0.00	41.7
	Week 38	32	71.61	19.84	25.0	83.33	100.0	29	7.18	22.57	-41.7	0.00	75.0
	Week 41	28	66.37	22.16	16.7	75.00	91.7	24	2.08	20.15	-58.3	4.17	41.7
	Week 44	21	68.65	22.81	0.0	75.00	91.7	20	-1.67	27.12	-91.7	0.00	33.3
	Week 47	24	66.32	22.04	16.7	66.67	100.0	23	-3.26	28.84	-66.7	0.00	58.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
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Table 302.1.3002.9.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	23	67.03	21.97	16.7	66.67	100.0	20	-1.67	19.98	-41.7	0.00	50.0
	Week 53	17	72.55	18.34	33.3	66.67	100.0	14	-1.19	22.14	-50.0	0.00	33.3
	Week 56	20	73.75	15.36	50.0	79.17	100.0	17	5.39	23.56	-50.0	8.33	50.0
	Week 59	17	68.14	21.90	16.7	66.67	100.0	14	-1.78	31.38	-66.7	0.00	41.7
	Week 62	14	75.60	16.49	50.0	79.17	100.0	13	1.92	23.61	-41.7	0.00	33.3
	Week 65	12	77.08	13.35	50.0	83.33	100.0	9	3.70	14.50	-16.7	0.00	33.3
	Week 68	10	77.50	6.86	66.7	79.17	83.3	9	-9.26	12.11	-33.3	-8.33	0.0
	Week 71	10	73.33	12.91	41.7	75.00	83.3	8	-15.62	15.06	-41.7	-12.50	0.0
	Week 74	10	75.83	12.08	58.3	75.00	100.0	9	-9.26	20.17	-41.7	-8.33	16.7
	Plat+Gem (N= 51)												
	BASELINE	42	67.46	20.48	25.0	66.67	100.0						
	Week 1	41	59.96	21.43	16.7	58.33	100.0	36	-6.71	17.34	-50.0	-8.33	33.3
	Week 2	38	55.92	22.25	8.3	54.17	83.3	33	-11.11	23.17	-75.0	-8.33	33.3
	Week 3	40	65.42	17.56	33.3	66.67	100.0	35	-6.19	21.42	-50.0	-8.33	50.0
	Week 4	35	62.86	19.42	25.0	66.67	100.0	29	-6.03	20.40	-58.3	-8.33	41.7
	Week 5	39	58.97	18.87	25.0	58.33	91.7	32	-11.20	21.13	-58.3	-8.34	41.7
	Week 6	34	57.84	17.03	25.0	58.33	91.7	30	-8.61	18.76	-33.3	-8.34	33.3
	Week 7	42	60.52	17.56	33.3	62.50	100.0	37	-7.88	21.69	-50.0	-8.33	41.7
	Week 8	39	58.97	17.46	16.7	58.33	83.3	33	-9.34	25.83	-66.7	-8.33	33.3
	Week 9	39	59.62	17.68	25.0	58.33	100.0	33	-5.30	20.60	-41.7	-8.33	33.3
	Week 10	39	57.27	17.12	25.0	50.00	100.0	32	-8.07	23.99	-41.7	-8.34	41.7
	Week 11	39	60.26	15.93	33.3	58.33	83.3	33	-5.81	23.52	-58.3	0.00	41.7
	Week 12	36	59.49	15.19	33.3	50.00	83.3	32	-8.59	22.75	-50.0	-8.33	41.7
	Week 14	34	56.62	20.08	25.0	50.00	100.0	29	-10.34	25.84	-58.3	-16.66	50.0
	Week 17	37	56.53	17.25	33.3	58.33	100.0	31	-12.36	23.75	-58.3	-8.34	50.0
	Week 20	27	62.96	18.82	25.0	66.67	100.0	23	-2.17	27.43	-50.0	-8.33	58.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 23	27	65.12	19.75	25.0	66.67	100.0	23	-0.72	25.74	-50.0	0.00	41.7
	Week 26	28	63.39	20.07	25.0	66.67	100.0	25	-4.33	22.32	-58.3	-8.33	41.7
	Week 29	29	64.37	21.70	0.0	66.67	100.0	25	-6.00	24.00	-83.3	0.00	25.0
	Week 32	17	61.27	15.85	25.0	58.33	91.7	17	-7.84	22.53	-33.3	-16.66	33.3
	Week 35	16	60.42	15.06	33.3	62.50	83.3	15	-10.00	21.87	-50.0	-16.66	16.7
	Week 38	16	58.33	17.21	33.3	58.34	83.3	13	-8.97	18.47	-50.0	-16.66	16.7
	Week 41	16	58.85	17.60	33.3	58.34	83.3	13	-8.33	16.31	-33.3	-8.34	16.7
	Week 44	13	62.18	15.45	33.3	66.67	83.3	11	-9.09	16.85	-41.7	-16.66	16.7
	Week 47	11	61.36	14.56	33.3	66.67	83.3	9	-13.89	19.54	-50.0	-16.66	16.7
	Week 50	17	60.78	19.04	25.0	58.33	100.0	15	-6.67	19.21	-33.3	-16.66	33.3
	Week 53	13	66.03	13.80	50.0	66.67	83.3	11	-9.09	14.17	-33.3	-8.34	16.7
	Week 56	11	56.06	23.89	16.7	58.33	83.3	9	-14.81	25.61	-66.7	-8.34	16.7
	Week 59	11	62.88	22.16	16.7	66.67	91.7	9	-16.66	25.00	-66.7	-16.66	16.7
	Week 62	11	68.18	26.57	16.7	66.67	100.0	9	-11.11	26.68	-66.7	-8.33	16.7
	Week 65	10	60.83	28.34	0.0	66.67	100.0	8	-15.62	32.25	-83.3	-12.50	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Rest of World	EV+Pembro (N= 85)												
	BASELINE	80	62.29	20.45	0.0	66.67	100.0						
	Week 1	77	58.23	22.11	0.0	58.33	100.0	76	-4.50	17.07	-66.7	0.00	33.3
	Week 2	80	57.29	21.96	0.0	62.50	100.0	76	-5.81	22.44	-66.7	0.00	50.0
	Week 3	76	54.93	23.73	0.0	50.00	100.0	73	-7.88	22.69	-66.7	0.00	33.3
	Week 4	72	61.92	23.48	0.0	66.67	100.0	68	-0.98	19.82	-50.0	0.00	50.0
	Week 5	73	62.67	21.66	0.0	66.67	100.0	70	-0.24	20.90	-66.7	0.00	50.0
	Week 6	74	63.63	20.25	16.7	66.67	100.0	70	-0.71	19.23	-50.0	0.00	50.0
	Week 7	71	62.32	23.35	0.0	66.67	100.0	66	-1.39	24.70	-58.3	0.00	58.3
	Week 8	72	62.50	23.36	0.0	66.67	100.0	68	0.12	25.17	-66.7	0.00	66.7
	Week 9	71	62.79	21.63	16.7	66.67	100.0	68	1.23	21.66	-50.0	0.00	66.7
	Week 10	73	62.21	20.70	16.7	66.67	100.0	69	0.36	23.11	-66.7	0.00	50.0
	Week 11	71	64.91	21.12	0.0	66.67	100.0	67	2.74	22.68	-50.0	0.00	50.0
	Week 12	69	61.47	23.70	0.0	66.67	100.0	66	-2.27	23.73	-50.0	0.00	66.7
	Week 14	68	60.05	23.46	0.0	66.67	100.0	64	-2.99	25.56	-66.7	0.00	66.7
	Week 17	68	64.22	21.55	0.0	66.67	100.0	63	0.53	21.42	-50.0	0.00	58.3
	Week 20	59	60.03	22.89	0.0	66.67	100.0	56	-4.61	23.35	-66.7	0.00	50.0
	Week 23	63	58.33	23.38	8.3	58.33	100.0	59	-4.94	26.54	-66.7	-8.33	50.0
	Week 26	59	57.77	23.51	0.0	58.33	100.0	57	-6.14	26.52	-83.3	0.00	50.0
	Week 29	56	60.27	20.60	0.0	66.67	100.0	54	-4.01	24.64	-83.3	0.00	50.0
	Week 32	52	60.42	23.15	16.7	66.67	100.0	49	-3.74	26.84	-66.7	0.00	50.0
	Week 35	43	59.69	22.27	0.0	58.33	100.0	40	-3.75	24.38	-66.7	0.00	50.0
	Week 38	49	57.14	22.24	0.0	58.33	100.0	47	-5.14	23.86	-50.0	-8.33	50.0
	Week 41	49	55.61	23.16	16.7	50.00	100.0	47	-4.79	25.58	-50.0	-8.33	50.0
	Week 44	44	59.85	20.75	16.7	58.33	100.0	41	-1.83	25.31	-50.0	0.00	50.0
	Week 47	37	59.01	23.02	16.7	50.00	100.0	35	-3.81	24.28	-50.0	-8.33	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	29	58.05	19.73	16.7	50.00	100.0	28	-2.68	23.58	-50.0	0.00	50.0
	Week 53	34	59.31	20.39	16.7	58.33	100.0	33	-5.30	21.83	-41.7	-8.33	50.0
	Week 56	31	62.37	21.82	16.7	66.67	100.0	30	0.56	22.52	-50.0	0.00	50.0
	Week 59	28	61.31	20.56	16.7	62.50	100.0	27	0.62	22.04	-33.3	0.00	50.0
	Week 62	28	61.31	22.48	16.7	66.67	100.0	27	-3.09	21.45	-58.3	-8.33	41.7
	Week 65	23	56.88	21.71	16.7	58.33	100.0	22	-4.17	23.25	-50.0	-4.17	41.7
	Week 68	22	53.41	20.03	16.7	50.00	91.7	22	-7.58	25.58	-50.0	-12.51	41.7
	Week 71	22	55.68	21.58	16.7	58.33	100.0	22	-4.17	23.81	-58.3	-8.34	41.7
	Week 74	22	59.09	19.23	25.0	66.67	100.0	22	-1.52	22.37	-41.7	0.00	41.7
	Week 77	18	54.17	22.00	16.7	50.00	100.0	17	-7.35	27.93	-50.0	-16.66	41.7
	Week 80	16	50.52	22.66	0.0	50.00	83.3	15	-11.11	21.97	-41.7	-8.33	41.7
	Week 83	16	46.87	19.21	8.3	50.00	83.3	15	-12.78	25.56	-58.3	-16.67	41.7
	Week 86	13	51.28	22.01	16.7	66.67	83.3	12	-10.42	28.23	-58.3	-12.50	41.7
	Week 89	12	49.31	21.46	16.7	50.00	83.3	12	-11.11	31.04	-58.3	-20.83	50.0
	Plat+Gem (N= 89)												
	BASELINE	75	57.22	25.01	0.0	58.33	100.0						
	Week 1	61	58.88	20.46	0.0	66.67	91.7	61	-2.19	17.14	-66.7	0.00	41.7
	Week 2	66	58.96	19.90	16.7	66.67	100.0	62	-0.67	17.87	-50.0	0.00	41.7
	Week 3	76	63.71	20.08	25.0	66.67	100.0	71	5.16	19.64	-25.0	0.00	83.3
	Week 4	73	60.84	20.63	0.0	66.67	100.0	68	1.84	18.82	-66.7	0.00	50.0
	Week 5	71	58.57	18.95	0.0	58.33	100.0	64	-1.17	20.35	-50.0	0.00	66.7
	Week 6	70	62.26	20.05	8.3	66.67	100.0	63	3.31	22.87	-50.0	0.00	83.3
	Week 7	72	60.76	20.29	0.0	66.67	100.0	65	0.26	21.75	-50.0	0.00	66.7
	Week 8	63	62.17	20.84	0.0	66.67	100.0	58	0.00	24.18	-75.0	0.00	50.0
	Week 9	68	62.25	18.80	16.7	66.67	100.0	62	0.81	23.46	-50.0	0.00	58.3
	Week 10	67	59.08	21.16	0.0	58.33	100.0	61	-0.82	25.90	-66.7	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	65	63.08	19.04	25.0	66.67	100.0	60	0.28	21.59	-50.0	0.00	50.0
	Week 12	63	63.49	20.38	0.0	66.67	100.0	58	2.73	22.91	-58.3	0.00	75.0
	Week 14	63	62.04	20.51	0.0	66.67	100.0	57	0.73	22.56	-50.0	0.00	50.0
	Week 17	60	62.64	22.73	16.7	66.67	100.0	55	1.21	21.18	-50.0	0.00	41.7
	Week 20	52	65.22	24.01	0.0	66.67	100.0	50	2.83	21.40	-58.3	0.00	41.7
	Week 23	44	66.10	23.94	0.0	66.67	100.0	42	2.58	22.58	-58.3	0.00	41.7
	Week 26	41	71.54	19.89	16.7	83.33	100.0	40	4.38	19.88	-50.0	0.00	50.0
	Week 29	37	64.41	24.43	16.7	66.67	100.0	36	-2.55	24.46	-83.3	0.00	33.3
	Week 32	33	72.98	21.75	16.7	83.33	100.0	32	6.25	21.17	-41.7	0.00	50.0
	Week 35	30	71.39	19.78	33.3	66.67	100.0	30	4.17	20.62	-41.7	0.00	50.0
	Week 38	32	72.92	19.74	33.3	83.33	100.0	31	7.53	23.31	-50.0	0.00	66.7
	Week 41	27	73.46	24.68	0.0	83.33	100.0	26	8.65	23.51	-50.0	12.50	66.7
	Week 44	27	74.38	19.60	33.3	83.33	100.0	26	6.73	22.49	-33.3	0.00	83.3
	Week 47	29	71.26	19.62	16.7	83.33	100.0	28	4.17	21.58	-33.3	0.00	66.7
	Week 50	23	72.83	22.78	33.3	83.33	100.0	22	7.96	22.19	-33.3	8.33	50.0
	Week 53	22	73.11	18.71	33.3	83.33	100.0	21	5.95	22.54	-33.3	0.00	50.0
	Week 56	18	68.98	27.68	0.0	83.33	100.0	17	-0.49	26.43	-66.7	0.00	33.3
	Week 59	17	80.39	14.71	50.0	83.33	100.0	16	14.58	23.27	-25.0	12.50	50.0
	Week 62	16	75.00	17.21	50.0	83.33	100.0	15	12.78	23.54	-33.3	8.33	66.7
	Week 65	15	75.56	16.80	50.0	83.33	100.0	14	9.53	27.51	-33.3	12.50	66.7
	Week 68	12	72.92	22.23	33.3	83.33	100.0	11	9.85	28.82	-33.3	8.33	66.7
	Week 71	13	62.18	30.74	0.0	66.67	100.0	12	0.00	35.18	-83.3	4.17	50.0
	Week 74	10	72.50	21.89	25.0	70.84	100.0	10	10.83	30.19	-33.3	12.50	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	EV+Pembro (N=198)												
	BASELINE	170	63.38	23.19	0.0	66.67	100.0						
	Week 1	157	61.47	22.79	0.0	66.67	100.0	152	-2.41	16.82	-66.7	0.00	33.3
	Week 2	167	60.33	21.86	0.0	66.67	100.0	155	-4.46	20.24	-66.7	0.00	50.0
	Week 3	161	58.13	22.26	0.0	58.33	100.0	147	-5.39	21.41	-66.7	0.00	41.7
	Week 4	158	63.55	22.25	0.0	66.67	100.0	145	-1.32	22.71	-66.7	0.00	66.7
	Week 5	154	65.26	21.76	0.0	66.67	100.0	140	0.77	21.71	-66.7	0.00	50.0
	Week 6	153	65.36	21.31	0.0	66.67	100.0	138	1.03	21.15	-50.0	0.00	66.7
	Week 7	159	64.88	22.68	0.0	66.67	100.0	142	0.41	21.91	-58.3	0.00	50.0
	Week 8	154	65.64	22.06	0.0	66.67	100.0	135	2.47	23.15	-66.7	0.00	66.7
	Week 9	162	63.17	21.84	16.7	66.67	100.0	146	-0.40	22.30	-75.0	0.00	66.7
	Week 10	159	65.30	21.21	16.7	66.67	100.0	144	1.50	22.77	-66.7	0.00	66.7
	Week 11	161	65.27	21.45	0.0	66.67	100.0	143	1.92	23.67	-66.7	0.00	66.7
	Week 12	154	64.88	23.38	0.0	66.67	100.0	140	1.13	25.27	-100.0	0.00	75.0
	Week 14	154	64.50	22.38	0.0	66.67	100.0	137	0.43	24.28	-66.7	0.00	83.3
	Week 17	145	66.26	20.91	0.0	66.67	100.0	130	2.44	22.70	-58.3	0.00	83.3
	Week 20	139	65.77	22.74	0.0	66.67	100.0	126	0.86	24.42	-66.7	0.00	66.7
	Week 23	133	63.91	23.38	8.3	66.67	100.0	122	-1.50	26.98	-66.7	0.00	66.7
	Week 26	129	64.99	22.13	0.0	66.67	100.0	118	0.49	24.44	-83.3	0.00	66.7
	Week 29	131	65.27	21.01	0.0	66.67	100.0	120	-1.39	23.00	-83.3	0.00	66.7
	Week 32	111	64.11	21.61	16.7	66.67	100.0	102	-0.57	22.38	-66.7	0.00	50.0
	Week 35	109	65.75	20.95	0.0	66.67	100.0	100	-0.17	22.32	-66.7	0.00	50.0
	Week 38	107	65.11	22.05	0.0	66.67	100.0	100	0.92	22.53	-50.0	0.00	75.0
	Week 41	103	63.27	22.18	16.7	66.67	100.0	94	-0.35	22.33	-58.3	0.00	58.3
	Week 44	88	65.72	21.01	16.7	66.67	100.0	81	0.00	22.20	-50.0	0.00	50.0
	Week 47	80	64.90	21.37	0.0	66.67	100.0	75	-2.00	25.37	-83.3	0.00	58.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	73	66.78	20.95	16.7	66.67	100.0	68	0.37	20.89	-50.0	0.00	50.0
	Week 53	64	68.10	20.66	16.7	66.67	100.0	59	-1.84	21.78	-66.7	0.00	50.0
	Week 56	66	67.17	21.63	0.0	66.67	100.0	61	0.68	24.12	-83.3	0.00	50.0
	Week 59	58	66.38	21.23	0.0	66.67	100.0	54	-0.93	24.10	-83.3	0.00	50.0
	Week 62	54	65.74	22.87	16.7	66.67	100.0	52	-3.53	23.36	-66.7	0.00	41.7
	Week 65	51	67.48	23.29	16.7	66.67	100.0	47	-1.77	22.85	-66.7	0.00	41.7
	Week 68	49	66.84	21.07	16.7	66.67	100.0	48	-4.17	20.84	-50.0	0.00	41.7
	Week 71	47	67.38	22.51	16.7	66.67	100.0	45	-4.07	22.73	-58.3	-8.33	41.7
	Week 74	42	70.24	19.23	25.0	66.67	100.0	41	-1.22	22.01	-41.7	0.00	41.7
	Week 77	38	66.89	22.47	25.0	66.67	100.0	36	-3.01	24.49	-50.0	0.00	41.7
	Week 80	35	66.19	22.95	0.0	66.67	100.0	32	-2.60	20.02	-41.7	0.00	41.7
	Week 83	32	66.67	23.67	8.3	66.67	100.0	30	-0.28	22.90	-58.3	0.00	41.7
	Week 86	30	69.17	21.68	16.7	66.67	100.0	27	-1.23	21.89	-58.3	0.00	41.7
	Week 89	28	65.48	21.24	16.7	66.67	100.0	26	-4.81	24.51	-58.3	-8.33	50.0
	Week 92	24	68.75	22.69	0.0	66.67	100.0	22	-2.27	19.45	-41.7	0.00	33.3
	Week 95	21	66.67	24.15	16.7	66.67	100.0	20	-2.92	20.10	-33.3	0.00	33.3
	Week 98	16	65.62	24.70	16.7	66.67	100.0	15	-2.22	21.70	-33.3	0.00	33.3
	Week 101	12	69.44	25.21	16.7	75.00	100.0	12	-9.72	21.27	-50.0	-8.33	33.3
	Week 104	10	70.00	25.52	33.3	79.17	100.0	10	-5.00	25.52	-50.0	0.00	33.3
	Plat+Gem (N=185)												
	BASELINE	146	59.82	25.94	0.0	66.67	100.0						
	Week 1	131	58.40	24.36	0.0	66.67	100.0	120	-2.64	17.11	-66.7	0.00	41.7
	Week 2	128	56.38	22.78	0.0	58.33	100.0	115	-3.70	20.54	-83.3	0.00	50.0
	Week 3	141	61.64	22.31	0.0	66.67	100.0	126	0.79	21.46	-41.7	0.00	83.3
	Week 4	139	59.77	20.53	8.3	66.67	100.0	119	-1.26	20.05	-66.7	0.00	66.7
	Week 5	143	58.16	20.38	8.3	66.67	100.0	120	-4.72	21.95	-58.3	-8.33	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 6	133	60.21	20.20	0.0	58.33	100.0	114	-0.95	24.16	-58.3	0.00	83.3
	Week 7	142	59.57	20.70	0.0	66.67	100.0	120	-2.99	22.32	-58.3	-8.33	66.7
	Week 8	125	59.47	21.41	0.0	66.67	100.0	109	-3.59	25.39	-75.0	0.00	50.0
	Week 9	135	59.81	20.10	0.0	66.67	100.0	115	-2.83	23.70	-50.0	0.00	58.3
	Week 10	131	57.32	20.98	0.0	58.33	100.0	111	-3.68	25.69	-66.7	0.00	50.0
	Week 11	128	60.29	19.94	0.0	58.33	100.0	109	-2.14	23.99	-58.3	0.00	75.0
	Week 12	124	60.89	19.10	16.7	66.67	100.0	108	-1.47	24.70	-66.7	0.00	75.0
	Week 14	121	58.33	20.41	16.7	58.33	100.0	101	-4.95	26.70	-58.3	0.00	50.0
	Week 17	121	59.64	20.10	16.7	58.33	100.0	101	-4.13	25.21	-58.3	-8.33	50.0
	Week 20	98	63.18	20.96	0.0	66.67	100.0	86	-0.29	26.55	-66.7	0.00	66.7
	Week 23	93	65.59	21.22	16.7	66.67	100.0	78	0.53	24.59	-58.3	0.00	41.7
	Week 26	86	66.96	20.63	0.0	66.67	100.0	75	0.67	21.61	-58.3	0.00	50.0
	Week 29	76	63.93	24.92	0.0	66.67	100.0	65	-3.08	27.27	-83.3	0.00	41.7
	Week 32	62	68.55	20.77	25.0	66.67	100.0	56	2.38	24.35	-50.0	0.00	58.3
	Week 35	58	66.38	20.77	0.0	66.67	100.0	52	0.16	24.23	-75.0	0.00	66.7
	Week 38	60	65.83	22.16	16.7	66.67	100.0	52	1.12	23.57	-58.3	0.00	66.7
	Week 41	52	63.94	23.09	0.0	66.67	100.0	44	-1.33	26.10	-58.3	-4.17	66.7
	Week 44	46	67.03	20.93	33.3	66.67	100.0	40	-0.83	22.86	-41.7	0.00	83.3
	Week 47	44	67.42	21.17	0.0	66.67	100.0	38	-3.29	24.85	-75.0	0.00	66.7
	Week 50	42	66.47	24.59	0.0	66.67	100.0	38	0.88	24.26	-75.0	0.00	50.0
	Week 53	38	70.39	17.51	33.3	66.67	100.0	34	-0.98	22.17	-58.3	0.00	50.0
	Week 56	32	64.84	24.84	0.0	70.84	100.0	28	-7.74	26.25	-66.7	-4.17	33.3
	Week 59	31	71.51	22.23	16.7	75.00	100.0	27	-0.62	29.68	-66.7	0.00	50.0
	Week 62	29	71.26	21.43	16.7	75.00	100.0	26	0.32	29.10	-66.7	0.00	66.7
	Week 65	25	67.00	24.35	0.0	66.67	100.0	21	-1.59	32.23	-83.3	0.00	66.7
	Week 68	20	63.33	26.41	0.0	66.67	100.0	16	-1.56	34.05	-83.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 71	17	62.25	30.21	0.0	66.67	100.0	14	0.60	28.77	-66.7	0.00	50.0
	Week 74	17	69.12	21.40	8.3	66.67	100.0	14	7.74	25.62	-33.3	4.17	66.7
	Week 77	16	67.19	25.54	0.0	75.00	100.0	13	10.26	27.88	-50.0	8.34	66.7
	Week 80	13	66.03	18.47	33.3	66.67	100.0	12	0.00	22.19	-50.0	8.33	25.0
	Week 83	11	68.18	18.94	33.3	66.67	100.0	10	5.00	29.45	-33.3	0.00	66.7
	Week 86	12	70.14	18.62	33.3	70.84	100.0	11	8.33	25.00	-25.0	0.00	66.7
	Week 89	11	70.46	17.23	50.0	66.67	100.0	10	9.17	27.34	-33.3	4.17	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	EV+Pembro (N= 42)												
	BASELINE	36	65.05	21.07	16.7	66.67	100.0						
	Week 1	33	61.36	25.07	0.0	66.67	100.0	32	-3.12	13.18	-33.3	0.00	16.7
	Week 2	36	58.80	23.14	16.7	50.00	100.0	34	-6.37	19.03	-58.3	0.00	33.3
	Week 3	37	52.48	26.99	0.0	50.00	100.0	35	-9.52	19.82	-50.0	-8.33	25.0
	Week 4	36	64.35	21.42	16.7	66.67	100.0	34	-0.74	18.28	-50.0	0.00	33.3
	Week 5	36	65.28	18.95	33.3	66.67	100.0	33	-0.25	20.68	-41.7	0.00	50.0
	Week 6	35	69.29	18.39	25.0	75.00	100.0	32	1.30	23.00	-41.7	0.00	50.0
	Week 7	36	68.52	20.03	33.3	75.00	100.0	34	3.92	24.81	-50.0	4.17	58.3
	Week 8	37	66.89	20.93	33.3	66.67	100.0	36	1.85	26.96	-33.3	0.00	66.7
	Week 9	35	68.33	21.18	25.0	75.00	100.0	34	3.19	22.57	-41.7	0.00	66.7
	Week 10	32	69.27	21.84	0.0	79.17	100.0	31	6.72	24.85	-33.3	0.00	66.7
	Week 11	33	70.45	22.06	0.0	75.00	100.0	32	7.29	24.29	-41.7	0.00	66.7
	Week 12	32	66.93	24.64	16.7	70.84	100.0	31	3.23	28.03	-41.7	0.00	66.7
	Week 14	31	62.37	24.52	0.0	66.67	100.0	30	-2.50	26.46	-66.7	0.00	66.7
	Week 17	33	67.17	19.87	16.7	66.67	100.0	32	1.56	22.44	-33.3	0.00	58.3
	Week 20	28	65.77	19.42	16.7	66.67	100.0	28	-1.19	22.65	-50.0	0.00	50.0
	Week 23	29	66.09	23.14	16.7	66.67	100.0	29	0.00	23.36	-41.7	0.00	50.0
	Week 26	27	67.90	24.21	8.3	66.67	100.0	26	4.17	22.51	-33.3	0.00	50.0
	Week 29	26	67.95	23.30	25.0	70.84	100.0	25	1.33	24.38	-50.0	0.00	58.3
	Week 32	24	65.28	22.61	25.0	66.67	100.0	23	-3.62	25.72	-58.3	0.00	50.0
	Week 35	23	65.58	21.37	25.0	66.67	100.0	22	-3.79	23.25	-50.0	-4.17	41.7
	Week 38	25	65.67	18.53	33.3	66.67	100.0	24	-3.47	20.69	-33.3	-8.33	33.3
	Week 41	26	61.22	20.13	33.3	62.50	100.0	25	-4.67	24.19	-50.0	-8.33	41.7
	Week 44	20	65.42	22.99	0.0	70.84	100.0	19	-4.82	28.37	-91.7	0.00	50.0
	Week 47	20	56.25	27.69	16.7	50.00	100.0	19	-9.21	27.06	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	16	61.46	18.22	16.7	66.67	83.3	16	-6.77	16.73	-33.3	-8.34	16.7
	Week 53	15	58.33	23.36	16.7	66.67	100.0	15	-3.33	22.45	-33.3	-8.33	33.3
	Week 56	15	63.33	21.55	16.7	66.67	100.0	15	-1.67	19.47	-33.3	-8.33	33.3
	Week 59	14	64.88	24.93	16.7	66.67	100.0	14	1.19	23.99	-41.7	0.00	33.3
	Week 62	11	73.49	18.56	41.7	66.67	100.0	11	5.30	17.98	-16.7	0.00	33.3
	Plat+Gem (N= 57)												
	BASELINE	42	59.92	23.01	0.0	62.50	100.0						
	Week 1	42	51.59	17.39	0.0	50.00	91.7	38	-8.55	15.68	-50.0	-8.33	16.7
	Week 2	43	51.16	22.17	16.7	50.00	100.0	36	-9.95	24.79	-66.7	-12.50	58.3
	Week 3	43	61.82	19.86	25.0	66.67	100.0	36	-0.23	20.17	-50.0	0.00	50.0
	Week 4	44	59.85	22.47	0.0	58.33	100.0	37	-3.60	20.65	-66.7	0.00	33.3
	Week 5	44	52.46	21.08	0.0	50.00	100.0	36	-9.95	19.80	-50.0	-8.33	41.7
	Week 6	41	54.68	21.89	0.0	58.33	100.0	35	-5.48	21.29	-58.3	0.00	41.7
	Week 7	44	54.55	21.30	0.0	50.00	100.0	37	-8.33	20.13	-58.3	-8.33	50.0
	Week 8	42	51.39	21.06	0.0	50.00	100.0	35	-11.43	24.68	-66.7	-8.34	41.7
	Week 9	42	54.36	20.76	8.3	50.00	100.0	35	-2.86	20.31	-50.0	0.00	33.3
	Week 10	35	54.29	18.23	25.0	50.00	100.0	28	-8.63	23.29	-41.7	-12.50	41.7
	Week 11	40	54.79	18.86	16.7	50.00	100.0	34	-8.09	22.89	-58.3	-8.33	33.3
	Week 12	35	57.86	20.00	0.0	66.67	100.0	30	-4.72	19.41	-33.3	-8.33	50.0
	Week 14	32	48.96	23.74	0.0	50.00	100.0	27	-13.27	20.71	-66.7	-16.66	25.0
	Week 17	34	54.90	24.46	0.0	58.33	100.0	29	-5.75	17.27	-50.0	0.00	25.0
	Week 20	28	63.10	23.18	0.0	66.67	100.0	24	1.39	15.86	-33.3	0.00	25.0
	Week 23	22	63.26	25.41	0.0	66.67	100.0	19	3.07	21.55	-33.3	0.00	33.3
	Week 26	22	64.77	23.42	8.3	66.67	100.0	20	0.00	22.78	-58.3	0.00	33.3
	Week 29	24	65.28	16.42	16.7	66.67	100.0	21	-0.79	25.13	-66.7	0.00	41.7
	Week 32	21	57.94	23.49	8.3	66.67	100.0	20	-6.25	23.55	-58.3	0.00	41.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 35	18	55.56	20.81	16.7	50.00	100.0	17	-9.31	26.82	-50.0	0.00	50.0
	Week 38	14	57.74	22.52	16.7	66.67	100.0	13	-3.84	26.05	-50.0	-8.33	41.7
	Week 41	13	64.74	21.56	33.3	66.67	100.0	12	4.17	21.17	-25.0	4.17	50.0
	Week 44	14	66.67	14.98	50.0	66.67	100.0	13	1.92	18.05	-33.3	0.00	33.3
	Week 47	12	56.94	11.70	50.0	50.00	83.3	11	-5.30	19.81	-33.3	0.00	25.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Visceral metastases	EV+Pembro (N=170)												
	BASELINE	146	60.33	23.10	0.0	66.67	100.0						
	Week 1	135	59.14	23.52	0.0	58.33	100.0	131	-0.89	15.92	-50.0	0.00	33.3
	Week 2	145	59.14	21.52	0.0	58.33	100.0	134	-2.86	18.51	-50.0	0.00	50.0
	Week 3	141	55.79	24.23	0.0	58.33	100.0	129	-4.13	21.83	-66.7	0.00	41.7
	Week 4	136	60.72	22.38	0.0	62.50	100.0	125	-1.07	23.40	-66.7	0.00	66.7
	Week 5	131	64.12	22.00	0.0	66.67	100.0	118	3.11	22.11	-66.7	0.00	50.0
	Week 6	127	65.35	21.22	16.7	66.67	100.0	113	3.61	22.76	-50.0	0.00	66.7
	Week 7	135	63.33	22.66	0.0	66.67	100.0	121	3.10	24.06	-58.3	0.00	58.3
	Week 8	131	65.08	23.34	0.0	66.67	100.0	118	4.94	25.67	-66.7	0.00	66.7
	Week 9	136	64.15	21.95	16.7	66.67	100.0	124	3.02	22.90	-75.0	0.00	66.7
	Week 10	135	65.43	21.42	16.7	66.67	100.0	124	4.70	25.02	-66.7	0.00	66.7
	Week 11	134	66.79	21.51	0.0	66.67	100.0	121	6.40	24.81	-66.7	0.00	66.7
	Week 12	131	66.35	23.26	0.0	66.67	100.0	120	5.14	24.85	-58.3	0.00	75.0
	Week 14	130	64.81	22.12	0.0	66.67	100.0	117	3.28	25.99	-66.7	0.00	83.3
	Week 17	124	66.73	20.92	8.3	66.67	100.0	111	6.38	24.26	-58.3	0.00	83.3
	Week 20	115	67.32	21.58	0.0	66.67	100.0	105	5.16	24.36	-50.0	0.00	66.7
	Week 23	111	65.54	22.57	8.3	66.67	100.0	103	4.45	25.88	-66.7	0.00	66.7
	Week 26	106	67.37	20.90	0.0	66.67	100.0	97	6.10	22.87	-83.3	0.00	66.7
	Week 29	106	66.12	21.89	0.0	66.67	100.0	98	2.64	24.22	-83.3	0.00	66.7
	Week 32	92	65.13	21.99	16.7	66.67	100.0	85	2.84	22.44	-66.7	0.00	50.0
	Week 35	86	68.12	20.70	16.7	66.67	100.0	79	4.11	21.51	-66.7	0.00	50.0
	Week 38	90	65.46	21.94	0.0	66.67	100.0	84	3.67	22.72	-50.0	0.00	75.0
	Week 41	87	64.46	20.47	16.7	66.67	100.0	81	3.09	22.22	-50.0	0.00	58.3
	Week 44	73	65.87	21.75	0.0	66.67	100.0	68	2.57	24.86	-91.7	0.00	50.0
	Week 47	68	63.24	22.59	0.0	66.67	100.0	63	-0.93	26.86	-83.3	0.00	58.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	61	65.30	21.20	16.7	66.67	100.0	57	1.02	21.13	-50.0	0.00	50.0
	Week 53	54	66.05	22.48	16.7	66.67	100.0	50	-1.17	23.02	-66.7	0.00	41.7
	Week 56	58	67.82	21.03	0.0	66.67	100.0	54	2.62	23.45	-83.3	0.00	50.0
	Week 59	50	66.17	23.05	0.0	66.67	100.0	47	0.36	26.97	-83.3	0.00	50.0
	Week 62	45	67.96	20.94	16.7	66.67	100.0	43	0.97	23.09	-66.7	0.00	41.7
	Week 65	37	69.59	22.50	16.7	75.00	100.0	34	1.47	23.52	-66.7	0.00	41.7
	Week 68	35	68.33	18.39	33.3	66.67	100.0	34	-0.74	19.93	-50.0	0.00	41.7
	Week 71	31	67.74	21.16	25.0	66.67	100.0	30	0.00	22.74	-50.0	0.00	41.7
	Week 74	29	71.55	19.35	33.3	66.67	100.0	28	2.68	21.28	-33.3	0.00	41.7
	Week 77	26	64.10	24.13	16.7	66.67	100.0	25	-2.33	25.52	-50.0	0.00	41.7
	Week 80	22	68.56	19.06	33.3	66.67	100.0	21	1.19	22.56	-41.7	0.00	41.7
	Week 83	23	69.20	21.39	33.3	66.67	100.0	22	1.14	23.47	-33.3	0.00	41.7
	Week 86	21	68.65	20.23	33.3	66.67	100.0	20	-0.83	21.61	-33.3	0.00	41.7
	Week 89	21	67.06	20.15	33.3	66.67	100.0	20	-0.83	22.11	-33.3	0.00	41.7
	Week 92	18	71.30	17.20	33.3	66.67	100.0	17	0.00	19.09	-33.3	0.00	33.3
	Week 95	13	75.00	17.01	50.0	75.00	100.0	12	1.39	18.40	-33.3	0.00	33.3
	Week 98	11	72.73	18.67	33.3	83.33	100.0	11	4.54	16.40	-16.7	0.00	33.3
	Week 101	11	68.18	22.61	16.7	75.00	100.0	11	-3.79	23.08	-50.0	0.00	33.3
	Plat+Gem (N=161)												
	BASELINE	129	57.75	24.92	0.0	58.33	100.0						
	Week 1	113	55.38	23.20	0.0	50.00	100.0	105	-2.86	15.28	-33.3	0.00	41.7
	Week 2	108	53.55	21.50	0.0	50.00	100.0	98	-4.59	20.17	-50.0	-8.33	50.0
	Week 3	121	60.95	21.06	0.0	66.67	100.0	109	1.22	22.70	-41.7	0.00	83.3
	Week 4	116	59.84	18.93	8.3	66.67	100.0	101	-0.16	18.93	-58.3	0.00	66.7
	Week 5	121	56.34	20.16	8.3	50.00	100.0	104	-4.65	22.00	-58.3	-8.33	66.7
	Week 6	118	59.60	19.63	0.0	58.33	100.0	102	-0.82	24.53	-58.3	0.00	83.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 7	121	58.06	19.89	0.0	58.33	100.0	104	-2.80	24.01	-58.3	-8.33	66.7
	Week 8	108	59.10	19.68	0.0	58.33	100.0	96	-2.86	25.27	-66.7	0.00	50.0
	Week 9	114	59.21	19.25	8.3	58.33	100.0	99	-0.84	22.32	-50.0	0.00	58.3
	Week 10	109	56.57	20.91	0.0	58.33	100.0	94	-1.95	25.38	-66.7	0.00	50.0
	Week 11	109	59.40	19.51	0.0	58.33	100.0	95	-1.84	24.50	-58.3	0.00	50.0
	Week 12	103	59.38	17.99	16.7	58.33	100.0	91	-1.56	25.94	-66.7	0.00	75.0
	Week 14	98	56.55	20.91	16.7	58.33	100.0	85	-5.20	27.03	-66.7	-8.33	50.0
	Week 17	103	58.17	21.07	16.7	58.33	100.0	89	-2.62	23.92	-58.3	0.00	50.0
	Week 20	82	62.09	20.38	0.0	66.67	100.0	75	1.78	25.68	-66.7	0.00	66.7
	Week 23	77	64.50	21.94	16.7	66.67	100.0	68	2.70	24.91	-58.3	8.33	41.7
	Week 26	71	66.90	19.77	8.3	66.67	100.0	65	2.56	21.90	-58.3	0.00	41.7
	Week 29	65	63.85	22.35	0.0	66.67	100.0	59	-1.55	28.26	-83.3	0.00	41.7
	Week 32	52	65.87	21.34	16.7	66.67	100.0	49	1.19	26.02	-50.0	0.00	58.3
	Week 35	47	62.77	20.62	0.0	66.67	100.0	44	-1.70	25.89	-75.0	0.00	66.7
	Week 38	42	63.49	22.08	25.0	66.67	100.0	39	0.21	24.22	-58.3	0.00	41.7
	Week 41	35	63.33	22.61	8.3	66.67	100.0	32	2.34	25.60	-58.3	0.00	50.0
	Week 44	36	63.19	18.30	33.3	66.67	100.0	33	-3.03	19.63	-33.3	0.00	41.7
	Week 47	32	64.58	21.17	0.0	66.67	100.0	30	-3.89	24.24	-75.0	0.00	41.7
	Week 50	30	63.89	23.50	0.0	66.67	100.0	29	-0.29	28.13	-75.0	0.00	50.0
	Week 53	25	67.33	17.66	33.3	66.67	100.0	24	-5.56	22.74	-58.3	-8.34	33.3
	Week 56	22	57.95	26.29	0.0	66.67	100.0	21	-12.70	28.58	-66.7	-16.66	33.3
	Week 59	22	70.46	20.04	16.7	66.67	100.0	21	-3.97	30.69	-66.7	0.00	50.0
	Week 62	19	69.30	20.98	16.7	66.67	100.0	18	-2.78	28.87	-66.7	0.00	33.3
	Week 65	19	67.54	23.39	0.0	66.67	100.0	18	-5.55	31.05	-83.3	-4.17	41.7
	Week 68	13	63.46	27.54	0.0	66.67	100.0	12	-6.94	33.11	-83.3	-4.17	50.0
	Week 71	13	53.85	30.73	0.0	50.00	100.0	12	-12.50	35.44	-83.3	-8.33	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 74	11	64.40	17.91	25.0	66.67	100.0	11	-1.51	22.61	-33.3	0.00	33.3
	Week 77	10	72.50	18.02	50.0	75.00	100.0	10	10.83	17.15	-8.3	8.33	41.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Lymph node only	EV+Pembro (N= 60)												
	BASELINE	53	72.80	19.82	0.0	75.00	100.0						
	Week 1	49	66.50	22.08	16.7	66.67	100.0	47	-7.62	16.56	-66.7	-8.33	33.3
	Week 2	50	61.83	23.93	16.7	66.67	100.0	48	-10.76	23.69	-66.7	-8.33	33.3
	Week 3	50	59.67	21.12	0.0	58.33	100.0	47	-11.35	19.38	-50.0	-8.34	33.3
	Week 4	50	70.00	20.96	16.7	70.84	100.0	47	-3.19	18.02	-50.0	0.00	33.3
	Week 5	53	67.29	20.14	25.0	66.67	100.0	49	-5.61	19.79	-50.0	0.00	33.3
	Week 6	53	67.77	20.67	0.0	66.67	100.0	50	-4.50	18.46	-41.7	-4.17	50.0
	Week 7	52	71.95	19.39	33.3	75.00	100.0	48	-2.78	18.46	-50.0	0.00	33.3
	Week 8	52	67.95	18.55	25.0	66.67	100.0	47	-3.19	18.92	-33.3	0.00	41.7
	Week 9	53	63.68	21.87	16.7	66.67	100.0	49	-6.46	21.06	-66.7	0.00	33.3
	Week 10	48	67.71	21.38	0.0	66.67	100.0	44	-3.22	17.72	-50.0	0.00	41.7
	Week 11	53	64.78	20.97	0.0	66.67	100.0	48	-5.38	19.79	-58.3	0.00	41.7
	Week 12	48	61.63	25.48	0.0	66.67	100.0	45	-8.33	26.89	-100.0	0.00	50.0
	Week 14	48	62.33	23.63	0.0	66.67	100.0	44	-8.71	19.60	-66.7	-8.34	41.7
	Week 17	46	65.76	20.95	0.0	66.67	100.0	44	-7.58	15.02	-50.0	-8.33	16.7
	Week 20	44	62.88	22.77	0.0	66.67	100.0	42	-9.72	20.57	-66.7	-8.34	25.0
	Week 23	43	63.76	23.35	16.7	66.67	100.0	41	-12.40	22.76	-66.7	-16.66	33.3
	Week 26	42	63.69	24.89	0.0	66.67	100.0	40	-7.71	22.68	-66.7	-4.17	41.7
	Week 29	45	65.00	20.69	16.7	66.67	100.0	42	-8.33	19.13	-50.0	-8.34	33.3
	Week 32	38	62.50	21.81	16.7	66.67	100.0	36	-9.95	21.99	-58.3	-8.33	33.3
	Week 35	42	60.91	21.66	0.0	66.67	100.0	40	-10.21	21.47	-66.7	-8.34	33.3
	Week 38	38	65.57	20.52	16.7	66.67	100.0	36	-6.94	18.20	-50.0	-8.33	33.3
	Week 41	37	57.66	24.48	16.7	66.67	100.0	34	-11.52	21.52	-58.3	-8.33	33.3
	Week 44	31	64.52	21.30	16.7	66.67	100.0	29	-9.20	18.41	-50.0	-8.34	33.3
	Week 47	28	65.48	23.10	16.7	66.67	100.0	27	-6.48	19.93	-50.0	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	25	69.00	18.71	33.3	66.67	100.0	24	-3.47	15.72	-41.7	0.00	33.3
	Week 53	23	68.84	18.33	33.3	66.67	100.0	22	-2.65	18.26	-50.0	0.00	50.0
	Week 56	21	64.68	22.35	25.0	66.67	100.0	20	-4.58	19.95	-50.0	0.00	33.3
	Week 59	20	67.08	19.40	33.3	66.67	100.0	19	-1.76	13.77	-33.3	0.00	33.3
	Week 62	19	67.54	23.39	25.0	66.67	100.0	19	-5.70	17.58	-41.7	-8.33	33.3
	Week 65	20	63.33	22.36	16.7	62.50	100.0	19	-2.63	18.01	-41.7	0.00	33.3
	Week 68	17	62.74	25.36	16.7	66.67	100.0	17	-8.33	19.09	-50.0	-8.33	33.3
	Week 71	19	66.67	22.22	16.7	66.67	100.0	18	-6.95	16.48	-33.3	-8.34	33.3
	Week 74	17	64.22	19.93	25.0	66.67	100.0	17	-7.35	19.52	-41.7	0.00	33.3
	Week 77	17	66.18	21.75	33.3	66.67	100.0	16	-3.13	19.69	-33.3	0.00	33.3
	Week 80	17	60.29	26.76	0.0	66.67	100.0	15	-5.00	12.12	-25.0	0.00	16.7
	Week 83	13	58.97	26.01	8.3	58.33	100.0	12	-2.09	16.72	-33.3	0.00	33.3
	Week 86	12	67.36	25.24	16.7	66.67	100.0	10	0.83	16.87	-25.0	0.00	33.3
	Week 89	11	58.33	21.73	16.7	58.33	100.0	10	-7.50	22.72	-25.0	-8.34	50.0
	Plat+Gem (N= 67)												
	BASELINE	49	66.50	24.03	0.0	66.67	100.0						
	Week 1	51	60.95	22.51	0.0	66.67	100.0	45	-5.37	18.48	-50.0	0.00	41.7
	Week 2	53	57.08	25.65	8.3	58.33	100.0	44	-7.58	25.72	-83.3	0.00	58.3
	Week 3	53	62.42	23.72	0.0	66.67	100.0	44	-2.27	17.64	-50.0	0.00	50.0
	Week 4	58	61.06	23.28	0.0	62.50	100.0	47	-4.26	21.27	-66.7	0.00	33.3
	Week 5	56	57.74	22.69	0.0	62.50	100.0	44	-8.90	20.91	-50.0	-8.33	41.7
	Week 6	48	57.99	23.51	0.0	58.33	100.0	40	-4.79	21.92	-58.3	-8.33	41.7
	Week 7	56	58.93	23.29	0.0	62.50	100.0	46	-6.52	17.03	-33.3	-8.34	41.7
	Week 8	52	54.17	25.43	0.0	50.00	100.0	42	-11.90	26.10	-75.0	-4.17	41.7
	Week 9	53	57.70	22.87	0.0	58.33	100.0	42	-7.74	23.53	-50.0	0.00	33.3
	Week 10	47	57.98	19.81	16.7	50.00	100.0	36	-11.34	22.99	-50.0	-16.66	41.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	51	57.84	21.17	16.7	50.00	100.0	41	-7.93	23.57	-58.3	-8.33	75.0
	Week 12	47	61.70	22.96	0.0	66.67	100.0	39	-5.34	17.78	-41.7	0.00	41.7
	Week 14	47	56.20	23.54	0.0	50.00	100.0	36	-12.50	21.96	-58.3	-4.17	41.7
	Week 17	45	59.44	22.30	0.0	66.67	100.0	35	-8.81	23.74	-50.0	-8.33	50.0
	Week 20	38	66.89	22.22	0.0	66.67	100.0	30	-2.50	22.44	-50.0	0.00	50.0
	Week 23	32	66.41	23.99	0.0	66.67	100.0	25	-4.33	21.80	-50.0	0.00	33.3
	Week 26	30	67.50	23.81	0.0	66.67	100.0	24	-5.56	18.00	-58.3	0.00	16.7
	Week 29	28	67.26	24.63	0.0	70.84	100.0	21	-5.16	24.22	-83.3	0.00	33.3
	Week 32	26	66.67	24.27	8.3	66.67	100.0	22	-3.79	21.48	-58.3	0.00	33.3
	Week 35	23	65.94	24.35	16.7	58.33	100.0	19	-6.14	23.71	-50.0	0.00	50.0
	Week 38	26	64.74	24.53	16.7	66.67	100.0	20	-3.33	22.03	-50.0	0.00	33.3
	Week 41	24	63.89	23.53	0.0	66.67	100.0	18	-8.80	20.31	-50.0	-12.50	25.0
	Week 44	18	70.83	20.86	33.3	70.84	100.0	14	-2.38	17.73	-41.7	0.00	25.0
	Week 47	18	64.81	19.50	33.3	66.67	100.0	13	-10.90	16.80	-50.0	0.00	8.3
	Week 50	16	66.67	25.82	25.0	62.50	100.0	13	-5.13	17.85	-33.3	0.00	25.0
	Week 53	15	68.89	16.51	50.0	66.67	100.0	12	-4.17	16.86	-33.3	0.00	25.0
	Week 56	15	69.44	23.92	8.3	83.33	100.0	11	-0.76	19.88	-41.7	0.00	25.0
	Week 59	12	72.92	23.06	16.7	75.00	100.0	9	0.00	20.83	-33.3	0.00	25.0
	Week 62	10	71.67	21.23	33.3	79.17	100.0	8	-5.21	22.68	-41.7	0.00	25.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
EV+Pembro (N=202)												
BASELINE	160	60.73	21.99	0.0	66.67	100.0						
Week 1	141	59.40	21.24	0.0	58.33	100.0	129	-3.36	18.71	-75.0	0.00	41.7
Week 2	150	55.50	22.43	0.0	50.00	100.0	133	-5.14	18.68	-58.3	-8.33	50.0
Week 3	139	55.70	23.01	0.0	50.00	100.0	122	-4.78	21.02	-83.3	0.00	41.7
Week 4	145	59.66	22.90	0.0	58.33	100.0	129	-0.45	19.16	-66.7	0.00	41.7
Week 5	137	61.25	20.90	0.0	58.33	100.0	121	0.76	19.60	-66.7	0.00	50.0
Week 6	146	59.76	22.83	0.0	58.33	100.0	124	-1.88	24.11	-75.0	0.00	50.0
Week 7	147	62.07	22.42	0.0	66.67	100.0	124	-0.13	24.94	-91.7	0.00	58.3
Week 8	147	60.37	22.34	0.0	66.67	100.0	124	-1.55	24.59	-75.0	0.00	50.0
Week 9	142	61.27	22.98	0.0	66.67	100.0	121	-0.96	25.80	-100.0	0.00	66.7
Week 10	139	60.85	23.39	0.0	66.67	100.0	118	-1.55	26.15	-100.0	0.00	50.0
Week 11	137	64.11	21.64	0.0	66.67	100.0	115	1.23	24.31	-75.0	0.00	58.3
Week 12	142	62.56	23.06	0.0	66.67	100.0	119	0.98	24.24	-83.3	0.00	58.3
Week 14	139	63.73	21.09	0.0	66.67	100.0	116	0.86	23.53	-66.7	0.00	58.3
Week 17	132	65.21	18.63	16.7	66.67	100.0	111	2.25	21.38	-58.3	0.00	66.7
Week 20	120	64.79	20.40	8.3	66.67	100.0	103	1.70	22.09	-75.0	0.00	58.3
Week 23	117	64.46	21.70	16.7	66.67	100.0	97	-0.34	25.29	-83.3	0.00	58.3
Week 26	112	64.51	20.47	0.0	66.67	100.0	94	1.15	23.27	-66.7	0.00	66.7
Week 29	107	63.01	19.60	0.0	66.67	100.0	93	-1.34	24.89	-66.7	0.00	58.3
Week 32	102	63.89	20.02	0.0	66.67	100.0	88	0.28	24.51	-83.3	0.00	50.0
Week 35	98	61.90	21.47	0.0	66.67	100.0	86	-3.59	24.64	-83.3	0.00	58.3
Week 38	97	63.14	17.79	25.0	66.67	100.0	86	-0.97	20.02	-41.7	0.00	50.0
Week 41	95	65.00	19.77	8.3	66.67	100.0	84	0.79	21.82	-66.7	0.00	50.0
Week 44	86	61.63	19.86	0.0	66.67	100.0	74	-2.48	21.09	-66.7	0.00	50.0
Week 47	79	65.51	18.91	16.7	66.67	100.0	70	2.14	21.08	-41.7	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	74	61.26	20.43	0.0	66.67	100.0	64	-2.87	22.77	-66.7	0.00	50.0
Week 53	74	59.46	22.68	0.0	66.67	100.0	63	-2.78	22.99	-66.7	0.00	66.7
Week 56	72	61.92	20.45	0.0	66.67	100.0	61	2.05	20.95	-58.3	0.00	58.3
Week 59	69	61.84	19.67	16.7	66.67	100.0	57	0.58	22.65	-58.3	0.00	66.7
Week 62	62	59.95	18.22	16.7	58.33	100.0	52	-2.24	21.71	-66.7	0.00	50.0
Week 65	43	61.24	18.53	33.3	58.33	100.0	40	0.21	20.19	-58.3	0.00	50.0
Week 68	46	61.96	19.69	25.0	66.67	100.0	42	-0.60	24.51	-58.3	0.00	50.0
Week 71	42	61.51	17.74	33.3	62.50	91.7	38	0.44	20.68	-50.0	0.00	50.0
Week 74	38	61.62	20.18	0.0	66.67	100.0	35	-1.43	24.13	-58.3	0.00	50.0
Week 77	37	63.96	18.11	16.7	66.67	91.7	33	2.27	21.58	-50.0	0.00	50.0
Week 80	36	61.11	19.31	25.0	58.33	100.0	34	-1.96	22.76	-50.0	0.00	50.0
Week 83	30	61.39	21.61	16.7	66.67	100.0	29	-0.57	21.70	-33.3	0.00	66.7
Week 86	26	58.33	22.24	25.0	50.00	100.0	25	-6.00	27.90	-75.0	0.00	50.0
Week 89	20	63.75	19.73	25.0	66.67	100.0	19	-2.19	20.38	-33.3	0.00	33.3
Week 92	19	63.16	21.03	8.3	66.67	83.3	18	-2.32	24.89	-58.3	0.00	33.3
Week 95	14	67.86	18.16	33.3	66.67	100.0	13	2.56	15.73	-33.3	0.00	25.0
Week 98	10	75.00	12.42	58.3	70.84	100.0	9	6.48	10.01	-8.3	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Plat+Gem (N=202)												
BASELINE	165	60.56	25.62	0.0	66.67	100.0						
Week 1	144	60.71	23.40	0.0	66.67	100.0	139	-0.96	21.52	-83.3	0.00	66.7
Week 2	147	56.86	23.50	0.0	66.67	100.0	135	-5.25	22.07	-50.0	0.00	66.7
Week 3	149	59.62	23.72	0.0	66.67	100.0	136	-3.74	24.11	-100.0	0.00	66.7
Week 4	150	60.50	24.01	0.0	66.67	100.0	135	-2.78	26.23	-66.7	0.00	83.3
Week 5	153	58.44	23.08	0.0	66.67	100.0	138	-4.05	24.75	-75.0	0.00	66.7
Week 6	145	59.60	24.99	0.0	66.67	100.0	131	-3.31	28.43	-83.3	0.00	66.7
Week 7	148	60.30	20.76	0.0	58.33	100.0	134	-3.36	27.56	-66.7	0.00	66.7
Week 8	145	58.39	22.75	0.0	58.33	100.0	132	-4.23	28.58	-75.0	0.00	66.7
Week 9	141	59.46	22.43	0.0	58.33	100.0	125	-2.60	27.12	-75.0	0.00	66.7
Week 10	142	60.27	23.01	0.0	66.67	100.0	130	-2.82	27.44	-66.7	0.00	66.7
Week 11	126	59.13	22.59	0.0	66.67	100.0	114	-4.75	26.68	-100.0	-8.33	66.7
Week 12	130	58.53	22.91	0.0	58.33	100.0	115	-3.84	27.51	-83.3	0.00	66.7
Week 14	125	56.33	23.75	0.0	58.33	100.0	109	-7.57	29.63	-100.0	-8.33	66.7
Week 17	120	59.58	22.31	8.3	66.67	100.0	106	-5.27	26.26	-75.0	0.00	66.7
Week 20	104	64.02	22.67	0.0	66.67	100.0	91	-1.19	24.83	-66.7	0.00	66.7
Week 23	88	67.80	21.56	25.0	66.67	100.0	80	2.40	23.84	-58.3	0.00	66.7
Week 26	81	66.36	22.26	8.3	66.67	100.0	75	0.56	27.51	-66.7	0.00	66.7
Week 29	77	65.15	25.10	0.0	66.67	100.0	71	-2.23	30.08	-66.7	0.00	83.3
Week 32	63	64.68	22.78	0.0	66.67	100.0	58	-4.02	26.78	-91.7	0.00	50.0
Week 35	62	65.05	21.70	16.7	66.67	100.0	56	-3.87	27.52	-66.7	0.00	66.7
Week 38	56	61.16	25.64	0.0	66.67	100.0	50	-11.67	29.88	-83.3	-4.17	66.7
Week 41	52	62.50	24.61	0.0	66.67	100.0	47	-6.92	28.14	-100.0	0.00	50.0
Week 44	49	56.63	24.88	0.0	58.33	100.0	44	-11.17	32.35	-83.3	0.00	50.0
Week 47	43	61.43	25.52	16.7	66.67	100.0	39	-5.98	28.22	-66.7	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	36	62.50	26.54	0.0	66.67	100.0	31	-3.76	30.57	-75.0	0.00	50.0
Week 53	31	60.48	26.52	0.0	58.33	100.0	28	-3.87	32.98	-75.0	0.00	50.0
Week 56	30	57.22	22.61	0.0	62.50	91.7	29	-7.47	26.29	-58.3	0.00	50.0
Week 59	23	59.78	24.44	16.7	58.33	100.0	21	0.79	33.11	-58.3	0.00	58.3
Week 62	20	58.33	19.12	16.7	58.33	83.3	20	-2.92	28.90	-50.0	-4.17	50.0
Week 65	17	58.33	21.65	16.7	66.67	91.7	16	-1.04	28.36	-50.0	-8.33	50.0
Week 68	13	61.54	20.84	16.7	66.67	91.7	13	-2.56	23.42	-41.7	0.00	50.0
Week 71	13	62.18	19.13	33.3	66.67	83.3	13	-3.20	26.03	-50.0	0.00	50.0
Week 74	11	62.12	13.62	33.3	66.67	83.3	11	-4.54	25.92	-41.7	-8.33	50.0
Week 77	11	67.42	16.44	33.3	66.67	83.3	11	-1.52	25.23	-33.3	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Present	EV+Pembro (N= 50)												
	BASELINE	40	59.58	20.72	16.7	62.50	100.0						
	Week 1	38	53.95	18.46	16.7	50.00	100.0	34	-7.11	20.53	-50.0	-16.66	41.7
	Week 2	35	52.62	20.79	0.0	50.00	83.3	32	-7.03	18.10	-50.0	-8.33	25.0
	Week 3	32	55.47	22.26	8.3	50.00	100.0	30	-6.39	22.92	-66.7	0.00	33.3
	Week 4	35	58.33	21.95	16.7	58.33	100.0	31	-2.15	21.19	-66.7	0.00	33.3
	Week 5	32	61.46	20.05	0.0	58.33	100.0	28	0.30	17.34	-50.0	0.00	41.7
	Week 6	35	60.00	20.39	25.0	58.33	100.0	30	0.00	23.77	-41.7	0.00	50.0
	Week 7	35	63.57	19.91	16.7	66.67	91.7	29	0.29	18.96	-50.0	0.00	50.0
	Week 8	38	58.55	21.79	16.7	58.33	100.0	31	-5.11	23.73	-50.0	0.00	50.0
	Week 9	33	60.86	19.60	16.7	66.67	100.0	29	-1.44	21.72	-41.7	0.00	50.0
	Week 10	30	63.06	19.78	33.3	66.67	100.0	25	2.67	21.34	-33.3	0.00	50.0
	Week 11	31	65.32	23.28	0.0	66.67	100.0	27	1.54	24.02	-50.0	0.00	50.0
	Week 12	32	62.24	22.99	0.0	66.67	91.7	28	-1.19	21.96	-50.0	0.00	41.7
	Week 14	36	64.82	21.37	0.0	66.67	100.0	31	2.42	22.38	-50.0	8.33	50.0
	Week 17	33	66.67	19.65	33.3	66.67	100.0	27	4.63	21.85	-33.3	0.00	66.7
	Week 20	28	61.01	22.11	16.7	66.67	100.0	25	-2.33	26.85	-66.7	0.00	50.0
	Week 23	28	60.12	20.71	16.7	66.67	91.7	24	-5.21	27.23	-66.7	0.00	50.0
	Week 26	28	57.74	23.56	0.0	66.67	83.3	24	-5.90	25.24	-66.7	-8.33	50.0
	Week 29	27	65.12	16.35	33.3	66.67	91.7	25	2.33	21.98	-50.0	8.33	50.0
	Week 32	25	64.00	21.61	0.0	66.67	83.3	23	-1.45	27.94	-83.3	8.33	50.0
	Week 35	26	58.01	20.61	0.0	58.33	83.3	24	-5.90	26.29	-83.3	0.00	41.7
	Week 38	26	59.30	16.04	33.3	62.50	83.3	24	-4.86	21.83	-41.7	0.00	50.0
	Week 41	25	63.33	20.13	33.3	66.67	100.0	23	-2.54	21.68	-33.3	0.00	50.0
	Week 44	22	62.88	14.71	25.0	66.67	83.3	20	-0.42	17.20	-33.3	0.00	33.3
	Week 47	14	61.31	23.25	16.7	70.84	83.3	13	0.00	22.57	-33.3	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	57.08	24.07	0.0	66.67	83.3	17	-6.86	23.80	-50.0	-8.33	33.3
	Week 53	21	57.54	25.13	0.0	66.67	83.3	18	-4.63	25.60	-66.7	0.00	33.3
	Week 56	18	59.72	18.80	16.7	62.50	83.3	15	1.11	14.04	-25.0	0.00	16.7
	Week 59	18	59.26	18.28	16.7	66.67	83.3	15	-1.67	21.18	-33.3	0.00	33.3
	Week 62	13	62.82	21.41	16.7	66.67	83.3	11	3.03	21.50	-50.0	8.33	33.3
	Week 68	12	63.89	20.20	25.0	66.67	83.3	11	0.00	26.87	-58.3	0.00	33.3
	Plat+Gem (N= 50)												
	BASELINE	40	51.04	28.44	0.0	50.00	100.0						
	Week 1	35	53.57	24.69	8.3	50.00	83.3	33	-1.01	16.24	-25.0	0.00	33.3
	Week 2	33	51.51	25.89	0.0	50.00	91.7	30	-5.56	20.10	-41.7	0.00	50.0
	Week 3	33	55.81	26.64	0.0	66.67	91.7	29	-1.72	19.59	-41.7	0.00	33.3
	Week 4	36	57.41	24.13	16.7	50.00	100.0	32	1.82	22.17	-58.3	0.00	41.7
	Week 5	36	53.93	26.01	0.0	54.17	100.0	32	-1.30	28.41	-75.0	0.00	66.7
	Week 6	32	58.33	25.49	0.0	58.33	100.0	29	0.57	26.72	-58.3	0.00	58.3
	Week 7	35	55.71	24.07	0.0	58.33	100.0	31	2.15	25.64	-41.7	0.00	66.7
	Week 8	35	55.00	23.59	16.7	50.00	100.0	31	0.81	28.82	-75.0	0.00	50.0
	Week 9	34	52.94	22.46	0.0	54.17	100.0	30	1.39	30.49	-75.0	0.00	58.3
	Week 10	33	55.55	25.74	8.3	58.33	100.0	30	0.83	24.31	-58.3	0.00	50.0
	Week 11	30	56.67	24.21	8.3	58.33	100.0	26	3.20	25.72	-58.3	0.00	50.0
	Week 12	32	53.39	25.56	0.0	50.00	100.0	27	1.23	27.22	-58.3	0.00	50.0
	Week 14	27	49.69	25.47	8.3	50.00	100.0	22	-6.44	27.21	-58.3	-8.33	33.3
	Week 17	28	56.55	22.72	16.7	50.00	100.0	23	-5.07	26.56	-75.0	0.00	33.3
	Week 20	20	61.25	27.34	0.0	66.67	100.0	16	5.21	18.97	-25.0	0.00	50.0
	Week 23	15	65.56	24.37	25.0	66.67	100.0	14	2.98	20.83	-41.7	8.34	33.3
	Week 26	15	63.89	25.91	8.3	66.67	100.0	14	0.00	19.61	-25.0	-4.17	33.3
	Week 29	13	64.74	29.30	0.0	66.67	100.0	12	-6.94	27.49	-50.0	-8.33	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Absent	EV+Pembro (N=152)												
	BASELINE	120	61.11	22.46	0.0	66.67	100.0						
	Week 1	103	61.41	21.92	0.0	66.67	100.0	95	-2.02	17.94	-75.0	0.00	41.7
	Week 2	115	56.38	22.92	0.0	50.00	100.0	101	-4.54	18.91	-58.3	0.00	50.0
	Week 3	107	55.76	23.33	0.0	50.00	100.0	92	-4.26	20.47	-83.3	0.00	41.7
	Week 4	110	60.08	23.27	0.0	58.33	100.0	98	0.08	18.56	-50.0	0.00	41.7
	Week 5	105	61.19	21.24	0.0	58.33	100.0	93	0.90	20.32	-66.7	0.00	50.0
	Week 6	111	59.68	23.64	0.0	58.33	100.0	94	-2.48	24.31	-75.0	0.00	41.7
	Week 7	112	61.61	23.21	0.0	66.67	100.0	95	-0.26	26.59	-91.7	0.00	58.3
	Week 8	109	61.01	22.59	0.0	66.67	100.0	93	-0.36	24.88	-75.0	0.00	50.0
	Week 9	109	61.39	23.99	0.0	66.67	100.0	92	-0.82	27.07	-100.0	0.00	66.7
	Week 10	109	60.24	24.34	0.0	66.67	100.0	93	-2.69	27.29	-100.0	0.00	50.0
	Week 11	106	63.76	21.24	0.0	66.67	100.0	88	1.14	24.54	-75.0	0.00	58.3
	Week 12	110	62.65	23.18	0.0	66.67	100.0	91	1.65	24.98	-83.3	0.00	58.3
	Week 14	103	63.35	21.08	0.0	66.67	100.0	85	0.29	24.04	-66.7	0.00	58.3
	Week 17	99	64.73	18.36	16.7	66.67	100.0	84	1.49	21.30	-58.3	0.00	58.3
	Week 20	92	65.94	19.83	8.3	66.67	100.0	78	2.99	20.37	-75.0	0.00	58.3
	Week 23	89	65.82	21.94	16.7	66.67	100.0	73	1.26	24.60	-83.3	0.00	58.3
	Week 26	84	66.77	18.94	16.7	66.67	100.0	70	3.57	22.23	-33.3	0.00	66.7
	Week 29	80	62.29	20.63	0.0	66.67	100.0	68	-2.70	25.89	-66.7	0.00	58.3
	Week 32	77	63.85	19.62	0.0	66.67	100.0	65	0.90	23.39	-75.0	0.00	50.0
	Week 35	72	63.31	21.74	0.0	66.67	100.0	62	-2.69	24.13	-75.0	0.00	58.3
	Week 38	71	64.55	18.30	25.0	66.67	100.0	62	0.54	19.26	-41.7	0.00	50.0
	Week 41	70	65.59	19.76	8.3	66.67	100.0	61	2.05	21.92	-66.7	0.00	50.0
	Week 44	64	61.20	21.43	0.0	66.67	100.0	54	-3.24	22.46	-66.7	0.00	50.0
	Week 47	65	66.41	17.92	16.7	66.67	100.0	57	2.63	20.90	-41.7	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	54	62.81	18.93	33.3	66.67	100.0	47	-1.42	22.48	-66.7	0.00	50.0
	Week 53	53	60.22	21.84	16.7	58.33	100.0	45	-2.04	22.13	-50.0	0.00	66.7
	Week 56	54	62.65	21.09	0.0	66.67	100.0	46	2.35	22.88	-58.3	0.00	58.3
	Week 59	51	62.74	20.23	16.7	66.67	100.0	42	1.39	23.35	-58.3	0.00	66.7
	Week 62	49	59.18	17.45	33.3	58.33	100.0	41	-3.66	21.81	-66.7	0.00	50.0
	Week 65	36	60.65	19.68	33.3	58.33	100.0	33	-0.25	20.88	-58.3	0.00	50.0
	Week 68	34	61.27	19.77	25.0	66.67	100.0	31	-0.81	24.09	-58.3	0.00	50.0
	Week 71	33	60.35	18.28	33.3	50.00	91.7	30	-0.28	19.76	-41.7	0.00	50.0
	Week 74	33	60.10	21.12	0.0	66.67	100.0	30	-3.06	25.00	-58.3	0.00	50.0
	Week 77	31	63.44	19.21	16.7	66.67	91.7	27	0.93	22.57	-50.0	0.00	50.0
	Week 80	31	60.75	19.63	25.0	58.33	100.0	29	-3.45	23.62	-50.0	0.00	50.0
	Week 83	25	62.67	20.99	16.7	66.67	100.0	24	0.35	22.85	-33.3	0.00	66.7
	Week 86	23	58.33	22.75	25.0	50.00	100.0	22	-4.92	29.17	-75.0	0.00	50.0
	Week 89	18	62.96	20.66	25.0	66.67	100.0	17	-1.96	21.56	-33.3	0.00	33.3
	Week 92	16	65.62	17.71	33.3	70.84	83.3	15	-0.56	26.63	-58.3	0.00	33.3
	Week 95	12	67.36	19.61	33.3	66.67	100.0	11	3.79	16.82	-33.3	0.00	25.0
	Plat+Gem (N=152)												
	BASELINE	125	63.60	23.98	0.0	66.67	100.0						
	Week 1	109	63.00	22.61	0.0	66.67	100.0	106	-0.94	22.98	-83.3	0.00	66.7
	Week 2	114	58.41	22.65	0.0	66.67	100.0	105	-5.16	22.69	-50.0	0.00	66.7
	Week 3	116	60.70	22.84	0.0	66.67	100.0	107	-4.28	25.24	-100.0	0.00	66.7
	Week 4	114	61.48	23.99	0.0	66.67	100.0	103	-4.21	27.31	-66.7	-8.33	83.3
	Week 5	117	59.83	22.04	0.0	66.67	100.0	106	-4.87	23.62	-66.7	-8.33	66.7
	Week 6	113	59.96	24.95	0.0	66.67	100.0	102	-4.41	28.93	-83.3	0.00	66.7
	Week 7	113	61.73	19.53	16.7	66.67	100.0	103	-5.02	28.01	-66.7	-8.33	66.7
	Week 8	110	59.47	22.48	0.0	66.67	100.0	101	-5.77	28.47	-75.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	107	61.53	22.13	0.0	66.67	100.0	95	-3.86	26.01	-66.7	0.00	66.7
	Week 10	109	61.70	22.05	0.0	66.67	100.0	100	-3.92	28.34	-66.7	-8.33	66.7
	Week 11	96	59.90	22.14	0.0	66.67	100.0	88	-7.10	26.64	-100.0	-8.34	66.7
	Week 12	98	60.20	21.85	0.0	66.67	100.0	88	-5.40	27.57	-83.3	0.00	66.7
	Week 14	98	58.16	23.05	0.0	62.50	100.0	87	-7.85	30.35	-100.0	-8.33	66.7
	Week 17	92	60.51	22.23	8.3	66.67	100.0	83	-5.32	26.34	-66.7	0.00	66.7
	Week 20	84	64.68	21.55	16.7	66.67	100.0	75	-2.56	25.81	-66.7	0.00	66.7
	Week 23	73	68.26	21.09	25.0	66.67	100.0	66	2.27	24.57	-58.3	0.00	66.7
	Week 26	66	66.92	21.53	16.7	66.67	100.0	61	0.68	29.16	-66.7	0.00	66.7
	Week 29	64	65.23	24.42	0.0	66.67	100.0	59	-1.27	30.71	-66.7	0.00	83.3
	Week 32	54	65.12	21.42	0.0	66.67	100.0	49	-2.55	24.43	-58.3	0.00	50.0
	Week 35	54	64.66	21.77	16.7	66.67	100.0	48	-3.82	28.66	-66.7	0.00	66.7
	Week 38	47	60.82	24.07	16.7	66.67	100.0	42	-9.52	29.94	-83.3	0.00	66.7
	Week 41	45	62.22	25.35	0.0	66.67	100.0	40	-6.88	29.65	-100.0	0.00	50.0
	Week 44	41	56.50	24.47	0.0	66.67	100.0	36	-10.42	33.41	-83.3	0.00	50.0
	Week 47	35	61.43	25.33	16.7	66.67	100.0	31	-4.84	27.87	-66.7	0.00	50.0
	Week 50	29	63.51	25.43	0.0	66.67	100.0	24	-0.69	28.12	-66.7	0.00	50.0
	Week 53	25	61.00	25.88	0.0	58.33	100.0	22	-2.27	30.77	-66.7	0.00	50.0
	Week 56	26	58.01	23.03	0.0	66.67	91.7	25	-4.33	25.24	-50.0	0.00	50.0
	Week 59	20	58.75	25.14	16.7	58.34	100.0	18	2.78	34.30	-58.3	0.00	58.3
	Week 62	17	57.84	19.65	16.7	58.33	83.3	17	-0.49	29.82	-50.0	0.00	50.0
	Week 65	15	56.67	21.18	16.7	66.67	83.3	14	-1.19	30.29	-50.0	-8.33	50.0
	Week 68	11	59.85	20.35	16.7	66.67	83.3	11	-3.03	25.35	-41.7	0.00	50.0
	Week 71	12	60.42	18.85	33.3	66.67	83.3	12	-3.47	27.17	-50.0	-4.17	50.0
	Week 74	10	60.00	12.30	33.3	66.67	75.0	10	-5.00	27.27	-41.7	-12.50	50.0
	Week 77	10	65.83	16.41	33.3	66.67	83.3	10	-1.67	26.58	-33.3	-4.17	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
< 65 years	EV+Pembro (N= 39)												
	BASELINE	32	58.33	19.63	16.7	50.00	100.0						
	Week 1	27	61.42	18.80	16.7	66.67	100.0	26	0.00	15.81	-33.3	0.00	33.3
	Week 2	30	62.22	19.54	33.3	58.33	100.0	29	1.15	15.22	-41.7	0.00	33.3
	Week 3	31	61.02	20.00	16.7	66.67	100.0	29	1.44	18.91	-41.7	0.00	41.7
	Week 4	30	69.17	17.66	16.7	75.00	91.7	27	8.95	16.81	-33.3	8.33	41.7
	Week 5	28	68.45	15.44	41.7	66.67	100.0	26	9.62	16.62	-25.0	8.34	50.0
	Week 6	29	65.23	18.64	33.3	66.67	100.0	26	6.09	21.55	-33.3	0.00	50.0
	Week 7	30	68.06	18.96	33.3	66.67	100.0	26	9.62	21.30	-33.3	8.34	50.0
	Week 8	30	69.17	18.97	33.3	66.67	100.0	26	7.05	23.53	-50.0	8.33	50.0
	Week 9	28	65.18	19.52	25.0	66.67	100.0	27	5.86	24.22	-50.0	8.33	50.0
	Week 10	26	62.18	25.41	0.0	70.84	100.0	23	0.36	28.26	-66.7	0.00	50.0
	Week 11	28	66.96	20.35	25.0	75.00	100.0	25	5.00	21.78	-33.3	0.00	50.0
	Week 12	28	66.07	22.78	0.0	75.00	83.3	25	5.33	20.39	-41.7	0.00	33.3
	Week 14	26	71.15	20.03	16.7	70.84	100.0	23	10.51	23.60	-41.7	16.66	50.0
	Week 17	28	67.56	19.29	33.3	66.67	100.0	24	10.42	22.29	-33.3	8.33	66.7
	Week 20	27	67.90	17.40	33.3	66.67	100.0	24	9.03	19.02	-16.7	8.33	50.0
	Week 23	26	69.23	19.11	16.7	70.84	100.0	23	8.70	21.83	-33.3	8.33	50.0
	Week 26	24	70.14	14.31	33.3	70.84	83.3	22	9.47	21.41	-33.3	16.66	50.0
	Week 29	25	66.33	16.58	25.0	66.67	91.7	23	5.44	27.48	-50.0	8.33	50.0
	Week 32	25	67.00	15.11	33.3	66.67	83.3	23	9.42	22.09	-33.3	8.34	50.0
	Week 35	24	64.24	17.97	25.0	66.67	83.3	22	3.03	30.16	-75.0	4.17	58.3
	Week 38	23	65.94	15.67	33.3	66.67	83.3	22	6.06	20.12	-25.0	8.33	50.0
	Week 41	25	69.67	14.81	33.3	66.67	91.7	23	7.61	24.86	-33.3	8.33	50.0
	Week 44	22	65.91	14.53	25.0	66.67	91.7	20	1.25	20.28	-33.3	0.00	33.3
	Week 47	20	70.83	18.44	16.7	79.17	91.7	18	4.17	28.04	-41.7	4.17	50.0

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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Table 302.1.3002.9.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	19	70.61	14.80	33.3	66.67	91.7	17	6.86	21.90	-33.3	0.00	41.7
	Week 53	20	66.25	19.02	33.3	70.84	91.7	18	2.78	22.32	-33.3	-4.17	41.7
	Week 56	17	68.14	23.05	0.0	66.67	100.0	15	6.67	25.82	-50.0	8.33	50.0
	Week 59	17	68.14	17.98	33.3	75.00	100.0	15	6.11	22.38	-33.3	0.00	50.0
	Week 62	15	64.44	15.26	33.3	66.67	83.3	14	-1.79	15.74	-33.3	0.00	16.7
	Week 65	14	65.48	16.94	33.3	62.50	100.0	13	3.20	16.85	-16.7	0.00	33.3
	Week 68	11	72.73	12.96	50.0	75.00	83.3	10	11.67	19.33	-16.7	12.50	33.3
	Week 71	13	63.46	12.05	50.0	66.67	83.3	12	4.17	14.87	-16.7	0.00	33.3
	Week 74	14	63.10	14.88	33.3	66.67	83.3	13	-1.92	20.17	-50.0	0.00	33.3
	Week 77	14	63.10	13.76	50.0	58.33	91.7	13	0.64	19.68	-33.3	0.00	33.3
	Week 80	14	60.12	19.93	33.3	58.33	91.7	13	-5.13	20.28	-50.0	-8.33	33.3
	Week 83	12	60.42	20.45	16.7	66.67	83.3	11	-3.79	16.82	-33.3	0.00	25.0
	Plat+Gem (N= 29)												
	BASELINE	22	66.67	21.82	16.7	66.67	100.0						
	Week 1	21	65.87	22.19	16.7	66.67	100.0	20	-1.25	18.59	-33.3	0.00	41.7
	Week 2	24	55.56	25.38	8.3	50.00	100.0	20	-11.25	16.73	-41.7	-8.34	16.7
	Week 3	23	64.13	22.53	25.0	66.67	100.0	20	-2.50	19.70	-50.0	0.00	25.0
	Week 4	23	58.70	24.93	0.0	66.67	100.0	19	-9.21	22.89	-58.3	-8.33	33.3
	Week 5	25	58.67	23.99	0.0	66.67	100.0	20	-5.83	19.52	-41.7	0.00	25.0
	Week 6	22	60.61	27.84	8.3	58.33	100.0	18	-7.87	22.23	-58.3	-8.33	33.3
	Week 7	24	61.81	20.10	25.0	66.67	100.0	21	-4.76	19.47	-41.7	0.00	33.3
	Week 8	21	63.89	22.41	16.7	66.67	100.0	19	-4.82	19.51	-50.0	0.00	33.3
	Week 9	20	59.17	23.40	0.0	62.50	100.0	17	-6.86	15.65	-25.0	-8.34	33.3
	Week 10	21	55.95	25.02	8.3	58.33	100.0	18	-12.04	26.39	-66.7	-12.50	25.0
	Week 11	20	62.08	23.80	8.3	66.67	100.0	17	-3.92	19.12	-41.7	-8.33	33.3
	Week 12	21	63.10	19.82	33.3	66.67	100.0	17	-2.94	16.12	-33.3	-8.33	25.0

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Table 302.1.3002.9.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 14	22	54.55	25.68	8.3	58.33	100.0	18	-13.89	28.87	-66.7	-16.66	33.3
	Week 17	20	62.08	22.70	8.3	66.67	100.0	17	-5.39	24.64	-58.3	0.00	33.3
	Week 20	18	61.11	26.20	16.7	66.67	100.0	15	-5.00	20.84	-58.3	0.00	25.0
	Week 23	18	69.91	19.83	33.3	66.67	100.0	16	1.04	18.23	-41.7	0.00	25.0
	Week 26	16	69.27	22.71	16.7	66.67	100.0	14	-1.19	16.62	-25.0	0.00	33.3
	Week 29	15	68.89	19.79	25.0	66.67	100.0	13	-0.64	16.83	-33.3	-8.33	25.0
	Week 32	15	66.67	25.00	16.7	66.67	100.0	13	-3.21	20.56	-50.0	0.00	25.0
	Week 35	15	62.78	23.54	16.7	66.67	100.0	13	-8.98	20.26	-50.0	0.00	25.0
	Week 38	14	55.95	28.95	0.0	62.50	100.0	12	-16.67	25.87	-66.7	-20.84	25.0
	Week 41	11	56.82	27.08	16.7	58.33	100.0	9	-13.89	19.98	-58.3	-8.33	0.0
	Week 44	11	51.52	36.10	0.0	50.00	100.0	9	-25.00	35.11	-75.0	-16.67	16.7
	Week 47	11	62.88	30.13	16.7	58.33	100.0	9	-3.70	19.14	-25.0	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>= 65 years	EV+Pembro (N=163)												
	BASELINE	128	61.33	22.57	0.0	66.67	100.0						
	Week 1	114	58.92	21.83	0.0	58.33	100.0	103	-4.21	19.35	-75.0	0.00	41.7
	Week 2	120	53.82	22.86	0.0	50.00	100.0	104	-6.89	19.24	-58.3	-8.33	50.0
	Week 3	108	54.17	23.67	0.0	50.00	100.0	93	-6.72	21.36	-83.3	0.00	33.3
	Week 4	115	57.17	23.52	0.0	58.33	100.0	102	-2.94	19.04	-66.7	0.00	41.7
	Week 5	109	59.40	21.76	0.0	58.33	100.0	95	-1.67	19.74	-66.7	0.00	41.7
	Week 6	117	58.40	23.63	0.0	58.33	100.0	98	-4.00	24.41	-75.0	0.00	41.7
	Week 7	117	60.54	23.04	0.0	66.67	100.0	98	-2.72	25.29	-91.7	0.00	58.3
	Week 8	117	58.12	22.65	0.0	58.33	100.0	98	-3.83	24.47	-75.0	0.00	50.0
	Week 9	114	60.31	23.73	0.0	66.67	100.0	94	-2.93	26.03	-100.0	0.00	66.7
	Week 10	113	60.55	23.01	0.0	66.67	100.0	95	-2.02	25.75	-100.0	0.00	50.0
	Week 11	109	63.38	21.99	0.0	66.67	100.0	90	0.19	24.98	-75.0	0.00	58.3
	Week 12	114	61.70	23.14	0.0	66.67	100.0	94	-0.18	25.13	-83.3	0.00	58.3
	Week 14	113	62.02	21.04	0.0	66.67	100.0	93	-1.52	23.02	-66.7	0.00	58.3
	Week 17	104	64.58	18.50	16.7	66.67	100.0	87	0.00	20.69	-58.3	0.00	58.3
	Week 20	93	63.89	21.19	8.3	66.67	100.0	79	-0.53	22.58	-75.0	0.00	58.3
	Week 23	91	63.10	22.30	16.7	66.67	100.0	74	-3.15	25.76	-83.3	0.00	58.3
	Week 26	88	62.97	21.66	0.0	66.67	100.0	72	-1.39	23.36	-66.7	0.00	66.7
	Week 29	82	61.99	20.42	0.0	66.67	100.0	70	-3.57	23.76	-66.7	0.00	58.3
	Week 32	77	62.88	21.35	0.0	66.67	100.0	65	-2.95	24.67	-83.3	0.00	50.0
	Week 35	74	61.15	22.55	0.0	66.67	100.0	64	-5.86	22.26	-83.3	0.00	50.0
	Week 38	74	62.28	18.41	25.0	66.67	100.0	64	-3.39	19.57	-41.7	0.00	50.0
	Week 41	70	63.33	21.11	8.3	66.67	100.0	61	-1.78	20.19	-66.7	0.00	50.0
	Week 44	64	60.16	21.28	0.0	66.67	100.0	54	-3.86	21.40	-66.7	0.00	50.0
	Week 47	59	63.70	18.87	16.7	66.67	100.0	52	1.44	18.35	-41.7	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	55	58.03	21.21	0.0	58.33	100.0	47	-6.38	22.27	-66.7	0.00	50.0
	Week 53	54	56.94	23.56	0.0	50.00	100.0	45	-5.00	23.12	-66.7	0.00	66.7
	Week 56	55	60.00	19.40	16.7	58.33	100.0	46	0.54	19.20	-58.3	0.00	58.3
	Week 59	52	59.78	19.92	16.7	66.67	100.0	42	-1.39	22.69	-58.3	0.00	66.7
	Week 62	47	58.51	18.99	16.7	50.00	100.0	38	-2.41	23.72	-66.7	0.00	50.0
	Week 65	29	59.20	19.20	33.3	50.00	100.0	27	-1.23	21.77	-58.3	0.00	50.0
	Week 68	35	58.57	20.36	25.0	50.00	100.0	32	-4.43	24.95	-58.3	0.00	50.0
	Week 71	29	60.63	19.91	33.3	50.00	91.7	26	-1.28	22.94	-50.0	0.00	50.0
	Week 74	24	60.76	22.98	0.0	66.67	100.0	22	-1.14	26.64	-58.3	0.00	50.0
	Week 77	23	64.49	20.60	16.7	66.67	91.7	20	3.33	23.16	-50.0	4.17	50.0
	Week 80	22	61.74	19.36	25.0	62.50	100.0	21	0.00	24.44	-41.7	0.00	50.0
	Week 83	18	62.04	22.91	16.7	66.67	100.0	18	1.39	24.46	-33.3	4.17	66.7
	Week 86	18	53.24	22.71	25.0	50.00	100.0	18	-8.33	27.56	-75.0	0.00	50.0
	Week 89	12	61.80	24.48	25.0	62.50	100.0	12	-2.09	18.51	-33.3	0.00	16.7
	Week 92	10	64.17	19.66	33.3	66.67	83.3	10	-5.00	24.59	-58.3	0.00	16.7
	Plat+Gem (N=173)												
	BASELINE	143	59.62	26.10	0.0	58.33	100.0						
	Week 1	123	59.82	23.57	0.0	66.67	100.0	119	-0.91	22.04	-83.3	0.00	66.7
	Week 2	123	57.11	23.22	0.0	66.67	100.0	115	-4.20	22.77	-50.0	0.00	66.7
	Week 3	126	58.80	23.93	0.0	66.67	100.0	116	-3.95	24.85	-100.0	0.00	66.7
	Week 4	127	60.83	23.93	0.0	66.67	100.0	116	-1.72	26.68	-66.7	0.00	83.3
	Week 5	128	58.40	22.99	0.0	66.67	100.0	118	-3.74	25.59	-75.0	0.00	66.7
	Week 6	123	59.42	24.56	0.0	66.67	100.0	113	-2.58	29.32	-83.3	0.00	66.7
	Week 7	124	60.01	20.96	0.0	58.33	100.0	113	-3.10	28.87	-66.7	0.00	66.7
	Week 8	124	57.46	22.76	0.0	58.33	100.0	113	-4.13	29.90	-75.0	0.00	66.7
	Week 9	121	59.50	22.37	0.0	58.33	100.0	108	-1.93	28.50	-75.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	121	61.02	22.67	0.0	66.67	100.0	112	-1.34	27.44	-66.7	0.00	66.7
	Week 11	106	58.57	22.43	0.0	62.50	100.0	97	-4.90	27.87	-100.0	-8.33	66.7
	Week 12	109	57.65	23.44	0.0	58.33	100.0	98	-4.00	29.09	-83.3	0.00	66.7
	Week 14	103	56.72	23.43	0.0	58.33	100.0	91	-6.32	29.77	-100.0	-8.33	66.7
	Week 17	100	59.08	22.32	16.7	62.50	100.0	89	-5.24	26.69	-75.0	0.00	66.7
	Week 20	86	64.63	21.99	0.0	66.67	100.0	76	-0.44	25.60	-66.7	0.00	66.7
	Week 23	70	67.26	22.09	25.0	66.67	100.0	64	2.73	25.16	-58.3	0.00	66.7
	Week 26	65	65.64	22.27	8.3	66.67	100.0	61	0.96	29.55	-66.7	0.00	66.7
	Week 29	62	64.25	26.28	0.0	66.67	100.0	58	-2.59	32.41	-66.7	0.00	83.3
	Week 32	48	64.06	22.29	0.0	66.67	100.0	45	-4.26	28.52	-91.7	0.00	50.0
	Week 35	47	65.78	21.30	16.7	66.67	100.0	43	-2.33	29.40	-66.7	0.00	66.7
	Week 38	42	62.90	24.57	16.7	66.67	100.0	38	-10.09	31.19	-83.3	0.00	66.7
	Week 41	41	64.02	24.04	0.0	66.67	100.0	38	-5.26	29.73	-100.0	0.00	50.0
	Week 44	38	58.11	21.00	16.7	62.50	100.0	35	-7.62	31.14	-83.3	0.00	50.0
	Week 47	32	60.94	24.27	16.7	66.67	100.0	30	-6.67	30.67	-66.7	-4.17	50.0
	Week 50	29	64.65	24.97	8.3	66.67	100.0	26	-5.13	32.92	-75.0	0.00	50.0
	Week 53	25	61.00	23.66	8.3	58.33	100.0	24	-6.25	34.07	-75.0	0.00	50.0
	Week 56	26	58.01	20.20	16.7	62.50	91.7	26	-8.65	27.44	-58.3	-4.17	50.0
	Week 59	20	63.75	23.14	16.7	66.67	100.0	20	1.25	33.91	-58.3	0.00	58.3
	Week 62	19	59.65	18.69	16.7	58.33	83.3	19	-2.63	29.66	-50.0	0.00	50.0
	Week 65	16	60.94	19.42	33.3	66.67	91.7	16	-1.04	28.36	-50.0	-8.33	50.0
	Week 68	13	61.54	20.84	16.7	66.67	91.7	13	-2.56	23.42	-41.7	0.00	50.0
	Week 71	13	62.18	19.13	33.3	66.67	83.3	13	-3.20	26.03	-50.0	0.00	50.0
	Week 74	11	62.12	13.62	33.3	66.67	83.3	11	-4.54	25.92	-41.7	-8.33	50.0
	Week 77	10	68.33	17.03	33.3	70.84	83.3	10	-3.33	25.82	-33.3	-4.17	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Europe	EV+Pembro (N= 74)												
	BASELINE	53	61.32	20.74	16.7	66.67	100.0						
	Week 1	48	56.08	20.82	0.0	50.00	91.7	42	-8.33	20.08	-75.0	-8.33	25.0
	Week 2	53	56.45	20.52	0.0	58.33	91.7	44	-5.68	18.92	-58.3	-8.33	25.0
	Week 3	50	53.83	19.94	16.7	50.00	100.0	41	-5.69	22.40	-66.7	-8.33	33.3
	Week 4	51	57.03	20.71	0.0	50.00	100.0	44	-4.17	21.45	-66.7	0.00	41.7
	Week 5	46	57.97	18.84	0.0	58.33	100.0	41	-3.05	21.06	-50.0	0.00	41.7
	Week 6	50	55.17	20.61	0.0	50.00	91.7	39	-6.41	25.47	-58.3	0.00	50.0
	Week 7	50	60.83	19.72	8.3	66.67	91.7	39	-3.63	27.82	-66.7	0.00	50.0
	Week 8	51	59.31	19.76	16.7	58.33	100.0	41	-5.28	24.91	-75.0	-8.33	50.0
	Week 9	47	57.45	19.68	16.7	66.67	91.7	37	-4.73	24.34	-66.7	-8.33	50.0
	Week 10	45	59.44	20.99	0.0	66.67	91.7	34	-1.96	24.37	-58.3	0.00	50.0
	Week 11	48	62.67	19.37	25.0	66.67	100.0	37	-1.80	20.24	-50.0	0.00	41.7
	Week 12	51	60.13	22.75	0.0	66.67	91.7	39	-2.78	23.67	-50.0	0.00	50.0
	Week 14	50	64.67	19.09	0.0	66.67	100.0	38	0.44	24.88	-66.7	4.17	50.0
	Week 17	43	64.34	18.66	33.3	66.67	100.0	33	3.03	21.73	-50.0	0.00	66.7
	Week 20	41	64.84	20.03	16.7	66.67	100.0	33	1.01	24.36	-66.7	0.00	50.0
	Week 23	41	61.18	21.13	16.7	66.67	91.7	30	-2.22	28.10	-83.3	8.33	50.0
	Week 26	37	61.94	18.89	16.7	66.67	83.3	28	-0.60	24.52	-66.7	0.00	50.0
	Week 29	37	66.89	17.84	16.7	66.67	91.7	29	2.59	22.28	-66.7	0.00	50.0
	Week 32	34	65.20	15.82	33.3	66.67	83.3	26	2.24	21.55	-50.0	8.33	50.0
	Week 35	31	62.10	18.86	25.0	66.67	83.3	25	-4.34	24.55	-41.7	-8.33	58.3
	Week 38	31	60.21	17.04	33.3	66.67	83.3	26	-5.45	19.43	-41.7	-4.17	50.0
	Week 41	28	63.99	21.52	8.3	66.67	100.0	23	1.09	21.22	-33.3	0.00	50.0
	Week 44	27	64.51	17.39	25.0	66.67	83.3	22	-1.14	15.71	-33.3	0.00	33.3
	Week 47	25	67.00	16.04	33.3	66.67	83.3	21	1.98	19.17	-41.7	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	26	58.97	22.96	0.0	66.67	83.3	23	-7.97	23.90	-58.3	-8.33	33.3
	Week 53	26	55.77	25.90	0.0	58.33	83.3	21	-10.72	26.24	-66.7	-8.33	33.3
	Week 56	25	56.67	19.84	0.0	50.00	83.3	21	-6.35	21.72	-58.3	0.00	16.7
	Week 59	23	63.04	17.38	33.3	66.67	83.3	18	-6.02	22.47	-58.3	0.00	33.3
	Week 62	20	58.33	15.30	33.3	58.33	83.3	17	-8.82	25.93	-66.7	0.00	16.7
	Week 65	13	56.41	16.01	33.3	58.33	83.3	13	-8.33	23.07	-58.3	-8.33	25.0
	Week 68	15	56.67	19.47	25.0	66.67	83.3	15	-8.33	30.86	-58.3	-8.33	33.3
	Week 71	13	58.33	18.32	33.3	58.33	83.3	13	-5.13	25.81	-50.0	0.00	33.3
	Week 74	10	60.84	15.74	33.3	66.67	75.0	9	-5.55	27.00	-58.3	0.00	33.3
	Plat+Gem (N= 95)												
	BASELINE	75	63.22	23.93	8.3	66.67	100.0						
	Week 1	71	59.16	23.11	8.3	66.67	100.0	69	-3.14	16.18	-66.7	0.00	25.0
	Week 2	71	54.69	25.19	0.0	58.33	100.0	63	-8.60	20.19	-50.0	0.00	25.0
	Week 3	72	59.84	24.95	0.0	66.67	100.0	65	-4.87	22.86	-66.7	0.00	33.3
	Week 4	69	58.57	25.48	0.0	66.67	100.0	62	-6.85	24.31	-66.7	-8.33	41.7
	Week 5	71	56.57	25.70	0.0	66.67	100.0	63	-6.35	21.20	-75.0	0.00	50.0
	Week 6	69	58.33	26.85	0.0	58.33	100.0	61	-6.42	27.44	-83.3	0.00	58.3
	Week 7	69	57.00	21.08	8.3	58.33	100.0	62	-7.66	24.58	-66.7	-8.33	58.3
	Week 8	67	57.46	21.08	0.0	58.33	100.0	60	-7.08	24.20	-75.0	-8.33	50.0
	Week 9	66	59.85	22.16	0.0	66.67	100.0	57	-3.80	23.94	-66.7	0.00	58.3
	Week 10	70	58.10	23.91	0.0	66.67	100.0	63	-5.95	24.20	-66.7	0.00	50.0
	Week 11	63	57.41	22.61	0.0	66.67	100.0	56	-6.55	25.71	-100.0	-8.33	50.0
	Week 12	66	56.82	20.62	16.7	58.33	100.0	56	-7.59	24.22	-83.3	-8.33	50.0
	Week 14	66	52.15	23.13	0.0	50.00	100.0	56	-13.99	28.48	-100.0	-8.34	41.7
	Week 17	61	56.01	23.23	8.3	58.33	100.0	53	-8.80	23.65	-66.7	-8.33	41.7
	Week 20	54	61.11	21.90	8.3	66.67	100.0	48	-5.03	21.66	-66.7	0.00	33.3

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 23	44	64.96	20.38	33.3	66.67	100.0	40	-2.50	21.45	-50.0	0.00	50.0
	Week 26	42	61.31	20.56	16.7	62.50	100.0	39	-4.91	20.56	-41.7	0.00	50.0
	Week 29	39	59.83	23.94	0.0	58.33	100.0	36	-8.10	26.31	-66.7	-4.17	50.0
	Week 32	32	58.59	26.31	0.0	66.67	100.0	30	-10.28	28.92	-91.7	-4.17	41.7
	Week 35	32	58.59	22.75	16.7	62.50	100.0	30	-9.44	24.14	-58.3	-4.17	50.0
	Week 38	28	55.36	24.13	16.7	62.50	100.0	26	-16.67	27.89	-83.3	-16.66	33.3
	Week 41	25	54.33	27.44	0.0	58.33	100.0	23	-13.41	31.56	-100.0	-8.33	50.0
	Week 44	24	53.13	25.40	0.0	54.17	100.0	22	-14.39	31.72	-83.3	-4.17	41.7
	Week 47	22	56.06	26.00	16.7	58.34	100.0	20	-9.17	30.09	-66.7	-4.17	50.0
	Week 50	17	56.37	28.03	0.0	58.33	91.7	15	-8.89	31.41	-75.0	0.00	50.0
	Week 53	15	54.44	30.84	0.0	58.33	100.0	14	-10.12	37.15	-75.0	-4.17	50.0
	Week 56	15	52.22	24.29	0.0	50.00	83.3	14	-16.67	25.11	-50.0	-16.67	41.7
	Week 59	11	53.03	26.16	16.7	58.33	91.7	10	-13.33	31.72	-58.3	-12.50	50.0
	Week 62	11	56.06	21.76	16.7	58.33	83.3	11	-13.63	26.68	-50.0	-16.66	50.0
	Week 65	10	59.17	22.03	33.3	58.34	91.7	10	-9.17	22.38	-50.0	-8.33	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
North America	EV+Pembro (N= 46)												
	BASELINE	33	65.40	20.64	16.7	66.67	100.0						
	Week 1	30	62.50	21.19	16.7	66.67	100.0	27	-3.39	15.89	-33.3	0.00	25.0
	Week 2	30	57.78	24.46	0.0	54.17	100.0	26	-8.33	17.79	-50.0	-8.33	25.0
	Week 3	25	63.33	25.46	0.0	66.67	100.0	21	-6.35	23.56	-83.3	0.00	16.7
	Week 4	30	61.94	23.64	0.0	62.50	100.0	24	-2.43	17.11	-50.0	0.00	33.3
	Week 5	29	63.79	21.97	0.0	58.33	100.0	21	-0.40	19.80	-66.7	0.00	41.7
	Week 6	31	65.32	21.20	25.0	66.67	100.0	23	-3.26	22.86	-75.0	0.00	33.3
	Week 7	33	63.38	20.51	33.3	66.67	100.0	23	-2.90	18.22	-66.7	0.00	33.3
	Week 8	29	66.09	19.79	33.3	66.67	100.0	20	2.08	25.06	-66.7	8.33	33.3
	Week 9	27	70.06	19.24	33.3	66.67	100.0	21	-0.40	21.65	-66.7	0.00	33.3
	Week 10	29	68.39	21.86	25.0	66.67	100.0	23	2.17	25.03	-75.0	8.33	50.0
	Week 11	28	68.45	24.36	0.0	66.67	100.0	21	2.78	23.17	-50.0	0.00	50.0
	Week 12	29	70.98	20.97	33.3	66.67	100.0	22	5.30	20.01	-33.3	4.17	50.0
	Week 14	28	68.75	19.46	33.3	66.67	100.0	21	-0.79	22.81	-33.3	0.00	33.3
	Week 17	29	68.39	18.55	33.3	66.67	100.0	23	-0.36	22.54	-50.0	0.00	50.0
	Week 20	23	68.48	20.71	25.0	66.67	100.0	18	2.32	28.12	-75.0	0.00	50.0
	Week 23	22	65.53	24.97	16.7	66.67	100.0	17	-6.86	29.79	-66.7	0.00	50.0
	Week 26	21	66.67	25.14	0.0	66.67	100.0	16	0.00	17.74	-25.0	-4.17	50.0
	Week 29	20	64.58	19.66	33.3	66.67	100.0	17	-6.37	25.60	-58.3	0.00	33.3
	Week 32	21	65.08	25.36	0.0	66.67	100.0	18	-2.78	33.09	-83.3	4.17	50.0
	Week 35	22	65.91	23.56	0.0	66.67	100.0	19	-2.19	27.19	-83.3	0.00	50.0
	Week 38	20	67.92	17.99	33.3	66.67	100.0	17	-0.49	21.54	-41.7	0.00	33.3
	Week 41	21	66.67	20.75	16.7	66.67	100.0	17	-3.43	23.58	-66.7	0.00	33.3
	Week 44	16	64.06	19.42	25.0	66.67	91.7	12	-5.56	29.16	-66.7	4.17	16.7
	Week 47	16	67.19	23.47	16.7	75.00	100.0	13	0.00	18.00	-33.3	0.00	25.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	16	65.63	18.97	33.3	66.67	91.7	11	-3.79	24.82	-66.7	0.00	33.3
	Week 53	15	69.45	18.00	33.3	66.67	100.0	11	5.30	11.35	-16.7	8.33	16.7
	Week 56	17	66.18	22.53	16.7	75.00	91.7	12	8.33	12.31	-16.7	8.33	25.0
	Week 59	17	65.20	21.50	16.7	66.67	91.7	12	6.94	20.36	-33.3	8.33	41.7
	Week 62	14	68.45	20.19	16.7	75.00	91.7	9	7.41	19.74	-33.3	8.33	33.3
	Week 68	11	78.03	7.70	66.7	75.00	91.7	8	9.37	17.50	-25.0	8.33	33.3
	Week 71	11	72.73	13.99	50.0	75.00	91.7	8	3.13	15.39	-16.7	0.00	25.0
	Plat+Gem (N= 34)												
	BASELINE	27	57.41	28.99	0.0	58.33	100.0						
	Week 1	19	69.30	19.85	33.3	66.67	100.0	17	7.35	19.29	-25.0	0.00	50.0
	Week 2	20	60.83	25.23	16.7	66.67	100.0	18	-7.87	22.41	-50.0	-8.34	50.0
	Week 3	20	63.75	20.46	16.7	66.67	91.7	17	-4.41	17.21	-41.7	-8.33	25.0
	Week 4	23	69.57	19.07	33.3	66.67	100.0	19	2.19	22.20	-25.0	0.00	66.7
	Week 5	25	62.33	20.00	16.7	66.67	91.7	22	-3.03	20.82	-33.3	-4.17	50.0
	Week 6	20	64.58	23.08	16.7	75.00	100.0	17	0.98	26.98	-33.3	-8.33	50.0
	Week 7	23	65.58	18.34	16.7	66.67	91.7	20	-2.08	27.29	-50.0	-4.17	58.3
	Week 8	24	55.90	21.49	16.7	54.17	91.7	22	-7.58	31.28	-75.0	0.00	50.0
	Week 9	23	63.40	17.18	33.3	58.33	100.0	19	-3.51	27.96	-66.7	-8.33	50.0
	Week 10	20	65.83	20.03	33.3	62.50	100.0	18	0.93	28.99	-50.0	0.00	58.3
	Week 11	18	64.82	21.11	25.0	66.67	100.0	16	-7.29	25.62	-41.7	-4.17	41.7
	Week 12	17	66.18	17.05	33.3	66.67	91.7	16	3.65	28.86	-41.7	4.17	50.0
	Week 14	16	61.46	21.92	25.0	58.33	100.0	14	-7.14	23.99	-41.7	-4.17	33.3
	Week 17	19	60.53	23.87	16.7	58.33	100.0	17	-10.78	32.11	-66.7	-16.67	66.7
	Week 20	16	69.79	22.13	33.3	70.84	100.0	13	-1.92	33.36	-33.3	-16.67	66.7
	Week 23	15	69.44	25.13	25.0	83.33	100.0	13	0.64	27.53	-33.3	0.00	66.7
	Week 26	13	74.36	19.97	33.3	75.00	100.0	12	2.08	33.55	-66.7	0.00	58.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 29	14	66.67	27.54	0.0	66.67	100.0	13	-7.05	33.65	-50.0	-8.34	66.7
	Week 32	11	75.00	11.78	58.3	83.33	91.7	10	-2.50	18.45	-33.3	0.00	25.0
	Week 35	13	72.44	15.36	41.7	66.67	100.0	11	-1.52	27.84	-33.3	0.00	66.7
	Week 38	10	63.33	28.38	0.0	70.84	91.7	9	-19.45	27.95	-66.7	-25.00	25.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Rest of World	EV+Pembro (N= 82)												
	BASELINE	74	58.22	23.31	0.0	58.33	100.0						
	Week 1	63	60.45	21.58	33.3	58.33	100.0	60	0.14	18.38	-50.0	0.00	41.7
	Week 2	67	53.73	23.13	0.0	50.00	100.0	63	-3.44	18.97	-58.3	0.00	50.0
	Week 3	64	54.17	23.99	0.0	50.00	100.0	60	-3.61	19.37	-58.3	0.00	41.7
	Week 4	64	60.68	24.33	0.0	66.67	100.0	61	3.01	17.81	-41.7	0.00	41.7
	Week 5	62	62.50	21.85	0.0	66.67	100.0	59	3.81	18.27	-50.0	0.00	50.0
	Week 6	65	60.64	24.76	0.0	58.33	100.0	62	1.48	23.55	-66.7	0.00	41.7
	Week 7	64	62.37	25.41	0.0	66.67	100.0	62	3.09	25.12	-91.7	0.00	58.3
	Week 8	67	58.71	24.98	0.0	58.33	100.0	63	-0.26	24.32	-58.3	0.00	50.0
	Week 9	68	60.42	25.69	0.0	66.67	100.0	63	1.06	27.94	-100.0	0.00	66.7
	Week 10	65	58.46	25.19	0.0	50.00	100.0	61	-2.73	27.75	-100.0	0.00	50.0
	Week 11	61	63.25	22.12	0.0	66.67	100.0	57	2.63	27.19	-75.0	0.00	58.3
	Week 12	62	60.62	23.67	0.0	66.67	100.0	58	1.87	26.03	-83.3	8.33	58.3
	Week 14	61	60.66	23.08	0.0	66.67	100.0	57	1.75	23.24	-58.3	0.00	58.3
	Week 17	60	64.31	18.80	16.7	66.67	100.0	55	2.88	20.98	-58.3	0.00	58.3
	Week 20	56	63.24	20.71	8.3	66.67	100.0	52	1.92	18.42	-33.3	0.00	58.3
	Week 23	54	66.51	20.82	16.7	66.67	100.0	50	3.00	21.61	-50.0	0.00	58.3
	Week 26	54	65.43	19.72	16.7	66.67	100.0	50	2.50	24.41	-33.3	0.00	66.7
	Week 29	50	59.50	20.55	0.0	62.50	100.0	47	-1.95	26.25	-50.0	0.00	58.3
	Week 32	47	62.41	20.40	0.0	66.67	91.7	44	0.38	22.52	-50.0	0.00	50.0
	Week 35	45	59.81	22.28	0.0	66.67	100.0	42	-3.77	24.08	-75.0	0.00	50.0
	Week 38	46	63.04	18.14	25.0	66.67	100.0	43	1.55	19.78	-41.7	0.00	50.0
	Week 41	46	64.85	18.58	25.0	66.67	100.0	44	2.27	21.74	-33.3	0.00	50.0
	Week 44	43	58.91	21.47	0.0	66.67	100.0	40	-2.29	21.35	-50.0	0.00	50.0
	Week 47	38	63.82	18.91	16.7	66.67	100.0	36	3.01	23.50	-41.7	0.00	50.0

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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Table 302.1.3002.9.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	32	60.94	19.22	33.3	58.33	100.0	30	1.39	21.00	-33.3	0.00	50.0
	Week 53	33	57.83	21.14	16.7	50.00	100.0	31	-0.27	22.72	-33.3	0.00	66.7
	Week 56	30	63.89	19.49	33.3	62.50	100.0	28	5.65	21.88	-25.0	0.00	58.3
	Week 59	29	58.91	20.52	16.7	50.00	100.0	27	2.16	23.41	-33.3	0.00	66.7
	Week 62	28	56.85	18.43	33.3	50.00	100.0	26	-1.28	18.51	-41.7	0.00	50.0
	Week 65	22	56.82	18.12	33.3	50.00	100.0	21	1.19	17.93	-25.0	0.00	50.0
	Week 68	20	57.08	20.28	25.0	50.00	100.0	19	1.32	20.27	-25.0	0.00	50.0
	Week 71	18	56.94	17.21	33.3	50.00	91.7	17	3.43	18.65	-25.0	0.00	50.0
	Week 74	19	53.51	21.39	0.0	50.00	100.0	19	-4.39	24.59	-58.3	0.00	50.0
	Week 77	19	57.89	16.31	33.3	50.00	91.7	18	1.39	22.55	-33.3	0.00	50.0
	Week 80	19	57.89	20.31	25.0	50.00	100.0	18	-0.93	23.55	-50.0	0.00	50.0
	Week 83	17	56.37	20.94	16.7	50.00	100.0	17	-0.49	24.38	-33.3	0.00	66.7
	Week 86	14	54.76	22.34	25.0	50.00	100.0	14	-1.19	27.71	-41.7	0.00	50.0
	Week 89	11	59.85	22.61	25.0	50.00	100.0	11	-2.27	23.30	-33.3	0.00	33.3
	Plat+Gem (N= 73)												
	BASELINE	63	58.73	26.16	0.0	58.33	100.0						
	Week 1	54	59.72	24.64	0.0	66.67	100.0	53	-0.79	27.26	-83.3	0.00	66.7
	Week 2	56	58.18	20.63	0.0	66.67	83.3	54	-0.46	23.54	-50.0	0.00	66.7
	Week 3	57	57.90	23.38	0.0	66.67	91.7	54	-2.16	27.48	-100.0	0.00	66.7
	Week 4	58	59.20	23.50	0.0	66.67	100.0	54	0.15	29.25	-66.7	0.00	83.3
	Week 5	57	59.06	20.91	16.7	66.67	100.0	53	-1.73	29.84	-66.7	0.00	66.7
	Week 6	56	59.38	23.41	0.0	66.67	100.0	53	-1.10	30.09	-66.7	0.00	66.7
	Week 7	56	62.20	20.96	0.0	66.67	100.0	52	1.28	30.58	-66.7	0.00	66.7
	Week 8	54	60.65	25.36	0.0	66.67	100.0	50	0.67	31.94	-75.0	0.00	66.7
	Week 9	52	57.21	24.81	0.0	58.33	100.0	49	-0.85	30.54	-75.0	0.00	66.7
	Week 10	52	61.06	22.85	0.0	66.67	100.0	49	-0.17	30.74	-66.7	-8.33	66.7

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Table 302.1.3002.9.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	45	59.26	23.25	0.0	66.67	100.0	42	-1.39	28.57	-58.3	-4.17	66.7
	Week 12	47	58.16	27.28	0.0	66.67	100.0	43	-1.74	30.73	-83.3	0.00	66.7
	Week 14	43	60.85	24.64	0.0	66.67	100.0	39	1.50	31.29	-66.7	0.00	66.7
	Week 17	40	64.58	19.50	16.7	66.67	100.0	36	2.55	25.88	-75.0	0.00	50.0
	Week 20	34	65.93	24.04	0.0	66.67	100.0	30	5.28	25.00	-58.3	0.00	50.0
	Week 23	29	71.26	21.55	25.0	66.67	100.0	27	10.49	24.09	-58.3	0.00	66.7
	Week 26	26	70.51	24.63	8.3	66.67	100.0	24	8.68	32.83	-66.7	4.17	66.7
	Week 29	24	72.92	24.36	0.0	83.33	100.0	22	10.23	31.28	-50.0	4.17	83.3
	Week 32	20	68.75	18.71	33.3	66.67	100.0	18	5.56	25.08	-50.0	0.00	50.0
	Week 35	17	71.57	21.05	33.3	83.33	100.0	15	5.55	32.38	-66.7	0.00	66.7
	Week 38	18	68.98	25.53	16.7	75.00	100.0	15	1.67	31.84	-50.0	0.00	66.7
	Week 41	18	70.37	19.85	41.7	70.84	100.0	16	4.69	24.90	-58.3	0.00	50.0
	Week 44	16	58.33	25.82	0.0	66.67	100.0	14	0.00	35.51	-75.0	4.17	50.0
	Week 47	12	67.36	28.31	25.0	70.84	100.0	11	2.27	21.11	-25.0	0.00	50.0
	Week 50	11	68.94	26.64	33.3	83.33	100.0	9	11.11	21.25	-16.7	8.33	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	EV+Pembro (N=146)												
	BASELINE	119	62.82	21.14	0.0	66.67	100.0						
	Week 1	102	61.19	21.45	0.0	62.50	100.0	97	-4.04	18.25	-75.0	0.00	41.7
	Week 2	106	56.60	21.14	0.0	50.00	100.0	98	-7.40	18.30	-58.3	-8.33	33.3
	Week 3	94	57.45	22.45	16.7	50.00	100.0	88	-6.44	22.13	-83.3	0.00	41.7
	Week 4	101	62.54	20.97	16.7	66.67	100.0	93	-0.54	20.22	-66.7	0.00	41.7
	Week 5	96	65.28	18.72	16.7	66.67	100.0	89	0.47	20.23	-66.7	0.00	50.0
	Week 6	105	62.78	20.90	16.7	66.67	100.0	93	-0.54	23.21	-75.0	0.00	50.0
	Week 7	102	64.13	21.65	0.0	66.67	100.0	89	-1.50	25.67	-91.7	0.00	50.0
	Week 8	101	63.04	21.06	16.7	66.67	100.0	91	-1.74	24.39	-75.0	0.00	50.0
	Week 9	100	63.75	22.36	0.0	66.67	100.0	89	-1.69	25.57	-100.0	0.00	50.0
	Week 10	99	63.05	22.81	0.0	66.67	100.0	87	-1.63	26.41	-100.0	0.00	50.0
	Week 11	95	66.32	22.11	0.0	66.67	100.0	84	-0.89	25.15	-75.0	0.00	58.3
	Week 12	99	63.47	24.04	0.0	66.67	100.0	87	-0.86	25.13	-83.3	0.00	58.3
	Week 14	95	65.44	20.77	0.0	66.67	100.0	84	-0.20	23.71	-66.7	0.00	50.0
	Week 17	97	66.32	18.08	16.7	66.67	100.0	84	0.99	21.11	-58.3	0.00	66.7
	Week 20	90	66.48	20.37	8.3	66.67	100.0	79	1.37	22.62	-75.0	0.00	58.3
	Week 23	86	66.09	21.42	16.7	66.67	100.0	74	-1.24	26.23	-83.3	0.00	50.0
	Week 26	83	64.26	21.60	0.0	66.67	100.0	72	-2.08	22.15	-66.7	-4.17	50.0
	Week 29	80	63.75	20.42	0.0	66.67	100.0	71	-2.58	25.18	-66.7	0.00	50.0
	Week 32	74	65.99	20.82	0.0	66.67	100.0	66	-1.14	25.44	-83.3	0.00	50.0
	Week 35	73	62.56	21.83	0.0	66.67	100.0	66	-4.92	24.55	-83.3	0.00	50.0
	Week 38	75	63.89	17.88	25.0	66.67	100.0	67	-1.87	19.93	-41.7	0.00	50.0
	Week 41	71	67.37	19.56	8.3	66.67	100.0	64	1.43	21.54	-66.7	0.00	50.0
	Week 44	64	63.02	19.69	0.0	66.67	100.0	56	-3.57	21.25	-66.7	0.00	33.3
	Week 47	56	66.67	19.85	16.7	66.67	100.0	50	1.33	19.87	-41.7	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	55	62.58	21.02	0.0	66.67	100.0	48	-2.60	22.69	-66.7	0.00	41.7
	Week 53	55	60.76	23.17	0.0	66.67	100.0	48	-3.99	23.06	-66.7	0.00	41.7
	Week 56	53	61.63	21.27	0.0	66.67	100.0	46	0.91	19.74	-50.0	0.00	50.0
	Week 59	51	62.91	20.09	16.7	66.67	100.0	43	0.77	20.64	-33.3	0.00	50.0
	Week 62	42	59.13	19.72	16.7	62.50	100.0	36	-6.02	20.95	-66.7	0.00	33.3
	Week 65	31	60.48	17.87	33.3	58.33	100.0	30	-3.33	19.65	-58.3	-8.33	33.3
	Week 68	31	62.10	20.39	25.0	66.67	100.0	29	-3.74	25.16	-58.3	0.00	33.3
	Week 71	30	61.94	18.27	33.3	66.67	91.7	28	-2.08	19.46	-50.0	0.00	33.3
	Week 74	29	63.22	20.47	0.0	66.67	100.0	27	-2.16	23.52	-58.3	0.00	33.3
	Week 77	26	64.74	17.84	16.7	66.67	91.7	24	-0.35	20.78	-50.0	0.00	33.3
	Week 80	26	61.22	18.99	25.0	58.33	100.0	26	-4.81	20.30	-41.7	0.00	33.3
	Week 83	21	59.52	22.86	16.7	66.67	100.0	21	-4.76	17.59	-33.3	0.00	25.0
	Week 86	17	56.86	22.87	25.0	50.00	100.0	17	-10.79	28.07	-75.0	-8.33	33.3
	Week 89	11	62.88	24.26	25.0	66.67	100.0	11	-7.58	21.56	-33.3	-8.33	33.3
	Week 92	13	62.82	23.48	8.3	75.00	83.3	13	-3.21	27.12	-58.3	0.00	33.3
	Plat+Gem (N=151)												
	BASELINE	123	60.98	26.10	0.0	66.67	100.0						
	Week 1	108	62.42	23.69	8.3	66.67	100.0	103	0.32	19.90	-50.0	0.00	66.7
	Week 2	116	57.61	23.66	0.0	66.67	100.0	105	-5.56	21.55	-50.0	0.00	66.7
	Week 3	114	60.45	22.96	0.0	66.67	100.0	103	-3.32	23.03	-100.0	0.00	66.7
	Week 4	116	61.13	23.15	0.0	66.67	100.0	103	-2.75	24.21	-66.7	0.00	83.3
	Week 5	119	59.94	23.20	0.0	66.67	100.0	106	-2.28	23.95	-58.3	0.00	66.7
	Week 6	109	60.47	24.17	0.0	66.67	100.0	98	-3.57	26.11	-66.7	0.00	66.7
	Week 7	115	60.36	21.42	0.0	66.67	100.0	105	-3.41	26.34	-66.7	0.00	66.7
	Week 8	111	59.68	22.40	0.0	66.67	100.0	102	-3.68	27.99	-75.0	0.00	66.7
	Week 9	107	58.72	22.41	0.0	58.33	100.0	95	-3.68	25.55	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	107	60.36	22.97	0.0	66.67	100.0	98	-3.91	26.79	-66.7	0.00	66.7
	Week 11	97	59.62	22.35	0.0	66.67	100.0	87	-5.08	27.21	-100.0	-8.33	66.7
	Week 12	100	58.67	22.28	0.0	62.50	100.0	88	-4.26	27.27	-83.3	0.00	66.7
	Week 14	99	56.14	23.77	0.0	58.33	100.0	86	-8.04	29.36	-100.0	-8.33	66.7
	Week 17	94	58.95	22.74	8.3	62.50	100.0	82	-6.81	24.68	-75.0	-8.33	50.0
	Week 20	84	61.90	23.22	0.0	66.67	100.0	72	-3.01	24.56	-66.7	0.00	50.0
	Week 23	70	66.07	21.58	25.0	66.67	100.0	62	0.67	22.24	-58.3	0.00	50.0
	Week 26	61	64.07	22.23	8.3	66.67	100.0	55	-2.73	25.76	-66.7	0.00	66.7
	Week 29	59	64.55	24.15	0.0	66.67	100.0	53	-4.09	29.03	-66.7	0.00	83.3
	Week 32	50	63.67	23.85	0.0	66.67	100.0	45	-5.56	27.35	-91.7	0.00	50.0
	Week 35	50	63.00	21.96	16.7	66.67	100.0	44	-7.01	25.60	-66.7	0.00	66.7
	Week 38	46	60.51	24.43	16.7	66.67	100.0	40	-12.08	28.62	-83.3	-8.34	66.7
	Week 41	42	60.91	25.07	0.0	66.67	100.0	37	-6.98	28.83	-100.0	0.00	50.0
	Week 44	39	56.41	24.89	0.0	66.67	100.0	34	-11.03	32.35	-83.3	-4.17	50.0
	Week 47	33	59.85	24.42	16.7	66.67	100.0	29	-5.17	27.50	-66.7	0.00	50.0
	Week 50	27	61.42	26.27	0.0	66.67	100.0	22	-1.14	30.57	-66.7	0.00	50.0
	Week 53	23	59.42	24.14	0.0	58.33	91.7	20	-0.83	29.97	-41.7	0.00	50.0
	Week 56	20	55.83	22.80	0.0	62.50	83.3	19	-5.70	26.21	-58.3	-8.33	50.0
	Week 59	17	57.84	24.73	16.7	58.33	100.0	15	0.00	34.50	-58.3	0.00	58.3
	Week 62	14	59.52	21.15	16.7	62.50	83.3	14	-2.98	29.89	-41.7	-4.17	50.0
	Week 65	13	62.18	21.41	16.7	66.67	91.7	12	2.78	25.70	-33.3	-8.33	50.0
	Week 68	10	60.83	22.58	16.7	66.67	91.7	10	-3.33	25.82	-41.7	-4.17	50.0
	Week 71	10	60.83	20.43	33.3	66.67	83.3	10	-5.83	26.94	-50.0	-4.17	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	EV+Pembro (N= 56)												
	BASELINE	41	54.68	23.50	0.0	50.00	100.0						
	Week 1	39	54.70	20.21	16.7	50.00	100.0	32	-1.30	20.20	-50.0	0.00	41.7
	Week 2	44	52.84	25.35	0.0	50.00	100.0	35	1.19	18.54	-41.7	0.00	50.0
	Week 3	45	52.04	23.98	0.0	50.00	100.0	34	-0.49	17.40	-41.7	0.00	33.3
	Week 4	44	53.03	25.86	0.0	50.00	91.7	36	-0.23	16.36	-33.3	0.00	33.3
	Week 5	41	51.83	22.86	0.0	50.00	91.7	32	1.56	18.02	-33.3	0.00	41.7
	Week 6	41	52.03	25.87	0.0	50.00	100.0	31	-5.91	26.63	-66.7	0.00	41.7
	Week 7	45	57.41	23.65	8.3	50.00	100.0	35	3.33	22.97	-50.0	8.33	58.3
	Week 8	46	54.53	24.13	0.0	50.00	100.0	33	-1.01	25.50	-58.3	0.00	50.0
	Week 9	42	55.36	23.63	0.0	50.00	100.0	32	1.04	26.75	-50.0	0.00	66.7
	Week 10	40	55.42	24.21	0.0	50.00	100.0	31	-1.34	25.83	-66.7	0.00	41.7
	Week 11	42	59.13	19.89	16.7	50.00	100.0	31	6.99	21.20	-33.3	8.33	50.0
	Week 12	43	60.46	20.74	8.3	66.67	100.0	32	5.99	21.19	-41.7	8.33	50.0
	Week 14	44	60.04	21.53	0.0	54.17	100.0	32	3.64	23.18	-41.7	0.00	58.3
	Week 17	35	62.14	20.04	16.7	58.33	100.0	27	6.17	22.12	-33.3	8.33	58.3
	Week 20	30	59.72	19.95	16.7	62.50	100.0	24	2.78	20.66	-33.3	0.00	50.0
	Week 23	31	59.95	22.20	16.7	58.33	100.0	23	2.54	22.25	-33.3	0.00	58.3
	Week 26	29	65.23	17.12	33.3	66.67	100.0	22	11.74	24.22	-33.3	12.50	66.7
	Week 29	27	60.80	17.11	33.3	58.33	91.7	22	2.65	24.04	-33.3	0.00	58.3
	Week 32	28	58.33	16.82	33.3	58.33	91.7	22	4.55	21.48	-33.3	0.00	50.0
	Week 35	25	60.00	20.69	8.3	58.33	100.0	20	0.83	25.06	-41.7	0.00	58.3
	Week 38	22	60.61	17.66	33.3	66.67	83.3	19	2.19	20.57	-25.0	0.00	50.0
	Week 41	24	57.99	19.11	25.0	50.00	91.7	20	-1.25	23.14	-33.3	0.00	50.0
	Week 44	22	57.58	20.24	8.3	66.67	83.3	18	0.93	20.79	-33.3	0.00	50.0
	Week 47	23	62.68	16.45	33.3	58.33	91.7	20	4.17	24.26	-41.7	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
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Table 302.1.3002.9.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	19	57.46	18.61	33.3	50.00	91.7	16	-3.65	23.76	-58.3	0.00	50.0
	Week 53	19	55.70	21.35	16.7	50.00	91.7	15	1.11	23.12	-33.3	0.00	66.7
	Week 56	19	62.72	18.50	33.3	66.67	91.7	15	5.55	24.73	-58.3	0.00	58.3
	Week 59	18	58.80	18.63	16.7	66.67	83.3	14	0.00	28.87	-58.3	0.00	66.7
	Week 62	20	61.67	14.91	33.3	58.33	83.3	16	6.25	21.62	-58.3	8.33	50.0
	Week 65	12	63.19	20.86	33.3	62.50	100.0	10	10.83	18.86	-16.7	4.17	50.0
	Week 68	15	61.67	18.85	25.0	66.67	83.3	13	6.41	22.35	-41.7	8.33	50.0
	Week 71	12	60.42	17.09	33.3	50.00	83.3	10	7.50	23.39	-41.7	4.17	50.0
	Week 77	11	62.12	19.49	33.3	50.00	91.7	9	9.26	23.36	-33.3	16.66	50.0
	Week 80	10	60.83	21.17	33.3	50.00	91.7	8	7.29	29.02	-50.0	12.50	50.0
	Plat+Gem (N= 51)												
	BASELINE	42	59.33	24.43	8.3	66.67	100.0						
	Week 1	36	55.56	22.00	0.0	54.17	100.0	36	-4.63	25.54	-83.3	0.00	33.3
	Week 2	31	54.03	23.06	0.0	50.00	83.3	30	-4.17	24.15	-50.0	-8.34	50.0
	Week 3	35	56.90	26.23	0.0	58.33	91.7	33	-5.05	27.56	-66.7	0.00	50.0
	Week 4	34	58.33	26.98	0.0	62.50	100.0	32	-2.86	32.35	-66.7	-8.33	66.7
	Week 5	34	53.19	22.19	8.3	50.00	83.3	32	-9.90	26.81	-75.0	-8.34	50.0
	Week 6	36	56.94	27.49	0.0	62.50	100.0	33	-2.53	34.89	-83.3	-8.33	66.7
	Week 7	33	60.10	18.61	33.3	58.33	100.0	29	-3.16	32.08	-58.3	-8.33	66.7
	Week 8	34	54.17	23.68	0.0	50.00	100.0	30	-6.11	30.94	-66.7	-8.33	66.7
	Week 9	34	61.76	22.67	0.0	62.50	100.0	30	0.83	31.82	-75.0	0.00	66.7
	Week 10	35	60.00	23.47	0.0	58.33	100.0	32	0.52	29.55	-66.7	0.00	66.7
	Week 11	29	57.47	23.71	0.0	58.33	100.0	27	-3.70	25.35	-58.3	-8.33	41.7
	Week 12	30	58.06	25.28	0.0	58.33	100.0	27	-2.47	28.76	-83.3	0.00	50.0
	Week 14	26	57.05	24.12	0.0	58.33	100.0	23	-5.80	31.22	-66.7	-8.34	66.7
	Week 17	26	61.86	20.97	16.7	66.67	100.0	24	0.00	31.08	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 20	20	72.92	18.11	33.3	66.67	100.0	19	5.70	25.31	-33.3	8.33	66.7
	Week 23	18	74.54	20.70	41.7	83.33	100.0	18	8.33	28.58	-41.7	4.17	66.7
	Week 26	20	73.33	21.39	33.3	75.00	100.0	20	9.58	30.74	-58.3	8.33	66.7
	Week 29	18	67.13	28.65	0.0	70.84	100.0	18	3.24	33.23	-50.0	4.17	66.7
	Week 32	13	68.59	18.37	41.7	66.67	100.0	13	1.28	24.96	-41.7	8.33	50.0
	Week 35	12	73.61	19.08	41.7	75.00	100.0	12	7.64	32.26	-41.7	0.00	66.7
	Week 38	10	64.17	31.93	0.0	66.67	100.0	10	-10.00	36.18	-66.7	4.17	33.3
	Week 41	10	69.17	22.58	33.3	66.67	100.0	10	-6.67	26.87	-50.0	0.00	33.3
	Week 44	10	57.50	26.19	16.7	54.17	100.0	10	-11.67	34.07	-50.0	4.17	33.3
	Week 47	10	66.67	29.66	16.7	75.00	100.0	10	-8.33	31.67	-66.7	-4.17	41.7
	Week 56	10	60.00	23.18	33.3	58.34	91.7	10	-10.83	27.51	-50.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Visceral metastases	EV+Pembro (N=148)												
	BASELINE	119	58.54	23.23	0.0	58.33	100.0						
	Week 1	105	57.70	21.64	0.0	50.00	100.0	99	-3.03	19.65	-75.0	0.00	41.7
	Week 2	109	52.98	22.41	0.0	50.00	100.0	100	-5.00	19.46	-58.3	-4.17	50.0
	Week 3	98	55.78	24.06	0.0	50.00	100.0	88	-2.37	22.53	-83.3	0.00	41.7
	Week 4	103	58.66	23.25	0.0	58.33	100.0	93	0.72	20.40	-66.7	0.00	41.7
	Week 5	100	60.67	21.55	0.0	58.33	100.0	90	2.04	20.27	-66.7	0.00	50.0
	Week 6	105	60.71	22.64	0.0	58.33	100.0	90	0.93	23.98	-75.0	0.00	50.0
	Week 7	108	63.50	22.20	8.3	66.67	100.0	91	3.02	24.74	-66.7	0.00	58.3
	Week 8	105	60.87	23.03	0.0	66.67	100.0	89	0.94	25.48	-75.0	0.00	50.0
	Week 9	105	60.95	23.44	0.0	66.67	100.0	91	0.73	25.63	-66.7	0.00	66.7
	Week 10	101	60.56	23.80	0.0	66.67	100.0	86	0.58	26.38	-75.0	0.00	50.0
	Week 11	97	64.09	22.71	0.0	66.67	100.0	83	3.41	23.82	-75.0	0.00	50.0
	Week 12	100	61.92	23.87	0.0	66.67	100.0	85	2.75	24.61	-83.3	0.00	50.0
	Week 14	102	63.81	22.11	0.0	66.67	100.0	87	2.39	24.64	-66.7	0.00	58.3
	Week 17	96	65.36	20.03	16.7	66.67	100.0	81	3.81	23.39	-58.3	0.00	66.7
	Week 20	87	64.46	21.05	8.3	66.67	100.0	76	2.30	23.20	-75.0	0.00	50.0
	Week 23	85	64.51	22.54	16.7	66.67	100.0	71	1.17	27.43	-83.3	0.00	58.3
	Week 26	79	64.87	20.96	0.0	66.67	100.0	66	1.77	24.83	-66.7	0.00	66.7
	Week 29	72	63.54	17.15	33.3	66.67	100.0	64	0.52	24.48	-58.3	0.00	58.3
	Week 32	71	65.14	19.84	0.0	66.67	100.0	62	2.42	26.75	-83.3	8.33	50.0
	Week 35	70	62.50	21.46	0.0	66.67	100.0	63	-3.04	26.49	-83.3	0.00	58.3
	Week 38	70	63.93	17.70	25.0	66.67	100.0	63	0.00	21.64	-41.7	0.00	50.0
	Week 41	66	66.03	19.41	8.3	66.67	100.0	60	2.08	23.35	-66.7	0.00	50.0
	Week 44	59	62.15	18.00	8.3	66.67	100.0	53	0.00	20.41	-66.7	0.00	50.0
	Week 47	52	67.15	18.85	16.7	70.84	100.0	48	4.51	22.80	-41.7	0.00	50.0

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	49	60.03	21.11	0.0	66.67	100.0	43	-2.52	26.07	-66.7	0.00	50.0
	Week 53	50	57.67	23.56	0.0	66.67	100.0	44	-2.46	25.52	-66.7	0.00	66.7
	Week 56	45	61.30	21.48	0.0	58.33	100.0	39	2.56	22.55	-58.3	0.00	58.3
	Week 59	44	60.80	19.82	16.7	66.67	100.0	38	-0.22	25.15	-58.3	0.00	66.7
	Week 62	38	60.96	21.06	16.7	62.50	100.0	33	-2.02	25.43	-66.7	0.00	50.0
	Week 65	25	62.33	17.37	33.3	58.33	100.0	24	2.43	23.24	-58.3	0.00	50.0
	Week 68	31	65.05	18.93	25.0	66.67	100.0	29	0.57	27.18	-58.3	0.00	50.0
	Week 71	27	65.12	15.68	33.3	66.67	91.7	25	2.33	22.12	-50.0	0.00	50.0
	Week 74	23	62.32	21.45	0.0	66.67	100.0	22	-2.27	27.96	-58.3	0.00	50.0
	Week 77	24	64.58	15.20	33.3	66.67	91.7	23	2.17	21.65	-33.3	0.00	50.0
	Week 80	22	60.61	19.28	33.3	58.33	100.0	22	-1.89	25.58	-50.0	0.00	50.0
	Week 83	19	61.84	20.66	16.7	66.67	100.0	19	-0.88	23.72	-33.3	0.00	66.7
	Week 86	14	58.93	24.12	25.0	50.00	100.0	14	-4.76	35.31	-75.0	0.00	50.0
	Week 89	10	66.67	19.64	33.3	66.67	100.0	10	0.83	19.82	-33.3	0.00	33.3
	Week 92	11	62.12	23.08	8.3	66.67	83.3	11	-3.03	29.17	-58.3	0.00	33.3
	Plat+Gem (N=157)												
	BASELINE	128	58.53	25.65	0.0	58.33	100.0						
	Week 1	111	60.29	23.68	0.0	58.33	100.0	107	0.23	20.23	-83.3	0.00	66.7
	Week 2	110	57.27	23.14	0.0	66.67	100.0	102	-3.19	19.16	-50.0	0.00	66.7
	Week 3	112	59.38	22.90	0.0	66.67	100.0	103	-1.62	21.33	-66.7	0.00	66.7
	Week 4	112	59.45	23.85	0.0	66.67	100.0	102	-1.55	23.30	-58.3	0.00	66.7
	Week 5	113	57.37	23.93	0.0	66.67	100.0	103	-3.07	24.75	-75.0	0.00	66.7
	Week 6	107	59.50	25.27	0.0	66.67	100.0	98	-1.36	26.51	-83.3	0.00	66.7
	Week 7	109	60.32	21.60	0.0	58.33	100.0	100	-1.25	25.72	-58.3	0.00	66.7
	Week 8	106	58.73	22.37	0.0	58.33	100.0	98	-1.70	26.43	-75.0	0.00	66.7
	Week 9	105	58.97	23.22	0.0	66.67	100.0	94	-1.42	26.40	-75.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	104	58.65	24.60	0.0	62.50	100.0	96	-2.26	27.16	-66.7	0.00	66.7
	Week 11	91	58.24	23.46	0.0	66.67	100.0	83	-3.61	26.29	-100.0	0.00	66.7
	Week 12	94	57.45	23.62	0.0	58.33	100.0	84	-2.78	26.71	-83.3	0.00	66.7
	Week 14	90	55.28	25.00	0.0	58.33	100.0	79	-6.22	29.79	-100.0	0.00	66.7
	Week 17	90	58.98	22.63	8.3	62.50	100.0	80	-4.06	24.77	-75.0	0.00	50.0
	Week 20	74	62.61	23.34	0.0	66.67	100.0	64	-0.26	23.00	-66.7	0.00	50.0
	Week 23	63	67.33	22.27	25.0	66.67	100.0	58	3.59	21.80	-50.0	8.33	66.7
	Week 26	55	65.61	22.05	8.3	66.67	100.0	52	2.08	22.19	-41.7	0.00	66.7
	Week 29	53	62.26	24.49	0.0	66.67	100.0	50	-4.33	27.26	-66.7	0.00	50.0
	Week 32	42	65.87	23.34	0.0	66.67	100.0	40	-2.08	25.51	-91.7	0.00	50.0
	Week 35	39	65.81	21.78	16.7	66.67	100.0	36	-3.47	20.93	-58.3	0.00	50.0
	Week 38	37	58.78	28.73	0.0	66.67	100.0	34	-13.73	29.65	-83.3	0.00	33.3
	Week 41	33	60.86	25.64	0.0	66.67	100.0	31	-6.99	25.10	-100.0	0.00	33.3
	Week 44	32	56.77	26.39	0.0	58.33	100.0	30	-10.00	31.06	-83.3	0.00	41.7
	Week 47	28	58.93	26.83	16.7	58.33	100.0	26	-7.37	24.98	-66.7	0.00	33.3
	Week 50	22	62.12	28.49	0.0	70.84	100.0	20	-7.92	30.53	-75.0	0.00	41.7
	Week 53	19	60.53	28.31	0.0	58.33	100.0	17	-4.90	31.46	-75.0	0.00	41.7
	Week 56	18	54.63	23.08	0.0	54.17	91.7	17	-9.80	24.87	-58.3	-8.33	33.3
	Week 59	13	57.69	26.45	16.7	50.00	100.0	12	-2.08	36.08	-58.3	0.00	58.3
	Week 62	11	58.33	20.07	33.3	58.33	83.3	11	-6.82	26.83	-50.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Lymph node only	EV+Pembro (N= 43)												
	BASELINE	33	68.43	15.70	33.3	66.67	100.0						
	Week 1	30	63.61	19.63	33.3	66.67	100.0	24	-5.56	16.24	-50.0	0.00	16.7
	Week 2	34	62.25	21.34	25.0	58.33	100.0	27	-5.25	17.63	-58.3	0.00	25.0
	Week 3	35	56.19	20.45	16.7	50.00	100.0	28	-9.82	14.35	-33.3	-8.33	16.7
	Week 4	36	62.96	22.40	16.7	66.67	100.0	30	-1.95	15.43	-33.3	0.00	33.3
	Week 5	33	61.87	19.88	25.0	66.67	100.0	27	-3.40	17.49	-50.0	0.00	25.0
	Week 6	34	57.84	23.74	0.0	66.67	91.7	28	-9.23	24.25	-66.7	-8.33	25.0
	Week 7	34	56.86	23.52	0.0	58.33	100.0	28	-9.82	25.06	-91.7	-8.33	33.3
	Week 8	35	59.52	20.43	8.3	58.33	100.0	29	-7.18	21.56	-58.3	-8.33	33.3
	Week 9	30	62.22	22.50	0.0	66.67	91.7	24	-5.21	28.85	-100.0	4.17	33.3
	Week 10	31	62.90	21.17	0.0	66.67	100.0	26	-6.41	25.75	-100.0	-4.17	16.7
	Week 11	34	64.71	18.81	33.3	66.67	100.0	27	-3.70	26.59	-66.7	-8.33	58.3
	Week 12	35	65.95	19.53	8.3	66.67	100.0	28	-2.08	22.75	-41.7	0.00	58.3
	Week 14	30	65.28	17.52	16.7	66.67	100.0	23	-3.26	20.06	-41.7	-8.33	33.3
	Week 17	30	67.22	13.12	41.7	66.67	91.7	24	-1.39	14.04	-25.0	0.00	25.0
	Week 20	27	66.67	19.34	16.7	66.67	100.0	21	0.79	20.40	-33.3	0.00	58.3
	Week 23	27	64.20	20.12	16.7	66.67	100.0	21	-4.37	18.56	-58.3	0.00	16.7
	Week 26	27	64.20	20.26	16.7	66.67	83.3	22	0.38	20.97	-33.3	8.33	41.7
	Week 29	28	61.90	26.00	0.0	70.84	100.0	23	-5.44	26.30	-66.7	-8.33	33.3
	Week 32	24	60.42	22.01	0.0	66.67	91.7	20	-6.25	18.11	-50.0	0.00	16.7
	Week 35	22	58.71	23.36	0.0	66.67	83.3	18	-5.56	20.41	-50.0	0.00	25.0
	Week 38	21	61.90	17.39	33.3	66.67	83.3	17	-2.94	14.72	-25.0	0.00	16.7
	Week 41	22	64.39	20.76	16.7	66.67	91.7	17	-0.98	16.64	-25.0	0.00	33.3
	Week 44	22	60.23	24.39	0.0	66.67	83.3	16	-8.86	23.07	-58.3	0.00	16.7
	Week 47	21	63.89	19.78	16.7	66.67	91.7	16	-1.56	13.68	-33.3	0.00	16.7

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.9.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	63.33	19.76	33.3	66.67	91.7	16	-3.13	14.23	-33.3	0.00	33.3
	Week 53	18	64.35	21.73	16.7	70.84	91.7	14	-4.17	17.53	-33.3	-4.17	33.3
	Week 56	21	61.90	20.17	25.0	66.67	100.0	17	0.49	19.43	-33.3	0.00	50.0
	Week 59	21	63.89	20.64	16.7	66.67	100.0	16	2.60	18.44	-33.3	0.00	50.0
	Week 62	19	59.21	13.86	41.7	66.67	83.3	15	-1.67	11.87	-25.0	0.00	16.7
	Week 65	16	61.46	21.05	33.3	58.33	100.0	14	-2.38	15.48	-33.3	-4.17	25.0
	Week 68	13	56.41	20.74	25.0	50.00	83.3	11	-4.55	14.13	-33.3	0.00	16.7
	Week 71	13	57.05	20.37	33.3	50.00	83.3	11	-3.03	17.19	-33.3	0.00	25.0
	Week 74	13	60.90	19.95	33.3	66.67	83.3	11	-2.27	14.48	-33.3	0.00	16.7
	Week 77	13	62.82	23.23	16.7	66.67	91.7	10	2.50	22.58	-50.0	12.50	25.0
	Week 80	13	60.26	19.88	25.0	58.33	91.7	11	-0.76	17.66	-33.3	8.33	16.7
	Week 83	11	60.61	24.18	16.7	66.67	91.7	10	0.00	18.43	-33.3	8.33	16.7
	Week 86	11	56.82	21.67	25.0	50.00	91.7	10	-5.00	13.72	-33.3	0.00	8.3
	Plat+Gem (N= 37)												
	BASELINE	29	67.82	23.65	16.7	75.00	100.0						
	Week 1	26	60.26	23.37	16.7	66.67	100.0	25	-7.67	25.45	-66.7	0.00	58.3
	Week 2	30	54.17	25.78	8.3	54.17	100.0	26	-14.42	26.20	-50.0	-12.50	50.0
	Week 3	30	61.39	25.94	0.0	66.67	100.0	26	-9.30	27.42	-66.7	-8.33	50.0
	Week 4	32	62.50	25.04	0.0	66.67	100.0	27	-8.64	31.22	-66.7	-8.33	83.3
	Week 5	33	59.85	21.29	0.0	66.67	91.7	28	-8.33	23.57	-41.7	-8.33	50.0
	Week 6	32	59.90	25.61	0.0	66.67	100.0	27	-9.88	31.78	-66.7	-16.66	66.7
	Week 7	31	59.14	17.92	33.3	58.33	91.7	26	-11.86	30.11	-66.7	-12.50	58.3
	Week 8	32	55.73	24.90	0.0	58.33	100.0	27	-15.12	33.89	-75.0	-16.66	58.3
	Week 9	30	59.72	21.23	0.0	58.33	91.7	25	-7.33	29.79	-66.7	-8.34	58.3
	Week 10	30	62.78	18.14	8.3	66.67	100.0	26	-7.37	26.70	-66.7	-12.50	50.0
	Week 11	29	60.92	19.93	8.3	66.67	100.0	25	-9.33	26.50	-58.3	-16.66	50.0

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Table 302.1.3002.9.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status/QoL by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 12	28	61.01	21.76	16.7	66.67	100.0	23	-7.61	28.42	-83.3	-8.33	66.7
	Week 14	28	60.71	20.77	8.3	66.67	100.0	23	-11.23	29.15	-66.7	-16.66	66.7
	Week 17	25	59.33	20.32	16.7	66.67	91.7	21	-11.11	26.13	-66.7	-16.66	50.0
	Week 20	23	66.30	21.09	16.7	66.67	100.0	20	-5.00	25.28	-58.3	0.00	50.0
	Week 23	20	68.75	20.03	33.3	66.67	100.0	17	-0.98	23.73	-41.7	0.00	50.0
	Week 26	21	66.67	22.82	16.7	66.67	100.0	18	-4.63	35.15	-66.7	0.00	66.7
	Week 29	19	68.42	26.58	0.0	83.33	100.0	16	-0.52	34.22	-50.0	0.00	83.3
	Week 32	18	63.43	23.42	0.0	66.67	83.3	15	-6.11	30.29	-58.3	-8.33	50.0
	Week 35	19	62.28	21.04	16.7	66.67	83.3	16	-7.29	31.60	-50.0	-8.33	66.7
	Week 38	15	64.44	17.67	33.3	66.67	83.3	12	-6.94	31.75	-50.0	-16.67	66.7
	Week 41	15	63.89	23.50	16.7	66.67	83.3	12	-6.25	34.29	-58.3	0.00	50.0
	Week 44	14	56.55	24.72	0.0	66.67	83.3	11	-12.12	38.79	-75.0	-8.33	50.0
	Week 47	12	65.28	21.56	16.7	70.84	83.3	10	-3.33	39.91	-66.7	-8.33	50.0
	Week 50	11	61.36	23.94	16.7	66.67	91.7	8	6.25	35.56	-41.7	4.17	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
EV+Pembro (N=240)												
BASELINE	206	79.16	21.89	6.7	86.67	100.0						
Week 1	190	76.00	23.80	0.0	80.00	100.0	184	-3.48	14.18	-60.0	0.00	53.3
Week 2	203	74.09	23.93	6.7	80.00	100.0	189	-6.10	15.09	-73.3	0.00	33.3
Week 3	198	72.96	23.99	6.7	80.00	100.0	182	-6.12	13.40	-60.0	0.00	26.7
Week 4	194	77.35	22.03	0.0	80.00	100.0	179	-3.05	17.09	-73.3	0.00	60.0
Week 5	190	77.40	21.08	6.7	80.00	100.0	173	-3.20	16.07	-60.0	0.00	53.3
Week 6	188	78.44	20.37	6.7	80.00	100.0	170	-2.75	17.06	-80.0	0.00	46.7
Week 7	195	78.46	19.84	0.0	80.00	100.0	176	-2.16	19.07	-80.0	0.00	60.0
Week 8	191	78.53	20.65	0.0	86.67	100.0	171	-1.91	18.86	-73.3	0.00	60.0
Week 9	197	76.78	21.71	0.0	80.00	100.0	180	-3.89	18.02	-66.7	0.00	53.3
Week 10	191	77.84	19.95	6.7	80.00	100.0	175	-2.06	18.91	-60.0	0.00	60.0
Week 11	194	77.97	20.60	0.0	80.00	100.0	175	-1.33	20.38	-53.3	0.00	66.7
Week 12	186	77.03	22.87	0.0	80.00	100.0	171	-2.03	22.71	-93.3	0.00	60.0
Week 14	185	78.38	20.18	0.0	80.00	100.0	167	-1.88	21.24	-73.3	0.00	60.0
Week 17	178	78.50	19.73	26.7	80.00	100.0	162	-1.89	21.07	-60.0	0.00	66.7
Week 20	167	75.41	23.22	0.0	80.00	100.0	154	-5.15	24.88	-80.0	0.00	60.0
Week 23	162	73.95	23.82	0.0	80.00	100.0	151	-6.14	25.48	-100.0	-6.66	60.0
Week 26	156	74.40	23.38	0.0	80.00	100.0	144	-5.83	25.70	-100.0	0.00	53.3
Week 29	157	74.78	20.99	0.0	80.00	100.0	145	-5.75	22.16	-73.3	0.00	53.3
Week 32	135	74.02	21.05	13.3	80.00	100.0	125	-7.95	21.73	-66.7	-6.67	53.3
Week 35	132	74.29	21.15	0.0	80.00	100.0	122	-8.42	20.30	-73.3	-6.67	40.0
Week 38	132	72.98	22.79	0.0	76.67	100.0	124	-7.85	21.52	-66.7	-6.67	53.3
Week 41	129	72.92	21.09	6.7	73.33	100.0	119	-9.13	20.61	-66.7	-6.67	40.0
Week 44	108	72.22	21.71	0.0	73.33	100.0	100	-11.80	23.87	-86.7	-6.67	53.3
Week 47	100	72.80	22.50	0.0	73.33	100.0	94	-10.85	23.85	-73.3	-6.67	40.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	89	72.81	21.91	20.0	73.33	100.0	84	-13.17	20.88	-66.7	-10.00	33.3
Week 53	79	75.70	19.74	6.7	80.00	100.0	74	-9.01	21.09	-66.7	-6.67	40.0
Week 56	81	73.00	22.11	0.0	80.00	100.0	76	-11.14	22.48	-73.3	-6.67	40.0
Week 59	72	74.35	20.68	0.0	80.00	100.0	68	-10.78	21.76	-73.3	-6.67	40.0
Week 62	65	75.59	22.74	0.0	80.00	100.0	63	-11.32	22.74	-73.3	-6.67	33.3
Week 65	58	73.91	22.93	6.7	73.33	100.0	54	-10.25	22.72	-73.3	-6.67	40.0
Week 68	53	75.22	22.16	20.0	80.00	100.0	52	-10.26	22.54	-66.7	-6.67	40.0
Week 71	51	73.46	24.24	13.3	80.00	100.0	49	-12.24	23.90	-73.3	-6.67	40.0
Week 74	47	72.06	23.12	20.0	73.33	100.0	46	-14.06	22.85	-80.0	-13.33	40.0
Week 77	44	67.88	24.50	20.0	66.67	100.0	42	-15.40	21.36	-53.3	-16.67	33.3
Week 80	40	69.33	25.88	13.3	73.33	100.0	37	-12.43	23.58	-53.3	-13.33	40.0
Week 83	37	68.29	24.96	20.0	73.33	100.0	35	-12.76	24.06	-53.3	-13.33	40.0
Week 86	34	68.24	23.90	26.7	73.33	100.0	31	-13.33	21.64	-53.3	-13.33	26.7
Week 89	33	65.25	26.02	13.3	66.67	100.0	31	-15.70	24.07	-60.0	-13.33	33.3
Week 92	27	67.90	27.30	20.0	80.00	100.0	25	-14.13	22.39	-60.0	-13.33	26.7
Week 95	22	66.67	26.75	26.7	76.67	100.0	21	-16.51	22.27	-66.7	-13.33	20.0
Week 98	18	72.59	23.86	26.7	80.00	100.0	17	-9.41	17.80	-53.3	-6.67	20.0
Week 101	14	68.57	29.86	20.0	83.34	100.0	14	-17.62	24.75	-60.0	-6.67	6.7
Week 104	10	72.00	26.63	26.7	73.34	100.0	10	-18.00	19.13	-46.7	-20.00	6.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Plat+Gem (N=242)												
BASELINE	188	73.83	23.51	0.0	76.67	100.0						
Week 1	173	71.25	23.26	0.0	80.00	100.0	158	-3.80	15.43	-60.0	0.00	46.7
Week 2	171	70.21	22.79	0.0	73.33	100.0	151	-5.25	16.84	-46.7	-6.66	60.0
Week 3	184	72.10	22.35	0.0	73.33	100.0	162	-3.00	16.25	-53.3	0.00	60.0
Week 4	183	72.24	21.59	0.0	73.33	100.0	156	-3.21	16.36	-73.3	0.00	60.0
Week 5	187	71.34	23.01	0.0	80.00	100.0	156	-5.04	18.15	-80.0	-6.66	66.7
Week 6	174	70.54	23.95	0.0	73.33	100.0	149	-4.38	19.12	-80.0	0.00	60.0
Week 7	186	72.15	22.35	0.0	80.00	100.0	157	-4.46	18.88	-60.0	0.00	60.0
Week 8	167	69.90	24.11	0.0	73.33	100.0	144	-7.22	22.43	-100.0	-6.67	40.0
Week 9	177	71.75	21.54	6.7	73.33	100.0	150	-5.07	21.62	-86.7	-6.66	46.7
Week 10	166	70.64	22.21	0.0	73.33	100.0	139	-5.23	21.84	-86.7	0.00	46.7
Week 11	168	72.22	21.82	0.0	80.00	100.0	143	-4.75	20.93	-66.7	-6.66	60.0
Week 12	159	71.61	21.44	6.7	73.33	100.0	138	-5.36	21.40	-73.3	-6.67	60.0
Week 14	153	71.33	21.70	13.3	73.33	100.0	128	-5.73	21.60	-60.0	-6.67	53.3
Week 17	155	72.09	21.53	13.3	80.00	100.0	130	-6.72	21.67	-66.7	-6.67	46.7
Week 20	126	74.97	21.58	0.0	80.00	100.0	110	-4.24	22.32	-66.7	0.00	53.3
Week 23	115	73.68	23.71	0.0	80.00	100.0	97	-5.91	22.30	-60.0	-6.66	60.0
Week 26	108	75.00	23.54	0.0	80.00	100.0	95	-5.05	22.21	-73.3	0.00	60.0
Week 29	100	75.80	21.29	0.0	80.00	100.0	86	-5.74	21.65	-100.0	0.00	46.7
Week 32	83	75.90	21.10	6.7	80.00	100.0	76	-4.47	21.46	-73.3	0.00	46.7
Week 35	76	75.88	22.47	0.0	80.00	100.0	69	-4.35	23.70	-80.0	0.00	46.7
Week 38	74	76.04	22.48	0.0	86.67	100.0	65	-4.51	24.36	-80.0	0.00	46.7
Week 41	65	76.41	18.52	13.3	80.00	100.0	56	-4.05	20.56	-60.0	-3.33	46.7
Week 44	60	72.00	23.67	0.0	73.33	100.0	53	-6.29	25.47	-93.3	0.00	33.3
Week 47	56	76.90	19.57	0.0	80.00	100.0	49	-4.08	22.39	-73.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	51	72.55	23.95	0.0	73.33	100.0	47	-3.40	21.21	-73.3	0.00	40.0
Week 53	46	78.12	14.58	53.3	80.00	100.0	42	-0.32	17.91	-33.3	0.00	40.0
Week 56	39	70.60	24.46	0.0	73.33	100.0	34	-8.24	22.27	-73.3	-6.67	33.3
Week 59	37	79.46	14.35	40.0	80.00	100.0	33	-1.01	14.92	-40.0	0.00	33.3
Week 62	32	79.58	15.70	33.3	83.34	100.0	29	-0.23	21.34	-66.7	0.00	46.7
Week 65	30	76.89	18.67	13.3	80.00	100.0	26	-3.33	23.65	-86.7	0.00	46.7
Week 68	25	74.67	19.15	33.3	80.00	100.0	21	-5.72	16.64	-60.0	-6.66	26.7
Week 71	22	70.91	26.39	6.7	80.00	100.0	19	-8.42	20.71	-53.3	-6.67	20.0
Week 74	21	76.19	21.25	13.3	80.00	100.0	18	-1.85	8.80	-13.3	0.00	13.3
Week 77	18	75.93	24.75	0.0	86.67	100.0	15	-1.33	14.30	-33.3	0.00	20.0
Week 80	14	80.00	12.27	53.3	80.00	100.0	13	-1.54	10.59	-20.0	0.00	13.3
Week 83	13	77.43	14.54	53.3	73.33	100.0	12	-5.56	12.66	-33.3	-6.67	13.3
Week 86	12	82.22	12.17	60.0	86.67	100.0	11	-1.21	16.00	-40.0	0.00	20.0
Week 89	11	81.82	10.79	66.7	80.00	100.0	10	-0.67	15.54	-33.3	3.34	13.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Present	EV+Pembro (N= 48)												
	BASELINE	39	69.57	25.21	6.7	73.33	100.0						
	Week 1	32	66.67	26.61	0.0	66.67	100.0	32	-3.96	14.15	-40.0	0.00	20.0
	Week 2	37	61.80	26.79	6.7	60.00	100.0	33	-9.70	17.41	-46.7	-6.66	26.7
	Week 3	34	56.86	27.77	6.7	56.67	100.0	29	-8.74	18.53	-60.0	0.00	26.7
	Week 4	36	65.74	27.88	0.0	76.67	100.0	31	-4.73	22.59	-73.3	0.00	60.0
	Week 5	30	64.22	23.84	6.7	70.00	100.0	24	-6.39	21.13	-60.0	0.00	33.3
	Week 6	31	66.02	27.34	6.7	73.33	100.0	25	-5.07	20.75	-53.3	0.00	26.7
	Week 7	34	69.41	23.68	0.0	73.33	100.0	28	-0.71	24.97	-80.0	3.33	33.3
	Week 8	35	69.52	22.94	13.3	73.33	100.0	30	0.67	19.83	-46.7	0.00	60.0
	Week 9	34	64.90	27.77	0.0	66.67	100.0	30	-8.00	18.81	-66.7	-3.33	26.7
	Week 10	34	69.22	24.78	6.7	73.33	100.0	30	-2.89	21.28	-60.0	0.00	40.0
	Week 11	33	63.64	28.19	0.0	73.33	100.0	28	-4.76	26.90	-53.3	0.00	60.0
	Week 12	33	68.48	29.40	0.0	80.00	100.0	29	0.23	25.73	-60.0	0.00	60.0
	Week 14	31	71.61	25.87	6.7	80.00	100.0	26	3.59	25.94	-73.3	0.00	60.0
	Week 17	31	73.76	22.17	26.7	80.00	100.0	25	4.53	25.51	-40.0	0.00	66.7
	Week 20	27	68.64	26.01	13.3	73.33	100.0	24	-1.39	26.08	-60.0	0.00	40.0
	Week 23	26	72.82	23.09	33.3	80.00	100.0	23	3.77	25.01	-46.7	0.00	46.7
	Week 26	25	76.00	19.91	33.3	80.00	100.0	22	6.36	22.86	-40.0	3.33	46.7
	Week 29	23	72.46	24.81	0.0	73.33	100.0	22	-1.21	25.58	-60.0	0.00	40.0
	Week 32	21	70.16	22.17	26.7	73.33	100.0	19	-1.75	25.22	-66.7	-6.66	40.0
	Week 35	19	65.61	26.69	0.0	66.67	100.0	17	-9.02	27.17	-66.7	-6.67	33.3
	Week 38	18	58.15	29.97	0.0	66.67	100.0	17	-7.84	30.20	-60.0	-6.67	46.7
	Week 41	20	69.00	20.66	26.7	73.33	100.0	19	-6.67	22.22	-53.3	-6.67	40.0
	Week 44	17	65.10	22.67	26.7	66.67	100.0	15	-14.22	24.80	-66.7	-6.67	40.0
	Week 47	18	60.00	28.19	0.0	63.34	100.0	16	-16.25	29.91	-60.0	-13.34	40.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	12	67.22	25.34	26.7	66.67	100.0	11	-17.57	20.93	-60.0	-13.33	6.7
	Week 53	12	67.22	28.91	6.7	76.67	100.0	11	-16.97	25.36	-66.7	-6.67	20.0
	Week 56	13	61.54	33.13	0.0	66.67	100.0	12	-18.33	31.28	-73.3	-16.67	40.0
	Week 59	12	72.22	28.83	0.0	76.67	100.0	11	-8.48	27.66	-73.3	-6.67	40.0
	Week 62	10	71.33	34.00	0.0	90.00	100.0	9	-13.33	28.09	-73.3	-6.67	33.3
	Week 65	10	64.67	32.06	6.7	70.00	100.0	9	-16.29	28.30	-66.7	-20.00	40.0
	Plat+Gem (N= 48)												
	BASELINE	33	71.52	26.73	0.0	80.00	100.0						
	Week 1	31	69.25	27.47	0.0	73.33	100.0	27	-3.21	18.71	-33.3	-6.67	46.7
	Week 2	29	68.05	24.71	0.0	66.67	100.0	24	-3.89	23.00	-46.7	-6.66	60.0
	Week 3	32	76.46	22.01	13.3	80.00	100.0	27	2.47	17.26	-33.3	0.00	60.0
	Week 4	32	72.08	22.49	26.7	73.33	100.0	24	1.39	18.02	-26.7	0.00	60.0
	Week 5	36	71.67	26.35	13.3	80.00	100.0	28	-0.24	20.33	-53.3	0.00	66.7
	Week 6	35	65.52	30.66	0.0	80.00	100.0	27	-1.48	19.42	-40.0	0.00	60.0
	Week 7	38	71.23	26.08	6.7	80.00	100.0	29	2.07	17.74	-26.7	0.00	60.0
	Week 8	31	75.70	23.51	0.0	86.67	100.0	25	0.53	15.74	-26.7	-6.66	33.3
	Week 9	32	73.96	23.05	6.7	80.00	100.0	25	4.00	17.64	-20.0	0.00	40.0
	Week 10	34	71.76	24.12	0.0	80.00	100.0	26	4.10	19.42	-26.7	0.00	46.7
	Week 11	30	78.22	20.71	13.3	86.67	100.0	24	8.61	19.41	-13.3	3.33	60.0
	Week 12	28	75.24	21.91	13.3	86.67	100.0	23	6.09	22.38	-33.3	0.00	60.0
	Week 14	26	75.38	18.26	40.0	76.67	100.0	21	1.90	25.22	-53.3	0.00	53.3
	Week 17	30	77.33	18.58	40.0	86.67	100.0	25	2.40	19.80	-53.3	6.67	40.0
	Week 20	23	79.71	19.85	40.0	86.67	100.0	21	4.44	23.51	-53.3	6.67	53.3
	Week 23	22	76.97	24.75	26.7	86.67	100.0	19	-1.40	25.97	-53.3	0.00	60.0
	Week 26	19	81.40	20.68	33.3	86.67	100.0	18	-0.74	21.19	-33.3	0.00	60.0
	Week 29	16	78.33	18.30	46.7	83.34	100.0	14	-2.38	16.66	-46.7	0.00	20.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 32	11	77.58	12.03	60.0	73.33	93.3	11	-7.88	8.85	-20.0	-6.67	13.3
	Week 35	10	78.00	15.41	53.3	83.34	100.0	9	-3.70	10.60	-13.3	-6.66	13.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Absent	EV+Pembro (N=192)												
	BASELINE	167	81.40	20.49	6.7	86.67	100.0						
	Week 1	158	77.89	22.82	6.7	86.67	100.0	152	-3.38	14.23	-60.0	0.00	53.3
	Week 2	166	76.83	22.43	6.7	80.00	100.0	156	-5.34	14.50	-73.3	0.00	33.3
	Week 3	164	76.30	21.77	13.3	80.00	100.0	153	-5.62	12.21	-46.7	0.00	20.0
	Week 4	158	80.00	19.64	20.0	86.67	100.0	148	-2.70	15.78	-53.3	0.00	40.0
	Week 5	160	79.87	19.63	20.0	86.67	100.0	149	-2.68	15.13	-46.7	0.00	53.3
	Week 6	157	80.89	17.80	13.3	86.67	100.0	145	-2.35	16.40	-80.0	0.00	46.7
	Week 7	161	80.37	18.46	20.0	86.67	100.0	148	-2.43	17.84	-53.3	0.00	60.0
	Week 8	156	80.56	19.62	0.0	86.67	100.0	141	-2.46	18.68	-73.3	0.00	53.3
	Week 9	163	79.26	19.43	0.0	80.00	100.0	150	-3.07	17.81	-60.0	0.00	53.3
	Week 10	157	79.70	18.31	20.0	86.67	100.0	145	-1.89	18.45	-53.3	0.00	60.0
	Week 11	161	80.91	17.38	20.0	86.67	100.0	147	-0.68	18.93	-46.7	0.00	66.7
	Week 12	153	78.87	20.87	0.0	86.67	100.0	142	-2.49	22.11	-93.3	0.00	60.0
	Week 14	154	79.74	18.64	0.0	86.67	100.0	141	-2.88	20.21	-73.3	0.00	53.3
	Week 17	147	79.50	19.11	26.7	80.00	100.0	137	-3.07	20.05	-60.0	0.00	60.0
	Week 20	140	76.71	22.51	0.0	80.00	100.0	130	-5.85	24.69	-80.0	0.00	60.0
	Week 23	136	74.17	24.04	0.0	80.00	100.0	128	-7.92	25.25	-100.0	-6.66	60.0
	Week 26	131	74.10	24.05	0.0	80.00	100.0	122	-8.03	25.65	-100.0	-6.66	53.3
	Week 29	134	75.17	20.35	13.3	80.00	100.0	123	-6.56	21.51	-73.3	-6.66	53.3
	Week 32	114	74.74	20.87	13.3	80.00	100.0	106	-9.06	20.98	-66.7	-6.67	53.3
	Week 35	113	75.75	19.84	6.7	80.00	100.0	105	-8.32	19.12	-73.3	-6.67	40.0
	Week 38	114	75.32	20.65	20.0	80.00	100.0	107	-7.85	20.00	-66.7	-6.67	53.3
	Week 41	109	73.64	21.19	6.7	73.33	100.0	100	-9.60	20.37	-66.7	-10.00	40.0
	Week 44	91	73.55	21.39	0.0	80.00	100.0	85	-11.37	23.83	-86.7	-6.67	53.3
	Week 47	82	75.61	20.18	13.3	80.00	100.0	78	-9.74	22.48	-73.3	-6.67	40.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	77	73.68	21.38	20.0	80.00	100.0	73	-12.51	20.93	-66.7	-6.67	33.3
	Week 53	67	77.21	17.49	33.3	80.00	100.0	63	-7.62	20.17	-53.3	-6.67	40.0
	Week 56	68	75.20	18.89	26.7	80.00	100.0	64	-9.79	20.47	-60.0	-6.67	33.3
	Week 59	60	74.78	18.94	33.3	80.00	100.0	57	-11.23	20.71	-60.0	-6.67	33.3
	Week 62	55	76.36	20.40	33.3	80.00	100.0	54	-10.99	22.02	-66.7	-6.67	33.3
	Week 65	48	75.83	20.47	26.7	76.67	100.0	45	-9.04	21.61	-73.3	-6.67	33.3
	Week 68	46	75.94	20.87	26.7	80.00	100.0	45	-10.07	21.82	-66.7	-6.67	33.3
	Week 71	44	74.24	22.94	20.0	76.67	100.0	42	-12.54	23.29	-73.3	-10.00	33.3
	Week 74	40	72.83	22.05	20.0	73.33	100.0	39	-14.53	22.32	-80.0	-13.34	33.3
	Week 77	38	69.47	21.73	20.0	66.67	100.0	36	-15.18	20.01	-53.3	-16.67	33.3
	Week 80	35	71.43	23.57	13.3	73.33	100.0	32	-12.08	22.04	-53.3	-10.00	26.7
	Week 83	32	69.58	23.70	20.0	73.33	100.0	30	-13.33	23.23	-53.3	-13.33	40.0
	Week 86	29	68.51	23.16	26.7	73.33	100.0	26	-14.10	21.19	-53.3	-16.67	20.0
	Week 89	29	65.52	25.33	13.3	66.67	100.0	27	-16.79	23.12	-60.0	-13.33	26.7
	Week 92	24	68.06	27.10	20.0	76.67	100.0	22	-13.03	22.77	-60.0	-10.00	26.7
	Week 95	20	69.67	26.00	26.7	80.00	100.0	19	-15.09	22.31	-66.7	-13.33	20.0
	Week 98	18	72.59	23.86	26.7	80.00	100.0	17	-9.41	17.80	-53.3	-6.67	20.0
	Week 101	13	72.31	27.47	33.3	86.67	100.0	13	-14.87	23.44	-60.0	-6.67	6.7
	Plat+Gem (N=194)												
	BASELINE	155	74.32	22.83	6.7	73.33	100.0						
	Week 1	142	71.69	22.32	0.0	80.00	100.0	131	-3.92	14.74	-60.0	0.00	33.3
	Week 2	142	70.66	22.44	0.0	73.33	100.0	127	-5.51	15.51	-46.7	-6.66	33.3
	Week 3	152	71.18	22.39	0.0	73.33	100.0	135	-4.10	15.88	-53.3	0.00	53.3
	Week 4	151	72.27	21.47	0.0	73.33	100.0	132	-4.04	15.97	-73.3	0.00	33.3
	Week 5	151	71.26	22.23	0.0	73.33	100.0	128	-6.09	17.55	-80.0	-6.66	33.3
	Week 6	139	71.80	21.90	6.7	73.33	100.0	122	-5.03	19.08	-80.0	0.00	40.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 7	148	72.39	21.38	0.0	76.67	100.0	128	-5.94	18.88	-60.0	0.00	40.0
	Week 8	136	68.58	24.14	0.0	73.33	100.0	119	-8.85	23.32	-100.0	-6.67	40.0
	Week 9	145	71.26	21.25	6.7	73.33	100.0	125	-6.88	21.95	-86.7	-6.66	46.7
	Week 10	132	70.35	21.78	6.7	73.33	100.0	113	-7.37	21.88	-86.7	-6.66	46.7
	Week 11	138	70.92	21.91	0.0	73.33	100.0	119	-7.45	20.25	-66.7	-6.66	46.7
	Week 12	131	70.84	21.34	6.7	73.33	100.0	115	-7.65	20.54	-73.3	-6.67	40.0
	Week 14	127	70.50	22.31	13.3	73.33	100.0	107	-7.23	20.62	-60.0	-6.67	46.7
	Week 17	125	70.83	22.06	13.3	73.33	100.0	105	-8.89	21.62	-66.7	-6.67	46.7
	Week 20	103	73.92	21.90	0.0	80.00	100.0	89	-6.29	21.66	-66.7	0.00	53.3
	Week 23	93	72.90	23.53	0.0	80.00	100.0	78	-7.01	21.35	-60.0	-6.66	33.3
	Week 26	89	73.63	23.99	0.0	80.00	100.0	77	-6.06	22.46	-73.3	0.00	40.0
	Week 29	84	75.32	21.87	0.0	80.00	100.0	72	-6.39	22.53	-100.0	-6.66	46.7
	Week 32	72	75.65	22.21	6.7	80.00	100.0	65	-3.90	22.91	-73.3	0.00	46.7
	Week 35	66	75.56	23.43	0.0	80.00	100.0	60	-4.44	25.14	-80.0	0.00	46.7
	Week 38	66	75.35	23.30	0.0	86.67	100.0	57	-3.98	25.51	-80.0	0.00	46.7
	Week 41	62	76.56	18.69	13.3	80.00	100.0	53	-4.15	20.97	-60.0	0.00	46.7
	Week 44	55	73.09	22.62	0.0	73.33	100.0	48	-4.31	22.83	-73.3	0.00	33.3
	Week 47	51	78.04	19.88	0.0	80.00	100.0	44	-2.27	21.80	-73.3	0.00	33.3
	Week 50	48	71.81	24.42	0.0	73.33	100.0	44	-4.24	21.38	-73.3	-3.33	40.0
	Week 53	41	77.72	15.32	53.3	80.00	100.0	37	0.72	18.04	-33.3	0.00	40.0
	Week 56	34	71.37	24.32	0.0	73.33	100.0	29	-6.21	20.47	-73.3	-6.67	33.3
	Week 59	32	79.17	14.34	40.0	80.00	100.0	28	0.24	13.99	-26.7	0.00	33.3
	Week 62	27	80.74	13.75	53.3	86.67	100.0	24	3.05	17.36	-20.0	0.00	46.7
	Week 65	25	79.20	15.19	46.7	80.00	100.0	21	1.59	14.89	-20.0	0.00	46.7
	Week 68	23	76.23	18.51	33.3	80.00	100.0	19	-2.81	11.62	-26.7	0.00	26.7
	Week 71	21	72.06	26.47	6.7	80.00	100.0	18	-5.93	18.13	-46.7	-3.34	20.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 74	20	76.33	21.79	13.3	80.00	100.0	17	-1.57	8.98	-13.3	0.00	13.3
	Week 77	16	75.42	26.19	0.0	86.67	100.0	13	-1.54	15.19	-33.3	0.00	20.0
	Week 80	12	79.44	12.54	53.3	80.00	100.0	11	-2.42	10.44	-20.0	0.00	13.3
	Week 83	11	78.18	15.80	53.3	73.33	100.0	10	-5.34	13.98	-33.3	-3.34	13.3
	Week 86	10	82.67	13.03	60.0	86.67	100.0	9	-1.48	17.57	-40.0	0.00	20.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
< 65 years	EV+Pembro (N=105)												
	BASELINE	92	77.97	23.96	6.7	86.67	100.0						
	Week 1	88	75.91	25.28	6.7	80.00	100.0	85	-2.98	12.87	-46.7	0.00	33.3
	Week 2	92	76.74	24.00	6.7	86.67	100.0	86	-3.18	12.92	-40.0	0.00	33.3
	Week 3	93	74.26	24.90	6.7	80.00	100.0	84	-3.49	13.82	-46.7	0.00	26.7
	Week 4	90	80.67	21.39	0.0	86.67	100.0	82	1.95	17.07	-40.0	0.00	60.0
	Week 5	90	80.00	20.84	20.0	86.67	100.0	81	0.33	17.09	-60.0	0.00	53.3
	Week 6	90	82.15	17.98	33.3	86.67	100.0	81	3.29	14.19	-26.7	0.00	46.7
	Week 7	85	82.20	18.56	20.0	86.67	100.0	77	2.60	16.90	-33.3	0.00	60.0
	Week 8	89	82.62	17.97	13.3	86.67	100.0	80	2.83	17.96	-46.7	0.00	60.0
	Week 9	93	80.29	19.03	26.7	86.67	100.0	85	-0.24	17.68	-66.7	0.00	46.7
	Week 10	88	81.74	18.73	26.7	86.67	100.0	81	3.21	18.92	-60.0	0.00	60.0
	Week 11	93	82.15	17.56	26.7	86.67	100.0	84	3.81	21.11	-53.3	0.00	66.7
	Week 12	86	82.17	18.45	20.0	86.67	100.0	79	3.97	21.58	-46.7	0.00	60.0
	Week 14	84	81.27	18.41	33.3	86.67	100.0	76	2.11	20.23	-46.7	0.00	60.0
	Week 17	83	82.17	18.95	33.3	86.67	100.0	77	3.55	22.85	-60.0	0.00	66.7
	Week 20	79	78.23	22.26	26.7	86.67	100.0	73	-0.46	25.12	-66.7	0.00	60.0
	Week 23	78	76.75	24.54	0.0	80.00	100.0	73	-1.83	25.71	-80.0	0.00	60.0
	Week 26	78	78.20	20.43	13.3	80.00	100.0	72	-0.19	22.18	-73.3	0.00	53.3
	Week 29	74	78.02	19.23	33.3	80.00	100.0	67	-0.99	19.53	-53.3	0.00	53.3
	Week 32	64	76.46	21.18	13.3	80.00	100.0	59	-4.52	18.75	-40.0	-6.66	53.3
	Week 35	62	79.35	17.73	26.7	80.00	100.0	58	-4.71	14.72	-33.3	0.00	33.3
	Week 38	62	76.77	20.72	20.0	80.00	100.0	59	-3.62	20.16	-46.7	0.00	53.3
	Week 41	64	76.04	21.04	6.7	80.00	100.0	59	-5.54	17.73	-46.7	-6.66	40.0
	Week 44	50	77.47	19.70	26.7	83.34	100.0	48	-5.69	20.21	-60.0	-6.66	53.3
	Week 47	47	73.05	22.97	20.0	73.33	100.0	46	-10.29	23.67	-73.3	-6.67	40.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	44	74.09	20.65	20.0	80.00	100.0	41	-12.36	20.47	-66.7	-13.33	26.7
	Week 53	40	76.00	20.63	6.7	80.00	100.0	37	-8.29	20.93	-66.7	-6.67	40.0
	Week 56	44	74.70	22.85	0.0	80.00	100.0	41	-9.92	22.12	-73.3	-6.66	40.0
	Week 59	42	74.76	21.72	0.0	80.00	100.0	39	-11.28	22.95	-73.3	-13.33	40.0
	Week 62	37	75.31	25.14	0.0	80.00	100.0	36	-10.93	23.81	-73.3	-6.67	33.3
	Week 65	34	74.31	24.18	6.7	76.67	100.0	31	-11.61	24.58	-73.3	-13.33	40.0
	Week 68	34	73.53	23.70	20.0	80.00	100.0	33	-12.32	23.52	-66.7	-13.33	40.0
	Week 71	32	71.67	26.29	13.3	80.00	100.0	30	-14.67	25.33	-73.3	-13.33	40.0
	Week 74	29	71.03	25.03	20.0	73.33	100.0	28	-15.00	25.05	-80.0	-13.33	40.0
	Week 77	25	66.13	24.94	20.0	66.67	100.0	24	-17.78	24.29	-53.3	-23.33	33.3
	Week 80	24	67.50	25.58	13.3	73.33	100.0	22	-16.06	24.74	-53.3	-20.00	40.0
	Week 83	23	67.83	25.00	20.0	66.67	100.0	22	-14.54	26.16	-53.3	-16.67	40.0
	Week 86	20	63.00	24.23	26.7	60.00	100.0	18	-17.78	22.75	-46.7	-20.00	26.7
	Week 89	19	63.51	25.76	13.3	60.00	100.0	17	-17.25	25.50	-60.0	-13.33	33.3
	Week 92	14	67.14	25.28	26.7	70.00	100.0	12	-15.55	19.56	-46.7	-13.33	6.7
	Week 95	12	62.78	28.63	26.7	73.34	100.0	11	-20.60	24.84	-66.7	-13.33	6.7
	Plat+Gem (N=106)												
	BASELINE	83	76.79	20.99	20.0	80.00	100.0						
	Week 1	75	71.91	21.03	13.3	80.00	100.0	71	-6.67	14.21	-40.0	-6.67	33.3
	Week 2	76	70.18	23.31	0.0	73.33	100.0	68	-5.88	15.69	-46.7	0.00	33.3
	Week 3	80	72.83	21.78	13.3	73.33	100.0	73	-5.21	16.11	-53.3	0.00	33.3
	Week 4	79	73.67	20.11	20.0	73.33	100.0	67	-3.28	13.90	-33.3	0.00	33.3
	Week 5	80	73.42	22.09	13.3	73.33	100.0	67	-5.87	16.52	-53.3	-6.66	33.3
	Week 6	76	71.75	23.40	6.7	73.33	100.0	67	-4.88	17.27	-46.7	0.00	33.3
	Week 7	81	73.66	21.88	6.7	80.00	100.0	71	-4.32	18.28	-53.3	0.00	40.0
	Week 8	72	74.35	20.22	6.7	76.67	100.0	64	-4.79	20.38	-73.3	-6.66	40.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	78	74.27	17.81	33.3	73.33	100.0	69	-3.38	20.91	-40.0	-6.66	46.7
	Week 10	78	72.31	19.84	6.7	80.00	100.0	68	-4.22	20.89	-66.7	-3.33	46.7
	Week 11	75	73.87	19.07	20.0	80.00	100.0	66	-3.33	20.93	-60.0	-6.66	46.7
	Week 12	74	74.77	19.15	6.7	73.33	100.0	66	-2.93	21.21	-73.3	0.00	46.7
	Week 14	68	75.98	19.59	20.0	80.00	100.0	58	-0.35	20.99	-46.7	0.00	53.3
	Week 17	68	73.04	22.14	13.3	80.00	100.0	58	-4.48	20.76	-53.3	-6.67	40.0
	Week 20	60	76.78	21.21	0.0	80.00	100.0	52	-1.80	21.94	-53.3	0.00	53.3
	Week 23	51	76.99	23.64	0.0	86.67	100.0	44	-1.82	23.73	-60.0	0.00	60.0
	Week 26	47	78.01	22.32	6.7	86.67	100.0	42	0.32	21.49	-60.0	0.00	60.0
	Week 29	42	79.52	18.59	13.3	80.00	100.0	37	-0.36	19.05	-53.3	0.00	46.7
	Week 32	37	76.76	19.09	20.0	80.00	100.0	34	-3.33	23.46	-60.0	0.00	46.7
	Week 35	34	78.24	21.67	20.0	83.34	100.0	31	-0.43	27.38	-80.0	0.00	46.7
	Week 38	33	79.19	20.60	26.7	86.67	100.0	28	1.90	24.80	-60.0	0.00	46.7
	Week 41	27	80.00	20.09	40.0	86.67	100.0	22	0.91	24.80	-60.0	0.00	46.7
	Week 44	28	75.71	19.98	40.0	80.00	100.0	24	1.11	22.81	-46.7	0.00	33.3
	Week 47	24	80.28	17.42	46.7	83.34	100.0	21	1.27	18.69	-33.3	0.00	33.3
	Week 50	26	76.41	21.10	26.7	80.00	100.0	24	3.06	19.36	-33.3	0.00	40.0
	Week 53	19	79.30	16.47	53.3	80.00	100.0	17	7.45	21.07	-33.3	0.00	40.0
	Week 56	13	76.92	22.55	20.0	86.67	100.0	11	3.03	25.71	-60.0	0.00	33.3
	Week 59	14	82.38	17.27	40.0	80.00	100.0	12	5.55	15.53	-20.0	0.00	33.3
	Week 62	13	85.13	14.18	53.3	86.67	100.0	12	8.89	21.34	-20.0	0.00	46.7
	Week 65	13	81.03	16.96	46.7	86.67	100.0	11	2.42	19.15	-20.0	0.00	46.7
	Week 68	10	76.00	20.42	33.3	76.67	100.0	8	0.00	12.85	-13.3	0.00	26.7
	Week 77	10	74.67	29.62	0.0	86.67	100.0	8	-0.83	10.95	-13.3	0.00	20.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>= 65 years	EV+Pembro (N=135)												
	BASELINE	114	80.12	20.13	20.0	86.67	100.0						
	Week 1	102	76.08	22.58	0.0	80.00	100.0	99	-3.91	15.27	-60.0	0.00	53.3
	Week 2	111	71.89	23.76	6.7	80.00	100.0	103	-8.54	16.34	-73.3	-6.66	33.3
	Week 3	105	71.81	23.21	6.7	73.33	100.0	98	-8.37	12.67	-60.0	-6.67	13.3
	Week 4	104	74.49	22.28	0.0	80.00	100.0	97	-7.28	16.02	-73.3	-6.66	33.3
	Week 5	100	75.07	21.12	6.7	80.00	100.0	92	-6.30	14.50	-46.7	-3.33	40.0
	Week 6	98	75.03	21.88	6.7	80.00	100.0	89	-8.24	17.67	-80.0	-6.66	40.0
	Week 7	110	75.58	20.40	0.0	80.00	100.0	99	-5.86	19.92	-80.0	-6.66	40.0
	Week 8	102	74.97	22.21	0.0	80.00	100.0	91	-6.08	18.74	-73.3	-6.66	53.3
	Week 9	104	73.65	23.51	0.0	80.00	100.0	95	-7.16	17.78	-60.0	-6.67	53.3
	Week 10	103	74.50	20.44	6.7	80.00	100.0	94	-6.60	17.77	-60.0	-6.67	53.3
	Week 11	101	74.13	22.46	0.0	80.00	100.0	91	-6.08	18.56	-53.3	-6.66	53.3
	Week 12	100	72.60	25.35	0.0	80.00	100.0	92	-7.17	22.50	-93.3	-6.67	53.3
	Week 14	101	75.97	21.34	0.0	80.00	100.0	91	-5.20	21.61	-73.3	0.00	53.3
	Week 17	95	75.30	19.95	26.7	80.00	100.0	85	-6.82	18.08	-53.3	-6.67	53.3
	Week 20	88	72.88	23.89	0.0	80.00	100.0	81	-9.38	24.03	-80.0	-6.67	53.3
	Week 23	84	71.35	22.97	0.0	73.33	100.0	78	-10.17	24.75	-100.0	-6.67	60.0
	Week 26	78	70.60	25.57	0.0	80.00	100.0	72	-11.48	27.82	-100.0	-6.67	46.7
	Week 29	83	71.89	22.16	0.0	73.33	100.0	78	-9.83	23.56	-73.3	-6.67	40.0
	Week 32	71	71.83	20.85	13.3	73.33	100.0	66	-11.01	23.81	-66.7	-6.67	40.0
	Week 35	70	69.81	22.97	0.0	73.33	100.0	64	-11.77	23.90	-73.3	-13.33	40.0
	Week 38	70	69.62	24.12	0.0	73.33	100.0	65	-11.69	22.14	-66.7	-6.67	40.0
	Week 41	65	69.85	20.85	20.0	73.33	100.0	60	-12.67	22.69	-66.7	-13.33	40.0
	Week 44	58	67.70	22.51	0.0	73.33	100.0	52	-17.44	25.74	-86.7	-20.00	40.0
	Week 47	53	72.58	22.29	0.0	80.00	100.0	48	-11.39	24.25	-73.3	-10.00	40.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	45	71.56	23.24	20.0	73.33	100.0	43	-13.95	21.47	-60.0	-6.67	33.3
	Week 53	39	75.38	19.05	33.3	80.00	100.0	37	-9.73	21.52	-60.0	-6.67	40.0
	Week 56	37	70.99	21.33	20.0	80.00	100.0	35	-12.57	23.14	-66.7	-13.33	33.3
	Week 59	30	73.78	19.49	33.3	73.33	100.0	29	-10.12	20.44	-46.7	-6.67	33.3
	Week 62	28	75.95	19.57	40.0	76.67	100.0	27	-11.85	21.67	-60.0	-6.67	33.3
	Week 65	24	73.33	21.54	26.7	73.33	100.0	23	-8.41	20.32	-46.7	-6.67	26.7
	Week 68	19	78.25	19.35	40.0	86.67	100.0	19	-6.67	20.85	-46.7	-6.67	33.3
	Week 71	19	76.49	20.65	26.7	73.33	100.0	19	-8.42	21.53	-46.7	-6.67	33.3
	Week 74	18	73.70	20.26	33.3	73.33	100.0	18	-12.59	19.52	-53.3	-13.34	26.7
	Week 77	19	70.18	24.38	20.0	73.33	100.0	18	-12.22	16.84	-40.0	-10.00	20.0
	Week 80	16	72.08	26.91	26.7	80.00	100.0	15	-7.11	21.45	-53.3	0.00	26.7
	Week 83	14	69.05	25.83	20.0	73.33	100.0	13	-9.74	20.66	-53.3	-6.67	26.7
	Week 86	14	75.71	22.13	33.3	80.00	100.0	13	-7.18	19.14	-53.3	-6.67	20.0
	Week 89	14	67.62	27.16	20.0	70.00	100.0	14	-13.81	23.01	-53.3	-13.34	26.7
	Week 92	13	68.72	30.35	20.0	80.00	100.0	13	-12.82	25.45	-60.0	-6.67	26.7
	Week 95	10	71.33	24.95	33.3	76.67	100.0	10	-12.00	19.32	-46.7	-10.00	20.0
	Week 98	10	68.67	27.04	26.7	70.00	100.0	10	-12.67	20.23	-53.3	-10.00	20.0
	Plat+Gem (N=136)												
	BASELINE	105	71.49	25.17	0.0	73.33	100.0						
	Week 1	98	70.75	24.92	0.0	73.33	100.0	87	-1.46	16.06	-60.0	0.00	46.7
	Week 2	95	70.25	22.49	0.0	73.33	100.0	83	-4.74	17.81	-46.7	-6.66	60.0
	Week 3	104	71.54	22.87	0.0	73.33	100.0	89	-1.20	16.22	-46.7	0.00	60.0
	Week 4	104	71.15	22.69	0.0	73.33	100.0	89	-3.15	18.07	-73.3	0.00	60.0
	Week 5	107	69.78	23.66	0.0	80.00	100.0	89	-4.42	19.36	-80.0	-6.66	66.7
	Week 6	98	69.59	24.44	0.0	73.33	100.0	82	-3.98	20.60	-80.0	0.00	60.0
	Week 7	105	70.98	22.74	0.0	80.00	100.0	86	-4.57	19.46	-60.0	0.00	60.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 8	95	66.53	26.29	0.0	73.33	100.0	80	-9.17	23.89	-100.0	-6.67	33.3
	Week 9	99	69.76	23.99	6.7	73.33	100.0	81	-6.50	22.24	-86.7	-6.66	33.3
	Week 10	88	69.17	24.14	0.0	73.33	100.0	71	-6.20	22.83	-86.7	0.00	46.7
	Week 11	93	70.90	23.83	0.0	80.00	100.0	77	-5.97	20.99	-66.7	-6.66	60.0
	Week 12	85	68.86	23.01	13.3	73.33	100.0	72	-7.59	21.47	-73.3	-6.67	60.0
	Week 14	85	67.61	22.68	13.3	73.33	100.0	70	-10.19	21.22	-60.0	-6.67	26.7
	Week 17	87	71.34	21.13	26.7	73.33	100.0	72	-8.52	22.36	-66.7	-6.67	46.7
	Week 20	66	73.33	21.94	13.3	76.67	100.0	58	-6.44	22.61	-66.7	0.00	53.3
	Week 23	64	71.04	23.61	13.3	80.00	100.0	53	-9.31	20.64	-60.0	-6.66	33.3
	Week 26	61	72.68	24.36	0.0	80.00	100.0	53	-9.31	22.05	-73.3	-6.66	26.7
	Week 29	58	73.10	22.82	0.0	80.00	100.0	49	-9.80	22.77	-100.0	-6.66	26.7
	Week 32	46	75.22	22.78	6.7	80.00	100.0	42	-5.40	19.93	-73.3	-3.33	26.7
	Week 35	42	73.97	23.18	0.0	80.00	100.0	38	-7.54	20.04	-80.0	-6.67	26.7
	Week 38	41	73.50	23.83	0.0	80.00	100.0	37	-9.37	23.17	-80.0	-6.66	33.3
	Week 41	38	73.86	17.15	13.3	73.33	100.0	34	-7.26	16.93	-53.3	-6.67	26.7
	Week 44	32	68.75	26.37	0.0	73.33	100.0	29	-12.41	26.29	-93.3	-6.66	26.7
	Week 47	32	74.37	20.95	0.0	76.67	100.0	28	-8.10	24.37	-73.3	-3.33	33.3
	Week 50	25	68.53	26.42	0.0	73.33	100.0	23	-10.14	21.35	-73.3	-6.67	33.3
	Week 53	27	77.28	13.37	53.3	80.00	100.0	25	-5.60	13.43	-26.7	-6.67	20.0
	Week 56	26	67.44	25.18	0.0	73.33	100.0	23	-13.62	18.69	-73.3	-13.33	13.3
	Week 59	23	77.68	12.33	53.3	80.00	100.0	21	-4.76	13.52	-40.0	-6.66	20.0
	Week 62	19	75.79	15.90	33.3	80.00	100.0	17	-6.67	19.44	-66.7	-6.66	13.3
	Week 65	17	73.73	19.79	13.3	73.33	100.0	15	-7.56	26.29	-86.7	-6.66	20.0
	Week 68	15	73.78	18.94	33.3	80.00	100.0	13	-9.23	18.16	-60.0	-6.67	13.3
	Week 71	15	68.89	23.73	13.3	73.33	100.0	13	-12.31	23.23	-53.3	-6.67	20.0
	Week 74	12	78.33	16.85	33.3	80.00	100.0	11	-0.61	9.64	-13.3	0.00	13.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Europe	EV+Pembro (N= 98)												
	BASELINE	79	80.25	20.71	6.7	86.67	100.0						
	Week 1	74	77.66	23.16	6.7	80.00	100.0	71	-3.47	12.89	-46.7	0.00	20.0
	Week 2	79	77.64	22.06	13.3	80.00	100.0	71	-4.98	12.17	-40.0	0.00	33.3
	Week 3	78	74.87	22.99	13.3	80.00	100.0	69	-6.96	12.65	-46.7	-6.66	20.0
	Week 4	78	80.09	20.87	20.0	86.67	100.0	70	-3.52	16.79	-73.3	0.00	40.0
	Week 5	70	79.90	19.31	20.0	80.00	100.0	62	-2.80	13.42	-40.0	0.00	46.7
	Week 6	70	80.57	20.70	6.7	86.67	100.0	61	-3.17	18.48	-80.0	0.00	46.7
	Week 7	78	80.26	19.02	26.7	80.00	100.0	68	-1.76	17.72	-53.3	0.00	60.0
	Week 8	72	81.02	21.34	13.3	86.67	100.0	61	-2.29	18.21	-46.7	0.00	53.3
	Week 9	80	79.17	19.71	13.3	83.34	100.0	70	-4.19	16.80	-46.7	0.00	53.3
	Week 10	71	79.72	20.45	20.0	86.67	100.0	62	-0.75	18.11	-33.3	0.00	60.0
	Week 11	76	80.26	21.09	20.0	86.67	100.0	66	-0.61	19.42	-46.7	0.00	66.7
	Week 12	73	78.63	23.33	6.7	86.67	100.0	65	-2.56	23.47	-93.3	0.00	60.0
	Week 14	74	82.70	17.55	33.3	86.67	100.0	64	-0.52	18.53	-46.7	0.00	53.3
	Week 17	70	83.24	18.04	33.3	86.67	100.0	62	1.18	20.89	-60.0	0.00	60.0
	Week 20	70	79.24	22.66	13.3	86.67	100.0	63	-3.17	25.59	-80.0	0.00	60.0
	Week 23	61	78.58	23.35	0.0	86.67	100.0	57	-4.56	26.58	-80.0	0.00	60.0
	Week 26	62	79.68	19.14	33.3	86.67	100.0	55	-2.55	20.71	-66.7	0.00	46.7
	Week 29	63	76.51	21.21	0.0	80.00	100.0	57	-5.61	19.14	-60.0	-6.66	46.7
	Week 32	51	76.21	19.83	26.7	80.00	100.0	47	-6.95	19.06	-46.7	-6.66	33.3
	Week 35	56	75.12	22.72	0.0	80.00	100.0	52	-8.46	17.96	-60.0	-6.67	33.3
	Week 38	51	75.69	22.93	0.0	80.00	100.0	48	-7.64	19.97	-60.0	-6.67	53.3
	Week 41	52	76.15	19.82	20.0	80.00	100.0	48	-6.81	18.93	-46.7	-6.67	40.0
	Week 44	43	74.73	21.36	20.0	80.00	100.0	39	-10.43	19.27	-46.7	-13.33	33.3
	Week 47	39	72.65	24.60	0.0	80.00	100.0	36	-12.22	25.32	-73.3	-10.00	40.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	37	78.74	21.25	20.0	86.67	100.0	36	-7.96	20.08	-66.7	-6.67	33.3
	Week 53	28	78.10	22.14	6.7	83.34	100.0	27	-4.94	22.16	-66.7	-6.66	40.0
	Week 56	30	75.78	24.35	0.0	80.00	100.0	29	-11.03	22.20	-73.3	-6.66	26.7
	Week 59	27	79.26	21.35	0.0	86.67	100.0	27	-9.13	20.93	-73.3	-6.67	33.3
	Week 62	23	77.39	25.80	0.0	86.67	100.0	23	-10.43	24.69	-73.3	-6.66	26.7
	Week 65	23	76.81	25.73	6.7	86.67	100.0	23	-7.83	21.52	-66.7	-6.67	33.3
	Week 68	21	80.32	21.45	20.0	86.67	100.0	21	-6.03	19.88	-53.3	0.00	26.7
	Week 71	19	78.60	24.50	13.3	86.67	100.0	19	-8.07	21.38	-60.0	-6.66	26.7
	Week 74	15	78.22	24.23	20.0	86.67	100.0	15	-8.44	22.74	-53.3	-6.67	33.3
	Week 77	19	74.39	26.97	20.0	86.67	100.0	19	-12.28	20.52	-53.3	-6.67	33.3
	Week 80	17	77.25	27.29	20.0	86.67	100.0	17	-7.06	22.30	-53.3	0.00	26.7
	Week 83	16	78.33	24.16	26.7	86.67	100.0	16	-5.00	21.98	-46.7	-6.67	40.0
	Week 86	14	79.52	23.60	26.7	86.67	100.0	14	-8.09	16.78	-46.7	-3.34	20.0
	Week 89	14	77.62	23.18	26.7	86.67	100.0	14	-9.05	18.78	-46.7	-6.67	26.7
	Week 92	11	85.46	21.25	26.7	86.67	100.0	11	-4.85	18.40	-46.7	0.00	26.7
	Week 95	10	78.67	24.30	26.7	86.67	100.0	10	-10.00	14.82	-46.7	-10.00	6.7
	Plat+Gem (N=102)												
	BASELINE	71	71.17	27.32	0.0	73.33	100.0						
	Week 1	71	67.04	27.67	0.0	80.00	100.0	61	-5.57	14.87	-60.0	0.00	13.3
	Week 2	67	66.37	25.52	0.0	66.67	100.0	56	-6.67	16.08	-46.7	-6.66	33.3
	Week 3	68	68.24	25.71	0.0	73.33	100.0	56	-3.93	14.98	-46.7	0.00	26.7
	Week 4	75	69.24	25.32	0.0	73.33	100.0	59	-6.10	16.53	-73.3	-6.66	26.7
	Week 5	77	67.79	25.40	0.0	73.33	100.0	60	-8.67	17.63	-80.0	-6.67	26.7
	Week 6	70	66.48	26.06	0.0	66.67	100.0	56	-8.81	16.14	-53.3	-6.67	20.0
	Week 7	72	67.32	25.74	0.0	66.67	100.0	55	-9.09	18.30	-53.3	-6.67	40.0
	Week 8	65	63.38	27.82	0.0	66.67	100.0	53	-12.70	24.57	-100.0	-6.67	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	70	68.10	23.78	6.7	73.33	100.0	55	-9.09	23.39	-86.7	-6.66	33.3
	Week 10	60	65.78	25.20	0.0	73.33	100.0	46	-10.29	24.17	-86.7	-6.67	40.0
	Week 11	64	67.50	25.10	0.0	73.33	100.0	50	-9.07	19.41	-60.0	-6.67	33.3
	Week 12	60	66.56	23.63	6.7	66.67	100.0	48	-10.42	21.30	-73.3	-6.67	26.7
	Week 14	56	65.24	23.64	20.0	66.67	100.0	42	-13.49	22.93	-53.3	-13.34	33.3
	Week 17	58	69.08	22.91	13.3	73.33	100.0	44	-10.30	24.71	-53.3	-6.67	46.7
	Week 20	47	73.62	21.62	0.0	80.00	100.0	37	-7.03	23.25	-53.3	-6.66	53.3
	Week 23	44	74.70	22.81	13.3	80.00	100.0	32	-10.00	21.28	-53.3	-6.67	33.3
	Week 26	39	76.07	22.72	6.7	80.00	100.0	30	-8.67	21.74	-73.3	-3.33	20.0
	Week 29	34	74.31	21.78	0.0	80.00	100.0	25	-9.60	24.95	-100.0	-6.67	20.0
	Week 32	33	75.15	21.68	6.7	80.00	100.0	27	-6.91	23.05	-73.3	-6.67	33.3
	Week 35	30	70.89	22.93	0.0	66.67	100.0	24	-11.11	25.46	-80.0	-10.00	40.0
	Week 38	26	70.26	25.87	0.0	73.33	100.0	21	-12.70	28.59	-80.0	-13.33	40.0
	Week 41	22	72.73	16.83	40.0	73.33	100.0	17	-12.55	18.99	-60.0	-13.33	13.3
	Week 44	20	63.33	26.97	0.0	63.34	100.0	16	-18.33	32.16	-93.3	-13.33	33.3
	Week 47	16	66.25	23.78	0.0	73.33	93.3	12	-18.33	25.76	-73.3	-13.34	13.3
	Week 50	11	58.18	28.45	0.0	66.67	100.0	10	-16.00	24.78	-73.3	-10.01	6.7
	Week 53	11	70.91	14.99	53.3	73.33	93.3	10	-7.34	16.16	-26.7	-6.67	26.7
	Week 56	10	70.67	26.14	6.7	76.67	93.3	8	-6.67	5.04	-13.3	-6.67	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
North America	EV+Pembro (N= 57)												
	BASELINE	47	78.30	25.61	6.7	86.67	100.0						
	Week 1	39	71.79	28.26	13.3	86.67	100.0	37	-7.03	12.95	-53.3	0.00	6.7
	Week 2	44	67.12	29.20	6.7	80.00	100.0	42	-11.11	16.57	-60.0	-6.67	26.7
	Week 3	44	69.39	28.41	6.7	80.00	100.0	40	-6.67	12.36	-33.3	-6.66	13.3
	Week 4	44	73.49	24.25	0.0	80.00	100.0	41	-3.41	18.74	-46.7	-6.66	60.0
	Week 5	47	72.06	23.00	20.0	80.00	100.0	41	-8.13	16.77	-60.0	-6.66	26.7
	Week 6	44	74.09	20.75	33.3	76.67	100.0	39	-4.62	16.41	-53.3	0.00	40.0
	Week 7	46	77.68	19.84	20.0	83.34	100.0	42	-1.90	14.82	-26.7	0.00	40.0
	Week 8	47	77.73	17.93	33.3	86.67	100.0	42	-1.90	16.94	-40.0	0.00	60.0
	Week 9	46	73.62	22.92	20.0	80.00	100.0	42	-4.92	18.33	-66.7	-6.66	40.0
	Week 10	47	77.59	19.33	26.7	86.67	100.0	44	-3.03	17.16	-60.0	0.00	40.0
	Week 11	47	77.16	18.79	26.7	80.00	100.0	42	-1.43	21.36	-53.3	0.00	60.0
	Week 12	44	75.15	21.73	0.0	80.00	100.0	40	-1.67	21.86	-53.3	-6.66	60.0
	Week 14	43	76.59	19.10	26.7	86.67	100.0	39	0.00	19.88	-40.0	0.00	60.0
	Week 17	40	75.17	19.68	26.7	80.00	100.0	37	-3.60	20.58	-40.0	0.00	66.7
	Week 20	38	73.51	23.63	0.0	80.00	100.0	35	-6.67	21.87	-80.0	0.00	33.3
	Week 23	38	74.21	22.52	13.3	80.00	100.0	35	-5.90	20.50	-60.0	-6.66	40.0
	Week 26	35	76.19	22.77	20.0	86.67	100.0	32	-2.29	23.01	-66.7	0.00	46.7
	Week 29	38	77.89	19.36	26.7	80.00	100.0	34	-2.75	22.81	-73.3	0.00	40.0
	Week 32	32	74.17	22.77	20.0	80.00	100.0	29	-9.66	22.51	-66.7	-6.66	33.3
	Week 35	33	77.58	19.92	26.7	86.67	100.0	30	-8.22	21.35	-66.7	-6.66	26.7
	Week 38	32	75.83	21.87	26.7	83.34	100.0	29	-5.98	23.66	-66.7	0.00	46.7
	Week 41	28	79.52	18.23	26.7	83.34	100.0	24	-5.83	18.68	-53.3	-6.67	40.0
	Week 44	21	71.43	25.05	0.0	80.00	100.0	20	-17.33	27.65	-86.7	-10.00	26.7
	Week 47	24	76.11	21.62	13.3	80.00	100.0	23	-9.57	25.09	-73.3	-6.67	40.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	23	69.57	22.55	26.7	73.33	100.0	20	-17.67	21.44	-60.0	-20.00	20.0
	Week 53	17	77.65	18.55	33.3	80.00	100.0	14	-13.33	22.95	-60.0	-13.33	20.0
	Week 56	20	72.67	19.21	26.7	80.00	100.0	17	-12.16	24.41	-66.7	-13.33	20.0
	Week 59	17	74.12	15.44	46.7	73.33	100.0	14	-12.86	18.39	-46.7	-10.00	20.0
	Week 62	14	79.53	15.35	46.7	80.00	100.0	13	-12.31	20.70	-53.3	-6.66	26.7
	Week 65	12	80.56	14.62	53.3	86.67	100.0	9	-8.15	20.49	-46.7	-13.33	20.0
	Week 68	10	83.33	14.49	60.0	86.67	100.0	9	-11.11	15.63	-40.0	-13.33	13.3
	Week 71	10	81.33	16.27	53.3	83.34	100.0	8	-14.17	22.09	-46.7	-10.00	20.0
	Week 74	10	78.67	18.27	46.7	76.67	100.0	9	-14.81	21.28	-53.3	-13.33	20.0
	Plat+Gem (N= 51)												
	BASELINE	42	78.25	21.03	20.0	80.00	100.0						
	Week 1	41	73.66	20.44	26.7	80.00	100.0	36	-2.96	13.56	-33.3	0.00	33.3
	Week 2	38	71.23	22.25	20.0	73.33	100.0	33	-7.88	18.14	-46.7	-6.66	26.7
	Week 3	40	75.67	20.79	20.0	80.00	100.0	35	-5.52	19.83	-53.3	-6.66	53.3
	Week 4	35	75.24	20.49	20.0	80.00	100.0	29	-3.45	14.76	-40.0	0.00	26.7
	Week 5	39	73.85	22.86	13.3	80.00	100.0	32	-5.42	17.88	-53.3	0.00	26.7
	Week 6	34	72.75	22.28	26.7	80.00	100.0	30	-4.00	18.08	-40.0	0.00	40.0
	Week 7	42	75.71	19.47	20.0	80.00	100.0	37	-3.24	16.60	-40.0	0.00	33.3
	Week 8	39	73.67	21.35	20.0	80.00	100.0	33	-3.84	18.71	-33.3	-6.66	40.0
	Week 9	39	72.82	19.55	26.7	73.33	100.0	33	-3.03	20.35	-40.0	-6.67	46.7
	Week 10	39	73.33	19.35	20.0	80.00	100.0	32	-3.33	20.39	-33.3	-3.33	46.7
	Week 11	39	75.56	18.44	40.0	80.00	100.0	33	-1.82	22.19	-60.0	0.00	46.7
	Week 12	36	73.52	18.75	26.7	80.00	100.0	32	-3.33	20.60	-53.3	-6.67	46.7
	Week 14	34	75.69	21.01	13.3	80.00	100.0	29	0.00	21.82	-40.0	0.00	53.3
	Week 17	37	72.97	18.19	26.7	80.00	100.0	31	-6.67	19.47	-53.3	-6.67	33.3
	Week 20	27	78.77	16.75	20.0	80.00	100.0	23	2.90	18.51	-26.7	0.00	53.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 23	27	74.07	26.56	0.0	86.67	100.0	23	1.16	24.42	-60.0	0.00	60.0
	Week 26	28	73.10	24.84	6.7	76.67	100.0	25	-1.33	24.94	-53.3	0.00	60.0
	Week 29	29	72.87	23.70	13.3	80.00	100.0	25	-6.13	23.25	-53.3	0.00	46.7
	Week 32	17	67.45	23.20	26.7	66.67	100.0	17	-8.23	24.10	-60.0	-6.67	46.7
	Week 35	16	73.33	25.88	13.3	80.00	100.0	15	-3.11	25.31	-80.0	0.00	33.3
	Week 38	16	74.17	20.20	26.7	83.34	100.0	13	-2.56	18.17	-26.7	-6.66	46.7
	Week 41	16	74.17	22.03	13.3	80.00	100.0	13	-1.54	18.69	-26.7	-6.67	46.7
	Week 44	13	68.21	21.97	6.7	73.33	93.3	11	-3.03	14.10	-33.3	-6.66	20.0
	Week 47	11	78.79	11.86	60.0	73.33	100.0	9	-3.70	7.53	-13.3	-6.67	13.3
	Week 50	17	71.76	23.04	0.0	73.33	100.0	15	-0.44	17.90	-20.0	-6.67	40.0
	Week 53	13	76.92	11.74	53.3	80.00	93.3	11	0.00	21.29	-26.7	-6.67	40.0
	Week 56	11	61.82	17.66	20.0	66.67	86.7	9	-17.78	27.49	-60.0	-13.34	33.3
	Week 59	11	75.76	13.09	53.3	73.33	100.0	9	-5.93	20.12	-40.0	-6.66	33.3
	Week 62	11	76.97	18.23	33.3	86.67	100.0	9	-5.92	29.71	-66.7	-6.66	46.7
	Week 65	10	72.00	22.18	13.3	80.00	86.7	8	-10.00	37.54	-86.7	-10.00	46.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Rest of World	EV+Pembro (N= 85)												
	BASELINE	80	78.58	20.89	20.0	80.00	100.0						
	Week 1	77	76.54	21.97	0.0	80.00	100.0	76	-1.75	15.68	-60.0	0.00	53.3
	Week 2	80	74.42	21.90	6.7	80.00	100.0	76	-4.39	16.24	-73.3	0.00	33.3
	Week 3	76	73.07	22.24	6.7	80.00	100.0	73	-5.02	14.69	-60.0	0.00	26.7
	Week 4	72	76.76	21.75	0.0	80.00	100.0	68	-2.35	16.60	-53.3	0.00	40.0
	Week 5	73	78.45	21.10	6.7	86.67	100.0	70	-0.67	17.33	-46.7	0.00	53.3
	Week 6	74	79.01	19.70	6.7	80.00	100.0	70	-1.33	16.23	-46.7	0.00	40.0
	Week 7	71	77.00	20.83	0.0	80.00	100.0	66	-2.73	22.73	-80.0	0.00	46.7
	Week 8	72	76.57	21.61	0.0	80.00	100.0	68	-1.57	20.74	-73.3	0.00	40.0
	Week 9	71	76.15	23.03	0.0	80.00	100.0	68	-2.94	19.22	-60.0	0.00	46.7
	Week 10	73	76.16	19.97	6.7	80.00	100.0	69	-2.61	20.78	-60.0	0.00	46.7
	Week 11	71	76.06	21.25	0.0	80.00	100.0	67	-1.99	20.95	-53.3	0.00	53.3
	Week 12	69	76.52	23.31	0.0	80.00	100.0	66	-1.72	22.77	-73.3	0.00	53.3
	Week 14	68	74.80	22.77	0.0	80.00	100.0	64	-4.38	24.44	-73.3	0.00	40.0
	Week 17	68	75.59	20.72	26.7	80.00	100.0	63	-3.92	21.51	-53.3	0.00	53.3
	Week 20	59	72.09	23.34	6.7	73.33	100.0	56	-6.43	26.08	-66.7	-6.66	46.7
	Week 23	63	69.31	24.50	0.0	73.33	100.0	59	-7.80	27.29	-100.0	-6.66	46.7
	Week 26	59	67.80	26.38	0.0	73.33	100.0	57	-10.99	30.59	-100.0	-6.66	53.3
	Week 29	56	70.71	21.52	13.3	76.67	100.0	54	-7.78	24.77	-66.7	-6.66	53.3
	Week 32	52	71.79	21.31	13.3	73.33	100.0	49	-7.89	23.95	-66.7	-6.67	53.3
	Week 35	43	70.70	19.85	6.7	73.33	100.0	40	-8.50	22.74	-73.3	-10.00	40.0
	Week 38	49	68.30	22.91	6.7	73.33	100.0	47	-9.22	22.05	-60.0	-6.67	40.0
	Week 41	49	65.71	22.19	6.7	73.33	100.0	47	-13.19	22.82	-66.7	-13.33	40.0
	Week 44	44	70.15	20.61	33.3	73.33	100.0	41	-10.41	25.99	-60.0	-6.67	53.3
	Week 47	37	70.81	21.04	20.0	73.33	100.0	35	-10.29	22.01	-60.0	-6.67	40.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	29	67.81	21.16	20.0	73.33	100.0	28	-16.67	20.73	-60.0	-13.34	13.3
	Week 53	34	72.74	18.38	33.3	73.33	100.0	33	-10.51	19.44	-46.7	-13.33	40.0
	Week 56	31	70.54	21.96	26.7	73.33	100.0	30	-10.67	22.39	-53.3	-10.00	40.0
	Week 59	28	69.76	22.33	33.3	73.33	100.0	27	-11.36	24.66	-60.0	-6.67	40.0
	Week 62	28	72.14	23.38	33.3	73.33	100.0	27	-11.61	22.77	-66.7	-6.67	33.3
	Week 65	23	67.54	22.77	26.7	73.33	100.0	22	-13.64	25.24	-73.3	-13.34	40.0
	Week 68	22	66.67	23.55	26.7	70.00	100.0	22	-13.94	27.05	-66.7	-13.33	40.0
	Week 71	22	65.45	25.50	20.0	73.33	100.0	22	-15.15	26.92	-73.3	-16.67	40.0
	Week 74	22	64.85	23.11	20.0	70.00	100.0	22	-17.58	23.78	-80.0	-20.00	40.0
	Week 77	18	58.52	21.88	20.0	60.00	100.0	17	-21.18	22.01	-53.3	-26.66	33.3
	Week 80	16	60.00	25.76	13.3	63.34	100.0	15	-19.55	23.57	-53.3	-20.00	40.0
	Week 83	16	55.42	22.01	20.0	56.67	100.0	15	-21.33	23.12	-53.3	-26.66	40.0
	Week 86	13	55.38	19.51	26.7	53.33	86.7	12	-19.44	24.69	-46.7	-23.33	26.7
	Week 89	12	52.78	23.69	13.3	53.33	93.3	12	-23.33	28.21	-60.0	-30.00	33.3
	Plat+Gem (N= 89)												
	BASELINE	75	73.87	20.67	20.0	73.33	100.0						
	Week 1	61	74.54	18.52	33.3	73.33	100.0	61	-2.51	17.00	-40.0	-6.66	46.7
	Week 2	66	73.54	19.71	20.0	76.67	100.0	62	-2.58	16.70	-46.7	0.00	60.0
	Week 3	76	73.68	19.53	13.3	76.67	100.0	71	-1.03	15.23	-40.0	0.00	60.0
	Week 4	73	73.88	17.45	33.3	73.33	100.0	68	-0.59	16.64	-33.3	0.00	60.0
	Week 5	71	73.80	19.98	13.3	80.00	100.0	64	-1.46	18.34	-46.7	0.00	66.7
	Week 6	70	73.52	22.21	6.7	80.00	100.0	63	-0.64	21.38	-80.0	0.00	60.0
	Week 7	72	74.91	19.52	6.7	80.00	100.0	65	-1.23	20.03	-60.0	0.00	60.0
	Week 8	63	74.29	20.14	6.7	80.00	100.0	58	-4.14	21.70	-60.0	0.00	33.3
	Week 9	68	74.90	19.89	6.7	73.33	100.0	62	-2.58	20.43	-80.0	0.00	40.0
	Week 10	67	73.43	20.42	6.7	80.00	100.0	61	-2.40	20.37	-66.7	0.00	46.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	65	74.87	19.61	26.7	80.00	100.0	60	-2.78	21.20	-66.7	0.00	60.0
	Week 12	63	75.34	20.02	13.3	80.00	100.0	58	-2.30	21.50	-73.3	0.00	60.0
	Week 14	63	74.39	19.24	20.0	73.33	100.0	57	-2.92	19.11	-60.0	0.00	33.3
	Week 17	60	74.44	22.03	13.3	80.00	100.0	55	-3.88	20.15	-66.7	0.00	40.0
	Week 20	52	74.23	23.80	13.3	80.00	100.0	50	-5.47	22.92	-66.7	0.00	40.0
	Week 23	44	72.42	23.25	20.0	80.00	100.0	42	-6.67	21.44	-60.0	-6.66	33.3
	Week 26	41	75.28	23.91	0.0	86.67	100.0	40	-4.67	20.88	-66.7	0.00	33.3
	Week 29	37	79.46	18.75	26.7	86.67	100.0	36	-2.78	17.92	-53.3	0.00	33.3
	Week 32	33	81.01	18.34	20.0	86.67	100.0	32	-0.42	18.39	-60.0	0.00	26.7
	Week 35	30	82.22	19.04	33.3	86.67	100.0	30	0.45	20.78	-53.3	0.00	46.7
	Week 38	32	81.67	19.75	26.7	86.67	100.0	31	0.21	22.74	-60.0	0.00	33.3
	Week 41	27	80.74	17.38	40.0	80.00	100.0	26	0.26	21.46	-53.3	0.00	33.3
	Week 44	27	80.25	19.52	40.0	86.67	100.0	26	-0.26	22.67	-60.0	0.00	33.3
	Week 47	29	82.07	17.47	33.3	86.67	100.0	28	1.90	21.84	-66.7	0.00	33.3
	Week 50	23	80.00	19.70	33.3	86.67	100.0	22	0.30	20.31	-40.0	0.00	33.3
	Week 53	22	82.42	14.91	53.3	86.67	100.0	21	2.86	16.68	-33.3	0.00	33.3
	Week 56	18	75.93	26.68	0.0	83.34	100.0	17	-3.92	23.69	-73.3	0.00	33.3
	Week 59	17	84.31	12.68	66.7	80.00	100.0	16	5.42	11.73	-13.3	0.00	33.3
	Week 62	16	84.58	13.27	53.3	86.67	100.0	15	8.44	14.14	-13.3	6.66	40.0
	Week 65	15	85.78	13.06	66.7	86.67	100.0	14	4.76	10.92	-13.3	3.33	26.7
	Week 68	12	80.56	19.38	33.3	83.34	100.0	11	0.00	13.66	-26.7	0.00	26.7
	Week 71	13	75.38	27.27	13.3	86.67	100.0	12	-5.56	21.43	-46.7	0.00	20.0
	Week 74	10	82.67	20.17	33.3	86.67	100.0	10	2.00	8.34	-13.3	0.00	13.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	EV+Pembro (N=198)												
	BASELINE	170	78.59	22.11	6.7	86.67	100.0						
	Week 1	157	76.52	23.83	0.0	80.00	100.0	152	-2.37	14.40	-60.0	0.00	53.3
	Week 2	167	74.29	24.21	6.7	80.00	100.0	155	-5.55	15.71	-73.3	0.00	33.3
	Week 3	161	73.58	24.62	6.7	80.00	100.0	147	-5.40	13.63	-60.0	0.00	26.7
	Week 4	158	77.55	22.50	0.0	80.00	100.0	145	-2.57	18.09	-73.3	0.00	60.0
	Week 5	154	77.49	21.87	6.7	80.00	100.0	140	-2.71	16.37	-60.0	0.00	53.3
	Week 6	153	78.17	20.88	6.7	80.00	100.0	138	-2.27	17.47	-80.0	0.00	40.0
	Week 7	159	78.11	20.83	0.0	80.00	100.0	142	-2.07	19.17	-80.0	0.00	46.7
	Week 8	154	78.36	21.44	0.0	86.67	100.0	135	-1.68	19.46	-73.3	0.00	60.0
	Week 9	162	76.25	22.59	0.0	80.00	100.0	146	-3.88	18.92	-66.7	0.00	53.3
	Week 10	159	77.44	20.01	6.7	80.00	100.0	144	-2.18	19.15	-60.0	0.00	53.3
	Week 11	161	77.47	21.28	0.0	80.00	100.0	143	-1.26	20.81	-53.3	0.00	60.0
	Week 12	154	76.80	23.40	0.0	80.00	100.0	140	-1.95	23.29	-93.3	0.00	60.0
	Week 14	154	77.71	20.54	0.0	80.00	100.0	137	-2.04	22.54	-73.3	0.00	60.0
	Week 17	145	78.07	20.18	26.7	80.00	100.0	130	-1.80	21.69	-60.0	0.00	66.7
	Week 20	139	74.68	23.97	0.0	80.00	100.0	126	-5.34	25.98	-80.0	0.00	53.3
	Week 23	133	72.58	24.91	0.0	80.00	100.0	122	-7.10	26.55	-100.0	-6.66	60.0
	Week 26	129	74.00	24.05	0.0	80.00	100.0	118	-5.88	26.90	-100.0	0.00	53.3
	Week 29	131	74.10	21.33	0.0	80.00	100.0	120	-6.28	22.92	-73.3	-3.33	53.3
	Week 32	111	73.63	21.56	13.3	80.00	100.0	102	-7.25	22.67	-66.7	-6.67	53.3
	Week 35	109	73.82	21.84	0.0	80.00	100.0	100	-8.33	20.83	-73.3	-6.67	40.0
	Week 38	107	72.02	24.17	0.0	73.33	100.0	100	-7.93	21.72	-66.7	-6.67	46.7
	Week 41	103	73.33	20.79	6.7	73.33	100.0	94	-8.87	20.16	-53.3	-6.67	40.0
	Week 44	88	72.35	21.07	20.0	73.33	100.0	81	-10.62	23.99	-66.7	-6.67	53.3
	Week 47	80	74.08	21.08	0.0	73.33	100.0	75	-10.13	23.21	-60.0	-6.67	40.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	73	73.52	21.52	20.0	73.33	100.0	68	-11.96	21.29	-60.0	-6.67	33.3
	Week 53	64	76.25	19.30	6.7	80.00	100.0	59	-9.38	21.45	-66.7	-6.67	40.0
	Week 56	66	72.73	22.97	0.0	76.67	100.0	61	-10.93	24.19	-73.3	-6.67	40.0
	Week 59	58	74.94	20.76	0.0	80.00	100.0	54	-10.12	22.76	-73.3	-6.67	40.0
	Week 62	54	75.18	22.56	0.0	80.00	100.0	52	-11.15	23.94	-73.3	-6.67	33.3
	Week 65	51	75.03	22.97	6.7	80.00	100.0	47	-10.07	23.26	-73.3	-6.67	40.0
	Week 68	49	76.46	21.82	20.0	80.00	100.0	48	-9.58	22.84	-66.7	-6.67	40.0
	Week 71	47	74.47	24.45	13.3	80.00	100.0	45	-11.85	24.82	-73.3	-6.67	40.0
	Week 74	42	73.02	23.88	20.0	73.33	100.0	41	-13.82	24.10	-80.0	-13.33	40.0
	Week 77	38	68.95	25.01	20.0	66.67	100.0	36	-15.93	22.44	-53.3	-16.67	33.3
	Week 80	35	70.10	26.73	13.3	73.33	100.0	32	-13.33	24.89	-53.3	-13.34	40.0
	Week 83	32	68.75	26.15	20.0	76.67	100.0	30	-12.44	25.65	-53.3	-13.33	40.0
	Week 86	30	68.89	24.78	26.7	76.67	100.0	27	-13.09	22.83	-53.3	-13.33	26.7
	Week 89	28	67.86	26.23	13.3	73.34	100.0	26	-15.13	26.10	-60.0	-10.00	33.3
	Week 92	24	70.56	26.37	26.7	83.34	100.0	22	-13.03	23.14	-60.0	-10.00	26.7
	Week 95	21	66.03	27.24	26.7	73.33	100.0	20	-17.00	22.73	-66.7	-13.33	20.0
	Week 98	16	75.00	22.24	40.0	80.00	100.0	15	-9.33	18.99	-53.3	0.00	20.0
	Week 101	12	70.56	30.41	20.0	86.67	100.0	12	-19.44	26.43	-60.0	-10.00	6.7
	Week 104	10	72.00	26.63	26.7	73.34	100.0	10	-18.00	19.13	-46.7	-20.00	6.7
	Plat+Gem (N=185)												
	BASELINE	146	74.11	24.47	0.0	80.00	100.0						
	Week 1	131	73.08	22.80	0.0	80.00	100.0	120	-3.06	14.72	-40.0	0.00	46.7
	Week 2	128	69.64	23.59	0.0	73.33	100.0	115	-5.51	16.57	-46.7	-6.66	60.0
	Week 3	141	72.53	22.91	0.0	80.00	100.0	126	-2.80	16.21	-46.7	0.00	60.0
	Week 4	139	72.42	22.07	0.0	80.00	100.0	119	-2.91	16.30	-73.3	0.00	60.0
	Week 5	143	72.07	23.19	0.0	80.00	100.0	120	-4.72	18.42	-80.0	-6.66	66.7

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 6	133	71.18	24.18	0.0	80.00	100.0	114	-4.15	18.78	-53.3	0.00	60.0
	Week 7	142	72.91	23.12	0.0	80.00	100.0	120	-3.28	19.27	-60.0	0.00	60.0
	Week 8	125	71.41	23.03	0.0	73.33	100.0	109	-6.61	21.82	-100.0	-6.67	40.0
	Week 9	135	72.59	21.26	6.7	73.33	100.0	115	-5.28	22.10	-86.7	-6.66	46.7
	Week 10	131	71.09	21.86	0.0	80.00	100.0	111	-4.26	21.59	-86.7	0.00	46.7
	Week 11	128	73.44	21.62	0.0	80.00	100.0	109	-3.85	20.61	-60.0	-6.66	60.0
	Week 12	124	71.77	21.71	6.7	76.67	100.0	108	-5.00	22.35	-73.3	-6.67	60.0
	Week 14	121	72.84	21.19	13.3	73.33	100.0	101	-4.23	21.47	-53.3	-6.66	53.3
	Week 17	121	73.22	21.22	13.3	80.00	100.0	101	-5.61	20.86	-53.3	-6.66	46.7
	Week 20	98	75.65	22.21	0.0	80.00	100.0	86	-4.34	23.34	-66.7	0.00	53.3
	Week 23	93	73.76	23.73	0.0	80.00	100.0	78	-5.90	23.07	-60.0	-3.33	60.0
	Week 26	86	75.43	23.10	6.7	80.00	100.0	75	-5.60	23.38	-73.3	0.00	60.0
	Week 29	76	75.88	21.94	0.0	80.00	100.0	65	-6.77	23.05	-100.0	0.00	46.7
	Week 32	62	79.68	18.16	26.7	86.67	100.0	56	-1.79	18.44	-60.0	0.00	46.7
	Week 35	58	79.66	19.20	13.3	86.67	100.0	52	-1.03	19.28	-46.7	0.00	46.7
	Week 38	60	78.44	20.33	20.0	86.67	100.0	52	-2.95	22.65	-60.0	0.00	46.7
	Week 41	52	77.95	19.06	13.3	80.00	100.0	44	-3.33	21.40	-60.0	-3.34	46.7
	Week 44	46	73.62	25.18	0.0	80.00	100.0	40	-4.50	27.52	-93.3	0.00	33.3
	Week 47	44	78.79	20.09	0.0	80.00	100.0	38	-3.69	23.49	-73.3	0.00	33.3
	Week 50	42	74.13	24.65	0.0	76.67	100.0	38	-1.58	22.38	-73.3	0.00	40.0
	Week 53	38	80.35	13.24	53.3	80.00	100.0	34	1.37	18.55	-26.7	0.00	40.0
	Week 56	32	73.75	22.46	0.0	80.00	100.0	28	-8.10	24.50	-73.3	-6.67	33.3
	Week 59	31	80.86	13.85	40.0	80.00	100.0	27	-0.99	15.77	-40.0	0.00	33.3
	Week 62	29	82.07	14.27	33.3	86.67	100.0	26	0.26	22.35	-66.7	0.00	46.7
	Week 65	25	78.40	18.79	13.3	80.00	100.0	21	-3.81	25.78	-86.7	0.00	46.7
	Week 68	20	76.67	17.10	33.3	80.00	100.0	16	-5.42	18.89	-60.0	-3.33	26.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 71	17	74.51	23.83	6.7	80.00	100.0	14	-5.71	22.01	-53.3	0.00	20.0
	Week 74	17	78.43	19.37	13.3	80.00	100.0	14	0.00	8.67	-13.3	0.00	13.3
	Week 77	16	75.83	24.93	0.0	86.67	100.0	13	-0.51	15.02	-33.3	0.00	20.0
	Week 80	13	82.05	9.96	66.7	80.00	100.0	12	-0.56	10.43	-20.0	0.00	13.3
	Week 83	11	80.60	13.15	60.0	73.33	100.0	10	-3.34	12.67	-33.3	-3.34	13.3
	Week 86	12	82.22	12.17	60.0	86.67	100.0	11	-1.21	16.00	-40.0	0.00	20.0
	Week 89	11	81.82	10.79	66.7	80.00	100.0	10	-0.67	15.54	-33.3	3.34	13.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	EV+Pembro (N= 42)												
	BASELINE	36	81.85	20.94	6.7	86.67	100.0						
	Week 1	33	73.54	23.89	13.3	80.00	100.0	32	-8.75	11.91	-40.0	-6.67	6.7
	Week 2	36	73.15	22.90	20.0	80.00	100.0	34	-8.63	11.67	-40.0	-6.67	13.3
	Week 3	37	70.27	21.12	13.3	73.33	100.0	35	-9.14	12.11	-40.0	-6.67	13.3
	Week 4	36	76.48	20.12	26.7	80.00	100.0	34	-5.10	11.95	-33.3	-6.66	33.3
	Week 5	36	77.04	17.56	40.0	80.00	100.0	33	-5.25	14.79	-40.0	0.00	46.7
	Week 6	35	79.62	18.22	40.0	80.00	100.0	32	-4.79	15.26	-46.7	0.00	46.7
	Week 7	36	80.00	14.86	46.7	80.00	100.0	34	-2.55	18.93	-40.0	0.00	60.0
	Week 8	37	79.28	17.20	33.3	80.00	100.0	36	-2.78	16.67	-33.3	0.00	53.3
	Week 9	35	79.24	17.17	40.0	86.67	100.0	34	-3.92	13.74	-40.0	0.00	33.3
	Week 10	32	79.79	19.85	20.0	86.67	100.0	31	-1.51	18.03	-40.0	0.00	60.0
	Week 11	33	80.40	16.99	33.3	80.00	100.0	32	-1.67	18.63	-40.0	0.00	66.7
	Week 12	32	78.12	20.48	26.7	80.00	100.0	31	-2.37	20.19	-53.3	0.00	60.0
	Week 14	31	81.72	18.21	33.3	86.67	100.0	30	-1.11	14.12	-46.7	0.00	33.3
	Week 17	33	80.40	17.79	33.3	80.00	100.0	32	-2.29	18.67	-53.3	0.00	60.0
	Week 20	28	79.05	19.00	26.7	83.34	100.0	28	-4.29	19.56	-46.7	0.00	60.0
	Week 23	29	80.23	16.95	33.3	86.67	100.0	29	-2.07	20.25	-46.7	0.00	60.0
	Week 26	27	76.30	20.20	33.3	80.00	100.0	26	-5.64	19.84	-53.3	0.00	40.0
	Week 29	26	78.20	19.19	20.0	80.00	100.0	25	-3.20	18.27	-46.7	0.00	46.7
	Week 32	24	75.83	18.84	40.0	76.67	100.0	23	-11.01	17.01	-46.7	-6.67	13.3
	Week 35	23	76.52	17.74	40.0	80.00	100.0	22	-8.79	18.10	-53.3	-3.34	26.7
	Week 38	25	77.07	15.28	46.7	80.00	100.0	24	-7.50	21.11	-46.7	-6.67	53.3
	Week 41	26	71.28	22.61	26.7	80.00	100.0	25	-10.13	22.62	-66.7	-13.33	40.0
	Week 44	20	71.67	24.93	0.0	76.67	100.0	19	-16.84	23.35	-86.7	-13.33	13.3
	Week 47	20	67.67	27.47	13.3	80.00	100.0	19	-13.68	26.71	-73.3	-6.67	40.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	16	69.58	24.09	26.7	76.67	100.0	16	-18.33	18.78	-66.7	-16.67	6.7
	Week 53	15	73.33	22.11	33.3	80.00	100.0	15	-7.56	20.29	-46.7	-6.67	40.0
	Week 56	15	74.22	18.49	33.3	80.00	100.0	15	-12.00	14.07	-46.7	-13.33	13.3
	Week 59	14	71.91	20.95	33.3	76.67	100.0	14	-13.33	17.93	-46.7	-13.33	20.0
	Week 62	11	77.58	24.63	26.7	86.67	100.0	11	-12.12	16.82	-46.7	0.00	0.0
	Plat+Gem (N= 57)												
	BASELINE	42	72.86	20.05	6.7	73.33	100.0						
	Week 1	42	65.56	24.01	13.3	66.67	100.0	38	-6.14	17.49	-60.0	-6.67	26.7
	Week 2	43	71.94	20.40	33.3	73.33	100.0	36	-4.44	17.89	-40.0	0.00	33.3
	Week 3	43	70.70	20.63	26.7	73.33	100.0	36	-3.70	16.60	-53.3	0.00	26.7
	Week 4	44	71.67	20.24	20.0	73.33	100.0	37	-4.14	16.73	-40.0	0.00	33.3
	Week 5	44	68.94	22.50	20.0	73.33	100.0	36	-6.11	17.41	-46.7	0.00	26.7
	Week 6	41	68.46	23.33	13.3	73.33	100.0	35	-5.14	20.46	-80.0	0.00	26.7
	Week 7	44	69.70	19.69	20.0	73.33	100.0	37	-8.29	17.24	-53.3	-6.66	26.7
	Week 8	42	65.40	26.88	6.7	73.33	100.0	35	-9.14	24.47	-73.3	-6.66	26.7
	Week 9	42	69.05	22.47	20.0	73.33	100.0	35	-4.38	20.26	-46.7	0.00	26.7
	Week 10	35	68.95	23.76	6.7	73.33	100.0	28	-9.05	22.82	-66.7	0.00	26.7
	Week 11	40	68.33	22.28	26.7	73.33	100.0	34	-7.65	21.97	-66.7	-6.66	26.7
	Week 12	35	71.05	20.77	26.7	73.33	100.0	30	-6.67	17.85	-66.7	-6.67	26.7
	Week 14	32	65.62	22.98	20.0	70.00	100.0	27	-11.36	21.55	-60.0	-13.33	26.7
	Week 17	34	68.04	22.43	26.7	73.33	100.0	29	-10.57	24.27	-66.7	-6.67	26.7
	Week 20	28	72.62	19.40	33.3	73.33	100.0	24	-3.89	18.64	-53.3	-3.33	26.7
	Week 23	22	73.33	24.17	20.0	80.00	100.0	19	-5.97	19.36	-40.0	-6.66	26.7
	Week 26	22	73.33	25.70	0.0	83.34	100.0	20	-3.00	17.50	-46.7	-3.33	20.0
	Week 29	24	75.56	19.53	26.7	76.67	100.0	21	-2.54	16.66	-53.3	0.00	26.7
	Week 32	21	64.76	25.40	6.7	73.33	100.0	20	-12.00	27.41	-73.3	-6.67	20.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 35	18	63.70	28.03	0.0	66.67	100.0	17	-14.51	32.51	-80.0	-6.66	20.0
	Week 38	14	65.71	28.63	0.0	66.67	100.0	13	-10.77	30.49	-80.0	0.00	20.0
	Week 41	13	70.26	15.30	40.0	73.33	100.0	12	-6.67	17.75	-46.7	-3.33	26.7
	Week 44	14	66.67	17.54	40.0	66.67	100.0	13	-11.79	17.46	-46.7	-6.66	13.3
	Week 47	12	70.00	16.45	46.7	70.00	100.0	11	-5.46	19.05	-33.3	0.00	20.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Visceral metastases	EV+Pembro (N=170)												
	BASELINE	146	76.85	22.76	6.7	80.00	100.0						
	Week 1	135	72.89	25.00	0.0	80.00	100.0	131	-3.71	14.28	-53.3	0.00	53.3
	Week 2	145	71.86	24.08	6.7	80.00	100.0	134	-6.37	15.20	-60.0	-6.66	33.3
	Week 3	141	70.02	25.79	6.7	73.33	100.0	129	-6.41	14.37	-60.0	0.00	26.7
	Week 4	136	73.58	23.48	0.0	80.00	100.0	125	-4.37	18.45	-73.3	0.00	60.0
	Week 5	131	74.66	22.61	6.7	80.00	100.0	118	-3.50	17.73	-60.0	0.00	53.3
	Week 6	127	76.06	20.89	6.7	80.00	100.0	113	-3.01	18.37	-80.0	0.00	46.7
	Week 7	135	76.15	20.69	0.0	80.00	100.0	121	-1.43	21.01	-80.0	0.00	60.0
	Week 8	131	76.34	21.47	0.0	80.00	100.0	118	-1.19	19.93	-73.3	0.00	60.0
	Week 9	136	75.20	23.02	0.0	80.00	100.0	124	-3.49	18.44	-66.7	0.00	53.3
	Week 10	135	76.74	20.16	6.7	80.00	100.0	124	-1.34	19.46	-60.0	0.00	60.0
	Week 11	134	76.32	21.50	0.0	80.00	100.0	121	-0.83	21.39	-53.3	0.00	66.7
	Week 12	131	76.49	23.22	0.0	80.00	100.0	120	-0.44	22.45	-73.3	0.00	60.0
	Week 14	130	77.38	20.58	0.0	80.00	100.0	117	-0.74	23.21	-73.3	0.00	60.0
	Week 17	124	78.33	19.77	26.7	80.00	100.0	111	0.12	23.18	-60.0	0.00	66.7
	Week 20	115	76.58	21.96	6.7	80.00	100.0	105	-1.97	25.13	-66.7	0.00	60.0
	Week 23	111	76.10	21.66	0.0	80.00	100.0	103	-1.75	25.36	-80.0	0.00	60.0
	Week 26	106	76.54	22.30	6.7	80.00	100.0	97	-1.65	25.80	-73.3	0.00	53.3
	Week 29	106	76.73	19.67	13.3	80.00	100.0	98	-2.31	22.51	-73.3	0.00	53.3
	Week 32	92	74.35	22.41	13.3	80.00	100.0	85	-5.25	23.03	-66.7	0.00	53.3
	Week 35	86	74.73	21.62	6.7	80.00	100.0	79	-6.50	21.35	-73.3	-6.66	40.0
	Week 38	90	72.74	22.67	6.7	73.33	100.0	84	-5.64	22.13	-66.7	0.00	53.3
	Week 41	87	71.80	21.80	6.7	73.33	100.0	81	-7.90	22.09	-66.7	-6.67	40.0
	Week 44	73	71.69	23.14	0.0	73.33	100.0	68	-9.90	26.10	-86.7	-6.67	53.3
	Week 47	68	75.20	21.01	13.3	80.00	100.0	63	-6.35	24.90	-73.3	-6.66	40.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	61	73.55	21.57	20.0	80.00	100.0	57	-10.76	21.30	-60.0	-6.67	33.3
	Week 53	54	74.69	20.53	6.7	80.00	100.0	50	-8.27	23.35	-66.7	-6.67	40.0
	Week 56	58	73.91	21.17	0.0	80.00	100.0	54	-9.14	24.10	-73.3	-6.67	40.0
	Week 59	50	74.40	20.44	0.0	80.00	100.0	47	-9.22	23.24	-73.3	-6.67	40.0
	Week 62	45	75.85	22.03	0.0	80.00	100.0	43	-9.92	24.45	-73.3	-6.67	33.3
	Week 65	37	75.32	22.05	6.7	80.00	100.0	34	-7.65	24.13	-66.7	-6.67	40.0
	Week 68	35	74.48	20.74	20.0	80.00	100.0	34	-9.80	23.63	-53.3	-10.00	40.0
	Week 71	31	74.41	22.32	13.3	80.00	100.0	30	-9.33	25.16	-60.0	-10.00	40.0
	Week 74	29	72.64	21.33	20.0	73.33	100.0	28	-12.14	23.73	-53.3	-13.33	40.0
	Week 77	26	70.26	21.18	20.0	73.33	100.0	25	-12.80	22.19	-53.3	-13.33	33.3
	Week 80	22	71.21	23.04	20.0	76.67	100.0	21	-9.21	26.45	-53.3	-6.67	40.0
	Week 83	23	71.88	21.74	26.7	73.33	100.0	22	-10.61	26.40	-53.3	-13.33	40.0
	Week 86	21	71.75	21.80	26.7	80.00	100.0	20	-12.00	23.15	-53.3	-10.00	26.7
	Week 89	21	66.67	24.59	20.0	66.67	100.0	20	-14.00	24.56	-53.3	-13.33	33.3
	Week 92	18	69.63	26.49	20.0	80.00	100.0	17	-13.33	23.45	-60.0	-13.33	26.7
	Week 95	13	69.23	27.15	26.7	80.00	100.0	12	-17.22	25.18	-66.7	-13.33	20.0
	Week 98	11	76.97	22.97	26.7	80.00	100.0	11	-9.09	19.15	-53.3	-6.67	20.0
	Week 101	11	66.67	29.52	20.0	80.00	100.0	11	-18.79	26.97	-60.0	-6.67	6.7
	Plat+Gem (N=161)												
	BASELINE	129	71.21	24.17	0.0	73.33	100.0						
	Week 1	113	68.91	24.44	0.0	73.33	100.0	105	-3.94	14.76	-40.0	-6.66	46.7
	Week 2	108	67.90	24.13	0.0	73.33	100.0	98	-4.56	17.46	-46.7	-6.66	60.0
	Week 3	121	71.18	22.51	0.0	73.33	100.0	109	-1.84	16.10	-53.3	0.00	60.0
	Week 4	116	70.40	22.47	0.0	73.33	100.0	101	-1.91	16.18	-40.0	0.00	60.0
	Week 5	121	70.58	24.73	0.0	80.00	100.0	104	-2.56	17.73	-53.3	0.00	66.7
	Week 6	118	69.10	24.95	0.0	73.33	100.0	102	-3.46	17.77	-46.7	0.00	60.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 7	121	70.80	23.16	0.0	73.33	100.0	104	-3.40	18.83	-53.3	-3.33	60.0
	Week 8	108	70.19	24.04	0.0	73.33	100.0	96	-4.93	20.66	-73.3	-6.66	33.3
	Week 9	114	72.92	22.48	6.7	80.00	100.0	99	-1.82	21.46	-80.0	0.00	40.0
	Week 10	109	69.97	22.51	0.0	73.33	100.0	94	-3.26	21.94	-66.7	0.00	46.7
	Week 11	109	72.48	21.72	0.0	80.00	100.0	95	-2.32	20.04	-60.0	0.00	60.0
	Week 12	103	71.00	21.01	13.3	73.33	100.0	91	-3.88	21.41	-73.3	-6.66	60.0
	Week 14	98	70.27	21.32	20.0	73.33	100.0	85	-4.86	22.29	-53.3	-6.66	53.3
	Week 17	103	71.65	22.15	13.3	73.33	100.0	89	-4.79	22.11	-53.3	-6.66	46.7
	Week 20	82	73.82	22.12	0.0	80.00	100.0	75	-3.02	23.02	-66.7	0.00	53.3
	Week 23	77	72.38	24.58	0.0	80.00	100.0	68	-4.80	23.03	-60.0	-6.66	60.0
	Week 26	71	75.96	23.00	0.0	80.00	100.0	65	-2.97	20.55	-60.0	0.00	60.0
	Week 29	65	76.21	19.04	13.3	80.00	100.0	59	-4.29	17.01	-53.3	-6.66	33.3
	Week 32	52	76.41	19.51	20.0	76.67	100.0	49	-4.22	20.17	-60.0	-6.66	33.3
	Week 35	47	75.04	21.78	20.0	80.00	100.0	44	-4.39	24.23	-80.0	-6.66	40.0
	Week 38	42	75.87	21.94	20.0	83.34	100.0	39	-4.96	23.13	-60.0	-6.66	40.0
	Week 41	35	75.24	19.31	40.0	73.33	100.0	32	-5.84	19.87	-60.0	-6.67	33.3
	Week 44	36	71.11	25.75	0.0	73.33	100.0	33	-7.07	28.28	-93.3	0.00	33.3
	Week 47	32	76.04	21.54	0.0	80.00	100.0	30	-4.89	23.42	-73.3	0.00	33.3
	Week 50	30	70.44	24.80	0.0	73.33	100.0	29	-5.52	21.97	-73.3	-6.66	40.0
	Week 53	25	79.73	14.72	53.3	80.00	100.0	24	-0.28	16.39	-33.3	-6.66	40.0
	Week 56	22	69.70	26.49	0.0	73.33	100.0	21	-12.06	25.35	-73.3	-6.67	33.3
	Week 59	22	80.00	13.33	60.0	80.00	100.0	21	-2.22	16.24	-40.0	0.00	33.3
	Week 62	19	78.24	17.19	33.3	80.00	100.0	18	-3.34	23.12	-66.7	-3.33	46.7
	Week 65	19	77.54	20.51	13.3	80.00	100.0	18	-4.82	27.80	-86.7	-6.67	46.7
	Week 68	13	75.38	22.67	33.3	80.00	100.0	12	-11.11	18.28	-60.0	-6.67	13.3
	Week 71	13	70.26	27.97	13.3	80.00	100.0	12	-13.33	23.27	-53.3	-6.67	20.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 74	11	80.00	21.08	33.3	86.67	100.0	11	-2.43	10.01	-13.3	-6.66	13.3
	Week 77	10	85.33	15.01	53.3	86.67	100.0	10	1.33	10.33	-13.3	0.00	13.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Lymph node only	EV+Pembro (N= 60)												
	BASELINE	53	85.79	17.35	26.7	93.33	100.0						
	Week 1	49	84.49	16.35	33.3	86.67	100.0	47	-2.41	14.21	-60.0	0.00	33.3
	Week 2	50	79.60	22.55	20.0	86.67	100.0	48	-6.25	14.96	-73.3	0.00	13.3
	Week 3	50	81.07	16.46	40.0	86.67	100.0	47	-4.54	10.32	-33.3	0.00	20.0
	Week 4	50	86.67	15.36	46.7	93.33	100.0	47	-0.57	10.10	-33.3	0.00	26.7
	Week 5	53	83.90	15.16	46.7	86.67	100.0	49	-2.45	12.07	-33.3	0.00	33.3
	Week 6	53	83.40	19.06	6.7	86.67	100.0	50	-3.07	13.48	-53.3	0.00	33.3
	Week 7	52	85.38	14.58	40.0	86.67	100.0	48	-3.06	13.61	-33.3	0.00	40.0
	Week 8	52	83.85	18.02	13.3	86.67	100.0	47	-3.40	16.44	-46.7	0.00	33.3
	Week 9	53	80.63	18.41	13.3	86.67	100.0	49	-5.17	15.94	-46.7	-6.67	33.3
	Week 10	48	80.56	19.97	20.0	86.67	100.0	44	-4.39	16.64	-40.0	0.00	26.7
	Week 11	53	80.63	18.73	20.0	86.67	100.0	48	-4.45	15.58	-46.7	-6.66	33.3
	Week 12	48	76.67	23.01	6.7	86.67	100.0	45	-8.30	21.98	-93.3	-6.67	33.3
	Week 14	48	80.69	18.72	33.3	86.67	100.0	44	-4.39	16.13	-46.7	-3.33	33.3
	Week 17	46	79.13	19.66	33.3	86.67	100.0	44	-6.82	13.14	-40.0	-3.33	20.0
	Week 20	44	72.27	25.60	0.0	80.00	100.0	42	-13.18	22.50	-80.0	-6.67	20.0
	Week 23	43	73.18	23.66	13.3	80.00	100.0	41	-12.03	20.12	-66.7	-13.33	33.3
	Week 26	42	73.02	22.90	13.3	80.00	100.0	40	-12.33	20.68	-73.3	-6.67	33.3
	Week 29	45	71.85	23.09	0.0	80.00	100.0	42	-12.38	20.43	-60.0	-6.67	26.7
	Week 32	38	74.04	17.86	40.0	80.00	100.0	36	-13.15	18.13	-60.0	-13.33	20.0
	Week 35	42	73.65	21.39	0.0	80.00	100.0	40	-11.00	18.21	-60.0	-6.67	26.7
	Week 38	38	74.91	23.53	0.0	80.00	100.0	36	-10.56	19.61	-60.0	-6.67	40.0
	Week 41	37	75.86	19.77	33.3	73.33	100.0	34	-10.20	17.23	-40.0	-6.67	40.0
	Week 44	31	73.55	18.58	33.3	73.33	100.0	29	-14.94	18.66	-60.0	-13.33	20.0
	Week 47	28	70.24	24.91	0.0	73.33	100.0	27	-17.04	16.47	-60.0	-13.33	6.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	25	74.67	20.28	26.7	80.00	100.0	24	-14.72	15.97	-46.7	-10.00	13.3
	Week 53	23	79.71	16.99	33.3	80.00	100.0	22	-9.09	15.47	-33.3	-6.67	33.3
	Week 56	21	72.70	23.84	20.0	73.33	100.0	20	-14.33	16.79	-40.0	-10.00	13.3
	Week 59	20	76.33	20.69	33.3	76.67	100.0	19	-12.63	17.90	-60.0	-6.67	20.0
	Week 62	19	77.19	23.45	33.3	80.00	100.0	19	-12.98	18.25	-66.7	-6.67	6.7
	Week 65	20	73.00	24.32	26.7	73.33	100.0	19	-13.68	19.93	-73.3	-13.33	20.0
	Week 68	17	79.61	22.67	33.3	86.67	100.0	17	-9.02	19.57	-66.7	0.00	20.0
	Week 71	19	74.74	25.30	26.7	80.00	100.0	18	-14.82	20.27	-73.3	-6.67	6.7
	Week 74	17	72.55	26.45	20.0	73.33	100.0	17	-16.47	22.25	-80.0	-6.67	6.7
	Week 77	17	67.06	27.53	20.0	60.00	100.0	16	-17.08	18.69	-46.7	-13.34	6.7
	Week 80	17	68.63	29.60	13.3	73.33	100.0	15	-15.56	19.30	-46.7	-13.34	13.3
	Week 83	13	65.64	27.87	20.0	60.00	100.0	12	-13.33	17.29	-40.0	-13.34	13.3
	Week 86	12	65.55	25.72	33.3	53.33	100.0	10	-12.67	17.34	-46.7	-13.34	13.3
	Week 89	11	67.27	26.07	26.7	60.00	100.0	10	-14.67	20.80	-46.7	-6.67	13.3
	Plat+Gem (N= 67)												
	BASELINE	49	80.68	20.83	20.0	86.67	100.0						
	Week 1	51	74.77	20.45	20.0	80.00	100.0	45	-4.59	16.50	-60.0	0.00	33.3
	Week 2	53	73.46	21.02	26.7	73.33	100.0	44	-7.27	15.80	-46.7	-3.34	26.7
	Week 3	53	72.33	23.18	20.0	80.00	100.0	44	-6.82	17.04	-46.7	-6.66	53.3
	Week 4	58	75.17	20.32	6.7	80.00	100.0	47	-6.10	17.18	-73.3	0.00	20.0
	Week 5	56	72.38	20.04	20.0	73.33	100.0	44	-9.70	18.44	-80.0	-10.00	20.0
	Week 6	48	73.33	21.66	13.3	73.33	100.0	40	-6.50	21.80	-80.0	-3.33	40.0
	Week 7	56	74.17	20.42	26.7	80.00	100.0	46	-6.09	18.37	-60.0	0.00	33.3
	Week 8	52	69.36	24.88	0.0	73.33	100.0	42	-12.22	25.41	-100.0	-6.67	40.0
	Week 9	53	69.18	20.64	13.3	73.33	100.0	42	-12.06	22.20	-86.7	-10.00	46.7
	Week 10	47	72.06	22.10	13.3	80.00	100.0	36	-9.07	21.74	-86.7	-6.67	46.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	51	71.24	23.30	20.0	80.00	100.0	41	-10.57	23.14	-66.7	-6.67	46.7
	Week 12	47	72.48	22.14	6.7	73.33	100.0	39	-8.72	21.58	-73.3	-6.67	40.0
	Week 14	47	72.06	23.37	13.3	80.00	100.0	36	-9.07	21.68	-60.0	-6.67	46.7
	Week 17	45	72.30	20.74	26.7	80.00	100.0	35	-11.62	21.10	-66.7	-6.67	20.0
	Week 20	38	79.47	18.23	20.0	80.00	100.0	30	-4.89	19.41	-53.3	0.00	33.3
	Week 23	32	75.42	22.87	13.3	80.00	100.0	25	-9.07	20.98	-60.0	0.00	33.3
	Week 26	30	72.89	26.20	6.7	80.00	100.0	24	-9.72	25.25	-73.3	-3.33	40.0
	Week 29	28	73.81	26.85	0.0	80.00	100.0	21	-10.79	30.66	-100.0	0.00	46.7
	Week 32	26	73.85	25.43	6.7	83.34	100.0	22	-7.27	26.10	-73.3	-3.34	46.7
	Week 35	23	77.39	26.03	0.0	86.67	100.0	19	-5.96	26.47	-80.0	0.00	46.7
	Week 38	26	75.90	25.37	0.0	86.67	100.0	20	-5.67	29.99	-80.0	0.00	46.7
	Week 41	24	75.83	18.94	13.3	80.00	100.0	18	-5.56	23.12	-53.3	-3.34	46.7
	Week 44	18	71.11	22.64	6.7	76.67	100.0	14	-9.05	23.18	-60.0	-6.67	33.3
	Week 47	18	76.67	18.61	33.3	83.34	100.0	13	-7.18	24.41	-66.7	-6.67	33.3
	Week 50	16	73.33	25.42	0.0	76.67	100.0	13	-2.56	23.18	-33.3	-6.67	33.3
	Week 53	15	75.11	15.83	53.3	73.33	100.0	12	-2.22	24.01	-26.7	-3.34	33.3
	Week 56	15	71.56	23.70	6.7	80.00	100.0	11	-2.42	16.13	-20.0	-6.67	33.3
	Week 59	12	78.89	17.72	40.0	80.00	100.0	9	-0.74	13.92	-13.3	0.00	33.3
	Week 62	10	83.33	14.49	60.0	86.67	100.0	8	5.00	21.31	-20.0	0.00	40.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
EV+Pembro (N=202)												
BASELINE	160	72.92	23.22	20.0	80.00	100.0						
Week 1	141	70.87	23.18	0.0	73.33	100.0	129	-2.74	13.81	-46.7	0.00	60.0
Week 2	150	70.04	22.91	6.7	73.33	100.0	133	-3.66	14.08	-53.3	0.00	53.3
Week 3	139	71.18	23.62	0.0	73.33	100.0	122	-2.02	19.28	-53.3	0.00	60.0
Week 4	145	73.01	22.67	0.0	80.00	100.0	129	-1.45	17.32	-46.7	0.00	60.0
Week 5	137	72.55	22.23	0.0	73.33	100.0	121	-1.49	18.15	-53.3	0.00	60.0
Week 6	146	71.92	23.31	0.0	80.00	100.0	124	-2.15	22.03	-66.7	0.00	60.0
Week 7	147	74.56	21.08	0.0	80.00	100.0	124	-0.64	22.09	-73.3	0.00	60.0
Week 8	147	72.24	22.10	0.0	73.33	100.0	124	-2.15	21.72	-86.7	0.00	60.0
Week 9	142	71.83	22.38	0.0	80.00	100.0	121	-2.09	23.46	-100.0	0.00	60.0
Week 10	139	73.96	23.15	0.0	80.00	100.0	118	-0.23	23.24	-100.0	0.00	60.0
Week 11	137	75.82	21.00	0.0	80.00	100.0	115	-0.41	22.79	-100.0	0.00	60.0
Week 12	142	75.02	22.92	0.0	80.00	100.0	119	-0.73	22.68	-73.3	0.00	60.0
Week 14	139	74.96	22.51	0.0	80.00	100.0	116	-0.63	21.06	-73.3	0.00	60.0
Week 17	132	75.61	19.39	0.0	80.00	100.0	111	0.06	21.11	-73.3	0.00	53.3
Week 20	120	75.00	19.18	20.0	80.00	100.0	103	-2.59	22.60	-60.0	0.00	60.0
Week 23	117	75.04	19.04	20.0	80.00	100.0	97	-2.54	22.18	-73.3	-6.66	60.0
Week 26	112	75.36	21.29	6.7	80.00	100.0	94	-1.70	23.05	-80.0	0.00	60.0
Week 29	107	73.08	21.82	0.0	80.00	100.0	93	-5.30	25.32	-100.0	-6.67	60.0
Week 32	102	73.33	20.85	0.0	80.00	100.0	88	-5.61	22.55	-100.0	-6.66	60.0
Week 35	98	72.11	21.31	0.0	76.67	100.0	86	-6.20	25.64	-100.0	-6.67	53.3
Week 38	97	72.30	20.98	13.3	80.00	100.0	86	-4.88	25.04	-86.7	-6.66	60.0
Week 41	95	71.86	20.24	6.7	73.33	100.0	84	-5.08	22.57	-60.0	-6.66	53.3
Week 44	86	70.62	20.21	6.7	73.33	100.0	74	-6.13	20.46	-66.7	-6.67	40.0
Week 47	79	70.89	20.95	13.3	73.33	100.0	70	-5.52	19.76	-46.7	-6.67	46.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	74	69.28	21.33	0.0	73.33	100.0	64	-8.23	20.11	-46.7	-10.00	46.7
Week 53	74	67.30	21.80	6.7	66.67	100.0	63	-8.25	19.70	-46.7	-6.67	53.3
Week 56	72	67.78	21.05	20.0	66.67	100.0	61	-6.56	19.23	-46.7	-6.67	40.0
Week 59	69	68.31	19.28	20.0	73.33	100.0	57	-7.72	20.15	-46.7	-6.67	46.7
Week 62	62	67.74	20.53	13.3	73.33	100.0	52	-9.74	20.34	-66.7	-13.33	46.7
Week 65	43	68.37	19.36	20.0	73.33	100.0	40	-9.00	22.87	-46.7	-13.33	40.0
Week 68	46	66.96	23.72	6.7	66.67	100.0	42	-9.52	22.58	-66.7	-6.67	40.0
Week 71	42	68.57	23.25	13.3	73.33	100.0	38	-5.96	22.18	-60.0	-6.66	40.0
Week 74	38	71.05	19.25	20.0	73.33	100.0	35	-6.48	23.85	-60.0	-6.66	46.7
Week 77	37	72.07	17.90	33.3	73.33	100.0	33	-4.24	22.10	-46.7	-6.66	46.7
Week 80	36	71.11	19.12	33.3	73.33	100.0	34	-5.10	22.02	-46.7	-3.34	46.7
Week 83	30	71.33	20.20	13.3	73.33	100.0	29	-5.75	22.66	-66.7	-6.67	40.0
Week 86	26	67.69	22.29	13.3	66.67	100.0	25	-10.93	23.80	-73.3	-6.67	40.0
Week 89	20	72.00	20.13	13.3	70.00	100.0	19	-13.68	19.43	-66.7	-13.33	20.0
Week 92	19	68.42	23.71	13.3	66.67	100.0	18	-10.37	17.75	-53.3	-6.67	26.7
Week 95	14	79.52	15.35	53.3	80.00	100.0	13	-6.15	12.31	-33.3	0.00	6.7
Week 98	10	78.00	18.87	46.7	80.00	100.0	9	-6.67	11.54	-33.3	-6.67	6.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Plat+Gem (N=202)												
BASELINE	165	71.64	25.14	0.0	80.00	100.0						
Week 1	144	67.36	25.07	0.0	73.33	100.0	139	-4.08	14.14	-66.7	-6.66	26.7
Week 2	147	66.08	24.23	0.0	66.67	100.0	135	-7.46	16.73	-80.0	-6.66	26.7
Week 3	149	67.70	25.01	0.0	73.33	100.0	136	-6.57	17.53	-73.3	-6.66	53.3
Week 4	150	68.76	22.72	0.0	73.33	100.0	135	-5.09	17.60	-53.3	-6.66	40.0
Week 5	153	68.71	22.91	0.0	73.33	100.0	138	-4.98	18.51	-53.3	-6.66	40.0
Week 6	145	66.67	24.77	0.0	73.33	100.0	131	-6.62	21.25	-80.0	-6.66	53.3
Week 7	148	67.07	23.10	13.3	70.00	100.0	134	-7.66	22.28	-66.7	-6.67	80.0
Week 8	145	66.57	24.31	0.0	73.33	100.0	132	-7.68	21.71	-80.0	-6.67	60.0
Week 9	141	66.05	24.52	0.0	73.33	100.0	125	-8.27	23.85	-80.0	-6.66	60.0
Week 10	142	67.42	23.70	0.0	73.33	100.0	130	-5.74	22.97	-66.7	-6.66	66.7
Week 11	126	66.14	24.55	0.0	73.33	100.0	114	-8.19	23.48	-86.7	-6.67	73.3
Week 12	130	66.36	24.09	0.0	70.00	100.0	115	-7.48	21.85	-53.3	-6.67	73.3
Week 14	125	66.56	23.40	0.0	73.33	100.0	109	-7.89	22.32	-60.0	-6.67	53.3
Week 17	120	66.39	24.33	6.7	66.67	100.0	106	-9.50	24.24	-80.0	-6.67	46.7
Week 20	104	70.26	23.54	6.7	80.00	100.0	91	-4.91	19.75	-73.3	0.00	53.3
Week 23	88	73.33	22.08	13.3	80.00	100.0	80	-3.25	18.92	-46.7	0.00	53.3
Week 26	81	71.28	23.47	0.0	80.00	100.0	75	-4.18	21.39	-66.7	0.00	66.7
Week 29	77	70.30	25.14	0.0	80.00	100.0	71	-8.17	24.23	-93.3	-6.67	53.3
Week 32	63	72.59	22.63	6.7	80.00	100.0	58	-4.94	24.52	-80.0	0.00	60.0
Week 35	62	73.33	20.56	20.0	80.00	100.0	56	-5.12	21.61	-46.7	-6.66	46.7
Week 38	56	73.57	23.34	6.7	80.00	100.0	50	-7.33	25.56	-93.3	-6.66	53.3
Week 41	52	70.26	23.22	6.7	73.33	100.0	47	-8.09	22.71	-53.3	-6.67	53.3
Week 44	49	65.17	24.77	6.7	66.67	100.0	44	-11.52	27.33	-80.0	-6.67	53.3
Week 47	43	66.98	27.18	0.0	73.33	100.0	39	-10.60	25.94	-66.7	-6.67	53.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	36	70.00	25.07	13.3	80.00	100.0	31	-5.81	28.06	-66.7	0.00	66.7
Week 53	31	69.03	26.14	13.3	80.00	100.0	28	-5.71	28.03	-66.7	-6.67	60.0
Week 56	30	67.56	27.56	0.0	76.67	100.0	29	-4.14	32.29	-80.0	-6.66	66.7
Week 59	23	68.12	26.51	20.0	73.33	100.0	21	-0.32	31.45	-66.7	0.00	66.7
Week 62	20	68.33	23.98	26.7	80.00	100.0	20	1.00	29.36	-66.7	0.00	60.0
Week 65	17	64.31	20.94	26.7	66.67	93.3	16	-6.25	23.66	-46.7	-3.33	60.0
Week 68	13	67.18	22.52	26.7	66.67	93.3	13	-1.54	26.41	-40.0	0.00	66.7
Week 71	13	65.13	24.97	13.3	73.33	93.3	13	-3.08	27.44	-53.3	0.00	60.0
Week 74	11	75.15	18.40	26.7	80.00	93.3	11	-1.21	22.87	-26.7	-6.66	60.0
Week 77	11	80.00	15.20	53.3	86.67	93.3	11	-5.46	23.06	-46.7	-6.67	46.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Present	EV+Pembro (N= 50)												
	BASELINE	40	70.00	24.39	20.0	73.33	100.0						
	Week 1	38	63.86	25.07	0.0	63.34	100.0	34	-6.67	16.25	-46.7	-3.33	40.0
	Week 2	35	69.14	24.04	6.7	73.33	100.0	32	-1.25	13.90	-33.3	0.00	26.7
	Week 3	32	71.67	24.25	0.0	80.00	100.0	30	0.22	22.59	-53.3	0.00	46.7
	Week 4	35	69.33	22.53	6.7	73.33	100.0	31	-2.37	16.20	-46.7	0.00	40.0
	Week 5	32	71.25	20.21	0.0	66.67	100.0	28	-0.95	16.70	-33.3	-3.33	46.7
	Week 6	35	70.29	21.41	6.7	80.00	100.0	30	0.44	23.02	-46.7	-6.67	60.0
	Week 7	35	75.05	18.74	26.7	80.00	100.0	29	2.07	19.69	-33.3	0.00	46.7
	Week 8	38	67.54	21.71	0.0	73.33	100.0	31	-5.81	22.49	-80.0	-6.66	33.3
	Week 9	33	69.90	20.08	26.7	73.33	100.0	29	-1.61	21.80	-53.3	-6.66	60.0
	Week 10	30	73.78	18.77	26.7	73.33	100.0	25	4.27	21.16	-33.3	0.00	46.7
	Week 11	31	76.13	20.13	6.7	80.00	100.0	27	0.25	24.70	-73.3	0.00	53.3
	Week 12	32	77.29	18.46	26.7	80.00	100.0	28	3.57	21.04	-26.7	0.00	53.3
	Week 14	36	74.26	22.03	20.0	80.00	100.0	31	1.07	20.15	-46.7	0.00	40.0
	Week 17	33	75.76	18.70	33.3	80.00	100.0	27	1.98	18.29	-26.7	0.00	40.0
	Week 20	28	74.05	20.07	33.3	73.33	100.0	25	-4.53	22.75	-53.3	-6.67	46.7
	Week 23	28	72.38	17.75	33.3	73.33	100.0	24	-4.44	19.03	-40.0	-6.67	33.3
	Week 26	28	71.90	21.80	6.7	73.33	100.0	24	-5.00	26.54	-80.0	0.00	40.0
	Week 29	27	72.84	22.34	0.0	80.00	100.0	25	-2.93	27.76	-100.0	-6.66	40.0
	Week 32	25	72.27	22.91	0.0	73.33	100.0	23	-6.67	25.98	-100.0	-6.67	40.0
	Week 35	26	67.69	21.56	0.0	66.67	93.3	24	-9.17	30.82	-100.0	-13.33	46.7
	Week 38	26	66.92	19.82	13.3	70.00	93.3	24	-10.00	27.03	-86.7	-13.33	33.3
	Week 41	25	69.07	17.73	26.7	73.33	100.0	23	-9.27	23.76	-60.0	-6.67	40.0
	Week 44	22	68.79	16.12	33.3	66.67	100.0	20	-4.67	19.95	-33.3	-6.67	33.3
	Week 47	14	66.67	20.92	20.0	70.00	93.3	13	-3.59	21.19	-46.7	-6.67	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	65.00	25.85	0.0	73.33	93.3	17	-8.63	23.07	-46.7	-6.67	33.3
	Week 53	21	62.22	22.84	6.7	66.67	93.3	18	-10.37	19.02	-46.7	-10.00	26.7
	Week 56	18	64.07	17.44	26.7	60.00	93.3	15	-7.11	18.77	-46.7	-6.67	20.0
	Week 59	18	63.33	19.84	20.0	66.67	93.3	15	-8.44	19.10	-46.7	-6.67	20.0
	Week 62	13	67.69	14.62	46.7	66.67	93.3	11	-9.70	21.78	-46.7	-6.67	40.0
	Week 68	12	63.89	23.35	6.7	66.67	93.3	11	-12.12	26.80	-66.7	-6.67	40.0
	Plat+Gem (N= 50)												
	BASELINE	40	65.00	24.47	13.3	60.00	100.0						
	Week 1	35	61.52	25.05	0.0	60.00	93.3	33	-5.25	14.02	-33.3	-6.66	20.0
	Week 2	33	60.61	24.12	20.0	66.67	93.3	30	-9.33	20.24	-80.0	-6.66	20.0
	Week 3	33	66.26	22.60	20.0	73.33	100.0	29	-4.37	14.50	-53.3	0.00	13.3
	Week 4	36	63.70	20.87	20.0	66.67	100.0	32	-4.37	15.67	-46.7	0.00	20.0
	Week 5	36	63.33	25.32	13.3	70.00	100.0	32	-5.00	22.21	-53.3	0.00	40.0
	Week 6	32	64.38	25.71	6.7	70.00	100.0	29	-3.91	24.98	-66.7	0.00	40.0
	Week 7	35	61.71	24.22	13.3	66.67	100.0	31	-6.88	22.67	-60.0	-6.66	40.0
	Week 8	35	62.86	26.48	6.7	66.67	100.0	31	-6.02	26.41	-80.0	0.00	40.0
	Week 9	34	59.80	25.29	6.7	63.34	100.0	30	-9.11	30.80	-80.0	-3.33	40.0
	Week 10	33	60.81	25.43	13.3	66.67	100.0	30	-4.89	26.84	-66.7	0.00	46.7
	Week 11	30	60.22	25.70	6.7	66.67	100.0	26	-8.97	25.36	-73.3	0.00	40.0
	Week 12	32	59.17	26.76	6.7	66.67	100.0	27	-9.14	23.69	-46.7	-6.66	46.7
	Week 14	27	63.46	26.30	6.7	73.33	100.0	22	-7.57	25.22	-60.0	0.00	40.0
	Week 17	28	63.57	25.69	6.7	63.34	100.0	23	-6.67	23.78	-66.7	-6.66	46.7
	Week 20	20	63.67	26.88	13.3	73.34	100.0	16	-2.92	13.33	-40.0	0.00	20.0
	Week 23	15	71.11	24.90	13.3	80.00	100.0	14	-0.48	16.63	-40.0	0.00	26.7
	Week 26	15	69.33	25.67	6.7	80.00	100.0	14	-2.38	15.16	-33.3	0.00	20.0
	Week 29	13	66.15	29.50	0.0	80.00	100.0	12	-16.11	32.09	-93.3	-6.67	6.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Absent	EV+Pembro (N=152)												
	BASELINE	120	73.89	22.84	20.0	80.00	100.0						
	Week 1	103	73.46	22.01	20.0	80.00	100.0	95	-1.33	12.63	-33.3	0.00	60.0
	Week 2	115	70.32	22.65	20.0	73.33	100.0	101	-4.42	14.12	-53.3	0.00	53.3
	Week 3	107	71.03	23.54	6.7	73.33	100.0	92	-2.75	18.15	-46.7	0.00	60.0
	Week 4	110	74.18	22.69	0.0	80.00	100.0	98	-1.16	17.73	-46.7	0.00	60.0
	Week 5	105	72.95	22.89	0.0	80.00	100.0	93	-1.65	18.64	-53.3	0.00	60.0
	Week 6	111	72.43	23.94	0.0	80.00	100.0	94	-2.98	21.76	-66.7	0.00	60.0
	Week 7	112	74.41	21.84	0.0	80.00	100.0	95	-1.47	22.81	-73.3	0.00	60.0
	Week 8	109	73.88	22.09	6.7	80.00	100.0	93	-0.93	21.44	-86.7	0.00	60.0
	Week 9	109	72.42	23.08	0.0	80.00	100.0	92	-2.25	24.07	-100.0	0.00	60.0
	Week 10	109	74.01	24.29	0.0	80.00	100.0	93	-1.43	23.73	-100.0	0.00	60.0
	Week 11	106	75.72	21.34	0.0	80.00	100.0	88	-0.61	22.32	-100.0	0.00	60.0
	Week 12	110	74.36	24.10	0.0	80.00	100.0	91	-2.05	23.11	-73.3	0.00	60.0
	Week 14	103	75.21	22.78	0.0	80.00	100.0	85	-1.25	21.47	-73.3	0.00	60.0
	Week 17	99	75.56	19.70	0.0	80.00	100.0	84	-0.56	22.01	-73.3	0.00	53.3
	Week 20	92	75.29	19.00	20.0	80.00	100.0	78	-1.97	22.67	-60.0	0.00	60.0
	Week 23	89	75.88	19.45	20.0	80.00	100.0	73	-1.92	23.21	-73.3	0.00	60.0
	Week 26	84	76.51	21.12	13.3	80.00	100.0	70	-0.57	21.82	-53.3	0.00	60.0
	Week 29	80	73.17	21.79	0.0	80.00	100.0	68	-6.18	24.52	-80.0	-6.67	60.0
	Week 32	77	73.68	20.29	6.7	80.00	100.0	65	-5.23	21.42	-53.3	-6.66	60.0
	Week 35	72	73.70	21.14	6.7	80.00	100.0	62	-5.05	23.52	-66.7	-6.66	53.3
	Week 38	71	74.27	21.18	13.3	80.00	100.0	62	-2.90	24.16	-66.7	0.00	60.0
	Week 41	70	72.86	21.09	6.7	73.33	100.0	61	-3.50	22.10	-60.0	0.00	53.3
	Week 44	64	71.25	21.51	6.7	73.33	100.0	54	-6.67	20.80	-66.7	-6.67	40.0
	Week 47	65	71.79	21.01	13.3	73.33	100.0	57	-5.97	19.59	-46.7	-6.67	46.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	54	70.86	19.44	20.0	73.33	100.0	47	-8.09	19.21	-46.7	-13.33	46.7
	Week 53	53	69.31	21.26	26.7	73.33	100.0	45	-7.41	20.11	-46.7	-6.67	53.3
	Week 56	54	69.01	22.14	20.0	70.00	100.0	46	-6.38	19.57	-46.7	-6.67	40.0
	Week 59	51	70.07	18.97	33.3	73.33	100.0	42	-7.46	20.73	-46.7	-6.67	46.7
	Week 62	49	67.76	21.96	13.3	73.33	100.0	41	-9.76	20.23	-66.7	-13.33	46.7
	Week 65	36	67.22	20.24	20.0	73.33	100.0	33	-10.10	21.99	-46.7	-13.33	40.0
	Week 68	34	68.04	24.11	6.7	70.00	100.0	31	-8.60	21.31	-66.7	-6.67	40.0
	Week 71	33	70.51	23.16	20.0	73.33	100.0	30	-5.55	20.94	-60.0	-6.66	40.0
	Week 74	33	71.11	19.91	20.0	73.33	100.0	30	-7.78	23.49	-60.0	-6.66	40.0
	Week 77	31	73.12	17.93	33.3	73.33	100.0	27	-5.43	21.17	-46.7	-6.66	40.0
	Week 80	31	71.40	19.41	33.3	73.33	100.0	29	-6.67	20.78	-46.7	-6.67	40.0
	Week 83	25	72.53	20.67	13.3	73.33	100.0	24	-6.67	22.33	-66.7	-6.67	40.0
	Week 86	23	69.28	19.87	26.7	66.67	100.0	22	-8.48	21.30	-53.3	-10.00	40.0
	Week 89	18	71.48	20.43	13.3	70.00	100.0	17	-14.51	20.44	-66.7	-13.33	20.0
	Week 92	16	70.83	20.49	33.3	73.34	100.0	15	-9.33	18.48	-53.3	-6.67	26.7
	Week 95	12	79.44	15.69	53.3	80.00	100.0	11	-6.67	13.33	-33.3	0.00	6.7
	Plat+Gem (N=152)												
	BASELINE	125	73.76	25.07	0.0	80.00	100.0						
	Week 1	109	69.24	24.89	0.0	80.00	100.0	106	-3.71	14.23	-66.7	-6.66	26.7
	Week 2	114	67.66	24.13	0.0	73.33	100.0	105	-6.92	15.66	-53.3	-6.67	26.7
	Week 3	116	68.10	25.73	0.0	76.67	100.0	107	-7.16	18.28	-73.3	-6.67	53.3
	Week 4	114	70.35	23.13	0.0	73.33	100.0	103	-5.31	18.23	-53.3	-6.66	40.0
	Week 5	117	70.37	21.96	0.0	73.33	100.0	106	-4.97	17.36	-46.7	-6.66	40.0
	Week 6	113	67.32	24.57	0.0	73.33	100.0	102	-7.39	20.14	-80.0	-6.66	53.3
	Week 7	113	68.73	22.59	13.3	73.33	100.0	103	-7.90	22.26	-66.7	-6.67	80.0
	Week 8	110	67.76	23.58	0.0	73.33	100.0	101	-8.19	20.17	-80.0	-6.67	60.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	107	68.04	24.05	0.0	73.33	100.0	95	-8.00	21.39	-80.0	-6.67	60.0
	Week 10	109	69.42	22.90	0.0	73.33	100.0	100	-6.00	21.82	-46.7	-6.67	66.7
	Week 11	96	67.99	24.02	0.0	73.33	100.0	88	-7.95	23.05	-86.7	-6.67	73.3
	Week 12	98	68.71	22.80	0.0	73.33	100.0	88	-6.97	21.37	-53.3	-6.67	73.3
	Week 14	98	67.41	22.61	0.0	73.33	100.0	87	-7.97	21.68	-60.0	-6.67	53.3
	Week 17	92	67.25	23.98	13.3	73.33	100.0	83	-10.28	24.45	-80.0	-6.67	46.7
	Week 20	84	71.83	22.56	6.7	80.00	100.0	75	-5.33	20.91	-73.3	0.00	53.3
	Week 23	73	73.79	21.61	13.3	80.00	100.0	66	-3.84	19.43	-46.7	0.00	53.3
	Week 26	66	71.72	23.13	0.0	80.00	100.0	61	-4.59	22.66	-66.7	0.00	66.7
	Week 29	64	71.15	24.34	0.0	80.00	100.0	59	-6.55	22.30	-60.0	-6.67	53.3
	Week 32	54	73.95	21.83	6.7	80.00	100.0	49	-2.99	22.28	-53.3	0.00	60.0
	Week 35	54	73.21	20.82	20.0	80.00	100.0	48	-5.28	22.00	-46.7	-6.67	46.7
	Week 38	47	74.18	23.08	6.7	80.00	100.0	42	-6.19	24.87	-93.3	-6.66	53.3
	Week 41	45	70.07	24.23	6.7	73.33	100.0	40	-8.50	23.73	-53.3	-6.67	53.3
	Week 44	41	65.69	25.15	6.7	66.67	100.0	36	-10.56	26.40	-80.0	-10.00	53.3
	Week 47	35	68.57	27.42	0.0	73.33	100.0	31	-8.60	23.74	-53.3	-6.67	53.3
	Week 50	29	70.80	24.72	26.7	80.00	100.0	24	-4.72	27.27	-46.7	0.00	66.7
	Week 53	25	71.73	25.33	13.3	80.00	100.0	22	-2.73	25.17	-40.0	-6.67	60.0
	Week 56	26	71.28	24.50	20.0	80.00	100.0	25	1.60	27.24	-40.0	0.00	66.7
	Week 59	20	69.33	26.96	20.0	76.67	100.0	18	3.70	29.75	-46.7	3.33	66.7
	Week 62	17	69.41	24.16	26.7	80.00	100.0	17	5.10	26.72	-33.3	0.00	60.0
	Week 65	15	63.11	21.51	26.7	66.67	93.3	14	-6.67	25.35	-46.7	-3.33	60.0
	Week 68	11	66.06	23.75	26.7	66.67	93.3	11	-1.21	28.88	-40.0	0.00	66.7
	Week 71	12	63.33	25.19	13.3	70.00	93.3	12	-2.78	28.63	-53.3	0.00	60.0
	Week 74	10	74.00	18.97	26.7	80.00	93.3	10	-0.67	24.03	-26.7	-3.34	60.0
	Week 77	10	79.33	15.85	53.3	83.34	93.3	10	-5.34	24.30	-46.7	-6.67	46.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
< 65 years	EV+Pembro (N= 39)												
	BASELINE	32	73.13	23.67	20.0	76.67	100.0						
	Week 1	27	76.30	19.33	26.7	73.33	100.0	26	1.79	14.43	-20.0	0.00	60.0
	Week 2	30	75.78	18.40	26.7	73.33	100.0	29	0.69	15.15	-26.7	0.00	53.3
	Week 3	31	78.28	15.49	33.3	80.00	100.0	29	3.45	18.05	-20.0	0.00	60.0
	Week 4	30	80.89	13.07	53.3	80.00	100.0	27	3.95	16.46	-13.3	0.00	60.0
	Week 5	28	79.76	12.89	53.3	80.00	100.0	26	4.36	15.77	-13.3	0.00	53.3
	Week 6	29	80.46	14.02	53.3	80.00	100.0	26	5.64	20.80	-20.0	0.00	60.0
	Week 7	30	80.44	13.09	46.7	80.00	100.0	26	5.13	20.16	-33.3	0.00	60.0
	Week 8	30	82.22	13.82	53.3	80.00	100.0	26	4.36	12.50	-13.3	0.00	33.3
	Week 9	28	82.14	11.63	60.0	80.00	100.0	27	8.40	20.47	-13.3	0.00	60.0
	Week 10	26	82.82	15.34	53.3	86.67	100.0	23	6.09	20.09	-33.3	0.00	46.7
	Week 11	28	83.57	14.11	40.0	80.00	100.0	25	6.13	15.14	-13.3	0.00	53.3
	Week 12	28	83.33	13.27	46.7	80.00	100.0	25	6.40	18.90	-20.0	0.00	53.3
	Week 14	26	83.85	16.02	33.3	86.67	100.0	23	8.12	14.49	-13.3	6.67	40.0
	Week 17	28	80.48	16.32	46.7	80.00	100.0	24	4.17	20.51	-46.7	0.00	53.3
	Week 20	27	79.26	15.40	40.0	80.00	100.0	24	2.50	26.21	-53.3	0.00	60.0
	Week 23	26	81.54	11.82	60.0	80.00	100.0	23	1.45	20.49	-33.3	0.00	60.0
	Week 26	24	83.61	12.89	53.3	86.67	100.0	22	3.94	21.93	-33.3	0.00	60.0
	Week 29	25	77.07	13.48	40.0	80.00	100.0	23	-1.74	24.22	-40.0	-6.67	60.0
	Week 32	25	76.27	16.23	40.0	80.00	100.0	23	-1.45	19.79	-53.3	-6.66	46.7
	Week 35	24	74.17	13.67	33.3	76.67	100.0	22	-3.33	24.84	-60.0	-6.67	46.7
	Week 38	23	78.84	14.86	40.0	80.00	100.0	22	0.00	23.00	-53.3	0.00	60.0
	Week 41	25	73.60	14.59	33.3	73.33	100.0	23	-4.06	24.27	-60.0	-6.66	53.3
	Week 44	22	73.94	12.16	53.3	73.33	100.0	20	-4.33	17.34	-40.0	-6.67	40.0
	Week 47	20	73.67	13.76	46.7	73.33	100.0	18	-4.44	18.15	-40.0	-6.67	46.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	19	76.84	12.25	53.3	73.33	100.0	17	-3.14	16.85	-40.0	0.00	33.3
	Week 53	20	74.67	13.26	46.7	73.33	100.0	18	-4.07	18.87	-26.7	-6.67	53.3
	Week 56	17	72.94	18.48	40.0	66.67	100.0	15	-1.78	18.59	-33.3	0.00	33.3
	Week 59	17	72.16	17.03	40.0	73.33	100.0	15	-3.11	17.25	-26.7	-6.67	33.3
	Week 62	15	73.78	16.03	46.7	73.33	100.0	14	-7.14	14.43	-26.7	-6.67	26.7
	Week 65	14	69.52	18.06	40.0	66.67	100.0	13	-7.69	19.02	-46.7	-6.67	26.7
	Week 68	11	74.55	16.82	53.3	66.67	100.0	10	-2.00	14.76	-20.0	-3.33	33.3
	Week 71	13	70.26	21.54	33.3	73.33	100.0	12	-3.89	19.17	-53.3	-6.67	26.7
	Week 74	14	70.48	16.27	46.7	66.67	100.0	13	-9.74	18.78	-53.3	-6.67	26.7
	Week 77	14	70.95	18.42	40.0	66.67	100.0	13	-6.67	18.26	-46.7	-6.67	26.7
	Week 80	14	70.00	17.10	33.3	73.33	100.0	13	-9.23	16.67	-40.0	-6.67	13.3
	Week 83	12	68.89	17.83	46.7	63.34	100.0	11	-9.09	18.20	-40.0	-6.67	26.7
	Plat+Gem (N= 29)												
	BASELINE	22	82.12	21.12	26.7	86.67	100.0						
	Week 1	21	80.64	18.61	46.7	86.67	100.0	20	0.00	10.60	-26.7	0.00	20.0
	Week 2	24	81.11	22.90	13.3	86.67	100.0	20	0.00	8.09	-13.3	0.00	13.3
	Week 3	23	79.13	25.29	6.7	86.67	100.0	20	-2.33	9.98	-33.3	0.00	13.3
	Week 4	23	76.23	25.57	0.0	86.67	100.0	19	-4.56	10.19	-33.3	-6.66	13.3
	Week 5	25	77.87	24.47	0.0	86.67	100.0	20	-1.00	11.90	-20.0	0.00	40.0
	Week 6	22	76.67	22.32	20.0	83.34	100.0	18	-0.74	12.08	-20.0	0.00	40.0
	Week 7	24	74.17	21.74	13.3	76.67	100.0	21	-6.35	13.58	-33.3	-6.67	40.0
	Week 8	21	81.27	17.33	26.7	86.67	100.0	19	-3.16	14.97	-33.3	-6.66	40.0
	Week 9	20	76.33	24.32	0.0	80.00	100.0	17	-4.31	17.79	-40.0	-6.66	40.0
	Week 10	21	77.14	22.37	6.7	80.00	100.0	18	-4.45	18.44	-46.7	-6.67	46.7
	Week 11	20	76.67	22.43	6.7	83.34	100.0	17	-3.92	15.29	-33.3	-6.66	40.0
	Week 12	21	76.19	22.56	20.0	80.00	100.0	17	-3.92	17.33	-33.3	-6.67	46.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 14	22	65.76	27.70	20.0	70.00	100.0	18	-16.67	28.40	-60.0	-6.67	40.0
	Week 17	20	72.33	27.47	13.3	86.67	100.0	17	-8.63	26.11	-80.0	-6.66	46.7
	Week 20	18	71.48	27.89	6.7	80.00	100.0	15	-7.56	11.51	-26.7	-6.66	13.3
	Week 23	18	80.00	23.43	13.3	90.00	100.0	16	-3.75	10.60	-20.0	-3.33	20.0
	Week 26	16	80.42	20.00	33.3	90.00	100.0	14	-6.19	11.54	-33.3	-6.66	13.3
	Week 29	15	78.22	21.00	26.7	86.67	100.0	13	-6.67	10.54	-26.7	-6.66	6.7
	Week 32	15	78.67	22.84	20.0	86.67	100.0	13	-6.15	13.73	-40.0	0.00	13.3
	Week 35	15	79.11	19.98	33.3	86.67	100.0	13	-8.72	15.25	-40.0	-6.66	20.0
	Week 38	14	73.33	25.88	26.7	83.34	100.0	12	-13.89	22.10	-66.7	-6.67	13.3
	Week 41	11	66.67	26.16	33.3	60.00	100.0	9	-19.26	23.44	-53.3	-13.33	13.3
	Week 44	11	63.03	29.11	6.7	60.00	100.0	9	-23.70	31.47	-80.0	-20.00	13.3
	Week 47	11	66.67	31.13	20.0	66.67	100.0	9	-17.78	28.86	-66.7	-6.67	13.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>= 65 years	EV+Pembro (N=163)												
	BASELINE	128	72.86	23.20	20.0	80.00	100.0						
	Week 1	114	69.59	23.90	0.0	73.33	100.0	103	-3.88	13.48	-46.7	0.00	40.0
	Week 2	120	68.61	23.75	6.7	73.33	100.0	104	-4.87	13.60	-53.3	0.00	26.7
	Week 3	108	69.14	25.17	0.0	73.33	100.0	93	-3.73	19.42	-53.3	0.00	53.3
	Week 4	115	70.96	24.19	0.0	73.33	100.0	102	-2.88	17.34	-46.7	0.00	60.0
	Week 5	109	70.70	23.74	0.0	73.33	100.0	95	-3.09	18.50	-53.3	0.00	60.0
	Week 6	117	69.80	24.68	0.0	73.33	100.0	98	-4.22	21.98	-66.7	0.00	53.3
	Week 7	117	73.05	22.48	0.0	80.00	100.0	98	-2.18	22.43	-73.3	0.00	46.7
	Week 8	117	69.69	23.12	0.0	73.33	100.0	98	-3.88	23.31	-86.7	0.00	60.0
	Week 9	114	69.30	23.66	0.0	73.33	100.0	94	-5.11	23.49	-100.0	0.00	46.7
	Week 10	113	71.92	24.19	0.0	73.33	100.0	95	-1.75	23.78	-100.0	0.00	60.0
	Week 11	109	73.82	22.05	0.0	80.00	100.0	90	-2.22	24.25	-100.0	0.00	60.0
	Week 12	114	72.98	24.34	0.0	80.00	100.0	94	-2.62	23.30	-73.3	0.00	60.0
	Week 14	113	72.92	23.34	0.0	80.00	100.0	93	-2.80	21.92	-73.3	0.00	60.0
	Week 17	104	74.29	20.00	0.0	80.00	100.0	87	-1.07	21.25	-73.3	0.00	46.7
	Week 20	93	73.76	20.04	20.0	73.33	100.0	79	-4.13	21.33	-60.0	0.00	60.0
	Week 23	91	73.19	20.32	20.0	73.33	100.0	74	-3.78	22.67	-73.3	-6.66	60.0
	Week 26	88	73.11	22.59	6.7	76.67	100.0	72	-3.43	23.26	-80.0	0.00	60.0
	Week 29	82	71.87	23.73	0.0	76.67	100.0	70	-6.48	25.73	-100.0	-6.66	46.7
	Week 32	77	72.38	22.16	0.0	73.33	100.0	65	-7.08	23.42	-100.0	-6.66	60.0
	Week 35	74	71.44	23.29	0.0	76.67	100.0	64	-7.19	26.03	-100.0	-6.67	53.3
	Week 38	74	70.27	22.24	13.3	73.33	100.0	64	-6.56	25.66	-86.7	-6.67	53.3
	Week 41	70	71.24	21.97	6.7	73.33	100.0	61	-5.46	22.09	-60.0	-6.66	46.7
	Week 44	64	69.48	22.28	6.7	73.33	100.0	54	-6.79	21.61	-66.7	-6.67	40.0
	Week 47	59	69.94	22.91	13.3	73.33	100.0	52	-5.90	20.44	-46.7	-6.67	46.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	55	66.67	23.20	0.0	73.33	100.0	47	-10.07	21.03	-46.7	-13.33	46.7
	Week 53	54	64.57	23.73	6.7	66.67	100.0	45	-9.93	19.98	-46.7	-6.67	46.7
	Week 56	55	66.18	21.69	20.0	66.67	100.0	46	-8.12	19.37	-46.7	-6.67	40.0
	Week 59	52	67.05	19.95	20.0	70.00	100.0	42	-9.36	21.03	-46.7	-13.33	46.7
	Week 62	47	65.82	21.56	13.3	73.33	100.0	38	-10.70	22.22	-66.7	-13.33	46.7
	Week 65	29	67.82	20.24	20.0	73.33	100.0	27	-9.63	24.83	-46.7	-13.33	40.0
	Week 68	35	64.57	25.24	6.7	66.67	100.0	32	-11.87	24.23	-66.7	-13.33	40.0
	Week 71	29	67.82	24.30	13.3	73.33	100.0	26	-6.92	23.74	-60.0	-6.66	40.0
	Week 74	24	71.39	21.13	20.0	76.67	100.0	22	-4.55	26.62	-60.0	0.00	46.7
	Week 77	23	72.75	17.97	33.3	73.33	100.0	20	-2.67	24.60	-46.7	0.00	46.7
	Week 80	22	71.82	20.67	33.3	73.33	100.0	21	-2.54	24.81	-46.7	0.00	46.7
	Week 83	18	72.96	21.99	13.3	73.33	100.0	18	-3.70	25.28	-66.7	-3.33	40.0
	Week 86	18	67.41	24.93	13.3	63.34	100.0	18	-11.48	26.94	-73.3	-3.34	40.0
	Week 89	12	73.33	24.45	13.3	73.33	100.0	12	-11.11	23.15	-66.7	-3.34	20.0
	Week 92	10	72.67	24.64	33.3	83.34	100.0	10	-10.00	18.92	-53.3	-6.67	6.7
	Plat+Gem (N=173)												
	BASELINE	143	70.02	25.38	0.0	80.00	100.0						
	Week 1	123	65.09	25.38	0.0	73.33	100.0	119	-4.76	14.58	-66.7	-6.66	26.7
	Week 2	123	63.14	23.46	0.0	66.67	100.0	115	-8.75	17.51	-80.0	-6.67	26.7
	Week 3	126	65.61	24.49	0.0	73.33	100.0	116	-7.30	18.46	-73.3	-6.67	53.3
	Week 4	127	67.40	22.00	0.0	73.33	100.0	116	-5.17	18.57	-53.3	-6.66	40.0
	Week 5	128	66.93	22.25	6.7	73.33	100.0	118	-5.65	19.37	-53.3	-6.66	40.0
	Week 6	123	64.88	24.84	0.0	73.33	100.0	113	-7.55	22.26	-80.0	-6.67	53.3
	Week 7	124	65.70	23.18	13.3	66.67	100.0	113	-7.91	23.58	-66.7	-6.67	80.0
	Week 8	124	64.09	24.49	0.0	66.67	100.0	113	-8.44	22.61	-80.0	-6.67	60.0
	Week 9	121	64.35	24.23	0.0	66.67	100.0	108	-8.89	24.68	-80.0	-6.67	60.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	121	65.73	23.61	0.0	73.33	100.0	112	-5.95	23.68	-66.7	-6.66	66.7
	Week 11	106	64.15	24.52	0.0	73.33	100.0	97	-8.93	24.62	-86.7	-6.67	73.3
	Week 12	109	64.46	24.00	0.0	66.67	100.0	98	-8.10	22.56	-53.3	-6.67	73.3
	Week 14	103	66.73	22.53	0.0	73.33	100.0	91	-6.15	20.66	-60.0	-6.67	53.3
	Week 17	100	65.20	23.62	6.7	66.67	100.0	89	-9.66	24.02	-66.7	-6.67	46.7
	Week 20	86	70.00	22.70	6.7	76.67	100.0	76	-4.39	21.01	-73.3	0.00	53.3
	Week 23	70	71.62	21.56	13.3	73.33	100.0	64	-3.13	20.54	-46.7	0.00	53.3
	Week 26	65	69.03	23.85	0.0	80.00	100.0	61	-3.72	23.11	-66.7	0.00	66.7
	Week 29	62	68.39	25.83	0.0	80.00	100.0	58	-8.51	26.40	-93.3	-6.67	53.3
	Week 32	48	70.69	22.46	6.7	80.00	100.0	45	-4.59	26.96	-80.0	0.00	60.0
	Week 35	47	71.49	20.60	20.0	80.00	100.0	43	-4.03	23.24	-46.7	-6.66	46.7
	Week 38	42	73.65	22.76	6.7	80.00	100.0	38	-5.26	26.49	-93.3	0.00	53.3
	Week 41	41	71.22	22.63	6.7	73.33	100.0	38	-5.44	22.02	-46.7	-6.66	53.3
	Week 44	38	65.79	23.77	6.7	66.67	100.0	35	-8.38	25.74	-53.3	-6.66	53.3
	Week 47	32	67.08	26.23	0.0	73.33	100.0	30	-8.44	25.12	-53.3	-6.67	53.3
	Week 50	29	71.03	24.32	13.3	80.00	100.0	26	-5.39	28.97	-66.7	0.00	66.7
	Week 53	25	68.80	25.07	20.0	80.00	100.0	24	-6.67	29.68	-66.7	-6.67	60.0
	Week 56	26	67.18	27.12	0.0	76.67	100.0	26	-4.36	34.09	-80.0	-3.33	66.7
	Week 59	20	69.33	25.17	20.0	76.67	100.0	20	-0.33	32.26	-66.7	0.00	66.7
	Week 62	19	66.67	23.41	26.7	80.00	100.0	19	1.05	30.17	-66.7	0.00	60.0
	Week 65	16	65.00	21.43	26.7	70.00	93.3	16	-6.25	23.66	-46.7	-3.33	60.0
	Week 68	13	67.18	22.52	26.7	66.67	93.3	13	-1.54	26.41	-40.0	0.00	66.7
	Week 71	13	65.13	24.97	13.3	73.33	93.3	13	-3.08	27.44	-53.3	0.00	60.0
	Week 74	11	75.15	18.40	26.7	80.00	93.3	11	-1.21	22.87	-26.7	-6.66	60.0
	Week 77	10	79.33	15.85	53.3	83.34	93.3	10	-4.67	24.15	-46.7	-6.67	46.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Europe	EV+Pembro (N= 74)												
	BASELINE	53	72.96	24.37	20.0	80.00	100.0						
	Week 1	48	70.83	25.64	0.0	80.00	100.0	42	-1.91	12.94	-33.3	0.00	40.0
	Week 2	53	71.19	24.21	6.7	80.00	100.0	44	-1.21	13.35	-33.3	0.00	26.7
	Week 3	50	69.33	21.88	20.0	73.33	100.0	41	-1.30	20.51	-46.7	0.00	46.7
	Week 4	51	72.55	21.57	0.0	80.00	100.0	44	-0.91	19.11	-46.7	0.00	60.0
	Week 5	46	68.84	21.96	0.0	73.33	100.0	41	-3.58	21.19	-53.3	-6.66	46.7
	Week 6	50	69.47	23.56	0.0	80.00	100.0	39	-3.42	25.40	-66.7	-6.66	60.0
	Week 7	50	74.80	17.73	20.0	80.00	100.0	39	-1.37	22.28	-73.3	0.00	46.7
	Week 8	51	72.68	18.73	33.3	73.33	100.0	41	-1.63	15.19	-40.0	0.00	26.7
	Week 9	47	71.77	19.37	13.3	80.00	100.0	37	0.36	18.25	-26.7	0.00	60.0
	Week 10	45	72.74	20.69	13.3	73.33	100.0	34	2.16	21.38	-33.3	0.00	53.3
	Week 11	48	75.00	17.96	26.7	80.00	100.0	37	-0.72	18.11	-33.3	-6.66	53.3
	Week 12	51	75.56	18.46	26.7	80.00	100.0	39	0.00	20.23	-33.3	0.00	53.3
	Week 14	50	73.73	20.58	20.0	80.00	100.0	38	-1.05	15.46	-46.7	0.00	33.3
	Week 17	43	76.59	16.68	33.3	80.00	100.0	33	3.03	18.57	-33.3	0.00	53.3
	Week 20	41	75.45	18.04	33.3	80.00	100.0	33	-1.62	21.92	-53.3	0.00	46.7
	Week 23	41	73.33	16.40	33.3	80.00	100.0	30	-1.78	20.93	-53.3	-3.33	33.3
	Week 26	37	74.41	21.75	6.7	80.00	100.0	28	-0.95	23.36	-80.0	0.00	46.7
	Week 29	37	71.89	23.68	0.0	80.00	100.0	29	-3.91	23.74	-80.0	-6.66	40.0
	Week 32	34	73.14	20.00	6.7	80.00	100.0	26	-3.33	14.64	-26.7	-6.67	33.3
	Week 35	31	73.33	15.59	40.0	80.00	100.0	25	-3.47	23.42	-46.7	-6.67	46.7
	Week 38	31	67.96	17.92	13.3	73.33	86.7	26	-8.72	18.93	-46.7	-13.33	33.3
	Week 41	28	69.52	20.56	6.7	73.33	100.0	23	-4.06	18.17	-46.7	-6.67	33.3
	Week 44	27	71.11	19.39	26.7	73.33	100.0	22	-4.85	15.28	-33.3	-6.67	26.7
	Week 47	25	66.93	23.45	13.3	73.33	93.3	21	-9.21	17.19	-46.7	-6.67	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	26	68.46	26.23	0.0	76.67	100.0	23	-8.99	19.24	-46.7	-13.33	26.7
	Week 53	26	62.57	25.30	6.7	66.67	93.3	21	-12.06	15.29	-46.7	-13.33	26.7
	Week 56	25	64.53	22.42	20.0	66.67	100.0	21	-7.94	16.55	-40.0	-6.67	26.7
	Week 59	23	70.44	15.81	33.3	73.33	93.3	18	-8.52	14.79	-33.3	-13.33	20.0
	Week 62	20	66.67	21.63	20.0	70.00	93.3	17	-10.20	13.15	-26.7	-13.33	20.0
	Week 65	13	71.28	17.29	40.0	66.67	93.3	13	-9.23	18.77	-46.7	-13.33	20.0
	Week 68	15	62.67	28.93	6.7	66.67	93.3	15	-13.78	19.75	-66.7	-13.33	20.0
	Week 71	13	62.56	30.62	13.3	66.67	100.0	13	-12.82	22.52	-60.0	-6.67	20.0
	Week 74	10	64.00	19.68	26.7	63.34	93.3	9	-14.07	17.78	-46.7	-6.67	13.3
	Plat+Gem (N= 95)												
	BASELINE	75	71.11	25.00	6.7	80.00	100.0						
	Week 1	71	66.67	26.14	0.0	73.33	100.0	69	-3.77	13.26	-33.3	-6.66	26.7
	Week 2	71	66.48	24.64	6.7	73.33	100.0	63	-5.50	18.34	-80.0	0.00	26.7
	Week 3	72	67.59	26.06	6.7	73.33	100.0	65	-5.02	16.42	-46.7	0.00	33.3
	Week 4	69	69.08	23.60	0.0	73.33	100.0	62	-3.87	19.07	-53.3	-3.33	40.0
	Week 5	71	67.89	24.20	0.0	73.33	100.0	63	-2.96	18.03	-46.7	0.00	40.0
	Week 6	69	67.54	24.49	6.7	73.33	100.0	61	-4.37	22.17	-80.0	-6.66	53.3
	Week 7	69	66.86	23.93	13.3	66.67	100.0	62	-6.67	24.23	-66.7	-6.66	80.0
	Week 8	67	68.76	22.98	20.0	73.33	100.0	60	-4.00	19.53	-40.0	-6.66	60.0
	Week 9	66	66.36	24.57	0.0	73.33	100.0	57	-6.20	23.46	-80.0	0.00	60.0
	Week 10	70	67.43	23.39	6.7	73.33	100.0	63	-3.92	22.93	-46.7	0.00	66.7
	Week 11	63	65.08	23.64	6.7	73.33	100.0	56	-6.31	25.18	-86.7	-3.33	73.3
	Week 12	66	66.06	23.87	6.7	66.67	100.0	56	-6.31	22.93	-53.3	-6.67	73.3
	Week 14	66	64.65	23.15	6.7	66.67	100.0	56	-9.29	22.19	-60.0	-10.00	46.7
	Week 17	61	63.83	26.00	6.7	66.67	100.0	53	-9.94	23.85	-80.0	-6.67	40.0
	Week 20	54	69.01	23.81	6.7	76.67	100.0	48	-2.36	17.96	-53.3	0.00	33.3

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 23	44	71.97	21.79	26.7	80.00	100.0	40	-1.00	18.52	-46.7	0.00	40.0
	Week 26	42	67.62	25.48	0.0	76.67	100.0	39	-3.76	23.48	-66.7	0.00	66.7
	Week 29	39	67.18	24.58	20.0	80.00	100.0	36	-4.26	19.85	-46.7	-6.67	53.3
	Week 32	32	66.04	26.69	6.7	76.67	100.0	30	-4.22	27.65	-80.0	0.00	46.7
	Week 35	32	67.50	23.81	20.0	76.67	100.0	30	-4.89	22.35	-46.7	-6.67	46.7
	Week 38	28	70.95	26.24	6.7	80.00	100.0	26	-7.44	24.82	-93.3	-6.66	53.3
	Week 41	25	65.87	27.51	6.7	73.33	100.0	23	-6.38	21.69	-53.3	-6.66	53.3
	Week 44	24	61.11	29.60	6.7	63.34	100.0	22	-10.30	26.33	-80.0	-3.33	40.0
	Week 47	22	61.52	29.88	0.0	66.67	100.0	20	-7.00	25.08	-53.3	-6.66	53.3
	Week 50	17	61.96	27.16	13.3	60.00	100.0	15	-4.00	29.15	-66.7	0.00	53.3
	Week 53	15	60.00	29.49	13.3	60.00	100.0	14	-5.71	27.41	-60.0	-3.33	53.3
	Week 56	15	55.11	29.00	0.0	60.00	93.3	14	-9.05	29.77	-80.0	-6.67	46.7
	Week 59	11	59.39	26.74	20.0	60.00	100.0	10	-2.67	26.33	-46.7	0.00	53.3
	Week 62	11	64.24	24.64	26.7	66.67	100.0	11	0.61	20.32	-26.7	0.00	53.3
	Week 65	10	59.33	21.65	26.7	56.67	86.7	10	-6.67	11.76	-33.3	-3.33	6.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
North America	EV+Pembro (N= 46)												
	BASELINE	33	73.33	22.67	26.7	73.33	100.0						
	Week 1	30	67.78	23.50	13.3	70.00	100.0	27	-6.91	14.14	-46.7	-6.66	13.3
	Week 2	30	71.33	21.09	26.7	76.67	100.0	26	-5.13	15.00	-40.0	0.00	26.7
	Week 3	25	76.27	17.96	33.3	73.33	100.0	21	-3.17	17.08	-46.7	0.00	33.3
	Week 4	30	74.67	20.07	33.3	80.00	100.0	24	-2.78	15.72	-46.7	-3.33	40.0
	Week 5	29	75.40	17.56	46.7	80.00	100.0	21	-2.22	16.10	-46.7	0.00	40.0
	Week 6	31	72.04	21.25	6.7	73.33	100.0	23	-6.66	14.36	-40.0	-6.67	13.3
	Week 7	33	74.95	19.58	33.3	80.00	100.0	23	-2.61	18.72	-46.7	-6.67	46.7
	Week 8	29	71.95	17.49	46.7	73.33	100.0	20	-1.67	20.28	-40.0	-6.66	46.7
	Week 9	27	72.59	19.33	26.7	73.33	100.0	21	-5.40	24.82	-60.0	-6.66	40.0
	Week 10	29	78.62	15.26	46.7	80.00	100.0	23	3.19	20.58	-33.3	0.00	40.0
	Week 11	28	76.90	19.24	26.7	76.67	100.0	21	0.00	19.89	-26.7	0.00	40.0
	Week 12	29	78.16	17.72	40.0	80.00	100.0	22	2.12	18.67	-20.0	0.00	40.0
	Week 14	28	76.90	18.28	40.0	76.67	100.0	21	0.32	18.56	-33.3	0.00	40.0
	Week 17	29	77.01	17.60	53.3	80.00	100.0	23	-0.87	22.14	-46.7	0.00	46.7
	Week 20	23	76.52	19.99	40.0	80.00	100.0	18	-1.48	27.49	-60.0	0.00	60.0
	Week 23	22	77.27	23.15	26.7	83.34	100.0	17	-4.31	29.24	-73.3	0.00	60.0
	Week 26	21	73.33	20.00	33.3	73.33	100.0	16	-1.67	25.47	-40.0	-3.33	60.0
	Week 29	20	72.67	23.78	0.0	80.00	100.0	17	-8.23	30.60	-100.0	-13.33	40.0
	Week 32	21	72.38	24.88	0.0	80.00	100.0	18	-7.04	34.18	-100.0	-3.33	60.0
	Week 35	22	73.94	23.18	0.0	80.00	100.0	19	-4.91	30.38	-100.0	-6.67	53.3
	Week 38	20	74.00	24.75	13.3	80.00	100.0	17	-3.92	33.00	-86.7	0.00	53.3
	Week 41	21	77.46	17.45	40.0	80.00	100.0	17	-0.78	22.59	-60.0	0.00	46.7
	Week 44	16	76.67	12.65	60.0	73.33	100.0	12	3.89	15.17	-13.3	3.34	33.3
	Week 47	16	76.25	17.03	46.7	76.67	100.0	13	1.54	11.60	-13.3	0.00	26.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	16	74.17	15.56	40.0	73.33	100.0	11	-0.61	17.75	-26.7	0.00	33.3
	Week 53	15	73.33	16.90	46.7	73.33	100.0	11	1.21	12.23	-13.3	0.00	20.0
	Week 56	17	72.55	17.30	40.0	73.33	100.0	12	2.22	11.13	-13.3	0.00	20.0
	Week 59	17	71.37	16.96	46.7	73.33	100.0	12	2.22	18.05	-20.0	0.00	46.7
	Week 62	14	73.81	12.93	46.7	73.33	100.0	9	-0.74	18.69	-20.0	0.00	40.0
	Week 68	11	78.18	16.89	40.0	80.00	100.0	8	6.67	17.82	-13.3	0.00	40.0
	Week 71	11	73.94	16.18	46.7	73.33	100.0	8	2.50	20.76	-20.0	0.00	40.0
	Plat+Gem (N= 34)												
	BASELINE	27	71.85	30.85	0.0	86.67	100.0						
	Week 1	19	72.28	21.57	26.7	80.00	100.0	17	-0.78	11.52	-26.7	0.00	13.3
	Week 2	20	73.33	24.47	20.0	80.00	100.0	18	-5.93	10.70	-26.7	-3.33	6.7
	Week 3	20	74.00	23.29	20.0	80.00	100.0	17	-8.63	14.29	-40.0	-6.67	13.3
	Week 4	23	75.07	21.01	20.0	80.00	100.0	19	-6.67	13.52	-33.3	-6.67	20.0
	Week 5	25	75.73	23.48	13.3	86.67	100.0	22	-6.67	13.49	-40.0	-3.33	26.7
	Week 6	20	71.33	26.68	6.7	76.67	100.0	17	-9.02	18.40	-46.7	-6.67	20.0
	Week 7	23	71.02	25.71	13.3	80.00	100.0	20	-11.00	20.43	-66.7	-6.67	20.0
	Week 8	24	69.45	21.97	13.3	70.00	100.0	22	-10.61	17.54	-46.7	-6.67	20.0
	Week 9	23	73.04	21.60	26.7	80.00	100.0	19	-10.53	24.38	-66.7	-6.67	33.3
	Week 10	20	70.00	26.27	13.3	80.00	100.0	18	-11.11	21.93	-46.7	-13.34	40.0
	Week 11	18	75.19	23.41	13.3	80.00	100.0	16	-13.75	16.77	-46.7	-10.00	6.7
	Week 12	17	70.59	25.50	13.3	80.00	100.0	16	-12.08	20.40	-46.7	-6.67	20.0
	Week 14	16	75.83	21.76	26.7	80.00	100.0	14	-9.52	22.45	-60.0	-6.67	20.0
	Week 17	19	70.17	25.08	33.3	80.00	100.0	17	-18.04	24.70	-66.7	-20.00	20.0
	Week 20	16	77.92	20.03	40.0	83.34	100.0	13	-12.82	23.01	-60.0	-13.34	20.0
	Week 23	15	79.55	21.45	33.3	86.67	100.0	13	-9.23	18.77	-40.0	-6.67	20.0
	Week 26	13	78.97	19.02	33.3	80.00	100.0	12	-12.22	17.02	-33.3	-13.33	20.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 29	14	74.76	31.40	0.0	86.67	100.0	13	-18.46	28.43	-73.3	-13.33	26.7
	Week 32	11	86.67	16.87	40.0	86.67	100.0	10	-10.67	19.17	-60.0	-3.33	6.7
	Week 35	13	84.10	15.04	53.3	86.67	100.0	11	-7.88	19.28	-46.7	-6.66	26.7
	Week 38	10	76.67	26.90	26.7	86.67	100.0	9	-21.48	25.98	-66.7	-13.33	6.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Rest of World	EV+Pembro (N= 82)												
	BASELINE	74	72.70	22.94	20.0	73.33	100.0						
	Week 1	63	72.38	21.21	26.7	73.33	100.0	60	-1.44	14.11	-33.3	0.00	60.0
	Week 2	67	68.56	22.88	20.0	66.67	100.0	63	-4.76	14.19	-53.3	0.00	53.3
	Week 3	64	70.63	26.71	0.0	76.67	100.0	60	-2.11	19.43	-53.3	0.00	60.0
	Week 4	64	72.60	24.86	6.7	80.00	100.0	61	-1.31	16.81	-46.7	0.00	60.0
	Week 5	62	73.98	24.25	0.0	73.33	100.0	59	0.23	16.61	-46.7	0.00	60.0
	Week 6	65	73.74	24.21	6.7	80.00	100.0	62	0.32	22.07	-66.7	0.00	60.0
	Week 7	64	74.17	24.30	0.0	80.00	100.0	62	0.54	23.35	-66.7	0.00	60.0
	Week 8	67	72.04	26.16	0.0	80.00	100.0	63	-2.65	25.70	-86.7	0.00	60.0
	Week 9	68	71.57	25.51	0.0	80.00	100.0	63	-2.43	25.80	-100.0	0.00	60.0
	Week 10	65	72.72	27.33	0.0	80.00	100.0	61	-2.84	25.14	-100.0	0.00	60.0
	Week 11	61	75.96	24.08	0.0	80.00	100.0	57	-0.35	26.56	-100.0	0.00	60.0
	Week 12	62	73.12	27.97	0.0	80.00	100.0	58	-2.30	25.64	-73.3	0.00	60.0
	Week 14	61	75.08	25.82	0.0	80.00	100.0	57	-0.70	25.09	-73.3	0.00	60.0
	Week 17	60	74.22	22.04	0.0	80.00	100.0	55	-1.33	22.27	-73.3	0.00	46.7
	Week 20	56	74.05	19.93	20.0	76.67	100.0	52	-3.59	21.59	-53.3	-6.66	60.0
	Week 23	54	75.43	19.33	20.0	80.00	100.0	50	-2.40	20.59	-40.0	-6.66	60.0
	Week 26	54	76.79	21.74	13.3	80.00	100.0	50	-2.13	22.56	-53.3	0.00	60.0
	Week 29	50	74.13	19.92	26.7	80.00	100.0	47	-5.11	24.68	-46.7	-6.67	60.0
	Week 32	47	73.90	19.94	33.3	73.33	100.0	44	-6.36	20.93	-53.3	-3.33	46.7
	Week 35	45	70.37	23.93	6.7	73.33	100.0	42	-8.41	25.03	-66.7	-6.67	46.7
	Week 38	46	74.49	21.14	20.0	80.00	100.0	43	-2.95	25.04	-66.7	0.00	60.0
	Week 41	46	70.72	21.15	26.7	73.33	100.0	44	-7.27	24.73	-60.0	-6.67	53.3
	Week 44	43	68.06	22.70	6.7	73.33	100.0	40	-9.83	23.39	-66.7	-6.67	40.0
	Week 47	38	71.23	20.69	33.3	73.33	100.0	36	-5.93	22.97	-46.7	-6.67	46.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	32	67.50	19.58	33.3	66.67	100.0	30	-10.44	21.49	-46.7	-13.33	46.7
	Week 53	33	68.28	20.55	26.7	66.67	100.0	31	-9.03	23.51	-46.7	-6.67	53.3
	Week 56	30	67.78	21.94	26.7	66.67	100.0	28	-9.29	22.90	-46.7	-13.33	40.0
	Week 59	29	64.83	22.81	20.0	66.67	100.0	27	-11.60	23.07	-46.7	-13.33	33.3
	Week 62	28	65.48	22.74	13.3	63.34	100.0	26	-12.56	24.17	-66.7	-13.33	46.7
	Week 65	22	61.82	20.90	20.0	60.00	100.0	21	-15.24	22.23	-46.7	-20.00	40.0
	Week 68	20	64.00	21.67	13.3	66.67	100.0	19	-12.98	24.29	-66.7	-13.33	40.0
	Week 71	18	69.63	20.99	20.0	73.33	100.0	17	-4.70	22.21	-60.0	-6.66	40.0
	Week 74	19	69.83	19.92	20.0	66.67	100.0	19	-9.12	25.36	-60.0	-6.66	40.0
	Week 77	19	68.42	18.70	33.3	66.67	100.0	18	-8.15	22.47	-46.7	-6.67	40.0
	Week 80	19	68.07	20.19	33.3	66.67	100.0	18	-8.52	21.67	-46.7	-6.67	40.0
	Week 83	17	66.27	21.28	13.3	60.00	100.0	17	-10.59	24.95	-66.7	-6.67	40.0
	Week 86	14	63.81	24.77	13.3	63.34	100.0	14	-11.91	27.82	-73.3	-13.33	40.0
	Week 89	11	65.45	21.67	13.3	66.67	100.0	11	-18.18	20.46	-66.7	-13.33	6.7
	Plat+Gem (N= 73)												
	BASELINE	63	72.17	22.92	13.3	80.00	100.0						
	Week 1	54	66.54	24.99	0.0	73.33	100.0	53	-5.53	15.94	-66.7	-6.67	26.7
	Week 2	56	62.98	23.44	0.0	66.67	100.0	54	-10.25	16.26	-53.3	-6.67	26.7
	Week 3	57	65.61	24.29	0.0	73.33	100.0	54	-7.78	19.76	-73.3	-6.67	53.3
	Week 4	58	65.86	22.13	0.0	73.33	100.0	54	-5.93	17.31	-46.7	-6.67	33.3
	Week 5	57	66.67	20.70	6.7	73.33	100.0	53	-6.67	20.80	-53.3	-6.67	40.0
	Week 6	56	63.93	24.55	0.0	66.67	100.0	53	-8.43	21.13	-66.7	-6.66	40.0
	Week 7	56	65.71	21.10	13.3	66.67	100.0	52	-7.56	20.75	-60.0	-6.67	40.0
	Week 8	54	62.59	26.68	0.0	66.67	100.0	50	-10.80	25.27	-80.0	-10.00	40.0
	Week 9	52	62.56	25.40	0.0	66.67	100.0	49	-9.80	24.39	-80.0	-13.33	46.7
	Week 10	52	66.41	23.50	0.0	73.33	100.0	49	-6.12	23.52	-66.7	-6.66	53.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	45	64.00	25.95	0.0	73.33	100.0	42	-8.57	23.43	-73.3	-6.67	46.7
	Week 12	47	65.25	24.24	0.0	66.67	100.0	43	-7.29	21.17	-40.0	-6.67	53.3
	Week 14	43	66.05	24.07	0.0	73.33	100.0	39	-5.30	22.80	-60.0	-6.67	53.3
	Week 17	40	68.50	21.30	20.0	73.33	100.0	36	-4.82	24.10	-66.7	-3.33	46.7
	Week 20	34	68.63	24.54	6.7	73.33	100.0	30	-5.56	20.72	-73.3	-3.33	53.3
	Week 23	29	72.18	23.03	13.3	73.33	100.0	27	-3.71	19.60	-46.7	0.00	53.3
	Week 26	26	73.33	21.58	6.7	76.67	100.0	24	-0.83	19.39	-46.7	0.00	40.0
	Week 29	24	72.78	22.32	0.0	76.67	100.0	22	-8.49	27.31	-93.3	-6.67	46.7
	Week 32	20	75.33	12.81	53.3	73.33	100.0	18	-2.96	22.20	-40.0	0.00	60.0
	Week 35	17	76.08	13.14	53.3	80.00	100.0	15	-3.56	22.94	-46.7	0.00	46.7
	Week 38	18	75.93	16.19	46.7	76.67	100.0	15	1.33	24.33	-40.0	0.00	46.7
	Week 41	18	73.70	15.92	53.3	70.00	100.0	16	-3.33	23.85	-46.7	-6.67	53.3
	Week 44	16	66.25	15.86	40.0	66.67	100.0	14	-5.24	29.84	-53.3	-10.00	53.3
	Week 47	12	71.11	22.26	33.3	70.00	100.0	11	-7.88	26.30	-53.3	-6.67	46.7
	Week 50	11	74.55	25.44	26.7	80.00	100.0	9	0.74	32.22	-46.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	EV+Pembro (N=146)												
	BASELINE	119	73.50	23.36	20.0	80.00	100.0						
	Week 1	102	73.40	22.62	0.0	80.00	100.0	97	-2.06	13.86	-46.7	0.00	60.0
	Week 2	106	72.08	22.41	6.7	73.33	100.0	98	-3.67	14.49	-53.3	0.00	53.3
	Week 3	94	74.96	21.21	6.7	80.00	100.0	88	-0.68	20.79	-53.3	0.00	60.0
	Week 4	101	74.98	19.85	26.7	80.00	100.0	93	-1.43	18.09	-46.7	0.00	60.0
	Week 5	96	75.42	19.28	6.7	80.00	100.0	89	-1.57	18.64	-53.3	0.00	60.0
	Week 6	105	74.35	21.16	6.7	80.00	100.0	93	-1.65	22.58	-66.7	0.00	60.0
	Week 7	102	75.36	20.78	0.0	80.00	100.0	89	-1.65	22.81	-73.3	0.00	60.0
	Week 8	101	73.14	21.84	0.0	80.00	100.0	91	-2.86	21.93	-86.7	0.00	60.0
	Week 9	100	73.27	21.76	0.0	80.00	100.0	89	-2.25	24.45	-100.0	0.00	60.0
	Week 10	99	74.95	23.33	0.0	80.00	100.0	87	-0.77	24.64	-100.0	0.00	60.0
	Week 11	95	76.56	21.59	0.0	80.00	100.0	84	-2.46	23.48	-100.0	0.00	60.0
	Week 12	99	75.42	23.92	0.0	80.00	100.0	87	-1.99	23.30	-73.3	0.00	60.0
	Week 14	95	76.00	22.67	0.0	80.00	100.0	84	-1.83	21.81	-73.3	0.00	60.0
	Week 17	97	75.81	19.28	0.0	80.00	100.0	84	-1.35	21.65	-73.3	0.00	46.7
	Week 20	90	74.22	19.10	20.0	73.33	100.0	79	-3.97	23.28	-60.0	-6.66	60.0
	Week 23	86	74.73	19.22	20.0	80.00	100.0	74	-3.96	23.14	-73.3	-6.66	60.0
	Week 26	83	74.78	21.64	6.7	80.00	100.0	72	-4.17	23.72	-80.0	0.00	60.0
	Week 29	80	72.50	22.31	0.0	80.00	100.0	71	-7.51	25.79	-100.0	-6.67	60.0
	Week 32	74	73.96	21.34	0.0	80.00	100.0	66	-7.88	23.12	-100.0	-6.67	60.0
	Week 35	73	72.15	22.18	0.0	80.00	100.0	66	-7.47	26.88	-100.0	-6.67	53.3
	Week 38	75	71.82	21.83	13.3	80.00	100.0	67	-6.17	26.04	-86.7	-6.67	60.0
	Week 41	71	72.68	21.44	6.7	73.33	100.0	64	-5.52	22.43	-60.0	-6.66	53.3
	Week 44	64	71.87	18.95	6.7	73.33	100.0	56	-6.55	20.52	-66.7	-6.67	40.0
	Week 47	56	71.67	19.75	13.3	73.33	100.0	50	-5.60	17.84	-46.7	-6.67	46.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	55	69.45	21.30	0.0	73.33	100.0	48	-8.75	18.81	-46.7	-6.67	33.3
	Week 53	55	67.76	21.46	6.7	66.67	100.0	48	-9.58	19.05	-46.7	-6.67	53.3
	Week 56	53	67.42	19.94	26.7	66.67	100.0	46	-8.41	18.51	-46.7	-6.67	33.3
	Week 59	51	68.24	19.07	20.0	66.67	100.0	43	-9.30	20.38	-46.7	-13.33	46.7
	Week 62	42	66.67	19.48	13.3	66.67	100.0	36	-13.33	19.26	-66.7	-13.33	40.0
	Week 65	31	67.96	18.49	20.0	66.67	100.0	30	-11.11	22.44	-46.7	-13.34	40.0
	Week 68	31	64.95	25.47	6.7	66.67	100.0	29	-12.18	23.78	-66.7	-13.33	40.0
	Week 71	30	66.00	24.90	13.3	66.67	100.0	28	-9.29	23.05	-60.0	-6.67	40.0
	Week 74	29	68.74	20.17	20.0	66.67	100.0	27	-8.64	23.08	-60.0	-6.67	46.7
	Week 77	26	69.49	18.10	33.3	66.67	100.0	24	-7.50	23.37	-46.7	-6.67	46.7
	Week 80	26	68.20	19.07	33.3	63.34	100.0	26	-8.46	21.38	-46.7	-6.67	46.7
	Week 83	21	67.94	21.97	13.3	66.67	100.0	21	-9.21	23.04	-66.7	-6.67	40.0
	Week 86	17	62.35	23.80	13.3	60.00	100.0	17	-18.04	22.95	-73.3	-13.33	20.0
	Week 89	11	69.09	24.64	13.3	66.67	100.0	11	-19.39	19.88	-66.7	-13.33	0.0
	Week 92	13	63.59	26.33	13.3	66.67	100.0	13	-12.82	19.53	-53.3	-6.67	26.7
	Plat+Gem (N=151)												
	BASELINE	123	72.95	25.34	6.7	80.00	100.0						
	Week 1	108	68.52	25.34	0.0	80.00	100.0	103	-4.47	13.98	-66.7	-6.66	26.7
	Week 2	116	67.47	23.81	6.7	73.33	100.0	105	-7.94	16.80	-80.0	-6.66	26.7
	Week 3	114	69.53	23.53	6.7	73.33	100.0	103	-6.02	17.40	-73.3	0.00	53.3
	Week 4	116	69.48	22.05	0.0	73.33	100.0	103	-6.08	17.52	-53.3	-6.66	40.0
	Week 5	119	69.52	23.39	0.0	73.33	100.0	106	-4.84	18.67	-53.3	-6.66	40.0
	Week 6	109	68.38	23.19	6.7	73.33	100.0	98	-6.05	21.54	-80.0	-6.66	53.3
	Week 7	115	67.77	23.48	13.3	73.33	100.0	105	-7.87	23.22	-66.7	-6.67	80.0
	Week 8	111	68.53	22.85	0.0	73.33	100.0	102	-6.86	21.95	-80.0	-6.66	60.0
	Week 9	107	67.23	23.90	0.0	73.33	100.0	95	-7.79	24.46	-80.0	-6.67	60.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	107	69.10	23.39	6.7	73.33	100.0	98	-5.44	24.13	-66.7	-6.66	66.7
	Week 11	97	67.01	23.83	6.7	73.33	100.0	87	-8.66	25.15	-86.7	-6.67	73.3
	Week 12	100	66.80	23.93	6.7	73.33	100.0	88	-7.58	22.99	-53.3	-6.67	73.3
	Week 14	99	67.54	22.37	6.7	73.33	100.0	86	-7.83	22.46	-60.0	-6.67	53.3
	Week 17	94	66.52	24.26	6.7	73.33	100.0	82	-10.57	24.45	-80.0	-6.67	46.7
	Week 20	84	68.97	24.48	6.7	76.67	100.0	72	-7.04	19.12	-73.3	-3.33	53.3
	Week 23	70	72.48	21.92	13.3	76.67	100.0	62	-4.52	19.75	-46.7	-3.33	53.3
	Week 26	61	70.05	23.31	0.0	80.00	100.0	55	-6.55	22.17	-66.7	-6.67	66.7
	Week 29	59	70.40	24.20	0.0	80.00	100.0	53	-9.56	25.10	-93.3	-6.67	53.3
	Week 32	50	72.13	23.82	6.7	80.00	100.0	45	-6.07	25.58	-80.0	0.00	60.0
	Week 35	50	72.00	20.56	20.0	80.00	100.0	44	-6.67	21.47	-46.7	-6.66	46.7
	Week 38	46	73.62	22.70	6.7	80.00	100.0	40	-6.83	25.55	-93.3	-6.66	53.3
	Week 41	42	69.36	23.47	6.7	73.33	100.0	37	-7.39	23.82	-53.3	-6.66	53.3
	Week 44	39	65.81	24.29	6.7	66.67	100.0	34	-10.78	27.66	-80.0	-6.67	53.3
	Week 47	33	67.88	26.22	0.0	73.33	100.0	29	-7.82	23.71	-53.3	-6.67	53.3
	Week 50	27	71.36	23.08	26.7	80.00	100.0	22	-1.82	27.69	-46.7	0.00	66.7
	Week 53	23	68.41	24.80	13.3	73.33	100.0	20	-1.67	28.60	-66.7	-3.33	60.0
	Week 56	20	71.33	25.42	20.0	80.00	100.0	19	0.70	31.50	-73.3	-6.66	66.7
	Week 59	17	67.06	28.72	20.0	73.33	100.0	15	1.78	33.47	-66.7	0.00	66.7
	Week 62	14	70.95	25.57	26.7	80.00	100.0	14	3.33	31.46	-66.7	0.00	60.0
	Week 65	13	64.62	21.15	26.7	66.67	93.3	12	-2.78	23.86	-33.3	0.00	60.0
	Week 68	10	68.67	23.74	26.7	76.67	93.3	10	1.33	27.00	-40.0	0.00	66.7
	Week 71	10	64.67	27.23	13.3	76.67	93.3	10	-6.67	29.65	-53.3	-3.33	60.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	EV+Pembro (N= 56)												
	BASELINE	41	71.22	23.02	20.0	73.33	100.0						
	Week 1	39	64.27	23.62	13.3	60.00	100.0	32	-4.79	13.68	-33.3	0.00	26.7
	Week 2	44	65.15	23.62	20.0	66.67	100.0	35	-3.62	13.07	-40.0	0.00	20.0
	Week 3	45	63.26	26.54	0.0	66.67	100.0	34	-5.49	14.35	-33.3	-3.33	26.7
	Week 4	44	68.48	27.82	0.0	73.33	100.0	36	-1.48	15.38	-33.3	0.00	40.0
	Week 5	41	65.85	27.05	0.0	73.33	100.0	32	-1.25	16.97	-46.7	-3.33	33.3
	Week 6	41	65.69	27.39	0.0	73.33	100.0	31	-3.66	20.57	-66.7	0.00	26.7
	Week 7	45	72.74	21.87	6.7	73.33	100.0	35	1.91	20.23	-66.7	0.00	33.3
	Week 8	46	70.29	22.78	6.7	73.33	100.0	33	-0.20	21.31	-66.7	0.00	26.7
	Week 9	42	68.41	23.70	13.3	73.33	100.0	32	-1.67	20.81	-60.0	0.00	33.3
	Week 10	40	71.50	22.80	13.3	73.33	100.0	31	1.29	19.04	-33.3	0.00	46.7
	Week 11	42	74.13	19.77	26.7	73.33	100.0	31	5.16	20.13	-33.3	0.00	53.3
	Week 12	43	74.11	20.69	13.3	73.33	100.0	32	2.71	20.87	-60.0	0.00	53.3
	Week 14	44	72.73	22.27	20.0	73.33	100.0	32	2.50	18.91	-46.7	0.00	46.7
	Week 17	35	75.05	19.96	33.3	80.00	100.0	27	4.44	19.04	-26.7	0.00	53.3
	Week 20	30	77.33	19.54	33.3	80.00	100.0	24	1.94	20.00	-40.0	0.00	46.7
	Week 23	31	75.91	18.83	33.3	80.00	100.0	23	2.03	18.47	-26.7	0.00	33.3
	Week 26	29	77.01	20.52	20.0	80.00	100.0	22	6.36	19.02	-26.7	0.00	46.7
	Week 29	27	74.81	20.62	26.7	80.00	100.0	22	1.82	22.83	-46.7	0.00	46.7
	Week 32	28	71.67	19.76	33.3	73.33	100.0	22	1.21	19.69	-33.3	0.00	46.7
	Week 35	25	72.00	18.95	33.3	73.33	100.0	20	-2.00	21.09	-33.3	-3.34	40.0
	Week 38	22	73.94	18.16	33.3	76.67	100.0	19	-0.35	21.14	-33.3	0.00	40.0
	Week 41	24	69.44	16.32	26.7	73.33	100.0	20	-3.67	23.54	-46.7	-6.67	40.0
	Week 44	22	66.97	23.59	26.7	73.33	100.0	18	-4.81	20.81	-33.3	-3.33	40.0
	Week 47	23	68.99	24.00	20.0	73.33	100.0	20	-5.33	24.44	-46.7	-6.67	46.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	19	68.77	22.01	20.0	73.33	100.0	16	-6.67	24.22	-33.3	-13.34	46.7
	Week 53	19	65.97	23.29	26.7	73.33	100.0	15	-4.00	21.79	-40.0	-6.67	46.7
	Week 56	19	68.77	24.45	20.0	80.00	100.0	15	-0.89	20.91	-33.3	-6.66	40.0
	Week 59	18	68.52	20.43	33.3	76.67	100.0	14	-2.86	19.34	-33.3	-3.33	33.3
	Week 62	20	70.00	22.94	20.0	80.00	100.0	16	-1.67	21.01	-33.3	-3.33	46.7
	Week 65	12	69.44	22.28	26.7	73.33	93.3	10	-2.67	24.18	-46.7	-3.33	40.0
	Week 68	15	71.11	19.79	33.3	80.00	93.3	13	-3.59	19.17	-33.3	-6.66	40.0
	Week 71	12	75.00	17.78	33.3	76.67	100.0	10	3.33	17.29	-20.0	3.33	40.0
	Week 77	11	78.18	16.62	40.0	80.00	100.0	9	4.44	16.33	-13.3	0.00	40.0
	Week 80	10	78.67	18.00	40.0	76.67	100.0	8	5.83	21.80	-33.3	6.67	40.0
	Plat+Gem (N= 51)												
	BASELINE	42	67.78	24.41	0.0	73.33	100.0						
	Week 1	36	63.89	24.24	0.0	70.00	100.0	36	-2.96	14.73	-33.3	-6.67	26.7
	Week 2	31	60.86	25.46	0.0	66.67	100.0	30	-5.78	16.68	-40.0	-6.67	26.7
	Week 3	35	61.72	28.89	0.0	66.67	100.0	33	-8.28	18.11	-46.7	-6.67	26.7
	Week 4	34	66.27	25.05	0.0	73.33	100.0	32	-1.88	17.78	-46.7	0.00	40.0
	Week 5	34	65.88	21.19	20.0	70.00	100.0	32	-5.42	18.27	-46.7	-6.66	33.3
	Week 6	36	61.48	28.78	0.0	73.33	100.0	33	-8.28	20.62	-53.3	-6.67	40.0
	Week 7	33	64.65	21.89	13.3	66.67	100.0	29	-6.90	18.81	-53.3	-6.66	26.7
	Week 8	34	60.20	27.97	0.0	63.34	100.0	30	-10.44	20.99	-80.0	-6.67	26.7
	Week 9	34	62.35	26.41	0.0	66.67	100.0	30	-9.78	22.13	-80.0	-6.66	20.0
	Week 10	35	62.29	24.25	0.0	66.67	100.0	32	-6.67	19.31	-40.0	-6.67	40.0
	Week 11	29	63.22	27.06	0.0	66.67	100.0	27	-6.67	17.35	-46.7	0.00	26.7
	Week 12	30	64.89	24.94	0.0	63.34	100.0	27	-7.16	18.02	-40.0	-6.67	26.7
	Week 14	26	62.82	27.14	0.0	63.34	100.0	23	-8.12	22.29	-60.0	-13.33	26.7
	Week 17	26	65.90	25.04	13.3	66.67	100.0	24	-5.83	23.62	-53.3	-6.67	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 20	20	75.67	18.64	26.7	80.00	100.0	19	3.16	20.53	-53.3	6.66	33.3
	Week 23	18	76.67	23.01	33.3	86.67	100.0	18	1.11	15.38	-33.3	0.00	26.7
	Week 26	20	75.00	24.17	26.7	86.67	100.0	20	2.33	18.00	-40.0	3.33	26.7
	Week 29	18	70.00	28.77	0.0	80.00	100.0	18	-4.07	21.59	-53.3	0.00	33.3
	Week 32	13	74.36	18.02	33.3	73.33	100.0	13	-1.03	20.88	-33.3	-6.66	33.3
	Week 35	12	78.89	20.47	26.7	83.34	100.0	12	0.56	22.10	-40.0	-3.33	33.3
	Week 38	10	73.33	27.40	26.7	80.00	100.0	10	-9.33	26.89	-66.7	-3.34	26.7
	Week 41	10	74.00	22.98	26.7	76.67	100.0	10	-10.67	18.91	-40.0	-10.01	20.0
	Week 44	10	62.67	27.79	26.7	60.00	100.0	10	-14.00	27.48	-60.0	-10.00	13.3
	Week 47	10	64.00	31.46	26.7	70.00	100.0	10	-18.67	31.55	-66.7	-13.33	20.0
	Week 56	10	60.00	31.43	0.0	63.33	100.0	10	-13.34	33.41	-80.0	-6.67	40.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Visceral metastases	EV+Pembro (N=148)												
	BASELINE	119	69.80	24.50	20.0	73.33	100.0						
	Week 1	105	68.83	23.97	0.0	73.33	100.0	99	-1.62	14.13	-46.7	0.00	60.0
	Week 2	109	67.46	23.74	6.7	66.67	100.0	100	-3.40	14.54	-53.3	0.00	53.3
	Week 3	98	70.41	24.80	0.0	73.33	100.0	88	0.23	19.72	-46.7	0.00	60.0
	Week 4	103	71.07	23.50	0.0	73.33	100.0	93	-0.72	18.74	-46.7	0.00	60.0
	Week 5	100	71.20	22.56	0.0	73.33	100.0	90	0.30	18.72	-46.7	0.00	60.0
	Week 6	105	71.11	24.05	0.0	73.33	100.0	90	0.22	22.80	-66.7	0.00	60.0
	Week 7	108	73.89	21.55	6.7	80.00	100.0	91	1.17	23.51	-73.3	0.00	60.0
	Week 8	105	71.81	22.12	6.7	73.33	100.0	89	0.08	20.39	-66.7	0.00	60.0
	Week 9	105	71.68	22.22	13.3	73.33	100.0	91	0.73	22.69	-60.0	0.00	60.0
	Week 10	101	73.73	23.05	0.0	80.00	100.0	86	2.95	21.95	-73.3	0.00	60.0
	Week 11	97	76.15	20.52	0.0	80.00	100.0	83	2.25	21.14	-73.3	0.00	60.0
	Week 12	100	74.93	23.12	6.7	80.00	100.0	85	1.80	22.31	-66.7	0.00	60.0
	Week 14	102	74.57	23.35	0.0	80.00	100.0	87	1.15	21.14	-73.3	0.00	60.0
	Week 17	96	75.49	20.51	0.0	80.00	100.0	81	2.47	21.25	-73.3	0.00	53.3
	Week 20	87	74.41	19.39	20.0	73.33	100.0	76	-1.49	23.34	-53.3	0.00	60.0
	Week 23	85	74.27	19.49	20.0	80.00	100.0	71	-0.84	22.98	-53.3	0.00	60.0
	Week 26	79	76.03	19.64	6.7	80.00	100.0	66	-0.10	23.81	-80.0	0.00	60.0
	Week 29	72	74.07	20.16	0.0	80.00	100.0	64	-2.60	25.63	-100.0	-3.33	60.0
	Week 32	71	73.62	20.20	0.0	73.33	100.0	62	-3.55	24.55	-100.0	0.00	60.0
	Week 35	70	72.95	20.77	0.0	76.67	100.0	63	-4.13	26.73	-100.0	-6.66	53.3
	Week 38	70	73.24	20.94	13.3	80.00	100.0	63	-2.86	27.32	-86.7	0.00	60.0
	Week 41	66	73.33	19.57	6.7	73.33	100.0	60	-1.67	23.15	-60.0	-3.33	53.3
	Week 44	59	69.60	19.15	26.7	73.33	100.0	53	-4.65	21.67	-66.7	-6.67	40.0
	Week 47	52	71.41	20.68	20.0	73.33	100.0	48	-2.92	21.83	-46.7	-6.67	46.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	49	68.03	22.77	0.0	73.33	100.0	43	-6.82	22.65	-46.7	-6.67	46.7
	Week 53	50	67.20	21.42	6.7	66.67	100.0	44	-6.06	21.37	-46.7	-6.67	53.3
	Week 56	45	66.82	20.57	20.0	66.67	100.0	39	-5.98	20.22	-46.7	-6.66	40.0
	Week 59	44	68.94	19.02	20.0	73.33	100.0	38	-5.79	20.86	-46.7	-6.67	46.7
	Week 62	38	69.83	20.07	13.3	73.33	100.0	33	-8.48	22.93	-66.7	-6.67	46.7
	Week 65	25	69.87	17.86	26.7	73.33	100.0	24	-6.39	25.82	-46.7	-10.00	40.0
	Week 68	31	68.39	22.24	6.7	66.67	100.0	29	-9.20	25.97	-66.7	-6.67	40.0
	Week 71	27	70.12	21.83	13.3	73.33	100.0	25	-4.80	24.38	-60.0	-6.66	40.0
	Week 74	23	71.30	19.74	20.0	73.33	100.0	22	-6.36	27.33	-60.0	-6.66	46.7
	Week 77	24	71.67	18.78	33.3	70.00	100.0	23	-4.93	24.14	-46.7	-6.67	46.7
	Week 80	22	71.21	19.78	33.3	73.33	100.0	22	-4.85	23.92	-46.7	-6.67	46.7
	Week 83	19	69.47	22.26	13.3	73.33	100.0	19	-7.37	26.28	-66.7	-6.67	40.0
	Week 86	14	65.71	26.26	13.3	66.67	100.0	14	-12.38	29.34	-73.3	-10.00	40.0
	Week 89	10	71.33	25.73	13.3	73.34	100.0	10	-15.33	22.23	-66.7	-10.00	6.7
	Week 92	11	67.27	27.40	13.3	66.67	100.0	11	-9.70	21.37	-53.3	-6.67	26.7
	Plat+Gem (N=157)												
	BASELINE	128	70.21	25.39	0.0	80.00	100.0						
	Week 1	111	66.31	25.58	0.0	73.33	100.0	107	-3.80	14.66	-66.7	-6.66	26.7
	Week 2	110	64.91	25.07	0.0	66.67	100.0	102	-7.65	17.83	-80.0	-6.66	26.7
	Week 3	112	66.79	25.50	0.0	73.33	100.0	103	-5.82	18.40	-73.3	-6.66	53.3
	Week 4	112	67.50	24.00	0.0	73.33	100.0	102	-4.84	17.50	-53.3	-6.66	40.0
	Week 5	113	68.32	24.57	0.0	73.33	100.0	103	-3.95	18.63	-53.3	0.00	40.0
	Week 6	107	66.42	25.79	0.0	73.33	100.0	98	-5.58	20.99	-80.0	-6.66	40.0
	Week 7	109	67.22	24.23	13.3	73.33	100.0	100	-6.33	20.38	-66.7	-6.66	40.0
	Week 8	106	65.97	25.75	0.0	70.00	100.0	98	-7.01	21.35	-80.0	-3.33	40.0
	Week 9	105	66.41	25.35	0.0	73.33	100.0	94	-7.31	23.69	-80.0	0.00	40.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	104	67.50	24.80	0.0	73.33	100.0	96	-3.89	22.20	-66.7	0.00	53.3
	Week 11	91	65.27	25.83	0.0	73.33	100.0	83	-7.79	22.35	-86.7	-6.66	53.3
	Week 12	94	65.18	26.16	0.0	66.67	100.0	84	-6.67	20.17	-53.3	-6.67	46.7
	Week 14	90	67.48	24.86	0.0	73.33	100.0	79	-5.65	21.27	-60.0	-6.67	46.7
	Week 17	90	66.37	24.96	6.7	66.67	100.0	80	-8.08	23.54	-80.0	-6.66	46.7
	Week 20	74	68.65	24.69	6.7	80.00	100.0	64	-4.90	16.98	-60.0	0.00	33.3
	Week 23	63	71.64	22.88	13.3	73.33	100.0	58	-3.91	16.28	-46.7	0.00	40.0
	Week 26	55	70.18	23.02	6.7	73.33	100.0	52	-4.49	16.47	-46.7	0.00	40.0
	Week 29	53	69.31	25.50	0.0	80.00	100.0	50	-10.00	21.85	-93.3	-6.67	33.3
	Week 32	42	73.02	23.37	6.7	80.00	100.0	40	-5.33	20.66	-80.0	0.00	33.3
	Week 35	39	73.85	20.14	20.0	80.00	100.0	36	-5.00	16.04	-46.7	0.00	33.3
	Week 38	37	72.25	25.84	6.7	80.00	100.0	34	-7.84	26.33	-93.3	0.00	46.7
	Week 41	33	70.30	23.81	6.7	73.33	100.0	31	-5.81	19.07	-53.3	0.00	53.3
	Week 44	32	65.83	25.04	6.7	66.67	100.0	30	-8.44	24.13	-60.0	0.00	53.3
	Week 47	28	65.24	28.88	0.0	70.00	100.0	26	-10.51	23.49	-66.7	-3.33	20.0
	Week 50	22	70.30	26.00	13.3	80.00	100.0	20	-6.33	24.32	-66.7	0.00	26.7
	Week 53	19	67.02	28.41	13.3	73.33	100.0	17	-6.67	26.04	-66.7	0.00	33.3
	Week 56	18	66.30	30.12	0.0	76.67	100.0	17	-3.53	32.67	-80.0	0.00	53.3
	Week 59	13	65.13	28.57	20.0	60.00	100.0	12	2.22	25.48	-66.7	6.66	40.0
	Week 62	11	66.67	25.99	26.7	66.67	100.0	11	1.82	27.01	-66.7	0.00	40.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Lymph node only	EV+Pembro (N= 43)												
	BASELINE	33	82.83	14.53	40.0	86.67	100.0						
	Week 1	30	77.56	19.30	40.0	86.67	100.0	24	-4.44	11.58	-33.3	0.00	13.3
	Week 2	34	77.65	19.06	33.3	80.00	100.0	27	-1.73	11.19	-26.7	0.00	20.0
	Week 3	35	73.90	19.22	26.7	73.33	100.0	28	-5.24	15.33	-46.7	0.00	26.7
	Week 4	36	79.07	19.27	13.3	83.34	100.0	30	-0.44	10.78	-26.7	0.00	20.0
	Week 5	33	75.35	21.63	26.7	80.00	100.0	27	-6.67	16.33	-53.3	-6.66	20.0
	Week 6	34	74.71	21.51	6.7	80.00	100.0	28	-6.67	18.85	-66.7	0.00	26.7
	Week 7	34	77.06	19.98	0.0	80.00	100.0	28	-4.05	17.53	-66.7	0.00	20.0
	Week 8	35	74.29	19.34	13.3	80.00	100.0	29	-6.21	21.08	-86.7	0.00	13.3
	Week 9	30	73.33	21.51	0.0	80.00	100.0	24	-7.78	24.13	-100.0	-3.33	20.0
	Week 10	31	75.91	21.61	0.0	80.00	100.0	26	-7.95	24.44	-100.0	-3.33	20.0
	Week 11	34	77.06	19.91	0.0	80.00	100.0	27	-5.19	24.27	-100.0	0.00	33.3
	Week 12	35	76.57	19.96	26.7	80.00	100.0	28	-5.71	21.75	-73.3	-3.33	26.7
	Week 14	30	79.78	16.84	33.3	86.67	100.0	23	-2.61	18.17	-66.7	0.00	26.7
	Week 17	30	78.67	14.27	46.7	80.00	100.0	24	-4.44	20.68	-53.3	0.00	33.3
	Week 20	27	78.27	18.27	40.0	86.67	100.0	21	-4.13	22.46	-60.0	0.00	33.3
	Week 23	27	76.79	18.15	26.7	80.00	100.0	21	-6.35	21.44	-73.3	-6.66	20.0
	Week 26	27	74.57	24.04	13.3	86.67	100.0	22	-4.24	23.05	-53.3	0.00	33.3
	Week 29	28	72.86	24.07	0.0	80.00	100.0	23	-10.14	26.12	-80.0	-6.67	33.3
	Week 32	24	74.72	19.56	33.3	80.00	100.0	20	-9.67	17.50	-53.3	-6.66	20.0
	Week 35	22	68.79	24.03	6.7	76.67	100.0	18	-11.85	24.26	-66.7	-6.67	20.0
	Week 38	21	71.11	18.54	33.3	73.33	100.0	17	-9.02	18.55	-53.3	-6.66	20.0
	Week 41	22	70.61	19.37	33.3	70.00	100.0	17	-11.77	19.51	-60.0	-6.67	13.3
	Week 44	22	71.52	23.20	6.7	73.33	100.0	16	-9.58	18.69	-66.7	-6.67	13.3
	Week 47	21	71.75	19.54	33.3	80.00	100.0	16	-9.17	13.74	-33.3	-10.00	13.3

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	71.00	18.77	33.3	73.33	100.0	16	-10.00	14.61	-33.3	-10.00	20.0
	Week 53	18	70.37	19.02	26.7	70.00	100.0	14	-13.33	14.56	-40.0	-13.34	13.3
	Week 56	21	71.43	20.13	33.3	66.67	100.0	17	-6.67	19.86	-40.0	-6.67	33.3
	Week 59	21	69.52	18.81	33.3	66.67	100.0	16	-9.17	19.15	-33.3	-13.33	33.3
	Week 62	19	69.12	16.81	40.0	73.33	100.0	15	-9.78	16.11	-40.0	-13.33	20.0
	Week 65	16	68.75	19.43	40.0	73.33	100.0	14	-10.00	16.07	-46.7	-10.00	20.0
	Week 68	13	67.18	23.49	26.7	66.67	100.0	11	-8.48	13.03	-26.7	-6.66	20.0
	Week 71	13	68.21	24.52	26.7	73.33	100.0	11	-7.27	19.43	-53.3	-6.66	20.0
	Week 74	13	73.33	15.87	46.7	80.00	100.0	11	-6.06	18.96	-46.7	0.00	20.0
	Week 77	13	72.82	16.88	40.0	73.33	100.0	10	-2.67	17.55	-33.3	-3.33	20.0
	Week 80	13	70.77	19.54	40.0	73.33	100.0	11	-3.64	18.70	-40.0	0.00	20.0
	Week 83	11	74.55	16.55	53.3	80.00	100.0	10	-2.67	14.12	-26.7	-3.33	20.0
	Week 86	11	69.09	17.96	46.7	60.00	100.0	10	-8.00	15.65	-33.3	-3.34	13.3
	Plat+Gem (N= 37)												
	BASELINE	29	73.56	25.48	6.7	80.00	100.0						
	Week 1	26	66.67	23.63	13.3	70.00	100.0	25	-5.87	13.24	-33.3	-6.67	20.0
	Week 2	30	68.00	23.38	26.7	66.67	100.0	26	-6.15	13.85	-33.3	-3.34	26.7
	Week 3	30	68.00	25.21	6.7	80.00	100.0	26	-8.72	14.08	-40.0	-6.67	33.3
	Week 4	32	70.63	19.15	20.0	73.33	100.0	27	-5.68	18.83	-46.7	-6.67	40.0
	Week 5	33	68.69	19.04	20.0	73.33	100.0	28	-6.19	18.85	-46.7	-6.67	40.0
	Week 6	32	66.67	23.40	6.7	73.33	100.0	27	-8.89	22.64	-46.7	-6.66	53.3
	Week 7	31	65.16	21.41	13.3	66.67	93.3	26	-10.51	29.82	-66.7	-6.67	80.0
	Week 8	32	67.50	21.67	26.7	73.33	100.0	27	-8.39	24.64	-40.0	-13.33	60.0
	Week 9	30	63.56	23.73	0.0	66.67	100.0	25	-10.13	26.26	-46.7	-13.33	60.0
	Week 10	30	66.00	22.17	13.3	73.33	100.0	26	-9.49	26.74	-40.0	-13.34	66.7
	Week 11	29	68.28	21.06	20.0	66.67	100.0	25	-7.73	28.13	-46.7	-13.33	73.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.10.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 12	28	68.81	19.03	26.7	73.33	100.0	23	-7.54	28.73	-40.0	-13.33	73.3
	Week 14	28	63.81	21.04	20.0	63.34	100.0	23	-11.89	26.36	-53.3	-13.33	53.3
	Week 17	25	65.07	24.14	13.3	73.33	100.0	21	-13.65	27.69	-66.7	-13.33	46.7
	Week 20	23	72.75	22.10	6.7	73.33	100.0	20	-2.67	27.39	-73.3	-3.33	53.3
	Week 23	20	77.67	20.78	33.3	80.00	100.0	17	1.18	25.41	-46.7	0.00	53.3
	Week 26	21	71.43	25.92	0.0	80.00	100.0	18	-2.96	32.11	-66.7	-6.67	66.7
	Week 29	19	70.53	25.85	0.0	80.00	100.0	16	-2.50	30.59	-53.3	-6.67	53.3
	Week 32	18	71.48	22.96	13.3	80.00	100.0	15	-1.78	33.85	-53.3	-13.33	60.0
	Week 35	19	71.23	22.45	20.0	80.00	100.0	16	-5.00	30.45	-46.7	-13.33	46.7
	Week 38	15	74.67	18.89	26.7	80.00	100.0	12	-5.00	27.43	-40.0	-13.33	53.3
	Week 41	15	69.33	24.66	26.7	80.00	100.0	12	-10.56	31.71	-53.3	-13.33	53.3
	Week 44	14	64.76	27.23	6.7	73.34	93.3	11	-15.15	36.04	-80.0	-20.00	46.7
	Week 47	12	70.56	23.35	26.7	76.67	100.0	10	-8.00	32.93	-40.0	-16.67	53.3
	Week 50	11	67.27	25.38	26.7	73.33	100.0	8	-2.50	40.46	-40.0	-16.67	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
EV+Pembro (N=240)												
BASELINE	206	78.48	27.85	0.0	100.00	100.0						
Week 1	190	73.86	29.16	0.0	83.33	100.0	184	-5.80	20.75	-83.3	0.00	50.0
Week 2	203	70.28	29.12	0.0	66.67	100.0	189	-9.26	22.04	-100.0	0.00	50.0
Week 3	198	67.68	28.68	0.0	66.67	100.0	182	-11.17	24.66	-100.0	0.00	66.7
Week 4	194	74.06	26.98	0.0	83.33	100.0	179	-5.87	26.17	-100.0	0.00	66.7
Week 5	190	73.33	28.06	0.0	75.00	100.0	173	-6.17	27.62	-100.0	0.00	83.3
Week 6	188	75.36	26.73	0.0	66.67	100.0	170	-4.41	26.62	-100.0	0.00	83.3
Week 7	195	74.53	25.62	0.0	66.67	100.0	176	-5.21	29.22	-100.0	0.00	66.7
Week 8	191	76.27	25.50	0.0	83.33	100.0	171	-3.02	29.02	-100.0	0.00	83.3
Week 9	197	72.84	27.76	0.0	66.67	100.0	180	-6.67	29.14	-100.0	0.00	83.3
Week 10	191	76.44	25.60	0.0	83.33	100.0	175	-1.52	29.43	-100.0	0.00	83.3
Week 11	194	74.40	26.78	0.0	66.67	100.0	175	-3.81	30.45	-100.0	0.00	83.3
Week 12	186	74.46	27.68	0.0	66.67	100.0	171	-3.61	30.76	-100.0	0.00	66.7
Week 14	185	74.23	26.06	0.0	66.67	100.0	167	-4.09	29.24	-100.0	0.00	83.3
Week 17	178	74.25	24.62	0.0	66.67	100.0	162	-4.42	28.65	-66.7	0.00	83.3
Week 20	167	71.36	27.92	0.0	66.67	100.0	154	-8.01	32.29	-100.0	0.00	83.3
Week 23	162	69.44	28.79	0.0	66.67	100.0	151	-10.15	30.91	-100.0	0.00	66.7
Week 26	156	71.15	29.11	0.0	66.67	100.0	144	-8.33	33.45	-100.0	0.00	66.7
Week 29	157	73.99	24.63	0.0	66.67	100.0	145	-7.13	31.35	-83.3	0.00	83.3
Week 32	135	71.11	26.17	0.0	66.67	100.0	125	-10.93	30.02	-83.3	0.00	66.7
Week 35	132	69.32	25.54	0.0	66.67	100.0	122	-13.52	28.53	-83.3	-16.66	66.7
Week 38	132	68.81	24.66	0.0	66.67	100.0	124	-12.36	29.52	-66.7	0.00	66.7
Week 41	129	70.41	25.45	0.0	66.67	100.0	119	-11.90	29.36	-66.7	0.00	66.7
Week 44	108	68.36	27.34	0.0	66.67	100.0	100	-17.00	33.75	-100.0	-16.66	66.7
Week 47	100	68.83	27.79	0.0	66.67	100.0	94	-15.60	32.68	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	89	67.23	26.29	0.0	66.67	100.0	84	-17.46	30.82	-100.0	-16.67	66.7
Week 53	79	71.73	24.22	0.0	66.67	100.0	74	-16.44	30.90	-100.0	0.00	66.7
Week 56	81	69.14	25.43	0.0	66.67	100.0	76	-14.69	31.15	-100.0	-16.66	66.7
Week 59	72	69.45	24.55	0.0	66.67	100.0	68	-16.91	28.87	-100.0	-16.66	66.7
Week 62	65	71.80	26.50	0.0	66.67	100.0	63	-16.67	30.96	-100.0	0.00	66.7
Week 65	58	69.25	27.89	0.0	66.67	100.0	54	-16.97	31.47	-100.0	-8.33	66.7
Week 68	53	72.01	26.91	0.0	66.67	100.0	52	-16.02	31.13	-100.0	-16.66	66.7
Week 71	51	72.55	27.04	0.0	66.67	100.0	49	-16.33	29.56	-100.0	-16.66	66.7
Week 74	47	70.21	25.99	0.0	66.67	100.0	46	-17.75	28.20	-100.0	-16.67	66.7
Week 77	44	63.64	30.13	0.0	66.67	100.0	42	-19.84	33.38	-100.0	-25.00	66.7
Week 80	40	67.08	28.37	0.0	66.67	100.0	37	-15.31	31.76	-100.0	-16.66	66.7
Week 83	37	64.42	28.37	0.0	66.67	100.0	35	-17.62	30.77	-100.0	-16.67	66.7
Week 86	34	66.18	28.27	0.0	66.67	100.0	31	-17.20	28.38	-100.0	-16.66	50.0
Week 89	33	64.65	27.25	0.0	66.67	100.0	31	-18.28	32.02	-100.0	-16.66	66.7
Week 92	27	65.43	29.21	0.0	66.67	100.0	25	-20.00	23.57	-50.0	-33.33	33.3
Week 95	22	62.12	30.51	0.0	66.67	100.0	21	-23.81	25.04	-66.7	-33.33	33.3
Week 98	18	73.15	29.23	0.0	66.67	100.0	17	-12.74	24.67	-50.0	0.00	33.3
Week 101	14	71.43	28.06	33.3	75.00	100.0	14	-19.05	25.20	-66.7	-8.33	0.0
Week 104	10	68.33	25.40	33.3	66.67	100.0	10	-26.67	25.09	-66.7	-33.33	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Plat+Gem (N=242)												
BASELINE	188	73.05	27.80	0.0	66.67	100.0						
Week 1	173	68.21	27.97	0.0	66.67	100.0	158	-6.43	22.55	-83.3	0.00	50.0
Week 2	171	64.33	29.61	0.0	66.67	100.0	151	-11.48	27.02	-100.0	0.00	66.7
Week 3	184	72.01	25.25	0.0	66.67	100.0	162	-2.26	24.96	-83.3	0.00	83.3
Week 4	183	68.58	27.59	0.0	66.67	100.0	156	-6.52	23.99	-83.3	0.00	83.3
Week 5	187	66.13	27.32	0.0	66.67	100.0	156	-11.22	27.38	-100.0	0.00	83.3
Week 6	174	68.97	27.02	0.0	66.67	100.0	149	-5.82	26.28	-100.0	0.00	83.3
Week 7	186	68.91	27.61	0.0	66.67	100.0	157	-7.11	27.49	-100.0	0.00	50.0
Week 8	167	67.96	27.80	0.0	66.67	100.0	144	-8.80	30.53	-100.0	0.00	66.7
Week 9	177	67.42	26.16	0.0	66.67	100.0	150	-8.44	29.01	-100.0	0.00	66.7
Week 10	166	66.37	27.06	0.0	66.67	100.0	139	-9.59	27.51	-100.0	0.00	50.0
Week 11	168	69.05	26.20	0.0	66.67	100.0	143	-8.16	29.33	-100.0	0.00	83.3
Week 12	159	69.50	25.86	0.0	66.67	100.0	138	-7.25	29.59	-100.0	0.00	83.3
Week 14	153	68.19	26.03	0.0	66.67	100.0	128	-7.55	30.59	-100.0	0.00	66.7
Week 17	155	68.06	25.90	0.0	66.67	100.0	130	-10.26	28.48	-100.0	-8.33	66.7
Week 20	126	71.16	24.98	0.0	66.67	100.0	110	-7.12	28.77	-83.3	0.00	83.3
Week 23	115	71.30	26.72	0.0	66.67	100.0	97	-7.90	26.69	-66.7	0.00	50.0
Week 26	108	72.84	26.04	0.0	66.67	100.0	95	-7.37	25.92	-66.7	0.00	83.3
Week 29	100	73.33	24.96	0.0	66.67	100.0	86	-9.50	26.51	-100.0	0.00	33.3
Week 32	83	75.30	25.15	0.0	83.33	100.0	76	-7.68	27.00	-83.3	0.00	66.7
Week 35	76	73.68	26.14	0.0	66.67	100.0	69	-8.94	27.65	-83.3	0.00	33.3
Week 38	74	75.23	28.57	0.0	83.33	100.0	65	-7.95	30.63	-83.3	0.00	83.3
Week 41	65	72.82	25.95	0.0	66.67	100.0	56	-8.04	28.95	-66.7	0.00	83.3
Week 44	60	71.94	28.21	0.0	66.67	100.0	53	-9.12	32.94	-100.0	0.00	83.3
Week 47	56	73.81	22.89	0.0	66.67	100.0	49	-7.82	30.06	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	51	69.61	26.61	0.0	66.67	100.0	47	-9.57	27.75	-100.0	0.00	83.3
Week 53	46	76.45	21.25	33.3	66.67	100.0	42	-7.54	26.08	-66.7	0.00	83.3
Week 56	39	68.80	31.57	0.0	66.67	100.0	34	-13.24	32.77	-83.3	0.00	83.3
Week 59	37	80.18	22.85	0.0	83.33	100.0	33	-2.53	26.72	-66.7	0.00	66.7
Week 62	32	76.56	17.38	33.3	66.67	100.0	29	-5.75	28.27	-66.7	0.00	83.3
Week 65	30	75.56	26.89	0.0	75.00	100.0	26	-7.69	27.98	-100.0	0.00	33.3
Week 68	25	76.67	25.00	0.0	66.67	100.0	21	-8.73	21.48	-50.0	0.00	33.3
Week 71	22	71.97	28.35	0.0	66.67	100.0	19	-11.40	27.81	-66.7	0.00	33.3
Week 74	21	76.19	26.65	0.0	66.67	100.0	18	-4.63	19.64	-33.3	0.00	33.3
Week 77	18	76.85	26.90	0.0	75.00	100.0	15	-2.22	18.76	-33.3	0.00	33.3
Week 80	14	78.57	18.98	33.3	83.33	100.0	13	-7.69	19.97	-33.3	0.00	33.3
Week 83	13	78.21	17.19	50.0	66.67	100.0	12	-6.95	22.98	-33.3	-8.34	33.3
Week 86	12	86.11	15.62	66.7	91.67	100.0	11	0.00	19.72	-33.3	0.00	33.3
Week 89	11	80.30	16.36	66.7	66.67	100.0	10	-5.00	27.27	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Present	EV+Pembro (N= 48)												
	BASELINE	39	68.80	30.39	0.0	66.67	100.0						
	Week 1	32	68.23	30.63	0.0	66.67	100.0	32	-2.08	16.26	-33.3	0.00	33.3
	Week 2	37	58.11	30.59	0.0	66.67	100.0	33	-12.12	24.75	-66.7	0.00	33.3
	Week 3	34	51.96	30.91	0.0	50.00	100.0	29	-13.22	27.23	-83.3	0.00	33.3
	Week 4	36	62.50	31.97	0.0	66.67	100.0	31	-8.06	31.29	-83.3	0.00	66.7
	Week 5	30	58.33	37.07	0.0	66.67	100.0	24	-9.03	39.00	-100.0	0.00	66.7
	Week 6	31	62.90	33.25	0.0	66.67	100.0	25	-5.33	31.08	-100.0	0.00	50.0
	Week 7	34	65.69	28.11	0.0	66.67	100.0	28	-1.78	33.44	-100.0	0.00	50.0
	Week 8	35	70.00	26.13	0.0	66.67	100.0	30	5.00	31.91	-66.7	0.00	66.7
	Week 9	34	58.82	34.39	0.0	66.67	100.0	30	-10.00	32.93	-100.0	0.00	33.3
	Week 10	34	68.14	30.53	0.0	66.67	100.0	30	-1.67	35.38	-100.0	0.00	50.0
	Week 11	33	56.57	33.58	0.0	66.67	100.0	28	-10.12	41.91	-100.0	0.00	66.7
	Week 12	33	62.63	34.87	0.0	66.67	100.0	29	-2.87	37.29	-100.0	0.00	66.7
	Week 14	31	65.05	28.01	0.0	66.67	100.0	26	-0.64	33.16	-100.0	0.00	66.7
	Week 17	31	66.67	26.53	0.0	66.67	100.0	25	4.00	30.15	-50.0	0.00	83.3
	Week 20	27	61.73	31.63	0.0	66.67	100.0	24	-6.25	35.72	-100.0	0.00	33.3
	Week 23	26	66.03	26.03	16.7	66.67	100.0	23	-2.90	30.84	-66.7	0.00	50.0
	Week 26	25	72.00	29.16	0.0	83.33	100.0	22	5.30	32.28	-66.7	0.00	66.7
	Week 29	23	73.19	28.31	0.0	66.67	100.0	22	1.52	39.81	-66.7	0.00	83.3
	Week 32	21	71.43	26.43	33.3	66.67	100.0	19	3.51	36.25	-66.7	0.00	66.7
	Week 35	19	67.54	29.12	0.0	66.67	100.0	17	-4.90	36.69	-66.7	0.00	66.7
	Week 38	18	53.70	25.92	0.0	50.00	100.0	17	-10.78	36.30	-66.7	0.00	50.0
	Week 41	20	66.67	24.78	33.3	66.67	100.0	19	-3.51	33.14	-66.7	0.00	66.7
	Week 44	17	62.75	29.19	0.0	66.67	100.0	15	-16.67	41.31	-100.0	-16.66	66.7
	Week 47	18	59.26	34.41	0.0	50.00	100.0	16	-15.63	40.58	-66.7	-8.33	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	12	69.45	28.28	16.7	66.67	100.0	11	-13.63	36.38	-83.3	0.00	33.3
	Week 53	12	68.06	31.35	0.0	75.00	100.0	11	-16.67	40.14	-100.0	0.00	50.0
	Week 56	13	60.26	35.71	0.0	66.67	100.0	12	-16.67	45.51	-100.0	-8.33	66.7
	Week 59	12	72.22	31.25	0.0	66.67	100.0	11	-3.03	41.38	-100.0	0.00	66.7
	Week 62	10	71.67	36.89	0.0	91.67	100.0	9	-11.11	47.14	-100.0	0.00	66.7
	Week 65	10	63.33	39.13	0.0	75.00	100.0	9	-16.67	47.14	-100.0	0.00	66.7
	Plat+Gem (N= 48)												
	BASELINE	33	71.21	30.98	0.0	83.33	100.0						
	Week 1	31	64.52	31.25	0.0	66.67	100.0	27	-8.02	25.89	-50.0	0.00	50.0
	Week 2	29	54.60	29.51	0.0	66.67	100.0	24	-22.92	29.41	-83.3	-16.67	33.3
	Week 3	32	75.52	23.94	0.0	83.33	100.0	27	0.00	28.49	-50.0	0.00	83.3
	Week 4	32	70.83	29.63	0.0	75.00	100.0	24	-2.08	27.94	-33.3	0.00	83.3
	Week 5	36	64.35	31.41	0.0	66.67	100.0	28	-10.12	33.13	-66.7	-8.33	83.3
	Week 6	35	66.67	33.82	0.0	66.67	100.0	27	0.00	26.95	-33.3	0.00	83.3
	Week 7	38	68.42	31.90	0.0	66.67	100.0	29	1.15	27.79	-66.7	0.00	50.0
	Week 8	31	72.04	30.55	0.0	83.33	100.0	25	-4.00	28.98	-66.7	0.00	50.0
	Week 9	32	66.67	27.44	0.0	66.67	100.0	25	-2.67	20.23	-33.3	0.00	50.0
	Week 10	34	69.61	29.44	0.0	66.67	100.0	26	1.28	20.51	-33.3	0.00	50.0
	Week 11	30	77.78	25.27	16.7	83.33	100.0	24	5.56	31.72	-66.7	0.00	83.3
	Week 12	28	75.00	22.91	33.3	66.67	100.0	23	4.35	28.08	-50.0	0.00	83.3
	Week 14	26	73.08	18.90	33.3	66.67	100.0	21	-3.97	28.34	-50.0	0.00	66.7
	Week 17	30	76.11	20.38	33.3	83.33	100.0	25	0.00	23.57	-33.3	0.00	66.7
	Week 20	23	80.43	18.57	33.3	83.33	100.0	21	3.97	26.30	-33.3	0.00	83.3
	Week 23	22	69.70	28.93	33.3	75.00	100.0	19	-10.53	28.98	-66.7	0.00	33.3
	Week 26	19	82.46	23.22	33.3	100.00	100.0	18	-1.85	19.71	-33.3	0.00	33.3
	Week 29	16	77.08	25.00	33.3	83.33	100.0	14	-5.95	24.12	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 32	11	74.24	25.12	16.7	66.67	100.0	11	-15.15	20.35	-50.0	-16.66	16.7
	Week 35	10	75.00	22.57	33.3	75.00	100.0	9	-9.26	14.70	-33.3	-16.66	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Absent	EV+Pembro (N=192)												
	BASELINE	167	80.74	26.82	0.0	100.00	100.0						
	Week 1	158	75.00	28.82	0.0	83.33	100.0	152	-6.58	21.54	-83.3	0.00	50.0
	Week 2	166	72.99	28.16	0.0	83.33	100.0	156	-8.65	21.46	-100.0	0.00	50.0
	Week 3	164	70.94	27.17	0.0	66.67	100.0	153	-10.78	24.22	-100.0	0.00	66.7
	Week 4	158	76.69	25.09	0.0	83.33	100.0	148	-5.41	25.06	-100.0	0.00	66.7
	Week 5	160	76.15	25.19	0.0	83.33	100.0	149	-5.70	25.47	-83.3	0.00	83.3
	Week 6	157	77.81	24.63	0.0	83.33	100.0	145	-4.25	25.89	-100.0	0.00	83.3
	Week 7	161	76.40	24.76	0.0	83.33	100.0	148	-5.86	28.43	-100.0	0.00	66.7
	Week 8	156	77.67	25.22	0.0	83.33	100.0	141	-4.73	28.19	-100.0	0.00	83.3
	Week 9	163	75.77	25.34	0.0	66.67	100.0	150	-6.00	28.40	-100.0	0.00	83.3
	Week 10	157	78.24	24.14	0.0	83.33	100.0	145	-1.49	28.19	-100.0	0.00	83.3
	Week 11	161	78.05	23.67	0.0	83.33	100.0	147	-2.61	27.77	-83.3	0.00	83.3
	Week 12	153	77.02	25.29	0.0	83.33	100.0	142	-3.76	29.40	-100.0	0.00	66.7
	Week 14	154	76.08	25.35	0.0	66.67	100.0	141	-4.73	28.54	-100.0	0.00	83.3
	Week 17	147	75.85	23.98	0.0	66.67	100.0	137	-5.96	28.20	-66.7	0.00	83.3
	Week 20	140	73.21	26.87	0.0	66.67	100.0	130	-8.33	31.76	-100.0	0.00	83.3
	Week 23	136	70.10	29.34	0.0	66.67	100.0	128	-11.46	30.86	-100.0	0.00	66.7
	Week 26	131	70.99	29.21	0.0	66.67	100.0	122	-10.79	33.19	-100.0	0.00	66.7
	Week 29	134	74.13	24.06	0.0	66.67	100.0	123	-8.67	29.52	-83.3	0.00	66.7
	Week 32	114	71.05	26.24	0.0	66.67	100.0	106	-13.52	28.18	-83.3	0.00	66.7
	Week 35	113	69.62	25.02	0.0	66.67	100.0	105	-14.92	26.95	-83.3	-16.66	50.0
	Week 38	114	71.20	23.70	0.0	66.67	100.0	107	-12.62	28.49	-66.7	0.00	66.7
	Week 41	109	71.10	25.62	0.0	66.67	100.0	100	-13.50	28.50	-66.7	-8.33	50.0
	Week 44	91	69.41	27.02	0.0	66.67	100.0	85	-17.06	32.53	-100.0	-16.66	66.7
	Week 47	82	70.94	25.90	0.0	66.67	100.0	78	-15.60	31.13	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	77	66.88	26.14	0.0	66.67	100.0	73	-18.04	30.14	-100.0	-16.67	66.7
	Week 53	67	72.39	22.95	16.7	66.67	100.0	63	-16.40	29.40	-83.3	-16.66	66.7
	Week 56	68	70.83	22.92	0.0	66.67	100.0	64	-14.32	28.15	-83.3	-16.66	66.7
	Week 59	60	68.89	23.26	0.0	66.67	100.0	57	-19.59	25.42	-100.0	-16.67	16.7
	Week 62	55	71.82	24.61	0.0	66.67	100.0	54	-17.59	27.93	-100.0	-16.66	66.7
	Week 65	48	70.49	25.32	0.0	66.67	100.0	45	-17.04	28.09	-100.0	-16.66	33.3
	Week 68	46	72.10	25.59	0.0	66.67	100.0	45	-17.78	27.62	-100.0	-16.66	33.3
	Week 71	44	71.59	26.56	0.0	66.67	100.0	42	-19.84	26.35	-100.0	-16.67	33.3
	Week 74	40	70.00	25.65	0.0	66.67	100.0	39	-20.51	25.50	-100.0	-16.67	33.3
	Week 77	38	64.04	28.08	0.0	66.67	100.0	36	-21.76	30.03	-100.0	-33.33	50.0
	Week 80	35	68.10	27.53	0.0	66.67	100.0	32	-16.67	29.02	-100.0	-16.67	33.3
	Week 83	32	66.15	25.57	0.0	66.67	100.0	30	-18.33	26.02	-100.0	-16.67	33.3
	Week 86	29	64.37	28.43	0.0	66.67	100.0	26	-21.15	26.90	-100.0	-25.00	33.3
	Week 89	29	63.79	26.75	0.0	66.67	100.0	27	-21.60	28.80	-100.0	-16.67	33.3
	Week 92	24	63.20	29.07	0.0	66.67	100.0	22	-20.45	23.53	-50.0	-33.33	33.3
	Week 95	20	63.33	31.34	0.0	66.67	100.0	19	-22.81	26.18	-66.7	-33.33	33.3
	Week 98	18	73.15	29.23	0.0	66.67	100.0	17	-12.74	24.67	-50.0	0.00	33.3
	Week 101	13	74.36	26.89	33.3	83.33	100.0	13	-15.38	22.01	-66.7	0.00	0.0
	Plat+Gem (N=194)												
	BASELINE	155	73.44	27.17	0.0	66.67	100.0						
	Week 1	142	69.01	27.26	0.0	66.67	100.0	131	-6.11	21.90	-83.3	0.00	50.0
	Week 2	142	66.32	29.34	0.0	66.67	100.0	127	-9.32	26.11	-100.0	0.00	66.7
	Week 3	152	71.27	25.53	0.0	66.67	100.0	135	-2.72	24.28	-83.3	0.00	66.7
	Week 4	151	68.10	27.21	0.0	66.67	100.0	132	-7.32	23.23	-83.3	0.00	50.0
	Week 5	151	66.56	26.35	0.0	66.67	100.0	128	-11.46	26.10	-100.0	0.00	50.0
	Week 6	139	69.54	25.13	0.0	66.67	100.0	122	-7.10	26.06	-100.0	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 7	148	69.03	26.51	0.0	66.67	100.0	128	-8.98	27.18	-100.0	0.00	50.0
	Week 8	136	67.03	27.18	0.0	66.67	100.0	119	-9.80	30.87	-100.0	0.00	66.7
	Week 9	145	67.59	25.97	0.0	66.67	100.0	125	-9.60	30.40	-100.0	0.00	66.7
	Week 10	132	65.53	26.47	0.0	66.67	100.0	113	-12.09	28.37	-100.0	0.00	50.0
	Week 11	138	67.15	26.10	0.0	66.67	100.0	119	-10.92	28.16	-100.0	0.00	66.7
	Week 12	131	68.32	26.38	0.0	66.67	100.0	115	-9.57	29.46	-100.0	0.00	66.7
	Week 14	127	67.19	27.21	0.0	66.67	100.0	107	-8.26	31.09	-100.0	0.00	66.7
	Week 17	125	66.13	26.77	0.0	66.67	100.0	105	-12.70	29.10	-100.0	-16.66	66.7
	Week 20	103	69.09	25.82	0.0	66.67	100.0	89	-9.74	28.85	-83.3	0.00	66.7
	Week 23	93	71.68	26.33	0.0	66.67	100.0	78	-7.27	26.26	-66.7	0.00	50.0
	Week 26	89	70.79	26.27	0.0	66.67	100.0	77	-8.66	27.12	-66.7	0.00	83.3
	Week 29	84	72.62	25.04	0.0	66.67	100.0	72	-10.18	27.06	-100.0	0.00	33.3
	Week 32	72	75.46	25.33	0.0	83.33	100.0	65	-6.41	27.90	-83.3	0.00	66.7
	Week 35	66	73.49	26.79	0.0	66.67	100.0	60	-8.89	29.19	-83.3	0.00	33.3
	Week 38	66	75.00	29.27	0.0	83.33	100.0	57	-6.73	31.79	-83.3	0.00	83.3
	Week 41	62	73.12	25.85	0.0	66.67	100.0	53	-7.55	29.52	-66.7	0.00	83.3
	Week 44	55	72.42	28.55	0.0	66.67	100.0	48	-7.64	33.33	-100.0	0.00	83.3
	Week 47	51	74.84	23.66	0.0	66.67	100.0	44	-5.68	30.49	-100.0	0.00	66.7
	Week 50	48	69.45	27.36	0.0	66.67	100.0	44	-9.85	28.15	-100.0	0.00	83.3
	Week 53	41	76.02	21.75	33.3	66.67	100.0	37	-6.76	27.06	-66.7	0.00	83.3
	Week 56	34	72.55	30.12	0.0	66.67	100.0	29	-8.05	30.41	-66.7	0.00	83.3
	Week 59	32	81.25	22.30	0.0	83.33	100.0	28	0.60	25.45	-50.0	0.00	66.7
	Week 62	27	77.78	16.01	50.0	66.67	100.0	24	-2.08	27.50	-33.3	0.00	83.3
	Week 65	25	79.33	24.66	0.0	83.33	100.0	21	-0.79	20.73	-33.3	0.00	33.3
	Week 68	23	77.54	25.43	0.0	66.67	100.0	19	-6.14	20.19	-33.3	0.00	33.3
	Week 71	21	73.81	27.67	0.0	66.67	100.0	18	-8.33	25.08	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 74	20	75.83	27.29	0.0	66.67	100.0	17	-3.92	20.01	-33.3	0.00	33.3
	Week 77	16	77.08	28.46	0.0	83.34	100.0	13	-1.28	19.79	-33.3	0.00	33.3
	Week 80	12	80.56	19.89	33.3	83.33	100.0	11	-6.06	20.10	-33.3	0.00	33.3
	Week 83	11	78.79	18.39	50.0	66.67	100.0	10	-6.67	25.09	-33.3	-8.34	33.3
	Week 86	10	88.33	15.81	66.7	100.00	100.0	9	1.85	21.15	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
< 65 years	EV+Pembro (N=105)												
	BASELINE	92	74.28	30.00	0.0	83.33	100.0						
	Week 1	88	72.16	29.55	0.0	75.00	100.0	85	-3.73	18.43	-66.7	0.00	50.0
	Week 2	92	69.75	29.23	0.0	66.67	100.0	86	-6.59	21.73	-66.7	0.00	50.0
	Week 3	93	65.95	29.17	0.0	66.67	100.0	84	-9.13	26.05	-100.0	0.00	50.0
	Week 4	90	74.44	26.35	0.0	83.33	100.0	82	0.41	24.84	-66.7	0.00	66.7
	Week 5	90	73.15	28.45	0.0	83.33	100.0	81	-2.26	29.43	-100.0	0.00	83.3
	Week 6	90	77.59	25.25	16.7	83.33	100.0	81	3.70	25.95	-66.7	0.00	83.3
	Week 7	85	75.69	23.79	16.7	66.67	100.0	77	1.95	26.07	-66.7	0.00	66.7
	Week 8	89	78.09	22.42	0.0	83.33	100.0	80	3.54	26.61	-66.7	0.00	83.3
	Week 9	93	73.66	26.04	0.0	66.67	100.0	85	-1.96	28.80	-100.0	0.00	83.3
	Week 10	88	78.41	25.16	0.0	83.33	100.0	81	4.94	30.67	-100.0	0.00	83.3
	Week 11	93	76.52	24.11	0.0	83.33	100.0	84	2.98	31.60	-100.0	0.00	83.3
	Week 12	86	76.16	24.19	0.0	66.67	100.0	79	2.11	30.00	-66.7	0.00	66.7
	Week 14	84	73.22	26.51	0.0	66.67	100.0	76	0.44	29.81	-66.7	0.00	83.3
	Week 17	83	75.30	24.05	0.0	66.67	100.0	77	0.22	31.82	-66.7	0.00	83.3
	Week 20	79	71.52	26.44	0.0	66.67	100.0	73	-2.28	33.72	-100.0	0.00	83.3
	Week 23	78	69.44	27.97	0.0	66.67	100.0	73	-6.39	29.61	-66.7	0.00	66.7
	Week 26	78	72.44	26.02	0.0	66.67	100.0	72	-2.08	30.76	-66.7	0.00	66.7
	Week 29	74	74.78	22.11	33.3	66.67	100.0	67	-2.74	30.51	-66.7	0.00	83.3
	Week 32	64	70.83	28.17	0.0	66.67	100.0	59	-7.91	28.93	-66.7	0.00	66.7
	Week 35	62	70.97	25.95	0.0	66.67	100.0	58	-10.34	26.09	-66.7	0.00	66.7
	Week 38	62	68.82	23.47	0.0	66.67	100.0	59	-9.60	28.57	-66.7	0.00	66.7
	Week 41	64	70.31	25.97	0.0	66.67	100.0	59	-7.91	27.40	-66.7	0.00	66.7
	Week 44	50	71.00	26.26	0.0	66.67	100.0	48	-10.07	29.32	-66.7	0.00	66.7
	Week 47	47	66.67	29.69	0.0	66.67	100.0	46	-15.22	34.22	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	44	64.39	24.80	0.0	66.67	100.0	41	-19.92	31.45	-100.0	-33.33	66.7
	Week 53	40	70.42	24.31	0.0	66.67	100.0	37	-16.22	32.51	-100.0	0.00	66.7
	Week 56	44	68.94	26.07	0.0	66.67	100.0	41	-13.01	30.16	-100.0	0.00	66.7
	Week 59	42	67.46	24.68	0.0	66.67	100.0	39	-18.37	32.17	-100.0	-16.67	66.7
	Week 62	37	71.17	27.68	0.0	66.67	100.0	36	-13.43	35.15	-100.0	0.00	66.7
	Week 65	34	67.65	26.57	0.0	66.67	100.0	31	-17.20	34.29	-100.0	0.00	66.7
	Week 68	34	70.10	27.46	0.0	66.67	100.0	33	-15.15	34.20	-100.0	-16.66	66.7
	Week 71	32	69.27	29.06	0.0	66.67	100.0	30	-18.33	32.56	-100.0	-16.67	66.7
	Week 74	29	63.79	27.84	0.0	66.67	100.0	28	-22.02	31.77	-100.0	-33.33	66.7
	Week 77	25	60.00	28.06	0.0	66.67	100.0	24	-21.53	35.26	-100.0	-33.33	66.7
	Week 80	24	61.81	27.13	0.0	66.67	100.0	22	-19.70	33.19	-100.0	-33.33	66.7
	Week 83	23	60.87	27.80	0.0	66.67	100.0	22	-18.94	33.84	-100.0	-25.00	66.7
	Week 86	20	57.50	27.82	0.0	66.67	100.0	18	-21.30	30.68	-100.0	-33.33	50.0
	Week 89	19	57.90	27.98	0.0	66.67	100.0	17	-22.55	37.70	-100.0	-33.33	66.7
	Week 92	14	58.34	29.05	0.0	66.67	100.0	12	-27.78	19.24	-50.0	-33.33	0.0
	Week 95	12	55.56	30.43	0.0	66.67	100.0	11	-28.79	19.85	-66.7	-33.33	0.0
	Plat+Gem (N=106)												
	BASELINE	83	73.70	24.57	16.7	66.67	100.0						
	Week 1	75	67.78	25.31	0.0	66.67	100.0	71	-9.15	24.20	-66.7	0.00	50.0
	Week 2	76	64.25	31.35	0.0	66.67	100.0	68	-8.82	27.39	-83.3	0.00	66.7
	Week 3	80	71.88	25.52	0.0	66.67	100.0	73	-2.05	27.63	-83.3	0.00	66.7
	Week 4	79	67.72	27.00	0.0	66.67	100.0	67	-5.47	23.82	-83.3	0.00	50.0
	Week 5	80	68.13	26.54	0.0	66.67	100.0	67	-9.70	27.70	-83.3	0.00	50.0
	Week 6	76	70.61	25.07	0.0	66.67	100.0	67	-3.73	23.72	-66.7	0.00	50.0
	Week 7	81	69.34	28.19	0.0	66.67	100.0	71	-5.40	26.09	-83.3	0.00	50.0
	Week 8	72	71.53	24.30	0.0	66.67	100.0	64	-4.69	31.07	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	78	67.74	23.62	16.7	66.67	100.0	69	-5.31	30.59	-83.3	0.00	66.7
	Week 10	78	67.74	23.32	0.0	66.67	100.0	68	-5.64	26.17	-66.7	0.00	50.0
	Week 11	75	68.22	25.44	0.0	66.67	100.0	66	-5.30	31.37	-100.0	0.00	83.3
	Week 12	74	70.95	22.08	0.0	66.67	100.0	66	-3.53	28.57	-100.0	0.00	66.7
	Week 14	68	70.10	23.32	0.0	66.67	100.0	58	-1.72	30.86	-66.7	0.00	66.7
	Week 17	68	66.18	25.75	0.0	66.67	100.0	58	-7.47	28.81	-66.7	0.00	66.7
	Week 20	60	72.50	22.93	0.0	66.67	100.0	52	-2.56	28.27	-66.7	0.00	83.3
	Week 23	51	72.22	25.09	0.0	66.67	100.0	44	-4.17	25.45	-66.7	0.00	50.0
	Week 26	47	72.34	25.60	0.0	66.67	100.0	42	-2.78	26.78	-66.7	0.00	83.3
	Week 29	42	74.60	21.54	16.7	66.67	100.0	37	-4.05	22.01	-66.7	0.00	33.3
	Week 32	37	72.07	23.59	16.7	66.67	100.0	34	-6.86	27.86	-66.7	0.00	66.7
	Week 35	34	73.53	24.66	16.7	66.67	100.0	31	-4.84	27.95	-83.3	0.00	33.3
	Week 38	33	75.76	28.59	0.0	83.33	100.0	28	-1.19	32.37	-66.7	0.00	83.3
	Week 41	27	72.22	25.32	33.3	66.67	100.0	22	-1.52	32.49	-66.7	0.00	83.3
	Week 44	28	71.43	28.28	16.7	66.67	100.0	24	-3.47	34.74	-66.7	0.00	83.3
	Week 47	24	75.70	21.41	33.3	66.67	100.0	21	-1.59	27.84	-33.3	0.00	66.7
	Week 50	26	69.23	25.25	0.0	66.67	100.0	24	-5.56	26.31	-50.0	0.00	83.3
	Week 53	19	77.19	24.35	33.3	83.33	100.0	17	0.98	29.15	-50.0	0.00	83.3
	Week 56	13	70.51	33.44	0.0	66.67	100.0	11	-4.55	36.58	-66.7	0.00	83.3
	Week 59	14	78.57	27.29	0.0	83.33	100.0	12	5.56	27.83	-33.3	0.00	66.7
	Week 62	13	84.62	15.90	66.7	83.33	100.0	12	5.56	28.72	-33.3	0.00	83.3
	Week 65	13	75.64	30.13	0.0	83.33	100.0	11	-3.03	22.13	-33.3	0.00	33.3
	Week 68	10	78.33	31.48	0.0	91.67	100.0	8	-2.08	18.77	-33.3	0.00	33.3
	Week 77	10	71.67	32.44	0.0	75.00	100.0	8	-4.17	19.42	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>= 65 years	EV+Pembro (N=135)												
	BASELINE	114	81.87	25.63	0.0	100.00	100.0						
	Week 1	102	75.33	28.89	0.0	83.33	100.0	99	-7.57	22.50	-83.3	0.00	33.3
	Week 2	111	70.72	29.15	0.0	66.67	100.0	103	-11.49	22.14	-100.0	0.00	50.0
	Week 3	105	69.21	28.29	0.0	66.67	100.0	98	-12.92	23.39	-83.3	0.00	66.7
	Week 4	104	73.72	27.64	0.0	75.00	100.0	97	-11.17	26.21	-100.0	0.00	66.7
	Week 5	100	73.50	27.84	0.0	66.67	100.0	92	-9.60	25.59	-100.0	0.00	66.7
	Week 6	98	73.30	27.98	0.0	66.67	100.0	89	-11.80	25.15	-100.0	0.00	33.3
	Week 7	110	73.64	27.03	0.0	66.67	100.0	99	-10.77	30.43	-100.0	0.00	66.7
	Week 8	102	74.67	27.92	0.0	83.33	100.0	91	-8.79	29.95	-100.0	0.00	66.7
	Week 9	104	72.12	29.33	0.0	66.67	100.0	95	-10.88	28.95	-100.0	0.00	66.7
	Week 10	103	74.76	25.97	0.0	66.67	100.0	94	-7.09	27.27	-100.0	0.00	66.7
	Week 11	101	72.44	29.01	0.0	66.67	100.0	91	-10.07	28.10	-100.0	0.00	66.7
	Week 12	100	73.00	30.41	0.0	66.67	100.0	92	-8.51	30.71	-100.0	0.00	66.7
	Week 14	101	75.08	25.78	0.0	66.67	100.0	91	-7.87	28.37	-100.0	0.00	66.7
	Week 17	95	73.33	25.19	0.0	66.67	100.0	85	-8.63	24.88	-66.7	0.00	66.7
	Week 20	88	71.21	29.33	0.0	66.67	100.0	81	-13.17	30.24	-100.0	0.00	66.7
	Week 23	84	69.44	29.71	0.0	66.67	100.0	78	-13.67	31.87	-100.0	0.00	66.7
	Week 26	78	69.87	32.01	0.0	66.67	100.0	72	-14.58	35.04	-100.0	0.00	66.7
	Week 29	83	73.29	26.79	0.0	66.67	100.0	78	-10.90	31.76	-83.3	0.00	66.7
	Week 32	71	71.36	24.43	16.7	66.67	100.0	66	-13.64	30.93	-83.3	-8.33	50.0
	Week 35	70	67.86	25.27	0.0	66.67	100.0	64	-16.41	30.50	-83.3	-16.66	50.0
	Week 38	70	68.81	25.84	0.0	66.67	100.0	65	-14.87	30.35	-66.7	0.00	50.0
	Week 41	65	70.51	25.13	16.7	66.67	100.0	60	-15.83	30.90	-66.7	-16.66	50.0
	Week 44	58	66.09	28.26	0.0	66.67	100.0	52	-23.40	36.49	-100.0	-16.67	66.7
	Week 47	53	70.76	26.13	0.0	66.67	100.0	48	-15.97	31.50	-100.0	-8.33	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	45	70.00	27.66	16.7	66.67	100.0	43	-15.12	30.39	-83.3	0.00	33.3
	Week 53	39	73.08	24.37	16.7	66.67	100.0	37	-16.67	29.66	-83.3	0.00	33.3
	Week 56	37	69.37	25.00	16.7	66.67	100.0	35	-16.66	32.59	-83.3	-16.66	66.7
	Week 59	30	72.22	24.50	16.7	66.67	100.0	29	-14.94	24.13	-66.7	0.00	16.7
	Week 62	28	72.62	25.34	33.3	66.67	100.0	27	-20.99	24.28	-66.7	-16.66	16.7
	Week 65	24	71.53	30.09	0.0	75.00	100.0	23	-16.67	27.98	-66.7	-16.66	33.3
	Week 68	19	75.44	26.27	0.0	66.67	100.0	19	-17.54	25.74	-100.0	-16.66	16.7
	Week 71	19	78.07	22.94	33.3	83.33	100.0	19	-13.16	24.58	-50.0	-16.66	33.3
	Week 74	18	80.56	19.17	50.0	75.00	100.0	18	-11.11	20.61	-50.0	-8.33	33.3
	Week 77	19	68.42	32.82	0.0	66.67	100.0	18	-17.59	31.56	-66.7	-8.33	33.3
	Week 80	16	75.00	29.19	0.0	75.00	100.0	15	-8.89	29.46	-83.3	0.00	33.3
	Week 83	14	70.24	29.37	0.0	66.67	100.0	13	-15.38	25.87	-66.7	-16.66	33.3
	Week 86	14	78.57	24.83	33.3	83.34	100.0	13	-11.54	24.89	-50.0	0.00	33.3
	Week 89	14	73.81	24.21	33.3	66.67	100.0	14	-13.09	23.73	-50.0	-16.66	33.3
	Week 92	13	73.08	28.50	33.3	66.67	100.0	13	-12.82	25.60	-50.0	0.00	33.3
	Week 95	10	70.00	30.23	33.3	75.00	100.0	10	-18.33	29.87	-50.0	-25.00	33.3
	Week 98	10	75.00	27.50	33.3	83.34	100.0	10	-10.00	29.61	-50.0	0.00	33.3
	Plat+Gem (N=136)												
	BASELINE	105	72.54	30.22	0.0	83.33	100.0						
	Week 1	98	68.54	29.98	0.0	66.67	100.0	87	-4.21	20.99	-83.3	0.00	50.0
	Week 2	95	64.39	28.31	0.0	66.67	100.0	83	-13.65	26.69	-100.0	-16.66	50.0
	Week 3	104	72.12	25.17	0.0	66.67	100.0	89	-2.43	22.69	-50.0	0.00	83.3
	Week 4	104	69.23	28.14	0.0	66.67	100.0	89	-7.30	24.22	-83.3	0.00	83.3
	Week 5	107	64.64	27.92	0.0	66.67	100.0	89	-12.36	27.24	-100.0	0.00	83.3
	Week 6	98	67.69	28.50	0.0	66.67	100.0	82	-7.52	28.23	-100.0	0.00	83.3
	Week 7	105	68.57	27.28	0.0	66.67	100.0	86	-8.53	28.67	-100.0	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 8	95	65.26	30.04	0.0	66.67	100.0	80	-12.08	29.88	-100.0	0.00	50.0
	Week 9	99	67.17	28.12	0.0	66.67	100.0	81	-11.11	27.51	-100.0	0.00	50.0
	Week 10	88	65.15	30.07	0.0	66.67	100.0	71	-13.38	28.40	-100.0	0.00	50.0
	Week 11	93	69.71	26.91	0.0	66.67	100.0	77	-10.61	27.43	-83.3	0.00	83.3
	Week 12	85	68.23	28.82	0.0	66.67	100.0	72	-10.65	30.30	-100.0	-8.33	83.3
	Week 14	85	66.67	28.05	0.0	66.67	100.0	70	-12.38	29.72	-100.0	0.00	66.7
	Week 17	87	69.54	26.07	0.0	66.67	100.0	72	-12.50	28.22	-100.0	-16.66	66.7
	Week 20	66	69.95	26.83	0.0	66.67	100.0	58	-11.21	28.85	-83.3	0.00	66.7
	Week 23	64	70.57	28.13	0.0	66.67	100.0	53	-11.01	27.53	-66.7	0.00	33.3
	Week 26	61	73.22	26.58	0.0	66.67	100.0	53	-11.01	24.88	-66.7	0.00	33.3
	Week 29	58	72.41	27.31	0.0	66.67	100.0	49	-13.61	29.00	-100.0	0.00	33.3
	Week 32	46	77.90	26.31	0.0	83.33	100.0	42	-8.33	26.61	-83.3	0.00	50.0
	Week 35	42	73.81	27.58	0.0	83.33	100.0	38	-12.28	27.31	-83.3	-8.33	33.3
	Week 38	41	74.80	28.90	0.0	83.33	100.0	37	-13.06	28.63	-83.3	0.00	33.3
	Week 41	38	73.25	26.72	0.0	66.67	100.0	34	-12.26	26.05	-66.7	0.00	50.0
	Week 44	32	72.40	28.59	0.0	75.00	100.0	29	-13.79	31.20	-100.0	0.00	33.3
	Week 47	32	72.40	24.17	0.0	66.67	100.0	28	-12.50	31.30	-100.0	0.00	50.0
	Week 50	25	70.00	28.46	0.0	66.67	100.0	23	-13.77	29.15	-100.0	0.00	33.3
	Week 53	27	75.93	19.24	33.3	66.67	100.0	25	-13.33	22.57	-66.7	0.00	33.3
	Week 56	26	67.95	31.24	0.0	66.67	100.0	23	-17.39	30.76	-83.3	0.00	33.3
	Week 59	23	81.16	20.29	33.3	83.33	100.0	21	-7.14	25.59	-66.7	0.00	33.3
	Week 62	19	71.05	16.52	33.3	66.67	100.0	17	-13.72	25.84	-66.7	-16.67	33.3
	Week 65	17	75.49	25.08	0.0	66.67	100.0	15	-11.11	31.91	-100.0	0.00	33.3
	Week 68	15	75.56	20.77	33.3	66.67	100.0	13	-12.82	22.72	-50.0	0.00	33.3
	Week 71	15	72.22	24.93	33.3	66.67	100.0	13	-14.10	30.31	-66.7	0.00	33.3
	Week 74	12	77.78	21.71	33.3	66.67	100.0	11	-6.06	20.10	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Europe	EV+Pembro (N= 98)												
	BASELINE	79	78.48	27.63	0.0	83.33	100.0						
	Week 1	74	74.10	28.55	0.0	83.33	100.0	71	-5.87	22.38	-83.3	0.00	50.0
	Week 2	79	72.78	27.89	0.0	83.33	100.0	71	-7.51	20.47	-66.7	0.00	50.0
	Week 3	78	67.31	27.19	0.0	66.67	100.0	69	-13.29	27.05	-100.0	0.00	50.0
	Week 4	78	76.50	24.83	16.7	83.33	100.0	70	-5.48	27.47	-83.3	0.00	66.7
	Week 5	70	76.91	25.27	0.0	83.33	100.0	62	-3.23	27.63	-66.7	0.00	83.3
	Week 6	70	78.10	26.70	0.0	91.67	100.0	61	-1.64	32.30	-100.0	0.00	83.3
	Week 7	78	76.28	24.84	0.0	66.67	100.0	68	-3.92	32.72	-100.0	0.00	66.7
	Week 8	72	76.39	27.23	0.0	83.33	100.0	61	-3.83	32.12	-100.0	0.00	83.3
	Week 9	80	75.00	25.02	0.0	66.67	100.0	70	-6.90	31.40	-83.3	0.00	83.3
	Week 10	71	77.70	24.87	0.0	83.33	100.0	62	0.00	32.92	-100.0	0.00	83.3
	Week 11	76	75.44	26.17	0.0	75.00	100.0	66	-3.79	33.94	-83.3	0.00	83.3
	Week 12	73	75.34	27.51	0.0	66.67	100.0	65	-4.61	32.21	-100.0	0.00	66.7
	Week 14	74	78.38	24.32	16.7	83.33	100.0	64	-1.56	28.28	-50.0	0.00	83.3
	Week 17	70	79.76	22.68	33.3	83.33	100.0	62	-0.27	30.70	-66.7	0.00	83.3
	Week 20	70	75.48	25.49	0.0	66.67	100.0	63	-4.76	32.85	-100.0	0.00	83.3
	Week 23	61	72.68	27.22	0.0	66.67	100.0	57	-8.77	32.44	-100.0	0.00	66.7
	Week 26	62	76.61	22.07	16.7	66.67	100.0	55	-4.54	29.65	-83.3	0.00	66.7
	Week 29	63	75.93	22.36	0.0	66.67	100.0	57	-6.72	29.52	-66.7	0.00	66.7
	Week 32	51	69.94	27.49	0.0	66.67	100.0	47	-12.41	29.38	-83.3	0.00	33.3
	Week 35	56	68.45	25.36	0.0	66.67	100.0	52	-15.70	29.04	-83.3	-16.66	33.3
	Week 38	51	70.92	24.00	0.0	66.67	100.0	48	-13.19	29.96	-66.7	0.00	66.7
	Week 41	52	68.91	22.63	16.7	66.67	100.0	48	-13.19	27.28	-66.7	-16.66	50.0
	Week 44	43	67.05	26.60	0.0	66.67	100.0	39	-18.80	30.87	-100.0	-16.66	33.3
	Week 47	39	68.80	25.98	0.0	66.67	100.0	36	-18.05	31.47	-100.0	-16.66	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	37	72.52	24.91	0.0	66.67	100.0	36	-14.81	30.02	-100.0	0.00	33.3
	Week 53	28	72.62	26.92	0.0	66.67	100.0	27	-13.58	34.91	-100.0	0.00	66.7
	Week 56	30	70.00	27.47	0.0	66.67	100.0	29	-18.39	28.64	-100.0	0.00	16.7
	Week 59	27	72.84	26.21	0.0	66.67	100.0	27	-17.28	26.34	-100.0	0.00	16.7
	Week 62	23	73.19	27.40	0.0	66.67	100.0	23	-17.39	26.82	-100.0	0.00	16.7
	Week 65	23	71.74	29.91	0.0	66.67	100.0	23	-14.49	28.12	-100.0	0.00	33.3
	Week 68	21	75.40	25.61	0.0	66.67	100.0	21	-11.11	26.00	-100.0	0.00	16.7
	Week 71	19	75.44	24.45	33.3	83.33	100.0	19	-14.03	24.38	-66.7	0.00	33.3
	Week 74	15	71.11	23.96	33.3	66.67	100.0	15	-16.67	22.71	-66.7	-16.66	16.7
	Week 77	19	69.30	31.06	0.0	66.67	100.0	19	-15.79	29.65	-66.7	0.00	50.0
	Week 80	17	73.53	25.04	33.3	66.67	100.0	17	-10.78	22.78	-66.7	0.00	33.3
	Week 83	16	67.71	29.48	0.0	66.67	100.0	16	-15.63	27.53	-66.7	0.00	33.3
	Week 86	14	76.19	20.37	33.3	66.67	100.0	14	-13.09	16.25	-33.3	0.00	0.0
	Week 89	14	71.43	24.83	33.3	66.67	100.0	14	-17.86	23.99	-66.7	0.00	0.0
	Week 92	11	80.30	19.46	50.0	66.67	100.0	11	-15.15	18.94	-50.0	0.00	0.0
	Week 95	10	71.67	22.29	33.3	66.67	100.0	10	-21.67	19.32	-50.0	-33.33	0.0
	Plat+Gem (N=102)												
	BASELINE	71	70.66	33.15	0.0	83.33	100.0						
	Week 1	71	62.44	34.01	0.0	66.67	100.0	61	-9.29	25.55	-83.3	0.00	50.0
	Week 2	67	61.94	33.69	0.0	66.67	100.0	56	-12.20	32.33	-83.3	-8.33	66.7
	Week 3	68	66.67	28.21	0.0	66.67	100.0	56	-5.95	25.11	-66.7	0.00	66.7
	Week 4	75	63.78	30.31	0.0	66.67	100.0	59	-12.99	22.33	-83.3	0.00	33.3
	Week 5	77	63.85	30.64	0.0	66.67	100.0	60	-14.44	25.94	-100.0	0.00	33.3
	Week 6	70	63.81	28.65	0.0	66.67	100.0	56	-11.31	23.81	-83.3	-16.66	33.3
	Week 7	72	65.51	30.94	0.0	66.67	100.0	55	-12.12	26.54	-100.0	0.00	50.0
	Week 8	65	60.00	31.71	0.0	66.67	100.0	53	-15.72	30.91	-100.0	-16.66	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	70	61.90	29.10	0.0	66.67	100.0	55	-15.15	27.64	-100.0	-16.67	50.0
	Week 10	60	60.00	30.87	0.0	66.67	100.0	46	-19.20	25.57	-100.0	-16.67	33.3
	Week 11	64	62.50	29.55	0.0	66.67	100.0	50	-17.67	23.18	-100.0	-16.67	33.3
	Week 12	60	63.89	25.52	0.0	66.67	100.0	48	-15.28	25.69	-100.0	-16.67	33.3
	Week 14	56	58.93	29.98	0.0	66.67	100.0	42	-20.63	30.53	-100.0	-16.67	66.7
	Week 17	58	63.51	29.69	0.0	66.67	100.0	44	-15.91	30.49	-100.0	-16.67	66.7
	Week 20	47	69.50	25.61	0.0	66.67	100.0	37	-12.16	27.96	-83.3	-16.66	66.7
	Week 23	44	70.45	26.87	0.0	66.67	100.0	32	-14.58	24.96	-66.7	-16.66	33.3
	Week 26	39	69.66	27.27	0.0	66.67	100.0	30	-16.67	20.06	-66.7	-16.66	0.0
	Week 29	34	71.57	24.46	0.0	66.67	100.0	25	-14.67	26.93	-100.0	-16.66	33.3
	Week 32	33	72.73	26.29	0.0	83.33	100.0	27	-15.43	26.52	-83.3	0.00	33.3
	Week 35	30	66.11	29.84	0.0	66.67	100.0	24	-22.22	30.56	-83.3	-25.00	33.3
	Week 38	26	66.67	33.99	0.0	75.00	100.0	21	-23.02	32.26	-83.3	-16.67	33.3
	Week 41	22	62.88	26.69	33.3	66.67	100.0	17	-22.55	22.78	-66.7	-16.67	0.0
	Week 44	20	59.17	31.75	0.0	58.34	100.0	16	-29.17	34.69	-100.0	-16.67	33.3
	Week 47	16	60.42	27.81	0.0	66.67	100.0	12	-26.39	32.92	-100.0	-25.00	33.3
	Week 50	11	50.00	31.62	0.0	50.00	100.0	10	-33.33	29.40	-100.0	-33.33	0.0
	Week 53	11	57.58	17.26	33.3	66.67	83.3	10	-30.00	18.92	-50.0	-33.33	16.7
	Week 56	10	55.00	27.27	0.0	66.67	100.0	8	-29.17	14.77	-50.0	-33.33	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
North America	EV+Pembro (N= 57)												
	BASELINE	47	71.63	32.21	0.0	83.33	100.0						
	Week 1	39	66.67	36.07	0.0	66.67	100.0	37	-4.96	18.37	-66.7	0.00	33.3
	Week 2	44	59.09	35.48	0.0	66.67	100.0	42	-13.49	23.92	-66.7	0.00	16.7
	Week 3	44	59.85	35.46	0.0	66.67	100.0	40	-9.58	22.92	-83.3	0.00	33.3
	Week 4	44	64.02	30.06	0.0	66.67	100.0	41	-6.91	24.43	-66.7	0.00	50.0
	Week 5	47	62.41	33.42	0.0	66.67	100.0	41	-11.38	29.45	-100.0	0.00	33.3
	Week 6	44	68.56	31.79	0.0	66.67	100.0	39	-2.14	23.63	-100.0	0.00	33.3
	Week 7	46	71.38	27.14	16.7	66.67	100.0	42	-1.19	21.59	-50.0	0.00	50.0
	Week 8	47	72.70	27.01	0.0	66.67	100.0	42	0.40	25.37	-66.7	0.00	66.7
	Week 9	46	64.85	32.06	0.0	66.67	100.0	42	-5.16	29.33	-100.0	0.00	50.0
	Week 10	47	75.18	27.34	0.0	83.33	100.0	44	3.03	26.24	-100.0	0.00	66.7
	Week 11	47	68.09	29.45	0.0	66.67	100.0	42	-3.17	30.85	-100.0	0.00	66.7
	Week 12	44	68.56	27.66	0.0	66.67	100.0	40	1.25	28.84	-50.0	0.00	66.7
	Week 14	43	70.93	27.24	0.0	66.67	100.0	39	1.71	28.30	-66.7	0.00	66.7
	Week 17	40	67.50	26.94	0.0	66.67	100.0	37	-3.60	28.36	-50.0	0.00	83.3
	Week 20	38	67.98	29.61	0.0	66.67	100.0	35	-3.81	28.32	-66.7	0.00	50.0
	Week 23	38	67.54	33.10	0.0	66.67	100.0	35	-5.24	27.94	-66.7	0.00	50.0
	Week 26	35	68.57	34.95	0.0	83.33	100.0	32	-1.56	35.26	-100.0	0.00	66.7
	Week 29	38	74.56	26.21	16.7	75.00	100.0	34	0.49	33.20	-66.7	0.00	83.3
	Week 32	32	71.35	28.16	0.0	66.67	100.0	29	-8.62	30.41	-66.7	0.00	50.0
	Week 35	33	70.20	26.60	0.0	66.67	100.0	30	-9.44	27.92	-66.7	0.00	50.0
	Week 38	32	69.79	22.97	33.3	66.67	100.0	29	-5.17	27.85	-66.7	0.00	50.0
	Week 41	28	80.36	21.78	33.3	83.33	100.0	24	2.08	27.94	-66.7	0.00	50.0
	Week 44	21	69.05	31.31	0.0	66.67	100.0	20	-18.33	38.96	-100.0	-8.34	66.7
	Week 47	24	70.14	32.22	0.0	66.67	100.0	23	-10.87	40.39	-100.0	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	23	65.22	29.69	16.7	66.67	100.0	20	-14.17	35.57	-83.3	-8.34	66.7
	Week 53	17	76.47	22.87	33.3	66.67	100.0	14	-15.48	31.67	-66.7	0.00	33.3
	Week 56	20	70.00	24.54	16.7	66.67	100.0	17	-6.86	39.99	-83.3	0.00	66.7
	Week 59	17	68.63	20.31	16.7	66.67	100.0	14	-16.66	23.57	-50.0	-33.33	16.7
	Week 62	14	76.19	20.37	33.3	66.67	100.0	13	-11.54	32.90	-66.7	0.00	66.7
	Week 65	12	81.95	16.60	66.7	75.00	100.0	9	-3.70	26.06	-33.3	0.00	33.3
	Week 68	10	83.33	15.71	66.7	83.33	100.0	9	-11.11	14.43	-33.3	0.00	0.0
	Week 71	10	86.67	17.21	66.7	100.00	100.0	8	-8.33	23.57	-33.3	0.00	33.3
	Week 74	10	85.00	16.57	66.7	91.67	100.0	9	-7.41	23.73	-33.3	0.00	33.3
	Plat+Gem (N= 51)												
	BASELINE	42	75.40	23.92	33.3	66.67	100.0						
	Week 1	41	68.29	26.04	0.0	66.67	100.0	36	-9.26	17.57	-66.7	0.00	16.7
	Week 2	38	64.04	25.57	0.0	66.67	100.0	33	-13.64	23.74	-66.7	-16.66	33.3
	Week 3	40	72.92	24.37	16.7	75.00	100.0	35	-6.67	26.87	-83.3	0.00	33.3
	Week 4	35	71.90	24.51	0.0	66.67	100.0	29	-5.75	20.55	-50.0	0.00	33.3
	Week 5	39	61.97	24.47	16.7	66.67	100.0	32	-19.27	28.12	-66.7	-33.33	33.3
	Week 6	34	70.59	26.92	0.0	66.67	100.0	30	-6.67	20.34	-50.0	0.00	33.3
	Week 7	42	67.86	24.80	16.7	66.67	100.0	37	-9.91	24.36	-66.7	-16.67	33.3
	Week 8	39	67.95	25.47	16.7	66.67	100.0	33	-9.60	32.82	-66.7	-16.67	66.7
	Week 9	39	67.52	21.95	16.7	66.67	100.0	33	-8.08	26.72	-50.0	-16.66	66.7
	Week 10	39	67.09	25.79	0.0	66.67	100.0	32	-8.85	28.08	-66.7	0.00	33.3
	Week 11	39	69.23	22.79	33.3	66.67	100.0	33	-6.57	33.06	-66.7	0.00	66.7
	Week 12	36	70.37	26.16	0.0	66.67	100.0	32	-4.69	30.60	-66.7	0.00	66.7
	Week 14	34	70.59	22.50	0.0	66.67	100.0	29	-2.87	30.23	-66.7	0.00	66.7
	Week 17	37	65.32	21.29	16.7	66.67	100.0	31	-12.90	23.85	-66.7	-16.66	33.3
	Week 20	27	69.14	21.03	16.7	66.67	100.0	23	-5.80	22.25	-33.3	0.00	50.0

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Table 302.1.3002.11.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 23	27	67.90	29.93	0.0	66.67	100.0	23	-3.62	24.08	-66.7	0.00	33.3
	Week 26	28	68.45	26.58	0.0	66.67	100.0	25	-4.00	23.71	-50.0	0.00	50.0
	Week 29	29	63.79	26.75	16.7	66.67	100.0	25	-13.33	29.66	-83.3	-16.66	33.3
	Week 32	17	69.61	29.60	0.0	66.67	100.0	17	-4.90	25.52	-50.0	0.00	33.3
	Week 35	16	67.71	24.70	16.7	66.67	100.0	15	-6.67	25.82	-83.3	0.00	16.7
	Week 38	16	75.00	25.09	16.7	66.67	100.0	13	-1.28	18.58	-33.3	0.00	33.3
	Week 41	16	67.71	24.70	0.0	66.67	100.0	13	-8.97	26.89	-66.7	0.00	33.3
	Week 44	13	66.67	26.35	0.0	66.67	100.0	11	-7.58	20.23	-33.3	-16.66	33.3
	Week 47	11	74.24	13.67	66.7	66.67	100.0	9	-9.26	14.70	-33.3	0.00	0.0
	Week 50	17	65.69	22.42	0.0	66.67	100.0	15	-7.78	18.76	-33.3	0.00	16.7
	Week 53	13	73.08	18.68	33.3	66.67	100.0	11	-9.09	22.81	-66.7	0.00	16.7
	Week 56	11	60.61	33.56	0.0	66.67	100.0	9	-24.07	36.43	-83.3	0.00	0.0
	Week 59	11	77.27	21.44	33.3	66.67	100.0	9	-7.41	27.78	-66.7	0.00	33.3
	Week 62	11	72.73	18.67	33.3	66.67	100.0	9	-12.96	28.60	-66.7	0.00	33.3
	Week 65	10	68.33	26.58	0.0	66.67	100.0	8	-16.67	38.83	-100.0	-8.34	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Rest of World	EV+Pembro (N= 85)												
	BASELINE	80	82.50	24.72	16.7	100.00	100.0						
	Week 1	77	77.27	25.35	16.7	83.33	100.0	76	-6.14	20.52	-66.7	0.00	33.3
	Week 2	80	73.96	25.00	0.0	66.67	100.0	76	-8.55	22.36	-100.0	0.00	50.0
	Week 3	76	72.59	24.90	0.0	66.67	100.0	73	-10.04	23.36	-66.7	0.00	66.7
	Week 4	72	77.55	26.12	0.0	83.33	100.0	68	-5.64	26.17	-100.0	0.00	66.7
	Week 5	73	76.94	25.25	0.0	83.33	100.0	70	-5.71	26.45	-83.3	0.00	66.7
	Week 6	74	76.80	22.88	16.7	66.67	100.0	70	-8.09	22.30	-66.7	0.00	50.0
	Week 7	71	74.65	25.64	0.0	66.67	100.0	66	-9.09	29.55	-100.0	0.00	66.7
	Week 8	72	78.47	22.63	0.0	83.33	100.0	68	-4.41	28.45	-100.0	0.00	66.7
	Week 9	71	75.59	27.14	0.0	66.67	100.0	68	-7.35	26.92	-100.0	0.00	50.0
	Week 10	73	76.03	25.46	0.0	66.67	100.0	69	-5.80	27.83	-100.0	0.00	66.7
	Week 11	71	77.47	25.21	0.0	66.67	100.0	67	-4.23	26.80	-100.0	0.00	66.7
	Week 12	69	77.30	27.71	0.0	83.33	100.0	66	-5.55	30.57	-100.0	0.00	66.7
	Week 14	68	71.82	26.90	0.0	66.67	100.0	64	-10.15	30.08	-100.0	0.00	66.7
	Week 17	68	72.55	24.22	0.0	66.67	100.0	63	-8.99	26.41	-66.7	0.00	66.7
	Week 20	59	68.64	29.37	0.0	66.67	100.0	56	-14.28	33.55	-100.0	-16.66	66.7
	Week 23	63	67.46	27.67	0.0	66.67	100.0	59	-14.41	31.02	-100.0	-16.67	66.7
	Week 26	59	66.95	31.33	0.0	66.67	100.0	57	-15.79	34.99	-100.0	0.00	66.7
	Week 29	56	71.43	26.15	0.0	66.67	100.0	54	-12.34	31.59	-83.3	-16.66	66.7
	Week 32	52	72.12	23.96	16.7	66.67	100.0	49	-10.88	30.91	-66.7	-16.66	66.7
	Week 35	43	69.77	25.53	0.0	66.67	100.0	40	-13.75	28.72	-83.3	-16.67	66.7
	Week 38	49	65.99	26.56	0.0	66.67	100.0	47	-15.96	29.89	-66.7	-16.67	66.7
	Week 41	49	66.33	28.97	0.0	66.67	100.0	47	-17.73	30.38	-66.7	-16.67	66.7
	Week 44	44	69.32	26.64	0.0	66.67	100.0	41	-14.63	34.40	-66.7	-16.67	66.7
	Week 47	37	68.02	27.32	0.0	66.67	100.0	35	-16.19	28.72	-66.7	-16.66	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	29	62.07	24.76	0.0	66.67	100.0	28	-23.21	28.45	-66.7	-33.33	33.3
	Week 53	34	68.63	22.76	16.7	66.67	100.0	33	-19.19	27.68	-66.7	-33.33	50.0
	Week 56	31	67.74	24.70	0.0	66.67	100.0	30	-15.55	28.00	-66.7	-16.67	66.7
	Week 59	28	66.67	25.66	0.0	66.67	100.0	27	-16.67	34.28	-100.0	-16.66	66.7
	Week 62	28	68.45	28.81	0.0	66.67	100.0	27	-18.52	34.07	-100.0	-16.66	66.7
	Week 65	23	60.15	28.31	0.0	66.67	100.0	22	-25.00	35.54	-100.0	-33.33	66.7
	Week 68	22	63.64	30.27	0.0	66.67	100.0	22	-22.73	39.36	-100.0	-33.33	66.7
	Week 71	22	63.64	30.27	0.0	66.67	100.0	22	-21.21	35.33	-100.0	-25.00	66.7
	Week 74	22	62.88	28.61	0.0	66.67	100.0	22	-22.73	32.75	-100.0	-33.33	66.7
	Week 77	18	53.70	31.08	0.0	66.67	100.0	17	-29.41	35.12	-100.0	-33.33	66.7
	Week 80	16	55.21	31.46	0.0	66.67	100.0	15	-26.66	37.16	-100.0	-33.33	66.7
	Week 83	16	55.21	26.33	0.0	66.67	100.0	15	-25.55	33.25	-100.0	-33.33	66.7
	Week 86	13	51.28	31.52	0.0	66.67	100.0	12	-27.78	36.47	-100.0	-33.33	50.0
	Week 89	12	54.17	28.54	0.0	66.67	100.0	12	-26.39	40.49	-100.0	-33.33	66.7
	Plat+Gem (N= 89)												
	BASELINE	75	74.00	24.24	16.7	66.67	100.0						
	Week 1	61	74.86	18.91	33.3	66.67	100.0	61	-1.91	21.54	-33.3	0.00	50.0
	Week 2	66	66.92	27.50	0.0	66.67	100.0	62	-9.68	23.48	-100.0	0.00	33.3
	Week 3	76	76.32	22.15	0.0	75.00	100.0	71	2.82	23.23	-50.0	0.00	83.3
	Week 4	73	71.92	25.59	0.0	66.67	100.0	68	-1.22	25.65	-83.3	0.00	83.3
	Week 5	71	70.89	24.51	0.0	66.67	100.0	64	-4.17	27.05	-83.3	0.00	83.3
	Week 6	70	73.33	24.80	0.0	66.67	100.0	63	-0.53	29.93	-100.0	0.00	83.3
	Week 7	72	72.92	25.40	0.0	66.67	100.0	65	-1.28	29.21	-100.0	0.00	50.0
	Week 8	63	76.19	22.34	16.7	66.67	100.0	58	-2.01	27.76	-83.3	0.00	50.0
	Week 9	68	73.04	24.27	0.0	66.67	100.0	62	-2.69	30.51	-100.0	0.00	66.7
	Week 10	67	71.64	23.03	16.7	66.67	100.0	61	-2.73	26.90	-83.3	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	65	75.39	23.22	16.7	66.67	100.0	60	-1.11	30.04	-83.3	0.00	83.3
	Week 12	63	74.34	25.37	0.0	66.67	100.0	58	-2.01	31.07	-100.0	0.00	83.3
	Week 14	63	75.13	21.56	16.7	66.67	100.0	57	-0.29	28.08	-83.3	0.00	66.7
	Week 17	60	74.17	23.66	16.7	66.67	100.0	55	-4.24	28.55	-83.3	0.00	66.7
	Week 20	52	73.72	26.47	0.0	66.67	100.0	50	-4.00	31.86	-83.3	0.00	83.3
	Week 23	44	74.24	24.76	16.7	66.67	100.0	42	-5.16	28.86	-66.7	0.00	50.0
	Week 26	41	78.86	23.87	16.7	83.33	100.0	40	-2.50	29.61	-66.7	0.00	83.3
	Week 29	37	82.43	21.13	33.3	100.00	100.0	36	-3.24	23.17	-66.7	0.00	33.3
	Week 32	33	80.81	20.88	33.3	83.33	100.0	32	-2.60	27.47	-66.7	0.00	66.7
	Week 35	30	84.45	19.04	33.3	100.00	100.0	30	0.56	22.09	-33.3	0.00	33.3
	Week 38	32	82.29	23.92	33.3	100.00	100.0	31	-0.54	30.58	-66.7	0.00	83.3
	Week 41	27	83.95	22.40	33.3	100.00	100.0	26	1.92	30.30	-66.7	0.00	83.3
	Week 44	27	83.95	21.42	33.3	100.00	100.0	26	2.56	31.16	-66.7	0.00	83.3
	Week 47	29	81.03	19.78	33.3	83.33	100.0	28	0.59	29.56	-66.7	0.00	66.7
	Week 50	23	81.89	20.67	33.3	100.00	100.0	22	0.00	26.72	-33.3	0.00	83.3
	Week 53	22	87.88	17.20	50.0	100.00	100.0	21	3.97	24.10	-33.3	0.00	83.3
	Week 56	18	81.48	29.09	0.0	100.00	100.0	17	0.00	32.81	-66.7	0.00	83.3
	Week 59	17	89.22	15.52	66.7	100.00	100.0	16	8.33	25.82	-33.3	0.00	66.7
	Week 62	16	82.29	16.63	66.7	75.00	100.0	15	4.44	28.50	-33.3	0.00	83.3
	Week 65	15	88.89	16.26	66.7	100.00	100.0	14	2.38	20.52	-33.3	0.00	33.3
	Week 68	12	88.89	21.71	33.3	100.00	100.0	11	0.00	21.08	-33.3	0.00	33.3
	Week 71	13	79.49	24.68	33.3	83.33	100.0	12	-5.56	28.72	-66.7	0.00	33.3
	Week 74	10	86.67	23.31	33.3	100.00	100.0	10	3.33	18.92	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	EV+Pembro (N=198)												
	BASELINE	170	78.14	27.99	0.0	91.67	100.0						
	Week 1	157	74.63	28.47	0.0	83.33	100.0	152	-4.71	20.16	-66.7	0.00	50.0
	Week 2	167	70.36	29.24	0.0	66.67	100.0	155	-9.14	21.84	-100.0	0.00	50.0
	Week 3	161	68.63	28.22	0.0	66.67	100.0	147	-10.54	23.41	-83.3	0.00	66.7
	Week 4	158	74.16	27.30	0.0	83.33	100.0	145	-5.86	25.95	-100.0	0.00	66.7
	Week 5	154	73.59	28.56	0.0	83.33	100.0	140	-5.59	26.72	-100.0	0.00	66.7
	Week 6	153	74.73	26.77	0.0	66.67	100.0	138	-4.23	25.95	-100.0	0.00	66.7
	Week 7	159	73.38	26.59	0.0	66.67	100.0	142	-5.87	29.52	-100.0	0.00	66.7
	Week 8	154	75.43	26.00	0.0	83.33	100.0	135	-3.58	29.18	-100.0	0.00	66.7
	Week 9	162	70.78	28.84	0.0	66.67	100.0	146	-8.33	29.05	-100.0	0.00	66.7
	Week 10	159	75.68	25.42	0.0	66.67	100.0	144	-2.20	28.78	-100.0	0.00	66.7
	Week 11	161	73.19	27.40	0.0	66.67	100.0	143	-4.66	29.96	-100.0	0.00	66.7
	Week 12	154	74.03	27.94	0.0	66.67	100.0	140	-3.69	30.85	-100.0	0.00	66.7
	Week 14	154	72.94	26.34	0.0	66.67	100.0	137	-5.11	30.02	-100.0	0.00	66.7
	Week 17	145	72.99	25.54	0.0	66.67	100.0	130	-5.64	28.50	-66.7	0.00	83.3
	Week 20	139	70.14	28.34	0.0	66.67	100.0	126	-9.26	32.43	-100.0	0.00	66.7
	Week 23	133	67.67	29.57	0.0	66.67	100.0	122	-12.02	31.00	-100.0	0.00	66.7
	Week 26	129	70.28	29.68	0.0	66.67	100.0	118	-8.76	34.64	-100.0	0.00	66.7
	Week 29	131	73.16	25.45	0.0	66.67	100.0	120	-8.47	31.39	-83.3	0.00	83.3
	Week 32	111	70.27	26.44	0.0	66.67	100.0	102	-11.11	30.25	-83.3	0.00	66.7
	Week 35	109	68.66	26.03	0.0	66.67	100.0	100	-13.67	28.17	-83.3	-8.33	66.7
	Week 38	107	68.22	25.45	0.0	66.67	100.0	100	-11.83	29.04	-66.7	0.00	66.7
	Week 41	103	69.26	26.07	0.0	66.67	100.0	94	-13.47	28.74	-66.7	-8.33	66.7
	Week 44	88	68.75	27.08	0.0	66.67	100.0	81	-15.64	33.68	-100.0	-16.66	66.7
	Week 47	80	69.38	26.31	0.0	66.67	100.0	75	-16.00	30.19	-100.0	-16.66	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	73	67.81	26.11	0.0	66.67	100.0	68	-16.67	31.28	-83.3	-16.67	66.7
	Week 53	64	72.40	24.71	0.0	66.67	100.0	59	-18.08	30.21	-100.0	-33.33	50.0
	Week 56	66	68.44	26.33	0.0	66.67	100.0	61	-15.30	32.67	-100.0	-16.66	66.7
	Week 59	58	70.98	24.49	0.0	66.67	100.0	54	-16.05	28.77	-100.0	-16.66	66.7
	Week 62	54	70.99	26.73	0.0	66.67	100.0	52	-18.27	31.70	-100.0	-16.66	66.7
	Week 65	51	70.59	28.40	0.0	66.67	100.0	47	-17.38	31.46	-100.0	-16.66	66.7
	Week 68	49	73.47	25.44	0.0	66.67	100.0	48	-15.97	28.76	-100.0	-16.66	66.7
	Week 71	47	73.40	27.51	0.0	66.67	100.0	45	-17.04	30.67	-100.0	-16.66	66.7
	Week 74	42	70.64	26.50	0.0	66.67	100.0	41	-19.10	29.00	-100.0	-16.67	66.7
	Week 77	38	63.60	31.45	0.0	66.67	100.0	36	-22.68	34.08	-100.0	-33.33	66.7
	Week 80	35	67.14	29.29	0.0	66.67	100.0	32	-18.75	32.17	-100.0	-25.00	66.7
	Week 83	32	64.06	29.36	0.0	66.67	100.0	30	-19.44	32.19	-100.0	-25.00	66.7
	Week 86	30	66.11	28.86	0.0	66.67	100.0	27	-19.75	29.25	-100.0	-33.33	50.0
	Week 89	28	65.48	27.57	0.0	66.67	100.0	26	-20.51	33.77	-100.0	-16.67	66.7
	Week 92	24	66.67	28.66	0.0	66.67	100.0	22	-21.21	22.53	-50.0	-33.33	33.3
	Week 95	21	60.32	30.04	0.0	66.67	100.0	20	-25.83	23.86	-66.7	-33.33	33.3
	Week 98	16	72.92	29.74	0.0	66.67	100.0	15	-16.67	23.57	-50.0	-16.67	33.3
	Week 101	12	75.00	27.98	33.3	83.33	100.0	12	-20.83	26.71	-66.7	-8.34	0.0
	Week 104	10	68.33	25.40	33.3	66.67	100.0	10	-26.67	25.09	-66.7	-33.33	0.0
	Plat+Gem (N=185)												
	BASELINE	146	73.06	27.98	0.0	66.67	100.0						
	Week 1	131	69.85	27.97	0.0	66.67	100.0	120	-5.00	20.68	-66.7	0.00	50.0
	Week 2	128	64.06	29.90	0.0	66.67	100.0	115	-10.72	24.60	-100.0	0.00	33.3
	Week 3	141	71.63	25.95	0.0	66.67	100.0	126	-2.51	23.76	-66.7	0.00	83.3
	Week 4	139	68.71	28.41	0.0	66.67	100.0	119	-5.74	24.30	-83.3	0.00	83.3
	Week 5	143	66.90	27.19	0.0	66.67	100.0	120	-10.14	27.53	-100.0	0.00	83.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 6	133	69.55	27.18	0.0	66.67	100.0	114	-5.12	25.96	-83.3	0.00	83.3
	Week 7	142	69.25	28.23	0.0	66.67	100.0	120	-6.39	27.00	-100.0	0.00	50.0
	Week 8	125	68.40	27.50	0.0	66.67	100.0	109	-8.87	30.39	-100.0	0.00	66.7
	Week 9	135	68.64	26.47	0.0	66.67	100.0	115	-7.97	29.89	-100.0	0.00	66.7
	Week 10	131	66.41	27.42	0.0	66.67	100.0	111	-7.96	27.60	-100.0	0.00	50.0
	Week 11	128	69.53	27.12	0.0	66.67	100.0	109	-6.88	30.28	-100.0	0.00	83.3
	Week 12	124	69.76	26.41	0.0	66.67	100.0	108	-5.86	29.74	-100.0	0.00	83.3
	Week 14	121	69.70	24.63	0.0	66.67	100.0	101	-5.12	29.70	-83.3	0.00	66.7
	Week 17	121	70.11	26.26	0.0	66.67	100.0	101	-7.43	27.43	-83.3	0.00	66.7
	Week 20	98	72.62	25.01	0.0	66.67	100.0	86	-4.26	27.91	-83.3	0.00	83.3
	Week 23	93	70.43	27.05	0.0	66.67	100.0	78	-7.69	26.28	-66.7	0.00	50.0
	Week 26	86	72.87	26.33	0.0	66.67	100.0	75	-6.89	27.14	-66.7	0.00	83.3
	Week 29	76	72.37	26.60	0.0	66.67	100.0	65	-11.03	26.56	-100.0	0.00	33.3
	Week 32	62	78.76	23.79	0.0	83.33	100.0	56	-4.76	24.35	-66.7	0.00	66.7
	Week 35	58	75.86	24.62	0.0	83.33	100.0	52	-7.37	24.12	-83.3	0.00	33.3
	Week 38	60	78.06	28.04	0.0	100.00	100.0	52	-5.45	30.02	-83.3	0.00	83.3
	Week 41	52	74.36	26.70	0.0	75.00	100.0	44	-6.82	29.49	-66.7	0.00	83.3
	Week 44	46	74.28	29.55	0.0	83.33	100.0	40	-5.83	34.29	-100.0	0.00	83.3
	Week 47	44	75.76	22.86	0.0	66.67	100.0	38	-6.58	31.61	-100.0	0.00	66.7
	Week 50	42	70.24	27.68	0.0	66.67	100.0	38	-9.21	29.69	-100.0	0.00	83.3
	Week 53	38	79.39	20.66	33.3	75.00	100.0	34	-5.39	26.50	-66.7	0.00	83.3
	Week 56	32	72.40	31.00	0.0	66.67	100.0	28	-12.50	34.43	-83.3	0.00	83.3
	Week 59	31	82.26	23.54	0.0	100.00	100.0	27	-1.23	26.52	-66.7	0.00	66.7
	Week 62	29	77.59	17.97	33.3	66.67	100.0	26	-7.69	28.76	-66.7	0.00	83.3
	Week 65	25	77.33	27.59	0.0	83.33	100.0	21	-7.94	28.68	-100.0	0.00	33.3
	Week 68	20	79.17	25.29	0.0	83.33	100.0	16	-9.38	23.54	-50.0	0.00	33.3

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 71	17	75.49	30.11	0.0	83.33	100.0	14	-8.33	31.18	-66.7	0.00	33.3
	Week 74	17	78.43	26.85	0.0	83.33	100.0	14	-3.57	20.85	-33.3	0.00	33.3
	Week 77	16	77.08	27.13	0.0	75.00	100.0	13	-1.28	19.79	-33.3	0.00	33.3
	Week 80	13	82.05	14.37	66.7	83.33	100.0	12	-5.56	19.24	-33.3	0.00	33.3
	Week 83	11	81.82	15.73	66.7	83.33	100.0	10	-3.33	23.31	-33.3	0.00	33.3
	Week 86	12	86.11	15.62	66.7	91.67	100.0	11	0.00	19.72	-33.3	0.00	33.3
	Week 89	11	80.30	16.36	66.7	66.67	100.0	10	-5.00	27.27	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	EV+Pembro (N= 42)												
	BASELINE	36	80.09	27.55	0.0	100.00	100.0						
	Week 1	33	70.20	32.48	0.0	66.67	100.0	32	-10.94	23.04	-83.3	0.00	16.7
	Week 2	36	69.91	28.96	0.0	66.67	100.0	34	-9.80	23.25	-50.0	0.00	50.0
	Week 3	37	63.51	30.64	0.0	66.67	100.0	35	-13.81	29.56	-100.0	-16.66	50.0
	Week 4	36	73.61	25.93	0.0	66.67	100.0	34	-5.88	27.49	-66.7	0.00	66.7
	Week 5	36	72.22	26.13	0.0	66.67	100.0	33	-8.59	31.49	-66.7	0.00	83.3
	Week 6	35	78.10	26.74	16.7	100.00	100.0	32	-5.21	29.76	-83.3	0.00	83.3
	Week 7	36	79.63	20.36	33.3	83.33	100.0	34	-2.45	28.17	-66.7	0.00	66.7
	Week 8	37	79.73	23.28	0.0	83.33	100.0	36	-0.93	28.71	-66.7	0.00	83.3
	Week 9	35	82.38	19.78	33.3	83.33	100.0	34	0.49	28.86	-66.7	0.00	83.3
	Week 10	32	80.21	26.58	0.0	100.00	100.0	31	1.61	32.59	-100.0	0.00	83.3
	Week 11	33	80.30	22.99	0.0	83.33	100.0	32	0.00	32.79	-66.7	0.00	83.3
	Week 12	32	76.56	26.73	0.0	83.33	100.0	31	-3.23	30.86	-83.3	0.00	66.7
	Week 14	31	80.65	24.00	0.0	100.00	100.0	30	0.56	25.33	-33.3	0.00	83.3
	Week 17	33	79.80	19.43	33.3	66.67	100.0	32	0.52	29.17	-50.0	0.00	83.3
	Week 20	28	77.38	25.34	0.0	75.00	100.0	28	-2.38	31.66	-66.7	0.00	83.3
	Week 23	29	77.59	23.69	16.7	83.33	100.0	29	-2.30	29.79	-66.7	0.00	66.7
	Week 26	27	75.31	26.30	0.0	66.67	100.0	26	-6.41	27.92	-66.7	0.00	66.7
	Week 29	26	78.21	19.87	33.3	75.00	100.0	25	-0.67	30.99	-66.7	0.00	66.7
	Week 32	24	75.00	25.06	33.3	66.67	100.0	23	-10.14	29.62	-66.7	0.00	50.0
	Week 35	23	72.46	23.36	33.3	66.67	100.0	22	-12.88	30.83	-66.7	-16.67	50.0
	Week 38	25	71.33	21.26	33.3	66.67	100.0	24	-14.58	31.97	-66.7	-16.67	66.7
	Week 41	26	75.00	22.73	33.3	66.67	100.0	25	-6.00	31.51	-66.7	0.00	50.0
	Week 44	20	66.67	29.12	0.0	66.67	100.0	19	-22.81	34.34	-100.0	-16.66	33.3
	Week 47	20	66.67	33.77	0.0	66.67	100.0	19	-14.03	42.04	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	16	64.58	27.81	0.0	66.67	100.0	16	-20.83	29.50	-100.0	-25.00	16.7
	Week 53	15	68.89	22.60	33.3	66.67	100.0	15	-10.00	33.81	-66.7	0.00	66.7
	Week 56	15	72.22	21.52	33.3	66.67	100.0	15	-12.22	24.77	-66.7	0.00	33.3
	Week 59	14	63.10	24.62	33.3	66.67	100.0	14	-20.24	30.09	-66.7	-8.33	16.7
	Week 62	11	75.76	26.21	33.3	66.67	100.0	11	-9.09	27.25	-66.7	0.00	33.3
	Plat+Gem (N= 57)												
	BASELINE	42	73.02	27.53	0.0	75.00	100.0						
	Week 1	42	63.10	27.68	0.0	66.67	100.0	38	-10.96	27.47	-83.3	0.00	50.0
	Week 2	43	65.12	29.05	0.0	66.67	100.0	36	-13.89	33.92	-83.3	-16.67	66.7
	Week 3	43	73.26	23.04	16.7	83.33	100.0	36	-1.39	29.11	-83.3	0.00	66.7
	Week 4	44	68.18	25.11	0.0	66.67	100.0	37	-9.01	23.11	-50.0	0.00	50.0
	Week 5	44	63.64	27.91	0.0	66.67	100.0	36	-14.81	26.96	-66.7	-16.67	33.3
	Week 6	41	67.07	26.74	0.0	66.67	100.0	35	-8.10	27.53	-100.0	0.00	33.3
	Week 7	44	67.80	25.77	0.0	66.67	100.0	37	-9.46	29.28	-100.0	0.00	50.0
	Week 8	42	66.67	28.98	16.7	66.67	100.0	35	-8.57	31.41	-83.3	0.00	33.3
	Week 9	42	63.49	25.03	0.0	66.67	100.0	35	-10.00	26.26	-66.7	0.00	33.3
	Week 10	35	66.19	26.04	0.0	66.67	100.0	28	-16.07	26.64	-66.7	-16.67	33.3
	Week 11	40	67.50	23.25	16.7	66.67	100.0	34	-12.26	26.05	-66.7	-8.33	33.3
	Week 12	35	68.57	24.18	0.0	66.67	100.0	30	-12.22	29.01	-100.0	-16.66	33.3
	Week 14	32	62.50	30.53	0.0	66.67	100.0	27	-16.67	32.68	-100.0	0.00	33.3
	Week 17	34	60.79	23.53	0.0	66.67	100.0	29	-20.11	30.33	-100.0	-16.67	33.3
	Week 20	28	66.07	24.63	16.7	66.67	100.0	24	-17.36	30.09	-83.3	-16.67	33.3
	Week 23	22	75.00	25.59	33.3	75.00	100.0	19	-8.77	29.06	-66.7	-16.66	33.3
	Week 26	22	72.73	25.48	16.7	66.67	100.0	20	-9.17	21.27	-50.0	0.00	16.7
	Week 29	24	76.39	18.98	33.3	66.67	100.0	21	-4.76	26.43	-66.7	0.00	33.3
	Week 32	21	65.08	26.82	0.0	66.67	100.0	20	-15.83	32.66	-83.3	-25.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 35	18	66.67	30.25	0.0	66.67	100.0	17	-13.72	36.91	-83.3	-16.67	33.3
	Week 38	14	63.10	28.63	0.0	66.67	100.0	13	-17.95	32.25	-83.3	-16.67	33.3
	Week 41	13	66.67	22.57	33.3	66.67	100.0	12	-12.50	27.64	-50.0	-16.67	50.0
	Week 44	14	64.29	22.51	16.7	66.67	100.0	13	-19.23	27.09	-66.7	-16.67	33.3
	Week 47	12	66.67	22.47	33.3	66.67	100.0	11	-12.12	24.82	-33.3	-16.67	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Visceral metastases	EV+Pembro (N=170)												
	BASELINE	146	76.26	29.35	0.0	83.33	100.0						
	Week 1	135	69.14	30.65	0.0	66.67	100.0	131	-7.51	20.69	-83.3	0.00	33.3
	Week 2	145	68.28	29.42	0.0	66.67	100.0	134	-9.20	21.59	-66.7	0.00	50.0
	Week 3	141	65.13	30.85	0.0	66.67	100.0	129	-11.37	25.17	-83.3	0.00	66.7
	Week 4	136	69.98	28.53	0.0	66.67	100.0	125	-7.87	28.29	-100.0	0.00	66.7
	Week 5	131	70.10	30.22	0.0	66.67	100.0	118	-6.36	28.82	-100.0	0.00	66.7
	Week 6	127	71.92	27.91	0.0	66.67	100.0	113	-6.05	27.19	-100.0	0.00	50.0
	Week 7	135	71.73	26.65	0.0	66.67	100.0	121	-4.54	31.40	-100.0	0.00	66.7
	Week 8	131	74.81	25.52	0.0	66.67	100.0	118	-1.27	30.91	-100.0	0.00	66.7
	Week 9	136	70.34	29.02	0.0	66.67	100.0	124	-6.72	29.60	-100.0	0.00	66.7
	Week 10	135	74.57	26.22	0.0	66.67	100.0	124	-1.88	30.22	-100.0	0.00	66.7
	Week 11	134	73.63	27.59	0.0	66.67	100.0	121	-2.20	31.69	-100.0	0.00	83.3
	Week 12	131	74.05	28.88	0.0	66.67	100.0	120	-1.53	31.46	-100.0	0.00	66.7
	Week 14	130	72.44	26.95	0.0	66.67	100.0	117	-2.85	31.05	-100.0	0.00	66.7
	Week 17	124	74.33	25.09	0.0	66.67	100.0	111	-1.65	29.64	-66.7	0.00	83.3
	Week 20	115	72.32	26.48	0.0	66.67	100.0	105	-4.92	31.09	-100.0	0.00	66.7
	Week 23	111	71.32	27.26	0.0	66.67	100.0	103	-5.34	30.89	-83.3	0.00	66.7
	Week 26	106	73.74	29.27	0.0	83.33	100.0	97	-2.58	34.39	-100.0	0.00	66.7
	Week 29	106	75.63	25.22	0.0	66.67	100.0	98	-3.23	32.43	-83.3	0.00	83.3
	Week 32	92	72.28	27.10	0.0	66.67	100.0	85	-6.47	30.22	-83.3	0.00	66.7
	Week 35	86	71.71	24.26	0.0	66.67	100.0	79	-8.44	29.22	-83.3	0.00	66.7
	Week 38	90	69.07	24.55	0.0	66.67	100.0	84	-8.53	30.45	-66.7	0.00	66.7
	Week 41	87	69.92	25.78	0.0	66.67	100.0	81	-9.05	32.17	-66.7	0.00	66.7
	Week 44	73	69.41	27.92	0.0	66.67	100.0	68	-12.74	36.78	-100.0	0.00	66.7
	Week 47	68	69.61	26.85	0.0	66.67	100.0	63	-11.64	34.60	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	61	68.31	25.04	16.7	66.67	100.0	57	-13.74	32.90	-83.3	0.00	66.7
	Week 53	54	71.91	23.97	0.0	66.67	100.0	50	-14.33	34.17	-100.0	0.00	66.7
	Week 56	58	69.25	24.54	0.0	66.67	100.0	54	-12.65	34.86	-100.0	0.00	66.7
	Week 59	50	69.67	25.57	0.0	66.67	100.0	47	-15.25	31.63	-100.0	0.00	66.7
	Week 62	45	71.85	26.55	0.0	66.67	100.0	43	-15.50	34.19	-100.0	0.00	66.7
	Week 65	37	72.07	26.37	0.0	66.67	100.0	34	-13.23	33.78	-100.0	0.00	66.7
	Week 68	35	71.43	27.88	0.0	66.67	100.0	34	-16.67	35.30	-100.0	-16.66	66.7
	Week 71	31	73.12	25.70	0.0	66.67	100.0	30	-12.78	33.81	-100.0	0.00	66.7
	Week 74	29	72.42	23.69	0.0	66.67	100.0	28	-14.28	31.66	-100.0	-16.66	66.7
	Week 77	26	67.95	27.05	0.0	66.67	100.0	25	-15.33	38.77	-100.0	-16.67	66.7
	Week 80	22	68.94	24.83	0.0	66.67	100.0	21	-11.11	37.39	-100.0	0.00	66.7
	Week 83	23	69.57	24.95	0.0	66.67	100.0	22	-14.39	35.37	-100.0	-16.66	66.7
	Week 86	21	70.64	25.77	0.0	66.67	100.0	20	-13.33	31.34	-100.0	-8.33	50.0
	Week 89	21	65.08	27.84	0.0	66.67	100.0	20	-17.50	36.06	-100.0	-16.67	66.7
	Week 92	18	66.67	27.42	0.0	66.67	100.0	17	-18.63	24.92	-50.0	-33.33	33.3
	Week 95	13	69.23	27.93	0.0	66.67	100.0	12	-18.06	27.02	-66.7	-25.00	33.3
	Week 98	11	80.30	19.46	50.0	66.67	100.0	11	-6.06	23.89	-33.3	0.00	33.3
	Week 101	11	69.70	26.69	33.3	66.67	100.0	11	-19.70	25.62	-66.7	-16.66	0.0
	Plat+Gem (N=161)												
	BASELINE	129	70.03	28.59	0.0	66.67	100.0						
	Week 1	113	65.34	28.88	0.0	66.67	100.0	105	-6.03	22.18	-50.0	0.00	50.0
	Week 2	108	60.80	30.00	0.0	66.67	100.0	98	-11.73	25.24	-83.3	0.00	66.7
	Week 3	121	71.21	25.73	0.0	66.67	100.0	109	-0.61	25.75	-83.3	0.00	83.3
	Week 4	116	67.96	27.47	0.0	66.67	100.0	101	-3.30	22.49	-66.7	0.00	83.3
	Week 5	121	64.60	28.35	0.0	66.67	100.0	104	-8.65	26.88	-66.7	0.00	83.3
	Week 6	118	67.94	27.75	0.0	66.67	100.0	102	-3.92	23.47	-50.0	0.00	83.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 7	121	67.91	28.23	0.0	66.67	100.0	104	-4.81	25.72	-100.0	0.00	50.0
	Week 8	108	68.67	27.69	0.0	66.67	100.0	96	-5.21	29.35	-83.3	0.00	66.7
	Week 9	114	68.71	25.87	0.0	66.67	100.0	99	-4.38	27.62	-100.0	0.00	66.7
	Week 10	109	66.51	26.50	0.0	66.67	100.0	94	-6.91	24.97	-83.3	0.00	50.0
	Week 11	109	69.88	26.59	0.0	66.67	100.0	95	-5.61	29.13	-83.3	0.00	83.3
	Week 12	103	69.09	25.82	0.0	66.67	100.0	91	-5.49	30.13	-100.0	0.00	83.3
	Week 14	98	68.37	24.35	0.0	66.67	100.0	85	-5.69	30.70	-66.7	0.00	66.7
	Week 17	103	67.48	26.34	0.0	66.67	100.0	89	-8.80	27.76	-83.3	-16.66	66.7
	Week 20	82	70.12	23.97	0.0	66.67	100.0	75	-5.78	28.14	-83.3	0.00	83.3
	Week 23	77	68.83	27.75	0.0	66.67	100.0	68	-7.84	27.99	-66.7	0.00	33.3
	Week 26	71	72.54	25.53	0.0	66.67	100.0	65	-6.67	23.72	-66.7	0.00	50.0
	Week 29	65	73.85	22.62	16.7	66.67	100.0	59	-8.19	25.21	-83.3	0.00	33.3
	Week 32	52	74.04	23.20	16.7	66.67	100.0	49	-10.20	25.42	-66.7	0.00	50.0
	Week 35	47	71.99	25.56	0.0	66.67	100.0	44	-8.71	28.64	-83.3	0.00	33.3
	Week 38	42	72.62	27.75	0.0	66.67	100.0	39	-12.39	28.54	-83.3	0.00	33.3
	Week 41	35	70.95	27.22	33.3	66.67	100.0	32	-10.42	29.56	-66.7	0.00	50.0
	Week 44	36	68.06	28.28	0.0	66.67	100.0	33	-13.64	32.40	-100.0	-16.66	33.3
	Week 47	32	72.92	22.70	0.0	66.67	100.0	30	-10.00	29.23	-100.0	0.00	50.0
	Week 50	30	66.67	24.76	0.0	66.67	100.0	29	-13.79	28.20	-100.0	0.00	33.3
	Week 53	25	76.00	21.02	33.3	66.67	100.0	24	-9.72	20.80	-50.0	0.00	33.3
	Week 56	22	62.12	32.20	0.0	66.67	100.0	21	-22.22	32.63	-83.3	-33.33	33.3
	Week 59	22	81.82	19.18	33.3	83.33	100.0	21	-5.56	26.53	-66.7	0.00	33.3
	Week 62	19	73.69	16.96	33.3	66.67	100.0	18	-10.18	27.50	-66.7	0.00	33.3
	Week 65	19	75.44	25.68	0.0	83.33	100.0	18	-12.04	31.73	-100.0	-8.34	33.3
	Week 68	13	79.49	22.72	33.3	83.33	100.0	12	-11.11	22.84	-50.0	0.00	33.3
	Week 71	13	67.95	24.97	33.3	66.67	100.0	12	-18.06	30.53	-66.7	-16.67	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 74	11	80.30	22.13	33.3	83.33	100.0	11	-4.55	18.39	-33.3	0.00	33.3
	Week 77	10	83.33	19.24	50.0	91.67	100.0	10	-3.33	17.21	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Lymph node only	EV+Pembro (N= 60)												
	BASELINE	53	84.59	22.61	16.7	100.00	100.0						
	Week 1	49	86.05	21.34	33.3	100.00	100.0	47	-1.06	20.09	-66.7	0.00	50.0
	Week 2	50	74.67	28.42	0.0	83.33	100.0	48	-10.42	23.97	-100.0	0.00	50.0
	Week 3	50	74.33	21.62	0.0	66.67	100.0	47	-10.28	23.96	-100.0	0.00	50.0
	Week 4	50	83.67	20.62	16.7	91.67	100.0	47	-2.13	18.59	-33.3	0.00	66.7
	Week 5	53	80.50	20.60	33.3	83.33	100.0	49	-5.78	25.58	-50.0	0.00	83.3
	Week 6	53	81.13	23.35	0.0	100.00	100.0	50	-3.00	24.67	-66.7	0.00	83.3
	Week 7	52	82.05	20.83	16.7	91.67	100.0	48	-6.25	23.97	-50.0	0.00	66.7
	Week 8	52	79.17	26.17	0.0	83.33	100.0	47	-7.09	24.51	-66.7	0.00	83.3
	Week 9	53	77.99	24.63	0.0	83.33	100.0	49	-7.48	28.07	-66.7	0.00	83.3
	Week 10	48	80.56	23.65	0.0	100.00	100.0	44	-1.14	25.52	-33.3	0.00	83.3
	Week 11	53	74.22	25.44	0.0	66.67	100.0	48	-10.07	26.12	-66.7	0.00	83.3
	Week 12	48	73.61	25.46	0.0	66.67	100.0	45	-11.11	28.20	-100.0	0.00	66.7
	Week 14	48	78.13	23.36	0.0	66.67	100.0	44	-7.20	24.74	-66.7	0.00	83.3
	Week 17	46	73.19	23.70	0.0	66.67	100.0	44	-11.74	25.31	-66.7	-8.33	83.3
	Week 20	44	68.18	32.31	0.0	66.67	100.0	42	-15.87	34.13	-100.0	0.00	83.3
	Week 23	43	68.60	29.59	0.0	66.67	100.0	41	-17.48	26.86	-100.0	-16.67	50.0
	Week 26	42	69.84	25.57	0.0	66.67	100.0	40	-17.50	26.67	-83.3	-8.33	33.3
	Week 29	45	71.85	22.98	0.0	66.67	100.0	42	-14.29	28.65	-66.7	-16.67	50.0
	Week 32	38	70.18	23.62	16.7	66.67	100.0	36	-18.98	27.65	-66.7	-16.67	50.0
	Week 35	42	65.87	28.26	0.0	66.67	100.0	40	-21.25	24.75	-83.3	-16.67	50.0
	Week 38	38	70.61	24.94	0.0	66.67	100.0	36	-17.59	25.49	-66.7	-16.67	50.0
	Week 41	37	72.52	25.82	0.0	66.67	100.0	34	-16.18	21.90	-66.7	-16.67	50.0
	Week 44	31	67.74	26.50	0.0	66.67	100.0	29	-24.14	24.23	-66.7	-33.33	16.7
	Week 47	28	72.02	27.61	0.0	66.67	100.0	27	-18.52	22.80	-66.7	-16.67	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	25	68.67	26.93	0.0	66.67	100.0	24	-21.53	20.55	-66.7	-33.33	0.0
	Week 53	23	73.19	24.99	16.7	66.67	100.0	22	-19.70	23.36	-66.7	-16.67	16.7
	Week 56	21	70.64	28.34	0.0	66.67	100.0	20	-18.33	19.42	-50.0	-16.67	0.0
	Week 59	20	70.00	23.32	33.3	66.67	100.0	19	-20.17	22.62	-66.7	-16.67	16.7
	Week 62	19	73.68	26.25	33.3	66.67	100.0	19	-18.42	23.50	-66.7	0.00	16.7
	Week 65	20	65.83	30.34	0.0	66.67	100.0	19	-22.81	27.33	-66.7	-16.67	16.7
	Week 68	17	75.49	24.38	33.3	66.67	100.0	17	-13.73	22.23	-66.7	0.00	16.7
	Week 71	19	73.68	29.04	0.0	66.67	100.0	18	-21.30	21.24	-66.7	-16.67	0.0
	Week 74	17	68.63	29.39	0.0	66.67	100.0	17	-22.55	22.00	-66.7	-16.67	0.0
	Week 77	17	58.82	34.42	0.0	66.67	100.0	16	-26.04	23.54	-66.7	-25.00	0.0
	Week 80	17	66.67	32.81	0.0	66.67	100.0	15	-20.00	22.89	-83.3	-16.67	0.0
	Week 83	13	57.69	33.07	0.0	66.67	100.0	12	-22.22	21.71	-66.7	-16.67	0.0
	Week 86	12	62.50	30.26	0.0	66.67	100.0	10	-21.67	20.86	-50.0	-25.00	0.0
	Week 89	11	68.18	24.10	33.3	66.67	100.0	10	-16.67	23.57	-50.0	-8.33	16.7
	Plat+Gem (N= 67)												
	BASELINE	49	80.95	22.82	16.7	83.33	100.0						
	Week 1	51	72.55	25.13	0.0	66.67	100.0	45	-8.15	23.74	-83.3	0.00	33.3
	Week 2	53	69.18	30.03	0.0	66.67	100.0	44	-12.50	31.36	-100.0	0.00	50.0
	Week 3	53	72.33	25.31	16.7	66.67	100.0	44	-6.82	24.46	-66.7	0.00	33.3
	Week 4	58	69.25	28.41	0.0	66.67	100.0	47	-12.77	27.19	-83.3	0.00	33.3
	Week 5	56	66.96	25.92	0.0	66.67	100.0	44	-17.80	28.84	-100.0	-8.33	33.3
	Week 6	48	71.88	25.53	0.0	66.67	100.0	40	-9.17	30.88	-100.0	0.00	50.0
	Week 7	56	70.24	25.76	16.7	66.67	100.0	46	-10.51	28.62	-83.3	0.00	50.0
	Week 8	52	66.67	29.15	0.0	66.67	100.0	42	-16.27	32.40	-100.0	0.00	33.3
	Week 9	53	64.15	28.00	0.0	66.67	100.0	42	-17.86	31.96	-100.0	-16.67	50.0
	Week 10	47	66.31	28.97	0.0	66.67	100.0	36	-14.82	30.02	-100.0	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	51	66.67	26.67	0.0	66.67	100.0	41	-14.23	30.41	-100.0	0.00	50.0
	Week 12	47	68.79	26.83	0.0	66.67	100.0	39	-11.97	30.09	-100.0	-16.66	50.0
	Week 14	47	66.31	29.38	0.0	66.67	100.0	36	-13.89	32.49	-100.0	-16.66	50.0
	Week 17	45	68.52	25.68	0.0	66.67	100.0	35	-13.33	32.03	-100.0	0.00	33.3
	Week 20	38	75.00	25.04	16.7	75.00	100.0	30	-7.22	30.54	-83.3	0.00	66.7
	Week 23	32	73.96	24.66	0.0	66.67	100.0	25	-8.00	25.06	-66.7	0.00	50.0
	Week 26	30	71.67	28.75	0.0	66.67	100.0	24	-8.33	32.97	-66.7	0.00	83.3
	Week 29	28	69.05	29.30	0.0	66.67	100.0	21	-14.29	29.00	-100.0	0.00	33.3
	Week 32	26	76.28	30.25	0.0	83.33	100.0	22	-3.03	31.97	-83.3	0.00	66.7
	Week 35	23	76.81	28.31	0.0	83.33	100.0	19	-9.65	27.39	-83.3	0.00	33.3
	Week 38	26	76.28	31.68	0.0	83.33	100.0	20	-3.33	35.29	-83.3	0.00	83.3
	Week 41	24	72.92	25.92	0.0	66.67	100.0	18	-6.48	30.86	-66.7	0.00	83.3
	Week 44	18	74.07	29.83	0.0	75.00	100.0	14	-4.76	36.65	-66.7	0.00	83.3
	Week 47	18	71.30	24.79	33.3	66.67	100.0	13	-7.69	34.44	-66.7	0.00	66.7
	Week 50	16	71.88	32.04	0.0	66.67	100.0	13	-3.85	31.29	-33.3	0.00	83.3
	Week 53	15	73.33	23.40	33.3	66.67	100.0	12	-8.33	36.58	-66.7	0.00	83.3
	Week 56	15	76.67	30.73	0.0	100.00	100.0	11	1.52	31.14	-50.0	0.00	83.3
	Week 59	12	75.00	29.73	0.0	75.00	100.0	9	0.00	30.04	-50.0	0.00	66.7
	Week 62	10	83.33	19.24	50.0	91.67	100.0	8	4.17	34.21	-33.3	0.00	83.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
EV+Pembro (N=202)												
BASELINE	160	72.08	28.57	0.0	66.67	100.0						
Week 1	141	70.09	27.64	0.0	66.67	100.0	129	-3.10	18.95	-50.0	0.00	33.3
Week 2	150	66.89	29.47	0.0	66.67	100.0	133	-5.76	21.62	-83.3	0.00	66.7
Week 3	139	68.11	29.59	0.0	66.67	100.0	122	-3.28	24.86	-66.7	0.00	66.7
Week 4	145	69.31	27.89	0.0	66.67	100.0	129	-3.36	24.77	-66.7	0.00	66.7
Week 5	137	69.34	28.38	0.0	66.67	100.0	121	-1.65	25.86	-83.3	0.00	66.7
Week 6	146	70.55	28.17	0.0	66.67	100.0	124	-1.48	28.28	-83.3	0.00	66.7
Week 7	147	72.56	26.37	0.0	66.67	100.0	124	-0.13	29.10	-83.3	0.00	66.7
Week 8	147	69.84	28.16	0.0	66.67	100.0	124	-2.15	30.28	-100.0	0.00	66.7
Week 9	142	69.60	26.87	0.0	66.67	100.0	121	-1.65	30.08	-100.0	0.00	100.0
Week 10	139	73.26	26.67	0.0	66.67	100.0	118	1.27	30.29	-100.0	0.00	66.7
Week 11	137	73.12	25.74	0.0	66.67	100.0	115	0.15	29.99	-100.0	0.00	66.7
Week 12	142	71.13	27.78	0.0	66.67	100.0	119	-1.96	29.04	-66.7	0.00	66.7
Week 14	139	72.66	26.08	0.0	66.67	100.0	116	-0.43	29.44	-66.7	0.00	66.7
Week 17	132	70.58	24.00	0.0	66.67	100.0	111	-3.30	30.47	-66.7	0.00	66.7
Week 20	120	75.28	22.56	0.0	66.67	100.0	103	0.32	29.15	-66.7	0.00	66.7
Week 23	117	73.65	21.69	0.0	66.67	100.0	97	-2.23	29.03	-66.7	0.00	66.7
Week 26	112	73.36	22.97	0.0	66.67	100.0	94	-0.35	26.99	-66.7	0.00	66.7
Week 29	107	69.32	25.20	0.0	66.67	100.0	93	-8.60	32.75	-100.0	0.00	66.7
Week 32	102	72.55	22.70	0.0	66.67	100.0	88	-2.65	29.13	-100.0	0.00	83.3
Week 35	98	70.58	23.30	0.0	66.67	100.0	86	-6.20	30.79	-100.0	0.00	66.7
Week 38	97	69.25	23.37	0.0	66.67	100.0	86	-6.20	28.82	-100.0	0.00	66.7
Week 41	95	70.70	22.64	0.0	66.67	100.0	84	-5.36	28.94	-83.3	0.00	66.7
Week 44	86	67.44	23.42	0.0	66.67	100.0	74	-9.68	27.86	-66.7	0.00	66.7
Week 47	79	68.78	25.23	0.0	66.67	100.0	70	-6.19	27.24	-83.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	74	66.89	24.28	0.0	66.67	100.0	64	-8.85	28.94	-100.0	0.00	66.7
Week 53	74	66.22	25.88	0.0	66.67	100.0	63	-7.67	28.69	-83.3	0.00	33.3
Week 56	72	66.90	24.62	0.0	66.67	100.0	61	-4.37	25.07	-66.7	0.00	33.3
Week 59	69	64.98	24.28	0.0	66.67	100.0	57	-6.14	29.32	-66.7	0.00	66.7
Week 62	62	66.40	24.79	0.0	66.67	100.0	52	-5.13	27.12	-66.7	0.00	66.7
Week 65	43	65.89	21.81	33.3	66.67	100.0	40	-9.58	28.22	-66.7	-8.33	66.7
Week 68	46	66.31	23.70	0.0	66.67	100.0	42	-8.73	27.61	-83.3	0.00	66.7
Week 71	42	69.84	25.83	0.0	66.67	100.0	38	-1.32	28.58	-66.7	0.00	66.7
Week 74	38	69.74	23.84	16.7	66.67	100.0	35	-6.67	32.39	-66.7	0.00	66.7
Week 77	37	71.17	22.79	33.3	66.67	100.0	33	-4.04	31.19	-66.7	0.00	66.7
Week 80	36	67.13	24.07	16.7	66.67	100.0	34	-8.33	33.65	-83.3	0.00	66.7
Week 83	30	73.89	21.30	33.3	66.67	100.0	29	-1.15	30.19	-66.7	0.00	66.7
Week 86	26	66.03	28.08	0.0	66.67	100.0	25	-14.00	34.25	-100.0	0.00	33.3
Week 89	20	69.17	27.19	0.0	66.67	100.0	19	-14.91	31.86	-100.0	0.00	33.3
Week 92	19	71.05	22.11	16.7	66.67	100.0	18	-13.89	23.04	-50.0	-8.33	16.7
Week 95	14	78.57	20.07	50.0	66.67	100.0	13	-8.97	21.10	-33.3	0.00	16.7
Week 98	10	78.34	15.81	66.7	66.67	100.0	9	-9.26	16.90	-33.3	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Plat+Gem (N=202)												
BASELINE	165	73.54	30.96	0.0	83.33	100.0						
Week 1	144	69.56	29.91	0.0	66.67	100.0	139	-5.16	21.69	-83.3	0.00	83.3
Week 2	147	65.99	29.90	0.0	66.67	100.0	135	-10.00	27.56	-100.0	0.00	100.0
Week 3	149	66.44	31.18	0.0	66.67	100.0	136	-10.17	23.50	-83.3	0.00	66.7
Week 4	150	69.44	29.25	0.0	66.67	100.0	135	-6.54	25.11	-66.7	0.00	100.0
Week 5	153	65.90	29.51	0.0	66.67	100.0	138	-9.90	26.76	-83.3	0.00	100.0
Week 6	145	67.36	30.23	0.0	66.67	100.0	131	-8.27	29.63	-100.0	0.00	100.0
Week 7	148	66.44	30.18	0.0	66.67	100.0	134	-8.33	29.95	-100.0	0.00	100.0
Week 8	145	64.83	28.74	0.0	66.67	100.0	132	-10.35	30.44	-100.0	0.00	66.7
Week 9	141	64.78	29.35	0.0	66.67	100.0	125	-10.27	31.02	-100.0	0.00	100.0
Week 10	142	66.43	28.76	0.0	66.67	100.0	130	-9.36	30.00	-83.3	0.00	100.0
Week 11	126	65.87	29.65	0.0	66.67	100.0	114	-9.36	28.91	-83.3	0.00	100.0
Week 12	130	65.00	29.12	0.0	66.67	100.0	115	-10.00	29.35	-83.3	0.00	100.0
Week 14	125	63.73	30.01	0.0	66.67	100.0	109	-11.01	31.53	-100.0	-16.66	100.0
Week 17	120	65.42	29.56	0.0	66.67	100.0	106	-12.74	33.22	-100.0	-16.66	100.0
Week 20	104	69.71	27.94	0.0	66.67	100.0	91	-7.33	30.55	-83.3	0.00	100.0
Week 23	88	72.92	26.30	16.7	66.67	100.0	80	-7.50	24.86	-66.7	0.00	66.7
Week 26	81	70.17	28.83	0.0	66.67	100.0	75	-8.44	29.17	-100.0	0.00	66.7
Week 29	77	71.43	28.47	0.0	66.67	100.0	71	-10.80	34.63	-100.0	0.00	66.7
Week 32	63	71.43	30.30	0.0	83.33	100.0	58	-10.63	33.44	-100.0	0.00	66.7
Week 35	62	70.70	24.64	16.7	66.67	100.0	56	-10.42	32.03	-66.7	0.00	66.7
Week 38	56	73.21	28.90	0.0	75.00	100.0	50	-10.00	32.65	-100.0	0.00	66.7
Week 41	52	68.91	31.14	0.0	66.67	100.0	47	-15.25	32.94	-100.0	-16.66	66.7
Week 44	49	62.58	31.46	0.0	66.67	100.0	44	-17.80	31.83	-66.7	-16.66	66.7
Week 47	43	65.89	32.93	0.0	66.67	100.0	39	-14.96	34.16	-83.3	-16.66	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	36	66.20	30.73	0.0	66.67	100.0	31	-13.98	29.22	-66.7	0.00	66.7
Week 53	31	69.36	29.84	0.0	66.67	100.0	28	-10.12	34.05	-83.3	0.00	66.7
Week 56	30	63.33	30.76	0.0	66.67	100.0	29	-11.49	34.25	-66.7	0.00	66.7
Week 59	23	65.22	30.12	0.0	66.67	100.0	21	-7.94	32.33	-66.7	0.00	66.7
Week 62	20	63.33	27.36	0.0	66.67	100.0	20	-9.17	39.91	-100.0	-16.66	66.7
Week 65	17	65.69	26.00	16.7	66.67	100.0	16	-16.67	24.34	-66.7	-16.66	33.3
Week 68	13	66.67	29.66	0.0	66.67	100.0	13	-17.95	30.78	-100.0	-16.66	33.3
Week 71	13	64.10	31.80	0.0	66.67	100.0	13	-17.95	33.65	-100.0	-16.67	33.3
Week 74	11	74.24	25.13	33.3	66.67	100.0	11	-16.67	16.67	-33.3	-16.67	0.0
Week 77	11	80.30	26.68	16.7	100.00	100.0	11	-4.54	43.52	-83.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Present	EV+Pembro (N= 50)												
	BASELINE	40	69.58	31.10	0.0	66.67	100.0						
	Week 1	38	63.60	26.81	0.0	66.67	100.0	34	-7.35	22.17	-50.0	0.00	33.3
	Week 2	35	62.86	29.73	0.0	66.67	100.0	32	-7.29	23.92	-50.0	0.00	33.3
	Week 3	32	70.31	28.31	0.0	66.67	100.0	30	-3.33	25.29	-66.7	0.00	50.0
	Week 4	35	64.29	27.75	0.0	66.67	100.0	31	-8.60	25.41	-66.7	0.00	50.0
	Week 5	32	67.71	29.62	0.0	66.67	100.0	28	-3.57	23.73	-66.7	0.00	50.0
	Week 6	35	64.29	28.34	0.0	66.67	100.0	30	-4.44	34.72	-83.3	0.00	66.7
	Week 7	35	69.05	26.86	0.0	66.67	100.0	29	-3.45	27.59	-66.7	0.00	50.0
	Week 8	38	61.84	29.74	0.0	66.67	100.0	31	-9.68	34.10	-100.0	0.00	50.0
	Week 9	33	69.70	26.83	0.0	66.67	100.0	29	0.00	34.50	-66.7	0.00	100.0
	Week 10	30	76.67	20.34	33.3	66.67	100.0	25	6.00	27.59	-33.3	0.00	50.0
	Week 11	31	71.51	28.61	0.0	66.67	100.0	27	-3.09	32.04	-100.0	0.00	66.7
	Week 12	32	65.63	32.22	0.0	66.67	100.0	28	-8.33	29.57	-66.7	0.00	66.7
	Week 14	36	70.83	29.91	0.0	75.00	100.0	31	0.00	29.19	-66.7	0.00	66.7
	Week 17	33	68.18	28.98	0.0	66.67	100.0	27	-4.32	31.21	-66.7	0.00	66.7
	Week 20	28	72.02	26.47	0.0	66.67	100.0	25	-6.67	28.46	-66.7	0.00	33.3
	Week 23	28	65.48	26.42	0.0	66.67	100.0	24	-11.11	26.77	-66.7	-16.67	50.0
	Week 26	28	67.86	24.82	0.0	66.67	100.0	24	-6.25	25.45	-33.3	0.00	66.7
	Week 29	27	67.90	28.84	0.0	66.67	100.0	25	-10.67	32.94	-100.0	-16.67	66.7
	Week 32	25	67.33	23.80	0.0	66.67	100.0	23	-8.70	33.28	-100.0	0.00	83.3
	Week 35	26	66.03	25.60	0.0	66.67	100.0	24	-10.42	34.34	-100.0	-8.34	66.7
	Week 38	26	60.26	27.52	0.0	66.67	100.0	24	-16.67	32.97	-100.0	-25.00	66.7
	Week 41	25	67.34	20.68	16.7	66.67	100.0	23	-13.77	33.58	-83.3	-16.67	66.7
	Week 44	22	65.91	21.50	0.0	66.67	100.0	20	-10.83	31.19	-66.7	-16.67	66.7
	Week 47	14	66.67	23.57	33.3	66.67	100.0	13	-6.41	29.30	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	60.00	29.32	0.0	66.67	100.0	17	-12.75	38.43	-100.0	-16.67	66.7
	Week 53	21	59.52	27.17	0.0	66.67	100.0	18	-13.89	30.38	-83.3	0.00	33.3
	Week 56	18	62.96	21.81	33.3	66.67	100.0	15	-6.67	23.40	-33.3	-16.67	33.3
	Week 59	18	61.11	25.57	0.0	66.67	100.0	15	-5.56	29.99	-50.0	-16.67	66.7
	Week 62	13	60.26	18.68	33.3	66.67	100.0	11	-10.60	30.98	-33.3	-16.67	66.7
	Week 68	12	58.34	21.91	0.0	66.67	83.3	11	-15.15	32.88	-50.0	-33.33	66.7
	Plat+Gem (N= 50)												
	BASELINE	40	65.83	32.46	0.0	66.67	100.0						
	Week 1	35	63.33	31.52	0.0	66.67	100.0	33	-6.56	17.65	-33.3	0.00	33.3
	Week 2	33	60.10	31.44	0.0	66.67	100.0	30	-12.78	25.78	-83.3	-8.33	33.3
	Week 3	33	61.11	35.03	0.0	66.67	100.0	29	-10.92	24.10	-66.7	0.00	50.0
	Week 4	36	66.20	32.24	0.0	66.67	100.0	32	-1.56	25.53	-50.0	0.00	66.7
	Week 5	36	59.72	32.94	0.0	66.67	100.0	32	-9.90	28.35	-66.7	0.00	50.0
	Week 6	32	65.10	31.78	0.0	66.67	100.0	29	-5.17	28.90	-66.7	0.00	50.0
	Week 7	35	57.62	32.43	0.0	50.00	100.0	31	-9.68	27.14	-66.7	0.00	50.0
	Week 8	35	59.52	27.80	0.0	66.67	100.0	31	-8.60	30.99	-66.7	0.00	66.7
	Week 9	34	60.79	27.79	0.0	66.67	100.0	30	-6.11	34.60	-100.0	0.00	66.7
	Week 10	33	61.11	35.03	0.0	66.67	100.0	30	-7.22	36.01	-83.3	0.00	83.3
	Week 11	30	60.56	31.71	0.0	66.67	100.0	26	-8.97	30.99	-83.3	-8.33	83.3
	Week 12	32	58.85	29.33	0.0	66.67	100.0	27	-9.88	23.69	-66.7	-16.67	33.3
	Week 14	27	54.94	34.84	0.0	66.67	100.0	22	-12.88	36.71	-100.0	-8.33	66.7
	Week 17	28	63.10	30.21	0.0	66.67	100.0	23	-6.52	31.68	-66.7	0.00	66.7
	Week 20	20	62.50	32.84	0.0	66.67	100.0	16	-5.21	19.92	-33.3	0.00	50.0
	Week 23	15	72.22	28.64	16.7	66.67	100.0	14	-3.57	13.36	-33.3	0.00	16.7
	Week 26	15	68.89	31.41	0.0	66.67	100.0	14	-7.14	18.16	-33.3	0.00	16.7
	Week 29	13	67.95	33.65	0.0	66.67	100.0	12	-19.44	33.96	-100.0	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Absent	EV+Pembro (N=152)												
	BASELINE	120	72.92	27.76	0.0	66.67	100.0						
	Week 1	103	72.49	27.68	0.0	66.67	100.0	95	-1.58	17.54	-33.3	0.00	33.3
	Week 2	115	68.12	29.42	0.0	66.67	100.0	101	-5.28	20.94	-83.3	0.00	66.7
	Week 3	107	67.45	30.06	0.0	66.67	100.0	92	-3.26	24.86	-66.7	0.00	66.7
	Week 4	110	70.91	27.87	0.0	66.67	100.0	98	-1.70	24.46	-66.7	0.00	66.7
	Week 5	105	69.84	28.13	0.0	66.67	100.0	93	-1.08	26.56	-83.3	0.00	66.7
	Week 6	111	72.52	27.95	0.0	66.67	100.0	94	-0.53	26.03	-66.7	0.00	66.7
	Week 7	112	73.66	26.25	0.0	66.67	100.0	95	0.88	29.61	-83.3	0.00	66.7
	Week 8	109	72.63	27.17	0.0	66.67	100.0	93	0.36	28.66	-66.7	0.00	66.7
	Week 9	109	69.57	27.01	0.0	66.67	100.0	92	-2.17	28.73	-100.0	0.00	66.7
	Week 10	109	72.32	28.17	0.0	66.67	100.0	93	0.00	30.99	-100.0	0.00	66.7
	Week 11	106	73.59	24.97	0.0	66.67	100.0	88	1.14	29.45	-100.0	0.00	66.7
	Week 12	110	72.73	26.30	0.0	66.67	100.0	91	0.00	28.76	-66.7	0.00	66.7
	Week 14	103	73.30	24.74	0.0	66.67	100.0	85	-0.59	29.71	-66.7	0.00	66.7
	Week 17	99	71.38	22.21	0.0	66.67	100.0	84	-2.98	30.41	-66.7	0.00	66.7
	Week 20	92	76.27	21.29	33.3	66.67	100.0	78	2.56	29.19	-66.7	0.00	66.7
	Week 23	89	76.22	19.44	33.3	66.67	100.0	73	0.69	29.32	-66.7	0.00	66.7
	Week 26	84	75.20	22.18	0.0	66.67	100.0	70	1.67	27.39	-66.7	0.00	66.7
	Week 29	80	69.79	24.03	0.0	66.67	100.0	68	-7.84	32.89	-100.0	0.00	66.7
	Week 32	77	74.24	22.22	33.3	66.67	100.0	65	-0.51	27.48	-66.7	0.00	66.7
	Week 35	72	72.22	22.38	0.0	66.67	100.0	62	-4.57	29.44	-66.7	0.00	66.7
	Week 38	71	72.54	20.91	0.0	66.67	100.0	62	-2.15	26.22	-66.7	0.00	66.7
	Week 41	70	71.91	23.32	0.0	66.67	100.0	61	-2.19	26.61	-66.7	0.00	66.7
	Week 44	64	67.97	24.18	0.0	66.67	100.0	54	-9.26	26.83	-66.7	0.00	66.7
	Week 47	65	69.23	25.72	0.0	66.67	100.0	57	-6.14	27.03	-83.3	0.00	66.7

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	54	69.45	21.90	0.0	66.67	100.0	47	-7.45	25.01	-66.7	0.00	33.3
	Week 53	53	68.87	25.12	33.3	66.67	100.0	45	-5.18	27.94	-66.7	0.00	33.3
	Week 56	54	68.21	25.55	0.0	66.67	100.0	46	-3.62	25.80	-66.7	0.00	33.3
	Week 59	51	66.34	23.92	33.3	66.67	100.0	42	-6.35	29.44	-66.7	0.00	33.3
	Week 62	49	68.03	26.10	0.0	66.67	100.0	41	-3.66	26.22	-66.7	0.00	50.0
	Week 65	36	66.67	22.89	33.3	66.67	100.0	33	-9.09	25.03	-66.7	0.00	33.3
	Week 68	34	69.12	23.97	16.7	66.67	100.0	31	-6.45	25.70	-83.3	0.00	33.3
	Week 71	33	73.74	23.95	33.3	66.67	100.0	30	0.56	24.56	-66.7	0.00	33.3
	Week 74	33	72.73	23.50	16.7	66.67	100.0	30	-5.55	29.79	-66.7	0.00	33.3
	Week 77	31	74.19	22.71	33.3	66.67	100.0	27	-3.09	29.97	-66.7	0.00	33.3
	Week 80	31	69.36	24.38	16.7	66.67	100.0	29	-7.47	31.05	-83.3	0.00	33.3
	Week 83	25	77.33	20.91	33.3	83.33	100.0	24	0.00	26.01	-66.7	0.00	33.3
	Week 86	23	68.84	26.26	16.7	66.67	100.0	22	-10.61	30.23	-83.3	0.00	33.3
	Week 89	18	69.45	28.73	0.0	66.67	100.0	17	-15.69	32.53	-100.0	0.00	33.3
	Week 92	16	75.00	19.24	50.0	66.67	100.0	15	-12.22	21.33	-50.0	0.00	16.7
	Week 95	12	80.56	21.12	50.0	83.34	100.0	11	-9.09	20.23	-33.3	0.00	16.7
	Plat+Gem (N=152)												
	BASELINE	125	76.00	30.19	0.0	83.33	100.0						
	Week 1	109	71.56	29.25	0.0	83.33	100.0	106	-4.72	22.86	-83.3	0.00	83.3
	Week 2	114	67.69	29.36	0.0	66.67	100.0	105	-9.21	28.12	-100.0	0.00	100.0
	Week 3	116	67.96	29.99	0.0	66.67	100.0	107	-9.97	23.44	-83.3	0.00	66.7
	Week 4	114	70.47	28.31	0.0	66.67	100.0	103	-8.09	24.90	-66.7	0.00	100.0
	Week 5	117	67.81	28.26	0.0	66.67	100.0	106	-9.90	26.40	-83.3	0.00	100.0
	Week 6	113	67.99	29.89	0.0	66.67	100.0	102	-9.15	29.91	-100.0	0.00	100.0
	Week 7	113	69.17	29.06	0.0	66.67	100.0	103	-7.93	30.86	-100.0	0.00	100.0
	Week 8	110	66.52	28.96	0.0	66.67	100.0	101	-10.89	30.41	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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Table 302.1.3002.11.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	107	66.04	29.84	0.0	66.67	100.0	95	-11.58	29.88	-100.0	0.00	100.0
	Week 10	109	68.04	26.56	0.0	66.67	100.0	100	-10.00	28.13	-66.7	-16.66	100.0
	Week 11	96	67.54	28.96	0.0	66.67	100.0	88	-9.47	28.45	-66.7	0.00	100.0
	Week 12	98	67.01	28.92	0.0	66.67	100.0	88	-10.04	31.00	-83.3	0.00	100.0
	Week 14	98	66.16	28.26	0.0	66.67	100.0	87	-10.54	30.30	-83.3	-16.66	100.0
	Week 17	92	66.12	29.49	0.0	66.67	100.0	83	-14.46	33.61	-100.0	-16.66	100.0
	Week 20	84	71.43	26.58	0.0	66.67	100.0	75	-7.78	32.46	-83.3	0.00	100.0
	Week 23	73	73.06	26.00	16.7	66.67	100.0	66	-8.33	26.68	-66.7	0.00	66.7
	Week 26	66	70.45	28.46	0.0	66.67	100.0	61	-8.74	31.27	-100.0	0.00	66.7
	Week 29	64	72.14	27.55	0.0	66.67	100.0	59	-9.04	34.79	-100.0	0.00	66.7
	Week 32	54	72.53	29.52	0.0	83.33	100.0	49	-8.50	32.65	-100.0	0.00	66.7
	Week 35	54	70.06	24.74	16.7	66.67	100.0	48	-10.42	33.62	-66.7	-8.33	66.7
	Week 38	47	72.70	29.58	0.0	66.67	100.0	42	-9.52	34.36	-100.0	0.00	66.7
	Week 41	45	67.41	31.97	0.0	66.67	100.0	40	-17.08	34.49	-100.0	-16.66	66.7
	Week 44	41	61.79	32.97	0.0	66.67	100.0	36	-17.59	33.56	-66.7	-16.67	66.7
	Week 47	35	66.19	33.70	0.0	66.67	100.0	31	-13.44	36.37	-83.3	0.00	66.7
	Week 50	29	67.24	28.69	16.7	66.67	100.0	24	-11.81	30.88	-66.7	0.00	66.7
	Week 53	25	72.67	28.41	0.0	66.67	100.0	22	-6.06	34.33	-66.7	0.00	66.7
	Week 56	26	66.67	29.82	0.0	66.67	100.0	25	-6.67	33.68	-66.7	0.00	66.7
	Week 59	20	65.00	30.54	0.0	66.67	100.0	18	-4.63	31.73	-66.7	0.00	66.7
	Week 62	17	65.69	24.63	16.7	66.67	100.0	17	-2.94	36.44	-66.7	0.00	66.7
	Week 65	15	64.45	27.36	16.7	66.67	100.0	14	-16.67	26.15	-66.7	-8.33	33.3
	Week 68	11	65.15	32.02	0.0	66.67	100.0	11	-18.18	33.71	-100.0	-16.66	33.3
	Week 71	12	62.50	32.66	0.0	66.67	100.0	12	-18.05	35.15	-100.0	-8.34	33.3
	Week 74	10	73.33	26.29	33.3	66.67	100.0	10	-16.67	17.57	-33.3	-16.67	0.0
	Week 77	10	78.34	27.27	16.7	83.34	100.0	10	-5.00	45.85	-83.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
< 65 years	EV+Pembro (N= 39)												
	BASELINE	32	69.79	31.80	0.0	66.67	100.0						
	Week 1	27	70.99	27.96	0.0	66.67	100.0	26	-1.92	19.05	-50.0	0.00	33.3
	Week 2	30	72.22	23.30	16.7	66.67	100.0	29	-1.15	25.56	-50.0	0.00	66.7
	Week 3	31	70.97	26.16	0.0	66.67	100.0	29	-1.72	28.29	-50.0	0.00	66.7
	Week 4	30	74.45	23.46	0.0	66.67	100.0	27	-1.85	29.36	-66.7	0.00	66.7
	Week 5	28	76.19	21.96	33.3	83.33	100.0	26	2.56	27.36	-66.7	0.00	50.0
	Week 6	29	79.89	20.60	33.3	83.33	100.0	26	6.41	26.28	-50.0	0.00	66.7
	Week 7	30	79.45	19.91	33.3	83.33	100.0	26	5.77	24.01	-33.3	0.00	50.0
	Week 8	30	78.89	18.53	50.0	66.67	100.0	26	4.49	24.75	-33.3	0.00	66.7
	Week 9	28	73.81	21.00	33.3	66.67	100.0	27	1.85	34.07	-66.7	0.00	100.0
	Week 10	26	78.85	24.29	0.0	75.00	100.0	23	2.17	28.56	-50.0	0.00	66.7
	Week 11	28	76.79	24.15	16.7	75.00	100.0	25	2.00	23.73	-33.3	0.00	50.0
	Week 12	28	75.60	24.21	0.0	66.67	100.0	25	-0.67	27.42	-66.7	0.00	50.0
	Week 14	26	79.49	17.83	33.3	75.00	100.0	23	6.52	23.96	-33.3	0.00	50.0
	Week 17	28	72.62	19.36	33.3	66.67	100.0	24	-2.08	28.79	-50.0	0.00	33.3
	Week 20	27	74.07	21.35	33.3	66.67	100.0	24	0.70	29.27	-50.0	0.00	66.7
	Week 23	26	75.64	17.15	33.3	66.67	100.0	23	-2.17	29.86	-33.3	0.00	50.0
	Week 26	24	75.00	15.54	50.0	66.67	100.0	22	-1.51	31.25	-50.0	0.00	50.0
	Week 29	25	72.00	18.46	33.3	66.67	100.0	23	-7.25	33.64	-66.7	0.00	50.0
	Week 32	25	69.33	20.79	33.3	66.67	100.0	23	-5.07	22.72	-33.3	0.00	33.3
	Week 35	24	70.14	15.52	50.0	66.67	100.0	22	-5.30	30.60	-50.0	0.00	50.0
	Week 38	23	72.47	11.90	66.7	66.67	100.0	22	-4.54	23.67	-33.3	0.00	33.3
	Week 41	25	70.67	17.53	33.3	66.67	100.0	23	-5.07	31.15	-66.7	0.00	50.0
	Week 44	22	69.70	15.12	33.3	66.67	100.0	20	-7.50	27.82	-50.0	-8.33	33.3
	Week 47	20	69.17	21.81	16.7	66.67	100.0	18	-7.41	31.94	-83.3	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	19	71.93	12.49	50.0	66.67	100.0	17	-4.90	27.49	-50.0	0.00	33.3
	Week 53	20	70.00	18.42	33.3	66.67	100.0	18	-6.48	26.90	-50.0	0.00	33.3
	Week 56	17	74.51	22.14	16.7	66.67	100.0	15	2.22	25.87	-50.0	0.00	33.3
	Week 59	17	64.71	20.31	33.3	66.67	100.0	15	-4.44	27.79	-50.0	0.00	33.3
	Week 62	15	72.22	19.59	33.3	66.67	100.0	14	0.00	22.65	-33.3	0.00	33.3
	Week 65	14	65.48	22.14	33.3	66.67	100.0	13	-7.69	24.17	-33.3	-16.67	33.3
	Week 68	11	68.18	17.41	50.0	66.67	100.0	10	-1.66	22.84	-33.3	0.00	33.3
	Week 71	13	70.51	24.68	33.3	66.67	100.0	12	1.39	24.06	-33.3	0.00	33.3
	Week 74	14	65.48	17.86	33.3	66.67	100.0	13	-8.97	31.64	-66.7	-16.67	33.3
	Week 77	14	67.86	24.86	33.3	66.67	100.0	13	-8.97	30.14	-66.7	0.00	33.3
	Week 80	14	65.48	25.71	16.7	66.67	100.0	13	-15.38	32.96	-83.3	0.00	33.3
	Week 83	12	68.06	18.06	50.0	66.67	100.0	11	-6.06	27.16	-50.0	0.00	33.3
	Plat+Gem (N= 29)												
	BASELINE	22	78.79	29.63	16.7	100.00	100.0						
	Week 1	21	73.81	23.90	16.7	83.33	100.0	20	-5.83	19.70	-50.0	0.00	33.3
	Week 2	24	74.31	30.68	0.0	83.33	100.0	20	-4.17	15.17	-33.3	0.00	33.3
	Week 3	23	73.19	29.19	0.0	83.33	100.0	20	-4.17	18.63	-33.3	0.00	33.3
	Week 4	23	74.64	30.51	0.0	83.33	100.0	19	-6.14	15.92	-33.3	0.00	33.3
	Week 5	25	70.67	30.15	0.0	66.67	100.0	20	-5.00	19.57	-50.0	0.00	33.3
	Week 6	22	71.97	30.60	0.0	83.33	100.0	18	-8.33	23.74	-66.7	0.00	33.3
	Week 7	24	69.44	29.76	0.0	66.67	100.0	21	-7.14	26.65	-66.7	0.00	50.0
	Week 8	21	74.60	27.19	0.0	66.67	100.0	19	-7.89	25.68	-66.7	0.00	33.3
	Week 9	20	65.00	29.57	0.0	66.67	100.0	17	-15.69	23.18	-66.7	-16.67	33.3
	Week 10	21	69.05	30.86	0.0	66.67	100.0	18	-14.81	24.18	-66.7	0.00	33.3
	Week 11	20	75.00	30.83	0.0	75.00	100.0	17	-3.92	22.46	-33.3	0.00	33.3
	Week 12	21	75.40	26.15	33.3	83.33	100.0	17	-2.94	24.46	-33.3	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 14	22	65.15	40.14	0.0	75.00	100.0	18	-12.96	43.37	-100.0	0.00	66.7
	Week 17	20	71.67	33.81	0.0	83.33	100.0	17	-9.80	34.89	-83.3	0.00	50.0
	Week 20	18	67.59	32.58	0.0	75.00	100.0	15	-10.00	28.03	-66.7	0.00	50.0
	Week 23	18	79.63	25.28	33.3	91.67	100.0	16	-4.17	19.72	-33.3	0.00	50.0
	Week 26	16	80.21	27.36	0.0	91.67	100.0	14	-3.57	23.73	-33.3	0.00	66.7
	Week 29	15	80.00	25.35	16.7	100.00	100.0	13	-3.85	25.60	-33.3	0.00	66.7
	Week 32	15	77.78	31.91	0.0	83.33	100.0	13	-5.13	29.17	-50.0	0.00	66.7
	Week 35	15	73.33	25.82	33.3	66.67	100.0	13	-12.82	32.03	-66.7	0.00	66.7
	Week 38	14	72.62	32.43	0.0	75.00	100.0	12	-9.72	31.35	-50.0	0.00	66.7
	Week 41	11	63.64	30.57	16.7	66.67	100.0	9	-24.07	25.15	-66.7	-33.33	0.0
	Week 44	11	63.64	35.60	0.0	66.67	100.0	9	-24.07	27.78	-66.7	-16.67	0.0
	Week 47	11	63.64	35.61	0.0	66.67	100.0	9	-14.82	42.04	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>= 65 years	EV+Pembro (N=163)												
	BASELINE	128	72.66	27.81	0.0	66.67	100.0						
	Week 1	114	69.88	27.68	0.0	66.67	100.0	103	-3.40	19.01	-50.0	0.00	33.3
	Week 2	120	65.56	30.76	0.0	66.67	100.0	104	-7.05	20.34	-83.3	0.00	33.3
	Week 3	108	67.28	30.56	0.0	66.67	100.0	93	-3.76	23.84	-66.7	0.00	50.0
	Week 4	115	67.97	28.88	0.0	66.67	100.0	102	-3.76	23.56	-66.7	0.00	66.7
	Week 5	109	67.58	29.64	0.0	66.67	100.0	95	-2.81	25.46	-83.3	0.00	66.7
	Week 6	117	68.23	29.36	0.0	66.67	100.0	98	-3.57	28.54	-83.3	0.00	66.7
	Week 7	117	70.80	27.59	0.0	66.67	100.0	98	-1.70	30.22	-83.3	0.00	66.7
	Week 8	117	67.52	29.75	0.0	66.67	100.0	98	-3.91	31.46	-100.0	0.00	66.7
	Week 9	114	68.57	28.11	0.0	66.67	100.0	94	-2.66	28.95	-100.0	0.00	66.7
	Week 10	113	71.98	27.12	0.0	66.67	100.0	95	1.05	30.83	-100.0	0.00	66.7
	Week 11	109	72.17	26.16	0.0	66.67	100.0	90	-0.37	31.60	-100.0	0.00	66.7
	Week 12	114	70.03	28.58	0.0	66.67	100.0	94	-2.31	29.59	-66.7	0.00	66.7
	Week 14	113	71.09	27.46	0.0	66.67	100.0	93	-2.15	30.52	-66.7	0.00	66.7
	Week 17	104	70.03	25.16	0.0	66.67	100.0	87	-3.64	31.07	-66.7	0.00	66.7
	Week 20	93	75.63	22.99	0.0	66.67	100.0	79	0.21	29.30	-66.7	0.00	66.7
	Week 23	91	73.08	22.87	0.0	66.67	100.0	74	-2.25	28.98	-66.7	0.00	66.7
	Week 26	88	72.92	24.67	0.0	66.67	100.0	72	0.00	25.79	-66.7	0.00	66.7
	Week 29	82	68.50	26.96	0.0	66.67	100.0	70	-9.05	32.69	-100.0	0.00	66.7
	Week 32	77	73.59	23.31	0.0	66.67	100.0	65	-1.79	31.20	-100.0	0.00	83.3
	Week 35	74	70.72	25.41	0.0	66.67	100.0	64	-6.51	31.09	-100.0	0.00	66.7
	Week 38	74	68.24	25.90	0.0	66.67	100.0	64	-6.77	30.53	-100.0	0.00	66.7
	Week 41	70	70.72	24.32	0.0	66.67	100.0	61	-5.46	28.34	-83.3	0.00	66.7
	Week 44	64	66.67	25.72	0.0	66.67	100.0	54	-10.49	28.09	-66.7	0.00	66.7
	Week 47	59	68.64	26.46	0.0	66.67	100.0	52	-5.77	25.75	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	55	65.15	27.08	0.0	66.67	100.0	47	-10.28	29.60	-100.0	0.00	66.7
	Week 53	54	64.81	28.16	0.0	66.67	100.0	45	-8.15	29.65	-83.3	0.00	33.3
	Week 56	55	64.55	25.06	0.0	66.67	100.0	46	-6.52	24.72	-66.7	0.00	33.3
	Week 59	52	65.06	25.62	0.0	66.67	100.0	42	-6.75	30.15	-66.7	0.00	66.7
	Week 62	47	64.54	26.15	0.0	66.67	100.0	38	-7.02	28.64	-66.7	0.00	66.7
	Week 65	29	66.09	22.04	33.3	66.67	100.0	27	-10.49	30.37	-66.7	0.00	66.7
	Week 68	35	65.71	25.55	0.0	66.67	100.0	32	-10.94	28.90	-83.3	-8.34	66.7
	Week 71	29	69.54	26.75	0.0	66.67	100.0	26	-2.56	30.80	-66.7	0.00	66.7
	Week 74	24	72.22	26.77	16.7	66.67	100.0	22	-5.30	33.49	-66.7	0.00	66.7
	Week 77	23	73.19	21.75	33.3	66.67	100.0	20	-0.83	32.21	-66.7	0.00	66.7
	Week 80	22	68.18	23.52	33.3	66.67	100.0	21	-3.97	34.12	-66.7	0.00	66.7
	Week 83	18	77.78	22.87	33.3	83.33	100.0	18	1.85	32.28	-66.7	0.00	66.7
	Week 86	18	65.74	31.56	0.0	66.67	100.0	18	-12.96	36.41	-100.0	0.00	33.3
	Week 89	12	73.61	29.69	0.0	66.67	100.0	12	-9.72	34.42	-100.0	0.00	33.3
	Week 92	10	80.00	18.92	50.0	75.00	100.0	10	-10.00	19.56	-50.0	0.00	16.7
	Plat+Gem (N=173)												
	BASELINE	143	72.73	31.18	0.0	83.33	100.0						
	Week 1	123	68.83	30.85	0.0	66.67	100.0	119	-5.04	22.08	-83.3	0.00	83.3
	Week 2	123	64.36	29.59	0.0	66.67	100.0	115	-11.01	29.11	-100.0	0.00	100.0
	Week 3	126	65.21	31.48	0.0	66.67	100.0	116	-11.21	24.15	-83.3	0.00	66.7
	Week 4	127	68.50	29.04	0.0	66.67	100.0	116	-6.61	26.36	-66.7	0.00	100.0
	Week 5	128	64.97	29.42	0.0	66.67	100.0	118	-10.73	27.78	-83.3	-16.66	100.0
	Week 6	123	66.53	30.22	0.0	66.67	100.0	113	-8.26	30.55	-100.0	0.00	100.0
	Week 7	124	65.86	30.34	0.0	66.67	100.0	113	-8.55	30.63	-100.0	0.00	100.0
	Week 8	124	63.17	28.77	0.0	66.67	100.0	113	-10.77	31.25	-100.0	0.00	66.7
	Week 9	121	64.74	29.44	0.0	66.67	100.0	108	-9.41	32.09	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	121	65.98	28.50	0.0	66.67	100.0	112	-8.48	30.84	-83.3	-8.33	100.0
	Week 11	106	64.15	29.26	0.0	66.67	100.0	97	-10.31	29.90	-83.3	-16.66	100.0
	Week 12	109	63.00	29.34	0.0	66.67	100.0	98	-11.22	30.06	-83.3	-16.66	100.0
	Week 14	103	63.43	27.62	0.0	66.67	100.0	91	-10.62	28.92	-66.7	-16.66	100.0
	Week 17	100	64.17	28.66	0.0	66.67	100.0	89	-13.30	33.07	-100.0	-16.67	100.0
	Week 20	86	70.16	27.07	0.0	66.67	100.0	76	-6.80	31.17	-83.3	0.00	100.0
	Week 23	70	71.19	26.45	16.7	66.67	100.0	64	-8.33	26.06	-66.7	0.00	66.7
	Week 26	65	67.69	28.85	0.0	66.67	100.0	61	-9.56	30.35	-100.0	0.00	66.7
	Week 29	62	69.35	28.98	0.0	66.67	100.0	58	-12.36	36.35	-100.0	0.00	66.7
	Week 32	48	69.44	29.84	0.0	66.67	100.0	45	-12.22	34.71	-100.0	-16.66	66.7
	Week 35	47	69.86	24.48	16.7	66.67	100.0	43	-9.69	32.37	-66.7	0.00	66.7
	Week 38	42	73.41	28.05	0.0	75.00	100.0	38	-10.09	33.46	-100.0	0.00	66.7
	Week 41	41	70.32	31.52	0.0	83.33	100.0	38	-13.16	34.48	-100.0	-8.33	66.7
	Week 44	38	62.28	30.68	0.0	66.67	100.0	35	-16.19	32.96	-66.7	-16.66	66.7
	Week 47	32	66.67	32.52	0.0	66.67	100.0	30	-15.00	32.27	-83.3	-16.67	66.7
	Week 50	29	67.24	30.37	0.0	66.67	100.0	26	-16.03	26.87	-66.7	-8.34	66.7
	Week 53	25	69.33	27.92	16.7	66.67	100.0	24	-14.58	32.72	-83.3	-16.67	66.7
	Week 56	26	63.46	29.45	0.0	66.67	100.0	26	-14.74	33.77	-66.7	-8.33	66.7
	Week 59	20	69.17	28.24	33.3	66.67	100.0	20	-10.00	31.72	-66.7	0.00	66.7
	Week 62	19	63.16	28.10	0.0	66.67	100.0	19	-11.40	39.70	-100.0	-16.66	66.7
	Week 65	16	66.67	26.53	16.7	66.67	100.0	16	-16.67	24.34	-66.7	-16.66	33.3
	Week 68	13	66.67	29.66	0.0	66.67	100.0	13	-17.95	30.78	-100.0	-16.66	33.3
	Week 71	13	64.10	31.80	0.0	66.67	100.0	13	-17.95	33.65	-100.0	-16.67	33.3
	Week 74	11	74.24	25.13	33.3	66.67	100.0	11	-16.67	16.67	-33.3	-16.67	0.0
	Week 77	10	78.34	27.27	16.7	83.34	100.0	10	-11.67	38.53	-83.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Europe	EV+Pembro (N= 74)												
	BASELINE	53	71.38	27.81	0.0	66.67	100.0						
	Week 1	48	67.71	29.85	0.0	66.67	100.0	42	-3.57	20.34	-50.0	0.00	33.3
	Week 2	53	70.75	29.76	0.0	66.67	100.0	44	-2.27	19.88	-50.0	0.00	33.3
	Week 3	50	63.33	28.77	0.0	66.67	100.0	41	-4.07	28.08	-66.7	0.00	50.0
	Week 4	51	66.01	27.07	0.0	66.67	100.0	44	-6.06	24.67	-50.0	0.00	50.0
	Week 5	46	62.32	29.07	0.0	66.67	100.0	41	-7.72	28.16	-83.3	0.00	50.0
	Week 6	50	66.67	29.35	0.0	66.67	100.0	39	-5.98	33.44	-66.7	0.00	66.7
	Week 7	50	71.00	24.70	16.7	66.67	100.0	39	-5.13	33.15	-83.3	0.00	50.0
	Week 8	51	72.22	26.60	0.0	66.67	100.0	41	-1.63	32.02	-66.7	0.00	66.7
	Week 9	47	68.80	23.98	16.7	66.67	100.0	37	-0.90	31.41	-50.0	0.00	100.0
	Week 10	45	71.48	26.02	0.0	66.67	100.0	34	1.47	30.25	-66.7	0.00	66.7
	Week 11	48	72.22	21.01	16.7	66.67	100.0	37	-1.35	25.27	-50.0	0.00	50.0
	Week 12	51	69.28	27.36	0.0	66.67	100.0	39	-5.56	30.91	-66.7	0.00	66.7
	Week 14	50	75.33	20.55	16.7	66.67	100.0	38	1.75	29.20	-66.7	0.00	66.7
	Week 17	43	70.54	23.24	0.0	66.67	100.0	33	-3.03	29.60	-66.7	0.00	66.7
	Week 20	41	74.80	22.71	33.3	66.67	100.0	33	0.00	31.18	-66.7	0.00	66.7
	Week 23	41	71.55	21.81	0.0	66.67	100.0	30	-3.33	31.38	-66.7	0.00	66.7
	Week 26	37	73.88	22.41	16.7	66.67	100.0	28	2.98	27.61	-33.3	0.00	50.0
	Week 29	37	72.07	26.66	0.0	66.67	100.0	29	-6.90	34.07	-100.0	0.00	50.0
	Week 32	34	71.08	21.05	33.3	66.67	100.0	26	-1.92	23.72	-33.3	0.00	50.0
	Week 35	31	72.58	19.03	33.3	66.67	100.0	25	-4.00	26.48	-50.0	0.00	50.0
	Week 38	31	66.13	22.15	0.0	66.67	100.0	26	-10.90	24.47	-66.7	0.00	16.7
	Week 41	28	68.45	21.91	0.0	66.67	100.0	23	-5.07	27.26	-66.7	0.00	50.0
	Week 44	27	69.14	24.77	0.0	66.67	100.0	22	-9.85	27.54	-66.7	-16.67	50.0
	Week 47	25	66.00	23.80	0.0	66.67	100.0	21	-11.11	19.24	-33.3	-16.66	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	26	64.74	27.62	0.0	66.67	100.0	23	-14.49	30.28	-100.0	-16.67	33.3
	Week 53	26	60.90	26.64	0.0	66.67	100.0	21	-14.29	30.86	-83.3	0.00	16.7
	Week 56	25	62.00	26.58	0.0	66.67	100.0	21	-7.14	27.17	-66.7	0.00	33.3
	Week 59	23	69.57	21.70	33.3	66.67	100.0	18	-3.70	29.46	-66.7	0.00	33.3
	Week 62	20	63.33	26.82	0.0	66.67	100.0	17	-4.90	27.49	-33.3	0.00	50.0
	Week 65	13	65.39	20.93	33.3	66.67	100.0	13	-12.82	21.68	-33.3	-16.67	33.3
	Week 68	15	62.22	25.56	0.0	66.67	100.0	15	-14.44	22.59	-50.0	-16.67	33.3
	Week 71	13	64.10	28.74	0.0	66.67	100.0	13	-7.69	26.01	-50.0	0.00	33.3
	Week 74	10	58.34	23.90	16.7	66.67	100.0	9	-18.52	17.57	-33.3	-16.67	16.7
	Plat+Gem (N= 95)												
	BASELINE	75	71.33	32.14	0.0	83.33	100.0						
	Week 1	71	69.25	31.33	0.0	83.33	100.0	69	-1.93	20.12	-33.3	0.00	83.3
	Week 2	71	66.90	29.61	0.0	66.67	100.0	63	-4.76	27.50	-83.3	0.00	100.0
	Week 3	72	65.28	33.89	0.0	66.67	100.0	65	-6.67	22.59	-66.7	0.00	66.7
	Week 4	69	67.87	30.69	0.0	66.67	100.0	62	-3.76	25.50	-66.7	0.00	100.0
	Week 5	71	66.67	32.24	0.0	66.67	100.0	63	-3.70	27.34	-50.0	0.00	100.0
	Week 6	69	67.63	31.56	0.0	66.67	100.0	61	-4.10	32.58	-100.0	0.00	100.0
	Week 7	69	66.43	30.58	0.0	66.67	100.0	62	-5.38	31.47	-83.3	0.00	100.0
	Week 8	67	66.42	28.65	0.0	66.67	100.0	60	-4.72	28.64	-50.0	0.00	66.7
	Week 9	66	65.66	31.06	0.0	66.67	100.0	57	-4.97	34.21	-100.0	0.00	100.0
	Week 10	70	67.14	28.65	0.0	66.67	100.0	63	-4.23	32.79	-66.7	0.00	100.0
	Week 11	63	64.29	29.91	0.0	66.67	100.0	56	-5.36	32.12	-66.7	0.00	100.0
	Week 12	66	64.14	29.56	0.0	66.67	100.0	56	-8.63	34.52	-83.3	-8.33	100.0
	Week 14	66	62.63	30.25	0.0	66.67	100.0	56	-9.23	34.07	-100.0	-16.66	100.0
	Week 17	61	65.30	31.08	0.0	66.67	100.0	53	-8.80	35.14	-100.0	0.00	100.0
	Week 20	54	69.14	28.85	0.0	66.67	100.0	48	-2.08	32.91	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 23	44	69.70	28.59	16.7	66.67	100.0	40	-5.00	25.93	-66.7	0.00	66.7
	Week 26	42	65.08	31.84	0.0	66.67	100.0	39	-5.98	31.64	-100.0	0.00	66.7
	Week 29	39	71.37	27.56	16.7	66.67	100.0	36	-1.39	30.44	-66.7	0.00	66.7
	Week 32	32	61.46	34.76	0.0	66.67	100.0	30	-11.11	40.90	-100.0	-8.33	66.7
	Week 35	32	66.67	26.10	16.7	66.67	100.0	30	-8.33	32.09	-66.7	0.00	66.7
	Week 38	28	67.86	33.31	0.0	66.67	100.0	26	-11.54	33.92	-100.0	0.00	66.7
	Week 41	25	62.67	35.12	0.0	66.67	100.0	23	-10.14	34.36	-83.3	0.00	66.7
	Week 44	24	54.86	36.28	0.0	50.00	100.0	22	-17.42	35.81	-66.7	0.00	66.7
	Week 47	22	59.85	34.76	0.0	66.67	100.0	20	-10.83	33.01	-66.7	-16.67	66.7
	Week 50	17	53.92	32.56	0.0	33.33	100.0	15	-17.78	33.02	-66.7	-16.67	66.7
	Week 53	15	62.22	33.01	0.0	66.67	100.0	14	-10.71	31.08	-66.7	-8.33	66.7
	Week 56	15	53.33	30.99	0.0	66.67	100.0	14	-14.28	35.12	-66.7	-16.67	66.7
	Week 59	11	59.09	32.80	0.0	66.67	100.0	10	-10.00	34.43	-66.7	-8.33	66.7
	Week 62	11	59.09	26.21	16.7	66.67	100.0	11	-12.12	37.34	-66.7	-16.67	66.7
	Week 65	10	56.67	26.29	16.7	66.67	100.0	10	-18.33	28.82	-66.7	-16.67	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
North America	EV+Pembro (N= 46)												
	BASELINE	33	70.71	30.06	0.0	66.67	100.0						
	Week 1	30	65.00	31.97	0.0	66.67	100.0	27	-6.79	20.29	-33.3	0.00	33.3
	Week 2	30	62.22	29.99	0.0	66.67	100.0	26	-12.82	24.63	-83.3	-8.33	33.3
	Week 3	25	75.33	25.96	16.7	66.67	100.0	21	-2.38	20.61	-50.0	0.00	33.3
	Week 4	30	67.22	27.85	0.0	66.67	100.0	24	-4.86	26.23	-66.7	0.00	66.7
	Week 5	29	70.11	29.00	0.0	66.67	100.0	21	0.00	22.97	-66.7	0.00	50.0
	Week 6	31	66.67	28.22	33.3	66.67	100.0	23	-5.07	24.33	-66.7	0.00	33.3
	Week 7	33	68.18	26.47	16.7	66.67	100.0	23	-2.17	22.08	-50.0	0.00	50.0
	Week 8	29	66.67	26.35	33.3	66.67	100.0	20	3.33	30.87	-33.3	0.00	66.7
	Week 9	27	72.22	22.17	33.3	66.67	100.0	21	3.18	29.17	-50.0	0.00	66.7
	Week 10	29	77.01	21.09	33.3	66.67	100.0	23	8.70	25.56	-33.3	0.00	66.7
	Week 11	28	73.22	28.09	0.0	66.67	100.0	21	4.76	25.35	-33.3	0.00	66.7
	Week 12	29	74.14	25.81	0.0	66.67	100.0	22	6.06	24.96	-33.3	0.00	66.7
	Week 14	28	73.81	26.23	0.0	66.67	100.0	21	3.97	25.22	-50.0	0.00	66.7
	Week 17	29	68.97	25.09	16.7	66.67	100.0	23	-2.90	30.01	-66.7	0.00	66.7
	Week 20	23	76.81	26.94	0.0	83.33	100.0	18	9.26	32.45	-66.7	8.34	66.7
	Week 23	22	75.00	26.10	0.0	75.00	100.0	17	1.96	29.39	-50.0	0.00	66.7
	Week 26	21	71.43	25.90	0.0	66.67	100.0	16	3.13	29.33	-33.3	0.00	66.7
	Week 29	20	65.83	30.34	0.0	66.67	100.0	17	-9.80	38.22	-100.0	0.00	66.7
	Week 32	21	73.81	28.17	0.0	83.33	100.0	18	0.93	42.19	-100.0	0.00	83.3
	Week 35	22	67.43	26.96	0.0	66.67	100.0	19	-7.02	36.14	-100.0	0.00	66.7
	Week 38	20	68.33	30.54	0.0	66.67	100.0	17	-3.92	37.05	-100.0	0.00	66.7
	Week 41	21	74.60	20.83	16.7	66.67	100.0	17	-1.96	31.67	-83.3	0.00	66.7
	Week 44	16	70.84	17.74	33.3	66.67	100.0	12	-1.39	26.07	-33.3	0.00	66.7
	Week 47	16	73.96	27.19	16.7	66.67	100.0	13	1.28	28.43	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	16	68.75	25.73	0.0	66.67	100.0	11	4.55	30.81	-33.3	0.00	66.7
	Week 53	15	71.11	25.56	33.3	66.67	100.0	11	4.55	18.40	-33.3	0.00	33.3
	Week 56	17	70.59	25.37	33.3	66.67	100.0	12	5.56	17.88	-16.7	0.00	33.3
	Week 59	17	62.74	26.70	0.0	66.67	100.0	12	4.17	26.71	-33.3	0.00	66.7
	Week 62	14	67.86	26.53	33.3	66.67	100.0	9	3.70	26.06	-33.3	0.00	66.7
	Week 68	11	74.24	21.56	33.3	66.67	100.0	8	4.17	30.54	-33.3	0.00	66.7
	Week 71	11	72.73	26.11	33.3	66.67	100.0	8	6.25	35.57	-33.3	0.00	66.7
	Plat+Gem (N= 34)												
	BASELINE	27	69.14	35.42	0.0	83.33	100.0						
	Week 1	19	73.68	22.44	33.3	66.67	100.0	17	-1.96	17.56	-50.0	0.00	16.7
	Week 2	20	74.17	25.06	16.7	83.33	100.0	18	-2.78	20.81	-50.0	0.00	33.3
	Week 3	20	70.00	28.92	0.0	75.00	100.0	17	-10.78	17.62	-33.3	-16.67	33.3
	Week 4	23	78.26	24.84	16.7	83.33	100.0	19	-2.63	19.45	-33.3	0.00	50.0
	Week 5	25	65.33	28.84	0.0	66.67	100.0	22	-14.39	27.36	-66.7	-16.66	50.0
	Week 6	20	70.00	31.34	0.0	83.33	100.0	17	-9.80	32.84	-83.3	0.00	50.0
	Week 7	23	68.12	35.86	0.0	83.33	100.0	20	-10.83	34.74	-100.0	-8.34	50.0
	Week 8	24	59.72	31.82	0.0	66.67	100.0	22	-17.42	39.33	-100.0	-16.67	33.3
	Week 9	23	65.22	25.08	16.7	66.67	100.0	19	-14.91	30.38	-66.7	-16.66	50.0
	Week 10	20	66.67	25.36	16.7	66.67	100.0	18	-14.81	30.19	-66.7	-16.66	50.0
	Week 11	18	74.08	23.72	0.0	66.67	100.0	16	-11.46	24.88	-33.3	-16.67	33.3
	Week 12	17	62.75	29.19	0.0	66.67	100.0	16	-13.54	28.03	-66.7	-16.67	50.0
	Week 14	16	69.79	28.69	16.7	66.67	100.0	14	-10.71	36.17	-83.3	-8.33	66.7
	Week 17	19	62.28	27.13	16.7	66.67	100.0	17	-21.57	34.74	-66.7	-33.33	50.0
	Week 20	16	73.96	26.51	16.7	75.00	100.0	13	-11.54	34.95	-50.0	-16.67	50.0
	Week 23	15	74.44	24.29	16.7	83.33	100.0	13	-8.97	32.36	-50.0	-16.67	50.0
	Week 26	13	78.21	20.84	33.3	66.67	100.0	12	-9.72	35.15	-66.7	-8.33	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 29	14	67.86	37.25	0.0	75.00	100.0	13	-23.08	49.32	-100.0	-33.33	66.7
	Week 32	11	86.36	20.84	33.3	100.00	100.0	10	-8.33	33.57	-66.7	-8.34	66.7
	Week 35	13	76.92	19.88	50.0	66.67	100.0	11	-9.09	37.54	-50.0	-33.33	66.7
	Week 38	10	80.00	24.60	33.3	91.67	100.0	9	-14.81	38.59	-66.7	-16.67	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Rest of World	EV+Pembro (N= 82)												
	BASELINE	74	73.20	28.78	0.0	66.67	100.0						
	Week 1	63	74.34	23.15	16.7	66.67	100.0	60	-1.11	17.32	-33.3	0.00	33.3
	Week 2	67	65.92	29.08	0.0	66.67	100.0	63	-5.29	21.13	-66.7	0.00	66.7
	Week 3	64	69.01	31.27	0.0	66.67	100.0	60	-3.06	24.26	-66.7	0.00	66.7
	Week 4	64	72.92	28.56	0.0	66.67	100.0	61	-0.82	24.42	-66.7	0.00	66.7
	Week 5	62	74.19	26.94	0.0	66.67	100.0	59	1.98	24.78	-66.7	0.00	66.7
	Week 6	65	75.39	26.86	16.7	66.67	100.0	62	2.69	25.82	-83.3	0.00	66.7
	Week 7	64	76.04	27.52	0.0	83.33	100.0	62	3.76	28.54	-66.7	0.00	66.7
	Week 8	67	69.40	30.23	0.0	66.67	100.0	63	-4.23	29.17	-100.0	0.00	66.7
	Week 9	68	69.12	30.51	0.0	66.67	100.0	63	-3.70	29.85	-100.0	0.00	66.7
	Week 10	65	72.82	29.40	0.0	66.67	100.0	61	-1.64	31.87	-100.0	0.00	66.7
	Week 11	61	73.77	28.29	0.0	66.67	100.0	57	-0.58	34.35	-100.0	0.00	66.7
	Week 12	62	71.24	29.29	0.0	66.67	100.0	58	-2.59	29.09	-66.7	0.00	66.7
	Week 14	61	69.95	29.94	0.0	66.67	100.0	57	-3.51	31.14	-66.7	0.00	66.7
	Week 17	60	71.39	24.37	0.0	66.67	100.0	55	-3.64	31.70	-66.7	0.00	66.7
	Week 20	56	75.00	20.84	33.3	66.67	100.0	52	-2.56	26.48	-50.0	0.00	66.7
	Week 23	54	74.69	19.89	33.3	66.67	100.0	50	-3.00	27.91	-66.7	0.00	66.7
	Week 26	54	73.77	22.57	0.0	66.67	100.0	50	-3.33	26.08	-66.7	0.00	50.0
	Week 29	50	68.67	21.99	33.3	66.67	100.0	47	-9.22	30.46	-66.7	0.00	66.7
	Week 32	47	73.05	21.58	33.3	66.67	100.0	44	-4.54	26.01	-66.7	0.00	66.7
	Week 35	45	70.74	24.40	0.0	66.67	100.0	42	-7.14	31.27	-66.7	0.00	66.7
	Week 38	46	71.74	20.75	33.3	66.67	100.0	43	-4.26	27.96	-66.7	0.00	66.7
	Week 41	46	70.29	24.07	16.7	66.67	100.0	44	-6.82	29.27	-83.3	0.00	66.7
	Week 44	43	65.12	24.62	0.0	66.67	100.0	40	-12.08	28.74	-66.7	0.00	66.7
	Week 47	38	68.42	25.64	16.7	66.67	100.0	36	-6.02	30.64	-83.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	32	67.71	21.14	33.3	66.67	100.0	30	-9.44	26.51	-66.7	0.00	33.3
	Week 53	33	68.18	25.47	33.3	66.67	100.0	31	-7.53	29.45	-66.7	0.00	33.3
	Week 56	30	68.89	22.63	33.3	66.67	100.0	28	-6.55	25.80	-66.7	0.00	33.3
	Week 59	29	62.64	25.06	33.3	66.67	100.0	27	-12.35	29.81	-66.7	0.00	33.3
	Week 62	28	67.86	23.10	33.3	66.67	100.0	26	-8.33	27.59	-66.7	0.00	33.3
	Week 65	22	59.85	21.62	33.3	66.67	100.0	21	-14.28	29.01	-66.7	-16.66	33.3
	Week 68	20	65.00	23.51	16.7	66.67	100.0	19	-9.65	29.56	-83.3	0.00	33.3
	Week 71	18	72.22	24.25	33.3	66.67	100.0	17	0.00	27.64	-66.7	0.00	33.3
	Week 74	19	69.30	23.74	33.3	66.67	100.0	19	-7.89	37.01	-66.7	0.00	33.3
	Week 77	19	70.18	23.95	33.3	66.67	100.0	18	-4.63	34.68	-66.7	0.00	33.3
	Week 80	19	65.79	26.92	16.7	66.67	100.0	18	-8.33	36.72	-83.3	0.00	33.3
	Week 83	17	69.61	23.74	33.3	66.67	100.0	17	-4.90	32.69	-66.7	0.00	33.3
	Week 86	14	61.91	32.31	0.0	66.67	100.0	14	-16.67	39.77	-100.0	0.00	33.3
	Week 89	11	63.64	30.57	0.0	66.67	100.0	11	-21.21	36.58	-100.0	0.00	16.7
	Plat+Gem (N= 73)												
	BASELINE	63	78.04	27.24	0.0	83.33	100.0						
	Week 1	54	68.52	30.66	0.0	66.67	100.0	53	-10.38	24.07	-83.3	0.00	33.3
	Week 2	56	61.91	31.58	0.0	66.67	100.0	54	-18.52	27.79	-100.0	-16.67	33.3
	Week 3	57	66.67	28.70	0.0	66.67	100.0	54	-14.20	25.78	-83.3	-8.33	66.7
	Week 4	58	67.82	28.93	0.0	66.67	100.0	54	-11.11	26.10	-66.7	0.00	66.7
	Week 5	57	65.21	26.59	0.0	66.67	100.0	53	-15.41	24.64	-83.3	-16.66	33.3
	Week 6	56	66.07	28.60	0.0	66.67	100.0	53	-12.58	24.44	-66.7	-16.66	33.3
	Week 7	56	65.77	27.60	0.0	66.67	100.0	52	-10.90	26.17	-66.7	0.00	33.3
	Week 8	54	65.12	27.71	0.0	66.67	100.0	50	-14.00	27.43	-100.0	0.00	33.3
	Week 9	52	63.46	29.34	0.0	66.67	100.0	49	-14.62	26.71	-100.0	-16.66	33.3
	Week 10	52	65.39	30.58	0.0	66.67	100.0	49	-13.95	25.31	-83.3	-16.67	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	45	64.82	31.43	0.0	66.67	100.0	42	-13.89	25.48	-83.3	0.00	33.3
	Week 12	47	67.02	28.97	0.0	66.67	100.0	43	-10.47	22.13	-66.7	0.00	33.3
	Week 14	43	63.18	30.55	0.0	66.67	100.0	39	-13.67	26.18	-66.7	0.00	33.3
	Week 17	40	67.08	28.87	0.0	66.67	100.0	36	-14.35	29.32	-66.7	-8.33	50.0
	Week 20	34	68.63	27.76	0.0	66.67	100.0	30	-13.89	23.19	-83.3	0.00	16.7
	Week 23	29	77.01	23.74	33.3	83.33	100.0	27	-10.49	19.14	-66.7	0.00	16.7
	Week 26	26	74.36	26.34	0.0	66.67	100.0	24	-11.81	21.69	-66.7	0.00	16.7
	Week 29	24	73.61	25.02	0.0	66.67	100.0	22	-18.94	27.36	-100.0	-8.33	16.7
	Week 32	20	79.17	20.85	33.3	83.33	100.0	18	-11.11	17.15	-50.0	0.00	16.7
	Week 35	17	73.53	25.04	33.3	66.67	100.0	15	-15.56	29.19	-66.7	0.00	33.3
	Week 38	18	77.78	22.87	33.3	75.00	100.0	15	-4.44	27.79	-66.7	0.00	50.0
	Week 41	18	75.93	21.56	33.3	66.67	100.0	16	-14.58	28.46	-66.7	-8.33	50.0
	Week 44	16	69.79	25.25	33.3	66.67	100.0	14	-10.71	27.43	-66.7	-8.33	50.0
	Week 47	12	73.61	30.53	16.7	83.33	100.0	11	-18.18	26.30	-66.7	0.00	0.0
	Week 50	11	72.73	30.07	33.3	83.33	100.0	9	-12.96	23.24	-66.7	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	EV+Pembro (N=146)												
	BASELINE	119	72.97	28.62	0.0	66.67	100.0						
	Week 1	102	72.22	26.98	0.0	66.67	100.0	97	-3.26	20.07	-50.0	0.00	33.3
	Week 2	106	68.55	29.75	0.0	66.67	100.0	98	-6.29	23.51	-83.3	0.00	66.7
	Week 3	94	72.16	27.48	0.0	66.67	100.0	88	-1.52	25.73	-66.7	0.00	66.7
	Week 4	101	71.12	26.34	0.0	66.67	100.0	93	-3.05	26.12	-66.7	0.00	66.7
	Week 5	96	72.05	27.31	0.0	66.67	100.0	89	-1.50	27.37	-83.3	0.00	66.7
	Week 6	105	73.17	26.90	0.0	66.67	100.0	93	-0.36	28.23	-83.3	0.00	66.7
	Week 7	102	73.20	26.55	0.0	66.67	100.0	89	-0.94	29.77	-83.3	0.00	66.7
	Week 8	101	71.29	27.40	0.0	66.67	100.0	91	-2.93	30.49	-100.0	0.00	66.7
	Week 9	100	72.00	27.00	0.0	66.67	100.0	89	-0.56	30.92	-100.0	0.00	100.0
	Week 10	99	75.76	26.44	0.0	66.67	100.0	87	2.87	30.84	-100.0	0.00	66.7
	Week 11	95	74.74	26.39	0.0	66.67	100.0	84	-1.39	31.18	-100.0	0.00	66.7
	Week 12	99	71.89	29.22	0.0	66.67	100.0	87	-3.26	30.16	-66.7	0.00	66.7
	Week 14	95	74.21	26.16	0.0	83.33	100.0	84	-0.79	30.16	-66.7	0.00	66.7
	Week 17	97	70.96	22.86	0.0	66.67	100.0	84	-4.56	30.10	-66.7	0.00	66.7
	Week 20	90	76.67	22.04	0.0	66.67	100.0	79	1.27	30.29	-66.7	0.00	66.7
	Week 23	86	74.81	20.89	0.0	66.67	100.0	74	-2.48	29.28	-66.7	0.00	66.7
	Week 26	83	73.70	23.44	0.0	66.67	100.0	72	-2.08	26.68	-66.7	0.00	66.7
	Week 29	80	68.96	25.68	0.0	66.67	100.0	71	-10.56	33.48	-100.0	-16.66	66.7
	Week 32	74	73.87	22.26	0.0	66.67	100.0	66	-3.79	30.77	-100.0	0.00	83.3
	Week 35	73	70.78	24.97	0.0	66.67	100.0	66	-7.58	32.32	-100.0	0.00	66.7
	Week 38	75	69.78	23.68	0.0	66.67	100.0	67	-6.47	30.01	-100.0	0.00	66.7
	Week 41	71	73.01	22.78	0.0	66.67	100.0	64	-4.69	29.32	-83.3	0.00	66.7
	Week 44	64	70.31	21.51	0.0	66.67	100.0	56	-8.63	28.60	-66.7	0.00	66.7
	Week 47	56	70.83	23.19	16.7	66.67	100.0	50	-4.67	26.73	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	55	67.58	24.30	0.0	66.67	100.0	48	-8.68	31.13	-100.0	-8.33	66.7
	Week 53	55	66.36	26.16	0.0	66.67	100.0	48	-8.33	29.97	-83.3	0.00	33.3
	Week 56	53	66.98	22.29	16.7	66.67	100.0	46	-4.35	25.44	-66.7	0.00	33.3
	Week 59	51	64.71	24.42	0.0	66.67	100.0	43	-6.59	30.02	-66.7	0.00	66.7
	Week 62	42	66.27	21.62	33.3	66.67	100.0	36	-6.94	29.38	-66.7	0.00	66.7
	Week 65	31	65.05	21.24	33.3	66.67	100.0	30	-11.67	29.08	-66.7	-8.34	66.7
	Week 68	31	63.98	24.38	0.0	66.67	100.0	29	-12.07	29.17	-83.3	-16.67	66.7
	Week 71	30	67.78	27.31	0.0	66.67	100.0	28	-3.57	29.52	-66.7	0.00	66.7
	Week 74	29	68.97	23.45	16.7	66.67	100.0	27	-7.41	32.47	-66.7	0.00	66.7
	Week 77	26	67.31	21.33	33.3	66.67	100.0	24	-8.33	32.97	-66.7	0.00	66.7
	Week 80	26	64.10	20.92	33.3	66.67	100.0	26	-10.90	31.60	-66.7	0.00	66.7
	Week 83	21	72.22	20.64	33.3	66.67	100.0	21	-3.97	31.58	-66.7	0.00	66.7
	Week 86	17	60.79	27.60	0.0	66.67	100.0	17	-22.55	32.78	-100.0	-16.66	16.7
	Week 89	11	68.18	28.34	0.0	66.67	100.0	11	-22.73	30.07	-100.0	-16.66	0.0
	Week 92	13	66.67	21.52	16.7	66.67	100.0	13	-17.95	20.93	-50.0	-16.66	16.7
	Plat+Gem (N=151)												
	BASELINE	123	74.12	31.30	0.0	83.33	100.0						
	Week 1	108	71.76	29.49	0.0	83.33	100.0	103	-3.72	21.76	-83.3	0.00	83.3
	Week 2	116	66.24	30.09	0.0	66.67	100.0	105	-10.79	27.73	-100.0	0.00	100.0
	Week 3	114	68.13	30.69	0.0	66.67	100.0	103	-9.06	24.56	-83.3	0.00	66.7
	Week 4	116	70.40	28.41	0.0	66.67	100.0	103	-6.31	25.26	-66.7	0.00	100.0
	Week 5	119	65.69	28.97	0.0	66.67	100.0	106	-9.59	27.11	-66.7	0.00	100.0
	Week 6	109	69.11	28.13	0.0	66.67	100.0	98	-6.97	29.59	-100.0	0.00	100.0
	Week 7	115	66.96	30.27	0.0	66.67	100.0	105	-7.94	30.23	-100.0	0.00	100.0
	Week 8	111	66.52	28.56	0.0	66.67	100.0	102	-9.15	31.95	-100.0	0.00	66.7
	Week 9	107	65.27	29.06	0.0	66.67	100.0	95	-9.47	31.38	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	107	66.82	29.81	0.0	66.67	100.0	98	-9.86	30.26	-83.3	0.00	100.0
	Week 11	97	67.01	29.75	0.0	66.67	100.0	87	-9.19	31.21	-83.3	0.00	100.0
	Week 12	100	65.33	27.59	0.0	66.67	100.0	88	-9.28	30.20	-66.7	-8.33	100.0
	Week 14	99	63.47	29.90	0.0	66.67	100.0	86	-11.63	31.84	-83.3	-16.66	100.0
	Week 17	94	66.31	28.92	0.0	66.67	100.0	82	-12.80	34.67	-83.3	-16.66	100.0
	Week 20	84	67.66	29.20	0.0	66.67	100.0	72	-10.19	30.59	-83.3	0.00	100.0
	Week 23	70	72.38	25.99	16.7	66.67	100.0	62	-8.33	25.56	-66.7	0.00	66.7
	Week 26	61	69.67	28.63	0.0	66.67	100.0	55	-10.91	31.30	-100.0	-16.66	66.7
	Week 29	59	72.03	27.41	0.0	66.67	100.0	53	-11.95	34.18	-100.0	0.00	66.7
	Week 32	50	71.00	32.09	0.0	83.33	100.0	45	-12.22	35.60	-100.0	-16.66	66.7
	Week 35	50	69.33	25.50	16.7	66.67	100.0	44	-12.88	31.51	-66.7	-8.33	66.7
	Week 38	46	72.46	30.07	0.0	75.00	100.0	40	-10.42	34.94	-100.0	0.00	66.7
	Week 41	42	68.25	31.19	0.0	66.67	100.0	37	-15.77	34.01	-100.0	-16.66	66.7
	Week 44	39	61.97	32.43	0.0	66.67	100.0	34	-19.12	33.87	-66.7	-16.67	66.7
	Week 47	33	67.17	33.97	0.0	66.67	100.0	29	-12.07	36.97	-83.3	0.00	66.7
	Week 50	27	67.90	29.57	16.7	66.67	100.0	22	-10.61	31.52	-66.7	0.00	66.7
	Week 53	23	71.02	28.52	0.0	66.67	100.0	20	-4.17	36.22	-83.3	0.00	66.7
	Week 56	20	70.00	28.41	0.0	66.67	100.0	19	-6.14	34.79	-66.7	0.00	66.7
	Week 59	17	67.65	31.99	0.0	66.67	100.0	15	-4.44	34.77	-66.7	0.00	66.7
	Week 62	14	64.29	31.93	0.0	66.67	100.0	14	-11.90	44.06	-100.0	-16.67	66.7
	Week 65	13	67.95	28.43	16.7	66.67	100.0	12	-15.28	27.02	-66.7	-8.33	33.3
	Week 68	10	66.67	34.25	0.0	75.00	100.0	10	-21.67	30.48	-100.0	-16.67	0.0
	Week 71	10	65.00	36.39	0.0	75.00	100.0	10	-25.00	31.67	-100.0	-16.67	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	EV+Pembro (N= 56)												
	BASELINE	41	69.51	28.60	0.0	66.67	100.0						
	Week 1	39	64.53	28.91	0.0	66.67	100.0	32	-2.60	15.33	-33.3	0.00	33.3
	Week 2	44	62.88	28.73	0.0	66.67	100.0	35	-4.29	15.31	-33.3	0.00	16.7
	Week 3	45	59.63	32.27	0.0	66.67	100.0	34	-7.84	22.18	-50.0	0.00	33.3
	Week 4	44	65.15	31.09	0.0	66.67	100.0	36	-4.17	21.22	-50.0	0.00	66.7
	Week 5	41	63.01	30.16	0.0	66.67	100.0	32	-2.08	21.48	-50.0	0.00	50.0
	Week 6	41	63.82	30.48	0.0	66.67	100.0	31	-4.84	28.61	-66.7	0.00	50.0
	Week 7	45	71.11	26.21	0.0	66.67	100.0	35	1.90	27.64	-66.7	0.00	50.0
	Week 8	46	66.67	29.81	0.0	66.67	100.0	33	0.00	30.05	-66.7	0.00	50.0
	Week 9	42	63.89	26.01	0.0	66.67	100.0	32	-4.69	27.84	-66.7	0.00	50.0
	Week 10	40	67.08	26.55	0.0	66.67	100.0	31	-3.23	28.68	-66.7	0.00	66.7
	Week 11	42	69.45	24.11	16.7	66.67	100.0	31	4.30	26.52	-33.3	0.00	66.7
	Week 12	43	69.38	24.38	33.3	66.67	100.0	32	1.56	25.87	-33.3	0.00	66.7
	Week 14	44	69.32	25.91	0.0	66.67	100.0	32	0.52	27.92	-50.0	0.00	66.7
	Week 17	35	69.52	27.26	0.0	66.67	100.0	27	0.62	31.85	-66.7	0.00	66.7
	Week 20	30	71.11	23.95	33.3	66.67	100.0	24	-2.78	25.38	-66.7	0.00	50.0
	Week 23	31	70.43	23.85	0.0	66.67	100.0	23	-1.45	28.83	-66.7	0.00	50.0
	Week 26	29	72.41	21.95	33.3	66.67	100.0	22	5.30	27.88	-50.0	0.00	50.0
	Week 29	27	70.37	24.17	33.3	66.67	100.0	22	-2.27	30.12	-66.7	0.00	66.7
	Week 32	28	69.05	23.88	33.3	66.67	100.0	22	0.76	23.84	-50.0	0.00	50.0
	Week 35	25	70.00	18.00	33.3	66.67	100.0	20	-1.67	25.31	-50.0	0.00	50.0
	Week 38	22	67.43	22.70	0.0	66.67	100.0	19	-5.26	24.88	-66.7	0.00	33.3
	Week 41	24	63.89	21.24	33.3	66.67	100.0	20	-7.50	28.34	-66.7	0.00	50.0
	Week 44	22	59.09	27.08	0.0	66.67	100.0	18	-12.96	25.92	-66.7	0.00	33.3
	Week 47	23	63.77	29.58	0.0	66.67	100.0	20	-10.00	28.82	-83.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	19	64.91	24.78	0.0	66.67	100.0	16	-9.37	21.92	-50.0	0.00	33.3
	Week 53	19	65.79	25.75	33.3	66.67	100.0	15	-5.55	24.93	-50.0	0.00	33.3
	Week 56	19	66.67	30.93	0.0	66.67	100.0	15	-4.44	24.77	-50.0	0.00	33.3
	Week 59	18	65.74	24.57	33.3	66.67	100.0	14	-4.76	28.06	-50.0	0.00	33.3
	Week 62	20	66.67	31.06	0.0	66.67	100.0	16	-1.04	21.49	-50.0	0.00	33.3
	Week 65	12	68.06	24.06	33.3	66.67	100.0	10	-3.33	25.82	-50.0	-8.33	33.3
	Week 68	15	71.11	22.24	33.3	66.67	100.0	13	-1.28	23.04	-33.3	0.00	33.3
	Week 71	12	75.00	21.90	33.3	66.67	100.0	10	5.00	26.12	-33.3	8.34	33.3
	Week 77	11	80.30	24.52	33.3	100.00	100.0	9	7.41	23.73	-33.3	0.00	33.3
	Week 80	10	75.00	30.68	16.7	83.34	100.0	8	0.00	40.82	-83.3	8.34	33.3
	Plat+Gem (N= 51)												
	BASELINE	42	71.83	30.24	0.0	83.33	100.0						
	Week 1	36	62.96	30.63	0.0	66.67	100.0	36	-9.26	21.25	-66.7	-16.67	50.0
	Week 2	31	65.05	29.61	0.0	66.67	100.0	30	-7.22	27.22	-83.3	0.00	50.0
	Week 3	35	60.95	32.58	0.0	66.67	100.0	33	-13.64	19.74	-50.0	-16.66	50.0
	Week 4	34	66.18	32.17	0.0	66.67	100.0	32	-7.29	25.02	-66.7	0.00	50.0
	Week 5	34	66.67	31.78	0.0	66.67	100.0	32	-10.94	25.96	-83.3	-16.66	50.0
	Week 6	36	62.04	35.77	0.0	66.67	100.0	33	-12.12	29.84	-83.3	0.00	50.0
	Week 7	33	64.65	30.26	0.0	66.67	100.0	29	-9.77	29.38	-66.7	0.00	50.0
	Week 8	34	59.31	29.07	0.0	66.67	100.0	30	-14.44	24.66	-66.7	-16.66	33.3
	Week 9	34	63.24	30.64	0.0	66.67	100.0	30	-12.78	30.22	-100.0	-16.67	50.0
	Week 10	35	65.24	25.68	0.0	66.67	100.0	32	-7.81	29.63	-50.0	-16.67	50.0
	Week 11	29	62.07	29.51	0.0	66.67	100.0	27	-9.88	20.29	-50.0	0.00	33.3
	Week 12	30	63.89	34.21	0.0	66.67	100.0	27	-12.34	26.79	-83.3	0.00	33.3
	Week 14	26	64.74	31.03	0.0	66.67	100.0	23	-8.69	30.93	-100.0	0.00	33.3
	Week 17	26	62.18	32.17	0.0	66.67	100.0	24	-12.50	28.34	-100.0	-16.66	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 20	20	78.33	20.30	33.3	83.33	100.0	19	3.51	28.64	-33.3	0.00	50.0
	Week 23	18	75.00	28.15	16.7	75.00	100.0	18	-4.63	22.73	-33.3	0.00	50.0
	Week 26	20	71.67	30.16	0.0	75.00	100.0	20	-1.67	21.56	-50.0	0.00	33.3
	Week 29	18	69.44	32.46	0.0	66.67	100.0	18	-7.41	36.70	-83.3	0.00	66.7
	Week 32	13	73.08	23.11	33.3	66.67	100.0	13	-5.13	24.89	-50.0	0.00	33.3
	Week 35	12	76.39	20.67	33.3	66.67	100.0	12	-1.39	33.68	-50.0	0.00	50.0
	Week 38	10	76.67	23.83	33.3	75.00	100.0	10	-8.33	22.57	-50.0	0.00	33.3
	Week 41	10	71.67	32.44	0.0	83.33	100.0	10	-13.33	30.22	-83.3	-8.33	33.3
	Week 44	10	65.00	28.81	16.7	66.67	100.0	10	-13.33	24.59	-66.7	0.00	16.7
	Week 47	10	61.67	30.48	16.7	58.34	100.0	10	-23.33	23.83	-66.7	-25.00	0.0
	Week 56	10	50.00	32.40	0.0	33.33	100.0	10	-21.67	32.44	-66.7	-16.67	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Visceral metastases	EV+Pembro (N=148)												
	BASELINE	119	70.17	30.21	0.0	66.67	100.0						
	Week 1	105	67.78	29.26	0.0	66.67	100.0	99	-3.70	19.42	-50.0	0.00	33.3
	Week 2	109	64.22	31.74	0.0	66.67	100.0	100	-6.00	22.29	-83.3	0.00	66.7
	Week 3	98	67.86	30.86	0.0	66.67	100.0	88	-1.52	23.66	-50.0	0.00	66.7
	Week 4	103	66.99	29.24	0.0	66.67	100.0	93	-4.30	24.44	-66.7	0.00	66.7
	Week 5	100	68.83	29.08	0.0	66.67	100.0	90	-0.19	24.92	-66.7	0.00	66.7
	Week 6	105	70.32	28.49	0.0	66.67	100.0	90	0.00	25.72	-66.7	0.00	66.7
	Week 7	108	73.15	26.56	0.0	66.67	100.0	91	0.73	28.64	-83.3	0.00	66.7
	Week 8	105	70.32	28.49	0.0	66.67	100.0	89	-0.37	29.30	-66.7	0.00	66.7
	Week 9	105	69.21	26.93	0.0	66.67	100.0	91	0.18	30.17	-66.7	0.00	100.0
	Week 10	101	72.94	26.76	0.0	66.67	100.0	86	2.52	29.21	-66.7	0.00	66.7
	Week 11	97	73.03	25.73	0.0	66.67	100.0	83	1.21	27.27	-66.7	0.00	66.7
	Week 12	100	69.17	28.76	0.0	66.67	100.0	85	-2.75	28.96	-66.7	0.00	66.7
	Week 14	102	72.06	26.86	0.0	66.67	100.0	87	0.19	29.15	-66.7	0.00	66.7
	Week 17	96	70.66	25.45	0.0	66.67	100.0	81	-1.85	29.93	-66.7	0.00	66.7
	Week 20	87	74.14	24.21	0.0	66.67	100.0	76	-0.66	30.24	-66.7	0.00	66.7
	Week 23	85	72.75	22.54	0.0	66.67	100.0	71	-3.29	30.29	-66.7	0.00	66.7
	Week 26	79	73.21	20.91	0.0	66.67	100.0	66	-1.51	26.10	-50.0	0.00	66.7
	Week 29	72	68.29	23.60	0.0	66.67	100.0	64	-10.42	31.64	-100.0	0.00	66.7
	Week 32	71	71.13	22.71	0.0	66.67	100.0	62	-4.03	32.04	-100.0	0.00	83.3
	Week 35	70	70.72	23.30	0.0	66.67	100.0	63	-6.61	32.73	-100.0	0.00	66.7
	Week 38	70	69.76	23.79	0.0	66.67	100.0	63	-6.88	31.77	-100.0	0.00	66.7
	Week 41	66	71.21	20.58	0.0	66.67	100.0	60	-4.44	29.25	-83.3	0.00	66.7
	Week 44	59	64.97	21.82	0.0	66.67	100.0	53	-12.26	29.26	-66.7	-16.67	66.7
	Week 47	52	68.59	25.28	0.0	66.67	100.0	48	-6.60	30.70	-83.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	49	63.95	25.54	0.0	66.67	100.0	43	-12.01	33.20	-100.0	-16.67	66.7
	Week 53	50	64.67	25.56	0.0	66.67	100.0	44	-9.85	30.78	-83.3	0.00	33.3
	Week 56	45	67.04	23.97	16.7	66.67	100.0	39	-6.41	26.11	-66.7	0.00	33.3
	Week 59	44	64.02	24.10	0.0	66.67	100.0	38	-9.21	30.19	-66.7	0.00	66.7
	Week 62	38	67.11	22.42	33.3	66.67	100.0	33	-11.11	27.85	-66.7	0.00	66.7
	Week 65	25	66.67	19.25	33.3	66.67	100.0	24	-11.11	33.93	-66.7	-16.67	66.7
	Week 68	31	65.59	22.74	0.0	66.67	100.0	29	-13.22	30.98	-83.3	-16.67	66.7
	Week 71	27	70.37	26.28	0.0	66.67	100.0	25	-4.00	33.43	-66.7	0.00	66.7
	Week 74	23	68.12	24.06	33.3	66.67	100.0	22	-11.36	37.93	-66.7	-8.34	66.7
	Week 77	24	68.75	24.73	33.3	66.67	100.0	23	-8.69	34.04	-66.7	0.00	66.7
	Week 80	22	62.88	24.09	16.7	66.67	100.0	22	-14.39	37.90	-83.3	-8.34	66.7
	Week 83	19	70.18	23.29	33.3	66.67	100.0	19	-6.14	33.89	-66.7	0.00	66.7
	Week 86	14	59.53	30.46	0.0	66.67	100.0	14	-22.62	42.17	-100.0	-8.33	33.3
	Week 89	10	66.67	32.39	0.0	66.67	100.0	10	-25.00	37.06	-100.0	-25.00	16.7
	Week 92	11	66.67	25.82	16.7	66.67	100.0	11	-16.66	27.89	-50.0	-16.66	16.7
	Plat+Gem (N=157)												
	BASELINE	128	72.40	31.40	0.0	83.33	100.0						
	Week 1	111	68.32	31.22	0.0	66.67	100.0	107	-5.61	22.07	-83.3	0.00	83.3
	Week 2	110	65.15	31.08	0.0	66.67	100.0	102	-10.62	27.73	-100.0	0.00	100.0
	Week 3	112	65.48	31.93	0.0	66.67	100.0	103	-9.87	24.64	-83.3	0.00	66.7
	Week 4	112	68.30	31.40	0.0	66.67	100.0	102	-6.21	26.00	-66.7	0.00	100.0
	Week 5	113	65.04	30.94	0.0	66.67	100.0	103	-9.22	24.67	-66.7	0.00	100.0
	Week 6	107	67.29	31.80	0.0	66.67	100.0	98	-7.65	28.54	-100.0	0.00	100.0
	Week 7	109	66.82	31.06	0.0	66.67	100.0	100	-6.67	28.23	-83.3	0.00	100.0
	Week 8	106	65.57	29.39	0.0	66.67	100.0	98	-8.33	29.43	-100.0	0.00	66.7
	Week 9	105	65.87	30.17	0.0	66.67	100.0	94	-8.51	30.31	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	104	66.51	30.68	0.0	66.67	100.0	96	-7.99	29.52	-83.3	0.00	100.0
	Week 11	91	65.39	30.55	0.0	66.67	100.0	83	-8.43	28.68	-83.3	0.00	100.0
	Week 12	94	64.01	29.87	0.0	66.67	100.0	84	-8.73	26.57	-66.7	0.00	100.0
	Week 14	90	63.89	31.73	0.0	66.67	100.0	79	-9.49	32.10	-100.0	0.00	100.0
	Week 17	90	65.74	31.24	0.0	66.67	100.0	80	-10.42	34.41	-100.0	0.00	100.0
	Week 20	74	69.14	27.54	0.0	66.67	100.0	64	-5.47	28.49	-66.7	0.00	100.0
	Week 23	63	72.75	27.16	16.7	66.67	100.0	58	-6.03	20.16	-66.7	0.00	50.0
	Week 26	55	70.61	28.50	0.0	66.67	100.0	52	-6.73	23.16	-66.7	0.00	66.7
	Week 29	53	70.13	29.30	0.0	66.67	100.0	50	-12.00	31.41	-100.0	0.00	66.7
	Week 32	42	72.22	32.02	0.0	83.33	100.0	40	-9.17	29.95	-100.0	0.00	66.7
	Week 35	39	71.80	25.41	16.7	66.67	100.0	36	-8.33	26.58	-66.7	0.00	66.7
	Week 38	37	73.42	30.29	0.0	83.33	100.0	34	-6.37	32.83	-100.0	0.00	66.7
	Week 41	33	69.19	29.50	0.0	66.67	100.0	31	-10.75	27.74	-66.7	0.00	50.0
	Week 44	32	61.98	31.18	0.0	66.67	100.0	30	-13.89	27.71	-66.7	0.00	50.0
	Week 47	28	64.88	35.82	0.0	66.67	100.0	26	-10.90	33.32	-66.7	0.00	66.7
	Week 50	22	66.67	33.33	0.0	75.00	100.0	20	-11.67	25.99	-66.7	0.00	50.0
	Week 53	19	67.54	32.62	0.0	66.67	100.0	17	-5.88	34.33	-83.3	0.00	66.7
	Week 56	18	60.19	32.41	0.0	66.67	100.0	17	-6.86	29.50	-66.7	0.00	50.0
	Week 59	13	60.26	32.30	0.0	50.00	100.0	12	-1.39	26.07	-66.7	0.00	33.3
	Week 62	11	56.06	30.98	0.0	66.67	100.0	11	-7.57	41.74	-100.0	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Lymph node only	EV+Pembro (N= 43)												
	BASELINE	33	78.79	21.36	33.3	83.33	100.0						
	Week 1	30	77.78	20.68	33.3	66.67	100.0	24	2.08	16.53	-33.3	0.00	33.3
	Week 2	34	75.98	19.33	33.3	66.67	100.0	27	0.00	16.67	-33.3	0.00	33.3
	Week 3	35	68.57	27.05	0.0	66.67	100.0	28	-5.95	28.04	-66.7	0.00	33.3
	Week 4	36	75.00	24.40	0.0	75.00	100.0	30	1.11	26.60	-50.0	0.00	66.7
	Week 5	33	69.19	27.36	16.7	66.67	100.0	27	-6.17	30.36	-83.3	0.00	33.3
	Week 6	34	71.57	27.69	0.0	66.67	100.0	28	-3.57	34.65	-66.7	0.00	50.0
	Week 7	34	70.59	27.23	0.0	66.67	100.0	28	-1.19	32.05	-66.7	0.00	50.0
	Week 8	35	69.52	25.40	33.3	66.67	100.0	29	-3.45	30.34	-66.7	0.00	33.3
	Week 9	30	71.11	26.60	0.0	66.67	100.0	24	-3.47	30.68	-100.0	0.00	50.0
	Week 10	31	75.27	25.41	0.0	83.33	100.0	26	-1.28	33.64	-100.0	0.00	50.0
	Week 11	34	75.00	24.01	0.0	66.67	100.0	27	-0.62	34.43	-100.0	0.00	66.7
	Week 12	35	78.57	21.61	33.3	83.33	100.0	28	2.98	29.76	-33.3	0.00	66.7
	Week 14	30	78.89	19.54	33.3	66.67	100.0	23	3.62	28.41	-66.7	0.00	66.7
	Week 17	30	72.78	19.32	33.3	66.67	100.0	24	-4.86	33.87	-66.7	0.00	66.7
	Week 20	27	78.40	17.79	50.0	66.67	100.0	21	3.17	28.68	-50.0	0.00	50.0
	Week 23	27	75.31	19.81	33.3	66.67	100.0	21	1.59	28.34	-50.0	0.00	50.0
	Week 26	27	74.69	27.10	0.0	66.67	100.0	22	4.55	32.60	-66.7	0.00	50.0
	Week 29	28	73.81	28.12	0.0	83.33	100.0	23	-2.17	38.70	-100.0	0.00	66.7
	Week 32	24	77.08	22.42	33.3	75.00	100.0	20	1.67	23.51	-33.3	0.00	50.0
	Week 35	22	66.67	24.13	0.0	66.67	100.0	18	-7.41	28.14	-66.7	0.00	33.3
	Week 38	21	68.26	17.40	33.3	66.67	100.0	17	-2.94	20.61	-33.3	0.00	33.3
	Week 41	22	72.73	24.96	33.3	66.67	100.0	17	-2.94	27.15	-66.7	0.00	33.3
	Week 44	22	71.97	26.42	0.0	66.67	100.0	16	-2.08	25.73	-66.7	0.00	50.0
	Week 47	21	70.64	23.51	33.3	66.67	100.0	16	-3.13	19.45	-33.3	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	71.67	22.36	33.3	66.67	100.0	16	-1.04	17.71	-33.3	0.00	33.3
	Week 53	18	71.30	24.79	33.3	66.67	100.0	14	-1.19	25.71	-66.7	0.00	33.3
	Week 56	21	68.26	22.30	33.3	66.67	100.0	17	0.00	26.35	-66.7	0.00	33.3
	Week 59	21	69.05	24.88	33.3	66.67	100.0	16	4.17	27.56	-66.7	0.00	33.3
	Week 62	19	68.42	26.00	33.3	66.67	100.0	15	8.89	23.46	-33.3	0.00	50.0
	Week 65	16	66.67	25.82	33.3	66.67	100.0	14	-3.57	14.88	-33.3	0.00	33.3
	Week 68	13	69.23	26.22	33.3	66.67	100.0	11	3.03	14.57	-16.7	0.00	33.3
	Week 71	13	69.23	24.39	33.3	66.67	100.0	11	4.54	16.82	-16.7	0.00	33.3
	Week 74	13	74.36	18.78	33.3	66.67	100.0	11	3.03	19.46	-33.3	0.00	33.3
	Week 77	13	75.64	18.78	50.0	66.67	100.0	10	6.67	21.08	-33.3	0.00	33.3
	Week 80	13	71.80	22.96	33.3	66.67	100.0	11	3.03	22.13	-33.3	0.00	33.3
	Week 83	11	80.30	16.36	50.0	83.33	100.0	10	8.33	19.64	-33.3	8.33	33.3
	Week 86	11	71.21	23.68	33.3	66.67	100.0	10	-3.33	17.21	-33.3	0.00	33.3
	Plat+Gem (N= 37)												
	BASELINE	29	75.86	31.68	0.0	100.00	100.0						
	Week 1	26	71.15	26.06	16.7	83.33	100.0	25	-5.33	21.90	-50.0	0.00	50.0
	Week 2	30	67.78	29.01	16.7	66.67	100.0	26	-7.69	28.76	-83.3	0.00	50.0
	Week 3	30	69.44	30.03	0.0	66.67	100.0	26	-9.62	18.96	-66.7	0.00	33.3
	Week 4	32	71.35	22.49	16.7	66.67	100.0	27	-8.64	20.86	-33.3	0.00	50.0
	Week 5	33	67.17	27.16	0.0	66.67	100.0	28	-11.90	33.29	-83.3	-16.66	66.7
	Week 6	32	66.67	27.11	0.0	66.67	100.0	27	-9.88	33.10	-83.3	-16.66	66.7
	Week 7	31	63.44	28.68	0.0	66.67	100.0	26	-14.10	35.49	-100.0	-16.67	66.7
	Week 8	32	61.98	29.09	0.0	66.67	100.0	27	-16.67	33.97	-100.0	-16.67	66.7
	Week 9	30	60.56	28.19	0.0	66.67	100.0	25	-15.33	32.25	-66.7	-16.66	66.7
	Week 10	30	66.11	24.17	0.0	66.67	100.0	26	-12.18	31.47	-66.7	-16.67	66.7
	Week 11	29	67.24	28.69	0.0	66.67	100.0	25	-10.67	29.22	-50.0	-16.67	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.11.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 12	28	68.45	29.52	0.0	66.67	100.0	23	-11.59	39.39	-83.3	0.00	100.0
	Week 14	28	63.10	27.73	0.0	66.67	100.0	23	-14.49	30.69	-66.7	-16.67	66.7
	Week 17	25	64.67	25.60	0.0	66.67	100.0	21	-19.05	27.53	-50.0	-16.67	66.7
	Week 20	23	71.01	31.07	0.0	83.33	100.0	20	-10.83	35.57	-83.3	0.00	66.7
	Week 23	20	72.50	23.12	33.3	66.67	100.0	17	-11.76	33.21	-50.0	-16.67	66.7
	Week 26	21	69.05	31.75	0.0	66.67	100.0	18	-11.11	41.62	-100.0	-8.34	66.7
	Week 29	19	71.93	27.81	0.0	66.67	100.0	16	-9.37	44.71	-83.3	-16.67	66.7
	Week 32	18	68.52	28.52	0.0	66.67	100.0	15	-13.33	44.63	-100.0	-16.67	66.7
	Week 35	19	69.30	23.74	33.3	66.67	100.0	16	-13.54	40.01	-66.7	-25.00	66.7
	Week 38	15	71.11	27.79	16.7	66.67	100.0	12	-18.06	35.15	-66.7	-25.00	66.7
	Week 41	15	67.78	36.98	0.0	83.33	100.0	12	-23.61	45.20	-100.0	-16.67	66.7
	Week 44	14	65.48	35.48	0.0	75.00	100.0	11	-22.73	42.34	-66.7	-16.67	66.7
	Week 47	12	69.44	25.46	16.7	75.00	100.0	10	-20.00	37.52	-83.3	-25.00	66.7
	Week 50	11	63.64	28.69	33.3	66.67	100.0	8	-16.67	40.83	-66.7	-25.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
EV+Pembro (N=240)												
BASELINE	206	75.81	20.26	8.3	75.00	100.0						
Week 1	190	79.08	19.37	16.7	83.33	100.0	184	2.67	15.49	-50.0	0.00	58.3
Week 2	203	78.78	19.50	0.0	83.33	100.0	189	2.29	16.69	-58.3	0.00	66.7
Week 3	198	78.12	19.93	0.0	83.33	100.0	182	1.74	19.05	-50.0	0.00	91.7
Week 4	194	80.58	19.63	0.0	83.33	100.0	179	3.59	18.25	-50.0	0.00	91.7
Week 5	190	81.71	17.65	16.7	83.33	100.0	173	4.72	20.04	-58.3	0.00	91.7
Week 6	188	80.94	19.66	16.7	83.33	100.0	170	3.82	20.05	-66.7	0.00	58.3
Week 7	195	80.51	20.72	0.0	83.33	100.0	176	3.50	20.11	-75.0	0.00	91.7
Week 8	191	79.63	21.18	0.0	83.33	100.0	171	3.22	19.93	-66.7	0.00	91.7
Week 9	197	80.03	19.32	16.7	83.33	100.0	180	3.66	19.50	-75.0	0.00	66.7
Week 10	191	80.72	19.82	0.0	83.33	100.0	175	4.48	19.85	-58.3	0.00	58.3
Week 11	194	80.93	20.45	8.3	91.67	100.0	175	4.62	20.64	-75.0	0.00	91.7
Week 12	186	80.38	20.33	0.0	83.33	100.0	171	2.78	20.57	-83.3	0.00	66.7
Week 14	185	79.28	21.42	0.0	83.33	100.0	167	2.50	19.35	-75.0	0.00	66.7
Week 17	178	80.67	18.31	8.3	83.33	100.0	162	2.98	18.94	-50.0	0.00	66.7
Week 20	167	79.44	21.27	0.0	83.33	100.0	154	2.00	21.54	-75.0	0.00	66.7
Week 23	162	79.78	20.79	0.0	83.33	100.0	151	1.82	21.83	-75.0	0.00	58.3
Week 26	156	79.27	20.62	16.7	83.33	100.0	144	1.74	21.79	-75.0	0.00	66.7
Week 29	157	81.53	19.66	8.3	83.33	100.0	145	3.28	18.59	-58.3	0.00	58.3
Week 32	135	80.31	19.65	0.0	83.33	100.0	125	2.33	19.10	-83.3	0.00	50.0
Week 35	132	80.93	20.63	8.3	83.33	100.0	122	2.12	17.39	-58.3	0.00	41.7
Week 38	132	81.69	18.32	25.0	83.33	100.0	124	2.42	19.03	-66.7	0.00	58.3
Week 41	129	78.49	21.69	8.3	83.33	100.0	119	-0.21	21.60	-75.0	0.00	58.3
Week 44	108	79.48	19.94	25.0	83.33	100.0	100	0.67	22.12	-66.7	0.00	58.3
Week 47	100	79.83	21.33	8.3	83.33	100.0	94	0.53	20.18	-58.3	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	89	81.37	20.30	16.7	91.67	100.0	84	1.79	20.86	-66.7	0.00	41.7
Week 53	79	80.49	21.76	8.3	91.67	100.0	74	-0.23	20.08	-58.3	0.00	50.0
Week 56	81	80.45	20.33	16.7	83.33	100.0	76	2.30	19.94	-50.0	0.00	50.0
Week 59	72	80.32	20.43	25.0	83.33	100.0	68	0.86	19.22	-58.3	0.00	41.7
Week 62	65	81.03	20.23	16.7	83.33	100.0	63	0.79	19.09	-50.0	0.00	41.7
Week 65	58	77.44	23.21	0.0	75.00	100.0	54	-1.85	20.20	-50.0	0.00	41.7
Week 68	53	79.56	20.71	33.3	83.33	100.0	52	0.32	18.45	-50.0	0.00	41.7
Week 71	51	81.54	19.03	33.3	83.33	100.0	49	1.36	19.27	-58.3	0.00	41.7
Week 74	47	81.03	21.75	33.3	91.67	100.0	46	1.27	20.26	-50.0	0.00	41.7
Week 77	44	77.65	20.55	33.3	75.00	100.0	42	-0.60	22.57	-50.0	0.00	41.7
Week 80	40	78.96	19.24	41.7	75.00	100.0	37	2.70	21.25	-50.0	8.33	41.7
Week 83	37	77.70	20.04	33.3	75.00	100.0	35	1.90	21.30	-58.3	8.33	41.7
Week 86	34	79.66	19.48	41.7	75.00	100.0	31	3.23	22.12	-50.0	8.33	41.7
Week 89	33	75.76	22.08	33.3	66.67	100.0	31	1.34	20.54	-33.3	0.00	41.7
Week 92	27	76.24	24.10	25.0	75.00	100.0	25	-1.00	22.99	-50.0	0.00	33.3
Week 95	22	75.38	19.33	33.3	70.84	100.0	21	0.00	20.92	-41.7	0.00	25.0
Week 98	18	78.24	20.84	41.7	70.84	100.0	17	3.43	25.53	-58.3	8.33	41.7
Week 101	14	76.79	26.79	33.3	87.50	100.0	14	0.00	23.34	-66.7	8.33	25.0
Week 104	10	72.50	27.23	33.3	70.84	100.0	10	0.83	26.19	-66.7	8.33	25.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Plat+Gem (N=242)												
BASELINE	188	73.49	21.84	0.0	75.00	100.0						
Week 1	173	75.82	22.28	0.0	83.33	100.0	158	2.32	17.59	-66.7	0.00	50.0
Week 2	171	75.15	22.15	0.0	75.00	100.0	151	0.88	17.98	-66.7	0.00	75.0
Week 3	184	78.76	20.90	8.3	83.33	100.0	162	4.32	17.68	-41.7	0.00	66.7
Week 4	183	78.64	19.99	0.0	83.33	100.0	156	3.47	18.91	-75.0	0.00	75.0
Week 5	187	77.27	21.63	0.0	83.33	100.0	156	1.60	19.01	-66.7	0.00	41.7
Week 6	174	78.21	22.25	0.0	83.33	100.0	149	3.36	16.86	-58.3	0.00	41.7
Week 7	186	78.18	20.59	8.3	79.17	100.0	157	2.97	17.83	-66.7	0.00	75.0
Week 8	167	76.05	22.91	0.0	83.33	100.0	144	1.22	20.98	-100.0	0.00	58.3
Week 9	177	77.17	20.59	16.7	75.00	100.0	150	3.11	18.28	-66.7	0.00	50.0
Week 10	166	77.11	21.47	0.0	75.00	100.0	139	2.52	18.49	-100.0	0.00	50.0
Week 11	168	77.03	22.51	0.0	83.33	100.0	143	2.62	17.73	-41.7	0.00	50.0
Week 12	159	77.78	20.81	33.3	75.00	100.0	138	2.78	18.93	-58.3	0.00	50.0
Week 14	153	76.47	21.59	0.0	75.00	100.0	128	1.82	20.11	-58.3	0.00	66.7
Week 17	155	77.74	21.72	0.0	75.00	100.0	130	1.41	21.62	-91.7	0.00	58.3
Week 20	126	80.29	20.43	16.7	83.33	100.0	110	3.79	19.11	-58.3	0.00	58.3
Week 23	115	82.90	19.99	8.3	91.67	100.0	97	5.24	19.74	-66.7	8.33	58.3
Week 26	108	79.94	23.10	0.0	83.33	100.0	95	0.53	20.59	-66.7	0.00	41.7
Week 29	100	83.33	18.50	33.3	91.67	100.0	86	2.42	18.61	-58.3	0.00	41.7
Week 32	83	81.73	20.80	16.7	83.33	100.0	76	2.52	18.76	-66.7	0.00	33.3
Week 35	76	82.68	17.94	33.3	83.33	100.0	69	3.50	16.75	-33.3	0.00	41.7
Week 38	74	85.14	17.35	25.0	91.67	100.0	65	4.23	20.04	-66.7	0.00	41.7
Week 41	65	83.59	19.32	33.3	91.67	100.0	56	2.83	19.67	-66.7	0.00	41.7
Week 44	60	81.67	19.09	33.3	83.33	100.0	53	-0.63	18.91	-66.7	0.00	41.7
Week 47	56	84.67	17.54	33.3	91.67	100.0	49	1.87	19.71	-66.7	0.00	41.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	51	85.79	16.44	50.0	91.67	100.0	47	1.95	18.16	-33.3	0.00	33.3
Week 53	46	87.14	14.98	50.0	95.84	100.0	42	1.79	16.31	-33.3	0.00	25.0
Week 56	39	83.33	20.59	16.7	100.00	100.0	34	1.22	18.82	-41.7	0.00	33.3
Week 59	37	86.26	15.74	41.7	91.67	100.0	33	0.25	18.34	-50.0	0.00	25.0
Week 62	32	85.68	15.59	50.0	91.67	100.0	29	2.30	15.89	-33.3	0.00	25.0
Week 65	30	90.83	11.65	66.7	91.67	100.0	26	3.85	13.17	-33.3	4.17	25.0
Week 68	25	86.67	15.40	50.0	91.67	100.0	21	0.00	14.67	-25.0	0.00	25.0
Week 71	22	81.82	21.46	25.0	91.67	100.0	19	-3.51	17.42	-41.7	0.00	25.0
Week 74	21	82.54	21.07	33.3	91.67	100.0	18	0.46	16.78	-33.3	0.00	25.0
Week 77	18	82.87	24.00	33.3	100.00	100.0	15	1.11	24.37	-66.7	0.00	33.3
Week 80	14	88.69	17.17	50.0	100.00	100.0	13	6.41	16.72	-25.0	0.00	33.3
Week 83	13	87.18	15.82	50.0	91.67	100.0	12	6.95	18.06	-25.0	4.17	33.3
Week 86	12	92.36	12.54	66.7	100.00	100.0	11	8.33	15.37	-25.0	8.33	25.0
Week 89	11	88.64	15.03	66.7	100.00	100.0	10	6.67	19.95	-33.3	12.50	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Present	EV+Pembro (N= 48)												
	BASELINE	39	68.16	23.09	25.0	66.67	100.0						
	Week 1	32	73.18	22.57	25.0	75.00	100.0	32	5.47	17.41	-41.7	8.33	33.3
	Week 2	37	73.20	20.24	33.3	75.00	100.0	33	4.04	18.53	-41.7	0.00	50.0
	Week 3	34	68.87	24.04	0.0	70.84	100.0	29	1.44	20.66	-41.7	0.00	50.0
	Week 4	36	72.22	23.06	0.0	75.00	100.0	31	2.96	19.90	-50.0	0.00	50.0
	Week 5	30	72.78	22.20	16.7	75.00	100.0	24	7.64	23.69	-41.7	8.33	58.3
	Week 6	31	73.12	22.23	16.7	75.00	100.0	25	4.67	22.70	-66.7	0.00	58.3
	Week 7	34	72.55	25.75	0.0	75.00	100.0	28	5.95	24.41	-75.0	0.00	50.0
	Week 8	35	70.00	26.98	0.0	75.00	100.0	30	2.78	19.74	-41.7	0.00	41.7
	Week 9	34	69.61	22.18	16.7	75.00	100.0	30	1.94	24.14	-58.3	0.00	58.3
	Week 10	34	73.04	25.87	0.0	75.00	100.0	30	4.72	24.24	-58.3	8.33	50.0
	Week 11	33	70.45	26.69	8.3	75.00	100.0	28	1.49	24.75	-75.0	4.17	41.7
	Week 12	33	74.50	24.82	0.0	75.00	100.0	29	5.75	27.38	-83.3	8.33	50.0
	Week 14	31	72.58	26.89	0.0	75.00	100.0	26	4.17	25.41	-75.0	8.33	50.0
	Week 17	31	72.58	21.21	33.3	75.00	100.0	25	5.67	20.09	-33.3	0.00	50.0
	Week 20	27	70.37	22.92	25.0	75.00	100.0	24	2.78	26.20	-50.0	0.00	58.3
	Week 23	26	72.76	24.67	25.0	75.00	100.0	23	5.80	23.36	-50.0	0.00	41.7
	Week 26	25	78.00	23.06	16.7	83.33	100.0	22	10.23	20.24	-25.0	4.17	50.0
	Week 29	23	83.33	21.76	16.7	91.67	100.0	22	11.37	17.54	-8.3	4.17	58.3
	Week 32	21	75.79	24.57	0.0	83.33	100.0	19	10.09	18.96	-25.0	8.34	41.7
	Week 35	19	75.88	25.44	8.3	75.00	100.0	17	6.37	16.28	-16.7	0.00	41.7
	Week 38	18	75.46	22.23	33.3	70.84	100.0	17	5.88	17.62	-25.0	0.00	41.7
	Week 41	20	75.42	24.40	16.7	75.00	100.0	19	7.90	19.34	-25.0	0.00	41.7
	Week 44	17	77.45	19.93	41.7	75.00	100.0	15	5.56	18.28	-25.0	0.00	41.7
	Week 47	18	76.85	29.37	8.3	91.67	100.0	16	-0.52	24.81	-50.0	0.00	41.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	12	82.64	26.22	16.7	100.00	100.0	11	6.06	15.85	-16.7	0.00	33.3
	Week 53	12	79.86	30.04	8.3	95.84	100.0	11	4.55	18.01	-25.0	0.00	41.7
	Week 56	13	77.57	27.30	16.7	91.67	100.0	12	0.70	23.15	-50.0	0.00	41.7
	Week 59	12	87.50	23.44	25.0	100.00	100.0	11	9.85	15.28	-8.3	0.00	41.7
	Week 62	10	81.67	27.44	16.7	95.84	100.0	9	6.48	18.06	-16.7	0.00	41.7
	Week 65	10	76.67	35.09	0.0	95.84	100.0	9	0.93	27.78	-50.0	0.00	41.7
	Plat+Gem (N= 48)												
	BASELINE	33	68.44	19.96	25.0	66.67	100.0						
	Week 1	31	70.43	25.17	0.0	75.00	100.0	27	2.78	17.90	-50.0	0.00	41.7
	Week 2	29	73.56	22.61	33.3	75.00	100.0	24	7.29	19.40	-33.3	0.00	66.7
	Week 3	32	80.21	21.87	8.3	83.33	100.0	27	10.18	21.35	-41.7	8.33	50.0
	Week 4	32	80.73	20.02	8.3	83.33	100.0	24	7.64	21.55	-41.7	8.33	66.7
	Week 5	36	77.55	21.16	16.7	79.17	100.0	28	7.44	17.47	-33.3	4.17	41.7
	Week 6	35	76.19	24.43	0.0	75.00	100.0	27	8.95	17.89	-33.3	8.33	41.7
	Week 7	38	76.75	21.59	25.0	75.00	100.0	29	8.05	17.18	-33.3	8.33	41.7
	Week 8	31	80.11	15.91	41.7	83.33	100.0	25	5.67	13.76	-16.7	8.33	33.3
	Week 9	32	76.30	19.18	33.3	75.00	100.0	25	11.00	13.11	-16.7	8.33	33.3
	Week 10	34	75.74	23.60	0.0	75.00	100.0	26	8.33	18.56	-33.3	8.33	41.7
	Week 11	30	80.00	21.29	33.3	87.50	100.0	24	12.85	15.73	-25.0	8.33	41.7
	Week 12	28	81.55	17.91	33.3	87.50	100.0	23	11.59	13.93	-8.3	8.33	41.7
	Week 14	26	80.13	15.29	50.0	79.17	100.0	21	12.30	12.25	0.0	8.33	33.3
	Week 17	30	79.45	18.79	25.0	75.00	100.0	25	9.33	15.28	-16.7	8.33	33.3
	Week 20	23	79.71	19.60	25.0	75.00	100.0	21	9.52	16.09	-25.0	8.33	33.3
	Week 23	22	80.30	20.01	33.3	83.33	100.0	19	8.77	11.94	-8.3	8.33	33.3
	Week 26	19	85.09	17.03	41.7	91.67	100.0	18	10.65	11.36	0.0	8.33	33.3
	Week 29	16	84.38	16.91	50.0	87.50	100.0	14	8.33	21.93	-41.7	8.33	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 32	11	84.09	16.01	66.7	83.33	100.0	11	15.91	13.67	0.0	16.67	33.3
	Week 35	10	83.34	16.20	66.7	83.34	100.0	9	9.26	20.17	-33.3	8.33	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Absent	EV+Pembro (N=192)												
	BASELINE	167	77.60	19.19	8.3	83.33	100.0						
	Week 1	158	80.27	18.51	16.7	83.33	100.0	152	2.08	15.05	-50.0	0.00	58.3
	Week 2	166	80.02	19.18	0.0	83.33	100.0	156	1.92	16.31	-58.3	0.00	66.7
	Week 3	164	80.03	18.48	25.0	83.33	100.0	153	1.80	18.80	-50.0	0.00	91.7
	Week 4	158	82.49	18.32	0.0	83.33	100.0	148	3.72	17.96	-50.0	0.00	91.7
	Week 5	160	83.39	16.20	41.7	83.33	100.0	149	4.25	19.44	-58.3	0.00	91.7
	Week 6	157	82.48	18.80	25.0	91.67	100.0	145	3.68	19.64	-66.7	0.00	58.3
	Week 7	161	82.20	19.17	8.3	91.67	100.0	148	3.04	19.25	-66.7	0.00	91.7
	Week 8	156	81.79	19.09	0.0	83.33	100.0	141	3.31	20.04	-66.7	0.00	91.7
	Week 9	163	82.21	17.99	25.0	83.33	100.0	150	4.00	18.51	-75.0	0.00	66.7
	Week 10	157	82.38	17.93	33.3	83.33	100.0	145	4.43	18.92	-41.7	0.00	58.3
	Week 11	161	83.08	18.29	8.3	91.67	100.0	147	5.22	19.80	-50.0	0.00	91.7
	Week 12	153	81.65	19.08	8.3	83.33	100.0	142	2.17	18.95	-50.0	0.00	66.7
	Week 14	154	80.63	19.98	0.0	83.33	100.0	141	2.19	18.11	-58.3	0.00	66.7
	Week 17	147	82.37	17.24	8.3	83.33	100.0	137	2.49	18.75	-50.0	0.00	66.7
	Week 20	140	81.19	20.57	0.0	83.33	100.0	130	1.86	20.68	-75.0	0.00	66.7
	Week 23	136	81.13	19.78	0.0	83.33	100.0	128	1.11	21.57	-75.0	0.00	58.3
	Week 26	131	79.52	20.21	25.0	83.33	100.0	122	0.21	21.79	-75.0	0.00	66.7
	Week 29	134	81.22	19.35	8.3	83.33	100.0	123	1.83	18.47	-58.3	0.00	50.0
	Week 32	114	81.14	18.62	0.0	83.33	100.0	106	0.94	18.87	-83.3	0.00	50.0
	Week 35	113	81.78	19.72	8.3	83.33	100.0	105	1.43	17.54	-58.3	0.00	41.7
	Week 38	114	82.68	17.53	25.0	83.33	100.0	107	1.87	19.27	-66.7	0.00	58.3
	Week 41	109	79.05	21.23	8.3	83.33	100.0	100	-1.75	21.75	-75.0	0.00	58.3
	Week 44	91	79.85	20.03	25.0	83.33	100.0	85	-0.20	22.71	-66.7	0.00	58.3
	Week 47	82	80.49	19.30	25.0	83.33	100.0	78	0.75	19.28	-58.3	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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Table 302.1.3002.12.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	77	81.17	19.42	33.3	83.33	100.0	73	1.14	21.53	-66.7	0.00	41.7
	Week 53	67	80.60	20.23	33.3	83.33	100.0	63	-1.06	20.44	-58.3	0.00	50.0
	Week 56	68	81.01	18.93	33.3	83.33	100.0	64	2.60	19.47	-41.7	0.00	50.0
	Week 59	60	78.89	19.68	33.3	79.17	100.0	57	-0.88	19.52	-58.3	0.00	33.3
	Week 62	55	80.91	18.95	33.3	83.33	100.0	54	-0.16	19.26	-50.0	0.00	33.3
	Week 65	48	77.60	20.42	33.3	75.00	100.0	45	-2.41	18.69	-41.7	0.00	33.3
	Week 68	46	78.62	20.46	33.3	79.17	100.0	45	-1.67	18.26	-50.0	0.00	25.0
	Week 71	44	81.63	18.64	33.3	83.33	100.0	42	-0.20	19.43	-58.3	0.00	33.3
	Week 74	40	81.46	20.89	33.3	91.67	100.0	39	0.00	20.94	-50.0	0.00	33.3
	Week 77	38	78.73	18.95	41.7	75.00	100.0	36	-1.16	21.56	-50.0	0.00	33.3
	Week 80	35	79.76	18.44	41.7	75.00	100.0	32	1.56	20.79	-50.0	4.17	41.7
	Week 83	32	78.65	19.16	33.3	75.00	100.0	30	0.83	21.03	-58.3	8.33	25.0
	Week 86	29	79.60	18.84	41.7	75.00	100.0	26	1.28	22.32	-50.0	8.33	33.3
	Week 89	29	75.29	22.10	33.3	66.67	100.0	27	-1.54	19.62	-33.3	0.00	33.3
	Week 92	24	75.70	23.56	25.0	70.84	100.0	22	-1.52	24.48	-50.0	4.17	33.3
	Week 95	20	77.08	19.47	33.3	79.17	100.0	19	0.00	20.41	-41.7	0.00	25.0
	Week 98	18	78.24	20.84	41.7	70.84	100.0	17	3.43	25.53	-58.3	8.33	41.7
	Week 101	13	79.49	25.82	33.3	91.67	100.0	13	-0.64	24.17	-66.7	8.33	25.0
	Plat+Gem (N=194)												
	BASELINE	155	74.57	22.13	0.0	75.00	100.0						
	Week 1	142	77.00	21.52	0.0	83.33	100.0	131	2.23	17.60	-66.7	0.00	50.0
	Week 2	142	75.47	22.12	0.0	75.00	100.0	127	-0.33	17.52	-66.7	0.00	75.0
	Week 3	152	78.45	20.76	8.3	83.33	100.0	135	3.15	16.69	-41.7	0.00	66.7
	Week 4	151	78.20	20.02	0.0	83.33	100.0	132	2.72	18.38	-75.0	0.00	75.0
	Week 5	151	77.21	21.81	0.0	83.33	100.0	128	0.33	19.15	-66.7	0.00	41.7
	Week 6	139	78.72	21.73	0.0	83.33	100.0	122	2.12	16.44	-58.3	0.00	41.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 7	148	78.55	20.39	8.3	83.33	100.0	128	1.82	17.84	-66.7	0.00	75.0
	Week 8	136	75.12	24.17	0.0	79.17	100.0	119	0.28	22.13	-100.0	0.00	58.3
	Week 9	145	77.36	20.94	16.7	75.00	100.0	125	1.53	18.80	-66.7	0.00	50.0
	Week 10	132	77.46	20.97	0.0	75.00	100.0	113	1.18	18.29	-100.0	0.00	50.0
	Week 11	138	76.39	22.80	0.0	83.33	100.0	119	0.56	17.45	-41.7	0.00	50.0
	Week 12	131	76.97	21.36	33.3	75.00	100.0	115	1.01	19.34	-58.3	0.00	50.0
	Week 14	127	75.72	22.64	0.0	75.00	100.0	107	-0.23	20.75	-58.3	0.00	66.7
	Week 17	125	77.33	22.42	0.0	83.33	100.0	105	-0.48	22.52	-91.7	0.00	58.3
	Week 20	103	80.42	20.70	16.7	83.33	100.0	89	2.43	19.59	-58.3	0.00	58.3
	Week 23	93	83.51	20.04	8.3	91.67	100.0	78	4.38	21.18	-66.7	4.17	58.3
	Week 26	89	78.84	24.13	0.0	83.33	100.0	77	-1.84	21.57	-66.7	0.00	41.7
	Week 29	84	83.14	18.88	33.3	91.67	100.0	72	1.27	17.84	-58.3	0.00	41.7
	Week 32	72	81.37	21.51	16.7	87.50	100.0	65	0.26	18.63	-66.7	0.00	33.3
	Week 35	66	82.58	18.30	33.3	83.33	100.0	60	2.64	16.20	-33.3	0.00	41.7
	Week 38	66	84.85	17.78	25.0	91.67	100.0	57	3.95	20.96	-66.7	0.00	41.7
	Week 41	62	84.54	18.53	33.3	91.67	100.0	53	2.99	20.22	-66.7	0.00	41.7
	Week 44	55	81.82	19.52	33.3	83.33	100.0	48	-0.52	18.94	-66.7	0.00	41.7
	Week 47	51	85.13	17.82	33.3	91.67	100.0	44	2.46	19.57	-66.7	0.00	41.7
	Week 50	48	85.76	16.57	50.0	91.67	100.0	44	1.70	17.29	-33.3	0.00	33.3
	Week 53	41	86.99	15.26	50.0	100.00	100.0	37	1.35	15.65	-33.3	0.00	25.0
	Week 56	34	84.56	21.03	16.7	100.00	100.0	29	2.87	17.58	-41.7	0.00	33.3
	Week 59	32	87.24	16.12	41.7	91.67	100.0	28	0.89	17.91	-50.0	0.00	25.0
	Week 62	27	86.42	16.20	50.0	91.67	100.0	24	3.12	14.91	-33.3	0.00	25.0
	Week 65	25	92.33	11.00	66.7	100.00	100.0	21	4.76	10.73	-16.7	0.00	25.0
	Week 68	23	86.23	15.81	50.0	91.67	100.0	19	-0.88	14.14	-25.0	0.00	25.0
	Week 71	21	82.14	21.94	25.0	91.67	100.0	18	-2.78	17.62	-41.7	0.00	25.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 74	20	81.67	21.22	33.3	87.50	100.0	17	-0.98	16.11	-33.3	0.00	16.7
	Week 77	16	80.73	24.67	33.3	91.67	100.0	13	-3.21	23.21	-66.7	0.00	25.0
	Week 80	12	86.81	17.93	50.0	100.00	100.0	11	2.27	14.48	-25.0	0.00	25.0
	Week 83	11	85.61	16.70	50.0	91.67	100.0	10	3.33	17.65	-25.0	0.00	33.3
	Week 86	10	91.67	13.61	66.7	100.00	100.0	9	4.63	14.50	-25.0	0.00	25.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
< 65 years	EV+Pembro (N=105)												
	BASELINE	92	72.92	21.42	16.7	75.00	100.0						
	Week 1	88	78.22	18.93	25.0	83.33	100.0	85	3.73	13.39	-41.7	0.00	33.3
	Week 2	92	77.99	19.98	16.7	79.17	100.0	86	4.36	15.00	-58.3	0.00	50.0
	Week 3	93	78.59	18.73	33.3	83.33	100.0	84	4.86	16.98	-41.7	0.00	58.3
	Week 4	90	81.30	17.64	33.3	83.33	100.0	82	7.32	16.11	-50.0	0.00	58.3
	Week 5	90	83.80	15.27	33.3	87.50	100.0	81	8.95	19.13	-25.0	8.33	66.7
	Week 6	90	84.72	17.09	33.3	91.67	100.0	81	9.88	17.03	-33.3	8.33	58.3
	Week 7	85	83.53	16.86	41.7	83.33	100.0	77	8.55	17.52	-25.0	0.00	66.7
	Week 8	89	81.93	19.35	16.7	91.67	100.0	80	8.44	18.73	-33.3	0.00	58.3
	Week 9	93	80.47	18.37	16.7	83.33	100.0	85	7.35	19.09	-41.7	8.33	66.7
	Week 10	88	82.29	16.94	33.3	83.33	100.0	81	8.75	18.63	-33.3	8.33	58.3
	Week 11	93	82.89	16.86	33.3	83.33	100.0	84	10.42	18.52	-33.3	8.33	66.7
	Week 12	86	81.78	17.13	33.3	83.33	100.0	79	6.75	19.57	-33.3	0.00	66.7
	Week 14	84	79.17	21.74	0.0	83.33	100.0	76	6.03	19.98	-50.0	0.00	66.7
	Week 17	83	81.13	17.42	41.7	83.33	100.0	77	6.93	20.87	-50.0	0.00	66.7
	Week 20	79	78.48	20.91	16.7	83.33	100.0	73	4.91	24.88	-75.0	0.00	66.7
	Week 23	78	79.60	18.05	25.0	83.33	100.0	73	5.14	21.46	-50.0	0.00	58.3
	Week 26	78	80.02	18.72	33.3	83.33	100.0	72	6.13	22.16	-41.7	0.00	66.7
	Week 29	74	79.39	21.69	8.3	83.33	100.0	67	5.35	22.04	-58.3	0.00	58.3
	Week 32	64	79.30	17.38	33.3	83.33	100.0	59	5.37	19.06	-50.0	0.00	50.0
	Week 35	62	80.78	21.16	8.3	83.33	100.0	58	4.88	17.32	-50.0	4.17	41.7
	Week 38	62	81.59	18.91	25.0	83.33	100.0	59	4.52	20.55	-66.7	0.00	58.3
	Week 41	64	79.17	22.07	16.7	83.33	100.0	59	2.83	21.42	-66.7	0.00	58.3
	Week 44	50	77.83	21.73	25.0	75.00	100.0	48	2.43	23.88	-66.7	0.00	58.3
	Week 47	47	77.84	23.40	8.3	83.33	100.0	46	1.09	21.20	-58.3	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	44	79.36	21.75	16.7	87.50	100.0	41	3.46	21.33	-50.0	8.33	41.7
	Week 53	40	80.21	23.92	8.3	87.50	100.0	37	1.12	22.32	-58.3	0.00	50.0
	Week 56	44	81.63	19.98	16.7	83.33	100.0	41	6.50	18.49	-25.0	8.33	50.0
	Week 59	42	80.56	20.80	25.0	87.50	100.0	39	3.63	20.75	-58.3	0.00	41.7
	Week 62	37	79.50	21.12	16.7	83.33	100.0	36	2.55	20.69	-50.0	0.00	41.7
	Week 65	34	76.72	24.34	0.0	75.00	100.0	31	1.88	20.72	-33.3	0.00	41.7
	Week 68	34	78.68	20.43	33.3	79.17	100.0	33	3.28	18.04	-41.7	8.33	41.7
	Week 71	32	80.21	20.60	33.3	83.33	100.0	30	3.33	22.60	-58.3	0.00	41.7
	Week 74	29	77.59	24.20	33.3	91.67	100.0	28	0.60	23.12	-50.0	0.00	41.7
	Week 77	25	76.33	19.50	41.7	75.00	100.0	24	2.78	23.01	-50.0	8.33	41.7
	Week 80	24	76.39	18.17	41.7	70.84	100.0	22	5.68	22.33	-41.7	8.34	41.7
	Week 83	23	73.19	19.62	33.3	66.67	100.0	22	1.52	23.52	-58.3	8.33	41.7
	Week 86	20	75.00	19.31	41.7	66.67	100.0	18	3.24	25.11	-50.0	8.33	41.7
	Week 89	19	72.37	21.88	33.3	66.67	100.0	17	3.92	20.44	-33.3	0.00	41.7
	Week 92	14	71.43	20.34	41.7	66.67	100.0	12	-0.69	22.32	-50.0	0.00	33.3
	Week 95	12	70.83	13.99	50.0	66.67	100.0	11	0.76	16.44	-25.0	0.00	25.0
	Plat+Gem (N=106)												
	BASELINE	83	71.59	19.74	25.0	66.67	100.0						
	Week 1	75	74.22	21.19	0.0	75.00	100.0	71	2.70	16.11	-58.3	0.00	33.3
	Week 2	76	72.26	24.21	16.7	75.00	100.0	68	0.00	17.28	-66.7	0.00	33.3
	Week 3	80	75.52	24.06	8.3	83.33	100.0	73	2.97	17.37	-41.7	0.00	50.0
	Week 4	79	76.69	19.99	8.3	75.00	100.0	67	3.11	13.98	-41.7	0.00	33.3
	Week 5	80	75.31	23.21	16.7	75.00	100.0	67	2.49	18.75	-33.3	0.00	41.7
	Week 6	76	77.63	21.65	16.7	79.17	100.0	67	5.10	16.28	-33.3	0.00	41.7
	Week 7	81	77.78	21.61	8.3	83.33	100.0	71	6.10	15.10	-33.3	8.33	33.3
	Week 8	72	76.39	20.70	16.7	83.33	100.0	64	4.43	16.53	-41.7	0.00	41.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	78	75.53	19.06	33.3	75.00	100.0	69	4.23	16.27	-33.3	8.33	41.7
	Week 10	78	75.32	21.72	0.0	75.00	100.0	68	3.80	15.20	-33.3	0.00	33.3
	Week 11	75	75.33	23.23	0.0	75.00	100.0	66	4.17	17.98	-41.7	4.17	50.0
	Week 12	74	78.27	20.31	33.3	83.33	100.0	66	5.30	17.27	-50.0	8.33	50.0
	Week 14	68	77.21	20.75	16.7	79.17	100.0	58	3.59	20.60	-58.3	8.33	50.0
	Week 17	68	77.08	22.92	0.0	79.17	100.0	58	3.02	20.51	-58.3	0.00	50.0
	Week 20	60	79.86	19.96	25.0	83.33	100.0	52	5.61	18.80	-58.3	8.33	41.7
	Week 23	51	82.35	21.84	8.3	91.67	100.0	44	7.58	19.42	-50.0	8.34	41.7
	Week 26	47	78.55	24.86	0.0	83.33	100.0	42	2.98	22.00	-66.7	4.17	41.7
	Week 29	42	82.54	18.93	41.7	87.50	100.0	37	6.31	18.47	-41.7	8.33	41.7
	Week 32	37	79.96	19.69	16.7	75.00	100.0	34	4.66	14.82	-25.0	4.17	33.3
	Week 35	34	84.07	16.71	41.7	91.67	100.0	31	7.53	17.39	-33.3	8.33	41.7
	Week 38	33	85.35	16.54	25.0	83.33	100.0	28	8.93	18.69	-25.0	8.33	41.7
	Week 41	27	84.57	16.46	41.7	83.33	100.0	22	8.71	15.32	-16.7	8.33	41.7
	Week 44	28	80.66	19.91	33.3	79.17	100.0	24	1.04	19.86	-41.7	4.17	41.7
	Week 47	24	87.85	14.74	66.7	100.00	100.0	21	6.75	19.12	-33.3	8.34	41.7
	Week 50	26	86.22	16.99	50.0	91.67	100.0	24	4.86	17.54	-33.3	8.33	33.3
	Week 53	19	88.16	13.98	66.7	100.00	100.0	17	4.90	16.68	-33.3	8.33	25.0
	Week 56	13	86.54	15.79	66.7	100.00	100.0	11	5.30	19.10	-33.3	8.33	25.0
	Week 59	14	89.29	14.03	66.7	95.84	100.0	12	3.47	16.07	-33.3	8.33	25.0
	Week 62	13	83.98	17.83	50.0	91.67	100.0	12	2.08	18.84	-33.3	8.33	25.0
	Week 65	13	89.74	12.80	66.7	91.67	100.0	11	1.52	17.00	-33.3	8.33	25.0
	Week 68	10	87.50	15.84	58.3	95.84	100.0	8	2.08	17.11	-25.0	8.33	25.0
	Week 77	10	84.17	22.38	33.3	91.67	100.0	8	7.29	18.06	-16.7	8.33	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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Table 302.1.3002.12.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>= 65 years	EV+Pembro (N=135)												
	BASELINE	114	78.14	19.05	8.3	83.33	100.0						
	Week 1	102	79.82	19.81	16.7	83.33	100.0	99	1.77	17.10	-50.0	0.00	58.3
	Week 2	111	79.43	19.16	0.0	83.33	100.0	103	0.57	17.86	-41.7	0.00	66.7
	Week 3	105	77.70	21.01	0.0	83.33	100.0	98	-0.94	20.37	-50.0	0.00	91.7
	Week 4	104	79.97	21.27	0.0	83.33	100.0	97	0.43	19.41	-50.0	0.00	91.7
	Week 5	100	79.83	19.43	16.7	83.33	100.0	92	1.00	20.18	-58.3	0.00	91.7
	Week 6	98	77.47	21.24	16.7	75.00	100.0	89	-1.68	21.07	-66.7	0.00	58.3
	Week 7	110	78.18	23.08	0.0	83.33	100.0	99	-0.42	21.17	-75.0	0.00	91.7
	Week 8	102	77.62	22.56	0.0	83.33	100.0	91	-1.37	19.92	-66.7	0.00	91.7
	Week 9	104	79.65	20.21	25.0	79.17	100.0	95	0.35	19.37	-75.0	0.00	58.3
	Week 10	103	79.37	21.98	0.0	83.33	100.0	94	0.80	20.23	-58.3	0.00	58.3
	Week 11	101	79.13	23.20	8.3	91.67	100.0	91	-0.73	21.14	-75.0	0.00	91.7
	Week 12	100	79.17	22.74	0.0	83.33	100.0	92	-0.63	20.90	-83.3	0.00	50.0
	Week 14	101	79.37	21.27	0.0	83.33	100.0	91	-0.46	18.40	-75.0	0.00	50.0
	Week 17	95	80.26	19.14	8.3	83.33	100.0	85	-0.59	16.31	-50.0	0.00	33.3
	Week 20	88	80.30	21.67	0.0	83.33	100.0	81	-0.62	17.76	-50.0	0.00	33.3
	Week 23	84	79.96	23.14	0.0	83.33	100.0	78	-1.28	21.87	-75.0	0.00	33.3
	Week 26	78	78.53	22.45	16.7	83.33	100.0	72	-2.66	20.64	-75.0	0.00	41.7
	Week 29	83	83.43	17.58	16.7	83.33	100.0	78	1.50	14.94	-33.3	0.00	33.3
	Week 32	71	81.22	21.58	0.0	83.33	100.0	66	-0.38	18.86	-83.3	0.00	41.7
	Week 35	70	81.07	20.31	8.3	83.33	100.0	64	-0.39	17.21	-58.3	0.00	33.3
	Week 38	70	81.79	17.91	33.3	83.33	100.0	65	0.51	17.48	-66.7	0.00	33.3
	Week 41	65	77.82	21.46	8.3	75.00	100.0	60	-3.19	21.54	-75.0	0.00	33.3
	Week 44	58	80.89	18.34	33.3	83.33	100.0	52	-0.96	20.46	-66.7	0.00	33.3
	Week 47	53	81.60	19.36	33.3	83.33	100.0	48	0.00	19.37	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	45	83.33	18.80	33.3	91.67	100.0	43	0.19	20.53	-66.7	0.00	33.3
	Week 53	39	80.77	19.60	33.3	91.67	100.0	37	-1.58	17.77	-50.0	0.00	25.0
	Week 56	37	79.05	20.94	33.3	83.33	100.0	35	-2.62	20.69	-50.0	0.00	33.3
	Week 59	30	80.00	20.25	33.3	83.33	100.0	29	-2.87	16.56	-41.7	0.00	25.0
	Week 62	28	83.03	19.18	33.3	83.33	100.0	27	-1.55	16.83	-41.7	0.00	25.0
	Week 65	24	78.47	21.97	33.3	75.00	100.0	23	-6.89	18.74	-50.0	0.00	25.0
	Week 68	19	81.14	21.67	33.3	83.33	100.0	19	-4.83	18.49	-50.0	0.00	25.0
	Week 71	19	83.77	16.31	50.0	83.33	100.0	19	-1.75	12.29	-25.0	0.00	25.0
	Week 74	18	86.57	16.20	50.0	95.84	100.0	18	2.31	15.34	-25.0	0.00	25.0
	Week 77	19	79.39	22.29	33.3	75.00	100.0	18	-5.09	21.79	-50.0	0.00	25.0
	Week 80	16	82.81	20.74	41.7	95.84	100.0	15	-1.67	19.47	-50.0	0.00	25.0
	Week 83	14	85.12	19.11	41.7	95.84	100.0	13	2.56	17.80	-25.0	0.00	25.0
	Week 86	14	86.31	18.38	41.7	95.84	100.0	13	3.21	18.17	-33.3	0.00	25.0
	Week 89	14	80.36	22.31	41.7	87.50	100.0	14	-1.79	20.97	-33.3	4.17	25.0
	Week 92	13	81.41	27.46	25.0	100.00	100.0	13	-1.28	24.50	-41.7	8.33	25.0
	Week 95	10	80.83	23.91	33.3	91.67	100.0	10	-0.84	25.90	-41.7	8.33	25.0
	Week 98	10	77.50	24.23	41.7	83.34	100.0	10	-3.33	29.19	-58.3	8.33	25.0
	Plat+Gem (N=136)												
	BASELINE	105	75.00	23.34	0.0	75.00	100.0						
	Week 1	98	77.04	23.11	0.0	83.33	100.0	87	2.01	18.81	-66.7	0.00	50.0
	Week 2	95	77.46	20.19	0.0	83.33	100.0	83	1.61	18.61	-50.0	0.00	75.0
	Week 3	104	81.25	17.83	33.3	83.33	100.0	89	5.43	17.95	-41.7	0.00	66.7
	Week 4	104	80.13	19.95	0.0	83.33	100.0	89	3.75	21.98	-75.0	0.00	75.0
	Week 5	107	78.74	20.36	0.0	83.33	100.0	89	0.94	19.28	-66.7	0.00	41.7
	Week 6	98	78.66	22.80	0.0	83.33	100.0	82	1.93	17.29	-58.3	0.00	41.7
	Week 7	105	78.49	19.87	25.0	75.00	100.0	86	0.39	19.51	-66.7	0.00	75.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 8	95	75.79	24.55	0.0	75.00	100.0	80	-1.35	23.74	-100.0	0.00	58.3
	Week 9	99	78.45	21.72	16.7	83.33	100.0	81	2.16	19.89	-66.7	0.00	50.0
	Week 10	88	78.69	21.25	0.0	83.33	100.0	71	1.29	21.21	-100.0	0.00	50.0
	Week 11	93	78.41	21.95	16.7	83.33	100.0	77	1.30	17.52	-41.7	0.00	41.7
	Week 12	85	77.35	21.35	33.3	75.00	100.0	72	0.46	20.17	-58.3	0.00	50.0
	Week 14	85	75.88	22.35	0.0	75.00	100.0	70	0.36	19.73	-50.0	0.00	66.7
	Week 17	87	78.26	20.86	8.3	75.00	100.0	72	0.12	22.53	-91.7	0.00	58.3
	Week 20	66	80.68	20.99	16.7	83.33	100.0	58	2.15	19.41	-50.0	0.00	58.3
	Week 23	64	83.33	18.54	33.3	91.67	100.0	53	3.30	19.97	-66.7	0.00	58.3
	Week 26	61	81.01	21.79	0.0	83.33	100.0	53	-1.42	19.39	-66.7	0.00	33.3
	Week 29	58	83.91	18.33	33.3	91.67	100.0	49	-0.51	18.35	-58.3	0.00	33.3
	Week 32	46	83.15	21.77	25.0	91.67	100.0	42	0.79	21.45	-66.7	0.00	33.3
	Week 35	42	81.55	19.00	33.3	83.33	100.0	38	0.22	15.68	-33.3	0.00	33.3
	Week 38	41	84.96	18.18	33.3	91.67	100.0	37	0.67	20.54	-66.7	0.00	33.3
	Week 41	38	82.90	21.31	33.3	91.67	100.0	34	-0.98	21.40	-66.7	0.00	33.3
	Week 44	32	82.55	18.62	33.3	87.50	100.0	29	-2.01	18.32	-66.7	0.00	25.0
	Week 47	32	82.29	19.25	33.3	87.50	100.0	28	-1.79	19.69	-66.7	0.00	25.0
	Week 50	25	85.33	16.19	58.3	91.67	100.0	23	-1.09	18.68	-33.3	0.00	33.3
	Week 53	27	86.42	15.87	50.0	91.67	100.0	25	-0.33	16.04	-33.3	0.00	25.0
	Week 56	26	81.73	22.73	16.7	95.84	100.0	23	-0.73	18.79	-41.7	0.00	33.3
	Week 59	23	84.42	16.72	41.7	91.67	100.0	21	-1.59	19.65	-50.0	0.00	25.0
	Week 62	19	86.84	14.25	58.3	91.67	100.0	17	2.45	14.06	-33.3	0.00	25.0
	Week 65	17	91.67	11.02	66.7	91.67	100.0	15	5.56	9.79	-8.3	0.00	25.0
	Week 68	15	86.11	15.64	50.0	91.67	100.0	13	-1.28	13.54	-16.7	0.00	25.0
	Week 71	15	82.22	20.62	25.0	91.67	100.0	13	-5.77	18.13	-41.7	0.00	25.0
	Week 74	12	86.81	17.57	41.7	91.67	100.0	11	1.51	14.35	-25.0	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Europe	EV+Pembro (N= 98)												
	BASELINE	79	72.47	22.89	16.7	75.00	100.0						
	Week 1	74	78.49	20.60	16.7	83.33	100.0	71	5.16	14.60	-33.3	0.00	41.7
	Week 2	79	78.59	21.25	0.0	83.33	100.0	71	4.23	17.64	-58.3	0.00	50.0
	Week 3	78	77.35	19.64	33.3	75.00	100.0	69	4.47	17.77	-41.7	0.00	58.3
	Week 4	78	80.56	20.57	0.0	83.33	100.0	70	5.48	17.02	-50.0	4.17	41.7
	Week 5	70	81.79	16.62	33.3	83.33	100.0	62	6.59	19.68	-41.7	8.33	58.3
	Week 6	70	82.50	18.56	16.7	91.67	100.0	61	6.97	20.42	-66.7	8.33	41.7
	Week 7	78	81.20	18.53	25.0	83.33	100.0	68	6.01	16.41	-33.3	0.00	50.0
	Week 8	72	79.17	20.60	16.7	83.33	100.0	61	6.15	18.87	-41.7	0.00	50.0
	Week 9	80	78.75	20.06	25.0	75.00	100.0	70	3.93	19.33	-58.3	0.00	58.3
	Week 10	71	80.63	19.51	33.3	83.33	100.0	62	8.47	19.65	-33.3	8.33	50.0
	Week 11	76	79.72	21.49	8.3	91.67	100.0	66	6.44	20.87	-75.0	8.33	58.3
	Week 12	73	79.79	22.35	0.0	83.33	100.0	65	4.23	20.79	-83.3	0.00	41.7
	Week 14	74	79.39	20.97	0.0	83.33	100.0	64	5.60	17.70	-50.0	0.00	41.7
	Week 17	70	80.48	17.08	33.3	83.33	100.0	62	6.05	17.67	-50.0	4.17	50.0
	Week 20	70	78.57	20.14	16.7	83.33	100.0	63	4.37	20.02	-50.0	0.00	50.0
	Week 23	61	78.28	20.54	25.0	83.33	100.0	57	3.80	21.88	-50.0	0.00	50.0
	Week 26	62	80.65	18.83	25.0	83.33	100.0	55	6.67	16.07	-33.3	0.00	41.7
	Week 29	63	79.50	20.24	8.3	83.33	100.0	57	4.24	17.12	-58.3	0.00	41.7
	Week 32	51	77.94	18.77	33.3	75.00	100.0	47	5.50	15.08	-50.0	0.00	33.3
	Week 35	56	80.06	19.18	41.7	83.33	100.0	52	3.20	15.05	-50.0	0.00	41.7
	Week 38	51	81.54	18.58	25.0	83.33	100.0	48	3.47	18.26	-66.7	0.00	33.3
	Week 41	52	77.40	22.77	16.7	83.33	100.0	48	2.08	17.82	-66.7	0.00	41.7
	Week 44	43	78.68	20.44	25.0	75.00	100.0	39	2.56	19.42	-66.7	0.00	58.3
	Week 47	39	76.28	24.15	8.3	75.00	100.0	36	0.93	20.68	-58.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	37	82.88	20.31	16.7	91.67	100.0	36	6.95	17.65	-50.0	8.33	41.7
	Week 53	28	80.06	26.48	8.3	95.84	100.0	27	4.01	21.85	-58.3	8.33	50.0
	Week 56	30	78.89	22.40	16.7	83.33	100.0	29	4.60	18.17	-50.0	8.33	33.3
	Week 59	27	83.33	22.05	25.0	100.00	100.0	27	7.72	18.48	-58.3	8.33	33.3
	Week 62	23	80.07	23.53	16.7	91.67	100.0	23	2.90	17.70	-50.0	0.00	25.0
	Week 65	23	76.09	28.46	0.0	91.67	100.0	23	0.00	20.26	-50.0	0.00	25.0
	Week 68	21	81.75	22.15	33.3	91.67	100.0	21	6.75	13.60	-41.7	8.33	25.0
	Week 71	19	82.90	21.06	33.3	91.67	100.0	19	7.02	20.08	-58.3	8.33	33.3
	Week 74	15	80.00	25.55	41.7	91.67	100.0	15	3.89	19.38	-50.0	8.33	33.3
	Week 77	19	76.75	23.17	33.3	75.00	100.0	19	2.63	22.58	-50.0	8.33	33.3
	Week 80	17	81.37	20.73	41.7	91.67	100.0	17	8.33	19.54	-41.7	8.33	41.7
	Week 83	16	76.04	22.95	33.3	70.84	100.0	16	4.17	20.41	-58.3	8.33	25.0
	Week 86	14	81.55	21.72	41.7	91.67	100.0	14	6.55	19.39	-50.0	8.33	33.3
	Week 89	14	79.17	22.59	33.3	83.34	100.0	14	4.17	17.83	-33.3	8.33	33.3
	Week 92	11	82.58	23.99	41.7	100.00	100.0	11	6.06	21.11	-50.0	8.33	33.3
	Week 95	10	76.67	17.48	58.3	66.67	100.0	10	2.50	18.86	-25.0	8.33	25.0
	Plat+Gem (N=102)												
	BASELINE	71	68.90	24.36	0.0	75.00	100.0						
	Week 1	71	71.36	26.00	0.0	83.33	100.0	61	3.28	20.14	-66.7	0.00	50.0
	Week 2	67	72.14	23.59	0.0	75.00	100.0	56	1.94	19.40	-41.7	0.00	75.0
	Week 3	68	75.98	22.33	8.3	83.33	100.0	56	6.10	19.69	-41.7	4.17	66.7
	Week 4	75	77.00	19.51	8.3	83.33	100.0	59	4.66	17.32	-41.7	0.00	66.7
	Week 5	77	75.76	24.42	0.0	83.33	100.0	60	1.67	23.26	-66.7	0.00	41.7
	Week 6	70	76.19	22.53	16.7	79.17	100.0	56	4.91	17.61	-58.3	4.17	41.7
	Week 7	72	75.35	22.40	8.3	75.00	100.0	55	3.03	19.67	-66.7	0.00	75.0
	Week 8	65	70.39	25.26	0.0	66.67	100.0	53	0.63	26.19	-100.0	0.00	58.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	70	72.26	23.39	16.7	70.84	100.0	55	2.88	20.30	-66.7	8.33	50.0
	Week 10	60	70.14	24.47	0.0	66.67	100.0	46	-1.99	22.44	-100.0	0.00	50.0
	Week 11	64	69.79	25.18	0.0	66.67	100.0	50	-2.00	17.62	-33.3	0.00	33.3
	Week 12	60	73.20	21.65	33.3	75.00	100.0	48	1.91	19.69	-50.0	0.00	50.0
	Week 14	56	69.20	23.94	0.0	66.67	100.0	42	-2.18	24.21	-58.3	0.00	66.7
	Week 17	58	74.57	21.48	8.3	75.00	100.0	44	1.33	23.50	-91.7	0.00	58.3
	Week 20	47	80.85	19.50	41.7	83.33	100.0	37	6.98	19.50	-41.7	8.33	58.3
	Week 23	44	82.77	17.65	41.7	87.50	100.0	32	8.33	19.97	-41.7	8.33	58.3
	Week 26	39	75.86	24.02	0.0	75.00	100.0	30	-0.28	17.30	-58.3	0.00	25.0
	Week 29	34	78.92	21.44	33.3	83.33	100.0	25	3.67	19.99	-33.3	0.00	41.7
	Week 32	33	78.54	22.25	25.0	83.33	100.0	27	1.85	20.59	-41.7	0.00	33.3
	Week 35	30	79.17	19.67	33.3	79.17	100.0	24	4.86	18.70	-33.3	0.00	41.7
	Week 38	26	82.05	20.37	25.0	87.50	100.0	21	3.97	21.18	-50.0	8.33	33.3
	Week 41	22	79.55	22.53	33.3	87.50	100.0	17	1.47	18.69	-41.7	0.00	41.7
	Week 44	20	77.08	22.11	33.3	79.17	100.0	16	-1.04	15.77	-41.7	0.00	25.0
	Week 47	16	82.81	19.36	33.3	91.67	100.0	12	4.17	19.30	-25.0	4.17	41.7
	Week 50	11	81.06	17.11	58.3	75.00	100.0	10	-0.83	22.03	-33.3	0.00	33.3
	Week 53	11	84.09	14.65	66.7	83.33	100.0	10	0.00	15.71	-25.0	0.00	25.0
	Week 56	10	80.83	28.34	16.7	95.84	100.0	8	4.17	21.36	-41.7	4.17	25.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
North America	EV+Pembro (N= 57)												
	BASELINE	47	77.66	16.31	33.3	75.00	100.0						
	Week 1	39	79.49	19.95	16.7	83.33	100.0	37	1.35	16.14	-41.7	0.00	25.0
	Week 2	44	78.60	19.80	16.7	83.33	100.0	42	0.79	14.35	-33.3	0.00	25.0
	Week 3	44	77.84	18.41	25.0	83.33	100.0	40	0.00	15.45	-41.7	0.00	25.0
	Week 4	44	80.11	17.81	33.3	79.17	100.0	41	2.03	15.34	-41.7	0.00	33.3
	Week 5	47	81.38	16.60	33.3	83.33	100.0	41	2.24	14.91	-25.0	0.00	33.3
	Week 6	44	79.17	22.48	25.0	83.33	100.0	39	2.14	17.80	-50.0	0.00	50.0
	Week 7	46	80.25	20.74	8.3	83.33	100.0	42	1.79	15.78	-41.7	0.00	33.3
	Week 8	47	81.21	19.92	16.7	83.33	100.0	42	2.98	16.85	-33.3	0.00	50.0
	Week 9	46	78.81	19.22	16.7	79.17	100.0	42	1.19	16.11	-41.7	0.00	33.3
	Week 10	47	81.74	18.77	33.3	91.67	100.0	44	3.41	17.08	-41.7	0.00	33.3
	Week 11	47	83.16	19.15	8.3	91.67	100.0	42	5.16	15.28	-41.7	4.17	33.3
	Week 12	44	80.11	19.04	25.0	83.33	100.0	40	2.08	17.06	-33.3	0.00	41.7
	Week 14	43	79.07	20.60	25.0	83.33	100.0	39	0.64	14.98	-58.3	0.00	25.0
	Week 17	40	79.38	21.01	8.3	83.33	100.0	37	-0.23	19.09	-50.0	0.00	33.3
	Week 20	38	80.70	23.97	0.0	91.67	100.0	35	3.33	22.07	-50.0	0.00	58.3
	Week 23	38	82.68	22.04	0.0	91.67	100.0	35	4.05	20.65	-50.0	0.00	41.7
	Week 26	35	84.05	18.67	41.7	91.67	100.0	32	6.25	21.59	-41.7	0.00	50.0
	Week 29	38	85.53	18.95	16.7	91.67	100.0	34	5.88	19.08	-33.3	0.00	58.3
	Week 32	32	83.85	19.74	0.0	83.33	100.0	29	1.44	22.83	-83.3	0.00	41.7
	Week 35	33	84.60	20.21	8.3	91.67	100.0	30	5.00	16.46	-33.3	8.33	33.3
	Week 38	32	86.20	14.29	50.0	91.67	100.0	29	6.03	13.16	-16.7	8.33	33.3
	Week 41	28	88.10	13.31	58.3	91.67	100.0	24	8.33	17.89	-33.3	8.33	50.0
	Week 44	21	83.33	17.08	41.7	83.33	100.0	20	2.92	22.66	-58.3	4.17	33.3
	Week 47	24	86.11	15.86	58.3	91.67	100.0	23	3.99	17.92	-25.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	23	82.97	16.57	33.3	83.33	100.0	20	3.33	20.48	-50.0	0.00	41.7
	Week 53	17	86.77	13.52	66.7	91.67	100.0	14	4.17	16.90	-25.0	4.17	25.0
	Week 56	20	86.25	13.32	58.3	91.67	100.0	17	10.29	19.88	-33.3	16.66	50.0
	Week 59	17	80.88	14.96	58.3	75.00	100.0	14	0.00	17.90	-33.3	-4.17	25.0
	Week 62	14	87.50	13.77	58.3	87.50	100.0	13	7.05	19.50	-25.0	0.00	33.3
	Week 65	12	86.11	13.91	66.7	87.50	100.0	9	6.48	15.46	-8.3	0.00	33.3
	Week 68	10	85.00	15.62	58.3	87.50	100.0	9	-1.85	16.02	-33.3	0.00	25.0
	Week 71	10	90.00	12.91	66.7	95.84	100.0	8	2.08	18.23	-16.7	0.00	33.3
	Week 74	10	92.50	12.70	66.7	100.00	100.0	9	8.33	18.63	-25.0	8.33	33.3
	Plat+Gem (N= 51)												
	BASELINE	42	78.77	18.33	25.0	75.00	100.0						
	Week 1	41	78.46	20.66	8.3	83.33	100.0	36	0.93	11.58	-25.0	0.00	33.3
	Week 2	38	78.73	19.25	25.0	75.00	100.0	33	-0.25	10.52	-25.0	0.00	25.0
	Week 3	40	83.75	17.80	16.7	91.67	100.0	35	3.57	11.12	-16.7	0.00	33.3
	Week 4	35	82.38	18.83	33.3	91.67	100.0	29	1.72	15.33	-58.3	0.00	16.7
	Week 5	39	81.41	16.16	41.7	83.33	100.0	32	2.34	12.39	-25.0	0.00	33.3
	Week 6	34	84.07	18.39	33.3	91.67	100.0	30	4.44	9.72	-25.0	0.00	25.0
	Week 7	42	85.52	17.37	41.7	91.67	100.0	37	5.86	12.86	-25.0	0.00	33.3
	Week 8	39	83.76	18.63	33.3	91.67	100.0	33	3.53	15.46	-33.3	0.00	41.7
	Week 9	39	82.69	18.07	33.3	91.67	100.0	33	4.29	15.18	-33.3	0.00	41.7
	Week 10	39	83.55	20.10	33.3	91.67	100.0	32	6.25	13.88	-25.0	0.00	33.3
	Week 11	39	84.40	17.75	33.3	91.67	100.0	33	7.07	15.61	-25.0	0.00	50.0
	Week 12	36	85.19	16.20	41.7	91.67	100.0	32	5.99	14.24	-25.0	4.17	50.0
	Week 14	34	86.28	13.74	41.7	91.67	100.0	29	8.05	17.75	-33.3	8.33	50.0
	Week 17	37	83.11	17.62	25.0	83.33	100.0	31	2.96	17.55	-33.3	0.00	50.0
	Week 20	27	79.94	15.72	41.7	83.33	100.0	23	1.81	13.29	-25.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 23	27	85.49	19.42	41.7	91.67	100.0	23	3.26	15.02	-41.7	8.33	25.0
	Week 26	28	81.85	22.46	8.3	91.67	100.0	25	0.33	19.47	-66.7	0.00	33.3
	Week 29	29	84.20	17.59	41.7	91.67	100.0	25	0.67	17.33	-41.7	0.00	25.0
	Week 32	17	82.35	23.36	16.7	100.00	100.0	17	1.96	13.35	-25.0	0.00	33.3
	Week 35	16	83.33	19.00	41.7	91.67	100.0	15	0.56	12.39	-33.3	0.00	16.7
	Week 38	16	86.98	12.53	66.7	91.67	100.0	13	2.56	14.98	-25.0	0.00	33.3
	Week 41	16	85.42	13.44	66.7	83.33	100.0	13	1.92	18.37	-33.3	0.00	33.3
	Week 44	13	85.26	14.09	66.7	83.33	100.0	11	-3.03	14.56	-25.0	0.00	16.7
	Week 47	11	90.15	11.07	66.7	91.67	100.0	9	0.00	13.82	-16.7	0.00	25.0
	Week 50	17	88.24	15.33	50.0	91.67	100.0	15	2.22	17.95	-25.0	0.00	33.3
	Week 53	13	88.46	13.83	66.7	91.67	100.0	11	0.00	17.08	-33.3	0.00	25.0
	Week 56	11	85.61	17.52	58.3	100.00	100.0	9	-0.93	17.90	-33.3	0.00	33.3
	Week 59	11	87.12	14.12	66.7	91.67	100.0	9	-2.78	9.32	-16.7	0.00	8.3
	Week 62	11	90.15	11.68	66.7	91.67	100.0	9	0.92	8.78	-8.3	0.00	16.7
	Week 65	10	89.17	11.82	66.7	91.67	100.0	8	2.08	8.62	-8.3	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Rest of World	EV+Pembro (N= 85)												
	BASELINE	80	78.02	19.36	8.3	83.33	100.0						
	Week 1	77	79.44	18.06	25.0	83.33	100.0	76	0.99	15.87	-50.0	0.00	58.3
	Week 2	80	79.06	17.69	33.3	75.00	100.0	76	1.32	17.00	-41.7	0.00	66.7
	Week 3	76	79.06	21.23	0.0	83.33	100.0	73	0.11	21.76	-50.0	0.00	91.7
	Week 4	72	80.90	19.90	0.0	83.33	100.0	68	2.57	20.98	-50.0	0.00	91.7
	Week 5	73	81.85	19.41	16.7	83.33	100.0	70	4.52	22.86	-58.3	0.00	91.7
	Week 6	74	80.52	19.03	25.0	83.33	100.0	70	2.02	20.82	-66.7	0.00	58.3
	Week 7	71	79.93	23.13	0.0	83.33	100.0	66	2.02	25.36	-75.0	0.00	91.7
	Week 8	72	79.05	22.72	0.0	83.33	100.0	68	0.74	22.39	-66.7	0.00	91.7
	Week 9	71	82.28	18.58	25.0	83.33	100.0	68	4.90	21.61	-75.0	0.00	66.7
	Week 10	73	80.14	21.00	0.0	83.33	100.0	69	1.57	21.31	-58.3	0.00	58.3
	Week 11	71	80.75	20.29	16.7	83.33	100.0	67	2.49	23.26	-58.3	0.00	91.7
	Week 12	69	81.16	19.10	16.7	83.33	100.0	66	1.77	22.43	-58.3	0.00	66.7
	Week 14	68	79.29	22.70	0.0	83.33	100.0	64	0.52	22.85	-75.0	0.00	66.7
	Week 17	68	81.62	18.07	33.3	83.33	100.0	63	1.85	19.88	-33.3	0.00	66.7
	Week 20	59	79.66	21.06	16.7	83.33	100.0	56	-1.49	22.76	-75.0	0.00	66.7
	Week 23	63	79.50	20.40	25.0	83.33	100.0	59	-1.41	22.43	-75.0	0.00	58.3
	Week 26	59	75.00	22.90	16.7	75.00	100.0	57	-5.56	24.82	-75.0	0.00	66.7
	Week 29	56	81.10	19.43	16.7	83.33	100.0	54	0.62	19.75	-41.7	0.00	50.0
	Week 32	52	80.45	20.47	0.0	83.33	100.0	49	-0.17	20.09	-50.0	0.00	50.0
	Week 35	43	79.26	22.81	8.3	83.33	100.0	40	-1.46	20.49	-58.3	0.00	41.7
	Week 38	49	78.91	20.06	33.3	75.00	100.0	47	-0.89	22.40	-66.7	0.00	58.3
	Week 41	49	74.15	23.03	8.3	66.67	100.0	47	-6.91	24.96	-75.0	-8.33	58.3
	Week 44	44	78.41	20.91	33.3	79.17	100.0	41	-2.24	24.37	-66.7	0.00	58.3
	Week 47	37	79.51	20.84	16.7	83.33	100.0	35	-2.14	21.23	-50.0	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	29	78.16	23.08	33.3	83.33	100.0	28	-5.95	23.22	-66.7	0.00	33.3
	Week 53	34	77.70	20.69	33.3	83.33	100.0	33	-5.56	19.06	-41.7	-8.33	41.7
	Week 56	31	78.23	21.80	33.3	75.00	100.0	30	-4.44	20.03	-41.7	0.00	41.7
	Week 59	28	77.08	21.83	33.3	79.17	100.0	27	-5.56	18.92	-41.7	0.00	41.7
	Week 62	28	78.57	19.96	33.3	79.17	100.0	27	-4.01	19.53	-41.7	0.00	41.7
	Week 65	23	74.28	20.86	33.3	75.00	100.0	22	-7.20	21.10	-41.7	-4.17	41.7
	Week 68	22	75.00	21.21	33.3	75.00	100.0	22	-4.92	21.92	-50.0	0.00	41.7
	Week 71	22	76.52	18.66	33.3	75.00	100.0	22	-3.79	18.32	-33.3	-4.17	41.7
	Week 74	22	76.52	21.15	33.3	79.17	100.0	22	-3.41	21.16	-50.0	0.00	41.7
	Week 77	18	75.93	19.98	41.7	66.67	100.0	17	-4.90	24.84	-50.0	-8.33	41.7
	Week 80	16	77.61	19.65	41.7	75.00	100.0	15	-3.89	23.96	-50.0	-8.33	41.7
	Week 83	16	74.48	17.60	41.7	70.84	100.0	15	-5.00	22.45	-41.7	-8.33	41.7
	Week 86	13	71.80	18.17	41.7	66.67	100.0	12	-4.86	26.22	-41.7	-4.17	41.7
	Week 89	12	70.14	20.86	41.7	66.67	100.0	12	-5.55	24.45	-33.3	-8.33	41.7
	Plat+Gem (N= 89)												
	BASELINE	75	74.89	20.48	8.3	75.00	100.0						
	Week 1	61	79.24	17.59	41.7	83.33	100.0	61	2.19	18.00	-58.3	0.00	41.7
	Week 2	66	76.14	22.12	25.0	75.00	100.0	62	0.54	19.90	-66.7	0.00	66.7
	Week 3	76	78.62	20.88	16.7	83.33	100.0	71	3.29	18.71	-33.3	0.00	50.0
	Week 4	73	78.54	21.01	0.0	83.33	100.0	68	3.19	21.60	-75.0	0.00	75.0
	Week 5	71	76.64	21.02	16.7	75.00	100.0	64	1.17	17.50	-33.3	0.00	41.7
	Week 6	70	77.38	23.45	0.0	75.00	100.0	63	1.46	18.79	-33.3	0.00	41.7
	Week 7	72	76.74	19.68	25.0	75.00	100.0	65	1.28	18.65	-66.7	0.00	41.7
	Week 8	63	77.12	21.48	0.0	75.00	100.0	58	0.43	18.43	-50.0	0.00	41.7
	Week 9	68	79.05	17.84	33.3	75.00	100.0	62	2.69	18.16	-33.3	0.00	41.7
	Week 10	67	79.60	17.60	33.3	75.00	100.0	61	3.96	16.85	-33.3	0.00	41.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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Table 302.1.3002.12.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	65	79.74	20.46	33.3	83.33	100.0	60	4.03	18.31	-41.7	0.00	41.7
	Week 12	63	77.91	21.39	33.3	75.00	100.0	58	1.72	20.58	-58.3	0.00	41.7
	Week 14	63	77.65	20.78	16.7	75.00	100.0	57	1.61	17.28	-41.7	0.00	33.3
	Week 17	60	77.50	23.83	0.0	83.33	100.0	55	0.61	22.44	-66.7	0.00	41.7
	Week 20	52	79.97	23.53	16.7	91.67	100.0	50	2.33	21.03	-58.3	0.00	33.3
	Week 23	44	81.44	22.65	8.3	91.67	100.0	42	3.97	21.87	-66.7	0.00	33.3
	Week 26	41	82.52	22.65	0.0	91.67	100.0	40	1.25	23.76	-66.7	0.00	41.7
	Week 29	37	86.71	15.77	41.7	91.67	100.0	36	2.78	18.90	-58.3	4.17	33.3
	Week 32	33	84.60	17.94	33.3	91.67	100.0	32	3.39	20.06	-66.7	8.33	33.3
	Week 35	30	85.83	15.34	58.3	91.67	100.0	30	3.89	17.33	-33.3	0.00	33.3
	Week 38	32	86.72	16.91	33.3	100.00	100.0	31	5.11	21.59	-66.7	0.00	41.7
	Week 41	27	85.80	19.59	33.3	100.00	100.0	26	4.17	21.51	-66.7	4.17	41.7
	Week 44	27	83.33	18.78	33.3	91.67	100.0	26	0.64	22.48	-66.7	0.00	41.7
	Week 47	29	83.62	18.56	33.3	91.67	100.0	28	1.49	21.88	-66.7	8.33	41.7
	Week 50	23	86.23	17.15	50.0	100.00	100.0	22	3.03	17.16	-33.3	0.00	33.3
	Week 53	22	87.88	16.21	50.0	100.00	100.0	21	3.57	16.79	-33.3	8.33	25.0
	Week 56	18	83.33	18.30	50.0	91.67	100.0	17	0.98	19.07	-33.3	0.00	25.0
	Week 59	17	87.26	14.47	66.7	91.67	100.0	16	2.61	17.67	-33.3	0.00	25.0
	Week 62	16	84.90	15.28	66.7	87.50	100.0	15	3.89	18.06	-33.3	8.33	25.0
	Week 65	15	91.67	11.36	66.7	91.67	100.0	14	1.79	15.39	-33.3	0.00	25.0
	Week 68	12	86.11	16.79	50.0	91.67	100.0	11	-1.52	15.73	-25.0	0.00	25.0
	Week 71	13	84.62	22.53	25.0	100.00	100.0	12	-4.86	19.93	-41.7	0.00	25.0
	Week 74	10	89.17	18.86	41.7	100.00	100.0	10	2.50	16.22	-25.0	4.17	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	EV+Pembro (N=198)												
	BASELINE	170	76.13	20.53	8.3	79.17	100.0						
	Week 1	157	79.99	18.84	16.7	83.33	100.0	152	2.91	15.44	-50.0	0.00	58.3
	Week 2	167	79.04	20.06	0.0	83.33	100.0	155	1.99	17.41	-58.3	0.00	66.7
	Week 3	161	78.93	20.07	0.0	83.33	100.0	147	1.98	19.29	-50.0	0.00	91.7
	Week 4	158	80.80	20.38	0.0	83.33	100.0	145	3.33	18.82	-50.0	0.00	91.7
	Week 5	154	82.47	18.08	16.7	83.33	100.0	140	4.64	20.59	-58.3	0.00	91.7
	Week 6	153	81.75	20.00	16.7	91.67	100.0	138	4.41	20.07	-66.7	0.00	58.3
	Week 7	159	80.56	21.82	0.0	91.67	100.0	142	2.93	21.29	-75.0	0.00	91.7
	Week 8	154	79.65	22.55	0.0	83.33	100.0	135	2.78	20.69	-66.7	0.00	91.7
	Week 9	162	79.53	20.24	16.7	83.33	100.0	146	2.85	20.09	-75.0	0.00	66.7
	Week 10	159	80.24	20.89	0.0	83.33	100.0	144	3.41	20.54	-58.3	0.00	58.3
	Week 11	161	80.85	21.30	8.3	91.67	100.0	143	4.02	21.02	-75.0	0.00	91.7
	Week 12	154	80.25	21.37	0.0	83.33	100.0	140	1.96	21.59	-83.3	0.00	66.7
	Week 14	154	79.71	21.95	0.0	83.33	100.0	137	2.37	20.06	-75.0	0.00	66.7
	Week 17	145	80.86	18.87	8.3	83.33	100.0	130	2.12	19.28	-50.0	0.00	66.7
	Week 20	139	79.20	22.33	0.0	83.33	100.0	126	0.86	22.60	-75.0	0.00	66.7
	Week 23	133	79.51	21.80	0.0	83.33	100.0	122	0.96	23.21	-75.0	0.00	58.3
	Week 26	129	79.39	21.32	16.7	83.33	100.0	118	1.55	22.57	-75.0	0.00	66.7
	Week 29	131	81.68	20.50	8.3	83.33	100.0	120	2.29	19.20	-58.3	0.00	58.3
	Week 32	111	81.08	18.73	0.0	83.33	100.0	102	2.86	18.30	-50.0	0.00	50.0
	Week 35	109	81.27	21.52	8.3	91.67	100.0	100	2.17	17.87	-58.3	0.00	41.7
	Week 38	107	81.78	19.29	25.0	83.33	100.0	100	2.25	20.10	-66.7	0.00	58.3
	Week 41	103	79.05	22.59	8.3	83.33	100.0	94	0.00	22.70	-75.0	0.00	58.3
	Week 44	88	80.78	20.11	25.0	83.33	100.0	81	1.75	22.58	-66.7	0.00	58.3
	Week 47	80	79.79	21.62	8.3	83.33	100.0	75	0.33	20.52	-58.3	0.00	50.0

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	73	82.76	20.19	16.7	91.67	100.0	68	3.06	21.01	-66.7	4.17	41.7
	Week 53	64	81.38	21.91	8.3	91.67	100.0	59	0.28	20.99	-58.3	0.00	50.0
	Week 56	66	81.06	20.70	16.7	83.33	100.0	61	3.14	20.53	-50.0	0.00	50.0
	Week 59	58	82.47	20.09	25.0	91.67	100.0	54	2.62	19.14	-58.3	0.00	41.7
	Week 62	54	80.86	20.06	16.7	83.33	100.0	52	0.64	18.95	-50.0	0.00	41.7
	Week 65	51	79.90	23.04	0.0	91.67	100.0	47	-0.53	20.29	-50.0	0.00	41.7
	Week 68	49	80.61	20.30	33.3	83.33	100.0	48	0.69	17.85	-50.0	0.00	41.7
	Week 71	47	81.56	19.50	33.3	83.33	100.0	45	0.00	19.14	-58.3	0.00	41.7
	Week 74	42	82.94	21.85	33.3	91.67	100.0	41	1.83	20.88	-50.0	0.00	41.7
	Week 77	38	79.39	21.55	33.3	79.17	100.0	36	-0.23	23.78	-50.0	0.00	41.7
	Week 80	35	80.48	20.10	41.7	83.33	100.0	32	3.12	21.87	-50.0	8.33	41.7
	Week 83	32	79.17	21.06	33.3	83.33	100.0	30	2.22	22.10	-58.3	8.33	41.7
	Week 86	30	80.84	20.43	41.7	91.67	100.0	27	3.09	22.55	-50.0	8.33	41.7
	Week 89	28	78.27	22.72	33.3	83.34	100.0	26	2.24	20.62	-33.3	0.00	41.7
	Week 92	24	78.82	23.57	25.0	91.67	100.0	22	0.76	22.26	-50.0	4.17	33.3
	Week 95	21	75.40	19.80	33.3	66.67	100.0	20	-0.83	21.10	-41.7	0.00	25.0
	Week 98	16	79.17	21.94	41.7	79.17	100.0	15	3.33	26.87	-58.3	8.33	41.7
	Week 101	12	79.17	27.87	33.3	95.84	100.0	12	0.69	23.69	-66.7	8.33	25.0
	Week 104	10	72.50	27.23	33.3	70.84	100.0	10	0.83	26.19	-66.7	8.33	25.0
	Plat+Gem (N=185)												
	BASELINE	146	74.26	21.77	0.0	75.00	100.0						
	Week 1	131	75.95	23.38	0.0	83.33	100.0	120	1.39	18.38	-66.7	0.00	41.7
	Week 2	128	74.94	22.42	0.0	75.00	100.0	115	-0.51	16.57	-66.7	0.00	66.7
	Week 3	141	78.43	21.46	8.3	83.33	100.0	126	2.71	16.73	-41.7	0.00	50.0
	Week 4	139	79.02	19.25	8.3	83.33	100.0	119	3.08	16.91	-41.7	0.00	75.0
	Week 5	143	77.51	22.03	0.0	83.33	100.0	120	1.25	18.95	-66.7	0.00	41.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 6	133	77.88	22.14	0.0	83.33	100.0	114	1.68	16.38	-58.3	0.00	41.7
	Week 7	142	77.52	21.70	8.3	83.33	100.0	120	1.32	17.42	-66.7	0.00	41.7
	Week 8	125	77.07	23.13	0.0	83.33	100.0	109	0.38	20.17	-100.0	0.00	41.7
	Week 9	135	78.09	20.63	33.3	83.33	100.0	115	2.17	17.77	-66.7	0.00	41.7
	Week 10	131	77.93	22.34	0.0	75.00	100.0	111	2.18	19.42	-100.0	0.00	50.0
	Week 11	128	78.06	22.62	0.0	83.33	100.0	109	2.06	18.04	-41.7	0.00	50.0
	Week 12	124	78.97	21.16	33.3	83.33	100.0	108	2.55	18.70	-58.3	0.00	50.0
	Week 14	121	78.31	20.57	16.7	83.33	100.0	101	1.57	21.17	-58.3	0.00	66.7
	Week 17	121	79.20	22.00	0.0	83.33	100.0	101	0.99	22.03	-91.7	0.00	50.0
	Week 20	98	81.21	20.46	16.7	83.33	100.0	86	3.10	19.60	-58.3	0.00	58.3
	Week 23	93	83.42	20.61	8.3	91.67	100.0	78	4.06	19.73	-66.7	4.17	58.3
	Week 26	86	81.30	24.05	0.0	91.67	100.0	75	0.22	21.75	-66.7	0.00	41.7
	Week 29	76	84.76	19.07	33.3	91.67	100.0	65	1.15	18.92	-58.3	0.00	33.3
	Week 32	62	84.81	19.35	16.7	95.84	100.0	56	2.98	17.51	-66.7	4.17	33.3
	Week 35	58	84.63	17.16	33.3	91.67	100.0	52	2.72	15.46	-33.3	0.00	33.3
	Week 38	60	87.08	16.12	33.3	95.84	100.0	52	4.17	19.77	-66.7	0.00	41.7
	Week 41	52	83.81	20.37	33.3	91.67	100.0	44	0.95	19.38	-66.7	0.00	41.7
	Week 44	46	83.70	19.32	33.3	91.67	100.0	40	-0.83	19.50	-66.7	0.00	41.7
	Week 47	44	87.50	15.51	33.3	91.67	100.0	38	1.75	18.60	-66.7	0.00	41.7
	Week 50	42	86.11	16.63	50.0	95.84	100.0	38	0.44	18.37	-33.3	0.00	33.3
	Week 53	38	89.47	13.93	66.7	100.00	100.0	34	2.21	15.66	-33.3	0.00	25.0
	Week 56	32	86.98	17.19	50.0	100.00	100.0	28	1.49	16.83	-41.7	0.00	25.0
	Week 59	31	87.90	15.93	41.7	100.00	100.0	27	-0.31	17.97	-50.0	0.00	25.0
	Week 62	29	87.36	14.71	58.3	91.67	100.0	26	1.60	16.50	-33.3	0.00	25.0
	Week 65	25	92.33	11.52	66.7	100.00	100.0	21	3.17	12.21	-33.3	0.00	25.0
	Week 68	20	90.83	12.06	66.7	100.00	100.0	16	0.00	14.27	-25.0	0.00	25.0

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 71	17	86.77	18.88	33.3	91.67	100.0	14	-0.59	12.85	-25.0	0.00	25.0
	Week 74	17	87.26	18.89	33.3	100.00	100.0	14	2.98	15.54	-33.3	0.00	25.0
	Week 77	16	84.37	24.70	33.3	100.00	100.0	13	1.92	25.72	-66.7	0.00	33.3
	Week 80	13	91.67	13.61	66.7	100.00	100.0	12	6.94	17.35	-25.0	4.17	33.3
	Week 83	11	89.40	11.84	66.7	91.67	100.0	10	5.00	17.66	-25.0	4.17	25.0
	Week 86	12	92.36	12.54	66.7	100.00	100.0	11	8.33	15.37	-25.0	8.33	25.0
	Week 89	11	88.64	15.03	66.7	100.00	100.0	10	6.67	19.95	-33.3	12.50	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	EV+Pembro (N= 42)												
	BASELINE	36	74.31	19.15	16.7	75.00	100.0						
	Week 1	33	74.75	21.50	25.0	75.00	100.0	32	1.56	15.90	-41.7	0.00	33.3
	Week 2	36	77.55	16.88	41.7	75.00	100.0	34	3.68	13.01	-16.7	0.00	50.0
	Week 3	37	74.55	19.14	33.3	75.00	100.0	35	0.71	18.23	-41.7	0.00	58.3
	Week 4	36	79.63	16.12	50.0	75.00	100.0	34	4.66	15.78	-25.0	0.00	41.7
	Week 5	36	78.47	15.48	33.3	75.00	100.0	33	5.05	17.79	-25.0	0.00	58.3
	Week 6	35	77.38	17.92	33.3	75.00	100.0	32	1.30	20.09	-66.7	0.00	41.7
	Week 7	36	80.32	15.19	33.3	83.33	100.0	34	5.88	14.14	-16.7	0.00	50.0
	Week 8	37	79.51	14.38	41.7	83.33	100.0	36	4.86	16.95	-33.3	0.00	50.0
	Week 9	35	82.38	14.26	58.3	75.00	100.0	34	7.11	16.56	-16.7	0.00	58.3
	Week 10	32	83.07	13.30	66.7	83.33	100.0	31	9.41	15.63	-8.3	8.33	50.0
	Week 11	33	81.31	15.87	41.7	91.67	100.0	32	7.29	18.90	-50.0	0.00	58.3
	Week 12	32	80.99	14.55	58.3	75.00	100.0	31	6.45	14.86	-25.0	0.00	41.7
	Week 14	31	77.15	18.75	25.0	75.00	100.0	30	3.06	16.00	-41.7	0.00	41.7
	Week 17	33	79.80	15.87	50.0	75.00	100.0	32	6.51	17.29	-16.7	0.00	50.0
	Week 20	28	80.66	15.22	50.0	79.17	100.0	28	7.14	15.17	-16.7	4.17	50.0
	Week 23	29	81.03	15.57	50.0	83.33	100.0	29	5.46	14.48	-16.7	0.00	41.7
	Week 26	27	78.71	17.19	41.7	66.67	100.0	26	2.57	18.22	-25.0	0.00	41.7
	Week 29	26	80.77	15.05	41.7	83.33	100.0	25	8.00	14.73	-8.3	0.00	33.3
	Week 32	24	76.74	23.57	0.0	79.17	100.0	23	0.00	22.61	-83.3	0.00	41.7
	Week 35	23	79.35	16.06	50.0	75.00	100.0	22	1.89	15.42	-33.3	0.00	33.3
	Week 38	25	81.33	13.67	66.7	83.33	100.0	24	3.13	14.08	-16.7	0.00	33.3
	Week 41	26	76.28	17.90	41.7	75.00	100.0	25	-1.00	17.23	-33.3	0.00	41.7
	Week 44	20	73.75	18.59	41.7	75.00	100.0	19	-3.95	19.91	-58.3	0.00	25.0
	Week 47	20	80.00	20.66	16.7	79.17	100.0	19	1.32	19.30	-50.0	0.00	33.3

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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Table 302.1.3002.12.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	16	75.00	20.18	33.3	70.84	100.0	16	-3.65	19.95	-50.0	0.00	33.3
	Week 53	15	76.67	21.41	33.3	83.33	100.0	15	-2.22	16.51	-41.7	0.00	33.3
	Week 56	15	77.78	19.07	33.3	83.33	100.0	15	-1.11	17.50	-41.7	0.00	25.0
	Week 59	14	71.43	20.07	33.3	66.67	100.0	14	-5.95	18.61	-41.7	-8.33	25.0
	Week 62	11	81.82	21.99	33.3	83.33	100.0	11	1.51	20.69	-41.7	0.00	25.0
	Plat+Gem (N= 57)												
	BASELINE	42	70.83	22.11	8.3	70.84	100.0						
	Week 1	42	75.40	18.68	33.3	79.17	100.0	38	5.26	14.68	-16.7	0.00	50.0
	Week 2	43	75.78	21.58	25.0	83.33	100.0	36	5.32	21.56	-41.7	0.00	75.0
	Week 3	43	79.85	19.18	33.3	83.33	100.0	36	9.95	19.90	-25.0	4.17	66.7
	Week 4	44	77.46	22.34	0.0	83.33	100.0	37	4.73	24.50	-75.0	0.00	66.7
	Week 5	44	76.52	20.51	25.0	75.00	100.0	36	2.78	19.42	-33.3	0.00	41.7
	Week 6	41	79.27	22.83	0.0	83.33	100.0	35	8.81	17.50	-25.0	8.34	41.7
	Week 7	44	80.30	16.58	25.0	75.00	100.0	37	8.33	18.32	-25.0	8.33	75.0
	Week 8	42	73.02	22.22	0.0	75.00	100.0	35	3.81	23.43	-50.0	0.00	58.3
	Week 9	42	74.21	20.40	16.7	75.00	100.0	35	6.19	19.84	-50.0	8.33	50.0
	Week 10	35	74.05	17.82	33.3	75.00	100.0	28	3.87	14.43	-25.0	0.00	33.3
	Week 11	40	73.75	22.13	16.7	75.00	100.0	34	4.41	16.82	-25.0	0.00	33.3
	Week 12	35	73.57	19.23	33.3	66.67	100.0	30	3.61	20.02	-41.7	4.17	33.3
	Week 14	32	69.53	24.19	0.0	70.84	100.0	27	2.78	15.84	-50.0	8.33	25.0
	Week 17	34	72.55	20.16	16.7	75.00	100.0	29	2.87	20.45	-33.3	0.00	58.3
	Week 20	28	77.08	20.36	16.7	75.00	100.0	24	6.25	17.42	-33.3	8.33	41.7
	Week 23	22	80.68	17.32	41.7	83.33	100.0	19	10.09	19.56	-33.3	8.33	41.7
	Week 26	22	74.62	18.45	33.3	70.84	100.0	20	1.67	15.90	-33.3	0.00	25.0
	Week 29	24	78.82	16.11	41.7	83.33	100.0	21	6.35	17.46	-25.0	0.00	41.7
	Week 32	21	72.62	22.69	25.0	75.00	100.0	20	1.25	22.34	-41.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 35	18	76.39	19.44	33.3	75.00	100.0	17	5.88	20.57	-33.3	0.00	41.7
	Week 38	14	76.79	20.46	25.0	75.00	100.0	13	4.49	21.95	-25.0	0.00	33.3
	Week 41	13	82.69	15.01	58.3	83.33	100.0	12	9.72	20.05	-25.0	16.66	41.7
	Week 44	14	75.00	17.30	33.3	70.84	100.0	13	0.00	17.68	-33.3	0.00	25.0
	Week 47	12	74.31	21.16	33.3	75.00	100.0	11	2.27	24.18	-33.3	0.00	41.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Visceral metastases	EV+Pembro (N=170)												
	BASELINE	146	74.49	20.46	8.3	75.00	100.0						
	Week 1	135	78.58	20.27	16.7	83.33	100.0	131	3.69	16.77	-50.0	0.00	58.3
	Week 2	145	78.97	20.08	0.0	83.33	100.0	134	3.73	16.81	-58.3	0.00	66.7
	Week 3	141	78.13	20.88	0.0	83.33	100.0	129	2.84	20.56	-50.0	0.00	91.7
	Week 4	136	79.60	21.22	0.0	83.33	100.0	125	3.80	19.59	-50.0	0.00	91.7
	Week 5	131	82.19	18.51	16.7	83.33	100.0	118	6.78	20.09	-41.7	0.00	91.7
	Week 6	127	82.09	18.99	25.0	91.67	100.0	113	5.90	18.99	-50.0	0.00	58.3
	Week 7	135	80.56	22.16	0.0	83.33	100.0	121	5.23	21.63	-75.0	0.00	91.7
	Week 8	131	79.64	22.93	0.0	83.33	100.0	118	4.87	21.39	-66.7	0.00	91.7
	Week 9	136	80.76	19.10	16.7	83.33	100.0	124	5.65	18.42	-41.7	0.00	66.7
	Week 10	135	81.42	20.05	0.0	83.33	100.0	124	6.05	20.37	-58.3	0.00	58.3
	Week 11	134	82.77	20.37	8.3	91.67	100.0	121	7.65	19.56	-58.3	0.00	91.7
	Week 12	131	82.51	19.17	16.7	83.33	100.0	120	6.18	19.88	-58.3	0.00	66.7
	Week 14	130	79.62	21.91	0.0	83.33	100.0	117	4.20	19.90	-75.0	0.00	66.7
	Week 17	124	81.99	19.17	8.3	87.50	100.0	111	5.26	19.33	-50.0	0.00	66.7
	Week 20	115	82.32	20.27	0.0	83.33	100.0	105	5.08	21.45	-50.0	0.00	66.7
	Week 23	111	82.96	20.11	0.0	91.67	100.0	103	6.63	20.75	-50.0	0.00	58.3
	Week 26	106	82.71	19.94	16.7	91.67	100.0	97	6.79	20.81	-50.0	0.00	66.7
	Week 29	106	85.14	19.31	8.3	91.67	100.0	98	7.57	17.55	-33.3	0.00	58.3
	Week 32	92	82.52	19.73	0.0	83.33	100.0	85	5.98	19.31	-83.3	0.00	50.0
	Week 35	86	84.30	18.59	8.3	91.67	100.0	79	6.54	16.05	-33.3	0.00	41.7
	Week 38	90	84.45	16.82	33.3	91.67	100.0	84	7.54	16.34	-33.3	8.33	58.3
	Week 41	87	81.71	20.48	8.3	91.67	100.0	81	5.45	19.51	-66.7	0.00	58.3
	Week 44	73	82.53	18.33	33.3	83.33	100.0	68	5.88	20.97	-58.3	4.17	58.3
	Week 47	68	82.35	21.23	8.3	91.67	100.0	63	4.76	19.73	-50.0	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	61	82.65	20.43	16.7	91.67	100.0	57	4.97	19.97	-58.3	8.33	41.7
	Week 53	54	81.94	22.36	8.3	91.67	100.0	50	3.17	19.70	-50.0	0.00	50.0
	Week 56	58	83.48	19.28	16.7	91.67	100.0	54	6.64	18.20	-41.7	4.17	50.0
	Week 59	50	83.33	19.34	25.0	91.67	100.0	47	4.08	17.19	-41.7	0.00	41.7
	Week 62	45	82.78	20.05	16.7	83.33	100.0	43	5.04	16.78	-41.7	0.00	41.7
	Week 65	37	81.53	22.32	0.0	91.67	100.0	34	3.92	17.44	-41.7	0.00	41.7
	Week 68	35	83.81	17.84	33.3	91.67	100.0	34	7.11	14.38	-41.7	8.33	41.7
	Week 71	31	83.33	16.53	41.7	91.67	100.0	30	8.06	13.92	-16.7	8.33	41.7
	Week 74	29	84.48	19.38	41.7	91.67	100.0	28	8.63	16.12	-25.0	8.33	41.7
	Week 77	26	81.41	17.84	41.7	79.17	100.0	25	9.33	16.89	-25.0	8.33	41.7
	Week 80	22	79.93	17.57	41.7	75.00	100.0	21	9.52	16.31	-25.0	8.34	41.7
	Week 83	23	81.52	18.28	41.7	83.33	100.0	22	10.61	15.04	-25.0	8.34	41.7
	Week 86	21	84.13	17.66	41.7	91.67	100.0	20	12.92	16.10	-25.0	12.51	41.7
	Week 89	21	79.37	21.67	33.3	91.67	100.0	20	10.00	18.06	-33.3	8.34	41.7
	Week 92	18	80.09	22.17	33.3	91.67	100.0	17	7.35	18.84	-41.7	8.33	33.3
	Week 95	13	78.85	16.53	58.3	75.00	100.0	12	12.50	14.44	-16.7	16.67	25.0
	Week 98	11	84.85	16.17	66.7	91.67	100.0	11	15.15	14.82	-8.3	16.67	41.7
	Week 101	11	77.27	25.84	33.3	83.33	100.0	11	6.06	14.95	-25.0	8.33	25.0
Plat+Gem (N=161)													
	BASELINE	129	72.16	20.19	8.3	75.00	100.0						
	Week 1	113	74.19	22.19	0.0	75.00	100.0	105	2.38	15.75	-50.0	0.00	41.7
	Week 2	108	73.69	21.68	0.0	75.00	100.0	98	1.87	16.34	-41.7	0.00	66.7
	Week 3	121	79.41	19.46	8.3	83.33	100.0	109	5.89	16.83	-41.7	0.00	50.0
	Week 4	116	79.24	18.41	8.3	83.33	100.0	101	5.28	18.85	-58.3	0.00	75.0
	Week 5	121	76.86	20.17	16.7	75.00	100.0	104	3.69	17.68	-41.7	0.00	41.7
	Week 6	118	77.83	20.48	0.0	75.00	100.0	102	4.49	17.38	-33.3	0.00	41.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 7	121	77.48	19.50	25.0	75.00	100.0	104	3.93	16.34	-33.3	0.00	41.7
	Week 8	108	78.01	18.67	16.7	75.00	100.0	96	4.25	18.02	-33.3	0.00	58.3
	Week 9	114	77.63	19.24	33.3	75.00	100.0	99	5.98	16.75	-33.3	8.33	41.7
	Week 10	109	76.91	20.71	0.0	75.00	100.0	94	4.79	16.91	-33.3	0.00	50.0
	Week 11	109	77.29	20.97	25.0	75.00	100.0	95	3.68	19.25	-41.7	0.00	50.0
	Week 12	103	77.19	19.66	33.3	75.00	100.0	91	2.75	20.53	-58.3	0.00	50.0
	Week 14	98	76.87	20.01	16.7	75.00	100.0	85	4.22	21.81	-58.3	8.33	66.7
	Week 17	103	77.91	19.90	25.0	75.00	100.0	89	3.56	20.10	-58.3	0.00	50.0
	Week 20	82	79.68	19.69	25.0	75.00	100.0	75	4.44	20.93	-58.3	8.33	58.3
	Week 23	77	81.28	18.79	33.3	83.33	100.0	68	6.98	19.46	-41.7	8.33	58.3
	Week 26	71	80.28	21.28	8.3	83.33	100.0	65	3.33	18.33	-66.7	8.33	41.7
	Week 29	65	82.95	18.19	41.7	83.33	100.0	59	4.80	18.71	-41.7	8.33	41.7
	Week 32	52	79.49	19.56	16.7	83.33	100.0	49	3.57	16.84	-41.7	0.00	33.3
	Week 35	47	79.97	17.86	33.3	83.33	100.0	44	4.17	17.75	-33.3	0.00	41.7
	Week 38	42	82.54	17.05	25.0	83.33	100.0	39	4.27	17.51	-33.3	0.00	41.7
	Week 41	35	80.00	20.53	33.3	83.33	100.0	32	4.69	17.19	-25.0	0.00	41.7
	Week 44	36	78.24	19.65	33.3	75.00	100.0	33	-0.76	19.69	-41.7	0.00	41.7
	Week 47	32	82.81	15.69	33.3	83.33	100.0	30	3.61	19.41	-33.3	8.33	41.7
	Week 50	30	82.22	16.63	50.0	87.50	100.0	29	1.15	20.01	-33.3	0.00	33.3
	Week 53	25	86.33	14.61	66.7	91.67	100.0	24	1.39	17.66	-33.3	8.33	25.0
	Week 56	22	79.17	19.03	50.0	70.84	100.0	21	-3.57	20.17	-41.7	0.00	25.0
	Week 59	22	82.96	16.56	41.7	87.50	100.0	21	-1.59	21.35	-50.0	0.00	25.0
	Week 62	19	83.33	15.96	50.0	83.33	100.0	18	1.39	16.97	-33.3	0.00	25.0
	Week 65	19	89.04	12.12	66.7	91.67	100.0	18	3.70	14.91	-33.3	8.33	25.0
	Week 68	13	86.54	16.85	50.0	91.67	100.0	12	0.00	14.65	-16.7	0.00	25.0
	Week 71	13	79.49	21.41	25.0	75.00	100.0	12	-6.94	20.05	-41.7	-4.17	25.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 74	11	82.58	21.55	41.7	91.67	100.0	11	0.00	19.72	-33.3	0.00	25.0
	Week 77	10	89.17	15.74	58.3	100.00	100.0	10	8.33	17.12	-16.7	8.33	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Lymph node only	EV+Pembro (N= 60)												
	BASELINE	53	79.40	20.19	16.7	83.33	100.0						
	Week 1	49	80.95	17.35	41.7	83.33	100.0	47	0.53	12.09	-41.7	0.00	33.3
	Week 2	50	77.50	18.69	16.7	75.00	100.0	48	-2.08	16.62	-41.7	0.00	50.0
	Week 3	50	76.83	17.60	33.3	75.00	100.0	47	-1.95	15.07	-33.3	0.00	58.3
	Week 4	50	82.00	15.28	50.0	79.17	100.0	47	1.95	15.07	-25.0	0.00	41.7
	Week 5	53	80.03	15.70	41.7	75.00	100.0	49	-0.68	20.19	-58.3	0.00	58.3
	Week 6	53	77.36	21.70	16.7	83.33	100.0	50	-1.50	22.63	-66.7	0.00	41.7
	Week 7	52	80.13	16.35	41.7	79.17	100.0	48	-0.87	16.06	-50.0	0.00	33.3
	Week 8	52	79.33	16.38	41.7	83.33	100.0	47	-0.89	15.95	-41.7	0.00	50.0
	Week 9	53	77.52	19.79	25.0	75.00	100.0	49	-1.70	21.98	-75.0	0.00	58.3
	Week 10	48	78.65	19.37	33.3	75.00	100.0	44	0.38	18.85	-41.7	0.00	50.0
	Week 11	53	75.16	20.51	8.3	75.00	100.0	48	-3.47	22.14	-75.0	0.00	58.3
	Week 12	48	73.44	22.72	0.0	75.00	100.0	45	-6.85	20.67	-83.3	0.00	41.7
	Week 14	48	77.95	20.52	0.0	79.17	100.0	44	-2.08	18.07	-50.0	0.00	41.7
	Week 17	46	77.54	15.99	41.7	75.00	100.0	44	-2.08	16.97	-25.0	0.00	50.0
	Week 20	44	71.78	23.45	16.7	70.84	100.0	42	-5.56	21.04	-75.0	0.00	50.0
	Week 23	43	74.23	20.07	33.3	66.67	100.0	41	-7.32	18.47	-50.0	0.00	50.0
	Week 26	42	73.21	20.04	25.0	66.67	100.0	40	-7.71	17.94	-41.7	0.00	33.3
	Week 29	45	75.00	18.38	33.3	75.00	100.0	42	-5.16	17.26	-58.3	0.00	25.0
	Week 32	38	76.32	19.33	33.3	75.00	100.0	36	-5.56	15.43	-50.0	0.00	16.7
	Week 35	42	74.60	23.64	8.3	75.00	100.0	40	-6.88	17.18	-58.3	0.00	16.7
	Week 38	38	77.19	20.48	25.0	75.00	100.0	36	-8.10	20.17	-66.7	0.00	33.3
	Week 41	37	71.40	23.70	25.0	66.67	100.0	34	-13.24	21.72	-75.0	-8.33	16.7
	Week 44	31	72.58	22.69	25.0	66.67	100.0	29	-11.21	21.28	-66.7	0.00	16.7
	Week 47	28	75.60	21.63	33.3	75.00	100.0	27	-8.33	19.88	-58.3	0.00	25.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	25	80.00	20.83	33.3	91.67	100.0	24	-4.17	22.39	-66.7	0.00	25.0
	Week 53	23	77.54	21.24	33.3	83.33	100.0	22	-7.58	20.24	-58.3	0.00	25.0
	Week 56	21	73.41	22.30	33.3	66.67	100.0	20	-7.92	21.03	-50.0	0.00	16.7
	Week 59	20	72.92	22.28	33.3	66.67	100.0	19	-7.02	22.95	-58.3	0.00	25.0
	Week 62	19	78.07	20.64	41.7	83.33	100.0	19	-7.02	20.65	-50.0	0.00	25.0
	Week 65	20	70.00	24.09	33.3	66.67	100.0	19	-11.40	21.73	-50.0	0.00	33.3
	Week 68	17	71.57	24.48	33.3	66.67	100.0	17	-11.77	19.11	-50.0	0.00	8.3
	Week 71	19	78.51	23.13	33.3	83.33	100.0	18	-9.26	22.67	-58.3	-8.34	33.3
	Week 74	17	74.51	25.08	33.3	83.33	100.0	17	-10.78	21.60	-50.0	0.00	33.3
	Week 77	17	72.06	24.11	33.3	66.67	100.0	16	-15.10	23.02	-50.0	-8.34	16.7
	Week 80	17	77.45	22.20	41.7	83.33	100.0	15	-6.11	24.90	-50.0	0.00	41.7
	Week 83	13	71.15	22.72	33.3	66.67	100.0	12	-12.50	23.71	-58.3	-8.34	25.0
	Week 86	12	74.31	20.55	41.7	70.84	100.0	10	-11.67	20.11	-50.0	0.00	8.3
	Week 89	11	68.94	23.30	33.3	66.67	100.0	10	-14.17	15.74	-33.3	-16.67	8.3
	Plat+Gem (N= 67)												
	BASELINE	49	76.70	23.26	8.3	83.33	100.0						
	Week 1	51	79.90	21.09	0.0	83.33	100.0	45	3.15	20.67	-66.7	0.00	50.0
	Week 2	53	77.99	22.89	16.7	83.33	100.0	44	0.57	20.21	-50.0	0.00	75.0
	Week 3	53	76.89	24.60	8.3	83.33	100.0	44	1.89	19.68	-41.7	0.00	66.7
	Week 4	58	77.87	20.50	16.7	83.33	100.0	47	1.60	16.81	-33.3	0.00	66.7
	Week 5	56	76.94	25.38	0.0	91.67	100.0	44	-2.46	21.00	-66.7	0.00	33.3
	Week 6	48	78.47	26.57	0.0	91.67	100.0	40	1.04	16.69	-58.3	0.00	25.0
	Week 7	56	79.02	22.81	8.3	87.50	100.0	46	1.81	21.30	-66.7	0.00	75.0
	Week 8	52	72.92	29.28	0.0	83.33	100.0	42	-4.56	25.72	-100.0	0.00	58.3
	Week 9	53	76.89	23.38	16.7	83.33	100.0	42	-1.19	20.46	-66.7	0.00	50.0
	Week 10	47	77.66	24.40	0.0	83.33	100.0	36	-1.39	21.03	-100.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	51	76.96	25.36	0.0	83.33	100.0	41	0.41	15.25	-33.3	0.00	33.3
	Week 12	47	78.90	22.71	33.3	83.33	100.0	39	4.49	14.03	-33.3	0.00	33.3
	Week 14	47	76.24	24.45	0.0	83.33	100.0	36	-2.55	15.91	-50.0	0.00	25.0
	Week 17	45	76.48	26.19	0.0	83.33	100.0	35	-3.33	26.06	-91.7	0.00	58.3
	Week 20	38	82.46	20.11	16.7	83.33	100.0	30	3.61	15.27	-41.7	0.00	33.3
	Week 23	32	85.68	23.11	8.3	100.00	100.0	25	1.67	21.65	-66.7	8.33	33.3
	Week 26	30	79.44	28.43	0.0	91.67	100.0	24	-3.82	25.54	-66.7	0.00	33.3
	Week 29	28	84.23	20.20	33.3	91.67	100.0	21	-1.98	19.35	-58.3	0.00	25.0
	Week 32	26	85.26	23.61	25.0	100.00	100.0	22	1.14	24.44	-66.7	8.33	33.3
	Week 35	23	87.68	17.92	33.3	100.00	100.0	19	3.95	16.98	-33.3	0.00	33.3
	Week 38	26	88.46	17.81	33.3	100.00	100.0	20	5.00	26.82	-66.7	4.17	41.7
	Week 41	24	87.50	17.55	33.3	100.00	100.0	18	0.00	26.04	-66.7	4.17	41.7
	Week 44	18	86.11	17.85	33.3	91.67	100.0	14	-1.19	21.15	-66.7	0.00	16.7
	Week 47	18	87.96	18.57	33.3	100.00	100.0	13	0.00	22.57	-66.7	0.00	25.0
	Week 50	16	90.10	15.58	50.0	100.00	100.0	13	3.21	17.53	-33.3	0.00	33.3
	Week 53	15	90.00	13.44	66.7	100.00	100.0	12	5.56	16.02	-33.3	8.33	25.0
	Week 56	15	89.44	22.37	16.7	100.00	100.0	11	10.61	14.48	-16.7	8.33	33.3
	Week 59	12	92.36	13.03	66.7	100.00	100.0	9	5.56	12.50	-16.7	0.00	25.0
	Week 62	10	92.50	12.70	66.7	100.00	100.0	8	9.38	8.26	0.0	12.50	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
EV+Pembro (N=202)												
BASELINE	160	75.00	21.25	0.0	75.00	100.0						
Week 1	141	77.66	22.10	0.0	83.33	100.0	129	2.13	15.25	-66.7	0.00	41.7
Week 2	150	75.50	22.15	0.0	75.00	100.0	133	0.69	17.83	-50.0	0.00	83.3
Week 3	139	77.46	21.05	16.7	83.33	100.0	122	2.60	16.60	-33.3	0.00	75.0
Week 4	145	79.89	21.89	25.0	83.33	100.0	129	3.29	18.65	-58.3	0.00	41.7
Week 5	137	80.78	19.71	33.3	83.33	100.0	121	4.00	18.85	-50.0	0.00	41.7
Week 6	146	79.22	21.65	0.0	83.33	100.0	124	3.97	20.62	-83.3	0.00	58.3
Week 7	147	79.88	21.52	8.3	83.33	100.0	124	4.64	20.20	-66.7	0.00	66.7
Week 8	147	80.05	21.82	0.0	83.33	100.0	124	4.57	22.90	-83.3	8.33	66.7
Week 9	142	79.28	23.81	0.0	91.67	100.0	121	2.89	23.32	-83.3	0.00	66.7
Week 10	139	81.53	21.01	0.0	91.67	100.0	118	4.31	19.14	-66.7	4.17	41.7
Week 11	137	82.54	20.78	8.3	91.67	100.0	115	5.22	20.40	-66.7	0.00	58.3
Week 12	142	81.10	22.26	0.0	91.67	100.0	119	4.69	19.28	-58.3	0.00	50.0
Week 14	139	81.30	21.23	16.7	91.67	100.0	116	5.24	22.70	-66.7	8.33	66.7
Week 17	132	80.94	21.12	16.7	91.67	100.0	111	4.20	19.81	-58.3	0.00	58.3
Week 20	120	83.33	16.84	33.3	87.50	100.0	103	4.53	19.62	-50.0	0.00	66.7
Week 23	117	82.91	17.64	16.7	83.33	100.0	97	4.38	20.27	-41.7	0.00	66.7
Week 26	112	82.59	17.92	25.0	83.33	100.0	94	2.57	21.48	-58.3	0.00	91.7
Week 29	107	83.10	17.26	25.0	91.67	100.0	93	3.05	20.37	-50.0	0.00	50.0
Week 32	102	81.62	19.03	25.0	83.33	100.0	88	3.22	20.85	-58.3	0.00	75.0
Week 35	98	80.53	20.62	0.0	83.33	100.0	86	1.16	22.55	-75.0	0.00	75.0
Week 38	97	82.13	18.67	25.0	83.33	100.0	86	2.71	21.25	-50.0	0.00	75.0
Week 41	95	79.12	18.83	0.0	83.33	100.0	84	0.10	22.79	-66.7	0.00	66.7
Week 44	86	79.65	21.60	0.0	83.33	100.0	74	-0.34	22.93	-75.0	0.00	66.7
Week 47	79	79.11	20.45	25.0	83.33	100.0	70	0.83	23.58	-41.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	74	79.73	20.28	25.0	83.33	100.0	64	-0.39	22.83	-66.7	0.00	75.0
Week 53	74	77.82	20.84	16.7	75.00	100.0	63	-0.66	22.42	-75.0	0.00	66.7
Week 56	72	77.32	21.50	8.3	83.33	100.0	61	-1.78	21.95	-66.7	0.00	75.0
Week 59	69	78.14	21.68	25.0	83.33	100.0	57	0.73	22.01	-50.0	0.00	75.0
Week 62	62	80.65	17.78	33.3	83.33	100.0	52	3.21	20.42	-41.7	0.00	66.7
Week 65	43	76.74	23.33	25.0	83.33	100.0	40	2.08	22.94	-41.7	0.00	66.7
Week 68	46	75.91	20.43	33.3	79.17	100.0	42	-1.39	22.83	-50.0	0.00	66.7
Week 71	42	76.59	18.88	33.3	70.84	100.0	38	-0.66	22.46	-41.7	0.00	66.7
Week 74	38	76.76	20.43	33.3	79.17	100.0	35	-1.19	25.50	-50.0	0.00	66.7
Week 77	37	79.05	19.11	33.3	75.00	100.0	33	1.52	25.04	-58.3	0.00	66.7
Week 80	36	75.70	20.83	33.3	75.00	100.0	34	0.49	27.82	-50.0	0.00	66.7
Week 83	30	77.22	18.94	41.7	79.17	100.0	29	0.86	25.62	-50.0	0.00	66.7
Week 86	26	71.47	23.59	25.0	70.84	100.0	25	-2.33	28.11	-66.7	0.00	66.7
Week 89	20	78.75	19.02	33.3	79.17	100.0	19	0.00	21.34	-50.0	0.00	33.3
Week 92	19	70.18	21.57	33.3	66.67	100.0	18	0.00	19.39	-33.3	0.00	33.3
Week 95	14	84.52	14.57	58.3	87.50	100.0	13	3.85	16.53	-33.3	0.00	33.3
Week 98	10	84.17	15.44	58.3	87.50	100.0	9	3.70	8.45	-8.3	8.33	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Plat+Gem (N=202)												
BASELINE	165	76.06	22.05	8.3	83.33	100.0						
Week 1	144	77.43	21.48	8.3	83.33	100.0	139	1.68	15.58	-33.3	0.00	58.3
Week 2	147	76.25	22.38	0.0	83.33	100.0	135	-0.74	19.09	-66.7	0.00	58.3
Week 3	149	76.57	23.68	0.0	83.33	100.0	136	-0.80	20.03	-66.7	0.00	58.3
Week 4	150	78.44	20.82	0.0	83.33	100.0	135	0.56	18.02	-50.0	0.00	58.3
Week 5	153	76.04	20.82	8.3	75.00	100.0	138	-2.17	19.61	-50.0	0.00	66.7
Week 6	145	76.90	23.11	0.0	83.33	100.0	131	-0.83	20.90	-66.7	0.00	66.7
Week 7	148	77.31	20.87	8.3	75.00	100.0	134	-1.06	20.65	-66.7	0.00	66.7
Week 8	145	75.98	22.71	0.0	75.00	100.0	132	-1.83	21.24	-75.0	0.00	58.3
Week 9	141	75.89	23.27	0.0	75.00	100.0	125	-1.07	21.66	-66.7	0.00	50.0
Week 10	142	77.29	22.22	8.3	83.33	100.0	130	0.58	21.37	-58.3	0.00	75.0
Week 11	126	77.25	23.44	0.0	83.33	100.0	114	0.88	21.51	-66.7	0.00	58.3
Week 12	130	77.82	21.75	0.0	83.33	100.0	115	2.46	19.28	-41.7	0.00	58.3
Week 14	125	76.47	22.95	0.0	83.33	100.0	109	-1.76	19.74	-66.7	0.00	41.7
Week 17	120	77.85	22.00	8.3	83.33	100.0	106	-1.57	22.16	-58.3	0.00	58.3
Week 20	104	79.09	20.54	16.7	83.33	100.0	91	0.64	19.61	-50.0	0.00	50.0
Week 23	88	82.29	18.73	25.0	83.33	100.0	80	2.81	17.54	-41.7	0.00	58.3
Week 26	81	79.42	20.84	0.0	83.33	100.0	75	1.56	22.75	-75.0	0.00	58.3
Week 29	77	78.79	21.31	0.0	83.33	100.0	71	-1.17	24.12	-100.0	0.00	58.3
Week 32	63	78.84	21.21	16.7	75.00	100.0	58	-0.72	19.70	-58.3	0.00	58.3
Week 35	62	77.96	22.39	0.0	83.33	100.0	56	-0.30	20.10	-58.3	0.00	50.0
Week 38	56	76.19	25.20	0.0	75.00	100.0	50	-2.67	20.44	-66.7	0.00	50.0
Week 41	52	80.13	20.82	25.0	87.50	100.0	47	-0.89	19.21	-50.0	0.00	50.0
Week 44	49	75.68	23.93	16.7	75.00	100.0	44	-3.60	23.11	-66.7	0.00	50.0
Week 47	43	78.10	22.57	25.0	83.33	100.0	39	-1.07	20.70	-58.3	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	36	77.55	25.42	16.7	91.67	100.0	31	-1.88	20.94	-50.0	0.00	25.0
Week 53	31	82.26	20.94	33.3	91.67	100.0	28	2.08	17.51	-41.7	8.33	25.0
Week 56	30	74.44	23.15	33.3	79.17	100.0	29	-2.87	17.15	-41.7	0.00	33.3
Week 59	23	72.10	21.70	25.0	75.00	100.0	21	-5.16	20.32	-50.0	0.00	25.0
Week 62	20	70.83	22.38	33.3	75.00	100.0	20	-5.00	19.57	-50.0	-4.17	25.0
Week 65	17	71.08	25.02	33.3	75.00	100.0	16	-6.25	20.53	-66.7	0.00	16.7
Week 68	13	72.44	26.22	33.3	75.00	100.0	13	-4.49	21.95	-58.3	0.00	16.7
Week 71	13	69.87	30.91	8.3	75.00	100.0	13	-5.13	27.96	-91.7	0.00	16.7
Week 74	11	79.55	19.85	50.0	91.67	100.0	11	-2.27	14.95	-33.3	0.00	16.7
Week 77	11	84.09	24.28	25.0	91.67	100.0	11	-3.79	20.20	-41.7	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Present	EV+Pembro (N= 50)												
	BASELINE	40	75.63	21.05	25.0	83.33	100.0						
	Week 1	38	74.34	26.16	0.0	83.33	100.0	34	-0.49	19.35	-66.7	0.00	33.3
	Week 2	35	76.91	23.92	0.0	83.33	100.0	32	1.82	21.56	-50.0	0.00	50.0
	Week 3	32	77.09	20.63	16.7	83.33	100.0	30	1.67	17.43	-33.3	0.00	41.7
	Week 4	35	81.43	21.11	33.3	91.67	100.0	31	4.03	19.94	-33.3	0.00	41.7
	Week 5	32	80.73	19.79	41.7	87.50	100.0	28	2.68	18.43	-41.7	0.00	41.7
	Week 6	35	81.19	18.78	33.3	91.67	100.0	30	8.06	20.82	-50.0	8.33	58.3
	Week 7	35	79.29	21.52	33.3	83.33	100.0	29	4.60	20.00	-58.3	8.33	41.7
	Week 8	38	77.85	24.53	8.3	91.67	100.0	31	2.42	26.46	-83.3	8.33	41.7
	Week 9	33	78.28	25.08	8.3	91.67	100.0	29	4.60	26.13	-83.3	0.00	66.7
	Week 10	30	82.22	20.15	33.3	91.67	100.0	25	8.33	18.94	-41.7	8.33	41.7
	Week 11	31	84.95	17.54	25.0	91.67	100.0	27	5.25	20.82	-41.7	8.33	41.7
	Week 12	32	84.90	18.14	33.3	91.67	100.0	28	6.25	17.37	-41.7	8.33	33.3
	Week 14	36	84.49	18.91	25.0	91.67	100.0	31	8.87	21.40	-66.7	8.33	50.0
	Week 17	33	80.56	24.97	25.0	91.67	100.0	27	3.70	19.25	-41.7	0.00	41.7
	Week 20	28	81.85	18.43	41.7	91.67	100.0	25	2.00	21.95	-50.0	0.00	41.7
	Week 23	28	79.76	20.59	16.7	83.33	100.0	24	1.74	23.05	-41.7	4.17	50.0
	Week 26	28	78.87	21.93	25.0	83.34	100.0	24	0.00	23.95	-58.3	0.00	50.0
	Week 29	27	83.95	18.77	33.3	91.67	100.0	25	4.33	21.13	-50.0	8.33	33.3
	Week 32	25	83.33	18.63	25.0	91.67	100.0	23	4.35	17.38	-33.3	0.00	33.3
	Week 35	26	84.62	17.11	33.3	91.67	100.0	24	3.13	19.94	-33.3	0.00	33.3
	Week 38	26	81.09	20.49	25.0	83.33	100.0	24	-0.35	22.04	-50.0	0.00	33.3
	Week 41	25	77.00	22.98	0.0	83.33	100.0	23	-4.35	24.34	-66.7	0.00	33.3
	Week 44	22	78.79	18.50	33.3	79.17	100.0	20	-1.25	21.34	-50.0	0.00	33.3
	Week 47	14	76.79	22.21	33.3	79.17	100.0	13	-4.49	20.87	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	79.58	21.54	25.0	83.33	100.0	17	-3.92	23.22	-66.7	0.00	33.3
	Week 53	21	76.59	22.30	16.7	75.00	100.0	18	-6.02	23.19	-75.0	0.00	33.3
	Week 56	18	71.76	27.14	8.3	83.33	100.0	15	-10.00	24.03	-66.7	0.00	33.3
	Week 59	18	77.78	25.08	25.0	83.33	100.0	15	-0.56	19.02	-33.3	0.00	33.3
	Week 62	13	81.41	18.37	41.7	83.33	100.0	11	0.76	16.44	-33.3	0.00	33.3
	Week 68	12	81.95	15.01	58.3	83.33	100.0	11	-0.76	20.57	-33.3	0.00	33.3
	Plat+Gem (N= 50)												
	BASELINE	40	72.08	23.16	8.3	83.33	100.0						
	Week 1	35	76.43	20.46	8.3	83.33	100.0	33	0.00	20.09	-33.3	0.00	58.3
	Week 2	33	72.73	22.37	33.3	75.00	100.0	30	-4.44	22.40	-66.7	0.00	33.3
	Week 3	33	75.76	20.34	33.3	83.33	100.0	29	-1.15	23.96	-58.3	0.00	58.3
	Week 4	36	77.78	18.90	33.3	79.17	100.0	32	3.39	23.46	-50.0	4.17	58.3
	Week 5	36	76.16	25.05	8.3	83.33	100.0	32	1.04	24.02	-50.0	0.00	66.7
	Week 6	32	80.47	18.53	33.3	83.33	100.0	29	4.02	24.05	-33.3	0.00	66.7
	Week 7	35	75.71	21.04	33.3	75.00	100.0	31	2.15	24.53	-41.7	0.00	66.7
	Week 8	35	77.38	22.65	25.0	83.33	100.0	31	2.96	24.21	-41.7	8.33	58.3
	Week 9	34	78.19	21.32	33.3	79.17	100.0	30	4.17	22.40	-58.3	8.33	50.0
	Week 10	33	77.27	22.17	16.7	83.33	100.0	30	5.56	25.36	-50.0	8.33	75.0
	Week 11	30	76.67	23.41	25.0	79.17	100.0	26	2.56	22.21	-50.0	8.33	33.3
	Week 12	32	78.13	22.17	16.7	83.33	100.0	27	6.48	18.10	-25.0	8.33	50.0
	Week 14	27	80.56	15.85	50.0	83.33	100.0	22	0.76	17.43	-41.7	0.00	33.3
	Week 17	28	80.95	19.88	33.3	83.33	100.0	23	2.54	20.33	-50.0	8.33	41.7
	Week 20	20	76.25	26.53	16.7	87.50	100.0	16	0.00	15.21	-33.3	8.33	25.0
	Week 23	15	81.67	23.19	25.0	91.67	100.0	14	4.17	11.67	-16.7	8.33	25.0
	Week 26	15	81.11	17.67	50.0	83.33	100.0	14	4.76	20.86	-25.0	8.33	50.0
	Week 29	13	78.85	29.58	0.0	83.33	100.0	12	-4.86	32.66	-100.0	8.33	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Absent	EV+Pembro (N=152)												
	BASELINE	120	74.79	21.40	0.0	75.00	100.0						
	Week 1	103	78.88	20.41	8.3	83.33	100.0	95	3.07	13.48	-50.0	0.00	41.7
	Week 2	115	75.07	21.67	0.0	75.00	100.0	101	0.33	16.58	-50.0	0.00	83.3
	Week 3	107	77.57	21.27	16.7	83.33	100.0	92	2.90	16.41	-33.3	0.00	75.0
	Week 4	110	79.39	22.20	25.0	83.33	100.0	98	3.06	18.32	-58.3	0.00	41.7
	Week 5	105	80.79	19.79	33.3	83.33	100.0	93	4.39	19.06	-50.0	0.00	41.7
	Week 6	111	78.60	22.52	0.0	83.33	100.0	94	2.66	20.49	-83.3	0.00	41.7
	Week 7	112	80.06	21.61	8.3	83.33	100.0	95	4.65	20.37	-66.7	0.00	66.7
	Week 8	109	80.81	20.86	0.0	83.33	100.0	93	5.29	21.70	-41.7	0.00	66.7
	Week 9	109	79.59	23.53	0.0	91.67	100.0	92	2.36	22.49	-58.3	0.00	66.7
	Week 10	109	81.35	21.33	0.0	91.67	100.0	93	3.23	19.16	-66.7	0.00	33.3
	Week 11	106	81.84	21.66	8.3	91.67	100.0	88	5.21	20.39	-66.7	0.00	58.3
	Week 12	110	80.00	23.28	0.0	91.67	100.0	91	4.21	19.89	-58.3	0.00	50.0
	Week 14	103	80.18	21.96	16.7	83.33	100.0	85	3.92	23.13	-58.3	0.00	66.7
	Week 17	99	81.06	19.81	16.7	83.33	100.0	84	4.37	20.10	-58.3	0.00	58.3
	Week 20	92	83.79	16.41	33.3	83.33	100.0	78	5.34	18.90	-50.0	0.00	66.7
	Week 23	89	83.90	16.61	33.3	83.33	100.0	73	5.25	19.37	-33.3	0.00	66.7
	Week 26	84	83.83	16.33	25.0	83.33	100.0	70	3.45	20.68	-41.7	0.00	91.7
	Week 29	80	82.81	16.84	25.0	83.33	100.0	68	2.57	20.22	-41.7	0.00	50.0
	Week 32	77	81.06	19.24	33.3	83.33	100.0	65	2.82	22.06	-58.3	0.00	75.0
	Week 35	72	79.05	21.67	0.0	83.33	100.0	62	0.40	23.59	-75.0	0.00	75.0
	Week 38	71	82.51	18.10	33.3	91.67	100.0	62	3.90	21.00	-41.7	0.00	75.0
	Week 41	70	79.88	17.23	33.3	83.33	100.0	61	1.78	22.16	-50.0	0.00	66.7
	Week 44	64	79.95	22.70	0.0	87.50	100.0	54	0.00	23.68	-75.0	0.00	66.7
	Week 47	65	79.62	20.20	25.0	83.33	100.0	57	2.05	24.16	-41.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	54	79.78	20.00	33.3	83.33	100.0	47	0.89	22.80	-50.0	0.00	75.0
	Week 53	53	78.30	20.43	25.0	75.00	100.0	45	1.48	22.00	-58.3	0.00	66.7
	Week 56	54	79.17	19.21	33.3	83.33	100.0	46	0.91	20.80	-50.0	0.00	75.0
	Week 59	51	78.27	20.62	25.0	83.33	100.0	42	1.19	23.18	-50.0	0.00	75.0
	Week 62	49	80.44	17.80	33.3	83.33	100.0	41	3.86	21.50	-41.7	0.00	66.7
	Week 65	36	74.54	24.31	25.0	75.00	100.0	33	0.50	24.11	-41.7	0.00	66.7
	Week 68	34	73.78	21.82	33.3	70.84	100.0	31	-1.61	23.90	-50.0	0.00	66.7
	Week 71	33	77.27	18.55	33.3	75.00	100.0	30	-0.28	21.94	-41.7	0.00	66.7
	Week 74	33	77.78	19.84	33.3	83.33	100.0	30	-0.28	24.81	-50.0	0.00	66.7
	Week 77	31	79.30	19.59	33.3	83.33	100.0	27	0.62	25.52	-58.3	0.00	66.7
	Week 80	31	75.27	21.68	33.3	75.00	100.0	29	-0.29	28.65	-50.0	0.00	66.7
	Week 83	25	78.00	17.98	41.7	83.33	100.0	24	1.04	25.10	-50.0	0.00	66.7
	Week 86	23	72.10	22.98	25.0	75.00	100.0	22	-0.38	26.16	-58.3	0.00	66.7
	Week 89	18	78.24	19.20	33.3	79.17	100.0	17	-0.98	22.22	-50.0	0.00	33.3
	Week 92	16	69.79	21.70	33.3	66.67	100.0	15	-1.11	20.86	-33.3	0.00	33.3
	Week 95	12	85.42	14.70	58.3	87.50	100.0	11	3.79	18.01	-33.3	0.00	33.3
	Plat+Gem (N=152)												
	BASELINE	125	77.33	21.63	16.7	83.33	100.0						
	Week 1	109	77.75	21.87	8.3	83.33	100.0	106	2.20	13.96	-25.0	0.00	41.7
	Week 2	114	77.27	22.37	0.0	83.33	100.0	105	0.32	18.01	-66.7	0.00	58.3
	Week 3	116	76.80	24.62	0.0	83.33	100.0	107	-0.70	18.95	-66.7	0.00	41.7
	Week 4	114	78.66	21.47	0.0	83.33	100.0	103	-0.32	16.00	-41.7	0.00	41.7
	Week 5	117	76.00	19.46	25.0	75.00	100.0	106	-3.14	18.09	-41.7	0.00	33.3
	Week 6	113	75.89	24.23	0.0	75.00	100.0	102	-2.21	19.83	-66.7	0.00	41.7
	Week 7	113	77.80	20.88	8.3	75.00	100.0	103	-2.02	19.37	-66.7	0.00	41.7
	Week 8	110	75.53	22.81	0.0	75.00	100.0	101	-3.30	20.14	-75.0	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	107	75.16	23.90	0.0	75.00	100.0	95	-2.72	21.28	-66.7	0.00	50.0
	Week 10	109	77.29	22.33	8.3	83.33	100.0	100	-0.92	19.92	-58.3	0.00	50.0
	Week 11	96	77.43	23.57	0.0	83.33	100.0	88	0.38	21.40	-66.7	0.00	58.3
	Week 12	98	77.72	21.73	0.0	83.33	100.0	88	1.23	19.56	-41.7	0.00	58.3
	Week 14	98	75.34	24.49	0.0	79.17	100.0	87	-2.39	20.33	-66.7	0.00	41.7
	Week 17	92	76.90	22.62	8.3	75.00	100.0	83	-2.71	22.62	-58.3	0.00	58.3
	Week 20	84	79.76	18.98	33.3	79.17	100.0	75	0.78	20.51	-50.0	0.00	50.0
	Week 23	73	82.42	17.87	33.3	83.33	100.0	66	2.53	18.60	-41.7	0.00	58.3
	Week 26	66	79.04	21.59	0.0	83.33	100.0	61	0.82	23.26	-75.0	0.00	58.3
	Week 29	64	78.78	19.53	25.0	83.33	100.0	59	-0.42	22.29	-75.0	0.00	58.3
	Week 32	54	77.93	21.67	16.7	75.00	100.0	49	-1.19	21.04	-58.3	0.00	58.3
	Week 35	54	76.85	23.10	0.0	79.17	100.0	48	-1.04	21.31	-58.3	0.00	50.0
	Week 38	47	77.13	22.15	33.3	75.00	100.0	42	-1.98	19.11	-50.0	0.00	50.0
	Week 41	45	79.82	20.83	25.0	83.33	100.0	40	-1.46	20.32	-50.0	0.00	50.0
	Week 44	41	74.19	24.71	16.7	75.00	100.0	36	-4.86	24.83	-66.7	0.00	50.0
	Week 47	35	77.14	22.90	25.0	75.00	100.0	31	-1.61	22.09	-58.3	0.00	50.0
	Week 50	29	76.15	24.47	25.0	91.67	100.0	24	-2.43	21.49	-50.0	0.00	25.0
	Week 53	25	82.33	20.17	41.7	91.67	100.0	22	2.65	18.07	-41.7	8.34	25.0
	Week 56	26	75.32	22.91	33.3	83.33	100.0	25	-1.67	16.84	-41.7	0.00	33.3
	Week 59	20	71.25	22.86	25.0	75.00	100.0	18	-4.63	21.24	-50.0	0.00	25.0
	Week 62	17	70.10	23.58	33.3	75.00	100.0	17	-3.92	19.79	-50.0	0.00	25.0
	Week 65	15	69.45	26.10	33.3	66.67	100.0	14	-7.14	21.65	-66.7	0.00	16.7
	Week 68	11	69.70	27.20	33.3	75.00	100.0	11	-6.06	23.00	-58.3	0.00	16.7
	Week 71	12	67.36	30.87	8.3	70.84	100.0	12	-6.95	28.39	-91.7	0.00	16.7
	Week 74	10	77.50	19.66	50.0	79.17	100.0	10	-4.17	14.30	-33.3	-4.17	16.7
	Week 77	10	83.33	25.46	25.0	95.84	100.0	10	-5.00	20.86	-41.7	0.00	16.7

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
< 65 years	EV+Pembro (N= 39)												
	BASELINE	32	73.70	18.71	33.3	75.00	100.0						
	Week 1	27	77.47	19.17	33.3	83.33	100.0	26	1.92	12.98	-25.0	0.00	33.3
	Week 2	30	77.50	19.22	41.7	75.00	100.0	29	2.30	17.38	-25.0	0.00	41.7
	Week 3	31	79.84	16.49	41.7	83.33	100.0	29	5.46	14.82	-25.0	0.00	33.3
	Week 4	30	83.89	18.30	33.3	91.67	100.0	27	7.41	16.56	-33.3	8.33	41.7
	Week 5	28	85.12	15.77	41.7	87.50	100.0	26	10.90	16.46	-16.7	0.00	41.7
	Week 6	29	83.05	15.67	41.7	83.33	100.0	26	9.30	18.76	-25.0	0.00	58.3
	Week 7	30	83.06	19.87	41.7	91.67	100.0	26	9.94	18.56	-33.3	8.33	41.7
	Week 8	30	84.72	17.52	33.3	91.67	100.0	26	8.65	18.33	-33.3	8.33	41.7
	Week 9	28	83.63	20.22	16.7	91.67	100.0	27	8.95	23.79	-50.0	8.33	66.7
	Week 10	26	83.65	17.24	33.3	87.50	100.0	23	6.16	20.29	-33.3	0.00	41.7
	Week 11	28	81.55	21.32	33.3	91.67	100.0	25	6.00	20.34	-33.3	8.33	41.7
	Week 12	28	83.93	16.03	41.7	87.50	100.0	25	7.67	15.76	-16.7	8.33	41.7
	Week 14	26	83.33	15.28	50.0	83.33	100.0	23	8.70	17.85	-25.0	0.00	33.3
	Week 17	28	77.38	21.14	41.7	75.00	100.0	24	5.90	17.46	-25.0	0.00	41.7
	Week 20	27	81.48	16.07	41.7	83.33	100.0	24	4.86	17.71	-33.3	4.17	41.7
	Week 23	26	84.30	15.15	50.0	87.50	100.0	23	7.25	19.51	-33.3	0.00	50.0
	Week 26	24	82.64	16.65	41.7	83.33	100.0	22	4.92	20.68	-33.3	0.00	50.0
	Week 29	25	81.00	19.32	25.0	83.33	100.0	23	6.16	20.29	-41.7	8.34	33.3
	Week 32	25	81.33	18.52	33.3	83.33	100.0	23	6.88	19.41	-33.3	8.33	41.7
	Week 35	24	79.86	20.55	33.3	79.17	100.0	22	5.68	21.27	-33.3	4.17	41.7
	Week 38	23	80.07	16.81	33.3	75.00	100.0	22	4.92	21.00	-33.3	0.00	41.7
	Week 41	25	78.67	17.02	50.0	75.00	100.0	23	2.90	24.31	-50.0	0.00	41.7
	Week 44	22	78.03	18.64	41.7	70.84	100.0	20	0.42	17.83	-33.3	0.00	33.3
	Week 47	20	77.92	21.68	33.3	75.00	100.0	18	-1.39	20.46	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	19	83.77	19.34	33.3	91.67	100.0	17	5.39	19.75	-33.3	8.33	33.3
	Week 53	20	80.42	17.78	41.7	75.00	100.0	18	1.85	17.98	-33.3	0.00	33.3
	Week 56	17	79.41	17.95	50.0	83.33	100.0	15	1.11	16.02	-33.3	0.00	33.3
	Week 59	17	76.96	21.76	33.3	83.33	100.0	15	1.11	18.33	-33.3	0.00	33.3
	Week 62	15	82.78	14.93	66.7	91.67	100.0	14	1.19	16.94	-33.3	0.00	33.3
	Week 65	14	78.57	16.89	50.0	70.84	100.0	13	1.28	16.96	-33.3	0.00	25.0
	Week 68	11	81.06	15.41	66.7	75.00	100.0	10	1.67	18.34	-33.3	4.17	25.0
	Week 71	13	78.21	19.99	33.3	75.00	100.0	12	0.00	17.04	-33.3	0.00	25.0
	Week 74	14	76.19	21.40	33.3	75.00	100.0	13	-5.13	19.41	-33.3	0.00	25.0
	Week 77	14	77.38	17.73	41.7	75.00	100.0	13	0.00	20.69	-58.3	0.00	25.0
	Week 80	14	74.41	20.53	33.3	66.67	100.0	13	-6.41	17.06	-41.7	0.00	16.7
	Week 83	12	74.31	21.75	41.7	66.67	100.0	11	-4.55	19.14	-50.0	0.00	16.7
	Plat+Gem (N= 29)												
	BASELINE	22	87.50	14.03	41.7	87.50	100.0						
	Week 1	21	83.33	16.46	50.0	83.33	100.0	20	-3.33	11.60	-25.0	0.00	16.7
	Week 2	24	82.64	14.10	58.3	79.17	100.0	20	-2.92	16.29	-33.3	0.00	25.0
	Week 3	23	87.68	13.96	58.3	91.67	100.0	20	-0.42	13.65	-33.3	0.00	16.7
	Week 4	23	79.71	15.25	41.7	83.33	100.0	19	-7.45	10.72	-25.0	-8.33	8.3
	Week 5	25	80.00	15.77	50.0	83.33	100.0	20	-5.00	14.41	-33.3	0.00	16.7
	Week 6	22	81.44	16.25	50.0	83.33	100.0	18	-4.17	14.36	-33.3	0.00	16.7
	Week 7	24	82.64	19.18	41.7	91.67	100.0	21	-3.57	15.04	-33.3	0.00	16.7
	Week 8	21	82.54	17.66	41.7	83.33	100.0	19	-4.82	15.79	-41.7	0.00	16.7
	Week 9	20	80.42	17.99	41.7	83.33	100.0	17	-3.92	13.21	-33.3	0.00	16.7
	Week 10	21	80.16	18.35	41.7	83.33	100.0	18	-5.56	15.39	-41.7	0.00	16.7
	Week 11	20	82.50	17.71	41.7	87.50	100.0	17	-1.47	11.12	-25.0	0.00	16.7
	Week 12	21	84.52	17.34	58.3	91.67	100.0	17	0.98	14.40	-33.3	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 14	22	77.65	24.58	16.7	87.50	100.0	18	-6.48	20.92	-66.7	0.00	16.7
	Week 17	20	85.83	18.56	33.3	95.84	100.0	17	0.98	15.84	-41.7	0.00	16.7
	Week 20	18	81.48	18.20	41.7	79.17	100.0	15	-5.55	18.55	-41.7	0.00	16.7
	Week 23	18	88.43	12.50	66.7	91.67	100.0	16	1.04	13.22	-25.0	0.00	25.0
	Week 26	16	85.42	16.24	41.7	91.67	100.0	14	-0.59	19.47	-58.3	4.17	25.0
	Week 29	15	87.22	15.39	50.0	91.67	100.0	13	0.64	17.50	-50.0	0.00	16.7
	Week 32	15	82.78	18.49	41.7	91.67	100.0	13	-3.20	17.85	-33.3	0.00	16.7
	Week 35	15	73.33	29.41	0.0	83.33	100.0	13	-7.69	22.68	-58.3	0.00	16.7
	Week 38	14	69.05	30.74	0.0	66.67	100.0	12	-13.19	23.96	-66.7	-8.33	16.7
	Week 41	11	77.27	23.00	25.0	75.00	100.0	9	-11.11	22.82	-50.0	0.00	16.7
	Week 44	11	75.00	24.15	33.3	83.33	100.0	9	-12.04	20.03	-50.0	-8.33	8.3
	Week 47	11	77.27	24.18	33.3	83.33	100.0	9	-6.48	21.56	-58.3	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>= 65 years	EV+Pembro (N=163)												
	BASELINE	128	75.33	21.90	0.0	75.00	100.0						
	Week 1	114	77.70	22.82	0.0	83.33	100.0	103	2.18	15.83	-66.7	0.00	41.7
	Week 2	120	75.00	22.87	0.0	75.00	100.0	104	0.24	18.01	-50.0	0.00	83.3
	Week 3	108	76.78	22.21	16.7	79.17	100.0	93	1.70	17.09	-33.3	0.00	75.0
	Week 4	115	78.84	22.68	25.0	83.33	100.0	102	2.21	19.09	-58.3	0.00	41.7
	Week 5	109	79.66	20.52	33.3	83.33	100.0	95	2.11	19.10	-50.0	0.00	41.7
	Week 6	117	78.28	22.85	0.0	83.33	100.0	98	2.55	20.95	-83.3	0.00	41.7
	Week 7	117	79.06	21.93	8.3	83.33	100.0	98	3.23	20.47	-66.7	0.00	66.7
	Week 8	117	78.85	22.70	0.0	83.33	100.0	98	3.49	23.93	-83.3	4.17	66.7
	Week 9	114	78.22	24.58	0.0	83.33	100.0	94	1.15	23.01	-83.3	0.00	66.7
	Week 10	113	81.05	21.83	0.0	91.67	100.0	95	3.86	18.94	-66.7	8.33	33.3
	Week 11	109	82.80	20.73	8.3	91.67	100.0	90	5.00	20.52	-66.7	0.00	58.3
	Week 12	114	80.41	23.54	0.0	91.67	100.0	94	3.90	20.11	-58.3	0.00	50.0
	Week 14	113	80.83	22.41	16.7	91.67	100.0	93	4.39	23.75	-66.7	8.33	66.7
	Week 17	104	81.89	21.11	16.7	91.67	100.0	87	3.74	20.48	-58.3	0.00	58.3
	Week 20	93	83.87	17.10	33.3	91.67	100.0	79	4.43	20.27	-50.0	0.00	66.7
	Week 23	91	82.51	18.34	16.7	83.33	100.0	74	3.49	20.55	-41.7	0.00	66.7
	Week 26	88	82.58	18.34	25.0	83.33	100.0	72	1.85	21.81	-58.3	0.00	91.7
	Week 29	82	83.74	16.66	33.3	91.67	100.0	70	2.02	20.43	-50.0	0.00	50.0
	Week 32	77	81.71	19.31	25.0	83.33	100.0	65	1.92	21.34	-58.3	0.00	75.0
	Week 35	74	80.74	20.78	0.0	83.33	100.0	64	-0.39	22.93	-75.0	0.00	75.0
	Week 38	74	82.77	19.28	25.0	91.67	100.0	64	1.95	21.45	-50.0	0.00	75.0
	Week 41	70	79.29	19.54	0.0	83.33	100.0	61	-0.96	22.31	-66.7	0.00	66.7
	Week 44	64	80.21	22.64	0.0	91.67	100.0	54	-0.62	24.70	-75.0	0.00	66.7
	Week 47	59	79.52	20.20	25.0	83.33	100.0	52	1.60	24.70	-41.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	55	78.33	20.58	25.0	75.00	100.0	47	-2.48	23.69	-66.7	0.00	75.0
	Week 53	54	76.85	21.94	16.7	75.00	100.0	45	-1.67	24.07	-75.0	0.00	66.7
	Week 56	55	76.67	22.59	8.3	83.33	100.0	46	-2.72	23.64	-66.7	0.00	75.0
	Week 59	52	78.53	21.85	25.0	83.33	100.0	42	0.60	23.38	-50.0	0.00	75.0
	Week 62	47	79.97	18.69	33.3	83.33	100.0	38	3.95	21.72	-41.7	0.00	66.7
	Week 65	29	75.86	26.10	25.0	83.33	100.0	27	2.47	25.61	-41.7	0.00	66.7
	Week 68	35	74.29	21.71	33.3	83.33	100.0	32	-2.34	24.25	-50.0	0.00	66.7
	Week 71	29	75.86	18.68	33.3	66.67	100.0	26	-0.96	24.87	-41.7	0.00	66.7
	Week 74	24	77.08	20.30	33.3	79.17	100.0	22	1.14	28.67	-50.0	4.17	66.7
	Week 77	23	80.07	20.22	33.3	83.33	100.0	20	2.50	27.98	-50.0	8.33	66.7
	Week 80	22	76.52	21.46	33.3	79.17	100.0	21	4.76	32.44	-50.0	8.33	66.7
	Week 83	18	79.17	17.21	41.7	83.33	100.0	18	4.17	28.90	-50.0	8.33	66.7
	Week 86	18	71.30	23.61	25.0	70.84	100.0	18	-0.46	31.50	-66.7	0.00	66.7
	Week 89	12	79.17	20.26	33.3	83.34	100.0	12	2.09	23.87	-50.0	4.17	33.3
	Week 92	10	76.67	21.44	41.7	75.00	100.0	10	5.00	20.86	-33.3	8.34	33.3
	Plat+Gem (N=173)												
	BASELINE	143	74.30	22.56	8.3	75.00	100.0						
	Week 1	123	76.42	22.12	8.3	83.33	100.0	119	2.52	16.04	-33.3	0.00	58.3
	Week 2	123	75.00	23.50	0.0	83.33	100.0	115	-0.36	19.57	-66.7	0.00	58.3
	Week 3	126	74.54	24.55	0.0	83.33	100.0	116	-0.86	20.98	-66.7	0.00	58.3
	Week 4	127	78.22	21.72	0.0	83.33	100.0	116	1.87	18.65	-50.0	0.00	58.3
	Week 5	128	75.26	21.63	8.3	75.00	100.0	118	-1.69	20.37	-50.0	0.00	66.7
	Week 6	123	76.08	24.09	0.0	75.00	100.0	113	-0.29	21.76	-66.7	0.00	66.7
	Week 7	124	76.28	21.09	8.3	75.00	100.0	113	-0.59	21.56	-66.7	0.00	66.7
	Week 8	124	74.87	23.33	0.0	75.00	100.0	113	-1.33	22.04	-75.0	0.00	58.3
	Week 9	121	75.14	24.01	0.0	75.00	100.0	108	-0.62	22.72	-66.7	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	121	76.79	22.85	8.3	83.33	100.0	112	1.56	22.08	-58.3	0.00	75.0
	Week 11	106	76.26	24.31	0.0	83.33	100.0	97	1.29	22.86	-66.7	0.00	58.3
	Week 12	109	76.53	22.34	0.0	83.33	100.0	98	2.72	20.05	-41.7	0.00	58.3
	Week 14	103	76.21	22.70	0.0	83.33	100.0	91	-0.82	19.49	-58.3	0.00	41.7
	Week 17	100	76.25	22.36	8.3	75.00	100.0	89	-2.06	23.21	-58.3	0.00	58.3
	Week 20	86	78.59	21.06	16.7	83.33	100.0	76	1.86	19.70	-50.0	0.00	50.0
	Week 23	70	80.71	19.79	25.0	83.33	100.0	64	3.26	18.52	-41.7	0.00	58.3
	Week 26	65	77.95	21.67	0.0	83.33	100.0	61	2.05	23.55	-75.0	0.00	58.3
	Week 29	62	76.75	22.13	0.0	75.00	100.0	58	-1.58	25.48	-100.0	0.00	58.3
	Week 32	48	77.60	22.02	16.7	75.00	100.0	45	0.00	20.33	-58.3	0.00	58.3
	Week 35	47	79.43	19.80	33.3	83.33	100.0	43	1.94	18.97	-33.3	0.00	50.0
	Week 38	42	78.57	23.00	33.3	75.00	100.0	38	0.66	18.32	-41.7	0.00	50.0
	Week 41	41	80.90	20.43	33.3	91.67	100.0	38	1.54	17.74	-33.3	0.00	50.0
	Week 44	38	75.88	24.18	16.7	75.00	100.0	35	-1.43	23.61	-66.7	0.00	50.0
	Week 47	32	78.39	22.39	25.0	79.17	100.0	30	0.56	20.52	-41.7	0.00	50.0
	Week 50	29	79.02	25.65	16.7	91.67	100.0	26	-0.96	20.05	-50.0	0.00	25.0
	Week 53	25	84.00	19.83	33.3	91.67	100.0	24	1.74	18.22	-41.7	4.17	25.0
	Week 56	26	74.04	24.19	33.3	79.17	100.0	26	-3.20	17.65	-41.7	0.00	33.3
	Week 59	20	74.58	21.54	25.0	79.17	100.0	20	-3.75	19.77	-50.0	0.00	25.0
	Week 62	19	71.05	22.97	33.3	75.00	100.0	19	-4.39	19.91	-50.0	0.00	25.0
	Week 65	16	72.92	24.63	33.3	79.17	100.0	16	-6.25	20.53	-66.7	0.00	16.7
	Week 68	13	72.44	26.22	33.3	75.00	100.0	13	-4.49	21.95	-58.3	0.00	16.7
	Week 71	13	69.87	30.91	8.3	75.00	100.0	13	-5.13	27.96	-91.7	0.00	16.7
	Week 74	11	79.55	19.85	50.0	91.67	100.0	11	-2.27	14.95	-33.3	0.00	16.7
	Week 77	10	83.33	25.46	25.0	95.84	100.0	10	-5.00	20.86	-41.7	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Europe	EV+Pembro (N= 74)												
	BASELINE	53	75.47	21.71	8.3	75.00	100.0						
	Week 1	48	75.52	25.29	0.0	83.33	100.0	42	1.19	18.18	-66.7	0.00	33.3
	Week 2	53	74.69	25.47	0.0	83.33	100.0	44	0.57	19.72	-50.0	0.00	50.0
	Week 3	50	74.67	22.59	16.7	75.00	100.0	41	3.66	16.46	-25.0	0.00	41.7
	Week 4	51	77.78	22.40	25.0	83.33	100.0	44	2.08	20.34	-58.3	0.00	41.7
	Week 5	46	77.54	21.36	33.3	79.17	100.0	41	2.03	22.42	-50.0	0.00	41.7
	Week 6	50	78.50	21.37	25.0	83.33	100.0	39	4.92	20.57	-50.0	0.00	58.3
	Week 7	50	79.83	22.84	16.7	83.33	100.0	39	3.21	22.83	-58.3	0.00	41.7
	Week 8	51	80.72	23.60	0.0	91.67	100.0	41	5.08	23.64	-83.3	8.33	41.7
	Week 9	47	79.61	26.91	0.0	91.67	100.0	37	3.83	24.89	-83.3	0.00	66.7
	Week 10	45	81.85	22.21	0.0	91.67	100.0	34	3.43	18.36	-50.0	0.00	41.7
	Week 11	48	82.81	20.37	33.3	91.67	100.0	37	4.28	18.60	-50.0	0.00	41.7
	Week 12	51	81.70	21.22	33.3	91.67	100.0	39	4.49	19.39	-58.3	0.00	33.3
	Week 14	50	84.00	19.84	25.0	91.67	100.0	38	9.43	22.86	-66.7	12.51	50.0
	Week 17	43	81.98	22.41	25.0	91.67	100.0	33	6.31	20.73	-50.0	0.00	58.3
	Week 20	41	83.33	16.14	41.7	91.67	100.0	33	4.29	19.45	-50.0	0.00	41.7
	Week 23	41	83.54	18.02	33.3	83.33	100.0	30	6.39	20.84	-33.3	4.17	50.0
	Week 26	37	80.86	18.20	33.3	83.33	100.0	28	-1.19	20.25	-58.3	0.00	50.0
	Week 29	37	86.94	15.78	41.7	91.67	100.0	29	4.89	19.35	-50.0	8.33	41.7
	Week 32	34	82.35	18.44	33.3	87.50	100.0	26	5.45	17.31	-50.0	0.00	33.3
	Week 35	31	84.95	19.77	33.3	91.67	100.0	25	3.33	19.25	-41.7	0.00	33.3
	Week 38	31	83.33	16.81	33.3	91.67	100.0	26	1.28	16.78	-41.7	0.00	33.3
	Week 41	28	78.87	16.89	33.3	83.33	100.0	23	-3.62	19.60	-50.0	0.00	33.3
	Week 44	27	82.41	18.82	41.7	91.67	100.0	22	-4.17	17.40	-50.0	0.00	25.0
	Week 47	25	80.00	18.63	50.0	83.33	100.0	21	0.00	18.82	-41.7	0.00	41.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	26	80.13	21.35	25.0	83.33	100.0	23	-5.43	21.26	-66.7	0.00	33.3
	Week 53	26	78.21	24.16	16.7	83.33	100.0	21	-4.37	24.95	-75.0	0.00	25.0
	Week 56	25	77.00	22.09	25.0	83.33	100.0	21	-6.35	20.23	-66.7	0.00	25.0
	Week 59	23	84.42	16.72	33.3	91.67	100.0	18	1.39	11.52	-25.0	0.00	25.0
	Week 62	20	85.00	17.23	33.3	91.67	100.0	17	5.88	12.76	-16.7	8.33	25.0
	Week 65	13	78.21	23.95	33.3	83.33	100.0	13	6.41	14.09	-16.7	0.00	25.0
	Week 68	15	76.11	22.46	33.3	83.33	100.0	15	0.00	18.90	-33.3	0.00	25.0
	Week 71	13	82.05	14.37	66.7	75.00	100.0	13	2.57	16.10	-25.0	8.33	25.0
	Week 74	10	80.00	21.59	33.3	87.50	100.0	9	5.56	17.68	-33.3	8.34	25.0
	Plat+Gem (N= 95)												
	BASELINE	75	71.78	24.46	8.3	75.00	100.0						
	Week 1	71	73.71	23.43	8.3	83.33	100.0	69	3.74	16.88	-25.0	0.00	58.3
	Week 2	71	74.53	21.26	16.7	75.00	100.0	63	2.91	16.48	-41.7	0.00	58.3
	Week 3	72	74.07	25.00	0.0	79.17	100.0	65	1.92	20.40	-58.3	0.00	58.3
	Week 4	69	78.14	21.35	8.3	83.33	100.0	62	4.30	18.40	-33.3	0.00	58.3
	Week 5	71	74.77	22.76	8.3	75.00	100.0	63	1.32	20.59	-50.0	0.00	66.7
	Week 6	69	73.67	25.55	0.0	75.00	100.0	61	0.68	23.78	-66.7	0.00	66.7
	Week 7	69	75.12	23.20	8.3	75.00	100.0	62	0.67	22.29	-66.7	0.00	66.7
	Week 8	67	76.24	21.43	25.0	75.00	100.0	60	2.08	21.73	-50.0	0.00	58.3
	Week 9	66	74.87	24.04	8.3	83.33	100.0	57	2.34	23.35	-66.7	0.00	50.0
	Week 10	70	77.38	21.80	16.7	83.33	100.0	63	4.76	22.44	-41.7	0.00	75.0
	Week 11	63	77.38	23.64	0.0	83.33	100.0	56	5.51	21.86	-66.7	8.33	58.3
	Week 12	66	75.51	22.87	16.7	79.17	100.0	56	4.02	22.19	-41.7	0.00	58.3
	Week 14	66	75.00	23.02	8.3	83.33	100.0	56	-0.45	19.36	-58.3	0.00	41.7
	Week 17	61	77.87	21.78	25.0	83.33	100.0	53	2.67	24.17	-58.3	0.00	58.3
	Week 20	54	79.48	19.13	33.3	83.33	100.0	48	3.30	21.11	-41.7	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 23	44	82.20	18.47	33.3	83.33	100.0	40	7.29	17.92	-25.0	0.00	58.3
	Week 26	42	75.99	22.56	0.0	75.00	100.0	39	1.71	25.59	-75.0	0.00	58.3
	Week 29	39	79.49	19.10	33.3	75.00	100.0	36	4.17	18.84	-33.3	0.00	58.3
	Week 32	32	76.56	23.71	16.7	79.17	100.0	30	1.39	22.11	-58.3	0.00	58.3
	Week 35	32	75.26	23.52	0.0	79.17	100.0	30	1.39	19.34	-33.3	0.00	50.0
	Week 38	28	75.00	24.22	33.3	75.00	100.0	26	-3.21	19.73	-41.7	0.00	50.0
	Week 41	25	76.67	23.81	25.0	75.00	100.0	23	-1.09	20.77	-50.0	0.00	50.0
	Week 44	24	76.04	25.81	16.7	79.17	100.0	22	-0.76	25.71	-66.7	0.00	50.0
	Week 47	22	78.03	24.87	25.0	87.50	100.0	20	2.50	21.48	-41.7	0.00	50.0
	Week 50	17	74.02	29.30	16.7	83.33	100.0	15	-5.00	24.15	-50.0	0.00	25.0
	Week 53	15	77.78	25.13	33.3	83.33	100.0	14	-2.38	20.26	-41.7	0.00	25.0
	Week 56	15	71.67	25.94	33.3	75.00	100.0	14	-3.57	18.98	-41.7	0.00	33.3
	Week 59	11	72.73	23.00	25.0	75.00	100.0	10	-8.33	23.90	-50.0	-4.17	25.0
	Week 62	11	67.42	25.40	33.3	75.00	100.0	11	-8.33	20.41	-50.0	-8.33	25.0
	Week 65	10	70.00	27.56	33.3	70.84	100.0	10	-7.50	24.67	-66.7	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
North America	EV+Pembro (N= 46)												
	BASELINE	33	78.79	13.83	50.0	83.33	100.0						
	Week 1	30	80.56	18.22	25.0	87.50	100.0	27	2.78	12.23	-33.3	0.00	33.3
	Week 2	30	80.56	18.87	16.7	79.17	100.0	26	0.96	15.87	-50.0	4.17	25.0
	Week 3	25	87.33	12.29	66.7	91.67	100.0	21	5.95	9.91	-8.3	8.33	25.0
	Week 4	30	85.00	17.70	33.3	91.67	100.0	24	5.21	12.49	-33.3	8.33	25.0
	Week 5	29	83.91	19.66	33.3	91.67	100.0	21	5.16	12.49	-16.7	8.33	33.3
	Week 6	31	83.60	14.98	50.0	91.67	100.0	23	5.80	11.63	-33.3	8.33	25.0
	Week 7	33	81.82	18.45	33.3	91.67	100.0	23	6.16	9.80	-16.7	8.33	25.0
	Week 8	29	84.20	16.86	41.7	91.67	100.0	20	9.58	13.59	-25.0	8.34	33.3
	Week 9	27	83.95	16.65	41.7	91.67	100.0	21	4.76	20.84	-58.3	8.33	33.3
	Week 10	29	87.07	13.29	58.3	91.67	100.0	23	9.42	15.35	-33.3	8.34	33.3
	Week 11	28	83.04	20.09	25.0	91.67	100.0	21	7.54	16.01	-25.0	8.33	33.3
	Week 12	29	86.78	16.89	33.3	91.67	100.0	22	9.47	11.30	-16.7	8.33	33.3
	Week 14	28	81.85	21.52	33.3	91.67	100.0	21	2.78	23.02	-50.0	8.33	33.3
	Week 17	29	83.62	17.60	41.7	91.67	100.0	23	6.88	16.21	-33.3	8.33	33.3
	Week 20	23	86.96	15.04	50.0	91.67	100.0	18	5.56	21.58	-50.0	8.33	33.3
	Week 23	22	90.53	11.87	66.7	91.67	100.0	17	9.80	15.09	-25.0	8.34	33.3
	Week 26	21	87.30	12.53	66.7	91.67	100.0	16	5.21	16.06	-25.0	4.17	33.3
	Week 29	20	87.08	13.38	58.3	91.67	100.0	17	5.39	20.19	-41.7	8.33	33.3
	Week 32	21	84.92	17.00	41.7	91.67	100.0	18	3.70	22.18	-58.3	8.33	33.3
	Week 35	22	84.85	13.02	66.7	87.50	100.0	19	2.63	16.44	-33.3	0.00	33.3
	Week 38	20	84.58	18.59	33.3	91.67	100.0	17	1.47	22.09	-50.0	0.00	33.3
	Week 41	21	85.32	14.17	50.0	91.67	100.0	17	2.94	19.31	-33.3	0.00	33.3
	Week 44	16	88.54	15.77	50.0	95.84	100.0	12	7.64	22.60	-50.0	8.34	33.3
	Week 47	16	85.94	17.93	33.3	91.67	100.0	13	3.85	22.21	-33.3	8.34	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	16	85.94	13.51	58.3	91.67	100.0	11	6.06	21.76	-41.7	8.34	33.3
	Week 53	15	83.33	14.77	66.7	83.33	100.0	11	6.06	17.51	-16.7	0.00	33.3
	Week 56	17	82.84	15.44	41.7	83.33	100.0	12	6.25	15.13	-16.7	4.17	33.3
	Week 59	17	79.41	21.06	25.0	83.33	100.0	12	4.17	18.63	-33.3	8.34	33.3
	Week 62	14	82.74	17.13	41.7	91.67	100.0	9	6.48	19.88	-25.0	8.34	33.3
	Week 68	11	87.12	12.00	66.7	91.67	100.0	8	6.25	20.77	-33.3	8.34	33.3
	Week 71	11	79.55	21.20	33.3	91.67	100.0	8	-3.12	23.54	-33.3	0.00	33.3
	Plat+Gem (N= 34)												
	BASELINE	27	77.16	19.14	33.3	83.33	100.0						
	Week 1	19	80.70	13.34	50.0	83.33	100.0	17	-1.47	12.23	-25.0	0.00	25.0
	Week 2	20	85.00	16.36	41.7	91.67	100.0	18	1.39	12.54	-25.0	0.00	16.7
	Week 3	20	82.50	16.86	33.3	83.33	100.0	17	-0.49	13.33	-33.3	0.00	16.7
	Week 4	23	82.97	19.22	33.3	83.33	100.0	19	0.88	12.08	-33.3	0.00	16.7
	Week 5	25	81.67	18.00	41.7	83.33	100.0	22	1.14	15.49	-25.0	0.00	33.3
	Week 6	20	83.33	17.31	33.3	83.33	100.0	17	1.47	16.20	-33.3	0.00	33.3
	Week 7	23	81.52	20.56	25.0	83.33	100.0	20	-0.83	17.29	-41.7	0.00	33.3
	Week 8	24	77.78	22.21	25.0	79.17	100.0	22	-3.03	18.28	-41.7	0.00	33.3
	Week 9	23	80.07	21.72	16.7	75.00	100.0	19	-0.88	20.01	-50.0	0.00	33.3
	Week 10	20	78.33	23.79	8.3	79.17	100.0	18	-2.78	20.61	-58.3	0.00	33.3
	Week 11	18	81.48	20.12	25.0	83.33	100.0	16	-3.12	16.63	-41.7	0.00	16.7
	Week 12	17	87.26	15.62	58.3	91.67	100.0	16	8.86	13.77	-25.0	8.34	33.3
	Week 14	16	79.69	23.37	33.3	87.50	100.0	14	-1.79	25.78	-66.7	0.00	33.3
	Week 17	19	80.26	21.91	33.3	83.33	100.0	17	-3.92	17.46	-41.7	0.00	16.7
	Week 20	16	82.29	23.54	16.7	95.84	100.0	13	-1.92	19.88	-41.7	0.00	16.7
	Week 23	15	86.67	20.61	25.0	100.00	100.0	13	5.77	13.77	-25.0	8.33	25.0
	Week 26	13	86.54	17.19	41.7	91.67	100.0	12	3.47	23.42	-58.3	16.67	25.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 29	14	76.19	22.37	25.0	83.33	100.0	13	-8.97	27.53	-75.0	-8.33	16.7
	Week 32	11	87.12	10.78	75.0	91.67	100.0	10	3.33	11.25	-25.0	8.33	16.7
	Week 35	13	86.54	16.85	41.7	83.33	100.0	11	3.03	22.44	-58.3	16.66	16.7
	Week 38	10	76.67	32.35	0.0	87.50	100.0	9	-7.41	30.46	-66.7	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Rest of World	EV+Pembro (N= 82)												
	BASELINE	74	72.97	23.52	0.0	75.00	100.0						
	Week 1	63	77.91	21.33	8.3	83.33	100.0	60	2.50	14.42	-50.0	0.00	41.7
	Week 2	67	73.88	20.61	25.0	75.00	100.0	63	0.66	17.47	-50.0	0.00	83.3
	Week 3	64	75.78	21.66	16.7	75.00	100.0	60	0.69	18.43	-33.3	0.00	75.0
	Week 4	64	79.17	23.15	25.0	83.33	100.0	61	3.41	19.57	-58.3	0.00	41.7
	Week 5	62	81.72	18.41	33.3	91.67	100.0	59	4.94	18.19	-41.7	0.00	41.7
	Week 6	65	77.69	24.39	0.0	83.33	100.0	62	2.69	23.27	-83.3	0.00	41.7
	Week 7	64	78.91	22.17	8.3	83.33	100.0	62	4.97	21.47	-66.7	0.00	66.7
	Week 8	67	77.74	22.30	33.3	83.33	100.0	63	2.64	24.72	-66.7	0.00	66.7
	Week 9	68	77.21	23.99	16.7	83.33	100.0	63	1.72	23.44	-58.3	0.00	66.7
	Week 10	65	78.85	22.68	8.3	83.33	100.0	61	2.87	20.74	-66.7	0.00	41.7
	Week 11	61	82.10	21.72	8.3	91.67	100.0	57	4.97	23.03	-66.7	0.00	58.3
	Week 12	62	77.96	24.89	0.0	83.33	100.0	58	3.02	21.44	-58.3	0.00	50.0
	Week 14	61	78.83	22.23	16.7	83.33	100.0	57	3.36	22.49	-58.3	0.00	66.7
	Week 17	60	78.89	21.83	16.7	79.17	100.0	55	1.82	20.64	-58.3	0.00	50.0
	Week 20	56	81.85	18.06	33.3	83.33	100.0	52	4.33	19.42	-33.3	0.00	66.7
	Week 23	54	79.32	18.51	16.7	79.17	100.0	50	1.33	21.25	-41.7	0.00	66.7
	Week 26	54	81.94	19.41	25.0	83.33	100.0	50	3.83	23.64	-33.3	0.00	91.7
	Week 29	50	78.67	18.84	25.0	75.00	100.0	47	1.06	21.25	-41.7	0.00	50.0
	Week 32	47	79.61	20.40	25.0	83.33	100.0	44	1.70	22.49	-33.3	0.00	75.0
	Week 35	45	75.37	23.23	0.0	75.00	100.0	42	-0.79	26.66	-75.0	0.00	75.0
	Week 38	46	80.25	20.06	25.0	79.17	100.0	43	4.07	23.60	-33.3	0.00	75.0
	Week 41	46	76.45	21.32	0.0	75.00	100.0	44	0.95	25.62	-66.7	0.00	66.7
	Week 44	43	74.61	23.98	0.0	66.67	100.0	40	-0.62	25.49	-75.0	0.00	66.7
	Week 47	38	75.66	22.21	25.0	75.00	100.0	36	0.23	26.84	-41.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	32	76.30	21.91	33.3	70.84	100.0	30	1.11	24.24	-33.3	0.00	75.0
	Week 53	33	75.00	20.41	33.3	66.67	100.0	31	-0.54	22.25	-33.3	0.00	66.7
	Week 56	30	74.45	23.87	8.3	75.00	100.0	28	-1.79	25.09	-50.0	0.00	75.0
	Week 59	29	72.41	24.51	25.0	66.67	100.0	27	-1.23	28.28	-50.0	0.00	75.0
	Week 62	28	76.49	18.15	41.7	70.84	100.0	26	0.32	24.55	-41.7	0.00	66.7
	Week 65	22	68.94	23.31	25.0	66.67	100.0	21	-5.16	26.68	-41.7	0.00	66.7
	Week 68	20	69.58	20.64	33.3	66.67	100.0	19	-5.70	26.36	-50.0	0.00	66.7
	Week 71	18	70.83	19.65	33.3	66.67	100.0	17	-1.96	26.77	-41.7	0.00	66.7
	Week 74	19	71.05	19.32	33.3	66.67	100.0	19	-4.82	29.44	-50.0	-8.33	66.7
	Week 77	19	71.93	19.49	33.3	75.00	100.0	18	-1.85	28.80	-58.3	0.00	66.7
	Week 80	19	71.49	22.79	33.3	66.67	100.0	18	-2.32	28.70	-50.0	0.00	66.7
	Week 83	17	73.04	19.88	41.7	66.67	100.0	17	-1.47	29.79	-50.0	0.00	66.7
	Week 86	14	65.48	25.29	25.0	66.67	100.0	14	-6.55	33.84	-66.7	-4.17	66.7
	Week 89	11	74.24	21.88	33.3	66.67	100.0	11	-3.79	23.68	-50.0	0.00	33.3
	Plat+Gem (N= 73)												
	BASELINE	63	80.69	19.33	25.0	83.33	100.0						
	Week 1	54	81.17	20.55	8.3	83.33	100.0	53	0.00	14.62	-33.3	0.00	41.7
	Week 2	56	75.30	25.07	0.0	83.33	100.0	54	-5.71	22.60	-66.7	0.00	33.3
	Week 3	57	77.63	23.89	0.0	83.33	100.0	54	-4.17	21.09	-66.7	0.00	33.3
	Week 4	58	77.01	20.90	0.0	75.00	100.0	54	-3.86	18.58	-50.0	0.00	33.3
	Week 5	57	75.15	19.32	33.3	66.67	100.0	53	-7.70	18.98	-50.0	-8.33	33.3
	Week 6	56	78.57	21.37	0.0	83.33	100.0	53	-3.30	18.66	-41.7	0.00	41.7
	Week 7	56	78.27	17.74	33.3	75.00	100.0	52	-3.20	19.95	-41.7	0.00	33.3
	Week 8	54	74.85	24.74	0.0	75.00	100.0	50	-6.00	21.37	-75.0	0.00	33.3
	Week 9	52	75.32	23.16	0.0	75.00	100.0	49	-5.10	19.90	-58.3	0.00	33.3
	Week 10	52	76.76	22.59	8.3	83.33	100.0	49	-3.57	19.54	-50.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	45	75.37	24.62	0.0	75.00	100.0	42	-3.77	21.79	-50.0	0.00	33.3
	Week 12	47	77.66	21.50	0.0	75.00	100.0	43	-1.94	16.04	-33.3	0.00	33.3
	Week 14	43	77.52	23.04	0.0	75.00	100.0	39	-3.63	18.22	-41.7	0.00	33.3
	Week 17	40	76.67	22.82	8.3	75.00	100.0	36	-6.71	20.20	-58.3	0.00	16.7
	Week 20	34	76.96	21.62	33.3	75.00	100.0	30	-2.50	16.83	-50.0	0.00	33.3
	Week 23	29	80.17	18.42	33.3	83.33	100.0	27	-5.25	16.20	-41.7	0.00	16.7
	Week 26	26	81.41	19.05	33.3	91.67	100.0	24	0.35	17.80	-25.0	0.00	50.0
	Week 29	24	79.17	24.70	0.0	87.50	100.0	22	-5.30	28.47	-100.0	4.17	16.7
	Week 32	20	77.92	20.99	33.3	75.00	100.0	18	-6.48	18.65	-41.7	0.00	16.7
	Week 35	17	76.47	23.43	33.3	75.00	100.0	15	-6.11	20.04	-41.7	0.00	25.0
	Week 38	18	77.78	23.74	33.3	79.17	100.0	15	1.11	14.39	-25.0	0.00	25.0
	Week 41	18	85.19	17.28	50.0	91.67	100.0	16	1.04	18.73	-33.3	8.33	25.0
	Week 44	16	72.40	24.29	33.3	66.67	100.0	14	-8.93	23.90	-50.0	-4.17	25.0
	Week 47	12	75.00	24.36	33.3	75.00	100.0	11	-7.57	23.99	-58.3	0.00	16.7
	Week 50	11	76.52	24.95	33.3	91.67	100.0	9	0.93	22.61	-50.0	8.34	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	EV+Pembro (N=146)												
	BASELINE	119	76.40	20.91	8.3	75.00	100.0						
	Week 1	102	78.02	22.55	0.0	83.33	100.0	97	1.03	15.88	-66.7	0.00	41.7
	Week 2	106	75.55	23.21	0.0	75.00	100.0	98	-1.19	16.54	-50.0	0.00	41.7
	Week 3	94	79.43	19.58	16.7	83.33	100.0	88	1.99	14.79	-33.3	0.00	33.3
	Week 4	101	80.53	21.29	25.0	83.33	100.0	93	2.87	18.53	-58.3	0.00	41.7
	Week 5	96	83.07	17.95	33.3	91.67	100.0	89	3.37	17.93	-41.7	0.00	41.7
	Week 6	105	81.03	19.70	16.7	83.33	100.0	93	3.23	19.66	-83.3	0.00	58.3
	Week 7	102	81.05	20.38	33.3	83.33	100.0	89	2.62	18.53	-58.3	0.00	41.7
	Week 8	101	81.68	21.05	0.0	91.67	100.0	91	3.66	21.63	-83.3	0.00	50.0
	Week 9	100	80.50	23.67	0.0	91.67	100.0	89	1.69	23.00	-83.3	0.00	66.7
	Week 10	99	82.74	20.83	0.0	91.67	100.0	87	3.35	20.19	-66.7	0.00	41.7
	Week 11	95	83.68	20.70	8.3	91.67	100.0	84	2.48	18.96	-66.7	0.00	41.7
	Week 12	99	81.82	22.88	0.0	91.67	100.0	87	2.30	18.96	-58.3	0.00	41.7
	Week 14	95	81.49	21.44	16.7	83.33	100.0	84	2.28	22.79	-66.7	0.00	41.7
	Week 17	97	82.30	20.06	16.7	91.67	100.0	84	2.38	20.06	-58.3	0.00	58.3
	Week 20	90	82.96	17.12	33.3	87.50	100.0	79	1.69	19.03	-50.0	0.00	41.7
	Week 23	86	82.85	17.77	16.7	83.33	100.0	74	1.35	19.70	-41.7	0.00	50.0
	Week 26	83	82.33	18.15	25.0	83.33	100.0	72	-1.04	18.97	-58.3	0.00	50.0
	Week 29	80	83.65	16.42	33.3	91.67	100.0	71	0.94	19.65	-50.0	0.00	41.7
	Week 32	74	82.66	17.60	25.0	83.33	100.0	66	0.13	19.09	-58.3	0.00	41.7
	Week 35	73	80.94	20.25	0.0	83.33	100.0	66	-1.64	21.79	-75.0	0.00	41.7
	Week 38	75	82.56	17.82	25.0	83.33	100.0	67	0.12	19.81	-50.0	0.00	50.0
	Week 41	71	79.11	19.56	0.0	83.33	100.0	64	-2.47	22.79	-66.7	0.00	41.7
	Week 44	64	80.47	21.32	0.0	91.67	100.0	56	-3.12	22.22	-75.0	0.00	41.7
	Week 47	56	80.51	19.35	25.0	83.33	100.0	50	-2.00	20.03	-41.7	0.00	41.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	55	81.67	19.67	25.0	91.67	100.0	48	-2.60	22.02	-66.7	0.00	33.3
	Week 53	55	77.73	21.64	16.7	75.00	100.0	48	-4.17	21.47	-75.0	0.00	33.3
	Week 56	53	77.67	21.29	8.3	83.33	100.0	46	-4.53	19.93	-66.7	0.00	33.3
	Week 59	51	79.09	22.57	25.0	91.67	100.0	43	-2.33	20.28	-50.0	0.00	33.3
	Week 62	42	79.56	18.61	33.3	83.33	100.0	36	-1.85	18.38	-41.7	0.00	33.3
	Week 65	31	77.15	23.57	25.0	83.33	100.0	30	-1.67	20.22	-41.7	0.00	33.3
	Week 68	31	74.46	21.51	33.3	66.67	100.0	29	-7.47	22.09	-50.0	-8.33	33.3
	Week 71	30	76.11	18.27	33.3	66.67	100.0	28	-5.95	19.75	-41.7	0.00	33.3
	Week 74	29	76.44	20.18	33.3	83.33	100.0	27	-5.25	23.24	-50.0	0.00	33.3
	Week 77	26	78.85	19.33	33.3	75.00	100.0	24	-5.21	23.80	-58.3	0.00	33.3
	Week 80	26	75.00	19.15	33.3	70.84	100.0	26	-4.49	25.74	-50.0	0.00	58.3
	Week 83	21	76.19	18.87	41.7	75.00	100.0	21	-4.76	22.76	-50.0	0.00	33.3
	Week 86	17	69.61	24.64	25.0	75.00	100.0	17	-8.82	25.43	-66.7	0.00	25.0
	Week 89	11	77.27	21.11	33.3	66.67	100.0	11	-6.06	23.00	-50.0	0.00	16.7
	Week 92	13	71.15	19.13	41.7	66.67	100.0	13	-1.28	18.90	-33.3	0.00	33.3
	Plat+Gem (N=151)												
	BASELINE	123	79.34	19.57	16.7	83.33	100.0						
	Week 1	108	80.32	19.15	33.3	83.33	100.0	103	1.13	14.05	-33.3	0.00	41.7
	Week 2	116	78.74	20.69	0.0	83.33	100.0	105	-1.83	19.02	-66.7	0.00	33.3
	Week 3	114	79.39	21.65	0.0	83.33	100.0	103	-1.46	19.58	-66.7	0.00	41.7
	Week 4	116	80.89	19.63	33.3	83.33	100.0	103	0.24	16.81	-50.0	0.00	41.7
	Week 5	119	78.43	19.60	33.3	83.33	100.0	106	-1.57	18.62	-50.0	0.00	33.3
	Week 6	109	79.59	20.89	0.0	83.33	100.0	98	-1.19	19.33	-66.7	0.00	41.7
	Week 7	115	78.48	20.71	8.3	75.00	100.0	105	-2.54	19.51	-66.7	0.00	41.7
	Week 8	111	78.15	21.82	0.0	75.00	100.0	102	-2.53	20.64	-75.0	0.00	50.0
	Week 9	107	78.43	22.14	8.3	83.33	100.0	95	-1.40	21.36	-66.7	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	107	78.97	22.18	8.3	83.33	100.0	98	-0.85	20.29	-58.3	0.00	41.7
	Week 11	97	79.98	21.20	25.0	83.33	100.0	87	-0.10	21.47	-50.0	0.00	58.3
	Week 12	100	80.17	19.05	33.3	83.33	100.0	88	1.71	19.38	-41.7	0.00	58.3
	Week 14	99	79.38	19.72	16.7	83.33	100.0	86	-1.16	19.64	-66.7	0.00	41.7
	Week 17	94	80.23	19.93	33.3	83.33	100.0	82	-1.52	21.48	-58.3	0.00	50.0
	Week 20	84	79.66	20.55	16.7	83.33	100.0	72	-0.69	19.62	-50.0	0.00	50.0
	Week 23	70	82.50	18.61	25.0	83.33	100.0	62	1.61	18.28	-41.7	0.00	58.3
	Week 26	61	79.51	19.70	0.0	83.33	100.0	55	-1.67	22.59	-75.0	0.00	58.3
	Week 29	59	80.65	19.66	0.0	83.33	100.0	53	-1.89	22.33	-100.0	0.00	58.3
	Week 32	50	80.33	20.81	16.7	83.33	100.0	45	-1.30	20.33	-58.3	0.00	58.3
	Week 35	50	77.33	22.65	0.0	83.33	100.0	44	-2.84	20.88	-58.3	0.00	50.0
	Week 38	46	77.90	22.72	33.3	75.00	100.0	40	-1.46	19.69	-50.0	0.00	50.0
	Week 41	42	80.36	21.29	25.0	91.67	100.0	37	-2.25	20.47	-50.0	0.00	50.0
	Week 44	39	75.86	24.98	16.7	75.00	100.0	34	-5.64	25.19	-66.7	0.00	50.0
	Week 47	33	77.78	23.26	25.0	83.33	100.0	29	-2.87	21.39	-58.3	0.00	50.0
	Week 50	27	79.63	24.50	25.0	91.67	100.0	22	-0.76	22.55	-50.0	4.17	25.0
	Week 53	23	81.88	21.12	41.7	91.67	100.0	20	0.83	19.10	-41.7	0.00	25.0
	Week 56	20	79.17	19.96	33.3	83.33	100.0	19	-3.95	17.43	-41.7	0.00	16.7
	Week 59	17	74.02	22.02	25.0	75.00	100.0	15	-7.78	21.47	-50.0	0.00	16.7
	Week 62	14	75.00	20.41	33.3	75.00	100.0	14	-8.93	18.63	-50.0	-8.33	16.7
	Week 65	13	75.00	24.30	33.3	83.33	100.0	12	-7.64	22.32	-66.7	0.00	16.7
	Week 68	10	75.83	25.89	33.3	79.17	100.0	10	-6.67	24.47	-58.3	0.00	16.7
	Week 71	10	75.83	32.26	8.3	91.67	100.0	10	-8.33	31.43	-91.7	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	EV+Pembro (N= 56)												
	BASELINE	41	70.93	21.98	0.0	75.00	100.0						
	Week 1	39	76.71	21.13	25.0	83.33	100.0	32	5.47	12.81	-25.0	4.17	33.3
	Week 2	44	75.38	19.60	41.7	75.00	100.0	35	5.95	20.37	-25.0	0.00	83.3
	Week 3	45	73.33	23.54	25.0	75.00	100.0	34	4.17	20.75	-25.0	0.00	75.0
	Week 4	44	78.41	23.39	25.0	83.33	100.0	36	4.40	19.16	-58.3	8.33	41.7
	Week 5	41	75.41	22.67	33.3	75.00	100.0	32	5.73	21.42	-50.0	4.17	33.3
	Week 6	41	74.59	25.68	0.0	83.33	100.0	31	6.18	23.47	-75.0	8.34	41.7
	Week 7	45	77.22	23.93	8.3	83.33	100.0	35	9.76	23.44	-66.7	8.34	66.7
	Week 8	46	76.45	23.26	25.0	79.17	100.0	33	7.07	26.28	-66.7	8.33	66.7
	Week 9	42	76.39	24.20	8.3	79.17	100.0	32	6.25	24.23	-50.0	0.00	66.7
	Week 10	40	78.54	21.43	33.3	83.33	100.0	31	6.99	15.83	-33.3	8.33	33.3
	Week 11	42	79.96	20.99	25.0	87.50	100.0	31	12.64	22.55	-33.3	8.34	58.3
	Week 12	43	79.46	20.92	33.3	83.33	100.0	32	11.20	18.89	-25.0	8.34	50.0
	Week 14	44	80.87	21.00	33.3	91.67	100.0	32	13.02	20.84	-41.7	12.51	66.7
	Week 17	35	77.14	23.69	25.0	83.33	100.0	27	9.88	18.20	-25.0	8.33	50.0
	Week 20	30	84.45	16.19	50.0	87.50	100.0	24	13.89	18.98	-8.3	8.34	66.7
	Week 23	31	83.07	17.54	50.0	91.67	100.0	23	14.13	19.37	-16.7	8.34	66.7
	Week 26	29	83.33	17.54	41.7	83.33	100.0	22	14.39	25.22	-25.0	8.33	91.7
	Week 29	27	81.48	19.79	25.0	91.67	100.0	22	9.85	21.62	-41.7	8.34	50.0
	Week 32	28	78.87	22.51	33.3	83.33	100.0	22	12.50	23.54	-33.3	12.50	75.0
	Week 35	25	79.33	22.06	33.3	91.67	100.0	20	10.42	23.08	-33.3	8.34	75.0
	Week 38	22	80.68	21.73	33.3	87.50	100.0	19	11.84	24.11	-33.3	8.34	75.0
	Week 41	24	79.17	16.85	33.3	83.33	100.0	20	8.33	21.29	-33.3	4.17	66.7
	Week 44	22	77.27	22.74	33.3	75.00	100.0	18	8.33	23.57	-33.3	8.34	66.7
	Week 47	23	75.73	23.02	33.3	75.00	100.0	20	7.92	30.16	-33.3	4.17	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	19	74.12	21.50	33.3	75.00	100.0	16	6.25	24.63	-33.3	0.00	75.0
	Week 53	19	78.07	18.88	41.7	75.00	100.0	15	10.56	22.38	-25.0	8.33	66.7
	Week 56	19	76.32	22.61	33.3	83.33	100.0	15	6.67	26.20	-41.7	0.00	75.0
	Week 59	18	75.46	19.27	41.7	75.00	100.0	14	10.12	25.14	-25.0	4.17	75.0
	Week 62	20	82.92	16.10	58.3	87.50	100.0	16	14.58	20.75	-8.3	12.51	66.7
	Week 65	12	75.70	23.69	33.3	75.00	100.0	10	13.33	27.83	-33.3	8.34	66.7
	Week 68	15	78.89	18.33	33.3	83.33	100.0	13	12.18	18.82	-8.3	8.33	66.7
	Week 71	12	77.78	21.12	33.3	75.00	100.0	10	14.17	23.91	-16.7	12.51	66.7
	Week 77	11	79.55	19.50	33.3	83.33	100.0	9	19.45	19.54	0.0	16.67	66.7
	Week 80	10	77.50	25.78	33.3	87.50	100.0	8	16.67	29.88	-33.3	16.67	66.7
	Plat+Gem (N= 51)												
	BASELINE	42	66.47	26.06	8.3	70.84	100.0						
	Week 1	36	68.75	25.69	8.3	75.00	100.0	36	3.24	19.44	-25.0	0.00	58.3
	Week 2	31	66.94	26.13	0.0	75.00	100.0	30	3.06	19.14	-33.3	0.00	58.3
	Week 3	35	67.38	27.74	0.0	75.00	100.0	33	1.26	21.56	-58.3	0.00	58.3
	Week 4	34	70.10	22.86	0.0	75.00	100.0	32	1.56	21.73	-25.0	0.00	58.3
	Week 5	34	67.65	23.01	8.3	70.84	100.0	32	-4.17	22.80	-50.0	0.00	66.7
	Week 6	36	68.75	27.56	0.0	75.00	100.0	33	0.25	25.30	-58.3	0.00	66.7
	Week 7	33	73.23	21.22	16.7	75.00	100.0	29	4.31	23.95	-41.7	0.00	66.7
	Week 8	34	68.87	24.39	8.3	66.67	100.0	30	0.56	23.36	-41.7	0.00	58.3
	Week 9	34	67.89	25.22	0.0	66.67	100.0	30	0.00	22.95	-50.0	0.00	50.0
	Week 10	35	72.14	21.86	8.3	75.00	100.0	32	4.95	24.21	-41.7	0.00	75.0
	Week 11	29	68.10	28.27	0.0	75.00	100.0	27	4.01	21.73	-66.7	8.33	41.7
	Week 12	30	70.00	27.99	0.0	75.00	100.0	27	4.94	19.10	-33.3	8.33	50.0
	Week 14	26	65.39	30.43	0.0	66.67	100.0	23	-3.98	20.39	-58.3	0.00	33.3
	Week 17	26	69.23	26.95	8.3	75.00	100.0	24	-1.74	24.82	-58.3	0.00	58.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 20	20	76.67	20.87	33.3	75.00	100.0	19	5.70	19.25	-41.7	8.33	41.7
	Week 23	18	81.48	19.71	41.7	87.50	100.0	18	6.95	14.36	-33.3	8.33	25.0
	Week 26	20	79.17	24.56	25.0	87.50	100.0	20	10.42	21.27	-41.7	8.34	50.0
	Week 29	18	72.69	25.69	25.0	79.17	100.0	18	0.93	29.41	-75.0	8.34	41.7
	Week 32	13	73.08	22.61	33.3	75.00	100.0	13	1.28	17.95	-33.3	0.00	41.7
	Week 35	12	80.56	22.00	33.3	87.50	100.0	12	9.03	13.97	-8.3	8.34	41.7
	Week 38	10	68.33	34.87	0.0	79.17	100.0	10	-7.50	23.72	-66.7	0.00	16.7
	Week 41	10	79.17	19.74	41.7	79.17	100.0	10	4.17	13.18	-16.7	4.17	25.0
	Week 44	10	75.00	20.41	41.7	75.00	100.0	10	3.33	12.55	-8.3	0.00	33.3
	Week 47	10	79.17	21.25	41.7	83.34	100.0	10	4.17	18.53	-33.3	8.33	33.3
	Week 56	10	65.00	27.16	33.3	70.84	100.0	10	-0.83	17.33	-25.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Visceral metastases	EV+Pembro (N=148)												
	BASELINE	119	73.18	22.66	0.0	75.00	100.0						
	Week 1	105	75.40	23.09	0.0	83.33	100.0	99	2.10	15.63	-66.7	0.00	41.7
	Week 2	109	73.32	23.67	0.0	75.00	100.0	100	0.42	19.51	-50.0	0.00	83.3
	Week 3	98	76.62	21.73	16.7	79.17	100.0	88	3.79	17.69	-33.3	0.00	75.0
	Week 4	103	78.72	22.01	25.0	83.33	100.0	93	3.67	19.25	-58.3	0.00	41.7
	Week 5	100	80.25	19.70	33.3	83.33	100.0	90	4.45	19.60	-50.0	0.00	41.7
	Week 6	105	79.52	20.35	16.7	83.33	100.0	90	6.11	20.63	-83.3	8.33	58.3
	Week 7	108	80.32	19.72	33.3	83.33	100.0	91	6.04	20.23	-58.3	8.33	66.7
	Week 8	105	79.13	22.38	0.0	83.33	100.0	89	5.43	24.59	-83.3	8.33	66.7
	Week 9	105	78.65	24.62	0.0	91.67	100.0	91	4.12	24.39	-83.3	8.33	66.7
	Week 10	101	80.86	21.23	0.0	91.67	100.0	86	5.43	18.82	-50.0	8.33	41.7
	Week 11	97	81.70	20.79	8.3	91.67	100.0	83	5.22	21.96	-66.7	8.33	58.3
	Week 12	100	80.92	22.39	0.0	91.67	100.0	85	5.98	20.07	-58.3	8.33	50.0
	Week 14	102	79.90	21.60	16.7	83.33	100.0	87	5.08	24.32	-66.7	8.33	66.7
	Week 17	96	79.78	21.62	16.7	83.33	100.0	81	4.22	20.92	-58.3	0.00	58.3
	Week 20	87	82.09	17.40	33.3	83.33	100.0	76	4.06	21.58	-50.0	4.17	66.7
	Week 23	85	81.28	18.63	16.7	83.33	100.0	71	4.46	22.71	-41.7	0.00	66.7
	Week 26	79	81.96	19.22	25.0	83.33	100.0	66	2.65	24.20	-58.3	0.00	91.7
	Week 29	72	82.52	17.87	25.0	91.67	100.0	64	4.30	22.12	-50.0	0.00	50.0
	Week 32	71	81.93	19.92	25.0	83.33	100.0	62	5.24	23.34	-58.3	0.00	75.0
	Week 35	70	81.07	19.76	33.3	87.50	100.0	63	3.31	23.02	-58.3	0.00	75.0
	Week 38	70	83.69	17.17	25.0	91.67	100.0	63	4.89	22.58	-50.0	0.00	75.0
	Week 41	66	80.30	17.52	33.3	83.33	100.0	60	2.78	23.55	-50.0	0.00	66.7
	Week 44	59	79.66	19.28	33.3	75.00	100.0	53	1.42	23.55	-50.0	0.00	66.7
	Week 47	52	79.33	19.42	33.3	79.17	100.0	48	2.78	25.52	-33.3	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	49	78.74	20.06	25.0	75.00	100.0	43	-0.58	25.48	-66.7	0.00	75.0
	Week 53	50	76.17	21.36	16.7	75.00	100.0	44	-0.19	24.34	-75.0	0.00	66.7
	Week 56	45	75.74	21.16	8.3	83.33	100.0	39	-2.78	24.43	-66.7	0.00	75.0
	Week 59	44	76.71	22.56	25.0	79.17	100.0	38	0.22	23.92	-50.0	0.00	75.0
	Week 62	38	79.83	18.85	33.3	79.17	100.0	33	3.54	22.92	-41.7	0.00	66.7
	Week 65	25	80.00	21.78	33.3	83.33	100.0	24	6.60	23.44	-33.3	4.17	66.7
	Week 68	31	79.03	18.37	33.3	83.33	100.0	29	0.57	24.29	-50.0	0.00	66.7
	Week 71	27	77.78	18.92	33.3	66.67	100.0	25	-0.33	25.28	-41.7	0.00	66.7
	Week 74	23	73.91	23.48	33.3	66.67	100.0	22	-2.27	29.90	-50.0	0.00	66.7
	Week 77	24	77.43	19.58	33.3	70.84	100.0	23	-0.72	27.74	-58.3	0.00	66.7
	Week 80	22	71.97	22.06	33.3	66.67	100.0	22	-1.51	31.56	-50.0	0.00	66.7
	Week 83	19	72.81	21.49	41.7	66.67	100.0	19	-2.63	29.27	-50.0	0.00	66.7
	Week 86	14	65.48	28.84	25.0	66.67	100.0	14	-2.98	35.30	-66.7	0.00	66.7
	Week 89	10	80.00	24.28	33.3	91.67	100.0	10	0.00	22.22	-50.0	4.17	33.3
	Week 92	11	73.49	24.10	41.7	66.67	100.0	11	6.06	17.91	-25.0	0.00	33.3
	Plat+Gem (N=157)												
	BASELINE	128	75.46	22.70	8.3	83.33	100.0						
	Week 1	111	76.95	22.02	8.3	83.33	100.0	107	1.01	16.14	-33.3	0.00	58.3
	Week 2	110	76.21	23.24	0.0	83.33	100.0	102	-1.39	19.66	-66.7	0.00	58.3
	Week 3	112	76.49	24.82	0.0	83.33	100.0	103	-0.57	20.98	-66.7	0.00	58.3
	Week 4	112	78.57	20.98	0.0	83.33	100.0	102	1.06	18.86	-50.0	0.00	58.3
	Week 5	113	76.62	21.50	8.3	83.33	100.0	103	-1.13	20.31	-50.0	0.00	66.7
	Week 6	107	77.65	24.14	0.0	83.33	100.0	98	-0.25	21.15	-66.7	0.00	66.7
	Week 7	109	77.98	21.23	8.3	75.00	100.0	100	-0.33	21.19	-66.7	0.00	66.7
	Week 8	106	77.44	22.91	0.0	79.17	100.0	98	-0.17	21.84	-75.0	0.00	58.3
	Week 9	105	77.62	23.58	0.0	83.33	100.0	94	0.09	22.58	-66.7	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	104	78.37	22.83	8.3	83.33	100.0	96	2.34	21.89	-50.0	0.00	75.0
	Week 11	91	78.85	21.99	0.0	83.33	100.0	83	2.31	20.34	-50.0	0.00	58.3
	Week 12	94	79.96	22.04	0.0	83.33	100.0	84	4.76	18.49	-33.3	0.00	58.3
	Week 14	90	78.98	21.50	0.0	83.33	100.0	79	0.53	19.35	-66.7	0.00	41.7
	Week 17	90	80.19	20.66	8.3	83.33	100.0	80	1.35	21.81	-58.3	0.00	58.3
	Week 20	74	79.39	21.02	16.7	83.33	100.0	64	1.95	19.34	-41.7	0.00	50.0
	Week 23	63	82.01	20.20	25.0	91.67	100.0	58	3.16	17.09	-41.7	0.00	58.3
	Week 26	55	81.06	17.01	33.3	83.33	100.0	52	4.01	20.51	-58.3	0.00	58.3
	Week 29	53	79.40	22.21	0.0	83.33	100.0	50	-0.17	24.37	-100.0	0.00	58.3
	Week 32	42	80.56	21.36	25.0	83.33	100.0	40	0.83	18.08	-41.7	0.00	58.3
	Week 35	39	77.99	24.22	0.0	83.33	100.0	36	0.69	18.94	-58.3	0.00	50.0
	Week 38	37	75.68	27.67	0.0	83.33	100.0	34	-0.74	22.13	-66.7	0.00	50.0
	Week 41	33	81.82	20.35	33.3	91.67	100.0	31	2.15	18.25	-41.7	8.33	50.0
	Week 44	32	78.65	23.37	33.3	87.50	100.0	30	1.11	21.41	-50.0	0.00	50.0
	Week 47	28	79.76	22.15	25.0	83.33	100.0	26	1.28	20.91	-58.3	0.00	50.0
	Week 50	22	81.44	24.39	16.7	91.67	100.0	20	0.42	19.58	-50.0	8.33	25.0
	Week 53	19	84.65	21.56	33.3	100.00	100.0	17	5.39	15.29	-25.0	8.34	25.0
	Week 56	18	76.39	22.73	33.3	83.33	100.0	17	0.49	17.05	-25.0	0.00	33.3
	Week 59	13	76.92	18.99	41.7	75.00	100.0	12	1.39	17.71	-33.3	4.17	25.0
	Week 62	11	75.76	20.57	33.3	75.00	100.0	11	0.76	17.66	-33.3	0.00	25.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Lymph node only	EV+Pembro (N= 43)												
	BASELINE	33	81.31	15.59	50.0	75.00	100.0						
	Week 1	30	86.67	13.95	50.0	91.67	100.0	24	4.86	10.97	-8.3	0.00	33.3
	Week 2	34	83.09	15.14	50.0	83.33	100.0	27	3.70	10.92	-16.7	0.00	25.0
	Week 3	35	81.43	17.75	33.3	83.33	100.0	28	2.08	11.70	-25.0	0.00	25.0
	Week 4	36	84.72	19.16	33.3	91.67	100.0	30	4.72	15.27	-25.0	0.00	41.7
	Week 5	33	80.56	20.48	33.3	83.33	100.0	27	1.85	17.50	-41.7	0.00	33.3
	Week 6	34	80.64	24.25	0.0	83.33	100.0	28	-0.60	20.90	-75.0	0.00	33.3
	Week 7	34	79.41	26.21	8.3	87.50	100.0	28	2.38	20.52	-66.7	0.00	33.3
	Week 8	35	83.10	19.65	33.3	83.33	100.0	29	2.87	17.86	-41.7	0.00	33.3
	Week 9	30	82.22	20.85	33.3	87.50	100.0	24	0.35	19.88	-41.7	0.00	33.3
	Week 10	31	85.48	16.24	33.3	91.67	100.0	26	3.21	16.17	-33.3	0.00	33.3
	Week 11	34	86.27	19.23	25.0	91.67	100.0	27	7.41	14.50	-16.7	0.00	33.3
	Week 12	35	83.09	20.56	33.3	91.67	100.0	28	3.27	14.76	-25.0	0.00	33.3
	Week 14	30	87.78	16.34	33.3	91.67	100.0	23	8.33	12.81	-8.3	8.33	33.3
	Week 17	30	87.22	16.04	50.0	91.67	100.0	24	6.60	14.11	-16.7	0.00	33.3
	Week 20	27	88.27	15.02	50.0	100.00	100.0	21	7.54	13.92	-8.3	0.00	33.3
	Week 23	27	88.58	13.10	50.0	91.67	100.0	21	5.95	12.12	-16.7	0.00	33.3
	Week 26	27	86.73	12.07	58.3	83.33	100.0	22	4.92	13.77	-16.7	0.00	33.3
	Week 29	28	84.82	16.36	58.3	91.67	100.0	23	0.00	17.59	-25.0	0.00	41.7
	Week 32	24	80.56	18.00	33.3	83.33	100.0	20	-2.50	13.27	-33.3	0.00	16.7
	Week 35	22	77.65	24.31	0.0	79.17	100.0	18	-5.56	23.22	-75.0	-4.17	33.3
	Week 38	21	79.76	21.18	33.3	75.00	100.0	17	-1.96	17.06	-33.3	-8.33	33.3
	Week 41	22	81.44	13.83	58.3	83.33	100.0	17	-2.45	15.52	-25.0	-8.33	33.3
	Week 44	22	79.17	26.45	0.0	87.50	100.0	16	-5.73	21.88	-75.0	0.00	25.0
	Week 47	21	80.16	22.44	25.0	91.67	100.0	16	-2.60	20.12	-41.7	0.00	25.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	82.50	21.27	41.7	91.67	100.0	16	1.56	18.56	-25.0	0.00	33.3
	Week 53	18	80.56	21.20	33.3	91.67	100.0	14	-2.38	20.00	-33.3	0.00	33.3
	Week 56	21	78.97	23.37	33.3	91.67	100.0	17	0.49	19.43	-41.7	0.00	33.3
	Week 59	21	80.56	20.47	25.0	91.67	100.0	16	3.65	19.00	-41.7	0.00	33.3
	Week 62	19	83.77	16.31	41.7	91.67	100.0	15	5.56	15.00	-25.0	8.33	25.0
	Week 65	16	76.04	23.94	25.0	83.33	100.0	14	-0.60	18.91	-41.7	0.00	25.0
	Week 68	13	73.72	22.27	33.3	66.67	100.0	11	-2.27	18.67	-33.3	0.00	25.0
	Week 71	13	75.64	20.54	33.3	75.00	100.0	11	-1.52	17.80	-25.0	0.00	25.0
	Week 74	13	83.33	14.03	66.7	83.33	100.0	11	0.76	17.66	-33.3	0.00	25.0
	Week 77	13	82.05	18.59	33.3	83.33	100.0	10	6.67	17.48	-33.3	8.33	25.0
	Week 80	13	80.77	18.44	33.3	83.33	100.0	11	5.30	20.51	-33.3	8.33	33.3
	Week 83	11	84.85	10.42	66.7	83.33	100.0	10	7.50	15.94	-16.7	8.33	33.3
	Week 86	11	78.79	14.12	58.3	75.00	100.0	10	0.83	15.44	-33.3	0.00	25.0
	Plat+Gem (N= 37)												
	BASELINE	29	76.72	19.21	25.0	75.00	100.0						
	Week 1	26	76.92	20.72	33.3	79.17	100.0	25	3.33	14.43	-25.0	0.00	33.3
	Week 2	30	75.83	20.57	25.0	83.33	100.0	26	3.21	14.73	-25.0	0.00	33.3
	Week 3	30	77.22	22.09	25.0	79.17	100.0	26	2.24	15.73	-33.3	0.00	33.3
	Week 4	32	77.08	21.59	8.3	75.00	100.0	27	0.93	14.86	-33.3	0.00	33.3
	Week 5	33	74.24	20.24	33.3	75.00	100.0	28	-2.68	16.21	-25.0	-4.17	25.0
	Week 6	32	74.48	21.05	25.0	75.00	100.0	27	-2.47	17.88	-50.0	0.00	25.0
	Week 7	31	75.27	21.57	25.0	75.00	100.0	26	-1.92	16.72	-41.7	0.00	25.0
	Week 8	32	70.05	22.98	25.0	66.67	100.0	27	-7.41	18.10	-50.0	0.00	25.0
	Week 9	30	68.89	22.63	16.7	66.67	100.0	25	-6.00	17.43	-58.3	0.00	25.0
	Week 10	30	73.06	21.74	8.3	66.67	100.0	26	-4.49	18.89	-58.3	0.00	25.0
	Week 11	29	72.13	28.20	0.0	83.33	100.0	25	-3.33	24.65	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.12.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 12	28	71.73	22.03	16.7	66.67	100.0	23	-1.81	18.29	-41.7	0.00	33.3
	Week 14	28	69.64	27.89	8.3	66.67	100.0	23	-6.16	18.67	-58.3	0.00	16.7
	Week 17	25	70.67	25.01	25.0	66.67	100.0	21	-7.94	17.97	-41.7	0.00	16.7
	Week 20	23	77.17	21.50	33.3	83.33	100.0	20	-0.42	21.71	-50.0	0.00	33.3
	Week 23	20	83.75	15.41	50.0	87.50	100.0	17	4.90	17.93	-33.3	0.00	58.3
	Week 26	21	75.79	28.25	0.0	83.33	100.0	18	-1.85	24.85	-75.0	0.00	33.3
	Week 29	19	75.88	20.95	25.0	75.00	100.0	16	-3.12	25.07	-75.0	0.00	41.7
	Week 32	18	75.93	22.67	16.7	75.00	100.0	15	-0.55	23.24	-58.3	0.00	41.7
	Week 35	19	77.19	20.19	41.7	75.00	100.0	16	0.00	21.73	-41.7	0.00	41.7
	Week 38	15	77.22	22.38	33.3	75.00	100.0	12	-4.86	14.42	-41.7	0.00	16.7
	Week 41	15	77.78	24.12	25.0	75.00	100.0	12	-4.17	19.30	-50.0	0.00	16.7
	Week 44	14	72.62	25.20	16.7	66.67	100.0	11	-7.58	19.88	-58.3	0.00	16.7
	Week 47	12	77.08	24.65	33.3	75.00	100.0	10	-1.67	15.62	-41.7	0.00	16.7
	Week 50	11	71.21	28.96	25.0	66.67	100.0	8	-3.13	20.86	-50.0	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
EV+Pembro (N=240)												
BASELINE	206	78.16	27.00	0.0	83.33	100.0						
Week 1	190	76.84	25.58	0.0	83.33	100.0	184	-1.63	23.12	-66.7	0.00	100.0
Week 2	203	76.19	24.59	0.0	83.33	100.0	189	-3.17	25.36	-66.7	0.00	83.3
Week 3	198	73.99	26.25	0.0	66.67	100.0	182	-3.85	24.22	-83.3	0.00	100.0
Week 4	194	77.15	24.39	0.0	83.33	100.0	179	-1.49	27.10	-100.0	0.00	100.0
Week 5	190	76.14	25.04	0.0	83.33	100.0	173	-2.50	25.92	-83.3	0.00	100.0
Week 6	188	77.93	23.10	0.0	83.33	100.0	170	-0.59	25.18	-83.3	0.00	66.7
Week 7	195	77.44	22.85	0.0	83.33	100.0	176	-1.70	27.08	-100.0	0.00	100.0
Week 8	191	77.31	24.12	0.0	83.33	100.0	171	-1.46	28.29	-83.3	0.00	100.0
Week 9	197	75.80	24.77	0.0	83.33	100.0	180	-2.68	27.75	-83.3	0.00	66.7
Week 10	191	77.14	23.09	0.0	83.33	100.0	175	-0.67	28.10	-66.7	0.00	66.7
Week 11	194	76.89	24.53	0.0	83.33	100.0	175	-0.67	29.70	-83.3	0.00	100.0
Week 12	186	77.51	25.94	0.0	83.33	100.0	171	-1.46	28.00	-83.3	0.00	83.3
Week 14	185	76.04	25.93	0.0	83.33	100.0	167	-2.29	27.62	-100.0	0.00	66.7
Week 17	178	77.25	23.48	0.0	83.33	100.0	162	-1.34	27.49	-66.7	0.00	66.7
Week 20	167	75.15	26.75	0.0	83.33	100.0	154	-5.41	29.76	-100.0	0.00	66.7
Week 23	162	74.07	26.53	0.0	66.67	100.0	151	-6.73	29.95	-100.0	0.00	66.7
Week 26	156	76.07	24.77	0.0	83.33	100.0	144	-3.12	30.53	-100.0	0.00	100.0
Week 29	157	77.39	22.80	0.0	83.33	100.0	145	-3.33	29.96	-83.3	0.00	83.3
Week 32	135	77.04	23.99	0.0	83.33	100.0	125	-4.53	29.13	-83.3	0.00	66.7
Week 35	132	75.88	23.60	0.0	83.33	100.0	122	-6.28	28.85	-83.3	0.00	66.7
Week 38	132	73.36	25.38	0.0	66.67	100.0	124	-7.93	28.07	-83.3	0.00	66.7
Week 41	129	73.64	25.15	0.0	66.67	100.0	119	-7.42	29.65	-83.3	0.00	66.7
Week 44	108	76.08	24.36	0.0	83.33	100.0	100	-6.50	30.23	-100.0	0.00	66.7
Week 47	100	73.33	27.01	0.0	75.00	100.0	94	-7.45	32.21	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	89	73.41	23.53	16.7	66.67	100.0	84	-9.92	28.71	-83.3	0.00	66.7
Week 53	79	75.53	23.99	0.0	66.67	100.0	74	-8.33	29.23	-100.0	0.00	66.7
Week 56	81	75.52	24.31	0.0	66.67	100.0	76	-6.36	31.85	-100.0	0.00	66.7
Week 59	72	74.77	22.90	0.0	66.67	100.0	68	-6.62	31.82	-100.0	0.00	66.7
Week 62	65	78.46	24.95	0.0	83.33	100.0	63	-6.08	31.01	-100.0	0.00	66.7
Week 65	58	75.00	24.23	0.0	83.33	100.0	54	-6.48	30.10	-83.3	0.00	66.7
Week 68	53	77.67	20.66	33.3	66.67	100.0	52	-4.49	29.17	-66.7	0.00	66.7
Week 71	51	76.47	22.89	0.0	83.33	100.0	49	-4.76	29.85	-66.7	0.00	66.7
Week 74	47	74.47	23.27	0.0	66.67	100.0	46	-7.97	30.78	-100.0	0.00	66.7
Week 77	44	70.83	25.70	0.0	66.67	100.0	42	-10.71	32.26	-83.3	-8.33	66.7
Week 80	40	70.83	23.19	0.0	66.67	100.0	37	-7.21	29.80	-66.7	0.00	66.7
Week 83	37	70.27	26.10	0.0	66.67	100.0	35	-6.67	32.89	-83.3	0.00	66.7
Week 86	34	72.55	22.80	33.3	66.67	100.0	31	-4.30	32.48	-66.7	0.00	66.7
Week 89	33	70.20	21.55	33.3	66.67	100.0	31	-5.37	29.31	-50.0	0.00	66.7
Week 92	27	72.22	22.65	33.3	66.67	100.0	25	-8.00	26.40	-66.7	0.00	33.3
Week 95	22	68.18	27.17	0.0	66.67	100.0	21	-13.49	34.81	-83.3	-16.66	33.3
Week 98	18	74.08	19.99	33.3	66.67	100.0	17	-4.90	22.64	-50.0	0.00	33.3
Week 101	14	77.38	22.27	33.3	66.67	100.0	14	-10.71	24.98	-50.0	-8.33	33.3
Week 104	10	75.00	23.90	33.3	66.67	100.0	10	-11.67	27.27	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Plat+Gem (N=242)												
BASELINE	188	74.91	26.45	0.0	75.00	100.0						
Week 1	173	72.93	24.73	0.0	66.67	100.0	158	-2.22	23.50	-66.7	0.00	66.7
Week 2	171	70.66	28.16	0.0	66.67	100.0	151	-5.19	26.96	-100.0	0.00	83.3
Week 3	184	74.19	25.59	0.0	83.33	100.0	162	-1.96	24.10	-83.3	0.00	66.7
Week 4	183	72.04	26.95	0.0	66.67	100.0	156	-4.27	24.68	-66.7	0.00	66.7
Week 5	187	71.21	26.07	0.0	66.67	100.0	156	-5.66	25.92	-66.7	0.00	83.3
Week 6	174	72.13	25.35	0.0	66.67	100.0	149	-4.25	24.44	-66.7	0.00	50.0
Week 7	186	73.48	24.35	0.0	66.67	100.0	157	-2.97	26.85	-83.3	0.00	66.7
Week 8	167	71.76	25.59	0.0	66.67	100.0	144	-4.98	27.10	-100.0	0.00	66.7
Week 9	177	72.22	24.85	0.0	66.67	100.0	150	-4.33	26.51	-100.0	0.00	66.7
Week 10	166	72.69	24.83	0.0	66.67	100.0	139	-3.72	28.38	-100.0	0.00	83.3
Week 11	168	72.22	24.99	0.0	66.67	100.0	143	-4.78	26.95	-100.0	0.00	83.3
Week 12	159	74.00	25.41	0.0	66.67	100.0	138	-3.50	27.35	-100.0	0.00	83.3
Week 14	153	71.24	24.50	0.0	66.67	100.0	128	-5.34	26.37	-66.7	0.00	66.7
Week 17	155	71.83	26.43	0.0	66.67	100.0	130	-5.26	27.84	-83.3	0.00	66.7
Week 20	126	76.46	25.23	0.0	83.33	100.0	110	-1.36	26.34	-66.7	0.00	66.7
Week 23	115	77.97	25.03	0.0	83.33	100.0	97	0.17	25.40	-66.7	0.00	66.7
Week 26	108	78.09	24.82	0.0	83.33	100.0	95	-1.93	24.05	-83.3	0.00	50.0
Week 29	100	78.83	24.26	0.0	83.33	100.0	86	-3.30	25.41	-83.3	0.00	33.3
Week 32	83	78.72	25.28	0.0	83.33	100.0	76	-1.97	24.79	-83.3	0.00	66.7
Week 35	76	79.83	22.82	0.0	83.33	100.0	69	-1.93	22.42	-66.7	0.00	66.7
Week 38	74	77.93	24.69	0.0	83.33	100.0	65	-4.62	23.66	-66.7	0.00	33.3
Week 41	65	78.46	24.60	0.0	83.33	100.0	56	-2.98	22.50	-66.7	0.00	33.3
Week 44	60	78.61	23.39	16.7	83.33	100.0	53	-2.52	23.20	-66.7	0.00	33.3
Week 47	56	79.76	21.25	0.0	83.33	100.0	49	-3.06	24.46	-100.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	51	75.49	26.74	0.0	83.33	100.0	47	-4.61	25.94	-100.0	0.00	33.3
Week 53	46	82.25	20.61	33.3	83.33	100.0	42	-0.40	18.22	-33.3	0.00	33.3
Week 56	39	78.63	25.06	0.0	83.33	100.0	34	-2.45	25.67	-50.0	0.00	50.0
Week 59	37	84.69	21.65	0.0	100.00	100.0	33	2.02	21.55	-33.3	0.00	66.7
Week 62	32	80.21	17.68	50.0	66.67	100.0	29	-2.87	23.60	-50.0	0.00	33.3
Week 65	30	78.33	22.81	16.7	83.33	100.0	26	-5.13	22.98	-50.0	0.00	33.3
Week 68	25	80.00	25.00	0.0	83.33	100.0	21	-3.17	17.17	-33.3	0.00	33.3
Week 71	22	77.27	28.89	0.0	83.33	100.0	19	-5.26	28.36	-66.7	0.00	50.0
Week 74	21	82.54	26.07	0.0	100.00	100.0	18	2.78	21.58	-33.3	0.00	50.0
Week 77	18	81.48	22.79	16.7	83.33	100.0	15	3.33	21.08	-33.3	0.00	50.0
Week 80	14	86.91	17.51	50.0	100.00	100.0	13	7.69	16.13	-16.7	0.00	33.3
Week 83	13	80.77	17.80	50.0	83.33	100.0	12	2.78	22.28	-33.3	0.00	33.3
Week 86	12	81.95	21.86	33.3	91.67	100.0	11	-1.51	22.92	-33.3	0.00	33.3
Week 89	11	90.91	13.67	66.7	100.00	100.0	10	10.00	19.56	-16.7	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Present	EV+Pembro (N= 48)												
	BASELINE	39	67.52	33.76	0.0	66.67	100.0						
	Week 1	32	69.27	29.97	0.0	66.67	100.0	32	3.13	26.92	-33.3	0.00	100.0
	Week 2	37	67.57	26.63	0.0	66.67	100.0	33	-1.01	31.44	-66.7	0.00	83.3
	Week 3	34	54.41	33.41	0.0	66.67	100.0	29	-5.75	26.08	-83.3	0.00	33.3
	Week 4	36	66.67	29.28	0.0	66.67	100.0	31	3.76	34.88	-100.0	0.00	66.7
	Week 5	30	62.22	27.66	0.0	66.67	100.0	24	2.08	25.69	-50.0	0.00	66.7
	Week 6	31	67.20	25.99	0.0	66.67	100.0	25	6.67	34.02	-83.3	0.00	66.7
	Week 7	34	71.08	25.72	0.0	66.67	100.0	28	11.91	32.98	-100.0	0.00	66.7
	Week 8	35	69.05	28.91	0.0	66.67	100.0	30	7.78	34.11	-83.3	0.00	83.3
	Week 9	34	62.75	31.80	0.0	66.67	100.0	30	-2.78	37.16	-83.3	0.00	66.7
	Week 10	34	72.55	26.55	0.0	66.67	100.0	30	9.44	32.37	-66.7	0.00	66.7
	Week 11	33	63.64	30.18	0.0	66.67	100.0	28	0.59	42.91	-83.3	0.00	83.3
	Week 12	33	68.18	32.10	0.0	66.67	100.0	29	3.45	38.67	-83.3	0.00	83.3
	Week 14	31	70.43	28.45	0.0	66.67	100.0	26	9.62	36.57	-100.0	0.00	66.7
	Week 17	31	70.97	26.16	16.7	66.67	100.0	25	10.00	32.63	-66.7	0.00	66.7
	Week 20	27	66.67	32.69	0.0	66.67	100.0	24	-3.47	38.69	-100.0	0.00	66.7
	Week 23	26	69.23	28.16	0.0	66.67	100.0	23	0.72	33.51	-100.0	0.00	66.7
	Week 26	25	74.67	29.31	0.0	83.33	100.0	22	9.85	36.61	-50.0	0.00	100.0
	Week 29	23	78.26	25.34	0.0	83.33	100.0	22	6.82	38.72	-83.3	0.00	83.3
	Week 32	21	78.57	24.80	16.7	83.33	100.0	19	7.02	31.58	-50.0	0.00	66.7
	Week 35	19	74.56	28.53	0.0	83.33	100.0	17	0.98	39.74	-83.3	0.00	66.7
	Week 38	18	57.41	34.41	0.0	66.67	100.0	17	-7.84	40.45	-83.3	0.00	66.7
	Week 41	20	75.00	25.07	33.3	75.00	100.0	19	2.63	36.12	-66.7	0.00	66.7
	Week 44	17	74.51	26.43	33.3	66.67	100.0	15	-2.22	33.26	-66.7	0.00	66.7
	Week 47	18	62.04	38.27	0.0	66.67	100.0	16	-12.50	45.34	-100.0	0.00	66.7

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	12	79.17	23.70	50.0	91.67	100.0	11	-7.58	25.13	-50.0	0.00	33.3
	Week 53	12	66.67	36.93	0.0	75.00	100.0	11	-16.67	37.27	-100.0	0.00	50.0
	Week 56	13	65.38	36.93	0.0	66.67	100.0	12	-18.06	46.31	-100.0	-8.34	66.7
	Week 59	12	75.00	32.18	0.0	83.33	100.0	11	-6.06	41.01	-100.0	0.00	66.7
	Week 62	10	78.33	33.38	0.0	100.00	100.0	9	-3.70	44.71	-100.0	0.00	66.7
	Week 65	10	76.67	34.43	0.0	91.67	100.0	9	-7.41	45.73	-83.3	0.00	66.7
	Plat+Gem (N= 48)												
	BASELINE	33	69.70	27.78	16.7	66.67	100.0						
	Week 1	31	71.51	28.61	0.0	66.67	100.0	27	0.62	20.92	-50.0	0.00	50.0
	Week 2	29	67.24	31.96	0.0	66.67	100.0	24	-2.08	31.97	-50.0	0.00	83.3
	Week 3	32	76.04	23.55	16.7	83.33	100.0	27	4.32	24.28	-33.3	0.00	66.7
	Week 4	32	77.08	26.35	0.0	83.33	100.0	24	6.25	25.92	-50.0	0.00	66.7
	Week 5	36	71.30	28.62	0.0	66.67	100.0	28	2.38	26.34	-50.0	0.00	83.3
	Week 6	35	69.53	28.44	0.0	66.67	100.0	27	2.47	24.33	-50.0	0.00	50.0
	Week 7	38	74.56	24.73	16.7	75.00	100.0	29	9.77	26.17	-66.7	0.00	66.7
	Week 8	31	79.57	20.51	33.3	83.33	100.0	25	4.67	18.95	-50.0	0.00	33.3
	Week 9	32	75.00	22.40	33.3	66.67	100.0	25	7.33	21.02	-50.0	0.00	33.3
	Week 10	34	74.51	25.04	16.7	75.00	100.0	26	10.90	28.26	-66.7	8.33	83.3
	Week 11	30	80.56	21.48	33.3	83.33	100.0	24	12.50	24.20	-33.3	8.33	83.3
	Week 12	28	79.76	20.96	33.3	83.33	100.0	23	11.59	25.34	-33.3	0.00	83.3
	Week 14	26	73.08	21.64	33.3	66.67	100.0	21	3.97	24.10	-33.3	0.00	33.3
	Week 17	30	78.89	22.71	33.3	75.00	100.0	25	10.67	17.27	-33.3	16.66	33.3
	Week 20	23	82.61	22.18	16.7	100.00	100.0	21	12.70	22.91	-33.3	16.67	66.7
	Week 23	22	80.30	23.92	33.3	91.67	100.0	19	8.77	16.07	-16.7	0.00	50.0
	Week 26	19	85.09	19.16	50.0	100.00	100.0	18	9.26	15.36	-16.7	0.00	33.3
	Week 29	16	83.33	21.08	33.3	91.67	100.0	14	8.33	16.98	-16.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 32	11	84.85	17.41	66.7	100.00	100.0	11	6.06	11.24	0.0	0.00	33.3
	Week 35	10	85.00	19.95	50.0	100.00	100.0	9	1.85	17.57	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
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Table 302.1.3002.13.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Absent	EV+Pembro (N=192)												
	BASELINE	167	80.64	24.63	0.0	83.33	100.0						
	Week 1	158	78.38	24.42	0.0	83.33	100.0	152	-2.63	22.21	-66.7	0.00	66.7
	Week 2	166	78.11	23.77	0.0	83.33	100.0	156	-3.63	23.97	-66.7	0.00	66.7
	Week 3	164	78.05	22.59	0.0	83.33	100.0	153	-3.49	23.93	-66.7	0.00	100.0
	Week 4	158	79.54	22.57	0.0	83.33	100.0	148	-2.59	25.18	-66.7	0.00	100.0
	Week 5	160	78.75	23.71	0.0	83.33	100.0	149	-3.24	25.97	-83.3	0.00	100.0
	Week 6	157	80.04	21.96	0.0	83.33	100.0	145	-1.84	23.25	-83.3	0.00	66.7
	Week 7	161	78.78	22.05	0.0	83.33	100.0	148	-4.28	25.13	-83.3	0.00	100.0
	Week 8	156	79.17	22.61	0.0	83.33	100.0	141	-3.43	26.62	-66.7	0.00	100.0
	Week 9	163	78.53	22.20	0.0	83.33	100.0	150	-2.67	25.62	-66.7	0.00	66.7
	Week 10	157	78.13	22.24	0.0	83.33	100.0	145	-2.76	26.79	-66.7	0.00	66.7
	Week 11	161	79.61	22.36	0.0	83.33	100.0	147	-0.91	26.66	-66.7	0.00	100.0
	Week 12	153	79.52	24.07	0.0	83.33	100.0	142	-2.46	25.34	-83.3	0.00	66.7
	Week 14	154	77.16	25.35	0.0	83.33	100.0	141	-4.49	25.19	-83.3	0.00	66.7
	Week 17	147	78.57	22.75	0.0	83.33	100.0	137	-3.41	26.05	-66.7	0.00	66.7
	Week 20	140	76.79	25.26	0.0	83.33	100.0	130	-5.77	27.97	-83.3	0.00	66.7
	Week 23	136	75.00	26.21	0.0	83.33	100.0	128	-8.07	29.21	-100.0	0.00	66.7
	Week 26	131	76.34	23.93	0.0	83.33	100.0	122	-5.46	28.86	-100.0	0.00	66.7
	Week 29	134	77.24	22.44	0.0	66.67	100.0	123	-5.15	27.92	-66.7	0.00	66.7
	Week 32	114	76.75	23.94	0.0	83.33	100.0	106	-6.60	28.33	-83.3	0.00	66.7
	Week 35	113	76.11	22.81	16.7	83.33	100.0	105	-7.46	26.75	-83.3	0.00	66.7
	Week 38	114	75.88	22.84	0.0	66.67	100.0	107	-7.94	25.83	-66.7	0.00	66.7
	Week 41	109	73.39	25.27	0.0	66.67	100.0	100	-9.33	28.06	-83.3	0.00	66.7
	Week 44	91	76.37	24.10	0.0	83.33	100.0	85	-7.25	29.82	-100.0	0.00	66.7
	Week 47	82	75.81	23.45	0.0	83.33	100.0	78	-6.41	29.08	-100.0	0.00	66.7

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Table 302.1.3002.13.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	77	72.51	23.53	16.7	66.67	100.0	73	-10.27	29.35	-83.3	0.00	66.7
	Week 53	67	77.12	20.89	33.3	66.67	100.0	63	-6.88	27.70	-66.7	0.00	66.7
	Week 56	68	77.45	20.92	33.3	66.67	100.0	64	-4.17	28.33	-66.7	0.00	66.7
	Week 59	60	74.72	20.92	16.7	66.67	100.0	57	-6.72	30.19	-83.3	0.00	66.7
	Week 62	55	78.49	23.50	33.3	83.33	100.0	54	-6.48	28.67	-66.7	0.00	66.7
	Week 65	48	74.65	22.01	33.3	66.67	100.0	45	-6.30	26.66	-66.7	0.00	66.7
	Week 68	46	76.45	20.96	33.3	66.67	100.0	45	-5.92	28.24	-66.7	0.00	66.7
	Week 71	44	76.52	21.96	0.0	75.00	100.0	42	-5.55	28.43	-66.7	0.00	66.7
	Week 74	40	74.58	20.32	33.3	66.67	100.0	39	-8.97	26.45	-66.7	-16.66	66.7
	Week 77	38	71.49	22.89	33.3	66.67	100.0	36	-11.11	27.31	-66.7	-16.66	33.3
	Week 80	35	71.43	21.98	0.0	66.67	100.0	32	-7.81	25.04	-66.7	0.00	50.0
	Week 83	32	71.88	22.97	0.0	66.67	100.0	30	-6.11	26.44	-66.7	0.00	50.0
	Week 86	29	71.84	22.32	33.3	66.67	100.0	26	-5.77	29.04	-66.7	-8.33	33.3
	Week 89	29	68.39	21.52	33.3	66.67	100.0	27	-8.64	26.30	-50.0	-16.66	50.0
	Week 92	24	71.53	21.13	33.3	66.67	100.0	22	-6.06	24.96	-33.3	-8.33	33.3
	Week 95	20	73.33	21.90	33.3	66.67	100.0	19	-7.02	29.56	-66.7	-16.66	33.3
	Week 98	18	74.08	19.99	33.3	66.67	100.0	17	-4.90	22.64	-50.0	0.00	33.3
	Week 101	13	78.21	22.96	33.3	66.67	100.0	13	-8.97	25.10	-50.0	0.00	33.3
	Plat+Gem (N=194)												
	BASELINE	155	76.02	26.12	0.0	83.33	100.0						
	Week 1	142	73.24	23.90	0.0	66.67	100.0	131	-2.80	24.03	-66.7	0.00	66.7
	Week 2	142	71.36	27.39	0.0	66.67	100.0	127	-5.77	26.01	-100.0	0.00	66.7
	Week 3	152	73.79	26.06	0.0	66.67	100.0	135	-3.21	23.96	-83.3	0.00	66.7
	Week 4	151	70.97	27.04	0.0	66.67	100.0	132	-6.19	24.05	-66.7	0.00	50.0
	Week 5	151	71.19	25.53	0.0	66.67	100.0	128	-7.42	25.60	-66.7	0.00	50.0
	Week 6	139	72.78	24.59	0.0	66.67	100.0	122	-5.74	24.32	-66.7	0.00	50.0

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Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 7	148	73.20	24.33	0.0	66.67	100.0	128	-5.86	26.26	-83.3	0.00	66.7
	Week 8	136	69.98	26.36	0.0	66.67	100.0	119	-7.00	28.17	-100.0	0.00	66.7
	Week 9	145	71.61	25.39	0.0	66.67	100.0	125	-6.67	26.94	-100.0	0.00	66.7
	Week 10	132	72.22	24.85	0.0	66.67	100.0	113	-7.08	27.44	-100.0	0.00	50.0
	Week 11	138	70.41	25.39	0.0	66.67	100.0	119	-8.26	26.21	-100.0	0.00	50.0
	Week 12	131	72.77	26.17	0.0	66.67	100.0	115	-6.52	26.83	-100.0	0.00	50.0
	Week 14	127	70.87	25.11	0.0	66.67	100.0	107	-7.17	26.51	-66.7	0.00	66.7
	Week 17	125	70.13	27.05	0.0	66.67	100.0	105	-9.05	28.59	-83.3	0.00	66.7
	Week 20	103	75.08	25.76	0.0	83.33	100.0	89	-4.68	26.11	-66.7	0.00	66.7
	Week 23	93	77.42	25.38	0.0	83.33	100.0	78	-1.92	26.86	-66.7	0.00	66.7
	Week 26	89	76.59	25.71	0.0	83.33	100.0	77	-4.55	25.02	-83.3	0.00	50.0
	Week 29	84	77.98	24.84	0.0	83.33	100.0	72	-5.56	26.24	-83.3	0.00	33.3
	Week 32	72	77.78	26.24	0.0	83.33	100.0	65	-3.33	26.22	-83.3	0.00	66.7
	Week 35	66	79.04	23.26	0.0	83.33	100.0	60	-2.50	23.13	-66.7	0.00	66.7
	Week 38	66	77.53	25.23	0.0	83.33	100.0	57	-3.51	24.55	-66.7	0.00	33.3
	Week 41	62	78.76	24.73	0.0	83.33	100.0	53	-3.46	22.96	-66.7	0.00	33.3
	Week 44	55	78.48	23.93	16.7	83.33	100.0	48	-1.39	23.53	-66.7	0.00	33.3
	Week 47	51	80.07	21.86	0.0	83.33	100.0	44	-1.52	24.86	-100.0	0.00	33.3
	Week 50	48	75.35	27.29	0.0	83.33	100.0	44	-4.55	26.26	-100.0	0.00	33.3
	Week 53	41	82.52	21.39	33.3	83.33	100.0	37	1.35	17.73	-33.3	0.00	33.3
	Week 56	34	79.90	22.39	33.3	83.33	100.0	29	0.00	25.59	-50.0	0.00	50.0
	Week 59	32	84.90	21.73	0.0	100.00	100.0	28	4.17	21.09	-33.3	0.00	66.7
	Week 62	27	80.25	17.92	50.0	66.67	100.0	24	-0.69	23.81	-50.0	0.00	33.3
	Week 65	25	80.00	22.57	16.7	83.33	100.0	21	-0.79	21.39	-33.3	0.00	33.3
	Week 68	23	80.44	24.95	0.0	83.33	100.0	19	-1.75	16.57	-33.3	0.00	33.3
	Week 71	21	77.78	29.50	0.0	83.33	100.0	18	-4.63	29.04	-66.7	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 74	20	81.67	26.44	0.0	91.67	100.0	17	2.94	22.23	-33.3	0.00	50.0
	Week 77	16	81.25	23.47	16.7	83.33	100.0	13	2.56	22.41	-33.3	0.00	50.0
	Week 80	12	88.89	14.79	66.7	100.00	100.0	11	9.09	17.26	-16.7	0.00	33.3
	Week 83	11	80.30	17.98	50.0	83.33	100.0	10	1.67	24.15	-33.3	0.00	33.3
	Week 86	10	85.00	16.57	66.7	91.67	100.0	9	0.00	25.00	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
< 65 years	EV+Pembro (N=105)												
	BASELINE	92	74.64	27.79	0.0	83.33	100.0						
	Week 1	88	74.43	26.74	0.0	83.33	100.0	85	-0.39	18.36	-50.0	0.00	50.0
	Week 2	92	76.27	23.34	0.0	75.00	100.0	86	-0.58	25.37	-66.7	0.00	66.7
	Week 3	93	75.81	25.48	0.0	83.33	100.0	84	1.59	25.03	-66.7	0.00	66.7
	Week 4	90	78.89	22.60	16.7	83.33	100.0	82	4.47	27.60	-66.7	0.00	66.7
	Week 5	90	78.52	24.00	16.7	83.33	100.0	81	3.09	27.27	-66.7	0.00	66.7
	Week 6	90	81.67	20.46	33.3	83.33	100.0	81	7.41	23.57	-66.7	0.00	66.7
	Week 7	85	79.61	19.82	16.7	83.33	100.0	77	4.33	27.09	-66.7	0.00	66.7
	Week 8	89	81.27	19.76	33.3	83.33	100.0	80	6.67	26.73	-50.0	0.00	83.3
	Week 9	93	78.32	22.49	16.7	83.33	100.0	85	2.55	28.35	-83.3	0.00	66.7
	Week 10	88	80.49	21.33	33.3	83.33	100.0	81	6.38	29.41	-50.0	0.00	66.7
	Week 11	93	79.03	21.55	16.7	83.33	100.0	84	4.96	31.24	-66.7	0.00	83.3
	Week 12	86	78.30	23.72	0.0	83.33	100.0	79	2.74	28.17	-83.3	0.00	83.3
	Week 14	84	75.99	26.30	0.0	83.33	100.0	76	2.41	28.64	-66.7	0.00	66.7
	Week 17	83	78.11	23.56	0.0	83.33	100.0	77	4.11	30.13	-66.7	0.00	66.7
	Week 20	79	75.53	26.53	0.0	83.33	100.0	73	-1.14	29.44	-66.7	0.00	66.7
	Week 23	78	74.36	28.64	0.0	83.33	100.0	73	-3.42	30.55	-100.0	0.00	66.7
	Week 26	78	77.14	23.89	16.7	83.33	100.0	72	1.16	28.43	-50.0	0.00	66.7
	Week 29	74	79.96	20.27	33.3	83.33	100.0	67	3.23	27.71	-50.0	0.00	83.3
	Week 32	64	77.60	24.53	16.7	83.33	100.0	59	-0.56	30.32	-66.7	0.00	66.7
	Week 35	62	77.42	23.20	16.7	83.33	100.0	58	-1.72	28.22	-66.7	0.00	66.7
	Week 38	62	73.39	26.04	0.0	75.00	100.0	59	-3.11	29.11	-66.7	0.00	66.7
	Week 41	64	75.78	24.83	0.0	83.33	100.0	59	-0.56	27.68	-66.7	0.00	66.7
	Week 44	50	77.00	23.78	16.7	83.33	100.0	48	-1.04	28.02	-50.0	0.00	66.7
	Week 47	47	72.34	28.93	0.0	66.67	100.0	46	-5.43	32.78	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	44	74.62	23.15	16.7	75.00	100.0	41	-6.10	28.81	-83.3	0.00	66.7
	Week 53	40	74.58	25.87	0.0	66.67	100.0	37	-5.40	30.44	-100.0	0.00	66.7
	Week 56	44	76.89	23.08	0.0	66.67	100.0	41	-2.44	29.94	-100.0	0.00	66.7
	Week 59	42	73.81	22.13	0.0	66.67	100.0	39	-5.98	32.10	-100.0	0.00	66.7
	Week 62	37	77.93	25.78	0.0	83.33	100.0	36	-4.63	33.00	-100.0	0.00	66.7
	Week 65	34	74.02	23.28	33.3	83.33	100.0	31	-3.76	31.54	-66.7	0.00	66.7
	Week 68	34	76.96	20.11	33.3	66.67	100.0	33	-2.52	31.21	-66.7	0.00	66.7
	Week 71	32	72.40	24.54	0.0	66.67	100.0	30	-6.67	32.64	-66.7	0.00	66.7
	Week 74	29	71.84	25.63	0.0	66.67	100.0	28	-8.33	35.57	-100.0	-8.33	66.7
	Week 77	25	70.67	24.67	33.3	66.67	100.0	24	-6.25	34.34	-66.7	0.00	66.7
	Week 80	24	65.97	22.24	0.0	66.67	100.0	22	-10.60	32.35	-66.7	-8.33	66.7
	Week 83	23	69.57	23.38	0.0	66.67	100.0	22	-6.82	33.99	-66.7	-8.33	66.7
	Week 86	20	67.50	25.64	33.3	66.67	100.0	18	-5.56	38.35	-66.7	-8.33	66.7
	Week 89	19	65.79	23.22	33.3	66.67	100.0	17	-3.92	31.47	-33.3	0.00	66.7
	Week 92	14	66.67	22.65	33.3	66.67	100.0	12	-12.50	28.54	-66.7	-8.34	33.3
	Week 95	12	63.89	24.45	33.3	66.67	100.0	11	-13.64	37.13	-66.7	-16.66	33.3
	Plat+Gem (N=106)												
	BASELINE	83	74.90	24.74	0.0	66.67	100.0						
	Week 1	75	71.78	23.25	0.0	66.67	100.0	71	-3.52	23.22	-50.0	0.00	50.0
	Week 2	76	67.32	29.24	0.0	66.67	100.0	68	-8.82	26.31	-83.3	0.00	50.0
	Week 3	80	73.54	24.83	16.7	66.67	100.0	73	-2.51	25.71	-83.3	0.00	66.7
	Week 4	79	70.46	25.73	0.0	66.67	100.0	67	-5.22	24.82	-66.7	0.00	50.0
	Week 5	80	69.58	24.70	0.0	66.67	100.0	67	-7.46	23.80	-66.7	0.00	50.0
	Week 6	76	71.71	22.94	0.0	66.67	100.0	67	-3.73	24.07	-66.7	0.00	50.0
	Week 7	81	73.46	24.83	0.0	66.67	100.0	71	-1.88	25.60	-66.7	0.00	66.7
	Week 8	72	72.22	21.67	16.7	66.67	100.0	64	-2.60	25.75	-83.3	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	78	71.80	20.69	33.3	66.67	100.0	69	-3.14	24.30	-66.7	0.00	33.3
	Week 10	78	71.15	23.82	0.0	66.67	100.0	68	-3.68	27.89	-83.3	0.00	50.0
	Week 11	75	70.67	22.23	0.0	66.67	100.0	66	-4.04	26.16	-100.0	0.00	50.0
	Week 12	74	74.78	22.11	0.0	66.67	100.0	66	-1.26	25.70	-100.0	0.00	50.0
	Week 14	68	70.10	22.41	0.0	66.67	100.0	58	-3.16	24.47	-66.7	0.00	50.0
	Week 17	68	70.34	26.52	0.0	66.67	100.0	58	-2.59	26.27	-83.3	0.00	50.0
	Week 20	60	75.00	24.45	16.7	75.00	100.0	52	-0.64	26.81	-66.7	0.00	66.7
	Week 23	51	77.12	23.80	0.0	83.33	100.0	44	2.65	25.91	-50.0	0.00	66.7
	Week 26	47	75.53	23.79	16.7	66.67	100.0	42	1.59	22.33	-50.0	0.00	50.0
	Week 29	42	78.18	18.94	33.3	75.00	100.0	37	0.90	19.62	-33.3	0.00	33.3
	Week 32	37	75.68	26.23	0.0	66.67	100.0	34	0.00	24.62	-83.3	0.00	66.7
	Week 35	34	80.39	19.45	33.3	83.33	100.0	31	1.61	24.48	-66.7	0.00	66.7
	Week 38	33	78.79	22.93	33.3	83.33	100.0	28	1.79	20.46	-33.3	0.00	33.3
	Week 41	27	77.78	22.65	33.3	83.33	100.0	22	0.76	22.70	-66.7	0.00	33.3
	Week 44	28	73.81	24.19	33.3	66.67	100.0	24	0.00	24.57	-66.7	0.00	33.3
	Week 47	24	79.17	16.48	50.0	83.33	100.0	21	0.79	18.62	-33.3	0.00	33.3
	Week 50	26	76.92	25.42	33.3	83.33	100.0	24	4.17	19.19	-33.3	0.00	33.3
	Week 53	19	76.32	26.25	33.3	83.33	100.0	17	0.98	19.07	-33.3	0.00	33.3
	Week 56	13	74.36	31.63	0.0	83.33	100.0	11	0.00	25.82	-50.0	0.00	33.3
	Week 59	14	83.33	27.73	0.0	100.00	100.0	12	5.56	21.71	-33.3	0.00	33.3
	Week 62	13	85.90	16.45	66.7	100.00	100.0	12	4.17	23.70	-33.3	0.00	33.3
	Week 65	13	82.05	24.02	16.7	83.33	100.0	11	1.52	20.35	-33.3	0.00	33.3
	Week 68	10	76.67	32.58	0.0	91.67	100.0	8	2.08	10.68	-16.7	0.00	16.7
	Week 77	10	76.67	27.44	16.7	83.33	100.0	8	2.08	13.91	-16.7	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>= 65 years	EV+Pembro (N=135)												
	BASELINE	114	80.99	26.13	0.0	100.00	100.0						
	Week 1	102	78.92	24.48	0.0	83.33	100.0	99	-2.69	26.59	-66.7	0.00	100.0
	Week 2	111	76.13	25.68	0.0	83.33	100.0	103	-5.34	25.27	-66.7	0.00	83.3
	Week 3	105	72.38	26.94	0.0	66.67	100.0	98	-8.50	22.61	-83.3	0.00	100.0
	Week 4	104	75.64	25.85	0.0	83.33	100.0	97	-6.53	25.75	-100.0	0.00	100.0
	Week 5	100	74.00	25.88	0.0	66.67	100.0	92	-7.43	23.75	-83.3	0.00	100.0
	Week 6	98	74.49	24.89	0.0	66.67	100.0	89	-7.86	24.50	-83.3	0.00	66.7
	Week 7	110	75.76	24.90	0.0	83.33	100.0	99	-6.40	26.27	-100.0	0.00	100.0
	Week 8	102	73.86	27.00	0.0	66.67	100.0	91	-8.61	27.82	-83.3	0.00	100.0
	Week 9	104	73.56	26.54	0.0	66.67	100.0	95	-7.37	26.49	-83.3	0.00	66.7
	Week 10	103	74.27	24.23	0.0	66.67	100.0	94	-6.74	25.55	-66.7	0.00	66.7
	Week 11	101	74.92	26.94	0.0	83.33	100.0	91	-5.86	27.37	-83.3	0.00	100.0
	Week 12	100	76.83	27.82	0.0	83.33	100.0	92	-5.07	27.48	-83.3	0.00	66.7
	Week 14	101	76.07	25.76	0.0	83.33	100.0	91	-6.23	26.25	-100.0	0.00	66.7
	Week 17	95	76.49	23.51	0.0	83.33	100.0	85	-6.27	23.98	-66.7	0.00	66.7
	Week 20	88	74.81	27.10	0.0	66.67	100.0	81	-9.26	29.70	-100.0	0.00	66.7
	Week 23	84	73.81	24.58	0.0	66.67	100.0	78	-9.83	29.23	-100.0	0.00	66.7
	Week 26	78	75.00	25.73	0.0	83.33	100.0	72	-7.41	32.12	-100.0	0.00	100.0
	Week 29	83	75.10	24.74	0.0	66.67	100.0	78	-8.97	30.82	-83.3	0.00	66.7
	Week 32	71	76.53	23.67	0.0	83.33	100.0	66	-8.08	27.77	-83.3	0.00	66.7
	Week 35	70	74.52	24.03	0.0	66.67	100.0	64	-10.42	29.02	-83.3	0.00	50.0
	Week 38	70	73.33	24.96	0.0	66.67	100.0	65	-12.31	26.56	-83.3	0.00	50.0
	Week 41	65	71.54	25.47	0.0	66.67	100.0	60	-14.17	30.20	-83.3	-16.66	50.0
	Week 44	58	75.29	25.02	0.0	75.00	100.0	52	-11.54	31.58	-100.0	0.00	66.7
	Week 47	53	74.21	25.44	0.0	83.33	100.0	48	-9.37	31.87	-83.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	45	72.22	24.10	33.3	66.67	100.0	43	-13.57	28.47	-66.7	-16.66	50.0
	Week 53	39	76.50	22.20	33.3	66.67	100.0	37	-11.26	28.07	-66.7	0.00	66.7
	Week 56	37	73.87	25.92	0.0	66.67	100.0	35	-10.95	33.81	-83.3	0.00	66.7
	Week 59	30	76.11	24.24	16.7	75.00	100.0	29	-7.47	31.99	-83.3	0.00	66.7
	Week 62	28	79.17	24.27	33.3	91.67	100.0	27	-8.02	28.63	-66.7	0.00	50.0
	Week 65	24	76.39	25.97	0.0	75.00	100.0	23	-10.14	28.31	-83.3	0.00	50.0
	Week 68	19	78.95	22.11	33.3	66.67	100.0	19	-7.89	25.68	-66.7	0.00	50.0
	Week 71	19	83.33	18.42	50.0	83.33	100.0	19	-1.75	25.39	-33.3	0.00	66.7
	Week 74	18	78.71	18.79	50.0	66.67	100.0	18	-7.41	22.30	-50.0	0.00	33.3
	Week 77	19	71.05	27.69	0.0	66.67	100.0	18	-16.67	29.15	-83.3	-16.66	33.3
	Week 80	16	78.13	23.35	33.3	75.00	100.0	15	-2.22	25.87	-50.0	0.00	50.0
	Week 83	14	71.43	30.96	0.0	66.67	100.0	13	-6.41	32.30	-83.3	0.00	33.3
	Week 86	14	79.76	16.25	66.7	66.67	100.0	13	-2.56	23.42	-33.3	0.00	33.3
	Week 89	14	76.19	18.16	50.0	66.67	100.0	14	-7.14	27.51	-50.0	-8.33	50.0
	Week 92	13	78.21	21.93	50.0	66.67	100.0	13	-3.84	24.68	-33.3	0.00	33.3
	Week 95	10	73.34	30.63	0.0	66.67	100.0	10	-13.33	34.06	-83.3	-16.66	33.3
	Week 98	10	73.33	17.92	50.0	66.67	100.0	10	-13.33	18.92	-50.0	-16.66	16.7
	Plat+Gem (N=136)												
	BASELINE	105	74.92	27.84	0.0	83.33	100.0						
	Week 1	98	73.81	25.89	0.0	66.67	100.0	87	-1.15	23.81	-66.7	0.00	66.7
	Week 2	95	73.33	27.11	0.0	83.33	100.0	83	-2.21	27.27	-100.0	0.00	83.3
	Week 3	104	74.68	26.27	0.0	83.33	100.0	89	-1.50	22.84	-66.7	0.00	66.7
	Week 4	104	73.24	27.91	0.0	66.67	100.0	89	-3.56	24.68	-66.7	0.00	66.7
	Week 5	107	72.43	27.10	0.0	66.67	100.0	89	-4.31	27.47	-66.7	0.00	83.3
	Week 6	98	72.45	27.19	0.0	66.67	100.0	82	-4.67	24.88	-66.7	0.00	50.0
	Week 7	105	73.49	24.10	16.7	66.67	100.0	86	-3.88	27.97	-83.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 8	95	71.40	28.32	0.0	66.67	100.0	80	-6.88	28.15	-100.0	0.00	66.7
	Week 9	99	72.56	27.80	0.0	66.67	100.0	81	-5.35	28.36	-100.0	0.00	66.7
	Week 10	88	74.05	25.75	0.0	75.00	100.0	71	-3.76	29.03	-100.0	0.00	83.3
	Week 11	93	73.48	27.06	0.0	66.67	100.0	77	-5.41	27.76	-83.3	0.00	83.3
	Week 12	85	73.33	28.08	0.0	66.67	100.0	72	-5.56	28.80	-100.0	0.00	83.3
	Week 14	85	72.16	26.15	0.0	66.67	100.0	70	-7.14	27.88	-66.7	0.00	66.7
	Week 17	87	72.99	26.44	0.0	66.67	100.0	72	-7.41	29.06	-66.7	0.00	66.7
	Week 20	66	77.78	26.04	0.0	83.33	100.0	58	-2.01	26.13	-66.7	0.00	66.7
	Week 23	64	78.65	26.14	0.0	83.33	100.0	53	-1.89	25.03	-66.7	0.00	66.7
	Week 26	61	80.05	25.61	0.0	83.33	100.0	53	-4.72	25.19	-83.3	0.00	33.3
	Week 29	58	79.31	27.63	0.0	100.00	100.0	49	-6.46	28.83	-83.3	0.00	33.3
	Week 32	46	81.16	24.50	0.0	91.67	100.0	42	-3.57	25.11	-66.7	0.00	50.0
	Week 35	42	79.37	25.45	0.0	91.67	100.0	38	-4.82	20.47	-66.7	0.00	33.3
	Week 38	41	77.24	26.29	0.0	83.33	100.0	37	-9.46	25.01	-66.7	0.00	33.3
	Week 41	38	78.95	26.19	0.0	91.67	100.0	34	-5.39	22.37	-66.7	0.00	33.3
	Week 44	32	82.81	22.19	16.7	83.33	100.0	29	-4.60	22.23	-66.7	0.00	33.3
	Week 47	32	80.21	24.48	0.0	83.33	100.0	28	-5.95	28.04	-100.0	0.00	33.3
	Week 50	25	74.00	28.50	0.0	66.67	100.0	23	-13.77	29.15	-100.0	0.00	33.3
	Week 53	27	86.42	14.64	66.7	83.33	100.0	25	-1.33	17.95	-33.3	0.00	33.3
	Week 56	26	80.77	21.44	33.3	83.33	100.0	23	-3.62	26.09	-50.0	0.00	50.0
	Week 59	23	85.51	17.63	50.0	100.00	100.0	21	0.00	21.73	-33.3	0.00	66.7
	Week 62	19	76.32	17.84	50.0	66.67	100.0	17	-7.84	22.91	-50.0	0.00	33.3
	Week 65	17	75.49	22.14	33.3	66.67	100.0	15	-10.00	24.23	-50.0	0.00	33.3
	Week 68	15	82.22	19.38	50.0	83.33	100.0	13	-6.41	19.88	-33.3	0.00	33.3
	Week 71	15	77.78	26.48	16.7	83.33	100.0	13	-8.97	31.63	-66.7	0.00	50.0
	Week 74	12	86.11	21.12	33.3	100.00	100.0	11	3.03	24.52	-33.3	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Europe	EV+Pembro (N= 98)												
	BASELINE	79	81.01	23.83	0.0	100.00	100.0						
	Week 1	74	78.15	23.88	0.0	83.33	100.0	71	-3.52	21.25	-50.0	0.00	66.7
	Week 2	79	79.75	22.28	16.7	83.33	100.0	71	-1.64	25.84	-66.7	0.00	66.7
	Week 3	78	79.06	21.56	16.7	83.33	100.0	69	-2.41	25.45	-66.7	0.00	66.7
	Week 4	78	81.84	22.18	0.0	83.33	100.0	70	0.00	31.08	-100.0	0.00	66.7
	Week 5	70	82.62	18.91	33.3	83.33	100.0	62	0.81	25.86	-50.0	0.00	66.7
	Week 6	70	84.05	21.50	0.0	100.00	100.0	61	1.91	27.90	-83.3	0.00	66.7
	Week 7	78	82.91	19.55	33.3	83.33	100.0	68	1.72	26.73	-66.7	0.00	66.7
	Week 8	72	82.18	22.08	0.0	83.33	100.0	61	-0.27	29.89	-83.3	0.00	66.7
	Week 9	80	80.83	22.52	0.0	83.33	100.0	70	-1.67	30.58	-83.3	0.00	66.7
	Week 10	71	83.10	20.99	33.3	100.00	100.0	62	3.23	31.48	-66.7	0.00	66.7
	Week 11	76	79.17	25.26	0.0	83.33	100.0	66	-1.01	33.95	-83.3	0.00	66.7
	Week 12	73	81.51	25.54	0.0	100.00	100.0	65	-0.26	30.97	-83.3	0.00	66.7
	Week 14	74	82.21	22.80	16.7	100.00	100.0	64	-0.52	28.32	-66.7	0.00	66.7
	Week 17	70	81.67	20.09	33.3	83.33	100.0	62	1.61	28.26	-66.7	0.00	66.7
	Week 20	70	80.24	23.96	0.0	91.67	100.0	63	-1.06	30.95	-83.3	0.00	66.7
	Week 23	61	77.05	25.31	0.0	83.33	100.0	57	-6.14	31.28	-100.0	0.00	66.7
	Week 26	62	83.60	21.01	0.0	100.00	100.0	55	2.12	29.41	-100.0	0.00	66.7
	Week 29	63	79.89	22.63	0.0	83.33	100.0	57	-2.34	28.77	-83.3	0.00	66.7
	Week 32	51	81.70	22.17	16.7	100.00	100.0	47	0.00	28.45	-66.7	0.00	66.7
	Week 35	56	76.79	25.56	0.0	83.33	100.0	52	-6.73	30.83	-83.3	0.00	66.7
	Week 38	51	76.47	24.98	0.0	83.33	100.0	48	-9.37	27.91	-83.3	0.00	50.0
	Week 41	52	77.56	22.60	16.7	83.33	100.0	48	-5.21	29.00	-66.7	0.00	66.7
	Week 44	43	78.29	23.72	16.7	83.33	100.0	39	-6.41	25.82	-66.7	0.00	33.3
	Week 47	39	74.36	27.80	0.0	83.33	100.0	36	-10.18	35.47	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	37	76.58	23.72	16.7	83.33	100.0	36	-7.41	29.67	-83.3	0.00	33.3
	Week 53	28	76.19	29.89	0.0	91.67	100.0	27	-4.32	31.21	-100.0	0.00	66.7
	Week 56	30	75.00	28.62	0.0	75.00	100.0	29	-8.62	32.92	-100.0	0.00	33.3
	Week 59	27	77.16	24.08	0.0	66.67	100.0	27	-5.55	28.12	-100.0	0.00	33.3
	Week 62	23	79.71	27.04	0.0	83.33	100.0	23	-5.80	33.18	-100.0	0.00	50.0
	Week 65	23	74.64	29.25	0.0	83.33	100.0	23	-5.07	31.15	-83.3	0.00	50.0
	Week 68	21	82.54	17.85	50.0	83.33	100.0	21	3.18	22.74	-33.3	0.00	50.0
	Week 71	19	80.70	21.70	33.3	83.33	100.0	19	1.75	27.16	-66.7	0.00	66.7
	Week 74	15	76.67	26.58	0.0	66.67	100.0	15	-4.44	31.79	-100.0	0.00	33.3
	Week 77	19	73.68	29.56	0.0	83.33	100.0	19	-7.89	33.50	-83.3	0.00	33.3
	Week 80	17	76.47	22.87	33.3	83.33	100.0	17	0.00	28.87	-66.7	0.00	50.0
	Week 83	16	76.04	27.87	0.0	83.33	100.0	16	1.04	34.68	-83.3	0.00	50.0
	Week 86	14	78.57	25.68	33.3	91.67	100.0	14	2.38	30.56	-66.7	0.00	33.3
	Week 89	14	77.38	23.21	33.3	75.00	100.0	14	1.19	27.32	-50.0	0.00	50.0
	Week 92	11	78.79	23.68	33.3	83.33	100.0	11	-3.03	26.69	-66.7	0.00	33.3
	Week 95	10	71.67	33.38	0.0	75.00	100.0	10	-13.33	37.51	-83.3	0.00	33.3
	Plat+Gem (N=102)												
	BASELINE	71	71.13	33.21	0.0	83.33	100.0						
	Week 1	71	70.19	28.86	0.0	66.67	100.0	61	-1.91	28.40	-66.7	0.00	66.7
	Week 2	67	70.90	30.06	0.0	66.67	100.0	56	-0.30	28.34	-66.7	0.00	66.7
	Week 3	68	71.81	29.68	0.0	83.33	100.0	56	-1.19	25.79	-83.3	0.00	66.7
	Week 4	75	69.56	29.17	0.0	66.67	100.0	59	-4.24	25.26	-66.7	0.00	50.0
	Week 5	77	71.86	26.94	0.0	66.67	100.0	60	-1.11	26.73	-66.7	0.00	50.0
	Week 6	70	68.10	27.76	0.0	66.67	100.0	56	-5.06	27.87	-66.7	0.00	50.0
	Week 7	72	70.37	26.57	0.0	66.67	100.0	55	-4.55	29.82	-83.3	0.00	66.7
	Week 8	65	65.13	28.22	0.0	66.67	100.0	53	-7.86	30.77	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	70	67.38	28.30	0.0	66.67	100.0	55	-6.67	28.62	-100.0	0.00	33.3
	Week 10	60	65.28	29.00	0.0	66.67	100.0	46	-11.23	33.53	-100.0	0.00	50.0
	Week 11	64	69.53	27.14	0.0	66.67	100.0	50	-7.67	27.40	-100.0	0.00	33.3
	Week 12	60	70.83	27.72	0.0	66.67	100.0	48	-5.90	28.03	-100.0	0.00	33.3
	Week 14	56	66.07	28.95	0.0	66.67	100.0	42	-8.33	29.96	-66.7	0.00	66.7
	Week 17	58	70.98	28.37	0.0	66.67	100.0	44	-4.17	28.10	-66.7	0.00	66.7
	Week 20	47	80.14	22.69	16.7	83.33	100.0	37	3.60	24.89	-50.0	0.00	66.7
	Week 23	44	78.79	25.00	33.3	83.33	100.0	32	3.12	27.90	-50.0	0.00	66.7
	Week 26	39	79.49	26.06	0.0	100.00	100.0	30	1.11	25.50	-83.3	0.00	50.0
	Week 29	34	78.43	25.47	0.0	83.33	100.0	25	-0.67	26.99	-83.3	0.00	33.3
	Week 32	33	77.27	25.62	0.0	83.33	100.0	27	0.00	28.12	-83.3	0.00	66.7
	Week 35	30	76.67	23.41	16.7	66.67	100.0	24	-2.08	27.94	-50.0	0.00	66.7
	Week 38	26	76.28	27.56	16.7	83.34	100.0	21	-5.56	21.30	-50.0	0.00	33.3
	Week 41	22	72.73	24.42	33.3	66.67	100.0	17	-5.88	25.65	-66.7	0.00	33.3
	Week 44	20	73.33	24.42	33.3	75.00	100.0	16	-1.04	23.15	-33.3	0.00	33.3
	Week 47	16	68.75	26.44	0.0	66.67	100.0	12	-11.11	32.83	-100.0	0.00	33.3
	Week 50	11	65.15	35.32	0.0	66.67	100.0	10	-8.33	37.06	-100.0	0.00	33.3
	Week 53	11	71.21	25.92	33.3	83.33	100.0	10	0.00	17.57	-16.7	0.00	33.3
	Week 56	10	80.00	24.60	33.3	91.67	100.0	8	6.25	28.08	-50.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
North America	EV+Pembro (N= 57)												
	BASELINE	47	75.89	28.83	0.0	83.33	100.0						
	Week 1	39	70.51	31.41	0.0	66.67	100.0	37	-4.05	19.80	-50.0	0.00	50.0
	Week 2	44	70.45	30.47	0.0	83.33	100.0	42	-8.73	20.57	-50.0	0.00	33.3
	Week 3	44	67.05	31.23	0.0	66.67	100.0	40	-7.50	21.66	-83.3	0.00	33.3
	Week 4	44	74.62	27.49	0.0	83.33	100.0	41	-0.81	21.72	-50.0	0.00	66.7
	Week 5	47	70.21	29.27	0.0	66.67	100.0	41	-5.28	21.55	-50.0	0.00	33.3
	Week 6	44	71.59	26.06	0.0	66.67	100.0	39	-1.71	22.55	-50.0	0.00	50.0
	Week 7	46	75.36	23.50	16.7	75.00	100.0	42	-1.98	22.15	-50.0	0.00	66.7
	Week 8	47	73.40	24.73	0.0	66.67	100.0	42	-2.38	24.57	-50.0	0.00	83.3
	Week 9	46	71.02	26.40	0.0	66.67	100.0	42	-3.97	22.03	-83.3	0.00	33.3
	Week 10	47	74.47	24.78	0.0	66.67	100.0	44	-1.14	22.56	-50.0	0.00	66.7
	Week 11	47	74.47	24.29	0.0	66.67	100.0	42	0.00	24.42	-66.7	0.00	83.3
	Week 12	44	73.49	24.99	0.0	66.67	100.0	40	-0.42	26.82	-66.7	0.00	83.3
	Week 14	43	74.42	24.76	0.0	83.33	100.0	39	2.14	24.24	-50.0	0.00	66.7
	Week 17	40	74.58	25.31	0.0	83.33	100.0	37	0.45	27.91	-50.0	0.00	66.7
	Week 20	38	74.12	28.13	0.0	83.33	100.0	35	-0.48	25.08	-66.7	0.00	33.3
	Week 23	38	74.12	28.92	0.0	75.00	100.0	35	-3.81	29.17	-66.7	0.00	66.7
	Week 26	35	74.76	25.36	16.7	83.33	100.0	32	1.56	24.45	-50.0	0.00	33.3
	Week 29	38	80.26	21.17	0.0	83.33	100.0	34	3.43	26.84	-50.0	0.00	83.3
	Week 32	32	80.21	20.49	33.3	83.33	100.0	29	-1.15	21.79	-50.0	0.00	33.3
	Week 35	33	80.81	20.88	16.7	83.33	100.0	30	-2.22	22.63	-50.0	0.00	33.3
	Week 38	32	78.12	24.11	0.0	83.33	100.0	29	0.00	27.10	-50.0	0.00	66.7
	Week 41	28	80.36	18.73	50.0	83.33	100.0	24	-0.69	24.32	-50.0	0.00	50.0
	Week 44	21	80.16	26.15	0.0	83.33	100.0	20	-4.17	35.82	-100.0	0.00	66.7
	Week 47	24	76.39	24.04	33.3	83.33	100.0	23	-4.35	33.79	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	23	73.91	22.93	33.3	66.67	100.0	20	-9.17	23.86	-50.0	-8.33	33.3
	Week 53	17	80.39	14.71	66.7	83.33	100.0	14	-9.52	21.40	-33.3	0.00	33.3
	Week 56	20	80.00	18.42	50.0	75.00	100.0	17	-0.98	31.99	-50.0	0.00	66.7
	Week 59	17	78.43	16.42	50.0	66.67	100.0	14	-2.38	30.56	-33.3	0.00	66.7
	Week 62	14	88.10	16.57	66.7	100.00	100.0	13	0.00	22.57	-33.3	0.00	33.3
	Week 65	12	83.33	14.21	66.7	83.33	100.0	9	-5.55	22.05	-33.3	0.00	33.3
	Week 68	10	83.33	15.71	66.7	83.33	100.0	9	-9.26	16.90	-33.3	0.00	16.7
	Week 71	10	85.00	14.59	66.7	83.33	100.0	8	-8.33	25.20	-33.3	-8.34	33.3
	Week 74	10	85.00	14.59	66.7	83.33	100.0	9	-3.70	23.24	-33.3	0.00	33.3
	Plat+Gem (N= 51)												
	BASELINE	42	76.59	19.84	16.7	66.67	100.0						
	Week 1	41	71.55	22.44	0.0	66.67	100.0	36	-5.09	19.85	-50.0	0.00	16.7
	Week 2	38	67.98	24.62	0.0	66.67	100.0	33	-10.61	17.09	-50.0	-16.66	16.7
	Week 3	40	73.33	22.90	33.3	66.67	100.0	35	-6.19	24.62	-66.7	0.00	33.3
	Week 4	35	70.00	26.75	0.0	66.67	100.0	29	-9.20	20.21	-66.7	0.00	16.7
	Week 5	39	70.09	23.63	0.0	66.67	100.0	32	-9.38	21.56	-66.7	-8.33	33.3
	Week 6	34	72.06	23.47	16.7	66.67	100.0	30	-6.67	19.38	-50.0	0.00	16.7
	Week 7	42	73.81	21.51	16.7	66.67	100.0	37	-3.15	21.46	-33.3	0.00	50.0
	Week 8	39	71.80	21.68	16.7	66.67	100.0	33	-7.58	23.60	-50.0	0.00	33.3
	Week 9	39	73.08	19.73	33.3	66.67	100.0	33	-2.53	20.46	-50.0	0.00	33.3
	Week 10	39	74.79	21.24	33.3	66.67	100.0	32	-0.52	23.75	-50.0	0.00	33.3
	Week 11	39	74.36	20.89	33.3	66.67	100.0	33	0.00	24.30	-66.7	0.00	50.0
	Week 12	36	75.00	21.64	0.0	83.33	100.0	32	-2.61	26.47	-66.7	0.00	50.0
	Week 14	34	72.55	21.67	0.0	66.67	100.0	29	-3.45	27.23	-66.7	0.00	50.0
	Week 17	37	67.57	26.34	0.0	66.67	100.0	31	-9.14	33.56	-83.3	0.00	50.0
	Week 20	27	70.37	25.46	0.0	66.67	100.0	23	-6.52	28.75	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 23	27	74.07	27.86	0.0	83.33	100.0	23	-2.90	25.94	-66.7	0.00	50.0
	Week 26	28	73.22	23.72	0.0	66.67	100.0	25	-3.33	20.41	-66.7	0.00	33.3
	Week 29	29	74.71	25.05	0.0	83.33	100.0	25	-7.33	26.82	-66.7	0.00	33.3
	Week 32	17	70.59	29.77	0.0	66.67	100.0	17	-9.80	24.34	-66.7	0.00	33.3
	Week 35	16	70.83	26.18	0.0	66.67	100.0	15	-12.22	24.78	-66.7	0.00	16.7
	Week 38	16	69.79	25.25	0.0	66.67	100.0	13	-12.82	19.43	-66.7	0.00	0.0
	Week 41	16	72.92	27.81	0.0	75.00	100.0	13	-8.98	22.17	-66.7	0.00	16.7
	Week 44	13	75.64	26.89	16.7	83.33	100.0	11	-6.06	20.10	-50.0	0.00	33.3
	Week 47	11	81.82	13.85	66.7	83.33	100.0	9	-3.71	11.11	-16.7	0.00	16.7
	Week 50	17	73.53	26.39	0.0	66.67	100.0	15	-4.45	26.33	-66.7	0.00	33.3
	Week 53	13	83.33	15.21	66.7	83.33	100.0	11	-1.52	18.93	-33.3	0.00	33.3
	Week 56	11	71.21	31.70	0.0	66.67	100.0	9	-11.11	27.64	-50.0	0.00	33.3
	Week 59	11	83.33	18.26	50.0	83.33	100.0	9	-1.85	19.44	-33.3	0.00	33.3
	Week 62	11	83.33	16.67	66.7	83.33	100.0	9	-1.85	19.44	-33.3	0.00	33.3
	Week 65	10	78.33	20.86	33.3	83.33	100.0	8	-6.25	23.46	-50.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Rest of World	EV+Pembro (N= 85)												
	BASELINE	80	76.67	28.88	0.0	83.33	100.0						
	Week 1	77	78.79	23.67	16.7	83.33	100.0	76	1.32	26.07	-66.7	0.00	100.0
	Week 2	80	75.83	22.80	0.0	66.67	100.0	76	-1.53	27.10	-66.7	0.00	83.3
	Week 3	76	72.81	26.78	0.0	66.67	100.0	73	-3.20	24.48	-50.0	0.00	100.0
	Week 4	72	73.61	24.18	0.0	66.67	100.0	68	-3.43	25.85	-66.7	0.00	100.0
	Week 5	73	73.74	26.19	0.0	66.67	100.0	70	-3.81	28.26	-83.3	0.00	100.0
	Week 6	74	75.90	21.57	33.3	66.67	100.0	70	-2.14	24.23	-66.7	0.00	66.7
	Week 7	71	72.77	24.76	0.0	66.67	100.0	66	-5.05	30.10	-100.0	0.00	100.0
	Week 8	72	75.00	25.17	0.0	66.67	100.0	68	-1.96	29.30	-66.7	0.00	100.0
	Week 9	71	73.24	25.43	0.0	66.67	100.0	68	-2.94	28.21	-66.7	0.00	66.7
	Week 10	73	73.06	23.01	0.0	66.67	100.0	69	-3.86	28.03	-66.7	0.00	66.7
	Week 11	71	76.06	24.03	16.7	66.67	100.0	67	-0.75	28.64	-66.7	0.00	100.0
	Week 12	69	75.85	26.74	0.0	83.33	100.0	66	-3.28	25.86	-83.3	0.00	66.7
	Week 14	68	70.34	28.63	0.0	66.67	100.0	64	-6.77	28.59	-100.0	0.00	66.7
	Week 17	68	74.27	25.17	0.0	66.67	100.0	63	-5.29	26.41	-66.7	0.00	66.7
	Week 20	59	69.77	28.28	0.0	66.67	100.0	56	-13.39	29.89	-100.0	0.00	50.0
	Week 23	63	71.16	26.30	0.0	66.67	100.0	59	-9.04	29.41	-100.0	0.00	66.7
	Week 26	59	68.93	26.16	0.0	66.67	100.0	57	-10.82	33.41	-83.3	-16.66	100.0
	Week 29	56	72.62	23.66	16.7	66.67	100.0	54	-8.64	32.50	-66.7	0.00	66.7
	Week 32	52	70.51	26.53	0.0	66.67	100.0	49	-10.88	32.73	-83.3	0.00	66.7
	Week 35	43	70.93	22.45	33.3	66.67	100.0	40	-8.75	30.66	-66.7	-16.66	66.7
	Week 38	49	67.01	25.80	0.0	66.67	100.0	47	-11.35	28.47	-66.7	-16.66	66.7
	Week 41	49	65.65	28.95	0.0	66.67	100.0	47	-13.12	32.22	-83.3	-16.66	66.7
	Week 44	44	71.97	24.05	33.3	66.67	100.0	41	-7.72	31.86	-66.7	-16.66	66.7
	Week 47	37	70.27	28.36	0.0	66.67	100.0	35	-6.67	28.07	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	29	68.97	23.87	33.3	66.67	100.0	28	-13.69	31.12	-66.7	-16.67	66.7
	Week 53	34	72.55	22.43	33.3	66.67	100.0	33	-11.11	30.81	-66.7	-16.66	66.7
	Week 56	31	73.12	23.44	33.3	66.67	100.0	30	-7.22	31.47	-66.7	-16.66	66.7
	Week 59	28	70.24	24.99	16.7	66.67	100.0	27	-9.88	36.47	-83.3	-16.66	66.7
	Week 62	28	72.62	25.75	33.3	66.67	100.0	27	-9.26	33.12	-66.7	-16.66	66.7
	Week 65	23	71.02	22.60	33.3	66.67	100.0	22	-8.33	32.83	-66.7	-16.66	66.7
	Week 68	22	70.46	23.53	33.3	66.67	100.0	22	-9.85	36.97	-66.7	-16.66	66.7
	Week 71	22	68.94	25.35	0.0	66.67	100.0	22	-9.09	33.62	-66.7	-16.66	66.7
	Week 74	22	68.18	22.95	33.3	66.67	100.0	22	-12.12	33.41	-66.7	-16.66	66.7
	Week 77	18	66.67	21.39	33.3	66.67	100.0	17	-15.68	31.44	-66.7	-16.67	66.7
	Week 80	16	62.50	24.72	0.0	66.67	100.0	15	-16.66	28.87	-66.7	-16.66	66.7
	Week 83	16	60.42	24.25	0.0	66.67	100.0	15	-17.77	29.19	-66.7	-16.66	66.7
	Week 86	13	64.10	17.80	33.3	66.67	100.0	12	-13.89	35.42	-66.7	-16.66	66.7
	Week 89	12	65.28	16.60	33.3	66.67	100.0	12	-12.50	33.43	-33.3	-33.33	66.7
	Plat+Gem (N= 89)												
	BASELINE	75	77.56	22.00	16.7	83.33	100.0						
	Week 1	61	77.05	20.45	33.3	66.67	100.0	61	-0.82	20.05	-33.3	0.00	50.0
	Week 2	66	71.97	28.37	0.0	66.67	100.0	62	-6.72	29.49	-100.0	0.00	83.3
	Week 3	76	76.75	22.95	0.0	83.33	100.0	71	-0.47	22.53	-66.7	0.00	66.7
	Week 4	73	75.57	24.55	16.7	83.33	100.0	68	-2.21	25.90	-66.7	0.00	66.7
	Week 5	71	71.13	26.72	0.0	66.67	100.0	64	-8.07	26.89	-66.7	0.00	83.3
	Week 6	70	76.19	23.32	0.0	66.67	100.0	63	-2.38	23.54	-66.7	0.00	50.0
	Week 7	72	76.39	23.53	16.7	83.33	100.0	65	-1.54	27.28	-66.7	0.00	66.7
	Week 8	63	78.57	23.46	0.0	83.33	100.0	58	-0.86	25.25	-66.7	0.00	66.7
	Week 9	68	76.72	23.06	0.0	83.33	100.0	62	-3.23	27.63	-100.0	0.00	66.7
	Week 10	67	78.11	21.16	33.3	83.33	100.0	61	0.27	25.55	-66.7	0.00	83.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	65	73.59	25.15	0.0	66.67	100.0	60	-5.00	28.01	-83.3	0.00	83.3
	Week 12	63	76.46	25.16	0.0	83.33	100.0	58	-2.01	27.59	-100.0	0.00	83.3
	Week 14	63	75.13	20.93	33.3	66.67	100.0	57	-4.09	23.21	-66.7	0.00	33.3
	Week 17	60	75.28	24.45	0.0	75.00	100.0	55	-3.94	24.21	-66.7	0.00	33.3
	Week 20	52	76.28	27.09	0.0	83.33	100.0	50	-2.67	26.16	-66.7	0.00	33.3
	Week 23	44	79.55	23.53	33.3	83.33	100.0	42	-0.40	23.42	-66.7	0.00	33.3
	Week 26	41	80.08	24.50	16.7	83.33	100.0	40	-3.33	25.37	-66.7	0.00	33.3
	Week 29	37	82.43	22.55	33.3	100.00	100.0	36	-2.32	23.62	-66.7	0.00	33.3
	Week 32	33	84.34	21.63	16.7	100.00	100.0	32	0.52	21.79	-66.7	0.00	50.0
	Week 35	30	87.78	18.01	33.3	100.00	100.0	30	3.33	13.42	-33.3	0.00	33.3
	Week 38	32	83.33	21.17	33.3	100.00	100.0	31	-0.54	26.35	-66.7	0.00	33.3
	Week 41	27	86.42	21.20	33.3	100.00	100.0	26	1.92	20.18	-66.7	0.00	33.3
	Week 44	27	83.95	20.40	33.3	100.00	100.0	26	-1.92	25.09	-66.7	0.00	33.3
	Week 47	29	85.06	18.55	33.3	100.00	100.0	28	0.60	23.34	-66.7	0.00	33.3
	Week 50	23	81.88	21.27	33.3	83.33	100.0	22	-3.03	20.34	-33.3	0.00	33.3
	Week 53	22	87.12	19.20	33.3	100.00	100.0	21	0.00	19.00	-33.3	0.00	33.3
	Week 56	18	82.41	20.98	33.3	91.67	100.0	17	-1.96	23.48	-33.3	0.00	50.0
	Week 59	17	91.18	14.57	66.7	100.00	100.0	16	4.17	24.72	-33.3	0.00	66.7
	Week 62	16	82.29	16.63	66.7	75.00	100.0	15	-1.11	23.96	-33.3	0.00	33.3
	Week 65	15	85.56	16.51	66.7	100.00	100.0	14	-4.76	23.05	-33.3	0.00	33.3
	Week 68	12	87.50	18.97	50.0	100.00	100.0	11	-3.03	19.46	-33.3	0.00	33.3
	Week 71	13	80.77	27.93	16.7	100.00	100.0	12	-8.33	33.71	-66.7	0.00	50.0
	Week 74	10	86.67	21.94	33.3	100.00	100.0	10	1.67	26.59	-33.3	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	EV+Pembro (N=198)												
	BASELINE	170	78.24	26.83	0.0	83.33	100.0						
	Week 1	157	77.71	25.22	0.0	83.33	100.0	152	-1.21	23.42	-66.7	0.00	100.0
	Week 2	167	76.85	24.94	0.0	83.33	100.0	155	-3.01	25.16	-66.7	0.00	83.3
	Week 3	161	74.85	26.56	0.0	83.33	100.0	147	-3.40	24.51	-83.3	0.00	100.0
	Week 4	158	77.64	24.58	0.0	83.33	100.0	145	-1.15	26.76	-100.0	0.00	100.0
	Week 5	154	76.95	25.08	0.0	83.33	100.0	140	-1.90	24.33	-83.3	0.00	100.0
	Week 6	153	78.43	23.09	0.0	83.33	100.0	138	0.12	24.12	-83.3	0.00	66.7
	Week 7	159	77.46	23.88	0.0	83.33	100.0	142	-1.29	26.56	-100.0	0.00	100.0
	Week 8	154	77.38	24.89	0.0	83.33	100.0	135	-1.48	27.65	-83.3	0.00	100.0
	Week 9	162	75.93	25.06	0.0	83.33	100.0	146	-2.40	26.48	-83.3	0.00	66.7
	Week 10	159	76.31	23.75	0.0	83.33	100.0	144	-1.74	27.36	-66.7	0.00	66.7
	Week 11	161	76.40	25.31	0.0	83.33	100.0	143	-1.51	28.93	-83.3	0.00	100.0
	Week 12	154	76.73	26.91	0.0	83.33	100.0	140	-2.50	28.27	-83.3	0.00	83.3
	Week 14	154	76.08	26.05	0.0	83.33	100.0	137	-2.07	27.22	-100.0	0.00	66.7
	Week 17	145	77.36	24.03	0.0	83.33	100.0	130	-1.41	26.58	-66.7	0.00	66.7
	Week 20	139	75.78	27.08	0.0	83.33	100.0	126	-5.16	29.47	-100.0	0.00	66.7
	Week 23	133	73.18	27.36	0.0	66.67	100.0	122	-7.65	30.24	-100.0	0.00	66.7
	Week 26	129	76.10	24.72	0.0	83.33	100.0	118	-3.25	30.84	-100.0	0.00	100.0
	Week 29	131	77.35	23.03	0.0	83.33	100.0	120	-3.61	29.64	-83.3	0.00	83.3
	Week 32	111	76.73	24.75	0.0	83.33	100.0	102	-3.92	28.74	-83.3	0.00	66.7
	Week 35	109	74.92	24.07	0.0	66.67	100.0	100	-6.83	28.44	-83.3	0.00	66.7
	Week 38	107	72.12	26.48	0.0	66.67	100.0	100	-8.17	27.68	-83.3	0.00	66.7
	Week 41	103	73.14	25.80	0.0	66.67	100.0	94	-7.80	27.94	-83.3	0.00	66.7
	Week 44	88	75.95	23.69	16.7	75.00	100.0	81	-6.79	29.20	-66.7	0.00	66.7
	Week 47	80	73.13	25.78	0.0	66.67	100.0	75	-8.00	32.11	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	73	73.06	23.51	33.3	66.67	100.0	68	-9.80	28.69	-66.7	0.00	66.7
	Week 53	64	76.04	23.17	0.0	66.67	100.0	59	-8.19	30.38	-100.0	0.00	66.7
	Week 56	66	73.99	24.83	0.0	66.67	100.0	61	-7.38	33.13	-100.0	0.00	66.7
	Week 59	58	74.71	21.91	0.0	66.67	100.0	54	-6.17	31.77	-100.0	0.00	66.7
	Week 62	54	76.54	25.19	0.0	83.33	100.0	52	-8.01	31.74	-100.0	0.00	66.7
	Week 65	51	76.14	23.86	0.0	83.33	100.0	47	-6.03	30.38	-83.3	0.00	66.7
	Week 68	49	78.57	20.13	33.3	66.67	100.0	48	-4.17	28.45	-66.7	0.00	66.7
	Week 71	47	76.60	23.48	0.0	66.67	100.0	45	-6.30	30.21	-66.7	0.00	66.7
	Week 74	42	75.40	24.20	0.0	66.67	100.0	41	-8.13	30.76	-100.0	0.00	66.7
	Week 77	38	70.18	27.17	0.0	66.67	100.0	36	-12.50	32.94	-83.3	-8.33	66.7
	Week 80	35	70.00	24.19	0.0	66.67	100.0	32	-9.37	30.21	-66.7	0.00	66.7
	Week 83	32	69.79	27.58	0.0	66.67	100.0	30	-7.78	33.26	-83.3	0.00	66.7
	Week 86	30	71.67	23.63	33.3	66.67	100.0	27	-6.79	33.09	-66.7	-16.66	66.7
	Week 89	28	70.24	23.29	33.3	66.67	100.0	26	-6.41	30.21	-50.0	-8.33	66.7
	Week 92	24	72.92	22.42	33.3	66.67	100.0	22	-8.33	26.10	-66.7	0.00	33.3
	Week 95	21	66.67	26.87	0.0	66.67	100.0	20	-15.83	33.97	-83.3	-16.66	33.3
	Week 98	16	75.00	20.18	33.3	66.67	100.0	15	-4.44	22.24	-50.0	0.00	33.3
	Week 101	12	76.39	22.98	33.3	66.67	100.0	12	-13.89	23.39	-50.0	-8.33	33.3
	Week 104	10	75.00	23.90	33.3	66.67	100.0	10	-11.67	27.27	-66.7	0.00	33.3
	Plat+Gem (N=185)												
	BASELINE	146	76.14	26.40	0.0	83.33	100.0						
	Week 1	131	73.79	24.29	0.0	66.67	100.0	120	-2.92	22.83	-66.7	0.00	66.7
	Week 2	128	69.53	28.69	0.0	66.67	100.0	115	-7.25	26.78	-100.0	0.00	83.3
	Week 3	141	74.11	25.39	0.0	83.33	100.0	126	-2.91	23.29	-83.3	0.00	66.7
	Week 4	139	72.78	27.30	0.0	66.67	100.0	119	-3.78	24.20	-66.7	0.00	66.7
	Week 5	143	70.63	26.83	0.0	66.67	100.0	120	-7.08	26.34	-66.7	0.00	83.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 6	133	71.81	25.39	0.0	66.67	100.0	114	-5.99	24.60	-66.7	0.00	50.0
	Week 7	142	74.18	24.60	0.0	66.67	100.0	120	-2.78	27.36	-66.7	0.00	66.7
	Week 8	125	72.40	25.14	0.0	66.67	100.0	109	-5.81	26.39	-100.0	0.00	66.7
	Week 9	135	72.72	24.57	0.0	66.67	100.0	115	-6.23	27.26	-100.0	0.00	66.7
	Week 10	131	73.16	25.03	0.0	66.67	100.0	111	-3.00	28.27	-100.0	0.00	83.3
	Week 11	128	73.70	24.45	0.0	66.67	100.0	109	-4.74	26.36	-100.0	0.00	83.3
	Week 12	124	74.46	25.45	0.0	83.33	100.0	108	-3.86	28.24	-100.0	0.00	83.3
	Week 14	121	72.04	24.55	0.0	66.67	100.0	101	-5.28	26.35	-66.7	0.00	66.7
	Week 17	121	73.55	26.06	0.0	66.67	100.0	101	-4.79	27.82	-83.3	0.00	66.7
	Week 20	98	76.19	25.66	0.0	83.33	100.0	86	-2.91	26.22	-66.7	0.00	66.7
	Week 23	93	77.60	25.83	0.0	83.33	100.0	78	-0.43	24.61	-66.7	0.00	66.7
	Week 26	86	78.30	25.32	0.0	83.33	100.0	75	-3.56	24.09	-83.3	0.00	33.3
	Week 29	76	77.19	25.51	0.0	83.33	100.0	65	-6.92	26.00	-83.3	0.00	33.3
	Week 32	62	80.65	23.80	0.0	83.33	100.0	56	-1.79	23.72	-66.7	0.00	66.7
	Week 35	58	80.46	21.43	0.0	83.33	100.0	52	-2.56	21.74	-66.7	0.00	66.7
	Week 38	60	79.17	24.28	0.0	83.33	100.0	52	-3.85	23.71	-66.7	0.00	33.3
	Week 41	52	77.24	26.20	0.0	83.33	100.0	44	-5.68	22.72	-66.7	0.00	33.3
	Week 44	46	78.99	24.95	16.7	83.33	100.0	40	-3.33	22.39	-66.7	0.00	33.3
	Week 47	44	80.68	22.72	0.0	83.33	100.0	38	-4.39	25.32	-100.0	0.00	33.3
	Week 50	42	76.19	27.09	0.0	83.33	100.0	38	-5.26	27.97	-100.0	0.00	33.3
	Week 53	38	83.33	20.13	33.3	83.33	100.0	34	-0.98	18.32	-33.3	0.00	33.3
	Week 56	32	79.17	26.77	0.0	91.67	100.0	28	-4.17	25.91	-50.0	0.00	50.0
	Week 59	31	86.02	22.40	0.0	100.00	100.0	27	1.23	23.08	-33.3	0.00	66.7
	Week 62	29	81.61	18.01	50.0	83.33	100.0	26	-4.49	23.83	-50.0	0.00	33.3
	Week 65	25	79.33	24.19	16.7	83.33	100.0	21	-6.35	23.26	-50.0	0.00	33.3
	Week 68	20	82.50	25.63	0.0	100.00	100.0	16	-5.21	17.97	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 71	17	81.37	28.19	0.0	100.00	100.0	14	-3.57	27.87	-66.7	0.00	50.0
	Week 74	17	85.29	25.61	0.0	100.00	100.0	14	2.38	20.52	-33.3	0.00	50.0
	Week 77	16	82.29	22.33	16.7	83.33	100.0	13	2.56	22.41	-33.3	0.00	50.0
	Week 80	13	88.46	17.19	50.0	100.00	100.0	12	5.56	14.80	-16.7	0.00	33.3
	Week 83	11	83.33	16.67	66.7	83.33	100.0	10	0.00	23.57	-33.3	0.00	33.3
	Week 86	12	81.95	21.86	33.3	91.67	100.0	11	-1.51	22.92	-33.3	0.00	33.3
	Week 89	11	90.91	13.67	66.7	100.00	100.0	10	10.00	19.56	-16.7	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	EV+Pembro (N= 42)												
	BASELINE	36	77.78	28.17	0.0	83.33	100.0						
	Week 1	33	72.73	27.27	0.0	66.67	100.0	32	-3.65	21.89	-50.0	0.00	33.3
	Week 2	36	73.15	22.98	0.0	66.67	100.0	34	-3.92	26.61	-66.7	0.00	66.7
	Week 3	37	70.27	24.89	0.0	66.67	100.0	35	-5.71	23.20	-50.0	0.00	66.7
	Week 4	36	75.00	23.74	0.0	66.67	100.0	34	-2.94	28.86	-66.7	0.00	66.7
	Week 5	36	72.69	24.93	16.7	66.67	100.0	33	-5.05	32.14	-66.7	0.00	66.7
	Week 6	35	75.71	23.34	33.3	83.33	100.0	32	-3.65	29.55	-66.7	0.00	66.7
	Week 7	36	77.32	17.88	33.3	66.67	100.0	34	-3.43	29.52	-66.7	0.00	66.7
	Week 8	37	77.03	20.92	16.7	66.67	100.0	36	-1.39	30.96	-50.0	0.00	66.7
	Week 9	35	75.24	23.70	0.0	66.67	100.0	34	-3.92	33.09	-66.7	0.00	66.7
	Week 10	32	81.25	19.28	33.3	83.33	100.0	31	4.30	31.32	-50.0	0.00	66.7
	Week 11	33	79.29	20.42	33.3	83.33	100.0	32	3.13	33.18	-66.7	0.00	83.3
	Week 12	32	81.25	20.63	16.7	83.33	100.0	31	3.23	26.67	-50.0	0.00	66.7
	Week 14	31	75.81	25.76	0.0	66.67	100.0	30	-3.33	29.81	-66.7	0.00	66.7
	Week 17	33	76.77	21.22	16.7	66.67	100.0	32	-1.04	31.38	-66.7	0.00	66.7
	Week 20	28	72.02	25.28	0.0	66.67	100.0	28	-6.55	31.54	-66.7	0.00	66.7
	Week 23	29	78.16	22.32	33.3	83.33	100.0	29	-2.87	28.89	-66.7	0.00	66.7
	Week 26	27	75.93	25.46	0.0	83.33	100.0	26	-2.56	29.70	-50.0	0.00	66.7
	Week 29	26	77.57	22.08	33.3	66.67	100.0	25	-2.00	32.03	-66.7	0.00	66.7
	Week 32	24	78.47	20.55	33.3	83.33	100.0	23	-7.25	31.31	-66.7	0.00	66.7
	Week 35	23	80.44	21.11	33.3	83.33	100.0	22	-3.79	31.26	-66.7	0.00	66.7
	Week 38	25	78.67	19.55	33.3	83.33	100.0	24	-6.94	30.26	-66.7	0.00	50.0
	Week 41	26	75.64	22.72	33.3	66.67	100.0	25	-6.00	35.97	-66.7	0.00	66.7
	Week 44	20	76.67	27.78	0.0	83.33	100.0	19	-5.26	35.16	-100.0	0.00	33.3
	Week 47	20	74.17	32.21	0.0	83.33	100.0	19	-5.26	33.36	-100.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	16	75.00	24.34	16.7	66.67	100.0	16	-10.41	29.74	-83.3	0.00	33.3
	Week 53	15	73.33	28.03	0.0	66.67	100.0	15	-8.89	25.09	-66.7	0.00	33.3
	Week 56	15	82.22	21.33	33.3	100.00	100.0	15	-2.22	26.63	-66.7	0.00	33.3
	Week 59	14	75.00	27.54	16.7	75.00	100.0	14	-8.33	33.17	-83.3	0.00	33.3
	Week 62	11	87.88	22.47	33.3	100.00	100.0	11	3.03	26.69	-66.7	0.00	33.3
	Plat+Gem (N= 57)												
	BASELINE	42	70.64	26.50	0.0	66.67	100.0						
	Week 1	42	70.24	26.17	0.0	66.67	100.0	38	0.00	25.70	-33.3	0.00	66.7
	Week 2	43	74.03	26.55	16.7	83.33	100.0	36	1.39	26.84	-33.3	0.00	66.7
	Week 3	43	74.42	26.56	0.0	66.67	100.0	36	1.39	26.84	-66.7	0.00	50.0
	Week 4	44	69.70	25.99	16.7	66.67	100.0	37	-5.86	26.41	-50.0	0.00	33.3
	Week 5	44	73.11	23.63	0.0	66.67	100.0	36	-0.93	24.22	-66.7	0.00	50.0
	Week 6	41	73.17	25.52	0.0	66.67	100.0	35	1.43	23.35	-66.7	0.00	50.0
	Week 7	44	71.21	23.67	16.7	66.67	100.0	37	-3.60	25.50	-83.3	0.00	33.3
	Week 8	42	69.84	27.11	0.0	66.67	100.0	35	-2.38	29.47	-66.7	0.00	66.7
	Week 9	42	70.64	25.98	0.0	66.67	100.0	35	1.90	23.14	-66.7	0.00	33.3
	Week 10	35	70.95	24.37	0.0	66.67	100.0	28	-6.55	29.16	-83.3	0.00	50.0
	Week 11	40	67.50	26.41	0.0	66.67	100.0	34	-4.90	29.17	-83.3	0.00	33.3
	Week 12	35	72.38	25.55	0.0	66.67	100.0	30	-2.22	24.26	-66.7	0.00	33.3
	Week 14	32	68.23	24.45	33.3	66.67	100.0	27	-5.56	26.95	-66.7	0.00	33.3
	Week 17	34	65.69	27.20	0.0	66.67	100.0	29	-6.90	28.35	-66.7	0.00	33.3
	Week 20	28	77.38	24.09	0.0	83.33	100.0	24	4.17	26.58	-66.7	0.00	33.3
	Week 23	22	79.54	21.78	33.3	83.33	100.0	19	2.63	29.01	-33.3	0.00	66.7
	Week 26	22	77.27	23.31	16.7	83.33	100.0	20	4.17	23.49	-50.0	0.00	50.0
	Week 29	24	84.03	19.34	33.3	91.67	100.0	21	7.94	20.15	-33.3	0.00	33.3
	Week 32	21	73.02	29.10	0.0	66.67	100.0	20	-2.50	28.24	-83.3	0.00	33.3

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 35	18	77.78	27.42	16.7	91.67	100.0	17	0.00	25.00	-66.7	0.00	33.3
	Week 38	14	72.62	26.64	16.7	66.67	100.0	13	-7.69	24.17	-50.0	0.00	33.3
	Week 41	13	83.33	16.67	66.7	83.33	100.0	12	6.95	19.41	-33.3	0.00	33.3
	Week 44	14	77.38	18.03	33.3	83.33	100.0	13	0.00	26.35	-66.7	0.00	33.3
	Week 47	12	76.39	15.00	66.7	66.67	100.0	11	1.52	21.67	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Visceral metastases	EV+Pembro (N=170)												
	BASELINE	146	75.91	28.16	0.0	83.33	100.0						
	Week 1	135	73.95	26.67	0.0	66.67	100.0	131	-2.04	23.84	-50.0	0.00	100.0
	Week 2	145	75.86	25.60	0.0	83.33	100.0	134	-1.74	25.47	-66.7	0.00	83.3
	Week 3	141	72.10	28.42	0.0	66.67	100.0	129	-3.36	25.21	-83.3	0.00	100.0
	Week 4	136	74.88	26.06	0.0	83.33	100.0	125	-1.47	28.48	-100.0	0.00	100.0
	Week 5	131	74.94	26.66	0.0	83.33	100.0	118	-0.99	26.45	-83.3	0.00	100.0
	Week 6	127	76.77	23.77	0.0	83.33	100.0	113	0.74	25.82	-83.3	0.00	66.7
	Week 7	135	76.05	24.65	0.0	83.33	100.0	121	0.28	29.26	-100.0	0.00	100.0
	Week 8	131	76.85	25.28	0.0	83.33	100.0	118	1.13	29.21	-66.7	0.00	100.0
	Week 9	136	75.61	26.21	0.0	66.67	100.0	124	-0.54	28.19	-83.3	0.00	66.7
	Week 10	135	76.30	23.96	0.0	83.33	100.0	124	0.54	29.44	-66.7	0.00	66.7
	Week 11	134	76.62	25.86	0.0	83.33	100.0	121	1.38	30.93	-66.7	0.00	100.0
	Week 12	131	78.12	25.83	0.0	83.33	100.0	120	1.67	29.02	-83.3	0.00	83.3
	Week 14	130	76.41	25.82	0.0	83.33	100.0	117	0.57	29.44	-100.0	0.00	66.7
	Week 17	124	78.76	23.41	0.0	83.33	100.0	111	2.85	27.88	-66.7	0.00	66.7
	Week 20	115	76.23	25.94	0.0	83.33	100.0	105	-2.54	30.12	-100.0	0.00	66.7
	Week 23	111	76.43	24.36	0.0	83.33	100.0	103	-1.62	29.10	-100.0	0.00	66.7
	Week 26	106	78.93	24.27	0.0	83.33	100.0	97	2.06	30.74	-66.7	0.00	100.0
	Week 29	106	80.50	22.00	0.0	83.33	100.0	98	2.04	29.82	-66.7	0.00	83.3
	Week 32	92	78.99	23.42	16.7	83.33	100.0	85	-0.20	28.58	-66.7	0.00	66.7
	Week 35	86	78.29	22.30	16.7	83.33	100.0	79	-2.74	28.80	-66.7	0.00	66.7
	Week 38	90	74.44	25.38	0.0	66.67	100.0	84	-4.56	29.76	-66.7	0.00	66.7
	Week 41	87	74.71	24.36	0.0	83.33	100.0	81	-4.32	31.38	-66.7	0.00	66.7
	Week 44	73	78.31	23.68	0.0	83.33	100.0	68	-2.70	31.62	-100.0	0.00	66.7
	Week 47	68	75.98	25.49	0.0	83.33	100.0	63	-2.38	33.31	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	61	75.68	21.85	33.3	66.67	100.0	57	-6.43	27.77	-66.7	0.00	66.7
	Week 53	54	76.24	25.20	0.0	75.00	100.0	50	-8.00	32.34	-100.0	0.00	66.7
	Week 56	58	77.30	23.30	0.0	75.00	100.0	54	-4.32	33.83	-100.0	0.00	66.7
	Week 59	50	74.67	23.87	0.0	66.67	100.0	47	-7.09	34.71	-100.0	0.00	66.7
	Week 62	45	80.74	24.09	0.0	100.00	100.0	43	-2.32	33.05	-100.0	0.00	66.7
	Week 65	37	79.28	19.41	33.3	83.33	100.0	34	-1.47	31.35	-66.7	0.00	66.7
	Week 68	35	79.53	18.56	33.3	66.67	100.0	34	-1.47	30.53	-66.7	0.00	66.7
	Week 71	31	77.96	19.90	33.3	83.33	100.0	30	0.00	32.16	-66.7	0.00	66.7
	Week 74	29	75.29	22.55	0.0	66.67	100.0	28	-4.17	34.43	-100.0	0.00	66.7
	Week 77	26	76.28	21.69	33.3	75.00	100.0	25	-3.33	32.63	-66.7	0.00	66.7
	Week 80	22	72.73	19.62	33.3	66.67	100.0	21	-3.17	35.21	-66.7	0.00	66.7
	Week 83	23	75.36	19.38	33.3	66.67	100.0	22	-1.51	35.23	-66.7	0.00	66.7
	Week 86	21	77.78	20.64	33.3	83.33	100.0	20	0.83	36.06	-66.7	0.00	66.7
	Week 89	21	74.60	17.96	33.3	66.67	100.0	20	0.00	31.06	-33.3	0.00	66.7
	Week 92	18	72.22	22.14	33.3	66.67	100.0	17	-6.86	28.30	-66.7	0.00	33.3
	Week 95	13	71.79	24.89	33.3	66.67	100.0	12	-9.72	37.91	-66.7	-8.33	33.3
	Week 98	11	77.27	17.11	50.0	66.67	100.0	11	-3.03	20.84	-33.3	0.00	33.3
	Week 101	11	77.27	18.67	50.0	66.67	100.0	11	-9.09	25.12	-33.3	-16.66	33.3
	Plat+Gem (N=161)												
	BASELINE	129	70.93	28.05	0.0	66.67	100.0						
	Week 1	113	71.09	25.00	0.0	66.67	100.0	105	0.48	22.70	-50.0	0.00	66.7
	Week 2	108	68.06	28.65	0.0	66.67	100.0	98	-2.55	25.14	-66.7	0.00	83.3
	Week 3	121	73.83	25.53	0.0	83.33	100.0	109	1.07	23.71	-66.7	0.00	66.7
	Week 4	116	71.70	26.67	0.0	66.67	100.0	101	0.00	24.15	-66.7	0.00	66.7
	Week 5	121	69.97	25.42	0.0	66.67	100.0	104	-1.92	25.47	-50.0	0.00	83.3
	Week 6	118	72.18	24.66	0.0	66.67	100.0	102	-0.82	24.53	-66.7	0.00	50.0

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 7	121	72.59	24.71	0.0	66.67	100.0	104	-0.16	28.68	-83.3	0.00	66.7
	Week 8	108	73.92	23.71	0.0	66.67	100.0	96	0.69	25.24	-50.0	0.00	66.7
	Week 9	114	73.39	23.85	0.0	66.67	100.0	99	1.18	24.43	-100.0	0.00	66.7
	Week 10	109	71.25	25.55	0.0	66.67	100.0	94	-0.36	28.92	-83.3	0.00	83.3
	Week 11	109	73.24	24.11	16.7	66.67	100.0	95	-0.88	26.23	-66.7	0.00	83.3
	Week 12	103	73.79	24.43	0.0	83.33	100.0	91	0.18	27.61	-100.0	0.00	83.3
	Week 14	98	70.41	23.88	0.0	66.67	100.0	85	-2.94	28.66	-66.7	0.00	66.7
	Week 17	103	72.01	25.16	0.0	66.67	100.0	89	-1.69	27.30	-83.3	0.00	66.7
	Week 20	82	76.63	23.40	16.7	83.33	100.0	75	2.67	26.71	-66.7	0.00	66.7
	Week 23	77	77.92	23.95	0.0	83.33	100.0	68	3.43	25.36	-50.0	0.00	66.7
	Week 26	71	78.17	22.64	16.7	83.33	100.0	65	1.79	22.46	-50.0	0.00	50.0
	Week 29	65	79.49	21.20	33.3	83.33	100.0	59	0.56	22.09	-50.0	0.00	33.3
	Week 32	52	77.89	25.29	0.0	83.33	100.0	49	0.00	25.91	-83.3	0.00	66.7
	Week 35	47	79.43	21.48	33.3	83.33	100.0	44	1.14	23.13	-66.7	0.00	66.7
	Week 38	42	76.98	22.07	33.3	83.33	100.0	39	-3.42	22.35	-33.3	0.00	33.3
	Week 41	35	79.52	21.42	33.3	83.33	100.0	32	2.08	18.33	-33.3	0.00	33.3
	Week 44	36	75.93	22.34	33.3	75.00	100.0	33	-1.52	24.43	-66.7	0.00	33.3
	Week 47	32	79.17	21.17	0.0	83.33	100.0	30	-1.67	27.46	-100.0	0.00	33.3
	Week 50	30	72.22	25.27	0.0	66.67	100.0	29	-5.17	27.85	-100.0	0.00	33.3
	Week 53	25	80.67	19.65	33.3	83.33	100.0	24	-2.08	18.59	-33.3	0.00	33.3
	Week 56	22	75.00	27.58	0.0	75.00	100.0	21	-7.94	29.64	-50.0	0.00	50.0
	Week 59	22	87.12	17.00	50.0	100.00	100.0	21	0.79	25.54	-33.3	0.00	66.7
	Week 62	19	78.07	16.71	50.0	66.67	100.0	18	-5.55	27.42	-50.0	0.00	33.3
	Week 65	19	79.83	18.90	33.3	83.33	100.0	18	-6.48	26.90	-50.0	0.00	33.3
	Week 68	13	80.77	21.35	50.0	83.33	100.0	12	-8.33	20.72	-33.3	-8.34	33.3
	Week 71	13	75.64	26.89	16.7	83.33	100.0	12	-8.33	35.18	-66.7	-8.33	50.0

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Table 302.1.3002.13.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 74	11	84.85	21.67	33.3	100.00	100.0	11	3.03	26.69	-33.3	0.00	50.0
	Week 77	10	86.67	17.21	50.0	91.67	100.0	10	8.33	21.16	-16.7	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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Table 302.1.3002.13.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Lymph node only	EV+Pembro (N= 60)												
	BASELINE	53	82.39	24.11	0.0	83.33	100.0						
	Week 1	49	83.33	21.78	33.3	100.00	100.0	47	0.35	22.11	-66.7	0.00	50.0
	Week 2	50	76.33	22.86	16.7	83.33	100.0	48	-6.25	25.87	-66.7	0.00	66.7
	Week 3	50	77.00	19.60	33.3	66.67	100.0	47	-4.96	22.77	-50.0	0.00	66.7
	Week 4	50	82.00	19.30	33.3	83.33	100.0	47	-0.71	24.32	-66.7	0.00	66.7
	Week 5	53	77.67	21.17	33.3	83.33	100.0	49	-5.44	25.77	-66.7	0.00	66.7
	Week 6	53	78.93	22.20	0.0	83.33	100.0	50	-3.00	25.35	-83.3	0.00	50.0
	Week 7	52	80.77	15.96	50.0	83.33	100.0	48	-4.51	21.12	-50.0	0.00	50.0
	Week 8	52	78.53	21.98	0.0	83.33	100.0	47	-5.32	25.56	-83.3	0.00	66.7
	Week 9	53	75.16	22.08	0.0	83.33	100.0	49	-6.80	27.83	-83.3	0.00	66.7
	Week 10	48	78.82	19.97	33.3	83.33	100.0	44	-1.89	24.96	-50.0	0.00	66.7
	Week 11	53	75.79	21.57	0.0	66.67	100.0	48	-5.55	28.00	-83.3	0.00	66.7
	Week 12	48	73.96	27.05	0.0	66.67	100.0	45	-9.63	25.50	-83.3	0.00	33.3
	Week 14	48	74.31	26.62	0.0	66.67	100.0	44	-8.33	22.30	-66.7	0.00	33.3
	Week 17	46	72.10	22.24	0.0	66.67	100.0	44	-10.23	25.47	-66.7	-16.66	66.7
	Week 20	44	70.45	30.04	0.0	66.67	100.0	42	-12.30	29.92	-83.3	0.00	33.3
	Week 23	43	69.38	28.16	0.0	66.67	100.0	41	-15.85	27.12	-83.3	0.00	33.3
	Week 26	42	71.03	23.59	0.0	66.67	100.0	40	-11.25	26.52	-100.0	0.00	33.3
	Week 29	45	70.37	24.33	0.0	66.67	100.0	42	-13.89	28.49	-83.3	0.00	33.3
	Week 32	38	72.81	26.12	0.0	66.67	100.0	36	-12.96	29.58	-83.3	0.00	33.3
	Week 35	42	71.43	26.36	0.0	66.67	100.0	40	-12.50	29.17	-83.3	-8.33	33.3
	Week 38	38	71.93	26.31	0.0	66.67	100.0	36	-12.96	22.58	-83.3	-8.33	33.3
	Week 41	37	71.17	28.50	0.0	66.67	100.0	34	-12.74	25.64	-83.3	0.00	33.3
	Week 44	31	71.51	26.60	33.3	66.67	100.0	29	-13.22	26.12	-66.7	0.00	33.3
	Week 47	28	70.24	28.46	0.0	66.67	100.0	27	-13.58	23.59	-83.3	0.00	16.7

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Table 302.1.3002.13.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	25	70.00	25.91	33.3	66.67	100.0	24	-14.58	28.37	-66.7	0.00	33.3
	Week 53	23	73.19	21.75	33.3	66.67	100.0	22	-9.09	22.84	-66.7	0.00	33.3
	Week 56	21	69.84	27.19	0.0	66.67	100.0	20	-11.66	27.62	-83.3	-8.33	33.3
	Week 59	20	75.00	21.96	50.0	75.00	100.0	19	-4.38	25.96	-50.0	0.00	50.0
	Week 62	19	72.81	27.34	33.3	66.67	100.0	19	-14.03	25.62	-66.7	0.00	33.3
	Week 65	20	65.83	29.85	0.0	66.67	100.0	19	-15.79	26.92	-83.3	-16.66	33.3
	Week 68	17	74.51	25.08	33.3	66.67	100.0	17	-8.82	26.43	-66.7	0.00	33.3
	Week 71	19	74.56	27.98	0.0	83.33	100.0	18	-11.11	24.92	-66.7	0.00	33.3
	Week 74	17	71.57	24.84	33.3	66.67	100.0	17	-14.70	24.21	-66.7	-16.66	33.3
	Week 77	17	62.75	30.35	0.0	66.67	100.0	16	-20.83	30.12	-83.3	-16.66	33.3
	Week 80	17	68.63	28.19	0.0	66.67	100.0	15	-11.11	20.57	-50.0	0.00	33.3
	Week 83	13	61.54	34.95	0.0	66.67	100.0	12	-13.89	28.28	-83.3	-8.33	33.3
	Week 86	12	65.28	25.09	33.3	66.67	100.0	10	-10.00	21.08	-33.3	-8.33	33.3
	Week 89	11	62.12	26.97	33.3	50.00	100.0	10	-13.33	24.59	-50.0	-8.33	33.3
	Plat+Gem (N= 67)												
	BASELINE	49	82.31	19.66	33.3	83.33	100.0						
	Week 1	51	75.82	24.34	0.0	83.33	100.0	45	-6.30	24.44	-66.7	0.00	66.7
	Week 2	53	74.84	27.08	0.0	83.33	100.0	44	-9.47	29.94	-100.0	0.00	66.7
	Week 3	53	73.90	27.05	0.0	66.67	100.0	44	-7.58	25.02	-83.3	0.00	33.3
	Week 4	58	71.84	28.13	0.0	66.67	100.0	47	-12.06	24.75	-66.7	0.00	33.3
	Week 5	56	73.21	28.19	0.0	66.67	100.0	44	-12.12	26.50	-66.7	0.00	33.3
	Week 6	48	71.18	28.09	0.0	66.67	100.0	40	-11.67	23.33	-66.7	0.00	33.3
	Week 7	56	73.81	23.97	33.3	66.67	100.0	46	-8.70	22.43	-66.7	0.00	33.3
	Week 8	52	67.31	30.24	0.0	66.67	100.0	42	-17.06	27.91	-100.0	0.00	33.3
	Week 9	53	69.50	27.88	0.0	66.67	100.0	42	-15.08	27.50	-100.0	0.00	33.3
	Week 10	47	75.18	25.03	0.0	66.67	100.0	36	-10.19	25.91	-100.0	0.00	33.3

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Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	51	70.92	26.84	0.0	66.67	100.0	41	-11.38	25.94	-100.0	0.00	33.3
	Week 12	47	73.05	28.77	0.0	66.67	100.0	39	-11.11	26.31	-100.0	0.00	33.3
	Week 14	47	73.05	25.90	0.0	66.67	100.0	36	-10.19	20.42	-66.7	0.00	33.3
	Week 17	45	70.37	30.13	0.0	66.67	100.0	35	-12.86	28.89	-66.7	0.00	50.0
	Week 20	38	77.19	27.51	0.0	83.33	100.0	30	-8.89	24.66	-66.7	0.00	50.0
	Week 23	32	75.00	28.40	0.0	83.33	100.0	25	-8.67	25.96	-66.7	0.00	33.3
	Week 26	30	75.56	30.87	0.0	83.33	100.0	24	-10.42	28.15	-83.3	0.00	16.7
	Week 29	28	75.00	31.59	0.0	91.67	100.0	21	-12.70	33.71	-83.3	0.00	33.3
	Week 32	26	77.56	26.64	0.0	83.33	100.0	22	-6.82	25.02	-66.7	0.00	33.3
	Week 35	23	78.26	26.80	0.0	83.33	100.0	19	-7.89	22.48	-66.7	0.00	16.7
	Week 38	26	77.57	29.42	0.0	100.00	100.0	20	-5.83	27.72	-66.7	0.00	33.3
	Week 41	24	75.69	28.65	0.0	83.33	100.0	18	-9.26	26.34	-66.7	0.00	33.3
	Week 44	18	80.56	27.56	16.7	100.00	100.0	14	-3.57	25.47	-66.7	0.00	33.3
	Week 47	18	78.70	23.44	33.3	83.33	100.0	13	-3.85	21.68	-66.7	0.00	33.3
	Week 50	16	77.08	31.55	0.0	100.00	100.0	13	-3.85	27.35	-66.7	0.00	33.3
	Week 53	15	82.22	23.96	33.3	100.00	100.0	12	5.55	19.25	-33.3	0.00	33.3
	Week 56	15	83.33	21.82	33.3	100.00	100.0	11	7.57	15.57	-16.7	0.00	33.3
	Week 59	12	80.56	30.01	0.0	100.00	100.0	9	7.41	12.11	0.0	0.00	33.3
	Week 62	10	85.00	19.95	50.0	100.00	100.0	8	6.25	12.40	0.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
EV+Pembro (N=202)												
BASELINE	160	75.94	27.84	0.0	83.33	100.0						
Week 1	141	77.42	24.57	0.0	83.33	100.0	129	-0.65	16.06	-50.0	0.00	50.0
Week 2	150	71.33	27.59	0.0	66.67	100.0	133	-4.76	21.08	-66.7	0.00	66.7
Week 3	139	73.62	25.05	0.0	83.33	100.0	122	-2.46	21.39	-50.0	0.00	66.7
Week 4	145	74.48	24.93	0.0	83.33	100.0	129	-2.07	20.52	-66.7	0.00	66.7
Week 5	137	75.18	24.93	0.0	66.67	100.0	121	-1.24	24.83	-100.0	0.00	66.7
Week 6	146	74.43	26.92	0.0	83.33	100.0	124	-2.82	26.94	-100.0	0.00	66.7
Week 7	147	76.19	24.67	0.0	83.33	100.0	124	0.00	24.42	-66.7	0.00	66.7
Week 8	147	73.92	25.88	0.0	83.33	100.0	124	-1.48	27.79	-100.0	0.00	66.7
Week 9	142	75.12	26.24	0.0	83.33	100.0	121	-1.65	27.67	-83.3	0.00	66.7
Week 10	139	75.54	26.03	0.0	83.33	100.0	118	-0.14	26.10	-100.0	0.00	66.7
Week 11	137	77.49	25.13	0.0	83.33	100.0	115	0.15	26.81	-100.0	0.00	66.7
Week 12	142	77.58	25.88	0.0	83.33	100.0	119	-0.14	27.83	-83.3	0.00	66.7
Week 14	139	79.74	24.55	0.0	83.33	100.0	116	2.87	26.40	-66.7	0.00	83.3
Week 17	132	77.65	22.26	0.0	83.33	100.0	111	0.60	26.30	-66.7	0.00	66.7
Week 20	120	80.28	20.27	33.3	83.33	100.0	103	1.29	24.77	-66.7	0.00	66.7
Week 23	117	77.21	24.13	0.0	83.33	100.0	97	-2.75	25.65	-66.7	0.00	66.7
Week 26	112	78.72	22.28	0.0	83.33	100.0	94	0.89	27.80	-66.7	0.00	66.7
Week 29	107	77.26	21.89	0.0	83.33	100.0	93	-3.76	25.20	-100.0	0.00	66.7
Week 32	102	76.80	23.94	0.0	75.00	100.0	88	-2.08	26.72	-100.0	0.00	66.7
Week 35	98	75.51	23.47	0.0	66.67	100.0	86	-4.84	29.25	-100.0	0.00	100.0
Week 38	97	75.77	22.70	0.0	66.67	100.0	86	-3.10	26.63	-100.0	0.00	66.7
Week 41	95	75.26	24.54	0.0	66.67	100.0	84	-2.78	28.56	-66.7	0.00	66.7
Week 44	86	72.48	25.66	0.0	66.67	100.0	74	-7.66	26.49	-66.7	0.00	33.3
Week 47	79	74.26	22.93	33.3	66.67	100.0	70	-3.33	24.51	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	74	71.17	23.62	0.0	66.67	100.0	64	-8.85	27.21	-100.0	0.00	66.7
Week 53	74	72.97	25.24	0.0	66.67	100.0	63	-5.03	26.88	-100.0	0.00	66.7
Week 56	72	71.30	25.82	0.0	66.67	100.0	61	-4.10	25.21	-66.7	0.00	50.0
Week 59	69	73.43	23.97	16.7	66.67	100.0	57	-3.22	26.06	-66.7	0.00	33.3
Week 62	62	74.73	22.93	0.0	66.67	100.0	52	-1.28	23.30	-50.0	0.00	33.3
Week 65	43	74.03	23.09	33.3	66.67	100.0	40	-5.00	28.04	-66.7	0.00	50.0
Week 68	46	72.10	22.79	16.7	66.67	100.0	42	-6.75	26.56	-66.7	0.00	50.0
Week 71	42	75.79	25.82	0.0	83.33	100.0	38	1.76	26.79	-66.7	0.00	66.7
Week 74	38	73.25	21.41	33.3	66.67	100.0	35	0.00	25.88	-50.0	0.00	50.0
Week 77	37	77.48	21.95	33.3	83.33	100.0	33	2.02	23.85	-50.0	0.00	50.0
Week 80	36	77.32	22.59	33.3	83.33	100.0	34	0.49	23.39	-50.0	0.00	50.0
Week 83	30	76.67	23.81	16.7	75.00	100.0	29	0.58	29.03	-50.0	0.00	50.0
Week 86	26	75.64	25.05	16.7	83.33	100.0	25	-6.00	25.86	-66.7	0.00	33.3
Week 89	20	77.50	24.35	16.7	83.33	100.0	19	-2.63	25.01	-66.7	0.00	33.3
Week 92	19	85.96	19.45	50.0	100.00	100.0	18	4.63	18.79	-33.3	0.00	33.3
Week 95	14	83.33	20.67	33.3	91.67	100.0	13	0.00	19.24	-33.3	0.00	33.3
Week 98	10	91.67	14.16	66.7	100.00	100.0	9	11.11	16.67	0.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Plat+Gem (N=202)												
BASELINE	165	78.08	25.95	0.0	83.33	100.0						
Week 1	144	76.74	27.18	0.0	83.33	100.0	139	-1.92	23.41	-100.0	0.00	66.7
Week 2	147	74.26	28.55	0.0	83.33	100.0	135	-4.94	25.76	-66.7	0.00	66.7
Week 3	149	74.05	28.17	0.0	83.33	100.0	136	-7.48	23.20	-66.7	0.00	50.0
Week 4	150	76.44	26.28	0.0	83.33	100.0	135	-3.83	23.30	-66.7	0.00	66.7
Week 5	153	73.20	27.79	0.0	83.33	100.0	138	-5.92	24.73	-66.7	0.00	50.0
Week 6	145	73.45	29.63	0.0	83.33	100.0	131	-6.36	25.86	-66.7	0.00	66.7
Week 7	148	75.45	27.25	0.0	83.33	100.0	134	-4.23	25.34	-66.7	0.00	66.7
Week 8	145	72.99	28.54	0.0	83.33	100.0	132	-5.05	26.61	-100.0	0.00	66.7
Week 9	141	73.76	27.33	0.0	83.33	100.0	125	-5.47	26.84	-100.0	0.00	66.7
Week 10	142	75.12	27.05	0.0	83.33	100.0	130	-3.97	24.80	-66.7	0.00	66.7
Week 11	126	72.62	28.16	0.0	83.33	100.0	114	-7.16	27.42	-83.3	0.00	66.7
Week 12	130	71.41	26.84	0.0	66.67	100.0	115	-6.96	27.21	-83.3	0.00	66.7
Week 14	125	74.13	26.22	0.0	83.33	100.0	109	-5.66	27.89	-66.7	0.00	66.7
Week 17	120	72.36	26.33	0.0	66.67	100.0	106	-8.96	25.63	-66.7	0.00	50.0
Week 20	104	74.36	26.78	0.0	83.33	100.0	91	-4.76	23.61	-66.7	0.00	66.7
Week 23	88	79.92	23.59	0.0	83.33	100.0	80	-2.71	22.57	-66.7	0.00	66.7
Week 26	81	77.98	25.39	0.0	83.33	100.0	75	-4.22	23.43	-66.7	0.00	66.7
Week 29	77	76.62	27.74	0.0	83.33	100.0	71	-5.87	25.84	-100.0	0.00	66.7
Week 32	63	80.16	25.37	0.0	100.00	100.0	58	-3.16	24.47	-83.3	0.00	66.7
Week 35	62	79.57	25.14	0.0	83.33	100.0	56	-2.38	23.01	-50.0	0.00	66.7
Week 38	56	82.74	26.01	0.0	100.00	100.0	50	-2.33	24.52	-100.0	0.00	50.0
Week 41	52	79.17	26.38	0.0	91.67	100.0	47	-6.38	20.72	-66.7	0.00	33.3
Week 44	49	75.51	25.71	16.7	83.33	100.0	44	-9.09	25.02	-83.3	0.00	33.3
Week 47	43	77.91	28.80	0.0	100.00	100.0	39	-7.27	25.01	-66.7	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	36	76.39	27.42	16.7	83.33	100.0	31	-8.06	28.50	-83.3	0.00	50.0
Week 53	31	76.88	29.40	0.0	100.00	100.0	28	-4.76	28.28	-66.7	0.00	50.0
Week 56	30	74.44	29.60	0.0	83.33	100.0	29	-5.17	28.56	-66.7	0.00	50.0
Week 59	23	68.12	33.30	0.0	83.33	100.0	21	-6.35	27.63	-83.3	0.00	33.3
Week 62	20	75.83	22.60	33.3	83.33	100.0	20	-0.83	27.82	-66.7	0.00	50.0
Week 65	17	76.47	25.73	33.3	83.33	100.0	16	-6.25	24.25	-66.7	0.00	33.3
Week 68	13	79.49	25.60	33.3	83.33	100.0	13	-7.69	25.11	-66.7	0.00	33.3
Week 71	13	75.64	26.89	33.3	83.33	100.0	13	-6.41	27.67	-66.7	0.00	33.3
Week 74	11	83.33	23.57	33.3	100.00	100.0	11	-3.03	17.98	-33.3	0.00	33.3
Week 77	11	78.79	29.90	0.0	83.33	100.0	11	-9.09	28.25	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Present	EV+Pembro (N= 50)												
	BASELINE	40	77.92	28.09	16.7	100.00	100.0						
	Week 1	38	74.12	24.41	0.0	83.33	100.0	34	-4.41	14.97	-33.3	0.00	16.7
	Week 2	35	68.10	30.62	0.0	66.67	100.0	32	-6.77	16.32	-33.3	0.00	33.3
	Week 3	32	75.00	26.77	0.0	83.33	100.0	30	-3.89	19.42	-33.3	0.00	50.0
	Week 4	35	71.43	29.03	0.0	83.33	100.0	31	-3.76	17.06	-33.3	0.00	33.3
	Week 5	32	71.35	26.85	0.0	66.67	100.0	28	-5.95	23.66	-50.0	0.00	33.3
	Week 6	35	68.57	26.74	0.0	66.67	100.0	30	-7.22	27.57	-66.7	0.00	50.0
	Week 7	35	76.67	24.32	16.7	83.33	100.0	29	1.72	14.33	-16.7	0.00	33.3
	Week 8	38	68.42	27.89	0.0	66.67	100.0	31	-9.14	28.49	-100.0	0.00	33.3
	Week 9	33	72.22	27.85	0.0	83.33	100.0	29	-5.75	21.49	-66.7	0.00	50.0
	Week 10	30	75.56	27.24	0.0	83.33	100.0	25	5.33	23.92	-33.3	0.00	66.7
	Week 11	31	77.42	30.29	0.0	83.33	100.0	27	2.47	28.76	-100.0	0.00	66.7
	Week 12	32	75.52	33.33	0.0	100.00	100.0	28	-0.59	28.14	-83.3	0.00	66.7
	Week 14	36	79.17	28.28	0.0	100.00	100.0	31	4.30	19.23	-16.7	0.00	66.7
	Week 17	33	75.25	28.60	0.0	83.33	100.0	27	0.00	30.31	-66.7	0.00	66.7
	Week 20	28	80.36	23.59	33.3	83.33	100.0	25	0.00	25.46	-66.7	0.00	66.7
	Week 23	28	72.02	32.41	0.0	75.00	100.0	24	-8.33	27.37	-66.7	0.00	66.7
	Week 26	28	77.38	27.67	0.0	83.33	100.0	24	-2.78	26.32	-66.7	0.00	66.7
	Week 29	27	75.31	28.26	0.0	83.33	100.0	25	-4.67	27.86	-100.0	0.00	50.0
	Week 32	25	76.67	26.79	0.0	83.33	100.0	23	-5.07	31.16	-100.0	0.00	50.0
	Week 35	26	71.80	25.28	0.0	66.67	100.0	24	-10.42	31.01	-100.0	-8.34	33.3
	Week 38	26	71.80	30.47	0.0	75.00	100.0	24	-10.42	32.16	-100.0	0.00	33.3
	Week 41	25	76.67	25.00	33.3	83.33	100.0	23	-6.52	28.31	-66.7	0.00	50.0
	Week 44	22	75.00	28.05	0.0	66.67	100.0	20	-6.67	27.25	-66.7	0.00	33.3
	Week 47	14	73.81	23.31	33.3	66.67	100.0	13	-2.56	20.24	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	67.50	29.36	0.0	66.67	100.0	17	-15.69	29.15	-100.0	-16.67	33.3
	Week 53	21	68.25	29.77	0.0	66.67	100.0	18	-12.04	27.89	-100.0	0.00	33.3
	Week 56	18	67.59	29.41	0.0	66.67	100.0	15	-8.89	21.70	-33.3	-16.67	33.3
	Week 59	18	67.59	26.49	16.7	66.67	100.0	15	-12.22	25.56	-50.0	-16.67	33.3
	Week 62	13	71.80	21.93	33.3	66.67	100.0	11	-6.06	26.11	-33.3	0.00	33.3
	Week 68	12	70.83	20.26	16.7	66.67	100.0	11	-12.12	22.47	-33.3	-16.67	33.3
	Plat+Gem (N= 50)												
	BASELINE	40	71.67	25.93	0.0	66.67	100.0						
	Week 1	35	70.95	27.81	0.0	66.67	100.0	33	-3.03	22.23	-50.0	0.00	50.0
	Week 2	33	68.69	32.21	0.0	83.33	100.0	30	-8.33	20.88	-66.7	0.00	16.7
	Week 3	33	69.19	29.20	0.0	66.67	100.0	29	-8.05	22.98	-66.7	0.00	33.3
	Week 4	36	71.76	28.12	16.7	66.67	100.0	32	-0.52	21.79	-50.0	0.00	50.0
	Week 5	36	68.52	31.57	0.0	66.67	100.0	32	-3.65	28.00	-66.7	0.00	50.0
	Week 6	32	67.19	32.65	0.0	66.67	100.0	29	-6.90	26.92	-66.7	0.00	33.3
	Week 7	35	64.29	32.12	0.0	66.67	100.0	31	-8.07	23.12	-66.7	0.00	33.3
	Week 8	35	67.14	30.65	0.0	66.67	100.0	31	-5.38	27.01	-66.7	0.00	50.0
	Week 9	34	68.63	28.65	0.0	66.67	100.0	30	-2.78	27.71	-50.0	0.00	50.0
	Week 10	33	66.67	31.18	0.0	66.67	100.0	30	-3.89	27.57	-66.7	0.00	33.3
	Week 11	30	65.56	29.66	0.0	66.67	100.0	26	-10.26	29.09	-83.3	0.00	33.3
	Week 12	32	67.19	30.37	0.0	66.67	100.0	27	-3.70	24.60	-50.0	0.00	50.0
	Week 14	27	70.99	31.21	16.7	83.33	100.0	22	-2.27	33.84	-66.7	0.00	50.0
	Week 17	28	68.45	25.80	0.0	66.67	100.0	23	-5.80	24.93	-66.7	0.00	50.0
	Week 20	20	70.00	34.88	0.0	83.33	100.0	16	5.21	16.91	-33.3	0.00	33.3
	Week 23	15	75.56	30.12	0.0	83.33	100.0	14	0.00	16.01	-33.3	0.00	16.7
	Week 26	15	75.56	27.36	33.3	83.33	100.0	14	-4.76	20.07	-33.3	0.00	33.3
	Week 29	13	75.64	30.13	0.0	83.33	100.0	12	-9.72	31.35	-100.0	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Absent	EV+Pembro (N=152)												
	BASELINE	120	75.28	27.84	0.0	83.33	100.0						
	Week 1	103	78.64	24.63	0.0	83.33	100.0	95	0.70	16.29	-50.0	0.00	50.0
	Week 2	115	72.32	26.66	0.0	66.67	100.0	101	-4.13	22.41	-66.7	0.00	66.7
	Week 3	107	73.21	24.63	16.7	66.67	100.0	92	-1.99	22.08	-50.0	0.00	66.7
	Week 4	110	75.45	23.54	16.7	83.33	100.0	98	-1.53	21.55	-66.7	0.00	66.7
	Week 5	105	76.35	24.33	0.0	83.33	100.0	93	0.18	25.12	-100.0	0.00	66.7
	Week 6	111	76.28	26.83	0.0	83.33	100.0	94	-1.42	26.74	-100.0	0.00	66.7
	Week 7	112	76.04	24.89	0.0	83.33	100.0	95	-0.53	26.79	-66.7	0.00	66.7
	Week 8	109	75.84	25.00	0.0	83.33	100.0	93	1.08	27.23	-66.7	0.00	66.7
	Week 9	109	75.99	25.80	0.0	83.33	100.0	92	-0.36	29.34	-83.3	0.00	66.7
	Week 10	109	75.54	25.82	0.0	83.33	100.0	93	-1.61	26.59	-100.0	0.00	66.7
	Week 11	106	77.52	23.57	0.0	83.33	100.0	88	-0.57	26.32	-66.7	0.00	66.7
	Week 12	110	78.18	23.43	0.0	83.33	100.0	91	0.00	27.89	-66.7	0.00	66.7
	Week 14	103	79.94	23.26	0.0	83.33	100.0	85	2.35	28.66	-66.7	0.00	83.3
	Week 17	99	78.45	19.81	33.3	83.33	100.0	84	0.79	25.07	-66.7	0.00	66.7
	Week 20	92	80.25	19.29	33.3	83.33	100.0	78	1.71	24.70	-33.3	0.00	66.7
	Week 23	89	78.84	20.84	33.3	83.33	100.0	73	-0.91	24.98	-66.7	0.00	66.7
	Week 26	84	79.17	20.35	33.3	83.33	100.0	70	2.14	28.36	-66.7	0.00	66.7
	Week 29	80	77.92	19.45	33.3	75.00	100.0	68	-3.43	24.36	-66.7	0.00	66.7
	Week 32	77	76.84	23.12	16.7	66.67	100.0	65	-1.02	25.15	-83.3	0.00	66.7
	Week 35	72	76.85	22.82	0.0	66.67	100.0	62	-2.69	28.50	-83.3	0.00	100.0
	Week 38	71	77.23	19.16	33.3	66.67	100.0	62	-0.27	23.86	-66.7	0.00	66.7
	Week 41	70	74.76	24.53	0.0	66.67	100.0	61	-1.37	28.75	-66.7	0.00	66.7
	Week 44	64	71.61	24.97	0.0	66.67	100.0	54	-8.02	26.45	-66.7	0.00	33.3
	Week 47	65	74.36	23.03	33.3	66.67	100.0	57	-3.51	25.54	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	54	72.53	21.27	33.3	66.67	100.0	47	-6.38	26.37	-66.7	0.00	66.7
	Week 53	53	74.84	23.26	33.3	66.67	100.0	45	-2.22	26.26	-66.7	0.00	66.7
	Week 56	54	72.53	24.69	33.3	66.67	100.0	46	-2.54	26.29	-66.7	0.00	50.0
	Week 59	51	75.49	22.94	33.3	66.67	100.0	42	0.00	25.77	-66.7	0.00	33.3
	Week 62	49	75.51	23.35	0.0	83.33	100.0	41	0.00	22.67	-50.0	0.00	33.3
	Week 65	36	71.30	23.78	33.3	66.67	100.0	33	-6.56	27.93	-66.7	0.00	33.3
	Week 68	34	72.55	23.88	16.7	66.67	100.0	31	-4.84	27.95	-66.7	0.00	50.0
	Week 71	33	77.27	23.13	16.7	83.33	100.0	30	2.22	27.59	-66.7	0.00	66.7
	Week 74	33	73.74	20.43	33.3	66.67	100.0	30	-0.55	24.95	-50.0	0.00	50.0
	Week 77	31	77.42	21.75	33.3	83.33	100.0	27	1.23	23.54	-50.0	0.00	33.3
	Week 80	31	77.42	22.17	33.3	83.33	100.0	29	0.00	22.71	-50.0	0.00	33.3
	Week 83	25	75.33	24.11	16.7	66.67	100.0	24	0.00	28.66	-50.0	0.00	50.0
	Week 86	23	76.09	24.53	16.7	83.33	100.0	22	-4.55	23.67	-66.7	0.00	33.3
	Week 89	18	76.85	25.01	16.7	83.33	100.0	17	-2.94	26.51	-66.7	0.00	33.3
	Week 92	16	85.42	20.97	50.0	100.00	100.0	15	5.56	19.58	-33.3	0.00	33.3
	Week 95	12	81.95	21.86	33.3	91.67	100.0	11	-1.51	20.35	-33.3	0.00	33.3
	Plat+Gem (N=152)												
	BASELINE	125	80.13	25.72	0.0	100.00	100.0						
	Week 1	109	78.59	26.84	0.0	100.00	100.0	106	-1.57	23.85	-100.0	0.00	66.7
	Week 2	114	75.88	27.34	0.0	83.33	100.0	105	-3.97	27.01	-66.7	0.00	66.7
	Week 3	116	75.43	27.84	0.0	83.33	100.0	107	-7.32	23.37	-66.7	0.00	50.0
	Week 4	114	77.92	25.62	0.0	83.33	100.0	103	-4.85	23.76	-66.7	0.00	66.7
	Week 5	117	74.64	26.50	0.0	83.33	100.0	106	-6.60	23.76	-66.7	0.00	50.0
	Week 6	113	75.22	28.62	0.0	83.33	100.0	102	-6.21	25.68	-66.7	0.00	66.7
	Week 7	113	78.91	24.70	0.0	83.33	100.0	103	-3.07	25.96	-66.7	0.00	66.7
	Week 8	110	74.85	27.72	0.0	83.33	100.0	101	-4.95	26.62	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	107	75.39	26.83	0.0	83.33	100.0	95	-6.32	26.65	-100.0	0.00	66.7
	Week 10	109	77.68	25.28	0.0	83.33	100.0	100	-4.00	24.06	-66.7	0.00	66.7
	Week 11	96	74.83	27.47	0.0	83.33	100.0	88	-6.25	27.02	-83.3	0.00	66.7
	Week 12	98	72.79	25.60	0.0	66.67	100.0	88	-7.95	28.02	-83.3	0.00	66.7
	Week 14	98	75.00	24.78	0.0	83.33	100.0	87	-6.51	26.33	-66.7	0.00	66.7
	Week 17	92	73.55	26.51	0.0	83.33	100.0	83	-9.84	25.90	-66.7	0.00	50.0
	Week 20	84	75.40	24.61	16.7	83.33	100.0	75	-6.89	24.37	-66.7	0.00	66.7
	Week 23	73	80.82	22.17	33.3	83.33	100.0	66	-3.28	23.79	-66.7	0.00	66.7
	Week 26	66	78.54	25.11	0.0	83.33	100.0	61	-4.10	24.28	-66.7	0.00	66.7
	Week 29	64	76.82	27.48	0.0	83.33	100.0	59	-5.08	24.81	-66.7	0.00	66.7
	Week 32	54	79.63	25.83	0.0	91.67	100.0	49	-3.40	25.90	-83.3	0.00	66.7
	Week 35	54	79.94	24.95	0.0	83.33	100.0	48	-1.74	23.38	-50.0	0.00	66.7
	Week 38	47	83.69	24.45	0.0	100.00	100.0	42	-0.40	19.99	-33.3	0.00	50.0
	Week 41	45	78.89	26.69	0.0	83.33	100.0	40	-7.50	21.33	-66.7	0.00	33.3
	Week 44	41	73.98	26.89	16.7	83.33	100.0	36	-11.11	25.20	-83.3	-8.33	33.3
	Week 47	35	77.14	30.27	0.0	100.00	100.0	31	-8.60	25.77	-66.7	0.00	50.0
	Week 50	29	75.86	27.67	16.7	83.33	100.0	24	-9.72	30.26	-83.3	0.00	50.0
	Week 53	25	78.00	29.16	0.0	100.00	100.0	22	-4.55	26.32	-66.7	0.00	50.0
	Week 56	26	75.00	29.53	0.0	83.33	100.0	25	-4.00	27.34	-66.7	0.00	50.0
	Week 59	20	67.50	33.97	0.0	83.33	100.0	18	-4.63	25.44	-83.3	0.00	33.3
	Week 62	17	75.49	22.91	33.3	83.33	100.0	17	0.98	27.30	-66.7	0.00	50.0
	Week 65	15	73.33	25.82	33.3	83.33	100.0	14	-9.53	24.21	-66.7	0.00	33.3
	Week 68	11	75.76	26.21	33.3	83.33	100.0	11	-12.12	24.82	-66.7	-16.67	33.3
	Week 71	12	73.61	27.02	33.3	75.00	100.0	12	-8.33	27.98	-66.7	0.00	33.3
	Week 74	10	81.67	24.15	33.3	91.67	100.0	10	-5.00	17.66	-33.3	0.00	33.3
	Week 77	10	76.67	30.63	0.0	83.33	100.0	10	-11.67	28.38	-66.7	-8.34	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
< 65 years	EV+Pembro (N= 39)												
	BASELINE	32	67.19	31.25	0.0	66.67	100.0						
	Week 1	27	76.54	27.83	0.0	83.33	100.0	26	5.13	18.72	-16.7	0.00	50.0
	Week 2	30	74.45	20.87	0.0	66.67	100.0	29	4.60	20.36	-33.3	0.00	50.0
	Week 3	31	76.88	20.04	33.3	83.33	100.0	29	5.75	23.26	-33.3	0.00	50.0
	Week 4	30	76.11	23.85	16.7	83.33	100.0	27	4.94	22.56	-33.3	0.00	50.0
	Week 5	28	78.57	21.21	33.3	75.00	100.0	26	7.05	21.69	-33.3	0.00	50.0
	Week 6	29	79.89	19.61	33.3	83.33	100.0	26	7.05	23.18	-33.3	0.00	66.7
	Week 7	30	79.44	20.85	33.3	83.33	100.0	26	8.97	23.68	-33.3	0.00	66.7
	Week 8	30	80.56	20.57	33.3	83.33	100.0	26	10.26	27.92	-33.3	0.00	66.7
	Week 9	28	80.36	17.00	50.0	83.33	100.0	27	9.88	25.00	-33.3	0.00	66.7
	Week 10	26	76.92	27.92	0.0	91.67	100.0	23	7.25	26.98	-50.0	0.00	66.7
	Week 11	28	79.76	23.29	16.7	83.33	100.0	25	9.33	26.39	-33.3	0.00	66.7
	Week 12	28	85.12	16.57	50.0	83.33	100.0	25	11.33	26.67	-33.3	0.00	66.7
	Week 14	26	83.33	18.26	50.0	83.33	100.0	23	15.22	29.69	-33.3	0.00	83.3
	Week 17	28	79.76	17.78	33.3	83.33	100.0	24	11.11	27.66	-33.3	0.00	66.7
	Week 20	27	80.86	18.89	33.3	83.33	100.0	24	10.42	29.00	-33.3	0.00	66.7
	Week 23	26	82.05	18.81	33.3	83.33	100.0	23	7.97	24.55	-33.3	0.00	66.7
	Week 26	24	84.72	16.96	50.0	91.67	100.0	22	10.61	28.43	-33.3	0.00	66.7
	Week 29	25	79.33	17.53	50.0	66.67	100.0	23	2.90	24.95	-33.3	0.00	66.7
	Week 32	25	76.00	19.88	33.3	66.67	100.0	23	3.62	24.60	-33.3	0.00	66.7
	Week 35	24	78.47	15.91	50.0	66.67	100.0	22	6.82	32.39	-33.3	0.00	100.0
	Week 38	23	76.09	17.28	33.3	66.67	100.0	22	0.00	19.92	-33.3	0.00	33.3
	Week 41	25	74.00	24.57	0.0	66.67	100.0	23	2.90	32.43	-66.7	0.00	66.7
	Week 44	22	73.49	20.35	33.3	66.67	100.0	20	-1.67	23.51	-50.0	0.00	33.3
	Week 47	20	77.50	21.81	33.3	66.67	100.0	18	2.78	22.32	-50.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	19	79.83	18.90	33.3	83.33	100.0	17	1.96	22.73	-50.0	0.00	33.3
	Week 53	20	75.00	19.87	33.3	66.67	100.0	18	-0.92	20.19	-33.3	0.00	33.3
	Week 56	17	77.45	26.31	0.0	83.33	100.0	15	5.56	24.12	-33.3	0.00	33.3
	Week 59	17	71.57	24.13	16.7	66.67	100.0	15	3.33	24.56	-33.3	0.00	33.3
	Week 62	15	78.89	14.73	66.7	66.67	100.0	14	9.53	20.38	-33.3	8.33	33.3
	Week 65	14	79.76	19.80	50.0	75.00	100.0	13	5.13	23.95	-33.3	0.00	33.3
	Week 68	11	80.30	14.56	66.7	83.33	100.0	10	3.33	25.82	-33.3	0.00	33.3
	Week 71	13	80.77	21.35	33.3	83.33	100.0	12	9.72	22.98	-33.3	0.00	33.3
	Week 74	14	71.43	21.11	33.3	66.67	100.0	13	3.85	29.78	-50.0	0.00	50.0
	Week 77	14	76.19	22.37	33.3	83.33	100.0	13	2.56	21.35	-33.3	0.00	33.3
	Week 80	14	76.19	25.08	33.3	75.00	100.0	13	-1.28	19.79	-33.3	0.00	33.3
	Week 83	12	75.00	21.90	33.3	66.67	100.0	11	1.52	26.31	-33.3	0.00	33.3
	Plat+Gem (N= 29)												
	BASELINE	22	78.03	29.72	0.0	100.00	100.0						
	Week 1	21	80.95	24.88	0.0	83.33	100.0	20	3.33	19.19	-33.3	0.00	50.0
	Week 2	24	74.31	27.79	0.0	75.00	100.0	20	0.00	28.10	-66.7	0.00	66.7
	Week 3	23	79.71	26.57	16.7	100.00	100.0	20	0.83	14.78	-33.3	0.00	33.3
	Week 4	23	80.44	19.88	33.3	83.33	100.0	19	0.00	17.57	-33.3	0.00	33.3
	Week 5	25	69.33	27.08	0.0	66.67	100.0	20	-2.50	23.12	-50.0	0.00	50.0
	Week 6	22	73.49	25.54	16.7	66.67	100.0	18	-4.63	18.79	-50.0	0.00	16.7
	Week 7	24	77.08	26.38	16.7	83.33	100.0	21	-2.38	24.88	-50.0	0.00	50.0
	Week 8	21	76.98	31.83	0.0	83.33	100.0	19	0.88	32.62	-100.0	0.00	50.0
	Week 9	20	77.50	26.09	0.0	83.33	100.0	17	0.00	28.26	-33.3	0.00	50.0
	Week 10	21	74.60	30.56	0.0	83.33	100.0	18	-4.63	22.73	-33.3	0.00	50.0
	Week 11	20	77.50	28.24	16.7	83.33	100.0	17	0.98	23.91	-50.0	0.00	50.0
	Week 12	21	73.81	21.45	33.3	66.67	100.0	17	-2.94	25.84	-50.0	0.00	50.0

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 14	22	73.49	26.05	33.3	66.67	100.0	18	-2.78	33.46	-66.7	0.00	50.0
	Week 17	20	75.00	28.87	0.0	83.33	100.0	17	-3.92	31.47	-50.0	0.00	50.0
	Week 20	18	67.59	24.57	16.7	66.67	100.0	15	-5.55	29.99	-50.0	0.00	50.0
	Week 23	18	81.48	21.30	33.3	91.67	100.0	16	0.00	20.18	-50.0	0.00	50.0
	Week 26	16	81.25	25.73	16.7	100.00	100.0	14	-1.19	21.15	-50.0	0.00	50.0
	Week 29	15	78.89	29.19	0.0	100.00	100.0	13	-1.28	22.01	-50.0	0.00	50.0
	Week 32	15	75.56	30.77	16.7	100.00	100.0	13	-6.41	30.08	-83.3	0.00	50.0
	Week 35	15	75.56	28.78	0.0	83.33	100.0	13	-5.13	24.89	-33.3	0.00	50.0
	Week 38	14	71.43	35.46	0.0	83.33	100.0	12	-9.72	35.15	-100.0	0.00	50.0
	Week 41	11	63.64	34.01	0.0	66.67	100.0	9	-24.07	23.73	-66.7	-16.67	0.0
	Week 44	11	71.21	26.97	16.7	66.67	100.0	9	-18.52	21.16	-66.7	-16.66	0.0
	Week 47	11	69.70	35.60	0.0	83.33	100.0	9	-12.96	34.13	-66.7	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>= 65 years	EV+Pembro (N=163)												
	BASELINE	128	78.12	26.60	0.0	83.33	100.0						
	Week 1	114	77.63	23.86	0.0	83.33	100.0	103	-2.10	15.07	-50.0	0.00	33.3
	Week 2	120	70.56	29.05	0.0	66.67	100.0	104	-7.37	20.62	-66.7	0.00	66.7
	Week 3	108	72.69	26.32	0.0	66.67	100.0	93	-5.02	20.23	-50.0	0.00	66.7
	Week 4	115	74.06	25.29	0.0	83.33	100.0	102	-3.92	19.65	-66.7	0.00	66.7
	Week 5	109	74.31	25.81	0.0	66.67	100.0	95	-3.51	25.25	-100.0	0.00	66.7
	Week 6	117	73.08	28.35	0.0	66.67	100.0	98	-5.44	27.37	-100.0	0.00	66.7
	Week 7	117	75.36	25.58	0.0	83.33	100.0	98	-2.38	24.17	-66.7	0.00	66.7
	Week 8	117	72.22	26.89	0.0	66.67	100.0	98	-4.59	27.05	-100.0	0.00	66.7
	Week 9	114	73.83	27.96	0.0	83.33	100.0	94	-4.96	27.63	-83.3	0.00	66.7
	Week 10	113	75.22	25.70	0.0	83.33	100.0	95	-1.93	25.71	-100.0	0.00	66.7
	Week 11	109	76.91	25.65	0.0	83.33	100.0	90	-2.41	26.51	-100.0	0.00	66.7
	Week 12	114	75.73	27.44	0.0	83.33	100.0	94	-3.19	27.47	-83.3	0.00	66.7
	Week 14	113	78.91	25.78	0.0	83.33	100.0	93	-0.18	24.76	-66.7	0.00	66.7
	Week 17	104	77.08	23.36	0.0	83.33	100.0	87	-2.30	25.31	-66.7	0.00	66.7
	Week 20	93	80.11	20.74	33.3	83.33	100.0	79	-1.48	22.83	-66.7	0.00	66.7
	Week 23	91	75.82	25.37	0.0	83.33	100.0	74	-6.08	25.22	-66.7	0.00	66.7
	Week 26	88	77.08	23.34	0.0	83.33	100.0	72	-2.08	27.11	-66.7	0.00	66.7
	Week 29	82	76.63	23.11	0.0	83.33	100.0	70	-5.95	25.07	-100.0	0.00	50.0
	Week 32	77	77.06	25.22	0.0	83.33	100.0	65	-4.10	27.33	-100.0	0.00	50.0
	Week 35	74	74.55	25.47	0.0	66.67	100.0	64	-8.85	27.21	-100.0	0.00	50.0
	Week 38	74	75.68	24.24	0.0	83.33	100.0	64	-4.17	28.64	-100.0	0.00	66.7
	Week 41	70	75.71	24.69	0.0	75.00	100.0	61	-4.92	26.93	-66.7	0.00	66.7
	Week 44	64	72.14	27.39	0.0	66.67	100.0	54	-9.88	27.38	-66.7	0.00	33.3
	Week 47	59	73.16	23.37	33.3	66.67	100.0	52	-5.45	25.08	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	55	68.18	24.49	0.0	66.67	100.0	47	-12.77	27.85	-100.0	-16.66	66.7
	Week 53	54	72.22	27.09	0.0	66.67	100.0	45	-6.67	29.17	-100.0	0.00	66.7
	Week 56	55	69.39	25.61	33.3	66.67	100.0	46	-7.25	25.01	-66.7	-8.33	50.0
	Week 59	52	74.04	24.12	33.3	66.67	100.0	42	-5.56	26.46	-66.7	0.00	33.3
	Week 62	47	73.40	24.98	0.0	66.67	100.0	38	-5.26	23.28	-50.0	0.00	33.3
	Week 65	29	71.26	24.36	33.3	66.67	100.0	27	-9.88	28.96	-66.7	-16.66	50.0
	Week 68	35	69.52	24.42	16.7	66.67	100.0	32	-9.90	26.39	-66.7	-8.33	50.0
	Week 71	29	73.56	27.64	0.0	83.33	100.0	26	-1.92	28.02	-66.7	0.00	66.7
	Week 74	24	74.31	21.97	33.3	66.67	100.0	22	-2.27	23.74	-50.0	0.00	33.3
	Week 77	23	78.26	22.15	33.3	83.33	100.0	20	1.67	25.88	-50.0	0.00	50.0
	Week 80	22	78.03	21.45	33.3	83.33	100.0	21	1.59	25.77	-50.0	0.00	50.0
	Week 83	18	77.78	25.56	16.7	83.33	100.0	18	0.00	31.31	-50.0	0.00	50.0
	Week 86	18	73.15	27.50	16.7	83.33	100.0	18	-10.19	26.90	-66.7	0.00	33.3
	Week 89	12	79.17	24.74	16.7	83.33	100.0	12	-1.39	26.07	-66.7	0.00	33.3
	Week 92	10	91.67	18.00	50.0	100.00	100.0	10	6.67	17.92	-33.3	8.34	33.3
	Plat+Gem (N=173)												
	BASELINE	143	78.09	25.44	0.0	83.33	100.0						
	Week 1	123	76.02	27.59	0.0	83.33	100.0	119	-2.80	24.00	-100.0	0.00	66.7
	Week 2	123	74.25	28.81	0.0	83.33	100.0	115	-5.80	25.37	-66.7	0.00	66.7
	Week 3	126	73.02	28.43	0.0	83.33	100.0	116	-8.91	24.12	-66.7	0.00	50.0
	Week 4	127	75.72	27.28	0.0	83.33	100.0	116	-4.45	24.11	-66.7	0.00	66.7
	Week 5	128	73.96	27.96	0.0	83.33	100.0	118	-6.50	25.04	-66.7	0.00	50.0
	Week 6	123	73.44	30.39	0.0	83.33	100.0	113	-6.64	26.87	-66.7	0.00	66.7
	Week 7	124	75.13	27.51	0.0	83.33	100.0	113	-4.57	25.52	-66.7	0.00	66.7
	Week 8	124	72.31	28.02	0.0	83.33	100.0	113	-6.05	25.50	-100.0	0.00	66.7
	Week 9	121	73.14	27.59	0.0	66.67	100.0	108	-6.33	26.64	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	121	75.21	26.54	0.0	83.33	100.0	112	-3.87	25.21	-66.7	0.00	66.7
	Week 11	106	71.70	28.19	0.0	66.67	100.0	97	-8.59	27.86	-83.3	0.00	66.7
	Week 12	109	70.95	27.82	0.0	66.67	100.0	98	-7.65	27.51	-83.3	0.00	66.7
	Week 14	103	74.27	26.38	0.0	83.33	100.0	91	-6.23	26.83	-66.7	0.00	66.7
	Week 17	100	71.83	25.92	0.0	66.67	100.0	89	-9.92	24.45	-66.7	0.00	50.0
	Week 20	86	75.77	27.14	0.0	83.33	100.0	76	-4.61	22.38	-66.7	0.00	66.7
	Week 23	70	79.52	24.27	0.0	83.33	100.0	64	-3.39	23.23	-66.7	0.00	66.7
	Week 26	65	77.18	25.44	0.0	83.33	100.0	61	-4.92	24.03	-66.7	0.00	66.7
	Week 29	62	76.08	27.60	0.0	83.33	100.0	58	-6.90	26.68	-100.0	0.00	66.7
	Week 32	48	81.60	23.63	0.0	91.67	100.0	45	-2.22	22.92	-50.0	0.00	66.7
	Week 35	47	80.85	24.07	0.0	83.33	100.0	43	-1.55	22.66	-50.0	0.00	66.7
	Week 38	42	86.51	21.22	33.3	100.00	100.0	38	0.00	20.13	-50.0	0.00	50.0
	Week 41	41	83.33	22.67	33.3	100.00	100.0	38	-2.19	17.83	-33.3	0.00	33.3
	Week 44	38	76.76	25.57	16.7	83.33	100.0	35	-6.67	25.63	-83.3	0.00	33.3
	Week 47	32	80.73	26.13	0.0	100.00	100.0	30	-5.56	22.03	-66.7	0.00	33.3
	Week 50	29	81.61	23.29	33.3	100.00	100.0	26	-5.13	22.49	-66.7	0.00	33.3
	Week 53	25	80.00	25.46	33.3	100.00	100.0	24	-5.56	26.77	-66.7	0.00	33.3
	Week 56	26	76.92	25.85	33.3	83.33	100.0	26	-5.77	26.64	-66.7	0.00	33.3
	Week 59	20	73.33	30.78	16.7	83.33	100.0	20	-7.50	27.82	-83.3	0.00	33.3
	Week 62	19	75.44	23.15	33.3	83.33	100.0	19	-2.63	27.37	-66.7	0.00	50.0
	Week 65	16	79.17	23.96	33.3	83.33	100.0	16	-6.25	24.25	-66.7	0.00	33.3
	Week 68	13	79.49	25.60	33.3	83.33	100.0	13	-7.69	25.11	-66.7	0.00	33.3
	Week 71	13	75.64	26.89	33.3	83.33	100.0	13	-6.41	27.67	-66.7	0.00	33.3
	Week 74	11	83.33	23.57	33.3	100.00	100.0	11	-3.03	17.98	-33.3	0.00	33.3
	Week 77	10	80.00	31.23	0.0	91.67	100.0	10	-11.67	28.38	-66.7	-8.34	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Europe	EV+Pembro (N= 74)												
	BASELINE	53	79.87	27.61	0.0	100.00	100.0						
	Week 1	48	80.56	23.90	0.0	83.33	100.0	42	-0.79	14.23	-33.3	0.00	33.3
	Week 2	53	73.90	28.21	0.0	83.33	100.0	44	-7.58	20.48	-66.7	0.00	33.3
	Week 3	50	74.33	22.39	33.3	83.33	100.0	41	-4.07	25.49	-50.0	0.00	66.7
	Week 4	51	77.45	23.29	16.7	83.33	100.0	44	-4.55	19.48	-66.7	0.00	50.0
	Week 5	46	73.19	26.64	0.0	75.00	100.0	41	-8.13	28.66	-100.0	0.00	50.0
	Week 6	50	76.67	26.08	0.0	83.33	100.0	39	-7.26	30.54	-100.0	0.00	66.7
	Week 7	50	78.33	24.80	0.0	83.33	100.0	39	-2.99	26.73	-66.7	0.00	66.7
	Week 8	51	77.12	24.49	0.0	83.33	100.0	41	-4.47	27.65	-66.7	0.00	66.7
	Week 9	47	77.66	24.64	0.0	83.33	100.0	37	-4.05	28.71	-66.7	0.00	66.7
	Week 10	45	79.63	24.85	0.0	83.33	100.0	34	-0.98	19.65	-50.0	0.00	33.3
	Week 11	48	80.90	20.34	16.7	83.33	100.0	37	-3.15	24.80	-66.7	0.00	66.7
	Week 12	51	79.08	25.13	0.0	83.33	100.0	39	-5.13	26.26	-83.3	0.00	50.0
	Week 14	50	85.00	20.55	33.3	100.00	100.0	38	3.07	23.84	-50.0	0.00	83.3
	Week 17	43	81.01	21.08	33.3	83.33	100.0	33	0.50	24.82	-50.0	0.00	66.7
	Week 20	41	82.93	21.89	33.3	100.00	100.0	33	0.51	24.11	-66.7	0.00	66.7
	Week 23	41	77.64	25.44	0.0	83.33	100.0	30	-6.11	26.80	-66.7	0.00	66.7
	Week 26	37	81.53	21.80	0.0	83.33	100.0	28	4.17	28.19	-66.7	0.00	66.7
	Week 29	37	81.98	20.93	33.3	83.33	100.0	29	-2.30	24.28	-50.0	0.00	66.7
	Week 32	34	79.90	23.49	33.3	91.67	100.0	26	-1.28	23.06	-50.0	0.00	66.7
	Week 35	31	81.72	18.93	33.3	83.33	100.0	25	-2.67	31.80	-50.0	0.00	100.0
	Week 38	31	74.73	23.91	0.0	83.33	100.0	26	-10.90	23.54	-66.7	-8.33	33.3
	Week 41	28	76.79	25.39	0.0	75.00	100.0	23	-0.72	25.86	-33.3	0.00	66.7
	Week 44	27	74.69	27.88	0.0	83.33	100.0	22	-12.12	26.32	-66.7	0.00	33.3
	Week 47	25	77.33	23.51	33.3	66.67	100.0	21	-5.55	18.51	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	26	70.51	28.01	0.0	66.67	100.0	23	-16.67	27.06	-100.0	-16.66	33.3
	Week 53	26	73.72	28.35	0.0	75.00	100.0	21	-9.52	28.66	-100.0	0.00	33.3
	Week 56	25	75.33	25.51	33.3	83.33	100.0	21	-5.56	23.77	-50.0	-16.66	33.3
	Week 59	23	83.33	20.10	33.3	100.00	100.0	18	-2.78	23.74	-50.0	0.00	33.3
	Week 62	20	76.67	28.31	0.0	83.33	100.0	17	-1.96	19.44	-33.3	0.00	33.3
	Week 65	13	80.77	19.06	50.0	83.33	100.0	13	-7.69	18.78	-33.3	-16.66	33.3
	Week 68	15	73.33	16.43	33.3	66.67	100.0	15	-16.67	16.66	-33.3	-16.67	16.7
	Week 71	13	80.77	20.24	33.3	83.33	100.0	13	-5.13	20.84	-33.3	0.00	33.3
	Week 74	10	76.67	21.08	33.3	75.00	100.0	9	-1.85	29.40	-33.3	0.00	50.0
	Plat+Gem (N= 95)												
	BASELINE	75	79.11	25.13	0.0	83.33	100.0						
	Week 1	71	74.65	28.71	0.0	83.33	100.0	69	-3.14	25.45	-100.0	0.00	66.7
	Week 2	71	75.35	27.58	0.0	83.33	100.0	63	-2.12	25.13	-66.7	0.00	66.7
	Week 3	72	72.45	29.76	0.0	66.67	100.0	65	-8.97	23.40	-66.7	0.00	50.0
	Week 4	69	78.50	28.17	0.0	83.33	100.0	62	-1.88	23.59	-66.7	0.00	66.7
	Week 5	71	73.94	30.31	0.0	83.33	100.0	63	-3.70	21.26	-66.7	0.00	50.0
	Week 6	69	74.64	29.51	0.0	83.33	100.0	61	-4.64	25.48	-66.7	0.00	66.7
	Week 7	69	75.60	28.95	0.0	83.33	100.0	62	-4.57	23.21	-66.7	0.00	66.7
	Week 8	67	74.13	26.95	0.0	83.33	100.0	60	-3.33	20.77	-50.0	0.00	66.7
	Week 9	66	74.24	28.07	0.0	83.33	100.0	57	-4.68	23.31	-100.0	0.00	50.0
	Week 10	70	76.19	27.88	0.0	83.33	100.0	63	-2.65	20.13	-33.3	0.00	50.0
	Week 11	63	74.60	27.57	0.0	83.33	100.0	56	-3.57	22.85	-66.7	0.00	66.7
	Week 12	66	72.98	27.23	0.0	83.33	100.0	56	-6.25	23.69	-83.3	0.00	50.0
	Week 14	66	75.00	25.86	0.0	83.33	100.0	56	-4.76	23.72	-66.7	0.00	50.0
	Week 17	61	71.86	27.81	0.0	66.67	100.0	53	-7.23	22.53	-66.7	0.00	50.0
	Week 20	54	75.93	27.02	0.0	83.33	100.0	48	-1.39	22.76	-50.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 23	44	79.92	23.73	33.3	91.67	100.0	40	0.42	20.15	-50.0	0.00	66.7
	Week 26	42	74.21	28.32	0.0	83.33	100.0	39	-4.70	25.92	-66.7	0.00	66.7
	Week 29	39	76.50	26.41	0.0	83.33	100.0	36	-0.46	18.89	-33.3	0.00	66.7
	Week 32	32	77.60	27.63	0.0	83.33	100.0	30	-0.56	21.66	-50.0	0.00	66.7
	Week 35	32	76.56	28.35	0.0	83.33	100.0	30	-0.56	22.95	-50.0	0.00	66.7
	Week 38	28	82.74	27.77	0.0	100.00	100.0	26	-1.28	16.28	-33.3	0.00	33.3
	Week 41	25	77.33	30.76	0.0	100.00	100.0	23	-2.90	14.78	-33.3	0.00	33.3
	Week 44	24	75.70	30.29	16.7	91.67	100.0	22	-5.30	24.34	-83.3	0.00	33.3
	Week 47	22	77.27	32.34	0.0	100.00	100.0	20	-3.33	19.19	-50.0	0.00	33.3
	Week 50	17	74.51	28.94	33.3	83.33	100.0	15	-4.45	23.96	-66.7	0.00	33.3
	Week 53	15	75.55	33.85	0.0	100.00	100.0	14	-2.38	26.03	-66.7	0.00	33.3
	Week 56	15	73.33	32.61	0.0	83.33	100.0	14	-4.76	23.05	-66.7	0.00	33.3
	Week 59	11	68.18	36.86	0.0	83.33	100.0	10	-8.33	30.68	-83.3	0.00	33.3
	Week 62	11	74.24	25.13	33.3	83.33	100.0	11	-7.58	25.13	-66.7	0.00	33.3
	Week 65	10	80.00	26.99	33.3	91.67	100.0	10	-3.33	24.60	-66.7	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
North America	EV+Pembro (N= 46)												
	BASELINE	33	72.73	30.85	0.0	83.33	100.0						
	Week 1	30	69.44	28.05	0.0	66.67	100.0	27	-4.94	14.48	-33.3	0.00	16.7
	Week 2	30	71.11	23.54	33.3	66.67	100.0	26	-2.56	21.96	-50.0	0.00	50.0
	Week 3	25	78.00	22.42	33.3	83.33	100.0	21	-0.79	15.34	-33.3	0.00	33.3
	Week 4	30	71.11	27.66	16.7	66.67	100.0	24	0.70	17.36	-33.3	0.00	50.0
	Week 5	29	74.71	23.41	33.3	66.67	100.0	21	0.00	20.41	-33.3	0.00	50.0
	Week 6	31	69.89	25.61	33.3	66.67	100.0	23	-2.90	19.24	-66.7	0.00	33.3
	Week 7	33	73.23	24.98	16.7	66.67	100.0	23	4.35	16.83	-33.3	0.00	33.3
	Week 8	29	71.26	23.53	33.3	66.67	100.0	20	7.50	22.61	-33.3	0.00	66.7
	Week 9	27	73.46	25.43	16.7	66.67	100.0	21	0.00	24.72	-66.7	0.00	50.0
	Week 10	29	77.01	22.89	33.3	83.33	100.0	23	10.87	24.42	-16.7	0.00	66.7
	Week 11	28	76.19	27.38	0.0	66.67	100.0	21	7.94	21.49	-33.3	0.00	66.7
	Week 12	29	79.89	24.55	0.0	83.33	100.0	22	9.09	23.98	-33.3	0.00	66.7
	Week 14	28	79.17	21.09	33.3	83.33	100.0	21	9.52	25.04	-33.3	0.00	66.7
	Week 17	29	76.44	22.50	33.3	66.67	100.0	23	6.52	27.40	-33.3	0.00	66.7
	Week 20	23	77.54	21.09	33.3	83.33	100.0	18	8.33	26.35	-33.3	0.00	66.7
	Week 23	22	75.00	28.05	0.0	75.00	100.0	17	0.98	29.74	-50.0	0.00	66.7
	Week 26	21	73.81	25.59	16.7	66.67	100.0	16	3.13	28.69	-33.3	0.00	66.7
	Week 29	20	73.33	27.78	0.0	83.33	100.0	17	-1.96	31.67	-100.0	0.00	50.0
	Week 32	21	72.22	29.03	0.0	66.67	100.0	18	0.93	35.46	-100.0	0.00	50.0
	Week 35	22	71.21	27.30	0.0	66.67	100.0	19	-3.51	32.67	-100.0	0.00	50.0
	Week 38	20	72.50	28.24	0.0	66.67	100.0	17	0.98	33.06	-100.0	0.00	50.0
	Week 41	21	79.36	19.65	33.3	83.33	100.0	17	3.92	23.22	-66.7	0.00	50.0
	Week 44	16	76.04	24.32	33.3	75.00	100.0	12	4.17	20.26	-33.3	0.00	33.3
	Week 47	16	78.13	21.70	33.3	83.33	100.0	13	3.85	19.43	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	16	76.04	18.22	50.0	75.00	100.0	11	1.51	17.41	-16.7	0.00	33.3
	Week 53	15	78.89	23.12	33.3	83.33	100.0	11	7.58	17.26	-16.7	0.00	33.3
	Week 56	17	70.59	29.77	0.0	66.67	100.0	12	1.39	20.67	-33.3	0.00	33.3
	Week 59	17	70.59	26.04	16.7	66.67	100.0	12	2.78	23.39	-33.3	8.33	33.3
	Week 62	14	76.19	21.40	33.3	66.67	100.0	9	7.41	23.73	-33.3	0.00	33.3
	Week 68	11	78.79	24.82	16.7	83.33	100.0	8	8.33	19.92	-16.7	8.34	33.3
	Week 71	11	72.73	32.72	0.0	66.67	100.0	8	6.25	21.71	-33.3	0.00	33.3
	Plat+Gem (N= 34)												
	BASELINE	27	74.07	31.12	0.0	83.33	100.0						
	Week 1	19	85.09	22.15	33.3	100.00	100.0	17	0.98	16.11	-33.3	0.00	50.0
	Week 2	20	79.17	29.56	0.0	100.00	100.0	18	-3.70	21.05	-33.3	0.00	50.0
	Week 3	20	80.00	22.03	33.3	83.33	100.0	17	-3.92	23.22	-50.0	0.00	33.3
	Week 4	23	84.06	21.60	33.3	100.00	100.0	19	0.88	18.82	-33.3	0.00	50.0
	Week 5	25	74.67	23.63	33.3	83.33	100.0	22	-4.55	24.22	-50.0	0.00	50.0
	Week 6	20	79.17	30.05	0.0	100.00	100.0	17	-3.92	22.46	-66.7	0.00	33.3
	Week 7	23	76.81	31.68	0.0	83.33	100.0	20	-5.00	21.70	-50.0	0.00	50.0
	Week 8	24	68.75	34.86	0.0	83.33	100.0	22	-8.33	31.18	-100.0	0.00	50.0
	Week 9	23	78.26	28.62	0.0	83.33	100.0	19	-2.63	31.56	-83.3	0.00	50.0
	Week 10	20	76.67	24.42	33.3	83.33	100.0	18	-4.63	23.43	-50.0	0.00	33.3
	Week 11	18	77.78	28.01	0.0	83.33	100.0	16	-11.46	28.36	-83.3	0.00	33.3
	Week 12	17	70.59	27.34	0.0	66.67	100.0	16	-8.33	27.89	-66.7	-8.34	50.0
	Week 14	16	80.21	25.25	16.7	91.67	100.0	14	-7.14	28.28	-50.0	0.00	50.0
	Week 17	19	72.81	27.34	16.7	83.33	100.0	17	-16.67	27.64	-50.0	-16.67	50.0
	Week 20	16	76.04	30.41	0.0	91.67	100.0	13	-10.26	26.82	-50.0	0.00	50.0
	Week 23	15	78.89	29.19	0.0	83.33	100.0	13	-8.97	26.89	-66.7	0.00	50.0
	Week 26	13	91.03	12.94	66.7	100.00	100.0	12	-1.39	21.86	-33.3	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 29	14	76.19	36.23	0.0	100.00	100.0	13	-14.10	31.07	-66.7	0.00	50.0
	Week 32	11	90.91	15.57	66.7	100.00	100.0	10	-1.67	22.84	-33.3	0.00	50.0
	Week 35	13	88.46	17.19	50.0	100.00	100.0	11	-6.06	25.03	-50.0	0.00	50.0
	Week 38	10	78.33	32.44	0.0	91.67	100.0	9	-18.52	41.20	-100.0	-16.67	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Rest of World	EV+Pembro (N= 82)												
	BASELINE	74	74.55	26.64	16.7	83.33	100.0						
	Week 1	63	78.84	22.84	16.7	83.33	100.0	60	1.39	17.71	-50.0	0.00	50.0
	Week 2	67	69.40	28.95	0.0	66.67	100.0	63	-3.70	21.26	-50.0	0.00	66.7
	Week 3	64	71.35	27.93	0.0	66.67	100.0	60	-1.94	20.38	-50.0	0.00	33.3
	Week 4	64	73.70	24.99	0.0	66.67	100.0	61	-1.37	22.42	-50.0	0.00	66.7
	Week 5	62	76.88	24.58	0.0	75.00	100.0	59	3.11	22.63	-50.0	0.00	66.7
	Week 6	65	74.87	28.28	0.0	66.67	100.0	62	0.00	26.99	-66.7	0.00	66.7
	Week 7	64	76.04	24.64	0.0	75.00	100.0	62	0.27	25.34	-66.7	0.00	66.7
	Week 8	67	72.64	27.93	0.0	66.67	100.0	63	-2.38	29.15	-100.0	0.00	66.7
	Week 9	68	74.02	27.83	0.0	75.00	100.0	63	-0.79	28.31	-83.3	0.00	66.7
	Week 10	65	72.05	27.97	0.0	66.67	100.0	61	-3.82	28.93	-100.0	0.00	66.7
	Week 11	61	75.41	27.49	0.0	66.67	100.0	57	-0.58	29.54	-100.0	0.00	66.7
	Week 12	62	75.27	27.28	0.0	66.67	100.0	58	-0.29	29.70	-66.7	0.00	66.7
	Week 14	61	75.68	28.31	0.0	83.33	100.0	57	0.29	28.43	-66.7	0.00	66.7
	Week 17	60	75.83	23.05	0.0	66.67	100.0	55	-1.82	26.77	-66.7	0.00	66.7
	Week 20	56	79.47	18.80	33.3	83.33	100.0	52	-0.64	24.69	-33.3	0.00	66.7
	Week 23	54	77.78	21.72	33.3	75.00	100.0	50	-2.00	23.72	-66.7	0.00	50.0
	Week 26	54	78.70	21.33	33.3	83.33	100.0	50	-1.67	27.61	-66.7	0.00	66.7
	Week 29	50	75.33	19.70	33.3	66.67	100.0	47	-5.32	23.60	-66.7	0.00	33.3
	Week 32	47	76.60	21.89	16.7	66.67	100.0	44	-3.79	25.13	-83.3	0.00	33.3
	Week 35	45	73.33	23.94	0.0	66.67	100.0	42	-6.74	26.56	-83.3	0.00	33.3
	Week 38	46	77.90	19.26	33.3	66.67	100.0	43	0.00	25.20	-66.7	0.00	66.7
	Week 41	46	72.46	26.11	0.0	66.67	100.0	44	-6.44	31.59	-66.7	0.00	66.7
	Week 44	43	69.77	25.00	0.0	66.67	100.0	40	-8.75	27.73	-66.7	0.00	33.3
	Week 47	38	70.61	23.07	33.3	66.67	100.0	36	-4.63	28.90	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	32	69.27	22.45	33.3	66.67	100.0	30	-6.67	29.23	-66.7	0.00	66.7
	Week 53	33	69.70	23.74	33.3	66.67	100.0	31	-6.45	27.78	-66.7	0.00	66.7
	Week 56	30	68.33	24.11	33.3	66.67	100.0	28	-5.36	28.35	-66.7	0.00	50.0
	Week 59	29	67.24	23.77	33.3	66.67	100.0	27	-6.17	28.92	-66.7	0.00	33.3
	Week 62	28	72.62	19.88	33.3	66.67	100.0	26	-3.85	25.52	-50.0	0.00	33.3
	Week 65	22	64.39	23.74	33.3	66.67	100.0	21	-8.73	31.46	-66.7	0.00	33.3
	Week 68	20	67.50	25.64	16.7	66.67	100.0	19	-5.26	32.42	-66.7	0.00	50.0
	Week 71	18	74.07	25.71	16.7	75.00	100.0	17	4.90	32.68	-66.7	0.00	66.7
	Week 74	19	68.42	20.71	33.3	66.67	100.0	19	-3.51	27.54	-50.0	0.00	33.3
	Week 77	19	70.18	22.62	33.3	66.67	100.0	18	0.93	25.87	-50.0	8.33	33.3
	Week 80	19	71.05	22.80	33.3	66.67	100.0	18	1.85	25.49	-50.0	0.00	33.3
	Week 83	17	66.67	24.30	16.7	66.67	100.0	17	-2.94	32.93	-50.0	0.00	50.0
	Week 86	14	64.29	27.62	16.7	66.67	100.0	14	-5.95	32.43	-66.7	0.00	33.3
	Week 89	11	72.73	28.16	16.7	66.67	100.0	11	-1.51	31.14	-66.7	0.00	33.3
	Plat+Gem (N= 73)												
	BASELINE	63	78.57	24.76	0.0	83.33	100.0						
	Week 1	54	76.54	26.60	0.0	83.33	100.0	53	-1.26	22.84	-50.0	0.00	50.0
	Week 2	56	71.13	29.56	0.0	83.33	100.0	54	-8.64	27.80	-66.7	0.00	66.7
	Week 3	57	73.98	28.17	0.0	83.33	100.0	54	-6.79	23.24	-66.7	0.00	33.3
	Week 4	58	70.98	24.89	0.0	66.67	100.0	54	-7.72	24.17	-66.7	0.00	33.3
	Week 5	57	71.64	26.53	0.0	66.67	100.0	53	-9.12	28.60	-66.7	0.00	50.0
	Week 6	56	69.94	29.72	0.0	66.67	100.0	53	-9.12	27.46	-66.7	0.00	50.0
	Week 7	56	74.70	23.35	16.7	66.67	100.0	52	-3.53	29.21	-66.7	0.00	66.7
	Week 8	54	73.46	27.76	0.0	83.33	100.0	50	-5.67	30.79	-100.0	0.00	66.7
	Week 9	52	71.15	26.01	0.0	66.67	100.0	49	-7.48	29.08	-66.7	0.00	66.7
	Week 10	52	73.08	27.25	0.0	83.33	100.0	49	-5.44	30.50	-66.7	0.00	66.7

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	45	67.78	28.96	0.0	66.67	100.0	42	-10.32	32.29	-83.3	0.00	50.0
	Week 12	47	69.50	26.54	0.0	66.67	100.0	43	-7.36	31.56	-66.7	0.00	66.7
	Week 14	43	70.54	27.18	0.0	66.67	100.0	39	-6.41	33.47	-66.7	0.00	66.7
	Week 17	40	72.92	24.07	16.7	66.67	100.0	36	-7.87	28.86	-66.7	0.00	50.0
	Week 20	34	71.08	25.06	16.7	66.67	100.0	30	-7.78	23.46	-66.7	0.00	33.3
	Week 23	29	80.46	20.93	33.3	83.33	100.0	27	-4.32	23.84	-66.7	0.00	33.3
	Week 26	26	77.56	23.54	33.3	83.33	100.0	24	-4.86	20.55	-50.0	0.00	33.3
	Week 29	24	77.08	25.45	0.0	83.33	100.0	22	-9.85	31.14	-100.0	0.00	33.3
	Week 32	20	78.33	25.42	16.7	83.33	100.0	18	-8.33	29.84	-83.3	0.00	33.3
	Week 35	17	78.43	23.40	33.3	83.33	100.0	15	-3.33	22.89	-50.0	0.00	33.3
	Week 38	18	85.18	19.71	33.3	91.67	100.0	15	5.55	20.57	-16.7	0.00	50.0
	Week 41	18	80.56	22.32	33.3	83.33	100.0	16	-6.25	28.46	-66.7	0.00	33.3
	Week 44	16	72.92	21.84	33.3	66.67	100.0	14	-9.52	29.75	-66.7	-16.66	33.3
	Week 47	12	80.56	27.37	33.3	100.00	100.0	11	-10.61	27.15	-66.7	0.00	33.3
	Week 50	11	71.21	31.70	16.7	66.67	100.0	9	-18.52	34.80	-83.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	EV+Pembro (N=146)												
	BASELINE	119	76.33	27.23	0.0	83.33	100.0						
	Week 1	102	79.90	22.78	0.0	83.33	100.0	97	0.86	16.38	-50.0	0.00	50.0
	Week 2	106	72.33	26.71	0.0	83.33	100.0	98	-4.42	19.81	-50.0	0.00	50.0
	Week 3	94	76.24	22.47	16.7	83.33	100.0	88	-1.51	20.47	-50.0	0.00	66.7
	Week 4	101	76.57	23.23	16.7	83.33	100.0	93	-0.18	19.89	-33.3	0.00	66.7
	Week 5	96	78.82	21.42	0.0	83.33	100.0	89	0.56	22.95	-50.0	0.00	66.7
	Week 6	105	76.67	26.11	0.0	83.33	100.0	93	-0.72	25.05	-66.7	0.00	66.7
	Week 7	102	79.08	22.70	0.0	83.33	100.0	89	1.69	22.48	-66.7	0.00	66.7
	Week 8	101	76.40	26.28	0.0	83.33	100.0	91	-0.55	28.16	-100.0	0.00	66.7
	Week 9	100	77.00	26.25	0.0	83.33	100.0	89	-0.19	25.93	-83.3	0.00	66.7
	Week 10	99	76.94	25.72	0.0	83.33	100.0	87	1.34	27.28	-100.0	0.00	66.7
	Week 11	95	79.12	25.61	0.0	83.33	100.0	84	0.00	27.98	-100.0	0.00	66.7
	Week 12	99	77.78	27.35	0.0	83.33	100.0	87	-0.77	29.19	-83.3	0.00	66.7
	Week 14	95	80.53	24.75	0.0	100.00	100.0	84	2.38	25.89	-66.7	0.00	66.7
	Week 17	97	78.52	21.51	33.3	83.33	100.0	84	-0.40	25.87	-66.7	0.00	66.7
	Week 20	90	80.56	20.18	33.3	83.33	100.0	79	1.06	23.92	-66.7	0.00	66.7
	Week 23	86	78.68	23.66	0.0	83.33	100.0	74	-2.70	24.37	-66.7	0.00	66.7
	Week 26	83	77.71	23.32	0.0	83.33	100.0	72	-2.08	26.97	-66.7	0.00	66.7
	Week 29	80	77.50	22.20	0.0	83.33	100.0	71	-4.93	24.30	-100.0	0.00	66.7
	Week 32	74	78.60	23.49	0.0	83.33	100.0	66	-2.27	25.64	-100.0	0.00	66.7
	Week 35	73	74.43	24.39	0.0	66.67	100.0	66	-7.83	27.46	-100.0	0.00	50.0
	Week 38	75	77.11	21.53	0.0	66.67	100.0	67	-2.98	25.11	-100.0	0.00	50.0
	Week 41	71	76.76	25.12	0.0	83.33	100.0	64	-3.12	26.37	-66.7	0.00	66.7
	Week 44	64	75.52	24.12	0.0	66.67	100.0	56	-5.95	23.88	-66.7	0.00	33.3
	Week 47	56	76.79	21.24	33.3	66.67	100.0	50	-0.67	20.19	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	55	72.43	22.50	0.0	66.67	100.0	48	-8.33	24.55	-100.0	0.00	33.3
	Week 53	55	74.55	24.61	0.0	66.67	100.0	48	-5.55	25.11	-100.0	0.00	33.3
	Week 56	53	71.70	24.80	0.0	66.67	100.0	46	-4.35	23.16	-50.0	0.00	33.3
	Week 59	51	75.16	24.35	16.7	66.67	100.0	43	-2.32	24.55	-50.0	0.00	33.3
	Week 62	42	78.18	20.33	33.3	83.33	100.0	36	0.46	22.71	-50.0	0.00	33.3
	Week 65	31	74.19	21.45	33.3	66.67	100.0	30	-5.55	26.38	-66.7	0.00	50.0
	Week 68	31	73.12	22.23	16.7	66.67	100.0	29	-5.75	25.31	-50.0	0.00	33.3
	Week 71	30	71.11	26.60	0.0	66.67	100.0	28	-2.38	26.34	-66.7	0.00	33.3
	Week 74	29	72.99	21.55	33.3	66.67	100.0	27	0.00	25.32	-50.0	0.00	50.0
	Week 77	26	76.92	22.15	33.3	83.33	100.0	24	0.69	25.29	-50.0	0.00	50.0
	Week 80	26	76.92	22.65	33.3	75.00	100.0	26	0.00	24.49	-50.0	0.00	50.0
	Week 83	21	76.98	22.03	33.3	66.67	100.0	21	0.00	28.38	-50.0	0.00	33.3
	Week 86	17	74.51	25.76	16.7	83.33	100.0	17	-8.82	27.08	-66.7	0.00	33.3
	Week 89	11	80.30	25.62	16.7	83.33	100.0	11	0.00	28.87	-66.7	0.00	33.3
	Week 92	13	85.90	20.24	50.0	100.00	100.0	13	3.85	16.88	-33.3	0.00	33.3
	Plat+Gem (N=151)												
	BASELINE	123	78.05	25.99	0.0	83.33	100.0						
	Week 1	108	78.70	27.33	0.0	100.00	100.0	103	0.16	24.20	-100.0	0.00	66.7
	Week 2	116	74.86	28.53	0.0	83.33	100.0	105	-4.60	25.79	-66.7	0.00	66.7
	Week 3	114	76.02	25.86	0.0	83.33	100.0	103	-5.02	22.36	-66.7	0.00	50.0
	Week 4	116	77.87	24.85	0.0	83.33	100.0	103	-1.94	23.60	-66.7	0.00	66.7
	Week 5	119	73.81	27.41	0.0	83.33	100.0	106	-3.62	25.41	-66.7	0.00	50.0
	Week 6	109	75.38	28.38	0.0	83.33	100.0	98	-4.42	26.17	-66.7	0.00	66.7
	Week 7	115	75.94	26.87	0.0	83.33	100.0	105	-3.33	24.28	-66.7	0.00	66.7
	Week 8	111	74.02	28.22	0.0	83.33	100.0	102	-3.76	27.24	-100.0	0.00	66.7
	Week 9	107	75.23	27.12	0.0	83.33	100.0	95	-3.33	26.59	-100.0	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	107	77.26	27.22	0.0	83.33	100.0	98	-1.70	24.35	-66.7	0.00	50.0
	Week 11	97	74.40	26.90	0.0	83.33	100.0	87	-4.98	28.09	-83.3	0.00	66.7
	Week 12	100	73.17	25.72	0.0	66.67	100.0	88	-3.98	25.89	-66.7	0.00	50.0
	Week 14	99	75.76	24.43	16.7	83.33	100.0	86	-3.49	26.21	-66.7	0.00	50.0
	Week 17	94	73.23	26.57	0.0	66.67	100.0	82	-7.11	27.22	-66.7	0.00	50.0
	Week 20	84	74.80	27.07	0.0	83.33	100.0	72	-2.78	23.90	-66.7	0.00	66.7
	Week 23	70	78.81	24.40	0.0	83.33	100.0	62	-2.15	24.79	-66.7	0.00	66.7
	Week 26	61	79.24	23.30	16.7	83.33	100.0	55	-3.03	23.59	-66.7	0.00	66.7
	Week 29	59	78.53	26.27	0.0	83.33	100.0	53	-4.09	25.92	-100.0	0.00	66.7
	Week 32	50	81.00	26.94	0.0	100.00	100.0	45	-2.59	26.10	-83.3	0.00	66.7
	Week 35	50	79.00	26.47	0.0	83.33	100.0	44	-2.65	24.89	-50.0	0.00	66.7
	Week 38	46	84.06	24.33	0.0	100.00	100.0	40	-0.42	21.51	-50.0	0.00	50.0
	Week 41	42	79.36	27.25	0.0	100.00	100.0	37	-5.41	21.89	-66.7	0.00	33.3
	Week 44	39	76.07	26.98	16.7	83.33	100.0	34	-9.31	26.65	-83.3	0.00	33.3
	Week 47	33	75.76	31.21	0.0	100.00	100.0	29	-8.05	28.74	-66.7	0.00	50.0
	Week 50	27	76.54	28.96	16.7	100.00	100.0	22	-6.06	31.93	-83.3	0.00	50.0
	Week 53	23	75.36	31.33	0.0	100.00	100.0	20	-2.50	32.12	-66.7	0.00	50.0
	Week 56	20	75.83	31.75	0.0	91.67	100.0	19	-4.39	32.79	-66.7	0.00	50.0
	Week 59	17	67.65	36.55	0.0	83.33	100.0	15	-6.67	32.00	-83.3	0.00	33.3
	Week 62	14	77.38	24.99	33.3	83.33	100.0	14	-2.38	29.86	-66.7	0.00	33.3
	Week 65	13	78.20	27.54	33.3	83.33	100.0	12	-4.17	26.71	-66.7	0.00	33.3
	Week 68	10	81.67	27.72	33.3	100.00	100.0	10	-5.00	28.38	-66.7	0.00	33.3
	Week 71	10	78.33	27.27	33.3	91.67	100.0	10	-10.00	28.54	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	EV+Pembro (N= 56)												
	BASELINE	41	74.80	29.84	0.0	83.33	100.0						
	Week 1	39	70.94	28.02	0.0	66.67	100.0	32	-5.21	14.32	-33.3	0.00	16.7
	Week 2	44	68.94	29.77	0.0	66.67	100.0	35	-5.71	24.57	-66.7	0.00	66.7
	Week 3	45	68.15	29.26	0.0	66.67	100.0	34	-4.90	23.76	-50.0	0.00	50.0
	Week 4	44	69.70	28.14	0.0	75.00	100.0	36	-6.95	21.59	-66.7	0.00	33.3
	Week 5	41	66.67	30.28	0.0	66.67	100.0	32	-6.25	29.25	-100.0	0.00	50.0
	Week 6	41	68.70	28.43	0.0	66.67	100.0	31	-9.14	31.58	-100.0	0.00	33.3
	Week 7	45	69.63	27.82	0.0	66.67	100.0	35	-4.29	28.68	-66.7	0.00	50.0
	Week 8	46	68.48	24.40	0.0	66.67	100.0	33	-4.04	27.01	-66.7	0.00	66.7
	Week 9	42	70.64	25.98	0.0	66.67	100.0	32	-5.73	32.13	-66.7	0.00	66.7
	Week 10	40	72.08	26.79	0.0	75.00	100.0	31	-4.30	22.35	-50.0	0.00	33.3
	Week 11	42	73.81	23.90	0.0	66.67	100.0	31	0.54	23.76	-50.0	0.00	33.3
	Week 12	43	77.13	22.43	0.0	83.33	100.0	32	1.56	24.08	-50.0	0.00	50.0
	Week 14	44	78.03	24.32	0.0	83.33	100.0	32	4.17	28.08	-66.7	0.00	83.3
	Week 17	35	75.24	24.38	0.0	66.67	100.0	27	3.70	27.86	-50.0	0.00	66.7
	Week 20	30	79.44	20.85	33.3	83.33	100.0	24	2.08	27.94	-33.3	0.00	66.7
	Week 23	31	73.12	25.34	0.0	66.67	100.0	23	-2.90	30.01	-66.7	0.00	33.3
	Week 26	29	81.61	19.08	33.3	83.33	100.0	22	10.61	28.89	-33.3	8.34	66.7
	Week 29	27	76.54	21.31	33.3	83.33	100.0	22	0.00	28.17	-66.7	0.00	33.3
	Week 32	28	72.02	24.87	16.7	66.67	100.0	22	-1.51	30.39	-83.3	0.00	33.3
	Week 35	25	78.67	20.70	33.3	83.33	100.0	20	5.00	33.38	-33.3	0.00	100.0
	Week 38	22	71.21	26.32	0.0	66.67	100.0	19	-3.51	32.19	-66.7	0.00	66.7
	Week 41	24	70.83	22.66	33.3	66.67	100.0	20	-1.67	35.42	-66.7	0.00	66.7
	Week 44	22	63.64	28.47	0.0	66.67	100.0	18	-12.96	33.61	-66.7	0.00	33.3
	Week 47	23	68.12	26.07	33.3	66.67	100.0	20	-10.00	32.63	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	19	67.54	26.92	33.3	66.67	100.0	16	-10.42	34.90	-66.7	0.00	66.7
	Week 53	19	68.42	27.16	33.3	66.67	100.0	15	-3.33	32.86	-66.7	0.00	66.7
	Week 56	19	70.17	29.18	33.3	83.33	100.0	15	-3.33	31.62	-66.7	0.00	50.0
	Week 59	18	68.52	22.79	33.3	66.67	100.0	14	-5.95	31.08	-66.7	0.00	33.3
	Week 62	20	67.50	26.75	0.0	66.67	100.0	16	-5.21	24.89	-50.0	0.00	33.3
	Week 65	12	73.61	27.94	33.3	75.00	100.0	10	-3.33	34.07	-66.7	0.00	33.3
	Week 68	15	70.00	24.56	16.7	83.33	100.0	13	-8.98	30.14	-66.7	0.00	50.0
	Week 71	12	87.50	20.26	33.3	100.00	100.0	10	13.33	25.82	-16.7	8.33	66.7
	Week 77	11	78.79	22.47	33.3	83.33	100.0	9	5.56	20.41	-33.3	16.66	33.3
	Week 80	10	78.33	23.64	33.3	83.33	100.0	8	2.08	20.77	-33.3	0.00	33.3
	Plat+Gem (N= 51)												
	BASELINE	42	78.17	26.16	0.0	83.33	100.0						
	Week 1	36	70.83	26.24	16.7	66.67	100.0	36	-7.87	20.11	-50.0	0.00	33.3
	Week 2	31	72.04	28.99	0.0	83.33	100.0	30	-6.11	26.07	-50.0	0.00	66.7
	Week 3	35	67.62	34.29	0.0	66.67	100.0	33	-15.15	24.43	-66.7	0.00	16.7
	Week 4	34	71.57	30.58	0.0	83.33	100.0	32	-9.90	21.53	-66.7	0.00	16.7
	Week 5	34	71.08	29.39	0.0	83.33	100.0	32	-13.54	20.93	-66.7	-8.33	16.7
	Week 6	36	67.59	32.84	0.0	83.33	100.0	33	-12.12	24.39	-66.7	-16.66	50.0
	Week 7	33	73.74	28.88	0.0	83.33	100.0	29	-7.47	29.07	-66.7	0.00	66.7
	Week 8	34	69.61	29.72	0.0	75.00	100.0	30	-9.45	24.25	-66.7	0.00	66.7
	Week 9	34	69.12	27.87	0.0	66.67	100.0	30	-12.22	26.96	-66.7	-8.33	66.7
	Week 10	35	68.57	25.81	0.0	66.67	100.0	32	-10.94	25.26	-50.0	-16.67	66.7
	Week 11	29	66.67	31.81	0.0	66.67	100.0	27	-14.20	24.33	-66.7	0.00	50.0
	Week 12	30	65.56	29.99	0.0	66.67	100.0	27	-16.67	29.60	-83.3	-16.66	66.7
	Week 14	26	67.95	31.95	0.0	66.67	100.0	23	-13.77	32.82	-66.7	0.00	66.7
	Week 17	26	69.23	25.69	0.0	66.67	100.0	24	-15.28	18.33	-66.7	-16.66	16.7

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 20	20	72.50	26.09	33.3	75.00	100.0	19	-12.28	21.40	-50.0	0.00	16.7
	Week 23	18	84.26	20.19	33.3	100.00	100.0	18	-4.63	12.53	-33.3	0.00	16.7
	Week 26	20	74.17	31.29	0.0	83.33	100.0	20	-7.50	23.24	-66.7	0.00	33.3
	Week 29	18	70.37	32.11	0.0	75.00	100.0	18	-11.11	25.57	-66.7	0.00	33.3
	Week 32	13	76.92	18.68	50.0	66.67	100.0	13	-5.13	18.49	-33.3	0.00	33.3
	Week 35	12	81.94	19.41	50.0	83.33	100.0	12	-1.39	15.01	-16.7	0.00	33.3
	Week 38	10	76.67	33.52	0.0	83.33	100.0	10	-10.00	34.43	-100.0	0.00	16.7
	Week 41	10	78.33	23.64	33.3	83.33	100.0	10	-10.00	16.10	-33.3	-8.34	16.7
	Week 44	10	73.33	21.08	50.0	66.67	100.0	10	-8.33	19.64	-33.3	-8.34	33.3
	Week 47	10	85.00	18.34	50.0	91.67	100.0	10	-5.00	8.05	-16.7	0.00	0.0
	Week 56	10	71.67	26.12	33.3	66.67	100.0	10	-6.67	19.56	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Visceral metastases	EV+Pembro (N=148)												
	BASELINE	119	73.53	29.47	0.0	83.33	100.0						
	Week 1	105	74.29	26.56	0.0	83.33	100.0	99	-0.50	16.40	-50.0	0.00	50.0
	Week 2	109	67.89	29.98	0.0	66.67	100.0	100	-5.00	21.52	-50.0	0.00	66.7
	Week 3	98	73.13	26.18	0.0	66.67	100.0	88	0.00	20.53	-50.0	0.00	66.7
	Week 4	103	72.98	26.52	0.0	66.67	100.0	93	-1.25	19.23	-66.7	0.00	50.0
	Week 5	100	74.00	25.88	0.0	66.67	100.0	90	0.00	24.86	-100.0	0.00	50.0
	Week 6	105	74.92	26.06	0.0	83.33	100.0	90	0.19	23.77	-66.7	0.00	66.7
	Week 7	108	77.16	23.41	0.0	83.33	100.0	91	3.48	20.26	-33.3	0.00	66.7
	Week 8	105	73.49	25.81	0.0	83.33	100.0	89	0.56	24.55	-66.7	0.00	66.7
	Week 9	105	73.65	26.63	0.0	83.33	100.0	91	-0.37	25.46	-66.7	0.00	66.7
	Week 10	101	75.25	26.10	0.0	83.33	100.0	86	2.91	22.89	-50.0	0.00	66.7
	Week 11	97	76.98	26.07	0.0	83.33	100.0	83	2.01	23.77	-66.7	0.00	66.7
	Week 12	100	77.50	26.74	0.0	83.33	100.0	85	2.35	26.25	-83.3	0.00	66.7
	Week 14	102	78.60	25.41	0.0	83.33	100.0	87	3.26	25.65	-66.7	0.00	83.3
	Week 17	96	77.60	22.66	0.0	75.00	100.0	81	2.47	25.43	-50.0	0.00	66.7
	Week 20	87	79.50	21.07	33.3	83.33	100.0	76	1.75	24.28	-66.7	0.00	66.7
	Week 23	85	76.47	25.50	0.0	83.33	100.0	71	-1.64	25.54	-66.7	0.00	66.7
	Week 26	79	78.48	22.35	0.0	83.33	100.0	66	1.77	26.33	-66.7	0.00	66.7
	Week 29	72	76.16	22.17	0.0	66.67	100.0	64	-3.38	25.05	-100.0	0.00	50.0
	Week 32	71	76.29	24.34	0.0	83.33	100.0	62	-1.34	27.54	-100.0	0.00	50.0
	Week 35	70	75.24	23.70	0.0	66.67	100.0	63	-4.23	30.38	-100.0	0.00	100.0
	Week 38	70	76.91	23.28	0.0	83.33	100.0	63	-1.06	28.22	-100.0	0.00	66.7
	Week 41	66	76.52	25.31	0.0	83.33	100.0	60	0.56	28.78	-66.7	0.00	66.7
	Week 44	59	72.60	25.66	0.0	66.67	100.0	53	-6.60	27.22	-66.7	0.00	33.3
	Week 47	52	75.64	22.01	33.3	66.67	100.0	48	-0.69	25.26	-50.0	0.00	66.7

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Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	49	70.75	25.12	0.0	66.67	100.0	43	-8.14	30.29	-100.0	0.00	66.7
	Week 53	50	71.67	26.35	0.0	66.67	100.0	44	-6.06	29.22	-100.0	0.00	66.7
	Week 56	45	70.37	26.33	0.0	66.67	100.0	39	-4.27	26.41	-66.7	0.00	50.0
	Week 59	44	70.83	23.88	16.7	66.67	100.0	38	-5.70	28.02	-66.7	0.00	33.3
	Week 62	38	76.32	21.09	33.3	75.00	100.0	33	-1.01	25.33	-50.0	0.00	33.3
	Week 65	25	79.33	21.13	33.3	83.33	100.0	24	0.70	30.09	-66.7	0.00	50.0
	Week 68	31	74.73	20.58	16.7	66.67	100.0	29	-5.17	28.90	-66.7	0.00	50.0
	Week 71	27	77.16	27.01	0.0	83.33	100.0	25	2.67	29.53	-66.7	0.00	66.7
	Week 74	23	74.64	22.96	33.3	66.67	100.0	22	0.76	27.93	-50.0	0.00	33.3
	Week 77	24	78.47	22.78	33.3	83.33	100.0	23	3.62	26.09	-50.0	0.00	50.0
	Week 80	22	75.00	23.99	33.3	75.00	100.0	22	0.76	24.39	-50.0	0.00	50.0
	Week 83	19	77.19	23.71	33.3	83.33	100.0	19	2.63	30.56	-50.0	0.00	50.0
	Week 86	14	73.81	26.73	16.7	75.00	100.0	14	-5.95	32.43	-66.7	0.00	33.3
	Week 89	10	76.67	30.63	16.7	91.67	100.0	10	-8.33	29.66	-66.7	0.00	33.3
	Week 92	11	84.85	20.35	50.0	100.00	100.0	11	3.03	17.98	-33.3	0.00	33.3
	Plat+Gem (N=157)												
	BASELINE	128	77.86	25.45	0.0	83.33	100.0						
	Week 1	111	76.73	27.27	0.0	83.33	100.0	107	-2.18	23.47	-100.0	0.00	50.0
	Week 2	110	73.18	30.38	0.0	83.33	100.0	102	-6.37	23.92	-66.7	0.00	50.0
	Week 3	112	74.26	28.55	0.0	83.33	100.0	103	-6.31	22.28	-66.7	0.00	50.0
	Week 4	112	75.74	26.84	0.0	83.33	100.0	102	-3.59	22.45	-66.7	0.00	50.0
	Week 5	113	71.98	28.46	0.0	66.67	100.0	103	-5.99	24.12	-66.7	0.00	50.0
	Week 6	107	72.59	31.16	0.0	83.33	100.0	98	-6.80	24.74	-66.7	0.00	50.0
	Week 7	109	74.62	28.20	0.0	83.33	100.0	100	-4.50	24.37	-66.7	0.00	50.0
	Week 8	106	72.33	30.16	0.0	83.33	100.0	98	-5.10	26.26	-100.0	0.00	50.0
	Week 9	105	73.97	27.73	0.0	83.33	100.0	94	-4.61	26.37	-100.0	0.00	50.0

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	104	74.84	28.06	0.0	83.33	100.0	96	-3.82	24.84	-66.7	0.00	50.0
	Week 11	91	72.34	28.35	0.0	83.33	100.0	83	-6.63	26.15	-83.3	0.00	50.0
	Week 12	94	71.10	27.45	0.0	66.67	100.0	84	-6.15	25.45	-66.7	0.00	50.0
	Week 14	90	74.07	27.15	0.0	83.33	100.0	79	-5.06	27.39	-66.7	0.00	50.0
	Week 17	90	71.67	26.26	0.0	66.67	100.0	80	-7.71	26.11	-66.7	0.00	50.0
	Week 20	74	72.52	27.92	0.0	83.33	100.0	64	-4.17	22.81	-50.0	0.00	50.0
	Week 23	63	78.04	24.47	0.0	83.33	100.0	58	-2.59	21.81	-66.7	0.00	50.0
	Week 26	55	76.06	25.61	16.7	83.33	100.0	52	-4.81	20.70	-50.0	0.00	50.0
	Week 29	53	75.16	29.17	0.0	83.33	100.0	50	-6.67	25.86	-100.0	0.00	50.0
	Week 32	42	76.98	28.02	0.0	83.33	100.0	40	-6.25	24.95	-83.3	0.00	50.0
	Week 35	39	77.35	28.22	0.0	83.33	100.0	36	-4.17	21.96	-50.0	0.00	50.0
	Week 38	37	81.08	29.70	0.0	100.00	100.0	34	-1.96	26.83	-100.0	0.00	50.0
	Week 41	33	78.79	26.44	33.3	100.00	100.0	31	-5.38	20.36	-66.7	0.00	33.3
	Week 44	32	75.52	25.04	16.7	75.00	100.0	30	-7.78	23.05	-66.7	0.00	33.3
	Week 47	28	74.40	31.91	0.0	91.67	100.0	26	-8.33	25.06	-66.7	0.00	50.0
	Week 50	22	74.24	29.87	16.7	91.67	100.0	20	-10.00	28.82	-83.3	0.00	50.0
	Week 53	19	73.68	33.02	0.0	100.00	100.0	17	-3.92	29.19	-66.7	0.00	50.0
	Week 56	18	69.44	31.44	0.0	75.00	100.0	17	-3.92	29.77	-66.7	0.00	50.0
	Week 59	13	61.54	35.61	0.0	66.67	100.0	12	-5.56	22.85	-66.7	0.00	16.7
	Week 62	11	72.73	23.89	33.3	83.33	100.0	11	3.03	26.69	-50.0	0.00	50.0

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.13.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Lymph node only	EV+Pembro (N= 43)												
	BASELINE	33	83.33	19.09	33.3	83.33	100.0						
	Week 1	30	86.11	14.57	66.7	83.33	100.0	24	0.70	14.31	-33.3	0.00	33.3
	Week 2	34	80.39	17.63	33.3	83.33	100.0	27	-1.85	20.33	-66.7	0.00	33.3
	Week 3	35	74.29	22.99	16.7	83.33	100.0	28	-6.55	22.83	-50.0	0.00	50.0
	Week 4	36	78.70	20.93	33.3	83.33	100.0	30	-0.56	22.95	-33.3	0.00	66.7
	Week 5	33	78.28	23.01	33.3	83.33	100.0	27	-3.09	25.34	-50.0	0.00	66.7
	Week 6	34	74.02	31.30	0.0	83.33	100.0	28	-7.74	34.99	-100.0	0.00	66.7
	Week 7	34	72.55	29.55	0.0	83.33	100.0	28	-7.74	33.79	-66.7	0.00	66.7
	Week 8	35	75.71	24.70	33.3	83.33	100.0	29	-4.02	31.70	-66.7	0.00	66.7
	Week 9	30	80.00	24.91	16.7	100.00	100.0	24	-1.39	33.30	-83.3	0.00	66.7
	Week 10	31	75.81	26.82	0.0	83.33	100.0	26	-7.69	32.05	-100.0	0.00	50.0
	Week 11	34	81.37	20.00	33.3	83.33	100.0	27	-1.23	29.57	-66.7	0.00	66.7
	Week 12	35	78.57	24.45	0.0	83.33	100.0	28	-5.36	30.45	-66.7	0.00	66.7
	Week 14	30	85.00	21.60	33.3	100.00	100.0	23	6.52	25.49	-50.0	0.00	66.7
	Week 17	30	81.67	19.25	33.3	83.33	100.0	24	1.39	24.03	-50.0	0.00	50.0
	Week 20	27	84.57	15.96	50.0	83.33	100.0	21	3.97	26.82	-33.3	0.00	66.7
	Week 23	27	79.63	21.35	33.3	83.33	100.0	21	-2.38	27.02	-50.0	0.00	66.7
	Week 26	27	80.86	23.44	33.3	100.00	100.0	22	2.27	33.05	-66.7	0.00	66.7
	Week 29	28	80.36	20.81	33.3	83.33	100.0	23	-2.17	26.73	-50.0	0.00	66.7
	Week 32	24	79.86	23.56	33.3	91.67	100.0	20	-0.83	25.63	-33.3	0.00	66.7
	Week 35	22	75.00	25.07	0.0	66.67	100.0	18	-4.63	27.89	-66.7	0.00	50.0
	Week 38	21	74.60	19.45	33.3	66.67	100.0	17	-4.90	18.41	-33.3	0.00	33.3
	Week 41	22	74.24	21.66	33.3	66.67	100.0	17	-6.86	19.59	-33.3	0.00	16.7
	Week 44	22	71.21	26.32	0.0	66.67	100.0	16	-7.29	22.75	-66.7	0.00	33.3
	Week 47	21	73.81	24.48	33.3	66.67	100.0	16	-4.17	18.76	-33.3	0.00	33.3

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Table 302.1.3002.13.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	73.33	20.52	33.3	66.67	100.0	16	-4.17	14.27	-33.3	0.00	33.3
	Week 53	18	75.93	23.02	33.3	66.67	100.0	14	-3.57	19.81	-33.3	0.00	33.3
	Week 56	21	73.81	26.65	33.3	83.33	100.0	17	-2.94	23.74	-33.3	0.00	33.3
	Week 59	21	80.16	23.93	33.3	100.00	100.0	16	5.21	20.83	-33.3	0.00	33.3
	Week 62	19	75.44	21.78	33.3	66.67	100.0	15	-1.11	20.38	-33.3	0.00	33.3
	Week 65	16	69.79	23.74	33.3	66.67	100.0	14	-8.33	18.20	-33.3	-8.33	16.7
	Week 68	13	67.95	26.75	16.7	66.67	100.0	11	-12.12	22.47	-50.0	0.00	16.7
	Week 71	13	75.64	23.19	33.3	83.33	100.0	11	0.00	23.57	-33.3	0.00	33.3
	Week 74	13	73.08	17.40	33.3	66.67	100.0	11	-1.51	25.22	-33.3	0.00	50.0
	Week 77	13	75.64	21.10	33.3	83.33	100.0	10	-1.67	18.34	-33.3	0.00	16.7
	Week 80	13	79.49	20.59	33.3	83.33	100.0	11	0.00	23.57	-33.3	0.00	33.3
	Week 83	11	75.76	25.12	16.7	66.67	100.0	10	-3.33	26.99	-50.0	0.00	33.3
	Week 86	11	75.76	24.00	33.3	83.33	100.0	10	-6.67	16.10	-33.3	0.00	16.7
	Plat+Gem (N= 37)												
	BASELINE	29	78.74	24.76	0.0	83.33	100.0						
	Week 1	26	75.00	27.99	0.0	83.33	100.0	25	-3.33	24.53	-50.0	0.00	66.7
	Week 2	30	75.56	23.46	33.3	66.67	100.0	26	-3.20	30.92	-50.0	0.00	66.7
	Week 3	30	73.33	28.57	0.0	75.00	100.0	26	-9.62	27.96	-66.7	0.00	33.3
	Week 4	32	76.56	26.05	0.0	83.33	100.0	27	-5.56	27.74	-66.7	0.00	66.7
	Week 5	33	75.25	27.36	0.0	83.33	100.0	28	-5.36	27.98	-66.7	0.00	50.0
	Week 6	32	75.52	26.43	0.0	83.33	100.0	27	-4.94	29.89	-66.7	0.00	66.7
	Week 7	31	77.42	25.29	0.0	83.33	100.0	26	-4.49	28.50	-66.7	0.00	66.7
	Week 8	32	74.48	24.31	33.3	83.33	100.0	27	-6.17	27.41	-66.7	0.00	66.7
	Week 9	30	72.22	28.14	0.0	83.33	100.0	25	-8.67	26.40	-83.3	0.00	33.3
	Week 10	30	75.00	25.43	16.7	83.33	100.0	26	-5.77	24.47	-50.0	0.00	50.0
	Week 11	29	70.69	29.09	0.0	66.67	100.0	25	-11.33	32.17	-83.3	0.00	66.7

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Table 302.1.3002.13.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 12	28	71.43	26.78	0.0	66.67	100.0	23	-10.87	32.41	-83.3	0.00	33.3
	Week 14	28	72.62	25.75	0.0	66.67	100.0	23	-10.87	27.80	-66.7	0.00	33.3
	Week 17	25	72.67	28.82	0.0	83.33	100.0	21	-11.91	26.43	-66.7	0.00	33.3
	Week 20	23	75.36	24.55	16.7	83.33	100.0	20	-8.33	27.84	-66.7	-8.33	66.7
	Week 23	20	83.33	22.30	33.3	100.00	100.0	17	-0.98	27.30	-66.7	0.00	66.7
	Week 26	21	80.16	26.68	0.0	83.33	100.0	18	-0.93	32.07	-66.7	0.00	66.7
	Week 29	19	77.19	26.18	0.0	83.33	100.0	16	-2.08	29.11	-66.7	0.00	66.7
	Week 32	18	85.19	18.86	50.0	100.00	100.0	15	5.56	24.13	-33.3	0.00	66.7
	Week 35	19	81.58	19.95	33.3	83.33	100.0	16	3.13	27.37	-33.3	0.00	66.7
	Week 38	15	84.44	18.33	50.0	83.33	100.0	12	-1.39	21.86	-33.3	0.00	33.3
	Week 41	15	78.89	29.86	0.0	100.00	100.0	12	-5.56	23.92	-33.3	0.00	33.3
	Week 44	14	76.19	30.46	16.7	91.67	100.0	11	-7.58	31.94	-83.3	0.00	33.3
	Week 47	12	83.33	23.57	33.3	100.00	100.0	10	-3.33	29.19	-66.7	0.00	33.3
	Week 50	11	78.79	25.92	33.3	83.33	100.0	8	0.00	32.12	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
EV+Pembro (N=240)												
BASELINE	206	86.33	19.49	0.0	100.00	100.0						
Week 1	190	86.23	18.20	0.0	100.00	100.0	184	0.00	15.09	-33.3	0.00	50.0
Week 2	203	84.73	19.54	0.0	100.00	100.0	189	-2.29	16.77	-66.7	0.00	66.7
Week 3	198	85.10	19.54	0.0	100.00	100.0	182	-1.47	18.81	-66.7	0.00	66.7
Week 4	194	85.65	18.86	0.0	100.00	100.0	179	-0.93	19.49	-66.7	0.00	66.7
Week 5	190	86.58	19.24	16.7	100.00	100.0	173	0.10	20.37	-50.0	0.00	66.7
Week 6	188	86.79	19.46	16.7	100.00	100.0	170	-0.29	17.90	-66.7	0.00	66.7
Week 7	195	87.18	19.17	0.0	100.00	100.0	176	-0.09	20.82	-100.0	0.00	66.7
Week 8	191	86.21	20.06	0.0	100.00	100.0	171	-0.19	20.05	-66.7	0.00	66.7
Week 9	197	86.63	18.18	16.7	100.00	100.0	180	-0.65	20.19	-66.7	0.00	66.7
Week 10	191	87.00	18.60	16.7	100.00	100.0	175	0.00	21.07	-83.3	0.00	66.7
Week 11	194	87.37	18.57	0.0	100.00	100.0	175	0.86	21.24	-100.0	0.00	66.7
Week 12	186	86.83	17.88	16.7	100.00	100.0	171	-0.29	21.12	-66.7	0.00	100.0
Week 14	185	86.04	19.55	0.0	100.00	100.0	167	-0.70	23.81	-100.0	0.00	100.0
Week 17	178	86.61	17.81	16.7	100.00	100.0	162	-0.31	21.22	-66.7	0.00	66.7
Week 20	167	84.63	19.70	0.0	100.00	100.0	154	-2.92	24.04	-100.0	0.00	83.3
Week 23	162	83.64	19.87	16.7	100.00	100.0	151	-3.75	24.20	-66.7	0.00	100.0
Week 26	156	84.83	19.16	33.3	100.00	100.0	144	-2.55	23.76	-66.7	0.00	83.3
Week 29	157	85.77	17.48	33.3	83.33	100.0	145	-1.49	21.86	-66.7	0.00	83.3
Week 32	135	83.83	19.52	0.0	100.00	100.0	125	-2.80	21.87	-66.7	0.00	66.7
Week 35	132	85.48	17.03	33.3	83.33	100.0	122	-2.46	20.18	-50.0	0.00	83.3
Week 38	132	83.59	21.60	0.0	100.00	100.0	124	-3.23	21.43	-66.7	0.00	66.7
Week 41	129	82.95	20.46	33.3	100.00	100.0	119	-5.60	22.47	-66.7	0.00	66.7
Week 44	108	82.25	20.16	16.7	83.33	100.0	100	-5.33	22.46	-66.7	0.00	66.7
Week 47	100	84.67	19.63	33.3	100.00	100.0	94	-3.37	23.00	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	89	83.89	20.01	33.3	83.33	100.0	84	-5.75	20.94	-66.7	0.00	66.7
Week 53	79	81.43	21.18	16.7	83.33	100.0	74	-7.43	22.60	-83.3	0.00	66.7
Week 56	81	84.16	20.73	16.7	100.00	100.0	76	-4.17	22.30	-83.3	0.00	66.7
Week 59	72	82.64	21.38	16.7	83.33	100.0	68	-5.15	23.61	-83.3	0.00	66.7
Week 62	65	83.33	20.41	16.7	100.00	100.0	63	-5.55	22.60	-83.3	0.00	66.7
Week 65	58	79.31	23.22	16.7	83.33	100.0	54	-8.33	24.60	-83.3	0.00	66.7
Week 68	53	83.96	20.92	33.3	100.00	100.0	52	-4.49	23.60	-66.7	0.00	66.7
Week 71	51	83.33	19.44	33.3	83.33	100.0	49	-3.40	21.24	-66.7	0.00	66.7
Week 74	47	81.92	21.37	33.3	100.00	100.0	46	-5.07	25.31	-66.7	0.00	66.7
Week 77	44	79.17	20.37	33.3	83.33	100.0	42	-8.73	23.92	-66.7	0.00	50.0
Week 80	40	80.00	20.04	33.3	83.33	100.0	37	-4.95	20.74	-66.7	0.00	33.3
Week 83	37	77.93	21.17	33.3	83.33	100.0	35	-7.14	22.61	-50.0	0.00	33.3
Week 86	34	78.43	21.53	33.3	83.33	100.0	31	-6.45	23.44	-50.0	0.00	33.3
Week 89	33	75.76	22.47	33.3	83.33	100.0	31	-7.53	21.87	-50.0	0.00	33.3
Week 92	27	78.40	21.09	16.7	83.33	100.0	25	-8.00	21.04	-50.0	0.00	16.7
Week 95	22	81.82	19.86	33.3	83.33	100.0	21	-4.76	19.11	-33.3	0.00	33.3
Week 98	18	78.70	19.64	50.0	75.00	100.0	17	-0.98	19.96	-33.3	0.00	33.3
Week 101	14	78.57	18.98	50.0	75.00	100.0	14	-5.95	19.18	-50.0	0.00	16.7
Week 104	10	80.00	20.49	50.0	83.33	100.0	10	-6.67	22.50	-50.0	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Plat+Gem (N=242)												
BASELINE	188	82.89	20.06	16.7	83.33	100.0						
Week 1	173	81.31	20.74	0.0	83.33	100.0	158	-2.85	17.26	-66.7	0.00	50.0
Week 2	171	79.92	21.69	0.0	83.33	100.0	151	-3.53	21.22	-66.7	0.00	83.3
Week 3	184	83.42	19.05	16.7	83.33	100.0	162	-0.93	18.32	-66.7	0.00	50.0
Week 4	183	82.88	20.18	0.0	83.33	100.0	156	-1.39	18.45	-66.7	0.00	83.3
Week 5	187	81.73	20.53	16.7	83.33	100.0	156	-3.31	16.55	-50.0	0.00	50.0
Week 6	174	82.28	20.52	0.0	83.33	100.0	149	-1.34	16.27	-50.0	0.00	50.0
Week 7	186	82.35	20.07	33.3	83.33	100.0	157	-1.49	17.64	-66.7	0.00	66.7
Week 8	167	80.44	21.02	16.7	83.33	100.0	144	-4.63	20.24	-83.3	0.00	50.0
Week 9	177	80.51	21.28	0.0	83.33	100.0	150	-2.89	19.86	-50.0	0.00	50.0
Week 10	166	79.32	21.33	16.7	83.33	100.0	139	-5.28	20.27	-83.3	0.00	50.0
Week 11	168	80.85	21.55	0.0	83.33	100.0	143	-2.56	18.05	-50.0	0.00	50.0
Week 12	159	80.92	21.37	0.0	83.33	100.0	138	-2.66	18.37	-50.0	0.00	50.0
Week 14	153	80.39	19.69	0.0	83.33	100.0	128	-4.04	18.79	-50.0	0.00	50.0
Week 17	155	80.54	21.64	0.0	83.33	100.0	130	-3.85	21.42	-66.7	0.00	50.0
Week 20	126	81.75	19.60	0.0	83.33	100.0	110	-3.48	18.07	-66.7	0.00	33.3
Week 23	115	82.61	21.67	0.0	83.33	100.0	97	-2.92	22.18	-66.7	0.00	50.0
Week 26	108	82.72	21.61	0.0	83.33	100.0	95	-4.21	19.44	-66.7	0.00	50.0
Week 29	100	85.00	17.65	33.3	83.33	100.0	86	-3.88	16.30	-50.0	0.00	50.0
Week 32	83	82.53	20.48	0.0	83.33	100.0	76	-4.39	17.92	-66.7	0.00	33.3
Week 35	76	83.55	19.53	16.7	83.33	100.0	69	-4.11	20.09	-66.7	0.00	50.0
Week 38	74	83.78	19.70	0.0	83.33	100.0	65	-4.10	20.84	-66.7	0.00	50.0
Week 41	65	81.54	20.65	0.0	83.33	100.0	56	-5.65	19.66	-66.7	0.00	50.0
Week 44	60	81.39	21.72	0.0	83.33	100.0	53	-7.86	20.31	-66.7	0.00	50.0
Week 47	56	82.74	20.09	0.0	83.33	100.0	49	-6.80	23.55	-100.0	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	51	79.74	22.44	0.0	83.33	100.0	47	-10.28	19.83	-66.7	0.00	33.3
Week 53	46	86.23	15.83	50.0	91.67	100.0	42	-3.57	15.85	-50.0	0.00	50.0
Week 56	39	82.91	21.11	16.7	83.33	100.0	34	-3.43	21.23	-50.0	0.00	50.0
Week 59	37	84.68	19.79	16.7	100.00	100.0	33	-3.54	16.01	-50.0	0.00	16.7
Week 62	32	86.46	16.63	50.0	100.00	100.0	29	-1.72	16.27	-50.0	0.00	50.0
Week 65	30	86.11	18.61	33.3	100.00	100.0	26	-2.56	12.19	-33.3	0.00	16.7
Week 68	25	83.33	19.24	33.3	83.33	100.0	21	-6.35	19.35	-50.0	0.00	33.3
Week 71	22	80.30	22.79	16.7	83.33	100.0	19	-7.02	16.02	-33.3	0.00	16.7
Week 74	21	85.71	20.61	33.3	100.00	100.0	18	-3.70	17.67	-50.0	0.00	33.3
Week 77	18	84.26	21.75	33.3	100.00	100.0	15	-6.67	15.17	-50.0	0.00	16.7
Week 80	14	85.71	14.41	66.7	83.33	100.0	13	-7.69	11.00	-33.3	0.00	0.0
Week 83	13	84.62	14.37	66.7	83.33	100.0	12	-8.33	13.29	-33.3	0.00	0.0
Week 86	12	88.89	14.79	66.7	100.00	100.0	11	-4.55	13.10	-33.3	0.00	16.7
Week 89	11	84.85	20.35	50.0	100.00	100.0	10	-6.67	17.92	-50.0	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Present	EV+Pembro (N= 48)												
	BASELINE	39	80.34	26.46	0.0	83.33	100.0						
	Week 1	32	82.29	21.14	33.3	83.33	100.0	32	2.60	19.91	-33.3	0.00	50.0
	Week 2	37	78.38	22.52	33.3	83.33	100.0	33	-3.03	21.43	-50.0	0.00	50.0
	Week 3	34	73.04	28.43	0.0	75.00	100.0	29	-4.02	26.60	-66.7	0.00	50.0
	Week 4	36	75.46	24.07	0.0	66.67	100.0	31	-3.76	26.77	-66.7	0.00	50.0
	Week 5	30	79.44	23.03	16.7	83.33	100.0	24	1.39	28.20	-50.0	0.00	66.7
	Week 6	31	80.11	26.32	16.7	100.00	100.0	25	0.00	23.07	-50.0	0.00	50.0
	Week 7	34	78.43	27.07	0.0	83.33	100.0	28	0.59	27.77	-100.0	0.00	50.0
	Week 8	35	77.14	26.53	0.0	83.33	100.0	30	-1.11	20.03	-50.0	0.00	50.0
	Week 9	34	80.88	22.89	16.7	83.33	100.0	30	0.00	25.14	-50.0	0.00	66.7
	Week 10	34	78.92	23.32	16.7	83.33	100.0	30	0.00	26.26	-83.3	0.00	66.7
	Week 11	33	78.28	24.82	0.0	83.33	100.0	28	-1.79	31.21	-100.0	0.00	50.0
	Week 12	33	83.33	22.44	16.7	100.00	100.0	29	2.30	30.77	-50.0	0.00	100.0
	Week 14	31	78.49	25.53	0.0	83.33	100.0	26	-1.92	36.31	-100.0	0.00	100.0
	Week 17	31	76.34	23.08	16.7	83.33	100.0	25	-4.67	29.86	-66.7	0.00	66.7
	Week 20	27	75.93	25.04	0.0	83.33	100.0	24	-5.56	36.00	-100.0	0.00	66.7
	Week 23	26	80.13	17.65	50.0	83.33	100.0	23	0.72	29.51	-50.0	0.00	100.0
	Week 26	25	84.00	18.31	50.0	83.33	100.0	22	3.03	30.27	-50.0	0.00	83.3
	Week 29	23	86.96	16.63	50.0	100.00	100.0	22	3.03	28.93	-50.0	0.00	83.3
	Week 32	21	80.16	17.96	50.0	83.33	100.0	19	0.00	24.84	-50.0	0.00	50.0
	Week 35	19	86.84	13.12	66.7	83.33	100.0	17	3.92	27.97	-33.3	0.00	83.3
	Week 38	18	73.15	34.84	0.0	91.67	100.0	17	-4.90	27.49	-66.7	0.00	50.0
	Week 41	20	81.67	22.88	33.3	91.67	100.0	19	-4.39	27.13	-66.7	0.00	50.0
	Week 44	17	81.37	18.52	50.0	83.33	100.0	15	-4.44	24.77	-50.0	0.00	50.0
	Week 47	18	83.33	20.61	33.3	91.67	100.0	16	-3.13	26.68	-66.7	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	12	86.11	23.39	33.3	100.00	100.0	11	-7.58	22.81	-66.7	0.00	16.7
	Week 53	12	79.17	28.54	16.7	91.67	100.0	11	-12.12	31.70	-83.3	0.00	33.3
	Week 56	13	83.33	26.35	16.7	100.00	100.0	12	-6.94	30.53	-83.3	0.00	50.0
	Week 59	12	84.72	27.02	16.7	100.00	100.0	11	-6.06	31.86	-83.3	0.00	50.0
	Week 62	10	85.00	27.72	16.7	100.00	100.0	9	-5.55	34.36	-83.3	0.00	50.0
	Week 65	10	83.33	29.40	16.7	100.00	100.0	9	-7.41	35.46	-83.3	0.00	50.0
	Plat+Gem (N= 48)												
	BASELINE	33	81.82	19.70	33.3	83.33	100.0						
	Week 1	31	78.49	22.02	0.0	83.33	100.0	27	-2.47	19.99	-66.7	0.00	33.3
	Week 2	29	78.74	26.69	0.0	83.33	100.0	24	-2.78	24.90	-66.7	0.00	66.7
	Week 3	32	85.42	15.12	50.0	83.33	100.0	27	1.23	18.45	-16.7	0.00	50.0
	Week 4	32	85.42	17.33	50.0	91.67	100.0	24	0.69	19.95	-33.3	0.00	66.7
	Week 5	36	83.33	20.31	33.3	100.00	100.0	28	-1.79	13.10	-33.3	0.00	33.3
	Week 6	35	80.95	22.92	0.0	83.33	100.0	27	1.23	13.81	-33.3	0.00	33.3
	Week 7	38	83.33	22.59	33.3	100.00	100.0	29	2.87	20.92	-50.0	0.00	66.7
	Week 8	31	84.41	17.18	50.0	83.33	100.0	25	-0.67	14.01	-16.7	0.00	33.3
	Week 9	32	80.73	19.90	16.7	83.33	100.0	25	3.33	15.21	-16.7	0.00	50.0
	Week 10	34	80.88	19.30	33.3	83.33	100.0	26	1.28	19.39	-33.3	0.00	50.0
	Week 11	30	85.00	21.60	16.7	100.00	100.0	24	4.86	13.44	-16.7	0.00	33.3
	Week 12	28	85.71	19.09	33.3	100.00	100.0	23	6.52	13.04	-16.7	0.00	33.3
	Week 14	26	83.33	15.63	50.0	83.33	100.0	21	-0.79	11.15	-16.7	0.00	16.7
	Week 17	30	82.78	18.82	33.3	83.33	100.0	25	1.33	19.20	-33.3	0.00	50.0
	Week 20	23	86.23	15.61	66.7	100.00	100.0	21	0.79	13.41	-33.3	0.00	33.3
	Week 23	22	84.09	20.88	16.7	91.67	100.0	19	-1.75	22.83	-50.0	0.00	50.0
	Week 26	19	88.60	15.76	66.7	100.00	100.0	18	-0.93	13.37	-33.3	0.00	33.3
	Week 29	16	88.54	14.55	66.7	100.00	100.0	14	-1.19	15.28	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 32	11	86.36	16.36	66.7	100.00	100.0	11	-4.54	10.78	-33.3	0.00	0.0
	Week 35	10	91.67	11.79	66.7	100.00	100.0	9	-1.85	5.56	-16.7	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Absent	EV+Pembro (N=192)												
	BASELINE	167	87.72	17.28	0.0	100.00	100.0						
	Week 1	158	87.03	17.51	0.0	100.00	100.0	152	-0.55	13.89	-33.3	0.00	33.3
	Week 2	166	86.14	18.59	0.0	100.00	100.0	156	-2.14	15.69	-66.7	0.00	66.7
	Week 3	164	87.60	16.16	33.3	100.00	100.0	153	-0.98	17.02	-50.0	0.00	66.7
	Week 4	158	87.97	16.71	16.7	100.00	100.0	148	-0.34	17.65	-50.0	0.00	66.7
	Week 5	160	87.92	18.21	16.7	100.00	100.0	149	-0.11	18.93	-50.0	0.00	66.7
	Week 6	157	88.11	17.61	16.7	100.00	100.0	145	-0.34	16.95	-66.7	0.00	66.7
	Week 7	161	89.03	16.57	33.3	100.00	100.0	148	-0.22	19.34	-66.7	0.00	66.7
	Week 8	156	88.25	17.78	0.0	100.00	100.0	141	0.00	20.12	-66.7	0.00	66.7
	Week 9	163	87.83	16.88	33.3	100.00	100.0	150	-0.78	19.15	-66.7	0.00	66.7
	Week 10	157	88.75	17.01	33.3	100.00	100.0	145	0.00	19.93	-66.7	0.00	66.7
	Week 11	161	89.23	16.50	16.7	100.00	100.0	147	1.36	18.86	-50.0	0.00	66.7
	Week 12	153	87.58	16.72	33.3	100.00	100.0	142	-0.82	18.66	-66.7	0.00	66.7
	Week 14	154	87.55	17.83	33.3	100.00	100.0	141	-0.47	20.89	-66.7	0.00	66.7
	Week 17	147	88.78	15.75	33.3	100.00	100.0	137	0.49	19.27	-50.0	0.00	66.7
	Week 20	140	86.31	18.13	16.7	100.00	100.0	130	-2.44	21.28	-50.0	0.00	83.3
	Week 23	136	84.31	20.26	16.7	100.00	100.0	128	-4.56	23.17	-66.7	0.00	66.7
	Week 26	131	84.99	19.38	33.3	100.00	100.0	122	-3.55	22.39	-66.7	0.00	66.7
	Week 29	134	85.57	17.67	33.3	83.33	100.0	123	-2.30	20.39	-66.7	0.00	66.7
	Week 32	114	84.50	19.80	0.0	100.00	100.0	106	-3.30	21.38	-66.7	0.00	66.7
	Week 35	113	85.25	17.64	33.3	83.33	100.0	105	-3.49	18.59	-50.0	0.00	66.7
	Week 38	114	85.23	18.39	33.3	100.00	100.0	107	-2.96	20.45	-50.0	0.00	66.7
	Week 41	109	83.18	20.09	33.3	100.00	100.0	100	-5.83	21.63	-50.0	0.00	66.7
	Week 44	91	82.42	20.54	16.7	83.33	100.0	85	-5.49	22.18	-66.7	0.00	66.7
	Week 47	82	84.96	19.53	33.3	100.00	100.0	78	-3.42	22.37	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	77	83.55	19.59	33.3	83.33	100.0	73	-5.48	20.80	-66.7	0.00	66.7
	Week 53	67	81.84	19.83	33.3	83.33	100.0	63	-6.61	20.86	-66.7	0.00	66.7
	Week 56	68	84.31	19.72	33.3	100.00	100.0	64	-3.65	20.67	-66.7	0.00	66.7
	Week 59	60	82.22	20.32	16.7	83.33	100.0	57	-4.97	22.04	-66.7	0.00	66.7
	Week 62	55	83.03	19.11	33.3	83.33	100.0	54	-5.56	20.48	-50.0	0.00	66.7
	Week 65	48	78.47	22.00	16.7	83.33	100.0	45	-8.52	22.37	-50.0	0.00	66.7
	Week 68	46	84.06	20.47	33.3	91.67	100.0	45	-4.07	22.80	-50.0	0.00	66.7
	Week 71	44	84.09	18.66	33.3	83.33	100.0	42	-2.78	19.79	-50.0	0.00	66.7
	Week 74	40	82.50	20.31	33.3	91.67	100.0	39	-4.70	23.55	-66.7	0.00	66.7
	Week 77	38	78.07	20.17	33.3	83.33	100.0	36	-9.72	22.67	-66.7	0.00	16.7
	Week 80	35	80.48	19.17	33.3	83.33	100.0	32	-4.17	17.96	-33.3	0.00	16.7
	Week 83	32	77.60	21.42	33.3	75.00	100.0	30	-7.22	21.74	-50.0	0.00	33.3
	Week 86	29	78.16	21.87	33.3	83.33	100.0	26	-6.41	22.65	-50.0	0.00	33.3
	Week 89	29	75.86	22.97	33.3	83.33	100.0	27	-7.41	20.33	-50.0	0.00	16.7
	Week 92	24	77.08	21.32	16.7	75.00	100.0	22	-7.58	21.66	-50.0	0.00	16.7
	Week 95	20	81.67	20.16	33.3	83.33	100.0	19	-3.51	18.90	-33.3	0.00	33.3
	Week 98	18	78.70	19.64	50.0	75.00	100.0	17	-0.98	19.96	-33.3	0.00	33.3
	Week 101	13	80.77	17.80	50.0	83.33	100.0	13	-2.56	14.98	-33.3	0.00	16.7
	Plat+Gem (N=194)												
	BASELINE	155	83.12	20.19	16.7	83.33	100.0						
	Week 1	142	81.93	20.48	0.0	83.33	100.0	131	-2.93	16.73	-33.3	0.00	50.0
	Week 2	142	80.16	20.62	0.0	83.33	100.0	127	-3.67	20.56	-66.7	0.00	83.3
	Week 3	152	83.00	19.79	16.7	83.33	100.0	135	-1.36	18.33	-66.7	0.00	50.0
	Week 4	151	82.34	20.75	0.0	83.33	100.0	132	-1.77	18.22	-66.7	0.00	83.3
	Week 5	151	81.35	20.63	16.7	83.33	100.0	128	-3.65	17.24	-50.0	0.00	50.0
	Week 6	139	82.61	19.95	16.7	83.33	100.0	122	-1.91	16.76	-50.0	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 7	148	82.09	19.45	33.3	83.33	100.0	128	-2.47	16.74	-66.7	0.00	50.0
	Week 8	136	79.53	21.75	16.7	83.33	100.0	119	-5.46	21.27	-83.3	0.00	50.0
	Week 9	145	80.46	21.64	0.0	83.33	100.0	125	-4.13	20.48	-50.0	0.00	50.0
	Week 10	132	78.91	21.88	16.7	83.33	100.0	113	-6.78	20.25	-83.3	0.00	50.0
	Week 11	138	79.95	21.52	0.0	83.33	100.0	119	-4.06	18.53	-50.0	0.00	50.0
	Week 12	131	79.90	21.75	0.0	83.33	100.0	115	-4.49	18.77	-50.0	0.00	50.0
	Week 14	127	79.79	20.43	0.0	83.33	100.0	107	-4.67	19.93	-50.0	0.00	50.0
	Week 17	125	80.00	22.30	0.0	83.33	100.0	105	-5.08	21.82	-66.7	0.00	50.0
	Week 20	103	80.74	20.31	0.0	83.33	100.0	89	-4.49	18.93	-66.7	0.00	33.3
	Week 23	93	82.26	21.95	0.0	83.33	100.0	78	-3.21	22.16	-66.7	0.00	50.0
	Week 26	89	81.46	22.53	0.0	83.33	100.0	77	-4.98	20.60	-66.7	0.00	50.0
	Week 29	84	84.32	18.17	33.3	83.33	100.0	72	-4.40	16.55	-50.0	0.00	50.0
	Week 32	72	81.94	21.07	0.0	83.33	100.0	65	-4.36	18.93	-66.7	0.00	33.3
	Week 35	66	82.32	20.23	16.7	83.33	100.0	60	-4.44	21.45	-66.7	0.00	50.0
	Week 38	66	82.83	20.25	0.0	83.33	100.0	57	-4.09	22.11	-66.7	0.00	50.0
	Week 41	62	81.99	20.53	0.0	83.33	100.0	53	-5.35	20.09	-66.7	0.00	50.0
	Week 44	55	80.91	22.32	0.0	83.33	100.0	48	-7.64	21.18	-66.7	0.00	50.0
	Week 47	51	82.35	20.66	0.0	83.33	100.0	44	-6.44	24.70	-100.0	0.00	50.0
	Week 50	48	78.82	22.74	0.0	83.33	100.0	44	-10.61	20.36	-66.7	0.00	33.3
	Week 53	41	85.77	16.48	50.0	100.00	100.0	37	-3.60	16.26	-50.0	0.00	50.0
	Week 56	34	82.84	21.90	16.7	91.67	100.0	29	-1.72	21.98	-50.0	0.00	50.0
	Week 59	32	83.33	20.30	16.7	83.33	100.0	28	-4.17	16.74	-50.0	0.00	16.7
	Week 62	27	85.19	16.88	50.0	100.00	100.0	24	-2.08	17.25	-50.0	0.00	50.0
	Week 65	25	86.67	18.00	33.3	100.00	100.0	21	-0.79	8.29	-16.7	0.00	16.7
	Week 68	23	84.78	16.60	50.0	83.33	100.0	19	-4.39	17.43	-50.0	0.00	33.3
	Week 71	21	80.95	23.14	16.7	83.33	100.0	18	-6.48	16.31	-33.3	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 74	20	85.00	20.87	33.3	100.00	100.0	17	-3.92	18.19	-50.0	0.00	33.3
	Week 77	16	83.33	22.77	33.3	100.00	100.0	13	-6.41	16.01	-50.0	0.00	16.7
	Week 80	12	84.72	15.00	66.7	83.33	100.0	11	-7.58	11.46	-33.3	0.00	0.0
	Week 83	11	84.85	13.85	66.7	83.33	100.0	10	-6.67	11.65	-33.3	0.00	0.0
	Week 86	10	88.33	15.81	66.7	100.00	100.0	9	-3.70	13.89	-33.3	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
< 65 years	EV+Pembro (N=105)												
	BASELINE	92	87.32	17.54	33.3	100.00	100.0						
	Week 1	88	87.69	16.86	50.0	100.00	100.0	85	0.00	15.00	-33.3	0.00	50.0
	Week 2	92	86.78	17.74	16.7	100.00	100.0	86	-1.74	16.57	-66.7	0.00	33.3
	Week 3	93	89.07	14.84	50.0	100.00	100.0	84	1.79	18.66	-50.0	0.00	66.7
	Week 4	90	88.89	14.99	50.0	100.00	100.0	82	1.02	18.21	-50.0	0.00	66.7
	Week 5	90	90.19	15.18	50.0	100.00	100.0	81	2.68	18.34	-50.0	0.00	66.7
	Week 6	90	90.56	14.79	33.3	100.00	100.0	81	2.47	18.47	-50.0	0.00	66.7
	Week 7	85	91.96	13.01	50.0	100.00	100.0	77	3.90	18.12	-50.0	0.00	66.7
	Week 8	89	90.64	15.68	50.0	100.00	100.0	80	2.71	20.10	-50.0	0.00	66.7
	Week 9	93	90.14	14.38	50.0	100.00	100.0	85	1.77	18.90	-50.0	0.00	66.7
	Week 10	88	90.91	15.56	33.3	100.00	100.0	81	3.29	19.79	-66.7	0.00	66.7
	Week 11	93	91.04	13.80	50.0	100.00	100.0	84	3.77	19.76	-50.0	0.00	66.7
	Week 12	86	89.54	15.13	50.0	100.00	100.0	79	1.69	19.35	-50.0	0.00	50.0
	Week 14	84	87.90	17.61	33.3	100.00	100.0	76	0.44	23.72	-66.7	0.00	66.7
	Week 17	83	89.36	14.39	33.3	100.00	100.0	77	2.60	21.81	-66.7	0.00	66.7
	Week 20	79	86.50	18.70	0.0	100.00	100.0	73	-2.28	24.74	-100.0	0.00	66.7
	Week 23	78	85.04	19.29	33.3	100.00	100.0	73	-2.97	24.11	-66.7	0.00	66.7
	Week 26	78	87.61	16.65	33.3	100.00	100.0	72	-0.46	22.37	-50.0	0.00	66.7
	Week 29	74	87.39	16.51	33.3	100.00	100.0	67	-0.25	22.94	-66.7	0.00	66.7
	Week 32	64	86.98	17.68	33.3	100.00	100.0	59	0.00	22.10	-50.0	0.00	66.7
	Week 35	62	87.37	15.88	33.3	100.00	100.0	58	-1.15	20.91	-50.0	0.00	66.7
	Week 38	62	86.56	19.98	0.0	100.00	100.0	59	-0.56	23.56	-66.7	0.00	66.7
	Week 41	64	86.46	19.22	33.3	100.00	100.0	59	-2.26	24.65	-66.7	0.00	66.7
	Week 44	50	86.33	19.54	33.3	100.00	100.0	48	-0.35	24.43	-50.0	0.00	66.7
	Week 47	47	86.52	17.60	33.3	100.00	100.0	46	-1.45	25.78	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	44	83.71	20.80	33.3	83.33	100.0	41	-6.50	24.69	-66.7	0.00	66.7
	Week 53	40	82.92	21.84	16.7	100.00	100.0	37	-5.40	27.51	-83.3	0.00	66.7
	Week 56	44	84.85	20.59	16.7	100.00	100.0	41	-3.25	25.06	-83.3	0.00	66.7
	Week 59	42	84.52	19.61	16.7	100.00	100.0	39	-4.27	24.99	-83.3	0.00	66.7
	Week 62	37	85.14	19.16	16.7	100.00	100.0	36	-4.63	26.61	-83.3	0.00	66.7
	Week 65	34	80.39	20.30	16.7	83.33	100.0	31	-5.91	29.04	-83.3	0.00	66.7
	Week 68	34	84.80	18.97	33.3	91.67	100.0	33	-3.53	26.27	-66.7	0.00	66.7
	Week 71	32	83.33	19.40	33.3	83.33	100.0	30	-2.78	26.29	-66.7	0.00	66.7
	Week 74	29	81.03	22.59	33.3	83.33	100.0	28	-6.55	30.54	-66.7	0.00	66.7
	Week 77	25	76.67	20.97	33.3	83.33	100.0	24	-11.81	28.44	-66.7	-16.66	50.0
	Week 80	24	78.47	19.34	33.3	83.33	100.0	22	-6.06	24.96	-66.7	0.00	33.3
	Week 83	23	77.54	18.54	33.3	66.67	100.0	22	-9.09	26.09	-50.0	-8.33	33.3
	Week 86	20	76.67	21.22	33.3	75.00	100.0	18	-8.33	28.73	-50.0	0.00	33.3
	Week 89	19	75.44	21.78	33.3	66.67	100.0	17	-5.88	24.96	-50.0	0.00	33.3
	Week 92	14	77.38	16.80	50.0	66.67	100.0	12	-9.72	24.06	-50.0	-8.33	16.7
	Week 95	12	81.95	16.60	66.7	75.00	100.0	11	-6.06	22.70	-33.3	0.00	33.3
	Plat+Gem (N=106)												
	BASELINE	83	84.94	17.96	33.3	83.33	100.0						
	Week 1	75	82.67	18.87	0.0	83.33	100.0	71	-3.99	18.36	-66.7	0.00	50.0
	Week 2	76	78.95	22.50	0.0	83.33	100.0	68	-6.62	19.35	-66.7	0.00	50.0
	Week 3	80	83.96	19.20	33.3	91.67	100.0	73	-1.60	18.25	-66.7	0.00	50.0
	Week 4	79	82.70	20.23	33.3	83.33	100.0	67	-2.99	15.60	-33.3	0.00	50.0
	Week 5	80	83.54	19.93	33.3	91.67	100.0	67	-2.98	16.90	-50.0	0.00	50.0
	Week 6	76	84.43	17.92	33.3	83.33	100.0	67	0.75	16.52	-50.0	0.00	50.0
	Week 7	81	83.74	20.24	33.3	100.00	100.0	71	0.00	18.47	-50.0	0.00	66.7
	Week 8	72	82.41	19.95	33.3	83.33	100.0	64	-3.65	19.58	-50.0	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	78	82.05	19.51	33.3	83.33	100.0	69	-1.93	18.86	-50.0	0.00	50.0
	Week 10	78	79.06	21.05	16.7	83.33	100.0	68	-5.64	20.08	-33.3	0.00	50.0
	Week 11	75	82.22	19.82	33.3	83.33	100.0	66	-1.52	17.47	-50.0	0.00	50.0
	Week 12	74	83.33	19.51	33.3	91.67	100.0	66	-1.51	18.66	-50.0	0.00	50.0
	Week 14	68	83.82	17.03	33.3	83.33	100.0	58	-1.15	18.43	-50.0	0.00	50.0
	Week 17	68	82.11	21.61	0.0	83.33	100.0	58	-3.16	20.81	-50.0	0.00	50.0
	Week 20	60	82.78	18.66	33.3	83.33	100.0	52	-3.53	17.57	-50.0	0.00	33.3
	Week 23	51	84.97	21.67	16.7	100.00	100.0	44	-1.52	22.96	-50.0	0.00	50.0
	Week 26	47	84.40	19.47	33.3	100.00	100.0	42	-3.17	17.74	-50.0	0.00	50.0
	Week 29	42	84.92	18.34	33.3	83.33	100.0	37	-2.70	16.44	-33.3	0.00	50.0
	Week 32	37	82.43	18.82	33.3	83.33	100.0	34	-3.92	16.94	-33.3	0.00	33.3
	Week 35	34	86.27	18.10	33.3	100.00	100.0	31	-0.54	21.72	-50.0	0.00	50.0
	Week 38	33	85.35	17.06	50.0	83.33	100.0	28	1.19	21.72	-33.3	0.00	50.0
	Week 41	27	82.10	17.25	50.0	83.33	100.0	22	-3.03	19.68	-50.0	0.00	50.0
	Week 44	28	83.93	19.50	33.3	91.67	100.0	24	-3.47	20.25	-50.0	0.00	50.0
	Week 47	24	87.50	13.23	66.7	83.33	100.0	21	-1.59	18.93	-33.3	0.00	50.0
	Week 50	26	85.26	20.18	33.3	100.00	100.0	24	-5.56	16.79	-50.0	0.00	33.3
	Week 53	19	89.47	13.85	50.0	100.00	100.0	17	0.98	18.13	-33.3	0.00	50.0
	Week 56	13	92.31	12.94	66.7	100.00	100.0	11	4.55	22.47	-33.3	0.00	50.0
	Week 59	14	89.29	23.21	16.7	100.00	100.0	12	4.17	7.54	0.0	0.00	16.7
	Week 62	13	93.59	12.80	66.7	100.00	100.0	12	6.95	15.01	0.0	0.00	50.0
	Week 65	13	88.46	20.84	33.3	100.00	100.0	11	0.00	12.91	-33.3	0.00	16.7
	Week 68	10	88.33	17.66	50.0	100.00	100.0	8	4.17	14.77	-16.7	0.00	33.3
	Week 77	10	86.67	21.94	33.3	100.00	100.0	8	-2.08	10.68	-16.7	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>= 65 years	EV+Pembro (N=135)												
	BASELINE	114	85.53	20.98	0.0	100.00	100.0						
	Week 1	102	84.97	19.27	0.0	83.33	100.0	99	0.00	15.25	-33.3	0.00	50.0
	Week 2	111	83.03	20.84	0.0	83.33	100.0	103	-2.75	17.01	-50.0	0.00	66.7
	Week 3	105	81.59	22.40	0.0	83.33	100.0	98	-4.25	18.59	-66.7	0.00	66.7
	Week 4	104	82.85	21.34	0.0	83.33	100.0	97	-2.58	20.46	-66.7	0.00	66.7
	Week 5	100	83.33	21.84	16.7	91.67	100.0	92	-2.17	21.85	-50.0	0.00	66.7
	Week 6	98	83.33	22.45	16.7	100.00	100.0	89	-2.81	17.09	-66.7	0.00	33.3
	Week 7	110	83.48	22.18	0.0	100.00	100.0	99	-3.20	22.29	-100.0	0.00	66.7
	Week 8	102	82.35	22.60	0.0	83.33	100.0	91	-2.75	19.76	-66.7	0.00	66.7
	Week 9	104	83.49	20.58	16.7	91.67	100.0	95	-2.81	21.15	-66.7	0.00	66.7
	Week 10	103	83.66	20.34	16.7	83.33	100.0	94	-2.84	21.81	-83.3	0.00	66.7
	Week 11	101	83.99	21.59	0.0	100.00	100.0	91	-1.83	22.28	-100.0	0.00	66.7
	Week 12	100	84.50	19.71	16.7	100.00	100.0	92	-1.99	22.49	-66.7	0.00	100.0
	Week 14	101	84.49	20.98	0.0	100.00	100.0	91	-1.65	23.97	-100.0	0.00	100.0
	Week 17	95	84.21	20.10	16.7	100.00	100.0	85	-2.94	20.44	-50.0	0.00	66.7
	Week 20	88	82.95	20.53	16.7	83.33	100.0	81	-3.50	23.53	-66.7	0.00	83.3
	Week 23	84	82.34	20.43	16.7	83.33	100.0	78	-4.49	24.42	-66.7	0.00	100.0
	Week 26	78	82.05	21.11	33.3	83.33	100.0	72	-4.63	25.05	-66.7	0.00	83.3
	Week 29	83	84.34	18.28	33.3	83.33	100.0	78	-2.56	20.99	-50.0	0.00	83.3
	Week 32	71	80.99	20.76	0.0	83.33	100.0	66	-5.30	21.51	-66.7	0.00	66.7
	Week 35	70	83.81	17.94	33.3	83.33	100.0	64	-3.65	19.58	-50.0	0.00	83.3
	Week 38	70	80.95	22.75	0.0	83.33	100.0	65	-5.64	19.16	-50.0	0.00	33.3
	Week 41	65	79.49	21.20	33.3	83.33	100.0	60	-8.89	19.76	-50.0	0.00	33.3
	Week 44	58	78.74	20.18	16.7	83.33	100.0	52	-9.94	19.60	-66.7	0.00	33.3
	Week 47	53	83.02	21.31	33.3	100.00	100.0	48	-5.21	20.09	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	45	84.07	19.45	33.3	83.33	100.0	43	-5.04	16.88	-66.7	0.00	33.3
	Week 53	39	79.91	20.65	33.3	83.33	100.0	37	-9.46	16.45	-66.7	0.00	16.7
	Week 56	37	83.33	21.15	33.3	100.00	100.0	35	-5.24	18.86	-66.7	0.00	33.3
	Week 59	30	80.00	23.73	16.7	83.33	100.0	29	-6.32	22.01	-66.7	0.00	33.3
	Week 62	28	80.95	22.09	33.3	83.33	100.0	27	-6.79	16.19	-50.0	0.00	16.7
	Week 65	24	77.78	27.22	16.7	91.67	100.0	23	-11.59	16.99	-50.0	0.00	0.0
	Week 68	19	82.46	24.52	33.3	100.00	100.0	19	-6.14	18.60	-50.0	0.00	16.7
	Week 71	19	83.33	20.03	33.3	83.33	100.0	19	-4.39	9.37	-33.3	0.00	0.0
	Week 74	18	83.33	19.80	50.0	100.00	100.0	18	-2.78	14.29	-33.3	0.00	16.7
	Week 77	19	82.46	19.62	33.3	83.33	100.0	18	-4.63	15.97	-33.3	0.00	16.7
	Week 80	16	82.29	21.49	33.3	91.67	100.0	15	-3.33	12.91	-33.3	0.00	16.7
	Week 83	14	78.57	25.68	33.3	91.67	100.0	13	-3.85	15.45	-33.3	0.00	16.7
	Week 86	14	80.95	22.51	33.3	83.33	100.0	13	-3.85	13.87	-33.3	0.00	16.7
	Week 89	14	76.19	24.21	33.3	83.33	100.0	14	-9.52	18.16	-50.0	-8.33	16.7
	Week 92	13	79.49	25.60	16.7	83.33	100.0	13	-6.41	18.68	-50.0	0.00	16.7
	Week 95	10	81.67	24.15	33.3	91.67	100.0	10	-3.34	15.32	-33.3	0.00	16.7
	Week 98	10	78.33	20.86	50.0	75.00	100.0	10	-5.00	17.65	-33.3	0.00	16.7
	Plat+Gem (N=136)												
	BASELINE	105	81.27	21.52	16.7	83.33	100.0						
	Week 1	98	80.27	22.11	0.0	83.33	100.0	87	-1.92	16.36	-33.3	0.00	33.3
	Week 2	95	80.70	21.10	0.0	83.33	100.0	83	-1.00	22.44	-66.7	0.00	83.3
	Week 3	104	83.01	19.01	16.7	83.33	100.0	89	-0.37	18.46	-50.0	0.00	50.0
	Week 4	104	83.01	20.24	0.0	83.33	100.0	89	-0.19	20.33	-66.7	0.00	83.3
	Week 5	107	80.37	20.96	16.7	83.33	100.0	89	-3.56	16.37	-50.0	0.00	33.3
	Week 6	98	80.61	22.28	0.0	83.33	100.0	82	-3.05	15.96	-33.3	0.00	33.3
	Week 7	105	81.27	19.98	33.3	83.33	100.0	86	-2.71	16.93	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 8	95	78.95	21.77	16.7	83.33	100.0	80	-5.42	20.84	-83.3	0.00	50.0
	Week 9	99	79.29	22.60	0.0	83.33	100.0	81	-3.70	20.75	-50.0	0.00	33.3
	Week 10	88	79.55	21.70	16.7	83.33	100.0	71	-4.93	20.59	-83.3	0.00	33.3
	Week 11	93	79.75	22.90	0.0	83.33	100.0	77	-3.46	18.60	-50.0	0.00	33.3
	Week 12	85	78.82	22.77	0.0	83.33	100.0	72	-3.70	18.18	-50.0	0.00	33.3
	Week 14	85	77.65	21.29	0.0	83.33	100.0	70	-6.43	18.88	-50.0	0.00	50.0
	Week 17	87	79.31	21.71	0.0	83.33	100.0	72	-4.40	22.02	-66.7	0.00	50.0
	Week 20	66	80.81	20.51	0.0	83.33	100.0	58	-3.45	18.67	-66.7	0.00	33.3
	Week 23	64	80.73	21.66	0.0	83.33	100.0	53	-4.09	21.66	-66.7	0.00	33.3
	Week 26	61	81.42	23.19	0.0	83.33	100.0	53	-5.03	20.82	-66.7	0.00	33.3
	Week 29	58	85.06	17.29	33.3	83.33	100.0	49	-4.76	16.31	-50.0	0.00	33.3
	Week 32	46	82.61	21.93	0.0	83.33	100.0	42	-4.76	18.87	-66.7	0.00	33.3
	Week 35	42	81.35	20.56	16.7	83.33	100.0	38	-7.02	18.43	-66.7	0.00	33.3
	Week 38	41	82.52	21.71	0.0	83.33	100.0	37	-8.11	19.49	-66.7	0.00	33.3
	Week 41	38	81.14	22.98	0.0	83.33	100.0	34	-7.35	19.76	-66.7	0.00	33.3
	Week 44	32	79.17	23.57	0.0	83.33	100.0	29	-11.49	19.97	-66.7	0.00	16.7
	Week 47	32	79.17	23.57	0.0	83.33	100.0	28	-10.71	26.14	-100.0	0.00	33.3
	Week 50	25	74.00	23.61	0.0	66.67	100.0	23	-15.22	21.85	-66.7	-16.66	33.3
	Week 53	27	83.95	16.97	50.0	83.33	100.0	25	-6.67	13.61	-50.0	0.00	16.7
	Week 56	26	78.21	22.98	16.7	83.33	100.0	23	-7.25	19.99	-50.0	0.00	16.7
	Week 59	23	81.88	17.34	50.0	83.33	100.0	21	-7.94	17.96	-50.0	0.00	16.7
	Week 62	19	81.58	17.47	50.0	83.33	100.0	17	-7.84	14.57	-50.0	0.00	0.0
	Week 65	17	84.31	17.15	50.0	83.33	100.0	15	-4.44	11.73	-33.3	0.00	16.7
	Week 68	15	80.00	20.12	33.3	83.33	100.0	13	-12.82	19.43	-50.0	-16.66	16.7
	Week 71	15	77.78	18.54	50.0	66.67	100.0	13	-11.54	17.19	-33.3	0.00	16.7
	Week 74	12	84.72	20.67	50.0	100.00	100.0	11	-6.06	21.44	-50.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Europe	EV+Pembro (N= 98)												
	BASELINE	79	90.93	13.82	50.0	100.00	100.0						
	Week 1	74	89.86	14.55	50.0	100.00	100.0	71	-2.11	11.93	-33.3	0.00	33.3
	Week 2	79	89.45	14.66	33.3	100.00	100.0	71	-3.76	15.48	-50.0	0.00	33.3
	Week 3	78	88.03	14.93	50.0	100.00	100.0	69	-3.38	13.88	-50.0	0.00	33.3
	Week 4	78	88.89	15.35	33.3	100.00	100.0	70	-3.33	16.45	-50.0	0.00	33.3
	Week 5	70	89.76	16.12	33.3	100.00	100.0	62	-2.15	16.93	-50.0	0.00	33.3
	Week 6	70	90.95	14.93	33.3	100.00	100.0	61	-0.82	16.22	-50.0	0.00	33.3
	Week 7	78	91.45	14.15	50.0	100.00	100.0	68	-0.49	14.67	-33.3	0.00	33.3
	Week 8	72	90.74	14.50	50.0	100.00	100.0	61	-1.64	16.30	-50.0	0.00	33.3
	Week 9	80	90.62	14.96	50.0	100.00	100.0	70	-1.43	15.73	-50.0	0.00	33.3
	Week 10	71	89.67	16.27	33.3	100.00	100.0	62	-1.34	17.67	-66.7	0.00	33.3
	Week 11	76	90.57	16.63	16.7	100.00	100.0	66	0.00	17.05	-50.0	0.00	33.3
	Week 12	73	90.18	15.92	33.3	100.00	100.0	65	-1.03	16.63	-50.0	0.00	33.3
	Week 14	74	89.86	16.28	33.3	100.00	100.0	64	-2.08	19.36	-66.7	0.00	33.3
	Week 17	70	89.52	15.06	33.3	100.00	100.0	62	-0.81	17.96	-66.7	0.00	33.3
	Week 20	70	87.62	18.32	0.0	100.00	100.0	63	-2.91	22.11	-100.0	0.00	33.3
	Week 23	61	85.52	19.12	33.3	100.00	100.0	57	-4.97	18.62	-66.7	0.00	33.3
	Week 26	62	88.71	15.02	50.0	100.00	100.0	55	-3.03	13.64	-50.0	0.00	16.7
	Week 29	63	88.09	16.24	33.3	100.00	100.0	57	-2.92	15.15	-66.7	0.00	16.7
	Week 32	51	88.24	15.74	50.0	100.00	100.0	47	-2.13	14.59	-50.0	0.00	33.3
	Week 35	56	90.18	14.49	50.0	100.00	100.0	52	-2.24	13.21	-33.3	0.00	33.3
	Week 38	51	90.85	13.46	50.0	100.00	100.0	48	-1.04	13.49	-50.0	0.00	33.3
	Week 41	52	87.18	19.42	33.3	100.00	100.0	48	-5.21	18.56	-66.7	0.00	33.3
	Week 44	43	85.66	19.10	33.3	100.00	100.0	39	-5.13	18.79	-50.0	0.00	33.3
	Week 47	39	88.46	18.00	33.3	100.00	100.0	36	-3.70	20.36	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	37	88.29	16.60	33.3	100.00	100.0	36	-2.78	17.59	-66.7	0.00	33.3
	Week 53	28	85.71	22.09	16.7	100.00	100.0	27	-4.94	22.56	-83.3	0.00	33.3
	Week 56	30	88.33	21.06	16.7	100.00	100.0	29	-4.02	21.66	-83.3	0.00	33.3
	Week 59	27	85.80	20.52	16.7	100.00	100.0	27	-6.17	21.26	-83.3	0.00	33.3
	Week 62	23	85.51	20.90	16.7	100.00	100.0	23	-6.52	23.96	-83.3	0.00	33.3
	Week 65	23	84.78	21.27	16.7	100.00	100.0	23	-5.80	22.81	-83.3	0.00	33.3
	Week 68	21	86.51	21.49	33.3	100.00	100.0	21	-3.97	24.67	-66.7	0.00	33.3
	Week 71	19	85.09	19.16	33.3	100.00	100.0	19	-3.51	21.93	-66.7	0.00	33.3
	Week 74	15	81.11	25.09	33.3	100.00	100.0	15	-8.89	29.46	-66.7	0.00	33.3
	Week 77	19	80.70	20.98	33.3	83.33	100.0	19	-10.53	23.71	-66.7	0.00	16.7
	Week 80	17	87.25	19.12	33.3	100.00	100.0	17	-2.94	21.44	-66.7	0.00	16.7
	Week 83	16	87.50	17.74	50.0	100.00	100.0	16	-2.08	21.84	-50.0	0.00	33.3
	Week 86	14	85.71	19.45	50.0	100.00	100.0	14	-4.76	23.05	-50.0	0.00	33.3
	Week 89	14	88.10	16.57	50.0	100.00	100.0	14	-2.38	18.32	-50.0	0.00	16.7
	Week 92	11	86.36	17.98	50.0	100.00	100.0	11	-3.03	22.13	-50.0	0.00	16.7
	Week 95	10	93.33	11.65	66.7	100.00	100.0	10	-1.67	18.34	-33.3	0.00	33.3
	Plat+Gem (N=102)												
	BASELINE	71	82.86	20.89	16.7	83.33	100.0						
	Week 1	71	78.87	24.55	0.0	83.33	100.0	61	-4.92	17.04	-66.7	0.00	33.3
	Week 2	67	79.35	23.41	0.0	83.33	100.0	56	-3.87	20.35	-66.7	0.00	66.7
	Week 3	68	83.58	20.05	16.7	83.33	100.0	56	0.00	16.51	-33.3	0.00	50.0
	Week 4	75	82.67	18.06	33.3	83.33	100.0	59	-1.70	17.15	-33.3	0.00	50.0
	Week 5	77	83.12	20.85	16.7	100.00	100.0	60	-2.50	16.47	-50.0	0.00	33.3
	Week 6	70	81.19	20.45	16.7	83.33	100.0	56	-2.98	14.94	-33.3	0.00	33.3
	Week 7	72	81.71	19.81	33.3	83.33	100.0	55	-2.12	16.37	-50.0	0.00	33.3
	Week 8	65	79.23	21.86	16.7	83.33	100.0	53	-5.35	22.59	-83.3	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	70	77.86	22.83	16.7	83.33	100.0	55	-5.45	19.53	-50.0	0.00	33.3
	Week 10	60	73.89	22.21	16.7	66.67	100.0	46	-12.32	20.32	-83.3	0.00	33.3
	Week 11	64	77.08	22.32	16.7	83.33	100.0	50	-6.33	17.46	-50.0	0.00	33.3
	Week 12	60	78.06	22.02	33.3	83.33	100.0	48	-4.51	17.44	-50.0	0.00	33.3
	Week 14	56	76.49	19.79	33.3	83.33	100.0	42	-8.73	19.21	-50.0	0.00	50.0
	Week 17	58	80.17	19.86	16.7	83.33	100.0	44	-4.92	20.52	-66.7	0.00	50.0
	Week 20	47	81.92	18.00	33.3	83.33	100.0	37	-4.95	17.51	-50.0	0.00	33.3
	Week 23	44	85.61	16.70	50.0	91.67	100.0	32	-2.08	19.28	-50.0	0.00	33.3
	Week 26	39	82.48	24.17	0.0	100.00	100.0	30	-6.67	19.38	-66.7	0.00	33.3
	Week 29	34	85.29	17.29	33.3	83.33	100.0	25	-4.67	15.60	-33.3	0.00	33.3
	Week 32	33	82.32	18.61	33.3	83.33	100.0	27	-4.94	17.79	-33.3	0.00	33.3
	Week 35	30	81.67	20.22	16.7	83.33	100.0	24	-7.64	21.97	-66.7	0.00	33.3
	Week 38	26	84.62	18.21	50.0	91.67	100.0	21	-4.76	17.59	-33.3	0.00	33.3
	Week 41	22	81.82	17.75	50.0	83.33	100.0	17	-7.84	19.65	-50.0	0.00	33.3
	Week 44	20	76.67	21.90	33.3	83.33	100.0	16	-16.67	19.24	-50.0	-16.67	16.7
	Week 47	16	78.13	26.33	0.0	83.33	100.0	12	-18.06	28.83	-100.0	-8.34	0.0
	Week 50	11	75.76	25.13	33.3	83.33	100.0	10	-20.00	24.60	-66.7	-8.34	0.0
	Week 53	11	78.79	16.82	50.0	83.33	100.0	10	-10.00	14.05	-33.3	0.00	0.0
	Week 56	10	78.33	22.29	33.3	83.33	100.0	8	-4.17	21.36	-50.0	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
North America	EV+Pembro (N= 57)												
	BASELINE	47	85.11	21.21	0.0	100.00	100.0						
	Week 1	39	87.18	20.75	0.0	100.00	100.0	37	3.60	16.26	-33.3	0.00	50.0
	Week 2	44	83.71	24.51	0.0	100.00	100.0	42	-0.40	14.49	-66.7	0.00	33.3
	Week 3	44	87.88	16.22	50.0	100.00	100.0	40	2.92	15.51	-33.3	0.00	50.0
	Week 4	44	89.39	17.27	16.7	100.00	100.0	41	4.47	16.26	-33.3	0.00	50.0
	Week 5	47	87.94	20.17	16.7	100.00	100.0	41	3.66	17.68	-50.0	0.00	50.0
	Week 6	44	87.88	20.45	16.7	100.00	100.0	39	2.14	17.60	-50.0	0.00	50.0
	Week 7	46	90.58	15.17	50.0	100.00	100.0	42	4.76	18.14	-50.0	0.00	50.0
	Week 8	47	89.36	16.82	50.0	100.00	100.0	42	4.76	17.38	-33.3	0.00	50.0
	Week 9	46	90.22	14.30	50.0	100.00	100.0	42	4.76	16.58	-33.3	0.00	66.7
	Week 10	47	91.49	13.84	50.0	100.00	100.0	44	5.68	16.45	-16.7	0.00	66.7
	Week 11	47	90.07	14.18	66.7	100.00	100.0	42	5.56	17.91	-33.3	0.00	66.7
	Week 12	44	87.88	14.98	50.0	100.00	100.0	40	4.17	20.24	-33.3	0.00	66.7
	Week 14	43	89.15	14.94	50.0	100.00	100.0	39	5.98	20.05	-33.3	0.00	66.7
	Week 17	40	90.00	14.02	66.7	100.00	100.0	37	8.11	22.09	-33.3	0.00	66.7
	Week 20	38	88.16	18.14	16.7	100.00	100.0	35	4.29	24.37	-50.0	0.00	83.3
	Week 23	38	85.97	20.70	16.7	100.00	100.0	35	0.48	24.08	-66.7	0.00	66.7
	Week 26	35	88.57	16.55	33.3	100.00	100.0	32	4.69	24.04	-33.3	0.00	66.7
	Week 29	38	88.16	12.80	66.7	83.33	100.0	34	3.92	21.73	-33.3	0.00	66.7
	Week 32	32	84.90	16.59	50.0	91.67	100.0	29	0.58	22.04	-50.0	0.00	66.7
	Week 35	33	87.37	15.04	33.3	83.33	100.0	30	0.55	20.29	-50.0	0.00	50.0
	Week 38	32	86.46	21.77	0.0	100.00	100.0	29	1.72	24.54	-66.7	0.00	50.0
	Week 41	28	89.88	13.86	66.7	100.00	100.0	24	2.78	16.79	-33.3	0.00	33.3
	Week 44	21	84.13	20.05	16.7	83.33	100.0	20	-4.17	20.14	-66.7	0.00	33.3
	Week 47	24	90.28	12.92	66.7	100.00	100.0	23	2.17	18.33	-16.7	0.00	50.0

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	23	88.40	16.23	33.3	100.00	100.0	20	-3.33	12.80	-16.7	0.00	33.3
	Week 53	17	89.21	14.36	50.0	100.00	100.0	14	-4.76	12.10	-33.3	0.00	16.7
	Week 56	20	85.83	17.33	50.0	91.67	100.0	17	-1.96	16.54	-33.3	0.00	33.3
	Week 59	17	87.25	15.06	50.0	83.33	100.0	14	0.00	17.29	-33.3	0.00	33.3
	Week 62	14	88.10	15.23	66.7	100.00	100.0	13	-5.13	15.79	-33.3	0.00	16.7
	Week 65	12	86.11	18.58	50.0	100.00	100.0	9	-9.26	14.70	-33.3	0.00	0.0
	Week 68	10	91.67	11.79	66.7	100.00	100.0	9	-7.41	12.11	-33.3	0.00	0.0
	Week 71	10	95.00	8.05	83.3	100.00	100.0	8	0.00	0.00	0.0	0.00	0.0
	Week 74	10	93.33	14.05	66.7	100.00	100.0	9	0.00	8.33	-16.7	0.00	16.7
	Plat+Gem (N= 51)												
	BASELINE	42	85.32	17.34	50.0	91.67	100.0						
	Week 1	41	82.11	18.78	33.3	83.33	100.0	36	-4.17	15.62	-33.3	0.00	33.3
	Week 2	38	78.07	18.22	33.3	83.33	100.0	33	-8.59	13.26	-33.3	0.00	16.7
	Week 3	40	80.42	20.29	33.3	83.33	100.0	35	-8.57	15.32	-66.7	0.00	16.7
	Week 4	35	78.57	26.37	0.0	83.33	100.0	29	-10.34	15.69	-66.7	0.00	0.0
	Week 5	39	78.63	20.57	16.7	83.33	100.0	32	-10.42	13.88	-33.3	-16.66	16.7
	Week 6	34	83.33	20.10	33.3	100.00	100.0	30	-3.89	12.13	-33.3	0.00	33.3
	Week 7	42	80.56	20.80	33.3	83.33	100.0	37	-5.86	15.82	-33.3	0.00	33.3
	Week 8	39	77.35	23.10	16.7	83.33	100.0	33	-11.11	18.00	-50.0	-16.66	33.3
	Week 9	39	77.78	26.03	0.0	83.33	100.0	33	-8.59	21.29	-50.0	0.00	33.3
	Week 10	39	79.91	24.24	16.7	100.00	100.0	32	-7.29	17.93	-33.3	0.00	33.3
	Week 11	39	79.49	24.02	0.0	83.33	100.0	33	-6.57	18.61	-50.0	0.00	33.3
	Week 12	36	81.02	23.95	0.0	91.67	100.0	32	-6.25	19.74	-50.0	0.00	33.3
	Week 14	34	82.84	21.12	0.0	83.33	100.0	29	-4.02	19.24	-50.0	0.00	50.0
	Week 17	37	78.83	23.78	0.0	83.33	100.0	31	-8.06	23.12	-50.0	0.00	50.0
	Week 20	27	75.31	24.62	0.0	83.33	100.0	23	-11.59	16.23	-50.0	-16.66	16.7

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 23	27	75.31	31.48	0.0	83.33	100.0	23	-14.49	25.28	-66.7	0.00	33.3
	Week 26	28	79.76	22.84	16.7	83.33	100.0	25	-8.00	19.91	-66.7	0.00	33.3
	Week 29	29	81.03	20.76	33.3	83.33	100.0	25	-8.67	16.75	-33.3	-16.66	33.3
	Week 32	17	72.55	27.60	0.0	83.33	100.0	17	-13.73	16.91	-50.0	-16.67	16.7
	Week 35	16	72.92	24.25	16.7	75.00	100.0	15	-14.44	16.51	-50.0	-16.66	0.0
	Week 38	16	75.00	25.09	0.0	83.33	100.0	13	-14.10	19.06	-50.0	0.00	0.0
	Week 41	16	75.00	26.53	0.0	83.33	100.0	13	-10.26	19.88	-50.0	0.00	16.7
	Week 44	13	79.49	27.35	0.0	83.33	100.0	11	-9.09	18.80	-50.0	0.00	16.7
	Week 47	11	81.82	13.85	66.7	83.33	100.0	9	-12.96	13.89	-33.3	-16.66	0.0
	Week 50	17	72.55	25.64	0.0	66.67	100.0	15	-18.89	15.26	-50.0	-16.67	0.0
	Week 53	13	85.90	16.45	50.0	83.33	100.0	11	-6.06	17.12	-50.0	0.00	16.7
	Week 56	11	81.82	18.94	50.0	83.33	100.0	9	-11.11	20.41	-50.0	0.00	16.7
	Week 59	11	81.82	18.94	50.0	83.33	100.0	9	-9.26	18.84	-50.0	0.00	16.7
	Week 62	11	81.82	18.94	50.0	83.33	100.0	9	-9.26	18.84	-50.0	0.00	16.7
	Week 65	10	83.33	19.24	50.0	91.67	100.0	8	-6.25	15.27	-33.3	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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Table 302.1.3002.14.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Rest of World	EV+Pembro (N= 85)												
	BASELINE	80	82.50	22.33	0.0	83.33	100.0						
	Week 1	77	82.25	19.37	33.3	83.33	100.0	76	0.22	16.89	-33.3	0.00	50.0
	Week 2	80	80.63	19.92	16.7	83.33	100.0	76	-1.97	19.05	-33.3	0.00	66.7
	Week 3	76	80.48	24.25	0.0	83.33	100.0	73	-2.05	23.72	-66.7	0.00	66.7
	Week 4	72	79.86	21.84	0.0	83.33	100.0	68	-1.72	23.42	-66.7	0.00	66.7
	Week 5	73	82.65	20.87	16.7	83.33	100.0	70	0.00	24.24	-50.0	0.00	66.7
	Week 6	74	82.21	21.78	16.7	83.33	100.0	70	-1.19	19.52	-66.7	0.00	66.7
	Week 7	71	80.28	23.96	0.0	83.33	100.0	66	-2.78	26.73	-100.0	0.00	66.7
	Week 8	72	79.63	24.74	0.0	83.33	100.0	68	-1.96	24.01	-66.7	0.00	66.7
	Week 9	71	79.81	21.62	16.7	83.33	100.0	68	-3.19	25.31	-66.7	0.00	66.7
	Week 10	73	81.51	21.97	16.7	83.33	100.0	69	-2.41	25.61	-83.3	0.00	66.7
	Week 11	71	82.16	21.88	0.0	83.33	100.0	67	-1.24	26.16	-100.0	0.00	66.7
	Week 12	69	82.61	20.70	16.7	100.00	100.0	66	-2.27	25.13	-66.7	0.00	100.0
	Week 14	68	79.90	23.67	0.0	83.33	100.0	64	-3.39	28.97	-100.0	0.00	100.0
	Week 17	68	81.62	21.19	16.7	83.33	100.0	63	-4.76	22.49	-50.0	0.00	66.7
	Week 20	59	78.81	21.18	33.3	83.33	100.0	56	-7.44	25.21	-66.7	0.00	66.7
	Week 23	63	80.42	19.98	33.3	83.33	100.0	59	-5.08	28.74	-50.0	0.00	100.0
	Week 26	59	78.53	22.75	33.3	83.33	100.0	57	-6.14	29.99	-66.7	0.00	83.3
	Week 29	56	81.55	20.76	33.3	83.33	100.0	54	-3.40	27.16	-50.0	0.00	83.3
	Week 32	52	78.85	23.36	0.0	83.33	100.0	49	-5.44	27.09	-66.7	0.00	66.7
	Week 35	43	77.91	19.15	33.3	83.33	100.0	40	-5.00	26.74	-50.0	0.00	83.3
	Week 38	49	74.15	25.01	0.0	83.33	100.0	47	-8.51	25.03	-50.0	0.00	66.7
	Week 41	49	74.49	22.07	33.3	66.67	100.0	47	-10.28	27.27	-50.0	-16.66	66.7
	Week 44	44	78.03	20.89	33.3	83.33	100.0	41	-6.10	26.81	-66.7	0.00	66.7
	Week 47	37	77.03	22.69	33.3	83.33	100.0	35	-6.67	27.77	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	29	74.71	23.83	33.3	83.33	100.0	28	-11.31	27.98	-66.7	-8.33	66.7
	Week 53	34	74.02	21.40	33.3	66.67	100.0	33	-10.61	25.96	-66.7	-16.66	66.7
	Week 56	31	79.03	21.93	33.3	83.33	100.0	30	-5.56	26.02	-66.7	0.00	66.7
	Week 59	28	76.79	24.57	16.7	83.33	100.0	27	-6.79	28.59	-66.7	0.00	66.7
	Week 62	28	79.17	22.05	33.3	83.33	100.0	27	-4.94	24.81	-50.0	0.00	66.7
	Week 65	23	70.29	25.10	16.7	66.67	100.0	22	-10.61	29.79	-50.0	-16.66	66.7
	Week 68	22	78.03	22.65	33.3	83.33	100.0	22	-3.79	26.69	-50.0	0.00	66.7
	Week 71	22	76.52	20.99	33.3	75.00	100.0	22	-4.55	24.76	-50.0	0.00	66.7
	Week 74	22	77.27	20.28	33.3	66.67	100.0	22	-4.54	27.30	-50.0	0.00	66.7
	Week 77	18	74.07	21.56	33.3	66.67	100.0	17	-9.80	27.68	-50.0	-16.66	50.0
	Week 80	16	73.96	20.16	33.3	66.67	100.0	15	-7.78	22.60	-33.3	0.00	33.3
	Week 83	16	65.63	20.61	33.3	66.67	100.0	15	-14.44	24.29	-50.0	-16.67	33.3
	Week 86	13	66.67	22.57	33.3	66.67	100.0	12	-11.11	27.83	-50.0	-16.67	33.3
	Week 89	12	65.28	19.41	33.3	66.67	100.0	12	-12.50	24.75	-50.0	-16.67	33.3
	Plat+Gem (N= 89)												
	BASELINE	75	81.56	20.79	16.7	83.33	100.0						
	Week 1	61	83.61	16.80	33.3	83.33	100.0	61	0.00	18.26	-33.3	0.00	50.0
	Week 2	66	81.57	21.90	33.3	83.33	100.0	62	-0.54	24.88	-66.7	0.00	83.3
	Week 3	76	84.87	17.46	33.3	83.33	100.0	71	2.11	20.10	-50.0	0.00	50.0
	Week 4	73	85.16	18.75	16.7	83.33	100.0	68	2.70	19.45	-33.3	0.00	83.3
	Week 5	71	81.92	20.27	33.3	83.33	100.0	64	-0.52	17.05	-33.3	0.00	50.0
	Week 6	70	82.86	21.04	0.0	83.33	100.0	63	1.32	18.77	-50.0	0.00	50.0
	Week 7	72	84.03	20.06	33.3	91.67	100.0	65	1.54	19.26	-66.7	0.00	66.7
	Week 8	63	83.60	18.57	33.3	83.33	100.0	58	-0.29	18.33	-50.0	0.00	50.0
	Week 9	68	84.80	15.44	50.0	83.33	100.0	62	2.42	18.32	-33.3	0.00	50.0
	Week 10	67	83.83	17.64	33.3	83.33	100.0	61	1.09	19.69	-50.0	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	65	85.39	18.52	33.3	100.00	100.0	60	2.78	17.13	-33.3	0.00	50.0
	Week 12	63	83.60	19.05	50.0	100.00	100.0	58	0.86	18.05	-33.3	0.00	50.0
	Week 14	63	82.54	18.56	33.3	83.33	100.0	57	-0.58	17.81	-50.0	0.00	50.0
	Week 17	60	81.95	22.19	0.0	83.33	100.0	55	-0.61	21.02	-50.0	0.00	50.0
	Week 20	52	84.94	17.54	33.3	83.33	100.0	50	1.33	18.08	-66.7	0.00	33.3
	Week 23	44	84.09	17.96	33.3	83.33	100.0	42	2.78	20.47	-66.7	0.00	50.0
	Week 26	41	84.96	18.18	33.3	83.33	100.0	40	0.00	18.87	-66.7	0.00	50.0
	Week 29	37	87.84	15.03	50.0	100.00	100.0	36	0.00	15.94	-50.0	0.00	50.0
	Week 32	33	87.88	16.28	33.3	100.00	100.0	32	1.04	16.90	-66.7	0.00	33.3
	Week 35	30	91.11	12.17	66.7	100.00	100.0	30	3.89	17.33	-33.3	0.00	50.0
	Week 38	32	87.50	16.93	33.3	100.00	100.0	31	0.54	22.56	-66.7	0.00	50.0
	Week 41	27	85.19	18.68	33.3	100.00	100.0	26	-1.92	19.62	-66.7	0.00	50.0
	Week 44	27	85.80	18.32	33.3	100.00	100.0	26	-1.92	20.18	-66.7	0.00	50.0
	Week 47	29	85.63	18.22	33.3	100.00	100.0	28	0.00	21.75	-66.7	0.00	50.0
	Week 50	23	86.96	16.63	50.0	100.00	100.0	22	0.00	15.43	-33.3	0.00	33.3
	Week 53	22	90.15	14.23	66.7	100.00	100.0	21	0.79	15.34	-16.7	0.00	50.0
	Week 56	18	86.11	22.32	16.7	100.00	100.0	17	0.98	21.63	-50.0	0.00	50.0
	Week 59	17	91.18	13.33	66.7	100.00	100.0	16	1.04	7.37	-16.7	0.00	16.7
	Week 62	16	90.63	14.87	66.7	100.00	100.0	15	4.44	13.31	0.0	0.00	50.0
	Week 65	15	90.00	15.17	66.7	100.00	100.0	14	-2.38	11.05	-33.3	0.00	16.7
	Week 68	12	93.06	11.14	66.7	100.00	100.0	11	1.52	13.85	-16.7	0.00	33.3
	Week 71	13	84.62	19.79	50.0	100.00	100.0	12	-6.94	18.06	-33.3	0.00	16.7
	Week 74	10	88.33	17.66	50.0	100.00	100.0	10	-5.00	13.72	-33.3	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	EV+Pembro (N=198)												
	BASELINE	170	86.27	20.54	0.0	100.00	100.0						
	Week 1	157	86.09	18.76	0.0	100.00	100.0	152	0.11	15.16	-33.3	0.00	50.0
	Week 2	167	84.73	19.91	0.0	100.00	100.0	155	-2.15	17.48	-66.7	0.00	66.7
	Week 3	161	85.92	19.32	16.7	100.00	100.0	147	-0.57	19.05	-50.0	0.00	66.7
	Week 4	158	86.08	18.51	16.7	100.00	100.0	145	-0.34	19.69	-50.0	0.00	66.7
	Week 5	154	87.12	18.62	16.7	100.00	100.0	140	0.95	20.37	-50.0	0.00	66.7
	Week 6	153	87.36	19.12	16.7	100.00	100.0	138	0.60	17.60	-50.0	0.00	66.7
	Week 7	159	87.53	19.75	0.0	100.00	100.0	142	0.47	22.01	-100.0	0.00	66.7
	Week 8	154	86.69	20.82	0.0	100.00	100.0	135	0.49	20.96	-66.7	0.00	66.7
	Week 9	162	87.14	17.94	16.7	100.00	100.0	146	-0.11	20.39	-66.7	0.00	66.7
	Week 10	159	86.48	19.23	16.7	100.00	100.0	144	-0.35	22.51	-83.3	0.00	66.7
	Week 11	161	87.99	18.75	0.0	100.00	100.0	143	1.52	22.28	-100.0	0.00	66.7
	Week 12	154	86.90	17.56	33.3	100.00	100.0	140	-0.12	21.76	-66.7	0.00	100.0
	Week 14	154	86.26	20.09	0.0	100.00	100.0	137	-0.73	25.23	-100.0	0.00	100.0
	Week 17	145	86.78	17.88	16.7	100.00	100.0	130	-0.26	22.16	-66.7	0.00	66.7
	Week 20	139	84.53	20.13	0.0	100.00	100.0	126	-3.17	25.45	-100.0	0.00	83.3
	Week 23	133	83.08	20.62	16.7	100.00	100.0	122	-4.37	26.14	-66.7	0.00	100.0
	Week 26	129	85.27	19.28	33.3	100.00	100.0	118	-1.84	25.20	-66.7	0.00	83.3
	Week 29	131	86.13	17.92	33.3	100.00	100.0	120	-1.39	22.82	-66.7	0.00	83.3
	Week 32	111	83.93	20.22	0.0	100.00	100.0	102	-1.96	22.77	-66.7	0.00	66.7
	Week 35	109	85.63	17.64	33.3	83.33	100.0	100	-2.00	20.82	-50.0	0.00	83.3
	Week 38	107	83.33	22.78	0.0	100.00	100.0	100	-2.83	22.10	-66.7	0.00	66.7
	Week 41	103	83.82	20.80	33.3	100.00	100.0	94	-4.43	23.47	-66.7	0.00	66.7
	Week 44	88	83.90	19.65	33.3	83.33	100.0	81	-3.50	22.93	-66.7	0.00	66.7
	Week 47	80	84.37	20.60	33.3	100.00	100.0	75	-3.11	24.77	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	73	84.47	20.47	33.3	100.00	100.0	68	-4.66	21.90	-66.7	0.00	66.7
	Week 53	64	82.55	20.88	16.7	91.67	100.0	59	-5.37	22.41	-83.3	0.00	66.7
	Week 56	66	85.61	20.44	16.7	100.00	100.0	61	-2.19	22.04	-83.3	0.00	66.7
	Week 59	58	84.48	19.71	16.7	91.67	100.0	54	-2.78	21.90	-83.3	0.00	66.7
	Week 62	54	83.33	20.22	16.7	91.67	100.0	52	-5.45	23.27	-83.3	0.00	66.7
	Week 65	51	80.72	22.94	16.7	83.33	100.0	47	-6.38	24.95	-83.3	0.00	66.7
	Week 68	49	85.03	20.20	33.3	100.00	100.0	48	-3.13	23.48	-66.7	0.00	66.7
	Week 71	47	83.69	19.81	33.3	83.33	100.0	45	-2.59	21.89	-66.7	0.00	66.7
	Week 74	42	83.73	20.98	33.3	100.00	100.0	41	-3.66	25.42	-66.7	0.00	66.7
	Week 77	38	79.82	21.28	33.3	83.33	100.0	36	-8.80	25.04	-66.7	0.00	50.0
	Week 80	35	81.43	20.91	33.3	83.33	100.0	32	-3.65	21.05	-66.7	0.00	33.3
	Week 83	32	79.17	21.59	33.3	83.33	100.0	30	-6.11	22.95	-50.0	0.00	33.3
	Week 86	30	79.44	21.75	33.3	83.33	100.0	27	-5.56	23.11	-50.0	0.00	33.3
	Week 89	28	77.98	22.70	33.3	83.33	100.0	26	-5.77	21.57	-50.0	0.00	33.3
	Week 92	24	79.86	21.41	16.7	83.33	100.0	22	-7.58	21.04	-50.0	0.00	16.7
	Week 95	21	82.54	20.05	33.3	83.33	100.0	20	-5.83	18.94	-33.3	0.00	33.3
	Week 98	16	81.25	19.12	50.0	83.33	100.0	15	0.00	18.90	-33.3	0.00	33.3
	Week 101	12	80.56	19.89	50.0	83.33	100.0	12	-6.95	19.41	-50.0	0.00	16.7
	Week 104	10	80.00	20.49	50.0	83.33	100.0	10	-6.67	22.50	-50.0	0.00	16.7
	Plat+Gem (N=185)												
	BASELINE	146	82.19	20.31	16.7	83.33	100.0						
	Week 1	131	80.53	21.79	0.0	83.33	100.0	120	-2.92	18.03	-66.7	0.00	50.0
	Week 2	128	78.39	22.46	0.0	83.33	100.0	115	-4.35	21.75	-66.7	0.00	83.3
	Week 3	141	82.03	19.11	16.7	83.33	100.0	126	-1.19	18.03	-50.0	0.00	50.0
	Week 4	139	82.37	19.43	33.3	83.33	100.0	119	-0.70	18.08	-33.3	0.00	83.3
	Week 5	143	80.77	21.24	16.7	83.33	100.0	120	-3.75	17.35	-50.0	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 6	133	81.58	19.92	0.0	83.33	100.0	114	-1.90	17.00	-50.0	0.00	50.0
	Week 7	142	81.69	20.27	33.3	83.33	100.0	120	-1.53	18.46	-66.7	0.00	66.7
	Week 8	125	78.93	21.39	16.7	83.33	100.0	109	-6.27	20.64	-83.3	0.00	50.0
	Week 9	135	79.63	21.80	0.0	83.33	100.0	115	-3.91	20.63	-50.0	0.00	50.0
	Week 10	131	79.64	22.00	16.7	83.33	100.0	111	-4.65	21.57	-83.3	0.00	50.0
	Week 11	128	80.73	21.88	0.0	83.33	100.0	109	-2.60	19.00	-50.0	0.00	50.0
	Week 12	124	80.78	21.68	0.0	83.33	100.0	108	-3.09	19.49	-50.0	0.00	50.0
	Week 14	121	80.30	20.07	0.0	83.33	100.0	101	-4.46	19.98	-50.0	0.00	50.0
	Week 17	121	80.03	21.80	0.0	83.33	100.0	101	-4.46	22.22	-66.7	0.00	50.0
	Week 20	98	80.27	20.50	0.0	83.33	100.0	86	-4.85	19.11	-66.7	0.00	33.3
	Week 23	93	81.00	22.60	0.0	83.33	100.0	78	-4.49	23.05	-66.7	0.00	50.0
	Week 26	86	81.01	23.03	0.0	83.33	100.0	75	-5.33	20.71	-66.7	0.00	50.0
	Week 29	76	84.21	18.84	33.3	83.33	100.0	65	-4.36	16.74	-50.0	0.00	50.0
	Week 32	62	81.45	21.99	0.0	83.33	100.0	56	-5.06	18.51	-66.7	0.00	33.3
	Week 35	58	83.62	18.60	16.7	83.33	100.0	52	-3.53	18.77	-33.3	0.00	50.0
	Week 38	60	83.33	20.58	0.0	83.33	100.0	52	-4.49	21.92	-66.7	0.00	50.0
	Week 41	52	81.09	21.65	0.0	83.33	100.0	44	-4.92	21.14	-66.7	0.00	50.0
	Week 44	46	80.07	23.73	0.0	83.33	100.0	40	-8.75	22.00	-66.7	0.00	50.0
	Week 47	44	82.20	21.38	0.0	83.33	100.0	38	-6.14	25.83	-100.0	0.00	50.0
	Week 50	42	78.17	23.42	0.0	83.33	100.0	38	-11.40	20.90	-66.7	0.00	33.3
	Week 53	38	87.28	15.71	50.0	100.00	100.0	34	-3.43	16.81	-50.0	0.00	50.0
	Week 56	32	84.38	20.71	16.7	100.00	100.0	28	-4.17	22.51	-50.0	0.00	50.0
	Week 59	31	85.48	20.97	16.7	100.00	100.0	27	-3.70	16.88	-50.0	0.00	16.7
	Week 62	29	87.36	17.05	50.0	100.00	100.0	26	-1.28	16.95	-50.0	0.00	50.0
	Week 65	25	87.33	19.41	33.3	100.00	100.0	21	-1.59	12.81	-33.3	0.00	16.7
	Week 68	20	85.00	20.16	33.3	91.67	100.0	16	-6.25	20.97	-50.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 71	17	83.33	22.82	16.7	100.00	100.0	14	-4.76	15.23	-33.3	0.00	16.7
	Week 74	17	86.27	20.61	33.3	100.00	100.0	14	-4.76	15.23	-50.0	0.00	16.7
	Week 77	16	84.37	22.34	33.3	100.00	100.0	13	-6.41	16.01	-50.0	0.00	16.7
	Week 80	13	87.18	13.87	66.7	83.33	100.0	12	-6.95	11.14	-33.3	0.00	0.0
	Week 83	11	86.36	14.56	66.7	83.33	100.0	10	-10.00	14.05	-33.3	0.00	0.0
	Week 86	12	88.89	14.79	66.7	100.00	100.0	11	-4.55	13.10	-33.3	0.00	16.7
	Week 89	11	84.85	20.35	50.0	100.00	100.0	10	-6.67	17.92	-50.0	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	EV+Pembro (N= 42)												
	BASELINE	36	86.57	13.70	50.0	83.33	100.0						
	Week 1	33	86.87	15.45	50.0	83.33	100.0	32	-0.52	14.96	-33.3	0.00	33.3
	Week 2	36	84.72	17.98	33.3	83.33	100.0	34	-2.94	13.28	-33.3	0.00	33.3
	Week 3	37	81.53	20.33	0.0	83.33	100.0	35	-5.24	17.51	-66.7	0.00	16.7
	Week 4	36	83.80	20.50	0.0	83.33	100.0	34	-3.43	18.70	-66.7	0.00	33.3
	Week 5	36	84.26	21.80	16.7	100.00	100.0	33	-3.53	20.31	-50.0	0.00	50.0
	Week 6	35	84.29	20.98	33.3	100.00	100.0	32	-4.17	18.93	-66.7	0.00	33.3
	Week 7	36	85.65	16.50	33.3	83.33	100.0	34	-2.45	14.87	-33.3	0.00	16.7
	Week 8	37	84.23	16.64	33.3	83.33	100.0	36	-2.78	16.18	-33.3	0.00	33.3
	Week 9	35	84.29	19.36	16.7	83.33	100.0	34	-2.94	19.45	-50.0	0.00	33.3
	Week 10	32	89.58	15.12	50.0	100.00	100.0	31	1.61	12.44	-33.3	0.00	33.3
	Week 11	33	84.34	17.65	33.3	83.33	100.0	32	-2.08	15.70	-33.3	0.00	33.3
	Week 12	32	86.46	19.60	16.7	100.00	100.0	31	-1.07	18.22	-50.0	0.00	33.3
	Week 14	31	84.95	16.86	33.3	83.33	100.0	30	-0.56	16.07	-33.3	0.00	33.3
	Week 17	33	85.86	17.74	33.3	100.00	100.0	32	-0.52	17.19	-33.3	0.00	33.3
	Week 20	28	85.12	17.77	33.3	91.67	100.0	28	-1.78	16.57	-33.3	0.00	33.3
	Week 23	29	86.21	16.10	50.0	100.00	100.0	29	-1.15	13.31	-33.3	0.00	16.7
	Week 26	27	82.72	18.77	33.3	83.33	100.0	26	-5.77	15.59	-33.3	0.00	33.3
	Week 29	26	83.97	15.26	50.0	83.33	100.0	25	-2.00	16.89	-33.3	0.00	33.3
	Week 32	24	83.33	16.30	50.0	83.33	100.0	23	-6.52	17.22	-50.0	0.00	16.7
	Week 35	23	84.78	14.13	66.7	83.33	100.0	22	-4.54	17.20	-33.3	0.00	33.3
	Week 38	25	84.67	15.90	50.0	83.33	100.0	24	-4.86	18.70	-33.3	0.00	33.3
	Week 41	26	79.49	19.04	33.3	83.33	100.0	25	-10.00	18.00	-50.0	0.00	16.7
	Week 44	20	75.00	21.29	16.7	75.00	100.0	19	-13.16	18.90	-66.7	-16.66	16.7
	Week 47	20	85.83	15.55	66.7	91.67	100.0	19	-4.38	14.53	-33.3	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	16	81.25	18.13	50.0	83.33	100.0	16	-10.42	15.96	-33.3	0.00	16.7
	Week 53	15	76.67	22.54	33.3	83.33	100.0	15	-15.56	22.24	-66.7	-16.66	16.7
	Week 56	15	77.78	21.52	33.3	66.67	100.0	15	-12.22	22.24	-66.7	0.00	16.7
	Week 59	14	75.00	26.75	16.7	83.33	100.0	14	-14.29	28.39	-66.7	-8.33	33.3
	Week 62	11	83.33	22.36	33.3	100.00	100.0	11	-6.06	20.10	-50.0	0.00	16.7
	Plat+Gem (N= 57)												
	BASELINE	42	85.32	19.20	16.7	91.67	100.0						
	Week 1	42	83.73	17.06	33.3	83.33	100.0	38	-2.63	14.77	-33.3	0.00	16.7
	Week 2	43	84.50	18.69	33.3	83.33	100.0	36	-0.93	19.49	-33.3	0.00	66.7
	Week 3	43	87.98	18.30	33.3	100.00	100.0	36	0.00	19.52	-66.7	0.00	50.0
	Week 4	44	84.47	22.56	0.0	100.00	100.0	37	-3.60	19.69	-66.7	0.00	50.0
	Week 5	44	84.85	17.91	33.3	91.67	100.0	36	-1.85	13.67	-33.3	0.00	33.3
	Week 6	41	84.55	22.48	16.7	100.00	100.0	35	0.48	13.70	-33.3	0.00	33.3
	Week 7	44	84.47	19.49	33.3	91.67	100.0	37	-1.35	14.90	-33.3	0.00	33.3
	Week 8	42	84.92	19.41	33.3	100.00	100.0	35	0.48	18.29	-33.3	0.00	50.0
	Week 9	42	83.33	19.48	33.3	91.67	100.0	35	0.48	16.90	-50.0	0.00	33.3
	Week 10	35	78.10	18.86	33.3	83.33	100.0	28	-7.74	13.97	-33.3	0.00	16.7
	Week 11	40	81.25	20.74	33.3	83.33	100.0	34	-2.45	14.87	-33.3	0.00	33.3
	Week 12	35	81.43	20.52	33.3	83.33	100.0	30	-1.11	13.79	-33.3	0.00	16.7
	Week 14	32	80.73	18.51	50.0	83.33	100.0	27	-2.47	13.64	-33.3	0.00	16.7
	Week 17	34	82.35	21.30	33.3	91.67	100.0	29	-1.72	18.55	-50.0	0.00	33.3
	Week 20	28	86.91	15.29	66.7	100.00	100.0	24	1.39	12.92	-16.7	0.00	33.3
	Week 23	22	89.39	15.89	50.0	100.00	100.0	19	3.51	17.19	-33.3	0.00	33.3
	Week 26	22	89.39	13.16	66.7	100.00	100.0	20	0.00	13.24	-16.7	0.00	33.3
	Week 29	24	87.50	13.23	66.7	83.33	100.0	21	-2.38	15.17	-33.3	0.00	33.3
	Week 32	21	85.71	15.17	66.7	83.33	100.0	20	-2.50	16.47	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 35	18	83.33	22.87	16.7	91.67	100.0	17	-5.88	24.25	-66.7	0.00	33.3
	Week 38	14	85.72	15.82	66.7	91.67	100.0	13	-2.56	16.45	-16.7	0.00	33.3
	Week 41	13	83.33	16.67	66.7	83.33	100.0	12	-8.33	13.29	-33.3	-8.33	16.7
	Week 44	14	85.71	12.84	66.7	83.33	100.0	13	-5.13	14.25	-33.3	0.00	16.7
	Week 47	12	84.72	15.00	66.7	83.33	100.0	11	-9.09	13.67	-33.3	-16.66	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Visceral metastases	EV+Pembro (N=170)												
	BASELINE	146	85.50	21.11	0.0	100.00	100.0						
	Week 1	135	84.44	19.55	0.0	100.00	100.0	131	-0.76	15.99	-33.3	0.00	50.0
	Week 2	145	85.29	19.79	0.0	100.00	100.0	134	-0.99	16.82	-50.0	0.00	66.7
	Week 3	141	84.40	21.29	0.0	100.00	100.0	129	-1.42	20.73	-66.7	0.00	66.7
	Week 4	136	84.31	20.56	0.0	100.00	100.0	125	-1.07	21.97	-66.7	0.00	66.7
	Week 5	131	86.39	19.81	16.7	100.00	100.0	118	0.99	22.25	-50.0	0.00	66.7
	Week 6	127	87.40	19.78	16.7	100.00	100.0	113	1.47	18.31	-50.0	0.00	66.7
	Week 7	135	86.67	20.84	0.0	100.00	100.0	121	1.10	22.95	-100.0	0.00	66.7
	Week 8	131	86.00	21.76	0.0	100.00	100.0	118	1.41	21.41	-66.7	0.00	66.7
	Week 9	136	87.13	18.92	16.7	100.00	100.0	124	1.08	21.75	-66.7	0.00	66.7
	Week 10	135	86.79	19.65	16.7	100.00	100.0	124	0.67	23.13	-83.3	0.00	66.7
	Week 11	134	88.18	19.04	0.0	100.00	100.0	121	2.62	22.97	-100.0	0.00	66.7
	Week 12	131	87.91	18.03	16.7	100.00	100.0	120	1.81	22.43	-66.7	0.00	100.0
	Week 14	130	86.28	20.59	0.0	100.00	100.0	117	0.28	26.08	-100.0	0.00	100.0
	Week 17	124	86.96	18.72	16.7	100.00	100.0	111	0.90	23.34	-66.7	0.00	66.7
	Week 20	115	86.23	19.65	0.0	100.00	100.0	105	-0.95	25.72	-100.0	0.00	83.3
	Week 23	111	86.34	18.83	16.7	100.00	100.0	103	0.16	24.42	-66.7	0.00	100.0
	Week 26	106	87.42	17.64	33.3	100.00	100.0	97	1.55	24.42	-66.7	0.00	83.3
	Week 29	106	88.68	15.35	33.3	100.00	100.0	98	1.87	22.56	-50.0	0.00	83.3
	Week 32	92	84.60	19.96	0.0	100.00	100.0	85	-0.78	23.13	-66.7	0.00	66.7
	Week 35	86	87.02	15.21	33.3	91.67	100.0	79	0.00	21.35	-33.3	0.00	83.3
	Week 38	90	84.07	22.33	0.0	100.00	100.0	84	-1.39	22.29	-66.7	0.00	66.7
	Week 41	87	84.67	20.21	33.3	100.00	100.0	81	-3.09	23.73	-66.7	0.00	66.7
	Week 44	73	84.25	20.20	16.7	83.33	100.0	68	-2.45	23.44	-66.7	0.00	66.7
	Week 47	68	87.50	18.52	33.3	100.00	100.0	63	0.79	23.08	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	61	84.97	21.24	33.3	100.00	100.0	57	-4.39	22.61	-66.7	0.00	66.7
	Week 53	54	81.79	22.02	16.7	83.33	100.0	50	-7.67	25.02	-83.3	0.00	66.7
	Week 56	58	85.63	20.81	16.7	100.00	100.0	54	-3.09	24.24	-83.3	0.00	66.7
	Week 59	50	83.67	22.20	16.7	91.67	100.0	47	-4.61	26.85	-83.3	0.00	66.7
	Week 62	45	85.56	21.20	16.7	100.00	100.0	43	-3.10	24.74	-83.3	0.00	66.7
	Week 65	37	79.28	24.02	16.7	83.33	100.0	34	-7.35	29.07	-83.3	0.00	66.7
	Week 68	35	86.67	20.13	33.3	100.00	100.0	34	-0.98	25.93	-66.7	0.00	66.7
	Week 71	31	84.95	17.93	33.3	83.33	100.0	30	0.00	23.57	-66.7	0.00	66.7
	Week 74	29	85.63	19.78	33.3	100.00	100.0	28	0.60	26.64	-66.7	0.00	66.7
	Week 77	26	83.33	17.00	50.0	83.33	100.0	25	-2.67	22.91	-50.0	0.00	50.0
	Week 80	22	79.55	17.77	33.3	83.33	100.0	21	-3.97	24.10	-66.7	0.00	33.3
	Week 83	23	81.88	17.34	50.0	83.33	100.0	22	-3.03	23.36	-50.0	0.00	33.3
	Week 86	21	84.13	17.06	50.0	83.33	100.0	20	-1.67	23.51	-50.0	0.00	33.3
	Week 89	21	78.57	19.11	33.3	83.33	100.0	20	-5.00	23.63	-50.0	0.00	33.3
	Week 92	18	82.41	16.64	50.0	83.33	100.0	17	-5.88	19.49	-33.3	0.00	16.7
	Week 95	13	85.90	16.45	66.7	100.00	100.0	12	-1.39	21.85	-33.3	0.00	33.3
	Week 98	11	83.33	18.26	50.0	83.33	100.0	11	1.52	21.67	-33.3	0.00	33.3
	Week 101	11	77.27	17.11	50.0	66.67	100.0	11	-6.06	21.44	-50.0	0.00	16.7
	Plat+Gem (N=161)												
	BASELINE	129	82.82	19.76	16.7	83.33	100.0						
	Week 1	113	82.01	20.18	0.0	83.33	100.0	105	-1.43	17.77	-66.7	0.00	50.0
	Week 2	108	81.02	21.43	0.0	83.33	100.0	98	-2.04	20.90	-66.7	0.00	83.3
	Week 3	121	84.16	18.24	16.7	83.33	100.0	109	-0.31	18.84	-66.7	0.00	50.0
	Week 4	116	83.76	19.59	0.0	83.33	100.0	101	-0.33	20.54	-66.7	0.00	83.3
	Week 5	121	83.06	19.36	33.3	83.33	100.0	104	-0.80	15.99	-33.3	0.00	50.0
	Week 6	118	82.63	19.90	0.0	83.33	100.0	102	-0.65	16.90	-33.3	0.00	50.0

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 7	121	82.09	20.43	33.3	83.33	100.0	104	-1.12	18.47	-50.0	0.00	66.7
	Week 8	108	82.56	18.98	33.3	83.33	100.0	96	-1.91	18.71	-50.0	0.00	50.0
	Week 9	114	82.31	19.74	16.7	83.33	100.0	99	-0.17	19.27	-50.0	0.00	50.0
	Week 10	109	79.66	20.20	33.3	83.33	100.0	94	-3.55	19.69	-50.0	0.00	50.0
	Week 11	109	82.11	20.87	16.7	83.33	100.0	95	-1.93	18.81	-50.0	0.00	50.0
	Week 12	103	82.52	19.44	33.3	83.33	100.0	91	-1.83	19.16	-50.0	0.00	50.0
	Week 14	98	82.14	18.26	33.3	83.33	100.0	85	-2.55	20.33	-50.0	0.00	50.0
	Week 17	103	82.36	19.50	16.7	83.33	100.0	89	-0.75	21.45	-66.7	0.00	50.0
	Week 20	82	82.72	18.60	33.3	83.33	100.0	75	-2.89	18.86	-66.7	0.00	33.3
	Week 23	77	83.33	19.68	16.7	83.33	100.0	68	-1.47	22.07	-50.0	0.00	50.0
	Week 26	71	84.98	17.63	33.3	100.00	100.0	65	-2.05	17.80	-50.0	0.00	50.0
	Week 29	65	86.15	16.55	33.3	83.33	100.0	59	-2.83	17.55	-33.3	0.00	50.0
	Week 32	52	84.94	17.23	33.3	83.33	100.0	49	-3.74	14.93	-33.3	0.00	33.3
	Week 35	47	86.52	17.25	33.3	100.00	100.0	44	-1.89	18.40	-50.0	0.00	50.0
	Week 38	42	87.30	15.53	50.0	100.00	100.0	39	-2.14	17.60	-33.3	0.00	50.0
	Week 41	35	83.81	17.84	50.0	83.33	100.0	32	-3.65	17.83	-50.0	0.00	50.0
	Week 44	36	81.48	20.23	33.3	83.33	100.0	33	-9.09	19.58	-50.0	0.00	50.0
	Week 47	32	84.38	20.71	0.0	83.33	100.0	30	-5.56	25.27	-100.0	0.00	50.0
	Week 50	30	80.56	21.92	33.3	83.33	100.0	29	-10.92	20.06	-66.7	0.00	33.3
	Week 53	25	88.67	15.00	50.0	100.00	100.0	24	-4.86	12.51	-33.3	0.00	16.7
	Week 56	22	82.58	21.50	16.7	83.33	100.0	21	-7.94	17.96	-50.0	0.00	16.7
	Week 59	22	87.12	16.21	50.0	100.00	100.0	21	-5.55	14.27	-50.0	0.00	16.7
	Week 62	19	88.60	14.75	66.7	100.00	100.0	18	-2.78	10.31	-33.3	0.00	16.7
	Week 65	19	87.72	16.52	50.0	100.00	100.0	18	-4.63	12.53	-33.3	0.00	16.7
	Week 68	13	85.90	20.24	33.3	100.00	100.0	12	-9.72	15.01	-50.0	0.00	0.0
	Week 71	13	80.77	19.06	50.0	83.33	100.0	12	-9.72	16.60	-33.3	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 74	11	89.39	17.11	50.0	100.00	100.0	11	-4.55	10.78	-33.3	0.00	0.0
	Week 77	10	90.00	14.05	66.7	100.00	100.0	10	-5.00	8.05	-16.7	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Lymph node only	EV+Pembro (N= 60)												
	BASELINE	53	87.42	15.30	50.0	100.00	100.0						
	Week 1	49	90.82	13.20	50.0	100.00	100.0	47	2.84	12.68	-33.3	0.00	33.3
	Week 2	50	82.33	19.46	16.7	83.33	100.0	48	-5.21	17.24	-66.7	0.00	33.3
	Week 3	50	86.67	14.29	50.0	83.33	100.0	47	-0.71	13.44	-16.7	0.00	33.3
	Week 4	50	88.67	13.65	66.7	100.00	100.0	47	0.36	12.28	-33.3	0.00	33.3
	Week 5	53	86.79	18.59	16.7	100.00	100.0	49	-1.36	16.26	-50.0	0.00	33.3
	Week 6	53	85.22	19.52	33.3	100.00	100.0	50	-3.00	17.40	-66.7	0.00	33.3
	Week 7	52	88.78	14.28	50.0	100.00	100.0	48	-1.39	14.11	-33.3	0.00	33.3
	Week 8	52	87.50	15.08	50.0	100.00	100.0	47	-2.48	15.92	-33.3	0.00	50.0
	Week 9	53	85.22	16.56	50.0	83.33	100.0	49	-3.74	16.05	-50.0	0.00	33.3
	Week 10	48	87.50	15.94	50.0	100.00	100.0	44	-0.38	15.03	-33.3	0.00	33.3
	Week 11	53	85.22	17.80	16.7	83.33	100.0	48	-2.43	16.84	-50.0	0.00	33.3
	Week 12	48	83.33	17.53	33.3	83.33	100.0	45	-5.18	17.70	-50.0	0.00	33.3
	Week 14	48	85.42	17.40	33.3	91.67	100.0	44	-1.89	18.05	-50.0	0.00	33.3
	Week 17	46	86.23	15.44	50.0	83.33	100.0	44	-1.14	15.42	-33.3	0.00	33.3
	Week 20	44	81.06	18.88	16.7	83.33	100.0	42	-5.55	19.36	-50.0	0.00	33.3
	Week 23	43	78.29	20.74	33.3	83.33	100.0	41	-10.16	21.37	-50.0	0.00	33.3
	Week 26	42	80.56	20.13	33.3	83.33	100.0	40	-8.33	18.49	-66.7	0.00	16.7
	Week 29	45	80.00	19.66	33.3	83.33	100.0	42	-7.14	18.46	-66.7	0.00	16.7
	Week 32	38	82.46	17.31	50.0	83.33	100.0	36	-6.02	17.88	-50.0	0.00	33.3
	Week 35	42	81.75	20.10	33.3	83.33	100.0	40	-7.08	17.66	-50.0	0.00	16.7
	Week 38	38	83.77	19.17	33.3	83.33	100.0	36	-5.56	18.69	-50.0	0.00	33.3
	Week 41	37	79.73	20.08	33.3	83.33	100.0	34	-9.80	18.40	-50.0	0.00	16.7
	Week 44	31	79.03	18.74	33.3	83.33	100.0	29	-9.77	18.64	-50.0	0.00	33.3
	Week 47	28	79.17	21.09	33.3	83.33	100.0	27	-11.11	21.68	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	25	83.33	14.43	50.0	83.33	100.0	24	-6.94	15.48	-33.3	0.00	33.3
	Week 53	23	82.61	19.12	33.3	83.33	100.0	22	-5.30	16.58	-33.3	0.00	16.7
	Week 56	21	82.54	20.05	33.3	83.33	100.0	20	-5.00	16.31	-33.3	0.00	16.7
	Week 59	20	81.67	20.16	33.3	83.33	100.0	19	-5.26	14.75	-33.3	0.00	16.7
	Week 62	19	78.95	18.29	33.3	83.33	100.0	19	-10.53	16.86	-33.3	0.00	16.7
	Week 65	20	80.00	22.69	33.3	83.33	100.0	19	-9.65	15.03	-33.3	0.00	16.7
	Week 68	17	81.37	19.44	33.3	83.33	100.0	17	-8.82	14.57	-33.3	0.00	16.7
	Week 71	19	83.33	19.24	33.3	83.33	100.0	18	-6.48	12.96	-33.3	0.00	16.7
	Week 74	17	78.43	21.05	33.3	66.67	100.0	17	-11.76	19.33	-66.7	0.00	16.7
	Week 77	17	75.49	22.14	33.3	83.33	100.0	16	-15.63	22.34	-66.7	-8.33	16.7
	Week 80	17	82.35	22.42	33.3	100.00	100.0	15	-4.44	14.73	-33.3	0.00	16.7
	Week 83	13	74.36	24.17	33.3	66.67	100.0	12	-11.11	17.88	-33.3	0.00	16.7
	Week 86	12	72.22	23.92	33.3	66.67	100.0	10	-11.67	19.33	-50.0	-8.33	16.7
	Week 89	11	74.24	26.21	33.3	83.33	100.0	10	-8.33	14.17	-33.3	-8.33	16.7
	Plat+Gem (N= 67)												
	BASELINE	49	83.33	20.41	16.7	83.33	100.0						
	Week 1	51	80.07	19.73	33.3	83.33	100.0	45	-5.55	15.89	-33.3	0.00	16.7
	Week 2	53	77.36	22.67	33.3	83.33	100.0	44	-6.06	21.89	-66.7	0.00	66.7
	Week 3	53	81.13	21.44	33.3	83.33	100.0	44	-2.27	18.18	-50.0	0.00	50.0
	Week 4	58	80.75	21.58	16.7	83.33	100.0	47	-3.55	14.30	-33.3	0.00	50.0
	Week 5	56	77.98	23.38	16.7	83.33	100.0	44	-9.09	16.26	-50.0	0.00	16.7
	Week 6	48	79.86	22.79	16.7	83.33	100.0	40	-4.17	14.98	-50.0	0.00	16.7
	Week 7	56	81.55	20.02	33.3	83.33	100.0	46	-3.26	16.34	-66.7	0.00	33.3
	Week 8	52	75.32	24.81	16.7	83.33	100.0	42	-11.51	23.13	-83.3	0.00	50.0
	Week 9	53	76.10	24.79	0.0	83.33	100.0	42	-9.52	20.87	-50.0	0.00	33.3
	Week 10	47	77.66	25.13	16.7	83.33	100.0	36	-10.18	21.18	-83.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	51	77.12	23.56	0.0	83.33	100.0	41	-5.28	16.85	-50.0	0.00	33.3
	Week 12	47	76.24	25.00	0.0	83.33	100.0	39	-5.13	18.00	-50.0	0.00	16.7
	Week 14	47	75.89	22.74	0.0	66.67	100.0	36	-8.80	15.16	-50.0	0.00	16.7
	Week 17	45	75.56	25.77	0.0	83.33	100.0	35	-11.43	20.52	-50.0	0.00	33.3
	Week 20	38	79.83	20.92	0.0	83.33	100.0	30	-5.00	17.59	-50.0	0.00	33.3
	Week 23	32	78.65	26.52	0.0	83.33	100.0	25	-8.00	23.63	-66.7	0.00	33.3
	Week 26	30	75.56	29.27	0.0	83.33	100.0	24	-11.11	23.91	-66.7	0.00	16.7
	Week 29	28	80.95	20.14	33.3	83.33	100.0	21	-7.94	13.56	-50.0	0.00	0.0
	Week 32	26	76.28	25.89	0.0	83.33	100.0	22	-6.82	25.02	-66.7	0.00	33.3
	Week 35	23	76.81	23.96	16.7	83.33	100.0	19	-8.77	25.68	-66.7	0.00	33.3
	Week 38	26	77.56	24.92	0.0	83.33	100.0	20	-7.50	28.34	-66.7	0.00	50.0
	Week 41	24	76.39	24.53	0.0	83.33	100.0	18	-10.19	25.01	-66.7	0.00	16.7
	Week 44	18	77.78	26.20	0.0	83.33	100.0	14	-8.33	25.94	-66.7	0.00	16.7
	Week 47	18	77.78	19.80	33.3	75.00	100.0	13	-11.54	24.89	-66.7	-16.66	33.3
	Week 50	16	75.00	25.09	0.0	66.67	100.0	13	-11.54	22.96	-50.0	-16.66	33.3
	Week 53	15	82.22	17.21	50.0	83.33	100.0	12	0.00	23.57	-50.0	0.00	50.0
	Week 56	15	83.33	21.82	33.3	100.00	100.0	11	4.55	26.97	-50.0	0.00	50.0
	Week 59	12	79.17	25.75	16.7	83.33	100.0	9	0.00	22.05	-50.0	0.00	16.7
	Week 62	10	81.67	19.95	50.0	83.34	100.0	8	0.00	28.17	-50.0	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
EV+Pembro (N=202)												
BASELINE	160	81.77	19.50	16.7	83.33	100.0						
Week 1	141	82.51	20.83	0.0	83.33	100.0	129	0.52	13.97	-50.0	0.00	33.3
Week 2	150	80.56	22.39	0.0	83.33	100.0	133	-1.38	14.07	-50.0	0.00	33.3
Week 3	139	82.73	21.08	0.0	83.33	100.0	122	0.14	14.77	-50.0	0.00	50.0
Week 4	145	82.99	20.55	0.0	83.33	100.0	129	-0.26	16.14	-83.3	0.00	50.0
Week 5	137	83.82	21.86	0.0	100.00	100.0	121	0.83	17.06	-50.0	0.00	50.0
Week 6	146	81.74	22.60	0.0	83.33	100.0	124	-1.07	19.68	-83.3	0.00	50.0
Week 7	147	81.75	20.49	0.0	83.33	100.0	124	-0.54	17.39	-66.7	0.00	33.3
Week 8	147	80.95	22.50	0.0	83.33	100.0	124	-1.88	19.27	-66.7	0.00	50.0
Week 9	142	81.22	21.46	0.0	83.33	100.0	121	-1.65	18.68	-66.7	0.00	50.0
Week 10	139	82.01	22.44	0.0	83.33	100.0	118	-1.13	17.80	-50.0	0.00	33.3
Week 11	137	82.24	22.52	0.0	83.33	100.0	115	-0.87	18.18	-66.7	0.00	33.3
Week 12	142	83.22	20.58	0.0	83.33	100.0	119	0.28	17.08	-50.0	0.00	33.3
Week 14	139	83.81	19.86	0.0	83.33	100.0	116	1.29	16.17	-50.0	0.00	33.3
Week 17	132	82.95	19.26	16.7	83.33	100.0	111	0.15	17.04	-50.0	0.00	50.0
Week 20	120	85.28	15.90	33.3	83.33	100.0	103	1.94	17.51	-50.0	0.00	50.0
Week 23	117	83.48	17.02	16.7	83.33	100.0	97	0.52	15.49	-33.3	0.00	33.3
Week 26	112	83.93	15.96	33.3	83.33	100.0	94	-0.18	18.53	-33.3	0.00	66.7
Week 29	107	83.80	16.26	33.3	83.33	100.0	93	0.90	17.27	-50.0	0.00	50.0
Week 32	102	82.84	19.82	0.0	83.33	100.0	88	1.33	21.47	-66.7	0.00	66.7
Week 35	98	81.63	18.15	33.3	83.33	100.0	86	-1.55	19.74	-66.7	0.00	66.7
Week 38	97	82.99	16.49	50.0	83.33	100.0	86	0.00	19.30	-50.0	0.00	66.7
Week 41	95	81.05	17.46	33.3	83.33	100.0	84	-1.19	17.70	-33.3	0.00	50.0
Week 44	86	80.23	20.05	0.0	83.33	100.0	74	-2.03	18.90	-66.7	0.00	50.0
Week 47	79	82.49	19.41	16.7	83.33	100.0	70	1.67	19.69	-50.0	0.00	83.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	74	79.28	19.66	16.7	83.33	100.0	64	-3.39	19.29	-50.0	0.00	66.7
Week 53	74	76.13	21.56	0.0	83.33	100.0	63	-4.50	20.35	-50.0	0.00	50.0
Week 56	72	78.70	19.02	33.3	83.33	100.0	61	-3.01	19.37	-50.0	0.00	66.7
Week 59	69	80.19	18.80	33.3	83.33	100.0	57	-1.46	19.74	-50.0	0.00	66.7
Week 62	62	78.76	18.89	33.3	83.33	100.0	52	-2.24	17.47	-50.0	0.00	50.0
Week 65	43	80.23	20.00	16.7	83.33	100.0	40	0.42	19.05	-33.3	0.00	66.7
Week 68	46	78.62	22.68	0.0	83.33	100.0	42	-3.18	20.90	-83.3	0.00	50.0
Week 71	42	76.19	21.19	33.3	83.33	100.0	38	-5.26	21.61	-50.0	0.00	50.0
Week 74	38	76.32	19.23	33.3	83.33	100.0	35	-3.81	19.00	-33.3	0.00	50.0
Week 77	37	77.93	19.27	33.3	83.33	100.0	33	-2.53	20.46	-33.3	0.00	50.0
Week 80	36	74.54	21.26	33.3	66.67	100.0	34	-4.41	20.64	-33.3	0.00	50.0
Week 83	30	76.67	19.87	33.3	75.00	100.0	29	-2.87	20.45	-33.3	0.00	50.0
Week 86	26	71.80	22.49	16.7	66.67	100.0	25	-4.67	22.83	-66.7	0.00	50.0
Week 89	20	78.33	19.57	50.0	83.33	100.0	19	-2.63	12.75	-16.7	0.00	33.3
Week 92	19	75.44	24.45	16.7	66.67	100.0	18	-3.70	14.64	-33.3	0.00	16.7
Week 95	14	86.91	14.88	66.7	91.67	100.0	13	1.28	4.62	0.0	0.00	16.7
Week 98	10	85.00	18.34	50.0	91.67	100.0	9	0.00	8.34	-16.7	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Plat+Gem (N=202)												
BASELINE	165	84.95	19.67	16.7	83.33	100.0						
Week 1	144	84.61	19.72	0.0	100.00	100.0	139	-0.96	14.98	-33.3	0.00	50.0
Week 2	147	82.43	21.70	0.0	83.33	100.0	135	-2.10	17.57	-50.0	0.00	50.0
Week 3	149	83.00	20.27	0.0	83.33	100.0	136	-3.68	14.72	-50.0	0.00	50.0
Week 4	150	84.33	19.33	0.0	83.33	100.0	135	-1.48	14.75	-50.0	0.00	50.0
Week 5	153	83.22	20.99	0.0	83.33	100.0	138	-2.78	15.80	-50.0	0.00	50.0
Week 6	145	84.48	20.57	0.0	100.00	100.0	131	-1.40	17.42	-50.0	0.00	50.0
Week 7	148	82.09	20.95	0.0	83.33	100.0	134	-3.23	18.67	-66.7	0.00	50.0
Week 8	145	80.23	23.07	0.0	83.33	100.0	132	-4.67	20.10	-100.0	0.00	50.0
Week 9	141	80.02	22.73	0.0	83.33	100.0	125	-5.47	20.28	-83.3	0.00	50.0
Week 10	142	81.81	22.80	0.0	100.00	100.0	130	-3.72	19.72	-66.7	0.00	50.0
Week 11	126	80.82	22.61	0.0	83.33	100.0	114	-4.09	19.40	-66.7	0.00	50.0
Week 12	130	82.44	20.26	0.0	83.33	100.0	115	-2.17	19.06	-50.0	0.00	50.0
Week 14	125	81.33	21.33	0.0	83.33	100.0	109	-4.13	20.05	-50.0	0.00	66.7
Week 17	120	80.97	20.87	0.0	83.33	100.0	106	-5.66	22.05	-83.3	0.00	66.7
Week 20	104	81.41	19.88	33.3	83.33	100.0	91	-5.68	20.22	-50.0	0.00	50.0
Week 23	88	85.61	17.72	33.3	100.00	100.0	80	-2.29	17.94	-50.0	0.00	50.0
Week 26	81	82.30	21.30	16.7	83.33	100.0	75	-3.78	20.79	-66.7	0.00	66.7
Week 29	77	82.47	21.27	0.0	83.33	100.0	71	-6.81	23.33	-100.0	0.00	66.7
Week 32	63	82.54	20.18	16.7	83.33	100.0	58	-5.46	16.04	-50.0	0.00	33.3
Week 35	62	84.68	18.68	16.7	83.33	100.0	56	-3.57	16.12	-50.0	0.00	33.3
Week 38	56	81.55	21.95	0.0	83.33	100.0	50	-6.33	21.53	-83.3	0.00	33.3
Week 41	52	85.58	16.51	50.0	83.33	100.0	47	-2.48	17.71	-33.3	0.00	66.7
Week 44	49	82.65	17.66	50.0	83.33	100.0	44	-4.17	18.72	-50.0	0.00	50.0
Week 47	43	81.78	19.52	33.3	83.33	100.0	39	-4.27	22.20	-50.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	36	80.56	18.90	50.0	83.33	100.0	31	-5.38	20.36	-50.0	0.00	33.3
Week 53	31	80.64	18.80	33.3	83.33	100.0	28	-4.76	16.26	-33.3	0.00	16.7
Week 56	30	78.33	20.60	33.3	83.33	100.0	29	-4.60	23.53	-50.0	0.00	66.7
Week 59	23	71.74	23.27	33.3	66.67	100.0	21	-4.76	22.45	-50.0	0.00	33.3
Week 62	20	75.83	19.10	50.0	66.67	100.0	20	-4.17	17.83	-33.3	0.00	33.3
Week 65	17	75.49	21.34	33.3	83.33	100.0	16	-8.33	18.26	-50.0	0.00	16.7
Week 68	13	80.77	16.45	66.7	66.67	100.0	13	-3.84	16.88	-33.3	0.00	33.3
Week 71	13	70.51	22.72	16.7	66.67	100.0	13	-14.10	23.42	-66.7	-16.66	16.7
Week 74	11	78.79	15.07	50.0	83.33	100.0	11	-7.58	15.57	-33.3	-16.66	16.7
Week 77	11	84.85	17.41	50.0	83.33	100.0	11	-4.55	21.20	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Present	EV+Pembro (N= 50)												
	BASELINE	40	80.42	20.98	16.7	83.33	100.0						
	Week 1	38	79.39	21.73	33.3	83.33	100.0	34	0.49	15.07	-33.3	0.00	33.3
	Week 2	35	82.86	21.19	16.7	83.33	100.0	32	3.13	14.32	-33.3	0.00	33.3
	Week 3	32	86.46	17.16	50.0	100.00	100.0	30	5.00	17.59	-33.3	0.00	50.0
	Week 4	35	82.38	19.36	33.3	83.33	100.0	31	0.00	14.27	-33.3	0.00	33.3
	Week 5	32	85.94	18.98	33.3	100.00	100.0	28	2.38	16.80	-33.3	0.00	33.3
	Week 6	35	83.33	16.67	50.0	83.33	100.0	30	2.22	18.94	-33.3	0.00	50.0
	Week 7	35	83.33	17.15	33.3	83.33	100.0	29	2.87	15.48	-33.3	0.00	33.3
	Week 8	38	82.02	23.05	33.3	91.67	100.0	31	-1.07	22.33	-66.7	0.00	33.3
	Week 9	33	85.86	17.24	33.3	100.00	100.0	29	3.45	17.47	-33.3	0.00	50.0
	Week 10	30	86.11	18.61	33.3	100.00	100.0	25	7.33	14.50	-16.7	0.00	33.3
	Week 11	31	87.10	19.10	16.7	100.00	100.0	27	2.47	20.52	-66.7	0.00	33.3
	Week 12	32	87.50	16.39	50.0	100.00	100.0	28	2.38	16.17	-33.3	0.00	33.3
	Week 14	36	86.11	16.67	50.0	100.00	100.0	31	3.76	15.34	-16.7	0.00	33.3
	Week 17	33	86.36	16.90	33.3	100.00	100.0	27	2.47	15.12	-16.7	0.00	33.3
	Week 20	28	86.91	15.94	50.0	100.00	100.0	25	0.67	18.31	-33.3	0.00	33.3
	Week 23	28	85.71	16.17	50.0	83.33	100.0	24	2.08	15.00	-16.7	0.00	33.3
	Week 26	28	81.55	17.18	50.0	83.33	100.0	24	-4.17	18.55	-33.3	0.00	33.3
	Week 29	27	86.42	15.36	50.0	83.33	100.0	25	2.00	18.21	-50.0	0.00	33.3
	Week 32	25	84.67	20.93	33.3	100.00	100.0	23	-0.73	21.01	-66.7	0.00	33.3
	Week 35	26	84.62	18.21	33.3	91.67	100.0	24	-1.39	21.93	-66.7	0.00	33.3
	Week 38	26	82.05	18.81	50.0	83.33	100.0	24	-4.17	20.41	-50.0	0.00	33.3
	Week 41	25	82.67	19.53	33.3	83.33	100.0	23	-2.90	14.78	-33.3	0.00	33.3
	Week 44	22	81.82	19.86	33.3	83.33	100.0	20	-3.33	18.42	-50.0	0.00	33.3
	Week 47	14	79.76	26.29	16.7	83.33	100.0	13	-3.85	24.68	-50.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	78.33	25.42	16.7	83.33	100.0	17	-6.86	22.09	-50.0	0.00	33.3
	Week 53	21	72.22	27.05	0.0	66.67	100.0	18	-12.04	23.43	-50.0	0.00	33.3
	Week 56	18	75.93	23.72	33.3	83.33	100.0	15	-6.67	19.72	-50.0	-16.66	33.3
	Week 59	18	76.85	25.01	33.3	83.33	100.0	15	-8.89	21.70	-50.0	-16.66	33.3
	Week 62	13	76.92	22.09	33.3	83.33	100.0	11	-7.58	20.23	-50.0	0.00	16.7
	Week 68	12	80.55	27.37	0.0	83.33	100.0	11	-6.06	30.07	-83.3	0.00	33.3
	Plat+Gem (N= 50)												
	BASELINE	40	83.75	21.51	16.7	83.33	100.0						
	Week 1	35	84.29	17.59	33.3	83.33	100.0	33	-3.53	10.00	-16.7	0.00	16.7
	Week 2	33	79.29	20.85	16.7	83.33	100.0	30	-7.22	18.92	-50.0	0.00	50.0
	Week 3	33	82.83	18.86	16.7	83.33	100.0	29	-6.32	12.92	-33.3	0.00	16.7
	Week 4	36	85.18	16.32	50.0	83.33	100.0	32	-2.08	14.51	-33.3	0.00	33.3
	Week 5	36	81.02	22.94	0.0	83.33	100.0	32	-3.65	17.32	-50.0	0.00	50.0
	Week 6	32	86.98	17.32	33.3	100.00	100.0	29	-1.15	14.04	-33.3	0.00	33.3
	Week 7	35	77.62	23.89	16.7	83.33	100.0	31	-6.45	21.38	-66.7	0.00	50.0
	Week 8	35	76.67	25.95	16.7	83.33	100.0	31	-6.45	20.04	-50.0	0.00	16.7
	Week 9	34	80.39	20.71	16.7	83.33	100.0	30	-3.89	17.33	-33.3	0.00	50.0
	Week 10	33	83.33	20.41	33.3	83.33	100.0	30	-0.56	20.29	-66.7	0.00	50.0
	Week 11	30	77.22	22.95	0.0	83.33	100.0	26	-9.61	18.36	-50.0	-16.66	16.7
	Week 12	32	77.60	23.03	0.0	83.33	100.0	27	-4.32	19.39	-50.0	0.00	33.3
	Week 14	27	80.25	17.32	50.0	83.33	100.0	22	-3.03	19.68	-50.0	0.00	33.3
	Week 17	28	79.17	19.04	33.3	83.33	100.0	23	-7.25	18.68	-50.0	0.00	33.3
	Week 20	20	78.33	20.30	50.0	83.33	100.0	16	-4.17	16.67	-33.3	0.00	33.3
	Week 23	15	81.11	24.29	33.3	100.00	100.0	14	-2.38	18.32	-50.0	0.00	33.3
	Week 26	15	80.00	26.12	16.7	83.33	100.0	14	-5.95	20.26	-50.0	0.00	16.7
	Week 29	13	80.77	27.93	0.0	83.33	100.0	12	-9.72	29.69	-100.0	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Absent	EV+Pembro (N=152)												
	BASELINE	120	82.22	19.05	16.7	83.33	100.0						
	Week 1	103	83.66	20.48	0.0	83.33	100.0	95	0.53	13.63	-50.0	0.00	33.3
	Week 2	115	79.85	22.78	0.0	83.33	100.0	101	-2.81	13.76	-50.0	0.00	33.3
	Week 3	107	81.62	22.07	0.0	83.33	100.0	92	-1.45	13.45	-50.0	0.00	33.3
	Week 4	110	83.18	21.00	0.0	83.33	100.0	98	-0.34	16.75	-83.3	0.00	50.0
	Week 5	105	83.17	22.70	0.0	83.33	100.0	93	0.36	17.20	-50.0	0.00	50.0
	Week 6	111	81.23	24.22	0.0	83.33	100.0	94	-2.13	19.89	-83.3	0.00	33.3
	Week 7	112	81.25	21.47	0.0	83.33	100.0	95	-1.58	17.88	-66.7	0.00	33.3
	Week 8	109	80.58	22.40	0.0	83.33	100.0	93	-2.15	18.26	-50.0	0.00	50.0
	Week 9	109	79.82	22.46	0.0	83.33	100.0	92	-3.26	18.86	-66.7	0.00	50.0
	Week 10	109	80.89	23.33	0.0	83.33	100.0	93	-3.40	17.98	-50.0	0.00	33.3
	Week 11	106	80.82	23.32	0.0	83.33	100.0	88	-1.89	17.40	-50.0	0.00	33.3
	Week 12	110	81.97	21.55	0.0	83.33	100.0	91	-0.37	17.39	-50.0	0.00	33.3
	Week 14	103	83.01	20.87	0.0	83.33	100.0	85	0.39	16.46	-50.0	0.00	33.3
	Week 17	99	81.82	19.93	16.7	83.33	100.0	84	-0.59	17.63	-50.0	0.00	50.0
	Week 20	92	84.78	15.95	33.3	83.33	100.0	78	2.35	17.35	-50.0	0.00	50.0
	Week 23	89	82.77	17.31	16.7	83.33	100.0	73	0.00	15.71	-33.3	0.00	33.3
	Week 26	84	84.72	15.57	33.3	83.33	100.0	70	1.19	18.46	-33.3	0.00	66.7
	Week 29	80	82.92	16.55	33.3	83.33	100.0	68	0.49	17.03	-33.3	0.00	50.0
	Week 32	77	82.25	19.56	0.0	83.33	100.0	65	2.05	21.75	-50.0	0.00	66.7
	Week 35	72	80.56	18.13	33.3	83.33	100.0	62	-1.61	19.02	-33.3	0.00	66.7
	Week 38	71	83.33	15.68	50.0	83.33	100.0	62	1.61	18.78	-33.3	0.00	66.7
	Week 41	70	80.48	16.78	33.3	83.33	100.0	61	-0.55	18.75	-33.3	0.00	50.0
	Week 44	64	79.69	20.24	0.0	83.33	100.0	54	-1.54	19.23	-66.7	0.00	50.0
	Week 47	65	83.08	17.80	33.3	83.33	100.0	57	2.92	18.40	-33.3	0.00	83.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	54	79.63	17.33	50.0	83.33	100.0	47	-2.13	18.26	-50.0	0.00	66.7
	Week 53	53	77.67	19.04	16.7	83.33	100.0	45	-1.48	18.40	-33.3	0.00	50.0
	Week 56	54	79.63	17.33	33.3	83.33	100.0	46	-1.81	19.32	-33.3	0.00	66.7
	Week 59	51	81.37	16.21	33.3	83.33	100.0	42	1.19	18.55	-33.3	0.00	66.7
	Week 62	49	79.25	18.17	33.3	83.33	100.0	41	-0.81	16.65	-33.3	0.00	50.0
	Week 65	36	79.17	20.07	16.7	83.33	100.0	33	0.00	18.63	-33.3	0.00	66.7
	Week 68	34	77.94	21.21	16.7	83.33	100.0	31	-2.15	17.07	-33.3	0.00	50.0
	Week 71	33	76.77	19.52	33.3	66.67	100.0	30	-3.89	20.38	-33.3	0.00	50.0
	Week 74	33	77.27	18.55	33.3	83.33	100.0	30	-2.78	18.61	-33.3	0.00	50.0
	Week 77	31	78.49	18.35	33.3	83.33	100.0	27	-2.47	19.45	-33.3	0.00	50.0
	Week 80	31	73.12	21.81	33.3	66.67	100.0	29	-5.75	20.06	-33.3	0.00	50.0
	Week 83	25	75.33	20.48	33.3	66.67	100.0	24	-4.17	19.81	-33.3	0.00	50.0
	Week 86	23	72.46	21.68	16.7	66.67	100.0	22	-2.27	20.12	-50.0	0.00	50.0
	Week 89	18	77.78	19.80	50.0	83.33	100.0	17	-2.94	13.48	-16.7	0.00	33.3
	Week 92	16	75.00	25.82	16.7	75.00	100.0	15	-4.44	16.02	-33.3	0.00	16.7
	Week 95	12	87.50	14.43	66.7	91.67	100.0	11	1.52	5.03	0.0	0.00	16.7
	Plat+Gem (N=152)												
	BASELINE	125	85.33	19.12	16.7	83.33	100.0						
	Week 1	109	84.71	20.43	0.0	100.00	100.0	106	-0.16	16.18	-33.3	0.00	50.0
	Week 2	114	83.33	21.95	0.0	100.00	100.0	105	-0.63	16.97	-50.0	0.00	50.0
	Week 3	116	83.05	20.73	0.0	83.33	100.0	107	-2.96	15.15	-50.0	0.00	50.0
	Week 4	114	84.06	20.25	0.0	83.33	100.0	103	-1.29	14.89	-50.0	0.00	50.0
	Week 5	117	83.90	20.40	0.0	83.33	100.0	106	-2.51	15.39	-50.0	0.00	33.3
	Week 6	113	83.78	21.42	0.0	100.00	100.0	102	-1.47	18.33	-50.0	0.00	50.0
	Week 7	113	83.48	19.86	0.0	83.33	100.0	103	-2.26	17.78	-66.7	0.00	50.0
	Week 8	110	81.36	22.09	0.0	83.33	100.0	101	-4.12	20.19	-100.0	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	107	79.91	23.43	0.0	83.33	100.0	95	-5.96	21.18	-83.3	0.00	50.0
	Week 10	109	81.35	23.54	0.0	100.00	100.0	100	-4.67	19.55	-66.7	0.00	50.0
	Week 11	96	81.94	22.51	0.0	83.33	100.0	88	-2.46	19.50	-66.7	0.00	50.0
	Week 12	98	84.01	19.13	0.0	100.00	100.0	88	-1.51	19.02	-33.3	0.00	50.0
	Week 14	98	81.63	22.38	0.0	83.33	100.0	87	-4.41	20.25	-50.0	0.00	66.7
	Week 17	92	81.52	21.46	0.0	83.33	100.0	83	-5.22	22.98	-83.3	0.00	66.7
	Week 20	84	82.14	19.84	33.3	83.33	100.0	75	-6.00	20.98	-50.0	0.00	50.0
	Week 23	73	86.53	16.11	50.0	100.00	100.0	66	-2.27	18.00	-33.3	0.00	50.0
	Week 26	66	82.83	20.25	16.7	83.33	100.0	61	-3.28	21.04	-66.7	0.00	66.7
	Week 29	64	82.81	19.91	0.0	83.33	100.0	59	-6.21	22.08	-83.3	0.00	66.7
	Week 32	54	82.72	18.87	33.3	83.33	100.0	49	-5.44	15.73	-33.3	0.00	33.3
	Week 35	54	83.95	19.41	16.7	83.33	100.0	48	-4.17	17.02	-50.0	0.00	33.3
	Week 38	47	82.62	19.65	33.3	83.33	100.0	42	-5.56	19.71	-66.7	0.00	33.3
	Week 41	45	85.18	16.75	50.0	83.33	100.0	40	-3.33	18.57	-33.3	0.00	66.7
	Week 44	41	82.11	17.24	50.0	83.33	100.0	36	-4.17	19.67	-50.0	0.00	50.0
	Week 47	35	80.95	20.67	33.3	83.33	100.0	31	-4.30	24.33	-50.0	0.00	66.7
	Week 50	29	79.88	18.57	50.0	83.33	100.0	24	-4.86	20.55	-50.0	0.00	33.3
	Week 53	25	80.67	18.43	33.3	83.33	100.0	22	-3.79	15.37	-33.3	0.00	16.7
	Week 56	26	80.13	20.01	33.3	83.33	100.0	25	-2.00	22.73	-50.0	0.00	66.7
	Week 59	20	71.67	23.63	33.3	75.00	100.0	18	-3.70	23.26	-50.0	0.00	33.3
	Week 62	17	76.47	18.69	50.0	66.67	100.0	17	-2.94	17.91	-33.3	0.00	33.3
	Week 65	15	74.44	21.70	33.3	83.33	100.0	14	-9.52	19.30	-50.0	0.00	16.7
	Week 68	11	80.30	16.36	66.7	66.67	100.0	11	-4.54	18.39	-33.3	0.00	33.3
	Week 71	12	68.06	21.85	16.7	66.67	100.0	12	-15.28	24.05	-66.7	-16.67	16.7
	Week 74	10	76.67	14.05	50.0	83.33	100.0	10	-8.33	16.19	-33.3	-16.66	16.7
	Week 77	10	83.33	17.57	50.0	83.33	100.0	10	-5.00	22.29	-33.3	-8.33	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
< 65 years	EV+Pembro (N= 39)												
	BASELINE	32	81.77	17.12	50.0	83.33	100.0						
	Week 1	27	84.57	15.96	50.0	83.33	100.0	26	3.21	10.56	-16.7	0.00	33.3
	Week 2	30	83.33	18.57	16.7	83.33	100.0	29	1.15	15.38	-33.3	0.00	33.3
	Week 3	31	87.63	17.20	33.3	100.00	100.0	29	5.17	15.50	-16.7	0.00	50.0
	Week 4	30	86.67	17.72	33.3	100.00	100.0	27	2.47	12.83	-33.3	0.00	33.3
	Week 5	28	89.29	16.49	33.3	100.00	100.0	26	6.41	16.38	-33.3	0.00	50.0
	Week 6	29	89.08	13.57	66.7	100.00	100.0	26	6.41	14.20	-16.7	0.00	50.0
	Week 7	30	83.89	17.22	33.3	83.33	100.0	26	1.92	14.40	-33.3	0.00	33.3
	Week 8	30	87.22	17.88	33.3	100.00	100.0	26	2.56	12.19	-16.7	0.00	33.3
	Week 9	28	87.50	15.47	50.0	100.00	100.0	27	4.94	14.48	-16.7	0.00	50.0
	Week 10	26	84.62	19.96	33.3	91.67	100.0	23	0.00	15.89	-33.3	0.00	33.3
	Week 11	28	86.91	20.47	16.7	100.00	100.0	25	4.67	13.19	-16.7	0.00	33.3
	Week 12	28	88.69	14.38	66.7	100.00	100.0	25	5.33	12.47	-16.7	0.00	33.3
	Week 14	26	91.67	12.69	66.7	100.00	100.0	23	10.14	14.85	-16.7	0.00	33.3
	Week 17	28	83.93	17.85	33.3	83.33	100.0	24	4.86	15.13	-33.3	0.00	33.3
	Week 20	27	88.27	14.48	66.7	100.00	100.0	24	5.56	17.49	-33.3	0.00	33.3
	Week 23	26	87.82	13.79	66.7	91.67	100.0	23	3.62	17.37	-33.3	0.00	33.3
	Week 26	24	86.81	13.88	66.7	83.33	100.0	22	1.52	18.48	-33.3	0.00	50.0
	Week 29	25	86.00	14.97	66.7	83.33	100.0	23	2.90	14.78	-33.3	0.00	33.3
	Week 32	25	85.33	16.89	50.0	100.00	100.0	23	3.62	18.77	-33.3	0.00	50.0
	Week 35	24	82.64	16.65	50.0	83.33	100.0	22	0.00	21.82	-33.3	0.00	50.0
	Week 38	23	88.41	15.43	66.7	100.00	100.0	22	4.55	20.04	-33.3	0.00	50.0
	Week 41	25	84.67	15.90	50.0	83.33	100.0	23	3.62	19.43	-33.3	0.00	33.3
	Week 44	22	83.33	15.43	66.7	83.33	100.0	20	0.83	13.76	-33.3	0.00	33.3
	Week 47	20	82.50	21.27	16.7	83.33	100.0	18	0.00	20.61	-50.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	19	84.21	16.17	50.0	83.33	100.0	17	1.96	13.02	-16.7	0.00	33.3
	Week 53	20	81.67	19.42	50.0	83.33	100.0	18	-0.93	16.64	-33.3	0.00	33.3
	Week 56	17	82.35	17.15	50.0	83.33	100.0	15	0.00	16.67	-33.3	0.00	33.3
	Week 59	17	80.39	19.75	33.3	83.33	100.0	15	0.00	18.90	-33.3	0.00	33.3
	Week 62	15	81.11	16.51	50.0	83.33	100.0	14	-2.38	17.12	-33.3	0.00	33.3
	Week 65	14	86.90	16.25	50.0	91.67	100.0	13	3.85	13.87	-16.7	0.00	33.3
	Week 68	11	87.88	15.07	66.7	100.00	100.0	10	1.67	14.59	-16.7	0.00	33.3
	Week 71	13	80.77	22.41	33.3	83.33	100.0	12	-1.39	19.41	-33.3	0.00	33.3
	Week 74	14	72.62	19.18	33.3	66.67	100.0	13	-10.26	17.40	-33.3	-16.66	16.7
	Week 77	14	79.76	19.80	33.3	83.33	100.0	13	-1.28	19.79	-33.3	0.00	33.3
	Week 80	14	75.00	22.41	33.3	75.00	100.0	13	-8.97	18.78	-33.3	0.00	33.3
	Week 83	12	76.39	19.41	33.3	75.00	100.0	11	-4.55	19.85	-33.3	0.00	33.3
	Plat+Gem (N= 29)												
	BASELINE	22	90.91	12.31	66.7	100.00	100.0						
	Week 1	21	88.10	15.04	66.7	100.00	100.0	20	-3.33	11.60	-33.3	0.00	16.7
	Week 2	24	86.81	17.01	50.0	100.00	100.0	20	0.00	10.82	-16.7	0.00	33.3
	Week 3	23	90.58	12.13	66.7	100.00	100.0	20	0.83	11.44	-16.7	0.00	16.7
	Week 4	23	88.41	19.74	16.7	100.00	100.0	19	0.88	6.75	-16.7	0.00	16.7
	Week 5	25	88.67	17.82	33.3	100.00	100.0	20	2.50	9.79	-16.7	0.00	33.3
	Week 6	22	88.64	17.36	50.0	100.00	100.0	18	1.85	7.86	-16.7	0.00	16.7
	Week 7	24	87.50	14.12	66.7	91.67	100.0	21	-0.79	11.15	-16.7	0.00	16.7
	Week 8	21	88.89	16.10	50.0	100.00	100.0	19	-0.88	13.00	-16.7	0.00	33.3
	Week 9	20	83.33	18.73	50.0	83.33	100.0	17	-5.88	14.36	-33.3	0.00	16.7
	Week 10	21	84.13	22.65	33.3	100.00	100.0	18	-4.63	12.53	-33.3	0.00	16.7
	Week 11	20	84.17	21.27	33.3	91.67	100.0	17	-1.96	14.29	-16.7	0.00	33.3
	Week 12	21	85.71	15.17	66.7	83.33	100.0	17	-1.96	13.02	-16.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 14	22	79.55	21.16	33.3	83.33	100.0	18	-7.41	17.36	-50.0	-8.33	33.3
	Week 17	20	83.33	16.22	50.0	83.33	100.0	17	-5.88	15.52	-33.3	0.00	33.3
	Week 20	18	78.70	22.00	33.3	83.33	100.0	15	-8.89	16.51	-33.3	-16.66	33.3
	Week 23	18	86.11	15.39	66.7	91.67	100.0	16	-4.17	15.51	-33.3	0.00	33.3
	Week 26	16	83.33	20.18	33.3	83.33	100.0	14	-4.76	17.82	-50.0	0.00	33.3
	Week 29	15	84.44	17.21	50.0	83.33	100.0	13	-5.13	15.79	-33.3	0.00	33.3
	Week 32	15	85.56	16.51	66.7	100.00	100.0	13	-5.13	17.19	-33.3	0.00	33.3
	Week 35	15	80.00	24.56	16.7	83.33	100.0	13	-6.41	19.88	-50.0	0.00	33.3
	Week 38	14	73.81	32.50	0.0	83.34	100.0	12	-13.89	32.44	-83.3	0.00	33.3
	Week 41	11	78.79	18.39	50.0	66.67	100.0	9	-12.96	13.89	-33.3	-16.66	0.0
	Week 44	11	78.79	22.47	50.0	83.33	100.0	9	-12.96	18.21	-50.0	0.00	0.0
	Week 47	11	84.85	18.94	50.0	100.00	100.0	9	-3.70	18.21	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>= 65 years	EV+Pembro (N=163)												
	BASELINE	128	81.77	20.11	16.7	83.33	100.0						
	Week 1	114	82.02	21.85	0.0	83.33	100.0	103	-0.16	14.67	-50.0	0.00	33.3
	Week 2	120	79.86	23.26	0.0	83.33	100.0	104	-2.08	13.68	-50.0	0.00	33.3
	Week 3	108	81.33	21.94	0.0	83.33	100.0	93	-1.43	14.26	-50.0	0.00	33.3
	Week 4	115	82.03	21.19	0.0	83.33	100.0	102	-0.98	16.88	-83.3	0.00	50.0
	Week 5	109	82.42	22.89	0.0	83.33	100.0	95	-0.70	17.00	-50.0	0.00	33.3
	Week 6	117	79.91	24.03	0.0	83.33	100.0	98	-3.06	20.50	-83.3	0.00	33.3
	Week 7	117	81.20	21.28	0.0	83.33	100.0	98	-1.19	18.11	-66.7	0.00	33.3
	Week 8	117	79.34	23.33	0.0	83.33	100.0	98	-3.06	20.64	-66.7	0.00	50.0
	Week 9	114	79.68	22.48	0.0	83.33	100.0	94	-3.55	19.38	-66.7	0.00	50.0
	Week 10	113	81.42	23.01	0.0	83.33	100.0	95	-1.40	18.30	-50.0	0.00	33.3
	Week 11	109	81.04	22.96	0.0	83.33	100.0	90	-2.41	19.12	-66.7	0.00	33.3
	Week 12	114	81.87	21.67	0.0	83.33	100.0	94	-1.06	17.93	-50.0	0.00	33.3
	Week 14	113	82.01	20.79	0.0	83.33	100.0	93	-0.90	15.81	-50.0	0.00	33.3
	Week 17	104	82.69	19.70	16.7	83.33	100.0	87	-1.15	17.39	-50.0	0.00	50.0
	Week 20	93	84.41	16.26	33.3	83.33	100.0	79	0.84	17.48	-50.0	0.00	50.0
	Week 23	91	82.23	17.71	16.7	83.33	100.0	74	-0.45	14.85	-33.3	0.00	33.3
	Week 26	88	83.14	16.47	33.3	83.33	100.0	72	-0.69	18.65	-33.3	0.00	66.7
	Week 29	82	83.13	16.66	33.3	83.33	100.0	70	0.24	18.06	-50.0	0.00	50.0
	Week 32	77	82.03	20.73	0.0	83.33	100.0	65	0.51	22.43	-66.7	0.00	66.7
	Week 35	74	81.31	18.70	33.3	83.33	100.0	64	-2.08	19.13	-66.7	0.00	66.7
	Week 38	74	81.31	16.54	50.0	83.33	100.0	64	-1.56	18.95	-50.0	0.00	66.7
	Week 41	70	79.76	17.92	33.3	83.33	100.0	61	-3.01	16.81	-33.3	0.00	50.0
	Week 44	64	79.17	21.41	0.0	83.33	100.0	54	-3.09	20.50	-66.7	0.00	50.0
	Week 47	59	82.49	18.93	33.3	83.33	100.0	52	2.24	19.53	-50.0	0.00	83.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	55	77.58	20.59	16.7	83.33	100.0	47	-5.32	20.88	-50.0	0.00	66.7
	Week 53	54	74.07	22.12	0.0	83.33	100.0	45	-5.93	21.66	-50.0	0.00	50.0
	Week 56	55	77.58	19.57	33.3	83.33	100.0	46	-3.99	20.24	-50.0	0.00	66.7
	Week 59	52	80.13	18.68	33.3	83.33	100.0	42	-1.98	20.23	-50.0	0.00	66.7
	Week 62	47	78.01	19.69	33.3	83.33	100.0	38	-2.19	17.83	-50.0	0.00	50.0
	Week 65	29	77.01	21.09	16.7	66.67	100.0	27	-1.23	21.14	-33.3	0.00	66.7
	Week 68	35	75.71	24.03	0.0	83.33	100.0	32	-4.69	22.49	-83.3	0.00	50.0
	Week 71	29	74.14	20.70	33.3	66.67	100.0	26	-7.05	22.69	-50.0	0.00	50.0
	Week 74	24	78.47	19.34	33.3	83.33	100.0	22	0.00	19.25	-33.3	0.00	50.0
	Week 77	23	76.81	19.29	33.3	83.33	100.0	20	-3.33	21.36	-33.3	0.00	50.0
	Week 80	22	74.24	21.04	33.3	66.67	100.0	21	-1.59	21.67	-33.3	0.00	50.0
	Week 83	18	76.85	20.72	33.3	75.00	100.0	18	-1.85	21.31	-33.3	0.00	50.0
	Week 86	18	70.37	25.28	16.7	66.67	100.0	18	-5.56	26.81	-66.7	0.00	50.0
	Week 89	12	79.17	21.47	50.0	83.33	100.0	12	-1.39	15.01	-16.7	0.00	33.3
	Week 92	10	81.67	28.81	16.7	100.00	100.0	10	-1.67	14.59	-33.3	0.00	16.7
	Plat+Gem (N=173)												
	BASELINE	143	84.03	20.45	16.7	83.33	100.0						
	Week 1	123	84.01	20.40	0.0	83.33	100.0	119	-0.56	15.49	-33.3	0.00	50.0
	Week 2	123	81.57	22.46	0.0	83.33	100.0	115	-2.46	18.50	-50.0	0.00	50.0
	Week 3	126	81.61	21.17	0.0	83.33	100.0	116	-4.45	15.13	-50.0	0.00	50.0
	Week 4	127	83.60	19.24	0.0	83.33	100.0	116	-1.87	15.66	-50.0	0.00	50.0
	Week 5	128	82.16	21.45	0.0	83.33	100.0	118	-3.67	16.47	-50.0	0.00	50.0
	Week 6	123	83.74	21.07	0.0	100.00	100.0	113	-1.92	18.47	-50.0	0.00	50.0
	Week 7	124	81.05	21.91	0.0	83.33	100.0	113	-3.69	19.76	-66.7	0.00	50.0
	Week 8	124	78.76	23.79	0.0	83.33	100.0	113	-5.31	21.04	-100.0	0.00	50.0
	Week 9	121	79.48	23.35	0.0	83.33	100.0	108	-5.40	21.11	-83.3	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	121	81.41	22.89	0.0	100.00	100.0	112	-3.57	20.68	-66.7	0.00	50.0
	Week 11	106	80.19	22.90	0.0	83.33	100.0	97	-4.47	20.20	-66.7	0.00	50.0
	Week 12	109	81.80	21.10	0.0	83.33	100.0	98	-2.21	19.97	-50.0	0.00	50.0
	Week 14	103	81.72	21.45	0.0	83.33	100.0	91	-3.48	20.57	-50.0	0.00	66.7
	Week 17	100	80.50	21.72	0.0	83.33	100.0	89	-5.62	23.16	-83.3	0.00	66.7
	Week 20	86	81.98	19.51	33.3	83.33	100.0	76	-5.04	20.91	-50.0	0.00	50.0
	Week 23	70	85.48	18.37	33.3	100.00	100.0	64	-1.82	18.57	-50.0	0.00	50.0
	Week 26	65	82.05	21.71	16.7	83.33	100.0	61	-3.55	21.54	-66.7	0.00	66.7
	Week 29	62	81.99	22.24	0.0	83.33	100.0	58	-7.18	24.80	-100.0	0.00	66.7
	Week 32	48	81.60	21.26	16.7	83.33	100.0	45	-5.55	15.89	-50.0	0.00	33.3
	Week 35	47	86.17	16.42	50.0	83.33	100.0	43	-2.71	14.96	-33.3	0.00	33.3
	Week 38	42	84.13	16.85	50.0	83.33	100.0	38	-3.95	16.64	-33.3	0.00	33.3
	Week 41	41	87.40	15.71	50.0	100.00	100.0	38	0.00	17.76	-33.3	0.00	66.7
	Week 44	38	83.77	16.20	50.0	83.33	100.0	35	-1.90	18.42	-33.3	0.00	50.0
	Week 47	32	80.73	19.91	33.3	83.33	100.0	30	-4.44	23.54	-50.0	0.00	66.7
	Week 50	29	82.18	17.21	50.0	83.33	100.0	26	-4.49	17.99	-50.0	0.00	16.7
	Week 53	25	82.00	17.29	50.0	83.33	100.0	24	-4.86	15.91	-33.3	0.00	16.7
	Week 56	26	79.49	19.61	33.3	83.33	100.0	26	-4.49	23.83	-50.0	0.00	66.7
	Week 59	20	76.67	20.52	33.3	83.33	100.0	20	-4.17	22.86	-50.0	0.00	33.3
	Week 62	19	77.19	18.60	50.0	66.67	100.0	19	-3.51	18.07	-33.3	0.00	33.3
	Week 65	16	77.08	20.97	33.3	83.33	100.0	16	-8.33	18.26	-50.0	0.00	16.7
	Week 68	13	80.77	16.45	66.7	66.67	100.0	13	-3.84	16.88	-33.3	0.00	33.3
	Week 71	13	70.51	22.72	16.7	66.67	100.0	13	-14.10	23.42	-66.7	-16.66	16.7
	Week 74	11	78.79	15.07	50.0	83.33	100.0	11	-7.58	15.57	-33.3	-16.66	16.7
	Week 77	10	83.33	17.57	50.0	83.33	100.0	10	-8.33	18.00	-33.3	-8.33	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Europe	EV+Pembro (N= 74)												
	BASELINE	53	83.65	18.63	33.3	83.33	100.0						
	Week 1	48	80.90	22.54	0.0	83.33	100.0	42	-1.59	16.38	-50.0	0.00	33.3
	Week 2	53	82.08	22.37	16.7	83.33	100.0	44	-0.76	16.84	-50.0	0.00	33.3
	Week 3	50	81.67	21.63	0.0	83.33	100.0	41	-0.81	20.05	-50.0	0.00	50.0
	Week 4	51	82.35	19.27	16.7	83.33	100.0	44	-2.65	17.59	-83.3	0.00	33.3
	Week 5	46	82.97	22.63	0.0	91.67	100.0	41	0.81	19.70	-50.0	0.00	50.0
	Week 6	50	80.00	21.30	16.7	83.33	100.0	39	-4.27	20.13	-33.3	0.00	50.0
	Week 7	50	82.33	20.32	16.7	83.33	100.0	39	-2.56	16.01	-33.3	0.00	33.3
	Week 8	51	81.05	24.27	16.7	83.33	100.0	41	-2.85	18.97	-50.0	0.00	33.3
	Week 9	47	83.33	22.25	16.7	100.00	100.0	37	-1.80	19.16	-50.0	0.00	50.0
	Week 10	45	83.33	22.75	16.7	100.00	100.0	34	-2.45	18.41	-50.0	0.00	33.3
	Week 11	48	83.68	21.60	16.7	91.67	100.0	37	-0.90	16.17	-50.0	0.00	33.3
	Week 12	51	83.01	19.29	33.3	83.33	100.0	39	-0.85	14.78	-50.0	0.00	33.3
	Week 14	50	84.67	17.77	33.3	83.33	100.0	38	2.63	16.22	-50.0	0.00	33.3
	Week 17	43	82.95	22.56	16.7	100.00	100.0	33	2.02	14.88	-50.0	0.00	33.3
	Week 20	41	86.59	16.76	50.0	100.00	100.0	33	4.55	15.18	-33.3	0.00	33.3
	Week 23	41	83.33	19.36	16.7	83.33	100.0	30	5.00	14.61	-33.3	0.00	33.3
	Week 26	37	82.88	16.89	50.0	83.33	100.0	28	0.60	17.85	-33.3	0.00	50.0
	Week 29	37	86.04	15.96	50.0	100.00	100.0	29	4.02	15.85	-33.3	0.00	33.3
	Week 32	34	82.35	23.55	0.0	91.67	100.0	26	3.21	21.61	-50.0	0.00	50.0
	Week 35	31	84.41	17.71	33.3	83.33	100.0	25	1.33	18.58	-33.3	0.00	50.0
	Week 38	31	80.65	18.80	50.0	83.33	100.0	26	-4.49	17.98	-50.0	0.00	33.3
	Week 41	28	82.74	21.02	33.3	91.67	100.0	23	0.73	17.75	-33.3	0.00	33.3
	Week 44	27	85.80	17.72	50.0	100.00	100.0	22	0.00	15.43	-33.3	0.00	33.3
	Week 47	25	86.00	19.65	33.3	100.00	100.0	21	3.97	15.73	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	26	80.77	24.35	16.7	91.67	100.0	23	-3.62	18.77	-50.0	0.00	33.3
	Week 53	26	76.28	27.96	0.0	83.33	100.0	21	-5.56	21.94	-50.0	0.00	33.3
	Week 56	25	80.67	18.43	50.0	83.33	100.0	21	-3.17	16.34	-33.3	0.00	33.3
	Week 59	23	85.51	16.90	50.0	83.33	100.0	18	0.00	15.12	-16.7	0.00	33.3
	Week 62	20	76.67	25.59	33.3	83.33	100.0	17	-6.86	17.74	-50.0	0.00	16.7
	Week 65	13	80.77	26.22	16.7	100.00	100.0	13	0.00	16.67	-33.3	0.00	33.3
	Week 68	15	74.44	31.41	0.0	83.33	100.0	15	-7.78	25.09	-83.3	0.00	33.3
	Week 71	13	78.21	23.95	33.3	83.33	100.0	13	-5.13	19.70	-50.0	0.00	33.3
	Week 74	10	76.67	22.50	33.3	83.33	100.0	9	-5.56	11.79	-16.7	0.00	16.7
	Plat+Gem (N= 95)												
	BASELINE	75	86.22	18.46	33.3	100.00	100.0						
	Week 1	71	85.68	18.75	33.3	100.00	100.0	69	-0.48	13.09	-33.3	0.00	33.3
	Week 2	71	85.21	20.42	16.7	100.00	100.0	63	0.00	11.97	-33.3	0.00	33.3
	Week 3	72	85.65	19.24	33.3	100.00	100.0	65	-2.05	13.34	-50.0	0.00	33.3
	Week 4	69	87.44	18.83	16.7	100.00	100.0	62	1.08	10.83	-16.7	0.00	33.3
	Week 5	71	83.57	20.22	0.0	83.33	100.0	63	-2.64	11.67	-33.3	0.00	33.3
	Week 6	69	85.99	20.93	16.7	100.00	100.0	61	-0.55	14.58	-50.0	0.00	33.3
	Week 7	69	83.57	19.07	16.7	83.33	100.0	62	-3.49	15.43	-66.7	0.00	33.3
	Week 8	67	85.57	18.55	16.7	100.00	100.0	60	-0.55	13.71	-33.3	0.00	33.3
	Week 9	66	82.32	22.81	0.0	83.33	100.0	57	-4.38	17.96	-83.3	0.00	33.3
	Week 10	70	84.52	22.76	0.0	100.00	100.0	63	-1.06	15.23	-50.0	0.00	33.3
	Week 11	63	83.60	21.06	16.7	83.33	100.0	56	-1.78	15.14	-33.3	0.00	33.3
	Week 12	66	86.87	15.88	50.0	100.00	100.0	56	1.79	15.47	-33.3	0.00	33.3
	Week 14	66	82.58	21.17	16.7	91.67	100.0	56	-3.87	15.57	-50.0	0.00	33.3
	Week 17	61	81.97	20.70	0.0	83.33	100.0	53	-4.72	19.16	-83.3	0.00	33.3
	Week 20	54	82.72	21.22	33.3	91.67	100.0	48	-4.86	17.85	-50.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 23	44	90.15	15.80	33.3	100.00	100.0	40	3.33	16.10	-50.0	0.00	50.0
	Week 26	42	82.94	23.13	16.7	100.00	100.0	39	-1.28	20.73	-66.7	0.00	66.7
	Week 29	39	85.04	17.85	33.3	83.33	100.0	36	-0.93	16.40	-16.7	0.00	66.7
	Week 32	32	81.77	24.08	16.7	100.00	100.0	30	-2.78	13.19	-50.0	0.00	16.7
	Week 35	32	82.81	21.79	16.7	91.67	100.0	30	-2.78	13.19	-33.3	0.00	16.7
	Week 38	28	85.12	18.89	33.3	100.00	100.0	26	-1.28	15.58	-33.3	0.00	33.3
	Week 41	25	86.67	18.63	50.0	100.00	100.0	23	3.62	18.77	-33.3	0.00	66.7
	Week 44	24	86.11	17.49	50.0	100.00	100.0	22	2.27	15.68	-16.7	0.00	50.0
	Week 47	22	83.33	23.00	33.3	100.00	100.0	20	0.00	22.94	-50.0	0.00	66.7
	Week 50	17	80.39	23.00	50.0	100.00	100.0	15	-3.33	20.12	-50.0	0.00	16.7
	Week 53	15	82.22	22.24	33.3	100.00	100.0	14	-3.57	16.25	-33.3	0.00	16.7
	Week 56	15	78.89	24.77	33.3	83.33	100.0	14	-2.38	28.39	-50.0	0.00	66.7
	Week 59	11	72.73	26.11	33.3	66.67	100.0	10	-3.33	24.60	-50.0	0.00	33.3
	Week 62	11	80.30	16.36	66.7	66.67	100.0	11	0.00	16.67	-16.7	0.00	33.3
	Week 65	10	76.67	26.29	33.3	83.34	100.0	10	-8.33	19.64	-50.0	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
North America	EV+Pembro (N= 46)												
	BASELINE	33	85.86	14.51	50.0	83.33	100.0						
	Week 1	30	87.78	20.03	33.3	100.00	100.0	27	3.09	13.90	-33.3	0.00	33.3
	Week 2	30	85.56	16.80	50.0	83.33	100.0	26	-1.92	11.86	-33.3	0.00	16.7
	Week 3	25	92.00	13.71	50.0	100.00	100.0	21	1.59	11.67	-16.7	0.00	33.3
	Week 4	30	88.33	16.46	33.3	100.00	100.0	24	0.69	14.31	-33.3	0.00	33.3
	Week 5	29	89.65	16.91	33.3	100.00	100.0	21	-1.59	15.73	-33.3	0.00	33.3
	Week 6	31	87.10	20.05	16.7	100.00	100.0	23	-1.45	21.85	-83.3	0.00	33.3
	Week 7	33	84.34	18.13	33.3	83.33	100.0	23	-0.72	15.47	-33.3	0.00	33.3
	Week 8	29	87.36	15.85	50.0	100.00	100.0	20	2.50	18.16	-50.0	0.00	33.3
	Week 9	27	86.42	17.32	33.3	100.00	100.0	21	-2.38	21.91	-66.7	0.00	33.3
	Week 10	29	89.66	15.05	50.0	100.00	100.0	23	5.07	15.44	-33.3	0.00	33.3
	Week 11	28	89.88	19.42	16.7	100.00	100.0	21	6.35	14.41	-16.7	0.00	33.3
	Week 12	29	93.10	12.21	66.7	100.00	100.0	22	6.06	16.70	-33.3	0.00	33.3
	Week 14	28	92.26	13.21	66.7	100.00	100.0	21	3.97	16.59	-33.3	0.00	33.3
	Week 17	29	90.23	14.44	66.7	100.00	100.0	23	4.35	18.27	-33.3	0.00	33.3
	Week 20	23	91.30	14.10	50.0	100.00	100.0	18	2.78	20.01	-50.0	0.00	33.3
	Week 23	22	90.91	12.31	66.7	100.00	100.0	17	0.00	13.18	-16.7	0.00	16.7
	Week 26	21	91.27	10.03	66.7	100.00	100.0	16	2.08	14.75	-16.7	0.00	33.3
	Week 29	20	87.50	15.17	50.0	91.67	100.0	17	-1.96	18.52	-50.0	0.00	16.7
	Week 32	21	85.71	19.21	33.3	100.00	100.0	18	0.93	25.23	-66.7	0.00	33.3
	Week 35	22	84.85	19.18	33.3	91.67	100.0	19	-3.51	21.93	-66.7	0.00	33.3
	Week 38	20	87.50	16.11	50.0	100.00	100.0	17	0.98	18.13	-33.3	0.00	33.3
	Week 41	21	84.92	13.85	66.7	83.33	100.0	17	-1.96	16.54	-33.3	0.00	16.7
	Week 44	16	82.29	14.23	66.7	83.33	100.0	12	-4.17	16.09	-33.3	0.00	16.7
	Week 47	16	85.42	20.97	16.7	83.33	100.0	13	-1.28	18.59	-50.0	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	16	81.25	15.96	50.0	83.33	100.0	11	-9.09	20.23	-50.0	0.00	16.7
	Week 53	15	83.33	17.82	50.0	83.33	100.0	11	0.00	12.91	-16.7	0.00	16.7
	Week 56	17	82.35	19.96	33.3	83.33	100.0	12	0.00	15.89	-33.3	0.00	16.7
	Week 59	17	83.33	22.05	33.3	83.33	100.0	12	1.39	20.67	-33.3	0.00	33.3
	Week 62	14	83.33	16.01	50.0	83.33	100.0	9	-1.85	17.57	-33.3	0.00	16.7
	Week 68	11	90.91	11.46	66.7	100.00	100.0	8	4.17	17.25	-33.3	8.33	16.7
	Week 71	11	81.82	21.67	33.3	83.33	100.0	8	-10.42	21.71	-33.3	-8.33	16.7
	Plat+Gem (N= 34)												
	BASELINE	27	83.33	18.49	33.3	83.33	100.0						
	Week 1	19	84.21	17.98	33.3	83.33	100.0	17	-2.94	13.48	-33.3	0.00	16.7
	Week 2	20	85.83	18.95	33.3	91.67	100.0	18	0.00	15.13	-33.3	0.00	33.3
	Week 3	20	82.50	19.10	33.3	83.33	100.0	17	-5.88	15.52	-33.3	0.00	16.7
	Week 4	23	81.88	18.74	33.3	83.33	100.0	19	-5.26	14.75	-33.3	0.00	16.7
	Week 5	25	82.00	24.49	0.0	83.33	100.0	22	-3.03	20.98	-50.0	0.00	50.0
	Week 6	20	85.00	20.87	33.3	91.67	100.0	17	-0.98	10.98	-16.7	0.00	16.7
	Week 7	23	81.16	25.28	0.0	83.33	100.0	20	-3.33	21.36	-50.0	0.00	50.0
	Week 8	24	78.47	26.23	33.3	83.33	100.0	22	-6.06	20.92	-50.0	0.00	33.3
	Week 9	23	84.06	18.45	33.3	83.33	100.0	19	-0.88	17.98	-16.7	0.00	50.0
	Week 10	20	81.67	24.12	16.7	91.67	100.0	18	-3.70	21.81	-33.3	0.00	50.0
	Week 11	18	81.48	24.18	16.7	83.33	100.0	16	-7.29	21.92	-50.0	-8.33	33.3
	Week 12	17	85.29	18.52	50.0	100.00	100.0	16	2.09	17.08	-33.3	0.00	33.3
	Week 14	16	83.33	20.18	33.3	83.33	100.0	14	1.19	23.99	-50.0	0.00	33.3
	Week 17	19	79.82	21.93	33.3	83.33	100.0	17	-4.90	19.33	-33.3	0.00	33.3
	Week 20	16	82.29	17.71	50.0	83.33	100.0	13	-6.41	23.11	-33.3	0.00	33.3
	Week 23	15	82.22	21.33	33.3	83.33	100.0	13	-2.56	19.06	-33.3	0.00	33.3
	Week 26	13	85.90	17.80	50.0	83.33	100.0	12	-2.78	22.29	-50.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 29	14	80.95	26.03	0.0	83.33	100.0	13	-8.97	28.56	-83.3	0.00	33.3
	Week 32	11	86.36	12.51	66.7	83.33	100.0	10	-3.33	18.92	-33.3	0.00	33.3
	Week 35	13	89.74	10.84	66.7	83.33	100.0	11	1.52	17.41	-33.3	0.00	33.3
	Week 38	10	75.00	33.56	0.0	83.33	100.0	9	-16.67	37.27	-83.3	-16.66	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Rest of World	EV+Pembro (N= 82)												
	BASELINE	74	78.60	21.64	16.7	83.33	100.0						
	Week 1	63	81.22	19.74	33.3	83.33	100.0	60	0.83	12.05	-33.3	0.00	33.3
	Week 2	67	77.11	24.24	0.0	83.33	100.0	63	-1.59	12.95	-33.3	0.00	33.3
	Week 3	64	79.95	22.26	16.7	83.33	100.0	60	0.28	11.27	-33.3	0.00	33.3
	Week 4	64	80.99	22.98	0.0	83.33	100.0	61	1.09	15.77	-50.0	0.00	50.0
	Week 5	62	81.72	23.12	16.7	83.33	100.0	59	1.70	15.69	-50.0	0.00	33.3
	Week 6	65	80.51	24.57	0.0	83.33	100.0	62	1.08	18.57	-66.7	0.00	33.3
	Week 7	64	79.95	21.86	0.0	83.33	100.0	62	0.81	18.95	-66.7	0.00	33.3
	Week 8	67	78.11	23.25	0.0	83.33	100.0	63	-2.65	19.90	-66.7	0.00	50.0
	Week 9	68	77.70	22.04	0.0	83.33	100.0	63	-1.32	17.53	-50.0	0.00	50.0
	Week 10	65	77.69	24.17	0.0	83.33	100.0	61	-2.73	18.05	-33.3	0.00	33.3
	Week 11	61	77.60	23.74	0.0	83.33	100.0	57	-3.51	20.10	-66.7	0.00	33.3
	Week 12	62	78.76	23.21	0.0	83.33	100.0	58	-1.15	18.43	-50.0	0.00	33.3
	Week 14	61	79.23	22.70	0.0	83.33	100.0	57	-0.58	16.05	-50.0	0.00	33.3
	Week 17	60	79.44	17.99	33.3	83.33	100.0	55	-2.73	17.50	-33.3	0.00	50.0
	Week 20	56	81.85	15.33	33.3	83.33	100.0	52	0.00	18.08	-33.3	0.00	50.0
	Week 23	54	80.56	16.11	33.3	83.33	100.0	50	-2.00	16.37	-33.3	0.00	33.3
	Week 26	54	81.79	16.59	33.3	83.33	100.0	50	-1.33	20.16	-33.3	0.00	66.7
	Week 29	50	80.67	16.62	33.3	83.33	100.0	47	0.00	17.72	-33.3	0.00	50.0
	Week 32	47	81.92	17.32	33.3	83.33	100.0	44	0.38	20.17	-33.3	0.00	66.7
	Week 35	45	78.15	17.70	33.3	83.33	100.0	42	-2.38	19.68	-33.3	0.00	66.7
	Week 38	46	82.61	14.89	50.0	83.33	100.0	43	2.33	20.44	-33.3	0.00	66.7
	Week 41	46	78.26	16.43	50.0	83.33	100.0	44	-1.89	18.40	-33.3	0.00	50.0
	Week 44	43	75.97	22.51	0.0	83.33	100.0	40	-2.50	21.53	-66.7	0.00	50.0
	Week 47	38	78.95	18.45	33.3	83.33	100.0	36	1.39	22.32	-50.0	0.00	83.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	32	77.08	17.32	33.3	83.33	100.0	30	-1.11	19.54	-50.0	0.00	66.7
	Week 53	33	72.73	16.57	33.3	66.67	100.0	31	-5.38	21.68	-50.0	0.00	50.0
	Week 56	30	75.00	18.95	33.3	83.33	100.0	28	-4.17	22.96	-50.0	0.00	66.7
	Week 59	29	74.14	17.01	33.3	66.67	100.0	27	-3.70	22.33	-50.0	0.00	66.7
	Week 62	28	77.98	14.38	50.0	75.00	100.0	26	0.64	17.31	-33.3	0.00	50.0
	Week 65	22	75.00	16.06	50.0	66.67	100.0	21	-2.38	20.60	-33.3	0.00	66.7
	Week 68	20	75.00	17.52	50.0	75.00	100.0	19	-2.63	18.65	-33.3	0.00	50.0
	Week 71	18	71.30	18.79	33.3	66.67	100.0	17	-2.94	23.74	-33.3	0.00	50.0
	Week 74	19	71.93	15.76	50.0	66.67	100.0	19	-4.39	22.11	-33.3	0.00	50.0
	Week 77	19	71.93	18.47	33.3	66.67	100.0	18	-3.70	24.62	-33.3	0.00	50.0
	Week 80	19	68.42	20.71	33.3	66.67	100.0	18	-7.41	23.72	-33.3	-8.33	50.0
	Week 83	17	70.59	18.19	33.3	66.67	100.0	17	-3.92	21.67	-33.3	0.00	50.0
	Week 86	14	67.86	17.86	33.3	66.67	100.0	14	-2.38	26.03	-66.7	0.00	50.0
	Week 89	11	72.73	18.67	50.0	66.67	100.0	11	-1.52	15.73	-16.7	0.00	33.3
	Plat+Gem (N= 73)												
	BASELINE	63	84.13	21.67	16.7	100.00	100.0						
	Week 1	54	83.33	21.72	0.0	100.00	100.0	53	-0.94	17.73	-33.3	0.00	50.0
	Week 2	56	77.68	23.63	0.0	83.33	100.0	54	-5.25	22.85	-50.0	0.00	50.0
	Week 3	57	79.82	21.76	0.0	83.33	100.0	54	-4.94	16.07	-33.3	0.00	50.0
	Week 4	58	81.61	19.91	0.0	83.33	100.0	54	-3.09	18.05	-50.0	0.00	50.0
	Week 5	57	83.33	20.65	0.0	83.33	100.0	53	-2.83	17.82	-50.0	0.00	33.3
	Week 6	56	82.44	20.21	0.0	83.33	100.0	53	-2.52	21.78	-50.0	0.00	50.0
	Week 7	56	80.65	21.50	16.7	83.33	100.0	52	-2.88	21.32	-66.7	0.00	50.0
	Week 8	54	74.38	25.43	0.0	66.67	100.0	50	-9.00	25.02	-100.0	0.00	50.0
	Week 9	52	75.32	23.91	0.0	83.33	100.0	49	-8.50	23.35	-66.7	0.00	50.0
	Week 10	52	78.21	22.27	16.7	83.33	100.0	49	-7.14	23.57	-66.7	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	45	76.67	23.94	0.0	83.33	100.0	42	-5.95	23.23	-66.7	-8.33	50.0
	Week 12	47	75.18	24.29	0.0	66.67	100.0	43	-8.91	22.23	-50.0	0.00	50.0
	Week 14	43	78.68	22.22	0.0	83.33	100.0	39	-6.41	24.07	-50.0	0.00	66.7
	Week 17	40	80.00	21.08	33.3	83.33	100.0	36	-7.41	27.15	-66.7	-8.33	66.7
	Week 20	34	78.92	18.94	33.3	83.33	100.0	30	-6.67	22.99	-50.0	0.00	50.0
	Week 23	29	80.46	17.29	50.0	83.33	100.0	27	-10.49	17.39	-33.3	-16.66	33.3
	Week 26	26	79.49	20.17	16.7	83.33	100.0	24	-8.33	20.26	-50.0	0.00	33.3
	Week 29	24	79.17	23.70	0.0	83.33	100.0	22	-15.15	27.65	-100.0	-16.67	33.3
	Week 32	20	81.67	17.01	50.0	83.33	100.0	18	-11.11	18.08	-33.3	-8.33	33.3
	Week 35	17	84.31	17.15	50.0	83.33	100.0	15	-8.89	19.79	-50.0	0.00	33.3
	Week 38	18	79.63	18.57	50.0	83.33	100.0	15	-8.89	16.51	-33.3	0.00	16.7
	Week 41	18	83.33	15.12	50.0	83.33	100.0	16	-8.33	16.10	-33.3	0.00	16.7
	Week 44	16	77.08	18.13	50.0	83.33	100.0	14	-11.91	22.10	-50.0	-16.67	33.3
	Week 47	12	79.17	16.09	50.0	83.33	100.0	11	-12.12	19.85	-50.0	0.00	16.7
	Week 50	11	78.79	16.82	50.0	83.33	100.0	9	-9.26	22.22	-50.0	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	EV+Pembro (N=146)												
	BASELINE	119	83.33	17.63	16.7	83.33	100.0						
	Week 1	102	84.31	20.29	0.0	91.67	100.0	97	0.52	14.92	-50.0	0.00	33.3
	Week 2	106	82.86	20.37	16.7	83.33	100.0	98	-1.53	14.96	-50.0	0.00	33.3
	Week 3	94	85.64	20.10	0.0	100.00	100.0	88	0.57	15.46	-50.0	0.00	50.0
	Week 4	101	85.81	16.56	33.3	83.33	100.0	93	0.90	13.54	-33.3	0.00	33.3
	Week 5	96	87.15	19.27	0.0	100.00	100.0	89	1.12	15.45	-50.0	0.00	33.3
	Week 6	105	83.65	21.43	0.0	83.33	100.0	93	-1.07	19.32	-83.3	0.00	50.0
	Week 7	102	83.82	19.40	16.7	83.33	100.0	89	-0.94	16.54	-50.0	0.00	33.3
	Week 8	101	83.00	21.98	0.0	83.33	100.0	91	-2.56	18.41	-50.0	0.00	33.3
	Week 9	100	82.17	22.63	0.0	83.33	100.0	89	-2.81	18.50	-66.7	0.00	50.0
	Week 10	99	84.01	20.19	0.0	83.33	100.0	87	-1.34	17.65	-50.0	0.00	33.3
	Week 11	95	84.56	22.84	0.0	100.00	100.0	84	-1.79	18.11	-66.7	0.00	33.3
	Week 12	99	84.01	21.94	0.0	100.00	100.0	87	-1.34	17.28	-50.0	0.00	33.3
	Week 14	95	85.61	20.57	0.0	100.00	100.0	84	0.40	16.15	-50.0	0.00	33.3
	Week 17	97	85.40	17.88	16.7	100.00	100.0	84	-0.79	16.55	-50.0	0.00	33.3
	Week 20	90	86.67	16.23	33.3	100.00	100.0	79	0.63	17.79	-50.0	0.00	33.3
	Week 23	86	85.46	16.33	16.7	83.33	100.0	74	-1.13	14.68	-33.3	0.00	33.3
	Week 26	83	84.34	16.74	33.3	83.33	100.0	72	-3.24	16.46	-33.3	0.00	33.3
	Week 29	80	85.21	15.69	50.0	83.33	100.0	71	-0.94	16.40	-50.0	0.00	33.3
	Week 32	74	85.36	19.69	0.0	100.00	100.0	66	-0.76	19.92	-66.7	0.00	33.3
	Week 35	73	82.65	18.93	33.3	83.33	100.0	66	-3.53	18.61	-66.7	0.00	33.3
	Week 38	75	84.22	16.64	50.0	83.33	100.0	67	-1.24	17.96	-50.0	0.00	50.0
	Week 41	71	82.86	17.59	33.3	83.33	100.0	64	-2.86	16.94	-33.3	0.00	33.3
	Week 44	64	82.03	20.21	0.0	83.33	100.0	56	-3.57	18.18	-66.7	0.00	33.3
	Week 47	56	83.93	19.06	16.7	83.33	100.0	50	-0.67	17.80	-50.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	55	80.91	20.14	16.7	83.33	100.0	48	-5.21	18.88	-50.0	0.00	33.3
	Week 53	55	77.27	22.54	0.0	83.33	100.0	48	-6.94	19.09	-50.0	0.00	33.3
	Week 56	53	79.87	18.01	33.3	83.33	100.0	46	-4.35	16.64	-50.0	0.00	33.3
	Week 59	51	82.03	19.10	33.3	83.33	100.0	43	-3.88	18.84	-50.0	0.00	33.3
	Week 62	42	80.16	18.49	33.3	83.33	100.0	36	-5.56	15.43	-50.0	0.00	16.7
	Week 65	31	82.80	18.99	16.7	83.33	100.0	30	-0.56	16.66	-33.3	0.00	33.3
	Week 68	31	78.49	24.03	0.0	83.33	100.0	29	-6.32	22.01	-83.3	0.00	33.3
	Week 71	30	76.11	20.38	33.3	83.33	100.0	28	-8.33	20.03	-50.0	-8.33	33.3
	Week 74	29	76.44	19.68	33.3	83.33	100.0	27	-6.79	16.18	-33.3	0.00	16.7
	Week 77	26	78.21	19.30	33.3	83.33	100.0	24	-6.95	16.97	-33.3	0.00	33.3
	Week 80	26	75.00	20.14	33.3	66.67	100.0	26	-7.05	17.11	-33.3	0.00	33.3
	Week 83	21	80.16	17.17	50.0	83.33	100.0	21	-4.76	17.59	-33.3	0.00	33.3
	Week 86	17	71.57	25.52	16.7	66.67	100.0	17	-9.80	21.29	-66.7	0.00	16.7
	Week 89	11	80.30	19.46	50.0	83.33	100.0	11	-6.06	8.41	-16.7	0.00	0.0
	Week 92	13	78.21	23.94	16.7	83.33	100.0	13	-2.56	13.34	-33.3	0.00	16.7
	Plat+Gem (N=151)												
	BASELINE	123	85.77	18.69	16.7	100.00	100.0						
	Week 1	108	85.49	18.38	33.3	100.00	100.0	103	-1.46	14.02	-33.3	0.00	50.0
	Week 2	116	84.05	20.19	16.7	100.00	100.0	105	-1.75	17.28	-50.0	0.00	50.0
	Week 3	114	84.21	18.13	16.7	83.33	100.0	103	-3.07	15.08	-33.3	0.00	50.0
	Week 4	116	84.91	17.99	16.7	83.33	100.0	103	-1.62	15.74	-50.0	0.00	50.0
	Week 5	119	83.33	20.70	0.0	83.33	100.0	106	-2.83	16.50	-50.0	0.00	50.0
	Week 6	109	86.39	17.88	33.3	100.00	100.0	98	-0.51	17.17	-50.0	0.00	50.0
	Week 7	115	82.17	21.14	0.0	83.33	100.0	105	-3.81	18.53	-66.7	0.00	50.0
	Week 8	111	81.38	21.87	0.0	83.33	100.0	102	-4.25	20.00	-100.0	0.00	33.3
	Week 9	107	81.46	21.27	0.0	83.33	100.0	95	-4.56	20.11	-83.3	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	107	83.02	21.23	16.7	100.00	100.0	98	-3.57	19.18	-66.7	0.00	50.0
	Week 11	97	82.47	21.16	0.0	83.33	100.0	87	-3.45	19.21	-66.7	0.00	50.0
	Week 12	100	83.83	19.46	0.0	100.00	100.0	88	-1.70	18.92	-50.0	0.00	50.0
	Week 14	99	83.17	18.67	33.3	83.33	100.0	86	-3.29	19.94	-50.0	0.00	66.7
	Week 17	94	81.56	18.85	33.3	83.33	100.0	82	-5.08	20.90	-66.7	0.00	50.0
	Week 20	84	80.75	19.45	33.3	83.33	100.0	72	-6.48	19.49	-50.0	0.00	50.0
	Week 23	70	84.76	18.55	33.3	100.00	100.0	62	-3.23	18.07	-50.0	0.00	33.3
	Week 26	61	80.87	22.12	16.7	83.33	100.0	55	-6.36	20.41	-66.7	0.00	33.3
	Week 29	59	82.77	19.57	0.0	83.33	100.0	53	-6.60	20.24	-100.0	0.00	33.3
	Week 32	50	82.67	21.02	16.7	83.33	100.0	45	-5.18	16.97	-50.0	0.00	33.3
	Week 35	50	82.67	19.62	16.7	83.33	100.0	44	-4.92	17.82	-50.0	0.00	33.3
	Week 38	46	81.52	19.32	33.3	83.33	100.0	40	-4.58	20.32	-66.7	0.00	33.3
	Week 41	42	84.13	17.25	50.0	83.33	100.0	37	-3.60	15.78	-33.3	0.00	16.7
	Week 44	39	82.48	17.50	50.0	83.33	100.0	34	-4.41	18.03	-50.0	0.00	33.3
	Week 47	33	80.81	20.46	33.3	83.33	100.0	29	-4.02	19.75	-50.0	0.00	33.3
	Week 50	27	80.25	18.51	50.0	83.33	100.0	22	-3.79	21.16	-50.0	0.00	33.3
	Week 53	23	77.54	19.85	33.3	83.33	100.0	20	-3.33	17.60	-33.3	0.00	16.7
	Week 56	20	76.67	22.56	33.3	83.33	100.0	19	-4.39	20.67	-50.0	0.00	33.3
	Week 59	17	70.59	26.04	33.3	66.67	100.0	15	-4.44	23.96	-50.0	0.00	33.3
	Week 62	14	76.19	20.37	50.0	66.67	100.0	14	-4.76	17.82	-33.3	0.00	16.7
	Week 65	13	73.08	23.11	33.3	66.67	100.0	12	-8.33	20.72	-50.0	0.00	16.7
	Week 68	10	80.00	17.21	66.7	66.67	100.0	10	-1.67	18.34	-33.3	0.00	33.3
	Week 71	10	70.00	25.82	16.7	75.00	100.0	10	-15.00	26.58	-66.7	-8.34	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	EV+Pembro (N= 56)												
	BASELINE	41	77.24	23.79	16.7	83.33	100.0						
	Week 1	39	77.78	21.74	33.3	83.33	100.0	32	0.52	10.78	-16.7	0.00	16.7
	Week 2	44	75.00	26.04	0.0	83.33	100.0	35	-0.95	11.39	-33.3	0.00	33.3
	Week 3	45	76.67	22.02	16.7	83.33	100.0	34	-0.98	12.94	-33.3	0.00	33.3
	Week 4	44	76.52	26.73	0.0	83.33	100.0	36	-3.24	21.39	-83.3	0.00	50.0
	Week 5	41	76.02	25.56	16.7	83.33	100.0	32	0.00	21.17	-50.0	0.00	50.0
	Week 6	41	76.83	24.97	0.0	83.33	100.0	31	-1.07	21.05	-66.7	0.00	33.3
	Week 7	45	77.04	22.27	0.0	83.33	100.0	35	0.48	19.59	-66.7	0.00	33.3
	Week 8	46	76.45	23.19	33.3	83.33	100.0	33	0.00	21.65	-66.7	0.00	50.0
	Week 9	42	78.97	18.43	33.3	83.33	100.0	32	1.56	19.10	-33.3	0.00	50.0
	Week 10	40	77.08	26.87	0.0	83.33	100.0	31	-0.54	18.50	-50.0	0.00	33.3
	Week 11	42	76.98	21.13	16.7	83.33	100.0	31	1.61	18.44	-33.3	0.00	33.3
	Week 12	43	81.40	17.14	50.0	83.33	100.0	32	4.69	15.97	-16.7	0.00	33.3
	Week 14	44	79.92	17.82	33.3	83.33	100.0	32	3.65	16.25	-16.7	0.00	33.3
	Week 17	35	76.19	21.50	33.3	66.67	100.0	27	3.09	18.51	-33.3	0.00	50.0
	Week 20	30	81.11	14.34	66.7	83.33	100.0	24	6.25	16.16	-16.7	0.00	50.0
	Week 23	31	77.96	17.94	50.0	83.33	100.0	23	5.80	17.12	-16.7	0.00	33.3
	Week 26	29	82.76	13.72	66.7	83.33	100.0	22	9.85	21.61	-16.7	0.00	66.7
	Week 29	27	79.63	17.50	33.3	83.33	100.0	22	6.82	19.01	-33.3	0.00	50.0
	Week 32	28	76.19	18.94	33.3	75.00	100.0	22	7.58	25.05	-33.3	0.00	66.7
	Week 35	25	78.67	15.60	50.0	66.67	100.0	20	5.00	22.36	-16.7	0.00	66.7
	Week 38	22	78.79	15.58	50.0	75.00	100.0	19	4.39	23.46	-33.3	0.00	66.7
	Week 41	24	75.70	16.28	50.0	66.67	100.0	20	4.17	19.40	-16.7	0.00	50.0
	Week 44	22	75.00	19.07	33.3	66.67	100.0	18	2.78	20.81	-33.3	0.00	50.0
	Week 47	23	78.99	20.24	33.3	83.33	100.0	20	7.50	23.24	-33.3	0.00	83.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	19	74.56	17.89	50.0	66.67	100.0	16	2.08	20.07	-16.7	0.00	66.7
	Week 53	19	72.81	18.60	33.3	66.67	100.0	15	3.33	22.89	-33.3	0.00	50.0
	Week 56	19	75.44	21.78	33.3	83.33	100.0	15	1.11	26.33	-33.3	0.00	66.7
	Week 59	18	75.00	17.39	50.0	66.67	100.0	14	5.95	21.29	-16.7	0.00	66.7
	Week 62	20	75.83	19.85	33.3	66.67	100.0	16	5.21	19.93	-33.3	0.00	50.0
	Week 65	12	73.61	21.86	50.0	66.67	100.0	10	3.33	25.82	-16.7	0.00	66.7
	Week 68	15	78.89	20.38	50.0	83.33	100.0	13	3.85	16.88	-16.7	0.00	50.0
	Week 71	12	76.39	24.06	33.3	75.00	100.0	10	3.33	24.60	-33.3	0.00	50.0
	Week 77	11	77.27	20.10	33.3	83.33	100.0	9	9.26	25.15	-33.3	0.00	50.0
	Week 80	10	73.33	25.09	33.3	75.00	100.0	8	4.17	29.21	-33.3	0.00	50.0
	Plat+Gem (N= 51)												
	BASELINE	42	82.54	22.38	16.7	83.33	100.0						
	Week 1	36	81.94	23.36	0.0	91.67	100.0	36	0.46	17.59	-33.3	0.00	50.0
	Week 2	31	76.34	26.10	0.0	83.33	100.0	30	-3.33	18.78	-33.3	0.00	50.0
	Week 3	35	79.05	25.99	0.0	83.33	100.0	33	-5.56	13.61	-50.0	0.00	16.7
	Week 4	34	82.35	23.55	0.0	91.67	100.0	32	-1.04	11.15	-33.3	0.00	16.7
	Week 5	34	82.84	22.28	0.0	83.33	100.0	32	-2.60	13.46	-33.3	0.00	33.3
	Week 6	36	78.70	26.61	0.0	83.33	100.0	33	-4.04	18.18	-50.0	0.00	50.0
	Week 7	33	81.82	20.57	33.3	83.33	100.0	29	-1.15	19.38	-50.0	0.00	50.0
	Week 8	34	76.47	26.63	0.0	83.33	100.0	30	-6.11	20.75	-50.0	0.00	50.0
	Week 9	34	75.49	26.66	0.0	83.33	100.0	30	-8.33	20.88	-50.0	0.00	50.0
	Week 10	35	78.10	27.05	0.0	83.33	100.0	32	-4.17	21.59	-50.0	0.00	50.0
	Week 11	29	75.29	26.58	0.0	83.33	100.0	27	-6.17	20.23	-33.3	-16.66	50.0
	Week 12	30	77.78	22.46	0.0	83.33	100.0	27	-3.70	19.79	-33.3	0.00	50.0
	Week 14	26	74.36	28.76	0.0	83.33	100.0	23	-7.24	20.61	-33.3	0.00	50.0
	Week 17	26	78.85	27.31	0.0	83.33	100.0	24	-7.64	26.00	-83.3	-8.33	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 20	20	84.17	21.95	33.3	100.00	100.0	19	-2.63	23.08	-50.0	0.00	50.0
	Week 23	18	88.89	14.00	66.7	100.00	100.0	18	0.93	17.59	-16.7	0.00	50.0
	Week 26	20	86.67	18.42	33.3	100.00	100.0	20	3.33	20.66	-33.3	0.00	66.7
	Week 29	18	81.48	26.75	0.0	83.33	100.0	18	-7.41	31.43	-83.3	0.00	66.7
	Week 32	13	82.05	17.29	50.0	83.33	100.0	13	-6.41	12.80	-33.3	0.00	16.7
	Week 35	12	93.06	11.14	66.7	100.00	100.0	12	1.39	4.81	0.0	0.00	16.7
	Week 38	10	81.67	32.82	0.0	100.00	100.0	10	-13.33	25.82	-83.3	0.00	0.0
	Week 41	10	91.67	11.79	66.7	100.00	100.0	10	1.67	24.15	-16.7	0.00	66.7
	Week 44	10	83.33	19.25	50.0	83.33	100.0	10	-3.33	21.94	-33.3	0.00	50.0
	Week 47	10	85.00	16.57	50.0	83.33	100.0	10	-5.00	29.45	-50.0	-8.33	66.7
	Week 56	10	81.67	16.57	50.0	83.33	100.0	10	-5.00	29.45	-50.0	-8.33	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Visceral metastases	EV+Pembro (N=148)												
	BASELINE	119	79.69	20.72	16.7	83.33	100.0						
	Week 1	105	79.36	22.11	0.0	83.33	100.0	99	-0.50	15.14	-50.0	0.00	33.3
	Week 2	109	77.68	24.24	0.0	83.33	100.0	100	-2.17	15.47	-50.0	0.00	33.3
	Week 3	98	80.78	22.49	0.0	83.33	100.0	88	0.76	15.76	-50.0	0.00	50.0
	Week 4	103	81.07	22.02	0.0	83.33	100.0	93	-0.36	16.48	-83.3	0.00	33.3
	Week 5	100	81.17	23.41	0.0	83.33	100.0	90	-0.19	18.27	-50.0	0.00	50.0
	Week 6	105	80.32	22.74	0.0	83.33	100.0	90	-0.93	20.20	-83.3	0.00	50.0
	Week 7	108	80.71	20.02	16.7	83.33	100.0	91	0.18	16.94	-33.3	0.00	33.3
	Week 8	105	79.52	23.37	0.0	83.33	100.0	89	-1.69	20.26	-66.7	0.00	50.0
	Week 9	105	79.37	22.23	0.0	83.33	100.0	91	-1.83	19.32	-66.7	0.00	50.0
	Week 10	101	81.68	23.03	0.0	83.33	100.0	86	0.78	17.13	-50.0	0.00	33.3
	Week 11	97	81.79	22.06	0.0	83.33	100.0	83	-0.20	17.56	-50.0	0.00	33.3
	Week 12	100	81.83	22.11	0.0	83.33	100.0	85	0.98	18.43	-50.0	0.00	33.3
	Week 14	102	82.19	21.40	0.0	83.33	100.0	87	1.34	17.65	-50.0	0.00	33.3
	Week 17	96	81.42	20.36	16.7	83.33	100.0	81	0.41	18.06	-50.0	0.00	50.0
	Week 20	87	83.91	16.36	33.3	83.33	100.0	76	1.54	18.89	-50.0	0.00	50.0
	Week 23	85	81.76	17.93	16.7	83.33	100.0	71	0.94	16.40	-33.3	0.00	33.3
	Week 26	79	82.49	15.77	33.3	83.33	100.0	66	-0.50	19.60	-33.3	0.00	66.7
	Week 29	72	81.94	16.49	33.3	83.33	100.0	64	0.52	18.06	-50.0	0.00	50.0
	Week 32	71	81.92	21.22	0.0	83.33	100.0	62	1.61	23.32	-66.7	0.00	66.7
	Week 35	70	81.43	18.72	33.3	83.33	100.0	63	-1.06	20.93	-66.7	0.00	66.7
	Week 38	70	83.10	17.37	50.0	83.33	100.0	63	1.06	20.49	-50.0	0.00	66.7
	Week 41	66	81.06	17.99	33.3	83.33	100.0	60	0.56	17.62	-33.3	0.00	50.0
	Week 44	59	79.38	18.66	33.3	83.33	100.0	53	-1.57	18.28	-50.0	0.00	50.0
	Week 47	52	80.13	21.14	16.7	83.33	100.0	48	0.69	22.27	-50.0	0.00	83.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	49	76.53	20.95	16.7	83.33	100.0	43	-5.43	21.74	-50.0	0.00	66.7
	Week 53	50	72.33	22.49	0.0	66.67	100.0	44	-6.82	21.66	-50.0	0.00	50.0
	Week 56	45	76.67	20.23	33.3	83.33	100.0	39	-4.27	21.19	-50.0	0.00	66.7
	Week 59	44	78.41	20.20	33.3	83.33	100.0	38	-3.07	22.55	-50.0	0.00	66.7
	Week 62	38	77.19	19.92	33.3	83.33	100.0	33	-3.54	19.88	-50.0	0.00	50.0
	Week 65	25	80.67	21.34	16.7	83.33	100.0	24	2.08	23.21	-33.3	0.00	66.7
	Week 68	31	79.03	24.33	0.0	83.33	100.0	29	-4.60	24.35	-83.3	0.00	50.0
	Week 71	27	77.16	21.75	33.3	83.33	100.0	25	-6.67	24.06	-50.0	-16.66	50.0
	Week 74	23	74.64	20.64	33.3	66.67	100.0	22	-5.30	20.18	-33.3	-8.33	50.0
	Week 77	24	78.47	19.95	33.3	83.33	100.0	23	-2.90	22.28	-33.3	0.00	50.0
	Week 80	22	74.24	22.85	33.3	66.67	100.0	22	-4.55	21.93	-33.3	0.00	50.0
	Week 83	19	77.19	19.41	33.3	66.67	100.0	19	-2.63	23.08	-33.3	0.00	50.0
	Week 86	14	66.67	25.32	16.7	66.67	100.0	14	-8.33	27.54	-66.7	0.00	50.0
	Week 89	10	81.67	21.44	50.0	91.67	100.0	10	-1.67	9.46	-16.7	0.00	16.7
	Week 92	11	71.21	27.98	16.7	66.67	100.0	11	-4.54	16.82	-33.3	0.00	16.7
	Plat+Gem (N=157)												
	BASELINE	128	85.68	19.37	16.7	100.00	100.0						
	Week 1	111	84.08	20.15	0.0	83.33	100.0	107	-2.34	14.38	-33.3	0.00	50.0
	Week 2	110	82.12	22.66	0.0	83.33	100.0	102	-3.27	17.87	-50.0	0.00	50.0
	Week 3	112	83.33	20.99	0.0	83.33	100.0	103	-3.72	15.11	-50.0	0.00	50.0
	Week 4	112	84.82	19.83	0.0	83.33	100.0	102	-1.80	15.36	-50.0	0.00	50.0
	Week 5	113	83.78	21.18	0.0	100.00	100.0	103	-2.75	16.02	-50.0	0.00	50.0
	Week 6	107	84.89	21.17	0.0	100.00	100.0	98	-2.38	17.09	-50.0	0.00	50.0
	Week 7	109	81.96	20.55	16.7	83.33	100.0	100	-4.50	18.48	-66.7	0.00	50.0
	Week 8	106	80.35	24.43	0.0	83.33	100.0	98	-5.61	20.72	-100.0	0.00	33.3
	Week 9	105	79.84	24.21	0.0	83.33	100.0	94	-6.56	20.63	-83.3	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	104	83.01	22.87	0.0	100.00	100.0	96	-3.47	19.03	-66.7	0.00	50.0
	Week 11	91	81.14	23.20	0.0	83.33	100.0	83	-4.42	18.96	-66.7	0.00	50.0
	Week 12	94	82.98	21.44	0.0	100.00	100.0	84	-1.98	18.55	-50.0	0.00	50.0
	Week 14	90	82.04	20.79	0.0	83.33	100.0	79	-4.43	20.27	-50.0	0.00	66.7
	Week 17	90	81.11	20.48	0.0	83.33	100.0	80	-6.67	21.96	-83.3	0.00	50.0
	Week 20	74	81.53	19.62	33.3	83.33	100.0	64	-5.21	19.22	-50.0	0.00	50.0
	Week 23	63	85.19	18.48	33.3	100.00	100.0	58	-2.59	17.88	-50.0	0.00	50.0
	Week 26	55	83.33	21.52	16.7	100.00	100.0	52	-3.20	20.62	-50.0	0.00	66.7
	Week 29	53	82.39	21.29	0.0	83.33	100.0	50	-6.33	23.78	-100.0	0.00	66.7
	Week 32	42	80.56	22.67	16.7	83.33	100.0	40	-6.25	16.75	-50.0	0.00	33.3
	Week 35	39	84.62	19.64	16.7	83.33	100.0	36	-2.78	14.64	-33.3	0.00	33.3
	Week 38	37	79.73	24.58	0.0	83.33	100.0	34	-6.86	24.31	-83.3	0.00	33.3
	Week 41	33	85.86	16.73	50.0	100.00	100.0	31	-1.07	19.69	-33.3	0.00	66.7
	Week 44	32	82.29	18.90	50.0	83.33	100.0	30	-3.89	19.91	-50.0	0.00	50.0
	Week 47	28	82.74	18.97	33.3	83.33	100.0	26	-1.28	22.07	-33.3	0.00	66.7
	Week 50	22	81.06	19.45	50.0	83.33	100.0	20	-4.17	22.21	-50.0	0.00	33.3
	Week 53	19	78.95	20.67	33.3	83.33	100.0	17	-4.90	17.44	-33.3	0.00	16.7
	Week 56	18	75.93	21.56	33.3	75.00	100.0	17	-2.94	25.84	-50.0	0.00	66.7
	Week 59	13	69.23	21.35	33.3	66.67	100.0	12	-1.39	20.67	-33.3	0.00	33.3
	Week 62	11	69.70	20.84	50.0	66.67	100.0	11	-4.54	21.20	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Lymph node only	EV+Pembro (N= 43)												
	BASELINE	33	88.89	14.23	50.0	100.00	100.0						
	Week 1	30	92.22	12.93	50.0	100.00	100.0	24	3.47	8.48	0.0	0.00	33.3
	Week 2	34	89.71	13.62	50.0	100.00	100.0	27	1.23	7.91	-16.7	0.00	16.7
	Week 3	35	88.10	16.94	50.0	100.00	100.0	28	-1.79	12.29	-33.3	0.00	33.3
	Week 4	36	87.96	15.74	50.0	100.00	100.0	30	-0.56	16.07	-33.3	0.00	50.0
	Week 5	33	90.40	15.61	33.3	100.00	100.0	27	3.09	13.10	-33.3	0.00	33.3
	Week 6	34	86.27	23.38	0.0	100.00	100.0	28	-1.79	19.95	-66.7	0.00	33.3
	Week 7	34	84.31	22.82	0.0	100.00	100.0	28	-3.57	19.96	-66.7	0.00	33.3
	Week 8	35	85.24	19.29	33.3	100.00	100.0	29	-2.30	15.25	-33.3	0.00	33.3
	Week 9	30	86.11	19.12	33.3	100.00	100.0	24	-2.08	17.93	-50.0	0.00	33.3
	Week 10	31	83.33	21.52	16.7	83.33	100.0	26	-7.05	19.53	-50.0	0.00	33.3
	Week 11	34	85.29	22.39	16.7	100.00	100.0	27	-1.23	17.25	-33.3	0.00	33.3
	Week 12	35	87.62	16.34	50.0	100.00	100.0	28	-1.79	13.86	-33.3	0.00	33.3
	Week 14	30	90.56	13.62	50.0	100.00	100.0	23	1.45	11.14	-16.7	0.00	33.3
	Week 17	30	88.89	14.73	50.0	100.00	100.0	24	-0.69	14.31	-33.3	0.00	33.3
	Week 20	27	90.74	13.34	66.7	100.00	100.0	21	3.97	13.85	-16.7	0.00	33.3
	Week 23	27	88.27	13.72	66.7	100.00	100.0	21	-1.59	13.85	-33.3	0.00	33.3
	Week 26	27	88.89	15.33	50.0	100.00	100.0	22	0.76	17.42	-33.3	0.00	33.3
	Week 29	28	88.69	15.08	50.0	100.00	100.0	23	0.72	17.03	-33.3	0.00	33.3
	Week 32	24	85.42	16.53	50.0	91.67	100.0	20	-0.83	18.32	-33.3	0.00	33.3
	Week 35	22	81.82	17.75	33.3	83.33	100.0	18	-4.63	16.96	-33.3	0.00	16.7
	Week 38	21	82.54	14.41	66.7	83.33	100.0	17	-4.90	17.44	-33.3	0.00	16.7
	Week 41	22	81.82	16.19	50.0	83.33	100.0	17	-6.86	18.69	-33.3	0.00	33.3
	Week 44	22	80.30	24.47	0.0	83.33	100.0	16	-6.25	22.67	-66.7	0.00	33.3
	Week 47	21	87.30	14.82	50.0	83.33	100.0	16	3.12	13.90	-16.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	84.17	16.64	50.0	83.33	100.0	16	0.00	13.61	-16.7	0.00	33.3
	Week 53	18	84.26	18.50	33.3	83.33	100.0	14	0.00	18.49	-33.3	0.00	33.3
	Week 56	21	80.95	17.71	33.3	83.33	100.0	17	-1.96	17.56	-33.3	0.00	33.3
	Week 59	21	83.33	16.67	50.0	83.33	100.0	16	1.04	12.87	-16.7	0.00	16.7
	Week 62	19	82.46	18.82	33.3	83.33	100.0	15	1.11	13.32	-33.3	0.00	16.7
	Week 65	16	80.21	19.45	50.0	75.00	100.0	14	-1.19	10.26	-16.7	0.00	16.7
	Week 68	13	79.49	19.43	50.0	83.33	100.0	11	1.51	8.99	-16.7	0.00	16.7
	Week 71	13	75.64	21.10	33.3	66.67	100.0	11	-1.52	17.41	-33.3	0.00	33.3
	Week 74	13	80.77	16.45	50.0	83.33	100.0	11	0.00	18.26	-33.3	0.00	33.3
	Week 77	13	76.92	18.68	33.3	83.33	100.0	10	-1.67	16.57	-33.3	0.00	33.3
	Week 80	13	74.36	19.97	33.3	66.67	100.0	11	-3.03	19.46	-33.3	0.00	33.3
	Week 83	11	75.76	21.56	33.3	83.33	100.0	10	-3.33	15.32	-33.3	0.00	16.7
	Week 86	11	77.27	18.67	50.0	83.33	100.0	10	1.67	14.59	-16.7	0.00	33.3
	Plat+Gem (N= 37)												
	BASELINE	29	82.18	18.86	33.3	83.33	100.0						
	Week 1	26	85.26	18.46	33.3	91.67	100.0	25	2.67	17.13	-33.3	0.00	50.0
	Week 2	30	83.89	20.29	33.3	91.67	100.0	26	1.92	14.40	-33.3	0.00	33.3
	Week 3	30	81.11	19.44	33.3	83.33	100.0	26	-2.56	14.67	-33.3	0.00	16.7
	Week 4	32	81.25	18.33	33.3	83.33	100.0	27	-0.62	13.46	-16.7	0.00	16.7
	Week 5	33	80.30	21.83	0.0	83.33	100.0	28	-2.38	16.80	-50.0	0.00	33.3
	Week 6	32	84.37	19.83	33.3	91.67	100.0	27	2.47	14.40	-16.7	0.00	33.3
	Week 7	31	80.65	23.61	0.0	83.33	100.0	26	-1.28	18.81	-50.0	0.00	33.3
	Week 8	32	78.65	19.96	33.3	83.33	100.0	27	-3.70	16.88	-50.0	0.00	33.3
	Week 9	30	80.00	18.77	33.3	83.33	100.0	25	-2.67	16.44	-33.3	0.00	33.3
	Week 10	30	77.78	24.11	16.7	83.33	100.0	26	-5.13	20.96	-50.0	0.00	33.3
	Week 11	29	80.46	22.74	16.7	83.33	100.0	25	-3.33	18.00	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.14.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 12	28	82.14	18.10	50.0	83.33	100.0	23	-1.45	18.06	-33.3	0.00	33.3
	Week 14	28	79.76	24.99	16.7	100.00	100.0	23	-3.62	18.09	-33.3	0.00	33.3
	Week 17	25	79.33	22.71	16.7	83.33	100.0	21	-1.59	22.30	-33.3	0.00	66.7
	Week 20	23	80.43	22.28	33.3	83.33	100.0	20	-5.83	23.74	-50.0	0.00	50.0
	Week 23	20	86.67	16.75	50.0	100.00	100.0	17	0.00	17.68	-33.3	0.00	33.3
	Week 26	21	80.95	22.54	16.7	83.33	100.0	18	-1.85	21.30	-66.7	0.00	33.3
	Week 29	19	83.33	23.57	0.0	83.33	100.0	16	-6.25	24.25	-83.3	0.00	33.3
	Week 32	18	87.96	13.77	66.7	91.67	100.0	15	-1.11	13.31	-16.7	0.00	33.3
	Week 35	19	85.09	17.48	50.0	83.33	100.0	16	-4.17	18.76	-50.0	0.00	33.3
	Week 38	15	86.67	16.90	50.0	100.00	100.0	12	-1.39	13.21	-33.3	0.00	16.7
	Week 41	15	86.67	18.04	50.0	100.00	100.0	12	-1.39	13.22	-33.3	0.00	16.7
	Week 44	14	85.71	15.82	50.0	83.33	100.0	11	0.00	14.91	-16.7	0.00	33.3
	Week 47	12	84.72	19.41	33.3	83.33	100.0	10	-3.33	18.92	-50.0	0.00	16.7
	Week 50	11	81.82	18.94	50.0	83.33	100.0	8	-2.08	16.51	-33.3	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
EV+Pembro (N=240)												
BASELINE	206	30.85	25.07	0.0	33.33	100.0						
Week 1	190	33.80	24.40	0.0	33.33	100.0	184	3.86	19.43	-100.0	0.00	66.7
Week 2	203	37.60	24.77	0.0	33.33	100.0	189	8.05	18.90	-66.7	0.00	66.7
Week 3	198	40.68	24.71	0.0	33.33	100.0	182	10.32	22.65	-55.6	11.11	88.9
Week 4	194	35.62	23.34	0.0	33.33	100.0	179	6.02	22.85	-66.7	0.00	66.7
Week 5	190	34.68	23.71	0.0	33.33	100.0	173	5.46	23.07	-66.7	0.00	88.9
Week 6	188	32.80	23.11	0.0	33.33	100.0	170	3.79	22.75	-55.6	0.00	77.8
Week 7	195	33.67	22.25	0.0	33.33	100.0	176	3.60	24.75	-66.7	0.00	77.8
Week 8	191	32.75	22.76	0.0	33.33	100.0	171	3.57	24.87	-66.7	0.00	77.8
Week 9	197	35.14	22.88	0.0	33.33	100.0	180	6.05	26.06	-88.9	0.00	77.8
Week 10	191	33.10	21.08	0.0	33.33	88.9	175	3.24	24.47	-66.7	0.00	77.8
Week 11	194	33.22	23.59	0.0	33.33	100.0	175	3.24	27.22	-66.7	0.00	88.9
Week 12	186	32.79	23.20	0.0	33.33	100.0	171	2.99	26.37	-66.7	0.00	100.0
Week 14	185	33.45	23.46	0.0	33.33	100.0	167	4.39	25.38	-66.7	0.00	100.0
Week 17	178	34.71	23.43	0.0	33.33	100.0	162	5.62	25.54	-66.7	0.00	88.9
Week 20	167	35.46	24.30	0.0	33.33	100.0	154	7.79	26.98	-66.7	0.00	88.9
Week 23	162	35.73	24.20	0.0	33.33	100.0	151	8.32	26.30	-66.7	0.00	77.8
Week 26	156	35.04	23.99	0.0	33.33	100.0	144	6.71	27.73	-66.7	0.00	88.9
Week 29	157	33.12	23.49	0.0	33.33	100.0	145	5.82	26.71	-66.7	0.00	88.9
Week 32	135	33.50	23.67	0.0	33.33	100.0	125	7.38	24.36	-66.7	0.00	66.7
Week 35	132	34.34	21.64	0.0	33.33	100.0	122	7.92	22.65	-44.5	0.00	66.7
Week 38	132	34.51	24.26	0.0	33.33	100.0	124	6.99	25.36	-66.7	0.00	66.7
Week 41	129	34.80	22.80	0.0	33.33	100.0	119	8.68	24.98	-66.7	0.00	88.9
Week 44	108	33.54	22.74	0.0	33.33	100.0	100	9.78	26.25	-66.7	11.11	88.9
Week 47	100	34.55	24.15	0.0	33.33	100.0	94	10.40	26.71	-66.7	11.11	88.9

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	89	34.58	24.01	0.0	33.33	100.0	84	11.77	23.86	-33.3	11.11	77.8
Week 53	79	30.66	21.88	0.0	33.33	100.0	74	8.56	26.88	-66.7	11.11	100.0
Week 56	81	35.39	24.79	0.0	33.33	100.0	76	11.40	27.22	-66.7	11.11	100.0
Week 59	72	31.48	24.32	0.0	33.33	100.0	68	8.01	26.10	-66.7	11.11	100.0
Week 62	65	31.11	26.29	0.0	33.33	100.0	63	9.52	27.86	-66.7	11.11	100.0
Week 65	58	34.29	25.60	0.0	33.33	100.0	54	10.08	28.49	-66.7	5.56	100.0
Week 68	53	32.70	23.51	0.0	33.33	100.0	52	12.18	25.87	-66.7	11.11	66.7
Week 71	51	31.15	24.95	0.0	33.33	100.0	49	10.66	26.15	-66.7	11.11	66.7
Week 74	47	32.15	24.55	0.0	33.33	88.9	46	10.15	26.17	-66.7	11.11	77.8
Week 77	44	36.62	25.09	0.0	33.33	100.0	42	13.76	30.63	-66.7	11.11	77.8
Week 80	40	35.28	24.38	0.0	33.33	100.0	37	8.41	24.90	-66.7	11.11	66.7
Week 83	37	36.33	22.32	0.0	33.33	100.0	35	10.16	25.48	-66.7	11.11	66.7
Week 86	34	34.31	23.75	0.0	33.33	100.0	31	9.32	25.35	-66.7	11.11	66.7
Week 89	33	36.70	25.68	0.0	33.33	100.0	31	11.11	24.85	-66.7	11.11	55.6
Week 92	27	33.74	26.06	0.0	33.33	100.0	25	11.11	25.05	-33.3	11.11	66.7
Week 95	22	36.36	23.80	0.0	33.33	77.8	21	14.82	22.31	-22.2	11.11	55.6
Week 98	18	33.95	23.33	0.0	33.33	66.7	17	8.50	19.85	-11.1	0.00	55.6
Week 101	14	29.36	22.90	0.0	33.33	66.7	14	6.35	26.76	-33.3	5.56	66.7
Week 104	10	32.22	22.50	0.0	33.33	66.7	10	17.78	22.35	-11.1	11.12	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Plat+Gem (N=242)												
BASELINE	188	34.81	23.94	0.0	33.33	100.0						
Week 1	173	41.04	24.39	0.0	33.33	100.0	158	7.31	20.37	-33.3	0.00	77.8
Week 2	171	43.40	25.55	0.0	33.33	100.0	151	10.60	23.32	-44.5	0.00	100.0
Week 3	184	39.55	23.08	0.0	33.33	100.0	162	5.14	19.19	-55.6	0.00	66.7
Week 4	183	39.53	22.09	0.0	33.33	100.0	156	7.12	20.58	-66.7	0.00	66.7
Week 5	187	42.48	22.71	0.0	33.33	100.0	156	10.47	20.90	-44.5	5.56	77.8
Week 6	174	40.42	25.18	0.0	33.33	100.0	149	6.12	22.76	-55.6	0.00	88.9
Week 7	186	39.07	23.57	0.0	33.33	100.0	157	5.45	22.25	-55.6	0.00	88.9
Week 8	167	41.38	23.36	0.0	33.33	100.0	144	9.65	24.17	-55.6	11.11	100.0
Week 9	177	39.11	23.66	0.0	33.33	100.0	150	6.30	23.89	-33.3	0.00	100.0
Week 10	166	40.43	24.07	0.0	33.33	100.0	139	7.35	24.94	-33.3	0.00	100.0
Week 11	168	39.68	23.85	0.0	33.33	100.0	143	7.54	23.20	-55.6	0.00	77.8
Week 12	159	37.87	23.43	0.0	33.33	100.0	138	5.39	24.36	-55.6	0.00	77.8
Week 14	153	39.14	25.27	0.0	33.33	100.0	128	6.42	24.02	-66.7	0.00	66.7
Week 17	155	39.43	24.82	0.0	33.33	100.0	130	8.38	24.20	-66.7	11.11	66.7
Week 20	126	35.36	22.24	0.0	33.33	100.0	110	5.56	23.74	-55.6	0.00	66.7
Week 23	115	33.14	25.15	0.0	33.33	100.0	97	5.04	22.68	-55.6	0.00	55.6
Week 26	108	31.27	24.55	0.0	33.33	100.0	95	3.28	22.63	-44.5	0.00	66.7
Week 29	100	30.22	22.17	0.0	33.33	100.0	86	3.36	20.53	-44.4	0.00	55.6
Week 32	83	31.06	22.54	0.0	33.33	100.0	76	2.63	22.73	-44.5	0.00	66.7
Week 35	76	29.68	22.55	0.0	33.33	100.0	69	1.93	23.02	-66.7	0.00	55.6
Week 38	74	32.88	23.73	0.0	33.33	100.0	65	4.79	22.99	-44.5	0.00	66.7
Week 41	65	33.67	22.39	0.0	33.33	100.0	56	5.56	21.40	-44.5	0.00	66.7
Week 44	60	32.22	24.61	0.0	33.33	100.0	53	5.03	24.42	-33.3	0.00	66.7
Week 47	56	30.36	23.55	0.0	33.33	100.0	49	5.90	26.46	-44.5	0.00	88.9

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	51	33.55	25.87	0.0	33.33	100.0	47	5.91	20.18	-44.5	0.00	66.7
Week 53	46	27.78	17.80	0.0	33.33	66.7	42	2.38	19.09	-55.6	0.00	33.3
Week 56	39	35.33	25.73	0.0	33.33	100.0	34	8.50	26.39	-44.5	0.00	66.7
Week 59	37	30.03	23.70	0.0	33.33	100.0	33	5.72	23.26	-33.3	0.00	66.7
Week 62	32	29.86	19.02	0.0	33.33	77.8	29	5.75	24.06	-55.6	0.00	66.7
Week 65	30	27.78	24.02	0.0	33.33	100.0	26	4.27	18.88	-33.3	0.00	66.7
Week 68	25	30.66	20.36	0.0	33.33	77.8	21	4.23	20.02	-33.3	0.00	44.4
Week 71	22	33.84	25.77	0.0	33.33	100.0	19	8.19	18.46	-33.3	0.00	33.3
Week 74	21	25.39	23.34	0.0	33.33	100.0	18	0.62	16.38	-33.3	0.00	33.3
Week 77	18	27.16	21.63	0.0	27.78	66.7	15	3.70	22.49	-33.3	0.00	55.6
Week 80	14	29.36	19.30	0.0	33.33	66.7	13	9.40	18.06	-33.3	11.11	33.3
Week 83	13	27.35	13.31	0.0	33.33	44.4	12	2.78	19.02	-33.3	0.00	33.3
Week 86	12	26.85	16.72	0.0	33.33	55.6	11	6.06	18.16	-33.3	11.11	33.3
Week 89	11	21.21	14.45	0.0	22.22	44.4	10	-3.33	17.41	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Present	EV+Pembro (N= 48)												
	BASELINE	39	41.88	30.74	0.0	44.44	100.0						
	Week 1	32	42.36	30.84	0.0	33.33	100.0	32	1.04	25.77	-100.0	0.00	44.4
	Week 2	37	51.05	25.99	0.0	44.44	100.0	33	11.78	23.72	-66.7	11.11	55.6
	Week 3	34	54.58	28.08	0.0	55.56	100.0	29	9.19	25.56	-55.6	0.00	66.7
	Week 4	36	46.60	27.96	0.0	44.44	100.0	31	6.81	29.21	-55.6	0.00	66.7
	Week 5	30	52.59	30.03	0.0	50.00	100.0	24	9.72	28.25	-44.4	5.56	88.9
	Week 6	31	44.80	27.44	0.0	44.44	100.0	25	3.55	27.54	-33.3	0.00	66.7
	Week 7	34	43.46	25.27	0.0	33.33	100.0	28	-1.19	25.54	-44.5	0.00	77.8
	Week 8	35	41.27	25.79	0.0	33.33	100.0	30	-0.37	30.53	-55.6	0.00	77.8
	Week 9	34	44.77	27.56	0.0	38.89	100.0	30	6.67	33.47	-88.9	11.11	77.8
	Week 10	34	38.89	24.20	0.0	33.33	88.9	30	-0.74	31.56	-66.7	0.00	77.8
	Week 11	33	47.81	29.20	0.0	44.44	100.0	28	7.14	34.38	-55.6	0.00	77.8
	Week 12	33	42.42	28.39	0.0	33.33	100.0	29	3.06	30.27	-66.7	0.00	66.7
	Week 14	31	40.86	26.67	0.0	33.33	100.0	26	0.43	32.43	-66.7	0.00	77.8
	Week 17	31	40.86	24.24	0.0	33.33	100.0	25	0.00	30.26	-66.7	0.00	66.7
	Week 20	27	42.80	26.99	0.0	33.33	88.9	24	6.48	31.24	-44.5	0.00	77.8
	Week 23	26	38.46	23.98	0.0	33.33	77.8	23	0.97	26.99	-55.6	0.00	55.6
	Week 26	25	34.67	24.07	0.0	33.33	66.7	22	-4.55	30.22	-66.7	0.00	66.7
	Week 29	23	36.23	27.87	0.0	33.33	100.0	22	1.51	33.30	-66.7	0.00	66.7
	Week 32	21	35.98	27.87	0.0	33.33	66.7	19	0.00	31.21	-66.7	0.00	66.7
	Week 35	19	41.52	28.17	0.0	33.33	88.9	17	7.19	28.58	-33.3	0.00	66.7
	Week 38	18	48.77	29.31	0.0	50.00	100.0	17	8.50	29.54	-44.5	11.11	66.7
	Week 41	20	36.67	24.48	0.0	33.33	88.9	19	4.09	31.91	-66.7	0.00	88.9
	Week 44	17	34.64	20.37	0.0	33.33	66.7	15	5.92	27.82	-66.7	0.00	55.6
	Week 47	18	43.21	34.70	0.0	38.89	100.0	16	10.42	35.94	-66.7	0.00	88.9

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	12	31.48	32.08	0.0	22.22	77.8	11	11.11	28.11	-22.2	0.00	77.8
	Week 53	12	37.04	34.92	0.0	33.33	100.0	11	15.15	36.94	-44.5	0.00	100.0
	Week 56	13	37.61	34.71	0.0	33.33	100.0	12	11.11	36.70	-66.7	11.11	100.0
	Week 59	12	29.63	31.90	0.0	22.22	100.0	11	3.03	41.00	-66.7	0.00	100.0
	Week 62	10	24.44	37.33	0.0	0.00	100.0	9	2.47	43.67	-66.7	0.00	100.0
	Week 65	10	36.67	34.76	0.0	33.33	100.0	9	8.64	42.59	-66.7	0.00	100.0
	Plat+Gem (N= 48)												
	BASELINE	33	38.38	24.39	0.0	33.33	88.9						
	Week 1	31	44.80	24.59	0.0	44.44	100.0	27	5.76	16.98	-33.3	0.00	44.4
	Week 2	29	50.19	29.94	0.0	44.44	100.0	24	13.89	35.18	-44.5	11.11	100.0
	Week 3	32	36.80	23.35	0.0	33.33	100.0	27	-2.06	22.44	-55.6	0.00	44.4
	Week 4	32	37.15	22.86	0.0	33.33	100.0	24	1.85	26.14	-66.7	5.56	44.4
	Week 5	36	42.28	24.46	0.0	33.33	100.0	28	5.56	17.50	-44.5	0.00	44.4
	Week 6	35	40.32	28.28	0.0	33.33	100.0	27	-1.65	25.17	-55.6	0.00	33.3
	Week 7	38	39.77	26.30	0.0	33.33	100.0	29	-4.21	20.66	-55.6	0.00	33.3
	Week 8	31	35.12	19.05	0.0	33.33	66.7	25	2.67	17.65	-44.5	0.00	33.3
	Week 9	32	37.85	22.02	0.0	33.33	88.9	25	-2.67	17.06	-33.3	0.00	33.3
	Week 10	34	39.87	23.87	0.0	33.33	88.9	26	-3.85	16.31	-33.3	0.00	33.3
	Week 11	30	31.48	21.46	0.0	33.33	77.8	24	-7.41	21.40	-55.6	-5.56	33.3
	Week 12	28	33.33	20.95	0.0	33.33	66.7	23	-7.25	21.09	-55.6	0.00	33.3
	Week 14	26	39.32	16.99	11.1	33.33	77.8	21	1.59	19.97	-33.3	0.00	33.3
	Week 17	30	35.18	20.65	0.0	33.33	77.8	25	-1.78	18.05	-44.4	0.00	22.2
	Week 20	23	29.95	17.87	0.0	22.22	66.7	21	-6.35	20.05	-33.3	-11.11	33.3
	Week 23	22	30.81	26.32	0.0	22.22	88.9	19	-2.92	23.96	-55.6	0.00	44.5
	Week 26	19	24.56	23.59	0.0	22.22	66.7	18	-6.17	20.60	-44.5	-5.56	33.3
	Week 29	16	24.31	26.67	0.0	16.67	88.9	14	-7.94	24.82	-44.4	-11.11	55.6

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 32	11	26.26	11.41	0.0	33.33	33.3	11	-6.06	14.37	-33.3	0.00	11.1
	Week 35	10	31.11	22.71	0.0	33.33	66.7	9	-2.47	20.62	-33.3	0.00	44.5

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Absent	EV+Pembro (N=192)												
	BASELINE	167	28.28	22.90	0.0	33.33	100.0						
	Week 1	158	32.07	22.61	0.0	33.33	100.0	152	4.46	17.87	-33.3	0.00	66.7
	Week 2	166	34.60	23.54	0.0	33.33	100.0	156	7.27	17.70	-33.3	0.00	66.7
	Week 3	164	37.80	23.02	0.0	33.33	100.0	153	10.53	22.14	-55.6	11.11	88.9
	Week 4	158	33.12	21.48	0.0	33.33	100.0	148	5.86	21.39	-66.7	0.00	55.6
	Week 5	160	31.32	20.77	0.0	33.33	88.9	149	4.77	22.16	-66.7	0.00	66.7
	Week 6	157	30.43	21.47	0.0	33.33	100.0	145	3.83	21.93	-55.6	0.00	77.8
	Week 7	161	31.61	21.07	0.0	33.33	100.0	148	4.50	24.59	-66.7	0.00	66.7
	Week 8	156	30.84	21.66	0.0	33.33	100.0	141	4.41	23.53	-66.7	0.00	66.7
	Week 9	163	33.13	21.33	0.0	33.33	100.0	150	5.93	24.45	-55.6	0.00	77.8
	Week 10	157	31.85	20.21	0.0	33.33	88.9	145	4.06	22.79	-66.7	0.00	66.7
	Week 11	161	30.23	21.16	0.0	33.33	100.0	147	2.49	25.71	-66.7	0.00	88.9
	Week 12	153	30.72	21.47	0.0	33.33	100.0	142	2.97	25.62	-66.7	0.00	100.0
	Week 14	154	31.96	22.56	0.0	33.33	100.0	141	5.12	23.92	-55.6	0.00	100.0
	Week 17	147	33.41	23.14	0.0	33.33	100.0	137	6.65	24.57	-66.7	0.00	88.9
	Week 20	140	34.05	23.59	0.0	33.33	100.0	130	8.03	26.25	-66.7	0.00	88.9
	Week 23	136	35.21	24.29	0.0	33.33	100.0	128	9.64	26.06	-66.7	11.11	77.8
	Week 26	131	35.11	24.06	0.0	33.33	100.0	122	8.74	26.89	-66.7	0.00	88.9
	Week 29	134	32.59	22.73	0.0	33.33	100.0	123	6.59	25.44	-66.7	0.00	88.9
	Week 32	114	33.04	22.92	0.0	33.33	100.0	106	8.70	22.85	-33.3	0.00	66.7
	Week 35	113	33.14	20.25	0.0	33.33	100.0	105	8.04	21.71	-44.5	0.00	66.7
	Week 38	114	32.26	22.71	0.0	33.33	100.0	107	6.75	24.79	-66.7	0.00	66.7
	Week 41	109	34.45	22.58	0.0	33.33	100.0	100	9.56	23.53	-66.7	11.11	66.7
	Week 44	91	33.33	23.25	0.0	33.33	100.0	85	10.46	26.08	-33.3	11.11	88.9
	Week 47	82	32.65	20.98	0.0	33.33	88.9	78	10.40	24.71	-66.7	11.11	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	77	35.06	22.73	0.0	33.33	100.0	73	11.87	23.38	-33.3	11.11	66.7
	Week 53	67	29.52	18.81	0.0	33.33	77.8	63	7.41	24.93	-66.7	11.11	55.6
	Week 56	68	34.97	22.74	0.0	33.33	100.0	64	11.46	25.43	-33.3	11.11	88.9
	Week 59	60	31.85	22.82	0.0	33.33	100.0	57	8.97	22.56	-33.3	11.11	66.7
	Week 62	55	32.32	24.03	0.0	33.33	100.0	54	10.70	24.70	-33.3	11.11	77.8
	Week 65	48	33.80	23.71	0.0	33.33	88.9	45	10.37	25.45	-33.3	11.11	55.6
	Week 68	46	33.09	23.13	0.0	33.33	100.0	45	13.09	23.49	-33.3	11.11	66.7
	Week 71	44	31.31	24.35	0.0	33.33	100.0	42	11.90	23.84	-33.3	11.11	66.7
	Week 74	40	31.94	22.81	0.0	33.33	88.9	39	10.83	24.25	-33.3	11.11	77.8
	Week 77	38	36.84	22.98	0.0	33.33	100.0	36	15.43	27.89	-33.3	11.11	55.6
	Week 80	35	35.24	23.41	0.0	33.33	100.0	32	10.07	20.23	-33.3	11.11	44.5
	Week 83	32	35.76	19.90	0.0	33.33	100.0	30	11.48	20.94	-33.3	11.11	55.6
	Week 86	29	35.25	22.04	0.0	33.33	100.0	26	11.54	19.49	-33.3	11.11	55.6
	Week 89	29	37.93	24.94	0.0	33.33	100.0	27	13.58	20.52	-22.2	11.11	55.6
	Week 92	24	34.26	26.40	0.0	33.33	100.0	22	9.60	24.80	-33.3	11.11	66.7
	Week 95	20	35.00	24.52	0.0	33.33	77.8	19	14.04	22.17	-22.2	11.11	55.6
	Week 98	18	33.95	23.33	0.0	33.33	66.7	17	8.50	19.85	-11.1	0.00	55.6
	Week 101	13	26.49	21.05	0.0	33.33	55.6	13	1.71	21.20	-33.3	0.00	33.3
	Plat+Gem (N=194)												
	BASELINE	155	34.05	23.85	0.0	33.33	100.0						
	Week 1	142	40.22	24.36	0.0	33.33	100.0	131	7.63	21.04	-33.3	0.00	77.8
	Week 2	142	42.02	24.44	0.0	33.33	100.0	127	9.97	20.47	-33.3	0.00	66.7
	Week 3	152	40.13	23.06	0.0	33.33	100.0	135	6.58	18.23	-44.5	0.00	66.7
	Week 4	151	40.03	21.97	0.0	33.33	100.0	132	8.08	19.37	-44.5	0.00	66.7
	Week 5	151	42.53	22.36	0.0	33.33	100.0	128	11.55	21.48	-33.3	11.11	77.8
	Week 6	139	40.45	24.45	0.0	33.33	100.0	122	7.83	21.93	-33.3	0.00	88.9

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 7	148	38.89	22.91	0.0	33.33	100.0	128	7.64	22.08	-44.5	5.56	88.9
	Week 8	136	42.81	24.06	0.0	33.33	100.0	119	11.11	25.14	-55.6	11.11	100.0
	Week 9	145	39.39	24.07	0.0	33.33	100.0	125	8.09	24.70	-33.3	0.00	100.0
	Week 10	132	40.57	24.21	0.0	33.33	100.0	113	9.93	25.91	-33.3	0.00	100.0
	Week 11	138	41.46	24.04	0.0	33.33	100.0	119	10.55	22.45	-33.3	11.11	77.8
	Week 12	131	38.85	23.89	0.0	33.33	100.0	115	7.92	24.26	-55.6	0.00	77.8
	Week 14	127	39.11	26.70	0.0	33.33	100.0	107	7.37	24.70	-66.7	0.00	66.7
	Week 17	125	40.44	25.69	0.0	33.33	100.0	105	10.79	24.92	-66.7	11.11	66.7
	Week 20	103	36.57	23.01	0.0	33.33	100.0	89	8.36	23.77	-55.6	0.00	66.7
	Week 23	93	33.69	24.98	0.0	33.33	100.0	78	6.98	22.09	-44.5	0.00	55.6
	Week 26	89	32.71	24.64	0.0	33.33	100.0	77	5.48	22.63	-44.5	0.00	66.7
	Week 29	84	31.35	21.21	0.0	33.33	100.0	72	5.56	19.02	-33.3	0.00	55.6
	Week 32	72	31.79	23.76	0.0	33.33	100.0	65	4.10	23.62	-44.5	0.00	66.7
	Week 35	66	29.46	22.69	0.0	33.33	100.0	60	2.59	23.45	-66.7	0.00	55.6
	Week 38	66	33.67	24.73	0.0	33.33	100.0	57	4.68	24.39	-44.5	0.00	66.7
	Week 41	62	33.51	22.72	0.0	33.33	100.0	53	5.87	21.86	-44.5	0.00	66.7
	Week 44	55	31.11	23.95	0.0	33.33	88.9	48	3.70	23.97	-33.3	0.00	66.7
	Week 47	51	29.85	24.59	0.0	33.33	100.0	44	4.80	27.26	-44.5	0.00	88.9
	Week 50	48	33.56	26.68	0.0	33.33	100.0	44	6.06	20.82	-44.5	0.00	66.7
	Week 53	41	27.37	18.77	0.0	33.33	66.7	37	1.20	19.56	-55.6	0.00	33.3
	Week 56	34	32.02	23.17	0.0	33.33	100.0	29	4.21	24.02	-44.5	0.00	66.7
	Week 59	32	27.78	22.04	0.0	33.33	100.0	28	2.38	21.46	-33.3	0.00	55.6
	Week 62	27	27.98	18.33	0.0	33.33	77.8	24	2.78	24.35	-55.6	0.00	66.7
	Week 65	25	24.44	21.52	0.0	33.33	88.9	21	-0.53	13.82	-33.3	0.00	33.3
	Week 68	23	28.98	19.75	0.0	33.33	77.8	19	2.34	19.80	-33.3	0.00	44.4
	Week 71	21	32.27	25.31	0.0	33.33	100.0	18	6.79	17.93	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 74	20	25.00	23.88	0.0	27.78	100.0	17	0.00	16.67	-33.3	0.00	33.3
	Week 77	16	26.39	22.91	0.0	22.22	66.7	13	3.42	24.17	-33.3	0.00	55.6
	Week 80	12	28.70	20.90	0.0	33.33	66.7	11	10.10	19.53	-33.3	11.11	33.3
	Week 83	11	26.26	14.29	0.0	33.33	44.4	10	2.22	20.82	-33.3	0.00	33.3
	Week 86	10	24.44	17.21	0.0	27.78	55.6	9	4.94	20.12	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
< 65 years	EV+Pembro (N=105)												
	BASELINE	92	33.21	25.81	0.0	33.33	100.0						
	Week 1	88	34.72	25.60	0.0	33.33	100.0	85	3.66	15.84	-33.3	0.00	44.5
	Week 2	92	36.35	24.88	0.0	33.33	100.0	86	5.81	18.34	-33.3	0.00	44.5
	Week 3	93	38.83	25.41	0.0	33.33	100.0	84	5.95	21.64	-44.4	0.00	88.9
	Week 4	90	32.59	22.15	0.0	33.33	100.0	82	0.68	22.65	-55.6	0.00	55.6
	Week 5	90	32.34	21.95	0.0	33.33	100.0	81	1.23	23.57	-66.7	0.00	88.9
	Week 6	90	28.52	20.54	0.0	33.33	77.8	81	-3.57	21.36	-55.6	0.00	55.6
	Week 7	85	29.41	20.27	0.0	33.33	100.0	77	-3.46	22.60	-66.7	0.00	33.3
	Week 8	89	28.84	20.36	0.0	33.33	77.8	80	-2.64	25.33	-66.7	0.00	77.8
	Week 9	93	31.30	20.13	0.0	33.33	88.9	85	0.26	25.83	-55.6	0.00	77.8
	Week 10	88	29.92	20.17	0.0	33.33	77.8	81	-3.02	25.16	-66.7	0.00	77.8
	Week 11	93	28.67	19.06	0.0	33.33	77.8	84	-4.23	27.54	-66.7	0.00	66.7
	Week 12	86	30.10	19.42	0.0	33.33	77.8	79	-2.53	26.57	-66.7	0.00	66.7
	Week 14	84	30.82	21.98	0.0	33.33	88.9	76	-0.15	24.98	-66.7	0.00	66.7
	Week 17	83	31.46	21.59	0.0	33.33	100.0	77	-1.01	27.11	-66.7	0.00	66.7
	Week 20	79	33.19	23.23	0.0	33.33	100.0	73	2.13	27.76	-66.7	0.00	88.9
	Week 23	78	34.47	25.49	0.0	33.33	100.0	73	4.72	26.77	-66.7	0.00	66.7
	Week 26	78	32.19	22.76	0.0	33.33	100.0	72	0.62	25.43	-66.7	0.00	66.7
	Week 29	74	30.03	21.90	0.0	33.33	77.8	67	0.50	24.11	-66.7	0.00	55.6
	Week 32	64	30.21	23.46	0.0	33.33	88.9	59	3.20	22.70	-66.7	0.00	66.7
	Week 35	62	31.54	21.22	0.0	33.33	88.9	58	5.75	18.29	-33.3	0.00	66.7
	Week 38	62	31.36	21.72	0.0	33.33	100.0	59	3.77	24.38	-66.7	0.00	66.7
	Week 41	64	32.46	22.69	0.0	33.33	88.9	59	5.08	24.70	-66.7	0.00	88.9
	Week 44	50	28.67	22.35	0.0	33.33	88.9	48	3.93	24.20	-66.7	0.00	66.7
	Week 47	47	34.75	26.98	0.0	33.33	100.0	46	9.42	29.35	-66.7	11.11	88.9

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	44	35.86	24.89	0.0	33.33	100.0	41	12.74	24.79	-33.3	11.11	77.8
	Week 53	40	29.44	25.36	0.0	33.33	100.0	37	5.71	30.61	-66.7	0.00	100.0
	Week 56	44	34.85	28.21	0.0	33.33	100.0	41	10.30	31.56	-66.7	11.11	100.0
	Week 59	42	32.01	24.81	0.0	33.33	100.0	39	7.69	29.74	-66.7	11.11	100.0
	Week 62	37	32.13	27.69	0.0	33.33	100.0	36	7.41	31.32	-66.7	0.00	100.0
	Week 65	34	35.29	27.28	0.0	33.33	100.0	31	11.83	33.57	-66.7	11.11	100.0
	Week 68	34	33.01	24.08	0.0	33.33	100.0	33	11.78	29.78	-66.7	11.11	66.7
	Week 71	32	30.90	26.88	0.0	33.33	100.0	30	9.26	31.03	-66.7	5.56	66.7
	Week 74	29	34.10	26.88	0.0	33.33	88.9	28	11.51	30.61	-66.7	11.11	77.8
	Week 77	25	39.11	25.48	0.0	33.33	100.0	24	16.20	32.60	-66.7	11.12	77.8
	Week 80	24	38.89	25.59	0.0	33.33	100.0	22	12.12	29.68	-66.7	22.22	66.7
	Week 83	23	38.65	23.66	0.0	33.33	100.0	22	13.13	29.02	-66.7	16.67	66.7
	Week 86	20	40.56	24.26	0.0	33.33	100.0	18	13.58	28.41	-66.7	11.12	66.7
	Week 89	19	37.43	24.63	0.0	33.33	100.0	17	12.42	28.02	-66.7	11.11	55.6
	Week 92	14	35.71	21.43	0.0	33.33	77.8	12	17.59	22.95	-22.2	22.22	55.6
	Week 95	12	36.11	18.43	0.0	33.33	66.7	11	19.19	18.65	-11.1	22.22	44.4
	Plat+Gem (N=106)												
	BASELINE	83	33.33	22.02	0.0	33.33	88.9						
	Week 1	75	42.22	23.18	0.0	33.33	100.0	71	10.33	22.49	-33.3	11.11	77.8
	Week 2	76	43.42	26.74	0.0	33.33	100.0	68	10.13	22.61	-33.3	0.00	66.7
	Week 3	80	38.47	23.12	0.0	33.33	100.0	73	4.72	19.50	-33.3	0.00	66.7
	Week 4	79	39.10	21.85	0.0	33.33	100.0	67	7.96	18.53	-33.3	0.00	66.7
	Week 5	80	41.39	24.94	0.0	33.33	100.0	67	9.95	20.02	-22.2	0.00	66.7
	Week 6	76	38.16	23.82	0.0	33.33	100.0	67	4.81	21.82	-44.5	0.00	66.7
	Week 7	81	38.13	24.97	0.0	33.33	100.0	71	5.16	21.57	-55.6	11.11	55.6
	Week 8	72	37.19	19.75	0.0	33.33	100.0	64	5.38	22.31	-44.5	0.00	66.7

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	78	37.89	21.45	0.0	33.33	88.9	69	4.19	21.90	-33.3	0.00	55.6
	Week 10	78	40.17	23.43	0.0	33.33	100.0	68	6.54	23.06	-33.3	0.00	66.7
	Week 11	75	40.15	23.46	0.0	33.33	100.0	66	7.07	23.12	-33.3	0.00	77.8
	Week 12	74	34.08	19.41	0.0	33.33	100.0	66	2.69	20.73	-44.5	0.00	66.7
	Week 14	68	36.44	23.66	0.0	33.33	100.0	58	2.87	22.66	-66.7	0.00	55.6
	Week 17	68	41.67	27.38	0.0	33.33	100.0	58	9.58	22.36	-66.7	11.11	44.5
	Week 20	60	34.44	21.23	0.0	33.33	100.0	52	3.42	21.28	-33.3	0.00	66.7
	Week 23	51	29.63	27.19	0.0	33.33	100.0	44	1.01	23.21	-55.6	0.00	55.6
	Week 26	47	31.68	24.52	0.0	33.33	100.0	42	0.26	19.71	-44.5	0.00	33.3
	Week 29	42	27.25	19.97	0.0	33.33	100.0	37	-2.70	16.85	-44.4	0.00	33.3
	Week 32	37	29.73	19.08	0.0	33.33	66.7	34	-0.98	16.50	-44.5	0.00	33.3
	Week 35	34	28.43	21.40	0.0	33.33	66.7	31	-1.43	24.80	-66.7	0.00	44.5
	Week 38	33	33.00	25.23	0.0	33.33	100.0	28	0.40	22.12	-44.5	0.00	66.7
	Week 41	27	32.51	22.63	0.0	33.33	77.8	22	0.51	20.43	-44.5	0.00	44.5
	Week 44	28	29.76	25.13	0.0	33.33	88.9	24	-1.39	22.06	-33.3	0.00	55.6
	Week 47	24	25.46	20.59	0.0	33.33	66.7	21	-2.65	21.06	-44.5	0.00	33.3
	Week 50	26	32.05	26.17	0.0	33.33	100.0	24	0.93	16.68	-44.5	0.00	33.3
	Week 53	19	25.15	21.23	0.0	22.22	66.7	17	-3.27	21.07	-55.6	0.00	33.3
	Week 56	13	29.06	24.65	0.0	33.33	88.9	11	1.01	24.58	-33.3	0.00	55.6
	Week 59	14	26.98	24.54	0.0	27.78	100.0	12	0.00	11.61	-33.3	0.00	11.1
	Week 62	13	21.37	14.67	0.0	33.33	33.3	12	-5.56	19.82	-55.6	0.00	11.1
	Week 65	13	24.78	25.32	0.0	33.33	88.9	11	2.02	11.98	-22.2	0.00	22.2
	Week 68	10	27.78	22.38	0.0	33.33	77.8	8	-2.78	14.24	-33.3	0.00	11.1
	Week 77	10	24.44	22.10	0.0	27.78	66.7	8	-2.78	7.86	-11.1	0.00	11.1

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>= 65 years	EV+Pembro (N=135)												
	BASELINE	114	28.95	24.41	0.0	33.33	100.0						
	Week 1	102	33.01	23.43	0.0	33.33	100.0	99	4.04	22.13	-100.0	0.00	66.7
	Week 2	111	38.64	24.75	0.0	33.33	100.0	103	9.92	19.24	-66.7	0.00	66.7
	Week 3	105	42.33	24.07	0.0	33.33	100.0	98	14.06	22.93	-55.6	11.11	66.7
	Week 4	104	38.25	24.13	0.0	33.33	100.0	97	10.54	22.13	-66.7	11.11	66.7
	Week 5	100	36.78	25.11	0.0	33.33	100.0	92	9.18	22.08	-66.7	11.11	66.7
	Week 6	98	36.73	24.69	0.0	33.33	100.0	89	10.49	21.99	-33.3	11.11	77.8
	Week 7	110	36.97	23.23	0.0	33.33	100.0	99	9.09	25.07	-66.7	11.11	77.8
	Week 8	102	36.16	24.26	0.0	33.33	100.0	91	9.04	23.24	-66.7	0.00	66.7
	Week 9	104	38.57	24.67	0.0	33.33	100.0	95	11.23	25.29	-88.9	11.11	77.8
	Week 10	103	35.81	21.56	0.0	33.33	88.9	94	8.63	22.65	-66.7	5.56	66.7
	Week 11	101	37.40	26.52	0.0	33.33	100.0	91	10.13	25.16	-66.7	11.11	88.9
	Week 12	100	35.11	25.89	0.0	33.33	100.0	92	7.73	25.40	-33.3	0.00	100.0
	Week 14	101	35.64	24.51	0.0	33.33	100.0	91	8.18	25.22	-44.5	11.11	100.0
	Week 17	95	37.54	24.70	0.0	33.33	100.0	85	11.63	22.55	-33.3	11.11	88.9
	Week 20	88	37.50	25.18	0.0	33.33	100.0	81	12.89	25.37	-44.4	11.11	88.9
	Week 23	84	36.90	23.02	0.0	33.33	100.0	78	11.68	25.57	-44.5	11.11	77.8
	Week 26	78	37.89	24.97	0.0	33.33	100.0	72	12.81	28.75	-66.7	11.11	88.9
	Week 29	83	35.88	24.62	0.0	33.33	100.0	78	10.40	28.11	-55.6	0.00	88.9
	Week 32	71	36.46	23.62	0.0	33.33	100.0	66	11.11	25.34	-33.3	11.11	66.7
	Week 35	70	36.82	21.86	0.0	33.33	100.0	64	9.90	25.97	-44.5	11.11	66.7
	Week 38	70	37.30	26.15	0.0	33.33	100.0	65	9.92	26.07	-44.5	0.00	66.7
	Week 41	65	37.09	22.85	0.0	33.33	100.0	60	12.22	24.95	-44.5	11.11	66.7
	Week 44	58	37.74	22.41	0.0	33.33	100.0	52	15.17	27.13	-33.3	11.11	88.9
	Week 47	53	34.38	21.60	0.0	33.33	88.9	48	11.34	24.20	-33.3	11.11	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	45	33.33	23.33	0.0	33.33	88.9	43	10.85	23.19	-33.3	11.11	55.6
	Week 53	39	31.91	17.88	0.0	33.33	77.8	37	11.41	22.60	-44.5	11.11	44.5
	Week 56	37	36.03	20.36	0.0	33.33	77.8	35	12.70	21.41	-33.3	11.11	55.6
	Week 59	30	30.74	24.01	0.0	33.33	77.8	29	8.43	20.71	-33.3	11.11	55.6
	Week 62	28	29.76	24.76	0.0	27.78	88.9	27	12.35	22.72	-22.2	11.11	66.7
	Week 65	24	32.87	23.51	0.0	33.33	77.8	23	7.73	20.22	-33.3	0.00	44.5
	Week 68	19	32.16	23.10	0.0	33.33	88.9	19	12.87	17.86	-11.1	11.11	55.6
	Week 71	19	31.58	21.99	0.0	33.33	66.7	19	12.87	16.26	-11.1	11.11	55.6
	Week 74	18	29.01	20.57	0.0	33.33	66.7	18	8.03	17.80	-33.3	11.11	44.5
	Week 77	19	33.33	24.85	0.0	33.33	66.7	18	10.50	28.39	-33.3	11.11	55.6
	Week 80	16	29.86	22.12	0.0	33.33	66.7	15	2.96	14.83	-22.2	0.00	33.3
	Week 83	14	32.54	20.19	0.0	33.33	66.7	13	5.13	17.92	-33.3	0.00	33.3
	Week 86	14	25.40	20.64	0.0	33.33	66.7	13	3.42	19.97	-33.3	0.00	33.3
	Week 89	14	35.71	27.97	0.0	33.33	88.9	14	9.53	21.29	-22.2	5.56	55.6
	Week 92	13	31.62	31.05	0.0	33.33	100.0	13	5.13	26.30	-33.3	0.00	66.7
	Week 95	10	36.67	30.11	0.0	38.89	77.8	10	10.00	25.90	-22.2	0.00	55.6
	Week 98	10	35.56	27.12	0.0	33.33	66.7	10	6.67	22.95	-11.1	0.00	55.6
	Plat+Gem (N=136)												
	BASELINE	105	35.98	25.39	0.0	33.33	100.0						
	Week 1	98	40.13	25.36	0.0	33.33	100.0	87	4.85	18.23	-33.3	0.00	66.7
	Week 2	95	43.39	24.69	0.0	33.33	100.0	83	10.98	24.01	-44.5	11.11	100.0
	Week 3	104	40.38	23.13	0.0	33.33	100.0	89	5.49	19.03	-55.6	0.00	55.6
	Week 4	104	39.85	22.36	0.0	33.33	100.0	89	6.49	22.08	-66.7	11.11	55.6
	Week 5	107	43.30	20.98	0.0	33.33	100.0	89	10.86	21.65	-44.5	11.11	77.8
	Week 6	98	42.18	26.17	0.0	33.33	100.0	82	7.18	23.58	-55.6	0.00	88.9
	Week 7	105	39.79	22.53	0.0	33.33	100.0	86	5.69	22.91	-55.6	0.00	88.9

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 8	95	44.56	25.40	0.0	33.33	100.0	80	13.06	25.18	-55.6	11.11	100.0
	Week 9	99	40.07	25.34	0.0	33.33	100.0	81	8.09	25.46	-33.3	0.00	100.0
	Week 10	88	40.66	24.75	0.0	33.33	100.0	71	8.14	26.76	-33.3	0.00	100.0
	Week 11	93	39.31	24.28	0.0	33.33	100.0	77	7.94	23.42	-55.6	0.00	66.7
	Week 12	85	41.18	26.11	0.0	33.33	100.0	72	7.87	27.18	-55.6	0.00	77.8
	Week 14	85	41.31	26.43	0.0	33.33	100.0	70	9.37	24.86	-55.6	0.00	66.7
	Week 17	87	37.67	22.63	0.0	33.33	100.0	72	7.41	25.71	-44.5	0.00	66.7
	Week 20	66	36.19	23.25	0.0	33.33	100.0	58	7.47	25.78	-55.6	5.56	66.7
	Week 23	64	35.94	23.24	0.0	33.33	88.9	53	8.39	21.89	-44.5	0.00	55.6
	Week 26	61	30.96	24.77	0.0	33.33	100.0	53	5.66	24.62	-44.5	0.00	66.7
	Week 29	58	32.37	23.57	0.0	33.33	100.0	49	7.94	21.99	-33.3	0.00	55.6
	Week 32	46	32.12	25.15	0.0	33.33	100.0	42	5.56	26.57	-44.5	0.00	66.7
	Week 35	42	30.69	23.64	0.0	33.33	100.0	38	4.68	21.40	-33.3	0.00	55.6
	Week 38	41	32.79	22.76	0.0	33.33	100.0	37	8.11	23.37	-33.3	0.00	66.7
	Week 41	38	34.50	22.49	0.0	33.33	100.0	34	8.82	21.67	-33.3	0.00	66.7
	Week 44	32	34.37	24.34	0.0	33.33	100.0	29	10.35	25.36	-33.3	0.00	66.7
	Week 47	32	34.03	25.23	0.0	33.33	100.0	28	12.30	28.58	-44.5	5.56	88.9
	Week 50	25	35.11	26.00	0.0	33.33	100.0	23	11.11	22.47	-33.3	11.11	66.7
	Week 53	27	29.63	15.10	0.0	33.33	55.6	25	6.22	17.00	-33.3	0.00	33.3
	Week 56	26	38.46	26.15	0.0	33.33	100.0	23	12.08	26.99	-44.5	11.11	66.7
	Week 59	23	31.88	23.52	0.0	33.33	100.0	21	8.99	27.58	-33.3	0.00	66.7
	Week 62	19	35.67	19.80	0.0	33.33	77.8	17	13.73	24.07	-33.3	0.00	66.7
	Week 65	17	30.06	23.49	0.0	33.33	100.0	15	5.93	22.95	-33.3	0.00	66.7
	Week 68	15	32.59	19.46	0.0	33.33	66.7	13	8.55	22.29	-33.3	0.00	44.4
	Week 71	15	35.55	21.90	0.0	33.33	66.7	13	11.11	21.28	-33.3	11.11	33.3
	Week 74	12	23.15	16.04	0.0	33.33	44.4	11	1.01	20.15	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Europe	EV+Pembro (N= 98)												
	BASELINE	79	27.00	23.52	0.0	22.22	100.0						
	Week 1	74	32.58	24.21	0.0	33.33	100.0	71	6.57	16.44	-33.3	0.00	55.6
	Week 2	79	34.18	23.32	0.0	33.33	88.9	71	9.08	18.14	-33.3	0.00	44.5
	Week 3	78	38.75	22.71	0.0	33.33	100.0	69	13.04	20.87	-33.3	11.11	66.7
	Week 4	78	32.34	22.16	0.0	33.33	100.0	70	8.89	20.25	-44.4	0.00	66.7
	Week 5	70	29.52	19.28	0.0	33.33	100.0	62	5.02	20.29	-66.7	0.00	44.5
	Week 6	70	26.82	20.50	0.0	27.78	100.0	61	3.28	23.95	-55.6	0.00	77.8
	Week 7	78	30.48	20.69	0.0	33.33	77.8	68	5.39	24.02	-66.7	0.00	55.6
	Week 8	72	29.17	22.26	0.0	33.33	100.0	61	5.83	24.56	-66.7	0.00	77.8
	Week 9	80	31.80	21.27	0.0	33.33	100.0	70	8.41	23.05	-44.5	5.56	66.7
	Week 10	71	30.05	21.20	0.0	33.33	88.9	62	3.94	25.30	-66.7	0.00	77.8
	Week 11	76	31.29	23.98	0.0	33.33	100.0	66	5.22	25.95	-66.7	0.00	77.8
	Week 12	73	29.07	21.57	0.0	33.33	100.0	65	3.42	25.61	-66.7	0.00	100.0
	Week 14	74	27.93	20.75	0.0	33.33	88.9	64	3.12	22.70	-44.5	0.00	66.7
	Week 17	70	31.11	22.35	0.0	33.33	100.0	62	6.09	27.12	-66.7	0.00	66.7
	Week 20	70	30.16	21.41	0.0	33.33	88.9	63	5.82	26.91	-66.7	0.00	77.8
	Week 23	61	31.69	23.20	0.0	33.33	100.0	57	8.38	27.48	-66.7	11.11	66.7
	Week 26	62	29.21	20.64	0.0	33.33	66.7	55	5.45	24.46	-66.7	0.00	66.7
	Week 29	63	29.98	23.33	0.0	33.33	100.0	57	5.65	23.68	-66.7	0.00	66.7
	Week 32	51	30.94	23.45	0.0	33.33	88.9	47	6.86	24.69	-33.3	0.00	66.7
	Week 35	56	33.33	21.82	0.0	33.33	88.9	52	10.68	22.22	-33.3	11.11	66.7
	Week 38	51	28.76	22.90	0.0	33.33	88.9	48	6.71	26.21	-66.7	0.00	66.7
	Week 41	52	32.48	21.88	0.0	33.33	88.9	48	9.26	25.45	-66.7	11.11	88.9
	Week 44	43	31.78	22.30	0.0	33.33	100.0	39	10.26	21.69	-33.3	11.11	55.6
	Week 47	39	35.90	25.04	0.0	33.33	88.9	36	14.82	29.93	-66.7	22.22	88.9

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	37	30.33	23.52	0.0	33.33	77.8	36	12.04	24.54	-33.3	5.56	77.8
	Week 53	28	27.78	24.66	0.0	27.78	100.0	27	6.17	30.87	-66.7	11.11	100.0
	Week 56	30	32.96	25.69	0.0	33.33	100.0	29	13.79	27.80	-33.3	11.11	100.0
	Week 59	27	27.16	24.33	0.0	33.33	100.0	27	9.05	27.40	-33.3	11.11	100.0
	Week 62	23	30.43	27.26	0.0	33.33	100.0	23	12.08	29.95	-33.3	11.11	100.0
	Week 65	23	32.85	28.52	0.0	33.33	100.0	23	12.08	28.80	-33.3	11.11	100.0
	Week 68	21	26.98	20.66	0.0	33.33	66.7	21	8.99	22.67	-33.3	11.11	66.7
	Week 71	19	25.73	25.41	0.0	33.33	66.7	19	8.19	26.41	-33.3	0.00	66.7
	Week 74	15	28.15	26.52	0.0	22.22	88.9	15	8.89	23.46	-33.3	11.11	55.6
	Week 77	19	36.26	26.92	0.0	33.33	77.8	19	17.54	29.70	-33.3	11.11	77.8
	Week 80	17	28.76	22.24	0.0	22.22	66.7	17	7.84	22.49	-33.3	11.11	66.7
	Week 83	16	34.03	23.12	0.0	33.33	77.8	16	11.81	22.76	-33.3	16.67	66.7
	Week 86	14	27.78	21.24	0.0	33.33	66.7	14	13.49	20.52	-11.1	11.11	66.7
	Week 89	14	29.36	24.89	0.0	27.78	66.7	14	14.29	20.64	-22.2	11.11	55.6
	Week 92	11	19.19	21.13	0.0	11.11	55.6	11	8.08	21.71	-22.2	0.00	55.6
	Week 95	10	26.67	23.54	0.0	22.22	66.7	10	12.22	21.88	-11.1	0.00	55.6
	Plat+Gem (N=102)												
	BASELINE	71	36.62	26.65	0.0	33.33	100.0						
	Week 1	71	46.79	26.29	0.0	33.33	100.0	61	10.20	18.95	-22.2	11.11	66.7
	Week 2	67	47.76	28.89	0.0	44.44	100.0	56	14.09	27.01	-33.3	11.11	100.0
	Week 3	68	45.26	26.42	0.0	33.33	100.0	56	8.53	18.95	-33.3	11.11	55.6
	Week 4	75	44.44	24.78	0.0	33.33	100.0	59	13.56	19.03	-22.2	11.11	66.7
	Week 5	77	45.89	26.02	0.0	33.33	100.0	60	14.82	22.66	-22.2	11.11	77.8
	Week 6	70	45.71	27.97	0.0	44.44	100.0	56	12.10	20.02	-44.5	11.11	55.6
	Week 7	72	45.22	27.11	0.0	38.89	100.0	55	11.52	20.06	-22.2	11.11	66.7
	Week 8	65	47.52	26.10	0.0	44.44	100.0	53	15.09	25.33	-55.6	11.11	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	70	44.92	26.04	0.0	38.89	100.0	55	12.73	24.88	-33.3	11.11	100.0
	Week 10	60	45.93	27.56	0.0	33.33	100.0	46	16.67	24.87	-33.3	11.11	100.0
	Week 11	64	45.14	26.99	0.0	38.89	100.0	50	13.78	22.40	-33.3	11.11	66.7
	Week 12	60	42.78	23.58	0.0	33.33	100.0	48	10.88	21.19	-22.2	5.56	77.8
	Week 14	56	48.21	30.14	0.0	44.44	100.0	42	19.05	27.25	-55.6	22.22	66.7
	Week 17	58	43.68	26.32	0.0	38.89	100.0	44	13.38	26.42	-44.5	11.11	66.7
	Week 20	47	37.11	23.20	0.0	33.33	100.0	37	9.31	26.00	-55.6	11.11	66.7
	Week 23	44	33.84	26.36	0.0	33.33	88.9	32	9.72	22.89	-33.3	5.56	55.6
	Week 26	39	34.47	26.22	0.0	33.33	100.0	30	10.74	22.69	-33.3	0.00	66.7
	Week 29	34	33.01	21.27	0.0	33.33	77.8	25	6.22	20.31	-33.3	0.00	44.5
	Week 32	33	35.35	21.78	0.0	33.33	100.0	27	6.58	23.92	-33.3	0.00	66.7
	Week 35	30	35.93	24.01	0.0	33.33	88.9	24	6.48	25.99	-44.4	0.00	55.6
	Week 38	26	41.02	29.44	0.0	33.33	100.0	21	12.70	26.36	-22.2	0.00	66.7
	Week 41	22	42.93	22.82	0.0	44.44	77.8	17	16.99	20.08	-11.1	22.22	44.5
	Week 44	20	45.00	28.04	0.0	44.44	100.0	16	18.06	24.30	-11.1	11.11	66.7
	Week 47	16	44.44	28.69	0.0	38.89	100.0	12	25.00	26.43	-11.1	27.78	88.9
	Week 50	11	47.47	31.85	0.0	44.44	100.0	10	18.89	22.25	-11.1	16.67	66.7
	Week 53	11	36.36	18.65	0.0	33.33	66.7	10	8.89	15.54	-11.1	11.11	33.3
	Week 56	10	41.11	27.74	0.0	33.33	88.9	8	9.72	34.85	-44.5	5.56	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
North America	EV+Pembro (N= 57)												
	BASELINE	47	38.06	28.91	0.0	33.33	100.0						
	Week 1	39	41.02	28.40	0.0	33.33	100.0	37	5.11	17.88	-33.3	0.00	44.5
	Week 2	44	45.20	27.78	0.0	33.33	100.0	42	9.52	17.45	-22.2	5.56	44.5
	Week 3	44	51.01	27.46	0.0	44.44	100.0	40	12.22	25.88	-33.3	11.11	88.9
	Week 4	44	43.43	23.70	0.0	44.44	100.0	41	5.15	26.54	-55.6	0.00	55.6
	Week 5	47	45.63	25.72	0.0	33.33	100.0	41	11.38	27.27	-44.5	11.11	88.9
	Week 6	44	44.44	24.79	0.0	33.33	100.0	39	6.55	27.89	-55.6	0.00	66.7
	Week 7	46	37.20	20.32	0.0	33.33	100.0	42	-0.27	23.47	-66.7	0.00	55.6
	Week 8	47	39.95	22.42	0.0	33.33	100.0	42	3.44	26.26	-55.6	0.00	55.6
	Week 9	46	41.79	21.75	0.0	33.33	100.0	42	4.76	28.64	-55.6	0.00	77.8
	Week 10	47	37.59	19.32	0.0	33.33	77.8	44	2.02	23.63	-66.7	0.00	66.7
	Week 11	47	36.88	22.24	0.0	33.33	100.0	42	0.26	31.48	-55.6	0.00	88.9
	Week 12	44	39.65	22.27	0.0	33.33	100.0	40	0.28	29.51	-66.7	0.00	88.9
	Week 14	43	41.34	23.92	0.0	33.33	100.0	39	4.84	27.90	-66.7	0.00	100.0
	Week 17	40	41.67	25.01	0.0	33.33	100.0	37	5.41	26.14	-66.7	0.00	88.9
	Week 20	38	42.98	27.60	0.0	33.33	100.0	35	9.52	26.70	-44.5	0.00	88.9
	Week 23	38	37.72	25.25	0.0	33.33	100.0	35	5.08	21.79	-44.5	0.00	66.7
	Week 26	35	38.73	25.48	0.0	33.33	100.0	32	2.78	27.65	-44.5	0.00	88.9
	Week 29	38	32.75	22.36	0.0	33.33	88.9	34	0.00	26.66	-44.5	0.00	88.9
	Week 32	32	31.25	21.20	0.0	33.33	88.9	29	4.60	19.13	-33.3	0.00	66.7
	Week 35	33	29.96	20.50	0.0	33.33	88.9	30	1.48	20.37	-44.5	0.00	44.4
	Week 38	32	32.64	23.77	0.0	33.33	100.0	29	0.00	23.19	-44.5	0.00	44.4
	Week 41	28	29.76	19.14	0.0	22.22	66.7	24	2.78	18.61	-44.5	0.00	44.4
	Week 44	21	28.57	19.43	0.0	33.33	88.9	20	8.33	26.21	-22.2	0.00	88.9
	Week 47	24	28.24	21.48	0.0	22.22	77.8	23	1.45	20.18	-33.3	0.00	44.4

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	23	35.26	24.54	0.0	33.33	88.9	20	7.22	20.48	-33.3	11.11	33.3
	Week 53	17	24.83	14.97	0.0	33.33	44.4	14	3.97	27.77	-44.5	0.00	44.4
	Week 56	20	30.55	17.24	0.0	33.33	66.7	17	3.27	21.79	-33.3	0.00	33.3
	Week 59	17	28.76	20.05	0.0	22.22	66.7	14	2.38	20.52	-33.3	0.00	33.3
	Week 62	14	21.43	13.41	0.0	22.22	33.3	13	-2.56	18.23	-33.3	0.00	33.3
	Week 65	12	24.07	14.86	0.0	22.22	44.4	9	-2.47	19.07	-33.3	0.00	22.2
	Week 68	10	23.33	9.73	11.1	22.22	33.3	9	9.88	17.07	-11.1	11.11	33.3
	Week 71	10	22.22	15.71	0.0	27.78	44.4	8	12.50	12.51	0.0	11.11	33.3
	Week 74	10	22.22	11.71	0.0	22.22	33.3	9	7.41	19.24	-33.3	11.11	22.2
	Plat+Gem (N= 51)												
	BASELINE	42	31.22	20.86	0.0	33.33	77.8						
	Week 1	41	39.84	22.50	0.0	33.33	100.0	36	8.95	19.12	-33.3	11.11	44.5
	Week 2	38	46.20	20.27	0.0	44.44	100.0	33	13.81	17.58	-11.1	11.11	66.7
	Week 3	40	36.39	18.49	0.0	33.33	77.8	35	7.62	21.52	-44.5	0.00	66.7
	Week 4	35	37.78	19.66	11.1	33.33	100.0	29	8.81	18.87	-33.3	11.11	55.6
	Week 5	39	41.31	20.07	0.0	33.33	77.8	32	9.03	19.03	-33.3	5.56	44.5
	Week 6	34	41.50	20.89	0.0	38.89	88.9	30	7.41	20.08	-22.2	0.00	66.7
	Week 7	42	35.45	18.07	0.0	33.33	77.8	37	3.90	17.02	-33.3	0.00	33.3
	Week 8	39	43.30	23.20	0.0	33.33	100.0	33	12.12	21.76	-33.3	0.00	55.6
	Week 9	39	38.75	21.61	0.0	33.33	100.0	33	4.71	23.74	-33.3	0.00	55.6
	Week 10	39	42.45	19.89	11.1	33.33	100.0	32	9.03	20.63	-22.2	0.00	66.7
	Week 11	39	36.18	23.32	0.0	33.33	88.9	33	4.04	24.19	-33.3	0.00	77.8
	Week 12	36	37.96	24.11	0.0	33.33	100.0	32	6.95	28.05	-55.6	0.00	66.7
	Week 14	34	37.58	21.89	0.0	33.33	88.9	29	3.45	22.24	-66.7	0.00	44.5
	Week 17	37	40.54	22.26	0.0	33.33	100.0	31	8.96	24.08	-66.7	11.11	44.5
	Week 20	27	35.39	18.24	0.0	33.33	100.0	23	2.90	17.48	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 23	27	31.69	23.41	0.0	33.33	100.0	23	0.97	20.08	-55.6	0.00	33.3
	Week 26	28	30.95	26.77	0.0	33.33	100.0	25	-0.44	22.33	-44.5	0.00	33.3
	Week 29	29	33.33	28.17	0.0	33.33	100.0	25	6.22	22.24	-33.3	0.00	55.6
	Week 32	17	36.60	24.14	0.0	33.33	100.0	17	4.57	10.44	-11.1	0.00	33.3
	Week 35	16	34.03	22.76	0.0	33.33	100.0	15	4.44	18.21	-33.3	0.00	33.3
	Week 38	16	35.41	16.34	11.1	33.33	77.8	13	6.84	8.53	0.0	0.00	22.2
	Week 41	16	33.33	22.22	11.1	33.33	100.0	13	2.56	15.15	-22.2	0.00	33.3
	Week 44	13	32.48	20.01	0.0	33.33	77.8	11	3.03	21.14	-22.2	0.00	55.6
	Week 47	11	28.28	20.71	0.0	33.33	66.7	9	8.64	19.86	-22.2	0.00	44.4
	Week 50	17	36.60	24.77	0.0	33.33	100.0	15	8.15	13.59	-11.1	0.00	33.3
	Week 53	13	29.91	13.14	11.1	33.33	55.6	11	7.07	12.45	-11.1	0.00	33.3
	Week 56	11	41.41	27.26	11.1	33.33	100.0	9	22.22	25.46	0.0	22.22	66.7
	Week 59	11	32.32	25.07	11.1	33.33	100.0	9	14.81	22.22	0.0	11.11	66.7
	Week 62	11	31.31	17.79	11.1	33.33	77.8	9	13.58	16.46	0.0	11.11	44.5
	Week 65	10	28.89	28.78	0.0	33.33	100.0	8	9.72	26.18	-22.2	0.00	66.7

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Table 302.1.3002.15.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Rest of World	EV+Pembro (N= 85)												
	BASELINE	80	30.42	23.50	0.0	33.33	100.0						
	Week 1	77	31.31	21.91	0.0	33.33	88.9	76	0.73	22.32	-100.0	0.00	66.7
	Week 2	80	36.80	23.82	0.0	33.33	100.0	76	6.29	20.39	-66.7	0.00	66.7
	Week 3	76	36.69	23.66	0.0	33.33	100.0	73	6.70	22.20	-55.6	0.00	66.7
	Week 4	72	34.41	23.60	0.0	33.33	100.0	68	3.59	22.99	-66.7	0.00	55.6
	Week 5	73	32.57	24.24	0.0	33.33	100.0	70	2.38	22.37	-66.7	0.00	55.6
	Week 6	74	31.53	22.15	0.0	33.33	100.0	70	2.70	18.29	-33.3	0.00	44.5
	Week 7	71	34.90	24.80	0.0	33.33	100.0	66	4.21	26.35	-66.7	0.00	77.8
	Week 8	72	31.63	22.74	0.0	33.33	88.9	68	1.63	24.45	-66.7	0.00	55.6
	Week 9	71	34.58	24.67	0.0	33.33	100.0	68	4.41	27.50	-88.9	0.00	77.8
	Week 10	73	33.18	21.79	0.0	33.33	88.9	69	3.38	24.57	-66.7	0.00	55.6
	Week 11	71	32.86	24.08	0.0	33.33	100.0	67	3.15	25.79	-66.7	0.00	66.7
	Week 12	69	32.37	24.75	0.0	33.33	100.0	66	4.21	25.40	-66.7	0.00	66.7
	Week 14	68	34.48	24.67	0.0	33.33	100.0	64	5.38	26.63	-55.6	0.00	77.8
	Week 17	68	34.31	23.02	0.0	33.33	100.0	63	5.29	23.94	-66.7	0.00	44.5
	Week 20	59	36.91	24.19	0.0	33.33	88.9	56	8.93	27.58	-44.5	0.00	88.9
	Week 23	63	38.45	24.35	0.0	33.33	100.0	59	10.17	27.78	-44.5	11.11	77.8
	Week 26	59	38.98	25.47	0.0	33.33	100.0	57	10.14	30.67	-66.7	11.11	77.8
	Week 29	56	36.90	24.26	0.0	33.33	100.0	54	9.67	29.44	-66.7	11.11	66.7
	Week 32	52	37.39	25.19	0.0	33.33	100.0	49	9.52	26.93	-66.7	11.11	66.7
	Week 35	43	39.02	21.87	0.0	33.33	100.0	40	9.17	24.38	-33.3	0.00	66.7
	Week 38	49	41.72	24.59	0.0	33.33	100.0	47	11.58	25.27	-44.5	11.11	66.7
	Week 41	49	40.14	24.93	0.0	33.33	100.0	47	11.11	27.22	-66.7	11.11	66.7
	Week 44	44	37.63	24.35	0.0	33.33	88.9	41	10.03	30.51	-66.7	11.11	77.8
	Week 47	37	37.24	24.74	0.0	33.33	100.0	35	11.75	26.26	-66.7	11.11	66.7

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Table 302.1.3002.15.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	29	39.46	24.05	0.0	33.33	100.0	28	14.68	25.49	-33.3	11.11	66.7
	Week 53	34	35.95	21.72	0.0	33.33	77.8	33	12.46	23.03	-44.5	11.11	55.6
	Week 56	31	40.86	27.58	0.0	33.33	100.0	30	13.70	29.28	-66.7	11.11	88.9
	Week 59	28	37.30	26.23	0.0	33.33	100.0	27	9.88	27.79	-66.7	11.11	66.7
	Week 62	28	36.51	29.45	0.0	33.33	100.0	27	13.17	29.08	-66.7	11.11	77.8
	Week 65	23	41.06	25.83	0.0	44.44	88.9	22	13.13	30.98	-66.7	11.11	55.6
	Week 68	22	42.42	27.36	0.0	33.33	100.0	22	16.16	31.56	-66.7	11.11	66.7
	Week 71	22	39.90	26.04	0.0	33.33	100.0	22	12.12	30.07	-66.7	11.11	66.7
	Week 74	22	39.39	26.05	0.0	33.33	88.9	22	12.12	30.84	-66.7	11.11	77.8
	Week 77	18	40.74	26.41	0.0	33.33	100.0	17	14.38	31.37	-66.7	11.11	55.6
	Week 80	16	40.97	29.18	0.0	33.33	100.0	15	11.85	30.13	-66.7	11.11	44.5
	Week 83	16	41.67	23.13	0.0	33.33	100.0	15	12.59	28.75	-66.7	11.11	55.6
	Week 86	13	42.73	26.78	0.0	44.44	100.0	12	11.11	31.07	-66.7	11.11	55.6
	Week 89	12	41.67	28.48	0.0	33.33	100.0	12	11.11	32.48	-66.7	11.11	55.6
	Plat+Gem (N= 89)												
	BASELINE	75	35.11	22.89	0.0	33.33	88.9						
	Week 1	61	35.15	22.05	0.0	33.33	88.9	61	3.46	22.09	-33.3	0.00	77.8
	Week 2	66	37.37	23.76	0.0	33.33	100.0	62	5.74	21.83	-44.5	0.00	66.7
	Week 3	76	36.11	21.25	0.0	33.33	100.0	71	1.25	17.67	-55.6	0.00	33.3
	Week 4	73	35.31	19.37	0.0	33.33	77.8	68	0.82	20.97	-66.7	0.00	55.6
	Week 5	71	39.44	19.86	0.0	33.33	100.0	64	7.12	19.64	-44.5	0.00	66.7
	Week 6	70	34.60	23.13	0.0	33.33	100.0	63	0.18	24.96	-55.6	0.00	88.9
	Week 7	72	35.03	21.48	0.0	33.33	100.0	65	1.20	25.54	-55.6	0.00	88.9
	Week 8	63	33.86	18.12	0.0	33.33	88.9	58	3.26	23.27	-44.5	0.00	88.9
	Week 9	68	33.33	20.94	0.0	33.33	100.0	62	1.43	22.08	-33.3	0.00	66.7
	Week 10	67	34.33	21.78	0.0	33.33	100.0	61	-0.55	24.80	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	65	36.41	19.89	0.0	33.33	77.8	60	4.26	22.60	-55.6	0.00	55.6
	Week 12	63	33.16	22.27	0.0	33.33	100.0	58	0.00	23.91	-55.6	0.00	66.7
	Week 14	63	31.92	19.40	0.0	33.33	77.8	57	-1.36	18.19	-33.3	0.00	55.6
	Week 17	60	34.63	24.39	0.0	33.33	100.0	55	4.04	21.95	-44.4	0.00	66.7
	Week 20	52	33.76	23.49	0.0	33.33	100.0	50	4.00	24.57	-33.3	0.00	66.7
	Week 23	44	33.33	25.47	0.0	33.33	100.0	42	3.70	23.75	-44.5	0.00	55.6
	Week 26	41	28.45	21.38	0.0	33.33	77.8	40	0.00	21.94	-33.3	0.00	66.7
	Week 29	37	25.22	16.70	0.0	33.33	55.6	36	-0.62	19.33	-44.4	0.00	44.4
	Week 32	33	23.90	21.18	0.0	22.22	88.9	32	-1.74	26.04	-44.5	0.00	66.7
	Week 35	30	21.11	18.54	0.0	22.22	66.7	30	-2.96	22.40	-66.7	0.00	33.3
	Week 38	32	25.00	19.35	0.0	22.22	66.7	31	-1.43	23.44	-44.5	0.00	66.7
	Week 41	27	26.34	20.01	0.0	33.33	66.7	26	-0.43	22.55	-44.5	0.00	66.7
	Week 44	27	22.63	19.85	0.0	22.22	66.7	26	-2.14	23.31	-33.3	0.00	66.7
	Week 47	29	23.37	18.15	0.0	22.22	66.7	28	-3.17	24.35	-44.5	0.00	66.7
	Week 50	23	24.64	20.64	0.0	33.33	77.8	22	-1.52	20.37	-44.5	0.00	33.3
	Week 53	22	22.22	18.47	0.0	22.22	66.7	21	-3.17	22.26	-55.6	0.00	33.3
	Week 56	18	28.39	23.25	0.0	33.33	100.0	17	0.65	20.21	-33.3	0.00	33.3
	Week 59	17	21.57	13.87	0.0	33.33	33.3	16	-2.78	17.92	-33.3	0.00	33.3
	Week 62	16	22.91	15.43	0.0	33.33	44.4	15	-5.93	21.77	-55.6	0.00	33.3
	Week 65	15	20.00	15.82	0.0	33.33	33.3	14	-0.79	15.38	-33.3	0.00	33.3
	Week 68	12	23.15	21.43	0.0	27.78	66.7	11	-1.01	20.16	-33.3	0.00	33.3
	Week 71	13	28.20	23.84	0.0	33.33	66.7	12	6.48	19.80	-33.3	0.00	33.3
	Week 74	10	15.55	16.73	0.0	11.11	33.3	10	-3.33	16.60	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	EV+Pembro (N=198)												
	BASELINE	170	30.85	25.43	0.0	33.33	100.0						
	Week 1	157	33.33	24.30	0.0	33.33	100.0	152	3.29	20.33	-100.0	0.00	66.7
	Week 2	167	37.19	24.66	0.0	33.33	100.0	155	8.17	19.33	-66.7	0.00	66.7
	Week 3	161	40.79	24.43	0.0	33.33	100.0	147	11.19	22.58	-55.6	11.11	88.9
	Week 4	158	35.93	23.20	0.0	33.33	100.0	145	6.59	23.37	-66.7	0.00	66.7
	Week 5	154	34.63	24.07	0.0	33.33	100.0	140	5.87	23.52	-66.7	0.00	88.9
	Week 6	153	33.04	23.74	0.0	33.33	100.0	138	3.86	23.43	-55.6	0.00	77.8
	Week 7	159	33.75	22.88	0.0	33.33	100.0	142	4.30	25.07	-66.7	0.00	77.8
	Week 8	154	33.19	23.63	0.0	33.33	100.0	135	4.44	25.55	-66.7	0.00	77.8
	Week 9	162	36.01	23.13	0.0	33.33	100.0	146	7.23	26.60	-88.9	0.00	77.8
	Week 10	159	33.82	21.12	0.0	33.33	88.9	144	4.32	25.01	-66.7	0.00	77.8
	Week 11	161	33.33	24.25	0.0	33.33	100.0	143	3.88	28.47	-66.7	0.00	88.9
	Week 12	154	33.40	24.12	0.0	33.33	100.0	140	4.13	27.07	-66.7	0.00	100.0
	Week 14	154	34.13	23.74	0.0	33.33	100.0	137	5.51	26.34	-66.7	0.00	100.0
	Week 17	145	35.71	23.90	0.0	33.33	100.0	130	7.26	25.84	-66.7	0.00	88.9
	Week 20	139	35.97	24.54	0.0	33.33	100.0	126	8.64	27.82	-44.5	0.00	88.9
	Week 23	133	36.92	25.46	0.0	33.33	100.0	122	10.20	26.71	-55.6	11.11	77.8
	Week 26	129	35.40	24.76	0.0	33.33	100.0	118	7.63	28.16	-66.7	0.00	88.9
	Week 29	131	33.33	23.79	0.0	33.33	100.0	120	7.04	26.99	-66.7	0.00	88.9
	Week 32	111	34.73	23.84	0.0	33.33	100.0	102	8.82	25.52	-66.7	0.00	66.7
	Week 35	109	35.17	22.66	0.0	33.33	100.0	100	9.67	22.98	-33.3	5.56	66.7
	Week 38	107	35.10	25.32	0.0	33.33	100.0	100	7.89	24.28	-44.5	0.00	66.7
	Week 41	103	35.06	23.22	0.0	33.33	100.0	94	10.76	24.52	-66.7	11.11	88.9
	Week 44	88	32.32	21.68	0.0	33.33	88.9	81	9.74	26.43	-66.7	11.11	77.8
	Week 47	80	33.75	24.14	0.0	33.33	88.9	75	11.41	26.28	-66.7	11.11	88.9

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	73	33.64	24.22	0.0	33.33	100.0	68	11.44	24.36	-33.3	11.11	77.8
	Week 53	64	30.03	21.48	0.0	33.33	100.0	59	10.36	25.76	-44.5	11.11	100.0
	Week 56	66	34.85	25.70	0.0	33.33	100.0	61	11.84	28.68	-66.7	11.11	100.0
	Week 59	58	29.88	24.82	0.0	33.33	100.0	54	8.03	27.42	-66.7	11.11	100.0
	Week 62	54	31.07	26.11	0.0	33.33	100.0	52	10.26	28.93	-66.7	11.11	100.0
	Week 65	51	33.11	26.25	0.0	33.33	100.0	47	11.58	29.39	-66.7	0.00	100.0
	Week 68	49	30.84	22.48	0.0	33.33	100.0	48	12.04	25.92	-66.7	11.11	66.7
	Week 71	47	30.02	25.37	0.0	33.33	100.0	45	11.36	27.06	-66.7	11.11	66.7
	Week 74	42	30.69	24.40	0.0	33.33	88.9	41	11.11	27.22	-66.7	11.11	77.8
	Week 77	38	35.67	26.24	0.0	33.33	100.0	36	16.98	31.26	-66.7	11.11	77.8
	Week 80	35	33.33	24.85	0.0	33.33	100.0	32	10.07	26.23	-66.7	11.11	66.7
	Week 83	32	35.07	22.77	0.0	33.33	100.0	30	11.48	26.98	-66.7	16.67	66.7
	Week 86	30	32.59	24.23	0.0	33.33	100.0	27	10.29	26.85	-66.7	11.11	66.7
	Week 89	28	34.13	25.29	0.0	33.33	100.0	26	12.82	26.61	-66.7	11.11	55.6
	Week 92	24	31.94	26.88	0.0	33.33	100.0	22	12.63	24.80	-33.3	11.11	66.7
	Week 95	21	36.51	24.38	0.0	33.33	77.8	20	16.11	22.07	-22.2	11.11	55.6
	Week 98	16	31.94	23.26	0.0	33.33	66.7	15	11.11	19.70	-11.1	0.00	55.6
	Week 101	12	28.70	24.37	0.0	33.33	66.7	12	12.04	24.37	-22.2	11.12	66.7
	Week 104	10	32.22	22.50	0.0	33.33	66.7	10	17.78	22.35	-11.1	11.12	66.7
	Plat+Gem (N=185)												
	BASELINE	146	34.78	24.91	0.0	33.33	100.0						
	Week 1	131	39.35	24.39	0.0	33.33	100.0	120	6.30	19.74	-33.3	0.00	77.8
	Week 2	128	43.49	25.98	0.0	33.33	100.0	115	10.24	23.46	-44.5	0.00	100.0
	Week 3	141	39.40	23.96	0.0	33.33	100.0	126	4.85	18.51	-55.6	0.00	66.7
	Week 4	139	38.21	22.11	0.0	33.33	100.0	119	5.32	20.19	-66.7	0.00	66.7
	Week 5	143	41.65	23.20	0.0	33.33	100.0	120	9.91	20.11	-44.5	0.00	77.8

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 6	133	39.93	24.01	0.0	33.33	100.0	114	6.24	22.18	-55.6	0.00	88.9
	Week 7	142	38.26	23.99	0.0	33.33	100.0	120	4.44	22.10	-55.6	0.00	88.9
	Week 8	125	39.82	23.24	0.0	33.33	100.0	109	9.07	24.34	-44.5	0.00	100.0
	Week 9	135	37.36	23.65	0.0	33.33	100.0	115	4.93	23.69	-33.3	0.00	100.0
	Week 10	131	39.10	24.40	0.0	33.33	100.0	111	5.61	24.93	-33.3	0.00	100.0
	Week 11	128	38.97	24.43	0.0	33.33	100.0	109	6.73	23.81	-55.6	0.00	77.8
	Week 12	124	37.10	23.83	0.0	33.33	100.0	108	4.53	24.17	-55.6	0.00	66.7
	Week 14	121	37.19	24.03	0.0	33.33	100.0	101	4.95	24.11	-66.7	0.00	66.7
	Week 17	121	38.02	24.79	0.0	33.33	100.0	101	7.26	24.06	-66.7	0.00	66.7
	Week 20	98	34.35	22.23	0.0	33.33	100.0	86	4.78	24.08	-55.6	0.00	66.7
	Week 23	93	33.57	25.64	0.0	33.33	100.0	78	5.70	23.26	-55.6	0.00	55.6
	Week 26	86	31.14	25.04	0.0	33.33	100.0	75	3.11	22.93	-44.5	0.00	66.7
	Week 29	76	30.55	23.53	0.0	33.33	100.0	65	4.62	21.05	-33.3	0.00	55.6
	Week 32	62	27.96	21.17	0.0	33.33	100.0	56	0.20	21.56	-44.5	0.00	66.7
	Week 35	58	27.39	22.92	0.0	27.78	100.0	52	0.43	23.18	-66.7	0.00	55.6
	Week 38	60	29.81	22.08	0.0	33.33	100.0	52	2.14	21.56	-44.5	0.00	66.7
	Week 41	52	32.48	22.32	0.0	33.33	100.0	44	4.80	22.02	-44.5	0.00	66.7
	Week 44	46	30.43	25.17	0.0	33.33	100.0	40	3.33	25.56	-33.3	0.00	66.7
	Week 47	44	27.52	23.90	0.0	33.33	100.0	38	4.09	28.47	-44.5	0.00	88.9
	Week 50	42	33.07	27.05	0.0	33.33	100.0	38	4.97	21.57	-44.5	0.00	66.7
	Week 53	38	25.44	16.52	0.0	33.33	66.7	34	0.98	19.22	-55.6	0.00	33.3
	Week 56	32	34.37	26.53	0.0	33.33	100.0	28	9.92	28.26	-44.5	0.00	66.7
	Week 59	31	30.46	25.33	0.0	33.33	100.0	27	7.41	24.27	-33.3	0.00	66.7
	Week 62	29	29.12	19.79	0.0	33.33	77.8	26	6.41	25.37	-55.6	0.00	66.7
	Week 65	25	27.55	25.88	0.0	33.33	100.0	21	4.76	20.05	-33.3	0.00	66.7
	Week 68	20	30.55	21.89	0.0	33.33	77.8	16	5.56	21.85	-33.3	0.00	44.4

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 71	17	32.68	27.91	0.0	33.33	100.0	14	7.94	19.70	-33.3	0.00	33.3
	Week 74	17	25.49	24.77	0.0	33.33	100.0	14	2.38	16.98	-33.3	0.00	33.3
	Week 77	16	28.47	21.84	0.0	27.78	66.7	13	4.27	24.23	-33.3	0.00	55.6
	Week 80	13	26.49	16.69	0.0	33.33	55.6	12	7.41	17.30	-33.3	5.56	33.3
	Week 83	11	26.26	13.40	0.0	33.33	33.3	10	4.44	19.03	-33.3	0.00	33.3
	Week 86	12	26.85	16.72	0.0	33.33	55.6	11	6.06	18.16	-33.3	11.11	33.3
	Week 89	11	21.21	14.45	0.0	22.22	44.4	10	-3.33	17.41	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	EV+Pembro (N= 42)												
	BASELINE	36	30.86	23.62	0.0	33.33	100.0						
	Week 1	33	36.03	25.16	0.0	33.33	100.0	32	6.60	14.35	-11.1	0.00	33.3
	Week 2	36	39.51	25.54	0.0	33.33	100.0	34	7.52	17.02	-22.2	0.00	44.5
	Week 3	37	40.24	26.24	0.0	33.33	100.0	35	6.67	22.90	-44.4	0.00	55.6
	Week 4	36	34.26	24.25	0.0	33.33	100.0	34	3.59	20.60	-44.5	0.00	44.5
	Week 5	36	34.87	22.41	0.0	33.33	100.0	33	3.70	21.28	-66.7	0.00	33.3
	Week 6	35	31.74	20.37	0.0	33.33	100.0	32	3.47	19.84	-55.6	0.00	44.5
	Week 7	36	33.33	19.52	0.0	33.33	88.9	34	0.65	23.52	-66.7	0.00	55.6
	Week 8	37	30.93	18.91	0.0	33.33	88.9	36	0.31	22.14	-66.7	0.00	44.5
	Week 9	35	31.11	21.53	0.0	33.33	88.9	34	0.98	23.27	-33.3	0.00	77.8
	Week 10	32	29.51	20.86	0.0	22.22	88.9	31	-1.79	21.49	-66.7	0.00	44.5
	Week 11	33	32.66	20.40	0.0	33.33	88.9	32	0.35	20.83	-66.7	0.00	44.5
	Week 12	32	29.86	18.17	0.0	33.33	66.7	31	-2.15	22.67	-66.7	0.00	44.5
	Week 14	31	30.11	22.07	0.0	33.33	88.9	30	-0.74	19.99	-44.5	0.00	44.5
	Week 17	33	30.30	21.02	0.0	33.33	88.9	32	-1.04	23.50	-66.7	0.00	44.5
	Week 20	28	32.93	23.32	0.0	33.33	100.0	28	3.97	22.87	-66.7	0.00	44.5
	Week 23	29	30.27	16.51	0.0	33.33	66.7	29	0.38	23.29	-66.7	0.00	44.5
	Week 26	27	33.33	20.21	0.0	33.33	66.7	26	2.56	25.78	-66.7	0.00	44.5
	Week 29	26	32.05	22.30	0.0	33.33	100.0	25	0.00	25.05	-66.7	0.00	44.5
	Week 32	24	27.78	22.46	0.0	22.22	88.9	23	0.97	17.38	-33.3	0.00	33.3
	Week 35	23	30.43	15.79	0.0	33.33	66.7	22	0.00	19.70	-44.5	0.00	33.3
	Week 38	25	32.00	19.33	0.0	33.33	88.9	24	3.24	29.76	-66.7	0.00	55.6
	Week 41	26	33.76	21.43	0.0	33.33	88.9	25	0.89	25.64	-66.7	0.00	44.5
	Week 44	20	38.89	26.86	0.0	33.33	100.0	19	9.94	26.16	-22.2	0.00	88.9
	Week 47	20	37.78	24.56	0.0	33.33	100.0	19	6.43	28.76	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	16	38.89	23.31	0.0	33.33	77.8	16	13.20	22.30	-22.2	11.11	66.7
	Week 53	15	33.33	24.13	0.0	33.33	100.0	15	1.48	30.82	-66.7	11.11	33.3
	Week 56	15	37.78	20.92	0.0	33.33	77.8	15	9.63	20.94	-22.2	11.11	33.3
	Week 59	14	38.09	21.67	0.0	33.33	77.8	14	7.94	21.09	-22.2	5.56	44.5
	Week 62	11	31.31	28.47	0.0	22.22	88.9	11	6.06	22.97	-22.2	0.00	55.6
	Plat+Gem (N= 57)												
	BASELINE	42	34.92	20.47	0.0	33.33	88.9						
	Week 1	42	46.30	23.91	0.0	38.89	100.0	38	10.53	22.22	-33.3	11.11	66.7
	Week 2	43	43.15	24.51	0.0	44.44	100.0	36	11.73	23.15	-33.3	11.11	66.7
	Week 3	43	40.05	20.16	0.0	33.33	77.8	36	6.18	21.65	-33.3	0.00	44.5
	Week 4	44	43.69	21.75	0.0	38.89	100.0	37	12.91	21.04	-33.3	11.11	55.6
	Week 5	44	45.20	21.08	22.2	33.33	100.0	36	12.35	23.58	-22.2	11.11	66.7
	Week 6	41	42.00	28.92	0.0	33.33	100.0	35	5.72	24.90	-44.4	11.11	66.7
	Week 7	44	41.67	22.24	0.0	33.33	88.9	37	8.71	22.70	-44.4	11.11	66.7
	Week 8	42	46.03	23.36	0.0	38.89	100.0	35	11.43	23.88	-55.6	11.11	66.7
	Week 9	42	44.71	23.09	0.0	44.44	88.9	35	10.80	24.33	-33.3	11.11	44.5
	Week 10	35	45.40	22.45	0.0	33.33	100.0	28	14.29	24.17	-33.3	11.11	66.7
	Week 11	40	41.94	22.01	0.0	33.33	100.0	34	10.13	21.25	-33.3	11.11	55.6
	Week 12	35	40.63	22.05	0.0	33.33	88.9	30	8.52	25.22	-33.3	5.56	77.8
	Week 14	32	46.53	28.70	0.0	33.33	100.0	27	11.94	23.25	-22.2	11.11	55.6
	Week 17	34	44.44	24.62	0.0	44.44	100.0	29	12.26	24.73	-44.4	11.11	66.7
	Week 20	28	38.89	22.33	0.0	33.33	88.9	24	8.33	22.76	-33.3	5.56	66.7
	Week 23	22	31.31	23.42	0.0	33.33	66.7	19	2.34	20.48	-33.3	0.00	33.3
	Week 26	22	31.82	23.08	0.0	33.33	77.8	20	3.89	22.01	-33.3	0.00	44.5
	Week 29	24	29.17	17.59	0.0	33.33	55.6	21	-0.53	18.75	-44.4	0.00	33.3
	Week 32	21	40.21	24.46	0.0	33.33	100.0	20	9.45	25.05	-22.2	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 35	18	37.04	20.17	0.0	33.33	66.7	17	6.54	22.59	-44.4	0.00	33.3
	Week 38	14	46.03	26.82	11.1	38.89	100.0	13	15.39	26.27	-22.2	11.11	66.7
	Week 41	13	38.46	22.96	0.0	33.33	77.8	12	8.34	19.61	-22.2	5.56	44.5
	Week 44	14	38.09	22.53	11.1	33.33	88.9	13	10.26	20.52	-22.2	11.11	55.6
	Week 47	12	40.74	19.73	0.0	38.89	66.7	11	12.12	17.54	-22.2	11.11	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Visceral metastases	EV+Pembro (N=170)												
	BASELINE	146	33.33	25.54	0.0	33.33	100.0						
	Week 1	135	36.46	25.35	0.0	33.33	100.0	131	3.31	20.93	-100.0	0.00	66.7
	Week 2	145	38.85	23.32	0.0	33.33	100.0	134	7.05	19.58	-66.7	0.00	55.6
	Week 3	141	43.26	26.05	0.0	33.33	100.0	129	9.82	24.52	-55.6	0.00	88.9
	Week 4	136	38.40	24.64	0.0	33.33	100.0	125	6.13	24.94	-66.7	0.00	66.7
	Week 5	131	36.39	25.45	0.0	33.33	100.0	118	3.86	25.59	-66.7	0.00	88.9
	Week 6	127	34.12	23.81	0.0	33.33	100.0	113	3.05	24.05	-55.6	0.00	77.8
	Week 7	135	35.47	22.69	0.0	33.33	100.0	121	1.93	26.28	-66.7	0.00	77.8
	Week 8	131	32.91	23.36	0.0	33.33	100.0	118	0.56	26.86	-66.7	0.00	77.8
	Week 9	136	33.90	22.64	0.0	33.33	100.0	124	3.05	26.10	-88.9	0.00	77.8
	Week 10	135	33.33	21.42	0.0	33.33	88.9	124	1.43	25.19	-66.7	0.00	77.8
	Week 11	134	32.75	24.46	0.0	33.33	100.0	121	0.73	27.51	-66.7	0.00	88.9
	Week 12	131	31.72	24.00	0.0	33.33	100.0	120	-0.28	26.19	-66.7	0.00	88.9
	Week 14	130	32.99	23.76	0.0	33.33	100.0	117	1.42	27.63	-66.7	0.00	100.0
	Week 17	124	33.69	23.15	0.0	33.33	100.0	111	2.20	27.33	-66.7	0.00	88.9
	Week 20	115	33.53	22.94	0.0	33.33	100.0	105	4.13	27.49	-66.7	0.00	88.9
	Week 23	111	33.73	23.35	0.0	33.33	100.0	103	3.56	25.43	-66.7	0.00	66.7
	Week 26	106	32.60	23.77	0.0	33.33	100.0	97	1.72	28.44	-66.7	0.00	88.9
	Week 29	106	31.34	22.68	0.0	33.33	100.0	98	1.93	27.54	-66.7	0.00	88.9
	Week 32	92	32.25	24.33	0.0	33.33	100.0	85	3.79	24.76	-66.7	0.00	66.7
	Week 35	86	32.69	21.18	0.0	33.33	100.0	79	4.08	23.62	-33.3	0.00	66.7
	Week 38	90	33.95	24.95	0.0	33.33	100.0	84	3.44	26.44	-66.7	0.00	66.7
	Week 41	87	33.97	22.31	0.0	33.33	88.9	81	4.80	25.52	-66.7	0.00	88.9
	Week 44	73	31.66	20.51	0.0	33.33	88.9	68	4.90	26.97	-66.7	0.00	88.9
	Week 47	68	31.37	22.63	0.0	33.33	100.0	63	4.23	27.83	-66.7	0.00	88.9

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	61	33.51	23.53	0.0	33.33	88.9	57	7.60	24.41	-33.3	0.00	77.8
	Week 53	54	29.42	21.92	0.0	33.33	100.0	50	3.78	29.58	-66.7	0.00	100.0
	Week 56	58	34.10	23.26	0.0	33.33	100.0	54	8.02	29.31	-66.7	5.56	100.0
	Week 59	50	29.78	22.50	0.0	33.33	100.0	47	4.49	28.25	-66.7	0.00	100.0
	Week 62	45	29.38	23.59	0.0	33.33	100.0	43	5.43	29.43	-66.7	0.00	100.0
	Week 65	37	30.93	23.74	0.0	33.33	100.0	34	4.25	30.34	-66.7	0.00	100.0
	Week 68	35	31.74	20.90	0.0	33.33	88.9	34	8.50	28.04	-66.7	11.11	66.7
	Week 71	31	29.75	20.76	0.0	33.33	66.7	30	5.93	28.40	-66.7	5.56	66.7
	Week 74	29	28.35	21.53	0.0	33.33	88.9	28	3.57	26.89	-66.7	5.56	55.6
	Week 77	26	33.33	21.77	0.0	33.33	77.8	25	7.11	33.93	-66.7	0.00	77.8
	Week 80	22	33.33	20.57	0.0	33.33	66.7	21	3.17	27.92	-66.7	11.11	66.7
	Week 83	23	32.85	17.88	0.0	33.33	77.8	22	5.55	28.43	-66.7	11.11	66.7
	Week 86	21	30.16	20.83	0.0	33.33	66.7	20	2.78	27.19	-66.7	5.56	66.7
	Week 89	21	33.33	22.77	0.0	33.33	88.9	20	4.44	24.29	-66.7	11.11	44.4
	Week 92	18	29.63	19.43	0.0	33.33	55.6	17	5.88	24.57	-33.3	11.11	55.6
	Week 95	13	30.77	17.66	0.0	33.33	55.6	12	10.19	21.43	-22.2	11.11	44.4
	Week 98	11	28.28	16.75	0.0	33.33	66.7	11	2.02	16.34	-11.1	0.00	33.3
	Week 101	11	30.30	22.82	0.0	33.33	66.7	11	4.04	29.51	-33.3	0.00	66.7
	Plat+Gem (N=161)												
	BASELINE	129	37.04	23.13	0.0	33.33	100.0						
	Week 1	113	43.07	23.15	0.0	33.33	100.0	105	6.56	19.23	-33.3	0.00	66.7
	Week 2	108	45.47	25.63	0.0	44.44	100.0	98	9.64	24.13	-44.5	0.00	100.0
	Week 3	121	41.14	21.45	0.0	33.33	100.0	109	3.87	19.03	-55.6	0.00	66.7
	Week 4	116	40.23	21.47	0.0	33.33	100.0	101	5.50	19.79	-66.7	0.00	55.6
	Week 5	121	43.80	23.19	0.0	33.33	100.0	104	8.76	20.17	-44.5	0.00	66.7
	Week 6	118	40.77	24.49	0.0	33.33	100.0	102	4.58	21.35	-55.6	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 7	121	40.13	22.79	0.0	33.33	100.0	104	3.42	21.29	-55.6	0.00	66.7
	Week 8	108	38.68	20.91	0.0	33.33	100.0	96	5.32	22.97	-55.6	0.00	66.7
	Week 9	114	38.01	22.90	0.0	33.33	100.0	99	3.25	22.29	-33.3	0.00	66.7
	Week 10	109	39.65	23.20	0.0	33.33	100.0	94	3.43	23.50	-33.3	0.00	66.7
	Week 11	109	39.04	23.84	0.0	33.33	100.0	95	5.50	24.03	-55.6	0.00	77.8
	Week 12	103	38.73	22.11	0.0	33.33	100.0	91	4.64	25.40	-55.6	0.00	77.8
	Week 14	98	39.68	23.56	0.0	33.33	100.0	85	5.36	26.04	-66.7	0.00	66.7
	Week 17	103	38.83	23.90	0.0	33.33	100.0	89	5.62	24.34	-66.7	11.11	66.7
	Week 20	82	34.82	20.57	0.0	33.33	100.0	75	3.11	23.00	-55.6	0.00	55.6
	Week 23	77	33.62	25.68	0.0	33.33	100.0	68	3.43	22.57	-55.6	0.00	55.6
	Week 26	71	30.67	23.11	0.0	33.33	100.0	65	1.54	20.96	-44.5	0.00	44.5
	Week 29	65	28.72	21.05	0.0	33.33	100.0	59	0.75	21.23	-44.4	0.00	55.6
	Week 32	52	29.27	19.68	0.0	33.33	88.9	49	0.68	21.45	-44.5	0.00	66.7
	Week 35	47	30.97	22.46	0.0	33.33	88.9	44	1.52	22.17	-33.3	0.00	55.6
	Week 38	42	33.07	24.72	0.0	33.33	100.0	39	4.84	22.91	-33.3	0.00	66.7
	Week 41	35	35.24	21.30	0.0	33.33	77.8	32	6.25	20.73	-33.3	0.00	44.5
	Week 44	36	34.88	25.36	0.0	33.33	100.0	33	7.74	24.77	-33.3	0.00	66.7
	Week 47	32	29.86	21.76	0.0	33.33	100.0	30	5.56	26.54	-44.5	0.00	88.9
	Week 50	30	34.81	23.84	0.0	33.33	77.8	29	6.51	20.25	-33.3	0.00	66.7
	Week 53	25	28.00	17.89	0.0	33.33	66.7	24	5.09	16.04	-33.3	0.00	33.3
	Week 56	22	40.40	27.76	0.0	33.33	100.0	21	17.99	24.96	-33.3	11.11	66.7
	Week 59	22	30.81	23.99	0.0	33.33	100.0	21	10.05	25.07	-33.3	0.00	66.7
	Week 62	19	31.58	18.62	0.0	33.33	77.8	18	10.49	22.70	-33.3	0.00	66.7
	Week 65	19	27.48	22.34	0.0	33.33	100.0	18	6.79	22.27	-33.3	5.56	66.7
	Week 68	13	29.91	20.98	0.0	33.33	66.7	12	8.33	18.43	-33.3	5.56	33.3
	Week 71	13	35.90	22.29	0.0	33.33	66.7	12	11.11	20.10	-33.3	11.11	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 74	11	21.21	17.53	0.0	33.33	44.4	11	1.01	16.07	-33.3	0.00	33.3
	Week 77	10	17.78	15.00	0.0	16.67	33.3	10	-3.33	15.76	-33.3	0.00	22.2

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Lymph node only	EV+Pembro (N= 60)												
	BASELINE	53	23.69	21.90	0.0	22.22	77.8						
	Week 1	49	27.21	20.29	0.0	33.33	77.8	47	5.44	15.69	-22.2	0.00	44.5
	Week 2	50	33.78	27.12	0.0	33.33	100.0	48	11.11	17.61	-11.1	5.56	66.7
	Week 3	50	34.22	19.29	0.0	33.33	66.7	47	11.58	18.09	-33.3	11.11	44.5
	Week 4	50	30.00	18.95	0.0	33.33	100.0	47	8.04	16.00	-33.3	11.11	44.5
	Week 5	53	31.44	18.71	0.0	33.33	88.9	49	9.75	16.61	-33.3	11.11	44.5
	Week 6	53	30.82	22.18	0.0	33.33	100.0	50	7.11	19.28	-33.3	11.11	44.5
	Week 7	52	27.78	17.94	0.0	33.33	66.7	48	6.71	21.59	-66.7	0.00	55.6
	Week 8	52	31.19	20.99	0.0	33.33	100.0	47	9.22	18.72	-44.5	11.11	44.5
	Week 9	53	38.15	23.22	0.0	33.33	100.0	49	14.06	24.93	-44.5	11.11	77.8
	Week 10	48	31.48	19.09	0.0	33.33	88.9	44	8.08	22.91	-66.7	11.11	44.5
	Week 11	53	35.64	22.26	0.0	33.33	100.0	48	11.11	25.42	-55.6	11.11	55.6
	Week 12	48	36.34	21.71	0.0	33.33	100.0	45	12.59	24.34	-44.5	11.11	100.0
	Week 14	48	34.03	22.39	0.0	33.33	88.9	44	11.62	17.76	-33.3	11.11	55.6
	Week 17	46	36.47	22.43	0.0	33.33	100.0	44	13.38	19.41	-33.3	16.67	44.5
	Week 20	44	39.14	26.52	0.0	33.33	100.0	42	16.14	25.88	-44.5	16.67	88.9
	Week 23	43	36.69	21.89	0.0	33.33	88.9	41	16.26	24.86	-44.5	11.11	66.7
	Week 26	42	37.30	21.37	0.0	33.33	88.9	40	15.56	22.90	-33.3	11.11	66.7
	Week 29	45	35.80	24.61	0.0	33.33	100.0	42	14.02	24.05	-44.5	11.11	66.7
	Week 32	38	34.79	20.69	0.0	33.33	88.9	36	14.51	22.35	-33.3	11.12	66.7
	Week 35	42	38.09	23.04	0.0	33.33	88.9	40	15.28	19.76	-44.5	11.11	55.6
	Week 38	38	34.50	23.36	0.0	33.33	88.9	36	13.58	22.24	-44.5	11.11	66.7
	Week 41	37	36.03	23.63	0.0	33.33	100.0	34	16.34	22.26	-44.5	11.11	66.7
	Week 44	31	37.27	25.91	0.0	33.33	100.0	29	20.31	21.84	-22.2	22.22	66.7
	Week 47	28	38.89	26.45	0.0	33.33	88.9	27	21.40	18.47	0.0	22.22	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	25	33.33	22.45	0.0	33.33	88.9	24	17.59	17.62	-11.1	11.12	55.6
	Week 53	23	31.40	20.83	0.0	33.33	77.8	22	18.18	16.99	-22.2	22.22	44.5
	Week 56	21	35.98	26.51	0.0	33.33	77.8	20	18.33	18.48	-11.1	11.11	55.6
	Week 59	20	32.22	25.47	0.0	33.33	66.7	19	14.04	17.31	-11.1	11.11	66.7
	Week 62	19	31.58	28.75	0.0	22.22	77.8	19	16.38	21.07	-11.1	11.11	77.8
	Week 65	20	37.78	26.59	0.0	44.44	77.8	19	18.71	22.24	-11.1	11.11	55.6
	Week 68	17	30.72	24.07	0.0	33.33	66.7	17	16.99	18.48	0.0	11.11	66.7
	Week 71	19	29.82	27.23	0.0	33.33	77.8	18	16.05	19.14	-11.1	11.11	66.7
	Week 74	17	35.29	26.13	0.0	33.33	77.8	17	18.96	21.79	-11.1	11.12	77.8
	Week 77	17	37.91	26.08	0.0	44.44	66.7	16	21.53	21.65	0.0	11.11	55.6
	Week 80	17	34.64	26.61	0.0	33.33	100.0	15	13.33	17.92	-11.1	11.11	44.4
	Week 83	13	37.61	23.37	0.0	33.33	66.7	12	14.82	14.47	0.0	16.67	33.3
	Week 86	12	36.11	21.78	0.0	33.33	66.7	10	17.78	13.04	0.0	16.67	33.3
	Week 89	11	37.37	25.47	0.0	33.33	77.8	10	20.00	20.15	0.0	22.22	55.6
	Plat+Gem (N= 67)												
	BASELINE	49	29.70	23.83	0.0	22.22	88.9						
	Week 1	51	37.04	25.69	0.0	33.33	100.0	45	8.15	22.02	-33.3	0.00	66.7
	Week 2	53	40.04	26.72	0.0	33.33	100.0	44	11.87	21.88	-22.2	11.11	66.7
	Week 3	53	38.99	26.57	0.0	33.33	100.0	44	9.60	19.70	-44.5	11.11	44.5
	Week 4	58	38.89	24.12	0.0	33.33	100.0	47	10.17	22.32	-33.3	11.11	66.7
	Week 5	56	40.67	21.95	0.0	33.33	100.0	44	13.13	21.47	-33.3	11.11	77.8
	Week 6	48	40.28	26.60	0.0	33.33	100.0	40	9.72	22.67	-22.2	0.00	66.7
	Week 7	56	38.09	24.42	0.0	33.33	100.0	46	9.18	20.99	-22.2	11.11	66.7
	Week 8	52	46.58	27.31	0.0	38.89	100.0	42	17.73	23.16	-22.2	11.12	100.0
	Week 9	53	42.56	25.48	0.0	33.33	100.0	42	13.49	26.94	-33.3	5.56	100.0
	Week 10	47	43.03	26.58	0.0	33.33	100.0	36	16.36	24.41	-33.3	11.11	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	51	41.83	24.71	0.0	33.33	100.0	41	12.20	20.76	-33.3	11.11	55.6
	Week 12	47	38.53	26.40	0.0	33.33	100.0	39	8.83	22.97	-55.6	0.00	66.7
	Week 14	47	39.24	29.29	0.0	33.33	100.0	36	10.49	20.56	-33.3	5.56	55.6
	Week 17	45	41.48	27.16	0.0	33.33	100.0	35	13.97	23.24	-33.3	11.11	66.7
	Week 20	38	34.50	24.48	0.0	33.33	100.0	30	8.52	24.01	-33.3	0.00	66.7
	Week 23	32	33.68	25.48	0.0	33.33	100.0	25	8.89	23.79	-33.3	0.00	55.6
	Week 26	30	33.33	29.33	0.0	33.33	100.0	24	7.41	27.54	-44.5	0.00	66.7
	Week 29	28	34.13	25.83	0.0	33.33	100.0	21	10.05	18.22	-11.1	0.00	44.5
	Week 32	26	36.32	28.03	0.0	33.33	100.0	22	7.07	27.55	-44.5	0.00	66.7
	Week 35	23	27.05	24.35	0.0	22.22	100.0	19	0.00	25.66	-66.7	0.00	33.3
	Week 38	26	35.47	23.31	0.0	33.33	88.9	20	5.55	26.37	-44.5	0.00	66.7
	Week 41	24	34.26	25.36	0.0	33.33	100.0	18	4.94	26.19	-44.5	0.00	66.7
	Week 44	18	33.33	23.80	0.0	33.33	77.8	14	3.17	28.05	-33.3	0.00	66.7
	Week 47	18	34.57	28.24	0.0	33.33	100.0	13	8.55	32.13	-44.5	0.00	66.7
	Week 50	16	36.11	31.03	0.0	33.33	100.0	13	5.98	23.40	-44.5	11.11	33.3
	Week 53	15	29.63	17.65	0.0	33.33	55.6	12	-3.71	25.22	-55.6	0.00	33.3
	Week 56	15	29.63	22.87	0.0	33.33	88.9	11	-9.09	22.67	-44.5	0.00	33.3
	Week 59	12	29.63	26.52	0.0	33.33	100.0	9	-3.71	20.79	-33.3	0.00	33.3
	Week 62	10	26.67	22.95	0.0	33.33	77.8	8	-5.56	28.48	-55.6	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
EV+Pembro (N=202)												
BASELINE	160	36.25	24.72	0.0	33.33	100.0						
Week 1	141	39.95	26.23	0.0	33.33	100.0	129	4.65	18.41	-44.4	0.00	55.6
Week 2	150	40.74	24.95	0.0	33.33	100.0	133	4.93	18.22	-44.5	0.00	66.7
Week 3	139	39.57	25.91	0.0	33.33	100.0	122	4.46	21.13	-44.5	0.00	77.8
Week 4	145	38.47	25.39	0.0	33.33	100.0	129	3.79	22.25	-66.7	0.00	77.8
Week 5	137	37.63	26.58	0.0	33.33	100.0	121	2.75	23.89	-55.6	0.00	88.9
Week 6	146	38.05	25.33	0.0	33.33	100.0	124	3.85	26.28	-55.6	0.00	88.9
Week 7	147	36.05	23.10	0.0	33.33	100.0	124	1.61	24.98	-55.6	0.00	77.8
Week 8	147	37.34	25.78	0.0	33.33	100.0	124	2.51	28.05	-55.6	0.00	88.9
Week 9	142	37.32	25.19	0.0	33.33	100.0	121	3.31	26.79	-55.6	0.00	88.9
Week 10	139	36.05	25.13	0.0	33.33	100.0	118	2.35	26.74	-66.7	0.00	77.8
Week 11	137	33.58	22.81	0.0	33.33	100.0	115	0.48	26.14	-66.7	0.00	77.8
Week 12	142	34.27	24.20	0.0	33.33	100.0	119	0.00	23.68	-55.6	0.00	66.7
Week 14	139	33.81	24.33	0.0	33.33	100.0	116	-1.34	26.06	-66.7	0.00	66.7
Week 17	132	33.25	21.64	0.0	33.33	100.0	111	-1.90	25.47	-77.8	0.00	66.7
Week 20	120	33.42	20.75	0.0	33.33	100.0	103	0.32	26.10	-66.7	0.00	77.8
Week 23	117	33.71	20.84	0.0	33.33	77.8	97	0.80	24.86	-44.5	0.00	77.8
Week 26	112	32.84	20.47	0.0	33.33	100.0	94	-0.12	25.48	-66.7	0.00	66.7
Week 29	107	36.03	21.14	0.0	33.33	88.9	93	4.42	26.48	-55.6	0.00	77.8
Week 32	102	35.18	22.66	0.0	33.33	100.0	88	1.14	27.22	-66.7	0.00	77.8
Week 35	98	36.17	22.64	0.0	33.33	100.0	86	4.00	28.47	-66.7	0.00	77.8
Week 38	97	37.23	20.60	0.0	33.33	100.0	86	4.00	24.46	-66.7	0.00	55.6
Week 41	95	35.91	20.72	0.0	33.33	100.0	84	2.78	25.28	-55.6	0.00	55.6
Week 44	86	37.85	23.08	0.0	33.33	100.0	74	4.80	24.75	-66.7	0.00	55.6
Week 47	79	36.99	20.11	0.0	33.33	100.0	70	2.54	24.31	-66.7	0.00	55.6

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	74	36.94	22.00	0.0	33.33	100.0	64	3.82	25.83	-66.7	0.00	55.6
Week 53	74	39.19	25.17	0.0	33.33	100.0	63	3.00	25.50	-66.7	0.00	66.7
Week 56	72	39.20	24.46	0.0	33.33	100.0	61	1.82	27.23	-66.7	0.00	66.7
Week 59	69	38.49	24.37	0.0	33.33	100.0	57	1.56	27.65	-55.6	0.00	66.7
Week 62	62	36.38	20.34	0.0	33.33	66.7	52	0.85	28.76	-66.7	0.00	66.7
Week 65	43	39.53	23.67	0.0	33.33	88.9	40	4.17	30.16	-66.7	0.00	66.7
Week 68	46	37.44	23.93	0.0	33.33	88.9	42	2.12	30.18	-66.7	0.00	66.7
Week 71	42	38.09	23.56	0.0	33.33	88.9	38	1.46	30.70	-66.7	0.00	66.7
Week 74	38	32.75	22.66	0.0	33.33	77.8	35	-0.32	35.19	-66.7	0.00	66.7
Week 77	37	33.63	19.86	0.0	33.33	66.7	33	-2.36	31.28	-66.7	0.00	66.7
Week 80	36	37.65	24.09	0.0	33.33	88.9	34	1.63	33.63	-66.7	0.00	77.8
Week 83	30	35.55	22.49	0.0	33.33	77.8	29	0.38	35.07	-66.7	0.00	66.7
Week 86	26	40.60	23.30	0.0	44.44	77.8	25	4.89	35.30	-66.7	0.00	77.8
Week 89	20	36.11	23.61	0.0	33.33	88.9	19	2.92	34.52	-66.7	0.00	77.8
Week 92	19	38.60	23.82	0.0	33.33	88.9	18	4.94	29.58	-66.7	11.11	55.6
Week 95	14	28.57	18.34	0.0	33.33	66.7	13	-2.57	29.10	-66.7	0.00	33.3
Week 98	10	28.89	19.74	0.0	33.33	66.7	9	-3.70	24.85	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Plat+Gem (N=202)												
BASELINE	165	36.16	28.24	0.0	33.33	100.0						
Week 1	144	39.43	25.37	0.0	33.33	100.0	139	3.60	19.39	-44.5	0.00	66.7
Week 2	147	44.14	25.08	0.0	33.33	100.0	135	9.79	23.16	-55.6	11.11	88.9
Week 3	149	41.76	26.71	0.0	33.33	100.0	136	9.15	20.86	-44.5	11.11	55.6
Week 4	150	39.04	23.80	0.0	33.33	100.0	135	6.34	22.45	-66.7	11.11	66.7
Week 5	153	42.92	26.09	0.0	33.33	100.0	138	9.10	26.18	-55.6	11.11	77.8
Week 6	145	41.00	26.04	0.0	33.33	100.0	131	7.72	26.54	-55.6	11.11	77.8
Week 7	148	41.74	27.27	0.0	33.33	100.0	134	8.79	29.38	-66.7	11.11	77.8
Week 8	145	44.14	25.86	0.0	33.33	100.0	132	10.19	27.32	-55.6	11.11	77.8
Week 9	141	42.87	25.18	0.0	33.33	100.0	125	9.51	30.55	-55.6	11.11	88.9
Week 10	142	40.61	25.35	0.0	33.33	100.0	130	7.35	28.24	-55.6	5.56	66.7
Week 11	126	40.83	24.26	0.0	33.33	100.0	114	7.50	28.80	-55.6	11.11	88.9
Week 12	130	41.62	24.49	0.0	33.33	100.0	115	7.44	28.79	-55.6	0.00	88.9
Week 14	125	41.24	23.35	0.0	33.33	100.0	109	8.77	28.77	-44.5	11.11	77.8
Week 17	120	40.83	25.94	0.0	33.33	100.0	106	7.97	29.13	-44.5	0.00	77.8
Week 20	104	39.10	25.54	0.0	33.33	100.0	91	6.72	28.49	-55.6	0.00	88.9
Week 23	88	33.33	22.73	0.0	33.33	100.0	80	2.78	25.95	-55.6	0.00	66.7
Week 26	81	35.12	25.18	0.0	33.33	100.0	75	2.07	26.64	-55.6	0.00	66.7
Week 29	77	34.63	24.45	0.0	33.33	100.0	71	6.10	29.33	-55.6	0.00	88.9
Week 32	63	34.74	22.97	0.0	33.33	100.0	58	5.36	26.84	-55.6	0.00	77.8
Week 35	62	31.90	21.43	0.0	33.33	100.0	56	3.17	28.88	-55.6	0.00	66.7
Week 38	56	35.91	26.55	0.0	33.33	100.0	50	8.67	30.97	-55.6	0.00	100.0
Week 41	52	39.96	24.92	0.0	33.33	100.0	47	10.64	27.61	-66.7	11.11	77.8
Week 44	49	41.04	24.45	0.0	33.33	100.0	44	9.85	28.07	-66.7	5.56	66.7
Week 47	43	40.83	25.28	0.0	33.33	100.0	39	9.69	23.94	-33.3	11.11	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	36	40.74	26.30	0.0	33.33	100.0	31	9.68	26.57	-33.3	11.11	66.7
Week 53	31	39.07	25.64	0.0	33.33	100.0	28	6.35	32.91	-55.6	5.56	77.8
Week 56	30	46.30	24.25	0.0	38.89	100.0	29	9.58	30.68	-55.6	11.11	66.7
Week 59	23	46.38	29.14	0.0	33.33	100.0	21	4.76	34.71	-55.6	11.11	88.9
Week 62	20	45.55	26.22	0.0	38.89	88.9	20	3.33	35.34	-66.7	11.11	88.9
Week 65	17	41.18	24.14	11.1	33.33	88.9	16	5.55	22.22	-44.5	0.00	44.5
Week 68	13	44.44	27.22	0.0	33.33	88.9	13	9.40	23.50	-22.2	11.11	66.7
Week 71	13	44.44	28.33	0.0	33.33	100.0	13	7.69	29.53	-55.6	11.11	44.5
Week 74	11	41.41	23.36	11.1	33.33	100.0	11	16.16	20.71	-22.2	11.11	55.6
Week 77	11	33.33	21.66	0.0	33.33	77.8	11	8.08	32.62	-44.5	11.11	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Present	EV+Pembro (N= 50)												
	BASELINE	40	43.33	26.25	0.0	44.44	100.0						
	Week 1	38	50.88	28.96	0.0	55.56	100.0	34	6.21	19.76	-33.3	0.00	55.6
	Week 2	35	45.40	24.61	0.0	33.33	100.0	32	2.08	18.60	-33.3	0.00	44.4
	Week 3	32	43.05	24.56	0.0	33.33	100.0	30	2.59	23.47	-33.3	0.00	66.7
	Week 4	35	46.98	26.28	0.0	44.44	100.0	31	5.02	24.65	-33.3	0.00	77.8
	Week 5	32	44.10	26.10	0.0	33.33	100.0	28	1.19	23.69	-44.5	0.00	55.6
	Week 6	35	42.54	22.63	11.1	33.33	100.0	30	0.37	29.25	-55.6	0.00	66.7
	Week 7	35	40.63	21.72	0.0	33.33	77.8	29	-0.38	25.97	-44.5	0.00	55.6
	Week 8	38	44.44	26.09	0.0	33.33	100.0	31	4.66	29.92	-44.5	0.00	77.8
	Week 9	33	41.41	22.61	0.0	33.33	88.9	29	0.38	24.03	-44.5	0.00	44.5
	Week 10	30	36.67	21.87	0.0	33.33	77.8	25	-6.67	25.86	-66.7	0.00	44.5
	Week 11	31	33.69	21.18	0.0	33.33	100.0	27	-4.94	33.24	-66.7	-11.11	77.8
	Week 12	32	33.33	25.71	0.0	33.33	100.0	28	-7.54	26.55	-55.6	0.00	55.6
	Week 14	36	34.88	24.37	0.0	33.33	88.9	31	-7.17	30.44	-66.7	-11.11	55.6
	Week 17	33	34.68	23.53	0.0	33.33	88.9	27	-7.41	25.04	-66.7	0.00	33.3
	Week 20	28	31.35	19.14	0.0	33.33	66.7	25	-4.00	27.57	-66.7	0.00	55.6
	Week 23	28	41.27	18.85	11.1	33.33	77.8	24	4.63	24.28	-33.3	0.00	77.8
	Week 26	28	36.51	20.03	0.0	33.33	77.8	24	0.46	27.90	-44.5	0.00	66.7
	Week 29	27	35.80	21.43	0.0	33.33	77.8	25	-1.34	25.32	-33.3	0.00	55.6
	Week 32	25	35.55	23.35	0.0	33.33	100.0	23	-1.45	26.23	-33.3	0.00	77.8
	Week 35	26	41.88	19.20	22.2	33.33	100.0	24	2.78	26.27	-33.3	0.00	77.8
	Week 38	26	45.73	23.17	22.2	33.33	100.0	24	7.87	25.69	-44.5	11.11	55.6
	Week 41	25	39.55	17.30	11.1	33.33	66.7	23	3.86	23.84	-44.5	0.00	44.5
	Week 44	22	40.91	20.97	11.1	33.33	100.0	20	0.55	23.77	-33.3	0.00	55.6
	Week 47	14	44.44	22.65	11.1	38.89	100.0	13	0.85	21.50	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	40.55	27.28	0.0	33.33	100.0	17	1.31	26.02	-33.3	0.00	44.4
	Week 53	21	45.50	28.09	0.0	33.33	100.0	18	3.08	22.80	-33.3	0.00	44.4
	Week 56	18	41.36	24.94	0.0	38.89	88.9	15	0.00	23.38	-33.3	0.00	44.4
	Week 59	18	42.59	29.09	0.0	33.33	100.0	15	-0.74	26.72	-55.6	0.00	33.3
	Week 62	13	34.19	16.64	0.0	33.33	66.7	11	-4.04	29.93	-66.7	0.00	33.3
	Week 68	12	41.67	27.27	11.1	33.33	88.9	11	4.04	29.51	-55.6	22.22	33.3
	Plat+Gem (N= 50)												
	BASELINE	40	45.56	30.90	0.0	44.44	100.0						
	Week 1	35	46.35	25.35	0.0	44.44	100.0	33	3.70	16.12	-22.2	0.00	44.5
	Week 2	33	49.83	27.52	0.0	44.44	100.0	30	12.22	26.48	-44.5	5.56	88.9
	Week 3	33	46.46	26.13	0.0	44.44	100.0	29	10.34	22.21	-44.5	11.11	55.6
	Week 4	36	45.06	23.90	0.0	44.44	100.0	32	5.56	22.93	-44.5	0.00	66.7
	Week 5	36	47.22	30.68	0.0	38.89	100.0	32	5.21	31.68	-55.6	0.00	77.8
	Week 6	32	40.62	26.42	0.0	33.33	100.0	29	2.30	30.92	-55.6	0.00	66.7
	Week 7	35	49.84	30.65	0.0	55.56	100.0	31	8.24	35.13	-55.6	0.00	77.8
	Week 8	35	50.79	26.72	0.0	55.56	100.0	31	8.96	31.74	-44.5	0.00	77.8
	Week 9	34	50.65	25.54	0.0	55.56	100.0	30	9.26	39.16	-55.6	0.00	88.9
	Week 10	33	48.48	27.19	0.0	33.33	100.0	30	6.30	33.36	-55.6	0.00	66.7
	Week 11	30	45.56	25.99	0.0	44.44	100.0	26	7.69	32.63	-55.6	0.00	88.9
	Week 12	32	46.18	25.73	0.0	44.44	100.0	27	4.53	28.62	-44.5	0.00	66.7
	Week 14	27	40.74	23.47	0.0	33.33	88.9	22	3.03	31.09	-44.5	0.00	55.6
	Week 17	28	41.67	25.59	0.0	38.89	100.0	23	3.38	29.10	-44.5	0.00	55.6
	Week 20	20	40.56	27.99	0.0	38.89	88.9	16	0.00	22.59	-44.4	0.00	33.3
	Week 23	15	34.81	25.84	0.0	33.33	88.9	14	-0.79	20.19	-33.3	0.00	44.4
	Week 26	15	33.33	31.98	0.0	33.33	100.0	14	0.79	20.66	-33.3	0.00	33.3
	Week 29	13	31.62	25.19	0.0	33.33	100.0	12	8.33	32.18	-44.5	0.00	88.9

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Absent	EV+Pembro (N=152)												
	BASELINE	120	33.89	23.84	0.0	33.33	100.0						
	Week 1	103	35.92	24.06	0.0	33.33	100.0	95	4.09	17.98	-44.4	0.00	55.6
	Week 2	115	39.32	24.99	0.0	33.33	100.0	101	5.83	18.09	-44.5	0.00	66.7
	Week 3	107	38.52	26.32	0.0	33.33	100.0	92	5.07	20.40	-44.5	0.00	77.8
	Week 4	110	35.76	24.61	0.0	33.33	100.0	98	3.40	21.55	-66.7	0.00	66.7
	Week 5	105	35.66	26.54	0.0	33.33	100.0	93	3.23	24.06	-55.6	0.00	88.9
	Week 6	111	36.64	26.06	0.0	33.33	100.0	94	4.96	25.33	-55.6	0.00	88.9
	Week 7	112	34.62	23.43	0.0	33.33	100.0	95	2.22	24.77	-55.6	0.00	77.8
	Week 8	109	34.86	25.32	0.0	33.33	100.0	93	1.79	27.53	-55.6	0.00	88.9
	Week 9	109	36.09	25.89	0.0	33.33	100.0	92	4.23	27.66	-55.6	0.00	88.9
	Week 10	109	35.88	26.04	0.0	33.33	100.0	93	4.78	26.59	-44.5	0.00	77.8
	Week 11	106	33.54	23.36	0.0	33.33	100.0	88	2.15	23.52	-55.6	0.00	66.7
	Week 12	110	34.54	23.86	0.0	33.33	100.0	91	2.32	22.38	-55.6	0.00	66.7
	Week 14	103	33.44	24.43	0.0	33.33	100.0	85	0.78	24.11	-66.7	0.00	66.7
	Week 17	99	32.77	21.08	0.0	33.33	100.0	84	-0.13	25.50	-77.8	0.00	66.7
	Week 20	92	34.06	21.28	0.0	33.33	100.0	78	1.71	25.65	-55.6	0.00	77.8
	Week 23	89	31.33	20.96	0.0	33.33	77.8	73	-0.46	25.08	-44.5	0.00	66.7
	Week 26	84	31.61	20.59	0.0	33.33	100.0	70	-0.32	24.81	-66.7	0.00	55.6
	Week 29	80	36.11	21.18	0.0	33.33	88.9	68	6.54	26.76	-55.6	11.11	77.8
	Week 32	77	35.06	22.59	0.0	33.33	88.9	65	2.05	27.70	-66.7	0.00	55.6
	Week 35	72	34.10	23.54	0.0	33.33	100.0	62	4.48	29.47	-66.7	0.00	66.7
	Week 38	71	34.11	18.81	0.0	33.33	66.7	62	2.51	24.01	-66.7	0.00	55.6
	Week 41	70	34.60	21.78	0.0	33.33	100.0	61	2.37	25.99	-55.6	0.00	55.6
	Week 44	64	36.80	23.83	0.0	33.33	100.0	54	6.38	25.14	-66.7	5.56	55.6
	Week 47	65	35.38	19.34	0.0	33.33	77.8	57	2.92	25.07	-66.7	0.00	55.6

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	54	35.60	19.83	0.0	33.33	66.7	47	4.73	25.98	-66.7	0.00	55.6
	Week 53	53	36.69	23.73	0.0	33.33	88.9	45	2.96	26.74	-66.7	0.00	66.7
	Week 56	54	38.48	24.49	0.0	33.33	100.0	46	2.42	28.59	-66.7	0.00	66.7
	Week 59	51	37.04	22.63	0.0	33.33	100.0	42	2.38	28.25	-55.6	0.00	66.7
	Week 62	49	36.96	21.32	0.0	33.33	66.7	41	2.17	28.68	-66.7	0.00	66.7
	Week 65	36	39.20	23.68	0.0	33.33	88.9	33	3.70	29.22	-66.7	0.00	66.7
	Week 68	34	35.95	22.90	0.0	33.33	77.8	31	1.43	30.87	-66.7	0.00	66.7
	Week 71	33	35.69	23.04	0.0	33.33	66.7	30	1.48	32.59	-66.7	0.00	66.7
	Week 74	33	32.32	22.46	0.0	33.33	77.8	30	1.48	34.49	-66.7	0.00	66.7
	Week 77	31	32.61	18.80	0.0	33.33	66.7	27	-0.41	31.65	-66.7	0.00	66.7
	Week 80	31	37.63	23.60	0.0	33.33	88.9	29	3.45	33.74	-66.7	0.00	77.8
	Week 83	25	34.67	20.87	0.0	33.33	66.7	24	1.85	33.36	-66.7	5.56	66.7
	Week 86	23	39.13	23.42	0.0	44.44	77.8	22	3.03	34.66	-66.7	0.00	77.8
	Week 89	18	36.42	24.64	0.0	33.33	88.9	17	4.57	36.02	-66.7	0.00	77.8
	Week 92	16	36.11	22.41	0.0	33.33	77.8	15	5.93	30.54	-66.7	11.11	55.6
	Week 95	12	27.78	19.82	0.0	33.33	66.7	11	-1.01	30.00	-66.7	0.00	33.3
	Plat+Gem (N=152)												
	BASELINE	125	33.15	26.77	0.0	33.33	100.0						
	Week 1	109	37.21	25.09	0.0	33.33	100.0	106	3.56	20.38	-44.5	0.00	66.7
	Week 2	114	42.49	24.21	0.0	33.33	100.0	105	9.10	22.21	-55.6	11.11	77.8
	Week 3	116	40.42	26.84	0.0	33.33	100.0	107	8.83	20.58	-44.5	11.11	55.6
	Week 4	114	37.13	23.55	0.0	33.33	100.0	103	6.58	22.41	-66.7	11.11	44.5
	Week 5	117	41.59	24.51	0.0	33.33	100.0	106	10.27	24.33	-55.6	11.11	55.6
	Week 6	113	41.10	26.05	0.0	33.33	100.0	102	9.26	25.12	-55.6	11.11	77.8
	Week 7	113	39.23	25.76	0.0	33.33	100.0	103	8.95	27.62	-66.7	11.11	77.8
	Week 8	110	42.02	25.34	0.0	33.33	100.0	101	10.56	25.98	-55.6	11.11	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	107	40.39	24.68	0.0	33.33	100.0	95	9.59	27.54	-55.6	11.11	77.8
	Week 10	109	38.22	24.40	0.0	33.33	100.0	100	7.67	26.69	-55.6	11.11	66.7
	Week 11	96	39.35	23.64	0.0	33.33	100.0	88	7.45	27.77	-55.6	11.11	66.7
	Week 12	98	40.13	24.02	0.0	33.33	100.0	88	8.33	28.95	-55.6	11.11	88.9
	Week 14	98	41.38	23.44	0.0	33.33	100.0	87	10.22	28.16	-44.5	11.11	77.8
	Week 17	92	40.58	26.17	0.0	33.33	100.0	83	9.24	29.18	-44.5	0.00	77.8
	Week 20	84	38.76	25.08	0.0	33.33	100.0	75	8.15	29.53	-55.6	0.00	88.9
	Week 23	73	33.03	22.22	0.0	33.33	100.0	66	3.54	27.09	-55.6	0.00	66.7
	Week 26	66	35.52	23.65	0.0	33.33	100.0	61	2.37	27.97	-55.6	0.00	66.7
	Week 29	64	35.24	24.45	0.0	33.33	100.0	59	5.65	28.99	-55.6	0.00	77.8
	Week 32	54	34.57	22.71	0.0	33.33	100.0	49	4.31	25.14	-55.6	0.00	44.5
	Week 35	54	31.89	21.59	0.0	33.33	100.0	48	3.01	28.70	-55.6	0.00	66.7
	Week 38	47	34.99	24.63	0.0	33.33	100.0	42	6.61	30.66	-55.6	0.00	100.0
	Week 41	45	40.74	26.49	0.0	33.33	100.0	40	11.67	28.24	-66.7	11.11	77.8
	Week 44	41	41.19	23.21	0.0	33.33	100.0	36	9.26	26.89	-66.7	5.56	66.7
	Week 47	35	41.27	25.08	0.0	33.33	100.0	31	9.32	22.06	-33.3	11.11	44.5
	Week 50	29	41.00	26.74	0.0	33.33	100.0	24	8.80	25.38	-33.3	11.11	66.7
	Week 53	25	36.89	23.73	0.0	33.33	88.9	22	3.03	28.93	-55.6	5.56	44.5
	Week 56	26	43.59	23.08	0.0	33.33	100.0	25	4.44	28.15	-55.6	11.11	44.5
	Week 59	20	45.56	29.49	0.0	33.33	100.0	18	0.00	31.20	-55.6	5.56	66.7
	Week 62	17	44.44	26.06	0.0	44.44	88.9	17	-1.96	31.49	-66.7	11.11	44.5
	Week 65	15	42.22	25.62	11.1	33.33	88.9	14	5.55	23.77	-44.5	0.00	44.5
	Week 68	11	46.46	29.32	0.0	33.33	88.9	11	10.10	25.56	-22.2	11.11	66.7
	Week 71	12	45.37	29.38	0.0	33.33	100.0	12	7.41	30.83	-55.6	11.11	44.5
	Week 74	10	42.22	24.46	11.1	33.33	100.0	10	16.67	21.76	-22.2	16.67	55.6
	Week 77	10	33.33	22.83	0.0	27.78	77.8	10	7.78	34.37	-44.5	11.11	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
< 65 years	EV+Pembro (N= 39)												
	BASELINE	32	39.24	23.44	0.0	33.33	77.8						
	Week 1	27	43.21	24.14	0.0	44.44	100.0	26	6.41	21.36	-33.3	11.11	55.6
	Week 2	30	40.00	17.89	0.0	38.89	66.7	29	1.92	20.16	-44.5	0.00	33.3
	Week 3	31	40.86	19.12	0.0	33.33	77.8	29	3.07	23.55	-44.5	0.00	44.5
	Week 4	30	35.18	18.01	0.0	33.33	66.7	27	-1.65	18.42	-44.5	0.00	33.3
	Week 5	28	34.13	21.79	0.0	33.33	88.9	26	-3.85	26.28	-44.5	0.00	66.7
	Week 6	29	36.01	20.07	0.0	33.33	66.7	26	-2.14	27.22	-55.6	0.00	44.5
	Week 7	30	34.44	20.50	0.0	33.33	77.8	26	-4.27	23.95	-44.5	0.00	33.3
	Week 8	30	31.11	17.85	0.0	33.33	66.7	26	-4.70	22.26	-44.5	0.00	33.3
	Week 9	28	37.30	18.94	0.0	33.33	77.8	27	0.00	27.04	-44.5	0.00	55.6
	Week 10	26	34.61	28.52	0.0	33.33	100.0	23	0.00	36.08	-66.7	0.00	77.8
	Week 11	28	32.14	19.21	0.0	33.33	77.8	25	-5.33	25.28	-66.7	0.00	33.3
	Week 12	28	30.55	21.09	0.0	33.33	88.9	25	-5.33	22.93	-55.6	0.00	44.5
	Week 14	26	28.20	17.56	0.0	33.33	55.6	23	-11.11	24.62	-66.7	-11.11	33.3
	Week 17	28	31.35	17.65	0.0	33.33	55.6	24	-7.41	27.55	-66.7	0.00	33.3
	Week 20	27	34.98	20.37	0.0	33.33	100.0	24	-0.93	30.90	-66.7	0.00	55.6
	Week 23	26	31.62	17.97	0.0	33.33	55.6	23	-3.38	23.07	-44.5	0.00	33.3
	Week 26	24	31.94	15.13	0.0	33.33	55.6	22	1.52	24.08	-33.3	0.00	55.6
	Week 29	25	32.89	16.19	0.0	33.33	66.7	23	-2.42	28.42	-44.5	0.00	55.6
	Week 32	25	34.67	19.33	0.0	33.33	66.7	23	-3.86	24.76	-44.5	0.00	44.5
	Week 35	24	36.11	21.04	0.0	33.33	77.8	22	1.52	32.59	-44.5	0.00	55.6
	Week 38	23	35.75	17.07	0.0	33.33	66.7	22	-1.01	22.98	-44.5	0.00	44.5
	Week 41	25	35.55	18.70	0.0	33.33	77.8	23	0.48	29.30	-44.5	0.00	55.6
	Week 44	22	38.89	18.70	0.0	33.33	77.8	20	2.78	23.05	-33.3	0.00	44.5
	Week 47	20	41.67	20.98	0.0	33.33	100.0	18	6.17	24.76	-44.5	0.00	44.5

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	19	29.82	16.59	0.0	33.33	55.6	17	-4.58	22.25	-44.5	0.00	33.3
	Week 53	20	37.78	19.55	0.0	33.33	66.7	18	1.23	19.39	-33.3	0.00	44.5
	Week 56	17	39.21	32.90	0.0	33.33	100.0	15	-2.96	27.04	-44.5	0.00	44.5
	Week 59	17	39.87	28.35	0.0	33.33	100.0	15	-0.74	24.66	-33.3	0.00	33.3
	Week 62	15	35.55	20.23	0.0	33.33	66.7	14	-0.79	28.07	-33.3	-5.56	44.5
	Week 65	14	44.44	24.27	11.1	38.89	88.9	13	5.13	26.30	-22.2	0.00	66.7
	Week 68	11	33.33	28.11	0.0	22.22	88.9	10	-4.45	31.08	-44.5	-5.56	55.6
	Week 71	13	41.03	21.46	11.1	33.33	77.8	12	0.00	23.69	-33.3	0.00	44.5
	Week 74	14	36.51	19.70	11.1	33.33	77.8	13	0.00	29.75	-44.5	0.00	55.6
	Week 77	14	37.30	15.48	11.1	33.33	66.7	13	-2.57	21.35	-44.5	0.00	33.3
	Week 80	14	42.06	19.58	11.1	33.33	77.8	13	6.84	22.92	-33.3	11.11	44.5
	Week 83	12	36.11	20.17	11.1	33.33	77.8	11	-1.01	26.04	-33.3	11.11	44.5
	Plat+Gem (N= 29)												
	BASELINE	22	26.77	25.12	0.0	27.78	88.9						
	Week 1	21	35.45	17.08	0.0	33.33	77.8	20	8.89	20.89	-33.3	5.56	44.5
	Week 2	24	37.96	23.84	0.0	33.33	100.0	20	9.44	19.84	-22.2	0.00	55.6
	Week 3	23	29.47	21.87	0.0	22.22	88.9	20	3.33	19.11	-44.5	0.00	33.3
	Week 4	23	38.16	25.70	0.0	33.33	100.0	19	14.04	23.08	-33.3	11.12	66.7
	Week 5	25	37.78	25.26	0.0	33.33	100.0	20	7.78	22.25	-55.6	11.11	33.3
	Week 6	22	36.36	26.82	0.0	33.33	100.0	18	8.64	22.08	-55.6	11.11	33.3
	Week 7	24	35.18	20.38	0.0	33.33	77.8	21	7.94	23.61	-55.6	11.11	55.6
	Week 8	21	32.80	20.93	0.0	33.33	100.0	19	7.60	20.64	-44.5	11.11	55.6
	Week 9	20	37.22	22.59	0.0	33.33	88.9	17	9.80	27.19	-55.6	11.11	66.7
	Week 10	21	35.98	26.27	0.0	33.33	100.0	18	11.73	25.70	-55.6	16.67	66.7
	Week 11	20	33.89	26.11	0.0	33.33	100.0	17	6.53	21.54	-44.5	11.11	33.3
	Week 12	21	37.57	25.21	0.0	33.33	88.9	17	8.50	24.07	-44.5	11.11	44.4

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 14	22	43.43	28.26	0.0	33.33	100.0	18	18.52	32.79	-44.5	11.11	77.8
	Week 17	20	34.44	30.78	0.0	22.22	100.0	17	7.84	29.86	-44.5	0.00	77.8
	Week 20	18	37.65	30.52	0.0	33.33	100.0	15	9.63	27.50	-22.2	0.00	66.7
	Week 23	18	28.40	22.30	0.0	27.78	66.7	16	4.17	20.24	-22.2	0.00	55.6
	Week 26	16	27.08	24.33	0.0	22.22	77.8	14	6.35	26.41	-55.6	11.11	55.6
	Week 29	15	26.66	23.31	0.0	22.22	88.9	13	4.27	23.37	-55.6	11.11	44.4
	Week 32	15	28.89	28.11	0.0	22.22	100.0	13	5.98	19.57	-33.3	11.11	33.3
	Week 35	15	22.96	19.91	0.0	22.22	66.7	13	3.42	22.85	-44.5	0.00	44.4
	Week 38	14	34.92	34.28	0.0	33.33	100.0	12	12.96	33.11	-55.6	11.11	66.7
	Week 41	11	48.48	33.80	0.0	33.33	100.0	9	28.40	28.93	0.0	33.33	77.8
	Week 44	11	38.38	35.96	0.0	33.33	100.0	9	20.99	26.90	-11.1	11.11	66.7
	Week 47	11	40.40	31.14	0.0	33.33	88.9	9	14.81	26.65	-33.3	11.11	44.5

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>= 65 years	EV+Pembro (N=163)												
	BASELINE	128	35.50	25.06	0.0	33.33	100.0						
	Week 1	114	39.18	26.74	0.0	33.33	100.0	103	4.21	17.68	-44.4	0.00	55.6
	Week 2	120	40.93	26.48	0.0	33.33	100.0	104	5.77	17.65	-33.3	0.00	66.7
	Week 3	108	39.20	27.62	0.0	33.33	100.0	93	4.90	20.43	-33.3	0.00	77.8
	Week 4	115	39.32	26.99	0.0	33.33	100.0	102	5.23	23.02	-66.7	0.00	77.8
	Week 5	109	38.53	27.70	0.0	33.33	100.0	95	4.56	23.01	-55.6	0.00	88.9
	Week 6	117	38.56	26.53	0.0	33.33	100.0	98	5.44	25.94	-55.6	0.00	88.9
	Week 7	117	36.47	23.79	0.0	33.33	100.0	98	3.17	25.13	-55.6	0.00	77.8
	Week 8	117	38.94	27.28	0.0	33.33	100.0	98	4.42	29.19	-55.6	0.00	88.9
	Week 9	114	37.33	26.57	0.0	33.33	100.0	94	4.26	26.78	-55.6	0.00	88.9
	Week 10	113	36.38	24.41	0.0	33.33	100.0	95	2.92	24.16	-44.5	0.00	77.8
	Week 11	109	33.94	23.71	0.0	33.33	100.0	90	2.10	26.28	-55.6	0.00	77.8
	Week 12	114	35.18	24.91	0.0	33.33	100.0	94	1.42	23.79	-55.6	0.00	66.7
	Week 14	113	35.10	25.53	0.0	33.33	100.0	93	1.07	25.96	-66.7	0.00	66.7
	Week 17	104	33.76	22.65	0.0	33.33	100.0	87	-0.38	24.81	-77.8	0.00	66.7
	Week 20	93	32.97	20.95	0.0	33.33	88.9	79	0.70	24.68	-55.6	0.00	77.8
	Week 23	91	34.31	21.64	0.0	33.33	77.8	74	2.10	25.40	-44.5	0.00	77.8
	Week 26	88	33.08	21.77	0.0	33.33	100.0	72	-0.62	26.03	-66.7	0.00	66.7
	Week 29	82	36.99	22.43	0.0	33.33	88.9	70	6.67	25.62	-55.6	11.11	77.8
	Week 32	77	35.35	23.76	0.0	33.33	100.0	65	2.91	28.01	-66.7	11.11	77.8
	Week 35	74	36.19	23.27	0.0	33.33	100.0	64	4.86	27.14	-66.7	0.00	77.8
	Week 38	74	37.69	21.67	0.0	33.33	100.0	64	5.73	24.88	-66.7	0.00	55.6
	Week 41	70	36.03	21.52	0.0	33.33	100.0	61	3.64	23.81	-55.6	0.00	55.6
	Week 44	64	37.50	24.53	0.0	33.33	100.0	54	5.55	25.52	-66.7	5.56	55.6
	Week 47	59	35.40	19.74	0.0	33.33	77.8	52	1.28	24.27	-66.7	0.00	55.6

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	55	39.39	23.21	0.0	33.33	100.0	47	6.86	26.57	-66.7	0.00	55.6
	Week 53	54	39.71	27.10	0.0	33.33	100.0	45	3.70	27.73	-66.7	0.00	66.7
	Week 56	55	39.19	21.58	0.0	33.33	88.9	46	3.38	27.41	-66.7	0.00	66.7
	Week 59	52	38.03	23.22	0.0	33.33	100.0	42	2.38	28.89	-55.6	0.00	66.7
	Week 62	47	36.64	20.58	0.0	33.33	66.7	38	1.46	29.36	-66.7	0.00	66.7
	Week 65	29	37.16	23.44	0.0	33.33	77.8	27	3.70	32.32	-66.7	11.11	55.6
	Week 68	35	38.73	22.77	0.0	33.33	88.9	32	4.17	30.10	-66.7	11.11	66.7
	Week 71	29	36.78	24.69	0.0	33.33	88.9	26	2.14	33.85	-66.7	5.56	66.7
	Week 74	24	30.56	24.36	0.0	33.33	66.7	22	-0.51	38.72	-66.7	0.00	66.7
	Week 77	23	31.40	22.14	0.0	33.33	66.7	20	-2.22	36.87	-66.7	0.00	66.7
	Week 80	22	34.85	26.63	0.0	33.33	88.9	21	-1.59	39.02	-66.7	0.00	77.8
	Week 83	18	35.19	24.48	0.0	38.89	66.7	18	1.24	40.31	-66.7	0.00	66.7
	Week 86	18	38.27	26.19	0.0	44.44	77.8	18	4.32	38.14	-66.7	0.00	77.8
	Week 89	12	31.48	25.44	0.0	33.33	77.8	12	3.70	40.57	-66.7	0.00	77.8
	Week 92	10	32.22	26.94	0.0	27.78	77.8	10	7.78	31.88	-66.7	16.67	55.6
	Plat+Gem (N=173)												
	BASELINE	143	37.61	28.49	0.0	33.33	100.0						
	Week 1	123	40.11	26.53	0.0	33.33	100.0	119	2.71	19.08	-44.5	0.00	66.7
	Week 2	123	45.35	25.23	0.0	33.33	100.0	115	9.86	23.77	-55.6	11.11	88.9
	Week 3	126	44.00	26.98	0.0	33.33	100.0	116	10.15	21.06	-44.5	11.11	55.6
	Week 4	127	39.19	23.54	0.0	33.33	100.0	116	5.08	22.19	-66.7	5.56	55.6
	Week 5	128	43.92	26.23	0.0	33.33	100.0	118	9.32	26.87	-55.6	11.11	77.8
	Week 6	123	41.82	25.93	0.0	33.33	100.0	113	7.57	27.27	-55.6	11.11	77.8
	Week 7	124	43.01	28.30	0.0	33.33	100.0	113	8.95	30.42	-66.7	11.11	77.8
	Week 8	124	46.06	26.19	0.0	44.44	100.0	113	10.62	28.34	-55.6	11.11	77.8
	Week 9	121	43.80	25.55	0.0	33.33	100.0	108	9.47	31.16	-55.6	11.11	88.9

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	121	41.41	25.22	0.0	33.33	100.0	112	6.65	28.67	-55.6	0.00	66.7
	Week 11	106	42.14	23.79	0.0	33.33	100.0	97	7.67	29.98	-55.6	11.11	88.9
	Week 12	109	42.40	24.39	0.0	33.33	100.0	98	7.26	29.64	-55.6	0.00	88.9
	Week 14	103	40.78	22.30	0.0	33.33	100.0	91	6.84	27.71	-44.5	11.11	66.7
	Week 17	100	42.11	24.84	0.0	33.33	100.0	89	7.99	29.16	-44.5	11.11	66.7
	Week 20	86	39.40	24.56	0.0	33.33	100.0	76	6.14	28.83	-55.6	0.00	88.9
	Week 23	70	34.60	22.82	0.0	33.33	100.0	64	2.43	27.32	-55.6	0.00	66.7
	Week 26	65	37.09	25.18	0.0	33.33	100.0	61	1.09	26.81	-55.6	0.00	66.7
	Week 29	62	36.56	24.51	0.0	33.33	100.0	58	6.51	30.66	-55.6	0.00	88.9
	Week 32	48	36.57	21.13	0.0	33.33	100.0	45	5.18	28.78	-55.6	0.00	77.8
	Week 35	47	34.75	21.31	0.0	33.33	100.0	43	3.10	30.70	-55.6	0.00	66.7
	Week 38	42	36.24	23.93	0.0	33.33	100.0	38	7.31	30.60	-55.6	0.00	100.0
	Week 41	41	37.67	21.93	0.0	33.33	88.9	38	6.43	25.92	-66.7	5.56	66.7
	Week 44	38	41.81	20.58	11.1	33.33	100.0	35	6.98	28.02	-66.7	0.00	66.7
	Week 47	32	40.97	23.52	0.0	33.33	100.0	30	8.15	23.33	-33.3	0.00	66.7
	Week 50	29	39.08	24.78	0.0	33.33	100.0	26	8.55	26.35	-33.3	5.56	55.6
	Week 53	25	39.55	25.07	0.0	33.33	100.0	24	7.87	33.81	-55.6	5.56	77.8
	Week 56	26	46.58	21.78	11.1	38.89	100.0	26	10.68	32.13	-55.6	11.11	66.7
	Week 59	20	43.33	28.13	0.0	33.33	88.9	20	6.11	35.04	-55.6	11.11	88.9
	Week 62	19	45.61	26.94	0.0	33.33	88.9	19	4.09	36.14	-66.7	11.11	88.9
	Week 65	16	39.58	23.99	11.1	33.33	88.9	16	5.55	22.22	-44.5	0.00	44.5
	Week 68	13	44.44	27.22	0.0	33.33	88.9	13	9.40	23.50	-22.2	11.11	66.7
	Week 71	13	44.44	28.33	0.0	33.33	100.0	13	7.69	29.53	-55.6	11.11	44.5
	Week 74	11	41.41	23.36	11.1	33.33	100.0	11	16.16	20.71	-22.2	11.11	55.6
	Week 77	10	34.44	22.50	0.0	33.33	77.8	10	12.22	31.19	-44.5	11.11	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Europe	EV+Pembro (N= 74)												
	BASELINE	53	36.69	22.60	0.0	33.33	66.7						
	Week 1	48	42.59	28.10	0.0	44.44	100.0	42	5.03	19.20	-22.2	0.00	55.6
	Week 2	53	38.78	21.64	0.0	33.33	100.0	44	2.27	16.36	-33.3	0.00	44.4
	Week 3	50	46.00	23.76	0.0	44.44	88.9	41	7.32	22.99	-33.3	0.00	66.7
	Week 4	51	42.05	22.91	0.0	33.33	100.0	44	6.82	24.11	-33.3	0.00	77.8
	Week 5	46	45.89	26.15	0.0	44.44	100.0	41	8.94	26.32	-33.3	0.00	66.7
	Week 6	50	44.00	24.38	0.0	38.89	100.0	39	8.55	25.30	-33.3	0.00	77.8
	Week 7	50	39.33	21.32	0.0	33.33	88.9	39	7.12	26.80	-44.5	0.00	77.8
	Week 8	51	40.09	25.64	0.0	33.33	100.0	41	5.69	22.52	-33.3	0.00	66.7
	Week 9	47	42.08	23.96	0.0	44.44	88.9	37	7.21	21.15	-44.5	0.00	66.7
	Week 10	45	39.75	25.13	0.0	33.33	100.0	34	4.90	25.69	-33.3	0.00	77.8
	Week 11	48	34.03	18.11	0.0	33.33	66.7	37	0.60	22.37	-44.5	0.00	55.6
	Week 12	51	38.34	24.17	0.0	33.33	100.0	39	3.70	22.71	-44.5	0.00	55.6
	Week 14	50	34.22	23.85	0.0	33.33	100.0	38	-1.76	23.61	-44.5	0.00	55.6
	Week 17	43	35.40	20.75	0.0	33.33	77.8	33	-3.03	22.95	-44.5	0.00	66.7
	Week 20	41	34.96	20.87	0.0	33.33	100.0	33	0.00	24.22	-44.5	0.00	55.6
	Week 23	41	39.84	18.42	11.1	33.33	77.8	30	2.59	25.89	-44.5	0.00	77.8
	Week 26	37	39.64	19.16	0.0	33.33	77.8	28	3.17	23.79	-33.3	0.00	66.7
	Week 29	37	36.94	22.69	0.0	33.33	88.9	29	4.21	25.10	-33.3	0.00	77.8
	Week 32	34	38.56	19.20	0.0	33.33	88.9	26	-0.43	20.96	-33.3	0.00	33.3
	Week 35	31	38.35	16.94	0.0	33.33	66.7	25	3.56	21.45	-44.4	0.00	44.5
	Week 38	31	48.03	20.16	11.1	44.44	100.0	26	13.68	24.20	-44.5	11.11	55.6
	Week 41	28	38.89	20.40	0.0	33.33	100.0	23	3.38	24.72	-44.5	0.00	55.6
	Week 44	27	41.15	23.64	0.0	33.33	100.0	22	7.58	18.90	-33.3	5.56	55.6
	Week 47	25	41.33	18.01	11.1	33.33	77.8	21	5.82	19.76	-33.3	0.00	55.6

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	26	41.03	26.81	0.0	33.33	100.0	23	7.25	27.75	-33.3	0.00	55.6
	Week 53	26	41.45	28.21	0.0	33.33	100.0	21	5.82	23.99	-33.3	0.00	44.5
	Week 56	25	42.67	27.53	0.0	33.33	100.0	21	3.70	26.14	-55.6	11.11	44.5
	Week 59	23	35.26	23.61	0.0	33.33	100.0	18	1.85	19.89	-33.3	5.56	33.3
	Week 62	20	37.78	17.44	0.0	38.89	66.7	17	2.61	26.51	-55.6	0.00	44.5
	Week 65	13	48.72	22.47	22.2	44.44	88.9	13	10.26	25.45	-33.3	11.11	66.7
	Week 68	15	42.96	24.44	0.0	33.33	88.9	15	5.18	25.15	-44.5	11.12	33.3
	Week 71	13	47.86	23.30	22.2	33.33	88.9	13	7.69	25.41	-44.5	11.11	44.5
	Week 74	10	37.78	15.89	11.1	33.33	66.7	9	2.47	19.86	-33.3	0.00	33.3
	Plat+Gem (N= 95)												
	BASELINE	75	37.48	29.50	0.0	33.33	100.0						
	Week 1	71	40.53	27.80	0.0	33.33	100.0	69	2.41	19.33	-44.5	0.00	66.7
	Week 2	71	46.48	27.04	0.0	33.33	100.0	63	9.35	21.97	-55.6	11.11	77.8
	Week 3	72	43.36	27.67	0.0	33.33	100.0	65	8.20	18.87	-44.5	11.11	55.6
	Week 4	69	39.93	24.28	0.0	33.33	100.0	62	6.09	23.09	-66.7	11.11	66.7
	Week 5	71	43.19	27.70	0.0	33.33	100.0	63	6.53	26.37	-55.6	11.11	55.6
	Week 6	69	42.35	27.10	0.0	33.33	100.0	61	6.74	27.91	-55.6	11.11	77.8
	Week 7	69	43.16	27.72	0.0	33.33	100.0	62	8.78	30.12	-66.7	11.11	77.8
	Week 8	67	42.29	24.94	0.0	33.33	100.0	60	6.11	27.25	-55.6	5.56	66.7
	Week 9	66	43.43	26.13	0.0	33.33	100.0	57	7.80	32.60	-55.6	11.11	77.8
	Week 10	70	40.79	24.72	0.0	33.33	100.0	63	5.11	28.56	-55.6	0.00	66.7
	Week 11	63	40.92	23.43	0.0	33.33	100.0	56	5.16	26.63	-55.6	11.11	55.6
	Week 12	66	43.94	24.22	0.0	33.33	100.0	56	8.93	31.24	-55.6	11.11	88.9
	Week 14	66	42.59	23.60	0.0	33.33	100.0	56	8.73	28.25	-44.5	11.11	77.8
	Week 17	61	42.80	28.17	0.0	33.33	100.0	53	7.55	29.06	-44.5	11.11	77.8
	Week 20	54	41.36	26.47	0.0	33.33	100.0	48	6.71	28.24	-55.6	0.00	77.8

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 23	44	34.59	23.26	0.0	33.33	100.0	40	1.67	25.48	-55.6	0.00	66.7
	Week 26	42	39.95	26.44	0.0	33.33	100.0	39	4.56	23.87	-55.6	0.00	44.5
	Week 29	39	37.04	22.85	0.0	33.33	88.9	36	2.47	24.65	-55.6	0.00	55.6
	Week 32	32	40.28	27.90	0.0	33.33	100.0	30	5.92	30.71	-55.6	0.00	77.8
	Week 35	32	35.07	22.60	0.0	33.33	100.0	30	1.85	26.28	-55.6	5.56	55.6
	Week 38	28	37.30	28.88	0.0	33.33	100.0	26	9.83	26.36	-33.3	0.00	100.0
	Week 41	25	42.22	26.84	0.0	33.33	100.0	23	8.21	26.21	-44.5	11.11	66.7
	Week 44	24	44.44	25.80	0.0	44.44	100.0	22	9.60	24.56	-44.5	5.56	44.5
	Week 47	22	43.94	26.22	0.0	38.89	100.0	20	7.78	23.11	-33.3	5.56	44.5
	Week 50	17	48.37	26.63	11.1	44.44	100.0	15	11.11	27.22	-33.3	11.11	55.6
	Week 53	15	47.41	29.24	11.1	33.33	100.0	14	11.11	31.43	-44.5	16.67	66.7
	Week 56	15	55.56	25.89	11.1	55.56	100.0	14	15.87	25.68	-33.3	16.67	66.7
	Week 59	11	51.51	29.51	22.2	33.33	100.0	10	11.11	27.72	-44.5	11.11	66.7
	Week 62	11	48.48	27.79	0.0	33.33	88.9	11	9.09	28.03	-66.7	11.11	44.5
	Week 65	10	44.44	28.69	11.1	33.33	88.9	10	6.67	22.95	-44.5	5.56	44.5

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
North America	EV+Pembro (N= 46)												
	BASELINE	33	39.06	22.42	0.0	33.33	66.7						
	Week 1	30	44.81	26.34	0.0	33.33	100.0	27	7.41	17.16	-22.2	0.00	44.4
	Week 2	30	42.22	25.84	0.0	33.33	88.9	26	6.84	19.65	-33.3	0.00	55.6
	Week 3	25	33.33	21.52	0.0	33.33	88.9	21	1.59	22.85	-33.3	0.00	77.8
	Week 4	30	37.78	25.03	0.0	33.33	100.0	24	0.93	15.34	-33.3	0.00	44.5
	Week 5	29	39.46	24.23	0.0	33.33	100.0	21	3.70	25.66	-44.4	0.00	88.9
	Week 6	31	36.92	22.66	0.0	33.33	100.0	23	2.42	24.84	-33.3	0.00	88.9
	Week 7	33	38.05	22.91	0.0	33.33	88.9	23	0.00	23.93	-33.3	0.00	77.8
	Week 8	29	38.31	22.92	0.0	33.33	88.9	20	0.00	31.22	-44.4	0.00	77.8
	Week 9	27	35.80	24.72	0.0	33.33	100.0	21	0.00	30.43	-33.3	0.00	88.9
	Week 10	29	29.88	22.24	0.0	33.33	66.7	23	-8.70	27.21	-66.7	-11.11	55.6
	Week 11	28	35.32	24.95	0.0	33.33	77.8	21	-3.18	26.56	-66.7	0.00	33.3
	Week 12	29	31.80	21.77	0.0	33.33	100.0	22	-6.57	22.13	-44.5	0.00	33.3
	Week 14	28	34.52	23.88	0.0	33.33	88.9	21	-4.23	30.53	-66.7	0.00	55.6
	Week 17	29	32.18	21.28	0.0	33.33	66.7	23	-5.31	26.78	-66.7	0.00	44.4
	Week 20	23	33.33	22.72	0.0	33.33	88.9	18	-3.09	35.92	-66.7	0.00	77.8
	Week 23	22	33.33	20.58	0.0	33.33	77.8	17	1.31	28.02	-44.4	0.00	66.7
	Week 26	21	28.04	18.13	0.0	33.33	77.8	16	-9.03	20.78	-44.5	0.00	22.2
	Week 29	20	37.22	22.01	0.0	33.33	77.8	17	3.92	29.38	-33.3	0.00	55.6
	Week 32	21	33.33	27.22	0.0	33.33	100.0	18	0.00	32.56	-44.4	0.00	77.8
	Week 35	22	33.84	22.35	0.0	33.33	100.0	19	-1.17	30.07	-44.4	0.00	77.8
	Week 38	20	33.89	20.86	0.0	33.33	77.8	17	-1.96	22.31	-33.3	0.00	44.5
	Week 41	21	30.16	18.97	0.0	33.33	66.7	17	-4.58	23.59	-44.4	0.00	55.6
	Week 44	16	31.94	13.98	0.0	33.33	66.7	12	-4.63	27.00	-33.3	-5.56	55.6
	Week 47	16	34.03	22.40	0.0	33.33	100.0	13	-1.71	20.71	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	16	34.03	14.89	0.0	33.33	66.7	11	-1.01	27.42	-33.3	0.00	44.5
	Week 53	15	33.33	23.38	0.0	33.33	88.9	11	-8.08	17.28	-33.3	0.00	11.1
	Week 56	17	39.21	19.69	11.1	33.33	100.0	12	-5.56	19.82	-33.3	-5.56	22.2
	Week 59	17	37.25	24.52	0.0	33.33	88.9	12	-11.11	23.69	-55.6	0.00	22.2
	Week 62	14	32.54	19.72	0.0	33.33	66.7	9	-11.11	27.22	-66.7	0.00	11.1
	Week 68	11	28.28	25.03	0.0	33.33	88.9	8	-11.11	25.20	-55.6	-5.56	22.2
	Week 71	11	32.32	26.04	0.0	33.33	66.7	8	-1.39	28.13	-33.3	0.00	55.6
	Plat+Gem (N= 34)												
	BASELINE	27	39.09	31.18	0.0	33.33	100.0						
	Week 1	19	37.43	17.85	11.1	33.33	77.8	17	3.27	20.70	-33.3	0.00	44.5
	Week 2	20	42.78	18.13	22.2	33.33	77.8	18	12.96	21.64	-22.2	11.11	55.6
	Week 3	20	36.67	19.78	0.0	33.33	77.8	17	9.80	18.79	-22.2	11.11	33.3
	Week 4	23	32.85	23.08	0.0	33.33	100.0	19	4.68	17.10	-33.3	0.00	33.3
	Week 5	25	40.00	25.05	0.0	33.33	100.0	22	9.60	25.03	-44.4	11.11	55.6
	Week 6	20	38.89	25.36	0.0	33.33	88.9	17	8.50	27.37	-33.3	0.00	66.7
	Week 7	23	40.58	32.59	0.0	33.33	100.0	20	8.89	28.75	-44.4	11.11	55.6
	Week 8	24	45.83	24.81	11.1	44.44	100.0	22	13.13	26.70	-33.3	11.11	55.6
	Week 9	23	40.10	22.66	0.0	33.33	88.9	19	10.53	28.08	-33.3	0.00	77.8
	Week 10	20	42.22	25.13	0.0	33.33	88.9	18	13.58	26.00	-33.3	16.67	66.7
	Week 11	18	33.95	21.38	0.0	33.33	100.0	16	8.33	27.96	-44.4	11.11	55.6
	Week 12	17	38.56	20.83	0.0	33.33	77.8	16	3.47	27.43	-44.4	0.00	55.6
	Week 14	16	36.11	23.48	0.0	33.33	77.8	14	5.56	33.40	-44.4	5.56	77.8
	Week 17	19	38.60	25.49	0.0	33.33	88.9	17	11.11	31.18	-33.3	0.00	66.7
	Week 20	16	31.94	20.64	0.0	33.33	66.7	13	8.55	32.44	-44.4	11.11	66.7
	Week 23	15	29.63	22.87	0.0	22.22	88.9	13	2.56	27.65	-33.3	0.00	55.6
	Week 26	13	28.20	24.27	0.0	22.22	66.7	12	3.71	34.27	-55.6	11.11	55.6

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 29	14	32.54	30.96	0.0	33.33	100.0	13	12.82	38.45	-55.6	11.11	77.8
	Week 32	11	25.25	11.21	0.0	22.22	44.4	10	6.67	23.54	-33.3	0.00	44.4
	Week 35	13	25.64	19.45	0.0	22.22	66.7	11	5.05	34.91	-44.5	0.00	66.7
	Week 38	10	35.56	32.63	0.0	27.78	100.0	9	17.28	43.43	-55.6	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Rest of World	EV+Pembro (N= 82)												
	BASELINE	74	34.68	27.21	0.0	33.33	100.0						
	Week 1	63	35.63	24.37	0.0	33.33	88.9	60	3.15	18.53	-44.4	0.00	44.5
	Week 2	67	41.62	27.17	0.0	44.44	100.0	63	6.00	18.91	-44.5	0.00	66.7
	Week 3	64	36.98	28.28	0.0	33.33	100.0	60	3.52	19.25	-44.5	0.00	55.6
	Week 4	64	35.94	27.41	0.0	33.33	100.0	61	2.73	23.19	-66.7	0.00	66.7
	Week 5	62	30.64	26.44	0.0	33.33	100.0	59	-1.88	20.65	-55.6	0.00	33.3
	Week 6	65	34.02	26.71	0.0	33.33	100.0	62	1.43	27.40	-55.6	0.00	66.7
	Week 7	64	32.46	24.35	0.0	33.33	100.0	62	-1.25	23.99	-55.6	0.00	66.7
	Week 8	67	34.83	27.14	0.0	33.33	100.0	63	1.23	30.41	-55.6	0.00	88.9
	Week 9	68	34.64	26.08	0.0	33.33	100.0	63	2.12	28.56	-55.6	0.00	77.8
	Week 10	65	36.24	26.15	0.0	33.33	100.0	61	5.10	26.50	-44.5	0.00	77.8
	Week 11	61	32.42	25.28	0.0	33.33	100.0	57	1.75	28.47	-55.6	0.00	77.8
	Week 12	62	32.08	25.22	0.0	33.33	100.0	58	0.00	24.72	-55.6	0.00	66.7
	Week 14	61	33.15	25.30	0.0	33.33	100.0	57	0.00	26.23	-66.7	0.00	66.7
	Week 17	60	32.22	22.66	0.0	33.33	100.0	55	0.20	26.58	-77.8	0.00	66.7
	Week 20	56	32.34	20.13	0.0	33.33	77.8	52	1.71	23.64	-55.6	0.00	55.6
	Week 23	54	29.22	21.83	0.0	33.33	77.8	50	-0.44	23.54	-44.5	0.00	66.7
	Week 26	54	30.04	21.33	0.0	33.33	100.0	50	0.89	27.48	-66.7	0.00	55.6
	Week 29	50	34.89	19.95	0.0	33.33	66.7	47	4.73	26.80	-55.6	11.11	66.7
	Week 32	47	33.57	22.99	0.0	33.33	88.9	44	2.53	28.64	-66.7	0.00	55.6
	Week 35	45	35.80	26.26	0.0	33.33	100.0	42	6.61	31.53	-66.7	0.00	66.7
	Week 38	46	31.40	18.19	0.0	33.33	66.7	43	0.52	24.24	-66.7	0.00	44.5
	Week 41	46	36.71	21.58	0.0	33.33	77.8	44	5.30	26.20	-55.6	0.00	55.6
	Week 44	43	37.98	25.34	0.0	33.33	100.0	40	6.11	26.74	-66.7	0.00	55.6
	Week 47	38	35.38	20.48	0.0	33.33	77.8	36	2.16	27.96	-66.7	0.00	44.5

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	32	35.07	20.76	0.0	33.33	66.7	30	2.96	24.23	-66.7	0.00	55.6
	Week 53	33	40.07	23.73	0.0	33.33	88.9	31	5.02	28.38	-66.7	11.11	66.7
	Week 56	30	36.30	24.58	0.0	33.33	88.9	28	3.57	30.85	-66.7	0.00	66.7
	Week 59	29	41.76	25.31	0.0	33.33	100.0	27	7.00	32.34	-55.6	0.00	66.7
	Week 62	28	37.30	22.88	0.0	33.33	66.7	26	3.85	30.62	-66.7	0.00	66.7
	Week 65	22	41.92	22.99	0.0	38.89	77.8	21	6.88	32.10	-66.7	11.11	55.6
	Week 68	20	38.33	22.65	0.0	33.33	77.8	19	5.26	35.21	-66.7	0.00	66.7
	Week 71	18	34.57	21.18	0.0	33.33	66.7	17	-1.96	36.06	-66.7	0.00	66.7
	Week 74	19	37.43	22.90	0.0	33.33	77.8	19	4.68	41.13	-66.7	11.11	66.7
	Week 77	19	36.26	17.70	0.0	33.33	66.7	18	1.23	35.53	-66.7	5.56	66.7
	Week 80	19	36.84	22.55	0.0	33.33	77.8	18	1.85	37.00	-66.7	5.56	77.8
	Week 83	17	38.56	22.61	0.0	33.33	66.7	17	3.27	38.45	-66.7	11.11	66.7
	Week 86	14	42.06	27.63	0.0	44.45	77.8	14	4.76	43.52	-66.7	0.00	77.8
	Week 89	11	34.34	22.47	0.0	33.33	77.8	11	4.04	39.21	-66.7	11.11	77.8
	Plat+Gem (N= 73)												
	BASELINE	63	33.33	25.48	0.0	33.33	100.0						
	Week 1	54	38.68	24.59	0.0	33.33	100.0	53	5.24	19.32	-44.5	0.00	33.3
	Week 2	56	41.67	24.73	0.0	33.33	100.0	54	9.26	25.24	-44.5	0.00	88.9
	Week 3	57	41.52	27.74	0.0	33.33	100.0	54	10.08	23.87	-44.5	11.11	55.6
	Week 4	58	40.42	23.52	0.0	33.33	100.0	54	7.20	23.66	-44.5	11.11	55.6
	Week 5	57	43.86	24.80	0.0	33.33	100.0	53	11.95	26.59	-55.6	11.11	77.8
	Week 6	56	40.08	25.31	0.0	33.33	100.0	53	8.60	25.10	-55.6	11.11	66.7
	Week 7	56	40.48	24.66	0.0	33.33	100.0	52	8.76	29.30	-55.6	11.11	77.8
	Week 8	54	45.68	27.70	0.0	38.89	100.0	50	13.78	27.55	-44.5	11.11	77.8
	Week 9	52	43.38	25.40	0.0	33.33	100.0	49	11.11	29.49	-55.6	11.11	88.9
	Week 10	52	39.74	26.71	0.0	33.33	100.0	49	7.94	28.78	-55.6	11.11	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	45	43.46	26.36	0.0	33.33	100.0	42	10.32	32.13	-55.6	11.11	88.9
	Week 12	47	39.48	26.19	0.0	33.33	100.0	43	6.98	26.34	-44.5	0.00	66.7
	Week 14	43	41.08	23.20	0.0	33.33	100.0	39	9.97	28.48	-44.5	11.11	66.7
	Week 17	40	38.89	22.79	0.0	33.33	88.9	36	7.10	28.99	-44.5	0.00	66.7
	Week 20	34	38.89	26.13	0.0	33.33	100.0	30	5.93	28.10	-44.5	0.00	88.9
	Week 23	29	33.33	22.42	0.0	33.33	88.9	27	4.53	26.74	-44.5	0.00	66.7
	Week 26	26	30.77	22.73	0.0	33.33	100.0	24	-2.78	27.27	-44.5	0.00	66.7
	Week 29	24	31.94	23.47	0.0	33.33	100.0	22	8.08	30.90	-55.6	0.00	88.9
	Week 32	20	31.11	16.36	0.0	33.33	66.7	18	3.70	22.55	-44.5	0.00	44.5
	Week 35	17	30.72	20.61	0.0	33.33	66.7	15	4.44	31.09	-55.6	0.00	66.7
	Week 38	18	33.95	19.61	0.0	33.33	66.7	15	1.48	30.54	-55.6	0.00	66.7
	Week 41	18	38.27	20.95	0.0	33.33	66.7	16	8.33	29.68	-66.7	5.56	66.7
	Week 44	16	36.80	20.97	0.0	33.33	66.7	14	2.38	33.53	-66.7	0.00	66.7
	Week 47	12	37.04	25.22	0.0	33.33	77.8	11	11.11	21.66	-22.2	11.11	44.5
	Week 50	11	35.35	30.56	0.0	33.33	100.0	9	4.94	27.84	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	EV+Pembro (N=146)												
	BASELINE	119	34.64	23.69	0.0	33.33	77.8						
	Week 1	102	38.02	25.86	0.0	33.33	100.0	97	5.04	19.18	-44.4	0.00	55.6
	Week 2	106	39.62	24.39	0.0	33.33	100.0	98	6.58	18.66	-44.5	0.00	66.7
	Week 3	94	36.41	24.08	0.0	33.33	88.9	88	4.29	21.47	-44.5	0.00	77.8
	Week 4	101	37.73	24.75	0.0	33.33	100.0	93	5.26	22.38	-44.5	0.00	77.8
	Week 5	96	35.07	25.36	0.0	33.33	100.0	89	3.00	25.17	-55.6	0.00	88.9
	Week 6	105	36.93	25.67	0.0	33.33	100.0	93	4.42	27.22	-55.6	0.00	88.9
	Week 7	102	34.97	23.58	0.0	33.33	100.0	89	3.12	26.49	-44.5	0.00	77.8
	Week 8	101	36.52	27.23	0.0	33.33	100.0	91	4.64	28.79	-44.5	0.00	88.9
	Week 9	100	36.11	26.45	0.0	33.33	100.0	89	4.37	28.11	-55.6	0.00	88.9
	Week 10	99	34.01	25.09	0.0	33.33	100.0	87	2.04	26.93	-66.7	0.00	77.8
	Week 11	95	32.86	24.14	0.0	33.33	100.0	84	3.44	26.44	-66.7	0.00	77.8
	Week 12	99	34.34	25.00	0.0	33.33	100.0	87	1.66	23.69	-55.6	0.00	66.7
	Week 14	95	33.22	24.66	0.0	33.33	100.0	84	1.59	26.62	-66.7	0.00	66.7
	Week 17	97	32.99	21.30	0.0	33.33	100.0	84	1.06	25.09	-66.7	0.00	66.7
	Week 20	90	32.22	19.50	0.0	33.33	88.9	79	0.98	26.76	-66.7	0.00	77.8
	Week 23	86	33.98	20.41	0.0	33.33	77.8	74	4.20	25.20	-44.5	0.00	77.8
	Week 26	83	33.47	21.36	0.0	33.33	100.0	72	4.63	23.35	-44.5	0.00	66.7
	Week 29	80	36.80	21.91	0.0	33.33	88.9	71	8.14	26.16	-44.5	11.11	77.8
	Week 32	74	34.38	22.76	0.0	33.33	100.0	66	5.05	25.05	-44.5	0.00	77.8
	Week 35	73	36.68	23.11	0.0	33.33	100.0	66	7.07	27.19	-44.5	0.00	77.8
	Week 38	75	36.59	20.32	0.0	33.33	88.9	67	5.80	20.50	-33.3	0.00	55.6
	Week 41	71	33.96	21.41	0.0	33.33	100.0	64	3.99	24.12	-44.5	0.00	55.6
	Week 44	64	36.11	21.32	0.0	33.33	100.0	56	7.34	21.53	-33.3	0.00	55.6
	Week 47	56	35.71	20.07	0.0	33.33	100.0	50	5.11	20.35	-44.5	0.00	44.5

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	55	36.97	22.54	0.0	33.33	100.0	48	6.48	24.46	-44.5	0.00	55.6
	Week 53	55	37.98	27.19	0.0	33.33	100.0	48	5.79	24.47	-33.3	0.00	66.7
	Week 56	53	38.15	24.80	0.0	33.33	100.0	46	5.31	26.06	-44.5	5.56	66.7
	Week 59	51	36.82	26.62	0.0	33.33	100.0	43	4.13	26.78	-55.6	0.00	66.7
	Week 62	42	36.24	20.25	0.0	33.33	66.7	36	7.41	26.16	-66.7	5.56	66.7
	Week 65	31	39.78	24.64	0.0	33.33	88.9	30	11.48	28.06	-55.6	11.11	66.7
	Week 68	31	37.99	26.26	0.0	33.33	88.9	29	9.58	26.85	-55.6	11.12	66.7
	Week 71	30	41.11	24.44	0.0	33.33	88.9	28	9.52	25.79	-33.3	11.11	66.7
	Week 74	29	33.72	22.71	0.0	33.33	66.7	27	4.94	31.78	-66.7	0.00	66.7
	Week 77	26	34.61	21.62	0.0	33.33	66.7	24	5.09	30.21	-66.7	0.00	66.7
	Week 80	26	38.89	24.19	0.0	33.33	88.9	26	7.69	29.44	-66.7	5.56	77.8
	Week 83	21	38.09	22.93	0.0	44.44	77.8	21	8.47	30.61	-66.7	11.11	66.7
	Week 86	17	44.44	22.22	0.0	44.44	77.8	17	16.34	29.43	-33.3	11.11	77.8
	Week 89	11	36.36	24.39	0.0	33.33	77.8	11	16.16	31.18	-33.3	11.11	77.8
	Week 92	13	43.59	24.20	0.0	33.33	88.9	13	11.97	23.34	-33.3	22.22	55.6
	Plat+Gem (N=151)												
	BASELINE	123	34.24	27.72	0.0	33.33	100.0						
	Week 1	108	36.52	23.63	0.0	33.33	100.0	103	3.02	17.48	-44.5	0.00	44.5
	Week 2	116	41.76	22.83	0.0	33.33	100.0	105	10.16	21.91	-44.5	11.11	88.9
	Week 3	114	39.08	24.75	0.0	33.33	100.0	103	9.06	21.15	-44.5	11.11	55.6
	Week 4	116	37.07	22.41	0.0	33.33	100.0	103	6.69	21.35	-66.7	11.11	55.6
	Week 5	119	41.55	25.94	0.0	33.33	100.0	106	8.91	25.45	-55.6	11.11	77.8
	Week 6	109	38.84	24.74	0.0	33.33	100.0	98	7.60	26.92	-55.6	11.11	77.8
	Week 7	115	41.06	26.78	0.0	33.33	100.0	105	9.95	29.60	-66.7	11.11	77.8
	Week 8	111	43.34	26.34	0.0	33.33	100.0	102	11.22	28.85	-55.6	11.11	77.8
	Week 9	107	43.09	25.39	0.0	33.33	100.0	95	11.11	31.89	-55.6	11.11	88.9

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	107	39.77	25.95	0.0	33.33	100.0	98	8.50	28.08	-55.6	11.11	66.7
	Week 11	97	39.98	23.11	0.0	33.33	100.0	87	8.43	28.76	-55.6	11.11	88.9
	Week 12	100	40.67	22.74	0.0	33.33	100.0	88	7.07	28.10	-55.6	0.00	66.7
	Week 14	99	40.52	22.58	0.0	33.33	100.0	86	9.43	29.45	-44.5	11.11	77.8
	Week 17	94	41.25	25.28	0.0	33.33	100.0	82	10.30	28.84	-44.5	11.11	77.8
	Week 20	84	40.34	25.98	0.0	33.33	100.0	72	8.64	28.30	-55.6	0.00	88.9
	Week 23	70	34.92	22.96	0.0	33.33	100.0	62	4.84	26.51	-55.6	0.00	66.7
	Week 26	61	36.61	25.37	0.0	33.33	100.0	55	5.86	27.04	-55.6	0.00	66.7
	Week 29	59	34.65	24.25	0.0	33.33	100.0	53	7.13	28.75	-55.6	0.00	88.9
	Week 32	50	34.89	23.97	0.0	33.33	100.0	45	6.42	26.75	-55.6	0.00	77.8
	Week 35	50	33.78	20.93	0.0	33.33	100.0	44	5.81	28.20	-55.6	0.00	66.7
	Week 38	46	35.75	25.97	0.0	33.33	100.0	40	7.50	31.16	-55.6	0.00	100.0
	Week 41	42	41.80	26.18	0.0	33.33	100.0	37	10.51	30.31	-66.7	11.11	77.8
	Week 44	39	41.59	23.04	0.0	33.33	100.0	34	10.13	28.21	-66.7	5.56	66.7
	Week 47	33	41.08	24.92	0.0	33.33	100.0	29	6.51	24.76	-33.3	0.00	66.7
	Week 50	27	40.74	25.78	0.0	33.33	100.0	22	5.05	27.37	-33.3	0.00	66.7
	Week 53	23	39.13	23.90	0.0	33.33	88.9	20	-0.56	33.52	-55.6	0.00	77.8
	Week 56	20	43.89	22.36	11.1	33.33	100.0	19	5.26	27.56	-55.6	11.11	66.7
	Week 59	17	46.40	31.49	0.0	33.33	100.0	15	2.22	33.12	-44.5	11.11	88.9
	Week 62	14	42.06	28.64	0.0	33.33	88.9	14	2.38	37.28	-66.7	11.11	88.9
	Week 65	13	38.46	24.69	11.1	33.33	88.9	12	2.78	22.78	-44.5	0.00	44.4
	Week 68	10	40.00	27.82	0.0	33.33	88.9	10	6.67	17.53	-22.2	11.11	33.3
	Week 71	10	43.33	32.05	0.0	33.33	100.0	10	13.33	20.82	-22.2	11.11	44.4

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	EV+Pembro (N= 56)												
	BASELINE	41	40.92	27.27	0.0	33.33	100.0						
	Week 1	39	45.01	26.85	0.0	44.44	100.0	32	3.47	16.07	-22.2	0.00	55.6
	Week 2	44	43.43	26.34	0.0	44.44	100.0	35	0.32	16.28	-33.3	0.00	44.5
	Week 3	45	46.17	28.52	0.0	44.44	100.0	34	4.90	20.51	-33.3	0.00	44.5
	Week 4	44	40.15	27.03	0.0	33.33	100.0	36	0.00	21.74	-66.7	0.00	55.6
	Week 5	41	43.63	28.70	0.0	33.33	100.0	32	2.08	20.24	-33.3	0.00	44.5
	Week 6	41	40.92	24.53	0.0	33.33	100.0	31	2.15	23.56	-55.6	0.00	44.5
	Week 7	45	38.52	22.05	0.0	33.33	88.9	35	-2.22	20.49	-55.6	0.00	33.3
	Week 8	46	39.13	22.44	0.0	33.33	88.9	33	-3.37	25.38	-55.6	0.00	66.7
	Week 9	42	40.21	21.94	0.0	38.89	88.9	32	0.35	22.84	-44.5	0.00	55.6
	Week 10	40	41.11	24.81	0.0	33.33	100.0	31	3.23	26.64	-44.5	0.00	77.8
	Week 11	42	35.18	19.62	0.0	33.33	77.8	31	-7.53	23.90	-55.6	0.00	33.3
	Week 12	43	34.11	22.54	0.0	33.33	88.9	32	-4.52	23.42	-55.6	0.00	44.5
	Week 14	44	35.10	23.84	0.0	33.33	100.0	32	-9.03	23.18	-66.7	0.00	33.3
	Week 17	35	33.97	22.86	0.0	33.33	88.9	27	-11.11	24.85	-77.8	0.00	33.3
	Week 20	30	37.04	24.12	0.0	33.33	100.0	24	-1.85	24.23	-55.6	0.00	55.6
	Week 23	31	32.97	22.31	0.0	33.33	77.8	23	-10.15	20.63	-44.5	0.00	22.2
	Week 26	29	31.03	17.91	0.0	33.33	66.7	22	-15.66	26.49	-66.7	-5.56	22.2
	Week 29	27	33.74	18.87	0.0	33.33	66.7	22	-7.58	24.34	-55.6	0.00	44.5
	Week 32	28	37.30	22.67	0.0	33.33	88.9	22	-10.61	30.57	-66.7	-5.56	33.3
	Week 35	25	34.67	21.59	0.0	33.33	77.8	20	-6.11	30.90	-66.7	0.00	55.6
	Week 38	22	39.39	21.88	0.0	33.33	100.0	19	-2.34	35.06	-66.7	0.00	55.6
	Week 41	24	41.67	17.72	11.1	33.33	77.8	20	-1.11	29.04	-55.6	0.00	55.6
	Week 44	22	42.93	27.50	0.0	33.33	100.0	18	-3.09	32.30	-66.7	0.00	55.6
	Week 47	23	40.10	20.31	0.0	33.33	77.8	20	-3.89	31.90	-66.7	0.00	55.6

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	19	36.84	20.97	0.0	33.33	66.7	16	-4.17	28.94	-66.7	0.00	55.6
	Week 53	19	42.69	18.25	11.1	33.33	77.8	15	-5.93	27.50	-66.7	0.00	33.3
	Week 56	19	42.10	23.88	11.1	33.33	100.0	15	-8.89	28.85	-66.7	0.00	33.3
	Week 59	18	43.21	16.12	11.1	38.89	66.7	14	-6.35	29.79	-55.6	0.00	33.3
	Week 62	20	36.67	21.05	0.0	33.33	66.7	16	-13.89	29.68	-66.7	-5.56	44.4
	Week 65	12	38.89	21.97	0.0	33.33	77.8	10	-17.78	26.30	-66.7	-11.12	11.1
	Week 68	15	36.29	19.00	0.0	33.33	66.7	13	-14.53	31.55	-66.7	-11.11	33.3
	Week 71	12	30.55	20.17	0.0	33.33	66.7	10	-21.11	33.31	-66.7	-22.23	33.3
	Week 77	11	31.31	15.57	11.1	33.33	66.7	9	-22.23	26.06	-66.7	-22.23	11.1
	Week 80	10	34.44	24.82	0.0	33.33	66.7	8	-18.06	40.69	-66.7	-27.78	44.5
	Plat+Gem (N= 51)												
	BASELINE	42	41.80	29.33	0.0	33.33	100.0						
	Week 1	36	48.15	28.61	0.0	33.33	100.0	36	5.25	24.27	-44.5	5.56	66.7
	Week 2	31	53.05	30.99	0.0	55.56	100.0	30	8.52	27.48	-55.6	5.56	77.8
	Week 3	35	50.48	31.12	0.0	44.44	100.0	33	9.43	20.25	-44.5	11.11	33.3
	Week 4	34	45.75	27.32	0.0	44.44	100.0	32	5.21	26.02	-55.6	11.11	66.7
	Week 5	34	47.71	26.46	0.0	38.89	100.0	32	9.72	28.89	-55.6	11.11	55.6
	Week 6	36	47.53	29.05	0.0	44.44	100.0	33	8.08	25.80	-33.3	11.11	66.7
	Week 7	33	44.11	29.20	0.0	33.33	100.0	29	4.60	28.72	-55.6	11.11	66.7
	Week 8	34	46.73	24.43	0.0	44.44	100.0	30	6.67	21.36	-33.3	11.11	44.5
	Week 9	34	42.16	24.89	0.0	33.33	100.0	30	4.44	25.71	-44.5	0.00	55.6
	Week 10	35	43.17	23.61	0.0	33.33	100.0	32	3.82	28.87	-55.6	0.00	55.6
	Week 11	29	43.68	28.01	0.0	33.33	100.0	27	4.53	29.28	-55.6	0.00	55.6
	Week 12	30	44.81	29.83	0.0	44.44	100.0	27	8.64	31.48	-55.6	11.11	88.9
	Week 14	26	44.02	26.39	0.0	44.44	100.0	23	6.28	26.56	-33.3	11.11	66.7
	Week 17	26	39.32	28.67	0.0	38.89	100.0	24	0.00	29.31	-44.5	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 20	20	33.89	23.50	0.0	38.89	66.7	19	-0.58	28.80	-44.5	0.00	44.5
	Week 23	18	27.16	21.30	0.0	27.78	66.7	18	-4.32	23.23	-44.5	-11.11	33.3
	Week 26	20	30.55	24.68	0.0	33.33	88.9	20	-8.33	23.05	-44.5	-5.56	33.3
	Week 29	18	34.57	25.82	0.0	33.33	100.0	18	3.09	31.61	-55.6	0.00	77.8
	Week 32	13	34.19	19.49	0.0	33.33	66.7	13	1.71	27.91	-44.5	0.00	44.5
	Week 35	12	24.07	22.64	0.0	27.78	66.7	12	-6.48	30.51	-55.6	-11.11	55.6
	Week 38	10	36.67	30.56	0.0	27.78	100.0	10	13.33	31.34	-44.5	11.11	66.7
	Week 41	10	32.22	17.72	0.0	33.33	55.6	10	11.11	14.81	0.0	0.00	33.3
	Week 44	10	38.89	30.65	0.0	38.89	100.0	10	8.89	29.07	-44.5	5.56	66.7
	Week 47	10	40.00	27.82	0.0	44.45	77.8	10	18.89	19.64	-11.1	16.67	44.5
	Week 56	10	51.11	28.30	0.0	55.56	100.0	10	17.78	35.99	-55.6	27.78	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Visceral metastases	EV+Pembro (N=148)												
	BASELINE	119	39.59	25.62	0.0	33.33	100.0						
	Week 1	105	43.07	26.99	0.0	33.33	100.0	99	4.27	19.03	-44.4	0.00	55.6
	Week 2	109	43.02	26.06	0.0	33.33	100.0	100	4.11	18.86	-44.5	0.00	66.7
	Week 3	98	39.68	27.31	0.0	33.33	100.0	88	1.26	21.07	-44.5	0.00	77.8
	Week 4	103	40.24	25.90	0.0	33.33	100.0	93	2.63	22.01	-44.5	0.00	77.8
	Week 5	100	37.44	27.11	0.0	33.33	100.0	90	-0.25	24.19	-55.6	0.00	88.9
	Week 6	105	38.31	25.55	0.0	33.33	100.0	90	0.74	26.48	-55.6	0.00	88.9
	Week 7	108	35.39	22.85	0.0	33.33	100.0	91	-1.59	25.37	-55.6	0.00	77.8
	Week 8	105	37.67	26.22	0.0	33.33	100.0	89	-0.75	28.12	-55.6	0.00	88.9
	Week 9	105	37.57	25.57	0.0	33.33	100.0	91	-0.37	25.85	-55.6	0.00	88.9
	Week 10	101	36.74	25.28	0.0	33.33	100.0	86	0.13	26.05	-66.7	0.00	77.8
	Week 11	97	33.45	22.60	0.0	33.33	100.0	83	-2.14	26.34	-66.7	0.00	66.7
	Week 12	100	35.22	25.52	0.0	33.33	100.0	85	-2.09	24.64	-55.6	0.00	66.7
	Week 14	102	34.86	25.84	0.0	33.33	100.0	87	-3.45	26.65	-66.7	0.00	66.7
	Week 17	96	32.99	22.94	0.0	33.33	100.0	81	-5.90	25.65	-77.8	0.00	66.7
	Week 20	87	34.99	22.26	0.0	33.33	100.0	76	-0.29	27.58	-66.7	0.00	77.8
	Week 23	85	34.12	22.08	0.0	33.33	77.8	71	-1.57	25.70	-44.5	0.00	77.8
	Week 26	79	32.07	19.97	0.0	33.33	77.8	66	-1.85	27.19	-66.7	0.00	66.7
	Week 29	72	35.65	21.09	0.0	33.33	88.9	64	0.69	27.35	-55.6	0.00	66.7
	Week 32	71	34.58	23.05	0.0	33.33	100.0	62	-2.51	29.67	-66.7	0.00	77.8
	Week 35	70	34.92	23.04	0.0	33.33	100.0	63	0.88	30.22	-66.7	0.00	77.8
	Week 38	70	36.19	21.38	0.0	33.33	100.0	63	1.23	26.33	-66.7	0.00	55.6
	Week 41	66	36.36	21.22	0.0	33.33	100.0	60	0.18	26.56	-55.6	0.00	55.6
	Week 44	59	38.61	23.10	0.0	33.33	100.0	53	1.05	26.44	-66.7	0.00	55.6
	Week 47	52	36.11	21.55	0.0	33.33	100.0	48	-1.62	26.53	-66.7	0.00	55.6

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	49	38.09	22.34	0.0	33.33	100.0	43	0.77	28.63	-66.7	0.00	55.6
	Week 53	50	41.33	26.28	0.0	33.33	100.0	44	0.25	27.06	-66.7	0.00	66.7
	Week 56	45	39.01	24.12	0.0	33.33	100.0	39	-0.86	27.85	-66.7	0.00	66.7
	Week 59	44	39.65	25.97	0.0	33.33	100.0	38	0.00	30.46	-55.6	0.00	66.7
	Week 62	38	33.92	19.32	0.0	33.33	66.7	33	-2.36	30.65	-66.7	0.00	66.7
	Week 65	25	36.44	21.64	0.0	33.33	88.9	24	-1.39	31.99	-66.7	0.00	55.6
	Week 68	31	33.69	24.26	0.0	33.33	88.9	29	-0.77	32.52	-66.7	0.00	66.7
	Week 71	27	36.62	23.63	0.0	33.33	88.9	25	-0.89	32.86	-66.7	0.00	66.7
	Week 74	23	29.47	23.83	0.0	33.33	77.8	22	-5.56	40.68	-66.7	0.00	66.7
	Week 77	24	32.87	20.06	0.0	33.33	66.7	23	-3.38	33.74	-66.7	0.00	66.7
	Week 80	22	37.37	25.79	0.0	33.33	77.8	22	0.00	38.95	-66.7	0.00	77.8
	Week 83	19	35.09	24.36	0.0	33.33	77.8	19	-2.92	40.88	-66.7	0.00	66.7
	Week 86	14	43.65	26.32	0.0	50.00	77.8	14	4.76	44.81	-66.7	5.56	77.8
	Week 89	10	33.33	22.83	0.0	33.33	77.8	10	-1.11	37.57	-66.7	0.00	77.8
	Week 92	11	39.39	28.27	0.0	33.33	88.9	11	-4.04	34.53	-66.7	0.00	55.6
	Plat+Gem (N=157)												
	BASELINE	128	37.59	28.51	0.0	33.33	100.0						
	Week 1	111	39.84	26.40	0.0	33.33	100.0	107	2.91	17.76	-44.5	0.00	44.5
	Week 2	110	43.33	25.45	0.0	33.33	100.0	102	8.39	23.06	-55.6	0.00	88.9
	Week 3	112	41.86	28.30	0.0	33.33	100.0	103	7.98	21.64	-44.5	11.11	55.6
	Week 4	112	39.88	25.25	0.0	33.33	100.0	102	5.88	23.39	-55.6	0.00	66.7
	Week 5	113	42.18	27.22	0.0	33.33	100.0	103	6.58	26.29	-55.6	11.11	77.8
	Week 6	107	39.87	26.78	0.0	33.33	100.0	98	5.67	25.34	-55.6	0.00	77.8
	Week 7	109	41.18	27.69	0.0	33.33	100.0	100	7.11	28.84	-55.6	11.11	77.8
	Week 8	106	44.86	26.56	0.0	38.89	100.0	98	9.86	27.49	-44.5	11.11	77.8
	Week 9	105	42.22	25.39	0.0	33.33	100.0	94	8.39	30.52	-55.6	0.00	88.9

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	104	40.60	26.22	0.0	33.33	100.0	96	6.37	27.49	-55.6	0.00	66.7
	Week 11	91	41.15	24.76	0.0	33.33	100.0	83	6.96	27.80	-55.6	0.00	88.9
	Week 12	94	40.78	24.95	0.0	33.33	100.0	84	4.89	26.96	-55.6	0.00	66.7
	Week 14	90	39.13	23.45	0.0	33.33	100.0	79	5.91	27.67	-44.5	0.00	77.8
	Week 17	90	40.99	26.37	0.0	33.33	100.0	80	7.22	28.95	-44.5	0.00	77.8
	Week 20	74	39.49	25.69	0.0	33.33	100.0	64	5.56	24.65	-44.4	0.00	77.8
	Week 23	63	34.57	23.79	0.0	33.33	100.0	58	2.68	23.02	-44.5	0.00	66.7
	Week 26	55	34.75	25.40	0.0	33.33	100.0	52	1.92	25.54	-55.6	0.00	55.6
	Week 29	53	34.17	24.05	0.0	33.33	100.0	50	5.78	27.24	-55.6	0.00	88.9
	Week 32	42	33.33	24.54	0.0	33.33	100.0	40	5.00	25.16	-44.5	0.00	77.8
	Week 35	39	30.77	20.94	0.0	33.33	66.7	36	3.39	26.40	-55.6	0.00	66.7
	Week 38	37	37.24	29.77	0.0	33.33	100.0	34	8.82	33.59	-55.6	0.00	100.0
	Week 41	33	37.04	23.68	0.0	33.33	88.9	31	6.81	27.02	-66.7	11.11	77.8
	Week 44	32	40.28	24.40	0.0	33.33	100.0	30	7.78	28.76	-66.7	0.00	66.7
	Week 47	28	39.68	26.78	0.0	33.33	100.0	26	7.69	24.09	-33.3	0.00	66.7
	Week 50	22	38.38	27.59	0.0	33.33	100.0	20	9.44	27.28	-33.3	5.56	66.7
	Week 53	19	39.76	28.28	0.0	33.33	100.0	17	5.88	37.29	-55.6	11.11	77.8
	Week 56	18	46.30	26.75	0.0	38.89	100.0	17	7.19	32.62	-55.6	11.11	66.7
	Week 59	13	48.72	30.61	0.0	33.33	100.0	12	0.93	34.64	-55.6	0.00	88.9
	Week 62	11	46.46	26.68	0.0	33.33	88.9	11	2.02	38.11	-55.6	0.00	88.9

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Lymph node only	EV+Pembro (N= 43)												
	BASELINE	33	25.59	18.73	0.0	22.22	66.7						
	Week 1	30	30.37	22.78	0.0	33.33	77.8	24	4.17	17.59	-33.3	0.00	44.5
	Week 2	34	32.68	20.64	0.0	33.33	88.9	27	3.29	13.72	-22.2	0.00	33.3
	Week 3	35	39.36	22.28	0.0	33.33	88.9	28	11.51	19.24	-22.2	5.56	44.5
	Week 4	36	33.33	23.00	0.0	33.33	88.9	30	4.44	22.15	-66.7	5.56	33.3
	Week 5	33	40.07	25.90	0.0	33.33	100.0	27	12.76	22.16	-33.3	11.11	66.7
	Week 6	34	36.60	25.00	0.0	33.33	100.0	28	9.92	24.07	-33.3	0.00	77.8
	Week 7	34	38.23	24.34	0.0	33.33	88.9	28	9.52	22.77	-33.3	0.00	77.8
	Week 8	35	36.19	23.55	0.0	33.33	88.9	29	9.96	24.73	-33.3	0.00	66.7
	Week 9	30	36.30	24.92	0.0	33.33	77.8	24	12.96	29.06	-33.3	5.56	77.8
	Week 10	31	33.69	26.21	0.0	33.33	100.0	26	8.12	29.41	-44.5	0.00	77.8
	Week 11	34	32.02	21.67	0.0	33.33	88.9	27	5.76	22.30	-33.3	11.11	44.5
	Week 12	35	31.11	21.36	0.0	33.33	77.8	28	4.76	22.11	-44.5	0.00	33.3
	Week 14	30	27.41	18.39	0.0	33.33	66.7	23	1.93	21.62	-44.5	0.00	44.4
	Week 17	30	32.96	19.24	0.0	33.33	66.7	24	9.26	23.09	-44.5	11.11	66.7
	Week 20	27	28.80	16.09	0.0	33.33	66.7	21	1.59	24.16	-33.3	11.11	55.6
	Week 23	27	33.33	17.70	0.0	33.33	66.7	21	6.88	23.70	-33.3	0.00	66.7
	Week 26	27	34.57	22.29	0.0	33.33	100.0	22	3.03	23.05	-44.5	0.00	55.6
	Week 29	28	36.51	21.57	0.0	33.33	88.9	23	13.04	24.99	-33.3	11.11	77.8
	Week 32	24	35.65	20.98	0.0	33.33	77.8	20	10.00	20.04	-33.3	11.11	44.5
	Week 35	22	41.41	23.05	11.1	33.33	100.0	18	14.20	23.74	-22.2	5.56	55.6
	Week 38	21	41.80	18.56	11.1	33.33	66.7	17	13.73	17.80	-11.1	11.11	44.5
	Week 41	22	34.85	20.37	0.0	33.33	77.8	17	9.80	20.37	-22.2	0.00	55.6
	Week 44	22	38.38	24.42	0.0	33.33	100.0	16	16.67	18.15	-11.1	11.12	55.6
	Week 47	21	39.15	19.44	11.1	33.33	77.8	16	12.50	14.56	-11.1	11.12	44.5

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	36.67	22.83	0.0	33.33	66.7	16	11.11	20.29	-22.2	0.00	55.6
	Week 53	18	33.95	24.84	0.0	33.33	66.7	14	11.11	20.90	-22.2	11.11	44.5
	Week 56	21	39.15	27.58	0.0	33.33	100.0	17	5.88	28.63	-55.6	11.11	44.5
	Week 59	21	34.92	23.12	0.0	33.33	77.8	16	2.08	21.93	-33.3	0.00	44.5
	Week 62	19	38.60	23.53	0.0	33.33	66.7	15	4.45	25.82	-55.6	0.00	44.5
	Week 65	16	40.97	26.52	0.0	33.33	88.9	14	8.73	25.48	-33.3	0.00	66.7
	Week 68	13	42.73	22.61	0.0	33.33	77.8	11	7.07	24.98	-33.3	11.11	55.6
	Week 71	13	39.32	24.69	0.0	33.33	66.7	11	6.06	29.13	-44.5	11.11	44.5
	Week 74	13	35.90	21.35	0.0	33.33	66.7	11	9.09	22.67	-22.2	11.11	44.5
	Week 77	13	35.04	20.21	0.0	33.33	66.7	10	0.00	26.19	-44.5	5.56	44.5
	Week 80	13	38.46	22.96	0.0	33.33	88.9	11	2.02	20.98	-33.3	0.00	33.3
	Week 83	11	36.36	19.93	0.0	33.33	66.7	10	6.67	20.42	-33.3	5.56	33.3
	Week 86	11	37.37	20.65	0.0	44.44	55.6	10	2.22	18.00	-11.1	0.00	44.5
	Plat+Gem (N= 37)												
	BASELINE	29	34.48	28.69	0.0	33.33	88.9						
	Week 1	26	39.74	23.13	0.0	33.33	100.0	25	4.00	26.04	-44.5	11.11	66.7
	Week 2	30	47.41	26.25	0.0	44.44	100.0	26	12.39	25.01	-33.3	11.11	77.8
	Week 3	30	41.48	23.15	0.0	38.89	100.0	26	9.83	16.43	-33.3	11.11	33.3
	Week 4	32	37.50	20.50	0.0	33.33	100.0	27	6.99	20.01	-66.7	11.11	33.3
	Week 5	33	45.12	24.68	0.0	33.33	100.0	28	13.89	25.24	-55.6	11.11	55.6
	Week 6	32	44.79	24.68	0.0	33.33	100.0	27	12.35	28.80	-55.6	11.11	66.7
	Week 7	31	44.44	27.82	0.0	33.33	100.0	26	11.97	31.42	-66.7	11.11	66.7
	Week 8	32	43.06	25.83	0.0	33.33	100.0	27	9.88	27.79	-55.6	22.22	44.5
	Week 9	30	44.81	26.34	0.0	33.33	100.0	25	9.33	30.55	-55.6	22.22	55.6
	Week 10	30	40.74	24.82	0.0	33.33	100.0	26	6.84	31.44	-55.6	0.00	66.7
	Week 11	29	39.08	23.69	11.1	33.33	100.0	25	5.33	31.77	-55.6	11.11	55.6

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.15.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 12	28	43.25	25.54	0.0	33.33	100.0	23	10.14	35.44	-55.6	0.00	88.9
	Week 14	28	46.03	24.70	11.1	33.33	100.0	23	13.04	32.94	-44.5	22.22	66.7
	Week 17	25	41.33	25.57	11.1	33.33	100.0	21	8.46	28.96	-44.5	11.11	55.6
	Week 20	23	38.65	27.19	0.0	33.33	100.0	20	6.11	38.23	-55.6	0.00	88.9
	Week 23	20	29.44	19.17	0.0	33.33	66.7	17	-0.65	32.03	-55.6	0.00	55.6
	Week 26	21	37.04	25.90	0.0	33.33	100.0	18	-0.62	27.87	-55.6	0.00	44.4
	Week 29	19	37.43	26.25	0.0	33.33	100.0	16	5.55	35.14	-55.6	5.56	77.8
	Week 32	18	37.65	21.27	11.1	33.33	100.0	15	3.70	32.44	-55.6	0.00	44.5
	Week 35	19	33.92	22.37	0.0	33.33	100.0	16	0.69	32.58	-55.6	5.56	55.6
	Week 38	15	33.33	18.78	0.0	33.33	77.8	12	4.63	22.95	-33.3	0.00	44.5
	Week 41	15	45.18	29.54	0.0	33.33	100.0	12	13.89	28.08	-33.3	11.11	66.7
	Week 44	14	39.68	26.77	0.0	33.33	100.0	11	8.08	24.39	-33.3	0.00	44.5
	Week 47	12	42.59	21.63	11.1	33.33	77.8	10	10.00	25.37	-33.3	11.11	44.5
	Week 50	11	48.48	25.47	11.1	44.44	100.0	8	9.72	31.67	-33.3	0.00	55.6

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
EV+Pembro (N=240)												
BASELINE	206	30.42	28.70	0.0	33.33	100.0						
Week 1	190	32.02	27.43	0.0	33.33	100.0	184	1.45	19.58	-66.7	0.00	66.7
Week 2	203	32.35	26.41	0.0	33.33	100.0	189	3.44	21.64	-66.7	0.00	66.7
Week 3	198	33.59	26.10	0.0	33.33	100.0	182	2.66	24.48	-66.7	0.00	66.7
Week 4	194	24.74	23.34	0.0	16.67	100.0	179	-4.75	24.81	-100.0	0.00	83.3
Week 5	190	23.60	24.01	0.0	16.67	100.0	173	-5.20	24.75	-100.0	0.00	66.7
Week 6	188	25.97	24.26	0.0	33.33	100.0	170	-3.14	27.01	-66.7	0.00	83.3
Week 7	195	25.04	25.57	0.0	16.67	100.0	176	-4.64	28.82	-100.0	0.00	83.3
Week 8	191	23.82	24.68	0.0	16.67	100.0	171	-5.85	30.38	-100.0	0.00	83.3
Week 9	197	27.33	26.23	0.0	33.33	100.0	180	-2.96	29.28	-100.0	0.00	83.3
Week 10	191	24.61	22.54	0.0	16.67	100.0	175	-4.76	27.90	-100.0	0.00	66.7
Week 11	194	23.63	23.42	0.0	16.67	100.0	175	-6.48	28.24	-100.0	0.00	83.3
Week 12	186	24.01	24.81	0.0	16.67	100.0	171	-6.43	28.88	-100.0	0.00	66.7
Week 14	185	23.69	23.15	0.0	16.67	100.0	167	-5.69	27.91	-100.0	0.00	83.3
Week 17	178	24.81	24.44	0.0	16.67	100.0	162	-3.91	29.05	-100.0	0.00	66.7
Week 20	167	26.25	24.84	0.0	33.33	100.0	154	-1.95	28.32	-66.7	0.00	66.7
Week 23	162	26.54	25.91	0.0	33.33	100.0	151	-0.44	29.12	-83.3	0.00	66.7
Week 26	156	24.79	25.71	0.0	16.67	100.0	144	-4.40	32.15	-100.0	0.00	83.3
Week 29	157	22.40	22.06	0.0	16.67	100.0	145	-4.02	28.41	-100.0	0.00	83.3
Week 32	135	24.94	23.99	0.0	33.33	83.3	125	0.13	27.64	-83.3	0.00	83.3
Week 35	132	27.40	24.46	0.0	33.33	100.0	122	0.82	27.34	-83.3	0.00	83.3
Week 38	132	24.87	25.26	0.0	33.33	100.0	124	-2.29	30.08	-100.0	0.00	66.7
Week 41	129	25.19	23.86	0.0	33.33	100.0	119	-0.56	29.51	-83.3	0.00	66.7
Week 44	108	24.23	23.72	0.0	25.00	100.0	100	-0.33	32.65	-83.3	0.00	100.0
Week 47	100	24.33	24.55	0.0	16.67	100.0	94	-0.18	32.01	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	89	24.16	21.91	0.0	33.33	66.7	84	0.99	25.92	-50.0	0.00	66.7
Week 53	79	22.78	23.29	0.0	16.67	100.0	74	0.22	31.99	-83.3	0.00	83.3
Week 56	81	22.02	25.39	0.0	16.67	100.0	76	-2.19	33.59	-83.3	0.00	83.3
Week 59	72	23.61	24.67	0.0	16.67	100.0	68	0.00	32.45	-83.3	0.00	83.3
Week 62	65	23.08	26.79	0.0	16.67	100.0	63	1.32	33.51	-66.7	0.00	83.3
Week 65	58	27.01	26.64	0.0	33.33	100.0	54	1.23	32.83	-83.3	0.00	83.3
Week 68	53	23.27	24.75	0.0	16.67	83.3	52	-1.60	32.38	-83.3	0.00	66.7
Week 71	51	24.51	25.46	0.0	16.67	83.3	49	0.34	32.54	-83.3	0.00	66.7
Week 74	47	24.11	23.52	0.0	33.33	66.7	46	0.00	32.20	-83.3	0.00	66.7
Week 77	44	29.92	27.98	0.0	33.33	100.0	42	2.78	35.29	-66.7	0.00	66.7
Week 80	40	26.25	25.84	0.0	33.33	100.0	37	-4.96	31.88	-83.3	0.00	66.7
Week 83	37	26.58	24.68	0.0	33.33	83.3	35	-5.72	31.81	-66.7	0.00	83.3
Week 86	34	25.98	25.36	0.0	33.33	83.3	31	-5.38	30.85	-66.7	0.00	83.3
Week 89	33	29.80	29.39	0.0	33.33	100.0	31	-2.15	32.41	-66.7	0.00	83.3
Week 92	27	29.63	29.72	0.0	33.33	100.0	25	1.33	29.63	-50.0	0.00	66.7
Week 95	22	34.09	31.49	0.0	33.33	100.0	21	3.17	31.01	-50.0	0.00	50.0
Week 98	18	24.07	28.71	0.0	16.67	83.3	17	-6.86	27.04	-50.0	-16.66	50.0
Week 101	14	22.62	27.43	0.0	8.34	83.3	14	-1.19	28.09	-50.0	0.00	66.7
Week 104	10	25.00	30.68	0.0	8.34	66.7	10	0.00	29.40	-33.3	-8.33	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Plat+Gem (N=242)												
BASELINE	188	33.07	27.87	0.0	33.33	100.0						
Week 1	173	33.14	27.02	0.0	33.33	100.0	158	0.53	20.98	-100.0	0.00	83.3
Week 2	171	32.94	27.05	0.0	33.33	100.0	151	2.10	23.75	-100.0	0.00	66.7
Week 3	184	30.25	26.47	0.0	33.33	100.0	162	-1.54	24.91	-100.0	0.00	100.0
Week 4	183	28.32	26.51	0.0	33.33	100.0	156	-3.53	24.10	-100.0	0.00	83.3
Week 5	187	28.52	25.70	0.0	33.33	100.0	156	-0.43	25.68	-100.0	0.00	83.3
Week 6	174	28.16	26.56	0.0	33.33	100.0	149	-2.01	27.39	-100.0	0.00	100.0
Week 7	186	27.06	24.92	0.0	33.33	100.0	157	-2.87	25.19	-100.0	0.00	83.3
Week 8	167	29.04	24.54	0.0	33.33	100.0	144	0.93	28.41	-83.3	0.00	83.3
Week 9	177	26.74	24.63	0.0	33.33	100.0	150	-2.89	28.36	-83.3	0.00	100.0
Week 10	166	25.70	24.04	0.0	33.33	100.0	139	-3.96	26.74	-100.0	0.00	83.3
Week 11	168	26.09	24.03	0.0	33.33	100.0	143	-2.80	25.17	-100.0	0.00	66.7
Week 12	159	25.89	23.91	0.0	33.33	100.0	138	-2.54	26.02	-100.0	0.00	66.7
Week 14	153	27.34	22.91	0.0	33.33	100.0	128	-1.69	23.09	-66.7	0.00	66.7
Week 17	155	28.39	25.99	0.0	33.33	100.0	130	0.13	27.49	-66.7	0.00	83.3
Week 20	126	22.62	22.65	0.0	25.00	100.0	110	-5.46	25.25	-83.3	0.00	66.7
Week 23	115	25.51	26.24	0.0	33.33	100.0	97	-1.03	26.66	-83.3	0.00	66.7
Week 26	108	27.31	26.42	0.0	33.33	100.0	95	0.70	26.95	-66.7	0.00	66.7
Week 29	100	25.83	20.29	0.0	33.33	66.7	86	0.19	20.85	-33.3	0.00	66.7
Week 32	83	26.10	24.44	0.0	33.33	100.0	76	2.41	24.30	-66.7	0.00	66.7
Week 35	76	26.75	22.46	0.0	33.33	100.0	69	3.14	25.29	-50.0	0.00	66.7
Week 38	74	23.65	26.46	0.0	16.67	100.0	65	-0.26	27.56	-66.7	0.00	66.7
Week 41	65	25.64	26.37	0.0	16.67	100.0	56	2.68	26.17	-66.7	0.00	66.7
Week 44	60	30.28	27.01	0.0	33.33	100.0	53	4.72	26.83	-66.7	0.00	66.7
Week 47	56	24.70	23.78	0.0	33.33	83.3	49	1.02	24.15	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	51	28.10	28.96	0.0	33.33	100.0	47	2.13	25.45	-66.7	0.00	66.7
Week 53	46	22.10	23.05	0.0	16.67	83.3	42	1.19	22.21	-66.7	0.00	66.7
Week 56	39	27.35	26.07	0.0	33.33	100.0	34	3.92	26.92	-50.0	0.00	83.3
Week 59	37	20.27	19.69	0.0	16.67	83.3	33	-0.51	23.75	-66.7	0.00	66.7
Week 62	32	19.27	17.51	0.0	16.67	66.7	29	-1.15	23.12	-50.0	0.00	66.7
Week 65	30	17.22	20.29	0.0	8.34	66.7	26	-2.56	20.92	-66.7	0.00	33.3
Week 68	25	25.33	26.40	0.0	16.67	83.3	21	4.76	19.11	-33.3	0.00	33.3
Week 71	22	26.51	28.48	0.0	25.00	100.0	19	4.39	16.52	-16.7	0.00	33.3
Week 74	21	26.19	30.99	0.0	33.33	100.0	18	0.93	19.36	-33.3	0.00	33.3
Week 77	18	28.70	31.73	0.0	16.67	100.0	15	2.22	25.87	-33.3	0.00	66.7
Week 80	14	22.62	18.03	0.0	25.00	50.0	13	3.85	15.45	-16.7	0.00	33.3
Week 83	13	23.08	18.68	0.0	33.33	50.0	12	0.00	18.80	-33.3	0.00	33.3
Week 86	12	12.50	17.59	0.0	0.00	50.0	11	-6.06	17.11	-33.3	0.00	16.7
Week 89	11	16.67	16.67	0.0	16.67	33.3	10	-3.33	21.94	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Present	EV+Pembro (N= 48)												
	BASELINE	39	40.60	33.07	0.0	33.33	100.0						
	Week 1	32	40.62	31.66	0.0	33.33	100.0	32	-1.56	22.14	-66.7	0.00	50.0
	Week 2	37	41.89	30.84	0.0	33.33	100.0	33	4.04	31.19	-66.7	0.00	66.7
	Week 3	34	40.20	27.56	0.0	33.33	100.0	29	-8.62	25.44	-66.7	0.00	33.3
	Week 4	36	33.80	28.03	0.0	33.33	100.0	31	-4.84	34.21	-100.0	0.00	83.3
	Week 5	30	33.33	28.03	0.0	33.33	83.3	24	-9.03	34.40	-100.0	0.00	50.0
	Week 6	31	34.95	26.65	0.0	33.33	100.0	25	-5.33	30.32	-66.7	0.00	33.3
	Week 7	34	34.31	30.13	0.0	33.33	100.0	28	-8.33	39.93	-100.0	-8.33	83.3
	Week 8	35	32.86	27.56	0.0	33.33	100.0	30	-10.56	38.78	-100.0	0.00	83.3
	Week 9	34	35.78	33.62	0.0	33.33	100.0	30	-6.67	33.51	-100.0	0.00	66.7
	Week 10	34	28.92	27.00	0.0	33.33	100.0	30	-12.22	35.54	-100.0	0.00	50.0
	Week 11	33	35.35	28.79	0.0	33.33	100.0	28	-6.55	40.40	-100.0	0.00	83.3
	Week 12	33	30.30	29.89	0.0	33.33	100.0	29	-12.07	36.70	-100.0	0.00	66.7
	Week 14	31	28.49	24.79	0.0	33.33	100.0	26	-13.46	41.90	-100.0	-16.67	83.3
	Week 17	31	32.80	26.35	0.0	33.33	100.0	25	-8.67	41.98	-100.0	0.00	66.7
	Week 20	27	37.04	25.04	0.0	33.33	83.3	24	-0.70	30.49	-50.0	0.00	66.7
	Week 23	26	32.69	23.32	0.0	33.33	83.3	23	-5.80	29.99	-83.3	0.00	66.7
	Week 26	25	22.67	23.51	0.0	16.67	66.7	22	-19.70	36.60	-100.0	-8.33	33.3
	Week 29	23	21.74	23.26	0.0	16.67	83.3	22	-12.88	33.31	-100.0	0.00	33.3
	Week 32	21	29.36	21.02	0.0	33.33	66.7	19	-5.26	31.94	-83.3	0.00	50.0
	Week 35	19	31.58	28.27	0.0	33.33	83.3	17	-3.92	27.34	-83.3	0.00	33.3
	Week 38	18	34.26	34.05	0.0	33.33	100.0	17	-7.84	40.87	-100.0	0.00	50.0
	Week 41	20	24.17	20.57	0.0	25.00	66.7	19	-11.40	30.96	-83.3	0.00	33.3
	Week 44	17	25.49	21.34	0.0	33.33	66.7	15	-6.67	34.39	-83.3	0.00	33.3
	Week 47	18	34.26	33.56	0.0	33.33	100.0	16	2.08	45.49	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	12	19.45	18.58	0.0	16.67	66.7	11	1.51	15.73	-33.3	0.00	16.7
	Week 53	12	26.39	31.35	0.0	25.00	100.0	11	4.54	40.88	-83.3	0.00	83.3
	Week 56	13	25.64	35.76	0.0	0.00	100.0	12	-1.39	44.07	-83.3	0.00	83.3
	Week 59	12	19.45	32.44	0.0	0.00	100.0	11	-7.58	43.05	-83.3	0.00	83.3
	Week 62	10	21.67	34.29	0.0	8.34	100.0	9	0.00	39.09	-66.7	0.00	83.3
	Week 65	10	33.33	37.68	0.0	25.00	100.0	9	3.70	45.47	-83.3	0.00	83.3
	Plat+Gem (N= 48)												
	BASELINE	33	36.36	28.09	0.0	33.33	100.0						
	Week 1	31	34.95	29.30	0.0	33.33	100.0	27	-3.09	25.33	-100.0	0.00	50.0
	Week 2	29	37.93	31.78	0.0	33.33	100.0	24	2.78	34.29	-100.0	0.00	66.7
	Week 3	32	24.48	23.18	0.0	16.67	83.3	27	-8.64	29.00	-100.0	0.00	33.3
	Week 4	32	27.60	31.00	0.0	16.67	100.0	24	-9.03	29.48	-100.0	0.00	50.0
	Week 5	36	25.93	30.46	0.0	16.67	100.0	28	-7.14	31.24	-100.0	0.00	66.7
	Week 6	35	29.52	33.60	0.0	16.67	100.0	27	-8.64	32.81	-100.0	0.00	50.0
	Week 7	38	23.25	24.97	0.0	25.00	100.0	29	-14.37	25.48	-100.0	0.00	33.3
	Week 8	31	22.04	19.90	0.0	16.67	66.7	25	-4.00	18.81	-33.3	0.00	33.3
	Week 9	32	23.44	21.11	0.0	25.00	66.7	25	-10.00	19.84	-66.7	0.00	16.7
	Week 10	34	17.65	18.78	0.0	16.67	66.7	26	-20.51	25.95	-100.0	-16.67	16.7
	Week 11	30	16.67	18.57	0.0	16.67	66.7	24	-19.44	27.66	-100.0	-16.66	16.7
	Week 12	28	21.43	23.94	0.0	16.67	100.0	23	-14.49	31.10	-100.0	0.00	33.3
	Week 14	26	26.92	19.48	0.0	33.33	66.7	21	-4.76	19.82	-50.0	0.00	33.3
	Week 17	30	21.11	23.54	0.0	16.67	66.7	25	-12.00	18.95	-50.0	-16.66	50.0
	Week 20	23	15.22	18.74	0.0	0.00	50.0	21	-15.87	27.63	-83.3	-16.67	50.0
	Week 23	22	22.73	27.96	0.0	8.34	83.3	19	-8.77	30.61	-83.3	-16.67	66.7
	Week 26	19	14.91	18.34	0.0	16.67	66.7	18	-12.96	21.05	-66.7	-16.66	33.3
	Week 29	16	23.96	20.16	0.0	33.33	66.7	14	-5.95	20.26	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 32	11	30.30	22.13	0.0	33.33	66.7	11	4.54	23.68	-33.3	16.66	33.3
	Week 35	10	30.00	17.21	0.0	33.33	66.7	9	0.00	18.63	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Absent	EV+Pembro (N=192)												
	BASELINE	167	28.04	27.14	0.0	33.33	100.0						
	Week 1	158	30.27	26.26	0.0	33.33	100.0	152	2.08	19.02	-50.0	0.00	66.7
	Week 2	166	30.22	24.93	0.0	33.33	100.0	156	3.31	19.16	-50.0	0.00	66.7
	Week 3	164	32.22	25.66	0.0	33.33	100.0	153	4.79	23.78	-50.0	0.00	66.7
	Week 4	158	22.68	21.71	0.0	16.67	83.3	148	-4.73	22.51	-66.7	0.00	66.7
	Week 5	160	21.77	22.82	0.0	16.67	100.0	149	-4.59	22.91	-66.7	0.00	66.7
	Week 6	157	24.20	23.45	0.0	33.33	100.0	145	-2.76	26.50	-66.7	0.00	83.3
	Week 7	161	23.08	24.16	0.0	16.67	100.0	148	-3.94	26.32	-66.7	0.00	83.3
	Week 8	156	21.79	23.62	0.0	16.67	100.0	141	-4.85	28.35	-100.0	0.00	66.7
	Week 9	163	25.56	24.16	0.0	33.33	100.0	150	-2.22	28.42	-66.7	0.00	83.3
	Week 10	157	23.67	21.44	0.0	16.67	83.3	145	-3.22	25.93	-83.3	0.00	66.7
	Week 11	161	21.22	21.49	0.0	16.67	100.0	147	-6.46	25.47	-66.7	0.00	66.7
	Week 12	153	22.66	23.46	0.0	16.67	100.0	142	-5.28	27.03	-66.7	0.00	66.7
	Week 14	154	22.73	22.77	0.0	16.67	100.0	141	-4.26	24.43	-66.7	0.00	50.0
	Week 17	147	23.13	23.77	0.0	16.67	100.0	137	-3.04	26.14	-83.3	0.00	66.7
	Week 20	140	24.17	24.35	0.0	16.67	100.0	130	-2.18	28.03	-66.7	0.00	66.7
	Week 23	136	25.37	26.29	0.0	16.67	100.0	128	0.52	28.98	-66.7	0.00	66.7
	Week 26	131	25.19	26.18	0.0	16.67	100.0	122	-1.64	30.63	-66.7	0.00	83.3
	Week 29	134	22.51	21.94	0.0	16.67	100.0	123	-2.44	27.30	-66.7	0.00	83.3
	Week 32	114	24.12	24.50	0.0	16.67	83.3	106	1.10	26.85	-66.7	0.00	83.3
	Week 35	113	26.70	23.84	0.0	33.33	100.0	105	1.59	27.40	-66.7	0.00	83.3
	Week 38	114	23.39	23.44	0.0	16.67	100.0	107	-1.40	28.14	-66.7	0.00	66.7
	Week 41	109	25.38	24.49	0.0	33.33	100.0	100	1.50	28.93	-66.7	0.00	66.7
	Week 44	91	23.99	24.24	0.0	16.67	100.0	85	0.78	32.42	-66.7	0.00	100.0
	Week 47	82	22.15	21.76	0.0	16.67	83.3	78	-0.64	28.86	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	77	24.89	22.40	0.0	33.33	66.7	73	0.91	27.20	-50.0	0.00	66.7
	Week 53	67	22.14	21.79	0.0	16.67	83.3	63	-0.53	30.52	-66.7	0.00	66.7
	Week 56	68	21.32	23.19	0.0	16.67	83.3	64	-2.34	31.69	-66.7	0.00	66.7
	Week 59	60	24.44	23.06	0.0	16.67	83.3	57	1.46	30.26	-66.7	0.00	66.7
	Week 62	55	23.33	25.58	0.0	16.67	83.3	54	1.54	32.90	-66.7	0.00	83.3
	Week 65	48	25.69	24.06	0.0	33.33	83.3	45	0.74	30.35	-50.0	0.00	66.7
	Week 68	46	22.46	23.36	0.0	16.67	66.7	45	-1.85	30.41	-66.7	0.00	66.7
	Week 71	44	24.62	25.03	0.0	25.00	83.3	42	1.19	31.54	-66.7	0.00	66.7
	Week 74	40	25.00	22.96	0.0	33.33	66.7	39	1.71	31.71	-66.7	0.00	66.7
	Week 77	38	29.39	27.24	0.0	33.33	100.0	36	4.17	35.72	-66.7	0.00	66.7
	Week 80	35	25.71	25.99	0.0	33.33	100.0	32	-3.65	30.45	-66.7	0.00	66.7
	Week 83	32	25.52	24.68	0.0	33.33	83.3	30	-5.00	32.21	-66.7	0.00	83.3
	Week 86	29	25.86	25.81	0.0	33.33	83.3	26	-4.49	31.11	-50.0	-8.34	83.3
	Week 89	29	29.88	30.01	0.0	33.33	100.0	27	-0.62	32.19	-50.0	0.00	83.3
	Week 92	24	30.56	30.56	0.0	33.33	100.0	22	0.00	30.86	-50.0	0.00	66.7
	Week 95	20	31.67	31.94	0.0	33.33	100.0	19	0.88	30.67	-50.0	0.00	50.0
	Week 98	18	24.07	28.71	0.0	16.67	83.3	17	-6.86	27.04	-50.0	-16.66	50.0
	Week 101	13	17.95	22.01	0.0	0.00	50.0	13	-6.41	21.01	-50.0	0.00	33.3
	Plat+Gem (N=194)												
	BASELINE	155	32.37	27.87	0.0	33.33	100.0						
	Week 1	142	32.75	26.59	0.0	33.33	100.0	131	1.27	20.00	-66.7	0.00	83.3
	Week 2	142	31.92	25.99	0.0	33.33	100.0	127	1.97	21.37	-66.7	0.00	66.7
	Week 3	152	31.47	27.03	0.0	33.33	100.0	135	-0.12	23.88	-50.0	0.00	100.0
	Week 4	151	28.48	25.57	0.0	33.33	100.0	132	-2.53	22.98	-50.0	0.00	83.3
	Week 5	151	29.14	24.51	0.0	33.33	100.0	128	1.04	24.19	-66.7	0.00	83.3
	Week 6	139	27.82	24.61	0.0	33.33	100.0	122	-0.55	25.97	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 7	148	28.04	24.90	0.0	33.33	100.0	128	-0.26	24.48	-50.0	0.00	83.3
	Week 8	136	30.64	25.27	0.0	33.33	100.0	119	1.96	30.00	-83.3	0.00	83.3
	Week 9	145	27.47	25.35	0.0	33.33	100.0	125	-1.47	29.64	-83.3	0.00	100.0
	Week 10	132	27.78	24.85	0.0	33.33	100.0	113	-0.15	25.54	-66.7	0.00	83.3
	Week 11	138	28.14	24.65	0.0	33.33	100.0	119	0.56	23.36	-66.7	0.00	66.7
	Week 12	131	26.84	23.89	0.0	33.33	100.0	115	-0.15	24.33	-66.7	0.00	66.7
	Week 14	127	27.43	23.62	0.0	33.33	100.0	107	-1.09	23.71	-66.7	0.00	66.7
	Week 17	125	30.13	26.33	0.0	33.33	100.0	105	3.02	28.47	-66.7	0.00	83.3
	Week 20	103	24.27	23.19	0.0	33.33	100.0	89	-3.00	24.17	-66.7	0.00	66.7
	Week 23	93	26.16	25.94	0.0	33.33	100.0	78	0.85	25.47	-50.0	0.00	66.7
	Week 26	89	29.96	27.20	0.0	33.33	100.0	77	3.90	27.29	-50.0	0.00	66.7
	Week 29	84	26.19	20.42	0.0	33.33	66.7	72	1.39	20.89	-33.3	0.00	66.7
	Week 32	72	25.46	24.86	0.0	25.00	100.0	65	2.05	24.56	-66.7	0.00	66.7
	Week 35	66	26.26	23.22	0.0	33.33	100.0	60	3.61	26.23	-50.0	0.00	66.7
	Week 38	66	23.48	26.95	0.0	16.67	100.0	57	-1.46	28.92	-66.7	0.00	66.7
	Week 41	62	25.54	26.60	0.0	16.67	100.0	53	3.14	26.77	-66.7	0.00	66.7
	Week 44	55	29.39	26.44	0.0	33.33	100.0	48	3.47	25.72	-66.7	0.00	66.7
	Week 47	51	23.86	24.10	0.0	33.33	83.3	44	0.00	23.84	-66.7	0.00	66.7
	Week 50	48	29.17	29.27	0.0	33.33	100.0	44	3.79	25.13	-66.7	0.00	66.7
	Week 53	41	21.54	23.93	0.0	16.67	83.3	37	0.00	21.52	-66.7	0.00	66.7
	Week 56	34	24.51	23.65	0.0	33.33	100.0	29	0.57	22.04	-50.0	0.00	33.3
	Week 59	32	19.27	18.50	0.0	16.67	83.3	28	-2.38	21.14	-66.7	0.00	33.3
	Week 62	27	17.90	15.28	0.0	16.67	33.3	24	-3.47	19.65	-50.0	0.00	33.3
	Week 65	25	17.33	21.23	0.0	0.00	66.7	21	-3.17	20.83	-66.7	0.00	33.3
	Week 68	23	27.54	26.40	0.0	16.67	83.3	19	7.02	17.84	-16.7	0.00	33.3
	Week 71	21	26.19	29.14	0.0	16.67	100.0	18	2.78	15.39	-16.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 74	20	27.50	31.19	0.0	33.33	100.0	17	2.94	17.91	-33.3	0.00	33.3
	Week 77	16	31.25	32.70	0.0	25.00	100.0	13	6.41	25.04	-33.3	0.00	66.7
	Week 80	12	22.22	19.24	0.0	25.00	50.0	11	6.06	15.41	-16.7	0.00	33.3
	Week 83	11	24.24	18.80	0.0	33.33	50.0	10	3.33	17.21	-16.7	0.00	33.3
	Week 86	10	13.33	18.92	0.0	0.00	50.0	9	-1.85	15.47	-33.3	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
< 65 years	EV+Pembro (N=105)												
	BASELINE	92	35.69	30.52	0.0	33.33	100.0						
	Week 1	88	33.90	28.19	0.0	33.33	100.0	85	-0.59	18.62	-50.0	0.00	66.7
	Week 2	92	33.51	25.85	0.0	33.33	100.0	86	-0.39	21.54	-66.7	0.00	66.7
	Week 3	93	33.69	25.54	0.0	33.33	100.0	84	-2.58	24.48	-66.7	0.00	50.0
	Week 4	90	23.89	23.71	0.0	16.67	100.0	82	-10.98	24.60	-100.0	0.00	50.0
	Week 5	90	22.04	21.32	0.0	16.67	83.3	81	-11.11	26.09	-100.0	0.00	50.0
	Week 6	90	23.52	21.18	0.0	33.33	83.3	81	-11.52	26.57	-66.7	0.00	50.0
	Week 7	85	22.16	22.91	0.0	16.67	100.0	77	-12.99	27.39	-100.0	0.00	33.3
	Week 8	89	20.41	22.30	0.0	16.67	100.0	80	-14.38	31.46	-100.0	-16.66	83.3
	Week 9	93	24.01	22.31	0.0	33.33	83.3	85	-10.20	30.11	-100.0	0.00	66.7
	Week 10	88	23.29	20.61	0.0	33.33	83.3	81	-12.35	29.67	-100.0	0.00	33.3
	Week 11	93	22.58	21.09	0.0	16.67	66.7	84	-13.69	29.74	-100.0	0.00	33.3
	Week 12	86	23.64	24.18	0.0	33.33	100.0	79	-13.08	32.32	-100.0	0.00	66.7
	Week 14	84	25.20	25.41	0.0	33.33	100.0	76	-10.53	29.04	-100.0	0.00	50.0
	Week 17	83	24.70	25.15	0.0	16.67	100.0	77	-9.74	33.15	-100.0	0.00	66.7
	Week 20	79	28.06	25.81	0.0	33.33	100.0	73	-6.16	31.12	-66.7	0.00	66.7
	Week 23	78	27.78	27.48	0.0	33.33	100.0	73	-5.02	30.64	-83.3	0.00	66.7
	Week 26	78	23.72	25.84	0.0	16.67	100.0	72	-10.65	34.29	-100.0	0.00	66.7
	Week 29	74	21.17	20.88	0.0	16.67	66.7	67	-10.45	29.85	-100.0	0.00	66.7
	Week 32	64	24.74	24.84	0.0	33.33	83.3	59	-4.24	27.44	-83.3	0.00	50.0
	Week 35	62	24.46	25.38	0.0	16.67	100.0	58	-4.60	26.64	-83.3	0.00	66.7
	Week 38	62	24.19	24.64	0.0	33.33	100.0	59	-6.78	34.20	-100.0	0.00	66.7
	Week 41	64	22.13	23.77	0.0	33.33	100.0	59	-9.04	27.56	-83.3	0.00	66.7
	Week 44	50	21.33	22.60	0.0	16.67	66.7	48	-8.68	30.75	-83.3	0.00	66.7
	Week 47	47	24.47	27.33	0.0	16.67	100.0	46	-5.07	36.15	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	44	25.76	22.00	0.0	33.33	66.7	41	1.22	30.14	-50.0	0.00	66.7
	Week 53	40	22.08	25.15	0.0	16.67	100.0	37	-3.60	35.82	-83.3	0.00	83.3
	Week 56	44	19.70	24.71	0.0	8.34	100.0	41	-7.72	35.57	-83.3	0.00	83.3
	Week 59	42	23.41	24.71	0.0	16.67	100.0	39	-2.14	36.11	-83.3	0.00	83.3
	Week 62	37	22.97	27.60	0.0	16.67	100.0	36	-1.85	37.96	-66.7	0.00	83.3
	Week 65	34	27.94	27.13	0.0	33.33	100.0	31	1.61	39.05	-83.3	0.00	83.3
	Week 68	34	23.53	25.00	0.0	16.67	83.3	33	-3.03	36.91	-83.3	0.00	66.7
	Week 71	32	25.52	25.40	0.0	33.33	66.7	30	-1.67	36.97	-83.3	0.00	66.7
	Week 74	29	28.73	24.36	0.0	33.33	66.7	28	1.78	37.22	-83.3	0.00	66.7
	Week 77	25	30.00	24.06	0.0	33.33	66.7	24	-2.08	36.55	-66.7	0.00	66.7
	Week 80	24	29.17	26.12	0.0	33.33	100.0	22	-6.06	36.57	-83.3	0.00	66.7
	Week 83	23	31.16	25.77	0.0	33.33	83.3	22	-3.79	37.42	-66.7	0.00	83.3
	Week 86	20	35.00	26.44	0.0	33.33	83.3	18	-1.85	37.00	-66.7	0.00	83.3
	Week 89	19	35.09	28.81	0.0	33.33	100.0	17	-1.96	37.21	-66.7	0.00	83.3
	Week 92	14	36.90	30.79	0.0	33.33	100.0	12	5.55	30.43	-33.3	0.00	66.7
	Week 95	12	45.83	29.41	0.0	41.67	100.0	11	12.12	31.70	-33.3	0.00	50.0
	Plat+Gem (N=106)												
	BASELINE	83	34.94	26.24	0.0	33.33	100.0						
	Week 1	75	33.11	24.12	0.0	33.33	100.0	71	0.94	21.98	-66.7	0.00	83.3
	Week 2	76	35.75	28.38	0.0	33.33	100.0	68	0.74	24.17	-66.7	0.00	66.7
	Week 3	80	33.75	25.98	0.0	33.33	100.0	73	-1.14	27.12	-66.7	0.00	100.0
	Week 4	79	32.28	26.33	0.0	33.33	100.0	67	-3.23	24.32	-50.0	0.00	83.3
	Week 5	80	28.96	24.84	0.0	33.33	100.0	67	-3.23	26.63	-66.7	0.00	66.7
	Week 6	76	30.70	27.76	0.0	33.33	100.0	67	-4.23	28.63	-66.7	0.00	100.0
	Week 7	81	30.66	25.06	0.0	33.33	100.0	71	-3.76	24.59	-66.7	0.00	66.7
	Week 8	72	27.78	22.38	0.0	33.33	83.3	64	-3.65	28.86	-66.7	0.00	83.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	78	26.07	22.41	0.0	33.33	66.7	69	-8.45	28.82	-66.7	0.00	66.7
	Week 10	78	27.35	22.31	0.0	33.33	100.0	68	-8.09	24.85	-66.7	0.00	83.3
	Week 11	75	27.78	22.32	0.0	33.33	100.0	66	-5.81	25.74	-66.7	0.00	66.7
	Week 12	74	26.13	20.47	0.0	33.33	66.7	66	-7.07	26.16	-66.7	0.00	66.7
	Week 14	68	28.19	21.21	0.0	33.33	100.0	58	-5.75	23.06	-50.0	0.00	33.3
	Week 17	68	31.13	26.69	0.0	33.33	100.0	58	-3.16	25.45	-66.7	0.00	50.0
	Week 20	60	22.78	21.25	0.0	25.00	100.0	52	-10.58	25.78	-83.3	0.00	33.3
	Week 23	51	23.53	22.40	0.0	33.33	83.3	44	-8.33	27.26	-83.3	0.00	66.7
	Week 26	47	28.01	24.35	0.0	33.33	100.0	42	-6.75	26.81	-66.7	0.00	50.0
	Week 29	42	27.78	19.36	0.0	33.33	66.7	37	-3.60	17.63	-33.3	0.00	33.3
	Week 32	37	27.03	23.02	0.0	33.33	66.7	34	-1.47	23.70	-66.7	0.00	33.3
	Week 35	34	24.51	18.91	0.0	33.33	66.7	31	-3.76	24.23	-50.0	0.00	50.0
	Week 38	33	24.24	25.03	0.0	16.67	83.3	28	-7.14	28.84	-66.7	0.00	50.0
	Week 41	27	25.93	25.04	0.0	33.33	66.7	22	-1.51	29.06	-66.7	0.00	66.7
	Week 44	28	28.57	24.37	0.0	33.33	66.7	24	-3.47	26.91	-66.7	0.00	66.7
	Week 47	24	28.47	23.81	0.0	33.33	66.7	21	-2.38	25.97	-66.7	0.00	33.3
	Week 50	26	26.92	27.11	0.0	33.33	83.3	24	-5.56	25.38	-66.7	0.00	50.0
	Week 53	19	24.56	25.07	0.0	16.67	66.7	17	-3.92	23.96	-66.7	0.00	33.3
	Week 56	13	24.36	26.89	0.0	16.67	83.3	11	-4.54	26.97	-50.0	0.00	50.0
	Week 59	14	17.86	23.08	0.0	16.67	83.3	12	-9.72	22.98	-66.7	0.00	16.7
	Week 62	13	14.10	14.98	0.0	16.67	33.3	12	-11.11	19.24	-50.0	0.00	16.7
	Week 65	13	17.95	23.04	0.0	0.00	66.7	11	-4.54	21.20	-33.3	0.00	33.3
	Week 68	10	23.33	28.54	0.0	16.67	83.3	8	-6.25	15.27	-33.3	0.00	16.7
	Week 77	10	26.67	33.52	0.0	16.67	100.0	8	-6.25	19.79	-33.3	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>= 65 years	EV+Pembro (N=135)												
	BASELINE	114	26.17	26.51	0.0	16.67	100.0						
	Week 1	102	30.39	26.78	0.0	33.33	100.0	99	3.20	20.30	-66.7	0.00	66.7
	Week 2	111	31.38	26.94	0.0	33.33	100.0	103	6.63	21.31	-50.0	0.00	66.7
	Week 3	105	33.49	26.70	0.0	33.33	100.0	98	7.14	23.69	-50.0	0.00	66.7
	Week 4	104	25.48	23.10	0.0	33.33	83.3	97	0.52	23.87	-66.7	0.00	83.3
	Week 5	100	25.00	26.22	0.0	16.67	100.0	92	0.00	22.37	-66.7	0.00	66.7
	Week 6	98	28.23	26.69	0.0	33.33	100.0	89	4.49	25.22	-50.0	0.00	83.3
	Week 7	110	27.27	27.35	0.0	25.00	100.0	99	1.85	28.36	-66.7	0.00	83.3
	Week 8	102	26.80	26.34	0.0	25.00	100.0	91	1.65	27.45	-66.7	0.00	66.7
	Week 9	104	30.29	29.08	0.0	33.33	100.0	95	3.51	27.06	-66.7	0.00	83.3
	Week 10	103	25.73	24.12	0.0	16.67	100.0	94	1.77	24.62	-50.0	0.00	66.7
	Week 11	101	24.59	25.45	0.0	16.67	100.0	91	0.18	25.15	-66.7	0.00	83.3
	Week 12	100	24.33	25.45	0.0	16.67	100.0	92	-0.73	24.32	-50.0	0.00	66.7
	Week 14	101	22.44	21.14	0.0	16.67	100.0	91	-1.65	26.42	-66.7	0.00	83.3
	Week 17	95	24.91	23.93	0.0	33.33	100.0	85	1.37	23.74	-50.0	0.00	66.7
	Week 20	88	24.62	23.97	0.0	25.00	100.0	81	1.85	25.14	-50.0	0.00	66.7
	Week 23	84	25.40	24.47	0.0	16.67	100.0	78	3.85	27.12	-66.7	0.00	66.7
	Week 26	78	25.85	25.71	0.0	33.33	100.0	72	1.85	28.74	-50.0	0.00	83.3
	Week 29	83	23.49	23.14	0.0	33.33	100.0	78	1.50	26.07	-50.0	0.00	83.3
	Week 32	71	25.12	23.38	0.0	16.67	83.3	66	4.04	27.43	-50.0	0.00	83.3
	Week 35	70	30.00	23.50	0.0	33.33	83.3	64	5.73	27.25	-50.0	0.00	83.3
	Week 38	70	25.48	25.96	0.0	25.00	100.0	65	1.79	25.37	-50.0	0.00	66.7
	Week 41	65	28.20	23.74	0.0	33.33	100.0	60	7.78	29.19	-50.0	0.00	66.7
	Week 44	58	26.72	24.57	0.0	33.33	100.0	52	7.37	32.74	-50.0	0.00	100.0
	Week 47	53	24.21	22.06	0.0	16.67	83.3	48	4.51	27.01	-50.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	45	22.59	21.95	0.0	16.67	66.7	43	0.78	21.50	-33.3	0.00	50.0
	Week 53	39	23.50	21.53	0.0	33.33	83.3	37	4.05	27.61	-50.0	0.00	66.7
	Week 56	37	24.77	26.24	0.0	16.67	83.3	35	4.29	30.34	-50.0	0.00	66.7
	Week 59	30	23.89	25.02	0.0	16.67	83.3	29	2.87	27.12	-50.0	0.00	66.7
	Week 62	28	23.21	26.19	0.0	16.67	83.3	27	5.56	26.56	-50.0	0.00	50.0
	Week 65	24	25.69	26.46	0.0	16.67	83.3	23	0.72	22.74	-33.3	0.00	50.0
	Week 68	19	22.81	24.98	0.0	16.67	66.7	19	0.88	23.22	-50.0	0.00	33.3
	Week 71	19	22.81	26.18	0.0	16.67	83.3	19	3.51	24.58	-33.3	0.00	50.0
	Week 74	18	16.67	20.61	0.0	8.34	66.7	18	-2.78	23.04	-50.0	0.00	33.3
	Week 77	19	29.82	33.14	0.0	33.33	100.0	18	9.26	33.44	-50.0	0.00	66.7
	Week 80	16	21.88	25.62	0.0	8.34	66.7	15	-3.33	24.56	-50.0	0.00	33.3
	Week 83	14	19.05	21.54	0.0	8.34	50.0	13	-8.97	19.97	-50.0	0.00	16.7
	Week 86	14	13.10	17.51	0.0	0.00	50.0	13	-10.26	19.88	-50.0	0.00	16.7
	Week 89	14	22.62	29.68	0.0	8.34	100.0	14	-2.38	26.84	-50.0	0.00	50.0
	Week 92	13	21.80	27.54	0.0	0.00	66.7	13	-2.56	29.54	-50.0	0.00	66.7
	Week 95	10	20.00	29.19	0.0	0.00	83.3	10	-6.67	28.54	-50.0	0.00	50.0
	Week 98	10	23.34	30.63	0.0	8.34	66.7	10	-3.33	30.23	-50.0	-8.33	50.0
	Plat+Gem (N=136)												
	BASELINE	105	31.59	29.14	0.0	33.33	100.0						
	Week 1	98	33.16	29.16	0.0	33.33	100.0	87	0.19	20.25	-100.0	0.00	50.0
	Week 2	95	30.70	25.88	0.0	33.33	100.0	83	3.21	23.49	-100.0	0.00	66.7
	Week 3	104	27.56	26.66	0.0	25.00	100.0	89	-1.87	23.09	-100.0	0.00	33.3
	Week 4	104	25.32	26.38	0.0	16.67	100.0	89	-3.75	24.07	-100.0	0.00	83.3
	Week 5	107	28.19	26.44	0.0	33.33	100.0	89	1.68	24.88	-100.0	0.00	83.3
	Week 6	98	26.19	25.55	0.0	16.67	100.0	82	-0.20	26.38	-100.0	0.00	83.3
	Week 7	105	24.29	24.57	0.0	16.67	100.0	86	-2.13	25.79	-100.0	0.00	83.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 8	95	30.00	26.14	0.0	33.33	100.0	80	4.58	27.68	-83.3	0.00	83.3
	Week 9	99	27.27	26.35	0.0	16.67	100.0	81	1.85	27.26	-83.3	0.00	100.0
	Week 10	88	24.24	25.51	0.0	16.67	100.0	71	0.00	28.03	-100.0	0.00	83.3
	Week 11	93	24.73	25.37	0.0	16.67	100.0	77	-0.22	24.56	-100.0	0.00	66.7
	Week 12	85	25.69	26.67	0.0	16.67	100.0	72	1.62	25.35	-100.0	0.00	66.7
	Week 14	85	26.67	24.29	0.0	33.33	83.3	70	1.67	22.73	-66.7	0.00	66.7
	Week 17	87	26.24	25.37	0.0	16.67	100.0	72	2.78	28.94	-66.7	0.00	83.3
	Week 20	66	22.47	24.02	0.0	25.00	100.0	58	-0.86	24.07	-66.7	0.00	66.7
	Week 23	64	27.08	29.02	0.0	25.00	100.0	53	5.03	24.80	-33.3	0.00	66.7
	Week 26	61	26.78	28.10	0.0	16.67	100.0	53	6.60	25.81	-33.3	0.00	66.7
	Week 29	58	24.42	20.99	0.0	33.33	66.7	49	3.06	22.74	-33.3	0.00	66.7
	Week 32	46	25.36	25.76	0.0	16.67	100.0	42	5.56	24.60	-33.3	0.00	66.7
	Week 35	42	28.57	25.04	0.0	33.33	100.0	38	8.77	25.03	-33.3	0.00	66.7
	Week 38	41	23.17	27.86	0.0	16.67	100.0	37	4.95	25.72	-33.3	0.00	66.7
	Week 41	38	25.44	27.60	0.0	16.67	100.0	34	5.39	24.18	-33.3	0.00	66.7
	Week 44	32	31.77	29.44	0.0	33.33	100.0	29	11.49	25.24	-33.3	0.00	66.7
	Week 47	32	21.87	23.74	0.0	16.67	83.3	28	3.57	22.84	-33.3	0.00	66.7
	Week 50	25	29.33	31.28	0.0	16.67	100.0	23	10.15	23.43	-16.7	0.00	66.7
	Week 53	27	20.37	21.84	0.0	16.67	83.3	25	4.67	20.70	-33.3	0.00	66.7
	Week 56	26	28.85	26.06	0.0	33.33	100.0	23	7.97	26.53	-33.3	0.00	83.3
	Week 59	23	21.74	17.72	0.0	33.33	66.7	21	4.76	23.06	-50.0	0.00	66.7
	Week 62	19	22.81	18.60	0.0	33.33	66.7	17	5.88	23.53	-33.3	0.00	66.7
	Week 65	17	16.67	18.63	0.0	16.67	50.0	15	-1.11	21.33	-66.7	0.00	33.3
	Week 68	15	26.67	25.82	0.0	33.33	83.3	13	11.54	18.49	-16.7	16.66	33.3
	Week 71	15	25.55	26.63	0.0	33.33	100.0	13	3.85	16.88	-16.7	0.00	33.3
	Week 74	12	26.39	27.94	0.0	33.33	100.0	11	6.06	18.67	-16.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Europe	EV+Pembro (N= 98)												
	BASELINE	79	29.54	26.41	0.0	33.33	100.0						
	Week 1	74	30.63	25.88	0.0	33.33	100.0	71	1.64	18.72	-33.3	0.00	66.7
	Week 2	79	28.90	24.27	0.0	33.33	100.0	71	0.47	17.81	-50.0	0.00	66.7
	Week 3	78	32.69	26.52	0.0	33.33	100.0	69	4.35	24.20	-50.0	0.00	66.7
	Week 4	78	24.57	23.22	0.0	33.33	83.3	70	-0.48	24.40	-50.0	0.00	83.3
	Week 5	70	24.29	22.10	0.0	16.67	66.7	62	-2.42	22.35	-50.0	0.00	66.7
	Week 6	70	24.29	23.86	0.0	16.67	100.0	61	-2.73	27.42	-66.7	0.00	83.3
	Week 7	78	24.36	23.52	0.0	16.67	100.0	68	-3.68	25.73	-66.7	0.00	83.3
	Week 8	72	23.15	23.99	0.0	16.67	100.0	61	-3.28	28.68	-66.7	0.00	83.3
	Week 9	80	25.00	24.01	0.0	33.33	83.3	70	-2.38	27.84	-66.7	0.00	83.3
	Week 10	71	22.07	21.04	0.0	16.67	66.7	62	-5.11	24.63	-66.7	0.00	66.7
	Week 11	76	23.46	23.75	0.0	16.67	100.0	66	-5.81	24.55	-66.7	0.00	66.7
	Week 12	73	21.69	23.19	0.0	16.67	100.0	65	-6.67	25.65	-66.7	0.00	66.7
	Week 14	74	22.52	21.97	0.0	16.67	83.3	64	-4.95	24.07	-50.0	0.00	50.0
	Week 17	70	23.33	21.50	0.0	16.67	66.7	62	-5.38	26.96	-83.3	0.00	66.7
	Week 20	70	24.76	22.65	0.0	33.33	83.3	63	-1.32	26.15	-66.7	0.00	50.0
	Week 23	61	23.22	24.21	0.0	16.67	100.0	57	-4.09	27.33	-66.7	0.00	66.7
	Week 26	62	21.24	23.02	0.0	16.67	83.3	55	-6.06	23.87	-50.0	0.00	66.7
	Week 29	63	20.63	20.46	0.0	16.67	83.3	57	-4.68	21.76	-50.0	0.00	50.0
	Week 32	51	24.84	24.35	0.0	33.33	83.3	47	-1.77	22.85	-50.0	0.00	50.0
	Week 35	56	27.38	24.91	0.0	33.33	83.3	52	1.28	25.75	-50.0	0.00	66.7
	Week 38	51	24.18	24.11	0.0	16.67	100.0	48	-2.78	26.92	-50.0	0.00	50.0
	Week 41	52	24.04	22.73	0.0	33.33	66.7	48	-3.13	24.95	-50.0	0.00	66.7
	Week 44	43	24.42	24.76	0.0	16.67	100.0	39	0.00	31.30	-66.7	0.00	100.0
	Week 47	39	27.35	25.50	0.0	33.33	83.3	36	1.85	32.31	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	37	24.32	21.01	0.0	33.33	66.7	36	-1.39	25.63	-50.0	0.00	50.0
	Week 53	28	25.00	28.87	0.0	16.67	100.0	27	-4.32	33.52	-66.7	0.00	83.3
	Week 56	30	25.00	30.87	0.0	8.34	100.0	29	-1.15	36.71	-66.7	0.00	83.3
	Week 59	27	22.84	26.61	0.0	16.67	100.0	27	-1.85	33.12	-66.7	0.00	83.3
	Week 62	23	23.91	29.66	0.0	16.67	100.0	23	-0.72	35.70	-66.7	0.00	83.3
	Week 65	23	28.26	29.06	0.0	33.33	100.0	23	-2.17	29.86	-50.0	0.00	83.3
	Week 68	21	19.05	25.97	0.0	0.00	83.3	21	-11.11	29.97	-66.7	-16.66	66.7
	Week 71	19	22.81	27.89	0.0	0.00	83.3	19	-7.02	29.56	-66.7	0.00	50.0
	Week 74	15	20.00	23.74	0.0	0.00	66.7	15	-8.89	25.09	-66.7	0.00	33.3
	Week 77	19	28.95	31.84	0.0	33.33	100.0	19	-0.88	33.55	-66.7	0.00	66.7
	Week 80	17	17.65	19.96	0.0	16.67	50.0	17	-14.71	23.48	-66.7	-16.67	33.3
	Week 83	16	19.79	22.95	0.0	8.34	66.7	16	-13.54	24.51	-66.7	0.00	16.7
	Week 86	14	17.86	23.08	0.0	0.00	66.7	14	-10.72	16.80	-33.3	-16.67	16.7
	Week 89	14	25.00	25.11	0.0	33.33	66.7	14	-3.57	16.25	-33.3	0.00	33.3
	Week 92	11	16.67	19.72	0.0	0.00	50.0	11	-7.58	18.80	-33.3	0.00	33.3
	Week 95	10	26.67	22.50	0.0	33.33	66.7	10	0.00	22.22	-33.3	0.00	50.0
	Plat+Gem (N=102)												
	BASELINE	71	37.32	31.68	0.0	33.33	100.0						
	Week 1	71	38.97	29.13	0.0	33.33	100.0	61	0.82	21.18	-50.0	0.00	50.0
	Week 2	67	37.81	28.36	0.0	33.33	100.0	56	2.98	24.84	-33.3	0.00	66.7
	Week 3	68	34.56	30.24	0.0	33.33	100.0	56	-2.38	26.67	-66.7	0.00	100.0
	Week 4	75	32.44	28.85	0.0	33.33	100.0	59	-1.98	22.12	-50.0	0.00	83.3
	Week 5	77	30.52	28.79	0.0	33.33	100.0	60	0.00	26.57	-66.7	0.00	66.7
	Week 6	70	28.33	27.85	0.0	25.00	100.0	56	-3.27	29.55	-66.7	0.00	100.0
	Week 7	72	27.78	26.09	0.0	33.33	100.0	55	-4.24	27.07	-66.7	0.00	83.3
	Week 8	65	32.82	27.16	0.0	33.33	100.0	53	2.52	31.76	-83.3	0.00	83.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	70	28.33	27.27	0.0	25.00	100.0	55	-2.73	34.06	-83.3	0.00	100.0
	Week 10	60	29.44	28.19	0.0	33.33	100.0	46	0.72	31.42	-66.7	0.00	83.3
	Week 11	64	31.25	27.94	0.0	33.33	100.0	50	1.00	25.73	-66.7	0.00	66.7
	Week 12	60	28.61	26.94	0.0	33.33	100.0	48	-0.70	27.71	-66.7	0.00	66.7
	Week 14	56	31.84	26.64	0.0	33.33	100.0	42	0.00	26.80	-66.7	0.00	66.7
	Week 17	58	29.02	28.54	0.0	25.00	100.0	44	-1.52	27.33	-66.7	0.00	50.0
	Week 20	47	25.89	22.47	0.0	33.33	100.0	37	-4.51	25.05	-66.7	0.00	50.0
	Week 23	44	22.73	26.44	0.0	8.34	83.3	32	-1.04	24.66	-50.0	0.00	66.7
	Week 26	39	30.34	29.09	0.0	33.33	100.0	30	5.55	28.81	-50.0	0.00	66.7
	Week 29	34	26.47	18.85	0.0	33.33	66.7	25	-2.67	21.34	-33.3	0.00	50.0
	Week 32	33	26.77	25.32	0.0	33.33	100.0	27	0.62	26.75	-50.0	0.00	66.7
	Week 35	30	33.89	24.17	0.0	33.33	100.0	24	9.03	33.33	-50.0	8.33	66.7
	Week 38	26	32.05	29.03	0.0	33.33	100.0	21	9.52	30.54	-50.0	0.00	66.7
	Week 41	22	31.06	26.87	0.0	33.33	100.0	17	8.82	26.43	-33.3	0.00	66.7
	Week 44	20	40.00	30.78	0.0	50.00	100.0	16	12.50	30.73	-33.3	0.00	66.7
	Week 47	16	27.08	25.73	0.0	33.33	66.7	12	4.17	18.97	-33.3	0.00	33.3
	Week 50	11	39.39	34.38	0.0	33.33	100.0	10	11.67	31.48	-33.3	8.34	66.7
	Week 53	11	28.79	24.82	0.0	33.33	66.7	10	3.33	21.94	-33.3	0.00	33.3
	Week 56	10	36.67	30.23	0.0	33.33	100.0	8	6.25	23.46	-33.3	8.33	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
North America	EV+Pembro (N= 57)												
	BASELINE	47	35.46	30.62	0.0	33.33	100.0						
	Week 1	39	37.61	31.46	0.0	33.33	100.0	37	1.35	19.40	-50.0	0.00	66.7
	Week 2	44	39.02	32.54	0.0	33.33	100.0	42	5.56	22.89	-50.0	0.00	66.7
	Week 3	44	37.50	30.31	0.0	33.33	100.0	40	0.00	22.96	-50.0	0.00	66.7
	Week 4	44	27.27	27.40	0.0	16.67	100.0	41	-9.76	26.35	-100.0	0.00	50.0
	Week 5	47	25.53	26.43	0.0	16.67	100.0	41	-8.13	26.91	-100.0	0.00	50.0
	Week 6	44	28.03	24.84	0.0	33.33	100.0	39	-9.83	24.40	-66.7	0.00	33.3
	Week 7	46	24.64	26.93	0.0	25.00	100.0	42	-10.72	24.64	-100.0	0.00	33.3
	Week 8	47	25.18	28.21	0.0	16.67	100.0	42	-9.13	32.34	-100.0	0.00	66.7
	Week 9	46	30.07	28.89	0.0	33.33	100.0	42	-6.75	28.53	-66.7	0.00	66.7
	Week 10	47	25.18	25.03	0.0	16.67	83.3	44	-9.47	29.73	-100.0	0.00	33.3
	Week 11	47	24.82	23.28	0.0	16.67	83.3	42	-12.30	27.81	-100.0	0.00	33.3
	Week 12	44	27.65	27.12	0.0	33.33	83.3	40	-11.67	33.16	-100.0	0.00	50.0
	Week 14	43	22.09	25.64	0.0	16.67	100.0	39	-13.68	27.80	-100.0	0.00	33.3
	Week 17	40	29.17	28.68	0.0	25.00	100.0	37	-5.41	29.67	-100.0	0.00	33.3
	Week 20	38	26.75	28.09	0.0	33.33	100.0	35	-7.62	29.52	-66.7	0.00	50.0
	Week 23	38	25.00	27.33	0.0	16.67	100.0	35	-5.24	22.42	-50.0	0.00	33.3
	Week 26	35	22.86	29.45	0.0	16.67	100.0	32	-13.02	34.84	-100.0	-8.33	33.3
	Week 29	38	19.30	22.44	0.0	16.67	100.0	34	-13.24	30.09	-100.0	-8.33	33.3
	Week 32	32	20.31	24.22	0.0	8.34	83.3	29	-5.75	26.08	-66.7	0.00	50.0
	Week 35	33	21.72	25.51	0.0	16.67	100.0	30	-5.56	26.02	-66.7	0.00	50.0
	Week 38	32	18.75	26.35	0.0	0.00	100.0	29	-10.92	31.90	-100.0	0.00	50.0
	Week 41	28	16.67	17.57	0.0	16.67	50.0	24	-8.33	25.54	-50.0	-8.33	50.0
	Week 44	21	15.87	20.73	0.0	16.67	83.3	20	-6.67	31.25	-50.0	-8.33	83.3
	Week 47	24	15.97	20.55	0.0	0.00	66.7	23	-7.25	30.50	-100.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	23	21.01	22.60	0.0	16.67	66.7	20	-2.50	23.74	-50.0	0.00	33.3
	Week 53	17	11.76	14.15	0.0	0.00	33.3	14	-4.76	24.83	-50.0	0.00	33.3
	Week 56	20	15.00	18.65	0.0	8.34	66.7	17	-13.73	25.16	-50.0	-16.66	33.3
	Week 59	17	21.57	24.13	0.0	16.67	83.3	14	-1.19	28.84	-50.0	0.00	50.0
	Week 62	14	13.10	17.51	0.0	0.00	50.0	13	-8.97	28.56	-50.0	0.00	50.0
	Week 65	12	11.11	14.79	0.0	0.00	33.3	9	-9.26	20.60	-33.3	0.00	16.7
	Week 68	10	18.33	16.57	0.0	25.00	33.3	9	3.70	21.69	-33.3	0.00	33.3
	Week 71	10	16.67	15.71	0.0	16.67	33.3	8	2.08	24.29	-33.3	0.00	33.3
	Week 74	10	18.33	16.57	0.0	25.00	33.3	9	-1.85	32.75	-50.0	0.00	33.3
	Plat+Gem (N= 51)												
	BASELINE	42	25.79	23.34	0.0	33.33	83.3						
	Week 1	41	28.86	26.62	0.0	16.67	100.0	36	2.78	12.91	-33.3	0.00	33.3
	Week 2	38	28.95	24.41	0.0	33.33	100.0	33	4.04	17.20	-50.0	0.00	33.3
	Week 3	40	26.67	21.28	0.0	33.33	83.3	35	3.81	23.60	-50.0	0.00	66.7
	Week 4	35	23.33	21.47	0.0	16.67	66.7	29	-1.15	21.33	-50.0	0.00	33.3
	Week 5	39	27.35	23.10	0.0	33.33	100.0	32	4.17	22.80	-33.3	0.00	66.7
	Week 6	34	25.98	21.39	0.0	25.00	100.0	30	-0.56	19.32	-50.0	0.00	33.3
	Week 7	42	23.41	22.10	0.0	16.67	66.7	37	-0.45	20.97	-50.0	0.00	33.3
	Week 8	39	26.07	20.16	0.0	33.33	66.7	33	2.02	25.94	-50.0	0.00	50.0
	Week 9	39	25.21	22.90	0.0	16.67	66.7	33	-2.52	28.30	-50.0	0.00	66.7
	Week 10	39	23.50	19.01	0.0	33.33	66.7	32	-4.69	20.84	-50.0	0.00	33.3
	Week 11	39	21.37	18.71	0.0	16.67	66.7	33	-5.56	23.07	-50.0	0.00	33.3
	Week 12	36	23.61	19.67	0.0	25.00	66.7	32	-3.12	24.48	-66.7	0.00	33.3
	Week 14	34	20.10	14.67	0.0	25.00	33.3	29	-4.60	19.87	-50.0	0.00	33.3
	Week 17	37	28.38	21.11	0.0	33.33	66.7	31	3.76	30.03	-50.0	0.00	66.7
	Week 20	27	17.90	17.25	0.0	16.67	50.0	23	-10.14	27.40	-83.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 23	27	27.78	25.32	0.0	33.33	83.3	23	-2.17	34.56	-83.3	0.00	66.7
	Week 26	28	29.17	22.05	0.0	33.33	66.7	25	0.00	26.35	-66.7	0.00	33.3
	Week 29	29	28.16	18.42	0.0	33.33	50.0	25	3.33	19.84	-33.3	0.00	50.0
	Week 32	17	29.41	20.01	0.0	33.33	66.7	17	7.84	17.79	-16.7	16.66	33.3
	Week 35	16	25.00	18.26	0.0	33.33	50.0	15	4.44	18.33	-33.3	0.00	33.3
	Week 38	16	21.87	24.13	0.0	16.67	66.7	13	-3.85	18.20	-50.0	0.00	16.7
	Week 41	16	29.17	27.55	0.0	33.33	83.3	13	7.69	24.17	-33.3	0.00	50.0
	Week 44	13	28.20	20.84	0.0	33.33	66.7	11	3.03	14.56	-16.7	0.00	33.3
	Week 47	11	30.30	22.13	0.0	33.33	66.7	9	9.26	14.70	0.0	0.00	33.3
	Week 50	17	27.45	26.96	0.0	33.33	100.0	15	-2.22	24.29	-50.0	0.00	50.0
	Week 53	13	23.08	18.68	0.0	33.33	50.0	11	4.55	16.82	-16.7	0.00	33.3
	Week 56	11	37.88	27.98	0.0	33.33	83.3	9	20.37	34.13	-33.3	16.67	83.3
	Week 59	11	25.76	18.80	0.0	33.33	66.7	9	11.11	23.57	-16.7	0.00	66.7
	Week 62	11	22.73	21.44	0.0	33.33	66.7	9	7.41	26.50	-33.3	0.00	66.7
	Week 65	10	20.00	15.31	0.0	25.00	33.3	8	2.08	18.77	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Rest of World	EV+Pembro (N= 85)												
	BASELINE	80	28.33	29.70	0.0	16.67	100.0						
	Week 1	77	30.52	26.68	0.0	33.33	100.0	76	1.32	20.69	-66.7	0.00	66.7
	Week 2	80	32.08	24.27	0.0	33.33	100.0	76	5.04	24.04	-66.7	0.00	66.7
	Week 3	76	32.24	22.99	0.0	33.33	100.0	73	2.51	25.71	-66.7	0.00	66.7
	Week 4	72	23.38	20.87	0.0	16.67	83.3	68	-6.13	23.90	-66.7	0.00	33.3
	Week 5	73	21.69	24.32	0.0	16.67	83.3	70	-5.95	25.54	-83.3	0.00	50.0
	Week 6	74	26.35	24.52	0.0	33.33	100.0	70	0.24	27.73	-66.7	0.00	66.7
	Week 7	71	26.06	27.13	0.0	16.67	100.0	66	-1.77	33.73	-100.0	0.00	83.3
	Week 8	72	23.61	23.19	0.0	25.00	100.0	68	-6.13	30.87	-100.0	0.00	66.7
	Week 9	71	28.17	26.96	0.0	33.33	100.0	68	-1.23	31.32	-100.0	0.00	66.7
	Week 10	73	26.71	22.35	0.0	33.33	100.0	69	-1.45	29.39	-100.0	0.00	50.0
	Week 11	71	23.00	23.46	0.0	16.67	100.0	67	-3.48	31.59	-100.0	0.00	83.3
	Week 12	69	24.15	25.01	0.0	16.67	100.0	66	-3.03	29.08	-100.0	0.00	66.7
	Week 14	68	25.98	22.92	0.0	33.33	100.0	64	-1.56	30.82	-100.0	0.00	83.3
	Week 17	68	23.77	24.66	0.0	16.67	100.0	63	-1.59	30.92	-100.0	0.00	66.7
	Week 20	59	27.68	25.45	0.0	33.33	100.0	56	0.89	29.89	-66.7	0.00	66.7
	Week 23	63	30.69	26.47	0.0	33.33	100.0	59	5.93	33.30	-83.3	0.00	66.7
	Week 26	59	29.66	25.72	0.0	33.33	83.3	57	2.05	36.47	-100.0	0.00	83.3
	Week 29	56	26.49	23.31	0.0	33.33	83.3	54	2.47	32.12	-83.3	0.00	83.3
	Week 32	52	27.88	23.51	0.0	33.33	83.3	49	5.44	31.98	-83.3	16.66	83.3
	Week 35	43	31.78	22.66	0.0	33.33	83.3	40	5.00	30.00	-83.3	0.00	83.3
	Week 38	49	29.59	25.29	0.0	33.33	100.0	47	3.55	31.27	-83.3	0.00	66.7
	Week 41	49	31.29	26.71	0.0	33.33	100.0	47	6.03	34.48	-83.3	0.00	66.7
	Week 44	44	28.03	23.51	0.0	33.33	66.7	41	2.44	34.87	-83.3	0.00	66.7
	Week 47	37	26.58	25.29	0.0	33.33	100.0	35	2.38	32.88	-83.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	29	26.44	22.94	0.0	33.33	66.7	28	6.55	27.72	-50.0	0.00	66.7
	Week 53	34	26.47	20.56	0.0	33.33	66.7	33	6.06	33.29	-83.3	16.66	66.7
	Week 56	31	23.66	23.08	0.0	33.33	66.7	30	3.33	34.02	-83.3	0.00	66.7
	Week 59	28	25.60	23.78	0.0	33.33	66.7	27	2.47	34.50	-83.3	0.00	66.7
	Week 62	28	27.38	27.67	0.0	16.67	83.3	27	8.03	33.45	-66.7	0.00	83.3
	Week 65	23	34.06	26.34	0.0	33.33	83.3	22	9.09	38.74	-83.3	0.00	66.7
	Week 68	22	29.55	26.19	0.0	33.33	66.7	22	5.30	36.87	-83.3	8.33	66.7
	Week 71	22	29.55	26.69	0.0	25.00	83.3	22	6.06	37.28	-83.3	0.00	66.7
	Week 74	22	29.55	25.68	0.0	33.33	66.7	22	6.82	35.88	-83.3	0.00	66.7
	Week 77	18	35.19	26.75	0.0	33.33	83.3	17	11.77	38.08	-66.7	16.66	66.7
	Week 80	16	35.42	27.81	0.0	33.33	100.0	15	10.00	36.08	-83.3	16.66	66.7
	Week 83	16	35.42	23.47	0.0	33.33	83.3	15	7.78	35.56	-66.7	16.66	83.3
	Week 86	13	35.90	25.32	0.0	33.33	83.3	12	6.95	41.11	-66.7	16.67	83.3
	Week 89	12	33.33	23.57	0.0	33.33	83.3	12	4.17	43.30	-66.7	8.33	83.3
	Plat+Gem (N= 89)												
	BASELINE	75	33.11	25.78	0.0	33.33	100.0						
	Week 1	61	29.23	23.70	0.0	33.33	100.0	61	-1.09	24.51	-100.0	0.00	83.3
	Week 2	66	30.30	26.78	0.0	33.33	100.0	62	0.27	25.87	-100.0	0.00	66.7
	Week 3	76	28.29	25.10	0.0	33.33	100.0	71	-3.52	24.06	-100.0	0.00	33.3
	Week 4	73	26.48	25.88	0.0	33.33	100.0	68	-5.88	26.82	-100.0	0.00	83.3
	Week 5	71	26.99	23.63	0.0	33.33	83.3	64	-3.13	26.20	-100.0	0.00	83.3
	Week 6	70	29.05	27.76	0.0	33.33	100.0	63	-1.59	28.98	-100.0	0.00	83.3
	Week 7	72	28.47	25.40	0.0	33.33	100.0	65	-3.08	26.00	-100.0	0.00	66.7
	Week 8	63	26.98	24.03	0.0	33.33	83.3	58	-1.15	26.83	-66.7	0.00	83.3
	Week 9	68	25.98	22.93	0.0	33.33	83.3	62	-3.23	22.75	-50.0	0.00	66.7
	Week 10	67	23.63	22.50	0.0	33.33	100.0	61	-7.10	25.54	-100.0	0.00	83.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	65	23.85	22.04	0.0	16.67	83.3	60	-4.44	25.83	-100.0	0.00	66.7
	Week 12	63	24.60	23.16	0.0	33.33	83.3	58	-3.74	25.75	-100.0	0.00	66.7
	Week 14	63	27.25	22.26	0.0	33.33	66.7	57	-1.46	21.89	-50.0	0.00	33.3
	Week 17	60	27.78	26.52	0.0	33.33	100.0	55	-0.61	26.44	-66.7	0.00	83.3
	Week 20	52	22.11	25.07	0.0	16.67	100.0	50	-4.00	24.64	-66.7	0.00	66.7
	Week 23	44	26.89	26.95	0.0	33.33	100.0	42	-0.40	23.71	-50.0	0.00	50.0
	Week 26	41	23.17	26.58	0.0	16.67	100.0	40	-2.50	26.03	-50.0	0.00	66.7
	Week 29	37	23.42	23.06	0.0	16.67	66.7	36	0.00	21.46	-33.3	0.00	66.7
	Week 32	33	23.74	26.03	0.0	16.67	83.3	32	1.04	25.38	-66.7	0.00	66.7
	Week 35	30	20.56	21.30	0.0	16.67	66.7	30	-2.22	19.93	-33.3	0.00	50.0
	Week 38	32	17.71	24.30	0.0	0.00	83.3	31	-5.38	27.68	-66.7	0.00	50.0
	Week 41	27	19.14	24.77	0.0	0.00	66.7	26	-3.85	26.38	-66.7	0.00	66.7
	Week 44	27	24.07	25.46	0.0	16.67	66.7	26	0.64	28.08	-66.7	0.00	66.7
	Week 47	29	21.26	23.53	0.0	16.67	83.3	28	-2.98	27.98	-66.7	0.00	66.7
	Week 50	23	23.19	27.40	0.0	16.67	83.3	22	0.76	23.28	-66.7	0.00	50.0
	Week 53	22	18.18	24.62	0.0	0.00	83.3	21	-1.59	25.22	-66.7	0.00	66.7
	Week 56	18	15.74	17.59	0.0	8.34	50.0	17	-5.88	20.36	-50.0	0.00	33.3
	Week 59	17	13.73	14.71	0.0	16.67	33.3	16	-7.29	23.55	-66.7	0.00	33.3
	Week 62	16	17.71	15.48	0.0	16.67	33.3	15	-6.67	19.72	-50.0	0.00	33.3
	Week 65	15	12.22	19.38	0.0	0.00	50.0	14	-4.76	23.05	-66.7	0.00	33.3
	Week 68	12	22.22	27.83	0.0	8.34	83.3	11	9.09	18.80	-16.7	0.00	33.3
	Week 71	13	19.23	29.54	0.0	0.00	100.0	12	0.00	14.21	-16.7	0.00	33.3
	Week 74	10	18.33	31.87	0.0	0.00	100.0	10	1.67	19.95	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	EV+Pembro (N=198)												
	BASELINE	170	30.69	29.14	0.0	33.33	100.0						
	Week 1	157	32.06	26.92	0.0	33.33	100.0	152	1.32	20.35	-66.7	0.00	66.7
	Week 2	167	31.84	26.37	0.0	33.33	100.0	155	2.69	21.45	-50.0	0.00	66.7
	Week 3	161	33.85	26.77	0.0	33.33	100.0	147	3.17	25.08	-50.0	0.00	66.7
	Week 4	158	25.21	23.17	0.0	33.33	100.0	145	-4.48	25.78	-100.0	0.00	83.3
	Week 5	154	23.59	23.78	0.0	16.67	100.0	140	-5.48	25.32	-100.0	0.00	66.7
	Week 6	153	27.34	24.75	0.0	33.33	100.0	138	-2.66	27.78	-66.7	0.00	83.3
	Week 7	159	26.21	26.22	0.0	33.33	100.0	142	-3.87	28.74	-100.0	0.00	83.3
	Week 8	154	23.70	24.16	0.0	16.67	100.0	135	-6.30	29.99	-100.0	0.00	83.3
	Week 9	162	29.01	26.57	0.0	33.33	100.0	146	-1.71	29.54	-66.7	0.00	83.3
	Week 10	159	25.68	22.64	0.0	33.33	100.0	144	-4.05	27.75	-100.0	0.00	66.7
	Week 11	161	24.74	24.23	0.0	33.33	100.0	143	-5.48	28.58	-100.0	0.00	83.3
	Week 12	154	24.46	25.15	0.0	16.67	100.0	140	-6.55	28.81	-100.0	0.00	66.7
	Week 14	154	24.46	24.12	0.0	33.33	100.0	137	-5.23	28.64	-100.0	0.00	83.3
	Week 17	145	25.63	25.00	0.0	16.67	100.0	130	-3.21	28.99	-100.0	0.00	66.7
	Week 20	139	26.50	25.21	0.0	33.33	100.0	126	-2.25	29.24	-66.7	0.00	66.7
	Week 23	133	27.44	26.76	0.0	33.33	100.0	122	0.27	30.45	-83.3	0.00	66.7
	Week 26	129	24.42	26.27	0.0	16.67	100.0	118	-4.66	32.53	-100.0	0.00	83.3
	Week 29	131	22.65	22.65	0.0	16.67	100.0	120	-3.89	29.92	-100.0	0.00	83.3
	Week 32	111	25.07	24.61	0.0	33.33	83.3	102	-1.14	28.84	-83.3	0.00	83.3
	Week 35	109	26.91	24.94	0.0	33.33	100.0	100	-0.50	27.26	-83.3	0.00	83.3
	Week 38	107	24.92	26.44	0.0	33.33	100.0	100	-3.33	31.07	-100.0	0.00	66.7
	Week 41	103	24.59	24.35	0.0	33.33	100.0	94	-1.06	29.51	-83.3	0.00	66.7
	Week 44	88	22.54	23.44	0.0	16.67	100.0	81	-2.26	32.99	-83.3	0.00	100.0
	Week 47	80	23.12	23.64	0.0	16.67	83.3	75	-0.89	33.99	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	73	23.06	21.63	0.0	16.67	66.7	68	-0.98	26.53	-50.0	0.00	66.7
	Week 53	64	22.13	23.01	0.0	16.67	100.0	59	0.28	32.82	-83.3	0.00	83.3
	Week 56	66	20.96	25.71	0.0	8.34	100.0	61	-3.83	34.21	-83.3	0.00	83.3
	Week 59	58	22.13	24.26	0.0	16.67	100.0	54	-1.54	33.06	-83.3	0.00	83.3
	Week 62	54	23.46	26.60	0.0	16.67	100.0	52	1.92	34.87	-66.7	0.00	83.3
	Week 65	51	25.82	27.14	0.0	33.33	100.0	47	1.06	34.30	-83.3	0.00	83.3
	Week 68	49	21.77	24.11	0.0	16.67	83.3	48	-2.43	33.15	-83.3	0.00	66.7
	Week 71	47	23.76	25.71	0.0	16.67	83.3	45	0.37	33.80	-83.3	0.00	66.7
	Week 74	42	22.22	22.29	0.0	33.33	66.7	41	-0.41	32.59	-83.3	0.00	66.7
	Week 77	38	28.51	28.45	0.0	33.33	100.0	36	3.24	36.26	-66.7	0.00	66.7
	Week 80	35	24.29	25.67	0.0	16.67	100.0	32	-5.73	32.13	-83.3	0.00	66.7
	Week 83	32	26.04	25.02	0.0	33.33	83.3	30	-5.56	33.14	-66.7	0.00	83.3
	Week 86	30	24.44	24.26	0.0	33.33	83.3	27	-6.17	30.71	-66.7	0.00	83.3
	Week 89	28	27.38	27.30	0.0	33.33	100.0	26	-3.21	32.32	-66.7	0.00	83.3
	Week 92	24	27.78	28.94	0.0	25.00	100.0	22	0.00	25.72	-33.3	0.00	66.7
	Week 95	21	35.71	31.31	0.0	33.33	100.0	20	5.83	29.26	-33.3	0.00	50.0
	Week 98	16	22.92	27.81	0.0	16.67	83.3	15	-5.55	25.72	-33.3	-16.66	50.0
	Week 101	12	22.22	27.83	0.0	8.34	83.3	12	2.78	26.43	-33.3	0.00	66.7
	Week 104	10	25.00	30.68	0.0	8.34	66.7	10	0.00	29.40	-33.3	-8.33	50.0
	Plat+Gem (N=185)												
	BASELINE	146	32.19	28.68	0.0	33.33	100.0						
	Week 1	131	31.43	28.01	0.0	33.33	100.0	120	0.83	20.37	-100.0	0.00	83.3
	Week 2	128	32.68	28.01	0.0	33.33	100.0	115	2.61	23.84	-100.0	0.00	66.7
	Week 3	141	30.02	27.18	0.0	33.33	100.0	126	-1.19	24.96	-100.0	0.00	100.0
	Week 4	139	28.90	27.04	0.0	33.33	100.0	119	-3.36	23.73	-100.0	0.00	83.3
	Week 5	143	28.09	26.12	0.0	33.33	100.0	120	0.14	25.52	-100.0	0.00	83.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 6	133	28.32	26.19	0.0	33.33	100.0	114	-0.73	27.46	-100.0	0.00	100.0
	Week 7	142	26.06	24.35	0.0	33.33	100.0	120	-3.61	24.18	-100.0	0.00	66.7
	Week 8	125	27.87	24.02	0.0	33.33	100.0	109	1.22	27.47	-83.3	0.00	83.3
	Week 9	135	25.56	23.64	0.0	33.33	100.0	115	-2.03	26.78	-66.7	0.00	100.0
	Week 10	131	24.17	23.68	0.0	33.33	100.0	111	-5.56	25.66	-100.0	0.00	83.3
	Week 11	128	23.83	23.26	0.0	16.67	100.0	109	-4.28	24.68	-100.0	0.00	66.7
	Week 12	124	24.33	23.51	0.0	33.33	100.0	108	-4.01	25.77	-100.0	0.00	66.7
	Week 14	121	26.03	22.45	0.0	33.33	100.0	101	-1.82	22.84	-66.7	0.00	50.0
	Week 17	121	26.72	25.77	0.0	33.33	100.0	101	-0.17	26.93	-66.7	0.00	66.7
	Week 20	98	22.62	23.84	0.0	16.67	100.0	86	-4.07	26.31	-83.3	0.00	66.7
	Week 23	93	24.37	25.84	0.0	16.67	83.3	78	-0.86	26.85	-83.3	0.00	66.7
	Week 26	86	25.78	25.39	0.0	16.67	100.0	75	1.56	27.29	-66.7	0.00	66.7
	Week 29	76	24.34	20.26	0.0	33.33	66.7	65	1.79	22.07	-33.3	0.00	66.7
	Week 32	62	22.31	21.96	0.0	16.67	66.7	56	2.38	23.01	-66.7	0.00	66.7
	Week 35	58	23.85	20.73	0.0	33.33	83.3	52	3.21	22.88	-33.3	0.00	66.7
	Week 38	60	20.83	24.09	0.0	16.67	100.0	52	-1.60	25.41	-66.7	0.00	66.7
	Week 41	52	24.04	27.30	0.0	16.67	100.0	44	3.41	27.75	-66.7	0.00	66.7
	Week 44	46	28.26	28.08	0.0	25.00	100.0	40	5.00	28.55	-66.7	0.00	66.7
	Week 47	44	21.21	22.55	0.0	16.67	66.7	38	0.00	23.57	-66.7	0.00	50.0
	Week 50	42	27.78	30.06	0.0	25.00	100.0	38	3.07	27.36	-66.7	0.00	66.7
	Week 53	38	17.98	20.64	0.0	8.34	66.7	34	-0.49	19.88	-66.7	0.00	33.3
	Week 56	32	25.00	25.04	0.0	25.00	83.3	28	6.55	28.45	-50.0	0.00	83.3
	Week 59	31	19.89	20.82	0.0	16.67	83.3	27	2.47	23.89	-66.7	0.00	66.7
	Week 62	29	18.39	18.01	0.0	16.67	66.7	26	0.64	23.32	-50.0	0.00	66.7
	Week 65	25	15.33	19.20	0.0	0.00	66.7	21	-1.59	17.40	-33.3	0.00	33.3
	Week 68	20	21.67	23.63	0.0	16.67	83.3	16	5.21	18.97	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 71	17	19.61	22.23	0.0	16.67	83.3	14	1.19	13.81	-16.7	0.00	33.3
	Week 74	17	22.55	28.22	0.0	16.67	100.0	14	0.00	19.61	-33.3	0.00	33.3
	Week 77	16	30.21	32.90	0.0	16.67	100.0	13	2.57	27.93	-33.3	0.00	66.7
	Week 80	13	20.51	16.88	0.0	16.67	50.0	12	2.78	15.62	-16.7	0.00	33.3
	Week 83	11	19.70	17.98	0.0	16.67	50.0	10	0.00	19.24	-33.3	0.00	33.3
	Week 86	12	12.50	17.59	0.0	0.00	50.0	11	-6.06	17.11	-33.3	0.00	16.7
	Week 89	11	16.67	16.67	0.0	16.67	33.3	10	-3.33	21.94	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	EV+Pembro (N= 42)												
	BASELINE	36	29.17	26.84	0.0	33.33	100.0						
	Week 1	33	31.82	30.15	0.0	33.33	100.0	32	2.08	15.70	-33.3	0.00	33.3
	Week 2	36	34.72	26.84	0.0	33.33	100.0	34	6.86	22.52	-66.7	0.00	66.7
	Week 3	37	32.43	23.22	0.0	33.33	100.0	35	0.48	21.95	-66.7	0.00	50.0
	Week 4	36	22.69	24.28	0.0	16.67	83.3	34	-5.88	20.47	-33.3	0.00	33.3
	Week 5	36	23.61	25.31	0.0	16.67	83.3	33	-4.04	22.45	-50.0	0.00	50.0
	Week 6	35	20.00	21.31	0.0	16.67	100.0	32	-5.21	23.74	-50.0	0.00	66.7
	Week 7	36	19.91	22.12	0.0	16.67	100.0	34	-7.84	29.37	-100.0	0.00	66.7
	Week 8	37	24.32	27.10	0.0	16.67	100.0	36	-4.17	32.21	-100.0	0.00	66.7
	Week 9	35	19.52	23.39	0.0	16.67	100.0	34	-8.33	27.90	-100.0	0.00	66.7
	Week 10	32	19.27	21.63	0.0	16.67	83.3	31	-8.06	28.83	-100.0	0.00	50.0
	Week 11	33	18.18	18.33	0.0	16.67	66.7	32	-10.94	26.64	-100.0	0.00	33.3
	Week 12	32	21.87	23.35	0.0	25.00	83.3	31	-5.91	29.67	-100.0	0.00	50.0
	Week 14	31	19.89	17.44	0.0	16.67	66.7	30	-7.78	24.66	-100.0	0.00	33.3
	Week 17	33	21.21	21.76	0.0	16.67	66.7	32	-6.77	29.59	-100.0	0.00	33.3
	Week 20	28	25.00	23.35	0.0	25.00	83.3	28	-0.60	24.21	-50.0	0.00	50.0
	Week 23	29	22.41	21.49	0.0	16.67	66.7	29	-3.45	22.88	-50.0	0.00	50.0
	Week 26	27	26.54	23.23	0.0	33.33	66.7	26	-3.21	30.92	-100.0	0.00	33.3
	Week 29	26	21.15	19.18	0.0	16.67	66.7	25	-4.67	20.14	-50.0	0.00	33.3
	Week 32	24	24.31	21.41	0.0	25.00	66.7	23	5.80	21.09	-50.0	0.00	50.0
	Week 35	23	29.71	22.45	0.0	33.33	66.7	22	6.82	27.53	-50.0	0.00	66.7
	Week 38	25	24.67	19.91	0.0	33.33	66.7	24	2.08	25.68	-50.0	0.00	50.0
	Week 41	26	27.56	22.08	0.0	33.33	66.7	25	1.33	30.01	-66.7	0.00	50.0
	Week 44	20	31.67	24.12	0.0	33.33	83.3	19	7.90	30.61	-50.0	0.00	83.3
	Week 47	20	29.17	28.03	0.0	33.33	100.0	19	2.63	23.08	-50.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	16	29.17	23.17	0.0	33.33	66.7	16	9.37	21.92	-33.3	0.00	50.0
	Week 53	15	25.56	25.09	0.0	16.67	66.7	15	0.00	29.55	-50.0	0.00	66.7
	Week 56	15	26.67	24.23	0.0	16.67	66.7	15	4.45	31.16	-50.0	0.00	66.7
	Week 59	14	29.76	26.29	0.0	25.00	66.7	14	5.95	30.39	-50.0	0.00	66.7
	Week 62	11	21.21	28.95	0.0	16.67	83.3	11	-1.51	27.34	-50.0	0.00	50.0
	Plat+Gem (N= 57)												
	BASELINE	42	36.11	24.94	0.0	33.33	100.0						
	Week 1	42	38.49	23.13	0.0	33.33	83.3	38	-0.44	23.08	-50.0	0.00	50.0
	Week 2	43	33.72	24.26	0.0	33.33	83.3	36	0.46	23.73	-33.3	0.00	66.7
	Week 3	43	31.01	24.28	0.0	33.33	83.3	36	-2.78	25.04	-50.0	0.00	50.0
	Week 4	44	26.52	24.99	0.0	33.33	100.0	37	-4.05	25.58	-33.3	-16.66	83.3
	Week 5	44	29.92	24.53	0.0	33.33	83.3	36	-2.32	26.47	-33.3	-8.33	66.7
	Week 6	41	27.64	28.04	0.0	33.33	100.0	35	-6.19	27.14	-66.7	0.00	83.3
	Week 7	44	30.30	26.72	0.0	33.33	100.0	37	-0.45	28.46	-33.3	0.00	83.3
	Week 8	42	32.54	26.02	0.0	33.33	83.3	35	0.00	31.57	-66.7	0.00	66.7
	Week 9	42	30.56	27.53	0.0	33.33	83.3	35	-5.71	33.32	-83.3	0.00	66.7
	Week 10	35	31.43	24.84	0.0	33.33	100.0	28	2.38	30.33	-33.3	0.00	83.3
	Week 11	40	33.33	25.32	0.0	33.33	83.3	34	1.96	26.52	-33.3	0.00	66.7
	Week 12	35	31.43	24.84	0.0	33.33	83.3	30	2.78	26.65	-33.3	0.00	66.7
	Week 14	32	32.29	24.30	0.0	33.33	83.3	27	-1.23	24.43	-50.0	0.00	66.7
	Week 17	34	34.31	26.25	0.0	33.33	100.0	29	1.15	29.86	-33.3	0.00	83.3
	Week 20	28	22.62	18.26	0.0	33.33	50.0	24	-10.42	20.74	-50.0	-8.34	33.3
	Week 23	22	30.30	28.00	0.0	33.33	100.0	19	-1.75	26.58	-50.0	0.00	50.0
	Week 26	22	33.33	29.99	0.0	33.33	100.0	20	-2.50	26.09	-50.0	0.00	33.3
	Week 29	24	30.56	20.06	0.0	33.33	66.7	21	-4.76	15.94	-33.3	0.00	33.3
	Week 32	21	37.30	28.34	0.0	33.33	100.0	20	2.50	28.24	-50.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 35	18	36.11	25.73	0.0	33.33	100.0	17	2.94	32.40	-50.0	0.00	66.7
	Week 38	14	35.71	33.24	0.0	33.33	100.0	13	5.13	35.61	-50.0	0.00	66.7
	Week 41	13	32.05	22.01	0.0	33.33	66.7	12	0.00	20.10	-33.3	0.00	33.3
	Week 44	14	36.90	22.81	0.0	41.67	66.7	13	3.85	21.68	-33.3	0.00	50.0
	Week 47	12	37.50	24.75	0.0	33.33	83.3	11	4.55	26.97	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Visceral metastases	EV+Pembro (N=170)												
	BASELINE	146	32.08	30.20	0.0	33.33	100.0						
	Week 1	135	34.20	29.10	0.0	33.33	100.0	131	0.76	19.71	-66.7	0.00	66.7
	Week 2	145	32.64	26.20	0.0	33.33	100.0	134	2.11	22.24	-66.7	0.00	66.7
	Week 3	141	34.52	27.29	0.0	33.33	100.0	129	1.16	25.19	-66.7	0.00	66.7
	Week 4	136	26.59	24.29	0.0	33.33	100.0	125	-4.80	26.25	-100.0	0.00	83.3
	Week 5	131	23.54	24.54	0.0	16.67	100.0	118	-7.63	26.03	-100.0	0.00	66.7
	Week 6	127	26.77	24.77	0.0	33.33	100.0	113	-3.54	29.08	-66.7	0.00	83.3
	Week 7	135	26.54	26.57	0.0	33.33	100.0	121	-5.92	31.69	-100.0	0.00	83.3
	Week 8	131	24.43	24.66	0.0	16.67	100.0	118	-7.77	30.64	-100.0	0.00	83.3
	Week 9	136	26.84	27.46	0.0	33.33	100.0	124	-4.97	29.68	-100.0	0.00	83.3
	Week 10	135	24.44	22.47	0.0	33.33	100.0	124	-6.18	28.94	-100.0	0.00	66.7
	Week 11	134	24.13	23.71	0.0	16.67	100.0	121	-7.30	29.73	-100.0	0.00	83.3
	Week 12	131	22.39	24.00	0.0	16.67	100.0	120	-9.45	30.00	-100.0	0.00	66.7
	Week 14	130	23.46	22.13	0.0	33.33	100.0	117	-7.84	30.05	-100.0	0.00	83.3
	Week 17	124	24.46	24.27	0.0	16.67	100.0	111	-5.86	32.23	-100.0	0.00	66.7
	Week 20	115	25.22	23.50	0.0	33.33	100.0	105	-4.29	29.24	-66.7	0.00	66.7
	Week 23	111	24.92	24.81	0.0	16.67	100.0	103	-3.72	30.78	-83.3	0.00	66.7
	Week 26	106	22.80	25.54	0.0	16.67	100.0	97	-8.76	33.77	-100.0	0.00	83.3
	Week 29	106	19.97	21.38	0.0	16.67	100.0	98	-7.82	29.33	-100.0	0.00	83.3
	Week 32	92	23.91	23.87	0.0	16.67	83.3	85	-3.33	28.96	-83.3	0.00	83.3
	Week 35	86	24.61	23.39	0.0	33.33	83.3	79	-3.17	29.12	-83.3	0.00	83.3
	Week 38	90	22.78	25.78	0.0	16.67	100.0	84	-6.35	31.04	-100.0	0.00	66.7
	Week 41	87	24.14	23.95	0.0	33.33	100.0	81	-4.53	31.29	-83.3	0.00	66.7
	Week 44	73	22.37	23.11	0.0	16.67	100.0	68	-5.15	33.61	-83.3	0.00	100.0
	Week 47	68	22.06	23.47	0.0	16.67	100.0	63	-4.50	32.54	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	61	23.50	21.60	0.0	16.67	66.7	57	-0.58	25.19	-50.0	0.00	66.7
	Week 53	54	22.84	25.14	0.0	16.67	100.0	50	-1.00	34.41	-83.3	0.00	83.3
	Week 56	58	20.69	25.80	0.0	8.34	100.0	54	-4.32	35.93	-83.3	0.00	83.3
	Week 59	50	22.33	25.33	0.0	16.67	100.0	47	-1.42	34.72	-83.3	0.00	83.3
	Week 62	45	19.63	24.95	0.0	16.67	100.0	43	-3.49	33.44	-66.7	0.00	83.3
	Week 65	37	24.32	25.64	0.0	16.67	100.0	34	-2.94	33.70	-83.3	0.00	83.3
	Week 68	35	20.95	23.69	0.0	16.67	83.3	34	-5.88	32.54	-83.3	0.00	66.7
	Week 71	31	20.97	23.95	0.0	16.67	83.3	30	-7.22	33.53	-83.3	0.00	66.7
	Week 74	29	18.97	23.45	0.0	0.00	66.7	28	-8.33	32.87	-83.3	0.00	66.7
	Week 77	26	28.20	27.39	0.0	33.33	100.0	25	-2.67	38.69	-66.7	0.00	66.7
	Week 80	22	23.48	23.38	0.0	25.00	66.7	21	-12.70	34.12	-83.3	-16.67	33.3
	Week 83	23	21.01	20.85	0.0	16.67	66.7	22	-12.88	30.83	-66.7	0.00	33.3
	Week 86	21	21.43	23.65	0.0	16.67	66.7	20	-11.67	29.17	-66.7	-8.34	33.3
	Week 89	21	27.78	31.77	0.0	16.67	100.0	20	-8.33	29.37	-66.7	0.00	50.0
	Week 92	18	27.78	29.70	0.0	25.00	100.0	17	-1.96	31.11	-50.0	0.00	66.7
	Week 95	13	29.49	32.74	0.0	16.67	100.0	12	-1.39	35.15	-50.0	0.00	50.0
	Week 98	11	15.15	21.67	0.0	0.00	66.7	11	-13.64	24.52	-50.0	-16.66	33.3
	Week 101	11	22.73	29.13	0.0	0.00	83.3	11	-3.03	31.46	-50.0	0.00	66.7
	Plat+Gem (N=161)												
	BASELINE	129	37.08	27.81	0.0	33.33	100.0						
	Week 1	113	35.25	26.33	0.0	33.33	100.0	105	-1.11	21.09	-100.0	0.00	50.0
	Week 2	108	36.42	28.01	0.0	33.33	100.0	98	0.00	23.45	-100.0	0.00	66.7
	Week 3	121	31.27	25.14	0.0	33.33	100.0	109	-4.13	24.34	-100.0	0.00	66.7
	Week 4	116	30.17	26.18	0.0	33.33	100.0	101	-6.77	23.12	-100.0	0.00	50.0
	Week 5	121	28.79	25.91	0.0	33.33	100.0	104	-4.33	24.14	-100.0	0.00	66.7
	Week 6	118	29.52	26.37	0.0	33.33	100.0	102	-4.74	25.52	-100.0	0.00	50.0

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 7	121	27.96	24.36	0.0	33.33	100.0	104	-5.77	24.88	-100.0	0.00	83.3
	Week 8	108	27.16	22.39	0.0	33.33	100.0	96	-4.86	25.58	-83.3	0.00	50.0
	Week 9	114	25.29	21.98	0.0	33.33	66.7	99	-8.25	25.35	-83.3	0.00	50.0
	Week 10	109	24.77	22.18	0.0	33.33	100.0	94	-9.40	25.35	-100.0	0.00	83.3
	Week 11	109	25.38	22.97	0.0	33.33	100.0	95	-7.37	24.52	-100.0	0.00	50.0
	Week 12	103	27.02	22.64	0.0	33.33	100.0	91	-5.68	26.67	-100.0	0.00	50.0
	Week 14	98	28.57	22.58	0.0	33.33	100.0	85	-4.12	23.56	-66.7	0.00	66.7
	Week 17	103	27.67	24.65	0.0	33.33	100.0	89	-4.87	25.40	-66.7	0.00	66.7
	Week 20	82	23.58	22.82	0.0	33.33	100.0	75	-8.67	25.90	-83.3	0.00	66.7
	Week 23	77	27.06	27.58	0.0	33.33	100.0	68	-4.17	27.83	-83.3	0.00	66.7
	Week 26	71	27.23	25.70	0.0	33.33	100.0	65	-2.82	24.40	-66.7	0.00	50.0
	Week 29	65	25.13	19.79	0.0	33.33	66.7	59	-3.96	17.60	-33.3	0.00	33.3
	Week 32	52	26.92	22.42	0.0	33.33	83.3	49	0.34	21.91	-50.0	0.00	33.3
	Week 35	47	28.37	20.83	0.0	33.33	83.3	44	0.00	24.90	-50.0	0.00	50.0
	Week 38	42	25.00	26.61	0.0	16.67	100.0	39	-2.14	27.35	-50.0	0.00	66.7
	Week 41	35	26.19	27.50	0.0	16.67	100.0	32	0.52	25.57	-33.3	0.00	66.7
	Week 44	36	32.87	28.03	0.0	33.33	100.0	33	5.05	26.18	-33.3	0.00	66.7
	Week 47	32	24.48	22.39	0.0	33.33	66.7	30	-2.78	20.10	-50.0	0.00	33.3
	Week 50	30	27.78	29.14	0.0	16.67	100.0	29	-1.72	24.54	-50.0	0.00	66.7
	Week 53	25	22.00	21.90	0.0	16.67	66.7	24	1.39	20.21	-33.3	0.00	33.3
	Week 56	22	28.03	25.91	0.0	33.33	83.3	21	7.14	31.43	-33.3	0.00	83.3
	Week 59	22	20.45	17.77	0.0	16.67	66.7	21	2.38	24.88	-50.0	0.00	66.7
	Week 62	19	21.93	18.47	0.0	33.33	66.7	18	1.85	26.75	-33.3	0.00	66.7
	Week 65	19	16.67	19.24	0.0	16.67	50.0	18	-1.85	24.18	-66.7	0.00	33.3
	Week 68	13	19.23	25.32	0.0	16.67	83.3	12	5.56	21.71	-33.3	0.00	33.3
	Week 71	13	28.20	30.72	0.0	33.33	100.0	12	8.33	18.12	-16.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 74	11	22.73	30.07	0.0	16.67	100.0	11	3.03	19.46	-33.3	0.00	33.3
	Week 77	10	13.33	15.31	0.0	8.34	33.3	10	-5.00	15.81	-33.3	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
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Table 302.1.3002.16.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Lymph node only	EV+Pembro (N= 60)												
	BASELINE	53	26.41	23.67	0.0	33.33	100.0						
	Week 1	49	26.53	22.29	0.0	33.33	83.3	47	2.13	19.85	-33.3	0.00	66.7
	Week 2	50	33.00	27.66	0.0	33.33	100.0	48	7.64	20.62	-33.3	0.00	66.7
	Week 3	50	31.33	23.48	0.0	33.33	100.0	47	5.32	21.45	-33.3	0.00	66.7
	Week 4	50	20.00	20.48	0.0	16.67	83.3	47	-4.96	18.69	-50.0	0.00	33.3
	Week 5	53	24.21	23.70	0.0	16.67	83.3	49	-0.34	21.65	-50.0	0.00	50.0
	Week 6	53	25.47	24.15	0.0	16.67	100.0	50	-1.67	22.14	-50.0	0.00	66.7
	Week 7	52	20.83	20.31	0.0	16.67	100.0	48	-2.78	18.94	-50.0	0.00	66.7
	Week 8	52	22.76	25.36	0.0	16.67	100.0	47	-2.48	28.86	-100.0	0.00	66.7
	Week 9	53	29.24	22.86	0.0	33.33	100.0	49	1.70	25.51	-66.7	0.00	66.7
	Week 10	48	24.65	22.28	0.0	16.67	83.3	44	-2.27	23.18	-83.3	0.00	50.0
	Week 11	53	23.58	23.67	0.0	16.67	100.0	48	-3.47	24.30	-50.0	0.00	66.7
	Week 12	48	29.86	27.28	0.0	33.33	100.0	45	2.59	24.09	-50.0	0.00	66.7
	Week 14	48	23.61	24.02	0.0	16.67	83.3	44	-2.27	21.44	-50.0	0.00	50.0
	Week 17	46	26.09	23.48	0.0	33.33	100.0	44	0.38	19.19	-50.0	0.00	33.3
	Week 20	44	28.41	27.74	0.0	33.33	100.0	42	2.38	25.12	-66.7	0.00	50.0
	Week 23	43	26.74	25.75	0.0	33.33	100.0	41	2.85	22.02	-33.3	0.00	66.7
	Week 26	42	27.38	24.09	0.0	33.33	83.3	40	2.50	25.19	-50.0	0.00	66.7
	Week 29	45	27.04	22.55	0.0	33.33	83.3	42	1.98	23.91	-66.7	0.00	66.7
	Week 32	38	27.63	24.90	0.0	33.33	66.7	36	6.02	22.94	-50.0	0.00	66.7
	Week 35	42	32.14	25.87	0.0	33.33	100.0	40	5.83	19.81	-50.0	0.00	50.0
	Week 38	38	27.19	23.70	0.0	33.33	83.3	36	2.31	23.28	-50.0	0.00	66.7
	Week 41	37	27.03	23.36	0.0	33.33	83.3	34	5.39	21.21	-33.3	0.00	50.0
	Week 44	31	26.34	23.87	0.0	33.33	66.7	29	6.32	25.36	-33.3	0.00	66.7
	Week 47	28	26.19	26.23	0.0	33.33	83.3	27	3.70	26.28	-50.0	0.00	66.7

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Table 302.1.3002.16.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	25	22.67	21.98	0.0	33.33	66.7	24	0.00	24.08	-50.0	0.00	33.3
	Week 53	23	20.29	17.38	0.0	16.67	50.0	22	0.00	24.12	-66.7	0.00	33.3
	Week 56	21	23.02	23.85	0.0	16.67	83.3	20	0.00	24.18	-50.0	0.00	33.3
	Week 59	20	24.17	22.60	0.0	25.00	66.7	19	0.00	24.22	-33.3	0.00	50.0
	Week 62	19	28.95	29.31	0.0	33.33	83.3	19	8.77	30.11	-33.3	0.00	83.3
	Week 65	20	30.00	27.89	0.0	33.33	83.3	19	5.26	28.36	-50.0	0.00	66.7
	Week 68	17	25.49	25.77	0.0	33.33	66.7	17	2.94	28.40	-50.0	0.00	66.7
	Week 71	19	28.07	26.67	0.0	33.33	83.3	18	9.26	25.06	-33.3	0.00	66.7
	Week 74	17	30.39	20.61	0.0	33.33	66.7	17	9.80	24.34	-33.3	0.00	66.7
	Week 77	17	30.39	29.01	0.0	33.33	83.3	16	7.29	25.80	-33.3	0.00	50.0
	Week 80	17	27.45	28.22	0.0	33.33	100.0	15	1.11	21.33	-50.0	0.00	33.3
	Week 83	13	32.05	25.87	0.0	33.33	83.3	12	0.00	21.32	-50.0	0.00	33.3
	Week 86	12	29.17	23.70	0.0	33.33	66.7	10	-1.67	19.95	-33.3	0.00	33.3
	Week 89	11	28.79	21.20	0.0	33.33	50.0	10	1.67	27.72	-50.0	0.00	50.0
	Plat+Gem (N= 67)												
	BASELINE	49	24.49	25.48	0.0	16.67	83.3						
	Week 1	51	28.10	25.49	0.0	16.67	83.3	45	1.85	18.20	-33.3	0.00	50.0
	Week 2	53	27.36	24.04	0.0	33.33	83.3	44	5.30	22.95	-33.3	0.00	66.7
	Week 3	53	29.56	30.25	0.0	16.67	100.0	44	3.41	27.28	-50.0	0.00	100.0
	Week 4	58	24.71	25.79	0.0	25.00	83.3	47	0.00	22.52	-33.3	0.00	83.3
	Week 5	56	27.68	25.68	0.0	33.33	100.0	44	4.92	26.31	-50.0	0.00	66.7
	Week 6	48	24.31	26.40	0.0	16.67	100.0	40	1.67	29.91	-50.0	0.00	100.0
	Week 7	56	26.19	26.37	0.0	16.67	100.0	46	1.45	26.02	-50.0	0.00	66.7
	Week 8	52	32.69	28.58	0.0	33.33	100.0	42	11.91	31.30	-33.3	0.00	83.3
	Week 9	53	30.19	28.88	0.0	33.33	100.0	42	7.54	32.34	-50.0	0.00	100.0
	Week 10	47	27.66	26.98	0.0	33.33	100.0	36	6.48	26.21	-33.3	0.00	83.3

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Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	51	27.78	25.53	0.0	33.33	83.3	41	5.69	24.33	-50.0	0.00	66.7
	Week 12	47	25.18	25.98	0.0	33.33	100.0	39	3.42	23.63	-33.3	0.00	66.7
	Week 14	47	24.47	23.27	0.0	33.33	83.3	36	2.31	22.94	-50.0	0.00	33.3
	Week 17	45	30.00	27.89	0.0	33.33	100.0	35	9.52	28.38	-50.0	0.00	66.7
	Week 20	38	19.30	18.79	0.0	16.67	50.0	30	-1.67	20.22	-33.3	0.00	33.3
	Week 23	32	22.40	23.04	0.0	25.00	66.7	25	5.33	22.42	-33.3	0.00	66.7
	Week 26	30	27.22	29.19	0.0	25.00	100.0	24	6.94	31.44	-50.0	0.00	66.7
	Week 29	28	26.19	21.48	0.0	33.33	66.7	21	7.14	23.32	-33.3	0.00	50.0
	Week 32	26	24.36	28.38	0.0	16.67	100.0	22	5.30	29.72	-66.7	0.00	66.7
	Week 35	23	26.09	24.53	0.0	16.67	100.0	19	10.53	25.59	-33.3	0.00	66.7
	Week 38	26	22.44	27.06	0.0	8.34	100.0	20	1.67	29.07	-66.7	0.00	66.7
	Week 41	24	27.08	26.38	0.0	33.33	83.3	18	6.48	29.23	-66.7	0.00	66.7
	Week 44	18	29.63	24.63	0.0	33.33	66.7	14	4.76	30.26	-66.7	0.00	66.7
	Week 47	18	26.85	23.67	0.0	33.33	66.7	13	7.69	28.56	-66.7	0.00	50.0
	Week 50	16	31.25	32.13	0.0	33.33	100.0	13	8.97	30.14	-66.7	0.00	50.0
	Week 53	15	22.22	22.42	0.0	33.33	50.0	12	-2.78	23.39	-66.7	0.00	33.3
	Week 56	15	27.78	27.94	0.0	16.67	100.0	11	-1.51	18.94	-50.0	0.00	16.7
	Week 59	12	20.83	24.74	0.0	16.67	83.3	9	-5.56	25.00	-66.7	0.00	16.7
	Week 62	10	15.00	16.57	0.0	8.34	33.3	8	-6.25	17.68	-50.0	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
EV+Pembro (N=202)												
BASELINE	160	31.87	28.80	0.0	33.33	100.0						
Week 1	141	33.22	29.45	0.0	33.33	100.0	129	0.26	18.04	-50.0	0.00	66.7
Week 2	150	35.67	29.29	0.0	33.33	100.0	133	3.63	19.06	-50.0	0.00	66.7
Week 3	139	33.09	27.51	0.0	33.33	100.0	122	-0.68	24.19	-83.3	0.00	66.7
Week 4	145	26.55	25.57	0.0	33.33	100.0	129	-5.30	24.11	-83.3	0.00	66.7
Week 5	137	24.21	24.33	0.0	16.67	100.0	121	-7.44	24.24	-100.0	0.00	50.0
Week 6	146	25.00	24.07	0.0	33.33	100.0	124	-7.53	28.38	-100.0	0.00	66.7
Week 7	147	23.02	23.11	0.0	16.67	100.0	124	-7.66	28.47	-100.0	0.00	83.3
Week 8	147	23.47	23.55	0.0	16.67	100.0	124	-8.06	31.27	-100.0	0.00	100.0
Week 9	142	25.00	24.61	0.0	16.67	100.0	121	-6.06	31.03	-83.3	0.00	100.0
Week 10	139	22.06	24.84	0.0	16.67	100.0	118	-8.47	29.86	-100.0	0.00	83.3
Week 11	137	20.80	23.81	0.0	16.67	100.0	115	-9.42	28.96	-100.0	0.00	66.7
Week 12	142	21.95	24.98	0.0	16.67	100.0	119	-7.98	30.13	-100.0	0.00	66.7
Week 14	139	19.90	23.47	0.0	16.67	100.0	116	-10.63	28.94	-100.0	0.00	66.7
Week 17	132	19.70	20.05	0.0	16.67	100.0	111	-9.46	27.94	-100.0	0.00	50.0
Week 20	120	20.14	20.02	0.0	16.67	83.3	103	-8.09	27.30	-100.0	0.00	50.0
Week 23	117	18.66	20.78	0.0	16.67	66.7	97	-8.42	29.67	-100.0	0.00	66.7
Week 26	112	21.13	20.50	0.0	16.67	83.3	94	-6.38	28.93	-100.0	0.00	66.7
Week 29	107	22.12	23.21	0.0	16.67	83.3	93	-3.41	30.45	-100.0	0.00	83.3
Week 32	102	19.77	20.81	0.0	16.67	83.3	88	-8.52	30.53	-100.0	0.00	83.3
Week 35	98	23.30	22.80	0.0	16.67	83.3	86	-3.68	29.19	-100.0	0.00	66.7
Week 38	97	22.51	21.11	0.0	16.67	66.7	86	-7.36	27.96	-100.0	0.00	66.7
Week 41	95	21.40	22.24	0.0	16.67	100.0	84	-6.94	28.83	-100.0	0.00	66.7
Week 44	86	24.42	24.61	0.0	25.00	100.0	74	-3.38	30.09	-100.0	0.00	83.3
Week 47	79	24.26	23.08	0.0	33.33	83.3	70	-3.33	30.90	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	74	24.55	26.92	0.0	16.67	100.0	64	-3.65	29.62	-100.0	0.00	50.0
Week 53	74	27.93	27.46	0.0	33.33	100.0	63	-2.38	33.04	-100.0	0.00	66.7
Week 56	72	24.77	23.73	0.0	33.33	100.0	61	-7.92	30.97	-100.0	0.00	66.7
Week 59	69	28.02	25.96	0.0	33.33	100.0	57	-4.39	31.42	-100.0	0.00	66.7
Week 62	62	26.61	23.66	0.0	33.33	83.3	52	-3.53	28.65	-100.0	0.00	66.7
Week 65	43	24.42	24.49	0.0	16.67	66.7	40	-3.33	37.21	-100.0	0.00	66.7
Week 68	46	27.17	24.69	0.0	33.33	100.0	42	0.79	34.91	-100.0	0.00	83.3
Week 71	42	23.81	25.00	0.0	16.67	83.3	38	-5.26	35.33	-100.0	0.00	66.7
Week 74	38	24.12	26.19	0.0	16.67	100.0	35	-1.43	37.35	-100.0	0.00	83.3
Week 77	37	22.07	23.91	0.0	16.67	66.7	33	-6.57	33.32	-100.0	0.00	66.7
Week 80	36	28.24	24.82	0.0	33.33	66.7	34	-0.49	32.17	-100.0	0.00	66.7
Week 83	30	27.22	24.95	0.0	33.33	83.3	29	-1.15	35.34	-100.0	0.00	66.7
Week 86	26	24.36	25.49	0.0	16.67	66.7	25	0.00	34.02	-100.0	0.00	66.7
Week 89	20	18.33	24.72	0.0	8.34	83.3	19	0.88	31.66	-33.3	0.00	83.3
Week 92	19	22.81	21.67	0.0	16.67	66.7	18	0.00	24.25	-33.3	0.00	50.0
Week 95	14	15.48	16.62	0.0	8.34	33.3	13	-1.28	18.58	-33.3	0.00	33.3
Week 98	10	16.67	19.24	0.0	8.34	50.0	9	-5.55	14.43	-33.3	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Plat+Gem (N=202)												
BASELINE	165	32.83	30.99	0.0	33.33	100.0						
Week 1	144	34.49	30.26	0.0	33.33	100.0	139	1.08	22.09	-66.7	0.00	100.0
Week 2	147	35.03	27.15	0.0	33.33	100.0	135	4.32	23.21	-66.7	0.00	50.0
Week 3	149	31.43	28.04	0.0	33.33	100.0	136	1.10	22.88	-83.3	0.00	66.7
Week 4	150	29.44	26.58	0.0	33.33	100.0	135	-1.98	27.25	-100.0	0.00	66.7
Week 5	153	29.85	27.55	0.0	33.33	100.0	138	-0.60	28.58	-100.0	0.00	83.3
Week 6	145	27.24	28.11	0.0	33.33	100.0	131	-2.80	29.97	-100.0	0.00	83.3
Week 7	148	30.86	29.44	0.0	33.33	100.0	134	1.12	29.49	-83.3	0.00	83.3
Week 8	145	32.07	28.67	0.0	33.33	100.0	132	2.02	31.97	-83.3	0.00	100.0
Week 9	141	30.38	26.15	0.0	33.33	100.0	125	0.40	29.74	-100.0	0.00	66.7
Week 10	142	28.64	27.39	0.0	33.33	100.0	130	-1.15	28.99	-100.0	0.00	66.7
Week 11	126	31.48	29.00	0.0	33.33	100.0	114	2.63	28.01	-83.3	0.00	66.7
Week 12	130	29.36	26.48	0.0	33.33	100.0	115	0.00	28.01	-100.0	0.00	83.3
Week 14	125	29.47	26.79	0.0	33.33	100.0	109	0.00	30.17	-83.3	0.00	83.3
Week 17	120	29.31	28.34	0.0	33.33	100.0	106	2.04	30.40	-66.7	0.00	83.3
Week 20	104	25.00	27.48	0.0	16.67	100.0	91	-2.56	28.64	-83.3	0.00	66.7
Week 23	88	22.92	24.01	0.0	16.67	83.3	80	-3.13	27.19	-83.3	0.00	83.3
Week 26	81	27.98	27.62	0.0	33.33	100.0	75	-0.89	28.85	-83.3	0.00	83.3
Week 29	77	29.44	28.60	0.0	33.33	100.0	71	5.87	29.29	-83.3	0.00	83.3
Week 32	63	30.42	29.41	0.0	33.33	100.0	58	6.90	29.62	-83.3	0.00	100.0
Week 35	62	28.49	27.23	0.0	33.33	100.0	56	4.46	26.49	-83.3	0.00	66.7
Week 38	56	29.46	30.98	0.0	16.67	100.0	50	6.67	32.30	-83.3	0.00	100.0
Week 41	52	31.41	30.19	0.0	25.00	100.0	47	8.16	29.05	-83.3	0.00	83.3
Week 44	49	35.37	30.74	0.0	33.33	100.0	44	10.23	30.12	-83.3	16.67	66.7
Week 47	43	32.95	35.17	0.0	16.67	100.0	39	9.40	31.94	-83.3	0.00	83.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	36	32.41	29.53	0.0	33.33	100.0	31	6.99	27.48	-83.3	0.00	83.3
Week 53	31	31.18	31.25	0.0	16.67	100.0	28	4.76	30.72	-83.3	0.00	66.7
Week 56	30	33.33	31.26	0.0	33.33	100.0	29	4.02	32.63	-83.3	0.00	66.7
Week 59	23	28.26	28.62	0.0	16.67	83.3	21	-5.56	34.69	-83.3	0.00	66.7
Week 62	20	35.00	26.98	0.0	33.33	83.3	20	1.67	33.29	-83.3	0.00	66.7
Week 65	17	29.41	32.56	0.0	16.67	83.3	16	3.13	33.45	-83.3	0.00	66.7
Week 68	13	32.05	35.00	0.0	33.33	100.0	13	5.13	39.90	-83.3	0.00	83.3
Week 71	13	34.62	34.33	0.0	33.33	100.0	13	3.85	39.76	-83.3	0.00	83.3
Week 74	11	21.21	25.92	0.0	16.67	66.7	11	-4.55	27.98	-83.3	0.00	16.7
Week 77	11	21.21	25.92	0.0	16.67	83.3	11	6.06	20.10	-16.7	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Present	EV+Pembro (N= 50)												
	BASELINE	40	37.50	29.42	0.0	33.33	100.0						
	Week 1	38	40.35	27.57	0.0	33.33	100.0	34	2.45	20.97	-33.3	0.00	66.7
	Week 2	35	38.57	27.65	0.0	33.33	100.0	32	2.08	16.80	-33.3	0.00	50.0
	Week 3	32	31.77	25.17	0.0	33.33	83.3	30	-1.67	21.60	-50.0	0.00	50.0
	Week 4	35	28.09	23.84	0.0	33.33	83.3	31	-6.45	22.23	-50.0	0.00	50.0
	Week 5	32	22.92	20.19	0.0	25.00	66.7	28	-10.72	24.09	-66.7	0.00	33.3
	Week 6	35	26.19	22.97	0.0	33.33	83.3	30	-11.67	27.73	-66.7	0.00	50.0
	Week 7	35	19.52	18.29	0.0	16.67	50.0	29	-12.07	25.93	-66.7	0.00	33.3
	Week 8	38	21.93	20.54	0.0	16.67	66.7	31	-12.37	25.81	-66.7	0.00	50.0
	Week 9	33	21.21	19.22	0.0	16.67	66.7	29	-12.65	25.84	-66.7	0.00	16.7
	Week 10	30	16.67	18.57	0.0	16.67	50.0	25	-19.33	25.31	-66.7	-16.67	33.3
	Week 11	31	15.05	24.85	0.0	0.00	100.0	27	-16.67	30.31	-66.7	-16.67	66.7
	Week 12	32	23.44	28.35	0.0	16.67	100.0	28	-10.12	29.16	-66.7	0.00	50.0
	Week 14	36	18.52	24.16	0.0	8.34	83.3	31	-17.21	26.70	-83.3	-16.66	16.7
	Week 17	33	18.18	19.70	0.0	16.67	66.7	27	-16.05	24.23	-66.7	-16.67	16.7
	Week 20	28	19.05	19.62	0.0	16.67	66.7	25	-10.67	23.01	-66.7	0.00	16.7
	Week 23	28	18.45	20.95	0.0	16.67	66.7	24	-10.42	26.38	-66.7	0.00	16.7
	Week 26	28	23.81	23.76	0.0	16.67	83.3	24	-6.25	29.41	-66.7	0.00	66.7
	Week 29	27	24.69	20.86	0.0	33.33	66.7	25	-6.67	24.53	-66.7	0.00	33.3
	Week 32	25	15.33	20.37	0.0	0.00	66.7	23	-13.77	28.27	-66.7	0.00	16.7
	Week 35	26	23.08	22.65	0.0	16.67	66.7	24	-9.03	27.79	-66.7	0.00	50.0
	Week 38	26	23.08	22.15	0.0	25.00	66.7	24	-9.72	28.20	-66.7	0.00	16.7
	Week 41	25	18.67	19.44	0.0	16.67	66.7	23	-9.42	25.54	-66.7	0.00	16.7
	Week 44	22	25.00	25.07	0.0	25.00	83.3	20	-7.50	30.34	-66.7	0.00	50.0
	Week 47	14	25.00	29.05	0.0	16.67	83.3	13	-7.69	34.44	-66.7	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	27.50	32.57	0.0	16.67	100.0	17	-4.90	31.60	-66.7	0.00	50.0
	Week 53	21	26.19	29.14	0.0	16.67	100.0	18	-6.48	28.66	-66.7	0.00	50.0
	Week 56	18	29.63	22.55	0.0	33.33	83.3	15	-7.78	29.46	-66.7	0.00	33.3
	Week 59	18	36.11	29.84	0.0	33.33	100.0	15	-4.45	26.33	-66.7	0.00	33.3
	Week 62	13	25.64	24.17	0.0	33.33	83.3	11	-6.06	25.02	-66.7	0.00	16.7
	Week 68	12	27.78	25.95	0.0	25.00	100.0	11	0.00	34.16	-66.7	0.00	66.7
	Plat+Gem (N= 50)												
	BASELINE	40	47.50	29.85	0.0	50.00	100.0						
	Week 1	35	43.81	26.53	0.0	33.33	100.0	33	-1.01	20.39	-50.0	0.00	66.7
	Week 2	33	42.42	26.38	0.0	33.33	83.3	30	2.78	18.09	-33.3	0.00	50.0
	Week 3	33	31.82	27.12	0.0	33.33	83.3	29	-4.60	20.36	-50.0	0.00	50.0
	Week 4	36	31.02	23.28	0.0	33.33	83.3	32	-12.50	24.32	-83.3	0.00	33.3
	Week 5	36	30.56	29.95	0.0	16.67	100.0	32	-9.38	31.94	-100.0	0.00	66.7
	Week 6	32	21.35	24.77	0.0	16.67	100.0	29	-18.39	30.97	-100.0	-16.67	33.3
	Week 7	35	32.38	29.13	0.0	33.33	100.0	31	-9.68	29.74	-66.7	0.00	33.3
	Week 8	35	33.33	29.15	0.0	33.33	100.0	31	-10.22	36.18	-66.7	-16.67	50.0
	Week 9	34	35.29	25.87	0.0	33.33	100.0	30	-7.78	34.39	-66.7	-16.67	66.7
	Week 10	33	28.79	28.34	0.0	33.33	100.0	30	-13.89	29.39	-66.7	-16.67	50.0
	Week 11	30	34.44	30.30	0.0	33.33	100.0	26	-4.49	30.39	-66.7	0.00	66.7
	Week 12	32	31.25	26.35	0.0	33.33	83.3	27	-8.64	28.63	-66.7	-16.67	50.0
	Week 14	27	32.10	23.08	0.0	33.33	66.7	22	-6.82	28.01	-66.7	0.00	50.0
	Week 17	28	28.57	26.00	0.0	33.33	100.0	23	-6.52	35.44	-66.7	0.00	83.3
	Week 20	20	24.17	27.82	0.0	16.67	83.3	16	-15.63	26.15	-66.7	-8.34	16.7
	Week 23	15	26.67	25.82	0.0	16.67	66.7	14	-8.33	21.43	-66.7	0.00	16.7
	Week 26	15	27.78	30.65	0.0	16.67	100.0	14	-8.33	22.41	-50.0	-8.34	33.3
	Week 29	13	28.21	31.46	0.0	16.67	100.0	12	4.17	34.91	-50.0	0.00	83.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Absent	EV+Pembro (N=152)												
	BASELINE	120	30.00	28.47	0.0	33.33	100.0						
	Week 1	103	30.58	29.80	0.0	33.33	100.0	95	-0.53	16.92	-50.0	0.00	50.0
	Week 2	115	34.78	29.83	0.0	33.33	100.0	101	4.13	19.78	-50.0	0.00	66.7
	Week 3	107	33.49	28.27	0.0	33.33	100.0	92	-0.36	25.07	-83.3	0.00	66.7
	Week 4	110	26.06	26.18	0.0	16.67	100.0	98	-4.93	24.78	-83.3	0.00	66.7
	Week 5	105	24.60	25.54	0.0	16.67	100.0	93	-6.45	24.33	-100.0	0.00	50.0
	Week 6	111	24.62	24.50	0.0	33.33	100.0	94	-6.21	28.61	-100.0	0.00	66.7
	Week 7	112	24.11	24.39	0.0	16.67	100.0	95	-6.32	29.19	-100.0	0.00	83.3
	Week 8	109	24.01	24.58	0.0	16.67	100.0	93	-6.63	32.89	-100.0	0.00	100.0
	Week 9	109	26.15	26.00	0.0	16.67	100.0	92	-3.99	32.34	-83.3	0.00	100.0
	Week 10	109	23.55	26.18	0.0	16.67	100.0	93	-5.56	30.43	-100.0	0.00	83.3
	Week 11	106	22.48	23.35	0.0	16.67	100.0	88	-7.20	28.34	-100.0	0.00	66.7
	Week 12	110	21.51	24.04	0.0	16.67	100.0	91	-7.33	30.55	-100.0	0.00	66.7
	Week 14	103	20.39	23.33	0.0	16.67	100.0	85	-8.23	29.50	-100.0	0.00	66.7
	Week 17	99	20.20	20.24	0.0	16.67	100.0	84	-7.34	28.85	-100.0	0.00	50.0
	Week 20	92	20.47	20.24	0.0	16.67	83.3	78	-7.26	28.63	-100.0	0.00	50.0
	Week 23	89	18.73	20.84	0.0	16.67	66.7	73	-7.76	30.82	-100.0	0.00	66.7
	Week 26	84	20.24	19.37	0.0	16.67	66.7	70	-6.43	28.98	-100.0	0.00	50.0
	Week 29	80	21.25	24.01	0.0	16.67	83.3	68	-2.21	32.44	-100.0	0.00	83.3
	Week 32	77	21.21	20.88	0.0	16.67	83.3	65	-6.67	31.29	-100.0	0.00	83.3
	Week 35	72	23.38	23.01	0.0	25.00	83.3	62	-1.61	29.68	-100.0	0.00	66.7
	Week 38	71	22.30	20.88	0.0	16.67	66.7	62	-6.45	28.04	-100.0	0.00	66.7
	Week 41	70	22.38	23.21	0.0	16.67	100.0	61	-6.01	30.13	-100.0	0.00	66.7
	Week 44	64	24.22	24.65	0.0	25.00	100.0	54	-1.85	30.14	-100.0	0.00	83.3
	Week 47	65	24.10	21.86	0.0	33.33	83.3	57	-2.34	30.28	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	54	23.46	24.77	0.0	16.67	100.0	47	-3.19	29.21	-100.0	0.00	50.0
	Week 53	53	28.62	27.03	0.0	33.33	100.0	45	-0.74	34.81	-100.0	0.00	66.7
	Week 56	54	23.15	24.10	0.0	16.67	100.0	46	-7.97	31.77	-100.0	-16.66	66.7
	Week 59	51	25.16	24.12	0.0	16.67	66.7	42	-4.36	33.35	-100.0	0.00	66.7
	Week 62	49	26.87	23.77	0.0	33.33	66.7	41	-2.85	29.79	-100.0	0.00	66.7
	Week 65	36	25.93	24.70	0.0	25.00	66.7	33	-1.51	36.88	-100.0	0.00	66.7
	Week 68	34	26.96	24.62	0.0	33.33	83.3	31	1.08	35.73	-100.0	0.00	83.3
	Week 71	33	22.73	23.87	0.0	16.67	66.7	30	-5.00	35.06	-100.0	0.00	66.7
	Week 74	33	24.24	26.71	0.0	16.67	100.0	30	0.00	37.40	-100.0	0.00	83.3
	Week 77	31	20.43	22.65	0.0	16.67	66.7	27	-6.17	33.38	-100.0	0.00	66.7
	Week 80	31	27.42	24.93	0.0	33.33	66.7	29	0.58	32.27	-100.0	0.00	66.7
	Week 83	25	26.00	23.11	0.0	33.33	66.7	24	0.00	34.75	-100.0	0.00	66.7
	Week 86	23	23.19	25.00	0.0	16.67	66.7	22	-1.51	33.69	-100.0	0.00	66.7
	Week 89	18	19.44	25.72	0.0	8.34	83.3	17	2.94	32.40	-33.3	0.00	83.3
	Week 92	16	20.83	19.72	0.0	16.67	50.0	15	1.11	24.77	-33.3	0.00	50.0
	Week 95	12	15.28	16.60	0.0	8.34	33.3	11	0.00	16.66	-33.3	0.00	33.3
	Plat+Gem (N=152)												
	BASELINE	125	28.13	29.96	0.0	16.67	100.0						
	Week 1	109	31.50	30.88	0.0	33.33	100.0	106	1.73	22.65	-66.7	0.00	100.0
	Week 2	114	32.89	27.11	0.0	33.33	100.0	105	4.76	24.54	-66.7	0.00	50.0
	Week 3	116	31.32	28.42	0.0	33.33	100.0	107	2.65	23.36	-83.3	0.00	66.7
	Week 4	114	28.95	27.61	0.0	33.33	100.0	103	1.29	27.38	-100.0	0.00	66.7
	Week 5	117	29.63	26.90	0.0	33.33	100.0	106	2.04	27.09	-83.3	0.00	83.3
	Week 6	113	28.91	28.87	0.0	33.33	100.0	102	1.63	28.29	-100.0	0.00	83.3
	Week 7	113	30.38	29.65	0.0	33.33	100.0	103	4.37	28.77	-83.3	0.00	83.3
	Week 8	110	31.67	28.64	0.0	33.33	100.0	101	5.78	29.76	-83.3	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	107	28.82	26.16	0.0	33.33	100.0	95	2.98	27.82	-100.0	0.00	66.7
	Week 10	109	28.59	27.23	0.0	33.33	100.0	100	2.67	27.90	-100.0	0.00	66.7
	Week 11	96	30.56	28.68	0.0	33.33	100.0	88	4.73	27.09	-83.3	0.00	66.7
	Week 12	98	28.74	26.63	0.0	33.33	100.0	88	2.65	27.44	-100.0	0.00	83.3
	Week 14	98	28.74	27.78	0.0	33.33	100.0	87	1.72	30.61	-83.3	0.00	83.3
	Week 17	92	29.53	29.14	0.0	33.33	100.0	83	4.42	28.64	-66.7	0.00	83.3
	Week 20	84	25.20	27.56	0.0	16.67	100.0	75	0.22	28.54	-83.3	0.00	66.7
	Week 23	73	22.15	23.74	0.0	16.67	83.3	66	-2.02	28.27	-83.3	0.00	83.3
	Week 26	66	28.03	27.14	0.0	33.33	100.0	61	0.82	30.03	-83.3	0.00	83.3
	Week 29	64	29.69	28.25	0.0	33.33	100.0	59	6.21	28.35	-83.3	0.00	66.7
	Week 32	54	30.55	27.99	0.0	33.33	100.0	49	7.14	27.00	-83.3	0.00	66.7
	Week 35	54	29.32	27.08	0.0	33.33	100.0	48	5.90	26.52	-83.3	0.00	66.7
	Week 38	47	28.37	30.08	0.0	16.67	100.0	42	5.56	32.44	-83.3	0.00	100.0
	Week 41	45	33.33	30.77	0.0	33.33	100.0	40	10.42	30.36	-83.3	8.33	83.3
	Week 44	41	35.37	31.67	0.0	33.33	100.0	36	10.65	31.66	-83.3	16.67	66.7
	Week 47	35	35.71	35.96	0.0	33.33	100.0	31	13.44	32.32	-83.3	0.00	83.3
	Week 50	29	33.33	30.21	0.0	33.33	100.0	24	9.03	29.48	-83.3	0.00	83.3
	Week 53	25	29.33	28.58	0.0	16.67	83.3	22	4.55	29.18	-83.3	0.00	66.7
	Week 56	26	32.05	28.64	0.0	33.33	83.3	25	2.00	33.10	-83.3	0.00	66.7
	Week 59	20	29.17	28.03	0.0	25.00	83.3	18	-8.33	34.89	-83.3	0.00	66.7
	Week 62	17	37.25	25.37	0.0	33.33	83.3	17	0.00	33.85	-83.3	0.00	66.7
	Week 65	15	33.33	32.73	0.0	33.33	83.3	14	4.76	35.46	-83.3	0.00	66.7
	Week 68	11	37.88	35.03	0.0	33.33	100.0	11	7.58	43.05	-83.3	0.00	83.3
	Week 71	12	37.50	34.18	0.0	41.67	100.0	12	5.56	41.03	-83.3	0.00	83.3
	Week 74	10	23.33	26.29	0.0	16.67	66.7	10	-3.33	29.19	-83.3	0.00	16.7
	Week 77	10	21.67	27.27	0.0	16.67	83.3	10	6.67	21.08	-16.7	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
< 65 years	EV+Pembro (N= 39)												
	BASELINE	32	36.46	28.54	0.0	33.33	100.0						
	Week 1	27	36.42	26.57	0.0	33.33	100.0	26	3.21	19.45	-33.3	0.00	50.0
	Week 2	30	35.00	26.39	0.0	33.33	83.3	29	2.30	18.21	-50.0	0.00	33.3
	Week 3	31	31.18	23.07	0.0	33.33	83.3	29	-4.60	24.76	-50.0	0.00	50.0
	Week 4	30	18.89	17.90	0.0	16.67	50.0	27	-12.35	22.45	-83.3	-16.66	33.3
	Week 5	28	16.07	18.41	0.0	8.34	50.0	26	-16.67	21.60	-66.7	-16.67	16.7
	Week 6	29	23.56	23.79	0.0	33.33	66.7	26	-11.54	30.10	-66.7	-16.67	66.7
	Week 7	30	20.55	21.74	0.0	16.67	83.3	26	-12.82	23.71	-66.7	-8.33	33.3
	Week 8	30	19.44	19.12	0.0	16.67	66.7	26	-11.54	28.97	-83.3	0.00	50.0
	Week 9	28	21.43	23.07	0.0	25.00	66.7	27	-14.20	33.87	-83.3	-16.67	66.7
	Week 10	26	22.44	27.87	0.0	16.67	100.0	23	-7.97	34.03	-50.0	-16.66	83.3
	Week 11	28	20.83	22.05	0.0	16.67	66.7	25	-9.33	22.61	-50.0	0.00	50.0
	Week 12	28	19.05	20.14	0.0	16.67	83.3	25	-12.00	24.30	-66.7	-16.66	33.3
	Week 14	26	12.82	15.85	0.0	0.00	33.3	23	-19.57	30.83	-83.3	-16.67	33.3
	Week 17	28	17.86	18.10	0.0	16.67	66.7	24	-12.50	25.65	-66.7	-16.67	50.0
	Week 20	27	22.22	20.15	0.0	33.33	83.3	24	-7.64	26.91	-66.7	0.00	50.0
	Week 23	26	15.38	16.95	0.0	8.34	50.0	23	-12.32	28.52	-66.7	-16.66	33.3
	Week 26	24	19.44	18.82	0.0	16.67	66.7	22	-8.33	31.18	-66.7	0.00	50.0
	Week 29	25	21.33	23.82	0.0	16.67	83.3	23	-6.52	35.44	-66.7	0.00	83.3
	Week 32	25	20.67	21.13	0.0	16.67	66.7	23	-10.15	28.75	-66.7	-16.66	50.0
	Week 35	24	25.69	23.56	0.0	33.33	66.7	22	-3.79	35.98	-66.7	-16.66	66.7
	Week 38	23	19.56	18.57	0.0	16.67	66.7	22	-11.36	25.91	-66.7	-8.33	33.3
	Week 41	25	21.33	21.79	0.0	33.33	66.7	23	-8.70	33.28	-83.3	-16.66	50.0
	Week 44	22	20.45	20.53	0.0	16.67	66.7	20	-7.50	29.85	-66.7	-16.66	50.0
	Week 47	20	25.00	25.07	0.0	33.33	83.3	18	-0.93	35.91	-66.7	0.00	66.7

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Table 302.1.3002.16.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	19	15.79	19.62	0.0	0.00	66.7	17	-9.80	30.08	-66.7	0.00	50.0
	Week 53	20	20.00	19.19	0.0	25.00	66.7	18	-5.56	28.00	-66.7	0.00	50.0
	Week 56	17	15.69	16.10	0.0	16.67	33.3	15	-14.44	25.87	-66.7	-16.66	33.3
	Week 59	17	27.45	25.65	0.0	33.33	66.7	15	-7.78	28.77	-33.3	-16.66	50.0
	Week 62	15	23.33	21.64	0.0	16.67	66.7	14	-5.95	22.27	-33.3	0.00	50.0
	Week 65	14	17.86	16.62	0.0	16.67	50.0	13	-14.10	27.93	-50.0	-16.67	50.0
	Week 68	11	25.76	15.57	0.0	33.33	50.0	10	-6.67	29.61	-50.0	-8.33	50.0
	Week 71	13	24.36	23.19	0.0	16.67	66.7	12	-6.94	32.15	-50.0	-8.33	66.7
	Week 74	14	26.19	27.51	0.0	33.33	100.0	13	0.00	35.35	-50.0	0.00	83.3
	Week 77	14	28.57	23.96	0.0	25.00	66.7	13	-1.28	27.61	-50.0	0.00	50.0
	Week 80	14	35.72	24.34	0.0	33.33	66.7	13	8.97	23.19	-16.7	0.00	50.0
	Week 83	12	34.72	27.94	0.0	33.33	83.3	11	6.06	30.07	-33.3	0.00	50.0
	Plat+Gem (N= 29)												
	BASELINE	22	28.79	27.30	0.0	25.00	100.0						
	Week 1	21	29.37	27.34	0.0	33.33	66.7	20	0.83	17.50	-33.3	0.00	50.0
	Week 2	24	29.86	28.65	0.0	33.33	100.0	20	3.33	19.94	-33.3	0.00	50.0
	Week 3	23	29.71	27.50	0.0	33.33	100.0	20	1.67	14.20	-16.7	0.00	33.3
	Week 4	23	28.99	32.26	0.0	33.33	100.0	19	0.88	17.10	-16.7	0.00	33.3
	Week 5	25	30.67	32.16	0.0	33.33	100.0	20	-0.83	16.64	-16.7	0.00	33.3
	Week 6	22	25.00	27.09	0.0	25.00	83.3	18	-5.56	16.17	-33.3	0.00	33.3
	Week 7	24	30.56	29.35	0.0	33.33	100.0	21	0.00	14.91	-33.3	0.00	33.3
	Week 8	21	23.01	30.03	0.0	0.00	100.0	19	-3.51	26.40	-33.3	0.00	83.3
	Week 9	20	31.67	26.43	0.0	33.33	100.0	17	4.90	22.64	-33.3	0.00	50.0
	Week 10	21	23.81	25.59	0.0	33.33	100.0	18	-3.71	15.71	-33.3	0.00	33.3
	Week 11	20	28.33	29.17	0.0	33.33	100.0	17	0.00	20.41	-33.3	0.00	33.3
	Week 12	21	26.19	23.32	0.0	33.33	66.7	17	-0.98	14.99	-16.7	0.00	33.3

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Table 302.1.3002.16.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 14	22	34.85	29.05	0.0	33.33	83.3	18	8.33	28.15	-33.3	0.00	66.7
	Week 17	20	26.67	27.25	0.0	25.00	66.7	17	0.98	27.93	-33.3	0.00	66.7
	Week 20	18	28.70	31.73	0.0	33.33	100.0	15	-2.22	19.79	-33.3	0.00	33.3
	Week 23	18	20.37	23.95	0.0	8.34	66.7	16	-4.17	15.51	-33.3	0.00	16.7
	Week 26	16	22.92	27.81	0.0	8.34	83.3	14	-1.19	19.02	-33.3	0.00	33.3
	Week 29	15	25.56	22.60	0.0	33.33	66.7	13	1.28	14.37	-16.7	0.00	16.7
	Week 32	15	31.11	32.04	0.0	33.33	83.3	13	6.41	24.09	-33.3	0.00	50.0
	Week 35	15	26.67	24.23	0.0	33.33	66.7	13	5.13	21.93	-33.3	0.00	33.3
	Week 38	14	36.91	35.31	0.0	33.33	100.0	12	11.11	32.04	-16.7	0.00	83.3
	Week 41	11	40.91	35.25	0.0	33.33	100.0	9	18.52	24.21	0.0	0.00	66.7
	Week 44	11	33.33	29.81	0.0	33.33	100.0	9	12.96	21.69	-16.7	0.00	50.0
	Week 47	11	30.30	34.01	0.0	16.67	83.3	9	5.56	32.27	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>= 65 years	EV+Pembro (N=163)												
	BASELINE	128	30.73	28.86	0.0	33.33	100.0						
	Week 1	114	32.46	30.15	0.0	33.33	100.0	103	-0.49	17.69	-50.0	0.00	66.7
	Week 2	120	35.83	30.07	0.0	33.33	100.0	104	4.01	19.36	-50.0	0.00	66.7
	Week 3	108	33.64	28.73	0.0	33.33	100.0	93	0.54	24.01	-83.3	0.00	66.7
	Week 4	115	28.55	26.93	0.0	33.33	100.0	102	-3.43	24.30	-83.3	0.00	66.7
	Week 5	109	26.30	25.29	0.0	33.33	100.0	95	-4.91	24.42	-100.0	0.00	50.0
	Week 6	117	25.36	24.23	0.0	33.33	100.0	98	-6.46	27.97	-100.0	0.00	66.7
	Week 7	117	23.65	23.49	0.0	16.67	100.0	98	-6.29	29.56	-100.0	0.00	83.3
	Week 8	117	24.50	24.52	0.0	16.67	100.0	98	-7.14	31.93	-100.0	0.00	100.0
	Week 9	114	25.88	25.00	0.0	16.67	100.0	94	-3.72	29.95	-83.3	0.00	100.0
	Week 10	113	21.98	24.22	0.0	16.67	100.0	95	-8.60	28.96	-100.0	0.00	83.3
	Week 11	109	20.80	24.34	0.0	16.67	100.0	90	-9.44	30.60	-100.0	0.00	66.7
	Week 12	114	22.66	26.06	0.0	16.67	100.0	94	-6.92	31.53	-100.0	0.00	66.7
	Week 14	113	21.53	24.67	0.0	16.67	100.0	93	-8.42	28.19	-100.0	0.00	66.7
	Week 17	104	20.19	20.60	0.0	16.67	100.0	87	-8.62	28.63	-100.0	0.00	50.0
	Week 20	93	19.53	20.06	0.0	16.67	66.7	79	-8.23	27.59	-100.0	0.00	50.0
	Week 23	91	19.60	21.74	0.0	16.67	66.7	74	-7.21	30.10	-100.0	0.00	66.7
	Week 26	88	21.59	21.01	0.0	16.67	83.3	72	-5.79	28.41	-100.0	0.00	66.7
	Week 29	82	22.36	23.16	0.0	16.67	83.3	70	-2.38	28.84	-100.0	0.00	66.7
	Week 32	77	19.48	20.84	0.0	16.67	83.3	65	-7.95	31.33	-100.0	0.00	83.3
	Week 35	74	22.52	22.65	0.0	16.67	83.3	64	-3.65	26.80	-100.0	0.00	66.7
	Week 38	74	23.42	21.88	0.0	25.00	66.7	64	-5.99	28.69	-100.0	0.00	66.7
	Week 41	70	21.43	22.55	0.0	16.67	100.0	61	-6.28	27.24	-100.0	0.00	66.7
	Week 44	64	25.78	25.88	0.0	33.33	100.0	54	-1.85	30.31	-100.0	0.00	83.3
	Week 47	59	24.01	22.59	0.0	16.67	83.3	52	-4.17	29.31	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	55	27.58	28.55	0.0	16.67	100.0	47	-1.42	29.45	-100.0	0.00	50.0
	Week 53	54	30.86	29.57	0.0	33.33	100.0	45	-1.11	35.07	-100.0	0.00	66.7
	Week 56	55	27.58	25.10	0.0	33.33	100.0	46	-5.80	32.44	-100.0	0.00	66.7
	Week 59	52	28.21	26.31	0.0	33.33	100.0	42	-3.17	32.56	-100.0	0.00	66.7
	Week 62	47	27.66	24.40	0.0	33.33	83.3	38	-2.63	30.88	-100.0	0.00	66.7
	Week 65	29	27.59	27.20	0.0	16.67	66.7	27	1.85	40.39	-100.0	0.00	66.7
	Week 68	35	27.62	27.10	0.0	16.67	100.0	32	3.13	36.52	-100.0	0.00	83.3
	Week 71	29	23.56	26.17	0.0	16.67	83.3	26	-4.49	37.29	-100.0	0.00	66.7
	Week 74	24	22.92	25.92	0.0	16.67	66.7	22	-2.27	39.27	-100.0	0.00	66.7
	Week 77	23	18.12	23.52	0.0	0.00	66.7	20	-10.00	36.83	-100.0	0.00	66.7
	Week 80	22	23.49	24.48	0.0	16.67	66.7	21	-6.35	35.93	-100.0	0.00	66.7
	Week 83	18	22.22	22.14	0.0	16.67	66.7	18	-5.56	38.35	-100.0	0.00	66.7
	Week 86	18	25.00	26.35	0.0	16.67	66.7	18	1.85	36.10	-100.0	0.00	66.7
	Week 89	12	18.06	27.02	0.0	0.00	83.3	12	1.39	35.86	-33.3	0.00	83.3
	Week 92	10	16.67	19.24	0.0	8.34	50.0	10	3.33	25.82	-33.3	0.00	50.0
	Plat+Gem (N=173)												
	BASELINE	143	33.45	31.55	0.0	33.33	100.0						
	Week 1	123	35.37	30.75	0.0	33.33	100.0	119	1.12	22.83	-66.7	0.00	100.0
	Week 2	123	36.04	26.85	0.0	33.33	100.0	115	4.49	23.81	-66.7	0.00	50.0
	Week 3	126	31.75	28.24	0.0	33.33	100.0	116	1.01	24.11	-83.3	0.00	66.7
	Week 4	127	29.53	25.56	0.0	33.33	100.0	116	-2.44	28.59	-100.0	0.00	66.7
	Week 5	128	29.69	26.70	0.0	33.33	100.0	118	-0.57	30.19	-100.0	0.00	83.3
	Week 6	123	27.64	28.38	0.0	33.33	100.0	113	-2.36	31.64	-100.0	0.00	83.3
	Week 7	124	30.91	29.58	0.0	33.33	100.0	113	1.33	31.51	-83.3	0.00	83.3
	Week 8	124	33.60	28.27	0.0	33.33	100.0	113	2.95	32.83	-83.3	0.00	100.0
	Week 9	121	30.17	26.20	0.0	33.33	100.0	108	-0.31	30.74	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	121	29.48	27.70	0.0	33.33	100.0	112	-0.74	30.62	-100.0	0.00	66.7
	Week 11	106	32.08	29.07	0.0	33.33	100.0	97	3.09	29.20	-83.3	0.00	66.7
	Week 12	109	29.97	27.10	0.0	33.33	100.0	98	0.17	29.75	-100.0	0.00	83.3
	Week 14	103	28.32	26.28	0.0	33.33	100.0	91	-1.65	30.43	-83.3	0.00	83.3
	Week 17	100	29.83	28.65	0.0	33.33	100.0	89	2.25	31.00	-66.7	0.00	83.3
	Week 20	86	24.22	26.65	0.0	16.67	83.3	76	-2.63	30.19	-83.3	0.00	66.7
	Week 23	70	23.57	24.16	0.0	16.67	83.3	64	-2.86	29.48	-83.3	0.00	83.3
	Week 26	65	29.23	27.64	0.0	33.33	100.0	61	-0.82	30.80	-83.3	0.00	83.3
	Week 29	62	30.38	29.96	0.0	33.33	100.0	58	6.90	31.69	-83.3	0.00	83.3
	Week 32	48	30.21	28.90	0.0	33.33	100.0	45	7.04	31.28	-83.3	0.00	100.0
	Week 35	47	29.08	28.33	0.0	33.33	100.0	43	4.26	27.96	-83.3	0.00	66.7
	Week 38	42	26.98	29.44	0.0	16.67	100.0	38	5.26	32.67	-83.3	0.00	100.0
	Week 41	41	28.86	28.63	0.0	16.67	100.0	38	5.70	29.83	-83.3	0.00	83.3
	Week 44	38	35.97	31.37	0.0	33.33	100.0	35	9.52	32.16	-83.3	16.67	66.7
	Week 47	32	33.85	36.04	0.0	25.00	100.0	30	10.56	32.31	-83.3	0.00	83.3
	Week 50	29	29.89	30.34	0.0	16.67	100.0	26	6.41	28.70	-83.3	0.00	83.3
	Week 53	25	29.33	30.15	0.0	16.67	100.0	24	6.25	31.40	-83.3	0.00	66.7
	Week 56	26	32.69	31.44	0.0	33.33	100.0	26	4.49	34.50	-83.3	0.00	66.7
	Week 59	20	24.17	26.20	0.0	16.67	83.3	20	-5.00	35.50	-83.3	0.00	66.7
	Week 62	19	35.09	27.72	0.0	33.33	83.3	19	1.75	34.20	-83.3	0.00	66.7
	Week 65	16	27.08	32.13	0.0	8.34	83.3	16	3.13	33.45	-83.3	0.00	66.7
	Week 68	13	32.05	35.00	0.0	33.33	100.0	13	5.13	39.90	-83.3	0.00	83.3
	Week 71	13	34.62	34.33	0.0	33.33	100.0	13	3.85	39.76	-83.3	0.00	83.3
	Week 74	11	21.21	25.92	0.0	16.67	66.7	11	-4.55	27.98	-83.3	0.00	16.7
	Week 77	10	21.67	27.27	0.0	16.67	83.3	10	8.33	19.64	-16.7	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Europe	EV+Pembro (N= 74)												
	BASELINE	53	31.76	27.79	0.0	33.33	100.0						
	Week 1	48	34.38	31.02	0.0	33.33	100.0	42	2.38	15.43	-33.3	0.00	50.0
	Week 2	53	32.07	27.71	0.0	33.33	100.0	44	3.41	17.45	-33.3	0.00	33.3
	Week 3	50	36.67	28.97	0.0	33.33	100.0	41	1.22	26.19	-66.7	0.00	66.7
	Week 4	51	25.16	25.90	0.0	16.67	100.0	44	-5.30	22.38	-66.7	0.00	33.3
	Week 5	46	25.00	26.00	0.0	16.67	100.0	41	-6.10	26.29	-66.7	0.00	50.0
	Week 6	50	26.33	23.59	0.0	33.33	83.3	39	-3.85	29.48	-66.7	0.00	66.7
	Week 7	50	21.00	21.77	0.0	16.67	66.7	39	-4.70	26.20	-66.7	0.00	66.7
	Week 8	51	22.88	21.85	0.0	16.67	66.7	41	-5.28	23.40	-66.7	0.00	50.0
	Week 9	47	24.11	23.00	0.0	16.67	66.7	37	-7.66	28.22	-66.7	0.00	66.7
	Week 10	45	20.74	25.16	0.0	16.67	100.0	34	-9.80	30.46	-66.7	0.00	66.7
	Week 11	48	17.71	21.85	0.0	16.67	83.3	37	-9.46	25.62	-66.7	0.00	66.7
	Week 12	51	20.26	25.24	0.0	16.67	100.0	39	-6.84	24.70	-50.0	0.00	50.0
	Week 14	50	16.00	19.62	0.0	0.00	66.7	38	-11.84	24.78	-66.7	-8.33	33.3
	Week 17	43	15.89	17.80	0.0	0.00	50.0	33	-11.11	27.22	-66.7	-16.67	50.0
	Week 20	41	17.07	18.06	0.0	16.67	66.7	33	-12.12	24.75	-66.7	-16.66	50.0
	Week 23	41	14.63	19.43	0.0	0.00	66.7	30	-13.33	26.77	-66.7	-16.67	66.7
	Week 26	37	20.27	20.08	0.0	16.67	83.3	28	-8.33	25.05	-66.7	0.00	66.7
	Week 29	37	16.22	20.60	0.0	0.00	66.7	29	-9.20	23.82	-66.7	0.00	50.0
	Week 32	34	14.22	19.30	0.0	0.00	66.7	26	-14.10	25.25	-66.7	-16.67	33.3
	Week 35	31	20.97	21.50	0.0	16.67	66.7	25	-4.67	26.58	-66.7	0.00	50.0
	Week 38	31	20.43	21.39	0.0	16.67	66.7	26	-7.69	24.14	-66.7	0.00	33.3
	Week 41	28	20.24	23.73	0.0	16.67	100.0	23	-10.87	25.43	-66.7	0.00	50.0
	Week 44	27	16.67	24.46	0.0	0.00	83.3	22	-9.09	27.08	-66.7	0.00	50.0
	Week 47	25	18.00	19.79	0.0	16.67	66.7	21	-7.14	25.59	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	26	23.08	33.36	0.0	8.34	100.0	23	-2.17	28.12	-66.7	0.00	50.0
	Week 53	26	27.56	33.65	0.0	16.67	100.0	21	-0.79	35.15	-66.7	0.00	66.7
	Week 56	25	26.67	25.00	0.0	33.33	100.0	21	-7.14	29.14	-66.7	0.00	50.0
	Week 59	23	21.01	22.03	0.0	16.67	66.7	18	-8.33	25.08	-50.0	-8.33	33.3
	Week 62	20	23.33	21.22	0.0	16.67	66.7	17	-4.90	22.64	-50.0	0.00	33.3
	Week 65	13	16.67	16.67	0.0	16.67	50.0	13	-5.13	25.81	-50.0	0.00	33.3
	Week 68	15	30.00	26.87	0.0	33.33	100.0	15	6.67	28.03	-33.3	0.00	66.7
	Week 71	13	23.08	28.49	0.0	16.67	83.3	13	-3.85	28.18	-33.3	0.00	50.0
	Week 74	10	23.33	26.29	0.0	16.67	66.7	9	3.70	32.03	-33.3	0.00	66.7
	Plat+Gem (N= 95)												
	BASELINE	75	32.00	32.16	0.0	16.67	100.0						
	Week 1	71	35.45	31.36	0.0	33.33	100.0	69	2.42	18.58	-33.3	0.00	66.7
	Week 2	71	33.80	27.45	0.0	33.33	100.0	63	3.17	22.77	-50.0	0.00	50.0
	Week 3	72	29.86	28.38	0.0	25.00	100.0	65	-0.51	23.75	-83.3	0.00	50.0
	Week 4	69	29.47	27.29	0.0	33.33	100.0	62	-0.81	28.54	-100.0	0.00	66.7
	Week 5	71	30.75	28.82	0.0	16.67	100.0	63	-0.26	26.52	-66.7	0.00	83.3
	Week 6	69	26.81	28.18	0.0	16.67	100.0	61	-2.73	31.06	-100.0	0.00	83.3
	Week 7	69	30.19	29.74	0.0	16.67	100.0	62	1.61	27.78	-83.3	0.00	66.7
	Week 8	67	29.85	26.99	0.0	33.33	100.0	60	0.00	28.95	-66.7	0.00	66.7
	Week 9	66	30.05	25.19	0.0	33.33	100.0	57	1.17	28.67	-100.0	0.00	66.7
	Week 10	70	26.67	26.53	0.0	33.33	100.0	63	-2.65	28.43	-100.0	0.00	66.7
	Week 11	63	31.22	26.69	0.0	33.33	100.0	56	2.08	26.22	-66.7	0.00	66.7
	Week 12	66	29.55	26.76	0.0	33.33	83.3	56	0.30	28.16	-100.0	0.00	83.3
	Week 14	66	30.56	26.41	0.0	33.33	100.0	56	2.08	29.48	-83.3	0.00	83.3
	Week 17	61	30.33	27.64	0.0	33.33	100.0	53	3.46	26.02	-50.0	0.00	66.7
	Week 20	54	27.47	30.91	0.0	16.67	100.0	48	0.00	27.72	-66.7	0.00	66.7

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 23	44	28.79	26.26	0.0	16.67	83.3	40	1.25	24.86	-50.0	0.00	83.3
	Week 26	42	33.73	29.33	0.0	33.33	100.0	39	3.85	27.96	-50.0	0.00	83.3
	Week 29	39	34.62	28.96	0.0	33.33	100.0	36	6.48	27.10	-50.0	0.00	66.7
	Week 32	32	38.02	32.58	0.0	33.33	100.0	30	10.00	30.83	-33.3	0.00	100.0
	Week 35	32	32.81	29.17	0.0	33.33	100.0	30	7.22	22.18	-33.3	0.00	66.7
	Week 38	28	32.14	33.31	0.0	16.67	100.0	26	8.33	29.15	-16.7	0.00	100.0
	Week 41	25	37.33	34.45	0.0	33.33	100.0	23	7.25	26.03	-33.3	0.00	83.3
	Week 44	24	44.45	33.21	0.0	50.00	100.0	22	13.64	23.92	-16.7	16.67	66.7
	Week 47	22	41.67	37.00	0.0	33.33	100.0	20	10.83	31.66	-33.3	0.00	83.3
	Week 50	17	40.20	32.31	0.0	33.33	100.0	15	7.78	27.36	-33.3	0.00	83.3
	Week 53	15	37.78	34.77	0.0	33.33	100.0	14	7.14	27.51	-33.3	0.00	66.7
	Week 56	15	46.67	30.34	0.0	33.33	100.0	14	14.28	28.39	-33.3	25.00	66.7
	Week 59	11	37.88	29.90	0.0	33.33	83.3	10	6.67	30.63	-33.3	0.00	66.7
	Week 62	11	42.42	29.22	0.0	33.33	83.3	11	13.64	24.51	-16.7	16.66	66.7
	Week 65	10	40.00	33.52	0.0	50.00	83.3	10	16.67	26.06	-16.7	8.33	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
North America	EV+Pembro (N= 46)												
	BASELINE	33	31.31	27.56	0.0	33.33	83.3						
	Week 1	30	36.67	30.76	0.0	33.33	100.0	27	0.62	17.59	-33.3	0.00	33.3
	Week 2	30	37.22	29.91	0.0	33.33	100.0	26	3.85	23.72	-50.0	0.00	66.7
	Week 3	25	26.67	22.57	0.0	33.33	83.3	21	-3.18	18.72	-50.0	0.00	16.7
	Week 4	30	30.00	21.62	0.0	33.33	83.3	24	-4.86	20.55	-66.7	0.00	33.3
	Week 5	29	27.59	23.26	0.0	33.33	83.3	21	-7.14	22.71	-66.7	0.00	33.3
	Week 6	31	27.96	25.60	0.0	33.33	83.3	23	-4.35	23.69	-66.7	0.00	50.0
	Week 7	33	23.74	22.83	0.0	16.67	83.3	23	-11.59	23.27	-66.7	-16.66	33.3
	Week 8	29	21.84	23.61	0.0	16.67	83.3	20	-17.50	29.36	-83.3	-8.33	16.7
	Week 9	27	19.75	18.51	0.0	16.67	66.7	21	-12.70	24.67	-83.3	0.00	16.7
	Week 10	29	17.82	16.62	0.0	16.67	50.0	23	-15.94	20.40	-66.7	-16.66	16.7
	Week 11	28	20.24	25.80	0.0	8.34	100.0	21	-15.87	23.85	-66.7	-16.66	33.3
	Week 12	29	19.54	20.45	0.0	16.67	66.7	22	-12.88	27.66	-83.3	0.00	33.3
	Week 14	28	17.86	20.75	0.0	16.67	66.7	21	-11.90	23.06	-66.7	0.00	33.3
	Week 17	29	19.54	19.95	0.0	16.67	66.7	23	-11.59	23.80	-66.7	0.00	33.3
	Week 20	23	15.94	17.75	0.0	16.67	50.0	18	-13.89	25.08	-83.3	0.00	16.7
	Week 23	22	12.88	15.37	0.0	8.34	50.0	17	-9.80	24.34	-83.3	0.00	16.7
	Week 26	21	18.25	17.40	0.0	16.67	50.0	16	-10.42	25.00	-83.3	0.00	16.7
	Week 29	20	19.17	18.94	0.0	16.67	66.7	17	-7.84	22.14	-66.7	0.00	33.3
	Week 32	21	15.87	15.34	0.0	16.67	33.3	18	-17.59	28.85	-83.3	-8.33	16.7
	Week 35	22	18.94	18.75	0.0	16.67	66.7	19	-13.16	25.20	-83.3	0.00	16.7
	Week 38	20	20.00	18.42	0.0	25.00	50.0	17	-10.78	26.97	-66.7	0.00	16.7
	Week 41	21	19.05	19.21	0.0	16.67	66.7	17	-7.84	25.08	-66.7	0.00	33.3
	Week 44	16	20.83	16.67	0.0	25.00	50.0	12	-11.11	23.92	-66.7	0.00	16.7
	Week 47	16	23.96	28.52	0.0	16.67	83.3	13	-7.69	26.89	-66.7	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	16	22.92	21.84	0.0	16.67	66.7	11	-10.60	26.11	-66.7	0.00	16.7
	Week 53	15	23.33	18.69	0.0	33.33	50.0	11	-13.64	25.63	-66.7	0.00	16.7
	Week 56	17	20.59	20.01	0.0	16.67	66.7	12	-19.44	21.12	-66.7	-16.66	0.0
	Week 59	17	30.39	27.79	0.0	33.33	100.0	12	-13.89	26.43	-66.7	-8.33	33.3
	Week 62	14	26.19	26.73	0.0	25.00	83.3	9	-12.96	21.70	-66.7	0.00	0.0
	Week 68	11	16.67	18.26	0.0	16.67	50.0	8	-18.75	24.30	-66.7	-8.33	0.0
	Week 71	11	21.21	25.92	0.0	16.67	66.7	8	-10.42	36.67	-66.7	0.00	33.3
	Plat+Gem (N= 34)												
	BASELINE	27	36.42	32.70	0.0	33.33	100.0						
	Week 1	19	26.32	27.40	0.0	16.67	66.7	17	-6.86	20.46	-50.0	0.00	50.0
	Week 2	20	30.83	30.24	0.0	33.33	83.3	18	0.92	20.19	-16.7	0.00	50.0
	Week 3	20	31.67	28.05	0.0	33.33	100.0	17	2.94	18.85	-33.3	0.00	50.0
	Week 4	23	19.57	22.84	0.0	16.67	66.7	19	-8.77	27.98	-83.3	0.00	33.3
	Week 5	25	25.33	25.96	0.0	33.33	100.0	22	-3.03	33.98	-100.0	0.00	33.3
	Week 6	20	18.33	25.88	0.0	0.00	100.0	17	-10.79	31.15	-100.0	0.00	33.3
	Week 7	23	29.71	36.22	0.0	33.33	100.0	20	0.83	35.24	-66.7	0.00	83.3
	Week 8	24	35.42	34.16	0.0	33.33	100.0	22	5.30	38.62	-66.7	0.00	83.3
	Week 9	23	25.36	22.96	0.0	33.33	83.3	19	-3.51	30.22	-66.7	0.00	50.0
	Week 10	20	27.50	24.94	0.0	33.33	83.3	18	0.00	29.15	-66.7	0.00	33.3
	Week 11	18	25.00	26.96	0.0	25.00	100.0	16	6.25	23.47	-33.3	0.00	50.0
	Week 12	17	23.53	21.29	0.0	33.33	66.7	16	-5.21	29.01	-66.7	0.00	66.7
	Week 14	16	21.87	27.02	0.0	8.34	83.3	14	-4.76	32.31	-66.7	-8.33	66.7
	Week 17	19	22.81	31.04	0.0	0.00	83.3	17	0.98	39.73	-66.7	0.00	83.3
	Week 20	16	18.75	18.13	0.0	25.00	50.0	13	-2.57	34.59	-66.7	0.00	33.3
	Week 23	15	13.33	16.90	0.0	0.00	33.3	13	-8.98	29.36	-66.7	0.00	33.3
	Week 26	13	20.51	21.68	0.0	33.33	66.7	12	1.39	27.02	-50.0	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 29	14	26.19	30.46	0.0	25.00	100.0	13	11.54	31.46	-50.0	0.00	66.7
	Week 32	11	16.67	22.36	0.0	0.00	66.7	10	5.00	22.29	-16.7	0.00	50.0
	Week 35	13	20.51	21.68	0.0	16.67	66.7	11	1.52	28.34	-50.0	0.00	50.0
	Week 38	10	30.00	34.07	0.0	25.00	100.0	9	22.22	31.18	-16.7	16.66	83.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Rest of World	EV+Pembro (N= 82)												
	BASELINE	74	32.21	30.39	0.0	33.33	100.0						
	Week 1	63	30.69	27.79	0.0	33.33	100.0	60	-1.39	19.95	-50.0	0.00	66.7
	Week 2	67	37.81	30.37	0.0	33.33	100.0	63	3.70	18.32	-50.0	0.00	50.0
	Week 3	64	32.81	28.01	0.0	33.33	100.0	60	-1.11	24.71	-83.3	0.00	50.0
	Week 4	64	26.04	27.20	0.0	16.67	100.0	61	-5.46	26.83	-83.3	0.00	66.7
	Week 5	62	22.04	23.72	0.0	16.67	100.0	59	-8.47	23.65	-100.0	0.00	33.3
	Week 6	65	22.56	23.83	0.0	16.67	100.0	62	-11.02	29.25	-100.0	0.00	66.7
	Week 7	64	24.22	24.47	0.0	16.67	100.0	62	-8.06	31.61	-100.0	0.00	83.3
	Week 8	67	24.63	25.02	0.0	16.67	100.0	63	-6.88	35.88	-100.0	0.00	100.0
	Week 9	68	27.70	27.56	0.0	25.00	100.0	63	-2.91	34.33	-83.3	0.00	100.0
	Week 10	65	24.87	27.50	0.0	16.67	100.0	61	-4.92	32.25	-100.0	0.00	83.3
	Week 11	61	23.50	24.41	0.0	16.67	100.0	57	-7.02	32.57	-100.0	0.00	66.7
	Week 12	62	24.46	26.78	0.0	16.67	100.0	58	-6.90	34.35	-100.0	0.00	66.7
	Week 14	61	24.04	26.96	0.0	16.67	100.0	57	-9.36	33.48	-100.0	0.00	66.7
	Week 17	60	22.50	21.44	0.0	33.33	100.0	55	-7.58	30.23	-100.0	0.00	50.0
	Week 20	56	24.11	21.77	0.0	25.00	83.3	52	-3.53	29.21	-100.0	0.00	50.0
	Week 23	54	24.07	22.59	0.0	16.67	66.7	50	-5.00	32.86	-100.0	0.00	66.7
	Week 26	54	22.84	22.03	0.0	16.67	66.7	50	-4.00	32.22	-100.0	0.00	50.0
	Week 29	50	27.67	25.56	0.0	33.33	83.3	47	1.77	35.82	-100.0	0.00	83.3
	Week 32	47	25.53	22.75	0.0	33.33	83.3	44	-1.52	32.91	-100.0	0.00	83.3
	Week 35	45	27.04	25.20	0.0	33.33	83.3	42	1.19	31.75	-100.0	0.00	66.7
	Week 38	46	25.00	22.15	0.0	33.33	66.7	43	-5.81	30.83	-100.0	0.00	66.7
	Week 41	46	23.19	22.90	0.0	25.00	66.7	44	-4.55	32.02	-100.0	0.00	66.7
	Week 44	43	30.62	25.96	0.0	33.33	100.0	40	2.08	32.73	-100.0	0.00	83.3
	Week 47	38	28.51	22.23	0.0	33.33	83.3	36	0.46	35.07	-100.0	0.00	66.7

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	32	26.56	23.90	0.0	33.33	66.7	30	-2.22	32.38	-100.0	0.00	50.0
	Week 53	33	30.30	25.84	0.0	33.33	66.7	31	0.54	34.02	-100.0	0.00	66.7
	Week 56	30	25.55	25.04	0.0	33.33	83.3	28	-3.57	35.24	-100.0	0.00	66.7
	Week 59	29	32.18	27.43	0.0	33.33	66.7	27	2.47	36.31	-100.0	0.00	66.7
	Week 62	28	29.17	24.27	0.0	33.33	66.7	26	0.64	33.82	-100.0	0.00	66.7
	Week 65	22	33.33	28.17	0.0	33.33	66.7	21	4.76	43.19	-100.0	0.00	66.7
	Week 68	20	30.83	25.52	0.0	33.33	83.3	19	4.39	41.51	-100.0	0.00	83.3
	Week 71	18	25.93	23.03	0.0	25.00	66.7	17	-3.92	41.05	-100.0	0.00	66.7
	Week 74	19	29.82	28.64	0.0	33.33	100.0	19	3.51	41.04	-100.0	0.00	83.3
	Week 77	19	26.32	24.42	0.0	33.33	66.7	18	-2.78	38.45	-100.0	0.00	66.7
	Week 80	19	29.82	27.54	0.0	33.33	66.7	18	0.93	37.69	-100.0	0.00	66.7
	Week 83	17	31.37	24.92	0.0	33.33	66.7	17	2.94	40.07	-100.0	0.00	66.7
	Week 86	14	27.38	29.68	0.0	16.67	66.7	14	-2.38	41.27	-100.0	0.00	66.7
	Week 89	11	25.76	28.25	0.0	16.67	83.3	11	6.06	34.38	-33.3	0.00	83.3
	Plat+Gem (N= 73)												
	BASELINE	63	32.28	29.16	0.0	33.33	100.0						
	Week 1	54	36.11	29.81	0.0	33.33	100.0	53	1.89	26.28	-66.7	0.00	100.0
	Week 2	56	38.09	25.76	0.0	33.33	100.0	54	6.79	24.77	-66.7	8.33	50.0
	Week 3	57	33.33	27.99	0.0	33.33	100.0	54	2.47	23.21	-50.0	0.00	66.7
	Week 4	58	33.33	26.49	0.0	33.33	100.0	54	-0.93	25.58	-66.7	0.00	50.0
	Week 5	57	30.70	26.87	0.0	33.33	83.3	53	0.00	29.05	-83.3	0.00	83.3
	Week 6	56	30.95	28.50	0.0	33.33	100.0	53	-0.31	28.40	-83.3	0.00	66.7
	Week 7	56	32.14	26.37	0.0	33.33	100.0	52	0.64	29.70	-83.3	0.00	66.7
	Week 8	54	33.33	28.41	0.0	33.33	100.0	50	3.00	32.77	-83.3	0.00	100.0
	Week 9	52	33.01	28.68	0.0	33.33	100.0	49	1.02	31.26	-83.3	0.00	66.7
	Week 10	52	31.73	29.57	0.0	33.33	100.0	49	0.34	30.14	-83.3	0.00	66.7

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Table 302.1.3002.16.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	45	34.44	32.84	0.0	33.33	100.0	42	1.98	32.13	-83.3	0.00	66.7
	Week 12	47	31.21	27.94	0.0	33.33	100.0	43	1.55	27.89	-83.3	0.00	66.7
	Week 14	43	30.62	27.44	0.0	33.33	100.0	39	-1.28	30.92	-83.3	0.00	66.7
	Week 17	40	30.83	28.38	0.0	33.33	100.0	36	0.46	32.24	-66.7	0.00	83.3
	Week 20	34	24.02	25.36	0.0	25.00	83.3	30	-6.67	27.89	-83.3	0.00	66.7
	Week 23	29	18.97	21.70	0.0	16.67	66.7	27	-6.79	29.33	-83.3	0.00	66.7
	Week 26	26	22.44	26.22	0.0	16.67	100.0	24	-9.72	30.26	-83.3	0.00	50.0
	Week 29	24	22.92	26.38	0.0	25.00	100.0	22	1.52	32.08	-83.3	0.00	83.3
	Week 32	20	25.83	24.47	0.0	33.33	66.7	18	2.78	31.96	-83.3	0.00	50.0
	Week 35	17	26.47	27.04	0.0	33.33	66.7	15	1.11	33.61	-83.3	0.00	66.7
	Week 38	18	25.00	26.35	0.0	25.00	66.7	15	-5.56	35.45	-83.3	0.00	50.0
	Week 41	18	23.15	22.97	0.0	16.67	66.7	16	1.04	33.59	-83.3	0.00	50.0
	Week 44	16	26.04	25.07	0.0	25.00	66.7	14	-1.19	40.01	-83.3	0.00	50.0
	Week 47	12	26.39	34.42	0.0	8.34	100.0	11	7.58	38.27	-83.3	0.00	66.7
	Week 50	11	31.82	29.30	0.0	16.67	66.7	9	5.56	37.27	-83.3	16.67	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	EV+Pembro (N=146)												
	BASELINE	119	31.23	28.58	0.0	33.33	100.0						
	Week 1	102	30.56	26.44	0.0	33.33	100.0	97	-0.34	17.84	-33.3	0.00	66.7
	Week 2	106	34.12	27.25	0.0	33.33	100.0	98	3.91	18.81	-50.0	0.00	66.7
	Week 3	94	31.56	25.45	0.0	33.33	100.0	88	0.38	24.76	-66.7	0.00	66.7
	Week 4	101	24.92	22.93	0.0	33.33	100.0	93	-5.73	23.51	-83.3	0.00	50.0
	Week 5	96	22.05	21.96	0.0	16.67	100.0	89	-8.61	25.14	-100.0	0.00	50.0
	Week 6	105	23.49	22.73	0.0	16.67	100.0	93	-7.17	28.17	-100.0	0.00	66.7
	Week 7	102	20.75	20.77	0.0	16.67	83.3	89	-8.24	28.22	-100.0	0.00	66.7
	Week 8	101	20.96	22.69	0.0	16.67	100.0	91	-8.97	30.86	-100.0	0.00	100.0
	Week 9	100	23.00	23.54	0.0	16.67	100.0	89	-7.68	30.98	-83.3	0.00	100.0
	Week 10	99	19.70	22.63	0.0	16.67	100.0	87	-11.30	30.02	-100.0	0.00	83.3
	Week 11	95	18.95	23.27	0.0	16.67	100.0	84	-8.73	27.44	-100.0	0.00	66.7
	Week 12	99	21.55	25.56	0.0	16.67	100.0	87	-7.09	29.60	-100.0	0.00	66.7
	Week 14	95	18.60	22.66	0.0	16.67	100.0	84	-10.12	26.89	-100.0	0.00	33.3
	Week 17	97	19.93	20.50	0.0	16.67	100.0	84	-8.53	25.68	-66.7	0.00	50.0
	Week 20	90	19.63	18.96	0.0	16.67	83.3	79	-7.59	25.01	-83.3	0.00	50.0
	Week 23	86	18.80	20.89	0.0	16.67	66.7	74	-6.31	28.76	-83.3	0.00	66.7
	Week 26	83	20.48	20.88	0.0	16.67	83.3	72	-4.63	26.72	-83.3	0.00	66.7
	Week 29	80	21.67	22.41	0.0	16.67	83.3	71	-2.82	27.89	-66.7	0.00	83.3
	Week 32	74	17.12	18.08	0.0	16.67	66.7	66	-8.84	28.53	-83.3	0.00	50.0
	Week 35	73	23.06	23.01	0.0	16.67	83.3	66	-3.03	29.51	-83.3	0.00	66.7
	Week 38	75	20.89	18.40	0.0	16.67	66.7	67	-7.96	26.65	-100.0	0.00	33.3
	Week 41	71	19.95	21.01	0.0	16.67	100.0	64	-7.55	26.88	-83.3	0.00	50.0
	Week 44	64	22.40	22.07	0.0	16.67	100.0	56	-3.27	26.86	-66.7	0.00	66.7
	Week 47	56	22.62	21.65	0.0	16.67	83.3	50	-4.00	27.47	-66.7	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	55	23.94	26.21	0.0	16.67	100.0	48	-3.47	28.76	-66.7	0.00	50.0
	Week 53	55	26.36	26.78	0.0	33.33	100.0	48	-2.43	31.70	-66.7	0.00	66.7
	Week 56	53	25.16	22.08	0.0	33.33	83.3	46	-7.61	29.75	-66.7	0.00	66.7
	Week 59	51	28.10	25.49	0.0	33.33	100.0	43	-4.65	28.71	-66.7	0.00	66.7
	Week 62	42	27.38	22.64	0.0	33.33	83.3	36	-1.39	27.42	-66.7	0.00	66.7
	Week 65	31	24.19	22.71	0.0	16.67	66.7	30	-2.22	34.67	-66.7	0.00	66.7
	Week 68	31	28.49	24.42	0.0	33.33	100.0	29	2.87	33.94	-66.7	0.00	83.3
	Week 71	30	27.22	24.56	0.0	33.33	83.3	28	-1.19	33.92	-66.7	0.00	66.7
	Week 74	29	24.71	22.55	0.0	33.33	66.7	27	-0.62	33.49	-66.7	0.00	66.7
	Week 77	26	25.64	24.60	0.0	33.33	66.7	24	-0.69	32.41	-66.7	0.00	66.7
	Week 80	26	30.77	23.89	0.0	33.33	66.7	26	3.21	27.49	-66.7	0.00	66.7
	Week 83	21	31.75	23.51	0.0	33.33	83.3	21	3.17	30.56	-66.7	0.00	66.7
	Week 86	17	28.43	23.40	0.0	33.33	66.7	17	5.88	28.83	-33.3	0.00	66.7
	Week 89	11	21.21	26.97	0.0	16.67	83.3	11	4.55	34.23	-33.3	0.00	83.3
	Week 92	13	28.20	20.84	0.0	33.33	66.7	13	0.00	25.46	-33.3	0.00	50.0
	Plat+Gem (N=151)												
	BASELINE	123	28.86	29.88	0.0	16.67	100.0						
	Week 1	108	30.25	28.20	0.0	33.33	100.0	103	0.32	21.00	-50.0	0.00	100.0
	Week 2	116	33.05	26.46	0.0	33.33	100.0	105	6.03	20.56	-50.0	0.00	50.0
	Week 3	114	29.82	26.28	0.0	33.33	100.0	103	3.72	21.25	-50.0	0.00	66.7
	Week 4	116	28.16	24.91	0.0	33.33	100.0	103	0.97	23.55	-83.3	0.00	66.7
	Week 5	119	29.55	27.40	0.0	33.33	100.0	106	2.83	28.03	-100.0	0.00	83.3
	Week 6	109	26.15	26.58	0.0	33.33	100.0	98	0.51	28.46	-100.0	0.00	83.3
	Week 7	115	30.72	29.00	0.0	33.33	100.0	105	5.08	27.55	-83.3	0.00	83.3
	Week 8	111	30.03	28.05	0.0	33.33	100.0	102	4.08	31.68	-83.3	0.00	100.0
	Week 9	107	30.22	24.56	0.0	33.33	100.0	95	3.86	26.68	-83.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	107	27.26	26.83	0.0	33.33	100.0	98	1.87	25.98	-83.3	0.00	66.7
	Week 11	97	30.93	29.07	0.0	33.33	100.0	87	6.90	26.60	-83.3	0.00	66.7
	Week 12	100	28.50	25.77	0.0	33.33	83.3	88	3.03	26.69	-83.3	0.00	83.3
	Week 14	99	29.46	26.50	0.0	33.33	100.0	86	3.88	28.32	-83.3	0.00	83.3
	Week 17	94	26.95	26.79	0.0	33.33	100.0	82	4.47	29.98	-66.7	0.00	83.3
	Week 20	84	25.99	27.67	0.0	25.00	100.0	72	3.01	26.44	-83.3	0.00	66.7
	Week 23	70	23.33	23.98	0.0	16.67	83.3	62	1.88	27.01	-83.3	0.00	83.3
	Week 26	61	28.96	28.20	0.0	33.33	100.0	55	6.36	28.24	-83.3	0.00	83.3
	Week 29	59	28.25	27.90	0.0	33.33	100.0	53	9.43	28.21	-83.3	0.00	83.3
	Week 32	50	30.00	30.12	0.0	33.33	100.0	45	10.37	31.04	-83.3	0.00	100.0
	Week 35	50	29.67	28.43	0.0	33.33	100.0	44	8.71	26.04	-83.3	0.00	66.7
	Week 38	46	28.62	30.56	0.0	16.67	100.0	40	7.08	32.22	-83.3	0.00	100.0
	Week 41	42	30.95	31.14	0.0	25.00	100.0	37	9.01	32.06	-83.3	0.00	83.3
	Week 44	39	34.19	32.43	0.0	33.33	100.0	34	13.24	31.46	-83.3	16.67	66.7
	Week 47	33	31.82	34.45	0.0	16.67	100.0	29	10.92	32.82	-83.3	0.00	83.3
	Week 50	27	29.63	28.99	0.0	33.33	100.0	22	6.82	31.14	-83.3	0.00	83.3
	Week 53	23	31.16	30.28	0.0	16.67	83.3	20	5.00	34.24	-83.3	0.00	66.7
	Week 56	20	27.50	27.18	0.0	33.33	83.3	19	3.51	37.09	-83.3	0.00	66.7
	Week 59	17	29.41	30.35	0.0	16.67	83.3	15	-1.11	38.56	-83.3	0.00	66.7
	Week 62	14	30.95	29.86	0.0	33.33	83.3	14	4.76	36.65	-83.3	0.00	66.7
	Week 65	13	29.49	34.80	0.0	0.00	83.3	12	5.56	37.15	-83.3	0.00	66.7
	Week 68	10	31.67	37.23	0.0	16.67	100.0	10	6.67	43.88	-83.3	0.00	83.3
	Week 71	10	31.67	37.23	0.0	16.67	100.0	10	6.67	43.88	-83.3	0.00	83.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	EV+Pembro (N= 56)												
	BASELINE	41	33.74	29.69	0.0	33.33	100.0						
	Week 1	39	40.17	35.61	0.0	33.33	100.0	32	2.08	18.81	-50.0	0.00	50.0
	Week 2	44	39.39	33.74	0.0	33.33	100.0	35	2.86	20.00	-33.3	0.00	33.3
	Week 3	45	36.30	31.44	0.0	33.33	100.0	34	-3.43	22.76	-83.3	0.00	50.0
	Week 4	44	30.30	30.77	0.0	25.00	100.0	36	-4.17	25.93	-50.0	0.00	66.7
	Week 5	41	29.27	28.81	0.0	33.33	100.0	32	-4.17	21.58	-33.3	0.00	33.3
	Week 6	41	28.86	27.14	0.0	33.33	83.3	31	-8.60	29.46	-66.7	-16.66	50.0
	Week 7	45	28.15	27.25	0.0	33.33	100.0	35	-6.19	29.45	-83.3	0.00	83.3
	Week 8	46	28.99	24.70	0.0	33.33	100.0	33	-5.56	32.72	-83.3	0.00	83.3
	Week 9	42	29.76	26.68	0.0	33.33	100.0	32	-1.56	31.21	-66.7	0.00	83.3
	Week 10	40	27.92	29.09	0.0	16.67	100.0	31	-0.54	28.38	-50.0	0.00	83.3
	Week 11	42	25.00	24.76	0.0	25.00	66.7	31	-11.29	33.16	-100.0	0.00	50.0
	Week 12	43	22.87	23.86	0.0	16.67	83.3	32	-10.42	31.89	-100.0	-8.33	66.7
	Week 14	44	22.73	25.18	0.0	16.67	83.3	32	-11.98	34.19	-100.0	0.00	66.7
	Week 17	35	19.05	19.02	0.0	16.67	66.7	27	-12.35	34.47	-100.0	-16.66	50.0
	Week 20	30	21.67	23.22	0.0	25.00	66.7	24	-9.72	34.37	-100.0	0.00	50.0
	Week 23	31	18.28	20.80	0.0	16.67	66.7	23	-15.22	32.14	-100.0	-16.66	50.0
	Week 26	29	22.99	19.63	0.0	33.33	66.7	22	-12.12	35.33	-100.0	0.00	50.0
	Week 29	27	23.46	25.84	0.0	16.67	83.3	22	-5.30	38.28	-100.0	0.00	66.7
	Week 32	28	26.79	25.80	0.0	33.33	83.3	22	-7.58	36.63	-100.0	0.00	83.3
	Week 35	25	24.00	22.61	0.0	33.33	66.7	20	-5.83	28.75	-100.0	0.00	50.0
	Week 38	22	28.03	28.35	0.0	25.00	66.7	19	-5.26	32.89	-100.0	0.00	66.7
	Week 41	24	25.69	25.53	0.0	25.00	66.7	20	-5.00	35.09	-100.0	0.00	66.7
	Week 44	22	30.30	30.70	0.0	33.33	83.3	18	-3.70	39.42	-100.0	0.00	83.3
	Week 47	23	28.26	26.32	0.0	33.33	83.3	20	-1.67	38.96	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	19	26.32	29.56	0.0	16.67	100.0	16	-4.17	33.05	-100.0	0.00	50.0
	Week 53	19	32.46	29.65	0.0	33.33	83.3	15	-2.22	38.25	-100.0	0.00	66.7
	Week 56	19	23.68	28.50	0.0	16.67	100.0	15	-8.89	35.56	-100.0	0.00	66.7
	Week 59	18	27.78	28.01	0.0	33.33	66.7	14	-3.57	39.86	-100.0	0.00	66.7
	Week 62	20	25.00	26.21	0.0	16.67	66.7	16	-8.33	31.62	-100.0	0.00	50.0
	Week 65	12	25.00	29.73	0.0	8.34	66.7	10	-6.67	45.95	-100.0	0.00	66.7
	Week 68	15	24.44	25.87	0.0	16.67	66.7	13	-3.85	37.98	-100.0	0.00	66.7
	Week 71	12	15.28	25.09	0.0	0.00	66.7	10	-16.67	38.49	-100.0	0.00	33.3
	Week 77	11	13.64	20.84	0.0	0.00	66.7	9	-22.22	32.28	-100.0	-16.66	0.0
	Week 80	10	21.67	27.27	0.0	8.34	66.7	8	-12.50	44.32	-100.0	0.00	50.0
	Plat+Gem (N= 51)												
	BASELINE	42	44.44	31.59	0.0	33.33	100.0						
	Week 1	36	47.22	32.97	0.0	33.33	100.0	36	3.24	25.14	-66.7	0.00	66.7
	Week 2	31	42.47	28.82	0.0	33.33	100.0	30	-1.67	30.43	-66.7	0.00	50.0
	Week 3	35	36.67	33.04	0.0	33.33	100.0	33	-7.07	26.03	-83.3	0.00	33.3
	Week 4	34	33.82	31.65	0.0	33.33	100.0	32	-11.46	35.53	-100.0	0.00	66.7
	Week 5	34	30.88	28.47	0.0	33.33	83.3	32	-11.98	27.83	-66.7	-16.66	83.3
	Week 6	36	30.56	32.49	0.0	33.33	100.0	33	-12.63	32.55	-100.0	-16.66	50.0
	Week 7	33	31.31	31.39	0.0	33.33	100.0	29	-13.22	32.24	-83.3	-16.67	66.7
	Week 8	34	38.73	30.07	0.0	33.33	100.0	30	-5.00	32.50	-66.7	0.00	66.7
	Week 9	34	30.88	31.01	0.0	25.00	100.0	30	-10.56	36.22	-100.0	0.00	66.7
	Week 10	35	32.86	29.01	0.0	33.33	100.0	32	-10.42	35.61	-100.0	-8.34	66.7
	Week 11	29	33.33	29.21	0.0	33.33	100.0	27	-11.11	28.50	-66.7	-16.66	66.7
	Week 12	30	32.22	29.01	0.0	33.33	100.0	27	-9.88	30.40	-100.0	-16.66	66.7
	Week 14	26	29.49	28.41	0.0	33.33	100.0	23	-14.49	33.07	-83.3	-16.67	66.7
	Week 17	26	37.82	32.51	0.0	33.33	100.0	24	-6.25	31.01	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 20	20	20.83	26.97	0.0	0.00	66.7	19	-23.68	27.40	-66.7	-16.67	33.3
	Week 23	18	21.30	24.79	0.0	16.67	66.7	18	-20.37	20.26	-66.7	-16.67	0.0
	Week 26	20	25.00	26.21	0.0	16.67	66.7	20	-20.83	20.14	-50.0	-25.00	16.7
	Week 29	18	33.33	31.31	0.0	33.33	100.0	18	-4.63	30.68	-50.0	0.00	66.7
	Week 32	13	32.05	27.61	0.0	33.33	83.3	13	-5.13	20.84	-50.0	0.00	33.3
	Week 35	12	23.61	21.86	0.0	25.00	66.7	12	-11.11	22.84	-50.0	0.00	16.7
	Week 38	10	33.33	34.25	0.0	25.00	100.0	10	5.00	34.29	-50.0	0.00	83.3
	Week 41	10	33.34	27.22	0.0	25.00	66.7	10	5.00	13.72	-16.7	0.00	33.3
	Week 44	10	40.00	23.83	0.0	41.67	66.7	10	0.00	23.57	-50.0	0.00	33.3
	Week 47	10	36.67	39.13	0.0	25.00	100.0	10	5.00	30.48	-33.3	0.00	66.7
	Week 56	10	45.00	36.89	0.0	66.67	100.0	10	5.00	23.64	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Visceral metastases	EV+Pembro (N=148)												
	BASELINE	119	34.73	30.50	0.0	33.33	100.0						
	Week 1	105	35.56	30.23	0.0	33.33	100.0	99	0.17	17.74	-33.3	0.00	50.0
	Week 2	109	39.45	29.80	0.0	33.33	100.0	100	4.50	19.08	-50.0	0.00	66.7
	Week 3	98	34.69	28.08	0.0	33.33	100.0	88	-2.46	24.96	-83.3	0.00	50.0
	Week 4	103	29.13	26.37	0.0	33.33	100.0	93	-5.38	25.20	-83.3	0.00	66.7
	Week 5	100	26.67	24.73	0.0	33.33	100.0	90	-7.59	26.10	-100.0	0.00	50.0
	Week 6	105	25.71	24.02	0.0	33.33	100.0	90	-10.19	28.01	-100.0	0.00	66.7
	Week 7	108	23.15	22.31	0.0	16.67	100.0	91	-9.52	29.83	-100.0	0.00	83.3
	Week 8	105	23.02	22.57	0.0	16.67	100.0	89	-11.05	32.27	-100.0	0.00	83.3
	Week 9	105	25.24	23.36	0.0	33.33	100.0	91	-8.97	29.32	-83.3	0.00	83.3
	Week 10	101	23.27	24.73	0.0	16.67	100.0	86	-10.27	29.17	-100.0	0.00	83.3
	Week 11	97	21.48	24.88	0.0	16.67	100.0	83	-10.84	30.74	-100.0	0.00	66.7
	Week 12	100	23.00	24.93	0.0	16.67	100.0	85	-8.82	32.18	-100.0	0.00	66.7
	Week 14	102	21.24	24.50	0.0	16.67	100.0	87	-11.11	30.99	-100.0	0.00	66.7
	Week 17	96	20.66	20.91	0.0	16.67	100.0	81	-11.32	28.85	-100.0	0.00	50.0
	Week 20	87	21.46	20.63	0.0	16.67	83.3	76	-8.33	29.63	-100.0	0.00	50.0
	Week 23	85	19.02	21.07	0.0	16.67	66.7	71	-9.86	32.31	-100.0	0.00	66.7
	Week 26	79	21.94	20.77	0.0	16.67	83.3	66	-6.06	31.84	-100.0	0.00	66.7
	Week 29	72	23.38	22.49	0.0	25.00	83.3	64	-3.39	32.55	-100.0	0.00	83.3
	Week 32	71	19.01	19.98	0.0	16.67	83.3	62	-10.48	32.67	-100.0	0.00	83.3
	Week 35	70	22.62	22.17	0.0	16.67	66.7	63	-5.56	30.82	-100.0	0.00	66.7
	Week 38	70	21.67	20.53	0.0	16.67	66.7	63	-9.52	30.04	-100.0	0.00	66.7
	Week 41	66	22.73	23.32	0.0	33.33	100.0	60	-6.39	30.85	-100.0	0.00	66.7
	Week 44	59	25.71	24.04	0.0	33.33	83.3	53	-4.72	31.58	-100.0	0.00	83.3
	Week 47	52	25.32	24.81	0.0	33.33	83.3	48	-3.82	34.42	-100.0	0.00	66.7

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	49	27.89	28.13	0.0	33.33	100.0	43	-3.49	31.61	-100.0	0.00	50.0
	Week 53	50	31.00	28.17	0.0	33.33	100.0	44	-1.89	34.89	-100.0	0.00	66.7
	Week 56	45	27.78	25.38	0.0	33.33	100.0	39	-7.27	33.72	-100.0	0.00	66.7
	Week 59	44	30.68	26.64	0.0	33.33	100.0	38	-3.51	33.14	-100.0	0.00	66.7
	Week 62	38	25.00	23.17	0.0	33.33	83.3	33	-2.53	30.08	-100.0	0.00	66.7
	Week 65	25	23.33	22.57	0.0	16.67	66.7	24	-4.17	42.35	-100.0	0.00	66.7
	Week 68	31	26.34	24.64	0.0	33.33	100.0	29	1.72	38.66	-100.0	0.00	83.3
	Week 71	27	24.07	24.17	0.0	16.67	83.3	25	-5.33	36.87	-100.0	0.00	66.7
	Week 74	23	24.64	26.05	0.0	33.33	100.0	22	-2.27	42.19	-100.0	0.00	83.3
	Week 77	24	23.61	25.02	0.0	16.67	66.7	23	-6.52	36.15	-100.0	0.00	66.7
	Week 80	22	33.33	26.23	0.0	33.33	66.7	22	2.27	36.11	-100.0	0.00	66.7
	Week 83	19	31.58	27.72	0.0	33.33	83.3	19	0.88	40.63	-100.0	0.00	66.7
	Week 86	14	29.76	28.63	0.0	25.00	66.7	14	3.57	43.45	-100.0	0.00	66.7
	Week 89	10	23.33	29.61	0.0	16.67	83.3	10	8.33	33.56	-33.3	0.00	83.3
	Week 92	11	28.79	23.68	0.0	33.33	66.7	11	3.03	25.62	-33.3	0.00	50.0
	Plat+Gem (N=157)												
	BASELINE	128	33.85	30.73	0.0	33.33	100.0						
	Week 1	111	35.89	31.48	0.0	33.33	100.0	107	2.02	21.80	-50.0	0.00	100.0
	Week 2	110	35.61	28.60	0.0	33.33	100.0	102	5.23	21.10	-50.0	0.00	50.0
	Week 3	112	31.25	29.01	0.0	33.33	100.0	103	0.97	21.75	-50.0	0.00	66.7
	Week 4	112	29.76	27.16	0.0	33.33	100.0	102	-1.80	25.03	-83.3	0.00	50.0
	Week 5	113	30.09	28.60	0.0	16.67	100.0	103	-0.65	29.05	-100.0	0.00	83.3
	Week 6	107	26.32	28.87	0.0	16.67	100.0	98	-3.74	27.24	-100.0	0.00	83.3
	Week 7	109	29.82	29.49	0.0	33.33	100.0	100	-0.33	26.27	-83.3	0.00	66.7
	Week 8	106	30.66	29.56	0.0	33.33	100.0	98	0.34	31.20	-66.7	0.00	100.0
	Week 9	105	29.05	26.66	0.0	33.33	100.0	94	-0.89	27.04	-83.3	0.00	66.7

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	104	27.56	27.75	0.0	33.33	100.0	96	-2.60	25.63	-66.7	0.00	50.0
	Week 11	91	31.32	29.90	0.0	33.33	100.0	83	2.01	24.61	-66.7	0.00	66.7
	Week 12	94	28.19	27.44	0.0	25.00	100.0	84	-1.19	25.06	-66.7	0.00	83.3
	Week 14	90	30.19	27.47	0.0	33.33	100.0	79	0.63	27.01	-66.7	0.00	66.7
	Week 17	90	28.52	28.73	0.0	33.33	100.0	80	2.08	31.08	-66.7	0.00	83.3
	Week 20	74	25.90	26.91	0.0	25.00	83.3	64	-2.34	25.87	-66.7	0.00	50.0
	Week 23	63	23.28	24.78	0.0	16.67	83.3	58	-2.59	24.94	-66.7	0.00	83.3
	Week 26	55	27.88	27.42	0.0	33.33	100.0	52	-0.64	25.98	-66.7	0.00	50.0
	Week 29	53	29.25	29.03	0.0	33.33	100.0	50	6.00	26.68	-50.0	0.00	83.3
	Week 32	42	28.97	30.81	0.0	33.33	100.0	40	6.25	28.91	-50.0	0.00	100.0
	Week 35	39	27.35	27.96	0.0	33.33	100.0	36	4.63	21.68	-50.0	0.00	50.0
	Week 38	37	30.63	32.99	0.0	16.67	100.0	34	6.86	32.34	-66.7	0.00	100.0
	Week 41	33	28.28	28.41	0.0	16.67	83.3	31	4.84	24.03	-66.7	0.00	66.7
	Week 44	32	32.29	31.66	0.0	33.33	100.0	30	6.11	27.15	-66.7	0.00	50.0
	Week 47	28	28.57	35.39	0.0	8.34	100.0	26	3.21	24.50	-33.3	0.00	66.7
	Week 50	22	30.30	28.00	0.0	33.33	83.3	20	5.00	18.02	-33.3	0.00	50.0
	Week 53	19	32.46	33.09	0.0	16.67	100.0	17	3.92	27.34	-33.3	0.00	66.7
	Week 56	18	32.41	33.07	0.0	33.33	100.0	17	-1.96	26.93	-66.7	0.00	50.0
	Week 59	13	28.21	29.96	0.0	16.67	83.3	12	-12.50	26.71	-50.0	-16.66	50.0
	Week 62	11	33.33	29.82	0.0	33.33	66.7	11	-6.06	25.03	-50.0	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.16.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Lymph node only	EV+Pembro (N= 43)												
	BASELINE	33	22.22	20.27	0.0	16.67	66.7						
	Week 1	30	25.00	25.43	0.0	16.67	83.3	24	-3.47	15.53	-50.0	0.00	33.3
	Week 2	34	25.49	25.04	0.0	25.00	83.3	27	-1.85	17.50	-33.3	0.00	33.3
	Week 3	35	28.57	25.43	0.0	33.33	83.3	28	1.19	21.24	-33.3	0.00	66.7
	Week 4	36	18.52	21.37	0.0	16.67	83.3	30	-8.89	19.93	-50.0	0.00	33.3
	Week 5	33	18.18	22.96	0.0	0.00	83.3	27	-8.02	19.26	-50.0	0.00	33.3
	Week 6	34	22.55	25.58	0.0	16.67	83.3	28	-2.38	30.67	-50.0	0.00	66.7
	Week 7	34	22.06	25.86	0.0	16.67	83.3	28	-4.76	24.78	-50.0	0.00	66.7
	Week 8	35	25.24	26.62	0.0	16.67	100.0	29	0.00	28.87	-33.3	0.00	100.0
	Week 9	30	24.45	28.61	0.0	16.67	100.0	24	1.39	37.72	-33.3	0.00	100.0
	Week 10	31	16.13	22.15	0.0	0.00	83.3	26	-6.41	29.84	-33.3	-8.34	83.3
	Week 11	34	19.12	22.15	0.0	16.67	66.7	27	-6.17	24.96	-50.0	0.00	50.0
	Week 12	35	16.67	22.51	0.0	0.00	66.7	28	-8.93	22.90	-50.0	-16.66	50.0
	Week 14	30	12.78	18.92	0.0	0.00	66.7	23	-12.32	21.45	-50.0	-16.66	33.3
	Week 17	30	15.00	17.15	0.0	8.34	50.0	24	-5.56	26.77	-50.0	0.00	50.0
	Week 20	27	16.05	18.77	0.0	16.67	66.7	21	-7.94	21.49	-50.0	0.00	33.3
	Week 23	27	17.90	21.15	0.0	16.67	66.7	21	-5.55	23.17	-50.0	0.00	33.3
	Week 26	27	18.52	20.32	0.0	16.67	66.7	22	-8.33	23.43	-50.0	0.00	33.3
	Week 29	28	19.05	25.14	0.0	8.34	83.3	23	-4.35	28.96	-50.0	0.00	50.0
	Week 32	24	23.61	24.53	0.0	16.67	66.7	20	-2.50	26.09	-50.0	0.00	50.0
	Week 35	22	26.52	26.56	0.0	25.00	83.3	18	1.85	27.35	-33.3	0.00	66.7
	Week 38	21	24.60	22.74	0.0	33.33	66.7	17	-1.96	21.15	-33.3	0.00	33.3
	Week 41	22	18.94	20.76	0.0	16.67	66.7	17	-8.82	27.08	-50.0	-16.66	50.0
	Week 44	22	21.97	27.40	0.0	16.67	100.0	16	-1.04	30.10	-33.3	0.00	66.7
	Week 47	21	22.22	19.95	0.0	16.67	66.7	16	-2.08	24.25	-50.0	0.00	33.3

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Table 302.1.3002.16.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	17.50	24.47	0.0	0.00	66.7	16	-6.25	29.11	-50.0	0.00	50.0
	Week 53	18	20.37	26.54	0.0	0.00	66.7	14	-3.57	32.80	-50.0	0.00	66.7
	Week 56	21	19.05	20.61	0.0	16.67	66.7	17	-9.80	28.90	-50.0	-16.66	50.0
	Week 59	21	20.64	23.51	0.0	16.67	66.7	16	-11.46	27.02	-50.0	-16.66	33.3
	Week 62	19	28.07	26.09	0.0	16.67	66.7	15	-7.78	28.77	-50.0	0.00	50.0
	Week 65	16	23.96	27.20	0.0	16.67	66.7	14	-4.76	29.55	-50.0	0.00	50.0
	Week 68	13	28.21	26.69	0.0	16.67	66.7	11	0.00	27.89	-33.3	0.00	50.0
	Week 71	13	21.80	28.37	0.0	0.00	66.7	11	-4.54	36.58	-50.0	0.00	66.7
	Week 74	13	19.23	26.22	0.0	0.00	66.7	11	-1.51	31.14	-33.3	0.00	66.7
	Week 77	13	19.23	22.41	0.0	16.67	66.7	10	-6.67	27.44	-33.3	-8.33	33.3
	Week 80	13	21.80	20.84	0.0	16.67	66.7	11	-6.06	25.02	-33.3	-16.66	33.3
	Week 83	11	19.70	17.98	0.0	16.67	50.0	10	-5.00	23.63	-33.3	-8.33	33.3
	Week 86	11	19.70	20.84	0.0	16.67	66.7	10	-5.00	17.65	-33.3	0.00	33.3
	Plat+Gem (N= 37)												
	BASELINE	29	32.76	33.48	0.0	33.33	100.0						
	Week 1	26	29.49	26.79	0.0	33.33	100.0	25	-6.00	20.91	-66.7	0.00	16.7
	Week 2	30	33.33	21.88	0.0	33.33	66.7	26	-1.92	29.18	-66.7	0.00	50.0
	Week 3	30	31.11	26.53	0.0	25.00	100.0	26	-2.56	27.36	-83.3	0.00	50.0
	Week 4	32	30.21	25.55	0.0	33.33	100.0	27	-2.47	35.42	-100.0	0.00	66.7
	Week 5	33	31.31	25.60	0.0	33.33	83.3	28	-0.59	27.77	-83.3	0.00	50.0
	Week 6	32	30.21	25.55	0.0	33.33	100.0	27	-3.09	34.60	-100.0	0.00	50.0
	Week 7	31	34.95	30.54	0.0	33.33	100.0	26	3.21	37.12	-83.3	0.00	83.3
	Week 8	32	38.54	25.90	0.0	33.33	83.3	27	7.41	34.69	-83.3	0.00	66.7
	Week 9	30	37.22	25.02	0.0	33.33	100.0	25	4.00	39.17	-100.0	0.00	66.7
	Week 10	30	32.22	27.66	0.0	33.33	83.3	26	0.00	38.01	-100.0	0.00	66.7
	Week 11	29	31.61	27.94	0.0	33.33	100.0	25	0.67	35.51	-83.3	0.00	66.7

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Table 302.1.3002.16.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 12	28	30.95	25.14	0.0	33.33	83.3	23	-2.90	35.41	-100.0	0.00	50.0
	Week 14	28	27.38	26.53	0.0	33.33	100.0	23	-5.07	37.75	-83.3	0.00	83.3
	Week 17	25	33.33	28.46	0.0	33.33	100.0	21	0.79	27.12	-66.7	0.00	50.0
	Week 20	23	25.36	31.33	0.0	16.67	100.0	20	-2.50	36.38	-83.3	0.00	66.7
	Week 23	20	23.33	21.22	0.0	16.67	66.7	17	-5.88	30.01	-83.3	0.00	50.0
	Week 26	21	30.95	29.48	0.0	33.33	100.0	18	-1.85	34.25	-83.3	0.00	83.3
	Week 29	19	31.58	29.86	0.0	33.33	100.0	16	5.21	35.86	-83.3	0.00	66.7
	Week 32	18	34.26	27.70	0.0	33.33	83.3	15	6.67	33.21	-83.3	0.00	66.7
	Week 35	19	31.58	26.00	0.0	33.33	83.3	16	4.17	31.91	-83.3	0.00	66.7
	Week 38	15	28.89	28.50	0.0	16.67	83.3	12	4.17	36.32	-83.3	0.00	66.7
	Week 41	15	38.89	36.00	0.0	33.33	100.0	12	12.50	40.90	-83.3	8.34	83.3
	Week 44	14	41.67	31.18	0.0	33.33	100.0	11	16.67	38.73	-83.3	16.67	66.7
	Week 47	12	41.67	31.38	0.0	33.33	100.0	10	20.00	44.99	-83.3	33.33	83.3
	Week 50	11	36.36	34.01	0.0	33.33	100.0	8	6.25	46.24	-83.3	0.00	83.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
EV+Pembro (N=240)												
BASELINE	206	5.83	14.30	0.0	0.00	66.7						
Week 1	190	8.33	17.38	0.0	0.00	100.0	184	2.72	14.11	-33.3	0.00	100.0
Week 2	203	9.28	17.24	0.0	0.00	100.0	189	3.88	17.18	-66.7	0.00	100.0
Week 3	198	9.09	15.07	0.0	0.00	83.3	182	3.57	16.18	-50.0	0.00	66.7
Week 4	194	5.58	10.54	0.0	0.00	50.0	179	0.28	14.51	-66.7	0.00	50.0
Week 5	190	6.67	12.69	0.0	0.00	66.7	173	1.16	15.73	-50.0	0.00	50.0
Week 6	188	6.03	13.09	0.0	0.00	66.7	170	0.39	16.41	-66.7	0.00	66.7
Week 7	195	5.64	12.18	0.0	0.00	100.0	176	-0.09	18.04	-66.7	0.00	83.3
Week 8	191	5.24	9.91	0.0	0.00	50.0	171	-0.78	15.95	-66.7	0.00	33.3
Week 9	197	5.58	13.36	0.0	0.00	83.3	180	0.09	16.76	-66.7	0.00	66.7
Week 10	191	4.19	10.11	0.0	0.00	66.7	175	-2.19	16.86	-66.7	0.00	50.0
Week 11	194	4.21	9.34	0.0	0.00	50.0	175	-2.00	16.79	-66.7	0.00	50.0
Week 12	186	4.66	11.46	0.0	0.00	66.7	171	-1.95	17.04	-66.7	0.00	50.0
Week 14	185	5.41	12.44	0.0	0.00	100.0	167	0.60	15.51	-66.7	0.00	83.3
Week 17	178	4.87	9.77	0.0	0.00	50.0	162	-0.10	16.03	-66.7	0.00	50.0
Week 20	167	4.09	11.20	0.0	0.00	83.3	154	-1.30	16.45	-66.7	0.00	66.7
Week 23	162	5.04	12.19	0.0	0.00	83.3	151	0.66	17.84	-66.7	0.00	83.3
Week 26	156	3.42	11.16	0.0	0.00	66.7	144	-1.97	17.01	-66.7	0.00	66.7
Week 29	157	2.23	7.80	0.0	0.00	66.7	145	-2.41	14.96	-66.7	0.00	66.7
Week 32	135	2.22	9.93	0.0	0.00	83.3	125	-1.20	14.07	-66.7	0.00	83.3
Week 35	132	1.52	4.81	0.0	0.00	16.7	122	-2.60	12.50	-66.7	0.00	16.7
Week 38	132	2.40	7.17	0.0	0.00	33.3	124	-0.81	12.00	-66.7	0.00	33.3
Week 41	129	3.88	11.69	0.0	0.00	100.0	119	-0.84	16.36	-66.7	0.00	83.3
Week 44	108	1.39	4.63	0.0	0.00	16.7	100	-2.17	11.52	-66.7	0.00	16.7
Week 47	100	3.83	8.49	0.0	0.00	33.3	94	-1.06	15.23	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	89	2.06	5.52	0.0	0.00	16.7	84	-0.99	10.14	-66.7	0.00	16.7
Week 53	79	4.22	10.83	0.0	0.00	66.7	74	0.45	16.77	-66.7	0.00	66.7
Week 56	81	3.50	10.11	0.0	0.00	66.7	76	0.88	13.58	-66.7	0.00	66.7
Week 59	72	3.24	9.54	0.0	0.00	66.7	68	0.49	13.80	-66.7	0.00	66.7
Week 62	65	2.05	9.09	0.0	0.00	66.7	63	-1.32	13.82	-66.7	0.00	66.7
Week 65	58	2.59	6.84	0.0	0.00	33.3	54	-0.62	12.94	-66.7	0.00	33.3
Week 68	53	3.15	8.68	0.0	0.00	50.0	52	-0.32	13.40	-66.7	0.00	50.0
Week 71	51	2.94	9.25	0.0	0.00	50.0	49	-0.68	13.59	-66.7	0.00	50.0
Week 74	47	1.77	6.25	0.0	0.00	33.3	46	-2.54	12.16	-66.7	0.00	16.7
Week 77	44	1.89	6.45	0.0	0.00	33.3	42	-0.79	9.71	-33.3	0.00	33.3
Week 80	40	2.50	7.11	0.0	0.00	33.3	37	-2.25	12.52	-50.0	0.00	33.3
Week 83	37	1.35	4.61	0.0	0.00	16.7	35	-3.81	12.84	-66.7	0.00	16.7
Week 86	34	0.98	3.98	0.0	0.00	16.7	31	-4.84	13.74	-66.7	0.00	16.7
Week 89	33	3.03	7.74	0.0	0.00	33.3	31	-2.15	15.95	-66.7	0.00	33.3
Week 92	27	2.47	7.60	0.0	0.00	33.3	25	-2.67	16.44	-66.7	0.00	33.3
Week 95	22	0.76	3.55	0.0	0.00	16.7	21	-1.59	5.01	-16.7	0.00	0.0
Week 98	18	1.85	5.39	0.0	0.00	16.7	17	0.00	5.89	-16.7	0.00	16.7
Week 101	14	4.76	10.19	0.0	0.00	33.3	14	2.38	8.91	-16.7	0.00	16.7
Week 104	10	1.67	5.27	0.0	0.00	16.7	10	0.00	0.00	0.0	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Plat+Gem (N=242)												
BASELINE	188	5.94	11.25	0.0	0.00	66.7						
Week 1	173	16.96	21.00	0.0	16.67	100.0	158	11.29	19.57	-33.3	0.00	100.0
Week 2	171	14.23	18.58	0.0	16.67	100.0	151	9.49	20.77	-50.0	0.00	100.0
Week 3	184	9.96	14.59	0.0	0.00	66.7	162	5.14	16.85	-50.0	0.00	66.7
Week 4	183	13.84	18.06	0.0	16.67	83.3	156	8.44	19.81	-50.0	0.00	83.3
Week 5	187	14.08	16.60	0.0	16.67	83.3	156	8.55	19.35	-50.0	0.00	83.3
Week 6	174	10.54	14.80	0.0	0.00	100.0	149	5.37	16.92	-50.0	0.00	100.0
Week 7	186	13.80	17.26	0.0	16.67	83.3	157	7.75	20.20	-66.7	0.00	83.3
Week 8	167	14.17	17.03	0.0	16.67	83.3	144	9.14	20.18	-50.0	0.00	83.3
Week 9	177	11.77	16.70	0.0	0.00	66.7	150	6.78	18.73	-50.0	0.00	66.7
Week 10	166	14.56	19.08	0.0	16.67	100.0	139	9.35	20.96	-50.0	0.00	100.0
Week 11	168	16.17	19.60	0.0	16.67	100.0	143	11.77	23.31	-50.0	0.00	100.0
Week 12	159	11.64	17.26	0.0	0.00	100.0	138	7.00	20.71	-50.0	0.00	100.0
Week 14	153	15.14	19.44	0.0	16.67	83.3	128	9.38	24.19	-50.0	0.00	83.3
Week 17	155	15.70	21.17	0.0	16.67	100.0	130	11.15	26.61	-66.7	0.00	100.0
Week 20	126	9.13	14.39	0.0	0.00	83.3	110	4.39	17.44	-50.0	0.00	83.3
Week 23	115	6.52	13.37	0.0	0.00	83.3	97	2.23	17.62	-50.0	0.00	83.3
Week 26	108	6.17	11.30	0.0	0.00	50.0	95	2.63	14.24	-33.3	0.00	50.0
Week 29	100	5.50	12.55	0.0	0.00	66.7	86	2.33	15.79	-50.0	0.00	66.7
Week 32	83	4.62	10.19	0.0	0.00	50.0	76	0.22	13.47	-50.0	0.00	50.0
Week 35	76	5.04	11.87	0.0	0.00	66.7	69	1.69	14.33	-50.0	0.00	50.0
Week 38	74	6.31	16.02	0.0	0.00	83.3	65	3.59	15.73	-16.7	0.00	66.7
Week 41	65	5.64	15.67	0.0	0.00	100.0	56	2.98	19.36	-50.0	0.00	100.0
Week 44	60	4.72	11.10	0.0	0.00	50.0	53	3.46	13.22	-16.7	0.00	50.0
Week 47	56	4.76	12.99	0.0	0.00	66.7	49	2.72	15.72	-16.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	51	5.88	12.83	0.0	0.00	66.7	47	2.48	12.99	-16.7	0.00	50.0
Week 53	46	5.44	13.63	0.0	0.00	66.7	42	2.78	14.22	-16.7	0.00	66.7
Week 56	39	5.56	12.87	0.0	0.00	66.7	34	1.96	16.29	-16.7	0.00	66.7
Week 59	37	1.80	5.25	0.0	0.00	16.7	33	-0.51	8.83	-16.7	0.00	16.7
Week 62	32	2.08	7.02	0.0	0.00	33.3	29	-0.58	10.43	-16.7	0.00	33.3
Week 65	30	3.33	8.07	0.0	0.00	33.3	26	0.00	11.55	-16.7	0.00	33.3
Week 68	25	2.00	5.53	0.0	0.00	16.7	21	0.00	9.13	-16.7	0.00	16.7
Week 71	22	3.79	8.81	0.0	0.00	33.3	19	2.63	10.04	-16.7	0.00	33.3
Week 74	21	4.76	11.95	0.0	0.00	50.0	18	3.70	13.47	-16.7	0.00	50.0
Week 77	18	6.48	16.31	0.0	0.00	66.7	15	3.33	19.11	-16.7	0.00	66.7
Week 80	14	7.14	18.16	0.0	0.00	66.7	13	3.85	22.72	-33.3	0.00	66.7
Week 83	13	2.56	6.26	0.0	0.00	16.7	12	-1.39	8.58	-16.7	0.00	16.7
Week 86	12	2.78	6.49	0.0	0.00	16.7	11	-1.51	8.99	-16.7	0.00	16.7
Week 89	11	0.00	0.00	0.0	0.00	0.0	10	-5.00	11.25	-33.3	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Present	EV+Pembro (N= 48)												
	BASELINE	39	11.97	18.32	0.0	0.00	66.7						
	Week 1	32	18.75	26.35	0.0	16.67	100.0	32	4.69	22.89	-33.3	0.00	100.0
	Week 2	37	15.77	23.55	0.0	0.00	100.0	33	3.54	18.98	-33.3	0.00	83.3
	Week 3	34	15.20	19.83	0.0	16.67	83.3	29	1.15	14.73	-50.0	0.00	33.3
	Week 4	36	6.02	10.66	0.0	0.00	33.3	31	-5.38	17.42	-50.0	0.00	33.3
	Week 5	30	8.89	14.99	0.0	0.00	50.0	24	-5.56	21.79	-50.0	0.00	50.0
	Week 6	31	8.06	15.44	0.0	0.00	50.0	25	-5.33	23.43	-66.7	0.00	50.0
	Week 7	34	9.80	20.15	0.0	0.00	100.0	28	-4.17	27.07	-50.0	0.00	83.3
	Week 8	35	7.14	12.96	0.0	0.00	50.0	30	-6.11	19.81	-66.7	0.00	33.3
	Week 9	34	7.35	13.73	0.0	0.00	50.0	30	-4.45	21.41	-66.7	0.00	33.3
	Week 10	34	8.82	16.02	0.0	0.00	66.7	30	-3.89	25.78	-66.7	0.00	50.0
	Week 11	33	8.08	13.89	0.0	0.00	50.0	28	-7.14	22.42	-66.7	0.00	50.0
	Week 12	33	9.09	18.21	0.0	0.00	66.7	29	-5.75	24.10	-66.7	0.00	50.0
	Week 14	31	12.37	21.50	0.0	0.00	100.0	26	-1.92	30.30	-66.7	0.00	83.3
	Week 17	31	6.45	10.25	0.0	0.00	33.3	25	-8.67	22.63	-66.7	0.00	16.7
	Week 20	27	6.79	14.07	0.0	0.00	50.0	24	-6.25	21.88	-66.7	0.00	33.3
	Week 23	26	3.85	8.57	0.0	0.00	33.3	23	-8.70	20.02	-66.7	0.00	16.7
	Week 26	25	4.67	14.04	0.0	0.00	50.0	22	-10.61	23.31	-66.7	0.00	50.0
	Week 29	23	0.72	3.48	0.0	0.00	16.7	22	-8.33	15.21	-50.0	0.00	0.0
	Week 32	21	1.59	7.27	0.0	0.00	33.3	19	-7.90	16.07	-50.0	0.00	16.7
	Week 35	19	0.88	3.82	0.0	0.00	16.7	17	-8.82	15.72	-50.0	0.00	0.0
	Week 38	18	2.78	8.57	0.0	0.00	33.3	17	-7.84	16.79	-50.0	0.00	16.7
	Week 41	20	1.67	7.45	0.0	0.00	33.3	19	-11.40	20.83	-66.7	0.00	16.7
	Week 44	17	0.98	4.04	0.0	0.00	16.7	15	-10.00	18.69	-66.7	0.00	0.0
	Week 47	18	3.70	7.13	0.0	0.00	16.7	16	-7.29	14.87	-50.0	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	12	0.00	0.00	0.0	0.00	0.0	11	-4.55	10.78	-33.3	0.00	0.0
	Week 53	12	1.39	4.81	0.0	0.00	16.7	11	-6.06	11.24	-33.3	0.00	0.0
	Week 56	13	1.28	4.62	0.0	0.00	16.7	12	-4.17	7.54	-16.7	0.00	0.0
	Week 59	12	1.39	4.81	0.0	0.00	16.7	11	-4.55	10.78	-33.3	0.00	0.0
	Week 62	10	0.00	0.00	0.0	0.00	0.0	9	-7.41	12.11	-33.3	0.00	0.0
	Week 65	10	1.67	5.27	0.0	0.00	16.7	9	-5.56	11.78	-33.3	0.00	0.0
	Plat+Gem (N= 48)												
	BASELINE	33	10.61	16.04	0.0	0.00	66.7						
	Week 1	31	12.90	19.58	0.0	16.67	100.0	27	4.32	15.74	-33.3	0.00	50.0
	Week 2	29	10.92	14.96	0.0	0.00	50.0	24	1.39	23.53	-50.0	0.00	50.0
	Week 3	32	5.21	9.87	0.0	0.00	33.3	27	-6.17	19.69	-50.0	0.00	33.3
	Week 4	32	11.46	16.09	0.0	0.00	66.7	24	-1.39	16.97	-50.0	0.00	16.7
	Week 5	36	10.19	13.96	0.0	0.00	50.0	28	-0.60	18.42	-50.0	0.00	33.3
	Week 6	35	8.57	13.02	0.0	0.00	50.0	27	-3.70	19.79	-50.0	0.00	33.3
	Week 7	38	11.40	16.94	0.0	0.00	66.7	29	-4.02	20.73	-66.7	0.00	33.3
	Week 8	31	12.37	12.89	0.0	16.67	33.3	25	2.00	22.73	-50.0	0.00	33.3
	Week 9	32	11.98	17.06	0.0	0.00	66.7	25	-0.67	20.12	-50.0	0.00	33.3
	Week 10	34	15.69	22.82	0.0	16.67	83.3	26	1.92	24.19	-50.0	0.00	66.7
	Week 11	30	11.67	17.04	0.0	8.34	83.3	24	1.39	23.53	-50.0	0.00	66.7
	Week 12	28	9.52	15.34	0.0	0.00	66.7	23	-1.45	23.52	-50.0	0.00	50.0
	Week 14	26	12.82	19.61	0.0	0.00	66.7	21	0.79	29.57	-50.0	0.00	66.7
	Week 17	30	13.89	21.92	0.0	0.00	83.3	25	1.33	30.40	-66.7	0.00	66.7
	Week 20	23	8.70	14.10	0.0	0.00	50.0	21	-5.56	22.57	-50.0	0.00	33.3
	Week 23	22	6.82	13.27	0.0	0.00	50.0	19	-3.51	21.21	-50.0	0.00	50.0
	Week 26	19	7.89	12.87	0.0	0.00	33.3	18	1.85	16.06	-33.3	0.00	33.3
	Week 29	16	7.29	12.12	0.0	0.00	33.3	14	0.00	21.68	-50.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 32	11	6.06	11.24	0.0	0.00	33.3	11	-4.55	19.85	-50.0	0.00	33.3
	Week 35	10	3.33	7.03	0.0	0.00	16.7	9	-5.56	18.63	-50.0	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Absent	EV+Pembro (N=192)												
	BASELINE	167	4.39	12.83	0.0	0.00	66.7						
	Week 1	158	6.22	14.14	0.0	0.00	66.7	152	2.30	11.52	-33.3	0.00	50.0
	Week 2	166	7.83	15.21	0.0	0.00	100.0	156	3.95	16.84	-66.7	0.00	100.0
	Week 3	164	7.83	13.62	0.0	0.00	66.7	153	4.03	16.45	-50.0	0.00	66.7
	Week 4	158	5.49	10.55	0.0	0.00	50.0	148	1.46	13.60	-66.7	0.00	50.0
	Week 5	160	6.25	12.22	0.0	0.00	66.7	149	2.24	14.32	-50.0	0.00	50.0
	Week 6	157	5.63	12.60	0.0	0.00	66.7	145	1.38	14.77	-66.7	0.00	66.7
	Week 7	161	4.76	9.58	0.0	0.00	66.7	148	0.68	15.78	-66.7	0.00	66.7
	Week 8	156	4.81	9.08	0.0	0.00	33.3	141	0.35	14.84	-66.7	0.00	33.3
	Week 9	163	5.22	13.29	0.0	0.00	83.3	150	1.00	15.60	-66.7	0.00	66.7
	Week 10	157	3.18	8.04	0.0	0.00	33.3	145	-1.84	14.45	-66.7	0.00	33.3
	Week 11	161	3.42	7.93	0.0	0.00	33.3	147	-1.02	15.39	-66.7	0.00	33.3
	Week 12	153	3.70	9.21	0.0	0.00	50.0	142	-1.17	15.20	-66.7	0.00	33.3
	Week 14	154	4.00	9.15	0.0	0.00	50.0	141	1.06	10.95	-66.7	0.00	50.0
	Week 17	147	4.54	9.67	0.0	0.00	50.0	137	1.46	14.07	-66.7	0.00	50.0
	Week 20	140	3.57	10.54	0.0	0.00	83.3	130	-0.38	15.17	-66.7	0.00	66.7
	Week 23	136	5.27	12.78	0.0	0.00	83.3	128	2.34	16.96	-66.7	0.00	83.3
	Week 26	131	3.18	10.56	0.0	0.00	66.7	122	-0.41	15.22	-66.7	0.00	66.7
	Week 29	134	2.49	8.30	0.0	0.00	66.7	123	-1.36	14.72	-66.7	0.00	66.7
	Week 32	114	2.34	10.37	0.0	0.00	83.3	106	0.00	13.41	-66.7	0.00	83.3
	Week 35	113	1.62	4.96	0.0	0.00	16.7	105	-1.59	11.68	-66.7	0.00	16.7
	Week 38	114	2.34	6.97	0.0	0.00	33.3	107	0.31	10.73	-66.7	0.00	33.3
	Week 41	109	4.28	12.30	0.0	0.00	100.0	100	1.17	14.65	-66.7	0.00	83.3
	Week 44	91	1.47	4.75	0.0	0.00	16.7	85	-0.78	9.24	-66.7	0.00	16.7
	Week 47	82	3.86	8.80	0.0	0.00	33.3	78	0.21	15.07	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	77	2.38	5.87	0.0	0.00	16.7	73	-0.46	10.01	-66.7	0.00	16.7
	Week 53	67	4.73	11.53	0.0	0.00	66.7	63	1.59	17.38	-66.7	0.00	66.7
	Week 56	68	3.92	10.82	0.0	0.00	66.7	64	1.82	14.28	-66.7	0.00	66.7
	Week 59	60	3.61	10.22	0.0	0.00	66.7	57	1.46	14.19	-66.7	0.00	66.7
	Week 62	55	2.42	9.84	0.0	0.00	66.7	54	-0.31	13.92	-66.7	0.00	66.7
	Week 65	48	2.78	7.16	0.0	0.00	33.3	45	0.37	13.05	-66.7	0.00	33.3
	Week 68	46	3.26	9.04	0.0	0.00	50.0	45	0.74	13.27	-66.7	0.00	50.0
	Week 71	44	1.89	6.45	0.0	0.00	33.3	42	-0.79	11.01	-66.7	0.00	16.7
	Week 74	40	2.08	6.74	0.0	0.00	33.3	39	-1.28	11.71	-66.7	0.00	16.7
	Week 77	38	2.19	6.90	0.0	0.00	33.3	36	0.93	7.91	-16.7	0.00	33.3
	Week 80	35	2.38	7.17	0.0	0.00	33.3	32	-1.04	12.66	-50.0	0.00	33.3
	Week 83	32	1.04	4.10	0.0	0.00	16.7	30	-2.78	13.19	-66.7	0.00	16.7
	Week 86	29	0.57	3.10	0.0	0.00	16.7	26	-3.85	14.38	-66.7	0.00	16.7
	Week 89	29	2.87	7.80	0.0	0.00	33.3	27	-0.62	16.33	-66.7	0.00	33.3
	Week 92	24	2.78	8.03	0.0	0.00	33.3	22	-2.27	17.29	-66.7	0.00	33.3
	Week 95	20	0.83	3.73	0.0	0.00	16.7	19	-0.88	3.82	-16.7	0.00	0.0
	Week 98	18	1.85	5.39	0.0	0.00	16.7	17	0.00	5.89	-16.7	0.00	16.7
	Week 101	13	2.56	6.26	0.0	0.00	16.7	13	1.28	8.23	-16.7	0.00	16.7
	Plat+Gem (N=194)												
	BASELINE	155	4.95	9.72	0.0	0.00	50.0						
	Week 1	142	17.84	21.25	0.0	16.67	100.0	131	12.72	20.02	-16.7	0.00	100.0
	Week 2	142	14.91	19.22	0.0	16.67	100.0	127	11.02	19.95	-16.7	0.00	100.0
	Week 3	152	10.97	15.24	0.0	0.00	66.7	135	7.41	15.33	-16.7	0.00	66.7
	Week 4	151	14.35	18.46	0.0	16.67	83.3	132	10.23	19.82	-33.3	0.00	83.3
	Week 5	151	15.01	17.08	0.0	16.67	83.3	128	10.55	19.04	-16.7	0.00	83.3
	Week 6	139	11.03	15.22	0.0	0.00	100.0	122	7.38	15.61	-16.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 7	148	14.41	17.35	0.0	16.67	83.3	128	10.42	19.17	-16.7	0.00	83.3
	Week 8	136	14.58	17.85	0.0	16.67	83.3	119	10.64	19.38	-16.7	0.00	83.3
	Week 9	145	11.72	16.68	0.0	0.00	66.7	125	8.27	18.16	-33.3	0.00	66.7
	Week 10	132	14.27	18.09	0.0	16.67	100.0	113	11.06	19.87	-16.7	0.00	100.0
	Week 11	138	17.15	20.03	0.0	16.67	100.0	119	13.87	22.79	-33.3	16.66	100.0
	Week 12	131	12.09	17.67	0.0	0.00	100.0	115	8.70	19.79	-16.7	0.00	100.0
	Week 14	127	15.62	19.44	0.0	16.67	83.3	107	11.06	22.77	-33.3	0.00	83.3
	Week 17	125	16.13	21.05	0.0	16.67	100.0	105	13.49	25.22	-33.3	0.00	100.0
	Week 20	103	9.22	14.52	0.0	0.00	83.3	89	6.74	15.23	-16.7	0.00	83.3
	Week 23	93	6.45	13.47	0.0	0.00	83.3	78	3.63	16.48	-33.3	0.00	83.3
	Week 26	89	5.81	10.98	0.0	0.00	50.0	77	2.81	13.89	-33.3	0.00	50.0
	Week 29	84	5.16	12.67	0.0	0.00	66.7	72	2.78	14.54	-33.3	0.00	66.7
	Week 32	72	4.40	10.08	0.0	0.00	50.0	65	1.03	12.10	-33.3	0.00	50.0
	Week 35	66	5.30	12.46	0.0	0.00	66.7	60	2.78	13.43	-33.3	0.00	50.0
	Week 38	66	6.82	16.79	0.0	0.00	83.3	57	4.09	16.45	-16.7	0.00	66.7
	Week 41	62	5.65	15.95	0.0	0.00	100.0	53	3.77	18.39	-33.3	0.00	100.0
	Week 44	55	4.24	10.74	0.0	0.00	50.0	48	3.12	12.71	-16.7	0.00	50.0
	Week 47	51	4.58	13.37	0.0	0.00	66.7	44	2.65	16.05	-16.7	0.00	66.7
	Week 50	48	5.90	13.09	0.0	0.00	66.7	44	3.41	12.75	-16.7	0.00	50.0
	Week 53	41	5.69	14.25	0.0	0.00	66.7	37	3.15	14.61	-16.7	0.00	66.7
	Week 56	34	5.39	13.44	0.0	0.00	66.7	29	2.87	16.71	-16.7	0.00	66.7
	Week 59	32	1.56	4.94	0.0	0.00	16.7	28	-0.60	8.47	-16.7	0.00	16.7
	Week 62	27	1.85	7.06	0.0	0.00	33.3	24	-0.70	10.40	-16.7	0.00	33.3
	Week 65	25	3.33	8.33	0.0	0.00	33.3	21	0.00	11.79	-16.7	0.00	33.3
	Week 68	23	1.45	4.80	0.0	0.00	16.7	19	0.00	7.86	-16.7	0.00	16.7
	Week 71	21	3.17	8.53	0.0	0.00	33.3	18	1.85	9.72	-16.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 74	20	5.00	12.21	0.0	0.00	50.0	17	4.90	12.86	0.0	0.00	50.0
	Week 77	16	6.25	17.08	0.0	0.00	66.7	13	6.41	18.68	0.0	0.00	66.7
	Week 80	12	8.33	19.46	0.0	0.00	66.7	11	9.09	20.23	0.0	0.00	66.7
	Week 83	11	1.52	5.03	0.0	0.00	16.7	10	1.67	5.27	0.0	0.00	16.7
	Week 86	10	1.67	5.27	0.0	0.00	16.7	9	1.85	5.56	0.0	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
< 65 years	EV+Pembro (N=105)												
	BASELINE	92	6.88	15.46	0.0	0.00	66.7						
	Week 1	88	10.23	19.48	0.0	0.00	100.0	85	4.12	13.09	-33.3	0.00	50.0
	Week 2	92	8.15	12.96	0.0	0.00	50.0	86	2.13	15.92	-66.7	0.00	33.3
	Week 3	93	7.71	13.80	0.0	0.00	83.3	84	0.79	12.91	-50.0	0.00	33.3
	Week 4	90	6.11	10.44	0.0	0.00	33.3	82	-0.20	10.96	-33.3	0.00	16.7
	Week 5	90	5.37	11.94	0.0	0.00	66.7	81	-1.44	13.49	-50.0	0.00	33.3
	Week 6	90	5.00	12.35	0.0	0.00	66.7	81	-1.23	16.62	-66.7	0.00	50.0
	Week 7	85	4.51	10.09	0.0	0.00	66.7	77	-2.38	18.08	-66.7	0.00	66.7
	Week 8	89	4.49	9.32	0.0	0.00	33.3	80	-2.92	17.75	-66.7	0.00	33.3
	Week 9	93	3.58	9.15	0.0	0.00	50.0	85	-1.96	16.15	-66.7	0.00	33.3
	Week 10	88	2.46	6.46	0.0	0.00	33.3	81	-4.73	16.92	-66.7	0.00	16.7
	Week 11	93	4.12	9.08	0.0	0.00	33.3	84	-2.98	17.95	-66.7	0.00	33.3
	Week 12	86	3.68	9.36	0.0	0.00	50.0	79	-4.01	18.72	-66.7	0.00	33.3
	Week 14	84	4.76	10.85	0.0	0.00	50.0	76	0.66	13.99	-66.7	0.00	50.0
	Week 17	83	5.22	10.39	0.0	0.00	50.0	77	-1.08	16.52	-66.7	0.00	50.0
	Week 20	79	3.38	9.39	0.0	0.00	50.0	73	-2.97	15.80	-66.7	0.00	33.3
	Week 23	78	6.20	14.24	0.0	0.00	83.3	73	-0.23	20.69	-66.7	0.00	83.3
	Week 26	78	4.06	12.36	0.0	0.00	66.7	72	-2.55	19.51	-66.7	0.00	66.7
	Week 29	74	2.93	10.08	0.0	0.00	66.7	67	-3.48	17.78	-66.7	0.00	66.7
	Week 32	64	3.39	13.34	0.0	0.00	83.3	59	0.28	15.63	-33.3	0.00	83.3
	Week 35	62	2.15	5.63	0.0	0.00	16.7	58	-2.59	12.01	-66.7	0.00	16.7
	Week 38	62	3.49	8.61	0.0	0.00	33.3	59	-1.13	13.79	-66.7	0.00	33.3
	Week 41	64	3.91	8.78	0.0	0.00	33.3	59	-1.70	15.07	-66.7	0.00	33.3
	Week 44	50	1.33	4.57	0.0	0.00	16.7	48	-3.13	12.23	-66.7	0.00	16.7
	Week 47	47	2.84	6.33	0.0	0.00	16.7	46	-3.26	15.16	-66.7	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	44	2.65	6.17	0.0	0.00	16.7	41	0.00	8.33	-33.3	0.00	16.7
	Week 53	40	3.75	8.00	0.0	0.00	33.3	37	-1.35	14.90	-66.7	0.00	33.3
	Week 56	44	3.03	7.43	0.0	0.00	33.3	41	0.00	8.33	-16.7	0.00	33.3
	Week 59	42	2.38	5.90	0.0	0.00	16.7	39	-0.43	8.10	-33.3	0.00	16.7
	Week 62	37	1.35	4.61	0.0	0.00	16.7	36	-2.32	8.12	-33.3	0.00	16.7
	Week 65	34	3.43	7.98	0.0	0.00	33.3	31	0.00	11.39	-33.3	0.00	33.3
	Week 68	34	2.45	5.99	0.0	0.00	16.7	33	-1.01	7.14	-33.3	0.00	16.7
	Week 71	32	3.13	7.85	0.0	0.00	33.3	30	-0.56	8.17	-33.3	0.00	16.7
	Week 74	29	2.87	7.80	0.0	0.00	33.3	28	-1.19	8.99	-33.3	0.00	16.7
	Week 77	25	2.00	7.33	0.0	0.00	33.3	24	-2.08	11.33	-33.3	0.00	33.3
	Week 80	24	2.08	7.47	0.0	0.00	33.3	22	-2.27	10.66	-16.7	0.00	33.3
	Week 83	23	2.17	5.74	0.0	0.00	16.7	22	-2.27	7.79	-16.7	0.00	16.7
	Week 86	20	1.67	5.13	0.0	0.00	16.7	18	-3.70	9.14	-16.7	0.00	16.7
	Week 89	19	1.75	5.26	0.0	0.00	16.7	17	-2.94	8.81	-16.7	0.00	16.7
	Week 92	14	3.57	9.65	0.0	0.00	33.3	12	0.00	12.31	-16.7	0.00	33.3
	Week 95	12	1.39	4.81	0.0	0.00	16.7	11	-1.52	5.03	-16.7	0.00	0.0
	Plat+Gem (N=106)												
	BASELINE	83	6.23	12.13	0.0	0.00	66.7						
	Week 1	75	20.22	24.09	0.0	16.67	100.0	71	13.85	19.92	-16.7	16.67	100.0
	Week 2	76	15.79	20.16	0.0	16.67	100.0	68	10.54	21.53	-33.3	0.00	100.0
	Week 3	80	9.38	14.73	0.0	0.00	50.0	73	3.65	16.95	-50.0	0.00	50.0
	Week 4	79	14.35	16.82	0.0	16.67	66.7	67	8.46	17.50	-33.3	0.00	66.7
	Week 5	80	17.29	18.07	0.0	16.67	66.7	67	11.19	20.59	-33.3	0.00	66.7
	Week 6	76	9.43	13.43	0.0	0.00	50.0	67	4.73	16.62	-50.0	0.00	50.0
	Week 7	81	13.79	17.64	0.0	16.67	83.3	71	7.28	21.22	-66.7	0.00	83.3
	Week 8	72	15.97	19.27	0.0	16.67	66.7	64	10.42	21.92	-50.0	16.66	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	78	12.39	17.50	0.0	0.00	66.7	69	7.25	20.51	-33.3	0.00	66.7
	Week 10	78	15.81	19.35	0.0	16.67	100.0	68	10.05	21.77	-50.0	0.00	100.0
	Week 11	75	20.45	23.66	0.0	16.67	100.0	66	15.40	26.84	-50.0	16.67	100.0
	Week 12	74	11.94	18.41	0.0	0.00	100.0	66	7.83	21.72	-50.0	0.00	100.0
	Week 14	68	17.89	20.02	0.0	16.67	66.7	58	11.78	26.12	-50.0	8.34	66.7
	Week 17	68	16.67	22.30	0.0	16.67	100.0	58	12.36	28.02	-66.7	0.00	100.0
	Week 20	60	7.78	12.82	0.0	0.00	50.0	52	3.85	15.70	-50.0	0.00	33.3
	Week 23	51	6.86	13.81	0.0	0.00	50.0	44	1.51	17.91	-33.3	0.00	50.0
	Week 26	47	6.38	11.81	0.0	0.00	50.0	42	2.78	15.14	-33.3	0.00	50.0
	Week 29	42	3.17	8.42	0.0	0.00	33.3	37	-1.35	11.37	-33.3	0.00	33.3
	Week 32	37	3.60	9.73	0.0	0.00	50.0	34	-1.47	11.87	-33.3	0.00	50.0
	Week 35	34	3.43	8.97	0.0	0.00	33.3	31	0.00	10.54	-33.3	0.00	33.3
	Week 38	33	6.57	17.15	0.0	0.00	66.7	28	4.17	16.74	-16.7	0.00	66.7
	Week 41	27	3.70	9.62	0.0	0.00	33.3	22	3.03	9.81	-16.7	0.00	33.3
	Week 44	28	1.19	6.30	0.0	0.00	33.3	24	-1.39	9.73	-16.7	0.00	33.3
	Week 47	24	1.39	6.80	0.0	0.00	33.3	21	0.00	9.13	-16.7	0.00	33.3
	Week 50	26	6.41	14.97	0.0	0.00	66.7	24	2.08	14.17	-16.7	0.00	50.0
	Week 53	19	5.26	13.67	0.0	0.00	50.0	17	0.98	10.98	-16.7	0.00	33.3
	Week 56	13	2.56	6.26	0.0	0.00	16.7	11	-3.03	10.05	-16.7	0.00	16.7
	Week 59	14	0.00	0.00	0.0	0.00	0.0	12	-2.78	6.49	-16.7	0.00	0.0
	Week 62	13	0.00	0.00	0.0	0.00	0.0	12	-2.78	6.49	-16.7	0.00	0.0
	Week 65	13	2.56	6.26	0.0	0.00	16.7	11	-1.52	8.99	-16.7	0.00	16.7
	Week 68	10	0.00	0.00	0.0	0.00	0.0	8	-2.08	5.89	-16.7	0.00	0.0
	Week 77	10	3.33	7.03	0.0	0.00	16.7	8	-4.17	7.71	-16.7	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>= 65 years	EV+Pembro (N=135)												
	BASELINE	114	4.97	13.29	0.0	0.00	66.7						
	Week 1	102	6.70	15.25	0.0	0.00	100.0	99	1.52	14.89	-33.3	0.00	100.0
	Week 2	111	10.21	20.12	0.0	0.00	100.0	103	5.34	18.11	-33.3	0.00	100.0
	Week 3	105	10.32	16.08	0.0	0.00	66.7	98	5.95	18.27	-50.0	0.00	66.7
	Week 4	104	5.13	10.66	0.0	0.00	50.0	97	0.69	17.00	-66.7	0.00	50.0
	Week 5	100	7.83	13.29	0.0	0.00	50.0	92	3.44	17.21	-50.0	0.00	50.0
	Week 6	98	6.97	13.73	0.0	0.00	66.7	89	1.87	16.18	-66.7	0.00	66.7
	Week 7	110	6.52	13.56	0.0	0.00	100.0	99	1.68	17.90	-66.7	0.00	83.3
	Week 8	102	5.88	10.40	0.0	0.00	50.0	91	1.10	14.01	-50.0	0.00	33.3
	Week 9	104	7.37	16.06	0.0	0.00	83.3	95	1.93	17.17	-66.7	0.00	66.7
	Week 10	103	5.66	12.25	0.0	0.00	66.7	94	0.00	16.58	-66.7	0.00	50.0
	Week 11	101	4.29	9.62	0.0	0.00	50.0	91	-1.10	15.68	-66.7	0.00	50.0
	Week 12	100	5.50	12.99	0.0	0.00	66.7	92	-0.18	15.33	-66.7	0.00	50.0
	Week 14	101	5.94	13.66	0.0	0.00	100.0	91	0.55	16.75	-66.7	0.00	83.3
	Week 17	95	4.56	9.24	0.0	0.00	33.3	85	0.78	15.62	-66.7	0.00	33.3
	Week 20	88	4.74	12.62	0.0	0.00	83.3	81	0.21	16.98	-66.7	0.00	66.7
	Week 23	84	3.97	9.89	0.0	0.00	66.7	78	1.50	14.76	-66.7	0.00	66.7
	Week 26	78	2.78	9.84	0.0	0.00	50.0	72	-1.39	14.19	-66.7	0.00	33.3
	Week 29	83	1.61	4.95	0.0	0.00	16.7	78	-1.50	12.07	-66.7	0.00	16.7
	Week 32	71	1.17	5.14	0.0	0.00	33.3	66	-2.53	12.49	-66.7	0.00	33.3
	Week 35	70	0.95	3.90	0.0	0.00	16.7	64	-2.60	13.02	-66.7	0.00	16.7
	Week 38	70	1.43	5.49	0.0	0.00	33.3	65	-0.51	10.19	-50.0	0.00	33.3
	Week 41	65	3.85	14.06	0.0	0.00	100.0	60	0.00	17.63	-66.7	0.00	83.3
	Week 44	58	1.44	4.72	0.0	0.00	16.7	52	-1.28	10.87	-66.7	0.00	16.7
	Week 47	53	4.72	10.01	0.0	0.00	33.3	48	1.04	15.15	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	45	1.48	4.80	0.0	0.00	16.7	43	-1.94	11.62	-66.7	0.00	16.7
	Week 53	39	4.70	13.22	0.0	0.00	66.7	37	2.25	18.49	-66.7	0.00	66.7
	Week 56	37	4.05	12.67	0.0	0.00	66.7	35	1.90	17.97	-66.7	0.00	66.7
	Week 59	30	4.45	13.08	0.0	0.00	66.7	29	1.72	19.08	-66.7	0.00	66.7
	Week 62	28	2.98	12.87	0.0	0.00	66.7	27	0.00	19.06	-66.7	0.00	66.7
	Week 65	24	1.39	4.71	0.0	0.00	16.7	23	-1.45	15.00	-66.7	0.00	16.7
	Week 68	19	4.39	12.23	0.0	0.00	50.0	19	0.88	20.39	-66.7	0.00	50.0
	Week 71	19	2.63	11.47	0.0	0.00	50.0	19	-0.88	19.62	-66.7	0.00	50.0
	Week 74	18	0.00	0.00	0.0	0.00	0.0	18	-4.63	15.97	-66.7	0.00	0.0
	Week 77	19	1.75	5.26	0.0	0.00	16.7	18	0.93	6.94	-16.7	0.00	16.7
	Week 80	16	3.13	6.72	0.0	0.00	16.7	15	-2.22	15.26	-50.0	0.00	16.7
	Week 83	14	0.00	0.00	0.0	0.00	0.0	13	-6.41	18.68	-66.7	0.00	0.0
	Week 86	14	0.00	0.00	0.0	0.00	0.0	13	-6.41	18.68	-66.7	0.00	0.0
	Week 89	14	4.76	10.19	0.0	0.00	33.3	14	-1.19	22.14	-66.7	0.00	33.3
	Week 92	13	1.28	4.62	0.0	0.00	16.7	13	-5.13	19.70	-66.7	0.00	16.7
	Week 95	10	0.00	0.00	0.0	0.00	0.0	10	-1.67	5.27	-16.7	0.00	0.0
	Week 98	10	1.67	5.27	0.0	0.00	16.7	10	0.00	7.86	-16.7	0.00	16.7
	Plat+Gem (N=136)												
	BASELINE	105	5.71	10.55	0.0	0.00	50.0						
	Week 1	98	14.46	18.01	0.0	16.67	66.7	87	9.20	19.15	-33.3	0.00	66.7
	Week 2	95	12.98	17.22	0.0	16.67	66.7	83	8.64	20.22	-50.0	0.00	66.7
	Week 3	104	10.42	14.54	0.0	0.00	66.7	89	6.37	16.76	-50.0	0.00	66.7
	Week 4	104	13.46	19.02	0.0	0.00	83.3	89	8.43	21.49	-50.0	0.00	83.3
	Week 5	107	11.68	15.05	0.0	16.67	83.3	89	6.55	18.23	-50.0	0.00	83.3
	Week 6	98	11.40	15.80	0.0	0.00	100.0	82	5.89	17.25	-50.0	0.00	100.0
	Week 7	105	13.81	17.06	0.0	16.67	83.3	86	8.14	19.43	-50.0	0.00	83.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 8	95	12.81	15.07	0.0	16.67	83.3	80	8.13	18.75	-50.0	0.00	83.3
	Week 9	99	11.28	16.12	0.0	0.00	66.7	81	6.38	17.19	-50.0	0.00	66.7
	Week 10	88	13.45	18.89	0.0	0.00	83.3	71	8.69	20.29	-50.0	0.00	66.7
	Week 11	93	12.73	14.83	0.0	16.67	66.7	77	8.66	19.42	-50.0	0.00	66.7
	Week 12	85	11.37	16.31	0.0	0.00	66.7	72	6.25	19.87	-50.0	0.00	66.7
	Week 14	85	12.94	18.79	0.0	0.00	83.3	70	7.38	22.46	-50.0	0.00	83.3
	Week 17	87	14.94	20.34	0.0	16.67	83.3	72	10.19	25.57	-50.0	0.00	83.3
	Week 20	66	10.35	15.68	0.0	0.00	83.3	58	4.89	18.99	-50.0	0.00	83.3
	Week 23	64	6.25	13.11	0.0	0.00	83.3	53	2.83	17.52	-50.0	0.00	83.3
	Week 26	61	6.01	10.98	0.0	0.00	33.3	53	2.52	13.63	-33.3	0.00	33.3
	Week 29	58	7.18	14.68	0.0	0.00	66.7	49	5.10	18.07	-50.0	0.00	66.7
	Week 32	46	5.44	10.57	0.0	0.00	33.3	42	1.59	14.64	-50.0	0.00	33.3
	Week 35	42	6.35	13.75	0.0	0.00	66.7	38	3.07	16.83	-50.0	0.00	50.0
	Week 38	41	6.10	15.25	0.0	0.00	83.3	37	3.15	15.13	-16.7	0.00	66.7
	Week 41	38	7.02	18.84	0.0	0.00	100.0	34	2.94	23.74	-50.0	0.00	100.0
	Week 44	32	7.81	13.38	0.0	0.00	50.0	29	7.47	14.49	-16.7	0.00	50.0
	Week 47	32	7.29	15.80	0.0	0.00	66.7	28	4.76	19.17	-16.7	0.00	66.7
	Week 50	25	5.33	10.45	0.0	0.00	33.3	23	2.90	11.95	-16.7	0.00	33.3
	Week 53	27	5.56	13.87	0.0	0.00	66.7	25	4.00	16.16	-16.7	0.00	66.7
	Week 56	26	7.05	15.04	0.0	0.00	66.7	23	4.35	18.27	-16.7	0.00	66.7
	Week 59	23	2.90	6.46	0.0	0.00	16.7	21	0.79	9.83	-16.7	0.00	16.7
	Week 62	19	3.51	8.92	0.0	0.00	33.3	17	0.98	12.46	-16.7	0.00	33.3
	Week 65	17	3.92	9.37	0.0	0.00	33.3	15	1.11	13.31	-16.7	0.00	33.3
	Week 68	15	3.33	6.90	0.0	0.00	16.7	13	1.28	10.68	-16.7	0.00	16.7
	Week 71	15	4.44	9.89	0.0	0.00	33.3	13	3.85	12.08	-16.7	0.00	33.3
	Week 74	12	6.95	15.01	0.0	0.00	50.0	11	7.58	15.57	0.0	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Europe	EV+Pembro (N= 98)												
	BASELINE	79	5.06	13.96	0.0	0.00	66.7						
	Week 1	74	8.11	18.56	0.0	0.00	100.0	71	3.05	14.72	-33.3	0.00	100.0
	Week 2	79	5.91	12.53	0.0	0.00	50.0	71	1.17	14.18	-66.7	0.00	33.3
	Week 3	78	9.19	15.58	0.0	0.00	66.7	69	4.59	19.15	-50.0	0.00	66.7
	Week 4	78	4.91	11.11	0.0	0.00	50.0	70	-0.24	16.42	-66.7	0.00	50.0
	Week 5	70	4.76	10.29	0.0	0.00	33.3	62	0.54	14.77	-50.0	0.00	33.3
	Week 6	70	2.62	6.74	0.0	0.00	33.3	61	-1.09	13.90	-66.7	0.00	33.3
	Week 7	78	4.06	8.98	0.0	0.00	50.0	68	-1.47	16.22	-66.7	0.00	33.3
	Week 8	72	4.63	10.91	0.0	0.00	50.0	61	-0.55	15.51	-66.7	0.00	33.3
	Week 9	80	2.92	9.48	0.0	0.00	50.0	70	-1.90	13.77	-66.7	0.00	33.3
	Week 10	71	2.35	6.48	0.0	0.00	33.3	62	-4.03	15.59	-66.7	0.00	16.7
	Week 11	76	2.85	7.88	0.0	0.00	33.3	66	-3.03	16.77	-66.7	0.00	33.3
	Week 12	73	2.74	8.34	0.0	0.00	50.0	65	-3.08	16.90	-66.7	0.00	33.3
	Week 14	74	3.83	9.37	0.0	0.00	50.0	64	-0.26	14.70	-66.7	0.00	33.3
	Week 17	70	2.14	5.62	0.0	0.00	16.7	62	-3.23	15.92	-66.7	0.00	16.7
	Week 20	70	1.91	5.34	0.0	0.00	16.7	63	-3.70	15.97	-66.7	0.00	16.7
	Week 23	61	3.55	9.68	0.0	0.00	50.0	57	-0.88	17.08	-66.7	0.00	50.0
	Week 26	62	1.61	8.91	0.0	0.00	50.0	55	-3.94	18.97	-66.7	0.00	50.0
	Week 29	63	1.59	9.33	0.0	0.00	66.7	57	-3.80	18.90	-66.7	0.00	66.7
	Week 32	51	2.94	13.62	0.0	0.00	83.3	47	-2.13	21.03	-66.7	0.00	83.3
	Week 35	56	1.19	4.33	0.0	0.00	16.7	52	-3.53	14.51	-66.7	0.00	16.7
	Week 38	51	1.31	5.62	0.0	0.00	33.3	48	-2.43	13.75	-66.7	0.00	16.7
	Week 41	52	2.56	7.66	0.0	0.00	33.3	48	-3.82	17.61	-66.7	0.00	33.3
	Week 44	43	1.16	4.30	0.0	0.00	16.7	39	-2.14	13.34	-66.7	0.00	16.7
	Week 47	39	2.99	7.52	0.0	0.00	33.3	36	-2.78	17.14	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	37	1.35	4.61	0.0	0.00	16.7	36	-2.31	13.31	-66.7	0.00	16.7
	Week 53	28	3.57	9.47	0.0	0.00	33.3	27	-3.09	21.70	-66.7	0.00	33.3
	Week 56	30	2.22	7.24	0.0	0.00	33.3	29	-1.72	15.00	-66.7	0.00	33.3
	Week 59	27	1.85	5.34	0.0	0.00	16.7	27	-2.47	15.12	-66.7	0.00	16.7
	Week 62	23	2.90	13.90	0.0	0.00	66.7	23	-2.17	21.50	-66.7	0.00	66.7
	Week 65	23	1.45	4.80	0.0	0.00	16.7	23	-3.62	15.86	-66.7	0.00	16.7
	Week 68	21	0.79	3.64	0.0	0.00	16.7	21	-4.76	15.94	-66.7	0.00	0.0
	Week 71	19	0.88	3.82	0.0	0.00	16.7	19	-5.26	16.72	-66.7	0.00	0.0
	Week 74	15	0.00	0.00	0.0	0.00	0.0	15	-7.78	18.76	-66.7	0.00	0.0
	Week 77	19	2.63	8.36	0.0	0.00	33.3	19	0.00	12.42	-33.3	0.00	33.3
	Week 80	17	3.92	9.37	0.0	0.00	33.3	17	-2.94	15.85	-50.0	0.00	33.3
	Week 83	16	2.08	5.69	0.0	0.00	16.7	16	-5.21	17.97	-66.7	0.00	16.7
	Week 86	14	2.38	6.05	0.0	0.00	16.7	14	-5.95	19.18	-66.7	0.00	16.7
	Week 89	14	2.38	6.05	0.0	0.00	16.7	14	-5.95	19.18	-66.7	0.00	16.7
	Week 92	11	3.03	10.05	0.0	0.00	33.3	11	-4.55	23.68	-66.7	0.00	33.3
	Week 95	10	0.00	0.00	0.0	0.00	0.0	10	-1.67	5.27	-16.7	0.00	0.0
	Plat+Gem (N=102)												
	BASELINE	71	5.87	12.31	0.0	0.00	66.7						
	Week 1	71	19.02	25.87	0.0	16.67	100.0	61	13.39	22.94	-16.7	0.00	100.0
	Week 2	67	14.68	19.36	0.0	16.67	100.0	56	9.23	23.34	-50.0	0.00	100.0
	Week 3	68	12.75	17.54	0.0	0.00	66.7	56	8.04	21.32	-50.0	0.00	66.7
	Week 4	75	13.78	18.46	0.0	0.00	83.3	59	7.91	22.61	-50.0	0.00	83.3
	Week 5	77	14.94	17.64	0.0	16.67	83.3	60	9.72	21.98	-50.0	0.00	83.3
	Week 6	70	13.57	19.10	0.0	0.00	100.0	56	6.85	22.65	-50.0	0.00	100.0
	Week 7	72	16.20	18.76	0.0	16.67	83.3	55	10.00	24.76	-66.7	0.00	83.3
	Week 8	65	16.92	18.04	0.0	16.67	66.7	53	12.58	24.44	-50.0	16.67	66.7

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	70	15.24	18.55	0.0	16.67	66.7	55	10.00	21.18	-50.0	0.00	66.7
	Week 10	60	18.33	22.69	0.0	16.67	100.0	46	12.32	26.63	-50.0	8.33	100.0
	Week 11	64	18.75	21.52	0.0	16.67	100.0	50	15.67	29.05	-50.0	16.67	100.0
	Week 12	60	13.89	20.85	0.0	0.00	100.0	48	9.38	27.05	-50.0	0.00	100.0
	Week 14	56	19.94	23.23	0.0	16.67	83.3	42	14.68	30.84	-50.0	16.67	83.3
	Week 17	58	16.95	20.59	0.0	16.67	83.3	44	11.74	28.21	-66.7	0.00	83.3
	Week 20	47	10.28	14.56	0.0	0.00	50.0	37	4.96	19.19	-50.0	0.00	33.3
	Week 23	44	8.71	12.70	0.0	0.00	50.0	32	2.08	18.81	-50.0	0.00	50.0
	Week 26	39	8.55	13.17	0.0	0.00	50.0	30	3.89	16.19	-33.3	0.00	50.0
	Week 29	34	4.41	10.31	0.0	0.00	33.3	25	0.00	14.43	-50.0	0.00	33.3
	Week 32	33	5.05	11.40	0.0	0.00	50.0	27	-1.24	15.96	-50.0	0.00	50.0
	Week 35	30	5.00	13.94	0.0	0.00	66.7	24	-0.70	18.04	-50.0	0.00	50.0
	Week 38	26	8.97	21.72	0.0	0.00	83.3	21	3.97	22.30	-16.7	0.00	66.7
	Week 41	22	1.52	4.91	0.0	0.00	16.7	17	-4.90	16.42	-50.0	0.00	16.7
	Week 44	20	5.83	11.18	0.0	0.00	33.3	16	4.17	14.27	-16.7	0.00	33.3
	Week 47	16	5.21	13.22	0.0	0.00	50.0	12	1.39	18.06	-16.7	0.00	50.0
	Week 50	11	7.58	20.23	0.0	0.00	66.7	10	3.33	18.92	-16.7	0.00	50.0
	Week 53	11	4.55	15.08	0.0	0.00	50.0	10	0.00	13.61	-16.7	0.00	33.3
	Week 56	10	1.67	5.27	0.0	0.00	16.7	8	-4.17	7.72	-16.7	0.00	0.0

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
North America	EV+Pembro (N= 57)												
	BASELINE	47	7.09	13.34	0.0	0.00	66.7						
	Week 1	39	9.40	13.13	0.0	0.00	50.0	37	3.15	15.13	-33.3	0.00	50.0
	Week 2	44	10.99	17.95	0.0	0.00	100.0	42	4.76	20.92	-66.7	0.00	100.0
	Week 3	44	13.26	14.64	0.0	16.67	66.7	40	5.83	14.88	-33.3	0.00	50.0
	Week 4	44	7.20	9.78	0.0	0.00	33.3	41	0.41	10.20	-33.3	0.00	16.7
	Week 5	47	6.74	13.31	0.0	0.00	66.7	41	-0.41	13.69	-33.3	0.00	33.3
	Week 6	44	8.33	14.60	0.0	0.00	66.7	39	0.43	21.79	-66.7	0.00	66.7
	Week 7	46	5.44	11.68	0.0	0.00	66.7	42	-1.19	18.91	-66.7	0.00	66.7
	Week 8	47	4.61	8.30	0.0	0.00	33.3	42	-2.38	15.86	-66.7	0.00	16.7
	Week 9	46	5.44	10.57	0.0	0.00	50.0	42	-0.40	16.66	-66.7	0.00	33.3
	Week 10	47	3.55	8.47	0.0	0.00	33.3	44	-3.79	15.19	-66.7	0.00	16.7
	Week 11	47	4.26	8.84	0.0	0.00	33.3	42	-3.17	14.83	-66.7	0.00	16.7
	Week 12	44	5.30	12.33	0.0	0.00	50.0	40	-3.33	16.96	-66.7	0.00	33.3
	Week 14	43	6.59	12.14	0.0	0.00	50.0	39	1.28	12.90	-33.3	0.00	50.0
	Week 17	40	6.67	11.20	0.0	0.00	33.3	37	1.35	13.25	-33.3	0.00	33.3
	Week 20	38	5.70	16.57	0.0	0.00	83.3	35	-0.48	19.59	-66.7	0.00	66.7
	Week 23	38	7.02	14.31	0.0	0.00	66.7	35	2.38	17.69	-66.7	0.00	66.7
	Week 26	35	1.43	4.73	0.0	0.00	16.7	32	-4.17	11.20	-33.3	0.00	16.7
	Week 29	38	2.19	5.71	0.0	0.00	16.7	34	-3.92	14.83	-66.7	0.00	16.7
	Week 32	32	3.13	8.92	0.0	0.00	33.3	29	-0.58	9.43	-16.7	0.00	33.3
	Week 35	33	0.51	2.90	0.0	0.00	16.7	30	-5.00	13.94	-66.7	0.00	0.0
	Week 38	32	2.08	5.60	0.0	0.00	16.7	29	-2.87	10.97	-33.3	0.00	16.7
	Week 41	28	2.98	9.13	0.0	0.00	33.3	24	1.39	9.73	-16.7	0.00	33.3
	Week 44	21	0.00	0.00	0.0	0.00	0.0	20	-2.50	6.11	-16.7	0.00	0.0
	Week 47	24	3.47	8.48	0.0	0.00	33.3	23	-0.72	12.79	-33.3	0.00	33.3

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Table 302.1.3002.17.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	23	2.17	5.74	0.0	0.00	16.7	20	-0.83	6.57	-16.7	0.00	16.7
	Week 53	17	0.98	4.04	0.0	0.00	16.7	14	1.19	4.46	0.0	0.00	16.7
	Week 56	20	3.33	8.72	0.0	0.00	33.3	17	1.96	10.00	-16.7	0.00	33.3
	Week 59	17	1.96	5.54	0.0	0.00	16.7	14	1.19	7.91	-16.7	0.00	16.7
	Week 62	14	2.38	6.05	0.0	0.00	16.7	13	0.00	6.81	-16.7	0.00	16.7
	Week 65	12	1.39	4.81	0.0	0.00	16.7	9	1.85	5.56	0.0	0.00	16.7
	Week 68	10	0.00	0.00	0.0	0.00	0.0	9	0.00	0.00	0.0	0.00	0.0
	Week 71	10	5.00	15.81	0.0	0.00	50.0	8	6.25	17.68	0.0	0.00	50.0
	Week 74	10	0.00	0.00	0.0	0.00	0.0	9	-1.85	5.56	-16.7	0.00	0.0
	Plat+Gem (N= 51)												
	BASELINE	42	6.75	11.08	0.0	0.00	33.3						
	Week 1	41	16.26	16.87	0.0	16.67	66.7	36	9.26	15.14	-16.7	0.00	50.0
	Week 2	38	15.35	17.49	0.0	16.67	66.7	33	9.60	16.15	-16.7	0.00	50.0
	Week 3	40	7.50	13.58	0.0	0.00	50.0	35	1.43	15.32	-33.3	0.00	50.0
	Week 4	35	13.33	15.02	0.0	16.67	50.0	29	6.90	14.45	-16.7	0.00	50.0
	Week 5	39	14.53	15.85	0.0	16.67	66.7	32	6.77	19.79	-33.3	0.00	66.7
	Week 6	34	9.32	10.21	0.0	8.34	33.3	30	4.45	13.80	-16.7	0.00	33.3
	Week 7	42	11.51	15.39	0.0	0.00	66.7	37	4.96	18.37	-33.3	0.00	66.7
	Week 8	39	12.82	15.51	0.0	16.67	66.7	33	6.06	16.57	-16.7	0.00	66.7
	Week 9	39	9.40	16.13	0.0	0.00	66.7	33	1.51	18.80	-33.3	0.00	66.7
	Week 10	39	13.25	15.85	0.0	16.67	50.0	32	7.29	18.42	-16.7	0.00	50.0
	Week 11	39	13.68	16.61	0.0	16.67	66.7	33	6.06	17.09	-16.7	0.00	66.7
	Week 12	36	11.11	13.80	0.0	0.00	50.0	32	4.69	15.40	-16.7	0.00	50.0
	Week 14	34	12.75	18.83	0.0	0.00	66.7	29	5.17	26.39	-33.3	0.00	66.7
	Week 17	37	14.87	19.56	0.0	0.00	66.7	31	9.68	26.45	-33.3	0.00	66.7
	Week 20	27	8.03	12.55	0.0	0.00	50.0	23	2.90	15.61	-33.3	0.00	33.3

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Table 302.1.3002.17.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 23	27	3.09	9.29	0.0	0.00	33.3	23	-1.45	15.82	-33.3	0.00	33.3
	Week 26	28	2.98	6.50	0.0	0.00	16.7	25	-2.00	13.02	-33.3	0.00	16.7
	Week 29	29	5.17	9.02	0.0	0.00	33.3	25	0.00	14.43	-33.3	0.00	33.3
	Week 32	17	2.94	6.55	0.0	0.00	16.7	17	-3.92	11.07	-33.3	0.00	16.7
	Week 35	16	3.13	6.72	0.0	0.00	16.7	15	-1.11	11.73	-33.3	0.00	16.7
	Week 38	16	3.13	6.72	0.0	0.00	16.7	13	1.28	8.23	-16.7	0.00	16.7
	Week 41	16	6.25	14.75	0.0	0.00	50.0	13	5.13	18.49	-16.7	0.00	50.0
	Week 44	13	3.85	13.87	0.0	0.00	50.0	11	1.51	17.41	-16.7	0.00	50.0
	Week 47	11	1.52	5.03	0.0	0.00	16.7	9	0.00	8.34	-16.7	0.00	16.7
	Week 50	17	4.90	7.83	0.0	0.00	16.7	15	0.00	12.60	-16.7	0.00	16.7
	Week 53	13	5.13	8.01	0.0	0.00	16.7	11	1.52	11.68	-16.7	0.00	16.7
	Week 56	11	6.06	8.41	0.0	0.00	16.7	9	0.00	14.44	-16.7	0.00	16.7
	Week 59	11	3.03	6.74	0.0	0.00	16.7	9	0.00	11.79	-16.7	0.00	16.7
	Week 62	11	3.03	6.74	0.0	0.00	16.7	9	0.00	11.79	-16.7	0.00	16.7
	Week 65	10	3.33	7.03	0.0	0.00	16.7	8	0.00	12.60	-16.7	0.00	16.7

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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Table 302.1.3002.17.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Rest of World	EV+Pembro (N= 85)												
	BASELINE	80	5.83	15.26	0.0	0.00	66.7						
	Week 1	77	8.01	18.26	0.0	0.00	100.0	76	2.19	13.15	-33.3	0.00	50.0
	Week 2	80	11.67	20.27	0.0	0.00	100.0	76	5.92	17.36	-33.3	0.00	83.3
	Week 3	76	6.58	14.42	0.0	0.00	83.3	73	1.37	13.54	-50.0	0.00	33.3
	Week 4	72	5.32	10.40	0.0	0.00	50.0	68	0.74	14.81	-50.0	0.00	50.0
	Week 5	73	8.45	14.20	0.0	0.00	50.0	70	2.62	17.64	-50.0	0.00	50.0
	Week 6	74	7.88	15.90	0.0	0.00	66.7	70	1.67	15.06	-66.7	0.00	50.0
	Week 7	71	7.51	15.12	0.0	0.00	100.0	66	2.02	19.29	-50.0	0.00	83.3
	Week 8	72	6.25	9.87	0.0	0.00	33.3	68	0.00	16.54	-66.7	0.00	33.3
	Week 9	71	8.69	17.56	0.0	0.00	83.3	68	2.45	19.37	-66.7	0.00	66.7
	Week 10	73	6.39	13.21	0.0	0.00	66.7	69	0.48	18.74	-66.7	0.00	50.0
	Week 11	71	5.63	10.89	0.0	0.00	50.0	67	-0.25	18.00	-66.7	0.00	50.0
	Week 12	69	6.28	13.44	0.0	0.00	66.7	66	0.00	17.30	-66.7	0.00	50.0
	Week 14	68	6.37	15.25	0.0	0.00	100.0	64	1.04	17.79	-66.7	0.00	83.3
	Week 17	68	6.62	11.57	0.0	0.00	50.0	63	2.12	17.32	-66.7	0.00	50.0
	Week 20	59	5.65	11.83	0.0	0.00	50.0	56	0.89	14.71	-66.7	0.00	33.3
	Week 23	63	5.29	12.99	0.0	0.00	83.3	59	1.13	18.79	-66.7	0.00	83.3
	Week 26	59	6.50	14.85	0.0	0.00	66.7	57	1.17	17.50	-66.7	0.00	66.7
	Week 29	56	2.98	7.18	0.0	0.00	33.3	54	0.00	9.16	-33.3	0.00	16.7
	Week 32	52	0.96	5.13	0.0	0.00	33.3	49	-0.68	5.85	-16.7	0.00	16.7
	Week 35	43	2.71	6.23	0.0	0.00	16.7	40	0.42	7.05	-16.7	0.00	16.7
	Week 38	49	3.74	9.17	0.0	0.00	33.3	47	2.13	10.20	-16.7	0.00	33.3
	Week 41	49	5.78	15.79	0.0	0.00	100.0	47	1.06	17.52	-66.7	0.00	83.3
	Week 44	44	2.27	5.79	0.0	0.00	16.7	41	-2.03	11.90	-66.7	0.00	16.7
	Week 47	37	4.96	9.51	0.0	0.00	33.3	35	0.48	14.85	-50.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	29	2.87	6.41	0.0	0.00	16.7	28	0.60	7.15	-16.7	0.00	16.7
	Week 53	34	6.37	13.62	0.0	0.00	66.7	33	3.03	15.28	-16.7	0.00	66.7
	Week 56	31	4.84	13.05	0.0	0.00	66.7	30	2.78	13.90	-16.7	0.00	66.7
	Week 59	28	5.36	13.65	0.0	0.00	66.7	27	3.09	14.65	-16.7	0.00	66.7
	Week 62	28	1.19	4.37	0.0	0.00	16.7	27	-1.23	6.42	-16.7	0.00	16.7
	Week 65	23	4.35	9.01	0.0	0.00	33.3	22	1.52	11.40	-16.7	0.00	33.3
	Week 68	22	6.82	12.24	0.0	0.00	50.0	22	3.79	12.53	-16.7	0.00	50.0
	Week 71	22	3.79	8.81	0.0	0.00	33.3	22	0.76	6.25	-16.7	0.00	16.7
	Week 74	22	3.79	8.81	0.0	0.00	33.3	22	0.76	6.25	-16.7	0.00	16.7
	Week 77	18	1.85	5.39	0.0	0.00	16.7	17	-0.98	7.15	-16.7	0.00	16.7
	Week 80	16	1.04	4.17	0.0	0.00	16.7	15	-2.22	8.61	-16.7	0.00	16.7
	Week 83	16	1.04	4.17	0.0	0.00	16.7	15	-2.22	5.87	-16.7	0.00	0.0
	Week 86	13	0.00	0.00	0.0	0.00	0.0	12	-4.17	7.54	-16.7	0.00	0.0
	Week 89	12	4.17	10.36	0.0	0.00	33.3	12	1.39	13.22	-16.7	0.00	33.3
	Plat+Gem (N= 89)												
	BASELINE	75	5.56	10.37	0.0	0.00	50.0						
	Week 1	61	15.03	16.86	0.0	16.67	66.7	61	10.38	18.30	-33.3	0.00	50.0
	Week 2	66	13.13	18.61	0.0	8.34	66.7	62	9.68	20.81	-33.3	0.00	66.7
	Week 3	76	8.77	11.70	0.0	0.00	50.0	71	4.69	12.97	-33.3	0.00	50.0
	Week 4	73	14.16	19.18	0.0	0.00	83.3	68	9.56	19.38	-33.3	0.00	83.3
	Week 5	71	12.91	15.99	0.0	16.67	66.7	64	8.33	16.53	-33.3	0.00	66.7
	Week 6	70	8.10	10.90	0.0	0.00	33.3	63	4.50	11.67	-33.3	0.00	33.3
	Week 7	72	12.73	16.67	0.0	0.00	66.7	65	7.44	16.68	-33.3	0.00	66.7
	Week 8	63	12.17	16.72	0.0	0.00	83.3	58	7.76	17.44	-33.3	0.00	83.3
	Week 9	68	9.56	14.49	0.0	0.00	50.0	62	6.72	15.81	-33.3	0.00	50.0
	Week 10	67	11.94	16.87	0.0	0.00	83.3	61	8.20	17.11	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	65	15.13	19.26	0.0	16.67	83.3	60	11.67	20.42	-33.3	0.00	66.7
	Week 12	63	9.79	15.16	0.0	0.00	66.7	58	6.32	17.05	-33.3	0.00	50.0
	Week 14	63	12.17	15.03	0.0	16.67	66.7	57	7.60	15.77	-33.3	0.00	50.0
	Week 17	60	15.00	22.90	0.0	8.34	100.0	55	11.52	25.83	-33.3	0.00	100.0
	Week 20	52	8.65	15.30	0.0	0.00	83.3	50	4.67	17.18	-33.3	0.00	83.3
	Week 23	44	6.44	15.76	0.0	0.00	83.3	42	4.37	17.68	-16.7	0.00	83.3
	Week 26	41	6.10	11.64	0.0	0.00	33.3	40	4.58	13.07	-16.7	0.00	33.3
	Week 29	37	6.76	16.42	0.0	0.00	66.7	36	5.56	17.37	-16.7	0.00	66.7
	Week 32	33	5.05	10.61	0.0	0.00	33.3	32	3.65	11.77	-16.7	0.00	33.3
	Week 35	30	6.11	11.97	0.0	0.00	33.3	30	5.00	11.70	-16.7	0.00	33.3
	Week 38	32	5.73	13.79	0.0	0.00	66.7	31	4.30	12.89	-16.7	0.00	50.0
	Week 41	27	8.64	20.86	0.0	0.00	100.0	26	7.05	20.64	-16.7	0.00	100.0
	Week 44	27	4.32	9.91	0.0	0.00	33.3	26	3.85	10.86	-16.7	0.00	33.3
	Week 47	29	5.75	14.96	0.0	0.00	66.7	28	4.17	16.74	-16.7	0.00	66.7
	Week 50	23	5.80	11.90	0.0	0.00	33.3	22	3.79	10.20	-16.7	0.00	33.3
	Week 53	22	6.06	15.89	0.0	0.00	66.7	21	4.76	15.94	-16.7	0.00	66.7
	Week 56	18	7.41	17.36	0.0	0.00	66.7	17	5.88	19.49	-16.7	0.00	66.7
	Week 59	17	1.96	5.54	0.0	0.00	16.7	16	1.04	7.38	-16.7	0.00	16.7
	Week 62	16	2.08	8.33	0.0	0.00	33.3	15	1.11	9.89	-16.7	0.00	33.3
	Week 65	15	3.33	9.34	0.0	0.00	33.3	14	2.38	11.05	-16.7	0.00	33.3
	Week 68	12	0.00	0.00	0.0	0.00	0.0	11	-1.52	5.03	-16.7	0.00	0.0
	Week 71	13	2.56	9.24	0.0	0.00	33.3	12	1.39	11.14	-16.7	0.00	33.3
	Week 74	10	5.00	15.81	0.0	0.00	50.0	10	5.00	15.81	0.0	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	EV+Pembro (N=198)												
	BASELINE	170	5.10	12.83	0.0	0.00	66.7						
	Week 1	157	6.90	15.45	0.0	0.00	100.0	152	2.08	14.01	-33.3	0.00	100.0
	Week 2	167	8.08	15.51	0.0	0.00	100.0	155	3.44	15.28	-66.7	0.00	83.3
	Week 3	161	7.56	13.43	0.0	0.00	66.7	147	3.17	15.77	-50.0	0.00	66.7
	Week 4	158	5.27	10.49	0.0	0.00	50.0	145	0.57	14.36	-66.7	0.00	50.0
	Week 5	154	5.63	12.38	0.0	0.00	66.7	140	0.95	14.52	-50.0	0.00	50.0
	Week 6	153	5.56	12.39	0.0	0.00	66.7	138	0.72	14.08	-66.7	0.00	50.0
	Week 7	159	5.24	12.60	0.0	0.00	100.0	142	0.59	17.24	-66.7	0.00	83.3
	Week 8	154	4.76	9.28	0.0	0.00	50.0	135	-0.49	14.24	-66.7	0.00	33.3
	Week 9	162	4.94	13.12	0.0	0.00	83.3	146	-0.11	15.47	-66.7	0.00	50.0
	Week 10	159	4.19	10.44	0.0	0.00	66.7	144	-1.39	15.46	-66.7	0.00	50.0
	Week 11	161	3.93	9.04	0.0	0.00	50.0	143	-1.40	15.38	-66.7	0.00	50.0
	Week 12	154	4.76	11.86	0.0	0.00	66.7	140	-0.95	15.84	-66.7	0.00	50.0
	Week 14	154	5.41	12.77	0.0	0.00	100.0	137	1.34	14.30	-66.7	0.00	83.3
	Week 17	145	4.60	9.31	0.0	0.00	50.0	130	0.64	13.03	-66.7	0.00	50.0
	Week 20	139	4.08	11.67	0.0	0.00	83.3	126	-0.66	14.82	-66.7	0.00	66.7
	Week 23	133	5.26	12.87	0.0	0.00	83.3	122	1.91	16.76	-66.7	0.00	83.3
	Week 26	129	2.97	10.71	0.0	0.00	66.7	118	-1.13	15.21	-66.7	0.00	66.7
	Week 29	131	2.42	8.30	0.0	0.00	66.7	120	-1.81	14.46	-66.7	0.00	66.7
	Week 32	111	2.40	10.50	0.0	0.00	83.3	102	-0.82	14.34	-66.7	0.00	83.3
	Week 35	109	1.22	4.37	0.0	0.00	16.7	100	-2.83	12.55	-66.7	0.00	16.7
	Week 38	107	2.34	7.04	0.0	0.00	33.3	100	-0.33	10.04	-50.0	0.00	33.3
	Week 41	103	3.88	12.39	0.0	0.00	100.0	94	0.35	14.86	-66.7	0.00	83.3
	Week 44	88	1.33	4.54	0.0	0.00	16.7	81	-1.44	9.57	-66.7	0.00	16.7
	Week 47	80	3.33	8.13	0.0	0.00	33.3	75	0.00	12.85	-66.7	0.00	33.3

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	73	2.06	5.52	0.0	0.00	16.7	68	-0.98	10.34	-66.7	0.00	16.7
	Week 53	64	2.86	7.60	0.0	0.00	33.3	59	0.00	12.38	-66.7	0.00	33.3
	Week 56	66	2.02	6.21	0.0	0.00	33.3	61	-0.27	11.18	-66.7	0.00	33.3
	Week 59	58	1.72	5.12	0.0	0.00	16.7	54	-0.62	10.72	-66.7	0.00	16.7
	Week 62	54	1.85	9.53	0.0	0.00	66.7	52	-0.96	14.16	-66.7	0.00	66.7
	Week 65	51	2.29	6.68	0.0	0.00	33.3	47	-0.35	12.28	-66.7	0.00	33.3
	Week 68	49	2.38	8.33	0.0	0.00	50.0	48	-0.35	12.63	-66.7	0.00	50.0
	Week 71	47	2.84	9.40	0.0	0.00	50.0	45	0.00	13.30	-66.7	0.00	50.0
	Week 74	42	1.59	6.17	0.0	0.00	33.3	41	-1.63	11.67	-66.7	0.00	16.7
	Week 77	38	1.32	5.98	0.0	0.00	33.3	36	0.00	7.97	-16.7	0.00	33.3
	Week 80	35	1.43	6.22	0.0	0.00	33.3	32	-2.08	11.79	-50.0	0.00	33.3
	Week 83	32	0.52	2.95	0.0	0.00	16.7	30	-3.33	13.42	-66.7	0.00	16.7
	Week 86	30	0.56	3.04	0.0	0.00	16.7	27	-3.70	14.12	-66.7	0.00	16.7
	Week 89	28	0.60	3.15	0.0	0.00	16.7	26	-3.85	14.38	-66.7	0.00	16.7
	Week 92	24	2.08	7.47	0.0	0.00	33.3	22	-3.03	16.78	-66.7	0.00	33.3
	Week 95	21	0.79	3.64	0.0	0.00	16.7	20	-0.83	3.73	-16.7	0.00	0.0
	Week 98	16	2.08	5.69	0.0	0.00	16.7	15	1.11	4.30	0.0	0.00	16.7
	Week 101	12	4.17	10.36	0.0	0.00	33.3	12	2.78	6.49	0.0	0.00	16.7
	Week 104	10	1.67	5.27	0.0	0.00	16.7	10	0.00	0.00	0.0	0.00	0.0
	Plat+Gem (N=185)												
	BASELINE	146	6.05	11.73	0.0	0.00	66.7						
	Week 1	131	13.61	16.64	0.0	16.67	100.0	120	8.89	15.11	-16.7	0.00	50.0
	Week 2	128	13.02	16.59	0.0	16.67	66.7	115	8.41	19.04	-50.0	0.00	66.7
	Week 3	141	8.51	12.38	0.0	0.00	50.0	126	3.70	14.59	-50.0	0.00	50.0
	Week 4	139	11.39	15.55	0.0	0.00	66.7	119	6.30	17.76	-50.0	0.00	66.7
	Week 5	143	12.70	15.32	0.0	16.67	66.7	120	7.50	17.93	-50.0	0.00	66.7

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
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Table 302.1.3002.17.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 6	133	9.27	12.21	0.0	0.00	50.0	114	4.53	15.41	-50.0	0.00	50.0
	Week 7	142	13.26	17.02	0.0	8.34	83.3	120	7.22	20.12	-66.7	0.00	83.3
	Week 8	125	12.27	14.99	0.0	16.67	66.7	109	7.49	18.49	-50.0	0.00	66.7
	Week 9	135	11.11	16.42	0.0	0.00	66.7	115	6.38	18.68	-50.0	0.00	66.7
	Week 10	131	13.11	17.78	0.0	16.67	100.0	111	7.96	20.08	-50.0	0.00	100.0
	Week 11	128	15.24	19.85	0.0	16.67	100.0	109	10.70	23.19	-50.0	0.00	100.0
	Week 12	124	10.89	17.14	0.0	0.00	100.0	108	6.17	20.33	-50.0	0.00	100.0
	Week 14	121	13.78	17.70	0.0	16.67	83.3	101	8.58	23.53	-50.0	0.00	83.3
	Week 17	121	14.60	20.36	0.0	0.00	100.0	101	9.74	25.42	-66.7	0.00	100.0
	Week 20	98	8.33	12.49	0.0	0.00	50.0	86	3.68	15.21	-50.0	0.00	33.3
	Week 23	93	4.66	9.63	0.0	0.00	50.0	78	0.00	14.71	-50.0	0.00	50.0
	Week 26	86	5.43	10.05	0.0	0.00	33.3	75	2.00	13.13	-33.3	0.00	33.3
	Week 29	76	5.04	11.55	0.0	0.00	66.7	65	1.79	15.34	-50.0	0.00	66.7
	Week 32	62	2.69	8.09	0.0	0.00	33.3	56	-1.79	12.58	-50.0	0.00	33.3
	Week 35	58	2.59	6.84	0.0	0.00	33.3	52	-0.96	12.09	-50.0	0.00	33.3
	Week 38	60	3.33	8.00	0.0	0.00	33.3	52	0.32	8.41	-16.7	0.00	16.7
	Week 41	52	3.53	10.08	0.0	0.00	50.0	44	0.38	15.03	-50.0	0.00	50.0
	Week 44	46	4.35	10.79	0.0	0.00	50.0	40	3.33	12.63	-16.7	0.00	50.0
	Week 47	44	3.79	11.85	0.0	0.00	66.7	38	2.19	14.59	-16.7	0.00	66.7
	Week 50	42	5.95	13.18	0.0	0.00	66.7	38	2.63	13.71	-16.7	0.00	50.0
	Week 53	38	3.51	9.62	0.0	0.00	50.0	34	0.98	10.00	-16.7	0.00	33.3
	Week 56	32	3.13	6.61	0.0	0.00	16.7	28	-0.60	10.62	-16.7	0.00	16.7
	Week 59	31	1.61	5.01	0.0	0.00	16.7	27	-0.62	8.63	-16.7	0.00	16.7
	Week 62	29	1.15	4.30	0.0	0.00	16.7	26	-1.28	8.06	-16.7	0.00	16.7
	Week 65	25	2.67	6.24	0.0	0.00	16.7	21	-0.79	9.83	-16.7	0.00	16.7
	Week 68	20	2.50	6.11	0.0	0.00	16.7	16	1.04	9.56	-16.7	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 71	17	2.94	6.55	0.0	0.00	16.7	14	1.19	7.91	-16.7	0.00	16.7
	Week 74	17	2.94	6.55	0.0	0.00	16.7	14	1.19	7.91	-16.7	0.00	16.7
	Week 77	16	7.29	17.18	0.0	0.00	66.7	13	3.85	20.59	-16.7	0.00	66.7
	Week 80	13	7.69	18.78	0.0	0.00	66.7	12	4.17	23.70	-33.3	0.00	66.7
	Week 83	11	3.03	6.74	0.0	0.00	16.7	10	-1.67	9.46	-16.7	0.00	16.7
	Week 86	12	2.78	6.49	0.0	0.00	16.7	11	-1.51	8.99	-16.7	0.00	16.7
	Week 89	11	0.00	0.00	0.0	0.00	0.0	10	-5.00	11.25	-33.3	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	EV+Pembro (N= 42)												
	BASELINE	36	9.26	19.70	0.0	0.00	66.7						
	Week 1	33	15.15	23.70	0.0	0.00	100.0	32	5.73	14.42	-33.3	0.00	33.3
	Week 2	36	14.82	23.15	0.0	0.00	100.0	34	5.88	24.23	-66.7	0.00	100.0
	Week 3	37	15.77	19.62	0.0	16.67	83.3	35	5.24	17.97	-50.0	0.00	50.0
	Week 4	36	6.95	10.82	0.0	0.00	33.3	34	-0.98	15.32	-50.0	0.00	33.3
	Week 5	36	11.11	13.21	0.0	0.00	33.3	33	2.02	20.31	-50.0	0.00	33.3
	Week 6	35	8.10	15.85	0.0	0.00	66.7	32	-1.04	24.30	-66.7	0.00	66.7
	Week 7	36	7.41	10.11	0.0	0.00	33.3	34	-2.94	21.11	-66.7	0.00	33.3
	Week 8	37	7.21	12.13	0.0	0.00	33.3	36	-1.85	21.37	-66.7	0.00	33.3
	Week 9	35	8.57	14.22	0.0	0.00	66.7	34	0.98	21.69	-66.7	0.00	66.7
	Week 10	32	4.17	8.47	0.0	0.00	33.3	31	-5.91	22.17	-66.7	0.00	33.3
	Week 11	33	5.56	10.76	0.0	0.00	33.3	32	-4.69	22.09	-66.7	0.00	33.3
	Week 12	32	4.17	9.47	0.0	0.00	33.3	31	-6.45	21.38	-66.7	0.00	33.3
	Week 14	31	5.38	10.88	0.0	0.00	33.3	30	-2.78	20.10	-66.7	0.00	33.3
	Week 17	33	6.06	11.65	0.0	0.00	33.3	32	-3.13	24.84	-66.7	0.00	33.3
	Week 20	28	4.17	8.64	0.0	0.00	33.3	28	-4.17	22.51	-66.7	0.00	33.3
	Week 23	29	4.02	8.52	0.0	0.00	33.3	29	-4.60	21.32	-66.7	0.00	16.7
	Week 26	27	5.56	13.07	0.0	0.00	50.0	26	-5.77	23.54	-66.7	0.00	33.3
	Week 29	26	1.28	4.53	0.0	0.00	16.7	25	-5.33	17.16	-66.7	0.00	16.7
	Week 32	24	1.39	6.80	0.0	0.00	33.3	23	-2.90	12.96	-33.3	0.00	33.3
	Week 35	23	2.90	6.46	0.0	0.00	16.7	22	-1.51	12.50	-33.3	0.00	16.7
	Week 38	25	2.67	7.88	0.0	0.00	33.3	24	-2.78	18.17	-66.7	0.00	33.3
	Week 41	26	3.85	8.57	0.0	0.00	33.3	25	-5.33	20.82	-66.7	0.00	33.3
	Week 44	20	1.67	5.13	0.0	0.00	16.7	19	-5.26	17.62	-66.7	0.00	16.7
	Week 47	20	5.83	9.79	0.0	0.00	33.3	19	-5.26	22.26	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	16	2.08	5.69	0.0	0.00	16.7	16	-1.04	9.56	-33.3	0.00	16.7
	Week 53	15	10.00	18.69	0.0	0.00	66.7	15	2.22	28.78	-66.7	0.00	66.7
	Week 56	15	10.00	18.69	0.0	0.00	66.7	15	5.56	20.57	-16.7	0.00	66.7
	Week 59	14	9.53	18.16	0.0	0.00	66.7	14	4.76	22.10	-33.3	0.00	66.7
	Week 62	11	3.03	6.74	0.0	0.00	16.7	11	-3.03	12.51	-33.3	0.00	16.7
	Plat+Gem (N= 57)												
	BASELINE	42	5.56	9.50	0.0	0.00	33.3						
	Week 1	42	27.38	28.71	0.0	16.67	100.0	38	18.86	28.52	-33.3	16.67	100.0
	Week 2	43	17.83	23.40	0.0	16.67	100.0	36	12.96	25.55	-33.3	0.00	100.0
	Week 3	43	14.73	19.66	0.0	0.00	66.7	36	10.19	22.64	-33.3	0.00	66.7
	Week 4	44	21.59	22.90	0.0	16.67	83.3	37	15.31	24.34	-33.3	0.00	83.3
	Week 5	44	18.56	19.76	0.0	16.67	83.3	36	12.04	23.44	-33.3	8.33	83.3
	Week 6	41	14.63	20.81	0.0	16.67	100.0	35	8.10	21.15	-33.3	0.00	100.0
	Week 7	44	15.53	18.11	0.0	16.67	83.3	37	9.46	20.62	-33.3	0.00	83.3
	Week 8	42	19.84	21.22	0.0	16.67	83.3	35	14.29	24.30	-33.3	16.66	83.3
	Week 9	42	13.89	17.62	0.0	0.00	66.7	35	8.09	19.12	-33.3	0.00	50.0
	Week 10	35	20.00	22.79	0.0	16.67	83.3	28	14.88	23.72	-33.3	8.33	66.7
	Week 11	40	19.17	18.70	0.0	16.67	66.7	34	15.20	23.70	-33.3	16.67	66.7
	Week 12	35	14.29	17.69	0.0	16.67	66.7	30	10.00	22.15	-33.3	0.00	66.7
	Week 14	32	20.31	24.59	0.0	16.67	83.3	27	12.35	26.79	-33.3	0.00	66.7
	Week 17	34	19.61	23.74	0.0	16.67	83.3	29	16.09	30.37	-33.3	16.67	83.3
	Week 20	28	11.91	19.70	0.0	0.00	83.3	24	6.94	24.03	-33.3	0.00	83.3
	Week 23	22	14.39	22.00	0.0	0.00	83.3	19	11.40	24.88	-16.7	0.00	83.3
	Week 26	22	9.09	15.19	0.0	0.00	50.0	20	5.00	18.02	-16.7	0.00	50.0
	Week 29	24	6.95	15.48	0.0	0.00	66.7	21	3.97	17.41	-16.7	0.00	66.7
	Week 32	21	10.32	13.41	0.0	0.00	50.0	20	5.83	14.59	-16.7	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 35	18	12.96	19.43	0.0	0.00	66.7	17	9.80	17.73	-16.7	0.00	50.0
	Week 38	14	19.05	30.56	0.0	0.00	83.3	13	16.67	28.05	-16.7	0.00	66.7
	Week 41	13	14.10	27.93	0.0	0.00	100.0	12	12.50	29.41	-16.7	0.00	100.0
	Week 44	14	5.95	12.41	0.0	0.00	33.3	13	3.85	15.45	-16.7	0.00	33.3
	Week 47	12	8.33	16.67	0.0	0.00	50.0	11	4.54	19.85	-16.7	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Visceral metastases	EV+Pembro (N=170)												
	BASELINE	146	6.16	14.25	0.0	0.00	66.7						
	Week 1	135	9.14	18.63	0.0	0.00	100.0	131	2.67	15.58	-33.3	0.00	100.0
	Week 2	145	9.54	16.52	0.0	0.00	100.0	134	3.86	15.95	-66.7	0.00	83.3
	Week 3	141	9.46	15.85	0.0	0.00	83.3	129	3.36	16.72	-50.0	0.00	66.7
	Week 4	136	5.76	11.00	0.0	0.00	50.0	125	-0.40	15.76	-66.7	0.00	50.0
	Week 5	131	6.11	11.91	0.0	0.00	50.0	118	0.14	16.67	-50.0	0.00	50.0
	Week 6	127	5.12	11.01	0.0	0.00	50.0	113	-0.88	16.19	-66.7	0.00	50.0
	Week 7	135	4.82	12.19	0.0	0.00	100.0	121	-1.79	17.98	-66.7	0.00	83.3
	Week 8	131	4.96	9.85	0.0	0.00	50.0	118	-1.55	15.10	-66.7	0.00	33.3
	Week 9	136	4.78	12.32	0.0	0.00	83.3	124	-1.08	15.14	-66.7	0.00	50.0
	Week 10	135	3.70	10.11	0.0	0.00	66.7	124	-2.82	16.83	-66.7	0.00	50.0
	Week 11	134	3.73	9.06	0.0	0.00	50.0	121	-3.17	16.15	-66.7	0.00	50.0
	Week 12	131	4.07	11.15	0.0	0.00	66.7	120	-2.92	16.55	-66.7	0.00	50.0
	Week 14	130	5.38	13.00	0.0	0.00	100.0	117	-0.43	16.73	-66.7	0.00	83.3
	Week 17	124	4.44	9.04	0.0	0.00	33.3	111	-1.50	17.34	-66.7	0.00	33.3
	Week 20	115	3.77	9.89	0.0	0.00	50.0	105	-1.90	16.23	-66.7	0.00	33.3
	Week 23	111	4.65	11.28	0.0	0.00	66.7	103	0.16	16.42	-66.7	0.00	66.7
	Week 26	106	2.99	10.74	0.0	0.00	50.0	97	-3.44	17.99	-66.7	0.00	50.0
	Week 29	106	2.52	8.54	0.0	0.00	66.7	98	-2.04	15.92	-66.7	0.00	66.7
	Week 32	92	1.81	7.60	0.0	0.00	50.0	85	-2.16	13.31	-66.7	0.00	50.0
	Week 35	86	1.36	4.59	0.0	0.00	16.7	79	-3.16	12.54	-66.7	0.00	16.7
	Week 38	90	2.22	7.15	0.0	0.00	33.3	84	-1.79	13.45	-66.7	0.00	33.3
	Week 41	87	3.64	12.82	0.0	0.00	100.0	81	-2.47	18.09	-66.7	0.00	83.3
	Week 44	73	1.37	4.61	0.0	0.00	16.7	68	-2.94	13.18	-66.7	0.00	16.7
	Week 47	68	2.94	6.40	0.0	0.00	16.7	63	-3.44	15.60	-66.7	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	61	2.19	5.67	0.0	0.00	16.7	57	-1.46	11.48	-66.7	0.00	16.7
	Week 53	54	3.70	11.06	0.0	0.00	66.7	50	-1.33	19.00	-66.7	0.00	66.7
	Week 56	58	3.45	10.71	0.0	0.00	66.7	54	0.31	15.01	-66.7	0.00	66.7
	Week 59	50	3.67	10.80	0.0	0.00	66.7	47	0.35	16.11	-66.7	0.00	66.7
	Week 62	45	2.96	10.83	0.0	0.00	66.7	43	-1.16	16.43	-66.7	0.00	66.7
	Week 65	37	1.80	5.25	0.0	0.00	16.7	34	-2.45	14.29	-66.7	0.00	16.7
	Week 68	35	3.33	9.74	0.0	0.00	50.0	34	-0.98	16.38	-66.7	0.00	50.0
	Week 71	31	3.23	10.02	0.0	0.00	50.0	30	-1.67	17.15	-66.7	0.00	50.0
	Week 74	29	0.57	3.10	0.0	0.00	16.7	28	-5.36	14.38	-66.7	0.00	0.0
	Week 77	26	1.92	5.43	0.0	0.00	16.7	25	-2.00	10.00	-33.3	0.00	16.7
	Week 80	22	4.55	9.18	0.0	0.00	33.3	21	-3.17	16.35	-50.0	0.00	33.3
	Week 83	23	1.45	4.80	0.0	0.00	16.7	22	-6.06	15.04	-66.7	0.00	0.0
	Week 86	21	0.79	3.64	0.0	0.00	16.7	20	-7.50	15.74	-66.7	0.00	0.0
	Week 89	21	3.97	8.98	0.0	0.00	33.3	20	-3.33	19.20	-66.7	0.00	33.3
	Week 92	18	0.93	3.93	0.0	0.00	16.7	17	-4.90	17.45	-66.7	0.00	16.7
	Week 95	13	0.00	0.00	0.0	0.00	0.0	12	-2.78	6.49	-16.7	0.00	0.0
	Week 98	11	1.52	5.03	0.0	0.00	16.7	11	0.00	7.46	-16.7	0.00	16.7
	Week 101	11	6.06	11.24	0.0	0.00	33.3	11	3.03	10.05	-16.7	0.00	16.7
	Plat+Gem (N=161)												
	BASELINE	129	7.62	12.67	0.0	0.00	66.7						
	Week 1	113	18.00	21.15	0.0	16.67	100.0	105	10.64	19.22	-33.3	0.00	100.0
	Week 2	108	14.82	18.13	0.0	16.67	100.0	98	8.67	21.57	-50.0	0.00	100.0
	Week 3	121	9.78	14.22	0.0	0.00	66.7	109	3.36	16.94	-50.0	0.00	66.7
	Week 4	116	13.79	16.49	0.0	16.67	66.7	101	6.77	18.59	-50.0	0.00	50.0
	Week 5	121	14.46	17.07	0.0	16.67	83.3	104	8.01	20.90	-50.0	0.00	83.3
	Week 6	118	9.89	12.56	0.0	0.00	50.0	102	3.92	16.11	-50.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 7	121	14.60	17.82	0.0	16.67	83.3	104	6.89	21.49	-66.7	0.00	83.3
	Week 8	108	14.51	17.22	0.0	16.67	83.3	96	9.20	21.61	-50.0	8.33	83.3
	Week 9	114	12.72	17.50	0.0	0.00	66.7	99	6.57	20.18	-50.0	0.00	66.7
	Week 10	109	15.44	19.60	0.0	16.67	83.3	94	8.87	21.82	-50.0	0.00	66.7
	Week 11	109	14.99	17.99	0.0	16.67	83.3	95	9.30	21.98	-50.0	0.00	66.7
	Week 12	103	12.95	16.98	0.0	0.00	66.7	91	6.96	21.24	-50.0	0.00	66.7
	Week 14	98	15.14	19.75	0.0	16.67	83.3	85	8.43	26.43	-50.0	0.00	83.3
	Week 17	103	16.51	20.81	0.0	16.67	83.3	89	10.30	27.35	-66.7	0.00	83.3
	Week 20	82	9.15	14.85	0.0	0.00	83.3	75	2.89	18.66	-50.0	0.00	83.3
	Week 23	77	7.36	14.93	0.0	0.00	83.3	68	1.96	20.27	-50.0	0.00	83.3
	Week 26	71	6.57	11.78	0.0	0.00	50.0	65	2.56	15.09	-33.3	0.00	50.0
	Week 29	65	5.13	9.74	0.0	0.00	33.3	59	0.85	13.99	-50.0	0.00	33.3
	Week 32	52	4.81	10.61	0.0	0.00	50.0	49	-0.34	15.02	-50.0	0.00	50.0
	Week 35	47	4.61	10.25	0.0	0.00	33.3	44	0.38	14.60	-50.0	0.00	33.3
	Week 38	42	5.56	15.03	0.0	0.00	66.7	39	3.42	15.85	-16.7	0.00	66.7
	Week 41	35	7.14	19.08	0.0	0.00	100.0	32	3.12	22.97	-50.0	0.00	100.0
	Week 44	36	5.09	10.40	0.0	0.00	33.3	33	3.03	12.81	-16.7	0.00	33.3
	Week 47	32	4.17	11.20	0.0	0.00	50.0	30	1.67	14.08	-16.7	0.00	50.0
	Week 50	30	8.33	15.00	0.0	0.00	66.7	29	3.45	14.35	-16.7	0.00	50.0
	Week 53	25	5.33	12.47	0.0	0.00	50.0	24	2.08	11.33	-16.7	0.00	33.3
	Week 56	22	7.58	16.04	0.0	0.00	66.7	21	3.17	19.45	-16.7	0.00	66.7
	Week 59	22	2.27	5.86	0.0	0.00	16.7	21	0.00	9.13	-16.7	0.00	16.7
	Week 62	19	2.63	8.36	0.0	0.00	33.3	18	0.00	11.43	-16.7	0.00	33.3
	Week 65	19	2.63	8.36	0.0	0.00	33.3	18	0.00	11.43	-16.7	0.00	33.3
	Week 68	13	1.28	4.62	0.0	0.00	16.7	12	-1.39	8.58	-16.7	0.00	16.7
	Week 71	13	3.85	9.99	0.0	0.00	33.3	12	2.78	11.96	-16.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 74	11	4.55	15.08	0.0	0.00	50.0	11	3.03	16.36	-16.7	0.00	50.0
	Week 77	10	1.67	5.27	0.0	0.00	16.7	10	-3.33	7.03	-16.7	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Lymph node only	EV+Pembro (N= 60)												
	BASELINE	53	4.40	12.72	0.0	0.00	66.7						
	Week 1	49	5.44	11.48	0.0	0.00	50.0	47	2.84	10.02	-16.7	0.00	33.3
	Week 2	50	8.67	19.41	0.0	0.00	100.0	48	4.51	21.12	-66.7	0.00	100.0
	Week 3	50	8.00	13.14	0.0	0.00	50.0	47	4.96	14.71	-33.3	0.00	50.0
	Week 4	50	4.67	8.93	0.0	0.00	33.3	47	2.13	10.20	-33.3	0.00	33.3
	Week 5	53	8.18	14.48	0.0	0.00	66.7	49	4.42	13.08	-33.3	0.00	33.3
	Week 6	53	7.23	15.51	0.0	0.00	66.7	50	2.67	17.61	-66.7	0.00	66.7
	Week 7	52	6.73	9.49	0.0	0.00	33.3	48	3.47	14.57	-66.7	0.00	33.3
	Week 8	52	5.77	9.84	0.0	0.00	33.3	47	2.13	15.78	-66.7	0.00	33.3
	Week 9	53	8.18	16.22	0.0	0.00	66.7	49	4.08	18.49	-66.7	0.00	66.7
	Week 10	48	5.90	10.59	0.0	0.00	33.3	44	0.38	15.03	-66.7	0.00	33.3
	Week 11	53	5.35	10.22	0.0	0.00	33.3	48	1.74	16.21	-66.7	0.00	33.3
	Week 12	48	6.25	12.69	0.0	0.00	50.0	45	1.48	16.21	-66.7	0.00	33.3
	Week 14	48	5.21	9.82	0.0	0.00	33.3	44	2.27	10.54	-33.3	0.00	33.3
	Week 17	46	5.44	11.14	0.0	0.00	50.0	44	3.41	11.69	-33.3	0.00	50.0
	Week 20	44	4.55	14.09	0.0	0.00	83.3	42	0.40	17.46	-66.7	0.00	66.7
	Week 23	43	6.59	15.06	0.0	0.00	83.3	41	3.25	19.44	-66.7	0.00	83.3
	Week 26	42	3.57	11.95	0.0	0.00	66.7	40	1.25	14.32	-33.3	0.00	66.7
	Week 29	45	1.11	4.21	0.0	0.00	16.7	42	-2.78	12.71	-66.7	0.00	16.7
	Week 32	38	3.51	14.58	0.0	0.00	83.3	36	0.93	16.40	-33.3	0.00	83.3
	Week 35	42	1.98	5.46	0.0	0.00	16.7	40	-1.67	12.97	-66.7	0.00	16.7
	Week 38	38	2.63	7.28	0.0	0.00	33.3	36	0.93	7.91	-16.7	0.00	33.3
	Week 41	37	4.05	8.25	0.0	0.00	33.3	34	1.96	10.67	-33.3	0.00	33.3
	Week 44	31	1.61	5.01	0.0	0.00	16.7	29	-0.57	7.02	-16.7	0.00	16.7
	Week 47	28	6.55	12.29	0.0	0.00	33.3	27	4.32	14.32	-16.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	25	1.33	4.62	0.0	0.00	16.7	24	-0.69	5.98	-16.7	0.00	16.7
	Week 53	23	3.62	8.64	0.0	0.00	33.3	22	2.27	7.79	0.0	0.00	33.3
	Week 56	21	3.17	8.53	0.0	0.00	33.3	20	1.67	9.21	-16.7	0.00	33.3
	Week 59	20	2.50	6.11	0.0	0.00	16.7	19	0.88	6.75	-16.7	0.00	16.7
	Week 62	19	0.00	0.00	0.0	0.00	0.0	19	-1.75	5.26	-16.7	0.00	0.0
	Week 65	20	4.17	9.17	0.0	0.00	33.3	19	2.63	10.04	-16.7	0.00	33.3
	Week 68	17	1.96	5.54	0.0	0.00	16.7	17	0.00	0.00	0.0	0.00	0.0
	Week 71	19	2.63	8.36	0.0	0.00	33.3	18	0.93	3.93	0.0	0.00	16.7
	Week 74	17	2.94	8.81	0.0	0.00	33.3	17	0.98	4.04	0.0	0.00	16.7
	Week 77	17	1.96	8.08	0.0	0.00	33.3	16	1.04	9.56	-16.7	0.00	33.3
	Week 80	17	0.00	0.00	0.0	0.00	0.0	15	-1.11	4.30	-16.7	0.00	0.0
	Week 83	13	1.28	4.62	0.0	0.00	16.7	12	0.00	7.11	-16.7	0.00	16.7
	Week 86	12	1.39	4.81	0.0	0.00	16.7	10	0.00	7.86	-16.7	0.00	16.7
	Week 89	11	1.52	5.03	0.0	0.00	16.7	10	0.00	7.86	-16.7	0.00	16.7
	Plat+Gem (N= 67)												
	BASELINE	49	2.72	6.23	0.0	0.00	16.7						
	Week 1	51	14.05	20.38	0.0	0.00	100.0	45	11.11	19.46	-16.7	0.00	83.3
	Week 2	53	11.32	17.53	0.0	0.00	66.7	44	8.71	16.66	-16.7	0.00	66.7
	Week 3	53	10.38	15.41	0.0	0.00	66.7	44	8.71	16.27	-16.7	0.00	66.7
	Week 4	58	12.93	18.48	0.0	0.00	83.3	47	9.93	18.93	-16.7	0.00	83.3
	Week 5	56	12.80	14.90	0.0	16.67	66.7	44	8.33	14.60	-16.7	0.00	66.7
	Week 6	48	12.50	19.60	0.0	0.00	100.0	40	9.17	19.59	-16.7	0.00	100.0
	Week 7	56	12.50	16.28	0.0	8.34	83.3	46	9.06	17.46	-16.7	0.00	83.3
	Week 8	52	13.78	17.38	0.0	16.67	66.7	42	8.73	17.75	-16.7	0.00	66.7
	Week 9	53	10.38	15.41	0.0	0.00	66.7	42	7.54	16.55	-16.7	0.00	66.7
	Week 10	47	13.83	19.13	0.0	0.00	100.0	36	11.57	21.01	-16.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	51	18.95	22.12	0.0	16.67	100.0	41	17.48	25.54	-16.7	16.67	100.0
	Week 12	47	9.93	18.60	0.0	0.00	100.0	39	7.26	21.22	-16.7	0.00	100.0
	Week 14	47	15.96	19.95	0.0	16.67	83.3	36	12.04	20.55	-16.7	0.00	66.7
	Week 17	45	13.70	20.81	0.0	0.00	100.0	35	12.38	24.03	-16.7	0.00	100.0
	Week 20	38	7.90	13.83	0.0	0.00	50.0	30	6.11	14.17	-16.7	0.00	33.3
	Week 23	32	4.69	8.71	0.0	0.00	33.3	25	3.33	9.62	-16.7	0.00	16.7
	Week 26	30	5.56	11.01	0.0	0.00	33.3	24	2.78	13.61	-16.7	0.00	33.3
	Week 29	28	2.38	7.47	0.0	0.00	33.3	21	0.00	7.45	-16.7	0.00	16.7
	Week 32	26	3.85	9.78	0.0	0.00	33.3	22	0.00	10.29	-16.7	0.00	33.3
	Week 35	23	5.80	15.58	0.0	0.00	66.7	19	3.51	15.29	-16.7	0.00	50.0
	Week 38	26	7.05	18.36	0.0	0.00	83.3	20	2.50	16.47	-16.7	0.00	66.7
	Week 41	24	3.47	10.97	0.0	0.00	50.0	18	1.85	15.01	-16.7	0.00	50.0
	Week 44	18	4.63	13.77	0.0	0.00	50.0	14	4.76	16.57	-16.7	0.00	50.0
	Week 47	18	6.48	17.28	0.0	0.00	66.7	13	5.13	21.93	-16.7	0.00	66.7
	Week 50	16	3.13	9.06	0.0	0.00	33.3	13	1.28	12.66	-16.7	0.00	33.3
	Week 53	15	2.22	5.87	0.0	0.00	16.7	12	-1.39	8.58	-16.7	0.00	16.7
	Week 56	15	2.22	5.87	0.0	0.00	16.7	11	-1.52	8.99	-16.7	0.00	16.7
	Week 59	12	0.00	0.00	0.0	0.00	0.0	9	-3.70	7.35	-16.7	0.00	0.0
	Week 62	10	0.00	0.00	0.0	0.00	0.0	8	-4.17	7.72	-16.7	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
EV+Pembro (N=202)												
BASELINE	160	6.88	16.12	0.0	0.00	100.0						
Week 1	141	10.64	20.44	0.0	0.00	100.0	129	2.71	13.47	-33.3	0.00	100.0
Week 2	150	11.89	21.09	0.0	0.00	100.0	133	6.64	18.80	-33.3	0.00	100.0
Week 3	139	9.59	16.30	0.0	0.00	100.0	122	3.14	14.59	-33.3	0.00	66.7
Week 4	145	7.70	12.73	0.0	0.00	66.7	129	2.33	12.63	-33.3	0.00	66.7
Week 5	137	8.52	17.16	0.0	0.00	100.0	121	2.75	18.05	-33.3	0.00	100.0
Week 6	146	8.90	16.74	0.0	0.00	100.0	124	4.03	17.31	-33.3	0.00	100.0
Week 7	147	8.39	15.89	0.0	0.00	66.7	124	2.55	16.33	-33.3	0.00	66.7
Week 8	147	9.64	16.54	0.0	0.00	66.7	124	3.90	15.19	-33.3	0.00	66.7
Week 9	142	10.09	16.95	0.0	0.00	83.3	121	4.55	17.74	-33.3	0.00	83.3
Week 10	139	9.35	19.05	0.0	0.00	100.0	118	4.10	21.23	-66.7	0.00	100.0
Week 11	137	7.30	14.56	0.0	0.00	66.7	115	1.88	14.60	-33.3	0.00	66.7
Week 12	142	5.75	13.17	0.0	0.00	66.7	119	0.70	13.96	-50.0	0.00	50.0
Week 14	139	4.08	8.71	0.0	0.00	33.3	116	-0.86	10.27	-50.0	0.00	33.3
Week 17	132	5.43	11.37	0.0	0.00	50.0	111	0.30	14.21	-50.0	0.00	50.0
Week 20	120	4.44	11.38	0.0	0.00	66.7	103	-0.32	14.38	-50.0	0.00	66.7
Week 23	117	3.56	8.43	0.0	0.00	33.3	97	0.17	10.35	-33.3	0.00	33.3
Week 26	112	4.17	10.13	0.0	0.00	50.0	94	-0.18	12.58	-33.3	0.00	50.0
Week 29	107	3.27	8.70	0.0	0.00	33.3	93	-0.72	12.27	-50.0	0.00	33.3
Week 32	102	4.74	12.49	0.0	0.00	83.3	88	0.19	14.41	-50.0	0.00	83.3
Week 35	98	3.74	11.10	0.0	0.00	66.7	86	-0.39	14.23	-33.3	0.00	66.7
Week 38	97	4.98	15.25	0.0	0.00	100.0	86	1.74	18.08	-33.3	0.00	100.0
Week 41	95	4.04	11.33	0.0	0.00	66.7	84	0.40	13.19	-33.3	0.00	66.7
Week 44	86	3.88	10.44	0.0	0.00	66.7	74	-0.45	14.59	-50.0	0.00	66.7
Week 47	79	3.80	13.33	0.0	0.00	100.0	70	-0.48	12.36	-33.3	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	74	4.50	10.06	0.0	0.00	33.3	64	1.30	13.71	-33.3	0.00	33.3
Week 53	74	4.28	12.04	0.0	0.00	66.7	63	-0.26	15.11	-33.3	0.00	66.7
Week 56	72	3.24	9.12	0.0	0.00	50.0	61	-1.91	11.43	-33.3	0.00	33.3
Week 59	69	2.66	7.36	0.0	0.00	33.3	57	-1.75	11.65	-33.3	0.00	33.3
Week 62	62	3.50	8.06	0.0	0.00	33.3	52	-1.60	11.56	-33.3	0.00	33.3
Week 65	43	4.26	10.35	0.0	0.00	33.3	40	-0.83	14.10	-33.3	0.00	33.3
Week 68	46	1.81	6.31	0.0	0.00	33.3	42	-2.78	11.59	-33.3	0.00	33.3
Week 71	42	2.38	7.87	0.0	0.00	33.3	38	-3.51	11.73	-33.3	0.00	33.3
Week 74	38	3.95	9.83	0.0	0.00	33.3	35	-1.91	15.54	-33.3	0.00	33.3
Week 77	37	6.31	14.35	0.0	0.00	66.7	33	-1.52	13.41	-33.3	0.00	33.3
Week 80	36	7.41	16.64	0.0	0.00	66.7	34	0.98	19.65	-33.3	0.00	66.7
Week 83	30	6.11	12.75	0.0	0.00	33.3	29	0.57	18.62	-33.3	0.00	33.3
Week 86	26	7.05	15.04	0.0	0.00	66.7	25	1.33	20.37	-33.3	0.00	66.7
Week 89	20	5.00	9.52	0.0	0.00	33.3	19	-1.75	15.61	-33.3	0.00	33.3
Week 92	19	4.39	10.89	0.0	0.00	33.3	18	-1.85	17.04	-33.3	0.00	33.3
Week 95	14	3.57	9.65	0.0	0.00	33.3	13	-3.85	15.45	-33.3	0.00	33.3
Week 98	10	1.67	5.27	0.0	0.00	16.7	9	-7.41	12.11	-33.3	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Plat+Gem (N=202)												
BASELINE	165	7.17	16.28	0.0	0.00	100.0						
Week 1	144	13.89	22.56	0.0	0.00	100.0	139	7.55	19.06	-33.3	0.00	100.0
Week 2	147	13.49	20.49	0.0	0.00	100.0	135	6.54	18.67	-50.0	0.00	83.3
Week 3	149	8.73	16.39	0.0	0.00	100.0	136	2.57	16.21	-66.7	0.00	66.7
Week 4	150	7.44	13.31	0.0	0.00	83.3	135	1.61	15.22	-50.0	0.00	66.7
Week 5	153	9.26	16.10	0.0	0.00	83.3	138	2.42	16.67	-66.7	0.00	66.7
Week 6	145	7.59	15.34	0.0	0.00	83.3	131	1.15	16.82	-66.7	0.00	83.3
Week 7	148	10.47	16.41	0.0	0.00	100.0	134	3.86	19.91	-83.3	0.00	83.3
Week 8	145	10.23	17.91	0.0	0.00	100.0	132	4.04	20.50	-66.7	0.00	100.0
Week 9	141	8.04	16.26	0.0	0.00	100.0	125	1.73	19.15	-83.3	0.00	100.0
Week 10	142	10.09	18.72	0.0	0.00	100.0	130	3.72	20.04	-50.0	0.00	100.0
Week 11	126	8.73	16.43	0.0	0.00	83.3	114	1.75	16.65	-50.0	0.00	83.3
Week 12	130	6.92	13.41	0.0	0.00	66.7	115	0.15	16.88	-83.3	0.00	50.0
Week 14	125	8.93	15.92	0.0	0.00	83.3	109	3.36	19.08	-83.3	0.00	66.7
Week 17	120	9.31	14.62	0.0	0.00	66.7	106	3.30	18.03	-83.3	0.00	66.7
Week 20	104	6.57	14.58	0.0	0.00	83.3	91	1.10	18.56	-83.3	0.00	66.7
Week 23	88	4.36	11.72	0.0	0.00	66.7	80	-0.63	16.01	-83.3	0.00	50.0
Week 26	81	6.17	15.91	0.0	0.00	100.0	75	-1.33	19.13	-83.3	0.00	50.0
Week 29	77	5.20	13.04	0.0	0.00	66.7	71	-1.41	20.85	-83.3	0.00	66.7
Week 32	63	3.17	9.86	0.0	0.00	50.0	58	-3.74	17.95	-83.3	0.00	33.3
Week 35	62	1.61	6.55	0.0	0.00	33.3	56	-5.95	17.24	-83.3	0.00	33.3
Week 38	56	5.95	16.34	0.0	0.00	100.0	50	-1.67	17.58	-83.3	0.00	50.0
Week 41	52	5.45	15.38	0.0	0.00	83.3	47	1.42	16.24	-50.0	0.00	66.7
Week 44	49	8.50	20.45	0.0	0.00	100.0	44	1.51	17.54	-50.0	0.00	66.7
Week 47	43	5.04	9.98	0.0	0.00	33.3	39	-2.14	14.40	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	36	7.87	12.90	0.0	0.00	33.3	31	0.54	15.80	-50.0	0.00	33.3
Week 53	31	5.91	15.84	0.0	0.00	66.7	28	-4.17	19.04	-83.3	0.00	33.3
Week 56	30	1.67	5.09	0.0	0.00	16.7	29	-8.62	21.19	-83.3	0.00	0.0
Week 59	23	8.70	18.71	0.0	0.00	66.7	21	-5.56	23.77	-83.3	0.00	33.3
Week 62	20	4.17	9.17	0.0	0.00	33.3	20	-10.00	23.82	-66.7	0.00	16.7
Week 65	17	6.86	13.25	0.0	0.00	33.3	16	-1.04	21.49	-66.7	0.00	33.3
Week 68	13	2.56	6.26	0.0	0.00	16.7	13	-3.85	19.43	-66.7	0.00	16.7
Week 71	13	6.41	16.01	0.0	0.00	50.0	13	-3.85	29.78	-66.7	0.00	50.0
Week 74	11	0.00	0.00	0.0	0.00	0.0	11	-1.52	5.03	-16.7	0.00	0.0
Week 77	11	3.03	10.05	0.0	0.00	33.3	11	-6.06	28.16	-83.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Present	EV+Pembro (N= 50)												
	BASELINE	40	10.83	21.20	0.0	0.00	100.0						
	Week 1	38	16.23	26.42	0.0	0.00	100.0	34	1.96	8.96	-16.7	0.00	33.3
	Week 2	35	11.91	23.42	0.0	0.00	100.0	32	4.69	18.08	-16.7	0.00	66.7
	Week 3	32	9.90	16.86	0.0	0.00	66.7	30	6.67	16.72	-16.7	0.00	66.7
	Week 4	35	8.10	15.32	0.0	0.00	66.7	31	3.76	13.41	-16.7	0.00	66.7
	Week 5	32	13.02	26.69	0.0	0.00	100.0	28	7.74	28.50	-33.3	0.00	100.0
	Week 6	35	9.05	19.94	0.0	0.00	100.0	30	5.56	22.88	-16.7	0.00	100.0
	Week 7	35	9.05	18.68	0.0	0.00	66.7	29	6.32	22.89	-33.3	0.00	66.7
	Week 8	38	9.21	17.20	0.0	0.00	66.7	31	8.60	20.13	-16.7	0.00	66.7
	Week 9	33	11.62	22.24	0.0	0.00	83.3	29	9.20	22.97	-16.7	0.00	83.3
	Week 10	30	11.67	26.32	0.0	0.00	100.0	25	10.67	31.87	-50.0	0.00	100.0
	Week 11	31	7.53	15.42	0.0	0.00	66.7	27	4.32	19.93	-33.3	0.00	66.7
	Week 12	32	3.65	10.99	0.0	0.00	50.0	28	0.60	15.37	-33.3	0.00	50.0
	Week 14	36	2.78	7.45	0.0	0.00	33.3	31	-1.08	13.56	-50.0	0.00	33.3
	Week 17	33	4.55	12.69	0.0	0.00	50.0	27	0.62	18.77	-50.0	0.00	50.0
	Week 20	28	5.36	12.87	0.0	0.00	50.0	25	2.00	18.83	-50.0	0.00	50.0
	Week 23	28	4.17	8.64	0.0	0.00	33.3	24	2.78	11.70	-33.3	0.00	33.3
	Week 26	28	3.57	8.31	0.0	0.00	33.3	24	2.08	11.33	-33.3	0.00	33.3
	Week 29	27	1.85	7.06	0.0	0.00	33.3	25	-2.00	14.69	-50.0	0.00	33.3
	Week 32	25	6.00	17.92	0.0	0.00	83.3	23	2.17	22.64	-50.0	0.00	83.3
	Week 35	26	5.13	14.73	0.0	0.00	66.7	24	1.39	18.98	-33.3	0.00	66.7
	Week 38	26	10.26	25.85	0.0	0.00	100.0	24	6.95	29.86	-33.3	0.00	100.0
	Week 41	25	5.33	15.00	0.0	0.00	66.7	23	2.17	19.01	-33.3	0.00	66.7
	Week 44	22	5.30	14.90	0.0	0.00	66.7	20	0.83	21.27	-50.0	0.00	66.7
	Week 47	14	9.52	27.51	0.0	0.00	100.0	13	3.85	19.43	-33.3	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	4.17	10.64	0.0	0.00	33.3	17	2.94	14.71	-33.3	0.00	33.3
	Week 53	21	7.14	17.14	0.0	0.00	66.7	18	3.70	22.55	-33.3	0.00	66.7
	Week 56	18	3.70	9.14	0.0	0.00	33.3	15	-2.22	15.26	-33.3	0.00	33.3
	Week 59	18	1.85	5.39	0.0	0.00	16.7	15	-3.33	12.91	-33.3	0.00	16.7
	Week 62	13	5.13	10.51	0.0	0.00	33.3	11	-3.03	12.51	-33.3	0.00	16.7
	Week 68	12	0.00	0.00	0.0	0.00	0.0	11	-3.03	10.05	-33.3	0.00	0.0
	Plat+Gem (N= 50)												
	BASELINE	40	10.83	14.88	0.0	0.00	50.0						
	Week 1	35	14.29	21.44	0.0	0.00	66.7	33	3.54	17.56	-33.3	0.00	50.0
	Week 2	33	12.12	15.74	0.0	0.00	50.0	30	0.56	15.46	-33.3	0.00	33.3
	Week 3	33	8.08	11.12	0.0	0.00	33.3	29	-0.57	17.53	-50.0	0.00	33.3
	Week 4	36	10.19	13.38	0.0	0.00	50.0	32	0.00	14.66	-33.3	0.00	33.3
	Week 5	36	13.89	22.36	0.0	0.00	83.3	32	2.08	21.48	-33.3	0.00	66.7
	Week 6	32	5.21	11.55	0.0	0.00	50.0	29	-7.47	15.16	-50.0	0.00	16.7
	Week 7	35	8.57	12.37	0.0	0.00	50.0	31	-2.69	16.72	-50.0	0.00	33.3
	Week 8	35	8.10	12.37	0.0	0.00	50.0	31	-3.23	19.92	-50.0	0.00	50.0
	Week 9	34	9.31	13.73	0.0	0.00	50.0	30	-1.67	17.15	-33.3	0.00	33.3
	Week 10	33	7.58	13.88	0.0	0.00	66.7	30	-6.11	15.46	-50.0	0.00	16.7
	Week 11	30	5.56	11.85	0.0	0.00	50.0	26	-6.41	12.54	-33.3	0.00	16.7
	Week 12	32	5.73	9.09	0.0	0.00	33.3	27	-3.09	14.64	-33.3	0.00	16.7
	Week 14	27	5.56	9.25	0.0	0.00	33.3	22	-4.55	15.59	-33.3	0.00	16.7
	Week 17	28	8.93	13.97	0.0	0.00	50.0	23	-2.17	19.00	-33.3	0.00	50.0
	Week 20	20	5.83	16.47	0.0	0.00	66.7	16	-2.08	19.12	-33.3	0.00	50.0
	Week 23	15	6.67	17.59	0.0	0.00	66.7	14	-5.95	22.27	-33.3	0.00	50.0
	Week 26	15	12.22	29.86	0.0	0.00	100.0	14	-2.38	26.84	-50.0	0.00	50.0
	Week 29	13	2.56	6.26	0.0	0.00	16.7	12	-8.33	19.46	-50.0	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Absent	EV+Pembro (N=152)												
	BASELINE	120	5.56	13.89	0.0	0.00	100.0						
	Week 1	103	8.58	17.44	0.0	0.00	100.0	95	2.98	14.78	-33.3	0.00	100.0
	Week 2	115	11.88	20.44	0.0	0.00	100.0	101	7.26	19.06	-33.3	0.00	100.0
	Week 3	107	9.50	16.21	0.0	0.00	100.0	92	1.99	13.72	-33.3	0.00	50.0
	Week 4	110	7.58	11.87	0.0	0.00	50.0	98	1.87	12.41	-33.3	0.00	33.3
	Week 5	105	7.14	12.84	0.0	0.00	50.0	93	1.25	13.29	-33.3	0.00	50.0
	Week 6	111	8.86	15.70	0.0	0.00	66.7	94	3.55	15.24	-33.3	0.00	66.7
	Week 7	112	8.18	15.01	0.0	0.00	66.7	95	1.40	13.68	-16.7	0.00	66.7
	Week 8	109	9.79	16.39	0.0	0.00	66.7	93	2.33	12.91	-33.3	0.00	50.0
	Week 9	109	9.63	15.09	0.0	0.00	66.7	92	3.08	15.61	-33.3	0.00	66.7
	Week 10	109	8.72	16.60	0.0	0.00	66.7	93	2.33	17.13	-66.7	0.00	66.7
	Week 11	106	7.23	14.37	0.0	0.00	66.7	88	1.14	12.58	-33.3	0.00	50.0
	Week 12	110	6.36	13.73	0.0	0.00	66.7	91	0.73	13.59	-50.0	0.00	50.0
	Week 14	103	4.53	9.10	0.0	0.00	33.3	85	-0.78	8.87	-33.3	0.00	16.7
	Week 17	99	5.72	10.95	0.0	0.00	50.0	84	0.20	12.54	-50.0	0.00	50.0
	Week 20	92	4.17	10.95	0.0	0.00	66.7	78	-1.07	12.70	-33.3	0.00	66.7
	Week 23	89	3.37	8.40	0.0	0.00	33.3	73	-0.69	9.80	-33.3	0.00	33.3
	Week 26	84	4.37	10.70	0.0	0.00	50.0	70	-0.95	12.97	-33.3	0.00	50.0
	Week 29	80	3.75	9.18	0.0	0.00	33.3	68	-0.25	11.33	-33.3	0.00	33.3
	Week 32	77	4.33	10.26	0.0	0.00	66.7	65	-0.51	10.19	-33.3	0.00	16.7
	Week 35	72	3.24	9.54	0.0	0.00	50.0	62	-1.08	12.02	-33.3	0.00	33.3
	Week 38	71	3.05	8.12	0.0	0.00	33.3	62	-0.27	10.23	-33.3	0.00	33.3
	Week 41	70	3.57	9.79	0.0	0.00	50.0	61	-0.27	10.32	-33.3	0.00	33.3
	Week 44	64	3.39	8.49	0.0	0.00	33.3	54	-0.93	11.41	-33.3	0.00	33.3
	Week 47	65	2.56	7.35	0.0	0.00	33.3	57	-1.46	10.10	-16.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	54	4.63	9.93	0.0	0.00	33.3	47	0.71	13.44	-33.3	0.00	33.3
	Week 53	53	3.14	9.28	0.0	0.00	50.0	45	-1.85	10.79	-33.3	0.00	33.3
	Week 56	54	3.09	9.20	0.0	0.00	50.0	46	-1.81	10.08	-33.3	0.00	16.7
	Week 59	51	2.94	7.96	0.0	0.00	33.3	42	-1.19	11.28	-33.3	0.00	33.3
	Week 62	49	3.06	7.36	0.0	0.00	33.3	41	-1.22	11.42	-33.3	0.00	33.3
	Week 65	36	5.09	11.14	0.0	0.00	33.3	33	0.00	14.43	-33.3	0.00	33.3
	Week 68	34	2.45	7.26	0.0	0.00	33.3	31	-2.69	12.25	-33.3	0.00	33.3
	Week 71	33	2.02	6.92	0.0	0.00	33.3	30	-2.78	11.65	-33.3	0.00	33.3
	Week 74	33	3.03	8.79	0.0	0.00	33.3	30	-1.11	13.08	-33.3	0.00	33.3
	Week 77	31	4.84	13.74	0.0	0.00	66.7	27	-1.85	12.52	-33.3	0.00	33.3
	Week 80	31	7.53	17.66	0.0	0.00	66.7	29	1.72	20.09	-33.3	0.00	66.7
	Week 83	25	6.00	12.62	0.0	0.00	33.3	24	0.69	18.04	-33.3	0.00	33.3
	Week 86	23	4.35	9.01	0.0	0.00	33.3	22	-0.76	14.07	-33.3	0.00	33.3
	Week 89	18	5.56	9.90	0.0	0.00	33.3	17	0.00	14.43	-33.3	0.00	33.3
	Week 92	16	5.21	11.74	0.0	0.00	33.3	15	0.00	16.67	-33.3	0.00	33.3
	Week 95	12	2.78	9.62	0.0	0.00	33.3	11	-3.03	16.36	-33.3	0.00	33.3
	Plat+Gem (N=152)												
	BASELINE	125	6.00	16.59	0.0	0.00	100.0						
	Week 1	109	13.76	23.00	0.0	0.00	100.0	106	8.81	19.41	-33.3	0.00	100.0
	Week 2	114	13.89	21.72	0.0	0.00	100.0	105	8.25	19.22	-50.0	0.00	83.3
	Week 3	116	8.91	17.64	0.0	0.00	100.0	107	3.43	15.82	-66.7	0.00	66.7
	Week 4	114	6.58	13.23	0.0	0.00	83.3	103	2.10	15.42	-50.0	0.00	66.7
	Week 5	117	7.84	13.41	0.0	0.00	66.7	106	2.52	15.05	-66.7	0.00	50.0
	Week 6	113	8.26	16.23	0.0	0.00	83.3	102	3.59	16.52	-66.7	0.00	83.3
	Week 7	113	11.06	17.48	0.0	0.00	100.0	103	5.83	20.44	-83.3	0.00	83.3
	Week 8	110	10.91	19.35	0.0	0.00	100.0	101	6.27	20.26	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	107	7.63	17.02	0.0	0.00	100.0	95	2.81	19.70	-83.3	0.00	100.0
	Week 10	109	10.86	19.95	0.0	0.00	100.0	100	6.67	20.38	-33.3	0.00	100.0
	Week 11	96	9.72	17.55	0.0	0.00	83.3	88	4.17	17.00	-50.0	0.00	83.3
	Week 12	98	7.31	14.57	0.0	0.00	66.7	88	1.14	17.47	-83.3	0.00	50.0
	Week 14	98	9.86	17.23	0.0	0.00	83.3	87	5.36	19.44	-83.3	0.00	66.7
	Week 17	92	9.42	14.89	0.0	0.00	66.7	83	4.82	17.56	-83.3	0.00	66.7
	Week 20	84	6.75	14.20	0.0	0.00	83.3	75	1.78	18.50	-83.3	0.00	66.7
	Week 23	73	3.88	10.21	0.0	0.00	50.0	66	0.50	14.31	-83.3	0.00	50.0
	Week 26	66	4.80	10.44	0.0	0.00	33.3	61	-1.09	17.18	-83.3	0.00	33.3
	Week 29	64	5.73	14.00	0.0	0.00	66.7	59	0.00	20.99	-83.3	0.00	66.7
	Week 32	54	3.09	10.28	0.0	0.00	50.0	49	-3.06	18.84	-83.3	0.00	33.3
	Week 35	54	1.54	6.69	0.0	0.00	33.3	48	-5.21	17.92	-83.3	0.00	33.3
	Week 38	47	4.26	10.11	0.0	0.00	50.0	42	-2.38	17.10	-83.3	0.00	33.3
	Week 41	45	5.56	15.89	0.0	0.00	83.3	40	2.50	14.40	-16.7	0.00	66.7
	Week 44	41	7.72	16.71	0.0	0.00	83.3	36	1.85	16.80	-50.0	0.00	66.7
	Week 47	35	5.24	9.71	0.0	0.00	33.3	31	-0.54	15.20	-66.7	0.00	33.3
	Week 50	29	9.77	13.74	0.0	0.00	33.3	24	2.78	16.79	-50.0	0.00	33.3
	Week 53	25	7.33	17.40	0.0	0.00	66.7	22	-3.03	20.98	-83.3	0.00	33.3
	Week 56	26	1.92	5.43	0.0	0.00	16.7	25	-9.33	22.61	-83.3	0.00	0.0
	Week 59	20	7.50	17.50	0.0	0.00	66.7	18	-8.33	23.74	-83.3	0.00	16.7
	Week 62	17	4.90	9.80	0.0	0.00	33.3	17	-10.78	25.64	-66.7	0.00	16.7
	Week 65	15	7.78	13.90	0.0	0.00	33.3	14	-1.19	23.08	-66.7	0.00	33.3
	Week 68	11	3.03	6.74	0.0	0.00	16.7	11	-4.55	21.20	-66.7	0.00	16.7
	Week 71	12	6.94	16.60	0.0	0.00	50.0	12	-4.17	31.08	-66.7	0.00	50.0
	Week 74	10	0.00	0.00	0.0	0.00	0.0	10	-1.67	5.27	-16.7	0.00	0.0
	Week 77	10	3.33	10.54	0.0	0.00	33.3	10	-6.67	29.61	-83.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
< 65 years	EV+Pembro (N= 39)												
	BASELINE	32	6.77	11.87	0.0	0.00	50.0						
	Week 1	27	10.49	17.39	0.0	0.00	66.7	26	1.92	8.60	-16.7	0.00	16.7
	Week 2	30	14.45	23.46	0.0	0.00	100.0	29	8.62	24.24	-16.7	0.00	100.0
	Week 3	31	10.75	16.41	0.0	0.00	66.7	29	4.02	15.85	-16.7	0.00	66.7
	Week 4	30	9.45	16.77	0.0	0.00	66.7	27	3.09	16.69	-16.7	0.00	66.7
	Week 5	28	9.52	20.50	0.0	0.00	100.0	26	3.85	24.18	-33.3	0.00	100.0
	Week 6	29	10.35	21.09	0.0	0.00	100.0	26	6.41	23.13	-16.7	0.00	100.0
	Week 7	30	8.89	16.22	0.0	0.00	66.7	26	1.28	18.21	-33.3	0.00	66.7
	Week 8	30	8.89	14.34	0.0	0.00	66.7	26	4.49	16.71	-16.7	0.00	66.7
	Week 9	28	10.72	15.85	0.0	0.00	66.7	27	6.17	16.76	-16.7	0.00	66.7
	Week 10	26	8.33	15.09	0.0	0.00	50.0	23	2.90	17.15	-50.0	0.00	50.0
	Week 11	28	8.33	16.04	0.0	0.00	66.7	25	1.33	15.90	-33.3	0.00	50.0
	Week 12	28	5.36	11.16	0.0	0.00	33.3	25	-0.67	14.01	-33.3	0.00	33.3
	Week 14	26	7.05	11.71	0.0	0.00	33.3	23	-0.72	15.47	-50.0	0.00	16.7
	Week 17	28	8.33	13.98	0.0	0.00	50.0	24	1.39	18.98	-50.0	0.00	50.0
	Week 20	27	6.17	11.46	0.0	0.00	33.3	24	-0.70	16.65	-50.0	0.00	33.3
	Week 23	26	5.77	11.49	0.0	0.00	33.3	23	1.45	14.14	-33.3	0.00	33.3
	Week 26	24	8.33	14.74	0.0	0.00	50.0	22	5.30	18.10	-33.3	0.00	50.0
	Week 29	25	6.00	11.67	0.0	0.00	33.3	23	0.72	18.45	-50.0	0.00	33.3
	Week 32	25	9.33	15.28	0.0	0.00	66.7	23	0.73	16.27	-50.0	0.00	33.3
	Week 35	24	4.86	10.40	0.0	0.00	33.3	22	-1.52	16.19	-33.3	0.00	33.3
	Week 38	23	8.70	16.57	0.0	0.00	66.7	22	3.03	19.68	-33.3	0.00	66.7
	Week 41	25	7.33	16.02	0.0	0.00	66.7	23	1.45	20.05	-33.3	0.00	66.7
	Week 44	22	8.33	16.86	0.0	0.00	66.7	20	2.50	23.12	-50.0	0.00	66.7
	Week 47	20	6.67	22.56	0.0	0.00	100.0	18	0.00	16.17	-33.3	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	19	5.26	11.18	0.0	0.00	33.3	17	1.96	15.46	-33.3	0.00	33.3
	Week 53	20	4.17	9.17	0.0	0.00	33.3	18	-1.85	15.00	-33.3	0.00	33.3
	Week 56	17	3.92	7.29	0.0	0.00	16.7	15	-3.33	14.36	-33.3	0.00	16.7
	Week 59	17	6.86	11.87	0.0	0.00	33.3	15	0.00	17.82	-33.3	0.00	33.3
	Week 62	15	6.67	12.28	0.0	0.00	33.3	14	-1.19	15.28	-33.3	0.00	33.3
	Week 65	14	4.76	12.10	0.0	0.00	33.3	13	0.00	15.21	-33.3	0.00	33.3
	Week 68	11	3.03	10.05	0.0	0.00	33.3	10	-1.67	16.57	-33.3	0.00	33.3
	Week 71	13	5.13	12.52	0.0	0.00	33.3	12	-2.78	15.62	-33.3	0.00	33.3
	Week 74	14	7.14	12.60	0.0	0.00	33.3	13	0.00	20.41	-33.3	0.00	33.3
	Week 77	14	7.14	10.77	0.0	0.00	33.3	13	-1.28	10.68	-16.7	0.00	16.7
	Week 80	14	4.76	13.76	0.0	0.00	50.0	13	0.00	18.00	-33.3	0.00	50.0
	Week 83	12	6.94	13.22	0.0	0.00	33.3	11	3.03	19.46	-33.3	0.00	33.3
	Plat+Gem (N= 29)												
	BASELINE	22	8.33	20.41	0.0	0.00	83.3						
	Week 1	21	13.49	20.83	0.0	0.00	66.7	20	9.17	18.32	-16.7	0.00	50.0
	Week 2	24	8.33	16.30	0.0	0.00	66.7	20	1.67	20.16	-50.0	0.00	50.0
	Week 3	23	6.52	13.05	0.0	0.00	50.0	20	-1.67	22.88	-66.7	0.00	33.3
	Week 4	23	10.87	15.58	0.0	0.00	50.0	19	5.26	16.71	-33.3	0.00	33.3
	Week 5	25	10.67	16.58	0.0	0.00	66.7	20	-1.67	18.65	-66.7	0.00	16.7
	Week 6	22	11.36	18.82	0.0	0.00	66.7	18	2.78	18.30	-50.0	0.00	50.0
	Week 7	24	12.50	16.48	0.0	0.00	50.0	21	1.59	26.82	-83.3	0.00	50.0
	Week 8	21	13.49	17.97	0.0	16.67	66.7	19	4.39	25.36	-66.7	0.00	50.0
	Week 9	20	11.67	23.63	0.0	0.00	100.0	17	2.94	34.98	-83.3	0.00	100.0
	Week 10	21	15.87	24.42	0.0	0.00	83.3	18	9.26	26.33	-50.0	0.00	66.7
	Week 11	20	15.83	19.85	0.0	8.34	66.7	17	2.94	18.85	-50.0	0.00	33.3
	Week 12	21	12.70	18.93	0.0	0.00	66.7	17	0.00	26.35	-83.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 14	22	18.18	22.95	0.0	16.67	83.3	18	9.26	34.40	-83.3	8.34	66.7
	Week 17	20	14.17	18.16	0.0	0.00	50.0	17	2.94	30.75	-83.3	0.00	50.0
	Week 20	18	12.96	23.26	0.0	0.00	83.3	15	2.22	30.77	-83.3	0.00	66.7
	Week 23	18	7.41	14.26	0.0	0.00	50.0	16	-4.17	26.87	-83.3	0.00	50.0
	Week 26	16	5.21	11.74	0.0	0.00	33.3	14	-8.33	26.75	-83.3	0.00	16.7
	Week 29	15	4.44	11.73	0.0	0.00	33.3	13	-10.26	26.82	-83.3	0.00	16.7
	Week 32	15	6.67	12.28	0.0	0.00	33.3	13	-7.69	25.10	-83.3	0.00	16.7
	Week 35	15	4.44	9.89	0.0	0.00	33.3	13	-10.26	24.09	-83.3	0.00	0.0
	Week 38	14	13.10	28.63	0.0	0.00	100.0	12	-2.78	30.01	-83.3	0.00	50.0
	Week 41	11	10.61	26.11	0.0	0.00	83.3	9	1.85	29.40	-50.0	0.00	66.7
	Week 44	11	21.21	36.58	0.0	0.00	100.0	9	12.96	27.36	-16.7	0.00	66.7
	Week 47	11	10.61	15.41	0.0	0.00	33.3	9	-7.41	26.50	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>= 65 years	EV+Pembro (N=163)												
	BASELINE	128	6.90	17.06	0.0	0.00	100.0						
	Week 1	114	10.67	21.17	0.0	0.00	100.0	103	2.91	14.47	-33.3	0.00	100.0
	Week 2	120	11.25	20.52	0.0	0.00	100.0	104	6.09	17.08	-33.3	0.00	83.3
	Week 3	108	9.26	16.33	0.0	0.00	100.0	93	2.87	14.25	-33.3	0.00	50.0
	Week 4	115	7.25	11.50	0.0	0.00	50.0	102	2.12	11.41	-33.3	0.00	33.3
	Week 5	109	8.26	16.30	0.0	0.00	100.0	95	2.46	16.12	-33.3	0.00	100.0
	Week 6	117	8.55	15.57	0.0	0.00	66.7	98	3.40	15.50	-33.3	0.00	66.7
	Week 7	117	8.26	15.88	0.0	0.00	66.7	98	2.89	15.88	-16.7	0.00	66.7
	Week 8	117	9.83	17.11	0.0	0.00	66.7	98	3.74	14.86	-33.3	0.00	50.0
	Week 9	114	9.94	17.28	0.0	0.00	83.3	94	4.08	18.07	-33.3	0.00	83.3
	Week 10	113	9.59	19.90	0.0	0.00	100.0	95	4.39	22.18	-66.7	0.00	100.0
	Week 11	109	7.03	14.22	0.0	0.00	66.7	90	2.04	14.32	-33.3	0.00	66.7
	Week 12	114	5.85	13.67	0.0	0.00	66.7	94	1.06	14.00	-50.0	0.00	50.0
	Week 14	113	3.39	7.77	0.0	0.00	33.3	93	-0.90	8.64	-33.3	0.00	33.3
	Week 17	104	4.65	10.50	0.0	0.00	50.0	87	0.00	12.71	-50.0	0.00	50.0
	Week 20	93	3.94	11.37	0.0	0.00	66.7	79	-0.21	13.74	-33.3	0.00	66.7
	Week 23	91	2.93	7.28	0.0	0.00	33.3	74	-0.23	8.94	-33.3	0.00	33.3
	Week 26	88	3.03	8.21	0.0	0.00	33.3	72	-1.85	9.91	-33.3	0.00	33.3
	Week 29	82	2.44	7.46	0.0	0.00	33.3	70	-1.19	9.55	-33.3	0.00	33.3
	Week 32	77	3.25	11.16	0.0	0.00	83.3	65	0.00	13.82	-33.3	0.00	83.3
	Week 35	74	3.38	11.37	0.0	0.00	66.7	64	0.00	13.61	-33.3	0.00	66.7
	Week 38	74	3.83	14.74	0.0	0.00	100.0	64	1.30	17.65	-33.3	0.00	100.0
	Week 41	70	2.86	8.96	0.0	0.00	50.0	61	0.00	9.62	-33.3	0.00	33.3
	Week 44	64	2.34	6.55	0.0	0.00	33.3	54	-1.54	9.86	-33.3	0.00	33.3
	Week 47	59	2.82	8.28	0.0	0.00	33.3	52	-0.64	10.93	-16.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	55	4.24	9.74	0.0	0.00	33.3	47	1.06	13.19	-33.3	0.00	33.3
	Week 53	54	4.32	13.03	0.0	0.00	66.7	45	0.37	15.28	-33.3	0.00	66.7
	Week 56	55	3.03	9.67	0.0	0.00	50.0	46	-1.45	10.44	-33.3	0.00	33.3
	Week 59	52	1.28	4.49	0.0	0.00	16.7	42	-2.38	8.69	-33.3	0.00	16.7
	Week 62	47	2.48	6.00	0.0	0.00	16.7	38	-1.75	10.10	-33.3	0.00	16.7
	Week 65	29	4.02	9.61	0.0	0.00	33.3	27	-1.24	13.81	-33.3	0.00	33.3
	Week 68	35	1.43	4.73	0.0	0.00	16.7	32	-3.13	9.87	-33.3	0.00	16.7
	Week 71	29	1.15	4.30	0.0	0.00	16.7	26	-3.85	9.78	-33.3	0.00	16.7
	Week 74	24	2.08	7.47	0.0	0.00	33.3	22	-3.03	12.21	-33.3	0.00	33.3
	Week 77	23	5.80	16.37	0.0	0.00	66.7	20	-1.67	15.20	-33.3	0.00	33.3
	Week 80	22	9.09	18.35	0.0	0.00	66.7	21	1.59	21.02	-33.3	0.00	66.7
	Week 83	18	5.56	12.78	0.0	0.00	33.3	18	-0.93	18.50	-33.3	0.00	33.3
	Week 86	18	7.41	16.39	0.0	0.00	66.7	18	0.93	20.98	-33.3	0.00	66.7
	Week 89	12	2.78	6.49	0.0	0.00	16.7	12	-4.17	12.56	-33.3	0.00	16.7
	Week 92	10	3.33	10.54	0.0	0.00	33.3	10	-3.33	17.21	-33.3	0.00	33.3
	Plat+Gem (N=173)												
	BASELINE	143	6.99	15.63	0.0	0.00	100.0						
	Week 1	123	13.96	22.92	0.0	0.00	100.0	119	7.28	19.24	-33.3	0.00	100.0
	Week 2	123	14.50	21.12	0.0	0.00	100.0	115	7.39	18.36	-33.3	0.00	83.3
	Week 3	126	9.13	16.95	0.0	0.00	100.0	116	3.30	14.78	-33.3	0.00	66.7
	Week 4	127	6.82	12.83	0.0	0.00	83.3	116	1.01	14.95	-50.0	0.00	66.7
	Week 5	128	8.99	16.05	0.0	0.00	83.3	118	3.11	16.30	-66.7	0.00	66.7
	Week 6	123	6.91	14.62	0.0	0.00	83.3	113	0.89	16.64	-66.7	0.00	83.3
	Week 7	124	10.08	16.44	0.0	0.00	100.0	113	4.28	18.47	-66.7	0.00	83.3
	Week 8	124	9.68	17.92	0.0	0.00	100.0	113	3.98	19.70	-66.7	0.00	100.0
	Week 9	121	7.44	14.74	0.0	0.00	83.3	108	1.54	15.54	-50.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	121	9.09	17.48	0.0	0.00	100.0	112	2.83	18.84	-33.3	0.00	100.0
	Week 11	106	7.39	15.44	0.0	0.00	83.3	97	1.55	16.33	-33.3	0.00	83.3
	Week 12	109	5.81	11.87	0.0	0.00	50.0	98	0.17	14.85	-66.7	0.00	50.0
	Week 14	103	6.96	13.31	0.0	0.00	66.7	91	2.20	14.32	-50.0	0.00	50.0
	Week 17	100	8.33	13.71	0.0	0.00	66.7	89	3.37	14.69	-33.3	0.00	66.7
	Week 20	86	5.23	11.79	0.0	0.00	66.7	76	0.88	15.37	-66.7	0.00	50.0
	Week 23	70	3.57	10.95	0.0	0.00	66.7	64	0.26	12.06	-33.3	0.00	50.0
	Week 26	65	6.41	16.85	0.0	0.00	100.0	61	0.27	16.80	-66.7	0.00	50.0
	Week 29	62	5.38	13.42	0.0	0.00	66.7	58	0.57	18.98	-66.7	0.00	66.7
	Week 32	48	2.08	8.85	0.0	0.00	50.0	45	-2.59	15.47	-66.7	0.00	33.3
	Week 35	47	0.71	4.86	0.0	0.00	33.3	43	-4.65	14.70	-66.7	0.00	33.3
	Week 38	42	3.57	8.66	0.0	0.00	33.3	38	-1.32	11.87	-50.0	0.00	33.3
	Week 41	41	4.07	11.04	0.0	0.00	50.0	38	1.32	11.87	-16.7	0.00	33.3
	Week 44	38	4.83	10.90	0.0	0.00	50.0	35	-1.43	13.02	-50.0	0.00	33.3
	Week 47	32	3.13	6.61	0.0	0.00	16.7	30	-0.56	8.17	-16.7	0.00	16.7
	Week 50	29	5.75	11.16	0.0	0.00	33.3	26	1.92	11.86	-16.7	0.00	33.3
	Week 53	25	2.00	7.33	0.0	0.00	33.3	24	-1.39	10.90	-16.7	0.00	33.3
	Week 56	26	1.28	4.53	0.0	0.00	16.7	26	-6.41	16.38	-66.7	0.00	0.0
	Week 59	20	5.00	13.36	0.0	0.00	50.0	20	-1.67	16.13	-50.0	0.00	33.3
	Week 62	19	3.51	8.92	0.0	0.00	33.3	19	-7.02	20.27	-66.7	0.00	16.7
	Week 65	16	5.21	11.74	0.0	0.00	33.3	16	-1.04	21.49	-66.7	0.00	33.3
	Week 68	13	2.56	6.26	0.0	0.00	16.7	13	-3.85	19.43	-66.7	0.00	16.7
	Week 71	13	6.41	16.01	0.0	0.00	50.0	13	-3.85	29.78	-66.7	0.00	50.0
	Week 74	11	0.00	0.00	0.0	0.00	0.0	11	-1.52	5.03	-16.7	0.00	0.0
	Week 77	10	3.33	10.54	0.0	0.00	33.3	10	1.67	12.30	-16.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Europe	EV+Pembro (N= 74)												
	BASELINE	53	6.29	13.95	0.0	0.00	66.7						
	Week 1	48	9.72	19.40	0.0	0.00	66.7	42	2.78	12.16	-16.7	0.00	66.7
	Week 2	53	8.49	17.49	0.0	0.00	66.7	44	3.79	17.92	-33.3	0.00	66.7
	Week 3	50	12.00	19.93	0.0	0.00	100.0	41	3.66	17.29	-33.3	0.00	50.0
	Week 4	51	8.17	12.64	0.0	0.00	50.0	44	3.03	13.58	-16.7	0.00	33.3
	Week 5	46	9.06	17.81	0.0	0.00	100.0	41	3.66	19.90	-33.3	0.00	100.0
	Week 6	50	11.67	17.25	0.0	0.00	66.7	39	7.27	19.04	-33.3	0.00	66.7
	Week 7	50	11.00	18.32	0.0	0.00	66.7	39	6.41	20.45	-16.7	0.00	66.7
	Week 8	51	10.13	15.30	0.0	0.00	66.7	41	4.88	13.56	-16.7	0.00	50.0
	Week 9	47	12.77	19.10	0.0	0.00	83.3	37	7.21	22.75	-33.3	0.00	83.3
	Week 10	45	11.48	22.98	0.0	0.00	100.0	34	7.84	28.20	-66.7	0.00	100.0
	Week 11	48	8.33	17.87	0.0	0.00	66.7	37	4.96	19.19	-33.3	0.00	66.7
	Week 12	51	5.88	15.21	0.0	0.00	66.7	39	1.28	15.94	-33.3	0.00	50.0
	Week 14	50	3.33	7.53	0.0	0.00	33.3	38	-0.44	9.08	-33.3	0.00	16.7
	Week 17	43	5.81	12.00	0.0	0.00	50.0	33	1.01	14.40	-33.3	0.00	50.0
	Week 20	41	5.69	14.72	0.0	0.00	66.7	33	3.03	18.84	-33.3	0.00	66.7
	Week 23	41	4.07	8.96	0.0	0.00	33.3	30	0.56	12.75	-33.3	0.00	33.3
	Week 26	37	2.70	7.36	0.0	0.00	33.3	28	-0.60	11.55	-33.3	0.00	16.7
	Week 29	37	2.25	6.99	0.0	0.00	33.3	29	-1.72	9.28	-33.3	0.00	16.7
	Week 32	34	6.37	18.36	0.0	0.00	83.3	26	1.28	18.81	-33.3	0.00	83.3
	Week 35	31	3.23	12.49	0.0	0.00	66.7	25	-0.67	17.66	-33.3	0.00	66.7
	Week 38	31	7.53	21.87	0.0	0.00	100.0	26	5.13	25.72	-33.3	0.00	100.0
	Week 41	28	4.76	12.71	0.0	0.00	50.0	23	-1.45	13.21	-33.3	0.00	33.3
	Week 44	27	3.70	8.44	0.0	0.00	33.3	22	0.00	10.29	-33.3	0.00	16.7
	Week 47	25	2.00	5.53	0.0	0.00	16.7	21	-2.38	9.55	-33.3	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	26	5.77	10.48	0.0	0.00	33.3	23	2.90	13.90	-33.3	0.00	33.3
	Week 53	26	7.05	17.11	0.0	0.00	66.7	21	4.76	18.37	-33.3	0.00	66.7
	Week 56	25	4.00	11.06	0.0	0.00	50.0	21	0.79	9.83	-33.3	0.00	16.7
	Week 59	23	2.90	8.18	0.0	0.00	33.3	18	0.93	10.65	-33.3	0.00	16.7
	Week 62	20	1.67	5.13	0.0	0.00	16.7	17	0.00	10.21	-33.3	0.00	16.7
	Week 65	13	7.69	14.62	0.0	0.00	33.3	13	3.85	16.88	-33.3	0.00	33.3
	Week 68	15	1.11	4.30	0.0	0.00	16.7	15	-1.11	9.89	-33.3	0.00	16.7
	Week 71	13	0.00	0.00	0.0	0.00	0.0	13	-2.56	9.24	-33.3	0.00	0.0
	Week 74	10	0.00	0.00	0.0	0.00	0.0	9	-3.70	11.11	-33.3	0.00	0.0
	Plat+Gem (N= 95)												
	BASELINE	75	5.56	11.41	0.0	0.00	66.7						
	Week 1	71	15.26	23.36	0.0	0.00	100.0	69	8.45	20.34	-33.3	0.00	100.0
	Week 2	71	13.38	22.29	0.0	0.00	100.0	63	6.88	14.86	-33.3	0.00	50.0
	Week 3	72	10.65	20.23	0.0	0.00	100.0	65	4.87	14.65	-33.3	0.00	66.7
	Week 4	69	8.45	15.02	0.0	0.00	83.3	62	3.49	15.43	-50.0	0.00	66.7
	Week 5	71	11.03	19.51	0.0	0.00	83.3	63	4.50	16.99	-66.7	0.00	66.7
	Week 6	69	8.70	17.53	0.0	0.00	83.3	61	2.46	18.22	-66.7	0.00	83.3
	Week 7	69	10.15	17.44	0.0	0.00	100.0	62	4.30	18.83	-66.7	0.00	83.3
	Week 8	67	7.71	15.17	0.0	0.00	66.7	60	1.94	16.26	-66.7	0.00	50.0
	Week 9	66	8.33	19.45	0.0	0.00	100.0	57	2.92	19.70	-50.0	0.00	100.0
	Week 10	70	8.57	17.20	0.0	0.00	83.3	63	2.12	14.51	-33.3	0.00	66.7
	Week 11	63	6.88	16.84	0.0	0.00	83.3	56	1.19	16.77	-33.3	0.00	83.3
	Week 12	66	7.32	15.23	0.0	0.00	66.7	56	1.49	15.66	-66.7	0.00	50.0
	Week 14	66	9.09	16.58	0.0	0.00	83.3	56	4.46	19.20	-50.0	0.00	66.7
	Week 17	61	9.56	14.42	0.0	0.00	50.0	53	3.77	13.73	-33.3	0.00	50.0
	Week 20	54	7.41	17.33	0.0	0.00	83.3	48	1.74	18.91	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 23	44	4.92	12.75	0.0	0.00	66.7	40	0.83	12.49	-33.3	0.00	50.0
	Week 26	42	6.35	14.23	0.0	0.00	66.7	39	0.00	17.52	-66.7	0.00	50.0
	Week 29	39	4.27	9.14	0.0	0.00	33.3	36	-1.85	15.32	-66.7	0.00	16.7
	Week 32	32	3.65	10.99	0.0	0.00	50.0	30	-2.22	15.62	-66.7	0.00	33.3
	Week 35	32	0.52	2.95	0.0	0.00	16.7	30	-5.56	13.37	-66.7	0.00	0.0
	Week 38	28	4.76	8.91	0.0	0.00	33.3	26	1.28	10.46	-16.7	0.00	33.3
	Week 41	25	8.00	19.91	0.0	0.00	83.3	23	3.62	18.77	-16.7	0.00	66.7
	Week 44	24	7.64	19.65	0.0	0.00	83.3	22	2.27	18.03	-16.7	0.00	66.7
	Week 47	22	3.03	6.58	0.0	0.00	16.7	20	-1.67	9.21	-16.7	0.00	16.7
	Week 50	17	5.88	11.70	0.0	0.00	33.3	15	0.00	12.60	-16.7	0.00	33.3
	Week 53	15	5.56	15.00	0.0	0.00	50.0	14	-2.38	12.84	-16.7	0.00	33.3
	Week 56	15	3.33	6.90	0.0	0.00	16.7	14	-5.95	18.03	-66.7	0.00	0.0
	Week 59	11	7.58	13.67	0.0	0.00	33.3	10	0.00	11.11	-16.7	0.00	16.7
	Week 62	11	6.06	11.24	0.0	0.00	33.3	11	-4.55	22.47	-66.7	0.00	16.7
	Week 65	10	5.00	11.25	0.0	0.00	33.3	10	-5.00	24.91	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
North America	EV+Pembro (N= 46)												
	BASELINE	33	10.10	21.22	0.0	0.00	100.0						
	Week 1	30	19.45	28.05	0.0	16.67	100.0	27	7.41	20.84	-16.7	0.00	100.0
	Week 2	30	10.56	17.77	0.0	0.00	83.3	26	5.77	19.97	-33.3	0.00	83.3
	Week 3	25	4.00	7.27	0.0	0.00	16.7	21	-0.79	8.29	-16.7	0.00	16.7
	Week 4	30	7.22	12.13	0.0	0.00	50.0	24	0.00	8.51	-16.7	0.00	16.7
	Week 5	29	6.90	10.46	0.0	0.00	33.3	21	0.00	14.91	-33.3	0.00	33.3
	Week 6	31	5.91	11.01	0.0	0.00	33.3	23	-1.45	9.94	-16.7	0.00	16.7
	Week 7	33	7.07	13.20	0.0	0.00	50.0	23	-2.17	11.57	-33.3	0.00	16.7
	Week 8	29	6.90	12.21	0.0	0.00	33.3	20	0.83	12.65	-16.7	0.00	33.3
	Week 9	27	6.79	13.28	0.0	0.00	50.0	21	0.00	9.13	-16.7	0.00	16.7
	Week 10	29	5.17	11.87	0.0	0.00	33.3	23	-2.90	12.96	-50.0	0.00	16.7
	Week 11	28	7.14	11.50	0.0	0.00	33.3	21	-2.38	10.91	-33.3	0.00	16.7
	Week 12	29	5.75	12.02	0.0	0.00	50.0	22	-0.76	12.04	-33.3	0.00	16.7
	Week 14	28	4.76	10.98	0.0	0.00	33.3	21	-3.18	13.56	-50.0	0.00	16.7
	Week 17	29	4.02	9.61	0.0	0.00	33.3	23	-3.62	13.26	-50.0	0.00	16.7
	Week 20	23	3.62	8.64	0.0	0.00	33.3	18	-4.63	13.77	-50.0	0.00	16.7
	Week 23	22	2.27	5.86	0.0	0.00	16.7	17	-0.98	7.15	-16.7	0.00	16.7
	Week 26	21	0.00	0.00	0.0	0.00	0.0	16	-5.21	10.03	-33.3	0.00	0.0
	Week 29	20	0.83	3.73	0.0	0.00	16.7	17	-5.88	14.36	-50.0	0.00	16.7
	Week 32	21	1.59	5.01	0.0	0.00	16.7	18	-3.70	14.64	-50.0	0.00	16.7
	Week 35	22	3.03	8.35	0.0	0.00	33.3	19	-2.63	11.47	-33.3	0.00	16.7
	Week 38	20	2.50	8.16	0.0	0.00	33.3	17	-2.94	13.48	-33.3	0.00	33.3
	Week 41	21	1.59	5.01	0.0	0.00	16.7	17	-2.94	10.60	-33.3	0.00	16.7
	Week 44	16	1.04	4.17	0.0	0.00	16.7	12	-6.95	15.01	-50.0	0.00	0.0
	Week 47	16	8.33	25.82	0.0	0.00	100.0	13	3.85	18.20	-16.7	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	16	2.08	8.33	0.0	0.00	33.3	11	1.51	11.68	-16.7	0.00	33.3
	Week 53	15	3.33	9.34	0.0	0.00	33.3	11	-3.03	16.36	-33.3	0.00	33.3
	Week 56	17	5.88	11.70	0.0	0.00	33.3	12	-2.78	15.62	-33.3	0.00	33.3
	Week 59	17	0.98	4.04	0.0	0.00	16.7	12	-5.56	10.86	-33.3	0.00	0.0
	Week 62	14	4.76	10.19	0.0	0.00	33.3	9	-5.56	8.34	-16.7	0.00	0.0
	Week 68	11	0.00	0.00	0.0	0.00	0.0	8	-4.17	7.72	-16.7	0.00	0.0
	Week 71	11	4.55	10.78	0.0	0.00	33.3	8	-2.08	10.68	-16.7	0.00	16.7
	Plat+Gem (N= 34)												
	BASELINE	27	14.81	29.36	0.0	0.00	100.0						
	Week 1	19	4.39	12.23	0.0	0.00	50.0	17	-0.98	9.26	-16.7	0.00	16.7
	Week 2	20	7.50	11.44	0.0	0.00	33.3	18	-1.85	18.86	-50.0	0.00	33.3
	Week 3	20	5.00	7.84	0.0	0.00	16.7	17	-4.90	22.64	-66.7	0.00	16.7
	Week 4	23	3.62	7.03	0.0	0.00	16.7	19	-2.63	11.47	-33.3	0.00	16.7
	Week 5	25	7.33	11.86	0.0	0.00	50.0	22	-1.51	21.15	-66.7	0.00	33.3
	Week 6	20	2.50	6.11	0.0	0.00	16.7	17	-4.90	16.42	-50.0	0.00	16.7
	Week 7	23	7.25	13.13	0.0	0.00	50.0	20	-4.17	27.51	-83.3	0.00	50.0
	Week 8	24	7.64	12.98	0.0	0.00	50.0	22	-1.51	22.95	-66.7	0.00	50.0
	Week 9	23	5.80	9.55	0.0	0.00	33.3	19	-4.39	25.36	-83.3	0.00	33.3
	Week 10	20	10.83	22.48	0.0	0.00	100.0	18	4.63	30.14	-50.0	0.00	100.0
	Week 11	18	8.33	13.10	0.0	0.00	33.3	16	-2.08	18.13	-50.0	0.00	33.3
	Week 12	17	3.92	7.29	0.0	0.00	16.7	16	-9.37	24.32	-83.3	0.00	16.7
	Week 14	16	2.08	5.69	0.0	0.00	16.7	14	-11.90	24.83	-83.3	0.00	16.7
	Week 17	19	6.14	9.95	0.0	0.00	33.3	17	-4.90	26.85	-83.3	0.00	33.3
	Week 20	16	5.21	10.03	0.0	0.00	33.3	13	-5.13	29.17	-83.3	0.00	33.3
	Week 23	15	6.67	15.17	0.0	0.00	50.0	13	-7.69	32.36	-83.3	0.00	50.0
	Week 26	13	2.56	6.26	0.0	0.00	16.7	12	-11.11	28.72	-83.3	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 29	14	5.95	18.03	0.0	0.00	66.7	13	-6.41	34.39	-83.3	0.00	66.7
	Week 32	11	1.52	5.03	0.0	0.00	16.7	10	-13.33	26.99	-83.3	0.00	0.0
	Week 35	13	1.28	4.62	0.0	0.00	16.7	11	-13.64	25.62	-83.3	0.00	0.0
	Week 38	10	10.00	31.62	0.0	0.00	100.0	9	-5.56	34.36	-83.3	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Rest of World	EV+Pembro (N= 82)												
	BASELINE	74	5.86	14.97	0.0	0.00	100.0						
	Week 1	63	7.14	15.47	0.0	0.00	66.7	60	0.56	9.19	-33.3	0.00	33.3
	Week 2	67	15.17	24.57	0.0	0.00	100.0	63	8.99	18.89	-16.7	0.00	100.0
	Week 3	64	9.90	15.35	0.0	0.00	66.7	60	4.17	14.27	-33.3	0.00	66.7
	Week 4	64	7.55	13.26	0.0	0.00	66.7	61	2.73	13.33	-33.3	0.00	66.7
	Week 5	62	8.87	19.26	0.0	0.00	100.0	59	3.11	17.91	-33.3	0.00	100.0
	Week 6	65	8.21	18.43	0.0	0.00	100.0	62	4.03	18.03	-33.3	0.00	100.0
	Week 7	64	7.03	15.09	0.0	0.00	66.7	62	1.88	14.51	-16.7	0.00	66.7
	Week 8	67	10.45	18.99	0.0	0.00	66.7	63	4.23	16.93	-33.3	0.00	66.7
	Week 9	68	9.56	16.62	0.0	0.00	66.7	63	4.50	16.45	-33.3	0.00	66.7
	Week 10	65	9.74	18.61	0.0	0.00	66.7	61	4.64	18.79	-33.3	0.00	66.7
	Week 11	61	6.56	13.01	0.0	0.00	50.0	57	1.46	11.90	-33.3	0.00	33.3
	Week 12	62	5.65	12.05	0.0	0.00	50.0	58	0.86	13.40	-50.0	0.00	33.3
	Week 14	61	4.37	8.55	0.0	0.00	33.3	57	-0.29	9.70	-33.3	0.00	33.3
	Week 17	60	5.83	11.82	0.0	0.00	50.0	55	1.52	14.44	-50.0	0.00	50.0
	Week 20	56	3.87	9.53	0.0	0.00	33.3	52	-0.96	10.65	-33.3	0.00	33.3
	Week 23	54	3.70	8.96	0.0	0.00	33.3	50	0.33	9.81	-16.7	0.00	33.3
	Week 26	54	6.79	12.75	0.0	0.00	50.0	50	1.67	13.57	-33.3	0.00	50.0
	Week 29	50	5.00	10.78	0.0	0.00	33.3	47	1.77	12.64	-16.7	0.00	33.3
	Week 32	47	4.97	9.14	0.0	0.00	33.3	44	1.14	11.02	-16.7	0.00	33.3
	Week 35	45	4.44	11.46	0.0	0.00	50.0	42	0.79	13.25	-33.3	0.00	33.3
	Week 38	46	4.35	11.88	0.0	0.00	66.7	43	1.55	13.52	-16.7	0.00	66.7
	Week 41	46	4.71	12.50	0.0	0.00	66.7	44	2.65	13.90	-16.7	0.00	66.7
	Week 44	43	5.04	12.88	0.0	0.00	66.7	40	1.25	16.18	-33.3	0.00	66.7
	Week 47	38	3.07	8.54	0.0	0.00	33.3	36	-0.93	11.23	-16.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	32	4.69	10.57	0.0	0.00	33.3	30	0.00	14.52	-33.3	0.00	33.3
	Week 53	33	2.53	7.36	0.0	0.00	33.3	31	-2.69	11.46	-33.3	0.00	33.3
	Week 56	30	1.11	4.23	0.0	0.00	16.7	28	-3.57	10.50	-33.3	0.00	16.7
	Week 59	29	3.45	8.19	0.0	0.00	33.3	27	-1.85	12.52	-33.3	0.00	33.3
	Week 62	28	4.17	8.64	0.0	0.00	33.3	26	-1.28	13.27	-33.3	0.00	33.3
	Week 65	22	3.79	8.81	0.0	0.00	33.3	21	-2.38	13.21	-33.3	0.00	33.3
	Week 68	20	3.33	8.72	0.0	0.00	33.3	19	-3.51	14.25	-33.3	0.00	33.3
	Week 71	18	2.78	8.57	0.0	0.00	33.3	17	-4.90	14.15	-33.3	0.00	33.3
	Week 74	19	7.02	12.81	0.0	0.00	33.3	19	0.88	17.98	-33.3	0.00	33.3
	Week 77	19	7.02	16.96	0.0	0.00	66.7	18	-2.78	15.39	-33.3	0.00	33.3
	Week 80	19	7.89	17.00	0.0	0.00	50.0	18	-0.93	19.36	-33.3	0.00	50.0
	Week 83	17	8.82	14.57	0.0	0.00	33.3	17	1.96	21.15	-33.3	0.00	33.3
	Week 86	14	9.52	19.30	0.0	0.00	66.7	14	2.38	24.34	-33.3	0.00	66.7
	Week 89	11	6.06	11.24	0.0	0.00	33.3	11	-1.52	17.41	-33.3	0.00	33.3
	Plat+Gem (N= 73)												
	BASELINE	63	5.82	12.40	0.0	0.00	50.0						
	Week 1	54	15.43	23.76	0.0	0.00	83.3	53	9.12	19.22	-33.3	0.00	50.0
	Week 2	56	15.77	20.45	0.0	16.67	83.3	54	8.95	21.89	-33.3	0.00	83.3
	Week 3	57	7.60	12.63	0.0	0.00	66.7	54	2.16	15.20	-33.3	0.00	50.0
	Week 4	58	7.76	12.95	0.0	0.00	50.0	54	0.93	16.00	-50.0	0.00	33.3
	Week 5	57	7.90	12.64	0.0	0.00	50.0	53	1.57	13.97	-33.3	0.00	50.0
	Week 6	56	8.04	14.56	0.0	0.00	66.7	53	1.57	15.07	-33.3	0.00	50.0
	Week 7	56	12.20	16.36	0.0	0.00	66.7	52	6.41	17.20	-33.3	0.00	50.0
	Week 8	54	14.51	21.97	0.0	0.00	100.0	50	9.00	23.14	-50.0	0.00	100.0
	Week 9	52	8.65	14.19	0.0	0.00	50.0	49	2.72	15.35	-50.0	0.00	50.0
	Week 10	52	11.86	19.34	0.0	0.00	100.0	49	5.44	21.89	-33.3	0.00	83.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	45	11.48	16.98	0.0	0.00	66.7	42	3.97	15.96	-33.3	0.00	50.0
	Week 12	47	7.45	12.44	0.0	0.00	50.0	43	1.94	14.18	-50.0	0.00	33.3
	Week 14	43	11.24	16.95	0.0	0.00	66.7	39	7.27	13.68	-16.7	0.00	50.0
	Week 17	40	10.42	16.75	0.0	0.00	66.7	36	6.48	17.94	-33.3	0.00	66.7
	Week 20	34	5.88	11.52	0.0	0.00	33.3	30	2.78	10.80	-16.7	0.00	33.3
	Week 23	29	2.30	7.35	0.0	0.00	33.3	27	0.62	5.63	-16.7	0.00	16.7
	Week 26	26	7.69	21.20	0.0	0.00	100.0	24	1.39	14.68	-33.3	0.00	50.0
	Week 29	24	6.25	15.40	0.0	0.00	66.7	22	2.27	18.76	-50.0	0.00	66.7
	Week 32	20	3.33	10.26	0.0	0.00	33.3	18	-0.93	14.54	-50.0	0.00	33.3
	Week 35	17	3.92	11.07	0.0	0.00	33.3	15	-1.11	16.02	-50.0	0.00	33.3
	Week 38	18	5.56	14.00	0.0	0.00	50.0	15	-4.44	13.31	-50.0	0.00	0.0
	Week 41	18	2.78	8.57	0.0	0.00	33.3	16	0.00	6.09	-16.7	0.00	16.7
	Week 44	16	6.25	11.98	0.0	0.00	33.3	14	-2.38	15.82	-50.0	0.00	16.7
	Week 47	12	6.94	13.22	0.0	0.00	33.3	11	4.55	10.78	0.0	0.00	33.3
	Week 50	11	9.09	13.67	0.0	0.00	33.3	9	5.56	11.78	0.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	EV+Pembro (N=146)												
	BASELINE	119	6.58	16.98	0.0	0.00	100.0						
	Week 1	102	10.13	21.00	0.0	0.00	100.0	97	2.41	13.17	-33.3	0.00	100.0
	Week 2	106	10.53	18.87	0.0	0.00	100.0	98	6.29	18.31	-33.3	0.00	100.0
	Week 3	94	7.09	13.72	0.0	0.00	66.7	88	3.03	15.07	-33.3	0.00	66.7
	Week 4	101	6.93	12.75	0.0	0.00	66.7	93	2.69	12.36	-33.3	0.00	66.7
	Week 5	96	7.12	15.25	0.0	0.00	100.0	89	3.00	16.96	-33.3	0.00	100.0
	Week 6	105	7.62	16.18	0.0	0.00	100.0	93	4.30	17.18	-33.3	0.00	100.0
	Week 7	102	7.35	15.30	0.0	0.00	66.7	89	2.62	15.67	-33.3	0.00	66.7
	Week 8	101	7.59	15.00	0.0	0.00	66.7	91	3.48	13.50	-33.3	0.00	66.7
	Week 9	100	8.50	15.80	0.0	0.00	83.3	89	4.49	16.81	-33.3	0.00	83.3
	Week 10	99	7.07	15.63	0.0	0.00	66.7	87	2.30	18.36	-66.7	0.00	66.7
	Week 11	95	4.91	10.56	0.0	0.00	50.0	84	0.99	11.38	-33.3	0.00	33.3
	Week 12	99	4.88	11.96	0.0	0.00	50.0	87	1.15	11.59	-33.3	0.00	33.3
	Week 14	95	2.98	7.68	0.0	0.00	33.3	84	-0.60	8.75	-50.0	0.00	33.3
	Week 17	97	4.64	10.69	0.0	0.00	50.0	84	0.99	12.77	-50.0	0.00	50.0
	Week 20	90	2.96	8.13	0.0	0.00	33.3	79	-1.05	11.11	-50.0	0.00	33.3
	Week 23	86	3.10	8.29	0.0	0.00	33.3	74	0.90	9.51	-33.3	0.00	33.3
	Week 26	83	3.21	9.19	0.0	0.00	50.0	72	0.00	11.53	-33.3	0.00	50.0
	Week 29	80	2.71	8.15	0.0	0.00	33.3	71	-0.23	11.78	-50.0	0.00	33.3
	Week 32	74	3.15	7.64	0.0	0.00	33.3	66	0.00	11.69	-50.0	0.00	33.3
	Week 35	73	2.74	9.22	0.0	0.00	50.0	66	-0.25	11.51	-33.3	0.00	33.3
	Week 38	75	4.22	12.88	0.0	0.00	66.7	67	1.99	15.22	-33.3	0.00	66.7
	Week 41	71	4.23	12.19	0.0	0.00	66.7	64	1.56	13.52	-33.3	0.00	66.7
	Week 44	64	3.13	10.66	0.0	0.00	66.7	56	-0.30	14.39	-50.0	0.00	66.7
	Week 47	56	3.27	14.36	0.0	0.00	100.0	50	-0.33	10.91	-16.7	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	55	4.85	10.48	0.0	0.00	33.3	48	2.78	13.46	-33.3	0.00	33.3
	Week 53	55	5.15	13.56	0.0	0.00	66.7	48	1.74	15.84	-33.3	0.00	66.7
	Week 56	53	4.09	10.29	0.0	0.00	50.0	46	-0.72	11.09	-33.3	0.00	33.3
	Week 59	51	2.29	7.47	0.0	0.00	33.3	43	-0.78	10.88	-33.3	0.00	33.3
	Week 62	42	3.57	8.66	0.0	0.00	33.3	36	0.00	11.27	-33.3	0.00	33.3
	Week 65	31	4.84	11.54	0.0	0.00	33.3	30	1.67	14.08	-33.3	0.00	33.3
	Week 68	31	2.15	7.13	0.0	0.00	33.3	29	-0.57	11.34	-33.3	0.00	33.3
	Week 71	30	2.78	8.84	0.0	0.00	33.3	28	-1.19	11.04	-33.3	0.00	33.3
	Week 74	29	3.45	9.32	0.0	0.00	33.3	27	-1.23	14.56	-33.3	0.00	33.3
	Week 77	26	5.13	11.32	0.0	0.00	33.3	24	0.69	14.31	-33.3	0.00	33.3
	Week 80	26	8.33	17.16	0.0	0.00	66.7	26	3.21	21.61	-33.3	0.00	66.7
	Week 83	21	8.73	14.55	0.0	0.00	33.3	21	4.76	19.11	-33.3	0.00	33.3
	Week 86	17	9.80	17.74	0.0	0.00	66.7	17	5.88	22.00	-33.3	0.00	66.7
	Week 89	11	3.03	6.74	0.0	0.00	16.7	11	-1.51	13.85	-33.3	0.00	16.7
	Week 92	13	5.13	12.52	0.0	0.00	33.3	13	1.28	17.29	-33.3	0.00	33.3
	Plat+Gem (N=151)												
	BASELINE	123	6.50	15.18	0.0	0.00	100.0						
	Week 1	108	12.50	20.40	0.0	0.00	100.0	103	6.80	16.57	-33.3	0.00	50.0
	Week 2	116	12.07	20.09	0.0	0.00	100.0	105	6.35	18.69	-50.0	0.00	83.3
	Week 3	114	6.43	12.25	0.0	0.00	83.3	103	1.46	14.96	-66.7	0.00	66.7
	Week 4	116	6.61	13.35	0.0	0.00	83.3	103	1.62	14.10	-33.3	0.00	66.7
	Week 5	119	8.40	16.07	0.0	0.00	83.3	106	1.89	14.96	-66.7	0.00	66.7
	Week 6	109	6.88	15.42	0.0	0.00	83.3	98	1.02	14.72	-33.3	0.00	83.3
	Week 7	115	10.44	17.02	0.0	0.00	100.0	105	4.29	18.92	-83.3	0.00	83.3
	Week 8	111	8.86	16.64	0.0	0.00	100.0	102	3.60	19.57	-66.7	0.00	100.0
	Week 9	107	7.01	15.36	0.0	0.00	100.0	95	1.93	18.49	-83.3	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	107	9.50	18.33	0.0	0.00	100.0	98	3.74	18.92	-33.3	0.00	100.0
	Week 11	97	7.56	15.96	0.0	0.00	83.3	87	0.96	16.34	-50.0	0.00	83.3
	Week 12	100	6.00	12.43	0.0	0.00	66.7	88	0.19	14.62	-83.3	0.00	33.3
	Week 14	99	8.25	15.86	0.0	0.00	83.3	86	3.68	18.51	-83.3	0.00	66.7
	Week 17	94	8.87	14.81	0.0	0.00	66.7	82	3.66	17.57	-83.3	0.00	66.7
	Week 20	84	6.35	15.28	0.0	0.00	83.3	72	1.62	18.16	-83.3	0.00	66.7
	Week 23	70	4.52	12.34	0.0	0.00	66.7	62	-0.27	17.20	-83.3	0.00	50.0
	Week 26	61	7.38	17.62	0.0	0.00	100.0	55	1.21	18.38	-83.3	0.00	50.0
	Week 29	59	3.67	8.23	0.0	0.00	33.3	53	-1.26	14.56	-83.3	0.00	16.7
	Week 32	50	1.67	6.94	0.0	0.00	33.3	45	-2.96	13.89	-83.3	0.00	16.7
	Week 35	50	1.67	6.94	0.0	0.00	33.3	44	-3.41	14.64	-83.3	0.00	33.3
	Week 38	46	4.71	10.92	0.0	0.00	50.0	40	-2.08	15.65	-83.3	0.00	33.3
	Week 41	42	5.56	16.32	0.0	0.00	83.3	37	2.25	15.30	-16.7	0.00	66.7
	Week 44	39	7.69	17.03	0.0	0.00	83.3	34	2.45	15.42	-16.7	0.00	66.7
	Week 47	33	5.05	9.76	0.0	0.00	33.3	29	-1.72	16.27	-66.7	0.00	33.3
	Week 50	27	8.64	13.37	0.0	0.00	33.3	22	0.00	17.82	-50.0	0.00	33.3
	Week 53	23	7.97	18.03	0.0	0.00	66.7	20	-5.00	22.36	-83.3	0.00	33.3
	Week 56	20	1.67	5.13	0.0	0.00	16.7	19	-7.02	19.50	-83.3	0.00	0.0
	Week 59	17	9.80	20.46	0.0	0.00	66.7	15	-5.56	24.93	-83.3	0.00	33.3
	Week 62	14	4.76	10.19	0.0	0.00	33.3	14	-5.95	20.26	-66.7	0.00	16.7
	Week 65	13	8.97	14.62	0.0	0.00	33.3	12	4.17	14.43	-16.7	0.00	33.3
	Week 68	10	3.33	7.03	0.0	0.00	16.7	10	1.67	5.27	0.0	0.00	16.7
	Week 71	10	8.33	18.00	0.0	0.00	50.0	10	6.67	19.56	-16.7	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	EV+Pembro (N= 56)												
	BASELINE	41	7.72	13.49	0.0	0.00	50.0						
	Week 1	39	11.97	19.10	0.0	0.00	66.7	32	3.65	14.50	-16.7	0.00	66.7
	Week 2	44	15.15	25.62	0.0	0.00	100.0	35	7.62	20.35	-16.7	0.00	66.7
	Week 3	45	14.82	19.85	0.0	16.67	100.0	34	3.43	13.47	-16.7	0.00	33.3
	Week 4	44	9.47	12.66	0.0	0.00	50.0	36	1.39	13.44	-33.3	0.00	33.3
	Week 5	41	11.79	20.83	0.0	0.00	100.0	32	2.08	21.06	-16.7	0.00	100.0
	Week 6	41	12.20	17.88	0.0	0.00	66.7	31	3.23	17.96	-16.7	0.00	50.0
	Week 7	45	10.74	17.10	0.0	0.00	66.7	35	2.38	18.14	-16.7	0.00	66.7
	Week 8	46	14.13	18.91	0.0	0.00	66.7	33	5.05	19.31	-16.7	0.00	50.0
	Week 9	42	13.89	19.10	0.0	0.00	66.7	32	4.69	20.41	-33.3	0.00	66.7
	Week 10	40	15.00	24.98	0.0	0.00	100.0	31	9.14	27.50	-33.3	0.00	100.0
	Week 11	42	12.70	20.10	0.0	0.00	66.7	31	4.30	21.07	-33.3	0.00	66.7
	Week 12	43	7.75	15.58	0.0	0.00	66.7	32	-0.52	19.16	-50.0	0.00	50.0
	Week 14	44	6.44	10.30	0.0	0.00	33.3	32	-1.56	13.63	-33.3	0.00	16.7
	Week 17	35	7.62	13.00	0.0	0.00	50.0	27	-1.85	18.10	-50.0	0.00	50.0
	Week 20	30	8.89	17.36	0.0	0.00	66.7	24	2.08	22.15	-33.3	0.00	66.7
	Week 23	31	4.84	8.81	0.0	0.00	33.3	23	-2.17	12.62	-33.3	0.00	16.7
	Week 26	29	6.90	12.21	0.0	0.00	33.3	22	-0.76	15.83	-33.3	0.00	33.3
	Week 29	27	4.94	10.14	0.0	0.00	33.3	22	-2.27	13.89	-33.3	0.00	33.3
	Week 32	28	8.93	20.02	0.0	0.00	83.3	22	0.76	20.88	-16.7	0.00	83.3
	Week 35	25	6.67	15.22	0.0	0.00	66.7	20	-0.83	21.27	-33.3	0.00	66.7
	Week 38	22	7.58	21.66	0.0	0.00	100.0	19	0.88	26.34	-33.3	0.00	100.0
	Week 41	24	3.47	8.48	0.0	0.00	33.3	20	-3.33	11.60	-33.3	0.00	16.7
	Week 44	22	6.06	9.69	0.0	0.00	33.3	18	-0.93	15.63	-33.3	0.00	33.3
	Week 47	23	5.07	10.58	0.0	0.00	33.3	20	-0.83	15.74	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	19	3.51	8.92	0.0	0.00	33.3	16	-3.13	13.90	-33.3	0.00	33.3
	Week 53	19	1.75	5.26	0.0	0.00	16.7	15	-6.67	10.54	-33.3	0.00	0.0
	Week 56	19	0.88	3.82	0.0	0.00	16.7	15	-5.56	12.06	-33.3	0.00	16.7
	Week 59	18	3.70	7.13	0.0	0.00	16.7	14	-4.76	13.76	-33.3	0.00	16.7
	Week 62	20	3.33	6.84	0.0	0.00	16.7	16	-5.21	11.74	-33.3	0.00	16.7
	Week 65	12	2.78	6.49	0.0	0.00	16.7	10	-8.33	11.79	-33.3	0.00	0.0
	Week 68	15	1.11	4.30	0.0	0.00	16.7	13	-7.69	11.00	-33.3	0.00	0.0
	Week 71	12	1.39	4.81	0.0	0.00	16.7	10	-10.00	11.65	-33.3	-8.34	0.0
	Week 77	11	9.09	20.23	0.0	0.00	66.7	9	-7.41	8.78	-16.7	0.00	0.0
	Week 80	10	5.00	15.81	0.0	0.00	50.0	8	-6.25	8.63	-16.7	0.00	0.0
	Plat+Gem (N= 51)												
	BASELINE	42	9.13	19.20	0.0	0.00	83.3						
	Week 1	36	18.06	28.00	0.0	0.00	100.0	36	9.72	25.00	-16.7	0.00	100.0
	Week 2	31	18.82	21.40	0.0	16.67	83.3	30	7.22	18.92	-33.3	0.00	50.0
	Week 3	35	16.19	24.42	0.0	0.00	100.0	33	6.06	19.46	-50.0	0.00	50.0
	Week 4	34	10.30	12.98	0.0	0.00	50.0	32	1.56	18.63	-50.0	0.00	33.3
	Week 5	34	12.26	16.05	0.0	0.00	50.0	32	4.17	21.59	-66.7	0.00	50.0
	Week 6	36	9.72	15.11	0.0	0.00	50.0	33	1.52	22.19	-66.7	0.00	50.0
	Week 7	33	10.61	14.32	0.0	0.00	50.0	29	2.30	23.45	-66.7	0.00	33.3
	Week 8	34	14.71	21.23	0.0	0.00	66.7	30	5.56	23.71	-66.7	0.00	50.0
	Week 9	34	11.28	18.68	0.0	0.00	83.3	30	1.11	21.41	-50.0	0.00	50.0
	Week 10	35	11.91	20.04	0.0	0.00	100.0	32	3.65	23.47	-50.0	0.00	83.3
	Week 11	29	12.64	17.62	0.0	0.00	66.7	27	4.32	17.66	-33.3	0.00	50.0
	Week 12	30	10.00	16.14	0.0	0.00	50.0	27	0.00	23.11	-66.7	0.00	50.0
	Week 14	26	11.54	16.17	0.0	0.00	66.7	23	2.17	21.50	-50.0	0.00	50.0
	Week 17	26	10.90	14.10	0.0	0.00	50.0	24	2.08	19.85	-33.3	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 20	20	7.50	11.44	0.0	0.00	33.3	19	-0.88	20.39	-66.7	0.00	33.3
	Week 23	18	3.70	9.14	0.0	0.00	33.3	18	-1.85	11.27	-33.3	0.00	16.7
	Week 26	20	2.50	8.16	0.0	0.00	33.3	20	-8.33	19.87	-66.7	0.00	16.7
	Week 29	18	10.19	22.24	0.0	0.00	66.7	18	-1.85	33.77	-66.7	0.00	66.7
	Week 32	13	8.97	16.12	0.0	0.00	50.0	13	-6.41	28.49	-66.7	0.00	33.3
	Week 35	12	1.39	4.81	0.0	0.00	16.7	12	-15.28	22.98	-66.7	0.00	0.0
	Week 38	10	11.67	31.48	0.0	0.00	100.0	10	0.00	24.85	-50.0	0.00	50.0
	Week 41	10	5.00	11.25	0.0	0.00	33.3	10	-1.67	19.95	-50.0	0.00	33.3
	Week 44	10	11.67	31.48	0.0	0.00	100.0	10	-1.67	24.15	-50.0	0.00	50.0
	Week 47	10	5.00	11.25	0.0	0.00	33.3	10	-3.33	7.03	-16.7	0.00	0.0
	Week 56	10	1.67	5.27	0.0	0.00	16.7	10	-11.67	24.91	-66.7	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Visceral metastases	EV+Pembro (N=148)												
	BASELINE	119	7.70	17.73	0.0	0.00	100.0						
	Week 1	105	12.06	22.59	0.0	0.00	100.0	99	3.54	14.34	-33.3	0.00	100.0
	Week 2	109	13.46	23.07	0.0	0.00	100.0	100	7.83	20.30	-33.3	0.00	100.0
	Week 3	98	10.03	17.21	0.0	0.00	100.0	88	3.03	14.42	-33.3	0.00	66.7
	Week 4	103	8.42	12.97	0.0	0.00	66.7	93	3.41	12.66	-33.3	0.00	66.7
	Week 5	100	9.33	18.70	0.0	0.00	100.0	90	3.52	19.91	-33.3	0.00	100.0
	Week 6	105	9.68	17.87	0.0	0.00	100.0	90	5.37	19.16	-33.3	0.00	100.0
	Week 7	108	7.41	15.17	0.0	0.00	66.7	91	2.56	17.38	-33.3	0.00	66.7
	Week 8	105	9.68	16.31	0.0	0.00	66.7	89	4.49	15.64	-16.7	0.00	66.7
	Week 9	105	10.00	17.08	0.0	0.00	83.3	91	5.13	18.21	-33.3	0.00	83.3
	Week 10	101	8.91	18.94	0.0	0.00	100.0	86	4.07	22.71	-66.7	0.00	100.0
	Week 11	97	5.84	12.04	0.0	0.00	66.7	83	1.20	14.67	-33.3	0.00	66.7
	Week 12	100	5.00	11.73	0.0	0.00	50.0	85	0.59	14.65	-50.0	0.00	50.0
	Week 14	102	4.25	8.68	0.0	0.00	33.3	87	-0.96	11.18	-50.0	0.00	33.3
	Week 17	96	5.21	11.68	0.0	0.00	50.0	81	-0.41	15.81	-50.0	0.00	50.0
	Week 20	87	4.60	12.11	0.0	0.00	66.7	76	0.00	15.15	-50.0	0.00	66.7
	Week 23	85	3.53	8.57	0.0	0.00	33.3	71	0.23	11.44	-33.3	0.00	33.3
	Week 26	79	3.80	9.97	0.0	0.00	50.0	66	0.00	12.40	-33.3	0.00	50.0
	Week 29	72	2.78	7.91	0.0	0.00	33.3	64	-1.04	13.57	-50.0	0.00	33.3
	Week 32	71	4.46	13.79	0.0	0.00	83.3	62	-0.54	16.24	-50.0	0.00	83.3
	Week 35	70	4.29	12.27	0.0	0.00	66.7	63	0.26	15.11	-33.3	0.00	66.7
	Week 38	70	5.95	17.50	0.0	0.00	100.0	63	2.65	20.78	-33.3	0.00	100.0
	Week 41	66	4.80	12.66	0.0	0.00	66.7	60	0.56	15.02	-33.3	0.00	66.7
	Week 44	59	4.24	11.41	0.0	0.00	66.7	53	0.00	15.68	-50.0	0.00	66.7
	Week 47	52	4.17	15.44	0.0	0.00	100.0	48	-0.35	13.53	-33.3	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	49	4.08	9.94	0.0	0.00	33.3	43	0.77	13.59	-33.3	0.00	33.3
	Week 53	50	5.67	14.13	0.0	0.00	66.7	44	1.14	17.01	-33.3	0.00	66.7
	Week 56	45	4.82	11.02	0.0	0.00	50.0	39	-1.28	12.32	-33.3	0.00	33.3
	Week 59	44	3.41	8.49	0.0	0.00	33.3	38	-0.88	12.82	-33.3	0.00	33.3
	Week 62	38	4.39	9.24	0.0	0.00	33.3	33	-0.51	12.83	-33.3	0.00	33.3
	Week 65	25	4.67	11.30	0.0	0.00	33.3	24	0.00	14.74	-33.3	0.00	33.3
	Week 68	31	2.15	7.13	0.0	0.00	33.3	29	-1.15	11.73	-33.3	0.00	33.3
	Week 71	27	2.47	8.90	0.0	0.00	33.3	25	-3.33	11.79	-33.3	0.00	33.3
	Week 74	23	5.80	11.90	0.0	0.00	33.3	22	0.00	17.82	-33.3	0.00	33.3
	Week 77	24	4.17	10.13	0.0	0.00	33.3	23	-1.45	11.14	-16.7	0.00	33.3
	Week 80	22	6.06	13.16	0.0	0.00	50.0	22	1.52	16.99	-33.3	0.00	50.0
	Week 83	19	7.02	13.96	0.0	0.00	33.3	19	2.63	18.64	-33.3	0.00	33.3
	Week 86	14	10.72	19.18	0.0	0.00	66.7	14	5.95	24.12	-33.3	0.00	66.7
	Week 89	10	5.00	11.25	0.0	0.00	33.3	10	0.00	17.57	-33.3	0.00	33.3
	Week 92	11	6.06	13.48	0.0	0.00	33.3	11	1.51	18.93	-33.3	0.00	33.3
	Plat+Gem (N=157)												
	BASELINE	128	7.94	17.12	0.0	0.00	100.0						
	Week 1	111	13.51	21.26	0.0	0.00	100.0	107	7.48	18.63	-33.3	0.00	100.0
	Week 2	110	12.12	17.18	0.0	0.00	83.3	102	5.56	17.91	-50.0	0.00	83.3
	Week 3	112	8.04	13.79	0.0	0.00	83.3	103	1.94	17.04	-66.7	0.00	66.7
	Week 4	112	7.59	13.77	0.0	0.00	83.3	102	1.63	15.29	-50.0	0.00	66.7
	Week 5	113	10.03	17.47	0.0	0.00	83.3	103	2.75	16.52	-66.7	0.00	66.7
	Week 6	107	7.48	15.57	0.0	0.00	83.3	98	0.85	15.76	-50.0	0.00	83.3
	Week 7	109	11.32	17.55	0.0	0.00	100.0	100	4.50	20.63	-83.3	0.00	83.3
	Week 8	106	10.54	18.16	0.0	0.00	100.0	98	4.25	21.18	-66.7	0.00	100.0
	Week 9	105	7.30	13.85	0.0	0.00	66.7	94	0.89	18.19	-83.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	104	9.30	17.04	0.0	0.00	100.0	96	2.78	18.36	-50.0	0.00	83.3
	Week 11	91	8.79	17.27	0.0	0.00	83.3	83	1.41	17.11	-50.0	0.00	83.3
	Week 12	94	6.56	12.75	0.0	0.00	66.7	84	-0.20	16.05	-83.3	0.00	33.3
	Week 14	90	8.52	15.45	0.0	0.00	66.7	79	2.53	18.70	-83.3	0.00	66.7
	Week 17	90	10.00	15.56	0.0	0.00	66.7	80	3.75	19.84	-83.3	0.00	66.7
	Week 20	74	6.31	13.14	0.0	0.00	66.7	64	0.52	17.31	-83.3	0.00	50.0
	Week 23	63	4.50	12.77	0.0	0.00	66.7	58	-1.15	18.17	-83.3	0.00	50.0
	Week 26	55	7.27	18.08	0.0	0.00	100.0	52	-0.64	20.60	-83.3	0.00	50.0
	Week 29	53	4.72	11.50	0.0	0.00	66.7	50	-1.67	20.55	-83.3	0.00	66.7
	Week 32	42	2.78	9.68	0.0	0.00	50.0	40	-4.17	18.39	-83.3	0.00	33.3
	Week 35	39	1.28	5.90	0.0	0.00	33.3	36	-6.48	18.38	-83.3	0.00	33.3
	Week 38	37	5.41	18.03	0.0	0.00	100.0	34	-3.43	20.42	-83.3	0.00	50.0
	Week 41	33	4.55	11.98	0.0	0.00	50.0	31	0.00	15.52	-50.0	0.00	33.3
	Week 44	32	7.81	19.85	0.0	0.00	100.0	30	0.00	16.95	-50.0	0.00	50.0
	Week 47	28	5.95	10.36	0.0	0.00	33.3	26	-3.21	17.01	-66.7	0.00	33.3
	Week 50	22	9.09	14.30	0.0	0.00	33.3	20	0.00	19.50	-50.0	0.00	33.3
	Week 53	19	4.39	12.23	0.0	0.00	50.0	17	-7.84	22.14	-83.3	0.00	16.7
	Week 56	18	2.78	6.39	0.0	0.00	16.7	17	-9.80	22.87	-83.3	0.00	0.0
	Week 59	13	8.97	17.50	0.0	0.00	50.0	12	-9.72	30.53	-83.3	0.00	33.3
	Week 62	11	6.06	11.24	0.0	0.00	33.3	11	-12.12	24.82	-66.7	0.00	16.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Lymph node only	EV+Pembro (N= 43)												
	BASELINE	33	5.56	10.76	0.0	0.00	33.3						
	Week 1	30	7.78	12.17	0.0	0.00	50.0	24	0.00	10.99	-33.3	0.00	16.7
	Week 2	34	7.84	14.35	0.0	0.00	50.0	27	1.85	12.52	-33.3	0.00	33.3
	Week 3	35	8.57	14.22	0.0	0.00	50.0	28	2.38	15.52	-33.3	0.00	50.0
	Week 4	36	6.02	12.69	0.0	0.00	50.0	30	-1.67	12.65	-33.3	0.00	33.3
	Week 5	33	7.07	12.52	0.0	0.00	50.0	27	0.62	11.77	-33.3	0.00	33.3
	Week 6	34	6.37	12.32	0.0	0.00	50.0	28	0.00	11.11	-33.3	0.00	16.7
	Week 7	34	11.77	18.59	0.0	0.00	50.0	28	1.79	13.86	-16.7	0.00	50.0
	Week 8	35	9.52	17.75	0.0	0.00	66.7	29	1.72	14.33	-33.3	0.00	50.0
	Week 9	30	10.00	17.29	0.0	0.00	66.7	24	1.39	16.97	-33.3	0.00	50.0
	Week 10	31	9.68	18.65	0.0	0.00	66.7	26	3.85	18.44	-33.3	0.00	66.7
	Week 11	34	9.80	17.94	0.0	0.00	66.7	27	3.09	15.36	-33.3	0.00	50.0
	Week 12	35	6.67	14.12	0.0	0.00	50.0	28	0.60	13.21	-33.3	0.00	33.3
	Week 14	30	3.89	9.47	0.0	0.00	33.3	23	-1.45	6.95	-16.7	0.00	16.7
	Week 17	30	6.67	11.24	0.0	0.00	33.3	24	2.08	8.95	-16.7	0.00	16.7
	Week 20	27	3.09	8.06	0.0	0.00	33.3	21	-3.97	10.41	-33.3	0.00	16.7
	Week 23	27	3.70	8.44	0.0	0.00	33.3	21	-0.79	6.40	-16.7	0.00	16.7
	Week 26	27	4.94	10.14	0.0	0.00	33.3	22	-2.27	12.90	-33.3	0.00	16.7
	Week 29	28	2.98	7.93	0.0	0.00	33.3	23	-1.45	6.95	-16.7	0.00	16.7
	Week 32	24	6.25	9.60	0.0	0.00	33.3	20	1.67	9.21	-16.7	0.00	16.7
	Week 35	22	1.52	4.91	0.0	0.00	16.7	18	-4.63	9.58	-33.3	0.00	0.0
	Week 38	21	2.38	5.98	0.0	0.00	16.7	17	-1.96	5.54	-16.7	0.00	0.0
	Week 41	22	2.27	7.79	0.0	0.00	33.3	17	-0.98	7.15	-16.7	0.00	16.7
	Week 44	22	2.27	5.86	0.0	0.00	16.7	16	-4.17	9.62	-33.3	0.00	0.0
	Week 47	21	2.38	5.98	0.0	0.00	16.7	16	-3.13	6.72	-16.7	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	5.00	9.52	0.0	0.00	33.3	16	1.04	14.23	-33.3	0.00	33.3
	Week 53	18	1.85	5.39	0.0	0.00	16.7	14	-4.76	10.19	-33.3	0.00	0.0
	Week 56	21	0.79	3.64	0.0	0.00	16.7	17	-3.92	11.07	-33.3	0.00	16.7
	Week 59	21	1.59	5.01	0.0	0.00	16.7	16	-4.17	9.62	-33.3	0.00	0.0
	Week 62	19	2.63	6.25	0.0	0.00	16.7	15	-4.44	9.89	-33.3	0.00	0.0
	Week 65	16	4.17	9.62	0.0	0.00	33.3	14	-2.38	14.41	-33.3	0.00	33.3
	Week 68	13	1.28	4.62	0.0	0.00	16.7	11	-7.58	11.46	-33.3	0.00	0.0
	Week 71	13	2.56	6.26	0.0	0.00	16.7	11	-4.55	13.10	-33.3	0.00	16.7
	Week 74	13	1.28	4.62	0.0	0.00	16.7	11	-6.06	11.24	-33.3	0.00	0.0
	Week 77	13	10.26	19.88	0.0	0.00	66.7	10	-1.67	18.34	-33.3	0.00	33.3
	Week 80	13	10.26	22.09	0.0	0.00	66.7	11	0.00	25.82	-33.3	0.00	66.7
	Week 83	11	4.55	10.78	0.0	0.00	33.3	10	-3.33	18.92	-33.3	0.00	33.3
	Week 86	11	3.03	6.74	0.0	0.00	16.7	10	-5.00	13.72	-33.3	0.00	16.7
	Plat+Gem (N= 37)												
	BASELINE	29	5.17	14.16	0.0	0.00	66.7						
	Week 1	26	19.23	28.94	0.0	0.00	100.0	25	10.67	22.51	-33.3	0.00	66.7
	Week 2	30	21.67	29.73	0.0	0.00	100.0	26	12.82	22.26	-33.3	0.00	66.7
	Week 3	30	12.78	24.64	0.0	0.00	100.0	26	5.77	14.10	-33.3	0.00	33.3
	Week 4	32	8.33	12.70	0.0	0.00	50.0	27	2.47	16.48	-50.0	0.00	33.3
	Week 5	33	8.59	11.87	0.0	0.00	33.3	28	2.38	19.09	-66.7	0.00	33.3
	Week 6	32	9.38	15.80	0.0	0.00	66.7	27	3.09	21.70	-66.7	0.00	50.0
	Week 7	31	9.14	12.79	0.0	0.00	50.0	26	1.92	19.05	-66.7	0.00	33.3
	Week 8	32	9.90	17.38	0.0	0.00	66.7	27	3.09	18.51	-66.7	0.00	50.0
	Week 9	30	11.67	23.63	0.0	0.00	100.0	25	5.33	23.92	-50.0	0.00	100.0
	Week 10	30	15.00	24.89	0.0	0.00	100.0	26	8.33	27.18	-33.3	0.00	100.0
	Week 11	29	9.20	14.49	0.0	0.00	50.0	25	2.67	15.72	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.17.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 12	28	8.93	16.66	0.0	0.00	50.0	23	0.72	21.60	-66.7	0.00	50.0
	Week 14	28	11.31	18.73	0.0	0.00	83.3	23	6.52	22.33	-50.0	0.00	66.7
	Week 17	25	8.67	11.90	0.0	0.00	33.3	21	3.17	11.33	-33.3	0.00	16.7
	Week 20	23	9.42	19.99	0.0	0.00	83.3	20	4.17	24.71	-66.7	0.00	66.7
	Week 23	20	5.00	9.52	0.0	0.00	33.3	17	1.96	8.09	-16.7	0.00	16.7
	Week 26	21	4.76	10.73	0.0	0.00	33.3	18	-2.78	17.39	-66.7	0.00	16.7
	Week 29	19	7.89	17.89	0.0	0.00	66.7	16	0.00	25.09	-66.7	0.00	66.7
	Week 32	18	4.63	11.15	0.0	0.00	33.3	15	-3.33	19.11	-66.7	0.00	16.7
	Week 35	19	2.63	8.36	0.0	0.00	33.3	16	-5.21	16.91	-66.7	0.00	0.0
	Week 38	15	8.89	13.90	0.0	0.00	50.0	12	2.78	9.62	-16.7	0.00	16.7
	Week 41	15	7.78	22.59	0.0	0.00	83.3	12	4.17	20.26	-16.7	0.00	66.7
	Week 44	14	11.90	23.95	0.0	0.00	83.3	11	6.06	21.44	-16.7	0.00	66.7
	Week 47	12	4.17	10.36	0.0	0.00	33.3	10	0.00	7.86	-16.7	0.00	16.7
	Week 50	11	6.06	11.24	0.0	0.00	33.3	8	0.00	0.00	0.0	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
EV+Pembro (N=240)												
BASELINE	206	11.00	19.42	0.0	0.00	100.0						
Week 1	190	12.28	20.89	0.0	0.00	100.0	184	2.35	18.12	-33.3	0.00	66.7
Week 2	203	13.30	21.58	0.0	0.00	100.0	189	3.00	20.26	-66.7	0.00	66.7
Week 3	198	16.83	24.62	0.0	0.00	100.0	182	6.04	21.46	-66.7	0.00	100.0
Week 4	194	13.40	22.59	0.0	0.00	100.0	179	3.72	21.17	-66.7	0.00	100.0
Week 5	190	13.86	23.53	0.0	0.00	100.0	173	4.62	23.66	-66.7	0.00	100.0
Week 6	188	11.70	19.93	0.0	0.00	100.0	170	3.53	20.20	-66.7	0.00	100.0
Week 7	195	14.70	21.41	0.0	0.00	100.0	176	4.36	22.25	-66.7	0.00	100.0
Week 8	191	13.09	21.02	0.0	0.00	100.0	171	4.48	22.27	-66.7	0.00	100.0
Week 9	197	15.23	22.95	0.0	0.00	100.0	180	6.11	22.42	-66.7	0.00	100.0
Week 10	191	13.61	21.10	0.0	0.00	100.0	175	2.67	22.16	-66.7	0.00	100.0
Week 11	194	15.63	22.29	0.0	0.00	100.0	175	5.14	22.72	-66.7	0.00	66.7
Week 12	186	16.13	22.79	0.0	0.00	100.0	171	6.04	22.78	-66.7	0.00	100.0
Week 14	185	15.13	22.77	0.0	0.00	100.0	167	3.59	24.55	-66.7	0.00	100.0
Week 17	178	13.48	21.09	0.0	0.00	100.0	162	4.94	22.97	-66.7	0.00	100.0
Week 20	167	17.16	25.57	0.0	0.00	100.0	154	7.14	26.94	-66.7	0.00	100.0
Week 23	162	16.87	24.71	0.0	0.00	100.0	151	6.84	27.30	-66.7	0.00	100.0
Week 26	156	14.32	18.97	0.0	0.00	66.7	144	4.86	21.94	-66.7	0.00	66.7
Week 29	157	13.59	19.95	0.0	0.00	100.0	145	4.60	23.45	-66.7	0.00	66.7
Week 32	135	14.57	19.79	0.0	0.00	100.0	125	4.27	23.56	-66.7	0.00	66.7
Week 35	132	12.88	20.86	0.0	0.00	100.0	122	4.10	20.81	-66.7	0.00	66.7
Week 38	132	15.40	21.95	0.0	0.00	100.0	124	5.65	21.56	-33.3	0.00	66.7
Week 41	129	15.50	23.22	0.0	0.00	100.0	119	6.16	24.92	-66.7	0.00	66.7
Week 44	108	17.90	23.43	0.0	0.00	100.0	100	8.67	23.98	-66.7	0.00	66.7
Week 47	100	14.33	22.85	0.0	0.00	100.0	94	4.61	24.73	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	89	13.86	23.47	0.0	0.00	100.0	84	5.56	26.80	-33.3	0.00	100.0
Week 53	79	12.24	19.38	0.0	0.00	66.7	74	2.70	20.46	-33.3	0.00	66.7
Week 56	81	12.34	20.71	0.0	0.00	100.0	76	4.39	25.73	-66.7	0.00	100.0
Week 59	72	12.50	20.51	0.0	0.00	100.0	68	3.92	25.45	-66.7	0.00	100.0
Week 62	65	12.31	21.71	0.0	0.00	100.0	63	4.76	26.68	-66.7	0.00	100.0
Week 65	58	13.79	25.00	0.0	0.00	100.0	54	5.56	30.20	-66.7	0.00	100.0
Week 68	53	14.46	24.03	0.0	0.00	100.0	52	6.41	29.55	-66.7	0.00	100.0
Week 71	51	12.42	23.06	0.0	0.00	100.0	49	5.44	29.14	-66.7	0.00	100.0
Week 74	47	11.35	21.17	0.0	0.00	100.0	46	3.62	26.51	-66.7	0.00	100.0
Week 77	44	13.64	19.45	0.0	0.00	66.7	42	4.76	26.10	-66.7	0.00	66.7
Week 80	40	15.00	21.28	0.0	0.00	66.7	37	4.50	26.25	-33.3	0.00	66.7
Week 83	37	12.61	18.17	0.0	0.00	66.7	35	2.86	21.95	-33.3	0.00	33.3
Week 86	34	15.69	22.07	0.0	0.00	66.7	31	4.30	22.35	-33.3	0.00	66.7
Week 89	33	17.17	22.24	0.0	0.00	66.7	31	6.45	23.44	-33.3	0.00	66.7
Week 92	27	12.35	20.98	0.0	0.00	66.7	25	4.00	22.19	-33.3	0.00	66.7
Week 95	22	12.12	21.93	0.0	0.00	66.7	21	7.94	23.34	-33.3	0.00	66.7
Week 98	18	9.26	15.36	0.0	0.00	33.3	17	-1.96	18.52	-33.3	0.00	33.3
Week 101	14	14.29	25.20	0.0	0.00	66.7	14	4.76	22.10	-33.3	0.00	66.7
Week 104	10	13.33	23.31	0.0	0.00	66.7	10	6.67	26.29	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Plat+Gem (N=242)												
BASELINE	188	15.07	22.15	0.0	0.00	100.0						
Week 1	173	13.68	23.00	0.0	0.00	100.0	158	-1.69	19.11	-66.7	0.00	66.7
Week 2	171	15.79	23.52	0.0	0.00	100.0	151	0.88	21.41	-66.7	0.00	100.0
Week 3	184	16.48	24.14	0.0	0.00	100.0	162	1.85	20.43	-66.7	0.00	66.7
Week 4	183	16.21	23.14	0.0	0.00	100.0	156	1.50	22.51	-33.3	0.00	100.0
Week 5	187	17.65	24.51	0.0	0.00	100.0	156	4.06	22.83	-66.7	0.00	66.7
Week 6	174	17.24	24.50	0.0	0.00	100.0	149	3.58	23.29	-66.7	0.00	66.7
Week 7	186	17.02	24.32	0.0	0.00	100.0	157	3.40	21.41	-66.7	0.00	66.7
Week 8	167	20.36	26.85	0.0	0.00	100.0	144	7.18	24.98	-33.3	0.00	66.7
Week 9	177	19.58	25.24	0.0	0.00	100.0	150	6.44	26.11	-66.7	0.00	100.0
Week 10	166	21.69	26.43	0.0	0.00	100.0	139	7.91	23.94	-33.3	0.00	66.7
Week 11	168	21.63	28.05	0.0	0.00	100.0	143	6.53	25.10	-66.7	0.00	66.7
Week 12	159	19.29	25.54	0.0	0.00	100.0	138	6.28	24.01	-66.7	0.00	66.7
Week 14	153	21.79	26.58	0.0	0.00	100.0	128	9.38	26.10	-66.7	0.00	66.7
Week 17	155	20.86	25.81	0.0	0.00	100.0	130	7.95	26.19	-66.7	0.00	66.7
Week 20	126	19.84	24.29	0.0	0.00	100.0	110	9.09	24.28	-33.3	0.00	100.0
Week 23	115	16.23	23.92	0.0	0.00	100.0	97	7.90	22.45	-33.3	0.00	100.0
Week 26	108	15.12	20.58	0.0	0.00	66.7	95	4.91	20.61	-33.3	0.00	66.7
Week 29	100	14.33	22.35	0.0	0.00	100.0	86	5.04	23.72	-33.3	0.00	100.0
Week 32	83	12.05	16.93	0.0	0.00	66.7	76	2.63	20.19	-66.7	0.00	33.3
Week 35	76	15.79	20.71	0.0	0.00	66.7	69	5.80	21.36	-66.7	0.00	66.7
Week 38	74	17.57	24.81	0.0	0.00	100.0	65	7.69	24.84	-66.7	0.00	100.0
Week 41	65	16.41	22.14	0.0	0.00	100.0	56	6.55	26.53	-66.7	0.00	100.0
Week 44	60	19.44	26.25	0.0	0.00	100.0	53	9.43	29.51	-66.7	0.00	100.0
Week 47	56	17.26	23.78	0.0	0.00	100.0	49	4.76	20.41	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	51	16.99	24.38	0.0	0.00	100.0	47	6.38	26.59	-66.7	0.00	100.0
Week 53	46	14.49	20.67	0.0	0.00	66.7	42	4.76	20.26	-33.3	0.00	33.3
Week 56	39	18.80	26.26	0.0	0.00	100.0	34	6.86	21.37	-33.3	0.00	66.7
Week 59	37	15.31	21.65	0.0	0.00	100.0	33	4.04	19.99	-33.3	0.00	33.3
Week 62	32	17.71	18.90	0.0	16.67	66.7	29	8.05	21.18	-33.3	0.00	33.3
Week 65	30	18.89	25.79	0.0	0.00	100.0	26	6.41	23.13	-33.3	0.00	66.7
Week 68	25	20.00	27.22	0.0	0.00	100.0	21	4.76	26.43	-33.3	0.00	66.7
Week 71	22	21.21	28.26	0.0	0.00	100.0	19	8.77	26.86	-33.3	0.00	66.7
Week 74	21	19.05	24.88	0.0	0.00	100.0	18	3.70	19.43	-33.3	0.00	33.3
Week 77	18	18.52	30.73	0.0	0.00	100.0	15	0.00	25.20	-33.3	0.00	66.7
Week 80	14	11.90	16.57	0.0	0.00	33.3	13	0.00	19.24	-33.3	0.00	33.3
Week 83	13	12.82	16.88	0.0	0.00	33.3	12	0.00	24.62	-33.3	0.00	33.3
Week 86	12	11.11	16.41	0.0	0.00	33.3	11	0.00	21.08	-33.3	0.00	33.3
Week 89	11	15.15	17.41	0.0	0.00	33.3	10	3.33	24.59	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Present	EV+Pembro (N= 48)												
	BASELINE	39	17.09	24.03	0.0	0.00	100.0						
	Week 1	32	18.75	26.69	0.0	0.00	100.0	32	2.08	26.69	-33.3	0.00	66.7
	Week 2	37	20.72	26.47	0.0	0.00	66.7	33	6.06	30.57	-66.7	0.00	66.7
	Week 3	34	26.47	24.32	0.0	33.33	66.7	29	5.75	23.69	-33.3	0.00	66.7
	Week 4	36	20.37	24.27	0.0	0.00	66.7	31	6.45	26.41	-33.3	0.00	66.7
	Week 5	30	25.55	28.61	0.0	33.33	100.0	24	12.50	35.18	-33.3	0.00	100.0
	Week 6	31	17.20	25.63	0.0	0.00	100.0	25	8.00	32.32	-66.7	0.00	100.0
	Week 7	34	21.57	24.46	0.0	33.33	100.0	28	3.57	29.17	-33.3	0.00	100.0
	Week 8	35	18.09	20.36	0.0	0.00	66.7	30	2.22	26.16	-66.7	0.00	66.7
	Week 9	34	17.65	23.55	0.0	0.00	66.7	30	2.22	28.94	-66.7	0.00	66.7
	Week 10	34	18.63	24.88	0.0	0.00	100.0	30	2.22	34.94	-66.7	0.00	100.0
	Week 11	33	23.23	24.27	0.0	33.33	66.7	28	8.33	35.86	-66.7	0.00	66.7
	Week 12	33	20.20	23.48	0.0	0.00	66.7	29	5.75	29.64	-66.7	0.00	66.7
	Week 14	31	16.13	24.15	0.0	0.00	100.0	26	0.00	33.99	-66.7	0.00	100.0
	Week 17	31	17.20	22.56	0.0	0.00	100.0	25	2.67	31.80	-66.7	0.00	100.0
	Week 20	27	17.28	26.75	0.0	0.00	100.0	24	0.00	36.78	-66.7	0.00	100.0
	Week 23	26	17.95	27.05	0.0	0.00	100.0	23	0.00	38.93	-66.7	0.00	100.0
	Week 26	25	14.67	16.89	0.0	0.00	33.3	22	-3.03	20.34	-66.7	0.00	33.3
	Week 29	23	5.80	12.92	0.0	0.00	33.3	22	-7.58	22.84	-66.7	0.00	33.3
	Week 32	21	12.70	16.59	0.0	0.00	33.3	19	-7.02	23.78	-66.7	0.00	33.3
	Week 35	19	15.79	20.39	0.0	0.00	66.7	17	0.00	23.57	-66.7	0.00	33.3
	Week 38	18	18.52	20.52	0.0	16.67	66.7	17	3.92	23.22	-33.3	0.00	66.7
	Week 41	20	20.00	25.13	0.0	0.00	66.7	19	0.00	35.14	-66.7	0.00	66.7
	Week 44	17	19.61	23.74	0.0	0.00	66.7	15	2.22	32.04	-66.7	0.00	66.7
	Week 47	18	14.81	20.52	0.0	0.00	66.7	16	2.08	28.46	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	12	22.22	32.82	0.0	0.00	100.0	11	9.09	33.63	-33.3	0.00	100.0
	Week 53	12	16.67	26.59	0.0	0.00	66.7	11	3.03	27.71	-33.3	0.00	66.7
	Week 56	13	10.26	21.01	0.0	0.00	66.7	12	-5.56	31.25	-66.7	0.00	66.7
	Week 59	12	11.11	21.71	0.0	0.00	66.7	11	-3.03	34.82	-66.7	0.00	66.7
	Week 62	10	16.67	32.39	0.0	0.00	100.0	9	3.70	45.47	-66.7	0.00	100.0
	Week 65	10	13.33	32.20	0.0	0.00	100.0	9	0.00	44.10	-66.7	0.00	100.0
	Plat+Gem (N= 48)												
	BASELINE	33	15.15	16.85	0.0	0.00	33.3						
	Week 1	31	11.83	22.02	0.0	0.00	100.0	27	-2.47	18.32	-33.3	0.00	66.7
	Week 2	29	12.64	18.72	0.0	0.00	66.7	24	-4.17	14.95	-33.3	0.00	33.3
	Week 3	32	13.54	18.66	0.0	0.00	66.7	27	-3.70	19.24	-33.3	0.00	33.3
	Week 4	32	13.54	18.66	0.0	0.00	66.7	24	-2.78	16.79	-33.3	0.00	33.3
	Week 5	36	12.96	21.50	0.0	0.00	100.0	28	-2.38	22.09	-33.3	0.00	33.3
	Week 6	35	16.19	24.75	0.0	0.00	100.0	27	0.00	26.15	-33.3	0.00	66.7
	Week 7	38	15.79	21.56	0.0	0.00	66.7	29	-1.15	18.86	-33.3	0.00	33.3
	Week 8	31	13.98	16.72	0.0	0.00	33.3	25	-1.33	22.52	-33.3	0.00	33.3
	Week 9	32	14.58	22.30	0.0	0.00	100.0	25	-1.33	22.52	-33.3	0.00	66.7
	Week 10	34	15.69	24.94	0.0	0.00	100.0	26	-2.56	22.94	-33.3	0.00	33.3
	Week 11	30	15.56	22.71	0.0	0.00	66.7	24	-2.78	21.79	-33.3	0.00	33.3
	Week 12	28	14.28	19.09	0.0	0.00	66.7	23	-1.45	21.27	-33.3	0.00	33.3
	Week 14	26	16.67	19.44	0.0	0.00	66.7	21	0.00	23.57	-33.3	0.00	33.3
	Week 17	30	15.56	22.71	0.0	0.00	66.7	25	0.00	25.46	-33.3	0.00	66.7
	Week 20	23	14.49	22.08	0.0	0.00	66.7	21	-1.59	22.30	-33.3	0.00	33.3
	Week 23	22	13.64	30.27	0.0	0.00	100.0	19	3.51	26.98	-33.3	0.00	66.7
	Week 26	19	10.53	22.37	0.0	0.00	66.7	18	0.00	19.80	-33.3	0.00	33.3
	Week 29	16	10.42	20.07	0.0	0.00	66.7	14	0.00	18.49	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 32	11	18.18	22.92	0.0	0.00	66.7	11	3.03	17.98	-33.3	0.00	33.3
	Week 35	10	20.00	23.31	0.0	16.67	66.7	9	7.41	14.70	0.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Absent	EV+Pembro (N=192)												
	BASELINE	167	9.58	17.96	0.0	0.00	66.7						
	Week 1	158	10.97	19.35	0.0	0.00	100.0	152	2.41	15.86	-33.3	0.00	66.7
	Week 2	166	11.65	20.06	0.0	0.00	100.0	156	2.35	17.40	-66.7	0.00	66.7
	Week 3	164	14.84	24.28	0.0	0.00	100.0	153	6.10	21.10	-66.7	0.00	100.0
	Week 4	158	11.81	21.96	0.0	0.00	100.0	148	3.15	19.95	-66.7	0.00	100.0
	Week 5	160	11.67	21.86	0.0	0.00	100.0	149	3.36	21.13	-66.7	0.00	100.0
	Week 6	157	10.61	18.50	0.0	0.00	100.0	145	2.76	17.35	-33.3	0.00	66.7
	Week 7	161	13.25	20.51	0.0	0.00	100.0	148	4.50	20.81	-66.7	0.00	100.0
	Week 8	156	11.96	21.06	0.0	0.00	100.0	141	4.96	21.43	-33.3	0.00	100.0
	Week 9	163	14.72	22.86	0.0	0.00	100.0	150	6.89	20.90	-33.3	0.00	100.0
	Week 10	157	12.53	20.12	0.0	0.00	100.0	145	2.76	18.63	-33.3	0.00	66.7
	Week 11	161	14.08	21.61	0.0	0.00	100.0	147	4.53	19.37	-66.7	0.00	66.7
	Week 12	153	15.25	22.62	0.0	0.00	100.0	142	6.10	21.24	-33.3	0.00	100.0
	Week 14	154	14.93	22.56	0.0	0.00	100.0	141	4.26	22.48	-66.7	0.00	100.0
	Week 17	147	12.70	20.77	0.0	0.00	100.0	137	5.35	21.09	-66.7	0.00	100.0
	Week 20	140	17.14	25.44	0.0	0.00	100.0	130	8.46	24.66	-66.7	0.00	100.0
	Week 23	136	16.67	24.34	0.0	0.00	100.0	128	8.07	24.66	-33.3	0.00	100.0
	Week 26	131	14.25	19.41	0.0	0.00	66.7	122	6.28	21.99	-66.7	0.00	66.7
	Week 29	134	14.92	20.67	0.0	0.00	100.0	123	6.77	22.97	-66.7	0.00	66.7
	Week 32	114	14.91	20.37	0.0	0.00	100.0	106	6.29	23.05	-66.7	0.00	66.7
	Week 35	113	12.39	20.98	0.0	0.00	100.0	105	4.76	20.37	-33.3	0.00	66.7
	Week 38	114	14.91	22.21	0.0	0.00	100.0	107	5.92	21.38	-33.3	0.00	66.7
	Week 41	109	14.68	22.87	0.0	0.00	100.0	100	7.33	22.51	-33.3	0.00	66.7
	Week 44	91	17.58	23.49	0.0	0.00	100.0	85	9.80	22.31	-33.3	0.00	66.7
	Week 47	82	14.23	23.44	0.0	0.00	100.0	78	5.13	24.07	-33.3	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	77	12.55	21.66	0.0	0.00	66.7	73	5.02	25.86	-33.3	0.00	66.7
	Week 53	67	11.44	17.93	0.0	0.00	66.7	63	2.65	19.21	-33.3	0.00	66.7
	Week 56	68	12.74	20.79	0.0	0.00	100.0	64	6.25	24.40	-33.3	0.00	100.0
	Week 59	60	12.78	20.44	0.0	0.00	100.0	57	5.26	23.39	-33.3	0.00	100.0
	Week 62	55	11.51	19.48	0.0	0.00	100.0	54	4.94	22.81	-33.3	0.00	100.0
	Week 65	48	13.89	23.65	0.0	0.00	100.0	45	6.67	27.15	-33.3	0.00	100.0
	Week 68	46	14.49	23.99	0.0	0.00	100.0	45	8.15	27.67	-33.3	0.00	100.0
	Week 71	44	11.36	20.26	0.0	0.00	100.0	42	6.35	24.68	-33.3	0.00	100.0
	Week 74	40	10.83	20.52	0.0	0.00	100.0	39	5.13	23.62	-33.3	0.00	100.0
	Week 77	38	13.16	18.24	0.0	0.00	66.7	36	6.48	22.28	-33.3	0.00	66.7
	Week 80	35	13.33	18.43	0.0	0.00	66.7	32	5.21	24.11	-33.3	0.00	66.7
	Week 83	32	11.46	16.08	0.0	0.00	33.3	30	4.44	20.96	-33.3	0.00	33.3
	Week 86	29	12.64	18.72	0.0	0.00	66.7	26	3.85	19.61	-33.3	0.00	33.3
	Week 89	29	14.94	19.08	0.0	0.00	66.7	27	7.41	19.24	-33.3	0.00	33.3
	Week 92	24	11.11	18.82	0.0	0.00	66.7	22	1.52	19.18	-33.3	0.00	33.3
	Week 95	20	10.00	19.04	0.0	0.00	66.7	19	5.26	20.07	-33.3	0.00	66.7
	Week 98	18	9.26	15.36	0.0	0.00	33.3	17	-1.96	18.52	-33.3	0.00	33.3
	Week 101	13	10.26	21.01	0.0	0.00	66.7	13	0.00	13.61	-33.3	0.00	33.3
	Plat+Gem (N=194)												
	BASELINE	155	15.05	23.17	0.0	0.00	100.0						
	Week 1	142	14.08	23.26	0.0	0.00	100.0	131	-1.53	19.33	-66.7	0.00	66.7
	Week 2	142	16.43	24.39	0.0	0.00	100.0	127	1.84	22.34	-66.7	0.00	100.0
	Week 3	152	17.10	25.15	0.0	0.00	100.0	135	2.96	20.55	-66.7	0.00	66.7
	Week 4	151	16.78	24.00	0.0	0.00	100.0	132	2.27	23.37	-33.3	0.00	100.0
	Week 5	151	18.76	25.11	0.0	0.00	100.0	128	5.47	22.83	-66.7	0.00	66.7
	Week 6	139	17.51	24.52	0.0	0.00	100.0	122	4.37	22.66	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 7	148	17.34	25.04	0.0	0.00	100.0	128	4.43	21.88	-66.7	0.00	66.7
	Week 8	136	21.81	28.51	0.0	0.00	100.0	119	8.96	25.19	-33.3	0.00	66.7
	Week 9	145	20.69	25.78	0.0	0.00	100.0	125	8.00	26.57	-66.7	0.00	100.0
	Week 10	132	23.23	26.67	0.0	33.33	100.0	113	10.32	23.60	-33.3	0.00	66.7
	Week 11	138	22.95	28.99	0.0	0.00	100.0	119	8.40	25.39	-66.7	0.00	66.7
	Week 12	131	20.36	26.66	0.0	0.00	100.0	115	7.83	24.32	-66.7	0.00	66.7
	Week 14	127	22.83	27.76	0.0	0.00	100.0	107	11.21	26.28	-66.7	0.00	66.7
	Week 17	125	22.13	26.42	0.0	0.00	100.0	105	9.84	26.12	-66.7	0.00	66.7
	Week 20	103	21.03	24.69	0.0	0.00	100.0	89	11.61	24.15	-33.3	0.00	100.0
	Week 23	93	16.84	22.32	0.0	0.00	100.0	78	8.97	21.27	-33.3	0.00	100.0
	Week 26	89	16.10	20.17	0.0	0.00	66.7	77	6.06	20.75	-33.3	0.00	66.7
	Week 29	84	15.08	22.79	0.0	0.00	100.0	72	6.02	24.59	-33.3	0.00	100.0
	Week 32	72	11.11	15.82	0.0	0.00	33.3	65	2.56	20.67	-66.7	0.00	33.3
	Week 35	66	15.15	20.41	0.0	0.00	66.7	60	5.56	22.27	-66.7	0.00	66.7
	Week 38	66	17.68	24.96	0.0	0.00	100.0	57	7.60	25.99	-66.7	0.00	100.0
	Week 41	62	16.13	22.37	0.0	0.00	100.0	53	6.29	27.00	-66.7	0.00	100.0
	Week 44	55	17.58	24.72	0.0	0.00	100.0	48	7.64	27.71	-66.7	0.00	100.0
	Week 47	51	16.34	24.38	0.0	0.00	100.0	44	3.79	20.61	-66.7	0.00	66.7
	Week 50	48	17.36	24.78	0.0	0.00	100.0	44	7.58	26.77	-66.7	0.00	100.0
	Week 53	41	14.63	21.15	0.0	0.00	66.7	37	4.50	21.03	-33.3	0.00	33.3
	Week 56	34	17.65	26.25	0.0	0.00	100.0	29	5.75	21.95	-33.3	0.00	66.7
	Week 59	32	16.67	22.40	0.0	0.00	100.0	28	4.76	21.68	-33.3	0.00	33.3
	Week 62	27	17.28	19.33	0.0	0.00	66.7	24	6.94	21.93	-33.3	0.00	33.3
	Week 65	25	17.33	25.68	0.0	0.00	100.0	21	3.17	20.83	-33.3	0.00	33.3
	Week 68	23	18.84	28.12	0.0	0.00	100.0	19	3.51	26.98	-33.3	0.00	66.7
	Week 71	21	20.63	28.82	0.0	0.00	100.0	18	7.41	26.95	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 74	20	18.33	25.30	0.0	0.00	100.0	17	3.92	20.01	-33.3	0.00	33.3
	Week 77	16	18.75	32.13	0.0	0.00	100.0	13	2.56	25.32	-33.3	0.00	66.7
	Week 80	12	11.11	16.41	0.0	0.00	33.3	11	3.03	17.98	-33.3	0.00	33.3
	Week 83	11	12.12	16.82	0.0	0.00	33.3	10	3.33	24.59	-33.3	0.00	33.3
	Week 86	10	10.00	16.10	0.0	0.00	33.3	9	3.70	20.03	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
< 65 years	EV+Pembro (N=105)												
	BASELINE	92	11.59	21.22	0.0	0.00	100.0						
	Week 1	88	12.50	20.41	0.0	0.00	66.7	85	2.74	19.39	-33.3	0.00	66.7
	Week 2	92	11.59	19.41	0.0	0.00	66.7	86	0.78	19.12	-66.7	0.00	66.7
	Week 3	93	18.28	27.15	0.0	0.00	100.0	84	6.75	23.59	-33.3	0.00	100.0
	Week 4	90	14.44	23.99	0.0	0.00	100.0	82	4.07	21.84	-66.7	0.00	100.0
	Week 5	90	13.33	22.23	0.0	0.00	100.0	81	4.12	21.33	-33.3	0.00	100.0
	Week 6	90	10.37	18.46	0.0	0.00	66.7	81	2.88	19.15	-66.7	0.00	66.7
	Week 7	85	12.55	19.90	0.0	0.00	66.7	77	2.60	20.78	-33.3	0.00	66.7
	Week 8	89	12.36	21.54	0.0	0.00	100.0	80	3.75	23.11	-66.7	0.00	100.0
	Week 9	93	12.54	20.21	0.0	0.00	100.0	85	2.74	21.34	-66.7	0.00	66.7
	Week 10	88	9.85	17.62	0.0	0.00	66.7	81	0.00	21.08	-66.7	0.00	66.7
	Week 11	93	13.98	21.04	0.0	0.00	100.0	84	4.36	21.82	-66.7	0.00	66.7
	Week 12	86	14.73	21.45	0.0	0.00	100.0	79	5.06	20.03	-66.7	0.00	66.7
	Week 14	84	13.89	22.08	0.0	0.00	100.0	76	3.95	24.32	-66.7	0.00	66.7
	Week 17	83	11.65	19.08	0.0	0.00	100.0	77	3.03	23.06	-66.7	0.00	100.0
	Week 20	79	16.46	27.15	0.0	0.00	100.0	73	5.94	27.97	-66.7	0.00	100.0
	Week 23	78	17.09	25.62	0.0	0.00	100.0	73	7.31	28.46	-66.7	0.00	100.0
	Week 26	78	13.25	18.87	0.0	0.00	66.7	72	4.63	23.94	-66.7	0.00	66.7
	Week 29	74	13.06	18.15	0.0	0.00	66.7	67	5.97	24.57	-66.7	0.00	66.7
	Week 32	64	13.02	18.42	0.0	0.00	66.7	59	3.39	24.52	-66.7	0.00	66.7
	Week 35	62	10.75	16.83	0.0	0.00	66.7	58	2.87	19.02	-66.7	0.00	33.3
	Week 38	62	12.36	17.32	0.0	0.00	66.7	59	5.65	19.72	-33.3	0.00	66.7
	Week 41	64	11.98	19.12	0.0	0.00	66.7	59	3.95	25.58	-66.7	0.00	66.7
	Week 44	50	14.00	20.30	0.0	0.00	66.7	48	5.56	24.15	-66.7	0.00	66.7
	Week 47	47	15.60	22.90	0.0	0.00	100.0	46	7.25	27.14	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	44	15.91	25.40	0.0	0.00	100.0	41	8.94	26.90	-33.3	0.00	100.0
	Week 53	40	12.50	19.52	0.0	0.00	66.7	37	4.50	22.44	-33.3	0.00	66.7
	Week 56	44	17.42	23.28	0.0	0.00	100.0	41	10.57	29.29	-66.7	0.00	100.0
	Week 59	42	12.70	22.03	0.0	0.00	100.0	39	3.42	28.40	-66.7	0.00	100.0
	Week 62	37	15.31	25.57	0.0	0.00	100.0	36	6.48	31.69	-66.7	0.00	100.0
	Week 65	34	14.71	26.20	0.0	0.00	100.0	31	6.45	32.68	-66.7	0.00	100.0
	Week 68	34	16.67	23.57	0.0	0.00	100.0	33	8.08	28.90	-66.7	0.00	100.0
	Week 71	32	16.67	26.77	0.0	0.00	100.0	30	8.89	34.94	-66.7	0.00	100.0
	Week 74	29	16.09	24.59	0.0	0.00	100.0	28	7.14	31.89	-66.7	0.00	100.0
	Week 77	25	17.33	21.77	0.0	0.00	66.7	24	6.94	29.45	-66.7	0.00	66.7
	Week 80	24	19.44	23.91	0.0	0.00	66.7	22	9.09	29.42	-33.3	0.00	66.7
	Week 83	23	14.49	19.66	0.0	0.00	66.7	22	3.03	22.79	-33.3	0.00	33.3
	Week 86	20	20.00	25.13	0.0	0.00	66.7	18	5.56	26.20	-33.3	0.00	66.7
	Week 89	19	19.30	23.08	0.0	0.00	66.7	17	5.88	26.96	-33.3	0.00	66.7
	Week 92	14	16.67	25.32	0.0	0.00	66.7	12	8.33	25.13	-33.3	0.00	66.7
	Week 95	12	13.89	22.29	0.0	0.00	66.7	11	12.12	22.47	0.0	0.00	66.7
	Plat+Gem (N=106)												
	BASELINE	83	13.25	20.12	0.0	0.00	100.0						
	Week 1	75	9.78	18.80	0.0	0.00	100.0	71	-2.82	18.47	-66.7	0.00	66.7
	Week 2	76	14.03	19.82	0.0	0.00	66.7	68	0.00	17.28	-33.3	0.00	66.7
	Week 3	80	13.75	22.31	0.0	0.00	100.0	73	0.46	19.64	-66.7	0.00	66.7
	Week 4	79	11.81	18.52	0.0	0.00	66.7	67	-1.49	18.74	-33.3	0.00	66.7
	Week 5	80	15.42	21.83	0.0	0.00	100.0	67	0.50	24.27	-66.7	0.00	33.3
	Week 6	76	15.35	22.07	0.0	0.00	100.0	67	1.49	22.79	-66.7	0.00	66.7
	Week 7	81	16.46	23.64	0.0	0.00	100.0	71	2.82	23.74	-66.7	0.00	66.7
	Week 8	72	15.74	21.65	0.0	0.00	66.7	64	1.04	20.55	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	78	18.38	23.20	0.0	0.00	100.0	69	4.35	26.14	-66.7	0.00	66.7
	Week 10	78	20.08	25.39	0.0	0.00	100.0	68	5.88	22.99	-33.3	0.00	66.7
	Week 11	75	20.00	26.85	0.0	0.00	100.0	66	4.04	23.76	-66.7	0.00	66.7
	Week 12	74	16.22	22.91	0.0	0.00	100.0	66	3.03	20.86	-66.7	0.00	66.7
	Week 14	68	19.61	24.59	0.0	0.00	100.0	58	7.47	25.01	-66.7	0.00	66.7
	Week 17	68	25.49	27.09	0.0	33.33	100.0	58	11.49	27.61	-66.7	0.00	66.7
	Week 20	60	19.44	22.37	0.0	0.00	66.7	52	7.69	20.47	-33.3	0.00	66.7
	Week 23	51	17.65	25.26	0.0	0.00	100.0	44	7.58	20.16	-33.3	0.00	66.7
	Week 26	47	17.02	21.84	0.0	0.00	66.7	42	4.76	20.26	-33.3	0.00	33.3
	Week 29	42	11.90	19.23	0.0	0.00	66.7	37	0.00	17.57	-33.3	0.00	33.3
	Week 32	37	10.81	15.82	0.0	0.00	33.3	34	-0.98	20.90	-66.7	0.00	33.3
	Week 35	34	13.72	20.30	0.0	0.00	66.7	31	2.15	20.97	-66.7	0.00	33.3
	Week 38	33	14.14	23.61	0.0	0.00	100.0	28	2.38	20.14	-66.7	0.00	33.3
	Week 41	27	14.81	21.35	0.0	0.00	66.7	22	3.03	22.79	-66.7	0.00	33.3
	Week 44	28	14.29	21.14	0.0	0.00	66.7	24	2.78	21.79	-66.7	0.00	33.3
	Week 47	24	18.05	25.97	0.0	0.00	100.0	21	3.17	20.83	-66.7	0.00	33.3
	Week 50	26	12.82	25.08	0.0	0.00	100.0	24	1.39	25.02	-66.7	0.00	66.7
	Week 53	19	15.79	20.39	0.0	0.00	66.7	17	7.84	18.74	-33.3	0.00	33.3
	Week 56	13	20.51	32.03	0.0	0.00	100.0	11	6.06	13.48	0.0	0.00	33.3
	Week 59	14	16.67	28.49	0.0	0.00	100.0	12	5.56	12.97	0.0	0.00	33.3
	Week 62	13	12.82	16.88	0.0	0.00	33.3	12	8.33	15.07	0.0	0.00	33.3
	Week 65	13	17.95	29.23	0.0	0.00	100.0	11	6.06	13.48	0.0	0.00	33.3
	Week 68	10	23.33	31.62	0.0	16.67	100.0	8	8.33	15.43	0.0	0.00	33.3
	Week 77	10	23.33	35.31	0.0	0.00	100.0	8	0.00	17.82	-33.3	0.00	33.3

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Table 302.1.3002.18.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>= 65 years	EV+Pembro (N=135)												
	BASELINE	114	10.53	17.91	0.0	0.00	66.7						
	Week 1	102	12.09	21.39	0.0	0.00	100.0	99	2.02	17.05	-33.3	0.00	66.7
	Week 2	111	14.71	23.22	0.0	0.00	100.0	103	4.85	21.09	-66.7	0.00	66.7
	Week 3	105	15.55	22.20	0.0	0.00	66.7	98	5.44	19.56	-66.7	0.00	66.7
	Week 4	104	12.50	21.38	0.0	0.00	100.0	97	3.44	20.69	-66.7	0.00	100.0
	Week 5	100	14.33	24.73	0.0	0.00	100.0	92	5.07	25.65	-66.7	0.00	100.0
	Week 6	98	12.92	21.21	0.0	0.00	100.0	89	4.12	21.21	-33.3	0.00	100.0
	Week 7	110	16.36	22.46	0.0	0.00	100.0	99	5.72	23.35	-66.7	0.00	100.0
	Week 8	102	13.72	20.63	0.0	0.00	100.0	91	5.13	21.62	-33.3	0.00	100.0
	Week 9	104	17.63	24.99	0.0	0.00	100.0	95	9.12	23.03	-33.3	0.00	100.0
	Week 10	103	16.83	23.28	0.0	0.00	100.0	94	4.96	22.91	-33.3	0.00	100.0
	Week 11	101	17.16	23.39	0.0	0.00	100.0	91	5.86	23.62	-66.7	0.00	66.7
	Week 12	100	17.33	23.91	0.0	0.00	100.0	92	6.88	24.97	-33.3	0.00	100.0
	Week 14	101	16.17	23.39	0.0	0.00	100.0	91	3.30	24.87	-66.7	0.00	100.0
	Week 17	95	15.09	22.68	0.0	0.00	100.0	85	6.67	22.89	-66.7	0.00	100.0
	Week 20	88	17.80	24.21	0.0	0.00	100.0	81	8.23	26.10	-66.7	0.00	100.0
	Week 23	84	16.67	23.99	0.0	0.00	100.0	78	6.41	26.35	-33.3	0.00	100.0
	Week 26	78	15.38	19.14	0.0	0.00	66.7	72	5.09	19.91	-33.3	0.00	66.7
	Week 29	83	14.06	21.54	0.0	0.00	100.0	78	3.42	22.53	-66.7	0.00	66.7
	Week 32	71	15.96	20.97	0.0	0.00	100.0	66	5.05	22.83	-66.7	0.00	66.7
	Week 35	70	14.76	23.83	0.0	0.00	100.0	64	5.21	22.39	-33.3	0.00	66.7
	Week 38	70	18.09	25.18	0.0	0.00	100.0	65	5.64	23.25	-33.3	0.00	66.7
	Week 41	65	18.97	26.33	0.0	0.00	100.0	60	8.33	24.26	-33.3	0.00	66.7
	Week 44	58	21.26	25.51	0.0	16.67	100.0	52	11.54	23.69	-33.3	0.00	66.7
	Week 47	53	13.21	22.96	0.0	0.00	100.0	48	2.08	22.18	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	45	11.85	21.50	0.0	0.00	66.7	43	2.33	26.62	-33.3	0.00	66.7
	Week 53	39	11.97	19.48	0.0	0.00	66.7	37	0.90	18.40	-33.3	0.00	66.7
	Week 56	37	6.31	15.39	0.0	0.00	66.7	35	-2.86	18.74	-33.3	0.00	66.7
	Week 59	30	12.22	18.53	0.0	0.00	66.7	29	4.60	21.31	-33.3	0.00	66.7
	Week 62	28	8.33	14.70	0.0	0.00	33.3	27	2.47	18.32	-33.3	0.00	33.3
	Week 65	24	12.50	23.70	0.0	0.00	100.0	23	4.35	27.16	-33.3	0.00	100.0
	Week 68	19	10.53	24.98	0.0	0.00	100.0	19	3.51	31.22	-33.3	0.00	100.0
	Week 71	19	5.26	12.49	0.0	0.00	33.3	19	0.00	15.71	-33.3	0.00	33.3
	Week 74	18	3.70	10.78	0.0	0.00	33.3	18	-1.85	13.87	-33.3	0.00	33.3
	Week 77	19	8.77	15.08	0.0	0.00	33.3	18	1.85	21.30	-33.3	0.00	33.3
	Week 80	16	8.33	14.91	0.0	0.00	33.3	15	-2.22	19.79	-33.3	0.00	33.3
	Week 83	14	9.52	15.63	0.0	0.00	33.3	13	2.56	21.35	-33.3	0.00	33.3
	Week 86	14	9.52	15.63	0.0	0.00	33.3	13	2.56	16.45	-33.3	0.00	33.3
	Week 89	14	14.29	21.54	0.0	0.00	66.7	14	7.14	19.30	-33.3	0.00	33.3
	Week 92	13	7.69	14.62	0.0	0.00	33.3	13	0.00	19.24	-33.3	0.00	33.3
	Week 95	10	10.00	22.50	0.0	0.00	66.7	10	3.33	24.60	-33.3	0.00	66.7
	Week 98	10	10.00	16.10	0.0	0.00	33.3	10	0.00	22.22	-33.3	0.00	33.3
	Plat+Gem (N=136)												
	BASELINE	105	16.51	23.63	0.0	0.00	100.0						
	Week 1	98	16.67	25.44	0.0	0.00	100.0	87	-0.77	19.67	-66.7	0.00	66.7
	Week 2	95	17.19	26.12	0.0	0.00	100.0	83	1.61	24.36	-66.7	0.00	100.0
	Week 3	104	18.59	25.37	0.0	0.00	100.0	89	3.00	21.11	-33.3	0.00	66.7
	Week 4	104	19.55	25.70	0.0	0.00	100.0	89	3.74	24.84	-33.3	0.00	100.0
	Week 5	107	19.31	26.32	0.0	0.00	100.0	89	6.74	21.43	-33.3	0.00	66.7
	Week 6	98	18.71	26.25	0.0	0.00	100.0	82	5.28	23.70	-33.3	0.00	66.7
	Week 7	105	17.46	24.93	0.0	0.00	100.0	86	3.88	19.41	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 8	95	23.86	29.84	0.0	0.00	100.0	80	12.08	27.17	-33.3	0.00	66.7
	Week 9	99	20.54	26.81	0.0	0.00	100.0	81	8.23	26.10	-33.3	0.00	100.0
	Week 10	88	23.11	27.38	0.0	33.33	100.0	71	9.86	24.81	-33.3	0.00	66.7
	Week 11	93	22.94	29.07	0.0	0.00	100.0	77	8.66	26.16	-33.3	0.00	66.7
	Week 12	85	21.96	27.48	0.0	0.00	100.0	72	9.26	26.37	-33.3	0.00	66.7
	Week 14	85	23.53	28.09	0.0	33.33	100.0	70	10.95	27.05	-33.3	0.00	66.7
	Week 17	87	17.24	24.31	0.0	0.00	100.0	72	5.09	24.81	-33.3	0.00	66.7
	Week 20	66	20.20	26.07	0.0	0.00	100.0	58	10.35	27.36	-33.3	0.00	100.0
	Week 23	64	15.10	22.95	0.0	0.00	100.0	53	8.18	24.38	-33.3	0.00	100.0
	Week 26	61	13.66	19.60	0.0	0.00	66.7	53	5.03	21.08	-33.3	0.00	66.7
	Week 29	58	16.09	24.38	0.0	0.00	100.0	49	8.84	27.02	-33.3	0.00	100.0
	Week 32	46	13.04	17.89	0.0	0.00	66.7	42	5.56	19.36	-33.3	0.00	33.3
	Week 35	42	17.46	21.13	0.0	0.00	66.7	38	8.77	21.48	-33.3	0.00	66.7
	Week 38	41	20.32	25.69	0.0	0.00	100.0	37	11.71	27.46	-33.3	0.00	100.0
	Week 41	38	17.54	22.91	0.0	0.00	100.0	34	8.82	28.79	-33.3	0.00	100.0
	Week 44	32	23.96	29.61	0.0	16.67	100.0	29	14.94	34.02	-33.3	0.00	100.0
	Week 47	32	16.67	22.40	0.0	0.00	100.0	28	5.95	20.39	-33.3	0.00	66.7
	Week 50	25	21.33	23.33	0.0	33.33	100.0	23	11.59	27.72	-33.3	0.00	100.0
	Week 53	27	13.58	21.20	0.0	0.00	66.7	25	2.67	21.34	-33.3	0.00	33.3
	Week 56	26	17.95	23.53	0.0	0.00	100.0	23	7.25	24.53	-33.3	0.00	66.7
	Week 59	23	14.49	16.89	0.0	0.00	33.3	21	3.17	23.34	-33.3	0.00	33.3
	Week 62	19	21.05	19.91	0.0	33.33	66.7	17	7.84	25.08	-33.3	0.00	33.3
	Week 65	17	19.61	23.74	0.0	0.00	66.7	15	6.67	28.73	-33.3	0.00	66.7
	Week 68	15	17.78	24.77	0.0	0.00	66.7	13	2.57	31.80	-33.3	0.00	66.7
	Week 71	15	20.00	24.56	0.0	0.00	66.7	13	7.69	30.89	-33.3	0.00	66.7
	Week 74	12	13.89	17.16	0.0	0.00	33.3	11	0.00	21.08	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Europe	EV+Pembro (N= 98)												
	BASELINE	79	10.13	20.22	0.0	0.00	100.0						
	Week 1	74	10.81	20.72	0.0	0.00	66.7	71	1.88	18.59	-33.3	0.00	66.7
	Week 2	79	10.55	21.71	0.0	0.00	100.0	71	1.88	16.80	-33.3	0.00	66.7
	Week 3	78	13.68	24.29	0.0	0.00	100.0	69	3.38	18.21	-33.3	0.00	66.7
	Week 4	78	11.97	22.78	0.0	0.00	66.7	70	2.86	17.71	-33.3	0.00	66.7
	Week 5	70	10.00	19.94	0.0	0.00	66.7	62	1.61	17.52	-33.3	0.00	66.7
	Week 6	70	9.05	19.59	0.0	0.00	100.0	61	3.82	22.03	-66.7	0.00	100.0
	Week 7	78	12.39	19.45	0.0	0.00	66.7	68	0.98	16.26	-33.3	0.00	33.3
	Week 8	72	9.26	19.56	0.0	0.00	100.0	61	3.28	19.91	-66.7	0.00	66.7
	Week 9	80	13.33	24.07	0.0	0.00	100.0	70	5.71	24.06	-66.7	0.00	66.7
	Week 10	71	12.21	22.00	0.0	0.00	100.0	62	0.54	22.17	-66.7	0.00	66.7
	Week 11	76	14.03	25.68	0.0	0.00	100.0	66	3.54	23.48	-66.7	0.00	66.7
	Week 12	73	15.98	26.12	0.0	0.00	100.0	65	6.67	24.44	-66.7	0.00	100.0
	Week 14	74	12.61	23.86	0.0	0.00	100.0	64	1.04	22.98	-66.7	0.00	66.7
	Week 17	70	10.48	20.10	0.0	0.00	100.0	62	3.23	23.15	-66.7	0.00	100.0
	Week 20	70	12.86	24.93	0.0	0.00	100.0	63	4.76	27.34	-66.7	0.00	100.0
	Week 23	61	10.93	22.54	0.0	0.00	100.0	57	3.51	27.95	-66.7	0.00	100.0
	Week 26	62	9.14	16.16	0.0	0.00	66.7	55	1.21	19.21	-66.7	0.00	33.3
	Week 29	63	11.11	17.96	0.0	0.00	66.7	57	3.51	19.60	-66.7	0.00	66.7
	Week 32	51	10.46	16.98	0.0	0.00	66.7	47	0.71	20.25	-66.7	0.00	33.3
	Week 35	56	8.33	15.89	0.0	0.00	66.7	52	1.28	17.42	-66.7	0.00	33.3
	Week 38	51	12.42	23.06	0.0	0.00	100.0	48	4.17	20.19	-33.3	0.00	66.7
	Week 41	52	12.18	20.90	0.0	0.00	100.0	48	1.39	22.76	-66.7	0.00	66.7
	Week 44	43	13.18	23.16	0.0	0.00	100.0	39	3.42	23.93	-66.7	0.00	66.7
	Week 47	39	13.67	23.84	0.0	0.00	100.0	36	3.70	23.61	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	37	10.81	23.64	0.0	0.00	100.0	36	4.63	25.39	-33.3	0.00	100.0
	Week 53	28	10.71	20.39	0.0	0.00	66.7	27	1.23	21.64	-33.3	0.00	66.7
	Week 56	30	11.11	18.22	0.0	0.00	66.7	29	3.45	24.14	-66.7	0.00	66.7
	Week 59	27	8.64	17.52	0.0	0.00	66.7	27	1.23	25.29	-66.7	0.00	66.7
	Week 62	23	11.59	23.80	0.0	0.00	100.0	23	2.90	31.64	-66.7	0.00	100.0
	Week 65	23	11.59	23.80	0.0	0.00	100.0	23	4.35	28.96	-66.7	0.00	100.0
	Week 68	21	12.70	19.65	0.0	0.00	66.7	21	4.76	26.43	-66.7	0.00	66.7
	Week 71	19	15.79	25.74	0.0	0.00	100.0	19	8.77	33.04	-66.7	0.00	100.0
	Week 74	15	15.55	21.33	0.0	0.00	66.7	15	6.67	31.37	-66.7	0.00	66.7
	Week 77	19	15.79	20.39	0.0	0.00	66.7	19	8.77	26.86	-66.7	0.00	66.7
	Week 80	17	19.61	23.74	0.0	0.00	66.7	17	11.76	26.20	-33.3	0.00	66.7
	Week 83	16	14.58	20.97	0.0	0.00	66.7	16	6.25	21.83	-33.3	0.00	33.3
	Week 86	14	14.29	25.20	0.0	0.00	66.7	14	4.76	25.68	-33.3	0.00	66.7
	Week 89	14	16.67	25.32	0.0	0.00	66.7	14	7.14	26.73	-33.3	0.00	66.7
	Week 92	11	9.09	21.56	0.0	0.00	66.7	11	6.06	25.03	-33.3	0.00	66.7
	Week 95	10	13.33	28.11	0.0	0.00	66.7	10	13.33	28.11	0.0	0.00	66.7
	Plat+Gem (N=102)												
	BASELINE	71	17.84	26.92	0.0	0.00	100.0						
	Week 1	71	17.37	26.94	0.0	0.00	100.0	61	1.09	23.54	-66.7	0.00	66.7
	Week 2	67	18.41	26.77	0.0	0.00	100.0	56	1.79	20.52	-66.7	0.00	66.7
	Week 3	68	21.57	30.89	0.0	0.00	100.0	56	4.17	22.97	-66.7	0.00	66.7
	Week 4	75	20.44	27.34	0.0	0.00	100.0	59	3.39	25.29	-33.3	0.00	100.0
	Week 5	77	20.78	29.14	0.0	0.00	100.0	60	7.78	24.06	-66.7	0.00	66.7
	Week 6	70	20.00	27.45	0.0	0.00	100.0	56	5.95	23.87	-66.7	0.00	66.7
	Week 7	72	20.83	29.30	0.0	0.00	100.0	55	6.06	22.31	-66.7	0.00	66.7
	Week 8	65	25.13	29.48	0.0	33.33	100.0	53	11.95	27.03	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	70	21.90	28.87	0.0	0.00	100.0	55	7.88	30.06	-66.7	0.00	100.0
	Week 10	60	26.11	28.85	0.0	33.33	100.0	46	12.32	24.70	-33.3	0.00	66.7
	Week 11	64	26.56	33.16	0.0	0.00	100.0	50	9.33	26.12	-66.7	0.00	66.7
	Week 12	60	26.67	28.66	0.0	33.33	100.0	48	11.11	26.93	-66.7	0.00	66.7
	Week 14	56	29.17	30.53	0.0	33.33	100.0	42	19.84	26.61	-33.3	16.67	66.7
	Week 17	58	25.86	29.32	0.0	33.33	100.0	44	13.64	25.23	-33.3	0.00	66.7
	Week 20	47	21.28	23.49	0.0	33.33	66.7	37	10.81	20.87	-33.3	0.00	66.7
	Week 23	44	18.94	26.31	0.0	0.00	100.0	32	13.54	23.74	-33.3	0.00	100.0
	Week 26	39	22.22	23.36	0.0	33.33	66.7	30	13.33	20.71	-33.3	0.00	66.7
	Week 29	34	20.59	27.23	0.0	0.00	100.0	25	16.00	29.06	-33.3	0.00	100.0
	Week 32	33	13.13	16.54	0.0	0.00	33.3	27	6.17	20.75	-66.7	0.00	33.3
	Week 35	30	14.44	18.94	0.0	0.00	66.7	24	5.56	21.23	-66.7	0.00	33.3
	Week 38	26	17.95	27.05	0.0	0.00	100.0	21	6.35	24.99	-66.7	0.00	66.7
	Week 41	22	21.21	24.22	0.0	16.67	66.7	17	13.72	29.01	-66.7	0.00	66.7
	Week 44	20	30.00	30.40	0.0	33.33	100.0	16	18.75	36.45	-66.7	16.67	100.0
	Week 47	16	27.08	34.89	0.0	16.67	100.0	12	11.11	32.82	-66.7	0.00	66.7
	Week 50	11	30.30	31.46	0.0	33.33	100.0	10	13.33	35.83	-66.7	16.67	66.7
	Week 53	11	30.30	23.36	0.0	33.33	66.7	10	16.67	17.57	0.0	16.67	33.3
	Week 56	10	26.67	30.63	0.0	33.33	100.0	8	8.33	23.57	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
North America	EV+Pembro (N= 57)												
	BASELINE	47	14.89	20.63	0.0	0.00	66.7						
	Week 1	39	17.95	25.18	0.0	0.00	100.0	37	5.41	20.05	-33.3	0.00	33.3
	Week 2	44	17.42	19.67	0.0	0.00	66.7	42	2.38	21.33	-66.7	0.00	33.3
	Week 3	44	23.48	26.49	0.0	33.33	100.0	40	10.83	26.57	-33.3	0.00	100.0
	Week 4	44	16.67	23.29	0.0	0.00	100.0	41	4.06	24.94	-66.7	0.00	100.0
	Week 5	47	19.15	22.78	0.0	0.00	100.0	41	8.13	23.31	-33.3	0.00	100.0
	Week 6	44	15.15	18.26	0.0	0.00	66.7	39	2.56	19.32	-33.3	0.00	66.7
	Week 7	46	17.39	20.77	0.0	0.00	66.7	42	5.56	21.98	-33.3	0.00	66.7
	Week 8	47	17.02	20.70	0.0	0.00	100.0	42	4.76	23.94	-33.3	0.00	100.0
	Week 9	46	18.11	19.51	0.0	16.67	66.7	42	4.76	20.26	-33.3	0.00	33.3
	Week 10	47	14.18	19.34	0.0	0.00	66.7	44	1.52	17.54	-33.3	0.00	66.7
	Week 11	47	17.73	19.47	0.0	0.00	66.7	42	5.56	19.36	-33.3	0.00	33.3
	Week 12	44	18.18	22.10	0.0	0.00	100.0	40	4.17	24.09	-33.3	0.00	100.0
	Week 14	43	16.28	18.36	0.0	0.00	66.7	39	1.71	20.16	-33.3	0.00	66.7
	Week 17	40	15.00	19.90	0.0	0.00	66.7	37	0.90	18.40	-33.3	0.00	33.3
	Week 20	38	18.42	24.13	0.0	0.00	100.0	35	1.90	24.18	-33.3	0.00	66.7
	Week 23	38	16.67	18.58	0.0	0.00	66.7	35	0.95	20.59	-33.3	0.00	33.3
	Week 26	35	12.38	16.34	0.0	0.00	33.3	32	-2.08	22.30	-66.7	0.00	33.3
	Week 29	38	11.40	16.02	0.0	0.00	33.3	34	-1.96	23.12	-66.7	0.00	33.3
	Week 32	32	11.46	16.08	0.0	0.00	33.3	29	-2.30	23.45	-66.7	0.00	33.3
	Week 35	33	13.13	18.52	0.0	0.00	66.7	30	1.11	18.53	-33.3	0.00	33.3
	Week 38	32	14.58	18.81	0.0	0.00	66.7	29	2.30	17.66	-33.3	0.00	33.3
	Week 41	28	11.90	20.72	0.0	0.00	66.7	24	2.78	23.91	-33.3	0.00	66.7
	Week 44	21	17.46	20.05	0.0	0.00	66.7	20	10.00	15.67	0.0	0.00	33.3
	Week 47	24	12.50	21.56	0.0	0.00	66.7	23	4.35	20.85	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	23	11.59	21.58	0.0	0.00	66.7	20	3.33	28.41	-33.3	0.00	66.7
	Week 53	17	9.80	15.65	0.0	0.00	33.3	14	0.00	13.07	-33.3	0.00	33.3
	Week 56	20	11.67	16.31	0.0	0.00	33.3	17	1.96	21.95	-33.3	0.00	33.3
	Week 59	17	9.80	15.65	0.0	0.00	33.3	14	0.00	18.49	-33.3	0.00	33.3
	Week 62	14	7.14	14.19	0.0	0.00	33.3	13	2.56	16.45	-33.3	0.00	33.3
	Week 65	12	5.56	12.97	0.0	0.00	33.3	9	-3.70	20.03	-33.3	0.00	33.3
	Week 68	10	10.00	16.10	0.0	0.00	33.3	9	3.70	20.03	-33.3	0.00	33.3
	Week 71	10	10.00	16.10	0.0	0.00	33.3	8	8.33	15.43	0.0	0.00	33.3
	Week 74	10	3.33	10.54	0.0	0.00	33.3	9	0.00	16.67	-33.3	0.00	33.3
	Plat+Gem (N= 51)												
	BASELINE	42	12.70	19.41	0.0	0.00	66.7						
	Week 1	41	12.19	19.37	0.0	0.00	66.7	36	-2.78	9.34	-33.3	0.00	0.0
	Week 2	38	13.16	19.82	0.0	0.00	66.7	33	0.00	14.44	-33.3	0.00	33.3
	Week 3	40	12.50	18.00	0.0	0.00	66.7	35	0.95	17.12	-33.3	0.00	33.3
	Week 4	35	11.43	17.97	0.0	0.00	66.7	29	0.00	17.82	-33.3	0.00	33.3
	Week 5	39	17.09	20.05	0.0	0.00	66.7	32	5.21	25.55	-66.7	0.00	66.7
	Week 6	34	11.76	19.90	0.0	0.00	66.7	30	0.00	24.76	-66.7	0.00	66.7
	Week 7	42	13.49	18.12	0.0	0.00	66.7	37	0.00	20.79	-33.3	0.00	33.3
	Week 8	39	17.95	22.74	0.0	0.00	66.7	33	5.05	20.62	-33.3	0.00	66.7
	Week 9	39	16.24	18.53	0.0	0.00	66.7	33	3.03	19.30	-33.3	0.00	66.7
	Week 10	39	21.37	24.77	0.0	0.00	66.7	32	7.29	20.28	-33.3	0.00	66.7
	Week 11	39	19.66	22.58	0.0	0.00	66.7	33	4.04	24.66	-33.3	0.00	66.7
	Week 12	36	16.67	23.23	0.0	0.00	100.0	32	7.29	20.27	-33.3	0.00	66.7
	Week 14	34	14.71	23.49	0.0	0.00	100.0	29	-1.15	22.68	-66.7	0.00	33.3
	Week 17	37	19.82	22.85	0.0	0.00	66.7	31	8.60	29.77	-66.7	0.00	66.7
	Week 20	27	17.28	16.97	0.0	33.33	33.3	23	8.69	22.95	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 23	27	9.88	15.51	0.0	0.00	33.3	23	1.45	15.82	-33.3	0.00	33.3
	Week 26	28	9.52	15.33	0.0	0.00	33.3	25	0.00	16.67	-33.3	0.00	33.3
	Week 29	29	11.49	20.46	0.0	0.00	66.7	25	0.00	21.52	-33.3	0.00	33.3
	Week 32	17	11.76	16.42	0.0	0.00	33.3	17	0.00	16.67	-33.3	0.00	33.3
	Week 35	16	20.83	23.96	0.0	16.67	66.7	15	6.67	22.54	-33.3	0.00	66.7
	Week 38	16	20.83	26.87	0.0	16.67	100.0	13	10.26	31.58	-33.3	0.00	100.0
	Week 41	16	18.75	27.13	0.0	0.00	100.0	13	5.13	32.90	-33.3	0.00	100.0
	Week 44	13	17.95	29.23	0.0	0.00	100.0	11	6.06	32.72	-33.3	0.00	100.0
	Week 47	11	15.15	17.41	0.0	0.00	33.3	9	0.00	16.67	-33.3	0.00	33.3
	Week 50	17	15.69	26.66	0.0	0.00	100.0	15	4.44	30.52	-33.3	0.00	100.0
	Week 53	13	15.38	22.01	0.0	0.00	66.7	11	3.03	23.35	-33.3	0.00	33.3
	Week 56	11	15.15	22.92	0.0	0.00	66.7	9	-3.70	20.03	-33.3	0.00	33.3
	Week 59	11	12.12	16.82	0.0	0.00	33.3	9	0.00	16.67	-33.3	0.00	33.3
	Week 62	11	15.15	17.41	0.0	0.00	33.3	9	3.70	20.03	-33.3	0.00	33.3
	Week 65	10	20.00	23.31	0.0	16.67	66.7	8	8.33	29.55	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Rest of World	EV+Pembro (N= 85)												
	BASELINE	80	9.58	17.74	0.0	0.00	66.7						
	Week 1	77	10.82	18.29	0.0	0.00	100.0	76	1.32	16.72	-33.3	0.00	66.7
	Week 2	80	13.75	22.31	0.0	0.00	100.0	76	4.39	22.67	-66.7	0.00	66.7
	Week 3	76	16.23	23.41	0.0	0.00	100.0	73	5.94	21.04	-66.7	0.00	66.7
	Week 4	72	12.96	22.06	0.0	0.00	100.0	68	4.41	22.23	-66.7	0.00	100.0
	Week 5	73	14.15	26.60	0.0	0.00	100.0	70	5.24	28.17	-66.7	0.00	100.0
	Week 6	74	12.16	21.06	0.0	0.00	100.0	70	3.81	19.28	-33.3	0.00	66.7
	Week 7	71	15.49	23.79	0.0	0.00	100.0	66	7.07	27.12	-66.7	0.00	100.0
	Week 8	72	14.35	22.26	0.0	0.00	100.0	68	5.39	23.47	-33.3	0.00	100.0
	Week 9	71	15.49	23.79	0.0	0.00	100.0	68	7.35	22.19	-33.3	0.00	100.0
	Week 10	73	14.61	21.51	0.0	0.00	100.0	69	5.31	24.67	-33.3	0.00	100.0
	Week 11	71	15.96	20.20	0.0	0.00	66.7	67	6.47	24.09	-66.7	0.00	66.7
	Week 12	69	14.97	19.42	0.0	0.00	66.7	66	6.57	20.44	-33.3	0.00	66.7
	Week 14	68	17.16	24.09	0.0	0.00	100.0	64	7.29	28.15	-66.7	0.00	100.0
	Week 17	68	15.69	22.65	0.0	0.00	100.0	63	8.99	24.83	-66.7	0.00	100.0
	Week 20	59	21.47	26.81	0.0	0.00	100.0	56	13.10	27.47	-66.7	0.00	100.0
	Week 23	63	22.75	28.60	0.0	0.00	100.0	59	13.56	29.11	-33.3	0.00	100.0
	Week 26	59	20.90	21.35	0.0	33.33	66.7	57	12.28	22.39	-33.3	0.00	66.7
	Week 29	56	17.86	23.75	0.0	0.00	100.0	54	9.88	26.41	-33.3	0.00	66.7
	Week 32	52	20.51	23.01	0.0	33.33	100.0	49	11.56	25.05	-33.3	0.00	66.7
	Week 35	43	18.60	26.53	0.0	0.00	100.0	40	10.00	25.26	-33.3	0.00	66.7
	Week 38	49	19.05	22.57	0.0	0.00	100.0	47	9.22	24.77	-33.3	0.00	66.7
	Week 41	49	21.09	26.08	0.0	0.00	100.0	47	12.77	26.51	-33.3	0.00	66.7
	Week 44	44	22.73	24.67	0.0	33.33	100.0	41	13.01	26.75	-33.3	0.00	66.7
	Week 47	37	16.22	23.07	0.0	0.00	100.0	35	5.71	28.57	-33.3	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	29	19.54	24.43	0.0	0.00	66.7	28	8.33	28.15	-33.3	0.00	66.7
	Week 53	34	14.71	20.42	0.0	0.00	66.7	33	5.05	22.24	-33.3	0.00	66.7
	Week 56	31	13.98	25.49	0.0	0.00	100.0	30	6.67	29.56	-33.3	0.00	100.0
	Week 59	28	17.86	24.82	0.0	0.00	100.0	27	8.64	28.63	-33.3	0.00	100.0
	Week 62	28	15.48	23.10	0.0	0.00	100.0	27	7.41	26.69	-33.3	0.00	100.0
	Week 65	23	20.29	29.71	0.0	0.00	100.0	22	10.61	34.71	-33.3	0.00	100.0
	Week 68	22	18.18	30.39	0.0	0.00	100.0	22	9.09	35.90	-33.3	0.00	100.0
	Week 71	22	10.61	23.87	0.0	0.00	100.0	22	1.52	29.95	-33.3	0.00	100.0
	Week 74	22	12.12	24.22	0.0	0.00	100.0	22	3.03	27.04	-33.3	0.00	100.0
	Week 77	18	12.96	20.26	0.0	0.00	66.7	17	1.96	27.56	-33.3	0.00	66.7
	Week 80	16	12.50	20.64	0.0	0.00	66.7	15	-2.22	26.63	-33.3	0.00	66.7
	Week 83	16	12.50	16.67	0.0	0.00	33.3	15	0.00	21.82	-33.3	0.00	33.3
	Week 86	13	17.95	17.29	0.0	33.33	33.3	12	5.56	19.24	-33.3	0.00	33.3
	Week 89	12	19.44	22.28	0.0	16.67	66.7	12	8.33	20.72	-33.3	0.00	33.3
	Plat+Gem (N= 89)												
	BASELINE	75	13.78	18.25	0.0	0.00	66.7						
	Week 1	61	10.38	19.76	0.0	0.00	100.0	61	-3.82	18.36	-33.3	0.00	66.7
	Week 2	66	14.65	21.98	0.0	0.00	100.0	62	0.54	25.24	-33.3	0.00	100.0
	Week 3	76	14.03	19.06	0.0	0.00	66.7	71	0.47	19.91	-33.3	0.00	33.3
	Week 4	73	14.15	19.97	0.0	0.00	100.0	68	0.49	21.92	-33.3	0.00	66.7
	Week 5	71	14.55	20.88	0.0	0.00	100.0	64	0.00	19.70	-33.3	0.00	33.3
	Week 6	70	17.14	23.22	0.0	0.00	100.0	63	3.17	22.17	-33.3	0.00	66.7
	Week 7	72	15.28	21.62	0.0	0.00	66.7	65	3.08	21.02	-33.3	0.00	66.7
	Week 8	63	16.93	26.01	0.0	0.00	100.0	58	4.02	25.04	-33.3	0.00	66.7
	Week 9	68	19.12	24.65	0.0	0.00	100.0	62	6.99	25.70	-33.3	0.00	66.7
	Week 10	67	17.91	24.84	0.0	0.00	100.0	61	4.92	24.97	-33.3	0.00	66.7

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	65	17.95	25.05	0.0	0.00	100.0	60	5.56	24.68	-33.3	0.00	66.7
	Week 12	63	13.76	22.11	0.0	0.00	100.0	58	1.72	22.87	-33.3	0.00	66.7
	Week 14	63	19.05	22.97	0.0	0.00	66.7	57	7.02	24.99	-33.3	0.00	66.7
	Week 17	60	16.67	23.37	0.0	0.00	66.7	55	3.03	24.24	-33.3	0.00	66.7
	Week 20	52	19.87	28.21	0.0	0.00	100.0	50	8.00	27.40	-33.3	0.00	100.0
	Week 23	44	17.42	25.40	0.0	0.00	100.0	42	7.14	23.90	-33.3	0.00	66.7
	Week 26	41	12.19	19.37	0.0	0.00	66.7	40	1.67	21.28	-33.3	0.00	33.3
	Week 29	37	10.81	17.66	0.0	0.00	66.7	36	0.93	18.66	-33.3	0.00	33.3
	Week 32	33	11.11	18.00	0.0	0.00	66.7	32	1.04	21.56	-33.3	0.00	33.3
	Week 35	30	14.44	20.87	0.0	0.00	66.7	30	5.56	21.59	-33.3	0.00	66.7
	Week 38	32	15.62	22.38	0.0	0.00	66.7	31	7.53	22.29	-33.3	0.00	66.7
	Week 41	27	11.11	16.01	0.0	0.00	33.3	26	2.56	20.92	-33.3	0.00	33.3
	Week 44	27	12.34	18.83	0.0	0.00	66.7	26	5.13	22.49	-33.3	0.00	66.7
	Week 47	29	12.64	16.46	0.0	0.00	33.3	28	3.57	13.87	-33.3	0.00	33.3
	Week 50	23	11.59	16.23	0.0	0.00	33.3	22	4.55	18.67	-33.3	0.00	33.3
	Week 53	22	6.06	13.16	0.0	0.00	33.3	21	0.00	18.26	-33.3	0.00	33.3
	Week 56	18	16.67	26.20	0.0	0.00	100.0	17	11.76	20.21	0.0	0.00	66.7
	Week 59	17	11.76	16.42	0.0	0.00	33.3	16	6.25	21.83	-33.3	0.00	33.3
	Week 62	16	12.50	16.67	0.0	0.00	33.3	15	4.44	21.33	-33.3	0.00	33.3
	Week 65	15	11.11	20.57	0.0	0.00	66.7	14	4.76	22.10	-33.3	0.00	33.3
	Week 68	12	16.67	26.59	0.0	0.00	66.7	11	9.09	30.15	-33.3	0.00	66.7
	Week 71	13	17.95	25.88	0.0	0.00	66.7	12	11.11	29.59	-33.3	0.00	66.7
	Week 74	10	10.00	16.10	0.0	0.00	33.3	10	3.33	24.59	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	EV+Pembro (N=198)												
	BASELINE	170	11.76	19.33	0.0	0.00	66.7						
	Week 1	157	12.10	21.07	0.0	0.00	100.0	152	1.54	18.53	-33.3	0.00	66.7
	Week 2	167	13.37	21.97	0.0	0.00	100.0	155	2.37	20.84	-66.7	0.00	66.7
	Week 3	161	16.77	23.90	0.0	0.00	100.0	147	5.22	20.90	-66.7	0.00	66.7
	Week 4	158	13.08	22.83	0.0	0.00	100.0	145	2.53	21.90	-66.7	0.00	100.0
	Week 5	154	14.28	23.76	0.0	0.00	100.0	140	4.29	24.92	-66.7	0.00	100.0
	Week 6	153	11.98	20.45	0.0	0.00	100.0	138	2.42	21.17	-66.7	0.00	100.0
	Week 7	159	14.25	21.69	0.0	0.00	100.0	142	3.52	23.39	-66.7	0.00	100.0
	Week 8	154	12.77	21.29	0.0	0.00	100.0	135	3.95	23.41	-66.7	0.00	100.0
	Week 9	162	15.43	23.54	0.0	0.00	100.0	146	5.94	23.39	-66.7	0.00	100.0
	Week 10	159	14.46	21.06	0.0	0.00	100.0	144	3.24	23.09	-66.7	0.00	100.0
	Week 11	161	15.53	21.74	0.0	0.00	100.0	143	4.89	23.05	-66.7	0.00	66.7
	Week 12	154	16.02	23.56	0.0	0.00	100.0	140	5.71	23.29	-33.3	0.00	100.0
	Week 14	154	14.72	22.54	0.0	0.00	100.0	137	3.16	25.53	-66.7	0.00	100.0
	Week 17	145	13.79	21.37	0.0	0.00	100.0	130	4.87	23.52	-66.7	0.00	100.0
	Week 20	139	17.98	26.40	0.0	0.00	100.0	126	7.14	27.52	-66.7	0.00	100.0
	Week 23	133	17.54	25.81	0.0	0.00	100.0	122	7.10	28.50	-66.7	0.00	100.0
	Week 26	129	13.69	19.37	0.0	0.00	66.7	118	3.95	21.86	-66.7	0.00	66.7
	Week 29	131	12.72	20.02	0.0	0.00	100.0	120	3.89	23.74	-66.7	0.00	66.7
	Week 32	111	14.11	19.87	0.0	0.00	100.0	102	3.92	23.59	-66.7	0.00	66.7
	Week 35	109	11.93	20.55	0.0	0.00	100.0	100	3.67	20.04	-33.3	0.00	66.7
	Week 38	107	14.64	21.07	0.0	0.00	100.0	100	4.33	22.05	-33.3	0.00	66.7
	Week 41	103	14.56	22.71	0.0	0.00	100.0	94	6.03	24.91	-66.7	0.00	66.7
	Week 44	88	17.04	23.16	0.0	0.00	100.0	81	8.64	24.02	-33.3	0.00	66.7
	Week 47	80	14.17	22.36	0.0	0.00	100.0	75	5.78	25.33	-33.3	0.00	100.0

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	73	15.07	24.24	0.0	0.00	100.0	68	7.35	28.12	-33.3	0.00	100.0
	Week 53	64	10.94	17.87	0.0	0.00	66.7	59	1.69	19.98	-33.3	0.00	66.7
	Week 56	66	13.13	20.98	0.0	0.00	100.0	61	6.01	24.73	-33.3	0.00	100.0
	Week 59	58	13.22	20.65	0.0	0.00	100.0	54	5.56	24.01	-33.3	0.00	100.0
	Week 62	54	13.58	22.91	0.0	0.00	100.0	52	7.05	26.68	-33.3	0.00	100.0
	Week 65	51	11.76	22.92	0.0	0.00	100.0	47	4.96	26.90	-33.3	0.00	100.0
	Week 68	49	12.92	21.32	0.0	0.00	100.0	48	6.25	25.41	-33.3	0.00	100.0
	Week 71	47	12.77	23.62	0.0	0.00	100.0	45	7.41	28.33	-33.3	0.00	100.0
	Week 74	42	11.11	21.67	0.0	0.00	100.0	41	4.88	25.34	-33.3	0.00	100.0
	Week 77	38	12.28	19.64	0.0	0.00	66.7	36	5.56	24.56	-33.3	0.00	66.7
	Week 80	35	14.28	20.27	0.0	0.00	66.7	32	6.25	26.01	-33.3	0.00	66.7
	Week 83	32	10.42	15.70	0.0	0.00	33.3	30	2.22	21.32	-33.3	0.00	33.3
	Week 86	30	14.44	20.87	0.0	0.00	66.7	27	4.94	22.08	-33.3	0.00	66.7
	Week 89	28	14.29	21.14	0.0	0.00	66.7	26	6.41	23.13	-33.3	0.00	66.7
	Week 92	24	11.11	21.23	0.0	0.00	66.7	22	3.03	22.79	-33.3	0.00	66.7
	Week 95	21	12.70	22.30	0.0	0.00	66.7	20	8.33	23.88	-33.3	0.00	66.7
	Week 98	16	10.42	15.96	0.0	0.00	33.3	15	0.00	17.82	-33.3	0.00	33.3
	Week 101	12	11.11	21.71	0.0	0.00	66.7	12	2.78	22.29	-33.3	0.00	66.7
	Week 104	10	13.33	23.31	0.0	0.00	66.7	10	6.67	26.29	-33.3	0.00	66.7
	Plat+Gem (N=185)												
	BASELINE	146	14.61	22.14	0.0	0.00	100.0						
	Week 1	131	14.76	24.16	0.0	0.00	100.0	120	-0.28	18.58	-33.3	0.00	66.7
	Week 2	128	15.36	23.63	0.0	0.00	100.0	115	0.87	20.92	-33.3	0.00	100.0
	Week 3	141	15.84	23.76	0.0	0.00	100.0	126	1.85	19.46	-33.3	0.00	66.7
	Week 4	139	17.03	24.53	0.0	0.00	100.0	119	2.80	23.60	-33.3	0.00	100.0
	Week 5	143	19.11	25.17	0.0	0.00	100.0	120	4.72	21.73	-66.7	0.00	66.7

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 6	133	18.29	25.45	0.0	0.00	100.0	114	4.39	22.83	-66.7	0.00	66.7
	Week 7	142	19.01	24.92	0.0	0.00	100.0	120	5.00	20.57	-33.3	0.00	66.7
	Week 8	125	20.00	26.44	0.0	0.00	100.0	109	6.73	23.47	-33.3	0.00	66.7
	Week 9	135	20.74	26.35	0.0	0.00	100.0	115	8.70	26.52	-66.7	0.00	100.0
	Week 10	131	22.14	27.61	0.0	0.00	100.0	111	8.41	24.81	-33.3	0.00	66.7
	Week 11	128	21.61	28.24	0.0	0.00	100.0	109	7.03	24.03	-33.3	0.00	66.7
	Week 12	124	19.35	26.24	0.0	0.00	100.0	108	7.41	23.39	-33.3	0.00	66.7
	Week 14	121	20.66	25.19	0.0	0.00	100.0	101	9.57	24.65	-66.7	0.00	66.7
	Week 17	121	21.49	26.13	0.0	0.00	100.0	101	9.57	25.53	-66.7	0.00	66.7
	Week 20	98	21.43	24.52	0.0	33.33	100.0	86	11.63	24.40	-33.3	0.00	100.0
	Week 23	93	15.41	22.82	0.0	0.00	100.0	78	7.26	23.20	-33.3	0.00	100.0
	Week 26	86	14.73	20.20	0.0	0.00	66.7	75	5.33	20.53	-33.3	0.00	66.7
	Week 29	76	14.47	23.31	0.0	0.00	100.0	65	6.15	23.49	-33.3	0.00	100.0
	Week 32	62	13.44	17.55	0.0	0.00	66.7	56	5.36	18.83	-33.3	0.00	33.3
	Week 35	58	14.94	19.91	0.0	0.00	66.7	52	6.41	20.91	-33.3	0.00	66.7
	Week 38	60	18.89	25.58	0.0	0.00	100.0	52	9.62	24.11	-33.3	0.00	100.0
	Week 41	52	18.59	23.26	0.0	0.00	100.0	44	9.09	25.28	-33.3	0.00	100.0
	Week 44	46	21.74	27.41	0.0	0.00	100.0	40	12.50	27.93	-33.3	0.00	100.0
	Week 47	44	18.94	25.31	0.0	0.00	100.0	38	6.14	17.08	-33.3	0.00	66.7
	Week 50	42	17.46	25.75	0.0	0.00	100.0	38	7.89	23.80	-33.3	0.00	100.0
	Week 53	38	15.79	21.56	0.0	0.00	66.7	34	6.86	19.73	-33.3	0.00	33.3
	Week 56	32	21.87	27.58	0.0	16.67	100.0	28	9.52	19.99	-33.3	0.00	66.7
	Week 59	31	16.13	22.56	0.0	0.00	100.0	27	4.94	17.79	-33.3	0.00	33.3
	Week 62	29	17.24	19.15	0.0	0.00	66.7	26	7.69	19.57	-33.3	0.00	33.3
	Week 65	25	21.33	27.01	0.0	0.00	100.0	21	7.94	23.34	-33.3	0.00	66.7
	Week 68	20	21.67	27.09	0.0	16.67	100.0	16	6.25	21.84	-33.3	0.00	33.3

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 71	17	21.57	28.73	0.0	0.00	100.0	14	7.14	23.31	-33.3	0.00	33.3
	Week 74	17	19.61	26.51	0.0	0.00	100.0	14	2.38	20.52	-33.3	0.00	33.3
	Week 77	16	20.83	31.91	0.0	0.00	100.0	13	0.00	27.22	-33.3	0.00	66.7
	Week 80	13	10.26	16.01	0.0	0.00	33.3	12	-2.78	17.16	-33.3	0.00	33.3
	Week 83	11	15.15	17.41	0.0	0.00	33.3	10	3.33	24.59	-33.3	0.00	33.3
	Week 86	12	11.11	16.41	0.0	0.00	33.3	11	0.00	21.08	-33.3	0.00	33.3
	Week 89	11	15.15	17.41	0.0	0.00	33.3	10	3.33	24.59	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	EV+Pembro (N= 42)												
	BASELINE	36	7.41	19.70	0.0	0.00	100.0						
	Week 1	33	13.13	20.31	0.0	0.00	66.7	32	6.25	15.70	-33.3	0.00	33.3
	Week 2	36	12.96	19.96	0.0	0.00	66.7	34	5.88	17.35	-33.3	0.00	33.3
	Week 3	37	17.12	27.91	0.0	0.00	100.0	35	9.52	23.67	-33.3	0.00	100.0
	Week 4	36	14.81	21.74	0.0	0.00	66.7	34	8.82	17.03	-33.3	0.00	33.3
	Week 5	36	12.04	22.75	0.0	0.00	66.7	33	6.06	17.59	-33.3	0.00	66.7
	Week 6	35	10.48	17.66	0.0	0.00	66.7	32	8.33	14.66	0.0	0.00	33.3
	Week 7	36	16.67	20.31	0.0	0.00	66.7	34	7.84	16.53	-33.3	0.00	33.3
	Week 8	37	14.41	20.09	0.0	0.00	66.7	36	6.48	17.49	-33.3	0.00	33.3
	Week 9	35	14.28	20.27	0.0	0.00	66.7	34	6.86	17.94	-33.3	0.00	33.3
	Week 10	32	9.37	21.14	0.0	0.00	100.0	31	0.00	17.21	-66.7	0.00	33.3
	Week 11	33	16.16	25.17	0.0	0.00	100.0	32	6.25	21.48	-66.7	0.00	66.7
	Week 12	32	16.67	18.93	0.0	0.00	66.7	31	7.53	20.57	-66.7	0.00	33.3
	Week 14	31	17.20	24.15	0.0	0.00	100.0	30	5.56	19.74	-66.7	0.00	33.3
	Week 17	33	12.12	20.10	0.0	0.00	66.7	32	5.21	20.93	-66.7	0.00	66.7
	Week 20	28	13.09	20.96	0.0	0.00	66.7	28	7.14	24.61	-66.7	0.00	66.7
	Week 23	29	13.79	18.93	0.0	0.00	66.7	29	5.75	21.95	-66.7	0.00	33.3
	Week 26	27	17.28	16.97	0.0	33.33	33.3	26	8.97	22.23	-66.7	0.00	33.3
	Week 29	26	17.95	19.39	0.0	16.67	66.7	25	8.00	22.11	-66.7	0.00	33.3
	Week 32	24	16.67	19.66	0.0	0.00	66.7	23	5.80	23.89	-66.7	0.00	33.3
	Week 35	23	17.39	22.18	0.0	0.00	66.7	22	6.06	24.42	-66.7	0.00	33.3
	Week 38	25	18.67	25.60	0.0	0.00	100.0	24	11.11	18.82	-33.3	0.00	33.3
	Week 41	26	19.23	25.25	0.0	0.00	100.0	25	6.67	25.46	-66.7	0.00	66.7
	Week 44	20	21.67	24.84	0.0	33.33	100.0	19	8.77	24.45	-66.7	0.00	33.3
	Week 47	20	15.00	25.30	0.0	0.00	100.0	19	0.00	22.22	-66.7	0.00	33.3

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
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Table 302.1.3002.18.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	16	8.33	19.25	0.0	0.00	66.7	16	-2.08	19.12	-33.3	0.00	33.3
	Week 53	15	17.78	24.77	0.0	0.00	66.7	15	6.67	22.54	-33.3	0.00	66.7
	Week 56	15	8.89	19.79	0.0	0.00	66.7	15	-2.22	29.46	-66.7	0.00	66.7
	Week 59	14	9.52	20.38	0.0	0.00	66.7	14	-2.38	30.56	-66.7	0.00	66.7
	Week 62	11	6.06	13.48	0.0	0.00	33.3	11	-6.06	25.03	-66.7	0.00	33.3
	Plat+Gem (N= 57)												
	BASELINE	42	16.67	22.39	0.0	0.00	66.7						
	Week 1	42	10.32	18.75	0.0	0.00	66.7	38	-6.14	20.29	-66.7	0.00	33.3
	Week 2	43	17.05	23.43	0.0	0.00	66.7	36	0.93	23.21	-66.7	0.00	66.7
	Week 3	43	18.60	25.51	0.0	0.00	100.0	36	1.85	23.83	-66.7	0.00	66.7
	Week 4	44	13.64	18.07	0.0	0.00	66.7	37	-2.70	18.22	-33.3	0.00	33.3
	Week 5	44	12.88	21.82	0.0	0.00	66.7	36	1.85	26.36	-66.7	0.00	66.7
	Week 6	41	13.82	21.05	0.0	0.00	66.7	35	0.95	24.90	-66.7	0.00	33.3
	Week 7	44	10.61	21.29	0.0	0.00	100.0	37	-1.80	23.50	-66.7	0.00	33.3
	Week 8	42	21.43	28.34	0.0	0.00	100.0	35	8.57	29.53	-33.3	0.00	66.7
	Week 9	42	15.87	21.13	0.0	0.00	66.7	35	-0.95	23.55	-66.7	0.00	33.3
	Week 10	35	20.00	21.69	0.0	33.33	66.7	28	5.95	20.39	-33.3	0.00	66.7
	Week 11	40	21.67	27.79	0.0	0.00	100.0	34	4.90	28.58	-66.7	0.00	66.7
	Week 12	35	19.05	23.27	0.0	0.00	66.7	30	2.22	26.16	-66.7	0.00	66.7
	Week 14	32	26.04	31.38	0.0	33.33	100.0	27	8.64	31.48	-33.3	0.00	66.7
	Week 17	34	18.63	24.88	0.0	0.00	100.0	29	2.30	28.07	-33.3	0.00	66.7
	Week 20	28	14.29	23.00	0.0	0.00	66.7	24	0.00	21.98	-33.3	0.00	66.7
	Week 23	22	19.70	28.47	0.0	0.00	100.0	19	10.53	19.41	-33.3	0.00	33.3
	Week 26	22	16.67	22.42	0.0	0.00	66.7	20	3.33	21.36	-33.3	0.00	33.3
	Week 29	24	13.89	19.45	0.0	0.00	66.7	21	1.59	24.67	-33.3	0.00	33.3
	Week 32	21	7.94	14.55	0.0	0.00	33.3	20	-5.00	22.36	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 35	18	18.52	23.49	0.0	0.00	66.7	17	3.92	23.22	-66.7	0.00	33.3
	Week 38	14	11.90	21.11	0.0	0.00	66.7	13	0.00	27.22	-66.7	0.00	33.3
	Week 41	13	7.69	14.62	0.0	0.00	33.3	12	-2.78	30.01	-66.7	0.00	33.3
	Week 44	14	11.90	21.11	0.0	0.00	66.7	13	0.00	33.33	-66.7	0.00	66.7
	Week 47	12	11.11	16.41	0.0	0.00	33.3	11	0.00	29.81	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Visceral metastases	EV+Pembro (N=170)												
	BASELINE	146	12.10	20.67	0.0	0.00	100.0						
	Week 1	135	13.58	22.78	0.0	0.00	100.0	131	2.29	19.91	-33.3	0.00	66.7
	Week 2	145	14.02	21.75	0.0	0.00	100.0	134	2.74	22.03	-66.7	0.00	66.7
	Week 3	141	19.15	25.58	0.0	0.00	100.0	129	6.98	24.18	-66.7	0.00	100.0
	Week 4	136	15.93	24.67	0.0	0.00	100.0	125	5.07	24.34	-66.7	0.00	100.0
	Week 5	131	16.54	24.94	0.0	0.00	100.0	118	6.21	26.85	-66.7	0.00	100.0
	Week 6	127	11.55	18.49	0.0	0.00	66.7	113	3.24	20.39	-66.7	0.00	66.7
	Week 7	135	16.05	21.49	0.0	0.00	100.0	121	4.68	24.08	-66.7	0.00	100.0
	Week 8	131	13.23	20.12	0.0	0.00	100.0	118	3.67	23.38	-66.7	0.00	100.0
	Week 9	136	14.95	23.59	0.0	0.00	100.0	124	4.84	23.16	-66.7	0.00	100.0
	Week 10	135	12.34	20.26	0.0	0.00	100.0	124	1.34	23.82	-66.7	0.00	100.0
	Week 11	134	14.43	21.80	0.0	0.00	100.0	121	3.58	23.88	-66.7	0.00	66.7
	Week 12	131	15.52	22.76	0.0	0.00	100.0	120	5.28	23.27	-66.7	0.00	100.0
	Week 14	130	15.13	23.15	0.0	0.00	100.0	117	2.85	27.53	-66.7	0.00	100.0
	Week 17	124	12.90	20.70	0.0	0.00	100.0	111	3.90	24.51	-66.7	0.00	100.0
	Week 20	115	15.36	23.48	0.0	0.00	100.0	105	5.08	26.87	-66.7	0.00	100.0
	Week 23	111	13.81	21.77	0.0	0.00	100.0	103	3.56	26.78	-66.7	0.00	100.0
	Week 26	106	11.32	16.51	0.0	0.00	66.7	97	1.37	20.93	-66.7	0.00	33.3
	Week 29	106	11.95	16.71	0.0	0.00	66.7	98	3.06	23.00	-66.7	0.00	33.3
	Week 32	92	12.68	17.00	0.0	0.00	66.7	85	2.35	24.55	-66.7	0.00	66.7
	Week 35	86	12.40	19.16	0.0	0.00	100.0	79	3.38	21.08	-66.7	0.00	66.7
	Week 38	90	15.55	19.48	0.0	0.00	66.7	84	6.35	21.00	-33.3	0.00	66.7
	Week 41	87	16.09	22.65	0.0	0.00	100.0	81	6.58	27.09	-66.7	0.00	66.7
	Week 44	73	15.52	20.09	0.0	0.00	66.7	68	7.35	24.33	-66.7	0.00	66.7
	Week 47	68	11.76	18.89	0.0	0.00	66.7	63	3.17	22.96	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	61	14.75	24.74	0.0	0.00	100.0	57	7.60	28.18	-33.3	0.00	100.0
	Week 53	54	11.11	19.43	0.0	0.00	66.7	50	2.67	22.17	-33.3	0.00	66.7
	Week 56	58	12.64	21.47	0.0	0.00	100.0	54	4.32	26.73	-66.7	0.00	100.0
	Week 59	50	9.33	17.87	0.0	0.00	66.7	47	1.42	24.03	-66.7	0.00	66.7
	Week 62	45	10.37	19.88	0.0	0.00	100.0	43	3.88	25.42	-66.7	0.00	100.0
	Week 65	37	13.51	25.41	0.0	0.00	100.0	34	4.90	31.92	-66.7	0.00	100.0
	Week 68	35	15.24	23.35	0.0	0.00	100.0	34	7.84	29.65	-66.7	0.00	100.0
	Week 71	31	12.90	22.24	0.0	0.00	100.0	30	6.67	28.23	-66.7	0.00	100.0
	Week 74	29	8.05	17.03	0.0	0.00	66.7	28	1.19	24.82	-66.7	0.00	66.7
	Week 77	26	14.10	19.26	0.0	0.00	66.7	25	5.33	26.67	-66.7	0.00	66.7
	Week 80	22	16.67	22.42	0.0	0.00	66.7	21	6.35	27.12	-33.3	0.00	66.7
	Week 83	23	11.59	19.09	0.0	0.00	66.7	22	3.03	22.79	-33.3	0.00	33.3
	Week 86	21	15.87	22.65	0.0	0.00	66.7	20	6.67	25.59	-33.3	0.00	66.7
	Week 89	21	14.29	22.54	0.0	0.00	66.7	20	3.33	26.27	-33.3	0.00	66.7
	Week 92	18	11.11	19.80	0.0	0.00	66.7	17	5.88	24.25	-33.3	0.00	66.7
	Week 95	13	7.69	19.97	0.0	0.00	66.7	12	5.56	23.92	-33.3	0.00	66.7
	Week 98	11	0.00	0.00	0.0	0.00	0.0	11	-9.09	15.57	-33.3	0.00	0.0
	Week 101	11	15.15	27.34	0.0	0.00	66.7	11	6.06	25.03	-33.3	0.00	66.7
	Plat+Gem (N=161)												
	BASELINE	129	16.54	22.49	0.0	0.00	100.0						
	Week 1	113	15.63	24.43	0.0	0.00	100.0	105	-1.90	17.80	-66.7	0.00	66.7
	Week 2	108	16.67	23.90	0.0	0.00	100.0	98	-0.34	18.84	-33.3	0.00	66.7
	Week 3	121	17.08	22.82	0.0	0.00	100.0	109	0.92	20.52	-66.7	0.00	66.7
	Week 4	116	17.24	22.19	0.0	0.00	100.0	101	0.66	21.59	-33.3	0.00	100.0
	Week 5	121	17.63	23.99	0.0	0.00	100.0	104	1.60	22.46	-66.7	0.00	66.7
	Week 6	118	17.51	24.54	0.0	0.00	100.0	102	1.96	24.74	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 7	121	17.08	23.62	0.0	0.00	100.0	104	2.24	21.42	-66.7	0.00	66.7
	Week 8	108	19.75	25.39	0.0	0.00	100.0	96	5.21	23.36	-33.3	0.00	66.7
	Week 9	114	19.30	25.43	0.0	0.00	100.0	99	4.71	25.20	-66.7	0.00	66.7
	Week 10	109	21.41	25.87	0.0	0.00	100.0	94	6.74	23.23	-33.3	0.00	66.7
	Week 11	109	22.02	27.67	0.0	0.00	100.0	95	5.97	26.62	-66.7	0.00	66.7
	Week 12	103	20.71	26.86	0.0	0.00	100.0	91	7.33	26.67	-66.7	0.00	66.7
	Week 14	98	23.13	25.96	0.0	33.33	100.0	85	9.02	27.40	-66.7	0.00	66.7
	Week 17	103	21.36	26.75	0.0	0.00	100.0	89	7.49	26.95	-66.7	0.00	66.7
	Week 20	82	20.32	24.43	0.0	0.00	100.0	75	8.89	24.09	-33.3	0.00	66.7
	Week 23	77	18.18	26.79	0.0	0.00	100.0	68	9.31	25.66	-33.3	0.00	100.0
	Week 26	71	17.37	20.98	0.0	0.00	66.7	65	6.67	20.58	-33.3	0.00	33.3
	Week 29	65	13.33	20.24	0.0	0.00	66.7	59	3.39	22.05	-33.3	0.00	66.7
	Week 32	52	10.90	17.11	0.0	0.00	66.7	49	0.00	20.41	-66.7	0.00	33.3
	Week 35	47	17.02	21.84	0.0	0.00	66.7	44	6.06	23.04	-66.7	0.00	66.7
	Week 38	42	17.46	23.56	0.0	0.00	66.7	39	8.55	25.04	-66.7	0.00	66.7
	Week 41	35	16.19	20.41	0.0	0.00	66.7	32	6.25	27.35	-66.7	0.00	66.7
	Week 44	36	20.37	26.76	0.0	0.00	100.0	33	11.11	30.81	-66.7	0.00	100.0
	Week 47	32	16.67	18.93	0.0	0.00	66.7	30	4.44	20.96	-66.7	0.00	33.3
	Week 50	30	16.67	19.08	0.0	0.00	66.7	29	6.90	27.28	-66.7	0.00	66.7
	Week 53	25	10.67	15.87	0.0	0.00	33.3	24	4.17	20.41	-33.3	0.00	33.3
	Week 56	22	19.70	26.55	0.0	0.00	100.0	21	12.70	22.30	-33.3	0.00	66.7
	Week 59	22	13.64	16.77	0.0	0.00	33.3	21	9.52	18.69	-33.3	0.00	33.3
	Week 62	19	19.30	16.91	0.0	33.33	33.3	18	12.96	20.25	-33.3	0.00	33.3
	Week 65	19	15.79	23.22	0.0	0.00	66.7	18	11.11	22.87	-33.3	0.00	66.7
	Week 68	13	20.51	25.60	0.0	0.00	66.7	12	13.89	26.43	-33.3	0.00	66.7
	Week 71	13	20.51	25.60	0.0	0.00	66.7	12	16.67	26.59	-33.3	16.67	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 74	11	12.12	16.82	0.0	0.00	33.3	11	6.06	20.10	-33.3	0.00	33.3
	Week 77	10	3.33	10.54	0.0	0.00	33.3	10	-6.67	14.05	-33.3	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Lymph node only	EV+Pembro (N= 60)												
	BASELINE	53	8.18	15.89	0.0	0.00	66.7						
	Week 1	49	8.84	14.87	0.0	0.00	33.3	47	2.13	12.82	-33.3	0.00	33.3
	Week 2	50	10.67	20.69	0.0	0.00	100.0	48	2.78	15.12	-33.3	0.00	66.7
	Week 3	50	10.67	18.37	0.0	0.00	66.7	47	2.84	9.40	0.0	0.00	33.3
	Week 4	50	7.33	15.49	0.0	0.00	66.7	47	0.71	10.97	-33.3	0.00	33.3
	Week 5	53	8.18	19.51	0.0	0.00	100.0	49	1.36	15.15	-33.3	0.00	66.7
	Week 6	53	12.58	23.77	0.0	0.00	100.0	50	4.67	21.31	-33.3	0.00	100.0
	Week 7	52	11.54	20.75	0.0	0.00	100.0	48	3.47	18.50	-33.3	0.00	66.7
	Week 8	52	14.10	24.11	0.0	0.00	100.0	47	7.09	20.78	-33.3	0.00	66.7
	Week 9	53	16.98	22.29	0.0	0.00	100.0	49	10.20	21.73	-33.3	0.00	66.7
	Week 10	48	18.05	23.78	0.0	0.00	100.0	44	6.82	18.44	-33.3	0.00	66.7
	Week 11	53	19.50	23.96	0.0	0.00	100.0	48	9.72	20.58	-33.3	0.00	66.7
	Week 12	48	18.75	23.73	0.0	0.00	100.0	45	8.89	22.92	-33.3	0.00	100.0
	Week 14	48	15.97	22.79	0.0	0.00	100.0	44	6.06	16.51	-33.3	0.00	33.3
	Week 17	46	15.22	21.89	0.0	0.00	100.0	44	7.58	20.16	-66.7	0.00	66.7
	Week 20	44	21.97	30.45	0.0	0.00	100.0	42	11.91	28.34	-66.7	0.00	100.0
	Week 23	43	23.26	29.58	0.0	0.00	100.0	41	13.01	26.75	-33.3	0.00	66.7
	Week 26	42	20.63	23.23	0.0	16.67	66.7	40	11.67	23.33	-33.3	0.00	66.7
	Week 29	45	17.04	25.25	0.0	0.00	100.0	42	7.94	23.06	-33.3	0.00	66.7
	Week 32	38	19.30	25.27	0.0	0.00	100.0	36	9.26	21.98	-33.3	0.00	66.7
	Week 35	42	15.08	24.64	0.0	0.00	100.0	40	5.83	21.20	-33.3	0.00	66.7
	Week 38	38	16.67	27.67	0.0	0.00	100.0	36	5.56	23.23	-33.3	0.00	66.7
	Week 41	37	16.22	25.61	0.0	0.00	100.0	34	6.86	19.73	-33.3	0.00	66.7
	Week 44	31	25.81	29.45	0.0	33.33	100.0	29	13.79	22.74	0.0	0.00	66.7
	Week 47	28	22.62	30.16	0.0	0.00	100.0	27	9.88	28.96	-33.3	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	25	13.33	21.52	0.0	0.00	66.7	24	2.78	23.91	-33.3	0.00	66.7
	Week 53	23	15.94	19.77	0.0	0.00	66.7	22	4.55	15.58	-33.3	0.00	33.3
	Week 56	21	9.52	18.69	0.0	0.00	66.7	20	3.33	23.94	-33.3	0.00	66.7
	Week 59	20	20.00	25.13	0.0	16.67	100.0	19	10.53	27.33	-33.3	0.00	100.0
	Week 62	19	17.54	25.74	0.0	0.00	100.0	19	8.77	29.06	-33.3	0.00	100.0
	Week 65	20	15.00	25.30	0.0	0.00	100.0	19	8.77	26.86	-33.3	0.00	100.0
	Week 68	17	13.72	26.51	0.0	0.00	100.0	17	5.88	29.43	-33.3	0.00	100.0
	Week 71	19	12.28	25.36	0.0	0.00	100.0	18	5.56	30.78	-33.3	0.00	100.0
	Week 74	17	17.65	26.66	0.0	0.00	100.0	17	9.80	28.29	-33.3	0.00	100.0
	Week 77	17	13.72	20.61	0.0	0.00	66.7	16	6.25	25.00	-33.3	0.00	66.7
	Week 80	17	13.72	20.61	0.0	0.00	66.7	15	4.44	24.77	-33.3	0.00	66.7
	Week 83	13	15.38	17.29	0.0	0.00	33.3	12	5.56	19.24	-33.3	0.00	33.3
	Week 86	12	16.67	22.47	0.0	0.00	66.7	10	3.33	10.54	0.0	0.00	33.3
	Week 89	11	21.21	22.47	0.0	33.33	66.7	10	13.33	17.21	0.0	0.00	33.3
	Plat+Gem (N= 67)												
	BASELINE	49	11.56	22.10	0.0	0.00	100.0						
	Week 1	51	9.15	20.09	0.0	0.00	100.0	45	-1.48	21.27	-66.7	0.00	33.3
	Week 2	53	15.09	24.08	0.0	0.00	100.0	44	3.79	26.13	-66.7	0.00	100.0
	Week 3	53	15.72	28.20	0.0	0.00	100.0	44	4.55	19.81	-33.3	0.00	66.7
	Week 4	58	14.94	25.87	0.0	0.00	100.0	47	3.55	24.31	-33.3	0.00	66.7
	Week 5	56	19.64	26.80	0.0	0.00	100.0	44	10.61	22.47	-33.3	0.00	66.7
	Week 6	48	17.36	24.78	0.0	0.00	100.0	40	7.50	19.23	-33.3	0.00	66.7
	Week 7	56	17.26	26.20	0.0	0.00	100.0	46	5.80	21.43	-33.3	0.00	66.7
	Week 8	52	21.79	30.17	0.0	0.00	100.0	42	11.11	29.14	-33.3	0.00	66.7
	Week 9	53	19.50	25.68	0.0	0.00	100.0	42	9.52	28.78	-66.7	0.00	100.0
	Week 10	47	22.69	27.01	0.0	0.00	100.0	36	11.11	25.20	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	51	20.91	29.79	0.0	0.00	100.0	41	8.13	20.79	-33.3	0.00	66.7
	Week 12	47	17.73	23.93	0.0	0.00	100.0	39	5.13	16.29	-33.3	0.00	66.7
	Week 14	47	19.15	28.44	0.0	0.00	100.0	36	12.04	22.75	-33.3	0.00	66.7
	Week 17	45	21.48	24.78	0.0	33.33	100.0	35	12.38	24.37	-33.3	0.00	66.7
	Week 20	38	16.67	20.13	0.0	0.00	66.7	30	6.67	20.34	-33.3	0.00	66.7
	Week 23	32	11.46	16.08	0.0	0.00	33.3	25	5.33	12.47	0.0	0.00	33.3
	Week 26	30	11.11	20.22	0.0	0.00	66.7	24	2.78	21.79	-33.3	0.00	66.7
	Week 29	28	16.67	27.96	0.0	0.00	100.0	21	11.11	28.55	-33.3	0.00	100.0
	Week 32	26	12.82	16.54	0.0	0.00	33.3	22	7.58	20.40	-33.3	0.00	33.3
	Week 35	23	13.04	19.43	0.0	0.00	66.7	19	5.26	20.07	-33.3	0.00	66.7
	Week 38	26	17.95	28.64	0.0	0.00	100.0	20	6.67	27.78	-33.3	0.00	100.0
	Week 41	24	18.05	25.97	0.0	0.00	100.0	18	9.26	27.55	-33.3	0.00	100.0
	Week 44	18	20.37	28.33	0.0	0.00	100.0	14	9.52	30.46	-33.3	0.00	100.0
	Week 47	18	18.52	32.78	0.0	0.00	100.0	13	5.13	22.96	-33.3	0.00	66.7
	Week 50	16	18.75	34.36	0.0	0.00	100.0	13	7.69	30.89	-33.3	0.00	100.0
	Week 53	15	22.22	27.22	0.0	0.00	66.7	12	8.33	20.72	-33.3	0.00	33.3
	Week 56	15	15.55	27.79	0.0	0.00	100.0	11	-3.03	17.98	-33.3	0.00	33.3
	Week 59	12	16.67	30.15	0.0	0.00	100.0	9	-7.41	14.70	-33.3	0.00	0.0
	Week 62	10	13.33	23.31	0.0	0.00	66.7	8	0.00	17.82	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
EV+Pembro (N=202)												
BASELINE	160	18.12	25.31	0.0	0.00	100.0						
Week 1	141	18.91	26.52	0.0	0.00	100.0	129	-0.52	20.83	-66.7	0.00	66.7
Week 2	150	18.44	23.66	0.0	0.00	100.0	133	2.00	18.69	-33.3	0.00	66.7
Week 3	139	15.59	21.72	0.0	0.00	100.0	122	2.46	19.25	-33.3	0.00	66.7
Week 4	145	17.93	24.22	0.0	0.00	100.0	129	3.62	22.53	-66.7	0.00	100.0
Week 5	137	18.49	24.23	0.0	0.00	100.0	121	3.86	22.44	-33.3	0.00	100.0
Week 6	146	18.72	24.75	0.0	0.00	100.0	124	4.30	22.88	-66.7	0.00	66.7
Week 7	147	17.91	25.06	0.0	0.00	100.0	124	3.23	23.05	-33.3	0.00	66.7
Week 8	147	20.63	26.84	0.0	0.00	100.0	124	5.91	26.56	-66.7	0.00	100.0
Week 9	142	19.72	25.16	0.0	0.00	100.0	121	6.89	25.79	-66.7	0.00	66.7
Week 10	139	17.98	24.17	0.0	0.00	100.0	118	4.80	26.96	-66.7	0.00	100.0
Week 11	137	16.54	21.44	0.0	0.00	100.0	115	3.48	23.93	-66.7	0.00	66.7
Week 12	142	16.90	24.71	0.0	0.00	100.0	119	3.08	24.93	-33.3	0.00	100.0
Week 14	139	16.55	23.18	0.0	0.00	100.0	116	2.87	23.08	-66.7	0.00	100.0
Week 17	132	16.92	22.74	0.0	0.00	100.0	111	3.00	21.34	-66.7	0.00	66.7
Week 20	120	15.28	20.68	0.0	0.00	66.7	103	1.62	20.55	-33.3	0.00	66.7
Week 23	117	13.10	20.97	0.0	0.00	100.0	97	1.72	25.63	-66.7	0.00	100.0
Week 26	112	13.69	21.71	0.0	0.00	100.0	94	1.06	23.16	-66.7	0.00	66.7
Week 29	107	18.07	23.91	0.0	0.00	100.0	93	4.66	25.34	-66.7	0.00	100.0
Week 32	102	16.01	22.85	0.0	0.00	100.0	88	4.92	21.76	-66.7	0.00	66.7
Week 35	98	17.35	22.05	0.0	0.00	100.0	86	5.04	22.59	-33.3	0.00	66.7
Week 38	97	14.09	19.14	0.0	0.00	66.7	86	3.10	20.85	-33.3	0.00	66.7
Week 41	95	14.38	20.43	0.0	0.00	100.0	84	3.57	19.37	-33.3	0.00	66.7
Week 44	86	14.73	22.64	0.0	0.00	100.0	74	4.05	22.04	-33.3	0.00	66.7
Week 47	79	14.77	19.79	0.0	0.00	66.7	70	3.81	20.88	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	74	14.86	22.17	0.0	0.00	100.0	64	2.60	21.66	-33.3	0.00	66.7
Week 53	74	15.76	22.22	0.0	0.00	100.0	63	4.76	23.84	-33.3	0.00	66.7
Week 56	72	13.43	19.91	0.0	0.00	66.7	61	2.19	21.83	-66.7	0.00	33.3
Week 59	69	13.53	21.63	0.0	0.00	100.0	57	1.75	22.20	-33.3	0.00	66.7
Week 62	62	11.29	19.03	0.0	0.00	66.7	52	-0.64	19.23	-33.3	0.00	33.3
Week 65	43	15.50	23.40	0.0	0.00	66.7	40	2.50	23.13	-33.3	0.00	66.7
Week 68	46	14.49	21.83	0.0	0.00	66.7	42	2.38	15.43	-33.3	0.00	33.3
Week 71	42	14.28	22.26	0.0	0.00	100.0	38	-0.88	22.58	-33.3	0.00	100.0
Week 74	38	13.16	19.82	0.0	0.00	66.7	35	0.95	20.59	-33.3	0.00	33.3
Week 77	37	18.02	21.65	0.0	0.00	66.7	33	4.04	21.66	-33.3	0.00	66.7
Week 80	36	17.59	24.54	0.0	0.00	66.7	34	3.92	25.64	-66.7	0.00	33.3
Week 83	30	17.78	22.71	0.0	0.00	66.7	29	4.60	24.76	-66.7	0.00	33.3
Week 86	26	23.08	24.53	0.0	33.33	100.0	25	9.33	29.69	-66.7	0.00	66.7
Week 89	20	16.67	17.10	0.0	16.67	33.3	19	7.02	23.77	-33.3	0.00	33.3
Week 92	19	24.56	21.78	0.0	33.33	66.7	18	14.81	23.49	-33.3	33.33	33.3
Week 95	14	14.28	17.12	0.0	0.00	33.3	13	5.13	22.96	-33.3	0.00	33.3
Week 98	10	13.33	17.21	0.0	0.00	33.3	9	7.41	22.22	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Plat+Gem (N=202)												
BASELINE	165	17.17	25.66	0.0	0.00	100.0						
Week 1	144	19.21	26.32	0.0	0.00	100.0	139	1.92	22.26	-66.7	0.00	66.7
Week 2	147	19.73	25.51	0.0	0.00	100.0	135	2.72	21.95	-66.7	0.00	66.7
Week 3	149	20.80	24.35	0.0	0.00	100.0	136	5.39	23.03	-100.0	0.00	66.7
Week 4	150	21.11	24.25	0.0	33.33	100.0	135	5.18	24.05	-66.7	0.00	66.7
Week 5	153	23.75	26.68	0.0	33.33	100.0	138	7.97	27.18	-66.7	0.00	100.0
Week 6	145	24.14	28.73	0.0	33.33	100.0	131	8.40	28.15	-66.7	0.00	100.0
Week 7	148	22.30	27.60	0.0	0.00	100.0	134	8.21	29.03	-66.7	0.00	100.0
Week 8	145	24.37	27.57	0.0	33.33	100.0	132	9.34	27.11	-66.7	0.00	100.0
Week 9	141	24.82	28.56	0.0	33.33	100.0	125	10.93	31.04	-66.7	0.00	100.0
Week 10	142	21.36	24.26	0.0	33.33	100.0	130	6.15	29.29	-66.7	0.00	100.0
Week 11	126	26.19	29.09	0.0	33.33	100.0	114	9.65	28.64	-66.7	0.00	100.0
Week 12	130	26.92	29.08	0.0	33.33	100.0	115	10.43	32.55	-66.7	0.00	100.0
Week 14	125	27.47	28.73	0.0	33.33	100.0	109	11.62	28.82	-66.7	0.00	100.0
Week 17	120	26.67	27.54	0.0	33.33	100.0	106	10.69	23.25	-66.7	0.00	66.7
Week 20	104	25.32	27.67	0.0	33.33	100.0	91	10.62	24.28	-66.7	0.00	66.7
Week 23	88	22.35	25.13	0.0	33.33	100.0	80	10.42	25.21	-66.7	0.00	66.7
Week 26	81	23.87	24.29	0.0	33.33	100.0	75	8.44	24.56	-66.7	0.00	66.7
Week 29	77	24.24	26.29	0.0	33.33	100.0	71	8.45	23.72	-66.7	0.00	100.0
Week 32	63	22.22	24.68	0.0	33.33	100.0	58	5.17	24.02	-66.7	0.00	100.0
Week 35	62	19.89	22.95	0.0	16.67	100.0	56	2.98	27.17	-66.7	0.00	100.0
Week 38	56	20.83	21.61	0.0	33.33	66.7	50	7.33	19.39	-33.3	0.00	33.3
Week 41	52	21.15	21.92	0.0	33.33	66.7	47	8.51	26.44	-33.3	0.00	66.7
Week 44	49	24.49	22.34	0.0	33.33	66.7	44	9.85	24.46	-33.3	0.00	66.7
Week 47	43	23.25	23.61	0.0	33.33	100.0	39	9.40	21.56	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	36	25.00	25.67	0.0	33.33	100.0	31	7.53	20.56	-33.3	0.00	33.3
Week 53	31	22.58	23.39	0.0	33.33	100.0	28	8.33	25.05	-33.3	0.00	66.7
Week 56	30	24.44	28.94	0.0	33.33	100.0	29	5.75	25.31	-66.7	0.00	66.7
Week 59	23	27.53	21.68	0.0	33.33	66.7	21	9.52	30.08	-33.3	0.00	66.7
Week 62	20	31.67	27.52	0.0	33.33	100.0	20	10.00	32.62	-33.3	0.00	100.0
Week 65	17	27.45	26.97	0.0	33.33	66.7	16	6.25	30.35	-33.3	0.00	66.7
Week 68	13	25.64	24.17	0.0	33.33	66.7	13	2.56	28.74	-33.3	0.00	66.7
Week 71	13	20.51	21.68	0.0	33.33	66.7	13	-2.57	25.32	-33.3	0.00	33.3
Week 74	11	15.15	22.92	0.0	0.00	66.7	11	3.03	31.46	-33.3	0.00	66.7
Week 77	11	15.15	17.41	0.0	0.00	33.3	11	0.00	25.82	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Present	EV+Pembro (N= 50)												
	BASELINE	40	23.33	29.43	0.0	0.00	100.0						
	Week 1	38	29.82	36.18	0.0	33.33	100.0	34	0.98	23.90	-66.7	0.00	66.7
	Week 2	35	23.81	27.50	0.0	33.33	100.0	32	3.13	19.60	-33.3	0.00	33.3
	Week 3	32	20.83	25.04	0.0	16.67	100.0	30	2.22	21.32	-33.3	0.00	33.3
	Week 4	35	23.81	29.78	0.0	0.00	100.0	31	5.38	22.93	-33.3	0.00	66.7
	Week 5	32	22.92	26.01	0.0	33.33	100.0	28	4.76	14.95	-33.3	0.00	33.3
	Week 6	35	25.71	32.42	0.0	0.00	100.0	30	6.67	23.81	-33.3	0.00	66.7
	Week 7	35	20.95	31.40	0.0	0.00	100.0	29	2.30	23.45	-33.3	0.00	66.7
	Week 8	38	30.70	34.12	0.0	33.33	100.0	31	12.90	28.12	-33.3	0.00	66.7
	Week 9	33	19.19	26.39	0.0	0.00	100.0	29	4.60	17.19	-33.3	0.00	33.3
	Week 10	30	25.55	25.80	0.0	33.33	100.0	25	8.00	25.96	-66.7	0.00	66.7
	Week 11	31	18.28	18.93	0.0	33.33	66.7	27	4.94	20.05	-33.3	0.00	33.3
	Week 12	32	15.62	20.71	0.0	0.00	66.7	28	0.00	20.29	-33.3	0.00	33.3
	Week 14	36	16.67	27.02	0.0	0.00	100.0	31	-2.15	20.97	-66.7	0.00	33.3
	Week 17	33	14.14	25.04	0.0	0.00	100.0	27	-1.23	19.57	-66.7	0.00	33.3
	Week 20	28	14.28	19.09	0.0	0.00	66.7	25	0.00	16.67	-33.3	0.00	33.3
	Week 23	28	11.90	22.62	0.0	0.00	66.7	24	-1.39	23.01	-66.7	0.00	33.3
	Week 26	28	8.33	17.27	0.0	0.00	66.7	24	-4.17	17.89	-66.7	0.00	33.3
	Week 29	27	17.28	28.30	0.0	0.00	100.0	25	4.00	30.91	-66.7	0.00	100.0
	Week 32	25	13.33	21.52	0.0	0.00	66.7	23	2.90	19.88	-66.7	0.00	33.3
	Week 35	26	16.67	23.57	0.0	0.00	66.7	24	5.56	23.40	-33.3	0.00	33.3
	Week 38	26	14.10	19.26	0.0	0.00	66.7	24	2.78	19.45	-33.3	0.00	33.3
	Week 41	25	10.67	18.56	0.0	0.00	66.7	23	1.45	18.74	-33.3	0.00	33.3
	Week 44	22	13.64	19.68	0.0	0.00	66.7	20	1.67	17.01	-33.3	0.00	33.3
	Week 47	14	14.29	21.54	0.0	0.00	66.7	13	0.00	19.25	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	15.00	27.52	0.0	0.00	100.0	17	3.92	16.17	-33.3	0.00	33.3
	Week 53	21	15.87	27.12	0.0	0.00	100.0	18	3.70	22.55	-33.3	0.00	66.7
	Week 56	18	14.81	23.49	0.0	0.00	66.7	15	4.44	11.73	0.0	0.00	33.3
	Week 59	18	12.96	20.26	0.0	0.00	66.7	15	2.22	15.26	-33.3	0.00	33.3
	Week 62	13	10.26	21.01	0.0	0.00	66.7	11	3.03	10.05	0.0	0.00	33.3
	Week 68	12	11.11	16.41	0.0	0.00	33.3	11	3.03	10.05	0.0	0.00	33.3
	Plat+Gem (N= 50)												
	BASELINE	40	22.50	27.62	0.0	0.00	100.0						
	Week 1	35	28.57	29.31	0.0	33.33	100.0	33	5.05	22.24	-66.7	0.00	66.7
	Week 2	33	24.24	27.98	0.0	33.33	100.0	30	3.33	16.02	-33.3	0.00	33.3
	Week 3	33	24.24	25.38	0.0	33.33	100.0	29	6.90	18.64	-33.3	0.00	66.7
	Week 4	36	24.07	21.98	0.0	33.33	66.7	32	4.17	22.00	-33.3	0.00	66.7
	Week 5	36	28.70	29.98	0.0	33.33	100.0	32	11.46	34.51	-33.3	0.00	100.0
	Week 6	32	23.96	28.38	0.0	16.67	100.0	29	4.60	27.78	-33.3	0.00	66.7
	Week 7	35	24.76	30.62	0.0	0.00	100.0	31	7.53	36.22	-66.7	0.00	100.0
	Week 8	35	22.86	23.94	0.0	33.33	100.0	31	6.45	26.41	-33.3	0.00	66.7
	Week 9	34	23.53	25.33	0.0	33.33	100.0	30	8.89	30.24	-33.3	0.00	100.0
	Week 10	33	25.25	28.90	0.0	33.33	100.0	30	7.78	37.84	-66.7	0.00	100.0
	Week 11	30	27.78	31.66	0.0	33.33	100.0	26	10.26	32.35	-66.7	0.00	100.0
	Week 12	32	28.12	25.55	0.0	33.33	100.0	27	11.11	34.59	-33.3	0.00	100.0
	Week 14	27	23.46	25.85	0.0	33.33	66.7	22	6.06	28.43	-33.3	0.00	66.7
	Week 17	28	23.81	25.43	0.0	33.33	100.0	23	5.80	23.89	-33.3	0.00	33.3
	Week 20	20	21.67	27.09	0.0	0.00	66.7	16	6.25	25.00	-33.3	0.00	33.3
	Week 23	15	24.44	26.63	0.0	33.33	66.7	14	14.29	25.20	-33.3	0.00	66.7
	Week 26	15	17.78	21.33	0.0	0.00	66.7	14	4.76	25.68	-33.3	0.00	66.7
	Week 29	13	25.64	30.89	0.0	33.33	100.0	12	13.89	33.21	-33.3	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Absent	EV+Pembro (N=152)												
	BASELINE	120	16.39	23.67	0.0	0.00	100.0						
	Week 1	103	14.89	20.73	0.0	0.00	100.0	95	-1.05	19.72	-66.7	0.00	33.3
	Week 2	115	16.81	22.24	0.0	0.00	100.0	101	1.65	18.48	-33.3	0.00	66.7
	Week 3	107	14.02	20.50	0.0	0.00	66.7	92	2.54	18.64	-33.3	0.00	66.7
	Week 4	110	16.06	22.00	0.0	0.00	100.0	98	3.06	22.49	-66.7	0.00	100.0
	Week 5	105	17.14	23.62	0.0	0.00	100.0	93	3.58	24.31	-33.3	0.00	100.0
	Week 6	111	16.52	21.50	0.0	0.00	100.0	94	3.55	22.65	-66.7	0.00	66.7
	Week 7	112	16.96	22.81	0.0	0.00	100.0	95	3.51	23.05	-33.3	0.00	66.7
	Week 8	109	17.12	22.96	0.0	0.00	100.0	93	3.58	25.75	-66.7	0.00	100.0
	Week 9	109	19.88	24.89	0.0	0.00	100.0	92	7.61	28.00	-66.7	0.00	66.7
	Week 10	109	15.90	23.39	0.0	0.00	100.0	93	3.94	27.30	-66.7	0.00	100.0
	Week 11	106	16.04	22.17	0.0	0.00	100.0	88	3.03	25.08	-66.7	0.00	66.7
	Week 12	110	17.27	25.83	0.0	0.00	100.0	91	4.03	26.22	-33.3	0.00	100.0
	Week 14	103	16.50	21.83	0.0	0.00	100.0	85	4.71	23.65	-33.3	0.00	100.0
	Week 17	99	17.84	21.98	0.0	0.00	100.0	84	4.36	21.82	-33.3	0.00	66.7
	Week 20	92	15.58	21.23	0.0	0.00	66.7	78	2.14	21.71	-33.3	0.00	66.7
	Week 23	89	13.48	20.55	0.0	0.00	100.0	73	2.74	26.50	-66.7	0.00	100.0
	Week 26	84	15.48	22.82	0.0	0.00	100.0	70	2.86	24.57	-33.3	0.00	66.7
	Week 29	80	18.33	22.44	0.0	0.00	100.0	68	4.90	23.23	-33.3	0.00	66.7
	Week 32	77	16.88	23.34	0.0	0.00	100.0	65	5.64	22.49	-33.3	0.00	66.7
	Week 35	72	17.59	21.65	0.0	0.00	100.0	62	4.84	22.46	-33.3	0.00	66.7
	Week 38	71	14.08	19.24	0.0	0.00	66.7	62	3.23	21.52	-33.3	0.00	66.7
	Week 41	70	15.71	21.02	0.0	0.00	100.0	61	4.37	19.70	-33.3	0.00	66.7
	Week 44	64	15.10	23.70	0.0	0.00	100.0	54	4.94	23.71	-33.3	0.00	66.7
	Week 47	65	14.87	19.57	0.0	0.00	66.7	57	4.68	21.30	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	54	14.81	20.13	0.0	0.00	66.7	47	2.13	23.47	-33.3	0.00	66.7
	Week 53	53	15.72	20.26	0.0	0.00	66.7	45	5.19	24.57	-33.3	0.00	66.7
	Week 56	54	12.96	18.78	0.0	0.00	66.7	46	1.45	24.30	-66.7	0.00	33.3
	Week 59	51	13.72	22.29	0.0	0.00	100.0	42	1.59	24.36	-33.3	0.00	66.7
	Week 62	49	11.56	18.70	0.0	0.00	66.7	41	-1.63	21.02	-33.3	0.00	33.3
	Week 65	36	15.74	24.54	0.0	0.00	66.7	33	1.01	24.27	-33.3	0.00	66.7
	Week 68	34	15.69	23.55	0.0	0.00	66.7	31	2.15	17.07	-33.3	0.00	33.3
	Week 71	33	11.11	18.00	0.0	0.00	66.7	30	-5.56	15.37	-33.3	0.00	33.3
	Week 74	33	11.11	18.00	0.0	0.00	66.7	30	0.00	21.44	-33.3	0.00	33.3
	Week 77	31	16.13	20.85	0.0	0.00	66.7	27	2.47	22.51	-33.3	0.00	66.7
	Week 80	31	16.13	22.56	0.0	0.00	66.7	29	2.30	26.62	-66.7	0.00	33.3
	Week 83	25	14.67	21.69	0.0	0.00	66.7	24	1.39	25.02	-66.7	0.00	33.3
	Week 86	23	18.84	19.66	0.0	33.33	66.7	22	6.06	28.43	-66.7	0.00	33.3
	Week 89	18	16.67	17.15	0.0	16.67	33.3	17	7.84	25.08	-33.3	0.00	33.3
	Week 92	16	22.92	23.47	0.0	33.33	66.7	15	13.33	24.56	-33.3	33.33	33.3
	Week 95	12	13.89	17.16	0.0	0.00	33.3	11	6.06	25.02	-33.3	0.00	33.3
	Plat+Gem (N=152)												
	BASELINE	125	15.47	24.88	0.0	0.00	100.0						
	Week 1	109	16.21	24.68	0.0	0.00	100.0	106	0.94	22.28	-66.7	0.00	66.7
	Week 2	114	18.42	24.73	0.0	0.00	100.0	105	2.54	23.43	-66.7	0.00	66.7
	Week 3	116	19.83	24.07	0.0	0.00	100.0	107	4.98	24.14	-100.0	0.00	66.7
	Week 4	114	20.17	24.94	0.0	0.00	100.0	103	5.50	24.74	-66.7	0.00	66.7
	Week 5	117	22.22	25.52	0.0	33.33	100.0	106	6.92	24.65	-66.7	0.00	66.7
	Week 6	113	24.19	28.95	0.0	33.33	100.0	102	9.48	28.29	-66.7	0.00	100.0
	Week 7	113	21.53	26.70	0.0	0.00	100.0	103	8.41	26.70	-66.7	0.00	100.0
	Week 8	110	24.85	28.71	0.0	33.33	100.0	101	10.23	27.38	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	107	25.23	29.62	0.0	33.33	100.0	95	11.58	31.42	-66.7	0.00	100.0
	Week 10	109	20.18	22.69	0.0	33.33	100.0	100	5.67	26.40	-66.7	0.00	66.7
	Week 11	96	25.69	28.40	0.0	33.33	100.0	88	9.47	27.66	-66.7	0.00	100.0
	Week 12	98	26.53	30.26	0.0	33.33	100.0	88	10.23	32.11	-66.7	0.00	100.0
	Week 14	98	28.57	29.51	0.0	33.33	100.0	87	13.03	28.92	-66.7	0.00	100.0
	Week 17	92	27.54	28.22	0.0	33.33	100.0	83	12.05	23.03	-66.7	0.00	66.7
	Week 20	84	26.19	27.90	0.0	33.33	100.0	75	11.55	24.19	-66.7	0.00	66.7
	Week 23	73	21.92	24.98	0.0	33.33	100.0	66	9.60	25.33	-66.7	0.00	66.7
	Week 26	66	25.25	24.85	0.0	33.33	100.0	61	9.29	24.44	-66.7	0.00	66.7
	Week 29	64	23.96	25.52	0.0	33.33	100.0	59	7.34	21.50	-66.7	0.00	66.7
	Week 32	54	24.07	25.42	0.0	33.33	100.0	49	6.12	25.16	-66.7	0.00	100.0
	Week 35	54	20.99	23.61	0.0	33.33	100.0	48	3.47	28.55	-66.7	0.00	100.0
	Week 38	47	20.57	21.48	0.0	33.33	66.7	42	7.14	20.21	-33.3	0.00	33.3
	Week 41	45	21.48	22.65	0.0	33.33	66.7	40	9.17	27.20	-33.3	0.00	66.7
	Week 44	41	25.20	22.09	0.0	33.33	66.7	36	10.19	24.97	-33.3	0.00	66.7
	Week 47	35	22.86	23.94	0.0	33.33	100.0	31	8.60	19.18	-33.3	0.00	66.7
	Week 50	29	28.73	26.31	0.0	33.33	100.0	24	9.72	20.80	-33.3	0.00	33.3
	Week 53	25	24.00	24.57	0.0	33.33	100.0	22	9.09	25.58	-33.3	0.00	66.7
	Week 56	26	25.64	30.27	0.0	33.33	100.0	25	5.33	26.67	-66.7	0.00	66.7
	Week 59	20	25.00	21.29	0.0	33.33	66.7	18	5.56	28.58	-33.3	0.00	66.7
	Week 62	17	27.45	24.25	0.0	33.33	66.7	17	3.92	26.04	-33.3	0.00	33.3
	Week 65	15	28.89	27.79	0.0	33.33	66.7	14	7.14	32.50	-33.3	0.00	66.7
	Week 68	11	30.30	23.36	0.0	33.33	66.7	11	6.06	29.13	-33.3	0.00	66.7
	Week 71	12	22.22	21.71	0.0	33.33	66.7	12	-2.78	26.43	-33.3	0.00	33.3
	Week 74	10	16.67	23.57	0.0	0.00	66.7	10	3.33	33.15	-33.3	0.00	66.7
	Week 77	10	13.33	17.21	0.0	0.00	33.3	10	-3.33	24.59	-33.3	0.00	33.3

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
< 65 years	EV+Pembro (N= 39)												
	BASELINE	32	10.42	15.70	0.0	0.00	33.3						
	Week 1	27	13.58	16.69	0.0	0.00	33.3	26	3.85	17.19	-33.3	0.00	33.3
	Week 2	30	17.78	22.71	0.0	0.00	66.7	29	6.90	22.50	-33.3	0.00	66.7
	Week 3	31	13.98	16.72	0.0	0.00	33.3	29	4.60	17.19	-33.3	0.00	33.3
	Week 4	30	14.44	18.94	0.0	0.00	66.7	27	2.47	18.32	-33.3	0.00	33.3
	Week 5	28	19.05	16.80	0.0	33.33	33.3	26	6.41	18.90	-33.3	0.00	33.3
	Week 6	29	16.09	19.15	0.0	0.00	66.7	26	5.13	20.42	-33.3	0.00	33.3
	Week 7	30	14.44	16.80	0.0	0.00	33.3	26	1.28	19.96	-33.3	0.00	33.3
	Week 8	30	13.33	18.77	0.0	0.00	66.7	26	5.13	22.49	-33.3	0.00	66.7
	Week 9	28	16.67	16.97	0.0	16.67	33.3	27	8.64	19.81	-33.3	0.00	33.3
	Week 10	26	20.51	21.24	0.0	33.33	66.7	23	13.04	24.08	-33.3	0.00	66.7
	Week 11	28	17.86	21.24	0.0	0.00	66.7	25	9.33	24.57	-33.3	0.00	66.7
	Week 12	28	11.90	18.62	0.0	0.00	66.7	25	1.33	20.37	-33.3	0.00	33.3
	Week 14	26	14.10	16.79	0.0	0.00	33.3	23	4.35	18.27	-33.3	0.00	33.3
	Week 17	28	19.05	19.09	0.0	33.33	66.7	24	5.56	18.82	-33.3	0.00	33.3
	Week 20	27	18.52	21.35	0.0	0.00	66.7	24	6.94	24.03	-33.3	0.00	66.7
	Week 23	26	14.10	19.26	0.0	0.00	66.7	23	5.80	21.68	-33.3	0.00	33.3
	Week 26	24	12.50	16.48	0.0	0.00	33.3	22	1.52	16.19	-33.3	0.00	33.3
	Week 29	25	21.33	25.24	0.0	33.33	100.0	23	8.70	32.12	-33.3	0.00	100.0
	Week 32	25	18.67	21.69	0.0	0.00	66.7	23	5.80	19.21	-33.3	0.00	66.7
	Week 35	24	13.89	19.45	0.0	0.00	66.7	22	0.00	20.57	-33.3	0.00	33.3
	Week 38	23	15.94	19.77	0.0	0.00	66.7	22	3.03	17.54	-33.3	0.00	33.3
	Week 41	25	18.66	16.89	0.0	33.33	33.3	23	8.69	20.64	-33.3	0.00	33.3
	Week 44	22	16.67	22.42	0.0	0.00	66.7	20	5.00	22.36	-33.3	0.00	33.3
	Week 47	20	18.33	20.16	0.0	16.67	66.7	18	7.41	21.56	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	19	14.03	16.91	0.0	0.00	33.3	17	0.00	20.41	-33.3	0.00	33.3
	Week 53	20	21.67	22.36	0.0	33.33	66.7	18	7.41	24.40	-33.3	0.00	66.7
	Week 56	17	19.61	20.61	0.0	33.33	66.7	15	4.44	21.33	-33.3	0.00	33.3
	Week 59	17	23.53	30.65	0.0	0.00	100.0	15	11.11	27.22	-33.3	0.00	66.7
	Week 62	15	13.33	21.08	0.0	0.00	66.7	14	0.00	18.49	-33.3	0.00	33.3
	Week 65	14	23.81	27.51	0.0	16.67	66.7	13	10.26	25.04	-33.3	0.00	66.7
	Week 68	11	12.12	22.47	0.0	0.00	66.7	10	0.00	15.71	-33.3	0.00	33.3
	Week 71	13	17.95	17.29	0.0	33.33	33.3	12	2.78	17.16	-33.3	0.00	33.3
	Week 74	14	19.05	21.54	0.0	16.67	66.7	13	5.13	22.96	-33.3	0.00	33.3
	Week 77	14	21.43	21.11	0.0	33.33	66.7	13	10.26	16.01	0.0	0.00	33.3
	Week 80	14	19.05	25.20	0.0	0.00	66.7	13	10.26	21.01	-33.3	0.00	33.3
	Week 83	12	25.00	20.72	0.0	33.33	66.7	11	18.18	17.41	0.0	33.33	33.3
	Plat+Gem (N= 29)												
	BASELINE	22	12.12	19.37	0.0	0.00	66.7						
	Week 1	21	14.28	19.92	0.0	0.00	66.7	20	1.67	17.01	-33.3	0.00	33.3
	Week 2	24	13.89	19.45	0.0	0.00	66.7	20	0.00	18.73	-33.3	0.00	66.7
	Week 3	23	10.14	15.68	0.0	0.00	33.3	20	0.00	10.81	-33.3	0.00	33.3
	Week 4	23	11.59	16.23	0.0	0.00	33.3	19	1.75	17.47	-33.3	0.00	33.3
	Week 5	25	20.00	23.57	0.0	33.33	100.0	20	5.00	12.21	0.0	0.00	33.3
	Week 6	22	21.21	26.32	0.0	16.67	100.0	18	5.56	20.61	-33.3	0.00	66.7
	Week 7	24	15.28	19.61	0.0	0.00	66.7	21	1.59	12.81	-33.3	0.00	33.3
	Week 8	21	12.70	19.65	0.0	0.00	66.7	19	0.00	11.11	-33.3	0.00	33.3
	Week 9	20	21.67	27.09	0.0	0.00	66.7	17	3.92	28.58	-66.7	0.00	66.7
	Week 10	21	20.63	26.82	0.0	0.00	100.0	18	7.41	18.28	0.0	0.00	66.7
	Week 11	20	20.00	25.13	0.0	16.67	100.0	17	5.88	13.10	0.0	0.00	33.3
	Week 12	21	19.05	24.88	0.0	0.00	66.7	17	5.88	13.10	0.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 14	22	25.76	28.97	0.0	33.33	100.0	18	11.11	19.80	0.0	0.00	66.7
	Week 17	20	21.67	27.09	0.0	16.67	100.0	17	7.84	18.74	-33.3	0.00	33.3
	Week 20	18	24.07	22.30	0.0	33.33	66.7	15	15.56	17.21	0.0	0.00	33.3
	Week 23	18	20.37	20.26	0.0	33.33	66.7	16	10.42	15.96	0.0	0.00	33.3
	Week 26	16	20.83	20.64	0.0	33.33	66.7	14	9.52	20.37	-33.3	0.00	33.3
	Week 29	15	20.00	27.60	0.0	0.00	100.0	13	5.13	18.49	-33.3	0.00	33.3
	Week 32	15	20.00	21.08	0.0	33.33	66.7	13	7.69	14.62	0.0	0.00	33.3
	Week 35	15	20.00	21.08	0.0	33.33	66.7	13	7.69	19.97	-33.3	0.00	33.3
	Week 38	14	23.81	24.21	0.0	33.33	66.7	12	11.11	16.41	0.0	0.00	33.3
	Week 41	11	24.24	26.21	0.0	33.33	66.7	9	14.82	24.22	0.0	0.00	66.7
	Week 44	11	24.24	21.56	0.0	33.33	66.7	9	14.81	17.57	0.0	0.00	33.3
	Week 47	11	24.24	30.15	0.0	33.33	100.0	9	11.11	16.67	0.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>= 65 years	EV+Pembro (N=163)												
	BASELINE	128	20.05	26.90	0.0	0.00	100.0						
	Week 1	114	20.17	28.26	0.0	0.00	100.0	103	-1.62	21.58	-66.7	0.00	66.7
	Week 2	120	18.61	23.98	0.0	0.00	100.0	104	0.64	17.37	-33.3	0.00	33.3
	Week 3	108	16.05	23.00	0.0	0.00	100.0	93	1.79	19.88	-33.3	0.00	66.7
	Week 4	115	18.84	25.41	0.0	0.00	100.0	102	3.92	23.59	-66.7	0.00	100.0
	Week 5	109	18.35	25.85	0.0	0.00	100.0	95	3.16	23.36	-33.3	0.00	100.0
	Week 6	117	19.37	25.98	0.0	0.00	100.0	98	4.08	23.58	-66.7	0.00	66.7
	Week 7	117	18.80	26.76	0.0	0.00	100.0	98	3.74	23.88	-33.3	0.00	66.7
	Week 8	117	22.51	28.31	0.0	0.00	100.0	98	6.12	27.64	-66.7	0.00	100.0
	Week 9	114	20.47	26.80	0.0	0.00	100.0	94	6.38	27.34	-66.7	0.00	66.7
	Week 10	113	17.40	24.84	0.0	0.00	100.0	95	2.81	27.36	-66.7	0.00	100.0
	Week 11	109	16.21	21.57	0.0	0.00	100.0	90	1.85	23.63	-66.7	0.00	66.7
	Week 12	114	18.13	25.91	0.0	0.00	100.0	94	3.55	26.08	-33.3	0.00	100.0
	Week 14	113	17.11	24.44	0.0	0.00	100.0	93	2.51	24.19	-66.7	0.00	100.0
	Week 17	104	16.35	23.68	0.0	0.00	100.0	87	2.30	22.04	-66.7	0.00	66.7
	Week 20	93	14.34	20.50	0.0	0.00	66.7	79	0.00	19.24	-33.3	0.00	66.7
	Week 23	91	12.82	21.53	0.0	0.00	100.0	74	0.45	26.74	-66.7	0.00	100.0
	Week 26	88	14.01	23.01	0.0	0.00	100.0	72	0.93	25.00	-66.7	0.00	66.7
	Week 29	82	17.07	23.57	0.0	0.00	100.0	70	3.33	22.81	-66.7	0.00	66.7
	Week 32	77	15.15	23.29	0.0	0.00	100.0	65	4.62	22.73	-66.7	0.00	66.7
	Week 35	74	18.47	22.84	0.0	0.00	100.0	64	6.77	23.14	-33.3	0.00	66.7
	Week 38	74	13.51	19.05	0.0	0.00	66.7	64	3.12	22.00	-33.3	0.00	66.7
	Week 41	70	12.86	21.45	0.0	0.00	100.0	61	1.64	18.68	-33.3	0.00	66.7
	Week 44	64	14.06	22.85	0.0	0.00	100.0	54	3.70	22.12	-33.3	0.00	66.7
	Week 47	59	13.56	19.69	0.0	0.00	66.7	52	2.56	20.71	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	55	15.15	23.85	0.0	0.00	100.0	47	3.55	22.24	-33.3	0.00	66.7
	Week 53	54	13.58	21.98	0.0	0.00	100.0	45	3.70	23.81	-33.3	0.00	66.7
	Week 56	55	11.51	19.48	0.0	0.00	66.7	46	1.45	22.17	-66.7	0.00	33.3
	Week 59	52	10.26	16.88	0.0	0.00	66.7	42	-1.59	19.41	-33.3	0.00	33.3
	Week 62	47	10.64	18.53	0.0	0.00	66.7	38	-0.88	19.74	-33.3	0.00	33.3
	Week 65	29	11.49	20.46	0.0	0.00	66.7	27	-1.23	21.64	-33.3	0.00	66.7
	Week 68	35	15.24	21.91	0.0	0.00	66.7	32	3.13	15.52	-33.3	0.00	33.3
	Week 71	29	12.64	24.26	0.0	0.00	100.0	26	-2.56	24.81	-33.3	0.00	100.0
	Week 74	24	9.72	18.33	0.0	0.00	66.7	22	-1.52	19.18	-33.3	0.00	33.3
	Week 77	23	15.94	22.18	0.0	0.00	66.7	20	0.00	24.18	-33.3	0.00	66.7
	Week 80	22	16.67	24.67	0.0	0.00	66.7	21	0.00	27.89	-66.7	0.00	33.3
	Week 83	18	12.96	23.26	0.0	0.00	66.7	18	-3.70	25.28	-66.7	0.00	33.3
	Week 86	18	18.52	26.13	0.0	0.00	100.0	18	1.85	31.25	-66.7	0.00	66.7
	Week 89	12	13.89	17.16	0.0	0.00	33.3	12	2.78	26.43	-33.3	0.00	33.3
	Week 92	10	16.67	23.57	0.0	0.00	66.7	10	3.33	24.59	-33.3	0.00	33.3
	Plat+Gem (N=173)												
	BASELINE	143	17.95	26.47	0.0	0.00	100.0						
	Week 1	123	20.05	27.24	0.0	0.00	100.0	119	1.96	23.08	-66.7	0.00	66.7
	Week 2	123	20.87	26.45	0.0	0.00	100.0	115	3.19	22.50	-66.7	0.00	66.7
	Week 3	126	22.75	25.18	0.0	33.33	100.0	116	6.32	24.44	-100.0	0.00	66.7
	Week 4	127	22.83	25.09	0.0	33.33	100.0	116	5.75	24.97	-66.7	0.00	66.7
	Week 5	128	24.48	27.27	0.0	33.33	100.0	118	8.47	28.97	-66.7	0.00	100.0
	Week 6	123	24.66	29.21	0.0	33.33	100.0	113	8.85	29.22	-66.7	0.00	100.0
	Week 7	124	23.65	28.76	0.0	33.33	100.0	113	9.44	31.01	-66.7	0.00	100.0
	Week 8	124	26.34	28.28	0.0	33.33	100.0	113	10.91	28.67	-66.7	0.00	100.0
	Week 9	121	25.34	28.88	0.0	33.33	100.0	108	12.04	31.40	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	121	21.49	23.91	0.0	33.33	100.0	112	5.95	30.75	-66.7	0.00	100.0
	Week 11	106	27.36	29.74	0.0	33.33	100.0	97	10.31	30.57	-66.7	0.00	100.0
	Week 12	109	28.44	29.68	0.0	33.33	100.0	98	11.22	34.83	-66.7	0.00	100.0
	Week 14	103	27.83	28.81	0.0	33.33	100.0	91	11.72	30.38	-66.7	0.00	100.0
	Week 17	100	27.67	27.65	0.0	33.33	100.0	89	11.24	24.07	-66.7	0.00	66.7
	Week 20	86	25.58	28.78	0.0	33.33	100.0	76	9.65	25.42	-66.7	0.00	66.7
	Week 23	70	22.86	26.34	0.0	33.33	100.0	64	10.42	27.14	-66.7	0.00	66.7
	Week 26	65	24.61	25.19	0.0	33.33	100.0	61	8.20	25.57	-66.7	0.00	66.7
	Week 29	62	25.27	26.09	0.0	33.33	100.0	58	9.19	24.81	-66.7	0.00	100.0
	Week 32	48	22.92	25.87	0.0	33.33	100.0	45	4.44	26.21	-66.7	0.00	100.0
	Week 35	47	19.86	23.73	0.0	0.00	100.0	43	1.55	29.05	-66.7	0.00	100.0
	Week 38	42	19.84	20.90	0.0	33.33	66.7	38	6.14	20.29	-33.3	0.00	33.3
	Week 41	41	20.32	20.92	0.0	33.33	66.7	38	7.02	27.02	-33.3	0.00	66.7
	Week 44	38	24.56	22.84	0.0	33.33	66.7	35	8.57	26.00	-33.3	0.00	66.7
	Week 47	32	22.92	21.48	0.0	33.33	66.7	30	8.89	23.05	-33.3	0.00	66.7
	Week 50	29	21.84	22.32	0.0	33.33	66.7	26	5.13	20.42	-33.3	0.00	33.3
	Week 53	25	24.00	24.57	0.0	33.33	100.0	24	8.33	26.47	-33.3	0.00	66.7
	Week 56	26	21.79	26.57	0.0	16.67	100.0	26	3.85	25.52	-66.7	0.00	66.7
	Week 59	20	28.33	22.36	0.0	33.33	66.7	20	10.00	30.78	-33.3	0.00	66.7
	Week 62	19	31.58	28.27	0.0	33.33	100.0	19	8.77	33.04	-33.3	0.00	100.0
	Week 65	16	27.08	27.81	0.0	33.33	66.7	16	6.25	30.35	-33.3	0.00	66.7
	Week 68	13	25.64	24.17	0.0	33.33	66.7	13	2.56	28.74	-33.3	0.00	66.7
	Week 71	13	20.51	21.68	0.0	33.33	66.7	13	-2.57	25.32	-33.3	0.00	33.3
	Week 74	11	15.15	22.92	0.0	0.00	66.7	11	3.03	31.46	-33.3	0.00	66.7
	Week 77	10	16.67	17.57	0.0	16.67	33.3	10	0.00	27.22	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Europe	EV+Pembro (N= 74)												
	BASELINE	53	18.24	23.17	0.0	0.00	66.7						
	Week 1	48	16.67	27.50	0.0	0.00	100.0	42	-2.38	22.56	-33.3	0.00	66.7
	Week 2	53	18.24	23.17	0.0	0.00	66.7	44	0.76	20.94	-33.3	0.00	66.7
	Week 3	50	14.67	20.38	0.0	0.00	66.7	41	0.81	22.96	-33.3	0.00	66.7
	Week 4	51	18.30	26.93	0.0	0.00	100.0	44	3.03	28.59	-33.3	0.00	100.0
	Week 5	46	20.29	24.82	0.0	0.00	100.0	41	4.07	27.07	-33.3	0.00	100.0
	Week 6	50	21.33	23.09	0.0	33.33	66.7	39	5.13	24.82	-33.3	0.00	66.7
	Week 7	50	16.67	23.57	0.0	0.00	100.0	39	1.71	26.43	-33.3	0.00	66.7
	Week 8	51	22.87	28.67	0.0	0.00	100.0	41	6.50	30.02	-33.3	0.00	100.0
	Week 9	47	21.99	27.17	0.0	0.00	100.0	37	9.01	27.94	-66.7	0.00	66.7
	Week 10	45	19.26	27.05	0.0	0.00	100.0	34	6.86	30.46	-66.7	0.00	66.7
	Week 11	48	17.36	22.79	0.0	0.00	66.7	37	3.60	29.17	-66.7	0.00	66.7
	Week 12	51	17.65	23.43	0.0	0.00	100.0	39	0.85	25.92	-33.3	0.00	100.0
	Week 14	50	17.33	24.50	0.0	0.00	100.0	38	0.00	26.85	-66.7	0.00	100.0
	Week 17	43	19.38	25.44	0.0	0.00	100.0	33	2.02	24.92	-66.7	0.00	66.7
	Week 20	41	17.89	22.48	0.0	0.00	66.7	33	-1.01	19.52	-33.3	0.00	33.3
	Week 23	41	13.82	21.05	0.0	0.00	66.7	30	-4.44	25.87	-66.7	0.00	33.3
	Week 26	37	18.02	23.03	0.0	0.00	66.7	28	2.38	31.33	-66.7	0.00	66.7
	Week 29	37	14.41	21.57	0.0	0.00	66.7	29	-4.60	23.10	-66.7	0.00	33.3
	Week 32	34	14.71	22.01	0.0	0.00	66.7	26	0.00	23.09	-66.7	0.00	66.7
	Week 35	31	16.13	20.85	0.0	0.00	66.7	25	0.00	27.22	-33.3	0.00	66.7
	Week 38	31	16.13	20.85	0.0	0.00	66.7	26	2.56	26.54	-33.3	0.00	66.7
	Week 41	28	19.05	24.73	0.0	0.00	100.0	23	5.80	23.89	-33.3	0.00	66.7
	Week 44	27	16.05	23.33	0.0	0.00	66.7	22	0.00	25.20	-33.3	0.00	66.7
	Week 47	25	16.00	21.77	0.0	0.00	66.7	21	4.76	28.45	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	26	15.38	27.05	0.0	0.00	100.0	23	0.00	28.43	-33.3	0.00	66.7
	Week 53	26	20.51	28.41	0.0	0.00	100.0	21	9.52	28.17	-33.3	0.00	66.7
	Week 56	25	13.33	21.52	0.0	0.00	66.7	21	0.00	21.08	-33.3	0.00	33.3
	Week 59	23	11.59	23.80	0.0	0.00	100.0	18	0.00	25.57	-33.3	0.00	66.7
	Week 62	20	6.67	13.68	0.0	0.00	33.3	17	-7.84	18.74	-33.3	0.00	33.3
	Week 65	13	20.51	25.60	0.0	0.00	66.7	13	0.00	23.57	-33.3	0.00	33.3
	Week 68	15	17.78	21.33	0.0	0.00	66.7	15	4.44	17.21	-33.3	0.00	33.3
	Week 71	13	17.95	29.23	0.0	0.00	100.0	13	0.00	36.00	-33.3	0.00	100.0
	Week 74	10	10.00	16.10	0.0	0.00	33.3	9	-11.11	23.57	-33.3	0.00	33.3
	Plat+Gem (N= 95)												
	BASELINE	75	22.67	28.56	0.0	0.00	100.0						
	Week 1	71	21.13	27.74	0.0	0.00	100.0	69	-1.45	23.17	-66.7	0.00	33.3
	Week 2	71	21.13	25.97	0.0	0.00	100.0	63	-2.65	23.42	-66.7	0.00	33.3
	Week 3	72	22.68	23.62	0.0	33.33	100.0	65	1.02	26.33	-100.0	0.00	66.7
	Week 4	69	23.67	24.98	0.0	33.33	100.0	62	2.69	26.52	-66.7	0.00	66.7
	Week 5	71	30.05	30.94	0.0	33.33	100.0	63	6.88	32.88	-66.7	0.00	100.0
	Week 6	69	27.54	30.76	0.0	33.33	100.0	61	6.01	31.92	-66.7	0.00	100.0
	Week 7	69	26.57	28.91	0.0	33.33	100.0	62	6.45	30.68	-66.7	0.00	100.0
	Week 8	67	24.87	28.63	0.0	33.33	100.0	60	3.33	29.24	-66.7	0.00	66.7
	Week 9	66	28.28	32.68	0.0	33.33	100.0	57	7.60	37.81	-66.7	0.00	100.0
	Week 10	70	23.81	25.47	0.0	33.33	100.0	63	1.59	34.62	-66.7	0.00	100.0
	Week 11	63	29.63	30.00	0.0	33.33	100.0	56	5.95	29.89	-66.7	0.00	100.0
	Week 12	66	30.30	33.45	0.0	33.33	100.0	56	8.93	41.92	-66.7	0.00	100.0
	Week 14	66	29.80	29.89	0.0	33.33	100.0	56	8.33	33.18	-66.7	0.00	100.0
	Week 17	61	29.51	29.88	0.0	33.33	100.0	53	7.55	26.67	-66.7	0.00	66.7
	Week 20	54	28.39	28.53	0.0	33.33	100.0	48	7.64	26.84	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 23	44	21.97	25.86	0.0	16.67	100.0	40	5.83	28.13	-66.7	0.00	66.7
	Week 26	42	23.81	27.83	0.0	33.33	100.0	39	3.42	25.13	-66.7	0.00	66.7
	Week 29	39	28.20	28.14	0.0	33.33	100.0	36	5.55	23.23	-66.7	0.00	33.3
	Week 32	32	28.12	28.22	0.0	33.33	100.0	30	4.44	29.99	-66.7	0.00	100.0
	Week 35	32	21.87	26.25	0.0	16.67	100.0	30	-1.11	33.31	-66.7	0.00	100.0
	Week 38	28	22.62	22.32	0.0	33.33	66.7	26	7.69	19.57	-33.3	0.00	33.3
	Week 41	25	22.67	20.91	0.0	33.33	66.7	23	5.80	25.92	-33.3	0.00	66.7
	Week 44	24	26.39	21.93	0.0	33.33	66.7	22	7.58	27.08	-33.3	0.00	66.7
	Week 47	22	31.82	26.18	0.0	33.33	100.0	20	11.67	27.09	-33.3	0.00	66.7
	Week 50	17	31.37	27.56	0.0	33.33	100.0	15	4.44	24.77	-33.3	0.00	33.3
	Week 53	15	31.11	26.63	0.0	33.33	100.0	14	9.52	30.46	-33.3	0.00	66.7
	Week 56	15	37.78	33.01	0.0	33.33	100.0	14	7.14	29.75	-66.7	0.00	66.7
	Week 59	11	33.33	14.91	0.0	33.33	66.7	10	3.33	33.15	-33.3	0.00	66.7
	Week 62	11	36.36	17.98	0.0	33.33	66.7	11	3.03	27.71	-33.3	0.00	33.3
	Week 65	10	36.67	29.19	0.0	33.33	66.7	10	3.33	36.68	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
North America	EV+Pembro (N= 46)												
	BASELINE	33	23.23	30.60	0.0	0.00	100.0						
	Week 1	30	22.22	28.14	0.0	16.67	100.0	27	-2.47	22.51	-66.7	0.00	33.3
	Week 2	30	20.00	24.13	0.0	16.67	100.0	26	3.85	17.20	-33.3	0.00	33.3
	Week 3	25	12.00	18.95	0.0	0.00	66.7	21	0.00	14.91	-33.3	0.00	33.3
	Week 4	30	21.11	20.50	0.0	33.33	66.7	24	5.56	23.40	-66.7	0.00	33.3
	Week 5	29	20.69	22.56	0.0	33.33	100.0	21	6.35	22.65	-33.3	0.00	66.7
	Week 6	31	22.58	30.29	0.0	0.00	100.0	23	7.25	30.08	-66.7	0.00	66.7
	Week 7	33	23.23	30.60	0.0	0.00	100.0	23	8.70	27.00	-33.3	0.00	66.7
	Week 8	29	25.29	31.69	0.0	33.33	100.0	20	15.00	31.48	-66.7	0.00	66.7
	Week 9	27	18.52	23.27	0.0	0.00	100.0	21	7.94	25.61	-33.3	0.00	66.7
	Week 10	29	20.69	22.56	0.0	33.33	66.7	23	7.25	26.51	-33.3	0.00	66.7
	Week 11	28	19.05	21.14	0.0	16.67	66.7	21	6.35	24.99	-33.3	0.00	33.3
	Week 12	29	17.24	21.12	0.0	0.00	66.7	22	4.55	23.67	-33.3	0.00	33.3
	Week 14	28	15.48	19.21	0.0	0.00	66.7	21	4.76	24.23	-33.3	0.00	33.3
	Week 17	29	17.24	21.12	0.0	0.00	66.7	23	2.90	24.44	-33.3	0.00	66.7
	Week 20	23	15.94	19.77	0.0	0.00	66.7	18	1.85	24.18	-33.3	0.00	66.7
	Week 23	22	13.64	24.47	0.0	0.00	100.0	17	1.96	34.30	-33.3	0.00	100.0
	Week 26	21	11.11	24.34	0.0	0.00	100.0	16	-4.17	26.87	-33.3	0.00	66.7
	Week 29	20	21.67	22.36	0.0	33.33	66.7	17	5.88	24.25	-33.3	0.00	33.3
	Week 32	21	19.05	22.54	0.0	0.00	66.7	18	5.56	20.61	-33.3	0.00	33.3
	Week 35	22	24.24	23.42	0.0	33.33	66.7	19	8.77	24.45	-33.3	0.00	33.3
	Week 38	20	18.33	20.16	0.0	16.67	66.7	17	3.92	20.01	-33.3	0.00	33.3
	Week 41	21	11.11	16.10	0.0	0.00	33.3	17	-1.96	18.52	-33.3	0.00	33.3
	Week 44	16	16.67	21.08	0.0	0.00	66.7	12	5.56	23.92	-33.3	0.00	33.3
	Week 47	16	14.58	17.08	0.0	0.00	33.3	13	0.00	13.61	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	16	14.58	20.97	0.0	0.00	66.7	11	3.03	17.98	-33.3	0.00	33.3
	Week 53	15	11.11	16.26	0.0	0.00	33.3	11	-3.03	23.35	-33.3	0.00	33.3
	Week 56	17	13.72	20.61	0.0	0.00	66.7	12	-2.78	30.01	-66.7	0.00	33.3
	Week 59	17	19.61	23.74	0.0	0.00	66.7	12	2.78	22.29	-33.3	0.00	33.3
	Week 62	14	14.29	21.54	0.0	0.00	66.7	9	0.00	16.67	-33.3	0.00	33.3
	Week 68	11	15.15	27.34	0.0	0.00	66.7	8	4.17	11.79	0.0	0.00	33.3
	Week 71	11	15.15	22.92	0.0	0.00	66.7	8	0.00	0.00	0.0	0.00	0.0
	Plat+Gem (N= 34)												
	BASELINE	27	17.28	31.17	0.0	0.00	100.0						
	Week 1	19	24.56	31.12	0.0	0.00	100.0	17	9.80	19.59	-33.3	0.00	33.3
	Week 2	20	21.67	31.11	0.0	0.00	100.0	18	9.26	19.15	0.0	0.00	66.7
	Week 3	20	18.33	27.52	0.0	0.00	100.0	17	9.80	15.65	0.0	0.00	33.3
	Week 4	23	18.84	22.08	0.0	0.00	66.7	19	10.53	19.41	-33.3	0.00	33.3
	Week 5	25	20.00	23.57	0.0	0.00	66.7	22	12.12	26.32	-33.3	0.00	66.7
	Week 6	20	25.00	28.36	0.0	33.33	100.0	17	13.72	26.51	-33.3	0.00	66.7
	Week 7	23	18.84	31.50	0.0	0.00	100.0	20	15.00	35.00	-33.3	0.00	100.0
	Week 8	24	25.00	26.47	0.0	33.33	100.0	22	15.15	26.68	-33.3	0.00	100.0
	Week 9	23	18.84	19.66	0.0	33.33	66.7	19	14.03	25.62	-33.3	0.00	66.7
	Week 10	20	13.33	16.75	0.0	0.00	33.3	18	9.26	19.15	-33.3	0.00	33.3
	Week 11	18	22.22	28.01	0.0	16.67	100.0	16	16.67	27.22	0.0	0.00	100.0
	Week 12	17	23.53	19.60	0.0	33.33	66.7	16	12.50	20.64	-33.3	0.00	33.3
	Week 14	16	29.17	26.87	0.0	33.33	100.0	14	23.81	20.37	0.0	33.33	66.7
	Week 17	19	28.07	25.49	0.0	33.33	100.0	17	21.57	16.42	0.0	33.33	33.3
	Week 20	16	20.83	20.64	0.0	33.33	66.7	13	23.08	16.01	0.0	33.33	33.3
	Week 23	15	22.22	20.57	0.0	33.33	66.7	13	17.95	17.29	0.0	33.33	33.3
	Week 26	13	28.20	22.96	0.0	33.33	66.7	12	25.00	25.13	0.0	33.33	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 29	14	19.05	17.12	0.0	33.33	33.3	13	12.82	16.88	0.0	0.00	33.3
	Week 32	11	12.12	16.82	0.0	0.00	33.3	10	6.67	14.05	0.0	0.00	33.3
	Week 35	13	12.82	16.88	0.0	0.00	33.3	11	9.09	15.57	0.0	0.00	33.3
	Week 38	10	20.00	17.21	0.0	33.33	33.3	9	14.81	17.57	0.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Rest of World	EV+Pembro (N= 82)												
	BASELINE	74	15.77	24.19	0.0	0.00	100.0						
	Week 1	63	19.05	25.20	0.0	0.00	100.0	60	1.67	18.84	-66.7	0.00	33.3
	Week 2	67	17.91	24.15	0.0	0.00	100.0	63	2.12	17.83	-33.3	0.00	33.3
	Week 3	64	17.71	23.73	0.0	0.00	100.0	60	4.44	17.86	-33.3	0.00	33.3
	Week 4	64	16.15	23.75	0.0	0.00	100.0	61	3.28	16.89	-33.3	0.00	33.3
	Week 5	62	16.13	24.70	0.0	0.00	100.0	59	2.82	18.86	-33.3	0.00	33.3
	Week 6	65	14.87	22.84	0.0	0.00	100.0	62	2.69	18.40	-33.3	0.00	33.3
	Week 7	64	16.15	23.00	0.0	0.00	100.0	62	2.15	18.96	-33.3	0.00	66.7
	Week 8	67	16.91	22.75	0.0	0.00	66.7	63	2.65	21.83	-33.3	0.00	66.7
	Week 9	68	18.63	24.69	0.0	0.00	100.0	63	5.29	24.83	-66.7	0.00	66.7
	Week 10	65	15.90	22.90	0.0	0.00	100.0	61	2.73	25.31	-66.7	0.00	100.0
	Week 11	61	14.75	20.66	0.0	0.00	100.0	57	2.34	19.78	-66.7	0.00	33.3
	Week 12	62	16.13	27.49	0.0	0.00	100.0	58	4.02	25.04	-33.3	0.00	100.0
	Week 14	61	16.39	24.05	0.0	0.00	100.0	57	4.09	19.99	-33.3	0.00	33.3
	Week 17	60	15.00	21.63	0.0	0.00	100.0	55	3.64	17.77	-33.3	0.00	33.3
	Week 20	56	13.09	19.77	0.0	0.00	66.7	52	3.21	20.09	-33.3	0.00	66.7
	Week 23	54	12.35	19.74	0.0	0.00	66.7	50	5.33	21.68	-66.7	0.00	66.7
	Week 26	54	11.73	19.59	0.0	0.00	66.7	50	2.00	15.66	-33.3	0.00	33.3
	Week 29	50	19.33	26.16	0.0	0.00	100.0	47	9.93	25.93	-33.3	0.00	100.0
	Week 32	47	15.60	23.93	0.0	0.00	100.0	44	7.58	21.40	-33.3	0.00	66.7
	Week 35	45	14.81	21.97	0.0	0.00	100.0	42	6.35	18.39	-33.3	0.00	66.7
	Week 38	46	10.87	17.29	0.0	0.00	66.7	43	3.10	17.54	-33.3	0.00	66.7
	Week 41	46	13.04	19.22	0.0	0.00	66.7	44	4.55	17.00	-33.3	0.00	33.3
	Week 44	43	13.18	23.16	0.0	0.00	100.0	40	5.83	19.81	-33.3	0.00	66.7
	Week 47	38	14.03	19.96	0.0	0.00	66.7	36	4.63	18.09	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	32	14.58	18.81	0.0	0.00	66.7	30	4.44	16.91	-33.3	0.00	33.3
	Week 53	33	14.14	18.69	0.0	0.00	66.7	31	4.30	20.62	-33.3	0.00	66.7
	Week 56	30	13.33	18.77	0.0	0.00	66.7	28	5.95	18.26	-33.3	0.00	33.3
	Week 59	29	11.49	18.42	0.0	0.00	66.7	27	2.47	20.52	-33.3	0.00	33.3
	Week 62	28	13.09	20.96	0.0	0.00	66.7	26	3.85	19.61	-33.3	0.00	33.3
	Week 65	22	15.15	24.62	0.0	0.00	66.7	21	4.76	24.24	-33.3	0.00	66.7
	Week 68	20	11.67	19.57	0.0	0.00	66.7	19	0.00	15.71	-33.3	0.00	33.3
	Week 71	18	11.11	16.17	0.0	0.00	33.3	17	-1.96	14.29	-33.3	0.00	33.3
	Week 74	19	17.54	23.22	0.0	0.00	66.7	19	7.02	21.02	-33.3	0.00	33.3
	Week 77	19	19.30	23.08	0.0	0.00	66.7	18	7.41	18.28	-33.3	0.00	33.3
	Week 80	19	19.30	25.62	0.0	0.00	66.7	18	7.41	21.56	-33.3	0.00	33.3
	Week 83	17	19.61	26.51	0.0	0.00	66.7	17	7.84	22.14	-33.3	0.00	33.3
	Week 86	14	26.19	29.75	0.0	33.33	100.0	14	14.29	28.39	-33.3	16.67	66.7
	Week 89	11	18.18	17.41	0.0	33.33	33.3	11	9.09	26.21	-33.3	0.00	33.3
	Plat+Gem (N= 73)												
	BASELINE	63	10.58	16.75	0.0	0.00	66.7						
	Week 1	54	14.81	22.12	0.0	0.00	100.0	53	3.77	21.34	-66.7	0.00	66.7
	Week 2	56	17.26	22.91	0.0	0.00	100.0	54	6.79	19.83	-33.3	0.00	66.7
	Week 3	57	19.30	24.35	0.0	0.00	100.0	54	9.26	19.87	-33.3	0.00	66.7
	Week 4	58	18.96	24.27	0.0	0.00	100.0	54	6.17	22.50	-33.3	0.00	66.7
	Week 5	57	17.54	20.02	0.0	0.00	100.0	53	7.55	19.22	-33.3	0.00	66.7
	Week 6	56	19.64	26.04	0.0	0.00	100.0	53	9.43	23.91	-33.3	0.00	66.7
	Week 7	56	18.45	23.71	0.0	0.00	100.0	52	7.69	24.36	-66.7	0.00	66.7
	Week 8	54	23.46	27.19	0.0	33.33	100.0	50	14.00	23.42	-33.3	0.00	66.7
	Week 9	52	23.08	26.02	0.0	33.33	100.0	49	13.61	23.49	-33.3	0.00	66.7
	Week 10	52	21.15	24.72	0.0	16.67	100.0	49	10.88	23.95	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	45	22.96	28.27	0.0	33.33	100.0	42	11.90	27.37	-66.7	0.00	66.7
	Week 12	47	23.40	24.98	0.0	33.33	100.0	43	11.63	20.42	-33.3	0.00	66.7
	Week 14	43	23.25	27.73	0.0	33.33	100.0	39	11.97	23.55	-33.3	0.00	66.7
	Week 17	40	21.67	24.52	0.0	33.33	100.0	36	10.19	19.22	-33.3	0.00	66.7
	Week 20	34	22.55	29.27	0.0	0.00	100.0	30	10.00	21.71	-33.3	0.00	66.7
	Week 23	29	22.99	26.88	0.0	33.33	100.0	27	13.58	23.13	-33.3	0.00	66.7
	Week 26	26	21.79	18.72	0.0	33.33	66.7	24	8.33	20.26	-33.3	0.00	33.3
	Week 29	24	20.83	27.47	0.0	0.00	100.0	22	10.61	27.96	-33.3	0.00	100.0
	Week 32	20	18.33	20.16	0.0	16.67	66.7	18	5.56	17.15	-33.3	0.00	33.3
	Week 35	17	21.57	20.21	0.0	33.33	66.7	15	6.67	18.69	-33.3	0.00	33.3
	Week 38	18	18.52	23.49	0.0	0.00	66.7	15	2.22	19.79	-33.3	0.00	33.3
	Week 41	18	20.37	23.26	0.0	16.67	66.7	16	8.33	28.54	-33.3	0.00	66.7
	Week 44	16	20.83	20.64	0.0	33.33	66.7	14	7.14	19.30	-33.3	0.00	33.3
	Week 47	12	16.67	17.41	0.0	16.67	33.3	11	9.09	15.57	0.0	0.00	33.3
	Week 50	11	21.21	26.97	0.0	0.00	66.7	9	7.41	14.70	0.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	EV+Pembro (N=146)												
	BASELINE	119	18.21	26.66	0.0	0.00	100.0						
	Week 1	102	18.63	25.51	0.0	0.00	100.0	97	-0.34	20.69	-66.7	0.00	66.7
	Week 2	106	19.81	23.81	0.0	0.00	100.0	98	3.74	17.83	-33.3	0.00	33.3
	Week 3	94	15.25	21.12	0.0	0.00	66.7	88	3.03	18.66	-33.3	0.00	33.3
	Week 4	101	16.17	21.40	0.0	0.00	66.7	93	2.51	18.54	-33.3	0.00	33.3
	Week 5	96	17.36	23.18	0.0	0.00	100.0	89	3.37	20.75	-33.3	0.00	66.7
	Week 6	105	19.68	25.61	0.0	0.00	100.0	93	6.81	22.28	-33.3	0.00	66.7
	Week 7	102	20.26	26.18	0.0	0.00	100.0	89	6.74	23.13	-33.3	0.00	66.7
	Week 8	101	21.45	27.32	0.0	0.00	100.0	91	8.79	25.26	-33.3	0.00	100.0
	Week 9	100	19.67	26.42	0.0	0.00	100.0	89	7.87	25.14	-66.7	0.00	66.7
	Week 10	99	17.84	24.43	0.0	0.00	100.0	87	4.98	26.18	-66.7	0.00	100.0
	Week 11	95	17.19	22.21	0.0	0.00	100.0	84	4.36	23.59	-66.7	0.00	66.7
	Week 12	99	17.17	26.24	0.0	0.00	100.0	87	5.36	24.84	-33.3	0.00	100.0
	Week 14	95	16.14	22.73	0.0	0.00	100.0	84	4.76	22.64	-33.3	0.00	100.0
	Week 17	97	16.84	23.63	0.0	0.00	100.0	84	4.37	19.89	-33.3	0.00	66.7
	Week 20	90	14.44	20.63	0.0	0.00	66.7	79	2.53	20.51	-33.3	0.00	66.7
	Week 23	86	13.57	21.31	0.0	0.00	100.0	74	4.05	25.25	-66.7	0.00	100.0
	Week 26	83	13.65	22.71	0.0	0.00	100.0	72	4.17	23.02	-33.3	0.00	66.7
	Week 29	80	19.17	25.86	0.0	0.00	100.0	71	7.51	25.94	-33.3	0.00	100.0
	Week 32	74	15.77	22.90	0.0	0.00	100.0	66	8.08	19.45	-33.3	0.00	66.7
	Week 35	73	18.72	22.90	0.0	0.00	100.0	66	8.08	23.43	-33.3	0.00	66.7
	Week 38	75	16.44	20.04	0.0	0.00	66.7	67	6.96	20.55	-33.3	0.00	66.7
	Week 41	71	14.55	21.63	0.0	0.00	100.0	64	4.17	19.24	-33.3	0.00	66.7
	Week 44	64	15.62	23.73	0.0	0.00	100.0	56	5.36	21.81	-33.3	0.00	66.7
	Week 47	56	15.48	21.05	0.0	0.00	66.7	50	5.33	20.60	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	55	16.97	23.89	0.0	0.00	100.0	48	4.17	22.41	-33.3	0.00	66.7
	Week 53	55	17.57	23.88	0.0	0.00	100.0	48	7.64	24.06	-33.3	0.00	66.7
	Week 56	53	16.35	21.31	0.0	0.00	66.7	46	4.35	20.62	-33.3	0.00	33.3
	Week 59	51	15.03	23.39	0.0	0.00	100.0	43	2.33	22.30	-33.3	0.00	66.7
	Week 62	42	11.90	20.59	0.0	0.00	66.7	36	0.93	18.66	-33.3	0.00	33.3
	Week 65	31	15.05	24.10	0.0	0.00	66.7	30	4.45	19.05	-33.3	0.00	66.7
	Week 68	31	15.05	22.51	0.0	0.00	66.7	29	4.60	14.70	-33.3	0.00	33.3
	Week 71	30	14.44	22.63	0.0	0.00	100.0	28	1.19	24.82	-33.3	0.00	100.0
	Week 74	29	14.94	21.06	0.0	0.00	66.7	27	2.47	20.52	-33.3	0.00	33.3
	Week 77	26	20.51	23.24	0.0	16.67	66.7	24	6.94	24.04	-33.3	0.00	66.7
	Week 80	26	21.79	26.57	0.0	0.00	66.7	26	7.69	25.49	-66.7	0.00	33.3
	Week 83	21	22.22	24.34	0.0	33.33	66.7	21	7.94	25.61	-66.7	0.00	33.3
	Week 86	17	29.41	26.04	0.0	33.33	100.0	17	13.72	31.31	-66.7	33.33	66.7
	Week 89	11	15.15	17.41	0.0	0.00	33.3	11	9.09	21.55	-33.3	0.00	33.3
	Week 92	13	30.77	21.35	0.0	33.33	66.7	13	20.51	21.68	-33.3	33.33	33.3
	Plat+Gem (N=151)												
	BASELINE	123	17.61	25.72	0.0	0.00	100.0						
	Week 1	108	20.68	26.07	0.0	0.00	100.0	103	3.56	19.75	-66.7	0.00	66.7
	Week 2	116	19.54	24.89	0.0	0.00	100.0	105	2.22	18.06	-33.3	0.00	66.7
	Week 3	114	19.88	22.92	0.0	0.00	100.0	103	4.21	22.23	-100.0	0.00	66.7
	Week 4	116	20.40	22.74	0.0	33.33	100.0	103	4.53	23.36	-66.7	0.00	66.7
	Week 5	119	23.25	25.51	0.0	33.33	100.0	106	6.60	26.99	-66.7	0.00	100.0
	Week 6	109	23.55	27.70	0.0	33.33	100.0	98	6.80	27.06	-66.7	0.00	100.0
	Week 7	115	24.35	28.72	0.0	33.33	100.0	105	10.16	28.16	-66.7	0.00	100.0
	Week 8	111	23.42	27.19	0.0	33.33	100.0	102	8.17	27.12	-66.7	0.00	100.0
	Week 9	107	24.61	27.60	0.0	33.33	100.0	95	10.17	31.54	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	107	21.18	23.96	0.0	33.33	100.0	98	5.78	28.33	-66.7	0.00	100.0
	Week 11	97	25.08	27.65	0.0	33.33	100.0	87	8.05	28.29	-66.7	0.00	100.0
	Week 12	100	26.00	27.86	0.0	33.33	100.0	88	9.47	31.54	-66.7	0.00	100.0
	Week 14	99	27.27	27.51	0.0	33.33	100.0	86	10.46	27.66	-66.7	0.00	66.7
	Week 17	94	27.66	27.93	0.0	33.33	100.0	82	11.38	24.13	-66.7	0.00	66.7
	Week 20	84	26.19	28.84	0.0	33.33	100.0	72	9.72	24.67	-66.7	0.00	66.7
	Week 23	70	24.76	25.81	0.0	33.33	100.0	62	11.29	26.95	-66.7	0.00	66.7
	Week 26	61	23.50	23.84	0.0	33.33	100.0	55	9.09	25.22	-66.7	0.00	66.7
	Week 29	59	25.99	27.03	0.0	33.33	100.0	53	9.43	23.91	-66.7	0.00	100.0
	Week 32	50	20.67	23.22	0.0	33.33	100.0	45	2.96	19.88	-66.7	0.00	33.3
	Week 35	50	20.00	21.30	0.0	33.33	66.7	44	2.27	23.18	-66.7	0.00	33.3
	Week 38	46	22.46	22.28	0.0	33.33	66.7	40	8.33	19.61	-33.3	0.00	33.3
	Week 41	42	20.63	22.03	0.0	33.33	66.7	37	7.21	26.22	-33.3	0.00	66.7
	Week 44	39	23.93	21.56	0.0	33.33	66.7	34	7.84	24.70	-33.3	0.00	66.7
	Week 47	33	23.23	24.27	0.0	33.33	100.0	29	6.90	20.66	-33.3	0.00	66.7
	Week 50	27	28.39	25.66	0.0	33.33	100.0	22	6.06	22.15	-33.3	0.00	33.3
	Week 53	23	27.53	23.89	0.0	33.33	100.0	20	8.33	28.36	-33.3	0.00	66.7
	Week 56	20	28.33	31.11	0.0	33.33	100.0	19	7.02	28.50	-66.7	0.00	66.7
	Week 59	17	29.41	23.22	0.0	33.33	66.7	15	8.89	32.04	-33.3	0.00	66.7
	Week 62	14	33.33	26.15	0.0	33.33	100.0	14	11.90	36.06	-33.3	0.00	100.0
	Week 65	13	25.64	24.17	0.0	33.33	66.7	12	2.78	30.01	-33.3	0.00	66.7
	Week 68	10	26.67	26.29	0.0	33.33	66.7	10	3.33	29.19	-33.3	0.00	66.7
	Week 71	10	23.33	22.50	0.0	33.33	66.7	10	3.33	24.59	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	EV+Pembro (N= 56)												
	BASELINE	41	17.89	21.21	0.0	0.00	66.7						
	Week 1	39	19.66	29.34	0.0	0.00	100.0	32	-1.04	21.56	-33.3	0.00	33.3
	Week 2	44	15.15	23.24	0.0	0.00	100.0	35	-2.86	20.41	-33.3	0.00	66.7
	Week 3	45	16.30	23.16	0.0	0.00	100.0	34	0.98	20.90	-33.3	0.00	66.7
	Week 4	44	21.97	29.59	0.0	0.00	100.0	36	6.48	30.67	-66.7	0.00	100.0
	Week 5	41	21.14	26.62	0.0	0.00	100.0	32	5.21	26.92	-33.3	0.00	100.0
	Week 6	41	16.26	22.51	0.0	0.00	100.0	31	-3.23	23.34	-66.7	0.00	33.3
	Week 7	45	12.59	21.66	0.0	0.00	100.0	35	-5.71	20.59	-33.3	0.00	33.3
	Week 8	46	18.84	25.97	0.0	0.00	100.0	33	-2.02	28.79	-66.7	0.00	66.7
	Week 9	42	19.84	22.16	0.0	16.67	66.7	32	4.17	27.76	-33.3	0.00	66.7
	Week 10	40	18.33	23.81	0.0	0.00	100.0	31	4.30	29.49	-33.3	0.00	66.7
	Week 11	42	15.08	19.76	0.0	0.00	66.7	31	1.07	25.07	-33.3	0.00	66.7
	Week 12	43	16.28	21.05	0.0	0.00	66.7	32	-3.13	24.48	-33.3	0.00	66.7
	Week 14	44	17.42	24.37	0.0	0.00	100.0	32	-2.08	23.85	-66.7	0.00	33.3
	Week 17	35	17.14	20.41	0.0	0.00	66.7	27	-1.24	25.29	-66.7	0.00	33.3
	Week 20	30	17.78	20.96	0.0	0.00	66.7	24	-1.39	20.80	-33.3	0.00	33.3
	Week 23	31	11.83	20.27	0.0	0.00	66.7	23	-5.80	25.92	-66.7	0.00	66.7
	Week 26	29	13.79	18.93	0.0	0.00	66.7	22	-9.09	21.04	-66.7	0.00	33.3
	Week 29	27	14.81	16.88	0.0	0.00	33.3	22	-4.55	21.32	-66.7	0.00	33.3
	Week 32	28	16.67	23.13	0.0	0.00	66.7	22	-4.55	25.81	-66.7	0.00	66.7
	Week 35	25	13.33	19.24	0.0	0.00	66.7	20	-5.00	16.31	-33.3	0.00	33.3
	Week 38	22	6.06	13.16	0.0	0.00	33.3	19	-10.53	15.92	-33.3	0.00	0.0
	Week 41	24	13.89	16.79	0.0	0.00	33.3	20	1.67	20.16	-33.3	0.00	33.3
	Week 44	22	12.12	19.37	0.0	0.00	66.7	18	0.00	22.87	-33.3	0.00	33.3
	Week 47	23	13.04	16.63	0.0	0.00	33.3	20	0.00	21.63	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	19	8.77	15.08	0.0	0.00	33.3	16	-2.08	19.12	-33.3	0.00	33.3
	Week 53	19	10.53	15.92	0.0	0.00	33.3	15	-4.44	21.33	-33.3	0.00	33.3
	Week 56	19	5.26	12.49	0.0	0.00	33.3	15	-4.44	24.77	-66.7	0.00	33.3
	Week 59	18	9.26	15.36	0.0	0.00	33.3	14	0.00	22.64	-33.3	0.00	33.3
	Week 62	20	10.00	15.67	0.0	0.00	33.3	16	-4.17	20.64	-33.3	0.00	33.3
	Week 65	12	16.67	22.47	0.0	0.00	66.7	10	-3.33	33.15	-33.3	0.00	66.7
	Week 68	15	13.33	21.08	0.0	0.00	66.7	13	-2.56	16.45	-33.3	0.00	33.3
	Week 71	12	13.89	22.29	0.0	0.00	66.7	10	-6.67	14.05	-33.3	0.00	0.0
	Week 77	11	12.12	16.82	0.0	0.00	33.3	9	-3.70	11.11	-33.3	0.00	0.0
	Week 80	10	6.67	14.05	0.0	0.00	33.3	8	-8.33	23.57	-33.3	0.00	33.3
	Plat+Gem (N= 51)												
	BASELINE	42	15.87	25.75	0.0	0.00	100.0						
	Week 1	36	14.81	26.96	0.0	0.00	100.0	36	-2.78	28.03	-66.7	0.00	66.7
	Week 2	31	20.43	28.12	0.0	0.00	100.0	30	4.44	32.44	-66.7	0.00	66.7
	Week 3	35	23.81	28.66	0.0	33.33	100.0	33	9.09	25.38	-33.3	0.00	66.7
	Week 4	34	23.53	29.05	0.0	16.67	100.0	32	7.29	26.42	-33.3	0.00	66.7
	Week 5	34	25.49	30.77	0.0	33.33	100.0	32	12.50	27.76	-33.3	0.00	100.0
	Week 6	36	25.93	31.98	0.0	16.67	100.0	33	13.13	31.11	-33.3	0.00	66.7
	Week 7	33	15.15	22.19	0.0	0.00	100.0	29	1.15	31.48	-66.7	0.00	66.7
	Week 8	34	27.45	28.98	0.0	33.33	100.0	30	13.33	27.12	-33.3	0.00	66.7
	Week 9	34	25.49	31.84	0.0	16.67	100.0	30	13.33	29.81	-66.7	0.00	66.7
	Week 10	35	21.90	25.49	0.0	33.33	100.0	32	7.29	32.50	-66.7	0.00	66.7
	Week 11	29	29.88	33.74	0.0	33.33	100.0	27	14.81	29.72	-66.7	0.00	66.7
	Week 12	30	30.00	33.16	0.0	33.33	100.0	27	13.58	36.11	-66.7	0.00	100.0
	Week 14	26	28.20	33.59	0.0	33.33	100.0	23	15.94	33.14	-33.3	0.00	100.0
	Week 17	26	23.08	26.28	0.0	33.33	100.0	24	8.33	20.26	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 20	20	21.67	22.36	0.0	33.33	66.7	19	14.03	23.08	-33.3	33.33	33.3
	Week 23	18	12.96	20.26	0.0	0.00	66.7	18	7.41	18.28	-33.3	0.00	33.3
	Week 26	20	25.00	26.21	0.0	33.33	100.0	20	6.67	23.20	-33.3	0.00	33.3
	Week 29	18	18.52	23.49	0.0	0.00	66.7	18	5.56	23.57	-33.3	0.00	66.7
	Week 32	13	28.20	29.96	0.0	33.33	100.0	13	12.82	34.80	-33.3	0.00	100.0
	Week 35	12	19.44	30.01	0.0	0.00	100.0	12	5.56	39.78	-66.7	0.00	100.0
	Week 38	10	13.33	17.21	0.0	0.00	33.3	10	3.33	18.92	-33.3	0.00	33.3
	Week 41	10	23.33	22.50	0.0	33.33	66.7	10	13.33	28.11	-33.3	0.00	66.7
	Week 44	10	26.67	26.29	0.0	33.33	66.7	10	16.67	23.57	0.0	0.00	66.7
	Week 47	10	23.33	22.50	0.0	33.33	66.7	10	16.67	23.57	0.0	0.00	66.7
	Week 56	10	16.67	23.57	0.0	0.00	66.7	10	3.33	18.92	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Visceral metastases	EV+Pembro (N=148)												
	BASELINE	119	19.61	27.24	0.0	0.00	100.0						
	Week 1	105	21.90	28.43	0.0	0.00	100.0	99	1.35	22.29	-66.7	0.00	66.7
	Week 2	109	21.10	25.52	0.0	0.00	100.0	100	4.67	18.36	-33.3	0.00	66.7
	Week 3	98	17.01	22.57	0.0	0.00	100.0	88	4.55	20.33	-33.3	0.00	66.7
	Week 4	103	19.09	25.40	0.0	0.00	100.0	93	5.38	24.72	-66.7	0.00	100.0
	Week 5	100	21.00	25.80	0.0	0.00	100.0	90	6.30	23.91	-33.3	0.00	100.0
	Week 6	105	20.63	26.30	0.0	0.00	100.0	90	6.67	24.58	-66.7	0.00	66.7
	Week 7	108	19.14	27.04	0.0	0.00	100.0	91	4.76	25.61	-33.3	0.00	66.7
	Week 8	105	23.49	28.84	0.0	0.00	100.0	89	8.99	28.76	-66.7	0.00	100.0
	Week 9	105	19.68	26.02	0.0	0.00	100.0	91	6.59	26.40	-66.7	0.00	66.7
	Week 10	101	19.47	25.06	0.0	0.00	100.0	86	5.81	27.15	-66.7	0.00	100.0
	Week 11	97	18.56	22.03	0.0	0.00	100.0	83	5.22	22.98	-66.7	0.00	66.7
	Week 12	100	18.00	25.26	0.0	0.00	100.0	85	3.92	25.93	-33.3	0.00	100.0
	Week 14	102	17.97	24.67	0.0	0.00	100.0	87	2.68	23.96	-66.7	0.00	100.0
	Week 17	96	16.32	23.19	0.0	0.00	100.0	81	1.65	21.02	-66.7	0.00	66.7
	Week 20	87	16.09	21.48	0.0	0.00	66.7	76	2.19	19.88	-33.3	0.00	66.7
	Week 23	85	12.16	19.82	0.0	0.00	66.7	71	0.94	24.54	-66.7	0.00	66.7
	Week 26	79	12.24	20.79	0.0	0.00	100.0	66	0.00	21.08	-66.7	0.00	66.7
	Week 29	72	19.44	24.23	0.0	0.00	100.0	64	6.25	25.80	-66.7	0.00	100.0
	Week 32	71	16.43	23.14	0.0	0.00	66.7	62	4.84	23.26	-66.7	0.00	66.7
	Week 35	70	17.14	21.79	0.0	0.00	66.7	63	5.82	22.03	-33.3	0.00	66.7
	Week 38	70	13.33	19.98	0.0	0.00	66.7	63	2.65	21.83	-33.3	0.00	66.7
	Week 41	66	15.66	22.05	0.0	0.00	100.0	60	4.44	19.85	-33.3	0.00	66.7
	Week 44	59	15.25	22.59	0.0	0.00	66.7	53	5.66	20.40	-33.3	0.00	66.7
	Week 47	52	14.74	20.25	0.0	0.00	66.7	48	4.17	20.19	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	49	16.33	23.69	0.0	0.00	100.0	43	6.20	19.59	-33.3	0.00	66.7
	Week 53	50	16.00	24.50	0.0	0.00	100.0	44	5.30	24.84	-33.3	0.00	66.7
	Week 56	45	14.07	21.89	0.0	0.00	66.7	39	4.27	21.87	-66.7	0.00	33.3
	Week 59	44	15.91	24.37	0.0	0.00	100.0	38	6.14	20.29	-33.3	0.00	66.7
	Week 62	38	12.28	21.11	0.0	0.00	66.7	33	4.04	18.18	-33.3	0.00	33.3
	Week 65	25	17.33	25.68	0.0	0.00	66.7	24	8.33	26.47	-33.3	0.00	66.7
	Week 68	31	12.90	22.24	0.0	0.00	66.7	29	3.45	16.29	-33.3	0.00	33.3
	Week 71	27	17.28	25.10	0.0	0.00	100.0	25	5.33	22.93	-33.3	0.00	100.0
	Week 74	23	15.94	22.18	0.0	0.00	66.7	22	6.06	19.62	-33.3	0.00	33.3
	Week 77	24	18.05	19.61	0.0	16.67	66.7	23	7.25	14.06	0.0	0.00	33.3
	Week 80	22	18.18	26.68	0.0	0.00	66.7	22	7.58	20.40	-33.3	0.00	33.3
	Week 83	19	21.05	22.80	0.0	33.33	66.7	19	10.53	19.41	-33.3	0.00	33.3
	Week 86	14	28.57	28.81	0.0	33.33	100.0	14	16.67	25.32	-33.3	16.67	66.7
	Week 89	10	16.67	17.57	0.0	16.67	33.3	10	6.67	21.08	-33.3	0.00	33.3
	Week 92	11	27.27	20.10	0.0	33.33	66.7	11	18.18	22.92	-33.3	33.33	33.3
	Plat+Gem (N=157)												
	BASELINE	128	17.19	25.44	0.0	0.00	100.0						
	Week 1	111	19.82	27.11	0.0	0.00	100.0	107	2.49	20.83	-66.7	0.00	66.7
	Week 2	110	20.91	27.04	0.0	0.00	100.0	102	3.92	20.06	-33.3	0.00	66.7
	Week 3	112	20.83	25.75	0.0	0.00	100.0	103	5.50	23.38	-100.0	0.00	66.7
	Week 4	112	21.13	25.70	0.0	0.00	100.0	102	5.56	25.30	-66.7	0.00	66.7
	Week 5	113	23.01	27.12	0.0	33.33	100.0	103	7.44	27.98	-66.7	0.00	100.0
	Week 6	107	23.99	30.30	0.0	0.00	100.0	98	8.50	28.44	-66.7	0.00	100.0
	Week 7	109	21.10	27.84	0.0	0.00	100.0	100	7.33	27.45	-66.7	0.00	100.0
	Week 8	106	23.27	27.67	0.0	33.33	100.0	98	8.50	25.47	-66.7	0.00	66.7
	Week 9	105	23.17	28.54	0.0	0.00	100.0	94	9.57	30.38	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	104	20.51	25.99	0.0	0.00	100.0	96	5.90	29.81	-66.7	0.00	100.0
	Week 11	91	25.64	30.26	0.0	33.33	100.0	83	9.24	27.70	-66.7	0.00	100.0
	Week 12	94	25.89	29.39	0.0	33.33	100.0	84	9.92	29.63	-66.7	0.00	100.0
	Week 14	90	24.81	28.95	0.0	16.67	100.0	79	8.86	26.53	-66.7	0.00	66.7
	Week 17	90	25.55	28.73	0.0	33.33	100.0	80	9.58	23.24	-66.7	0.00	66.7
	Week 20	74	23.42	29.05	0.0	0.00	100.0	64	8.85	23.94	-66.7	0.00	66.7
	Week 23	63	23.81	27.06	0.0	33.33	100.0	58	11.49	24.62	-66.7	0.00	66.7
	Week 26	55	21.82	22.42	0.0	33.33	66.7	52	8.33	22.75	-33.3	0.00	66.7
	Week 29	53	26.41	27.24	0.0	33.33	100.0	50	12.00	24.06	-33.3	0.00	100.0
	Week 32	42	20.63	22.03	0.0	33.33	66.7	40	5.00	19.32	-33.3	0.00	33.3
	Week 35	39	20.51	21.10	0.0	33.33	66.7	36	4.63	19.76	-33.3	0.00	33.3
	Week 38	37	21.62	23.85	0.0	33.33	66.7	34	8.82	18.91	-33.3	0.00	33.3
	Week 41	33	18.18	20.57	0.0	0.00	66.7	31	6.45	24.97	-33.3	0.00	66.7
	Week 44	32	22.92	21.48	0.0	33.33	66.7	30	10.00	23.41	-33.3	0.00	66.7
	Week 47	28	23.81	27.00	0.0	33.33	100.0	26	10.26	22.65	-33.3	0.00	66.7
	Week 50	22	22.73	26.00	0.0	33.33	100.0	20	10.00	21.90	-33.3	0.00	33.3
	Week 53	19	21.05	19.91	0.0	33.33	66.7	17	9.80	28.30	-33.3	0.00	66.7
	Week 56	18	20.37	28.33	0.0	0.00	100.0	17	3.92	30.92	-66.7	0.00	66.7
	Week 59	13	30.77	25.32	0.0	33.33	66.7	12	13.89	33.21	-33.3	0.00	66.7
	Week 62	11	39.39	29.13	0.0	33.33	100.0	11	21.21	37.34	-33.3	33.33	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Lymph node only	EV+Pembro (N= 43)												
	BASELINE	33	16.16	18.86	0.0	0.00	66.7						
	Week 1	30	11.11	18.22	0.0	0.00	66.7	24	-8.33	14.74	-33.3	0.00	0.0
	Week 2	34	11.76	16.17	0.0	0.00	33.3	27	-8.64	17.52	-33.3	0.00	33.3
	Week 3	35	13.33	20.13	0.0	0.00	66.7	28	-3.57	16.58	-33.3	0.00	33.3
	Week 4	36	15.74	20.29	0.0	0.00	66.7	30	-2.22	14.99	-33.3	0.00	33.3
	Week 5	33	13.13	18.52	0.0	0.00	66.7	27	-3.70	16.88	-33.3	0.00	33.3
	Week 6	34	14.71	20.42	0.0	0.00	66.7	28	-2.38	17.98	-33.3	0.00	33.3
	Week 7	34	15.69	18.78	0.0	0.00	66.7	28	-1.19	14.29	-33.3	0.00	33.3
	Week 8	35	14.28	20.27	0.0	0.00	66.7	29	-2.30	19.78	-33.3	0.00	33.3
	Week 9	30	22.22	23.71	0.0	33.33	66.7	24	8.33	26.47	-66.7	0.00	66.7
	Week 10	31	16.13	22.56	0.0	0.00	66.7	26	2.56	29.70	-66.7	0.00	66.7
	Week 11	34	11.76	19.90	0.0	0.00	66.7	27	-2.47	27.62	-66.7	0.00	66.7
	Week 12	35	15.24	24.71	0.0	0.00	100.0	28	1.19	24.82	-33.3	0.00	66.7
	Week 14	30	14.44	18.94	0.0	0.00	66.7	23	4.35	23.15	-33.3	0.00	33.3
	Week 17	30	21.11	22.29	0.0	33.33	66.7	24	8.33	24.57	-33.3	0.00	66.7
	Week 20	27	14.81	19.24	0.0	0.00	66.7	21	0.00	25.82	-33.3	0.00	66.7
	Week 23	27	17.28	25.10	0.0	0.00	100.0	21	4.76	32.12	-33.3	0.00	100.0
	Week 26	27	19.75	24.91	0.0	0.00	66.7	22	4.55	31.36	-33.3	0.00	66.7
	Week 29	28	15.48	24.82	0.0	0.00	100.0	23	0.00	26.59	-33.3	0.00	66.7
	Week 32	24	18.05	24.03	0.0	0.00	100.0	20	6.67	20.52	-33.3	0.00	66.7
	Week 35	22	19.70	24.47	0.0	16.67	100.0	18	3.70	27.74	-33.3	0.00	66.7
	Week 38	21	17.46	17.06	0.0	33.33	33.3	17	3.92	20.01	-33.3	0.00	33.3
	Week 41	22	13.64	16.77	0.0	0.00	33.3	17	1.96	21.95	-33.3	0.00	33.3
	Week 44	22	15.15	24.62	0.0	0.00	100.0	16	0.00	29.81	-33.3	0.00	66.7
	Week 47	21	17.46	20.05	0.0	0.00	66.7	16	4.17	26.87	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	13.33	19.94	0.0	0.00	66.7	16	-6.25	27.81	-33.3	0.00	66.7
	Week 53	18	14.81	17.04	0.0	0.00	33.3	14	0.00	22.64	-33.3	0.00	33.3
	Week 56	21	14.28	16.90	0.0	0.00	33.3	17	-3.92	23.22	-33.3	0.00	33.3
	Week 59	21	9.52	15.43	0.0	0.00	33.3	16	-10.42	23.47	-33.3	0.00	33.3
	Week 62	19	8.77	15.08	0.0	0.00	33.3	15	-13.33	16.90	-33.3	0.00	0.0
	Week 65	16	14.58	20.97	0.0	0.00	66.7	14	-7.14	14.19	-33.3	0.00	0.0
	Week 68	13	20.51	21.68	0.0	33.33	66.7	11	0.00	14.91	-33.3	0.00	33.3
	Week 71	13	10.26	16.01	0.0	0.00	33.3	11	-15.15	17.41	-33.3	0.00	0.0
	Week 74	13	7.69	14.62	0.0	0.00	33.3	11	-12.12	16.82	-33.3	0.00	0.0
	Week 77	13	17.95	25.88	0.0	0.00	66.7	10	-3.33	33.15	-33.3	0.00	66.7
	Week 80	13	15.38	22.01	0.0	0.00	66.7	11	-6.06	32.72	-66.7	0.00	33.3
	Week 83	11	12.12	22.47	0.0	0.00	66.7	10	-6.67	30.63	-66.7	0.00	33.3
	Week 86	11	15.15	17.41	0.0	0.00	33.3	10	-3.33	33.15	-66.7	0.00	33.3
	Plat+Gem (N= 37)												
	BASELINE	29	20.69	28.75	0.0	0.00	100.0						
	Week 1	26	17.95	25.35	0.0	0.00	100.0	25	-4.00	27.76	-66.7	0.00	33.3
	Week 2	30	15.55	19.04	0.0	0.00	66.7	26	-5.13	26.15	-66.7	0.00	33.3
	Week 3	30	21.11	20.50	0.0	33.33	66.7	26	2.56	22.94	-33.3	0.00	33.3
	Week 4	32	22.92	19.74	0.0	33.33	66.7	27	3.70	21.35	-33.3	0.00	33.3
	Week 5	33	28.28	26.51	0.0	33.33	100.0	28	9.52	27.00	-66.7	0.00	66.7
	Week 6	32	26.04	25.02	0.0	33.33	100.0	27	7.41	29.72	-66.7	0.00	66.7
	Week 7	31	27.96	28.67	0.0	33.33	100.0	26	10.26	37.44	-66.7	0.00	100.0
	Week 8	32	30.21	28.54	0.0	33.33	100.0	27	12.35	33.52	-66.7	0.00	100.0
	Week 9	30	30.00	28.16	0.0	33.33	100.0	25	12.00	33.17	-66.7	0.00	66.7
	Week 10	30	23.33	17.83	0.0	33.33	66.7	26	2.56	28.16	-66.7	0.00	33.3
	Week 11	29	27.58	26.83	0.0	33.33	100.0	25	8.00	32.32	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.18.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Shortness of Breath by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 12	28	29.76	31.87	0.0	33.33	100.0	23	7.25	44.90	-66.7	0.00	100.0
	Week 14	28	34.52	29.37	0.0	33.33	100.0	23	15.94	36.06	-66.7	0.00	100.0
	Week 17	25	32.00	24.50	0.0	33.33	100.0	21	14.28	24.88	-33.3	0.00	66.7
	Week 20	23	31.88	25.58	0.0	33.33	100.0	20	13.33	27.36	-33.3	16.67	66.7
	Week 23	20	18.33	20.16	0.0	16.67	66.7	17	5.88	29.43	-66.7	0.00	66.7
	Week 26	21	28.57	30.34	0.0	33.33	100.0	18	5.55	30.79	-66.7	0.00	66.7
	Week 29	19	22.81	24.97	0.0	33.33	100.0	16	0.00	24.34	-66.7	0.00	33.3
	Week 32	18	27.78	30.78	0.0	33.33	100.0	15	6.67	36.08	-66.7	0.00	100.0
	Week 35	19	19.30	27.92	0.0	0.00	100.0	16	-2.08	41.22	-66.7	0.00	100.0
	Week 38	15	22.22	16.26	0.0	33.33	33.3	12	5.55	23.92	-33.3	0.00	33.3
	Week 41	15	24.44	23.46	0.0	33.33	66.7	12	8.33	28.87	-33.3	0.00	66.7
	Week 44	14	30.95	24.34	0.0	33.33	66.7	11	12.12	30.81	-33.3	0.00	66.7
	Week 47	12	22.22	16.41	0.0	33.33	33.3	10	6.67	21.08	-33.3	0.00	33.3
	Week 50	11	33.33	25.82	0.0	33.33	66.7	8	4.17	21.36	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
EV+Pembro (N=240)												
BASELINE	206	21.52	28.62	0.0	0.00	100.0						
Week 1	190	23.68	27.55	0.0	33.33	100.0	184	2.72	24.11	-100.0	0.00	100.0
Week 2	203	30.38	30.62	0.0	33.33	100.0	189	10.05	28.75	-100.0	0.00	100.0
Week 3	198	32.32	33.06	0.0	33.33	100.0	182	10.81	33.96	-100.0	0.00	100.0
Week 4	194	27.15	28.92	0.0	33.33	100.0	179	5.96	32.60	-100.0	0.00	100.0
Week 5	190	24.56	29.78	0.0	33.33	100.0	173	5.01	35.77	-100.0	0.00	100.0
Week 6	188	23.23	26.45	0.0	33.33	100.0	170	2.74	33.12	-100.0	0.00	100.0
Week 7	195	23.08	26.17	0.0	33.33	100.0	176	2.27	35.38	-100.0	0.00	100.0
Week 8	191	23.04	26.80	0.0	33.33	100.0	171	2.53	34.87	-100.0	0.00	100.0
Week 9	197	25.38	28.15	0.0	33.33	100.0	180	5.19	34.67	-100.0	0.00	100.0
Week 10	191	21.99	24.77	0.0	33.33	100.0	175	0.57	35.28	-100.0	0.00	66.7
Week 11	194	23.20	27.05	0.0	33.33	100.0	175	0.76	36.08	-100.0	0.00	100.0
Week 12	186	23.12	27.68	0.0	16.67	100.0	171	0.97	37.30	-100.0	0.00	100.0
Week 14	185	23.60	26.26	0.0	33.33	100.0	167	2.39	34.43	-100.0	0.00	100.0
Week 17	178	25.09	27.12	0.0	33.33	100.0	162	4.11	35.00	-100.0	0.00	100.0
Week 20	167	22.16	27.53	0.0	0.00	100.0	154	1.95	35.60	-100.0	0.00	100.0
Week 23	162	22.84	26.91	0.0	16.67	100.0	151	3.75	35.60	-100.0	0.00	100.0
Week 26	156	21.79	27.99	0.0	0.00	100.0	144	1.39	31.26	-100.0	0.00	66.7
Week 29	157	19.32	23.91	0.0	0.00	100.0	145	1.38	31.88	-100.0	0.00	100.0
Week 32	135	17.04	22.99	0.0	0.00	100.0	125	-2.40	32.57	-100.0	0.00	66.7
Week 35	132	17.93	23.45	0.0	0.00	100.0	122	-0.82	29.21	-100.0	0.00	100.0
Week 38	132	17.93	25.19	0.0	0.00	100.0	124	-0.81	32.22	-100.0	0.00	66.7
Week 41	129	17.31	22.86	0.0	0.00	100.0	119	-1.68	30.02	-100.0	0.00	66.7
Week 44	108	13.89	22.84	0.0	0.00	100.0	100	-3.67	31.03	-66.7	0.00	100.0
Week 47	100	14.33	22.35	0.0	0.00	100.0	94	-3.55	28.70	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	89	12.36	20.34	0.0	0.00	66.7	84	-3.97	27.09	-66.7	0.00	66.7
Week 53	79	13.50	21.03	0.0	0.00	100.0	74	-1.35	27.28	-100.0	0.00	66.7
Week 56	81	11.52	19.12	0.0	0.00	66.7	76	-4.82	28.13	-100.0	0.00	66.7
Week 59	72	11.11	19.38	0.0	0.00	66.7	68	-4.41	28.74	-100.0	0.00	66.7
Week 62	65	12.82	20.15	0.0	0.00	66.7	63	-1.59	30.19	-100.0	0.00	66.7
Week 65	58	12.07	20.42	0.0	0.00	66.7	54	-4.32	29.71	-100.0	0.00	66.7
Week 68	53	11.95	19.71	0.0	0.00	66.7	52	-3.21	28.97	-100.0	0.00	66.7
Week 71	51	11.76	19.80	0.0	0.00	66.7	49	-3.40	29.85	-100.0	0.00	66.7
Week 74	47	10.64	18.53	0.0	0.00	66.7	46	-5.80	29.23	-100.0	0.00	66.7
Week 77	44	15.91	23.28	0.0	0.00	66.7	42	-0.79	31.65	-100.0	0.00	66.7
Week 80	40	13.33	19.68	0.0	0.00	66.7	37	-6.31	29.23	-100.0	0.00	33.3
Week 83	37	17.12	20.22	0.0	0.00	66.7	35	-4.76	29.31	-100.0	0.00	33.3
Week 86	34	14.70	18.70	0.0	0.00	66.7	31	-6.45	31.53	-100.0	0.00	33.3
Week 89	33	17.17	22.24	0.0	0.00	66.7	31	-4.30	31.90	-100.0	0.00	33.3
Week 92	27	17.28	28.30	0.0	0.00	100.0	25	-6.67	34.69	-100.0	0.00	66.7
Week 95	22	16.67	22.42	0.0	0.00	66.7	21	-3.17	25.61	-66.7	0.00	33.3
Week 98	18	16.67	20.61	0.0	0.00	66.7	17	-5.88	31.70	-66.7	0.00	66.7
Week 101	14	16.67	17.29	0.0	16.67	33.3	14	-7.14	29.75	-66.7	0.00	33.3
Week 104	10	13.33	17.21	0.0	0.00	33.3	10	-10.00	27.44	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Plat+Gem (N=242)												
BASELINE	188	25.00	28.76	0.0	33.33	100.0						
Week 1	173	33.91	30.81	0.0	33.33	100.0	158	10.13	30.03	-66.7	0.00	100.0
Week 2	171	33.14	32.24	0.0	33.33	100.0	151	10.15	32.43	-66.7	0.00	100.0
Week 3	184	26.09	27.36	0.0	33.33	100.0	162	1.85	27.36	-66.7	0.00	66.7
Week 4	183	29.33	27.88	0.0	33.33	100.0	156	6.20	32.09	-66.7	0.00	100.0
Week 5	187	29.59	27.72	0.0	33.33	100.0	156	6.20	32.53	-66.7	0.00	100.0
Week 6	174	26.63	28.67	0.0	33.33	100.0	149	1.12	31.34	-66.7	0.00	100.0
Week 7	186	27.78	27.05	0.0	33.33	100.0	157	4.46	30.22	-66.7	0.00	100.0
Week 8	167	27.34	26.96	0.0	33.33	100.0	144	4.17	36.10	-100.0	0.00	100.0
Week 9	177	24.10	27.00	0.0	33.33	100.0	150	0.67	31.25	-66.7	0.00	100.0
Week 10	166	27.11	28.80	0.0	33.33	100.0	139	2.88	34.63	-100.0	0.00	100.0
Week 11	168	27.78	29.56	0.0	33.33	100.0	143	5.83	32.94	-66.7	0.00	66.7
Week 12	159	22.64	27.13	0.0	0.00	100.0	138	-0.24	32.34	-100.0	0.00	66.7
Week 14	153	28.10	29.40	0.0	33.33	100.0	128	5.47	34.69	-100.0	0.00	100.0
Week 17	155	29.25	29.51	0.0	33.33	100.0	130	6.41	34.00	-100.0	0.00	100.0
Week 20	126	17.19	23.75	0.0	0.00	100.0	110	-4.24	28.95	-100.0	0.00	66.7
Week 23	115	16.52	25.12	0.0	0.00	100.0	97	-3.09	31.58	-66.7	0.00	66.7
Week 26	108	15.43	26.35	0.0	0.00	100.0	95	-2.81	31.76	-66.7	0.00	66.7
Week 29	100	15.67	23.90	0.0	0.00	100.0	86	-2.33	28.83	-66.7	0.00	66.7
Week 32	83	15.66	22.89	0.0	0.00	100.0	76	-3.51	25.87	-66.7	0.00	66.7
Week 35	76	15.35	25.20	0.0	0.00	100.0	69	-4.35	26.14	-66.7	0.00	66.7
Week 38	74	14.41	24.72	0.0	0.00	100.0	65	-4.10	27.96	-66.7	0.00	66.7
Week 41	65	15.90	25.76	0.0	0.00	100.0	56	-2.38	28.32	-66.7	0.00	66.7
Week 44	60	12.78	23.84	0.0	0.00	100.0	53	-5.66	29.04	-66.7	0.00	66.7
Week 47	56	15.48	21.99	0.0	0.00	66.7	49	-3.40	24.76	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	51	17.65	25.26	0.0	0.00	100.0	47	0.00	25.06	-33.3	0.00	66.7
Week 53	46	14.49	20.67	0.0	0.00	66.7	42	-3.97	26.75	-66.7	0.00	66.7
Week 56	39	13.67	22.58	0.0	0.00	66.7	34	-4.90	33.97	-66.7	0.00	66.7
Week 59	37	12.61	22.70	0.0	0.00	100.0	33	-4.04	34.11	-66.7	0.00	100.0
Week 62	32	10.42	17.83	0.0	0.00	66.7	29	-8.05	24.65	-33.3	0.00	66.7
Week 65	30	10.00	15.53	0.0	0.00	33.3	26	-8.97	24.14	-66.7	0.00	33.3
Week 68	25	10.67	15.87	0.0	0.00	33.3	21	-9.52	21.46	-66.7	0.00	33.3
Week 71	22	13.64	19.68	0.0	0.00	66.7	19	-7.02	28.50	-66.7	0.00	33.3
Week 74	21	14.29	24.88	0.0	0.00	66.7	18	-7.41	24.40	-66.7	0.00	33.3
Week 77	18	11.11	28.01	0.0	0.00	100.0	15	-8.89	23.46	-33.3	0.00	33.3
Week 80	14	11.90	21.11	0.0	0.00	66.7	13	-5.13	29.96	-33.3	0.00	66.7
Week 83	13	5.13	12.52	0.0	0.00	33.3	12	-16.67	22.47	-66.7	0.00	0.0
Week 86	12	5.56	12.97	0.0	0.00	33.3	11	-9.09	21.55	-33.3	0.00	33.3
Week 89	11	6.06	13.48	0.0	0.00	33.3	10	-10.00	22.50	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Present	EV+Pembro (N= 48)												
	BASELINE	39	32.48	35.45	0.0	33.33	100.0						
	Week 1	32	35.42	36.85	0.0	33.33	100.0	32	1.04	21.56	-66.7	0.00	33.3
	Week 2	37	44.14	32.45	0.0	33.33	100.0	33	12.12	32.08	-66.7	0.00	100.0
	Week 3	34	50.98	35.99	0.0	33.33	100.0	29	11.49	38.09	-66.7	0.00	100.0
	Week 4	36	39.81	33.64	0.0	33.33	100.0	31	9.68	38.68	-66.7	0.00	100.0
	Week 5	30	36.67	37.50	0.0	33.33	100.0	24	6.94	47.12	-100.0	0.00	100.0
	Week 6	31	30.11	35.86	0.0	0.00	100.0	25	-1.33	46.63	-100.0	0.00	100.0
	Week 7	34	27.45	32.28	0.0	16.67	100.0	28	-5.95	53.71	-100.0	0.00	100.0
	Week 8	35	24.76	29.53	0.0	0.00	100.0	30	-8.89	43.71	-100.0	0.00	66.7
	Week 9	34	34.31	37.14	0.0	33.33	100.0	30	3.33	47.42	-100.0	0.00	100.0
	Week 10	34	25.49	28.50	0.0	16.67	66.7	30	-5.56	45.56	-100.0	0.00	66.7
	Week 11	33	28.28	33.46	0.0	33.33	100.0	28	-8.33	48.54	-100.0	0.00	100.0
	Week 12	33	24.24	33.62	0.0	0.00	100.0	29	-12.64	47.49	-100.0	0.00	66.7
	Week 14	31	25.81	30.68	0.0	33.33	100.0	26	-8.97	48.59	-100.0	0.00	100.0
	Week 17	31	31.18	32.13	0.0	33.33	100.0	25	-5.33	49.70	-100.0	0.00	100.0
	Week 20	27	20.99	27.96	0.0	0.00	100.0	24	-12.50	43.75	-100.0	0.00	100.0
	Week 23	26	21.79	29.73	0.0	0.00	100.0	23	-10.14	49.68	-100.0	0.00	100.0
	Week 26	25	21.33	31.74	0.0	0.00	100.0	22	-16.67	36.73	-100.0	0.00	33.3
	Week 29	23	10.14	18.63	0.0	0.00	66.7	22	-18.18	35.23	-100.0	0.00	33.3
	Week 32	21	9.52	18.69	0.0	0.00	66.7	19	-22.81	35.23	-100.0	0.00	0.0
	Week 35	19	19.30	32.04	0.0	0.00	100.0	17	-11.76	38.98	-100.0	0.00	33.3
	Week 38	18	25.93	37.15	0.0	0.00	100.0	17	-11.76	49.92	-100.0	0.00	66.7
	Week 41	20	18.33	27.52	0.0	0.00	100.0	19	-14.04	38.99	-100.0	0.00	66.7
	Week 44	17	11.76	16.42	0.0	0.00	33.3	15	-13.33	24.56	-66.7	0.00	0.0
	Week 47	18	16.67	28.58	0.0	0.00	100.0	16	-8.33	22.77	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	12	8.33	15.07	0.0	0.00	33.3	11	-6.06	20.10	-33.3	0.00	33.3
	Week 53	12	16.67	30.15	0.0	0.00	100.0	11	3.03	27.71	-33.3	0.00	66.7
	Week 56	13	7.69	19.97	0.0	0.00	66.7	12	-8.33	20.72	-33.3	0.00	33.3
	Week 59	12	5.56	19.25	0.0	0.00	66.7	11	-9.09	21.56	-33.3	0.00	33.3
	Week 62	10	3.33	10.54	0.0	0.00	33.3	9	-11.11	16.67	-33.3	0.00	0.0
	Week 65	10	13.33	23.31	0.0	0.00	66.7	9	-7.41	22.22	-33.3	0.00	33.3
	Plat+Gem (N= 48)												
	BASELINE	33	34.34	33.84	0.0	33.33	100.0						
	Week 1	31	48.39	28.34	0.0	33.33	100.0	27	13.58	23.13	-33.3	0.00	66.7
	Week 2	29	45.98	34.98	0.0	33.33	100.0	24	12.50	33.78	-33.3	0.00	100.0
	Week 3	32	30.21	29.77	0.0	33.33	100.0	27	-6.17	27.79	-66.7	0.00	33.3
	Week 4	32	32.29	23.16	0.0	33.33	66.7	24	-1.39	30.26	-66.7	0.00	33.3
	Week 5	36	27.78	24.56	0.0	33.33	100.0	28	-9.52	28.48	-66.7	0.00	33.3
	Week 6	35	32.38	34.76	0.0	33.33	100.0	27	-7.41	29.72	-66.7	0.00	33.3
	Week 7	38	27.19	24.33	0.0	33.33	100.0	29	-11.49	27.13	-66.7	0.00	33.3
	Week 8	31	23.65	23.08	0.0	33.33	100.0	25	-5.33	32.89	-100.0	0.00	33.3
	Week 9	32	28.12	28.22	0.0	33.33	100.0	25	-9.33	28.09	-66.7	0.00	33.3
	Week 10	34	29.41	34.59	0.0	33.33	100.0	26	-10.26	29.47	-66.7	0.00	66.7
	Week 11	30	24.44	27.59	0.0	33.33	100.0	24	-9.72	30.26	-66.7	0.00	33.3
	Week 12	28	16.67	21.28	0.0	0.00	66.7	23	-17.39	31.57	-100.0	0.00	33.3
	Week 14	26	23.08	26.28	0.0	16.67	66.7	21	-9.52	36.73	-100.0	0.00	66.7
	Week 17	30	24.44	26.16	0.0	33.33	100.0	25	-8.00	35.07	-100.0	0.00	33.3
	Week 20	23	14.49	26.26	0.0	0.00	100.0	21	-17.46	29.10	-66.7	0.00	33.3
	Week 23	22	24.24	31.17	0.0	0.00	100.0	19	-1.75	35.96	-66.7	0.00	66.7
	Week 26	19	8.77	15.08	0.0	0.00	33.3	18	-12.96	28.33	-66.7	0.00	33.3
	Week 29	16	14.58	20.97	0.0	0.00	66.7	14	-11.91	30.96	-66.7	0.00	33.3

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 32	11	18.18	17.41	0.0	33.33	33.3	11	-12.12	26.97	-66.7	0.00	33.3
	Week 35	10	20.00	23.31	0.0	16.67	66.7	9	-14.82	29.40	-66.7	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
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Table 302.1.3002.19.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Absent	EV+Pembro (N=192)												
	BASELINE	167	18.96	26.25	0.0	0.00	100.0						
	Week 1	158	21.31	24.73	0.0	0.00	100.0	152	3.07	24.67	-100.0	0.00	100.0
	Week 2	166	27.31	29.43	0.0	33.33	100.0	156	9.62	28.08	-100.0	0.00	100.0
	Week 3	164	28.45	31.17	0.0	33.33	100.0	153	10.68	33.26	-100.0	0.00	100.0
	Week 4	158	24.26	27.04	0.0	33.33	100.0	148	5.18	31.28	-100.0	0.00	100.0
	Week 5	160	22.29	27.66	0.0	0.00	100.0	149	4.70	33.79	-100.0	0.00	100.0
	Week 6	157	21.87	24.08	0.0	33.33	100.0	145	3.45	30.36	-100.0	0.00	66.7
	Week 7	161	22.15	24.70	0.0	33.33	100.0	148	3.83	30.74	-100.0	0.00	66.7
	Week 8	156	22.65	26.23	0.0	33.33	100.0	141	4.96	32.35	-100.0	0.00	100.0
	Week 9	163	23.52	25.64	0.0	33.33	100.0	150	5.56	31.71	-100.0	0.00	66.7
	Week 10	157	21.23	23.92	0.0	33.33	100.0	145	1.84	32.82	-100.0	0.00	66.7
	Week 11	161	22.15	25.53	0.0	33.33	100.0	147	2.49	33.12	-100.0	0.00	66.7
	Week 12	153	22.87	26.34	0.0	33.33	100.0	142	3.76	34.40	-100.0	0.00	100.0
	Week 14	154	23.16	25.37	0.0	33.33	100.0	141	4.49	30.92	-100.0	0.00	100.0
	Week 17	147	23.81	25.88	0.0	33.33	100.0	137	5.84	31.54	-100.0	0.00	100.0
	Week 20	140	22.38	27.54	0.0	0.00	100.0	130	4.62	33.40	-100.0	0.00	100.0
	Week 23	136	23.04	26.45	0.0	33.33	100.0	128	6.25	32.06	-100.0	0.00	100.0
	Week 26	131	21.88	27.35	0.0	0.00	100.0	122	4.64	29.17	-66.7	0.00	66.7
	Week 29	134	20.89	24.41	0.0	0.00	100.0	123	4.88	30.08	-66.7	0.00	100.0
	Week 32	114	18.42	23.50	0.0	0.00	100.0	106	1.26	30.83	-66.7	0.00	66.7
	Week 35	113	17.70	21.85	0.0	0.00	100.0	105	0.95	27.13	-66.7	0.00	100.0
	Week 38	114	16.67	22.72	0.0	0.00	66.7	107	0.93	28.39	-66.7	0.00	66.7
	Week 41	109	17.12	22.04	0.0	0.00	66.7	100	0.67	27.62	-66.7	0.00	66.7
	Week 44	91	14.29	23.90	0.0	0.00	100.0	85	-1.96	31.85	-66.7	0.00	100.0
	Week 47	82	13.82	20.92	0.0	0.00	66.7	78	-2.56	29.80	-66.7	0.00	66.7

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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Table 302.1.3002.19.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	77	12.99	21.05	0.0	0.00	66.7	73	-3.65	28.09	-66.7	0.00	66.7
	Week 53	67	12.93	19.21	0.0	0.00	66.7	63	-2.12	27.35	-100.0	0.00	33.3
	Week 56	68	12.25	19.02	0.0	0.00	66.7	64	-4.17	29.40	-100.0	0.00	66.7
	Week 59	60	12.22	19.37	0.0	0.00	66.7	57	-3.51	30.00	-100.0	0.00	66.7
	Week 62	55	14.54	21.05	0.0	0.00	66.7	54	0.00	31.72	-100.0	0.00	66.7
	Week 65	48	11.81	20.03	0.0	0.00	66.7	45	-3.70	31.16	-100.0	0.00	66.7
	Week 68	46	13.04	20.46	0.0	0.00	66.7	45	-2.22	30.48	-100.0	0.00	66.7
	Week 71	44	12.88	20.61	0.0	0.00	66.7	42	-2.38	31.57	-100.0	0.00	66.7
	Week 74	40	11.67	19.32	0.0	0.00	66.7	39	-5.13	31.10	-100.0	0.00	66.7
	Week 77	38	16.67	24.20	0.0	0.00	66.7	36	0.93	33.32	-100.0	0.00	66.7
	Week 80	35	13.33	20.13	0.0	0.00	66.7	32	-5.21	30.65	-100.0	0.00	33.3
	Week 83	32	17.71	20.71	0.0	0.00	66.7	30	-3.33	30.76	-100.0	0.00	33.3
	Week 86	29	14.94	19.08	0.0	0.00	66.7	26	-6.41	34.02	-100.0	0.00	33.3
	Week 89	29	17.24	22.92	0.0	0.00	66.7	27	-3.70	33.76	-100.0	0.00	33.3
	Week 92	24	18.05	29.45	0.0	0.00	100.0	22	-7.58	36.99	-100.0	0.00	66.7
	Week 95	20	16.67	22.94	0.0	0.00	66.7	19	-1.75	25.99	-66.7	0.00	33.3
	Week 98	18	16.67	20.61	0.0	0.00	66.7	17	-5.88	31.70	-66.7	0.00	66.7
	Week 101	13	15.38	17.29	0.0	0.00	33.3	13	-7.69	30.89	-66.7	0.00	33.3
	Plat+Gem (N=194)												
	BASELINE	155	23.01	27.28	0.0	0.00	100.0						
	Week 1	142	30.75	30.51	0.0	33.33	100.0	131	9.42	31.29	-66.7	0.00	100.0
	Week 2	142	30.52	31.13	0.0	33.33	100.0	127	9.71	32.29	-66.7	0.00	100.0
	Week 3	152	25.22	26.85	0.0	33.33	100.0	135	3.46	27.10	-66.7	0.00	66.7
	Week 4	151	28.70	28.81	0.0	33.33	100.0	132	7.58	32.32	-66.7	0.00	100.0
	Week 5	151	30.02	28.48	0.0	33.33	100.0	128	9.64	32.44	-66.7	0.00	100.0
	Week 6	139	25.18	26.87	0.0	33.33	100.0	122	3.01	31.49	-66.7	0.00	100.0

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Table 302.1.3002.19.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 7	148	27.93	27.78	0.0	33.33	100.0	128	8.07	29.80	-66.7	0.00	100.0
	Week 8	136	28.19	27.78	0.0	33.33	100.0	119	6.16	36.56	-66.7	0.00	100.0
	Week 9	145	23.22	26.74	0.0	33.33	100.0	125	2.67	31.57	-66.7	0.00	100.0
	Week 10	132	26.51	27.24	0.0	33.33	100.0	113	5.90	35.14	-100.0	0.00	100.0
	Week 11	138	28.50	30.02	0.0	33.33	100.0	119	8.96	32.68	-66.7	0.00	66.7
	Week 12	131	23.92	28.13	0.0	0.00	100.0	115	3.19	31.52	-100.0	0.00	66.7
	Week 14	127	29.13	29.99	0.0	33.33	100.0	107	8.41	33.68	-66.7	0.00	100.0
	Week 17	125	30.40	30.24	0.0	33.33	100.0	105	9.84	32.99	-66.7	0.00	100.0
	Week 20	103	17.80	23.25	0.0	0.00	100.0	89	-1.12	28.18	-100.0	0.00	66.7
	Week 23	93	14.69	23.29	0.0	0.00	100.0	78	-3.42	30.67	-66.7	0.00	66.7
	Week 26	89	16.85	28.03	0.0	0.00	100.0	77	-0.43	32.22	-66.7	0.00	66.7
	Week 29	84	15.87	24.53	0.0	0.00	100.0	72	-0.46	28.25	-66.7	0.00	66.7
	Week 32	72	15.28	23.69	0.0	0.00	100.0	65	-2.05	25.60	-66.7	0.00	66.7
	Week 35	66	14.65	25.57	0.0	0.00	100.0	60	-2.78	25.52	-66.7	0.00	66.7
	Week 38	66	15.15	25.61	0.0	0.00	100.0	57	-4.09	29.59	-66.7	0.00	66.7
	Week 41	62	14.52	25.34	0.0	0.00	100.0	53	-2.52	28.38	-66.7	0.00	66.7
	Week 44	55	11.51	23.32	0.0	0.00	100.0	48	-6.94	29.14	-66.7	0.00	66.7
	Week 47	51	14.38	21.35	0.0	0.00	66.7	44	-5.30	22.67	-33.3	0.00	66.7
	Week 50	48	18.75	25.64	0.0	0.00	100.0	44	1.52	24.86	-33.3	0.00	66.7
	Week 53	41	14.63	21.15	0.0	0.00	66.7	37	-5.41	26.66	-66.7	0.00	66.7
	Week 56	34	11.76	21.53	0.0	0.00	66.7	29	-8.05	32.92	-66.7	0.00	66.7
	Week 59	32	10.42	17.83	0.0	0.00	66.7	28	-8.33	29.57	-66.7	0.00	66.7
	Week 62	27	8.64	14.88	0.0	0.00	33.3	24	-12.50	19.19	-33.3	0.00	33.3
	Week 65	25	9.33	15.27	0.0	0.00	33.3	21	-12.70	22.30	-66.7	0.00	33.3
	Week 68	23	10.14	15.68	0.0	0.00	33.3	19	-10.53	19.41	-66.7	0.00	0.0
	Week 71	21	12.70	19.65	0.0	0.00	66.7	18	-9.26	27.55	-66.7	0.00	33.3

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Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 74	20	15.00	25.31	0.0	0.00	66.7	17	-5.88	24.25	-66.7	0.00	33.3
	Week 77	16	12.50	29.50	0.0	0.00	100.0	13	-5.13	22.96	-33.3	0.00	33.3
	Week 80	12	13.89	22.29	0.0	0.00	66.7	11	0.00	29.81	-33.3	0.00	66.7
	Week 83	11	3.03	10.05	0.0	0.00	33.3	10	-16.67	23.57	-66.7	0.00	0.0
	Week 86	10	6.67	14.05	0.0	0.00	33.3	9	-3.70	20.03	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
< 65 years	EV+Pembro (N=105)												
	BASELINE	92	22.46	29.69	0.0	0.00	100.0						
	Week 1	88	25.00	29.58	0.0	33.33	100.0	85	4.31	22.29	-66.7	0.00	100.0
	Week 2	92	28.62	29.48	0.0	33.33	100.0	86	8.53	29.46	-66.7	0.00	100.0
	Week 3	93	30.47	30.16	0.0	33.33	100.0	84	7.14	31.08	-66.7	0.00	100.0
	Week 4	90	23.70	27.93	0.0	33.33	100.0	82	0.00	30.99	-66.7	0.00	100.0
	Week 5	90	22.59	28.19	0.0	0.00	100.0	81	1.23	32.68	-100.0	0.00	100.0
	Week 6	90	19.63	24.43	0.0	0.00	100.0	81	-2.88	31.27	-100.0	0.00	66.7
	Week 7	85	18.43	23.85	0.0	0.00	100.0	77	-3.90	32.88	-100.0	0.00	66.7
	Week 8	89	19.47	25.03	0.0	0.00	100.0	80	-1.25	34.14	-100.0	0.00	66.7
	Week 9	93	21.50	27.21	0.0	0.00	100.0	85	1.57	35.97	-100.0	0.00	100.0
	Week 10	88	15.53	20.81	0.0	0.00	66.7	81	-6.17	32.96	-100.0	0.00	66.7
	Week 11	93	18.28	22.80	0.0	0.00	66.7	84	-3.57	35.10	-100.0	0.00	66.7
	Week 12	86	20.93	28.49	0.0	0.00	100.0	79	-1.27	38.65	-100.0	0.00	100.0
	Week 14	84	21.82	26.63	0.0	0.00	100.0	76	0.44	34.21	-100.0	0.00	100.0
	Week 17	83	22.49	26.60	0.0	33.33	100.0	77	-0.87	35.03	-100.0	0.00	100.0
	Week 20	79	20.25	27.43	0.0	0.00	100.0	73	-0.46	34.91	-100.0	0.00	100.0
	Week 23	78	22.65	28.17	0.0	0.00	100.0	73	1.83	33.28	-100.0	0.00	100.0
	Week 26	78	24.36	29.75	0.0	0.00	100.0	72	0.93	30.11	-100.0	0.00	66.7
	Week 29	74	20.72	26.29	0.0	0.00	100.0	67	2.49	33.49	-100.0	0.00	100.0
	Week 32	64	18.75	23.66	0.0	0.00	100.0	59	-0.57	32.45	-100.0	0.00	66.7
	Week 35	62	18.82	26.05	0.0	0.00	100.0	58	1.15	30.57	-100.0	0.00	100.0
	Week 38	62	19.89	28.60	0.0	0.00	100.0	59	1.13	32.14	-100.0	0.00	66.7
	Week 41	64	17.71	24.47	0.0	0.00	100.0	59	-3.39	28.83	-100.0	0.00	66.7
	Week 44	50	11.33	20.88	0.0	0.00	100.0	48	-7.64	28.55	-66.7	0.00	100.0
	Week 47	47	15.60	22.90	0.0	0.00	100.0	46	-4.35	27.76	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	44	11.36	18.94	0.0	0.00	66.7	41	-3.25	26.67	-66.7	0.00	66.7
	Week 53	40	13.33	21.08	0.0	0.00	100.0	37	0.00	26.06	-66.7	0.00	66.7
	Week 56	44	11.36	17.52	0.0	0.00	66.7	41	-4.06	21.34	-33.3	0.00	33.3
	Week 59	42	11.90	19.23	0.0	0.00	66.7	39	-1.71	25.30	-66.7	0.00	66.7
	Week 62	37	14.41	20.09	0.0	0.00	66.7	36	0.00	27.60	-66.7	0.00	66.7
	Week 65	34	12.74	21.73	0.0	0.00	66.7	31	-1.07	29.17	-66.7	0.00	66.7
	Week 68	34	11.76	16.17	0.0	0.00	33.3	33	-2.02	24.91	-66.7	0.00	33.3
	Week 71	32	12.50	20.30	0.0	0.00	66.7	30	-1.11	29.66	-66.7	0.00	66.7
	Week 74	29	13.79	18.93	0.0	0.00	66.7	28	0.00	25.66	-33.3	0.00	66.7
	Week 77	25	18.67	23.73	0.0	0.00	66.7	24	4.17	26.58	-33.3	0.00	66.7
	Week 80	24	18.05	21.93	0.0	0.00	66.7	22	3.03	20.34	-33.3	0.00	33.3
	Week 83	23	20.29	19.43	0.0	33.33	66.7	22	3.03	22.79	-33.3	0.00	33.3
	Week 86	20	18.33	17.01	0.0	33.33	33.3	18	1.85	24.18	-33.3	0.00	33.3
	Week 89	19	19.30	23.08	0.0	0.00	66.7	17	1.96	21.95	-33.3	0.00	33.3
	Week 92	14	21.43	28.06	0.0	16.67	100.0	12	2.78	22.28	-33.3	0.00	33.3
	Week 95	12	13.89	17.16	0.0	0.00	33.3	11	0.00	21.08	-33.3	0.00	33.3
	Plat+Gem (N=106)												
	BASELINE	83	24.90	27.96	0.0	33.33	100.0						
	Week 1	75	34.67	30.24	0.0	33.33	100.0	71	10.80	29.69	-66.7	0.00	100.0
	Week 2	76	32.02	32.86	0.0	33.33	100.0	68	7.84	32.13	-66.7	0.00	100.0
	Week 3	80	21.67	26.04	0.0	0.00	100.0	73	-3.20	28.42	-66.7	0.00	66.7
	Week 4	79	26.58	26.36	0.0	33.33	100.0	67	2.98	32.69	-66.7	0.00	66.7
	Week 5	80	24.58	24.73	0.0	33.33	100.0	67	0.99	31.23	-66.7	0.00	66.7
	Week 6	76	20.61	24.32	0.0	0.00	100.0	67	-4.48	30.09	-66.7	0.00	66.7
	Week 7	81	24.69	26.76	0.0	33.33	100.0	71	1.41	27.85	-66.7	0.00	66.7
	Week 8	72	22.22	24.39	0.0	33.33	100.0	64	-1.56	35.35	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	78	20.08	23.01	0.0	0.00	66.7	69	-3.86	27.73	-66.7	0.00	66.7
	Week 10	78	22.65	25.48	0.0	33.33	100.0	68	-1.96	33.52	-100.0	0.00	66.7
	Week 11	75	23.56	27.82	0.0	0.00	100.0	66	0.51	34.34	-66.7	0.00	66.7
	Week 12	74	16.67	22.92	0.0	0.00	100.0	66	-6.06	30.89	-100.0	0.00	66.7
	Week 14	68	25.98	29.84	0.0	33.33	100.0	58	2.87	34.92	-100.0	0.00	66.7
	Week 17	68	26.96	26.55	0.0	33.33	100.0	58	4.60	32.71	-100.0	0.00	66.7
	Week 20	60	14.44	23.26	0.0	0.00	100.0	52	-7.05	26.68	-100.0	0.00	66.7
	Week 23	51	12.42	23.06	0.0	0.00	100.0	44	-6.82	28.37	-66.7	0.00	66.7
	Week 26	47	15.60	29.37	0.0	0.00	100.0	42	-5.55	34.47	-66.7	0.00	66.7
	Week 29	42	12.70	19.41	0.0	0.00	66.7	37	-9.01	27.94	-66.7	0.00	33.3
	Week 32	37	13.51	21.46	0.0	0.00	66.7	34	-6.86	21.37	-66.7	0.00	33.3
	Week 35	34	15.69	27.51	0.0	0.00	100.0	31	-5.38	27.35	-66.7	0.00	66.7
	Week 38	33	12.12	24.75	0.0	0.00	100.0	28	-7.14	27.75	-66.7	0.00	66.7
	Week 41	27	9.88	18.06	0.0	0.00	66.7	22	-9.09	18.35	-33.3	0.00	33.3
	Week 44	28	7.14	21.00	0.0	0.00	100.0	24	-12.50	25.65	-33.3	-16.67	66.7
	Week 47	24	11.11	21.23	0.0	0.00	66.7	21	-7.94	20.83	-33.3	0.00	33.3
	Week 50	26	14.10	26.95	0.0	0.00	100.0	24	-5.55	23.40	-33.3	0.00	66.7
	Week 53	19	10.53	22.37	0.0	0.00	66.7	17	-9.80	22.87	-33.3	0.00	33.3
	Week 56	13	5.13	12.52	0.0	0.00	33.3	11	-12.12	22.47	-33.3	0.00	33.3
	Week 59	14	2.38	8.91	0.0	0.00	33.3	12	-11.11	16.41	-33.3	0.00	0.0
	Week 62	13	2.56	9.24	0.0	0.00	33.3	12	-13.89	17.16	-33.3	0.00	0.0
	Week 65	13	5.13	12.52	0.0	0.00	33.3	11	-9.09	15.57	-33.3	0.00	0.0
	Week 68	10	6.67	14.05	0.0	0.00	33.3	8	-8.33	15.43	-33.3	0.00	0.0
	Week 77	10	13.33	32.20	0.0	0.00	100.0	8	-12.50	24.80	-33.3	-16.67	33.3

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Table 302.1.3002.19.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>= 65 years	EV+Pembro (N=135)												
	BASELINE	114	20.76	27.83	0.0	0.00	100.0						
	Week 1	102	22.55	25.76	0.0	33.33	100.0	99	1.35	25.61	-100.0	0.00	66.7
	Week 2	111	31.83	31.59	0.0	33.33	100.0	103	11.33	28.22	-100.0	0.00	100.0
	Week 3	105	33.97	35.50	0.0	33.33	100.0	98	13.95	36.11	-100.0	0.00	100.0
	Week 4	104	30.13	29.57	0.0	33.33	100.0	97	11.00	33.24	-100.0	0.00	100.0
	Week 5	100	26.33	31.17	0.0	33.33	100.0	92	8.33	38.16	-100.0	0.00	100.0
	Week 6	98	26.53	27.89	0.0	33.33	100.0	89	7.86	34.09	-100.0	0.00	100.0
	Week 7	110	26.67	27.39	0.0	33.33	100.0	99	7.07	36.66	-100.0	0.00	100.0
	Week 8	102	26.14	28.00	0.0	33.33	100.0	91	5.86	35.34	-100.0	0.00	100.0
	Week 9	104	28.85	28.66	0.0	33.33	100.0	95	8.42	33.32	-100.0	0.00	66.7
	Week 10	103	27.51	26.58	0.0	33.33	100.0	94	6.38	36.34	-100.0	0.00	66.7
	Week 11	101	27.72	29.84	0.0	33.33	100.0	91	4.76	36.71	-100.0	0.00	100.0
	Week 12	100	25.00	26.96	0.0	33.33	100.0	92	2.90	36.20	-100.0	0.00	66.7
	Week 14	101	25.08	25.99	0.0	33.33	100.0	91	4.03	34.72	-100.0	0.00	100.0
	Week 17	95	27.37	27.50	0.0	33.33	100.0	85	8.63	34.56	-100.0	0.00	100.0
	Week 20	88	23.86	27.66	0.0	33.33	100.0	81	4.11	36.28	-100.0	0.00	100.0
	Week 23	84	23.02	25.86	0.0	33.33	100.0	78	5.56	37.76	-100.0	0.00	100.0
	Week 26	78	19.23	26.05	0.0	0.00	100.0	72	1.85	32.57	-100.0	0.00	66.7
	Week 29	83	18.07	21.65	0.0	0.00	66.7	78	0.43	30.62	-100.0	0.00	66.7
	Week 32	71	15.49	22.42	0.0	0.00	66.7	66	-4.04	32.82	-100.0	0.00	66.7
	Week 35	70	17.14	21.04	0.0	0.00	100.0	64	-2.60	28.05	-100.0	0.00	33.3
	Week 38	70	16.19	21.79	0.0	0.00	66.7	65	-2.56	32.44	-100.0	0.00	66.7
	Week 41	65	16.92	21.35	0.0	0.00	66.7	60	0.00	31.29	-100.0	0.00	66.7
	Week 44	58	16.09	24.38	0.0	0.00	100.0	52	0.00	33.01	-66.7	0.00	100.0
	Week 47	53	13.21	22.01	0.0	0.00	66.7	48	-2.78	29.84	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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Table 302.1.3002.19.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	45	13.33	21.79	0.0	0.00	66.7	43	-4.65	27.78	-66.7	0.00	66.7
	Week 53	39	13.67	21.24	0.0	0.00	66.7	37	-2.70	28.74	-100.0	0.00	33.3
	Week 56	37	11.71	21.11	0.0	0.00	66.7	35	-5.71	34.76	-100.0	0.00	66.7
	Week 59	30	10.00	19.87	0.0	0.00	66.7	29	-8.05	32.92	-100.0	0.00	33.3
	Week 62	28	10.71	20.39	0.0	0.00	66.7	27	-3.70	33.76	-100.0	0.00	66.7
	Week 65	24	11.11	18.82	0.0	0.00	66.7	23	-8.70	30.51	-100.0	0.00	33.3
	Week 68	19	12.28	25.36	0.0	0.00	66.7	19	-5.26	35.60	-100.0	0.00	66.7
	Week 71	19	10.53	19.41	0.0	0.00	66.7	19	-7.02	30.59	-100.0	0.00	33.3
	Week 74	18	5.56	17.15	0.0	0.00	66.7	18	-14.81	32.79	-100.0	0.00	33.3
	Week 77	19	12.28	22.80	0.0	0.00	66.7	18	-7.41	37.15	-100.0	0.00	66.7
	Week 80	16	6.25	13.44	0.0	0.00	33.3	15	-20.00	35.19	-100.0	0.00	33.3
	Week 83	14	11.90	21.11	0.0	0.00	66.7	13	-17.95	35.00	-100.0	0.00	33.3
	Week 86	14	9.52	20.38	0.0	0.00	66.7	13	-17.95	37.55	-100.0	0.00	33.3
	Week 89	14	14.29	21.54	0.0	0.00	66.7	14	-11.91	40.53	-100.0	0.00	33.3
	Week 92	13	12.82	28.99	0.0	0.00	100.0	13	-15.38	42.20	-100.0	0.00	66.7
	Week 95	10	20.00	28.11	0.0	0.00	66.7	10	-6.67	30.63	-66.7	0.00	33.3
	Week 98	10	20.00	23.31	0.0	16.67	66.7	10	-6.67	37.84	-66.7	0.00	66.7
	Plat+Gem (N=136)												
	BASELINE	105	25.08	29.52	0.0	33.33	100.0						
	Week 1	98	33.33	31.39	0.0	33.33	100.0	87	9.58	30.46	-66.7	0.00	100.0
	Week 2	95	34.03	31.88	0.0	33.33	100.0	83	12.05	32.75	-66.7	0.00	100.0
	Week 3	104	29.49	27.99	0.0	33.33	100.0	89	5.99	25.90	-66.7	0.00	66.7
	Week 4	104	31.41	28.94	0.0	33.33	100.0	89	8.61	31.59	-66.7	0.00	100.0
	Week 5	107	33.33	29.32	0.0	33.33	100.0	89	10.11	33.11	-66.7	0.00	100.0
	Week 6	98	31.29	30.95	0.0	33.33	100.0	82	5.69	31.78	-66.7	0.00	100.0
	Week 7	105	30.16	27.16	0.0	33.33	100.0	86	6.98	31.98	-66.7	0.00	100.0

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Table 302.1.3002.19.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 8	95	31.23	28.27	0.0	33.33	100.0	80	8.75	36.26	-66.7	0.00	100.0
	Week 9	99	27.27	29.49	0.0	33.33	100.0	81	4.53	33.65	-66.7	0.00	100.0
	Week 10	88	31.06	31.07	0.0	33.33	100.0	71	7.51	35.28	-66.7	0.00	100.0
	Week 11	93	31.18	30.62	0.0	33.33	100.0	77	10.39	31.19	-66.7	0.00	66.7
	Week 12	85	27.84	29.48	0.0	33.33	100.0	72	5.09	32.94	-66.7	0.00	66.7
	Week 14	85	29.80	29.11	0.0	33.33	100.0	70	7.62	34.60	-66.7	0.00	100.0
	Week 17	87	31.03	31.66	0.0	33.33	100.0	72	7.87	35.16	-66.7	0.00	100.0
	Week 20	66	19.70	24.09	0.0	0.00	100.0	58	-1.72	30.86	-66.7	0.00	66.7
	Week 23	64	19.79	26.37	0.0	0.00	100.0	53	0.00	33.97	-66.7	0.00	66.7
	Week 26	61	15.30	24.02	0.0	0.00	100.0	53	-0.63	29.59	-66.7	0.00	66.7
	Week 29	58	17.82	26.65	0.0	0.00	100.0	49	2.72	28.74	-66.7	0.00	66.7
	Week 32	46	17.39	24.08	0.0	0.00	100.0	42	-0.79	28.97	-66.7	0.00	66.7
	Week 35	42	15.08	23.52	0.0	0.00	100.0	38	-3.51	25.46	-66.7	0.00	66.7
	Week 38	41	16.26	24.86	0.0	0.00	100.0	37	-1.80	28.27	-66.7	0.00	66.7
	Week 41	38	20.18	29.55	0.0	0.00	100.0	34	1.96	32.76	-66.7	0.00	66.7
	Week 44	32	17.71	25.38	0.0	0.00	100.0	29	0.00	30.86	-66.7	0.00	66.7
	Week 47	32	18.75	22.30	0.0	0.00	66.7	28	0.00	27.22	-33.3	0.00	66.7
	Week 50	25	21.33	23.33	0.0	33.33	66.7	23	5.80	25.92	-33.3	0.00	66.7
	Week 53	27	17.28	19.33	0.0	0.00	66.7	25	0.00	28.87	-66.7	0.00	66.7
	Week 56	26	17.95	25.35	0.0	0.00	66.7	23	-1.45	38.24	-66.7	0.00	66.7
	Week 59	23	18.84	26.26	0.0	0.00	100.0	21	0.00	40.83	-66.7	0.00	100.0
	Week 62	19	15.79	20.39	0.0	0.00	66.7	17	-3.92	28.58	-33.3	0.00	66.7
	Week 65	17	13.72	16.91	0.0	0.00	33.3	15	-8.89	29.46	-66.7	0.00	33.3
	Week 68	15	13.33	16.90	0.0	0.00	33.3	13	-10.26	25.04	-66.7	0.00	33.3
	Week 71	15	13.33	16.90	0.0	0.00	33.3	13	-7.69	30.89	-66.7	0.00	33.3
	Week 74	12	16.67	26.59	0.0	0.00	66.7	11	-6.06	29.13	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Europe	EV+Pembro (N= 98)												
	BASELINE	79	19.41	28.55	0.0	0.00	100.0						
	Week 1	74	22.52	28.73	0.0	0.00	100.0	71	3.29	25.91	-100.0	0.00	100.0
	Week 2	79	26.58	29.42	0.0	33.33	100.0	71	7.98	28.43	-66.7	0.00	100.0
	Week 3	78	32.48	32.67	0.0	33.33	100.0	69	14.49	35.46	-66.7	0.00	100.0
	Week 4	78	24.79	30.12	0.0	33.33	100.0	70	8.09	34.72	-66.7	0.00	100.0
	Week 5	70	20.00	28.03	0.0	0.00	100.0	62	3.23	35.04	-100.0	0.00	100.0
	Week 6	70	20.48	27.39	0.0	0.00	100.0	61	4.37	33.60	-100.0	0.00	66.7
	Week 7	78	20.08	24.82	0.0	0.00	100.0	68	1.96	34.98	-100.0	0.00	66.7
	Week 8	72	20.37	27.15	0.0	0.00	100.0	61	3.82	34.48	-100.0	0.00	100.0
	Week 9	80	20.42	27.30	0.0	0.00	100.0	70	3.81	33.83	-100.0	0.00	66.7
	Week 10	71	16.90	23.82	0.0	0.00	100.0	62	-3.23	36.07	-100.0	0.00	66.7
	Week 11	76	19.74	28.38	0.0	0.00	100.0	66	-1.51	38.53	-100.0	0.00	66.7
	Week 12	73	19.18	26.60	0.0	0.00	100.0	65	-1.54	38.83	-100.0	0.00	100.0
	Week 14	74	19.82	24.62	0.0	0.00	100.0	64	2.08	34.57	-100.0	0.00	66.7
	Week 17	70	19.52	24.40	0.0	0.00	100.0	62	1.07	34.66	-100.0	0.00	66.7
	Week 20	70	17.62	22.50	0.0	0.00	66.7	63	-0.53	34.13	-100.0	0.00	66.7
	Week 23	61	20.76	22.90	0.0	33.33	66.7	57	3.51	35.46	-100.0	0.00	66.7
	Week 26	62	15.59	22.35	0.0	0.00	100.0	55	-1.21	29.37	-100.0	0.00	66.7
	Week 29	63	16.40	23.85	0.0	0.00	100.0	57	0.58	34.21	-100.0	0.00	100.0
	Week 32	51	15.03	23.39	0.0	0.00	100.0	47	-4.26	29.99	-100.0	0.00	66.7
	Week 35	56	16.07	22.01	0.0	0.00	66.7	52	0.00	29.52	-100.0	0.00	66.7
	Week 38	51	12.42	22.07	0.0	0.00	100.0	48	-2.78	30.62	-100.0	0.00	66.7
	Week 41	52	16.03	24.24	0.0	0.00	100.0	48	-3.47	31.69	-100.0	0.00	66.7
	Week 44	43	9.30	16.79	0.0	0.00	66.7	39	-4.27	21.87	-66.7	0.00	33.3
	Week 47	39	11.11	19.24	0.0	0.00	66.7	36	-2.78	21.64	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	37	7.21	17.80	0.0	0.00	66.7	36	-5.56	20.32	-66.7	0.00	33.3
	Week 53	28	14.29	24.73	0.0	0.00	100.0	27	-1.23	25.29	-66.7	0.00	66.7
	Week 56	30	11.11	20.22	0.0	0.00	66.7	29	-3.45	25.74	-66.7	0.00	66.7
	Week 59	27	9.88	18.06	0.0	0.00	66.7	27	-3.70	21.35	-66.7	0.00	33.3
	Week 62	23	11.59	19.09	0.0	0.00	66.7	23	-2.90	26.43	-66.7	0.00	66.7
	Week 65	23	8.70	18.03	0.0	0.00	66.7	23	-7.25	22.38	-66.7	0.00	33.3
	Week 68	21	4.76	11.95	0.0	0.00	33.3	21	-11.11	19.25	-66.7	0.00	0.0
	Week 71	19	3.51	10.51	0.0	0.00	33.3	19	-10.53	22.37	-66.7	0.00	33.3
	Week 74	15	4.44	11.73	0.0	0.00	33.3	15	-13.33	21.08	-66.7	0.00	0.0
	Week 77	19	12.28	22.80	0.0	0.00	66.7	19	-1.75	23.50	-33.3	0.00	66.7
	Week 80	17	11.76	20.21	0.0	0.00	66.7	17	-7.84	22.14	-66.7	0.00	33.3
	Week 83	16	12.50	20.64	0.0	0.00	66.7	16	-8.33	14.91	-33.3	0.00	0.0
	Week 86	14	9.52	15.63	0.0	0.00	33.3	14	-7.14	23.31	-66.7	0.00	33.3
	Week 89	14	11.90	21.11	0.0	0.00	66.7	14	-4.76	25.68	-66.7	0.00	33.3
	Week 92	11	9.09	15.57	0.0	0.00	33.3	11	-9.09	26.21	-66.7	0.00	33.3
	Week 95	10	10.00	16.10	0.0	0.00	33.3	10	-3.33	18.92	-33.3	0.00	33.3
	Plat+Gem (N=102)												
	BASELINE	71	28.17	34.11	0.0	33.33	100.0						
	Week 1	71	38.50	33.64	0.0	33.33	100.0	61	11.48	33.27	-66.7	0.00	100.0
	Week 2	67	38.31	35.42	0.0	33.33	100.0	56	10.71	34.88	-66.7	0.00	100.0
	Week 3	68	29.41	29.10	0.0	33.33	100.0	56	1.19	31.12	-66.7	0.00	66.7
	Week 4	75	29.33	27.92	0.0	33.33	100.0	59	5.65	32.84	-66.7	0.00	66.7
	Week 5	77	33.33	31.06	0.0	33.33	100.0	60	8.89	40.65	-66.7	0.00	100.0
	Week 6	70	32.38	33.08	0.0	33.33	100.0	56	3.57	34.04	-66.7	0.00	100.0
	Week 7	72	31.02	31.31	0.0	33.33	100.0	55	6.06	36.90	-66.7	0.00	100.0
	Week 8	65	31.28	30.55	0.0	33.33	100.0	53	3.77	45.13	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	70	27.62	30.55	0.0	33.33	100.0	55	1.21	37.93	-66.7	0.00	100.0
	Week 10	60	28.89	32.16	0.0	33.33	100.0	46	4.35	41.34	-66.7	0.00	100.0
	Week 11	64	31.25	33.00	0.0	33.33	100.0	50	7.33	38.27	-66.7	0.00	66.7
	Week 12	60	27.22	32.18	0.0	0.00	100.0	48	1.39	40.07	-100.0	0.00	66.7
	Week 14	56	32.14	31.12	0.0	33.33	100.0	42	11.90	40.87	-100.0	33.33	100.0
	Week 17	58	33.33	33.04	0.0	33.33	100.0	44	8.33	40.11	-100.0	0.00	100.0
	Week 20	47	16.31	22.92	0.0	0.00	100.0	37	-7.21	31.56	-66.7	0.00	66.7
	Week 23	44	17.42	24.37	0.0	0.00	100.0	32	-3.13	35.28	-66.7	0.00	66.7
	Week 26	39	20.51	32.99	0.0	0.00	100.0	30	5.56	38.24	-66.7	0.00	66.7
	Week 29	34	19.61	28.57	0.0	0.00	100.0	25	1.33	29.63	-66.7	0.00	66.7
	Week 32	33	20.20	26.27	0.0	0.00	100.0	27	0.00	30.66	-66.7	0.00	66.7
	Week 35	30	20.00	31.07	0.0	0.00	100.0	24	-4.17	33.06	-66.7	0.00	66.7
	Week 38	26	17.95	31.60	0.0	0.00	100.0	21	-4.76	36.95	-66.7	0.00	66.7
	Week 41	22	21.21	28.26	0.0	0.00	100.0	17	3.92	28.58	-33.3	0.00	66.7
	Week 44	20	21.67	27.09	0.0	16.67	100.0	16	2.08	30.96	-33.3	0.00	66.7
	Week 47	16	27.08	27.81	0.0	33.33	66.7	12	2.78	30.01	-33.3	0.00	66.7
	Week 50	11	30.30	34.82	0.0	33.33	100.0	10	13.34	35.83	-33.3	0.00	66.7
	Week 53	11	21.21	26.97	0.0	0.00	66.7	10	-3.33	39.91	-66.7	0.00	66.7
	Week 56	10	13.33	23.31	0.0	0.00	66.7	8	-12.50	46.93	-66.7	-16.67	66.7

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
North America	EV+Pembro (N= 57)												
	BASELINE	47	30.50	32.47	0.0	33.33	100.0						
	Week 1	39	34.19	30.10	0.0	33.33	100.0	37	2.70	22.74	-66.7	0.00	33.3
	Week 2	44	37.12	35.38	0.0	33.33	100.0	42	11.11	24.04	-33.3	0.00	66.7
	Week 3	44	40.91	35.12	0.0	33.33	100.0	40	7.50	29.71	-66.7	0.00	66.7
	Week 4	44	31.82	29.60	0.0	33.33	100.0	41	-1.63	31.58	-66.7	0.00	66.7
	Week 5	47	32.62	32.96	0.0	33.33	100.0	41	4.07	37.41	-66.7	0.00	100.0
	Week 6	44	25.00	26.04	0.0	33.33	66.7	39	-7.69	33.74	-66.7	0.00	66.7
	Week 7	46	23.91	25.01	0.0	33.33	100.0	42	-4.76	29.05	-66.7	0.00	33.3
	Week 8	47	24.11	23.78	0.0	33.33	66.7	42	-3.97	33.90	-66.7	0.00	66.7
	Week 9	46	31.88	28.07	0.0	33.33	100.0	42	3.17	39.52	-100.0	0.00	100.0
	Week 10	47	23.40	25.93	0.0	33.33	66.7	44	-5.30	35.18	-100.0	0.00	66.7
	Week 11	47	23.40	23.99	0.0	33.33	100.0	42	-5.56	36.00	-100.0	0.00	66.7
	Week 12	44	28.79	29.28	0.0	33.33	100.0	40	-3.33	36.04	-100.0	0.00	66.7
	Week 14	43	25.58	27.06	0.0	33.33	100.0	39	-4.27	31.70	-66.7	0.00	66.7
	Week 17	40	34.17	27.72	0.0	33.33	100.0	37	3.60	35.82	-66.7	0.00	100.0
	Week 20	38	23.68	30.91	0.0	0.00	100.0	35	-3.81	34.08	-66.7	0.00	66.7
	Week 23	38	23.68	29.92	0.0	0.00	100.0	35	2.86	27.26	-66.7	0.00	66.7
	Week 26	35	19.05	28.34	0.0	0.00	100.0	32	-12.50	27.76	-66.7	0.00	33.3
	Week 29	38	18.42	22.86	0.0	0.00	66.7	34	-7.84	31.84	-66.7	0.00	66.7
	Week 32	32	13.54	22.17	0.0	0.00	66.7	29	-10.34	30.99	-66.7	0.00	33.3
	Week 35	33	15.15	23.70	0.0	0.00	100.0	30	-6.67	32.04	-66.7	0.00	100.0
	Week 38	32	18.75	28.00	0.0	0.00	100.0	29	-8.05	31.69	-66.7	0.00	66.7
	Week 41	28	11.90	18.62	0.0	0.00	66.7	24	-9.72	28.62	-66.7	0.00	66.7
	Week 44	21	9.52	23.90	0.0	0.00	100.0	20	-11.67	40.86	-66.7	0.00	100.0
	Week 47	24	9.72	18.33	0.0	0.00	66.7	23	-15.94	31.58	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	23	8.70	18.03	0.0	0.00	66.7	20	-13.33	25.13	-66.7	0.00	33.3
	Week 53	17	3.92	11.07	0.0	0.00	33.3	14	-7.14	19.30	-33.3	0.00	33.3
	Week 56	20	5.00	12.21	0.0	0.00	33.3	17	-15.69	29.15	-66.7	0.00	33.3
	Week 59	17	1.96	8.08	0.0	0.00	33.3	14	-14.29	28.39	-66.7	0.00	33.3
	Week 62	14	0.00	0.00	0.0	0.00	0.0	13	-12.82	21.68	-66.7	0.00	0.0
	Week 65	12	0.00	0.00	0.0	0.00	0.0	9	-11.11	16.67	-33.3	0.00	0.0
	Week 68	10	3.33	10.54	0.0	0.00	33.3	9	0.00	16.67	-33.3	0.00	33.3
	Week 71	10	6.67	14.05	0.0	0.00	33.3	8	0.00	17.82	-33.3	0.00	33.3
	Week 74	10	3.33	10.54	0.0	0.00	33.3	9	-7.41	27.78	-66.7	0.00	33.3
	Plat+Gem (N= 51)												
	BASELINE	42	20.63	23.23	0.0	16.67	66.7						
	Week 1	41	29.27	28.08	0.0	33.33	100.0	36	8.33	24.40	-33.3	0.00	66.7
	Week 2	38	31.58	31.90	0.0	33.33	100.0	33	10.10	29.45	-33.3	0.00	66.7
	Week 3	40	21.67	26.74	0.0	0.00	100.0	35	1.90	21.30	-33.3	0.00	33.3
	Week 4	35	25.71	28.11	0.0	33.33	100.0	29	6.90	32.59	-66.7	0.00	100.0
	Week 5	39	26.49	26.69	0.0	33.33	100.0	32	5.21	26.92	-33.3	0.00	66.7
	Week 6	34	24.51	25.04	0.0	33.33	66.7	30	1.11	28.34	-66.7	0.00	66.7
	Week 7	42	22.22	22.89	0.0	33.33	66.7	37	0.00	26.06	-66.7	0.00	66.7
	Week 8	39	23.93	26.43	0.0	33.33	100.0	33	3.03	32.66	-66.7	0.00	66.7
	Week 9	39	22.22	25.74	0.0	0.00	66.7	33	-2.02	26.27	-33.3	0.00	66.7
	Week 10	39	21.37	25.92	0.0	0.00	66.7	32	-5.21	28.22	-66.7	0.00	66.7
	Week 11	39	20.51	28.22	0.0	0.00	100.0	33	-3.03	29.30	-66.7	0.00	66.7
	Week 12	36	20.37	22.93	0.0	16.67	66.7	32	-2.08	23.85	-33.3	0.00	33.3
	Week 14	34	20.59	27.23	0.0	0.00	100.0	29	-3.45	32.55	-66.7	0.00	66.7
	Week 17	37	25.22	27.67	0.0	33.33	100.0	31	3.23	30.25	-66.7	0.00	66.7
	Week 20	27	14.81	19.24	0.0	0.00	66.7	23	-7.25	17.28	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 23	27	12.35	20.98	0.0	0.00	66.7	23	-4.35	28.96	-33.3	0.00	66.7
	Week 26	28	13.09	24.58	0.0	0.00	100.0	25	-6.67	30.43	-33.3	0.00	66.7
	Week 29	29	16.09	22.92	0.0	0.00	66.7	25	-2.67	28.74	-66.7	0.00	66.7
	Week 32	17	13.72	20.61	0.0	0.00	66.7	17	-9.80	15.65	-33.3	0.00	0.0
	Week 35	16	16.67	24.34	0.0	0.00	66.7	15	-2.22	19.79	-33.3	0.00	33.3
	Week 38	16	16.67	21.08	0.0	0.00	66.7	13	-2.56	21.35	-33.3	0.00	33.3
	Week 41	16	18.75	29.74	0.0	0.00	100.0	13	0.00	27.22	-33.3	0.00	66.7
	Week 44	13	12.82	28.99	0.0	0.00	100.0	11	-9.09	30.15	-33.3	0.00	66.7
	Week 47	11	12.12	16.82	0.0	0.00	33.3	9	-3.70	11.11	-33.3	0.00	0.0
	Week 50	17	19.61	26.51	0.0	0.00	66.7	15	-2.22	19.79	-33.3	0.00	33.3
	Week 53	13	12.82	16.88	0.0	0.00	33.3	11	-6.06	20.10	-33.3	0.00	33.3
	Week 56	11	15.15	22.92	0.0	0.00	66.7	9	-3.70	38.89	-66.7	0.00	66.7
	Week 59	11	15.15	31.14	0.0	0.00	100.0	9	0.00	40.82	-33.3	0.00	100.0
	Week 62	11	12.12	22.47	0.0	0.00	66.7	9	-3.70	30.93	-33.3	0.00	66.7
	Week 65	10	10.00	16.10	0.0	0.00	33.3	8	-8.33	23.57	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Rest of World	EV+Pembro (N= 85)												
	BASELINE	80	18.33	25.38	0.0	0.00	100.0						
	Week 1	77	19.48	23.79	0.0	0.00	100.0	76	2.19	23.31	-100.0	0.00	66.7
	Week 2	80	30.42	28.66	0.0	33.33	100.0	76	11.40	31.53	-100.0	0.00	100.0
	Week 3	76	27.19	31.60	0.0	33.33	100.0	73	9.13	34.81	-100.0	0.00	100.0
	Week 4	72	26.85	27.20	0.0	33.33	100.0	68	8.33	30.68	-100.0	0.00	66.7
	Week 5	73	23.74	28.59	0.0	33.33	100.0	70	7.14	35.84	-100.0	0.00	100.0
	Week 6	74	24.77	25.91	0.0	33.33	100.0	70	7.14	31.54	-100.0	0.00	100.0
	Week 7	71	25.82	28.28	0.0	33.33	100.0	66	7.07	39.01	-100.0	0.00	100.0
	Week 8	72	25.00	28.39	0.0	33.33	100.0	68	5.39	35.79	-100.0	0.00	66.7
	Week 9	71	26.76	28.52	0.0	33.33	100.0	68	7.84	32.64	-100.0	0.00	66.7
	Week 10	73	26.03	24.37	0.0	33.33	66.7	69	7.73	33.89	-100.0	0.00	66.7
	Week 11	71	26.76	27.38	0.0	33.33	100.0	67	6.96	33.10	-100.0	0.00	100.0
	Week 12	69	23.67	27.48	0.0	33.33	100.0	66	6.06	36.47	-100.0	0.00	100.0
	Week 14	68	26.47	27.35	0.0	33.33	100.0	64	6.77	35.72	-100.0	0.00	100.0
	Week 17	68	25.49	28.28	0.0	33.33	100.0	63	7.41	35.14	-100.0	0.00	100.0
	Week 20	59	26.55	30.18	0.0	33.33	100.0	56	8.33	37.74	-100.0	0.00	100.0
	Week 23	63	24.34	28.84	0.0	33.33	100.0	59	4.52	40.33	-100.0	0.00	100.0
	Week 26	59	29.94	31.38	0.0	33.33	100.0	57	11.70	31.81	-66.7	0.00	66.7
	Week 29	56	23.21	24.55	0.0	33.33	66.7	54	8.03	28.18	-66.7	0.00	66.7
	Week 32	52	21.15	22.89	0.0	33.33	66.7	49	4.08	35.11	-66.7	0.00	66.7
	Week 35	43	22.48	24.90	0.0	33.33	100.0	40	2.50	26.57	-66.7	0.00	33.3
	Week 38	49	23.13	25.64	0.0	33.33	66.7	47	5.67	33.56	-66.7	0.00	66.7
	Week 41	49	21.77	23.13	0.0	33.33	66.7	47	4.26	28.33	-66.7	0.00	66.7
	Week 44	44	20.45	26.13	0.0	0.00	100.0	41	0.81	32.90	-66.7	0.00	100.0
	Week 47	37	20.72	26.47	0.0	0.00	100.0	35	3.81	31.07	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	29	21.84	22.32	0.0	33.33	66.7	28	4.76	33.60	-66.7	0.00	66.7
	Week 53	34	17.65	20.49	0.0	0.00	66.7	33	1.01	31.71	-100.0	0.00	33.3
	Week 56	31	16.13	20.85	0.0	0.00	66.7	30	0.00	29.03	-100.0	0.00	33.3
	Week 59	28	17.86	23.10	0.0	0.00	66.7	27	0.00	34.59	-100.0	0.00	66.7
	Week 62	28	20.24	22.84	0.0	16.67	66.7	27	4.94	35.45	-100.0	0.00	66.7
	Week 65	23	21.74	23.80	0.0	33.33	66.7	22	1.52	39.14	-100.0	0.00	66.7
	Week 68	22	22.73	23.87	0.0	33.33	66.7	22	3.03	38.36	-100.0	0.00	66.7
	Week 71	22	21.21	24.22	0.0	16.67	66.7	22	1.52	37.77	-100.0	0.00	66.7
	Week 74	22	18.18	22.37	0.0	0.00	66.7	22	0.00	34.12	-100.0	0.00	66.7
	Week 77	18	24.07	25.06	0.0	33.33	66.7	17	5.88	37.70	-100.0	0.00	66.7
	Week 80	16	18.75	20.97	0.0	16.67	66.7	15	0.00	33.33	-100.0	0.00	33.3
	Week 83	16	22.92	20.07	0.0	33.33	66.7	15	2.22	36.66	-100.0	0.00	33.3
	Week 86	13	23.08	21.01	0.0	33.33	66.7	12	-2.78	38.82	-100.0	0.00	33.3
	Week 89	12	19.44	22.28	0.0	16.67	66.7	12	0.00	37.60	-100.0	0.00	33.3
	Plat+Gem (N= 89)												
	BASELINE	75	24.44	25.90	0.0	33.33	100.0						
	Week 1	61	31.69	28.82	0.0	33.33	100.0	61	9.84	30.03	-66.7	0.00	100.0
	Week 2	66	28.79	28.58	0.0	33.33	100.0	62	9.68	32.16	-66.7	0.00	100.0
	Week 3	76	25.44	26.03	0.0	33.33	100.0	71	2.35	27.21	-66.7	0.00	66.7
	Week 4	73	31.05	27.96	0.0	33.33	100.0	68	6.37	31.68	-66.7	0.00	66.7
	Week 5	71	27.23	24.11	0.0	33.33	66.7	64	4.17	26.23	-66.7	0.00	66.7
	Week 6	70	21.90	24.66	0.0	33.33	100.0	63	-1.06	30.51	-66.7	0.00	66.7
	Week 7	72	27.78	24.39	0.0	33.33	100.0	65	5.64	26.07	-66.7	0.00	66.7
	Week 8	63	25.40	22.97	0.0	33.33	100.0	58	5.17	28.48	-66.7	0.00	66.7
	Week 9	68	21.57	23.58	0.0	33.33	100.0	62	1.61	27.28	-66.7	0.00	66.7
	Week 10	67	28.85	27.15	0.0	33.33	100.0	61	6.01	31.92	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	65	28.72	26.27	0.0	33.33	100.0	60	9.44	29.49	-66.7	0.00	66.7
	Week 12	63	19.58	23.67	0.0	0.00	100.0	58	-0.57	29.61	-100.0	0.00	66.7
	Week 14	63	28.57	28.62	0.0	33.33	100.0	57	5.26	30.07	-66.7	0.00	66.7
	Week 17	60	27.78	26.87	0.0	33.33	100.0	55	6.67	31.03	-66.7	0.00	66.7
	Week 20	52	19.23	26.69	0.0	0.00	100.0	50	-0.67	31.22	-100.0	0.00	66.7
	Week 23	44	18.18	28.26	0.0	0.00	100.0	42	-2.38	30.70	-66.7	0.00	66.7
	Week 26	41	12.19	19.37	0.0	0.00	66.7	40	-6.67	26.37	-66.7	0.00	66.7
	Week 29	37	11.71	19.59	0.0	0.00	66.7	36	-4.63	28.90	-66.7	0.00	66.7
	Week 32	33	12.12	20.10	0.0	0.00	66.7	32	-3.12	25.90	-33.3	0.00	66.7
	Week 35	30	10.00	17.83	0.0	0.00	66.7	30	-5.56	23.30	-66.7	0.00	33.3
	Week 38	32	10.42	19.74	0.0	0.00	66.7	31	-4.30	23.95	-33.3	0.00	66.7
	Week 41	27	9.88	20.29	0.0	0.00	66.7	26	-7.69	28.76	-66.7	0.00	66.7
	Week 44	27	6.17	16.11	0.0	0.00	66.7	26	-8.97	27.58	-66.7	0.00	66.7
	Week 47	29	10.34	18.05	0.0	0.00	66.7	28	-5.95	25.74	-33.3	0.00	66.7
	Week 50	23	10.14	15.68	0.0	0.00	33.3	22	-4.55	21.32	-33.3	0.00	33.3
	Week 53	22	12.12	19.37	0.0	0.00	66.7	21	-3.17	23.34	-33.3	0.00	33.3
	Week 56	18	12.96	23.26	0.0	0.00	66.7	17	-1.96	24.92	-33.3	0.00	33.3
	Week 59	17	9.80	15.65	0.0	0.00	33.3	16	-4.17	20.64	-33.3	0.00	33.3
	Week 62	16	8.33	14.91	0.0	0.00	33.3	15	-8.89	19.79	-33.3	0.00	33.3
	Week 65	15	8.89	15.26	0.0	0.00	33.3	14	-4.76	17.82	-33.3	0.00	33.3
	Week 68	12	11.11	16.41	0.0	0.00	33.3	11	-6.06	13.48	-33.3	0.00	0.0
	Week 71	13	10.26	16.01	0.0	0.00	33.3	12	-5.56	27.83	-33.3	0.00	33.3
	Week 74	10	13.33	23.31	0.0	0.00	66.7	10	-3.33	18.92	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	EV+Pembro (N=198)												
	BASELINE	170	20.59	28.34	0.0	0.00	100.0						
	Week 1	157	21.44	26.15	0.0	0.00	100.0	152	1.32	24.23	-100.0	0.00	66.7
	Week 2	167	29.14	30.21	0.0	33.33	100.0	155	10.32	28.06	-100.0	0.00	100.0
	Week 3	161	32.30	33.42	0.0	33.33	100.0	147	12.70	34.97	-100.0	0.00	100.0
	Week 4	158	27.00	29.66	0.0	33.33	100.0	145	7.13	33.61	-100.0	0.00	100.0
	Week 5	154	24.89	30.86	0.0	0.00	100.0	140	6.43	35.29	-100.0	0.00	100.0
	Week 6	153	23.75	27.22	0.0	33.33	100.0	138	4.11	32.58	-100.0	0.00	100.0
	Week 7	159	23.90	27.59	0.0	33.33	100.0	142	4.69	33.82	-100.0	0.00	100.0
	Week 8	154	22.94	27.88	0.0	0.00	100.0	135	3.95	33.84	-100.0	0.00	100.0
	Week 9	162	26.13	29.42	0.0	33.33	100.0	146	7.53	33.62	-100.0	0.00	100.0
	Week 10	159	22.22	25.34	0.0	0.00	100.0	144	2.55	34.61	-100.0	0.00	66.7
	Week 11	161	22.15	26.60	0.0	0.00	100.0	143	1.40	35.13	-100.0	0.00	100.0
	Week 12	154	23.38	28.30	0.0	0.00	100.0	140	3.10	36.18	-100.0	0.00	100.0
	Week 14	154	23.59	26.11	0.0	33.33	100.0	137	3.89	33.84	-100.0	0.00	100.0
	Week 17	145	25.52	28.06	0.0	33.33	100.0	130	5.64	34.51	-100.0	0.00	100.0
	Week 20	139	22.78	28.39	0.0	0.00	100.0	126	3.70	35.33	-100.0	0.00	100.0
	Week 23	133	24.56	28.40	0.0	33.33	100.0	122	7.38	34.69	-100.0	0.00	100.0
	Week 26	129	21.70	27.53	0.0	0.00	100.0	118	3.11	29.87	-100.0	0.00	66.7
	Week 29	131	20.36	25.00	0.0	0.00	100.0	120	3.61	31.10	-100.0	0.00	100.0
	Week 32	111	18.92	23.62	0.0	0.00	100.0	102	0.65	32.15	-100.0	0.00	66.7
	Week 35	109	18.65	24.61	0.0	0.00	100.0	100	1.33	28.00	-100.0	0.00	100.0
	Week 38	107	19.00	26.74	0.0	0.00	100.0	100	1.33	31.40	-100.0	0.00	66.7
	Week 41	103	16.83	23.74	0.0	0.00	100.0	94	0.35	28.71	-100.0	0.00	66.7
	Week 44	88	13.26	22.34	0.0	0.00	100.0	81	-3.70	29.81	-66.7	0.00	100.0
	Week 47	80	13.33	21.61	0.0	0.00	66.7	75	-2.67	28.35	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	73	12.78	21.25	0.0	0.00	66.7	68	-3.43	28.30	-66.7	0.00	66.7
	Week 53	64	12.50	21.00	0.0	0.00	100.0	59	-0.56	27.33	-100.0	0.00	66.7
	Week 56	66	9.60	18.27	0.0	0.00	66.7	61	-5.46	28.01	-100.0	0.00	66.7
	Week 59	58	10.92	19.13	0.0	0.00	66.7	54	-2.47	28.11	-100.0	0.00	66.7
	Week 62	54	14.20	21.08	0.0	0.00	66.7	52	1.92	29.08	-100.0	0.00	66.7
	Week 65	51	13.07	21.16	0.0	0.00	66.7	47	-2.13	29.00	-100.0	0.00	66.7
	Week 68	49	10.88	18.49	0.0	0.00	66.7	48	-2.78	26.48	-100.0	0.00	33.3
	Week 71	47	12.06	20.17	0.0	0.00	66.7	45	-1.48	29.26	-100.0	0.00	66.7
	Week 74	42	10.32	18.75	0.0	0.00	66.7	41	-3.25	28.68	-100.0	0.00	66.7
	Week 77	38	15.79	22.91	0.0	0.00	66.7	36	2.78	31.24	-100.0	0.00	66.7
	Week 80	35	11.43	17.97	0.0	0.00	66.7	32	-4.17	29.02	-100.0	0.00	33.3
	Week 83	32	16.67	20.74	0.0	0.00	66.7	30	-2.22	28.94	-100.0	0.00	33.3
	Week 86	30	13.33	18.77	0.0	0.00	66.7	27	-3.70	31.12	-100.0	0.00	33.3
	Week 89	28	15.48	23.10	0.0	0.00	66.7	26	-3.85	31.73	-100.0	0.00	33.3
	Week 92	24	16.67	29.49	0.0	0.00	100.0	22	-4.55	34.57	-100.0	0.00	66.7
	Week 95	21	17.46	22.65	0.0	0.00	66.7	20	0.00	21.63	-33.3	0.00	33.3
	Week 98	16	16.67	21.08	0.0	0.00	66.7	15	-2.22	29.46	-66.7	0.00	66.7
	Week 101	12	16.67	17.41	0.0	16.67	33.3	12	-2.78	26.43	-66.7	0.00	33.3
	Week 104	10	13.33	17.21	0.0	0.00	33.3	10	-10.00	27.44	-66.7	0.00	33.3
	Plat+Gem (N=185)												
	BASELINE	146	23.74	28.76	0.0	0.00	100.0						
	Week 1	131	30.53	29.25	0.0	33.33	100.0	120	8.89	29.86	-66.7	0.00	100.0
	Week 2	128	34.90	33.17	0.0	33.33	100.0	115	13.33	31.78	-66.7	0.00	100.0
	Week 3	141	26.95	27.86	0.0	33.33	100.0	126	3.70	27.40	-66.7	0.00	66.7
	Week 4	139	27.82	26.50	0.0	33.33	100.0	119	6.44	31.08	-66.7	0.00	66.7
	Week 5	143	29.37	27.83	0.0	33.33	100.0	120	7.78	33.12	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 6	133	26.06	27.32	0.0	33.33	100.0	114	2.63	30.77	-66.7	0.00	100.0
	Week 7	142	26.52	26.49	0.0	33.33	100.0	120	4.72	29.08	-66.7	0.00	100.0
	Week 8	125	25.87	26.39	0.0	33.33	100.0	109	4.89	35.95	-100.0	0.00	100.0
	Week 9	135	25.18	26.85	0.0	33.33	100.0	115	3.48	31.95	-66.7	0.00	100.0
	Week 10	131	26.21	28.35	0.0	33.33	100.0	111	3.30	34.51	-100.0	0.00	100.0
	Week 11	128	26.30	27.95	0.0	33.33	100.0	109	5.20	31.48	-66.7	0.00	66.7
	Week 12	124	22.85	27.01	0.0	0.00	100.0	108	1.54	32.67	-100.0	0.00	66.7
	Week 14	121	25.89	27.72	0.0	33.33	100.0	101	5.28	34.23	-100.0	0.00	100.0
	Week 17	121	28.37	29.08	0.0	33.33	100.0	101	6.60	34.65	-100.0	0.00	100.0
	Week 20	98	17.35	22.57	0.0	0.00	100.0	86	-2.33	27.91	-100.0	0.00	66.7
	Week 23	93	16.49	23.89	0.0	0.00	100.0	78	-2.56	31.68	-66.7	0.00	66.7
	Week 26	86	13.95	23.13	0.0	0.00	100.0	75	-1.78	28.42	-66.7	0.00	66.7
	Week 29	76	14.47	23.31	0.0	0.00	100.0	65	-1.03	28.24	-66.7	0.00	66.7
	Week 32	62	12.36	18.34	0.0	0.00	66.7	56	-4.76	22.41	-66.7	0.00	66.7
	Week 35	58	12.07	20.42	0.0	0.00	66.7	52	-5.13	19.11	-66.7	0.00	33.3
	Week 38	60	11.11	20.04	0.0	0.00	66.7	52	-5.13	24.15	-66.7	0.00	66.7
	Week 41	52	16.67	27.61	0.0	0.00	100.0	44	0.00	28.75	-33.3	0.00	66.7
	Week 44	46	11.59	22.46	0.0	0.00	100.0	40	-4.17	27.41	-33.3	0.00	66.7
	Week 47	44	13.64	21.94	0.0	0.00	66.7	38	-2.63	24.97	-33.3	0.00	66.7
	Week 50	42	16.67	26.80	0.0	0.00	100.0	38	0.88	26.27	-33.3	0.00	66.7
	Week 53	38	11.40	19.41	0.0	0.00	66.7	34	-2.94	25.12	-33.3	0.00	66.7
	Week 56	32	12.50	22.00	0.0	0.00	66.7	28	-1.19	32.05	-66.7	0.00	66.7
	Week 59	31	11.83	23.65	0.0	0.00	100.0	27	0.00	33.33	-66.7	0.00	100.0
	Week 62	29	9.19	17.58	0.0	0.00	66.7	26	-5.13	24.39	-33.3	0.00	66.7
	Week 65	25	8.00	14.53	0.0	0.00	33.3	21	-7.94	23.34	-66.7	0.00	33.3
	Week 68	20	10.00	15.67	0.0	0.00	33.3	16	-2.08	14.75	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 71	17	13.72	20.61	0.0	0.00	66.7	14	-2.38	24.33	-33.3	0.00	33.3
	Week 74	17	13.73	23.74	0.0	0.00	66.7	14	-2.38	20.52	-33.3	0.00	33.3
	Week 77	16	12.50	29.50	0.0	0.00	100.0	13	-7.69	24.17	-33.3	0.00	33.3
	Week 80	13	12.82	21.68	0.0	0.00	66.7	12	-2.78	30.01	-33.3	0.00	66.7
	Week 83	11	6.06	13.48	0.0	0.00	33.3	10	-10.00	16.10	-33.3	0.00	0.0
	Week 86	12	5.56	12.97	0.0	0.00	33.3	11	-9.09	21.55	-33.3	0.00	33.3
	Week 89	11	6.06	13.48	0.0	0.00	33.3	10	-10.00	22.50	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	EV+Pembro (N= 42)												
	BASELINE	36	25.93	29.93	0.0	33.33	100.0						
	Week 1	33	34.34	31.72	0.0	33.33	100.0	32	9.38	22.77	-33.3	0.00	100.0
	Week 2	36	36.11	32.24	0.0	33.33	100.0	34	8.82	32.11	-66.7	0.00	100.0
	Week 3	37	32.43	31.90	0.0	33.33	100.0	35	2.86	28.44	-66.7	0.00	66.7
	Week 4	36	27.78	25.82	0.0	33.33	100.0	34	0.98	27.81	-66.7	0.00	33.3
	Week 5	36	23.15	24.97	0.0	33.33	100.0	33	-1.01	37.72	-100.0	0.00	66.7
	Week 6	35	20.95	22.99	0.0	33.33	66.7	32	-3.13	35.28	-100.0	0.00	66.7
	Week 7	36	19.44	18.47	0.0	33.33	66.7	34	-7.84	40.25	-100.0	0.00	33.3
	Week 8	37	23.42	22.03	0.0	33.33	66.7	36	-2.78	38.52	-100.0	0.00	66.7
	Week 9	35	21.90	21.30	0.0	33.33	66.7	34	-4.90	37.72	-100.0	0.00	66.7
	Week 10	32	20.83	22.00	0.0	33.33	66.7	31	-8.60	37.48	-100.0	0.00	33.3
	Week 11	33	28.28	29.01	0.0	33.33	100.0	32	-2.08	40.55	-100.0	0.00	66.7
	Week 12	32	21.87	24.84	0.0	33.33	100.0	31	-8.60	41.25	-100.0	0.00	66.7
	Week 14	31	23.65	27.48	0.0	33.33	100.0	30	-4.45	36.86	-100.0	0.00	33.3
	Week 17	33	23.23	22.80	0.0	33.33	66.7	32	-2.08	36.84	-100.0	0.00	66.7
	Week 20	28	19.05	23.00	0.0	0.00	66.7	28	-5.95	36.35	-100.0	0.00	66.7
	Week 23	29	14.94	16.87	0.0	0.00	33.3	29	-11.49	35.94	-100.0	0.00	33.3
	Week 26	27	22.22	30.66	0.0	0.00	100.0	26	-6.41	36.54	-100.0	0.00	66.7
	Week 29	26	14.10	16.79	0.0	0.00	33.3	25	-9.33	34.05	-100.0	0.00	33.3
	Week 32	24	8.33	17.72	0.0	0.00	66.7	23	-15.94	31.57	-100.0	0.00	33.3
	Week 35	23	14.49	16.89	0.0	0.00	33.3	22	-10.61	33.15	-100.0	0.00	33.3
	Week 38	25	13.33	16.67	0.0	0.00	33.3	24	-9.72	34.72	-100.0	0.00	33.3
	Week 41	26	19.23	19.26	0.0	33.33	66.7	25	-9.33	34.05	-100.0	0.00	33.3
	Week 44	20	16.67	25.36	0.0	0.00	100.0	19	-3.51	36.67	-66.7	0.00	100.0
	Week 47	20	18.33	25.30	0.0	0.00	100.0	19	-7.02	30.59	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	16	10.42	15.96	0.0	0.00	33.3	16	-6.25	21.84	-66.7	0.00	33.3
	Week 53	15	17.78	21.33	0.0	0.00	66.7	15	-4.44	27.79	-66.7	0.00	33.3
	Week 56	15	20.00	21.08	0.0	33.33	66.7	15	-2.22	29.46	-66.7	0.00	33.3
	Week 59	14	11.90	21.11	0.0	0.00	66.7	14	-11.90	30.96	-66.7	0.00	33.3
	Week 62	11	6.06	13.48	0.0	0.00	33.3	11	-18.18	31.14	-66.7	0.00	33.3
	Plat+Gem (N= 57)												
	BASELINE	42	29.36	28.71	0.0	33.33	100.0						
	Week 1	42	44.44	33.47	0.0	33.33	100.0	38	14.04	30.64	-33.3	0.00	100.0
	Week 2	43	27.91	29.03	0.0	33.33	100.0	36	0.00	32.85	-66.7	0.00	66.7
	Week 3	43	23.25	25.75	0.0	33.33	100.0	36	-4.63	26.61	-66.7	0.00	33.3
	Week 4	44	34.09	31.74	0.0	33.33	100.0	37	5.41	35.58	-66.7	0.00	100.0
	Week 5	44	30.30	27.67	0.0	33.33	100.0	36	0.93	30.33	-66.7	0.00	66.7
	Week 6	41	28.45	32.97	0.0	33.33	100.0	35	-3.81	33.11	-66.7	0.00	66.7
	Week 7	44	31.82	28.72	0.0	33.33	100.0	37	3.60	34.05	-66.7	0.00	66.7
	Week 8	42	31.75	28.47	0.0	33.33	100.0	35	1.90	37.00	-66.7	0.00	66.7
	Week 9	42	20.63	27.50	0.0	0.00	100.0	35	-8.57	27.23	-66.7	0.00	66.7
	Week 10	35	30.48	30.65	0.0	33.33	100.0	28	1.19	35.70	-66.7	0.00	66.7
	Week 11	40	32.50	34.17	0.0	33.33	100.0	34	7.84	37.66	-33.3	0.00	66.7
	Week 12	35	21.90	27.94	0.0	0.00	100.0	30	-6.67	30.83	-33.3	0.00	66.7
	Week 14	32	36.46	34.25	0.0	33.33	100.0	27	6.17	37.02	-66.7	0.00	66.7
	Week 17	34	32.35	31.23	0.0	33.33	100.0	29	5.75	32.21	-66.7	0.00	66.7
	Week 20	28	16.67	27.96	0.0	0.00	100.0	24	-11.11	32.10	-66.7	-16.67	66.7
	Week 23	22	16.67	30.43	0.0	0.00	100.0	19	-5.26	31.94	-33.3	0.00	66.7
	Week 26	22	21.21	36.44	0.0	0.00	100.0	20	-6.67	42.72	-66.7	-16.67	66.7
	Week 29	24	19.44	25.85	0.0	0.00	100.0	21	-6.35	30.95	-66.7	0.00	66.7
	Week 32	21	25.40	31.46	0.0	0.00	100.0	20	0.00	34.20	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 35	18	25.93	35.34	0.0	0.00	100.0	17	-1.96	41.62	-66.7	0.00	66.7
	Week 38	14	28.57	36.65	0.0	16.67	100.0	13	0.00	40.83	-66.7	0.00	66.7
	Week 41	13	12.82	16.88	0.0	0.00	33.3	12	-11.11	25.95	-66.7	0.00	33.3
	Week 44	14	16.67	28.49	0.0	0.00	100.0	13	-10.26	34.39	-66.7	0.00	66.7
	Week 47	12	22.22	21.71	0.0	33.33	66.7	11	-6.06	25.03	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Visceral metastases	EV+Pembro (N=170)												
	BASELINE	146	23.74	29.55	0.0	0.00	100.0						
	Week 1	135	26.17	28.91	0.0	33.33	100.0	131	2.54	23.25	-100.0	0.00	66.7
	Week 2	145	32.41	31.41	0.0	33.33	100.0	134	9.95	28.91	-66.7	0.00	100.0
	Week 3	141	35.22	34.91	0.0	33.33	100.0	129	11.63	36.48	-66.7	0.00	100.0
	Week 4	136	29.90	30.97	0.0	33.33	100.0	125	6.67	34.65	-66.7	0.00	100.0
	Week 5	131	24.94	30.76	0.0	0.00	100.0	118	2.54	37.28	-100.0	0.00	100.0
	Week 6	127	24.15	26.45	0.0	33.33	100.0	113	1.47	33.74	-100.0	0.00	100.0
	Week 7	135	22.72	26.60	0.0	0.00	100.0	121	-1.10	37.99	-100.0	0.00	100.0
	Week 8	131	22.65	27.82	0.0	0.00	100.0	118	-1.13	36.45	-100.0	0.00	100.0
	Week 9	136	24.26	27.95	0.0	33.33	100.0	124	2.42	34.84	-100.0	0.00	100.0
	Week 10	135	21.73	25.54	0.0	0.00	66.7	124	-1.34	35.66	-100.0	0.00	66.7
	Week 11	134	21.14	26.35	0.0	0.00	100.0	121	-3.58	34.91	-100.0	0.00	100.0
	Week 12	131	20.36	25.68	0.0	0.00	100.0	120	-4.44	35.35	-100.0	0.00	66.7
	Week 14	130	20.77	24.30	0.0	0.00	100.0	117	-1.71	35.25	-100.0	0.00	100.0
	Week 17	124	25.54	27.25	0.0	33.33	100.0	111	1.80	35.63	-100.0	0.00	100.0
	Week 20	115	21.16	26.24	0.0	0.00	100.0	105	-0.32	35.65	-100.0	0.00	100.0
	Week 23	111	20.42	25.09	0.0	0.00	100.0	103	-0.97	35.99	-100.0	0.00	100.0
	Week 26	106	19.18	25.59	0.0	0.00	100.0	97	-3.78	31.50	-100.0	0.00	66.7
	Week 29	106	17.61	23.55	0.0	0.00	100.0	98	-2.72	33.05	-100.0	0.00	100.0
	Week 32	92	15.58	22.89	0.0	0.00	100.0	85	-6.27	33.13	-100.0	0.00	66.7
	Week 35	86	16.67	22.72	0.0	0.00	100.0	79	-5.49	29.92	-100.0	0.00	66.7
	Week 38	90	16.30	25.11	0.0	0.00	100.0	84	-5.95	32.38	-100.0	0.00	66.7
	Week 41	87	15.32	22.04	0.0	0.00	100.0	81	-7.00	30.15	-100.0	0.00	66.7
	Week 44	73	12.78	21.25	0.0	0.00	100.0	68	-6.86	30.23	-66.7	0.00	100.0
	Week 47	68	11.76	20.58	0.0	0.00	100.0	63	-8.99	25.55	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	61	12.02	20.21	0.0	0.00	66.7	57	-5.26	27.31	-66.7	0.00	66.7
	Week 53	54	14.20	21.08	0.0	0.00	100.0	50	-2.00	28.10	-66.7	0.00	66.7
	Week 56	58	10.34	18.95	0.0	0.00	66.7	54	-6.17	28.28	-66.7	0.00	66.7
	Week 59	50	10.00	18.13	0.0	0.00	66.7	47	-6.38	28.35	-66.7	0.00	33.3
	Week 62	45	9.63	16.85	0.0	0.00	66.7	43	-5.43	28.11	-66.7	0.00	66.7
	Week 65	37	9.01	18.67	0.0	0.00	66.7	34	-8.82	27.60	-66.7	0.00	66.7
	Week 68	35	11.43	19.71	0.0	0.00	66.7	34	-3.92	29.32	-66.7	0.00	66.7
	Week 71	31	9.68	17.62	0.0	0.00	66.7	30	-8.89	27.59	-66.7	0.00	66.7
	Week 74	29	6.90	13.74	0.0	0.00	33.3	28	-10.71	25.75	-66.7	0.00	33.3
	Week 77	26	12.82	21.24	0.0	0.00	66.7	25	-5.33	29.94	-66.7	0.00	66.7
	Week 80	22	15.15	19.86	0.0	0.00	66.7	21	-7.94	29.64	-66.7	0.00	33.3
	Week 83	23	15.94	17.02	0.0	0.00	33.3	22	-6.06	26.50	-66.7	0.00	33.3
	Week 86	21	12.70	16.59	0.0	0.00	33.3	20	-10.00	28.82	-66.7	0.00	33.3
	Week 89	21	15.87	22.65	0.0	0.00	66.7	20	-8.33	28.36	-66.7	0.00	33.3
	Week 92	18	14.81	26.13	0.0	0.00	100.0	17	-11.76	26.20	-66.7	0.00	33.3
	Week 95	13	10.26	16.01	0.0	0.00	33.3	12	-8.33	28.87	-66.7	0.00	33.3
	Week 98	11	12.12	16.82	0.0	0.00	33.3	11	-9.09	26.21	-66.7	0.00	33.3
	Week 101	11	18.18	17.41	0.0	33.33	33.3	11	-3.03	27.71	-66.7	0.00	33.3
	Plat+Gem (N=161)												
	BASELINE	129	27.65	29.20	0.0	33.33	100.0						
	Week 1	113	35.69	29.45	0.0	33.33	100.0	105	8.57	29.25	-66.7	0.00	100.0
	Week 2	108	36.42	32.08	0.0	33.33	100.0	98	10.54	31.96	-66.7	0.00	100.0
	Week 3	121	27.55	26.76	0.0	33.33	100.0	109	-0.31	27.02	-66.7	0.00	33.3
	Week 4	116	31.03	25.90	0.0	33.33	100.0	101	4.29	31.50	-66.7	0.00	100.0
	Week 5	121	29.48	26.24	0.0	33.33	100.0	104	2.24	30.90	-66.7	0.00	66.7
	Week 6	118	25.99	27.61	0.0	33.33	100.0	102	-2.29	30.13	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 7	121	28.65	25.21	0.0	33.33	100.0	104	1.28	28.60	-66.7	0.00	100.0
	Week 8	108	27.78	25.98	0.0	33.33	100.0	96	3.47	34.70	-100.0	0.00	66.7
	Week 9	114	24.27	25.97	0.0	33.33	100.0	99	-2.02	30.79	-66.7	0.00	66.7
	Week 10	109	28.13	28.75	0.0	33.33	100.0	94	-0.35	34.74	-100.0	0.00	66.7
	Week 11	109	27.52	27.91	0.0	33.33	100.0	95	3.16	32.28	-66.7	0.00	66.7
	Week 12	103	22.33	26.15	0.0	0.00	100.0	91	-1.83	35.26	-100.0	0.00	66.7
	Week 14	98	28.57	29.89	0.0	33.33	100.0	85	3.14	38.36	-100.0	0.00	100.0
	Week 17	103	29.45	28.12	0.0	33.33	100.0	89	3.75	34.61	-100.0	0.00	100.0
	Week 20	82	15.04	20.39	0.0	0.00	100.0	75	-8.89	26.47	-100.0	0.00	33.3
	Week 23	77	17.32	24.55	0.0	0.00	100.0	68	-5.39	31.86	-66.7	0.00	66.7
	Week 26	71	14.08	25.61	0.0	0.00	100.0	65	-5.13	31.31	-66.7	0.00	66.7
	Week 29	65	15.90	21.33	0.0	0.00	66.7	59	-3.95	26.32	-66.7	0.00	66.7
	Week 32	52	16.02	21.38	0.0	0.00	66.7	49	-2.72	26.21	-66.7	0.00	66.7
	Week 35	47	15.60	24.92	0.0	0.00	100.0	44	-6.06	28.09	-66.7	0.00	66.7
	Week 38	42	15.08	24.64	0.0	0.00	100.0	39	-1.71	27.52	-66.7	0.00	66.7
	Week 41	35	18.09	23.35	0.0	0.00	66.7	32	-1.04	28.69	-66.7	0.00	66.7
	Week 44	36	13.89	23.06	0.0	0.00	100.0	33	-5.05	29.01	-66.7	0.00	66.7
	Week 47	32	16.67	22.40	0.0	0.00	66.7	30	-2.22	24.66	-33.3	0.00	66.7
	Week 50	30	21.11	26.96	0.0	0.00	100.0	29	3.45	27.23	-33.3	0.00	66.7
	Week 53	25	18.67	23.73	0.0	0.00	66.7	24	5.56	27.22	-33.3	0.00	66.7
	Week 56	22	19.70	26.55	0.0	0.00	66.7	21	4.76	32.12	-33.3	0.00	66.7
	Week 59	22	16.67	26.73	0.0	0.00	100.0	21	4.76	35.41	-33.3	0.00	100.0
	Week 62	19	10.53	19.41	0.0	0.00	66.7	18	-3.70	27.74	-33.3	0.00	66.7
	Week 65	19	8.77	15.08	0.0	0.00	33.3	18	-5.56	23.57	-33.3	0.00	33.3
	Week 68	13	7.69	14.62	0.0	0.00	33.3	12	-8.33	20.72	-33.3	0.00	33.3
	Week 71	13	10.26	16.01	0.0	0.00	33.3	12	-5.56	27.83	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 74	11	9.09	21.56	0.0	0.00	66.7	11	-9.09	21.55	-33.3	0.00	33.3
	Week 77	10	0.00	0.00	0.0	0.00	0.0	10	-16.67	17.57	-33.3	-16.67	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Lymph node only	EV+Pembro (N= 60)												
	BASELINE	53	15.09	24.08	0.0	0.00	100.0						
	Week 1	49	17.01	22.69	0.0	0.00	100.0	47	2.13	27.28	-100.0	0.00	100.0
	Week 2	50	25.33	27.40	0.0	33.33	100.0	48	11.11	30.23	-100.0	0.00	100.0
	Week 3	50	26.00	27.18	0.0	33.33	100.0	47	9.22	28.40	-100.0	0.00	66.7
	Week 4	50	20.67	22.22	0.0	33.33	66.7	47	5.67	27.20	-100.0	0.00	33.3
	Week 5	53	24.53	27.85	0.0	33.33	100.0	49	10.88	33.60	-100.0	0.00	100.0
	Week 6	53	22.64	27.56	0.0	0.00	100.0	50	8.00	31.99	-100.0	0.00	66.7
	Week 7	52	23.72	23.18	0.0	33.33	100.0	48	10.42	28.48	-100.0	0.00	66.7
	Week 8	52	24.36	23.91	0.0	33.33	100.0	47	11.35	29.71	-100.0	0.00	66.7
	Week 9	53	30.19	29.43	0.0	33.33	100.0	49	14.97	31.23	-100.0	0.00	66.7
	Week 10	48	24.30	23.56	0.0	33.33	100.0	44	8.33	31.44	-100.0	0.00	66.7
	Week 11	53	30.19	28.69	0.0	33.33	100.0	48	14.58	34.32	-100.0	0.00	66.7
	Week 12	48	32.64	31.88	0.0	33.33	100.0	45	18.52	35.93	-100.0	0.00	100.0
	Week 14	48	30.55	29.04	0.0	33.33	100.0	44	12.88	31.51	-100.0	0.00	100.0
	Week 17	46	24.64	28.49	0.0	33.33	100.0	44	11.36	32.90	-100.0	0.00	100.0
	Week 20	44	25.76	31.22	0.0	16.67	100.0	42	8.73	35.35	-100.0	0.00	100.0
	Week 23	43	27.13	29.33	0.0	33.33	100.0	41	13.82	34.14	-100.0	0.00	100.0
	Week 26	42	25.40	31.07	0.0	16.67	100.0	40	10.83	28.63	-66.7	0.00	66.7
	Week 29	45	22.96	24.44	0.0	33.33	66.7	42	9.52	27.83	-66.7	0.00	66.7
	Week 32	38	20.17	22.65	0.0	16.67	66.7	36	4.63	29.98	-66.7	0.00	66.7
	Week 35	42	22.22	25.15	0.0	33.33	100.0	40	9.17	26.13	-33.3	0.00	100.0
	Week 38	38	22.81	25.83	0.0	16.67	66.7	36	11.11	30.86	-66.7	0.00	66.7
	Week 41	37	20.72	24.03	0.0	0.00	66.7	34	7.84	27.29	-33.3	0.00	66.7
	Week 44	31	17.20	27.04	0.0	0.00	100.0	29	3.45	33.74	-66.7	0.00	100.0
	Week 47	28	20.24	26.20	0.0	0.00	66.7	27	7.41	33.76	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	25	14.67	21.69	0.0	0.00	66.7	24	0.00	27.80	-66.7	0.00	33.3
	Week 53	23	11.59	21.58	0.0	0.00	66.7	22	0.00	27.22	-100.0	0.00	33.3
	Week 56	21	14.28	19.92	0.0	0.00	66.7	20	-1.67	29.57	-100.0	0.00	33.3
	Week 59	20	13.33	22.69	0.0	0.00	66.7	19	0.00	31.43	-100.0	0.00	66.7
	Week 62	19	19.30	25.62	0.0	0.00	66.7	19	5.26	33.82	-100.0	0.00	66.7
	Week 65	20	18.33	22.88	0.0	0.00	66.7	19	3.51	33.14	-100.0	0.00	66.7
	Week 68	17	13.72	20.61	0.0	0.00	66.7	17	-1.96	29.98	-100.0	0.00	33.3
	Week 71	19	15.79	23.22	0.0	0.00	66.7	18	5.56	32.84	-100.0	0.00	66.7
	Week 74	17	17.65	23.91	0.0	0.00	66.7	17	1.96	34.30	-100.0	0.00	66.7
	Week 77	17	19.61	26.51	0.0	0.00	66.7	16	4.17	34.16	-100.0	0.00	66.7
	Week 80	17	11.76	20.21	0.0	0.00	66.7	15	-4.44	30.52	-100.0	0.00	33.3
	Week 83	13	20.51	25.60	0.0	0.00	66.7	12	-2.78	36.12	-100.0	0.00	33.3
	Week 86	12	19.44	22.28	0.0	16.67	66.7	10	0.00	38.49	-100.0	0.00	33.3
	Week 89	11	18.18	22.92	0.0	0.00	66.7	10	0.00	38.49	-100.0	0.00	33.3
	Plat+Gem (N= 67)												
	BASELINE	49	19.05	28.05	0.0	0.00	100.0						
	Week 1	51	30.72	34.54	0.0	33.33	100.0	45	14.07	32.94	-33.3	0.00	100.0
	Week 2	53	28.93	33.36	0.0	33.33	100.0	44	11.36	35.18	-66.7	0.00	100.0
	Week 3	53	23.90	30.23	0.0	0.00	100.0	44	6.82	29.27	-33.3	0.00	66.7
	Week 4	58	27.01	32.12	0.0	16.67	100.0	47	10.64	34.13	-66.7	0.00	66.7
	Week 5	56	30.36	30.67	0.0	33.33	100.0	44	14.39	34.77	-66.7	0.00	100.0
	Week 6	48	28.47	31.50	0.0	33.33	100.0	40	9.17	32.89	-66.7	0.00	100.0
	Week 7	56	26.19	31.60	0.0	33.33	100.0	46	9.42	33.45	-66.7	0.00	100.0
	Week 8	52	28.20	29.80	0.0	33.33	100.0	42	7.14	40.01	-66.7	0.00	100.0
	Week 9	53	24.53	30.07	0.0	0.00	100.0	42	7.14	33.36	-66.7	0.00	100.0
	Week 10	47	25.53	30.47	0.0	33.33	100.0	36	11.11	36.52	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	51	28.76	32.67	0.0	33.33	100.0	41	11.38	33.84	-66.7	0.00	66.7
	Week 12	47	24.11	30.85	0.0	0.00	100.0	39	3.42	27.35	-33.3	0.00	66.7
	Week 14	47	27.66	29.75	0.0	33.33	100.0	36	11.11	27.60	-33.3	0.00	66.7
	Week 17	45	30.37	33.20	0.0	33.33	100.0	35	14.29	33.61	-66.7	0.00	100.0
	Week 20	38	20.18	29.55	0.0	0.00	100.0	30	4.44	31.24	-66.7	0.00	66.7
	Week 23	32	16.67	28.08	0.0	0.00	100.0	25	5.33	31.45	-33.3	0.00	66.7
	Week 26	30	18.89	29.92	0.0	0.00	100.0	24	4.17	34.49	-33.3	0.00	66.7
	Week 29	28	14.29	29.30	0.0	0.00	100.0	21	1.59	34.12	-66.7	0.00	66.7
	Week 32	26	15.38	27.05	0.0	0.00	100.0	22	-4.55	27.79	-33.3	0.00	66.7
	Week 35	23	14.49	28.12	0.0	0.00	100.0	19	0.00	24.85	-33.3	0.00	66.7
	Week 38	26	15.38	27.05	0.0	0.00	100.0	20	-5.00	31.11	-66.7	0.00	66.7
	Week 41	24	15.28	31.05	0.0	0.00	100.0	18	0.00	30.25	-33.3	0.00	66.7
	Week 44	18	14.81	28.52	0.0	0.00	100.0	14	0.00	32.03	-33.3	0.00	66.7
	Week 47	18	14.81	23.49	0.0	0.00	66.7	13	-2.56	25.32	-33.3	0.00	66.7
	Week 50	16	14.58	24.25	0.0	0.00	66.7	13	-2.56	21.35	-33.3	0.00	33.3
	Week 53	15	8.89	15.26	0.0	0.00	33.3	12	-19.45	22.29	-66.7	-16.67	0.0
	Week 56	15	4.44	11.73	0.0	0.00	33.3	11	-24.24	33.64	-66.7	-33.33	33.3
	Week 59	12	2.78	9.62	0.0	0.00	33.3	9	-25.93	27.78	-66.7	-33.33	0.0
	Week 62	10	6.67	14.05	0.0	0.00	33.3	8	-20.83	17.25	-33.3	-33.33	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
EV+Pembro (N=202)												
BASELINE	160	28.75	31.61	0.0	33.33	100.0						
Week 1	141	31.21	32.66	0.0	33.33	100.0	129	2.07	17.56	-33.3	0.00	33.3
Week 2	150	34.67	31.82	0.0	33.33	100.0	133	9.02	24.66	-66.7	0.00	100.0
Week 3	139	34.05	33.21	0.0	33.33	100.0	122	8.74	27.38	-66.7	0.00	100.0
Week 4	145	28.73	30.33	0.0	33.33	100.0	129	2.58	28.45	-66.7	0.00	66.7
Week 5	137	30.17	29.67	0.0	33.33	100.0	121	5.23	29.51	-100.0	0.00	100.0
Week 6	146	34.02	33.56	0.0	33.33	100.0	124	9.41	34.15	-100.0	0.00	100.0
Week 7	147	30.16	32.01	0.0	33.33	100.0	124	3.49	30.89	-100.0	0.00	100.0
Week 8	147	30.61	29.59	0.0	33.33	100.0	124	5.38	33.84	-66.7	0.00	100.0
Week 9	142	32.16	31.86	0.0	33.33	100.0	121	6.89	34.14	-66.7	0.00	100.0
Week 10	139	28.78	30.88	0.0	33.33	100.0	118	4.24	34.19	-100.0	0.00	100.0
Week 11	137	28.47	30.13	0.0	33.33	100.0	115	4.35	35.74	-100.0	0.00	100.0
Week 12	142	26.53	30.11	0.0	33.33	100.0	119	0.84	31.13	-100.0	0.00	100.0
Week 14	139	24.94	28.40	0.0	33.33	100.0	116	0.29	34.47	-100.0	0.00	100.0
Week 17	132	25.50	28.19	0.0	33.33	100.0	111	0.00	33.64	-100.0	0.00	66.7
Week 20	120	20.55	25.27	0.0	0.00	100.0	103	-2.59	31.20	-100.0	0.00	100.0
Week 23	117	17.38	24.21	0.0	0.00	100.0	97	-3.09	30.46	-100.0	0.00	100.0
Week 26	112	16.96	23.25	0.0	0.00	100.0	94	-3.90	30.47	-66.7	0.00	66.7
Week 29	107	17.44	24.38	0.0	0.00	100.0	93	-5.02	34.03	-100.0	0.00	100.0
Week 32	102	16.99	26.01	0.0	0.00	100.0	88	-8.71	32.95	-100.0	0.00	66.7
Week 35	98	15.65	22.04	0.0	0.00	66.7	86	-6.98	31.98	-100.0	0.00	66.7
Week 38	97	18.90	23.03	0.0	0.00	100.0	86	-4.65	32.40	-100.0	0.00	66.7
Week 41	95	17.54	24.23	0.0	0.00	100.0	84	-4.37	31.80	-100.0	0.00	100.0
Week 44	86	18.60	25.36	0.0	0.00	100.0	74	-3.15	31.78	-66.7	0.00	100.0
Week 47	79	14.77	20.50	0.0	0.00	100.0	70	-8.57	27.03	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	74	19.37	23.41	0.0	0.00	100.0	64	-2.08	33.00	-100.0	0.00	66.7
Week 53	74	20.72	25.10	0.0	0.00	100.0	63	-5.29	32.36	-100.0	0.00	66.7
Week 56	72	18.52	22.99	0.0	0.00	66.7	61	-6.01	30.13	-66.7	0.00	33.3
Week 59	69	16.91	21.86	0.0	0.00	66.7	57	-6.43	29.84	-66.7	0.00	66.7
Week 62	62	12.90	20.34	0.0	0.00	66.7	52	-9.62	24.11	-66.7	0.00	33.3
Week 65	43	16.28	23.43	0.0	0.00	66.7	40	-6.67	28.45	-66.7	0.00	33.3
Week 68	46	16.67	24.09	0.0	0.00	66.7	42	-3.97	29.63	-66.7	0.00	66.7
Week 71	42	15.87	24.68	0.0	0.00	100.0	38	-8.77	26.49	-66.7	0.00	33.3
Week 74	38	13.16	21.28	0.0	0.00	66.7	35	-10.48	27.74	-66.7	0.00	33.3
Week 77	37	13.51	19.97	0.0	0.00	66.7	33	-10.10	28.24	-66.7	0.00	33.3
Week 80	36	19.44	25.67	0.0	0.00	66.7	34	-3.92	30.45	-66.7	0.00	66.7
Week 83	30	14.44	22.63	0.0	0.00	66.7	29	-6.90	38.19	-100.0	0.00	66.7
Week 86	26	12.82	21.24	0.0	0.00	66.7	25	-8.00	30.85	-66.7	0.00	66.7
Week 89	20	11.67	22.36	0.0	0.00	66.7	19	-5.26	27.81	-66.7	0.00	66.7
Week 92	19	14.03	20.23	0.0	0.00	66.7	18	-7.41	18.28	-33.3	0.00	33.3
Week 95	14	9.52	15.63	0.0	0.00	33.3	13	-2.56	21.35	-33.3	0.00	33.3
Week 98	10	6.67	14.05	0.0	0.00	33.3	9	-7.41	14.70	-33.3	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Plat+Gem (N=202)												
BASELINE	165	30.30	34.50	0.0	33.33	100.0						
Week 1	144	34.03	33.09	0.0	33.33	100.0	139	4.80	26.79	-100.0	0.00	100.0
Week 2	147	32.20	34.33	0.0	33.33	100.0	135	5.43	26.46	-66.7	0.00	100.0
Week 3	149	29.98	31.42	0.0	33.33	100.0	136	3.92	29.83	-66.7	0.00	100.0
Week 4	150	26.22	28.79	0.0	33.33	100.0	135	0.00	29.08	-66.7	0.00	66.7
Week 5	153	30.94	30.13	0.0	33.33	100.0	138	2.90	31.06	-100.0	0.00	100.0
Week 6	145	27.59	29.23	0.0	33.33	100.0	131	0.25	33.72	-100.0	0.00	100.0
Week 7	148	27.70	29.45	0.0	33.33	100.0	134	0.50	36.10	-100.0	0.00	66.7
Week 8	145	27.36	29.05	0.0	33.33	100.0	132	0.76	35.06	-100.0	0.00	100.0
Week 9	141	25.06	27.07	0.0	33.33	100.0	125	-1.87	37.46	-100.0	0.00	100.0
Week 10	142	23.24	26.33	0.0	33.33	100.0	130	-2.05	35.89	-100.0	0.00	66.7
Week 11	126	24.60	27.06	0.0	33.33	100.0	114	-1.46	34.46	-100.0	0.00	100.0
Week 12	130	27.18	29.58	0.0	33.33	100.0	115	0.29	37.07	-100.0	0.00	100.0
Week 14	125	25.33	25.89	0.0	33.33	100.0	109	-0.31	38.36	-100.0	0.00	100.0
Week 17	120	23.33	27.19	0.0	33.33	100.0	106	-4.09	39.50	-100.0	0.00	100.0
Week 20	104	20.51	26.81	0.0	0.00	100.0	91	-6.23	37.49	-100.0	0.00	100.0
Week 23	88	20.83	27.36	0.0	0.00	100.0	80	-4.58	38.15	-100.0	0.00	66.7
Week 26	81	20.58	28.17	0.0	0.00	100.0	75	-6.22	35.81	-100.0	0.00	100.0
Week 29	77	17.32	26.83	0.0	0.00	100.0	71	-6.57	30.66	-100.0	0.00	66.7
Week 32	63	17.99	28.60	0.0	0.00	100.0	58	-5.17	35.21	-100.0	0.00	100.0
Week 35	62	16.13	24.70	0.0	0.00	100.0	56	-7.14	37.45	-100.0	0.00	100.0
Week 38	56	17.26	23.78	0.0	0.00	100.0	50	-4.67	35.64	-100.0	0.00	66.7
Week 41	52	20.51	26.53	0.0	0.00	100.0	47	0.00	29.49	-100.0	0.00	66.7
Week 44	49	18.37	23.63	0.0	0.00	100.0	44	-3.79	36.81	-100.0	0.00	66.7
Week 47	43	17.05	24.53	0.0	0.00	100.0	39	-5.13	32.93	-100.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	36	20.37	22.93	0.0	16.67	66.7	31	-2.15	29.73	-100.0	0.00	33.3
Week 53	31	20.43	29.41	0.0	0.00	100.0	28	-2.38	44.38	-100.0	0.00	66.7
Week 56	30	21.11	23.95	0.0	33.33	100.0	29	-5.75	38.90	-100.0	0.00	66.7
Week 59	23	20.29	27.96	0.0	0.00	100.0	21	-11.11	39.91	-100.0	0.00	33.3
Week 62	20	23.33	28.82	0.0	16.67	100.0	20	-6.67	38.39	-100.0	0.00	66.7
Week 65	17	19.61	26.51	0.0	0.00	66.7	16	-2.08	35.42	-100.0	0.00	66.7
Week 68	13	15.38	25.88	0.0	0.00	66.7	13	0.00	27.22	-33.3	0.00	66.7
Week 71	13	15.38	22.01	0.0	0.00	66.7	13	-5.13	38.12	-100.0	0.00	66.7
Week 74	11	9.09	15.57	0.0	0.00	33.3	11	0.00	14.91	-33.3	0.00	33.3
Week 77	11	6.06	13.48	0.0	0.00	33.3	11	-15.15	43.11	-100.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Present	EV+Pembro (N= 50)												
	BASELINE	40	36.67	35.25	0.0	33.33	100.0						
	Week 1	38	42.98	38.68	0.0	33.33	100.0	34	3.92	17.91	-33.3	0.00	33.3
	Week 2	35	36.19	33.70	0.0	33.33	100.0	32	4.17	18.45	-33.3	0.00	33.3
	Week 3	32	34.37	31.09	0.0	33.33	100.0	30	6.67	26.84	-33.3	0.00	66.7
	Week 4	35	31.43	30.19	0.0	33.33	100.0	31	1.07	27.87	-66.7	0.00	66.7
	Week 5	32	27.08	26.01	0.0	33.33	100.0	28	-2.38	28.59	-100.0	0.00	33.3
	Week 6	35	32.38	33.81	0.0	33.33	100.0	30	0.00	39.15	-100.0	0.00	100.0
	Week 7	35	30.48	32.71	0.0	33.33	100.0	29	1.15	37.25	-100.0	0.00	66.7
	Week 8	38	35.96	29.39	0.0	33.33	100.0	31	11.83	38.05	-66.7	0.00	100.0
	Week 9	33	36.36	31.58	0.0	33.33	100.0	29	8.05	32.92	-66.7	0.00	66.7
	Week 10	30	27.78	27.80	0.0	33.33	100.0	25	-2.67	39.58	-100.0	0.00	66.7
	Week 11	31	23.66	27.48	0.0	33.33	100.0	27	-2.47	44.27	-100.0	0.00	100.0
	Week 12	32	22.92	28.63	0.0	0.00	100.0	28	-3.57	36.67	-100.0	0.00	66.7
	Week 14	36	19.44	25.67	0.0	0.00	66.7	31	-7.53	40.10	-100.0	0.00	66.7
	Week 17	33	17.17	25.17	0.0	0.00	66.7	27	-12.35	37.15	-100.0	0.00	66.7
	Week 20	28	19.05	29.30	0.0	0.00	100.0	25	-5.33	35.59	-100.0	0.00	66.7
	Week 23	28	17.86	24.82	0.0	0.00	100.0	24	-5.56	37.64	-66.7	0.00	100.0
	Week 26	28	13.10	22.84	0.0	0.00	66.7	24	-12.50	35.18	-66.7	0.00	66.7
	Week 29	27	16.05	26.75	0.0	0.00	100.0	25	-12.00	33.17	-100.0	0.00	33.3
	Week 32	25	14.67	29.00	0.0	0.00	100.0	23	-15.94	34.63	-100.0	0.00	33.3
	Week 35	26	14.10	21.44	0.0	0.00	66.7	24	-15.28	32.57	-100.0	0.00	33.3
	Week 38	26	17.95	27.05	0.0	0.00	100.0	24	-12.50	35.18	-100.0	0.00	66.7
	Week 41	25	17.33	27.42	0.0	0.00	100.0	23	-7.25	34.75	-66.7	0.00	100.0
	Week 44	22	22.73	29.79	0.0	0.00	100.0	20	-3.33	37.31	-66.7	0.00	100.0
	Week 47	14	16.67	28.49	0.0	0.00	100.0	13	-10.26	31.58	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	16.67	27.57	0.0	0.00	100.0	17	-3.92	37.05	-66.7	0.00	33.3
	Week 53	21	17.46	29.10	0.0	0.00	100.0	18	-5.56	36.60	-66.7	0.00	66.7
	Week 56	18	24.07	27.55	0.0	16.67	66.7	15	-4.44	35.34	-66.7	0.00	33.3
	Week 59	18	18.52	20.52	0.0	16.67	66.7	15	-6.67	33.81	-66.7	0.00	33.3
	Week 62	13	10.26	21.01	0.0	0.00	66.7	11	-12.12	22.47	-66.7	0.00	0.0
	Week 68	12	16.67	26.59	0.0	0.00	66.7	11	0.00	29.81	-66.7	0.00	33.3
	Plat+Gem (N= 50)												
	BASELINE	40	45.83	39.00	0.0	66.67	100.0						
	Week 1	35	40.00	34.11	0.0	33.33	100.0	33	-2.02	26.27	-66.7	0.00	33.3
	Week 2	33	44.44	39.68	0.0	33.33	100.0	30	5.56	29.14	-33.3	0.00	100.0
	Week 3	33	35.35	34.30	0.0	33.33	100.0	29	-3.45	30.01	-66.7	0.00	66.7
	Week 4	36	31.48	28.67	0.0	33.33	100.0	32	-8.33	35.92	-66.7	0.00	66.7
	Week 5	36	37.96	33.00	0.0	33.33	100.0	32	-7.29	35.66	-66.7	0.00	66.7
	Week 6	32	22.92	28.63	0.0	16.67	100.0	29	-16.09	40.45	-100.0	0.00	66.7
	Week 7	35	29.52	30.00	0.0	33.33	100.0	31	-11.83	44.35	-100.0	0.00	66.7
	Week 8	35	28.57	32.48	0.0	33.33	100.0	31	-11.83	38.05	-100.0	0.00	66.7
	Week 9	34	30.39	27.67	0.0	33.33	100.0	30	-12.22	45.89	-100.0	0.00	100.0
	Week 10	33	24.24	30.36	0.0	0.00	100.0	30	-13.33	41.62	-100.0	0.00	66.7
	Week 11	30	28.89	35.81	0.0	16.67	100.0	26	-7.69	42.49	-100.0	0.00	100.0
	Week 12	32	29.17	34.65	0.0	16.67	100.0	27	-11.11	45.29	-100.0	0.00	100.0
	Week 14	27	23.46	27.45	0.0	33.33	100.0	22	-10.61	47.57	-100.0	0.00	100.0
	Week 17	28	23.81	28.48	0.0	16.67	100.0	23	-13.04	42.33	-100.0	0.00	66.7
	Week 20	20	20.00	29.42	0.0	0.00	100.0	16	-18.75	38.43	-100.0	0.00	33.3
	Week 23	15	22.22	37.09	0.0	0.00	100.0	14	-11.91	38.36	-100.0	0.00	66.7
	Week 26	15	24.44	34.43	0.0	0.00	100.0	14	-7.14	39.61	-100.0	0.00	66.7
	Week 29	13	15.38	32.25	0.0	0.00	100.0	12	-11.11	32.82	-100.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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Table 302.1.3002.19.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Absent	EV+Pembro (N=152)												
	BASELINE	120	26.11	30.00	0.0	33.33	100.0						
	Week 1	103	26.86	29.17	0.0	33.33	100.0	95	1.40	17.47	-33.3	0.00	33.3
	Week 2	115	34.20	31.36	0.0	33.33	100.0	101	10.56	26.22	-66.7	0.00	100.0
	Week 3	107	33.96	33.95	0.0	33.33	100.0	92	9.42	27.66	-66.7	0.00	100.0
	Week 4	110	27.88	30.47	0.0	33.33	100.0	98	3.06	28.75	-66.7	0.00	66.7
	Week 5	105	31.11	30.76	0.0	33.33	100.0	93	7.53	29.54	-66.7	0.00	100.0
	Week 6	111	34.53	33.61	0.0	33.33	100.0	94	12.41	32.05	-66.7	0.00	100.0
	Week 7	112	30.06	31.94	0.0	33.33	100.0	95	4.21	28.86	-66.7	0.00	100.0
	Week 8	109	28.75	29.56	0.0	33.33	100.0	93	3.23	32.25	-66.7	0.00	100.0
	Week 9	109	30.89	31.98	0.0	33.33	100.0	92	6.52	34.68	-66.7	0.00	100.0
	Week 10	109	29.05	31.79	0.0	33.33	100.0	93	6.09	32.58	-66.7	0.00	100.0
	Week 11	106	29.87	30.84	0.0	33.33	100.0	88	6.44	32.70	-100.0	0.00	66.7
	Week 12	110	27.58	30.58	0.0	33.33	100.0	91	2.20	29.31	-66.7	0.00	100.0
	Week 14	103	26.86	29.17	0.0	33.33	100.0	85	3.14	31.97	-66.7	0.00	100.0
	Week 17	99	28.28	28.72	0.0	33.33	100.0	84	3.97	31.65	-66.7	0.00	66.7
	Week 20	92	21.01	24.07	0.0	16.67	100.0	78	-1.71	29.86	-100.0	0.00	100.0
	Week 23	89	17.23	24.16	0.0	0.00	100.0	73	-2.28	27.96	-100.0	0.00	66.7
	Week 26	84	18.25	23.37	0.0	0.00	100.0	70	-0.95	28.36	-66.7	0.00	66.7
	Week 29	80	17.92	23.69	0.0	0.00	100.0	68	-2.45	34.22	-100.0	0.00	100.0
	Week 32	77	17.75	25.12	0.0	0.00	100.0	65	-6.15	32.22	-100.0	0.00	66.7
	Week 35	72	16.20	22.37	0.0	0.00	66.7	62	-3.76	31.42	-100.0	0.00	66.7
	Week 38	71	19.25	21.57	0.0	0.00	66.7	62	-1.61	31.03	-100.0	0.00	66.7
	Week 41	70	17.62	23.21	0.0	0.00	100.0	61	-3.28	30.86	-100.0	0.00	66.7
	Week 44	64	17.19	23.75	0.0	0.00	100.0	54	-3.09	29.86	-66.7	0.00	66.7
	Week 47	65	14.36	18.60	0.0	0.00	66.7	57	-8.19	26.19	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	54	20.37	21.88	0.0	33.33	66.7	47	-1.42	31.82	-100.0	0.00	66.7
	Week 53	53	22.01	23.52	0.0	33.33	66.7	45	-5.19	30.94	-100.0	0.00	66.7
	Week 56	54	16.67	21.23	0.0	0.00	66.7	46	-6.52	28.65	-66.7	0.00	33.3
	Week 59	51	16.34	22.48	0.0	0.00	66.7	42	-6.35	28.74	-66.7	0.00	66.7
	Week 62	49	13.60	20.32	0.0	0.00	66.7	41	-8.94	24.75	-66.7	0.00	33.3
	Week 65	36	16.67	23.23	0.0	0.00	66.7	33	-7.07	27.33	-66.7	0.00	33.3
	Week 68	34	16.67	23.57	0.0	0.00	66.7	31	-5.38	29.93	-66.7	0.00	66.7
	Week 71	33	13.13	20.31	0.0	0.00	66.7	30	-10.00	24.99	-66.7	0.00	33.3
	Week 74	33	12.12	20.10	0.0	0.00	66.7	30	-10.00	26.48	-66.7	0.00	33.3
	Week 77	31	11.83	18.35	0.0	0.00	66.7	27	-9.88	27.45	-66.7	0.00	33.3
	Week 80	31	18.28	25.59	0.0	0.00	66.7	29	-3.45	30.01	-66.7	0.00	66.7
	Week 83	25	13.33	21.52	0.0	0.00	66.7	24	-6.94	36.75	-100.0	0.00	66.7
	Week 86	23	11.59	19.09	0.0	0.00	66.7	22	-10.61	27.96	-66.7	0.00	66.7
	Week 89	18	12.96	23.26	0.0	0.00	66.7	17	-3.92	28.58	-66.7	0.00	66.7
	Week 92	16	10.42	15.96	0.0	0.00	33.3	15	-11.11	16.27	-33.3	0.00	0.0
	Week 95	12	8.33	15.07	0.0	0.00	33.3	11	-3.03	23.35	-33.3	0.00	33.3
	Plat+Gem (N=152)												
	BASELINE	125	25.33	31.51	0.0	0.00	100.0						
	Week 1	109	32.11	32.69	0.0	33.33	100.0	106	6.92	26.71	-100.0	0.00	100.0
	Week 2	114	28.65	31.94	0.0	33.33	100.0	105	5.40	25.79	-66.7	0.00	100.0
	Week 3	116	28.45	30.54	0.0	33.33	100.0	107	5.92	29.61	-66.7	0.00	100.0
	Week 4	114	24.56	28.76	0.0	33.33	100.0	103	2.59	26.28	-66.7	0.00	66.7
	Week 5	117	28.77	29.00	0.0	33.33	100.0	106	5.97	29.02	-100.0	0.00	100.0
	Week 6	113	28.91	29.38	0.0	33.33	100.0	102	4.90	30.18	-100.0	0.00	100.0
	Week 7	113	27.14	29.40	0.0	33.33	100.0	103	4.21	32.57	-100.0	0.00	66.7
	Week 8	110	26.97	28.02	0.0	33.33	100.0	101	4.62	33.34	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	107	23.36	26.78	0.0	33.33	100.0	95	1.40	34.01	-100.0	0.00	66.7
	Week 10	109	22.93	25.13	0.0	33.33	100.0	100	1.33	33.47	-100.0	0.00	66.7
	Week 11	96	23.26	23.75	0.0	33.33	100.0	88	0.38	31.76	-100.0	0.00	66.7
	Week 12	98	26.53	27.89	0.0	33.33	100.0	88	3.79	33.69	-100.0	0.00	100.0
	Week 14	98	25.85	25.57	0.0	33.33	100.0	87	2.30	35.51	-100.0	0.00	66.7
	Week 17	92	23.19	26.95	0.0	33.33	100.0	83	-1.61	38.57	-100.0	0.00	100.0
	Week 20	84	20.63	26.34	0.0	0.00	100.0	75	-3.56	36.99	-100.0	0.00	100.0
	Week 23	73	20.55	25.23	0.0	0.00	100.0	66	-3.03	38.22	-100.0	0.00	66.7
	Week 26	66	19.70	26.78	0.0	0.00	100.0	61	-6.01	35.23	-100.0	0.00	100.0
	Week 29	64	17.71	25.87	0.0	0.00	100.0	59	-5.65	30.42	-100.0	0.00	66.7
	Week 32	54	18.52	27.98	0.0	0.00	100.0	49	-4.08	35.11	-100.0	0.00	100.0
	Week 35	54	16.05	23.11	0.0	0.00	100.0	48	-6.25	37.45	-100.0	0.00	100.0
	Week 38	47	16.31	20.70	0.0	0.00	66.7	42	-6.35	38.42	-100.0	0.00	66.7
	Week 41	45	20.00	24.00	0.0	0.00	66.7	40	1.67	27.16	-66.7	0.00	66.7
	Week 44	41	17.88	19.86	0.0	0.00	66.7	36	-2.78	36.84	-100.0	0.00	66.7
	Week 47	35	17.14	23.39	0.0	0.00	100.0	31	-3.23	32.61	-100.0	0.00	33.3
	Week 50	29	22.99	22.01	0.0	33.33	66.7	24	1.39	26.88	-66.7	0.00	33.3
	Week 53	25	20.00	28.87	0.0	0.00	100.0	22	-1.52	43.01	-100.0	0.00	66.7
	Week 56	26	21.79	24.84	0.0	33.33	100.0	25	-6.67	40.83	-100.0	0.00	66.7
	Week 59	20	21.67	29.17	0.0	0.00	100.0	18	-14.82	41.57	-100.0	0.00	33.3
	Week 62	17	25.49	30.11	0.0	33.33	100.0	17	-9.80	40.42	-100.0	0.00	66.7
	Week 65	15	22.22	27.22	0.0	0.00	66.7	14	-2.38	38.04	-100.0	0.00	66.7
	Week 68	11	18.18	27.34	0.0	0.00	66.7	11	0.00	29.81	-33.3	0.00	66.7
	Week 71	12	16.67	22.47	0.0	0.00	66.7	12	-5.56	39.78	-100.0	0.00	66.7
	Week 74	10	10.00	16.10	0.0	0.00	33.3	10	0.00	15.71	-33.3	0.00	33.3
	Week 77	10	6.67	14.05	0.0	0.00	33.3	10	-16.67	45.13	-100.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
< 65 years	EV+Pembro (N= 39)												
	BASELINE	32	28.12	29.46	0.0	33.33	100.0						
	Week 1	27	34.57	28.47	0.0	33.33	100.0	26	6.41	18.90	-33.3	0.00	33.3
	Week 2	30	32.22	28.34	0.0	33.33	100.0	29	8.05	21.19	-33.3	0.00	66.7
	Week 3	31	30.11	27.70	0.0	33.33	100.0	29	4.60	23.10	-33.3	0.00	66.7
	Week 4	30	24.44	23.05	0.0	33.33	66.7	27	3.70	21.35	-33.3	0.00	33.3
	Week 5	28	23.81	19.99	0.0	33.33	66.7	26	2.56	24.81	-33.3	0.00	33.3
	Week 6	29	29.88	25.74	0.0	33.33	66.7	26	7.69	28.76	-66.7	0.00	66.7
	Week 7	30	22.22	28.14	0.0	16.67	100.0	26	-2.56	22.94	-66.7	0.00	33.3
	Week 8	30	18.89	24.26	0.0	0.00	66.7	26	-2.56	29.70	-66.7	0.00	33.3
	Week 9	28	21.43	27.54	0.0	0.00	66.7	27	-4.94	30.25	-66.7	0.00	66.7
	Week 10	26	26.92	29.84	0.0	33.33	100.0	23	4.35	27.16	-33.3	0.00	66.7
	Week 11	28	26.19	29.20	0.0	33.33	100.0	25	2.67	28.74	-66.7	0.00	66.7
	Week 12	28	21.43	32.98	0.0	0.00	100.0	25	-1.33	32.60	-66.7	0.00	100.0
	Week 14	26	17.95	19.39	0.0	16.67	66.7	23	-7.25	30.08	-66.7	0.00	33.3
	Week 17	28	23.81	27.00	0.0	33.33	100.0	24	-2.78	29.35	-66.7	0.00	33.3
	Week 20	27	22.22	24.46	0.0	33.33	100.0	24	-1.39	25.02	-66.7	0.00	33.3
	Week 23	26	14.10	21.44	0.0	0.00	66.7	23	-7.25	22.37	-33.3	0.00	33.3
	Week 26	24	15.28	21.93	0.0	0.00	66.7	22	-1.52	26.18	-33.3	0.00	66.7
	Week 29	25	16.00	25.68	0.0	0.00	100.0	23	-7.25	28.35	-66.7	0.00	33.3
	Week 32	25	17.33	27.42	0.0	0.00	100.0	23	-7.25	28.35	-66.7	0.00	66.7
	Week 35	24	15.28	21.93	0.0	0.00	66.7	22	-9.09	23.42	-66.7	0.00	33.3
	Week 38	23	27.53	25.92	0.0	33.33	100.0	22	1.51	24.07	-33.3	0.00	33.3
	Week 41	25	22.67	20.91	0.0	33.33	66.7	23	-1.45	18.74	-33.3	0.00	33.3
	Week 44	22	22.73	26.00	0.0	16.67	66.7	20	0.00	24.18	-33.3	0.00	33.3
	Week 47	20	16.67	25.36	0.0	0.00	100.0	18	-5.56	23.57	-33.3	0.00	33.3

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	19	21.05	19.91	0.0	33.33	66.7	17	1.96	24.92	-33.3	0.00	33.3
	Week 53	20	18.33	22.88	0.0	0.00	66.7	18	-3.70	25.28	-33.3	0.00	66.7
	Week 56	17	21.57	23.40	0.0	33.33	66.7	15	-2.22	26.63	-33.3	0.00	33.3
	Week 59	17	15.69	23.91	0.0	0.00	66.7	15	-11.11	24.12	-66.7	0.00	33.3
	Week 62	15	15.56	24.77	0.0	0.00	66.7	14	-7.14	23.31	-33.3	0.00	33.3
	Week 65	14	16.67	21.68	0.0	0.00	66.7	13	-5.13	26.69	-33.3	0.00	33.3
	Week 68	11	12.12	22.47	0.0	0.00	66.7	10	-6.67	26.29	-33.3	0.00	33.3
	Week 71	13	15.38	22.01	0.0	0.00	66.7	12	-11.11	21.71	-33.3	0.00	33.3
	Week 74	14	16.67	25.32	0.0	0.00	66.7	13	-7.69	24.17	-33.3	0.00	33.3
	Week 77	14	19.05	21.54	0.0	16.67	66.7	13	-7.69	24.17	-33.3	0.00	33.3
	Week 80	14	23.81	27.51	0.0	16.67	66.7	13	0.00	23.57	-33.3	0.00	33.3
	Week 83	12	19.44	22.28	0.0	16.67	66.7	11	-6.06	29.13	-33.3	0.00	33.3
	Plat+Gem (N= 29)												
	BASELINE	22	27.27	33.55	0.0	16.67	100.0						
	Week 1	21	23.81	28.17	0.0	33.33	100.0	20	-1.67	25.31	-66.7	0.00	33.3
	Week 2	24	19.44	21.80	0.0	16.67	66.7	20	-3.33	18.42	-33.3	0.00	33.3
	Week 3	23	20.29	19.43	0.0	33.33	66.7	20	-8.33	23.88	-66.7	0.00	33.3
	Week 4	23	23.19	25.50	0.0	33.33	66.7	19	-3.51	33.14	-66.7	0.00	66.7
	Week 5	25	29.33	30.91	0.0	33.33	100.0	20	0.00	26.49	-66.7	0.00	33.3
	Week 6	22	27.27	33.55	0.0	16.67	100.0	18	0.00	36.16	-100.0	0.00	33.3
	Week 7	24	25.00	28.23	0.0	33.33	100.0	21	-6.35	37.44	-100.0	0.00	33.3
	Week 8	21	23.81	23.90	0.0	33.33	100.0	19	-1.76	37.64	-66.7	0.00	100.0
	Week 9	20	25.00	28.36	0.0	33.33	100.0	17	0.00	47.14	-100.0	0.00	66.7
	Week 10	21	20.63	24.67	0.0	0.00	66.7	18	-1.85	35.19	-66.7	0.00	66.7
	Week 11	20	18.33	20.16	0.0	16.67	66.7	17	-11.77	26.20	-66.7	0.00	33.3
	Week 12	21	20.63	24.67	0.0	0.00	66.7	17	-5.88	33.82	-100.0	0.00	33.3

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 14	22	21.21	21.93	0.0	33.33	66.7	18	-3.70	39.42	-100.0	0.00	33.3
	Week 17	20	16.67	17.10	0.0	16.67	33.3	17	-11.77	33.21	-100.0	0.00	33.3
	Week 20	18	22.22	28.01	0.0	0.00	66.7	15	-8.89	32.04	-100.0	0.00	33.3
	Week 23	18	18.52	28.52	0.0	0.00	100.0	16	-8.33	37.52	-100.0	0.00	66.7
	Week 26	16	12.50	16.67	0.0	0.00	33.3	14	-7.14	32.50	-100.0	0.00	33.3
	Week 29	15	8.89	15.26	0.0	0.00	33.3	13	-12.82	34.80	-100.0	0.00	33.3
	Week 32	15	13.33	21.08	0.0	0.00	66.7	13	-12.82	32.03	-100.0	0.00	33.3
	Week 35	15	17.78	17.21	0.0	33.33	33.3	13	-2.57	34.59	-100.0	0.00	33.3
	Week 38	14	26.19	29.75	0.0	33.33	100.0	12	8.33	40.51	-100.0	0.00	66.7
	Week 41	11	24.24	30.15	0.0	0.00	66.7	9	11.11	28.87	-33.3	0.00	66.7
	Week 44	11	24.24	30.15	0.0	33.33	100.0	9	11.11	16.67	0.0	0.00	33.3
	Week 47	11	27.27	25.03	0.0	33.33	66.7	9	7.41	32.39	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>= 65 years	EV+Pembro (N=163)												
	BASELINE	128	28.91	32.23	0.0	33.33	100.0						
	Week 1	114	30.41	33.65	0.0	33.33	100.0	103	0.97	17.12	-33.3	0.00	33.3
	Week 2	120	35.28	32.71	0.0	33.33	100.0	104	9.29	25.63	-66.7	0.00	100.0
	Week 3	108	35.18	34.66	0.0	33.33	100.0	93	10.04	28.57	-66.7	0.00	100.0
	Week 4	115	29.85	31.95	0.0	33.33	100.0	102	2.29	30.13	-66.7	0.00	66.7
	Week 5	109	31.80	31.55	0.0	33.33	100.0	95	5.96	30.74	-100.0	0.00	100.0
	Week 6	117	35.04	35.25	0.0	33.33	100.0	98	9.86	35.57	-100.0	0.00	100.0
	Week 7	117	32.19	32.73	0.0	33.33	100.0	98	5.10	32.59	-100.0	0.00	100.0
	Week 8	117	33.62	30.17	0.0	33.33	100.0	98	7.48	34.69	-66.7	0.00	100.0
	Week 9	114	34.80	32.40	0.0	33.33	100.0	94	10.28	34.58	-66.7	0.00	100.0
	Week 10	113	29.20	31.22	0.0	33.33	100.0	95	4.21	35.81	-100.0	0.00	100.0
	Week 11	109	29.05	30.46	0.0	33.33	100.0	90	4.81	37.58	-100.0	0.00	100.0
	Week 12	114	27.78	29.39	0.0	33.33	100.0	94	1.42	30.88	-100.0	0.00	66.7
	Week 14	113	26.55	29.93	0.0	33.33	100.0	93	2.15	35.38	-100.0	0.00	100.0
	Week 17	104	25.96	28.62	0.0	33.33	100.0	87	0.77	34.84	-100.0	0.00	66.7
	Week 20	93	20.07	25.60	0.0	0.00	100.0	79	-2.95	32.99	-100.0	0.00	100.0
	Week 23	91	18.31	24.98	0.0	0.00	100.0	74	-1.80	32.59	-100.0	0.00	100.0
	Week 26	88	17.42	23.69	0.0	0.00	100.0	72	-4.63	31.80	-66.7	0.00	66.7
	Week 29	82	17.89	24.11	0.0	0.00	100.0	70	-4.29	35.86	-100.0	0.00	100.0
	Week 32	77	16.88	25.72	0.0	0.00	100.0	65	-9.23	34.62	-100.0	0.00	66.7
	Week 35	74	15.77	22.22	0.0	0.00	66.7	64	-6.25	34.57	-100.0	0.00	66.7
	Week 38	74	16.22	21.54	0.0	0.00	66.7	64	-6.77	34.72	-100.0	0.00	66.7
	Week 41	70	15.71	25.20	0.0	0.00	100.0	61	-5.46	35.58	-100.0	0.00	100.0
	Week 44	64	17.19	25.19	0.0	0.00	100.0	54	-4.32	34.29	-66.7	0.00	100.0
	Week 47	59	14.12	18.78	0.0	0.00	66.7	52	-9.62	28.27	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	55	18.79	24.65	0.0	0.00	100.0	47	-3.55	35.60	-100.0	0.00	66.7
	Week 53	54	21.60	26.03	0.0	0.00	100.0	45	-5.93	35.03	-100.0	0.00	66.7
	Week 56	55	17.58	23.00	0.0	0.00	66.7	46	-7.25	31.36	-66.7	0.00	33.3
	Week 59	52	17.31	21.38	0.0	0.00	66.7	42	-4.76	31.73	-66.7	0.00	66.7
	Week 62	47	12.06	18.94	0.0	0.00	66.7	38	-10.53	24.64	-66.7	0.00	33.3
	Week 65	29	16.09	24.59	0.0	0.00	66.7	27	-7.41	29.72	-66.7	0.00	33.3
	Week 68	35	18.09	24.71	0.0	0.00	66.7	32	-3.13	30.95	-66.7	0.00	66.7
	Week 71	29	16.09	26.16	0.0	0.00	100.0	26	-7.69	28.76	-66.7	0.00	33.3
	Week 74	24	11.11	18.82	0.0	0.00	66.7	22	-12.12	30.07	-66.7	0.00	33.3
	Week 77	23	10.14	18.63	0.0	0.00	66.7	20	-11.67	31.11	-66.7	0.00	33.3
	Week 80	22	16.67	24.67	0.0	0.00	66.7	21	-6.35	34.35	-66.7	0.00	66.7
	Week 83	18	11.11	22.87	0.0	0.00	66.7	18	-7.41	43.62	-100.0	0.00	66.7
	Week 86	18	14.81	23.49	0.0	0.00	66.7	18	-3.70	34.09	-66.7	0.00	66.7
	Week 89	12	8.33	20.72	0.0	0.00	66.7	12	-5.56	31.25	-66.7	0.00	66.7
	Week 92	10	3.33	10.54	0.0	0.00	33.3	10	-10.00	16.10	-33.3	0.00	0.0
	Plat+Gem (N=173)												
	BASELINE	143	30.77	34.73	0.0	33.33	100.0						
	Week 1	123	35.77	33.65	0.0	33.33	100.0	119	5.88	26.98	-100.0	0.00	100.0
	Week 2	123	34.69	35.81	0.0	33.33	100.0	115	6.96	27.39	-66.7	0.00	100.0
	Week 3	126	31.75	32.89	0.0	33.33	100.0	116	6.03	30.33	-66.7	0.00	100.0
	Week 4	127	26.77	29.41	0.0	33.33	100.0	116	0.57	28.48	-66.7	0.00	66.7
	Week 5	128	31.25	30.09	0.0	33.33	100.0	118	3.39	31.84	-100.0	0.00	100.0
	Week 6	123	27.64	28.54	0.0	33.33	100.0	113	0.29	33.48	-100.0	0.00	100.0
	Week 7	124	28.23	29.77	0.0	33.33	100.0	113	1.77	35.87	-100.0	0.00	66.7
	Week 8	124	27.96	29.87	0.0	33.33	100.0	113	1.18	34.77	-100.0	0.00	100.0
	Week 9	121	25.07	26.97	0.0	33.33	100.0	108	-2.16	35.96	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	121	23.69	26.68	0.0	33.33	100.0	112	-2.08	36.15	-100.0	0.00	66.7
	Week 11	106	25.79	28.09	0.0	33.33	100.0	97	0.34	35.52	-100.0	0.00	100.0
	Week 12	109	28.44	30.37	0.0	33.33	100.0	98	1.36	37.66	-100.0	0.00	100.0
	Week 14	103	26.21	26.67	0.0	33.33	100.0	91	0.37	38.33	-100.0	0.00	100.0
	Week 17	100	24.67	28.67	0.0	33.33	100.0	89	-2.62	40.58	-100.0	0.00	100.0
	Week 20	86	20.15	26.71	0.0	0.00	100.0	76	-5.70	38.64	-100.0	0.00	100.0
	Week 23	70	21.43	27.24	0.0	0.00	100.0	64	-3.65	38.54	-100.0	0.00	66.7
	Week 26	65	22.56	30.11	0.0	0.00	100.0	61	-6.01	36.77	-100.0	0.00	100.0
	Week 29	62	19.35	28.66	0.0	0.00	100.0	58	-5.17	29.82	-100.0	0.00	66.7
	Week 32	48	19.44	30.62	0.0	0.00	100.0	45	-2.96	36.11	-100.0	0.00	100.0
	Week 35	47	15.60	26.79	0.0	0.00	100.0	43	-8.53	38.55	-100.0	0.00	100.0
	Week 38	42	14.29	21.01	0.0	0.00	66.7	38	-8.77	33.50	-100.0	0.00	66.7
	Week 41	41	19.51	25.79	0.0	0.00	100.0	38	-2.63	29.39	-100.0	0.00	33.3
	Week 44	38	16.67	21.57	0.0	0.00	66.7	35	-7.62	39.68	-100.0	0.00	66.7
	Week 47	32	13.54	23.74	0.0	0.00	100.0	30	-8.89	32.68	-100.0	0.00	33.3
	Week 50	29	18.39	22.86	0.0	0.00	66.7	26	-2.56	31.16	-100.0	0.00	33.3
	Week 53	25	17.33	29.06	0.0	0.00	100.0	24	-2.78	43.87	-100.0	0.00	66.7
	Week 56	26	20.51	23.24	0.0	33.33	100.0	26	-3.85	39.25	-100.0	0.00	66.7
	Week 59	20	13.33	19.94	0.0	0.00	66.7	20	-8.33	38.81	-100.0	0.00	33.3
	Week 62	19	21.05	27.69	0.0	0.00	100.0	19	-5.26	38.91	-100.0	0.00	66.7
	Week 65	16	16.67	24.34	0.0	0.00	66.7	16	-2.08	35.42	-100.0	0.00	66.7
	Week 68	13	15.38	25.88	0.0	0.00	66.7	13	0.00	27.22	-33.3	0.00	66.7
	Week 71	13	15.38	22.01	0.0	0.00	66.7	13	-5.13	38.12	-100.0	0.00	66.7
	Week 74	11	9.09	15.57	0.0	0.00	33.3	11	0.00	14.91	-33.3	0.00	33.3
	Week 77	10	6.67	14.05	0.0	0.00	33.3	10	-6.67	34.43	-100.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Europe	EV+Pembro (N= 74)												
	BASELINE	53	27.04	30.00	0.0	33.33	100.0						
	Week 1	48	28.47	35.06	0.0	0.00	100.0	42	0.79	17.25	-33.3	0.00	33.3
	Week 2	53	26.41	28.01	0.0	33.33	100.0	44	4.55	18.46	-33.3	0.00	33.3
	Week 3	50	36.67	32.47	0.0	33.33	100.0	41	9.76	30.04	-66.7	0.00	66.7
	Week 4	51	31.37	32.26	0.0	33.33	100.0	44	4.55	29.28	-66.7	0.00	66.7
	Week 5	46	32.61	29.39	0.0	33.33	100.0	41	8.13	28.66	-66.7	0.00	66.7
	Week 6	50	32.67	32.64	0.0	33.33	100.0	39	9.40	29.57	-66.7	0.00	66.7
	Week 7	50	34.00	32.64	0.0	33.33	100.0	39	9.40	30.54	-66.7	0.00	100.0
	Week 8	51	33.99	30.91	0.0	33.33	100.0	41	13.01	28.75	-66.7	0.00	100.0
	Week 9	47	37.59	35.86	0.0	33.33	100.0	37	11.71	37.86	-66.7	0.00	100.0
	Week 10	45	28.89	33.03	0.0	33.33	100.0	34	6.86	32.60	-66.7	0.00	66.7
	Week 11	48	25.69	28.55	0.0	33.33	100.0	37	6.31	32.24	-66.7	0.00	66.7
	Week 12	51	27.45	31.77	0.0	33.33	100.0	39	4.27	33.49	-66.7	0.00	100.0
	Week 14	50	23.33	26.30	0.0	33.33	100.0	38	2.63	32.31	-66.7	0.00	100.0
	Week 17	43	21.71	29.89	0.0	0.00	100.0	33	-6.06	32.76	-66.7	0.00	66.7
	Week 20	41	16.26	23.71	0.0	0.00	66.7	33	-5.05	29.01	-100.0	0.00	66.7
	Week 23	41	13.82	25.79	0.0	0.00	100.0	30	-6.67	37.55	-100.0	0.00	100.0
	Week 26	37	14.41	25.51	0.0	0.00	100.0	28	-8.33	30.93	-66.7	0.00	66.7
	Week 29	37	16.22	27.91	0.0	0.00	100.0	29	-4.60	36.43	-100.0	0.00	100.0
	Week 32	34	14.71	28.65	0.0	0.00	100.0	26	-11.54	29.73	-100.0	0.00	33.3
	Week 35	31	9.68	17.62	0.0	0.00	66.7	25	-12.00	27.01	-100.0	0.00	33.3
	Week 38	31	18.28	24.10	0.0	0.00	66.7	26	-3.85	34.42	-100.0	0.00	66.7
	Week 41	28	16.67	23.13	0.0	0.00	100.0	23	-7.25	30.08	-100.0	0.00	33.3
	Week 44	27	18.52	26.69	0.0	0.00	100.0	22	1.52	34.85	-66.7	0.00	100.0
	Week 47	25	12.00	16.33	0.0	0.00	33.3	21	-7.94	25.61	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	26	17.95	27.05	0.0	0.00	100.0	23	1.45	32.53	-66.7	0.00	66.7
	Week 53	26	19.23	28.56	0.0	0.00	100.0	21	-3.17	36.37	-66.7	0.00	66.7
	Week 56	25	17.33	25.68	0.0	0.00	66.7	21	-4.76	26.43	-66.7	0.00	33.3
	Week 59	23	10.14	15.68	0.0	0.00	33.3	18	-3.70	19.43	-33.3	0.00	33.3
	Week 62	20	8.33	14.81	0.0	0.00	33.3	17	-7.84	14.58	-33.3	0.00	0.0
	Week 65	13	15.38	25.88	0.0	0.00	66.7	13	0.00	19.25	-33.3	0.00	33.3
	Week 68	15	17.78	24.77	0.0	0.00	66.7	15	-2.22	19.79	-33.3	0.00	33.3
	Week 71	13	17.95	29.23	0.0	0.00	100.0	13	-2.56	21.35	-33.3	0.00	33.3
	Week 74	10	10.00	16.10	0.0	0.00	33.3	9	-11.11	16.67	-33.3	0.00	0.0
	Plat+Gem (N= 95)												
	BASELINE	75	29.78	34.04	0.0	33.33	100.0						
	Week 1	71	36.62	34.34	0.0	33.33	100.0	69	8.21	24.53	-33.3	0.00	100.0
	Week 2	71	31.45	36.90	0.0	33.33	100.0	63	6.88	26.20	-66.7	0.00	100.0
	Week 3	72	29.17	33.07	0.0	33.33	100.0	65	4.62	32.21	-66.7	0.00	100.0
	Week 4	69	22.70	29.97	0.0	0.00	100.0	62	-2.69	29.13	-66.7	0.00	66.7
	Week 5	71	30.99	33.01	0.0	33.33	100.0	63	3.17	30.94	-66.7	0.00	100.0
	Week 6	69	27.54	31.81	0.0	33.33	100.0	61	-1.09	35.47	-100.0	0.00	100.0
	Week 7	69	23.67	28.64	0.0	0.00	100.0	62	-3.23	36.07	-100.0	0.00	66.7
	Week 8	67	19.90	25.99	0.0	0.00	100.0	60	-5.56	30.79	-100.0	0.00	66.7
	Week 9	66	21.72	27.73	0.0	0.00	100.0	57	-4.09	36.77	-100.0	0.00	66.7
	Week 10	70	19.05	25.74	0.0	0.00	100.0	63	-6.35	36.35	-100.0	0.00	66.7
	Week 11	63	21.16	23.42	0.0	33.33	66.7	56	-4.76	32.05	-100.0	0.00	66.7
	Week 12	66	22.73	29.33	0.0	0.00	100.0	56	-2.38	33.55	-100.0	0.00	100.0
	Week 14	66	23.23	24.79	0.0	33.33	100.0	56	-1.19	34.21	-100.0	0.00	66.7
	Week 17	61	22.40	29.01	0.0	0.00	100.0	53	-5.03	36.63	-100.0	0.00	100.0
	Week 20	54	22.22	28.23	0.0	0.00	100.0	48	-4.17	37.43	-66.7	0.00	100.0

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 23	44	21.97	28.70	0.0	0.00	100.0	40	-3.33	38.34	-100.0	0.00	66.7
	Week 26	42	21.43	30.19	0.0	0.00	100.0	39	-5.98	38.90	-100.0	0.00	100.0
	Week 29	39	17.95	25.18	0.0	0.00	100.0	36	-6.48	28.53	-100.0	0.00	33.3
	Week 32	32	23.96	34.11	0.0	0.00	100.0	30	2.22	37.07	-100.0	0.00	100.0
	Week 35	32	17.71	28.06	0.0	0.00	100.0	30	-3.33	36.46	-100.0	0.00	100.0
	Week 38	28	17.86	23.10	0.0	0.00	66.7	26	0.00	28.28	-100.0	0.00	66.7
	Week 41	25	18.67	27.35	0.0	0.00	100.0	23	-2.90	31.64	-100.0	0.00	33.3
	Week 44	24	16.67	21.98	0.0	0.00	66.7	22	-6.06	37.99	-100.0	0.00	66.7
	Week 47	22	18.18	26.68	0.0	0.00	100.0	20	-5.00	32.94	-100.0	0.00	33.3
	Week 50	17	19.61	23.74	0.0	0.00	66.7	15	-8.89	36.66	-100.0	0.00	33.3
	Week 53	15	15.56	24.77	0.0	0.00	66.7	14	-14.29	40.75	-100.0	0.00	33.3
	Week 56	15	24.44	19.79	0.0	33.33	66.7	14	-4.76	34.24	-66.7	0.00	33.3
	Week 59	11	21.21	30.81	0.0	0.00	100.0	10	-3.33	36.68	-100.0	0.00	33.3
	Week 62	11	27.27	32.72	0.0	33.33	100.0	11	6.06	32.72	-66.7	0.00	66.7
	Week 65	10	13.33	23.31	0.0	0.00	66.7	10	-6.67	40.98	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
North America	EV+Pembro (N= 46)												
	BASELINE	33	32.32	34.85	0.0	33.33	100.0						
	Week 1	30	34.44	34.45	0.0	33.33	100.0	27	2.47	18.32	-33.3	0.00	33.3
	Week 2	30	37.78	35.81	0.0	33.33	100.0	26	12.82	29.93	-33.3	0.00	100.0
	Week 3	25	26.67	31.91	0.0	33.33	100.0	21	7.94	25.61	-33.3	0.00	100.0
	Week 4	30	25.55	27.24	0.0	33.33	100.0	24	0.00	29.49	-66.7	0.00	66.7
	Week 5	29	26.44	28.70	0.0	33.33	100.0	21	1.59	34.12	-100.0	0.00	66.7
	Week 6	31	32.26	33.87	0.0	33.33	100.0	23	7.25	38.87	-100.0	0.00	100.0
	Week 7	33	29.29	33.08	0.0	33.33	100.0	23	1.45	38.24	-100.0	0.00	100.0
	Week 8	29	32.18	28.84	0.0	33.33	100.0	20	3.33	43.13	-66.7	0.00	100.0
	Week 9	27	28.39	28.80	0.0	33.33	100.0	21	4.76	36.95	-66.7	0.00	100.0
	Week 10	29	27.59	29.64	0.0	33.33	100.0	23	0.00	38.93	-100.0	0.00	100.0
	Week 11	28	32.14	34.53	0.0	33.33	100.0	21	1.59	40.11	-100.0	0.00	66.7
	Week 12	29	27.59	28.27	0.0	33.33	66.7	22	0.00	32.53	-100.0	0.00	66.7
	Week 14	28	23.81	28.48	0.0	0.00	66.7	21	-3.17	45.83	-100.0	0.00	66.7
	Week 17	29	29.89	33.74	0.0	33.33	100.0	23	0.00	41.44	-100.0	0.00	66.7
	Week 20	23	21.74	31.15	0.0	0.00	100.0	18	-5.56	46.09	-100.0	0.00	100.0
	Week 23	22	15.15	19.86	0.0	0.00	66.7	17	-3.92	28.58	-66.7	0.00	33.3
	Week 26	21	9.52	15.43	0.0	0.00	33.3	16	-8.33	25.82	-66.7	0.00	33.3
	Week 29	20	16.67	27.57	0.0	0.00	100.0	17	-5.88	39.50	-100.0	0.00	66.7
	Week 32	21	19.05	30.86	0.0	0.00	100.0	18	-9.26	40.91	-100.0	0.00	66.7
	Week 35	22	15.15	24.62	0.0	0.00	66.7	19	-8.77	36.59	-100.0	0.00	66.7
	Week 38	20	18.33	29.57	0.0	0.00	100.0	17	-7.84	41.72	-100.0	0.00	66.7
	Week 41	21	9.52	21.46	0.0	0.00	66.7	17	-7.84	30.11	-66.7	0.00	66.7
	Week 44	16	12.50	23.96	0.0	0.00	66.7	12	-8.33	32.18	-66.7	0.00	66.7
	Week 47	16	12.50	26.87	0.0	0.00	100.0	13	-7.69	30.89	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	16	14.58	20.97	0.0	0.00	66.7	11	0.00	36.52	-66.7	0.00	66.7
	Week 53	15	11.11	20.57	0.0	0.00	66.7	11	-12.12	22.47	-66.7	0.00	0.0
	Week 56	17	13.73	23.74	0.0	0.00	66.7	12	-8.33	28.87	-66.7	0.00	33.3
	Week 59	17	13.72	20.61	0.0	0.00	66.7	12	-11.11	25.95	-66.7	0.00	33.3
	Week 62	14	9.52	20.38	0.0	0.00	66.7	9	-11.11	23.57	-66.7	0.00	0.0
	Week 68	11	6.06	13.48	0.0	0.00	33.3	8	-8.33	29.55	-66.7	0.00	33.3
	Week 71	11	12.12	22.47	0.0	0.00	66.7	8	-8.33	23.57	-66.7	0.00	0.0
	Plat+Gem (N= 34)												
	BASELINE	27	41.97	40.92	0.0	33.33	100.0						
	Week 1	19	26.31	32.54	0.0	33.33	100.0	17	-11.77	33.21	-100.0	0.00	33.3
	Week 2	20	30.00	32.26	0.0	33.33	100.0	18	-7.41	21.56	-66.7	0.00	33.3
	Week 3	20	23.33	26.71	0.0	33.33	100.0	17	-11.77	26.20	-66.7	0.00	33.3
	Week 4	23	18.84	24.26	0.0	0.00	66.7	19	-12.28	22.80	-66.7	0.00	33.3
	Week 5	25	21.33	23.33	0.0	33.33	66.7	22	-13.64	28.47	-100.0	0.00	33.3
	Week 6	20	20.00	25.13	0.0	0.00	66.7	17	-15.69	37.49	-100.0	0.00	33.3
	Week 7	23	27.54	35.75	0.0	0.00	100.0	20	-10.00	40.61	-100.0	0.00	66.7
	Week 8	24	33.33	32.60	0.0	33.33	100.0	22	-4.55	36.07	-66.7	0.00	100.0
	Week 9	23	18.84	22.08	0.0	0.00	66.7	19	-17.54	39.08	-100.0	0.00	33.3
	Week 10	20	21.67	22.36	0.0	33.33	66.7	18	-12.96	34.56	-100.0	0.00	33.3
	Week 11	18	12.96	16.72	0.0	0.00	33.3	16	-18.75	34.36	-100.0	0.00	33.3
	Week 12	17	25.49	30.12	0.0	0.00	66.7	16	-18.75	43.83	-100.0	0.00	66.7
	Week 14	16	10.42	20.07	0.0	0.00	66.7	14	-26.19	41.71	-100.0	0.00	0.0
	Week 17	19	15.79	28.04	0.0	0.00	100.0	17	-15.69	50.16	-100.0	0.00	66.7
	Week 20	16	12.50	20.64	0.0	0.00	66.7	13	-17.95	52.02	-100.0	0.00	33.3
	Week 23	15	17.78	24.77	0.0	0.00	66.7	13	-17.95	48.34	-100.0	0.00	66.7
	Week 26	13	25.64	30.89	0.0	33.33	100.0	12	-5.56	37.15	-100.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 29	14	23.81	33.15	0.0	0.00	100.0	13	-5.13	40.48	-100.0	0.00	66.7
	Week 32	11	12.12	22.47	0.0	0.00	66.7	10	-16.67	36.00	-100.0	0.00	33.3
	Week 35	13	10.26	21.01	0.0	0.00	66.7	11	-24.24	42.40	-100.0	0.00	33.3
	Week 38	10	23.33	35.31	0.0	0.00	100.0	9	-7.41	52.12	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Rest of World	EV+Pembro (N= 82)												
	BASELINE	74	28.38	31.54	0.0	33.33	100.0						
	Week 1	63	31.75	30.19	0.0	33.33	100.0	60	2.78	17.67	-33.3	0.00	33.3
	Week 2	67	39.80	31.91	0.0	33.33	100.0	63	10.58	25.98	-66.7	0.00	66.7
	Week 3	64	34.90	34.34	0.0	33.33	100.0	60	8.33	26.49	-33.3	0.00	100.0
	Week 4	64	28.12	30.41	0.0	33.33	100.0	61	2.19	27.80	-66.7	0.00	66.7
	Week 5	62	30.11	30.60	0.0	33.33	100.0	59	4.52	28.67	-33.3	0.00	100.0
	Week 6	65	35.90	34.52	0.0	33.33	100.0	62	10.22	35.50	-66.7	0.00	100.0
	Week 7	64	27.60	31.18	0.0	33.33	100.0	62	0.54	27.98	-66.7	0.00	66.7
	Week 8	67	27.36	28.97	0.0	33.33	100.0	63	1.06	33.32	-66.7	0.00	100.0
	Week 9	68	29.90	30.00	0.0	33.33	100.0	63	4.76	31.03	-66.7	0.00	66.7
	Week 10	65	29.23	30.34	0.0	33.33	100.0	61	4.37	33.60	-66.7	0.00	100.0
	Week 11	61	28.96	29.49	0.0	33.33	100.0	57	4.09	36.77	-100.0	0.00	100.0
	Week 12	62	25.27	29.99	0.0	16.67	100.0	58	-1.15	29.27	-66.7	0.00	66.7
	Week 14	61	26.78	30.32	0.0	33.33	100.0	57	0.00	31.50	-66.7	0.00	66.7
	Week 17	60	26.11	23.84	0.0	33.33	100.0	55	3.64	30.55	-66.7	0.00	66.7
	Week 20	56	23.21	23.72	0.0	33.33	66.7	52	0.00	26.40	-66.7	0.00	66.7
	Week 23	54	20.99	24.48	0.0	0.00	66.7	50	-0.67	26.51	-66.7	0.00	66.7
	Week 26	54	21.60	23.49	0.0	33.33	100.0	50	0.00	31.59	-66.7	0.00	66.7
	Week 29	50	18.67	20.38	0.0	16.67	66.7	47	-4.97	31.07	-66.7	0.00	33.3
	Week 32	47	17.73	21.81	0.0	0.00	66.7	44	-6.82	31.81	-66.7	0.00	66.7
	Week 35	45	20.00	22.92	0.0	0.00	66.7	42	-3.18	32.77	-100.0	0.00	66.7
	Week 38	46	19.56	19.34	0.0	33.33	66.7	43	-3.88	27.42	-66.7	0.00	33.3
	Week 41	46	21.74	25.55	0.0	16.67	100.0	44	-1.52	33.68	-100.0	0.00	100.0
	Week 44	43	20.93	25.22	0.0	0.00	100.0	40	-4.17	30.37	-66.7	0.00	66.7
	Week 47	38	17.54	20.11	0.0	0.00	66.7	36	-9.26	27.15	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	32	22.92	21.48	0.0	33.33	66.7	30	-5.56	32.85	-100.0	0.00	33.3
	Week 53	33	26.26	23.21	0.0	33.33	66.7	31	-4.30	33.05	-100.0	0.00	33.3
	Week 56	30	22.22	20.22	0.0	33.33	66.7	28	-5.95	34.01	-66.7	0.00	33.3
	Week 59	29	24.14	25.03	0.0	33.33	66.7	27	-6.17	37.02	-66.7	0.00	66.7
	Week 62	28	17.86	23.10	0.0	0.00	66.7	26	-10.26	29.47	-66.7	0.00	33.3
	Week 65	22	21.21	24.22	0.0	16.67	66.7	21	-7.94	33.17	-66.7	0.00	33.3
	Week 68	20	21.67	27.09	0.0	0.00	66.7	19	-3.51	36.68	-66.7	0.00	66.7
	Week 71	18	16.67	23.57	0.0	0.00	66.7	17	-13.73	31.31	-66.7	0.00	33.3
	Week 74	19	17.54	23.22	0.0	0.00	66.7	19	-8.77	33.04	-66.7	0.00	33.3
	Week 77	19	17.54	20.39	0.0	0.00	66.7	18	-11.11	32.34	-66.7	0.00	33.3
	Week 80	19	24.56	26.86	0.0	33.33	66.7	18	-3.70	35.95	-66.7	0.00	66.7
	Week 83	17	21.57	26.20	0.0	0.00	66.7	17	-5.88	46.00	-100.0	0.00	66.7
	Week 86	14	21.43	24.83	0.0	16.67	66.7	14	-7.14	39.61	-66.7	-16.67	66.7
	Week 89	11	15.15	27.34	0.0	0.00	66.7	11	-6.06	35.96	-66.7	0.00	66.7
	Plat+Gem (N= 73)												
	BASELINE	63	25.93	31.36	0.0	0.00	100.0						
	Week 1	54	33.33	31.72	0.0	33.33	100.0	53	5.66	25.93	-66.7	0.00	66.7
	Week 2	56	33.93	32.09	0.0	33.33	100.0	54	8.02	27.42	-66.7	0.00	100.0
	Week 3	57	33.33	30.86	0.0	33.33	100.0	54	8.02	26.65	-33.3	0.00	66.7
	Week 4	58	33.33	27.92	0.0	33.33	100.0	54	7.41	29.44	-66.7	0.00	66.7
	Week 5	57	35.09	28.47	0.0	33.33	100.0	53	9.43	30.23	-66.7	0.00	66.7
	Week 6	56	30.36	27.17	0.0	33.33	100.0	53	6.92	28.76	-100.0	0.00	66.7
	Week 7	56	32.74	27.33	0.0	33.33	100.0	52	8.97	33.08	-100.0	0.00	66.7
	Week 8	54	33.95	29.31	0.0	33.33	100.0	50	10.67	37.76	-100.0	0.00	100.0
	Week 9	52	32.05	27.19	0.0	33.33	100.0	49	6.80	35.99	-100.0	0.00	100.0
	Week 10	52	29.49	27.74	0.0	33.33	100.0	49	7.48	34.20	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	45	34.07	32.17	0.0	33.33	100.0	42	9.52	34.76	-100.0	0.00	100.0
	Week 12	47	34.04	29.07	0.0	33.33	100.0	43	10.85	36.17	-100.0	0.00	100.0
	Week 14	43	34.11	26.72	0.0	33.33	100.0	39	10.26	39.11	-100.0	33.33	100.0
	Week 17	40	28.33	23.33	0.0	33.33	66.7	36	2.78	37.69	-100.0	0.00	66.7
	Week 20	34	21.57	27.07	0.0	0.00	100.0	30	-4.44	29.98	-100.0	0.00	66.7
	Week 23	29	20.69	27.33	0.0	0.00	100.0	27	0.00	32.03	-66.7	0.00	66.7
	Week 26	26	16.67	23.57	0.0	0.00	100.0	24	-6.94	31.05	-100.0	0.00	33.3
	Week 29	24	12.50	25.66	0.0	0.00	100.0	22	-7.58	28.97	-100.0	0.00	33.3
	Week 32	20	11.67	19.57	0.0	0.00	66.7	18	-11.11	30.25	-100.0	0.00	33.3
	Week 35	17	17.65	20.81	0.0	0.00	66.7	15	-2.22	34.43	-100.0	0.00	33.3
	Week 38	18	12.96	16.72	0.0	0.00	33.3	15	-11.11	37.09	-100.0	0.00	33.3
	Week 41	18	18.52	23.49	0.0	0.00	66.7	16	0.00	27.22	-66.7	0.00	33.3
	Week 44	16	20.83	20.64	0.0	33.33	66.7	14	0.00	41.35	-100.0	0.00	66.7
	Week 47	12	19.44	22.28	0.0	16.67	66.7	11	9.09	21.55	-33.3	0.00	33.3
	Week 50	11	21.21	22.47	0.0	33.33	66.7	9	3.70	20.03	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	EV+Pembro (N=146)												
	BASELINE	119	27.73	31.69	0.0	33.33	100.0						
	Week 1	102	30.39	33.86	0.0	33.33	100.0	97	3.09	17.40	-33.3	0.00	33.3
	Week 2	106	35.53	32.29	0.0	33.33	100.0	98	11.22	25.30	-33.3	0.00	100.0
	Week 3	94	32.27	32.22	0.0	33.33	100.0	88	9.47	29.88	-66.7	0.00	100.0
	Week 4	101	28.38	29.59	0.0	33.33	100.0	93	3.94	29.43	-66.7	0.00	66.7
	Week 5	96	26.74	28.04	0.0	33.33	100.0	89	4.12	31.31	-100.0	0.00	100.0
	Week 6	105	34.29	34.42	0.0	33.33	100.0	93	11.83	36.00	-100.0	0.00	100.0
	Week 7	102	28.76	32.85	0.0	33.33	100.0	89	5.24	34.05	-100.0	0.00	100.0
	Week 8	101	29.04	29.31	0.0	33.33	100.0	91	6.59	34.86	-66.7	0.00	100.0
	Week 9	100	29.67	32.44	0.0	33.33	100.0	89	7.49	33.99	-66.7	0.00	100.0
	Week 10	99	26.94	30.00	0.0	33.33	100.0	87	3.45	34.86	-100.0	0.00	100.0
	Week 11	95	26.32	30.32	0.0	33.33	100.0	84	5.16	37.13	-100.0	0.00	100.0
	Week 12	99	25.25	30.53	0.0	0.00	100.0	87	1.92	30.23	-100.0	0.00	66.7
	Week 14	95	24.21	28.54	0.0	0.00	100.0	84	1.19	35.64	-100.0	0.00	66.7
	Week 17	97	25.09	28.48	0.0	33.33	100.0	84	2.78	35.55	-100.0	0.00	66.7
	Week 20	90	18.89	25.01	0.0	0.00	100.0	79	-2.11	33.48	-100.0	0.00	100.0
	Week 23	86	17.05	23.84	0.0	0.00	100.0	74	-1.80	31.64	-100.0	0.00	100.0
	Week 26	83	18.47	25.10	0.0	0.00	100.0	72	0.00	30.64	-66.7	0.00	66.7
	Week 29	80	17.92	25.95	0.0	0.00	100.0	71	-2.35	35.78	-100.0	0.00	100.0
	Week 32	74	14.41	24.72	0.0	0.00	100.0	66	-8.08	34.62	-100.0	0.00	66.7
	Week 35	73	15.07	22.25	0.0	0.00	66.7	66	-6.57	32.14	-100.0	0.00	66.7
	Week 38	75	17.78	23.46	0.0	0.00	100.0	67	-4.48	31.73	-100.0	0.00	66.7
	Week 41	71	17.37	25.11	0.0	0.00	100.0	64	-2.60	31.60	-100.0	0.00	100.0
	Week 44	64	17.19	22.22	0.0	0.00	66.7	56	-2.38	29.03	-66.7	0.00	66.7
	Week 47	56	14.88	21.00	0.0	0.00	100.0	50	-6.67	26.94	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	55	20.00	24.51	0.0	0.00	100.0	48	-0.70	31.13	-66.7	0.00	66.7
	Week 53	55	18.79	25.47	0.0	0.00	100.0	48	-5.56	31.01	-66.7	0.00	66.7
	Week 56	53	20.13	23.88	0.0	0.00	66.7	46	-5.07	29.79	-66.7	0.00	33.3
	Week 59	51	16.34	22.48	0.0	0.00	66.7	43	-5.43	28.11	-66.7	0.00	66.7
	Week 62	42	14.29	21.01	0.0	0.00	66.7	36	-6.48	22.28	-66.7	0.00	33.3
	Week 65	31	18.28	24.10	0.0	0.00	66.7	30	-2.22	26.16	-66.7	0.00	33.3
	Week 68	31	17.20	24.15	0.0	0.00	66.7	29	-1.15	27.43	-66.7	0.00	66.7
	Week 71	30	16.67	25.89	0.0	0.00	100.0	28	-5.95	24.09	-66.7	0.00	33.3
	Week 74	29	12.64	20.73	0.0	0.00	66.7	27	-8.64	23.74	-66.7	0.00	33.3
	Week 77	26	14.10	19.26	0.0	0.00	66.7	24	-5.56	27.22	-66.7	0.00	33.3
	Week 80	26	20.51	25.08	0.0	0.00	66.7	26	0.00	28.28	-66.7	0.00	66.7
	Week 83	21	14.29	22.54	0.0	0.00	66.7	21	-3.17	33.17	-66.7	0.00	66.7
	Week 86	17	13.73	23.74	0.0	0.00	66.7	17	-1.96	29.98	-33.3	0.00	66.7
	Week 89	11	12.12	22.47	0.0	0.00	66.7	11	0.00	25.82	-33.3	0.00	66.7
	Week 92	13	12.82	21.68	0.0	0.00	66.7	13	-7.69	19.97	-33.3	0.00	33.3
	Plat+Gem (N=151)												
	BASELINE	123	27.37	34.42	0.0	0.00	100.0						
	Week 1	108	29.32	32.13	0.0	33.33	100.0	103	3.56	27.97	-100.0	0.00	100.0
	Week 2	116	28.16	32.78	0.0	33.33	100.0	105	5.40	25.37	-66.7	0.00	100.0
	Week 3	114	27.19	30.26	0.0	33.33	100.0	103	5.18	29.06	-66.7	0.00	100.0
	Week 4	116	24.14	27.66	0.0	33.33	100.0	103	1.29	26.37	-66.7	0.00	66.7
	Week 5	119	28.57	30.47	0.0	33.33	100.0	106	2.83	29.86	-100.0	0.00	100.0
	Week 6	109	24.16	29.00	0.0	33.33	100.0	98	0.34	32.64	-100.0	0.00	100.0
	Week 7	115	26.09	29.55	0.0	33.33	100.0	105	2.22	34.67	-100.0	0.00	66.7
	Week 8	111	24.92	28.24	0.0	33.33	100.0	102	1.96	34.73	-100.0	0.00	100.0
	Week 9	107	23.68	26.70	0.0	33.33	100.0	95	0.35	35.56	-100.0	0.00	100.0

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	107	20.87	24.45	0.0	0.00	100.0	98	0.00	34.85	-100.0	0.00	66.7
	Week 11	97	24.05	26.68	0.0	33.33	100.0	87	1.53	34.44	-100.0	0.00	100.0
	Week 12	100	26.00	29.04	0.0	33.33	100.0	88	2.65	37.90	-100.0	0.00	100.0
	Week 14	99	23.57	24.40	0.0	33.33	100.0	86	1.94	38.72	-100.0	0.00	100.0
	Week 17	94	22.69	26.42	0.0	16.67	100.0	82	-1.63	38.81	-100.0	0.00	66.7
	Week 20	84	21.43	28.17	0.0	0.00	100.0	72	-3.24	35.45	-100.0	0.00	100.0
	Week 23	70	21.43	28.40	0.0	0.00	100.0	62	-1.61	39.78	-100.0	0.00	66.7
	Week 26	61	24.04	30.51	0.0	0.00	100.0	55	1.82	34.20	-100.0	0.00	100.0
	Week 29	59	15.25	25.01	0.0	0.00	100.0	53	-4.40	27.76	-100.0	0.00	33.3
	Week 32	50	15.33	26.26	0.0	0.00	100.0	45	-3.70	33.50	-100.0	0.00	100.0
	Week 35	50	17.33	23.56	0.0	0.00	100.0	44	-1.52	35.91	-100.0	0.00	100.0
	Week 38	46	15.94	20.77	0.0	0.00	66.7	40	-2.50	34.91	-100.0	0.00	66.7
	Week 41	42	18.25	24.64	0.0	0.00	66.7	37	0.00	31.43	-100.0	0.00	66.7
	Week 44	39	16.24	20.05	0.0	0.00	66.7	34	-1.96	37.55	-100.0	0.00	66.7
	Week 47	33	14.14	23.61	0.0	0.00	100.0	29	-6.90	37.14	-100.0	0.00	33.3
	Week 50	27	18.52	21.35	0.0	0.00	66.7	22	-4.55	33.01	-100.0	0.00	33.3
	Week 53	23	15.94	24.35	0.0	0.00	66.7	20	-8.33	46.99	-100.0	0.00	66.7
	Week 56	20	18.33	20.16	0.0	16.67	66.7	19	-3.51	33.14	-66.7	0.00	33.3
	Week 59	17	21.57	28.73	0.0	0.00	100.0	15	-11.11	39.17	-100.0	0.00	33.3
	Week 62	14	21.43	24.83	0.0	16.67	66.7	14	-4.76	36.65	-66.7	0.00	66.7
	Week 65	13	17.95	25.88	0.0	0.00	66.7	12	-2.78	38.82	-100.0	0.00	66.7
	Week 68	10	13.33	23.31	0.0	0.00	66.7	10	3.33	29.19	-33.3	0.00	66.7
	Week 71	10	16.67	23.57	0.0	0.00	66.7	10	6.67	26.29	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	EV+Pembro (N= 56)												
	BASELINE	41	31.71	31.58	0.0	33.33	100.0						
	Week 1	39	33.33	29.62	0.0	33.33	100.0	32	-1.04	17.93	-33.3	0.00	33.3
	Week 2	44	32.58	30.91	0.0	33.33	100.0	35	2.86	21.95	-66.7	0.00	33.3
	Week 3	45	37.78	35.25	0.0	33.33	100.0	34	6.86	19.73	-33.3	0.00	66.7
	Week 4	44	29.54	32.32	0.0	33.33	100.0	36	-0.93	25.80	-66.7	0.00	33.3
	Week 5	41	38.21	32.11	0.0	33.33	100.0	32	8.33	23.95	-33.3	0.00	66.7
	Week 6	41	33.33	31.62	0.0	33.33	100.0	31	2.15	27.13	-66.7	0.00	66.7
	Week 7	45	33.33	30.15	0.0	33.33	100.0	35	-0.95	20.59	-33.3	0.00	33.3
	Week 8	46	34.06	30.22	0.0	33.33	100.0	33	2.02	31.11	-66.7	0.00	66.7
	Week 9	42	38.10	29.97	0.0	33.33	100.0	32	5.21	35.02	-33.3	0.00	100.0
	Week 10	40	33.33	32.90	0.0	33.33	100.0	31	6.45	32.68	-66.7	0.00	66.7
	Week 11	42	33.33	29.45	0.0	33.33	100.0	31	2.15	32.13	-66.7	0.00	66.7
	Week 12	43	29.46	29.29	0.0	33.33	100.0	32	-2.08	33.80	-66.7	0.00	100.0
	Week 14	44	26.51	28.38	0.0	33.33	100.0	32	-2.08	31.61	-66.7	0.00	100.0
	Week 17	35	26.67	27.77	0.0	33.33	100.0	27	-8.64	25.48	-66.7	0.00	33.3
	Week 20	30	25.56	25.80	0.0	33.33	66.7	24	-4.17	22.66	-66.7	0.00	33.3
	Week 23	31	18.28	25.59	0.0	0.00	66.7	23	-7.25	26.51	-66.7	0.00	33.3
	Week 26	29	12.64	16.46	0.0	0.00	33.3	22	-16.67	26.73	-66.7	0.00	33.3
	Week 29	27	16.05	19.33	0.0	0.00	66.7	22	-13.64	26.55	-66.7	0.00	33.3
	Week 32	28	23.81	28.48	0.0	16.67	100.0	22	-10.61	27.96	-66.7	0.00	33.3
	Week 35	25	17.33	21.77	0.0	0.00	66.7	20	-8.33	32.22	-100.0	0.00	33.3
	Week 38	22	22.73	21.54	0.0	33.33	66.7	19	-5.26	35.60	-66.7	0.00	66.7
	Week 41	24	18.05	21.93	0.0	0.00	66.7	20	-10.00	32.62	-100.0	0.00	33.3
	Week 44	22	22.73	33.15	0.0	0.00	100.0	18	-5.56	40.02	-66.7	0.00	100.0
	Week 47	23	14.49	19.66	0.0	0.00	66.7	20	-13.33	27.36	-66.7	0.00	33.3

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	19	17.54	20.39	0.0	0.00	66.7	16	-6.25	38.91	-100.0	0.00	33.3
	Week 53	19	26.31	23.78	0.0	33.33	66.7	15	-4.44	37.52	-100.0	0.00	33.3
	Week 56	19	14.03	20.23	0.0	0.00	66.7	15	-8.89	32.04	-66.7	0.00	33.3
	Week 59	18	18.52	20.52	0.0	16.67	66.7	14	-9.52	35.64	-66.7	0.00	33.3
	Week 62	20	10.00	19.04	0.0	0.00	66.7	16	-16.67	27.22	-66.7	0.00	33.3
	Week 65	12	11.11	21.71	0.0	0.00	66.7	10	-20.00	32.20	-66.7	-16.67	33.3
	Week 68	15	15.56	24.77	0.0	0.00	66.7	13	-10.26	34.39	-66.7	0.00	33.3
	Week 71	12	13.89	22.29	0.0	0.00	66.7	10	-16.67	32.39	-66.7	0.00	33.3
	Week 77	11	12.12	22.47	0.0	0.00	66.7	9	-22.22	28.87	-66.7	0.00	0.0
	Week 80	10	16.67	28.33	0.0	0.00	66.7	8	-16.67	35.64	-66.7	0.00	33.3
	Plat+Gem (N= 51)												
	BASELINE	42	38.89	33.67	0.0	33.33	100.0						
	Week 1	36	48.15	32.31	0.0	33.33	100.0	36	8.33	23.06	-33.3	0.00	66.7
	Week 2	31	47.31	36.29	0.0	33.33	100.0	30	5.56	30.43	-66.7	0.00	66.7
	Week 3	35	39.05	33.81	0.0	33.33	100.0	33	0.00	32.28	-66.7	0.00	66.7
	Week 4	34	33.33	31.78	0.0	33.33	100.0	32	-4.17	36.66	-66.7	0.00	66.7
	Week 5	34	39.21	27.79	0.0	33.33	100.0	32	3.12	35.28	-66.7	0.00	66.7
	Week 6	36	37.96	27.78	0.0	33.33	100.0	33	0.00	37.27	-66.7	0.00	66.7
	Week 7	33	33.33	28.87	0.0	33.33	100.0	29	-5.75	40.89	-100.0	0.00	66.7
	Week 8	34	35.29	30.64	0.0	33.33	100.0	30	-3.33	36.46	-100.0	0.00	66.7
	Week 9	34	29.41	28.15	0.0	33.33	100.0	30	-8.89	42.83	-100.0	0.00	66.7
	Week 10	35	30.48	30.65	0.0	33.33	100.0	32	-8.33	38.80	-100.0	0.00	66.7
	Week 11	29	26.44	28.70	0.0	33.33	100.0	27	-11.11	33.33	-100.0	0.00	33.3
	Week 12	30	31.11	31.48	0.0	33.33	100.0	27	-7.41	33.76	-100.0	0.00	33.3
	Week 14	26	32.05	30.52	0.0	33.33	100.0	23	-8.70	36.54	-100.0	0.00	33.3
	Week 17	26	25.64	30.27	0.0	33.33	100.0	24	-12.50	41.49	-100.0	0.00	100.0

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 20	20	16.67	20.23	0.0	0.00	66.7	19	-17.54	43.56	-100.0	0.00	66.7
	Week 23	18	18.52	23.49	0.0	0.00	66.7	18	-14.82	30.73	-66.7	0.00	33.3
	Week 26	20	10.00	15.67	0.0	0.00	33.3	20	-28.33	31.11	-100.0	-33.33	0.0
	Week 29	18	24.07	31.94	0.0	0.00	100.0	18	-12.96	38.16	-100.0	0.00	66.7
	Week 32	13	28.20	35.61	0.0	33.33	100.0	13	-10.26	41.69	-100.0	0.00	66.7
	Week 35	12	11.11	29.59	0.0	0.00	100.0	12	-27.78	37.15	-100.0	-33.33	33.3
	Week 38	10	23.33	35.31	0.0	0.00	100.0	10	-13.33	39.13	-100.0	0.00	33.3
	Week 41	10	30.00	33.15	0.0	33.33	100.0	10	0.00	22.22	-33.3	0.00	33.3
	Week 44	10	26.67	34.43	0.0	16.67	100.0	10	-10.00	35.31	-100.0	0.00	33.3
	Week 47	10	26.67	26.29	0.0	33.33	66.7	10	0.00	15.71	-33.3	0.00	33.3
	Week 56	10	26.67	30.63	0.0	33.33	100.0	10	-10.00	49.82	-100.0	0.00	66.7

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Visceral metastases	EV+Pembro (N=148)												
	BASELINE	119	31.93	33.73	0.0	33.33	100.0						
	Week 1	105	34.29	33.80	0.0	33.33	100.0	99	2.69	17.61	-33.3	0.00	33.3
	Week 2	109	37.31	32.94	0.0	33.33	100.0	100	8.00	26.00	-66.7	0.00	100.0
	Week 3	98	34.35	34.99	0.0	33.33	100.0	88	6.82	27.29	-66.7	0.00	100.0
	Week 4	103	30.74	31.20	0.0	33.33	100.0	93	2.51	29.59	-66.7	0.00	66.7
	Week 5	100	29.33	29.31	0.0	33.33	100.0	90	2.59	28.80	-100.0	0.00	100.0
	Week 6	105	34.92	34.40	0.0	33.33	100.0	90	6.67	34.33	-100.0	0.00	100.0
	Week 7	108	29.94	31.55	0.0	33.33	100.0	91	1.46	31.00	-100.0	0.00	100.0
	Week 8	105	30.79	29.12	0.0	33.33	100.0	89	2.25	32.88	-66.7	0.00	100.0
	Week 9	105	34.60	33.31	0.0	33.33	100.0	91	6.59	35.56	-66.7	0.00	100.0
	Week 10	101	30.03	31.80	0.0	33.33	100.0	86	2.33	35.35	-100.0	0.00	100.0
	Week 11	97	29.21	28.57	0.0	33.33	100.0	83	3.61	37.55	-100.0	0.00	66.7
	Week 12	100	28.67	30.71	0.0	33.33	100.0	85	1.96	33.87	-100.0	0.00	100.0
	Week 14	102	25.82	29.26	0.0	33.33	100.0	87	-0.38	37.18	-100.0	0.00	100.0
	Week 17	96	25.69	27.14	0.0	33.33	100.0	81	-1.65	34.92	-100.0	0.00	66.7
	Week 20	87	21.84	25.83	0.0	0.00	100.0	76	-2.63	33.45	-100.0	0.00	100.0
	Week 23	85	18.04	24.96	0.0	0.00	100.0	71	-2.82	32.73	-100.0	0.00	100.0
	Week 26	79	17.72	22.54	0.0	0.00	100.0	66	-4.04	32.30	-66.7	0.00	66.7
	Week 29	72	16.67	23.07	0.0	0.00	100.0	64	-8.33	34.12	-100.0	0.00	66.7
	Week 32	71	16.90	24.48	0.0	0.00	100.0	62	-10.75	34.02	-100.0	0.00	66.7
	Week 35	70	14.76	20.96	0.0	0.00	66.7	63	-8.47	33.85	-100.0	0.00	66.7
	Week 38	70	18.57	22.44	0.0	0.00	100.0	63	-6.35	33.26	-100.0	0.00	66.7
	Week 41	66	18.18	24.24	0.0	0.00	100.0	60	-6.11	31.59	-100.0	0.00	66.7
	Week 44	59	22.03	27.41	0.0	0.00	100.0	53	-1.26	32.66	-66.7	0.00	100.0
	Week 47	52	15.38	21.35	0.0	0.00	100.0	48	-9.72	28.32	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	49	19.73	24.46	0.0	0.00	100.0	43	-3.88	36.52	-100.0	0.00	66.7
	Week 53	50	22.00	26.61	0.0	0.00	100.0	44	-6.82	32.61	-100.0	0.00	66.7
	Week 56	45	22.96	23.38	0.0	33.33	66.7	39	-5.13	30.15	-66.7	0.00	33.3
	Week 59	44	19.70	21.94	0.0	16.67	66.7	38	-6.14	32.75	-66.7	0.00	66.7
	Week 62	38	14.91	21.50	0.0	0.00	66.7	33	-8.08	25.04	-66.7	0.00	33.3
	Week 65	25	20.00	23.57	0.0	0.00	66.7	24	-4.17	31.57	-66.7	0.00	33.3
	Week 68	31	17.20	24.15	0.0	0.00	66.7	29	-1.15	30.19	-66.7	0.00	66.7
	Week 71	27	16.05	25.10	0.0	0.00	100.0	25	-8.00	25.96	-66.7	0.00	33.3
	Week 74	23	14.49	22.08	0.0	0.00	66.7	22	-10.61	27.96	-66.7	0.00	33.3
	Week 77	24	16.67	19.66	0.0	0.00	66.7	23	-7.25	30.08	-66.7	0.00	33.3
	Week 80	22	24.24	25.58	0.0	33.33	66.7	22	-1.52	33.30	-66.7	0.00	66.7
	Week 83	19	21.05	25.36	0.0	0.00	66.7	19	-3.51	42.88	-100.0	0.00	66.7
	Week 86	14	19.05	25.20	0.0	0.00	66.7	14	-7.14	37.39	-66.7	0.00	66.7
	Week 89	10	16.67	28.33	0.0	0.00	66.7	10	0.00	31.43	-33.3	0.00	66.7
	Week 92	11	21.21	22.47	0.0	33.33	66.7	11	-6.06	20.10	-33.3	0.00	33.3
	Plat+Gem (N=157)												
	BASELINE	128	32.55	35.85	0.0	33.33	100.0						
	Week 1	111	35.13	33.89	0.0	33.33	100.0	107	4.05	26.19	-66.7	0.00	66.7
	Week 2	110	33.03	35.12	0.0	33.33	100.0	102	4.25	25.12	-66.7	0.00	100.0
	Week 3	112	31.25	32.35	0.0	33.33	100.0	103	2.91	28.81	-66.7	0.00	66.7
	Week 4	112	27.98	29.87	0.0	33.33	100.0	102	-0.65	31.11	-66.7	0.00	66.7
	Week 5	113	30.97	31.09	0.0	33.33	100.0	103	0.65	29.51	-66.7	0.00	66.7
	Week 6	107	26.79	30.18	0.0	33.33	100.0	98	-1.70	32.24	-100.0	0.00	66.7
	Week 7	109	26.91	30.59	0.0	33.33	100.0	100	-1.67	37.42	-100.0	0.00	66.7
	Week 8	106	27.36	30.79	0.0	33.33	100.0	98	0.00	36.45	-100.0	0.00	100.0
	Week 9	105	25.08	27.65	0.0	33.33	100.0	94	-2.48	38.25	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.19.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	104	22.44	26.86	0.0	16.67	100.0	96	-3.13	34.90	-100.0	0.00	66.7
	Week 11	91	24.54	28.47	0.0	33.33	100.0	83	-2.01	33.07	-100.0	0.00	100.0
	Week 12	94	24.11	29.09	0.0	0.00	100.0	84	-3.17	37.53	-100.0	0.00	100.0
	Week 14	90	21.85	25.06	0.0	33.33	100.0	79	-3.38	37.97	-100.0	0.00	100.0
	Week 17	90	23.33	28.46	0.0	0.00	100.0	80	-5.00	40.08	-100.0	0.00	100.0
	Week 20	74	18.92	27.08	0.0	0.00	100.0	64	-9.37	35.37	-100.0	0.00	66.7
	Week 23	63	22.22	29.33	0.0	0.00	100.0	58	-4.60	36.65	-100.0	0.00	66.7
	Week 26	55	21.21	28.23	0.0	0.00	100.0	52	-5.77	34.76	-100.0	0.00	66.7
	Week 29	53	16.98	27.44	0.0	0.00	100.0	50	-6.00	29.88	-100.0	0.00	33.3
	Week 32	42	14.29	28.65	0.0	0.00	100.0	40	-6.67	34.76	-100.0	0.00	66.7
	Week 35	39	14.53	23.93	0.0	0.00	100.0	36	-7.41	32.96	-100.0	0.00	33.3
	Week 38	37	16.22	25.61	0.0	0.00	100.0	34	-3.92	33.60	-100.0	0.00	66.7
	Week 41	33	17.17	27.79	0.0	0.00	100.0	31	-1.08	30.41	-100.0	0.00	66.7
	Week 44	32	16.67	25.40	0.0	0.00	100.0	30	-3.33	35.40	-100.0	0.00	66.7
	Week 47	28	17.86	27.94	0.0	0.00	100.0	26	-2.56	29.70	-100.0	0.00	33.3
	Week 50	22	18.18	24.62	0.0	0.00	66.7	20	-1.67	29.57	-100.0	0.00	33.3
	Week 53	19	17.54	28.04	0.0	0.00	66.7	17	-5.88	42.88	-100.0	0.00	66.7
	Week 56	18	16.67	20.61	0.0	0.00	66.7	17	-11.77	35.24	-100.0	0.00	33.3
	Week 59	13	20.51	28.99	0.0	0.00	100.0	12	-16.67	38.93	-100.0	0.00	33.3
	Week 62	11	18.18	22.92	0.0	0.00	66.7	11	-15.15	37.60	-100.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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Table 302.1.3002.19.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Lymph node only	EV+Pembro (N= 43)												
	BASELINE	33	17.17	20.62	0.0	0.00	66.7						
	Week 1	30	21.11	25.50	0.0	0.00	66.7	24	-1.39	18.33	-33.3	0.00	33.3
	Week 2	34	25.49	27.29	0.0	33.33	100.0	27	9.88	20.29	-33.3	0.00	66.7
	Week 3	35	32.38	29.69	0.0	33.33	100.0	28	13.10	27.72	-33.3	0.00	66.7
	Week 4	36	23.15	28.53	0.0	16.67	100.0	30	2.22	27.59	-66.7	0.00	66.7
	Week 5	33	32.32	31.72	0.0	33.33	100.0	27	13.58	31.02	-33.3	0.00	66.7
	Week 6	34	28.43	30.85	0.0	33.33	100.0	28	14.29	29.30	-33.3	0.00	66.7
	Week 7	34	30.39	34.20	0.0	33.33	100.0	28	8.33	30.93	-33.3	0.00	100.0
	Week 8	35	24.76	29.53	0.0	33.33	100.0	29	8.05	34.10	-66.7	0.00	100.0
	Week 9	30	22.22	26.74	0.0	0.00	66.7	24	5.56	30.56	-33.3	0.00	66.7
	Week 10	31	23.66	28.80	0.0	0.00	100.0	26	11.54	32.58	-33.3	0.00	100.0
	Week 11	34	22.55	30.40	0.0	0.00	100.0	27	3.70	28.24	-66.7	0.00	66.7
	Week 12	35	16.19	23.39	0.0	0.00	66.7	28	-3.57	24.58	-66.7	0.00	33.3
	Week 14	30	16.67	22.74	0.0	0.00	66.7	23	-1.45	23.52	-66.7	0.00	33.3
	Week 17	30	23.33	31.74	0.0	0.00	100.0	24	5.56	32.10	-66.7	0.00	66.7
	Week 20	27	13.58	21.20	0.0	0.00	66.7	21	-3.17	25.61	-66.7	0.00	33.3
	Week 23	27	13.58	21.20	0.0	0.00	66.7	21	-4.76	24.23	-66.7	0.00	33.3
	Week 26	27	9.88	22.29	0.0	0.00	100.0	22	-6.06	26.50	-66.7	0.00	66.7
	Week 29	28	13.09	22.84	0.0	0.00	100.0	23	0.00	31.78	-66.7	0.00	100.0
	Week 32	24	11.11	23.40	0.0	0.00	66.7	20	-5.00	29.17	-66.7	0.00	66.7
	Week 35	22	15.15	24.62	0.0	0.00	66.7	18	-3.70	27.74	-33.3	0.00	66.7
	Week 38	21	19.05	24.88	0.0	0.00	66.7	17	3.92	28.58	-66.7	0.00	66.7
	Week 41	22	9.09	15.19	0.0	0.00	33.3	17	-3.92	26.04	-66.7	0.00	33.3
	Week 44	22	10.61	18.93	0.0	0.00	66.7	16	-6.25	32.70	-66.7	0.00	66.7
	Week 47	21	9.52	15.43	0.0	0.00	33.3	16	-6.25	25.00	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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Table 302.1.3002.19.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	16.67	20.23	0.0	0.00	66.7	16	2.08	25.73	-33.3	0.00	66.7
	Week 53	18	16.67	20.61	0.0	0.00	66.7	14	2.38	30.56	-33.3	0.00	66.7
	Week 56	21	9.52	18.69	0.0	0.00	66.7	17	-5.88	29.43	-66.7	0.00	33.3
	Week 59	21	7.94	14.55	0.0	0.00	33.3	16	-10.42	23.47	-66.7	0.00	33.3
	Week 62	19	5.26	12.49	0.0	0.00	33.3	15	-13.33	21.08	-66.7	0.00	0.0
	Week 65	16	4.17	11.38	0.0	0.00	33.3	14	-14.29	21.54	-66.7	0.00	0.0
	Week 68	13	10.26	21.01	0.0	0.00	66.7	11	-12.12	26.97	-66.7	0.00	33.3
	Week 71	13	10.26	21.01	0.0	0.00	66.7	11	-12.12	26.97	-66.7	0.00	33.3
	Week 74	13	5.13	12.52	0.0	0.00	33.3	11	-12.12	26.97	-66.7	0.00	33.3
	Week 77	13	7.69	19.97	0.0	0.00	66.7	10	-16.67	23.57	-66.7	0.00	0.0
	Week 80	13	12.82	25.60	0.0	0.00	66.7	11	-9.09	26.21	-66.7	0.00	33.3
	Week 83	11	3.03	10.05	0.0	0.00	33.3	10	-13.33	28.11	-66.7	0.00	33.3
	Week 86	11	6.06	13.48	0.0	0.00	33.3	10	-10.00	22.50	-33.3	0.00	33.3
	Plat+Gem (N= 37)												
	BASELINE	29	24.14	30.73	0.0	0.00	100.0						
	Week 1	26	33.33	32.66	0.0	33.33	100.0	25	9.33	32.66	-100.0	0.00	100.0
	Week 2	30	33.33	32.75	0.0	33.33	100.0	26	12.82	31.38	-66.7	0.00	100.0
	Week 3	30	26.67	30.83	0.0	33.33	100.0	26	6.41	36.54	-66.7	0.00	100.0
	Week 4	32	22.92	26.01	0.0	33.33	100.0	27	3.70	21.35	-66.7	0.00	33.3
	Week 5	33	31.31	29.98	0.0	33.33	100.0	28	8.33	38.09	-100.0	0.00	100.0
	Week 6	32	31.25	28.00	0.0	33.33	100.0	27	6.17	40.34	-100.0	0.00	100.0
	Week 7	31	30.11	29.00	0.0	33.33	100.0	26	5.13	33.59	-100.0	0.00	66.7
	Week 8	32	27.08	24.59	0.0	33.33	66.7	27	1.23	31.33	-100.0	0.00	66.7
	Week 9	30	24.44	26.16	0.0	33.33	100.0	25	-2.67	35.90	-100.0	0.00	66.7
	Week 10	30	24.44	24.66	0.0	33.33	66.7	26	-2.56	39.91	-100.0	0.00	66.7
	Week 11	29	24.14	21.63	0.0	33.33	66.7	25	-2.67	38.39	-100.0	0.00	66.7

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Table 302.1.3002.19.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Loss of Appetite by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 12	28	34.52	30.74	0.0	33.33	100.0	23	5.80	35.75	-66.7	0.00	100.0
	Week 14	28	35.71	27.11	0.0	33.33	100.0	23	7.25	42.59	-100.0	33.33	66.7
	Week 17	25	22.67	23.01	0.0	33.33	66.7	21	-4.76	36.95	-100.0	0.00	66.7
	Week 20	23	27.54	27.80	0.0	33.33	100.0	20	1.67	46.49	-100.0	0.00	100.0
	Week 23	20	16.67	20.23	0.0	0.00	66.7	17	-7.84	44.92	-100.0	0.00	66.7
	Week 26	21	22.22	30.43	0.0	0.00	100.0	18	-7.41	42.10	-100.0	0.00	100.0
	Week 29	19	21.05	27.69	0.0	0.00	100.0	16	-8.33	35.49	-66.7	0.00	66.7
	Week 32	18	27.78	28.58	0.0	33.33	100.0	15	-2.22	38.76	-66.7	0.00	100.0
	Week 35	19	21.05	27.69	0.0	0.00	100.0	16	-6.25	49.02	-100.0	0.00	100.0
	Week 38	15	20.00	21.08	0.0	33.33	66.7	12	-11.11	43.42	-100.0	0.00	66.7
	Week 41	15	24.44	26.63	0.0	33.33	66.7	12	-5.56	27.83	-66.7	0.00	33.3
	Week 44	14	19.05	21.54	0.0	16.67	66.7	11	-12.12	42.88	-100.0	0.00	66.7
	Week 47	12	13.89	17.16	0.0	0.00	33.3	10	-16.67	42.31	-100.0	0.00	33.3
	Week 50	11	21.21	22.47	0.0	33.33	66.7	8	-12.50	30.54	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
EV+Pembro (N=240)												
BASELINE	206	33.01	30.17	0.0	33.33	100.0						
Week 1	190	32.46	28.37	0.0	33.33	100.0	184	-0.18	25.25	-100.0	0.00	100.0
Week 2	203	30.54	27.31	0.0	33.33	100.0	189	-0.18	28.04	-100.0	0.00	100.0
Week 3	198	32.49	28.39	0.0	33.33	100.0	182	0.18	32.59	-100.0	0.00	100.0
Week 4	194	25.77	24.47	0.0	33.33	100.0	179	-6.70	31.48	-100.0	0.00	100.0
Week 5	190	26.84	28.25	0.0	33.33	100.0	173	-7.13	31.45	-100.0	0.00	66.7
Week 6	188	25.71	25.23	0.0	33.33	100.0	170	-6.67	31.11	-100.0	0.00	100.0
Week 7	195	26.15	26.75	0.0	33.33	100.0	176	-7.20	31.85	-100.0	0.00	66.7
Week 8	191	24.96	26.48	0.0	33.33	100.0	171	-7.41	31.47	-100.0	0.00	100.0
Week 9	197	26.56	27.13	0.0	33.33	100.0	180	-5.37	33.27	-100.0	0.00	100.0
Week 10	191	25.13	25.30	0.0	33.33	100.0	175	-8.00	31.76	-100.0	0.00	100.0
Week 11	194	25.77	26.72	0.0	33.33	100.0	175	-7.05	32.67	-100.0	0.00	100.0
Week 12	186	24.55	27.52	0.0	33.33	100.0	171	-8.97	34.64	-100.0	0.00	100.0
Week 14	185	23.78	25.99	0.0	33.33	100.0	167	-9.18	33.27	-100.0	0.00	100.0
Week 17	178	23.41	25.94	0.0	33.33	100.0	162	-9.05	33.24	-100.0	0.00	100.0
Week 20	167	24.55	27.91	0.0	33.33	100.0	154	-8.23	36.22	-100.0	0.00	100.0
Week 23	162	24.48	28.24	0.0	33.33	100.0	151	-6.62	34.43	-100.0	0.00	100.0
Week 26	156	23.72	27.83	0.0	33.33	100.0	144	-8.10	35.53	-100.0	0.00	100.0
Week 29	157	20.81	24.58	0.0	0.00	100.0	145	-8.97	32.93	-100.0	0.00	100.0
Week 32	135	20.74	25.06	0.0	0.00	100.0	125	-9.07	31.79	-66.7	0.00	100.0
Week 35	132	20.45	23.53	0.0	16.67	100.0	122	-10.38	31.52	-66.7	0.00	100.0
Week 38	132	20.20	22.84	0.0	33.33	100.0	124	-9.14	33.29	-100.0	0.00	100.0
Week 41	129	23.25	24.51	0.0	33.33	100.0	119	-5.88	31.79	-100.0	0.00	100.0
Week 44	108	20.99	23.50	0.0	33.33	100.0	100	-8.33	33.63	-100.0	0.00	100.0
Week 47	100	20.00	23.69	0.0	0.00	66.7	94	-7.80	35.73	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	89	20.22	24.93	0.0	0.00	100.0	84	-6.35	34.51	-100.0	0.00	100.0
Week 53	79	21.52	26.17	0.0	0.00	100.0	74	-5.86	33.72	-66.7	0.00	100.0
Week 56	81	21.81	25.91	0.0	0.00	100.0	76	-4.82	35.57	-100.0	0.00	100.0
Week 59	72	21.76	23.84	0.0	33.33	66.7	68	-6.37	31.15	-100.0	0.00	66.7
Week 62	65	16.92	21.35	0.0	0.00	66.7	63	-9.52	29.59	-100.0	0.00	33.3
Week 65	58	22.41	24.49	0.0	33.33	66.7	54	-5.56	31.56	-66.7	0.00	66.7
Week 68	53	17.61	24.11	0.0	0.00	66.7	52	-7.69	32.08	-66.7	0.00	66.7
Week 71	51	23.53	28.51	0.0	0.00	100.0	49	-4.08	35.77	-66.7	0.00	100.0
Week 74	47	22.69	25.16	0.0	33.33	100.0	46	-4.35	36.25	-66.7	0.00	100.0
Week 77	44	24.24	27.25	0.0	33.33	100.0	42	-1.59	34.49	-66.7	0.00	66.7
Week 80	40	24.17	23.86	0.0	33.33	66.7	37	-8.11	32.78	-100.0	0.00	33.3
Week 83	37	20.72	21.30	0.0	33.33	66.7	35	-12.38	34.38	-100.0	0.00	33.3
Week 86	34	25.49	27.29	0.0	33.33	100.0	31	-8.60	29.78	-66.7	0.00	33.3
Week 89	33	25.25	23.61	0.0	33.33	100.0	31	-6.45	29.08	-66.7	0.00	33.3
Week 92	27	18.52	21.35	0.0	0.00	66.7	25	-12.00	28.68	-66.7	0.00	33.3
Week 95	22	25.76	22.85	0.0	33.33	66.7	21	0.00	29.82	-66.7	0.00	66.7
Week 98	18	24.07	31.94	0.0	0.00	100.0	17	-1.96	32.21	-66.7	0.00	66.7
Week 101	14	26.19	23.31	0.0	33.33	66.7	14	2.38	33.24	-66.7	0.00	66.7
Week 104	10	20.00	23.31	0.0	16.67	66.7	10	-6.67	21.08	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Plat+Gem (N=242)												
BASELINE	188	34.40	29.84	0.0	33.33	100.0						
Week 1	173	33.53	28.64	0.0	33.33	100.0	158	-0.21	26.74	-66.7	0.00	66.7
Week 2	171	37.82	28.00	0.0	33.33	100.0	151	3.53	31.54	-66.7	0.00	100.0
Week 3	184	29.71	27.20	0.0	33.33	100.0	162	-4.73	30.15	-100.0	0.00	66.7
Week 4	183	28.05	24.76	0.0	33.33	100.0	156	-7.05	28.59	-100.0	0.00	66.7
Week 5	187	30.12	24.47	0.0	33.33	100.0	156	-2.99	31.76	-100.0	0.00	66.7
Week 6	174	27.59	24.94	0.0	33.33	100.0	149	-8.28	34.64	-100.0	0.00	100.0
Week 7	186	27.78	24.49	0.0	33.33	100.0	157	-5.73	30.94	-100.0	0.00	100.0
Week 8	167	27.54	26.38	0.0	33.33	100.0	144	-7.41	33.32	-100.0	0.00	100.0
Week 9	177	26.93	25.56	0.0	33.33	100.0	150	-7.56	32.80	-100.0	0.00	100.0
Week 10	166	28.71	23.76	0.0	33.33	100.0	139	-6.72	31.64	-100.0	0.00	100.0
Week 11	168	28.97	26.95	0.0	33.33	100.0	143	-6.29	31.39	-100.0	0.00	66.7
Week 12	159	26.41	24.61	0.0	33.33	100.0	138	-7.25	31.90	-100.0	0.00	66.7
Week 14	153	25.71	26.07	0.0	33.33	100.0	128	-11.46	30.29	-100.0	0.00	66.7
Week 17	155	25.81	26.19	0.0	33.33	100.0	130	-5.64	32.72	-100.0	0.00	100.0
Week 20	126	19.31	22.84	0.0	0.00	66.7	110	-13.64	30.72	-100.0	0.00	33.3
Week 23	115	22.61	27.41	0.0	0.00	100.0	97	-6.19	30.55	-100.0	0.00	100.0
Week 26	108	25.93	27.09	0.0	33.33	100.0	95	-4.21	29.67	-100.0	0.00	66.7
Week 29	100	23.67	24.29	0.0	33.33	100.0	86	-5.43	32.28	-100.0	0.00	66.7
Week 32	83	24.50	24.46	0.0	33.33	100.0	76	-5.70	33.28	-100.0	0.00	66.7
Week 35	76	23.68	24.23	0.0	33.33	100.0	69	-5.31	31.64	-100.0	0.00	66.7
Week 38	74	21.17	23.13	0.0	33.33	100.0	65	-5.13	29.60	-100.0	0.00	66.7
Week 41	65	23.08	24.24	0.0	33.33	100.0	56	-2.38	26.86	-66.7	0.00	66.7
Week 44	60	22.78	26.39	0.0	16.67	100.0	53	-4.40	29.98	-100.0	0.00	66.7
Week 47	56	25.00	25.62	0.0	33.33	100.0	49	0.00	27.22	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	51	24.18	29.12	0.0	33.33	100.0	47	-2.13	32.90	-66.7	0.00	66.7
Week 53	46	24.64	22.70	0.0	33.33	100.0	42	0.00	26.54	-66.7	0.00	66.7
Week 56	39	28.20	28.14	0.0	33.33	100.0	34	3.92	32.58	-66.7	0.00	100.0
Week 59	37	23.42	22.03	0.0	33.33	66.7	33	-2.02	27.56	-66.7	0.00	66.7
Week 62	32	22.92	23.09	0.0	33.33	66.7	29	-3.45	30.01	-66.7	0.00	66.7
Week 65	30	20.00	22.49	0.0	16.67	66.7	26	-7.69	28.76	-66.7	0.00	66.7
Week 68	25	32.00	28.02	0.0	33.33	100.0	21	6.35	30.95	-33.3	0.00	100.0
Week 71	22	28.79	27.79	0.0	33.33	100.0	19	1.75	32.35	-66.7	0.00	66.7
Week 74	21	19.05	27.02	0.0	0.00	100.0	18	-9.26	27.55	-66.7	0.00	33.3
Week 77	18	22.22	25.57	0.0	16.67	66.7	15	-6.67	38.21	-66.7	0.00	66.7
Week 80	14	23.81	20.37	0.0	33.33	66.7	13	-2.56	25.32	-66.7	0.00	33.3
Week 83	13	15.38	22.01	0.0	0.00	66.7	12	-13.89	33.21	-66.7	-16.67	66.7
Week 86	12	13.89	17.16	0.0	0.00	33.3	11	-12.12	30.81	-66.7	0.00	33.3
Week 89	11	18.18	17.41	0.0	33.33	33.3	10	-13.33	28.11	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Present	EV+Pembro (N= 48)												
	BASELINE	39	44.44	33.63	0.0	33.33	100.0						
	Week 1	32	35.42	32.72	0.0	33.33	100.0	32	-9.38	37.13	-100.0	0.00	66.7
	Week 2	37	32.43	21.50	0.0	33.33	66.7	33	-7.07	34.11	-100.0	0.00	66.7
	Week 3	34	36.27	30.00	0.0	33.33	100.0	29	-8.05	44.24	-100.0	0.00	66.7
	Week 4	36	37.96	31.02	0.0	33.33	100.0	31	-6.45	46.68	-100.0	0.00	100.0
	Week 5	30	40.00	35.45	0.0	33.33	100.0	24	-15.28	46.08	-100.0	0.00	66.7
	Week 6	31	29.03	28.21	0.0	33.33	100.0	25	-21.33	42.91	-100.0	0.00	66.7
	Week 7	34	29.41	29.32	0.0	33.33	100.0	28	-17.86	37.93	-100.0	-16.67	33.3
	Week 8	35	31.43	31.25	0.0	33.33	100.0	30	-12.22	41.51	-100.0	0.00	66.7
	Week 9	34	33.33	29.59	0.0	33.33	100.0	30	-8.89	41.00	-100.0	0.00	66.7
	Week 10	34	29.41	26.92	0.0	33.33	100.0	30	-16.67	39.88	-100.0	0.00	66.7
	Week 11	33	35.35	28.80	0.0	33.33	100.0	28	-9.53	38.34	-100.0	0.00	66.7
	Week 12	33	25.25	26.39	0.0	33.33	100.0	29	-18.39	38.41	-100.0	-33.33	66.7
	Week 14	31	27.96	27.35	0.0	33.33	100.0	26	-20.51	35.37	-100.0	-33.33	33.3
	Week 17	31	29.03	25.45	0.0	33.33	100.0	25	-18.67	42.03	-100.0	-33.33	66.7
	Week 20	27	35.80	30.56	0.0	33.33	100.0	24	-11.11	38.91	-100.0	0.00	33.3
	Week 23	26	29.49	21.76	0.0	33.33	66.7	23	-20.29	35.87	-100.0	-33.33	33.3
	Week 26	25	22.67	28.42	0.0	0.00	100.0	22	-22.73	46.45	-100.0	-33.33	100.0
	Week 29	23	20.29	29.71	0.0	0.00	100.0	22	-22.73	45.29	-100.0	-16.67	33.3
	Week 32	21	28.57	26.43	0.0	33.33	100.0	19	-21.05	37.20	-66.7	-33.33	33.3
	Week 35	19	31.58	26.00	0.0	33.33	66.7	17	-11.76	40.73	-66.7	0.00	33.3
	Week 38	18	18.52	23.49	0.0	0.00	66.7	17	-33.33	45.64	-100.0	-33.34	33.3
	Week 41	20	25.00	23.88	0.0	33.33	66.7	19	-19.30	40.55	-100.0	-33.33	33.3
	Week 44	17	21.57	20.21	0.0	33.33	66.7	15	-22.22	41.15	-100.0	-33.33	33.3
	Week 47	18	20.37	25.92	0.0	0.00	66.7	16	-20.83	50.00	-100.0	-16.67	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	12	13.89	22.29	0.0	0.00	66.7	11	-27.27	38.93	-100.0	-33.33	33.3
	Week 53	12	22.22	25.95	0.0	16.67	66.7	11	-15.15	34.53	-66.7	0.00	33.3
	Week 56	13	20.51	25.60	0.0	0.00	66.7	12	-19.44	41.34	-100.0	0.00	33.3
	Week 59	12	13.89	22.29	0.0	0.00	66.7	11	-27.27	35.96	-100.0	0.00	0.0
	Week 62	10	20.00	28.11	0.0	0.00	66.7	9	-14.81	29.40	-66.7	0.00	33.3
	Week 65	10	16.67	23.57	0.0	0.00	66.7	9	-22.22	33.34	-66.7	-33.33	33.3
	Plat+Gem (N= 48)												
	BASELINE	33	35.35	28.80	0.0	33.33	100.0						
	Week 1	31	31.18	25.73	0.0	33.33	100.0	27	-2.47	22.51	-66.7	0.00	33.3
	Week 2	29	41.38	24.65	0.0	33.33	100.0	24	2.78	30.95	-66.7	0.00	66.7
	Week 3	32	23.96	27.09	0.0	33.33	100.0	27	-8.64	30.09	-100.0	0.00	33.3
	Week 4	32	28.12	26.92	0.0	33.33	100.0	24	-12.50	30.79	-100.0	0.00	33.3
	Week 5	36	29.63	22.22	0.0	33.33	66.7	28	-4.76	32.35	-66.7	0.00	66.7
	Week 6	35	25.71	25.67	0.0	33.33	100.0	27	-14.82	35.00	-100.0	0.00	33.3
	Week 7	38	24.56	21.48	0.0	33.33	66.7	29	-13.79	27.48	-66.7	0.00	33.3
	Week 8	31	21.50	22.02	0.0	33.33	66.7	25	-12.00	33.17	-100.0	0.00	66.7
	Week 9	32	21.87	18.18	0.0	33.33	66.7	25	-14.67	29.00	-100.0	0.00	33.3
	Week 10	34	25.49	23.30	0.0	33.33	100.0	26	-12.82	29.93	-66.7	-33.33	66.7
	Week 11	30	24.44	26.16	0.0	33.33	100.0	24	-12.50	29.18	-66.7	0.00	66.7
	Week 12	28	22.62	24.09	0.0	33.33	100.0	23	-15.94	37.43	-100.0	0.00	33.3
	Week 14	26	20.51	26.79	0.0	0.00	100.0	21	-22.22	30.43	-100.0	-33.33	33.3
	Week 17	30	17.78	22.71	0.0	0.00	66.7	25	-17.33	27.42	-100.0	0.00	33.3
	Week 20	23	8.70	18.03	0.0	0.00	66.7	21	-28.57	28.45	-100.0	-33.33	0.0
	Week 23	22	24.24	32.82	0.0	0.00	100.0	19	-8.77	33.04	-66.7	0.00	100.0
	Week 26	19	19.30	20.23	0.0	33.33	66.7	18	-9.26	22.30	-66.7	0.00	33.3
	Week 29	16	22.92	23.47	0.0	33.33	66.7	14	-2.38	20.52	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 32	11	24.24	26.21	0.0	33.33	66.7	11	-9.09	30.15	-66.7	0.00	33.3
	Week 35	10	26.67	26.29	0.0	33.33	66.7	9	-3.70	26.06	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Absent	EV+Pembro (N=192)												
	BASELINE	167	30.34	28.77	0.0	33.33	100.0						
	Week 1	158	31.86	27.48	0.0	33.33	100.0	152	1.75	21.63	-66.7	0.00	100.0
	Week 2	166	30.12	28.48	0.0	33.33	100.0	156	1.28	26.47	-66.7	0.00	100.0
	Week 3	164	31.71	28.07	0.0	33.33	100.0	153	1.74	29.81	-66.7	0.00	100.0
	Week 4	158	22.99	21.91	0.0	33.33	100.0	148	-6.76	27.48	-66.7	0.00	66.7
	Week 5	160	24.37	26.10	0.0	33.33	100.0	149	-5.82	28.40	-66.7	0.00	66.7
	Week 6	157	25.05	24.65	0.0	33.33	100.0	145	-4.14	28.02	-66.7	0.00	100.0
	Week 7	161	25.46	26.22	0.0	33.33	100.0	148	-5.18	30.30	-66.7	0.00	66.7
	Week 8	156	23.50	25.18	0.0	33.33	100.0	141	-6.38	28.98	-66.7	0.00	100.0
	Week 9	163	25.15	26.47	0.0	33.33	100.0	150	-4.67	31.62	-66.7	0.00	100.0
	Week 10	157	24.20	24.93	0.0	33.33	100.0	145	-6.21	29.66	-100.0	0.00	100.0
	Week 11	161	23.81	25.93	0.0	33.33	100.0	147	-6.58	31.61	-100.0	0.00	100.0
	Week 12	153	24.40	27.84	0.0	33.33	100.0	142	-7.04	33.65	-100.0	0.00	100.0
	Week 14	154	22.94	25.71	0.0	33.33	100.0	141	-7.09	32.57	-100.0	0.00	100.0
	Week 17	147	22.22	25.98	0.0	33.33	100.0	137	-7.30	31.24	-100.0	0.00	100.0
	Week 20	140	22.38	26.95	0.0	0.00	100.0	130	-7.69	35.83	-100.0	0.00	100.0
	Week 23	136	23.53	29.29	0.0	0.00	100.0	128	-4.17	33.73	-100.0	0.00	100.0
	Week 26	131	23.92	27.82	0.0	33.33	100.0	122	-5.46	32.74	-66.7	0.00	100.0
	Week 29	134	20.89	23.72	0.0	33.33	100.0	123	-6.50	29.77	-66.7	0.00	100.0
	Week 32	114	19.30	24.65	0.0	0.00	100.0	106	-6.92	30.42	-66.7	0.00	100.0
	Week 35	113	18.58	22.69	0.0	0.00	100.0	105	-10.16	30.00	-66.7	0.00	100.0
	Week 38	114	20.47	22.83	0.0	33.33	100.0	107	-5.30	29.37	-66.7	0.00	100.0
	Week 41	109	22.93	24.72	0.0	33.33	100.0	100	-3.33	29.40	-66.7	0.00	100.0
	Week 44	91	20.88	24.16	0.0	0.00	100.0	85	-5.88	31.78	-66.7	0.00	100.0
	Week 47	82	19.92	23.34	0.0	0.00	66.7	78	-5.13	31.82	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	77	21.21	25.31	0.0	0.00	100.0	73	-3.20	32.94	-66.7	0.00	100.0
	Week 53	67	21.39	26.40	0.0	0.00	100.0	63	-4.23	33.60	-66.7	0.00	100.0
	Week 56	68	22.06	26.15	0.0	16.67	100.0	64	-2.08	34.05	-66.7	0.00	100.0
	Week 59	60	23.33	24.01	0.0	33.33	66.7	57	-2.34	28.77	-66.7	0.00	66.7
	Week 62	55	16.36	20.16	0.0	0.00	66.7	54	-8.64	29.80	-100.0	0.00	33.3
	Week 65	48	23.61	24.75	0.0	33.33	66.7	45	-2.22	30.48	-66.7	0.00	66.7
	Week 68	46	18.12	24.04	0.0	0.00	66.7	45	-5.18	30.94	-66.7	0.00	66.7
	Week 71	44	24.24	29.08	0.0	16.67	100.0	42	-0.79	34.91	-66.7	0.00	100.0
	Week 74	40	23.33	25.26	0.0	33.33	100.0	39	-0.86	35.45	-66.7	0.00	100.0
	Week 77	38	24.56	27.60	0.0	33.33	100.0	36	2.78	32.24	-66.7	0.00	66.7
	Week 80	35	22.86	22.54	0.0	33.33	66.7	32	-6.25	31.04	-100.0	0.00	33.3
	Week 83	32	19.79	20.49	0.0	33.33	66.7	30	-10.00	32.93	-100.0	0.00	33.3
	Week 86	29	25.29	27.68	0.0	33.33	100.0	26	-6.41	28.31	-66.7	0.00	33.3
	Week 89	29	25.29	22.98	0.0	33.33	100.0	27	-2.47	24.33	-33.3	0.00	33.3
	Week 92	24	19.44	21.80	0.0	16.67	66.7	22	-9.09	27.57	-66.7	0.00	33.3
	Week 95	20	25.00	23.88	0.0	33.33	66.7	19	1.75	30.38	-66.7	0.00	66.7
	Week 98	18	24.07	31.94	0.0	0.00	100.0	17	-1.96	32.21	-66.7	0.00	66.7
	Week 101	13	23.08	21.01	0.0	33.33	66.7	13	2.56	34.59	-66.7	0.00	66.7
	Plat+Gem (N=194)												
	BASELINE	155	34.19	30.14	0.0	33.33	100.0						
	Week 1	142	34.04	29.30	0.0	33.33	100.0	131	0.25	27.58	-66.7	0.00	66.7
	Week 2	142	37.09	28.66	0.0	33.33	100.0	127	3.67	31.77	-66.7	0.00	100.0
	Week 3	152	30.92	27.15	0.0	33.33	100.0	135	-3.95	30.22	-100.0	0.00	66.7
	Week 4	151	28.03	24.37	0.0	33.33	100.0	132	-6.06	28.18	-66.7	0.00	66.7
	Week 5	151	30.24	25.05	0.0	33.33	100.0	128	-2.60	31.75	-100.0	0.00	66.7
	Week 6	139	28.06	24.82	0.0	33.33	100.0	122	-6.83	34.54	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 7	148	28.60	25.20	0.0	33.33	100.0	128	-3.91	31.48	-100.0	0.00	100.0
	Week 8	136	28.92	27.16	0.0	33.33	100.0	119	-6.44	33.41	-100.0	0.00	100.0
	Week 9	145	28.05	26.84	0.0	33.33	100.0	125	-6.13	33.44	-100.0	0.00	100.0
	Week 10	132	29.54	23.89	0.0	33.33	100.0	113	-5.31	31.99	-100.0	0.00	100.0
	Week 11	138	29.95	27.10	0.0	33.33	100.0	119	-5.04	31.78	-100.0	0.00	66.7
	Week 12	131	27.23	24.74	0.0	33.33	100.0	115	-5.51	30.57	-100.0	0.00	66.7
	Week 14	127	26.77	25.90	0.0	33.33	100.0	107	-9.35	29.95	-100.0	0.00	66.7
	Week 17	125	27.73	26.69	0.0	33.33	100.0	105	-2.86	33.37	-66.7	0.00	100.0
	Week 20	103	21.68	23.20	0.0	33.33	66.7	89	-10.11	30.32	-100.0	0.00	33.3
	Week 23	93	22.22	26.16	0.0	33.33	100.0	78	-5.56	30.11	-100.0	0.00	66.7
	Week 26	89	27.34	28.23	0.0	33.33	100.0	77	-3.03	31.15	-100.0	0.00	66.7
	Week 29	84	23.81	24.58	0.0	33.33	100.0	72	-6.02	34.18	-100.0	0.00	66.7
	Week 32	72	24.54	24.38	0.0	33.33	100.0	65	-5.13	33.97	-100.0	0.00	66.7
	Week 35	66	23.23	24.09	0.0	33.33	100.0	60	-5.56	32.57	-100.0	0.00	66.7
	Week 38	66	21.21	23.85	0.0	33.33	100.0	57	-6.43	31.14	-100.0	0.00	66.7
	Week 41	62	22.58	24.72	0.0	33.33	100.0	53	-2.52	26.83	-66.7	0.00	66.7
	Week 44	55	22.42	26.49	0.0	0.00	100.0	48	-5.56	31.01	-100.0	0.00	66.7
	Week 47	51	24.18	25.89	0.0	33.33	100.0	44	-1.51	26.85	-66.7	0.00	66.7
	Week 50	48	25.00	29.58	0.0	33.33	100.0	44	-1.51	33.68	-66.7	0.00	66.7
	Week 53	41	24.39	22.39	0.0	33.33	100.0	37	-1.80	25.99	-66.7	0.00	66.7
	Week 56	34	26.47	26.94	0.0	33.33	66.7	29	1.15	30.19	-66.7	0.00	66.7
	Week 59	32	22.92	21.48	0.0	33.33	66.7	28	-4.76	26.78	-66.7	0.00	66.7
	Week 62	27	22.22	24.46	0.0	33.33	66.7	24	-6.94	31.05	-66.7	0.00	66.7
	Week 65	25	18.67	21.69	0.0	0.00	66.7	21	-12.70	26.82	-66.7	0.00	33.3
	Week 68	23	28.98	25.24	0.0	33.33	100.0	19	1.75	23.50	-33.3	0.00	33.3
	Week 71	21	26.98	27.12	0.0	33.33	100.0	18	-1.85	29.09	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 74	20	18.33	27.52	0.0	0.00	100.0	17	-9.80	28.30	-66.7	0.00	33.3
	Week 77	16	22.92	26.44	0.0	16.67	66.7	13	-5.13	40.48	-66.7	0.00	66.7
	Week 80	12	22.22	21.71	0.0	33.33	66.7	11	-3.03	27.71	-66.7	0.00	33.3
	Week 83	11	15.15	22.92	0.0	0.00	66.7	10	-13.33	35.83	-66.7	-16.67	66.7
	Week 86	10	10.00	16.10	0.0	0.00	33.3	9	-14.82	33.79	-66.7	-33.33	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
< 65 years	EV+Pembro (N=105)												
	BASELINE	92	34.06	30.85	0.0	33.33	100.0						
	Week 1	88	34.47	27.43	0.0	33.33	100.0	85	2.75	23.12	-66.7	0.00	66.7
	Week 2	92	32.97	27.29	0.0	33.33	100.0	86	1.55	27.49	-66.7	0.00	66.7
	Week 3	93	31.54	27.08	0.0	33.33	100.0	84	-1.98	32.05	-100.0	0.00	66.7
	Week 4	90	27.04	25.43	0.0	33.33	100.0	82	-7.32	35.15	-100.0	0.00	100.0
	Week 5	90	25.55	27.84	0.0	33.33	100.0	81	-10.70	32.84	-100.0	0.00	66.7
	Week 6	90	23.33	24.20	0.0	33.33	100.0	81	-12.76	28.17	-100.0	0.00	33.3
	Week 7	85	24.31	26.92	0.0	33.33	100.0	77	-11.69	32.79	-100.0	0.00	66.7
	Week 8	89	25.09	27.19	0.0	33.33	100.0	80	-10.83	31.72	-100.0	0.00	66.7
	Week 9	93	27.24	26.90	0.0	33.33	100.0	85	-7.45	33.48	-100.0	0.00	66.7
	Week 10	88	24.24	25.64	0.0	33.33	100.0	81	-10.70	32.84	-100.0	0.00	66.7
	Week 11	93	23.65	24.37	0.0	33.33	100.0	84	-12.70	31.86	-100.0	0.00	66.7
	Week 12	86	25.19	27.03	0.0	33.33	100.0	79	-10.55	34.82	-100.0	0.00	66.7
	Week 14	84	23.41	25.76	0.0	33.33	100.0	76	-10.96	35.86	-100.0	0.00	66.7
	Week 17	83	24.90	27.47	0.0	33.33	100.0	77	-10.82	35.64	-100.0	0.00	66.7
	Week 20	79	23.21	27.40	0.0	0.00	100.0	73	-10.96	37.29	-100.0	0.00	66.7
	Week 23	78	23.93	27.86	0.0	33.33	100.0	73	-10.05	35.00	-100.0	0.00	66.7
	Week 26	78	23.08	27.03	0.0	16.67	100.0	72	-10.65	34.41	-100.0	0.00	100.0
	Week 29	74	18.47	22.84	0.0	0.00	100.0	67	-12.94	31.76	-100.0	0.00	33.3
	Week 32	64	18.23	22.17	0.0	0.00	66.7	59	-12.43	28.97	-66.7	0.00	33.3
	Week 35	62	19.35	22.22	0.0	16.67	100.0	58	-11.49	28.31	-66.7	0.00	33.3
	Week 38	62	19.35	21.38	0.0	16.67	66.7	59	-11.30	31.93	-100.0	0.00	33.3
	Week 41	64	19.27	20.41	0.0	33.33	66.7	59	-10.17	29.85	-100.0	0.00	66.7
	Week 44	50	18.67	23.48	0.0	0.00	66.7	48	-10.42	33.09	-100.0	0.00	33.3
	Week 47	47	19.15	25.77	0.0	0.00	66.7	46	-7.97	37.31	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	44	21.21	25.00	0.0	16.67	100.0	41	-7.32	33.76	-100.0	0.00	66.7
	Week 53	40	20.83	26.89	0.0	0.00	100.0	37	-7.21	30.57	-66.7	0.00	66.7
	Week 56	44	18.94	22.04	0.0	0.00	66.7	41	-9.76	31.84	-100.0	0.00	33.3
	Week 59	42	21.43	23.07	0.0	33.33	66.7	39	-7.69	31.03	-100.0	0.00	66.7
	Week 62	37	16.22	20.22	0.0	0.00	66.7	36	-10.19	31.69	-100.0	0.00	33.3
	Week 65	34	22.55	24.23	0.0	33.33	66.7	31	-7.53	31.87	-66.7	0.00	33.3
	Week 68	34	19.61	23.38	0.0	0.00	66.7	33	-8.08	32.31	-66.7	0.00	33.3
	Week 71	32	25.00	29.33	0.0	16.67	100.0	30	-6.67	34.35	-66.7	0.00	33.3
	Week 74	29	22.99	22.01	0.0	33.33	66.7	28	-7.14	33.16	-66.7	0.00	66.7
	Week 77	25	25.33	25.96	0.0	33.33	66.7	24	-6.94	32.57	-66.7	0.00	66.7
	Week 80	24	26.39	25.97	0.0	33.33	66.7	22	-9.09	34.40	-100.0	0.00	33.3
	Week 83	23	23.19	21.16	0.0	33.33	66.7	22	-10.61	36.20	-100.0	0.00	33.3
	Week 86	20	33.33	28.61	0.0	33.33	100.0	18	-5.56	26.20	-33.3	0.00	33.3
	Week 89	19	24.56	26.86	0.0	33.33	100.0	17	-13.73	26.51	-66.7	0.00	33.3
	Week 92	14	26.19	23.31	0.0	33.33	66.7	12	-8.33	25.13	-33.3	0.00	33.3
	Week 95	12	22.22	21.71	0.0	33.33	66.7	11	-9.09	30.15	-66.7	0.00	33.3
	Plat+Gem (N=106)												
	BASELINE	83	37.75	29.80	0.0	33.33	100.0						
	Week 1	75	36.44	29.09	0.0	33.33	100.0	71	-0.47	27.89	-66.7	0.00	66.7
	Week 2	76	39.91	29.32	0.0	33.33	100.0	68	1.96	31.48	-66.7	0.00	66.7
	Week 3	80	32.50	29.99	0.0	33.33	100.0	73	-5.02	32.24	-100.0	0.00	66.7
	Week 4	79	30.38	23.98	0.0	33.33	100.0	67	-7.96	31.30	-66.7	0.00	66.7
	Week 5	80	32.50	24.86	0.0	33.33	100.0	67	-3.98	31.53	-100.0	0.00	66.7
	Week 6	76	30.70	24.80	0.0	33.33	100.0	67	-7.46	37.07	-100.0	0.00	100.0
	Week 7	81	29.63	24.72	0.0	33.33	100.0	71	-7.98	32.59	-100.0	0.00	66.7
	Week 8	72	27.31	25.22	0.0	33.33	100.0	64	-11.98	33.79	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	78	29.06	24.24	0.0	33.33	66.7	69	-9.66	33.38	-100.0	0.00	66.7
	Week 10	78	28.20	23.46	0.0	33.33	66.7	68	-9.80	35.53	-100.0	0.00	66.7
	Week 11	75	31.11	27.03	0.0	33.33	100.0	66	-7.07	35.81	-100.0	0.00	66.7
	Week 12	74	25.22	21.23	0.0	33.33	66.7	66	-11.11	32.73	-100.0	0.00	66.7
	Week 14	68	26.96	27.17	0.0	33.33	100.0	58	-13.22	32.41	-100.0	0.00	66.7
	Week 17	68	28.92	26.95	0.0	33.33	100.0	58	-5.75	32.53	-66.7	0.00	100.0
	Week 20	60	21.11	23.74	0.0	16.67	66.7	52	-14.74	31.25	-100.0	0.00	33.3
	Week 23	51	22.87	28.67	0.0	0.00	100.0	44	-9.85	31.81	-100.0	0.00	66.7
	Week 26	47	31.21	29.82	0.0	33.33	100.0	42	-6.35	30.57	-100.0	0.00	66.7
	Week 29	42	26.98	25.76	0.0	33.33	100.0	37	-9.01	33.01	-100.0	0.00	66.7
	Week 32	37	25.22	26.53	0.0	33.33	100.0	34	-8.82	37.88	-100.0	0.00	66.7
	Week 35	34	24.51	25.04	0.0	33.33	66.7	31	-10.75	34.84	-100.0	0.00	66.7
	Week 38	33	21.21	24.75	0.0	33.33	100.0	28	-9.52	25.43	-66.7	0.00	33.3
	Week 41	27	24.69	25.47	0.0	33.33	100.0	22	-6.06	26.50	-66.7	0.00	66.7
	Week 44	28	25.00	28.15	0.0	33.33	100.0	24	-6.94	34.02	-100.0	0.00	66.7
	Week 47	24	23.61	26.88	0.0	33.33	100.0	21	-4.76	24.23	-33.3	0.00	66.7
	Week 50	26	20.51	25.08	0.0	16.67	100.0	24	-12.50	29.18	-66.7	0.00	66.7
	Week 53	19	22.81	27.34	0.0	33.33	100.0	17	-3.92	28.58	-66.7	0.00	66.7
	Week 56	13	23.08	25.04	0.0	33.33	66.7	11	-3.03	17.98	-33.3	0.00	33.3
	Week 59	14	14.29	21.54	0.0	0.00	66.7	12	-11.11	16.41	-33.3	0.00	0.0
	Week 62	13	20.51	21.68	0.0	33.33	66.7	12	-2.78	22.28	-33.3	0.00	33.3
	Week 65	13	12.82	21.68	0.0	0.00	66.7	11	-12.12	16.82	-33.3	0.00	0.0
	Week 68	10	26.67	26.29	0.0	33.33	66.7	8	-4.17	21.36	-33.3	0.00	33.3
	Week 77	10	16.67	23.57	0.0	0.00	66.7	8	-16.67	17.82	-33.3	-16.67	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>= 65 years	EV+Pembro (N=135)												
	BASELINE	114	32.16	29.73	0.0	33.33	100.0						
	Week 1	102	30.72	29.18	0.0	33.33	100.0	99	-2.69	26.80	-100.0	0.00	100.0
	Week 2	111	28.53	27.28	0.0	33.33	100.0	103	-1.62	28.54	-100.0	0.00	100.0
	Week 3	105	33.33	29.60	0.0	33.33	100.0	98	2.04	33.10	-100.0	0.00	100.0
	Week 4	104	24.68	23.68	0.0	33.33	100.0	97	-6.19	28.19	-100.0	0.00	66.7
	Week 5	100	28.00	28.71	0.0	33.33	100.0	92	-3.99	30.00	-100.0	0.00	66.7
	Week 6	98	27.89	26.08	0.0	33.33	100.0	89	-1.12	32.74	-100.0	0.00	100.0
	Week 7	110	27.57	26.66	0.0	33.33	100.0	99	-3.70	30.82	-66.7	0.00	66.7
	Week 8	102	24.84	25.98	0.0	33.33	100.0	91	-4.40	31.12	-66.7	0.00	100.0
	Week 9	104	25.96	27.46	0.0	33.33	100.0	95	-3.51	33.15	-66.7	0.00	100.0
	Week 10	103	25.89	25.11	0.0	33.33	100.0	94	-5.67	30.78	-66.7	0.00	100.0
	Week 11	101	27.72	28.70	0.0	33.33	100.0	91	-1.83	32.72	-66.7	0.00	100.0
	Week 12	100	24.00	28.06	0.0	33.33	100.0	92	-7.61	34.63	-66.7	0.00	100.0
	Week 14	101	24.09	26.30	0.0	33.33	100.0	91	-7.69	31.06	-66.7	0.00	100.0
	Week 17	95	22.10	24.61	0.0	33.33	100.0	85	-7.45	31.02	-66.7	0.00	100.0
	Week 20	88	25.76	28.47	0.0	33.33	100.0	81	-5.76	35.27	-66.7	0.00	100.0
	Week 23	84	25.00	28.75	0.0	33.33	100.0	78	-3.42	33.80	-66.7	0.00	100.0
	Week 26	78	24.36	28.77	0.0	33.33	100.0	72	-5.56	36.69	-66.7	0.00	100.0
	Week 29	83	22.89	25.99	0.0	33.33	100.0	78	-5.56	33.73	-100.0	0.00	100.0
	Week 32	71	23.00	27.37	0.0	33.33	100.0	66	-6.06	34.05	-66.7	0.00	100.0
	Week 35	70	21.43	24.76	0.0	16.67	100.0	64	-9.38	34.36	-66.7	0.00	100.0
	Week 38	70	20.95	24.19	0.0	33.33	100.0	65	-7.18	34.61	-100.0	0.00	100.0
	Week 41	65	27.18	27.57	0.0	33.33	100.0	60	-1.67	33.29	-66.7	0.00	100.0
	Week 44	58	22.99	23.53	0.0	33.33	100.0	52	-6.41	34.32	-66.7	0.00	100.0
	Week 47	53	20.75	21.90	0.0	33.33	66.7	48	-7.64	34.55	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	45	19.26	25.11	0.0	0.00	100.0	43	-5.43	35.58	-66.7	0.00	100.0
	Week 53	39	22.22	25.74	0.0	33.33	100.0	37	-4.51	36.99	-66.7	0.00	100.0
	Week 56	37	25.22	29.82	0.0	33.33	100.0	35	0.95	39.18	-66.7	0.00	100.0
	Week 59	30	22.22	25.27	0.0	16.67	66.7	29	-4.60	31.78	-66.7	0.00	66.7
	Week 62	28	17.86	23.10	0.0	0.00	66.7	27	-8.64	27.10	-66.7	0.00	33.3
	Week 65	24	22.22	25.38	0.0	16.67	66.7	23	-2.90	31.64	-66.7	0.00	66.7
	Week 68	19	14.04	25.62	0.0	0.00	66.7	19	-7.02	32.54	-66.7	0.00	66.7
	Week 71	19	21.05	27.69	0.0	0.00	100.0	19	0.00	38.49	-66.7	0.00	100.0
	Week 74	18	22.22	30.25	0.0	0.00	100.0	18	0.00	41.22	-66.7	0.00	100.0
	Week 77	19	22.81	29.51	0.0	0.00	100.0	18	5.56	36.60	-66.7	0.00	66.7
	Week 80	16	20.83	20.64	0.0	33.33	66.7	15	-6.67	31.37	-66.7	0.00	33.3
	Week 83	14	16.67	21.68	0.0	0.00	66.7	13	-15.39	32.25	-66.7	0.00	33.3
	Week 86	14	14.29	21.54	0.0	0.00	66.7	13	-12.82	34.80	-66.7	0.00	33.3
	Week 89	14	26.19	19.30	0.0	33.33	66.7	14	2.38	30.56	-66.7	0.00	33.3
	Week 92	13	10.26	16.01	0.0	0.00	33.3	13	-15.39	32.25	-66.7	0.00	33.3
	Week 95	10	30.00	24.60	0.0	33.33	66.7	10	10.00	27.44	-33.3	0.00	66.7
	Week 98	10	23.33	31.62	0.0	0.00	66.7	10	6.67	37.84	-66.7	0.00	66.7
	Plat+Gem (N=136)												
	BASELINE	105	31.75	29.74	0.0	33.33	100.0						
	Week 1	98	31.29	28.24	0.0	33.33	100.0	87	0.00	25.92	-66.7	0.00	66.7
	Week 2	95	36.14	26.92	0.0	33.33	100.0	83	4.82	31.72	-66.7	0.00	100.0
	Week 3	104	27.56	24.77	0.0	33.33	100.0	89	-4.49	28.51	-100.0	0.00	66.7
	Week 4	104	26.28	25.30	0.0	33.33	100.0	89	-6.37	26.53	-100.0	0.00	33.3
	Week 5	107	28.35	24.14	0.0	33.33	100.0	89	-2.25	32.10	-66.7	0.00	66.7
	Week 6	98	25.17	24.90	0.0	33.33	100.0	82	-8.94	32.73	-100.0	0.00	66.7
	Week 7	105	26.35	24.33	0.0	33.33	100.0	86	-3.88	29.56	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 8	95	27.72	27.36	0.0	33.33	100.0	80	-3.75	32.69	-100.0	0.00	100.0
	Week 9	99	25.25	26.55	0.0	33.33	100.0	81	-5.76	32.40	-100.0	0.00	100.0
	Week 10	88	29.17	24.14	0.0	33.33	100.0	71	-3.76	27.34	-66.7	0.00	100.0
	Week 11	93	27.24	26.90	0.0	33.33	100.0	77	-5.63	27.25	-66.7	0.00	33.3
	Week 12	85	27.45	27.30	0.0	33.33	100.0	72	-3.70	30.93	-100.0	0.00	66.7
	Week 14	85	24.70	25.28	0.0	33.33	100.0	70	-10.00	28.57	-100.0	0.00	33.3
	Week 17	87	23.37	25.47	0.0	33.33	100.0	72	-5.56	33.10	-100.0	0.00	100.0
	Week 20	66	17.68	22.05	0.0	0.00	66.7	58	-12.64	30.48	-100.0	0.00	33.3
	Week 23	64	22.40	26.60	0.0	16.67	100.0	53	-3.14	29.43	-66.7	0.00	100.0
	Week 26	61	21.86	24.26	0.0	33.33	100.0	53	-2.52	29.13	-66.7	0.00	66.7
	Week 29	58	21.26	23.11	0.0	33.33	66.7	49	-2.72	31.80	-100.0	0.00	66.7
	Week 32	46	23.91	22.95	0.0	33.33	66.7	42	-3.17	29.27	-66.7	0.00	66.7
	Week 35	42	23.01	23.84	0.0	33.33	100.0	38	-0.88	28.46	-66.7	0.00	33.3
	Week 38	41	21.14	22.06	0.0	33.33	66.7	37	-1.80	32.34	-100.0	0.00	66.7
	Week 41	38	21.93	23.60	0.0	33.33	100.0	34	0.00	27.22	-66.7	0.00	66.7
	Week 44	32	20.83	25.05	0.0	0.00	66.7	29	-2.30	26.62	-66.7	0.00	66.7
	Week 47	32	26.04	25.02	0.0	33.33	66.7	28	3.57	29.17	-66.7	0.00	66.7
	Week 50	25	28.00	32.89	0.0	33.33	100.0	23	8.70	33.66	-33.3	0.00	66.7
	Week 53	27	25.92	19.24	0.0	33.33	66.7	25	2.67	25.31	-33.3	0.00	66.7
	Week 56	26	30.77	29.70	0.0	33.33	100.0	23	7.25	37.55	-66.7	0.00	100.0
	Week 59	23	28.98	20.85	0.0	33.33	66.7	21	3.17	31.46	-66.7	0.00	66.7
	Week 62	19	24.56	24.45	0.0	33.33	66.7	17	-3.92	35.12	-66.7	0.00	66.7
	Week 65	17	25.49	22.14	0.0	33.33	66.7	15	-4.44	35.34	-66.7	0.00	66.7
	Week 68	15	35.55	29.46	0.0	33.33	100.0	13	12.82	34.80	-33.3	0.00	100.0
	Week 71	15	31.11	23.46	0.0	33.33	66.7	13	7.69	36.40	-66.7	0.00	66.7
	Week 74	12	19.44	22.28	0.0	16.67	66.7	11	-3.03	31.46	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Europe	EV+Pembro (N= 98)												
	BASELINE	79	33.75	30.89	0.0	33.33	100.0						
	Week 1	74	32.43	29.70	0.0	33.33	100.0	71	-0.47	22.18	-66.7	0.00	66.7
	Week 2	79	27.43	28.62	0.0	33.33	100.0	71	-3.76	26.76	-66.7	0.00	66.7
	Week 3	78	31.62	29.37	0.0	33.33	100.0	69	0.00	33.33	-66.7	0.00	100.0
	Week 4	78	26.49	27.05	0.0	33.33	100.0	70	-3.81	31.87	-66.7	0.00	100.0
	Week 5	70	24.28	25.96	0.0	33.33	100.0	62	-9.68	28.56	-66.7	0.00	66.7
	Week 6	70	22.86	23.77	0.0	33.33	100.0	61	-9.29	31.11	-66.7	0.00	100.0
	Week 7	78	23.93	23.35	0.0	33.33	66.7	68	-8.33	30.68	-66.7	0.00	66.7
	Week 8	72	24.54	27.97	0.0	33.33	100.0	61	-6.56	33.23	-66.7	0.00	100.0
	Week 9	80	26.25	26.36	0.0	33.33	100.0	70	-3.81	34.77	-66.7	0.00	100.0
	Week 10	71	23.94	25.31	0.0	33.33	66.7	62	-9.68	31.01	-100.0	0.00	66.7
	Week 11	76	26.31	26.84	0.0	33.33	100.0	66	-6.06	33.54	-100.0	0.00	66.7
	Week 12	73	25.11	28.21	0.0	33.33	100.0	65	-8.72	36.93	-100.0	0.00	66.7
	Week 14	74	22.52	25.35	0.0	16.67	66.7	64	-10.94	34.66	-100.0	0.00	66.7
	Week 17	70	21.90	22.62	0.0	33.33	66.7	62	-13.98	32.81	-100.0	-16.67	66.7
	Week 20	70	20.95	26.72	0.0	0.00	100.0	63	-11.11	38.80	-100.0	0.00	100.0
	Week 23	61	24.04	31.11	0.0	0.00	100.0	57	-7.60	41.32	-100.0	0.00	100.0
	Week 26	62	18.28	25.38	0.0	0.00	100.0	55	-12.73	33.64	-66.7	0.00	100.0
	Week 29	63	17.99	22.26	0.0	0.00	66.7	57	-12.87	30.70	-100.0	0.00	66.7
	Week 32	51	18.95	24.27	0.0	0.00	100.0	47	-14.19	33.15	-66.7	0.00	100.0
	Week 35	56	22.02	24.02	0.0	33.33	100.0	52	-9.62	33.23	-66.7	0.00	100.0
	Week 38	51	20.26	22.19	0.0	33.33	66.7	48	-10.42	30.10	-100.0	0.00	33.3
	Week 41	52	23.72	24.11	0.0	33.33	66.7	48	-9.72	31.48	-66.7	0.00	66.7
	Week 44	43	17.83	21.02	0.0	0.00	66.7	39	-13.68	29.34	-66.7	0.00	33.3
	Week 47	39	20.51	24.92	0.0	0.00	66.7	36	-8.33	35.97	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	37	18.02	20.18	0.0	0.00	66.7	36	-10.19	32.68	-66.7	0.00	66.7
	Week 53	28	20.24	24.58	0.0	0.00	66.7	27	-14.81	33.76	-66.7	0.00	66.7
	Week 56	30	20.00	27.12	0.0	0.00	100.0	29	-8.05	36.36	-66.7	0.00	66.7
	Week 59	27	17.28	21.42	0.0	0.00	66.7	27	-12.35	30.87	-66.7	0.00	66.7
	Week 62	23	14.49	22.08	0.0	0.00	66.7	23	-15.94	33.14	-100.0	0.00	33.3
	Week 65	23	18.84	22.08	0.0	0.00	66.7	23	-11.59	32.74	-66.7	0.00	33.3
	Week 68	21	12.70	22.30	0.0	0.00	66.7	21	-19.05	32.61	-66.7	-33.33	33.3
	Week 71	19	15.79	25.75	0.0	0.00	66.7	19	-17.54	35.78	-66.7	-33.33	33.3
	Week 74	15	17.78	17.21	0.0	33.33	33.3	15	-20.00	32.85	-66.7	-33.33	33.3
	Week 77	19	22.81	29.51	0.0	0.00	100.0	19	-8.77	34.86	-66.7	0.00	66.7
	Week 80	17	17.65	23.91	0.0	0.00	66.7	17	-17.65	37.49	-100.0	0.00	33.3
	Week 83	16	14.58	20.97	0.0	0.00	66.7	16	-22.92	35.94	-100.0	0.00	33.3
	Week 86	14	16.67	21.68	0.0	0.00	66.7	14	-16.67	31.35	-66.7	-16.67	33.3
	Week 89	14	21.43	21.11	0.0	33.33	66.7	14	-9.53	30.46	-66.7	0.00	33.3
	Week 92	11	9.09	15.57	0.0	0.00	33.3	11	-24.24	26.21	-66.7	-33.33	0.0
	Week 95	10	13.33	17.21	0.0	0.00	33.3	10	-10.00	27.44	-66.7	0.00	33.3
	Plat+Gem (N=102)												
	BASELINE	71	37.56	31.84	0.0	33.33	100.0						
	Week 1	71	37.09	30.63	0.0	33.33	100.0	61	-0.55	31.32	-66.7	0.00	66.7
	Week 2	67	38.81	29.93	0.0	33.33	100.0	56	3.57	31.58	-66.7	0.00	100.0
	Week 3	68	31.37	29.86	0.0	33.33	100.0	56	-5.95	34.29	-100.0	0.00	66.7
	Week 4	75	29.33	26.26	0.0	33.33	100.0	59	-9.04	26.14	-66.7	0.00	66.7
	Week 5	77	29.00	26.13	0.0	33.33	100.0	60	-5.56	32.57	-100.0	0.00	66.7
	Week 6	70	30.00	24.84	0.0	33.33	100.0	56	-10.12	36.47	-100.0	0.00	66.7
	Week 7	72	28.24	26.63	0.0	33.33	100.0	55	-9.09	34.82	-100.0	0.00	100.0
	Week 8	65	31.28	28.79	0.0	33.33	100.0	53	-7.55	35.59	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	70	31.90	28.05	0.0	33.33	100.0	55	-4.24	36.88	-100.0	0.00	100.0
	Week 10	60	32.78	27.10	0.0	33.33	100.0	46	-3.62	36.67	-100.0	0.00	100.0
	Week 11	64	31.77	28.75	0.0	33.33	100.0	50	-8.67	32.16	-66.7	0.00	66.7
	Week 12	60	29.44	26.10	0.0	33.33	100.0	48	-7.64	31.69	-66.7	0.00	66.7
	Week 14	56	30.36	29.32	0.0	33.33	100.0	42	-15.08	35.46	-100.0	0.00	66.7
	Week 17	58	26.44	27.04	0.0	33.33	100.0	44	-8.33	38.80	-66.7	0.00	100.0
	Week 20	47	19.86	23.73	0.0	0.00	66.7	37	-15.32	27.88	-66.7	0.00	33.3
	Week 23	44	21.21	26.99	0.0	0.00	100.0	32	-9.37	29.61	-66.7	0.00	33.3
	Week 26	39	28.20	29.16	0.0	33.33	100.0	30	-5.56	26.38	-66.7	0.00	33.3
	Week 29	34	24.51	25.04	0.0	33.33	66.7	25	-9.33	31.21	-100.0	0.00	33.3
	Week 32	33	23.23	21.22	0.0	33.33	66.7	27	-12.35	34.77	-100.0	0.00	33.3
	Week 35	30	27.78	23.30	0.0	33.33	66.7	24	-4.17	35.87	-66.7	0.00	66.7
	Week 38	26	25.64	27.17	0.0	33.33	100.0	21	-1.59	34.12	-100.0	0.00	66.7
	Week 41	22	24.24	18.35	0.0	33.33	66.7	17	1.96	24.92	-33.3	0.00	33.3
	Week 44	20	26.67	27.78	0.0	33.33	66.7	16	-8.33	31.03	-100.0	0.00	33.3
	Week 47	16	33.33	27.22	0.0	33.33	66.7	12	2.78	26.43	-33.3	0.00	66.7
	Week 50	11	21.21	22.47	0.0	33.33	66.7	10	-6.67	34.43	-66.7	0.00	66.7
	Week 53	11	24.24	15.57	0.0	33.33	33.3	10	-10.00	27.44	-66.7	0.00	33.3
	Week 56	10	36.67	24.60	0.0	33.33	66.7	8	0.00	30.86	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
North America	EV+Pembro (N= 57)												
	BASELINE	47	34.75	34.02	0.0	33.33	100.0						
	Week 1	39	35.90	30.00	0.0	33.33	100.0	37	0.90	22.89	-66.7	0.00	66.7
	Week 2	44	35.61	29.99	0.0	33.33	100.0	42	5.56	26.46	-33.3	0.00	66.7
	Week 3	44	35.61	29.99	0.0	33.33	100.0	40	0.83	28.73	-100.0	0.00	66.7
	Week 4	44	31.06	23.18	0.0	33.33	66.7	41	-4.07	35.12	-100.0	0.00	66.7
	Week 5	47	31.20	32.90	0.0	33.33	100.0	41	-4.07	36.66	-100.0	0.00	66.7
	Week 6	44	31.06	29.11	0.0	33.33	100.0	39	-6.84	34.35	-100.0	0.00	66.7
	Week 7	46	26.81	29.50	0.0	33.33	100.0	42	-8.73	32.14	-100.0	0.00	66.7
	Week 8	47	23.40	27.73	0.0	33.33	100.0	42	-11.91	31.08	-100.0	0.00	33.3
	Week 9	46	26.81	31.91	0.0	33.33	100.0	42	-8.73	32.97	-66.7	0.00	66.7
	Week 10	47	23.40	27.73	0.0	33.33	100.0	44	-11.36	33.68	-100.0	0.00	66.7
	Week 11	47	24.82	27.34	0.0	33.33	100.0	42	-10.32	32.50	-100.0	0.00	66.7
	Week 12	44	25.00	29.75	0.0	16.67	100.0	40	-10.83	38.03	-100.0	0.00	100.0
	Week 14	43	24.03	29.39	0.0	0.00	100.0	39	-9.40	29.57	-66.7	0.00	66.7
	Week 17	40	23.33	29.43	0.0	0.00	100.0	37	-9.91	25.90	-100.0	0.00	33.3
	Week 20	38	27.19	30.86	0.0	33.33	100.0	35	-8.57	30.62	-66.7	0.00	33.3
	Week 23	38	18.42	27.62	0.0	0.00	100.0	35	-9.52	27.50	-66.7	0.00	33.3
	Week 26	35	24.76	29.53	0.0	33.33	100.0	32	-9.38	34.11	-100.0	0.00	33.3
	Week 29	38	17.54	22.91	0.0	0.00	100.0	34	-9.80	34.36	-100.0	0.00	33.3
	Week 32	32	16.67	25.40	0.0	0.00	100.0	29	-6.90	30.05	-66.7	0.00	66.7
	Week 35	33	12.12	23.30	0.0	0.00	100.0	30	-14.44	25.79	-66.7	0.00	33.3
	Week 38	32	11.46	16.08	0.0	0.00	33.3	29	-13.79	28.89	-100.0	0.00	33.3
	Week 41	28	13.09	16.58	0.0	0.00	33.3	24	-9.72	25.02	-66.7	0.00	33.3
	Week 44	21	19.05	22.54	0.0	0.00	66.7	20	-5.00	31.11	-66.7	0.00	66.7
	Week 47	24	12.50	21.56	0.0	0.00	66.7	23	-7.25	36.18	-100.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	23	15.94	26.34	0.0	0.00	100.0	20	-6.67	27.78	-66.7	0.00	33.3
	Week 53	17	13.72	20.61	0.0	0.00	66.7	14	0.00	18.49	-33.3	0.00	33.3
	Week 56	20	18.33	20.16	0.0	16.67	66.7	17	-5.88	29.43	-66.7	0.00	33.3
	Week 59	17	21.57	23.40	0.0	33.33	66.7	14	-4.76	22.10	-33.3	0.00	33.3
	Week 62	14	16.67	21.68	0.0	0.00	66.7	13	-10.26	34.39	-66.7	0.00	33.3
	Week 65	12	19.44	22.28	0.0	16.67	66.7	9	-3.70	20.03	-33.3	0.00	33.3
	Week 68	10	13.33	17.21	0.0	0.00	33.3	9	0.00	16.67	-33.3	0.00	33.3
	Week 71	10	30.00	29.19	0.0	33.33	100.0	8	12.50	24.80	-33.3	16.67	33.3
	Week 74	10	20.00	23.31	0.0	16.67	66.7	9	3.70	38.89	-66.7	0.00	66.7
	Plat+Gem (N= 51)												
	BASELINE	42	31.75	32.05	0.0	33.33	100.0						
	Week 1	41	34.15	30.27	0.0	33.33	100.0	36	2.78	28.03	-66.7	0.00	66.7
	Week 2	38	40.35	25.89	0.0	33.33	100.0	33	7.07	34.11	-66.7	0.00	100.0
	Week 3	40	27.50	26.03	0.0	33.33	100.0	35	-4.76	33.47	-66.7	0.00	66.7
	Week 4	35	26.66	19.47	0.0	33.33	66.7	29	-6.90	30.05	-66.7	0.00	33.3
	Week 5	39	31.62	18.65	0.0	33.33	66.7	32	0.00	37.86	-66.7	0.00	66.7
	Week 6	34	26.47	24.31	0.0	33.33	100.0	30	-8.89	37.07	-66.7	0.00	66.7
	Week 7	42	23.01	21.45	0.0	33.33	66.7	37	-8.11	31.82	-66.7	0.00	66.7
	Week 8	39	22.22	26.86	0.0	0.00	100.0	33	-14.14	35.39	-100.0	0.00	66.7
	Week 9	39	21.37	22.28	0.0	33.33	66.7	33	-14.14	33.37	-100.0	0.00	33.3
	Week 10	39	23.93	21.56	0.0	33.33	66.7	32	-14.58	34.84	-100.0	0.00	33.3
	Week 11	39	24.78	25.04	0.0	33.33	100.0	33	-11.11	36.00	-100.0	0.00	33.3
	Week 12	36	23.15	22.28	0.0	33.33	66.7	32	-9.38	35.15	-100.0	0.00	66.7
	Week 14	34	19.61	24.78	0.0	0.00	100.0	29	-14.94	30.32	-66.7	0.00	33.3
	Week 17	37	23.42	23.39	0.0	33.33	100.0	31	-5.38	27.35	-66.7	0.00	33.3
	Week 20	27	18.52	21.35	0.0	0.00	66.7	23	-20.29	37.25	-100.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 23	27	25.92	26.69	0.0	33.33	100.0	23	-5.80	38.47	-100.0	0.00	100.0
	Week 26	28	26.19	26.23	0.0	33.33	100.0	25	-8.00	36.36	-100.0	0.00	33.3
	Week 29	29	26.44	22.50	0.0	33.33	66.7	25	-8.00	35.07	-100.0	0.00	33.3
	Week 32	17	31.37	24.92	0.0	33.33	66.7	17	-5.88	35.82	-100.0	0.00	33.3
	Week 35	16	31.25	30.96	0.0	33.33	100.0	15	-6.67	38.21	-100.0	0.00	33.3
	Week 38	16	27.08	21.84	0.0	33.33	66.7	13	-7.69	27.73	-66.7	0.00	33.3
	Week 41	16	27.08	27.81	0.0	33.33	100.0	13	-5.13	29.96	-66.7	0.00	33.3
	Week 44	13	23.08	25.04	0.0	33.33	66.7	11	-6.06	29.13	-66.7	0.00	33.3
	Week 47	11	27.27	20.10	0.0	33.33	66.7	9	3.70	20.03	-33.3	0.00	33.3
	Week 50	17	37.25	28.58	0.0	33.33	100.0	15	2.22	38.76	-66.7	0.00	66.7
	Week 53	13	33.33	23.57	0.0	33.33	66.7	11	12.12	30.81	-33.3	0.00	66.7
	Week 56	11	33.33	33.33	0.0	33.33	100.0	9	11.11	47.14	-33.3	0.00	100.0
	Week 59	11	33.33	25.82	0.0	33.33	66.7	9	11.11	37.27	-33.3	0.00	66.7
	Week 62	11	33.33	25.82	0.0	33.33	66.7	9	11.11	33.33	-33.3	0.00	66.7
	Week 65	10	30.00	24.60	0.0	33.33	66.7	8	4.17	33.03	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Rest of World	EV+Pembro (N= 85)												
	BASELINE	80	31.25	27.22	0.0	33.33	100.0						
	Week 1	77	30.73	26.36	0.0	33.33	100.0	76	-0.44	29.06	-100.0	0.00	100.0
	Week 2	80	30.83	24.17	0.0	33.33	100.0	76	0.00	29.82	-100.0	0.00	100.0
	Week 3	76	31.58	26.61	0.0	33.33	100.0	73	0.00	34.25	-100.0	0.00	66.7
	Week 4	72	21.76	21.78	0.0	33.33	100.0	68	-11.28	28.57	-100.0	0.00	33.3
	Week 5	73	26.48	27.19	0.0	33.33	100.0	70	-6.67	30.88	-100.0	0.00	66.7
	Week 6	74	25.22	23.93	0.0	33.33	100.0	70	-4.29	29.45	-100.0	0.00	33.3
	Week 7	71	28.17	28.53	0.0	33.33	100.0	66	-5.05	33.20	-66.7	0.00	66.7
	Week 8	72	26.39	24.35	0.0	33.33	100.0	68	-5.39	30.26	-100.0	0.00	66.7
	Week 9	71	26.76	24.96	0.0	33.33	100.0	68	-4.90	32.20	-100.0	0.00	66.7
	Week 10	73	27.40	23.79	0.0	33.33	100.0	69	-4.35	31.27	-100.0	0.00	100.0
	Week 11	71	25.82	26.55	0.0	33.33	100.0	67	-5.97	32.27	-66.7	0.00	100.0
	Week 12	69	23.67	25.63	0.0	33.33	100.0	66	-8.08	30.42	-66.7	0.00	100.0
	Week 14	68	25.00	24.69	0.0	33.33	100.0	64	-7.29	34.36	-100.0	0.00	100.0
	Week 17	68	25.00	27.24	0.0	33.33	100.0	63	-3.70	36.96	-100.0	0.00	100.0
	Week 20	59	27.12	27.32	0.0	33.33	100.0	56	-4.76	36.75	-100.0	0.00	100.0
	Week 23	63	28.57	25.30	0.0	33.33	100.0	59	-3.96	31.00	-100.0	0.00	100.0
	Week 26	59	28.81	28.67	0.0	33.33	100.0	57	-2.92	37.94	-100.0	0.00	100.0
	Week 29	56	26.19	27.50	0.0	33.33	100.0	54	-4.32	34.29	-100.0	0.00	100.0
	Week 32	52	25.00	25.46	0.0	33.33	100.0	49	-5.44	31.44	-66.7	0.00	66.7
	Week 35	43	24.80	21.93	0.0	33.33	66.7	40	-8.33	33.55	-66.7	0.00	66.7
	Week 38	49	25.85	25.70	0.0	33.33	100.0	47	-4.97	38.69	-100.0	0.00	100.0
	Week 41	49	28.57	27.22	0.0	33.33	100.0	47	0.00	34.75	-100.0	0.00	100.0
	Week 44	44	25.00	26.04	0.0	33.33	100.0	41	-4.88	38.41	-100.0	0.00	100.0
	Week 47	37	24.32	23.11	0.0	33.33	66.7	35	-7.62	36.23	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	29	26.44	28.70	0.0	33.33	100.0	28	-1.19	41.06	-100.0	0.00	100.0
	Week 53	34	26.47	29.34	0.0	33.33	100.0	33	-1.01	37.72	-66.7	0.00	100.0
	Week 56	31	25.81	28.17	0.0	33.33	100.0	30	-1.11	38.64	-100.0	0.00	100.0
	Week 59	28	26.19	26.23	0.0	33.33	66.7	27	-1.23	35.18	-100.0	0.00	66.7
	Week 62	28	19.05	21.14	0.0	16.67	66.7	27	-3.70	23.27	-66.7	0.00	33.3
	Week 65	23	27.54	27.80	0.0	33.33	66.7	22	0.00	34.12	-66.7	0.00	66.7
	Week 68	22	24.24	27.57	0.0	16.67	66.7	22	0.00	34.12	-66.7	0.00	66.7
	Week 71	22	27.27	30.23	0.0	33.33	100.0	22	1.52	36.34	-66.7	0.00	100.0
	Week 74	22	27.27	30.23	0.0	33.33	100.0	22	3.03	35.50	-66.7	0.00	100.0
	Week 77	18	27.78	28.58	0.0	33.33	66.7	17	5.88	33.82	-66.7	0.00	66.7
	Week 80	16	27.08	25.00	0.0	33.33	66.7	15	0.00	28.17	-66.7	0.00	33.3
	Week 83	16	27.08	21.84	0.0	33.33	66.7	15	0.00	30.86	-66.7	0.00	33.3
	Week 86	13	33.33	27.22	0.0	33.33	66.7	12	2.78	26.43	-33.3	0.00	33.3
	Week 89	12	25.00	20.72	0.0	33.33	66.7	12	-2.78	30.01	-66.7	0.00	33.3
	Plat+Gem (N= 89)												
	BASELINE	75	32.89	26.56	0.0	33.33	100.0						
	Week 1	61	28.96	24.70	0.0	33.33	100.0	61	-1.64	20.57	-66.7	0.00	33.3
	Week 2	66	35.35	27.35	0.0	33.33	100.0	62	1.61	30.44	-66.7	0.00	100.0
	Week 3	76	29.38	25.51	0.0	33.33	100.0	71	-3.76	24.91	-100.0	0.00	66.7
	Week 4	73	27.40	25.67	0.0	33.33	100.0	68	-5.39	30.26	-100.0	0.00	66.7
	Week 5	71	30.52	25.66	0.0	33.33	100.0	64	-2.08	27.78	-66.7	0.00	66.7
	Week 6	70	25.71	25.49	0.0	33.33	100.0	63	-6.35	32.16	-100.0	0.00	100.0
	Week 7	72	30.09	23.84	0.0	33.33	100.0	65	-1.54	26.64	-66.7	0.00	66.7
	Week 8	63	26.98	23.08	0.0	33.33	100.0	58	-3.45	29.74	-100.0	0.00	66.7
	Week 9	68	25.00	24.01	0.0	33.33	100.0	62	-6.99	28.40	-100.0	0.00	66.7
	Week 10	67	27.86	21.40	0.0	33.33	66.7	61	-4.92	24.97	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	65	28.72	26.27	0.0	33.33	66.7	60	-1.67	27.74	-66.7	0.00	66.7
	Week 12	63	25.40	24.48	0.0	33.33	100.0	58	-5.75	30.68	-100.0	0.00	66.7
	Week 14	63	24.87	23.16	0.0	33.33	66.7	57	-7.02	25.77	-100.0	0.00	33.3
	Week 17	60	26.67	27.31	0.0	33.33	100.0	55	-3.64	30.55	-100.0	0.00	66.7
	Week 20	52	19.23	23.19	0.0	0.00	66.7	50	-9.33	29.39	-100.0	0.00	33.3
	Week 23	44	21.97	28.70	0.0	0.00	100.0	42	-3.97	26.75	-66.7	0.00	66.7
	Week 26	41	23.58	26.08	0.0	33.33	100.0	40	-0.83	27.72	-66.7	0.00	66.7
	Week 29	37	20.72	25.28	0.0	0.00	100.0	36	-0.93	31.36	-66.7	0.00	66.7
	Week 32	33	22.22	27.22	0.0	0.00	100.0	32	0.00	30.53	-66.7	0.00	66.7
	Week 35	30	15.55	19.04	0.0	0.00	66.7	30	-5.56	24.89	-66.7	0.00	33.3
	Week 38	32	14.58	18.81	0.0	0.00	66.7	31	-6.45	27.78	-66.7	0.00	66.7
	Week 41	27	19.75	26.57	0.0	0.00	100.0	26	-3.85	27.21	-66.7	0.00	66.7
	Week 44	27	19.75	26.57	0.0	0.00	100.0	26	-1.28	30.52	-66.7	0.00	66.7
	Week 47	29	19.54	26.00	0.0	0.00	100.0	28	-2.38	29.99	-66.7	0.00	66.7
	Week 50	23	15.94	29.93	0.0	0.00	100.0	22	-3.03	28.93	-33.3	0.00	66.7
	Week 53	22	19.70	24.47	0.0	16.67	100.0	21	-1.59	22.30	-33.3	0.00	66.7
	Week 56	18	20.37	25.92	0.0	0.00	66.7	17	1.96	24.92	-66.7	0.00	33.3
	Week 59	17	13.72	16.91	0.0	0.00	33.3	16	-8.33	22.77	-66.7	0.00	33.3
	Week 62	16	18.75	20.97	0.0	16.67	66.7	15	-6.67	28.73	-66.7	0.00	33.3
	Week 65	15	11.11	16.26	0.0	0.00	33.3	14	-11.91	28.06	-66.7	0.00	33.3
	Week 68	12	19.44	22.28	0.0	16.67	66.7	11	0.00	21.08	-33.3	0.00	33.3
	Week 71	13	23.08	25.04	0.0	33.33	66.7	12	-2.78	30.01	-66.7	0.00	33.3
	Week 74	10	13.33	23.31	0.0	0.00	66.7	10	-10.00	31.62	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	EV+Pembro (N=198)												
	BASELINE	170	34.71	31.06	0.0	33.33	100.0						
	Week 1	157	34.18	29.22	0.0	33.33	100.0	152	-0.66	26.15	-100.0	0.00	100.0
	Week 2	167	30.14	26.95	0.0	33.33	100.0	155	-1.94	28.49	-100.0	0.00	100.0
	Week 3	161	32.92	28.38	0.0	33.33	100.0	147	-0.91	33.32	-100.0	0.00	100.0
	Week 4	158	26.16	25.05	0.0	33.33	100.0	145	-8.05	32.70	-100.0	0.00	100.0
	Week 5	154	27.27	28.12	0.0	33.33	100.0	140	-7.62	31.57	-100.0	0.00	66.7
	Week 6	153	26.14	25.92	0.0	33.33	100.0	138	-7.97	31.08	-100.0	0.00	100.0
	Week 7	159	27.25	27.52	0.0	33.33	100.0	142	-8.45	32.36	-100.0	0.00	66.7
	Week 8	154	26.19	27.21	0.0	33.33	100.0	135	-8.15	32.19	-100.0	0.00	100.0
	Week 9	162	28.81	27.93	0.0	33.33	100.0	146	-5.25	34.28	-100.0	0.00	100.0
	Week 10	159	26.20	25.81	0.0	33.33	100.0	144	-9.03	32.32	-100.0	0.00	100.0
	Week 11	161	26.09	27.56	0.0	33.33	100.0	143	-8.86	33.56	-100.0	0.00	100.0
	Week 12	154	25.11	28.34	0.0	33.33	100.0	140	-10.24	35.74	-100.0	0.00	100.0
	Week 14	154	25.11	26.76	0.0	33.33	100.0	137	-9.49	34.29	-100.0	0.00	100.0
	Week 17	145	23.91	26.85	0.0	33.33	100.0	130	-10.51	34.24	-100.0	0.00	100.0
	Week 20	139	24.46	28.82	0.0	33.33	100.0	126	-10.05	37.06	-100.0	0.00	100.0
	Week 23	133	26.06	29.40	0.0	33.33	100.0	122	-6.01	36.11	-100.0	0.00	100.0
	Week 26	129	24.03	28.25	0.0	33.33	100.0	118	-9.60	36.23	-100.0	0.00	100.0
	Week 29	131	21.12	25.56	0.0	0.00	100.0	120	-9.72	33.86	-100.0	0.00	100.0
	Week 32	111	20.12	24.32	0.0	0.00	100.0	102	-11.77	31.69	-66.7	0.00	100.0
	Week 35	109	21.10	24.28	0.0	33.33	100.0	100	-11.67	32.26	-66.7	0.00	100.0
	Week 38	107	20.25	24.12	0.0	0.00	100.0	100	-11.00	34.51	-100.0	0.00	100.0
	Week 41	103	23.62	25.41	0.0	33.33	100.0	94	-7.45	32.85	-100.0	0.00	100.0
	Week 44	88	19.70	23.51	0.0	0.00	100.0	81	-11.11	34.16	-100.0	0.00	100.0
	Week 47	80	19.58	23.54	0.0	0.00	66.7	75	-9.33	35.33	-100.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	73	19.63	25.36	0.0	0.00	100.0	68	-8.33	34.73	-100.0	0.00	100.0
	Week 53	64	21.87	26.71	0.0	0.00	100.0	59	-7.34	33.94	-66.7	0.00	100.0
	Week 56	66	22.22	27.01	0.0	0.00	100.0	61	-6.01	36.77	-100.0	0.00	100.0
	Week 59	58	21.84	24.62	0.0	16.67	66.7	54	-8.02	32.33	-100.0	0.00	66.7
	Week 62	54	16.67	20.22	0.0	0.00	66.7	52	-10.26	28.42	-100.0	0.00	33.3
	Week 65	51	21.57	24.79	0.0	0.00	66.7	47	-6.38	31.58	-66.7	0.00	66.7
	Week 68	49	17.01	23.69	0.0	0.00	66.7	48	-7.64	30.94	-66.7	0.00	66.7
	Week 71	47	22.69	28.75	0.0	0.00	100.0	45	-3.70	36.39	-66.7	0.00	100.0
	Week 74	42	22.22	26.20	0.0	16.67	100.0	41	-3.25	36.37	-66.7	0.00	100.0
	Week 77	38	21.93	27.15	0.0	0.00	100.0	36	-2.78	34.16	-66.7	0.00	66.7
	Week 80	35	20.95	22.99	0.0	33.33	66.7	32	-10.42	33.27	-100.0	0.00	33.3
	Week 83	32	18.75	20.63	0.0	16.67	66.7	30	-13.33	33.45	-100.0	0.00	33.3
	Week 86	30	23.33	26.48	0.0	33.33	100.0	27	-8.64	28.63	-66.7	0.00	33.3
	Week 89	28	22.62	24.09	0.0	33.33	100.0	26	-10.26	27.92	-66.7	0.00	33.3
	Week 92	24	18.05	21.93	0.0	0.00	66.7	22	-12.12	26.32	-66.7	0.00	33.3
	Week 95	21	25.40	23.34	0.0	33.33	66.7	20	1.67	29.57	-66.7	0.00	66.7
	Week 98	16	22.92	31.55	0.0	0.00	100.0	15	-2.22	23.46	-33.3	0.00	66.7
	Week 101	12	25.00	20.72	0.0	33.33	66.7	12	2.78	22.28	-33.3	0.00	33.3
	Week 104	10	20.00	23.31	0.0	16.67	66.7	10	-6.67	21.08	-33.3	0.00	33.3
	Plat+Gem (N=185)												
	BASELINE	146	34.25	30.06	0.0	33.33	100.0						
	Week 1	131	33.59	29.09	0.0	33.33	100.0	120	0.56	25.56	-66.7	0.00	66.7
	Week 2	128	37.76	27.23	0.0	33.33	100.0	115	3.19	28.94	-66.7	0.00	100.0
	Week 3	141	31.44	27.82	0.0	33.33	100.0	126	-3.17	30.53	-100.0	0.00	66.7
	Week 4	139	29.02	24.68	0.0	33.33	100.0	119	-6.72	29.30	-100.0	0.00	66.7
	Week 5	143	31.47	25.26	0.0	33.33	100.0	120	-1.67	32.58	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 6	133	29.82	24.71	0.0	33.33	100.0	114	-6.14	34.23	-100.0	0.00	100.0
	Week 7	142	29.34	24.31	0.0	33.33	100.0	120	-4.17	31.03	-100.0	0.00	100.0
	Week 8	125	28.00	26.23	0.0	33.33	100.0	109	-5.50	33.49	-100.0	0.00	100.0
	Week 9	135	26.17	25.23	0.0	33.33	100.0	115	-7.25	32.08	-100.0	0.00	100.0
	Week 10	131	29.26	24.82	0.0	33.33	100.0	111	-6.01	32.78	-100.0	0.00	100.0
	Week 11	128	29.69	27.82	0.0	33.33	100.0	109	-5.81	31.70	-100.0	0.00	66.7
	Week 12	124	25.27	24.55	0.0	33.33	100.0	108	-8.33	31.94	-100.0	0.00	66.7
	Week 14	121	24.79	25.65	0.0	33.33	100.0	101	-11.55	30.35	-100.0	0.00	33.3
	Week 17	121	25.34	26.18	0.0	33.33	100.0	101	-5.61	32.00	-100.0	0.00	100.0
	Week 20	98	18.71	22.99	0.0	0.00	66.7	86	-14.34	31.74	-100.0	0.00	33.3
	Week 23	93	22.58	28.73	0.0	0.00	100.0	78	-5.98	30.74	-100.0	0.00	100.0
	Week 26	86	25.19	27.50	0.0	33.33	100.0	75	-4.00	30.98	-100.0	0.00	66.7
	Week 29	76	22.37	24.58	0.0	33.33	100.0	65	-5.13	34.98	-100.0	0.00	66.7
	Week 32	62	20.97	23.56	0.0	33.33	100.0	56	-8.33	33.79	-100.0	0.00	66.7
	Week 35	58	23.56	24.98	0.0	33.33	100.0	52	-4.49	33.02	-100.0	0.00	66.7
	Week 38	60	20.00	21.44	0.0	33.33	66.7	52	-5.77	30.76	-100.0	0.00	66.7
	Week 41	52	24.36	24.80	0.0	33.33	100.0	44	0.76	27.36	-66.7	0.00	66.7
	Week 44	46	22.46	27.27	0.0	0.00	100.0	40	-3.33	31.85	-100.0	0.00	66.7
	Week 47	44	23.48	25.50	0.0	33.33	100.0	38	1.75	27.89	-66.7	0.00	66.7
	Week 50	42	24.60	30.41	0.0	16.67	100.0	38	0.00	35.52	-66.7	0.00	66.7
	Week 53	38	23.68	23.13	0.0	33.33	100.0	34	2.94	27.67	-66.7	0.00	66.7
	Week 56	32	25.00	28.08	0.0	33.33	100.0	28	5.95	34.01	-66.7	0.00	100.0
	Week 59	31	22.58	21.75	0.0	33.33	66.7	27	1.23	28.47	-66.7	0.00	66.7
	Week 62	29	20.69	20.73	0.0	33.33	66.7	26	-2.56	29.70	-66.7	0.00	66.7
	Week 65	25	18.67	21.69	0.0	0.00	66.7	21	-6.35	30.95	-66.7	0.00	66.7
	Week 68	20	31.67	25.31	0.0	33.33	100.0	16	12.50	31.91	-33.3	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 71	17	25.49	27.71	0.0	33.33	100.0	14	0.00	34.59	-66.7	0.00	66.7
	Week 74	17	17.65	26.66	0.0	0.00	100.0	14	-9.52	27.51	-66.7	0.00	33.3
	Week 77	16	25.00	25.82	0.0	33.33	66.7	13	-5.13	40.48	-66.7	0.00	66.7
	Week 80	13	25.64	19.97	0.0	33.33	66.7	12	0.00	24.62	-66.7	0.00	33.3
	Week 83	11	15.15	22.92	0.0	0.00	66.7	10	-10.00	35.31	-66.7	0.00	66.7
	Week 86	12	13.89	17.16	0.0	0.00	33.3	11	-12.12	30.81	-66.7	0.00	33.3
	Week 89	11	18.18	17.41	0.0	33.33	33.3	10	-13.33	28.11	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	EV+Pembro (N= 42)												
	BASELINE	36	25.00	24.40	0.0	33.33	66.7						
	Week 1	33	24.24	22.47	0.0	33.33	66.7	32	2.08	20.63	-33.3	0.00	33.3
	Week 2	36	32.41	29.26	0.0	33.33	100.0	34	7.84	24.70	-33.3	0.00	66.7
	Week 3	37	30.63	28.74	0.0	33.33	100.0	35	4.76	29.31	-66.7	0.00	66.7
	Week 4	36	24.07	21.98	0.0	33.33	66.7	34	-0.98	25.27	-66.7	0.00	66.7
	Week 5	36	25.00	29.14	0.0	33.33	100.0	33	-5.05	31.32	-66.7	0.00	66.7
	Week 6	35	23.81	22.25	0.0	33.33	66.7	32	-1.04	31.09	-66.7	0.00	33.3
	Week 7	36	21.30	22.75	0.0	33.33	66.7	34	-1.96	29.52	-66.7	0.00	66.7
	Week 8	37	19.82	22.85	0.0	0.00	66.7	36	-4.63	28.90	-66.7	0.00	33.3
	Week 9	35	16.19	20.41	0.0	0.00	66.7	34	-5.88	28.98	-66.7	0.00	33.3
	Week 10	32	19.79	22.17	0.0	16.67	66.7	31	-3.23	29.00	-66.7	0.00	33.3
	Week 11	33	24.24	22.47	0.0	33.33	66.7	32	1.04	27.42	-66.7	0.00	66.7
	Week 12	32	21.87	23.36	0.0	33.33	66.7	31	-3.23	29.00	-66.7	0.00	33.3
	Week 14	31	17.20	20.85	0.0	0.00	66.7	30	-7.78	28.61	-66.7	0.00	33.3
	Week 17	33	21.21	21.76	0.0	33.33	66.7	32	-3.13	28.54	-66.7	0.00	33.3
	Week 20	28	25.00	23.35	0.0	33.33	66.7	28	0.00	31.43	-66.7	0.00	66.7
	Week 23	29	17.24	21.12	0.0	0.00	66.7	29	-9.20	26.57	-66.7	0.00	33.3
	Week 26	27	22.22	26.15	0.0	33.33	100.0	26	-1.28	31.95	-66.7	0.00	100.0
	Week 29	26	19.23	19.26	0.0	33.33	66.7	25	-5.33	28.35	-66.7	0.00	33.3
	Week 32	24	23.61	28.62	0.0	16.67	100.0	23	2.90	30.01	-66.7	0.00	66.7
	Week 35	23	17.39	19.77	0.0	0.00	66.7	22	-4.55	27.78	-66.7	0.00	33.3
	Week 38	25	20.00	16.67	0.0	33.33	33.3	24	-1.39	26.88	-66.7	0.00	33.3
	Week 41	26	21.79	20.96	0.0	33.33	66.7	25	0.00	27.22	-33.3	0.00	66.7
	Week 44	20	26.67	23.20	0.0	33.33	66.7	19	3.51	29.18	-33.3	0.00	66.7
	Week 47	20	21.67	24.84	0.0	16.67	66.7	19	-1.75	37.64	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	16	22.92	23.47	0.0	33.33	66.7	16	2.08	33.27	-66.7	0.00	66.7
	Week 53	15	20.00	24.56	0.0	0.00	66.7	15	0.00	33.33	-66.7	0.00	66.7
	Week 56	15	20.00	21.08	0.0	33.33	66.7	15	0.00	30.86	-33.3	0.00	66.7
	Week 59	14	21.43	21.11	0.0	33.33	66.7	14	0.00	26.15	-33.3	0.00	66.7
	Week 62	11	18.18	27.34	0.0	0.00	66.7	11	-6.06	35.96	-66.7	0.00	33.3
	Plat+Gem (N= 57)												
	BASELINE	42	34.92	29.41	0.0	33.33	100.0						
	Week 1	42	33.33	27.55	0.0	33.33	100.0	38	-2.63	30.40	-66.7	0.00	66.7
	Week 2	43	37.98	30.50	0.0	33.33	100.0	36	4.63	39.16	-66.7	0.00	100.0
	Week 3	43	24.03	24.48	0.0	33.33	100.0	36	-10.19	28.53	-66.7	0.00	66.7
	Week 4	44	25.00	25.03	0.0	33.33	66.7	37	-8.11	26.53	-66.7	0.00	33.3
	Week 5	44	25.76	21.40	0.0	33.33	66.7	36	-7.41	28.85	-66.7	0.00	33.3
	Week 6	41	20.32	24.58	0.0	0.00	100.0	35	-15.24	35.56	-66.7	-33.33	66.7
	Week 7	44	22.73	24.67	0.0	33.33	100.0	37	-10.81	30.48	-66.7	0.00	66.7
	Week 8	42	26.19	27.09	0.0	33.33	100.0	35	-13.33	32.54	-66.7	0.00	66.7
	Week 9	42	29.36	26.75	0.0	33.33	100.0	35	-8.57	35.56	-66.7	0.00	66.7
	Week 10	35	26.66	19.47	0.0	33.33	66.7	28	-9.52	27.00	-66.7	0.00	66.7
	Week 11	40	26.67	24.11	0.0	33.33	66.7	34	-7.84	30.77	-66.7	0.00	66.7
	Week 12	35	30.47	24.75	0.0	33.33	100.0	30	-3.33	31.99	-66.7	0.00	66.7
	Week 14	32	29.17	27.76	0.0	33.33	100.0	27	-11.11	30.66	-66.7	0.00	66.7
	Week 17	34	27.45	26.55	0.0	33.33	100.0	29	-5.75	35.71	-66.7	0.00	100.0
	Week 20	28	21.43	22.62	0.0	33.33	66.7	24	-11.11	27.22	-66.7	0.00	33.3
	Week 23	22	22.73	21.54	0.0	33.33	66.7	19	-7.02	30.59	-66.7	0.00	33.3
	Week 26	22	28.79	25.81	0.0	33.33	66.7	20	-5.00	24.84	-66.7	0.00	33.3
	Week 29	24	27.78	23.40	0.0	33.33	66.7	21	-6.35	22.65	-33.3	0.00	33.3
	Week 32	21	34.92	24.67	0.0	33.33	66.7	20	1.67	31.48	-100.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 35	18	24.07	22.30	0.0	33.33	66.7	17	-7.84	27.71	-66.7	0.00	33.3
	Week 38	14	26.19	29.75	0.0	33.33	100.0	13	-2.56	25.32	-33.3	0.00	33.3
	Week 41	13	17.95	22.01	0.0	0.00	66.7	12	-13.89	22.28	-33.3	-16.67	33.3
	Week 44	14	23.81	24.21	0.0	33.33	66.7	13	-7.69	24.17	-33.3	0.00	33.3
	Week 47	12	30.56	26.43	0.0	33.33	66.7	11	-6.06	25.02	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Visceral metastases	EV+Pembro (N=170)												
	BASELINE	146	33.79	30.82	0.0	33.33	100.0						
	Week 1	135	33.33	28.51	0.0	33.33	100.0	131	-1.27	24.95	-100.0	0.00	66.7
	Week 2	145	28.50	24.84	0.0	33.33	100.0	134	-2.99	26.32	-100.0	0.00	66.7
	Week 3	141	30.97	28.63	0.0	33.33	100.0	129	-1.81	32.36	-100.0	0.00	66.7
	Week 4	136	27.45	24.97	0.0	33.33	100.0	125	-6.40	32.98	-100.0	0.00	100.0
	Week 5	131	27.99	28.59	0.0	33.33	100.0	118	-7.91	32.23	-100.0	0.00	66.7
	Week 6	127	24.67	24.56	0.0	33.33	100.0	113	-8.26	32.89	-100.0	0.00	100.0
	Week 7	135	27.90	27.38	0.0	33.33	100.0	121	-6.61	32.95	-100.0	0.00	66.7
	Week 8	131	24.43	26.42	0.0	33.33	100.0	118	-9.04	33.09	-100.0	0.00	100.0
	Week 9	136	24.51	26.68	0.0	33.33	100.0	124	-7.53	33.43	-100.0	0.00	66.7
	Week 10	135	21.97	24.15	0.0	33.33	100.0	124	-11.29	32.06	-100.0	0.00	66.7
	Week 11	134	22.88	24.67	0.0	33.33	100.0	121	-10.47	32.50	-100.0	0.00	66.7
	Week 12	131	21.12	25.89	0.0	0.00	100.0	120	-12.78	33.53	-100.0	0.00	100.0
	Week 14	130	21.54	25.54	0.0	0.00	100.0	117	-12.54	33.83	-100.0	0.00	66.7
	Week 17	124	20.97	24.59	0.0	0.00	100.0	111	-12.31	33.31	-100.0	0.00	66.7
	Week 20	115	22.61	27.77	0.0	0.00	100.0	105	-10.48	36.20	-100.0	0.00	100.0
	Week 23	111	19.82	25.58	0.0	0.00	100.0	103	-12.30	33.33	-100.0	0.00	100.0
	Week 26	106	20.44	27.05	0.0	0.00	100.0	97	-12.37	36.11	-100.0	0.00	100.0
	Week 29	106	16.04	23.11	0.0	0.00	100.0	98	-14.63	32.49	-100.0	0.00	33.3
	Week 32	92	18.12	23.91	0.0	0.00	100.0	85	-13.73	29.68	-66.7	0.00	66.7
	Week 35	86	17.05	21.54	0.0	0.00	66.7	79	-15.19	29.62	-66.7	0.00	33.3
	Week 38	90	17.41	20.13	0.0	0.00	66.7	84	-13.89	33.22	-100.0	0.00	33.3
	Week 41	87	21.07	22.80	0.0	33.33	66.7	81	-10.70	32.42	-100.0	0.00	66.7
	Week 44	73	18.72	22.21	0.0	0.00	66.7	68	-12.75	32.59	-100.0	0.00	66.7
	Week 47	68	17.65	23.37	0.0	0.00	66.7	63	-12.17	36.57	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	61	18.03	24.78	0.0	0.00	100.0	57	-10.53	32.22	-100.0	0.00	33.3
	Week 53	54	21.60	26.82	0.0	0.00	100.0	50	-7.33	33.19	-66.7	0.00	66.7
	Week 56	58	19.54	25.00	0.0	0.00	100.0	54	-9.88	35.25	-100.0	0.00	66.7
	Week 59	50	19.33	23.42	0.0	0.00	66.7	47	-11.35	32.06	-100.0	0.00	66.7
	Week 62	45	16.30	22.04	0.0	0.00	66.7	43	-14.73	29.37	-100.0	0.00	33.3
	Week 65	37	18.92	24.27	0.0	0.00	66.7	34	-11.76	30.58	-66.7	0.00	33.3
	Week 68	35	14.29	23.27	0.0	0.00	66.7	34	-13.72	31.91	-66.7	0.00	33.3
	Week 71	31	19.35	24.00	0.0	0.00	66.7	30	-11.11	33.14	-66.7	0.00	33.3
	Week 74	29	18.39	21.06	0.0	0.00	66.7	28	-14.29	30.67	-66.7	0.00	33.3
	Week 77	26	24.36	27.58	0.0	33.33	100.0	25	-6.67	33.33	-66.7	0.00	66.7
	Week 80	22	24.24	25.58	0.0	33.33	66.7	21	-14.29	35.86	-100.0	0.00	33.3
	Week 83	23	20.29	21.88	0.0	33.33	66.7	22	-16.67	38.15	-100.0	0.00	33.3
	Week 86	21	23.81	23.90	0.0	33.33	66.7	20	-11.67	27.09	-66.7	0.00	33.3
	Week 89	21	20.63	19.65	0.0	33.33	66.7	20	-11.67	27.09	-66.7	0.00	33.3
	Week 92	18	16.67	20.61	0.0	0.00	66.7	17	-13.73	29.01	-66.7	0.00	33.3
	Week 95	13	20.51	21.68	0.0	33.33	66.7	12	-11.11	29.59	-66.7	0.00	33.3
	Week 98	11	15.15	22.92	0.0	0.00	66.7	11	-9.09	33.64	-66.7	0.00	66.7
	Week 101	11	27.27	25.03	0.0	33.33	66.7	11	-3.03	34.82	-66.7	0.00	66.7
	Plat+Gem (N=161)												
	BASELINE	129	36.17	28.88	0.0	33.33	100.0						
	Week 1	113	34.22	27.63	0.0	33.33	100.0	105	-1.27	26.12	-66.7	0.00	66.7
	Week 2	108	39.81	26.36	0.0	33.33	100.0	98	-0.34	30.08	-66.7	0.00	100.0
	Week 3	121	29.20	27.41	0.0	33.33	100.0	109	-7.03	29.77	-100.0	0.00	66.7
	Week 4	116	26.15	23.59	0.0	33.33	100.0	101	-12.54	28.62	-100.0	0.00	33.3
	Week 5	121	27.82	24.48	0.0	33.33	100.0	104	-8.97	30.89	-100.0	0.00	66.7
	Week 6	118	26.27	23.81	0.0	33.33	100.0	102	-13.40	33.58	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 7	121	25.89	22.15	0.0	33.33	100.0	104	-11.22	28.86	-100.0	0.00	66.7
	Week 8	108	25.00	23.73	0.0	33.33	100.0	96	-13.19	31.52	-100.0	0.00	66.7
	Week 9	114	23.98	23.68	0.0	33.33	100.0	99	-14.14	32.33	-100.0	0.00	66.7
	Week 10	109	27.83	22.00	0.0	33.33	100.0	94	-12.06	30.47	-100.0	0.00	66.7
	Week 11	109	27.52	27.53	0.0	33.33	100.0	95	-9.82	31.46	-100.0	0.00	66.7
	Week 12	103	24.59	23.78	0.0	33.33	100.0	91	-11.36	33.04	-100.0	0.00	66.7
	Week 14	98	24.15	26.98	0.0	33.33	100.0	85	-14.90	31.50	-100.0	0.00	33.3
	Week 17	103	22.98	25.15	0.0	33.33	100.0	89	-11.24	28.40	-100.0	0.00	33.3
	Week 20	82	18.29	23.51	0.0	0.00	66.7	75	-17.33	32.59	-100.0	0.00	33.3
	Week 23	77	23.81	28.54	0.0	33.33	100.0	68	-9.80	31.58	-100.0	0.00	100.0
	Week 26	71	26.29	26.38	0.0	33.33	100.0	65	-6.67	28.38	-100.0	0.00	33.3
	Week 29	65	23.59	22.61	0.0	33.33	66.7	59	-8.47	30.07	-100.0	0.00	33.3
	Week 32	52	23.72	23.19	0.0	33.33	66.7	49	-8.84	35.21	-100.0	0.00	33.3
	Week 35	47	24.82	22.49	0.0	33.33	66.7	44	-9.85	32.61	-100.0	0.00	33.3
	Week 38	42	23.01	23.84	0.0	33.33	100.0	39	-5.98	28.48	-66.7	0.00	66.7
	Week 41	35	21.90	19.71	0.0	33.33	66.7	32	-9.38	25.73	-66.7	0.00	33.3
	Week 44	36	23.15	24.97	0.0	33.33	66.7	33	-9.09	30.36	-100.0	0.00	33.3
	Week 47	32	23.96	21.14	0.0	33.33	66.7	30	-2.22	26.16	-66.7	0.00	66.7
	Week 50	30	21.11	25.50	0.0	16.67	100.0	29	-8.05	32.92	-66.7	0.00	66.7
	Week 53	25	21.33	18.95	0.0	33.33	66.7	24	-2.78	27.66	-66.7	0.00	66.7
	Week 56	22	30.30	28.93	0.0	33.33	100.0	21	9.52	36.73	-66.7	0.00	100.0
	Week 59	22	22.73	21.54	0.0	33.33	66.7	21	1.59	30.69	-66.7	0.00	66.7
	Week 62	19	24.56	24.45	0.0	33.33	66.7	18	0.00	36.16	-66.7	0.00	66.7
	Week 65	19	19.30	20.23	0.0	33.33	66.7	18	-3.70	32.11	-66.7	0.00	66.7
	Week 68	13	25.64	27.73	0.0	33.33	100.0	12	8.33	35.18	-33.3	0.00	100.0
	Week 71	13	28.20	26.69	0.0	33.33	66.7	12	2.78	36.12	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 74	11	18.18	22.92	0.0	0.00	66.7	11	-6.06	32.72	-66.7	0.00	33.3
	Week 77	10	10.00	16.10	0.0	0.00	33.3	10	-16.67	32.39	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Lymph node only	EV+Pembro (N= 60)												
	BASELINE	53	30.19	27.94	0.0	33.33	100.0						
	Week 1	49	30.61	28.74	0.0	33.33	100.0	47	2.84	27.65	-66.7	0.00	100.0
	Week 2	50	36.00	30.74	0.0	33.33	100.0	48	7.64	30.94	-66.7	0.00	100.0
	Week 3	50	36.00	28.44	0.0	33.33	100.0	47	4.96	34.04	-66.7	0.00	100.0
	Week 4	50	20.67	23.22	0.0	33.33	100.0	47	-7.09	27.75	-66.7	0.00	66.7
	Week 5	53	24.53	28.61	0.0	33.33	100.0	49	-5.44	29.93	-66.7	0.00	66.7
	Week 6	53	28.30	27.27	0.0	33.33	100.0	50	-2.67	28.44	-66.7	0.00	66.7
	Week 7	52	21.15	22.89	0.0	33.33	100.0	48	-9.03	28.13	-66.7	0.00	66.7
	Week 8	52	26.28	27.48	0.0	33.33	100.0	47	-4.26	28.33	-66.7	0.00	66.7
	Week 9	53	30.19	27.16	0.0	33.33	100.0	49	-1.36	30.40	-66.7	0.00	66.7
	Week 10	48	33.33	27.51	0.0	33.33	100.0	44	0.76	30.91	-66.7	0.00	100.0
	Week 11	53	32.70	30.31	0.0	33.33	100.0	48	2.08	33.27	-66.7	0.00	100.0
	Week 12	48	33.33	30.75	0.0	33.33	100.0	45	1.48	36.90	-66.7	0.00	100.0
	Week 14	48	29.86	25.02	0.0	33.33	100.0	44	-0.76	32.54	-66.7	0.00	100.0
	Week 17	46	29.71	27.42	0.0	33.33	100.0	44	-0.76	34.09	-66.7	0.00	100.0
	Week 20	44	30.30	26.72	0.0	33.33	100.0	42	-1.59	37.51	-66.7	0.00	100.0
	Week 23	43	34.11	31.28	0.0	33.33	100.0	41	5.69	35.67	-66.7	0.00	100.0
	Week 26	42	29.36	26.75	0.0	33.33	100.0	40	0.00	35.41	-66.7	0.00	100.0
	Week 29	45	31.11	22.92	0.0	33.33	100.0	42	2.38	32.42	-66.7	0.00	100.0
	Week 32	38	28.95	27.04	0.0	33.33	100.0	36	1.85	35.59	-66.7	0.00	100.0
	Week 35	42	28.57	26.10	0.0	33.33	100.0	40	-1.67	34.55	-66.7	0.00	100.0
	Week 38	38	26.31	28.11	0.0	33.33	100.0	36	0.00	32.86	-66.7	0.00	100.0
	Week 41	37	29.73	28.09	0.0	33.33	100.0	34	4.90	28.58	-66.7	0.00	100.0
	Week 44	31	27.96	25.96	0.0	33.33	100.0	29	2.30	35.56	-66.7	0.00	100.0
	Week 47	28	25.00	25.05	0.0	33.33	66.7	27	0.00	33.33	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	25	24.00	24.57	0.0	33.33	100.0	24	1.39	37.40	-66.7	0.00	100.0
	Week 53	23	21.74	25.84	0.0	33.33	100.0	22	-1.52	36.34	-66.7	0.00	100.0
	Week 56	21	26.98	29.10	0.0	33.33	100.0	20	8.33	35.66	-66.7	0.00	100.0
	Week 59	20	26.67	25.59	0.0	33.33	66.7	19	5.26	27.81	-66.7	0.00	66.7
	Week 62	19	17.54	20.39	0.0	0.00	66.7	19	1.75	28.27	-66.7	0.00	33.3
	Week 65	20	30.00	23.94	0.0	33.33	66.7	19	7.02	30.59	-66.7	0.00	66.7
	Week 68	17	23.53	25.73	0.0	33.33	66.7	17	3.92	30.92	-66.7	0.00	66.7
	Week 71	19	31.58	34.20	0.0	33.33	100.0	18	9.26	37.58	-66.7	0.00	100.0
	Week 74	17	31.37	29.98	0.0	33.33	100.0	17	13.72	39.19	-66.7	0.00	100.0
	Week 77	17	25.49	27.71	0.0	33.33	66.7	16	8.33	35.49	-66.7	0.00	66.7
	Week 80	17	25.49	22.14	0.0	33.33	66.7	15	2.22	26.63	-66.7	0.00	33.3
	Week 83	13	23.08	21.01	0.0	33.33	66.7	12	-2.78	26.43	-66.7	0.00	33.3
	Week 86	12	30.56	33.21	0.0	33.33	100.0	10	0.00	35.14	-66.7	0.00	33.3
	Week 89	11	36.36	27.71	0.0	33.33	100.0	10	6.67	30.63	-66.7	0.00	33.3
	Plat+Gem (N= 67)												
	BASELINE	49	30.61	31.80	0.0	33.33	100.0						
	Week 1	51	32.03	30.52	0.0	33.33	100.0	45	0.74	29.72	-66.7	0.00	66.7
	Week 2	53	35.22	29.54	0.0	33.33	100.0	44	10.61	32.77	-66.7	0.00	100.0
	Week 3	53	32.07	27.71	0.0	33.33	100.0	44	0.00	32.94	-66.7	0.00	66.7
	Week 4	58	32.76	26.11	0.0	33.33	100.0	47	2.84	26.77	-33.3	0.00	66.7
	Week 5	56	33.93	23.35	0.0	33.33	100.0	44	6.82	30.99	-66.7	0.00	66.7
	Week 6	48	30.55	27.36	0.0	33.33	100.0	40	1.67	35.37	-66.7	0.00	100.0
	Week 7	56	32.14	29.10	0.0	33.33	100.0	46	5.07	32.94	-33.3	0.00	100.0
	Week 8	52	33.33	31.66	0.0	33.33	100.0	42	4.76	35.74	-66.7	0.00	100.0
	Week 9	53	32.70	28.86	0.0	33.33	100.0	42	5.56	32.86	-66.7	0.00	100.0
	Week 10	47	30.50	28.51	0.0	33.33	100.0	36	3.70	32.64	-33.3	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	51	32.03	25.79	0.0	33.33	66.7	41	-0.81	31.17	-66.7	0.00	66.7
	Week 12	47	31.91	26.88	0.0	33.33	100.0	39	1.71	30.54	-33.3	0.00	66.7
	Week 14	47	28.37	24.06	0.0	33.33	100.0	36	-5.56	29.28	-66.7	0.00	66.7
	Week 17	45	30.37	26.42	0.0	33.33	100.0	35	2.86	38.24	-66.7	0.00	100.0
	Week 20	38	19.30	21.41	0.0	16.67	66.7	30	-7.78	25.79	-66.7	0.00	33.3
	Week 23	32	21.87	26.25	0.0	16.67	100.0	25	4.00	27.76	-33.3	0.00	66.7
	Week 26	30	25.55	29.92	0.0	33.33	100.0	24	0.00	32.60	-66.7	0.00	66.7
	Week 29	28	23.81	28.48	0.0	16.67	100.0	21	0.00	38.01	-100.0	0.00	66.7
	Week 32	26	28.20	27.80	0.0	33.33	100.0	22	1.52	31.67	-66.7	0.00	66.7
	Week 35	23	21.74	27.72	0.0	0.00	100.0	19	1.75	28.27	-66.7	0.00	33.3
	Week 38	26	20.51	23.24	0.0	16.67	66.7	20	-3.33	35.70	-100.0	0.00	66.7
	Week 41	24	27.78	30.56	0.0	33.33	100.0	18	11.11	28.01	-33.3	0.00	66.7
	Week 44	18	27.78	30.79	0.0	33.33	100.0	14	9.52	30.46	-33.3	0.00	66.7
	Week 47	18	31.48	33.28	0.0	33.33	100.0	13	7.69	33.76	-33.3	0.00	66.7
	Week 50	16	35.42	35.42	0.0	33.33	100.0	13	12.82	34.80	-33.3	0.00	66.7
	Week 53	15	35.55	26.63	0.0	33.33	100.0	12	8.33	28.87	-33.3	0.00	66.7
	Week 56	15	26.67	28.73	0.0	33.33	66.7	11	-6.06	25.03	-33.3	0.00	33.3
	Week 59	12	25.00	25.13	0.0	33.33	66.7	9	-11.11	23.57	-33.3	0.00	33.3
	Week 62	10	20.00	23.31	0.0	16.67	66.7	8	-12.50	17.25	-33.3	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
EV+Pembro (N=202)												
BASELINE	160	34.17	30.82	0.0	33.33	100.0						
Week 1	141	32.86	29.27	0.0	33.33	100.0	129	-1.29	24.44	-66.7	0.00	66.7
Week 2	150	33.55	29.54	0.0	33.33	100.0	133	-1.00	29.00	-66.7	0.00	100.0
Week 3	139	33.81	28.93	0.0	33.33	100.0	122	-1.91	32.16	-100.0	0.00	66.7
Week 4	145	30.34	27.19	0.0	33.33	100.0	129	-4.13	31.18	-100.0	0.00	66.7
Week 5	137	29.93	27.50	0.0	33.33	100.0	121	-3.86	31.97	-100.0	0.00	100.0
Week 6	146	30.59	28.90	0.0	33.33	100.0	124	-1.08	34.52	-100.0	0.00	100.0
Week 7	147	29.93	29.13	0.0	33.33	100.0	124	-3.23	32.49	-100.0	0.00	66.7
Week 8	147	24.94	27.27	0.0	33.33	100.0	124	-8.60	32.34	-100.0	0.00	66.7
Week 9	142	26.06	28.93	0.0	33.33	100.0	121	-5.79	32.68	-100.0	0.00	66.7
Week 10	139	26.38	27.94	0.0	33.33	100.0	118	-5.65	31.22	-100.0	0.00	66.7
Week 11	137	24.09	25.16	0.0	33.33	100.0	115	-6.96	31.06	-100.0	0.00	66.7
Week 12	142	25.35	28.61	0.0	33.33	100.0	119	-6.16	36.04	-100.0	0.00	66.7
Week 14	139	23.50	27.64	0.0	33.33	100.0	116	-8.62	29.20	-100.0	0.00	33.3
Week 17	132	21.21	24.46	0.0	33.33	100.0	111	-9.91	30.02	-100.0	0.00	66.7
Week 20	120	20.00	23.03	0.0	0.00	100.0	103	-8.74	29.51	-100.0	0.00	33.3
Week 23	117	19.66	23.63	0.0	0.00	100.0	97	-9.28	31.09	-100.0	0.00	66.7
Week 26	112	21.73	24.39	0.0	33.33	100.0	94	-7.80	31.46	-100.0	0.00	66.7
Week 29	107	21.49	25.18	0.0	0.00	100.0	93	-8.24	30.56	-100.0	0.00	66.7
Week 32	102	21.24	23.35	0.0	33.33	100.0	88	-9.47	30.30	-100.0	0.00	33.3
Week 35	98	20.41	24.70	0.0	0.00	100.0	86	-10.08	32.37	-100.0	0.00	66.7
Week 38	97	20.96	24.68	0.0	0.00	100.0	86	-9.30	32.20	-100.0	0.00	66.7
Week 41	95	19.30	21.51	0.0	33.33	100.0	84	-11.51	29.04	-100.0	0.00	33.3
Week 44	86	23.26	26.60	0.0	16.67	100.0	74	-7.21	34.13	-100.0	0.00	66.7
Week 47	79	21.10	24.56	0.0	0.00	100.0	70	-8.57	32.45	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	74	18.92	22.12	0.0	0.00	100.0	64	-12.50	28.79	-66.7	0.00	33.3
Week 53	74	20.72	21.86	0.0	33.33	66.7	63	-13.23	31.98	-100.0	0.00	33.3
Week 56	72	18.98	22.26	0.0	0.00	66.7	61	-11.48	33.27	-100.0	0.00	66.7
Week 59	69	21.26	25.55	0.0	0.00	100.0	57	-11.70	29.87	-100.0	0.00	33.3
Week 62	62	22.04	24.10	0.0	33.33	100.0	52	-11.54	33.58	-100.0	0.00	66.7
Week 65	43	20.15	21.99	0.0	33.33	66.7	40	-14.17	30.09	-66.7	0.00	33.3
Week 68	46	23.19	22.08	0.0	33.33	66.7	42	-6.35	33.12	-100.0	0.00	66.7
Week 71	42	23.81	27.83	0.0	33.33	100.0	38	-8.77	36.09	-100.0	0.00	66.7
Week 74	38	26.32	27.02	0.0	33.33	100.0	35	-4.76	40.54	-100.0	0.00	66.7
Week 77	37	25.22	22.78	0.0	33.33	66.7	33	-9.09	36.59	-66.7	0.00	66.7
Week 80	36	27.78	28.17	0.0	33.33	100.0	34	-4.90	32.96	-100.0	0.00	33.3
Week 83	30	30.00	30.76	0.0	33.33	100.0	29	-2.30	39.77	-100.0	0.00	66.7
Week 86	26	32.05	30.52	0.0	33.33	100.0	25	-1.33	44.60	-100.0	0.00	100.0
Week 89	20	30.00	28.41	0.0	33.33	100.0	19	-5.26	41.96	-100.0	0.00	66.7
Week 92	19	31.58	30.38	0.0	33.33	100.0	18	0.00	39.61	-100.0	0.00	66.7
Week 95	14	16.67	17.29	0.0	16.67	33.3	13	-10.26	34.39	-100.0	0.00	33.3
Week 98	10	13.33	17.21	0.0	0.00	33.3	9	-3.71	20.03	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Plat+Gem (N=202)												
BASELINE	165	31.11	34.56	0.0	33.33	100.0						
Week 1	144	31.25	31.10	0.0	33.33	100.0	139	0.72	27.94	-66.7	0.00	66.7
Week 2	147	30.84	30.24	0.0	33.33	100.0	135	1.48	28.76	-66.7	0.00	100.0
Week 3	149	27.74	26.68	0.0	33.33	100.0	136	1.47	29.22	-66.7	0.00	66.7
Week 4	150	28.00	27.33	0.0	33.33	100.0	135	-0.74	30.60	-100.0	0.00	66.7
Week 5	153	28.54	28.46	0.0	33.33	100.0	138	-1.21	33.07	-100.0	0.00	100.0
Week 6	145	27.13	27.77	0.0	33.33	100.0	131	-1.78	29.90	-66.7	0.00	66.7
Week 7	148	25.90	26.32	0.0	33.33	100.0	134	-2.74	30.33	-66.7	0.00	100.0
Week 8	145	26.90	28.41	0.0	33.33	100.0	132	-1.52	34.67	-100.0	0.00	66.7
Week 9	141	24.35	26.99	0.0	33.33	100.0	125	-4.27	35.67	-100.0	0.00	100.0
Week 10	142	23.94	26.74	0.0	33.33	100.0	130	-4.36	33.82	-100.0	0.00	66.7
Week 11	126	24.34	24.37	0.0	33.33	100.0	114	-2.92	33.06	-100.0	0.00	66.7
Week 12	130	23.59	25.06	0.0	33.33	100.0	115	-5.51	31.51	-100.0	0.00	66.7
Week 14	125	25.07	29.22	0.0	33.33	100.0	109	-0.61	31.09	-66.7	0.00	100.0
Week 17	120	25.55	25.83	0.0	33.33	100.0	106	-1.57	30.65	-66.7	0.00	66.7
Week 20	104	22.76	27.19	0.0	16.67	100.0	91	-3.30	29.84	-66.7	0.00	66.7
Week 23	88	20.83	23.87	0.0	33.33	100.0	80	-3.33	29.34	-66.7	0.00	66.7
Week 26	81	22.22	25.82	0.0	33.33	100.0	75	-4.00	27.38	-100.0	0.00	66.7
Week 29	77	24.67	28.31	0.0	33.33	100.0	71	1.88	33.75	-66.7	0.00	66.7
Week 32	63	21.16	23.42	0.0	33.33	66.7	58	-1.72	28.90	-66.7	0.00	66.7
Week 35	62	20.97	23.56	0.0	16.67	66.7	56	-4.17	31.18	-66.7	0.00	66.7
Week 38	56	23.21	26.15	0.0	33.33	100.0	50	1.33	30.83	-66.7	0.00	66.7
Week 41	52	28.20	28.30	0.0	33.33	100.0	47	6.38	33.07	-66.7	0.00	66.7
Week 44	49	29.25	26.90	0.0	33.33	100.0	44	5.30	35.18	-66.7	0.00	100.0
Week 47	43	25.58	27.06	0.0	33.33	100.0	39	0.85	33.76	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	36	25.93	28.85	0.0	33.33	100.0	31	-1.08	37.00	-66.7	0.00	100.0
Week 53	31	22.58	26.37	0.0	33.33	100.0	28	0.00	27.22	-66.7	0.00	33.3
Week 56	30	25.55	28.61	0.0	33.33	100.0	29	-1.15	31.47	-66.7	0.00	66.7
Week 59	23	31.88	29.26	0.0	33.33	100.0	21	1.59	35.71	-66.7	0.00	66.7
Week 62	20	28.33	31.11	0.0	33.33	100.0	20	0.00	34.20	-66.7	0.00	66.7
Week 65	17	27.45	29.43	0.0	33.33	100.0	16	2.08	25.73	-33.3	0.00	33.3
Week 68	13	23.08	31.58	0.0	0.00	100.0	13	2.56	28.74	-33.3	0.00	66.7
Week 71	13	25.64	27.73	0.0	33.33	100.0	13	-2.57	31.80	-66.7	0.00	33.3
Week 74	11	24.24	30.15	0.0	33.33	100.0	11	0.00	25.82	-33.3	0.00	33.3
Week 77	11	24.24	33.64	0.0	0.00	100.0	11	3.03	27.71	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Present	EV+Pembro (N= 50)												
	BASELINE	40	40.83	28.73	0.0	33.33	100.0						
	Week 1	38	41.23	31.42	0.0	33.33	100.0	34	-2.94	27.67	-66.7	0.00	33.3
	Week 2	35	37.14	27.74	0.0	33.33	100.0	32	-4.17	29.02	-66.7	0.00	33.3
	Week 3	32	31.25	28.00	0.0	33.33	100.0	30	-8.89	34.94	-66.7	0.00	66.7
	Week 4	35	38.09	29.31	0.0	33.33	100.0	31	-2.15	34.36	-66.7	0.00	66.7
	Week 5	32	29.17	29.02	0.0	33.33	100.0	28	-10.71	30.16	-66.7	0.00	33.3
	Week 6	35	32.38	31.81	0.0	33.33	100.0	30	-5.56	37.23	-66.7	0.00	100.0
	Week 7	35	34.28	29.69	0.0	33.33	100.0	29	-2.30	33.25	-66.7	0.00	66.7
	Week 8	38	32.46	31.47	0.0	33.33	100.0	31	-9.68	36.71	-66.7	0.00	66.7
	Week 9	33	28.28	33.46	0.0	33.33	100.0	29	-10.34	35.75	-66.7	0.00	66.7
	Week 10	30	31.11	32.68	0.0	33.33	100.0	25	-12.00	33.17	-66.7	-33.33	66.7
	Week 11	31	25.81	25.40	0.0	33.33	66.7	27	-12.35	29.45	-66.7	0.00	66.7
	Week 12	32	21.87	27.58	0.0	0.00	100.0	28	-20.24	36.67	-100.0	-33.33	66.7
	Week 14	36	26.85	29.62	0.0	33.33	100.0	31	-13.98	31.94	-100.0	0.00	33.3
	Week 17	33	21.21	29.84	0.0	0.00	100.0	27	-18.52	32.47	-100.0	0.00	33.3
	Week 20	28	22.62	27.30	0.0	16.67	100.0	25	-13.33	33.33	-66.7	0.00	33.3
	Week 23	28	21.43	24.37	0.0	16.67	66.7	24	-13.89	25.85	-66.7	0.00	33.3
	Week 26	28	22.62	24.09	0.0	33.33	66.7	24	-11.11	28.94	-66.7	0.00	33.3
	Week 29	27	22.22	26.15	0.0	0.00	66.7	25	-14.67	32.03	-100.0	0.00	33.3
	Week 32	25	18.67	23.73	0.0	0.00	100.0	23	-14.49	31.50	-100.0	0.00	33.3
	Week 35	26	17.95	19.39	0.0	16.67	66.7	24	-18.06	25.97	-66.7	0.00	33.3
	Week 38	26	23.08	20.59	0.0	33.33	66.7	24	-12.50	30.79	-66.7	0.00	33.3
	Week 41	25	20.00	19.24	0.0	33.33	66.7	23	-13.04	24.08	-66.7	0.00	33.3
	Week 44	22	24.24	27.57	0.0	16.67	66.7	20	-11.67	32.94	-66.7	-16.67	33.3
	Week 47	14	21.43	21.11	0.0	33.33	66.7	13	-12.82	32.03	-66.7	-33.33	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	15.00	25.30	0.0	0.00	100.0	17	-19.61	23.74	-66.7	-33.33	33.3
	Week 53	21	17.46	22.65	0.0	0.00	66.7	18	-18.52	32.78	-100.0	-16.67	33.3
	Week 56	18	20.37	25.92	0.0	0.00	66.7	15	-17.78	37.52	-100.0	-33.33	66.7
	Week 59	18	22.22	22.87	0.0	33.33	66.7	15	-13.33	30.34	-66.7	-33.33	33.3
	Week 62	13	23.08	28.49	0.0	33.33	100.0	11	-12.12	22.47	-33.3	0.00	33.3
	Week 68	12	22.22	16.41	0.0	33.33	33.3	11	-3.03	23.36	-33.3	0.00	33.3
	Plat+Gem (N= 50)												
	BASELINE	40	42.50	38.48	0.0	33.33	100.0						
	Week 1	35	41.90	28.40	0.0	33.33	100.0	33	1.01	26.98	-66.7	0.00	66.7
	Week 2	33	35.35	28.80	0.0	33.33	100.0	30	-2.22	24.66	-66.7	0.00	33.3
	Week 3	33	27.27	26.95	0.0	33.33	100.0	29	-3.45	27.23	-66.7	0.00	33.3
	Week 4	36	34.26	30.33	0.0	33.33	100.0	32	-3.13	29.77	-66.7	0.00	66.7
	Week 5	36	28.70	27.78	0.0	33.33	100.0	32	-10.42	35.36	-100.0	0.00	33.3
	Week 6	32	29.17	29.02	0.0	33.33	100.0	29	-3.45	31.30	-66.7	0.00	66.7
	Week 7	35	28.57	28.17	0.0	33.33	100.0	31	-8.60	35.45	-66.7	0.00	66.7
	Week 8	35	28.57	29.31	0.0	33.33	100.0	31	-8.60	44.70	-100.0	0.00	66.7
	Week 9	34	32.35	31.23	0.0	33.33	100.0	30	-7.78	42.60	-66.7	0.00	100.0
	Week 10	33	21.21	24.75	0.0	0.00	66.7	30	-15.56	35.81	-100.0	-16.67	66.7
	Week 11	30	21.11	20.50	0.0	33.33	66.7	26	-11.54	39.94	-100.0	0.00	66.7
	Week 12	32	19.79	23.74	0.0	0.00	66.7	27	-19.75	33.67	-66.7	0.00	66.7
	Week 14	27	20.99	24.72	0.0	0.00	66.7	22	-12.12	30.07	-66.7	0.00	33.3
	Week 17	28	21.43	20.72	0.0	33.33	66.7	23	-13.04	29.71	-66.7	0.00	66.7
	Week 20	20	21.67	27.09	0.0	16.67	100.0	16	-12.50	23.96	-66.7	0.00	33.3
	Week 23	15	15.55	21.33	0.0	0.00	66.7	14	-16.67	28.50	-66.7	0.00	33.3
	Week 26	15	22.22	32.53	0.0	0.00	100.0	14	-14.29	33.88	-100.0	0.00	33.3
	Week 29	13	17.95	29.23	0.0	0.00	100.0	12	-8.33	37.94	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Absent	EV+Pembro (N=152)												
	BASELINE	120	31.94	31.28	0.0	33.33	100.0						
	Week 1	103	29.77	27.97	0.0	33.33	100.0	95	-0.70	23.31	-66.7	0.00	66.7
	Week 2	115	32.46	30.10	0.0	33.33	100.0	101	0.00	29.06	-66.7	0.00	100.0
	Week 3	107	34.58	29.29	0.0	33.33	100.0	92	0.36	31.06	-100.0	0.00	66.7
	Week 4	110	27.88	26.15	0.0	33.33	100.0	98	-4.76	30.27	-100.0	0.00	66.7
	Week 5	105	30.16	27.16	0.0	33.33	100.0	93	-1.79	32.37	-100.0	0.00	100.0
	Week 6	111	30.03	28.05	0.0	33.33	100.0	94	0.35	33.69	-100.0	0.00	66.7
	Week 7	112	28.57	28.95	0.0	33.33	100.0	95	-3.51	32.43	-100.0	0.00	66.7
	Week 8	109	22.32	25.28	0.0	33.33	100.0	93	-8.24	30.95	-100.0	0.00	66.7
	Week 9	109	25.38	27.55	0.0	33.33	100.0	92	-4.35	31.73	-100.0	0.00	66.7
	Week 10	109	25.08	26.51	0.0	33.33	100.0	93	-3.94	30.63	-100.0	0.00	66.7
	Week 11	106	23.58	25.18	0.0	33.33	100.0	88	-5.30	31.52	-100.0	0.00	66.7
	Week 12	110	26.36	28.95	0.0	33.33	100.0	91	-1.83	34.91	-100.0	0.00	66.7
	Week 14	103	22.33	26.97	0.0	0.00	100.0	85	-6.67	28.08	-100.0	0.00	33.3
	Week 17	99	21.21	22.56	0.0	33.33	100.0	84	-7.14	28.84	-66.7	0.00	66.7
	Week 20	92	19.20	21.67	0.0	0.00	66.7	78	-7.27	28.25	-100.0	0.00	33.3
	Week 23	89	19.10	23.51	0.0	0.00	100.0	73	-7.76	32.64	-100.0	0.00	66.7
	Week 26	84	21.43	24.62	0.0	33.33	100.0	70	-6.67	32.40	-100.0	0.00	66.7
	Week 29	80	21.25	25.01	0.0	0.00	100.0	68	-5.88	29.89	-66.7	0.00	66.7
	Week 32	77	22.08	23.33	0.0	33.33	100.0	65	-7.69	29.91	-100.0	0.00	33.3
	Week 35	72	21.30	26.42	0.0	0.00	100.0	62	-6.99	34.22	-100.0	0.00	66.7
	Week 38	71	20.19	26.11	0.0	0.00	100.0	62	-8.07	32.89	-100.0	0.00	66.7
	Week 41	70	19.05	22.39	0.0	0.00	100.0	61	-10.93	30.87	-100.0	0.00	33.3
	Week 44	64	22.92	26.48	0.0	16.67	100.0	54	-5.56	34.72	-100.0	0.00	66.7
	Week 47	65	21.02	25.39	0.0	0.00	100.0	57	-7.60	32.74	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	54	20.37	20.90	0.0	33.33	66.7	47	-9.93	30.23	-66.7	0.00	33.3
	Week 53	53	22.01	21.63	0.0	33.33	66.7	45	-11.11	31.78	-100.0	0.00	33.3
	Week 56	54	18.52	21.15	0.0	0.00	66.7	46	-9.42	31.94	-66.7	0.00	66.7
	Week 59	51	20.91	26.63	0.0	0.00	100.0	42	-11.11	30.06	-100.0	0.00	33.3
	Week 62	49	21.77	23.13	0.0	33.33	66.7	41	-11.38	36.22	-100.0	0.00	66.7
	Week 65	36	21.30	22.75	0.0	33.33	66.7	33	-15.15	31.28	-66.7	0.00	33.3
	Week 68	34	23.53	23.97	0.0	33.33	66.7	31	-7.53	36.22	-100.0	0.00	66.7
	Week 71	33	23.23	25.66	0.0	33.33	100.0	30	-13.33	35.67	-100.0	0.00	33.3
	Week 74	33	26.26	27.33	0.0	33.33	100.0	30	-5.56	42.06	-100.0	0.00	66.7
	Week 77	31	25.81	22.29	0.0	33.33	66.7	27	-11.11	38.12	-66.7	0.00	66.7
	Week 80	31	29.03	28.21	0.0	33.33	100.0	29	-6.90	33.78	-100.0	0.00	33.3
	Week 83	25	32.00	31.15	0.0	33.33	100.0	24	-2.78	40.43	-100.0	0.00	66.7
	Week 86	23	31.88	30.94	0.0	33.33	100.0	22	-3.03	44.73	-100.0	0.00	100.0
	Week 89	18	31.48	29.09	0.0	33.33	100.0	17	-3.92	43.91	-100.0	0.00	66.7
	Week 92	16	29.17	29.50	0.0	33.33	100.0	15	-4.44	39.58	-100.0	0.00	33.3
	Week 95	12	16.67	17.41	0.0	16.67	33.3	11	-9.09	36.79	-100.0	0.00	33.3
	Plat+Gem (N=152)												
	BASELINE	125	27.47	32.54	0.0	33.33	100.0						
	Week 1	109	27.83	31.27	0.0	33.33	100.0	106	0.63	28.35	-66.7	0.00	66.7
	Week 2	114	29.53	30.65	0.0	33.33	100.0	105	2.54	29.85	-66.7	0.00	100.0
	Week 3	116	27.87	26.72	0.0	33.33	100.0	107	2.80	29.72	-66.7	0.00	66.7
	Week 4	114	26.02	26.15	0.0	33.33	100.0	103	0.00	30.96	-100.0	0.00	66.7
	Week 5	117	28.49	28.79	0.0	33.33	100.0	106	1.57	32.00	-100.0	0.00	100.0
	Week 6	113	26.55	27.52	0.0	33.33	100.0	102	-1.31	29.64	-66.7	0.00	66.7
	Week 7	113	25.07	25.79	0.0	33.33	100.0	103	-0.97	28.57	-66.7	0.00	100.0
	Week 8	110	26.36	28.23	0.0	33.33	100.0	101	0.66	30.91	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	107	21.81	25.12	0.0	33.33	100.0	95	-3.16	33.36	-100.0	0.00	66.7
	Week 10	109	24.77	27.37	0.0	33.33	100.0	100	-1.00	32.64	-100.0	0.00	66.7
	Week 11	96	25.35	25.48	0.0	33.33	100.0	88	-0.38	30.53	-100.0	0.00	66.7
	Week 12	98	24.83	25.47	0.0	33.33	100.0	88	-1.14	29.66	-100.0	0.00	66.7
	Week 14	98	26.19	30.37	0.0	33.33	100.0	87	2.30	30.83	-66.7	0.00	100.0
	Week 17	92	26.81	27.17	0.0	33.33	100.0	83	1.61	30.31	-66.7	0.00	66.7
	Week 20	84	23.02	27.37	0.0	16.67	100.0	75	-1.33	30.73	-66.7	0.00	66.7
	Week 23	73	21.92	24.36	0.0	33.33	100.0	66	-0.51	28.94	-66.7	0.00	66.7
	Week 26	66	22.22	24.34	0.0	33.33	100.0	61	-1.64	25.41	-66.7	0.00	66.7
	Week 29	64	26.04	28.15	0.0	33.33	100.0	59	3.95	32.80	-66.7	0.00	66.7
	Week 32	54	23.46	23.91	0.0	33.33	66.7	49	1.36	28.84	-66.7	0.00	66.7
	Week 35	54	22.22	24.23	0.0	33.33	66.7	48	-2.08	30.29	-66.7	0.00	66.7
	Week 38	47	24.82	24.54	0.0	33.33	66.7	42	2.38	29.81	-66.7	0.00	66.7
	Week 41	45	31.11	28.78	0.0	33.33	100.0	40	9.17	32.89	-33.3	0.00	66.7
	Week 44	41	31.71	27.84	0.0	33.33	100.0	36	9.26	33.44	-66.7	0.00	100.0
	Week 47	35	27.62	27.40	0.0	33.33	100.0	31	4.30	31.91	-33.3	0.00	66.7
	Week 50	29	29.88	30.01	0.0	33.33	100.0	24	4.17	35.86	-33.3	0.00	100.0
	Week 53	25	25.33	27.69	0.0	33.33	100.0	22	6.06	19.62	-33.3	0.00	33.3
	Week 56	26	26.92	29.84	0.0	33.33	100.0	25	-2.67	31.80	-66.7	0.00	66.7
	Week 59	20	33.33	28.61	0.0	33.33	100.0	18	0.00	34.30	-66.7	0.00	66.7
	Week 62	17	29.41	30.92	0.0	33.33	100.0	17	-1.96	32.21	-66.7	0.00	66.7
	Week 65	15	31.11	29.46	0.0	33.33	100.0	14	4.76	25.68	-33.3	0.00	33.3
	Week 68	11	27.27	32.72	0.0	33.33	100.0	11	6.06	29.13	-33.3	0.00	66.7
	Week 71	12	27.78	27.83	0.0	33.33	100.0	12	0.00	31.78	-66.7	0.00	33.3
	Week 74	10	26.67	30.63	0.0	33.33	100.0	10	3.33	24.60	-33.3	0.00	33.3
	Week 77	10	23.33	35.31	0.0	0.00	100.0	10	3.33	29.19	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
< 65 years	EV+Pembro (N= 39)												
	BASELINE	32	36.46	32.08	0.0	33.33	100.0						
	Week 1	27	34.57	26.93	0.0	33.33	100.0	26	1.28	19.96	-33.3	0.00	33.3
	Week 2	30	31.11	30.24	0.0	33.33	100.0	29	-3.45	30.01	-66.7	0.00	100.0
	Week 3	31	30.11	24.88	0.0	33.33	100.0	29	-5.75	26.83	-66.7	0.00	33.3
	Week 4	30	22.22	23.71	0.0	33.33	66.7	27	-8.64	27.10	-66.7	0.00	33.3
	Week 5	28	23.81	21.96	0.0	33.33	66.7	26	-8.98	27.58	-66.7	0.00	33.3
	Week 6	29	27.59	29.64	0.0	33.33	100.0	26	-10.26	36.23	-66.7	0.00	66.7
	Week 7	30	25.56	28.61	0.0	33.33	100.0	26	-12.82	32.77	-66.7	0.00	33.3
	Week 8	30	23.33	27.89	0.0	16.67	100.0	26	-10.26	32.35	-66.7	0.00	33.3
	Week 9	28	22.62	30.16	0.0	0.00	100.0	27	-11.11	38.12	-66.7	0.00	66.7
	Week 10	26	25.64	28.76	0.0	33.33	100.0	23	-8.70	33.66	-66.7	0.00	66.7
	Week 11	28	21.43	28.99	0.0	0.00	100.0	25	-12.00	33.17	-66.7	0.00	66.7
	Week 12	28	26.19	30.57	0.0	33.33	100.0	25	-6.67	37.27	-66.7	0.00	66.7
	Week 14	26	19.23	26.95	0.0	0.00	100.0	23	-15.94	33.14	-66.7	0.00	33.3
	Week 17	28	22.62	22.32	0.0	33.33	66.7	24	-13.89	32.48	-66.7	-16.67	33.3
	Week 20	27	16.05	19.33	0.0	0.00	66.7	24	-13.89	37.96	-100.0	0.00	33.3
	Week 23	26	15.38	19.39	0.0	0.00	66.7	23	-17.39	36.06	-100.0	0.00	33.3
	Week 26	24	20.83	27.47	0.0	0.00	100.0	22	-12.12	34.95	-66.7	0.00	33.3
	Week 29	25	22.67	26.74	0.0	33.33	100.0	23	-11.60	31.15	-66.7	0.00	33.3
	Week 32	25	24.00	26.39	0.0	33.33	100.0	23	-8.70	28.81	-66.7	0.00	33.3
	Week 35	24	25.00	26.47	0.0	33.33	100.0	22	-12.12	30.07	-66.7	0.00	33.3
	Week 38	23	24.64	30.51	0.0	33.33	100.0	22	-9.09	34.40	-100.0	0.00	33.3
	Week 41	25	22.67	23.01	0.0	33.33	66.7	23	-10.15	35.44	-100.0	0.00	33.3
	Week 44	22	30.30	30.71	0.0	33.33	100.0	20	-5.00	39.41	-66.7	0.00	66.7
	Week 47	20	28.33	27.09	0.0	33.33	100.0	18	-7.41	37.15	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	19	15.79	20.39	0.0	0.00	66.7	17	-19.61	31.31	-66.7	-33.33	33.3
	Week 53	20	21.67	22.36	0.0	33.33	66.7	18	-12.96	32.62	-66.7	-16.67	33.3
	Week 56	17	19.61	23.74	0.0	0.00	66.7	15	-13.33	43.28	-66.7	-33.33	66.7
	Week 59	17	29.41	30.92	0.0	33.33	100.0	15	-6.67	33.81	-66.7	0.00	33.3
	Week 62	15	26.67	22.54	0.0	33.33	66.7	14	-16.67	42.87	-66.7	-16.67	66.7
	Week 65	14	19.05	17.12	0.0	33.33	33.3	13	-15.39	37.55	-66.7	0.00	33.3
	Week 68	11	21.21	22.47	0.0	33.33	66.7	10	-10.00	35.31	-66.7	0.00	33.3
	Week 71	13	25.64	24.17	0.0	33.33	66.7	12	-16.67	38.93	-66.7	-16.67	33.3
	Week 74	14	33.33	32.03	0.0	33.33	100.0	13	-10.26	43.86	-66.7	0.00	66.7
	Week 77	14	30.95	27.63	0.0	33.33	66.7	13	-7.69	41.18	-66.7	0.00	66.7
	Week 80	14	28.57	31.64	0.0	33.33	100.0	13	-5.13	29.96	-66.7	0.00	33.3
	Week 83	12	36.11	33.21	0.0	33.33	100.0	11	0.00	39.44	-66.7	0.00	66.7
	Plat+Gem (N= 29)												
	BASELINE	22	27.27	28.43	0.0	33.33	100.0						
	Week 1	21	31.74	30.69	0.0	33.33	100.0	20	3.33	23.94	-33.3	0.00	66.7
	Week 2	24	26.39	29.45	0.0	33.33	100.0	20	-5.00	19.57	-33.3	0.00	33.3
	Week 3	23	20.29	16.63	0.0	33.33	33.3	20	-1.67	17.01	-33.3	0.00	33.3
	Week 4	23	30.43	28.27	0.0	33.33	100.0	19	5.26	16.71	-33.3	0.00	33.3
	Week 5	25	26.67	27.22	0.0	33.33	100.0	20	-5.00	27.09	-100.0	0.00	33.3
	Week 6	22	30.30	25.01	0.0	33.33	100.0	18	-1.85	26.75	-66.7	0.00	33.3
	Week 7	24	26.39	25.97	0.0	33.33	100.0	21	-3.17	23.35	-66.7	0.00	33.3
	Week 8	21	30.16	29.64	0.0	33.33	100.0	19	5.26	31.94	-66.7	0.00	66.7
	Week 9	20	26.67	23.20	0.0	33.33	66.7	17	-1.96	27.57	-66.7	0.00	33.3
	Week 10	21	25.40	23.34	0.0	33.33	66.7	18	0.00	25.57	-66.7	0.00	33.3
	Week 11	20	21.67	19.57	0.0	33.33	66.7	17	-3.92	23.22	-66.7	0.00	33.3
	Week 12	21	20.63	16.59	0.0	33.33	33.3	17	-3.92	23.22	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 14	22	28.79	25.81	0.0	33.33	100.0	18	5.56	28.58	-66.7	0.00	66.7
	Week 17	20	21.67	19.57	0.0	33.33	66.7	17	-1.96	27.56	-66.7	0.00	33.3
	Week 20	18	24.07	22.30	0.0	33.33	66.7	15	-2.22	29.46	-66.7	0.00	33.3
	Week 23	18	20.37	20.26	0.0	33.33	66.7	16	-4.17	23.96	-66.7	0.00	33.3
	Week 26	16	22.92	26.44	0.0	16.67	66.7	14	-2.38	35.72	-100.0	0.00	33.3
	Week 29	15	28.89	24.77	0.0	33.33	66.7	13	0.00	30.43	-66.7	0.00	33.3
	Week 32	15	28.89	21.33	0.0	33.33	66.7	13	2.56	34.59	-66.7	0.00	66.7
	Week 35	15	24.44	23.46	0.0	33.33	66.7	13	-2.56	34.59	-66.7	0.00	66.7
	Week 38	14	38.10	31.64	0.0	33.33	100.0	12	8.33	35.18	-66.7	0.00	66.7
	Week 41	11	39.39	32.72	0.0	33.33	100.0	9	14.82	29.40	-33.3	0.00	66.7
	Week 44	11	33.33	21.08	0.0	33.33	66.7	9	3.70	30.93	-66.7	0.00	33.3
	Week 47	11	33.33	29.82	0.0	33.33	66.7	9	0.00	40.83	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>= 65 years	EV+Pembro (N=163)												
	BASELINE	128	33.59	30.60	0.0	33.33	100.0						
	Week 1	114	32.46	29.90	0.0	33.33	100.0	103	-1.94	25.49	-66.7	0.00	66.7
	Week 2	120	34.17	29.46	0.0	33.33	100.0	104	-0.32	28.82	-66.7	0.00	66.7
	Week 3	108	34.88	30.02	0.0	33.33	100.0	93	-0.72	33.69	-100.0	0.00	66.7
	Week 4	115	32.46	27.74	0.0	33.33	100.0	102	-2.94	32.19	-100.0	0.00	66.7
	Week 5	109	31.50	28.63	0.0	33.33	100.0	95	-2.46	33.06	-100.0	0.00	100.0
	Week 6	117	31.34	28.80	0.0	33.33	100.0	98	1.36	33.82	-100.0	0.00	100.0
	Week 7	117	31.05	29.27	0.0	33.33	100.0	98	-0.68	32.10	-100.0	0.00	66.7
	Week 8	117	25.36	27.21	0.0	33.33	100.0	98	-8.16	32.49	-100.0	0.00	66.7
	Week 9	114	26.90	28.70	0.0	33.33	100.0	94	-4.26	31.01	-100.0	0.00	66.7
	Week 10	113	26.55	27.87	0.0	33.33	100.0	95	-4.91	30.74	-100.0	0.00	66.7
	Week 11	109	24.77	24.18	0.0	33.33	100.0	90	-5.56	30.50	-100.0	0.00	66.7
	Week 12	114	25.15	28.24	0.0	33.33	100.0	94	-6.03	35.91	-100.0	0.00	66.7
	Week 14	113	24.48	27.82	0.0	33.33	100.0	93	-6.81	28.04	-100.0	0.00	33.3
	Week 17	104	20.83	25.09	0.0	0.00	100.0	87	-8.81	29.40	-100.0	0.00	66.7
	Week 20	93	21.15	23.97	0.0	33.33	100.0	79	-7.17	26.51	-66.7	0.00	33.3
	Week 23	91	20.88	24.67	0.0	0.00	100.0	74	-6.76	29.19	-66.7	0.00	66.7
	Week 26	88	21.97	23.64	0.0	33.33	100.0	72	-6.48	30.46	-100.0	0.00	66.7
	Week 29	82	21.14	24.85	0.0	0.00	66.7	70	-7.14	30.51	-100.0	0.00	66.7
	Week 32	77	20.35	22.40	0.0	33.33	100.0	65	-9.74	31.03	-100.0	0.00	33.3
	Week 35	74	18.92	24.10	0.0	0.00	100.0	64	-9.38	33.32	-100.0	0.00	66.7
	Week 38	74	19.82	22.69	0.0	0.00	66.7	64	-9.38	31.69	-100.0	0.00	66.7
	Week 41	70	18.09	20.99	0.0	0.00	100.0	61	-12.02	26.55	-66.7	0.00	33.3
	Week 44	64	20.83	24.85	0.0	0.00	66.7	54	-8.02	32.34	-100.0	0.00	33.3
	Week 47	59	18.64	23.38	0.0	0.00	66.7	52	-8.97	31.04	-100.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	55	20.00	22.77	0.0	33.33	100.0	47	-9.93	27.73	-66.7	0.00	33.3
	Week 53	54	20.37	21.88	0.0	33.33	66.7	45	-13.33	32.10	-100.0	0.00	33.3
	Week 56	55	18.79	22.00	0.0	0.00	66.7	46	-10.87	29.86	-100.0	0.00	33.3
	Week 59	52	18.59	23.26	0.0	0.00	66.7	42	-13.49	28.57	-100.0	0.00	33.3
	Week 62	47	20.57	24.63	0.0	0.00	100.0	38	-9.65	29.92	-100.0	0.00	33.3
	Week 65	29	20.69	24.26	0.0	0.00	66.7	27	-13.58	26.57	-66.7	0.00	33.3
	Week 68	35	23.81	22.25	0.0	33.33	66.7	32	-5.21	32.91	-100.0	0.00	66.7
	Week 71	29	22.99	29.69	0.0	0.00	100.0	26	-5.13	34.89	-100.0	0.00	66.7
	Week 74	24	22.22	23.40	0.0	33.33	66.7	22	-1.52	39.14	-100.0	0.00	66.7
	Week 77	23	21.74	19.09	0.0	33.33	66.7	20	-10.00	34.37	-66.7	0.00	33.3
	Week 80	22	27.27	26.50	0.0	33.33	66.7	21	-4.76	35.41	-100.0	0.00	33.3
	Week 83	18	25.93	29.27	0.0	33.33	100.0	18	-3.70	41.05	-100.0	0.00	66.7
	Week 86	18	33.33	34.30	0.0	33.33	100.0	18	3.70	46.99	-100.0	0.00	100.0
	Week 89	12	25.00	25.13	0.0	33.33	66.7	12	-5.56	42.24	-100.0	0.00	66.7
	Week 92	10	20.00	28.11	0.0	0.00	66.7	10	-3.33	39.91	-100.0	0.00	33.3
	Plat+Gem (N=173)												
	BASELINE	143	31.70	35.46	0.0	33.33	100.0						
	Week 1	123	31.16	31.29	0.0	33.33	100.0	119	0.28	28.62	-66.7	0.00	66.7
	Week 2	123	31.71	30.44	0.0	33.33	100.0	115	2.61	29.99	-66.7	0.00	100.0
	Week 3	126	29.10	27.96	0.0	33.33	100.0	116	2.01	30.86	-66.7	0.00	66.7
	Week 4	127	27.56	27.25	0.0	33.33	100.0	116	-1.73	32.26	-100.0	0.00	66.7
	Week 5	128	28.91	28.79	0.0	33.33	100.0	118	-0.57	34.03	-100.0	0.00	100.0
	Week 6	123	26.56	28.30	0.0	33.33	100.0	113	-1.77	30.49	-66.7	0.00	66.7
	Week 7	124	25.81	26.49	0.0	33.33	100.0	113	-2.66	31.54	-66.7	0.00	100.0
	Week 8	124	26.34	28.28	0.0	33.33	100.0	113	-2.66	35.11	-100.0	0.00	66.7
	Week 9	121	23.97	27.63	0.0	33.33	100.0	108	-4.63	36.87	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	121	23.69	27.37	0.0	33.33	100.0	112	-5.06	35.01	-100.0	0.00	66.7
	Week 11	106	24.84	25.22	0.0	33.33	100.0	97	-2.75	34.58	-100.0	0.00	66.7
	Week 12	109	24.16	26.40	0.0	33.33	100.0	98	-5.78	32.82	-100.0	0.00	66.7
	Week 14	103	24.27	29.96	0.0	0.00	100.0	91	-1.83	31.57	-66.7	0.00	100.0
	Week 17	100	26.33	26.92	0.0	33.33	100.0	89	-1.50	31.35	-66.7	0.00	66.7
	Week 20	86	22.48	28.21	0.0	0.00	100.0	76	-3.51	30.10	-66.7	0.00	66.7
	Week 23	70	20.95	24.85	0.0	16.67	100.0	64	-3.13	30.70	-66.7	0.00	66.7
	Week 26	65	22.05	25.87	0.0	33.33	100.0	61	-4.37	25.44	-66.7	0.00	66.7
	Week 29	62	23.66	29.19	0.0	16.67	100.0	58	2.30	34.69	-66.7	0.00	66.7
	Week 32	48	18.75	23.73	0.0	0.00	66.7	45	-2.96	27.36	-66.7	0.00	66.7
	Week 35	47	19.86	23.73	0.0	0.00	66.7	43	-4.65	30.50	-66.7	0.00	66.7
	Week 38	42	18.25	22.33	0.0	0.00	66.7	38	-0.88	29.50	-66.7	0.00	66.7
	Week 41	41	25.20	26.65	0.0	33.33	66.7	38	4.39	33.93	-66.7	0.00	66.7
	Week 44	38	28.07	28.50	0.0	33.33	100.0	35	5.71	36.59	-66.7	0.00	100.0
	Week 47	32	22.92	26.01	0.0	33.33	100.0	30	1.11	32.14	-66.7	0.00	66.7
	Week 50	29	24.14	29.41	0.0	33.33	100.0	26	2.56	36.42	-66.7	0.00	100.0
	Week 53	25	20.00	28.87	0.0	0.00	100.0	24	2.78	25.85	-66.7	0.00	33.3
	Week 56	26	24.36	25.92	0.0	33.33	100.0	26	1.28	31.95	-66.7	0.00	66.7
	Week 59	20	28.33	29.17	0.0	33.33	100.0	20	1.67	36.64	-66.7	0.00	66.7
	Week 62	19	26.32	30.59	0.0	33.33	100.0	19	-1.76	34.20	-66.7	0.00	66.7
	Week 65	16	25.00	28.54	0.0	33.33	100.0	16	2.08	25.73	-33.3	0.00	33.3
	Week 68	13	23.08	31.58	0.0	0.00	100.0	13	2.56	28.74	-33.3	0.00	66.7
	Week 71	13	25.64	27.73	0.0	33.33	100.0	13	-2.57	31.80	-66.7	0.00	33.3
	Week 74	11	24.24	30.15	0.0	33.33	100.0	11	0.00	25.82	-33.3	0.00	33.3
	Week 77	10	26.67	34.43	0.0	16.67	100.0	10	6.67	26.30	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Europe	EV+Pembro (N= 74)												
	BASELINE	53	33.96	28.86	0.0	33.33	100.0						
	Week 1	48	34.03	28.76	0.0	33.33	100.0	42	-1.59	23.23	-66.7	0.00	33.3
	Week 2	53	28.93	26.98	0.0	33.33	100.0	44	-6.82	29.27	-66.7	0.00	66.7
	Week 3	50	34.00	29.73	0.0	33.33	100.0	41	-7.32	37.65	-100.0	0.00	66.7
	Week 4	51	31.37	29.37	0.0	33.33	100.0	44	-4.55	34.17	-100.0	0.00	66.7
	Week 5	46	28.99	31.90	0.0	33.33	100.0	41	-5.69	37.20	-100.0	0.00	100.0
	Week 6	50	25.33	25.70	0.0	33.33	100.0	39	-8.55	36.45	-100.0	0.00	66.7
	Week 7	50	28.67	32.30	0.0	33.33	100.0	39	-4.27	39.13	-100.0	0.00	66.7
	Week 8	51	21.57	27.34	0.0	0.00	100.0	41	-11.38	31.28	-66.7	0.00	33.3
	Week 9	47	23.40	31.02	0.0	0.00	100.0	37	-9.91	34.13	-100.0	0.00	66.7
	Week 10	45	21.48	27.67	0.0	0.00	100.0	34	-11.77	32.70	-100.0	0.00	66.7
	Week 11	48	22.22	24.15	0.0	33.33	100.0	37	-9.01	32.06	-100.0	0.00	66.7
	Week 12	51	18.95	27.69	0.0	0.00	100.0	39	-10.26	39.85	-100.0	0.00	66.7
	Week 14	50	18.00	26.26	0.0	0.00	100.0	38	-14.91	30.71	-100.0	0.00	33.3
	Week 17	43	17.83	27.55	0.0	0.00	100.0	33	-13.13	28.80	-66.7	0.00	33.3
	Week 20	41	17.07	23.71	0.0	0.00	100.0	33	-14.14	26.39	-66.7	0.00	33.3
	Week 23	41	20.32	25.69	0.0	0.00	100.0	30	-11.11	29.47	-66.7	0.00	66.7
	Week 26	37	19.82	22.85	0.0	0.00	66.7	28	-10.72	32.78	-66.7	0.00	66.7
	Week 29	37	17.12	21.69	0.0	0.00	66.7	29	-11.50	31.21	-66.7	0.00	66.7
	Week 32	34	18.63	22.00	0.0	16.67	100.0	26	-10.26	27.92	-66.7	0.00	33.3
	Week 35	31	17.20	20.85	0.0	0.00	66.7	25	-12.00	28.68	-66.7	0.00	33.3
	Week 38	31	19.35	25.49	0.0	0.00	100.0	26	-8.98	27.58	-66.7	0.00	33.3
	Week 41	28	17.86	23.10	0.0	0.00	100.0	23	-11.60	25.84	-66.7	0.00	33.3
	Week 44	27	14.81	23.27	0.0	0.00	66.7	22	-13.64	31.97	-66.7	0.00	33.3
	Week 47	25	16.00	19.53	0.0	0.00	66.7	21	-9.53	30.08	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	26	15.38	23.53	0.0	0.00	100.0	23	-11.60	29.49	-66.7	0.00	33.3
	Week 53	26	19.23	23.42	0.0	0.00	66.7	21	-9.52	30.08	-66.7	0.00	33.3
	Week 56	25	14.67	23.73	0.0	0.00	66.7	21	-12.70	30.69	-66.7	0.00	66.7
	Week 59	23	10.14	18.63	0.0	0.00	66.7	18	-12.96	23.26	-66.7	0.00	33.3
	Week 62	20	15.00	20.16	0.0	0.00	66.7	17	-13.73	29.01	-66.7	0.00	33.3
	Week 65	13	12.82	16.88	0.0	0.00	33.3	13	-15.39	29.24	-66.7	0.00	33.3
	Week 68	15	20.00	21.08	0.0	33.33	66.7	15	-6.67	28.73	-66.7	0.00	33.3
	Week 71	13	12.82	28.99	0.0	0.00	100.0	13	-12.82	34.80	-66.7	0.00	66.7
	Week 74	10	20.00	28.11	0.0	0.00	66.7	9	-7.41	46.48	-66.7	0.00	66.7
	Plat+Gem (N= 95)												
	BASELINE	75	29.33	35.07	0.0	0.00	100.0						
	Week 1	71	28.17	30.68	0.0	33.33	100.0	69	-2.42	25.77	-66.7	0.00	66.7
	Week 2	71	27.23	31.53	0.0	33.33	100.0	63	-3.18	27.25	-66.7	0.00	100.0
	Week 3	72	23.61	27.66	0.0	33.33	100.0	65	-3.08	26.17	-66.7	0.00	66.7
	Week 4	69	25.60	29.23	0.0	33.33	100.0	62	-3.76	28.38	-66.7	0.00	66.7
	Week 5	71	26.76	30.66	0.0	33.33	100.0	63	-4.76	32.16	-100.0	0.00	66.7
	Week 6	69	24.64	30.06	0.0	33.33	100.0	61	-6.01	29.51	-66.7	0.00	66.7
	Week 7	69	21.74	28.48	0.0	0.00	100.0	62	-6.99	29.65	-66.7	0.00	66.7
	Week 8	67	21.39	27.03	0.0	0.00	100.0	60	-8.33	29.19	-100.0	0.00	66.7
	Week 9	66	20.71	29.10	0.0	0.00	100.0	57	-8.19	35.79	-100.0	0.00	100.0
	Week 10	70	20.48	27.97	0.0	0.00	100.0	63	-9.52	36.13	-100.0	0.00	66.7
	Week 11	63	20.63	23.52	0.0	33.33	100.0	56	-7.74	33.63	-100.0	0.00	66.7
	Week 12	66	22.22	25.71	0.0	33.33	100.0	56	-7.14	31.60	-66.7	0.00	66.7
	Week 14	66	22.73	30.47	0.0	0.00	100.0	56	-3.57	30.93	-66.7	0.00	100.0
	Week 17	61	25.14	27.66	0.0	33.33	100.0	53	-5.03	28.79	-66.7	0.00	66.7
	Week 20	54	24.07	30.66	0.0	0.00	100.0	48	-2.78	31.39	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 23	44	20.45	27.10	0.0	0.00	100.0	40	-7.50	27.72	-66.7	0.00	33.3
	Week 26	42	21.43	26.36	0.0	0.00	100.0	39	-5.13	29.16	-100.0	0.00	33.3
	Week 29	39	22.22	28.95	0.0	0.00	100.0	36	-1.85	31.82	-66.7	0.00	66.7
	Week 32	32	20.83	23.57	0.0	16.67	66.7	30	-4.45	25.87	-66.7	0.00	33.3
	Week 35	32	20.83	23.57	0.0	16.67	66.7	30	-4.45	29.99	-66.7	0.00	33.3
	Week 38	28	19.05	23.00	0.0	0.00	66.7	26	-2.56	28.16	-66.7	0.00	33.3
	Week 41	25	26.67	28.87	0.0	33.33	66.7	23	1.45	34.05	-66.7	0.00	66.7
	Week 44	24	30.55	30.95	0.0	33.33	100.0	22	1.51	37.77	-66.7	0.00	100.0
	Week 47	22	27.27	30.23	0.0	33.33	100.0	20	-1.67	38.20	-66.7	0.00	66.7
	Week 50	17	29.41	35.12	0.0	33.33	100.0	15	-6.67	42.16	-66.7	0.00	100.0
	Week 53	15	26.67	33.81	0.0	33.33	100.0	14	-4.76	31.64	-66.7	0.00	33.3
	Week 56	15	28.89	37.52	0.0	0.00	100.0	14	0.00	29.23	-33.3	0.00	66.7
	Week 59	11	36.36	34.82	0.0	33.33	100.0	10	3.33	36.68	-66.7	0.00	66.7
	Week 62	11	27.27	35.96	0.0	0.00	100.0	11	0.00	29.81	-33.3	0.00	66.7
	Week 65	10	30.00	33.15	0.0	33.33	100.0	10	6.67	26.29	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
North America	EV+Pembro (N= 46)												
	BASELINE	33	37.37	28.58	0.0	33.33	100.0						
	Week 1	30	32.22	28.34	0.0	33.33	100.0	27	-4.94	23.94	-66.7	0.00	33.3
	Week 2	30	33.33	27.68	0.0	33.33	100.0	26	-2.56	29.70	-66.7	0.00	33.3
	Week 3	25	29.33	24.19	0.0	33.33	66.7	21	-6.35	24.99	-66.7	0.00	33.3
	Week 4	30	35.56	27.59	0.0	33.33	100.0	24	1.39	31.82	-66.7	0.00	66.7
	Week 5	29	35.63	25.09	0.0	33.33	100.0	21	1.59	32.45	-66.7	0.00	66.7
	Week 6	31	37.63	23.95	0.0	33.33	66.7	23	4.35	27.16	-66.7	0.00	33.3
	Week 7	33	32.32	24.28	0.0	33.33	66.7	23	-2.90	26.43	-66.7	0.00	33.3
	Week 8	29	22.99	22.01	0.0	33.33	66.7	20	-18.33	25.31	-66.7	-16.67	33.3
	Week 9	27	22.22	20.67	0.0	33.33	66.7	21	-11.11	28.55	-66.7	0.00	33.3
	Week 10	29	25.29	26.21	0.0	33.33	100.0	23	-13.04	24.08	-66.7	0.00	33.3
	Week 11	28	27.38	20.39	0.0	33.33	66.7	21	-6.35	22.65	-33.3	0.00	33.3
	Week 12	29	28.73	24.76	0.0	33.33	100.0	22	-12.12	33.41	-100.0	0.00	33.3
	Week 14	28	26.19	22.87	0.0	33.33	66.7	21	-9.52	31.87	-100.0	0.00	33.3
	Week 17	29	25.29	21.19	0.0	33.33	66.7	23	-11.59	29.49	-100.0	0.00	33.3
	Week 20	23	20.29	24.08	0.0	0.00	66.7	18	-16.67	28.58	-66.7	0.00	33.3
	Week 23	22	18.18	22.37	0.0	0.00	66.7	17	-13.73	31.31	-66.7	0.00	33.3
	Week 26	21	20.63	19.65	0.0	33.33	66.7	16	-14.58	24.25	-66.7	0.00	0.0
	Week 29	20	25.00	28.36	0.0	16.67	66.7	17	-7.84	32.34	-100.0	0.00	33.3
	Week 32	21	22.22	21.94	0.0	33.33	66.7	18	-12.96	34.56	-100.0	0.00	33.3
	Week 35	22	16.67	19.92	0.0	0.00	66.7	19	-17.54	28.04	-66.7	0.00	33.3
	Week 38	20	21.67	24.84	0.0	16.67	66.7	17	-11.77	28.73	-66.7	0.00	33.3
	Week 41	21	19.05	19.92	0.0	33.33	66.7	17	-11.77	26.20	-66.7	0.00	33.3
	Week 44	16	27.08	27.81	0.0	33.33	66.7	12	-2.78	22.29	-33.3	0.00	33.3
	Week 47	16	18.75	27.13	0.0	0.00	66.7	13	-7.69	27.74	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	16	18.75	20.97	0.0	16.67	66.7	11	-12.12	26.97	-66.7	0.00	33.3
	Week 53	15	15.55	21.33	0.0	0.00	66.7	11	-21.21	34.23	-100.0	-33.33	33.3
	Week 56	17	15.69	20.81	0.0	0.00	66.7	12	-19.45	33.21	-100.0	-16.67	33.3
	Week 59	17	23.53	25.73	0.0	33.33	66.7	12	-11.11	29.59	-66.7	0.00	33.3
	Week 62	14	26.19	32.50	0.0	16.67	100.0	9	0.00	23.57	-33.3	0.00	33.3
	Week 68	11	18.18	22.92	0.0	0.00	66.7	8	-4.17	21.36	-33.3	0.00	33.3
	Week 71	11	24.24	26.21	0.0	33.33	66.7	8	0.00	25.20	-33.3	0.00	33.3
	Plat+Gem (N= 34)												
	BASELINE	27	44.44	34.59	0.0	33.33	100.0						
	Week 1	19	38.60	31.94	0.0	33.33	100.0	17	-3.92	33.09	-66.7	0.00	66.7
	Week 2	20	33.33	28.61	0.0	33.33	100.0	18	0.00	30.25	-33.3	0.00	66.7
	Week 3	20	31.67	29.57	0.0	33.33	100.0	17	1.96	29.98	-33.3	0.00	66.7
	Week 4	23	27.54	27.80	0.0	33.33	66.7	19	-3.51	31.22	-66.7	0.00	66.7
	Week 5	25	30.67	30.31	0.0	33.33	100.0	22	-4.55	36.07	-66.7	0.00	100.0
	Week 6	20	26.67	23.20	0.0	33.33	66.7	17	-7.84	27.71	-33.3	0.00	33.3
	Week 7	23	31.88	29.26	0.0	33.33	100.0	20	-3.33	32.26	-66.7	0.00	100.0
	Week 8	24	34.72	31.82	0.0	33.33	100.0	22	0.00	39.84	-100.0	0.00	66.7
	Week 9	23	28.98	25.24	0.0	33.33	66.7	19	-3.51	31.22	-66.7	0.00	33.3
	Week 10	20	25.00	28.36	0.0	33.33	100.0	18	-7.41	26.95	-33.3	0.00	66.7
	Week 11	18	22.22	22.87	0.0	33.33	66.7	16	-4.17	31.92	-66.7	0.00	66.7
	Week 12	17	23.53	22.87	0.0	33.33	66.7	16	-16.67	27.22	-66.7	0.00	33.3
	Week 14	16	31.25	30.96	0.0	33.33	100.0	14	0.00	39.22	-66.7	0.00	66.7
	Week 17	19	21.05	19.91	0.0	33.33	66.7	17	-5.88	31.70	-66.7	0.00	33.3
	Week 20	16	16.67	21.08	0.0	0.00	66.7	13	-7.69	27.74	-33.3	0.00	33.3
	Week 23	15	15.55	21.33	0.0	0.00	66.7	13	-10.26	34.39	-66.7	0.00	33.3
	Week 26	13	17.95	22.01	0.0	0.00	66.7	12	-8.33	20.72	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 29	14	26.19	32.50	0.0	16.67	100.0	13	0.00	40.83	-66.7	0.00	66.7
	Week 32	11	6.06	13.48	0.0	0.00	33.3	10	-13.33	17.21	-33.3	0.00	0.0
	Week 35	13	15.38	17.29	0.0	0.00	33.3	11	-9.09	26.21	-66.7	0.00	33.3
	Week 38	10	30.00	33.15	0.0	33.33	100.0	9	11.11	33.33	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Rest of World	EV+Pembro (N= 82)												
	BASELINE	74	32.88	33.33	0.0	33.33	100.0						
	Week 1	63	32.27	30.51	0.0	33.33	100.0	60	0.56	25.67	-66.7	0.00	66.7
	Week 2	67	37.31	32.06	0.0	33.33	100.0	63	3.70	28.15	-66.7	0.00	100.0
	Week 3	64	35.42	30.21	0.0	33.33	100.0	60	3.33	29.88	-66.7	0.00	66.7
	Week 4	64	27.08	25.11	0.0	33.33	100.0	61	-6.01	28.87	-66.7	0.00	66.7
	Week 5	62	27.96	25.03	0.0	33.33	100.0	59	-4.52	28.00	-66.7	0.00	33.3
	Week 6	65	31.28	32.74	0.0	33.33	100.0	62	1.61	35.42	-66.7	0.00	100.0
	Week 7	64	29.69	29.17	0.0	33.33	100.0	62	-2.69	30.36	-66.7	0.00	66.7
	Week 8	67	28.36	29.16	0.0	33.33	100.0	63	-3.70	34.45	-100.0	0.00	66.7
	Week 9	68	29.41	30.22	0.0	33.33	100.0	63	-1.59	33.03	-66.7	0.00	66.7
	Week 10	65	30.26	28.70	0.0	33.33	100.0	61	0.55	31.91	-100.0	0.00	66.7
	Week 11	61	24.04	27.98	0.0	33.33	100.0	57	-5.85	33.41	-100.0	0.00	66.7
	Week 12	62	29.03	30.47	0.0	33.33	100.0	58	-1.15	34.18	-100.0	0.00	66.7
	Week 14	61	26.77	30.32	0.0	33.33	100.0	57	-4.09	26.78	-66.7	0.00	33.3
	Week 17	60	21.67	23.63	0.0	33.33	100.0	55	-7.27	31.22	-66.7	0.00	66.7
	Week 20	56	22.02	22.27	0.0	33.33	66.7	52	-2.56	30.85	-100.0	0.00	33.3
	Week 23	54	19.75	22.91	0.0	0.00	66.7	50	-6.67	32.30	-100.0	0.00	66.7
	Week 26	54	23.46	27.19	0.0	33.33	100.0	50	-4.00	32.74	-100.0	0.00	33.3
	Week 29	50	23.33	26.30	0.0	33.33	100.0	47	-6.38	30.01	-66.7	0.00	66.7
	Week 32	47	22.69	25.16	0.0	33.33	100.0	44	-7.58	30.38	-100.0	0.00	33.3
	Week 35	45	24.44	28.78	0.0	33.33	100.0	42	-5.56	36.01	-100.0	0.00	66.7
	Week 38	46	21.74	24.56	0.0	33.33	100.0	43	-8.53	36.44	-100.0	0.00	66.7
	Week 41	46	20.29	21.63	0.0	33.33	66.7	44	-11.36	32.10	-100.0	0.00	33.3
	Week 44	43	27.13	27.46	0.0	33.33	100.0	40	-5.00	38.16	-100.0	0.00	66.7
	Week 47	38	25.44	26.21	0.0	33.33	100.0	36	-8.33	35.97	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	32	21.87	21.77	0.0	33.33	66.7	30	-13.33	29.81	-66.7	0.00	33.3
	Week 53	33	24.24	20.87	0.0	33.33	66.7	31	-12.90	32.97	-100.0	0.00	33.3
	Week 56	30	24.44	21.32	0.0	33.33	66.7	28	-7.14	35.55	-66.7	0.00	66.7
	Week 59	29	28.73	27.78	0.0	33.33	100.0	27	-11.11	34.59	-100.0	0.00	33.3
	Week 62	28	25.00	21.52	0.0	33.33	66.7	26	-14.10	39.07	-100.0	0.00	66.7
	Week 65	22	28.79	21.32	0.0	33.33	66.7	21	-11.11	32.21	-66.7	0.00	33.3
	Week 68	20	28.33	22.36	0.0	33.33	66.7	19	-7.02	40.94	-100.0	0.00	66.7
	Week 71	18	31.48	26.75	0.0	33.33	100.0	17	-9.81	42.11	-100.0	0.00	33.3
	Week 74	19	35.09	26.00	0.0	33.33	100.0	19	-5.26	43.41	-100.0	0.00	66.7
	Week 77	19	35.09	20.71	0.0	33.33	66.7	18	-7.41	40.51	-66.7	0.00	66.7
	Week 80	19	33.33	27.22	0.0	33.33	100.0	18	-9.26	35.80	-100.0	0.00	33.3
	Week 83	17	41.18	32.34	0.0	33.33	100.0	17	-1.96	47.83	-100.0	0.00	66.7
	Week 86	14	40.48	26.73	0.0	33.33	100.0	14	-4.76	53.68	-100.0	0.00	100.0
	Week 89	11	39.39	32.72	0.0	33.33	100.0	11	0.00	49.44	-100.0	0.00	66.7
	Plat+Gem (N= 73)												
	BASELINE	63	27.51	33.09	0.0	33.33	100.0						
	Week 1	54	32.71	31.38	0.0	33.33	100.0	53	6.29	28.54	-66.7	0.00	66.7
	Week 2	56	34.52	29.10	0.0	33.33	100.0	54	7.41	29.44	-66.7	0.00	66.7
	Week 3	57	31.58	23.92	0.0	33.33	100.0	54	6.79	31.97	-66.7	0.00	66.7
	Week 4	58	31.03	24.87	0.0	33.33	100.0	54	3.70	32.81	-100.0	0.00	66.7
	Week 5	57	29.82	24.95	0.0	33.33	100.0	53	4.40	32.71	-100.0	0.00	66.7
	Week 6	56	30.36	26.42	0.0	33.33	100.0	53	5.03	30.24	-66.7	0.00	66.7
	Week 7	56	28.57	21.49	0.0	33.33	66.7	52	2.56	30.14	-66.7	0.00	66.7
	Week 8	54	30.25	27.68	0.0	33.33	100.0	50	6.00	37.31	-100.0	0.00	66.7
	Week 9	52	26.92	24.73	0.0	33.33	100.0	49	0.00	37.27	-100.0	0.00	66.7
	Week 10	52	28.20	24.15	0.0	33.33	100.0	49	3.40	32.09	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	45	30.37	25.45	0.0	33.33	100.0	42	3.97	32.26	-66.7	0.00	66.7
	Week 12	47	25.53	25.26	0.0	33.33	100.0	43	0.77	32.11	-100.0	0.00	66.7
	Week 14	43	26.36	26.78	0.0	33.33	100.0	39	3.42	28.40	-66.7	0.00	66.7
	Week 17	40	28.33	25.65	0.0	33.33	100.0	36	5.56	32.37	-66.7	0.00	66.7
	Week 20	34	23.53	23.97	0.0	33.33	66.7	30	-2.22	28.94	-66.7	0.00	66.7
	Week 23	29	24.14	19.71	0.0	33.33	66.7	27	6.17	27.79	-66.7	0.00	66.7
	Week 26	26	25.64	27.17	0.0	33.33	100.0	24	0.00	27.80	-66.7	0.00	66.7
	Week 29	24	27.78	25.38	0.0	33.33	100.0	22	9.09	32.83	-66.7	0.00	66.7
	Week 32	20	30.00	23.94	0.0	33.33	66.7	18	9.26	35.80	-66.7	0.00	66.7
	Week 35	17	25.49	27.71	0.0	33.33	66.7	15	0.00	37.80	-66.7	0.00	66.7
	Week 38	18	25.93	26.95	0.0	33.33	66.7	15	2.22	34.43	-66.7	0.00	66.7
	Week 41	18	27.78	26.20	0.0	33.33	66.7	16	8.33	28.55	-33.3	0.00	66.7
	Week 44	16	29.17	23.96	0.0	33.33	66.7	14	7.14	35.03	-66.7	0.00	66.7
	Week 47	12	25.00	25.13	0.0	33.33	66.7	11	3.03	27.71	-33.3	0.00	33.3
	Week 50	11	27.27	20.10	0.0	33.33	66.7	9	3.70	30.93	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	EV+Pembro (N=146)												
	BASELINE	119	31.37	29.21	0.0	33.33	100.0						
	Week 1	102	31.37	26.46	0.0	33.33	100.0	97	0.00	24.06	-66.7	0.00	66.7
	Week 2	106	34.91	29.59	0.0	33.33	100.0	98	3.74	26.60	-66.7	0.00	100.0
	Week 3	94	32.27	27.85	0.0	33.33	100.0	88	1.14	30.93	-66.7	0.00	66.7
	Week 4	101	31.35	26.59	0.0	33.33	100.0	93	0.00	29.08	-66.7	0.00	66.7
	Week 5	96	27.08	25.28	0.0	33.33	100.0	89	-2.62	30.25	-66.7	0.00	100.0
	Week 6	105	31.43	29.17	0.0	33.33	100.0	93	2.15	32.90	-66.7	0.00	100.0
	Week 7	102	31.04	29.01	0.0	33.33	100.0	89	1.50	30.11	-66.7	0.00	66.7
	Week 8	101	24.09	25.87	0.0	33.33	100.0	91	-5.86	30.47	-100.0	0.00	66.7
	Week 9	100	25.00	28.18	0.0	33.33	100.0	89	-4.12	33.27	-66.7	0.00	66.7
	Week 10	99	24.92	27.08	0.0	33.33	100.0	87	-4.60	30.57	-100.0	0.00	66.7
	Week 11	95	22.10	23.12	0.0	33.33	100.0	84	-4.76	28.88	-100.0	0.00	66.7
	Week 12	99	23.90	27.78	0.0	33.33	100.0	87	-5.36	35.90	-100.0	0.00	66.7
	Week 14	95	22.46	26.38	0.0	33.33	100.0	84	-5.56	27.79	-100.0	0.00	33.3
	Week 17	97	19.93	23.40	0.0	0.00	100.0	84	-7.14	29.30	-100.0	0.00	66.7
	Week 20	90	19.63	22.84	0.0	0.00	100.0	79	-6.75	29.42	-100.0	0.00	33.3
	Week 23	86	19.38	23.13	0.0	0.00	100.0	74	-4.50	29.36	-66.7	0.00	66.7
	Week 26	83	21.69	23.53	0.0	33.33	100.0	72	-2.32	28.71	-66.7	0.00	66.7
	Week 29	80	19.58	23.54	0.0	0.00	66.7	71	-5.16	30.16	-100.0	0.00	66.7
	Week 32	74	20.27	20.51	0.0	33.33	66.7	66	-4.04	26.48	-100.0	0.00	33.3
	Week 35	73	18.72	23.56	0.0	0.00	100.0	66	-6.57	30.51	-66.7	0.00	66.7
	Week 38	75	19.11	22.04	0.0	0.00	66.7	67	-5.97	30.66	-100.0	0.00	66.7
	Week 41	71	18.31	20.92	0.0	0.00	100.0	64	-7.29	28.15	-100.0	0.00	33.3
	Week 44	64	21.35	26.14	0.0	0.00	100.0	56	-2.98	31.32	-66.7	0.00	66.7
	Week 47	56	19.05	22.79	0.0	0.00	66.7	50	-4.00	29.85	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	55	16.97	21.15	0.0	0.00	100.0	48	-9.72	27.47	-66.7	0.00	33.3
	Week 53	55	19.39	20.97	0.0	33.33	66.7	48	-7.64	29.37	-100.0	0.00	33.3
	Week 56	53	18.24	21.25	0.0	0.00	66.7	46	-7.25	32.90	-100.0	0.00	66.7
	Week 59	51	18.95	24.27	0.0	0.00	100.0	43	-7.75	28.02	-66.7	0.00	33.3
	Week 62	42	20.63	24.36	0.0	16.67	100.0	36	-2.78	30.21	-66.7	0.00	66.7
	Week 65	31	15.05	18.93	0.0	0.00	66.7	30	-8.89	27.59	-66.7	0.00	33.3
	Week 68	31	21.50	22.02	0.0	33.33	66.7	29	3.45	28.65	-66.7	0.00	66.7
	Week 71	30	20.00	25.67	0.0	0.00	100.0	28	-2.38	32.62	-66.7	0.00	66.7
	Week 74	29	25.29	24.65	0.0	33.33	66.7	27	3.70	36.20	-66.7	0.00	66.7
	Week 77	26	23.08	22.65	0.0	33.33	66.7	24	1.39	34.72	-66.7	0.00	66.7
	Week 80	26	24.36	24.14	0.0	33.33	66.7	26	2.56	26.54	-33.3	0.00	33.3
	Week 83	21	26.98	27.12	0.0	33.33	66.7	21	6.35	35.93	-66.7	0.00	66.7
	Week 86	17	33.33	33.33	0.0	33.33	100.0	17	13.73	40.93	-66.7	0.00	100.0
	Week 89	11	30.30	27.71	0.0	33.33	66.7	11	15.15	34.53	-33.3	0.00	66.7
	Week 92	13	28.20	26.69	0.0	33.33	66.7	13	7.69	36.40	-66.7	0.00	66.7
	Plat+Gem (N=151)												
	BASELINE	123	28.46	33.52	0.0	33.33	100.0						
	Week 1	108	27.47	28.03	0.0	33.33	100.0	103	0.32	27.41	-66.7	0.00	66.7
	Week 2	116	29.88	27.93	0.0	33.33	100.0	105	5.08	28.03	-66.7	0.00	100.0
	Week 3	114	25.15	25.69	0.0	33.33	100.0	103	1.62	28.15	-66.7	0.00	66.7
	Week 4	116	27.01	26.71	0.0	33.33	100.0	103	1.29	27.98	-66.7	0.00	66.7
	Week 5	119	29.41	28.84	0.0	33.33	100.0	106	1.26	31.18	-100.0	0.00	100.0
	Week 6	109	27.52	26.78	0.0	33.33	100.0	98	1.70	29.26	-66.7	0.00	66.7
	Week 7	115	26.96	26.82	0.0	33.33	100.0	105	1.90	28.43	-66.7	0.00	100.0
	Week 8	111	26.13	27.85	0.0	33.33	100.0	102	0.33	33.99	-100.0	0.00	66.7
	Week 9	107	23.99	27.01	0.0	33.33	100.0	95	-2.46	33.42	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	107	22.43	24.56	0.0	33.33	100.0	98	-2.04	32.40	-100.0	0.00	66.7
	Week 11	97	22.68	23.84	0.0	33.33	100.0	87	-1.92	33.86	-100.0	0.00	66.7
	Week 12	100	23.67	24.75	0.0	33.33	100.0	88	-4.55	30.82	-66.7	0.00	66.7
	Week 14	99	24.24	27.69	0.0	33.33	100.0	86	1.55	30.64	-66.7	0.00	100.0
	Week 17	94	24.82	24.41	0.0	33.33	100.0	82	0.00	28.69	-66.7	0.00	66.7
	Week 20	84	23.81	27.17	0.0	33.33	100.0	72	0.00	27.97	-66.7	0.00	66.7
	Week 23	70	21.90	25.31	0.0	33.33	100.0	62	-0.54	26.65	-66.7	0.00	66.7
	Week 26	61	24.59	27.15	0.0	33.33	100.0	55	0.61	25.25	-66.7	0.00	66.7
	Week 29	59	25.42	27.92	0.0	33.33	100.0	53	3.14	29.43	-66.7	0.00	66.7
	Week 32	50	22.67	23.75	0.0	33.33	66.7	45	0.74	28.86	-66.7	0.00	66.7
	Week 35	50	24.00	24.32	0.0	33.33	66.7	44	0.00	30.50	-66.7	0.00	66.7
	Week 38	46	23.19	25.21	0.0	33.33	66.7	40	2.50	28.63	-66.7	0.00	66.7
	Week 41	42	30.95	29.81	0.0	33.33	100.0	37	7.21	35.26	-66.7	0.00	66.7
	Week 44	39	30.77	29.00	0.0	33.33	100.0	34	9.80	34.36	-66.7	0.00	100.0
	Week 47	33	25.25	28.90	0.0	33.33	100.0	29	0.00	34.50	-66.7	0.00	66.7
	Week 50	27	29.63	31.12	0.0	33.33	100.0	22	1.52	39.14	-66.7	0.00	100.0
	Week 53	23	26.09	28.35	0.0	33.33	100.0	20	1.67	27.52	-66.7	0.00	33.3
	Week 56	20	28.33	32.94	0.0	33.33	100.0	19	-1.75	30.37	-33.3	0.00	66.7
	Week 59	17	33.33	31.18	0.0	33.33	100.0	15	2.22	36.66	-66.7	0.00	66.7
	Week 62	14	33.33	34.59	0.0	33.33	100.0	14	4.76	34.24	-33.3	0.00	66.7
	Week 65	13	28.20	32.90	0.0	33.33	100.0	12	-5.56	23.92	-33.3	0.00	33.3
	Week 68	10	26.67	34.43	0.0	16.67	100.0	10	0.00	31.43	-33.3	0.00	66.7
	Week 71	10	30.00	29.19	0.0	33.33	100.0	10	3.33	29.19	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	EV+Pembro (N= 56)												
	BASELINE	41	42.28	34.18	0.0	33.33	100.0						
	Week 1	39	36.75	35.70	0.0	33.33	100.0	32	-5.21	25.55	-66.7	0.00	33.3
	Week 2	44	30.30	29.48	0.0	33.33	100.0	35	-14.29	31.61	-66.7	0.00	33.3
	Week 3	45	37.04	31.16	0.0	33.33	100.0	34	-9.81	34.36	-100.0	0.00	66.7
	Week 4	44	28.03	28.70	0.0	33.33	100.0	36	-14.82	34.22	-100.0	0.00	33.3
	Week 5	41	36.59	31.45	0.0	33.33	100.0	32	-7.29	36.65	-100.0	0.00	66.7
	Week 6	41	28.45	28.44	0.0	33.33	100.0	31	-10.75	37.90	-100.0	0.00	66.7
	Week 7	45	27.41	29.55	0.0	33.33	100.0	35	-15.24	35.56	-100.0	0.00	33.3
	Week 8	46	26.81	30.32	0.0	33.33	100.0	33	-16.16	36.44	-66.7	0.00	66.7
	Week 9	42	28.57	30.86	0.0	33.33	100.0	32	-10.42	31.04	-100.0	0.00	33.3
	Week 10	40	30.00	30.01	0.0	33.33	100.0	31	-8.60	33.30	-100.0	0.00	33.3
	Week 11	42	28.57	29.05	0.0	33.33	100.0	31	-12.90	36.19	-100.0	0.00	66.7
	Week 12	43	28.68	30.50	0.0	33.33	100.0	32	-8.33	36.91	-100.0	0.00	66.7
	Week 14	44	25.76	30.38	0.0	33.33	100.0	32	-16.67	31.68	-100.0	0.00	33.3
	Week 17	35	24.76	27.23	0.0	33.33	100.0	27	-18.52	31.12	-66.7	0.00	33.3
	Week 20	30	21.11	23.95	0.0	16.67	66.7	24	-15.28	29.46	-66.7	0.00	33.3
	Week 23	31	20.43	25.35	0.0	0.00	66.7	23	-24.64	32.13	-100.0	-33.33	33.3
	Week 26	29	21.84	27.13	0.0	0.00	100.0	22	-25.76	34.01	-100.0	-16.67	33.3
	Week 29	27	27.16	29.29	0.0	33.33	100.0	22	-18.18	30.39	-66.7	0.00	33.3
	Week 32	28	23.81	29.89	0.0	16.67	100.0	22	-25.76	35.53	-100.0	-33.33	33.3
	Week 35	25	25.33	27.69	0.0	33.33	100.0	20	-21.67	36.32	-100.0	-16.67	33.3
	Week 38	22	27.27	31.93	0.0	33.33	100.0	19	-21.05	35.50	-100.0	0.00	33.3
	Week 41	24	22.22	23.40	0.0	33.33	66.7	20	-25.00	28.36	-66.7	-33.33	33.3
	Week 44	22	28.79	27.79	0.0	33.33	66.7	18	-20.37	39.84	-100.0	0.00	33.3
	Week 47	23	26.09	28.35	0.0	33.33	100.0	20	-20.00	36.52	-100.0	-16.67	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	19	24.56	24.45	0.0	33.33	66.7	16	-20.84	31.91	-66.7	-33.33	33.3
	Week 53	19	24.56	24.45	0.0	33.33	66.7	15	-31.11	34.43	-100.0	-33.34	33.3
	Week 56	19	21.05	25.36	0.0	0.00	66.7	15	-24.45	32.04	-66.7	-33.33	33.3
	Week 59	18	27.78	28.58	0.0	33.33	66.7	14	-23.81	33.15	-100.0	0.00	0.0
	Week 62	20	25.00	23.88	0.0	33.33	66.7	16	-31.25	33.26	-100.0	-33.34	0.0
	Week 65	12	33.33	24.62	0.0	33.33	66.7	10	-30.00	33.15	-66.7	-33.34	33.3
	Week 68	15	26.67	22.54	0.0	33.33	66.7	13	-28.21	32.90	-100.0	-33.34	0.0
	Week 71	12	33.33	31.78	0.0	33.33	100.0	10	-26.67	40.98	-100.0	-16.67	33.3
	Week 77	11	30.30	23.36	0.0	33.33	66.7	9	-37.04	26.06	-66.7	-33.34	0.0
	Week 80	10	36.67	36.68	0.0	33.33	100.0	8	-29.17	41.55	-100.0	0.00	0.0
	Plat+Gem (N= 51)												
	BASELINE	42	38.89	36.75	0.0	33.33	100.0						
	Week 1	36	42.59	37.04	0.0	33.33	100.0	36	1.85	29.76	-66.7	0.00	66.7
	Week 2	31	34.41	37.99	0.0	33.33	100.0	30	-11.11	28.14	-66.7	0.00	33.3
	Week 3	35	36.19	28.44	0.0	33.33	100.0	33	1.01	32.79	-66.7	0.00	66.7
	Week 4	34	31.37	29.52	0.0	33.33	100.0	32	-7.29	37.61	-100.0	0.00	33.3
	Week 5	34	25.49	27.29	0.0	33.33	100.0	32	-9.38	38.09	-100.0	0.00	33.3
	Week 6	36	25.93	30.97	0.0	33.33	100.0	33	-12.12	29.84	-66.7	0.00	33.3
	Week 7	33	22.22	24.53	0.0	33.33	66.7	29	-19.54	31.52	-66.7	0.00	33.3
	Week 8	34	29.41	30.45	0.0	33.33	100.0	30	-7.78	36.81	-66.7	0.00	66.7
	Week 9	34	25.49	27.29	0.0	33.33	100.0	30	-10.00	42.12	-100.0	0.00	66.7
	Week 10	35	28.57	32.48	0.0	33.33	100.0	32	-11.46	37.49	-66.7	0.00	66.7
	Week 11	29	29.88	25.74	0.0	33.33	100.0	27	-6.17	30.72	-66.7	0.00	33.3
	Week 12	30	23.33	26.48	0.0	33.33	100.0	27	-8.64	34.09	-100.0	0.00	66.7
	Week 14	26	28.20	34.89	0.0	16.67	100.0	23	-8.70	32.13	-66.7	0.00	33.3
	Week 17	26	28.20	30.83	0.0	33.33	100.0	24	-6.95	36.75	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 20	20	18.33	27.52	0.0	0.00	100.0	19	-15.79	34.01	-66.7	0.00	33.3
	Week 23	18	16.67	17.15	0.0	16.67	33.3	18	-12.97	36.41	-66.7	0.00	33.3
	Week 26	20	15.00	20.16	0.0	0.00	66.7	20	-16.67	29.62	-100.0	0.00	33.3
	Week 29	18	22.22	30.25	0.0	0.00	100.0	18	-1.85	44.97	-66.7	0.00	66.7
	Week 32	13	15.38	22.01	0.0	0.00	66.7	13	-10.26	28.50	-66.7	0.00	33.3
	Week 35	12	8.33	15.07	0.0	0.00	33.3	12	-19.45	30.01	-66.7	0.00	0.0
	Week 38	10	23.33	31.62	0.0	16.67	100.0	10	-3.33	39.91	-66.7	0.00	66.7
	Week 41	10	16.67	17.57	0.0	16.67	33.3	10	3.33	24.59	-33.3	0.00	33.3
	Week 44	10	23.33	16.10	0.0	33.33	33.3	10	-10.00	35.31	-66.7	0.00	33.3
	Week 47	10	26.67	21.08	0.0	33.33	66.7	10	3.33	33.15	-66.7	0.00	33.3
	Week 56	10	20.00	17.21	0.0	33.33	33.3	10	0.00	35.14	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Visceral metastases	EV+Pembro (N=148)												
	BASELINE	119	36.41	31.89	0.0	33.33	100.0						
	Week 1	105	34.60	30.29	0.0	33.33	100.0	99	-2.02	23.24	-66.7	0.00	66.7
	Week 2	109	36.09	30.81	0.0	33.33	100.0	100	-0.33	29.40	-66.7	0.00	100.0
	Week 3	98	34.01	30.26	0.0	33.33	100.0	88	-3.41	33.92	-100.0	0.00	66.7
	Week 4	103	31.39	27.15	0.0	33.33	100.0	93	-5.02	33.32	-100.0	0.00	66.7
	Week 5	100	29.00	28.68	0.0	33.33	100.0	90	-6.30	34.22	-100.0	0.00	100.0
	Week 6	105	28.57	28.28	0.0	33.33	100.0	90	-4.45	34.33	-100.0	0.00	66.7
	Week 7	108	28.09	28.15	0.0	33.33	100.0	91	-6.23	32.55	-100.0	0.00	66.7
	Week 8	105	25.08	27.26	0.0	33.33	100.0	89	-11.61	32.61	-100.0	0.00	66.7
	Week 9	105	25.40	28.69	0.0	33.33	100.0	91	-9.52	32.31	-100.0	0.00	66.7
	Week 10	101	26.73	28.68	0.0	33.33	100.0	86	-7.75	32.61	-100.0	0.00	66.7
	Week 11	97	24.74	26.03	0.0	33.33	100.0	83	-8.84	31.70	-100.0	0.00	66.7
	Week 12	100	25.00	29.73	0.0	16.67	100.0	85	-9.41	37.31	-100.0	0.00	66.7
	Week 14	102	25.49	29.36	0.0	33.33	100.0	87	-9.58	29.60	-100.0	0.00	33.3
	Week 17	96	21.87	25.51	0.0	33.33	100.0	81	-11.93	30.87	-100.0	0.00	66.7
	Week 20	87	19.92	22.99	0.0	0.00	100.0	76	-9.21	31.08	-100.0	0.00	33.3
	Week 23	85	19.61	23.73	0.0	0.00	100.0	71	-11.27	32.34	-100.0	0.00	66.7
	Week 26	79	21.94	23.20	0.0	33.33	100.0	66	-9.09	30.69	-100.0	0.00	33.3
	Week 29	72	25.00	26.09	0.0	33.33	100.0	64	-8.33	30.86	-100.0	0.00	66.7
	Week 32	71	21.59	23.30	0.0	33.33	100.0	62	-12.37	29.71	-100.0	0.00	33.3
	Week 35	70	20.95	23.52	0.0	33.33	100.0	63	-13.23	32.54	-100.0	0.00	66.7
	Week 38	70	22.86	23.77	0.0	33.33	100.0	63	-10.58	34.82	-100.0	0.00	66.7
	Week 41	66	21.21	22.37	0.0	33.33	100.0	60	-13.33	28.92	-100.0	0.00	33.3
	Week 44	59	27.12	28.01	0.0	33.33	100.0	53	-6.92	35.42	-100.0	0.00	66.7
	Week 47	52	23.08	24.29	0.0	33.33	100.0	48	-9.72	34.35	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	49	20.41	23.39	0.0	33.33	100.0	43	-13.95	29.31	-66.7	0.00	33.3
	Week 53	50	22.00	21.94	0.0	33.33	66.7	44	-15.91	34.09	-100.0	0.00	33.3
	Week 56	45	20.74	21.66	0.0	33.33	66.7	39	-12.82	37.16	-100.0	0.00	66.7
	Week 59	44	23.48	25.50	0.0	33.33	100.0	38	-11.40	33.13	-100.0	0.00	33.3
	Week 62	38	22.81	24.64	0.0	33.33	100.0	33	-13.13	37.21	-100.0	0.00	66.7
	Week 65	25	20.00	21.52	0.0	33.33	66.7	24	-15.28	34.02	-66.7	0.00	33.3
	Week 68	31	25.81	22.29	0.0	33.33	66.7	29	-4.60	37.51	-100.0	0.00	66.7
	Week 71	27	23.46	25.84	0.0	33.33	100.0	25	-8.00	40.00	-100.0	0.00	66.7
	Week 74	23	28.98	27.16	0.0	33.33	100.0	22	-7.58	43.56	-100.0	0.00	66.7
	Week 77	24	25.00	22.52	0.0	33.33	66.7	23	-10.15	40.75	-66.7	0.00	66.7
	Week 80	22	30.30	28.93	0.0	33.33	100.0	22	-6.06	39.36	-100.0	0.00	33.3
	Week 83	19	33.33	31.43	0.0	33.33	100.0	19	-1.75	46.45	-100.0	0.00	66.7
	Week 86	14	40.48	35.03	0.0	33.33	100.0	14	-2.38	57.68	-100.0	0.00	100.0
	Week 89	10	30.00	36.68	0.0	16.67	100.0	10	-10.00	52.24	-100.0	0.00	66.7
	Week 92	11	36.36	34.82	0.0	33.33	100.0	11	-6.06	46.71	-100.0	0.00	66.7
	Plat+Gem (N=157)												
	BASELINE	128	33.33	35.25	0.0	33.33	100.0						
	Week 1	111	32.13	30.79	0.0	33.33	100.0	107	-0.62	28.22	-66.7	0.00	66.7
	Week 2	110	33.03	30.46	0.0	33.33	100.0	102	1.96	29.23	-66.7	0.00	100.0
	Week 3	112	27.38	26.17	0.0	33.33	100.0	103	-0.97	29.69	-66.7	0.00	66.7
	Week 4	112	29.17	27.99	0.0	33.33	100.0	102	-1.31	30.73	-100.0	0.00	66.7
	Week 5	113	28.61	27.41	0.0	33.33	100.0	103	-3.24	31.83	-100.0	0.00	66.7
	Week 6	107	27.10	29.01	0.0	33.33	100.0	98	-3.06	29.54	-66.7	0.00	66.7
	Week 7	109	26.30	27.24	0.0	33.33	100.0	100	-4.00	29.31	-66.7	0.00	66.7
	Week 8	106	28.62	29.26	0.0	33.33	100.0	98	-1.36	36.11	-100.0	0.00	66.7
	Week 9	105	25.40	28.69	0.0	33.33	100.0	94	-4.97	35.91	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	104	22.76	26.79	0.0	16.67	100.0	96	-6.25	32.20	-100.0	0.00	66.7
	Week 11	91	22.71	24.79	0.0	33.33	100.0	83	-5.62	31.59	-100.0	0.00	66.7
	Week 12	94	22.69	26.42	0.0	33.33	100.0	84	-7.94	29.10	-66.7	0.00	66.7
	Week 14	90	22.59	27.29	0.0	0.00	100.0	79	-3.38	30.00	-66.7	0.00	66.7
	Week 17	90	24.07	25.00	0.0	33.33	100.0	80	-4.58	30.35	-66.7	0.00	66.7
	Week 20	74	22.07	27.19	0.0	0.00	100.0	64	-6.25	27.78	-66.7	0.00	66.7
	Week 23	63	19.58	22.90	0.0	0.00	100.0	58	-5.17	27.07	-66.7	0.00	33.3
	Week 26	55	21.82	26.62	0.0	0.00	100.0	52	-6.41	28.04	-100.0	0.00	33.3
	Week 29	53	23.90	28.02	0.0	33.33	100.0	50	-1.33	32.96	-66.7	0.00	66.7
	Week 32	42	19.84	23.35	0.0	0.00	66.7	40	-5.83	28.13	-66.7	0.00	66.7
	Week 35	39	18.80	22.68	0.0	0.00	66.7	36	-9.26	30.46	-66.7	0.00	33.3
	Week 38	37	24.32	27.94	0.0	33.33	100.0	34	0.98	31.23	-66.7	0.00	66.7
	Week 41	33	26.26	28.58	0.0	33.33	100.0	31	3.23	32.61	-66.7	0.00	66.7
	Week 44	32	27.08	26.01	0.0	33.33	100.0	30	1.11	34.45	-66.7	0.00	66.7
	Week 47	28	25.00	28.15	0.0	33.33	100.0	26	-1.28	34.62	-66.7	0.00	66.7
	Week 50	22	24.24	29.42	0.0	16.67	100.0	20	-6.67	35.21	-66.7	0.00	66.7
	Week 53	19	22.81	24.97	0.0	33.33	100.0	17	-1.96	29.98	-66.7	0.00	33.3
	Week 56	18	25.92	31.43	0.0	33.33	100.0	17	-7.84	30.11	-66.7	0.00	33.3
	Week 59	13	33.33	33.33	0.0	33.33	100.0	12	-2.78	33.21	-66.7	0.00	66.7
	Week 62	11	33.33	33.33	0.0	33.33	100.0	11	-3.03	37.88	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Lymph node only	EV+Pembro (N= 43)												
	BASELINE	33	30.30	26.83	0.0	33.33	66.7						
	Week 1	30	27.78	26.38	0.0	33.33	100.0	24	-2.78	29.35	-66.7	0.00	33.3
	Week 2	34	26.47	25.66	0.0	33.33	100.0	27	-7.41	28.25	-66.7	0.00	33.3
	Week 3	35	33.33	25.57	0.0	33.33	66.7	28	-2.38	25.55	-66.7	0.00	33.3
	Week 4	36	27.78	27.02	0.0	33.33	100.0	30	-5.56	21.59	-66.7	0.00	33.3
	Week 5	33	34.34	24.28	0.0	33.33	66.7	27	3.70	25.04	-33.3	0.00	66.7
	Week 6	34	35.29	29.52	0.0	33.33	100.0	28	3.57	31.87	-66.7	0.00	66.7
	Week 7	34	36.27	32.17	0.0	33.33	100.0	28	2.38	31.33	-66.7	0.00	66.7
	Week 8	35	26.67	27.77	0.0	33.33	100.0	29	-3.45	30.01	-66.7	0.00	66.7
	Week 9	30	26.67	28.23	0.0	33.33	100.0	24	0.00	29.49	-66.7	0.00	66.7
	Week 10	31	24.73	25.77	0.0	33.33	66.7	26	-3.85	27.21	-66.7	0.00	66.7
	Week 11	34	23.53	22.52	0.0	33.33	66.7	27	-6.17	27.79	-66.7	0.00	33.3
	Week 12	35	26.67	26.57	0.0	33.33	100.0	28	-1.19	33.31	-66.7	0.00	33.3
	Week 14	30	17.78	20.96	0.0	0.00	66.7	23	-10.15	27.40	-66.7	0.00	33.3
	Week 17	30	18.89	22.63	0.0	0.00	66.7	24	-8.33	28.23	-66.7	0.00	33.3
	Week 20	27	19.75	23.13	0.0	0.00	66.7	21	-12.70	24.67	-66.7	0.00	33.3
	Week 23	27	18.52	23.27	0.0	0.00	66.7	21	-7.94	27.70	-66.7	0.00	33.3
	Week 26	27	20.99	27.96	0.0	0.00	100.0	22	-9.09	35.90	-66.7	0.00	66.7
	Week 29	28	15.48	23.10	0.0	0.00	66.7	23	-10.14	32.47	-66.7	0.00	66.7
	Week 32	24	23.61	25.02	0.0	33.33	66.7	20	-3.33	34.03	-66.7	0.00	33.3
	Week 35	22	21.21	30.07	0.0	0.00	100.0	18	-1.85	33.28	-66.7	0.00	66.7
	Week 38	21	15.87	29.10	0.0	0.00	100.0	17	-9.80	25.73	-66.7	0.00	33.3
	Week 41	22	15.15	19.86	0.0	0.00	66.7	17	-11.77	33.21	-66.7	0.00	33.3
	Week 44	22	13.64	22.20	0.0	0.00	66.7	16	-12.50	34.16	-66.7	0.00	33.3
	Week 47	21	15.87	24.99	0.0	0.00	66.7	16	-12.50	29.50	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	15.00	20.16	0.0	0.00	66.7	16	-14.58	29.74	-66.7	0.00	33.3
	Week 53	18	20.37	23.26	0.0	16.67	66.7	14	-9.52	30.46	-66.7	0.00	33.3
	Week 56	21	15.87	24.99	0.0	0.00	66.7	17	-13.73	26.51	-66.7	0.00	33.3
	Week 59	21	15.87	24.99	0.0	0.00	66.7	16	-16.67	21.08	-66.7	0.00	0.0
	Week 62	19	22.81	24.98	0.0	33.33	66.7	15	-11.11	27.22	-66.7	0.00	33.3
	Week 65	16	16.67	21.08	0.0	0.00	66.7	14	-16.67	21.68	-66.7	0.00	0.0
	Week 68	13	20.51	21.68	0.0	33.33	66.7	11	-9.09	21.56	-33.3	0.00	33.3
	Week 71	13	28.20	32.90	0.0	33.33	100.0	11	-9.09	30.15	-66.7	0.00	33.3
	Week 74	13	23.08	28.50	0.0	0.00	66.7	11	0.00	39.44	-66.7	0.00	66.7
	Week 77	13	25.64	24.17	0.0	33.33	66.7	10	-6.67	26.30	-33.3	0.00	33.3
	Week 80	13	25.64	27.74	0.0	33.33	66.7	11	-3.03	17.98	-33.3	0.00	33.3
	Week 83	11	24.24	30.15	0.0	33.33	100.0	10	-3.33	24.59	-33.3	0.00	33.3
	Week 86	11	21.21	22.47	0.0	33.33	66.7	10	-3.33	18.92	-33.3	0.00	33.3
	Plat+Gem (N= 37)												
	BASELINE	29	24.14	31.99	0.0	0.00	100.0						
	Week 1	26	23.08	29.47	0.0	16.67	100.0	25	0.00	27.22	-66.7	0.00	33.3
	Week 2	30	22.22	28.14	0.0	0.00	100.0	26	-2.56	28.16	-66.7	0.00	66.7
	Week 3	30	25.55	27.24	0.0	33.33	100.0	26	3.85	25.52	-33.3	0.00	66.7
	Week 4	32	26.04	26.42	0.0	33.33	100.0	27	1.23	29.93	-66.7	0.00	66.7
	Week 5	33	29.29	33.08	0.0	33.33	100.0	28	3.57	35.53	-100.0	0.00	100.0
	Week 6	32	26.04	25.02	0.0	33.33	100.0	27	0.00	29.23	-66.7	0.00	33.3
	Week 7	31	25.81	25.40	0.0	33.33	100.0	26	1.28	33.31	-66.7	0.00	100.0
	Week 8	32	21.87	26.25	0.0	16.67	100.0	27	-2.47	30.56	-100.0	0.00	33.3
	Week 9	30	21.11	20.50	0.0	33.33	66.7	25	-2.67	33.22	-100.0	0.00	33.3
	Week 10	30	25.55	28.61	0.0	33.33	100.0	26	-2.56	38.79	-100.0	0.00	66.7
	Week 11	29	26.44	22.50	0.0	33.33	66.7	25	1.33	36.62	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.20.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Sleep Disturbance by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 12	28	23.81	21.96	0.0	33.33	66.7	23	-2.90	37.49	-100.0	0.00	66.7
	Week 14	28	29.76	34.35	0.0	33.33	100.0	23	4.35	35.25	-66.7	0.00	100.0
	Week 17	25	30.67	28.74	0.0	33.33	100.0	21	6.35	24.99	-66.7	0.00	33.3
	Week 20	23	23.19	29.19	0.0	0.00	100.0	20	0.00	34.20	-66.7	0.00	66.7
	Week 23	20	21.67	27.09	0.0	16.67	100.0	17	-3.92	28.58	-66.7	0.00	33.3
	Week 26	21	22.22	24.34	0.0	33.33	66.7	18	-1.85	21.31	-33.3	0.00	33.3
	Week 29	19	26.32	30.59	0.0	33.33	100.0	16	8.33	31.03	-33.3	0.00	66.7
	Week 32	18	22.22	22.87	0.0	33.33	66.7	15	2.22	26.63	-33.3	0.00	66.7
	Week 35	19	24.56	24.45	0.0	33.33	66.7	16	4.17	23.96	-33.3	0.00	66.7
	Week 38	15	17.78	21.33	0.0	0.00	66.7	12	-8.33	25.13	-66.7	0.00	33.3
	Week 41	15	28.89	27.79	0.0	33.33	66.7	12	2.78	30.01	-33.3	0.00	66.7
	Week 44	14	33.33	29.24	0.0	33.33	100.0	11	9.09	36.79	-33.3	0.00	100.0
	Week 47	12	25.00	28.87	0.0	16.67	66.7	10	-3.33	33.15	-33.3	0.00	66.7
	Week 50	11	30.30	31.46	0.0	33.33	100.0	8	4.17	45.21	-33.3	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
EV+Pembro (N=240)												
BASELINE	206	19.09	26.99	0.0	0.00	100.0						
Week 1	190	22.63	30.42	0.0	0.00	100.0	184	3.99	26.92	-66.7	0.00	100.0
Week 2	203	18.06	25.73	0.0	0.00	100.0	189	-1.41	27.90	-100.0	0.00	100.0
Week 3	198	17.34	26.17	0.0	0.00	100.0	182	-1.28	30.22	-100.0	0.00	100.0
Week 4	194	18.90	24.19	0.0	0.00	100.0	179	-1.12	29.75	-100.0	0.00	100.0
Week 5	190	17.19	23.44	0.0	0.00	100.0	173	-2.31	29.77	-100.0	0.00	100.0
Week 6	188	17.02	22.73	0.0	0.00	100.0	170	-3.33	30.26	-100.0	0.00	100.0
Week 7	195	18.97	25.31	0.0	0.00	100.0	176	-2.08	35.30	-100.0	0.00	100.0
Week 8	191	16.75	24.15	0.0	0.00	100.0	171	-3.51	34.12	-100.0	0.00	100.0
Week 9	197	15.57	22.47	0.0	0.00	100.0	180	-4.44	32.18	-100.0	0.00	100.0
Week 10	191	15.88	23.15	0.0	0.00	100.0	175	-4.38	31.76	-100.0	0.00	100.0
Week 11	194	16.67	22.32	0.0	0.00	100.0	175	-4.38	30.74	-100.0	0.00	66.7
Week 12	186	16.31	22.52	0.0	0.00	100.0	171	-5.26	34.37	-100.0	0.00	100.0
Week 14	185	18.38	23.54	0.0	0.00	100.0	167	-2.60	32.31	-100.0	0.00	100.0
Week 17	178	17.23	22.47	0.0	0.00	100.0	162	-2.06	31.46	-100.0	0.00	66.7
Week 20	167	17.76	24.49	0.0	0.00	100.0	154	-2.81	31.65	-100.0	0.00	66.7
Week 23	162	19.55	24.26	0.0	0.00	100.0	151	-0.88	31.26	-100.0	0.00	100.0
Week 26	156	17.95	24.94	0.0	0.00	100.0	144	-2.55	33.00	-100.0	0.00	100.0
Week 29	157	17.62	23.44	0.0	0.00	100.0	145	-3.22	28.42	-100.0	0.00	66.7
Week 32	135	17.04	25.71	0.0	0.00	100.0	125	-3.73	30.59	-100.0	0.00	100.0
Week 35	132	17.42	23.83	0.0	0.00	100.0	122	-3.01	28.10	-100.0	0.00	66.7
Week 38	132	18.18	25.18	0.0	0.00	100.0	124	-2.42	31.57	-100.0	0.00	100.0
Week 41	129	18.86	25.63	0.0	0.00	100.0	119	-0.84	29.58	-66.7	0.00	100.0
Week 44	108	18.52	23.83	0.0	0.00	100.0	100	-1.33	29.17	-66.7	0.00	100.0
Week 47	100	16.33	23.92	0.0	0.00	100.0	94	-4.26	31.77	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	89	19.10	27.93	0.0	0.00	100.0	84	0.00	35.85	-100.0	0.00	100.0
Week 53	79	16.03	23.79	0.0	0.00	66.7	74	-0.90	33.09	-66.7	0.00	66.7
Week 56	81	17.69	25.87	0.0	0.00	100.0	76	-1.32	36.69	-100.0	0.00	100.0
Week 59	72	16.67	23.74	0.0	0.00	100.0	68	-2.94	34.91	-100.0	0.00	100.0
Week 62	65	17.44	26.42	0.0	0.00	100.0	63	-0.53	31.96	-66.7	0.00	100.0
Week 65	58	15.52	25.14	0.0	0.00	100.0	54	-4.94	27.78	-66.7	0.00	100.0
Week 68	53	13.84	24.84	0.0	0.00	100.0	52	-5.77	32.82	-66.7	0.00	100.0
Week 71	51	15.69	24.36	0.0	0.00	66.7	49	-3.40	32.09	-66.7	0.00	66.7
Week 74	47	18.44	25.83	0.0	0.00	66.7	46	-1.45	35.80	-66.7	0.00	66.7
Week 77	44	17.42	27.36	0.0	0.00	100.0	42	-4.76	36.49	-66.7	0.00	66.7
Week 80	40	13.33	23.63	0.0	0.00	66.7	37	-9.01	34.83	-100.0	0.00	66.7
Week 83	37	16.22	26.78	0.0	0.00	100.0	35	-6.67	34.11	-66.7	0.00	100.0
Week 86	34	14.71	26.20	0.0	0.00	100.0	31	-4.30	28.21	-66.7	0.00	66.7
Week 89	33	18.18	27.75	0.0	0.00	100.0	31	-3.23	37.86	-100.0	0.00	100.0
Week 92	27	14.81	25.04	0.0	0.00	100.0	25	-8.00	32.32	-100.0	0.00	33.3
Week 95	22	13.64	26.55	0.0	0.00	100.0	21	-7.94	20.83	-66.7	0.00	33.3
Week 98	18	9.26	15.36	0.0	0.00	33.3	17	-15.69	26.66	-66.7	0.00	33.3
Week 101	14	4.76	12.10	0.0	0.00	33.3	14	-14.29	31.25	-100.0	0.00	33.3
Week 104	10	3.33	10.54	0.0	0.00	33.3	10	-13.33	28.11	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Plat+Gem (N=242)												
BASELINE	188	24.29	28.96	0.0	0.00	100.0						
Week 1	173	34.87	32.51	0.0	33.33	100.0	158	12.66	27.55	-66.7	0.00	100.0
Week 2	171	31.19	30.71	0.0	33.33	100.0	151	8.61	31.14	-100.0	0.00	100.0
Week 3	184	22.10	26.67	0.0	0.00	100.0	162	-1.23	28.99	-100.0	0.00	100.0
Week 4	183	26.78	28.05	0.0	33.33	100.0	156	4.27	31.16	-100.0	0.00	100.0
Week 5	187	27.27	28.69	0.0	33.33	100.0	156	6.20	31.64	-100.0	0.00	100.0
Week 6	174	25.10	27.34	0.0	33.33	100.0	149	4.25	29.33	-66.7	0.00	100.0
Week 7	186	24.91	26.30	0.0	33.33	100.0	157	4.03	30.51	-66.7	0.00	100.0
Week 8	167	26.55	27.02	0.0	33.33	100.0	144	6.94	32.00	-66.7	0.00	100.0
Week 9	177	18.27	25.36	0.0	0.00	100.0	150	-0.67	29.28	-100.0	0.00	100.0
Week 10	166	24.90	27.87	0.0	33.33	100.0	139	4.08	31.46	-66.7	0.00	100.0
Week 11	168	24.01	27.28	0.0	33.33	100.0	143	3.26	30.21	-66.7	0.00	100.0
Week 12	159	23.48	26.40	0.0	33.33	100.0	138	2.42	31.10	-66.7	0.00	100.0
Week 14	153	27.67	28.30	0.0	33.33	100.0	128	6.51	34.51	-100.0	0.00	100.0
Week 17	155	26.88	26.62	0.0	33.33	100.0	130	7.44	31.41	-100.0	0.00	100.0
Week 20	126	18.78	24.04	0.0	0.00	100.0	110	0.00	28.91	-66.7	0.00	100.0
Week 23	115	17.10	25.88	0.0	0.00	100.0	97	-1.72	31.32	-100.0	0.00	100.0
Week 26	108	14.81	24.26	0.0	0.00	100.0	95	-4.21	34.12	-66.7	0.00	100.0
Week 29	100	13.33	24.62	0.0	0.00	100.0	86	-5.04	31.73	-66.7	0.00	100.0
Week 32	83	18.47	28.16	0.0	0.00	100.0	76	0.00	31.27	-66.7	0.00	100.0
Week 35	76	17.54	26.37	0.0	0.00	100.0	69	0.97	31.30	-66.7	0.00	100.0
Week 38	74	15.77	25.42	0.0	0.00	100.0	65	-1.03	27.62	-66.7	0.00	100.0
Week 41	65	20.00	28.75	0.0	0.00	100.0	56	2.98	30.00	-33.3	0.00	100.0
Week 44	60	17.22	25.67	0.0	0.00	100.0	53	0.63	28.86	-66.7	0.00	100.0
Week 47	56	17.26	26.20	0.0	0.00	100.0	49	0.00	34.02	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	51	15.69	27.77	0.0	0.00	100.0	47	-7.09	30.25	-66.7	0.00	100.0
Week 53	46	10.14	19.71	0.0	0.00	100.0	42	-5.56	26.46	-66.7	0.00	100.0
Week 56	39	12.82	18.12	0.0	0.00	66.7	34	-6.86	22.89	-66.7	0.00	33.3
Week 59	37	9.91	17.33	0.0	0.00	66.7	33	-5.05	18.86	-33.3	0.00	33.3
Week 62	32	7.29	14.00	0.0	0.00	33.3	29	-8.05	17.03	-33.3	0.00	33.3
Week 65	30	3.33	10.17	0.0	0.00	33.3	26	-11.54	16.17	-33.3	0.00	0.0
Week 68	25	6.67	16.67	0.0	0.00	66.7	21	-9.52	15.43	-33.3	0.00	0.0
Week 71	22	6.06	16.70	0.0	0.00	66.7	19	-12.28	16.52	-33.3	0.00	0.0
Week 74	21	12.70	22.30	0.0	0.00	66.7	18	-7.41	18.28	-33.3	0.00	33.3
Week 77	18	7.41	18.28	0.0	0.00	66.7	15	-13.33	21.08	-66.7	0.00	0.0
Week 80	14	9.52	20.38	0.0	0.00	66.7	13	-10.26	21.01	-33.3	0.00	33.3
Week 83	13	10.26	21.01	0.0	0.00	66.7	12	-11.11	16.41	-33.3	0.00	0.0
Week 86	12	8.33	15.07	0.0	0.00	33.3	11	-15.15	17.41	-33.3	0.00	0.0
Week 89	11	9.09	15.57	0.0	0.00	33.3	10	-16.67	17.57	-33.3	-16.67	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Present	EV+Pembro (N= 48)												
	BASELINE	39	15.38	26.32	0.0	0.00	100.0						
	Week 1	32	28.12	38.90	0.0	0.00	100.0	32	13.54	32.64	-33.3	0.00	100.0
	Week 2	37	18.02	30.02	0.0	0.00	100.0	33	0.00	38.19	-100.0	0.00	100.0
	Week 3	34	18.63	30.91	0.0	0.00	100.0	29	2.30	42.66	-100.0	0.00	100.0
	Week 4	36	21.30	31.02	0.0	0.00	100.0	31	4.30	39.20	-100.0	0.00	100.0
	Week 5	30	20.00	32.28	0.0	0.00	100.0	24	-4.17	44.30	-100.0	0.00	100.0
	Week 6	31	20.43	29.41	0.0	0.00	100.0	25	-4.00	42.30	-66.7	0.00	100.0
	Week 7	34	23.53	31.28	0.0	0.00	100.0	28	1.19	43.02	-100.0	0.00	100.0
	Week 8	35	17.14	29.56	0.0	0.00	100.0	30	-3.33	42.30	-100.0	0.00	100.0
	Week 9	34	16.67	24.96	0.0	0.00	100.0	30	-1.11	37.63	-100.0	0.00	100.0
	Week 10	34	21.57	29.45	0.0	0.00	100.0	30	2.22	41.00	-100.0	0.00	100.0
	Week 11	33	15.15	22.19	0.0	0.00	66.7	28	-8.33	34.69	-100.0	0.00	66.7
	Week 12	33	15.15	26.47	0.0	0.00	100.0	29	-5.75	37.87	-66.7	0.00	100.0
	Week 14	31	20.43	26.77	0.0	0.00	100.0	26	-1.28	38.27	-100.0	0.00	100.0
	Week 17	31	17.20	24.15	0.0	0.00	66.7	25	0.00	28.87	-66.7	0.00	66.7
	Week 20	27	18.52	23.27	0.0	0.00	66.7	24	-2.78	35.33	-100.0	0.00	66.7
	Week 23	26	20.51	21.24	0.0	33.33	66.7	23	0.00	37.61	-100.0	0.00	66.7
	Week 26	25	8.00	14.53	0.0	0.00	33.3	22	-18.18	30.39	-100.0	0.00	33.3
	Week 29	23	8.70	18.03	0.0	0.00	66.7	22	-10.61	26.00	-66.7	0.00	33.3
	Week 32	21	14.28	19.92	0.0	0.00	66.7	19	-10.53	27.34	-66.7	0.00	33.3
	Week 35	19	10.53	22.37	0.0	0.00	66.7	17	-11.76	26.20	-66.7	0.00	33.3
	Week 38	18	12.96	28.33	0.0	0.00	100.0	17	-13.72	23.74	-66.7	0.00	33.3
	Week 41	20	10.00	21.90	0.0	0.00	66.7	19	-7.02	23.78	-66.7	0.00	33.3
	Week 44	17	9.80	19.60	0.0	0.00	66.7	15	-13.33	21.08	-66.7	0.00	0.0
	Week 47	18	11.11	25.56	0.0	0.00	100.0	16	-8.33	25.82	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	12	13.89	26.43	0.0	0.00	66.7	11	-3.03	34.82	-66.7	0.00	66.7
	Week 53	12	13.89	22.29	0.0	0.00	66.7	11	-3.03	27.71	-66.7	0.00	33.3
	Week 56	13	12.82	21.68	0.0	0.00	66.7	12	-8.33	32.18	-66.7	0.00	33.3
	Week 59	12	5.56	12.97	0.0	0.00	33.3	11	-15.15	22.92	-66.7	0.00	0.0
	Week 62	10	0.00	0.00	0.0	0.00	0.0	9	-18.52	24.22	-66.7	0.00	0.0
	Week 65	10	6.67	14.05	0.0	0.00	33.3	9	-14.81	24.22	-66.7	0.00	0.0
	Plat+Gem (N= 48)												
	BASELINE	33	26.26	29.77	0.0	33.33	100.0						
	Week 1	31	43.01	37.71	0.0	33.33	100.0	27	18.52	32.47	-33.3	0.00	100.0
	Week 2	29	31.03	34.42	0.0	33.33	100.0	24	4.17	42.06	-66.7	0.00	100.0
	Week 3	32	18.75	23.85	0.0	0.00	66.7	27	-6.17	29.29	-66.7	0.00	66.7
	Week 4	32	21.87	27.58	0.0	0.00	100.0	24	1.39	30.26	-33.3	0.00	100.0
	Week 5	36	35.18	33.75	0.0	33.33	100.0	28	17.86	37.93	-33.3	0.00	100.0
	Week 6	35	27.62	26.18	0.0	33.33	66.7	27	4.94	31.63	-66.7	0.00	66.7
	Week 7	38	28.95	30.19	0.0	33.33	100.0	29	5.75	34.58	-66.7	0.00	66.7
	Week 8	31	27.96	25.96	0.0	33.33	100.0	25	5.33	34.27	-66.7	0.00	66.7
	Week 9	32	17.71	23.92	0.0	0.00	66.7	25	-5.33	26.67	-33.3	0.00	66.7
	Week 10	34	20.59	24.64	0.0	0.00	66.7	26	-5.13	29.35	-66.7	0.00	66.7
	Week 11	30	20.00	27.12	0.0	0.00	100.0	24	-6.95	27.77	-33.3	0.00	66.7
	Week 12	28	26.19	27.75	0.0	33.33	100.0	23	0.00	36.24	-66.7	0.00	66.7
	Week 14	26	26.92	29.84	0.0	33.33	100.0	21	1.59	46.52	-66.7	0.00	100.0
	Week 17	30	22.22	25.27	0.0	16.67	66.7	25	-5.33	24.87	-33.3	0.00	33.3
	Week 20	23	18.84	19.66	0.0	33.33	66.7	21	-4.76	26.43	-66.7	0.00	33.3
	Week 23	22	18.18	30.39	0.0	0.00	100.0	19	-8.77	33.04	-66.7	0.00	33.3
	Week 26	19	8.77	15.08	0.0	0.00	33.3	18	-14.82	34.72	-66.7	0.00	33.3
	Week 29	16	14.58	20.97	0.0	0.00	66.7	14	-11.91	30.96	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 32	11	24.24	21.56	0.0	33.33	66.7	11	3.03	27.71	-33.3	0.00	33.3
	Week 35	10	13.33	17.21	0.0	0.00	33.3	9	7.41	22.22	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Absent	EV+Pembro (N=192)												
	BASELINE	167	19.96	27.15	0.0	0.00	100.0						
	Week 1	158	21.52	28.42	0.0	0.00	100.0	152	1.97	25.22	-66.7	0.00	100.0
	Week 2	166	18.07	24.78	0.0	0.00	100.0	156	-1.71	25.34	-100.0	0.00	100.0
	Week 3	164	17.07	25.17	0.0	0.00	100.0	153	-1.96	27.37	-100.0	0.00	66.7
	Week 4	158	18.35	22.43	0.0	0.00	100.0	148	-2.25	27.40	-100.0	0.00	66.7
	Week 5	160	16.67	21.48	0.0	0.00	100.0	149	-2.01	26.91	-66.7	0.00	66.7
	Week 6	157	16.35	21.22	0.0	0.00	100.0	145	-3.22	27.87	-100.0	0.00	66.7
	Week 7	161	18.01	23.86	0.0	0.00	100.0	148	-2.70	33.79	-100.0	0.00	100.0
	Week 8	156	16.67	22.88	0.0	0.00	100.0	141	-3.55	32.29	-100.0	0.00	66.7
	Week 9	163	15.34	21.99	0.0	0.00	100.0	150	-5.11	31.07	-100.0	0.00	66.7
	Week 10	157	14.65	21.46	0.0	0.00	100.0	145	-5.75	29.49	-100.0	0.00	66.7
	Week 11	161	16.98	22.40	0.0	0.00	100.0	147	-3.63	30.00	-100.0	0.00	66.7
	Week 12	153	16.56	21.67	0.0	0.00	100.0	142	-5.16	33.76	-100.0	0.00	66.7
	Week 14	154	17.96	22.91	0.0	0.00	100.0	141	-2.84	31.24	-100.0	0.00	100.0
	Week 17	147	17.23	22.19	0.0	0.00	100.0	137	-2.43	31.99	-100.0	0.00	66.7
	Week 20	140	17.62	24.79	0.0	0.00	100.0	130	-2.82	31.07	-100.0	0.00	66.7
	Week 23	136	19.36	24.86	0.0	0.00	100.0	128	-1.04	30.15	-100.0	0.00	100.0
	Week 26	131	19.85	26.08	0.0	0.00	100.0	122	0.27	32.78	-100.0	0.00	100.0
	Week 29	134	19.15	23.97	0.0	0.00	100.0	123	-1.90	28.73	-100.0	0.00	66.7
	Week 32	114	17.54	26.69	0.0	0.00	100.0	106	-2.52	31.10	-100.0	0.00	100.0
	Week 35	113	18.58	23.96	0.0	0.00	100.0	105	-1.59	28.26	-100.0	0.00	66.7
	Week 38	114	19.01	24.68	0.0	0.00	100.0	107	-0.62	32.37	-100.0	0.00	100.0
	Week 41	109	20.49	26.02	0.0	0.00	100.0	100	0.33	30.52	-66.7	0.00	100.0
	Week 44	91	20.15	24.28	0.0	0.00	100.0	85	0.78	29.98	-66.7	0.00	100.0
	Week 47	82	17.48	23.56	0.0	0.00	100.0	78	-3.42	32.94	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	77	19.91	28.23	0.0	0.00	100.0	73	0.46	36.22	-100.0	0.00	100.0
	Week 53	67	16.42	24.19	0.0	0.00	66.7	63	-0.53	34.13	-66.7	0.00	66.7
	Week 56	68	18.63	26.63	0.0	0.00	100.0	64	0.00	37.56	-100.0	0.00	100.0
	Week 59	60	18.89	24.83	0.0	0.00	100.0	57	-0.59	36.46	-100.0	0.00	100.0
	Week 62	55	20.61	27.59	0.0	0.00	100.0	54	2.47	32.28	-66.7	0.00	100.0
	Week 65	48	17.36	26.62	0.0	0.00	100.0	45	-2.96	28.27	-66.7	0.00	100.0
	Week 68	46	15.22	26.02	0.0	0.00	100.0	45	-5.19	33.30	-66.7	0.00	100.0
	Week 71	44	17.42	25.41	0.0	0.00	66.7	42	-1.59	32.89	-66.7	0.00	66.7
	Week 74	40	20.00	25.93	0.0	0.00	66.7	39	0.00	36.68	-66.7	0.00	66.7
	Week 77	38	20.18	28.52	0.0	0.00	100.0	36	-1.85	37.33	-66.7	0.00	66.7
	Week 80	35	14.29	24.64	0.0	0.00	66.7	32	-9.38	37.13	-100.0	0.00	66.7
	Week 83	32	17.71	28.06	0.0	0.00	100.0	30	-6.67	36.52	-66.7	0.00	100.0
	Week 86	29	17.24	27.63	0.0	0.00	100.0	26	-3.85	30.30	-66.7	0.00	66.7
	Week 89	29	20.69	28.75	0.0	0.00	100.0	27	-2.47	40.22	-100.0	0.00	100.0
	Week 92	24	16.67	26.01	0.0	0.00	100.0	22	-9.09	34.40	-100.0	0.00	33.3
	Week 95	20	13.33	27.36	0.0	0.00	100.0	19	-8.77	21.78	-66.7	0.00	33.3
	Week 98	18	9.26	15.36	0.0	0.00	33.3	17	-15.69	26.66	-66.7	0.00	33.3
	Week 101	13	5.13	12.52	0.0	0.00	33.3	13	-15.38	32.25	-100.0	0.00	33.3
	Plat+Gem (N=194)												
	BASELINE	155	23.87	28.87	0.0	0.00	100.0						
	Week 1	142	33.10	31.13	0.0	33.33	100.0	131	11.45	26.40	-66.7	0.00	66.7
	Week 2	142	31.22	30.03	0.0	33.33	100.0	127	9.45	28.76	-100.0	0.00	100.0
	Week 3	152	22.81	27.24	0.0	0.00	100.0	135	-0.25	28.94	-100.0	0.00	100.0
	Week 4	151	27.81	28.14	0.0	33.33	100.0	132	4.80	31.40	-100.0	0.00	100.0
	Week 5	151	25.39	27.14	0.0	33.33	100.0	128	3.65	29.65	-100.0	0.00	100.0
	Week 6	139	24.46	27.68	0.0	33.33	100.0	122	4.10	28.93	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 7	148	23.87	25.21	0.0	33.33	100.0	128	3.65	29.65	-66.7	0.00	100.0
	Week 8	136	26.22	27.34	0.0	33.33	100.0	119	7.28	31.64	-66.7	0.00	100.0
	Week 9	145	18.39	25.74	0.0	0.00	100.0	125	0.27	29.78	-100.0	0.00	100.0
	Week 10	132	26.01	28.63	0.0	33.33	100.0	113	6.19	31.67	-66.7	0.00	100.0
	Week 11	138	24.88	27.33	0.0	33.33	100.0	119	5.32	30.37	-66.7	0.00	100.0
	Week 12	131	22.90	26.18	0.0	33.33	100.0	115	2.90	30.13	-66.7	0.00	100.0
	Week 14	127	27.82	28.10	0.0	33.33	100.0	107	7.48	31.82	-100.0	0.00	100.0
	Week 17	125	28.00	26.91	0.0	33.33	100.0	105	10.48	32.13	-100.0	0.00	100.0
	Week 20	103	18.77	24.99	0.0	0.00	100.0	89	1.12	29.49	-66.7	0.00	100.0
	Week 23	93	16.85	24.88	0.0	0.00	100.0	78	0.00	30.86	-100.0	0.00	100.0
	Week 26	89	16.10	25.68	0.0	0.00	100.0	77	-1.73	33.72	-66.7	0.00	100.0
	Week 29	84	13.09	25.36	0.0	0.00	100.0	72	-3.70	31.92	-66.7	0.00	100.0
	Week 32	72	17.59	29.06	0.0	0.00	100.0	65	-0.51	32.00	-66.7	0.00	100.0
	Week 35	66	18.18	27.54	0.0	0.00	100.0	60	0.00	32.48	-66.7	0.00	100.0
	Week 38	66	16.16	26.31	0.0	0.00	100.0	57	-2.92	28.37	-66.7	0.00	100.0
	Week 41	62	19.89	29.23	0.0	0.00	100.0	53	3.14	30.14	-33.3	0.00	100.0
	Week 44	55	17.58	26.34	0.0	0.00	100.0	48	-0.69	29.57	-66.7	0.00	100.0
	Week 47	51	16.34	26.14	0.0	0.00	100.0	44	-3.03	33.58	-66.7	0.00	100.0
	Week 50	48	16.67	28.35	0.0	0.00	100.0	44	-6.06	29.88	-66.7	0.00	100.0
	Week 53	41	10.57	20.33	0.0	0.00	100.0	37	-6.31	28.15	-66.7	0.00	100.0
	Week 56	34	11.76	18.13	0.0	0.00	66.7	29	-8.05	22.98	-66.7	0.00	33.3
	Week 59	32	10.42	17.83	0.0	0.00	66.7	28	-5.95	20.39	-33.3	0.00	33.3
	Week 62	27	8.64	14.88	0.0	0.00	33.3	24	-8.33	17.72	-33.3	0.00	33.3
	Week 65	25	4.00	11.05	0.0	0.00	33.3	21	-12.70	16.59	-33.3	0.00	0.0
	Week 68	23	7.25	17.28	0.0	0.00	66.7	19	-8.77	15.08	-33.3	0.00	0.0
	Week 71	21	6.35	17.06	0.0	0.00	66.7	18	-11.11	16.17	-33.3	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 74	20	13.33	22.69	0.0	0.00	66.7	17	-7.84	18.74	-33.3	0.00	33.3
	Week 77	16	8.33	19.25	0.0	0.00	66.7	13	-10.26	16.01	-33.3	0.00	0.0
	Week 80	12	8.33	20.72	0.0	0.00	66.7	11	-9.09	21.55	-33.3	0.00	33.3
	Week 83	11	9.09	21.56	0.0	0.00	66.7	10	-10.00	16.10	-33.3	0.00	0.0
	Week 86	10	6.67	14.05	0.0	0.00	33.3	9	-14.81	17.57	-33.3	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
< 65 years	EV+Pembro (N=105)												
	BASELINE	92	19.56	27.14	0.0	0.00	100.0						
	Week 1	88	20.83	28.73	0.0	0.00	100.0	85	3.53	26.74	-66.7	0.00	100.0
	Week 2	92	19.93	27.09	0.0	0.00	100.0	86	0.00	28.47	-66.7	0.00	100.0
	Week 3	93	17.92	24.36	0.0	0.00	100.0	84	0.40	30.39	-66.7	0.00	100.0
	Week 4	90	17.41	21.33	0.0	0.00	100.0	82	-1.63	30.04	-100.0	0.00	100.0
	Week 5	90	14.07	19.97	0.0	0.00	100.0	81	-4.12	27.07	-66.7	0.00	100.0
	Week 6	90	14.44	19.38	0.0	0.00	100.0	81	-5.35	30.49	-100.0	0.00	100.0
	Week 7	85	13.33	20.05	0.0	0.00	66.7	77	-8.23	33.40	-100.0	0.00	66.7
	Week 8	89	14.98	24.11	0.0	0.00	100.0	80	-5.00	33.59	-100.0	0.00	100.0
	Week 9	93	13.62	20.40	0.0	0.00	66.7	85	-6.27	31.91	-100.0	0.00	66.7
	Week 10	88	13.26	19.92	0.0	0.00	66.7	81	-7.41	29.81	-100.0	0.00	66.7
	Week 11	93	14.69	19.94	0.0	0.00	66.7	84	-6.35	30.38	-100.0	0.00	66.7
	Week 12	86	13.57	20.05	0.0	0.00	66.7	79	-7.60	33.31	-100.0	0.00	66.7
	Week 14	84	14.68	18.91	0.0	0.00	66.7	76	-5.70	27.96	-100.0	0.00	33.3
	Week 17	83	14.86	20.33	0.0	0.00	66.7	77	-5.20	32.92	-100.0	0.00	66.7
	Week 20	79	16.46	25.53	0.0	0.00	100.0	73	-5.02	34.55	-100.0	0.00	66.7
	Week 23	78	18.38	24.99	0.0	0.00	100.0	73	-5.02	34.55	-100.0	0.00	100.0
	Week 26	78	16.24	26.72	0.0	0.00	100.0	72	-5.09	32.94	-100.0	0.00	100.0
	Week 29	74	14.41	23.46	0.0	0.00	100.0	67	-6.47	26.74	-66.7	0.00	66.7
	Week 32	64	15.62	27.20	0.0	0.00	100.0	59	-3.95	31.00	-66.7	0.00	100.0
	Week 35	62	15.05	26.08	0.0	0.00	100.0	58	-4.02	27.27	-66.7	0.00	66.7
	Week 38	62	14.52	22.28	0.0	0.00	66.7	59	-5.65	27.09	-66.7	0.00	66.7
	Week 41	64	15.10	25.84	0.0	0.00	100.0	59	-5.08	30.21	-66.7	0.00	100.0
	Week 44	50	12.67	22.22	0.0	0.00	66.7	48	-6.94	27.47	-66.7	0.00	66.7
	Week 47	47	15.60	25.87	0.0	0.00	100.0	46	-5.07	32.94	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	44	18.94	29.11	0.0	0.00	100.0	41	0.00	36.52	-66.7	0.00	100.0
	Week 53	40	12.50	22.25	0.0	0.00	66.7	37	-4.50	32.55	-66.7	0.00	66.7
	Week 56	44	16.67	25.42	0.0	0.00	100.0	41	-1.63	37.23	-66.7	0.00	100.0
	Week 59	42	15.08	22.33	0.0	0.00	66.7	39	-3.42	32.26	-66.7	0.00	66.7
	Week 62	37	17.12	25.61	0.0	0.00	66.7	36	-1.85	30.80	-66.7	0.00	66.7
	Week 65	34	10.78	19.63	0.0	0.00	66.7	31	-9.68	26.10	-66.7	0.00	33.3
	Week 68	34	10.78	21.27	0.0	0.00	66.7	33	-10.10	32.79	-66.7	0.00	66.7
	Week 71	32	13.54	25.20	0.0	0.00	66.7	30	-5.56	36.18	-66.7	0.00	66.7
	Week 74	29	18.39	26.11	0.0	0.00	66.7	28	-4.76	39.25	-66.7	0.00	66.7
	Week 77	25	17.33	25.68	0.0	0.00	66.7	24	-6.94	40.50	-66.7	0.00	66.7
	Week 80	24	13.89	25.85	0.0	0.00	66.7	22	-9.09	37.35	-66.7	0.00	66.7
	Week 83	23	15.94	29.93	0.0	0.00	100.0	22	-10.61	39.02	-66.7	0.00	100.0
	Week 86	20	16.67	27.57	0.0	0.00	100.0	18	-5.56	34.77	-66.7	0.00	66.7
	Week 89	19	19.30	32.04	0.0	0.00	100.0	17	-1.96	39.91	-66.7	0.00	100.0
	Week 92	14	16.67	28.49	0.0	0.00	100.0	12	-5.56	31.25	-66.7	0.00	33.3
	Week 95	12	13.89	30.01	0.0	0.00	100.0	11	-12.12	22.47	-66.7	0.00	0.0
	Plat+Gem (N=106)												
	BASELINE	83	22.89	28.48	0.0	0.00	100.0						
	Week 1	75	35.11	30.95	0.0	33.33	100.0	71	13.15	26.71	-66.7	0.00	100.0
	Week 2	76	35.09	29.26	0.0	33.33	100.0	68	11.27	31.34	-100.0	0.00	100.0
	Week 3	80	22.08	24.84	0.0	33.33	100.0	73	-1.37	28.02	-66.7	0.00	66.7
	Week 4	79	26.16	28.08	0.0	33.33	100.0	67	2.98	29.43	-100.0	0.00	100.0
	Week 5	80	27.92	28.29	0.0	33.33	100.0	67	6.96	34.10	-100.0	0.00	100.0
	Week 6	76	22.81	28.39	0.0	0.00	100.0	67	0.00	29.01	-66.7	0.00	66.7
	Week 7	81	22.63	25.73	0.0	33.33	100.0	71	0.94	29.26	-66.7	0.00	66.7
	Week 8	72	23.15	24.79	0.0	33.33	100.0	64	3.12	32.38	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	78	17.95	24.44	0.0	0.00	100.0	69	-1.45	25.84	-66.7	0.00	66.7
	Week 10	78	24.79	28.14	0.0	33.33	100.0	68	0.00	29.93	-66.7	0.00	66.7
	Week 11	75	21.33	24.90	0.0	0.00	100.0	66	0.00	28.04	-66.7	0.00	66.7
	Week 12	74	19.37	22.07	0.0	0.00	66.7	66	-1.01	26.78	-66.7	0.00	66.7
	Week 14	68	27.45	28.76	0.0	33.33	100.0	58	4.02	33.67	-100.0	0.00	100.0
	Week 17	68	25.49	26.47	0.0	33.33	100.0	58	3.45	32.26	-100.0	0.00	66.7
	Week 20	60	15.55	22.52	0.0	0.00	100.0	52	-3.21	28.21	-66.7	0.00	100.0
	Week 23	51	11.76	18.65	0.0	0.00	66.7	44	-6.06	27.16	-66.7	0.00	33.3
	Week 26	47	13.47	21.60	0.0	0.00	100.0	42	-7.14	32.54	-66.7	0.00	100.0
	Week 29	42	5.56	12.57	0.0	0.00	33.3	37	-12.61	24.03	-66.7	0.00	33.3
	Week 32	37	14.41	21.57	0.0	0.00	66.7	34	-3.92	21.34	-33.3	0.00	33.3
	Week 35	34	16.67	24.96	0.0	0.00	66.7	31	-1.08	26.51	-33.3	0.00	66.7
	Week 38	33	13.13	20.31	0.0	0.00	66.7	28	-5.95	18.26	-33.3	0.00	33.3
	Week 41	27	14.81	21.35	0.0	0.00	66.7	22	-4.55	21.32	-33.3	0.00	33.3
	Week 44	28	13.09	18.90	0.0	0.00	66.7	24	-8.33	24.57	-66.7	0.00	33.3
	Week 47	24	12.50	19.19	0.0	0.00	66.7	21	-9.52	26.13	-66.7	0.00	33.3
	Week 50	26	10.26	18.30	0.0	0.00	66.7	24	-15.28	25.97	-66.7	0.00	33.3
	Week 53	19	7.02	13.96	0.0	0.00	33.3	17	-15.69	20.81	-66.7	0.00	0.0
	Week 56	13	12.82	16.88	0.0	0.00	33.3	11	-12.12	22.47	-33.3	0.00	33.3
	Week 59	14	11.90	21.11	0.0	0.00	66.7	12	-5.56	12.97	-33.3	0.00	0.0
	Week 62	13	12.82	16.88	0.0	0.00	33.3	12	-11.11	16.41	-33.3	0.00	0.0
	Week 65	13	5.13	12.52	0.0	0.00	33.3	11	-12.12	16.82	-33.3	0.00	0.0
	Week 68	10	13.33	23.31	0.0	0.00	66.7	8	-12.50	17.25	-33.3	0.00	0.0
	Week 77	10	13.33	23.31	0.0	0.00	66.7	8	-16.67	25.20	-66.7	0.00	0.0

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Table 302.1.3002.21.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>= 65 years	EV+Pembro (N=135)												
	BASELINE	114	18.71	26.99	0.0	0.00	100.0						
	Week 1	102	24.18	31.87	0.0	0.00	100.0	99	4.38	27.21	-66.7	0.00	100.0
	Week 2	111	16.52	24.57	0.0	0.00	100.0	103	-2.59	27.49	-100.0	0.00	100.0
	Week 3	105	16.82	27.78	0.0	0.00	100.0	98	-2.72	30.15	-100.0	0.00	100.0
	Week 4	104	20.19	26.45	0.0	0.00	100.0	97	-0.69	29.65	-100.0	0.00	100.0
	Week 5	100	20.00	25.95	0.0	0.00	100.0	92	-0.73	32.02	-100.0	0.00	100.0
	Week 6	98	19.39	25.29	0.0	0.00	100.0	89	-1.50	30.11	-66.7	0.00	100.0
	Week 7	110	23.33	28.03	0.0	16.67	100.0	99	2.69	36.16	-100.0	0.00	100.0
	Week 8	102	18.30	24.20	0.0	0.00	100.0	91	-2.20	34.71	-100.0	0.00	100.0
	Week 9	104	17.31	24.13	0.0	0.00	100.0	95	-2.81	32.49	-100.0	0.00	100.0
	Week 10	103	18.12	25.47	0.0	0.00	100.0	94	-1.77	33.29	-100.0	0.00	100.0
	Week 11	101	18.48	24.26	0.0	0.00	100.0	91	-2.56	31.12	-100.0	0.00	66.7
	Week 12	100	18.67	24.31	0.0	0.00	100.0	92	-3.26	35.31	-100.0	0.00	100.0
	Week 14	101	21.45	26.49	0.0	0.00	100.0	91	0.00	35.49	-100.0	0.00	100.0
	Week 17	95	19.30	24.11	0.0	0.00	100.0	85	0.78	29.98	-100.0	0.00	66.7
	Week 20	88	18.94	23.59	0.0	0.00	100.0	81	-0.82	28.86	-100.0	0.00	66.7
	Week 23	84	20.63	23.66	0.0	16.67	100.0	78	2.99	27.49	-100.0	0.00	66.7
	Week 26	78	19.66	23.07	0.0	0.00	100.0	72	0.00	33.10	-100.0	0.00	66.7
	Week 29	83	20.48	23.18	0.0	33.33	100.0	78	-0.43	29.67	-100.0	0.00	66.7
	Week 32	71	18.31	24.42	0.0	0.00	100.0	66	-3.54	30.45	-100.0	0.00	66.7
	Week 35	70	19.52	21.60	0.0	16.67	66.7	64	-2.08	29.02	-100.0	0.00	33.3
	Week 38	70	21.43	27.24	0.0	0.00	100.0	65	0.51	35.10	-100.0	0.00	100.0
	Week 41	65	22.56	25.08	0.0	33.33	66.7	60	3.33	28.59	-66.7	0.00	66.7
	Week 44	58	23.56	24.19	0.0	33.33	100.0	52	3.85	30.00	-66.7	0.00	100.0
	Week 47	53	16.98	22.29	0.0	0.00	100.0	48	-3.47	30.93	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	45	19.26	27.05	0.0	0.00	100.0	43	0.00	35.64	-100.0	0.00	100.0
	Week 53	39	19.66	25.04	0.0	0.00	66.7	37	2.70	33.68	-66.7	0.00	66.7
	Week 56	37	18.92	26.69	0.0	0.00	100.0	35	-0.95	36.59	-100.0	0.00	100.0
	Week 59	30	18.89	25.79	0.0	0.00	100.0	29	-2.30	38.76	-100.0	0.00	100.0
	Week 62	28	17.86	27.94	0.0	0.00	100.0	27	1.23	33.95	-66.7	0.00	100.0
	Week 65	24	22.22	30.56	0.0	0.00	100.0	23	1.45	29.26	-33.3	0.00	100.0
	Week 68	19	19.30	30.05	0.0	0.00	100.0	19	1.75	32.34	-66.7	0.00	100.0
	Week 71	19	19.30	23.08	0.0	0.00	66.7	19	0.00	24.85	-66.7	0.00	33.3
	Week 74	18	18.52	26.13	0.0	0.00	66.7	18	3.70	30.01	-66.7	0.00	66.7
	Week 77	19	17.54	30.16	0.0	0.00	100.0	18	-1.85	31.25	-66.7	0.00	66.7
	Week 80	16	12.50	20.64	0.0	0.00	66.7	15	-8.89	32.04	-100.0	0.00	33.3
	Week 83	14	16.67	21.68	0.0	0.00	66.7	13	0.00	23.57	-33.3	0.00	33.3
	Week 86	14	11.91	24.83	0.0	0.00	66.7	13	-2.56	16.45	-33.3	0.00	33.3
	Week 89	14	16.67	21.68	0.0	0.00	66.7	14	-4.76	36.65	-100.0	0.00	33.3
	Week 92	13	12.82	21.68	0.0	0.00	66.7	13	-10.26	34.39	-100.0	0.00	33.3
	Week 95	10	13.33	23.31	0.0	0.00	66.7	10	-3.33	18.92	-33.3	0.00	33.3
	Week 98	10	10.00	16.10	0.0	0.00	33.3	10	-13.33	23.31	-66.7	0.00	0.0
	Plat+Gem (N=136)												
	BASELINE	105	25.40	29.43	0.0	33.33	100.0						
	Week 1	98	34.69	33.82	0.0	33.33	100.0	87	12.26	28.36	-33.3	0.00	66.7
	Week 2	95	28.07	31.63	0.0	33.33	100.0	83	6.43	31.00	-66.7	0.00	100.0
	Week 3	104	22.12	28.11	0.0	0.00	100.0	89	-1.12	29.92	-100.0	0.00	100.0
	Week 4	104	27.24	28.16	0.0	33.33	100.0	89	5.24	32.53	-66.7	0.00	100.0
	Week 5	107	26.79	29.12	0.0	33.33	100.0	89	5.62	29.83	-66.7	0.00	100.0
	Week 6	98	26.87	26.50	0.0	33.33	100.0	82	7.72	29.30	-66.7	0.00	100.0
	Week 7	105	26.67	26.72	0.0	33.33	100.0	86	6.59	31.44	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 8	95	29.12	28.45	0.0	33.33	100.0	80	10.00	31.56	-66.7	0.00	100.0
	Week 9	99	18.52	26.18	0.0	0.00	100.0	81	0.00	32.06	-100.0	0.00	100.0
	Week 10	88	25.00	27.80	0.0	33.33	100.0	71	7.98	32.59	-66.7	0.00	100.0
	Week 11	93	26.16	29.01	0.0	33.33	100.0	77	6.06	31.87	-66.7	0.00	100.0
	Week 12	85	27.06	29.32	0.0	33.33	100.0	72	5.56	34.49	-66.7	0.00	100.0
	Week 14	85	27.84	28.10	0.0	33.33	100.0	70	8.57	35.30	-66.7	0.00	100.0
	Week 17	87	27.97	26.84	0.0	33.33	100.0	72	10.65	30.55	-33.3	0.00	100.0
	Week 20	66	21.72	25.14	0.0	33.33	100.0	58	2.87	29.48	-66.7	0.00	100.0
	Week 23	64	21.35	29.91	0.0	0.00	100.0	53	1.89	34.23	-100.0	0.00	100.0
	Week 26	61	15.85	26.25	0.0	0.00	100.0	53	-1.89	35.46	-66.7	0.00	100.0
	Week 29	58	18.96	29.36	0.0	0.00	100.0	49	0.68	35.67	-66.7	0.00	100.0
	Week 32	46	21.74	32.37	0.0	0.00	100.0	42	3.17	37.40	-66.7	0.00	100.0
	Week 35	42	18.25	27.74	0.0	0.00	100.0	38	2.63	34.99	-66.7	0.00	100.0
	Week 38	41	17.89	28.96	0.0	0.00	100.0	37	2.70	32.75	-66.7	0.00	100.0
	Week 41	38	23.68	32.80	0.0	0.00	100.0	34	7.84	33.89	-33.3	0.00	100.0
	Week 44	32	20.83	30.23	0.0	0.00	100.0	29	8.05	30.41	-33.3	0.00	100.0
	Week 47	32	20.83	30.23	0.0	0.00	100.0	28	7.14	37.80	-66.7	0.00	100.0
	Week 50	25	21.33	34.53	0.0	0.00	100.0	23	1.45	32.53	-33.3	0.00	100.0
	Week 53	27	12.34	22.92	0.0	0.00	100.0	25	1.33	28.02	-33.3	0.00	100.0
	Week 56	26	12.82	19.04	0.0	0.00	66.7	23	-4.35	23.15	-66.7	0.00	33.3
	Week 59	23	8.69	14.96	0.0	0.00	33.3	21	-4.76	21.82	-33.3	0.00	33.3
	Week 62	19	3.51	10.51	0.0	0.00	33.3	17	-5.88	17.62	-33.3	0.00	33.3
	Week 65	17	1.96	8.08	0.0	0.00	33.3	15	-11.11	16.26	-33.3	0.00	0.0
	Week 68	15	2.22	8.61	0.0	0.00	33.3	13	-7.69	14.62	-33.3	0.00	0.0
	Week 71	15	2.22	8.61	0.0	0.00	33.3	13	-12.82	16.88	-33.3	0.00	0.0
	Week 74	12	5.56	12.97	0.0	0.00	33.3	11	-6.06	20.10	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Europe	EV+Pembro (N= 98)												
	BASELINE	79	14.77	23.72	0.0	0.00	66.7						
	Week 1	74	18.02	27.69	0.0	0.00	100.0	71	3.29	25.30	-66.7	0.00	100.0
	Week 2	79	15.19	22.52	0.0	0.00	66.7	71	0.00	24.56	-66.7	0.00	66.7
	Week 3	78	12.82	23.56	0.0	0.00	100.0	69	-0.97	30.23	-66.7	0.00	66.7
	Week 4	78	12.82	18.79	0.0	0.00	66.7	70	-1.43	23.01	-66.7	0.00	33.3
	Week 5	70	12.38	20.60	0.0	0.00	100.0	62	-3.76	27.73	-66.7	0.00	100.0
	Week 6	70	13.33	20.77	0.0	0.00	100.0	61	-3.28	28.35	-66.7	0.00	100.0
	Week 7	78	17.52	25.61	0.0	0.00	100.0	68	2.94	33.45	-66.7	0.00	100.0
	Week 8	72	13.43	24.17	0.0	0.00	100.0	61	-1.64	31.87	-66.7	0.00	100.0
	Week 9	80	12.08	18.56	0.0	0.00	66.7	70	-1.91	23.32	-66.7	0.00	66.7
	Week 10	71	10.33	18.34	0.0	0.00	66.7	62	-5.38	27.12	-66.7	0.00	66.7
	Week 11	76	12.72	19.60	0.0	0.00	66.7	66	-4.04	25.83	-66.7	0.00	66.7
	Week 12	73	11.42	21.67	0.0	0.00	100.0	65	-5.13	32.93	-66.7	0.00	100.0
	Week 14	74	11.26	15.87	0.0	0.00	33.3	64	-4.17	25.55	-66.7	0.00	33.3
	Week 17	70	13.81	19.24	0.0	0.00	66.7	62	-1.08	27.64	-66.7	0.00	33.3
	Week 20	70	10.48	18.43	0.0	0.00	66.7	63	-5.82	27.79	-66.7	0.00	66.7
	Week 23	61	14.21	21.48	0.0	0.00	66.7	57	-1.17	28.15	-66.7	0.00	66.7
	Week 26	62	12.90	20.34	0.0	0.00	66.7	55	-2.43	27.86	-66.7	0.00	66.7
	Week 29	63	13.76	19.52	0.0	0.00	66.7	57	-2.34	26.62	-66.7	0.00	66.7
	Week 32	51	14.38	26.88	0.0	0.00	100.0	47	-2.84	28.51	-66.7	0.00	100.0
	Week 35	56	13.09	20.77	0.0	0.00	66.7	52	-3.85	28.51	-66.7	0.00	66.7
	Week 38	51	16.34	23.45	0.0	0.00	100.0	48	0.00	30.75	-66.7	0.00	66.7
	Week 41	52	13.46	22.15	0.0	0.00	66.7	48	-4.86	27.50	-66.7	0.00	66.7
	Week 44	43	13.95	23.27	0.0	0.00	66.7	39	-5.13	28.14	-66.7	0.00	66.7
	Week 47	39	12.82	23.71	0.0	0.00	100.0	36	-6.48	32.68	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	37	16.22	26.78	0.0	0.00	100.0	36	-2.78	35.97	-66.7	0.00	66.7
	Week 53	28	10.71	22.32	0.0	0.00	66.7	27	-7.41	33.76	-66.7	0.00	66.7
	Week 56	30	13.33	22.49	0.0	0.00	66.7	29	-5.75	34.58	-66.7	0.00	66.7
	Week 59	27	12.35	20.98	0.0	0.00	66.7	27	-6.17	33.38	-66.7	0.00	66.7
	Week 62	23	20.29	27.96	0.0	0.00	66.7	23	0.00	34.82	-66.7	0.00	66.7
	Week 65	23	10.14	18.63	0.0	0.00	66.7	23	-10.15	25.49	-66.7	0.00	33.3
	Week 68	21	7.94	17.97	0.0	0.00	66.7	21	-15.87	30.95	-66.7	0.00	33.3
	Week 71	19	8.77	21.78	0.0	0.00	66.7	19	-14.04	32.04	-66.7	0.00	66.7
	Week 74	15	8.89	19.79	0.0	0.00	66.7	15	-17.78	41.53	-66.7	0.00	66.7
	Week 77	19	12.28	27.69	0.0	0.00	100.0	19	-12.28	37.20	-66.7	0.00	66.7
	Week 80	17	7.84	14.57	0.0	0.00	33.3	17	-15.69	31.44	-66.7	0.00	33.3
	Week 83	16	6.25	13.44	0.0	0.00	33.3	16	-18.75	29.74	-66.7	0.00	33.3
	Week 86	14	9.52	20.38	0.0	0.00	66.7	14	-7.14	26.73	-66.7	0.00	33.3
	Week 89	14	9.52	15.63	0.0	0.00	33.3	14	-7.14	26.73	-66.7	0.00	33.3
	Week 92	11	6.06	13.48	0.0	0.00	33.3	11	-15.15	27.34	-66.7	0.00	33.3
	Week 95	10	6.67	14.05	0.0	0.00	33.3	10	-13.33	23.31	-66.7	0.00	0.0
	Plat+Gem (N=102)												
	BASELINE	71	22.53	28.61	0.0	0.00	100.0						
	Week 1	71	38.97	33.80	0.0	33.33	100.0	61	17.49	25.54	-33.3	0.00	66.7
	Week 2	67	31.84	30.94	0.0	33.33	100.0	56	10.12	28.37	-66.7	0.00	100.0
	Week 3	68	23.04	27.17	0.0	0.00	100.0	56	0.00	29.82	-100.0	0.00	66.7
	Week 4	75	28.00	30.04	0.0	33.33	100.0	59	6.21	32.45	-66.7	0.00	66.7
	Week 5	77	28.57	30.93	0.0	33.33	100.0	60	11.11	27.90	-66.7	0.00	100.0
	Week 6	70	30.48	30.95	0.0	33.33	100.0	56	13.69	27.54	-66.7	0.00	100.0
	Week 7	72	26.39	27.37	0.0	33.33	100.0	55	11.51	30.24	-66.7	0.00	66.7
	Week 8	65	29.74	31.80	0.0	33.33	100.0	53	15.72	30.39	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	70	19.52	27.51	0.0	0.00	100.0	55	6.06	29.46	-100.0	0.00	100.0
	Week 10	60	28.33	29.32	0.0	33.33	100.0	46	15.22	26.95	-66.7	0.00	66.7
	Week 11	64	27.08	30.79	0.0	33.33	100.0	50	12.00	25.87	-66.7	0.00	66.7
	Week 12	60	28.89	29.09	0.0	33.33	100.0	48	15.28	27.47	-33.3	0.00	66.7
	Week 14	56	32.74	32.09	0.0	33.33	100.0	42	16.67	33.13	-66.7	0.00	100.0
	Week 17	58	30.46	27.42	0.0	33.33	100.0	44	15.91	31.74	-66.7	0.00	100.0
	Week 20	47	25.53	26.20	0.0	33.33	100.0	37	10.81	23.64	-33.3	0.00	66.7
	Week 23	44	21.97	32.10	0.0	0.00	100.0	32	9.37	28.38	-66.7	0.00	100.0
	Week 26	39	15.38	29.47	0.0	0.00	100.0	30	2.22	38.09	-66.7	0.00	100.0
	Week 29	34	16.67	24.96	0.0	0.00	100.0	25	0.00	28.87	-66.7	0.00	66.7
	Week 32	33	18.18	27.75	0.0	0.00	100.0	27	3.70	32.47	-66.7	0.00	100.0
	Week 35	30	24.44	28.95	0.0	16.67	100.0	24	9.72	36.09	-33.3	0.00	100.0
	Week 38	26	20.51	25.08	0.0	16.67	100.0	21	4.76	32.12	-33.3	0.00	100.0
	Week 41	22	25.76	30.74	0.0	33.33	100.0	17	13.72	33.46	-33.3	0.00	100.0
	Week 44	20	21.67	27.09	0.0	0.00	66.7	16	12.50	29.50	-33.3	0.00	66.7
	Week 47	16	29.17	29.50	0.0	33.33	100.0	12	16.67	33.33	-33.3	0.00	100.0
	Week 50	11	30.30	37.87	0.0	33.33	100.0	10	13.33	42.17	-33.3	0.00	100.0
	Week 53	11	12.12	16.82	0.0	0.00	33.3	10	-6.67	21.08	-33.3	0.00	33.3
	Week 56	10	13.33	17.21	0.0	0.00	33.3	8	-4.17	27.82	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
North America	EV+Pembro (N= 57)												
	BASELINE	47	23.40	33.27	0.0	0.00	100.0						
	Week 1	39	33.33	35.04	0.0	33.33	100.0	37	12.61	30.78	-33.3	0.00	100.0
	Week 2	44	23.48	31.81	0.0	0.00	100.0	42	-0.79	27.04	-66.7	0.00	100.0
	Week 3	44	25.00	30.61	0.0	33.33	100.0	40	4.17	27.41	-66.7	0.00	100.0
	Week 4	44	25.76	28.63	0.0	33.33	100.0	41	2.44	36.05	-100.0	0.00	100.0
	Week 5	47	21.98	25.33	0.0	33.33	100.0	41	3.25	31.45	-66.7	0.00	66.7
	Week 6	44	17.42	23.28	0.0	0.00	100.0	39	-5.98	30.47	-100.0	0.00	33.3
	Week 7	46	17.39	24.08	0.0	0.00	100.0	42	-7.94	35.16	-100.0	0.00	33.3
	Week 8	47	14.18	21.70	0.0	0.00	66.7	42	-8.73	32.14	-100.0	0.00	33.3
	Week 9	46	18.12	25.05	0.0	0.00	100.0	42	-6.35	36.99	-100.0	0.00	66.7
	Week 10	47	14.89	21.77	0.0	0.00	66.7	44	-6.82	30.14	-100.0	0.00	33.3
	Week 11	47	17.73	20.68	0.0	0.00	66.7	42	-3.18	34.38	-100.0	0.00	66.7
	Week 12	44	17.42	23.28	0.0	0.00	100.0	40	-8.33	39.04	-100.0	0.00	66.7
	Week 14	43	24.03	27.53	0.0	33.33	100.0	39	0.00	40.47	-100.0	0.00	100.0
	Week 17	40	16.67	23.87	0.0	0.00	100.0	37	-7.21	36.96	-100.0	0.00	33.3
	Week 20	38	21.93	28.24	0.0	0.00	100.0	35	-2.86	36.49	-100.0	0.00	66.7
	Week 23	38	21.93	30.29	0.0	0.00	100.0	35	-0.95	40.00	-100.0	0.00	100.0
	Week 26	35	20.00	29.37	0.0	0.00	100.0	32	-3.13	40.92	-100.0	0.00	100.0
	Week 29	38	18.42	28.68	0.0	0.00	100.0	34	-6.86	30.46	-100.0	0.00	66.7
	Week 32	32	15.62	23.92	0.0	0.00	100.0	29	-8.05	32.92	-100.0	0.00	33.3
	Week 35	33	17.17	27.79	0.0	0.00	100.0	30	-6.67	30.82	-100.0	0.00	33.3
	Week 38	32	11.46	18.18	0.0	0.00	66.7	29	-10.35	33.46	-100.0	0.00	33.3
	Week 41	28	13.09	24.58	0.0	0.00	100.0	24	-4.17	33.06	-66.7	0.00	100.0
	Week 44	21	19.05	24.88	0.0	0.00	100.0	20	6.67	33.51	-33.3	0.00	100.0
	Week 47	24	9.72	15.48	0.0	0.00	33.3	23	-8.70	32.12	-100.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	23	14.49	29.86	0.0	0.00	100.0	20	-5.00	39.40	-100.0	0.00	100.0
	Week 53	17	11.76	20.21	0.0	0.00	66.7	14	-2.38	27.62	-66.7	0.00	33.3
	Week 56	20	11.67	19.57	0.0	0.00	66.7	17	-3.92	37.05	-100.0	0.00	66.7
	Week 59	17	7.84	14.57	0.0	0.00	33.3	14	-11.91	33.61	-100.0	0.00	33.3
	Week 62	14	14.29	21.54	0.0	0.00	66.7	13	2.56	28.74	-33.3	0.00	66.7
	Week 65	12	11.11	21.71	0.0	0.00	66.7	9	-7.41	22.22	-33.3	0.00	33.3
	Week 68	10	0.00	0.00	0.0	0.00	0.0	9	-3.70	11.11	-33.3	0.00	0.0
	Week 71	10	6.67	14.05	0.0	0.00	33.3	8	8.33	15.43	0.0	0.00	33.3
	Week 74	10	10.00	16.10	0.0	0.00	33.3	9	0.00	16.67	-33.3	0.00	33.3
	Plat+Gem (N= 51)												
	BASELINE	42	29.36	31.41	0.0	33.33	100.0						
	Week 1	41	34.15	32.90	0.0	33.33	100.0	36	6.48	27.39	-66.7	0.00	66.7
	Week 2	38	30.70	33.23	0.0	33.33	100.0	33	1.01	26.98	-100.0	0.00	33.3
	Week 3	40	17.50	25.02	0.0	0.00	100.0	35	-10.48	30.00	-66.7	0.00	66.7
	Week 4	35	20.00	20.13	0.0	33.33	66.7	29	-6.90	30.05	-100.0	0.00	33.3
	Week 5	39	27.35	28.48	0.0	33.33	66.7	32	-3.12	37.25	-100.0	0.00	66.7
	Week 6	34	21.57	23.04	0.0	33.33	66.7	30	-8.89	27.59	-66.7	0.00	33.3
	Week 7	42	19.05	24.58	0.0	0.00	100.0	37	-9.91	28.18	-66.7	0.00	33.3
	Week 8	39	18.80	23.93	0.0	0.00	100.0	33	-7.07	32.01	-66.7	0.00	66.7
	Week 9	39	12.82	21.10	0.0	0.00	66.7	33	-16.16	22.24	-66.7	0.00	33.3
	Week 10	39	24.79	28.32	0.0	33.33	100.0	32	-8.33	30.53	-66.7	0.00	66.7
	Week 11	39	17.09	21.46	0.0	0.00	66.7	33	-12.12	30.98	-66.7	0.00	66.7
	Week 12	36	15.74	21.80	0.0	0.00	66.7	32	-14.58	30.45	-66.7	0.00	33.3
	Week 14	34	20.59	23.23	0.0	16.67	66.7	29	-6.90	33.78	-100.0	0.00	66.7
	Week 17	37	23.42	24.68	0.0	33.33	66.7	31	-5.38	32.31	-100.0	0.00	66.7
	Week 20	27	9.88	18.06	0.0	0.00	66.7	23	-17.39	26.34	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 23	27	7.41	16.88	0.0	0.00	66.7	23	-21.74	31.16	-66.7	-33.33	33.3
	Week 26	28	8.33	17.27	0.0	0.00	66.7	25	-21.33	33.17	-66.7	0.00	33.3
	Week 29	29	8.05	21.18	0.0	0.00	100.0	25	-16.00	29.06	-66.7	0.00	33.3
	Week 32	17	15.69	29.15	0.0	0.00	100.0	17	-9.80	19.60	-33.3	0.00	33.3
	Week 35	16	10.42	23.47	0.0	0.00	66.7	15	-6.67	18.69	-33.3	0.00	33.3
	Week 38	16	12.50	26.87	0.0	0.00	100.0	13	-5.13	12.52	-33.3	0.00	0.0
	Week 41	16	18.75	29.74	0.0	0.00	100.0	13	2.56	21.35	-33.3	0.00	33.3
	Week 44	13	15.38	29.23	0.0	0.00	100.0	11	-12.12	22.47	-66.7	0.00	0.0
	Week 47	11	6.06	13.48	0.0	0.00	33.3	9	-11.11	23.57	-66.7	0.00	0.0
	Week 50	17	13.73	29.01	0.0	0.00	100.0	15	-13.33	27.60	-66.7	0.00	33.3
	Week 53	13	7.69	14.62	0.0	0.00	33.3	11	-3.03	17.98	-33.3	0.00	33.3
	Week 56	11	15.15	17.41	0.0	0.00	33.3	9	-3.70	20.03	-33.3	0.00	33.3
	Week 59	11	3.03	10.05	0.0	0.00	33.3	9	-7.41	14.70	-33.3	0.00	0.0
	Week 62	11	3.03	10.05	0.0	0.00	33.3	9	-11.11	16.67	-33.3	0.00	0.0
	Week 65	10	0.00	0.00	0.0	0.00	0.0	8	-12.50	17.25	-33.3	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Rest of World	EV+Pembro (N= 85)												
	BASELINE	80	20.83	25.64	0.0	0.00	100.0						
	Week 1	77	21.64	29.50	0.0	0.00	100.0	76	0.44	25.82	-66.7	0.00	100.0
	Week 2	80	17.92	24.84	0.0	0.00	100.0	76	-3.07	31.35	-100.0	0.00	100.0
	Week 3	76	17.54	25.22	0.0	0.00	100.0	73	-4.57	31.58	-100.0	0.00	100.0
	Week 4	72	21.30	25.21	0.0	33.33	100.0	68	-2.94	31.93	-100.0	0.00	100.0
	Week 5	73	18.72	24.21	0.0	0.00	100.0	70	-4.29	30.52	-100.0	0.00	100.0
	Week 6	74	20.27	23.93	0.0	0.00	100.0	70	-1.91	32.05	-66.7	0.00	100.0
	Week 7	71	21.60	25.88	0.0	33.33	100.0	66	-3.54	37.04	-100.0	0.00	100.0
	Week 8	72	21.76	25.12	0.0	16.67	100.0	68	-1.96	37.27	-100.0	0.00	100.0
	Week 9	71	17.84	24.45	0.0	0.00	100.0	68	-5.88	36.85	-100.0	0.00	100.0
	Week 10	73	21.92	26.77	0.0	0.00	100.0	69	-1.93	36.55	-100.0	0.00	100.0
	Week 11	71	20.19	25.50	0.0	0.00	100.0	67	-5.47	33.13	-100.0	0.00	66.7
	Week 12	69	20.77	22.22	0.0	33.33	66.7	66	-3.54	33.14	-100.0	0.00	66.7
	Week 14	68	22.55	26.04	0.0	16.67	100.0	64	-2.60	33.23	-100.0	0.00	100.0
	Week 17	68	21.08	24.37	0.0	0.00	66.7	63	0.00	31.68	-100.0	0.00	66.7
	Week 20	59	23.73	26.30	0.0	33.33	100.0	56	0.60	32.72	-100.0	0.00	66.7
	Week 23	63	23.28	22.11	0.0	33.33	66.7	59	-0.57	28.70	-100.0	0.00	33.3
	Week 26	59	22.03	25.98	0.0	33.33	100.0	57	-2.34	33.25	-100.0	0.00	66.7
	Week 29	56	21.43	23.29	0.0	33.33	66.7	54	-1.85	29.26	-66.7	0.00	66.7
	Week 32	52	20.51	25.70	0.0	0.00	100.0	49	-2.04	31.48	-66.7	0.00	100.0
	Week 35	43	23.25	23.61	0.0	33.33	66.7	40	0.83	25.58	-66.7	0.00	33.3
	Week 38	49	24.49	29.48	0.0	0.00	100.0	47	0.00	31.08	-66.7	0.00	100.0
	Week 41	49	27.89	27.51	0.0	33.33	100.0	47	4.96	29.47	-66.7	0.00	66.7
	Week 44	44	22.73	23.60	0.0	33.33	66.7	41	-1.63	27.84	-66.7	0.00	66.7
	Week 47	37	24.32	26.82	0.0	33.33	100.0	35	0.95	30.77	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	29	26.44	27.28	0.0	33.33	100.0	28	7.14	33.16	-33.3	0.00	100.0
	Week 53	34	22.55	25.59	0.0	16.67	66.7	33	5.05	34.48	-66.7	0.00	66.7
	Week 56	31	25.81	30.68	0.0	33.33	100.0	30	4.44	38.89	-66.7	0.00	100.0
	Week 59	28	26.19	27.75	0.0	33.33	100.0	27	4.94	36.64	-66.7	0.00	100.0
	Week 62	28	16.67	27.96	0.0	0.00	100.0	27	-2.47	31.93	-66.7	0.00	100.0
	Week 65	23	23.19	30.87	0.0	0.00	100.0	22	1.52	31.67	-33.3	0.00	100.0
	Week 68	22	25.76	30.74	0.0	16.67	100.0	22	3.03	38.37	-66.7	0.00	100.0
	Week 71	22	25.76	27.08	0.0	33.33	66.7	22	1.52	34.85	-66.7	0.00	66.7
	Week 74	22	28.79	29.63	0.0	33.33	66.7	22	9.09	34.40	-66.7	0.00	66.7
	Week 77	18	24.07	29.83	0.0	0.00	66.7	17	7.84	36.38	-66.7	0.00	66.7
	Week 80	16	18.75	29.74	0.0	0.00	66.7	15	4.45	33.02	-66.7	0.00	66.7
	Week 83	16	22.92	29.11	0.0	16.67	100.0	15	6.67	38.21	-66.7	0.00	100.0
	Week 86	13	17.95	25.88	0.0	0.00	66.7	12	0.00	34.82	-66.7	0.00	66.7
	Week 89	12	27.78	31.25	0.0	33.33	100.0	12	11.11	43.42	-66.7	16.67	100.0
	Plat+Gem (N= 89)												
	BASELINE	75	23.11	27.93	0.0	0.00	100.0						
	Week 1	61	30.60	30.61	0.0	33.33	100.0	61	11.48	29.11	-33.3	0.00	100.0
	Week 2	66	30.81	29.42	0.0	33.33	100.0	62	11.29	35.16	-66.7	0.00	100.0
	Week 3	76	23.68	27.12	0.0	33.33	100.0	71	2.35	27.21	-33.3	0.00	100.0
	Week 4	73	28.77	29.04	0.0	33.33	100.0	68	7.35	29.84	-66.7	0.00	100.0
	Week 5	71	25.82	26.55	0.0	33.33	100.0	64	6.25	31.36	-66.7	0.00	100.0
	Week 6	70	21.43	24.76	0.0	33.33	100.0	63	2.12	29.25	-66.7	0.00	100.0
	Week 7	72	26.85	26.03	0.0	33.33	100.0	65	5.64	29.80	-66.7	0.00	100.0
	Week 8	63	28.04	22.57	0.0	33.33	100.0	58	6.90	31.07	-66.7	0.00	100.0
	Week 9	68	20.10	25.20	0.0	0.00	100.0	62	1.61	29.83	-66.7	0.00	100.0
	Week 10	67	21.89	26.31	0.0	0.00	100.0	61	2.19	32.70	-66.7	0.00	100.0

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Table 302.1.3002.21.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	65	25.13	26.37	0.0	33.33	100.0	60	4.44	30.36	-33.3	0.00	100.0
	Week 12	63	22.75	25.28	0.0	33.33	100.0	58	1.15	29.92	-66.7	0.00	100.0
	Week 14	63	26.98	26.68	0.0	33.33	100.0	57	5.85	34.00	-66.7	0.00	100.0
	Week 17	60	25.55	27.01	0.0	33.33	100.0	55	7.88	28.66	-33.3	0.00	100.0
	Week 20	52	17.31	23.33	0.0	0.00	100.0	50	0.00	30.12	-66.7	0.00	100.0
	Week 23	44	18.18	22.10	0.0	0.00	100.0	42	0.79	28.97	-100.0	0.00	100.0
	Week 26	41	18.70	22.42	0.0	0.00	100.0	40	1.67	28.19	-66.7	0.00	100.0
	Week 29	37	14.41	26.69	0.0	0.00	100.0	36	-0.93	34.26	-66.7	0.00	100.0
	Week 32	33	20.20	28.79	0.0	0.00	100.0	32	2.08	34.84	-66.7	0.00	100.0
	Week 35	30	14.44	24.26	0.0	0.00	100.0	30	-2.22	31.48	-66.7	0.00	100.0
	Week 38	32	13.54	25.20	0.0	0.00	100.0	31	-3.23	29.00	-66.7	0.00	100.0
	Week 41	27	16.05	26.75	0.0	0.00	100.0	26	-3.85	30.30	-33.3	0.00	100.0
	Week 44	27	14.81	23.27	0.0	0.00	100.0	26	-1.28	29.03	-33.3	0.00	100.0
	Week 47	29	14.94	26.10	0.0	0.00	100.0	28	-3.57	35.53	-66.7	0.00	100.0
	Week 50	23	10.14	18.63	0.0	0.00	66.7	22	-12.12	21.93	-66.7	0.00	33.3
	Week 53	22	10.61	23.87	0.0	0.00	100.0	21	-6.35	32.69	-66.7	0.00	100.0
	Week 56	18	11.11	19.80	0.0	0.00	66.7	17	-9.80	22.87	-66.7	0.00	33.3
	Week 59	17	11.76	16.42	0.0	0.00	33.3	16	-4.17	20.64	-33.3	0.00	33.3
	Week 62	16	8.33	14.91	0.0	0.00	33.3	15	-8.89	15.26	-33.3	0.00	0.0
	Week 65	15	4.44	11.73	0.0	0.00	33.3	14	-11.90	16.57	-33.3	0.00	0.0
	Week 68	12	5.56	12.97	0.0	0.00	33.3	11	-12.12	16.82	-33.3	0.00	0.0
	Week 71	13	5.13	12.52	0.0	0.00	33.3	12	-13.89	17.16	-33.3	0.00	0.0
	Week 74	10	6.67	14.05	0.0	0.00	33.3	10	-13.33	17.21	-33.3	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	EV+Pembro (N=198)												
	BASELINE	170	19.02	27.09	0.0	0.00	100.0						
	Week 1	157	22.08	29.37	0.0	0.00	100.0	152	3.51	28.49	-66.7	0.00	100.0
	Week 2	167	18.36	26.55	0.0	0.00	100.0	155	-1.51	28.77	-100.0	0.00	100.0
	Week 3	161	17.60	26.37	0.0	0.00	100.0	147	-1.13	30.82	-100.0	0.00	100.0
	Week 4	158	18.35	24.25	0.0	0.00	100.0	145	-2.30	30.34	-100.0	0.00	100.0
	Week 5	154	17.10	24.17	0.0	0.00	100.0	140	-2.62	30.73	-100.0	0.00	100.0
	Week 6	153	16.77	22.66	0.0	0.00	100.0	138	-3.87	30.69	-100.0	0.00	100.0
	Week 7	159	18.24	25.63	0.0	0.00	100.0	142	-2.35	35.65	-100.0	0.00	100.0
	Week 8	154	17.32	25.06	0.0	0.00	100.0	135	-3.21	34.52	-100.0	0.00	100.0
	Week 9	162	16.25	22.97	0.0	0.00	100.0	146	-4.34	32.58	-100.0	0.00	100.0
	Week 10	159	16.98	23.97	0.0	0.00	100.0	144	-4.40	32.33	-100.0	0.00	100.0
	Week 11	161	17.18	22.70	0.0	0.00	100.0	143	-4.66	31.80	-100.0	0.00	66.7
	Week 12	154	16.45	22.94	0.0	0.00	100.0	140	-5.24	34.92	-100.0	0.00	100.0
	Week 14	154	17.96	23.84	0.0	0.00	100.0	137	-3.41	33.40	-100.0	0.00	100.0
	Week 17	145	17.01	21.91	0.0	0.00	100.0	130	-2.56	32.05	-100.0	0.00	66.7
	Week 20	139	17.75	24.18	0.0	0.00	100.0	126	-3.97	32.55	-100.0	0.00	66.7
	Week 23	133	19.05	25.05	0.0	0.00	100.0	122	-1.64	32.03	-100.0	0.00	100.0
	Week 26	129	17.83	25.02	0.0	0.00	100.0	118	-3.39	33.59	-100.0	0.00	100.0
	Week 29	131	18.57	24.52	0.0	0.00	100.0	120	-3.06	28.99	-100.0	0.00	66.7
	Week 32	111	17.72	25.75	0.0	0.00	100.0	102	-4.90	29.44	-100.0	0.00	100.0
	Week 35	109	18.65	25.02	0.0	0.00	100.0	100	-3.33	29.40	-100.0	0.00	66.7
	Week 38	107	18.07	25.20	0.0	0.00	100.0	100	-3.33	29.78	-100.0	0.00	66.7
	Week 41	103	18.45	25.87	0.0	0.00	100.0	94	-1.06	30.31	-66.7	0.00	100.0
	Week 44	88	15.91	22.02	0.0	0.00	66.7	81	-4.53	28.26	-66.7	0.00	66.7
	Week 47	80	14.17	22.98	0.0	0.00	100.0	75	-6.67	30.51	-100.0	0.00	66.7

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	73	18.26	27.80	0.0	0.00	100.0	68	-2.45	35.18	-100.0	0.00	100.0
	Week 53	64	15.10	22.95	0.0	0.00	66.7	59	-2.26	30.24	-66.7	0.00	66.7
	Week 56	66	15.66	24.26	0.0	0.00	100.0	61	-4.37	33.04	-66.7	0.00	100.0
	Week 59	58	14.94	20.87	0.0	0.00	66.7	54	-5.56	30.20	-66.7	0.00	66.7
	Week 62	54	15.43	24.84	0.0	0.00	66.7	52	-3.85	28.51	-66.7	0.00	66.7
	Week 65	51	13.73	22.29	0.0	0.00	66.7	47	-7.09	24.01	-66.7	0.00	33.3
	Week 68	49	11.56	22.10	0.0	0.00	66.7	48	-9.03	29.77	-66.7	0.00	66.7
	Week 71	47	15.60	24.92	0.0	0.00	66.7	45	-4.44	33.03	-66.7	0.00	66.7
	Week 74	42	17.46	25.76	0.0	0.00	66.7	41	-2.44	36.05	-66.7	0.00	66.7
	Week 77	38	14.91	26.51	0.0	0.00	100.0	36	-5.56	35.19	-66.7	0.00	66.7
	Week 80	35	12.38	22.99	0.0	0.00	66.7	32	-7.29	32.50	-66.7	0.00	66.7
	Week 83	32	14.58	28.00	0.0	0.00	100.0	30	-8.89	34.94	-66.7	0.00	100.0
	Week 86	30	14.44	27.24	0.0	0.00	100.0	27	-3.70	29.72	-66.7	0.00	66.7
	Week 89	28	17.86	29.37	0.0	0.00	100.0	26	-1.28	34.62	-66.7	0.00	100.0
	Week 92	24	13.89	25.85	0.0	0.00	100.0	22	-4.55	25.81	-66.7	0.00	33.3
	Week 95	21	12.70	26.82	0.0	0.00	100.0	20	-6.67	20.52	-66.7	0.00	33.3
	Week 98	16	6.25	13.44	0.0	0.00	33.3	15	-11.11	24.12	-66.7	0.00	33.3
	Week 101	12	2.78	9.62	0.0	0.00	33.3	12	-5.56	19.24	-33.3	0.00	33.3
	Week 104	10	3.33	10.54	0.0	0.00	33.3	10	-13.33	28.11	-66.7	0.00	33.3
	Plat+Gem (N=185)												
	BASELINE	146	23.97	28.70	0.0	0.00	100.0						
	Week 1	131	33.08	32.95	0.0	33.33	100.0	120	11.39	27.16	-66.7	0.00	100.0
	Week 2	128	29.43	29.47	0.0	33.33	100.0	115	7.25	29.87	-100.0	0.00	100.0
	Week 3	141	21.99	26.38	0.0	0.00	100.0	126	-1.06	26.31	-66.7	0.00	66.7
	Week 4	139	26.62	28.14	0.0	33.33	100.0	119	5.32	31.88	-100.0	0.00	100.0
	Week 5	143	27.74	28.25	0.0	33.33	100.0	120	6.39	30.65	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 6	133	24.31	26.63	0.0	33.33	100.0	114	3.51	27.82	-66.7	0.00	100.0
	Week 7	142	23.94	25.84	0.0	33.33	100.0	120	3.06	28.66	-66.7	0.00	66.7
	Week 8	125	26.40	26.20	0.0	33.33	100.0	109	6.42	30.92	-66.7	0.00	66.7
	Week 9	135	18.76	24.64	0.0	0.00	100.0	115	-0.29	27.04	-66.7	0.00	100.0
	Week 10	131	25.44	27.37	0.0	33.33	100.0	111	3.90	30.06	-66.7	0.00	66.7
	Week 11	128	24.22	26.36	0.0	33.33	100.0	109	3.06	28.16	-66.7	0.00	66.7
	Week 12	124	23.39	25.85	0.0	33.33	100.0	108	2.78	29.23	-66.7	0.00	66.7
	Week 14	121	27.27	26.53	0.0	33.33	100.0	101	6.27	31.17	-100.0	0.00	66.7
	Week 17	121	26.45	25.79	0.0	33.33	100.0	101	6.93	28.41	-100.0	0.00	66.7
	Week 20	98	18.03	23.53	0.0	0.00	100.0	86	-1.16	28.21	-66.7	0.00	100.0
	Week 23	93	17.20	25.83	0.0	0.00	100.0	78	-0.86	30.85	-100.0	0.00	100.0
	Week 26	86	15.89	24.38	0.0	0.00	100.0	75	-2.67	34.12	-66.7	0.00	100.0
	Week 29	76	13.16	23.14	0.0	0.00	100.0	65	-5.13	28.40	-66.7	0.00	66.7
	Week 32	62	14.52	24.61	0.0	0.00	100.0	56	-4.17	27.75	-66.7	0.00	100.0
	Week 35	58	16.67	25.17	0.0	0.00	100.0	52	1.92	29.82	-66.7	0.00	100.0
	Week 38	60	15.55	24.14	0.0	0.00	100.0	52	-0.64	25.98	-66.7	0.00	100.0
	Week 41	52	19.23	28.27	0.0	0.00	100.0	44	3.03	28.59	-33.3	0.00	100.0
	Week 44	46	14.49	23.99	0.0	0.00	100.0	40	-1.67	27.16	-66.7	0.00	66.7
	Week 47	44	14.39	23.18	0.0	0.00	100.0	38	-0.88	31.47	-66.7	0.00	100.0
	Week 50	42	17.46	29.67	0.0	0.00	100.0	38	-4.39	31.16	-66.7	0.00	100.0
	Week 53	38	7.89	14.36	0.0	0.00	33.3	34	-4.90	18.59	-33.3	0.00	33.3
	Week 56	32	11.46	16.08	0.0	0.00	33.3	28	-7.14	24.61	-66.7	0.00	33.3
	Week 59	31	8.60	14.83	0.0	0.00	33.3	27	-3.70	19.24	-33.3	0.00	33.3
	Week 62	29	5.75	12.81	0.0	0.00	33.3	26	-6.41	16.38	-33.3	0.00	33.3
	Week 65	25	1.33	6.67	0.0	0.00	33.3	21	-9.52	15.43	-33.3	0.00	0.0
	Week 68	20	3.33	10.26	0.0	0.00	33.3	16	-10.42	15.96	-33.3	0.00	0.0

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 71	17	1.96	8.08	0.0	0.00	33.3	14	-11.90	16.57	-33.3	0.00	0.0
	Week 74	17	9.80	19.60	0.0	0.00	66.7	14	-7.14	19.30	-33.3	0.00	33.3
	Week 77	16	4.17	11.38	0.0	0.00	33.3	13	-15.38	22.01	-66.7	0.00	0.0
	Week 80	13	5.13	12.52	0.0	0.00	33.3	12	-11.11	21.71	-33.3	0.00	33.3
	Week 83	11	6.06	13.48	0.0	0.00	33.3	10	-13.33	17.21	-33.3	0.00	0.0
	Week 86	12	8.33	15.07	0.0	0.00	33.3	11	-15.15	17.41	-33.3	0.00	0.0
	Week 89	11	9.09	15.57	0.0	0.00	33.3	10	-16.67	17.57	-33.3	-16.67	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	EV+Pembro (N= 42)												
	BASELINE	36	19.44	26.87	0.0	0.00	100.0						
	Week 1	33	25.25	35.39	0.0	0.00	100.0	32	6.25	17.83	-33.3	0.00	33.3
	Week 2	36	16.67	21.82	0.0	0.00	66.7	34	-0.98	23.90	-66.7	0.00	33.3
	Week 3	37	16.22	25.61	0.0	0.00	100.0	35	-1.91	27.94	-66.7	0.00	33.3
	Week 4	36	21.30	24.11	0.0	33.33	100.0	34	3.92	26.92	-66.7	0.00	33.3
	Week 5	36	17.59	20.29	0.0	0.00	66.7	33	-1.01	25.66	-66.7	0.00	33.3
	Week 6	35	18.09	23.35	0.0	0.00	66.7	32	-1.04	28.69	-66.7	0.00	66.7
	Week 7	36	22.22	23.90	0.0	33.33	100.0	34	-0.98	34.31	-100.0	0.00	66.7
	Week 8	37	14.41	20.09	0.0	0.00	66.7	36	-4.63	33.00	-100.0	0.00	66.7
	Week 9	35	12.38	19.94	0.0	0.00	66.7	34	-4.90	30.85	-100.0	0.00	66.7
	Week 10	32	10.42	17.83	0.0	0.00	66.7	31	-4.30	29.49	-66.7	0.00	33.3
	Week 11	33	14.14	20.46	0.0	0.00	66.7	32	-3.13	25.90	-66.7	0.00	33.3
	Week 12	32	15.62	20.71	0.0	0.00	66.7	31	-5.38	32.31	-100.0	0.00	33.3
	Week 14	31	20.43	22.24	0.0	33.33	66.7	30	1.11	26.96	-66.7	0.00	66.7
	Week 17	33	18.18	25.13	0.0	0.00	66.7	32	0.00	29.33	-100.0	0.00	33.3
	Week 20	28	17.86	26.42	0.0	0.00	100.0	28	2.38	27.11	-66.7	0.00	66.7
	Week 23	29	21.84	20.46	0.0	33.33	66.7	29	2.30	28.07	-66.7	0.00	33.3
	Week 26	27	18.52	25.04	0.0	0.00	100.0	26	1.28	30.52	-66.7	0.00	66.7
	Week 29	26	12.82	16.54	0.0	0.00	33.3	25	-4.00	26.03	-66.7	0.00	33.3
	Week 32	24	13.89	25.85	0.0	0.00	100.0	23	1.45	35.50	-100.0	0.00	100.0
	Week 35	23	11.59	16.23	0.0	0.00	33.3	22	-1.52	21.77	-66.7	0.00	33.3
	Week 38	25	18.67	25.60	0.0	0.00	100.0	24	1.39	38.67	-100.0	0.00	100.0
	Week 41	26	20.51	25.08	0.0	0.00	66.7	25	0.00	27.22	-66.7	0.00	33.3
	Week 44	20	30.00	28.41	0.0	33.33	100.0	19	12.28	29.84	-33.3	0.00	100.0
	Week 47	20	25.00	26.21	0.0	33.33	100.0	19	5.26	35.60	-66.7	0.00	66.7

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	16	22.92	29.11	0.0	16.67	100.0	16	10.42	37.95	-66.7	0.00	100.0
	Week 53	15	20.00	27.60	0.0	0.00	66.7	15	4.44	43.40	-66.7	0.00	66.7
	Week 56	15	26.67	31.37	0.0	33.33	100.0	15	11.11	48.25	-100.0	0.00	100.0
	Week 59	14	23.81	33.15	0.0	0.00	100.0	14	7.14	49.23	-100.0	0.00	100.0
	Week 62	11	27.27	32.72	0.0	33.33	100.0	11	15.15	43.11	-33.3	0.00	100.0
	Plat+Gem (N= 57)												
	BASELINE	42	25.40	30.18	0.0	16.67	100.0						
	Week 1	42	40.48	30.83	0.0	33.33	100.0	38	16.67	28.74	-33.3	33.33	66.7
	Week 2	43	36.43	33.97	0.0	33.33	100.0	36	12.96	34.98	-33.3	0.00	100.0
	Week 3	43	22.48	27.91	0.0	0.00	100.0	36	-1.85	37.33	-100.0	0.00	100.0
	Week 4	44	27.27	28.09	0.0	33.33	100.0	37	0.90	28.85	-66.7	0.00	100.0
	Week 5	44	25.76	30.38	0.0	33.33	100.0	36	5.56	35.19	-66.7	0.00	100.0
	Week 6	41	27.64	29.72	0.0	33.33	100.0	35	6.67	34.11	-66.7	0.00	100.0
	Week 7	44	28.03	27.79	0.0	33.33	100.0	37	7.21	36.12	-66.7	0.00	100.0
	Week 8	42	26.98	29.67	0.0	33.33	100.0	35	8.57	35.56	-66.7	0.00	100.0
	Week 9	42	16.67	27.79	0.0	0.00	100.0	35	-1.90	36.10	-100.0	0.00	100.0
	Week 10	35	22.86	30.00	0.0	0.00	100.0	28	4.76	37.09	-66.7	0.00	100.0
	Week 11	40	23.33	30.38	0.0	0.00	100.0	34	3.92	36.48	-66.7	0.00	100.0
	Week 12	35	23.81	28.67	0.0	0.00	100.0	30	1.11	37.64	-66.7	0.00	100.0
	Week 14	32	29.17	34.65	0.0	33.33	100.0	27	7.41	45.60	-66.7	0.00	100.0
	Week 17	34	28.43	29.74	0.0	33.33	100.0	29	9.20	40.72	-66.7	0.00	100.0
	Week 20	28	21.43	26.00	0.0	16.67	100.0	24	4.17	31.57	-33.3	0.00	100.0
	Week 23	22	16.67	26.73	0.0	0.00	100.0	19	-5.26	33.82	-66.7	0.00	100.0
	Week 26	22	10.61	23.87	0.0	0.00	100.0	20	-10.00	34.37	-66.7	0.00	100.0
	Week 29	24	13.89	29.35	0.0	0.00	100.0	21	-4.76	41.21	-66.7	0.00	100.0
	Week 32	21	30.16	34.81	0.0	33.33	100.0	20	11.67	37.89	-33.3	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 35	18	20.37	30.55	0.0	0.00	100.0	17	-1.96	36.27	-33.3	0.00	100.0
	Week 38	14	16.67	31.35	0.0	0.00	100.0	13	-2.56	34.59	-33.3	0.00	100.0
	Week 41	13	23.08	31.58	0.0	0.00	100.0	12	2.78	36.12	-33.3	0.00	100.0
	Week 44	14	26.19	29.75	0.0	33.33	100.0	13	7.69	33.76	-33.3	0.00	100.0
	Week 47	12	27.78	34.33	0.0	16.67	100.0	11	3.03	43.35	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Visceral metastases	EV+Pembro (N=170)												
	BASELINE	146	19.18	27.36	0.0	0.00	100.0						
	Week 1	135	24.44	32.12	0.0	0.00	100.0	131	4.83	28.08	-66.7	0.00	100.0
	Week 2	145	17.47	25.48	0.0	0.00	100.0	134	-2.24	27.48	-100.0	0.00	100.0
	Week 3	141	17.49	27.19	0.0	0.00	100.0	129	-1.55	31.97	-100.0	0.00	100.0
	Week 4	136	19.85	26.41	0.0	0.00	100.0	125	-0.80	30.37	-100.0	0.00	100.0
	Week 5	131	16.54	24.24	0.0	0.00	100.0	118	-4.24	32.19	-100.0	0.00	100.0
	Week 6	127	17.32	24.07	0.0	0.00	100.0	113	-3.25	29.87	-66.7	0.00	100.0
	Week 7	135	18.52	26.29	0.0	0.00	100.0	121	-3.31	36.36	-100.0	0.00	100.0
	Week 8	131	15.52	23.86	0.0	0.00	100.0	118	-5.93	35.57	-100.0	0.00	100.0
	Week 9	136	14.21	22.45	0.0	0.00	100.0	124	-5.65	32.01	-100.0	0.00	100.0
	Week 10	135	15.55	22.96	0.0	0.00	100.0	124	-5.38	32.20	-100.0	0.00	100.0
	Week 11	134	16.42	21.92	0.0	0.00	66.7	121	-5.23	31.33	-100.0	0.00	66.7
	Week 12	131	15.52	23.13	0.0	0.00	100.0	120	-6.11	34.57	-100.0	0.00	100.0
	Week 14	130	18.46	24.22	0.0	0.00	100.0	117	-3.13	34.46	-100.0	0.00	100.0
	Week 17	124	15.86	22.27	0.0	0.00	100.0	111	-4.50	31.30	-100.0	0.00	66.7
	Week 20	115	18.26	25.07	0.0	0.00	100.0	105	-2.22	31.78	-100.0	0.00	66.7
	Week 23	111	19.22	24.84	0.0	0.00	100.0	103	-1.62	31.09	-100.0	0.00	100.0
	Week 26	106	16.98	25.30	0.0	0.00	100.0	97	-5.15	33.45	-100.0	0.00	100.0
	Week 29	106	16.67	24.45	0.0	0.00	100.0	98	-5.10	28.86	-100.0	0.00	66.7
	Week 32	92	16.67	24.95	0.0	0.00	100.0	85	-7.06	30.47	-100.0	0.00	100.0
	Week 35	86	16.28	23.84	0.0	0.00	100.0	79	-6.33	29.27	-100.0	0.00	66.7
	Week 38	90	17.41	26.07	0.0	0.00	100.0	84	-6.35	33.72	-100.0	0.00	100.0
	Week 41	87	18.39	26.78	0.0	0.00	100.0	81	-3.29	31.89	-66.7	0.00	100.0
	Week 44	73	16.89	23.65	0.0	0.00	100.0	68	-4.90	30.07	-66.7	0.00	100.0
	Week 47	68	15.20	24.05	0.0	0.00	100.0	63	-7.94	33.18	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	61	21.31	31.05	0.0	0.00	100.0	57	0.00	39.84	-100.0	0.00	100.0
	Week 53	54	19.14	25.58	0.0	0.00	66.7	50	0.67	37.19	-66.7	0.00	66.7
	Week 56	58	18.39	27.34	0.0	0.00	100.0	54	-3.09	40.06	-100.0	0.00	100.0
	Week 59	50	16.67	24.51	0.0	0.00	100.0	47	-6.38	38.47	-100.0	0.00	100.0
	Week 62	45	18.52	27.11	0.0	0.00	100.0	43	-2.33	37.37	-66.7	0.00	100.0
	Week 65	37	17.12	27.91	0.0	0.00	100.0	34	-7.84	31.84	-66.7	0.00	100.0
	Week 68	35	15.24	26.00	0.0	0.00	100.0	34	-7.84	37.66	-66.7	0.00	100.0
	Week 71	31	16.13	24.15	0.0	0.00	66.7	30	-10.00	36.25	-66.7	0.00	66.7
	Week 74	29	17.24	26.16	0.0	0.00	66.7	28	-7.14	39.92	-66.7	0.00	66.7
	Week 77	26	20.51	29.93	0.0	0.00	100.0	25	-9.33	41.41	-66.7	0.00	66.7
	Week 80	22	13.64	22.20	0.0	0.00	66.7	21	-17.46	37.45	-100.0	0.00	33.3
	Week 83	23	15.94	24.35	0.0	0.00	100.0	22	-12.12	31.78	-66.7	0.00	33.3
	Week 86	21	14.29	27.02	0.0	0.00	100.0	20	-11.67	27.09	-66.7	0.00	33.3
	Week 89	21	17.46	24.99	0.0	0.00	100.0	20	-11.67	37.89	-100.0	0.00	33.3
	Week 92	18	14.81	26.13	0.0	0.00	100.0	17	-13.73	35.47	-100.0	0.00	33.3
	Week 95	13	12.82	28.99	0.0	0.00	100.0	12	-13.89	22.29	-66.7	0.00	0.0
	Week 98	11	9.09	15.57	0.0	0.00	33.3	11	-21.21	30.81	-66.7	-33.33	33.3
	Week 101	11	6.06	13.48	0.0	0.00	33.3	11	-15.15	34.52	-100.0	0.00	33.3
	Plat+Gem (N=161)												
	BASELINE	129	27.13	29.10	0.0	33.33	100.0						
	Week 1	113	36.28	33.79	0.0	33.33	100.0	105	10.79	27.93	-66.7	0.00	100.0
	Week 2	108	30.25	30.41	0.0	33.33	100.0	98	5.10	31.51	-100.0	0.00	100.0
	Week 3	121	21.76	24.99	0.0	0.00	100.0	109	-3.67	30.88	-100.0	0.00	66.7
	Week 4	116	25.86	26.41	0.0	33.33	100.0	101	1.32	31.60	-100.0	0.00	100.0
	Week 5	121	26.45	28.19	0.0	33.33	100.0	104	4.17	33.39	-100.0	0.00	100.0
	Week 6	118	24.58	25.94	0.0	33.33	100.0	102	2.94	29.33	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 7	121	25.62	26.09	0.0	33.33	100.0	104	1.92	32.12	-66.7	0.00	66.7
	Week 8	108	25.92	25.51	0.0	33.33	100.0	96	3.47	32.62	-66.7	0.00	100.0
	Week 9	114	17.25	23.98	0.0	0.00	100.0	99	-3.70	27.31	-66.7	0.00	66.7
	Week 10	109	23.55	26.57	0.0	33.33	100.0	94	0.00	30.92	-66.7	0.00	66.7
	Week 11	109	22.02	26.92	0.0	0.00	100.0	95	-1.05	30.92	-66.7	0.00	66.7
	Week 12	103	22.33	26.15	0.0	0.00	100.0	91	0.00	32.96	-66.7	0.00	66.7
	Week 14	98	28.23	28.46	0.0	33.33	100.0	85	4.71	36.43	-100.0	0.00	100.0
	Week 17	103	25.57	25.22	0.0	33.33	66.7	89	4.49	30.23	-100.0	0.00	66.7
	Week 20	82	19.92	23.34	0.0	0.00	100.0	75	-1.78	29.46	-66.7	0.00	100.0
	Week 23	77	16.88	25.72	0.0	0.00	100.0	68	-3.92	32.85	-100.0	0.00	100.0
	Week 26	71	14.08	22.30	0.0	0.00	100.0	65	-7.18	35.11	-66.7	0.00	100.0
	Week 29	65	12.31	20.89	0.0	0.00	100.0	59	-9.04	31.46	-66.7	0.00	100.0
	Week 32	52	20.51	28.13	0.0	0.00	100.0	49	0.00	33.33	-66.7	0.00	100.0
	Week 35	47	17.02	25.89	0.0	0.00	100.0	44	-3.03	31.19	-66.7	0.00	100.0
	Week 38	42	13.49	22.16	0.0	0.00	100.0	39	-4.27	28.80	-66.7	0.00	100.0
	Week 41	35	21.90	29.09	0.0	0.00	100.0	32	2.08	32.72	-33.3	0.00	100.0
	Week 44	36	18.52	23.16	0.0	0.00	66.7	33	1.01	30.60	-66.7	0.00	66.7
	Week 47	32	17.71	26.75	0.0	0.00	100.0	30	-2.22	37.07	-66.7	0.00	100.0
	Week 50	30	17.78	29.99	0.0	0.00	100.0	29	-8.05	37.43	-66.7	0.00	100.0
	Week 53	25	8.00	14.53	0.0	0.00	33.3	24	-11.11	23.40	-66.7	0.00	33.3
	Week 56	22	16.67	19.92	0.0	0.00	66.7	21	-6.35	27.12	-66.7	0.00	33.3
	Week 59	22	10.61	18.93	0.0	0.00	66.7	21	-6.35	22.65	-33.3	0.00	33.3
	Week 62	19	5.26	12.49	0.0	0.00	33.3	18	-11.11	19.80	-33.3	0.00	33.3
	Week 65	19	3.51	10.51	0.0	0.00	33.3	18	-14.81	17.04	-33.3	0.00	0.0
	Week 68	13	7.69	19.97	0.0	0.00	66.7	12	-11.11	16.41	-33.3	0.00	0.0
	Week 71	13	7.69	19.97	0.0	0.00	66.7	12	-16.67	17.41	-33.3	-16.67	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 74	11	9.09	21.56	0.0	0.00	66.7	11	-12.12	16.82	-33.3	0.00	0.0
	Week 77	10	6.67	21.08	0.0	0.00	66.7	10	-16.67	23.57	-66.7	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Lymph node only	EV+Pembro (N= 60)												
	BASELINE	53	16.98	24.13	0.0	0.00	100.0						
	Week 1	49	17.69	23.67	0.0	0.00	100.0	47	2.13	24.48	-33.3	0.00	100.0
	Week 2	50	20.67	26.84	0.0	0.00	100.0	48	3.47	28.55	-33.3	0.00	100.0
	Week 3	50	18.00	24.48	0.0	0.00	100.0	47	0.71	26.46	-66.7	0.00	66.7
	Week 4	50	18.00	16.78	0.0	33.33	33.3	47	2.84	23.91	-66.7	0.00	33.3
	Week 5	53	18.24	21.25	0.0	0.00	66.7	49	2.04	23.97	-66.7	0.00	33.3
	Week 6	53	17.61	20.26	0.0	0.00	66.7	50	-0.67	28.96	-66.7	0.00	66.7
	Week 7	52	21.15	22.89	0.0	33.33	66.7	48	3.47	27.71	-100.0	0.00	66.7
	Week 8	52	18.59	23.26	0.0	0.00	66.7	47	3.55	29.68	-100.0	0.00	66.7
	Week 9	53	20.12	22.96	0.0	0.00	66.7	49	2.04	29.19	-100.0	0.00	66.7
	Week 10	48	18.05	24.75	0.0	0.00	100.0	44	2.27	26.31	-66.7	0.00	66.7
	Week 11	53	19.50	23.96	0.0	0.00	100.0	48	2.08	25.18	-66.7	0.00	66.7
	Week 12	48	20.14	21.46	0.0	33.33	66.7	45	0.74	30.56	-100.0	0.00	66.7
	Week 14	48	20.14	22.53	0.0	16.67	66.7	44	1.51	23.79	-33.3	0.00	66.7
	Week 17	46	22.46	23.36	0.0	33.33	66.7	44	7.58	26.77	-66.7	0.00	66.7
	Week 20	44	17.42	24.37	0.0	0.00	66.7	42	-1.59	29.40	-100.0	0.00	33.3
	Week 23	43	19.38	22.10	0.0	0.00	66.7	41	1.63	27.84	-100.0	0.00	33.3
	Week 26	42	20.63	24.36	0.0	16.67	100.0	40	5.83	29.13	-66.7	0.00	66.7
	Week 29	45	20.74	21.66	0.0	33.33	66.7	42	1.59	28.47	-66.7	0.00	66.7
	Week 32	38	19.30	28.61	0.0	0.00	100.0	36	3.70	31.65	-66.7	0.00	100.0
	Week 35	42	19.84	24.48	0.0	0.00	100.0	40	2.50	25.47	-66.7	0.00	66.7
	Week 38	38	19.30	24.05	0.0	0.00	100.0	36	4.63	25.39	-66.7	0.00	66.7
	Week 41	37	20.72	24.03	0.0	0.00	66.7	34	3.92	24.29	-66.7	0.00	66.7
	Week 44	31	22.58	23.39	0.0	33.33	66.7	29	5.75	26.83	-66.7	0.00	66.7
	Week 47	28	17.86	23.10	0.0	0.00	66.7	27	1.23	26.92	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	25	13.33	19.24	0.0	0.00	66.7	24	-1.39	26.88	-66.7	0.00	33.3
	Week 53	23	8.70	18.03	0.0	0.00	66.7	22	-4.55	23.67	-66.7	0.00	33.3
	Week 56	21	15.87	22.65	0.0	0.00	66.7	20	3.33	28.41	-66.7	0.00	33.3
	Week 59	20	15.00	22.88	0.0	0.00	66.7	19	3.51	24.58	-66.7	0.00	33.3
	Week 62	19	15.79	25.75	0.0	0.00	66.7	19	3.51	15.29	-33.3	0.00	33.3
	Week 65	20	13.33	19.94	0.0	0.00	66.7	19	0.00	19.25	-33.3	0.00	33.3
	Week 68	17	11.76	23.40	0.0	0.00	66.7	17	-1.96	21.96	-66.7	0.00	33.3
	Week 71	19	12.28	22.80	0.0	0.00	66.7	18	3.70	15.71	-33.3	0.00	33.3
	Week 74	17	17.65	23.91	0.0	0.00	66.7	17	3.92	23.22	-66.7	0.00	33.3
	Week 77	17	9.80	19.60	0.0	0.00	66.7	16	-2.08	22.67	-66.7	0.00	33.3
	Week 80	17	9.80	22.87	0.0	0.00	66.7	15	-2.22	23.46	-66.7	0.00	33.3
	Week 83	13	10.26	21.01	0.0	0.00	66.7	12	-5.56	23.93	-66.7	0.00	33.3
	Week 86	12	11.11	21.71	0.0	0.00	66.7	10	3.33	18.92	-33.3	0.00	33.3
	Week 89	11	12.12	22.47	0.0	0.00	66.7	10	3.33	18.92	-33.3	0.00	33.3
	Plat+Gem (N= 67)												
	BASELINE	49	18.37	28.10	0.0	0.00	100.0						
	Week 1	51	33.33	29.06	0.0	33.33	100.0	45	16.30	27.18	-33.3	0.00	66.7
	Week 2	53	34.59	32.00	0.0	33.33	100.0	44	16.67	28.30	-33.3	0.00	100.0
	Week 3	53	23.27	28.93	0.0	0.00	100.0	44	3.03	21.35	-66.7	0.00	33.3
	Week 4	58	28.74	30.24	0.0	33.33	100.0	47	9.22	28.41	-66.7	0.00	66.7
	Week 5	56	30.36	29.32	0.0	33.33	100.0	44	10.61	23.60	-66.7	0.00	66.7
	Week 6	48	24.31	28.96	0.0	16.67	100.0	40	5.00	27.79	-66.7	0.00	100.0
	Week 7	56	22.02	25.65	0.0	0.00	66.7	46	5.07	24.31	-66.7	0.00	66.7
	Week 8	52	26.28	29.03	0.0	33.33	100.0	42	11.90	28.34	-66.7	0.00	66.7
	Week 9	53	19.50	27.30	0.0	0.00	100.0	42	3.97	29.63	-100.0	0.00	100.0
	Week 10	47	29.08	29.17	0.0	33.33	100.0	36	14.81	26.96	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	51	27.45	26.42	0.0	33.33	100.0	41	10.57	25.21	-66.7	0.00	66.7
	Week 12	47	24.11	26.65	0.0	33.33	100.0	39	4.27	23.17	-66.7	0.00	66.7
	Week 14	47	26.24	26.86	0.0	33.33	100.0	36	10.19	26.21	-33.3	0.00	100.0
	Week 17	45	30.37	27.36	0.0	33.33	100.0	35	11.43	31.25	-33.3	0.00	100.0
	Week 20	38	15.79	22.91	0.0	0.00	100.0	30	2.22	23.05	-66.7	0.00	33.3
	Week 23	32	16.67	23.95	0.0	0.00	100.0	25	0.00	21.52	-66.7	0.00	33.3
	Week 26	30	14.44	25.80	0.0	0.00	100.0	24	-2.78	27.66	-66.7	0.00	66.7
	Week 29	28	13.09	27.72	0.0	0.00	100.0	21	-1.59	22.30	-66.7	0.00	33.3
	Week 32	26	12.82	25.08	0.0	0.00	100.0	22	-4.55	21.32	-66.7	0.00	33.3
	Week 35	23	14.49	22.08	0.0	0.00	66.7	19	1.75	23.50	-33.3	0.00	66.7
	Week 38	26	17.95	27.05	0.0	0.00	100.0	20	0.00	18.73	-33.3	0.00	33.3
	Week 41	24	16.67	26.01	0.0	0.00	100.0	18	0.00	19.80	-33.3	0.00	33.3
	Week 44	18	12.96	25.92	0.0	0.00	100.0	14	-7.14	14.19	-33.3	0.00	0.0
	Week 47	18	14.81	20.52	0.0	0.00	66.7	13	-2.56	21.35	-33.3	0.00	33.3
	Week 50	16	14.58	27.13	0.0	0.00	100.0	13	-7.69	14.62	-33.3	0.00	0.0
	Week 53	15	8.89	15.26	0.0	0.00	33.3	12	-5.56	19.24	-33.3	0.00	33.3
	Week 56	15	8.89	15.26	0.0	0.00	33.3	11	-9.09	15.57	-33.3	0.00	0.0
	Week 59	12	8.33	15.07	0.0	0.00	33.3	9	-3.70	11.11	-33.3	0.00	0.0
	Week 62	10	10.00	16.10	0.0	0.00	33.3	8	-4.17	11.78	-33.3	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
EV+Pembro (N=202)												
BASELINE	160	21.46	28.56	0.0	0.00	100.0						
Week 1	141	23.64	28.88	0.0	0.00	100.0	129	2.58	21.90	-66.7	0.00	100.0
Week 2	150	21.78	28.64	0.0	0.00	100.0	133	-1.50	26.55	-100.0	0.00	66.7
Week 3	139	17.27	25.49	0.0	0.00	100.0	122	-3.55	30.24	-100.0	0.00	100.0
Week 4	145	21.38	28.51	0.0	0.00	100.0	129	-0.26	32.41	-100.0	0.00	100.0
Week 5	137	18.49	25.22	0.0	0.00	100.0	121	-3.86	29.87	-100.0	0.00	66.7
Week 6	146	15.98	24.20	0.0	0.00	100.0	124	-6.45	29.35	-100.0	0.00	66.7
Week 7	147	20.63	27.68	0.0	0.00	100.0	124	-3.23	32.49	-100.0	0.00	100.0
Week 8	147	17.91	26.54	0.0	0.00	100.0	124	-3.76	32.98	-100.0	0.00	100.0
Week 9	142	15.73	24.37	0.0	0.00	100.0	121	-6.34	28.32	-100.0	0.00	66.7
Week 10	139	16.79	24.20	0.0	0.00	100.0	118	-5.08	28.79	-100.0	0.00	66.7
Week 11	137	18.25	23.21	0.0	0.00	100.0	115	-2.90	28.81	-100.0	0.00	66.7
Week 12	142	14.55	22.27	0.0	0.00	100.0	119	-5.32	26.03	-100.0	0.00	66.7
Week 14	139	17.03	24.86	0.0	0.00	100.0	116	-4.89	32.38	-100.0	0.00	66.7
Week 17	132	14.90	23.77	0.0	0.00	100.0	111	-6.61	28.72	-100.0	0.00	66.7
Week 20	120	15.00	21.97	0.0	0.00	100.0	103	-5.83	28.93	-100.0	0.00	66.7
Week 23	117	14.81	22.51	0.0	0.00	100.0	97	-4.12	28.57	-100.0	0.00	66.7
Week 26	112	14.28	21.32	0.0	0.00	100.0	94	-3.55	26.98	-100.0	0.00	66.7
Week 29	107	16.20	26.84	0.0	0.00	100.0	93	-3.94	29.43	-100.0	0.00	100.0
Week 32	102	14.38	23.22	0.0	0.00	100.0	88	-3.79	29.66	-100.0	0.00	66.7
Week 35	98	13.26	20.16	0.0	0.00	100.0	86	-3.88	29.56	-100.0	0.00	66.7
Week 38	97	12.71	21.21	0.0	0.00	100.0	86	-6.20	28.70	-100.0	0.00	33.3
Week 41	95	16.84	24.73	0.0	0.00	100.0	84	-3.57	31.48	-100.0	0.00	66.7
Week 44	86	17.05	24.92	0.0	0.00	100.0	74	-1.35	32.85	-100.0	0.00	66.7
Week 47	79	14.77	22.49	0.0	0.00	100.0	70	-6.19	31.23	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	74	15.76	20.06	0.0	0.00	66.7	64	-3.65	29.17	-66.7	0.00	66.7
Week 53	74	17.57	24.81	0.0	0.00	100.0	63	-4.23	31.96	-100.0	0.00	66.7
Week 56	72	17.13	24.38	0.0	0.00	100.0	61	-4.92	29.08	-100.0	0.00	33.3
Week 59	69	17.87	25.30	0.0	0.00	100.0	57	-4.68	31.77	-100.0	0.00	66.7
Week 62	62	18.28	24.65	0.0	0.00	100.0	52	0.64	29.14	-66.7	0.00	66.7
Week 65	43	15.50	22.24	0.0	0.00	66.7	40	-5.00	35.04	-100.0	0.00	66.7
Week 68	46	18.84	25.00	0.0	0.00	100.0	42	-0.79	34.91	-100.0	0.00	66.7
Week 71	42	17.46	27.78	0.0	0.00	100.0	38	-2.63	34.99	-100.0	0.00	66.7
Week 74	38	18.42	22.85	0.0	0.00	100.0	35	0.95	31.81	-66.7	0.00	66.7
Week 77	37	18.92	26.69	0.0	0.00	100.0	33	-3.03	33.71	-66.7	0.00	66.7
Week 80	36	17.59	25.80	0.0	0.00	100.0	34	-3.92	34.59	-66.7	0.00	66.7
Week 83	30	15.55	20.96	0.0	0.00	66.7	29	-3.45	40.18	-100.0	0.00	66.7
Week 86	26	24.36	25.92	0.0	33.33	66.7	25	14.67	37.37	-66.7	0.00	66.7
Week 89	20	18.33	25.31	0.0	0.00	66.7	19	10.53	31.53	-66.7	0.00	66.7
Week 92	19	12.28	22.80	0.0	0.00	66.7	18	-1.85	31.25	-66.7	0.00	66.7
Week 95	14	7.14	14.19	0.0	0.00	33.3	13	-2.56	28.74	-66.7	0.00	33.3
Week 98	10	3.33	10.54	0.0	0.00	33.3	9	-3.70	20.03	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Plat+Gem (N=202)												
BASELINE	165	31.11	34.56	0.0	33.33	100.0						
Week 1	144	39.35	33.37	0.0	33.33	100.0	139	7.91	32.74	-66.7	0.00	100.0
Week 2	147	37.64	32.47	0.0	33.33	100.0	135	6.67	33.28	-66.7	0.00	100.0
Week 3	149	27.29	29.01	0.0	33.33	100.0	136	-2.21	32.76	-66.7	0.00	100.0
Week 4	150	30.67	28.52	0.0	33.33	100.0	135	1.73	32.66	-66.7	0.00	66.7
Week 5	153	27.67	26.16	0.0	33.33	100.0	138	-1.45	31.93	-100.0	0.00	100.0
Week 6	145	26.90	26.73	0.0	33.33	100.0	131	-2.29	36.33	-100.0	0.00	100.0
Week 7	148	25.68	26.96	0.0	33.33	100.0	134	-1.49	32.15	-66.7	0.00	100.0
Week 8	145	31.95	28.29	0.0	33.33	100.0	132	4.29	35.05	-100.0	0.00	100.0
Week 9	141	28.37	28.99	0.0	33.33	100.0	125	-0.53	35.92	-100.0	0.00	100.0
Week 10	142	27.93	28.53	0.0	33.33	100.0	130	-1.54	34.69	-100.0	0.00	66.7
Week 11	126	29.63	28.67	0.0	33.33	100.0	114	0.88	35.05	-100.0	0.00	66.7
Week 12	130	27.95	27.15	0.0	33.33	100.0	115	-2.32	36.06	-100.0	0.00	66.7
Week 14	125	29.87	27.05	0.0	33.33	100.0	109	2.14	36.37	-100.0	0.00	66.7
Week 17	120	30.83	29.68	0.0	33.33	100.0	106	1.57	40.21	-100.0	0.00	100.0
Week 20	104	24.36	26.37	0.0	33.33	100.0	91	-4.76	37.37	-100.0	0.00	66.7
Week 23	88	16.29	21.44	0.0	0.00	100.0	80	-10.83	31.72	-100.0	0.00	66.7
Week 26	81	15.23	23.00	0.0	0.00	100.0	75	-12.44	30.89	-100.0	0.00	66.7
Week 29	77	17.32	24.55	0.0	0.00	100.0	71	-7.04	33.29	-100.0	0.00	100.0
Week 32	63	19.05	27.25	0.0	0.00	100.0	58	-4.60	38.21	-100.0	0.00	100.0
Week 35	62	14.52	18.72	0.0	0.00	66.7	56	-9.52	32.23	-100.0	0.00	66.7
Week 38	56	18.45	27.65	0.0	0.00	100.0	50	-8.67	36.15	-100.0	0.00	66.7
Week 41	52	18.59	24.18	0.0	0.00	66.7	47	-9.22	35.24	-100.0	0.00	66.7
Week 44	49	21.77	25.05	0.0	33.33	100.0	44	-6.82	41.03	-100.0	0.00	100.0
Week 47	43	22.48	27.91	0.0	0.00	100.0	39	-3.42	33.15	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	36	19.44	23.06	0.0	0.00	66.7	31	-5.38	31.15	-66.7	0.00	66.7
Week 53	31	20.43	23.85	0.0	0.00	66.7	28	-5.95	36.35	-100.0	0.00	66.7
Week 56	30	23.33	29.23	0.0	0.00	100.0	29	-1.15	44.97	-100.0	0.00	100.0
Week 59	23	33.33	34.82	0.0	33.33	100.0	21	1.59	48.85	-100.0	0.00	100.0
Week 62	20	23.33	26.71	0.0	33.33	100.0	20	-8.33	44.43	-100.0	0.00	66.7
Week 65	17	35.29	29.98	0.0	33.33	66.7	16	6.25	36.96	-66.7	0.00	66.7
Week 68	13	28.20	18.49	0.0	33.33	66.7	13	2.56	28.74	-33.3	0.00	33.3
Week 71	13	33.33	27.22	0.0	33.33	66.7	13	2.56	46.07	-100.0	0.00	66.7
Week 74	11	33.33	36.52	0.0	33.33	100.0	11	3.03	34.82	-33.3	0.00	66.7
Week 77	11	33.33	36.51	0.0	33.33	100.0	11	6.06	44.27	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Present	EV+Pembro (N= 50)												
	BASELINE	40	25.83	31.57	0.0	0.00	100.0						
	Week 1	38	28.95	33.04	0.0	33.33	100.0	34	2.94	22.27	-33.3	0.00	66.7
	Week 2	35	20.95	28.11	0.0	0.00	100.0	32	-7.29	31.38	-100.0	0.00	33.3
	Week 3	32	17.71	25.38	0.0	0.00	100.0	30	-3.33	31.98	-100.0	0.00	66.7
	Week 4	35	22.86	30.00	0.0	0.00	100.0	31	-4.30	28.21	-66.7	0.00	66.7
	Week 5	32	21.87	24.84	0.0	33.33	100.0	28	-2.38	31.33	-100.0	0.00	33.3
	Week 6	35	18.09	23.35	0.0	0.00	66.7	30	-6.67	32.04	-100.0	0.00	66.7
	Week 7	35	20.95	31.40	0.0	0.00	100.0	29	-10.34	34.62	-100.0	0.00	66.7
	Week 8	38	20.17	30.55	0.0	0.00	100.0	31	-5.38	40.46	-100.0	0.00	100.0
	Week 9	33	15.15	25.13	0.0	0.00	100.0	29	-12.64	31.39	-100.0	0.00	33.3
	Week 10	30	16.67	28.70	0.0	0.00	100.0	25	-12.00	31.74	-100.0	0.00	33.3
	Week 11	31	19.35	22.40	0.0	0.00	66.7	27	-4.94	30.25	-66.7	0.00	33.3
	Week 12	32	15.62	22.38	0.0	0.00	66.7	28	-9.52	25.43	-66.7	0.00	33.3
	Week 14	36	13.89	23.06	0.0	0.00	66.7	31	-12.90	39.14	-100.0	0.00	66.7
	Week 17	33	13.13	23.48	0.0	0.00	100.0	27	-12.35	30.87	-100.0	0.00	33.3
	Week 20	28	15.48	21.24	0.0	0.00	66.7	25	-8.00	35.07	-100.0	0.00	33.3
	Week 23	28	13.09	20.96	0.0	0.00	66.7	24	-8.33	29.89	-100.0	0.00	33.3
	Week 26	28	14.28	19.09	0.0	0.00	66.7	24	-6.95	31.05	-100.0	0.00	33.3
	Week 29	27	18.52	31.12	0.0	0.00	100.0	25	-6.67	31.91	-100.0	0.00	33.3
	Week 32	25	13.33	28.87	0.0	0.00	100.0	23	-11.59	32.73	-100.0	0.00	33.3
	Week 35	26	16.67	25.39	0.0	0.00	100.0	24	-6.95	32.57	-100.0	0.00	66.7
	Week 38	26	16.67	25.39	0.0	0.00	100.0	24	-8.33	31.47	-100.0	0.00	33.3
	Week 41	25	18.67	23.73	0.0	0.00	66.7	23	-8.70	36.54	-100.0	0.00	66.7
	Week 44	22	21.21	26.32	0.0	16.67	100.0	20	-5.00	36.31	-100.0	0.00	66.7
	Week 47	14	19.05	31.25	0.0	0.00	100.0	13	-17.95	37.55	-100.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	16.67	20.23	0.0	0.00	66.7	17	-7.84	30.11	-66.7	0.00	33.3
	Week 53	21	22.22	30.43	0.0	0.00	100.0	18	-5.56	38.35	-100.0	0.00	66.7
	Week 56	18	24.07	29.83	0.0	16.67	100.0	15	-8.89	32.04	-100.0	0.00	33.3
	Week 59	18	25.93	29.27	0.0	33.33	100.0	15	-4.44	35.34	-100.0	0.00	33.3
	Week 62	13	17.95	29.23	0.0	0.00	100.0	11	-6.06	20.10	-66.7	0.00	0.0
	Week 68	12	19.44	33.21	0.0	0.00	100.0	11	-6.06	44.27	-100.0	0.00	66.7
	Plat+Gem (N= 50)												
	BASELINE	40	45.83	35.15	0.0	33.33	100.0						
	Week 1	35	46.67	31.52	0.0	33.33	100.0	33	0.00	31.18	-66.7	0.00	100.0
	Week 2	33	48.49	33.43	0.0	66.67	100.0	30	0.00	35.02	-66.7	0.00	100.0
	Week 3	33	32.32	29.45	0.0	33.33	100.0	29	-10.34	30.99	-66.7	0.00	66.7
	Week 4	36	38.89	28.17	0.0	33.33	100.0	32	-7.29	35.66	-66.7	0.00	66.7
	Week 5	36	33.33	26.43	0.0	33.33	100.0	32	-14.58	30.45	-66.7	0.00	66.7
	Week 6	32	27.08	26.01	0.0	33.33	66.7	29	-19.54	28.89	-66.7	0.00	33.3
	Week 7	35	32.38	31.82	0.0	33.33	100.0	31	-13.98	38.27	-66.7	-33.33	66.7
	Week 8	35	39.05	28.57	0.0	33.33	100.0	31	-7.53	37.23	-66.7	0.00	66.7
	Week 9	34	40.20	32.60	0.0	33.33	100.0	30	-8.89	40.05	-66.7	0.00	100.0
	Week 10	33	37.37	29.77	0.0	33.33	100.0	30	-10.00	41.20	-66.7	0.00	66.7
	Week 11	30	41.11	25.80	0.0	33.33	100.0	26	-5.13	42.89	-66.7	0.00	66.7
	Week 12	32	32.29	29.92	0.0	33.33	100.0	27	-22.22	34.59	-100.0	-33.33	33.3
	Week 14	27	30.86	27.62	0.0	33.33	100.0	22	-15.15	36.70	-66.7	0.00	33.3
	Week 17	28	29.76	30.55	0.0	33.33	100.0	23	-17.39	38.76	-100.0	-33.33	66.7
	Week 20	20	23.33	30.78	0.0	0.00	100.0	16	-31.25	28.46	-100.0	-33.33	0.0
	Week 23	15	15.55	21.33	0.0	0.00	66.7	14	-30.95	35.72	-100.0	-33.33	33.3
	Week 26	15	20.00	32.85	0.0	0.00	100.0	14	-19.05	28.39	-66.7	-16.67	33.3
	Week 29	13	15.38	29.23	0.0	0.00	100.0	12	-13.89	41.34	-66.7	-33.33	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Absent	EV+Pembro (N=152)												
	BASELINE	120	20.00	27.47	0.0	0.00	100.0						
	Week 1	103	21.68	27.10	0.0	0.00	100.0	95	2.46	21.88	-66.7	0.00	100.0
	Week 2	115	22.03	28.91	0.0	0.00	100.0	101	0.33	24.72	-66.7	0.00	66.7
	Week 3	107	17.13	25.64	0.0	0.00	100.0	92	-3.62	29.84	-100.0	0.00	100.0
	Week 4	110	20.91	28.15	0.0	0.00	100.0	98	1.02	33.66	-100.0	0.00	100.0
	Week 5	105	17.46	25.36	0.0	0.00	100.0	93	-4.30	29.58	-100.0	0.00	66.7
	Week 6	111	15.31	24.53	0.0	0.00	100.0	94	-6.38	28.62	-100.0	0.00	66.7
	Week 7	112	20.54	26.56	0.0	0.00	100.0	95	-1.05	31.68	-100.0	0.00	100.0
	Week 8	109	17.12	25.10	0.0	0.00	100.0	93	-3.23	30.32	-100.0	0.00	66.7
	Week 9	109	15.90	24.26	0.0	0.00	100.0	92	-4.35	27.16	-100.0	0.00	66.7
	Week 10	109	16.82	22.96	0.0	0.00	66.7	93	-3.23	27.83	-100.0	0.00	66.7
	Week 11	106	17.92	23.54	0.0	0.00	100.0	88	-2.27	28.50	-100.0	0.00	66.7
	Week 12	110	14.24	22.33	0.0	0.00	100.0	91	-4.03	26.22	-100.0	0.00	66.7
	Week 14	103	18.12	25.47	0.0	0.00	100.0	85	-1.96	29.26	-100.0	0.00	66.7
	Week 17	99	15.49	23.96	0.0	0.00	100.0	84	-4.76	27.93	-100.0	0.00	66.7
	Week 20	92	14.85	22.30	0.0	0.00	100.0	78	-5.13	26.90	-100.0	0.00	66.7
	Week 23	89	15.35	23.06	0.0	0.00	100.0	73	-2.74	28.19	-100.0	0.00	66.7
	Week 26	84	14.29	22.13	0.0	0.00	100.0	70	-2.38	25.58	-66.7	0.00	66.7
	Week 29	80	15.42	25.40	0.0	0.00	100.0	68	-2.94	28.64	-66.7	0.00	100.0
	Week 32	77	14.72	21.28	0.0	0.00	66.7	65	-1.03	28.24	-66.7	0.00	66.7
	Week 35	72	12.04	17.96	0.0	0.00	66.7	62	-2.69	28.50	-100.0	0.00	33.3
	Week 38	71	11.27	19.47	0.0	0.00	66.7	62	-5.38	27.79	-100.0	0.00	33.3
	Week 41	70	16.19	25.22	0.0	0.00	100.0	61	-1.64	29.46	-100.0	0.00	66.7
	Week 44	64	15.62	24.47	0.0	0.00	100.0	54	0.00	31.72	-66.7	0.00	66.7
	Week 47	65	13.85	20.32	0.0	0.00	66.7	57	-3.51	29.33	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	54	15.43	20.18	0.0	0.00	66.7	47	-2.13	29.00	-66.7	0.00	66.7
	Week 53	53	15.72	22.27	0.0	0.00	100.0	45	-3.70	29.49	-66.7	0.00	66.7
	Week 56	54	14.81	22.12	0.0	0.00	66.7	46	-3.62	28.31	-100.0	0.00	33.3
	Week 59	51	15.03	23.39	0.0	0.00	100.0	42	-4.76	30.86	-100.0	0.00	66.7
	Week 62	49	18.37	23.63	0.0	0.00	66.7	41	2.44	31.08	-66.7	0.00	66.7
	Week 65	36	16.67	23.23	0.0	0.00	66.7	33	-2.02	32.21	-66.7	0.00	66.7
	Week 68	34	18.63	22.01	0.0	0.00	66.7	31	1.07	31.60	-66.7	0.00	66.7
	Week 71	33	14.14	22.10	0.0	0.00	66.7	30	-1.11	29.66	-66.7	0.00	66.7
	Week 74	33	17.17	18.86	0.0	0.00	66.7	30	2.22	31.48	-66.7	0.00	66.7
	Week 77	31	18.28	24.10	0.0	0.00	100.0	27	1.23	32.66	-66.7	0.00	66.7
	Week 80	31	16.13	22.56	0.0	0.00	66.7	29	0.00	33.33	-66.7	0.00	66.7
	Week 83	25	18.67	21.69	0.0	0.00	66.7	24	2.78	36.67	-66.7	0.00	66.7
	Week 86	23	24.64	25.06	0.0	33.33	66.7	22	13.64	38.02	-66.7	16.67	66.7
	Week 89	18	20.37	25.92	0.0	0.00	66.7	17	11.76	33.21	-66.7	0.00	66.7
	Week 92	16	10.42	20.07	0.0	0.00	66.7	15	0.00	33.33	-66.7	0.00	66.7
	Week 95	12	8.33	15.07	0.0	0.00	33.3	11	-3.03	31.46	-66.7	0.00	33.3
	Plat+Gem (N=152)												
	BASELINE	125	26.40	33.14	0.0	0.00	100.0						
	Week 1	109	37.00	33.74	0.0	33.33	100.0	106	10.38	32.97	-66.7	0.00	100.0
	Week 2	114	34.50	31.65	0.0	33.33	100.0	105	8.57	32.70	-66.7	0.00	100.0
	Week 3	116	25.86	28.85	0.0	33.33	100.0	107	0.00	33.02	-66.7	0.00	100.0
	Week 4	114	28.07	28.25	0.0	33.33	100.0	103	4.53	31.33	-66.7	0.00	66.7
	Week 5	117	25.92	25.94	0.0	33.33	100.0	106	2.52	31.44	-100.0	0.00	100.0
	Week 6	113	26.84	27.04	0.0	33.33	100.0	102	2.61	36.84	-100.0	0.00	100.0
	Week 7	113	23.60	25.07	0.0	33.33	100.0	103	2.27	29.25	-66.7	0.00	100.0
	Week 8	110	29.70	27.96	0.0	33.33	100.0	101	7.92	33.71	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	107	24.61	26.83	0.0	33.33	100.0	95	2.10	34.32	-100.0	0.00	66.7
	Week 10	109	25.08	27.65	0.0	33.33	100.0	100	1.00	32.29	-100.0	0.00	66.7
	Week 11	96	26.04	28.70	0.0	33.33	100.0	88	2.65	32.45	-100.0	0.00	66.7
	Week 12	98	26.53	26.20	0.0	33.33	100.0	88	3.79	34.44	-100.0	0.00	66.7
	Week 14	98	29.59	27.03	0.0	33.33	100.0	87	6.51	35.16	-100.0	0.00	66.7
	Week 17	92	31.16	29.57	0.0	33.33	100.0	83	6.83	39.22	-100.0	0.00	100.0
	Week 20	84	24.60	25.41	0.0	33.33	100.0	75	0.89	36.75	-100.0	0.00	66.7
	Week 23	73	16.44	21.60	0.0	0.00	100.0	66	-6.57	29.36	-66.7	0.00	66.7
	Week 26	66	14.14	20.30	0.0	0.00	100.0	61	-10.93	31.46	-100.0	0.00	66.7
	Week 29	64	17.71	23.73	0.0	0.00	66.7	59	-5.65	31.66	-100.0	0.00	66.7
	Week 32	54	19.14	26.38	0.0	0.00	100.0	49	-3.40	38.64	-100.0	0.00	100.0
	Week 35	54	15.43	19.11	0.0	0.00	66.7	48	-7.64	33.15	-100.0	0.00	66.7
	Week 38	47	18.44	25.83	0.0	0.00	66.7	42	-7.94	35.92	-100.0	0.00	66.7
	Week 41	45	20.00	25.03	0.0	0.00	66.7	40	-7.50	36.58	-100.0	0.00	66.7
	Week 44	41	21.95	25.40	0.0	33.33	100.0	36	-6.48	42.78	-100.0	0.00	100.0
	Week 47	35	25.71	29.25	0.0	33.33	100.0	31	1.08	33.87	-66.7	0.00	100.0
	Week 50	29	22.99	23.74	0.0	33.33	66.7	24	0.00	31.08	-66.7	0.00	66.7
	Week 53	25	24.00	24.57	0.0	33.33	66.7	22	-1.52	37.76	-100.0	0.00	66.7
	Week 56	26	24.36	29.15	0.0	16.67	100.0	25	-2.67	46.07	-100.0	0.00	100.0
	Week 59	20	35.00	35.00	0.0	33.33	100.0	18	0.00	49.84	-100.0	0.00	100.0
	Week 62	17	25.49	27.71	0.0	33.33	100.0	17	-9.80	46.79	-100.0	0.00	66.7
	Week 65	15	40.00	28.73	0.0	33.33	66.7	14	9.53	37.96	-66.7	0.00	66.7
	Week 68	11	33.33	14.91	0.0	33.33	66.7	11	6.06	29.13	-33.3	0.00	33.3
	Week 71	12	36.11	26.43	0.0	33.33	66.7	12	5.56	46.78	-100.0	16.67	66.7
	Week 74	10	36.67	36.68	0.0	33.33	100.0	10	6.67	34.43	-33.3	0.00	66.7
	Week 77	10	36.67	36.68	0.0	33.33	100.0	10	10.00	44.58	-66.7	16.67	66.7

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
< 65 years	EV+Pembro (N= 39)												
	BASELINE	32	21.87	30.07	0.0	0.00	100.0						
	Week 1	27	25.93	31.12	0.0	33.33	100.0	26	3.85	28.79	-33.3	0.00	100.0
	Week 2	30	17.78	28.68	0.0	0.00	100.0	29	-4.60	30.50	-100.0	0.00	66.7
	Week 3	31	13.98	25.49	0.0	0.00	100.0	29	-2.30	36.66	-100.0	0.00	100.0
	Week 4	30	21.11	32.14	0.0	0.00	100.0	27	2.47	33.24	-66.7	0.00	100.0
	Week 5	28	15.48	23.10	0.0	0.00	66.7	26	-7.69	28.76	-100.0	0.00	66.7
	Week 6	29	11.49	22.32	0.0	0.00	66.7	26	-6.41	31.30	-100.0	0.00	66.7
	Week 7	30	21.11	32.14	0.0	0.00	100.0	26	1.28	40.53	-100.0	0.00	100.0
	Week 8	30	15.56	24.34	0.0	0.00	66.7	26	-3.85	35.69	-100.0	0.00	66.7
	Week 9	28	13.09	22.84	0.0	0.00	100.0	27	-3.70	29.72	-100.0	0.00	33.3
	Week 10	26	10.26	15.69	0.0	0.00	33.3	23	-10.15	30.87	-100.0	0.00	33.3
	Week 11	28	19.05	26.34	0.0	0.00	100.0	25	0.00	28.87	-66.7	0.00	66.7
	Week 12	28	13.09	18.90	0.0	0.00	66.7	25	-6.67	23.57	-66.7	0.00	33.3
	Week 14	26	11.54	18.72	0.0	0.00	66.7	23	-8.70	33.66	-100.0	0.00	33.3
	Week 17	28	16.67	26.45	0.0	0.00	100.0	24	-2.78	32.48	-100.0	0.00	66.7
	Week 20	27	14.81	23.27	0.0	0.00	100.0	24	-4.17	37.19	-100.0	0.00	66.7
	Week 23	26	10.26	18.30	0.0	0.00	66.7	23	-4.35	28.96	-100.0	0.00	33.3
	Week 26	24	12.50	16.48	0.0	0.00	33.3	22	-1.52	29.95	-100.0	0.00	33.3
	Week 29	25	16.00	25.68	0.0	0.00	100.0	23	-5.80	31.22	-100.0	0.00	33.3
	Week 32	25	14.67	27.35	0.0	0.00	100.0	23	-5.80	31.22	-100.0	0.00	33.3
	Week 35	24	15.28	25.97	0.0	0.00	100.0	22	-4.55	27.78	-100.0	0.00	33.3
	Week 38	23	15.94	26.34	0.0	0.00	100.0	22	-6.06	35.09	-100.0	0.00	33.3
	Week 41	25	20.00	28.87	0.0	0.00	100.0	23	-1.45	39.54	-100.0	0.00	66.7
	Week 44	22	22.73	33.15	0.0	0.00	100.0	20	3.33	41.75	-100.0	0.00	66.7
	Week 47	20	18.33	27.52	0.0	0.00	100.0	18	-3.70	35.95	-100.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	19	10.53	15.92	0.0	0.00	33.3	17	-5.88	31.70	-66.7	0.00	33.3
	Week 53	20	11.67	24.84	0.0	0.00	100.0	18	-9.26	33.93	-100.0	0.00	33.3
	Week 56	17	15.69	29.15	0.0	0.00	100.0	15	-8.89	32.04	-100.0	0.00	33.3
	Week 59	17	15.69	26.66	0.0	0.00	100.0	15	-8.89	34.43	-100.0	0.00	33.3
	Week 62	15	17.78	30.52	0.0	0.00	100.0	14	4.76	25.68	-33.3	0.00	66.7
	Week 65	14	11.90	16.57	0.0	0.00	33.3	13	-7.69	36.40	-100.0	0.00	33.3
	Week 68	11	12.12	16.82	0.0	0.00	33.3	10	-6.67	40.97	-100.0	0.00	33.3
	Week 71	13	12.82	28.99	0.0	0.00	100.0	12	-11.11	32.82	-100.0	0.00	33.3
	Week 74	14	23.81	27.51	0.0	33.33	100.0	13	7.69	24.17	-33.3	0.00	33.3
	Week 77	14	23.81	27.51	0.0	33.33	100.0	13	0.00	30.43	-66.7	0.00	33.3
	Week 80	14	23.81	27.51	0.0	33.33	100.0	13	0.00	30.43	-66.7	0.00	33.3
	Week 83	12	19.44	22.28	0.0	16.67	66.7	11	0.00	44.72	-100.0	0.00	66.7
	Plat+Gem (N= 29)												
	BASELINE	22	28.79	33.01	0.0	33.33	100.0						
	Week 1	21	30.16	29.64	0.0	33.33	100.0	20	-1.67	25.31	-66.7	0.00	33.3
	Week 2	24	34.72	33.30	0.0	33.33	100.0	20	8.33	23.88	-33.3	0.00	33.3
	Week 3	23	21.74	29.49	0.0	0.00	100.0	20	-5.00	19.57	-33.3	0.00	33.3
	Week 4	23	30.43	24.44	0.0	33.33	66.7	19	-1.75	23.50	-33.3	0.00	33.3
	Week 5	25	21.33	21.26	0.0	33.33	66.7	20	-3.33	23.94	-66.7	0.00	33.3
	Week 6	22	19.70	24.47	0.0	0.00	66.7	18	-7.41	29.27	-66.7	0.00	66.7
	Week 7	24	22.22	18.82	0.0	33.33	66.7	21	-4.76	26.43	-66.7	0.00	33.3
	Week 8	21	26.98	22.65	0.0	33.33	66.7	19	3.51	26.98	-66.7	0.00	33.3
	Week 9	20	28.33	27.09	0.0	33.33	66.7	17	-1.96	29.98	-66.7	0.00	66.7
	Week 10	21	38.09	30.34	0.0	33.33	100.0	18	7.41	31.43	-66.7	0.00	66.7
	Week 11	20	28.33	29.17	0.0	33.33	100.0	17	-1.96	27.56	-66.7	0.00	33.3
	Week 12	21	23.81	21.45	0.0	33.33	66.7	17	-5.88	33.82	-100.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 14	22	33.33	25.20	0.0	33.33	66.7	18	9.26	29.83	-66.7	0.00	66.7
	Week 17	20	28.33	27.09	0.0	33.33	100.0	17	3.92	37.05	-66.7	0.00	100.0
	Week 20	18	29.63	34.09	0.0	33.33	100.0	15	0.00	33.33	-66.7	0.00	66.7
	Week 23	18	12.96	16.72	0.0	0.00	33.3	16	-12.50	20.64	-66.7	0.00	0.0
	Week 26	16	8.33	14.91	0.0	0.00	33.3	14	-14.29	17.12	-33.3	0.00	0.0
	Week 29	15	17.78	21.33	0.0	0.00	66.7	13	-7.69	24.17	-33.3	0.00	33.3
	Week 32	15	8.89	15.26	0.0	0.00	33.3	13	-15.38	17.30	-33.3	0.00	0.0
	Week 35	15	13.33	16.90	0.0	0.00	33.3	13	-10.26	28.49	-66.7	0.00	33.3
	Week 38	14	21.43	33.61	0.0	0.00	100.0	12	-5.56	31.25	-66.7	0.00	66.7
	Week 41	11	27.27	29.13	0.0	33.33	66.7	9	0.00	16.67	-33.3	0.00	33.3
	Week 44	11	21.21	22.47	0.0	33.33	66.7	9	-11.11	23.57	-33.3	0.00	33.3
	Week 47	11	24.24	21.56	0.0	33.33	66.7	9	-3.70	20.03	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>= 65 years	EV+Pembro (N=163)												
	BASELINE	128	21.35	28.29	0.0	0.00	100.0						
	Week 1	114	23.10	28.44	0.0	0.00	100.0	103	2.27	19.95	-66.7	0.00	66.7
	Week 2	120	22.78	28.66	0.0	0.00	100.0	104	-0.64	25.43	-66.7	0.00	66.7
	Week 3	108	18.21	25.53	0.0	0.00	100.0	93	-3.94	28.17	-100.0	0.00	100.0
	Week 4	115	21.45	27.64	0.0	0.00	100.0	102	-0.98	32.31	-100.0	0.00	100.0
	Week 5	109	19.27	25.78	0.0	0.00	100.0	95	-2.81	30.23	-100.0	0.00	66.7
	Week 6	117	17.09	24.61	0.0	0.00	100.0	98	-6.46	28.98	-100.0	0.00	66.7
	Week 7	117	20.51	26.57	0.0	0.00	100.0	98	-4.42	30.13	-100.0	0.00	100.0
	Week 8	117	18.52	27.14	0.0	0.00	100.0	98	-3.74	32.42	-100.0	0.00	100.0
	Week 9	114	16.37	24.79	0.0	0.00	100.0	94	-7.09	28.03	-100.0	0.00	66.7
	Week 10	113	18.29	25.59	0.0	0.00	100.0	95	-3.86	28.29	-100.0	0.00	66.7
	Week 11	109	18.04	22.47	0.0	0.00	66.7	90	-3.70	28.90	-100.0	0.00	33.3
	Week 12	114	14.91	23.08	0.0	0.00	100.0	94	-4.96	26.75	-100.0	0.00	66.7
	Week 14	113	18.29	25.97	0.0	0.00	100.0	93	-3.94	32.17	-100.0	0.00	66.7
	Week 17	104	14.42	23.11	0.0	0.00	100.0	87	-7.66	27.70	-100.0	0.00	33.3
	Week 20	93	15.05	21.71	0.0	0.00	66.7	79	-6.33	26.19	-100.0	0.00	33.3
	Week 23	91	16.12	23.50	0.0	0.00	100.0	74	-4.05	28.64	-100.0	0.00	66.7
	Week 26	88	14.77	22.52	0.0	0.00	100.0	72	-4.17	26.20	-66.7	0.00	66.7
	Week 29	82	16.26	27.34	0.0	0.00	100.0	70	-3.33	29.02	-66.7	0.00	100.0
	Week 32	77	14.28	21.92	0.0	0.00	100.0	65	-3.08	29.30	-66.7	0.00	66.7
	Week 35	74	12.61	18.05	0.0	0.00	66.7	64	-3.65	30.35	-100.0	0.00	66.7
	Week 38	74	11.71	19.45	0.0	0.00	66.7	64	-6.25	26.48	-100.0	0.00	33.3
	Week 41	70	15.71	23.21	0.0	0.00	100.0	61	-4.37	28.20	-100.0	0.00	66.7
	Week 44	64	15.10	21.36	0.0	0.00	66.7	54	-3.09	29.15	-66.7	0.00	66.7
	Week 47	59	13.56	20.64	0.0	0.00	66.7	52	-7.05	29.77	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	55	17.57	21.13	0.0	0.00	66.7	47	-2.84	28.51	-66.7	0.00	66.7
	Week 53	54	19.75	24.67	0.0	0.00	100.0	45	-2.22	31.30	-66.7	0.00	66.7
	Week 56	55	17.58	23.00	0.0	0.00	66.7	46	-3.62	28.31	-100.0	0.00	33.3
	Week 59	52	18.59	25.06	0.0	0.00	100.0	42	-3.17	31.07	-100.0	0.00	66.7
	Week 62	47	18.44	22.85	0.0	0.00	66.7	38	-0.88	30.50	-66.7	0.00	66.7
	Week 65	29	17.24	24.59	0.0	0.00	66.7	27	-3.70	35.00	-66.7	0.00	66.7
	Week 68	35	20.95	26.92	0.0	0.00	100.0	32	1.04	33.32	-66.7	0.00	66.7
	Week 71	29	19.54	27.48	0.0	0.00	100.0	26	1.28	35.88	-66.7	0.00	66.7
	Week 74	24	15.28	19.61	0.0	0.00	66.7	22	-3.03	35.50	-66.7	0.00	66.7
	Week 77	23	15.94	26.34	0.0	0.00	100.0	20	-5.00	36.31	-66.7	0.00	66.7
	Week 80	22	13.64	24.47	0.0	0.00	66.7	21	-6.35	37.45	-66.7	0.00	66.7
	Week 83	18	12.96	20.26	0.0	0.00	66.7	18	-5.56	38.35	-66.7	0.00	66.7
	Week 86	18	25.93	26.95	0.0	33.33	66.7	18	11.11	41.22	-66.7	0.00	66.7
	Week 89	12	13.89	22.29	0.0	0.00	66.7	12	5.56	34.33	-66.7	0.00	66.7
	Week 92	10	10.00	22.50	0.0	0.00	66.7	10	-6.67	37.84	-66.7	0.00	66.7
	Plat+Gem (N=173)												
	BASELINE	143	31.47	34.89	0.0	33.33	100.0						
	Week 1	123	40.92	33.83	0.0	33.33	100.0	119	9.52	33.66	-66.7	0.00	100.0
	Week 2	123	38.21	32.42	0.0	33.33	100.0	115	6.38	34.74	-66.7	0.00	100.0
	Week 3	126	28.31	28.93	0.0	33.33	100.0	116	-1.72	34.57	-66.7	0.00	100.0
	Week 4	127	30.71	29.28	0.0	33.33	100.0	116	2.30	33.97	-66.7	0.00	66.7
	Week 5	128	28.91	26.91	0.0	33.33	100.0	118	-1.13	33.17	-100.0	0.00	100.0
	Week 6	123	28.18	27.00	0.0	33.33	100.0	113	-1.48	37.37	-100.0	0.00	100.0
	Week 7	124	26.34	28.28	0.0	33.33	100.0	113	-0.88	33.17	-66.7	0.00	100.0
	Week 8	124	32.80	29.14	0.0	33.33	100.0	113	4.42	36.33	-100.0	0.00	100.0
	Week 9	121	28.37	29.40	0.0	33.33	100.0	108	-0.31	36.88	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	121	26.17	27.96	0.0	33.33	100.0	112	-2.98	35.11	-100.0	0.00	66.7
	Week 11	106	29.87	28.70	0.0	33.33	100.0	97	1.37	36.30	-100.0	0.00	66.7
	Week 12	109	28.75	28.13	0.0	33.33	100.0	98	-1.70	36.57	-100.0	0.00	66.7
	Week 14	103	29.13	27.49	0.0	33.33	100.0	91	0.73	37.51	-100.0	0.00	66.7
	Week 17	100	31.33	30.27	0.0	33.33	100.0	89	1.12	40.96	-100.0	0.00	100.0
	Week 20	86	23.25	24.56	0.0	33.33	100.0	76	-5.70	38.25	-100.0	0.00	66.7
	Week 23	70	17.14	22.52	0.0	0.00	100.0	64	-10.42	34.05	-100.0	0.00	66.7
	Week 26	65	16.92	24.38	0.0	0.00	100.0	61	-12.02	33.35	-100.0	0.00	66.7
	Week 29	62	17.20	25.42	0.0	0.00	100.0	58	-6.90	35.19	-100.0	0.00	100.0
	Week 32	48	22.22	29.44	0.0	0.00	100.0	45	-1.48	42.02	-100.0	0.00	100.0
	Week 35	47	14.89	19.42	0.0	0.00	66.7	43	-9.30	33.59	-100.0	0.00	66.7
	Week 38	42	17.46	25.76	0.0	0.00	66.7	38	-9.65	37.89	-100.0	0.00	66.7
	Week 41	41	16.26	22.51	0.0	0.00	66.7	38	-11.40	38.19	-100.0	0.00	66.7
	Week 44	38	21.93	26.02	0.0	16.67	100.0	35	-5.71	44.64	-100.0	0.00	100.0
	Week 47	32	21.87	30.07	0.0	0.00	100.0	30	-3.33	36.46	-66.7	0.00	100.0
	Week 50	29	18.39	22.86	0.0	0.00	66.7	26	-2.56	31.16	-66.7	0.00	66.7
	Week 53	25	20.00	23.57	0.0	0.00	66.7	24	-4.17	38.46	-100.0	0.00	66.7
	Week 56	26	23.08	29.47	0.0	0.00	100.0	26	-2.56	45.14	-100.0	0.00	100.0
	Week 59	20	33.33	35.87	0.0	33.33	100.0	20	0.00	49.56	-100.0	0.00	100.0
	Week 62	19	24.56	26.86	0.0	33.33	100.0	19	-8.77	45.60	-100.0	0.00	66.7
	Week 65	16	33.33	29.82	0.0	33.33	66.7	16	6.25	36.96	-66.7	0.00	66.7
	Week 68	13	28.20	18.49	0.0	33.33	66.7	13	2.56	28.74	-33.3	0.00	33.3
	Week 71	13	33.33	27.22	0.0	33.33	66.7	13	2.56	46.07	-100.0	0.00	66.7
	Week 74	11	33.33	36.52	0.0	33.33	100.0	11	3.03	34.82	-33.3	0.00	66.7
	Week 77	10	33.33	38.49	0.0	33.33	100.0	10	3.33	45.68	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Europe	EV+Pembro (N= 74)												
	BASELINE	53	20.75	30.82	0.0	0.00	100.0						
	Week 1	48	22.92	29.30	0.0	0.00	100.0	42	1.59	22.03	-33.3	0.00	100.0
	Week 2	53	19.50	28.82	0.0	0.00	100.0	44	-3.03	27.67	-100.0	0.00	66.7
	Week 3	50	16.67	25.42	0.0	0.00	100.0	41	-8.13	34.79	-100.0	0.00	100.0
	Week 4	51	20.91	29.78	0.0	0.00	100.0	44	-3.03	35.81	-100.0	0.00	100.0
	Week 5	46	16.67	27.89	0.0	0.00	100.0	41	-7.32	31.19	-100.0	0.00	66.7
	Week 6	50	8.00	17.25	0.0	0.00	66.7	39	-17.09	33.22	-100.0	0.00	33.3
	Week 7	50	21.33	32.83	0.0	0.00	100.0	39	-1.71	42.54	-100.0	0.00	100.0
	Week 8	51	17.65	32.22	0.0	0.00	100.0	41	-2.44	38.29	-100.0	0.00	100.0
	Week 9	47	12.77	25.59	0.0	0.00	100.0	37	-10.81	30.48	-100.0	0.00	33.3
	Week 10	45	11.85	25.78	0.0	0.00	100.0	34	-11.77	33.72	-100.0	0.00	33.3
	Week 11	48	15.28	23.78	0.0	0.00	66.7	37	-3.60	30.21	-100.0	0.00	33.3
	Week 12	51	15.03	24.33	0.0	0.00	100.0	39	-4.27	29.79	-100.0	0.00	66.7
	Week 14	50	15.33	25.39	0.0	0.00	100.0	38	-4.39	34.81	-100.0	0.00	66.7
	Week 17	43	16.28	25.59	0.0	0.00	100.0	33	-3.03	32.66	-100.0	0.00	33.3
	Week 20	41	11.38	20.56	0.0	0.00	66.7	33	-9.09	32.57	-100.0	0.00	33.3
	Week 23	41	11.38	20.56	0.0	0.00	66.7	30	-10.00	31.74	-100.0	0.00	33.3
	Week 26	37	9.01	18.67	0.0	0.00	66.7	28	-8.33	25.05	-100.0	0.00	33.3
	Week 29	37	12.61	30.78	0.0	0.00	100.0	29	-9.20	34.38	-100.0	0.00	100.0
	Week 32	34	9.80	23.97	0.0	0.00	100.0	26	-8.97	33.41	-100.0	0.00	66.7
	Week 35	31	6.45	13.39	0.0	0.00	33.3	25	-9.33	28.09	-100.0	0.00	33.3
	Week 38	31	8.60	19.18	0.0	0.00	66.7	26	-12.82	29.93	-100.0	0.00	33.3
	Week 41	28	13.09	24.58	0.0	0.00	100.0	23	-11.59	35.69	-100.0	0.00	66.7
	Week 44	27	9.88	18.06	0.0	0.00	66.7	22	-9.09	35.90	-100.0	0.00	66.7
	Week 47	25	8.00	17.43	0.0	0.00	66.7	21	-12.70	35.71	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	26	12.82	16.54	0.0	0.00	33.3	23	-7.25	26.51	-66.7	0.00	33.3
	Week 53	26	14.10	23.43	0.0	0.00	66.7	21	-3.17	37.87	-100.0	0.00	66.7
	Week 56	25	17.33	23.80	0.0	0.00	66.7	21	-6.35	30.95	-100.0	0.00	33.3
	Week 59	23	15.94	24.35	0.0	0.00	66.7	18	-1.85	33.28	-100.0	0.00	66.7
	Week 62	20	20.00	25.13	0.0	0.00	66.7	17	9.80	25.73	-33.3	0.00	66.7
	Week 65	13	15.38	25.88	0.0	0.00	66.7	13	-2.56	41.86	-100.0	0.00	66.7
	Week 68	15	20.00	30.34	0.0	0.00	100.0	15	4.44	39.57	-100.0	0.00	66.7
	Week 71	13	20.51	34.80	0.0	0.00	100.0	13	5.13	42.70	-100.0	0.00	66.7
	Week 74	10	13.33	23.31	0.0	0.00	66.7	9	7.41	27.78	-33.3	0.00	66.7
	Plat+Gem (N= 95)												
	BASELINE	75	36.00	36.66	0.0	33.33	100.0						
	Week 1	71	46.01	36.67	0.0	33.33	100.0	69	8.69	31.65	-66.7	0.00	100.0
	Week 2	71	40.38	34.23	0.0	33.33	100.0	63	3.17	31.52	-66.7	0.00	100.0
	Week 3	72	27.31	29.25	0.0	33.33	100.0	65	-7.18	30.90	-66.7	0.00	66.7
	Week 4	69	33.33	28.58	0.0	33.33	100.0	62	-1.08	36.20	-66.7	0.00	66.7
	Week 5	71	28.64	28.34	0.0	33.33	100.0	63	-5.82	31.98	-100.0	0.00	33.3
	Week 6	69	28.50	25.74	0.0	33.33	100.0	61	-4.92	38.41	-100.0	0.00	66.7
	Week 7	69	28.02	28.94	0.0	33.33	100.0	62	-4.30	32.77	-66.7	0.00	100.0
	Week 8	67	30.85	28.02	0.0	33.33	100.0	60	-0.56	33.33	-100.0	0.00	66.7
	Week 9	66	28.28	28.79	0.0	33.33	100.0	57	-6.43	33.00	-100.0	0.00	66.7
	Week 10	70	29.52	31.87	0.0	33.33	100.0	63	-7.41	37.12	-100.0	0.00	66.7
	Week 11	63	31.75	28.35	0.0	33.33	100.0	56	-4.76	33.89	-100.0	0.00	66.7
	Week 12	66	27.78	27.79	0.0	33.33	100.0	56	-6.55	35.06	-100.0	0.00	66.7
	Week 14	66	31.31	28.57	0.0	33.33	100.0	56	-1.19	37.59	-100.0	0.00	66.7
	Week 17	61	28.96	30.72	0.0	33.33	100.0	53	-5.03	38.34	-100.0	0.00	100.0
	Week 20	54	28.39	29.25	0.0	33.33	100.0	48	-2.78	36.92	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 23	44	15.91	19.67	0.0	0.00	66.7	40	-12.50	29.90	-66.7	0.00	33.3
	Week 26	42	16.67	22.39	0.0	0.00	100.0	39	-12.82	29.24	-66.7	0.00	33.3
	Week 29	39	14.53	19.93	0.0	0.00	66.7	36	-11.11	29.81	-66.7	0.00	33.3
	Week 32	32	23.96	31.94	0.0	0.00	100.0	30	0.00	43.77	-66.7	0.00	100.0
	Week 35	32	14.58	18.81	0.0	0.00	66.7	30	-8.89	33.83	-66.7	0.00	66.7
	Week 38	28	15.48	24.82	0.0	0.00	66.7	26	-10.26	36.23	-66.7	0.00	66.7
	Week 41	25	17.33	25.68	0.0	0.00	66.7	23	-10.15	40.75	-66.7	0.00	66.7
	Week 44	24	22.22	27.22	0.0	16.67	100.0	22	-7.58	43.56	-66.7	0.00	100.0
	Week 47	22	25.76	32.42	0.0	16.67	100.0	20	-1.67	41.15	-66.7	0.00	100.0
	Week 50	17	27.45	24.25	0.0	33.33	66.7	15	-2.22	38.77	-66.7	0.00	66.7
	Week 53	15	22.22	27.22	0.0	0.00	66.7	14	-4.76	38.91	-66.7	0.00	66.7
	Week 56	15	28.89	33.02	0.0	33.33	100.0	14	9.52	42.22	-66.7	0.00	100.0
	Week 59	11	36.36	40.70	0.0	33.33	100.0	10	10.00	44.58	-66.7	0.00	100.0
	Week 62	11	27.27	29.13	0.0	33.33	100.0	11	0.00	39.44	-66.7	0.00	66.7
	Week 65	10	26.67	30.63	0.0	16.67	66.7	10	0.00	44.45	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
North America	EV+Pembro (N= 46)												
	BASELINE	33	21.21	28.65	0.0	0.00	100.0						
	Week 1	30	27.78	31.66	0.0	33.33	100.0	27	8.64	19.81	-33.3	0.00	66.7
	Week 2	30	27.78	29.14	0.0	33.33	100.0	26	3.85	23.71	-33.3	0.00	33.3
	Week 3	25	22.67	28.42	0.0	0.00	100.0	21	3.17	27.70	-33.3	0.00	66.7
	Week 4	30	27.78	36.18	0.0	0.00	100.0	24	4.17	33.06	-33.3	0.00	66.7
	Week 5	29	25.29	26.21	0.0	33.33	100.0	21	3.18	29.63	-33.3	0.00	66.7
	Week 6	31	20.43	23.85	0.0	33.33	100.0	23	0.00	28.43	-33.3	0.00	66.7
	Week 7	33	21.21	26.11	0.0	0.00	100.0	23	-2.90	26.42	-33.3	0.00	33.3
	Week 8	29	19.54	22.74	0.0	33.33	100.0	20	0.00	28.61	-33.3	0.00	66.7
	Week 9	27	12.34	18.83	0.0	0.00	66.7	21	-4.76	24.23	-66.7	0.00	33.3
	Week 10	29	14.94	19.08	0.0	0.00	66.7	23	-8.70	27.00	-66.7	0.00	33.3
	Week 11	28	21.43	24.37	0.0	33.33	100.0	21	1.59	32.45	-66.7	0.00	66.7
	Week 12	29	12.64	18.72	0.0	0.00	66.7	22	-10.61	26.00	-66.7	0.00	33.3
	Week 14	28	13.09	18.90	0.0	0.00	66.7	21	-9.52	33.57	-100.0	0.00	33.3
	Week 17	29	13.79	18.93	0.0	0.00	66.7	23	-10.14	25.49	-66.7	0.00	33.3
	Week 20	23	13.04	19.43	0.0	0.00	66.7	18	-9.26	29.83	-100.0	0.00	33.3
	Week 23	22	10.61	18.93	0.0	0.00	66.7	17	-5.88	24.25	-66.7	0.00	33.3
	Week 26	21	11.11	16.10	0.0	0.00	33.3	16	-8.33	28.54	-66.7	0.00	33.3
	Week 29	20	15.00	25.30	0.0	0.00	100.0	17	-5.88	26.96	-66.7	0.00	33.3
	Week 32	21	14.29	27.02	0.0	0.00	100.0	18	-5.56	28.58	-66.7	0.00	33.3
	Week 35	22	15.15	26.68	0.0	0.00	100.0	19	-3.51	31.22	-66.7	0.00	66.7
	Week 38	20	10.00	24.42	0.0	0.00	100.0	17	-9.80	25.72	-66.7	0.00	33.3
	Week 41	21	9.52	18.69	0.0	0.00	66.7	17	-7.84	25.08	-66.7	0.00	33.3
	Week 44	16	14.58	27.13	0.0	0.00	100.0	12	-2.78	26.43	-66.7	0.00	33.3
	Week 47	16	10.42	26.44	0.0	0.00	100.0	13	-12.82	25.60	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	16	4.17	11.38	0.0	0.00	33.3	11	-15.15	22.92	-66.7	0.00	0.0
	Week 53	15	11.11	27.22	0.0	0.00	100.0	11	-18.18	27.34	-66.7	-33.33	33.3
	Week 56	17	13.72	26.51	0.0	0.00	100.0	12	-8.33	25.13	-66.7	0.00	33.3
	Week 59	17	13.72	26.51	0.0	0.00	100.0	12	-11.11	25.95	-66.7	0.00	33.3
	Week 62	14	14.29	28.39	0.0	0.00	100.0	9	-7.41	27.78	-66.7	0.00	33.3
	Week 68	11	6.06	20.10	0.0	0.00	66.7	8	-16.67	25.20	-66.7	0.00	0.0
	Week 71	11	15.15	31.14	0.0	0.00	100.0	8	-8.33	29.55	-66.7	0.00	33.3
	Plat+Gem (N= 34)												
	BASELINE	27	29.63	35.00	0.0	33.33	100.0						
	Week 1	19	28.07	20.07	0.0	33.33	66.7	17	1.96	27.56	-66.7	0.00	33.3
	Week 2	20	28.33	29.17	0.0	33.33	66.7	18	9.26	27.55	-33.3	0.00	66.7
	Week 3	20	15.00	20.16	0.0	0.00	66.7	17	-3.92	20.01	-33.3	0.00	33.3
	Week 4	23	24.64	27.00	0.0	33.33	100.0	19	0.00	31.43	-66.7	0.00	66.7
	Week 5	25	22.67	20.91	0.0	33.33	66.7	22	-1.52	19.18	-66.7	0.00	33.3
	Week 6	20	20.00	22.69	0.0	16.67	66.7	17	-7.84	25.08	-66.7	0.00	33.3
	Week 7	23	14.49	19.66	0.0	0.00	66.7	20	-5.00	24.84	-66.7	0.00	33.3
	Week 8	24	25.00	28.23	0.0	33.33	100.0	22	1.52	31.67	-66.7	0.00	66.7
	Week 9	23	21.74	29.49	0.0	0.00	100.0	19	-1.75	32.34	-66.7	0.00	66.7
	Week 10	20	18.33	25.31	0.0	0.00	66.7	18	-3.70	30.01	-66.7	0.00	66.7
	Week 11	18	16.67	32.84	0.0	0.00	100.0	16	2.08	35.42	-66.7	0.00	66.7
	Week 12	17	19.61	26.51	0.0	0.00	66.7	16	-6.25	27.81	-66.7	0.00	33.3
	Week 14	16	16.67	21.08	0.0	0.00	66.7	14	2.38	27.63	-66.7	0.00	66.7
	Week 17	19	28.07	35.60	0.0	33.33	100.0	17	13.73	44.19	-100.0	0.00	100.0
	Week 20	16	16.67	24.34	0.0	0.00	66.7	13	0.00	40.82	-100.0	0.00	66.7
	Week 23	15	13.33	30.34	0.0	0.00	100.0	13	-7.69	38.86	-100.0	0.00	66.7
	Week 26	13	15.38	32.25	0.0	0.00	100.0	12	0.00	28.43	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 29	14	11.91	24.83	0.0	0.00	66.7	13	-2.56	25.32	-33.3	0.00	33.3
	Week 32	11	15.15	27.34	0.0	0.00	66.7	10	3.34	18.92	-33.3	0.00	33.3
	Week 35	13	15.38	22.01	0.0	0.00	66.7	11	0.00	21.08	-33.3	0.00	33.3
	Week 38	10	20.00	35.83	0.0	0.00	100.0	9	11.11	23.57	0.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Rest of World	EV+Pembro (N= 82)												
	BASELINE	74	22.07	27.19	0.0	0.00	100.0						
	Week 1	63	22.22	27.44	0.0	0.00	100.0	60	0.56	22.54	-66.7	0.00	66.7
	Week 2	67	20.89	28.33	0.0	0.00	100.0	63	-2.65	26.98	-66.7	0.00	66.7
	Week 3	64	15.62	24.46	0.0	0.00	100.0	60	-2.78	27.65	-66.7	0.00	100.0
	Week 4	64	18.75	22.91	0.0	0.00	100.0	61	0.00	29.81	-66.7	0.00	100.0
	Week 5	62	16.67	22.38	0.0	0.00	100.0	59	-3.96	29.09	-100.0	0.00	66.7
	Week 6	65	20.00	27.51	0.0	0.00	100.0	62	-2.15	25.52	-66.7	0.00	66.7
	Week 7	64	19.79	24.28	0.0	0.00	66.7	62	-4.30	27.32	-100.0	0.00	66.7
	Week 8	67	17.41	23.47	0.0	0.00	66.7	63	-5.82	30.84	-100.0	0.00	66.7
	Week 9	68	19.12	25.31	0.0	0.00	100.0	63	-4.23	28.39	-66.7	0.00	66.7
	Week 10	65	21.03	24.70	0.0	0.00	66.7	61	0.00	25.82	-66.7	0.00	66.7
	Week 11	61	19.12	22.33	0.0	0.00	66.7	57	-4.09	26.78	-66.7	0.00	33.3
	Week 12	62	15.05	22.32	0.0	0.00	100.0	58	-4.02	23.43	-66.7	0.00	66.7
	Week 14	61	20.22	26.72	0.0	0.00	100.0	57	-3.51	30.66	-100.0	0.00	66.7
	Week 17	60	14.44	24.83	0.0	0.00	100.0	55	-7.27	27.73	-100.0	0.00	66.7
	Week 20	56	18.45	23.71	0.0	0.00	100.0	52	-2.56	26.28	-100.0	0.00	66.7
	Week 23	54	19.13	24.74	0.0	0.00	100.0	50	0.00	27.77	-66.7	0.00	66.7
	Week 26	54	19.13	23.88	0.0	0.00	100.0	50	0.67	27.35	-66.7	0.00	66.7
	Week 29	50	19.33	24.37	0.0	0.00	66.7	47	0.00	26.92	-66.7	0.00	66.7
	Week 32	47	17.73	20.68	0.0	0.00	66.7	44	0.00	27.84	-66.7	0.00	33.3
	Week 35	45	17.04	19.62	0.0	0.00	66.7	42	-0.79	29.89	-100.0	0.00	33.3
	Week 38	46	16.67	20.79	0.0	0.00	66.7	43	-0.78	28.63	-100.0	0.00	33.3
	Week 41	46	22.46	26.34	0.0	16.67	100.0	44	2.27	30.84	-100.0	0.00	66.7
	Week 44	43	22.48	26.94	0.0	0.00	100.0	40	3.33	32.73	-66.7	0.00	66.7
	Week 47	38	21.05	22.49	0.0	33.33	66.7	36	0.00	29.81	-100.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	32	23.96	22.77	0.0	33.33	66.7	30	3.33	31.98	-66.7	0.00	66.7
	Week 53	33	23.23	24.27	0.0	33.33	100.0	31	0.00	28.54	-66.7	0.00	33.3
	Week 56	30	18.89	24.26	0.0	0.00	66.7	28	-2.38	29.99	-100.0	0.00	33.3
	Week 59	29	21.84	25.63	0.0	33.33	100.0	27	-3.70	33.76	-100.0	0.00	33.3
	Week 62	28	19.05	23.00	0.0	0.00	66.7	26	-2.57	31.16	-66.7	0.00	66.7
	Week 65	22	21.21	21.93	0.0	33.33	66.7	21	-1.59	32.45	-66.7	0.00	33.3
	Week 68	20	25.00	21.29	0.0	33.33	66.7	19	1.75	34.20	-66.7	0.00	33.3
	Week 71	18	16.67	20.61	0.0	0.00	66.7	17	-5.88	31.70	-66.7	0.00	33.3
	Week 74	19	22.80	15.92	0.0	33.33	33.3	19	5.26	33.82	-66.7	0.00	33.3
	Week 77	19	19.30	25.62	0.0	0.00	100.0	18	-1.85	33.28	-66.7	0.00	33.3
	Week 80	19	15.79	20.39	0.0	0.00	66.7	18	-3.71	32.11	-66.7	0.00	33.3
	Week 83	17	17.65	20.81	0.0	0.00	66.7	17	0.00	37.27	-66.7	0.00	66.7
	Week 86	14	28.57	22.10	0.0	33.33	66.7	14	14.28	38.60	-66.7	33.33	66.7
	Week 89	11	15.15	22.92	0.0	0.00	66.7	11	6.06	35.96	-66.7	0.00	66.7
	Plat+Gem (N= 73)												
	BASELINE	63	25.93	31.36	0.0	33.33	100.0						
	Week 1	54	34.57	31.03	0.0	33.33	100.0	53	8.80	35.90	-66.7	0.00	100.0
	Week 2	56	37.50	31.18	0.0	33.33	100.0	54	9.88	36.99	-66.7	0.00	100.0
	Week 3	57	31.58	30.49	0.0	33.33	100.0	54	4.32	37.22	-66.7	0.00	100.0
	Week 4	58	29.88	29.08	0.0	33.33	100.0	54	5.56	28.78	-33.3	0.00	66.7
	Week 5	57	28.65	25.54	0.0	33.33	100.0	53	3.77	35.60	-66.7	0.00	100.0
	Week 6	56	27.38	29.20	0.0	33.33	100.0	53	2.52	36.89	-66.7	0.00	100.0
	Week 7	56	27.38	26.29	0.0	33.33	100.0	52	3.21	33.83	-66.7	0.00	66.7
	Week 8	54	36.42	28.42	0.0	33.33	100.0	50	11.33	37.86	-66.7	0.00	100.0
	Week 9	52	31.41	29.08	0.0	33.33	100.0	49	6.80	39.66	-100.0	0.00	100.0
	Week 10	52	29.49	24.39	0.0	33.33	100.0	49	6.80	31.90	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	45	31.85	26.55	0.0	33.33	100.0	42	7.94	35.92	-100.0	0.00	66.7
	Week 12	47	31.20	26.38	0.0	33.33	100.0	43	4.65	39.56	-100.0	0.00	66.7
	Week 14	43	32.56	25.71	0.0	33.33	100.0	39	6.84	37.60	-100.0	0.00	66.7
	Week 17	40	35.00	24.98	0.0	33.33	66.7	36	5.56	40.24	-100.0	0.00	66.7
	Week 20	34	21.57	21.53	0.0	33.33	66.7	30	-10.00	37.29	-100.0	0.00	66.7
	Week 23	29	18.39	19.08	0.0	33.33	66.7	27	-9.88	31.78	-66.7	0.00	66.7
	Week 26	26	12.82	19.04	0.0	0.00	66.7	24	-18.06	34.02	-100.0	0.00	33.3
	Week 29	24	25.00	29.90	0.0	16.67	100.0	22	-3.03	42.30	-100.0	0.00	100.0
	Week 32	20	13.33	16.75	0.0	0.00	33.3	18	-16.67	34.77	-100.0	-16.67	33.3
	Week 35	17	13.72	16.91	0.0	0.00	33.3	15	-17.78	35.34	-100.0	0.00	33.3
	Week 38	18	22.22	28.01	0.0	0.00	66.7	15	-17.78	39.57	-100.0	0.00	33.3
	Week 41	18	20.37	23.26	0.0	16.67	66.7	16	-14.58	34.36	-100.0	0.00	33.3
	Week 44	16	16.67	17.21	0.0	16.67	33.3	14	-19.05	40.75	-100.0	0.00	33.3
	Week 47	12	16.67	26.59	0.0	0.00	66.7	11	-12.12	22.47	-33.3	0.00	33.3
	Week 50	11	12.12	22.47	0.0	0.00	66.7	9	-18.52	17.57	-33.3	-33.33	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	EV+Pembro (N=146)												
	BASELINE	119	20.73	27.44	0.0	0.00	100.0						
	Week 1	102	22.22	28.27	0.0	0.00	100.0	97	1.72	20.05	-33.3	0.00	66.7
	Week 2	106	17.30	25.71	0.0	0.00	100.0	98	-4.76	25.78	-100.0	0.00	66.7
	Week 3	94	16.31	25.75	0.0	0.00	100.0	88	-4.17	30.66	-100.0	0.00	100.0
	Week 4	101	22.44	30.59	0.0	0.00	100.0	93	0.00	32.60	-100.0	0.00	100.0
	Week 5	96	19.79	26.30	0.0	0.00	100.0	89	-2.25	28.34	-100.0	0.00	66.7
	Week 6	105	17.14	24.51	0.0	0.00	100.0	93	-5.02	30.67	-100.0	0.00	66.7
	Week 7	102	19.28	25.01	0.0	0.00	100.0	89	-4.49	30.23	-100.0	0.00	66.7
	Week 8	101	20.13	27.92	0.0	0.00	100.0	91	-3.30	33.72	-100.0	0.00	100.0
	Week 9	100	15.00	24.33	0.0	0.00	100.0	89	-7.12	29.50	-100.0	0.00	66.7
	Week 10	99	16.50	23.51	0.0	0.00	100.0	87	-6.51	30.43	-100.0	0.00	66.7
	Week 11	95	17.89	23.22	0.0	0.00	100.0	84	-3.57	29.28	-100.0	0.00	66.7
	Week 12	99	13.80	21.83	0.0	0.00	100.0	87	-6.90	25.99	-100.0	0.00	66.7
	Week 14	95	16.14	23.75	0.0	0.00	100.0	84	-6.75	32.22	-100.0	0.00	66.7
	Week 17	97	15.46	23.60	0.0	0.00	100.0	84	-5.95	28.42	-100.0	0.00	66.7
	Week 20	90	15.18	21.87	0.0	0.00	100.0	79	-5.91	30.08	-100.0	0.00	66.7
	Week 23	86	14.73	20.20	0.0	0.00	66.7	74	-4.96	29.55	-100.0	0.00	66.7
	Week 26	83	14.86	20.99	0.0	0.00	100.0	72	-3.24	28.06	-100.0	0.00	66.7
	Week 29	80	17.50	27.03	0.0	0.00	100.0	71	-2.35	31.03	-100.0	0.00	100.0
	Week 32	74	14.41	22.12	0.0	0.00	100.0	66	-3.03	30.23	-100.0	0.00	66.7
	Week 35	73	14.61	20.78	0.0	0.00	100.0	66	-3.03	29.07	-100.0	0.00	66.7
	Week 38	75	14.22	22.04	0.0	0.00	100.0	67	-4.48	28.95	-100.0	0.00	33.3
	Week 41	71	18.31	25.69	0.0	0.00	100.0	64	-2.08	33.00	-100.0	0.00	66.7
	Week 44	64	17.71	25.18	0.0	0.00	100.0	56	0.00	34.82	-100.0	0.00	66.7
	Week 47	56	15.48	23.75	0.0	0.00	100.0	50	-4.67	32.30	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	55	16.97	20.16	0.0	0.00	66.7	48	-1.39	30.72	-66.7	0.00	66.7
	Week 53	55	17.57	23.88	0.0	0.00	100.0	48	-2.78	33.57	-100.0	0.00	66.7
	Week 56	53	17.61	23.21	0.0	0.00	100.0	46	-4.35	27.76	-100.0	0.00	33.3
	Week 59	51	16.34	22.48	0.0	0.00	100.0	43	-3.88	29.28	-100.0	0.00	33.3
	Week 62	42	17.46	23.56	0.0	0.00	100.0	36	2.78	28.03	-66.7	0.00	66.7
	Week 65	31	13.98	18.80	0.0	0.00	66.7	30	-4.45	34.72	-100.0	0.00	66.7
	Week 68	31	17.20	24.15	0.0	0.00	100.0	29	-1.15	35.05	-100.0	0.00	66.7
	Week 71	30	16.67	27.33	0.0	0.00	100.0	28	-2.38	33.86	-100.0	0.00	66.7
	Week 74	29	19.54	24.42	0.0	0.00	100.0	27	3.70	29.72	-66.7	0.00	66.7
	Week 77	26	17.95	23.53	0.0	0.00	100.0	24	-1.39	31.82	-66.7	0.00	33.3
	Week 80	26	16.67	25.39	0.0	0.00	100.0	26	-2.56	32.55	-66.7	0.00	66.7
	Week 83	21	17.46	22.65	0.0	0.00	66.7	21	0.00	42.16	-100.0	0.00	66.7
	Week 86	17	25.49	27.71	0.0	33.33	66.7	17	19.61	35.47	-33.3	33.33	66.7
	Week 89	11	18.18	22.92	0.0	0.00	66.7	11	15.15	27.34	-33.3	0.00	66.7
	Week 92	13	17.95	25.88	0.0	0.00	66.7	13	2.56	31.80	-33.3	0.00	66.7
	Plat+Gem (N=151)												
	BASELINE	123	29.54	34.46	0.0	33.33	100.0						
	Week 1	108	36.42	31.09	0.0	33.33	100.0	103	6.47	32.36	-66.7	0.00	100.0
	Week 2	116	37.07	33.12	0.0	33.33	100.0	105	8.25	32.94	-66.7	0.00	100.0
	Week 3	114	26.02	27.61	0.0	33.33	100.0	103	-1.62	31.79	-66.7	0.00	100.0
	Week 4	116	31.03	28.05	0.0	33.33	100.0	103	3.24	31.83	-66.7	0.00	66.7
	Week 5	119	26.89	25.78	0.0	33.33	100.0	106	-0.32	32.37	-100.0	0.00	100.0
	Week 6	109	25.38	25.22	0.0	33.33	100.0	98	-2.38	36.22	-100.0	0.00	66.7
	Week 7	115	24.35	25.87	0.0	33.33	100.0	105	-2.54	31.25	-66.7	0.00	66.7
	Week 8	111	31.23	28.53	0.0	33.33	100.0	102	4.58	34.80	-100.0	0.00	100.0
	Week 9	107	28.04	27.91	0.0	33.33	100.0	95	0.35	34.55	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	107	27.10	27.90	0.0	33.33	100.0	98	-1.36	33.13	-100.0	0.00	66.7
	Week 11	97	28.18	27.36	0.0	33.33	100.0	87	0.00	33.72	-100.0	0.00	66.7
	Week 12	100	26.00	24.43	0.0	33.33	66.7	88	-3.41	34.29	-100.0	0.00	66.7
	Week 14	99	30.30	26.98	0.0	33.33	100.0	86	3.49	36.17	-100.0	0.00	66.7
	Week 17	94	32.62	30.13	0.0	33.33	100.0	82	5.28	39.36	-100.0	0.00	100.0
	Week 20	84	26.19	27.42	0.0	33.33	100.0	72	-0.46	36.04	-100.0	0.00	66.7
	Week 23	70	14.76	21.71	0.0	0.00	100.0	62	-9.68	32.16	-100.0	0.00	66.7
	Week 26	61	16.94	24.81	0.0	0.00	100.0	55	-7.88	29.37	-66.7	0.00	66.7
	Week 29	59	15.82	23.45	0.0	0.00	100.0	53	-4.40	30.69	-66.7	0.00	100.0
	Week 32	50	17.33	26.29	0.0	0.00	100.0	45	-3.70	36.39	-66.7	0.00	100.0
	Week 35	50	14.67	19.24	0.0	0.00	66.7	44	-6.06	30.73	-66.7	0.00	66.7
	Week 38	46	16.67	26.06	0.0	0.00	66.7	40	-8.33	33.55	-100.0	0.00	66.7
	Week 41	42	19.05	24.58	0.0	0.00	66.7	37	-9.01	37.39	-100.0	0.00	66.7
	Week 44	39	19.66	23.84	0.0	0.00	100.0	34	-6.86	41.67	-100.0	0.00	100.0
	Week 47	33	21.21	28.65	0.0	0.00	100.0	29	-4.60	36.43	-66.7	0.00	100.0
	Week 50	27	20.99	22.92	0.0	33.33	66.7	22	-3.03	33.98	-66.7	0.00	66.7
	Week 53	23	20.29	24.08	0.0	0.00	66.7	20	-6.67	41.32	-100.0	0.00	66.7
	Week 56	20	25.00	32.22	0.0	0.00	100.0	19	1.75	49.03	-100.0	0.00	100.0
	Week 59	17	33.33	37.27	0.0	33.33	100.0	15	4.44	50.18	-100.0	0.00	100.0
	Week 62	14	19.05	21.54	0.0	16.67	66.7	14	-9.53	40.15	-100.0	0.00	33.3
	Week 65	13	28.21	29.96	0.0	33.33	66.7	12	-2.78	36.12	-66.7	0.00	66.7
	Week 68	10	23.33	16.10	0.0	33.33	33.3	10	-3.34	29.19	-33.3	0.00	33.3
	Week 71	10	30.00	24.60	0.0	33.33	66.7	10	3.33	33.15	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	EV+Pembro (N= 56)												
	BASELINE	41	23.58	31.84	0.0	0.00	100.0						
	Week 1	39	27.35	30.47	0.0	33.33	100.0	32	5.21	26.92	-66.7	0.00	100.0
	Week 2	44	32.58	32.54	0.0	33.33	100.0	35	7.62	26.92	-66.7	0.00	66.7
	Week 3	45	19.26	25.11	0.0	0.00	100.0	34	-1.96	29.52	-66.7	0.00	100.0
	Week 4	44	18.94	23.18	0.0	0.00	100.0	36	-0.93	32.35	-66.7	0.00	100.0
	Week 5	41	15.45	22.48	0.0	0.00	66.7	32	-8.33	33.87	-100.0	0.00	66.7
	Week 6	41	13.01	23.43	0.0	0.00	100.0	31	-10.75	24.93	-66.7	0.00	33.3
	Week 7	45	23.70	33.05	0.0	0.00	100.0	35	0.00	37.92	-100.0	0.00	100.0
	Week 8	46	13.04	22.75	0.0	0.00	100.0	33	-5.05	31.31	-100.0	0.00	66.7
	Week 9	42	17.46	24.68	0.0	0.00	100.0	32	-4.17	25.04	-66.7	0.00	33.3
	Week 10	40	17.50	26.14	0.0	0.00	100.0	31	-1.08	23.55	-66.7	0.00	33.3
	Week 11	42	19.05	23.45	0.0	0.00	66.7	31	-1.08	27.87	-66.7	0.00	33.3
	Week 12	43	16.28	23.43	0.0	0.00	100.0	32	-1.04	26.07	-66.7	0.00	66.7
	Week 14	44	18.94	27.28	0.0	0.00	100.0	32	0.00	32.79	-100.0	0.00	66.7
	Week 17	35	13.33	24.52	0.0	0.00	100.0	27	-8.64	30.09	-100.0	0.00	33.3
	Week 20	30	14.44	22.63	0.0	0.00	66.7	24	-5.56	25.38	-100.0	0.00	33.3
	Week 23	31	15.05	28.33	0.0	0.00	100.0	23	-1.45	25.58	-66.7	0.00	33.3
	Week 26	29	12.64	22.56	0.0	0.00	66.7	22	-4.55	23.67	-66.7	0.00	33.3
	Week 29	27	12.35	26.39	0.0	0.00	100.0	22	-9.09	23.42	-66.7	0.00	33.3
	Week 32	28	14.29	26.34	0.0	0.00	100.0	22	-6.06	28.43	-66.7	0.00	33.3
	Week 35	25	9.33	18.05	0.0	0.00	66.7	20	-6.67	31.71	-100.0	0.00	33.3
	Week 38	22	7.58	17.61	0.0	0.00	66.7	19	-12.28	27.69	-100.0	0.00	0.0
	Week 41	24	12.50	21.56	0.0	0.00	66.7	20	-8.33	26.21	-100.0	0.00	33.3
	Week 44	22	15.15	24.62	0.0	0.00	66.7	18	-5.56	26.20	-66.7	0.00	33.3
	Week 47	23	13.04	19.43	0.0	0.00	66.7	20	-10.00	28.82	-100.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	19	12.28	19.91	0.0	0.00	66.7	16	-10.42	23.47	-66.7	0.00	0.0
	Week 53	19	17.54	28.04	0.0	0.00	100.0	15	-8.89	26.63	-66.7	0.00	33.3
	Week 56	19	15.79	28.04	0.0	0.00	66.7	15	-6.67	33.81	-100.0	0.00	33.3
	Week 59	18	22.22	32.34	0.0	0.00	100.0	14	-7.14	39.61	-100.0	0.00	66.7
	Week 62	20	20.00	27.36	0.0	0.00	66.7	16	-4.17	31.92	-66.7	0.00	66.7
	Week 65	12	19.45	30.01	0.0	0.00	66.7	10	-6.67	37.84	-66.7	0.00	66.7
	Week 68	15	22.22	27.22	0.0	0.00	66.7	13	0.00	36.01	-66.7	0.00	66.7
	Week 71	12	19.45	30.01	0.0	0.00	66.7	10	-3.33	39.91	-66.7	0.00	66.7
	Week 77	11	21.21	34.23	0.0	0.00	100.0	9	-7.41	40.06	-66.7	0.00	66.7
	Week 80	10	20.00	28.11	0.0	0.00	66.7	8	-8.33	42.73	-66.7	0.00	66.7
	Plat+Gem (N= 51)												
	BASELINE	42	35.71	34.84	0.0	33.33	100.0						
	Week 1	36	48.15	38.58	0.0	33.33	100.0	36	12.04	33.95	-66.7	0.00	100.0
	Week 2	31	39.78	30.33	0.0	33.33	100.0	30	1.11	34.45	-66.7	0.00	66.7
	Week 3	35	31.43	33.28	0.0	33.33	100.0	33	-4.04	36.09	-66.7	0.00	66.7
	Week 4	34	29.41	30.45	0.0	33.33	100.0	32	-3.13	35.28	-66.7	0.00	66.7
	Week 5	34	30.39	27.67	0.0	33.33	100.0	32	-5.21	30.66	-66.7	0.00	66.7
	Week 6	36	31.48	30.80	0.0	33.33	100.0	33	-2.02	37.21	-66.7	0.00	100.0
	Week 7	33	30.30	30.46	0.0	33.33	100.0	29	2.30	35.56	-66.7	0.00	100.0
	Week 8	34	34.31	27.81	0.0	33.33	100.0	30	3.33	36.46	-66.7	0.00	66.7
	Week 9	34	29.41	32.58	0.0	33.33	100.0	30	-3.33	40.45	-100.0	0.00	66.7
	Week 10	35	30.48	30.65	0.0	33.33	100.0	32	-2.08	39.66	-66.7	0.00	66.7
	Week 11	29	34.48	32.71	0.0	33.33	100.0	27	3.70	39.59	-100.0	0.00	66.7
	Week 12	30	34.44	34.45	0.0	33.33	100.0	27	1.23	41.84	-100.0	0.00	66.7
	Week 14	26	28.20	27.80	0.0	33.33	100.0	23	-2.90	37.49	-100.0	0.00	66.7
	Week 17	26	24.36	27.58	0.0	33.33	100.0	24	-11.11	41.32	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 20	20	16.67	20.23	0.0	0.00	66.7	19	-21.05	38.83	-100.0	0.00	33.3
	Week 23	18	22.22	19.80	0.0	33.33	66.7	18	-14.82	30.73	-66.7	-16.67	33.3
	Week 26	20	10.00	15.67	0.0	0.00	33.3	20	-25.00	32.22	-100.0	-33.33	33.3
	Week 29	18	22.22	28.01	0.0	0.00	66.7	18	-14.81	39.97	-100.0	-33.33	66.7
	Week 32	13	25.64	30.89	0.0	33.33	100.0	13	-7.69	45.45	-100.0	0.00	66.7
	Week 35	12	13.89	17.16	0.0	0.00	33.3	12	-22.22	35.77	-100.0	-16.67	33.3
	Week 38	10	26.67	34.43	0.0	16.67	100.0	10	-10.00	47.27	-100.0	0.00	66.7
	Week 41	10	16.67	23.57	0.0	0.00	66.7	10	-10.00	27.44	-66.7	0.00	33.3
	Week 44	10	30.00	29.19	0.0	33.33	66.7	10	-6.67	40.98	-100.0	0.00	33.3
	Week 47	10	26.67	26.29	0.0	33.33	66.7	10	0.00	22.23	-33.3	0.00	33.3
	Week 56	10	20.00	23.31	0.0	16.67	66.7	10	-6.67	37.84	-100.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Visceral metastases	EV+Pembro (N=148)												
	BASELINE	119	24.37	30.28	0.0	0.00	100.0						
	Week 1	105	25.71	29.69	0.0	33.33	100.0	99	3.37	23.08	-66.7	0.00	100.0
	Week 2	109	22.02	28.41	0.0	0.00	100.0	100	-2.33	27.32	-100.0	0.00	66.7
	Week 3	98	19.39	27.46	0.0	0.00	100.0	88	-3.03	33.00	-100.0	0.00	100.0
	Week 4	103	23.30	30.55	0.0	0.00	100.0	93	-0.36	36.28	-100.0	0.00	100.0
	Week 5	100	20.67	26.71	0.0	0.00	100.0	90	-4.44	32.84	-100.0	0.00	66.7
	Week 6	105	17.46	25.36	0.0	0.00	100.0	90	-7.04	31.00	-100.0	0.00	66.7
	Week 7	108	21.60	28.57	0.0	0.00	100.0	91	-5.49	32.68	-100.0	0.00	100.0
	Week 8	105	20.32	28.31	0.0	0.00	100.0	89	-4.49	34.88	-100.0	0.00	100.0
	Week 9	105	18.41	26.55	0.0	0.00	100.0	91	-6.59	29.49	-100.0	0.00	66.7
	Week 10	101	18.81	26.00	0.0	0.00	100.0	86	-7.75	29.67	-100.0	0.00	33.3
	Week 11	97	21.65	25.02	0.0	0.00	100.0	83	-2.41	30.26	-100.0	0.00	66.7
	Week 12	100	16.00	23.92	0.0	0.00	100.0	85	-7.06	28.22	-100.0	0.00	66.7
	Week 14	102	18.63	25.94	0.0	0.00	100.0	87	-6.90	34.15	-100.0	0.00	66.7
	Week 17	96	15.97	24.65	0.0	0.00	100.0	81	-7.82	30.85	-100.0	0.00	66.7
	Week 20	87	15.32	22.04	0.0	0.00	100.0	76	-7.90	31.21	-100.0	0.00	66.7
	Week 23	85	15.69	22.18	0.0	0.00	100.0	71	-5.63	31.36	-100.0	0.00	66.7
	Week 26	79	15.19	20.53	0.0	0.00	66.7	66	-4.55	29.17	-100.0	0.00	66.7
	Week 29	72	18.06	26.79	0.0	0.00	100.0	64	-5.73	31.74	-100.0	0.00	66.7
	Week 32	71	16.90	25.74	0.0	0.00	100.0	62	-5.38	33.71	-100.0	0.00	66.7
	Week 35	70	15.24	20.99	0.0	0.00	100.0	63	-4.23	32.51	-100.0	0.00	66.7
	Week 38	70	14.29	22.39	0.0	0.00	100.0	63	-7.94	32.08	-100.0	0.00	33.3
	Week 41	66	19.19	26.19	0.0	0.00	100.0	60	-4.45	33.31	-100.0	0.00	66.7
	Week 44	59	20.34	26.27	0.0	0.00	100.0	53	-1.89	36.05	-100.0	0.00	66.7
	Week 47	52	18.59	24.18	0.0	0.00	100.0	48	-7.64	36.54	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	49	17.69	20.53	0.0	0.00	66.7	43	-6.20	33.54	-66.7	0.00	66.7
	Week 53	50	20.67	25.10	0.0	0.00	100.0	44	-6.06	36.14	-100.0	0.00	66.7
	Week 56	45	21.48	26.74	0.0	0.00	100.0	39	-6.84	33.49	-100.0	0.00	33.3
	Week 59	44	21.97	24.84	0.0	33.33	100.0	38	-5.26	35.11	-100.0	0.00	33.3
	Week 62	38	21.93	26.02	0.0	16.67	100.0	33	1.01	31.72	-66.7	0.00	66.7
	Week 65	25	18.67	21.69	0.0	0.00	66.7	24	-6.95	40.50	-100.0	0.00	66.7
	Week 68	31	19.35	25.49	0.0	0.00	100.0	29	-3.45	37.10	-100.0	0.00	66.7
	Week 71	27	19.75	29.61	0.0	0.00	100.0	25	-5.33	39.30	-100.0	0.00	66.7
	Week 74	23	21.74	25.84	0.0	33.33	100.0	22	1.51	37.76	-66.7	0.00	66.7
	Week 77	24	18.05	24.03	0.0	0.00	100.0	23	-5.80	35.75	-66.7	0.00	33.3
	Week 80	22	21.21	26.32	0.0	16.67	100.0	22	-4.55	38.89	-66.7	0.00	66.7
	Week 83	19	17.54	20.39	0.0	0.00	66.7	19	-5.26	44.81	-100.0	0.00	66.7
	Week 86	14	35.71	24.34	0.0	33.33	66.7	14	23.81	40.15	-66.7	33.33	66.7
	Week 89	10	16.67	23.57	0.0	0.00	66.7	10	10.00	35.31	-66.7	0.00	66.7
	Week 92	11	21.21	26.97	0.0	0.00	66.7	11	6.06	35.96	-66.7	0.00	66.7
	Plat+Gem (N=157)												
	BASELINE	128	33.85	36.22	0.0	33.33	100.0						
	Week 1	111	39.34	34.58	0.0	33.33	100.0	107	4.36	33.36	-66.7	0.00	100.0
	Week 2	110	39.39	33.54	0.0	33.33	100.0	102	5.56	35.13	-66.7	0.00	100.0
	Week 3	112	28.57	31.28	0.0	33.33	100.0	103	-4.85	34.43	-66.7	0.00	100.0
	Week 4	112	31.25	29.78	0.0	33.33	100.0	102	-1.31	33.47	-66.7	0.00	66.7
	Week 5	113	25.96	26.63	0.0	33.33	100.0	103	-6.15	32.59	-100.0	0.00	100.0
	Week 6	107	25.54	27.31	0.0	33.33	100.0	98	-6.12	35.93	-100.0	0.00	66.7
	Week 7	109	24.46	27.08	0.0	33.33	100.0	100	-5.67	30.72	-66.7	0.00	66.7
	Week 8	106	32.39	29.26	0.0	33.33	100.0	98	2.38	36.53	-100.0	0.00	100.0
	Week 9	105	28.89	29.62	0.0	33.33	100.0	94	-2.48	37.31	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	104	27.56	29.90	0.0	33.33	100.0	96	-5.21	35.65	-100.0	0.00	66.7
	Week 11	91	29.30	28.90	0.0	33.33	100.0	83	-2.41	36.36	-100.0	0.00	66.7
	Week 12	94	25.53	26.52	0.0	33.33	100.0	84	-7.94	35.33	-100.0	0.00	66.7
	Week 14	90	28.89	27.46	0.0	33.33	100.0	79	-1.69	39.19	-100.0	0.00	66.7
	Week 17	90	28.15	28.67	0.0	33.33	100.0	80	-4.58	39.95	-100.0	0.00	100.0
	Week 20	74	21.62	24.32	0.0	33.33	100.0	64	-12.50	36.37	-100.0	0.00	66.7
	Week 23	63	14.28	21.35	0.0	0.00	100.0	58	-14.94	31.33	-100.0	0.00	66.7
	Week 26	55	13.33	22.77	0.0	0.00	100.0	52	-16.67	30.61	-100.0	0.00	33.3
	Week 29	53	15.72	24.11	0.0	0.00	100.0	50	-8.67	34.87	-100.0	0.00	100.0
	Week 32	42	13.49	26.61	0.0	0.00	100.0	40	-10.83	38.78	-100.0	0.00	100.0
	Week 35	39	11.11	17.66	0.0	0.00	66.7	36	-13.89	33.21	-100.0	0.00	66.7
	Week 38	37	16.22	27.91	0.0	0.00	100.0	34	-12.75	39.37	-100.0	0.00	66.7
	Week 41	33	14.14	23.62	0.0	0.00	66.7	31	-13.98	39.23	-100.0	0.00	66.7
	Week 44	32	17.71	25.38	0.0	0.00	100.0	30	-11.11	44.92	-100.0	0.00	100.0
	Week 47	28	20.24	22.84	0.0	33.33	100.0	26	-6.41	29.84	-66.7	0.00	33.3
	Week 50	22	16.67	19.92	0.0	0.00	66.7	20	-6.67	27.78	-66.7	0.00	33.3
	Week 53	19	14.03	20.23	0.0	0.00	66.7	17	-11.77	35.24	-100.0	0.00	33.3
	Week 56	18	18.52	26.13	0.0	0.00	66.7	17	-7.84	44.92	-100.0	0.00	66.7
	Week 59	13	23.08	28.50	0.0	0.00	66.7	12	-8.33	51.49	-100.0	0.00	66.7
	Week 62	11	18.18	22.92	0.0	0.00	66.7	11	-15.15	47.99	-100.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Lymph node only	EV+Pembro (N= 43)												
	BASELINE	33	11.11	19.84	0.0	0.00	66.7						
	Week 1	30	17.78	27.31	0.0	0.00	100.0	24	1.39	15.48	-33.3	0.00	33.3
	Week 2	34	22.55	31.48	0.0	0.00	100.0	27	2.47	24.33	-33.3	0.00	66.7
	Week 3	35	13.33	20.13	0.0	0.00	66.7	28	-2.38	20.14	-33.3	0.00	33.3
	Week 4	36	15.74	23.21	0.0	0.00	100.0	30	0.00	19.57	-33.3	0.00	33.3
	Week 5	33	13.13	20.31	0.0	0.00	66.7	27	-2.47	18.32	-33.3	0.00	33.3
	Week 6	34	10.78	19.63	0.0	0.00	66.7	28	-4.76	26.78	-66.7	0.00	66.7
	Week 7	34	18.63	26.20	0.0	0.00	100.0	28	4.76	32.35	-33.3	0.00	100.0
	Week 8	35	12.38	21.52	0.0	0.00	66.7	29	0.00	26.73	-33.3	0.00	66.7
	Week 9	30	7.78	14.34	0.0	0.00	33.3	24	-4.17	24.69	-66.7	0.00	33.3
	Week 10	31	10.75	18.03	0.0	0.00	66.7	26	1.28	25.79	-33.3	0.00	66.7
	Week 11	34	10.78	15.83	0.0	0.00	33.3	27	-2.47	22.50	-33.3	0.00	33.3
	Week 12	35	9.52	17.28	0.0	0.00	66.7	28	-3.57	18.90	-33.3	0.00	33.3
	Week 14	30	10.00	19.87	0.0	0.00	66.7	23	0.00	22.47	-33.3	0.00	66.7
	Week 17	30	10.00	21.71	0.0	0.00	100.0	24	-4.17	17.89	-33.3	0.00	33.3
	Week 20	27	13.58	23.13	0.0	0.00	66.7	21	-1.59	19.65	-33.3	0.00	33.3
	Week 23	27	12.35	24.72	0.0	0.00	100.0	21	0.00	18.26	-33.3	0.00	33.3
	Week 26	27	11.11	24.46	0.0	0.00	100.0	22	-3.03	22.79	-33.3	0.00	66.7
	Week 29	28	8.33	23.35	0.0	0.00	100.0	23	-5.80	12.92	-33.3	0.00	0.0
	Week 32	24	5.56	12.69	0.0	0.00	33.3	20	-3.33	14.91	-33.3	0.00	33.3
	Week 35	22	7.58	17.61	0.0	0.00	66.7	18	-3.70	19.43	-33.3	0.00	33.3
	Week 38	21	4.76	15.94	0.0	0.00	66.7	17	-5.88	13.10	-33.3	0.00	0.0
	Week 41	22	7.58	17.61	0.0	0.00	66.7	17	-3.92	20.01	-33.3	0.00	33.3
	Week 44	22	9.09	21.04	0.0	0.00	66.7	16	0.00	24.34	-33.3	0.00	66.7
	Week 47	21	4.76	15.94	0.0	0.00	66.7	16	-6.25	13.44	-33.3	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	10.00	19.04	0.0	0.00	66.7	16	0.00	17.21	-33.3	0.00	33.3
	Week 53	18	9.26	25.06	0.0	0.00	100.0	14	-4.76	17.82	-33.3	0.00	33.3
	Week 56	21	7.94	17.97	0.0	0.00	66.7	17	-5.88	17.62	-33.3	0.00	33.3
	Week 59	21	9.52	26.13	0.0	0.00	100.0	16	-4.17	23.96	-33.3	0.00	66.7
	Week 62	19	10.53	22.37	0.0	0.00	66.7	15	-2.22	23.46	-33.3	0.00	66.7
	Week 65	16	10.42	23.47	0.0	0.00	66.7	14	-2.38	24.33	-33.3	0.00	66.7
	Week 68	13	15.38	25.88	0.0	0.00	66.7	11	3.03	31.46	-33.3	0.00	66.7
	Week 71	13	10.26	25.04	0.0	0.00	66.7	11	0.00	25.82	-33.3	0.00	66.7
	Week 74	13	10.26	16.01	0.0	0.00	33.3	11	-3.03	17.98	-33.3	0.00	33.3
	Week 77	13	20.51	32.03	0.0	0.00	100.0	10	3.33	29.19	-33.3	0.00	66.7
	Week 80	13	12.82	25.60	0.0	0.00	66.7	11	-3.03	27.71	-33.3	0.00	66.7
	Week 83	11	12.12	22.47	0.0	0.00	66.7	10	0.00	31.43	-33.3	0.00	66.7
	Week 86	11	12.12	22.47	0.0	0.00	66.7	10	3.33	33.15	-33.3	0.00	66.7
	Plat+Gem (N= 37)												
	BASELINE	29	20.69	27.33	0.0	0.00	100.0						
	Week 1	26	41.02	30.27	0.0	33.33	100.0	25	21.33	28.68	-33.3	33.33	66.7
	Week 2	30	28.89	29.99	0.0	33.33	100.0	26	7.69	28.76	-66.7	0.00	66.7
	Week 3	30	21.11	20.50	0.0	33.33	66.7	26	5.13	26.15	-33.3	0.00	33.3
	Week 4	32	30.21	24.48	0.0	33.33	100.0	27	14.81	28.25	-33.3	0.00	66.7
	Week 5	33	31.31	24.92	0.0	33.33	100.0	28	11.90	26.00	-66.7	0.00	66.7
	Week 6	32	29.17	25.05	0.0	33.33	100.0	27	8.64	35.32	-66.7	0.00	100.0
	Week 7	31	29.03	26.86	0.0	33.33	100.0	26	12.82	36.61	-66.7	0.00	100.0
	Week 8	32	30.21	27.25	0.0	33.33	66.7	27	11.11	30.66	-66.7	0.00	66.7
	Week 9	30	26.67	28.23	0.0	33.33	100.0	25	4.00	30.91	-66.7	0.00	66.7
	Week 10	30	27.78	26.38	0.0	33.33	66.7	26	8.97	32.05	-66.7	0.00	66.7
	Week 11	29	31.03	30.77	0.0	33.33	100.0	25	12.00	30.25	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.21.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 12	28	33.33	30.09	0.0	33.33	100.0	23	13.04	35.87	-66.7	33.33	66.7
	Week 14	28	28.57	26.78	0.0	33.33	66.7	23	10.15	27.41	-66.7	0.00	66.7
	Week 17	25	37.33	33.78	0.0	33.33	100.0	21	20.63	37.23	-66.7	33.33	100.0
	Week 20	23	28.98	28.96	0.0	33.33	100.0	20	13.33	34.88	-66.7	0.00	66.7
	Week 23	20	20.00	22.69	0.0	16.67	66.7	17	0.00	31.18	-66.7	0.00	66.7
	Week 26	21	19.05	24.88	0.0	0.00	100.0	18	-1.85	31.25	-66.7	0.00	66.7
	Week 29	19	24.56	26.86	0.0	33.33	66.7	16	2.08	30.96	-66.7	0.00	33.3
	Week 32	18	29.63	27.75	0.0	33.33	100.0	15	11.11	34.89	-66.7	0.00	66.7
	Week 35	19	19.30	20.23	0.0	33.33	66.7	16	0.00	29.81	-66.7	0.00	33.3
	Week 38	15	22.22	29.99	0.0	0.00	66.7	12	0.00	28.43	-66.7	0.00	33.3
	Week 41	15	26.67	25.82	0.0	33.33	66.7	12	0.00	24.62	-66.7	0.00	33.3
	Week 44	14	28.57	25.68	0.0	33.33	66.7	11	3.03	31.47	-33.3	0.00	66.7
	Week 47	12	22.22	35.77	0.0	0.00	100.0	10	0.00	44.45	-66.7	0.00	100.0
	Week 50	11	27.27	29.13	0.0	33.33	66.7	8	4.17	41.55	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
EV+Pembro (N=240)												
BASELINE	206	16.50	26.08	0.0	0.00	100.0						
Week 1	190	16.67	25.60	0.0	0.00	100.0	184	0.72	16.70	-66.7	0.00	66.7
Week 2	203	14.78	23.70	0.0	0.00	100.0	189	-2.12	19.02	-100.0	0.00	33.3
Week 3	198	17.34	26.38	0.0	0.00	100.0	182	0.37	20.73	-100.0	0.00	66.7
Week 4	194	16.49	25.45	0.0	0.00	100.0	179	-0.74	21.19	-100.0	0.00	66.7
Week 5	190	15.61	24.88	0.0	0.00	100.0	173	-1.35	23.12	-100.0	0.00	100.0
Week 6	188	19.33	29.63	0.0	0.00	100.0	170	1.76	23.57	-100.0	0.00	100.0
Week 7	195	17.09	26.73	0.0	0.00	100.0	176	-0.38	23.36	-100.0	0.00	100.0
Week 8	191	19.89	28.40	0.0	0.00	100.0	171	2.53	25.05	-100.0	0.00	100.0
Week 9	197	18.61	27.62	0.0	0.00	100.0	180	1.30	22.66	-66.7	0.00	100.0
Week 10	191	20.07	28.79	0.0	0.00	100.0	175	2.67	23.82	-100.0	0.00	100.0
Week 11	194	19.07	28.13	0.0	0.00	100.0	175	0.57	24.62	-100.0	0.00	100.0
Week 12	186	18.46	28.37	0.0	0.00	100.0	171	0.78	24.77	-100.0	0.00	100.0
Week 14	185	20.72	30.05	0.0	0.00	100.0	167	2.79	23.55	-66.7	0.00	100.0
Week 17	178	18.35	27.22	0.0	0.00	100.0	162	1.44	23.01	-100.0	0.00	100.0
Week 20	167	20.36	29.46	0.0	0.00	100.0	154	3.68	26.01	-100.0	0.00	100.0
Week 23	162	19.14	26.48	0.0	0.00	100.0	151	1.77	23.03	-100.0	0.00	100.0
Week 26	156	19.66	28.05	0.0	0.00	100.0	144	1.85	23.58	-100.0	0.00	100.0
Week 29	157	18.05	25.46	0.0	0.00	100.0	145	1.84	24.15	-100.0	0.00	100.0
Week 32	135	19.51	28.62	0.0	0.00	100.0	125	4.53	24.81	-66.7	0.00	100.0
Week 35	132	20.45	28.13	0.0	0.00	100.0	122	5.46	22.42	-33.3	0.00	100.0
Week 38	132	21.46	28.57	0.0	0.00	100.0	124	5.11	24.06	-100.0	0.00	100.0
Week 41	129	21.45	28.20	0.0	0.00	100.0	119	5.60	25.42	-100.0	0.00	100.0
Week 44	108	18.21	27.49	0.0	0.00	100.0	100	4.00	22.86	-66.7	0.00	100.0
Week 47	100	20.67	28.34	0.0	0.00	100.0	94	6.03	26.76	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	89	19.10	27.93	0.0	0.00	100.0	84	5.16	23.42	-33.3	0.00	100.0
Week 53	79	21.10	27.83	0.0	0.00	100.0	74	7.66	25.61	-66.7	0.00	100.0
Week 56	81	19.75	28.76	0.0	0.00	100.0	76	4.39	22.00	-33.3	0.00	100.0
Week 59	72	22.22	30.13	0.0	0.00	100.0	68	6.86	25.47	-33.3	0.00	100.0
Week 62	65	16.92	27.72	0.0	0.00	100.0	63	4.23	23.56	-33.3	0.00	100.0
Week 65	58	25.29	32.03	0.0	0.00	100.0	54	8.03	25.02	-33.3	0.00	100.0
Week 68	53	21.38	32.09	0.0	0.00	100.0	52	5.13	27.52	-33.3	0.00	100.0
Week 71	51	22.22	33.78	0.0	0.00	100.0	49	5.44	27.51	-33.3	0.00	100.0
Week 74	47	23.40	32.54	0.0	0.00	100.0	46	8.70	30.98	-33.3	0.00	100.0
Week 77	44	25.76	31.22	0.0	16.67	100.0	42	10.32	29.89	-33.3	0.00	100.0
Week 80	40	25.83	30.65	0.0	16.67	100.0	37	9.91	27.06	-33.3	0.00	100.0
Week 83	37	27.03	34.10	0.0	0.00	100.0	35	9.52	29.78	-33.3	0.00	100.0
Week 86	34	24.51	29.94	0.0	0.00	100.0	31	6.45	29.09	-33.3	0.00	100.0
Week 89	33	31.31	33.27	0.0	33.33	100.0	31	13.98	29.53	-33.3	0.00	100.0
Week 92	27	22.22	30.66	0.0	0.00	100.0	25	9.33	28.09	-33.3	0.00	100.0
Week 95	22	33.33	37.09	0.0	33.33	100.0	21	15.87	30.95	-33.3	0.00	100.0
Week 98	18	22.22	25.57	0.0	16.67	66.7	17	7.84	18.74	-33.3	0.00	33.3
Week 101	14	28.57	38.91	0.0	0.00	100.0	14	19.05	36.31	0.0	0.00	100.0
Week 104	10	20.00	32.20	0.0	0.00	100.0	10	13.33	32.20	0.0	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Plat+Gem (N=242)												
BASELINE	188	15.07	23.95	0.0	0.00	100.0						
Week 1	173	16.76	27.29	0.0	0.00	100.0	158	2.53	20.10	-66.7	0.00	100.0
Week 2	171	16.37	27.14	0.0	0.00	100.0	151	2.43	24.37	-66.7	0.00	100.0
Week 3	184	14.13	22.97	0.0	0.00	100.0	162	0.21	20.85	-100.0	0.00	66.7
Week 4	183	15.85	24.16	0.0	0.00	100.0	156	1.50	21.20	-66.7	0.00	66.7
Week 5	187	16.40	24.53	0.0	0.00	100.0	156	2.99	21.54	-100.0	0.00	100.0
Week 6	174	16.47	24.77	0.0	0.00	100.0	149	4.03	22.90	-100.0	0.00	66.7
Week 7	186	16.13	25.76	0.0	0.00	100.0	157	4.03	23.37	-66.7	0.00	66.7
Week 8	167	16.17	25.05	0.0	0.00	100.0	144	4.40	22.73	-66.7	0.00	100.0
Week 9	177	16.20	23.60	0.0	0.00	100.0	150	4.22	20.54	-33.3	0.00	66.7
Week 10	166	17.47	24.81	0.0	0.00	100.0	139	4.08	24.89	-66.7	0.00	66.7
Week 11	168	17.66	24.99	0.0	0.00	100.0	143	4.66	24.58	-100.0	0.00	66.7
Week 12	159	18.24	24.22	0.0	0.00	100.0	138	4.59	25.21	-100.0	0.00	66.7
Week 14	153	18.95	25.00	0.0	0.00	100.0	128	5.99	25.25	-66.7	0.00	66.7
Week 17	155	17.20	25.30	0.0	0.00	100.0	130	6.41	25.28	-66.7	0.00	100.0
Week 20	126	17.99	26.55	0.0	0.00	100.0	110	5.15	23.54	-66.7	0.00	66.7
Week 23	115	17.39	25.11	0.0	0.00	100.0	97	5.50	25.77	-66.7	0.00	100.0
Week 26	108	16.97	25.17	0.0	0.00	100.0	95	3.16	25.76	-66.7	0.00	66.7
Week 29	100	15.00	24.79	0.0	0.00	100.0	86	2.33	20.95	-33.3	0.00	66.7
Week 32	83	18.87	26.64	0.0	0.00	100.0	76	4.82	22.90	-33.3	0.00	66.7
Week 35	76	16.23	24.64	0.0	0.00	100.0	69	2.90	19.59	-33.3	0.00	66.7
Week 38	74	14.86	24.76	0.0	0.00	100.0	65	2.05	22.73	-66.7	0.00	66.7
Week 41	65	17.44	26.42	0.0	0.00	100.0	56	4.76	23.29	-66.7	0.00	66.7
Week 44	60	16.11	22.54	0.0	0.00	100.0	53	3.77	23.26	-66.7	0.00	66.7
Week 47	56	14.88	20.02	0.0	0.00	66.7	49	2.72	23.41	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	51	20.26	25.01	0.0	0.00	100.0	47	5.67	24.39	-66.7	0.00	66.7
Week 53	46	15.94	21.93	0.0	0.00	66.7	42	4.76	22.78	-66.7	0.00	66.7
Week 56	39	18.80	25.13	0.0	0.00	100.0	34	5.88	23.88	-33.3	0.00	66.7
Week 59	37	9.91	15.44	0.0	0.00	33.3	33	0.00	18.63	-33.3	0.00	33.3
Week 62	32	14.58	20.63	0.0	0.00	66.7	29	3.45	22.44	-33.3	0.00	66.7
Week 65	30	11.11	15.98	0.0	0.00	33.3	26	2.56	18.67	-33.3	0.00	33.3
Week 68	25	10.67	18.56	0.0	0.00	66.7	21	3.17	20.83	-33.3	0.00	33.3
Week 71	22	16.67	24.67	0.0	0.00	100.0	19	8.77	29.06	-33.3	0.00	100.0
Week 74	21	14.28	24.88	0.0	0.00	100.0	18	5.56	30.78	-33.3	0.00	100.0
Week 77	18	12.96	20.26	0.0	0.00	66.7	15	0.00	21.82	-33.3	0.00	33.3
Week 80	14	9.52	15.63	0.0	0.00	33.3	13	-5.13	18.49	-33.3	0.00	33.3
Week 83	13	12.82	16.88	0.0	0.00	33.3	12	-2.78	17.16	-33.3	0.00	33.3
Week 86	12	13.89	22.29	0.0	0.00	66.7	11	0.00	21.08	-33.3	0.00	33.3
Week 89	11	12.12	16.82	0.0	0.00	33.3	10	-3.33	18.92	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Present	EV+Pembro (N= 48)												
	BASELINE	39	16.24	24.03	0.0	0.00	66.7						
	Week 1	32	18.75	29.25	0.0	0.00	100.0	32	2.08	18.81	-33.3	0.00	66.7
	Week 2	37	13.51	21.46	0.0	0.00	100.0	33	-4.04	20.00	-66.7	0.00	33.3
	Week 3	34	19.61	24.78	0.0	0.00	100.0	29	1.15	20.86	-33.3	0.00	33.3
	Week 4	36	18.52	25.75	0.0	0.00	100.0	31	1.07	23.54	-33.3	0.00	66.7
	Week 5	30	15.56	22.71	0.0	0.00	66.7	24	-2.78	25.85	-66.7	0.00	66.7
	Week 6	31	22.58	33.76	0.0	0.00	100.0	25	8.00	30.85	-33.3	0.00	100.0
	Week 7	34	19.61	26.10	0.0	0.00	100.0	28	-1.19	16.93	-33.3	0.00	33.3
	Week 8	35	22.86	33.11	0.0	0.00	100.0	30	6.67	29.56	-33.3	0.00	100.0
	Week 9	34	23.53	29.05	0.0	0.00	100.0	30	6.67	28.23	-33.3	0.00	100.0
	Week 10	34	23.53	33.36	0.0	0.00	100.0	30	7.78	28.61	-33.3	0.00	100.0
	Week 11	33	27.27	34.82	0.0	0.00	100.0	28	9.52	31.24	-33.3	0.00	100.0
	Week 12	33	21.21	33.14	0.0	0.00	100.0	29	3.45	36.02	-66.7	0.00	100.0
	Week 14	31	21.51	31.68	0.0	0.00	100.0	26	2.56	35.18	-66.7	0.00	100.0
	Week 17	31	17.20	28.38	0.0	0.00	100.0	25	0.00	25.46	-33.3	0.00	100.0
	Week 20	27	22.22	33.33	0.0	0.00	100.0	24	5.56	33.57	-33.3	0.00	100.0
	Week 23	26	24.36	32.05	0.0	0.00	100.0	23	10.14	30.87	-33.3	0.00	100.0
	Week 26	25	18.67	30.55	0.0	0.00	100.0	22	1.52	28.13	-33.3	0.00	100.0
	Week 29	23	18.84	29.86	0.0	0.00	100.0	22	4.55	27.79	-33.3	0.00	100.0
	Week 32	21	19.05	34.27	0.0	0.00	100.0	19	3.51	29.18	-33.3	0.00	100.0
	Week 35	19	22.81	38.57	0.0	0.00	100.0	17	7.84	34.42	-33.3	0.00	100.0
	Week 38	18	27.78	40.02	0.0	0.00	100.0	17	11.77	31.05	-33.3	0.00	100.0
	Week 41	20	16.67	29.62	0.0	0.00	100.0	19	5.26	31.94	-33.3	0.00	100.0
	Week 44	17	17.65	29.15	0.0	0.00	100.0	15	4.44	30.52	-33.3	0.00	100.0
	Week 47	18	27.78	34.77	0.0	16.67	100.0	16	12.50	34.16	-33.3	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	12	16.67	33.33	0.0	0.00	100.0	11	6.06	35.96	-33.3	0.00	100.0
	Week 53	12	16.67	33.33	0.0	0.00	100.0	11	9.09	39.70	-33.3	0.00	100.0
	Week 56	13	25.64	38.86	0.0	0.00	100.0	12	11.11	38.49	-33.3	0.00	100.0
	Week 59	12	19.44	33.21	0.0	0.00	100.0	11	6.06	35.96	-33.3	0.00	100.0
	Week 62	10	13.33	32.20	0.0	0.00	100.0	9	3.70	38.89	-33.3	0.00	100.0
	Week 65	10	23.33	41.72	0.0	0.00	100.0	9	7.41	46.48	-33.3	0.00	100.0
	Plat+Gem (N= 48)												
	BASELINE	33	15.15	25.13	0.0	0.00	100.0						
	Week 1	31	15.05	20.80	0.0	0.00	66.7	27	2.47	20.52	-66.7	0.00	33.3
	Week 2	29	17.24	26.16	0.0	0.00	100.0	24	1.39	31.82	-66.7	0.00	100.0
	Week 3	32	14.58	23.85	0.0	0.00	66.7	27	0.00	33.33	-100.0	0.00	66.7
	Week 4	32	16.67	25.40	0.0	0.00	100.0	24	0.00	29.49	-66.7	0.00	66.7
	Week 5	36	13.89	21.64	0.0	0.00	66.7	28	0.00	25.66	-100.0	0.00	33.3
	Week 6	35	18.09	26.00	0.0	0.00	100.0	27	4.94	30.25	-100.0	0.00	66.7
	Week 7	38	14.03	24.05	0.0	0.00	100.0	29	1.15	22.68	-66.7	0.00	33.3
	Week 8	31	17.20	25.63	0.0	0.00	100.0	25	8.00	25.96	-33.3	0.00	100.0
	Week 9	32	14.58	20.63	0.0	0.00	66.7	25	4.00	20.00	-33.3	0.00	33.3
	Week 10	34	17.65	22.07	0.0	0.00	66.7	26	3.85	27.21	-66.7	0.00	66.7
	Week 11	30	15.55	24.34	0.0	0.00	100.0	24	0.00	31.08	-100.0	0.00	66.7
	Week 12	28	15.48	23.10	0.0	0.00	66.7	23	1.45	32.53	-100.0	0.00	66.7
	Week 14	26	23.08	26.28	0.0	33.33	100.0	21	9.52	28.17	-33.3	0.00	66.7
	Week 17	30	17.78	25.87	0.0	0.00	100.0	25	6.67	23.57	-33.3	0.00	66.7
	Week 20	23	17.39	22.18	0.0	0.00	66.7	21	3.17	23.34	-33.3	0.00	33.3
	Week 23	22	16.67	22.42	0.0	0.00	66.7	19	7.02	23.78	-33.3	0.00	66.7
	Week 26	19	14.03	20.23	0.0	0.00	66.7	18	1.85	17.98	-33.3	0.00	33.3
	Week 29	16	10.42	15.96	0.0	0.00	33.3	14	-2.38	15.82	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 32	11	18.18	22.92	0.0	0.00	66.7	11	3.03	17.98	-33.3	0.00	33.3
	Week 35	10	6.67	14.05	0.0	0.00	33.3	9	0.00	16.67	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Absent	EV+Pembro (N=192)												
	BASELINE	167	16.57	26.60	0.0	0.00	100.0						
	Week 1	158	16.24	24.88	0.0	0.00	100.0	152	0.44	16.27	-66.7	0.00	66.7
	Week 2	166	15.06	24.22	0.0	0.00	100.0	156	-1.71	18.85	-100.0	0.00	33.3
	Week 3	164	16.87	26.75	0.0	0.00	100.0	153	0.22	20.77	-100.0	0.00	66.7
	Week 4	158	16.03	25.44	0.0	0.00	100.0	148	-1.13	20.73	-100.0	0.00	66.7
	Week 5	160	15.62	25.33	0.0	0.00	100.0	149	-1.12	22.73	-100.0	0.00	100.0
	Week 6	157	18.68	28.83	0.0	0.00	100.0	145	0.69	22.04	-100.0	0.00	100.0
	Week 7	161	16.56	26.91	0.0	0.00	100.0	148	-0.23	24.43	-100.0	0.00	100.0
	Week 8	156	19.23	27.31	0.0	0.00	100.0	141	1.65	24.01	-100.0	0.00	100.0
	Week 9	163	17.59	27.30	0.0	0.00	100.0	150	0.22	21.33	-66.7	0.00	100.0
	Week 10	157	19.32	27.77	0.0	0.00	100.0	145	1.61	22.68	-100.0	0.00	100.0
	Week 11	161	17.39	26.38	0.0	0.00	100.0	147	-1.13	22.89	-100.0	0.00	66.7
	Week 12	153	17.86	27.31	0.0	0.00	100.0	142	0.23	21.92	-100.0	0.00	100.0
	Week 14	154	20.56	29.81	0.0	0.00	100.0	141	2.84	20.89	-66.7	0.00	100.0
	Week 17	147	18.59	27.07	0.0	0.00	100.0	137	1.70	22.62	-100.0	0.00	100.0
	Week 20	140	20.00	28.78	0.0	0.00	100.0	130	3.33	24.50	-100.0	0.00	100.0
	Week 23	136	18.14	25.29	0.0	0.00	100.0	128	0.26	21.12	-100.0	0.00	33.3
	Week 26	131	19.85	27.67	0.0	0.00	100.0	122	1.91	22.80	-100.0	0.00	66.7
	Week 29	134	17.91	24.75	0.0	0.00	100.0	123	1.35	23.53	-100.0	0.00	66.7
	Week 32	114	19.59	27.63	0.0	0.00	100.0	106	4.72	24.10	-66.7	0.00	66.7
	Week 35	113	20.06	26.18	0.0	0.00	100.0	105	5.08	20.03	-33.3	0.00	66.7
	Week 38	114	20.47	26.43	0.0	0.00	100.0	107	4.05	22.76	-100.0	0.00	66.7
	Week 41	109	22.32	27.98	0.0	0.00	100.0	100	5.67	24.18	-100.0	0.00	66.7
	Week 44	91	18.31	27.34	0.0	0.00	100.0	85	3.92	21.46	-66.7	0.00	66.7
	Week 47	82	19.11	26.72	0.0	0.00	100.0	78	4.70	25.04	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	77	19.48	27.23	0.0	0.00	100.0	73	5.02	21.28	-33.3	0.00	66.7
	Week 53	67	21.89	26.94	0.0	0.00	100.0	63	7.41	22.75	-66.7	0.00	66.7
	Week 56	68	18.63	26.63	0.0	0.00	100.0	64	3.13	17.54	-33.3	0.00	66.7
	Week 59	60	22.78	29.75	0.0	0.00	100.0	57	7.02	23.35	-33.3	0.00	66.7
	Week 62	55	17.58	27.11	0.0	0.00	100.0	54	4.32	20.52	-33.3	0.00	66.7
	Week 65	48	25.69	30.16	0.0	16.67	100.0	45	8.15	19.01	-33.3	0.00	66.7
	Week 68	46	21.01	31.71	0.0	0.00	100.0	45	5.19	24.57	-33.3	0.00	100.0
	Week 71	44	22.73	33.54	0.0	0.00	100.0	42	5.56	24.32	-33.3	0.00	100.0
	Week 74	40	24.17	32.01	0.0	0.00	100.0	39	9.40	28.56	-33.3	0.00	100.0
	Week 77	38	24.56	29.70	0.0	16.67	100.0	36	10.19	26.21	-33.3	0.00	100.0
	Week 80	35	23.81	28.67	0.0	0.00	100.0	32	9.38	21.14	-33.3	0.00	66.7
	Week 83	32	23.96	30.80	0.0	0.00	100.0	30	7.78	22.63	-33.3	0.00	66.7
	Week 86	29	24.14	28.03	0.0	0.00	66.7	26	6.41	23.13	-33.3	0.00	66.7
	Week 89	29	31.03	32.04	0.0	33.33	100.0	27	14.81	23.27	-33.3	0.00	66.7
	Week 92	24	20.83	27.47	0.0	0.00	100.0	22	6.06	22.15	-33.3	0.00	66.7
	Week 95	20	26.67	31.72	0.0	16.67	100.0	19	8.77	21.78	-33.3	0.00	66.7
	Week 98	18	22.22	25.57	0.0	16.67	66.7	17	7.84	18.74	-33.3	0.00	33.3
	Week 101	13	23.08	34.39	0.0	0.00	100.0	13	12.82	28.99	0.0	0.00	100.0
	Plat+Gem (N=194)												
	BASELINE	155	15.05	23.78	0.0	0.00	100.0						
	Week 1	142	17.14	28.56	0.0	0.00	100.0	131	2.54	20.09	-66.7	0.00	100.0
	Week 2	142	16.20	27.43	0.0	0.00	100.0	127	2.62	22.85	-33.3	0.00	100.0
	Week 3	152	14.03	22.87	0.0	0.00	100.0	135	0.25	17.51	-66.7	0.00	33.3
	Week 4	151	15.67	23.98	0.0	0.00	100.0	132	1.77	19.46	-33.3	0.00	66.7
	Week 5	151	17.00	25.20	0.0	0.00	100.0	128	3.65	20.59	-33.3	0.00	100.0
	Week 6	139	16.07	24.53	0.0	0.00	100.0	122	3.83	21.08	-33.3	0.00	66.7

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Table 302.1.3002.22.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 7	148	16.67	26.23	0.0	0.00	100.0	128	4.69	23.56	-33.3	0.00	66.7
	Week 8	136	15.93	25.00	0.0	0.00	100.0	119	3.64	22.04	-66.7	0.00	66.7
	Week 9	145	16.55	24.26	0.0	0.00	100.0	125	4.27	20.73	-33.3	0.00	66.7
	Week 10	132	17.42	25.54	0.0	0.00	100.0	113	4.13	24.45	-66.7	0.00	66.7
	Week 11	138	18.12	25.19	0.0	0.00	100.0	119	5.60	23.09	-33.3	0.00	66.7
	Week 12	131	18.83	24.49	0.0	0.00	100.0	115	5.22	23.61	-66.7	0.00	66.7
	Week 14	127	18.11	24.76	0.0	0.00	100.0	107	5.30	24.72	-66.7	0.00	66.7
	Week 17	125	17.07	25.26	0.0	0.00	100.0	105	6.35	25.78	-66.7	0.00	100.0
	Week 20	103	18.12	27.53	0.0	0.00	100.0	89	5.62	23.70	-66.7	0.00	66.7
	Week 23	93	17.56	25.82	0.0	0.00	100.0	78	5.13	26.36	-66.7	0.00	100.0
	Week 26	89	17.60	26.16	0.0	0.00	100.0	77	3.46	27.35	-66.7	0.00	66.7
	Week 29	84	15.87	26.12	0.0	0.00	100.0	72	3.24	21.78	-33.3	0.00	66.7
	Week 32	72	18.98	27.31	0.0	0.00	100.0	65	5.13	23.74	-33.3	0.00	66.7
	Week 35	66	17.68	25.63	0.0	0.00	100.0	60	3.33	20.07	-33.3	0.00	66.7
	Week 38	66	15.66	25.63	0.0	0.00	100.0	57	2.34	23.45	-66.7	0.00	66.7
	Week 41	62	17.20	26.82	0.0	0.00	100.0	53	4.40	23.60	-66.7	0.00	66.7
	Week 44	55	16.36	23.02	0.0	0.00	100.0	48	4.17	23.44	-66.7	0.00	66.7
	Week 47	51	15.03	20.35	0.0	0.00	66.7	44	3.03	23.64	-66.7	0.00	66.7
	Week 50	48	20.14	25.49	0.0	0.00	100.0	44	6.06	24.14	-66.7	0.00	66.7
	Week 53	41	16.26	22.51	0.0	0.00	66.7	37	4.50	22.45	-66.7	0.00	66.7
	Week 56	34	17.65	22.07	0.0	0.00	66.7	29	4.60	21.31	-33.3	0.00	66.7
	Week 59	32	11.46	16.08	0.0	0.00	33.3	28	1.19	19.21	-33.3	0.00	33.3
	Week 62	27	16.05	21.42	0.0	0.00	66.7	24	4.17	22.66	-33.3	0.00	66.7
	Week 65	25	12.00	16.33	0.0	0.00	33.3	21	3.17	17.96	-33.3	0.00	33.3
	Week 68	23	11.59	19.09	0.0	0.00	66.7	19	5.26	20.07	-33.3	0.00	33.3
	Week 71	21	17.46	24.99	0.0	0.00	100.0	18	9.26	29.83	-33.3	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 74	20	15.00	25.30	0.0	0.00	100.0	17	7.84	30.11	-33.3	0.00	100.0
	Week 77	16	10.42	15.96	0.0	0.00	33.3	13	0.00	19.24	-33.3	0.00	33.3
	Week 80	12	8.33	15.07	0.0	0.00	33.3	11	-3.03	17.98	-33.3	0.00	33.3
	Week 83	11	12.12	16.82	0.0	0.00	33.3	10	0.00	15.71	-33.3	0.00	33.3
	Week 86	10	10.00	16.10	0.0	0.00	33.3	9	0.00	16.67	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
< 65 years	EV+Pembro (N=105)												
	BASELINE	92	22.46	28.00	0.0	0.00	100.0						
	Week 1	88	20.45	27.88	0.0	0.00	100.0	85	-0.78	17.04	-33.3	0.00	66.7
	Week 2	92	19.93	25.71	0.0	0.00	100.0	86	-2.71	19.94	-100.0	0.00	33.3
	Week 3	93	21.15	28.14	0.0	0.00	100.0	84	-0.79	21.94	-100.0	0.00	66.7
	Week 4	90	22.22	27.82	0.0	0.00	100.0	82	-1.63	22.77	-100.0	0.00	66.7
	Week 5	90	20.74	27.18	0.0	0.00	100.0	81	-2.06	23.77	-100.0	0.00	66.7
	Week 6	90	23.33	30.98	0.0	0.00	100.0	81	-0.82	22.96	-100.0	0.00	100.0
	Week 7	85	21.57	28.96	0.0	0.00	100.0	77	-3.46	23.93	-100.0	0.00	33.3
	Week 8	89	25.84	30.88	0.0	33.33	100.0	80	1.25	25.68	-100.0	0.00	100.0
	Week 9	93	24.01	31.61	0.0	0.00	100.0	85	0.00	23.57	-66.7	0.00	100.0
	Week 10	88	26.51	31.22	0.0	33.33	100.0	81	2.06	26.01	-100.0	0.00	100.0
	Week 11	93	24.37	30.35	0.0	0.00	100.0	84	-0.79	27.85	-100.0	0.00	100.0
	Week 12	86	24.81	31.18	0.0	0.00	100.0	79	-0.84	25.58	-100.0	0.00	100.0
	Week 14	84	26.98	32.51	0.0	16.67	100.0	76	2.63	24.80	-66.7	0.00	100.0
	Week 17	83	25.70	30.94	0.0	0.00	100.0	77	1.73	26.98	-100.0	0.00	100.0
	Week 20	79	27.00	32.50	0.0	33.33	100.0	73	4.11	27.19	-100.0	0.00	100.0
	Week 23	78	25.21	30.48	0.0	16.67	100.0	73	0.91	25.44	-100.0	0.00	100.0
	Week 26	78	25.64	30.82	0.0	33.33	100.0	72	1.39	27.08	-100.0	0.00	100.0
	Week 29	74	21.62	28.37	0.0	0.00	100.0	67	-1.00	27.81	-100.0	0.00	100.0
	Week 32	64	26.04	33.32	0.0	0.00	100.0	59	4.52	28.67	-66.7	0.00	100.0
	Week 35	62	23.12	31.70	0.0	0.00	100.0	58	2.87	23.60	-33.3	0.00	100.0
	Week 38	62	25.81	32.18	0.0	0.00	100.0	59	2.26	25.42	-100.0	0.00	100.0
	Week 41	64	25.52	31.28	0.0	16.67	100.0	59	2.26	26.16	-100.0	0.00	100.0
	Week 44	50	22.67	31.90	0.0	0.00	100.0	48	2.78	25.58	-66.7	0.00	100.0
	Week 47	47	24.11	30.85	0.0	0.00	100.0	46	4.35	30.31	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	44	27.27	33.16	0.0	0.00	100.0	41	7.32	29.36	-33.3	0.00	100.0
	Week 53	40	27.50	31.02	0.0	33.33	100.0	37	5.41	28.88	-66.7	0.00	100.0
	Week 56	44	24.24	29.96	0.0	16.67	100.0	41	2.44	22.84	-33.3	0.00	100.0
	Week 59	42	28.57	31.73	0.0	33.33	100.0	39	6.84	27.76	-33.3	0.00	100.0
	Week 62	37	21.62	31.64	0.0	0.00	100.0	36	4.63	26.61	-33.3	0.00	100.0
	Week 65	34	31.37	33.78	0.0	33.33	100.0	31	5.38	28.67	-33.3	0.00	100.0
	Week 68	34	27.45	35.27	0.0	16.67	100.0	33	5.05	30.19	-33.3	0.00	100.0
	Week 71	32	31.25	37.81	0.0	16.67	100.0	30	7.78	32.38	-33.3	0.00	100.0
	Week 74	29	31.03	35.56	0.0	33.33	100.0	28	11.90	35.39	-33.3	0.00	100.0
	Week 77	25	32.00	35.33	0.0	33.33	100.0	24	12.50	35.18	-33.3	0.00	100.0
	Week 80	24	31.94	33.30	0.0	33.33	100.0	22	12.12	31.78	-33.3	0.00	100.0
	Week 83	23	30.43	36.12	0.0	33.33	100.0	22	9.09	32.82	-33.3	0.00	100.0
	Week 86	20	33.33	32.45	0.0	33.33	100.0	18	9.26	35.80	-33.3	0.00	100.0
	Week 89	19	42.10	34.86	0.0	33.33	100.0	17	17.65	37.49	-33.3	0.00	100.0
	Week 92	14	30.95	35.72	0.0	33.33	100.0	12	13.89	36.12	-33.3	0.00	100.0
	Week 95	12	38.89	37.16	0.0	33.33	100.0	11	18.18	37.61	-33.3	0.00	100.0
	Plat+Gem (N=106)												
	BASELINE	83	19.28	24.48	0.0	0.00	100.0						
	Week 1	75	20.44	29.96	0.0	0.00	100.0	71	3.76	20.74	-66.7	0.00	33.3
	Week 2	76	22.81	29.42	0.0	0.00	100.0	68	4.90	25.28	-33.3	0.00	100.0
	Week 3	80	21.25	25.01	0.0	0.00	100.0	73	3.20	22.34	-66.7	0.00	66.7
	Week 4	79	22.78	26.98	0.0	0.00	100.0	67	3.98	21.34	-33.3	0.00	66.7
	Week 5	80	20.83	25.09	0.0	0.00	100.0	67	4.48	21.63	-33.3	0.00	66.7
	Week 6	76	22.37	26.33	0.0	0.00	100.0	67	4.98	23.39	-33.3	0.00	66.7
	Week 7	81	23.46	28.60	0.0	0.00	100.0	71	5.63	24.55	-33.3	0.00	66.7
	Week 8	72	23.61	27.66	0.0	16.67	100.0	64	6.77	26.68	-33.3	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	78	23.08	26.49	0.0	16.67	100.0	69	6.28	23.76	-33.3	0.00	66.7
	Week 10	78	23.50	27.45	0.0	16.67	100.0	68	6.37	28.37	-66.7	0.00	66.7
	Week 11	75	24.89	27.99	0.0	33.33	100.0	66	7.07	27.12	-33.3	0.00	66.7
	Week 12	74	24.32	25.46	0.0	33.33	66.7	66	6.57	26.94	-66.7	0.00	66.7
	Week 14	68	25.49	27.69	0.0	33.33	100.0	58	9.20	28.47	-33.3	0.00	66.7
	Week 17	68	23.53	28.25	0.0	16.67	100.0	58	10.35	28.07	-33.3	0.00	66.7
	Week 20	60	22.22	28.57	0.0	0.00	100.0	52	7.05	25.85	-33.3	0.00	66.7
	Week 23	51	23.53	29.28	0.0	0.00	100.0	44	8.33	30.61	-33.3	0.00	100.0
	Week 26	47	24.82	29.05	0.0	33.33	100.0	42	4.76	30.86	-66.7	0.00	66.7
	Week 29	42	19.84	25.57	0.0	0.00	100.0	37	0.00	22.22	-33.3	0.00	33.3
	Week 32	37	24.32	26.81	0.0	33.33	100.0	34	2.94	26.42	-33.3	0.00	66.7
	Week 35	34	22.55	26.87	0.0	16.67	100.0	31	2.15	25.73	-33.3	0.00	66.7
	Week 38	33	17.17	23.75	0.0	0.00	100.0	28	-2.38	28.59	-66.7	0.00	66.7
	Week 41	27	22.22	26.15	0.0	33.33	100.0	22	3.03	28.93	-66.7	0.00	66.7
	Week 44	28	20.24	20.96	0.0	33.33	66.7	24	2.78	29.35	-66.7	0.00	66.7
	Week 47	24	18.05	19.61	0.0	16.67	66.7	21	0.00	27.89	-66.7	0.00	33.3
	Week 50	26	21.79	26.57	0.0	16.67	100.0	24	2.78	27.66	-66.7	0.00	66.7
	Week 53	19	22.81	24.98	0.0	33.33	66.7	17	0.00	28.87	-66.7	0.00	33.3
	Week 56	13	28.20	29.96	0.0	33.33	100.0	11	3.03	34.82	-33.3	0.00	66.7
	Week 59	14	14.28	17.12	0.0	0.00	33.3	12	-5.56	23.92	-33.3	0.00	33.3
	Week 62	13	20.51	21.68	0.0	33.33	66.7	12	-2.78	26.43	-33.3	0.00	33.3
	Week 65	13	12.82	16.88	0.0	0.00	33.3	11	-3.03	23.35	-33.3	0.00	33.3
	Week 68	10	16.67	23.57	0.0	0.00	66.7	8	-4.17	27.82	-33.3	0.00	33.3
	Week 77	10	16.67	23.57	0.0	0.00	66.7	8	-4.17	27.82	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>= 65 years	EV+Pembro (N=135)												
	BASELINE	114	11.70	23.46	0.0	0.00	100.0						
	Week 1	102	13.40	23.10	0.0	0.00	100.0	99	2.02	16.37	-66.7	0.00	66.7
	Week 2	111	10.51	21.07	0.0	0.00	100.0	103	-1.62	18.30	-66.7	0.00	33.3
	Week 3	105	13.97	24.36	0.0	0.00	100.0	98	1.36	19.69	-100.0	0.00	66.7
	Week 4	104	11.54	22.16	0.0	0.00	100.0	97	0.00	19.84	-100.0	0.00	66.7
	Week 5	100	11.00	21.74	0.0	0.00	100.0	92	-0.72	22.63	-100.0	0.00	100.0
	Week 6	98	15.65	27.99	0.0	0.00	100.0	89	4.12	24.01	-66.7	0.00	100.0
	Week 7	110	13.64	24.44	0.0	0.00	100.0	99	2.02	22.75	-100.0	0.00	100.0
	Week 8	102	14.71	25.07	0.0	0.00	100.0	91	3.66	24.57	-100.0	0.00	100.0
	Week 9	104	13.78	22.57	0.0	0.00	100.0	95	2.46	21.87	-66.7	0.00	100.0
	Week 10	103	14.56	25.42	0.0	0.00	100.0	94	3.19	21.90	-66.7	0.00	100.0
	Week 11	101	14.19	25.10	0.0	0.00	100.0	91	1.83	21.29	-100.0	0.00	66.7
	Week 12	100	13.00	24.57	0.0	0.00	100.0	92	2.17	24.11	-66.7	0.00	100.0
	Week 14	101	15.51	26.90	0.0	0.00	100.0	91	2.93	22.58	-66.7	0.00	100.0
	Week 17	95	11.93	21.70	0.0	0.00	100.0	85	1.18	18.86	-33.3	0.00	100.0
	Week 20	88	14.39	25.17	0.0	0.00	100.0	81	3.29	25.06	-66.7	0.00	100.0
	Week 23	84	13.49	20.77	0.0	0.00	100.0	78	2.56	20.65	-66.7	0.00	66.7
	Week 26	78	13.68	23.68	0.0	0.00	66.7	72	2.32	19.64	-33.3	0.00	66.7
	Week 29	83	14.86	22.24	0.0	0.00	66.7	78	4.27	20.36	-33.3	0.00	66.7
	Week 32	71	13.61	22.24	0.0	0.00	100.0	66	4.55	20.99	-66.7	0.00	33.3
	Week 35	70	18.09	24.53	0.0	0.00	100.0	64	7.81	21.20	-33.3	0.00	66.7
	Week 38	70	17.62	24.55	0.0	0.00	100.0	65	7.69	22.65	-66.7	0.00	66.7
	Week 41	65	17.44	24.37	0.0	0.00	66.7	60	8.89	24.45	-66.7	0.00	66.7
	Week 44	58	14.37	22.61	0.0	0.00	66.7	52	5.13	20.22	-33.3	0.00	66.7
	Week 47	53	17.61	25.82	0.0	0.00	100.0	48	7.64	23.05	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	45	11.11	18.80	0.0	0.00	66.7	43	3.10	15.96	-33.3	0.00	33.3
	Week 53	39	14.53	22.68	0.0	0.00	66.7	37	9.91	22.03	-33.3	0.00	66.7
	Week 56	37	14.41	26.69	0.0	0.00	100.0	35	6.67	21.08	-33.3	0.00	66.7
	Week 59	30	13.33	25.67	0.0	0.00	66.7	29	6.90	22.50	-33.3	0.00	66.7
	Week 62	28	10.71	20.39	0.0	0.00	66.7	27	3.70	19.25	-33.3	0.00	33.3
	Week 65	24	16.67	27.80	0.0	0.00	100.0	23	11.59	19.09	0.0	0.00	66.7
	Week 68	19	10.53	22.37	0.0	0.00	66.7	19	5.26	22.94	-33.3	0.00	66.7
	Week 71	19	7.02	17.84	0.0	0.00	66.7	19	1.75	17.47	-33.3	0.00	33.3
	Week 74	18	11.11	22.87	0.0	0.00	66.7	18	3.70	22.55	-33.3	0.00	66.7
	Week 77	19	17.54	23.22	0.0	0.00	66.7	18	7.41	21.56	-33.3	0.00	33.3
	Week 80	16	16.67	24.34	0.0	0.00	66.7	15	6.67	18.69	-33.3	0.00	33.3
	Week 83	14	21.43	30.96	0.0	0.00	100.0	13	10.26	25.04	-33.3	0.00	66.7
	Week 86	14	11.90	21.11	0.0	0.00	66.7	13	2.56	16.45	-33.3	0.00	33.3
	Week 89	14	16.67	25.32	0.0	0.00	66.7	14	9.52	15.63	0.0	0.00	33.3
	Week 92	13	12.82	21.68	0.0	0.00	66.7	13	5.13	18.49	-33.3	0.00	33.3
	Week 95	10	26.67	37.84	0.0	0.00	100.0	10	13.33	23.31	0.0	0.00	66.7
	Week 98	10	20.00	28.11	0.0	0.00	66.7	10	10.00	16.10	0.0	0.00	33.3
	Plat+Gem (N=136)												
	BASELINE	105	11.75	23.10	0.0	0.00	100.0						
	Week 1	98	13.95	24.84	0.0	0.00	100.0	87	1.53	19.63	-66.7	0.00	100.0
	Week 2	95	11.23	24.12	0.0	0.00	100.0	83	0.40	23.57	-66.7	0.00	100.0
	Week 3	104	8.65	19.70	0.0	0.00	100.0	89	-2.25	19.33	-100.0	0.00	33.3
	Week 4	104	10.58	20.39	0.0	0.00	100.0	89	-0.37	21.02	-66.7	0.00	66.7
	Week 5	107	13.08	23.68	0.0	0.00	100.0	89	1.87	21.53	-100.0	0.00	100.0
	Week 6	98	11.90	22.58	0.0	0.00	100.0	82	3.25	22.59	-100.0	0.00	66.7
	Week 7	105	10.48	21.84	0.0	0.00	100.0	86	2.71	22.41	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 8	95	10.53	21.34	0.0	0.00	100.0	80	2.50	18.96	-66.7	0.00	66.7
	Week 9	99	10.77	19.53	0.0	0.00	100.0	81	2.47	17.30	-33.3	0.00	33.3
	Week 10	88	12.12	20.95	0.0	0.00	100.0	71	1.88	21.00	-66.7	0.00	66.7
	Week 11	93	11.83	20.64	0.0	0.00	100.0	77	2.60	22.14	-100.0	0.00	66.7
	Week 12	85	12.94	21.88	0.0	0.00	100.0	72	2.78	23.57	-100.0	0.00	66.7
	Week 14	85	13.72	21.39	0.0	0.00	100.0	70	3.33	22.09	-66.7	0.00	66.7
	Week 17	87	12.26	21.63	0.0	0.00	100.0	72	3.24	22.49	-66.7	0.00	100.0
	Week 20	66	14.14	24.15	0.0	0.00	100.0	58	3.45	21.35	-66.7	0.00	66.7
	Week 23	64	12.50	20.14	0.0	0.00	100.0	53	3.14	20.94	-66.7	0.00	66.7
	Week 26	61	10.93	19.93	0.0	0.00	66.7	53	1.89	21.10	-66.7	0.00	66.7
	Week 29	58	11.49	23.82	0.0	0.00	100.0	49	4.08	19.99	-33.3	0.00	66.7
	Week 32	46	14.49	25.96	0.0	0.00	100.0	42	6.35	19.81	-33.3	0.00	66.7
	Week 35	42	11.11	21.67	0.0	0.00	100.0	38	3.51	12.94	-33.3	0.00	33.3
	Week 38	41	13.01	25.69	0.0	0.00	100.0	37	5.41	16.69	-33.3	0.00	66.7
	Week 41	38	14.03	26.43	0.0	0.00	100.0	34	5.88	19.19	-33.3	0.00	66.7
	Week 44	32	12.50	23.57	0.0	0.00	100.0	29	4.60	17.19	-33.3	0.00	66.7
	Week 47	32	12.50	20.30	0.0	0.00	66.7	28	4.76	19.70	-33.3	0.00	66.7
	Week 50	25	18.67	23.73	0.0	0.00	66.7	23	8.70	20.64	-33.3	0.00	66.7
	Week 53	27	11.11	18.49	0.0	0.00	66.7	25	8.00	17.43	0.0	0.00	66.7
	Week 56	26	14.10	21.44	0.0	0.00	66.7	23	7.25	17.28	0.0	0.00	66.7
	Week 59	23	7.25	14.06	0.0	0.00	33.3	21	3.17	14.55	-33.3	0.00	33.3
	Week 62	19	10.53	19.41	0.0	0.00	66.7	17	7.84	18.74	0.0	0.00	66.7
	Week 65	17	9.80	15.65	0.0	0.00	33.3	15	6.67	13.80	0.0	0.00	33.3
	Week 68	15	6.67	13.80	0.0	0.00	33.3	13	7.69	14.62	0.0	0.00	33.3
	Week 71	15	15.55	27.79	0.0	0.00	100.0	13	12.82	28.99	0.0	0.00	100.0
	Week 74	12	13.89	30.01	0.0	0.00	100.0	11	12.12	30.81	0.0	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Europe	EV+Pembro (N= 98)												
	BASELINE	79	11.39	22.57	0.0	0.00	100.0						
	Week 1	74	10.36	22.02	0.0	0.00	100.0	71	-0.94	12.56	-33.3	0.00	33.3
	Week 2	79	8.86	18.26	0.0	0.00	100.0	71	-2.82	16.66	-100.0	0.00	33.3
	Week 3	78	12.39	24.68	0.0	0.00	100.0	69	0.00	18.96	-100.0	0.00	66.7
	Week 4	78	12.39	22.86	0.0	0.00	100.0	70	0.00	18.82	-100.0	0.00	66.7
	Week 5	70	13.33	25.00	0.0	0.00	100.0	62	-0.54	21.33	-100.0	0.00	66.7
	Week 6	70	16.67	29.35	0.0	0.00	100.0	61	3.28	27.69	-100.0	0.00	100.0
	Week 7	78	12.39	24.09	0.0	0.00	100.0	68	-0.49	21.92	-100.0	0.00	66.7
	Week 8	72	17.13	29.60	0.0	0.00	100.0	61	3.83	25.89	-100.0	0.00	100.0
	Week 9	80	14.58	25.90	0.0	0.00	100.0	70	3.33	21.35	-33.3	0.00	100.0
	Week 10	71	13.15	26.11	0.0	0.00	100.0	62	1.08	24.12	-100.0	0.00	100.0
	Week 11	76	14.91	27.97	0.0	0.00	100.0	66	2.02	24.72	-100.0	0.00	100.0
	Week 12	73	13.24	27.63	0.0	0.00	100.0	65	0.51	23.93	-100.0	0.00	100.0
	Week 14	74	15.77	27.71	0.0	0.00	100.0	64	4.69	21.30	-33.3	0.00	100.0
	Week 17	70	14.76	27.00	0.0	0.00	100.0	62	2.15	24.05	-100.0	0.00	100.0
	Week 20	70	15.24	27.62	0.0	0.00	100.0	63	2.65	26.30	-100.0	0.00	100.0
	Week 23	61	14.75	23.98	0.0	0.00	100.0	57	1.75	23.92	-100.0	0.00	100.0
	Week 26	62	13.44	24.49	0.0	0.00	100.0	55	0.61	24.42	-100.0	0.00	100.0
	Week 29	63	13.23	22.83	0.0	0.00	100.0	57	0.00	25.97	-100.0	0.00	100.0
	Week 32	51	14.38	27.69	0.0	0.00	100.0	47	2.84	22.87	-33.3	0.00	100.0
	Week 35	56	17.86	29.79	0.0	0.00	100.0	52	6.41	23.84	-33.3	0.00	100.0
	Week 38	51	18.30	30.05	0.0	0.00	100.0	48	6.94	25.69	-100.0	0.00	100.0
	Week 41	52	16.67	27.61	0.0	0.00	100.0	48	4.86	25.72	-100.0	0.00	100.0
	Week 44	43	20.15	31.82	0.0	0.00	100.0	39	8.55	23.84	-33.3	0.00	100.0
	Week 47	39	17.95	30.44	0.0	0.00	100.0	36	7.41	30.98	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	37	18.02	28.97	0.0	0.00	100.0	36	7.41	24.05	-33.3	0.00	100.0
	Week 53	28	19.05	30.67	0.0	0.00	100.0	27	6.17	27.79	-66.7	0.00	100.0
	Week 56	30	18.89	32.38	0.0	0.00	100.0	29	6.90	24.20	-33.3	0.00	100.0
	Week 59	27	16.05	29.77	0.0	0.00	100.0	27	4.94	22.08	-33.3	0.00	100.0
	Week 62	23	13.04	29.71	0.0	0.00	100.0	23	5.80	23.89	-33.3	0.00	100.0
	Week 65	23	23.19	36.84	0.0	0.00	100.0	23	8.70	28.81	-33.3	0.00	100.0
	Week 68	21	17.46	30.95	0.0	0.00	100.0	21	4.76	24.23	-33.3	0.00	100.0
	Week 71	19	19.30	33.91	0.0	0.00	100.0	19	7.02	26.24	-33.3	0.00	100.0
	Week 74	15	11.11	27.22	0.0	0.00	100.0	15	6.67	28.73	-33.3	0.00	100.0
	Week 77	19	17.54	28.04	0.0	0.00	100.0	19	8.77	26.86	-33.3	0.00	100.0
	Week 80	17	15.69	29.15	0.0	0.00	100.0	17	5.88	26.97	-33.3	0.00	100.0
	Week 83	16	18.75	34.36	0.0	0.00	100.0	16	8.33	31.03	-33.3	0.00	100.0
	Week 86	14	14.29	28.39	0.0	0.00	100.0	14	4.76	28.82	-33.3	0.00	100.0
	Week 89	14	19.05	31.25	0.0	0.00	100.0	14	9.52	30.46	-33.3	0.00	100.0
	Week 92	11	15.15	31.14	0.0	0.00	100.0	11	12.12	30.81	0.0	0.00	100.0
	Week 95	10	26.67	40.98	0.0	0.00	100.0	10	20.00	35.83	0.0	0.00	100.0
	Plat+Gem (N=102)												
	BASELINE	71	9.86	21.38	0.0	0.00	100.0						
	Week 1	71	11.74	23.30	0.0	0.00	100.0	61	2.19	20.97	-66.7	0.00	100.0
	Week 2	67	10.94	26.20	0.0	0.00	100.0	56	3.57	24.35	-33.3	0.00	100.0
	Week 3	68	6.86	17.81	0.0	0.00	100.0	56	-1.79	13.36	-66.7	0.00	33.3
	Week 4	75	10.67	20.62	0.0	0.00	100.0	59	2.26	16.22	-33.3	0.00	66.7
	Week 5	77	9.09	20.69	0.0	0.00	100.0	60	2.22	19.28	-33.3	0.00	100.0
	Week 6	70	10.48	20.10	0.0	0.00	66.7	56	5.95	19.18	-33.3	0.00	66.7
	Week 7	72	6.94	17.64	0.0	0.00	100.0	55	1.82	17.47	-33.3	0.00	66.7
	Week 8	65	8.20	15.62	0.0	0.00	66.7	53	1.89	16.56	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	70	9.52	18.94	0.0	0.00	66.7	55	3.03	17.30	-33.3	0.00	66.7
	Week 10	60	11.11	20.96	0.0	0.00	100.0	46	4.35	22.89	-66.7	0.00	66.7
	Week 11	64	12.50	21.00	0.0	0.00	100.0	50	6.00	20.96	-33.3	0.00	66.7
	Week 12	60	11.11	19.08	0.0	0.00	66.7	48	4.17	23.44	-66.7	0.00	66.7
	Week 14	56	11.90	21.49	0.0	0.00	100.0	42	5.56	25.41	-66.7	0.00	66.7
	Week 17	58	10.92	21.07	0.0	0.00	100.0	44	3.79	21.82	-66.7	0.00	66.7
	Week 20	47	9.93	20.75	0.0	0.00	100.0	37	0.90	21.50	-66.7	0.00	66.7
	Week 23	44	6.82	13.60	0.0	0.00	33.3	32	2.08	18.81	-33.3	0.00	33.3
	Week 26	39	5.98	12.96	0.0	0.00	33.3	30	-1.11	13.79	-33.3	0.00	33.3
	Week 29	34	6.86	13.68	0.0	0.00	33.3	25	0.00	16.67	-33.3	0.00	33.3
	Week 32	33	8.08	14.51	0.0	0.00	33.3	27	1.23	17.25	-33.3	0.00	33.3
	Week 35	30	7.78	16.80	0.0	0.00	66.7	24	1.39	15.48	-33.3	0.00	33.3
	Week 38	26	5.13	12.26	0.0	0.00	33.3	21	-3.17	14.55	-33.3	0.00	33.3
	Week 41	22	10.61	18.93	0.0	0.00	66.7	17	3.92	23.22	-33.3	0.00	66.7
	Week 44	20	8.33	14.81	0.0	0.00	33.3	16	-2.08	19.12	-33.3	0.00	33.3
	Week 47	16	4.17	11.38	0.0	0.00	33.3	12	-8.33	15.08	-33.3	0.00	0.0
	Week 50	11	9.09	21.56	0.0	0.00	66.7	10	0.00	15.71	-33.3	0.00	33.3
	Week 53	11	12.12	22.47	0.0	0.00	66.7	10	3.33	18.92	-33.3	0.00	33.3
	Week 56	10	3.33	10.54	0.0	0.00	33.3	8	-8.33	15.43	-33.3	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
North America	EV+Pembro (N= 57)												
	BASELINE	47	18.44	28.50	0.0	0.00	100.0						
	Week 1	39	17.95	29.46	0.0	0.00	100.0	37	1.80	15.61	-33.3	0.00	66.7
	Week 2	44	16.67	29.20	0.0	0.00	100.0	42	-3.97	16.79	-33.3	0.00	33.3
	Week 3	44	18.18	29.16	0.0	0.00	100.0	40	-0.83	17.68	-33.3	0.00	33.3
	Week 4	44	20.45	31.51	0.0	0.00	100.0	41	0.00	16.67	-33.3	0.00	33.3
	Week 5	47	15.60	25.87	0.0	0.00	100.0	41	-1.63	14.81	-33.3	0.00	33.3
	Week 6	44	22.73	35.05	0.0	0.00	100.0	39	0.00	15.29	-33.3	0.00	33.3
	Week 7	46	21.01	32.48	0.0	0.00	100.0	42	0.00	18.03	-33.3	0.00	33.3
	Week 8	47	22.69	28.75	0.0	0.00	100.0	42	2.38	17.09	-33.3	0.00	33.3
	Week 9	46	24.64	33.29	0.0	0.00	100.0	42	3.17	17.74	-33.3	0.00	33.3
	Week 10	47	24.82	31.45	0.0	0.00	100.0	44	3.79	14.76	-33.3	0.00	33.3
	Week 11	47	21.28	29.01	0.0	0.00	100.0	42	0.00	19.48	-100.0	0.00	33.3
	Week 12	44	25.76	31.22	0.0	33.33	100.0	40	4.17	13.48	-33.3	0.00	33.3
	Week 14	43	24.81	30.94	0.0	33.33	100.0	39	3.42	12.78	-33.3	0.00	33.3
	Week 17	40	22.50	30.56	0.0	0.00	100.0	37	2.70	14.44	-33.3	0.00	33.3
	Week 20	38	24.56	32.59	0.0	0.00	100.0	35	1.90	16.05	-66.7	0.00	33.3
	Week 23	38	21.93	30.29	0.0	0.00	100.0	35	0.95	15.09	-33.3	0.00	33.3
	Week 26	35	24.76	31.67	0.0	0.00	100.0	32	1.04	17.93	-33.3	0.00	66.7
	Week 29	38	21.05	30.43	0.0	0.00	100.0	34	1.96	18.24	-33.3	0.00	66.7
	Week 32	32	19.79	29.16	0.0	0.00	100.0	29	3.45	13.64	-33.3	0.00	33.3
	Week 35	33	20.20	27.56	0.0	0.00	100.0	30	5.56	15.37	-33.3	0.00	33.3
	Week 38	32	21.87	30.07	0.0	0.00	100.0	29	3.45	16.29	-33.3	0.00	66.7
	Week 41	28	23.81	29.89	0.0	16.67	100.0	24	6.94	13.83	0.0	0.00	33.3
	Week 44	21	9.52	15.43	0.0	0.00	33.3	20	1.67	13.13	-33.3	0.00	33.3
	Week 47	24	15.28	24.03	0.0	0.00	100.0	23	4.35	20.85	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	23	13.04	26.09	0.0	0.00	100.0	20	3.33	18.42	-33.3	0.00	66.7
	Week 53	17	15.69	23.91	0.0	0.00	66.7	14	7.14	14.19	0.0	0.00	33.3
	Week 56	20	18.33	27.52	0.0	0.00	100.0	17	3.92	11.07	0.0	0.00	33.3
	Week 59	17	23.53	30.65	0.0	0.00	100.0	14	4.76	17.82	-33.3	0.00	33.3
	Week 62	14	11.90	21.11	0.0	0.00	66.7	13	-2.56	16.45	-33.3	0.00	33.3
	Week 65	12	22.22	29.59	0.0	16.67	100.0	9	3.70	11.11	0.0	0.00	33.3
	Week 68	10	16.67	32.39	0.0	0.00	100.0	9	0.00	0.00	0.0	0.00	0.0
	Week 71	10	16.67	32.39	0.0	0.00	100.0	8	0.00	0.00	0.0	0.00	0.0
	Week 74	10	20.00	32.20	0.0	0.00	100.0	9	0.00	16.67	-33.3	0.00	33.3
	Plat+Gem (N= 51)												
	BASELINE	42	18.25	28.71	0.0	0.00	100.0						
	Week 1	41	22.76	35.31	0.0	0.00	100.0	36	5.56	14.91	-33.3	0.00	33.3
	Week 2	38	17.54	27.66	0.0	0.00	100.0	33	1.01	19.52	-33.3	0.00	33.3
	Week 3	40	19.17	28.13	0.0	0.00	100.0	35	3.81	21.04	-33.3	0.00	66.7
	Week 4	35	18.09	23.35	0.0	0.00	66.7	29	2.30	19.78	-33.3	0.00	33.3
	Week 5	39	22.22	26.86	0.0	0.00	100.0	32	6.25	19.74	-33.3	0.00	66.7
	Week 6	34	19.61	26.10	0.0	0.00	100.0	30	1.11	18.53	-33.3	0.00	33.3
	Week 7	42	18.25	24.64	0.0	0.00	100.0	37	2.70	16.44	-33.3	0.00	33.3
	Week 8	39	20.51	28.22	0.0	0.00	100.0	33	5.05	25.17	-33.3	0.00	100.0
	Week 9	39	20.51	28.22	0.0	0.00	100.0	33	5.05	18.86	-33.3	0.00	33.3
	Week 10	39	20.51	26.06	0.0	0.00	100.0	32	5.21	19.14	-33.3	0.00	66.7
	Week 11	39	17.09	25.21	0.0	0.00	100.0	33	0.00	16.67	-33.3	0.00	33.3
	Week 12	36	22.22	26.43	0.0	16.67	100.0	32	5.21	20.93	-33.3	0.00	66.7
	Week 14	34	21.57	27.07	0.0	0.00	100.0	29	4.60	26.31	-33.3	0.00	66.7
	Week 17	37	20.72	25.28	0.0	0.00	100.0	31	10.75	19.98	-33.3	0.00	66.7
	Week 20	27	25.93	33.76	0.0	0.00	100.0	23	8.70	18.03	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 23	27	28.39	32.95	0.0	33.33	100.0	23	11.59	27.72	-33.3	0.00	100.0
	Week 26	28	27.38	28.77	0.0	33.33	100.0	25	6.67	30.43	-66.7	0.00	66.7
	Week 29	29	22.99	30.99	0.0	0.00	100.0	25	4.00	20.00	-33.3	0.00	33.3
	Week 32	17	35.29	32.21	0.0	33.33	100.0	17	7.84	25.08	-33.3	0.00	33.3
	Week 35	16	35.42	35.42	0.0	33.33	100.0	15	8.89	26.63	-33.3	0.00	66.7
	Week 38	16	25.00	35.49	0.0	0.00	100.0	13	10.26	25.03	-33.3	0.00	66.7
	Week 41	16	22.92	33.82	0.0	0.00	100.0	13	7.69	14.62	0.0	0.00	33.3
	Week 44	13	20.51	28.99	0.0	0.00	100.0	11	6.06	13.48	0.0	0.00	33.3
	Week 47	11	15.15	17.41	0.0	0.00	33.3	9	11.11	16.67	0.0	0.00	33.3
	Week 50	17	19.61	23.74	0.0	0.00	66.7	15	0.00	17.82	-33.3	0.00	33.3
	Week 53	13	12.82	21.68	0.0	0.00	66.7	11	0.00	14.91	-33.3	0.00	33.3
	Week 56	11	21.21	30.81	0.0	0.00	100.0	9	14.81	24.22	0.0	0.00	66.7
	Week 59	11	9.09	15.57	0.0	0.00	33.3	9	3.70	11.11	0.0	0.00	33.3
	Week 62	11	9.09	15.57	0.0	0.00	33.3	9	3.70	11.11	0.0	0.00	33.3
	Week 65	10	10.00	16.10	0.0	0.00	33.3	8	4.17	11.78	0.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Rest of World	EV+Pembro (N= 85)												
	BASELINE	80	20.42	27.30	0.0	0.00	100.0						
	Week 1	77	22.08	25.71	0.0	0.00	100.0	76	1.75	20.29	-66.7	0.00	66.7
	Week 2	80	19.58	24.13	0.0	0.00	100.0	76	-0.44	22.11	-66.7	0.00	33.3
	Week 3	76	21.93	25.85	0.0	16.67	100.0	73	1.37	23.86	-100.0	0.00	66.7
	Week 4	72	18.52	23.66	0.0	0.00	100.0	68	-1.96	25.68	-100.0	0.00	66.7
	Week 5	73	17.81	24.27	0.0	0.00	100.0	70	-1.91	28.31	-100.0	0.00	100.0
	Week 6	74	19.82	26.41	0.0	0.00	100.0	70	1.43	23.70	-66.7	0.00	66.7
	Week 7	71	19.72	24.93	0.0	0.00	100.0	66	-0.51	27.73	-100.0	0.00	100.0
	Week 8	72	20.83	27.08	0.0	0.00	100.0	68	1.47	28.47	-100.0	0.00	100.0
	Week 9	71	19.25	24.98	0.0	0.00	100.0	68	-1.96	26.32	-66.7	0.00	100.0
	Week 10	73	23.74	28.59	0.0	0.00	100.0	69	3.38	28.09	-66.7	0.00	100.0
	Week 11	71	22.07	27.57	0.0	0.00	100.0	67	-0.50	27.52	-100.0	0.00	66.7
	Week 12	69	19.32	26.45	0.0	0.00	100.0	66	-1.01	30.37	-66.7	0.00	100.0
	Week 14	68	23.53	31.58	0.0	0.00	100.0	64	0.52	29.99	-66.7	0.00	100.0
	Week 17	68	19.61	25.26	0.0	0.00	100.0	63	0.00	26.10	-66.7	0.00	100.0
	Week 20	59	23.73	29.07	0.0	0.00	100.0	56	5.95	30.56	-66.7	0.00	100.0
	Week 23	63	21.69	26.21	0.0	0.00	100.0	59	2.26	26.16	-66.7	0.00	66.7
	Week 26	59	23.16	28.54	0.0	0.00	100.0	57	3.51	25.73	-66.7	0.00	66.7
	Week 29	56	21.43	24.15	0.0	16.67	66.7	54	3.70	25.63	-66.7	0.00	66.7
	Week 32	52	24.36	28.86	0.0	0.00	100.0	49	6.80	31.17	-66.7	0.00	66.7
	Week 35	43	24.03	26.55	0.0	33.33	100.0	40	4.17	25.25	-33.3	0.00	66.7
	Week 38	49	24.49	26.15	0.0	33.33	100.0	47	4.25	26.57	-66.7	0.00	33.3
	Week 41	49	25.17	27.67	0.0	33.33	66.7	47	5.67	29.75	-66.7	0.00	66.7
	Week 44	44	20.45	27.11	0.0	0.00	66.7	41	0.81	25.26	-66.7	0.00	33.3
	Week 47	37	27.03	28.15	0.0	33.33	66.7	35	5.72	26.18	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	29	25.29	27.68	0.0	33.33	66.7	28	3.57	26.20	-33.3	0.00	66.7
	Week 53	34	25.49	27.29	0.0	33.33	66.7	33	9.09	27.98	-33.3	0.00	66.7
	Week 56	31	21.51	26.60	0.0	0.00	66.7	30	2.22	24.66	-33.3	0.00	66.7
	Week 59	28	27.38	30.16	0.0	16.67	66.7	27	9.88	31.78	-33.3	0.00	66.7
	Week 62	28	22.62	28.77	0.0	0.00	66.7	27	6.17	26.21	-33.3	0.00	66.7
	Week 65	23	28.99	28.96	0.0	33.33	66.7	22	9.09	25.58	-33.3	0.00	66.7
	Week 68	22	27.27	33.55	0.0	16.67	100.0	22	7.58	35.53	-33.3	0.00	100.0
	Week 71	22	27.27	35.09	0.0	0.00	100.0	22	6.06	33.55	-33.3	0.00	100.0
	Week 74	22	33.33	34.12	0.0	33.33	100.0	22	13.64	36.60	-33.3	0.00	100.0
	Week 77	18	33.33	32.34	0.0	33.33	100.0	17	15.69	35.59	-33.3	0.00	100.0
	Week 80	16	35.42	33.26	0.0	33.33	100.0	15	17.78	27.79	-33.3	0.00	66.7
	Week 83	16	33.33	32.20	0.0	33.33	100.0	15	15.56	30.52	-33.3	0.00	66.7
	Week 86	13	33.33	30.43	0.0	33.33	66.7	12	13.89	33.21	-33.3	0.00	66.7
	Week 89	12	41.67	32.18	0.0	33.33	100.0	12	22.22	32.83	-33.3	33.33	66.7
	Plat+Gem (N= 89)												
	BASELINE	75	18.22	22.79	0.0	0.00	100.0						
	Week 1	61	18.58	24.74	0.0	0.00	100.0	61	1.09	21.91	-66.7	0.00	33.3
	Week 2	66	21.21	27.20	0.0	0.00	100.0	62	2.15	26.91	-66.7	0.00	100.0
	Week 3	76	17.98	22.73	0.0	0.00	66.7	71	0.00	25.20	-100.0	0.00	66.7
	Week 4	73	20.09	27.07	0.0	0.00	100.0	68	0.49	25.43	-66.7	0.00	66.7
	Week 5	71	21.13	25.35	0.0	0.00	100.0	64	2.08	24.40	-100.0	0.00	66.7
	Week 6	70	20.95	27.32	0.0	0.00	100.0	63	3.70	27.51	-100.0	0.00	66.7
	Week 7	72	24.07	30.24	0.0	0.00	100.0	65	6.67	30.16	-66.7	0.00	66.7
	Week 8	63	21.69	28.81	0.0	0.00	100.0	58	6.32	26.09	-33.3	0.00	66.7
	Week 9	68	20.59	23.77	0.0	0.00	66.7	62	4.84	24.03	-33.3	0.00	66.7
	Week 10	67	21.39	26.40	0.0	0.00	100.0	61	3.28	29.00	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	65	23.08	27.59	0.0	0.00	100.0	60	6.11	30.37	-100.0	0.00	66.7
	Week 12	63	22.75	25.98	0.0	0.00	66.7	58	4.60	28.92	-100.0	0.00	66.7
	Week 14	63	23.81	25.70	0.0	33.33	100.0	57	7.02	24.99	-33.3	0.00	66.7
	Week 17	60	21.11	28.10	0.0	0.00	100.0	55	6.06	30.15	-33.3	0.00	100.0
	Week 20	52	21.15	25.59	0.0	0.00	100.0	50	6.67	26.94	-33.3	0.00	66.7
	Week 23	44	21.21	25.00	0.0	16.67	100.0	42	4.76	29.05	-66.7	0.00	66.7
	Week 26	41	20.32	27.77	0.0	0.00	100.0	40	4.17	29.42	-66.7	0.00	66.7
	Week 29	37	16.22	25.61	0.0	0.00	100.0	36	2.78	24.40	-33.3	0.00	66.7
	Week 32	33	21.21	28.65	0.0	0.00	100.0	32	6.25	26.01	-33.3	0.00	66.7
	Week 35	30	14.44	18.94	0.0	0.00	66.7	30	1.11	18.53	-33.3	0.00	33.3
	Week 38	32	17.71	23.92	0.0	0.00	100.0	31	2.15	25.73	-66.7	0.00	66.7
	Week 41	27	19.75	26.57	0.0	0.00	100.0	26	3.85	27.21	-66.7	0.00	66.7
	Week 44	27	19.75	23.13	0.0	0.00	66.7	26	6.41	28.31	-66.7	0.00	66.7
	Week 47	29	20.69	22.56	0.0	33.33	66.7	28	4.76	26.78	-66.7	0.00	66.7
	Week 50	23	26.09	26.51	0.0	33.33	100.0	22	12.12	30.07	-66.7	0.00	66.7
	Week 53	22	19.70	22.20	0.0	16.67	66.7	21	7.94	27.70	-66.7	0.00	66.7
	Week 56	18	25.93	24.40	0.0	33.33	66.7	17	7.84	25.08	-33.3	0.00	66.7
	Week 59	17	13.72	16.91	0.0	0.00	33.3	16	2.08	22.67	-33.3	0.00	33.3
	Week 62	16	20.83	23.96	0.0	16.67	66.7	15	8.89	26.63	-33.3	0.00	66.7
	Week 65	15	13.33	16.90	0.0	0.00	33.3	14	7.14	19.30	-33.3	0.00	33.3
	Week 68	12	11.11	21.71	0.0	0.00	66.7	11	6.06	20.10	-33.3	0.00	33.3
	Week 71	13	20.51	28.99	0.0	0.00	100.0	12	13.89	33.21	-33.3	0.00	100.0
	Week 74	10	20.00	32.20	0.0	0.00	100.0	10	13.33	35.83	-33.3	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	EV+Pembro (N=198)												
	BASELINE	170	16.47	25.96	0.0	0.00	100.0						
	Week 1	157	16.35	26.04	0.0	0.00	100.0	152	0.66	16.49	-66.7	0.00	66.7
	Week 2	167	14.97	24.45	0.0	0.00	100.0	155	-2.15	16.85	-66.7	0.00	33.3
	Week 3	161	16.98	26.90	0.0	0.00	100.0	147	-0.23	18.09	-100.0	0.00	66.7
	Week 4	158	16.03	25.72	0.0	0.00	100.0	145	-1.84	19.95	-100.0	0.00	66.7
	Week 5	154	14.72	24.99	0.0	0.00	100.0	140	-2.62	21.56	-100.0	0.00	100.0
	Week 6	153	19.83	30.21	0.0	0.00	100.0	138	1.21	22.57	-66.7	0.00	100.0
	Week 7	159	16.56	27.01	0.0	0.00	100.0	142	-1.41	22.06	-100.0	0.00	100.0
	Week 8	154	19.91	29.40	0.0	0.00	100.0	135	2.22	24.50	-100.0	0.00	100.0
	Week 9	162	18.72	28.52	0.0	0.00	100.0	146	0.46	23.16	-66.7	0.00	100.0
	Week 10	159	20.33	29.75	0.0	0.00	100.0	144	2.31	22.87	-66.7	0.00	100.0
	Week 11	161	19.05	28.80	0.0	0.00	100.0	143	0.23	23.57	-100.0	0.00	100.0
	Week 12	154	18.83	29.50	0.0	0.00	100.0	140	0.71	24.15	-66.7	0.00	100.0
	Week 14	154	21.21	31.39	0.0	0.00	100.0	137	2.43	24.13	-66.7	0.00	100.0
	Week 17	145	17.93	27.22	0.0	0.00	100.0	130	0.51	20.75	-66.7	0.00	100.0
	Week 20	139	20.86	30.10	0.0	0.00	100.0	126	3.97	24.44	-66.7	0.00	100.0
	Week 23	133	19.80	27.84	0.0	0.00	100.0	122	2.19	21.74	-66.7	0.00	100.0
	Week 26	129	20.15	28.69	0.0	0.00	100.0	118	1.70	21.72	-66.7	0.00	100.0
	Week 29	131	17.81	26.25	0.0	0.00	100.0	120	0.83	23.46	-100.0	0.00	100.0
	Week 32	111	19.82	29.26	0.0	0.00	100.0	102	2.94	24.87	-66.7	0.00	100.0
	Week 35	109	21.10	28.92	0.0	0.00	100.0	100	4.67	22.73	-33.3	0.00	100.0
	Week 38	107	22.74	29.88	0.0	0.00	100.0	100	4.67	22.73	-66.7	0.00	100.0
	Week 41	103	23.30	29.46	0.0	0.00	100.0	94	6.38	24.58	-66.7	0.00	100.0
	Week 44	88	18.94	28.94	0.0	0.00	100.0	81	4.12	23.80	-66.7	0.00	100.0
	Week 47	80	22.08	29.98	0.0	0.00	100.0	75	7.11	25.29	-33.3	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	73	18.72	28.32	0.0	0.00	100.0	68	3.43	22.41	-33.3	0.00	100.0
	Week 53	64	20.83	28.79	0.0	0.00	100.0	59	7.34	24.03	-33.3	0.00	100.0
	Week 56	66	19.70	29.80	0.0	0.00	100.0	61	3.28	21.69	-33.3	0.00	100.0
	Week 59	58	21.26	30.40	0.0	0.00	100.0	54	4.94	24.58	-33.3	0.00	100.0
	Week 62	54	17.90	29.47	0.0	0.00	100.0	52	5.13	24.15	-33.3	0.00	100.0
	Week 65	51	25.49	33.06	0.0	0.00	100.0	47	7.80	25.26	-33.3	0.00	100.0
	Week 68	49	21.09	32.41	0.0	0.00	100.0	48	4.86	26.62	-33.3	0.00	100.0
	Week 71	47	21.99	34.25	0.0	0.00	100.0	45	5.93	27.79	-33.3	0.00	100.0
	Week 74	42	22.22	33.47	0.0	0.00	100.0	41	8.94	29.84	-33.3	0.00	100.0
	Week 77	38	26.32	33.02	0.0	0.00	100.0	36	12.04	29.98	-33.3	0.00	100.0
	Week 80	35	26.67	32.14	0.0	0.00	100.0	32	12.50	26.44	-33.3	0.00	100.0
	Week 83	32	28.12	36.03	0.0	0.00	100.0	30	12.22	29.66	-33.3	0.00	100.0
	Week 86	30	25.56	31.18	0.0	0.00	100.0	27	9.88	28.96	-33.3	0.00	100.0
	Week 89	28	30.95	35.05	0.0	33.33	100.0	26	15.39	30.16	-33.3	0.00	100.0
	Week 92	24	22.22	32.10	0.0	0.00	100.0	22	10.61	27.96	-33.3	0.00	100.0
	Week 95	21	31.75	37.23	0.0	33.33	100.0	20	16.67	31.53	-33.3	0.00	100.0
	Week 98	16	18.75	24.25	0.0	0.00	66.7	15	6.67	18.69	-33.3	0.00	33.3
	Week 101	12	19.44	33.21	0.0	0.00	100.0	12	13.89	30.01	0.0	0.00	100.0
	Week 104	10	20.00	32.20	0.0	0.00	100.0	10	13.33	32.20	0.0	0.00	100.0
	Plat+Gem (N=185)												
	BASELINE	146	16.44	25.14	0.0	0.00	100.0						
	Week 1	131	19.08	28.65	0.0	0.00	100.0	120	3.33	21.35	-66.7	0.00	100.0
	Week 2	128	18.75	28.60	0.0	0.00	100.0	115	4.06	26.18	-66.7	0.00	100.0
	Week 3	141	16.31	24.44	0.0	0.00	100.0	126	0.79	22.10	-100.0	0.00	66.7
	Week 4	139	18.22	26.08	0.0	0.00	100.0	119	1.96	22.67	-66.7	0.00	66.7
	Week 5	143	18.41	25.84	0.0	0.00	100.0	120	3.61	23.19	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 6	133	18.55	26.08	0.0	0.00	100.0	114	4.68	23.83	-100.0	0.00	66.7
	Week 7	142	18.07	27.40	0.0	0.00	100.0	120	5.00	23.53	-66.7	0.00	66.7
	Week 8	125	17.87	26.62	0.0	0.00	100.0	109	5.50	24.22	-66.7	0.00	100.0
	Week 9	135	17.78	25.04	0.0	0.00	100.0	115	4.93	21.29	-33.3	0.00	66.7
	Week 10	131	19.34	26.13	0.0	0.00	100.0	111	4.80	26.53	-66.7	0.00	66.7
	Week 11	128	19.79	26.93	0.0	0.00	100.0	109	5.50	26.26	-100.0	0.00	66.7
	Week 12	124	19.35	25.18	0.0	0.00	100.0	108	4.01	26.07	-100.0	0.00	66.7
	Week 14	121	20.94	26.22	0.0	0.00	100.0	101	7.26	26.08	-66.7	0.00	66.7
	Week 17	121	18.18	26.18	0.0	0.00	100.0	101	6.60	24.95	-66.7	0.00	66.7
	Week 20	98	20.07	28.61	0.0	0.00	100.0	86	6.20	24.79	-66.7	0.00	66.7
	Week 23	93	18.28	26.70	0.0	0.00	100.0	78	5.98	26.72	-66.7	0.00	100.0
	Week 26	86	17.44	25.93	0.0	0.00	100.0	75	3.11	26.38	-66.7	0.00	66.7
	Week 29	76	16.23	26.38	0.0	0.00	100.0	65	3.08	21.02	-33.3	0.00	66.7
	Week 32	62	19.89	27.30	0.0	0.00	100.0	56	4.76	22.41	-33.3	0.00	66.7
	Week 35	58	16.09	25.16	0.0	0.00	100.0	52	1.28	18.62	-33.3	0.00	33.3
	Week 38	60	15.00	26.34	0.0	0.00	100.0	52	1.92	23.26	-66.7	0.00	66.7
	Week 41	52	18.59	28.33	0.0	0.00	100.0	44	6.06	23.04	-66.7	0.00	66.7
	Week 44	46	14.49	22.93	0.0	0.00	100.0	40	1.67	21.28	-66.7	0.00	66.7
	Week 47	44	14.39	20.83	0.0	0.00	66.7	38	2.63	22.44	-66.7	0.00	66.7
	Week 50	42	18.25	24.64	0.0	0.00	100.0	38	3.51	24.25	-66.7	0.00	66.7
	Week 53	38	12.28	19.64	0.0	0.00	66.7	34	1.96	21.62	-66.7	0.00	33.3
	Week 56	32	16.67	25.40	0.0	0.00	100.0	28	3.57	20.96	-33.3	0.00	66.7
	Week 59	31	8.60	14.83	0.0	0.00	33.3	27	0.00	16.01	-33.3	0.00	33.3
	Week 62	29	12.64	18.72	0.0	0.00	66.7	26	2.56	18.67	-33.3	0.00	33.3
	Week 65	25	9.33	15.27	0.0	0.00	33.3	21	3.17	17.96	-33.3	0.00	33.3
	Week 68	20	10.00	19.04	0.0	0.00	66.7	16	4.17	20.64	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 71	17	9.80	15.65	0.0	0.00	33.3	14	4.76	17.82	-33.3	0.00	33.3
	Week 74	17	7.84	14.57	0.0	0.00	33.3	14	0.00	18.49	-33.3	0.00	33.3
	Week 77	16	12.50	20.64	0.0	0.00	66.7	13	2.56	21.35	-33.3	0.00	33.3
	Week 80	13	7.69	14.62	0.0	0.00	33.3	12	-2.78	17.16	-33.3	0.00	33.3
	Week 83	11	12.12	16.82	0.0	0.00	33.3	10	0.00	15.71	-33.3	0.00	33.3
	Week 86	12	13.89	22.29	0.0	0.00	66.7	11	0.00	21.08	-33.3	0.00	33.3
	Week 89	11	12.12	16.82	0.0	0.00	33.3	10	-3.33	18.92	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	EV+Pembro (N= 42)												
	BASELINE	36	16.67	27.02	0.0	0.00	100.0						
	Week 1	33	18.18	23.70	0.0	0.00	66.7	32	1.04	17.93	-33.3	0.00	33.3
	Week 2	36	13.89	20.12	0.0	0.00	66.7	34	-1.96	27.14	-100.0	0.00	33.3
	Week 3	37	18.92	24.27	0.0	0.00	100.0	35	2.86	29.56	-100.0	0.00	66.7
	Week 4	36	18.52	24.49	0.0	0.00	66.7	34	3.92	25.64	-100.0	0.00	33.3
	Week 5	36	19.44	24.40	0.0	0.00	66.7	33	4.04	28.58	-100.0	0.00	66.7
	Week 6	35	17.14	27.26	0.0	0.00	100.0	32	4.17	27.76	-100.0	0.00	66.7
	Week 7	36	19.44	25.67	0.0	0.00	100.0	34	3.92	28.15	-100.0	0.00	33.3
	Week 8	37	19.82	24.16	0.0	0.00	66.7	36	3.70	27.35	-100.0	0.00	33.3
	Week 9	35	18.09	23.35	0.0	0.00	66.7	34	4.90	20.32	-33.3	0.00	33.3
	Week 10	32	18.75	23.85	0.0	0.00	66.7	31	4.30	28.21	-100.0	0.00	33.3
	Week 11	33	19.19	25.04	0.0	0.00	66.7	32	2.08	29.25	-100.0	0.00	66.7
	Week 12	32	16.67	22.40	0.0	0.00	66.7	31	1.07	27.87	-100.0	0.00	33.3
	Week 14	31	18.28	22.51	0.0	0.00	66.7	30	4.44	20.96	-33.3	0.00	33.3
	Week 17	33	20.20	27.56	0.0	0.00	100.0	32	5.21	30.66	-100.0	0.00	66.7
	Week 20	28	17.86	26.42	0.0	0.00	100.0	28	2.38	32.62	-100.0	0.00	66.7
	Week 23	29	16.09	19.15	0.0	0.00	66.7	29	0.00	28.17	-100.0	0.00	33.3
	Week 26	27	17.28	25.10	0.0	0.00	66.7	26	2.56	31.16	-100.0	0.00	66.7
	Week 29	26	19.23	21.44	0.0	16.67	66.7	25	6.67	27.22	-66.7	0.00	66.7
	Week 32	24	18.06	25.97	0.0	0.00	66.7	23	11.59	23.80	-33.3	0.00	66.7
	Week 35	23	17.39	24.35	0.0	0.00	66.7	22	9.09	21.04	-33.3	0.00	66.7
	Week 38	25	16.00	21.77	0.0	0.00	66.7	24	6.94	29.45	-100.0	0.00	66.7
	Week 41	26	14.10	21.44	0.0	0.00	66.7	25	2.67	28.74	-100.0	0.00	66.7
	Week 44	20	15.00	20.16	0.0	0.00	66.7	19	3.51	18.91	-33.3	0.00	33.3
	Week 47	20	15.00	20.16	0.0	0.00	66.7	19	1.75	32.34	-100.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	16	20.83	26.87	0.0	0.00	66.7	16	12.50	26.88	-33.3	0.00	66.7
	Week 53	15	22.22	24.13	0.0	33.33	66.7	15	8.89	32.04	-66.7	0.00	66.7
	Week 56	15	20.00	24.56	0.0	0.00	66.7	15	8.89	23.46	-33.3	0.00	66.7
	Week 59	14	26.19	29.75	0.0	16.67	66.7	14	14.29	28.39	-33.3	0.00	66.7
	Week 62	11	12.12	16.82	0.0	0.00	33.3	11	0.00	21.08	-33.3	0.00	33.3
	Plat+Gem (N= 57)												
	BASELINE	42	10.32	18.75	0.0	0.00	66.7						
	Week 1	42	9.52	21.19	0.0	0.00	100.0	38	0.00	15.50	-33.3	0.00	33.3
	Week 2	43	9.30	20.99	0.0	0.00	100.0	36	-2.78	16.67	-33.3	0.00	33.3
	Week 3	43	6.98	15.53	0.0	0.00	66.7	36	-1.85	15.82	-33.3	0.00	33.3
	Week 4	44	8.33	14.60	0.0	0.00	33.3	37	0.00	15.71	-33.3	0.00	33.3
	Week 5	44	9.85	18.44	0.0	0.00	66.7	36	0.93	14.88	-33.3	0.00	33.3
	Week 6	41	9.76	18.62	0.0	0.00	66.7	35	1.90	19.71	-33.3	0.00	66.7
	Week 7	44	9.85	18.44	0.0	0.00	66.7	37	0.90	22.89	-33.3	0.00	66.7
	Week 8	42	11.11	19.01	0.0	0.00	66.7	35	0.95	17.12	-33.3	0.00	66.7
	Week 9	42	11.11	17.52	0.0	0.00	66.7	35	1.90	17.97	-33.3	0.00	33.3
	Week 10	35	10.48	17.66	0.0	0.00	66.7	28	1.19	16.93	-33.3	0.00	33.3
	Week 11	40	10.83	15.81	0.0	0.00	33.3	34	1.96	18.24	-33.3	0.00	33.3
	Week 12	35	14.28	20.27	0.0	0.00	66.7	30	6.67	22.15	-33.3	0.00	66.7
	Week 14	32	11.46	18.18	0.0	0.00	66.7	27	1.23	21.64	-33.3	0.00	66.7
	Week 17	34	13.72	21.89	0.0	0.00	100.0	29	5.75	26.83	-33.3	0.00	100.0
	Week 20	28	10.71	15.85	0.0	0.00	33.3	24	1.39	18.33	-33.3	0.00	33.3
	Week 23	22	13.64	16.77	0.0	0.00	33.3	19	3.51	21.93	-33.3	0.00	33.3
	Week 26	22	15.15	22.37	0.0	0.00	66.7	20	3.33	23.94	-33.3	0.00	66.7
	Week 29	24	11.11	18.82	0.0	0.00	66.7	21	0.00	21.08	-33.3	0.00	33.3
	Week 32	21	15.87	24.99	0.0	0.00	100.0	20	5.00	24.84	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 35	18	16.67	23.57	0.0	0.00	66.7	17	7.84	22.14	-33.3	0.00	66.7
	Week 38	14	14.28	17.12	0.0	0.00	33.3	13	2.56	21.35	-33.3	0.00	33.3
	Week 41	13	12.82	16.88	0.0	0.00	33.3	12	0.00	24.62	-33.3	0.00	33.3
	Week 44	14	21.43	21.11	0.0	33.33	66.7	13	10.26	28.50	-33.3	0.00	66.7
	Week 47	12	16.67	17.41	0.0	16.67	33.3	11	3.03	27.71	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Visceral metastases	EV+Pembro (N=170)												
	BASELINE	146	16.89	26.62	0.0	0.00	100.0						
	Week 1	135	18.27	27.83	0.0	0.00	100.0	131	0.76	17.28	-66.7	0.00	66.7
	Week 2	145	14.94	23.87	0.0	0.00	100.0	134	-2.49	20.28	-100.0	0.00	33.3
	Week 3	141	18.20	27.16	0.0	0.00	100.0	129	-0.26	22.24	-100.0	0.00	66.7
	Week 4	136	16.91	25.66	0.0	0.00	100.0	125	-1.33	23.34	-100.0	0.00	66.7
	Week 5	131	16.03	25.60	0.0	0.00	100.0	118	-2.82	25.25	-100.0	0.00	100.0
	Week 6	127	19.95	30.07	0.0	0.00	100.0	113	2.06	25.70	-100.0	0.00	100.0
	Week 7	135	17.78	27.86	0.0	0.00	100.0	121	-1.38	25.60	-100.0	0.00	100.0
	Week 8	131	19.59	28.90	0.0	0.00	100.0	118	0.85	27.03	-100.0	0.00	100.0
	Week 9	136	18.87	28.02	0.0	0.00	100.0	124	1.34	24.56	-66.7	0.00	100.0
	Week 10	135	20.25	29.67	0.0	0.00	100.0	124	2.15	26.11	-100.0	0.00	100.0
	Week 11	134	19.15	28.72	0.0	0.00	100.0	121	-0.28	24.91	-100.0	0.00	100.0
	Week 12	131	17.81	28.13	0.0	0.00	100.0	120	-0.28	27.16	-100.0	0.00	100.0
	Week 14	130	21.54	30.74	0.0	0.00	100.0	117	2.28	25.79	-66.7	0.00	100.0
	Week 17	124	18.01	27.35	0.0	0.00	100.0	111	0.00	24.20	-100.0	0.00	100.0
	Week 20	115	19.42	28.95	0.0	0.00	100.0	105	2.22	28.22	-100.0	0.00	100.0
	Week 23	111	19.82	26.73	0.0	0.00	100.0	103	0.97	26.18	-100.0	0.00	100.0
	Week 26	106	18.55	27.25	0.0	0.00	100.0	97	-0.34	24.77	-100.0	0.00	100.0
	Week 29	106	17.30	24.87	0.0	0.00	100.0	98	0.34	26.43	-100.0	0.00	100.0
	Week 32	92	18.12	28.13	0.0	0.00	100.0	85	2.35	24.01	-66.7	0.00	100.0
	Week 35	86	20.54	28.08	0.0	0.00	100.0	79	5.48	22.91	-33.3	0.00	100.0
	Week 38	90	21.11	28.90	0.0	0.00	100.0	84	3.57	26.39	-100.0	0.00	100.0
	Week 41	87	21.07	29.25	0.0	0.00	100.0	81	4.12	28.08	-100.0	0.00	100.0
	Week 44	73	17.35	26.71	0.0	0.00	100.0	68	1.96	23.66	-66.7	0.00	100.0
	Week 47	68	19.12	27.21	0.0	0.00	100.0	63	2.65	27.63	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	61	18.58	28.23	0.0	0.00	100.0	57	3.51	24.14	-33.3	0.00	100.0
	Week 53	54	19.75	27.87	0.0	0.00	100.0	50	6.67	27.77	-66.7	0.00	100.0
	Week 56	58	18.97	29.36	0.0	0.00	100.0	54	3.70	23.05	-33.3	0.00	100.0
	Week 59	50	22.00	31.31	0.0	0.00	100.0	47	6.38	26.59	-33.3	0.00	100.0
	Week 62	45	16.30	27.18	0.0	0.00	100.0	43	2.33	24.55	-33.3	0.00	100.0
	Week 65	37	23.42	31.29	0.0	0.00	100.0	34	4.90	26.12	-33.3	0.00	100.0
	Week 68	35	21.90	33.28	0.0	0.00	100.0	34	2.94	27.67	-33.3	0.00	100.0
	Week 71	31	20.43	34.08	0.0	0.00	100.0	30	1.11	26.96	-33.3	0.00	100.0
	Week 74	29	22.99	33.46	0.0	0.00	100.0	28	5.95	31.50	-33.3	0.00	100.0
	Week 77	26	24.36	30.63	0.0	16.67	100.0	25	5.33	29.94	-33.3	0.00	100.0
	Week 80	22	25.76	32.42	0.0	16.67	100.0	21	7.94	29.64	-33.3	0.00	100.0
	Week 83	23	24.64	33.66	0.0	0.00	100.0	22	4.54	29.63	-33.3	0.00	100.0
	Week 86	21	22.22	30.43	0.0	0.00	100.0	20	3.33	28.41	-33.3	0.00	100.0
	Week 89	21	33.33	34.96	0.0	33.33	100.0	20	13.33	29.42	-33.3	0.00	100.0
	Week 92	18	24.07	31.94	0.0	16.67	100.0	17	9.80	28.30	-33.3	0.00	100.0
	Week 95	13	35.90	37.17	0.0	33.33	100.0	12	16.67	30.15	0.0	0.00	100.0
	Week 98	11	24.24	26.21	0.0	33.33	66.7	11	12.12	16.82	0.0	0.00	33.3
	Week 101	11	36.36	40.70	0.0	33.33	100.0	11	24.24	39.70	0.0	0.00	100.0
	Plat+Gem (N=161)												
	BASELINE	129	17.05	23.98	0.0	0.00	100.0						
	Week 1	113	17.99	26.74	0.0	0.00	100.0	105	2.86	21.24	-66.7	0.00	100.0
	Week 2	108	19.14	27.80	0.0	0.00	100.0	98	2.72	25.63	-66.7	0.00	100.0
	Week 3	121	15.43	23.59	0.0	0.00	100.0	109	-0.31	21.99	-100.0	0.00	66.7
	Week 4	116	17.53	25.05	0.0	0.00	100.0	101	0.66	22.60	-66.7	0.00	66.7
	Week 5	121	17.91	24.36	0.0	0.00	100.0	104	2.24	20.91	-100.0	0.00	66.7
	Week 6	118	16.67	23.77	0.0	0.00	100.0	102	2.94	23.03	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 7	121	17.08	25.50	0.0	0.00	100.0	104	3.21	23.00	-66.7	0.00	66.7
	Week 8	108	16.36	23.90	0.0	0.00	100.0	96	3.13	24.22	-66.7	0.00	100.0
	Week 9	114	17.25	23.98	0.0	0.00	100.0	99	3.37	21.03	-33.3	0.00	66.7
	Week 10	109	19.57	25.34	0.0	0.00	100.0	94	3.90	26.26	-66.7	0.00	66.7
	Week 11	109	18.04	24.65	0.0	0.00	100.0	95	3.16	26.22	-100.0	0.00	66.7
	Week 12	103	18.77	23.65	0.0	0.00	66.7	91	3.66	26.50	-100.0	0.00	66.7
	Week 14	98	20.75	26.00	0.0	0.00	100.0	85	5.49	28.10	-66.7	0.00	66.7
	Week 17	103	18.12	24.15	0.0	0.00	100.0	89	4.49	25.72	-66.7	0.00	66.7
	Week 20	82	20.32	26.58	0.0	0.00	100.0	75	4.44	25.31	-66.7	0.00	66.7
	Week 23	77	17.32	23.95	0.0	0.00	100.0	68	3.43	26.48	-66.7	0.00	100.0
	Week 26	71	19.72	25.56	0.0	0.00	100.0	65	4.62	23.48	-33.3	0.00	66.7
	Week 29	65	15.38	22.88	0.0	0.00	100.0	59	0.56	20.98	-33.3	0.00	33.3
	Week 32	52	19.23	25.00	0.0	0.00	100.0	49	3.40	21.78	-33.3	0.00	66.7
	Week 35	47	17.73	24.92	0.0	0.00	100.0	44	2.27	19.55	-33.3	0.00	66.7
	Week 38	42	15.87	24.68	0.0	0.00	100.0	39	1.71	21.56	-33.3	0.00	66.7
	Week 41	35	17.14	21.95	0.0	0.00	100.0	32	3.12	19.60	-33.3	0.00	33.3
	Week 44	36	17.59	18.66	0.0	16.67	66.7	33	4.04	21.66	-33.3	0.00	66.7
	Week 47	32	16.67	18.93	0.0	0.00	66.7	30	0.00	19.57	-33.3	0.00	33.3
	Week 50	30	21.11	22.29	0.0	33.33	66.7	29	8.05	19.22	-33.3	0.00	66.7
	Week 53	25	16.00	19.53	0.0	0.00	66.7	24	5.56	16.05	-33.3	0.00	33.3
	Week 56	22	24.24	27.57	0.0	33.33	100.0	21	7.94	25.61	-33.3	0.00	66.7
	Week 59	22	10.61	15.89	0.0	0.00	33.3	21	0.00	18.26	-33.3	0.00	33.3
	Week 62	19	14.03	20.23	0.0	0.00	66.7	18	3.70	22.55	-33.3	0.00	66.7
	Week 65	19	12.28	16.52	0.0	0.00	33.3	18	1.85	17.98	-33.3	0.00	33.3
	Week 68	13	5.13	12.52	0.0	0.00	33.3	12	-2.78	17.16	-33.3	0.00	33.3
	Week 71	13	20.51	28.99	0.0	0.00	100.0	12	11.11	32.82	-33.3	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 74	11	18.18	31.14	0.0	0.00	100.0	11	6.06	35.96	-33.3	0.00	100.0
	Week 77	10	13.33	23.31	0.0	0.00	66.7	10	-3.33	18.92	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Lymph node only	EV+Pembro (N= 60)												
	BASELINE	53	15.09	23.17	0.0	0.00	100.0						
	Week 1	49	13.60	19.15	0.0	0.00	66.7	47	0.71	16.28	-33.3	0.00	66.7
	Week 2	50	14.00	21.39	0.0	0.00	100.0	48	-1.39	15.31	-33.3	0.00	33.3
	Week 3	50	16.67	25.42	0.0	0.00	100.0	47	2.13	17.59	-33.3	0.00	66.7
	Week 4	50	15.33	23.53	0.0	0.00	100.0	47	0.71	16.29	-33.3	0.00	33.3
	Week 5	53	15.72	24.11	0.0	0.00	100.0	49	2.04	18.52	-33.3	0.00	66.7
	Week 6	53	18.24	28.17	0.0	0.00	100.0	50	1.33	20.16	-33.3	0.00	66.7
	Week 7	52	15.38	22.35	0.0	0.00	100.0	48	2.08	18.71	-66.7	0.00	33.3
	Week 8	52	21.79	28.69	0.0	0.00	100.0	47	6.38	20.43	-33.3	0.00	66.7
	Week 9	53	18.24	25.79	0.0	0.00	100.0	49	1.36	19.20	-33.3	0.00	33.3
	Week 10	48	18.75	25.64	0.0	0.00	100.0	44	3.03	17.34	-33.3	0.00	33.3
	Week 11	53	18.87	25.75	0.0	0.00	100.0	48	2.78	25.58	-100.0	0.00	66.7
	Week 12	48	20.14	28.13	0.0	0.00	100.0	45	3.70	19.10	-33.3	0.00	66.7
	Week 14	48	18.75	27.42	0.0	0.00	100.0	44	4.55	18.46	-33.3	0.00	66.7
	Week 17	46	19.56	25.89	0.0	0.00	100.0	44	5.30	21.50	-33.3	0.00	66.7
	Week 20	44	23.48	30.14	0.0	0.00	100.0	42	7.94	21.85	-33.3	0.00	66.7
	Week 23	43	17.05	24.53	0.0	0.00	100.0	41	3.25	14.54	-33.3	0.00	33.3
	Week 26	42	21.43	29.28	0.0	0.00	100.0	40	5.83	21.20	-33.3	0.00	66.7
	Week 29	45	19.26	27.97	0.0	0.00	100.0	42	3.17	17.75	-33.3	0.00	33.3
	Week 32	38	21.93	30.29	0.0	0.00	100.0	36	7.41	25.34	-33.3	0.00	66.7
	Week 35	42	20.63	29.40	0.0	0.00	100.0	40	5.00	22.07	-33.3	0.00	66.7
	Week 38	38	21.93	29.28	0.0	0.00	100.0	36	7.41	18.02	-33.3	0.00	66.7
	Week 41	37	22.52	27.28	0.0	0.00	100.0	34	7.84	18.46	-33.3	0.00	66.7
	Week 44	31	19.35	29.53	0.0	0.00	100.0	29	6.90	18.65	-33.3	0.00	66.7
	Week 47	28	21.43	31.71	0.0	0.00	100.0	27	9.88	22.30	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	25	16.00	25.68	0.0	0.00	66.7	24	4.17	14.95	-33.3	0.00	33.3
	Week 53	23	21.74	27.72	0.0	0.00	66.7	22	7.58	17.62	-33.3	0.00	33.3
	Week 56	21	20.63	28.82	0.0	0.00	100.0	20	5.00	19.57	-33.3	0.00	66.7
	Week 59	20	20.00	27.36	0.0	0.00	66.7	19	5.26	20.07	-33.3	0.00	66.7
	Week 62	19	15.79	28.04	0.0	0.00	66.7	19	5.26	16.72	0.0	0.00	66.7
	Week 65	20	28.33	34.67	0.0	0.00	100.0	19	12.28	22.80	0.0	0.00	66.7
	Week 68	17	19.61	31.31	0.0	0.00	100.0	17	7.84	27.71	-33.3	0.00	100.0
	Week 71	19	22.81	33.43	0.0	0.00	100.0	18	9.26	25.06	0.0	0.00	100.0
	Week 74	17	21.57	31.05	0.0	0.00	100.0	17	9.80	28.30	-33.3	0.00	100.0
	Week 77	17	25.49	32.34	0.0	0.00	100.0	16	14.58	27.13	0.0	0.00	100.0
	Week 80	17	23.53	28.30	0.0	0.00	66.7	15	8.89	19.79	0.0	0.00	66.7
	Week 83	13	28.21	35.61	0.0	0.00	100.0	12	13.89	26.43	0.0	0.00	66.7
	Week 86	12	25.00	28.87	0.0	16.67	66.7	10	6.67	26.30	-33.3	0.00	66.7
	Week 89	11	24.24	30.15	0.0	0.00	66.7	10	10.00	27.45	-33.3	0.00	66.7
	Plat+Gem (N= 67)												
	BASELINE	49	11.56	25.05	0.0	0.00	100.0						
	Week 1	51	14.38	29.25	0.0	0.00	100.0	45	0.74	16.65	-66.7	0.00	33.3
	Week 2	53	11.95	26.23	0.0	0.00	100.0	44	0.76	20.94	-33.3	0.00	100.0
	Week 3	53	12.58	22.86	0.0	0.00	100.0	44	0.76	18.31	-66.7	0.00	33.3
	Week 4	58	13.79	23.39	0.0	0.00	100.0	47	2.84	18.16	-33.3	0.00	33.3
	Week 5	56	14.88	26.15	0.0	0.00	100.0	44	4.55	23.39	-33.3	0.00	100.0
	Week 6	48	18.06	28.32	0.0	0.00	100.0	40	7.50	23.25	-33.3	0.00	66.7
	Week 7	56	14.88	26.91	0.0	0.00	100.0	46	5.07	23.27	-33.3	0.00	66.7
	Week 8	52	16.03	27.61	0.0	0.00	100.0	42	5.56	17.91	-33.3	0.00	66.7
	Week 9	53	13.84	23.96	0.0	0.00	100.0	42	3.97	18.33	-33.3	0.00	33.3
	Week 10	47	12.77	24.63	0.0	0.00	100.0	36	1.85	21.00	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	51	17.65	26.96	0.0	0.00	100.0	41	7.32	20.43	-33.3	0.00	66.7
	Week 12	47	17.02	25.89	0.0	0.00	100.0	39	4.27	20.49	-66.7	0.00	33.3
	Week 14	47	16.31	23.95	0.0	0.00	100.0	36	6.48	17.49	-33.3	0.00	33.3
	Week 17	45	14.07	26.10	0.0	0.00	100.0	35	8.57	18.69	-33.3	0.00	66.7
	Week 20	38	12.28	26.19	0.0	0.00	100.0	30	3.33	16.02	-33.3	0.00	33.3
	Week 23	32	18.75	29.25	0.0	0.00	100.0	25	9.33	24.57	-33.3	0.00	66.7
	Week 26	30	12.22	25.50	0.0	0.00	100.0	24	-1.39	31.82	-66.7	0.00	66.7
	Week 29	28	15.48	30.74	0.0	0.00	100.0	21	6.35	20.05	-33.3	0.00	66.7
	Week 32	26	19.23	31.51	0.0	0.00	100.0	22	6.06	26.50	-33.3	0.00	66.7
	Week 35	23	11.59	25.84	0.0	0.00	100.0	19	-1.75	17.47	-33.3	0.00	33.3
	Week 38	26	14.10	26.95	0.0	0.00	100.0	20	0.00	26.49	-66.7	0.00	66.7
	Week 41	24	16.67	32.60	0.0	0.00	100.0	18	1.85	26.75	-66.7	0.00	66.7
	Week 44	18	14.82	30.73	0.0	0.00	100.0	14	0.00	29.24	-66.7	0.00	66.7
	Week 47	18	12.96	23.26	0.0	0.00	66.7	13	5.13	32.90	-66.7	0.00	66.7
	Week 50	16	18.75	32.13	0.0	0.00	100.0	13	-5.13	32.90	-66.7	0.00	66.7
	Week 53	15	11.11	24.13	0.0	0.00	66.7	12	-8.33	25.13	-66.7	0.00	33.3
	Week 56	15	11.11	20.57	0.0	0.00	66.7	11	0.00	21.08	-33.3	0.00	33.3
	Week 59	12	5.56	12.97	0.0	0.00	33.3	9	-7.41	14.70	-33.3	0.00	0.0
	Week 62	10	13.33	23.31	0.0	0.00	66.7	8	-4.17	21.36	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
EV+Pembro (N=202)												
BASELINE	160	15.83	25.62	0.0	0.00	100.0						
Week 1	141	14.66	25.31	0.0	0.00	100.0	129	-0.78	16.91	-33.3	0.00	100.0
Week 2	150	18.22	26.92	0.0	0.00	100.0	133	2.76	16.94	-66.7	0.00	66.7
Week 3	139	17.98	27.88	0.0	0.00	100.0	122	1.37	19.36	-66.7	0.00	66.7
Week 4	145	17.47	25.78	0.0	0.00	100.0	129	2.33	19.18	-66.7	0.00	66.7
Week 5	137	16.30	26.85	0.0	0.00	100.0	121	-0.28	18.51	-66.7	0.00	66.7
Week 6	146	16.67	26.04	0.0	0.00	100.0	124	1.88	20.95	-66.7	0.00	100.0
Week 7	147	16.55	25.09	0.0	0.00	100.0	124	2.15	21.98	-100.0	0.00	66.7
Week 8	147	18.59	27.35	0.0	0.00	100.0	124	3.49	21.60	-66.7	0.00	100.0
Week 9	142	19.25	28.16	0.0	0.00	100.0	121	3.86	24.03	-66.7	0.00	100.0
Week 10	139	18.22	26.99	0.0	0.00	100.0	118	1.98	22.77	-66.7	0.00	66.7
Week 11	137	18.98	27.05	0.0	0.00	100.0	115	5.22	22.77	-66.7	0.00	100.0
Week 12	142	17.84	25.93	0.0	0.00	100.0	119	3.36	24.32	-100.0	0.00	66.7
Week 14	139	15.59	23.16	0.0	0.00	100.0	116	1.72	23.61	-100.0	0.00	66.7
Week 17	132	16.92	23.48	0.0	0.00	100.0	111	2.70	23.84	-100.0	0.00	66.7
Week 20	120	16.39	22.03	0.0	0.00	100.0	103	1.94	22.78	-66.7	0.00	66.7
Week 23	117	17.38	24.21	0.0	0.00	100.0	97	3.78	22.50	-66.7	0.00	66.7
Week 26	112	16.37	21.92	0.0	0.00	100.0	94	2.84	23.27	-66.7	0.00	66.7
Week 29	107	17.13	21.65	0.0	0.00	100.0	93	4.30	24.19	-66.7	0.00	66.7
Week 32	102	17.32	23.79	0.0	0.00	100.0	88	4.55	21.55	-66.7	0.00	100.0
Week 35	98	19.05	27.50	0.0	0.00	100.0	86	5.04	25.32	-100.0	0.00	100.0
Week 38	97	15.81	23.62	0.0	0.00	100.0	86	1.55	25.00	-100.0	0.00	66.7
Week 41	95	20.70	26.26	0.0	0.00	100.0	84	5.56	26.80	-100.0	0.00	100.0
Week 44	86	21.32	28.43	0.0	0.00	100.0	74	8.11	25.77	-66.7	0.00	100.0
Week 47	79	23.21	27.92	0.0	33.33	100.0	70	9.52	23.50	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	74	21.17	25.63	0.0	0.00	100.0	64	7.81	23.57	-66.7	0.00	66.7
Week 53	74	21.62	24.94	0.0	16.67	100.0	63	9.52	21.11	-66.7	0.00	66.7
Week 56	72	21.76	26.34	0.0	0.00	100.0	61	7.65	22.27	-66.7	0.00	66.7
Week 59	69	20.77	25.63	0.0	0.00	100.0	57	7.02	21.58	-66.7	0.00	66.7
Week 62	62	19.35	25.28	0.0	0.00	100.0	52	5.77	23.54	-66.7	0.00	66.7
Week 65	43	24.03	31.14	0.0	0.00	100.0	40	10.00	21.62	-33.3	0.00	66.7
Week 68	46	22.46	26.34	0.0	16.67	100.0	42	8.73	23.35	-66.7	0.00	66.7
Week 71	42	22.22	30.06	0.0	0.00	100.0	38	5.26	23.92	-66.7	0.00	100.0
Week 74	38	25.44	29.44	0.0	33.33	100.0	35	7.62	24.37	-66.7	0.00	66.7
Week 77	37	22.52	28.39	0.0	0.00	100.0	33	4.04	23.21	-66.7	0.00	66.7
Week 80	36	21.30	25.39	0.0	16.67	100.0	34	4.90	23.40	-66.7	0.00	66.7
Week 83	30	18.89	22.63	0.0	0.00	66.7	29	4.60	24.76	-66.7	0.00	66.7
Week 86	26	19.23	23.42	0.0	0.00	66.7	25	8.00	27.69	-66.7	0.00	66.7
Week 89	20	23.33	21.90	0.0	33.33	66.7	19	7.02	28.50	-66.7	0.00	66.7
Week 92	19	22.81	24.98	0.0	33.33	66.7	18	9.26	25.06	-66.7	0.00	33.3
Week 95	14	19.05	21.54	0.0	16.67	66.7	13	0.00	23.57	-66.7	0.00	33.3
Week 98	10	16.67	23.57	0.0	0.00	66.7	9	-7.41	22.22	-66.7	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Plat+Gem (N=202)												
BASELINE	165	11.11	21.57	0.0	0.00	100.0						
Week 1	144	10.88	21.53	0.0	0.00	100.0	139	-0.48	17.49	-66.7	0.00	66.7
Week 2	147	14.74	26.21	0.0	0.00	100.0	135	2.96	20.55	-33.3	0.00	100.0
Week 3	149	12.08	24.27	0.0	0.00	100.0	136	1.72	17.36	-33.3	0.00	66.7
Week 4	150	12.00	23.26	0.0	0.00	100.0	135	2.47	18.94	-33.3	0.00	66.7
Week 5	153	12.20	22.21	0.0	0.00	100.0	138	3.14	20.09	-66.7	0.00	66.7
Week 6	145	13.56	23.73	0.0	0.00	100.0	131	3.82	20.10	-66.7	0.00	66.7
Week 7	148	10.81	20.65	0.0	0.00	100.0	134	0.75	20.22	-66.7	0.00	66.7
Week 8	145	13.10	23.01	0.0	0.00	100.0	132	3.79	22.80	-66.7	0.00	100.0
Week 9	141	13.00	22.46	0.0	0.00	100.0	125	3.73	21.26	-66.7	0.00	66.7
Week 10	142	12.91	23.44	0.0	0.00	100.0	130	2.82	20.77	-66.7	0.00	66.7
Week 11	126	15.08	25.16	0.0	0.00	100.0	114	4.97	22.71	-33.3	0.00	66.7
Week 12	130	12.56	22.07	0.0	0.00	100.0	115	2.61	20.30	-66.7	0.00	66.7
Week 14	125	13.07	24.65	0.0	0.00	100.0	109	3.36	22.20	-66.7	0.00	66.7
Week 17	120	13.33	24.21	0.0	0.00	100.0	106	5.66	22.29	-33.3	0.00	100.0
Week 20	104	15.38	25.83	0.0	0.00	100.0	91	5.49	23.45	-33.3	0.00	100.0
Week 23	88	13.64	24.05	0.0	0.00	100.0	80	4.58	21.70	-33.3	0.00	100.0
Week 26	81	15.64	26.92	0.0	0.00	100.0	75	6.67	23.89	-33.3	0.00	100.0
Week 29	77	14.72	25.07	0.0	0.00	100.0	71	6.10	24.11	-33.3	0.00	100.0
Week 32	63	12.70	20.24	0.0	0.00	66.7	58	4.02	19.82	-33.3	0.00	66.7
Week 35	62	10.21	20.55	0.0	0.00	100.0	56	2.98	19.36	-33.3	0.00	66.7
Week 38	56	11.31	22.27	0.0	0.00	100.0	50	4.67	23.34	-33.3	0.00	100.0
Week 41	52	13.46	24.04	0.0	0.00	100.0	47	4.96	23.03	-33.3	0.00	66.7
Week 44	49	14.29	24.53	0.0	0.00	100.0	44	6.06	21.89	-33.3	0.00	66.7
Week 47	43	12.40	20.60	0.0	0.00	66.7	39	4.27	21.87	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	36	9.26	23.38	0.0	0.00	100.0	31	2.15	28.46	-66.7	0.00	100.0
Week 53	31	9.68	19.61	0.0	0.00	66.7	28	4.76	23.51	-33.3	0.00	66.7
Week 56	30	11.11	22.03	0.0	0.00	66.7	29	3.45	22.44	-33.3	0.00	66.7
Week 59	23	11.59	23.80	0.0	0.00	100.0	21	1.59	28.82	-33.3	0.00	100.0
Week 62	20	13.33	19.94	0.0	0.00	66.7	20	3.33	21.36	-33.3	0.00	33.3
Week 65	17	15.69	29.15	0.0	0.00	100.0	16	8.33	35.49	-33.3	0.00	100.0
Week 68	13	10.26	21.01	0.0	0.00	66.7	13	5.13	26.69	-33.3	0.00	66.7
Week 71	13	15.38	29.23	0.0	0.00	100.0	13	7.69	33.76	-33.3	0.00	100.0
Week 74	11	3.03	10.05	0.0	0.00	33.3	11	-3.03	17.98	-33.3	0.00	33.3
Week 77	11	6.06	13.48	0.0	0.00	33.3	11	3.03	17.98	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Present	EV+Pembro (N= 50)												
	BASELINE	40	9.17	22.63	0.0	0.00	100.0						
	Week 1	38	9.65	24.39	0.0	0.00	100.0	34	0.00	11.60	-33.3	0.00	33.3
	Week 2	35	12.38	21.52	0.0	0.00	66.7	32	5.21	12.30	0.0	0.00	33.3
	Week 3	32	10.42	21.48	0.0	0.00	100.0	30	1.11	16.34	-66.7	0.00	33.3
	Week 4	35	11.43	24.18	0.0	0.00	100.0	31	4.30	14.25	0.0	0.00	66.7
	Week 5	32	15.62	26.75	0.0	0.00	100.0	28	5.95	15.85	0.0	0.00	66.7
	Week 6	35	10.48	17.66	0.0	0.00	66.7	30	3.33	20.25	-66.7	0.00	66.7
	Week 7	35	13.33	21.69	0.0	0.00	66.7	29	6.90	16.38	0.0	0.00	66.7
	Week 8	38	17.54	27.66	0.0	0.00	100.0	31	11.83	23.65	0.0	0.00	100.0
	Week 9	33	19.19	30.08	0.0	0.00	100.0	29	10.34	28.32	-66.7	0.00	100.0
	Week 10	30	17.78	27.31	0.0	0.00	100.0	25	8.00	25.96	-66.7	0.00	66.7
	Week 11	31	15.05	28.33	0.0	0.00	100.0	27	8.64	23.74	-33.3	0.00	100.0
	Week 12	32	12.50	25.04	0.0	0.00	100.0	28	5.95	18.27	-33.3	0.00	66.7
	Week 14	36	13.89	25.67	0.0	0.00	100.0	31	6.45	21.81	-66.7	0.00	66.7
	Week 17	33	16.16	27.79	0.0	0.00	100.0	27	7.41	25.04	-66.7	0.00	66.7
	Week 20	28	9.52	19.99	0.0	0.00	66.7	25	4.00	22.20	-66.7	0.00	66.7
	Week 23	28	14.29	24.73	0.0	0.00	100.0	24	12.50	21.56	0.0	0.00	66.7
	Week 26	28	11.90	22.62	0.0	0.00	66.7	24	9.72	20.80	0.0	0.00	66.7
	Week 29	27	13.58	24.91	0.0	0.00	100.0	25	8.00	22.11	-33.3	0.00	66.7
	Week 32	25	13.33	25.46	0.0	0.00	100.0	23	8.70	27.00	-33.3	0.00	100.0
	Week 35	26	15.38	27.05	0.0	0.00	100.0	24	9.72	23.01	0.0	0.00	100.0
	Week 38	26	15.38	30.16	0.0	0.00	100.0	24	9.72	20.80	0.0	0.00	66.7
	Week 41	25	18.67	29.00	0.0	0.00	100.0	23	13.04	21.88	0.0	0.00	66.7
	Week 44	22	15.15	30.39	0.0	0.00	100.0	20	8.33	18.34	0.0	0.00	66.7
	Week 47	14	23.81	35.63	0.0	0.00	100.0	13	15.38	22.01	0.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	16.67	29.62	0.0	0.00	100.0	17	13.73	23.74	0.0	0.00	66.7
	Week 53	21	15.87	24.99	0.0	0.00	66.7	18	9.26	19.15	0.0	0.00	66.7
	Week 56	18	22.22	32.34	0.0	0.00	100.0	15	15.56	21.33	0.0	0.00	66.7
	Week 59	18	12.96	25.92	0.0	0.00	100.0	15	6.67	13.80	0.0	0.00	33.3
	Week 62	13	17.95	29.23	0.0	0.00	100.0	11	9.09	26.21	-33.3	0.00	66.7
	Week 68	12	16.67	26.59	0.0	0.00	66.7	11	12.12	16.82	0.0	0.00	33.3
	Plat+Gem (N= 50)												
	BASELINE	40	10.83	21.86	0.0	0.00	66.7						
	Week 1	35	10.48	21.04	0.0	0.00	66.7	33	-1.01	17.65	-33.3	0.00	33.3
	Week 2	33	14.14	25.04	0.0	0.00	100.0	30	1.11	20.50	-33.3	0.00	66.7
	Week 3	33	11.11	24.53	0.0	0.00	100.0	29	-1.15	18.86	-33.3	0.00	66.7
	Week 4	36	11.11	19.52	0.0	0.00	66.7	32	2.08	18.81	-33.3	0.00	33.3
	Week 5	36	12.04	25.39	0.0	0.00	100.0	32	3.13	21.35	-33.3	0.00	66.7
	Week 6	32	12.50	23.57	0.0	0.00	100.0	29	2.30	17.66	-33.3	0.00	66.7
	Week 7	35	15.24	24.71	0.0	0.00	100.0	31	2.15	20.97	-33.3	0.00	66.7
	Week 8	35	15.24	26.00	0.0	0.00	100.0	31	4.30	23.95	-66.7	0.00	66.7
	Week 9	34	14.71	24.88	0.0	0.00	100.0	30	4.44	20.96	-33.3	0.00	66.7
	Week 10	33	15.15	27.75	0.0	0.00	100.0	30	4.44	20.96	-33.3	0.00	66.7
	Week 11	30	15.56	27.31	0.0	0.00	100.0	26	2.56	22.95	-33.3	0.00	66.7
	Week 12	32	11.46	21.77	0.0	0.00	100.0	27	3.70	19.24	-33.3	0.00	33.3
	Week 14	27	17.28	29.77	0.0	0.00	100.0	22	7.58	22.84	-33.3	0.00	66.7
	Week 17	28	14.29	23.00	0.0	0.00	66.7	23	7.25	24.53	-33.3	0.00	66.7
	Week 20	20	18.33	35.00	0.0	0.00	100.0	16	6.25	32.70	-33.3	0.00	100.0
	Week 23	15	11.11	27.22	0.0	0.00	100.0	14	4.76	31.64	-33.3	0.00	100.0
	Week 26	15	13.33	24.56	0.0	0.00	66.7	14	2.38	15.82	-33.3	0.00	33.3
	Week 29	13	10.26	28.49	0.0	0.00	100.0	12	8.33	32.18	-33.3	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Absent	EV+Pembro (N=152)												
	BASELINE	120	18.05	26.25	0.0	0.00	100.0						
	Week 1	103	16.50	25.51	0.0	0.00	100.0	95	-1.05	18.48	-33.3	0.00	100.0
	Week 2	115	20.00	28.20	0.0	0.00	100.0	101	1.98	18.15	-66.7	0.00	66.7
	Week 3	107	20.25	29.23	0.0	0.00	100.0	92	1.45	20.32	-66.7	0.00	66.7
	Week 4	110	19.39	26.09	0.0	0.00	100.0	98	1.70	20.52	-66.7	0.00	66.7
	Week 5	105	16.51	27.00	0.0	0.00	100.0	93	-2.15	18.91	-66.7	0.00	66.7
	Week 6	111	18.62	27.96	0.0	0.00	100.0	94	1.42	21.26	-66.7	0.00	100.0
	Week 7	112	17.56	26.07	0.0	0.00	100.0	95	0.70	23.31	-100.0	0.00	66.7
	Week 8	109	18.96	27.35	0.0	0.00	100.0	93	0.72	20.25	-66.7	0.00	66.7
	Week 9	109	19.27	27.70	0.0	0.00	100.0	92	1.81	22.30	-66.7	0.00	66.7
	Week 10	109	18.35	27.02	0.0	0.00	100.0	93	0.36	21.70	-66.7	0.00	66.7
	Week 11	106	20.12	26.70	0.0	0.00	100.0	88	4.17	22.50	-66.7	0.00	66.7
	Week 12	110	19.39	26.09	0.0	0.00	100.0	91	2.56	25.93	-100.0	0.00	66.7
	Week 14	103	16.18	22.32	0.0	0.00	100.0	85	0.00	24.12	-100.0	0.00	66.7
	Week 17	99	17.17	22.01	0.0	0.00	100.0	84	1.19	23.40	-100.0	0.00	33.3
	Week 20	92	18.48	22.30	0.0	0.00	100.0	78	1.28	23.07	-66.7	0.00	33.3
	Week 23	89	18.35	24.11	0.0	0.00	100.0	73	0.91	22.20	-66.7	0.00	33.3
	Week 26	84	17.86	21.61	0.0	0.00	100.0	70	0.48	23.73	-66.7	0.00	33.3
	Week 29	80	18.33	20.47	0.0	0.00	66.7	68	2.94	24.93	-66.7	0.00	66.7
	Week 32	77	18.61	23.25	0.0	0.00	100.0	65	3.08	19.30	-66.7	0.00	33.3
	Week 35	72	20.37	27.72	0.0	0.00	100.0	62	3.23	26.11	-100.0	0.00	66.7
	Week 38	71	15.96	20.97	0.0	0.00	100.0	62	-1.61	25.91	-100.0	0.00	33.3
	Week 41	70	21.43	25.40	0.0	16.67	100.0	61	2.73	28.08	-100.0	0.00	100.0
	Week 44	64	23.44	27.65	0.0	33.33	100.0	54	8.02	28.18	-66.7	0.00	100.0
	Week 47	65	23.08	26.30	0.0	33.33	100.0	57	8.19	23.81	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	54	22.84	24.08	0.0	33.33	100.0	47	5.67	23.38	-66.7	0.00	66.7
	Week 53	53	23.90	24.79	0.0	33.33	100.0	45	9.63	22.05	-66.7	0.00	66.7
	Week 56	54	21.60	24.36	0.0	33.33	100.0	46	5.07	22.19	-66.7	0.00	66.7
	Week 59	51	23.53	25.21	0.0	33.33	100.0	42	7.14	23.90	-66.7	0.00	66.7
	Week 62	49	19.73	24.46	0.0	0.00	66.7	41	4.88	23.05	-66.7	0.00	66.7
	Week 65	36	25.93	31.98	0.0	0.00	100.0	33	10.10	22.80	-33.3	0.00	66.7
	Week 68	34	24.51	26.35	0.0	33.33	100.0	31	7.53	25.40	-66.7	0.00	66.7
	Week 71	33	23.23	30.60	0.0	0.00	100.0	30	4.44	25.87	-66.7	0.00	100.0
	Week 74	33	25.25	27.68	0.0	33.33	100.0	30	6.67	25.37	-66.7	0.00	66.7
	Week 77	31	20.43	25.35	0.0	0.00	100.0	27	1.23	23.54	-66.7	0.00	66.7
	Week 80	31	19.35	24.00	0.0	0.00	100.0	29	3.45	24.14	-66.7	0.00	66.7
	Week 83	25	18.67	21.69	0.0	0.00	66.7	24	2.78	25.85	-66.7	0.00	66.7
	Week 86	23	18.84	22.08	0.0	0.00	66.7	22	6.06	26.50	-66.7	0.00	66.7
	Week 89	18	25.92	21.56	0.0	33.33	66.7	17	7.84	30.11	-66.7	0.00	66.7
	Week 92	16	20.83	23.96	0.0	16.67	66.7	15	6.67	25.82	-66.7	0.00	33.3
	Week 95	12	22.22	21.71	0.0	33.33	66.7	11	0.00	25.82	-66.7	0.00	33.3
	Plat+Gem (N=152)												
	BASELINE	125	11.20	21.56	0.0	0.00	100.0						
	Week 1	109	11.01	21.78	0.0	0.00	100.0	106	-0.31	17.51	-66.7	0.00	66.7
	Week 2	114	14.91	26.64	0.0	0.00	100.0	105	3.49	20.63	-33.3	0.00	100.0
	Week 3	116	12.36	24.29	0.0	0.00	100.0	107	2.49	16.95	-33.3	0.00	66.7
	Week 4	114	12.28	24.40	0.0	0.00	100.0	103	2.59	19.07	-33.3	0.00	66.7
	Week 5	117	12.25	21.26	0.0	0.00	100.0	106	3.14	19.80	-66.7	0.00	66.7
	Week 6	113	13.86	23.87	0.0	0.00	100.0	102	4.25	20.80	-66.7	0.00	66.7
	Week 7	113	9.44	19.14	0.0	0.00	100.0	103	0.32	20.07	-66.7	0.00	66.7
	Week 8	110	12.42	22.05	0.0	0.00	100.0	101	3.63	22.56	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	107	12.46	21.73	0.0	0.00	100.0	95	3.51	21.46	-66.7	0.00	66.7
	Week 10	109	12.23	22.06	0.0	0.00	100.0	100	2.33	20.79	-66.7	0.00	66.7
	Week 11	96	14.93	24.60	0.0	0.00	100.0	88	5.68	22.73	-33.3	0.00	66.7
	Week 12	98	12.92	22.26	0.0	0.00	100.0	88	2.27	20.71	-66.7	0.00	66.7
	Week 14	98	11.90	23.08	0.0	0.00	100.0	87	2.30	22.04	-66.7	0.00	66.7
	Week 17	92	13.04	24.69	0.0	0.00	100.0	83	5.22	21.77	-33.3	0.00	100.0
	Week 20	84	14.68	23.34	0.0	0.00	100.0	75	5.33	21.25	-33.3	0.00	66.7
	Week 23	73	14.15	23.52	0.0	0.00	100.0	66	4.55	19.29	-33.3	0.00	66.7
	Week 26	66	16.16	27.58	0.0	0.00	100.0	61	7.65	25.38	-33.3	0.00	100.0
	Week 29	64	15.62	24.46	0.0	0.00	100.0	59	5.65	22.45	-33.3	0.00	66.7
	Week 32	54	14.20	21.08	0.0	0.00	66.7	49	4.08	21.12	-33.3	0.00	66.7
	Week 35	54	11.11	21.48	0.0	0.00	100.0	48	2.78	20.44	-33.3	0.00	66.7
	Week 38	47	12.77	23.62	0.0	0.00	100.0	42	4.76	25.04	-33.3	0.00	100.0
	Week 41	45	14.81	25.18	0.0	0.00	100.0	40	5.00	24.52	-33.3	0.00	66.7
	Week 44	41	16.26	25.95	0.0	0.00	100.0	36	6.48	23.66	-33.3	0.00	66.7
	Week 47	35	14.29	21.82	0.0	0.00	66.7	31	4.30	23.95	-33.3	0.00	66.7
	Week 50	29	10.34	25.36	0.0	0.00	100.0	24	1.39	31.82	-66.7	0.00	100.0
	Week 53	25	10.67	20.91	0.0	0.00	66.7	22	4.55	25.81	-33.3	0.00	66.7
	Week 56	26	11.54	22.98	0.0	0.00	66.7	25	2.67	23.41	-33.3	0.00	66.7
	Week 59	20	11.67	24.84	0.0	0.00	100.0	18	0.00	30.25	-33.3	0.00	100.0
	Week 62	17	13.72	20.61	0.0	0.00	66.7	17	1.96	21.95	-33.3	0.00	33.3
	Week 65	15	17.78	30.52	0.0	0.00	100.0	14	9.52	37.96	-33.3	0.00	100.0
	Week 68	11	12.12	22.47	0.0	0.00	66.7	11	6.06	29.13	-33.3	0.00	66.7
	Week 71	12	16.67	30.15	0.0	0.00	100.0	12	8.33	35.18	-33.3	0.00	100.0
	Week 74	10	3.33	10.54	0.0	0.00	33.3	10	-3.33	18.92	-33.3	0.00	33.3
	Week 77	10	6.67	14.05	0.0	0.00	33.3	10	3.33	18.92	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
< 65 years	EV+Pembro (N= 39)												
	BASELINE	32	18.75	26.69	0.0	0.00	100.0						
	Week 1	27	16.05	28.30	0.0	0.00	100.0	26	2.56	24.81	-33.3	0.00	100.0
	Week 2	30	21.11	23.95	0.0	16.67	66.7	29	5.75	17.97	-33.3	0.00	66.7
	Week 3	31	16.13	18.99	0.0	0.00	66.7	29	1.15	20.86	-66.7	0.00	33.3
	Week 4	30	17.78	20.96	0.0	0.00	66.7	27	2.47	20.52	-33.3	0.00	66.7
	Week 5	28	14.29	23.00	0.0	0.00	66.7	26	-5.13	12.26	-33.3	0.00	0.0
	Week 6	29	14.94	21.06	0.0	0.00	66.7	26	-2.56	20.92	-66.7	0.00	33.3
	Week 7	30	18.89	25.79	0.0	0.00	100.0	26	1.28	22.07	-33.3	0.00	66.7
	Week 8	30	16.67	24.37	0.0	0.00	100.0	26	0.00	18.86	-33.3	0.00	33.3
	Week 9	28	20.24	22.84	0.0	16.67	66.7	27	1.23	23.54	-66.7	0.00	66.7
	Week 10	26	19.23	26.95	0.0	0.00	100.0	23	-1.45	23.52	-66.7	0.00	33.3
	Week 11	28	19.05	24.73	0.0	0.00	100.0	25	1.33	17.95	-33.3	0.00	33.3
	Week 12	28	17.86	24.82	0.0	0.00	66.7	25	2.67	25.31	-33.3	0.00	66.7
	Week 14	26	16.67	21.60	0.0	0.00	66.7	23	0.00	24.62	-66.7	0.00	33.3
	Week 17	28	17.86	19.21	0.0	16.67	66.7	24	0.00	21.98	-66.7	0.00	33.3
	Week 20	27	19.75	24.91	0.0	0.00	66.7	24	2.78	23.91	-66.7	0.00	33.3
	Week 23	26	15.38	23.53	0.0	0.00	66.7	23	1.45	18.74	-33.3	0.00	33.3
	Week 26	24	13.89	19.45	0.0	0.00	66.7	22	1.52	19.18	-33.3	0.00	33.3
	Week 29	25	20.00	21.52	0.0	33.33	66.7	23	5.80	19.21	-33.3	0.00	33.3
	Week 32	25	18.67	21.69	0.0	0.00	66.7	23	1.45	18.74	-33.3	0.00	33.3
	Week 35	24	18.06	24.04	0.0	0.00	66.7	22	1.52	16.19	-33.3	0.00	33.3
	Week 38	23	20.29	26.09	0.0	0.00	100.0	22	4.55	23.67	-66.7	0.00	33.3
	Week 41	25	22.67	31.51	0.0	0.00	100.0	23	5.80	29.56	-33.3	0.00	100.0
	Week 44	22	25.76	30.74	0.0	33.33	100.0	20	13.33	29.42	-33.3	0.00	100.0
	Week 47	20	23.33	26.71	0.0	33.33	100.0	18	9.26	22.30	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	19	19.30	23.08	0.0	0.00	66.7	17	5.88	26.97	-66.7	0.00	66.7
	Week 53	20	26.67	25.59	0.0	33.33	66.7	18	9.26	22.30	-33.3	0.00	66.7
	Week 56	17	25.49	30.11	0.0	33.33	100.0	15	4.44	21.33	-33.3	0.00	33.3
	Week 59	17	27.45	26.97	0.0	33.33	100.0	15	8.89	23.46	-33.3	0.00	33.3
	Week 62	15	17.78	21.33	0.0	0.00	66.7	14	-2.38	20.52	-33.3	0.00	33.3
	Week 65	14	28.57	28.82	0.0	33.33	66.7	13	10.26	21.02	0.0	0.00	66.7
	Week 68	11	27.27	25.03	0.0	33.33	66.7	10	6.67	21.08	-33.3	0.00	33.3
	Week 71	13	30.77	28.75	0.0	33.33	66.7	12	5.56	12.98	0.0	0.00	33.3
	Week 74	14	28.57	31.64	0.0	33.33	100.0	13	7.69	19.97	-33.3	0.00	33.3
	Week 77	14	30.95	30.56	0.0	33.33	100.0	13	7.69	19.97	-33.3	0.00	33.3
	Week 80	14	26.19	23.31	0.0	33.33	66.7	13	7.69	19.97	-33.3	0.00	33.3
	Week 83	12	27.78	23.93	0.0	33.33	66.7	11	9.09	21.56	-33.3	0.00	33.3
	Plat+Gem (N= 29)												
	BASELINE	22	16.67	26.73	0.0	0.00	100.0						
	Week 1	21	14.29	22.54	0.0	0.00	66.7	20	-3.33	14.91	-33.3	0.00	33.3
	Week 2	24	22.22	32.10	0.0	0.00	100.0	20	5.00	29.17	-33.3	0.00	100.0
	Week 3	23	15.94	28.19	0.0	0.00	100.0	20	0.00	15.29	-33.3	0.00	33.3
	Week 4	23	13.04	26.09	0.0	0.00	100.0	19	0.00	15.71	-33.3	0.00	33.3
	Week 5	25	18.67	29.00	0.0	0.00	100.0	20	3.33	18.42	-33.3	0.00	33.3
	Week 6	22	18.18	26.68	0.0	0.00	100.0	18	1.85	13.87	-33.3	0.00	33.3
	Week 7	24	16.67	26.01	0.0	0.00	100.0	21	0.00	14.91	-33.3	0.00	33.3
	Week 8	21	15.87	22.65	0.0	0.00	66.7	19	0.00	15.71	-33.3	0.00	33.3
	Week 9	20	13.33	22.69	0.0	0.00	66.7	17	-3.92	16.17	-33.3	0.00	33.3
	Week 10	21	17.46	27.12	0.0	0.00	100.0	18	-1.85	13.87	-33.3	0.00	33.3
	Week 11	20	15.00	25.30	0.0	0.00	100.0	17	0.00	16.67	-33.3	0.00	33.3
	Week 12	21	14.28	24.88	0.0	0.00	100.0	17	-1.96	14.29	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 14	22	12.12	24.22	0.0	0.00	100.0	18	-3.70	15.71	-33.3	0.00	33.3
	Week 17	20	13.33	25.13	0.0	0.00	100.0	17	-1.96	14.29	-33.3	0.00	33.3
	Week 20	18	18.52	26.13	0.0	0.00	100.0	15	0.00	12.60	-33.3	0.00	33.3
	Week 23	18	9.26	15.36	0.0	0.00	33.3	16	-2.08	14.75	-33.3	0.00	33.3
	Week 26	16	12.50	16.67	0.0	0.00	33.3	14	4.76	12.10	0.0	0.00	33.3
	Week 29	15	13.33	16.90	0.0	0.00	33.3	13	5.13	12.52	0.0	0.00	33.3
	Week 32	15	15.55	17.21	0.0	0.00	33.3	13	5.13	12.52	0.0	0.00	33.3
	Week 35	15	11.11	16.26	0.0	0.00	33.3	13	2.56	16.45	-33.3	0.00	33.3
	Week 38	14	16.67	21.68	0.0	0.00	66.7	12	11.11	16.41	0.0	0.00	33.3
	Week 41	11	24.24	26.21	0.0	33.33	66.7	9	14.82	24.22	0.0	0.00	66.7
	Week 44	11	18.18	22.92	0.0	0.00	66.7	9	11.11	16.67	0.0	0.00	33.3
	Week 47	11	18.18	22.92	0.0	0.00	66.7	9	14.81	24.22	0.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>= 65 years	EV+Pembro (N=163)												
	BASELINE	128	15.10	25.40	0.0	0.00	100.0						
	Week 1	114	14.33	24.68	0.0	0.00	100.0	103	-1.62	14.29	-33.3	0.00	33.3
	Week 2	120	17.50	27.66	0.0	0.00	100.0	104	1.92	16.64	-66.7	0.00	66.7
	Week 3	108	18.52	30.00	0.0	0.00	100.0	93	1.43	18.98	-66.7	0.00	66.7
	Week 4	115	17.39	26.98	0.0	0.00	100.0	102	2.29	18.91	-66.7	0.00	66.7
	Week 5	109	16.82	27.82	0.0	0.00	100.0	95	1.05	19.72	-66.7	0.00	66.7
	Week 6	117	17.09	27.20	0.0	0.00	100.0	98	3.06	20.91	-66.7	0.00	100.0
	Week 7	117	15.95	24.99	0.0	0.00	100.0	98	2.38	22.06	-100.0	0.00	66.7
	Week 8	117	19.09	28.13	0.0	0.00	100.0	98	4.42	22.26	-66.7	0.00	100.0
	Week 9	114	19.01	29.41	0.0	0.00	100.0	94	4.61	24.25	-66.7	0.00	100.0
	Week 10	113	17.99	27.11	0.0	0.00	100.0	95	2.81	22.63	-66.7	0.00	66.7
	Week 11	109	18.96	27.73	0.0	0.00	100.0	90	6.30	23.91	-66.7	0.00	100.0
	Week 12	114	17.84	26.30	0.0	0.00	100.0	94	3.55	24.18	-100.0	0.00	66.7
	Week 14	113	15.34	23.58	0.0	0.00	100.0	93	2.15	23.47	-100.0	0.00	66.7
	Week 17	104	16.67	24.58	0.0	0.00	100.0	87	3.45	24.40	-100.0	0.00	66.7
	Week 20	93	15.41	21.17	0.0	0.00	100.0	79	1.69	22.58	-66.7	0.00	66.7
	Week 23	91	17.95	24.50	0.0	0.00	100.0	74	4.50	23.62	-66.7	0.00	66.7
	Week 26	88	17.04	22.60	0.0	0.00	100.0	72	3.24	24.49	-66.7	0.00	66.7
	Week 29	82	16.26	21.75	0.0	0.00	100.0	70	3.81	25.72	-66.7	0.00	66.7
	Week 32	77	16.88	24.56	0.0	0.00	100.0	65	5.64	22.49	-66.7	0.00	100.0
	Week 35	74	19.37	28.67	0.0	0.00	100.0	64	6.25	27.78	-100.0	0.00	100.0
	Week 38	74	14.41	22.80	0.0	0.00	100.0	64	0.52	25.54	-100.0	0.00	66.7
	Week 41	70	20.00	24.34	0.0	0.00	100.0	61	5.46	25.95	-100.0	0.00	66.7
	Week 44	64	19.79	27.68	0.0	0.00	100.0	54	6.17	24.29	-66.7	0.00	66.7
	Week 47	59	23.16	28.54	0.0	0.00	100.0	52	9.62	24.11	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	55	21.82	26.62	0.0	0.00	100.0	47	8.51	22.49	-66.7	0.00	66.7
	Week 53	54	19.75	24.67	0.0	0.00	100.0	45	9.63	20.87	-66.7	0.00	66.7
	Week 56	55	20.61	25.25	0.0	0.00	100.0	46	8.70	22.70	-66.7	0.00	66.7
	Week 59	52	18.59	25.06	0.0	0.00	100.0	42	6.35	21.13	-66.7	0.00	66.7
	Week 62	47	19.86	26.61	0.0	0.00	100.0	38	8.77	24.12	-66.7	0.00	66.7
	Week 65	29	21.84	32.46	0.0	0.00	100.0	27	9.88	22.29	-33.3	0.00	66.7
	Week 68	35	20.95	26.92	0.0	0.00	100.0	32	9.37	24.30	-66.7	0.00	66.7
	Week 71	29	18.39	30.32	0.0	0.00	100.0	26	5.13	27.80	-66.7	0.00	100.0
	Week 74	24	23.61	28.62	0.0	16.67	100.0	22	7.58	27.08	-66.7	0.00	66.7
	Week 77	23	17.39	26.34	0.0	0.00	100.0	20	1.67	25.31	-66.7	0.00	66.7
	Week 80	22	18.18	26.68	0.0	0.00	100.0	21	3.17	25.61	-66.7	0.00	66.7
	Week 83	18	12.96	20.26	0.0	0.00	66.7	18	1.85	26.75	-66.7	0.00	66.7
	Week 86	18	14.81	20.52	0.0	0.00	66.7	18	3.70	27.75	-66.7	0.00	66.7
	Week 89	12	19.44	22.28	0.0	16.67	66.7	12	2.78	33.21	-66.7	0.00	66.7
	Week 92	10	13.33	23.31	0.0	0.00	66.7	10	0.00	27.22	-66.7	0.00	33.3
	Plat+Gem (N=173)												
	BASELINE	143	10.26	20.64	0.0	0.00	100.0						
	Week 1	123	10.30	21.40	0.0	0.00	100.0	119	0.00	17.89	-66.7	0.00	66.7
	Week 2	123	13.28	24.79	0.0	0.00	100.0	115	2.61	18.81	-33.3	0.00	66.7
	Week 3	126	11.38	23.54	0.0	0.00	100.0	116	2.01	17.74	-33.3	0.00	66.7
	Week 4	127	11.81	22.82	0.0	0.00	100.0	116	2.87	19.45	-33.3	0.00	66.7
	Week 5	128	10.94	20.54	0.0	0.00	100.0	118	3.11	20.44	-66.7	0.00	66.7
	Week 6	123	12.74	23.19	0.0	0.00	100.0	113	4.13	20.96	-66.7	0.00	66.7
	Week 7	124	9.68	19.37	0.0	0.00	100.0	113	0.88	21.11	-66.7	0.00	66.7
	Week 8	124	12.63	23.12	0.0	0.00	100.0	113	4.42	23.78	-66.7	0.00	100.0
	Week 9	121	12.95	22.51	0.0	0.00	100.0	108	4.94	21.77	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	121	12.12	22.77	0.0	0.00	100.0	112	3.57	21.62	-66.7	0.00	66.7
	Week 11	106	15.09	25.25	0.0	0.00	100.0	97	5.84	23.58	-33.3	0.00	66.7
	Week 12	109	12.23	21.59	0.0	0.00	100.0	98	3.40	21.13	-66.7	0.00	66.7
	Week 14	103	13.27	24.85	0.0	0.00	100.0	91	4.76	23.08	-66.7	0.00	66.7
	Week 17	100	13.33	24.16	0.0	0.00	100.0	89	7.12	23.29	-33.3	0.00	100.0
	Week 20	86	14.73	25.87	0.0	0.00	100.0	76	6.58	24.96	-33.3	0.00	100.0
	Week 23	70	14.76	25.78	0.0	0.00	100.0	64	6.25	22.91	-33.3	0.00	100.0
	Week 26	65	16.41	28.94	0.0	0.00	100.0	61	7.10	25.90	-33.3	0.00	100.0
	Week 29	62	15.05	26.77	0.0	0.00	100.0	58	6.32	26.09	-33.3	0.00	100.0
	Week 32	48	11.81	21.18	0.0	0.00	66.7	45	3.70	21.58	-33.3	0.00	66.7
	Week 35	47	9.93	21.89	0.0	0.00	100.0	43	3.10	20.33	-33.3	0.00	66.7
	Week 38	42	9.52	22.43	0.0	0.00	100.0	38	2.63	24.97	-33.3	0.00	100.0
	Week 41	41	10.57	22.90	0.0	0.00	100.0	38	2.63	22.44	-33.3	0.00	66.7
	Week 44	38	13.16	25.16	0.0	0.00	100.0	35	4.76	23.07	-33.3	0.00	66.7
	Week 47	32	10.42	19.74	0.0	0.00	66.7	30	1.11	20.50	-33.3	0.00	33.3
	Week 50	29	5.75	20.06	0.0	0.00	100.0	26	-1.28	27.46	-66.7	0.00	100.0
	Week 53	25	6.67	16.67	0.0	0.00	66.7	24	2.78	21.79	-33.3	0.00	66.7
	Week 56	26	8.97	20.13	0.0	0.00	66.7	26	1.28	19.96	-33.3	0.00	66.7
	Week 59	20	11.67	24.84	0.0	0.00	100.0	20	1.67	29.57	-33.3	0.00	100.0
	Week 62	19	14.03	20.23	0.0	0.00	66.7	19	3.51	21.93	-33.3	0.00	33.3
	Week 65	16	14.58	29.74	0.0	0.00	100.0	16	8.33	35.49	-33.3	0.00	100.0
	Week 68	13	10.26	21.01	0.0	0.00	66.7	13	5.13	26.69	-33.3	0.00	66.7
	Week 71	13	15.38	29.23	0.0	0.00	100.0	13	7.69	33.76	-33.3	0.00	100.0
	Week 74	11	3.03	10.05	0.0	0.00	33.3	11	-3.03	17.98	-33.3	0.00	33.3
	Week 77	10	6.67	14.05	0.0	0.00	33.3	10	3.33	18.92	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Europe	EV+Pembro (N= 74)												
	BASELINE	53	10.06	22.25	0.0	0.00	100.0						
	Week 1	48	5.56	15.88	0.0	0.00	66.7	42	-0.79	13.75	-33.3	0.00	33.3
	Week 2	53	10.06	19.15	0.0	0.00	66.7	44	2.27	13.25	-33.3	0.00	33.3
	Week 3	50	10.00	20.48	0.0	0.00	100.0	41	0.81	15.79	-66.7	0.00	33.3
	Week 4	51	13.07	23.17	0.0	0.00	100.0	44	6.06	19.39	-33.3	0.00	66.7
	Week 5	46	10.87	24.40	0.0	0.00	100.0	41	3.25	17.96	-33.3	0.00	66.7
	Week 6	50	13.33	25.20	0.0	0.00	100.0	39	5.13	21.00	-66.7	0.00	66.7
	Week 7	50	11.33	22.95	0.0	0.00	66.7	39	6.84	20.49	-33.3	0.00	66.7
	Week 8	51	11.76	24.79	0.0	0.00	100.0	41	7.32	21.75	-33.3	0.00	100.0
	Week 9	47	15.60	30.18	0.0	0.00	100.0	37	8.11	28.77	-66.7	0.00	100.0
	Week 10	45	12.59	23.88	0.0	0.00	66.7	34	6.86	19.73	-33.3	0.00	66.7
	Week 11	48	14.58	25.64	0.0	0.00	100.0	37	10.81	23.64	-33.3	0.00	100.0
	Week 12	51	12.42	22.07	0.0	0.00	66.7	39	9.40	21.56	-33.3	0.00	66.7
	Week 14	50	12.67	21.18	0.0	0.00	66.7	38	8.77	18.48	-33.3	0.00	66.7
	Week 17	43	11.63	22.87	0.0	0.00	100.0	33	7.07	20.00	-33.3	0.00	66.7
	Week 20	41	8.94	18.29	0.0	0.00	66.7	33	7.07	18.18	-33.3	0.00	66.7
	Week 23	41	13.01	23.43	0.0	0.00	100.0	30	10.00	21.71	-33.3	0.00	66.7
	Week 26	37	13.51	21.46	0.0	0.00	66.7	28	9.52	23.76	-33.3	0.00	66.7
	Week 29	37	14.41	24.27	0.0	0.00	100.0	29	11.49	22.32	0.0	0.00	66.7
	Week 32	34	11.76	19.90	0.0	0.00	66.7	26	5.13	18.12	-33.3	0.00	66.7
	Week 35	31	9.68	17.62	0.0	0.00	66.7	25	4.00	14.66	-33.3	0.00	33.3
	Week 38	31	10.75	21.75	0.0	0.00	100.0	26	7.69	17.15	0.0	0.00	66.7
	Week 41	28	11.90	18.62	0.0	0.00	66.7	23	7.25	17.28	-33.3	0.00	33.3
	Week 44	27	13.58	24.91	0.0	0.00	100.0	22	9.09	21.04	0.0	0.00	66.7
	Week 47	25	16.00	25.68	0.0	0.00	100.0	21	11.11	21.94	0.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	26	16.67	28.67	0.0	0.00	100.0	23	11.59	23.80	0.0	0.00	66.7
	Week 53	26	17.95	23.53	0.0	0.00	66.7	21	12.70	22.30	0.0	0.00	66.7
	Week 56	25	16.00	23.81	0.0	0.00	66.7	21	11.11	19.25	0.0	0.00	66.7
	Week 59	23	8.69	14.96	0.0	0.00	33.3	18	3.70	10.78	0.0	0.00	33.3
	Week 62	20	13.33	27.36	0.0	0.00	100.0	17	5.88	17.62	0.0	0.00	66.7
	Week 65	13	12.82	25.60	0.0	0.00	66.7	13	7.69	19.97	0.0	0.00	66.7
	Week 68	15	17.78	24.77	0.0	0.00	66.7	15	11.11	16.27	0.0	0.00	33.3
	Week 71	13	10.26	21.01	0.0	0.00	66.7	13	5.13	12.52	0.0	0.00	33.3
	Week 74	10	13.33	17.21	0.0	0.00	33.3	9	7.41	14.70	0.0	0.00	33.3
	Plat+Gem (N= 95)												
	BASELINE	75	8.44	20.57	0.0	0.00	100.0						
	Week 1	71	7.51	18.85	0.0	0.00	66.7	69	-0.97	15.09	-66.7	0.00	66.7
	Week 2	71	11.74	25.88	0.0	0.00	100.0	63	0.53	17.45	-33.3	0.00	100.0
	Week 3	72	10.65	23.62	0.0	0.00	100.0	65	1.54	12.40	-33.3	0.00	33.3
	Week 4	69	8.70	21.88	0.0	0.00	100.0	62	1.08	12.02	-33.3	0.00	33.3
	Week 5	71	8.92	21.05	0.0	0.00	100.0	63	0.00	10.37	-33.3	0.00	33.3
	Week 6	69	9.66	22.94	0.0	0.00	100.0	61	1.64	11.26	-33.3	0.00	33.3
	Week 7	69	7.73	20.73	0.0	0.00	100.0	62	0.00	10.45	-33.3	0.00	33.3
	Week 8	67	7.96	17.49	0.0	0.00	66.7	60	0.56	11.47	-33.3	0.00	33.3
	Week 9	66	7.58	18.30	0.0	0.00	66.7	57	-0.58	13.35	-33.3	0.00	33.3
	Week 10	70	7.62	18.10	0.0	0.00	100.0	63	-0.53	11.19	-33.3	0.00	33.3
	Week 11	63	8.47	19.83	0.0	0.00	100.0	56	1.79	14.80	-33.3	0.00	66.7
	Week 12	66	8.59	17.84	0.0	0.00	100.0	56	0.60	13.47	-33.3	0.00	33.3
	Week 14	66	6.57	17.75	0.0	0.00	100.0	56	-0.60	11.88	-33.3	0.00	33.3
	Week 17	61	9.29	19.37	0.0	0.00	100.0	53	2.52	12.82	-33.3	0.00	33.3
	Week 20	54	10.49	22.27	0.0	0.00	100.0	48	1.39	18.14	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 23	44	10.61	22.47	0.0	0.00	100.0	40	1.67	19.90	-33.3	0.00	100.0
	Week 26	42	12.70	25.45	0.0	0.00	100.0	39	4.27	21.87	-33.3	0.00	100.0
	Week 29	39	9.40	17.01	0.0	0.00	66.7	36	0.00	15.94	-33.3	0.00	33.3
	Week 32	32	10.42	19.74	0.0	0.00	66.7	30	2.22	14.99	-33.3	0.00	33.3
	Week 35	32	8.33	16.93	0.0	0.00	66.7	30	3.33	16.02	-33.3	0.00	33.3
	Week 38	28	5.95	13.00	0.0	0.00	33.3	26	1.28	14.85	-33.3	0.00	33.3
	Week 41	25	10.67	18.56	0.0	0.00	66.7	23	1.45	18.74	-33.3	0.00	33.3
	Week 44	24	12.50	23.70	0.0	0.00	66.7	22	4.55	23.67	-33.3	0.00	66.7
	Week 47	22	7.58	17.61	0.0	0.00	66.7	20	0.00	18.73	-33.3	0.00	33.3
	Week 50	17	5.88	24.25	0.0	0.00	100.0	15	-2.22	34.43	-66.7	0.00	100.0
	Week 53	15	4.44	17.21	0.0	0.00	66.7	14	0.00	22.65	-33.3	0.00	66.7
	Week 56	15	8.89	23.46	0.0	0.00	66.7	14	0.00	22.65	-33.3	0.00	66.7
	Week 59	11	12.12	30.81	0.0	0.00	100.0	10	0.00	38.49	-33.3	0.00	100.0
	Week 62	11	12.12	22.47	0.0	0.00	66.7	11	0.00	21.08	-33.3	0.00	33.3
	Week 65	10	13.33	32.20	0.0	0.00	100.0	10	6.67	37.84	-33.3	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
North America	EV+Pembro (N= 46)												
	BASELINE	33	15.15	28.98	0.0	0.00	100.0						
	Week 1	30	17.78	29.99	0.0	0.00	100.0	27	-3.70	14.12	-33.3	0.00	33.3
	Week 2	30	15.56	27.31	0.0	0.00	100.0	26	-1.28	17.59	-66.7	0.00	33.3
	Week 3	25	13.33	25.46	0.0	0.00	100.0	21	-3.17	17.97	-66.7	0.00	33.3
	Week 4	30	16.67	25.89	0.0	0.00	100.0	24	-2.78	16.79	-66.7	0.00	33.3
	Week 5	29	18.39	30.32	0.0	0.00	100.0	21	-3.17	20.83	-66.7	0.00	33.3
	Week 6	31	13.98	20.68	0.0	0.00	66.7	23	-1.45	15.82	-66.7	0.00	33.3
	Week 7	33	19.19	30.08	0.0	0.00	100.0	23	-2.90	24.44	-100.0	0.00	33.3
	Week 8	29	20.69	30.10	0.0	0.00	100.0	20	0.00	21.63	-66.7	0.00	33.3
	Week 9	27	22.22	29.24	0.0	0.00	100.0	21	4.76	24.24	-66.7	0.00	66.7
	Week 10	29	19.54	31.52	0.0	0.00	100.0	23	-1.45	23.53	-66.7	0.00	33.3
	Week 11	28	19.05	29.30	0.0	0.00	100.0	21	1.59	26.83	-66.7	0.00	66.7
	Week 12	29	18.39	27.58	0.0	0.00	100.0	22	-3.03	25.01	-66.7	0.00	33.3
	Week 14	28	9.52	17.82	0.0	0.00	66.7	21	-6.35	22.66	-66.7	0.00	33.3
	Week 17	29	19.54	26.00	0.0	0.00	100.0	23	0.00	26.59	-66.7	0.00	33.3
	Week 20	23	18.84	28.12	0.0	0.00	100.0	18	-5.56	30.79	-66.7	0.00	33.3
	Week 23	22	18.18	26.68	0.0	0.00	100.0	17	-1.96	27.56	-66.7	0.00	33.3
	Week 26	21	12.70	24.67	0.0	0.00	100.0	16	-6.25	25.00	-66.7	0.00	33.3
	Week 29	20	10.00	15.67	0.0	0.00	33.3	17	-7.84	25.08	-66.7	0.00	33.3
	Week 32	21	20.63	32.45	0.0	0.00	100.0	18	3.70	32.11	-66.7	0.00	100.0
	Week 35	22	22.73	33.15	0.0	0.00	100.0	19	5.26	29.95	-66.7	0.00	100.0
	Week 38	20	20.00	33.16	0.0	0.00	100.0	17	-1.96	29.98	-66.7	0.00	66.7
	Week 41	21	26.98	34.35	0.0	0.00	100.0	17	3.92	26.04	-66.7	0.00	66.7
	Week 44	16	22.92	35.94	0.0	0.00	100.0	12	-2.78	22.29	-66.7	0.00	33.3
	Week 47	16	27.08	34.89	0.0	16.67	100.0	13	2.56	25.32	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	16	22.92	29.11	0.0	16.67	100.0	11	0.00	25.82	-66.7	0.00	33.3
	Week 53	15	22.22	32.53	0.0	0.00	100.0	11	3.03	10.05	0.0	0.00	33.3
	Week 56	17	27.45	35.81	0.0	0.00	100.0	12	0.00	24.62	-66.7	0.00	33.3
	Week 59	17	27.45	35.81	0.0	0.00	100.0	12	0.00	24.62	-66.7	0.00	33.3
	Week 62	14	19.05	25.20	0.0	0.00	66.7	9	-7.41	27.78	-66.7	0.00	33.3
	Week 68	11	21.21	34.23	0.0	0.00	100.0	8	-4.17	27.82	-66.7	0.00	33.3
	Week 71	11	24.24	36.79	0.0	0.00	100.0	8	-8.33	23.57	-66.7	0.00	0.0
	Plat+Gem (N= 34)												
	BASELINE	27	6.17	20.75	0.0	0.00	100.0						
	Week 1	19	5.26	16.72	0.0	0.00	66.7	17	-1.96	8.08	-33.3	0.00	0.0
	Week 2	20	8.33	18.34	0.0	0.00	66.7	18	3.70	15.71	-33.3	0.00	33.3
	Week 3	20	6.67	23.19	0.0	0.00	100.0	17	1.96	8.08	0.0	0.00	33.3
	Week 4	23	8.70	18.03	0.0	0.00	66.7	19	3.51	15.29	-33.3	0.00	33.3
	Week 5	25	6.67	13.61	0.0	0.00	33.3	22	1.51	19.18	-66.7	0.00	33.3
	Week 6	20	6.67	17.44	0.0	0.00	66.7	17	0.00	26.35	-66.7	0.00	66.7
	Week 7	23	5.80	12.92	0.0	0.00	33.3	20	1.67	20.16	-66.7	0.00	33.3
	Week 8	24	8.33	14.74	0.0	0.00	33.3	22	3.03	20.34	-66.7	0.00	33.3
	Week 9	23	8.70	20.64	0.0	0.00	66.7	19	5.26	20.07	-33.3	0.00	66.7
	Week 10	20	11.67	22.36	0.0	0.00	66.7	18	5.56	20.61	-33.3	0.00	66.7
	Week 11	18	11.11	22.87	0.0	0.00	66.7	16	6.25	21.84	-33.3	0.00	66.7
	Week 12	17	7.84	18.74	0.0	0.00	66.7	16	2.08	14.75	-33.3	0.00	33.3
	Week 14	16	12.50	23.96	0.0	0.00	66.7	14	7.14	23.31	-33.3	0.00	66.7
	Week 17	19	14.03	27.92	0.0	0.00	100.0	17	9.80	19.60	0.0	0.00	66.7
	Week 20	16	14.58	29.74	0.0	0.00	100.0	13	10.26	31.58	-33.3	0.00	100.0
	Week 23	15	11.11	27.22	0.0	0.00	100.0	13	5.13	12.52	0.0	0.00	33.3
	Week 26	13	12.82	28.99	0.0	0.00	100.0	12	5.56	12.97	0.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 29	14	19.05	36.31	0.0	0.00	100.0	13	10.26	21.01	0.0	0.00	66.7
	Week 32	11	12.12	22.47	0.0	0.00	66.7	10	3.33	18.92	-33.3	0.00	33.3
	Week 35	13	10.26	28.49	0.0	0.00	100.0	11	3.03	10.05	0.0	0.00	33.3
	Week 38	10	20.00	35.83	0.0	0.00	100.0	9	11.11	37.27	-33.3	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Rest of World	EV+Pembro (N= 82)												
	BASELINE	74	20.27	25.77	0.0	0.00	100.0						
	Week 1	63	20.11	27.13	0.0	0.00	100.0	60	0.56	19.88	-33.3	0.00	100.0
	Week 2	67	25.87	30.05	0.0	33.33	100.0	63	4.76	18.80	-33.3	0.00	66.7
	Week 3	64	26.04	31.69	0.0	33.33	100.0	60	3.33	21.87	-66.7	0.00	66.7
	Week 4	64	21.35	27.45	0.0	0.00	100.0	61	1.64	19.65	-33.3	0.00	66.7
	Week 5	62	19.35	26.69	0.0	0.00	100.0	59	-1.70	17.96	-33.3	0.00	66.7
	Week 6	65	20.51	28.68	0.0	0.00	100.0	62	1.08	22.56	-33.3	0.00	100.0
	Week 7	64	19.27	23.61	0.0	0.00	100.0	62	1.07	21.73	-66.7	0.00	66.7
	Week 8	67	22.88	27.35	0.0	33.33	100.0	63	2.12	21.48	-33.3	0.00	66.7
	Week 9	68	20.59	26.41	0.0	0.00	100.0	63	1.06	20.71	-66.7	0.00	66.7
	Week 10	65	21.54	26.63	0.0	0.00	100.0	61	0.55	23.95	-66.7	0.00	66.7
	Week 11	61	22.40	27.03	0.0	33.33	100.0	57	2.92	20.20	-33.3	0.00	66.7
	Week 12	62	22.04	27.62	0.0	0.00	100.0	58	1.72	25.30	-100.0	0.00	66.7
	Week 14	61	20.76	25.94	0.0	0.00	100.0	57	0.00	25.97	-100.0	0.00	66.7
	Week 17	60	19.44	22.37	0.0	16.67	100.0	55	1.21	24.81	-100.0	0.00	33.3
	Week 20	56	20.83	20.66	0.0	33.33	66.7	52	1.28	21.85	-66.7	0.00	33.3
	Week 23	54	20.37	23.72	0.0	16.67	100.0	50	2.00	20.66	-66.7	0.00	33.3
	Week 26	54	19.75	21.00	0.0	33.33	66.7	50	2.00	21.73	-66.7	0.00	33.3
	Week 29	50	22.00	20.88	0.0	33.33	66.7	47	4.25	23.69	-66.7	0.00	33.3
	Week 32	47	19.86	21.60	0.0	33.33	66.7	44	4.55	18.46	-33.3	0.00	33.3
	Week 35	45	23.70	28.97	0.0	33.33	100.0	42	5.56	28.43	-100.0	0.00	66.7
	Week 38	46	17.39	19.55	0.0	0.00	66.7	43	-0.78	26.71	-100.0	0.00	33.3
	Week 41	46	23.19	25.21	0.0	33.33	100.0	44	5.30	31.29	-100.0	0.00	100.0
	Week 44	43	25.58	27.06	0.0	33.33	100.0	40	10.83	28.63	-66.7	0.00	100.0
	Week 47	38	26.31	25.89	0.0	33.33	100.0	36	11.11	23.91	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	32	23.96	21.14	0.0	33.33	66.7	30	7.78	22.63	-66.7	0.00	33.3
	Week 53	33	24.24	22.47	0.0	33.33	66.7	31	9.68	23.08	-66.7	0.00	33.3
	Week 56	30	23.33	21.71	0.0	33.33	66.7	28	8.33	23.35	-33.3	0.00	66.7
	Week 59	29	26.44	22.50	0.0	33.33	66.7	27	12.34	24.72	-33.3	0.00	66.7
	Week 62	28	23.81	23.76	0.0	33.33	66.7	26	10.26	24.53	-33.3	0.00	66.7
	Week 65	22	30.30	30.71	0.0	33.33	100.0	21	12.70	24.67	-33.3	0.00	66.7
	Week 68	20	26.67	23.20	0.0	33.33	66.7	19	12.28	25.36	-33.3	0.00	66.7
	Week 71	18	29.63	30.01	0.0	33.33	100.0	17	11.76	28.73	-33.3	0.00	100.0
	Week 74	19	28.07	25.49	0.0	33.33	66.7	19	12.28	25.36	-33.3	0.00	66.7
	Week 77	19	21.05	19.91	0.0	33.33	66.7	18	7.41	24.40	-33.3	0.00	66.7
	Week 80	19	22.81	19.41	0.0	33.33	66.7	18	9.26	25.06	-33.3	0.00	66.7
	Week 83	17	23.53	19.60	0.0	33.33	66.7	17	9.80	25.73	-33.3	0.00	66.7
	Week 86	14	26.19	23.31	0.0	33.33	66.7	14	16.67	28.50	-33.3	0.00	66.7
	Week 89	11	27.27	20.10	0.0	33.33	66.7	11	15.15	27.34	-33.3	0.00	66.7
	Plat+Gem (N= 73)												
	BASELINE	63	16.40	22.30	0.0	0.00	66.7						
	Week 1	54	17.28	24.86	0.0	0.00	100.0	53	0.63	22.16	-33.3	0.00	66.7
	Week 2	56	20.83	28.11	0.0	0.00	100.0	54	5.56	24.87	-33.3	0.00	66.7
	Week 3	57	15.79	25.28	0.0	0.00	100.0	54	1.85	23.72	-33.3	0.00	66.7
	Week 4	58	17.24	25.93	0.0	0.00	100.0	54	3.70	25.63	-33.3	0.00	66.7
	Week 5	57	18.71	25.21	0.0	0.00	100.0	53	7.55	27.46	-33.3	0.00	66.7
	Week 6	56	20.83	25.08	0.0	16.67	100.0	53	7.55	25.01	-33.3	0.00	66.7
	Week 7	56	16.67	22.02	0.0	0.00	100.0	52	1.28	27.98	-66.7	0.00	66.7
	Week 8	54	21.60	29.07	0.0	0.00	100.0	50	8.00	31.99	-66.7	0.00	100.0
	Week 9	52	21.79	25.47	0.0	33.33	100.0	49	8.16	27.66	-66.7	0.00	66.7
	Week 10	52	20.51	28.13	0.0	0.00	100.0	49	6.12	28.60	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	45	25.93	29.21	0.0	33.33	100.0	42	8.73	30.41	-33.3	0.00	66.7
	Week 12	47	19.86	26.61	0.0	0.00	100.0	43	5.43	28.11	-66.7	0.00	66.7
	Week 14	43	23.26	30.46	0.0	0.00	100.0	39	7.69	31.03	-66.7	0.00	66.7
	Week 17	40	19.17	28.13	0.0	0.00	100.0	36	8.33	32.24	-33.3	0.00	100.0
	Week 20	34	23.53	27.86	0.0	16.67	100.0	30	10.00	26.48	-33.3	0.00	66.7
	Week 23	29	19.54	24.43	0.0	0.00	66.7	27	8.64	27.10	-33.3	0.00	66.7
	Week 26	26	21.79	28.19	0.0	0.00	100.0	24	11.11	30.56	-33.3	0.00	100.0
	Week 29	24	20.83	27.47	0.0	0.00	100.0	22	13.64	33.58	-33.3	0.00	100.0
	Week 32	20	16.67	20.23	0.0	0.00	66.7	18	7.41	26.95	-33.3	0.00	66.7
	Week 35	17	13.72	20.61	0.0	0.00	66.7	15	2.22	29.46	-33.3	0.00	66.7
	Week 38	18	14.81	23.49	0.0	0.00	66.7	15	6.67	25.82	-33.3	0.00	66.7
	Week 41	18	18.52	26.13	0.0	0.00	66.7	16	12.50	31.91	-33.3	0.00	66.7
	Week 44	16	16.67	21.08	0.0	0.00	66.7	14	9.52	24.21	-33.3	0.00	66.7
	Week 47	12	19.44	22.28	0.0	16.67	66.7	11	12.12	26.97	-33.3	0.00	66.7
	Week 50	11	18.18	27.34	0.0	0.00	66.7	9	7.41	27.78	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	EV+Pembro (N=146)												
	BASELINE	119	15.97	26.34	0.0	0.00	100.0						
	Week 1	102	15.03	25.96	0.0	0.00	100.0	97	-0.34	16.31	-33.3	0.00	100.0
	Week 2	106	18.24	28.78	0.0	0.00	100.0	98	3.06	15.20	-33.3	0.00	66.7
	Week 3	94	17.73	27.52	0.0	0.00	100.0	88	1.14	17.10	-66.7	0.00	66.7
	Week 4	101	17.82	26.48	0.0	0.00	100.0	93	2.87	17.48	-33.3	0.00	66.7
	Week 5	96	15.28	26.89	0.0	0.00	100.0	89	-0.75	15.06	-33.3	0.00	66.7
	Week 6	105	14.92	25.31	0.0	0.00	100.0	93	0.36	17.37	-66.7	0.00	66.7
	Week 7	102	16.67	26.01	0.0	0.00	100.0	89	2.25	19.97	-66.7	0.00	66.7
	Week 8	101	18.15	28.49	0.0	0.00	100.0	91	3.66	19.53	-33.3	0.00	100.0
	Week 9	100	18.33	28.57	0.0	0.00	100.0	89	3.37	23.59	-66.7	0.00	100.0
	Week 10	99	17.17	26.24	0.0	0.00	100.0	87	1.53	20.28	-66.7	0.00	66.7
	Week 11	95	17.54	26.56	0.0	0.00	100.0	84	5.95	21.44	-33.3	0.00	100.0
	Week 12	99	17.51	26.66	0.0	0.00	100.0	87	4.21	23.74	-100.0	0.00	66.7
	Week 14	95	15.09	23.20	0.0	0.00	100.0	84	2.38	23.02	-100.0	0.00	66.7
	Week 17	97	15.81	21.57	0.0	0.00	100.0	84	2.38	21.82	-100.0	0.00	33.3
	Week 20	90	15.93	21.91	0.0	0.00	100.0	79	1.69	21.94	-66.7	0.00	33.3
	Week 23	86	15.89	22.71	0.0	0.00	100.0	74	2.70	19.71	-66.7	0.00	33.3
	Week 26	83	16.87	22.31	0.0	0.00	100.0	72	3.70	22.06	-66.7	0.00	66.7
	Week 29	80	15.83	20.52	0.0	0.00	66.7	71	3.76	22.22	-66.7	0.00	66.7
	Week 32	74	16.67	24.83	0.0	0.00	100.0	66	4.55	20.99	-66.7	0.00	100.0
	Week 35	73	19.18	29.88	0.0	0.00	100.0	66	6.06	25.43	-100.0	0.00	100.0
	Week 38	75	14.67	23.40	0.0	0.00	100.0	67	1.49	24.91	-100.0	0.00	66.7
	Week 41	71	20.66	27.24	0.0	0.00	100.0	64	6.77	27.33	-100.0	0.00	100.0
	Week 44	64	19.79	29.53	0.0	0.00	100.0	56	7.74	25.42	-66.7	0.00	100.0
	Week 47	56	22.62	29.20	0.0	0.00	100.0	50	9.33	22.38	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	55	19.39	25.41	0.0	0.00	100.0	48	6.94	21.70	-66.7	0.00	66.7
	Week 53	55	20.00	25.34	0.0	0.00	100.0	48	8.33	22.28	-66.7	0.00	66.7
	Week 56	53	20.13	27.22	0.0	0.00	100.0	46	7.25	19.77	-33.3	0.00	66.7
	Week 59	51	20.91	27.46	0.0	0.00	100.0	43	7.75	20.36	-33.3	0.00	66.7
	Week 62	42	16.67	23.57	0.0	0.00	66.7	36	5.56	21.82	-33.3	0.00	66.7
	Week 65	31	25.81	33.01	0.0	0.00	100.0	30	11.11	23.71	-33.3	0.00	66.7
	Week 68	31	21.50	27.95	0.0	0.00	100.0	29	9.19	21.63	-33.3	0.00	66.7
	Week 71	30	25.56	32.38	0.0	0.00	100.0	28	9.52	23.76	-33.3	0.00	100.0
	Week 74	29	26.44	31.34	0.0	33.33	100.0	27	9.88	22.29	-33.3	0.00	66.7
	Week 77	26	25.64	30.27	0.0	33.33	100.0	24	8.33	22.52	-33.3	0.00	66.7
	Week 80	26	23.08	27.92	0.0	16.67	100.0	26	6.41	21.12	-33.3	0.00	66.7
	Week 83	21	19.05	22.54	0.0	0.00	66.7	21	6.35	22.66	-33.3	0.00	66.7
	Week 86	17	19.61	23.74	0.0	0.00	66.7	17	11.76	26.20	-33.3	0.00	66.7
	Week 89	11	24.24	21.56	0.0	33.33	66.7	11	12.12	26.97	-33.3	0.00	66.7
	Week 92	13	20.51	25.60	0.0	0.00	66.7	13	12.82	16.88	0.0	0.00	33.3
	Plat+Gem (N=151)												
	BASELINE	123	10.30	20.96	0.0	0.00	100.0						
	Week 1	108	9.57	19.89	0.0	0.00	66.7	103	-0.65	16.16	-33.3	0.00	66.7
	Week 2	116	14.65	26.48	0.0	0.00	100.0	105	3.17	21.94	-33.3	0.00	100.0
	Week 3	114	10.82	23.25	0.0	0.00	100.0	103	0.32	16.50	-33.3	0.00	66.7
	Week 4	116	9.48	20.53	0.0	0.00	100.0	103	0.97	17.75	-33.3	0.00	66.7
	Week 5	119	11.20	22.66	0.0	0.00	100.0	106	2.20	20.71	-66.7	0.00	66.7
	Week 6	109	11.62	21.93	0.0	0.00	100.0	98	2.38	19.88	-66.7	0.00	66.7
	Week 7	115	10.43	20.41	0.0	0.00	100.0	105	0.63	20.14	-66.7	0.00	66.7
	Week 8	111	12.31	22.44	0.0	0.00	100.0	102	3.59	23.87	-66.7	0.00	100.0
	Week 9	107	12.15	21.67	0.0	0.00	100.0	95	3.16	21.23	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	107	12.46	23.58	0.0	0.00	100.0	98	3.40	21.13	-33.3	0.00	66.7
	Week 11	97	15.12	25.01	0.0	0.00	100.0	87	5.36	23.77	-33.3	0.00	66.7
	Week 12	100	12.33	21.53	0.0	0.00	100.0	88	2.27	20.71	-66.7	0.00	66.7
	Week 14	99	12.79	24.61	0.0	0.00	100.0	86	2.33	22.16	-66.7	0.00	66.7
	Week 17	94	13.83	24.64	0.0	0.00	100.0	82	4.88	22.30	-33.3	0.00	66.7
	Week 20	84	14.68	26.05	0.0	0.00	100.0	72	4.17	22.33	-33.3	0.00	100.0
	Week 23	70	13.81	24.40	0.0	0.00	100.0	62	4.30	22.16	-33.3	0.00	100.0
	Week 26	61	13.66	23.86	0.0	0.00	100.0	55	5.45	20.04	-33.3	0.00	66.7
	Week 29	59	13.56	24.07	0.0	0.00	100.0	53	5.66	23.33	-33.3	0.00	100.0
	Week 32	50	12.00	19.93	0.0	0.00	66.7	45	3.70	20.38	-33.3	0.00	66.7
	Week 35	50	12.00	22.09	0.0	0.00	100.0	44	4.55	19.81	-33.3	0.00	66.7
	Week 38	46	11.59	22.46	0.0	0.00	100.0	40	5.00	25.65	-33.3	0.00	100.0
	Week 41	42	15.08	25.72	0.0	0.00	100.0	37	7.21	25.01	-33.3	0.00	66.7
	Week 44	39	15.38	26.32	0.0	0.00	100.0	34	8.82	23.65	-33.3	0.00	66.7
	Week 47	33	13.13	21.95	0.0	0.00	66.7	29	5.75	23.69	-33.3	0.00	66.7
	Week 50	27	9.88	24.13	0.0	0.00	100.0	22	4.55	29.63	-33.3	0.00	100.0
	Week 53	23	10.14	21.17	0.0	0.00	66.7	20	5.00	27.09	-33.3	0.00	66.7
	Week 56	20	10.00	21.90	0.0	0.00	66.7	19	5.26	27.81	-33.3	0.00	66.7
	Week 59	17	11.76	26.20	0.0	0.00	100.0	15	4.44	33.01	-33.3	0.00	100.0
	Week 62	14	7.14	14.19	0.0	0.00	33.3	14	0.00	22.64	-33.3	0.00	33.3
	Week 65	13	15.38	32.25	0.0	0.00	100.0	12	5.56	39.78	-33.3	0.00	100.0
	Week 68	10	6.67	21.08	0.0	0.00	66.7	10	0.00	27.22	-33.3	0.00	66.7
	Week 71	10	13.33	32.20	0.0	0.00	100.0	10	6.67	37.84	-33.3	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	EV+Pembro (N= 56)												
	BASELINE	41	15.45	23.68	0.0	0.00	100.0						
	Week 1	39	13.67	23.84	0.0	0.00	100.0	32	-2.08	18.81	-33.3	0.00	33.3
	Week 2	44	18.18	22.10	0.0	0.00	66.7	35	1.90	21.30	-66.7	0.00	33.3
	Week 3	45	18.52	28.92	0.0	0.00	100.0	34	1.96	24.54	-66.7	0.00	66.7
	Week 4	44	16.67	24.38	0.0	0.00	100.0	36	0.93	23.21	-66.7	0.00	33.3
	Week 5	41	18.70	26.92	0.0	0.00	100.0	32	1.04	26.07	-66.7	0.00	66.7
	Week 6	41	21.14	27.64	0.0	0.00	100.0	31	6.45	29.08	-66.7	0.00	100.0
	Week 7	45	16.30	23.16	0.0	0.00	100.0	35	1.90	26.74	-100.0	0.00	33.3
	Week 8	46	19.56	24.92	0.0	0.00	100.0	33	3.03	26.83	-66.7	0.00	66.7
	Week 9	42	21.43	27.37	0.0	0.00	100.0	32	5.21	25.55	-66.7	0.00	66.7
	Week 10	40	20.83	28.93	0.0	0.00	100.0	31	3.23	29.00	-66.7	0.00	66.7
	Week 11	42	22.22	28.19	0.0	16.67	100.0	31	3.23	26.32	-66.7	0.00	33.3
	Week 12	43	18.60	24.45	0.0	0.00	100.0	32	1.04	26.07	-66.7	0.00	66.7
	Week 14	44	16.67	23.29	0.0	0.00	100.0	32	0.00	25.40	-66.7	0.00	33.3
	Week 17	35	20.00	28.24	0.0	0.00	100.0	27	3.70	29.72	-66.7	0.00	66.7
	Week 20	30	17.78	22.71	0.0	0.00	66.7	24	2.78	25.85	-66.7	0.00	66.7
	Week 23	31	21.50	27.95	0.0	0.00	100.0	23	7.25	30.08	-66.7	0.00	66.7
	Week 26	29	14.94	21.06	0.0	0.00	66.7	22	0.00	27.22	-66.7	0.00	66.7
	Week 29	27	20.99	24.72	0.0	33.33	100.0	22	6.06	30.23	-66.7	0.00	66.7
	Week 32	28	19.05	21.14	0.0	16.67	66.7	22	4.55	23.67	-33.3	0.00	66.7
	Week 35	25	18.67	19.44	0.0	33.33	66.7	20	1.67	25.30	-66.7	0.00	33.3
	Week 38	22	19.70	24.47	0.0	16.67	100.0	19	1.75	26.00	-66.7	0.00	66.7
	Week 41	24	20.83	23.70	0.0	16.67	66.7	20	1.67	25.31	-66.7	0.00	33.3
	Week 44	22	25.76	25.05	0.0	33.33	100.0	18	9.26	27.55	-66.7	0.00	66.7
	Week 47	23	24.64	25.06	0.0	33.33	100.0	20	10.00	26.71	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	19	26.31	26.24	0.0	33.33	100.0	16	10.42	29.11	-66.7	0.00	66.7
	Week 53	19	26.31	23.78	0.0	33.33	66.7	15	13.33	16.90	0.0	0.00	33.3
	Week 56	19	26.31	23.78	0.0	33.33	66.7	15	8.89	29.46	-66.7	0.00	66.7
	Week 59	18	20.37	20.26	0.0	33.33	66.7	14	4.76	25.68	-66.7	0.00	33.3
	Week 62	20	25.00	28.36	0.0	33.33	100.0	16	6.25	27.81	-66.7	0.00	66.7
	Week 65	12	19.44	26.43	0.0	0.00	66.7	10	6.67	14.05	0.0	0.00	33.3
	Week 68	15	24.44	23.46	0.0	33.33	66.7	13	7.69	27.74	-66.7	0.00	33.3
	Week 71	12	13.89	22.29	0.0	0.00	66.7	10	-6.67	21.08	-66.7	0.00	0.0
	Week 77	11	15.15	22.92	0.0	0.00	66.7	9	-7.41	22.22	-66.7	0.00	0.0
	Week 80	10	16.67	17.57	0.0	16.67	33.3	8	0.00	30.86	-66.7	0.00	33.3
	Plat+Gem (N= 51)												
	BASELINE	42	13.49	23.35	0.0	0.00	66.7						
	Week 1	36	14.81	25.75	0.0	0.00	100.0	36	0.00	21.08	-66.7	0.00	66.7
	Week 2	31	15.05	25.59	0.0	0.00	100.0	30	2.22	14.99	-33.3	0.00	33.3
	Week 3	35	16.19	27.26	0.0	0.00	100.0	33	6.06	19.46	-33.3	0.00	66.7
	Week 4	34	20.59	29.60	0.0	0.00	100.0	32	7.29	21.97	-33.3	0.00	66.7
	Week 5	34	15.69	20.49	0.0	0.00	66.7	32	6.25	17.83	-33.3	0.00	33.3
	Week 6	36	19.44	28.03	0.0	0.00	100.0	33	8.08	20.46	-33.3	0.00	66.7
	Week 7	33	12.12	21.76	0.0	0.00	100.0	29	1.15	20.86	-66.7	0.00	33.3
	Week 8	34	15.69	24.94	0.0	0.00	100.0	30	4.44	19.04	-33.3	0.00	66.7
	Week 9	34	15.69	24.94	0.0	0.00	100.0	30	5.56	21.59	-66.7	0.00	33.3
	Week 10	35	14.28	23.27	0.0	0.00	100.0	32	1.04	19.83	-66.7	0.00	33.3
	Week 11	29	14.94	26.10	0.0	0.00	100.0	27	3.70	19.25	-33.3	0.00	66.7
	Week 12	30	13.33	24.13	0.0	0.00	100.0	27	3.70	19.25	-33.3	0.00	66.7
	Week 14	26	14.10	25.25	0.0	0.00	100.0	23	7.25	22.37	-33.3	0.00	66.7
	Week 17	26	11.54	22.98	0.0	0.00	100.0	24	8.33	22.52	0.0	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 20	20	18.33	25.31	0.0	0.00	66.7	19	10.53	27.34	-33.3	0.00	66.7
	Week 23	18	12.96	23.26	0.0	0.00	66.7	18	5.56	20.61	-33.3	0.00	66.7
	Week 26	20	21.67	34.67	0.0	0.00	100.0	20	10.00	32.62	-33.3	0.00	100.0
	Week 29	18	18.52	28.52	0.0	0.00	100.0	18	7.41	26.95	-33.3	0.00	66.7
	Week 32	13	15.38	22.01	0.0	0.00	66.7	13	5.13	18.49	-33.3	0.00	33.3
	Week 35	12	2.78	9.62	0.0	0.00	33.3	12	-2.78	17.16	-33.3	0.00	33.3
	Week 38	10	10.00	22.50	0.0	0.00	66.7	10	3.33	10.54	0.0	0.00	33.3
	Week 41	10	6.67	14.05	0.0	0.00	33.3	10	-3.33	10.54	-33.3	0.00	0.0
	Week 44	10	10.00	16.10	0.0	0.00	33.3	10	-3.33	10.54	-33.3	0.00	0.0
	Week 47	10	10.00	16.10	0.0	0.00	33.3	10	0.00	15.71	-33.3	0.00	33.3
	Week 56	10	13.33	23.31	0.0	0.00	66.7	10	0.00	0.00	0.0	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Visceral metastases	EV+Pembro (N=148)												
	BASELINE	119	16.81	26.71	0.0	0.00	100.0						
	Week 1	105	15.24	26.57	0.0	0.00	100.0	99	-2.36	17.33	-33.3	0.00	100.0
	Week 2	109	19.88	28.37	0.0	0.00	100.0	100	3.33	17.41	-66.7	0.00	66.7
	Week 3	98	18.71	29.14	0.0	0.00	100.0	88	1.14	19.21	-66.7	0.00	66.7
	Week 4	103	17.80	27.93	0.0	0.00	100.0	93	1.79	19.26	-66.7	0.00	66.7
	Week 5	100	17.33	28.62	0.0	0.00	100.0	90	0.74	19.34	-66.7	0.00	66.7
	Week 6	105	15.24	24.90	0.0	0.00	100.0	90	0.74	19.97	-66.7	0.00	66.7
	Week 7	108	16.36	25.17	0.0	0.00	100.0	91	1.83	21.87	-100.0	0.00	66.7
	Week 8	105	19.36	28.79	0.0	0.00	100.0	89	4.12	22.93	-66.7	0.00	100.0
	Week 9	105	20.95	30.05	0.0	0.00	100.0	91	5.13	24.30	-66.7	0.00	100.0
	Week 10	101	19.14	28.03	0.0	0.00	100.0	86	1.94	22.50	-66.7	0.00	66.7
	Week 11	97	19.59	29.17	0.0	0.00	100.0	83	5.22	24.13	-66.7	0.00	100.0
	Week 12	100	15.33	25.26	0.0	0.00	100.0	85	0.78	24.11	-100.0	0.00	66.7
	Week 14	102	15.36	23.77	0.0	0.00	100.0	87	0.77	24.89	-100.0	0.00	66.7
	Week 17	96	16.32	23.69	0.0	0.00	100.0	81	1.65	24.67	-100.0	0.00	66.7
	Week 20	87	15.32	22.04	0.0	0.00	100.0	76	0.44	23.41	-66.7	0.00	66.7
	Week 23	85	16.47	24.46	0.0	0.00	100.0	71	3.76	23.60	-66.7	0.00	66.7
	Week 26	79	14.35	21.80	0.0	0.00	100.0	66	1.52	23.70	-66.7	0.00	66.7
	Week 29	72	15.28	20.89	0.0	0.00	100.0	64	3.12	25.70	-66.7	0.00	66.7
	Week 32	71	16.90	23.82	0.0	0.00	100.0	62	4.84	23.26	-66.7	0.00	100.0
	Week 35	70	17.62	26.45	0.0	0.00	100.0	63	4.23	27.75	-100.0	0.00	100.0
	Week 38	70	16.19	24.57	0.0	0.00	100.0	63	2.12	26.01	-100.0	0.00	66.7
	Week 41	66	19.19	26.19	0.0	0.00	100.0	60	5.00	28.67	-100.0	0.00	100.0
	Week 44	59	21.47	28.88	0.0	0.00	100.0	53	9.43	26.46	-66.7	0.00	100.0
	Week 47	52	21.79	27.12	0.0	16.67	100.0	48	9.03	24.54	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	49	20.41	26.19	0.0	0.00	100.0	43	10.08	23.61	-66.7	0.00	66.7
	Week 53	50	20.67	25.99	0.0	0.00	100.0	44	11.36	18.94	0.0	0.00	66.7
	Week 56	45	20.74	26.86	0.0	0.00	100.0	39	8.55	21.24	-66.7	0.00	66.7
	Week 59	44	18.94	25.31	0.0	0.00	100.0	38	8.77	21.48	-66.7	0.00	66.7
	Week 62	38	15.79	24.18	0.0	0.00	100.0	33	5.05	25.17	-66.7	0.00	66.7
	Week 65	25	21.33	28.67	0.0	0.00	100.0	24	12.50	21.56	0.0	0.00	66.7
	Week 68	31	20.43	26.77	0.0	0.00	100.0	29	10.34	23.74	-66.7	0.00	66.7
	Week 71	27	20.99	30.87	0.0	0.00	100.0	25	6.67	27.22	-66.7	0.00	100.0
	Week 74	23	23.19	30.87	0.0	0.00	100.0	22	7.58	27.08	-66.7	0.00	66.7
	Week 77	24	25.00	31.47	0.0	16.67	100.0	23	8.70	25.06	-66.7	0.00	66.7
	Week 80	22	25.76	28.97	0.0	33.33	100.0	22	7.58	25.05	-66.7	0.00	66.7
	Week 83	19	19.30	23.08	0.0	0.00	66.7	19	8.77	26.86	-66.7	0.00	66.7
	Week 86	14	19.05	25.20	0.0	0.00	66.7	14	9.52	33.15	-66.7	0.00	66.7
	Week 89	10	23.33	22.50	0.0	33.33	66.7	10	6.67	34.43	-66.7	0.00	66.7
	Week 92	11	21.21	22.47	0.0	33.33	66.7	11	6.06	29.13	-66.7	0.00	33.3
	Plat+Gem (N=157)												
	BASELINE	128	10.42	20.39	0.0	0.00	66.7						
	Week 1	111	10.21	21.46	0.0	0.00	100.0	107	-0.31	17.43	-66.7	0.00	66.7
	Week 2	110	13.94	27.23	0.0	0.00	100.0	102	3.27	21.24	-33.3	0.00	100.0
	Week 3	112	10.71	23.77	0.0	0.00	100.0	103	0.32	16.50	-33.3	0.00	66.7
	Week 4	112	12.20	24.51	0.0	0.00	100.0	102	2.61	19.16	-33.3	0.00	66.7
	Week 5	113	11.80	23.11	0.0	0.00	100.0	103	3.24	19.53	-33.3	0.00	66.7
	Week 6	107	14.02	25.09	0.0	0.00	100.0	98	4.76	17.91	-33.3	0.00	66.7
	Week 7	109	10.70	22.17	0.0	0.00	100.0	100	1.00	20.35	-66.7	0.00	66.7
	Week 8	106	12.58	23.66	0.0	0.00	100.0	98	3.74	22.39	-66.7	0.00	100.0
	Week 9	105	11.43	22.09	0.0	0.00	100.0	94	3.19	20.20	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	104	11.86	23.65	0.0	0.00	100.0	96	2.43	20.08	-66.7	0.00	66.7
	Week 11	91	15.02	25.47	0.0	0.00	100.0	83	4.82	21.55	-33.3	0.00	66.7
	Week 12	94	10.99	21.52	0.0	0.00	100.0	84	1.98	18.91	-66.7	0.00	33.3
	Week 14	90	11.85	24.64	0.0	0.00	100.0	79	2.11	20.91	-66.7	0.00	66.7
	Week 17	90	11.48	21.29	0.0	0.00	100.0	80	4.17	19.40	-33.3	0.00	66.7
	Week 20	74	15.77	26.59	0.0	0.00	100.0	64	6.25	23.66	-33.3	0.00	100.0
	Week 23	63	12.17	21.83	0.0	0.00	100.0	58	4.02	20.78	-33.3	0.00	100.0
	Week 26	55	13.33	22.77	0.0	0.00	100.0	52	4.49	17.50	-33.3	0.00	33.3
	Week 29	53	12.58	21.90	0.0	0.00	100.0	50	5.33	23.68	-33.3	0.00	100.0
	Week 32	42	11.90	19.23	0.0	0.00	66.7	40	5.00	17.78	-33.3	0.00	33.3
	Week 35	39	7.69	16.15	0.0	0.00	66.7	36	2.78	18.47	-33.3	0.00	33.3
	Week 38	37	9.91	22.03	0.0	0.00	100.0	34	5.88	22.43	-33.3	0.00	100.0
	Week 41	33	12.12	20.10	0.0	0.00	66.7	31	5.38	22.93	-33.3	0.00	66.7
	Week 44	32	11.46	18.18	0.0	0.00	66.7	30	5.56	17.69	-33.3	0.00	33.3
	Week 47	28	13.09	20.96	0.0	0.00	66.7	26	7.69	21.72	-33.3	0.00	66.7
	Week 50	22	7.58	20.40	0.0	0.00	66.7	20	1.67	25.31	-66.7	0.00	66.7
	Week 53	19	8.77	18.73	0.0	0.00	66.7	17	5.88	21.20	-33.3	0.00	66.7
	Week 56	18	14.81	23.49	0.0	0.00	66.7	17	5.88	21.20	-33.3	0.00	66.7
	Week 59	13	10.26	16.01	0.0	0.00	33.3	12	0.00	20.10	-33.3	0.00	33.3
	Week 62	11	15.15	22.92	0.0	0.00	66.7	11	3.03	17.98	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Lymph node only	EV+Pembro (N= 43)												
	BASELINE	33	11.11	19.84	0.0	0.00	66.7						
	Week 1	30	12.22	20.50	0.0	0.00	66.7	24	5.56	16.05	-33.3	0.00	33.3
	Week 2	34	11.76	21.53	0.0	0.00	66.7	27	0.00	16.01	-33.3	0.00	33.3
	Week 3	35	13.33	24.52	0.0	0.00	100.0	28	-1.19	19.21	-66.7	0.00	33.3
	Week 4	36	13.89	18.47	0.0	0.00	66.7	30	1.11	18.54	-33.3	0.00	33.3
	Week 5	33	12.12	20.10	0.0	0.00	66.7	27	-4.94	15.20	-33.3	0.00	33.3
	Week 6	34	18.63	28.65	0.0	0.00	100.0	28	4.76	25.20	-33.3	0.00	100.0
	Week 7	34	16.67	26.27	0.0	0.00	100.0	28	1.19	23.10	-66.7	0.00	66.7
	Week 8	35	13.33	23.15	0.0	0.00	100.0	29	-1.15	16.63	-33.3	0.00	33.3
	Week 9	30	13.33	22.49	0.0	0.00	66.7	24	0.00	19.66	-33.3	0.00	66.7
	Week 10	31	12.90	23.85	0.0	0.00	100.0	26	0.00	18.86	-33.3	0.00	33.3
	Week 11	34	16.67	22.09	0.0	0.00	100.0	27	3.70	19.24	-33.3	0.00	33.3
	Week 12	35	21.90	27.94	0.0	0.00	100.0	28	8.33	25.05	-33.3	0.00	66.7
	Week 14	30	12.22	20.50	0.0	0.00	66.7	23	1.45	18.74	-33.3	0.00	33.3
	Week 17	30	15.56	22.71	0.0	0.00	66.7	24	2.78	21.80	-66.7	0.00	33.3
	Week 20	27	16.05	21.42	0.0	0.00	66.7	21	3.17	20.83	-33.3	0.00	33.3
	Week 23	27	17.28	23.33	0.0	0.00	66.7	21	1.59	19.65	-33.3	0.00	33.3
	Week 26	27	18.52	21.35	0.0	0.00	66.7	22	3.03	22.79	-33.3	0.00	33.3
	Week 29	28	16.67	21.28	0.0	0.00	66.7	23	2.90	17.15	-33.3	0.00	33.3
	Week 32	24	13.89	23.91	0.0	0.00	66.7	20	0.00	15.30	-33.3	0.00	33.3
	Week 35	22	18.18	28.60	0.0	0.00	100.0	18	3.70	15.71	-33.3	0.00	33.3
	Week 38	21	9.52	18.69	0.0	0.00	66.7	17	-5.88	21.20	-66.7	0.00	33.3
	Week 41	22	19.70	26.55	0.0	0.00	66.7	17	0.00	20.41	-33.3	0.00	33.3
	Week 44	22	21.21	30.07	0.0	0.00	100.0	16	6.25	18.13	-33.3	0.00	33.3
	Week 47	21	22.22	30.43	0.0	0.00	100.0	16	6.25	21.84	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	18.33	22.88	0.0	0.00	66.7	16	-2.08	22.67	-66.7	0.00	33.3
	Week 53	18	20.37	23.26	0.0	16.67	66.7	14	0.00	26.15	-66.7	0.00	33.3
	Week 56	21	20.63	26.83	0.0	0.00	66.7	17	1.96	24.92	-33.3	0.00	66.7
	Week 59	21	20.63	26.83	0.0	0.00	66.7	16	0.00	21.08	-33.3	0.00	33.3
	Week 62	19	21.05	27.69	0.0	0.00	66.7	15	2.22	19.79	-33.3	0.00	33.3
	Week 65	16	25.00	35.49	0.0	0.00	100.0	14	4.76	22.10	-33.3	0.00	66.7
	Week 68	13	23.08	25.04	0.0	33.33	66.7	11	3.03	23.36	-33.3	0.00	33.3
	Week 71	13	20.51	28.99	0.0	0.00	66.7	11	0.00	14.91	-33.3	0.00	33.3
	Week 74	13	25.64	27.74	0.0	33.33	66.7	11	6.06	20.10	-33.3	0.00	33.3
	Week 77	13	17.95	22.01	0.0	0.00	66.7	10	-6.67	14.06	-33.3	0.00	0.0
	Week 80	13	12.82	16.88	0.0	0.00	33.3	11	-3.03	17.98	-33.3	0.00	33.3
	Week 83	11	18.18	22.92	0.0	0.00	66.7	10	-3.34	18.92	-33.3	0.00	33.3
	Week 86	11	18.18	22.92	0.0	0.00	66.7	10	3.33	18.92	-33.3	0.00	33.3
	Plat+Gem (N= 37)												
	BASELINE	29	14.94	27.58	0.0	0.00	100.0						
	Week 1	26	12.82	23.24	0.0	0.00	66.7	25	-2.67	19.05	-33.3	0.00	66.7
	Week 2	30	17.78	24.34	0.0	0.00	66.7	26	1.28	19.96	-33.3	0.00	33.3
	Week 3	30	15.56	25.87	0.0	0.00	100.0	26	3.85	19.61	-33.3	0.00	66.7
	Week 4	32	11.46	20.05	0.0	0.00	66.7	27	1.23	19.57	-33.3	0.00	66.7
	Week 5	33	12.12	20.10	0.0	0.00	66.7	28	0.00	22.22	-66.7	0.00	33.3
	Week 6	32	11.46	20.05	0.0	0.00	66.7	27	-1.23	26.92	-66.7	0.00	66.7
	Week 7	31	9.68	15.38	0.0	0.00	33.3	26	-2.56	20.92	-66.7	0.00	33.3
	Week 8	32	12.50	20.30	0.0	0.00	66.7	27	1.23	23.54	-66.7	0.00	66.7
	Week 9	30	15.56	22.71	0.0	0.00	66.7	25	1.33	22.52	-33.3	0.00	66.7
	Week 10	30	14.44	22.63	0.0	0.00	66.7	26	1.28	22.07	-33.3	0.00	66.7
	Week 11	29	14.94	24.54	0.0	0.00	66.7	25	4.00	26.03	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.22.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Impact by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 12	28	14.29	23.00	0.0	0.00	66.7	23	0.00	22.47	-33.3	0.00	66.7
	Week 14	28	14.29	24.73	0.0	0.00	66.7	23	4.35	25.24	-33.3	0.00	66.7
	Week 17	25	20.00	31.91	0.0	0.00	100.0	21	9.52	30.08	-33.3	0.00	100.0
	Week 20	23	14.49	24.26	0.0	0.00	66.7	20	1.67	22.88	-33.3	0.00	66.7
	Week 23	20	16.67	29.62	0.0	0.00	100.0	17	1.96	21.96	-33.3	0.00	66.7
	Week 26	21	22.22	35.49	0.0	0.00	100.0	18	11.11	36.15	-33.3	0.00	100.0
	Week 29	19	19.30	32.04	0.0	0.00	100.0	16	4.17	23.96	-33.3	0.00	66.7
	Week 32	18	11.11	19.80	0.0	0.00	66.7	15	-4.44	17.21	-33.3	0.00	33.3
	Week 35	19	14.03	25.62	0.0	0.00	100.0	16	0.00	17.21	-33.3	0.00	33.3
	Week 38	15	13.33	21.08	0.0	0.00	66.7	12	-2.78	22.28	-33.3	0.00	33.3
	Week 41	15	15.56	30.52	0.0	0.00	100.0	12	0.00	20.10	-33.3	0.00	33.3
	Week 44	14	19.05	33.88	0.0	0.00	100.0	11	3.03	27.71	-33.3	0.00	66.7
	Week 47	12	11.11	21.71	0.0	0.00	66.7	10	-6.67	21.08	-33.3	0.00	33.3
	Week 50	11	15.15	31.14	0.0	0.00	100.0	8	4.17	41.55	-33.3	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
EV+Pembro (N=240)												
BASELINE	206	6.80	15.69	0.0	0.00	66.7						
Week 1	190	7.72	18.11	0.0	0.00	100.0	184	1.63	18.53	-33.3	0.00	100.0
Week 2	203	12.31	24.07	0.0	0.00	100.0	189	5.47	22.79	-66.7	0.00	100.0
Week 3	198	14.14	24.26	0.0	0.00	100.0	182	7.33	23.66	-66.7	0.00	100.0
Week 4	194	9.62	19.17	0.0	0.00	100.0	179	3.17	22.26	-66.7	0.00	100.0
Week 5	190	9.47	21.50	0.0	0.00	100.0	173	2.50	21.87	-66.7	0.00	100.0
Week 6	188	12.23	23.59	0.0	0.00	100.0	170	4.90	22.25	-66.7	0.00	100.0
Week 7	195	9.74	21.45	0.0	0.00	100.0	176	2.84	22.50	-66.7	0.00	100.0
Week 8	191	9.07	19.92	0.0	0.00	100.0	171	1.56	21.02	-66.7	0.00	66.7
Week 9	197	11.34	22.11	0.0	0.00	100.0	180	4.63	23.84	-66.7	0.00	100.0
Week 10	191	8.73	20.36	0.0	0.00	100.0	175	1.90	19.48	-66.7	0.00	100.0
Week 11	194	8.25	19.80	0.0	0.00	100.0	175	0.57	22.17	-66.7	0.00	100.0
Week 12	186	10.04	22.08	0.0	0.00	100.0	171	2.14	24.02	-66.7	0.00	100.0
Week 14	185	8.29	21.50	0.0	0.00	100.0	167	1.60	23.94	-66.7	0.00	100.0
Week 17	178	5.80	14.95	0.0	0.00	66.7	162	-0.82	19.29	-66.7	0.00	66.7
Week 20	167	6.19	15.79	0.0	0.00	66.7	154	-0.43	20.87	-66.7	0.00	66.7
Week 23	162	6.79	15.38	0.0	0.00	66.7	151	-0.66	21.93	-66.7	0.00	66.7
Week 26	156	5.98	14.41	0.0	0.00	66.7	144	-0.23	20.29	-66.7	0.00	66.7
Week 29	157	5.94	15.33	0.0	0.00	100.0	145	-1.38	20.37	-66.7	0.00	100.0
Week 32	135	7.16	17.46	0.0	0.00	66.7	125	0.27	22.99	-66.7	0.00	66.7
Week 35	132	6.57	18.16	0.0	0.00	100.0	122	-1.91	24.73	-66.7	0.00	100.0
Week 38	132	8.59	16.79	0.0	0.00	66.7	124	0.27	21.46	-66.7	0.00	66.7
Week 41	129	8.79	19.77	0.0	0.00	100.0	119	0.28	25.85	-66.7	0.00	100.0
Week 44	108	5.86	14.29	0.0	0.00	66.7	100	-1.67	17.96	-66.7	0.00	66.7
Week 47	100	8.00	18.42	0.0	0.00	100.0	94	0.35	24.19	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	89	7.12	17.02	0.0	0.00	66.7	84	-2.38	24.70	-66.7	0.00	66.7
Week 53	79	6.75	18.01	0.0	0.00	100.0	74	-0.90	25.27	-66.7	0.00	100.0
Week 56	81	5.35	14.39	0.0	0.00	66.7	76	-3.95	23.07	-66.7	0.00	66.7
Week 59	72	4.17	12.43	0.0	0.00	66.7	68	-3.92	20.39	-66.7	0.00	66.7
Week 62	65	5.13	12.12	0.0	0.00	33.3	63	-2.65	18.26	-66.7	0.00	33.3
Week 65	58	4.60	11.59	0.0	0.00	33.3	54	-4.94	20.89	-66.7	0.00	33.3
Week 68	53	5.66	12.63	0.0	0.00	33.3	52	0.00	18.67	-66.7	0.00	33.3
Week 71	51	8.50	21.95	0.0	0.00	100.0	49	-0.68	24.05	-66.7	0.00	100.0
Week 74	47	7.80	14.26	0.0	0.00	33.3	46	0.72	17.90	-66.7	0.00	33.3
Week 77	44	8.33	16.27	0.0	0.00	66.7	42	0.00	22.09	-66.7	0.00	66.7
Week 80	40	6.67	13.50	0.0	0.00	33.3	37	-0.90	21.50	-66.7	0.00	33.3
Week 83	37	6.31	13.23	0.0	0.00	33.3	35	0.95	20.59	-66.7	0.00	33.3
Week 86	34	7.84	14.35	0.0	0.00	33.3	31	4.30	16.65	-33.3	0.00	33.3
Week 89	33	6.06	13.05	0.0	0.00	33.3	31	-1.08	18.22	-66.7	0.00	33.3
Week 92	27	4.94	12.07	0.0	0.00	33.3	25	-2.67	19.05	-66.7	0.00	33.3
Week 95	22	3.03	9.81	0.0	0.00	33.3	21	-6.35	13.41	-33.3	0.00	0.0
Week 98	18	3.70	10.78	0.0	0.00	33.3	17	-5.88	21.20	-66.7	0.00	33.3
Week 101	14	7.14	14.19	0.0	0.00	33.3	14	-2.38	24.33	-66.7	0.00	33.3
Week 104	10	3.33	10.54	0.0	0.00	33.3	10	-3.33	18.92	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Plat+Gem (N=242)												
BASELINE	188	5.14	14.32	0.0	0.00	66.7						
Week 1	173	6.36	16.22	0.0	0.00	100.0	158	1.69	16.31	-66.7	0.00	66.7
Week 2	171	10.72	20.97	0.0	0.00	100.0	151	5.96	22.80	-66.7	0.00	100.0
Week 3	184	6.88	16.00	0.0	0.00	100.0	162	2.06	18.08	-66.7	0.00	66.7
Week 4	183	5.10	15.17	0.0	0.00	100.0	156	-0.21	20.56	-66.7	0.00	100.0
Week 5	187	4.81	12.72	0.0	0.00	66.7	156	0.00	16.93	-66.7	0.00	66.7
Week 6	174	7.47	16.86	0.0	0.00	66.7	149	1.57	19.89	-66.7	0.00	66.7
Week 7	186	4.66	13.05	0.0	0.00	66.7	157	-1.27	18.45	-66.7	0.00	66.7
Week 8	167	4.39	12.96	0.0	0.00	66.7	144	-1.85	17.53	-66.7	0.00	66.7
Week 9	177	4.33	12.81	0.0	0.00	66.7	150	-0.89	18.09	-66.7	0.00	66.7
Week 10	166	5.42	14.36	0.0	0.00	66.7	139	0.00	18.39	-66.7	0.00	66.7
Week 11	168	5.36	14.74	0.0	0.00	100.0	143	0.23	19.18	-66.7	0.00	100.0
Week 12	159	5.87	15.25	0.0	0.00	100.0	138	0.97	18.87	-66.7	0.00	100.0
Week 14	153	6.75	16.82	0.0	0.00	100.0	128	2.08	18.11	-66.7	0.00	66.7
Week 17	155	6.45	14.76	0.0	0.00	66.7	130	1.79	19.60	-66.7	0.00	66.7
Week 20	126	4.23	11.14	0.0	0.00	33.3	110	-1.52	18.83	-66.7	0.00	33.3
Week 23	115	4.06	11.80	0.0	0.00	66.7	97	-1.72	19.47	-66.7	0.00	33.3
Week 26	108	6.17	15.88	0.0	0.00	100.0	95	0.35	20.91	-66.7	0.00	100.0
Week 29	100	3.33	10.05	0.0	0.00	33.3	86	-1.55	17.64	-66.7	0.00	33.3
Week 32	83	5.22	14.24	0.0	0.00	66.7	76	0.00	21.08	-66.7	0.00	66.7
Week 35	76	6.14	16.96	0.0	0.00	100.0	69	-1.45	17.56	-66.7	0.00	33.3
Week 38	74	6.31	16.25	0.0	0.00	66.7	65	1.54	22.38	-66.7	0.00	66.7
Week 41	65	4.61	11.60	0.0	0.00	33.3	56	-1.79	19.51	-66.7	0.00	33.3
Week 44	60	7.22	20.44	0.0	0.00	100.0	53	5.03	23.02	-33.3	0.00	100.0
Week 47	56	2.98	9.59	0.0	0.00	33.3	49	0.00	13.61	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	51	7.19	15.37	0.0	0.00	66.7	47	2.13	20.15	-66.7	0.00	66.7
Week 53	46	6.52	16.66	0.0	0.00	66.7	42	0.79	22.68	-66.7	0.00	66.7
Week 56	39	8.55	18.29	0.0	0.00	66.7	34	5.88	22.43	-33.3	0.00	66.7
Week 59	37	9.01	21.73	0.0	0.00	100.0	33	4.04	26.03	-33.3	0.00	100.0
Week 62	32	7.29	16.36	0.0	0.00	66.7	29	2.30	21.69	-33.3	0.00	66.7
Week 65	30	2.22	8.46	0.0	0.00	33.3	26	-2.56	16.12	-33.3	0.00	33.3
Week 68	25	2.67	9.23	0.0	0.00	33.3	21	-1.59	12.81	-33.3	0.00	33.3
Week 71	22	1.52	7.11	0.0	0.00	33.3	19	-5.26	12.49	-33.3	0.00	0.0
Week 74	21	1.59	7.27	0.0	0.00	33.3	18	-3.70	10.78	-33.3	0.00	0.0
Week 77	18	9.26	27.55	0.0	0.00	100.0	15	0.00	21.82	-33.3	0.00	66.7
Week 80	14	4.76	17.82	0.0	0.00	66.7	13	0.00	13.61	-33.3	0.00	33.3
Week 83	13	0.00	0.00	0.0	0.00	0.0	12	-2.78	9.62	-33.3	0.00	0.0
Week 86	12	2.78	9.62	0.0	0.00	33.3	11	-3.03	17.98	-33.3	0.00	33.3
Week 89	11	0.00	0.00	0.0	0.00	0.0	10	-6.67	14.05	-33.3	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Present	EV+Pembro (N= 48)												
	BASELINE	39	8.55	16.61	0.0	0.00	66.7						
	Week 1	32	5.21	17.16	0.0	0.00	66.7	32	-1.04	19.83	-33.3	0.00	66.7
	Week 2	37	18.92	31.95	0.0	0.00	100.0	33	9.09	27.98	-33.3	0.00	100.0
	Week 3	34	21.57	30.58	0.0	0.00	100.0	29	12.64	25.84	-33.3	0.00	66.7
	Week 4	36	12.96	24.27	0.0	0.00	100.0	31	7.53	25.40	-33.3	0.00	66.7
	Week 5	30	12.22	28.34	0.0	0.00	100.0	24	6.95	31.05	-33.3	0.00	100.0
	Week 6	31	18.28	30.84	0.0	0.00	100.0	25	10.67	32.94	-33.3	0.00	100.0
	Week 7	34	12.75	28.44	0.0	0.00	100.0	28	5.95	28.77	-33.3	0.00	66.7
	Week 8	35	12.38	22.99	0.0	0.00	66.7	30	6.67	23.81	-33.3	0.00	66.7
	Week 9	34	15.69	30.96	0.0	0.00	100.0	30	10.00	31.74	-33.3	0.00	100.0
	Week 10	34	14.71	29.80	0.0	0.00	100.0	30	7.78	29.92	-33.3	0.00	100.0
	Week 11	33	15.15	28.98	0.0	0.00	100.0	28	5.95	34.01	-33.3	0.00	100.0
	Week 12	33	15.15	28.98	0.0	0.00	100.0	29	3.45	28.65	-33.3	0.00	66.7
	Week 14	31	8.60	22.72	0.0	0.00	100.0	26	-1.28	22.07	-33.3	0.00	66.7
	Week 17	31	5.38	15.15	0.0	0.00	66.7	25	-1.33	15.15	-33.3	0.00	33.3
	Week 20	27	4.94	12.07	0.0	0.00	33.3	24	-2.78	16.79	-33.3	0.00	33.3
	Week 23	26	7.69	17.15	0.0	0.00	66.7	23	-1.45	23.52	-33.3	0.00	66.7
	Week 26	25	8.00	19.91	0.0	0.00	66.7	22	1.52	26.18	-33.3	0.00	66.7
	Week 29	23	8.69	14.96	0.0	0.00	33.3	22	-3.03	14.21	-33.3	0.00	33.3
	Week 32	21	4.76	11.95	0.0	0.00	33.3	19	-7.02	17.84	-33.3	0.00	33.3
	Week 35	19	5.26	16.72	0.0	0.00	66.7	17	-7.84	25.08	-33.3	0.00	66.7
	Week 38	18	11.11	22.87	0.0	0.00	66.7	17	-3.92	28.58	-33.3	0.00	66.7
	Week 41	20	10.00	24.42	0.0	0.00	100.0	19	-1.75	30.37	-33.3	0.00	100.0
	Week 44	17	11.76	20.21	0.0	0.00	66.7	15	-2.22	26.63	-33.3	0.00	66.7
	Week 47	18	12.96	28.33	0.0	0.00	100.0	16	4.17	34.16	-33.3	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	12	11.11	21.71	0.0	0.00	66.7	11	3.03	31.46	-33.3	0.00	66.7
	Week 53	12	11.11	29.59	0.0	0.00	100.0	11	0.00	36.51	-33.3	0.00	100.0
	Week 56	13	2.56	9.24	0.0	0.00	33.3	12	-8.33	20.72	-33.3	0.00	33.3
	Week 59	12	0.00	0.00	0.0	0.00	0.0	11	-9.09	15.57	-33.3	0.00	0.0
	Week 62	10	0.00	0.00	0.0	0.00	0.0	9	-11.11	16.67	-33.3	0.00	0.0
	Week 65	10	6.67	14.05	0.0	0.00	33.3	9	-3.70	20.03	-33.3	0.00	33.3
	Plat+Gem (N= 48)												
	BASELINE	33	6.06	17.59	0.0	0.00	66.7						
	Week 1	31	7.53	22.29	0.0	0.00	100.0	27	3.70	19.24	-33.3	0.00	66.7
	Week 2	29	14.94	27.58	0.0	0.00	100.0	24	12.50	29.18	-33.3	0.00	100.0
	Week 3	32	11.46	23.36	0.0	0.00	100.0	27	7.41	25.04	-66.7	0.00	66.7
	Week 4	32	5.21	14.93	0.0	0.00	66.7	24	-1.39	25.02	-66.7	0.00	66.7
	Week 5	36	5.56	14.91	0.0	0.00	66.7	28	-1.19	21.24	-66.7	0.00	66.7
	Week 6	35	4.76	11.83	0.0	0.00	33.3	27	-1.24	17.25	-66.7	0.00	33.3
	Week 7	38	6.14	17.08	0.0	0.00	66.7	29	0.00	26.73	-66.7	0.00	66.7
	Week 8	31	3.23	13.21	0.0	0.00	66.7	25	-2.67	16.44	-66.7	0.00	33.3
	Week 9	32	3.12	9.87	0.0	0.00	33.3	25	-2.67	23.41	-66.7	0.00	33.3
	Week 10	34	5.88	17.35	0.0	0.00	66.7	26	0.00	21.08	-66.7	0.00	66.7
	Week 11	30	3.33	13.42	0.0	0.00	66.7	24	-1.39	25.02	-66.7	0.00	66.7
	Week 12	28	3.57	10.50	0.0	0.00	33.3	23	-1.45	23.52	-66.7	0.00	33.3
	Week 14	26	8.97	20.13	0.0	0.00	66.7	21	1.59	22.30	-66.7	0.00	66.7
	Week 17	30	8.89	19.44	0.0	0.00	66.7	25	4.00	30.91	-66.7	0.00	66.7
	Week 20	23	1.45	6.95	0.0	0.00	33.3	21	-6.35	22.65	-66.7	0.00	33.3
	Week 23	22	1.52	7.11	0.0	0.00	33.3	19	-7.02	23.78	-66.7	0.00	33.3
	Week 26	19	5.26	12.49	0.0	0.00	33.3	18	-1.85	7.86	-33.3	0.00	0.0
	Week 29	16	2.08	8.33	0.0	0.00	33.3	14	-2.38	20.52	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 32	11	0.00	0.00	0.0	0.00	0.0	11	-9.09	21.56	-66.7	0.00	0.0
	Week 35	10	10.00	31.62	0.0	0.00	100.0	9	-7.41	22.22	-66.7	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Absent	EV+Pembro (N=192)												
	BASELINE	167	6.39	15.49	0.0	0.00	66.7						
	Week 1	158	8.23	18.31	0.0	0.00	100.0	152	2.19	18.27	-33.3	0.00	100.0
	Week 2	166	10.84	21.78	0.0	0.00	100.0	156	4.70	21.57	-66.7	0.00	100.0
	Week 3	164	12.60	22.54	0.0	0.00	100.0	153	6.32	23.18	-66.7	0.00	100.0
	Week 4	158	8.86	17.81	0.0	0.00	100.0	148	2.25	21.53	-66.7	0.00	100.0
	Week 5	160	8.96	20.04	0.0	0.00	100.0	149	1.79	20.05	-66.7	0.00	100.0
	Week 6	157	11.04	21.81	0.0	0.00	100.0	145	3.91	19.84	-66.7	0.00	100.0
	Week 7	161	9.11	19.72	0.0	0.00	100.0	148	2.25	21.18	-66.7	0.00	100.0
	Week 8	156	8.33	19.17	0.0	0.00	100.0	141	0.47	20.31	-66.7	0.00	66.7
	Week 9	163	10.43	19.78	0.0	0.00	100.0	150	3.56	21.90	-66.7	0.00	66.7
	Week 10	157	7.43	17.54	0.0	0.00	100.0	145	0.69	16.42	-66.7	0.00	66.7
	Week 11	161	6.83	17.13	0.0	0.00	100.0	147	-0.45	19.11	-66.7	0.00	66.7
	Week 12	153	8.93	20.23	0.0	0.00	100.0	142	1.88	23.07	-66.7	0.00	100.0
	Week 14	154	8.22	21.33	0.0	0.00	100.0	141	2.13	24.30	-66.7	0.00	100.0
	Week 17	147	5.90	14.96	0.0	0.00	66.7	137	-0.73	19.99	-66.7	0.00	66.7
	Week 20	140	6.43	16.44	0.0	0.00	66.7	130	0.00	21.57	-66.7	0.00	66.7
	Week 23	136	6.62	15.08	0.0	0.00	66.7	128	-0.52	21.73	-66.7	0.00	66.7
	Week 26	131	5.60	13.17	0.0	0.00	66.7	122	-0.55	19.16	-66.7	0.00	66.7
	Week 29	134	5.47	15.40	0.0	0.00	100.0	123	-1.08	21.31	-66.7	0.00	100.0
	Week 32	114	7.60	18.30	0.0	0.00	66.7	106	1.57	23.63	-66.7	0.00	66.7
	Week 35	113	6.78	18.45	0.0	0.00	100.0	105	-0.95	24.66	-66.7	0.00	100.0
	Week 38	114	8.19	15.72	0.0	0.00	66.7	107	0.93	20.20	-66.7	0.00	66.7
	Week 41	109	8.56	18.92	0.0	0.00	100.0	100	0.67	25.06	-66.7	0.00	100.0
	Week 44	91	4.76	12.74	0.0	0.00	66.7	85	-1.57	16.19	-66.7	0.00	66.7
	Week 47	82	6.91	15.48	0.0	0.00	66.7	78	-0.43	21.82	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	77	6.49	16.26	0.0	0.00	66.7	73	-3.20	23.68	-66.7	0.00	66.7
	Week 53	67	5.97	15.27	0.0	0.00	66.7	63	-1.06	23.16	-66.7	0.00	66.7
	Week 56	68	5.88	15.17	0.0	0.00	66.7	64	-3.13	23.55	-66.7	0.00	66.7
	Week 59	60	5.00	13.48	0.0	0.00	66.7	57	-2.92	21.16	-66.7	0.00	66.7
	Week 62	55	6.06	12.97	0.0	0.00	33.3	54	-1.23	18.27	-66.7	0.00	33.3
	Week 65	48	4.17	11.14	0.0	0.00	33.3	45	-5.19	21.27	-66.7	0.00	33.3
	Week 68	46	5.80	12.77	0.0	0.00	33.3	45	0.00	18.80	-66.7	0.00	33.3
	Week 71	44	6.82	18.44	0.0	0.00	100.0	42	-2.38	18.61	-66.7	0.00	33.3
	Week 74	40	9.17	15.07	0.0	0.00	33.3	39	2.56	17.74	-66.7	0.00	33.3
	Week 77	38	8.77	16.77	0.0	0.00	66.7	36	0.93	23.21	-66.7	0.00	66.7
	Week 80	35	4.76	11.83	0.0	0.00	33.3	32	-3.13	21.35	-66.7	0.00	33.3
	Week 83	32	5.21	12.30	0.0	0.00	33.3	30	0.00	19.57	-66.7	0.00	33.3
	Week 86	29	6.90	13.74	0.0	0.00	33.3	26	2.56	16.12	-33.3	0.00	33.3
	Week 89	29	5.75	12.81	0.0	0.00	33.3	27	-2.47	18.32	-66.7	0.00	33.3
	Week 92	24	5.56	12.69	0.0	0.00	33.3	22	-3.03	20.34	-66.7	0.00	33.3
	Week 95	20	3.33	10.26	0.0	0.00	33.3	19	-5.26	12.49	-33.3	0.00	0.0
	Week 98	18	3.70	10.78	0.0	0.00	33.3	17	-5.88	21.20	-66.7	0.00	33.3
	Week 101	13	5.13	12.52	0.0	0.00	33.3	13	-5.13	22.96	-66.7	0.00	33.3
	Plat+Gem (N=194)												
	BASELINE	155	4.95	13.59	0.0	0.00	66.7						
	Week 1	142	6.10	14.65	0.0	0.00	66.7	131	1.27	15.69	-66.7	0.00	66.7
	Week 2	142	9.86	19.36	0.0	0.00	100.0	127	4.72	21.30	-66.7	0.00	66.7
	Week 3	152	5.92	13.89	0.0	0.00	66.7	135	0.99	16.26	-66.7	0.00	66.7
	Week 4	151	5.08	15.27	0.0	0.00	100.0	132	0.00	19.75	-66.7	0.00	100.0
	Week 5	151	4.64	12.19	0.0	0.00	66.7	128	0.26	15.93	-66.7	0.00	33.3
	Week 6	139	8.15	17.87	0.0	0.00	66.7	122	2.19	20.43	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 7	148	4.28	11.84	0.0	0.00	66.7	128	-1.56	16.12	-66.7	0.00	66.7
	Week 8	136	4.66	12.94	0.0	0.00	66.7	119	-1.68	17.81	-66.7	0.00	66.7
	Week 9	145	4.60	13.39	0.0	0.00	66.7	125	-0.53	16.92	-66.7	0.00	66.7
	Week 10	132	5.30	13.55	0.0	0.00	66.7	113	0.00	17.82	-66.7	0.00	66.7
	Week 11	138	5.80	15.02	0.0	0.00	100.0	119	0.56	17.88	-66.7	0.00	100.0
	Week 12	131	6.36	16.07	0.0	0.00	100.0	115	1.45	17.87	-66.7	0.00	100.0
	Week 14	127	6.30	16.12	0.0	0.00	100.0	107	2.18	17.30	-66.7	0.00	66.7
	Week 17	125	5.87	13.43	0.0	0.00	66.7	105	1.27	15.96	-66.7	0.00	33.3
	Week 20	103	4.85	11.81	0.0	0.00	33.3	89	-0.37	17.76	-66.7	0.00	33.3
	Week 23	93	4.66	12.62	0.0	0.00	66.7	78	-0.43	18.21	-66.7	0.00	33.3
	Week 26	89	6.37	16.57	0.0	0.00	100.0	77	0.87	22.92	-66.7	0.00	100.0
	Week 29	84	3.57	10.37	0.0	0.00	33.3	72	-1.39	17.19	-66.7	0.00	33.3
	Week 32	72	6.02	15.14	0.0	0.00	66.7	65	1.54	20.77	-66.7	0.00	66.7
	Week 35	66	5.56	13.82	0.0	0.00	66.7	60	-0.56	16.80	-66.7	0.00	33.3
	Week 38	66	6.57	16.76	0.0	0.00	66.7	57	1.75	23.08	-66.7	0.00	66.7
	Week 41	62	4.84	11.84	0.0	0.00	33.3	53	-0.63	17.89	-66.7	0.00	33.3
	Week 44	55	5.45	16.68	0.0	0.00	100.0	48	2.78	19.24	-33.3	0.00	100.0
	Week 47	51	2.61	9.05	0.0	0.00	33.3	44	-0.76	13.43	-33.3	0.00	33.3
	Week 50	48	7.64	15.74	0.0	0.00	66.7	44	2.27	20.83	-66.7	0.00	66.7
	Week 53	41	6.50	17.03	0.0	0.00	66.7	37	0.90	22.89	-66.7	0.00	66.7
	Week 56	34	8.82	18.91	0.0	0.00	66.7	29	5.75	23.69	-33.3	0.00	66.7
	Week 59	32	10.42	23.09	0.0	0.00	100.0	28	5.95	27.30	-33.3	0.00	100.0
	Week 62	27	7.41	16.88	0.0	0.00	66.7	24	2.78	21.79	-33.3	0.00	66.7
	Week 65	25	1.33	6.67	0.0	0.00	33.3	21	-3.17	14.55	-33.3	0.00	33.3
	Week 68	23	2.90	9.60	0.0	0.00	33.3	19	-1.75	13.49	-33.3	0.00	33.3
	Week 71	21	1.59	7.27	0.0	0.00	33.3	18	-5.56	12.78	-33.3	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 74	20	1.67	7.45	0.0	0.00	33.3	17	-3.92	11.07	-33.3	0.00	0.0
	Week 77	16	10.42	29.11	0.0	0.00	100.0	13	0.00	23.57	-33.3	0.00	66.7
	Week 80	12	5.56	19.25	0.0	0.00	66.7	11	0.00	14.91	-33.3	0.00	33.3
	Week 83	11	0.00	0.00	0.0	0.00	0.0	10	-3.33	10.54	-33.3	0.00	0.0
	Week 86	10	3.33	10.54	0.0	0.00	33.3	9	-3.70	20.03	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
< 65 years	EV+Pembro (N=105)												
	BASELINE	92	7.25	16.99	0.0	0.00	66.7						
	Week 1	88	8.33	18.40	0.0	0.00	66.7	85	0.78	17.04	-33.3	0.00	66.7
	Week 2	92	12.32	23.03	0.0	0.00	100.0	86	5.04	24.26	-66.7	0.00	100.0
	Week 3	93	13.26	22.60	0.0	0.00	100.0	84	5.56	23.04	-66.7	0.00	66.7
	Week 4	90	7.41	15.62	0.0	0.00	66.7	82	-0.41	22.52	-66.7	0.00	66.7
	Week 5	90	8.52	19.07	0.0	0.00	100.0	81	-0.41	21.40	-66.7	0.00	66.7
	Week 6	90	9.63	21.34	0.0	0.00	100.0	81	1.65	20.34	-66.7	0.00	66.7
	Week 7	85	8.63	20.02	0.0	0.00	100.0	77	1.30	22.58	-66.7	0.00	100.0
	Week 8	89	7.49	17.23	0.0	0.00	100.0	80	-0.83	21.20	-66.7	0.00	33.3
	Week 9	93	10.75	20.36	0.0	0.00	100.0	85	4.31	25.09	-66.7	0.00	100.0
	Week 10	88	6.82	19.02	0.0	0.00	100.0	81	0.41	20.75	-66.7	0.00	100.0
	Week 11	93	7.17	17.62	0.0	0.00	100.0	84	0.40	25.08	-66.7	0.00	100.0
	Week 12	86	7.75	17.47	0.0	0.00	66.7	79	0.42	24.16	-66.7	0.00	66.7
	Week 14	84	6.75	21.82	0.0	0.00	100.0	76	0.88	26.09	-66.7	0.00	100.0
	Week 17	83	4.42	13.55	0.0	0.00	66.7	77	-2.60	21.47	-66.7	0.00	66.7
	Week 20	79	3.80	13.06	0.0	0.00	66.7	73	-5.02	21.28	-66.7	0.00	66.7
	Week 23	78	8.12	17.15	0.0	0.00	66.7	73	0.46	26.35	-66.7	0.00	66.7
	Week 26	78	5.98	15.89	0.0	0.00	66.7	72	-1.85	24.31	-66.7	0.00	66.7
	Week 29	74	7.21	18.52	0.0	0.00	100.0	67	-1.00	25.93	-66.7	0.00	100.0
	Week 32	64	8.33	18.78	0.0	0.00	66.7	59	0.57	25.89	-66.7	0.00	66.7
	Week 35	62	8.60	22.53	0.0	0.00	100.0	58	0.00	29.29	-66.7	0.00	100.0
	Week 38	62	8.60	17.00	0.0	0.00	66.7	59	0.00	23.16	-66.7	0.00	66.7
	Week 41	64	6.25	19.59	0.0	0.00	100.0	59	-1.69	27.97	-66.7	0.00	100.0
	Week 44	50	5.33	14.06	0.0	0.00	66.7	48	-2.78	20.44	-66.7	0.00	66.7
	Week 47	47	6.38	19.21	0.0	0.00	100.0	46	0.00	24.34	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	44	9.09	18.13	0.0	0.00	66.7	41	-1.63	25.77	-66.7	0.00	66.7
	Week 53	40	4.17	17.19	0.0	0.00	100.0	37	-2.70	25.31	-66.7	0.00	100.0
	Week 56	44	3.79	10.70	0.0	0.00	33.3	41	-5.69	18.11	-66.7	0.00	33.3
	Week 59	42	3.17	9.90	0.0	0.00	33.3	39	-5.13	18.00	-66.7	0.00	33.3
	Week 62	37	3.60	10.49	0.0	0.00	33.3	36	-4.63	16.24	-66.7	0.00	33.3
	Week 65	34	3.92	10.90	0.0	0.00	33.3	31	-4.30	22.35	-66.7	0.00	33.3
	Week 68	34	5.88	12.90	0.0	0.00	33.3	33	-1.01	19.52	-66.7	0.00	33.3
	Week 71	32	9.37	21.14	0.0	0.00	100.0	30	-1.11	22.29	-66.7	0.00	33.3
	Week 74	29	11.49	16.12	0.0	0.00	33.3	28	2.38	20.14	-66.7	0.00	33.3
	Week 77	25	10.67	18.56	0.0	0.00	66.7	24	2.78	25.85	-66.7	0.00	66.7
	Week 80	24	9.72	15.48	0.0	0.00	33.3	22	3.03	22.79	-66.7	0.00	33.3
	Week 83	23	8.69	14.96	0.0	0.00	33.3	22	1.51	24.07	-66.7	0.00	33.3
	Week 86	20	11.67	16.31	0.0	0.00	33.3	18	7.41	18.28	-33.3	0.00	33.3
	Week 89	19	7.02	13.96	0.0	0.00	33.3	17	1.96	14.29	-33.3	0.00	33.3
	Week 92	14	9.52	15.63	0.0	0.00	33.3	12	2.78	17.16	-33.3	0.00	33.3
	Week 95	12	2.78	9.62	0.0	0.00	33.3	11	-6.06	13.48	-33.3	0.00	0.0
	Plat+Gem (N=106)												
	BASELINE	83	6.43	16.01	0.0	0.00	66.7						
	Week 1	75	8.00	17.19	0.0	0.00	100.0	71	1.88	17.72	-66.7	0.00	33.3
	Week 2	76	10.09	20.38	0.0	0.00	66.7	68	4.41	24.37	-66.7	0.00	66.7
	Week 3	80	8.75	18.17	0.0	0.00	100.0	73	3.20	20.91	-66.7	0.00	66.7
	Week 4	79	4.64	12.78	0.0	0.00	66.7	67	-2.49	21.95	-66.7	0.00	66.7
	Week 5	80	4.58	11.55	0.0	0.00	33.3	67	-1.00	20.07	-66.7	0.00	33.3
	Week 6	76	6.58	17.23	0.0	0.00	66.7	67	0.50	24.27	-66.7	0.00	66.7
	Week 7	81	4.12	13.32	0.0	0.00	66.7	71	-3.29	20.44	-66.7	0.00	66.7
	Week 8	72	3.24	11.41	0.0	0.00	66.7	64	-4.17	19.25	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	78	4.27	13.55	0.0	0.00	66.7	69	-1.93	22.05	-66.7	0.00	66.7
	Week 10	78	4.70	14.93	0.0	0.00	66.7	68	-1.47	23.35	-66.7	0.00	66.7
	Week 11	75	5.33	16.48	0.0	0.00	100.0	66	0.00	23.39	-66.7	0.00	100.0
	Week 12	74	4.50	11.47	0.0	0.00	33.3	66	-1.01	16.51	-66.7	0.00	33.3
	Week 14	68	5.88	15.17	0.0	0.00	66.7	58	1.72	22.01	-66.7	0.00	66.7
	Week 17	68	4.41	13.99	0.0	0.00	66.7	58	-1.72	20.16	-66.7	0.00	66.7
	Week 20	60	2.78	9.29	0.0	0.00	33.3	52	-3.21	18.97	-66.7	0.00	33.3
	Week 23	51	3.92	10.85	0.0	0.00	33.3	44	-1.52	21.51	-66.7	0.00	33.3
	Week 26	47	7.80	19.92	0.0	0.00	100.0	42	2.38	25.92	-66.7	0.00	100.0
	Week 29	42	4.76	11.80	0.0	0.00	33.3	37	0.90	20.01	-66.7	0.00	33.3
	Week 32	37	3.60	13.11	0.0	0.00	66.7	34	-1.96	21.62	-66.7	0.00	66.7
	Week 35	34	1.96	7.96	0.0	0.00	33.3	31	-3.23	15.76	-66.7	0.00	33.3
	Week 38	33	3.03	9.73	0.0	0.00	33.3	28	-2.38	20.14	-66.7	0.00	33.3
	Week 41	27	3.70	10.67	0.0	0.00	33.3	22	-1.52	19.18	-66.7	0.00	33.3
	Week 44	28	2.38	8.74	0.0	0.00	33.3	24	1.39	11.95	-33.3	0.00	33.3
	Week 47	24	2.78	9.41	0.0	0.00	33.3	21	1.59	12.81	-33.3	0.00	33.3
	Week 50	26	6.41	16.38	0.0	0.00	66.7	24	1.39	23.01	-66.7	0.00	66.7
	Week 53	19	5.26	16.72	0.0	0.00	66.7	17	-1.96	27.56	-66.7	0.00	66.7
	Week 56	13	5.13	12.52	0.0	0.00	33.3	11	3.03	17.98	-33.3	0.00	33.3
	Week 59	14	4.76	12.10	0.0	0.00	33.3	12	-2.78	17.16	-33.3	0.00	33.3
	Week 62	13	5.13	12.52	0.0	0.00	33.3	12	0.00	20.10	-33.3	0.00	33.3
	Week 65	13	0.00	0.00	0.0	0.00	0.0	11	-6.06	13.48	-33.3	0.00	0.0
	Week 68	10	3.33	10.54	0.0	0.00	33.3	8	0.00	17.82	-33.3	0.00	33.3
	Week 77	10	10.00	31.62	0.0	0.00	100.0	8	-4.17	11.78	-33.3	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>= 65 years	EV+Pembro (N=135)												
	BASELINE	114	6.43	14.62	0.0	0.00	66.7						
	Week 1	102	7.19	17.94	0.0	0.00	100.0	99	2.36	19.78	-33.3	0.00	100.0
	Week 2	111	12.31	25.00	0.0	0.00	100.0	103	5.83	21.61	-66.7	0.00	100.0
	Week 3	105	14.92	25.73	0.0	0.00	100.0	98	8.84	24.19	-66.7	0.00	100.0
	Week 4	104	11.54	21.67	0.0	0.00	100.0	97	6.19	21.69	-66.7	0.00	100.0
	Week 5	100	10.33	23.54	0.0	0.00	100.0	92	5.07	22.06	-33.3	0.00	100.0
	Week 6	98	14.63	25.36	0.0	0.00	100.0	89	7.87	23.58	-33.3	0.00	100.0
	Week 7	110	10.61	22.55	0.0	0.00	100.0	99	4.04	22.47	-66.7	0.00	100.0
	Week 8	102	10.46	21.99	0.0	0.00	100.0	91	3.66	20.76	-66.7	0.00	66.7
	Week 9	104	11.86	23.65	0.0	0.00	100.0	95	4.91	22.79	-66.7	0.00	66.7
	Week 10	103	10.36	21.40	0.0	0.00	100.0	94	3.19	18.33	-33.3	0.00	66.7
	Week 11	101	9.24	21.66	0.0	0.00	100.0	91	0.73	19.23	-33.3	0.00	66.7
	Week 12	100	12.00	25.30	0.0	0.00	100.0	92	3.62	23.93	-66.7	0.00	100.0
	Week 14	101	9.57	21.26	0.0	0.00	100.0	91	2.20	22.11	-66.7	0.00	100.0
	Week 17	95	7.02	16.05	0.0	0.00	66.7	85	0.78	17.04	-66.7	0.00	33.3
	Week 20	88	8.33	17.69	0.0	0.00	66.7	81	3.70	19.72	-33.3	0.00	66.7
	Week 23	84	5.56	13.53	0.0	0.00	66.7	78	-1.71	16.90	-66.7	0.00	66.7
	Week 26	78	5.98	12.87	0.0	0.00	33.3	72	1.39	15.26	-33.3	0.00	33.3
	Week 29	83	4.82	11.79	0.0	0.00	33.3	78	-1.71	14.11	-66.7	0.00	33.3
	Week 32	71	6.10	16.24	0.0	0.00	66.7	66	0.00	20.25	-66.7	0.00	66.7
	Week 35	70	4.76	13.05	0.0	0.00	66.7	64	-3.65	19.80	-66.7	0.00	66.7
	Week 38	70	8.57	16.72	0.0	0.00	66.7	65	0.51	19.97	-66.7	0.00	33.3
	Week 41	65	11.28	19.79	0.0	0.00	66.7	60	2.22	23.66	-66.7	0.00	66.7
	Week 44	58	6.32	14.59	0.0	0.00	66.7	52	-0.64	15.47	-33.3	0.00	66.7
	Week 47	53	9.43	17.76	0.0	0.00	66.7	48	0.69	24.30	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	45	5.19	15.82	0.0	0.00	66.7	43	-3.10	23.92	-66.7	0.00	66.7
	Week 53	39	9.40	18.65	0.0	0.00	66.7	37	0.90	25.44	-66.7	0.00	66.7
	Week 56	37	7.21	17.80	0.0	0.00	66.7	35	-1.90	27.94	-66.7	0.00	66.7
	Week 59	30	5.56	15.37	0.0	0.00	66.7	29	-2.30	23.45	-66.7	0.00	66.7
	Week 62	28	7.14	13.93	0.0	0.00	33.3	27	0.00	20.67	-33.3	0.00	33.3
	Week 65	24	5.56	12.69	0.0	0.00	33.3	23	-5.80	19.21	-66.7	0.00	33.3
	Week 68	19	5.26	12.49	0.0	0.00	33.3	19	1.75	17.47	-33.3	0.00	33.3
	Week 71	19	7.02	23.78	0.0	0.00	100.0	19	0.00	27.22	-33.3	0.00	100.0
	Week 74	18	1.85	7.86	0.0	0.00	33.3	18	-1.85	13.87	-33.3	0.00	33.3
	Week 77	19	5.26	12.49	0.0	0.00	33.3	18	-3.70	15.71	-33.3	0.00	33.3
	Week 80	16	2.08	8.33	0.0	0.00	33.3	15	-6.67	18.69	-66.7	0.00	0.0
	Week 83	14	2.38	8.91	0.0	0.00	33.3	13	0.00	13.61	-33.3	0.00	33.3
	Week 86	14	2.38	8.91	0.0	0.00	33.3	13	0.00	13.61	-33.3	0.00	33.3
	Week 89	14	4.76	12.10	0.0	0.00	33.3	14	-4.76	22.10	-66.7	0.00	33.3
	Week 92	13	0.00	0.00	0.0	0.00	0.0	13	-7.69	19.97	-66.7	0.00	0.0
	Week 95	10	3.33	10.54	0.0	0.00	33.3	10	-6.67	14.05	-33.3	0.00	0.0
	Week 98	10	3.33	10.54	0.0	0.00	33.3	10	-10.00	22.50	-66.7	0.00	0.0
	Plat+Gem (N=136)												
	BASELINE	105	4.13	12.82	0.0	0.00	66.7						
	Week 1	98	5.10	15.40	0.0	0.00	66.7	87	1.53	15.17	-33.3	0.00	66.7
	Week 2	95	11.23	21.53	0.0	0.00	100.0	83	7.23	21.49	-33.3	0.00	100.0
	Week 3	104	5.45	14.02	0.0	0.00	66.7	89	1.12	15.45	-66.7	0.00	66.7
	Week 4	104	5.45	16.82	0.0	0.00	100.0	89	1.50	19.40	-66.7	0.00	100.0
	Week 5	107	4.98	13.58	0.0	0.00	66.7	89	0.75	14.19	-33.3	0.00	66.7
	Week 6	98	8.16	16.62	0.0	0.00	66.7	82	2.44	15.52	-33.3	0.00	66.7
	Week 7	105	5.08	12.89	0.0	0.00	66.7	86	0.39	16.56	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 8	95	5.26	14.02	0.0	0.00	66.7	80	0.00	15.91	-66.7	0.00	33.3
	Week 9	99	4.38	12.28	0.0	0.00	66.7	81	0.00	13.94	-66.7	0.00	33.3
	Week 10	88	6.06	13.88	0.0	0.00	66.7	71	1.41	11.87	-33.3	0.00	33.3
	Week 11	93	5.38	13.27	0.0	0.00	66.7	77	0.43	14.80	-66.7	0.00	66.7
	Week 12	85	7.06	17.89	0.0	0.00	100.0	72	2.78	20.74	-66.7	0.00	100.0
	Week 14	85	7.45	18.09	0.0	0.00	100.0	70	2.38	14.27	-33.3	0.00	66.7
	Week 17	87	8.05	15.22	0.0	0.00	66.7	72	4.63	18.81	-66.7	0.00	66.7
	Week 20	66	5.56	12.52	0.0	0.00	33.3	58	0.00	18.73	-66.7	0.00	33.3
	Week 23	64	4.17	12.60	0.0	0.00	66.7	53	-1.89	17.80	-66.7	0.00	33.3
	Week 26	61	4.92	11.92	0.0	0.00	33.3	53	-1.26	15.96	-33.3	0.00	33.3
	Week 29	58	2.30	8.52	0.0	0.00	33.3	49	-3.40	15.58	-66.7	0.00	33.3
	Week 32	46	6.52	15.10	0.0	0.00	66.7	42	1.59	20.76	-66.7	0.00	66.7
	Week 35	42	9.52	21.19	0.0	0.00	100.0	38	0.00	18.98	-66.7	0.00	33.3
	Week 38	41	8.94	19.75	0.0	0.00	66.7	37	4.50	23.78	-33.3	0.00	66.7
	Week 41	38	5.26	12.32	0.0	0.00	33.3	34	-1.96	20.00	-66.7	0.00	33.3
	Week 44	32	11.46	26.25	0.0	0.00	100.0	29	8.05	29.08	-33.3	0.00	100.0
	Week 47	32	3.12	9.87	0.0	0.00	33.3	28	-1.19	14.29	-33.3	0.00	33.3
	Week 50	25	8.00	14.53	0.0	0.00	33.3	23	2.90	17.15	-33.3	0.00	33.3
	Week 53	27	7.41	16.88	0.0	0.00	66.7	25	2.67	19.05	-33.3	0.00	66.7
	Week 56	26	10.26	20.59	0.0	0.00	66.7	23	7.25	24.53	-33.3	0.00	66.7
	Week 59	23	11.59	25.84	0.0	0.00	100.0	21	7.94	29.64	-33.3	0.00	100.0
	Week 62	19	8.77	18.73	0.0	0.00	66.7	17	3.92	23.22	-33.3	0.00	66.7
	Week 65	17	3.92	11.07	0.0	0.00	33.3	15	0.00	17.82	-33.3	0.00	33.3
	Week 68	15	2.22	8.61	0.0	0.00	33.3	13	-2.56	9.24	-33.3	0.00	0.0
	Week 71	15	0.00	0.00	0.0	0.00	0.0	13	-5.13	12.52	-33.3	0.00	0.0
	Week 74	12	0.00	0.00	0.0	0.00	0.0	11	-3.03	10.05	-33.3	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Europe	EV+Pembro (N= 98)												
	BASELINE	79	7.59	17.66	0.0	0.00	66.7						
	Week 1	74	8.11	20.50	0.0	0.00	100.0	71	2.35	20.57	-33.3	0.00	100.0
	Week 2	79	12.24	23.37	0.0	0.00	100.0	71	6.10	27.78	-66.7	0.00	100.0
	Week 3	78	17.52	23.25	0.0	0.00	100.0	69	10.63	25.88	-66.7	0.00	100.0
	Week 4	78	10.26	18.85	0.0	0.00	66.7	70	3.81	25.72	-66.7	0.00	66.7
	Week 5	70	8.09	16.48	0.0	0.00	66.7	62	-1.08	20.88	-66.7	0.00	66.7
	Week 6	70	10.48	22.37	0.0	0.00	100.0	61	1.09	22.74	-66.7	0.00	100.0
	Week 7	78	6.84	17.29	0.0	0.00	100.0	68	0.00	23.74	-66.7	0.00	100.0
	Week 8	72	6.48	15.46	0.0	0.00	66.7	61	-1.64	23.11	-66.7	0.00	33.3
	Week 9	80	7.08	19.63	0.0	0.00	100.0	70	0.48	24.40	-66.7	0.00	100.0
	Week 10	71	6.10	18.09	0.0	0.00	100.0	62	-1.08	22.56	-66.7	0.00	100.0
	Week 11	76	7.02	21.30	0.0	0.00	100.0	66	-1.01	28.63	-66.7	0.00	100.0
	Week 12	73	8.22	22.07	0.0	0.00	100.0	65	1.54	28.52	-66.7	0.00	100.0
	Week 14	74	6.31	17.16	0.0	0.00	100.0	64	1.56	24.79	-66.7	0.00	100.0
	Week 17	70	5.71	13.87	0.0	0.00	66.7	62	-1.61	22.93	-66.7	0.00	66.7
	Week 20	70	7.62	18.97	0.0	0.00	66.7	63	-0.53	25.75	-66.7	0.00	66.7
	Week 23	61	8.74	18.16	0.0	0.00	66.7	57	0.58	27.09	-66.7	0.00	66.7
	Week 26	62	6.99	16.12	0.0	0.00	66.7	55	0.00	24.00	-66.7	0.00	66.7
	Week 29	63	4.76	15.68	0.0	0.00	100.0	57	-4.09	24.45	-66.7	0.00	100.0
	Week 32	51	5.88	17.26	0.0	0.00	66.7	47	-0.71	25.53	-66.7	0.00	66.7
	Week 35	56	9.52	22.66	0.0	0.00	100.0	52	1.28	28.74	-66.7	0.00	100.0
	Week 38	51	7.84	18.36	0.0	0.00	66.7	48	-0.69	25.25	-66.7	0.00	66.7
	Week 41	52	4.49	16.21	0.0	0.00	100.0	48	-4.17	24.43	-66.7	0.00	100.0
	Week 44	43	6.20	15.01	0.0	0.00	66.7	39	-1.71	21.56	-66.7	0.00	66.7
	Week 47	39	6.84	19.01	0.0	0.00	100.0	36	-2.78	26.87	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	37	8.11	18.27	0.0	0.00	66.7	36	-1.85	27.54	-66.7	0.00	66.7
	Week 53	28	9.52	21.96	0.0	0.00	100.0	27	1.23	31.33	-66.7	0.00	100.0
	Week 56	30	4.44	14.47	0.0	0.00	66.7	29	-5.75	25.31	-66.7	0.00	66.7
	Week 59	27	0.00	0.00	0.0	0.00	0.0	27	-8.64	19.81	-66.7	0.00	0.0
	Week 62	23	5.80	12.92	0.0	0.00	33.3	23	-2.90	17.15	-33.3	0.00	33.3
	Week 65	23	4.35	11.48	0.0	0.00	33.3	23	-7.25	22.38	-66.7	0.00	33.3
	Week 68	21	1.59	7.27	0.0	0.00	33.3	21	-6.35	20.05	-66.7	0.00	33.3
	Week 71	19	1.75	7.65	0.0	0.00	33.3	19	-8.77	21.78	-66.7	0.00	33.3
	Week 74	15	2.22	8.61	0.0	0.00	33.3	15	-8.89	19.79	-66.7	0.00	0.0
	Week 77	19	5.26	12.49	0.0	0.00	33.3	19	-7.02	23.78	-66.7	0.00	33.3
	Week 80	17	9.80	15.65	0.0	0.00	33.3	17	0.00	23.57	-66.7	0.00	33.3
	Week 83	16	6.25	13.44	0.0	0.00	33.3	16	-2.08	25.73	-66.7	0.00	33.3
	Week 86	14	7.14	14.19	0.0	0.00	33.3	14	2.38	20.52	-33.3	0.00	33.3
	Week 89	14	7.14	14.19	0.0	0.00	33.3	14	0.00	18.49	-33.3	0.00	33.3
	Week 92	11	3.03	10.05	0.0	0.00	33.3	11	-3.03	17.98	-33.3	0.00	33.3
	Week 95	10	3.33	10.54	0.0	0.00	33.3	10	-10.00	16.10	-33.3	0.00	0.0
	Plat+Gem (N=102)												
	BASELINE	71	5.16	15.58	0.0	0.00	66.7						
	Week 1	71	5.63	17.80	0.0	0.00	100.0	61	0.55	11.37	-33.3	0.00	33.3
	Week 2	67	14.93	26.13	0.0	0.00	100.0	56	11.31	26.42	-33.3	0.00	100.0
	Week 3	68	8.82	20.46	0.0	0.00	100.0	56	5.36	19.87	-66.7	0.00	66.7
	Week 4	75	7.56	19.43	0.0	0.00	100.0	59	2.82	25.74	-66.7	0.00	100.0
	Week 5	77	4.76	12.93	0.0	0.00	66.7	60	0.00	15.03	-66.7	0.00	33.3
	Week 6	70	9.05	19.59	0.0	0.00	66.7	56	2.38	19.96	-66.7	0.00	66.7
	Week 7	72	5.56	14.80	0.0	0.00	66.7	55	-0.61	21.75	-66.7	0.00	66.7
	Week 8	65	5.64	15.10	0.0	0.00	66.7	53	-1.89	17.80	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	70	5.24	14.62	0.0	0.00	66.7	55	-0.61	20.78	-66.7	0.00	66.7
	Week 10	60	7.78	18.78	0.0	0.00	66.7	46	2.90	23.12	-66.7	0.00	66.7
	Week 11	64	4.69	14.39	0.0	0.00	66.7	50	0.00	21.30	-66.7	0.00	66.7
	Week 12	60	8.89	19.28	0.0	0.00	100.0	48	4.17	25.38	-66.7	0.00	100.0
	Week 14	56	8.93	20.59	0.0	0.00	100.0	42	3.97	19.76	-66.7	0.00	66.7
	Week 17	58	7.47	16.57	0.0	0.00	66.7	44	0.76	22.14	-66.7	0.00	66.7
	Week 20	47	5.67	12.66	0.0	0.00	33.3	37	-1.80	22.15	-66.7	0.00	33.3
	Week 23	44	3.03	9.69	0.0	0.00	33.3	32	-4.17	22.00	-66.7	0.00	33.3
	Week 26	39	8.55	19.82	0.0	0.00	100.0	30	1.11	23.95	-33.3	0.00	100.0
	Week 29	34	1.96	7.96	0.0	0.00	33.3	25	-2.67	16.44	-66.7	0.00	33.3
	Week 32	33	5.05	12.14	0.0	0.00	33.3	27	1.23	19.57	-66.7	0.00	33.3
	Week 35	30	8.89	23.05	0.0	0.00	100.0	24	0.00	17.03	-66.7	0.00	33.3
	Week 38	26	8.97	20.13	0.0	0.00	66.7	21	9.52	21.46	0.0	0.00	66.7
	Week 41	22	4.55	11.71	0.0	0.00	33.3	17	0.00	20.41	-66.7	0.00	33.3
	Week 44	20	8.33	23.88	0.0	0.00	100.0	16	8.33	25.82	0.0	0.00	100.0
	Week 47	16	2.08	8.33	0.0	0.00	33.3	12	2.78	9.62	0.0	0.00	33.3
	Week 50	11	6.06	13.48	0.0	0.00	33.3	10	3.33	10.54	0.0	0.00	33.3
	Week 53	11	9.09	21.56	0.0	0.00	66.7	10	10.00	22.50	0.0	0.00	66.7
	Week 56	10	16.67	28.33	0.0	0.00	66.7	8	20.83	30.54	0.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
North America	EV+Pembro (N= 57)												
	BASELINE	47	9.22	17.99	0.0	0.00	66.7						
	Week 1	39	8.55	19.82	0.0	0.00	66.7	37	-1.80	17.47	-33.3	0.00	33.3
	Week 2	44	15.15	29.16	0.0	0.00	100.0	42	3.17	19.21	-66.7	0.00	66.7
	Week 3	44	15.15	29.16	0.0	0.00	100.0	40	4.17	22.88	-66.7	0.00	66.7
	Week 4	44	13.64	23.09	0.0	0.00	100.0	41	3.25	25.61	-66.7	0.00	100.0
	Week 5	47	12.06	25.47	0.0	0.00	100.0	41	3.25	19.44	-33.3	0.00	66.7
	Week 6	44	16.67	28.30	0.0	0.00	100.0	39	9.40	21.56	-33.3	0.00	66.7
	Week 7	46	13.04	26.74	0.0	0.00	100.0	42	3.97	26.75	-66.7	0.00	100.0
	Week 8	47	12.06	25.47	0.0	0.00	100.0	42	2.38	22.56	-66.7	0.00	66.7
	Week 9	46	18.84	27.80	0.0	0.00	100.0	42	9.52	27.83	-66.7	0.00	66.7
	Week 10	47	9.22	20.50	0.0	0.00	100.0	44	1.52	16.00	-33.3	0.00	33.3
	Week 11	47	7.09	15.44	0.0	0.00	66.7	42	-1.59	12.65	-33.3	0.00	33.3
	Week 12	44	14.39	26.31	0.0	0.00	100.0	40	2.50	25.47	-66.7	0.00	100.0
	Week 14	43	9.30	23.37	0.0	0.00	100.0	39	-1.71	22.88	-66.7	0.00	100.0
	Week 17	40	7.50	17.68	0.0	0.00	66.7	37	-1.80	22.15	-66.7	0.00	66.7
	Week 20	38	3.51	12.94	0.0	0.00	66.7	35	-3.81	17.66	-33.3	0.00	66.7
	Week 23	38	1.75	7.54	0.0	0.00	33.3	35	-8.57	18.69	-66.7	0.00	0.0
	Week 26	35	2.86	9.47	0.0	0.00	33.3	32	-6.25	15.70	-66.7	0.00	0.0
	Week 29	38	6.14	15.22	0.0	0.00	66.7	34	-3.92	19.70	-66.7	0.00	33.3
	Week 32	32	10.42	19.74	0.0	0.00	66.7	29	-1.15	22.68	-66.7	0.00	66.7
	Week 35	33	5.05	14.72	0.0	0.00	66.7	30	-7.78	24.26	-66.7	0.00	66.7
	Week 38	32	7.29	14.00	0.0	0.00	33.3	29	-5.75	17.97	-66.7	0.00	33.3
	Week 41	28	4.76	14.95	0.0	0.00	66.7	24	-9.72	25.02	-66.7	0.00	33.3
	Week 44	21	4.76	11.95	0.0	0.00	33.3	20	-5.00	16.31	-33.3	0.00	33.3
	Week 47	24	6.94	16.97	0.0	0.00	66.7	23	-1.45	23.52	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	23	7.25	19.99	0.0	0.00	66.7	20	-10.00	28.82	-66.7	0.00	66.7
	Week 53	17	1.96	8.08	0.0	0.00	33.3	14	-11.90	21.11	-66.7	0.00	0.0
	Week 56	20	6.67	13.68	0.0	0.00	33.3	17	-9.80	25.72	-66.7	0.00	33.3
	Week 59	17	7.84	14.57	0.0	0.00	33.3	14	-4.76	25.68	-66.7	0.00	33.3
	Week 62	14	4.76	12.10	0.0	0.00	33.3	13	-7.69	24.17	-66.7	0.00	33.3
	Week 65	12	2.78	9.62	0.0	0.00	33.3	9	-14.81	24.22	-66.7	0.00	0.0
	Week 68	10	10.00	16.10	0.0	0.00	33.3	9	7.41	14.70	0.0	0.00	33.3
	Week 71	10	23.33	41.72	0.0	0.00	100.0	8	12.50	39.59	-33.3	0.00	100.0
	Week 74	10	10.00	16.10	0.0	0.00	33.3	9	3.70	11.11	0.0	0.00	33.3
	Plat+Gem (N= 51)												
	BASELINE	42	5.56	14.57	0.0	0.00	66.7						
	Week 1	41	6.50	13.37	0.0	0.00	33.3	36	0.00	21.08	-66.7	0.00	33.3
	Week 2	38	8.77	16.77	0.0	0.00	66.7	33	3.03	19.30	-33.3	0.00	66.7
	Week 3	40	5.83	12.83	0.0	0.00	33.3	35	-0.95	17.12	-66.7	0.00	33.3
	Week 4	35	5.71	15.09	0.0	0.00	66.7	29	1.15	20.86	-66.7	0.00	66.7
	Week 5	39	5.13	14.38	0.0	0.00	66.7	32	2.08	18.81	-33.3	0.00	66.7
	Week 6	34	7.84	16.53	0.0	0.00	66.7	30	2.22	23.05	-66.7	0.00	66.7
	Week 7	42	5.56	14.57	0.0	0.00	66.7	37	0.00	19.25	-66.7	0.00	66.7
	Week 8	39	7.69	16.15	0.0	0.00	66.7	33	4.04	21.66	-66.7	0.00	66.7
	Week 9	39	3.42	12.78	0.0	0.00	66.7	33	-1.01	19.52	-66.7	0.00	66.7
	Week 10	39	2.56	9.00	0.0	0.00	33.3	32	-3.13	15.52	-66.7	0.00	33.3
	Week 11	39	7.69	19.44	0.0	0.00	100.0	33	2.02	23.48	-66.7	0.00	100.0
	Week 12	36	3.70	10.62	0.0	0.00	33.3	32	0.00	14.66	-33.3	0.00	33.3
	Week 14	34	6.86	15.95	0.0	0.00	66.7	29	2.30	21.70	-66.7	0.00	66.7
	Week 17	37	6.31	15.39	0.0	0.00	66.7	31	5.38	17.42	-33.3	0.00	66.7
	Week 20	27	1.23	6.41	0.0	0.00	33.3	23	-4.35	18.27	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 23	27	2.47	8.90	0.0	0.00	33.3	23	-2.90	19.88	-66.7	0.00	33.3
	Week 26	28	3.57	13.88	0.0	0.00	66.7	25	-1.33	22.53	-66.7	0.00	66.7
	Week 29	29	4.60	11.70	0.0	0.00	33.3	25	-1.33	20.37	-66.7	0.00	33.3
	Week 32	17	9.80	22.87	0.0	0.00	66.7	17	3.92	30.92	-66.7	0.00	66.7
	Week 35	16	6.25	13.44	0.0	0.00	33.3	15	-2.22	26.63	-66.7	0.00	33.3
	Week 38	16	10.42	20.07	0.0	0.00	66.7	13	2.56	34.59	-66.7	0.00	66.7
	Week 41	16	8.33	14.91	0.0	0.00	33.3	13	0.00	27.22	-66.7	0.00	33.3
	Week 44	13	10.26	28.49	0.0	0.00	100.0	11	9.09	33.63	-33.3	0.00	100.0
	Week 47	11	0.00	0.00	0.0	0.00	0.0	9	-3.70	11.11	-33.3	0.00	0.0
	Week 50	17	7.84	14.57	0.0	0.00	33.3	15	2.22	23.46	-66.7	0.00	33.3
	Week 53	13	2.56	9.24	0.0	0.00	33.3	11	-9.09	26.21	-66.7	0.00	33.3
	Week 56	11	6.06	13.48	0.0	0.00	33.3	9	7.41	14.70	0.0	0.00	33.3
	Week 59	11	3.03	10.05	0.0	0.00	33.3	9	0.00	16.67	-33.3	0.00	33.3
	Week 62	11	3.03	10.05	0.0	0.00	33.3	9	0.00	16.67	-33.3	0.00	33.3
	Week 65	10	3.33	10.54	0.0	0.00	33.3	8	0.00	17.82	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Rest of World	EV+Pembro (N= 85)												
	BASELINE	80	4.58	11.55	0.0	0.00	33.3						
	Week 1	77	6.93	14.65	0.0	0.00	66.7	76	2.63	17.01	-33.3	0.00	66.7
	Week 2	80	10.83	21.72	0.0	0.00	100.0	76	6.14	19.41	-33.3	0.00	66.7
	Week 3	76	10.09	21.79	0.0	0.00	100.0	73	5.94	21.76	-33.3	0.00	100.0
	Week 4	72	6.48	16.44	0.0	0.00	100.0	68	2.45	15.58	-33.3	0.00	66.7
	Week 5	73	9.13	23.08	0.0	0.00	100.0	70	5.24	23.83	-33.3	0.00	100.0
	Week 6	74	11.26	21.56	0.0	0.00	100.0	70	5.71	21.96	-33.3	0.00	100.0
	Week 7	71	10.80	21.66	0.0	0.00	100.0	66	5.05	17.78	-33.3	0.00	66.7
	Week 8	72	9.72	19.73	0.0	0.00	66.7	68	3.92	17.78	-33.3	0.00	66.7
	Week 9	71	11.27	19.47	0.0	0.00	66.7	68	5.88	19.90	-33.3	0.00	66.7
	Week 10	73	10.96	22.26	0.0	0.00	100.0	69	4.83	18.32	-33.3	0.00	66.7
	Week 11	71	10.33	20.77	0.0	0.00	100.0	67	3.48	19.36	-33.3	0.00	66.7
	Week 12	69	9.18	18.86	0.0	0.00	100.0	66	2.53	17.84	-33.3	0.00	66.7
	Week 14	68	9.80	24.47	0.0	0.00	100.0	64	3.65	23.84	-33.3	0.00	100.0
	Week 17	68	4.90	14.41	0.0	0.00	66.7	63	0.53	12.69	-33.3	0.00	33.3
	Week 20	59	6.21	13.09	0.0	0.00	33.3	56	1.79	16.10	-33.3	0.00	33.3
	Week 23	63	7.94	15.51	0.0	0.00	66.7	59	2.82	16.71	-33.3	0.00	66.7
	Week 26	59	6.78	14.88	0.0	0.00	66.7	57	2.92	18.13	-33.3	0.00	66.7
	Week 29	56	7.14	15.19	0.0	0.00	66.7	54	3.09	14.86	-33.3	0.00	66.7
	Week 32	52	6.41	16.22	0.0	0.00	66.7	49	2.04	20.87	-33.3	0.00	66.7
	Week 35	43	3.88	13.03	0.0	0.00	66.7	40	-1.67	18.41	-33.3	0.00	66.7
	Week 38	49	10.20	16.95	0.0	0.00	66.7	47	4.96	18.36	-33.3	0.00	33.3
	Week 41	49	15.65	23.67	0.0	0.00	100.0	47	9.93	24.98	-33.3	0.00	100.0
	Week 44	44	6.06	14.86	0.0	0.00	66.7	41	0.00	14.91	-33.3	0.00	66.7
	Week 47	37	9.91	19.03	0.0	0.00	66.7	35	4.76	21.61	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	29	5.75	12.81	0.0	0.00	33.3	28	2.38	15.52	-33.3	0.00	33.3
	Week 53	34	6.86	17.94	0.0	0.00	66.7	33	2.02	20.31	-33.3	0.00	66.7
	Week 56	31	5.38	15.15	0.0	0.00	66.7	30	1.11	18.53	-33.3	0.00	66.7
	Week 59	28	5.95	15.85	0.0	0.00	66.7	27	1.23	17.25	-33.3	0.00	66.7
	Week 62	28	4.76	11.88	0.0	0.00	33.3	27	0.00	16.01	-33.3	0.00	33.3
	Week 65	23	5.80	12.92	0.0	0.00	33.3	22	1.52	16.19	-33.3	0.00	33.3
	Week 68	22	7.58	14.30	0.0	0.00	33.3	22	3.03	17.54	-33.3	0.00	33.3
	Week 71	22	7.58	14.30	0.0	0.00	33.3	22	1.52	16.19	-33.3	0.00	33.3
	Week 74	22	10.61	15.89	0.0	0.00	33.3	22	6.06	16.70	-33.3	0.00	33.3
	Week 77	18	9.26	19.15	0.0	0.00	66.7	17	7.84	18.74	0.0	0.00	66.7
	Week 80	16	6.25	13.44	0.0	0.00	33.3	15	4.44	11.73	0.0	0.00	33.3
	Week 83	16	6.25	13.44	0.0	0.00	33.3	15	4.44	17.21	-33.3	0.00	33.3
	Week 86	13	7.69	14.62	0.0	0.00	33.3	12	5.56	12.97	0.0	0.00	33.3
	Week 89	12	5.56	12.97	0.0	0.00	33.3	12	2.78	9.62	0.0	0.00	33.3
	Plat+Gem (N= 89)												
	BASELINE	75	4.89	13.07	0.0	0.00	66.7						
	Week 1	61	7.10	16.23	0.0	0.00	66.7	61	3.83	17.32	-33.3	0.00	66.7
	Week 2	66	7.58	16.32	0.0	0.00	66.7	62	2.69	20.29	-66.7	0.00	66.7
	Week 3	76	5.70	12.63	0.0	0.00	33.3	71	0.94	16.88	-66.7	0.00	33.3
	Week 4	73	2.28	8.48	0.0	0.00	33.3	68	-3.43	14.27	-66.7	0.00	33.3
	Week 5	71	4.69	11.68	0.0	0.00	33.3	64	-1.04	17.79	-66.7	0.00	33.3
	Week 6	70	5.71	13.87	0.0	0.00	66.7	63	0.53	18.44	-66.7	0.00	66.7
	Week 7	72	3.24	9.94	0.0	0.00	33.3	65	-2.56	14.80	-66.7	0.00	33.3
	Week 8	63	1.06	5.89	0.0	0.00	33.3	58	-5.17	13.68	-66.7	0.00	0.0
	Week 9	68	3.92	10.82	0.0	0.00	33.3	62	-1.08	14.74	-66.7	0.00	33.3
	Week 10	67	4.97	11.97	0.0	0.00	33.3	61	-0.55	15.51	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	65	4.61	11.60	0.0	0.00	33.3	60	-0.56	14.38	-66.7	0.00	33.3
	Week 12	63	4.23	12.69	0.0	0.00	66.7	58	-1.15	13.91	-66.7	0.00	33.3
	Week 14	63	4.76	13.19	0.0	0.00	66.7	57	0.58	14.76	-66.7	0.00	66.7
	Week 17	60	5.56	12.53	0.0	0.00	33.3	55	0.61	18.69	-66.7	0.00	33.3
	Week 20	52	4.49	11.49	0.0	0.00	33.3	50	0.00	16.49	-33.3	0.00	33.3
	Week 23	44	6.06	14.86	0.0	0.00	66.7	42	0.79	17.25	-33.3	0.00	33.3
	Week 26	41	5.69	12.70	0.0	0.00	33.3	40	0.83	17.68	-33.3	0.00	33.3
	Week 29	37	3.60	10.49	0.0	0.00	33.3	36	-0.93	16.88	-33.3	0.00	33.3
	Week 32	33	3.03	9.73	0.0	0.00	33.3	32	-3.12	15.52	-33.3	0.00	33.3
	Week 35	30	3.33	10.17	0.0	0.00	33.3	30	-2.22	12.17	-33.3	0.00	33.3
	Week 38	32	2.08	8.20	0.0	0.00	33.3	31	-4.30	14.25	-33.3	0.00	33.3
	Week 41	27	2.47	8.90	0.0	0.00	33.3	26	-3.85	14.38	-33.3	0.00	33.3
	Week 44	27	4.94	12.07	0.0	0.00	33.3	26	1.28	14.85	-33.3	0.00	33.3
	Week 47	29	4.60	11.70	0.0	0.00	33.3	28	0.00	15.71	-33.3	0.00	33.3
	Week 50	23	7.25	17.28	0.0	0.00	66.7	22	1.52	21.77	-33.3	0.00	66.7
	Week 53	22	7.58	17.61	0.0	0.00	66.7	21	1.59	19.65	-33.3	0.00	66.7
	Week 56	18	5.56	12.78	0.0	0.00	33.3	17	-1.96	18.52	-33.3	0.00	33.3
	Week 59	17	3.92	11.07	0.0	0.00	33.3	16	-4.17	16.67	-33.3	0.00	33.3
	Week 62	16	6.25	13.44	0.0	0.00	33.3	15	-2.22	19.79	-33.3	0.00	33.3
	Week 65	15	0.00	0.00	0.0	0.00	0.0	14	-7.14	14.19	-33.3	0.00	0.0
	Week 68	12	2.78	9.62	0.0	0.00	33.3	11	-6.06	13.48	-33.3	0.00	0.0
	Week 71	13	0.00	0.00	0.0	0.00	0.0	12	-8.33	15.07	-33.3	0.00	0.0
	Week 74	10	0.00	0.00	0.0	0.00	0.0	10	-6.67	14.05	-33.3	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	EV+Pembro (N=198)												
	BASELINE	170	5.88	14.21	0.0	0.00	66.7						
	Week 1	157	7.01	17.72	0.0	0.00	100.0	152	1.97	18.88	-33.3	0.00	100.0
	Week 2	167	12.18	24.37	0.0	0.00	100.0	155	6.02	22.30	-33.3	0.00	100.0
	Week 3	161	14.49	24.94	0.0	0.00	100.0	147	8.84	23.19	-33.3	0.00	100.0
	Week 4	158	10.34	19.87	0.0	0.00	100.0	145	5.06	21.63	-33.3	0.00	100.0
	Week 5	154	9.52	21.46	0.0	0.00	100.0	140	3.10	20.74	-33.3	0.00	100.0
	Week 6	153	12.20	23.80	0.0	0.00	100.0	138	5.56	22.27	-33.3	0.00	100.0
	Week 7	159	10.48	22.54	0.0	0.00	100.0	142	4.69	22.31	-33.3	0.00	100.0
	Week 8	154	9.31	19.98	0.0	0.00	100.0	135	2.72	19.55	-66.7	0.00	66.7
	Week 9	162	11.93	22.48	0.0	0.00	100.0	146	5.94	23.39	-33.3	0.00	100.0
	Week 10	159	8.60	20.95	0.0	0.00	100.0	144	2.31	19.57	-33.3	0.00	100.0
	Week 11	161	7.87	19.90	0.0	0.00	100.0	143	0.93	21.65	-66.7	0.00	100.0
	Week 12	154	10.17	22.97	0.0	0.00	100.0	140	3.10	23.62	-33.3	0.00	100.0
	Week 14	154	8.44	22.40	0.0	0.00	100.0	137	2.19	24.66	-66.7	0.00	100.0
	Week 17	145	5.75	14.88	0.0	0.00	66.7	130	0.51	18.55	-66.7	0.00	66.7
	Week 20	139	6.23	16.33	0.0	0.00	66.7	126	0.53	20.21	-66.7	0.00	66.7
	Week 23	133	7.52	16.21	0.0	0.00	66.7	122	1.64	21.36	-66.7	0.00	66.7
	Week 26	129	6.20	14.89	0.0	0.00	66.7	118	1.13	19.94	-66.7	0.00	66.7
	Week 29	131	6.87	16.39	0.0	0.00	100.0	120	0.83	19.06	-66.7	0.00	100.0
	Week 32	111	6.91	16.89	0.0	0.00	66.7	102	0.98	22.23	-66.7	0.00	66.7
	Week 35	109	7.03	19.28	0.0	0.00	100.0	100	0.00	25.07	-66.7	0.00	100.0
	Week 38	107	9.03	17.48	0.0	0.00	66.7	100	2.67	19.92	-33.3	0.00	66.7
	Week 41	103	7.77	18.79	0.0	0.00	100.0	94	0.35	24.19	-66.7	0.00	100.0
	Week 44	88	6.44	15.04	0.0	0.00	66.7	81	-0.41	17.87	-66.7	0.00	66.7
	Week 47	80	7.92	18.56	0.0	0.00	100.0	75	1.33	23.53	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	73	8.22	18.24	0.0	0.00	66.7	68	0.00	23.75	-66.7	0.00	66.7
	Week 53	64	5.73	16.32	0.0	0.00	100.0	59	0.57	20.05	-33.3	0.00	100.0
	Week 56	66	4.55	12.92	0.0	0.00	66.7	61	-3.82	19.34	-66.7	0.00	66.7
	Week 59	58	3.45	10.24	0.0	0.00	33.3	54	-3.09	16.21	-66.7	0.00	33.3
	Week 62	54	4.32	11.30	0.0	0.00	33.3	52	-3.85	18.26	-66.7	0.00	33.3
	Week 65	51	4.57	11.58	0.0	0.00	33.3	47	-2.84	18.16	-66.7	0.00	33.3
	Week 68	49	6.12	13.04	0.0	0.00	33.3	48	0.00	19.45	-66.7	0.00	33.3
	Week 71	47	9.22	22.74	0.0	0.00	100.0	45	0.74	23.01	-33.3	0.00	100.0
	Week 74	42	7.94	14.37	0.0	0.00	33.3	41	0.00	18.26	-66.7	0.00	33.3
	Week 77	38	8.77	16.77	0.0	0.00	66.7	36	0.93	23.21	-66.7	0.00	66.7
	Week 80	35	6.67	13.53	0.0	0.00	33.3	32	0.00	18.93	-66.7	0.00	33.3
	Week 83	32	5.21	12.30	0.0	0.00	33.3	30	-1.11	20.50	-66.7	0.00	33.3
	Week 86	30	7.78	14.34	0.0	0.00	33.3	27	3.70	16.88	-33.3	0.00	33.3
	Week 89	28	4.76	11.88	0.0	0.00	33.3	26	-1.28	11.47	-33.3	0.00	33.3
	Week 92	24	5.56	12.69	0.0	0.00	33.3	22	0.00	14.55	-33.3	0.00	33.3
	Week 95	21	3.17	10.03	0.0	0.00	33.3	20	-6.67	13.68	-33.3	0.00	0.0
	Week 98	16	4.17	11.38	0.0	0.00	33.3	15	-2.22	15.26	-33.3	0.00	33.3
	Week 101	12	8.33	15.07	0.0	0.00	33.3	12	2.78	17.16	-33.3	0.00	33.3
	Week 104	10	3.33	10.54	0.0	0.00	33.3	10	-3.33	18.92	-33.3	0.00	33.3
	Plat+Gem (N=185)												
	BASELINE	146	5.71	15.34	0.0	0.00	66.7						
	Week 1	131	6.11	16.43	0.0	0.00	100.0	120	1.11	17.78	-66.7	0.00	66.7
	Week 2	128	11.98	21.63	0.0	0.00	100.0	115	6.67	22.60	-66.7	0.00	100.0
	Week 3	141	7.56	17.07	0.0	0.00	100.0	126	1.85	19.46	-66.7	0.00	66.7
	Week 4	139	5.04	15.50	0.0	0.00	100.0	119	-0.84	21.90	-66.7	0.00	100.0
	Week 5	143	5.59	13.70	0.0	0.00	66.7	120	0.00	18.33	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 6	133	8.27	17.12	0.0	0.00	66.7	114	1.75	21.65	-66.7	0.00	66.7
	Week 7	142	5.40	14.11	0.0	0.00	66.7	120	-1.11	20.24	-66.7	0.00	66.7
	Week 8	125	4.53	12.94	0.0	0.00	66.7	109	-2.14	19.39	-66.7	0.00	66.7
	Week 9	135	4.94	13.82	0.0	0.00	66.7	115	-0.87	19.97	-66.7	0.00	66.7
	Week 10	131	5.34	14.80	0.0	0.00	66.7	111	0.00	20.10	-66.7	0.00	66.7
	Week 11	128	6.25	16.06	0.0	0.00	100.0	109	0.31	21.51	-66.7	0.00	100.0
	Week 12	124	5.91	14.75	0.0	0.00	100.0	108	0.62	20.37	-66.7	0.00	100.0
	Week 14	121	7.44	16.38	0.0	0.00	66.7	101	2.64	20.38	-66.7	0.00	66.7
	Week 17	121	7.16	15.64	0.0	0.00	66.7	101	1.65	21.28	-66.7	0.00	66.7
	Week 20	98	5.10	12.06	0.0	0.00	33.3	86	-1.55	20.39	-66.7	0.00	33.3
	Week 23	93	4.30	11.23	0.0	0.00	33.3	78	-2.56	21.33	-66.7	0.00	33.3
	Week 26	86	6.20	14.01	0.0	0.00	66.7	75	-0.89	19.74	-66.7	0.00	66.7
	Week 29	76	4.39	11.34	0.0	0.00	33.3	65	-2.05	20.31	-66.7	0.00	33.3
	Week 32	62	6.45	15.78	0.0	0.00	66.7	56	0.00	24.62	-66.7	0.00	66.7
	Week 35	58	7.47	18.78	0.0	0.00	100.0	52	-1.92	20.25	-66.7	0.00	33.3
	Week 38	60	7.78	17.75	0.0	0.00	66.7	52	1.92	25.06	-66.7	0.00	66.7
	Week 41	52	4.49	11.49	0.0	0.00	33.3	44	-3.03	21.35	-66.7	0.00	33.3
	Week 44	46	8.70	22.70	0.0	0.00	100.0	40	6.67	26.37	-33.3	0.00	100.0
	Week 47	44	3.03	9.69	0.0	0.00	33.3	38	-0.88	14.47	-33.3	0.00	33.3
	Week 50	42	7.14	13.84	0.0	0.00	33.3	38	0.88	19.74	-66.7	0.00	33.3
	Week 53	38	6.14	15.22	0.0	0.00	66.7	34	-0.98	22.45	-66.7	0.00	66.7
	Week 56	32	9.37	19.37	0.0	0.00	66.7	28	5.95	24.09	-33.3	0.00	66.7
	Week 59	31	10.75	23.39	0.0	0.00	100.0	27	4.94	28.80	-33.3	0.00	100.0
	Week 62	29	8.05	17.03	0.0	0.00	66.7	26	2.56	22.94	-33.3	0.00	66.7
	Week 65	25	2.67	9.23	0.0	0.00	33.3	21	-3.17	17.96	-33.3	0.00	33.3
	Week 68	20	3.33	10.26	0.0	0.00	33.3	16	-2.08	14.75	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 71	17	1.96	8.08	0.0	0.00	33.3	14	-7.14	14.19	-33.3	0.00	0.0
	Week 74	17	1.96	8.08	0.0	0.00	33.3	14	-4.76	12.10	-33.3	0.00	0.0
	Week 77	16	10.42	29.11	0.0	0.00	100.0	13	0.00	23.57	-33.3	0.00	66.7
	Week 80	13	5.13	18.49	0.0	0.00	66.7	12	0.00	14.21	-33.3	0.00	33.3
	Week 83	11	0.00	0.00	0.0	0.00	0.0	10	-3.33	10.54	-33.3	0.00	0.0
	Week 86	12	2.78	9.62	0.0	0.00	33.3	11	-3.03	17.98	-33.3	0.00	33.3
	Week 89	11	0.00	0.00	0.0	0.00	0.0	10	-6.67	14.05	-33.3	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	EV+Pembro (N= 42)												
	BASELINE	36	11.11	21.08	0.0	0.00	66.7						
	Week 1	33	11.11	19.84	0.0	0.00	66.7	32	0.00	16.93	-33.3	0.00	33.3
	Week 2	36	12.96	22.92	0.0	0.00	100.0	34	2.94	25.12	-66.7	0.00	66.7
	Week 3	37	12.61	21.30	0.0	0.00	66.7	35	0.95	24.90	-66.7	0.00	66.7
	Week 4	36	6.48	15.57	0.0	0.00	66.7	34	-4.90	23.40	-66.7	0.00	33.3
	Week 5	36	9.26	21.98	0.0	0.00	100.0	33	0.00	26.35	-66.7	0.00	66.7
	Week 6	35	12.38	22.99	0.0	0.00	100.0	32	2.08	22.30	-66.7	0.00	66.7
	Week 7	36	6.48	15.57	0.0	0.00	66.7	34	-4.90	21.92	-66.7	0.00	33.3
	Week 8	37	8.11	19.88	0.0	0.00	100.0	36	-2.78	25.67	-66.7	0.00	66.7
	Week 9	35	8.57	20.36	0.0	0.00	100.0	34	-0.98	25.27	-66.7	0.00	66.7
	Week 10	32	9.37	17.42	0.0	0.00	66.7	31	0.00	19.25	-66.7	0.00	33.3
	Week 11	33	10.10	19.52	0.0	0.00	66.7	32	-1.04	24.66	-66.7	0.00	66.7
	Week 12	32	9.37	17.42	0.0	0.00	66.7	31	-2.15	25.73	-66.7	0.00	33.3
	Week 14	31	7.53	16.58	0.0	0.00	66.7	30	-1.11	20.50	-66.7	0.00	33.3
	Week 17	33	6.06	15.49	0.0	0.00	66.7	32	-6.25	21.48	-66.7	0.00	33.3
	Week 20	28	5.95	13.00	0.0	0.00	33.3	28	-4.76	23.51	-66.7	0.00	33.3
	Week 23	29	3.45	10.33	0.0	0.00	33.3	29	-10.34	22.01	-66.7	0.00	0.0
	Week 26	27	4.94	12.07	0.0	0.00	33.3	26	-6.41	21.12	-66.7	0.00	33.3
	Week 29	26	1.28	6.54	0.0	0.00	33.3	25	-12.00	23.33	-66.7	0.00	0.0
	Week 32	24	8.33	20.26	0.0	0.00	66.7	23	-2.90	26.43	-66.7	0.00	66.7
	Week 35	23	4.35	11.48	0.0	0.00	33.3	22	-10.61	21.54	-66.7	0.00	0.0
	Week 38	25	6.67	13.61	0.0	0.00	33.3	24	-9.72	25.02	-66.7	0.00	33.3
	Week 41	26	12.82	23.24	0.0	0.00	66.7	25	0.00	31.91	-66.7	0.00	66.7
	Week 44	20	3.33	10.26	0.0	0.00	33.3	19	-7.02	17.84	-66.7	0.00	0.0
	Week 47	20	8.33	18.34	0.0	0.00	66.7	19	-3.51	26.98	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	16	2.08	8.33	0.0	0.00	33.3	16	-12.50	26.87	-66.7	0.00	33.3
	Week 53	15	11.11	24.13	0.0	0.00	66.7	15	-6.67	40.24	-66.7	0.00	66.7
	Week 56	15	8.89	19.79	0.0	0.00	66.7	15	-4.44	35.34	-66.7	0.00	66.7
	Week 59	14	7.14	19.30	0.0	0.00	66.7	14	-7.14	32.50	-66.7	0.00	66.7
	Week 62	11	9.09	15.57	0.0	0.00	33.3	11	3.03	17.98	-33.3	0.00	33.3
	Plat+Gem (N= 57)												
	BASELINE	42	3.17	9.90	0.0	0.00	33.3						
	Week 1	42	7.14	15.68	0.0	0.00	66.7	38	3.51	10.37	0.0	0.00	33.3
	Week 2	43	6.98	18.63	0.0	0.00	66.7	36	3.70	23.61	-33.3	0.00	66.7
	Week 3	43	4.65	11.69	0.0	0.00	33.3	36	2.78	12.28	-33.3	0.00	33.3
	Week 4	44	5.30	14.27	0.0	0.00	66.7	37	1.80	15.61	-33.3	0.00	66.7
	Week 5	44	2.27	8.50	0.0	0.00	33.3	36	0.00	11.27	-33.3	0.00	33.3
	Week 6	41	4.88	15.92	0.0	0.00	66.7	35	0.95	12.75	-33.3	0.00	66.7
	Week 7	44	2.27	8.50	0.0	0.00	33.3	37	-1.80	10.96	-33.3	0.00	33.3
	Week 8	42	3.97	13.17	0.0	0.00	66.7	35	-0.95	9.85	-33.3	0.00	33.3
	Week 9	42	2.38	8.69	0.0	0.00	33.3	35	-0.95	9.85	-33.3	0.00	33.3
	Week 10	35	5.71	12.74	0.0	0.00	33.3	28	0.00	9.07	-33.3	0.00	33.3
	Week 11	40	2.50	8.89	0.0	0.00	33.3	34	0.00	8.21	-33.3	0.00	33.3
	Week 12	35	5.71	17.12	0.0	0.00	66.7	30	2.22	12.17	-33.3	0.00	33.3
	Week 14	32	4.17	18.45	0.0	0.00	100.0	27	0.00	0.00	0.0	0.00	0.0
	Week 17	34	3.92	10.90	0.0	0.00	33.3	29	2.30	12.38	-33.3	0.00	33.3
	Week 20	28	1.19	6.30	0.0	0.00	33.3	24	-1.39	11.95	-33.3	0.00	33.3
	Week 23	22	3.03	14.21	0.0	0.00	66.7	19	1.75	7.65	0.0	0.00	33.3
	Week 26	22	6.06	22.15	0.0	0.00	100.0	20	5.00	24.84	-33.3	0.00	100.0
	Week 29	24	0.00	0.00	0.0	0.00	0.0	21	0.00	0.00	0.0	0.00	0.0
	Week 32	21	1.59	7.27	0.0	0.00	33.3	20	0.00	0.00	0.0	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 35	18	1.85	7.86	0.0	0.00	33.3	17	0.00	0.00	0.0	0.00	0.0
	Week 38	14	0.00	0.00	0.0	0.00	0.0	13	0.00	0.00	0.0	0.00	0.0
	Week 41	13	5.13	12.52	0.0	0.00	33.3	12	2.78	9.62	0.0	0.00	33.3
	Week 44	14	2.38	8.91	0.0	0.00	33.3	13	0.00	0.00	0.0	0.00	0.0
	Week 47	12	2.78	9.62	0.0	0.00	33.3	11	3.03	10.05	0.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Visceral metastases	EV+Pembro (N=170)												
	BASELINE	146	5.94	15.00	0.0	0.00	66.7						
	Week 1	135	7.65	18.64	0.0	0.00	100.0	131	2.04	18.84	-33.3	0.00	100.0
	Week 2	145	13.10	25.24	0.0	0.00	100.0	134	6.72	23.04	-66.7	0.00	100.0
	Week 3	141	14.66	24.68	0.0	0.00	100.0	129	8.53	24.04	-66.7	0.00	100.0
	Week 4	136	9.56	20.25	0.0	0.00	100.0	125	4.00	23.42	-66.7	0.00	100.0
	Week 5	131	8.91	22.58	0.0	0.00	100.0	118	3.11	22.64	-66.7	0.00	100.0
	Week 6	127	11.55	24.26	0.0	0.00	100.0	113	5.01	23.24	-66.7	0.00	100.0
	Week 7	135	10.12	22.03	0.0	0.00	100.0	121	4.41	23.15	-66.7	0.00	100.0
	Week 8	131	9.16	19.85	0.0	0.00	100.0	118	2.82	21.16	-66.7	0.00	66.7
	Week 9	136	11.03	21.49	0.0	0.00	100.0	124	5.91	22.91	-66.7	0.00	100.0
	Week 10	135	8.89	21.24	0.0	0.00	100.0	124	2.96	20.83	-66.7	0.00	100.0
	Week 11	134	6.96	17.85	0.0	0.00	100.0	121	1.10	20.61	-66.7	0.00	100.0
	Week 12	131	8.91	19.75	0.0	0.00	100.0	120	2.22	22.34	-66.7	0.00	100.0
	Week 14	130	7.44	20.45	0.0	0.00	100.0	117	1.42	22.06	-66.7	0.00	100.0
	Week 17	124	4.30	12.73	0.0	0.00	66.7	111	-0.90	17.67	-66.7	0.00	66.7
	Week 20	115	5.80	15.46	0.0	0.00	66.7	105	0.00	20.15	-66.7	0.00	66.7
	Week 23	111	6.61	16.09	0.0	0.00	66.7	103	0.32	22.62	-66.7	0.00	66.7
	Week 26	106	5.66	14.89	0.0	0.00	66.7	97	0.69	21.50	-66.7	0.00	66.7
	Week 29	106	5.35	15.35	0.0	0.00	100.0	98	-0.34	19.44	-66.7	0.00	100.0
	Week 32	92	7.25	16.99	0.0	0.00	66.7	85	1.57	21.15	-66.7	0.00	66.7
	Week 35	86	4.65	16.30	0.0	0.00	100.0	79	-2.11	23.47	-66.7	0.00	100.0
	Week 38	90	8.15	16.04	0.0	0.00	66.7	84	1.19	22.22	-66.7	0.00	66.7
	Week 41	87	8.43	20.47	0.0	0.00	100.0	81	0.82	27.88	-66.7	0.00	100.0
	Week 44	73	5.48	14.71	0.0	0.00	66.7	68	0.00	17.28	-33.3	0.00	66.7
	Week 47	68	8.82	20.46	0.0	0.00	100.0	63	2.12	26.01	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	61	9.29	19.37	0.0	0.00	66.7	57	1.17	25.17	-66.7	0.00	66.7
	Week 53	54	8.02	20.41	0.0	0.00	100.0	50	0.67	28.16	-66.7	0.00	100.0
	Week 56	58	5.75	15.47	0.0	0.00	66.7	54	-1.85	21.88	-66.7	0.00	66.7
	Week 59	50	3.33	12.14	0.0	0.00	66.7	47	-3.55	18.69	-66.7	0.00	66.7
	Week 62	45	4.44	11.46	0.0	0.00	33.3	43	-2.33	18.39	-66.7	0.00	33.3
	Week 65	37	3.60	10.49	0.0	0.00	33.3	34	-2.94	19.01	-66.7	0.00	33.3
	Week 68	35	4.76	11.83	0.0	0.00	33.3	34	0.98	15.32	-33.3	0.00	33.3
	Week 71	31	9.68	26.10	0.0	0.00	100.0	30	1.11	23.95	-33.3	0.00	100.0
	Week 74	29	5.75	12.81	0.0	0.00	33.3	28	0.00	12.83	-33.3	0.00	33.3
	Week 77	26	5.13	12.26	0.0	0.00	33.3	25	-1.33	15.15	-33.3	0.00	33.3
	Week 80	22	7.58	14.30	0.0	0.00	33.3	21	1.59	22.30	-66.7	0.00	33.3
	Week 83	23	8.69	14.96	0.0	0.00	33.3	22	6.06	16.70	-33.3	0.00	33.3
	Week 86	21	7.94	14.55	0.0	0.00	33.3	20	5.00	16.31	-33.3	0.00	33.3
	Week 89	21	4.76	11.95	0.0	0.00	33.3	20	-1.67	20.16	-66.7	0.00	33.3
	Week 92	18	3.70	10.78	0.0	0.00	33.3	17	-3.92	20.01	-66.7	0.00	33.3
	Week 95	13	2.56	9.24	0.0	0.00	33.3	12	-2.78	9.62	-33.3	0.00	0.0
	Week 98	11	3.03	10.05	0.0	0.00	33.3	11	-6.06	25.03	-66.7	0.00	33.3
	Week 101	11	9.09	15.57	0.0	0.00	33.3	11	0.00	25.82	-66.7	0.00	33.3
	Plat+Gem (N=161)												
	BASELINE	129	5.17	14.10	0.0	0.00	66.7						
	Week 1	113	7.37	17.10	0.0	0.00	100.0	105	3.49	16.62	-33.3	0.00	66.7
	Week 2	108	10.80	21.29	0.0	0.00	100.0	98	6.12	24.57	-66.7	0.00	100.0
	Week 3	121	7.71	17.08	0.0	0.00	100.0	109	2.75	19.84	-66.7	0.00	66.7
	Week 4	116	4.88	15.39	0.0	0.00	100.0	101	0.00	22.11	-66.7	0.00	100.0
	Week 5	121	4.68	12.40	0.0	0.00	66.7	104	-0.32	18.28	-66.7	0.00	66.7
	Week 6	118	6.50	15.26	0.0	0.00	66.7	102	1.63	20.11	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 7	121	4.68	13.81	0.0	0.00	66.7	104	-0.96	19.95	-66.7	0.00	66.7
	Week 8	108	3.39	12.01	0.0	0.00	66.7	96	-1.39	17.38	-66.7	0.00	66.7
	Week 9	114	2.92	10.46	0.0	0.00	66.7	99	-2.02	17.70	-66.7	0.00	66.7
	Week 10	109	4.28	13.68	0.0	0.00	66.7	94	-0.71	17.61	-66.7	0.00	66.7
	Week 11	109	4.89	14.92	0.0	0.00	100.0	95	0.35	20.34	-66.7	0.00	100.0
	Week 12	103	3.88	10.75	0.0	0.00	33.3	91	-0.73	18.58	-66.7	0.00	33.3
	Week 14	98	5.10	14.64	0.0	0.00	66.7	85	1.18	17.40	-66.7	0.00	66.7
	Week 17	103	5.82	15.07	0.0	0.00	66.7	89	1.12	21.58	-66.7	0.00	66.7
	Week 20	82	3.25	9.95	0.0	0.00	33.3	75	-2.22	18.45	-66.7	0.00	33.3
	Week 23	77	1.73	7.45	0.0	0.00	33.3	68	-3.92	16.82	-66.7	0.00	33.3
	Week 26	71	6.57	17.47	0.0	0.00	100.0	65	1.03	21.22	-33.3	0.00	100.0
	Week 29	65	3.59	10.41	0.0	0.00	33.3	59	-1.13	17.47	-66.7	0.00	33.3
	Week 32	52	3.21	11.92	0.0	0.00	66.7	49	-2.72	19.05	-66.7	0.00	66.7
	Week 35	47	4.26	16.47	0.0	0.00	100.0	44	-3.79	14.76	-66.7	0.00	33.3
	Week 38	42	4.76	13.91	0.0	0.00	66.7	39	-0.85	19.48	-33.3	0.00	66.7
	Week 41	35	1.90	7.85	0.0	0.00	33.3	32	-5.21	17.16	-66.7	0.00	33.3
	Week 44	36	6.48	19.22	0.0	0.00	100.0	33	4.04	21.66	-33.3	0.00	100.0
	Week 47	32	4.17	11.20	0.0	0.00	33.3	30	0.00	15.16	-33.3	0.00	33.3
	Week 50	30	6.67	16.14	0.0	0.00	66.7	29	2.30	17.66	-33.3	0.00	66.7
	Week 53	25	8.00	17.43	0.0	0.00	66.7	24	1.39	20.80	-33.3	0.00	66.7
	Week 56	22	10.61	18.93	0.0	0.00	66.7	21	6.35	22.65	-33.3	0.00	66.7
	Week 59	22	9.09	25.58	0.0	0.00	100.0	21	3.18	29.64	-33.3	0.00	100.0
	Week 62	19	5.26	12.49	0.0	0.00	33.3	18	-1.85	17.98	-33.3	0.00	33.3
	Week 65	19	1.75	7.65	0.0	0.00	33.3	18	-3.70	15.71	-33.3	0.00	33.3
	Week 68	13	5.13	12.52	0.0	0.00	33.3	12	0.00	14.21	-33.3	0.00	33.3
	Week 71	13	0.00	0.00	0.0	0.00	0.0	12	-5.56	12.97	-33.3	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 74	11	0.00	0.00	0.0	0.00	0.0	11	-3.03	10.05	-33.3	0.00	0.0
	Week 77	10	0.00	0.00	0.0	0.00	0.0	10	-3.33	10.54	-33.3	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Lymph node only	EV+Pembro (N= 60)												
	BASELINE	53	10.06	18.00	0.0	0.00	66.7						
	Week 1	49	8.16	17.39	0.0	0.00	66.7	47	0.00	18.39	-33.3	0.00	66.7
	Week 2	50	10.67	20.69	0.0	0.00	100.0	48	1.39	21.70	-33.3	0.00	66.7
	Week 3	50	14.00	24.36	0.0	0.00	100.0	47	4.26	23.69	-33.3	0.00	100.0
	Week 4	50	10.00	16.83	0.0	0.00	66.7	47	0.00	19.66	-66.7	0.00	33.3
	Week 5	53	11.95	19.71	0.0	0.00	100.0	49	1.36	21.47	-66.7	0.00	66.7
	Week 6	53	13.84	23.05	0.0	0.00	100.0	50	3.33	20.48	-33.3	0.00	66.7
	Week 7	52	7.69	16.98	0.0	0.00	66.7	48	-3.47	15.74	-33.3	0.00	33.3
	Week 8	52	9.62	21.22	0.0	0.00	100.0	47	-2.13	21.31	-66.7	0.00	66.7
	Week 9	53	12.58	23.77	0.0	0.00	100.0	49	0.68	25.90	-66.7	0.00	66.7
	Week 10	48	9.03	19.13	0.0	0.00	66.7	44	-1.52	16.00	-33.3	0.00	33.3
	Week 11	53	11.32	24.41	0.0	0.00	100.0	48	-2.08	26.10	-66.7	0.00	66.7
	Week 12	48	13.89	28.21	0.0	0.00	100.0	45	1.48	29.26	-66.7	0.00	100.0
	Week 14	48	9.03	21.46	0.0	0.00	100.0	44	-0.76	25.40	-66.7	0.00	100.0
	Week 17	46	8.70	17.83	0.0	0.00	66.7	44	-3.03	21.35	-66.7	0.00	33.3
	Week 20	44	8.33	17.79	0.0	0.00	66.7	42	-1.59	24.36	-66.7	0.00	66.7
	Week 23	43	8.53	14.71	0.0	0.00	33.3	41	-3.25	22.12	-66.7	0.00	33.3
	Week 26	42	7.14	13.84	0.0	0.00	33.3	40	-3.33	18.18	-66.7	0.00	33.3
	Week 29	45	8.15	16.14	0.0	0.00	66.7	42	-3.97	23.52	-66.7	0.00	66.7
	Week 32	38	7.02	19.23	0.0	0.00	66.7	36	-3.70	27.35	-66.7	0.00	66.7
	Week 35	42	11.11	21.67	0.0	0.00	100.0	40	-1.67	28.19	-66.7	0.00	100.0
	Week 38	38	10.53	19.15	0.0	0.00	66.7	36	-1.85	21.00	-66.7	0.00	33.3
	Week 41	37	10.81	19.33	0.0	0.00	66.7	34	-0.98	22.45	-66.7	0.00	33.3
	Week 44	31	6.45	13.39	0.0	0.00	33.3	29	-5.75	20.06	-66.7	0.00	33.3
	Week 47	28	7.14	13.93	0.0	0.00	33.3	27	-3.70	21.35	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	25	1.33	6.67	0.0	0.00	33.3	24	-12.50	21.56	-66.7	0.00	0.0
	Week 53	23	2.90	9.60	0.0	0.00	33.3	22	-6.06	16.70	-66.7	0.00	0.0
	Week 56	21	4.76	11.95	0.0	0.00	33.3	20	-10.00	26.71	-66.7	0.00	33.3
	Week 59	20	6.67	13.68	0.0	0.00	33.3	19	-5.26	25.49	-66.7	0.00	33.3
	Week 62	19	7.02	13.96	0.0	0.00	33.3	19	-3.51	18.90	-33.3	0.00	33.3
	Week 65	20	6.67	13.68	0.0	0.00	33.3	19	-8.77	24.45	-66.7	0.00	33.3
	Week 68	17	7.84	14.57	0.0	0.00	33.3	17	-1.96	24.92	-66.7	0.00	33.3
	Week 71	19	7.02	13.96	0.0	0.00	33.3	18	-3.70	25.28	-66.7	0.00	33.3
	Week 74	17	11.76	16.42	0.0	0.00	33.3	17	1.96	24.92	-66.7	0.00	33.3
	Week 77	17	13.72	20.61	0.0	0.00	66.7	16	2.08	30.96	-66.7	0.00	66.7
	Week 80	17	5.88	13.10	0.0	0.00	33.3	15	-4.44	21.33	-66.7	0.00	33.3
	Week 83	13	2.56	9.24	0.0	0.00	33.3	12	-8.33	25.13	-66.7	0.00	33.3
	Week 86	12	8.33	15.07	0.0	0.00	33.3	10	3.33	18.92	-33.3	0.00	33.3
	Week 89	11	9.09	15.57	0.0	0.00	33.3	10	0.00	15.71	-33.3	0.00	33.3
	Plat+Gem (N= 67)												
	BASELINE	49	6.12	16.21	0.0	0.00	66.7						
	Week 1	51	4.58	14.94	0.0	0.00	66.7	45	-2.96	15.61	-66.7	0.00	33.3
	Week 2	53	11.95	21.77	0.0	0.00	100.0	44	6.06	20.68	-33.3	0.00	66.7
	Week 3	53	5.66	14.23	0.0	0.00	66.7	44	0.00	14.38	-66.7	0.00	33.3
	Week 4	58	6.32	15.87	0.0	0.00	66.7	47	-0.71	19.02	-66.7	0.00	66.7
	Week 5	56	5.36	13.89	0.0	0.00	66.7	44	0.00	14.38	-33.3	0.00	33.3
	Week 6	48	11.11	21.01	0.0	0.00	66.7	40	1.67	21.28	-66.7	0.00	66.7
	Week 7	56	4.76	11.77	0.0	0.00	33.3	46	-2.90	15.44	-66.7	0.00	33.3
	Week 8	52	6.41	14.82	0.0	0.00	66.7	42	-3.17	19.21	-66.7	0.00	33.3
	Week 9	53	7.55	16.85	0.0	0.00	66.7	42	0.79	20.15	-66.7	0.00	66.7
	Week 10	47	8.51	16.25	0.0	0.00	66.7	36	0.93	21.80	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.1.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	51	7.19	15.37	0.0	0.00	66.7	41	0.00	18.26	-66.7	0.00	66.7
	Week 12	47	11.35	22.28	0.0	0.00	100.0	39	5.13	21.00	-33.3	0.00	100.0
	Week 14	47	11.35	21.17	0.0	0.00	100.0	36	4.63	21.31	-66.7	0.00	66.7
	Week 17	45	8.89	14.91	0.0	0.00	33.3	35	3.81	15.70	-33.3	0.00	33.3
	Week 20	38	7.02	13.77	0.0	0.00	33.3	30	0.00	21.44	-66.7	0.00	33.3
	Week 23	32	10.42	17.83	0.0	0.00	66.7	25	4.00	26.03	-66.7	0.00	33.3
	Week 26	30	6.67	13.56	0.0	0.00	33.3	24	-1.39	23.01	-66.7	0.00	33.3
	Week 29	28	3.57	10.50	0.0	0.00	33.3	21	-3.17	20.83	-66.7	0.00	33.3
	Week 32	26	10.26	18.30	0.0	0.00	66.7	22	6.06	26.50	-66.7	0.00	66.7
	Week 35	23	11.59	19.09	0.0	0.00	66.7	19	3.51	24.58	-66.7	0.00	33.3
	Week 38	26	10.26	20.59	0.0	0.00	66.7	20	6.67	29.81	-66.7	0.00	66.7
	Week 41	24	9.72	15.48	0.0	0.00	33.3	18	3.70	25.28	-66.7	0.00	33.3
	Week 44	18	11.11	25.56	0.0	0.00	100.0	14	9.52	30.46	-33.3	0.00	100.0
	Week 47	18	1.85	7.86	0.0	0.00	33.3	13	0.00	13.61	-33.3	0.00	33.3
	Week 50	16	10.42	15.96	0.0	0.00	33.3	13	2.56	28.74	-66.7	0.00	33.3
	Week 53	15	6.67	18.69	0.0	0.00	66.7	12	0.00	31.78	-66.7	0.00	66.7
	Week 56	15	6.67	18.69	0.0	0.00	66.7	11	6.06	25.03	-33.3	0.00	66.7
	Week 59	12	11.11	16.41	0.0	0.00	33.3	9	7.41	22.22	-33.3	0.00	33.3
	Week 62	10	10.00	22.50	0.0	0.00	66.7	8	8.33	29.55	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
EV+Pembro (N=202)												
BASELINE	160	5.62	14.59	0.0	0.00	66.7						
Week 1	141	6.86	17.60	0.0	0.00	100.0	129	0.52	15.58	-33.3	0.00	66.7
Week 2	150	11.56	22.84	0.0	0.00	100.0	133	6.77	21.22	-66.7	0.00	66.7
Week 3	139	14.63	23.09	0.0	0.00	100.0	122	9.29	23.96	-66.7	0.00	100.0
Week 4	145	8.74	20.04	0.0	0.00	100.0	129	3.36	21.18	-66.7	0.00	100.0
Week 5	137	9.00	17.85	0.0	0.00	100.0	121	3.03	18.76	-66.7	0.00	100.0
Week 6	146	12.78	20.44	0.0	0.00	100.0	124	6.99	22.20	-66.7	0.00	66.7
Week 7	147	10.20	20.87	0.0	0.00	100.0	124	4.30	21.24	-33.3	0.00	66.7
Week 8	147	11.11	20.77	0.0	0.00	100.0	124	5.38	20.99	-66.7	0.00	100.0
Week 9	142	12.91	22.05	0.0	0.00	100.0	121	7.16	24.42	-66.7	0.00	100.0
Week 10	139	9.35	18.40	0.0	0.00	66.7	118	4.24	18.77	-66.7	0.00	66.7
Week 11	137	8.76	17.74	0.0	0.00	66.7	115	2.90	20.97	-66.7	0.00	66.7
Week 12	142	10.56	19.19	0.0	0.00	100.0	119	4.76	19.06	-66.7	0.00	66.7
Week 14	139	9.35	20.08	0.0	0.00	100.0	116	5.17	23.10	-66.7	0.00	100.0
Week 17	132	8.59	19.15	0.0	0.00	100.0	111	5.41	22.27	-66.7	0.00	100.0
Week 20	120	7.78	18.20	0.0	0.00	100.0	103	3.24	22.15	-66.7	0.00	100.0
Week 23	117	7.12	14.40	0.0	0.00	66.7	97	2.06	19.13	-66.7	0.00	66.7
Week 26	112	7.14	15.13	0.0	0.00	66.7	94	2.48	19.08	-66.7	0.00	66.7
Week 29	107	7.79	18.07	0.0	0.00	100.0	93	3.23	21.46	-66.7	0.00	100.0
Week 32	102	8.82	16.86	0.0	0.00	66.7	88	3.41	20.24	-66.7	0.00	66.7
Week 35	98	7.48	16.25	0.0	0.00	66.7	86	2.71	20.59	-66.7	0.00	66.7
Week 38	97	7.56	17.01	0.0	0.00	100.0	86	3.10	20.85	-66.7	0.00	100.0
Week 41	95	8.77	18.96	0.0	0.00	100.0	84	5.16	21.64	-66.7	0.00	100.0
Week 44	86	6.20	15.77	0.0	0.00	100.0	74	2.70	19.71	-66.7	0.00	100.0
Week 47	79	5.06	13.17	0.0	0.00	66.7	70	0.95	18.80	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	74	9.46	18.73	0.0	0.00	66.7	64	5.73	21.87	-66.7	0.00	66.7
Week 53	74	5.41	14.63	0.0	0.00	66.7	63	0.53	17.45	-66.7	0.00	66.7
Week 56	72	4.63	14.05	0.0	0.00	66.7	61	0.00	16.10	-66.7	0.00	66.7
Week 59	69	3.86	12.18	0.0	0.00	66.7	57	0.00	16.67	-66.7	0.00	66.7
Week 62	62	3.23	9.93	0.0	0.00	33.3	52	0.00	13.20	-66.7	0.00	33.3
Week 65	43	3.10	9.80	0.0	0.00	33.3	40	-0.83	15.99	-66.7	0.00	33.3
Week 68	46	7.25	15.58	0.0	0.00	66.7	42	3.97	21.08	-66.7	0.00	66.7
Week 71	42	4.76	17.38	0.0	0.00	100.0	38	0.88	22.58	-66.7	0.00	100.0
Week 74	38	6.14	13.09	0.0	0.00	33.3	35	3.81	13.46	-33.3	0.00	33.3
Week 77	37	1.80	7.64	0.0	0.00	33.3	33	-1.01	13.13	-33.3	0.00	33.3
Week 80	36	3.70	10.62	0.0	0.00	33.3	34	0.98	15.32	-33.3	0.00	33.3
Week 83	30	3.33	10.17	0.0	0.00	33.3	29	0.00	15.43	-33.3	0.00	33.3
Week 86	26	3.85	10.86	0.0	0.00	33.3	25	1.33	15.15	-33.3	0.00	33.3
Week 89	20	8.33	14.81	0.0	0.00	33.3	19	3.51	15.29	-33.3	0.00	33.3
Week 92	19	8.77	15.08	0.0	0.00	33.3	18	1.85	17.98	-33.3	0.00	33.3
Week 95	14	4.76	12.10	0.0	0.00	33.3	13	2.56	16.45	-33.3	0.00	33.3
Week 98	10	0.00	0.00	0.0	0.00	0.0	9	-3.70	11.11	-33.3	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Plat+Gem (N=202)												
BASELINE	165	6.06	15.30	0.0	0.00	66.7						
Week 1	144	6.02	17.03	0.0	0.00	100.0	139	0.24	19.45	-66.7	0.00	100.0
Week 2	147	9.75	21.44	0.0	0.00	100.0	135	4.20	23.89	-66.7	0.00	100.0
Week 3	149	7.16	17.99	0.0	0.00	100.0	136	1.72	21.97	-66.7	0.00	100.0
Week 4	150	6.44	14.29	0.0	0.00	66.7	135	-0.25	18.44	-66.7	0.00	66.7
Week 5	153	8.06	17.53	0.0	0.00	66.7	138	1.93	18.79	-66.7	0.00	66.7
Week 6	145	8.96	18.53	0.0	0.00	100.0	131	3.05	20.44	-33.3	0.00	100.0
Week 7	148	4.95	14.21	0.0	0.00	100.0	134	-1.49	17.75	-66.7	0.00	100.0
Week 8	145	5.75	14.35	0.0	0.00	66.7	132	-0.51	16.97	-66.7	0.00	66.7
Week 9	141	4.96	11.91	0.0	0.00	33.3	125	-0.53	17.45	-66.7	0.00	33.3
Week 10	142	4.23	14.24	0.0	0.00	100.0	130	-1.54	16.53	-66.7	0.00	66.7
Week 11	126	4.76	12.45	0.0	0.00	66.7	114	-2.05	16.16	-66.7	0.00	66.7
Week 12	130	5.90	14.05	0.0	0.00	66.7	115	-0.29	19.99	-66.7	0.00	66.7
Week 14	125	4.53	11.47	0.0	0.00	33.3	109	-1.53	15.96	-66.7	0.00	33.3
Week 17	120	6.67	14.72	0.0	0.00	66.7	106	-0.94	18.09	-66.7	0.00	66.7
Week 20	104	6.73	13.44	0.0	0.00	33.3	91	0.00	18.59	-66.7	0.00	33.3
Week 23	88	6.44	15.04	0.0	0.00	66.7	80	0.00	21.21	-66.7	0.00	66.7
Week 26	81	4.53	12.64	0.0	0.00	66.7	75	-2.67	18.79	-66.7	0.00	66.7
Week 29	77	9.52	17.82	0.0	0.00	66.7	71	1.88	22.46	-66.7	0.00	66.7
Week 32	63	3.70	10.56	0.0	0.00	33.3	58	-4.02	15.39	-66.7	0.00	33.3
Week 35	62	5.91	14.19	0.0	0.00	66.7	56	-1.79	17.31	-66.7	0.00	33.3
Week 38	56	5.95	12.88	0.0	0.00	33.3	50	-2.00	17.05	-66.7	0.00	33.3
Week 41	52	6.41	13.26	0.0	0.00	33.3	47	-0.71	19.02	-66.7	0.00	33.3
Week 44	49	8.84	17.71	0.0	0.00	66.7	44	0.76	23.28	-66.7	0.00	66.7
Week 47	43	6.20	15.01	0.0	0.00	66.7	39	-3.42	25.12	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	36	9.26	18.87	0.0	0.00	66.7	31	0.00	22.77	-66.7	0.00	33.3
Week 53	31	11.83	23.65	0.0	0.00	100.0	28	-3.57	22.84	-66.7	0.00	33.3
Week 56	30	7.78	22.63	0.0	0.00	100.0	29	-3.45	22.44	-66.7	0.00	66.7
Week 59	23	7.25	19.99	0.0	0.00	66.7	21	-4.76	19.11	-66.7	0.00	33.3
Week 62	20	8.33	21.29	0.0	0.00	66.7	20	1.67	29.57	-66.7	0.00	66.7
Week 65	17	5.88	17.62	0.0	0.00	66.7	16	-2.08	14.75	-33.3	0.00	33.3
Week 68	13	7.69	14.62	0.0	0.00	33.3	13	5.13	18.49	-33.3	0.00	33.3
Week 71	13	7.69	14.62	0.0	0.00	33.3	13	5.13	18.49	-33.3	0.00	33.3
Week 74	11	3.03	10.05	0.0	0.00	33.3	11	0.00	14.91	-33.3	0.00	33.3
Week 77	11	3.03	10.05	0.0	0.00	33.3	11	-3.03	17.98	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Present	EV+Pembro (N= 50)												
	BASELINE	40	5.00	12.05	0.0	0.00	33.3						
	Week 1	38	7.89	21.13	0.0	0.00	100.0	34	-0.98	10.00	-33.3	0.00	33.3
	Week 2	35	20.00	31.52	0.0	0.00	100.0	32	11.46	23.36	-33.3	0.00	66.7
	Week 3	32	19.79	27.90	0.0	0.00	100.0	30	13.33	24.13	0.0	0.00	66.7
	Week 4	35	8.57	21.91	0.0	0.00	100.0	31	2.15	17.07	-33.3	0.00	66.7
	Week 5	32	7.29	16.36	0.0	0.00	66.7	28	0.00	15.71	-33.3	0.00	33.3
	Week 6	35	15.24	24.71	0.0	0.00	100.0	30	11.11	23.71	-33.3	0.00	66.7
	Week 7	35	10.48	21.04	0.0	0.00	66.7	29	6.90	24.20	-33.3	0.00	66.7
	Week 8	38	17.54	24.18	0.0	0.00	100.0	31	13.98	26.91	-33.3	0.00	100.0
	Week 9	33	13.13	18.52	0.0	0.00	66.7	29	8.05	19.22	-33.3	0.00	66.7
	Week 10	30	8.89	17.36	0.0	0.00	66.7	25	5.33	18.46	-33.3	0.00	66.7
	Week 11	31	7.53	18.68	0.0	0.00	66.7	27	4.94	22.08	-33.3	0.00	66.7
	Week 12	32	10.42	21.48	0.0	0.00	66.7	28	5.95	20.39	-33.3	0.00	66.7
	Week 14	36	6.48	19.22	0.0	0.00	66.7	31	2.15	20.97	-33.3	0.00	66.7
	Week 17	33	6.06	13.05	0.0	0.00	33.3	27	3.70	14.12	-33.3	0.00	33.3
	Week 20	28	13.09	24.58	0.0	0.00	100.0	25	12.00	23.33	-33.3	0.00	66.7
	Week 23	28	8.33	14.70	0.0	0.00	33.3	24	5.56	18.82	-33.3	0.00	33.3
	Week 26	28	5.95	13.00	0.0	0.00	33.3	24	4.17	14.95	-33.3	0.00	33.3
	Week 29	27	7.41	14.12	0.0	0.00	33.3	25	4.00	14.66	-33.3	0.00	33.3
	Week 32	25	4.00	11.05	0.0	0.00	33.3	23	1.45	12.22	-33.3	0.00	33.3
	Week 35	26	5.13	15.47	0.0	0.00	66.7	24	1.39	18.33	-33.3	0.00	66.7
	Week 38	26	8.97	22.23	0.0	0.00	100.0	24	5.56	25.38	-33.3	0.00	100.0
	Week 41	25	9.33	24.57	0.0	0.00	100.0	23	8.70	27.00	-33.3	0.00	100.0
	Week 44	22	7.58	22.84	0.0	0.00	100.0	20	5.00	24.84	-33.3	0.00	100.0
	Week 47	14	7.14	14.19	0.0	0.00	33.3	13	2.56	16.45	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	6.67	17.44	0.0	0.00	66.7	17	3.92	20.01	-33.3	0.00	66.7
	Week 53	21	1.59	7.27	0.0	0.00	33.3	18	-1.85	13.87	-33.3	0.00	33.3
	Week 56	18	1.85	7.86	0.0	0.00	33.3	15	0.00	12.60	-33.3	0.00	33.3
	Week 59	18	1.85	7.86	0.0	0.00	33.3	15	-2.22	15.26	-33.3	0.00	33.3
	Week 62	13	2.56	9.24	0.0	0.00	33.3	11	3.03	10.05	0.0	0.00	33.3
	Week 68	12	2.78	9.62	0.0	0.00	33.3	11	0.00	14.91	-33.3	0.00	33.3
	Plat+Gem (N= 50)												
	BASELINE	40	5.83	14.88	0.0	0.00	66.7						
	Week 1	35	5.71	17.12	0.0	0.00	66.7	33	1.01	21.22	-33.3	0.00	66.7
	Week 2	33	14.14	25.04	0.0	0.00	100.0	30	6.67	26.84	-33.3	0.00	100.0
	Week 3	33	5.05	12.14	0.0	0.00	33.3	29	-1.15	18.86	-66.7	0.00	33.3
	Week 4	36	2.78	9.34	0.0	0.00	33.3	32	-4.17	18.45	-66.7	0.00	33.3
	Week 5	36	9.26	20.49	0.0	0.00	66.7	32	3.13	22.97	-33.3	0.00	66.7
	Week 6	32	7.29	14.00	0.0	0.00	33.3	29	0.00	17.82	-33.3	0.00	33.3
	Week 7	35	5.71	18.93	0.0	0.00	100.0	31	-1.08	23.54	-33.3	0.00	100.0
	Week 8	35	7.62	18.23	0.0	0.00	66.7	31	1.08	18.22	-33.3	0.00	66.7
	Week 9	34	3.92	10.90	0.0	0.00	33.3	30	-3.33	20.25	-66.7	0.00	33.3
	Week 10	33	3.03	9.73	0.0	0.00	33.3	30	-5.56	17.69	-66.7	0.00	33.3
	Week 11	30	4.44	11.52	0.0	0.00	33.3	26	-3.85	17.20	-66.7	0.00	33.3
	Week 12	32	10.42	19.74	0.0	0.00	66.7	27	3.70	28.24	-66.7	0.00	66.7
	Week 14	27	2.47	8.90	0.0	0.00	33.3	22	-4.55	15.58	-33.3	0.00	33.3
	Week 17	28	3.57	10.50	0.0	0.00	33.3	23	-7.25	14.06	-33.3	0.00	0.0
	Week 20	20	8.33	14.81	0.0	0.00	33.3	16	-4.17	26.87	-66.7	0.00	33.3
	Week 23	15	13.33	24.56	0.0	0.00	66.7	14	0.00	36.98	-66.7	0.00	66.7
	Week 26	15	2.22	8.61	0.0	0.00	33.3	14	-14.29	21.54	-66.7	0.00	0.0
	Week 29	13	10.26	16.01	0.0	0.00	33.3	12	-5.56	19.24	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Absent	EV+Pembro (N=152)												
	BASELINE	120	5.83	15.38	0.0	0.00	66.7						
	Week 1	103	6.47	16.21	0.0	0.00	100.0	95	1.05	17.16	-33.3	0.00	66.7
	Week 2	115	8.99	18.90	0.0	0.00	100.0	101	5.28	20.40	-66.7	0.00	66.7
	Week 3	107	13.08	21.36	0.0	0.00	100.0	92	7.97	23.89	-66.7	0.00	100.0
	Week 4	110	8.79	19.51	0.0	0.00	100.0	98	3.74	22.39	-66.7	0.00	100.0
	Week 5	105	9.52	18.32	0.0	0.00	100.0	93	3.94	19.57	-66.7	0.00	100.0
	Week 6	111	12.01	18.96	0.0	0.00	66.7	94	5.67	21.66	-66.7	0.00	66.7
	Week 7	112	10.12	20.91	0.0	0.00	100.0	95	3.51	20.32	-33.3	0.00	66.7
	Week 8	109	8.87	19.05	0.0	0.00	66.7	93	2.51	17.88	-66.7	0.00	66.7
	Week 9	109	12.84	23.09	0.0	0.00	100.0	92	6.88	25.93	-66.7	0.00	100.0
	Week 10	109	9.48	18.75	0.0	0.00	66.7	93	3.94	18.94	-66.7	0.00	66.7
	Week 11	106	9.12	17.54	0.0	0.00	66.7	88	2.27	20.71	-66.7	0.00	66.7
	Week 12	110	10.61	18.58	0.0	0.00	100.0	91	4.40	18.73	-66.7	0.00	33.3
	Week 14	103	10.36	20.36	0.0	0.00	100.0	85	6.27	23.85	-66.7	0.00	100.0
	Week 17	99	9.43	20.78	0.0	0.00	100.0	84	5.95	24.36	-66.7	0.00	100.0
	Week 20	92	6.16	15.57	0.0	0.00	100.0	78	0.43	21.15	-66.7	0.00	100.0
	Week 23	89	6.74	14.37	0.0	0.00	66.7	73	0.91	19.22	-66.7	0.00	66.7
	Week 26	84	7.54	15.82	0.0	0.00	66.7	70	1.90	20.37	-66.7	0.00	66.7
	Week 29	80	7.92	19.30	0.0	0.00	100.0	68	2.94	23.56	-66.7	0.00	100.0
	Week 32	77	10.39	18.14	0.0	0.00	66.7	65	4.10	22.44	-66.7	0.00	66.7
	Week 35	72	8.33	16.55	0.0	0.00	66.7	62	3.23	21.52	-66.7	0.00	66.7
	Week 38	71	7.04	14.82	0.0	0.00	66.7	62	2.15	18.96	-66.7	0.00	66.7
	Week 41	70	8.57	16.72	0.0	0.00	66.7	61	3.82	19.34	-66.7	0.00	66.7
	Week 44	64	5.73	12.67	0.0	0.00	33.3	54	1.85	17.63	-66.7	0.00	33.3
	Week 47	65	4.62	13.01	0.0	0.00	66.7	57	0.58	19.41	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	54	10.49	19.23	0.0	0.00	66.7	47	6.38	22.67	-66.7	0.00	66.7
	Week 53	53	6.92	16.48	0.0	0.00	66.7	45	1.48	18.74	-66.7	0.00	66.7
	Week 56	54	5.56	15.53	0.0	0.00	66.7	46	0.00	17.21	-66.7	0.00	66.7
	Week 59	51	4.57	13.37	0.0	0.00	66.7	42	0.79	17.25	-66.7	0.00	66.7
	Week 62	49	3.40	10.19	0.0	0.00	33.3	41	-0.81	13.92	-66.7	0.00	33.3
	Week 65	36	3.70	10.62	0.0	0.00	33.3	33	0.00	16.67	-66.7	0.00	33.3
	Week 68	34	8.82	17.03	0.0	0.00	66.7	31	5.38	22.93	-66.7	0.00	66.7
	Week 71	33	6.06	19.46	0.0	0.00	100.0	30	2.22	24.66	-66.7	0.00	100.0
	Week 74	33	7.07	13.84	0.0	0.00	33.3	30	4.44	14.47	-33.3	0.00	33.3
	Week 77	31	2.15	8.32	0.0	0.00	33.3	27	0.00	13.07	-33.3	0.00	33.3
	Week 80	31	3.23	10.02	0.0	0.00	33.3	29	1.15	14.04	-33.3	0.00	33.3
	Week 83	25	2.67	9.23	0.0	0.00	33.3	24	0.00	13.90	-33.3	0.00	33.3
	Week 86	23	2.90	9.60	0.0	0.00	33.3	22	0.00	14.55	-33.3	0.00	33.3
	Week 89	18	9.26	15.36	0.0	0.00	33.3	17	3.92	16.17	-33.3	0.00	33.3
	Week 92	16	8.33	14.91	0.0	0.00	33.3	15	2.22	19.79	-33.3	0.00	33.3
	Week 95	12	5.56	12.97	0.0	0.00	33.3	11	3.03	17.98	-33.3	0.00	33.3
	Plat+Gem (N=152)												
	BASELINE	125	6.13	15.49	0.0	0.00	66.7						
	Week 1	109	6.12	17.07	0.0	0.00	100.0	106	0.00	18.97	-66.7	0.00	100.0
	Week 2	114	8.48	20.23	0.0	0.00	100.0	105	3.49	23.08	-66.7	0.00	100.0
	Week 3	116	7.76	19.34	0.0	0.00	100.0	107	2.49	22.76	-66.7	0.00	100.0
	Week 4	114	7.60	15.38	0.0	0.00	66.7	103	0.97	18.35	-66.7	0.00	66.7
	Week 5	117	7.69	16.60	0.0	0.00	66.7	106	1.57	17.45	-66.7	0.00	66.7
	Week 6	113	9.44	19.65	0.0	0.00	100.0	102	3.92	21.13	-33.3	0.00	100.0
	Week 7	113	4.72	12.49	0.0	0.00	66.7	103	-1.62	15.74	-66.7	0.00	66.7
	Week 8	110	5.15	12.92	0.0	0.00	66.7	101	-0.99	16.64	-66.7	0.00	33.3

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.2.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	107	5.30	12.24	0.0	0.00	33.3	95	0.35	16.48	-66.7	0.00	33.3
	Week 10	109	4.59	15.36	0.0	0.00	100.0	100	-0.33	16.06	-33.3	0.00	66.7
	Week 11	96	4.86	12.78	0.0	0.00	66.7	88	-1.52	15.91	-33.3	0.00	66.7
	Week 12	98	4.42	11.36	0.0	0.00	33.3	88	-1.52	16.69	-66.7	0.00	33.3
	Week 14	98	5.10	12.06	0.0	0.00	33.3	87	-0.77	16.06	-66.7	0.00	33.3
	Week 17	92	7.61	15.71	0.0	0.00	66.7	83	0.80	18.75	-66.7	0.00	66.7
	Week 20	84	6.35	13.17	0.0	0.00	33.3	75	0.89	16.41	-66.7	0.00	33.3
	Week 23	73	5.02	12.01	0.0	0.00	33.3	66	0.00	16.54	-66.7	0.00	33.3
	Week 26	66	5.05	13.39	0.0	0.00	66.7	61	0.00	17.21	-66.7	0.00	66.7
	Week 29	64	9.37	18.28	0.0	0.00	66.7	59	3.39	22.91	-66.7	0.00	66.7
	Week 32	54	3.70	10.57	0.0	0.00	33.3	49	-2.72	14.96	-66.7	0.00	33.3
	Week 35	54	4.94	11.95	0.0	0.00	33.3	48	-2.08	17.40	-66.7	0.00	33.3
	Week 38	47	4.96	11.99	0.0	0.00	33.3	42	-1.59	16.38	-66.7	0.00	33.3
	Week 41	45	5.93	12.89	0.0	0.00	33.3	40	0.00	18.49	-66.7	0.00	33.3
	Week 44	41	8.94	18.29	0.0	0.00	66.7	36	1.85	23.83	-66.7	0.00	66.7
	Week 47	35	6.67	15.76	0.0	0.00	66.7	31	-2.15	24.24	-66.7	0.00	33.3
	Week 50	29	9.19	17.58	0.0	0.00	66.7	24	1.39	25.02	-66.7	0.00	33.3
	Week 53	25	12.00	25.24	0.0	0.00	100.0	22	-3.03	22.79	-66.7	0.00	33.3
	Week 56	26	5.13	20.42	0.0	0.00	100.0	25	-5.33	18.46	-66.7	0.00	33.3
	Week 59	20	8.33	21.29	0.0	0.00	66.7	18	-5.56	20.61	-66.7	0.00	33.3
	Week 62	17	7.84	22.14	0.0	0.00	66.7	17	0.00	31.18	-66.7	0.00	66.7
	Week 65	15	6.67	18.69	0.0	0.00	66.7	14	-2.38	15.82	-33.3	0.00	33.3
	Week 68	11	9.09	15.57	0.0	0.00	33.3	11	6.06	20.10	-33.3	0.00	33.3
	Week 71	12	8.33	15.07	0.0	0.00	33.3	12	5.56	19.24	-33.3	0.00	33.3
	Week 74	10	3.33	10.54	0.0	0.00	33.3	10	0.00	15.71	-33.3	0.00	33.3
	Week 77	10	3.33	10.54	0.0	0.00	33.3	10	-3.33	18.92	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
< 65 years	EV+Pembro (N= 39)												
	BASELINE	32	6.25	15.70	0.0	0.00	66.7						
	Week 1	27	3.70	10.67	0.0	0.00	33.3	26	-1.28	11.47	-33.3	0.00	33.3
	Week 2	30	8.89	19.44	0.0	0.00	66.7	29	4.60	17.19	-33.3	0.00	66.7
	Week 3	31	16.13	20.85	0.0	0.00	66.7	29	10.34	18.05	0.0	0.00	66.7
	Week 4	30	11.11	22.03	0.0	0.00	66.7	27	4.94	22.08	-33.3	0.00	66.7
	Week 5	28	8.33	17.27	0.0	0.00	66.7	26	2.56	18.67	-33.3	0.00	33.3
	Week 6	29	17.24	22.92	0.0	0.00	66.7	26	10.26	22.65	-33.3	0.00	66.7
	Week 7	30	14.44	27.24	0.0	0.00	100.0	26	6.41	28.31	-33.3	0.00	66.7
	Week 8	30	12.22	20.50	0.0	0.00	66.7	26	7.69	19.57	-33.3	0.00	66.7
	Week 9	28	13.09	18.90	0.0	0.00	66.7	27	6.17	16.11	-33.3	0.00	33.3
	Week 10	26	10.26	20.59	0.0	0.00	66.7	23	4.35	20.85	-33.3	0.00	66.7
	Week 11	28	9.52	19.99	0.0	0.00	66.7	25	5.33	18.46	-33.3	0.00	66.7
	Week 12	28	14.29	21.14	0.0	0.00	66.7	25	9.33	20.46	-33.3	0.00	66.7
	Week 14	26	7.69	19.57	0.0	0.00	66.7	23	5.80	23.89	-33.3	0.00	66.7
	Week 17	28	5.95	13.00	0.0	0.00	33.3	24	2.78	16.79	-33.3	0.00	33.3
	Week 20	27	6.17	13.19	0.0	0.00	33.3	24	1.39	15.48	-33.3	0.00	33.3
	Week 23	26	7.69	14.32	0.0	0.00	33.3	23	1.45	15.82	-33.3	0.00	33.3
	Week 26	24	6.94	13.83	0.0	0.00	33.3	22	3.03	14.21	-33.3	0.00	33.3
	Week 29	25	5.33	12.47	0.0	0.00	33.3	23	1.45	15.82	-33.3	0.00	33.3
	Week 32	25	8.00	14.53	0.0	0.00	33.3	23	4.35	15.26	-33.3	0.00	33.3
	Week 35	24	11.11	18.82	0.0	0.00	66.7	22	6.06	19.62	-33.3	0.00	66.7
	Week 38	23	10.14	18.63	0.0	0.00	66.7	22	6.06	19.62	-33.3	0.00	66.7
	Week 41	25	10.67	20.91	0.0	0.00	66.7	23	7.25	22.38	-33.3	0.00	66.7
	Week 44	22	6.06	13.16	0.0	0.00	33.3	20	3.33	14.91	-33.3	0.00	33.3
	Week 47	20	8.33	14.81	0.0	0.00	33.3	18	3.70	15.71	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	19	14.03	23.08	0.0	0.00	66.7	17	9.80	25.72	-33.3	0.00	66.7
	Week 53	20	8.33	18.34	0.0	0.00	66.7	18	3.70	19.43	-33.3	0.00	66.7
	Week 56	17	5.88	17.62	0.0	0.00	66.7	15	0.00	21.82	-33.3	0.00	66.7
	Week 59	17	7.84	18.74	0.0	0.00	66.7	15	2.22	19.79	-33.3	0.00	66.7
	Week 62	15	6.67	13.80	0.0	0.00	33.3	14	2.38	8.91	0.0	0.00	33.3
	Week 65	14	4.76	12.10	0.0	0.00	33.3	13	0.00	13.61	-33.3	0.00	33.3
	Week 68	11	9.09	15.57	0.0	0.00	33.3	10	3.33	18.92	-33.3	0.00	33.3
	Week 71	13	7.69	14.62	0.0	0.00	33.3	12	2.78	17.16	-33.3	0.00	33.3
	Week 74	14	9.52	15.63	0.0	0.00	33.3	13	7.69	14.62	0.0	0.00	33.3
	Week 77	14	2.38	8.91	0.0	0.00	33.3	13	-2.56	16.45	-33.3	0.00	33.3
	Week 80	14	2.38	8.91	0.0	0.00	33.3	13	-2.56	16.45	-33.3	0.00	33.3
	Week 83	12	2.78	9.62	0.0	0.00	33.3	11	-3.03	17.98	-33.3	0.00	33.3
	Plat+Gem (N= 29)												
	BASELINE	22	6.06	16.70	0.0	0.00	66.7						
	Week 1	21	6.35	22.65	0.0	0.00	100.0	20	0.00	28.61	-66.7	0.00	100.0
	Week 2	24	4.17	11.26	0.0	0.00	33.3	20	1.67	13.13	-33.3	0.00	33.3
	Week 3	23	2.90	9.60	0.0	0.00	33.3	20	-1.67	17.01	-66.7	0.00	33.3
	Week 4	23	5.80	12.92	0.0	0.00	33.3	19	-3.51	18.90	-66.7	0.00	33.3
	Week 5	25	5.33	12.47	0.0	0.00	33.3	20	1.67	13.13	-33.3	0.00	33.3
	Week 6	22	9.09	23.42	0.0	0.00	100.0	18	5.56	26.20	-33.3	0.00	100.0
	Week 7	24	5.56	12.69	0.0	0.00	33.3	21	-1.59	12.81	-33.3	0.00	33.3
	Week 8	21	4.76	11.95	0.0	0.00	33.3	19	1.75	13.49	-33.3	0.00	33.3
	Week 9	20	3.33	10.26	0.0	0.00	33.3	17	0.00	11.78	-33.3	0.00	33.3
	Week 10	21	3.17	10.03	0.0	0.00	33.3	18	0.00	11.43	-33.3	0.00	33.3
	Week 11	20	5.00	12.21	0.0	0.00	33.3	17	0.00	11.78	-33.3	0.00	33.3
	Week 12	21	4.76	11.95	0.0	0.00	33.3	17	1.96	14.29	-33.3	0.00	33.3

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 14	22	4.55	11.71	0.0	0.00	33.3	18	0.00	11.43	-33.3	0.00	33.3
	Week 17	20	8.33	18.34	0.0	0.00	66.7	17	1.96	14.29	-33.3	0.00	33.3
	Week 20	18	5.56	12.78	0.0	0.00	33.3	15	2.22	15.26	-33.3	0.00	33.3
	Week 23	18	3.70	10.78	0.0	0.00	33.3	16	0.00	12.17	-33.3	0.00	33.3
	Week 26	16	2.08	8.33	0.0	0.00	33.3	14	-2.38	8.91	-33.3	0.00	0.0
	Week 29	15	6.67	13.80	0.0	0.00	33.3	13	2.56	9.24	0.0	0.00	33.3
	Week 32	15	2.22	8.61	0.0	0.00	33.3	13	-2.56	9.24	-33.3	0.00	0.0
	Week 35	15	6.67	13.80	0.0	0.00	33.3	13	0.00	13.61	-33.3	0.00	33.3
	Week 38	14	9.52	15.63	0.0	0.00	33.3	12	2.78	9.62	0.0	0.00	33.3
	Week 41	11	6.06	13.48	0.0	0.00	33.3	9	3.70	11.11	0.0	0.00	33.3
	Week 44	11	18.18	27.34	0.0	0.00	66.7	9	11.11	28.87	-33.3	0.00	66.7
	Week 47	11	15.15	22.92	0.0	0.00	66.7	9	7.41	22.22	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>= 65 years	EV+Pembro (N=163)												
	BASELINE	128	5.47	14.35	0.0	0.00	66.7						
	Week 1	114	7.60	18.83	0.0	0.00	100.0	103	0.97	16.47	-33.3	0.00	66.7
	Week 2	120	12.22	23.64	0.0	0.00	100.0	104	7.37	22.26	-66.7	0.00	66.7
	Week 3	108	14.20	23.77	0.0	0.00	100.0	93	8.96	25.60	-66.7	0.00	100.0
	Week 4	115	8.12	19.54	0.0	0.00	100.0	102	2.94	21.03	-66.7	0.00	100.0
	Week 5	109	9.17	18.07	0.0	0.00	100.0	95	3.16	18.88	-66.7	0.00	100.0
	Week 6	117	11.68	19.73	0.0	0.00	100.0	98	6.12	22.11	-66.7	0.00	66.7
	Week 7	117	9.12	18.89	0.0	0.00	66.7	98	3.74	19.08	-33.3	0.00	66.7
	Week 8	117	10.83	20.91	0.0	0.00	100.0	98	4.76	21.40	-66.7	0.00	100.0
	Week 9	114	12.87	22.83	0.0	0.00	100.0	94	7.45	26.39	-66.7	0.00	100.0
	Week 10	113	9.14	17.95	0.0	0.00	66.7	95	4.21	18.35	-66.7	0.00	66.7
	Week 11	109	8.56	17.21	0.0	0.00	66.7	90	2.22	21.67	-66.7	0.00	66.7
	Week 12	114	9.65	18.67	0.0	0.00	100.0	94	3.55	18.59	-66.7	0.00	33.3
	Week 14	113	9.73	20.26	0.0	0.00	100.0	93	5.02	23.02	-66.7	0.00	100.0
	Week 17	104	9.29	20.49	0.0	0.00	100.0	87	6.13	23.59	-66.7	0.00	100.0
	Week 20	93	8.24	19.45	0.0	0.00	100.0	79	3.80	23.86	-66.7	0.00	100.0
	Week 23	91	6.96	14.50	0.0	0.00	66.7	74	2.25	20.14	-66.7	0.00	66.7
	Week 26	88	7.20	15.53	0.0	0.00	66.7	72	2.31	20.42	-66.7	0.00	66.7
	Week 29	82	8.54	19.47	0.0	0.00	100.0	70	3.81	23.08	-66.7	0.00	100.0
	Week 32	77	9.09	17.63	0.0	0.00	66.7	65	3.08	21.83	-66.7	0.00	66.7
	Week 35	74	6.31	15.29	0.0	0.00	66.7	64	1.56	20.94	-66.7	0.00	66.7
	Week 38	74	6.76	16.53	0.0	0.00	100.0	64	2.08	21.31	-66.7	0.00	100.0
	Week 41	70	8.09	18.33	0.0	0.00	100.0	61	4.37	21.49	-66.7	0.00	100.0
	Week 44	64	6.25	16.67	0.0	0.00	100.0	54	2.47	21.33	-66.7	0.00	100.0
	Week 47	59	3.95	12.51	0.0	0.00	66.7	52	0.00	19.80	-66.7	0.00	66.7

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	55	7.88	16.93	0.0	0.00	66.7	47	4.25	20.40	-66.7	0.00	66.7
	Week 53	54	4.32	13.02	0.0	0.00	66.7	45	-0.74	16.65	-66.7	0.00	33.3
	Week 56	55	4.24	12.92	0.0	0.00	66.7	46	0.00	14.05	-66.7	0.00	33.3
	Week 59	52	2.56	8.97	0.0	0.00	33.3	42	-0.79	15.60	-66.7	0.00	33.3
	Week 62	47	2.13	8.24	0.0	0.00	33.3	38	-0.88	14.47	-66.7	0.00	33.3
	Week 65	29	2.30	8.60	0.0	0.00	33.3	27	-1.23	17.25	-66.7	0.00	33.3
	Week 68	35	6.67	15.76	0.0	0.00	66.7	32	4.17	22.00	-66.7	0.00	66.7
	Week 71	29	3.45	18.57	0.0	0.00	100.0	26	0.00	24.94	-66.7	0.00	100.0
	Week 74	24	4.17	11.26	0.0	0.00	33.3	22	1.52	12.50	-33.3	0.00	33.3
	Week 77	23	1.45	6.95	0.0	0.00	33.3	20	0.00	10.81	-33.3	0.00	33.3
	Week 80	22	4.55	11.71	0.0	0.00	33.3	21	3.17	14.55	-33.3	0.00	33.3
	Week 83	18	3.70	10.78	0.0	0.00	33.3	18	1.85	13.87	-33.3	0.00	33.3
	Week 86	18	3.70	10.78	0.0	0.00	33.3	18	1.85	13.87	-33.3	0.00	33.3
	Week 89	12	2.78	9.62	0.0	0.00	33.3	12	-2.78	9.62	-33.3	0.00	0.0
	Week 92	10	10.00	16.10	0.0	0.00	33.3	10	6.67	21.08	-33.3	0.00	33.3
	Plat+Gem (N=173)												
	BASELINE	143	6.06	15.13	0.0	0.00	66.7						
	Week 1	123	5.96	15.99	0.0	0.00	66.7	119	0.28	17.63	-33.3	0.00	66.7
	Week 2	123	10.84	22.78	0.0	0.00	100.0	115	4.64	25.32	-66.7	0.00	100.0
	Week 3	126	7.94	19.06	0.0	0.00	100.0	116	2.30	22.72	-66.7	0.00	100.0
	Week 4	127	6.56	14.57	0.0	0.00	66.7	116	0.29	18.39	-66.7	0.00	66.7
	Week 5	128	8.59	18.35	0.0	0.00	66.7	118	1.98	19.63	-66.7	0.00	66.7
	Week 6	123	8.94	17.63	0.0	0.00	100.0	113	2.65	19.49	-33.3	0.00	100.0
	Week 7	124	4.84	14.53	0.0	0.00	100.0	113	-1.47	18.57	-66.7	0.00	100.0
	Week 8	124	5.91	14.75	0.0	0.00	66.7	113	-0.88	17.51	-66.7	0.00	66.7
	Week 9	121	5.23	12.18	0.0	0.00	33.3	108	-0.62	18.22	-66.7	0.00	33.3

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Table 302.1.3002.23.2.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	121	4.41	14.87	0.0	0.00	100.0	112	-1.79	17.24	-66.7	0.00	66.7
	Week 11	106	4.72	12.55	0.0	0.00	66.7	97	-2.41	16.84	-66.7	0.00	66.7
	Week 12	109	6.12	14.46	0.0	0.00	66.7	98	-0.68	20.85	-66.7	0.00	66.7
	Week 14	103	4.53	11.48	0.0	0.00	33.3	91	-1.83	16.75	-66.7	0.00	33.3
	Week 17	100	6.33	13.97	0.0	0.00	66.7	89	-1.50	18.74	-66.7	0.00	66.7
	Week 20	86	6.98	13.64	0.0	0.00	33.3	76	-0.44	19.24	-66.7	0.00	33.3
	Week 23	70	7.14	15.94	0.0	0.00	66.7	64	0.00	23.00	-66.7	0.00	66.7
	Week 26	65	5.13	13.48	0.0	0.00	66.7	61	-2.73	20.45	-66.7	0.00	66.7
	Week 29	62	10.21	18.69	0.0	0.00	66.7	58	1.72	24.52	-66.7	0.00	66.7
	Week 32	48	4.17	11.14	0.0	0.00	33.3	45	-4.44	16.82	-66.7	0.00	33.3
	Week 35	47	5.67	14.44	0.0	0.00	66.7	43	-2.33	18.39	-66.7	0.00	33.3
	Week 38	42	4.76	11.80	0.0	0.00	33.3	38	-3.51	18.65	-66.7	0.00	33.3
	Week 41	41	6.50	13.37	0.0	0.00	33.3	38	-1.76	20.43	-66.7	0.00	33.3
	Week 44	38	6.14	13.09	0.0	0.00	33.3	35	-1.91	21.30	-66.7	0.00	33.3
	Week 47	32	3.12	9.87	0.0	0.00	33.3	30	-6.67	25.37	-66.7	0.00	33.3
	Week 50	29	9.19	17.58	0.0	0.00	66.7	26	1.28	24.00	-66.7	0.00	33.3
	Week 53	25	6.67	13.61	0.0	0.00	33.3	24	-4.17	22.66	-66.7	0.00	33.3
	Week 56	26	5.13	15.47	0.0	0.00	66.7	26	-3.85	23.72	-66.7	0.00	66.7
	Week 59	20	1.67	7.45	0.0	0.00	33.3	20	-5.00	19.57	-66.7	0.00	33.3
	Week 62	19	8.77	21.78	0.0	0.00	66.7	19	1.75	30.38	-66.7	0.00	66.7
	Week 65	16	2.08	8.33	0.0	0.00	33.3	16	-2.08	14.75	-33.3	0.00	33.3
	Week 68	13	7.69	14.62	0.0	0.00	33.3	13	5.13	18.49	-33.3	0.00	33.3
	Week 71	13	7.69	14.62	0.0	0.00	33.3	13	5.13	18.49	-33.3	0.00	33.3
	Week 74	11	3.03	10.05	0.0	0.00	33.3	11	0.00	14.91	-33.3	0.00	33.3
	Week 77	10	3.33	10.54	0.0	0.00	33.3	10	-3.33	18.92	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Europe	EV+Pembro (N= 74)												
	BASELINE	53	5.66	15.66	0.0	0.00	66.7						
	Week 1	48	7.64	18.50	0.0	0.00	100.0	42	1.59	14.64	-33.3	0.00	33.3
	Week 2	53	11.95	25.40	0.0	0.00	100.0	44	8.33	19.19	-33.3	0.00	66.7
	Week 3	50	18.00	25.39	0.0	0.00	100.0	41	13.82	23.54	-33.3	0.00	66.7
	Week 4	51	7.84	18.36	0.0	0.00	100.0	44	3.79	19.31	-33.3	0.00	100.0
	Week 5	46	7.97	16.00	0.0	0.00	66.7	41	2.44	15.62	-33.3	0.00	33.3
	Week 6	50	12.00	21.04	0.0	0.00	100.0	39	7.69	17.87	-33.3	0.00	66.7
	Week 7	50	10.00	19.34	0.0	0.00	66.7	39	6.84	20.49	-33.3	0.00	66.7
	Week 8	51	11.76	19.80	0.0	0.00	66.7	41	6.50	17.03	-33.3	0.00	66.7
	Week 9	47	9.93	19.55	0.0	0.00	66.7	37	5.41	20.05	-33.3	0.00	66.7
	Week 10	45	5.93	14.72	0.0	0.00	66.7	34	1.96	14.07	-33.3	0.00	33.3
	Week 11	48	5.56	14.31	0.0	0.00	66.7	37	0.90	16.64	-66.7	0.00	33.3
	Week 12	51	10.46	22.60	0.0	0.00	100.0	39	5.13	14.38	-33.3	0.00	33.3
	Week 14	50	6.67	16.50	0.0	0.00	66.7	38	0.88	16.42	-33.3	0.00	66.7
	Week 17	43	3.88	10.81	0.0	0.00	33.3	33	-1.01	15.56	-66.7	0.00	33.3
	Week 20	41	8.94	21.11	0.0	0.00	100.0	33	6.06	24.23	-66.7	0.00	66.7
	Week 23	41	7.32	15.83	0.0	0.00	66.7	30	2.22	23.05	-66.7	0.00	66.7
	Week 26	37	5.41	14.73	0.0	0.00	66.7	28	2.38	22.09	-66.7	0.00	66.7
	Week 29	37	9.01	21.73	0.0	0.00	100.0	29	3.45	25.73	-66.7	0.00	100.0
	Week 32	34	6.86	13.68	0.0	0.00	33.3	26	1.28	19.96	-66.7	0.00	33.3
	Week 35	31	7.53	18.68	0.0	0.00	66.7	25	1.33	26.32	-66.7	0.00	66.7
	Week 38	31	8.60	22.72	0.0	0.00	100.0	26	3.85	30.30	-66.7	0.00	100.0
	Week 41	28	9.52	19.99	0.0	0.00	66.7	23	4.35	20.85	-33.3	0.00	66.7
	Week 44	27	9.88	22.29	0.0	0.00	100.0	22	6.06	26.50	-33.3	0.00	100.0
	Week 47	25	8.00	17.43	0.0	0.00	66.7	21	3.17	25.61	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	26	14.10	23.43	0.0	0.00	66.7	23	10.14	27.40	-33.3	0.00	66.7
	Week 53	26	8.97	20.13	0.0	0.00	66.7	21	4.76	21.82	-33.3	0.00	66.7
	Week 56	25	6.67	19.25	0.0	0.00	66.7	21	3.17	17.97	-33.3	0.00	66.7
	Week 59	23	2.90	13.90	0.0	0.00	66.7	18	0.00	19.80	-33.3	0.00	66.7
	Week 62	20	3.33	10.26	0.0	0.00	33.3	17	1.96	8.08	0.0	0.00	33.3
	Week 65	13	2.56	9.24	0.0	0.00	33.3	13	0.00	13.61	-33.3	0.00	33.3
	Week 68	15	11.11	16.26	0.0	0.00	33.3	15	8.89	19.79	-33.3	0.00	33.3
	Week 71	13	5.13	12.52	0.0	0.00	33.3	13	2.56	16.45	-33.3	0.00	33.3
	Week 74	10	6.67	14.05	0.0	0.00	33.3	9	3.70	11.11	0.0	0.00	33.3
	Plat+Gem (N= 95)												
	BASELINE	75	7.56	17.82	0.0	0.00	66.7						
	Week 1	71	7.51	20.47	0.0	0.00	100.0	69	0.97	23.55	-66.7	0.00	100.0
	Week 2	71	10.33	22.95	0.0	0.00	100.0	63	3.70	25.48	-33.3	0.00	100.0
	Week 3	72	8.33	19.18	0.0	0.00	100.0	65	1.54	25.97	-66.7	0.00	100.0
	Week 4	69	6.76	15.74	0.0	0.00	66.7	62	-1.61	22.12	-66.7	0.00	66.7
	Week 5	71	9.39	19.67	0.0	0.00	66.7	63	1.59	20.24	-33.3	0.00	66.7
	Week 6	69	10.63	22.50	0.0	0.00	100.0	61	3.28	26.32	-33.3	0.00	100.0
	Week 7	69	5.80	17.11	0.0	0.00	100.0	62	-2.15	23.28	-66.7	0.00	100.0
	Week 8	67	5.97	15.27	0.0	0.00	66.7	60	-2.78	16.57	-66.7	0.00	33.3
	Week 9	66	4.55	11.53	0.0	0.00	33.3	57	-3.51	20.59	-66.7	0.00	33.3
	Week 10	70	4.29	13.81	0.0	0.00	66.7	63	-2.65	19.21	-66.7	0.00	66.7
	Week 11	63	4.76	13.19	0.0	0.00	66.7	56	-2.98	19.36	-66.7	0.00	66.7
	Week 12	66	5.56	13.82	0.0	0.00	66.7	56	-2.98	23.16	-66.7	0.00	66.7
	Week 14	66	4.55	11.53	0.0	0.00	33.3	56	-2.38	18.92	-66.7	0.00	33.3
	Week 17	61	5.46	13.85	0.0	0.00	66.7	53	-4.40	17.34	-66.7	0.00	33.3
	Week 20	54	5.56	12.54	0.0	0.00	33.3	48	-3.47	20.90	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 23	44	6.06	14.86	0.0	0.00	66.7	40	-4.17	22.88	-66.7	0.00	66.7
	Week 26	42	5.56	14.57	0.0	0.00	66.7	39	-4.27	21.87	-66.7	0.00	66.7
	Week 29	39	11.11	19.24	0.0	0.00	66.7	36	0.93	24.54	-66.7	0.00	66.7
	Week 32	32	2.08	8.20	0.0	0.00	33.3	30	-8.89	17.36	-66.7	0.00	0.0
	Week 35	32	6.25	15.70	0.0	0.00	66.7	30	-4.44	19.04	-66.7	0.00	33.3
	Week 38	28	7.14	13.93	0.0	0.00	33.3	26	-5.13	20.42	-66.7	0.00	33.3
	Week 41	25	6.67	13.61	0.0	0.00	33.3	23	-4.35	23.15	-66.7	0.00	33.3
	Week 44	24	8.33	14.74	0.0	0.00	33.3	22	-3.03	22.79	-66.7	0.00	33.3
	Week 47	22	3.03	9.81	0.0	0.00	33.3	20	-10.00	26.71	-66.7	0.00	33.3
	Week 50	17	9.80	19.60	0.0	0.00	66.7	15	-2.22	23.46	-33.3	0.00	33.3
	Week 53	15	11.11	27.22	0.0	0.00	100.0	14	-9.52	20.37	-33.3	0.00	33.3
	Week 56	15	11.11	27.22	0.0	0.00	100.0	14	-7.14	19.30	-33.3	0.00	33.3
	Week 59	11	9.09	21.56	0.0	0.00	66.7	10	-3.33	18.92	-33.3	0.00	33.3
	Week 62	11	12.12	26.97	0.0	0.00	66.7	11	6.06	32.72	-33.3	0.00	66.7
	Week 65	10	3.33	10.54	0.0	0.00	33.3	10	-3.33	18.92	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
North America	EV+Pembro (N= 46)												
	BASELINE	33	5.05	14.72	0.0	0.00	66.7						
	Week 1	30	6.67	13.56	0.0	0.00	33.3	27	2.47	12.83	-33.3	0.00	33.3
	Week 2	30	13.33	20.71	0.0	0.00	66.7	26	10.26	22.65	-33.3	0.00	66.7
	Week 3	25	16.00	25.68	0.0	0.00	100.0	21	11.11	26.53	-33.3	0.00	100.0
	Week 4	30	7.78	16.80	0.0	0.00	66.7	24	0.00	19.66	-66.7	0.00	33.3
	Week 5	29	8.05	14.52	0.0	0.00	33.3	21	1.59	19.65	-66.7	0.00	33.3
	Week 6	31	16.13	22.56	0.0	0.00	66.7	23	8.70	28.81	-66.7	0.00	66.7
	Week 7	33	11.11	23.07	0.0	0.00	100.0	23	1.45	15.82	-33.3	0.00	33.3
	Week 8	29	11.49	22.32	0.0	0.00	66.7	20	5.00	29.17	-66.7	0.00	66.7
	Week 9	27	18.52	29.72	0.0	0.00	100.0	21	12.70	35.71	-66.7	0.00	100.0
	Week 10	29	12.64	24.26	0.0	0.00	66.7	23	5.80	27.80	-66.7	0.00	66.7
	Week 11	28	13.10	22.84	0.0	0.00	66.7	21	4.76	28.45	-66.7	0.00	66.7
	Week 12	29	11.49	18.42	0.0	0.00	66.7	22	4.55	23.67	-66.7	0.00	33.3
	Week 14	28	11.90	22.62	0.0	0.00	66.7	21	7.94	31.46	-66.7	0.00	66.7
	Week 17	29	13.79	26.00	0.0	0.00	100.0	23	11.59	32.74	-66.7	0.00	100.0
	Week 20	23	11.59	23.80	0.0	0.00	100.0	18	5.56	34.77	-66.7	0.00	100.0
	Week 23	22	10.61	15.89	0.0	0.00	33.3	17	3.92	26.04	-66.7	0.00	33.3
	Week 26	21	11.11	19.24	0.0	0.00	66.7	16	2.08	25.73	-66.7	0.00	33.3
	Week 29	20	8.33	18.34	0.0	0.00	66.7	17	1.96	24.92	-66.7	0.00	33.3
	Week 32	21	9.52	21.46	0.0	0.00	66.7	18	0.00	25.57	-66.7	0.00	66.7
	Week 35	22	6.06	16.70	0.0	0.00	66.7	19	-1.75	20.71	-66.7	0.00	33.3
	Week 38	20	6.67	13.68	0.0	0.00	33.3	17	0.00	20.41	-66.7	0.00	33.3
	Week 41	21	3.17	10.03	0.0	0.00	33.3	17	-1.96	18.52	-66.7	0.00	33.3
	Week 44	16	2.08	8.33	0.0	0.00	33.3	12	-2.78	22.29	-66.7	0.00	33.3
	Week 47	16	2.08	8.33	0.0	0.00	33.3	13	-2.56	21.35	-66.7	0.00	33.3

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Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	16	6.25	18.13	0.0	0.00	66.7	11	0.00	29.82	-66.7	0.00	66.7
	Week 53	15	2.22	8.61	0.0	0.00	33.3	11	-6.06	20.10	-66.7	0.00	0.0
	Week 56	17	5.88	13.10	0.0	0.00	33.3	12	-2.78	22.29	-66.7	0.00	33.3
	Week 59	17	3.92	11.07	0.0	0.00	33.3	12	-5.56	19.25	-66.7	0.00	0.0
	Week 62	14	2.38	8.91	0.0	0.00	33.3	9	-7.41	22.22	-66.7	0.00	0.0
	Week 68	11	9.09	21.56	0.0	0.00	66.7	8	4.17	37.53	-66.7	0.00	66.7
	Week 71	11	9.09	30.15	0.0	0.00	100.0	8	4.17	45.21	-66.7	0.00	100.0
	Plat+Gem (N= 34)												
	BASELINE	27	6.17	16.11	0.0	0.00	66.7						
	Week 1	19	3.51	10.51	0.0	0.00	33.3	17	-3.92	11.07	-33.3	0.00	0.0
	Week 2	20	8.33	18.34	0.0	0.00	66.7	18	1.85	26.75	-66.7	0.00	66.7
	Week 3	20	10.00	19.04	0.0	0.00	66.7	17	3.92	26.04	-66.7	0.00	33.3
	Week 4	23	10.14	15.68	0.0	0.00	33.3	19	3.51	18.90	-33.3	0.00	33.3
	Week 5	25	6.67	16.67	0.0	0.00	66.7	22	-1.52	21.77	-66.7	0.00	33.3
	Week 6	20	6.67	13.68	0.0	0.00	33.3	17	0.00	16.67	-33.3	0.00	33.3
	Week 7	23	5.80	12.92	0.0	0.00	33.3	20	-3.33	14.91	-33.3	0.00	33.3
	Week 8	24	5.56	12.69	0.0	0.00	33.3	22	-1.52	21.77	-66.7	0.00	33.3
	Week 9	23	5.80	12.92	0.0	0.00	33.3	19	1.75	13.49	-33.3	0.00	33.3
	Week 10	20	3.33	10.26	0.0	0.00	33.3	18	-3.70	10.78	-33.3	0.00	0.0
	Week 11	18	3.70	10.78	0.0	0.00	33.3	16	-6.25	13.44	-33.3	0.00	0.0
	Week 12	17	9.80	15.65	0.0	0.00	33.3	16	2.08	19.12	-33.3	0.00	33.3
	Week 14	16	8.33	14.91	0.0	0.00	33.3	14	-2.38	15.82	-33.3	0.00	33.3
	Week 17	19	12.28	16.52	0.0	0.00	33.3	17	1.96	18.52	-33.3	0.00	33.3
	Week 20	16	16.67	17.21	0.0	16.67	33.3	13	7.69	19.97	-33.3	0.00	33.3
	Week 23	15	8.89	19.79	0.0	0.00	66.7	13	0.00	27.22	-66.7	0.00	66.7
	Week 26	13	2.56	9.24	0.0	0.00	33.3	12	-5.56	19.25	-66.7	0.00	0.0

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Table 302.1.3002.23.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 29	14	9.52	15.63	0.0	0.00	33.3	13	-2.56	25.32	-66.7	0.00	33.3
	Week 32	11	6.06	13.48	0.0	0.00	33.3	10	-3.33	10.54	-33.3	0.00	0.0
	Week 35	13	2.56	9.24	0.0	0.00	33.3	11	-6.06	13.48	-33.3	0.00	0.0
	Week 38	10	3.33	10.54	0.0	0.00	33.3	9	-3.70	11.11	-33.3	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Rest of World	EV+Pembro (N= 82)												
	BASELINE	74	5.86	13.91	0.0	0.00	66.7						
	Week 1	63	6.35	18.80	0.0	0.00	100.0	60	-1.11	17.32	-33.3	0.00	66.7
	Week 2	67	10.45	21.87	0.0	0.00	100.0	63	4.23	21.99	-66.7	0.00	66.7
	Week 3	64	11.46	19.89	0.0	0.00	66.7	60	5.56	23.10	-66.7	0.00	66.7
	Week 4	64	9.90	22.76	0.0	0.00	100.0	61	4.37	23.15	-33.3	0.00	100.0
	Week 5	62	10.21	20.55	0.0	0.00	100.0	59	3.95	20.61	-33.3	0.00	100.0
	Week 6	65	11.79	19.03	0.0	0.00	66.7	62	5.91	22.20	-33.3	0.00	66.7
	Week 7	64	9.90	21.15	0.0	0.00	66.7	62	3.76	23.46	-33.3	0.00	66.7
	Week 8	67	10.45	21.09	0.0	0.00	100.0	63	4.76	20.61	-33.3	0.00	100.0
	Week 9	68	12.74	19.97	0.0	0.00	66.7	63	6.35	22.29	-33.3	0.00	66.7
	Week 10	65	10.26	17.60	0.0	0.00	66.7	61	4.92	17.03	-33.3	0.00	66.7
	Week 11	61	9.29	17.35	0.0	0.00	66.7	57	3.51	20.59	-33.3	0.00	66.7
	Week 12	62	10.21	16.63	0.0	0.00	66.7	58	4.60	20.18	-66.7	0.00	66.7
	Week 14	61	10.38	21.55	0.0	0.00	100.0	57	7.02	23.35	-33.3	0.00	100.0
	Week 17	60	9.44	19.50	0.0	0.00	100.0	55	6.67	19.67	-33.3	0.00	66.7
	Week 20	56	5.36	12.35	0.0	0.00	33.3	52	0.64	13.99	-33.3	0.00	33.3
	Week 23	54	5.56	12.54	0.0	0.00	33.3	50	1.33	13.40	-33.3	0.00	33.3
	Week 26	54	6.79	13.55	0.0	0.00	33.3	50	2.67	14.81	-33.3	0.00	33.3
	Week 29	50	6.67	15.06	0.0	0.00	66.7	47	3.55	17.35	-33.3	0.00	66.7
	Week 32	47	9.93	16.90	0.0	0.00	66.7	44	6.06	18.00	-33.3	0.00	66.7
	Week 35	45	8.15	14.49	0.0	0.00	33.3	42	5.56	16.32	-33.3	0.00	33.3
	Week 38	46	7.25	13.90	0.0	0.00	33.3	43	3.88	13.03	-33.3	0.00	33.3
	Week 41	46	10.87	21.14	0.0	0.00	100.0	44	8.33	22.87	-33.3	0.00	100.0
	Week 44	43	5.43	12.45	0.0	0.00	33.3	40	2.50	13.89	-33.3	0.00	33.3
	Week 47	38	4.39	11.42	0.0	0.00	33.3	36	0.93	12.56	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	32	7.29	14.00	0.0	0.00	33.3	30	4.44	11.52	0.0	0.00	33.3
	Week 53	33	4.04	11.05	0.0	0.00	33.3	31	0.00	12.17	-33.3	0.00	33.3
	Week 56	30	2.22	8.46	0.0	0.00	33.3	28	-1.19	11.04	-33.3	0.00	33.3
	Week 59	29	4.60	11.70	0.0	0.00	33.3	27	2.47	12.83	-33.3	0.00	33.3
	Week 62	28	3.57	10.50	0.0	0.00	33.3	26	1.28	11.47	-33.3	0.00	33.3
	Week 65	22	3.03	9.81	0.0	0.00	33.3	21	0.00	10.54	-33.3	0.00	33.3
	Week 68	20	3.33	10.26	0.0	0.00	33.3	19	0.00	11.11	-33.3	0.00	33.3
	Week 71	18	1.85	7.86	0.0	0.00	33.3	17	-1.96	8.08	-33.3	0.00	0.0
	Week 74	19	7.02	13.96	0.0	0.00	33.3	19	3.51	15.29	-33.3	0.00	33.3
	Week 77	19	0.00	0.00	0.0	0.00	0.0	18	-3.70	10.78	-33.3	0.00	0.0
	Week 80	19	3.51	10.51	0.0	0.00	33.3	18	0.00	16.17	-33.3	0.00	33.3
	Week 83	17	3.92	11.07	0.0	0.00	33.3	17	0.00	16.67	-33.3	0.00	33.3
	Week 86	14	4.76	12.10	0.0	0.00	33.3	14	0.00	18.49	-33.3	0.00	33.3
	Week 89	11	6.06	13.48	0.0	0.00	33.3	11	3.03	17.98	-33.3	0.00	33.3
	Plat+Gem (N= 73)												
	BASELINE	63	4.23	11.19	0.0	0.00	33.3						
	Week 1	54	4.94	13.59	0.0	0.00	66.7	53	0.63	15.32	-33.3	0.00	66.7
	Week 2	56	9.52	20.81	0.0	0.00	100.0	54	5.56	21.23	-33.3	0.00	100.0
	Week 3	57	4.68	15.98	0.0	0.00	100.0	54	1.23	14.42	-33.3	0.00	66.7
	Week 4	58	4.60	11.59	0.0	0.00	33.3	54	0.00	12.95	-33.3	0.00	33.3
	Week 5	57	7.02	15.09	0.0	0.00	66.7	53	3.77	15.55	-33.3	0.00	66.7
	Week 6	56	7.74	14.20	0.0	0.00	33.3	53	3.77	12.51	-33.3	0.00	33.3
	Week 7	56	3.57	10.40	0.0	0.00	33.3	52	0.00	9.33	-33.3	0.00	33.3
	Week 8	54	5.56	14.11	0.0	0.00	66.7	50	2.67	14.81	-33.3	0.00	66.7
	Week 9	52	5.13	12.14	0.0	0.00	33.3	49	2.04	14.28	-33.3	0.00	33.3
	Week 10	52	4.49	16.21	0.0	0.00	100.0	49	0.68	14.42	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.2.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	45	5.18	12.22	0.0	0.00	33.3	42	0.79	11.61	-33.3	0.00	33.3
	Week 12	47	4.96	13.86	0.0	0.00	66.7	43	2.33	15.25	-33.3	0.00	66.7
	Week 14	43	3.10	9.80	0.0	0.00	33.3	39	0.00	10.81	-33.3	0.00	33.3
	Week 17	40	5.83	14.88	0.0	0.00	66.7	36	2.78	18.47	-33.3	0.00	66.7
	Week 20	34	3.92	10.90	0.0	0.00	33.3	30	2.22	12.17	-33.3	0.00	33.3
	Week 23	29	5.75	12.81	0.0	0.00	33.3	27	6.17	13.19	0.0	0.00	33.3
	Week 26	26	3.85	10.86	0.0	0.00	33.3	24	1.39	11.95	-33.3	0.00	33.3
	Week 29	24	6.94	16.97	0.0	0.00	66.7	22	6.06	16.70	0.0	0.00	66.7
	Week 32	20	5.00	12.21	0.0	0.00	33.3	18	3.70	10.78	0.0	0.00	33.3
	Week 35	17	7.84	14.57	0.0	0.00	33.3	15	6.67	13.80	0.0	0.00	33.3
	Week 38	18	5.56	12.78	0.0	0.00	33.3	15	4.44	11.73	0.0	0.00	33.3
	Week 41	18	7.41	14.26	0.0	0.00	33.3	16	6.25	13.44	0.0	0.00	33.3
	Week 44	16	12.50	23.96	0.0	0.00	66.7	14	9.52	20.38	0.0	0.00	66.7
	Week 47	12	16.67	22.47	0.0	0.00	66.7	11	12.12	16.82	0.0	0.00	33.3
	Week 50	11	12.12	22.47	0.0	0.00	66.7	9	7.41	14.70	0.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	EV+Pembro (N=146)												
	BASELINE	119	6.16	15.01	0.0	0.00	66.7						
	Week 1	102	7.19	17.94	0.0	0.00	100.0	97	0.34	15.59	-33.3	0.00	66.7
	Week 2	106	11.95	22.63	0.0	0.00	100.0	98	6.46	20.67	-66.7	0.00	66.7
	Week 3	94	14.18	23.69	0.0	0.00	100.0	88	9.47	24.73	-66.7	0.00	100.0
	Week 4	101	8.25	17.89	0.0	0.00	100.0	93	2.87	20.06	-33.3	0.00	100.0
	Week 5	96	8.68	17.60	0.0	0.00	100.0	89	3.00	19.23	-33.3	0.00	100.0
	Week 6	105	12.06	19.68	0.0	0.00	100.0	93	6.45	21.00	-33.3	0.00	66.7
	Week 7	102	9.48	19.55	0.0	0.00	66.7	89	3.75	21.58	-33.3	0.00	66.7
	Week 8	101	10.23	19.86	0.0	0.00	100.0	91	5.49	20.04	-33.3	0.00	100.0
	Week 9	100	12.00	21.98	0.0	0.00	100.0	89	7.49	25.00	-33.3	0.00	100.0
	Week 10	99	8.08	17.23	0.0	0.00	66.7	87	3.45	17.63	-33.3	0.00	66.7
	Week 11	95	7.72	17.16	0.0	0.00	66.7	84	2.78	21.46	-66.7	0.00	66.7
	Week 12	99	11.11	19.05	0.0	0.00	66.7	87	5.75	19.82	-66.7	0.00	66.7
	Week 14	95	7.37	17.65	0.0	0.00	66.7	84	3.17	21.09	-33.3	0.00	66.7
	Week 17	97	8.25	18.65	0.0	0.00	100.0	84	5.16	22.25	-66.7	0.00	100.0
	Week 20	90	7.41	19.21	0.0	0.00	100.0	79	3.80	22.64	-66.7	0.00	100.0
	Week 23	86	7.36	14.82	0.0	0.00	66.7	74	3.60	19.56	-66.7	0.00	66.7
	Week 26	83	7.23	15.66	0.0	0.00	66.7	72	2.31	17.98	-66.7	0.00	66.7
	Week 29	80	7.92	17.78	0.0	0.00	100.0	71	4.23	21.03	-66.7	0.00	100.0
	Week 32	74	8.56	16.61	0.0	0.00	66.7	66	4.04	18.96	-66.7	0.00	66.7
	Week 35	73	7.76	16.22	0.0	0.00	66.7	66	3.03	19.15	-66.7	0.00	66.7
	Week 38	75	7.55	15.08	0.0	0.00	66.7	67	3.48	17.54	-66.7	0.00	66.7
	Week 41	71	9.86	20.62	0.0	0.00	100.0	64	6.77	20.73	-33.3	0.00	100.0
	Week 44	64	5.73	12.67	0.0	0.00	33.3	56	2.98	14.60	-33.3	0.00	33.3
	Week 47	56	5.36	13.89	0.0	0.00	66.7	50	2.00	18.33	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	55	10.30	20.16	0.0	0.00	66.7	48	7.64	22.00	-33.3	0.00	66.7
	Week 53	55	6.06	15.83	0.0	0.00	66.7	48	2.78	16.61	-33.3	0.00	66.7
	Week 56	53	5.03	15.19	0.0	0.00	66.7	46	1.45	15.64	-33.3	0.00	66.7
	Week 59	51	4.57	13.37	0.0	0.00	66.7	43	1.55	16.19	-33.3	0.00	66.7
	Week 62	42	3.17	9.90	0.0	0.00	33.3	36	1.85	11.11	-33.3	0.00	33.3
	Week 65	31	4.30	11.36	0.0	0.00	33.3	30	1.11	13.79	-33.3	0.00	33.3
	Week 68	31	9.68	17.62	0.0	0.00	66.7	29	6.90	20.66	-33.3	0.00	66.7
	Week 71	30	5.56	19.74	0.0	0.00	100.0	28	2.38	22.09	-33.3	0.00	100.0
	Week 74	29	5.75	12.81	0.0	0.00	33.3	27	2.47	12.83	-33.3	0.00	33.3
	Week 77	26	1.28	6.54	0.0	0.00	33.3	24	-2.78	13.61	-33.3	0.00	33.3
	Week 80	26	5.13	12.26	0.0	0.00	33.3	26	1.28	17.59	-33.3	0.00	33.3
	Week 83	21	4.76	11.95	0.0	0.00	33.3	21	0.00	18.26	-33.3	0.00	33.3
	Week 86	17	3.92	11.07	0.0	0.00	33.3	17	0.00	16.67	-33.3	0.00	33.3
	Week 89	11	6.06	13.48	0.0	0.00	33.3	11	0.00	14.91	-33.3	0.00	33.3
	Week 92	13	10.26	16.01	0.0	0.00	33.3	13	2.56	21.35	-33.3	0.00	33.3
	Plat+Gem (N=151)												
	BASELINE	123	5.96	15.41	0.0	0.00	66.7						
	Week 1	108	6.79	18.09	0.0	0.00	100.0	103	0.65	20.34	-66.7	0.00	100.0
	Week 2	116	8.62	20.20	0.0	0.00	100.0	105	3.17	23.35	-66.7	0.00	100.0
	Week 3	114	6.72	16.70	0.0	0.00	100.0	103	1.62	22.57	-66.7	0.00	100.0
	Week 4	116	6.90	14.92	0.0	0.00	66.7	103	0.65	18.07	-66.7	0.00	66.7
	Week 5	119	8.40	16.93	0.0	0.00	66.7	106	2.83	20.11	-66.7	0.00	66.7
	Week 6	109	10.09	20.03	0.0	0.00	100.0	98	4.76	21.93	-33.3	0.00	100.0
	Week 7	115	5.80	15.46	0.0	0.00	100.0	105	-0.63	19.05	-66.7	0.00	100.0
	Week 8	111	6.01	13.63	0.0	0.00	66.7	102	0.65	18.15	-66.7	0.00	66.7
	Week 9	107	4.67	11.63	0.0	0.00	33.3	95	0.00	16.84	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	107	3.74	12.39	0.0	0.00	66.7	98	-1.70	14.65	-33.3	0.00	66.7
	Week 11	97	5.15	13.03	0.0	0.00	66.7	87	-1.15	15.62	-33.3	0.00	66.7
	Week 12	100	5.33	13.16	0.0	0.00	66.7	88	0.38	19.24	-66.7	0.00	66.7
	Week 14	99	3.37	10.09	0.0	0.00	33.3	86	-1.94	14.78	-66.7	0.00	33.3
	Week 17	94	7.09	15.36	0.0	0.00	66.7	82	-0.41	18.51	-66.7	0.00	66.7
	Week 20	84	6.35	13.17	0.0	0.00	33.3	72	0.00	17.69	-66.7	0.00	33.3
	Week 23	70	7.14	15.94	0.0	0.00	66.7	62	1.08	21.73	-66.7	0.00	66.7
	Week 26	61	5.46	13.85	0.0	0.00	66.7	55	-1.82	19.69	-66.7	0.00	66.7
	Week 29	59	9.60	17.56	0.0	0.00	66.7	53	1.89	23.03	-66.7	0.00	66.7
	Week 32	50	3.33	10.10	0.0	0.00	33.3	45	-4.44	15.24	-66.7	0.00	33.3
	Week 35	50	5.33	12.34	0.0	0.00	33.3	44	-1.52	17.54	-66.7	0.00	33.3
	Week 38	46	5.80	12.77	0.0	0.00	33.3	40	-1.67	18.41	-66.7	0.00	33.3
	Week 41	42	6.35	13.25	0.0	0.00	33.3	37	-0.90	20.01	-66.7	0.00	33.3
	Week 44	39	10.26	18.97	0.0	0.00	66.7	34	2.94	25.12	-66.7	0.00	66.7
	Week 47	33	8.08	16.73	0.0	0.00	66.7	29	-1.15	25.95	-66.7	0.00	33.3
	Week 50	27	7.41	16.88	0.0	0.00	66.7	22	-1.52	24.07	-66.7	0.00	33.3
	Week 53	23	14.49	26.26	0.0	0.00	100.0	20	-1.67	25.30	-66.7	0.00	33.3
	Week 56	20	10.00	26.71	0.0	0.00	100.0	19	-3.51	26.98	-66.7	0.00	66.7
	Week 59	17	9.80	22.87	0.0	0.00	66.7	15	-6.67	22.54	-66.7	0.00	33.3
	Week 62	14	11.91	24.83	0.0	0.00	66.7	14	2.38	35.72	-66.7	0.00	66.7
	Week 65	13	7.69	19.97	0.0	0.00	66.7	12	-2.78	17.16	-33.3	0.00	33.3
	Week 68	10	10.00	16.10	0.0	0.00	33.3	10	6.67	21.08	-33.3	0.00	33.3
	Week 71	10	10.00	16.10	0.0	0.00	33.3	10	6.67	21.08	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	EV+Pembro (N= 56)												
	BASELINE	41	4.06	13.32	0.0	0.00	66.7						
	Week 1	39	5.98	16.88	0.0	0.00	66.7	32	1.04	15.80	-33.3	0.00	66.7
	Week 2	44	10.61	23.60	0.0	0.00	100.0	35	7.62	22.99	-33.3	0.00	66.7
	Week 3	45	15.55	22.02	0.0	0.00	66.7	34	8.82	22.18	-33.3	0.00	66.7
	Week 4	44	9.85	24.46	0.0	0.00	100.0	36	4.63	24.11	-66.7	0.00	100.0
	Week 5	41	9.76	18.62	0.0	0.00	66.7	32	3.12	17.68	-66.7	0.00	33.3
	Week 6	41	14.63	22.42	0.0	0.00	66.7	31	8.60	25.77	-66.7	0.00	66.7
	Week 7	45	11.85	23.74	0.0	0.00	100.0	35	5.71	20.59	-33.3	0.00	66.7
	Week 8	46	13.04	22.75	0.0	0.00	66.7	33	5.05	23.75	-66.7	0.00	66.7
	Week 9	42	15.08	22.33	0.0	0.00	66.7	32	6.25	23.09	-66.7	0.00	66.7
	Week 10	40	12.50	20.93	0.0	0.00	66.7	31	6.45	21.81	-66.7	0.00	66.7
	Week 11	42	11.11	19.01	0.0	0.00	66.7	31	3.23	19.92	-66.7	0.00	33.3
	Week 12	43	9.30	19.69	0.0	0.00	100.0	32	2.08	16.80	-66.7	0.00	33.3
	Week 14	44	13.64	24.19	0.0	0.00	100.0	32	10.42	27.35	-66.7	0.00	100.0
	Week 17	35	9.52	20.72	0.0	0.00	100.0	27	6.17	22.72	-66.7	0.00	66.7
	Week 20	30	8.89	14.99	0.0	0.00	33.3	24	1.39	20.80	-66.7	0.00	33.3
	Week 23	31	6.45	13.39	0.0	0.00	33.3	23	-2.90	17.15	-66.7	0.00	33.3
	Week 26	29	6.90	13.74	0.0	0.00	33.3	22	3.03	22.79	-66.7	0.00	33.3
	Week 29	27	7.41	19.25	0.0	0.00	66.7	22	0.00	23.00	-66.7	0.00	66.7
	Week 32	28	9.52	17.82	0.0	0.00	66.7	22	1.52	24.08	-66.7	0.00	66.7
	Week 35	25	6.67	16.67	0.0	0.00	66.7	20	1.67	25.31	-66.7	0.00	66.7
	Week 38	22	7.58	22.84	0.0	0.00	100.0	19	1.75	30.38	-66.7	0.00	100.0
	Week 41	24	5.56	12.69	0.0	0.00	33.3	20	0.00	24.18	-66.7	0.00	33.3
	Week 44	22	7.58	22.84	0.0	0.00	100.0	18	1.85	31.25	-66.7	0.00	100.0
	Week 47	23	4.35	11.48	0.0	0.00	33.3	20	-1.67	20.16	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	19	7.02	13.96	0.0	0.00	33.3	16	0.00	21.08	-66.7	0.00	33.3
	Week 53	19	3.51	10.51	0.0	0.00	33.3	15	-6.67	18.69	-66.7	0.00	0.0
	Week 56	19	3.51	10.51	0.0	0.00	33.3	15	-4.44	17.21	-66.7	0.00	0.0
	Week 59	18	1.85	7.86	0.0	0.00	33.3	14	-4.76	17.82	-66.7	0.00	0.0
	Week 62	20	3.33	10.26	0.0	0.00	33.3	16	-4.17	16.67	-66.7	0.00	0.0
	Week 65	12	0.00	0.00	0.0	0.00	0.0	10	-6.67	21.08	-66.7	0.00	0.0
	Week 68	15	2.22	8.61	0.0	0.00	33.3	13	-2.56	21.35	-66.7	0.00	33.3
	Week 71	12	2.78	9.62	0.0	0.00	33.3	10	-3.33	24.60	-66.7	0.00	33.3
	Week 77	11	3.03	10.05	0.0	0.00	33.3	9	3.70	11.11	0.0	0.00	33.3
	Week 80	10	0.00	0.00	0.0	0.00	0.0	8	0.00	0.00	0.0	0.00	0.0
	Plat+Gem (N= 51)												
	BASELINE	42	6.35	15.16	0.0	0.00	66.7						
	Week 1	36	3.70	13.28	0.0	0.00	66.7	36	-0.93	16.88	-33.3	0.00	66.7
	Week 2	31	13.98	25.49	0.0	0.00	100.0	30	7.78	25.79	-33.3	0.00	100.0
	Week 3	35	8.57	21.91	0.0	0.00	100.0	33	2.02	20.31	-66.7	0.00	66.7
	Week 4	34	4.90	11.98	0.0	0.00	33.3	32	-3.13	19.60	-66.7	0.00	33.3
	Week 5	34	6.86	19.73	0.0	0.00	66.7	32	-1.04	13.34	-33.3	0.00	33.3
	Week 6	36	5.56	12.60	0.0	0.00	33.3	33	-2.02	14.29	-33.3	0.00	33.3
	Week 7	33	2.02	8.08	0.0	0.00	33.3	29	-4.60	11.70	-33.3	0.00	0.0
	Week 8	34	4.90	16.68	0.0	0.00	66.7	30	-4.44	11.52	-33.3	0.00	0.0
	Week 9	34	5.88	12.90	0.0	0.00	33.3	30	-2.22	19.44	-66.7	0.00	33.3
	Week 10	35	5.71	18.93	0.0	0.00	100.0	32	-1.04	21.56	-66.7	0.00	66.7
	Week 11	29	3.45	10.33	0.0	0.00	33.3	27	-4.94	17.79	-66.7	0.00	33.3
	Week 12	30	7.78	16.80	0.0	0.00	66.7	27	-2.47	22.51	-66.7	0.00	66.7
	Week 14	26	8.97	15.08	0.0	0.00	33.3	23	0.00	20.10	-33.3	0.00	33.3
	Week 17	26	5.13	12.26	0.0	0.00	33.3	24	-2.78	16.79	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.2.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 20	20	8.33	14.81	0.0	0.00	33.3	19	0.00	22.22	-66.7	0.00	33.3
	Week 23	18	3.70	10.78	0.0	0.00	33.3	18	-3.70	19.43	-66.7	0.00	33.3
	Week 26	20	1.67	7.45	0.0	0.00	33.3	20	-5.00	16.31	-66.7	0.00	0.0
	Week 29	18	9.26	19.15	0.0	0.00	66.7	18	1.85	21.31	-33.3	0.00	66.7
	Week 32	13	5.13	12.52	0.0	0.00	33.3	13	-2.56	16.45	-33.3	0.00	33.3
	Week 35	12	8.33	20.72	0.0	0.00	66.7	12	-2.78	17.16	-33.3	0.00	33.3
	Week 38	10	6.67	14.05	0.0	0.00	33.3	10	-3.33	10.54	-33.3	0.00	0.0
	Week 41	10	6.67	14.05	0.0	0.00	33.3	10	0.00	15.71	-33.3	0.00	33.3
	Week 44	10	3.33	10.54	0.0	0.00	33.3	10	-6.67	14.06	-33.3	0.00	0.0
	Week 47	10	0.00	0.00	0.0	0.00	0.0	10	-10.00	22.50	-66.7	0.00	0.0
	Week 56	10	3.33	10.54	0.0	0.00	33.3	10	-3.33	10.54	-33.3	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Visceral metastases	EV+Pembro (N=148)												
	BASELINE	119	5.60	14.60	0.0	0.00	66.7						
	Week 1	105	7.30	19.05	0.0	0.00	100.0	99	0.00	15.79	-33.3	0.00	66.7
	Week 2	109	13.46	25.30	0.0	0.00	100.0	100	7.33	22.51	-66.7	0.00	66.7
	Week 3	98	15.99	24.51	0.0	0.00	100.0	88	9.09	24.62	-66.7	0.00	100.0
	Week 4	103	9.38	21.60	0.0	0.00	100.0	93	3.94	23.49	-66.7	0.00	100.0
	Week 5	100	9.00	18.86	0.0	0.00	100.0	90	2.59	19.50	-66.7	0.00	100.0
	Week 6	105	12.06	20.21	0.0	0.00	100.0	90	5.56	22.49	-66.7	0.00	66.7
	Week 7	108	9.88	20.51	0.0	0.00	66.7	91	4.40	22.34	-33.3	0.00	66.7
	Week 8	105	11.11	19.97	0.0	0.00	66.7	89	5.99	21.65	-66.7	0.00	66.7
	Week 9	105	12.06	20.74	0.0	0.00	100.0	91	6.59	23.94	-66.7	0.00	100.0
	Week 10	101	9.90	19.17	0.0	0.00	66.7	86	4.65	20.56	-66.7	0.00	66.7
	Week 11	97	8.25	17.37	0.0	0.00	66.7	83	2.81	22.81	-66.7	0.00	66.7
	Week 12	100	10.33	18.77	0.0	0.00	66.7	85	4.71	20.67	-66.7	0.00	66.7
	Week 14	102	9.48	20.65	0.0	0.00	100.0	87	4.21	23.74	-66.7	0.00	100.0
	Week 17	96	9.72	21.04	0.0	0.00	100.0	81	6.17	24.78	-66.7	0.00	100.0
	Week 20	87	8.81	19.99	0.0	0.00	100.0	76	3.95	24.32	-66.7	0.00	100.0
	Week 23	85	7.45	14.89	0.0	0.00	66.7	71	1.41	20.65	-66.7	0.00	66.7
	Week 26	79	5.91	12.81	0.0	0.00	33.3	66	1.51	18.88	-66.7	0.00	33.3
	Week 29	72	6.48	15.46	0.0	0.00	66.7	64	1.56	20.08	-66.7	0.00	66.7
	Week 32	71	7.51	16.13	0.0	0.00	66.7	62	2.69	22.01	-66.7	0.00	66.7
	Week 35	70	6.67	14.58	0.0	0.00	66.7	63	2.12	20.63	-66.7	0.00	66.7
	Week 38	70	7.14	16.92	0.0	0.00	100.0	63	1.59	21.94	-66.7	0.00	100.0
	Week 41	66	7.58	16.32	0.0	0.00	66.7	60	2.78	18.71	-66.7	0.00	66.7
	Week 44	59	5.65	16.55	0.0	0.00	100.0	53	1.26	20.63	-66.7	0.00	100.0
	Week 47	52	3.20	9.92	0.0	0.00	33.3	48	-2.08	17.40	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	49	8.16	18.67	0.0	0.00	66.7	43	3.88	23.24	-66.7	0.00	66.7
	Week 53	50	3.33	12.14	0.0	0.00	66.7	44	-2.27	15.08	-66.7	0.00	33.3
	Week 56	45	2.96	11.94	0.0	0.00	66.7	39	-2.56	14.07	-66.7	0.00	33.3
	Week 59	44	2.27	8.50	0.0	0.00	33.3	38	-1.75	15.40	-66.7	0.00	33.3
	Week 62	38	1.75	7.54	0.0	0.00	33.3	33	-1.01	13.14	-66.7	0.00	33.3
	Week 65	25	2.67	9.23	0.0	0.00	33.3	24	-2.78	16.79	-66.7	0.00	33.3
	Week 68	31	7.53	16.58	0.0	0.00	66.7	29	3.45	22.44	-66.7	0.00	66.7
	Week 71	27	6.17	20.75	0.0	0.00	100.0	25	1.33	26.32	-66.7	0.00	100.0
	Week 74	23	8.69	14.96	0.0	0.00	33.3	22	7.58	14.30	0.0	0.00	33.3
	Week 77	24	2.78	9.41	0.0	0.00	33.3	23	0.00	14.21	-33.3	0.00	33.3
	Week 80	22	4.55	11.71	0.0	0.00	33.3	22	1.52	16.19	-33.3	0.00	33.3
	Week 83	19	3.51	10.51	0.0	0.00	33.3	19	0.00	15.71	-33.3	0.00	33.3
	Week 86	14	4.76	12.10	0.0	0.00	33.3	14	2.38	15.82	-33.3	0.00	33.3
	Week 89	10	10.00	16.10	0.0	0.00	33.3	10	10.00	16.10	0.0	0.00	33.3
	Week 92	11	6.06	13.48	0.0	0.00	33.3	11	0.00	14.91	-33.3	0.00	33.3
	Plat+Gem (N=157)												
	BASELINE	128	7.03	16.55	0.0	0.00	66.7						
	Week 1	111	6.91	18.04	0.0	0.00	100.0	107	0.00	20.98	-66.7	0.00	100.0
	Week 2	110	6.97	17.54	0.0	0.00	100.0	102	0.65	20.97	-66.7	0.00	100.0
	Week 3	112	5.65	17.26	0.0	0.00	100.0	103	-0.97	22.12	-66.7	0.00	100.0
	Week 4	112	5.65	13.34	0.0	0.00	66.7	102	-1.63	19.55	-66.7	0.00	66.7
	Week 5	113	6.78	16.16	0.0	0.00	66.7	103	0.65	19.79	-66.7	0.00	66.7
	Week 6	107	7.48	16.70	0.0	0.00	100.0	98	1.36	19.69	-33.3	0.00	100.0
	Week 7	109	4.89	14.92	0.0	0.00	100.0	100	-2.33	19.10	-66.7	0.00	100.0
	Week 8	106	4.40	13.07	0.0	0.00	66.7	98	-2.38	17.42	-66.7	0.00	66.7
	Week 9	105	4.44	11.38	0.0	0.00	33.3	94	-1.77	18.53	-66.7	0.00	33.3

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	104	3.85	14.17	0.0	0.00	100.0	96	-2.78	16.52	-66.7	0.00	66.7
	Week 11	91	4.40	12.38	0.0	0.00	66.7	83	-3.61	17.27	-66.7	0.00	66.7
	Week 12	94	5.67	14.37	0.0	0.00	66.7	84	-1.19	21.61	-66.7	0.00	66.7
	Week 14	90	3.70	10.53	0.0	0.00	33.3	79	-3.38	16.53	-66.7	0.00	33.3
	Week 17	90	6.30	14.90	0.0	0.00	66.7	80	-2.50	18.96	-66.7	0.00	66.7
	Week 20	74	7.21	13.81	0.0	0.00	33.3	64	-0.52	20.99	-66.7	0.00	33.3
	Week 23	63	7.41	16.33	0.0	0.00	66.7	58	0.00	24.18	-66.7	0.00	66.7
	Week 26	55	3.64	10.49	0.0	0.00	33.3	52	-4.49	19.83	-66.7	0.00	33.3
	Week 29	53	9.43	18.92	0.0	0.00	66.7	50	0.67	23.80	-66.7	0.00	66.7
	Week 32	42	4.76	11.80	0.0	0.00	33.3	40	-4.17	17.19	-66.7	0.00	33.3
	Week 35	39	6.84	15.63	0.0	0.00	66.7	36	-1.85	17.72	-66.7	0.00	33.3
	Week 38	37	6.31	13.23	0.0	0.00	33.3	34	-2.94	17.15	-66.7	0.00	33.3
	Week 41	33	8.08	14.51	0.0	0.00	33.3	31	0.00	21.08	-66.7	0.00	33.3
	Week 44	32	9.37	17.42	0.0	0.00	66.7	30	1.11	26.96	-66.7	0.00	66.7
	Week 47	28	5.95	13.00	0.0	0.00	33.3	26	-3.85	28.79	-66.7	0.00	33.3
	Week 50	22	10.61	18.93	0.0	0.00	66.7	20	1.67	25.30	-66.7	0.00	33.3
	Week 53	19	15.79	25.74	0.0	0.00	100.0	17	-1.96	27.56	-66.7	0.00	33.3
	Week 56	18	12.96	28.33	0.0	0.00	100.0	17	-1.96	27.57	-66.7	0.00	66.7
	Week 59	13	7.69	19.97	0.0	0.00	66.7	12	-2.78	22.29	-66.7	0.00	33.3
	Week 62	11	9.09	21.56	0.0	0.00	66.7	11	3.03	31.46	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Lymph node only	EV+Pembro (N= 43)												
	BASELINE	33	5.05	12.14	0.0	0.00	33.3						
	Week 1	30	5.56	12.63	0.0	0.00	33.3	24	1.39	15.48	-33.3	0.00	33.3
	Week 2	34	5.88	12.90	0.0	0.00	33.3	27	3.70	16.88	-33.3	0.00	33.3
	Week 3	35	9.52	17.28	0.0	0.00	66.7	28	7.14	21.00	-33.3	0.00	66.7
	Week 4	36	7.41	16.16	0.0	0.00	66.7	30	1.11	13.79	-33.3	0.00	33.3
	Week 5	33	9.09	15.07	0.0	0.00	33.3	27	3.70	16.88	-33.3	0.00	33.3
	Week 6	34	9.80	17.46	0.0	0.00	66.7	28	4.76	14.95	-33.3	0.00	33.3
	Week 7	34	9.80	20.97	0.0	0.00	100.0	28	1.19	14.29	-33.3	0.00	33.3
	Week 8	35	9.52	19.08	0.0	0.00	66.7	29	1.15	10.85	-33.3	0.00	33.3
	Week 9	30	12.22	23.95	0.0	0.00	66.7	24	4.17	22.66	-33.3	0.00	66.7
	Week 10	31	7.53	16.58	0.0	0.00	66.7	26	1.28	11.47	-33.3	0.00	33.3
	Week 11	34	7.84	16.53	0.0	0.00	66.7	27	0.00	9.24	-33.3	0.00	33.3
	Week 12	35	7.62	14.20	0.0	0.00	33.3	28	2.38	12.60	-33.3	0.00	33.3
	Week 14	30	6.67	16.14	0.0	0.00	66.7	23	4.35	18.27	-33.3	0.00	66.7
	Week 17	30	3.33	10.17	0.0	0.00	33.3	24	0.00	9.83	-33.3	0.00	33.3
	Week 20	27	3.70	10.67	0.0	0.00	33.3	21	-1.59	12.81	-33.3	0.00	33.3
	Week 23	27	4.94	12.07	0.0	0.00	33.3	21	1.59	12.81	-33.3	0.00	33.3
	Week 26	27	7.41	16.88	0.0	0.00	66.7	22	0.00	14.55	-33.3	0.00	33.3
	Week 29	28	7.14	21.00	0.0	0.00	100.0	23	4.35	25.23	-33.3	0.00	100.0
	Week 32	24	9.72	18.33	0.0	0.00	66.7	20	1.67	13.13	-33.3	0.00	33.3
	Week 35	22	9.09	21.04	0.0	0.00	66.7	18	1.85	21.30	-33.3	0.00	66.7
	Week 38	21	6.35	17.06	0.0	0.00	66.7	17	3.92	16.17	0.0	0.00	66.7
	Week 41	22	6.06	16.70	0.0	0.00	66.7	17	3.92	20.01	-33.3	0.00	66.7
	Week 44	22	6.06	13.16	0.0	0.00	33.3	16	4.17	16.67	-33.3	0.00	33.3
	Week 47	21	4.76	11.95	0.0	0.00	33.3	16	2.08	14.75	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	11.67	19.57	0.0	0.00	66.7	16	8.33	19.25	0.0	0.00	66.7
	Week 53	18	9.26	19.15	0.0	0.00	66.7	14	4.76	22.10	-33.3	0.00	66.7
	Week 56	21	7.94	17.97	0.0	0.00	66.7	17	3.92	20.01	-33.3	0.00	66.7
	Week 59	21	6.35	17.06	0.0	0.00	66.7	16	2.08	19.12	-33.3	0.00	66.7
	Week 62	19	3.51	10.51	0.0	0.00	33.3	15	0.00	12.60	-33.3	0.00	33.3
	Week 65	16	2.08	8.33	0.0	0.00	33.3	14	0.00	13.07	-33.3	0.00	33.3
	Week 68	13	5.13	12.52	0.0	0.00	33.3	11	3.03	17.98	-33.3	0.00	33.3
	Week 71	13	2.56	9.24	0.0	0.00	33.3	11	0.00	14.91	-33.3	0.00	33.3
	Week 74	13	2.56	9.24	0.0	0.00	33.3	11	-3.03	10.05	-33.3	0.00	0.0
	Week 77	13	0.00	0.00	0.0	0.00	0.0	10	-3.33	10.54	-33.3	0.00	0.0
	Week 80	13	2.56	9.24	0.0	0.00	33.3	11	0.00	14.91	-33.3	0.00	33.3
	Week 83	11	3.03	10.05	0.0	0.00	33.3	10	0.00	15.71	-33.3	0.00	33.3
	Week 86	11	3.03	10.05	0.0	0.00	33.3	10	0.00	15.71	-33.3	0.00	33.3
	Plat+Gem (N= 37)												
	BASELINE	29	2.30	8.60	0.0	0.00	33.3						
	Week 1	26	2.56	13.08	0.0	0.00	66.7	25	1.33	15.15	-33.3	0.00	66.7
	Week 2	30	21.11	30.93	0.0	0.00	100.0	26	19.23	31.51	0.0	0.00	100.0
	Week 3	30	11.11	18.22	0.0	0.00	66.7	26	10.26	20.59	-33.3	0.00	66.7
	Week 4	32	9.37	17.42	0.0	0.00	66.7	27	4.94	15.20	-33.3	0.00	33.3
	Week 5	33	11.11	19.84	0.0	0.00	66.7	28	4.76	14.95	-33.3	0.00	33.3
	Week 6	32	13.54	23.74	0.0	0.00	100.0	27	8.64	23.74	-33.3	0.00	100.0
	Week 7	31	5.38	12.46	0.0	0.00	33.3	26	1.28	14.85	-33.3	0.00	33.3
	Week 8	32	9.37	17.42	0.0	0.00	66.7	27	4.94	15.20	-33.3	0.00	33.3
	Week 9	30	6.67	13.56	0.0	0.00	33.3	25	4.00	14.66	-33.3	0.00	33.3
	Week 10	30	5.56	15.37	0.0	0.00	66.7	26	2.56	18.67	-33.3	0.00	66.7
	Week 11	29	4.60	11.70	0.0	0.00	33.3	25	1.33	11.71	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.23.2.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 12	28	4.76	11.88	0.0	0.00	33.3	23	0.00	14.21	-33.3	0.00	33.3
	Week 14	28	7.14	13.93	0.0	0.00	33.3	23	4.35	15.26	-33.3	0.00	33.3
	Week 17	25	8.00	14.53	0.0	0.00	33.3	21	4.76	15.93	-33.3	0.00	33.3
	Week 20	23	5.80	12.92	0.0	0.00	33.3	20	1.67	13.13	-33.3	0.00	33.3
	Week 23	20	3.33	10.26	0.0	0.00	33.3	17	0.00	11.78	-33.3	0.00	33.3
	Week 26	21	6.35	17.06	0.0	0.00	66.7	18	1.85	17.98	-33.3	0.00	66.7
	Week 29	19	10.53	15.92	0.0	0.00	33.3	16	6.25	18.13	-33.3	0.00	33.3
	Week 32	18	1.85	7.86	0.0	0.00	33.3	15	-4.44	11.73	-33.3	0.00	0.0
	Week 35	19	3.51	10.51	0.0	0.00	33.3	16	-2.08	14.75	-33.3	0.00	33.3
	Week 38	15	4.44	11.73	0.0	0.00	33.3	12	-2.78	17.16	-33.3	0.00	33.3
	Week 41	15	4.44	11.73	0.0	0.00	33.3	12	-2.78	17.16	-33.3	0.00	33.3
	Week 44	14	9.52	20.38	0.0	0.00	66.7	11	0.00	14.91	-33.3	0.00	33.3
	Week 47	12	8.33	20.72	0.0	0.00	66.7	10	-3.33	18.92	-33.3	0.00	33.3
	Week 50	11	6.06	20.10	0.0	0.00	66.7	8	-8.33	15.43	-33.3	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1: EQ-5D-5L - Observed Means and Change from Baseline of VAS - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
EV+Pembro (N=240)												
BASELINE	211	74.98	16.85	15.0	79.00	100.0						
Week 1	190	71.28	18.75	18.0	74.50	100.0	188	-3.95	14.94	-62.0	-2.00	66.0
Week 2	204	70.00	19.44	0.0	73.00	100.0	193	-5.47	16.21	-81.0	-2.00	31.0
Week 3	199	68.81	20.23	17.0	72.00	100.0	186	-6.00	17.14	-66.0	-3.00	31.0
Week 4	195	74.40	17.87	20.0	80.00	100.0	182	-1.49	16.94	-63.0	0.00	72.0
Week 5	193	74.01	18.14	25.0	79.00	100.0	178	-1.84	17.86	-69.0	-1.00	65.0
Week 6	191	75.04	17.79	11.0	79.00	100.0	175	-1.12	17.14	-60.0	0.00	58.0
Week 7	196	75.01	18.84	0.0	80.00	100.0	179	-1.66	18.86	-81.0	0.00	62.0
Week 8	193	74.61	18.49	5.0	80.00	100.0	175	-0.97	18.18	-65.0	1.00	70.0
Week 9	198	73.74	19.28	19.0	80.00	100.0	183	-1.91	18.85	-78.0	0.00	44.0
Week 10	191	75.51	16.94	28.0	80.00	100.0	177	0.49	16.93	-48.0	1.00	71.0
Week 11	196	75.55	17.34	11.0	79.50	100.0	179	-0.16	17.34	-44.0	0.00	71.0
Week 12	186	75.21	18.70	10.0	80.00	100.0	173	-0.90	18.77	-88.0	0.00	71.0
Week 14	186	74.10	19.04	6.0	79.50	100.0	169	-1.53	19.82	-85.0	0.00	73.0
Week 17	178	74.35	18.36	20.0	79.50	100.0	164	-1.67	18.92	-53.0	-2.00	73.0
Week 20	168	74.83	18.73	10.0	80.00	100.0	156	-1.39	19.01	-59.0	0.00	42.0
Week 23	162	72.66	20.10	1.0	80.00	100.0	152	-3.67	19.98	-68.0	-0.50	50.0
Week 26	157	73.40	19.57	23.0	78.00	100.0	146	-2.32	19.13	-56.0	-0.50	57.0
Week 29	157	72.78	18.72	13.0	78.00	100.0	146	-3.45	17.72	-60.0	-2.00	58.0
Week 32	135	72.04	19.05	19.0	75.00	100.0	125	-4.99	18.03	-60.0	-2.00	39.0
Week 35	133	73.89	18.83	19.0	79.00	100.0	123	-4.41	16.97	-57.0	-1.00	43.0
Week 38	133	73.53	19.23	13.0	76.00	100.0	125	-2.89	18.78	-60.0	-2.00	67.0
Week 41	129	74.06	19.33	17.0	79.00	100.0	119	-3.01	16.43	-50.0	-2.00	42.0
Week 44	108	73.19	18.31	13.0	76.50	100.0	100	-4.40	17.00	-49.0	-4.00	41.0
Week 47	100	72.58	20.44	20.0	78.50	100.0	94	-5.06	19.34	-60.0	-2.50	51.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1: EQ-5D-5L - Observed Means and Change from Baseline of VAS - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	89	74.55	18.92	29.0	80.00	100.0	84	-4.33	16.80	-60.0	-1.00	37.0
Week 53	79	73.91	19.57	20.0	79.00	100.0	74	-5.20	17.42	-65.0	-1.50	32.0
Week 56	81	74.80	19.44	14.0	80.00	100.0	76	-3.75	18.61	-71.0	0.00	35.0
Week 59	72	74.57	18.65	20.0	78.50	99.0	68	-5.26	17.11	-70.0	-2.00	29.0
Week 62	65	72.54	22.06	15.0	79.00	100.0	63	-7.22	20.01	-65.0	-1.00	31.0
Week 65	58	75.21	19.84	23.0	80.00	100.0	54	-5.04	18.80	-60.0	-0.50	35.0
Week 68	53	74.26	20.01	13.0	78.00	99.0	52	-6.12	18.95	-70.0	-2.00	35.0
Week 71	51	75.41	20.86	15.0	80.00	100.0	49	-5.61	19.27	-70.0	-1.00	34.0
Week 74	47	74.06	19.74	15.0	75.00	100.0	46	-6.07	18.69	-50.0	-4.50	35.0
Week 77	45	72.11	22.11	20.0	75.00	100.0	43	-8.53	21.23	-70.0	-6.00	33.0
Week 80	40	73.78	21.22	20.0	76.50	100.0	38	-7.08	19.81	-65.0	-6.00	34.0
Week 83	37	73.19	22.44	16.0	75.00	100.0	36	-5.86	21.20	-70.0	-5.00	37.0
Week 86	34	72.82	24.15	10.0	79.50	99.0	32	-7.50	22.44	-75.0	-5.50	33.0
Week 89	33	72.55	22.88	9.0	75.00	100.0	31	-6.77	21.58	-75.0	-5.00	35.0
Week 92	27	75.89	20.21	9.0	79.00	100.0	25	-5.48	18.96	-51.0	-1.00	35.0
Week 95	22	72.23	23.27	6.0	74.00	98.0	21	-8.33	20.87	-54.0	-6.00	26.0
Week 98	18	76.00	23.73	8.0	80.50	100.0	17	-3.59	19.75	-52.0	-1.00	35.0
Week 101	14	77.57	22.52	29.0	80.50	99.0	14	-3.00	20.91	-47.0	0.00	33.0
Week 104	10	77.10	17.32	48.0	75.00	97.0	10	-3.60	17.84	-33.0	-1.00	32.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1: EQ-5D-5L - Observed Means and Change from Baseline of VAS - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Plat+Gem (N=242)												
BASELINE	190	69.00	21.05	0.0	71.00	100.0						
Week 1	179	66.50	20.77	0.0	70.00	100.0	164	-3.14	17.37	-75.0	-2.00	66.0
Week 2	174	67.61	20.27	0.0	70.00	100.0	154	-2.10	19.29	-81.0	-1.00	65.0
Week 3	186	70.37	19.31	7.0	75.00	100.0	164	-0.52	17.99	-61.0	0.00	60.0
Week 4	184	69.83	18.92	9.0	72.00	100.0	158	-0.89	16.70	-53.0	-1.50	70.0
Week 5	188	69.22	19.18	0.0	71.50	100.0	158	-2.62	18.20	-42.0	-3.00	70.0
Week 6	174	67.93	20.02	11.0	71.00	100.0	151	-0.92	17.51	-53.0	-2.00	70.0
Week 7	188	68.09	19.37	1.0	70.00	100.0	161	-1.86	18.34	-49.0	-1.00	70.0
Week 8	168	67.25	20.05	0.0	69.50	100.0	147	-3.52	21.95	-86.0	-3.00	70.0
Week 9	178	67.76	20.20	10.0	70.00	100.0	153	-2.29	20.59	-70.0	-1.00	70.0
Week 10	166	66.85	20.14	9.0	70.00	100.0	141	-2.08	19.57	-63.0	-2.00	70.0
Week 11	168	68.85	19.53	5.0	70.00	100.0	145	-1.28	19.03	-56.0	-1.00	67.0
Week 12	160	69.46	19.38	1.0	71.00	100.0	141	-0.97	20.44	-59.0	-1.00	68.0
Week 14	154	68.80	19.61	10.0	70.00	100.0	130	-2.37	20.42	-61.0	-1.50	70.0
Week 17	156	68.59	21.13	8.0	70.50	100.0	133	-1.78	21.43	-49.0	-1.00	69.0
Week 20	127	72.41	19.72	10.0	78.00	100.0	111	0.69	18.56	-51.0	2.00	47.0
Week 23	117	72.62	21.72	2.0	79.00	100.0	100	-0.91	20.92	-50.0	0.00	64.0
Week 26	108	73.91	20.36	8.0	80.00	100.0	96	-1.21	22.10	-51.0	0.00	73.0
Week 29	100	74.19	20.48	3.0	78.00	100.0	87	-1.47	22.84	-86.0	0.00	64.0
Week 32	83	75.30	18.87	12.0	80.00	100.0	77	0.31	18.55	-38.0	-1.00	61.0
Week 35	76	73.75	18.00	20.0	79.50	100.0	70	-0.31	19.73	-45.0	-1.00	76.0
Week 38	74	71.72	22.21	20.0	78.50	100.0	66	-1.76	20.55	-55.0	-0.50	70.0
Week 41	65	73.22	19.43	27.0	78.00	100.0	57	-0.33	20.22	-49.0	0.00	71.0
Week 44	60	73.47	19.31	11.0	79.00	100.0	54	-1.24	19.31	-52.0	0.00	67.0
Week 47	57	74.07	19.35	0.0	79.00	100.0	51	-1.25	17.89	-39.0	-1.00	72.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1: EQ-5D-5L - Observed Means and Change from Baseline of VAS - Analysis Set mITT 1

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	51	72.80	21.03	1.0	78.00	100.0	47	-1.11	15.59	-38.0	0.00	52.0
Week 53	46	77.63	17.04	32.0	84.00	100.0	42	1.55	17.88	-36.0	0.00	74.0
Week 56	39	73.90	22.89	20.0	77.00	100.0	34	-0.18	24.78	-65.0	0.00	70.0
Week 59	37	79.51	17.59	23.0	84.00	100.0	33	3.79	22.14	-68.0	0.00	68.0
Week 62	32	77.44	18.43	11.0	78.00	100.0	29	1.34	25.40	-80.0	0.00	67.0
Week 65	30	76.40	20.77	9.0	79.50	100.0	26	1.46	27.58	-82.0	1.50	63.0
Week 68	25	72.96	23.25	13.0	82.00	100.0	21	0.52	26.81	-78.0	0.00	67.0
Week 71	22	70.23	25.69	16.0	76.00	100.0	19	1.11	31.48	-75.0	0.00	81.0
Week 74	21	70.90	20.47	20.0	74.00	100.0	18	4.11	20.51	-32.0	0.00	58.0
Week 77	18	71.50	26.23	0.0	79.50	100.0	15	3.67	25.10	-38.0	1.00	70.0
Week 80	14	75.50	15.43	50.0	77.50	100.0	13	0.85	14.44	-20.0	0.00	28.0
Week 83	13	74.46	14.96	49.0	71.00	100.0	12	1.67	16.70	-34.0	3.50	26.0
Week 86	12	83.00	13.38	56.0	90.00	100.0	11	4.36	10.84	-19.0	2.00	24.0
Week 89	11	80.64	16.81	40.0	89.00	100.0	10	2.80	13.09	-20.0	1.00	29.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1.1: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Present	EV+Pembro (N= 48)												
	BASELINE	39	68.82	19.21	15.0	70.00	100.0						
	Week 1	32	67.63	21.97	20.0	70.00	100.0	32	-1.97	22.47	-50.0	-3.00	66.0
	Week 2	38	57.16	23.51	0.0	60.00	93.0	34	-15.00	21.66	-81.0	-11.00	31.0
	Week 3	35	59.03	23.46	17.0	59.00	100.0	30	-8.07	19.09	-53.0	-2.00	25.0
	Week 4	36	68.69	17.89	32.0	69.00	99.0	31	-0.71	21.47	-38.0	0.00	72.0
	Week 5	31	67.48	17.93	31.0	72.00	99.0	25	-1.92	24.62	-54.0	0.00	65.0
	Week 6	32	65.78	21.18	11.0	70.00	95.0	26	-5.73	26.20	-60.0	-4.00	58.0
	Week 7	35	66.86	21.71	0.0	70.00	96.0	29	-2.24	25.18	-81.0	0.00	62.0
	Week 8	37	66.08	19.66	21.0	74.00	94.0	32	-3.78	25.31	-61.0	-2.50	70.0
	Week 9	35	65.91	23.22	19.0	68.00	100.0	31	-5.26	25.35	-71.0	-5.00	41.0
	Week 10	34	70.59	18.80	31.0	70.50	95.0	30	1.83	21.62	-35.0	2.50	71.0
	Week 11	35	67.14	21.20	11.0	70.00	96.0	30	-2.17	25.17	-44.0	0.00	71.0
	Week 12	33	70.64	21.93	28.0	76.00	97.0	29	2.38	25.01	-52.0	3.00	71.0
	Week 14	32	68.22	24.91	6.0	73.50	97.0	26	-1.04	32.84	-85.0	0.00	73.0
	Week 17	31	69.03	21.90	22.0	72.00	97.0	25	2.80	24.95	-48.0	2.00	73.0
	Week 20	27	69.81	20.29	29.0	76.00	97.0	24	-1.04	19.78	-41.0	-1.50	40.0
	Week 23	26	70.42	20.23	30.0	79.00	96.0	23	1.35	21.92	-47.0	5.00	49.0
	Week 26	26	72.38	20.30	25.0	78.00	98.0	23	4.09	22.39	-34.0	2.00	57.0
	Week 29	23	71.57	19.85	28.0	73.00	98.0	22	2.55	21.50	-43.0	1.00	58.0
	Week 32	21	69.29	19.13	30.0	68.00	94.0	19	-0.74	15.12	-35.0	0.00	30.0
	Week 35	20	69.00	20.14	31.0	70.50	92.0	18	-2.83	16.54	-27.0	-0.50	43.0
	Week 38	19	68.47	20.19	40.0	70.00	99.0	18	1.67	24.70	-35.0	-5.00	67.0
	Week 41	20	70.60	22.96	20.0	80.50	93.0	19	0.16	20.21	-47.0	0.00	40.0
	Week 44	17	67.94	20.68	25.0	70.00	95.0	15	-2.53	18.97	-28.0	-5.00	41.0
	Week 47	18	65.11	25.22	25.0	67.00	99.0	16	-5.56	26.59	-58.0	-1.50	51.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1.1: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	12	68.00	23.46	29.0	76.50	97.0	11	-5.82	16.37	-44.0	0.00	10.0
	Week 53	12	66.75	28.17	20.0	75.50	98.0	11	-7.27	22.59	-65.0	-5.00	28.0
	Week 56	13	67.46	26.54	14.0	79.00	98.0	12	-7.50	24.32	-71.0	-1.50	30.0
	Week 59	12	71.67	23.93	24.0	80.00	96.0	11	-5.45	21.57	-61.0	-2.00	29.0
	Week 62	10	74.30	26.94	20.0	87.00	97.0	9	-3.89	25.98	-65.0	1.00	31.0
	Week 65	10	71.70	24.54	28.0	81.50	95.0	9	-5.56	23.21	-57.0	0.00	30.0
	Plat+Gem (N= 48)												
	BASELINE	34	65.50	23.85	20.0	70.00	98.0						
	Week 1	32	63.03	22.43	28.0	60.50	100.0	29	-2.52	18.91	-44.0	0.00	24.0
	Week 2	29	61.41	20.52	16.0	64.00	93.0	24	-3.63	20.62	-56.0	-1.50	22.0
	Week 3	32	70.44	18.74	21.0	73.00	97.0	27	1.93	16.08	-31.0	1.00	47.0
	Week 4	32	70.47	17.20	35.0	71.00	99.0	24	2.13	16.61	-29.0	3.00	35.0
	Week 5	36	68.47	15.86	38.0	70.00	96.0	28	-0.32	17.22	-32.0	-1.50	45.0
	Week 6	35	65.17	21.55	18.0	67.00	100.0	28	3.96	17.82	-30.0	2.50	46.0
	Week 7	38	67.92	18.01	38.0	65.00	100.0	30	4.53	18.34	-41.0	6.50	36.0
	Week 8	31	69.32	14.54	47.0	68.00	94.0	26	-0.35	19.69	-41.0	-3.00	54.0
	Week 9	32	64.44	16.77	31.0	64.50	100.0	26	3.85	18.73	-40.0	3.50	47.0
	Week 10	34	65.26	18.42	28.0	67.50	97.0	27	4.52	18.13	-31.0	2.00	37.0
	Week 11	30	69.77	16.41	30.0	70.00	100.0	25	5.28	20.46	-35.0	0.00	47.0
	Week 12	28	69.96	16.45	40.0	70.50	100.0	24	8.04	21.13	-39.0	8.50	49.0
	Week 14	27	70.30	16.18	37.0	70.00	95.0	22	4.50	22.15	-40.0	0.00	51.0
	Week 17	30	69.83	19.21	19.0	70.00	100.0	26	5.46	20.68	-39.0	1.50	48.0
	Week 20	23	72.61	17.37	43.0	73.00	100.0	21	5.19	23.25	-38.0	4.00	47.0
	Week 23	22	70.68	24.57	8.0	73.00	97.0	19	2.58	22.55	-49.0	2.00	46.0
	Week 26	19	77.53	15.74	50.0	82.00	100.0	18	1.50	18.76	-40.0	1.00	40.0
	Week 29	16	72.88	23.09	15.0	81.50	97.0	14	-3.79	26.52	-76.0	1.00	31.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1.1: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 32	11	72.82	13.78	48.0	70.00	95.0	11	-1.91	19.57	-25.0	-6.00	38.0
	Week 35	10	70.20	20.02	40.0	68.50	93.0	9	-4.89	21.23	-28.0	-6.00	35.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1.1: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Absent	EV+Pembro (N=192)												
	BASELINE	172	76.37	16.00	20.0	80.00	100.0						
	Week 1	158	72.02	18.02	18.0	75.00	100.0	156	-4.36	12.94	-62.0	-2.00	40.0
	Week 2	166	72.95	17.16	20.0	75.00	100.0	159	-3.43	14.06	-49.0	-1.00	30.0
	Week 3	164	70.90	18.90	17.0	75.00	100.0	156	-5.60	16.78	-66.0	-3.50	31.0
	Week 4	159	75.69	17.67	20.0	80.00	100.0	151	-1.66	15.94	-63.0	0.00	40.0
	Week 5	162	75.26	17.97	25.0	80.00	100.0	153	-1.83	16.61	-69.0	-1.00	42.0
	Week 6	159	76.90	16.49	30.0	80.00	100.0	149	-0.32	15.00	-43.0	0.00	40.0
	Week 7	161	76.78	17.75	12.0	80.00	100.0	150	-1.55	17.49	-68.0	0.00	45.0
	Week 8	156	76.63	17.67	5.0	80.00	100.0	143	-0.34	16.21	-65.0	1.00	39.0
	Week 9	163	75.42	17.97	22.0	80.00	100.0	152	-1.22	17.25	-78.0	0.00	44.0
	Week 10	157	76.58	16.38	28.0	80.00	100.0	147	0.22	15.88	-48.0	1.00	53.0
	Week 11	161	77.37	15.88	26.0	80.00	100.0	149	0.24	15.38	-42.0	0.00	50.0
	Week 12	153	76.20	17.85	10.0	80.00	100.0	144	-1.56	17.28	-88.0	0.00	51.0
	Week 14	154	75.32	17.43	17.0	80.00	100.0	143	-1.62	16.58	-66.0	0.00	50.0
	Week 17	147	75.47	17.41	20.0	80.00	100.0	139	-2.47	17.62	-53.0	-2.00	50.0
	Week 20	141	75.79	18.34	10.0	80.00	100.0	132	-1.45	18.94	-59.0	0.00	42.0
	Week 23	136	73.09	20.12	1.0	80.00	100.0	129	-4.57	19.57	-68.0	-1.00	50.0
	Week 26	131	73.60	19.49	23.0	78.00	100.0	123	-3.52	18.31	-56.0	-1.00	45.0
	Week 29	134	72.99	18.59	13.0	79.00	100.0	124	-4.52	16.84	-60.0	-3.50	40.0
	Week 32	114	72.55	19.08	19.0	76.00	100.0	106	-5.75	18.46	-60.0	-2.00	39.0
	Week 35	113	74.75	18.55	19.0	80.00	100.0	105	-4.69	17.11	-57.0	-2.00	38.0
	Week 38	114	74.38	19.03	13.0	77.50	100.0	107	-3.65	17.63	-60.0	-2.00	37.0
	Week 41	109	74.70	18.64	17.0	79.00	100.0	100	-3.61	15.66	-50.0	-2.00	42.0
	Week 44	91	74.16	17.78	13.0	78.00	100.0	85	-4.73	16.73	-49.0	-3.00	38.0
	Week 47	82	74.22	19.03	20.0	79.50	100.0	78	-4.96	17.72	-60.0	-3.50	37.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1.1: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	77	75.57	18.09	30.0	80.00	100.0	73	-4.11	16.96	-60.0	-1.00	37.0
	Week 53	67	75.19	17.59	27.0	79.00	100.0	63	-4.84	16.56	-60.0	-1.00	32.0
	Week 56	68	76.21	17.68	20.0	80.00	100.0	64	-3.05	17.49	-65.0	0.00	35.0
	Week 59	60	75.15	17.60	20.0	77.50	99.0	57	-5.23	16.34	-70.0	-2.00	28.0
	Week 62	55	72.22	21.33	15.0	76.00	100.0	54	-7.78	19.08	-65.0	-1.00	26.0
	Week 65	48	75.94	18.94	23.0	80.00	100.0	45	-4.93	18.10	-60.0	-1.00	35.0
	Week 68	46	74.41	18.80	13.0	75.50	99.0	45	-6.64	18.15	-70.0	-3.00	33.0
	Week 71	44	76.70	19.45	15.0	80.00	100.0	42	-5.74	18.59	-70.0	-1.00	32.0
	Week 74	40	75.13	18.03	15.0	75.00	100.0	39	-6.41	18.39	-50.0	-5.00	35.0
	Week 77	39	73.44	20.22	20.0	75.00	100.0	37	-8.57	20.55	-70.0	-6.00	32.0
	Week 80	35	75.86	19.24	20.0	78.00	100.0	33	-6.94	19.22	-65.0	-6.00	34.0
	Week 83	32	75.00	20.71	16.0	76.50	100.0	31	-5.90	20.71	-70.0	-5.00	35.0
	Week 86	29	73.90	23.30	10.0	79.00	99.0	27	-8.52	22.49	-75.0	-6.00	33.0
	Week 89	29	73.62	21.74	9.0	75.00	100.0	27	-7.56	21.61	-75.0	-5.00	35.0
	Week 92	24	76.25	20.51	9.0	78.50	100.0	22	-4.68	19.02	-51.0	-1.00	35.0
	Week 95	20	74.25	23.33	6.0	77.50	98.0	19	-6.47	20.51	-54.0	0.00	26.0
	Week 98	18	76.00	23.73	8.0	80.50	100.0	17	-3.59	19.75	-52.0	-1.00	35.0
	Week 101	13	80.62	20.23	29.0	81.00	99.0	13	0.38	17.32	-35.0	1.00	33.0
	Plat+Gem (N=194)												
	BASELINE	156	69.76	20.39	0.0	73.00	100.0						
	Week 1	147	67.26	20.40	0.0	70.00	100.0	135	-3.27	17.09	-75.0	-2.00	66.0
	Week 2	145	68.86	20.06	0.0	70.00	100.0	130	-1.82	19.11	-81.0	-1.00	65.0
	Week 3	154	70.35	19.49	7.0	76.50	100.0	137	-1.00	18.36	-61.0	-1.00	60.0
	Week 4	152	69.69	19.31	9.0	72.00	100.0	134	-1.43	16.72	-53.0	-2.00	70.0
	Week 5	152	69.40	19.93	0.0	72.50	100.0	130	-3.12	18.43	-42.0	-3.50	70.0
	Week 6	139	68.63	19.63	11.0	71.00	100.0	123	-2.03	17.31	-53.0	-3.00	70.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1.1: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 7	150	68.13	19.76	1.0	71.00	100.0	131	-3.33	18.10	-49.0	-2.00	70.0
	Week 8	137	66.78	21.12	0.0	70.00	100.0	121	-4.21	22.43	-86.0	-4.00	70.0
	Week 9	146	68.49	20.85	10.0	70.00	100.0	127	-3.54	20.79	-70.0	-1.00	70.0
	Week 10	132	67.26	20.61	9.0	70.00	100.0	114	-3.64	19.65	-63.0	-3.00	70.0
	Week 11	138	68.64	20.19	5.0	70.00	100.0	120	-2.64	18.51	-56.0	-2.00	67.0
	Week 12	132	69.35	20.01	1.0	71.00	100.0	117	-2.82	19.89	-59.0	-1.00	68.0
	Week 14	127	68.48	20.31	10.0	70.00	100.0	108	-3.77	19.87	-61.0	-2.50	70.0
	Week 17	126	68.29	21.62	8.0	71.00	100.0	107	-3.54	21.33	-49.0	-2.00	69.0
	Week 20	104	72.37	20.28	10.0	79.00	100.0	90	-0.36	17.27	-51.0	0.50	44.0
	Week 23	95	73.06	21.13	2.0	80.00	100.0	81	-1.73	20.58	-50.0	0.00	64.0
	Week 26	89	73.13	21.21	8.0	80.00	100.0	78	-1.83	22.86	-51.0	0.00	73.0
	Week 29	84	74.44	20.09	3.0	78.00	100.0	73	-1.03	22.24	-86.0	0.00	64.0
	Week 32	72	75.68	19.58	12.0	80.00	100.0	66	0.68	18.51	-38.0	-0.50	61.0
	Week 35	66	74.29	17.78	20.0	80.00	100.0	61	0.36	19.59	-45.0	-1.00	76.0
	Week 38	66	71.15	22.74	20.0	77.00	100.0	58	-0.88	21.05	-55.0	0.00	70.0
	Week 41	62	73.35	19.79	27.0	78.00	100.0	54	-0.50	19.79	-49.0	0.00	71.0
	Week 44	55	74.22	18.58	11.0	80.00	100.0	49	0.04	18.31	-34.0	0.00	67.0
	Week 47	52	74.21	19.87	0.0	79.50	100.0	46	-0.76	17.88	-39.0	-1.50	72.0
	Week 50	48	72.23	21.44	1.0	77.00	100.0	44	-1.41	16.01	-38.0	-0.50	52.0
	Week 53	41	77.88	17.64	32.0	84.00	100.0	37	2.54	18.14	-36.0	0.00	74.0
	Week 56	34	75.88	21.95	20.0	82.50	100.0	29	3.07	21.89	-40.0	0.00	70.0
	Week 59	32	80.84	15.63	24.0	85.00	100.0	28	6.32	19.40	-20.0	0.00	68.0
	Week 62	27	79.07	14.50	48.0	79.00	100.0	24	4.29	21.98	-35.0	0.00	67.0
	Week 65	25	78.04	17.29	33.0	82.00	100.0	21	4.95	24.18	-52.0	1.00	63.0
	Week 68	23	75.57	20.47	30.0	85.00	100.0	19	4.58	20.94	-22.0	0.00	67.0
	Week 71	21	72.81	23.21	20.0	79.00	100.0	18	5.33	26.26	-47.0	0.00	81.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1.1: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Liver Metastases - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 74	20	70.95	21.00	20.0	75.50	100.0	17	4.41	21.10	-32.0	0.00	58.0
	Week 77	16	70.19	27.27	0.0	79.50	100.0	13	3.62	27.03	-38.0	1.00	70.0
	Week 80	12	75.08	16.06	50.0	77.50	100.0	11	1.00	15.71	-20.0	0.00	28.0
	Week 83	11	74.00	16.12	49.0	71.00	100.0	10	2.20	18.40	-34.0	8.00	26.0
	Week 86	10	83.50	14.03	56.0	91.00	100.0	9	4.78	12.01	-19.0	2.00	24.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1.2: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
< 65 years	EV+Pembro (N=105)												
	BASELINE	94	74.73	17.94	15.0	79.50	100.0						
	Week 1	88	71.38	19.25	20.0	72.00	100.0	87	-3.85	14.82	-50.0	-2.00	66.0
	Week 2	92	72.78	17.76	20.0	76.50	99.0	88	-3.19	13.42	-49.0	-1.00	31.0
	Week 3	93	71.11	20.20	20.0	75.00	100.0	86	-2.95	13.97	-50.0	0.00	25.0
	Week 4	90	76.87	18.08	30.0	80.50	100.0	83	1.81	16.20	-43.0	1.00	72.0
	Week 5	90	77.09	17.63	31.0	80.00	100.0	82	1.39	17.03	-54.0	0.00	65.0
	Week 6	91	78.44	16.65	35.0	80.00	100.0	83	3.12	16.53	-50.0	1.00	58.0
	Week 7	85	78.87	17.13	27.0	82.00	100.0	78	3.50	15.06	-25.0	1.50	62.0
	Week 8	90	76.76	18.73	10.0	80.00	100.0	82	1.44	17.74	-61.0	1.00	70.0
	Week 9	93	76.84	18.83	20.0	80.00	100.0	86	1.36	16.76	-71.0	0.50	34.0
	Week 10	88	79.43	16.00	28.0	84.50	100.0	82	4.26	16.50	-30.0	4.00	71.0
	Week 11	93	77.95	16.91	26.0	81.00	100.0	85	3.11	17.52	-38.0	1.00	71.0
	Week 12	86	78.85	16.25	29.0	82.00	100.0	80	2.74	17.38	-33.0	0.00	71.0
	Week 14	84	76.31	18.09	23.0	81.00	100.0	77	1.77	17.99	-45.0	0.00	73.0
	Week 17	83	77.40	18.31	20.0	83.00	100.0	78	2.83	19.78	-50.0	2.00	73.0
	Week 20	79	76.80	18.34	27.0	80.00	100.0	74	0.38	18.55	-47.0	0.00	40.0
	Week 23	78	74.35	21.45	1.0	83.00	100.0	73	-0.85	21.80	-68.0	0.00	50.0
	Week 26	78	76.22	19.02	25.0	82.00	100.0	73	0.73	19.93	-50.0	0.00	57.0
	Week 29	74	73.76	19.17	13.0	80.00	100.0	68	-1.37	18.24	-50.0	-1.50	58.0
	Week 32	64	74.44	18.32	30.0	79.50	100.0	59	-1.71	17.55	-60.0	0.00	30.0
	Week 35	62	75.85	16.45	31.0	80.00	100.0	58	-2.09	15.68	-32.0	-1.00	43.0
	Week 38	62	75.02	18.67	30.0	80.00	100.0	59	-0.73	20.54	-60.0	0.00	67.0
	Week 41	64	75.63	19.04	20.0	80.00	100.0	59	-1.47	17.13	-50.0	-1.00	40.0
	Week 44	50	75.08	17.59	25.0	80.00	100.0	48	-2.08	17.67	-40.0	-3.50	41.0
	Week 47	47	72.49	22.30	25.0	80.00	100.0	46	-5.00	21.85	-60.0	-1.50	51.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1.2: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	44	74.23	19.25	29.0	79.50	100.0	41	-5.61	17.26	-60.0	-1.00	25.0
	Week 53	40	74.05	21.83	20.0	79.00	100.0	37	-4.97	20.21	-65.0	0.00	32.0
	Week 56	44	76.27	20.66	14.0	80.50	100.0	41	-2.90	19.64	-71.0	0.00	35.0
	Week 59	42	74.57	20.31	20.0	80.50	98.0	39	-5.28	19.47	-70.0	-2.00	29.0
	Week 62	37	72.54	22.02	20.0	78.00	100.0	36	-5.36	21.00	-65.0	-0.50	31.0
	Week 65	34	74.97	20.46	28.0	80.00	100.0	31	-5.35	20.94	-60.0	0.00	35.0
	Week 68	34	73.71	20.79	20.0	80.00	99.0	33	-5.82	21.08	-70.0	-2.00	35.0
	Week 71	32	75.06	21.56	20.0	80.00	99.0	30	-4.93	21.38	-70.0	-0.50	34.0
	Week 74	29	73.59	19.66	23.0	75.00	100.0	28	-5.71	19.91	-50.0	-5.00	35.0
	Week 77	26	73.23	21.99	20.0	75.00	99.0	24	-6.54	21.86	-70.0	-6.00	33.0
	Week 80	24	72.25	20.82	20.0	72.50	99.0	22	-7.73	21.75	-65.0	-10.00	34.0
	Week 83	23	72.26	21.98	20.0	75.00	100.0	22	-5.36	22.57	-70.0	-5.00	37.0
	Week 86	20	68.00	25.05	15.0	71.00	98.0	18	-9.94	26.58	-75.0	-10.00	33.0
	Week 89	19	70.00	23.47	15.0	68.00	100.0	17	-8.18	24.36	-75.0	-8.00	35.0
	Week 92	14	75.93	15.72	49.0	73.50	100.0	12	-4.67	19.22	-36.0	-2.00	35.0
	Week 95	12	72.17	18.25	44.0	67.50	98.0	11	-8.64	20.21	-41.0	-9.00	26.0
	Plat+Gem (N=106)												
	BASELINE	84	69.99	19.85	20.0	71.50	100.0						
	Week 1	78	65.32	21.03	15.0	69.50	97.0	73	-4.03	16.01	-75.0	-2.00	30.0
	Week 2	77	67.12	22.25	0.0	70.00	100.0	69	-2.45	19.07	-81.0	0.00	30.0
	Week 3	80	70.14	21.58	7.0	80.00	100.0	73	-0.88	15.95	-61.0	0.00	30.0
	Week 4	79	70.32	20.32	9.0	74.00	100.0	68	-1.25	12.02	-49.0	0.00	30.0
	Week 5	80	69.68	20.20	0.0	74.00	100.0	68	-3.29	14.93	-41.0	-1.50	30.0
	Week 6	76	69.34	22.12	18.0	75.00	100.0	68	-0.56	14.27	-34.0	-2.00	30.0
	Week 7	81	69.69	18.71	38.0	72.00	100.0	72	-0.97	15.19	-40.0	0.00	36.0
	Week 8	72	70.94	17.60	20.0	74.50	100.0	65	-0.60	17.92	-70.0	-1.00	54.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1.2: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	78	70.37	18.54	30.0	70.00	100.0	70	0.49	16.34	-40.0	0.50	47.0
	Week 10	78	68.95	19.60	22.0	70.50	100.0	69	0.32	15.62	-50.0	0.00	48.0
	Week 11	75	71.41	18.52	22.0	73.00	100.0	67	0.96	14.94	-42.0	1.00	42.0
	Week 12	74	72.18	18.11	1.0	71.50	100.0	67	1.27	14.78	-50.0	0.00	45.0
	Week 14	68	72.63	17.79	33.0	75.50	100.0	59	1.42	14.29	-23.0	0.00	51.0
	Week 17	68	70.12	21.51	10.0	71.00	100.0	59	0.00	16.74	-42.0	-1.00	48.0
	Week 20	60	75.03	19.99	10.0	80.00	100.0	53	3.68	17.26	-45.0	4.00	47.0
	Week 23	51	79.45	17.14	30.0	82.00	100.0	45	6.00	16.10	-48.0	8.00	46.0
	Week 26	47	77.02	18.69	38.0	81.00	100.0	43	3.40	18.08	-45.0	3.00	50.0
	Week 29	42	78.95	15.17	47.0	79.50	100.0	38	2.50	14.75	-32.0	2.00	42.0
	Week 32	37	78.41	16.14	41.0	83.00	100.0	35	2.60	13.19	-28.0	0.00	41.0
	Week 35	34	77.79	13.49	49.0	80.50	100.0	32	2.22	14.71	-23.0	0.00	39.0
	Week 38	33	75.03	19.70	28.0	80.00	100.0	29	3.76	15.38	-23.0	4.00	41.0
	Week 41	27	74.44	18.56	27.0	81.00	100.0	23	0.96	14.99	-43.0	0.00	26.0
	Week 44	28	77.79	14.42	45.0	80.50	100.0	25	1.96	12.34	-31.0	0.00	21.0
	Week 47	25	72.64	17.56	34.0	77.00	100.0	23	-1.35	10.07	-22.0	0.00	20.0
	Week 50	26	73.19	19.29	40.0	79.50	100.0	24	0.17	10.67	-29.0	0.00	19.0
	Week 53	19	79.58	16.40	42.0	85.00	100.0	17	3.18	9.36	-11.0	0.00	22.0
	Week 56	13	77.85	18.47	38.0	85.00	100.0	11	0.91	19.42	-47.0	0.00	31.0
	Week 59	14	81.29	18.80	24.0	86.50	100.0	12	4.00	13.58	-9.0	0.00	39.0
	Week 62	13	85.15	13.92	51.0	92.00	100.0	12	4.75	15.56	-21.0	1.00	39.0
	Week 65	13	83.69	17.10	33.0	88.00	100.0	11	6.27	13.40	-6.0	2.00	43.0
	Week 68	10	74.10	20.81	32.0	77.50	100.0	8	1.88	14.17	-22.0	1.00	26.0
	Week 77	10	74.40	29.96	0.0	82.50	100.0	8	3.88	8.53	-8.0	0.50	19.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1.2: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>= 65 years	EV+Pembro (N=135)												
	BASELINE	117	75.17	15.99	20.0	78.00	100.0						
	Week 1	102	71.20	18.41	18.0	76.00	100.0	101	-4.04	15.12	-62.0	-1.00	40.0
	Week 2	112	67.72	20.52	0.0	70.00	100.0	105	-7.37	18.07	-81.0	-5.00	30.0
	Week 3	106	66.79	20.13	17.0	70.00	100.0	100	-8.62	19.14	-66.0	-6.00	31.0
	Week 4	105	72.29	17.50	20.0	75.00	100.0	99	-4.26	17.13	-63.0	-2.00	33.0
	Week 5	103	71.32	18.24	25.0	75.00	100.0	96	-4.60	18.18	-69.0	-2.00	42.0
	Week 6	100	71.94	18.31	11.0	74.50	100.0	92	-4.95	16.85	-60.0	-2.00	30.0
	Week 7	111	72.05	19.62	0.0	75.00	100.0	101	-5.65	20.54	-81.0	-4.00	42.0
	Week 8	103	72.73	18.15	5.0	75.00	100.0	93	-3.10	18.38	-65.0	0.00	34.0
	Week 9	105	70.99	19.35	19.0	76.00	100.0	97	-4.80	20.16	-78.0	-3.00	44.0
	Week 10	103	72.17	17.08	32.0	72.00	100.0	95	-2.76	16.70	-48.0	-1.00	33.0
	Week 11	103	73.38	17.53	11.0	77.00	99.0	94	-3.12	16.72	-44.0	-1.50	40.0
	Week 12	100	72.08	20.13	10.0	74.50	100.0	93	-4.02	19.44	-88.0	-1.00	35.0
	Week 14	102	72.28	19.69	6.0	77.50	100.0	92	-4.29	20.93	-85.0	-0.50	50.0
	Week 17	95	71.68	18.09	22.0	72.00	100.0	86	-5.76	17.22	-53.0	-4.50	39.0
	Week 20	89	73.08	19.01	10.0	78.00	100.0	82	-2.99	19.38	-59.0	-0.50	42.0
	Week 23	84	71.10	18.75	30.0	75.00	99.0	79	-6.28	17.87	-50.0	-5.00	36.0
	Week 26	79	70.62	19.82	23.0	73.00	100.0	73	-5.37	17.92	-56.0	-4.00	34.0
	Week 29	83	71.90	18.38	19.0	75.00	97.0	78	-5.27	17.17	-60.0	-2.00	38.0
	Week 32	71	69.89	19.56	19.0	74.00	98.0	66	-7.92	18.08	-52.0	-5.00	39.0
	Week 35	71	72.17	20.64	19.0	78.00	99.0	65	-6.49	17.92	-57.0	-2.00	38.0
	Week 38	71	72.24	19.75	13.0	74.00	100.0	66	-4.82	16.99	-55.0	-2.50	42.0
	Week 41	65	72.52	19.65	17.0	76.00	100.0	60	-4.52	15.71	-43.0	-2.00	42.0
	Week 44	58	71.55	18.90	13.0	74.00	97.0	52	-6.54	16.23	-49.0	-5.00	38.0
	Week 47	53	72.66	18.85	20.0	78.00	100.0	48	-5.13	16.83	-40.0	-4.50	37.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1.2: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	45	74.87	18.81	30.0	80.00	99.0	43	-3.12	16.46	-45.0	-1.00	37.0
	Week 53	39	73.77	17.23	27.0	76.00	96.0	37	-5.43	14.38	-42.0	-4.00	17.0
	Week 56	37	73.05	18.02	20.0	75.00	100.0	35	-4.74	17.55	-40.0	-4.00	32.0
	Week 59	30	74.57	16.39	22.0	75.50	99.0	29	-5.24	13.65	-38.0	-2.00	20.0
	Week 62	28	72.54	22.51	15.0	79.50	100.0	27	-9.70	18.70	-52.0	-1.00	21.0
	Week 65	24	75.54	19.35	23.0	79.50	100.0	23	-4.61	15.89	-40.0	-1.00	21.0
	Week 68	19	75.26	19.03	13.0	76.00	99.0	19	-6.63	15.09	-47.0	-1.00	12.0
	Week 71	19	76.00	20.20	15.0	80.00	100.0	19	-6.68	15.85	-45.0	-6.00	17.0
	Week 74	18	74.83	20.43	15.0	79.00	99.0	18	-6.61	17.16	-45.0	-2.00	18.0
	Week 77	19	70.58	22.78	22.0	73.00	100.0	19	-11.05	20.71	-49.0	-4.00	21.0
	Week 80	16	76.06	22.29	20.0	80.50	100.0	16	-6.19	17.43	-40.0	-1.00	19.0
	Week 83	14	74.71	23.94	16.0	80.00	99.0	14	-6.64	19.64	-44.0	-3.50	20.0
	Week 86	14	79.71	21.83	10.0	82.00	99.0	14	-4.36	16.08	-50.0	-1.50	17.0
	Week 89	14	76.00	22.44	9.0	79.50	99.0	14	-5.07	18.40	-51.0	-1.50	21.0
	Week 92	13	75.85	24.85	9.0	80.00	99.0	13	-6.23	19.47	-51.0	0.00	19.0
	Week 95	10	72.30	29.26	6.0	84.50	97.0	10	-8.00	22.67	-54.0	-2.00	17.0
	Week 98	10	72.90	28.80	8.0	80.50	100.0	10	-7.30	22.13	-52.0	-0.50	20.0
	Plat+Gem (N=136)												
	BASELINE	106	68.22	22.01	0.0	70.50	100.0						
	Week 1	101	67.42	20.63	0.0	70.00	100.0	91	-2.43	18.44	-64.0	-2.00	66.0
	Week 2	97	68.01	18.65	14.0	71.00	100.0	85	-1.82	19.58	-49.0	-3.00	65.0
	Week 3	106	70.54	17.50	19.0	72.50	100.0	91	-0.23	19.55	-41.0	-4.00	60.0
	Week 4	105	69.46	17.88	10.0	71.00	100.0	90	-0.62	19.58	-53.0	-3.00	70.0
	Week 5	108	68.89	18.49	8.0	70.50	100.0	90	-2.11	20.39	-42.0	-5.50	70.0
	Week 6	98	66.84	18.26	11.0	66.00	100.0	83	-1.22	19.85	-53.0	-3.00	70.0
	Week 7	107	66.88	19.85	1.0	70.00	100.0	89	-2.58	20.60	-49.0	-3.00	70.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1.2: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Age - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 8	96	64.48	21.39	0.0	65.00	100.0	82	-5.84	24.55	-86.0	-6.00	70.0
	Week 9	100	65.72	21.27	10.0	69.00	100.0	83	-4.63	23.43	-70.0	-1.00	70.0
	Week 10	88	64.99	20.54	9.0	66.50	100.0	72	-4.38	22.61	-63.0	-4.00	70.0
	Week 11	93	66.77	20.17	5.0	68.00	100.0	78	-3.19	21.86	-56.0	-3.00	67.0
	Week 12	86	67.12	20.23	9.0	70.00	100.0	74	-3.00	24.39	-59.0	-1.50	68.0
	Week 14	86	65.77	20.54	10.0	68.00	100.0	71	-5.52	24.03	-61.0	-6.00	70.0
	Week 17	88	67.41	20.88	8.0	70.50	100.0	74	-3.20	24.56	-49.0	-1.50	69.0
	Week 20	67	70.06	19.33	10.0	71.00	100.0	58	-2.03	19.42	-51.0	-1.00	44.0
	Week 23	66	67.33	23.48	2.0	70.50	100.0	55	-6.56	22.77	-50.0	-4.00	64.0
	Week 26	61	71.51	21.39	8.0	79.00	100.0	53	-4.94	24.42	-51.0	-3.00	73.0
	Week 29	58	70.74	23.12	3.0	77.00	100.0	49	-4.55	27.29	-86.0	-1.00	64.0
	Week 32	46	72.80	20.64	12.0	79.50	100.0	42	-1.60	22.04	-38.0	-2.00	61.0
	Week 35	42	70.48	20.54	20.0	72.00	100.0	38	-2.45	23.12	-45.0	-1.50	76.0
	Week 38	41	69.05	23.95	20.0	75.00	100.0	37	-6.08	23.12	-55.0	-6.00	70.0
	Week 41	38	72.34	20.22	30.0	75.50	100.0	34	-1.21	23.29	-49.0	-0.50	71.0
	Week 44	32	69.69	22.29	11.0	69.00	100.0	29	-4.00	23.63	-52.0	-4.00	67.0
	Week 47	32	75.19	20.86	0.0	79.50	97.0	28	-1.18	22.59	-39.0	-3.50	72.0
	Week 50	25	72.40	23.10	1.0	76.00	96.0	23	-2.43	19.63	-38.0	-2.00	52.0
	Week 53	27	76.26	17.65	32.0	80.00	95.0	25	0.44	22.02	-36.0	-1.00	74.0
	Week 56	26	71.92	24.92	20.0	76.50	96.0	23	-0.70	27.37	-65.0	0.00	70.0
	Week 59	23	78.43	17.15	23.0	80.00	97.0	21	3.67	26.13	-68.0	3.00	68.0
	Week 62	19	72.16	19.59	11.0	74.00	96.0	17	-1.06	30.78	-80.0	-1.00	67.0
	Week 65	17	70.82	22.06	9.0	71.00	98.0	15	-2.07	34.62	-82.0	1.00	63.0
	Week 68	15	72.20	25.43	13.0	85.00	100.0	13	-0.31	32.84	-78.0	-2.00	67.0
	Week 71	15	69.27	25.16	16.0	70.00	100.0	13	1.23	37.93	-75.0	0.00	81.0
	Week 74	12	69.75	17.18	30.0	74.00	90.0	11	5.64	25.28	-32.0	5.00	58.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1.3: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Europe	EV+Pembro (N= 98)												
	BASELINE	81	76.11	16.83	28.0	80.00	100.0						
	Week 1	74	72.59	18.71	18.0	76.50	100.0	73	-4.11	14.73	-62.0	-1.00	22.0
	Week 2	80	71.68	19.01	19.0	75.00	100.0	74	-5.45	15.00	-46.0	-2.00	29.0
	Week 3	79	69.70	18.52	29.0	74.00	100.0	72	-6.44	16.89	-63.0	-5.00	21.0
	Week 4	78	76.04	17.34	29.0	80.00	100.0	71	-2.62	15.75	-59.0	1.00	33.0
	Week 5	72	74.49	18.94	31.0	79.00	100.0	65	-3.31	18.47	-69.0	0.00	40.0
	Week 6	72	77.85	17.57	11.0	80.00	100.0	64	-1.38	18.10	-60.0	1.50	40.0
	Week 7	79	76.52	18.31	12.0	80.00	100.0	70	-2.61	18.01	-68.0	0.00	45.0
	Week 8	73	75.51	18.79	10.0	80.00	100.0	63	-1.75	15.80	-51.0	1.00	29.0
	Week 9	80	73.94	19.43	22.0	77.00	100.0	71	-3.39	18.40	-78.0	-2.00	34.0
	Week 10	71	74.87	18.48	28.0	78.00	100.0	63	-1.38	17.59	-48.0	0.00	53.0
	Week 11	78	75.82	17.45	30.0	80.00	99.0	69	-1.16	17.07	-44.0	0.00	50.0
	Week 12	73	76.01	19.66	10.0	80.00	100.0	66	-2.05	19.14	-88.0	0.00	51.0
	Week 14	75	75.11	19.16	6.0	79.00	100.0	65	-2.74	18.53	-85.0	0.00	31.0
	Week 17	70	75.49	17.76	26.0	80.00	100.0	63	-1.11	18.08	-51.0	-2.00	50.0
	Week 20	71	76.07	18.90	27.0	80.00	100.0	65	-1.05	18.94	-58.0	0.00	40.0
	Week 23	61	75.43	20.58	1.0	82.00	99.0	57	-2.05	21.29	-68.0	0.00	50.0
	Week 26	63	75.41	19.02	25.0	80.00	100.0	57	-2.05	17.33	-42.0	-2.00	45.0
	Week 29	63	74.00	18.59	28.0	79.00	99.0	58	-4.16	16.80	-51.0	-4.00	40.0
	Week 32	51	72.08	18.50	28.0	78.00	97.0	47	-5.94	16.89	-50.0	-5.00	29.0
	Week 35	57	73.11	19.77	27.0	79.00	99.0	53	-6.02	16.46	-57.0	-4.00	27.0
	Week 38	52	75.38	18.14	26.0	75.00	99.0	49	-3.43	16.23	-35.0	-3.00	35.0
	Week 41	52	74.54	19.40	20.0	77.50	100.0	48	-3.96	14.96	-47.0	-2.00	29.0
	Week 44	43	75.63	18.98	25.0	78.00	98.0	39	-4.18	13.88	-30.0	-6.00	31.0
	Week 47	39	72.38	21.37	25.0	80.00	99.0	36	-6.00	18.04	-58.0	-5.50	34.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1.3: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	37	75.41	20.70	29.0	80.00	99.0	36	-4.28	16.21	-45.0	-2.00	25.0
	Week 53	28	74.57	23.50	20.0	82.00	99.0	27	-3.85	20.26	-65.0	0.00	32.0
	Week 56	30	73.80	22.11	14.0	78.00	100.0	29	-6.72	19.54	-71.0	-4.00	35.0
	Week 59	27	76.11	20.91	24.0	79.00	99.0	27	-4.63	17.27	-61.0	-1.00	28.0
	Week 62	23	71.26	25.65	20.0	78.00	99.0	23	-8.48	23.78	-65.0	0.00	26.0
	Week 65	23	75.70	22.03	28.0	78.00	100.0	23	-5.39	18.87	-57.0	-1.00	35.0
	Week 68	21	78.14	20.93	28.0	80.00	99.0	21	-3.95	16.85	-48.0	-2.00	33.0
	Week 71	19	79.42	22.69	26.0	90.00	100.0	19	-2.32	17.94	-50.0	0.00	32.0
	Week 74	15	77.53	22.09	23.0	81.00	100.0	15	-3.53	18.86	-39.0	-5.00	35.0
	Week 77	19	72.74	24.84	22.0	75.00	100.0	19	-8.05	20.36	-49.0	-2.00	32.0
	Week 80	17	77.06	22.27	20.0	78.00	100.0	17	-3.71	16.14	-37.0	-1.00	34.0
	Week 83	16	76.75	22.57	20.0	79.00	100.0	16	-3.13	16.36	-32.0	-4.00	35.0
	Week 86	14	75.07	26.75	20.0	82.50	99.0	14	-6.43	20.68	-54.0	-4.00	33.0
	Week 89	14	75.07	22.12	21.0	74.00	100.0	14	-5.43	15.30	-27.0	-5.00	35.0
	Week 92	11	83.27	15.79	49.0	90.00	100.0	11	-2.00	18.03	-36.0	-1.00	35.0
	Week 95	10	78.20	20.27	44.0	82.50	98.0	10	-5.60	18.86	-41.0	-3.00	26.0
	Plat+Gem (N=102)												
	BASELINE	73	65.70	22.05	10.0	70.00	100.0						
	Week 1	73	62.73	22.71	0.0	61.00	100.0	64	-4.77	18.61	-75.0	-5.00	30.0
	Week 2	68	64.85	21.10	14.0	68.00	100.0	57	-2.75	18.71	-56.0	0.00	65.0
	Week 3	68	68.10	18.97	30.0	68.50	97.0	56	-0.38	18.19	-41.0	0.00	50.0
	Week 4	75	68.21	19.11	26.0	71.00	100.0	60	-1.43	18.14	-53.0	-2.00	69.0
	Week 5	77	66.96	19.11	20.0	70.00	100.0	61	-3.95	17.86	-39.0	-5.00	40.0
	Week 6	70	65.30	20.85	18.0	65.00	100.0	58	-2.45	18.45	-53.0	-5.00	49.0
	Week 7	73	65.49	19.17	20.0	64.00	100.0	58	-3.53	19.77	-45.0	-1.00	51.0
	Week 8	65	63.18	20.05	4.0	61.00	100.0	55	-5.56	24.97	-86.0	-4.00	50.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1.3: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	70	64.07	20.83	11.0	65.00	100.0	57	-3.79	23.33	-70.0	-1.00	50.0
	Week 10	60	63.20	20.01	22.0	67.00	98.0	48	-4.15	20.63	-63.0	-3.00	48.0
	Week 11	64	64.61	19.94	5.0	65.50	100.0	52	-2.31	17.42	-40.0	-1.50	37.0
	Week 12	60	65.05	17.69	1.0	65.00	100.0	50	-2.16	20.43	-50.0	-1.00	40.0
	Week 14	57	64.47	19.52	28.0	63.00	100.0	44	-7.05	20.18	-61.0	-6.50	36.0
	Week 17	59	64.58	20.22	18.0	67.00	100.0	47	-4.11	21.47	-49.0	-1.00	34.0
	Week 20	48	69.46	18.91	10.0	71.50	99.0	38	-1.45	21.97	-45.0	2.00	44.0
	Week 23	45	68.11	22.58	2.0	72.00	97.0	34	-3.06	22.52	-50.0	0.00	41.0
	Week 26	39	71.92	21.32	8.0	80.00	98.0	31	1.00	25.47	-51.0	1.00	50.0
	Week 29	34	70.88	23.98	3.0	76.00	100.0	26	1.96	28.90	-86.0	4.00	42.0
	Week 32	33	70.21	20.32	12.0	76.00	100.0	28	1.57	21.13	-35.0	2.00	46.0
	Week 35	30	65.17	20.45	20.0	68.50	93.0	25	-2.20	23.40	-45.0	-1.00	39.0
	Week 38	26	62.69	24.82	20.0	69.00	100.0	22	-4.41	24.52	-55.0	-3.50	42.0
	Week 41	22	66.41	18.77	30.0	69.00	97.0	18	-3.67	24.00	-49.0	0.50	36.0
	Week 44	20	62.60	22.50	11.0	63.50	95.0	17	-6.41	21.70	-52.0	0.00	21.0
	Week 47	17	65.29	23.32	0.0	70.00	95.0	14	-4.79	12.91	-39.0	0.00	11.0
	Week 50	11	59.00	25.88	1.0	64.00	92.0	10	-3.60	14.89	-38.0	2.00	10.0
	Week 53	11	67.18	13.98	42.0	67.00	90.0	10	4.20	11.17	-12.0	2.50	22.0
	Week 56	10	69.00	20.67	20.0	73.00	92.0	8	8.25	13.35	-8.0	4.50	31.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1.3: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
North America	EV+Pembro (N= 57)												
	BASELINE	49	74.90	19.26	15.0	80.00	99.0						
	Week 1	39	72.92	19.48	25.0	75.00	100.0	38	-1.89	17.53	-35.0	0.00	66.0
	Week 2	44	69.82	19.34	27.0	70.50	99.0	42	-5.31	13.94	-34.0	-2.50	31.0
	Week 3	44	68.75	21.37	27.0	72.00	97.0	40	-4.13	13.59	-37.0	-2.50	20.0
	Week 4	45	76.18	16.81	26.0	80.00	97.0	42	2.31	17.11	-47.0	2.00	72.0
	Week 5	48	74.17	16.68	30.0	77.50	99.0	42	-0.86	19.16	-46.0	-1.00	65.0
	Week 6	44	75.16	17.41	33.0	75.00	99.0	39	1.77	17.93	-40.0	0.00	58.0
	Week 7	46	77.07	15.65	27.0	81.00	98.0	42	2.52	16.61	-31.0	0.00	62.0
	Week 8	48	76.21	15.08	30.0	79.50	96.0	43	1.14	19.29	-61.0	2.00	70.0
	Week 9	46	74.91	17.60	20.0	80.00	98.0	42	0.52	18.64	-71.0	2.00	44.0
	Week 10	47	80.11	12.59	49.0	85.00	99.0	44	5.00	16.87	-33.0	4.00	71.0
	Week 11	47	77.94	14.97	48.0	81.00	99.0	42	3.33	19.22	-42.0	3.50	71.0
	Week 12	44	77.30	15.63	19.0	81.00	100.0	40	3.45	18.76	-35.0	3.00	71.0
	Week 14	43	77.37	15.64	37.0	84.00	95.0	39	4.28	19.69	-36.0	3.00	73.0
	Week 17	40	75.58	17.79	28.0	80.00	100.0	37	1.03	19.94	-32.0	2.00	73.0
	Week 20	38	76.74	18.60	10.0	80.00	100.0	35	0.86	17.74	-54.0	4.00	40.0
	Week 23	38	76.03	18.98	28.0	85.00	96.0	35	-0.34	16.84	-38.0	2.00	49.0
	Week 26	35	76.77	18.50	27.0	82.00	100.0	32	2.88	18.58	-26.0	2.50	57.0
	Week 29	38	76.97	17.97	13.0	83.50	97.0	34	1.50	18.25	-48.0	3.00	58.0
	Week 32	32	77.78	16.58	35.0	80.50	98.0	29	-0.66	16.16	-38.0	3.00	30.0
	Week 35	33	82.06	14.18	31.0	87.00	99.0	30	2.63	15.40	-28.0	4.50	43.0
	Week 38	32	79.22	16.36	40.0	83.50	100.0	29	3.34	19.08	-41.0	4.00	67.0
	Week 41	28	81.54	12.38	50.0	87.00	95.0	24	2.58	14.35	-35.0	3.50	40.0
	Week 44	21	78.38	14.57	44.0	83.00	96.0	20	0.05	19.33	-49.0	3.00	41.0
	Week 47	24	79.04	15.22	50.0	82.50	100.0	23	-0.26	19.48	-36.0	1.00	51.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1.3: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	23	78.70	16.76	37.0	85.00	99.0	20	-0.75	14.36	-30.0	3.50	26.0
	Week 53	17	80.59	13.93	43.0	85.00	95.0	14	-0.21	14.09	-33.0	3.50	17.0
	Week 56	20	82.30	11.63	56.0	85.00	99.0	17	4.06	12.21	-30.0	4.00	25.0
	Week 59	17	81.82	10.63	53.0	83.00	99.0	14	-0.57	12.57	-31.0	0.50	20.0
	Week 62	14	83.14	11.51	55.0	85.50	100.0	13	1.92	9.78	-23.0	2.00	21.0
	Week 65	12	86.33	6.14	80.0	84.50	99.0	9	5.11	7.99	-3.0	3.00	21.0
	Week 68	10	81.30	6.78	68.0	80.00	91.0	9	-2.22	13.08	-31.0	0.00	12.0
	Week 71	10	82.30	8.25	69.0	81.50	95.0	8	-2.63	13.91	-30.0	0.00	17.0
	Week 74	10	80.80	8.77	70.0	80.00	96.0	9	-2.00	14.35	-29.0	2.00	18.0
	Plat+Gem (N= 51)												
	BASELINE	42	71.95	19.95	25.0	79.50	98.0						
	Week 1	42	66.98	18.85	15.0	70.50	97.0	36	-2.17	17.01	-32.0	-2.00	66.0
	Week 2	39	68.28	17.19	31.0	72.00	97.0	34	-2.71	16.21	-49.0	-3.50	50.0
	Week 3	41	70.95	20.59	7.0	80.00	100.0	36	-4.44	21.67	-61.0	-4.00	60.0
	Week 4	35	72.03	20.18	9.0	72.00	99.0	29	-0.93	20.57	-49.0	-1.00	70.0
	Week 5	39	73.28	17.53	40.0	78.00	99.0	32	-0.44	18.67	-32.0	-2.00	70.0
	Week 6	34	70.26	19.29	33.0	74.00	98.0	30	0.37	18.78	-32.0	-2.00	70.0
	Week 7	42	70.02	19.83	9.0	73.00	97.0	37	-1.27	18.36	-41.0	-3.00	70.0
	Week 8	39	71.26	18.66	31.0	75.00	98.0	33	-1.55	21.12	-41.0	-1.00	70.0
	Week 9	39	69.18	18.19	30.0	70.00	100.0	33	-2.33	21.13	-40.0	-5.00	70.0
	Week 10	39	69.13	18.00	29.0	72.00	100.0	32	-1.16	20.27	-31.0	-4.00	70.0
	Week 11	39	69.77	19.35	29.0	72.00	100.0	33	-1.70	23.44	-51.0	-2.00	67.0
	Week 12	36	71.11	17.65	39.0	75.00	95.0	32	-2.38	21.61	-41.0	-2.00	68.0
	Week 14	34	71.71	19.93	33.0	72.00	100.0	29	-0.48	24.26	-40.0	-1.00	70.0
	Week 17	37	69.65	19.00	26.0	71.00	100.0	31	-2.45	23.04	-40.0	-5.00	59.0
	Week 20	27	72.56	18.09	39.0	80.00	99.0	23	1.74	18.78	-37.0	-2.00	47.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1.3: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 23	27	75.93	19.46	41.0	80.00	100.0	23	-0.74	21.37	-49.0	-1.00	46.0
	Week 26	28	74.25	18.38	40.0	79.50	100.0	25	-1.96	18.08	-27.0	-3.00	40.0
	Week 29	29	74.83	18.53	15.0	77.00	100.0	25	-4.72	20.70	-76.0	-3.00	30.0
	Week 32	17	75.65	15.71	49.0	78.00	98.0	17	-2.71	14.35	-28.0	-3.00	31.0
	Week 35	16	76.56	13.95	48.0	79.50	99.0	15	-1.47	14.49	-19.0	-6.00	34.0
	Week 38	16	67.19	18.55	32.0	71.00	98.0	13	-8.00	14.76	-24.0	-15.00	28.0
	Week 41	16	68.38	19.97	27.0	73.00	99.0	13	-4.00	12.70	-23.0	-6.00	29.0
	Week 44	13	72.46	14.59	39.0	70.00	98.0	11	-4.82	13.58	-22.0	-7.00	28.0
	Week 47	11	70.18	18.36	34.0	71.00	97.0	9	-4.44	13.89	-19.0	-5.00	27.0
	Week 50	17	69.59	16.34	37.0	72.00	94.0	15	-5.40	10.70	-29.0	-2.00	10.0
	Week 53	13	78.31	11.02	61.0	80.00	93.0	11	-5.73	13.19	-30.0	-4.00	23.0
	Week 56	11	64.45	23.27	26.0	70.00	93.0	9	-15.56	26.23	-65.0	-13.00	23.0
	Week 59	11	75.91	19.98	23.0	77.00	96.0	9	-9.78	24.93	-68.0	-5.00	26.0
	Week 62	11	74.09	23.60	11.0	75.00	95.0	9	-11.11	28.66	-80.0	-2.00	25.0
	Week 65	10	74.20	25.97	9.0	76.00	98.0	8	-9.88	31.93	-82.0	-0.50	28.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1.3: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Rest of World	EV+Pembro (N= 85)												
	BASELINE	81	73.89	15.39	20.0	75.00	100.0						
	Week 1	77	69.18	18.47	20.0	70.00	100.0	77	-4.82	13.83	-50.0	-3.00	40.0
	Week 2	80	68.44	20.02	0.0	70.00	99.0	77	-5.57	18.52	-81.0	-2.00	30.0
	Week 3	76	67.92	21.45	17.0	70.50	100.0	74	-6.58	19.13	-66.0	-2.00	31.0
	Week 4	72	71.51	18.92	20.0	78.00	100.0	69	-2.65	17.89	-63.0	-2.00	40.0
	Week 5	73	73.44	18.49	25.0	79.00	100.0	71	-1.08	16.62	-56.0	-1.00	42.0
	Week 6	75	72.27	18.03	30.0	75.00	100.0	72	-2.46	15.83	-43.0	-2.00	35.0
	Week 7	71	71.99	21.06	0.0	77.00	100.0	67	-3.30	20.84	-81.0	0.00	42.0
	Week 8	72	72.63	20.22	5.0	79.50	100.0	69	-1.58	19.60	-65.0	0.00	39.0
	Week 9	72	72.76	20.33	19.0	80.00	100.0	70	-1.86	19.52	-62.0	-0.50	41.0
	Week 10	73	73.18	17.45	35.0	80.00	100.0	70	-0.66	16.06	-44.0	0.00	32.0
	Week 11	71	73.66	18.66	11.0	76.00	100.0	68	-1.31	16.33	-44.0	-1.00	40.0
	Week 12	69	73.03	19.47	29.0	76.00	100.0	67	-2.36	18.29	-53.0	-1.00	40.0
	Week 14	68	70.93	20.59	17.0	76.00	100.0	65	-3.82	20.74	-66.0	-2.00	43.0
	Week 17	68	72.46	19.39	20.0	75.00	100.0	64	-3.78	19.19	-53.0	-3.00	39.0
	Week 20	59	72.10	18.62	24.0	76.00	100.0	56	-3.20	19.98	-59.0	-0.50	42.0
	Week 23	63	67.95	19.67	25.0	70.00	100.0	60	-7.15	20.16	-65.0	-5.50	40.0
	Week 26	59	69.25	20.34	23.0	72.00	100.0	57	-5.51	20.75	-56.0	-4.00	34.0
	Week 29	56	68.55	18.85	19.0	74.50	100.0	54	-5.81	18.06	-60.0	-5.50	38.0
	Week 32	52	68.48	20.43	19.0	72.00	100.0	49	-6.65	19.98	-60.0	-2.00	39.0
	Week 35	43	68.65	18.93	19.0	72.00	100.0	40	-7.58	17.65	-48.0	-7.00	38.0
	Week 38	49	67.86	20.89	13.0	70.00	100.0	47	-6.17	20.46	-60.0	-3.00	42.0
	Week 41	49	69.29	21.32	17.0	79.00	100.0	47	-4.89	18.44	-50.0	-2.00	42.0
	Week 44	44	68.32	18.44	13.0	70.00	100.0	41	-6.78	18.40	-47.0	-5.00	38.0
	Week 47	37	68.59	21.79	20.0	73.00	100.0	35	-7.26	20.53	-60.0	-5.00	37.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1.3: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	29	70.17	17.86	30.0	75.00	100.0	28	-6.96	19.11	-60.0	-2.00	37.0
	Week 53	34	70.03	17.90	27.0	72.00	100.0	33	-8.42	15.97	-60.0	-9.00	28.0
	Week 56	31	70.94	19.89	20.0	73.00	100.0	30	-5.30	19.94	-65.0	-0.50	32.0
	Week 59	28	68.68	18.84	20.0	70.00	94.0	27	-8.33	18.85	-70.0	-6.00	29.0
	Week 62	28	68.29	21.79	15.0	70.50	100.0	27	-10.56	19.41	-65.0	-6.00	31.0
	Week 65	23	68.91	20.15	23.0	70.00	99.0	22	-8.82	20.85	-60.0	-4.00	30.0
	Week 68	22	67.36	21.58	13.0	70.00	95.0	22	-9.77	22.62	-70.0	-7.00	35.0
	Week 71	22	68.82	21.98	15.0	75.00	97.0	22	-9.55	21.88	-70.0	-7.50	34.0
	Week 74	22	68.64	20.85	15.0	71.00	99.0	22	-9.45	20.23	-50.0	-7.00	32.0
	Week 77	18	64.89	19.95	20.0	69.00	93.0	18	-13.67	22.17	-70.0	-11.00	33.0
	Week 80	16	64.94	20.37	20.0	66.50	91.0	16	-16.06	21.79	-65.0	-12.00	31.0
	Week 83	16	65.63	22.91	16.0	72.50	97.0	16	-13.00	25.04	-70.0	-6.50	37.0
	Week 86	13	64.38	24.42	10.0	70.00	91.0	13	-15.15	25.36	-75.0	-11.00	31.0
	Week 89	12	62.67	25.65	9.0	67.00	90.0	12	-15.17	27.84	-75.0	-11.50	30.0
	Plat+Gem (N= 89)												
	BASELINE	75	70.56	20.49	0.0	78.00	100.0						
	Week 1	64	70.50	19.12	4.0	71.50	100.0	64	-2.06	16.39	-64.0	-0.50	27.0
	Week 2	67	70.03	20.99	0.0	71.00	100.0	63	-1.19	21.48	-81.0	0.00	64.0
	Week 3	77	72.05	18.96	19.0	78.00	100.0	72	1.33	15.60	-42.0	0.00	50.0
	Week 4	74	70.42	18.22	10.0	72.00	100.0	69	-0.41	13.56	-30.0	-2.00	51.0
	Week 5	72	69.44	19.97	0.0	74.50	100.0	65	-2.45	18.45	-42.0	-3.00	49.0
	Week 6	70	69.43	19.49	11.0	74.00	100.0	63	-0.13	16.12	-34.0	-1.00	46.0
	Week 7	73	69.58	19.28	1.0	70.00	100.0	66	-0.73	17.17	-49.0	0.00	36.0
	Week 8	64	68.94	20.44	0.0	71.50	100.0	59	-2.73	19.49	-70.0	-2.00	54.0
	Week 9	69	70.70	20.31	10.0	74.00	100.0	63	-0.90	17.69	-56.0	0.00	47.0
	Week 10	67	68.79	21.23	9.0	71.00	100.0	61	-0.93	18.52	-57.0	-1.00	38.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1.3: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Region - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	65	72.46	18.70	9.0	75.00	100.0	60	-0.15	17.92	-56.0	-1.00	50.0
	Week 12	64	72.66	21.25	9.0	74.50	100.0	59	0.80	20.02	-59.0	0.00	56.0
	Week 14	63	71.14	19.13	10.0	72.00	100.0	57	0.28	18.10	-33.0	0.00	66.0
	Week 17	60	71.88	22.86	8.0	78.00	100.0	55	0.58	20.59	-47.0	0.00	69.0
	Week 20	52	75.06	21.19	10.0	80.00	100.0	50	1.84	15.66	-51.0	4.00	31.0
	Week 23	45	75.13	21.83	10.0	82.00	100.0	43	0.70	19.68	-43.0	2.00	64.0
	Week 26	41	75.56	21.02	30.0	82.00	100.0	40	-2.45	21.99	-48.0	0.00	73.0
	Week 29	37	76.73	18.51	31.0	83.00	100.0	36	-1.69	19.36	-45.0	0.00	64.0
	Week 32	33	80.21	18.00	40.0	87.00	100.0	32	0.81	18.49	-38.0	0.00	61.0
	Week 35	30	80.83	13.66	47.0	81.50	100.0	30	1.83	19.06	-28.0	0.00	76.0
	Week 38	32	81.31	18.02	39.0	87.50	100.0	31	2.74	19.08	-35.0	3.00	70.0
	Week 41	27	81.63	16.95	40.0	86.00	100.0	26	3.81	20.35	-31.0	0.50	71.0
	Week 44	27	82.00	14.52	51.0	85.00	100.0	26	3.65	19.15	-30.0	0.00	67.0
	Week 47	29	80.69	14.83	43.0	82.00	100.0	28	1.54	20.92	-39.0	0.00	72.0
	Week 50	23	81.78	17.86	30.0	90.00	100.0	22	2.95	18.10	-30.0	0.50	52.0
	Week 53	22	82.45	19.43	32.0	91.00	100.0	21	4.10	21.75	-36.0	1.00	74.0
	Week 56	18	82.39	21.87	20.0	90.00	100.0	17	4.00	25.64	-40.0	0.00	70.0
	Week 59	17	85.18	13.41	54.0	90.00	100.0	16	8.25	20.82	-20.0	3.50	68.0
	Week 62	16	81.19	17.19	48.0	88.00	100.0	15	7.27	23.71	-35.0	10.00	67.0
	Week 65	15	82.07	16.18	47.0	87.00	100.0	14	5.86	25.90	-52.0	6.50	63.0
	Week 68	12	77.92	23.29	30.0	86.50	100.0	11	3.36	23.93	-22.0	0.00	67.0
	Week 71	13	77.92	22.81	29.0	81.00	100.0	12	5.25	31.08	-47.0	0.00	81.0
	Week 74	10	77.10	21.01	30.0	83.00	100.0	10	7.40	25.57	-32.0	2.50	58.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1.4: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	EV+Pembro (N=198)												
	BASELINE	175	74.45	16.89	15.0	78.00	100.0						
	Week 1	157	70.77	18.33	18.0	72.00	100.0	156	-4.15	15.05	-62.0	-2.00	66.0
	Week 2	168	69.74	19.26	0.0	72.00	100.0	159	-5.57	16.52	-81.0	-2.00	31.0
	Week 3	162	68.06	20.06	17.0	70.00	100.0	151	-6.50	17.93	-66.0	-4.00	31.0
	Week 4	159	73.73	18.03	20.0	77.00	100.0	148	-1.95	18.16	-63.0	0.00	72.0
	Week 5	157	73.37	18.23	25.0	79.00	100.0	145	-2.04	18.64	-69.0	-1.00	65.0
	Week 6	156	73.69	17.99	11.0	75.50	100.0	143	-1.85	17.57	-60.0	0.00	58.0
	Week 7	160	73.37	19.44	0.0	76.00	100.0	145	-2.86	19.74	-81.0	0.00	62.0
	Week 8	156	73.87	18.13	5.0	77.00	100.0	139	-1.18	19.14	-65.0	0.00	70.0
	Week 9	163	72.51	19.42	19.0	78.00	100.0	149	-2.68	19.77	-78.0	0.00	44.0
	Week 10	159	74.57	16.68	28.0	78.00	100.0	146	-0.17	17.12	-48.0	0.00	71.0
	Week 11	162	74.20	17.30	11.0	76.00	100.0	146	-1.18	17.70	-44.0	0.00	71.0
	Week 12	154	74.23	18.50	10.0	77.00	100.0	142	-1.48	19.13	-88.0	0.00	71.0
	Week 14	155	73.25	18.83	6.0	77.00	100.0	139	-1.89	20.88	-85.0	0.00	73.0
	Week 17	145	73.17	18.53	20.0	78.00	100.0	132	-2.52	19.78	-53.0	-2.00	73.0
	Week 20	140	73.71	18.68	10.0	78.00	100.0	128	-2.31	19.73	-59.0	0.00	42.0
	Week 23	133	71.00	20.29	1.0	75.00	100.0	123	-4.88	20.86	-68.0	-1.00	49.0
	Week 26	129	72.01	19.78	23.0	76.00	100.0	119	-3.36	19.84	-56.0	-1.00	57.0
	Week 29	131	71.23	18.37	13.0	74.00	100.0	121	-4.98	18.15	-60.0	-4.00	58.0
	Week 32	111	70.10	18.99	19.0	71.00	100.0	102	-6.26	18.81	-60.0	-4.00	39.0
	Week 35	109	72.37	19.25	19.0	74.00	100.0	100	-5.28	18.05	-57.0	-4.00	43.0
	Week 38	107	71.67	20.14	13.0	74.00	100.0	100	-3.59	20.08	-60.0	-2.00	67.0
	Week 41	103	73.35	19.51	17.0	77.00	100.0	94	-3.61	17.66	-50.0	-2.00	42.0
	Week 44	88	72.74	18.45	13.0	75.50	100.0	81	-4.36	17.81	-47.0	-4.00	41.0
	Week 47	80	73.16	19.97	20.0	79.50	100.0	75	-4.63	20.24	-60.0	-5.00	51.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1.4: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	73	74.04	19.35	30.0	80.00	100.0	68	-5.26	17.98	-60.0	-2.00	37.0
	Week 53	64	73.63	19.73	20.0	78.00	100.0	59	-6.85	18.57	-65.0	-4.00	32.0
	Week 56	66	74.36	19.52	14.0	79.00	100.0	61	-4.74	19.67	-71.0	0.00	35.0
	Week 59	58	73.95	18.77	20.0	77.50	99.0	54	-6.83	17.97	-70.0	-3.00	29.0
	Week 62	54	70.83	22.51	15.0	75.50	100.0	52	-9.44	21.12	-65.0	-1.00	31.0
	Week 65	51	75.45	19.83	23.0	80.00	100.0	47	-6.28	19.69	-60.0	-1.00	35.0
	Week 68	49	75.02	19.50	13.0	80.00	99.0	48	-6.73	19.52	-70.0	-2.50	35.0
	Week 71	47	76.06	20.36	15.0	80.00	100.0	45	-6.33	19.83	-70.0	-1.00	34.0
	Week 74	42	75.14	19.20	15.0	77.50	100.0	41	-6.59	19.63	-50.0	-4.00	35.0
	Week 77	39	72.74	21.85	20.0	75.00	100.0	37	-10.03	22.05	-70.0	-6.00	33.0
	Week 80	35	75.03	20.19	20.0	78.00	100.0	33	-7.70	20.62	-65.0	-6.00	34.0
	Week 83	32	73.91	21.88	16.0	76.50	100.0	31	-7.10	22.20	-70.0	-5.00	37.0
	Week 86	30	73.93	23.49	10.0	80.00	99.0	28	-8.14	23.67	-75.0	-4.50	33.0
	Week 89	28	73.57	22.53	9.0	76.00	100.0	26	-8.46	22.77	-75.0	-6.50	35.0
	Week 92	24	76.00	20.82	9.0	79.50	100.0	22	-6.00	19.39	-51.0	-1.00	35.0
	Week 95	21	71.14	23.26	6.0	73.00	98.0	20	-9.55	20.63	-54.0	-7.50	26.0
	Week 98	16	75.56	24.58	8.0	80.50	100.0	15	-4.73	20.41	-52.0	-1.00	35.0
	Week 101	12	77.25	23.78	29.0	80.50	99.0	12	-4.33	22.10	-47.0	0.00	33.0
	Week 104	10	77.10	17.32	48.0	75.00	97.0	10	-3.60	17.84	-33.0	-1.00	32.0
	Plat+Gem (N=185)												
	BASELINE	148	69.61	20.55	10.0	72.00	100.0						
	Week 1	137	68.15	19.89	0.0	70.00	100.0	126	-2.24	17.28	-75.0	-2.00	66.0
	Week 2	130	66.57	20.29	0.0	70.00	100.0	117	-3.79	19.38	-81.0	-2.00	64.0
	Week 3	143	69.96	18.89	20.0	75.00	100.0	128	-1.13	17.46	-56.0	-2.00	60.0
	Week 4	140	69.66	18.69	9.0	72.00	100.0	121	-1.24	16.66	-53.0	-2.00	70.0
	Week 5	144	69.22	19.47	0.0	73.00	100.0	122	-3.01	17.86	-42.0	-3.50	70.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1.4: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 6	133	68.21	19.52	18.0	71.00	100.0	116	-0.83	18.00	-53.0	-2.00	70.0
	Week 7	143	68.16	19.47	1.0	71.00	100.0	123	-1.64	18.79	-49.0	-2.00	70.0
	Week 8	126	66.83	20.72	0.0	70.00	100.0	112	-4.81	22.22	-86.0	-4.00	70.0
	Week 9	136	67.86	19.59	16.0	70.00	100.0	118	-3.24	21.34	-70.0	-1.50	70.0
	Week 10	131	66.65	19.50	23.0	70.00	100.0	113	-1.85	19.95	-63.0	-3.00	70.0
	Week 11	128	69.53	18.89	5.0	70.00	100.0	111	-1.05	19.72	-56.0	-1.00	67.0
	Week 12	125	69.30	18.94	1.0	70.00	100.0	111	-2.02	20.75	-59.0	-2.00	68.0
	Week 14	122	69.52	18.82	27.0	70.50	100.0	103	-2.34	21.96	-61.0	-2.00	70.0
	Week 17	122	69.15	20.28	10.0	70.50	100.0	104	-1.73	22.45	-49.0	-2.00	69.0
	Week 20	99	72.36	19.08	10.0	78.00	100.0	87	-0.05	19.45	-51.0	0.00	47.0
	Week 23	94	73.49	19.86	8.0	79.50	100.0	80	-1.41	20.67	-49.0	0.00	64.0
	Week 26	86	72.93	20.22	8.0	78.50	100.0	76	-2.38	21.72	-51.0	-0.50	73.0
	Week 29	76	73.50	21.59	3.0	78.50	100.0	66	-2.30	23.68	-86.0	0.00	64.0
	Week 32	62	77.21	17.62	29.0	80.00	100.0	57	1.63	18.45	-35.0	0.00	61.0
	Week 35	58	74.53	17.09	20.0	80.00	100.0	53	0.09	19.23	-45.0	-1.00	76.0
	Week 38	60	72.77	21.83	20.0	80.00	100.0	53	-1.49	20.35	-55.0	0.00	70.0
	Week 41	52	73.23	19.75	27.0	76.50	100.0	45	-0.31	20.53	-49.0	0.00	71.0
	Week 44	46	74.63	19.67	11.0	80.00	100.0	41	-0.49	20.04	-52.0	0.00	67.0
	Week 47	45	75.73	19.96	0.0	80.00	100.0	40	0.08	18.94	-39.0	-0.50	72.0
	Week 50	42	72.33	22.15	1.0	77.00	100.0	38	-1.13	16.84	-38.0	-0.50	52.0
	Week 53	38	79.74	15.10	42.0	85.00	100.0	34	2.59	17.62	-30.0	0.00	74.0
	Week 56	32	75.91	22.24	20.0	83.00	100.0	28	-1.18	25.97	-65.0	0.00	70.0
	Week 59	31	79.74	18.77	23.0	87.00	100.0	27	2.26	22.46	-68.0	0.00	68.0
	Week 62	29	78.07	19.09	11.0	80.00	100.0	26	0.19	25.51	-80.0	0.00	67.0
	Week 65	25	77.28	21.86	9.0	82.00	100.0	21	1.86	26.28	-82.0	1.00	63.0
	Week 68	20	74.90	23.88	13.0	85.00	100.0	16	-0.50	28.89	-78.0	-0.50	67.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1.4: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 71	17	72.06	26.13	16.0	79.00	100.0	14	1.21	35.93	-75.0	0.00	81.0
	Week 74	17	74.53	19.05	20.0	77.00	100.0	14	4.93	22.18	-32.0	0.00	58.0
	Week 77	16	72.06	27.25	0.0	79.50	100.0	13	3.31	27.01	-38.0	0.00	70.0
	Week 80	13	77.46	14.12	54.0	78.00	100.0	12	0.08	14.80	-20.0	0.00	28.0
	Week 83	11	78.18	12.83	61.0	76.00	100.0	10	-0.30	17.71	-34.0	0.00	26.0
	Week 86	12	83.00	13.38	56.0	90.00	100.0	11	4.36	10.84	-19.0	2.00	24.0
	Week 89	11	80.64	16.81	40.0	89.00	100.0	10	2.80	13.09	-20.0	1.00	29.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1.4: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	EV+Pembro (N= 42)												
	BASELINE	36	77.53	16.64	30.0	80.00	100.0						
	Week 1	33	73.70	20.80	20.0	80.00	100.0	32	-2.97	14.59	-50.0	0.00	22.0
	Week 2	36	71.25	20.51	11.0	73.50	98.0	34	-4.97	14.90	-59.0	-1.50	23.0
	Week 3	37	72.08	20.89	20.0	80.00	100.0	35	-3.83	13.21	-50.0	-1.00	19.0
	Week 4	36	77.36	17.07	31.0	82.00	98.0	34	0.50	9.96	-21.0	0.50	20.0
	Week 5	36	76.81	17.73	31.0	80.00	99.0	33	-0.97	14.12	-37.0	-1.00	40.0
	Week 6	35	81.06	15.77	37.0	87.00	99.0	32	2.13	14.86	-30.0	2.50	40.0
	Week 7	36	82.28	13.93	30.0	85.00	100.0	34	3.41	13.64	-20.0	5.00	45.0
	Week 8	37	77.70	19.90	10.0	86.00	97.0	36	-0.17	14.02	-31.0	1.50	29.0
	Week 9	35	79.46	17.77	30.0	86.00	100.0	34	1.47	13.86	-39.0	3.00	26.0
	Week 10	32	80.19	17.70	31.0	86.00	97.0	31	3.61	15.88	-35.0	5.00	53.0
	Week 11	34	81.94	16.31	32.0	87.50	98.0	33	4.33	15.05	-24.0	3.00	50.0
	Week 12	32	79.94	19.21	30.0	87.00	97.0	31	1.77	17.03	-35.0	0.00	51.0
	Week 14	31	78.35	19.81	21.0	84.00	97.0	30	0.13	14.04	-49.0	2.00	24.0
	Week 17	33	79.52	16.92	26.0	85.00	98.0	32	1.81	14.62	-25.0	-1.50	50.0
	Week 20	28	80.39	18.32	29.0	86.00	100.0	28	2.82	14.87	-37.0	1.50	40.0
	Week 23	29	80.28	17.54	30.0	88.00	96.0	29	1.45	14.90	-28.0	0.00	50.0
	Week 26	28	79.82	17.44	30.0	87.00	98.0	27	2.26	15.08	-31.0	2.00	45.0
	Week 29	26	80.58	18.85	30.0	87.00	99.0	25	3.96	13.49	-24.0	5.00	40.0
	Week 32	24	81.04	16.94	30.0	85.00	98.0	23	0.65	12.89	-40.0	0.00	19.0
	Week 35	24	80.79	15.25	31.0	81.50	98.0	23	-0.65	10.64	-30.0	0.00	19.0
	Week 38	26	81.19	12.53	44.0	85.00	97.0	25	-0.08	12.25	-26.0	-1.00	35.0
	Week 41	26	76.88	18.72	20.0	80.50	95.0	25	-0.76	10.61	-28.0	1.00	20.0
	Week 44	20	75.15	17.99	25.0	79.50	96.0	19	-4.58	13.39	-49.0	-3.00	17.0
	Week 47	20	70.25	22.63	25.0	75.00	99.0	19	-6.79	15.67	-40.0	-2.00	20.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1.4: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	16	76.88	17.24	29.0	79.50	95.0	16	-0.38	9.88	-31.0	0.50	11.0
	Week 53	15	75.13	19.51	21.0	81.00	95.0	15	1.27	9.87	-16.0	3.00	20.0
	Week 56	15	76.73	19.63	27.0	81.00	99.0	15	0.27	13.23	-37.0	1.00	20.0
	Week 59	14	77.14	18.60	28.0	82.00	99.0	14	0.79	11.96	-25.0	2.50	20.0
	Week 62	11	80.91	18.31	38.0	87.00	100.0	11	3.27	7.66	-7.0	0.00	21.0
	Plat+Gem (N= 57)												
	BASELINE	42	66.86	22.85	0.0	70.00	100.0						
	Week 1	42	61.14	22.86	4.0	60.00	100.0	38	-6.13	17.54	-64.0	-7.50	30.0
	Week 2	44	70.70	20.11	27.0	74.00	100.0	37	3.24	18.25	-25.0	0.00	65.0
	Week 3	43	71.72	20.83	7.0	77.00	100.0	36	1.64	19.87	-61.0	2.50	50.0
	Week 4	44	70.36	19.84	10.0	75.00	100.0	37	0.24	17.03	-31.0	-1.00	69.0
	Week 5	44	69.25	18.44	22.0	70.00	100.0	36	-1.31	19.50	-39.0	-2.50	49.0
	Week 6	41	67.02	21.78	11.0	70.00	100.0	35	-1.23	16.01	-30.0	-2.00	40.0
	Week 7	45	67.87	19.28	18.0	69.00	100.0	38	-2.58	17.04	-39.0	0.00	51.0
	Week 8	42	68.52	18.10	9.0	67.50	100.0	35	0.60	20.85	-40.0	-1.00	50.0
	Week 9	42	67.43	22.30	10.0	69.00	100.0	35	0.91	17.71	-35.0	0.00	39.0
	Week 10	35	67.60	22.67	9.0	75.00	100.0	28	-3.00	18.29	-45.0	-0.50	48.0
	Week 11	40	66.65	21.55	9.0	66.00	100.0	34	-2.00	16.81	-51.0	-1.00	37.0
	Week 12	35	70.03	21.18	9.0	71.00	100.0	30	2.90	19.10	-49.0	3.50	40.0
	Week 14	32	66.03	22.49	10.0	70.00	100.0	27	-2.48	13.34	-28.0	0.00	23.0
	Week 17	34	66.59	24.17	8.0	70.50	100.0	29	-1.97	17.62	-37.0	0.00	34.0
	Week 20	28	72.57	22.23	10.0	77.50	100.0	24	3.38	14.93	-27.0	6.50	32.0
	Week 23	23	69.04	28.36	2.0	75.00	100.0	20	1.10	22.31	-50.0	6.00	41.0
	Week 26	22	77.73	20.93	30.0	85.00	100.0	20	3.25	23.52	-48.0	5.50	50.0
	Week 29	24	76.38	16.73	25.0	77.00	100.0	21	1.14	20.26	-50.0	2.00	42.0
	Week 32	21	69.67	21.62	12.0	76.00	100.0	20	-3.45	18.80	-38.0	-3.00	41.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1.4: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Sex - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 35	18	71.22	21.02	21.0	73.00	100.0	17	-1.59	21.78	-37.0	-2.00	39.0
	Week 38	14	67.21	24.09	21.0	74.50	100.0	13	-2.85	22.17	-26.0	-10.00	41.0
	Week 41	13	73.15	18.87	38.0	79.00	100.0	12	-0.42	19.89	-37.0	0.00	29.0
	Week 44	14	69.64	18.23	41.0	69.00	100.0	13	-3.62	17.33	-34.0	-4.00	21.0
	Week 47	12	67.83	16.10	40.0	71.00	90.0	11	-6.09	13.00	-25.0	-9.00	21.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1.5: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Visceral metastases	EV+Pembro (N=170)												
	BASELINE	149	73.50	17.62	15.0	78.00	100.0						
	Week 1	135	69.38	19.77	18.0	72.00	100.0	134	-3.89	16.68	-62.0	-2.00	66.0
	Week 2	146	68.88	20.04	0.0	70.00	99.0	137	-5.34	16.92	-81.0	-2.00	31.0
	Week 3	142	67.47	20.76	17.0	70.00	100.0	132	-5.53	17.61	-66.0	-2.00	30.0
	Week 4	136	72.98	18.56	20.0	77.00	100.0	126	-1.20	17.94	-63.0	0.00	72.0
	Week 5	133	73.05	18.60	25.0	79.00	100.0	121	-0.74	18.95	-56.0	0.00	65.0
	Week 6	130	73.88	17.66	30.0	76.50	100.0	117	-0.67	17.64	-50.0	0.00	58.0
	Week 7	136	74.18	19.17	0.0	78.50	100.0	123	-0.58	20.25	-81.0	0.00	62.0
	Week 8	133	73.28	19.49	5.0	77.00	100.0	121	-0.31	19.50	-65.0	0.00	70.0
	Week 9	137	73.50	19.79	19.0	80.00	100.0	126	-0.45	19.24	-71.0	0.00	44.0
	Week 10	135	75.29	17.11	28.0	80.00	100.0	125	1.73	17.68	-44.0	3.00	71.0
	Week 11	136	75.30	17.73	11.0	78.00	100.0	124	1.34	18.21	-44.0	0.00	71.0
	Week 12	131	75.69	18.68	19.0	80.00	100.0	121	0.99	18.61	-53.0	0.00	71.0
	Week 14	131	73.74	19.85	6.0	78.00	100.0	118	-0.08	21.63	-85.0	0.00	73.0
	Week 17	124	74.54	19.47	20.0	80.00	100.0	112	0.63	20.23	-53.0	1.00	73.0
	Week 20	116	75.39	18.62	24.0	80.00	100.0	107	0.52	18.99	-59.0	0.00	42.0
	Week 23	111	73.39	19.99	1.0	80.00	100.0	103	-0.33	19.83	-68.0	1.00	50.0
	Week 26	107	75.26	19.04	23.0	80.00	100.0	99	1.64	19.14	-56.0	2.00	57.0
	Week 29	106	74.82	17.17	19.0	79.50	100.0	99	0.67	16.83	-60.0	1.00	58.0
	Week 32	92	73.49	18.43	27.0	77.50	100.0	85	-1.41	16.95	-52.0	0.00	39.0
	Week 35	87	75.67	17.83	27.0	80.00	100.0	80	-0.85	16.50	-48.0	0.00	43.0
	Week 38	91	75.19	18.25	26.0	80.00	100.0	85	1.59	18.55	-55.0	0.00	67.0
	Week 41	87	75.41	18.65	20.0	80.00	100.0	81	1.02	15.81	-47.0	1.00	42.0
	Week 44	73	74.79	17.28	25.0	80.00	100.0	68	0.04	16.34	-49.0	0.00	41.0
	Week 47	68	75.16	19.51	25.0	80.00	100.0	63	-0.57	18.98	-58.0	0.00	51.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1.5: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	61	75.08	18.83	29.0	80.00	100.0	57	-0.95	16.29	-45.0	0.00	37.0
	Week 53	54	73.52	19.50	20.0	75.50	100.0	50	-3.00	17.31	-65.0	-0.50	32.0
	Week 56	58	76.02	18.39	14.0	80.00	100.0	54	-0.06	17.64	-71.0	0.00	35.0
	Week 59	50	75.70	16.77	24.0	78.50	99.0	47	-1.70	15.08	-61.0	0.00	29.0
	Week 62	45	74.64	19.88	20.0	79.00	100.0	43	-2.47	17.80	-65.0	0.00	31.0
	Week 65	37	78.19	17.35	28.0	80.00	100.0	34	-0.15	17.05	-57.0	0.00	35.0
	Week 68	35	77.77	16.52	28.0	80.00	99.0	34	-0.53	15.96	-48.0	0.00	35.0
	Week 71	31	78.23	18.42	26.0	80.00	99.0	30	-0.17	16.66	-50.0	0.00	34.0
	Week 74	29	77.45	17.36	23.0	80.00	100.0	28	0.21	15.70	-39.0	1.00	35.0
	Week 77	26	75.12	20.61	22.0	76.50	100.0	25	-2.36	20.06	-49.0	-2.00	33.0
	Week 80	22	76.77	18.85	20.0	78.00	99.0	21	-0.71	17.80	-37.0	-1.00	34.0
	Week 83	23	79.17	18.06	20.0	80.00	100.0	22	2.55	16.83	-32.0	-0.50	37.0
	Week 86	21	77.90	18.38	20.0	80.00	98.0	20	0.65	16.25	-35.0	-1.50	33.0
	Week 89	21	77.57	17.92	21.0	79.00	100.0	20	1.25	16.00	-27.0	3.00	35.0
	Week 92	18	79.50	14.31	49.0	79.50	100.0	17	-0.41	16.94	-36.0	0.00	35.0
	Week 95	13	79.31	17.64	44.0	89.00	98.0	12	-0.92	19.24	-41.0	5.50	26.0
	Week 98	11	83.18	14.44	61.0	81.00	100.0	11	5.27	13.37	-10.0	0.00	35.0
	Week 101	11	76.91	24.11	29.0	80.00	99.0	11	-0.73	22.73	-47.0	2.00	33.0
	Plat+Gem (N=161)												
	BASELINE	131	68.08	20.19	20.0	70.00	100.0						
	Week 1	117	66.20	19.81	19.0	69.00	100.0	110	-2.42	17.78	-75.0	-1.00	66.0
	Week 2	111	65.31	20.67	0.0	70.00	100.0	101	-2.82	17.76	-81.0	-1.00	50.0
	Week 3	122	68.61	19.89	7.0	71.00	100.0	110	-1.21	18.46	-61.0	0.00	60.0
	Week 4	117	68.74	18.69	26.0	70.00	100.0	103	-1.24	16.17	-49.0	-2.00	70.0
	Week 5	122	68.21	19.95	0.0	70.00	100.0	106	-2.63	17.31	-42.0	-3.00	70.0
	Week 6	118	66.63	20.19	18.0	70.00	100.0	104	-1.17	18.47	-53.0	-2.00	70.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1.5: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 7	123	67.98	18.72	1.0	70.00	100.0	108	-1.07	18.52	-49.0	0.00	70.0
	Week 8	109	68.34	18.39	0.0	70.00	100.0	99	-2.46	21.24	-50.0	-3.00	70.0
	Week 9	115	67.74	19.14	16.0	69.00	100.0	102	-1.28	21.07	-56.0	0.00	70.0
	Week 10	109	67.50	18.49	28.0	70.00	100.0	96	0.13	19.22	-57.0	-1.00	70.0
	Week 11	109	69.21	18.55	5.0	70.00	100.0	97	-0.65	18.98	-56.0	-1.00	67.0
	Week 12	104	68.31	18.25	25.0	70.00	100.0	94	-1.84	21.26	-59.0	0.00	68.0
	Week 14	99	68.55	18.83	27.0	70.00	100.0	87	-2.46	21.13	-61.0	-3.00	70.0
	Week 17	103	68.82	20.78	10.0	70.00	100.0	91	-1.27	21.18	-49.0	-1.00	59.0
	Week 20	82	72.04	18.75	10.0	76.00	100.0	76	0.33	20.18	-51.0	3.50	47.0
	Week 23	78	71.44	22.27	2.0	77.00	100.0	70	-1.44	21.70	-50.0	0.50	46.0
	Week 26	71	72.80	19.62	30.0	80.00	100.0	66	-1.56	21.11	-48.0	0.50	50.0
	Week 29	65	75.09	18.44	15.0	78.00	100.0	60	-0.60	20.46	-76.0	2.00	42.0
	Week 32	52	75.37	16.81	40.0	80.00	100.0	50	-0.02	17.22	-38.0	-1.00	41.0
	Week 35	47	73.55	17.12	20.0	79.00	100.0	45	-1.02	17.86	-45.0	-1.00	39.0
	Week 38	42	70.50	21.44	20.0	77.50	100.0	40	-4.20	17.57	-55.0	-3.50	41.0
	Week 41	35	72.89	20.32	27.0	79.00	100.0	33	-0.30	19.33	-49.0	1.00	36.0
	Week 44	36	70.61	20.48	11.0	71.50	100.0	34	-4.12	18.39	-52.0	-0.50	28.0
	Week 47	33	73.42	20.89	0.0	77.00	100.0	32	-1.88	15.62	-39.0	0.00	31.0
	Week 50	30	72.23	22.59	1.0	79.50	100.0	29	-1.62	14.85	-38.0	0.00	30.0
	Week 53	25	77.72	16.91	39.0	84.00	100.0	24	-0.54	13.42	-30.0	0.00	30.0
	Week 56	22	72.32	25.13	20.0	78.50	100.0	21	-5.81	25.22	-65.0	0.00	46.0
	Week 59	22	79.68	17.30	23.0	85.00	100.0	21	0.00	21.35	-68.0	0.00	39.0
	Week 62	19	75.26	20.88	11.0	77.00	100.0	18	-2.78	26.06	-80.0	0.00	39.0
	Week 65	19	77.32	22.37	9.0	83.00	100.0	18	-2.06	28.37	-82.0	2.00	43.0
	Week 68	13	71.92	26.97	13.0	85.00	100.0	12	-7.08	25.10	-78.0	-2.50	26.0
	Week 71	13	66.62	26.52	16.0	73.00	100.0	12	-9.75	28.61	-75.0	-3.00	29.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1.5: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 74	11	70.64	19.24	30.0	74.00	100.0	11	-2.09	17.84	-32.0	0.00	34.0
	Week 77	10	77.80	16.41	51.0	82.50	100.0	10	4.00	9.78	-8.0	1.50	26.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1.5: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Lymph node only	EV+Pembro (N= 60)												
	BASELINE	55	78.96	14.28	40.0	81.00	100.0						
	Week 1	49	76.37	15.16	49.0	79.00	100.0	48	-3.81	9.01	-40.0	-1.50	14.0
	Week 2	50	72.68	17.75	31.0	78.50	100.0	49	-6.12	13.50	-46.0	-2.00	30.0
	Week 3	50	72.12	19.33	27.0	79.00	100.0	48	-7.15	16.33	-63.0	-6.00	31.0
	Week 4	51	76.98	16.54	38.0	81.00	100.0	49	-3.29	14.48	-59.0	0.00	31.0
	Week 5	54	75.63	17.64	31.0	80.00	100.0	51	-4.90	15.50	-69.0	-1.00	30.0
	Week 6	53	78.00	18.22	11.0	83.00	100.0	51	-1.84	16.35	-60.0	0.00	37.0
	Week 7	52	77.98	17.49	31.0	82.50	100.0	49	-3.41	15.73	-62.0	0.00	30.0
	Week 8	52	78.13	16.23	28.0	81.00	100.0	48	-2.08	14.78	-42.0	1.00	30.0
	Week 9	53	73.55	19.07	22.0	78.00	100.0	50	-6.16	17.80	-78.0	-3.00	30.0
	Week 10	48	75.67	17.48	32.0	80.00	100.0	45	-3.04	14.34	-48.0	-1.00	30.0
	Week 11	53	75.17	17.29	30.0	79.00	99.0	49	-4.63	14.69	-38.0	-1.00	30.0
	Week 12	48	72.63	19.68	10.0	75.50	100.0	46	-6.78	18.54	-88.0	-3.50	30.0
	Week 14	48	74.65	16.90	27.0	80.00	100.0	45	-5.16	15.11	-59.0	-3.00	30.0
	Week 17	46	73.63	16.38	32.0	78.50	100.0	45	-7.33	14.76	-51.0	-5.00	30.0
	Week 20	44	72.95	20.02	10.0	79.00	100.0	42	-6.38	18.64	-58.0	-4.00	25.0
	Week 23	43	73.84	18.70	25.0	80.00	99.0	42	-8.52	17.78	-65.0	-6.00	26.0
	Week 26	42	71.38	19.55	23.0	75.50	100.0	40	-9.03	14.56	-45.0	-5.50	13.0
	Week 29	45	68.73	21.49	13.0	74.00	97.0	42	-11.95	16.06	-51.0	-9.50	19.0
	Week 32	38	69.39	20.02	19.0	74.50	98.0	36	-11.81	16.66	-50.0	-5.50	14.0
	Week 35	42	70.43	20.60	19.0	72.50	98.0	40	-10.65	16.28	-57.0	-8.50	26.0
	Week 38	38	71.00	20.97	13.0	75.00	98.0	36	-11.33	14.31	-47.0	-9.00	9.0
	Week 41	37	71.32	20.89	17.0	78.00	97.0	34	-10.88	13.62	-43.0	-7.50	14.0
	Week 44	31	69.68	20.44	13.0	73.00	97.0	29	-13.21	14.37	-47.0	-12.00	10.0
	Week 47	28	69.18	21.17	20.0	70.00	98.0	27	-11.93	14.70	-40.0	-11.00	10.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1.5: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	25	75.92	17.71	37.0	80.00	99.0	24	-8.63	12.50	-30.0	-5.00	9.0
	Week 53	23	76.52	18.59	27.0	81.00	99.0	22	-7.45	13.94	-33.0	-2.00	12.0
	Week 56	21	73.86	20.47	20.0	78.00	100.0	20	-10.05	14.59	-40.0	-4.50	13.0
	Week 59	20	74.10	20.29	22.0	80.00	99.0	19	-10.53	14.60	-38.0	-7.00	11.0
	Week 62	19	70.05	24.91	15.0	80.00	98.0	19	-14.95	18.35	-45.0	-10.00	7.0
	Week 65	20	71.95	21.78	23.0	71.50	100.0	19	-10.89	16.07	-41.0	-5.00	12.0
	Week 68	17	70.24	22.21	13.0	72.00	99.0	17	-13.53	15.48	-47.0	-10.00	10.0
	Week 71	19	73.74	21.36	15.0	79.00	100.0	18	-11.11	15.70	-45.0	-9.00	10.0
	Week 74	17	70.29	22.02	15.0	75.00	99.0	17	-13.82	17.69	-47.0	-9.00	12.0
	Week 77	18	70.67	21.56	22.0	74.00	100.0	17	-14.00	15.87	-38.0	-10.00	6.0
	Week 80	17	72.76	21.66	20.0	75.00	100.0	16	-11.81	15.52	-40.0	-10.50	8.0
	Week 83	13	66.69	23.71	16.0	70.00	99.0	13	-15.15	15.79	-44.0	-10.00	3.0
	Week 86	12	68.75	27.65	10.0	74.00	99.0	11	-16.18	19.71	-54.0	-11.00	3.0
	Week 89	11	68.18	25.06	9.0	64.00	99.0	10	-16.00	16.03	-51.0	-14.50	1.0
	Plat+Gem (N= 67)												
	BASELINE	49	73.35	21.51	0.0	80.00	100.0						
	Week 1	52	69.31	19.86	15.0	73.00	100.0	45	-4.36	14.88	-32.0	-5.00	29.0
	Week 2	53	72.08	18.48	27.0	72.00	100.0	44	-1.32	19.44	-48.0	0.00	65.0
	Week 3	54	73.11	18.61	19.0	80.00	100.0	45	-0.87	16.49	-40.0	-2.00	50.0
	Week 4	58	71.88	19.84	9.0	75.50	100.0	47	-1.02	17.33	-53.0	-1.00	69.0
	Week 5	56	72.05	17.24	29.0	75.00	100.0	44	-2.34	19.79	-40.0	-3.50	49.0
	Week 6	48	71.90	19.35	11.0	79.00	100.0	40	0.23	15.13	-25.0	-1.50	40.0
	Week 7	56	68.73	21.07	9.0	70.50	100.0	46	-3.24	17.69	-45.0	-2.50	51.0
	Week 8	52	65.60	23.65	4.0	69.00	100.0	42	-6.88	23.93	-86.0	-7.50	50.0
	Week 9	53	68.92	22.99	10.0	71.00	100.0	42	-4.76	20.18	-70.0	-2.50	39.0
	Week 10	47	65.94	23.57	9.0	70.00	100.0	36	-7.44	19.95	-63.0	-4.50	30.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.1.5: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Metastases at Baseline - Analysis Set mITT 1

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	51	68.25	22.55	9.0	70.00	100.0	41	-4.05	18.28	-51.0	-3.00	37.0
	Week 12	47	72.49	21.28	1.0	72.00	100.0	39	0.90	16.04	-50.0	-1.00	40.0
	Week 14	47	68.74	21.57	10.0	70.00	100.0	36	-3.56	16.18	-38.0	-1.50	31.0
	Week 17	46	67.96	22.16	8.0	72.00	100.0	36	-3.64	19.54	-42.0	-2.00	34.0
	Week 20	39	74.87	20.42	10.0	80.00	100.0	30	2.13	14.09	-36.0	0.00	34.0
	Week 23	32	76.28	21.13	10.0	80.00	100.0	25	0.48	14.31	-34.0	0.00	30.0
	Week 26	30	76.33	22.49	8.0	82.50	100.0	24	-1.67	20.64	-51.0	0.00	38.0
	Week 29	28	73.43	24.77	3.0	79.00	100.0	21	-3.57	25.37	-86.0	0.00	40.0
	Week 32	26	75.31	23.09	12.0	79.50	100.0	22	-1.41	18.73	-34.0	-1.50	46.0
	Week 35	23	74.00	20.08	21.0	80.00	100.0	19	-2.42	18.80	-31.0	-3.00	37.0
	Week 38	26	72.81	24.73	21.0	78.50	100.0	20	-1.25	22.07	-42.0	-0.50	42.0
	Week 41	24	74.08	17.89	49.0	77.00	100.0	18	-3.50	16.49	-31.0	-3.00	29.0
	Week 44	18	78.33	17.52	39.0	80.50	100.0	14	-0.50	15.24	-22.0	-1.00	28.0
	Week 47	18	75.67	16.39	49.0	79.50	97.0	13	-5.00	13.03	-22.0	-3.00	27.0
	Week 50	16	72.81	20.49	37.0	73.00	97.0	13	-6.00	11.60	-22.0	-2.00	19.0
	Week 53	15	79.40	14.61	50.0	85.00	98.0	12	1.42	13.51	-18.0	-0.50	23.0
	Week 56	15	75.87	21.06	20.0	76.00	99.0	11	4.09	13.25	-14.0	0.00	26.0
	Week 59	12	80.75	20.00	24.0	83.50	98.0	9	7.33	15.26	-14.0	0.00	32.0
	Week 62	10	80.70	14.67	51.0	81.50	99.0	8	1.13	15.72	-21.0	-0.50	25.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.2: EQ-5D-5L - Observed Means and Change from Baseline of VAS - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
EV+Pembro (N=202)												
BASELINE	166	69.81	17.82	10.0	70.00	100.0						
Week 1	143	67.52	18.66	3.0	70.00	100.0	135	-3.61	17.24	-97.0	0.00	42.0
Week 2	156	64.79	18.77	4.0	65.00	100.0	143	-5.58	18.67	-86.0	-4.00	61.0
Week 3	141	65.85	20.58	10.0	69.00	100.0	128	-4.23	18.19	-70.0	-2.00	46.0
Week 4	147	68.31	19.77	10.0	70.00	100.0	134	-2.20	18.08	-59.0	-1.00	69.0
Week 5	139	68.59	19.14	10.0	70.00	100.0	126	-2.99	20.20	-59.0	-1.00	77.0
Week 6	150	67.45	19.68	11.0	70.00	100.0	130	-3.23	21.90	-71.0	-1.00	78.0
Week 7	152	69.34	18.06	17.0	71.00	100.0	130	-1.43	19.66	-59.0	0.00	79.0
Week 8	152	68.80	19.25	11.0	70.50	100.0	130	-1.84	21.56	-70.0	0.00	79.0
Week 9	144	69.09	19.16	19.0	70.00	100.0	127	-1.93	21.44	-72.0	0.00	79.0
Week 10	139	70.90	18.17	10.0	73.00	100.0	122	-0.66	19.68	-60.0	1.00	80.0
Week 11	138	71.64	20.05	11.0	77.50	100.0	119	0.84	20.85	-67.0	0.00	81.0
Week 12	143	70.12	19.41	12.0	75.00	100.0	123	-1.11	20.85	-69.0	1.00	79.0
Week 14	141	70.28	20.78	7.0	77.00	100.0	120	-0.58	22.59	-92.0	0.00	80.0
Week 17	133	72.65	17.02	30.0	76.00	100.0	115	1.24	18.29	-52.0	0.00	78.0
Week 20	120	72.87	18.31	23.0	75.00	100.0	106	-0.23	19.21	-57.0	0.00	60.0
Week 23	117	73.70	18.14	28.0	80.00	100.0	100	1.74	19.49	-53.0	2.00	79.0
Week 26	114	71.12	18.33	21.0	75.00	100.0	97	-0.91	18.68	-60.0	-1.00	81.0
Week 29	108	69.65	20.06	2.0	72.00	100.0	96	-3.07	21.97	-79.0	0.00	79.0
Week 32	104	70.17	19.15	7.0	73.00	100.0	92	-1.72	22.19	-77.0	0.00	79.0
Week 35	98	72.40	18.90	5.0	77.00	100.0	88	-1.01	19.24	-76.0	0.00	81.0
Week 38	97	72.39	17.08	29.0	77.00	100.0	88	0.39	17.59	-44.0	0.00	75.0
Week 41	96	69.97	18.10	7.0	70.00	100.0	88	-1.65	19.48	-72.0	-1.50	74.0
Week 44	86	69.47	18.35	4.0	72.00	99.0	77	-3.96	19.24	-77.0	-3.00	73.0
Week 47	79	72.01	16.87	30.0	75.00	100.0	72	-0.18	17.92	-43.0	0.00	78.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.2: EQ-5D-5L - Observed Means and Change from Baseline of VAS - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	75	70.88	19.80	5.0	75.00	100.0	66	-2.41	19.63	-62.0	0.50	71.0
Week 53	76	68.84	19.89	6.0	70.00	100.0	66	-3.23	20.08	-44.0	-1.50	78.0
Week 56	73	72.33	18.09	30.0	73.00	100.0	64	0.00	18.74	-39.0	0.00	81.0
Week 59	69	71.36	17.21	33.0	71.00	99.0	59	-0.08	19.21	-40.0	0.00	77.0
Week 62	62	72.39	16.64	36.0	70.50	100.0	54	-0.22	18.58	-41.0	-1.00	78.0
Week 65	43	70.14	17.55	33.0	70.00	100.0	41	-2.76	15.94	-41.0	0.00	25.0
Week 68	46	70.28	19.73	10.0	71.50	100.0	43	-1.28	21.14	-59.0	1.00	77.0
Week 71	43	71.35	17.04	38.0	70.00	99.0	40	0.20	18.63	-37.0	0.00	79.0
Week 74	38	73.05	17.69	35.0	74.50	99.0	36	-0.28	20.50	-43.0	1.50	70.0
Week 77	37	72.68	17.98	31.0	74.00	99.0	34	0.41	21.24	-39.0	1.50	76.0
Week 80	36	70.75	18.57	30.0	70.50	99.0	35	-2.03	21.20	-48.0	0.00	67.0
Week 83	30	69.23	19.33	20.0	69.00	100.0	30	-2.07	23.12	-61.0	-0.50	56.0
Week 86	26	63.54	22.10	28.0	60.00	99.0	26	-7.35	24.80	-54.0	0.00	38.0
Week 89	20	69.45	21.65	28.0	69.50	98.0	20	-6.50	20.33	-54.0	-0.50	34.0
Week 92	19	70.21	21.40	23.0	70.00	99.0	19	-2.84	22.72	-47.0	0.00	39.0
Week 95	14	77.50	17.55	46.0	76.50	100.0	14	4.00	13.37	-17.0	1.00	29.0
Week 98	10	82.20	14.88	67.0	81.00	100.0	10	6.40	8.91	-2.0	2.50	21.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.2: EQ-5D-5L - Observed Means and Change from Baseline of VAS - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Plat+Gem (N=202)												
BASELINE	168	70.21	20.40	5.0	72.50	100.0						
Week 1	146	66.60	21.57	3.0	70.00	100.0	142	-4.52	18.97	-59.0	-1.50	49.0
Week 2	153	65.33	20.73	3.0	70.00	100.0	141	-6.28	20.73	-79.0	-4.00	51.0
Week 3	150	66.77	21.60	2.0	70.00	100.0	138	-5.82	19.82	-87.0	-3.00	51.0
Week 4	152	68.38	20.12	1.0	71.00	100.0	138	-3.41	18.30	-48.0	-3.00	51.0
Week 5	157	66.83	21.04	10.0	70.00	100.0	141	-5.10	19.30	-71.0	-2.00	50.0
Week 6	146	68.15	20.68	2.0	70.00	100.0	131	-3.55	21.47	-68.0	-2.00	58.0
Week 7	150	66.74	21.35	6.0	68.50	100.0	137	-5.16	22.50	-75.0	-3.00	63.0
Week 8	147	66.90	20.56	5.0	70.00	100.0	134	-5.32	22.48	-74.0	-3.50	61.0
Week 9	142	66.06	22.00	0.0	70.00	100.0	127	-5.19	22.46	-53.0	-3.00	60.0
Week 10	143	67.54	21.66	2.0	70.00	100.0	130	-3.75	22.27	-73.0	-3.00	62.0
Week 11	127	66.50	21.01	1.0	68.00	100.0	116	-4.70	22.92	-69.0	-3.50	60.0
Week 12	130	67.31	21.52	2.0	70.00	100.0	116	-4.09	21.34	-62.0	-1.50	42.0
Week 14	125	65.50	22.11	1.0	70.00	100.0	110	-7.06	23.79	-67.0	-4.00	54.0
Week 17	120	66.61	21.43	10.0	70.00	100.0	108	-5.58	24.83	-65.0	-5.00	54.0
Week 20	104	68.98	22.67	10.0	74.50	100.0	93	-3.98	22.78	-65.0	-4.00	57.0
Week 23	89	74.42	19.69	23.0	80.00	100.0	82	1.72	20.51	-48.0	3.00	59.0
Week 26	81	73.77	20.84	6.0	79.00	100.0	76	1.00	23.37	-85.0	3.00	60.0
Week 29	77	71.58	22.30	8.0	79.00	100.0	71	-2.15	24.91	-92.0	0.00	61.0
Week 32	64	70.95	21.96	13.0	77.50	100.0	59	-1.69	23.10	-77.0	1.00	59.0
Week 35	62	71.11	22.19	10.0	76.00	100.0	57	-2.37	22.95	-60.0	2.00	59.0
Week 38	56	70.88	23.16	10.0	79.50	100.0	50	-4.94	22.85	-52.0	0.00	57.0
Week 41	52	68.73	23.38	7.0	70.50	100.0	47	-6.70	24.47	-64.0	-5.00	59.0
Week 44	49	66.71	23.55	11.0	73.00	100.0	44	-7.66	23.90	-78.0	-5.00	42.0
Week 47	43	68.95	24.43	11.0	75.00	100.0	39	-4.67	21.35	-54.0	-1.00	59.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.2: EQ-5D-5L - Observed Means and Change from Baseline of VAS - Analysis Set mITT 2

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Week 50	36	68.28	24.39	10.0	75.00	98.0	31	-5.48	24.58	-60.0	-2.00	60.0
Week 53	31	65.87	27.43	10.0	70.00	100.0	28	-7.04	30.17	-59.0	0.50	59.0
Week 56	30	68.23	22.98	9.0	71.00	100.0	29	-3.90	24.58	-61.0	1.00	57.0
Week 59	23	67.57	23.38	20.0	67.00	97.0	21	-1.52	26.89	-60.0	-1.00	60.0
Week 62	20	65.50	22.86	22.0	71.50	100.0	20	-3.10	26.01	-48.0	-6.50	59.0
Week 65	17	71.35	22.12	30.0	75.00	100.0	16	-0.63	24.42	-42.0	-2.50	60.0
Week 68	13	69.15	23.18	21.0	75.00	95.0	13	-3.31	16.94	-49.0	0.00	20.0
Week 71	13	64.23	24.11	30.0	75.00	95.0	13	-7.38	28.70	-60.0	-4.00	49.0
Week 74	11	71.36	17.75	30.0	75.00	90.0	11	-4.73	14.58	-41.0	-4.00	20.0
Week 77	11	78.45	12.10	62.0	78.00	98.0	11	4.27	25.12	-32.0	-2.00	59.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.2.1: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Present	EV+Pembro (N= 50)												
	BASELINE	41	64.73	17.19	14.0	68.00	94.0						
	Week 1	38	64.29	17.03	24.0	65.00	100.0	35	-0.40	16.39	-22.0	-1.00	42.0
	Week 2	36	62.50	19.10	8.0	65.00	92.0	34	-3.71	19.01	-44.0	-3.50	61.0
	Week 3	32	63.31	20.81	10.0	60.50	94.0	30	-2.07	22.41	-70.0	-1.50	46.0
	Week 4	35	64.37	18.98	19.0	65.00	96.0	31	-0.90	21.85	-50.0	-1.00	69.0
	Week 5	32	66.56	19.90	10.0	69.00	93.0	28	0.29	25.46	-54.0	1.50	77.0
	Week 6	36	67.53	15.83	35.0	69.00	94.0	31	2.65	23.05	-40.0	1.00	78.0
	Week 7	35	66.86	16.41	35.0	70.00	95.0	29	0.07	21.13	-48.0	0.00	79.0
	Week 8	38	67.16	17.32	22.0	69.50	98.0	31	-0.52	23.30	-40.0	-1.00	79.0
	Week 9	33	67.52	15.38	45.0	67.00	95.0	29	3.55	22.53	-40.0	1.00	79.0
	Week 10	30	72.20	14.56	48.0	71.50	95.0	25	8.16	19.78	-19.0	7.00	80.0
	Week 11	31	70.84	22.23	11.0	79.00	96.0	27	5.00	25.59	-47.0	7.00	81.0
	Week 12	32	70.91	18.75	28.0	75.00	96.0	28	4.39	23.43	-60.0	4.00	79.0
	Week 14	36	70.56	20.00	9.0	75.00	96.0	31	4.74	23.56	-44.0	7.00	80.0
	Week 17	33	73.03	16.92	40.0	75.00	98.0	27	7.85	20.30	-36.0	6.00	78.0
	Week 20	28	68.79	19.13	23.0	72.50	98.0	25	0.76	24.39	-57.0	-1.00	60.0
	Week 23	28	70.29	17.67	38.0	74.00	95.0	24	4.00	21.65	-44.0	5.50	79.0
	Week 26	28	67.79	18.37	22.0	70.50	96.0	24	0.04	23.56	-49.0	0.00	81.0
	Week 29	27	65.67	19.99	30.0	70.00	97.0	25	-3.40	24.77	-48.0	-2.00	79.0
	Week 32	26	66.54	20.72	17.0	71.50	94.0	24	-1.13	28.22	-77.0	1.50	79.0
	Week 35	26	68.12	17.75	30.0	70.00	95.0	24	-0.21	22.65	-48.0	-1.50	81.0
	Week 38	26	65.62	16.93	31.0	69.00	89.0	24	-3.83	23.38	-44.0	-2.00	75.0
	Week 41	25	68.68	16.42	30.0	70.00	93.0	23	-0.35	22.15	-39.0	-2.00	74.0
	Week 44	22	67.18	18.00	30.0	69.50	95.0	20	-1.35	21.88	-28.0	-1.00	73.0
	Week 47	14	70.36	18.68	31.0	73.50	96.0	13	8.62	25.40	-19.0	6.00	78.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.2.1: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	66.85	24.00	5.0	72.50	96.0	17	-0.71	28.92	-62.0	2.00	71.0
	Week 53	21	67.24	21.82	6.0	70.00	95.0	18	0.22	26.75	-44.0	0.50	78.0
	Week 56	18	71.28	18.74	37.0	73.00	96.0	15	5.13	25.09	-26.0	2.00	81.0
	Week 59	18	69.72	14.56	33.0	70.50	94.0	15	3.33	24.90	-36.0	1.00	77.0
	Week 62	13	70.77	14.71	36.0	70.00	92.0	11	7.82	27.22	-21.0	0.00	78.0
	Week 68	12	65.92	23.08	10.0	71.50	92.0	11	4.09	32.76	-59.0	1.00	77.0
	Plat+Gem (N= 50)												
	BASELINE	41	65.10	23.32	5.0	68.00	100.0						
	Week 1	35	63.43	23.50	17.0	67.00	95.0	34	-3.62	18.23	-49.0	-1.00	39.0
	Week 2	34	61.79	22.08	14.0	69.50	95.0	31	-5.35	19.98	-52.0	-3.00	45.0
	Week 3	33	65.30	22.31	11.0	70.00	95.0	30	-2.30	15.07	-50.0	0.50	22.0
	Week 4	36	65.33	20.85	15.0	64.00	96.0	33	-2.39	16.93	-36.0	0.00	25.0
	Week 5	37	64.92	24.79	10.0	67.00	96.0	33	-2.82	18.71	-50.0	4.00	20.0
	Week 6	33	67.27	22.51	17.0	70.00	100.0	29	0.62	17.94	-45.0	4.00	25.0
	Week 7	35	62.69	22.86	18.0	65.00	98.0	32	-2.16	20.88	-55.0	3.00	40.0
	Week 8	36	62.17	20.52	8.0	62.00	96.0	32	-5.09	23.63	-68.0	-0.50	32.0
	Week 9	34	61.97	21.94	0.0	67.00	95.0	30	-2.87	22.58	-50.0	1.00	37.0
	Week 10	34	61.91	25.01	9.0	68.50	97.0	30	-0.80	21.00	-40.0	2.00	48.0
	Week 11	30	65.43	20.45	11.0	68.50	98.0	26	2.12	22.14	-48.0	7.00	38.0
	Week 12	32	63.19	24.57	11.0	65.00	96.0	28	-1.96	19.81	-46.0	4.00	34.0
	Week 14	27	63.37	23.13	3.0	65.00	95.0	23	-5.91	22.16	-55.0	-3.00	29.0
	Week 17	28	67.46	19.51	10.0	69.00	95.0	24	-3.13	25.50	-58.0	0.00	31.0
	Week 20	20	64.25	27.09	18.0	70.50	96.0	17	-3.94	17.14	-50.0	-2.00	19.0
	Week 23	15	74.27	21.67	23.0	80.00	96.0	14	6.07	12.21	-18.0	5.00	28.0
	Week 26	15	76.07	18.04	38.0	79.00	96.0	14	6.50	15.52	-13.0	5.50	32.0
	Week 29	13	75.46	24.18	8.0	83.00	96.0	12	-2.33	30.83	-92.0	5.00	32.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.2.1: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Absent	EV+Pembro (N=152)												
	BASELINE	125	71.48	17.77	10.0	75.00	100.0						
	Week 1	105	68.69	19.16	3.0	70.00	100.0	100	-4.73	17.46	-97.0	0.00	39.0
	Week 2	120	65.48	18.69	4.0	63.50	100.0	109	-6.17	18.61	-86.0	-4.00	38.0
	Week 3	109	66.60	20.55	19.0	70.00	100.0	98	-4.90	16.77	-56.0	-2.50	32.0
	Week 4	112	69.54	19.93	10.0	71.50	100.0	103	-2.59	16.89	-59.0	0.00	37.0
	Week 5	107	69.20	18.96	11.0	71.00	100.0	98	-3.93	18.47	-59.0	-2.00	37.0
	Week 6	114	67.43	20.81	11.0	70.00	100.0	99	-5.07	21.32	-71.0	-2.00	50.0
	Week 7	117	70.08	18.53	17.0	71.00	100.0	101	-1.86	19.31	-59.0	0.00	40.0
	Week 8	114	69.34	19.89	11.0	71.00	100.0	99	-2.25	21.09	-70.0	0.00	40.0
	Week 9	111	69.56	20.18	19.0	75.00	100.0	98	-3.55	20.96	-72.0	-0.50	41.0
	Week 10	109	70.54	19.09	10.0	75.00	100.0	97	-2.94	19.11	-60.0	0.00	49.0
	Week 11	107	71.88	19.47	15.0	77.00	100.0	92	-0.38	19.24	-67.0	0.00	47.0
	Week 12	111	69.89	19.68	12.0	74.00	100.0	95	-2.74	19.87	-69.0	0.00	50.0
	Week 14	105	70.18	21.14	7.0	77.00	100.0	89	-2.43	22.08	-92.0	0.00	52.0
	Week 17	100	72.53	17.14	30.0	76.00	100.0	88	-0.78	17.25	-52.0	-0.50	46.0
	Week 20	92	74.11	17.98	29.0	77.50	100.0	81	-0.53	17.48	-52.0	0.00	51.0
	Week 23	89	74.78	18.25	28.0	80.00	100.0	76	1.03	18.85	-53.0	1.50	52.0
	Week 26	86	72.21	18.30	21.0	75.00	100.0	73	-1.22	16.95	-60.0	-1.00	38.0
	Week 29	81	70.98	20.02	2.0	75.00	100.0	71	-2.96	21.09	-79.0	0.00	47.0
	Week 32	78	71.38	18.58	7.0	73.00	100.0	68	-1.93	19.88	-74.0	0.00	44.0
	Week 35	72	73.94	19.18	5.0	80.00	100.0	64	-1.31	17.98	-76.0	0.00	49.0
	Week 38	71	74.87	16.57	29.0	80.00	100.0	64	1.97	14.78	-31.0	1.00	35.0
	Week 41	71	70.42	18.74	7.0	70.00	100.0	65	-2.11	18.62	-72.0	-1.00	35.0
	Week 44	64	70.25	18.55	4.0	75.00	99.0	57	-4.88	18.35	-77.0	-5.00	33.0
	Week 47	65	72.37	16.59	30.0	75.00	100.0	59	-2.12	15.45	-43.0	0.00	39.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.2.1: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	55	72.35	18.07	28.0	75.00	100.0	49	-3.00	15.55	-32.0	0.00	31.0
	Week 53	55	69.45	19.28	25.0	70.00	100.0	48	-4.52	17.10	-44.0	-4.00	25.0
	Week 56	55	72.67	18.03	30.0	73.00	100.0	49	-1.57	16.33	-39.0	0.00	40.0
	Week 59	51	71.94	18.15	34.0	71.00	99.0	44	-1.25	17.03	-40.0	-0.50	39.0
	Week 62	49	72.82	17.23	41.0	74.00	100.0	43	-2.28	15.42	-41.0	-2.00	34.0
	Week 65	36	69.86	18.34	33.0	70.00	100.0	34	-3.71	16.04	-41.0	-0.50	25.0
	Week 68	34	71.82	18.54	40.0	71.50	100.0	32	-3.13	15.68	-34.0	0.50	35.0
	Week 71	34	70.56	18.43	38.0	70.00	99.0	32	-2.78	14.48	-37.0	-1.00	30.0
	Week 74	33	72.97	18.83	35.0	75.00	99.0	31	-3.03	17.62	-43.0	1.00	29.0
	Week 77	31	72.58	19.19	31.0	74.00	99.0	28	-2.54	17.84	-39.0	1.50	37.0
	Week 80	31	70.68	19.77	30.0	70.00	99.0	30	-4.73	18.49	-48.0	-4.00	39.0
	Week 83	25	69.04	21.13	20.0	69.00	100.0	25	-5.12	22.00	-61.0	-6.00	39.0
	Week 86	23	64.22	22.97	28.0	59.00	99.0	23	-9.39	25.29	-54.0	0.00	38.0
	Week 89	18	69.67	22.87	28.0	70.50	98.0	18	-7.17	21.38	-54.0	-4.50	34.0
	Week 92	16	73.50	19.70	37.0	77.50	99.0	16	-0.38	21.96	-44.0	3.00	39.0
	Week 95	12	79.08	18.57	46.0	84.00	100.0	12	4.67	14.42	-17.0	3.00	29.0
	Plat+Gem (N=152)												
	BASELINE	127	71.86	19.17	20.0	76.00	100.0						
	Week 1	111	67.60	20.94	3.0	70.00	100.0	108	-4.81	19.27	-59.0	-1.50	49.0
	Week 2	119	66.34	20.31	3.0	70.00	100.0	110	-6.55	21.02	-79.0	-5.00	51.0
	Week 3	117	67.18	21.47	2.0	70.00	100.0	108	-6.80	20.90	-87.0	-4.50	51.0
	Week 4	116	69.33	19.89	1.0	74.00	100.0	105	-3.73	18.78	-48.0	-3.00	51.0
	Week 5	120	67.43	19.82	10.0	70.00	100.0	108	-5.80	19.51	-71.0	-3.00	50.0
	Week 6	113	68.41	20.21	2.0	70.00	100.0	102	-4.74	22.31	-68.0	-4.50	58.0
	Week 7	115	67.97	20.82	6.0	70.00	100.0	105	-6.08	22.99	-75.0	-5.00	63.0
	Week 8	111	68.44	20.42	5.0	70.00	100.0	102	-5.39	22.22	-74.0	-4.00	61.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.2.1: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Liver Metastases - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 9	108	67.35	21.96	0.0	71.50	100.0	97	-5.91	22.49	-53.0	-4.00	60.0
	Week 10	109	69.29	20.32	2.0	71.00	100.0	100	-4.64	22.66	-73.0	-6.00	62.0
	Week 11	97	66.82	21.27	1.0	67.00	100.0	90	-6.67	22.88	-69.0	-9.00	60.0
	Week 12	98	68.65	20.39	2.0	70.00	100.0	88	-4.77	21.87	-62.0	-3.50	42.0
	Week 14	98	66.09	21.91	1.0	70.00	100.0	87	-7.37	24.31	-67.0	-5.00	54.0
	Week 17	92	66.35	22.08	10.0	70.50	100.0	84	-6.29	24.75	-65.0	-7.50	54.0
	Week 20	84	70.11	21.51	10.0	75.00	100.0	76	-3.99	23.96	-65.0	-4.50	57.0
	Week 23	74	74.45	19.42	27.0	79.50	100.0	68	0.82	21.79	-48.0	2.00	59.0
	Week 26	66	73.24	21.52	6.0	79.00	100.0	62	-0.24	24.74	-85.0	1.50	60.0
	Week 29	64	70.80	22.02	17.0	76.00	100.0	59	-2.12	23.85	-61.0	-1.00	61.0
	Week 32	55	71.15	21.25	15.0	77.00	100.0	50	-1.40	21.48	-48.0	0.50	59.0
	Week 35	54	70.28	22.75	10.0	76.00	100.0	49	-3.69	23.86	-60.0	1.00	59.0
	Week 38	47	70.19	23.35	10.0	79.00	100.0	42	-5.55	24.22	-52.0	-0.50	57.0
	Week 41	45	67.62	24.06	7.0	70.00	100.0	40	-8.98	25.05	-64.0	-6.00	59.0
	Week 44	41	66.32	23.15	11.0	70.00	100.0	36	-8.86	24.21	-78.0	-5.00	42.0
	Week 47	35	67.40	25.92	11.0	75.00	100.0	31	-7.10	22.22	-54.0	-4.00	59.0
	Week 50	29	66.38	24.76	10.0	75.00	97.0	24	-8.13	25.65	-60.0	-4.00	60.0
	Week 53	25	66.84	26.55	18.0	70.00	100.0	22	-6.82	29.36	-59.0	0.00	59.0
	Week 56	26	68.27	23.66	9.0	71.00	100.0	25	-3.08	25.49	-61.0	1.00	57.0
	Week 59	20	66.25	24.27	20.0	67.00	97.0	18	-1.22	28.23	-60.0	-2.00	60.0
	Week 62	17	65.24	23.10	22.0	68.00	100.0	17	-1.41	25.62	-48.0	-6.00	59.0
	Week 65	15	68.93	22.48	30.0	75.00	100.0	14	-2.43	25.62	-42.0	-4.00	60.0
	Week 68	11	66.36	24.27	21.0	71.00	95.0	11	-5.18	17.59	-49.0	-1.00	20.0
	Week 71	12	62.08	23.85	30.0	72.00	95.0	12	-8.42	29.73	-60.0	-4.00	49.0
	Week 74	10	70.50	18.46	30.0	75.00	90.0	10	-4.70	15.37	-41.0	-4.00	20.0
	Week 77	10	78.30	12.75	62.0	76.50	98.0	10	5.20	26.28	-32.0	-0.50	59.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.2.2: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
< 65 years	EV+Pembro (N= 39)												
	BASELINE	33	70.18	19.91	10.0	70.00	100.0						
	Week 1	27	68.81	19.36	3.0	71.00	100.0	26	-3.92	21.05	-97.0	0.50	21.0
	Week 2	31	68.29	18.39	4.0	69.00	100.0	30	-4.67	20.81	-86.0	-0.50	27.0
	Week 3	31	72.26	16.75	30.0	75.00	97.0	30	0.27	14.70	-28.0	-1.00	32.0
	Week 4	30	77.60	13.30	39.0	80.00	95.0	28	4.32	12.63	-20.0	1.50	30.0
	Week 5	28	77.86	14.22	30.0	80.00	98.0	27	5.11	14.05	-20.0	2.00	37.0
	Week 6	29	77.66	12.48	56.0	80.00	94.0	27	4.52	15.01	-21.0	2.00	37.0
	Week 7	30	75.93	14.31	38.0	76.50	96.0	27	3.78	15.80	-31.0	2.00	33.0
	Week 8	30	78.23	15.50	38.0	82.00	98.0	27	4.44	15.87	-29.0	1.00	35.0
	Week 9	28	73.68	16.47	39.0	79.50	95.0	28	2.04	16.73	-39.0	-1.00	38.0
	Week 10	26	78.92	14.00	45.0	82.00	97.0	24	4.33	15.93	-21.0	4.00	49.0
	Week 11	28	78.96	16.60	30.0	82.50	96.0	26	5.96	15.84	-29.0	3.50	46.0
	Week 12	28	73.82	17.51	30.0	77.50	99.0	26	0.81	15.96	-30.0	1.50	44.0
	Week 14	26	78.85	16.27	21.0	82.50	96.0	24	6.92	15.64	-19.0	1.00	38.0
	Week 17	28	75.96	15.47	39.0	80.00	98.0	25	4.00	16.38	-28.0	0.00	38.0
	Week 20	27	78.11	13.46	50.0	80.00	99.0	25	5.40	15.15	-15.0	3.00	41.0
	Week 23	26	78.27	14.51	29.0	82.00	99.0	24	5.08	14.39	-18.0	3.50	38.0
	Week 26	24	78.50	11.99	52.0	80.00	96.0	22	4.09	15.93	-20.0	0.00	38.0
	Week 29	25	76.28	13.93	42.0	80.00	97.0	23	2.57	21.08	-31.0	0.00	47.0
	Week 32	25	75.04	15.36	42.0	78.00	97.0	23	3.74	19.79	-29.0	0.00	44.0
	Week 35	24	74.67	15.10	40.0	79.50	94.0	22	0.27	14.90	-29.0	0.50	27.0
	Week 38	23	77.04	10.01	54.0	80.00	91.0	22	3.77	14.92	-19.0	0.00	35.0
	Week 41	25	70.40	18.09	7.0	71.00	99.0	24	-2.88	23.29	-72.0	0.50	27.0
	Week 44	22	72.45	16.44	35.0	73.50	99.0	21	-3.52	20.54	-65.0	-2.00	33.0
	Week 47	20	75.20	13.36	48.0	73.50	99.0	19	-1.95	16.80	-31.0	-1.00	32.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
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Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.2.2: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	19	76.21	15.93	43.0	79.00	99.0	18	0.50	17.31	-32.0	1.00	31.0
	Week 53	20	75.25	14.05	51.0	75.50	99.0	19	-0.11	11.92	-20.0	0.00	25.0
	Week 56	17	77.41	17.05	33.0	81.00	98.0	16	0.63	16.31	-20.0	0.50	40.0
	Week 59	17	71.12	15.07	47.0	71.00	99.0	16	-1.69	15.05	-29.0	-1.00	39.0
	Week 62	15	74.73	12.72	61.0	69.00	97.0	15	-2.47	11.93	-25.0	0.00	21.0
	Week 65	14	72.07	15.45	51.0	69.50	99.0	14	-1.43	12.13	-21.0	1.00	25.0
	Week 68	11	76.36	14.65	58.0	71.00	99.0	11	-0.09	16.34	-29.0	1.00	35.0
	Week 71	13	73.31	14.32	50.0	69.00	99.0	13	-0.15	12.60	-20.0	-2.00	30.0
	Week 74	14	70.50	16.63	35.0	70.00	98.0	14	-5.07	17.09	-43.0	-0.50	26.0
	Week 77	14	72.43	14.90	51.0	69.00	99.0	14	-3.14	17.11	-39.0	-2.50	37.0
	Week 80	14	68.50	20.09	30.0	68.50	99.0	14	-9.29	16.44	-48.0	-11.50	14.0
	Week 83	12	69.42	14.58	49.0	68.50	99.0	12	-5.50	16.86	-29.0	-5.50	32.0
	Plat+Gem (N= 29)												
	BASELINE	22	72.05	19.85	20.0	80.00	100.0						
	Week 1	21	67.33	19.44	20.0	70.00	92.0	20	-7.00	14.71	-40.0	-9.50	18.0
	Week 2	24	66.46	21.26	20.0	70.00	95.0	20	-5.30	21.22	-50.0	-4.50	50.0
	Week 3	23	71.04	17.57	35.0	75.00	100.0	20	-2.15	14.72	-43.0	0.00	22.0
	Week 4	23	65.26	23.29	11.0	75.00	100.0	19	-10.42	15.87	-48.0	-5.00	9.0
	Week 5	25	69.00	23.77	10.0	78.00	100.0	20	-1.05	14.59	-36.0	-2.00	21.0
	Week 6	22	73.64	19.08	29.0	76.00	100.0	18	-0.89	17.79	-60.0	0.50	19.0
	Week 7	24	68.08	22.58	10.0	76.00	95.0	21	-5.57	21.01	-50.0	-1.00	23.0
	Week 8	21	69.33	23.63	7.0	80.00	95.0	19	-4.74	22.73	-74.0	-1.00	21.0
	Week 9	20	67.70	24.86	0.0	74.50	100.0	17	-2.71	11.92	-20.0	-2.00	24.0
	Week 10	21	71.24	18.53	31.0	76.00	100.0	18	-4.39	15.06	-30.0	-3.50	22.0
	Week 11	20	72.70	21.40	20.0	79.50	100.0	17	-1.06	17.83	-36.0	0.00	28.0
	Week 12	21	71.95	21.64	15.0	79.00	100.0	17	-0.53	19.30	-54.0	0.00	27.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.2.2: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 14	22	66.41	25.23	21.0	75.00	100.0	18	-9.61	27.00	-67.0	-3.50	23.0
	Week 17	20	67.90	26.10	10.0	79.50	100.0	17	-3.71	23.30	-49.0	0.00	31.0
	Week 20	18	67.39	25.97	18.0	74.50	100.0	15	-7.53	21.41	-65.0	-5.00	24.0
	Week 23	18	79.11	19.42	23.0	87.00	100.0	16	1.69	17.28	-37.0	1.50	31.0
	Week 26	16	75.94	20.56	35.0	84.00	100.0	14	-1.50	20.17	-36.0	0.00	30.0
	Week 29	15	74.33	19.89	30.0	80.00	100.0	13	-1.15	17.44	-31.0	0.00	25.0
	Week 32	15	74.13	24.62	15.0	80.00	100.0	13	-0.31	21.10	-48.0	1.00	26.0
	Week 35	15	72.67	22.60	19.0	76.00	100.0	13	-3.77	20.70	-39.0	0.00	24.0
	Week 38	14	69.71	20.28	37.0	69.50	100.0	12	-7.75	19.78	-38.0	-7.50	23.0
	Week 41	11	64.36	26.51	25.0	70.00	100.0	9	-15.56	27.62	-64.0	-10.00	19.0
	Week 44	11	63.00	28.36	11.0	69.00	96.0	9	-18.78	26.52	-78.0	-13.00	9.0
	Week 47	11	69.09	26.49	22.0	70.00	100.0	9	-1.67	17.61	-38.0	0.00	20.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.2.2: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
>= 65 years	EV+Pembro (N=163)												
	BASELINE	133	69.72	17.34	14.0	70.00	100.0						
	Week 1	116	67.22	18.57	14.0	69.00	100.0	109	-3.53	16.31	-64.0	-1.00	42.0
	Week 2	125	63.92	18.83	8.0	61.00	99.0	113	-5.82	18.15	-61.0	-5.00	61.0
	Week 3	110	64.05	21.26	10.0	67.00	100.0	98	-5.61	18.98	-70.0	-3.50	46.0
	Week 4	117	65.93	20.49	10.0	69.00	100.0	106	-3.92	18.95	-59.0	-2.50	69.0
	Week 5	111	66.25	19.56	10.0	70.00	100.0	99	-5.20	21.09	-59.0	-2.00	77.0
	Week 6	121	65.01	20.33	11.0	68.00	100.0	103	-5.26	23.00	-71.0	-2.00	78.0
	Week 7	122	67.71	18.56	17.0	70.00	100.0	103	-2.80	20.40	-59.0	0.00	79.0
	Week 8	122	66.48	19.43	11.0	70.00	100.0	103	-3.49	22.59	-70.0	0.00	79.0
	Week 9	116	67.98	19.66	19.0	70.00	100.0	99	-3.05	22.55	-72.0	0.00	79.0
	Week 10	113	69.05	18.57	10.0	71.00	100.0	98	-1.89	20.38	-60.0	0.00	80.0
	Week 11	110	69.78	20.48	11.0	74.50	100.0	93	-0.59	21.91	-67.0	0.00	81.0
	Week 12	115	69.22	19.82	12.0	74.00	100.0	97	-1.63	22.02	-69.0	1.00	79.0
	Week 14	115	68.34	21.26	7.0	73.00	100.0	96	-2.45	23.72	-92.0	0.00	80.0
	Week 17	105	71.77	17.38	30.0	75.00	100.0	90	0.48	18.80	-52.0	-0.50	78.0
	Week 20	93	71.34	19.29	23.0	73.00	100.0	81	-1.96	20.06	-57.0	-1.00	60.0
	Week 23	91	72.40	18.92	28.0	79.00	100.0	76	0.68	20.81	-53.0	1.00	79.0
	Week 26	90	69.16	19.26	21.0	70.00	100.0	75	-2.37	19.26	-60.0	-2.00	81.0
	Week 29	83	67.65	21.23	2.0	71.00	100.0	73	-4.85	22.09	-79.0	-1.00	79.0
	Week 32	79	68.63	20.04	7.0	72.00	100.0	69	-3.54	22.78	-77.0	-1.00	79.0
	Week 35	74	71.66	20.01	5.0	76.50	100.0	66	-1.44	20.56	-76.0	-0.50	81.0
	Week 38	74	70.95	18.56	29.0	75.00	100.0	66	-0.74	18.36	-44.0	0.00	75.0
	Week 41	71	69.82	18.23	30.0	70.00	100.0	64	-1.19	18.04	-39.0	-3.50	74.0
	Week 44	64	68.44	18.98	4.0	71.50	99.0	56	-4.13	18.92	-77.0	-4.00	73.0
	Week 47	59	70.93	17.88	30.0	75.00	100.0	53	0.45	18.42	-43.0	0.00	78.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.2.2: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	56	69.07	20.77	5.0	70.50	100.0	48	-3.50	20.50	-62.0	0.50	71.0
	Week 53	56	66.55	21.24	6.0	70.00	100.0	47	-4.49	22.54	-44.0	-4.00	78.0
	Week 56	56	70.79	18.25	30.0	71.00	100.0	48	-0.21	19.64	-39.0	0.00	81.0
	Week 59	52	71.44	17.99	33.0	70.50	97.0	43	0.51	20.67	-40.0	0.00	77.0
	Week 62	47	71.64	17.76	36.0	71.00	100.0	39	0.64	20.64	-41.0	-2.00	78.0
	Week 65	29	69.21	18.66	33.0	70.00	100.0	27	-3.44	17.78	-41.0	-1.00	24.0
	Week 68	35	68.37	20.89	10.0	72.00	100.0	32	-1.69	22.78	-59.0	0.50	77.0
	Week 71	30	70.50	18.26	38.0	70.50	99.0	27	0.37	21.16	-37.0	0.00	79.0
	Week 74	24	74.54	18.47	41.0	79.50	99.0	22	2.77	22.23	-41.0	2.50	70.0
	Week 77	23	72.83	19.94	31.0	78.00	98.0	20	2.90	23.83	-38.0	4.50	76.0
	Week 80	22	72.18	17.87	36.0	75.00	99.0	21	2.81	22.95	-32.0	3.00	67.0
	Week 83	18	69.11	22.36	20.0	70.00	100.0	18	0.22	26.72	-61.0	0.50	56.0
	Week 86	18	60.28	23.82	28.0	55.00	99.0	18	-9.67	26.78	-54.0	1.00	29.0
	Week 89	12	67.08	24.23	28.0	69.50	98.0	12	-8.00	23.10	-54.0	-4.50	34.0
	Week 92	10	75.20	20.24	37.0	80.50	98.0	10	1.80	22.67	-44.0	4.50	39.0
	Plat+Gem (N=173)												
	BASELINE	146	69.93	20.53	5.0	71.50	100.0						
	Week 1	125	66.48	21.98	3.0	70.00	100.0	122	-4.11	19.60	-59.0	-0.50	49.0
	Week 2	129	65.12	20.71	3.0	69.00	100.0	121	-6.45	20.74	-79.0	-4.00	51.0
	Week 3	127	65.99	22.22	2.0	70.00	99.0	118	-6.44	20.54	-87.0	-3.00	51.0
	Week 4	129	68.94	19.56	1.0	70.00	100.0	119	-2.29	18.48	-48.0	-2.00	51.0
	Week 5	132	66.42	20.55	10.0	70.00	98.0	121	-5.77	19.94	-71.0	-2.00	50.0
	Week 6	124	67.18	20.87	2.0	68.00	100.0	113	-3.97	22.04	-68.0	-4.00	58.0
	Week 7	126	66.48	21.20	6.0	68.00	100.0	116	-5.09	22.85	-75.0	-3.00	63.0
	Week 8	126	66.50	20.08	5.0	70.00	100.0	115	-5.42	22.54	-68.0	-4.00	61.0
	Week 9	122	65.80	21.60	0.0	69.50	100.0	110	-5.57	23.69	-53.0	-3.50	60.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.2.2: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Age - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	122	66.90	22.16	2.0	70.00	100.0	112	-3.65	23.27	-73.0	-3.00	62.0
	Week 11	107	65.34	20.83	1.0	66.00	99.0	99	-5.32	23.70	-69.0	-6.00	60.0
	Week 12	109	66.41	21.49	2.0	69.00	97.0	99	-4.71	21.71	-62.0	-2.00	42.0
	Week 14	103	65.31	21.52	1.0	68.00	99.0	92	-6.57	23.24	-60.0	-4.50	54.0
	Week 17	100	66.35	20.52	10.0	69.50	100.0	91	-5.93	25.22	-65.0	-5.00	54.0
	Week 20	86	69.31	22.07	10.0	73.50	99.0	78	-3.29	23.11	-60.0	-3.00	57.0
	Week 23	71	73.23	19.71	27.0	79.00	100.0	66	1.73	21.33	-48.0	3.00	59.0
	Week 26	65	73.23	21.03	6.0	78.00	100.0	62	1.56	24.15	-85.0	5.00	60.0
	Week 29	62	70.92	22.95	8.0	76.00	100.0	58	-2.38	26.42	-92.0	0.50	61.0
	Week 32	49	69.98	21.26	13.0	76.00	100.0	46	-2.09	23.84	-77.0	1.50	59.0
	Week 35	47	70.62	22.28	10.0	76.00	100.0	44	-1.95	23.78	-60.0	3.50	59.0
	Week 38	42	71.26	24.26	10.0	80.00	98.0	38	-4.05	23.91	-52.0	1.00	57.0
	Week 41	41	69.90	22.68	7.0	76.00	100.0	38	-4.61	23.58	-63.0	-4.50	59.0
	Week 44	38	67.79	22.29	17.0	75.00	100.0	35	-4.80	22.71	-53.0	-5.00	42.0
	Week 47	32	68.91	24.13	11.0	75.50	100.0	30	-5.57	22.54	-54.0	-2.50	59.0
	Week 50	29	70.24	23.10	10.0	75.00	98.0	26	-5.58	25.43	-60.0	-3.00	60.0
	Week 53	25	66.24	28.03	10.0	70.00	100.0	24	-8.29	31.45	-59.0	0.50	59.0
	Week 56	26	68.46	22.72	9.0	73.00	94.0	26	-5.38	25.09	-61.0	0.50	57.0
	Week 59	20	70.65	22.64	20.0	77.00	97.0	20	-2.10	27.45	-60.0	-2.00	60.0
	Week 62	19	66.74	22.78	22.0	75.00	100.0	19	-3.32	26.71	-48.0	-7.00	59.0
	Week 65	16	70.81	22.73	30.0	75.00	100.0	16	-0.63	24.42	-42.0	-2.50	60.0
	Week 68	13	69.15	23.18	21.0	75.00	95.0	13	-3.31	16.94	-49.0	0.00	20.0
	Week 71	13	64.23	24.11	30.0	75.00	95.0	13	-7.38	28.70	-60.0	-4.00	49.0
	Week 74	11	71.36	17.75	30.0	75.00	90.0	11	-4.73	14.58	-41.0	-4.00	20.0
	Week 77	10	80.10	11.39	64.0	79.00	98.0	10	2.60	25.83	-32.0	-3.50	59.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.2.3: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Europe	EV+Pembro (N= 74)												
	BASELINE	57	66.30	18.41	10.0	69.00	100.0						
	Week 1	48	64.60	18.14	20.0	69.50	92.0	45	-4.82	13.88	-50.0	-1.00	16.0
	Week 2	54	61.87	20.30	4.0	65.00	92.0	48	-6.31	19.62	-86.0	-3.00	31.0
	Week 3	50	60.96	19.09	19.0	60.50	96.0	43	-5.56	18.27	-53.0	-4.00	30.0
	Week 4	52	63.85	19.00	11.0	66.00	97.0	46	-4.15	18.24	-59.0	-1.00	29.0
	Week 5	47	61.64	19.14	11.0	60.00	98.0	43	-7.84	21.20	-59.0	-2.00	22.0
	Week 6	53	62.30	18.81	19.0	60.00	97.0	42	-6.81	21.17	-53.0	0.00	27.0
	Week 7	52	64.00	16.89	31.0	68.50	96.0	41	-5.27	18.23	-59.0	-1.00	27.0
	Week 8	53	65.60	19.69	11.0	69.00	98.0	43	-3.93	19.61	-52.0	-3.00	43.0
	Week 9	48	65.50	16.02	39.0	68.00	96.0	40	-1.35	17.52	-40.0	0.00	41.0
	Week 10	45	66.93	17.23	31.0	65.00	95.0	36	-0.58	16.68	-32.0	2.00	44.0
	Week 11	49	70.57	18.49	11.0	75.00	94.0	39	1.64	18.96	-47.0	4.00	47.0
	Week 12	52	67.23	17.40	28.0	70.00	94.0	41	-2.85	18.86	-60.0	1.00	50.0
	Week 14	52	67.52	21.59	9.0	71.00	96.0	40	-1.60	21.10	-61.0	0.00	49.0
	Week 17	43	71.67	15.81	39.0	75.00	97.0	34	4.97	14.64	-22.0	2.50	46.0
	Week 20	41	70.71	20.15	23.0	75.00	98.0	34	0.97	24.31	-57.0	0.50	51.0
	Week 23	41	69.98	17.34	29.0	75.00	95.0	31	2.81	20.87	-53.0	4.00	52.0
	Week 26	38	68.05	18.31	22.0	70.00	96.0	29	-1.03	16.00	-49.0	0.00	25.0
	Week 29	37	71.14	19.23	20.0	75.00	99.0	30	-0.27	20.25	-44.0	0.50	47.0
	Week 32	35	68.54	19.95	17.0	75.00	97.0	28	-2.89	22.75	-77.0	-0.50	42.0
	Week 35	31	69.32	17.35	37.0	70.00	98.0	26	-2.19	14.86	-58.0	0.50	24.0
	Week 38	31	67.84	16.47	29.0	70.00	91.0	27	-2.48	16.15	-44.0	0.00	33.0
	Week 41	28	66.75	14.90	41.0	68.50	96.0	24	0.46	14.46	-39.0	0.50	27.0
	Week 44	27	69.00	15.90	37.0	75.00	97.0	23	-0.83	10.91	-28.0	0.00	15.0
	Week 47	25	70.48	15.34	30.0	75.00	96.0	21	1.57	12.26	-25.0	0.00	26.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.2.3: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	27	66.85	22.84	5.0	75.00	96.0	23	-4.52	21.29	-62.0	0.00	31.0
	Week 53	28	63.82	22.68	6.0	67.50	95.0	23	-8.09	19.86	-44.0	-4.00	24.0
	Week 56	26	68.08	19.13	33.0	70.50	96.0	22	-2.09	15.57	-30.0	0.00	31.0
	Week 59	23	67.13	15.22	39.0	70.00	95.0	18	-3.39	15.38	-36.0	-1.00	24.0
	Week 62	20	69.45	16.80	36.0	69.50	95.0	17	-1.88	13.79	-21.0	-3.00	24.0
	Week 65	13	65.31	14.53	47.0	66.00	97.0	13	-5.00	13.06	-41.0	-1.00	10.0
	Week 68	15	61.47	20.34	10.0	66.00	98.0	15	-8.33	18.94	-59.0	0.00	14.0
	Week 71	14	66.93	14.99	41.0	68.00	98.0	14	-1.93	11.07	-31.0	-1.00	15.0
	Week 74	10	68.50	17.19	42.0	68.00	98.0	9	-3.22	13.81	-33.0	0.00	11.0
	Plat+Gem (N= 95)												
	BASELINE	76	69.00	20.18	20.0	70.00	100.0						
	Week 1	72	63.99	22.15	17.0	67.50	100.0	70	-5.06	18.33	-59.0	-0.50	42.0
	Week 2	72	62.17	21.17	10.0	69.00	98.0	64	-6.73	22.19	-79.0	-5.00	50.0
	Week 3	72	65.33	21.84	2.0	70.00	100.0	65	-5.77	21.85	-87.0	-3.00	51.0
	Week 4	69	65.91	20.27	11.0	66.00	100.0	62	-3.31	19.61	-48.0	-3.50	51.0
	Week 5	72	64.83	22.32	10.0	66.00	100.0	64	-3.63	19.74	-48.0	-1.00	50.0
	Week 6	69	65.70	21.48	18.0	68.00	100.0	61	-3.85	25.25	-68.0	-1.00	58.0
	Week 7	69	67.38	21.60	10.0	68.00	100.0	62	-2.35	21.83	-53.0	0.00	63.0
	Week 8	68	67.50	19.82	19.0	67.00	100.0	60	-1.93	22.58	-53.0	-1.00	61.0
	Week 9	66	65.73	22.34	0.0	69.00	100.0	57	-2.60	24.17	-53.0	-1.00	60.0
	Week 10	71	66.24	22.68	9.0	69.00	100.0	63	-2.92	24.36	-73.0	0.00	62.0
	Week 11	63	66.78	20.76	20.0	66.00	100.0	56	-2.18	24.35	-69.0	-0.50	60.0
	Week 12	66	65.83	21.81	15.0	68.50	100.0	56	-3.98	23.55	-62.0	-1.00	42.0
	Week 14	66	64.53	22.07	10.0	68.00	100.0	56	-5.07	25.13	-67.0	-3.00	54.0
	Week 17	61	64.25	23.88	10.0	68.00	100.0	53	-3.28	27.25	-59.0	-5.00	54.0
	Week 20	54	67.31	23.40	19.0	71.00	100.0	48	-3.50	25.83	-65.0	-1.00	57.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.2.3: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 23	45	72.38	20.59	29.0	79.00	100.0	41	1.00	22.40	-48.0	3.00	59.0
	Week 26	42	71.43	21.45	18.0	77.50	100.0	39	1.00	21.95	-52.0	0.00	60.0
	Week 29	39	69.51	23.59	19.0	70.00	100.0	36	-1.11	23.90	-51.0	-0.50	61.0
	Week 32	33	65.85	26.31	13.0	70.00	100.0	31	-3.77	27.46	-77.0	-1.00	59.0
	Week 35	32	66.50	26.49	10.0	76.50	100.0	30	-4.07	26.21	-60.0	1.50	59.0
	Week 38	28	69.79	25.49	18.0	81.00	100.0	26	-4.81	25.13	-52.0	0.00	57.0
	Week 41	25	66.48	27.98	7.0	68.00	100.0	23	-4.48	30.96	-64.0	-5.00	59.0
	Week 44	24	63.29	27.74	11.0	67.00	100.0	22	-9.32	28.34	-78.0	-6.50	42.0
	Week 47	22	64.82	28.83	11.0	73.00	100.0	20	-4.75	26.06	-54.0	-4.50	59.0
	Week 50	17	64.76	28.52	10.0	70.00	97.0	15	-4.93	31.29	-60.0	0.00	60.0
	Week 53	15	59.13	34.93	10.0	59.00	100.0	14	-7.43	37.72	-59.0	1.00	59.0
	Week 56	15	62.13	28.17	9.0	65.00	94.0	14	-7.29	30.70	-61.0	0.50	57.0
	Week 59	11	62.64	29.17	20.0	67.00	97.0	10	-5.00	34.95	-60.0	-0.50	60.0
	Week 62	11	66.55	27.31	22.0	78.00	100.0	11	-3.09	29.64	-48.0	-7.00	59.0
	Week 65	10	71.30	25.11	30.0	83.00	97.0	10	3.70	25.10	-28.0	-1.50	60.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.2.3: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
North America	EV+Pembro (N= 46)												
	BASELINE	35	72.57	14.90	30.0	72.00	99.0						
	Week 1	31	69.42	17.45	24.0	65.00	100.0	29	-0.79	16.49	-30.0	-1.00	42.0
	Week 2	31	69.13	18.87	21.0	70.00	100.0	29	-5.55	16.56	-60.0	-3.00	24.0
	Week 3	25	78.96	14.62	48.0	83.00	99.0	23	0.96	14.53	-43.0	2.00	27.0
	Week 4	30	73.93	16.36	38.0	79.50	100.0	26	-0.92	13.62	-20.0	-2.00	32.0
	Week 5	30	75.43	16.92	32.0	79.00	98.0	24	0.63	18.45	-59.0	0.50	41.0
	Week 6	31	74.45	17.30	35.0	75.00	100.0	25	0.56	18.04	-40.0	1.00	41.0
	Week 7	33	76.61	14.83	48.0	76.00	100.0	25	1.00	12.10	-19.0	0.00	27.0
	Week 8	29	76.45	14.68	49.0	75.00	98.0	22	4.91	14.44	-20.0	1.50	31.0
	Week 9	27	78.67	16.74	30.0	81.00	100.0	23	3.83	20.60	-61.0	3.00	39.0
	Week 10	29	80.21	13.38	49.0	80.00	100.0	25	4.84	16.19	-42.0	5.00	33.0
	Week 11	28	75.96	18.81	15.0	77.50	100.0	23	3.52	13.67	-20.0	1.00	31.0
	Week 12	29	79.48	15.13	47.0	81.00	100.0	24	5.04	14.37	-22.0	3.00	32.0
	Week 14	28	78.14	14.01	44.0	80.00	100.0	23	2.83	14.79	-27.0	1.00	35.0
	Week 17	29	78.48	15.87	48.0	81.00	100.0	25	3.16	17.15	-31.0	3.00	34.0
	Week 20	23	79.26	14.93	48.0	82.00	100.0	20	3.15	14.75	-29.0	5.00	23.0
	Week 23	22	79.27	18.34	30.0	81.00	100.0	19	1.05	16.53	-49.0	3.00	22.0
	Week 26	21	77.81	14.27	47.0	79.00	100.0	17	-0.18	11.23	-18.0	-2.00	19.0
	Week 29	20	73.85	19.62	30.0	76.50	100.0	18	-3.94	18.09	-48.0	0.50	22.0
	Week 32	21	75.14	17.25	40.0	75.00	100.0	19	-1.53	19.03	-38.0	1.00	23.0
	Week 35	22	77.05	18.85	30.0	82.50	100.0	20	-0.05	16.18	-48.0	1.00	21.0
	Week 38	20	78.15	16.91	41.0	82.00	100.0	18	0.28	14.03	-37.0	1.50	19.0
	Week 41	21	81.00	14.43	48.0	85.00	100.0	19	1.42	12.25	-20.0	1.00	25.0
	Week 44	16	78.75	14.35	47.0	80.00	99.0	14	-1.21	11.42	-21.0	-2.50	20.0
	Week 47	16	82.31	13.02	60.0	85.50	100.0	15	3.67	9.66	-9.0	3.00	24.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.2.3: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	16	83.56	11.59	63.0	83.50	100.0	13	4.38	8.58	-10.0	4.00	22.0
	Week 53	15	82.67	13.71	60.0	86.00	100.0	12	6.00	9.47	-6.0	4.00	26.0
	Week 56	17	84.53	11.81	60.0	88.00	98.0	14	8.00	8.87	-6.0	7.50	23.0
	Week 59	17	82.41	13.13	60.0	85.00	99.0	14	6.71	9.88	-9.0	5.00	26.0
	Week 62	14	83.29	13.19	60.0	88.00	97.0	11	7.18	9.83	-4.0	3.00	24.0
	Week 68	11	85.64	16.49	42.0	92.00	99.0	9	9.89	8.36	0.0	8.00	24.0
	Week 71	11	82.36	16.29	48.0	88.00	99.0	9	0.44	12.02	-22.0	3.00	16.0
	Plat+Gem (N= 34)												
	BASELINE	28	71.61	20.51	20.0	80.00	96.0						
	Week 1	20	79.30	15.24	33.0	80.00	100.0	18	2.22	16.62	-35.0	1.50	39.0
	Week 2	23	74.48	18.01	33.0	80.00	100.0	21	-4.00	16.08	-41.0	-1.00	29.0
	Week 3	21	76.48	13.68	49.0	81.00	92.0	18	-0.39	12.83	-31.0	-0.50	22.0
	Week 4	24	77.58	15.76	35.0	79.00	100.0	20	-0.75	12.92	-21.0	0.00	28.0
	Week 5	27	74.41	15.65	44.0	78.00	93.0	23	-3.39	15.98	-47.0	0.00	18.0
	Week 6	20	76.35	14.82	50.0	79.50	94.0	17	-1.47	12.30	-28.0	0.00	18.0
	Week 7	25	67.60	20.99	6.0	72.00	97.0	22	-9.59	22.04	-75.0	-7.50	22.0
	Week 8	24	68.29	20.08	7.0	72.50	92.0	22	-8.41	19.27	-74.0	-5.50	18.0
	Week 9	23	72.91	14.99	39.0	73.00	100.0	20	-3.65	17.59	-36.0	-1.00	23.0
	Week 10	20	74.15	14.58	42.0	78.00	94.0	18	-4.00	17.26	-46.0	-3.00	23.0
	Week 11	19	72.68	15.61	48.0	69.00	98.0	18	-6.56	19.71	-43.0	-7.50	28.0
	Week 12	17	72.94	14.94	45.0	69.00	96.0	16	-1.63	16.17	-31.0	0.50	27.0
	Week 14	16	68.56	19.73	21.0	70.50	97.0	14	-8.50	22.45	-60.0	-2.00	21.0
	Week 17	19	72.53	17.46	28.0	72.00	100.0	18	-5.39	23.71	-65.0	-7.00	31.0
	Week 20	16	74.63	18.21	40.0	78.00	98.0	14	-3.00	21.27	-47.0	-1.00	30.0
	Week 23	15	77.80	14.59	42.0	78.00	96.0	14	3.71	19.30	-38.0	7.50	31.0
	Week 26	13	75.38	16.44	45.0	81.00	96.0	13	-1.46	22.64	-36.0	1.00	30.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.2.3: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 29	14	73.07	20.73	17.0	75.50	100.0	13	-4.38	26.39	-61.0	2.00	29.0
	Week 32	11	78.36	9.34	64.0	77.00	96.0	10	0.90	16.93	-22.0	3.50	26.0
	Week 35	13	75.85	14.32	49.0	75.00	100.0	12	-0.33	20.64	-36.0	1.00	30.0
	Week 38	10	71.00	17.94	37.0	72.50	96.0	9	-7.44	19.51	-30.0	-13.00	23.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.2.3: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Rest of World	EV+Pembro (N= 82)												
	BASELINE	74	71.22	18.41	14.0	76.00	100.0						
	Week 1	64	68.78	19.61	3.0	70.00	100.0	61	-4.05	19.75	-97.0	0.00	39.0
	Week 2	71	65.11	17.33	21.0	62.00	99.0	66	-5.06	19.09	-61.0	-8.50	61.0
	Week 3	66	64.59	21.74	10.0	69.00	100.0	62	-5.24	19.24	-70.0	-6.00	46.0
	Week 4	65	69.29	21.22	10.0	74.00	99.0	62	-1.29	19.68	-45.0	0.00	69.0
	Week 5	62	70.55	18.77	10.0	76.50	100.0	59	-0.93	19.78	-36.0	-1.00	77.0
	Week 6	66	68.30	20.52	11.0	70.00	100.0	63	-2.35	23.67	-71.0	-2.00	78.0
	Week 7	67	69.90	19.24	17.0	70.00	99.0	64	0.08	22.59	-57.0	0.00	79.0
	Week 8	70	68.04	19.96	18.0	70.00	100.0	65	-2.74	24.43	-70.0	0.00	79.0
	Week 9	69	67.84	20.98	19.0	70.00	100.0	64	-4.36	23.73	-72.0	-2.00	79.0
	Week 10	65	69.49	19.43	10.0	72.00	98.0	61	-2.97	22.27	-60.0	-2.00	80.0
	Week 11	61	70.52	21.77	15.0	79.00	97.0	57	-0.79	24.34	-67.0	-2.00	81.0
	Week 12	62	68.16	21.60	12.0	73.00	100.0	58	-2.43	24.04	-69.0	-0.50	79.0
	Week 14	61	69.02	22.05	7.0	80.00	98.0	57	-1.23	26.13	-92.0	0.00	80.0
	Week 17	61	70.57	17.99	30.0	75.00	100.0	56	-1.88	20.41	-52.0	-2.00	78.0
	Week 20	56	71.82	17.87	29.0	73.50	100.0	52	-2.31	16.93	-32.0	-3.50	60.0
	Week 23	54	74.26	18.33	28.0	80.00	98.0	50	1.34	19.98	-43.0	0.50	79.0
	Week 26	55	70.69	19.34	21.0	75.00	99.0	51	-1.08	22.04	-60.0	-2.00	81.0
	Week 29	51	66.92	20.79	2.0	71.00	99.0	48	-4.50	24.43	-79.0	-3.50	79.0
	Week 32	48	69.19	19.37	7.0	70.50	99.0	45	-1.07	23.48	-74.0	0.00	79.0
	Week 35	45	72.24	19.87	5.0	80.00	100.0	42	-0.74	22.98	-76.0	-2.00	81.0
	Week 38	46	72.96	17.08	31.0	78.50	100.0	43	2.23	19.78	-31.0	0.00	75.0
	Week 41	47	66.96	19.61	7.0	70.00	100.0	45	-4.07	23.82	-72.0	-5.00	74.0
	Week 44	43	66.30	20.21	4.0	70.00	99.0	40	-6.73	24.38	-77.0	-9.00	73.0
	Week 47	38	68.68	17.88	31.0	70.00	95.0	36	-2.81	22.65	-43.0	-4.00	78.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.2.3: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	32	67.94	18.10	32.0	70.00	99.0	30	-3.73	21.53	-32.0	-8.50	71.0
	Week 53	33	66.82	17.17	25.0	70.00	97.0	31	-3.19	22.34	-44.0	-7.00	78.0
	Week 56	30	69.10	17.48	30.0	70.00	100.0	28	-2.36	23.47	-39.0	-8.00	81.0
	Week 59	29	68.24	18.44	33.0	70.00	97.0	27	-1.41	24.19	-40.0	-5.00	77.0
	Week 62	28	69.04	16.23	41.0	67.00	100.0	26	-2.27	23.26	-41.0	-8.00	78.0
	Week 65	22	65.68	16.73	33.0	69.00	100.0	21	-6.29	16.95	-37.0	-9.00	25.0
	Week 68	20	68.45	16.51	40.0	70.00	100.0	19	-1.00	25.08	-29.0	-9.00	77.0
	Week 71	18	68.06	16.84	38.0	70.00	99.0	17	1.82	25.84	-37.0	1.00	79.0
	Week 74	19	67.74	16.89	35.0	72.00	99.0	19	-2.21	26.07	-43.0	-3.00	70.0
	Week 77	19	67.63	17.22	36.0	70.00	96.0	18	0.22	27.74	-39.0	-1.50	76.0
	Week 80	19	65.63	19.58	30.0	70.00	99.0	18	-3.06	27.17	-48.0	-5.50	67.0
	Week 83	17	63.88	19.95	20.0	64.00	100.0	17	-4.71	29.07	-61.0	-6.00	56.0
	Week 86	14	59.14	23.14	28.0	60.00	99.0	14	-6.64	29.14	-54.0	1.50	38.0
	Week 89	11	66.27	19.69	28.0	70.00	98.0	11	-7.27	24.81	-54.0	-9.00	34.0
	Plat+Gem (N= 73)												
	BASELINE	64	71.03	20.84	5.0	74.50	100.0						
	Week 1	54	65.39	21.46	3.0	69.00	98.0	54	-6.07	20.32	-50.0	-5.00	49.0
	Week 2	58	65.64	20.40	3.0	65.50	97.0	56	-6.63	20.83	-55.0	-3.00	51.0
	Week 3	57	65.00	22.99	3.0	70.00	98.0	55	-7.65	19.11	-50.0	-6.00	47.0
	Week 4	59	67.53	20.76	1.0	70.00	98.0	56	-4.48	18.62	-41.0	-2.00	43.0
	Week 5	58	65.79	21.11	10.0	65.00	98.0	54	-7.57	20.11	-71.0	-4.00	43.0
	Week 6	57	68.25	21.00	2.0	69.00	100.0	53	-3.87	19.19	-44.0	-4.00	44.0
	Week 7	56	65.57	21.53	18.0	70.00	98.0	53	-6.60	23.44	-63.0	-5.00	49.0
	Week 8	55	65.56	21.91	5.0	70.00	96.0	52	-7.92	23.45	-68.0	-6.00	35.0
	Week 9	53	63.51	23.79	0.0	70.00	98.0	50	-8.76	22.08	-50.0	-5.50	50.0
	Week 10	52	66.77	22.39	2.0	70.00	100.0	49	-4.73	21.43	-40.0	-8.00	51.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.2.3: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Region - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 11	45	63.49	23.04	1.0	66.00	98.0	42	-7.26	22.35	-48.0	-7.00	45.0
	Week 12	47	67.34	23.12	2.0	71.00	96.0	44	-5.14	20.35	-50.0	-5.00	39.0
	Week 14	43	65.86	23.35	1.0	70.00	99.0	40	-9.35	22.60	-55.0	-7.00	45.0
	Week 17	40	67.40	18.88	19.0	70.00	95.0	37	-8.97	21.80	-58.0	-9.00	41.0
	Week 20	34	68.97	23.53	10.0	75.50	99.0	31	-5.16	18.66	-50.0	-5.00	35.0
	Week 23	29	75.83	20.76	23.0	83.00	100.0	27	1.78	18.68	-43.0	2.00	39.0
	Week 26	26	76.73	22.04	6.0	83.50	100.0	24	2.33	26.70	-85.0	6.00	43.0
	Week 29	24	74.08	21.59	8.0	80.00	100.0	22	-2.55	26.72	-92.0	1.50	40.0
	Week 32	20	75.30	17.04	42.0	80.50	100.0	18	0.44	17.91	-39.0	4.50	28.0
	Week 35	17	76.18	16.59	46.0	80.00	99.0	15	-0.60	18.33	-38.0	4.00	31.0
	Week 38	18	72.50	23.00	10.0	79.50	98.0	15	-3.67	21.81	-46.0	5.00	39.0
	Week 41	18	73.33	19.22	29.0	75.50	98.0	16	-5.13	14.49	-37.0	1.00	10.0
	Week 44	16	69.38	21.04	27.0	72.50	98.0	14	-3.43	21.89	-36.0	4.50	40.0
	Week 47	12	72.92	23.47	22.0	78.00	100.0	11	-7.18	17.59	-38.0	-1.00	15.0
	Week 50	11	72.00	24.49	17.0	75.00	98.0	9	-4.11	17.60	-43.0	3.00	14.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.2.4: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	EV+Pembro (N=146)												
	BASELINE	123	70.33	17.63	10.0	71.00	100.0						
	Week 1	104	69.10	18.05	3.0	70.00	100.0	102	-2.90	16.49	-97.0	-0.50	39.0
	Week 2	111	65.08	18.18	8.0	66.00	99.0	105	-5.78	17.80	-61.0	-5.00	61.0
	Week 3	96	66.83	19.92	10.0	70.00	100.0	92	-4.36	18.98	-70.0	-2.50	46.0
	Week 4	103	69.42	18.03	10.0	70.00	100.0	96	-1.50	17.42	-50.0	-1.50	69.0
	Week 5	98	71.35	16.15	30.0	75.00	100.0	92	-1.76	20.03	-59.0	-0.50	77.0
	Week 6	107	69.82	17.62	11.0	70.00	100.0	96	-2.03	21.78	-71.0	0.00	78.0
	Week 7	106	70.38	17.12	25.0	71.00	100.0	93	-0.87	19.66	-59.0	0.00	79.0
	Week 8	105	69.76	18.54	11.0	71.00	100.0	95	-1.48	21.57	-70.0	0.00	79.0
	Week 9	102	70.45	18.70	19.0	73.00	100.0	93	-1.62	21.68	-72.0	0.00	79.0
	Week 10	99	72.09	18.26	10.0	76.00	100.0	89	0.78	20.69	-60.0	2.00	80.0
	Week 11	96	73.54	18.90	11.0	79.00	100.0	86	1.66	20.69	-67.0	1.00	81.0
	Week 12	99	71.32	19.95	12.0	76.00	100.0	89	-0.43	22.48	-69.0	1.00	79.0
	Week 14	96	71.86	20.54	7.0	80.00	100.0	86	0.30	24.58	-92.0	0.50	80.0
	Week 17	97	73.71	16.05	30.0	76.00	100.0	86	1.08	19.33	-52.0	0.00	78.0
	Week 20	90	74.14	16.97	23.0	77.50	100.0	81	0.94	19.09	-57.0	0.00	60.0
	Week 23	86	75.17	16.73	30.0	80.00	100.0	76	1.99	20.33	-53.0	1.00	79.0
	Week 26	85	71.81	18.37	21.0	78.00	100.0	75	-1.87	19.45	-60.0	-2.00	81.0
	Week 29	81	70.20	20.13	2.0	75.00	100.0	74	-4.15	23.27	-79.0	-1.00	79.0
	Week 32	75	71.91	18.51	7.0	75.00	100.0	69	-2.12	23.10	-77.0	-1.00	79.0
	Week 35	73	73.22	17.53	5.0	79.00	100.0	68	-2.50	19.71	-76.0	-1.50	81.0
	Week 38	75	73.25	16.31	29.0	78.00	100.0	69	-0.23	18.48	-44.0	0.00	75.0
	Week 41	72	71.08	17.37	7.0	71.00	100.0	67	-2.93	19.44	-72.0	-4.00	74.0
	Week 44	64	70.67	16.55	4.0	75.00	99.0	58	-4.02	20.18	-77.0	-5.00	73.0
	Week 47	56	74.13	14.19	31.0	75.50	100.0	51	0.29	17.92	-43.0	0.00	78.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.2.4: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	55	72.05	19.24	5.0	76.00	100.0	49	-1.53	20.78	-62.0	0.00	71.0
	Week 53	57	69.70	19.56	6.0	70.00	100.0	50	-3.68	20.75	-44.0	-3.00	78.0
	Week 56	54	73.39	16.68	33.0	74.50	100.0	48	1.38	19.29	-31.0	0.00	81.0
	Week 59	51	72.04	15.71	33.0	71.00	97.0	44	0.50	18.58	-40.0	-1.00	77.0
	Week 62	42	71.48	15.95	36.0	70.50	100.0	37	-1.49	20.06	-41.0	-4.00	78.0
	Week 65	31	70.52	16.10	45.0	70.00	100.0	30	-3.93	15.51	-41.0	-1.50	25.0
	Week 68	31	70.06	19.82	10.0	72.00	100.0	29	-2.14	23.34	-59.0	0.00	77.0
	Week 71	31	71.87	15.76	41.0	70.00	99.0	29	0.38	20.23	-37.0	-2.00	79.0
	Week 74	29	72.45	16.32	41.0	74.00	99.0	27	-1.33	21.11	-41.0	0.00	70.0
	Week 77	26	72.15	17.30	31.0	73.00	96.0	24	-1.33	24.25	-39.0	-1.00	76.0
	Week 80	26	69.81	15.74	38.0	70.00	99.0	26	-4.04	20.77	-32.0	-9.00	67.0
	Week 83	21	68.90	18.67	20.0	69.00	100.0	21	-2.43	24.32	-61.0	-1.00	56.0
	Week 86	17	62.35	21.51	28.0	59.00	99.0	17	-8.35	26.24	-54.0	-1.00	38.0
	Week 89	11	63.27	23.66	28.0	66.00	98.0	11	-12.18	21.57	-54.0	-15.00	25.0
	Week 92	13	65.92	21.33	23.0	66.00	95.0	13	-6.38	22.76	-47.0	-1.00	33.0
	Plat+Gem (N=151)												
	BASELINE	126	71.19	20.97	5.0	76.00	100.0						
	Week 1	109	67.46	21.63	17.0	70.00	100.0	106	-4.36	18.42	-59.0	-1.50	49.0
	Week 2	119	65.47	20.70	10.0	70.00	100.0	109	-6.88	21.33	-79.0	-5.00	51.0
	Week 3	114	67.02	21.12	2.0	70.00	100.0	105	-6.29	19.35	-87.0	-3.00	51.0
	Week 4	117	68.97	19.66	11.0	73.00	100.0	106	-3.67	17.30	-48.0	-3.00	51.0
	Week 5	122	67.00	21.24	10.0	70.00	100.0	109	-5.17	19.37	-50.0	-3.00	50.0
	Week 6	110	68.42	20.74	17.0	70.00	100.0	98	-4.02	21.40	-60.0	-1.50	58.0
	Week 7	115	65.74	22.54	6.0	70.00	100.0	106	-6.80	22.78	-75.0	-4.50	63.0
	Week 8	112	66.82	20.79	7.0	70.00	98.0	103	-6.04	23.17	-74.0	-4.00	61.0
	Week 9	108	65.32	22.27	0.0	70.00	100.0	97	-6.24	21.88	-53.0	-4.00	60.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.2.4: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	107	68.17	20.93	12.0	70.00	100.0	98	-4.53	22.06	-73.0	-3.00	62.0
	Week 11	97	67.11	20.71	11.0	68.00	100.0	88	-4.50	23.88	-69.0	-3.50	60.0
	Week 12	100	66.95	21.40	11.0	70.00	100.0	89	-4.99	21.95	-62.0	-2.00	42.0
	Week 14	99	66.00	21.94	3.0	70.00	100.0	87	-7.82	24.59	-67.0	-5.00	54.0
	Week 17	94	66.35	21.81	10.0	70.00	100.0	84	-7.01	24.92	-65.0	-6.50	54.0
	Week 20	84	67.48	23.14	10.0	73.00	100.0	74	-5.30	22.88	-65.0	-5.00	57.0
	Week 23	71	72.45	20.72	23.0	79.00	100.0	64	-0.25	20.83	-48.0	1.00	59.0
	Week 26	61	72.69	20.22	18.0	78.00	100.0	56	-0.61	22.22	-52.0	0.00	60.0
	Week 29	59	71.64	22.62	8.0	79.00	100.0	53	-2.42	25.26	-92.0	0.00	61.0
	Week 32	51	70.02	23.40	13.0	78.00	100.0	46	-3.20	24.58	-77.0	-0.50	59.0
	Week 35	50	69.90	22.90	10.0	75.50	100.0	45	-4.40	23.62	-60.0	0.00	59.0
	Week 38	46	70.00	23.27	10.0	76.50	100.0	40	-5.83	23.22	-52.0	0.00	57.0
	Week 41	42	67.33	24.07	7.0	70.50	100.0	37	-7.22	25.89	-64.0	-7.00	59.0
	Week 44	39	66.41	23.56	11.0	75.00	98.0	34	-8.47	23.37	-78.0	-5.00	42.0
	Week 47	33	69.06	25.62	11.0	76.00	100.0	29	-2.76	21.86	-54.0	0.00	59.0
	Week 50	27	68.33	24.40	10.0	75.00	98.0	22	-2.50	25.52	-60.0	1.50	60.0
	Week 53	23	64.83	24.99	18.0	66.00	96.0	20	-5.50	30.22	-55.0	1.00	59.0
	Week 56	20	70.00	23.08	9.0	75.00	94.0	19	-1.42	23.85	-61.0	3.00	57.0
	Week 59	17	64.76	25.29	20.0	67.00	97.0	15	-2.67	28.42	-60.0	0.00	60.0
	Week 62	14	64.36	24.43	22.0	75.00	96.0	14	-5.29	25.77	-48.0	-6.50	59.0
	Week 65	13	74.31	21.04	30.0	80.00	100.0	12	0.83	26.22	-42.0	-1.50	60.0
	Week 68	10	68.70	25.12	21.0	77.50	95.0	10	-5.60	17.75	-49.0	0.00	14.0
	Week 71	10	60.30	23.57	30.0	72.00	90.0	10	-16.60	23.09	-60.0	-8.00	6.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.2.4: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	EV+Pembro (N= 56)												
	BASELINE	43	68.35	18.48	19.0	70.00	96.0						
	Week 1	39	63.31	19.82	14.0	63.00	100.0	33	-5.79	19.47	-64.0	0.00	42.0
	Week 2	45	64.07	20.35	4.0	61.00	100.0	38	-5.03	21.14	-86.0	-4.00	38.0
	Week 3	45	63.76	22.02	19.0	64.00	97.0	36	-3.92	16.24	-50.0	-2.00	30.0
	Week 4	44	65.73	23.38	11.0	69.50	97.0	38	-3.97	19.79	-59.0	0.00	37.0
	Week 5	41	62.00	23.85	10.0	60.00	98.0	34	-6.32	20.57	-59.0	-5.00	27.0
	Week 6	43	61.56	23.25	18.0	60.00	99.0	34	-6.62	22.22	-53.0	-4.50	41.0
	Week 7	46	66.93	20.07	17.0	66.50	97.0	37	-2.84	19.86	-55.0	0.00	30.0
	Week 8	47	66.64	20.79	18.0	70.00	97.0	35	-2.80	21.81	-60.0	0.00	43.0
	Week 9	42	65.79	20.07	27.0	64.50	96.0	34	-2.76	21.09	-62.0	-1.50	39.0
	Week 10	40	67.95	17.83	31.0	62.00	95.0	33	-4.55	16.33	-32.0	-2.00	30.0
	Week 11	42	67.31	22.08	18.0	71.00	97.0	33	-1.30	21.44	-60.0	-1.00	43.0
	Week 12	44	67.41	18.09	27.0	70.00	99.0	34	-2.91	16.00	-42.0	1.00	26.0
	Week 14	45	66.89	21.11	21.0	70.00	96.0	34	-2.79	16.65	-36.0	-1.50	35.0
	Week 17	36	69.81	19.37	30.0	75.00	96.0	29	1.72	15.10	-28.0	0.00	36.0
	Week 20	30	69.03	21.71	29.0	69.00	99.0	25	-4.00	19.50	-52.0	-1.00	30.0
	Week 23	31	69.61	21.36	28.0	71.00	99.0	24	0.96	16.94	-35.0	3.50	42.0
	Week 26	29	69.10	18.39	29.0	70.00	97.0	22	2.36	15.72	-33.0	2.00	33.0
	Week 29	27	68.00	20.11	32.0	70.00	99.0	22	0.55	16.85	-30.0	2.50	41.0
	Week 32	29	65.69	20.37	30.0	65.00	97.0	23	-0.52	19.66	-40.0	3.00	31.0
	Week 35	25	70.00	22.65	26.0	70.00	100.0	20	4.05	17.03	-29.0	3.50	49.0
	Week 38	22	69.45	19.61	37.0	70.00	94.0	19	2.63	14.10	-27.0	3.00	28.0
	Week 41	24	66.63	20.15	36.0	65.50	99.0	21	2.43	19.54	-34.0	3.00	35.0
	Week 44	22	65.95	22.90	29.0	69.50	99.0	19	-3.79	16.51	-35.0	1.00	29.0
	Week 47	23	66.87	21.60	30.0	70.00	99.0	21	-1.33	18.32	-38.0	3.00	39.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.2.4: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	67.65	21.47	40.0	69.00	99.0	17	-4.94	16.17	-32.0	2.00	22.0
	Week 53	19	66.26	21.19	25.0	64.00	99.0	16	-1.81	18.36	-44.0	0.00	26.0
	Week 56	19	69.32	21.82	30.0	69.00	98.0	16	-4.13	16.89	-39.0	0.00	22.0
	Week 59	18	69.44	21.31	34.0	70.00	99.0	15	-1.80	21.52	-36.0	3.00	39.0
	Week 62	20	74.30	18.27	42.0	72.00	97.0	17	2.53	15.03	-28.0	4.00	34.0
	Week 65	12	69.17	21.62	33.0	71.00	99.0	11	0.45	17.43	-37.0	3.00	24.0
	Week 68	15	70.73	20.22	40.0	71.00	99.0	14	0.50	16.32	-29.0	3.00	24.0
	Week 71	12	70.00	20.71	38.0	70.00	99.0	11	-0.27	14.42	-31.0	2.00	19.0
	Week 77	11	73.91	20.31	36.0	78.00	99.0	10	4.60	11.18	-9.0	4.00	29.0
	Week 80	10	73.20	25.38	30.0	79.00	99.0	9	3.78	22.61	-48.0	5.00	39.0
	Plat+Gem (N= 51)												
	BASELINE	42	67.26	18.48	28.0	68.00	100.0						
	Week 1	37	64.08	21.48	3.0	65.00	98.0	36	-5.00	20.76	-41.0	-3.50	30.0
	Week 2	34	64.85	21.14	3.0	69.50	95.0	32	-4.25	18.74	-42.0	-1.50	35.0
	Week 3	36	65.97	23.33	3.0	71.00	98.0	33	-4.33	21.50	-65.0	-2.00	33.0
	Week 4	35	66.43	21.77	1.0	70.00	98.0	32	-2.56	21.57	-48.0	0.50	41.0
	Week 5	35	66.26	20.60	20.0	71.00	95.0	32	-4.88	19.34	-71.0	-1.00	28.0
	Week 6	36	67.33	20.77	2.0	66.50	95.0	33	-2.15	21.95	-68.0	-4.00	35.0
	Week 7	35	70.03	16.76	39.0	68.00	95.0	31	0.45	20.93	-34.0	1.00	49.0
	Week 8	35	67.17	20.10	5.0	67.00	100.0	31	-2.94	20.17	-33.0	-1.00	35.0
	Week 9	34	68.41	21.26	3.0	70.50	95.0	30	-1.80	24.31	-50.0	2.00	50.0
	Week 10	36	65.67	23.92	2.0	69.50	97.0	32	-1.38	23.09	-39.0	-1.50	51.0
	Week 11	30	64.50	22.17	1.0	68.00	98.0	28	-5.32	19.96	-37.0	-3.50	26.0
	Week 12	30	68.50	22.26	2.0	70.00	97.0	27	-1.15	19.28	-36.0	0.00	39.0
	Week 14	26	63.62	23.07	1.0	64.50	99.0	23	-4.22	20.70	-40.0	-3.00	42.0
	Week 17	26	67.54	20.37	29.0	71.00	95.0	24	-0.58	24.37	-57.0	2.50	41.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.2.4: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Sex - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 20	20	75.30	19.85	28.0	75.50	99.0	19	1.16	22.27	-41.0	5.00	39.0
	Week 23	18	82.17	12.60	60.0	84.00	99.0	18	8.72	18.16	-31.0	7.00	39.0
	Week 26	20	77.05	22.85	6.0	82.50	99.0	20	5.50	26.41	-85.0	7.50	42.0
	Week 29	18	71.39	21.84	17.0	77.00	97.0	18	-1.39	24.55	-61.0	1.50	40.0
	Week 32	13	74.62	15.22	51.0	76.00	100.0	13	3.62	16.54	-30.0	8.00	28.0
	Week 35	12	76.17	18.95	39.0	77.50	99.0	12	5.25	19.20	-40.0	8.50	31.0
	Week 38	10	74.90	23.43	37.0	83.00	98.0	10	-1.40	22.11	-39.0	0.50	39.0
	Week 41	10	74.60	20.28	50.0	73.50	100.0	10	-4.80	19.36	-38.0	-1.00	30.0
	Week 44	10	67.90	24.73	24.0	66.50	100.0	10	-4.90	26.75	-45.0	-6.00	40.0
	Week 47	10	68.60	21.24	29.0	64.50	100.0	10	-10.20	19.80	-50.0	-7.00	10.0
	Week 56	10	64.70	23.58	29.0	66.00	100.0	10	-8.60	26.55	-50.0	-8.00	31.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.2.5: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Visceral metastases	EV+Pembro (N=148)												
	BASELINE	121	69.05	17.84	14.0	70.00	100.0						
	Week 1	107	65.87	19.35	3.0	67.00	100.0	103	-3.66	18.34	-97.0	-1.00	42.0
	Week 2	112	63.24	19.43	4.0	64.50	99.0	105	-6.14	19.83	-86.0	-5.00	61.0
	Week 3	100	65.91	20.96	19.0	68.50	99.0	91	-2.80	18.18	-56.0	-1.00	46.0
	Week 4	105	67.38	20.40	10.0	70.00	100.0	95	-2.39	19.53	-59.0	0.00	69.0
	Week 5	101	67.97	19.66	10.0	70.00	98.0	91	-2.89	21.73	-59.0	-1.00	77.0
	Week 6	109	67.33	18.91	11.0	70.00	100.0	93	-2.16	22.21	-71.0	-1.00	78.0
	Week 7	112	69.79	17.67	25.0	71.00	100.0	93	-0.16	20.49	-59.0	0.00	79.0
	Week 8	110	69.70	18.67	11.0	71.00	100.0	92	0.32	21.63	-60.0	0.00	79.0
	Week 9	106	68.83	19.15	19.0	70.00	100.0	93	-0.69	22.11	-62.0	0.00	79.0
	Week 10	101	70.71	18.50	10.0	72.00	100.0	87	0.24	20.94	-52.0	2.00	80.0
	Week 11	98	70.94	20.75	11.0	76.00	100.0	84	0.89	22.85	-67.0	0.50	81.0
	Week 12	101	70.51	19.47	13.0	75.00	100.0	86	0.07	22.04	-62.0	1.00	79.0
	Week 14	104	70.24	20.74	7.0	76.00	100.0	88	0.15	24.37	-92.0	0.00	80.0
	Week 17	96	73.47	16.60	30.0	76.00	100.0	81	2.62	18.81	-52.0	0.00	78.0
	Week 20	87	72.75	18.16	23.0	75.00	100.0	76	0.28	20.33	-57.0	0.00	60.0
	Week 23	85	74.04	17.65	29.0	80.00	100.0	71	3.04	20.10	-53.0	2.00	79.0
	Week 26	81	71.48	17.87	22.0	75.00	100.0	67	-0.70	19.43	-49.0	-2.00	81.0
	Week 29	72	70.88	18.37	22.0	71.50	100.0	64	-1.63	22.01	-56.0	0.00	79.0
	Week 32	72	70.69	17.98	17.0	74.50	100.0	63	-0.41	23.44	-77.0	1.00	79.0
	Week 35	70	73.61	17.54	30.0	78.00	100.0	63	0.19	19.56	-58.0	0.00	81.0
	Week 38	70	73.40	16.05	31.0	77.50	100.0	63	1.08	19.05	-44.0	0.00	75.0
	Week 41	66	71.85	16.34	30.0	70.50	100.0	60	0.53	19.43	-49.0	-1.00	74.0
	Week 44	59	69.71	17.72	29.0	71.00	99.0	53	-2.74	19.53	-65.0	-2.00	73.0
	Week 47	52	73.87	16.72	30.0	76.50	100.0	48	2.71	18.51	-30.0	0.50	78.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.2.5: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	49	70.41	20.56	5.0	74.00	100.0	43	-1.16	22.24	-62.0	1.00	71.0
	Week 53	50	68.64	19.83	6.0	70.00	100.0	44	-1.16	21.68	-44.0	0.50	78.0
	Week 56	45	71.71	18.83	33.0	71.00	100.0	39	0.90	20.48	-31.0	1.00	81.0
	Week 59	44	70.43	17.71	33.0	70.50	97.0	38	0.37	22.10	-40.0	1.00	77.0
	Week 62	38	73.08	17.11	36.0	70.00	100.0	33	2.09	20.97	-41.0	3.00	78.0
	Week 65	25	70.76	17.83	33.0	70.00	100.0	24	-1.88	18.00	-41.0	1.50	25.0
	Week 68	31	72.16	19.80	10.0	72.00	100.0	29	0.97	23.78	-59.0	2.00	77.0
	Week 71	27	73.93	16.42	45.0	71.00	99.0	25	3.04	22.07	-37.0	0.00	79.0
	Week 74	23	73.43	18.22	35.0	74.00	99.0	22	0.68	24.41	-43.0	1.00	70.0
	Week 77	24	75.33	15.52	44.0	78.00	98.0	23	3.87	22.15	-38.0	2.00	76.0
	Week 80	22	70.95	18.53	30.0	70.50	99.0	22	-0.86	24.39	-48.0	1.00	67.0
	Week 83	19	71.21	16.66	49.0	69.00	100.0	19	2.16	23.12	-32.0	0.00	56.0
	Week 86	14	63.21	21.36	28.0	60.00	99.0	14	-3.29	27.51	-54.0	1.50	38.0
	Week 89	10	71.20	23.56	28.0	71.00	98.0	10	-1.70	26.12	-54.0	2.50	34.0
	Week 92	11	67.09	22.73	23.0	66.00	98.0	11	-4.09	28.32	-47.0	0.00	39.0
	Plat+Gem (N=157)												
	BASELINE	130	69.38	21.00	5.0	71.50	100.0						
	Week 1	112	66.34	21.89	3.0	70.00	100.0	109	-4.41	18.48	-50.0	-2.00	49.0
	Week 2	114	65.37	21.70	3.0	70.00	97.0	106	-5.77	20.65	-79.0	-2.00	51.0
	Week 3	113	65.95	22.64	2.0	71.00	100.0	105	-5.62	19.88	-87.0	-2.00	47.0
	Week 4	114	67.96	20.21	1.0	71.00	100.0	105	-3.08	17.41	-48.0	-3.00	43.0
	Week 5	117	66.53	21.67	10.0	70.00	100.0	106	-4.58	18.36	-50.0	-2.00	43.0
	Week 6	108	68.56	20.97	2.0	70.50	100.0	98	-2.40	20.11	-68.0	0.00	44.0
	Week 7	109	66.99	21.48	10.0	70.00	98.0	101	-4.11	21.03	-63.0	0.00	49.0
	Week 8	107	66.39	20.86	5.0	70.00	97.0	99	-5.05	21.70	-74.0	-1.00	35.0
	Week 9	106	65.42	21.73	0.0	70.00	100.0	96	-5.49	21.64	-50.0	-1.50	50.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.2.5: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 10	105	67.41	22.26	2.0	70.00	100.0	96	-3.06	21.75	-73.0	-1.50	51.0
	Week 11	91	66.54	21.78	1.0	69.00	100.0	84	-3.56	22.39	-69.0	-0.50	45.0
	Week 12	94	67.64	22.36	2.0	70.00	100.0	85	-3.24	20.95	-62.0	0.00	39.0
	Week 14	90	66.32	22.62	1.0	70.00	100.0	80	-5.73	22.76	-60.0	-3.50	54.0
	Week 17	90	66.09	21.71	10.0	70.00	100.0	82	-5.32	24.57	-65.0	-5.00	54.0
	Week 20	74	67.53	22.42	18.0	71.50	100.0	66	-4.56	20.40	-60.0	-5.00	39.0
	Week 23	63	73.84	19.38	23.0	80.00	100.0	59	2.39	18.64	-48.0	4.00	40.0
	Week 26	55	74.02	19.29	30.0	78.00	100.0	53	2.45	19.43	-52.0	5.00	43.0
	Week 29	53	70.40	21.56	8.0	77.00	100.0	50	-2.72	22.21	-92.0	0.00	40.0
	Week 32	43	69.91	23.49	13.0	77.00	100.0	41	-2.27	20.77	-77.0	1.00	31.0
	Week 35	39	69.90	22.45	10.0	75.00	100.0	37	-3.22	18.36	-40.0	1.00	31.0
	Week 38	37	69.32	23.94	10.0	79.00	100.0	34	-6.24	18.96	-46.0	0.00	39.0
	Week 41	33	68.55	21.71	21.0	70.00	100.0	31	-6.58	17.90	-51.0	-2.00	34.0
	Week 44	32	66.00	23.48	20.0	74.00	98.0	30	-7.10	20.31	-45.0	-5.00	40.0
	Week 47	28	67.11	24.95	11.0	72.00	100.0	26	-4.46	17.82	-38.0	-0.50	31.0
	Week 50	22	69.32	23.97	17.0	75.00	98.0	20	-4.90	19.87	-43.0	1.50	30.0
	Week 53	19	64.47	26.21	10.0	65.00	96.0	17	-7.88	27.43	-59.0	1.00	32.0
	Week 56	18	68.67	20.45	30.0	70.00	100.0	17	-3.53	19.93	-40.0	0.00	31.0
	Week 59	13	63.38	23.54	25.0	60.00	95.0	12	-3.67	26.11	-60.0	1.50	40.0
	Week 62	11	64.36	21.90	30.0	75.00	88.0	11	-5.36	23.20	-47.0	-6.00	41.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.2.5: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Lymph node only	EV+Pembro (N= 43)												
	BASELINE	36	73.78	14.91	19.0	76.50	99.0						
	Week 1	30	72.00	15.67	39.0	71.50	100.0	26	-3.42	14.33	-43.0	0.00	27.0
	Week 2	37	69.46	16.57	29.0	73.00	100.0	32	-2.19	14.89	-22.0	-2.50	38.0
	Week 3	35	67.11	17.70	33.0	70.00	100.0	31	-5.29	15.29	-48.0	-7.00	30.0
	Week 4	36	71.17	18.35	25.0	77.00	97.0	33	-0.15	14.16	-40.0	0.00	37.0
	Week 5	34	69.38	18.51	36.0	73.00	100.0	31	-3.29	16.35	-46.0	0.00	27.0
	Week 6	34	69.18	22.06	18.0	77.50	100.0	31	-4.77	21.79	-53.0	0.00	29.0
	Week 7	34	67.79	19.97	17.0	70.00	99.0	31	-3.87	18.05	-53.0	0.00	29.0
	Week 8	35	65.69	21.38	18.0	69.00	95.0	32	-6.66	21.58	-70.0	-1.00	26.0
	Week 9	31	70.16	19.96	27.0	76.00	95.0	28	-3.96	20.65	-72.0	1.00	24.0
	Week 10	31	71.29	17.19	39.0	75.00	97.0	29	-2.72	16.70	-60.0	-2.00	30.0
	Week 11	34	74.38	17.93	31.0	78.50	96.0	30	2.53	13.61	-24.0	0.00	28.0
	Week 12	35	69.57	19.51	12.0	74.00	99.0	31	-2.97	18.43	-69.0	0.00	23.0
	Week 14	30	71.83	20.98	9.0	79.50	96.0	26	-0.77	17.20	-61.0	0.00	26.0
	Week 17	31	72.97	17.99	38.0	77.00	97.0	28	-0.04	16.99	-43.0	0.00	28.0
	Week 20	27	75.26	18.55	30.0	79.00	99.0	24	0.33	16.82	-35.0	0.00	27.0
	Week 23	27	72.70	20.62	28.0	80.00	99.0	24	-0.88	18.91	-49.0	2.50	26.0
	Week 26	27	71.26	20.20	21.0	77.00	96.0	24	0.04	18.42	-60.0	0.50	30.0
	Week 29	29	67.41	23.12	2.0	75.00	98.0	26	-4.73	23.05	-79.0	0.00	35.0
	Week 32	25	68.96	21.87	7.0	70.00	99.0	23	-3.70	20.65	-74.0	-1.00	28.0
	Week 35	22	67.14	23.04	5.0	72.50	96.0	20	-4.20	20.06	-76.0	0.00	24.0
	Week 38	21	70.90	18.53	37.0	75.00	97.0	19	0.37	12.79	-27.0	0.00	22.0
	Week 41	23	66.09	22.33	7.0	70.00	99.0	21	-5.52	20.93	-72.0	-1.00	35.0
	Week 44	22	68.00	20.99	4.0	75.50	99.0	19	-7.21	20.33	-77.0	-3.00	20.0
	Week 47	21	69.05	17.81	31.0	72.00	99.0	18	-5.83	15.23	-43.0	-1.00	17.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.2.5: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 50	20	70.00	19.02	28.0	74.50	99.0	18	-5.11	14.31	-32.0	-0.50	15.0
	Week 53	20	67.65	21.00	25.0	72.50	99.0	17	-8.65	17.83	-44.0	-8.00	21.0
	Week 56	22	71.82	18.50	30.0	73.50	98.0	20	-2.15	15.37	-39.0	0.00	25.0
	Week 59	21	72.29	16.84	39.0	71.00	99.0	18	-0.50	13.87	-21.0	0.00	24.0
	Week 62	19	71.84	14.74	45.0	74.00	97.0	17	-2.35	14.74	-25.0	-3.00	24.0
	Week 65	16	70.00	17.36	45.0	72.00	99.0	15	-3.40	13.47	-24.0	-1.00	21.0
	Week 68	13	66.69	20.27	40.0	65.00	99.0	12	-6.67	14.90	-29.0	-5.50	20.0
	Week 71	14	66.64	18.55	38.0	70.00	99.0	13	-5.77	9.39	-20.0	-2.00	4.0
	Week 74	13	73.69	17.43	42.0	75.00	98.0	12	-1.83	13.89	-30.0	2.00	16.0
	Week 77	13	67.77	21.62	31.0	74.00	99.0	11	-6.82	18.03	-39.0	-1.00	15.0
	Week 80	13	69.00	19.33	36.0	70.00	99.0	12	-3.42	15.52	-32.0	0.50	22.0
	Week 83	11	65.82	23.75	20.0	69.00	99.0	11	-9.36	22.27	-61.0	-6.00	19.0
	Week 86	11	62.45	24.48	29.0	56.00	99.0	11	-11.36	22.28	-52.0	0.00	16.0
	Plat+Gem (N= 37)												
	BASELINE	30	71.73	19.00	20.0	73.00	95.0						
	Week 1	26	64.96	21.22	20.0	69.50	100.0	25	-5.72	21.09	-59.0	-9.00	42.0
	Week 2	31	63.90	18.59	36.0	60.00	100.0	27	-7.93	23.12	-50.0	-8.00	50.0
	Week 3	30	67.53	18.83	29.0	69.00	99.0	26	-7.19	20.32	-43.0	-6.00	51.0
	Week 4	32	67.56	20.35	19.0	70.50	100.0	27	-6.26	21.19	-43.0	-7.00	51.0
	Week 5	33	66.58	19.89	20.0	70.00	98.0	28	-6.50	23.38	-71.0	-3.50	50.0
	Week 6	32	66.75	19.91	29.0	66.00	95.0	27	-6.07	25.79	-60.0	-5.00	58.0
	Week 7	33	64.45	22.00	6.0	63.00	100.0	28	-8.96	28.32	-75.0	-11.00	63.0
	Week 8	32	67.22	21.07	28.0	70.00	100.0	27	-6.30	26.84	-53.0	-10.00	61.0
	Week 9	30	66.40	24.03	0.0	69.50	100.0	25	-4.08	26.13	-53.0	-5.00	60.0
	Week 10	30	66.80	19.96	20.0	69.00	99.0	26	-5.65	25.31	-49.0	-10.50	62.0
	Week 11	30	66.37	18.93	43.0	60.00	98.0	26	-6.54	25.72	-43.0	-13.00	60.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3002.24.2.5: EQ-5D-5L - Observed Means and Change from Baseline of VAS by Metastases at Baseline - Analysis Set mITT 2

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Week 12	28	66.29	19.34	35.0	61.00	97.0	23	-4.91	24.03	-54.0	-4.00	42.0
	Week 14	28	62.29	21.69	10.0	62.00	97.0	23	-11.78	28.61	-67.0	-13.00	54.0
	Week 17	25	66.20	21.51	19.0	71.00	100.0	21	-7.57	27.10	-59.0	-9.00	52.0
	Week 20	23	70.13	25.01	10.0	77.00	99.0	20	-3.50	30.61	-65.0	0.50	57.0
	Week 23	21	74.67	21.62	27.0	81.00	96.0	18	0.67	25.69	-40.0	2.00	59.0
	Week 26	21	71.90	25.34	6.0	82.00	97.0	18	-1.83	32.85	-85.0	2.00	60.0
	Week 29	19	73.00	25.76	17.0	79.00	100.0	16	0.25	33.19	-61.0	3.50	61.0
	Week 32	18	73.61	19.93	27.0	80.00	96.0	15	2.00	29.33	-48.0	8.00	59.0
	Week 35	19	72.37	23.37	10.0	76.00	100.0	16	-0.56	31.54	-60.0	7.00	59.0
	Week 38	15	72.53	23.33	18.0	86.00	96.0	12	-0.33	32.76	-52.0	2.50	57.0
	Week 41	15	67.20	29.07	7.0	71.00	100.0	12	-5.67	39.17	-64.0	-7.50	59.0
	Week 44	14	68.64	26.92	11.0	77.00	100.0	11	-6.64	34.31	-78.0	0.00	42.0
	Week 47	12	71.75	25.14	16.0	81.50	96.0	10	-4.10	31.83	-54.0	-1.00	59.0
	Week 50	11	64.82	27.84	10.0	75.00	97.0	8	-5.25	38.56	-60.0	1.50	60.0

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; Max=maximum; Med=median; Min=minimum; mITT=modified intent-to-treat; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SD=standard deviation; VAS=visual analogue scale.
Note: Summary statistics will not be provided for the treatment arm at a visit if that arm has fewer than 10 subjects at that visit.
Baseline is the last available assessment on or before Cycle 1 Day 1.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.4.1.1: BPI-SF - Summary of Time to First Deterioration of Worst Pain in the last 24 hours (MID=2) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)	EV+Pembro vs. Plat+Gem
Number of patients at risk	240 (100.0%)	242 (100.0%)	
Number of patients with events	130 (54.2%)	113 (46.7%)	
Number of patients censored	110 (45.8%)	129 (53.3%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	48.0 [40.9, 54.8]	44.0 [36.5, 51.3]	
Month 6	41.1 [34.1, 48.0]	36.0 [28.5, 43.4]	
Month 9	34.1 [27.2, 41.2]	31.9 [24.2, 39.9]	
Month 12	33.1 [26.1, 40.2]	27.1 [18.4, 36.5]	
Month 18	27.1 [18.9, 35.9]	27.1 [18.4, 36.5]	
Month 24	27.1 [18.9, 35.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	2.0 [1.3, 4.5]	1.8 [1.1, 3.2]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.894 [0.681, 1.174]
Log-rank test			
Two-sided stratified log-rank p-value			0.4201

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=2 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.4.1.2: BPI-SF - Type of Events and Censoring of Worst Pain in the last 24 hours (MID=2) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)
Number of patients at risk	240 (100.0%)	242 (100.0%)
Number of patients with events	130 (54.2%)	113 (46.7%)
Deterioration of symptom	130 (54.2%)	113 (46.7%)
Number of patients censored	110 (45.8%)	129 (53.3%)
No deterioration possible	5 (2.1%)	6 (2.5%)
No baseline and/or follow-up	32 (13.3%)	59 (24.4%)
Subsequent anticancer treatment	7 (2.9%)	18 (7.4%)
Death	24 (10.0%)	17 (7.0%)
No deterioration	42 (17.5%)	29 (12.0%)

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.4.1.3: BPI-SF - Summary of Time to First Deterioration of Worst Pain in the last 24 hours by Subgroups (MID=2) - Analysis Set mITT 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	48	22 (45.8)	1.3 [0.6, 8.0]	48	18 (37.5)	3.5 [1.1, NC]	1.233 [0.618, 2.461]	0.5508	0.3376
Absent	192	108 (56.3)	2.7 [1.3, 5.3]	194	95 (49.0)	1.5 [1.1, 3.1]	0.843 [0.627, 1.133]	0.2585	
Age									
< 65 years	105	53 (50.5)	4.6 [2.7, 16.3]	106	49 (46.2)	1.8 [1.1, 7.3]	0.756 [0.495, 1.154]	0.1922	0.5207
>= 65 years	135	77 (57.0)	1.3 [0.7, 2.0]	136	64 (47.1)	1.4 [0.9, 3.2]	1.007 [0.706, 1.436]	0.9679	
Region									
Europe	98	47 (48.0)	3.2 [1.3, 8.0]	102	43 (42.2)	1.3 [0.6, 5.2]	0.749 [0.478, 1.174]	0.2066	0.6108
North America	57	31 (54.4)	2.7 [1.1, 12.8]	51	23 (45.1)	3.2 [1.1, NC]	0.907 [0.495, 1.662]	0.7610	
Rest of World	85	52 (61.2)	1.5 [0.6, 4.5]	89	47 (52.8)	1.4 [0.9, 3.2]	1.031 [0.682, 1.557]	0.8948	
Sex									
Male	198	106 (53.5)	2.0 [1.3, 4.5]	185	87 (47.0)	1.5 [1.1, 3.2]	0.974 [0.723, 1.313]	0.8721	0.7702
Female	42	24 (57.1)	3.3 [1.1, 8.7]	57	26 (45.6)	2.2 [0.8, 5.9]	0.572 [0.287, 1.140]	0.1039	
Metastases at Baseline									
Visceral metastases	170	86 (50.6)	2.0 [1.3, 5.3]	161	72 (44.7)	2.2 [1.3, 5.9]	1.007 [0.711, 1.427]	0.9854	0.9146
Lymph node only	60	38 (63.3)	2.0 [0.6, 6.6]	67	33 (49.3)	1.1 [0.6, 3.8]	0.744 [0.424, 1.304]	0.3049	

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=2 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.4.2.1: BPI-SF - Summary of Time to First Deterioration of Worst Pain in the last 24 hours (MID=2) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)	EV+Pembro vs. Plat+Gem
Number of patients at risk	202 (100.0%)	202 (100.0%)	
Number of patients with events	85 (42.1%)	105 (52.0%)	
Number of patients censored	117 (57.9%)	97 (48.0%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	52.6 [44.3, 60.2]	36.6 [28.8, 44.4]	
Month 6	44.8 [36.5, 52.7]	33.5 [25.6, 41.5]	
Month 9	42.8 [34.4, 50.8]	29.5 [21.5, 37.8]	
Month 12	41.4 [32.9, 49.6]	21.4 [13.2, 30.9]	
Month 18	39.4 [30.5, 48.1]	NC [NC, NC]	
Month 24	39.4 [30.5, 48.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	3.2 [1.6, 10.7]	1.3 [0.7, 2.2]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.681 [0.497, 0.935]
Log-rank test			
Two-sided stratified log-rank p-value			0.0158

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=2 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.4.2.2: BPI-SF - Type of Events and Censoring of Worst Pain in the last 24 hours (MID=2) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)
Number of patients at risk	202 (100.0%)	202 (100.0%)
Number of patients with events	85 (42.1%)	105 (52.0%)
Deterioration of symptom	85 (42.1%)	105 (52.0%)
Number of patients censored	117 (57.9%)	97 (48.0%)
No deterioration possible	5 (2.5%)	8 (4.0%)
No baseline and/or follow-up	42 (20.8%)	40 (19.8%)
Subsequent anticancer treatment	6 (3.0%)	16 (7.9%)
Death	20 (9.9%)	14 (6.9%)
No deterioration	44 (21.8%)	19 (9.4%)

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.4.2.3: BPI-SF - Summary of Time to First Deterioration of Worst Pain in the last 24 hours by Subgroups (MID=2) - Analysis Set mITT 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	20 (40.0)	5.9 [0.4, NC]	50	23 (46.0)	2.0 [0.4, 6.6]	0.971 [0.455, 2.072]	0.9184	0.5399
Absent	152	65 (42.8)	3.2 [1.5, NC]	152	82 (53.9)	1.1 [0.6, 2.2]	0.633 [0.447, 0.897]	0.0090	
Age									
< 65 years	39	15 (38.5)	10.7 [2.7, NC]	29	10 (34.5)	5.5 [0.8, NC]	0.999 [0.365, 2.734]	0.9847	0.3911
>= 65 years	163	70 (42.9)	2.5 [1.1, 8.7]	173	95 (54.9)	1.1 [0.6, 1.8]	0.653 [0.467, 0.912]	0.0113	
Region									
Europe	74	27 (36.5)	3.1 [1.1, NC]	95	51 (53.7)	0.8 [0.4, 2.0]	0.629 [0.376, 1.052]	0.0728	0.4011
North America	46	18 (39.1)	2.5 [0.5, NC]	34	14 (41.2)	1.8 [0.9, 9.4]	0.826 [0.363, 1.881]	0.6253	
Rest of World	82	40 (48.8)	3.8 [1.5, NC]	73	40 (54.8)	1.8 [0.4, 4.6]	0.684 [0.430, 1.087]	0.1060	
Sex									
Male	146	64 (43.8)	3.1 [1.5, 10.7]	151	80 (53.0)	1.3 [0.8, 2.4]	0.728 [0.510, 1.039]	0.0758	0.5197
Female	56	21 (37.5)	8.7 [0.9, NC]	51	25 (49.0)	1.3 [0.2, 6.6]	0.533 [0.266, 1.069]	0.0693	
Metastases at Baseline									
Visceral metastases	148	67 (45.3)	2.7 [1.1, 4.5]	157	79 (50.3)	1.7 [0.8, 2.5]	0.915 [0.621, 1.349]	0.6220	0.0210
Lymph node only	43	16 (37.2)	NC [1.5, NC]	37	22 (59.5)	0.5 [0.2, 2.4]	0.324 [0.144, 0.731]	0.0057	

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=2 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.5.1.1: BPI-SF - Summary of Time to First Deterioration of Pain Severity (MID=2) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)	EV+Pembro vs. Plat+Gem
Number of patients at risk	240 (100.0%)	242 (100.0%)	
Number of patients with events	87 (36.3%)	64 (26.4%)	
Number of patients censored	153 (63.8%)	178 (73.6%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	71.3 [64.5, 77.0]	71.0 [63.7, 77.2]	
Month 6	66.1 [59.0, 72.3]	67.0 [59.2, 73.7]	
Month 9	57.8 [50.2, 64.7]	63.0 [54.4, 70.5]	
Month 12	53.1 [45.0, 60.5]	52.7 [41.4, 62.8]	
Month 18	48.0 [38.7, 56.8]	52.7 [41.4, 62.8]	
Month 24	48.0 [38.7, 56.8]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	17.6 [9.3, NC]	NC [9.4, NC]	
Cox proportional hazards model			
Stratified HR [95% CI]			1.108 [0.776, 1.581]
Log-rank test			
Two-sided stratified log-rank p-value			0.5673

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=2 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.5.1.2: BPI-SF - Type of Events and Censoring of Pain Severity (MID=2) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)
Number of patients at risk	240 (100.0%)	242 (100.0%)
Number of patients with events	87 (36.3%)	64 (26.4%)
Deterioration of symptom	87 (36.3%)	64 (26.4%)
Number of patients censored	153 (63.8%)	178 (73.6%)
No deterioration possible	1 (0.4%)	1 (0.4%)
No baseline and/or follow-up	32 (13.3%)	59 (24.4%)
Subsequent anticancer treatment	18 (7.5%)	32 (13.2%)
Death	30 (12.5%)	42 (17.4%)
No deterioration	72 (30.0%)	44 (18.2%)

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.5.1.3: BPI-SF - Summary of Time to First Deterioration of Pain Severity by Subgroups (MID=2) - Analysis Set mITT 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	48	15 (31.3)	17.6 [5.2, NC]	48	11 (22.9)	10.8 [7.4, NC]	1.217 [0.479, 3.092]	0.6787	0.7199
Absent	192	72 (37.5)	13.5 [8.7, NC]	194	53 (27.3)	NC [9.4, NC]	1.090 [0.742, 1.601]	0.6543	
Age									
< 65 years	105	36 (34.3)	NC [8.7, NC]	106	31 (29.2)	NC [6.6, NC]	0.792 [0.461, 1.361]	0.3991	0.2244
>= 65 years	135	51 (37.8)	13.5 [6.6, NC]	136	33 (24.3)	NC [10.0, NC]	1.425 [0.885, 2.295]	0.1434	
Region									
Europe	98	37 (37.8)	10.1 [7.3, NC]	102	27 (26.5)	10.8 [4.5, NC]	1.153 [0.642, 2.072]	0.6238	0.3778
North America	57	16 (28.1)	NC [7.3, NC]	51	16 (31.4)	9.4 [6.6, NC]	0.621 [0.296, 1.305]	0.2054	
Rest of World	85	34 (40.0)	13.5 [6.6, NC]	89	21 (23.6)	NC [NC, NC]	1.481 [0.839, 2.611]	0.1710	
Sex									
Male	198	67 (33.8)	NC [10.1, NC]	185	46 (24.9)	NC [10.8, NC]	0.991 [0.665, 1.477]	0.9697	0.7611
Female	42	20 (47.6)	8.0 [1.3, NC]	57	18 (31.6)	9.4 [2.7, NC]	1.655 [0.772, 3.546]	0.1867	
Metastases at Baseline									
Visceral metastases	170	62 (36.5)	13.5 [7.3, NC]	161	38 (23.6)	NC [10.1, NC]	1.482 [0.938, 2.341]	0.0898	0.0730
Lymph node only	60	22 (36.7)	17.6 [8.7, NC]	67	21 (31.3)	10.0 [1.8, NC]	0.636 [0.307, 1.314]	0.2239	

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=2 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.5.2.1: BPI-SF - Summary of Time to First Deterioration of Pain Severity (MID=2) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)	EV+Pembro vs. Plat+Gem
Number of patients at risk	202 (100.0%)	202 (100.0%)	
Number of patients with events	57 (28.2%)	78 (38.6%)	
Number of patients censored	145 (71.8%)	124 (61.4%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	69.9 [61.9, 76.6]	55.9 [47.5, 63.5]	
Month 6	67.5 [59.2, 74.4]	51.1 [42.0, 59.4]	
Month 9	64.6 [56.0, 71.9]	41.6 [31.2, 51.7]	
Month 12	60.3 [50.9, 68.5]	41.6 [31.2, 51.7]	
Month 18	57.0 [45.8, 66.6]	30.3 [16.1, 45.9]	
Month 24	48.3 [33.2, 61.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	20.4 [17.6, NC]	6.6 [2.4, 12.8]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.561 [0.379, 0.829]
Log-rank test			
Two-sided stratified log-rank p-value			0.0035

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=2 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.5.2.2: BPI-SF - Type of Events and Censoring of Pain Severity (MID=2) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)
Number of patients at risk	202 (100.0%)	202 (100.0%)
Number of patients with events	57 (28.2%)	78 (38.6%)
Deterioration of symptom	57 (28.2%)	78 (38.6%)
Number of patients censored	145 (71.8%)	124 (61.4%)
No deterioration possible	2 (1.0%)	2 (1.0%)
No baseline and/or follow-up	42 (20.8%)	40 (19.8%)
Subsequent anticancer treatment	13 (6.4%)	22 (10.9%)
Death	26 (12.9%)	38 (18.8%)
No deterioration	62 (30.7%)	22 (10.9%)

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.5.2.3: BPI-SF - Summary of Time to First Deterioration of Pain Severity by Subgroups (MID=2) - Analysis Set mITT 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	14 (28.0)	NC [2.8, NC]	50	17 (34.0)	NC [1.8, NC]	0.649 [0.269, 1.562]	0.3464	0.5147
Absent	152	43 (28.3)	20.4 [17.6, NC]	152	61 (40.1)	6.6 [2.4, 12.8]	0.541 [0.349, 0.838]	0.0053	
Age									
< 65 years	39	8 (20.5)	NC [10.7, NC]	29	7 (24.1)	NC [6.0, NC]	0.402 [0.085, 1.912]	0.2452	0.8169
>= 65 years	163	49 (30.1)	19.0 [10.7, NC]	173	71 (41.0)	3.9 [2.0, 12.8]	0.574 [0.383, 0.860]	0.0068	
Region									
Europe	74	21 (28.4)	20.4 [2.7, NC]	95	37 (38.9)	6.6 [2.0, 20.4]	0.677 [0.370, 1.238]	0.2075	0.7170
North America	46	10 (21.7)	19.0 [17.6, NC]	34	9 (26.5)	NC [1.5, NC]	0.477 [0.163, 1.396]	0.1765	
Rest of World	82	26 (31.7)	NC [10.7, NC]	73	32 (43.8)	6.0 [1.7, 8.0]	0.498 [0.280, 0.886]	0.0155	
Sex									
Male	146	39 (26.7)	20.4 [17.6, NC]	151	64 (42.4)	5.9 [2.0, 8.0]	0.419 [0.264, 0.665]	0.0002	0.0471
Female	56	18 (32.1)	NC [2.7, NC]	51	14 (27.5)	20.4 [3.9, 20.4]	1.326 [0.614, 2.860]	0.4605	
Metastases at Baseline									
Visceral metastases	148	42 (28.4)	NC [10.7, NC]	157	56 (35.7)	7.3 [3.9, 12.8]	0.688 [0.424, 1.114]	0.1315	0.2698
Lymph node only	43	11 (25.6)	20.4 [19.0, NC]	37	16 (43.2)	2.4 [1.5, NC]	0.368 [0.116, 1.165]	0.0694	

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=2 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.6.1.1: BPI-SF - Summary of Time to First Deterioration of Pain Interference (MID=2) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)	EV+Pembro vs. Plat+Gem
Number of patients at risk	240 (100.0%)	242 (100.0%)	
Number of patients with events	122 (50.8%)	98 (40.5%)	
Number of patients censored	118 (49.2%)	144 (59.5%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	52.9 [45.7, 59.6]	54.2 [46.3, 61.3]	
Month 6	46.6 [39.4, 53.5]	42.3 [34.3, 50.1]	
Month 9	40.6 [33.4, 47.7]	38.2 [29.8, 46.6]	
Month 12	33.3 [25.9, 40.8]	33.5 [24.1, 43.2]	
Month 18	33.3 [25.9, 40.8]	33.5 [24.1, 43.2]	
Month 24	30.3 [21.7, 39.3]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	3.9 [2.0, 7.3]	4.5 [2.0, 7.3]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.957 [0.714, 1.282]
Log-rank test			
Two-sided stratified log-rank p-value			0.7617

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=2 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.6.1.2: BPI-SF - Type of Events and Censoring of Pain Interference (MID=2) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)
Number of patients at risk	240 (100.0%)	242 (100.0%)
Number of patients with events	122 (50.8%)	98 (40.5%)
Deterioration of symptom	122 (50.8%)	98 (40.5%)
Number of patients censored	118 (49.2%)	144 (59.5%)
No deterioration possible	6 (2.5%)	9 (3.7%)
No baseline and/or follow-up	32 (13.3%)	59 (24.4%)
Subsequent anticancer treatment	8 (3.3%)	17 (7.0%)
Death	22 (9.2%)	23 (9.5%)
No deterioration	50 (20.8%)	36 (14.9%)

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.6.1.3: BPI-SF - Summary of Time to First Deterioration of Pain Interference by Subgroups (MID=2) - Analysis Set mITT 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	48	20 (41.7)	3.9 [0.7, NC]	48	14 (29.2)	NC [1.4, NC]	1.310 [0.615, 2.792]	0.4976	0.4251
Absent	192	102 (53.1)	3.9 [2.0, 8.0]	194	84 (43.3)	3.8 [1.5, 5.9]	0.905 [0.659, 1.242]	0.5365	
Age									
< 65 years	105	53 (50.5)	7.3 [2.3, 10.1]	106	40 (37.7)	7.3 [1.8, NC]	0.960 [0.603, 1.528]	0.8663	0.6192
>= 65 years	135	69 (51.1)	2.7 [1.6, 6.6]	136	58 (42.6)	3.2 [1.3, 5.2]	0.955 [0.656, 1.391]	0.7995	
Region									
Europe	98	49 (50.0)	5.9 [1.5, 8.7]	102	43 (42.2)	1.7 [0.9, 4.5]	0.776 [0.483, 1.248]	0.2902	0.3516
North America	57	26 (45.6)	3.9 [1.1, NC]	51	21 (41.2)	6.0 [1.3, NC]	0.817 [0.443, 1.505]	0.5208	
Rest of World	85	47 (55.3)	3.2 [1.3, 9.3]	89	34 (38.2)	5.9 [2.7, NC]	1.279 [0.800, 2.045]	0.3021	
Sex									
Male	198	94 (47.5)	5.9 [2.7, 9.4]	185	71 (38.4)	5.2 [2.7, 11.5]	0.894 [0.647, 1.236]	0.4903	0.4807
Female	42	28 (66.7)	1.1 [0.4, 5.9]	57	27 (47.4)	2.0 [0.9, 5.3]	1.281 [0.654, 2.511]	0.4597	
Metastases at Baseline									
Visceral metastases	170	83 (48.8)	3.2 [1.7, 8.0]	161	61 (37.9)	5.2 [2.7, 11.5]	1.044 [0.715, 1.524]	0.8403	0.2949
Lymph node only	60	33 (55.0)	6.6 [1.5, 11.5]	67	29 (43.3)	2.0 [0.6, NC]	0.716 [0.393, 1.305]	0.2734	

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=2 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.6.2.1: BPI-SF - Summary of Time to First Deterioration of Pain Interference (MID=2) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)	EV+Pembro vs. Plat+Gem
Number of patients at risk	202 (100.0%)	202 (100.0%)	
Number of patients with events	79 (39.1%)	97 (48.0%)	
Number of patients censored	123 (60.9%)	105 (52.0%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	55.2 [46.8, 62.7]	42.6 [34.4, 50.5]	
Month 6	51.9 [43.4, 59.7]	36.0 [27.9, 44.2]	
Month 9	50.9 [42.4, 58.8]	29.8 [21.4, 38.8]	
Month 12	45.5 [36.4, 54.1]	29.8 [21.4, 38.8]	
Month 18	41.4 [31.5, 51.0]	18.6 [7.5, 33.7]	
Month 24	38.7 [28.1, 49.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	9.4 [1.8, 18.3]	1.8 [1.3, 3.2]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.786 [0.560, 1.104]
Log-rank test			
Two-sided stratified log-rank p-value			0.1683

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=2 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.6.2.2: BPI-SF - Type of Events and Censoring of Pain Interference (MID=2) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)
Number of patients at risk	202 (100.0%)	202 (100.0%)
Number of patients with events	79 (39.1%)	97 (48.0%)
Deterioration of symptom	79 (39.1%)	97 (48.0%)
Number of patients censored	123 (60.9%)	105 (52.0%)
No deterioration possible	5 (2.5%)	9 (4.5%)
No baseline and/or follow-up	42 (20.8%)	40 (19.8%)
Subsequent anticancer treatment	8 (4.0%)	16 (7.9%)
Death	21 (10.4%)	22 (10.9%)
No deterioration	47 (23.3%)	18 (8.9%)

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.6.2.3: BPI-SF - Summary of Time to First Deterioration of Pain Interference by Subgroups (MID=2) - Analysis Set mITT 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	18 (36.0)	5.9 [1.1, NC]	50	22 (44.0)	2.0 [0.6, 6.6]	1.243 [0.582, 2.658]	0.5712	0.7485
Absent	152	61 (40.1)	10.7 [1.7, 18.3]	152	75 (49.3)	1.6 [1.1, 3.9]	0.703 [0.481, 1.028]	0.0706	
Age									
< 65 years	39	12 (30.8)	NC [2.7, NC]	29	13 (44.8)	4.6 [2.0, NC]	0.505 [0.163, 1.567]	0.2401	0.6110
>= 65 years	163	67 (41.1)	5.9 [1.3, 15.6]	173	84 (48.6)	1.5 [1.1, 2.5]	0.822 [0.576, 1.173]	0.2854	
Region									
Europe	74	31 (41.9)	2.0 [0.7, 11.4]	95	50 (52.6)	1.8 [0.7, 3.2]	1.029 [0.617, 1.716]	0.9267	0.7087
North America	46	13 (28.3)	18.3 [1.5, NC]	34	11 (32.4)	NC [1.1, NC]	0.764 [0.306, 1.906]	0.5782	
Rest of World	82	35 (42.7)	11.5 [1.5, NC]	73	36 (49.3)	1.8 [0.4, 6.1]	0.614 [0.370, 1.021]	0.0595	
Sex									
Male	146	61 (41.8)	5.9 [1.5, 18.3]	151	75 (49.7)	1.8 [1.1, 2.7]	0.739 [0.506, 1.079]	0.1210	0.8875
Female	56	18 (32.1)	12.1 [0.9, NC]	51	22 (43.1)	1.8 [0.9, 6.6]	1.014 [0.476, 2.158]	0.9868	
Metastases at Baseline									
Visceral metastases	148	57 (38.5)	5.9 [1.3, NC]	157	71 (45.2)	2.0 [1.1, 3.9]	1.004 [0.663, 1.520]	0.9612	0.2553
Lymph node only	43	17 (39.5)	12.1 [2.0, NC]	37	20 (54.1)	1.7 [0.9, 12.8]	0.496 [0.189, 1.300]	0.1371	

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=2 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.7.1.1: BPI-SF - Summary of Time to Initiation of new Opioid medication for pain - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)	EV+Pembro vs. Plat+Gem
Number of patients at risk	240 (100.0%)	242 (100.0%)	
Number of patients with events	27 (11.3%)	23 (9.5%)	
Number of patients censored	213 (88.8%)	219 (90.5%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	89.2 [84.4, 92.6]	90.3 [85.3, 93.6]	
Month 6	88.7 [83.7, 92.2]	89.4 [84.1, 93.0]	
Month 9	88.7 [83.7, 92.2]	87.3 [81.1, 91.6]	
Month 12	88.7 [83.7, 92.2]	87.3 [81.1, 91.6]	
Month 18	86.2 [79.9, 90.7]	87.3 [81.1, 91.6]	
Month 24	86.2 [79.9, 90.7]	87.3 [81.1, 91.6]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.912 [0.505, 1.648]
Log-rank test			
Two-sided stratified log-rank p-value			0.7607

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to event is defined as time from randomization to the initiation of new opioid medication for pain. Censoring date is the date of last assessment for use of opioid medications for pain. Patients with no baseline and/or no post-baseline assessments are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.7.1.2: BPI-SF - Type of Events and Censoring of Initiation of new Opioid medication for pain (MID=2) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)
Number of patients at risk	240 (100.0%)	242 (100.0%)
Number of patients with events	27 (11.3%)	23 (9.5%)
Initiation of new Opioid medication for pain	27 (11.3%)	23 (9.5%)
Number of patients censored	213 (88.8%)	219 (90.5%)
No event	213 (88.8%)	219 (90.5%)

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.7.1.3: BPI-SF - Summary of Time to Initiation of new Opioid medication for pain by Subgroups - Analysis Set mITT 1

Subgroup	EV+Pembro N	EV+Pembro n (%)	EV+Pembro KME [95% CI](a)	Plat+Gem N	Plat+Gem n (%)	Plat+Gem KME [95% CI](a)	EV+Pembro vs. Plat+Gem HR [95% CI](b)	Log-rank p-value(c)	Test for Interaction p-value(d)
Liver Metastases									
Present	48	7 (14.6)	NC [NC, NC]	48	6 (12.5)	NC [NC, NC]	0.843 [0.250, 2.849]	0.7837	0.9361
Absent	192	20 (10.4)	NC [NC, NC]	194	17 (8.8)	NC [NC, NC]	0.934 [0.475, 1.840]	0.8447	
Age									
< 65 years	105	13 (12.4)	NC [NC, NC]	106	12 (11.3)	NC [NC, NC]	0.774 [0.332, 1.808]	0.5536	0.7149
>= 65 years	135	14 (10.4)	NC [NC, NC]	136	11 (8.1)	NC [NC, NC]	1.065 [0.466, 2.434]	0.8818	
Region									
Europe	98	13 (13.3)	NC [NC, NC]	102	12 (11.8)	NC [NC, NC]	0.820 [0.343, 1.964]	0.6564	0.7300
North America	57	8 (14.0)	NC [NC, NC]	51	8 (15.7)	NC [NC, NC]	0.745 [0.277, 2.002]	0.5581	
Rest of World	85	6 (7.1)	NC [NC, NC]	89	3 (3.4)	NC [NC, NC]	1.807 [0.420, 7.775]	0.4214	
Sex									
Male	198	25 (12.6)	NC [NC, NC]	185	17 (9.2)	NC [NC, NC]	1.009 [0.528, 1.928]	0.9791	0.1823
Female	42	2 (4.8)	NC [NC, NC]	57	6 (10.5)	NC [NC, NC]	0.505 [0.097, 2.640]	0.4109	
Metastases at Baseline									
Visceral metastases	170	22 (12.9)	NC [NC, NC]	161	15 (9.3)	NC [NC, NC]	1.150 [0.557, 2.373]	0.7054	0.2952
Lymph node only	60	5 (8.3)	NC [NC, NC]	67	8 (11.9)	NC [NC, NC]	0.636 [0.201, 2.007]	0.4368	

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to event is defined as time from randomization to the initiation of new opioid medication for pain. Censoring date is the date of last assessment for use of opioid medications for pain. Patients with no baseline and/or no post-baseline assessments are censored at the date of randomization.
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.7.2.1: BPI-SF - Summary of Time to Initiation of new Opioid medication for pain - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)	EV+Pembro vs. Plat+Gem
Number of patients at risk	202 (100.0%)	202 (100.0%)	
Number of patients with events	12 (5.9%)	14 (6.9%)	
Number of patients censored	190 (94.1%)	188 (93.1%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	93.8 [89.1, 96.5]	92.9 [87.8, 95.9]	
Month 6	93.1 [88.1, 96.0]	90.9 [84.9, 94.6]	
Month 9	93.1 [88.1, 96.0]	90.9 [84.9, 94.6]	
Month 12	93.1 [88.1, 96.0]	90.9 [84.9, 94.6]	
Month 18	93.1 [88.1, 96.0]	90.9 [84.9, 94.6]	
Month 24	93.1 [88.1, 96.0]	90.9 [84.9, 94.6]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.594 [0.259, 1.362]
Log-rank test			
Two-sided stratified log-rank p-value			0.2143

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Time to event is defined as time from randomization to the initiation of new opioid medication for pain. Censoring date is the date of last assessment for use of opioid medications for pain. Patients with no baseline and/or no post-baseline assessments are censored at the date of randomization.

(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.7.2.2: BPI-SF - Type of Events and Censoring of Initiation of new Opioid medication for pain (MID=2) - Analysis Set mITT 2

	EV+Pembro (N=202)	**Plat+Gem (N=202)**
Number of patients at risk	202 (100.0%)	202 (100.0%)
Number of patients with events	12 (5.9%)	14 (6.9%)
Initiation of new Opioid medication for pain	12 (5.9%)	14 (6.9%)
Number of patients censored	190 (94.1%)	188 (93.1%)
No event	190 (94.1%)	188 (93.1%)

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.7.2.3: BPI-SF - Summary of Time to Initiation of new Opioid medication for pain by Subgroups - Analysis Set mITT 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	2 (4.0)	NC [NC, NC]	50	2 (4.0)	NC [NC, NC]	0.627 [0.080, 4.909]	0.6548	0.8332
Absent	152	10 (6.6)	NC [NC, NC]	152	12 (7.9)	NC [NC, NC]	0.588 [0.237, 1.456]	0.2464	
Age									
< 65 years	39	2 (5.1)	NC [NC, NC]	29	1 (3.4)	NC [NC, NC]	0.943 [0.028, 32.092]	0.9739	0.5888
>= 65 years	163	10 (6.1)	NC [NC, NC]	173	13 (7.5)	NC [NC, NC]	0.578 [0.246, 1.359]	0.2043	
Region									
Europe	74	4 (5.4)	NC [NC, NC]	95	6 (6.3)	NC [NC, NC]	0.555 [0.132, 2.331]	0.4157	0.6047
North America	46	4 (8.7)	NC [NC, NC]	34	2 (5.9)	NC [NC, NC]	1.116 [0.201, 6.202]	0.9001	
Rest of World	82	4 (4.9)	NC [NC, NC]	73	6 (8.2)	NC [NC, NC]	0.419 [0.109, 1.613]	0.1953	
Sex									
Male	146	10 (6.8)	NC [NC, NC]	151	7 (4.6)	NC [NC, NC]	1.155 [0.419, 3.186]	0.7806	0.0331
Female	56	2 (3.6)	NC [NC, NC]	51	7 (13.7)	NC [NC, NC]	0.084 [0.009, 0.771]	0.0094	
Metastases at Baseline									
Visceral metastases	148	8 (5.4)	NC [NC, NC]	157	11 (7.0)	NC [NC, NC]	0.440 [0.168, 1.151]	0.0876	0.8796
Lymph node only	43	2 (4.7)	NC [NC, NC]	37	2 (5.4)	NC [NC, NC]	0.313 [0.022, 4.519]	0.3803	

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to event is defined as time from randomization to the initiation of new opioid medication for pain. Censoring date is the date of last assessment for use of opioid medications for pain. Patients with no baseline and/or no post-baseline assessments are censored at the date of randomization.
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.8.1.1: BPI-SF - Summary of Time to First Deterioration of Composite endpoint (MID=2) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)	EV+Pembro vs. Plat+Gem
Number of patients at risk	240 (100.0%)	242 (100.0%)	
Number of patients with events	130 (54.2%)	113 (46.7%)	
Number of patients censored	110 (45.8%)	129 (53.3%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	48.0 [40.9, 54.8]	42.9 [35.4, 50.1]	
Month 6	41.1 [34.1, 48.0]	36.2 [28.8, 43.7]	
Month 9	34.2 [27.2, 41.2]	32.2 [24.5, 40.2]	
Month 12	33.1 [26.1, 40.2]	27.3 [18.6, 36.8]	
Month 18	27.1 [18.9, 35.9]	27.3 [18.6, 36.8]	
Month 24	27.1 [18.9, 35.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	2.0 [1.3, 4.5]	1.5 [1.1, 3.1]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.899 [0.685, 1.180]
Log-rank test			
Two-sided stratified log-rank p-value			0.4424

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Composite endpoint=worst pain (Question 3) or initiation of new opioid medication for pain. Time to first deterioration is defined as time from randomization to the first observation with a >=2 point increase or initiation of new opioid medication for pain before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.8.1.2: BPI-SF - Type of Events and Censoring of Composite endpoint (MID=2) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)
Number of patients at risk	240 (100.0%)	242 (100.0%)
Number of patients with events	130 (54.2%)	113 (46.7%)
Deterioration of symptom or initiation of new opioid medication	130 (54.2%)	113 (46.7%)
Number of patients censored	110 (45.8%)	129 (53.3%)
No deterioration possible	5 (2.1%)	6 (2.5%)
No baseline and/or follow-up	32 (13.3%)	59 (24.4%)
Subsequent anticancer treatment	7 (2.9%)	18 (7.4%)
Death	24 (10.0%)	17 (7.0%)
No deterioration	42 (17.5%)	29 (12.0%)

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.8.1.3: BPI-SF - Summary of Time to First Deterioration of Composite endpoint by Subgroups (MID=2) - Analysis Set mITT 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	48	22 (45.8)	1.1 [0.6, 8.0]	48	18 (37.5)	3.5 [0.9, NC]	1.274 [0.641, 2.531]	0.4870	0.3243
Absent	192	108 (56.3)	2.7 [1.3, 5.3]	194	95 (49.0)	1.4 [0.9, 2.2]	0.842 [0.626, 1.132]	0.2573	
Age									
< 65 years	105	53 (50.5)	4.6 [2.7, 16.3]	106	49 (46.2)	1.8 [1.1, 7.3]	0.750 [0.491, 1.145]	0.1803	0.5207
>= 65 years	135	77 (57.0)	1.3 [0.7, 2.0]	136	64 (47.1)	1.3 [0.9, 2.2]	1.020 [0.715, 1.455]	0.9054	
Region									
Europe	98	47 (48.0)	3.2 [1.3, 8.0]	102	43 (42.2)	1.1 [0.6, 3.8]	0.745 [0.475, 1.168]	0.1979	0.5752
North America	57	31 (54.4)	2.7 [1.1, 12.8]	51	23 (45.1)	3.2 [1.1, NC]	0.893 [0.488, 1.635]	0.7219	
Rest of World	85	52 (61.2)	1.4 [0.6, 4.5]	89	47 (52.8)	1.4 [0.9, 3.2]	1.054 [0.698, 1.592]	0.8066	
Sex									
Male	198	106 (53.5)	2.0 [1.1, 4.5]	185	87 (47.0)	1.4 [1.1, 2.2]	0.980 [0.727, 1.320]	0.9041	0.7671
Female	42	24 (57.1)	3.3 [1.1, 8.7]	57	26 (45.6)	2.2 [0.7, 5.9]	0.572 [0.287, 1.140]	0.1039	
Metastases at Baseline									
Visceral metastases	170	86 (50.6)	2.0 [1.3, 5.3]	161	72 (44.7)	1.8 [1.3, 5.9]	1.015 [0.717, 1.438]	0.9462	0.9207
Lymph node only	60	38 (63.3)	2.0 [0.6, 6.6]	67	33 (49.3)	1.1 [0.6, 2.0]	0.744 [0.424, 1.304]	0.3049	

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Composite endpoint=worst pain (Question 3) or initiation of new opioid medication for pain. Time to first deterioration is defined as time from randomization to the first observation with a >=2 point increase or initiation of new opioid medication for pain before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.8.2.1: BPI-SF - Summary of Time to First Deterioration of Composite endpoint (MID=2) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)	EV+Pembro vs. Plat+Gem
Number of patients at risk	202 (100.0%)	202 (100.0%)	
Number of patients with events	85 (42.1%)	105 (52.0%)	
Number of patients censored	117 (57.9%)	97 (48.0%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	51.9 [43.6, 59.6]	36.8 [29.0, 44.6]	
Month 6	44.9 [36.6, 52.8]	33.7 [25.8, 41.6]	
Month 9	42.9 [34.5, 50.9]	29.6 [21.7, 38.0]	
Month 12	41.5 [33.0, 49.7]	21.5 [13.3, 31.1]	
Month 18	39.5 [30.6, 48.2]	NC [NC, NC]	
Month 24	39.5 [30.6, 48.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	3.2 [1.6, 10.7]	1.3 [0.6, 2.0]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.662 [0.482, 0.910]
Log-rank test			
Two-sided stratified log-rank p-value			0.0100

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Composite endpoint=worst pain (Question 3) or initiation of new opioid medication for pain. Time to first deterioration is defined as time from randomization to the first observation with a >=2 point increase or initiation of new opioid medication for pain before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.8.2.2: BPI-SF - Type of Events and Censoring of Composite endpoint (MID=2) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)
Number of patients at risk	202 (100.0%)	202 (100.0%)
Number of patients with events	85 (42.1%)	105 (52.0%)
Deterioration of symptom or initiation of new opioid medication	85 (42.1%)	105 (52.0%)
Number of patients censored	117 (57.9%)	97 (48.0%)
No deterioration possible	5 (2.5%)	8 (4.0%)
No baseline and/or follow-up	42 (20.8%)	40 (19.8%)
Subsequent anticancer treatment	6 (3.0%)	16 (7.9%)
Death	20 (9.9%)	14 (6.9%)
No deterioration	44 (21.8%)	19 (9.4%)

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.8.2.3: BPI-SF - Summary of Time to First Deterioration of Composite endpoint by Subgroups (MID=2) - Analysis Set mITT 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	20 (40.0)	5.9 [0.4, NC]	50	23 (46.0)	1.8 [0.4, 6.6]	0.958 [0.448, 2.047]	0.8948	0.5363
Absent	152	65 (42.8)	3.2 [1.5, NC]	152	82 (53.9)	1.1 [0.6, 1.8]	0.613 [0.431, 0.870]	0.0055	
Age									
< 65 years	39	15 (38.5)	10.7 [2.7, NC]	29	10 (34.5)	5.5 [0.8, NC]	0.999 [0.365, 2.734]	0.9847	0.3802
>= 65 years	163	70 (42.9)	2.3 [1.1, 8.7]	173	95 (54.9)	0.9 [0.4, 1.6]	0.632 [0.451, 0.885]	0.0068	
Region									
Europe	74	27 (36.5)	3.1 [1.1, NC]	95	51 (53.7)	0.7 [0.4, 1.5]	0.608 [0.363, 1.018]	0.0545	0.3963
North America	46	18 (39.1)	2.3 [0.5, NC]	34	14 (41.2)	1.8 [0.9, 9.4]	0.816 [0.359, 1.858]	0.6146	
Rest of World	82	40 (48.8)	3.8 [1.5, NC]	73	40 (54.8)	1.6 [0.4, 5.5]	0.664 [0.416, 1.061]	0.0840	
Sex									
Male	146	64 (43.8)	2.8 [1.5, 10.7]	151	80 (53.0)	1.3 [0.7, 2.4]	0.724 [0.507, 1.034]	0.0722	0.4453
Female	56	21 (37.5)	8.7 [0.9, NC]	51	25 (49.0)	0.6 [0.2, 6.6]	0.468 [0.228, 0.962]	0.0322	
Metastases at Baseline									
Visceral metastases	148	67 (45.3)	2.7 [1.1, 4.5]	157	79 (50.3)	1.3 [0.6, 2.4]	0.881 [0.595, 1.302]	0.4952	0.0245
Lymph node only	43	16 (37.2)	NC [1.5, NC]	37	22 (59.5)	0.5 [0.2, 2.4]	0.324 [0.144, 0.731]	0.0057	

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Composite endpoint=worst pain (Question 3) or initiation of new opioid medication for pain. Time to first deterioration is defined as time from randomization to the first observation with a >=2 point increase or initiation of new opioid medication for pain before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.9.1.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Global Health Status/QoL (MID=10) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)	EV+Pembro vs. Plat+Gem
Number of patients at risk	240 (100.0%)	242 (100.0%)	
Number of patients with events	158 (65.8%)	132 (54.5%)	
Number of patients censored	82 (34.2%)	110 (45.5%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	34.4 [27.8, 41.0]	30.5 [23.7, 37.6]	
Month 6	26.1 [20.1, 32.5]	23.9 [17.6, 30.9]	
Month 9	19.0 [13.6, 25.1]	22.7 [16.4, 29.8]	
Month 12	19.0 [13.6, 25.1]	18.4 [11.4, 26.7]	
Month 18	19.0 [13.6, 25.1]	13.8 [5.9, 24.9]	
Month 24	15.2 [8.2, 24.2]	13.8 [5.9, 24.9]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	0.7 [0.6, 1.3]	0.9 [0.6, 1.1]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.889 [0.687, 1.149]
Log-rank test			
Two-sided stratified log-rank p-value			0.3660

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.9.1.2: EORTC QLQ-C30 - Type of Events and Censoring of Global Health Status/QoL (MID=10) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)
Number of patients at risk	240 (100.0%)	242 (100.0%)
Number of patients with events	158 (65.8%)	132 (54.5%)
Deterioration of symptom	158 (65.8%)	132 (54.5%)
Number of patients censored	82 (34.2%)	110 (45.5%)
No deterioration possible	4 (1.7%)	7 (2.9%)
No baseline and/or follow-up	35 (14.6%)	61 (25.2%)
Subsequent anticancer treatment	4 (1.7%)	10 (4.1%)
Death	8 (3.3%)	16 (6.6%)
No deterioration	31 (12.9%)	16 (6.6%)

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.9.1.3: EORTC QLQ-C30 - Summary of Time to First Deterioration of Global Health Status/QoL by Subgroups (MID=10) - Analysis Set mITT 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	48	29 (60.4)	0.6 [0.4, 1.5]	48	19 (39.6)	1.0 [0.4, NC]	1.447 [0.734, 2.853]	0.2784	0.1884
Absent	192	129 (67.2)	0.8 [0.6, 2.0]	194	113 (58.2)	0.9 [0.6, 1.1]	0.817 [0.619, 1.079]	0.1479	
Age									
< 65 years	105	64 (61.0)	1.3 [0.6, 4.6]	106	56 (52.8)	1.1 [0.6, 1.4]	0.845 [0.563, 1.269]	0.4278	0.6004
>= 65 years	135	94 (69.6)	0.6 [0.6, 0.9]	136	76 (55.9)	0.7 [0.4, 1.1]	0.919 [0.659, 1.282]	0.6051	
Region									
Europe	98	58 (59.2)	0.9 [0.5, 2.2]	102	48 (47.1)	0.6 [0.4, 0.9]	0.825 [0.538, 1.267]	0.3971	0.3205
North America	57	36 (63.2)	0.9 [0.6, 2.2]	51	32 (62.7)	0.7 [0.4, 1.1]	0.795 [0.462, 1.367]	0.3930	
Rest of World	85	64 (75.3)	0.6 [0.5, 1.7]	89	52 (58.4)	1.3 [0.7, 2.2]	1.005 [0.676, 1.496]	0.9939	
Sex									
Male	198	124 (62.6)	0.9 [0.6, 2.0]	185	101 (54.6)	1.1 [0.7, 1.3]	0.914 [0.690, 1.211]	0.5300	0.8012
Female	42	34 (81.0)	0.6 [0.4, 1.3]	57	31 (54.4)	0.4 [0.2, 0.7]	0.769 [0.404, 1.460]	0.4087	
Metastases at Baseline									
Visceral metastases	170	103 (60.6)	0.9 [0.6, 2.2]	161	85 (52.8)	0.9 [0.6, 1.3]	0.786 [0.561, 1.100]	0.1659	0.4201
Lymph node only	60	49 (81.7)	0.6 [0.4, 0.9]	67	40 (59.7)	0.7 [0.4, 1.3]	0.866 [0.520, 1.441]	0.5322	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.9.2.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Global Health Status/QoL (MID=10) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)	EV+Pembro vs. Plat+Gem
Number of patients at risk	202 (100.0%)	202 (100.0%)	
Number of patients with events	118 (58.4%)	114 (56.4%)	
Number of patients censored	84 (41.6%)	88 (43.6%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	31.3 [24.0, 38.8]	29.5 [22.3, 37.1]	
Month 6	24.8 [18.0, 32.2]	25.1 [18.1, 32.6]	
Month 9	22.7 [16.0, 30.1]	23.1 [16.0, 31.1]	
Month 12	17.7 [10.9, 25.8]	18.0 [10.3, 27.4]	
Month 18	13.1 [6.5, 22.1]	13.5 [5.5, 25.1]	
Month 24	NC [NC, NC]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	1.1 [0.6, 1.6]	0.9 [0.6, 1.3]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.953 [0.703, 1.292]
Log-rank test			
Two-sided stratified log-rank p-value			0.7875

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.9.2.2: EORTC QLQ-C30 - Type of Events and Censoring of Global Health Status/QoL (MID=10) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)
Number of patients at risk	202 (100.0%)	202 (100.0%)
Number of patients with events	118 (58.4%)	114 (56.4%)
Deterioration of symptom	118 (58.4%)	114 (56.4%)
Number of patients censored	84 (41.6%)	88 (43.6%)
No deterioration possible	2 (1.0%)	4 (2.0%)
No baseline and/or follow-up	48 (23.8%)	42 (20.8%)
Subsequent anticancer treatment	6 (3.0%)	9 (4.5%)
Death	14 (6.9%)	18 (8.9%)
No deterioration	14 (6.9%)	15 (7.4%)

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.9.2.3: EORTC QLQ-C30 - Summary of Time to First Deterioration of Global Health Status/QoL by Subgroups (MID=10) - Analysis Set mITT 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	30 (60.0)	0.4 [0.2, 1.8]	50	23 (46.0)	0.9 [0.4, 3.9]	1.343 [0.646, 2.792]	0.4198	0.1852
Absent	152	88 (57.9)	1.3 [0.7, 1.8]	152	91 (59.9)	0.9 [0.6, 1.1]	0.885 [0.631, 1.240]	0.5008	
Age									
< 65 years	39	25 (64.1)	2.3 [1.1, 2.7]	29	17 (58.6)	1.0 [0.2, 2.5]	0.983 [0.381, 2.536]	0.9618	0.5681
>= 65 years	163	93 (57.1)	0.7 [0.5, 1.3]	173	97 (56.1)	0.9 [0.6, 1.1]	0.950 [0.689, 1.309]	0.7889	
Region									
Europe	74	42 (56.8)	0.9 [0.2, 2.0]	95	58 (61.1)	0.8 [0.4, 1.7]	0.924 [0.570, 1.497]	0.7793	0.8395
North America	46	22 (47.8)	0.6 [0.4, 2.3]	34	18 (52.9)	1.1 [0.4, 1.3]	0.760 [0.362, 1.598]	0.5029	
Rest of World	82	54 (65.9)	1.3 [0.7, 2.3]	73	38 (52.1)	1.1 [0.4, 2.5]	1.070 [0.674, 1.697]	0.7801	
Sex									
Male	146	88 (60.3)	1.1 [0.6, 1.5]	151	84 (55.6)	1.1 [0.6, 1.8]	1.039 [0.739, 1.463]	0.8112	0.2625
Female	56	30 (53.6)	1.3 [0.5, 2.3]	51	30 (58.8)	0.4 [0.4, 1.1]	0.681 [0.343, 1.351]	0.2723	
Metastases at Baseline									
Visceral metastases	148	84 (56.8)	1.3 [0.6, 2.0]	157	86 (54.8)	0.9 [0.6, 1.7]	0.972 [0.662, 1.426]	0.8793	0.8995
Lymph node only	43	29 (67.4)	0.8 [0.5, 1.3]	37	24 (64.9)	0.6 [0.2, 1.3]	0.715 [0.343, 1.489]	0.3933	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.10.1.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Physical Functioning (MID=10) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)	EV+Pembro vs. Plat+Gem
Number of patients at risk	240 (100.0%)	242 (100.0%)	
Number of patients with events	164 (68.3%)	137 (56.6%)	
Number of patients censored	76 (31.7%)	105 (43.4%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	32.4 [26.0, 38.8]	29.6 [23.0, 36.5]	
Month 6	26.3 [20.4, 32.6]	23.2 [17.0, 30.0]	
Month 9	22.3 [16.6, 28.6]	19.5 [13.4, 26.6]	
Month 12	14.6 [9.3, 21.0]	16.3 [10.1, 23.8]	
Month 18	13.5 [8.3, 19.9]	16.3 [10.1, 23.8]	
Month 24	10.1 [4.4, 18.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	1.1 [0.6, 1.6]	0.9 [0.6, 1.1]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.913 [0.712, 1.172]
Log-rank test			
Two-sided stratified log-rank p-value			0.4541

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.10.1.2: EORTC QLQ-C30 - Type of Events and Censoring of Physical Functioning (MID=10) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)
Number of patients at risk	240 (100.0%)	242 (100.0%)
Number of patients with events	164 (68.3%)	137 (56.6%)
Deterioration of symptom	164 (68.3%)	137 (56.6%)
Number of patients censored	76 (31.7%)	105 (43.4%)
No deterioration possible	2 (0.8%)	3 (1.2%)
No baseline and/or follow-up	35 (14.6%)	61 (25.2%)
Subsequent anticancer treatment	6 (2.5%)	12 (5.0%)
Death	9 (3.8%)	11 (4.5%)
No deterioration	24 (10.0%)	18 (7.4%)

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.10.1.3: EORTC QLQ-C30 - Summary of Time to First Deterioration of Physical Functioning by Subgroups (MID=10) - Analysis Set mITT 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	48	27 (56.3)	0.7 [0.4, 1.8]	48	24 (50.0)	1.3 [0.2, 3.8]	0.867 [0.452, 1.662]	0.6017	0.9395
Absent	192	137 (71.4)	1.1 [0.6, 1.8]	194	113 (58.2)	0.9 [0.6, 1.1]	0.922 [0.704, 1.207]	0.5518	
Age									
< 65 years	105	61 (58.1)	1.8 [0.9, 7.3]	106	61 (57.5)	0.6 [0.4, 1.2]	0.590 [0.396, 0.880]	0.0094	0.0047
>= 65 years	135	103 (76.3)	0.6 [0.5, 1.1]	136	76 (55.9)	1.1 [0.7, 1.5]	1.210 [0.877, 1.669]	0.2576	
Region									
Europe	98	61 (62.2)	1.1 [0.6, 1.8]	102	51 (50.0)	1.1 [0.4, 1.7]	1.039 [0.682, 1.583]	0.8465	0.7655
North America	57	39 (68.4)	0.6 [0.4, 1.3]	51	30 (58.8)	0.7 [0.4, 2.0]	0.996 [0.592, 1.674]	0.9610	
Rest of World	85	64 (75.3)	1.3 [0.6, 2.2]	89	56 (62.9)	0.9 [0.6, 1.8]	0.782 [0.532, 1.149]	0.1964	
Sex									
Male	198	133 (67.2)	1.3 [0.9, 1.8]	185	102 (55.1)	0.9 [0.6, 1.3]	0.918 [0.698, 1.207]	0.5405	0.5386
Female	42	31 (73.8)	0.4 [0.2, 0.6]	57	35 (61.4)	0.9 [0.2, 1.8]	0.895 [0.490, 1.635]	0.6426	
Metastases at Baseline									
Visceral metastases	170	113 (66.5)	0.9 [0.6, 1.3]	161	92 (57.1)	0.9 [0.4, 1.5]	0.921 [0.670, 1.266]	0.5511	0.8230
Lymph node only	60	44 (73.3)	1.6 [0.6, 2.0]	67	37 (55.2)	0.7 [0.4, 1.7]	0.790 [0.464, 1.347]	0.3697	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.10.2.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Physical Functioning (MID=10) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)	EV+Pembro vs. Plat+Gem
Number of patients at risk	202 (100.0%)	202 (100.0%)	
Number of patients with events	121 (59.9%)	124 (61.4%)	
Number of patients censored	81 (40.1%)	78 (38.6%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	33.7 [26.2, 41.3]	24.2 [17.5, 31.5]	
Month 6	26.4 [19.4, 33.9]	19.2 [12.6, 26.9]	
Month 9	22.0 [15.4, 29.4]	13.8 [7.4, 22.0]	
Month 12	15.4 [9.2, 23.1]	9.2 [3.6, 17.8]	
Month 18	11.0 [5.2, 19.4]	9.2 [3.6, 17.8]	
Month 24	8.3 [2.9, 17.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	1.1 [0.7, 1.6]	0.7 [0.4, 1.1]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.798 [0.597, 1.069]
Log-rank test			
Two-sided stratified log-rank p-value			0.1291

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.10.2.2: EORTC QLQ-C30 - Type of Events and Censoring of Physical Functioning (MID=10) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)
Number of patients at risk	202 (100.0%)	202 (100.0%)
Number of patients with events	121 (59.9%)	124 (61.4%)
Deterioration of symptom	121 (59.9%)	124 (61.4%)
Number of patients censored	81 (40.1%)	78 (38.6%)
No deterioration possible	0	1 (0.5%)
No baseline and/or follow-up	48 (23.8%)	42 (20.8%)
Subsequent anticancer treatment	3 (1.5%)	10 (5.0%)
Death	12 (5.9%)	13 (6.4%)
No deterioration	18 (8.9%)	12 (5.9%)

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.10.2.3: EORTC QLQ-C30 - Summary of Time to First Deterioration of Physical Functioning by Subgroups (MID=10) - Analysis Set mITT 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	29 (58.0)	0.9 [0.4, 2.0]	50	29 (58.0)	0.6 [0.4, 1.5]	0.929 [0.486, 1.776]	0.8162	0.9881
Absent	152	92 (60.5)	1.1 [0.7, 2.0]	152	95 (62.5)	0.7 [0.5, 1.1]	0.768 [0.554, 1.065]	0.1144	
Age									
< 65 years	39	23 (59.0)	3.2 [0.7, 10.7]	29	19 (65.5)	1.6 [0.8, 2.0]	0.582 [0.226, 1.498]	0.2584	0.4699
>= 65 years	163	98 (60.1)	0.9 [0.6, 1.3]	173	105 (60.7)	0.6 [0.4, 0.7]	0.826 [0.608, 1.122]	0.2223	
Region									
Europe	74	41 (55.4)	1.2 [0.6, 2.0]	95	59 (62.1)	0.6 [0.4, 1.3]	0.766 [0.478, 1.228]	0.2595	0.5821
North America	46	26 (56.5)	0.4 [0.4, 3.9]	34	18 (52.9)	0.7 [0.4, 1.3]	1.073 [0.546, 2.108]	0.8096	
Rest of World	82	54 (65.9)	1.3 [0.9, 2.3]	73	47 (64.4)	0.6 [0.4, 1.6]	0.728 [0.467, 1.137]	0.1646	
Sex									
Male	146	90 (61.6)	1.3 [0.7, 2.0]	151	90 (59.6)	0.8 [0.4, 1.3]	0.794 [0.571, 1.105]	0.1763	0.2842
Female	56	31 (55.4)	0.9 [0.4, 1.3]	51	34 (66.7)	0.6 [0.4, 0.7]	0.813 [0.439, 1.507]	0.4901	
Metastases at Baseline									
Visceral metastases	148	84 (56.8)	1.3 [0.7, 2.2]	157	95 (60.5)	0.6 [0.4, 1.1]	0.680 [0.473, 0.978]	0.0351	0.1980
Lymph node only	43	30 (69.8)	1.0 [0.6, 1.3]	37	22 (59.5)	0.7 [0.4, 1.6]	0.730 [0.339, 1.573]	0.4209	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.11.1.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Role Functioning (MID=10) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)	EV+Pembro vs. Plat+Gem
Number of patients at risk	240 (100.0%)	242 (100.0%)	
Number of patients with events	164 (68.3%)	140 (57.9%)	
Number of patients censored	76 (31.7%)	102 (42.1%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	28.8 [22.6, 35.2]	23.5 [17.4, 30.1]	
Month 6	22.7 [17.0, 28.9]	19.5 [13.7, 26.1]	
Month 9	18.1 [12.9, 24.1]	16.5 [10.6, 23.5]	
Month 12	17.1 [11.9, 23.1]	13.2 [6.6, 22.0]	
Month 18	9.8 [4.9, 16.7]	NC [NC, NC]	
Month 24	9.8 [4.9, 16.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	0.6 [0.4, 0.8]	0.4 [0.4, 0.9]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.898 [0.698, 1.154]
Log-rank test			
Two-sided stratified log-rank p-value			0.4531

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.11.1.2: EORTC QLQ-C30 - Type of Events and Censoring of Role Functioning (MID=10) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)
Number of patients at risk	240 (100.0%)	242 (100.0%)
Number of patients with events	164 (68.3%)	140 (57.9%)
Deterioration of symptom	164 (68.3%)	140 (57.9%)
Number of patients censored	76 (31.7%)	102 (42.1%)
No deterioration possible	7 (2.9%)	6 (2.5%)
No baseline and/or follow-up	35 (14.6%)	61 (25.2%)
Subsequent anticancer treatment	5 (2.1%)	11 (4.5%)
Death	10 (4.2%)	9 (3.7%)
No deterioration	19 (7.9%)	15 (6.2%)

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.11.1.3: EORTC QLQ-C30 - Summary of Time to First Deterioration of Role Functioning by Subgroups (MID=10) - Analysis Set mITT 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	48	27 (56.3)	0.6 [0.4, 0.9]	48	28 (58.3)	0.4 [0.2, 1.1]	0.607 [0.302, 1.223]	0.1541	0.1150
Absent	192	137 (71.4)	0.6 [0.4, 0.9]	194	112 (57.7)	0.6 [0.4, 0.9]	0.953 [0.727, 1.250]	0.8009	
Age									
< 65 years	105	69 (65.7)	0.7 [0.4, 1.1]	106	62 (58.5)	0.4 [0.2, 0.9]	0.831 [0.560, 1.233]	0.3695	0.3926
>= 65 years	135	95 (70.4)	0.6 [0.4, 0.8]	136	78 (57.4)	0.5 [0.4, 0.9]	0.947 [0.682, 1.313]	0.8219	
Region									
Europe	98	56 (57.1)	0.7 [0.5, 2.0]	102	51 (50.0)	0.4 [0.4, 0.9]	0.737 [0.478, 1.136]	0.1711	0.1324
North America	57	40 (70.2)	0.7 [0.4, 0.9]	51	33 (64.7)	0.4 [0.2, 0.9]	0.813 [0.478, 1.383]	0.5432	
Rest of World	85	68 (80.0)	0.5 [0.4, 0.7]	89	56 (62.9)	0.6 [0.4, 1.3]	1.098 [0.752, 1.603]	0.6228	
Sex									
Male	198	134 (67.7)	0.6 [0.4, 0.9]	185	108 (58.4)	0.6 [0.4, 0.9]	0.924 [0.702, 1.215]	0.5947	0.9023
Female	42	30 (71.4)	0.6 [0.2, 0.9]	57	32 (56.1)	0.4 [0.2, 0.9]	0.769 [0.406, 1.456]	0.5033	
Metastases at Baseline									
Visceral metastases	170	110 (64.7)	0.6 [0.4, 0.8]	161	94 (58.4)	0.4 [0.4, 0.9]	0.950 [0.685, 1.317]	0.7450	0.7915
Lymph node only	60	47 (78.3)	0.6 [0.5, 1.5]	67	38 (56.7)	0.6 [0.4, 1.1]	0.823 [0.486, 1.391]	0.4802	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.11.2.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Role Functioning (MID=10) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)	EV+Pembro vs. Plat+Gem
Number of patients at risk	202 (100.0%)	202 (100.0%)	
Number of patients with events	125 (61.9%)	136 (67.3%)	
Number of patients censored	77 (38.1%)	66 (32.7%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	26.2 [19.2, 33.8]	12.9 [8.0, 19.1]	
Month 6	21.0 [14.7, 28.2]	9.1 [4.8, 14.9]	
Month 9	15.3 [9.8, 22.0]	6.0 [2.4, 12.1]	
Month 12	13.3 [8.1, 19.9]	4.5 [1.4, 10.5]	
Month 18	9.2 [4.5, 15.9]	4.5 [1.4, 10.5]	
Month 24	5.1 [1.4, 12.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	0.7 [0.5, 1.1]	0.4 [0.4, 0.6]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.756 [0.563, 1.015]
Log-rank test			
Two-sided stratified log-rank p-value			0.0633

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.11.2.2: EORTC QLQ-C30 - Type of Events and Censoring of Role Functioning (MID=10) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)
Number of patients at risk	202 (100.0%)	202 (100.0%)
Number of patients with events	125 (61.9%)	136 (67.3%)
Deterioration of symptom	125 (61.9%)	136 (67.3%)
Number of patients censored	77 (38.1%)	66 (32.7%)
No deterioration possible	7 (3.5%)	5 (2.5%)
No baseline and/or follow-up	48 (23.8%)	42 (20.8%)
Subsequent anticancer treatment	2 (1.0%)	6 (3.0%)
Death	9 (4.5%)	6 (3.0%)
No deterioration	11 (5.4%)	7 (3.5%)

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.11.2.3: EORTC QLQ-C30 - Summary of Time to First Deterioration of Role Functioning by Subgroups (MID=10) - Analysis Set mITT 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	32 (64.0)	0.4 [0.2, 0.7]	50	34 (68.0)	0.4 [0.2, 0.6]	1.569 [0.801, 3.073]	0.1553	0.2161
Absent	152	93 (61.2)	0.9 [0.6, 1.3]	152	102 (67.1)	0.4 [0.4, 0.6]	0.636 [0.458, 0.885]	0.0063	
Age									
< 65 years	39	24 (61.5)	0.6 [0.4, 1.1]	29	17 (58.6)	1.0 [0.2, 7.3]	1.082 [0.412, 2.836]	0.8621	0.2102
>= 65 years	163	101 (62.0)	0.7 [0.5, 1.1]	173	119 (68.8)	0.4 [0.4, 0.6]	0.728 [0.534, 0.993]	0.0441	
Region									
Europe	74	45 (60.8)	0.6 [0.5, 0.8]	95	65 (68.4)	0.4 [0.4, 0.6]	0.831 [0.519, 1.331]	0.4252	0.2776
North America	46	26 (56.5)	0.4 [0.2, 1.4]	34	21 (61.8)	0.6 [0.4, 0.9]	0.944 [0.473, 1.882]	0.9109	
Rest of World	82	54 (65.9)	1.1 [0.4, 1.8]	73	50 (68.5)	0.4 [0.2, 0.4]	0.632 [0.404, 0.989]	0.0431	
Sex									
Male	146	91 (62.3)	0.7 [0.4, 1.1]	151	99 (65.6)	0.5 [0.4, 0.9]	0.849 [0.605, 1.191]	0.3601	0.0253
Female	56	34 (60.7)	0.7 [0.4, 1.1]	51	37 (72.5)	0.2 [0.2, 0.4]	0.522 [0.282, 0.966]	0.0306	
Metastases at Baseline									
Visceral metastases	148	90 (60.8)	0.6 [0.4, 0.9]	157	104 (66.2)	0.4 [0.4, 0.6]	0.909 [0.633, 1.305]	0.6102	0.5499
Lymph node only	43	28 (65.1)	1.1 [0.6, 3.0]	37	24 (64.9)	0.4 [0.2, 0.9]	0.654 [0.300, 1.425]	0.2891	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.12.1.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Emotional Functioning (MID=10) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)	EV+Pembro vs. Plat+Gem
Number of patients at risk	240 (100.0%)	242 (100.0%)	
Number of patients with events	120 (50.0%)	95 (39.3%)	
Number of patients censored	120 (50.0%)	147 (60.7%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	50.6 [43.5, 57.3]	53.1 [45.3, 60.2]	
Month 6	47.0 [39.9, 53.7]	46.7 [38.8, 54.1]	
Month 9	44.0 [37.0, 50.8]	43.2 [35.0, 51.0]	
Month 12	38.6 [31.3, 45.9]	40.8 [31.9, 49.5]	
Month 18	35.8 [28.1, 43.6]	37.1 [26.6, 47.6]	
Month 24	35.8 [28.1, 43.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	3.2 [2.0, 10.1]	3.8 [2.0, 11.4]	
Cox proportional hazards model			
Stratified HR [95% CI]			1.003 [0.748, 1.345]
Log-rank test			
Two-sided stratified log-rank p-value			0.9838

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.12.1.2: EORTC QLQ-C30 - Type of Events and Censoring of Emotional Functioning (MID=10) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)
Number of patients at risk	240 (100.0%)	242 (100.0%)
Number of patients with events	120 (50.0%)	95 (39.3%)
Deterioration of symptom	120 (50.0%)	95 (39.3%)
Number of patients censored	120 (50.0%)	147 (60.7%)
No deterioration possible	1 (0.4%)	4 (1.7%)
No baseline and/or follow-up	35 (14.6%)	61 (25.2%)
Subsequent anticancer treatment	9 (3.8%)	26 (10.7%)
Death	12 (5.0%)	19 (7.9%)
No deterioration	63 (26.3%)	37 (15.3%)

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.12.1.3: EORTC QLQ-C30 - Summary of Time to First Deterioration of Emotional Functioning by Subgroups (MID=10) - Analysis Set mITT 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	48	24 (50.0)	1.7 [0.9, 8.0]	48	13 (27.1)	NC [1.8, NC]	2.867 [1.265, 6.496]	0.0099	0.0463
Absent	192	96 (50.0)	3.9 [2.3, 10.7]	194	82 (42.3)	3.3 [1.5, 7.3]	0.843 [0.615, 1.155]	0.2939	
Age									
< 65 years	105	50 (47.6)	8.0 [2.7, NC]	106	41 (38.7)	3.9 [1.8, NC]	0.873 [0.547, 1.394]	0.5662	0.3280
>= 65 years	135	70 (51.9)	2.0 [1.1, 6.6]	136	54 (39.7)	3.8 [1.5, 11.4]	1.097 [0.752, 1.601]	0.6251	
Region									
Europe	98	42 (42.9)	6.6 [2.0, NC]	102	36 (35.3)	2.3 [1.3, NC]	0.807 [0.492, 1.322]	0.4046	0.1022
North America	57	31 (54.4)	2.0 [1.1, 10.1]	51	17 (33.3)	11.4 [2.0, NC]	1.916 [1.006, 3.649]	0.0468	
Rest of World	85	47 (55.3)	3.8 [2.0, 12.1]	89	42 (47.2)	3.2 [1.3, 12.8]	0.854 [0.545, 1.340]	0.4922	
Sex									
Male	198	102 (51.5)	2.8 [2.0, 6.6]	185	76 (41.1)	3.3 [1.8, 11.4]	1.047 [0.763, 1.438]	0.7814	0.8813
Female	42	18 (42.9)	10.1 [1.1, NC]	57	19 (33.3)	7.3 [1.1, NC]	0.765 [0.345, 1.696]	0.5252	
Metastases at Baseline									
Visceral metastases	170	81 (47.6)	6.6 [2.0, 10.7]	161	63 (39.1)	3.8 [2.0, NC]	0.953 [0.647, 1.402]	0.8083	0.7943
Lymph node only	60	34 (56.7)	2.2 [0.9, 16.3]	67	26 (38.8)	3.8 [0.9, NC]	1.194 [0.682, 2.092]	0.5243	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.12.2.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Emotional Functioning (MID=10) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)	EV+Pembro vs. Plat+Gem
Number of patients at risk	202 (100.0%)	202 (100.0%)	
Number of patients with events	90 (44.6%)	94 (46.5%)	
Number of patients censored	112 (55.4%)	108 (53.5%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	53.3 [44.9, 61.1]	44.5 [36.4, 52.4]	
Month 6	47.9 [39.4, 55.8]	36.6 [28.1, 45.3]	
Month 9	44.3 [35.8, 52.4]	34.4 [25.3, 43.6]	
Month 12	36.1 [27.4, 44.8]	31.5 [21.8, 41.6]	
Month 18	28.7 [19.5, 38.5]	28.3 [18.2, 39.3]	
Month 24	28.7 [19.5, 38.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	4.5 [2.1, 9.4]	2.0 [1.1, 3.2]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.733 [0.523, 1.029]
Log-rank test			
Two-sided stratified log-rank p-value			0.0796

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.12.2.2: EORTC QLQ-C30 - Type of Events and Censoring of Emotional Functioning (MID=10) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)
Number of patients at risk	202 (100.0%)	202 (100.0%)
Number of patients with events	90 (44.6%)	94 (46.5%)
Deterioration of symptom	90 (44.6%)	94 (46.5%)
Number of patients censored	112 (55.4%)	108 (53.5%)
No deterioration possible	2 (1.0%)	1 (0.5%)
No baseline and/or follow-up	48 (23.8%)	42 (20.8%)
Subsequent anticancer treatment	6 (3.0%)	15 (7.4%)
Death	20 (9.9%)	23 (11.4%)
No deterioration	36 (17.8%)	27 (13.4%)

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.12.2.3: EORTC QLQ-C30 - Summary of Time to First Deterioration of Emotional Functioning by Subgroups (MID=10) - Analysis Set mITT 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	23 (46.0)	2.8 [0.6, 12.8]	50	21 (42.0)	2.7 [0.6, NC]	1.126 [0.518, 2.446]	0.7390	0.5034
Absent	152	67 (44.1)	5.9 [2.5, 10.7]	152	73 (48.0)	1.8 [1.1, 3.2]	0.662 [0.453, 0.967]	0.0345	
Age									
< 65 years	39	20 (51.3)	4.5 [2.0, 14.2]	29	14 (48.3)	1.7 [0.4, NC]	0.642 [0.240, 1.719]	0.3579	0.8605
>= 65 years	163	70 (42.9)	3.4 [1.8, 10.1]	173	80 (46.2)	2.5 [1.1, 3.8]	0.747 [0.521, 1.071]	0.1249	
Region									
Europe	74	32 (43.2)	6.6 [0.9, 11.4]	95	40 (42.1)	3.1 [1.1, NC]	1.127 [0.641, 1.983]	0.6490	0.3291
North America	46	12 (26.1)	NC [2.5, NC]	34	13 (38.2)	2.5 [1.1, NC]	0.372 [0.133, 1.042]	0.0512	
Rest of World	82	46 (56.1)	2.7 [1.5, 6.6]	73	41 (56.2)	1.1 [0.7, 2.7]	0.645 [0.408, 1.018]	0.0630	
Sex									
Male	146	70 (47.9)	3.2 [1.7, 9.4]	151	67 (44.4)	2.7 [1.3, 5.9]	0.886 [0.603, 1.300]	0.5494	0.0143
Female	56	20 (35.7)	10.7 [1.8, NC]	51	27 (52.9)	0.9 [0.4, 1.1]	0.364 [0.167, 0.793]	0.0096	
Metastases at Baseline									
Visceral metastases	148	62 (41.9)	3.4 [1.8, 12.8]	157	75 (47.8)	1.8 [1.1, 3.1]	0.620 [0.411, 0.935]	0.0218	0.2181
Lymph node only	43	21 (48.8)	6.6 [1.5, 11.5]	37	13 (35.1)	12.1 [1.1, NC]	1.428 [0.550, 3.711]	0.4629	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.13.1.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Social Functioning (MID=10) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)	EV+Pembro vs. Plat+Gem
Number of patients at risk	240 (100.0%)	242 (100.0%)	
Number of patients with events	161 (67.1%)	129 (53.3%)	
Number of patients censored	79 (32.9%)	113 (46.7%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	28.8 [22.6, 35.2]	31.8 [24.9, 38.8]	
Month 6	23.7 [17.9, 29.9]	26.5 [19.9, 33.5]	
Month 9	19.0 [13.6, 25.1]	22.8 [16.2, 30.2]	
Month 12	19.0 [13.6, 25.1]	21.3 [14.6, 28.9]	
Month 18	16.0 [10.7, 22.2]	21.3 [14.6, 28.9]	
Month 24	12.0 [6.4, 19.4]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	0.7 [0.5, 1.1]	0.9 [0.6, 1.1]	
Cox proportional hazards model			
Stratified HR [95% CI]			1.169 [0.907, 1.505]
Log-rank test			
Two-sided stratified log-rank p-value			0.2101

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.13.1.2: EORTC QLQ-C30 - Type of Events and Censoring of Social Functioning (MID=10) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)
Number of patients at risk	240 (100.0%)	242 (100.0%)
Number of patients with events	161 (67.1%)	129 (53.3%)
Deterioration of symptom	161 (67.1%)	129 (53.3%)
Number of patients censored	79 (32.9%)	113 (46.7%)
No deterioration possible	8 (3.3%)	6 (2.5%)
No baseline and/or follow-up	35 (14.6%)	61 (25.2%)
Subsequent anticancer treatment	6 (2.5%)	16 (6.6%)
Death	5 (2.1%)	10 (4.1%)
No deterioration	25 (10.4%)	20 (8.3%)

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.13.1.3: EORTC QLQ-C30 - Summary of Time to First Deterioration of Social Functioning by Subgroups (MID=10) - Analysis Set mITT 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	48	27 (56.3)	0.7 [0.4, 2.0]	48	22 (45.8)	1.3 [0.4, 5.3]	1.429 [0.743, 2.749]	0.2477	0.9222
Absent	192	134 (69.8)	0.7 [0.5, 1.1]	194	107 (55.2)	0.9 [0.4, 1.1]	1.127 [0.857, 1.484]	0.3843	
Age									
< 65 years	105	66 (62.9)	2.0 [0.7, 3.9]	106	57 (53.8)	0.6 [0.4, 1.3]	0.848 [0.573, 1.255]	0.4362	0.0268
>= 65 years	135	95 (70.4)	0.6 [0.4, 0.7]	136	72 (52.9)	0.9 [0.6, 1.1]	1.465 [1.050, 2.044]	0.0215	
Region									
Europe	98	57 (58.2)	1.1 [0.4, 2.2]	102	49 (48.0)	0.6 [0.3, 1.4]	0.956 [0.620, 1.475]	0.8460	0.0867
North America	57	42 (73.7)	0.5 [0.4, 0.7]	51	29 (56.9)	0.5 [0.4, 1.1]	1.341 [0.795, 2.261]	0.2723	
Rest of World	85	62 (72.9)	0.8 [0.6, 1.1]	89	51 (57.3)	1.1 [0.6, 1.8]	1.270 [0.861, 1.873]	0.2002	
Sex									
Male	198	132 (66.7)	0.7 [0.6, 1.1]	185	97 (52.4)	0.9 [0.6, 1.3]	1.195 [0.904, 1.579]	0.1856	0.3709
Female	42	29 (69.0)	0.6 [0.4, 3.9]	57	32 (56.1)	0.6 [0.2, 1.1]	1.049 [0.568, 1.938]	0.9130	
Metastases at Baseline									
Visceral metastases	170	112 (65.9)	0.7 [0.4, 1.1]	161	78 (48.4)	1.1 [0.5, 1.8]	1.406 [1.011, 1.956]	0.0344	0.0429
Lymph node only	60	42 (70.0)	0.9 [0.4, 1.3]	67	42 (62.7)	0.6 [0.4, 0.9]	0.931 [0.557, 1.556]	0.7383	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.13.2.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Social Functioning (MID=10) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)	EV+Pembro vs. Plat+Gem
Number of patients at risk	202 (100.0%)	202 (100.0%)	
Number of patients with events	118 (58.4%)	111 (55.0%)	
Number of patients censored	84 (41.6%)	91 (45.0%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	31.6 [24.1, 39.2]	30.9 [23.6, 38.4]	
Month 6	26.4 [19.5, 33.8]	23.5 [16.4, 31.4]	
Month 9	22.4 [15.9, 29.7]	23.5 [16.4, 31.4]	
Month 12	18.5 [12.3, 25.6]	23.5 [16.4, 31.4]	
Month 18	17.4 [11.3, 24.5]	23.5 [16.4, 31.4]	
Month 24	11.6 [3.9, 24.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	0.9 [0.6, 1.3]	0.9 [0.4, 1.1]	
Cox proportional hazards model			
Stratified HR [95% CI]			1.056 [0.782, 1.427]
Log-rank test			
Two-sided stratified log-rank p-value			0.6973

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.13.2.2: EORTC QLQ-C30 - Type of Events and Censoring of Social Functioning (MID=10) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)
Number of patients at risk	202 (100.0%)	202 (100.0%)
Number of patients with events	118 (58.4%)	111 (55.0%)
Deterioration of symptom	118 (58.4%)	111 (55.0%)
Number of patients censored	84 (41.6%)	91 (45.0%)
No deterioration possible	3 (1.5%)	3 (1.5%)
No baseline and/or follow-up	48 (23.8%)	42 (20.8%)
Subsequent anticancer treatment	2 (1.0%)	7 (3.5%)
Death	9 (4.5%)	19 (9.4%)
No deterioration	22 (10.9%)	20 (9.9%)

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.13.2.3: EORTC QLQ-C30 - Summary of Time to First Deterioration of Social Functioning by Subgroups (MID=10) - Analysis Set mITT 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	33 (66.0)	0.5 [0.4, 1.5]	50	26 (52.0)	0.6 [0.4, 2.2]	1.741 [0.890, 3.408]	0.0938	0.2822
Absent	152	85 (55.9)	1.1 [0.6, 1.8]	152	85 (55.9)	0.9 [0.4, 1.3]	0.927 [0.661, 1.301]	0.6682	
Age									
< 65 years	39	19 (48.7)	4.5 [0.4, 12.8]	29	13 (44.8)	1.8 [0.4, NC]	1.045 [0.363, 3.007]	0.9295	0.7844
>= 65 years	163	99 (60.7)	0.7 [0.5, 1.3]	173	98 (56.6)	0.6 [0.4, 1.1]	1.057 [0.772, 1.447]	0.7045	
Region									
Europe	74	41 (55.4)	0.7 [0.5, 1.1]	95	52 (54.7)	0.7 [0.4, 1.8]	1.407 [0.876, 2.261]	0.1660	0.4435
North America	46	25 (54.3)	1.3 [0.2, 5.2]	34	17 (50.0)	1.1 [0.4, 3.9]	0.954 [0.459, 1.982]	0.9551	
Rest of World	82	52 (63.4)	1.1 [0.5, 2.7]	73	42 (57.5)	0.5 [0.4, 1.3]	0.851 [0.543, 1.333]	0.4964	
Sex									
Male	146	88 (60.3)	0.9 [0.5, 1.7]	151	77 (51.0)	1.3 [0.6, 2.3]	1.280 [0.907, 1.805]	0.1508	0.0109
Female	56	30 (53.6)	0.7 [0.4, 1.3]	51	34 (66.7)	0.4 [0.2, 0.6]	0.552 [0.289, 1.054]	0.0606	
Metastases at Baseline									
Visceral metastases	148	89 (60.1)	0.9 [0.5, 1.5]	157	86 (54.8)	0.7 [0.4, 1.1]	1.013 [0.702, 1.463]	0.9160	0.9432
Lymph node only	43	24 (55.8)	1.0 [0.5, 2.4]	37	19 (51.4)	1.4 [0.4, 4.5]	1.443 [0.662, 3.143]	0.3649	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.14.1.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Cognitive Functioning (MID=10) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)	EV+Pembro vs. Plat+Gem
Number of patients at risk	240 (100.0%)	242 (100.0%)	
Number of patients with events	143 (59.6%)	130 (53.7%)	
Number of patients censored	97 (40.4%)	112 (46.3%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	40.5 [33.7, 47.2]	36.3 [29.2, 43.3]	
Month 6	34.9 [28.3, 41.6]	27.8 [21.0, 35.0]	
Month 9	30.5 [24.0, 37.1]	23.2 [16.1, 31.2]	
Month 12	26.8 [20.4, 33.7]	17.6 [9.6, 27.6]	
Month 18	23.6 [16.7, 31.2]	17.6 [9.6, 27.6]	
Month 24	23.6 [16.7, 31.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	1.8 [1.1, 2.3]	0.9 [0.6, 1.5]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.854 [0.657, 1.110]
Log-rank test			
Two-sided stratified log-rank p-value			0.2470

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.14.1.2: EORTC QLQ-C30 - Type of Events and Censoring of Cognitive Functioning (MID=10) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)
Number of patients at risk	240 (100.0%)	242 (100.0%)
Number of patients with events	143 (59.6%)	130 (53.7%)
Deterioration of symptom	143 (59.6%)	130 (53.7%)
Number of patients censored	97 (40.4%)	112 (46.3%)
No deterioration possible	3 (1.3%)	0
No baseline and/or follow-up	35 (14.6%)	61 (25.2%)
Subsequent anticancer treatment	8 (3.3%)	15 (6.2%)
Death	13 (5.4%)	13 (5.4%)
No deterioration	38 (15.8%)	23 (9.5%)

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.14.1.3: EORTC QLQ-C30 - Summary of Time to First Deterioration of Cognitive Functioning by Subgroups (MID=10) - Analysis Set mITT 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	48	25 (52.1)	1.3 [0.4, 5.3]	48	23 (47.9)	0.7 [0.4, 5.3]	0.752 [0.388, 1.458]	0.4180	0.9518
Absent	192	118 (61.5)	1.8 [1.1, 2.7]	194	107 (55.2)	1.1 [0.6, 1.8]	0.874 [0.657, 1.164]	0.3626	
Age									
< 65 years	105	58 (55.2)	2.4 [1.3, 5.9]	106	58 (54.7)	0.7 [0.4, 1.8]	0.709 [0.473, 1.063]	0.1063	0.0758
>= 65 years	135	85 (63.0)	1.1 [0.6, 2.0]	136	72 (52.9)	1.1 [0.7, 2.2]	0.978 [0.692, 1.381]	0.8812	
Region									
Europe	98	54 (55.1)	1.9 [0.7, 5.2]	102	51 (50.0)	0.7 [0.4, 1.8]	0.696 [0.456, 1.062]	0.0993	0.0144
North America	57	31 (54.4)	2.6 [1.1, 8.0]	51	33 (64.7)	0.7 [0.4, 1.1]	0.501 [0.283, 0.886]	0.0172	
Rest of World	85	58 (68.2)	1.1 [0.4, 2.0]	89	46 (51.7)	2.3 [0.8, 5.9]	1.378 [0.909, 2.090]	0.1344	
Sex									
Male	198	117 (59.1)	2.0 [1.1, 2.7]	185	100 (54.1)	0.9 [0.6, 1.8]	0.834 [0.629, 1.106]	0.2249	0.5804
Female	42	26 (61.9)	0.9 [0.4, 7.4]	57	30 (52.6)	1.3 [0.6, 3.1]	0.987 [0.491, 1.983]	0.9306	
Metastases at Baseline									
Visceral metastases	170	98 (57.6)	1.9 [1.0, 3.9]	161	85 (52.8)	0.9 [0.6, 1.8]	0.910 [0.650, 1.274]	0.5967	0.7510
Lymph node only	60	39 (65.0)	1.5 [0.6, 3.2]	67	37 (55.2)	1.1 [0.4, 2.3]	0.651 [0.385, 1.101]	0.1086	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.14.2.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Cognitive Functioning (MID=10) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)	EV+Pembro vs. Plat+Gem
Number of patients at risk	202 (100.0%)	202 (100.0%)	
Number of patients with events	112 (55.4%)	114 (56.4%)	
Number of patients censored	90 (44.6%)	88 (43.6%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	36.5 [28.8, 44.3]	31.8 [24.6, 39.3]	
Month 6	30.1 [22.7, 37.8]	27.1 [20.0, 34.7]	
Month 9	26.4 [19.3, 34.1]	23.0 [15.8, 31.0]	
Month 12	23.8 [16.7, 31.7]	23.0 [15.8, 31.0]	
Month 18	18.4 [11.2, 27.1]	17.2 [7.8, 29.8]	
Month 24	15.8 [8.5, 25.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	1.5 [1.1, 1.8]	0.9 [0.6, 1.5]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.802 [0.596, 1.080]
Log-rank test			
Two-sided stratified log-rank p-value			0.1507

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.14.2.2: EORTC QLQ-C30 - Type of Events and Censoring of Cognitive Functioning (MID=10) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)
Number of patients at risk	202 (100.0%)	202 (100.0%)
Number of patients with events	112 (55.4%)	114 (56.4%)
Deterioration of symptom	112 (55.4%)	114 (56.4%)
Number of patients censored	90 (44.6%)	88 (43.6%)
No deterioration possible	0	0
No baseline and/or follow-up	48 (23.8%)	42 (20.8%)
Subsequent anticancer treatment	7 (3.5%)	8 (4.0%)
Death	15 (7.4%)	17 (8.4%)
No deterioration	20 (9.9%)	21 (10.4%)

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.14.2.3: EORTC QLQ-C30 - Summary of Time to First Deterioration of Cognitive Functioning by Subgroups (MID=10) - Analysis Set mITT 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	24 (48.0)	1.3 [0.6, 12.8]	50	25 (50.0)	0.6 [0.4, 7.3]	0.835 [0.418, 1.668]	0.6170	0.9812
Absent	152	88 (57.9)	1.5 [1.1, 2.3]	152	89 (58.6)	1.1 [0.6, 1.5]	0.795 [0.572, 1.106]	0.1759	
Age									
< 65 years	39	21 (53.8)	2.4 [0.9, 8.0]	29	15 (51.7)	1.7 [0.4, NC]	0.698 [0.252, 1.937]	0.4903	0.9279
>= 65 years	163	91 (55.8)	1.3 [0.9, 1.7]	173	99 (57.2)	0.9 [0.6, 1.3]	0.813 [0.595, 1.109]	0.1963	
Region									
Europe	74	40 (54.1)	1.1 [0.6, 2.0]	95	49 (51.6)	1.1 [0.7, 3.1]	1.232 [0.770, 1.970]	0.3789	0.0658
North America	46	16 (34.8)	1.5 [0.6, NC]	34	18 (52.9)	0.9 [0.4, 2.5]	0.600 [0.281, 1.281]	0.1730	
Rest of World	82	56 (68.3)	1.6 [1.1, 2.7]	73	47 (64.4)	0.6 [0.4, 1.3]	0.623 [0.405, 0.958]	0.0313	
Sex									
Male	146	84 (57.5)	1.5 [1.1, 2.6]	151	82 (54.3)	1.1 [0.6, 2.1]	0.918 [0.653, 1.292]	0.6354	0.1128
Female	56	28 (50.0)	1.5 [0.7, 2.1]	51	32 (62.7)	0.8 [0.4, 1.3]	0.524 [0.282, 0.972]	0.0374	
Metastases at Baseline									
Visceral metastases	148	81 (54.7)	1.3 [0.9, 1.8]	157	86 (54.8)	0.9 [0.6, 1.3]	0.730 [0.503, 1.059]	0.1007	0.8732
Lymph node only	43	26 (60.5)	1.6 [0.9, 2.7]	37	22 (59.5)	1.8 [0.6, 3.1]	1.224 [0.587, 2.553]	0.5670	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.15.1.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Fatigue (MID=10) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)	EV+Pembro vs. Plat+Gem
Number of patients at risk	240 (100.0%)	242 (100.0%)	
Number of patients with events	169 (70.4%)	157 (64.9%)	
Number of patients censored	71 (29.6%)	85 (35.1%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	26.3 [20.3, 32.5]	16.5 [11.4, 22.4]	
Month 6	23.4 [17.7, 29.6]	10.8 [6.5, 16.5]	
Month 9	17.6 [12.5, 23.5]	9.6 [5.4, 15.3]	
Month 12	12.0 [7.3, 18.0]	7.2 [3.0, 14.0]	
Month 18	7.0 [2.7, 14.0]	NC [NC, NC]	
Month 24	7.0 [2.7, 14.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	0.4 [0.4, 0.6]	0.4 [0.4, 0.6]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.796 [0.624, 1.016]
Log-rank test			
Two-sided stratified log-rank p-value			0.0788

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.15.1.2: EORTC QLQ-C30 - Type of Events and Censoring of Fatigue (MID=10) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)
Number of patients at risk	240 (100.0%)	242 (100.0%)
Number of patients with events	169 (70.4%)	157 (64.9%)
Deterioration of symptom	169 (70.4%)	157 (64.9%)
Number of patients censored	71 (29.6%)	85 (35.1%)
No deterioration possible	6 (2.5%)	2 (0.8%)
No baseline and/or follow-up	35 (14.6%)	61 (25.2%)
Subsequent anticancer treatment	6 (2.5%)	6 (2.5%)
Death	6 (2.5%)	6 (2.5%)
No deterioration	18 (7.5%)	10 (4.1%)

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.15.1.3: EORTC QLQ-C30 - Summary of Time to First Deterioration of Fatigue by Subgroups (MID=10) - Analysis Set mITT 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	48	30 (62.5)	0.4 [0.2, 0.7]	48	26 (54.2)	0.4 [0.3, 1.3]	0.985 [0.505, 1.924]	0.9663	0.2452
Absent	192	139 (72.4)	0.5 [0.4, 0.6]	194	131 (67.5)	0.4 [0.4, 0.6]	0.771 [0.594, 1.001]	0.0571	
Age									
< 65 years	105	71 (67.6)	0.6 [0.4, 1.6]	106	71 (67.0)	0.4 [0.2, 0.6]	0.560 [0.383, 0.818]	0.0028	0.0430
>= 65 years	135	98 (72.6)	0.4 [0.4, 0.5]	136	86 (63.2)	0.4 [0.4, 0.6]	1.023 [0.744, 1.405]	0.7999	
Region									
Europe	98	65 (66.3)	0.4 [0.2, 0.7]	102	61 (59.8)	0.3 [0.2, 0.4]	0.789 [0.528, 1.178]	0.2714	0.3400
North America	57	40 (70.2)	0.4 [0.2, 0.7]	51	38 (74.5)	0.4 [0.2, 0.4]	0.737 [0.447, 1.215]	0.2853	
Rest of World	85	64 (75.3)	0.6 [0.4, 1.1]	89	58 (65.2)	0.7 [0.4, 1.0]	0.842 [0.571, 1.241]	0.3588	
Sex									
Male	198	136 (68.7)	0.4 [0.4, 0.6]	185	119 (64.3)	0.4 [0.4, 0.6]	0.884 [0.678, 1.152]	0.4031	0.2471
Female	42	33 (78.6)	0.5 [0.2, 1.8]	57	38 (66.7)	0.2 [0.2, 0.4]	0.436 [0.226, 0.842]	0.0107	
Metastases at Baseline									
Visceral metastases	170	115 (67.6)	0.4 [0.4, 0.7]	161	104 (64.6)	0.4 [0.4, 0.6]	0.884 [0.643, 1.216]	0.4616	0.9826
Lymph node only	60	47 (78.3)	0.4 [0.2, 0.7]	67	45 (67.2)	0.4 [0.2, 0.6]	0.680 [0.420, 1.101]	0.1297	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.15.2.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Fatigue (MID=10) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)	EV+Pembro vs. Plat+Gem
Number of patients at risk	202 (100.0%)	202 (100.0%)	
Number of patients with events	130 (64.4%)	131 (64.9%)	
Number of patients censored	72 (35.6%)	71 (35.1%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	21.3 [15.1, 28.3]	17.7 [12.0, 24.4]	
Month 6	19.0 [13.0, 25.8]	13.8 [8.5, 20.3]	
Month 9	12.6 [7.6, 19.0]	9.6 [4.4, 17.2]	
Month 12	10.4 [5.7, 16.7]	9.6 [4.4, 17.2]	
Month 18	9.2 [4.8, 15.5]	9.6 [4.4, 17.2]	
Month 24	NC [NC, NC]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	0.6 [0.4, 0.8]	0.4 [0.4, 0.6]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.777 [0.587, 1.028]
Log-rank test			
Two-sided stratified log-rank p-value			0.0740

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.15.2.2: EORTC QLQ-C30 - Type of Events and Censoring of Fatigue (MID=10) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)
Number of patients at risk	202 (100.0%)	202 (100.0%)
Number of patients with events	130 (64.4%)	131 (64.9%)
Deterioration of symptom	130 (64.4%)	131 (64.9%)
Number of patients censored	72 (35.6%)	71 (35.1%)
No deterioration possible	1 (0.5%)	3 (1.5%)
No baseline and/or follow-up	48 (23.8%)	42 (20.8%)
Subsequent anticancer treatment	3 (1.5%)	8 (4.0%)
Death	8 (4.0%)	12 (5.9%)
No deterioration	12 (5.9%)	6 (3.0%)

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.15.2.3: EORTC QLQ-C30 - Summary of Time to First Deterioration of Fatigue by Subgroups (MID=10) - Analysis Set mITT 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	31 (62.0)	0.4 [0.2, 0.9]	50	28 (56.0)	0.6 [0.2, 1.8]	1.189 [0.630, 2.247]	0.6112	0.2098
Absent	152	99 (65.1)	0.6 [0.4, 1.1]	152	103 (67.8)	0.4 [0.4, 0.6]	0.701 [0.513, 0.959]	0.0249	
Age									
< 65 years	39	23 (59.0)	0.4 [0.2, 2.7]	29	17 (58.6)	0.4 [0.2, 2.0]	0.614 [0.239, 1.576]	0.2710	0.7798
>= 65 years	163	107 (65.6)	0.6 [0.4, 0.9]	173	114 (65.9)	0.4 [0.4, 0.6]	0.795 [0.593, 1.065]	0.1238	
Region									
Europe	74	45 (60.8)	0.6 [0.4, 0.9]	95	64 (67.4)	0.4 [0.2, 0.6]	0.723 [0.456, 1.148]	0.1931	0.8183
North America	46	26 (56.5)	0.4 [0.2, 1.3]	34	18 (52.9)	0.4 [0.4, 0.9]	0.865 [0.446, 1.676]	0.6563	
Rest of World	82	59 (72.0)	0.4 [0.4, 1.1]	73	49 (67.1)	0.4 [0.2, 0.9]	0.789 [0.519, 1.200]	0.2322	
Sex									
Male	146	100 (68.5)	0.5 [0.4, 0.7]	151	96 (63.6)	0.4 [0.4, 0.6]	0.979 [0.721, 1.330]	0.8984	0.0272
Female	56	30 (53.6)	0.7 [0.4, 2.2]	51	35 (68.6)	0.4 [0.2, 0.6]	0.205 [0.087, 0.480]	<.0001	
Metastases at Baseline									
Visceral metastases	148	94 (63.5)	0.6 [0.4, 1.1]	157	98 (62.4)	0.4 [0.4, 0.6]	0.847 [0.601, 1.192]	0.3331	0.9100
Lymph node only	43	29 (67.4)	0.6 [0.2, 1.1]	37	25 (67.6)	0.4 [0.2, 0.7]	1.009 [0.506, 2.013]	0.9951	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.16.1.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Pain (MID=10) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)	EV+Pembro vs. Plat+Gem
Number of patients at risk	240 (100.0%)	242 (100.0%)	
Number of patients with events	147 (61.3%)	130 (53.7%)	
Number of patients censored	93 (38.8%)	112 (46.3%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	35.7 [29.0, 42.4]	33.6 [26.6, 40.7]	
Month 6	30.9 [24.5, 37.6]	26.1 [19.4, 33.3]	
Month 9	24.8 [18.7, 31.4]	20.6 [13.7, 28.4]	
Month 12	21.3 [15.3, 28.0]	14.1 [6.6, 24.4]	
Month 18	19.8 [13.7, 26.7]	14.1 [6.6, 24.4]	
Month 24	19.8 [13.7, 26.7]	14.1 [6.6, 24.4]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	0.7 [0.5, 1.3]	1.1 [0.6, 1.4]	
Cox proportional hazards model			
Stratified HR [95% CI]			1.024 [0.790, 1.328]
Log-rank test			
Two-sided stratified log-rank p-value			0.8870

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.16.1.2: EORTC QLQ-C30 - Type of Events and Censoring of Pain (MID=10) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)
Number of patients at risk	240 (100.0%)	242 (100.0%)
Number of patients with events	147 (61.3%)	130 (53.7%)
Deterioration of symptom	147 (61.3%)	130 (53.7%)
Number of patients censored	93 (38.8%)	112 (46.3%)
No deterioration possible	9 (3.8%)	6 (2.5%)
No baseline and/or follow-up	35 (14.6%)	61 (25.2%)
Subsequent anticancer treatment	3 (1.3%)	12 (5.0%)
Death	13 (5.4%)	15 (6.2%)
No deterioration	33 (13.8%)	18 (7.4%)

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.16.1.3: EORTC QLQ-C30 - Summary of Time to First Deterioration of Pain by Subgroups (MID=10) - Analysis Set mITT 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	48	24 (50.0)	0.6 [0.4, 1.7]	48	22 (45.8)	1.3 [0.4, 3.1]	1.126 [0.539, 2.351]	0.7521	0.9906
Absent	192	123 (64.1)	0.7 [0.5, 1.3]	194	108 (55.7)	1.1 [0.6, 1.6]	1.010 [0.765, 1.334]	0.9747	
Age									
< 65 years	105	57 (54.3)	1.6 [0.6, 7.3]	106	57 (53.8)	0.9 [0.4, 1.7]	0.803 [0.532, 1.211]	0.2950	0.0819
>= 65 years	135	90 (66.7)	0.6 [0.4, 0.9]	136	73 (53.7)	1.1 [0.6, 1.5]	1.205 [0.860, 1.688]	0.2966	
Region									
Europe	98	58 (59.2)	0.9 [0.6, 3.2]	102	48 (47.1)	1.1 [0.4, 1.8]	0.835 [0.539, 1.295]	0.4372	0.7728
North America	57	35 (61.4)	0.5 [0.4, 1.6]	51	30 (58.8)	0.7 [0.4, 1.4]	1.198 [0.703, 2.041]	0.5636	
Rest of World	85	54 (63.5)	0.5 [0.4, 1.3]	89	52 (58.4)	1.2 [0.6, 1.8]	1.111 [0.742, 1.665]	0.6176	
Sex									
Male	198	122 (61.6)	0.7 [0.5, 1.3]	185	98 (53.0)	0.9 [0.6, 1.4]	1.042 [0.783, 1.387]	0.7922	0.6840
Female	42	25 (59.5)	0.6 [0.4, 7.3]	57	32 (56.1)	1.4 [0.4, 1.8]	0.942 [0.503, 1.764]	0.8168	
Metastases at Baseline									
Visceral metastases	170	98 (57.6)	0.6 [0.5, 1.3]	161	86 (53.4)	1.1 [0.7, 1.6]	1.064 [0.761, 1.487]	0.7165	0.8756
Lymph node only	60	42 (70.0)	0.7 [0.4, 2.5]	67	38 (56.7)	0.7 [0.4, 1.7]	1.136 [0.680, 1.899]	0.6345	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.16.2.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Pain (MID=10) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)	EV+Pembro vs. Plat+Gem
Number of patients at risk	202 (100.0%)	202 (100.0%)	
Number of patients with events	106 (52.5%)	118 (58.4%)	
Number of patients censored	96 (47.5%)	84 (41.6%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	35.5 [27.8, 43.2]	28.3 [21.1, 35.8]	
Month 6	28.7 [21.5, 36.3]	17.7 [11.2, 25.4]	
Month 9	26.7 [19.6, 34.4]	13.9 [7.6, 22.1]	
Month 12	25.2 [18.0, 33.0]	11.1 [5.0, 20.1]	
Month 18	25.2 [18.0, 33.0]	NC [NC, NC]	
Month 24	25.2 [18.0, 33.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	1.1 [0.7, 1.8]	0.9 [0.5, 1.3]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.781 [0.580, 1.052]
Log-rank test			
Two-sided stratified log-rank p-value			0.1000

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.16.2.2: EORTC QLQ-C30 - Type of Events and Censoring of Pain (MID=10) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)
Number of patients at risk	202 (100.0%)	202 (100.0%)
Number of patients with events	106 (52.5%)	118 (58.4%)
Deterioration of symptom	106 (52.5%)	118 (58.4%)
Number of patients censored	96 (47.5%)	84 (41.6%)
No deterioration possible	6 (3.0%)	7 (3.5%)
No baseline and/or follow-up	48 (23.8%)	42 (20.8%)
Subsequent anticancer treatment	5 (2.5%)	8 (4.0%)
Death	8 (4.0%)	15 (7.4%)
No deterioration	29 (14.4%)	12 (5.9%)

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.16.2.3: EORTC QLQ-C30 - Summary of Time to First Deterioration of Pain by Subgroups (MID=10) - Analysis Set mITT 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	25 (50.0)	1.6 [0.4, 3.8]	50	20 (40.0)	1.8 [0.5, NC]	1.089 [0.531, 2.235]	0.8517	0.1286
Absent	152	81 (53.3)	0.9 [0.6, 1.8]	152	98 (64.5)	0.6 [0.4, 1.1]	0.729 [0.525, 1.012]	0.0579	
Age									
< 65 years	39	20 (51.3)	1.3 [0.4, 8.7]	29	16 (55.2)	2.7 [0.4, 4.6]	0.846 [0.354, 2.021]	0.6934	0.6920
>= 65 years	163	86 (52.8)	1.1 [0.7, 1.8]	173	102 (59.0)	0.8 [0.4, 1.1]	0.773 [0.563, 1.061]	0.1081	
Region									
Europe	74	36 (48.6)	0.9 [0.5, 2.2]	95	56 (58.9)	0.8 [0.4, 1.5]	0.778 [0.482, 1.257]	0.2974	0.7672
North America	46	23 (50.0)	0.9 [0.4, 3.8]	34	17 (50.0)	1.1 [0.7, 2.7]	0.689 [0.329, 1.446]	0.3175	
Rest of World	82	47 (57.3)	1.3 [0.4, 3.1]	73	45 (61.6)	0.4 [0.4, 1.8]	0.819 [0.526, 1.276]	0.3785	
Sex									
Male	146	78 (53.4)	1.1 [0.7, 2.4]	151	87 (57.6)	1.1 [0.5, 1.5]	0.809 [0.579, 1.131]	0.2014	0.8364
Female	56	28 (50.0)	0.9 [0.4, 2.2]	51	31 (60.8)	0.6 [0.2, 1.8]	0.685 [0.356, 1.318]	0.2670	
Metastases at Baseline									
Visceral metastases	148	82 (55.4)	0.8 [0.4, 1.6]	157	89 (56.7)	1.1 [0.5, 1.5]	1.068 [0.739, 1.543]	0.7573	0.0855
Lymph node only	43	20 (46.5)	2.0 [1.1, NC]	37	22 (59.5)	0.7 [0.4, 2.7]	0.537 [0.247, 1.166]	0.1180	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.17.1.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Nausea and Vomiting (MID=10) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)	EV+Pembro vs. Plat+Gem
Number of patients at risk	240 (100.0%)	242 (100.0%)	
Number of patients with events	131 (54.6%)	142 (58.7%)	
Number of patients censored	109 (45.4%)	100 (41.3%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	47.6 [40.6, 54.2]	24.7 [18.6, 31.3]	
Month 6	40.0 [33.2, 46.8]	20.9 [15.1, 27.2]	
Month 9	37.0 [30.2, 43.7]	19.5 [13.6, 26.1]	
Month 12	37.0 [30.2, 43.7]	19.5 [13.6, 26.1]	
Month 18	33.2 [25.9, 40.6]	19.5 [13.6, 26.1]	
Month 24	27.5 [18.4, 37.3]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	2.0 [1.1, 4.6]	0.4 [0.4, 0.8]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.550 [0.422, 0.716]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.17.1.2: EORTC QLQ-C30 - Type of Events and Censoring of Nausea and Vomiting (MID=10) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)
Number of patients at risk	240 (100.0%)	242 (100.0%)
Number of patients with events	131 (54.6%)	142 (58.7%)
Deterioration of symptom	131 (54.6%)	142 (58.7%)
Number of patients censored	109 (45.4%)	100 (41.3%)
No deterioration possible	0	0
No baseline and/or follow-up	35 (14.6%)	61 (25.2%)
Subsequent anticancer treatment	8 (3.3%)	9 (3.7%)
Death	14 (5.8%)	9 (3.7%)
No deterioration	52 (21.7%)	21 (8.7%)

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.17.1.3: EORTC QLQ-C30 - Summary of Time to First Deterioration of Nausea and Vomiting by Subgroups (MID=10) - Analysis Set mITT 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	48	27 (56.3)	1.1 [0.4, 3.2]	48	20 (41.7)	1.1 [0.4, NC]	0.892 [0.452, 1.759]	0.7156	0.0100
Absent	192	104 (54.2)	3.1 [1.3, 5.9]	194	122 (62.9)	0.4 [0.3, 0.6]	0.505 [0.380, 0.673]	<.0001	
Age									
< 65 years	105	56 (53.3)	3.8 [1.3, 8.6]	106	64 (60.4)	0.4 [0.2, 0.7]	0.510 [0.340, 0.763]	0.0010	0.2705
>= 65 years	135	75 (55.6)	1.5 [0.6, 4.5]	136	78 (57.4)	0.6 [0.4, 1.1]	0.583 [0.411, 0.827]	0.0022	
Region									
Europe	98	47 (48.0)	3.8 [1.1, 13.5]	102	56 (54.9)	0.4 [0.2, 1.1]	0.458 [0.292, 0.718]	0.0007	0.2115
North America	57	32 (56.1)	1.3 [0.6, 7.3]	51	34 (66.7)	0.4 [0.2, 0.9]	0.571 [0.334, 0.978]	0.0342	
Rest of World	85	52 (61.2)	1.7 [0.6, 5.3]	89	52 (58.4)	0.6 [0.4, 2.0]	0.629 [0.417, 0.948]	0.0267	
Sex									
Male	198	104 (52.5)	3.1 [1.3, 5.9]	185	106 (57.3)	0.6 [0.4, 0.9]	0.553 [0.414, 0.739]	<.0001	0.6811
Female	42	27 (64.3)	0.6 [0.4, 2.0]	57	36 (63.2)	0.4 [0.2, 0.9]	0.534 [0.281, 1.014]	0.0502	
Metastases at Baseline									
Visceral metastases	170	96 (56.5)	1.7 [0.8, 4.5]	161	92 (57.1)	0.6 [0.4, 0.9]	0.636 [0.457, 0.884]	0.0059	0.1075
Lymph node only	60	31 (51.7)	2.0 [1.1, NC]	67	42 (62.7)	0.4 [0.2, 0.9]	0.485 [0.280, 0.837]	0.0076	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.17.2.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Nausea and Vomiting (MID=10) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)	EV+Pembro vs. Plat+Gem
Number of patients at risk	202 (100.0%)	202 (100.0%)	
Number of patients with events	102 (50.5%)	118 (58.4%)	
Number of patients censored	100 (49.5%)	84 (41.6%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	41.3 [33.3, 49.1]	33.0 [25.7, 40.5]	
Month 6	35.3 [27.6, 43.1]	26.5 [19.5, 34.1]	
Month 9	35.3 [27.6, 43.1]	24.1 [17.0, 31.8]	
Month 12	28.4 [20.6, 36.6]	19.7 [12.3, 28.5]	
Month 18	27.0 [19.3, 35.3]	15.8 [7.7, 26.5]	
Month 24	27.0 [19.3, 35.3]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	1.8 [1.1, 2.7]	0.9 [0.4, 1.5]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.708 [0.525, 0.955]
Log-rank test			
Two-sided stratified log-rank p-value			0.0276

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.17.2.2: EORTC QLQ-C30 - Type of Events and Censoring of Nausea and Vomiting (MID=10) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)
Number of patients at risk	202 (100.0%)	202 (100.0%)
Number of patients with events	102 (50.5%)	118 (58.4%)
Deterioration of symptom	102 (50.5%)	118 (58.4%)
Number of patients censored	100 (49.5%)	84 (41.6%)
No deterioration possible	2 (1.0%)	0
No baseline and/or follow-up	48 (23.8%)	42 (20.8%)
Subsequent anticancer treatment	5 (2.5%)	9 (4.5%)
Death	12 (5.9%)	20 (9.9%)
No deterioration	33 (16.3%)	13 (6.4%)

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.17.2.3: EORTC QLQ-C30 - Summary of Time to First Deterioration of Nausea and Vomiting by Subgroups (MID=10) - Analysis Set mITT 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	24 (48.0)	1.8 [0.7, 4.5]	50	21 (42.0)	1.8 [0.7, NC]	1.274 [0.644, 2.522]	0.4396	0.0780
Absent	152	78 (51.3)	1.8 [1.0, 3.1]	152	97 (63.8)	0.6 [0.4, 1.3]	0.615 [0.439, 0.860]	0.0047	
Age									
< 65 years	39	22 (56.4)	1.1 [0.4, 9.4]	29	15 (51.7)	1.4 [0.4, 3.2]	0.780 [0.250, 2.429]	0.6806	0.3516
>= 65 years	163	80 (49.1)	1.8 [1.3, 2.9]	173	103 (59.5)	0.9 [0.4, 1.3]	0.703 [0.516, 0.959]	0.0298	
Region									
Europe	74	35 (47.3)	2.0 [0.9, 5.3]	95	58 (61.1)	0.6 [0.4, 1.5]	0.651 [0.405, 1.047]	0.0821	0.1095
North America	46	20 (43.5)	2.0 [0.4, 2.9]	34	14 (41.2)	2.2 [1.1, NC]	1.290 [0.639, 2.606]	0.4622	
Rest of World	82	47 (57.3)	1.7 [0.7, 5.9]	73	46 (63.0)	0.7 [0.4, 1.5]	0.588 [0.369, 0.939]	0.0269	
Sex									
Male	146	77 (52.7)	1.8 [1.1, 3.1]	151	88 (58.3)	1.1 [0.4, 2.2]	0.713 [0.508, 1.000]	0.0589	0.3660
Female	56	25 (44.6)	1.8 [0.6, 10.8]	51	30 (58.8)	0.6 [0.4, 1.3]	0.694 [0.368, 1.309]	0.2548	
Metastases at Baseline									
Visceral metastases	148	76 (51.4)	1.3 [0.8, 2.9]	157	87 (55.4)	0.9 [0.4, 1.7]	0.783 [0.545, 1.123]	0.2027	0.1331
Lymph node only	43	22 (51.2)	2.2 [1.1, 11.5]	37	26 (70.3)	0.6 [0.4, 1.3]	0.561 [0.278, 1.134]	0.1046	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.18.1.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Shortness of Breath (MID=10) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)	EV+Pembro vs. Plat+Gem
Number of patients at risk	240 (100.0%)	242 (100.0%)	
Number of patients with events	134 (55.8%)	108 (44.6%)	
Number of patients censored	106 (44.2%)	134 (55.4%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	46.8 [39.8, 53.5]	45.8 [38.1, 53.2]	
Month 6	39.1 [32.2, 45.8]	36.3 [28.7, 44.0]	
Month 9	35.8 [29.1, 42.6]	33.9 [26.2, 41.8]	
Month 12	31.6 [24.8, 38.6]	31.1 [22.4, 40.2]	
Month 18	29.3 [22.3, 36.5]	20.7 [6.7, 40.0]	
Month 24	29.3 [22.3, 36.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	2.4 [1.6, 4.6]	2.0 [1.7, 3.9]	
Cox proportional hazards model			
Stratified HR [95% CI]			1.033 [0.782, 1.363]
Log-rank test			
Two-sided stratified log-rank p-value			0.7954

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.18.1.2: EORTC QLQ-C30 - Type of Events and Censoring of Shortness of Breath (MID=10) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)
Number of patients at risk	240 (100.0%)	242 (100.0%)
Number of patients with events	134 (55.8%)	108 (44.6%)
Deterioration of symptom	134 (55.8%)	108 (44.6%)
Number of patients censored	106 (44.2%)	134 (55.4%)
No deterioration possible	1 (0.4%)	3 (1.2%)
No baseline and/or follow-up	35 (14.6%)	61 (25.2%)
Subsequent anticancer treatment	11 (4.6%)	20 (8.3%)
Death	10 (4.2%)	21 (8.7%)
No deterioration	49 (20.4%)	29 (12.0%)

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.18.1.3: EORTC QLQ-C30 - Summary of Time to First Deterioration of Shortness of Breath by Subgroups (MID=10) - Analysis Set mITT 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	48	23 (47.9)	1.0 [0.4, NC]	48	19 (39.6)	2.4 [1.1, NC]	1.908 [0.950, 3.834]	0.0629	0.4395
Absent	192	111 (57.8)	2.7 [1.6, 5.2]	194	89 (45.9)	2.0 [1.6, 4.0]	0.917 [0.678, 1.240]	0.5922	
Age									
< 65 years	105	59 (56.2)	3.8 [1.6, 8.0]	106	45 (42.5)	3.1 [1.8, NC]	1.197 [0.771, 1.856]	0.4112	0.4740
>= 65 years	135	75 (55.6)	2.0 [1.1, 4.5]	136	63 (46.3)	1.8 [1.1, 4.5]	0.935 [0.654, 1.337]	0.7326	
Region									
Europe	98	49 (50.0)	3.8 [2.0, 8.6]	102	45 (44.1)	1.5 [0.9, 2.0]	0.686 [0.432, 1.089]	0.1126	0.0281
North America	57	28 (49.1)	1.8 [0.7, NC]	51	21 (41.2)	3.9 [1.8, 17.6]	1.357 [0.732, 2.515]	0.3237	
Rest of World	85	57 (67.1)	1.7 [0.7, 4.6]	89	42 (47.2)	2.8 [1.4, 11.4]	1.261 [0.830, 1.916]	0.2657	
Sex									
Male	198	114 (57.6)	2.7 [1.6, 4.6]	185	82 (44.3)	2.4 [1.5, 4.5]	1.038 [0.765, 1.407]	0.7917	0.6117
Female	42	20 (47.6)	1.6 [0.6, NC]	57	26 (45.6)	2.0 [1.4, 5.3]	1.008 [0.514, 1.978]	0.9634	
Metastases at Baseline									
Visceral metastases	170	96 (56.5)	2.0 [1.1, 5.2]	161	70 (43.5)	2.4 [1.8, 4.6]	1.273 [0.891, 1.819]	0.1792	0.1968
Lymph node only	60	33 (55.0)	2.7 [1.8, 10.1]	67	31 (46.3)	1.8 [0.9, 5.9]	0.831 [0.466, 1.480]	0.5545	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.18.2.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Shortness of Breath (MID=10) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)	EV+Pembro vs. Plat+Gem
Number of patients at risk	202 (100.0%)	202 (100.0%)	
Number of patients with events	101 (50.0%)	104 (51.5%)	
Number of patients censored	101 (50.0%)	98 (48.5%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	41.9 [33.8, 49.8]	38.2 [30.3, 46.0]	
Month 6	37.0 [29.0, 45.0]	30.1 [22.3, 38.4]	
Month 9	30.6 [22.9, 38.6]	27.8 [19.6, 36.7]	
Month 12	28.5 [20.8, 36.5]	19.9 [11.2, 30.5]	
Month 18	24.5 [16.5, 33.3]	19.9 [11.2, 30.5]	
Month 24	24.5 [16.5, 33.3]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	2.0 [1.3, 2.7]	1.5 [1.1, 2.2]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.858 [0.627, 1.175]
Log-rank test			
Two-sided stratified log-rank p-value			0.3512

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.18.2.2: EORTC QLQ-C30 - Type of Events and Censoring of Shortness of Breath (MID=10) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)
Number of patients at risk	202 (100.0%)	202 (100.0%)
Number of patients with events	101 (50.0%)	104 (51.5%)
Deterioration of symptom	101 (50.0%)	104 (51.5%)
Number of patients censored	101 (50.0%)	98 (48.5%)
No deterioration possible	4 (2.0%)	3 (1.5%)
No baseline and/or follow-up	48 (23.8%)	42 (20.8%)
Subsequent anticancer treatment	4 (2.0%)	9 (4.5%)
Death	11 (5.4%)	25 (12.4%)
No deterioration	34 (16.8%)	19 (9.4%)

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.18.2.3: EORTC QLQ-C30 - Summary of Time to First Deterioration of Shortness of Breath by Subgroups (MID=10) - Analysis Set mITT 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	29 (58.0)	0.9 [0.5, 1.8]	50	23 (46.0)	1.8 [0.9, NC]	1.750 [0.870, 3.523]	0.1129	0.0102
Absent	152	72 (47.4)	2.3 [1.5, 6.6]	152	81 (53.3)	1.3 [0.9, 2.7]	0.716 [0.503, 1.019]	0.0653	
Age									
< 65 years	39	26 (66.7)	2.0 [0.6, 5.2]	29	14 (48.3)	4.5 [1.1, 10.1]	2.458 [0.881, 6.854]	0.0790	0.0808
>= 65 years	163	75 (46.0)	2.0 [1.5, 4.6]	173	90 (52.0)	1.3 [0.9, 1.8]	0.756 [0.541, 1.057]	0.1049	
Region									
Europe	74	33 (44.6)	2.0 [1.1, 6.0]	95	43 (45.3)	1.5 [0.9, 3.1]	1.056 [0.633, 1.762]	0.8098	0.4057
North America	46	17 (37.0)	1.8 [0.7, NC]	34	20 (58.8)	1.1 [0.4, 2.7]	0.567 [0.264, 1.219]	0.1391	
Rest of World	82	51 (62.2)	2.0 [1.1, 5.2]	73	41 (56.2)	1.8 [0.9, 3.8]	0.846 [0.534, 1.339]	0.4857	
Sex									
Male	146	80 (54.8)	1.8 [1.3, 2.5]	151	79 (52.3)	1.8 [1.1, 2.7]	0.909 [0.640, 1.289]	0.6044	0.1031
Female	56	21 (37.5)	2.0 [0.9, NC]	51	25 (49.0)	0.9 [0.4, 2.7]	0.674 [0.327, 1.388]	0.2891	
Metastases at Baseline									
Visceral metastases	148	77 (52.0)	1.3 [0.9, 2.4]	157	77 (49.0)	1.7 [1.1, 3.1]	1.153 [0.788, 1.688]	0.4743	0.1006
Lymph node only	43	19 (44.2)	6.0 [2.0, NC]	37	20 (54.1)	1.5 [0.6, 2.8]	0.546 [0.238, 1.249]	0.1476	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.19.1.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Loss of Appetite (MID=10) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)	EV+Pembro vs. Plat+Gem
Number of patients at risk	240 (100.0%)	242 (100.0%)	
Number of patients with events	141 (58.8%)	130 (53.7%)	
Number of patients censored	99 (41.3%)	112 (46.3%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	34.6 [27.9, 41.3]	27.6 [21.0, 34.6]	
Month 6	30.6 [24.2, 37.2]	23.2 [17.0, 30.1]	
Month 9	28.7 [22.4, 35.3]	21.8 [15.4, 28.9]	
Month 12	28.0 [21.8, 34.6]	19.4 [12.5, 27.3]	
Month 18	24.6 [18.1, 31.6]	19.4 [12.5, 27.3]	
Month 24	24.6 [18.1, 31.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	0.9 [0.6, 1.7]	0.6 [0.4, 0.9]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.746 [0.576, 0.966]
Log-rank test			
Two-sided stratified log-rank p-value			0.0268

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.19.1.2: EORTC QLQ-C30 - Type of Events and Censoring of Loss of Appetite (MID=10) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)
Number of patients at risk	240 (100.0%)	242 (100.0%)
Number of patients with events	141 (58.8%)	130 (53.7%)
Deterioration of symptom	141 (58.8%)	130 (53.7%)
Number of patients censored	99 (41.3%)	112 (46.3%)
No deterioration possible	9 (3.8%)	9 (3.7%)
No baseline and/or follow-up	35 (14.6%)	61 (25.2%)
Subsequent anticancer treatment	6 (2.5%)	13 (5.4%)
Death	10 (4.2%)	15 (6.2%)
No deterioration	39 (16.3%)	14 (5.8%)

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.19.1.3: EORTC QLQ-C30 - Summary of Time to First Deterioration of Loss of Appetite by Subgroups (MID=10) - Analysis Set mITT 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	48	26 (54.2)	0.6 [0.4, 1.3]	48	22 (45.8)	0.4 [0.2, 1.3]	0.671 [0.344, 1.312]	0.2380	0.6407
Absent	192	115 (59.9)	1.1 [0.7, 2.0]	194	108 (55.7)	0.7 [0.4, 0.9]	0.760 [0.574, 1.006]	0.0569	
Age									
< 65 years	105	56 (53.3)	1.7 [0.6, 3.9]	106	59 (55.7)	0.6 [0.4, 0.9]	0.588 [0.391, 0.885]	0.0111	0.0851
>= 65 years	135	85 (63.0)	0.8 [0.6, 1.3]	136	71 (52.2)	0.8 [0.4, 1.5]	0.876 [0.627, 1.226]	0.4330	
Region									
Europe	98	53 (54.1)	0.9 [0.6, 2.1]	102	50 (49.0)	0.4 [0.2, 0.9]	0.633 [0.415, 0.967]	0.0326	0.1702
North America	57	29 (50.9)	1.7 [0.5, 3.2]	51	28 (54.9)	0.9 [0.4, 3.8]	0.846 [0.482, 1.485]	0.6147	
Rest of World	85	59 (69.4)	0.9 [0.4, 1.8]	89	52 (58.4)	0.8 [0.4, 1.3]	0.810 [0.544, 1.206]	0.2867	
Sex									
Male	198	115 (58.1)	0.9 [0.6, 1.8]	185	101 (54.6)	0.6 [0.4, 0.9]	0.720 [0.542, 0.956]	0.0230	0.6412
Female	42	26 (61.9)	1.0 [0.4, 5.9]	57	29 (50.9)	0.6 [0.2, 2.7]	0.888 [0.476, 1.656]	0.7186	
Metastases at Baseline									
Visceral metastases	170	97 (57.1)	0.9 [0.6, 2.0]	161	88 (54.7)	0.6 [0.4, 0.9]	0.658 [0.473, 0.916]	0.0114	0.6452
Lymph node only	60	39 (65.0)	0.9 [0.5, 1.9]	67	36 (53.7)	0.8 [0.4, 1.2]	0.712 [0.420, 1.205]	0.1983	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.19.2.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Loss of Appetite (MID=10) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)	EV+Pembro vs. Plat+Gem
Number of patients at risk	202 (100.0%)	202 (100.0%)	
Number of patients with events	116 (57.4%)	110 (54.5%)	
Number of patients censored	86 (42.6%)	92 (45.5%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	25.8 [18.8, 33.4]	29.6 [22.1, 37.4]	
Month 6	21.6 [15.1, 29.0]	21.1 [14.1, 29.0]	
Month 9	19.8 [13.5, 27.1]	19.6 [12.7, 27.6]	
Month 12	17.0 [10.7, 24.4]	10.9 [3.3, 23.6]	
Month 18	12.6 [6.9, 20.1]	10.9 [3.3, 23.6]	
Month 24	12.6 [6.9, 20.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	0.9 [0.7, 1.3]	1.1 [0.6, 1.5]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.940 [0.693, 1.276]
Log-rank test			
Two-sided stratified log-rank p-value			0.7482

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.19.2.2: EORTC QLQ-C30 - Type of Events and Censoring of Loss of Appetite (MID=10) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)
Number of patients at risk	202 (100.0%)	202 (100.0%)
Number of patients with events	116 (57.4%)	110 (54.5%)
Deterioration of symptom	116 (57.4%)	110 (54.5%)
Number of patients censored	86 (42.6%)	92 (45.5%)
No deterioration possible	8 (4.0%)	15 (7.4%)
No baseline and/or follow-up	48 (23.8%)	42 (20.8%)
Subsequent anticancer treatment	3 (1.5%)	9 (4.5%)
Death	11 (5.4%)	13 (6.4%)
No deterioration	16 (7.9%)	13 (6.4%)

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.19.2.3: EORTC QLQ-C30 - Summary of Time to First Deterioration of Loss of Appetite by Subgroups (MID=10) - Analysis Set mITT 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	29 (58.0)	0.9 [0.4, 1.8]	50	20 (40.0)	1.6 [0.4, 3.9]	2.092 [0.967, 4.526]	0.0440	0.1250
Absent	152	87 (57.2)	0.9 [0.6, 1.3]	152	90 (59.2)	1.1 [0.4, 1.3]	0.801 [0.573, 1.121]	0.2104	
Age									
< 65 years	39	23 (59.0)	0.9 [0.4, 2.5]	29	16 (55.2)	1.8 [0.4, 5.2]	2.115 [0.534, 8.377]	0.3093	0.6931
>= 65 years	163	93 (57.1)	0.9 [0.6, 1.3]	173	94 (54.3)	0.8 [0.4, 1.3]	0.900 [0.658, 1.231]	0.5656	
Region									
Europe	74	42 (56.8)	0.9 [0.6, 1.3]	95	54 (56.8)	1.1 [0.4, 1.6]	0.853 [0.523, 1.392]	0.5733	0.1701
North America	46	21 (45.7)	1.3 [0.5, 3.8]	34	10 (29.4)	4.6 [1.3, NC]	2.154 [0.910, 5.100]	0.0759	
Rest of World	82	53 (64.6)	0.9 [0.5, 1.7]	73	46 (63.0)	0.6 [0.4, 1.3]	0.800 [0.512, 1.250]	0.3385	
Sex									
Male	146	86 (58.9)	0.9 [0.6, 1.3]	151	79 (52.3)	1.4 [0.7, 2.2]	1.142 [0.805, 1.621]	0.4018	0.0344
Female	56	30 (53.6)	1.1 [0.6, 2.4]	51	31 (60.8)	0.4 [0.2, 0.8]	0.501 [0.264, 0.949]	0.0325	
Metastases at Baseline									
Visceral metastases	148	84 (56.8)	0.9 [0.7, 1.5]	157	80 (51.0)	1.3 [0.5, 1.7]	0.982 [0.676, 1.428]	0.9510	0.0605
Lymph node only	43	25 (58.1)	1.1 [0.6, 2.4]	37	23 (62.2)	0.6 [0.2, 1.3]	0.624 [0.294, 1.325]	0.2173	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.20.1.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Sleep Disturbance (MID=10) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)	EV+Pembro vs. Plat+Gem
Number of patients at risk	240 (100.0%)	242 (100.0%)	
Number of patients with events	125 (52.1%)	114 (47.1%)	
Number of patients censored	115 (47.9%)	128 (52.9%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	46.5 [39.3, 53.3]	44.6 [36.9, 52.0]	
Month 6	40.2 [33.2, 47.1]	35.6 [28.0, 43.4]	
Month 9	36.0 [29.0, 43.0]	22.7 [15.2, 31.2]	
Month 12	31.9 [24.7, 39.2]	22.7 [15.2, 31.2]	
Month 18	30.3 [22.9, 38.0]	18.9 [10.5, 29.3]	
Month 24	30.3 [22.9, 38.0]	18.9 [10.5, 29.3]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	2.3 [0.9, 4.5]	2.0 [0.9, 3.8]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.781 [0.589, 1.037]
Log-rank test			
Two-sided stratified log-rank p-value			0.0910

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.20.1.2: EORTC QLQ-C30 - Type of Events and Censoring of Sleep Disturbance (MID=10) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)
Number of patients at risk	240 (100.0%)	242 (100.0%)
Number of patients with events	125 (52.1%)	114 (47.1%)
Deterioration of symptom	125 (52.1%)	114 (47.1%)
Number of patients censored	115 (47.9%)	128 (52.9%)
No deterioration possible	11 (4.6%)	14 (5.8%)
No baseline and/or follow-up	35 (14.6%)	61 (25.2%)
Subsequent anticancer treatment	9 (3.8%)	11 (4.5%)
Death	15 (6.3%)	18 (7.4%)
No deterioration	45 (18.8%)	24 (9.9%)

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.20.1.3: EORTC QLQ-C30 - Summary of Time to First Deterioration of Sleep Disturbance by Subgroups (MID=10) - Analysis Set mITT 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	48	24 (50.0)	0.9 [0.5, 1.7]	48	18 (37.5)	2.0 [0.6, 8.0]	1.316 [0.640, 2.708]	0.4405	0.1316
Absent	192	101 (52.6)	2.7 [1.1, 5.9]	194	96 (49.5)	2.0 [0.9, 3.8]	0.710 [0.523, 0.965]	0.0300	
Age									
< 65 years	105	57 (54.3)	3.2 [1.1, 6.6]	106	54 (50.9)	2.0 [0.7, 5.2]	0.750 [0.493, 1.140]	0.1718	0.5873
>= 65 years	135	68 (50.4)	1.3 [0.7, 5.3]	136	60 (44.1)	2.0 [0.8, 5.9]	0.809 [0.552, 1.186]	0.2984	
Region									
Europe	98	48 (49.0)	2.7 [1.1, 6.6]	102	41 (40.2)	2.0 [0.7, 6.6]	0.775 [0.480, 1.251]	0.2963	0.8718
North America	57	29 (50.9)	1.1 [0.6, 7.4]	51	29 (56.9)	1.5 [0.4, 5.2]	0.677 [0.379, 1.211]	0.1989	
Rest of World	85	48 (56.5)	1.3 [0.6, 10.1]	89	44 (49.4)	2.5 [0.8, 5.9]	0.854 [0.550, 1.325]	0.4838	
Sex									
Male	198	101 (51.0)	2.4 [1.1, 5.2]	185	86 (46.5)	1.5 [0.9, 5.2]	0.802 [0.589, 1.092]	0.1660	0.8667
Female	42	24 (57.1)	0.9 [0.4, 10.1]	57	28 (49.1)	2.5 [0.4, 5.2]	0.683 [0.337, 1.386]	0.2982	
Metastases at Baseline									
Visceral metastases	170	85 (50.0)	2.3 [0.9, 7.4]	161	76 (47.2)	2.7 [1.1, 5.9]	0.789 [0.545, 1.143]	0.2161	0.5988
Lymph node only	60	35 (58.3)	1.2 [0.6, 5.3]	67	33 (49.3)	0.9 [0.4, 2.0]	0.677 [0.385, 1.192]	0.1746	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.20.2.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Sleep Disturbance (MID=10) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)	EV+Pembro vs. Plat+Gem
Number of patients at risk	202 (100.0%)	202 (100.0%)	
Number of patients with events	101 (50.0%)	92 (45.5%)	
Number of patients censored	101 (50.0%)	110 (54.5%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	35.8 [27.8, 43.9]	40.0 [31.7, 48.1]	
Month 6	33.2 [25.3, 41.3]	33.0 [24.6, 41.6]	
Month 9	26.6 [19.2, 34.6]	29.1 [20.4, 38.4]	
Month 12	25.4 [18.0, 33.5]	26.2 [17.0, 36.3]	
Month 18	20.8 [12.7, 30.1]	NC [NC, NC]	
Month 24	20.8 [12.7, 30.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	1.5 [1.1, 2.2]	1.3 [0.9, 2.2]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.900 [0.653, 1.241]
Log-rank test			
Two-sided stratified log-rank p-value			0.5439

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.20.2.2: EORTC QLQ-C30 - Type of Events and Censoring of Sleep Disturbance (MID=10) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)
Number of patients at risk	202 (100.0%)	202 (100.0%)
Number of patients with events	101 (50.0%)	92 (45.5%)
Deterioration of symptom	101 (50.0%)	92 (45.5%)
Number of patients censored	101 (50.0%)	110 (54.5%)
No deterioration possible	10 (5.0%)	15 (7.4%)
No baseline and/or follow-up	48 (23.8%)	42 (20.8%)
Subsequent anticancer treatment	6 (3.0%)	12 (5.9%)
Death	12 (5.9%)	20 (9.9%)
No deterioration	25 (12.4%)	21 (10.4%)

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.20.2.3: EORTC QLQ-C30 - Summary of Time to First Deterioration of Sleep Disturbance by Subgroups (MID=10) - Analysis Set mITT 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	25 (50.0)	1.5 [0.4, 6.6]	50	16 (32.0)	1.3 [0.6, NC]	1.051 [0.467, 2.362]	0.8487	0.2916
Absent	152	76 (50.0)	1.6 [1.1, 2.5]	152	76 (50.0)	1.3 [0.7, 2.2]	0.875 [0.617, 1.241]	0.4580	
Age									
< 65 years	39	17 (43.6)	2.7 [1.3, NC]	29	12 (41.4)	2.3 [0.9, 6.6]	0.622 [0.225, 1.724]	0.3995	0.7237
>= 65 years	163	84 (51.5)	1.3 [0.9, 1.8]	173	80 (46.2)	1.1 [0.7, 2.2]	0.937 [0.669, 1.313]	0.7157	
Region									
Europe	74	35 (47.3)	1.6 [0.7, 2.7]	95	38 (40.0)	2.3 [1.1, 6.6]	1.336 [0.798, 2.239]	0.2869	0.3214
North America	46	20 (43.5)	1.1 [0.5, 7.3]	34	13 (38.2)	1.8 [0.4, NC]	0.967 [0.443, 2.110]	0.9981	
Rest of World	82	46 (56.1)	1.8 [1.1, 2.7]	73	41 (56.2)	0.6 [0.4, 2.2]	0.642 [0.403, 1.022]	0.0640	
Sex									
Male	146	79 (54.1)	1.3 [0.9, 1.8]	151	66 (43.7)	1.8 [1.1, 4.6]	0.990 [0.688, 1.426]	0.9925	0.0254
Female	56	22 (39.3)	2.2 [1.1, 10.7]	51	26 (51.0)	0.8 [0.2, 1.3]	0.649 [0.328, 1.284]	0.1992	
Metastases at Baseline									
Visceral metastases	148	70 (47.3)	1.7 [1.1, 2.7]	157	66 (42.0)	1.6 [0.9, 4.5]	0.849 [0.567, 1.271]	0.4253	0.8409
Lymph node only	43	26 (60.5)	1.1 [0.7, 1.8]	37	19 (51.4)	1.1 [0.4, 2.7]	1.032 [0.485, 2.197]	0.8619	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.21.1.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Constipation (MID=10) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)	EV+Pembro vs. Plat+Gem
Number of patients at risk	240 (100.0%)	242 (100.0%)	
Number of patients with events	125 (52.1%)	133 (55.0%)	
Number of patients censored	115 (47.9%)	109 (45.0%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	47.2 [40.0, 54.0]	27.2 [20.6, 34.2]	
Month 6	40.6 [33.5, 47.6]	22.3 [15.9, 29.3]	
Month 9	36.5 [29.5, 43.5]	17.7 [11.3, 25.3]	
Month 12	33.9 [26.9, 41.1]	15.5 [9.0, 23.6]	
Month 18	30.7 [23.1, 38.6]	15.5 [9.0, 23.6]	
Month 24	30.7 [23.1, 38.6]	15.5 [9.0, 23.6]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	2.2 [1.5, 4.5]	0.7 [0.4, 1.3]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.594 [0.455, 0.776]
Log-rank test			
Two-sided stratified log-rank p-value			0.0001

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.21.1.2: EORTC QLQ-C30 - Type of Events and Censoring of Constipation (MID=10) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)
Number of patients at risk	240 (100.0%)	242 (100.0%)
Number of patients with events	125 (52.1%)	133 (55.0%)
Deterioration of symptom	125 (52.1%)	133 (55.0%)
Number of patients censored	115 (47.9%)	109 (45.0%)
No deterioration possible	7 (2.9%)	7 (2.9%)
No baseline and/or follow-up	35 (14.6%)	61 (25.2%)
Subsequent anticancer treatment	8 (3.3%)	9 (3.7%)
Death	13 (5.4%)	15 (6.2%)
No deterioration	52 (21.7%)	17 (7.0%)

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.21.1.3: EORTC QLQ-C30 - Summary of Time to First Deterioration of Constipation by Subgroups (MID=10) - Analysis Set mITT 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	48	22 (45.8)	1.5 [0.6, NC]	48	24 (50.0)	1.1 [0.2, 1.6]	0.522 [0.261, 1.045]	0.0743	0.9416
Absent	192	103 (53.6)	2.5 [1.5, 5.2]	194	109 (56.2)	0.6 [0.4, 1.3]	0.608 [0.456, 0.811]	0.0008	
Age									
< 65 years	105	54 (51.4)	3.8 [1.3, 10.1]	106	59 (55.7)	0.6 [0.4, 1.5]	0.566 [0.375, 0.854]	0.0067	0.5375
>= 65 years	135	71 (52.6)	1.8 [1.1, 3.9]	136	74 (54.4)	0.8 [0.4, 1.6]	0.616 [0.434, 0.873]	0.0075	
Region									
Europe	98	45 (45.9)	5.9 [1.5, 10.1]	102	57 (55.9)	0.6 [0.2, 1.1]	0.397 [0.255, 0.618]	<.0001	0.0243
North America	57	26 (45.6)	1.1 [0.6, NC]	51	29 (56.9)	0.6 [0.2, 2.2]	0.733 [0.417, 1.291]	0.2753	
Rest of World	85	54 (63.5)	1.8 [1.3, 4.5]	89	47 (52.8)	0.9 [0.4, 3.2]	0.769 [0.506, 1.169]	0.2207	
Sex									
Male	198	99 (50.0)	2.7 [1.5, 5.9]	185	104 (56.2)	0.9 [0.5, 1.6]	0.588 [0.439, 0.786]	0.0004	0.3907
Female	42	26 (61.9)	0.9 [0.4, 5.2]	57	29 (50.9)	0.3 [0.2, 1.3]	0.631 [0.326, 1.221]	0.1878	
Metastases at Baseline									
Visceral metastases	170	85 (50.0)	1.7 [1.3, 4.5]	161	86 (53.4)	0.9 [0.4, 1.6]	0.656 [0.467, 0.921]	0.0156	0.2826
Lymph node only	60	35 (58.3)	3.8 [1.1, 6.7]	67	39 (58.2)	0.6 [0.2, 0.9]	0.469 [0.268, 0.821]	0.0063	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.21.2.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Constipation (MID=10) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)	EV+Pembro vs. Plat+Gem
Number of patients at risk	202 (100.0%)	202 (100.0%)	
Number of patients with events	94 (46.5%)	112 (55.4%)	
Number of patients censored	108 (53.5%)	90 (44.6%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	43.8 [35.4, 51.8]	23.0 [16.2, 30.6]	
Month 6	37.5 [29.4, 45.5]	17.3 [10.9, 24.9]	
Month 9	34.6 [26.6, 42.7]	15.6 [9.3, 23.3]	
Month 12	33.3 [25.2, 41.5]	15.6 [9.3, 23.3]	
Month 18	30.0 [21.7, 38.7]	10.4 [3.3, 22.1]	
Month 24	25.7 [15.8, 36.8]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	2.2 [1.5, 3.1]	0.4 [0.4, 0.9]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.490 [0.357, 0.673]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.21.2.2: EORTC QLQ-C30 - Type of Events and Censoring of Constipation (MID=10) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)
Number of patients at risk	202 (100.0%)	202 (100.0%)
Number of patients with events	94 (46.5%)	112 (55.4%)
Deterioration of symptom	94 (46.5%)	112 (55.4%)
Number of patients censored	108 (53.5%)	90 (44.6%)
No deterioration possible	5 (2.5%)	17 (8.4%)
No baseline and/or follow-up	48 (23.8%)	42 (20.8%)
Subsequent anticancer treatment	3 (1.5%)	6 (3.0%)
Death	15 (7.4%)	14 (6.9%)
No deterioration	37 (18.3%)	11 (5.4%)

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.21.2.3: EORTC QLQ-C30 - Summary of Time to First Deterioration of Constipation by Subgroups (MID=10) - Analysis Set mITT 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	23 (46.0)	1.5 [0.4, 3.1]	50	20 (40.0)	2.0 [0.4, 7.3]	0.855 [0.405, 1.803]	0.7044	0.0389
Absent	152	71 (46.7)	2.3 [1.5, 5.2]	152	92 (60.5)	0.4 [0.4, 0.6]	0.432 [0.303, 0.616]	<.0001	
Age									
< 65 years	39	18 (46.2)	2.3 [0.6, NC]	29	15 (51.7)	0.8 [0.4, 2.2]	0.685 [0.256, 1.833]	0.4586	0.6211
>= 65 years	163	76 (46.6)	2.0 [1.1, 4.5]	173	97 (56.1)	0.4 [0.4, 0.9]	0.472 [0.337, 0.659]	<.0001	
Region									
Europe	74	31 (41.9)	2.3 [1.4, 4.5]	95	47 (49.5)	0.4 [0.2, 1.3]	0.467 [0.270, 0.808]	0.0072	0.6343
North America	46	20 (43.5)	0.9 [0.4, 2.5]	34	20 (58.8)	0.6 [0.4, 1.1]	0.637 [0.313, 1.294]	0.1782	
Rest of World	82	43 (52.4)	3.1 [1.1, 8.0]	73	45 (61.6)	0.4 [0.4, 1.1]	0.454 [0.285, 0.723]	0.0008	
Sex									
Male	146	68 (46.6)	2.3 [1.5, 4.5]	151	84 (55.6)	0.4 [0.4, 1.1]	0.492 [0.346, 0.702]	<.0001	0.9915
Female	56	26 (46.4)	1.5 [0.4, 8.0]	51	28 (54.9)	0.4 [0.2, 1.3]	0.480 [0.235, 0.981]	0.0347	
Metastases at Baseline									
Visceral metastases	148	71 (48.0)	2.0 [0.9, 3.1]	157	79 (50.3)	0.6 [0.4, 1.7]	0.589 [0.400, 0.867]	0.0083	0.0186
Lymph node only	43	20 (46.5)	2.1 [0.6, NC]	37	25 (67.6)	0.3 [0.2, 0.5]	0.329 [0.139, 0.779]	0.0076	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.22.1.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Financial Impact (MID=10) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)	EV+Pembro vs. Plat+Gem
Number of patients at risk	240 (100.0%)	242 (100.0%)	
Number of patients with events	96 (40.0%)	83 (34.3%)	
Number of patients censored	144 (60.0%)	159 (65.7%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	63.7 [56.5, 70.0]	58.5 [50.7, 65.4]	
Month 6	57.1 [49.7, 63.8]	54.9 [47.0, 62.1]	
Month 9	51.1 [43.5, 58.1]	50.5 [42.1, 58.3]	
Month 12	48.4 [40.7, 55.7]	45.7 [35.8, 55.0]	
Month 18	46.9 [38.8, 54.5]	45.7 [35.8, 55.0]	
Month 24	43.9 [34.5, 52.9]	45.7 [35.8, 55.0]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	10.7 [5.9, NC]	11.4 [3.2, NC]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.953 [0.696, 1.306]
Log-rank test			
Two-sided stratified log-rank p-value			0.7929

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.22.1.2: EORTC QLQ-C30 - Type of Events and Censoring of Financial Impact (MID=10) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)
Number of patients at risk	240 (100.0%)	242 (100.0%)
Number of patients with events	96 (40.0%)	83 (34.3%)
Deterioration of symptom	96 (40.0%)	83 (34.3%)
Number of patients censored	144 (60.0%)	159 (65.7%)
No deterioration possible	7 (2.9%)	4 (1.7%)
No baseline and/or follow-up	35 (14.6%)	61 (25.2%)
Subsequent anticancer treatment	16 (6.7%)	26 (10.7%)
Death	20 (8.3%)	29 (12.0%)
No deterioration	66 (27.5%)	39 (16.1%)

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.22.1.3: EORTC QLQ-C30 - Summary of Time to First Deterioration of Financial Impact by Subgroups (MID=10) - Analysis Set mITT 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	48	17 (35.4)	NC [1.7, NC]	48	14 (29.2)	7.4 [1.1, NC]	1.288 [0.604, 2.745]	0.4862	0.9516
Absent	192	79 (41.1)	9.4 [5.9, NC]	194	69 (35.6)	11.4 [3.2, NC]	0.895 [0.633, 1.265]	0.5424	
Age									
< 65 years	105	42 (40.0)	15.6 [4.6, NC]	106	44 (41.5)	2.7 [1.3, NC]	0.695 [0.437, 1.105]	0.1302	0.0750
>= 65 years	135	54 (40.0)	8.0 [5.2, NC]	136	39 (28.7)	11.4 [6.6, NC]	1.253 [0.812, 1.932]	0.2977	
Region									
Europe	98	30 (30.6)	NC [8.0, NC]	102	25 (24.5)	NC [3.2, NC]	0.751 [0.421, 1.341]	0.3384	0.4916
North America	57	17 (29.8)	NC [8.0, NC]	51	19 (37.3)	8.7 [1.1, NC]	0.822 [0.407, 1.658]	0.5940	
Rest of World	85	49 (57.6)	5.2 [2.0, 7.3]	89	39 (43.8)	4.5 [1.3, NC]	1.160 [0.745, 1.808]	0.4856	
Sex									
Male	198	78 (39.4)	10.8 [5.9, NC]	185	67 (36.2)	7.4 [1.8, NC]	0.890 [0.631, 1.256]	0.5288	0.1725
Female	42	18 (42.9)	8.7 [0.9, NC]	57	16 (28.1)	NC [5.9, NC]	1.354 [0.620, 2.956]	0.4460	
Metastases at Baseline									
Visceral metastases	170	69 (40.6)	8.7 [5.2, NC]	161	52 (32.3)	11.4 [5.9, NC]	1.185 [0.794, 1.767]	0.3853	0.2620
Lymph node only	60	23 (38.3)	NC [5.9, NC]	67	23 (34.3)	8.7 [1.3, NC]	0.550 [0.282, 1.070]	0.0745	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.22.2.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Financial Impact (MID=10) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)	EV+Pembro vs. Plat+Gem
Number of patients at risk	202 (100.0%)	202 (100.0%)	
Number of patients with events	76 (37.6%)	72 (35.6%)	
Number of patients censored	126 (62.4%)	130 (64.4%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	60.5 [51.8, 68.1]	57.2 [48.8, 64.8]	
Month 6	52.4 [43.6, 60.4]	54.0 [45.2, 61.9]	
Month 9	46.4 [37.4, 54.8]	50.1 [40.4, 59.0]	
Month 12	46.4 [37.4, 54.8]	44.0 [32.4, 55.0]	
Month 18	40.7 [30.7, 50.3]	38.5 [24.6, 52.3]	
Month 24	24.4 [9.0, 43.8]	38.5 [24.6, 52.3]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	6.6 [3.2, 21.1]	9.4 [2.7, NC]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.916 [0.630, 1.330]
Log-rank test			
Two-sided stratified log-rank p-value			0.6685

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.22.2.2: EORTC QLQ-C30 - Type of Events and Censoring of Financial Impact (MID=10) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)
Number of patients at risk	202 (100.0%)	202 (100.0%)
Number of patients with events	76 (37.6%)	72 (35.6%)
Deterioration of symptom	76 (37.6%)	72 (35.6%)
Number of patients censored	126 (62.4%)	130 (64.4%)
No deterioration possible	5 (2.5%)	2 (1.0%)
No baseline and/or follow-up	48 (23.8%)	42 (20.8%)
Subsequent anticancer treatment	6 (3.0%)	20 (9.9%)
Death	24 (11.9%)	37 (18.3%)
No deterioration	43 (21.3%)	29 (14.4%)

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.22.2.3: EORTC QLQ-C30 - Summary of Time to First Deterioration of Financial Impact by Subgroups (MID=10) - Analysis Set mITT 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	16 (32.0)	21.1 [1.8, NC]	50	15 (30.0)	NC [2.0, NC]	0.863 [0.344, 2.168]	0.7540	0.9157
Absent	152	60 (39.5)	6.0 [2.5, 15.6]	152	57 (37.5)	7.3 [2.5, NC]	0.926 [0.615, 1.394]	0.7428	
Age									
< 65 years	39	18 (46.2)	5.2 [0.8, NC]	29	11 (37.9)	8.6 [0.7, NC]	0.683 [0.237, 1.971]	0.4637	0.9393
>= 65 years	163	58 (35.6)	8.0 [3.1, NC]	173	61 (35.3)	9.4 [2.7, NC]	0.955 [0.640, 1.424]	0.8574	
Region									
Europe	74	25 (33.8)	12.1 [1.8, NC]	95	20 (21.1)	NC [NC, NC]	2.404 [1.263, 4.577]	0.0061	0.0106
North America	46	9 (19.6)	NC [3.8, NC]	34	10 (29.4)	7.3 [1.6, NC]	0.292 [0.082, 1.036]	0.0471	
Rest of World	82	42 (51.2)	3.2 [1.7, 12.8]	73	42 (57.5)	2.0 [0.9, 2.7]	0.662 [0.410, 1.069]	0.0938	
Sex									
Male	146	54 (37.0)	8.0 [3.2, NC]	151	54 (35.8)	9.4 [2.7, NC]	0.885 [0.577, 1.359]	0.5768	0.6944
Female	56	22 (39.3)	3.1 [1.1, 21.1]	51	18 (35.3)	3.8 [1.1, NC]	1.018 [0.475, 2.183]	0.8990	
Metastases at Baseline									
Visceral metastases	148	49 (33.1)	8.7 [3.9, 23.9]	157	56 (35.7)	9.4 [2.5, NC]	0.701 [0.438, 1.121]	0.1419	0.1768
Lymph node only	43	20 (46.5)	4.6 [1.3, NC]	37	11 (29.7)	NC [2.0, NC]	1.362 [0.568, 3.265]	0.4877	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.23.1.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Diarrhea (MID=10) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)	EV+Pembro vs. Plat+Gem
Number of patients at risk	240 (100.0%)	242 (100.0%)	
Number of patients with events	132 (55.0%)	98 (40.5%)	
Number of patients censored	108 (45.0%)	144 (59.5%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	45.1 [38.1, 51.7]	50.6 [42.9, 57.8]	
Month 6	41.4 [34.5, 48.1]	43.8 [36.0, 51.3]	
Month 9	38.2 [31.4, 45.0]	42.1 [33.9, 50.0]	
Month 12	36.7 [29.9, 43.5]	37.8 [28.5, 46.9]	
Month 18	27.9 [20.1, 36.3]	37.8 [28.5, 46.9]	
Month 24	27.9 [20.1, 36.3]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	2.0 [1.3, 3.8]	3.1 [2.0, 9.3]	
Cox proportional hazards model			
Stratified HR [95% CI]			1.142 [0.862, 1.513]
Log-rank test			
Two-sided stratified log-rank p-value			0.3453

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.23.1.2: EORTC QLQ-C30 - Type of Events and Censoring of Diarrhea (MID=10) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)
Number of patients at risk	240 (100.0%)	242 (100.0%)
Number of patients with events	132 (55.0%)	98 (40.5%)
Deterioration of symptom	132 (55.0%)	98 (40.5%)
Number of patients censored	108 (45.0%)	144 (59.5%)
No deterioration possible	0	0
No baseline and/or follow-up	35 (14.6%)	61 (25.2%)
Subsequent anticancer treatment	9 (3.8%)	21 (8.7%)
Death	7 (2.9%)	29 (12.0%)
No deterioration	57 (23.8%)	33 (13.6%)

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.23.1.3: EORTC QLQ-C30 - Summary of Time to First Deterioration of Diarrhea by Subgroups (MID=10) - Analysis Set mITT 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	48	28 (58.3)	1.1 [0.6, 1.7]	48	16 (33.3)	3.8 [0.6, NC]	1.311 [0.670, 2.564]	0.3964	0.2610
Absent	192	104 (54.2)	2.2 [1.3, 8.7]	194	82 (42.3)	3.1 [2.0, 8.7]	1.108 [0.813, 1.511]	0.5146	
Age									
< 65 years	105	54 (51.4)	2.0 [1.1, 17.0]	106	46 (43.4)	3.1 [1.1, 10.1]	0.938 [0.610, 1.444]	0.7791	0.1251
>= 65 years	135	78 (57.8)	1.5 [0.9, 3.8]	136	52 (38.2)	2.8 [1.7, NC]	1.321 [0.909, 1.921]	0.1365	
Region									
Europe	98	45 (45.9)	2.0 [0.9, NC]	102	40 (39.2)	2.0 [0.9, 8.7]	0.886 [0.556, 1.412]	0.6023	0.2470
North America	57	32 (56.1)	2.0 [1.1, 9.4]	51	21 (41.2)	5.2 [1.6, NC]	1.370 [0.763, 2.460]	0.2844	
Rest of World	85	55 (64.7)	1.7 [1.1, 3.8]	89	37 (41.6)	3.3 [1.3, NC]	1.290 [0.827, 2.011]	0.2471	
Sex									
Male	198	112 (56.6)	1.7 [1.3, 3.2]	185	77 (41.6)	2.8 [1.6, 8.7]	1.160 [0.854, 1.576]	0.3311	0.8994
Female	42	20 (47.6)	8.7 [0.7, NC]	57	21 (36.8)	5.9 [1.6, NC]	1.048 [0.512, 2.147]	0.8980	
Metastases at Baseline									
Visceral metastases	170	98 (57.6)	1.6 [1.1, 3.2]	161	66 (41.0)	3.1 [1.3, 10.1]	1.290 [0.907, 1.835]	0.1437	0.2032
Lymph node only	60	29 (48.3)	3.8 [1.3, NC]	67	29 (43.3)	2.7 [1.8, 9.3]	0.791 [0.433, 1.445]	0.4455	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.23.2.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Diarrhea (MID=10) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)	EV+Pembro vs. Plat+Gem
Number of patients at risk	202 (100.0%)	202 (100.0%)	
Number of patients with events	101 (50.0%)	78 (38.6%)	
Number of patients censored	101 (50.0%)	124 (61.4%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	43.9 [35.6, 51.8]	53.7 [45.3, 61.4]	
Month 6	33.2 [25.4, 41.2]	47.3 [38.5, 55.6]	
Month 9	31.3 [23.6, 39.4]	47.3 [38.5, 55.6]	
Month 12	26.6 [19.0, 34.8]	37.6 [25.7, 49.5]	
Month 18	25.2 [17.6, 33.5]	37.6 [25.7, 49.5]	
Month 24	25.2 [17.6, 33.5]	37.6 [25.7, 49.5]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	2.0 [1.3, 3.2]	4.5 [2.0, 11.0]	
Cox proportional hazards model			
Stratified HR [95% CI]			1.342 [0.965, 1.867]
Log-rank test			
Two-sided stratified log-rank p-value			0.0695

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.23.2.2: EORTC QLQ-C30 - Type of Events and Censoring of Diarrhea (MID=10) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)
Number of patients at risk	202 (100.0%)	202 (100.0%)
Number of patients with events	101 (50.0%)	78 (38.6%)
Deterioration of symptom	101 (50.0%)	78 (38.6%)
Number of patients censored	101 (50.0%)	124 (61.4%)
No deterioration possible	0	0
No baseline and/or follow-up	48 (23.8%)	42 (20.8%)
Subsequent anticancer treatment	4 (2.0%)	22 (10.9%)
Death	18 (8.9%)	38 (18.8%)
No deterioration	31 (15.3%)	22 (10.9%)

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.23.2.3: EORTC QLQ-C30 - Summary of Time to First Deterioration of Diarrhea by Subgroups (MID=10) - Analysis Set mITT 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	28 (56.0)	1.8 [0.6, 4.5]	50	18 (36.0)	4.5 [1.1, NC]	1.214 [0.615, 2.399]	0.5597	0.3533
Absent	152	73 (48.0)	2.4 [1.1, 5.2]	152	60 (39.5)	4.6 [1.8, 11.0]	1.384 [0.949, 2.017]	0.0795	
Age									
< 65 years	39	26 (66.7)	2.0 [0.6, 3.1]	29	11 (37.9)	10.8 [1.8, NC]	4.354 [1.333, 14.221]	0.0097	0.1724
>= 65 years	163	75 (46.0)	2.4 [1.1, 4.5]	173	67 (38.7)	4.5 [1.3, NC]	1.187 [0.838, 1.679]	0.3069	
Region									
Europe	74	33 (44.6)	2.0 [0.6, 4.5]	95	36 (37.9)	4.5 [1.3, NC]	1.147 [0.658, 1.998]	0.5924	0.7282
North America	46	23 (50.0)	1.4 [0.5, 3.9]	34	13 (38.2)	3.2 [0.7, NC]	1.744 [0.831, 3.661]	0.1193	
Rest of World	82	45 (54.9)	3.1 [1.1, 8.0]	73	29 (39.7)	5.2 [1.3, NC]	1.348 [0.816, 2.229]	0.2387	
Sex									
Male	146	77 (52.7)	2.3 [1.3, 3.8]	151	61 (40.4)	4.5 [1.8, 11.0]	1.407 [0.969, 2.044]	0.0623	0.9018
Female	56	24 (42.9)	2.0 [0.7, NC]	51	17 (33.3)	NC [0.9, NC]	1.128 [0.553, 2.301]	0.7295	
Metastases at Baseline									
Visceral metastases	148	78 (52.7)	2.3 [1.1, 3.9]	157	55 (35.0)	5.2 [2.7, NC]	1.416 [0.953, 2.102]	0.0794	0.0139
Lymph node only	43	16 (37.2)	3.1 [0.7, NC]	37	18 (48.6)	1.1 [0.5, NC]	0.623 [0.263, 1.474]	0.3010	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.24.1.1: EQ-5D-5L - Summary of Time to First Deterioration of VAS (MID=15) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)	EV+Pembro vs. Plat+Gem
Number of patients at risk	240 (100.0%)	242 (100.0%)	
Number of patients with events	138 (57.5%)	111 (45.9%)	
Number of patients censored	102 (42.5%)	131 (54.1%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	46.6 [39.7, 53.2]	44.5 [37.1, 51.7]	
Month 6	41.3 [34.5, 48.0]	37.2 [29.8, 44.6]	
Month 9	35.9 [29.2, 42.6]	34.5 [26.9, 42.3]	
Month 12	32.5 [25.7, 39.4]	34.5 [26.9, 42.3]	
Month 18	31.5 [24.7, 38.5]	27.6 [15.2, 41.6]	
Month 24	23.6 [14.9, 33.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	2.5 [1.3, 5.2]	2.2 [1.5, 3.2]	
Cox proportional hazards model			
Stratified HR [95% CI]			1.012 [0.772, 1.327]
Log-rank test			
Two-sided stratified log-rank p-value			0.9625

Abbreviations: CI=confidence interval; EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; VAS=visual analogue scale.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Time to first deterioration is defined as time from randomization to the first observation with a >=15 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.

ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.24.1.2: EQ-5D-5L - Type of Events and Censoring of VAS (MID=15) - Analysis Set mITT 1

	EV+Pembro (N=240)	Plat+Gem (N=242)
Number of patients at risk	240 (100.0%)	242 (100.0%)
Number of patients with events	138 (57.5%)	111 (45.9%)
Deterioration of symptom	138 (57.5%)	111 (45.9%)
Number of patients censored	102 (42.5%)	131 (54.1%)
No deterioration possible	0	3 (1.2%)
No baseline and/or follow-up	31 (12.9%)	58 (24.0%)
Subsequent anticancer treatment	9 (3.8%)	16 (6.6%)
Death	14 (5.8%)	23 (9.5%)
No deterioration	48 (20.0%)	31 (12.8%)

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; VAS=visual analogue scale.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.24.1.3: EQ-5D-5L - Summary of Time to First Deterioration of VAS by Subgroups (MID=15) - Analysis Set mITT 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	48	29 (60.4)	0.5 [0.4, 2.0]	48	17 (35.4)	5.9 [1.8, NC]	2.026 [1.001, 4.101]	0.0461	0.0198
Absent	192	109 (56.8)	2.8 [2.0, 6.6]	194	94 (48.5)	1.8 [1.3, 2.7]	0.892 [0.665, 1.195]	0.4283	
Age									
< 65 years	105	57 (54.3)	5.9 [1.8, 10.1]	106	47 (44.3)	2.2 [1.3, NC]	0.900 [0.588, 1.379]	0.6245	0.4514
>= 65 years	135	81 (60.0)	1.5 [0.7, 2.8]	136	64 (47.1)	2.2 [1.3, 4.5]	1.094 [0.771, 1.554]	0.6438	
Region									
Europe	98	52 (53.1)	3.2 [1.3, 8.0]	102	47 (46.1)	1.7 [1.1, 2.7]	0.880 [0.570, 1.361]	0.5643	0.2521
North America	57	31 (54.4)	2.2 [0.6, 10.8]	51	25 (49.0)	2.2 [1.1, 7.4]	0.951 [0.538, 1.678]	0.8375	
Rest of World	85	55 (64.7)	2.0 [0.6, 5.3]	89	39 (43.8)	3.2 [1.3, NC]	1.206 [0.779, 1.867]	0.4216	
Sex									
Male	198	117 (59.1)	2.2 [1.3, 3.9]	185	85 (45.9)	2.2 [1.5, 4.5]	1.112 [0.829, 1.490]	0.5039	0.0968
Female	42	21 (50.0)	9.3 [1.1, 21.1]	57	26 (45.6)	2.0 [0.4, 5.2]	0.564 [0.269, 1.181]	0.1311	
Metastases at Baseline									
Visceral metastases	170	92 (54.1)	2.3 [1.1, 8.0]	161	74 (46.0)	2.7 [1.7, 5.9]	1.062 [0.753, 1.499]	0.7945	0.8491
Lymph node only	60	40 (66.7)	2.6 [0.9, 6.6]	67	31 (46.3)	1.5 [0.6, 2.2]	0.796 [0.471, 1.345]	0.3627	

Abbreviations: CI=confidence interval; EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; VAS=visual analogue scale.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=15 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.3003.24.2.1: EQ-5D-5L - Summary of Time to First Deterioration of VAS (MID=15) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)	EV+Pembro vs. Plat+Gem
Number of patients at risk	202 (100.0%)	202 (100.0%)	
Number of patients with events	107 (53.0%)	110 (54.5%)	
Number of patients censored	95 (47.0%)	92 (45.5%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 3	42.9 [34.9, 50.5]	35.3 [27.9, 42.9]	
Month 6	35.2 [27.5, 42.9]	30.7 [23.3, 38.5]	
Month 9	31.6 [24.1, 39.4]	26.9 [18.9, 35.4]	
Month 12	30.2 [22.6, 38.2]	19.4 [9.7, 31.4]	
Month 18	28.0 [20.0, 36.6]	19.4 [9.7, 31.4]	
Month 24	21.6 [13.3, 31.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	1.5 [1.0, 3.2]	1.3 [0.9, 2.0]	
Cox proportional hazards model			
Stratified HR [95% CI]			0.884 [0.652, 1.198]
Log-rank test			
Two-sided stratified log-rank p-value			0.4681

Abbreviations: CI=confidence interval; EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; VAS=visual analogue scale.

Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.

Time to first deterioration is defined as time from randomization to the first observation with a >=15 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.

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Table 302.1.3003.24.2.2: EQ-5D-5L - Type of Events and Censoring of VAS (MID=15) - Analysis Set mITT 2

	EV+Pembro (N=202)	Plat+Gem (N=202)
Number of patients at risk	202 (100.0%)	202 (100.0%)
Number of patients with events	107 (53.0%)	110 (54.5%)
Deterioration of symptom	107 (53.0%)	110 (54.5%)
Number of patients censored	95 (47.0%)	92 (45.5%)
No deterioration possible	1 (0.5%)	1 (0.5%)
No baseline and/or follow-up	42 (20.8%)	40 (19.8%)
Subsequent anticancer treatment	4 (2.0%)	12 (5.9%)
Death	14 (6.9%)	19 (9.4%)
No deterioration	34 (16.8%)	20 (9.9%)

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; VAS=visual analogue scale.
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Table 302.1.3003.24.2.3: EQ-5D-5L - Summary of Time to First Deterioration of VAS by Subgroups (MID=15) - Analysis Set mITT 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	25 (50.0)	1.5 [0.5, 6.6]	50	21 (42.0)	2.2 [1.5, NC]	1.826 [0.891, 3.740]	0.0857	0.0897
Absent	152	82 (53.9)	1.5 [1.0, 3.2]	152	89 (58.6)	1.1 [0.6, 1.6]	0.749 [0.534, 1.052]	0.1020	
Age									
< 65 years	39	20 (51.3)	3.2 [0.6, 18.4]	29	15 (51.7)	2.1 [0.4, NC]	0.614 [0.222, 1.699]	0.3476	0.6448
>= 65 years	163	87 (53.4)	1.1 [0.9, 2.7]	173	95 (54.9)	1.3 [0.8, 1.8]	0.916 [0.666, 1.260]	0.6445	
Region									
Europe	74	38 (51.4)	1.5 [0.6, 2.7]	95	53 (55.8)	1.1 [0.6, 2.4]	1.038 [0.641, 1.683]	0.8352	0.9410
North America	46	18 (39.1)	3.8 [0.9, NC]	34	13 (38.2)	2.3 [0.9, NC]	0.763 [0.349, 1.669]	0.5658	
Rest of World	82	51 (62.2)	1.1 [0.6, 5.2]	73	44 (60.3)	1.1 [0.6, 1.8]	0.809 [0.517, 1.264]	0.3480	
Sex									
Male	146	82 (56.2)	1.5 [1.0, 3.2]	151	81 (53.6)	1.5 [0.9, 2.3]	0.873 [0.618, 1.233]	0.4953	0.2492
Female	56	25 (44.6)	1.3 [0.4, NC]	51	29 (56.9)	1.3 [0.4, 2.3]	0.922 [0.487, 1.747]	0.7936	
Metastases at Baseline									
Visceral metastases	148	77 (52.0)	1.5 [0.9, 3.2]	157	81 (51.6)	1.5 [0.9, 2.3]	1.038 [0.710, 1.517]	0.8030	0.1609
Lymph node only	43	24 (55.8)	1.7 [0.7, 14.9]	37	24 (64.9)	0.9 [0.4, 2.0]	0.690 [0.317, 1.502]	0.3259	

Abbreviations: CI=confidence interval; EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate (median) of time to event (months); MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; n=number of patients with event; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; VAS=visual analogue scale.
Note: The stratification factors are programmed cell death ligand-1 (PD-L1) expression (high [CPS>=10] or low [CPS<10]), liver metastases (present or absent), age (<65 or >=65 years), sex and region (North America, Europe, Rest of World). If a subgroup is identified as a stratification factor, the models will only be controlled for the other stratification factor.
Time to first deterioration is defined as time from randomization to the first observation with a >=15 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).
Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from stratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
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Table 302.1.2000.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Overall	239 (100.0%)	234 (99.2%)	473 (99.6%)
Gastrointestinal disorders	179 (74.9%)	184 (78.0%)	363 (76.4%)
Nausea	61 (25.5%)	120 (50.8%)	181 (38.1%)
Constipation	67 (28.0%)	76 (32.2%)	143 (30.1%)
Diarrhoea	89 (37.2%)	40 (16.9%)	129 (27.2%)
Vomiting	24 (10.0%)	42 (17.8%)	66 (13.9%)
Abdominal pain	27 (11.3%)	21 (8.9%)	48 (10.1%)
Stomatitis	27 (11.3%)	16 (6.8%)	43 (9.1%)
Dry mouth	24 (10.0%)	6 (2.5%)	30 (6.3%)
Dyspepsia	13 (5.4%)	11 (4.7%)	24 (5.1%)
Gastrooesophageal reflux disease	12 (5.0%)	9 (3.8%)	21 (4.4%)
Abdominal pain upper	12 (5.0%)	7 (3.0%)	19 (4.0%)
Haemorrhoids	10 (4.2%)	2 (0.8%)	12 (2.5%)
Colitis	7 (2.9%)	0	7 (1.5%)
Dysphagia	4 (1.7%)	2 (0.8%)	6 (1.3%)
Gastritis	4 (1.7%)	2 (0.8%)	6 (1.3%)
Abdominal discomfort	3 (1.3%)	2 (0.8%)	5 (1.1%)
Mouth ulceration	3 (1.3%)	2 (0.8%)	5 (1.1%)
Abdominal pain lower	1 (0.4%)	3 (1.3%)	4 (0.8%)
Ascites	3 (1.3%)	1 (0.4%)	4 (0.8%)
Flatulence	3 (1.3%)	1 (0.4%)	4 (0.8%)
Inguinal hernia	3 (1.3%)	1 (0.4%)	4 (0.8%)
Gastric ulcer	2 (0.8%)	1 (0.4%)	3 (0.6%)
Immune-mediated enterocolitis	3 (1.3%)	0	3 (0.6%)
Oral dysaesthesia	2 (0.8%)	1 (0.4%)	3 (0.6%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Pancreatitis	3 (1.3%)	0	3 (0.6%)
Toothache	2 (0.8%)	1 (0.4%)	3 (0.6%)
Abdominal distension	2 (0.8%)	0	2 (0.4%)
Dental caries	1 (0.4%)	1 (0.4%)	2 (0.4%)
Faeces soft	2 (0.8%)	0	2 (0.4%)
Haemorrhoidal haemorrhage	2 (0.8%)	0	2 (0.4%)
Oral pain	1 (0.4%)	1 (0.4%)	2 (0.4%)
Paraesthesia oral	1 (0.4%)	1 (0.4%)	2 (0.4%)
Proctalgia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Rectal haemorrhage	2 (0.8%)	0	2 (0.4%)
Abdominal rigidity	0	1 (0.4%)	1 (0.2%)
Anal erythema	1 (0.4%)	0	1 (0.2%)
Anal pruritus	1 (0.4%)	0	1 (0.2%)
Angular cheilitis	1 (0.4%)	0	1 (0.2%)
Autoimmune pancreatitis	1 (0.4%)	0	1 (0.2%)
Colonic fistula	1 (0.4%)	0	1 (0.2%)
Defaecation urgency	1 (0.4%)	0	1 (0.2%)
Duodenal stenosis	1 (0.4%)	0	1 (0.2%)
Duodenitis	0	1 (0.4%)	1 (0.2%)
Enterovesical fistula	1 (0.4%)	0	1 (0.2%)
Epigastric discomfort	0	1 (0.4%)	1 (0.2%)
Gingival bleeding	1 (0.4%)	0	1 (0.2%)
Haematochezia	0	1 (0.4%)	1 (0.2%)
Haemorrhagic erosive gastritis	1 (0.4%)	0	1 (0.2%)
Hernial eventration	1 (0.4%)	0	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Hypoaesthesia oral	1 (0.4%)	0	1 (0.2%)
Ileal ulcer	1 (0.4%)	0	1 (0.2%)
Ileus	1 (0.4%)	0	1 (0.2%)
Intestinal obstruction	1 (0.4%)	0	1 (0.2%)
Large intestine perforation	1 (0.4%)	0	1 (0.2%)
Lip dry	1 (0.4%)	0	1 (0.2%)
Lip ulceration	1 (0.4%)	0	1 (0.2%)
Melaena	0	1 (0.4%)	1 (0.2%)
Obstructive pancreatitis	0	1 (0.4%)	1 (0.2%)
Odynophagia	1 (0.4%)	0	1 (0.2%)
Oesophageal stenosis	1 (0.4%)	0	1 (0.2%)
Oral blood blister	1 (0.4%)	0	1 (0.2%)
Oral verrucous hyperplasia	1 (0.4%)	0	1 (0.2%)
Pancreatitis chronic	1 (0.4%)	0	1 (0.2%)
Periodontal disease	1 (0.4%)	0	1 (0.2%)
Rectal tenesmus	0	1 (0.4%)	1 (0.2%)
Regurgitation	0	1 (0.4%)	1 (0.2%)
Salivary gland calculus	1 (0.4%)	0	1 (0.2%)
Small intestinal obstruction	1 (0.4%)	0	1 (0.2%)
General disorders and administration site conditions	159 (66.5%)	167 (70.8%)	326 (68.6%)
Fatigue	79 (33.1%)	101 (42.8%)	180 (37.9%)
Asthenia	43 (18.0%)	45 (19.1%)	88 (18.5%)
Pyrexia	41 (17.2%)	32 (13.6%)	73 (15.4%)
Oedema peripheral	29 (12.1%)	22 (9.3%)	51 (10.7%)
Malaise	8 (3.3%)	5 (2.1%)	13 (2.7%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
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Table 302.1.2000.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Chills	7 (2.9%)	3 (1.3%)	10 (2.1%)
Non-cardiac chest pain	4 (1.7%)	5 (2.1%)	9 (1.9%)
Pain	3 (1.3%)	6 (2.5%)	9 (1.9%)
Gait disturbance	8 (3.3%)	0	8 (1.7%)
Infusion site extravasation	5 (2.1%)	0	5 (1.1%)
Peripheral swelling	3 (1.3%)	2 (0.8%)	5 (1.1%)
Chest discomfort	2 (0.8%)	2 (0.8%)	4 (0.8%)
General physical health deterioration	2 (0.8%)	2 (0.8%)	4 (0.8%)
Catheter site pain	2 (0.8%)	0	2 (0.4%)
Chest pain	2 (0.8%)	0	2 (0.4%)
Infusion site pain	0	2 (0.8%)	2 (0.4%)
Injection site reaction	0	2 (0.8%)	2 (0.4%)
Temperature intolerance	2 (0.8%)	0	2 (0.4%)
Catheter site erosion	1 (0.4%)	0	1 (0.2%)
Catheter site haematoma	0	1 (0.4%)	1 (0.2%)
Catheter site inflammation	0	1 (0.4%)	1 (0.2%)
Catheter site irritation	1 (0.4%)	0	1 (0.2%)
Catheter site pruritus	1 (0.4%)	0	1 (0.2%)
Catheter site related reaction	1 (0.4%)	0	1 (0.2%)
Catheter site swelling	0	1 (0.4%)	1 (0.2%)
Face oedema	0	1 (0.4%)	1 (0.2%)
Generalised oedema	0	1 (0.4%)	1 (0.2%)
Hyperthermia	1 (0.4%)	0	1 (0.2%)
Impaired healing	0	1 (0.4%)	1 (0.2%)
Influenza like illness	1 (0.4%)	0	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Infusion site reaction	0	1 (0.4%)	1 (0.2%)
Localised oedema	1 (0.4%)	0	1 (0.2%)
Multiple organ dysfunction syndrome	0	1 (0.4%)	1 (0.2%)
Oedema	0	1 (0.4%)	1 (0.2%)
Suprapubic pain	0	1 (0.4%)	1 (0.2%)
Swelling face	1 (0.4%)	0	1 (0.2%)
Nervous system disorders	186 (77.8%)	96 (40.7%)	282 (59.4%)
Peripheral sensory neuropathy	126 (52.7%)	34 (14.4%)	160 (33.7%)
Dysgeusia	47 (19.7%)	28 (11.9%)	75 (15.8%)
Dizziness	24 (10.0%)	26 (11.0%)	50 (10.5%)
Headache	19 (7.9%)	16 (6.8%)	35 (7.4%)
Paraesthesia	24 (10.0%)	6 (2.5%)	30 (6.3%)
Hypoaesthesia	12 (5.0%)	1 (0.4%)	13 (2.7%)
Peripheral motor neuropathy	11 (4.6%)	1 (0.4%)	12 (2.5%)
Taste disorder	10 (4.2%)	2 (0.8%)	12 (2.5%)
Peripheral sensorimotor neuropathy	10 (4.2%)	1 (0.4%)	11 (2.3%)
Ageusia	8 (3.3%)	0	8 (1.7%)
Lethargy	2 (0.8%)	6 (2.5%)	8 (1.7%)
Syncope	5 (2.1%)	3 (1.3%)	8 (1.7%)
Anosmia	7 (2.9%)	0	7 (1.5%)
Hypogeusia	3 (1.3%)	3 (1.3%)	6 (1.3%)
Tremor	4 (1.7%)	2 (0.8%)	6 (1.3%)
Balance disorder	4 (1.7%)	1 (0.4%)	5 (1.1%)
Neurotoxicity	5 (2.1%)	0	5 (1.1%)
Somnolence	1 (0.4%)	3 (1.3%)	4 (0.8%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
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Table 302.1.2000.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Dysaesthesia	2 (0.8%)	1 (0.4%)	3 (0.6%)
Cerebral infarction	0	2 (0.8%)	2 (0.4%)
Optic neuritis	2 (0.8%)	0	2 (0.4%)
Altered state of consciousness	1 (0.4%)	0	1 (0.2%)
Amnesia	0	1 (0.4%)	1 (0.2%)
Amputation stump pain	1 (0.4%)	0	1 (0.2%)
Aphasia	1 (0.4%)	0	1 (0.2%)
Brain fog	0	1 (0.4%)	1 (0.2%)
Burning sensation	0	1 (0.4%)	1 (0.2%)
Cerebral haemorrhage	1 (0.4%)	0	1 (0.2%)
Chronic inflammatory demyelinating polyradiculoneuropathy	1 (0.4%)	0	1 (0.2%)
Diabetic hyperglycaemic coma	1 (0.4%)	0	1 (0.2%)
Disturbance in attention	0	1 (0.4%)	1 (0.2%)
Dizziness postural	1 (0.4%)	0	1 (0.2%)
Dyskinesia	1 (0.4%)	0	1 (0.2%)
Epilepsy	0	1 (0.4%)	1 (0.2%)
Immune-mediated encephalitis	1 (0.4%)	0	1 (0.2%)
Intercostal neuralgia	0	1 (0.4%)	1 (0.2%)
Loss of consciousness	1 (0.4%)	0	1 (0.2%)
Lumbar radiculopathy	1 (0.4%)	0	1 (0.2%)
Memory impairment	0	1 (0.4%)	1 (0.2%)
Metabolic encephalopathy	0	1 (0.4%)	1 (0.2%)
Neuralgia	1 (0.4%)	0	1 (0.2%)
Partial seizures	1 (0.4%)	0	1 (0.2%)
Presyncope	0	1 (0.4%)	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Pronator teres syndrome	1 (0.4%)	0	1 (0.2%)
Radiculopathy	0	1 (0.4%)	1 (0.2%)
Seizure	1 (0.4%)	0	1 (0.2%)
Senile dementia	1 (0.4%)	0	1 (0.2%)
Ulnar nerve palsy	1 (0.4%)	0	1 (0.2%)
Skin and subcutaneous tissue disorders	204 (85.4%)	61 (25.8%)	265 (55.8%)
Pruritus	105 (43.9%)	13 (5.5%)	118 (24.8%)
Alopecia	91 (38.1%)	22 (9.3%)	113 (23.8%)
Rash maculo-papular	76 (31.8%)	9 (3.8%)	85 (17.9%)
Dry skin	39 (16.3%)	4 (1.7%)	43 (9.1%)
Rash macular	27 (11.3%)	2 (0.8%)	29 (6.1%)
Rash papular	21 (8.8%)	1 (0.4%)	22 (4.6%)
Skin hyperpigmentation	17 (7.1%)	0	17 (3.6%)
Erythema	12 (5.0%)	3 (1.3%)	15 (3.2%)
Dermatitis bullous	14 (5.9%)	0	14 (2.9%)
Eczema	12 (5.0%)	2 (0.8%)	14 (2.9%)
Rash erythematous	12 (5.0%)	2 (0.8%)	14 (2.9%)
Dermatitis	13 (5.4%)	0	13 (2.7%)
Hyperhidrosis	7 (2.9%)	4 (1.7%)	11 (2.3%)
Blister	10 (4.2%)	0	10 (2.1%)
Skin ulcer	9 (3.8%)	1 (0.4%)	10 (2.1%)
Dermatitis acneiform	7 (2.9%)	2 (0.8%)	9 (1.9%)
Rash	8 (3.3%)	1 (0.4%)	9 (1.9%)
Skin exfoliation	8 (3.3%)	0	8 (1.7%)
Night sweats	3 (1.3%)	4 (1.7%)	7 (1.5%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Rash pruritic	5 (2.1%)	1 (0.4%)	6 (1.3%)
Rash vesicular	5 (2.1%)	0	5 (1.1%)
Erythema multiforme	3 (1.3%)	1 (0.4%)	4 (0.8%)
Skin discolouration	4 (1.7%)	0	4 (0.8%)
Toxic skin eruption	4 (1.7%)	0	4 (0.8%)
Urticaria	4 (1.7%)	0	4 (0.8%)
Dermal cyst	3 (1.3%)	0	3 (0.6%)
Dermatitis exfoliative generalised	3 (1.3%)	0	3 (0.6%)
Onycholysis	3 (1.3%)	0	3 (0.6%)
Psoriasis	3 (1.3%)	0	3 (0.6%)
Skin hypopigmentation	3 (1.3%)	0	3 (0.6%)
Vitiligo	3 (1.3%)	0	3 (0.6%)
Dermatitis contact	2 (0.8%)	0	2 (0.4%)
Hyperkeratosis	2 (0.8%)	0	2 (0.4%)
Lichenoid keratosis	2 (0.8%)	0	2 (0.4%)
Nail dystrophy	2 (0.8%)	0	2 (0.4%)
Onychoclasis	2 (0.8%)	0	2 (0.4%)
Onychomadesis	2 (0.8%)	0	2 (0.4%)
Palmar-plantar erythrodysaesthesia syndrome	2 (0.8%)	0	2 (0.4%)
Purpura	2 (0.8%)	0	2 (0.4%)
Skin plaque	2 (0.8%)	0	2 (0.4%)
Toxic erythema of chemotherapy	2 (0.8%)	0	2 (0.4%)
Acne	1 (0.4%)	0	1 (0.2%)
Actinic keratosis	1 (0.4%)	0	1 (0.2%)
Angiolymphoid hyperplasia with eosinophilia	1 (0.4%)	0	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Anhidrosis	1 (0.4%)	0	1 (0.2%)
Brow ptosis	0	1 (0.4%)	1 (0.2%)
Cellulite	1 (0.4%)	0	1 (0.2%)
Cutaneous vasculitis	1 (0.4%)	0	1 (0.2%)
Dermatitis psoriasiform	1 (0.4%)	0	1 (0.2%)
Dermatomyositis	1 (0.4%)	0	1 (0.2%)
Drug eruption	1 (0.4%)	0	1 (0.2%)
Dyshidrotic eczema	1 (0.4%)	0	1 (0.2%)
Hair colour changes	0	1 (0.4%)	1 (0.2%)
Hand dermatitis	1 (0.4%)	0	1 (0.2%)
Lentigo	1 (0.4%)	0	1 (0.2%)
Lichen sclerosus	1 (0.4%)	0	1 (0.2%)
Madarosis	1 (0.4%)	0	1 (0.2%)
Nail discolouration	1 (0.4%)	0	1 (0.2%)
Nail discomfort	1 (0.4%)	0	1 (0.2%)
Nail toxicity	1 (0.4%)	0	1 (0.2%)
Pain of skin	1 (0.4%)	0	1 (0.2%)
Papule	0	1 (0.4%)	1 (0.2%)
Paradoxical psoriasis	1 (0.4%)	0	1 (0.2%)
Pemphigoid	1 (0.4%)	0	1 (0.2%)
Penile ulceration	1 (0.4%)	0	1 (0.2%)
Petechiae	0	1 (0.4%)	1 (0.2%)
Plantar erythema	1 (0.4%)	0	1 (0.2%)
Rash morbilliform	1 (0.4%)	0	1 (0.2%)
Seborrhoeic dermatitis	1 (0.4%)	0	1 (0.2%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Sensitive skin	1 (0.4%)	0	1 (0.2%)
SJS-TEN overlap	1 (0.4%)	0	1 (0.2%)
Skin depigmentation	1 (0.4%)	0	1 (0.2%)
Skin fissures	1 (0.4%)	0	1 (0.2%)
Skin fragility	1 (0.4%)	0	1 (0.2%)
Skin haemorrhage	0	1 (0.4%)	1 (0.2%)
Skin irritation	1 (0.4%)	0	1 (0.2%)
Skin toxicity	1 (0.4%)	0	1 (0.2%)
Subcutaneous emphysema	1 (0.4%)	0	1 (0.2%)
Symmetrical drug-related intertriginous and flexural exanthema	1 (0.4%)	0	1 (0.2%)
Toxic epidermal necrolysis	1 (0.4%)	0	1 (0.2%)
Xeroderma	1 (0.4%)	0	1 (0.2%)
Investigations	134 (56.1%)	107 (45.3%)	241 (50.7%)
Weight decreased	73 (30.5%)	23 (9.7%)	96 (20.2%)
Alanine aminotransferase increased	49 (20.5%)	13 (5.5%)	62 (13.1%)
Aspartate aminotransferase increased	47 (19.7%)	10 (4.2%)	57 (12.0%)
Blood creatinine increased	12 (5.0%)	27 (11.4%)	39 (8.2%)
Neutrophil count decreased	7 (2.9%)	32 (13.6%)	39 (8.2%)
Platelet count decreased	1 (0.4%)	30 (12.7%)	31 (6.5%)
Blood alkaline phosphatase increased	12 (5.0%)	8 (3.4%)	20 (4.2%)
Lipase increased	17 (7.1%)	0	17 (3.6%)
White blood cell count decreased	1 (0.4%)	14 (5.9%)	15 (3.2%)
Weight increased	6 (2.5%)	8 (3.4%)	14 (2.9%)
Gamma-glutamyltransferase increased	8 (3.3%)	2 (0.8%)	10 (2.1%)
Amylase increased	7 (2.9%)	2 (0.8%)	9 (1.9%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Blood lactate dehydrogenase increased	7 (2.9%)	1 (0.4%)	8 (1.7%)
Blood creatine phosphokinase increased	7 (2.9%)	0	7 (1.5%)
Blood bilirubin increased	5 (2.1%)	1 (0.4%)	6 (1.3%)
Lymphocyte count decreased	2 (0.8%)	1 (0.4%)	3 (0.6%)
Neutrophil count increased	2 (0.8%)	1 (0.4%)	3 (0.6%)
Blood bicarbonate decreased	2 (0.8%)	0	2 (0.4%)
Blood glucose increased	2 (0.8%)	0	2 (0.4%)
Blood thyroid stimulating hormone increased	2 (0.8%)	0	2 (0.4%)
C-reactive protein increased	1 (0.4%)	1 (0.4%)	2 (0.4%)
Creatinine renal clearance decreased	0	2 (0.8%)	2 (0.4%)
Troponin I increased	2 (0.8%)	0	2 (0.4%)
Apolipoprotein A-I increased	1 (0.4%)	0	1 (0.2%)
Basophil count increased	1 (0.4%)	0	1 (0.2%)
Blood albumin decreased	1 (0.4%)	0	1 (0.2%)
Blood creatine increased	1 (0.4%)	0	1 (0.2%)
Blood potassium increased	0	1 (0.4%)	1 (0.2%)
Blood triglycerides increased	1 (0.4%)	0	1 (0.2%)
Blood urea increased	1 (0.4%)	0	1 (0.2%)
Body temperature increased	1 (0.4%)	0	1 (0.2%)
Electrocardiogram QT prolonged	1 (0.4%)	0	1 (0.2%)
Glomerular filtration rate decreased	0	1 (0.4%)	1 (0.2%)
Glycosylated haemoglobin increased	1 (0.4%)	0	1 (0.2%)
International normalised ratio increased	1 (0.4%)	0	1 (0.2%)
Lymph node palpable	0	1 (0.4%)	1 (0.2%)
Nitrite urine present	1 (0.4%)	0	1 (0.2%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Oxygen saturation decreased	1 (0.4%)	0	1 (0.2%)
SARS-CoV-2 test positive	1 (0.4%)	0	1 (0.2%)
Thyroxine increased	1 (0.4%)	0	1 (0.2%)
Urine output decreased	1 (0.4%)	0	1 (0.2%)
White blood cell count increased	1 (0.4%)	0	1 (0.2%)
Metabolism and nutrition disorders	132 (55.2%)	109 (46.2%)	241 (50.7%)
Decreased appetite	72 (30.1%)	59 (25.0%)	131 (27.6%)
Hyperglycaemia	44 (18.4%)	6 (2.5%)	50 (10.5%)
Hypokalaemia	16 (6.7%)	16 (6.8%)	32 (6.7%)
Hyponatraemia	12 (5.0%)	19 (8.1%)	31 (6.5%)
Hypomagnesaemia	9 (3.8%)	20 (8.5%)	29 (6.1%)
Dehydration	7 (2.9%)	9 (3.8%)	16 (3.4%)
Hypophosphataemia	9 (3.8%)	7 (3.0%)	16 (3.4%)
Hyperkalaemia	5 (2.1%)	7 (3.0%)	12 (2.5%)
Hypocalcaemia	7 (2.9%)	5 (2.1%)	12 (2.5%)
Hypercalcaemia	6 (2.5%)	3 (1.3%)	9 (1.9%)
Hyperuricaemia	7 (2.9%)	0	7 (1.5%)
Hypoalbuminaemia	5 (2.1%)	2 (0.8%)	7 (1.5%)
Diabetes mellitus	4 (1.7%)	2 (0.8%)	6 (1.3%)
Hyperamylasaemia	2 (0.8%)	2 (0.8%)	4 (0.8%)
Hypercreatininaemia	3 (1.3%)	1 (0.4%)	4 (0.8%)
Hyperlipasaemia	2 (0.8%)	2 (0.8%)	4 (0.8%)
Hyperphosphataemia	4 (1.7%)	0	4 (0.8%)
Hypoglycaemia	3 (1.3%)	1 (0.4%)	4 (0.8%)
Gout	2 (0.8%)	1 (0.4%)	3 (0.6%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Hypercholesterolaemia	3 (1.3%)	0	3 (0.6%)
Type 2 diabetes mellitus	3 (1.3%)	0	3 (0.6%)
Glucose tolerance impaired	2 (0.8%)	0	2 (0.4%)
Hyperlipidaemia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Hypochloraemia	0	2 (0.8%)	2 (0.4%)
Metabolic acidosis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Alkalosis	0	1 (0.4%)	1 (0.2%)
Cachexia	1 (0.4%)	0	1 (0.2%)
Dyslipidaemia	1 (0.4%)	0	1 (0.2%)
Electrolyte imbalance	0	1 (0.4%)	1 (0.2%)
Folate deficiency	0	1 (0.4%)	1 (0.2%)
Hypertriglyceridaemia	1 (0.4%)	0	1 (0.2%)
Hypoproteinaemia	0	1 (0.4%)	1 (0.2%)
Hypovolaemia	1 (0.4%)	0	1 (0.2%)
Lactic acidosis	1 (0.4%)	0	1 (0.2%)
Malnutrition	1 (0.4%)	0	1 (0.2%)
Tumour lysis syndrome	1 (0.4%)	0	1 (0.2%)
Vitamin B12 deficiency	1 (0.4%)	0	1 (0.2%)
Vitamin D deficiency	1 (0.4%)	0	1 (0.2%)
Blood and lymphatic system disorders	69 (28.9%)	170 (72.0%)	239 (50.3%)
Anaemia	41 (17.2%)	132 (55.9%)	173 (36.4%)
Neutropenia	21 (8.8%)	86 (36.4%)	107 (22.5%)
Thrombocytopenia	9 (3.8%)	57 (24.2%)	66 (13.9%)
Leukopenia	9 (3.8%)	26 (11.0%)	35 (7.4%)
Febrile neutropenia	3 (1.3%)	4 (1.7%)	7 (1.5%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Lymphopenia	2 (0.8%)	5 (2.1%)	7 (1.5%)
Leukocytosis	4 (1.7%)	1 (0.4%)	5 (1.1%)
Pancytopenia	0	4 (1.7%)	4 (0.8%)
Thrombocytosis	2 (0.8%)	2 (0.8%)	4 (0.8%)
Eosinophilia	2 (0.8%)	0	2 (0.4%)
Anaemia of malignant disease	1 (0.4%)	0	1 (0.2%)
Haemolytic anaemia	1 (0.4%)	0	1 (0.2%)
Lymphadenitis	0	1 (0.4%)	1 (0.2%)
Lymphadenopathy	0	1 (0.4%)	1 (0.2%)
Neutrophilia	0	1 (0.4%)	1 (0.2%)
Platelet toxicity	0	1 (0.4%)	1 (0.2%)
Splenomegaly	1 (0.4%)	0	1 (0.2%)
Infections and infestations	145 (60.7%)	85 (36.0%)	230 (48.4%)
Urinary tract infection	43 (18.0%)	44 (18.6%)	87 (18.3%)
COVID-19	43 (18.0%)	12 (5.1%)	55 (11.6%)
Conjunctivitis	18 (7.5%)	0	18 (3.8%)
Pneumonia	12 (5.0%)	4 (1.7%)	16 (3.4%)
Oral candidiasis	9 (3.8%)	4 (1.7%)	13 (2.7%)
Upper respiratory tract infection	11 (4.6%)	1 (0.4%)	12 (2.5%)
Cellulitis	7 (2.9%)	1 (0.4%)	8 (1.7%)
Sepsis	2 (0.8%)	6 (2.5%)	8 (1.7%)
COVID-19 pneumonia	4 (1.7%)	2 (0.8%)	6 (1.3%)
Folliculitis	5 (2.1%)	1 (0.4%)	6 (1.3%)
Bronchitis	5 (2.1%)	0	5 (1.1%)
Cystitis	2 (0.8%)	3 (1.3%)	5 (1.1%)

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Table 302.1.2000.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Nasopharyngitis	4 (1.7%)	1 (0.4%)	5 (1.1%)
Respiratory tract infection	4 (1.7%)	1 (0.4%)	5 (1.1%)
Rhinitis	5 (2.1%)	0	5 (1.1%)
Skin infection	4 (1.7%)	1 (0.4%)	5 (1.1%)
Fungal skin infection	3 (1.3%)	1 (0.4%)	4 (0.8%)
Herpes zoster	4 (1.7%)	0	4 (0.8%)
Bacteriuria	1 (0.4%)	2 (0.8%)	3 (0.6%)
Device related infection	1 (0.4%)	2 (0.8%)	3 (0.6%)
Gingivitis	2 (0.8%)	1 (0.4%)	3 (0.6%)
Lower respiratory tract infection	2 (0.8%)	1 (0.4%)	3 (0.6%)
Pharyngitis	2 (0.8%)	1 (0.4%)	3 (0.6%)
Rash pustular	2 (0.8%)	1 (0.4%)	3 (0.6%)
Urosepsis	1 (0.4%)	2 (0.8%)	3 (0.6%)
Wound infection	1 (0.4%)	2 (0.8%)	3 (0.6%)
Bacteraemia	2 (0.8%)	0	2 (0.4%)
Influenza	2 (0.8%)	0	2 (0.4%)
Kidney infection	1 (0.4%)	1 (0.4%)	2 (0.4%)
Oral herpes	1 (0.4%)	1 (0.4%)	2 (0.4%)
Pneumonia bacterial	2 (0.8%)	0	2 (0.4%)
Pyelonephritis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Pyelonephritis chronic	0	2 (0.8%)	2 (0.4%)
Pyuria	1 (0.4%)	1 (0.4%)	2 (0.4%)
Sinusitis	2 (0.8%)	0	2 (0.4%)
Tinea cruris	1 (0.4%)	1 (0.4%)	2 (0.4%)
Abdominal abscess	0	1 (0.4%)	1 (0.2%)

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Table 302.1.2000.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Abdominal sepsis	1 (0.4%)	0	1 (0.2%)
Body tinea	1 (0.4%)	0	1 (0.2%)
Candida infection	1 (0.4%)	0	1 (0.2%)
Catheter site infection	1 (0.4%)	0	1 (0.2%)
Clostridium difficile infection	1 (0.4%)	0	1 (0.2%)
Diverticulitis	1 (0.4%)	0	1 (0.2%)
Ear infection	1 (0.4%)	0	1 (0.2%)
Epididymitis	0	1 (0.4%)	1 (0.2%)
Erysipelas	1 (0.4%)	0	1 (0.2%)
Escherichia infection	0	1 (0.4%)	1 (0.2%)
Escherichia urinary tract infection	0	1 (0.4%)	1 (0.2%)
Eyelid infection	1 (0.4%)	0	1 (0.2%)
Fungal foot infection	1 (0.4%)	0	1 (0.2%)
Furuncle	0	1 (0.4%)	1 (0.2%)
Gastroenteritis viral	1 (0.4%)	0	1 (0.2%)
Groin abscess	0	1 (0.4%)	1 (0.2%)
Herpes dermatitis	1 (0.4%)	0	1 (0.2%)
Hordeolum	0	1 (0.4%)	1 (0.2%)
Infectious pleural effusion	1 (0.4%)	0	1 (0.2%)
Injection site infection	0	1 (0.4%)	1 (0.2%)
Klebsiella urinary tract infection	1 (0.4%)	0	1 (0.2%)
Laryngopharyngitis	1 (0.4%)	0	1 (0.2%)
Lip infection	1 (0.4%)	0	1 (0.2%)
Localised infection	1 (0.4%)	0	1 (0.2%)
Lung abscess	1 (0.4%)	0	1 (0.2%)

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Table 302.1.2000.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Neutropenic sepsis	0	1 (0.4%)	1 (0.2%)
Oesophageal candidiasis	1 (0.4%)	0	1 (0.2%)
Onychomycosis	1 (0.4%)	0	1 (0.2%)
Oral fungal infection	1 (0.4%)	0	1 (0.2%)
Parotitis	1 (0.4%)	0	1 (0.2%)
Pelvic infection	1 (0.4%)	0	1 (0.2%)
Penile infection	1 (0.4%)	0	1 (0.2%)
Perineal abscess	0	1 (0.4%)	1 (0.2%)
Periodontitis	1 (0.4%)	0	1 (0.2%)
Pharyngitis streptococcal	1 (0.4%)	0	1 (0.2%)
Pneumocystis jirovecii pneumonia	1 (0.4%)	0	1 (0.2%)
Pneumonia haemophilus	0	1 (0.4%)	1 (0.2%)
Postoperative wound infection	1 (0.4%)	0	1 (0.2%)
Respiratory syncytial virus infection	0	1 (0.4%)	1 (0.2%)
Skin bacterial infection	1 (0.4%)	0	1 (0.2%)
Skin candida	0	1 (0.4%)	1 (0.2%)
Soft tissue infection	0	1 (0.4%)	1 (0.2%)
Staphylococcal bacteraemia	1 (0.4%)	0	1 (0.2%)
Subcutaneous abscess	1 (0.4%)	0	1 (0.2%)
Tinea pedis	1 (0.4%)	0	1 (0.2%)
Tonsillitis	0	1 (0.4%)	1 (0.2%)
Tooth abscess	1 (0.4%)	0	1 (0.2%)
Urinary tract infection bacterial	0	1 (0.4%)	1 (0.2%)
Urinary tract infection enterococcal	0	1 (0.4%)	1 (0.2%)
Urinary tract infection pseudomonal	0	1 (0.4%)	1 (0.2%)

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Table 302.1.2000.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Urinary tract infection staphylococcal	1 (0.4%)	0	1 (0.2%)
Viral infection	0	1 (0.4%)	1 (0.2%)
Viral upper respiratory tract infection	0	1 (0.4%)	1 (0.2%)
Vulvitis	0	1 (0.4%)	1 (0.2%)
Respiratory, thoracic and mediastinal disorders	100 (41.8%)	83 (35.2%)	183 (38.5%)
Dyspnoea	29 (12.1%)	24 (10.2%)	53 (11.2%)
Cough	26 (10.9%)	13 (5.5%)	39 (8.2%)
Hiccups	7 (2.9%)	22 (9.3%)	29 (6.1%)
Epistaxis	6 (2.5%)	19 (8.1%)	25 (5.3%)
Pulmonary embolism	8 (3.3%)	15 (6.4%)	23 (4.8%)
Pneumonitis	17 (7.1%)	1 (0.4%)	18 (3.8%)
Dysphonia	13 (5.4%)	4 (1.7%)	17 (3.6%)
Rhinorrhoea	8 (3.3%)	6 (2.5%)	14 (2.9%)
Nasal congestion	9 (3.8%)	1 (0.4%)	10 (2.1%)
Oropharyngeal pain	5 (2.1%)	4 (1.7%)	9 (1.9%)
Productive cough	3 (1.3%)	4 (1.7%)	7 (1.5%)
Dyspnoea exertional	3 (1.3%)	2 (0.8%)	5 (1.1%)
Immune-mediated lung disease	4 (1.7%)	0	4 (0.8%)
Interstitial lung disease	4 (1.7%)	0	4 (0.8%)
Aphonia	2 (0.8%)	1 (0.4%)	3 (0.6%)
Upper-airway cough syndrome	3 (1.3%)	0	3 (0.6%)
Chronic obstructive pulmonary disease	1 (0.4%)	1 (0.4%)	2 (0.4%)
Haemoptysis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Hypoxia	2 (0.8%)	0	2 (0.4%)
Nasal dryness	2 (0.8%)	0	2 (0.4%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Painful respiration	1 (0.4%)	1 (0.4%)	2 (0.4%)
Pleural effusion	1 (0.4%)	1 (0.4%)	2 (0.4%)
Pneumothorax	2 (0.8%)	0	2 (0.4%)
Respiratory failure	2 (0.8%)	0	2 (0.4%)
Rhinitis allergic	2 (0.8%)	0	2 (0.4%)
Acute pulmonary oedema	1 (0.4%)	0	1 (0.2%)
Acute respiratory failure	1 (0.4%)	0	1 (0.2%)
Aspiration	1 (0.4%)	0	1 (0.2%)
Catarrh	0	1 (0.4%)	1 (0.2%)
Dry throat	1 (0.4%)	0	1 (0.2%)
Laryngeal haemorrhage	0	1 (0.4%)	1 (0.2%)
Laryngeal inflammation	0	1 (0.4%)	1 (0.2%)
Lung disorder	1 (0.4%)	0	1 (0.2%)
Nasal polyps	1 (0.4%)	0	1 (0.2%)
Nocturnal dyspnoea	1 (0.4%)	0	1 (0.2%)
Organising pneumonia	1 (0.4%)	0	1 (0.2%)
Orthopnoea	1 (0.4%)	0	1 (0.2%)
Pharyngeal dyskinesia	1 (0.4%)	0	1 (0.2%)
Pharyngeal inflammation	1 (0.4%)	0	1 (0.2%)
Pleuritic pain	1 (0.4%)	0	1 (0.2%)
Pulmonary fibrosis	1 (0.4%)	0	1 (0.2%)
Pulmonary oedema	0	1 (0.4%)	1 (0.2%)
Pulmonary pain	0	1 (0.4%)	1 (0.2%)
Pulmonary toxicity	1 (0.4%)	0	1 (0.2%)
Respiratory distress	1 (0.4%)	0	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Sinus congestion	1 (0.4%)	0	1 (0.2%)
Musculoskeletal and connective tissue disorders	108 (45.2%)	68 (28.8%)	176 (37.1%)
Back pain	37 (15.5%)	21 (8.9%)	58 (12.2%)
Arthralgia	36 (15.1%)	11 (4.7%)	47 (9.9%)
Pain in extremity	21 (8.8%)	15 (6.4%)	36 (7.6%)
Myalgia	17 (7.1%)	7 (3.0%)	24 (5.1%)
Muscular weakness	13 (5.4%)	4 (1.7%)	17 (3.6%)
Flank pain	7 (2.9%)	7 (3.0%)	14 (2.9%)
Bone pain	4 (1.7%)	7 (3.0%)	11 (2.3%)
Muscle spasms	9 (3.8%)	1 (0.4%)	10 (2.1%)
Musculoskeletal chest pain	5 (2.1%)	1 (0.4%)	6 (1.3%)
Musculoskeletal discomfort	3 (1.3%)	3 (1.3%)	6 (1.3%)
Neck pain	4 (1.7%)	2 (0.8%)	6 (1.3%)
Arthritis	4 (1.7%)	1 (0.4%)	5 (1.1%)
Gouty arthritis	3 (1.3%)	0	3 (0.6%)
Limb discomfort	2 (0.8%)	1 (0.4%)	3 (0.6%)
Musculoskeletal pain	3 (1.3%)	0	3 (0.6%)
Musculoskeletal stiffness	2 (0.8%)	1 (0.4%)	3 (0.6%)
Joint stiffness	1 (0.4%)	1 (0.4%)	2 (0.4%)
Myositis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Osteopenia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Pain in jaw	0	2 (0.8%)	2 (0.4%)
Tendon pain	0	2 (0.8%)	2 (0.4%)
Arthropathy	1 (0.4%)	0	1 (0.2%)
Bone lesion	1 (0.4%)	0	1 (0.2%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Groin pain	0	1 (0.4%)	1 (0.2%)
Hypercreatinaemia	0	1 (0.4%)	1 (0.2%)
Joint range of motion decreased	1 (0.4%)	0	1 (0.2%)
Mobility decreased	0	1 (0.4%)	1 (0.2%)
Osteoarthritis	1 (0.4%)	0	1 (0.2%)
Osteoporosis	1 (0.4%)	0	1 (0.2%)
Pathological fracture	0	1 (0.4%)	1 (0.2%)
Rhabdomyolysis	0	1 (0.4%)	1 (0.2%)
Sjogren's syndrome	1 (0.4%)	0	1 (0.2%)
Renal and urinary disorders	74 (31.0%)	76 (32.2%)	150 (31.6%)
Haematuria	31 (13.0%)	20 (8.5%)	51 (10.7%)
Acute kidney injury	11 (4.6%)	25 (10.6%)	36 (7.6%)
Dysuria	13 (5.4%)	8 (3.4%)	21 (4.4%)
Urinary retention	8 (3.3%)	9 (3.8%)	17 (3.6%)
Pollakiuria	8 (3.3%)	6 (2.5%)	14 (2.9%)
Renal impairment	4 (1.7%)	5 (2.1%)	9 (1.9%)
Renal failure	2 (0.8%)	5 (2.1%)	7 (1.5%)
Hydronephrosis	4 (1.7%)	2 (0.8%)	6 (1.3%)
Chronic kidney disease	1 (0.4%)	4 (1.7%)	5 (1.1%)
Leukocyturia	3 (1.3%)	2 (0.8%)	5 (1.1%)
Nocturia	1 (0.4%)	4 (1.7%)	5 (1.1%)
Urinary tract pain	2 (0.8%)	3 (1.3%)	5 (1.1%)
Chromaturia	4 (1.7%)	0	4 (0.8%)
Bladder spasm	3 (1.3%)	0	3 (0.6%)
Proteinuria	2 (0.8%)	1 (0.4%)	3 (0.6%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Bladder pain	2 (0.8%)	0	2 (0.4%)
Calculus bladder	2 (0.8%)	0	2 (0.4%)
Micturition urgency	1 (0.4%)	1 (0.4%)	2 (0.4%)
Polyuria	1 (0.4%)	1 (0.4%)	2 (0.4%)
Urinary incontinence	2 (0.8%)	0	2 (0.4%)
Calculus urinary	1 (0.4%)	0	1 (0.2%)
Cystitis noninfective	0	1 (0.4%)	1 (0.2%)
Immune-mediated nephritis	1 (0.4%)	0	1 (0.2%)
Nephropathy	0	1 (0.4%)	1 (0.2%)
Oliguria	1 (0.4%)	0	1 (0.2%)
Postrenal failure	1 (0.4%)	0	1 (0.2%)
Prerenal failure	0	1 (0.4%)	1 (0.2%)
Renal colic	0	1 (0.4%)	1 (0.2%)
Renal pain	0	1 (0.4%)	1 (0.2%)
Stress urinary incontinence	1 (0.4%)	0	1 (0.2%)
Urethral stenosis	1 (0.4%)	0	1 (0.2%)
Urinary hesitation	0	1 (0.4%)	1 (0.2%)
Urinary tract obstruction	1 (0.4%)	0	1 (0.2%)
Urine abnormality	0	1 (0.4%)	1 (0.2%)
Urine odour abnormal	1 (0.4%)	0	1 (0.2%)
Eye disorders	88 (36.8%)	14 (5.9%)	102 (21.5%)
Dry eye	29 (12.1%)	3 (1.3%)	32 (6.7%)
Lacrimation increased	25 (10.5%)	1 (0.4%)	26 (5.5%)
Vision blurred	16 (6.7%)	4 (1.7%)	20 (4.2%)
Cataract	10 (4.2%)	1 (0.4%)	11 (2.3%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Blepharitis	6 (2.5%)	0	6 (1.3%)
Eye irritation	5 (2.1%)	0	5 (1.1%)
Keratitis	4 (1.7%)	0	4 (0.8%)
Visual acuity reduced	4 (1.7%)	0	4 (0.8%)
Vitreous floaters	2 (0.8%)	2 (0.8%)	4 (0.8%)
Xerophthalmia	4 (1.7%)	0	4 (0.8%)
Eye pruritus	3 (1.3%)	0	3 (0.6%)
Conjunctivitis allergic	2 (0.8%)	0	2 (0.4%)
Eye discharge	2 (0.8%)	0	2 (0.4%)
Eye pain	2 (0.8%)	0	2 (0.4%)
Eyelids pruritus	1 (0.4%)	1 (0.4%)	2 (0.4%)
Photopsia	0	2 (0.8%)	2 (0.4%)
Visual impairment	2 (0.8%)	0	2 (0.4%)
Asthenopia	1 (0.4%)	0	1 (0.2%)
Conjunctival haemorrhage	0	1 (0.4%)	1 (0.2%)
Conjunctival irritation	1 (0.4%)	0	1 (0.2%)
Corneal erosion	1 (0.4%)	0	1 (0.2%)
Corneal toxicity	1 (0.4%)	0	1 (0.2%)
Diplopia	1 (0.4%)	0	1 (0.2%)
Eczema eyelids	1 (0.4%)	0	1 (0.2%)
Entropion	1 (0.4%)	0	1 (0.2%)
Exposure keratitis	1 (0.4%)	0	1 (0.2%)
Meibomianitis	1 (0.4%)	0	1 (0.2%)
Myopia	1 (0.4%)	0	1 (0.2%)
Ocular hyperaemia	1 (0.4%)	0	1 (0.2%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Periorbital oedema	0	1 (0.4%)	1 (0.2%)
Photophobia	1 (0.4%)	0	1 (0.2%)
Pinguecula	1 (0.4%)	0	1 (0.2%)
Retinal degeneration	1 (0.4%)	0	1 (0.2%)
Retinal detachment	1 (0.4%)	0	1 (0.2%)
Retinal tear	1 (0.4%)	0	1 (0.2%)
Retinopathy hypertensive	1 (0.4%)	0	1 (0.2%)
Uveitis	1 (0.4%)	0	1 (0.2%)
Vitreous haemorrhage	1 (0.4%)	0	1 (0.2%)
Vascular disorders	38 (15.9%)	46 (19.5%)	84 (17.7%)
Hypertension	13 (5.4%)	17 (7.2%)	30 (6.3%)
Hypotension	7 (2.9%)	6 (2.5%)	13 (2.7%)
Deep vein thrombosis	2 (0.8%)	8 (3.4%)	10 (2.1%)
Hot flush	5 (2.1%)	0	5 (1.1%)
Phlebitis	0	5 (2.1%)	5 (1.1%)
Superficial vein thrombosis	0	5 (2.1%)	5 (1.1%)
Thrombophlebitis	1 (0.4%)	4 (1.7%)	5 (1.1%)
Flushing	2 (0.8%)	1 (0.4%)	3 (0.6%)
Lymphoedema	2 (0.8%)	1 (0.4%)	3 (0.6%)
Orthostatic hypotension	2 (0.8%)	1 (0.4%)	3 (0.6%)
Peripheral embolism	0	3 (1.3%)	3 (0.6%)
Capillary fragility	1 (0.4%)	0	1 (0.2%)
Intermittent claudication	1 (0.4%)	0	1 (0.2%)
Lymphocele	0	1 (0.4%)	1 (0.2%)
Pallor	1 (0.4%)	0	1 (0.2%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Pelvic venous thrombosis	1 (0.4%)	0	1 (0.2%)
Peripheral arterial occlusive disease	1 (0.4%)	0	1 (0.2%)
Phlebosclerosis	0	1 (0.4%)	1 (0.2%)
Vascular pain	1 (0.4%)	0	1 (0.2%)
Venous thrombosis	0	1 (0.4%)	1 (0.2%)
Psychiatric disorders	39 (16.3%)	24 (10.2%)	63 (13.3%)
Insomnia	22 (9.2%)	14 (5.9%)	36 (7.6%)
Anxiety	10 (4.2%)	3 (1.3%)	13 (2.7%)
Depression	5 (2.1%)	5 (2.1%)	10 (2.1%)
Delirium	4 (1.7%)	0	4 (0.8%)
Confusional state	3 (1.3%)	0	3 (0.6%)
Disorientation	1 (0.4%)	1 (0.4%)	2 (0.4%)
Affective disorder	1 (0.4%)	0	1 (0.2%)
Agitation	1 (0.4%)	0	1 (0.2%)
Depressed mood	0	1 (0.4%)	1 (0.2%)
Dysphemia	0	1 (0.4%)	1 (0.2%)
Emotional distress	0	1 (0.4%)	1 (0.2%)
Hallucination, auditory	1 (0.4%)	0	1 (0.2%)
Initial insomnia	1 (0.4%)	0	1 (0.2%)
Mixed anxiety and depressive disorder	1 (0.4%)	0	1 (0.2%)
Sleep disorder	1 (0.4%)	0	1 (0.2%)
Suicidal ideation	1 (0.4%)	0	1 (0.2%)
Ear and labyrinth disorders	17 (7.1%)	33 (14.0%)	50 (10.5%)
Tinnitus	5 (2.1%)	27 (11.4%)	32 (6.7%)
Hypoacusis	2 (0.8%)	3 (1.3%)	5 (1.1%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Vertigo	5 (2.1%)	0	5 (1.1%)
Ear discomfort	1 (0.4%)	1 (0.4%)	2 (0.4%)
Ear pain	2 (0.8%)	0	2 (0.4%)
Ototoxicity	0	2 (0.8%)	2 (0.4%)
Presbyacusis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Deafness	0	1 (0.4%)	1 (0.2%)
Vestibular disorder	1 (0.4%)	0	1 (0.2%)
Injury, poisoning and procedural complications	34 (14.2%)	16 (6.8%)	50 (10.5%)
Fall	11 (4.6%)	3 (1.3%)	14 (2.9%)
Urinary tract stoma complication	5 (2.1%)	2 (0.8%)	7 (1.5%)
Contusion	3 (1.3%)	1 (0.4%)	4 (0.8%)
Infusion related reaction	2 (0.8%)	2 (0.8%)	4 (0.8%)
Skin laceration	3 (1.3%)	1 (0.4%)	4 (0.8%)
Skin abrasion	2 (0.8%)	1 (0.4%)	3 (0.6%)
Thermal burn	1 (0.4%)	1 (0.4%)	2 (0.4%)
Eschar	1 (0.4%)	0	1 (0.2%)
Eye contusion	1 (0.4%)	0	1 (0.2%)
Fibula fracture	1 (0.4%)	0	1 (0.2%)
Foot fracture	1 (0.4%)	0	1 (0.2%)
Heat stroke	1 (0.4%)	0	1 (0.2%)
Ligament sprain	0	1 (0.4%)	1 (0.2%)
Limb traumatic amputation	1 (0.4%)	0	1 (0.2%)
Muscle rupture	0	1 (0.4%)	1 (0.2%)
Overdose	1 (0.4%)	0	1 (0.2%)
Penis injury	1 (0.4%)	0	1 (0.2%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Post vaccination fever	1 (0.4%)	0	1 (0.2%)
Procedural pain	1 (0.4%)	0	1 (0.2%)
Spinal fracture	1 (0.4%)	0	1 (0.2%)
Sternal fracture	0	1 (0.4%)	1 (0.2%)
Stoma site pain	0	1 (0.4%)	1 (0.2%)
Subcutaneous haematoma	0	1 (0.4%)	1 (0.2%)
Tibia fracture	0	1 (0.4%)	1 (0.2%)
Toxicity to various agents	0	1 (0.4%)	1 (0.2%)
Urinary tract procedural complication	1 (0.4%)	0	1 (0.2%)
Urostomy complication	0	1 (0.4%)	1 (0.2%)
Wound dehiscence	1 (0.4%)	0	1 (0.2%)
Cardiac disorders	22 (9.2%)	20 (8.5%)	42 (8.8%)
Atrial fibrillation	1 (0.4%)	5 (2.1%)	6 (1.3%)
Sinus tachycardia	3 (1.3%)	3 (1.3%)	6 (1.3%)
Tachycardia	3 (1.3%)	3 (1.3%)	6 (1.3%)
Palpitations	3 (1.3%)	2 (0.8%)	5 (1.1%)
Angina pectoris	1 (0.4%)	2 (0.8%)	3 (0.6%)
Bradycardia	2 (0.8%)	0	2 (0.4%)
Cardiac arrest	2 (0.8%)	0	2 (0.4%)
Pericardial effusion	1 (0.4%)	1 (0.4%)	2 (0.4%)
Supraventricular tachycardia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Acute coronary syndrome	1 (0.4%)	0	1 (0.2%)
Acute myocardial infarction	0	1 (0.4%)	1 (0.2%)
Acute right ventricular failure	0	1 (0.4%)	1 (0.2%)
Arrhythmia	0	1 (0.4%)	1 (0.2%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Atrioventricular block complete	1 (0.4%)	0	1 (0.2%)
Bundle branch block left	1 (0.4%)	0	1 (0.2%)
Bundle branch block right	1 (0.4%)	0	1 (0.2%)
Cardio-respiratory arrest	1 (0.4%)	0	1 (0.2%)
Cardiogenic shock	0	1 (0.4%)	1 (0.2%)
Cardiomyopathy	1 (0.4%)	0	1 (0.2%)
Diastolic dysfunction	1 (0.4%)	0	1 (0.2%)
Myocardial infarction	0	1 (0.4%)	1 (0.2%)
Myocarditis	1 (0.4%)	0	1 (0.2%)
Hepatobiliary disorders	32 (13.4%)	8 (3.4%)	40 (8.4%)
Hypertransaminasaemia	10 (4.2%)	5 (2.1%)	15 (3.2%)
Hepatic function abnormal	6 (2.5%)	1 (0.4%)	7 (1.5%)
Autoimmune hepatitis	3 (1.3%)	0	3 (0.6%)
Cholecystitis	3 (1.3%)	0	3 (0.6%)
Hepatotoxicity	3 (1.3%)	0	3 (0.6%)
Hepatic cytolysis	2 (0.8%)	0	2 (0.4%)
Hepatitis	2 (0.8%)	0	2 (0.4%)
Immune-mediated hepatitis	2 (0.8%)	0	2 (0.4%)
Cholelithiasis	1 (0.4%)	0	1 (0.2%)
Hepatic cirrhosis	1 (0.4%)	0	1 (0.2%)
Hepatic pain	0	1 (0.4%)	1 (0.2%)
Hepatic steatosis	1 (0.4%)	0	1 (0.2%)
Hepatitis toxic	0	1 (0.4%)	1 (0.2%)
Hyperbilirubinaemia	1 (0.4%)	0	1 (0.2%)
Endocrine disorders	34 (14.2%)	2 (0.8%)	36 (7.6%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Hypothyroidism	23 (9.6%)	1 (0.4%)	24 (5.1%)
Hyperthyroidism	9 (3.8%)	1 (0.4%)	10 (2.1%)
Adrenal insufficiency	4 (1.7%)	0	4 (0.8%)
Autoimmune thyroiditis	1 (0.4%)	0	1 (0.2%)
Hyperparathyroidism	1 (0.4%)	0	1 (0.2%)
Hypophysitis	1 (0.4%)	0	1 (0.2%)
Thyroiditis	1 (0.4%)	0	1 (0.2%)
Reproductive system and breast disorders	19 (7.9%)	6 (2.5%)	25 (5.3%)
Pelvic pain	4 (1.7%)	3 (1.3%)	7 (1.5%)
Penile pain	2 (0.8%)	2 (0.8%)	4 (0.8%)
Balanoposthitis	2 (0.8%)	0	2 (0.4%)
Penile erythema	2 (0.8%)	0	2 (0.4%)
Vaginal discharge	2 (0.8%)	0	2 (0.4%)
Vaginal haemorrhage	1 (0.4%)	1 (0.4%)	2 (0.4%)
Atrophic vulvovaginitis	1 (0.4%)	0	1 (0.2%)
Nipple pain	1 (0.4%)	0	1 (0.2%)
Oedema genital	1 (0.4%)	0	1 (0.2%)
Prostatic obstruction	1 (0.4%)	0	1 (0.2%)
Prostatitis	1 (0.4%)	0	1 (0.2%)
Pruritus genital	1 (0.4%)	0	1 (0.2%)
Scrotal pain	1 (0.4%)	0	1 (0.2%)
Testicular pain	1 (0.4%)	0	1 (0.2%)
Vaginal erosion	1 (0.4%)	0	1 (0.2%)
Vulvovaginal dryness	1 (0.4%)	0	1 (0.2%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	13 (5.4%)	7 (3.0%)	20 (4.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Cancer pain	2 (0.8%)	3 (1.3%)	5 (1.1%)
Seborrhoeic keratosis	4 (1.7%)	0	4 (0.8%)
Tumour pain	0	2 (0.8%)	2 (0.4%)
Acrochordon	1 (0.4%)	0	1 (0.2%)
Angiofibroma	1 (0.4%)	0	1 (0.2%)
Burkitt's lymphoma	1 (0.4%)	0	1 (0.2%)
Fibrous histiocytoma	1 (0.4%)	0	1 (0.2%)
Large intestine benign neoplasm	1 (0.4%)	0	1 (0.2%)
Metastases to central nervous system	0	1 (0.4%)	1 (0.2%)
Skin papilloma	1 (0.4%)	0	1 (0.2%)
Tumour associated fever	0	1 (0.4%)	1 (0.2%)
Tumour rupture	1 (0.4%)	0	1 (0.2%)
Immune system disorders	5 (2.1%)	2 (0.8%)	7 (1.5%)
Contrast media allergy	1 (0.4%)	2 (0.8%)	3 (0.6%)
Seasonal allergy	2 (0.8%)	0	2 (0.4%)
Drug hypersensitivity	1 (0.4%)	0	1 (0.2%)
Hypersensitivity	1 (0.4%)	0	1 (0.2%)
Product issues	1 (0.4%)	3 (1.3%)	4 (0.8%)
Device occlusion	0	2 (0.8%)	2 (0.4%)
Device kink	0	1 (0.4%)	1 (0.2%)
Thrombosis in device	1 (0.4%)	0	1 (0.2%)
Congenital, familial and genetic disorders	3 (1.3%)	0	3 (0.6%)
Dermoid cyst	1 (0.4%)	0	1 (0.2%)
Dolichocolon	1 (0.4%)	0	1 (0.2%)
Hydrocele	1 (0.4%)	0	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Overall	200 (99.5%)	193 (98.0%)	393 (98.7%)
Gastrointestinal disorders	151 (75.1%)	129 (65.5%)	280 (70.4%)
Constipation	49 (24.4%)	71 (36.0%)	120 (30.2%)
Nausea	55 (27.4%)	58 (29.4%)	113 (28.4%)
Diarrhoea	77 (38.3%)	29 (14.7%)	106 (26.6%)
Vomiting	27 (13.4%)	27 (13.7%)	54 (13.6%)
Abdominal pain	24 (11.9%)	6 (3.0%)	30 (7.5%)
Stomatitis	12 (6.0%)	11 (5.6%)	23 (5.8%)
Dyspepsia	13 (6.5%)	7 (3.6%)	20 (5.0%)
Dry mouth	17 (8.5%)	1 (0.5%)	18 (4.5%)
Abdominal distension	10 (5.0%)	2 (1.0%)	12 (3.0%)
Gastrooesophageal reflux disease	6 (3.0%)	6 (3.0%)	12 (3.0%)
Abdominal pain upper	5 (2.5%)	5 (2.5%)	10 (2.5%)
Dysphagia	7 (3.5%)	0	7 (1.8%)
Mouth ulceration	5 (2.5%)	1 (0.5%)	6 (1.5%)
Abdominal pain lower	1 (0.5%)	4 (2.0%)	5 (1.3%)
Haemorrhoids	4 (2.0%)	1 (0.5%)	5 (1.3%)
Gastritis	3 (1.5%)	1 (0.5%)	4 (1.0%)
Toothache	3 (1.5%)	1 (0.5%)	4 (1.0%)
Abdominal discomfort	1 (0.5%)	2 (1.0%)	3 (0.8%)
Haemorrhoidal haemorrhage	2 (1.0%)	1 (0.5%)	3 (0.8%)
Aphthous ulcer	2 (1.0%)	0	2 (0.5%)
Cheilitis	2 (1.0%)	0	2 (0.5%)
Colitis	2 (1.0%)	0	2 (0.5%)
Eructation	1 (0.5%)	1 (0.5%)	2 (0.5%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Faeces discoloured	0	2 (1.0%)	2 (0.5%)
Haematemesis	1 (0.5%)	1 (0.5%)	2 (0.5%)
Haematochezia	2 (1.0%)	0	2 (0.5%)
Intestinal obstruction	1 (0.5%)	1 (0.5%)	2 (0.5%)
Melaena	1 (0.5%)	1 (0.5%)	2 (0.5%)
Oesophagitis	1 (0.5%)	1 (0.5%)	2 (0.5%)
Pancreatitis acute	1 (0.5%)	1 (0.5%)	2 (0.5%)
Paraesthesia oral	2 (1.0%)	0	2 (0.5%)
Aerophagia	1 (0.5%)	0	1 (0.3%)
Anal eczema	1 (0.5%)	0	1 (0.3%)
Anal fissure	1 (0.5%)	0	1 (0.3%)
Anal haemorrhage	1 (0.5%)	0	1 (0.3%)
Anal incontinence	0	1 (0.5%)	1 (0.3%)
Colitis ulcerative	1 (0.5%)	0	1 (0.3%)
Defaecation urgency	1 (0.5%)	0	1 (0.3%)
Dental caries	1 (0.5%)	0	1 (0.3%)
Duodenal ulcer	1 (0.5%)	0	1 (0.3%)
Enterovesical fistula	1 (0.5%)	0	1 (0.3%)
Faecaloma	1 (0.5%)	0	1 (0.3%)
Flatulence	0	1 (0.5%)	1 (0.3%)
Gastric haemorrhage	0	1 (0.5%)	1 (0.3%)
Gastric ulcer	1 (0.5%)	0	1 (0.3%)
Gastritis erosive	1 (0.5%)	0	1 (0.3%)
Gastrointestinal haemorrhage	1 (0.5%)	0	1 (0.3%)
Gingival bleeding	0	1 (0.5%)	1 (0.3%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Gingival pain	0	1 (0.5%)	1 (0.3%)
Glossitis	1 (0.5%)	0	1 (0.3%)
Hypoaesthesia oral	1 (0.5%)	0	1 (0.3%)
Inguinal hernia	1 (0.5%)	0	1 (0.3%)
Large intestinal obstruction	1 (0.5%)	0	1 (0.3%)
Large intestinal ulcer haemorrhage	1 (0.5%)	0	1 (0.3%)
Leukoplakia oral	0	1 (0.5%)	1 (0.3%)
Lip dry	1 (0.5%)	0	1 (0.3%)
Malignant gastrointestinal obstruction	1 (0.5%)	0	1 (0.3%)
Mouth haemorrhage	0	1 (0.5%)	1 (0.3%)
Odynophagia	1 (0.5%)	0	1 (0.3%)
Oral lichen planus	1 (0.5%)	0	1 (0.3%)
Proctalgia	1 (0.5%)	0	1 (0.3%)
Proctitis	1 (0.5%)	0	1 (0.3%)
Rectal haemorrhage	1 (0.5%)	0	1 (0.3%)
Rectal ulcer haemorrhage	1 (0.5%)	0	1 (0.3%)
Small intestinal perforation	0	1 (0.5%)	1 (0.3%)
Thrombosis mesenteric vessel	1 (0.5%)	0	1 (0.3%)
General disorders and administration site conditions	136 (67.7%)	136 (69.0%)	272 (68.3%)
Fatigue	76 (37.8%)	69 (35.0%)	145 (36.4%)
Asthenia	34 (16.9%)	43 (21.8%)	77 (19.3%)
Pyrexia	36 (17.9%)	35 (17.8%)	71 (17.8%)
Oedema peripheral	31 (15.4%)	26 (13.2%)	57 (14.3%)
Chills	7 (3.5%)	6 (3.0%)	13 (3.3%)
Malaise	6 (3.0%)	6 (3.0%)	12 (3.0%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Gait disturbance	9 (4.5%)	0	9 (2.3%)
General physical health deterioration	0	8 (4.1%)	8 (2.0%)
Pain	4 (2.0%)	3 (1.5%)	7 (1.8%)
Non-cardiac chest pain	1 (0.5%)	5 (2.5%)	6 (1.5%)
Discomfort	0	3 (1.5%)	3 (0.8%)
Administration site extravasation	1 (0.5%)	1 (0.5%)	2 (0.5%)
Face oedema	0	2 (1.0%)	2 (0.5%)
Infusion site extravasation	2 (1.0%)	0	2 (0.5%)
Infusion site pain	1 (0.5%)	1 (0.5%)	2 (0.5%)
Multiple organ dysfunction syndrome	1 (0.5%)	1 (0.5%)	2 (0.5%)
Peripheral swelling	2 (1.0%)	0	2 (0.5%)
Catheter site granuloma	0	1 (0.5%)	1 (0.3%)
Catheter site pain	0	1 (0.5%)	1 (0.3%)
Chest discomfort	1 (0.5%)	0	1 (0.3%)
Condition aggravated	1 (0.5%)	0	1 (0.3%)
Death	1 (0.5%)	0	1 (0.3%)
Feeling cold	1 (0.5%)	0	1 (0.3%)
Generalised oedema	1 (0.5%)	0	1 (0.3%)
Injection site reaction	1 (0.5%)	0	1 (0.3%)
Performance status decreased	1 (0.5%)	0	1 (0.3%)
Physical deconditioning	0	1 (0.5%)	1 (0.3%)
Sudden death	1 (0.5%)	0	1 (0.3%)
Blood and lymphatic system disorders	88 (43.8%)	170 (86.3%)	258 (64.8%)
Anaemia	67 (33.3%)	135 (68.5%)	202 (50.8%)
Neutropenia	22 (10.9%)	95 (48.2%)	117 (29.4%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Thrombocytopenia	10 (5.0%)	96 (48.7%)	106 (26.6%)
Leukopenia	8 (4.0%)	21 (10.7%)	29 (7.3%)
Febrile neutropenia	1 (0.5%)	10 (5.1%)	11 (2.8%)
Lymphopenia	3 (1.5%)	8 (4.1%)	11 (2.8%)
Leukocytosis	5 (2.5%)	2 (1.0%)	7 (1.8%)
Eosinophilia	6 (3.0%)	0	6 (1.5%)
Thrombocytosis	2 (1.0%)	4 (2.0%)	6 (1.5%)
Pancytopenia	0	4 (2.0%)	4 (1.0%)
Disseminated intravascular coagulation	0	1 (0.5%)	1 (0.3%)
Haematotoxicity	0	1 (0.5%)	1 (0.3%)
Haemolytic anaemia	0	1 (0.5%)	1 (0.3%)
Haemorrhagic diathesis	0	1 (0.5%)	1 (0.3%)
Hyperfibrinogenaemia	0	1 (0.5%)	1 (0.3%)
Immune thrombocytopenia	1 (0.5%)	0	1 (0.3%)
Iron deficiency anaemia	0	1 (0.5%)	1 (0.3%)
Myelosuppression	0	1 (0.5%)	1 (0.3%)
Neutrophilia	0	1 (0.5%)	1 (0.3%)
Thrombocytopenic purpura	0	1 (0.5%)	1 (0.3%)
Skin and subcutaneous tissue disorders	162 (80.6%)	51 (25.9%)	213 (53.5%)
Pruritus	77 (38.3%)	16 (8.1%)	93 (23.4%)
Rash maculo-papular	70 (34.8%)	6 (3.0%)	76 (19.1%)
Alopecia	61 (30.3%)	12 (6.1%)	73 (18.3%)
Dry skin	37 (18.4%)	2 (1.0%)	39 (9.8%)
Rash macular	17 (8.5%)	4 (2.0%)	21 (5.3%)
Eczema	17 (8.5%)	2 (1.0%)	19 (4.8%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Rash papular	13 (6.5%)	2 (1.0%)	15 (3.8%)
Dermatitis	10 (5.0%)	1 (0.5%)	11 (2.8%)
Erythema	5 (2.5%)	2 (1.0%)	7 (1.8%)
Skin hyperpigmentation	7 (3.5%)	0	7 (1.8%)
Urticaria	4 (2.0%)	2 (1.0%)	6 (1.5%)
Palmar-plantar erythrodysaesthesia syndrome	4 (2.0%)	1 (0.5%)	5 (1.3%)
Rash erythematous	3 (1.5%)	2 (1.0%)	5 (1.3%)
Dermatitis acneiform	3 (1.5%)	1 (0.5%)	4 (1.0%)
Dermatitis bullous	3 (1.5%)	1 (0.5%)	4 (1.0%)
Rash	2 (1.0%)	2 (1.0%)	4 (1.0%)
Skin exfoliation	4 (2.0%)	0	4 (1.0%)
Acne	3 (1.5%)	0	3 (0.8%)
Blister	3 (1.5%)	0	3 (0.8%)
Decubitus ulcer	2 (1.0%)	1 (0.5%)	3 (0.8%)
Lichen planus	3 (1.5%)	0	3 (0.8%)
Night sweats	2 (1.0%)	1 (0.5%)	3 (0.8%)
Purpura	2 (1.0%)	1 (0.5%)	3 (0.8%)
Rash pruritic	2 (1.0%)	1 (0.5%)	3 (0.8%)
Skin toxicity	3 (1.5%)	0	3 (0.8%)
Skin ulcer	3 (1.5%)	0	3 (0.8%)
Vitiligo	3 (1.5%)	0	3 (0.8%)
Erythema multiforme	2 (1.0%)	0	2 (0.5%)
Hyperhidrosis	2 (1.0%)	0	2 (0.5%)
Madarosis	2 (1.0%)	0	2 (0.5%)
Pemphigoid	2 (1.0%)	0	2 (0.5%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Rash vesicular	2 (1.0%)	0	2 (0.5%)
Skin hypopigmentation	2 (1.0%)	0	2 (0.5%)
Toxic epidermal necrolysis	2 (1.0%)	0	2 (0.5%)
Acquired porokeratosis	1 (0.5%)	0	1 (0.3%)
Acute generalised exanthematous pustulosis	0	1 (0.5%)	1 (0.3%)
Dermal cyst	1 (0.5%)	0	1 (0.3%)
Dermatitis contact	1 (0.5%)	0	1 (0.3%)
Dermatitis exfoliative	1 (0.5%)	0	1 (0.3%)
Ecchymosis	0	1 (0.5%)	1 (0.3%)
Intertrigo	1 (0.5%)	0	1 (0.3%)
Lentigo	1 (0.5%)	0	1 (0.3%)
Leukoderma	1 (0.5%)	0	1 (0.3%)
Lichenoid keratosis	1 (0.5%)	0	1 (0.3%)
Lipohypertrophy	0	1 (0.5%)	1 (0.3%)
Melanosis	1 (0.5%)	0	1 (0.3%)
Nail ridging	0	1 (0.5%)	1 (0.3%)
Nail toxicity	1 (0.5%)	0	1 (0.3%)
Onychoclasis	0	1 (0.5%)	1 (0.3%)
Onychomadesis	0	1 (0.5%)	1 (0.3%)
Papule	1 (0.5%)	0	1 (0.3%)
Petechiae	0	1 (0.5%)	1 (0.3%)
Pseudocellulitis	0	1 (0.5%)	1 (0.3%)
Rash morbilliform	1 (0.5%)	0	1 (0.3%)
Scab	1 (0.5%)	0	1 (0.3%)
Seborrhoeic dermatitis	1 (0.5%)	0	1 (0.3%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Skin atrophy	1 (0.5%)	0	1 (0.3%)
Skin burning sensation	1 (0.5%)	0	1 (0.3%)
Skin discolouration	1 (0.5%)	0	1 (0.3%)
Skin disorder	1 (0.5%)	0	1 (0.3%)
Skin erosion	1 (0.5%)	0	1 (0.3%)
Skin induration	0	1 (0.5%)	1 (0.3%)
Skin lesion	1 (0.5%)	0	1 (0.3%)
Stasis dermatitis	1 (0.5%)	0	1 (0.3%)
Toxic skin eruption	1 (0.5%)	0	1 (0.3%)
Metabolism and nutrition disorders	122 (60.7%)	86 (43.7%)	208 (52.3%)
Decreased appetite	73 (36.3%)	53 (26.9%)	126 (31.7%)
Hyponatraemia	28 (13.9%)	11 (5.6%)	39 (9.8%)
Hyperglycaemia	28 (13.9%)	5 (2.5%)	33 (8.3%)
Hypophosphataemia	22 (10.9%)	10 (5.1%)	32 (8.0%)
Hypokalaemia	20 (10.0%)	9 (4.6%)	29 (7.3%)
Hyperkalaemia	8 (4.0%)	14 (7.1%)	22 (5.5%)
Hypocalcaemia	9 (4.5%)	11 (5.6%)	20 (5.0%)
Hypoalbuminaemia	11 (5.5%)	6 (3.0%)	17 (4.3%)
Hypomagnesaemia	10 (5.0%)	7 (3.6%)	17 (4.3%)
Dehydration	12 (6.0%)	4 (2.0%)	16 (4.0%)
Hypercalcaemia	7 (3.5%)	4 (2.0%)	11 (2.8%)
Type 2 diabetes mellitus	2 (1.0%)	2 (1.0%)	4 (1.0%)
Diabetes mellitus	3 (1.5%)	0	3 (0.8%)
Hypercreatininaemia	3 (1.5%)	0	3 (0.8%)
Hyperuricaemia	1 (0.5%)	2 (1.0%)	3 (0.8%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Metabolic acidosis	2 (1.0%)	1 (0.5%)	3 (0.8%)
Cachexia	1 (0.5%)	1 (0.5%)	2 (0.5%)
Gout	2 (1.0%)	0	2 (0.5%)
Hyperamylasaemia	2 (1.0%)	0	2 (0.5%)
Hyperlipasaemia	2 (1.0%)	0	2 (0.5%)
Hypoglycaemia	2 (1.0%)	0	2 (0.5%)
Hypozincaemia	2 (1.0%)	0	2 (0.5%)
Malnutrition	0	2 (1.0%)	2 (0.5%)
Polydipsia	1 (0.5%)	1 (0.5%)	2 (0.5%)
Failure to thrive	0	1 (0.5%)	1 (0.3%)
Hypercholesterolaemia	1 (0.5%)	0	1 (0.3%)
Hypermagnesaemia	0	1 (0.5%)	1 (0.3%)
Hypernatraemia	0	1 (0.5%)	1 (0.3%)
Hyperphosphataemia	1 (0.5%)	0	1 (0.3%)
Hypertriglyceridaemia	1 (0.5%)	0	1 (0.3%)
Hypochloraemia	1 (0.5%)	0	1 (0.3%)
Impaired fasting glucose	1 (0.5%)	0	1 (0.3%)
Lactic acidosis	0	1 (0.5%)	1 (0.3%)
Type 1 diabetes mellitus	1 (0.5%)	0	1 (0.3%)
Vitamin D deficiency	0	1 (0.5%)	1 (0.3%)
Investigations	111 (55.2%)	87 (44.2%)	198 (49.7%)
Weight decreased	72 (35.8%)	15 (7.6%)	87 (21.9%)
Blood creatinine increased	27 (13.4%)	23 (11.7%)	50 (12.6%)
Alanine aminotransferase increased	27 (13.4%)	20 (10.2%)	47 (11.8%)
Aspartate aminotransferase increased	22 (10.9%)	17 (8.6%)	39 (9.8%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Platelet count decreased	3 (1.5%)	34 (17.3%)	37 (9.3%)
Neutrophil count decreased	9 (4.5%)	24 (12.2%)	33 (8.3%)
Blood alkaline phosphatase increased	10 (5.0%)	8 (4.1%)	18 (4.5%)
Blood lactate dehydrogenase increased	6 (3.0%)	9 (4.6%)	15 (3.8%)
White blood cell count decreased	4 (2.0%)	11 (5.6%)	15 (3.8%)
Lymphocyte count decreased	8 (4.0%)	3 (1.5%)	11 (2.8%)
Weight increased	6 (3.0%)	2 (1.0%)	8 (2.0%)
Gamma-glutamyltransferase increased	3 (1.5%)	4 (2.0%)	7 (1.8%)
Amylase increased	2 (1.0%)	4 (2.0%)	6 (1.5%)
Lipase increased	3 (1.5%)	2 (1.0%)	5 (1.3%)
Blood bilirubin increased	3 (1.5%)	1 (0.5%)	4 (1.0%)
Blood bicarbonate decreased	3 (1.5%)	0	3 (0.8%)
Blood urea increased	0	3 (1.5%)	3 (0.8%)
Blood thyroid stimulating hormone increased	2 (1.0%)	0	2 (0.5%)
International normalised ratio increased	1 (0.5%)	1 (0.5%)	2 (0.5%)
Apolipoprotein B increased	1 (0.5%)	0	1 (0.3%)
Blood cholesterol increased	1 (0.5%)	0	1 (0.3%)
Blood creatine phosphokinase increased	1 (0.5%)	0	1 (0.3%)
Blood glucose increased	1 (0.5%)	0	1 (0.3%)
Blood lactate dehydrogenase	1 (0.5%)	0	1 (0.3%)
Blood lactic acid increased	1 (0.5%)	0	1 (0.3%)
Blood magnesium decreased	0	1 (0.5%)	1 (0.3%)
Blood phosphorus decreased	0	1 (0.5%)	1 (0.3%)
Blood potassium decreased	1 (0.5%)	0	1 (0.3%)
Blood triglycerides increased	1 (0.5%)	0	1 (0.3%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
C-reactive protein increased	0	1 (0.5%)	1 (0.3%)
Electrocardiogram QT prolonged	1 (0.5%)	0	1 (0.3%)
False positive investigation result	0	1 (0.5%)	1 (0.3%)
Glomerular filtration rate decreased	0	1 (0.5%)	1 (0.3%)
Platelet count increased	0	1 (0.5%)	1 (0.3%)
Prothrombin time prolonged	1 (0.5%)	0	1 (0.3%)
Respiratory rate decreased	1 (0.5%)	0	1 (0.3%)
SARS-CoV-2 test positive	1 (0.5%)	0	1 (0.3%)
Waist circumference increased	1 (0.5%)	0	1 (0.3%)
White blood cell count increased	0	1 (0.5%)	1 (0.3%)
Infections and infestations	120 (59.7%)	75 (38.1%)	195 (49.0%)
Urinary tract infection	48 (23.9%)	39 (19.8%)	87 (21.9%)
COVID-19	20 (10.0%)	9 (4.6%)	29 (7.3%)
Pneumonia	15 (7.5%)	3 (1.5%)	18 (4.5%)
Oral candidiasis	9 (4.5%)	2 (1.0%)	11 (2.8%)
Pyelonephritis	5 (2.5%)	6 (3.0%)	11 (2.8%)
Conjunctivitis	9 (4.5%)	0	9 (2.3%)
Respiratory tract infection	4 (2.0%)	4 (2.0%)	8 (2.0%)
Sepsis	6 (3.0%)	2 (1.0%)	8 (2.0%)
Skin infection	4 (2.0%)	2 (1.0%)	6 (1.5%)
Bronchitis	4 (2.0%)	1 (0.5%)	5 (1.3%)
Cellulitis	4 (2.0%)	1 (0.5%)	5 (1.3%)
Cystitis	3 (1.5%)	2 (1.0%)	5 (1.3%)
Upper respiratory tract infection	4 (2.0%)	1 (0.5%)	5 (1.3%)
Nasopharyngitis	3 (1.5%)	1 (0.5%)	4 (1.0%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Pneumonia aspiration	4 (2.0%)	0	4 (1.0%)
Rhinitis	4 (2.0%)	0	4 (1.0%)
Urosepsis	1 (0.5%)	3 (1.5%)	4 (1.0%)
COVID-19 pneumonia	2 (1.0%)	1 (0.5%)	3 (0.8%)
Gastroenteritis	3 (1.5%)	0	3 (0.8%)
Influenza	2 (1.0%)	1 (0.5%)	3 (0.8%)
Pharyngitis	3 (1.5%)	0	3 (0.8%)
Pyelonephritis acute	1 (0.5%)	2 (1.0%)	3 (0.8%)
Septic shock	3 (1.5%)	0	3 (0.8%)
Bacteraemia	0	2 (1.0%)	2 (0.5%)
Bronchitis viral	1 (0.5%)	1 (0.5%)	2 (0.5%)
Clostridium difficile colitis	2 (1.0%)	0	2 (0.5%)
Clostridium difficile infection	2 (1.0%)	0	2 (0.5%)
Cytomegalovirus colitis	2 (1.0%)	0	2 (0.5%)
Device related infection	2 (1.0%)	0	2 (0.5%)
Eye infection	2 (1.0%)	0	2 (0.5%)
Neutropenic sepsis	1 (0.5%)	1 (0.5%)	2 (0.5%)
Peritonitis	0	2 (1.0%)	2 (0.5%)
Rash pustular	2 (1.0%)	0	2 (0.5%)
Skin candida	1 (0.5%)	1 (0.5%)	2 (0.5%)
Tinea pedis	2 (1.0%)	0	2 (0.5%)
Abdominal infection	0	1 (0.5%)	1 (0.3%)
Bronchopulmonary aspergillosis	1 (0.5%)	0	1 (0.3%)
Campylobacter gastroenteritis	1 (0.5%)	0	1 (0.3%)
Campylobacter infection	1 (0.5%)	0	1 (0.3%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Candida infection	1 (0.5%)	0	1 (0.3%)
Cystitis escherichia	0	1 (0.5%)	1 (0.3%)
Diverticulitis	0	1 (0.5%)	1 (0.3%)
Enterobacter bacteraemia	0	1 (0.5%)	1 (0.3%)
Enterocolitis infectious	1 (0.5%)	0	1 (0.3%)
Folliculitis	0	1 (0.5%)	1 (0.3%)
Fungal foot infection	1 (0.5%)	0	1 (0.3%)
Gastritis viral	1 (0.5%)	0	1 (0.3%)
Gastroenteritis viral	1 (0.5%)	0	1 (0.3%)
Gingivitis	1 (0.5%)	0	1 (0.3%)
Herpes simplex	1 (0.5%)	0	1 (0.3%)
Herpes zoster	1 (0.5%)	0	1 (0.3%)
Infectious pleural effusion	1 (0.5%)	0	1 (0.3%)
Intestinal fistula infection	1 (0.5%)	0	1 (0.3%)
Klebsiella sepsis	0	1 (0.5%)	1 (0.3%)
Mumps	0	1 (0.5%)	1 (0.3%)
Nail infection	1 (0.5%)	0	1 (0.3%)
Oesophageal candidiasis	0	1 (0.5%)	1 (0.3%)
Oral herpes	1 (0.5%)	0	1 (0.3%)
Paronychia	0	1 (0.5%)	1 (0.3%)
Penile infection	1 (0.5%)	0	1 (0.3%)
Peritonsillar abscess	0	1 (0.5%)	1 (0.3%)
Pharyngitis streptococcal	1 (0.5%)	0	1 (0.3%)
Pyuria	1 (0.5%)	0	1 (0.3%)
Respiratory syncytial virus infection	0	1 (0.5%)	1 (0.3%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Respiratory tract infection bacterial	0	1 (0.5%)	1 (0.3%)
Salmonellosis	1 (0.5%)	0	1 (0.3%)
Sinusitis	1 (0.5%)	0	1 (0.3%)
Stitch abscess	1 (0.5%)	0	1 (0.3%)
Subcutaneous abscess	1 (0.5%)	0	1 (0.3%)
Tonsillitis	0	1 (0.5%)	1 (0.3%)
Urinary tract infection bacterial	1 (0.5%)	0	1 (0.3%)
Viral infection	0	1 (0.5%)	1 (0.3%)
Nervous system disorders	143 (71.1%)	48 (24.4%)	191 (48.0%)
Peripheral sensory neuropathy	103 (51.2%)	10 (5.1%)	113 (28.4%)
Dysgeusia	46 (22.9%)	9 (4.6%)	55 (13.8%)
Dizziness	12 (6.0%)	17 (8.6%)	29 (7.3%)
Headache	14 (7.0%)	10 (5.1%)	24 (6.0%)
Paraesthesia	12 (6.0%)	2 (1.0%)	14 (3.5%)
Peripheral motor neuropathy	10 (5.0%)	0	10 (2.5%)
Peripheral sensorimotor neuropathy	7 (3.5%)	0	7 (1.8%)
Hypoaesthesia	5 (2.5%)	0	5 (1.3%)
Taste disorder	4 (2.0%)	1 (0.5%)	5 (1.3%)
Cerebrovascular accident	2 (1.0%)	1 (0.5%)	3 (0.8%)
Peroneal nerve palsy	3 (1.5%)	0	3 (0.8%)
Somnolence	2 (1.0%)	1 (0.5%)	3 (0.8%)
Syncope	1 (0.5%)	2 (1.0%)	3 (0.8%)
Hypogeusia	2 (1.0%)	0	2 (0.5%)
Neuralgia	2 (1.0%)	0	2 (0.5%)
Tremor	1 (0.5%)	1 (0.5%)	2 (0.5%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Ageusia	1 (0.5%)	0	1 (0.3%)
Anosmia	1 (0.5%)	0	1 (0.3%)
Balance disorder	1 (0.5%)	0	1 (0.3%)
Burning sensation	0	1 (0.5%)	1 (0.3%)
Carotid arteriosclerosis	1 (0.5%)	0	1 (0.3%)
Cognitive disorder	1 (0.5%)	0	1 (0.3%)
Dementia	1 (0.5%)	0	1 (0.3%)
Disturbance in attention	1 (0.5%)	0	1 (0.3%)
Dizziness postural	0	1 (0.5%)	1 (0.3%)
Dysarthria	1 (0.5%)	0	1 (0.3%)
Embolic stroke	0	1 (0.5%)	1 (0.3%)
Hypergeusia	0	1 (0.5%)	1 (0.3%)
Immune-mediated neuropathy	1 (0.5%)	0	1 (0.3%)
Lethargy	0	1 (0.5%)	1 (0.3%)
Migraine	1 (0.5%)	0	1 (0.3%)
Nervous system disorder	1 (0.5%)	0	1 (0.3%)
Neuropathy peripheral	0	1 (0.5%)	1 (0.3%)
Pseudoparalysis	1 (0.5%)	0	1 (0.3%)
Restless legs syndrome	1 (0.5%)	0	1 (0.3%)
Seizure	1 (0.5%)	0	1 (0.3%)
Respiratory, thoracic and mediastinal disorders	82 (40.8%)	61 (31.0%)	143 (35.9%)
Dyspnoea	29 (14.4%)	27 (13.7%)	56 (14.1%)
Cough	28 (13.9%)	10 (5.1%)	38 (9.5%)
Pulmonary embolism	9 (4.5%)	9 (4.6%)	18 (4.5%)
Epistaxis	5 (2.5%)	8 (4.1%)	13 (3.3%)

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Table 302.1.2000.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Hiccups	6 (3.0%)	7 (3.6%)	13 (3.3%)
Pneumonitis	12 (6.0%)	0	12 (3.0%)
Dysphonia	9 (4.5%)	0	9 (2.3%)
Pleural effusion	5 (2.5%)	3 (1.5%)	8 (2.0%)
Productive cough	6 (3.0%)	2 (1.0%)	8 (2.0%)
Rhinorrhoea	7 (3.5%)	0	7 (1.8%)
Chronic obstructive pulmonary disease	1 (0.5%)	3 (1.5%)	4 (1.0%)
Dyspnoea exertional	1 (0.5%)	3 (1.5%)	4 (1.0%)
Nasal congestion	4 (2.0%)	0	4 (1.0%)
Oropharyngeal pain	2 (1.0%)	2 (1.0%)	4 (1.0%)
Pneumothorax	2 (1.0%)	2 (1.0%)	4 (1.0%)
Hypoxia	3 (1.5%)	0	3 (0.8%)
Immune-mediated lung disease	3 (1.5%)	0	3 (0.8%)
Wheezing	2 (1.0%)	1 (0.5%)	3 (0.8%)
Acute respiratory failure	2 (1.0%)	0	2 (0.5%)
Haemoptysis	0	2 (1.0%)	2 (0.5%)
Respiratory failure	1 (0.5%)	1 (0.5%)	2 (0.5%)
Tachypnoea	2 (1.0%)	0	2 (0.5%)
Throat irritation	2 (1.0%)	0	2 (0.5%)
Alveolitis	0	1 (0.5%)	1 (0.3%)
Asthma	0	1 (0.5%)	1 (0.3%)
Autoimmune lung disease	1 (0.5%)	0	1 (0.3%)
Bronchospasm	0	1 (0.5%)	1 (0.3%)
Catarrh	1 (0.5%)	0	1 (0.3%)
Emphysema	1 (0.5%)	0	1 (0.3%)

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Table 302.1.2000.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Interstitial lung disease	1 (0.5%)	0	1 (0.3%)
Lung opacity	1 (0.5%)	0	1 (0.3%)
Nasal dryness	1 (0.5%)	0	1 (0.3%)
Oropharyngeal discomfort	1 (0.5%)	0	1 (0.3%)
Pharyngeal erythema	1 (0.5%)	0	1 (0.3%)
Rales	0	1 (0.5%)	1 (0.3%)
Respiratory acidosis	0	1 (0.5%)	1 (0.3%)
Respiratory disorder	1 (0.5%)	0	1 (0.3%)
Rhinitis allergic	1 (0.5%)	0	1 (0.3%)
Sinus pain	1 (0.5%)	0	1 (0.3%)
Sneezing	0	1 (0.5%)	1 (0.3%)
Throat clearing	0	1 (0.5%)	1 (0.3%)
Upper-airway cough syndrome	1 (0.5%)	0	1 (0.3%)
Musculoskeletal and connective tissue disorders	78 (38.8%)	53 (26.9%)	131 (32.9%)
Arthralgia	22 (10.9%)	10 (5.1%)	32 (8.0%)
Back pain	16 (8.0%)	13 (6.6%)	29 (7.3%)
Pain in extremity	11 (5.5%)	9 (4.6%)	20 (5.0%)
Muscular weakness	16 (8.0%)	3 (1.5%)	19 (4.8%)
Myalgia	9 (4.5%)	4 (2.0%)	13 (3.3%)
Flank pain	7 (3.5%)	0	7 (1.8%)
Arthritis	3 (1.5%)	3 (1.5%)	6 (1.5%)
Muscle spasms	5 (2.5%)	1 (0.5%)	6 (1.5%)
Musculoskeletal chest pain	3 (1.5%)	3 (1.5%)	6 (1.5%)
Groin pain	2 (1.0%)	3 (1.5%)	5 (1.3%)
Bone pain	1 (0.5%)	3 (1.5%)	4 (1.0%)

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Table 302.1.2000.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Musculoskeletal pain	4 (2.0%)	0	4 (1.0%)
Spinal pain	1 (0.5%)	3 (1.5%)	4 (1.0%)
Neck pain	0	3 (1.5%)	3 (0.8%)
Bursitis	2 (1.0%)	0	2 (0.5%)
Immune-mediated arthritis	2 (1.0%)	0	2 (0.5%)
Joint swelling	2 (1.0%)	0	2 (0.5%)
Musculoskeletal discomfort	1 (0.5%)	1 (0.5%)	2 (0.5%)
Osteoarthritis	1 (0.5%)	1 (0.5%)	2 (0.5%)
Pathological fracture	1 (0.5%)	1 (0.5%)	2 (0.5%)
Pubic pain	1 (0.5%)	1 (0.5%)	2 (0.5%)
Intervertebral disc degeneration	0	1 (0.5%)	1 (0.3%)
Joint range of motion decreased	1 (0.5%)	0	1 (0.3%)
Muscle contracture	0	1 (0.5%)	1 (0.3%)
Myositis	1 (0.5%)	0	1 (0.3%)
Osteopenia	1 (0.5%)	0	1 (0.3%)
Osteoporotic fracture	1 (0.5%)	0	1 (0.3%)
Rhabdomyolysis	1 (0.5%)	0	1 (0.3%)
Sacral pain	1 (0.5%)	0	1 (0.3%)
Renal and urinary disorders	69 (34.3%)	49 (24.9%)	118 (29.6%)
Haematuria	27 (13.4%)	19 (9.6%)	46 (11.6%)
Acute kidney injury	16 (8.0%)	8 (4.1%)	24 (6.0%)
Dysuria	8 (4.0%)	5 (2.5%)	13 (3.3%)
Proteinuria	5 (2.5%)	4 (2.0%)	9 (2.3%)
Renal impairment	5 (2.5%)	4 (2.0%)	9 (2.3%)
Hydronephrosis	2 (1.0%)	5 (2.5%)	7 (1.8%)

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Table 302.1.2000.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Pollakiuria	5 (2.5%)	2 (1.0%)	7 (1.8%)
Renal failure	4 (2.0%)	2 (1.0%)	6 (1.5%)
Bladder spasm	0	4 (2.0%)	4 (1.0%)
Chronic kidney disease	1 (0.5%)	3 (1.5%)	4 (1.0%)
Urinary tract obstruction	2 (1.0%)	1 (0.5%)	3 (0.8%)
Chromaturia	1 (0.5%)	1 (0.5%)	2 (0.5%)
Immune-mediated nephritis	2 (1.0%)	0	2 (0.5%)
Leukocyturia	1 (0.5%)	1 (0.5%)	2 (0.5%)
Nocturia	2 (1.0%)	0	2 (0.5%)
Urinary retention	0	2 (1.0%)	2 (0.5%)
Urine odour abnormal	2 (1.0%)	0	2 (0.5%)
Azotaemia	1 (0.5%)	0	1 (0.3%)
Bladder irritation	1 (0.5%)	0	1 (0.3%)
Costovertebral angle tenderness	0	1 (0.5%)	1 (0.3%)
Cystitis noninfective	1 (0.5%)	0	1 (0.3%)
Hypertonic bladder	1 (0.5%)	0	1 (0.3%)
Nephroangiosclerosis	1 (0.5%)	0	1 (0.3%)
Nephropathy	0	1 (0.5%)	1 (0.3%)
Polyuria	1 (0.5%)	0	1 (0.3%)
Renal pain	0	1 (0.5%)	1 (0.3%)
Renal tubular necrosis	1 (0.5%)	0	1 (0.3%)
Strangury	0	1 (0.5%)	1 (0.3%)
Tubulointerstitial nephritis	1 (0.5%)	0	1 (0.3%)
Ureteric obstruction	1 (0.5%)	0	1 (0.3%)
Urinary incontinence	1 (0.5%)	0	1 (0.3%)

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Table 302.1.2000.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Urine flow decreased	1 (0.5%)	0	1 (0.3%)
Urinoma	0	1 (0.5%)	1 (0.3%)
Urogenital fistula	1 (0.5%)	0	1 (0.3%)
Eye disorders	64 (31.8%)	12 (6.1%)	76 (19.1%)
Dry eye	21 (10.4%)	2 (1.0%)	23 (5.8%)
Cataract	12 (6.0%)	0	12 (3.0%)
Lacrimation increased	11 (5.5%)	1 (0.5%)	12 (3.0%)
Vision blurred	10 (5.0%)	1 (0.5%)	11 (2.8%)
Eye pain	3 (1.5%)	1 (0.5%)	4 (1.0%)
Eye pruritus	3 (1.5%)	0	3 (0.8%)
Blepharitis	2 (1.0%)	0	2 (0.5%)
Conjunctival haemorrhage	2 (1.0%)	0	2 (0.5%)
Conjunctivitis allergic	2 (1.0%)	0	2 (0.5%)
Epiretinal membrane	2 (1.0%)	0	2 (0.5%)
Eye discharge	2 (1.0%)	0	2 (0.5%)
Keratitis	2 (1.0%)	0	2 (0.5%)
Meibomian gland dysfunction	2 (1.0%)	0	2 (0.5%)
Photophobia	1 (0.5%)	1 (0.5%)	2 (0.5%)
Punctate keratitis	2 (1.0%)	0	2 (0.5%)
Visual acuity reduced	1 (0.5%)	1 (0.5%)	2 (0.5%)
Visual impairment	1 (0.5%)	1 (0.5%)	2 (0.5%)
Xerophthalmia	2 (1.0%)	0	2 (0.5%)
Angle closure glaucoma	0	1 (0.5%)	1 (0.3%)
Arteriosclerotic retinopathy	1 (0.5%)	0	1 (0.3%)
Conjunctival cyst	1 (0.5%)	0	1 (0.3%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Conjunctival hyperaemia	1 (0.5%)	0	1 (0.3%)
Corneal degeneration	1 (0.5%)	0	1 (0.3%)
Corneal erosion	1 (0.5%)	0	1 (0.3%)
Dacryostenosis acquired	1 (0.5%)	0	1 (0.3%)
Erythema of eyelid	1 (0.5%)	0	1 (0.3%)
Exfoliation glaucoma	1 (0.5%)	0	1 (0.3%)
Exophthalmos	1 (0.5%)	0	1 (0.3%)
Eye irritation	0	1 (0.5%)	1 (0.3%)
Eye oedema	0	1 (0.5%)	1 (0.3%)
Keratoconus	1 (0.5%)	0	1 (0.3%)
Macular oedema	1 (0.5%)	0	1 (0.3%)
Normal tension glaucoma	1 (0.5%)	0	1 (0.3%)
Ocular discomfort	0	1 (0.5%)	1 (0.3%)
Ocular hyperaemia	1 (0.5%)	0	1 (0.3%)
Periorbital oedema	0	1 (0.5%)	1 (0.3%)
Posterior capsule opacification	1 (0.5%)	0	1 (0.3%)
Presbyopia	1 (0.5%)	0	1 (0.3%)
Scleritis	1 (0.5%)	0	1 (0.3%)
Psychiatric disorders	37 (18.4%)	20 (10.2%)	57 (14.3%)
Insomnia	23 (11.4%)	10 (5.1%)	33 (8.3%)
Anxiety	9 (4.5%)	3 (1.5%)	12 (3.0%)
Depression	6 (3.0%)	2 (1.0%)	8 (2.0%)
Confusional state	3 (1.5%)	3 (1.5%)	6 (1.5%)
Delirium	5 (2.5%)	0	5 (1.3%)
Affect lability	0	2 (1.0%)	2 (0.5%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Agitation	1 (0.5%)	0	1 (0.3%)
Emotional distress	0	1 (0.5%)	1 (0.3%)
Hallucination	1 (0.5%)	0	1 (0.3%)
Mental status changes	0	1 (0.5%)	1 (0.3%)
Panic attack	1 (0.5%)	0	1 (0.3%)
Vascular disorders	30 (14.9%)	27 (13.7%)	57 (14.3%)
Hypotension	9 (4.5%)	1 (0.5%)	10 (2.5%)
Hypertension	5 (2.5%)	4 (2.0%)	9 (2.3%)
Thrombophlebitis	1 (0.5%)	6 (3.0%)	7 (1.8%)
Deep vein thrombosis	2 (1.0%)	3 (1.5%)	5 (1.3%)
Hot flush	2 (1.0%)	3 (1.5%)	5 (1.3%)
Haematoma	2 (1.0%)	2 (1.0%)	4 (1.0%)
Orthostatic hypotension	2 (1.0%)	1 (0.5%)	3 (0.8%)
Superficial vein thrombosis	1 (0.5%)	2 (1.0%)	3 (0.8%)
Flushing	1 (0.5%)	1 (0.5%)	2 (0.5%)
Lymphoedema	0	2 (1.0%)	2 (0.5%)
Peripheral venous disease	1 (0.5%)	1 (0.5%)	2 (0.5%)
Phlebitis	0	2 (1.0%)	2 (0.5%)
Aortic aneurysm rupture	1 (0.5%)	0	1 (0.3%)
Aortic dilatation	1 (0.5%)	0	1 (0.3%)
Hypertensive crisis	1 (0.5%)	0	1 (0.3%)
Iliac artery occlusion	1 (0.5%)	0	1 (0.3%)
Peripheral coldness	1 (0.5%)	0	1 (0.3%)
Peripheral embolism	1 (0.5%)	0	1 (0.3%)
Post thrombotic syndrome	0	1 (0.5%)	1 (0.3%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Raynaud's phenomenon	1 (0.5%)	0	1 (0.3%)
Shock	0	1 (0.5%)	1 (0.3%)
Vascular pain	0	1 (0.5%)	1 (0.3%)
Injury, poisoning and procedural complications	27 (13.4%)	22 (11.2%)	49 (12.3%)
Fall	10 (5.0%)	5 (2.5%)	15 (3.8%)
Skin abrasion	6 (3.0%)	1 (0.5%)	7 (1.8%)
Contusion	3 (1.5%)	2 (1.0%)	5 (1.3%)
Infusion related reaction	1 (0.5%)	4 (2.0%)	5 (1.3%)
Femur fracture	2 (1.0%)	1 (0.5%)	3 (0.8%)
Urinary tract stoma complication	0	3 (1.5%)	3 (0.8%)
Radius fracture	2 (1.0%)	0	2 (0.5%)
Skin laceration	2 (1.0%)	0	2 (0.5%)
Tendon rupture	2 (1.0%)	0	2 (0.5%)
Thermal burn	2 (1.0%)	0	2 (0.5%)
Wound dehiscence	0	2 (1.0%)	2 (0.5%)
Wrist fracture	1 (0.5%)	1 (0.5%)	2 (0.5%)
Ankle fracture	1 (0.5%)	0	1 (0.3%)
Corneal abrasion	1 (0.5%)	0	1 (0.3%)
Foot fracture	1 (0.5%)	0	1 (0.3%)
Genital injury	1 (0.5%)	0	1 (0.3%)
Ligament sprain	1 (0.5%)	0	1 (0.3%)
Lumbar vertebral fracture	1 (0.5%)	0	1 (0.3%)
Post procedural haemorrhage	0	1 (0.5%)	1 (0.3%)
Rib fracture	1 (0.5%)	0	1 (0.3%)
Shoulder fracture	1 (0.5%)	0	1 (0.3%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Stoma site haemorrhage	0	1 (0.5%)	1 (0.3%)
Toxicity to various agents	0	1 (0.5%)	1 (0.3%)
Transfusion reaction	0	1 (0.5%)	1 (0.3%)
Urostomy complication	1 (0.5%)	0	1 (0.3%)
Hepatobiliary disorders	32 (15.9%)	13 (6.6%)	45 (11.3%)
Hypertransaminasaemia	10 (5.0%)	8 (4.1%)	18 (4.5%)
Hepatic function abnormal	3 (1.5%)	3 (1.5%)	6 (1.5%)
Hyperbilirubinaemia	2 (1.0%)	2 (1.0%)	4 (1.0%)
Drug-induced liver injury	1 (0.5%)	2 (1.0%)	3 (0.8%)
Hepatitis	3 (1.5%)	0	3 (0.8%)
Autoimmune hepatitis	2 (1.0%)	0	2 (0.5%)
Hepatotoxicity	2 (1.0%)	0	2 (0.5%)
Immune-mediated hepatitis	2 (1.0%)	0	2 (0.5%)
Biliary colic	1 (0.5%)	0	1 (0.3%)
Biliary dilatation	1 (0.5%)	0	1 (0.3%)
Cholangitis sclerosing	1 (0.5%)	0	1 (0.3%)
Cholecystitis	1 (0.5%)	0	1 (0.3%)
Gallbladder disorder	1 (0.5%)	0	1 (0.3%)
Hepatic pain	1 (0.5%)	0	1 (0.3%)
Hepatic steatosis	1 (0.5%)	0	1 (0.3%)
Immune-mediated hepatic disorder	1 (0.5%)	0	1 (0.3%)
Portal vein thrombosis	1 (0.5%)	0	1 (0.3%)
Endocrine disorders	36 (17.9%)	4 (2.0%)	40 (10.1%)
Hypothyroidism	23 (11.4%)	2 (1.0%)	25 (6.3%)
Hyperthyroidism	11 (5.5%)	1 (0.5%)	12 (3.0%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Adrenal insufficiency	3 (1.5%)	0	3 (0.8%)
Hypophysitis	2 (1.0%)	0	2 (0.5%)
Central hypothyroidism	1 (0.5%)	0	1 (0.3%)
Hypercalcaemia of malignancy	0	1 (0.5%)	1 (0.3%)
Immune-mediated hypothyroidism	1 (0.5%)	0	1 (0.3%)
Thyroiditis	1 (0.5%)	0	1 (0.3%)
Cardiac disorders	17 (8.5%)	13 (6.6%)	30 (7.5%)
Atrial fibrillation	3 (1.5%)	4 (2.0%)	7 (1.8%)
Acute myocardial infarction	2 (1.0%)	2 (1.0%)	4 (1.0%)
Palpitations	2 (1.0%)	2 (1.0%)	4 (1.0%)
Cardiac failure	3 (1.5%)	0	3 (0.8%)
Tachycardia	1 (0.5%)	1 (0.5%)	2 (0.5%)
Ventricular tachycardia	1 (0.5%)	1 (0.5%)	2 (0.5%)
Angina pectoris	0	1 (0.5%)	1 (0.3%)
Aortic valve disease	0	1 (0.5%)	1 (0.3%)
Atrial flutter	0	1 (0.5%)	1 (0.3%)
Atrial thrombosis	1 (0.5%)	0	1 (0.3%)
Bundle branch block right	1 (0.5%)	0	1 (0.3%)
Cardiac arrest	0	1 (0.5%)	1 (0.3%)
Cardiac discomfort	1 (0.5%)	0	1 (0.3%)
Cardiac flutter	0	1 (0.5%)	1 (0.3%)
Cardio-respiratory arrest	1 (0.5%)	0	1 (0.3%)
Immune-mediated myocarditis	1 (0.5%)	0	1 (0.3%)
Myocardial infarction	1 (0.5%)	0	1 (0.3%)
Myocardial ischaemia	0	1 (0.5%)	1 (0.3%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Myocarditis	1 (0.5%)	0	1 (0.3%)
Sinus tachycardia	1 (0.5%)	0	1 (0.3%)
Stress cardiomyopathy	0	1 (0.5%)	1 (0.3%)
Ventricular extrasystoles	1 (0.5%)	0	1 (0.3%)
Reproductive system and breast disorders	9 (4.5%)	7 (3.6%)	16 (4.0%)
Pelvic pain	5 (2.5%)	0	5 (1.3%)
Breast pain	0	1 (0.5%)	1 (0.3%)
Erectile dysfunction	1 (0.5%)	0	1 (0.3%)
Genital burning sensation	0	1 (0.5%)	1 (0.3%)
Genital paraesthesia	1 (0.5%)	0	1 (0.3%)
Ovarian vein thrombosis	0	1 (0.5%)	1 (0.3%)
Penile erythema	0	1 (0.5%)	1 (0.3%)
Prostatitis	0	1 (0.5%)	1 (0.3%)
Testicular pain	0	1 (0.5%)	1 (0.3%)
Vaginal haemorrhage	0	1 (0.5%)	1 (0.3%)
Vaginal prolapse	1 (0.5%)	0	1 (0.3%)
Vulval eczema	1 (0.5%)	0	1 (0.3%)
Vulvovaginal dryness	1 (0.5%)	0	1 (0.3%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	9 (4.5%)	4 (2.0%)	13 (3.3%)
Cancer pain	5 (2.5%)	2 (1.0%)	7 (1.8%)
Tumour pain	0	2 (1.0%)	2 (0.5%)
Chronic lymphocytic leukaemia	1 (0.5%)	0	1 (0.3%)
Monoclonal gammopathy	1 (0.5%)	0	1 (0.3%)
Neuroma	1 (0.5%)	0	1 (0.3%)
Pancreatic cystadenoma	1 (0.5%)	0	1 (0.3%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Ear and labyrinth disorders	3 (1.5%)	7 (3.6%)	10 (2.5%)
Tinnitus	1 (0.5%)	2 (1.0%)	3 (0.8%)
Vertigo	0	3 (1.5%)	3 (0.8%)
Hypoacusis	1 (0.5%)	1 (0.5%)	2 (0.5%)
Eustachian tube disorder	0	1 (0.5%)	1 (0.3%)
Otorrhoea	1 (0.5%)	0	1 (0.3%)
Immune system disorders	5 (2.5%)	0	5 (1.3%)
Contrast media allergy	2 (1.0%)	0	2 (0.5%)
Drug hypersensitivity	1 (0.5%)	0	1 (0.3%)
Sarcoidosis	1 (0.5%)	0	1 (0.3%)
Seasonal allergy	1 (0.5%)	0	1 (0.3%)
Product issues	0	1 (0.5%)	1 (0.3%)
Device occlusion	0	1 (0.5%)	1 (0.3%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Overall	239 (100.0%)	233 (98.7%)	472 (99.4%)
Gastrointestinal disorders	178 (74.5%)	181 (76.7%)	359 (75.6%)
Nausea	60 (25.1%)	117 (49.6%)	177 (37.3%)
Constipation	67 (28.0%)	75 (31.8%)	142 (29.9%)
Diarrhoea	88 (36.8%)	40 (16.9%)	128 (26.9%)
Vomiting	22 (9.2%)	39 (16.5%)	61 (12.8%)
Abdominal pain	25 (10.5%)	19 (8.1%)	44 (9.3%)
Stomatitis	27 (11.3%)	16 (6.8%)	43 (9.1%)
Dry mouth	24 (10.0%)	6 (2.5%)	30 (6.3%)
Dyspepsia	13 (5.4%)	11 (4.7%)	24 (5.1%)
Gastrooesophageal reflux disease	12 (5.0%)	9 (3.8%)	21 (4.4%)
Abdominal pain upper	12 (5.0%)	7 (3.0%)	19 (4.0%)
Haemorrhoids	10 (4.2%)	2 (0.8%)	12 (2.5%)
Dysphagia	4 (1.7%)	2 (0.8%)	6 (1.3%)
Gastritis	4 (1.7%)	2 (0.8%)	6 (1.3%)
Abdominal discomfort	3 (1.3%)	2 (0.8%)	5 (1.1%)
Mouth ulceration	3 (1.3%)	2 (0.8%)	5 (1.1%)
Abdominal pain lower	1 (0.4%)	3 (1.3%)	4 (0.8%)
Ascites	3 (1.3%)	1 (0.4%)	4 (0.8%)
Colitis	4 (1.7%)	0	4 (0.8%)
Flatulence	3 (1.3%)	1 (0.4%)	4 (0.8%)
Inguinal hernia	3 (1.3%)	1 (0.4%)	4 (0.8%)
Immune-mediated enterocolitis	3 (1.3%)	0	3 (0.6%)
Oral dysaesthesia	2 (0.8%)	1 (0.4%)	3 (0.6%)
Toothache	2 (0.8%)	1 (0.4%)	3 (0.6%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Abdominal distension	2 (0.8%)	0	2 (0.4%)
Faeces soft	2 (0.8%)	0	2 (0.4%)
Gastric ulcer	1 (0.4%)	1 (0.4%)	2 (0.4%)
Haemorrhoidal haemorrhage	2 (0.8%)	0	2 (0.4%)
Oral pain	1 (0.4%)	1 (0.4%)	2 (0.4%)
Paraesthesia oral	1 (0.4%)	1 (0.4%)	2 (0.4%)
Proctalgia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Rectal haemorrhage	2 (0.8%)	0	2 (0.4%)
Abdominal rigidity	0	1 (0.4%)	1 (0.2%)
Anal erythema	1 (0.4%)	0	1 (0.2%)
Anal pruritus	1 (0.4%)	0	1 (0.2%)
Angular cheilitis	1 (0.4%)	0	1 (0.2%)
Autoimmune pancreatitis	1 (0.4%)	0	1 (0.2%)
Defaecation urgency	1 (0.4%)	0	1 (0.2%)
Dental caries	1 (0.4%)	0	1 (0.2%)
Duodenitis	0	1 (0.4%)	1 (0.2%)
Epigastric discomfort	0	1 (0.4%)	1 (0.2%)
Gingival bleeding	1 (0.4%)	0	1 (0.2%)
Haematochezia	0	1 (0.4%)	1 (0.2%)
Haemorrhagic erosive gastritis	1 (0.4%)	0	1 (0.2%)
Hypoaesthesia oral	1 (0.4%)	0	1 (0.2%)
Ileal ulcer	1 (0.4%)	0	1 (0.2%)
Ileus	1 (0.4%)	0	1 (0.2%)
Lip dry	1 (0.4%)	0	1 (0.2%)
Lip ulceration	1 (0.4%)	0	1 (0.2%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Melaena	0	1 (0.4%)	1 (0.2%)
Odynophagia	1 (0.4%)	0	1 (0.2%)
Oesophageal stenosis	1 (0.4%)	0	1 (0.2%)
Oral blood blister	1 (0.4%)	0	1 (0.2%)
Oral verrucous hyperplasia	1 (0.4%)	0	1 (0.2%)
Pancreatitis chronic	1 (0.4%)	0	1 (0.2%)
Periodontal disease	1 (0.4%)	0	1 (0.2%)
Rectal tenesmus	0	1 (0.4%)	1 (0.2%)
Regurgitation	0	1 (0.4%)	1 (0.2%)
Salivary gland calculus	1 (0.4%)	0	1 (0.2%)
Small intestinal obstruction	1 (0.4%)	0	1 (0.2%)
General disorders and administration site conditions	157 (65.7%)	163 (69.1%)	320 (67.4%)
Fatigue	76 (31.8%)	97 (41.1%)	173 (36.4%)
Asthenia	41 (17.2%)	41 (17.4%)	82 (17.3%)
Pyrexia	41 (17.2%)	32 (13.6%)	73 (15.4%)
Oedema peripheral	29 (12.1%)	21 (8.9%)	50 (10.5%)
Malaise	8 (3.3%)	5 (2.1%)	13 (2.7%)
Chills	7 (2.9%)	2 (0.8%)	9 (1.9%)
Pain	3 (1.3%)	6 (2.5%)	9 (1.9%)
Gait disturbance	8 (3.3%)	0	8 (1.7%)
Non-cardiac chest pain	4 (1.7%)	4 (1.7%)	8 (1.7%)
Infusion site extravasation	5 (2.1%)	0	5 (1.1%)
Peripheral swelling	3 (1.3%)	2 (0.8%)	5 (1.1%)
Chest discomfort	2 (0.8%)	2 (0.8%)	4 (0.8%)
Catheter site pain	2 (0.8%)	0	2 (0.4%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Chest pain	2 (0.8%)	0	2 (0.4%)
General physical health deterioration	1 (0.4%)	1 (0.4%)	2 (0.4%)
Infusion site pain	0	2 (0.8%)	2 (0.4%)
Injection site reaction	0	2 (0.8%)	2 (0.4%)
Temperature intolerance	2 (0.8%)	0	2 (0.4%)
Catheter site erosion	1 (0.4%)	0	1 (0.2%)
Catheter site haematoma	0	1 (0.4%)	1 (0.2%)
Catheter site inflammation	0	1 (0.4%)	1 (0.2%)
Catheter site irritation	1 (0.4%)	0	1 (0.2%)
Catheter site pruritus	1 (0.4%)	0	1 (0.2%)
Catheter site related reaction	1 (0.4%)	0	1 (0.2%)
Catheter site swelling	0	1 (0.4%)	1 (0.2%)
Face oedema	0	1 (0.4%)	1 (0.2%)
Generalised oedema	0	1 (0.4%)	1 (0.2%)
Hyperthermia	1 (0.4%)	0	1 (0.2%)
Impaired healing	0	1 (0.4%)	1 (0.2%)
Influenza like illness	1 (0.4%)	0	1 (0.2%)
Infusion site reaction	0	1 (0.4%)	1 (0.2%)
Localised oedema	1 (0.4%)	0	1 (0.2%)
Oedema	0	1 (0.4%)	1 (0.2%)
Suprapubic pain	0	1 (0.4%)	1 (0.2%)
Swelling face	1 (0.4%)	0	1 (0.2%)
Nervous system disorders	182 (76.2%)	93 (39.4%)	275 (57.9%)
Peripheral sensory neuropathy	126 (52.7%)	34 (14.4%)	160 (33.7%)
Dysgeusia	47 (19.7%)	28 (11.9%)	75 (15.8%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Dizziness	24 (10.0%)	26 (11.0%)	50 (10.5%)
Headache	19 (7.9%)	15 (6.4%)	34 (7.2%)
Paraesthesia	24 (10.0%)	6 (2.5%)	30 (6.3%)
Hypoaesthesia	12 (5.0%)	1 (0.4%)	13 (2.7%)
Taste disorder	10 (4.2%)	2 (0.8%)	12 (2.5%)
Peripheral motor neuropathy	9 (3.8%)	1 (0.4%)	10 (2.1%)
Peripheral sensorimotor neuropathy	9 (3.8%)	1 (0.4%)	10 (2.1%)
Ageusia	8 (3.3%)	0	8 (1.7%)
Lethargy	2 (0.8%)	6 (2.5%)	8 (1.7%)
Anosmia	7 (2.9%)	0	7 (1.5%)
Hypogeusia	3 (1.3%)	3 (1.3%)	6 (1.3%)
Tremor	4 (1.7%)	2 (0.8%)	6 (1.3%)
Balance disorder	4 (1.7%)	1 (0.4%)	5 (1.1%)
Neurotoxicity	5 (2.1%)	0	5 (1.1%)
Syncope	4 (1.7%)	1 (0.4%)	5 (1.1%)
Somnolence	1 (0.4%)	3 (1.3%)	4 (0.8%)
Dysaesthesia	2 (0.8%)	1 (0.4%)	3 (0.6%)
Optic neuritis	2 (0.8%)	0	2 (0.4%)
Altered state of consciousness	1 (0.4%)	0	1 (0.2%)
Amnesia	0	1 (0.4%)	1 (0.2%)
Amputation stump pain	1 (0.4%)	0	1 (0.2%)
Aphasia	1 (0.4%)	0	1 (0.2%)
Brain fog	0	1 (0.4%)	1 (0.2%)
Burning sensation	0	1 (0.4%)	1 (0.2%)
Cerebral infarction	0	1 (0.4%)	1 (0.2%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Disturbance in attention	0	1 (0.4%)	1 (0.2%)
Dizziness postural	1 (0.4%)	0	1 (0.2%)
Dyskinesia	1 (0.4%)	0	1 (0.2%)
Epilepsy	0	1 (0.4%)	1 (0.2%)
Intercostal neuralgia	0	1 (0.4%)	1 (0.2%)
Loss of consciousness	1 (0.4%)	0	1 (0.2%)
Lumbar radiculopathy	1 (0.4%)	0	1 (0.2%)
Memory impairment	0	1 (0.4%)	1 (0.2%)
Metabolic encephalopathy	0	1 (0.4%)	1 (0.2%)
Neuralgia	1 (0.4%)	0	1 (0.2%)
Partial seizures	1 (0.4%)	0	1 (0.2%)
Presyncope	0	1 (0.4%)	1 (0.2%)
Pronator teres syndrome	1 (0.4%)	0	1 (0.2%)
Radiculopathy	0	1 (0.4%)	1 (0.2%)
Seizure	1 (0.4%)	0	1 (0.2%)
Senile dementia	1 (0.4%)	0	1 (0.2%)
Ulnar nerve palsy	1 (0.4%)	0	1 (0.2%)
Skin and subcutaneous tissue disorders	203 (84.9%)	61 (25.8%)	264 (55.6%)
Pruritus	105 (43.9%)	13 (5.5%)	118 (24.8%)
Alopecia	90 (37.7%)	22 (9.3%)	112 (23.6%)
Rash maculo-papular	74 (31.0%)	9 (3.8%)	83 (17.5%)
Dry skin	39 (16.3%)	4 (1.7%)	43 (9.1%)
Rash macular	27 (11.3%)	2 (0.8%)	29 (6.1%)
Rash papular	21 (8.8%)	1 (0.4%)	22 (4.6%)
Skin hyperpigmentation	17 (7.1%)	0	17 (3.6%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Erythema	12 (5.0%)	3 (1.3%)	15 (3.2%)
Eczema	12 (5.0%)	2 (0.8%)	14 (2.9%)
Dermatitis	13 (5.4%)	0	13 (2.7%)
Dermatitis bullous	13 (5.4%)	0	13 (2.7%)
Rash erythematous	11 (4.6%)	2 (0.8%)	13 (2.7%)
Hyperhidrosis	7 (2.9%)	4 (1.7%)	11 (2.3%)
Blister	10 (4.2%)	0	10 (2.1%)
Skin ulcer	9 (3.8%)	1 (0.4%)	10 (2.1%)
Dermatitis acneiform	7 (2.9%)	2 (0.8%)	9 (1.9%)
Rash	8 (3.3%)	1 (0.4%)	9 (1.9%)
Skin exfoliation	8 (3.3%)	0	8 (1.7%)
Night sweats	3 (1.3%)	4 (1.7%)	7 (1.5%)
Rash pruritic	5 (2.1%)	1 (0.4%)	6 (1.3%)
Rash vesicular	5 (2.1%)	0	5 (1.1%)
Erythema multiforme	3 (1.3%)	1 (0.4%)	4 (0.8%)
Skin discolouration	4 (1.7%)	0	4 (0.8%)
Toxic skin eruption	4 (1.7%)	0	4 (0.8%)
Urticaria	4 (1.7%)	0	4 (0.8%)
Dermal cyst	3 (1.3%)	0	3 (0.6%)
Onycholysis	3 (1.3%)	0	3 (0.6%)
Psoriasis	3 (1.3%)	0	3 (0.6%)
Skin hypopigmentation	3 (1.3%)	0	3 (0.6%)
Vitiligo	3 (1.3%)	0	3 (0.6%)
Dermatitis contact	2 (0.8%)	0	2 (0.4%)
Dermatitis exfoliative generalised	2 (0.8%)	0	2 (0.4%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Hyperkeratosis	2 (0.8%)	0	2 (0.4%)
Lichenoid keratosis	2 (0.8%)	0	2 (0.4%)
Nail dystrophy	2 (0.8%)	0	2 (0.4%)
Onychoclasis	2 (0.8%)	0	2 (0.4%)
Onychomadesis	2 (0.8%)	0	2 (0.4%)
Palmar-plantar erythrodysaesthesia syndrome	2 (0.8%)	0	2 (0.4%)
Purpura	2 (0.8%)	0	2 (0.4%)
Skin plaque	2 (0.8%)	0	2 (0.4%)
Toxic erythema of chemotherapy	2 (0.8%)	0	2 (0.4%)
Acne	1 (0.4%)	0	1 (0.2%)
Actinic keratosis	1 (0.4%)	0	1 (0.2%)
Angiolymphoid hyperplasia with eosinophilia	1 (0.4%)	0	1 (0.2%)
Anhidrosis	1 (0.4%)	0	1 (0.2%)
Brow ptosis	0	1 (0.4%)	1 (0.2%)
Cellulite	1 (0.4%)	0	1 (0.2%)
Cutaneous vasculitis	1 (0.4%)	0	1 (0.2%)
Dermatitis psoriasiform	1 (0.4%)	0	1 (0.2%)
Dermatomyositis	1 (0.4%)	0	1 (0.2%)
Drug eruption	1 (0.4%)	0	1 (0.2%)
Dyshidrotic eczema	1 (0.4%)	0	1 (0.2%)
Hair colour changes	0	1 (0.4%)	1 (0.2%)
Hand dermatitis	1 (0.4%)	0	1 (0.2%)
Lentigo	1 (0.4%)	0	1 (0.2%)
Lichen sclerosus	1 (0.4%)	0	1 (0.2%)
Madarosis	1 (0.4%)	0	1 (0.2%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Nail discolouration	1 (0.4%)	0	1 (0.2%)
Nail discomfort	1 (0.4%)	0	1 (0.2%)
Nail toxicity	1 (0.4%)	0	1 (0.2%)
Pain of skin	1 (0.4%)	0	1 (0.2%)
Papule	0	1 (0.4%)	1 (0.2%)
Paradoxical psoriasis	1 (0.4%)	0	1 (0.2%)
Pemphigoid	1 (0.4%)	0	1 (0.2%)
Penile ulceration	1 (0.4%)	0	1 (0.2%)
Petechiae	0	1 (0.4%)	1 (0.2%)
Plantar erythema	1 (0.4%)	0	1 (0.2%)
Seborrhoeic dermatitis	1 (0.4%)	0	1 (0.2%)
Sensitive skin	1 (0.4%)	0	1 (0.2%)
Skin depigmentation	1 (0.4%)	0	1 (0.2%)
Skin fissures	1 (0.4%)	0	1 (0.2%)
Skin fragility	1 (0.4%)	0	1 (0.2%)
Skin haemorrhage	0	1 (0.4%)	1 (0.2%)
Skin irritation	1 (0.4%)	0	1 (0.2%)
Skin toxicity	1 (0.4%)	0	1 (0.2%)
Subcutaneous emphysema	1 (0.4%)	0	1 (0.2%)
Symmetrical drug-related intertriginous and flexural exanthema	1 (0.4%)	0	1 (0.2%)
Toxic epidermal necrolysis	1 (0.4%)	0	1 (0.2%)
Xeroderma	1 (0.4%)	0	1 (0.2%)
Metabolism and nutrition disorders	128 (53.6%)	104 (44.1%)	232 (48.8%)
Decreased appetite	72 (30.1%)	58 (24.6%)	130 (27.4%)
Hyperglycaemia	38 (15.9%)	4 (1.7%)	42 (8.8%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
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Table 302.1.2000.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Hypokalaemia	15 (6.3%)	16 (6.8%)	31 (6.5%)
Hypomagnesaemia	8 (3.3%)	19 (8.1%)	27 (5.7%)
Hyponatraemia	10 (4.2%)	16 (6.8%)	26 (5.5%)
Hypophosphataemia	9 (3.8%)	5 (2.1%)	14 (2.9%)
Hyperkalaemia	5 (2.1%)	7 (3.0%)	12 (2.5%)
Dehydration	6 (2.5%)	5 (2.1%)	11 (2.3%)
Hypocalcaemia	7 (2.9%)	4 (1.7%)	11 (2.3%)
Hypercalcaemia	5 (2.1%)	3 (1.3%)	8 (1.7%)
Hyperuricaemia	7 (2.9%)	0	7 (1.5%)
Hypoalbuminaemia	4 (1.7%)	2 (0.8%)	6 (1.3%)
Diabetes mellitus	3 (1.3%)	2 (0.8%)	5 (1.1%)
Hyperphosphataemia	4 (1.7%)	0	4 (0.8%)
Gout	2 (0.8%)	1 (0.4%)	3 (0.6%)
Hyperamylasaemia	2 (0.8%)	1 (0.4%)	3 (0.6%)
Hypercholesterolaemia	3 (1.3%)	0	3 (0.6%)
Hypercreatininaemia	2 (0.8%)	1 (0.4%)	3 (0.6%)
Hyperlipasaemia	2 (0.8%)	1 (0.4%)	3 (0.6%)
Hypoglycaemia	2 (0.8%)	1 (0.4%)	3 (0.6%)
Type 2 diabetes mellitus	3 (1.3%)	0	3 (0.6%)
Glucose tolerance impaired	2 (0.8%)	0	2 (0.4%)
Hyperlipidaemia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Hypochloraemia	0	2 (0.8%)	2 (0.4%)
Metabolic acidosis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Alkalosis	0	1 (0.4%)	1 (0.2%)
Cachexia	1 (0.4%)	0	1 (0.2%)

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Table 302.1.2000.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Dyslipidaemia	1 (0.4%)	0	1 (0.2%)
Electrolyte imbalance	0	1 (0.4%)	1 (0.2%)
Folate deficiency	0	1 (0.4%)	1 (0.2%)
Hypertriglyceridaemia	1 (0.4%)	0	1 (0.2%)
Lactic acidosis	1 (0.4%)	0	1 (0.2%)
Malnutrition	1 (0.4%)	0	1 (0.2%)
Vitamin B12 deficiency	1 (0.4%)	0	1 (0.2%)
Vitamin D deficiency	1 (0.4%)	0	1 (0.2%)
Investigations	128 (53.6%)	102 (43.2%)	230 (48.4%)
Weight decreased	72 (30.1%)	22 (9.3%)	94 (19.8%)
Alanine aminotransferase increased	49 (20.5%)	12 (5.1%)	61 (12.8%)
Aspartate aminotransferase increased	47 (19.7%)	10 (4.2%)	57 (12.0%)
Blood creatinine increased	12 (5.0%)	27 (11.4%)	39 (8.2%)
Platelet count decreased	1 (0.4%)	25 (10.6%)	26 (5.5%)
Neutrophil count decreased	3 (1.3%)	21 (8.9%)	24 (5.1%)
Blood alkaline phosphatase increased	12 (5.0%)	8 (3.4%)	20 (4.2%)
White blood cell count decreased	1 (0.4%)	14 (5.9%)	15 (3.2%)
Weight increased	6 (2.5%)	8 (3.4%)	14 (2.9%)
Lipase increased	13 (5.4%)	0	13 (2.7%)
Amylase increased	6 (2.5%)	2 (0.8%)	8 (1.7%)
Blood lactate dehydrogenase increased	7 (2.9%)	1 (0.4%)	8 (1.7%)
Blood creatine phosphokinase increased	7 (2.9%)	0	7 (1.5%)
Gamma-glutamyltransferase increased	5 (2.1%)	2 (0.8%)	7 (1.5%)
Blood bilirubin increased	5 (2.1%)	1 (0.4%)	6 (1.3%)
Lymphocyte count decreased	2 (0.8%)	1 (0.4%)	3 (0.6%)

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Table 302.1.2000.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Neutrophil count increased	2 (0.8%)	1 (0.4%)	3 (0.6%)
Blood bicarbonate decreased	2 (0.8%)	0	2 (0.4%)
Blood glucose increased	2 (0.8%)	0	2 (0.4%)
Blood thyroid stimulating hormone increased	2 (0.8%)	0	2 (0.4%)
C-reactive protein increased	1 (0.4%)	1 (0.4%)	2 (0.4%)
Creatinine renal clearance decreased	0	2 (0.8%)	2 (0.4%)
Apolipoprotein A-I increased	1 (0.4%)	0	1 (0.2%)
Basophil count increased	1 (0.4%)	0	1 (0.2%)
Blood albumin decreased	1 (0.4%)	0	1 (0.2%)
Blood creatine increased	1 (0.4%)	0	1 (0.2%)
Blood potassium increased	0	1 (0.4%)	1 (0.2%)
Blood triglycerides increased	1 (0.4%)	0	1 (0.2%)
Blood urea increased	1 (0.4%)	0	1 (0.2%)
Body temperature increased	1 (0.4%)	0	1 (0.2%)
Electrocardiogram QT prolonged	1 (0.4%)	0	1 (0.2%)
Glomerular filtration rate decreased	0	1 (0.4%)	1 (0.2%)
Glycosylated haemoglobin increased	1 (0.4%)	0	1 (0.2%)
International normalised ratio increased	1 (0.4%)	0	1 (0.2%)
Lymph node palpable	0	1 (0.4%)	1 (0.2%)
Nitrite urine present	1 (0.4%)	0	1 (0.2%)
Oxygen saturation decreased	1 (0.4%)	0	1 (0.2%)
SARS-CoV-2 test positive	1 (0.4%)	0	1 (0.2%)
Thyroxine increased	1 (0.4%)	0	1 (0.2%)
Troponin I increased	1 (0.4%)	0	1 (0.2%)
White blood cell count increased	1 (0.4%)	0	1 (0.2%)

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Table 302.1.2000.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Blood and lymphatic system disorders	62 (25.9%)	157 (66.5%)	219 (46.1%)
Anaemia	39 (16.3%)	123 (52.1%)	162 (34.1%)
Neutropenia	16 (6.7%)	69 (29.2%)	85 (17.9%)
Thrombocytopenia	8 (3.3%)	48 (20.3%)	56 (11.8%)
Leukopenia	8 (3.3%)	23 (9.7%)	31 (6.5%)
Lymphopenia	2 (0.8%)	5 (2.1%)	7 (1.5%)
Leukocytosis	4 (1.7%)	1 (0.4%)	5 (1.1%)
Thrombocytosis	2 (0.8%)	2 (0.8%)	4 (0.8%)
Pancytopenia	0	3 (1.3%)	3 (0.6%)
Eosinophilia	2 (0.8%)	0	2 (0.4%)
Anaemia of malignant disease	1 (0.4%)	0	1 (0.2%)
Haemolytic anaemia	1 (0.4%)	0	1 (0.2%)
Lymphadenitis	0	1 (0.4%)	1 (0.2%)
Lymphadenopathy	0	1 (0.4%)	1 (0.2%)
Neutrophilia	0	1 (0.4%)	1 (0.2%)
Platelet toxicity	0	1 (0.4%)	1 (0.2%)
Splenomegaly	1 (0.4%)	0	1 (0.2%)
Infections and infestations	139 (58.2%)	67 (28.4%)	206 (43.4%)
Urinary tract infection	37 (15.5%)	34 (14.4%)	71 (14.9%)
COVID-19	43 (18.0%)	10 (4.2%)	53 (11.2%)
Conjunctivitis	18 (7.5%)	0	18 (3.8%)
Pneumonia	11 (4.6%)	3 (1.3%)	14 (2.9%)
Oral candidiasis	9 (3.8%)	4 (1.7%)	13 (2.7%)
Upper respiratory tract infection	11 (4.6%)	1 (0.4%)	12 (2.5%)
Cellulitis	7 (2.9%)	1 (0.4%)	8 (1.7%)

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Table 302.1.2000.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Folliculitis	5 (2.1%)	1 (0.4%)	6 (1.3%)
Bronchitis	5 (2.1%)	0	5 (1.1%)
Cystitis	2 (0.8%)	3 (1.3%)	5 (1.1%)
Nasopharyngitis	4 (1.7%)	1 (0.4%)	5 (1.1%)
Rhinitis	5 (2.1%)	0	5 (1.1%)
Skin infection	4 (1.7%)	1 (0.4%)	5 (1.1%)
Fungal skin infection	3 (1.3%)	1 (0.4%)	4 (0.8%)
Herpes zoster	4 (1.7%)	0	4 (0.8%)
Respiratory tract infection	3 (1.3%)	1 (0.4%)	4 (0.8%)
Bacteriuria	1 (0.4%)	2 (0.8%)	3 (0.6%)
Gingivitis	2 (0.8%)	1 (0.4%)	3 (0.6%)
Lower respiratory tract infection	2 (0.8%)	1 (0.4%)	3 (0.6%)
Pharyngitis	2 (0.8%)	1 (0.4%)	3 (0.6%)
Rash pustular	2 (0.8%)	1 (0.4%)	3 (0.6%)
Wound infection	1 (0.4%)	2 (0.8%)	3 (0.6%)
Bacteraemia	2 (0.8%)	0	2 (0.4%)
COVID-19 pneumonia	2 (0.8%)	0	2 (0.4%)
Influenza	2 (0.8%)	0	2 (0.4%)
Oral herpes	1 (0.4%)	1 (0.4%)	2 (0.4%)
Pneumonia bacterial	2 (0.8%)	0	2 (0.4%)
Pyelonephritis chronic	0	2 (0.8%)	2 (0.4%)
Pyuria	1 (0.4%)	1 (0.4%)	2 (0.4%)
Sinusitis	2 (0.8%)	0	2 (0.4%)
Tinea cruris	1 (0.4%)	1 (0.4%)	2 (0.4%)
Abdominal sepsis	1 (0.4%)	0	1 (0.2%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Body tinea	1 (0.4%)	0	1 (0.2%)
Candida infection	1 (0.4%)	0	1 (0.2%)
Catheter site infection	1 (0.4%)	0	1 (0.2%)
Clostridium difficile infection	1 (0.4%)	0	1 (0.2%)
Device related infection	0	1 (0.4%)	1 (0.2%)
Diverticulitis	1 (0.4%)	0	1 (0.2%)
Ear infection	1 (0.4%)	0	1 (0.2%)
Epididymitis	0	1 (0.4%)	1 (0.2%)
Erysipelas	1 (0.4%)	0	1 (0.2%)
Escherichia infection	0	1 (0.4%)	1 (0.2%)
Eyelid infection	1 (0.4%)	0	1 (0.2%)
Fungal foot infection	1 (0.4%)	0	1 (0.2%)
Furuncle	0	1 (0.4%)	1 (0.2%)
Gastroenteritis viral	1 (0.4%)	0	1 (0.2%)
Groin abscess	0	1 (0.4%)	1 (0.2%)
Herpes dermatitis	1 (0.4%)	0	1 (0.2%)
Hordeolum	0	1 (0.4%)	1 (0.2%)
Injection site infection	0	1 (0.4%)	1 (0.2%)
Klebsiella urinary tract infection	1 (0.4%)	0	1 (0.2%)
Laryngopharyngitis	1 (0.4%)	0	1 (0.2%)
Lip infection	1 (0.4%)	0	1 (0.2%)
Localised infection	1 (0.4%)	0	1 (0.2%)
Lung abscess	1 (0.4%)	0	1 (0.2%)
Oesophageal candidiasis	1 (0.4%)	0	1 (0.2%)
Onychomycosis	1 (0.4%)	0	1 (0.2%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Oral fungal infection	1 (0.4%)	0	1 (0.2%)
Penile infection	1 (0.4%)	0	1 (0.2%)
Periodontitis	1 (0.4%)	0	1 (0.2%)
Pharyngitis streptococcal	1 (0.4%)	0	1 (0.2%)
Pneumocystis jirovecii pneumonia	1 (0.4%)	0	1 (0.2%)
Postoperative wound infection	1 (0.4%)	0	1 (0.2%)
Pyelonephritis	1 (0.4%)	0	1 (0.2%)
Skin bacterial infection	1 (0.4%)	0	1 (0.2%)
Skin candida	0	1 (0.4%)	1 (0.2%)
Soft tissue infection	0	1 (0.4%)	1 (0.2%)
Staphylococcal bacteraemia	1 (0.4%)	0	1 (0.2%)
Subcutaneous abscess	1 (0.4%)	0	1 (0.2%)
Tinea pedis	1 (0.4%)	0	1 (0.2%)
Tonsillitis	0	1 (0.4%)	1 (0.2%)
Tooth abscess	1 (0.4%)	0	1 (0.2%)
Urinary tract infection enterococcal	0	1 (0.4%)	1 (0.2%)
Urinary tract infection staphylococcal	1 (0.4%)	0	1 (0.2%)
Urosepsis	1 (0.4%)	0	1 (0.2%)
Viral infection	0	1 (0.4%)	1 (0.2%)
Viral upper respiratory tract infection	0	1 (0.4%)	1 (0.2%)
Vulvitis	0	1 (0.4%)	1 (0.2%)
Respiratory, thoracic and mediastinal disorders	96 (40.2%)	77 (32.6%)	173 (36.4%)
Dyspnoea	29 (12.1%)	23 (9.7%)	52 (10.9%)
Cough	26 (10.9%)	12 (5.1%)	38 (8.0%)
Hiccups	7 (2.9%)	22 (9.3%)	29 (6.1%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Epistaxis	6 (2.5%)	19 (8.1%)	25 (5.3%)
Dysphonia	13 (5.4%)	4 (1.7%)	17 (3.6%)
Pneumonitis	16 (6.7%)	0	16 (3.4%)
Rhinorrhoea	8 (3.3%)	6 (2.5%)	14 (2.9%)
Nasal congestion	9 (3.8%)	1 (0.4%)	10 (2.1%)
Pulmonary embolism	3 (1.3%)	7 (3.0%)	10 (2.1%)
Oropharyngeal pain	5 (2.1%)	4 (1.7%)	9 (1.9%)
Productive cough	3 (1.3%)	4 (1.7%)	7 (1.5%)
Dyspnoea exertional	3 (1.3%)	2 (0.8%)	5 (1.1%)
Aphonia	2 (0.8%)	1 (0.4%)	3 (0.6%)
Interstitial lung disease	3 (1.3%)	0	3 (0.6%)
Upper-airway cough syndrome	3 (1.3%)	0	3 (0.6%)
Chronic obstructive pulmonary disease	1 (0.4%)	1 (0.4%)	2 (0.4%)
Immune-mediated lung disease	2 (0.8%)	0	2 (0.4%)
Nasal dryness	2 (0.8%)	0	2 (0.4%)
Painful respiration	1 (0.4%)	1 (0.4%)	2 (0.4%)
Pleural effusion	1 (0.4%)	1 (0.4%)	2 (0.4%)
Pneumothorax	2 (0.8%)	0	2 (0.4%)
Rhinitis allergic	2 (0.8%)	0	2 (0.4%)
Catarrh	0	1 (0.4%)	1 (0.2%)
Dry throat	1 (0.4%)	0	1 (0.2%)
Haemoptysis	0	1 (0.4%)	1 (0.2%)
Hypoxia	1 (0.4%)	0	1 (0.2%)
Laryngeal haemorrhage	0	1 (0.4%)	1 (0.2%)
Laryngeal inflammation	0	1 (0.4%)	1 (0.2%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Lung disorder	1 (0.4%)	0	1 (0.2%)
Nasal polyps	1 (0.4%)	0	1 (0.2%)
Nocturnal dyspnoea	1 (0.4%)	0	1 (0.2%)
Organising pneumonia	1 (0.4%)	0	1 (0.2%)
Orthopnoea	1 (0.4%)	0	1 (0.2%)
Pharyngeal dyskinesia	1 (0.4%)	0	1 (0.2%)
Pharyngeal inflammation	1 (0.4%)	0	1 (0.2%)
Pleuritic pain	1 (0.4%)	0	1 (0.2%)
Pulmonary fibrosis	1 (0.4%)	0	1 (0.2%)
Pulmonary pain	0	1 (0.4%)	1 (0.2%)
Pulmonary toxicity	1 (0.4%)	0	1 (0.2%)
Sinus congestion	1 (0.4%)	0	1 (0.2%)
Musculoskeletal and connective tissue disorders	106 (44.4%)	63 (26.7%)	169 (35.6%)
Back pain	36 (15.1%)	21 (8.9%)	57 (12.0%)
Arthralgia	36 (15.1%)	11 (4.7%)	47 (9.9%)
Pain in extremity	20 (8.4%)	14 (5.9%)	34 (7.2%)
Myalgia	17 (7.1%)	6 (2.5%)	23 (4.8%)
Muscular weakness	11 (4.6%)	4 (1.7%)	15 (3.2%)
Flank pain	7 (2.9%)	7 (3.0%)	14 (2.9%)
Bone pain	4 (1.7%)	6 (2.5%)	10 (2.1%)
Muscle spasms	9 (3.8%)	1 (0.4%)	10 (2.1%)
Musculoskeletal chest pain	5 (2.1%)	1 (0.4%)	6 (1.3%)
Musculoskeletal discomfort	3 (1.3%)	3 (1.3%)	6 (1.3%)
Neck pain	4 (1.7%)	2 (0.8%)	6 (1.3%)
Arthritis	4 (1.7%)	1 (0.4%)	5 (1.1%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Gouty arthritis	3 (1.3%)	0	3 (0.6%)
Limb discomfort	2 (0.8%)	1 (0.4%)	3 (0.6%)
Musculoskeletal pain	3 (1.3%)	0	3 (0.6%)
Musculoskeletal stiffness	2 (0.8%)	1 (0.4%)	3 (0.6%)
Joint stiffness	1 (0.4%)	1 (0.4%)	2 (0.4%)
Osteopenia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Pain in jaw	0	2 (0.8%)	2 (0.4%)
Tendon pain	0	2 (0.8%)	2 (0.4%)
Arthropathy	1 (0.4%)	0	1 (0.2%)
Bone lesion	1 (0.4%)	0	1 (0.2%)
Groin pain	0	1 (0.4%)	1 (0.2%)
Hypercreatinaemia	0	1 (0.4%)	1 (0.2%)
Joint range of motion decreased	1 (0.4%)	0	1 (0.2%)
Myositis	1 (0.4%)	0	1 (0.2%)
Osteoarthritis	1 (0.4%)	0	1 (0.2%)
Osteoporosis	1 (0.4%)	0	1 (0.2%)
Sjogren's syndrome	1 (0.4%)	0	1 (0.2%)
Renal and urinary disorders	66 (27.6%)	72 (30.5%)	138 (29.1%)
Haematuria	29 (12.1%)	17 (7.2%)	46 (9.7%)
Acute kidney injury	5 (2.1%)	21 (8.9%)	26 (5.5%)
Dysuria	13 (5.4%)	8 (3.4%)	21 (4.4%)
Pollakiuria	8 (3.3%)	6 (2.5%)	14 (2.9%)
Urinary retention	6 (2.5%)	7 (3.0%)	13 (2.7%)
Renal failure	2 (0.8%)	5 (2.1%)	7 (1.5%)
Renal impairment	3 (1.3%)	4 (1.7%)	7 (1.5%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Leukocyturia	3 (1.3%)	2 (0.8%)	5 (1.1%)
Nocturia	1 (0.4%)	4 (1.7%)	5 (1.1%)
Urinary tract pain	2 (0.8%)	3 (1.3%)	5 (1.1%)
Chromaturia	4 (1.7%)	0	4 (0.8%)
Chronic kidney disease	1 (0.4%)	3 (1.3%)	4 (0.8%)
Bladder spasm	3 (1.3%)	0	3 (0.6%)
Hydronephrosis	2 (0.8%)	1 (0.4%)	3 (0.6%)
Proteinuria	2 (0.8%)	1 (0.4%)	3 (0.6%)
Bladder pain	2 (0.8%)	0	2 (0.4%)
Micturition urgency	1 (0.4%)	1 (0.4%)	2 (0.4%)
Polyuria	1 (0.4%)	1 (0.4%)	2 (0.4%)
Urinary incontinence	2 (0.8%)	0	2 (0.4%)
Calculus bladder	1 (0.4%)	0	1 (0.2%)
Calculus urinary	1 (0.4%)	0	1 (0.2%)
Cystitis noninfective	0	1 (0.4%)	1 (0.2%)
Nephropathy	0	1 (0.4%)	1 (0.2%)
Oliguria	1 (0.4%)	0	1 (0.2%)
Prerenal failure	0	1 (0.4%)	1 (0.2%)
Renal colic	0	1 (0.4%)	1 (0.2%)
Renal pain	0	1 (0.4%)	1 (0.2%)
Stress urinary incontinence	1 (0.4%)	0	1 (0.2%)
Urethral stenosis	1 (0.4%)	0	1 (0.2%)
Urinary hesitation	0	1 (0.4%)	1 (0.2%)
Urine abnormality	0	1 (0.4%)	1 (0.2%)
Urine odour abnormal	1 (0.4%)	0	1 (0.2%)

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Table 302.1.2000.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Eye disorders	87 (36.4%)	14 (5.9%)	101 (21.3%)
Dry eye	29 (12.1%)	3 (1.3%)	32 (6.7%)
Lacrimation increased	25 (10.5%)	1 (0.4%)	26 (5.5%)
Vision blurred	16 (6.7%)	4 (1.7%)	20 (4.2%)
Cataract	8 (3.3%)	1 (0.4%)	9 (1.9%)
Blepharitis	6 (2.5%)	0	6 (1.3%)
Eye irritation	5 (2.1%)	0	5 (1.1%)
Keratitis	4 (1.7%)	0	4 (0.8%)
Visual acuity reduced	4 (1.7%)	0	4 (0.8%)
Vitreous floaters	2 (0.8%)	2 (0.8%)	4 (0.8%)
Xerophthalmia	4 (1.7%)	0	4 (0.8%)
Eye pruritus	3 (1.3%)	0	3 (0.6%)
Conjunctivitis allergic	2 (0.8%)	0	2 (0.4%)
Eye discharge	2 (0.8%)	0	2 (0.4%)
Eye pain	2 (0.8%)	0	2 (0.4%)
Eyelids pruritus	1 (0.4%)	1 (0.4%)	2 (0.4%)
Photopsia	0	2 (0.8%)	2 (0.4%)
Visual impairment	2 (0.8%)	0	2 (0.4%)
Asthenopia	1 (0.4%)	0	1 (0.2%)
Conjunctival haemorrhage	0	1 (0.4%)	1 (0.2%)
Conjunctival irritation	1 (0.4%)	0	1 (0.2%)
Corneal erosion	1 (0.4%)	0	1 (0.2%)
Corneal toxicity	1 (0.4%)	0	1 (0.2%)
Diplopia	1 (0.4%)	0	1 (0.2%)
Eczema eyelids	1 (0.4%)	0	1 (0.2%)

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Table 302.1.2000.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Entropion	1 (0.4%)	0	1 (0.2%)
Exposure keratitis	1 (0.4%)	0	1 (0.2%)
Meibomianitis	1 (0.4%)	0	1 (0.2%)
Myopia	1 (0.4%)	0	1 (0.2%)
Ocular hyperaemia	1 (0.4%)	0	1 (0.2%)
Periorbital oedema	0	1 (0.4%)	1 (0.2%)
Photophobia	1 (0.4%)	0	1 (0.2%)
Pinguecula	1 (0.4%)	0	1 (0.2%)
Retinal degeneration	1 (0.4%)	0	1 (0.2%)
Retinal detachment	1 (0.4%)	0	1 (0.2%)
Retinal tear	1 (0.4%)	0	1 (0.2%)
Uveitis	1 (0.4%)	0	1 (0.2%)
Vitreous haemorrhage	1 (0.4%)	0	1 (0.2%)
Vascular disorders	31 (13.0%)	44 (18.6%)	75 (15.8%)
Hypertension	9 (3.8%)	13 (5.5%)	22 (4.6%)
Hypotension	5 (2.1%)	6 (2.5%)	11 (2.3%)
Deep vein thrombosis	2 (0.8%)	8 (3.4%)	10 (2.1%)
Hot flush	5 (2.1%)	0	5 (1.1%)
Phlebitis	0	5 (2.1%)	5 (1.1%)
Superficial vein thrombosis	0	5 (2.1%)	5 (1.1%)
Thrombophlebitis	1 (0.4%)	4 (1.7%)	5 (1.1%)
Flushing	2 (0.8%)	1 (0.4%)	3 (0.6%)
Orthostatic hypotension	2 (0.8%)	1 (0.4%)	3 (0.6%)
Peripheral embolism	0	3 (1.3%)	3 (0.6%)
Lymphoedema	1 (0.4%)	1 (0.4%)	2 (0.4%)

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Table 302.1.2000.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Capillary fragility	1 (0.4%)	0	1 (0.2%)
Intermittent claudication	1 (0.4%)	0	1 (0.2%)
Lymphocele	0	1 (0.4%)	1 (0.2%)
Pallor	1 (0.4%)	0	1 (0.2%)
Pelvic venous thrombosis	1 (0.4%)	0	1 (0.2%)
Peripheral arterial occlusive disease	1 (0.4%)	0	1 (0.2%)
Phlebosclerosis	0	1 (0.4%)	1 (0.2%)
Vascular pain	1 (0.4%)	0	1 (0.2%)
Venous thrombosis	0	1 (0.4%)	1 (0.2%)
Psychiatric disorders	38 (15.9%)	24 (10.2%)	62 (13.1%)
Insomnia	22 (9.2%)	14 (5.9%)	36 (7.6%)
Anxiety	10 (4.2%)	3 (1.3%)	13 (2.7%)
Depression	5 (2.1%)	5 (2.1%)	10 (2.1%)
Delirium	4 (1.7%)	0	4 (0.8%)
Confusional state	2 (0.8%)	0	2 (0.4%)
Disorientation	1 (0.4%)	1 (0.4%)	2 (0.4%)
Affective disorder	1 (0.4%)	0	1 (0.2%)
Agitation	1 (0.4%)	0	1 (0.2%)
Depressed mood	0	1 (0.4%)	1 (0.2%)
Dysphemia	0	1 (0.4%)	1 (0.2%)
Emotional distress	0	1 (0.4%)	1 (0.2%)
Hallucination, auditory	1 (0.4%)	0	1 (0.2%)
Initial insomnia	1 (0.4%)	0	1 (0.2%)
Mixed anxiety and depressive disorder	1 (0.4%)	0	1 (0.2%)
Sleep disorder	1 (0.4%)	0	1 (0.2%)

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Table 302.1.2000.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Suicidal ideation	1 (0.4%)	0	1 (0.2%)
Ear and labyrinth disorders	16 (6.7%)	33 (14.0%)	49 (10.3%)
Tinnitus	5 (2.1%)	27 (11.4%)	32 (6.7%)
Hypoacusis	2 (0.8%)	3 (1.3%)	5 (1.1%)
Vertigo	4 (1.7%)	0	4 (0.8%)
Ear discomfort	1 (0.4%)	1 (0.4%)	2 (0.4%)
Ear pain	2 (0.8%)	0	2 (0.4%)
Ototoxicity	0	2 (0.8%)	2 (0.4%)
Presbyacusis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Deafness	0	1 (0.4%)	1 (0.2%)
Vestibular disorder	1 (0.4%)	0	1 (0.2%)
Injury, poisoning and procedural complications	30 (12.6%)	13 (5.5%)	43 (9.1%)
Fall	11 (4.6%)	3 (1.3%)	14 (2.9%)
Contusion	3 (1.3%)	1 (0.4%)	4 (0.8%)
Infusion related reaction	2 (0.8%)	2 (0.8%)	4 (0.8%)
Skin laceration	3 (1.3%)	1 (0.4%)	4 (0.8%)
Skin abrasion	2 (0.8%)	1 (0.4%)	3 (0.6%)
Urinary tract stoma complication	2 (0.8%)	1 (0.4%)	3 (0.6%)
Thermal burn	1 (0.4%)	1 (0.4%)	2 (0.4%)
Eschar	1 (0.4%)	0	1 (0.2%)
Eye contusion	1 (0.4%)	0	1 (0.2%)
Fibula fracture	1 (0.4%)	0	1 (0.2%)
Foot fracture	1 (0.4%)	0	1 (0.2%)
Ligament sprain	0	1 (0.4%)	1 (0.2%)
Limb traumatic amputation	1 (0.4%)	0	1 (0.2%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Muscle rupture	0	1 (0.4%)	1 (0.2%)
Overdose	1 (0.4%)	0	1 (0.2%)
Penis injury	1 (0.4%)	0	1 (0.2%)
Post vaccination fever	1 (0.4%)	0	1 (0.2%)
Procedural pain	1 (0.4%)	0	1 (0.2%)
Sternal fracture	0	1 (0.4%)	1 (0.2%)
Stoma site pain	0	1 (0.4%)	1 (0.2%)
Subcutaneous haematoma	0	1 (0.4%)	1 (0.2%)
Urinary tract procedural complication	1 (0.4%)	0	1 (0.2%)
Urostomy complication	0	1 (0.4%)	1 (0.2%)
Wound dehiscence	1 (0.4%)	0	1 (0.2%)
Endocrine disorders	34 (14.2%)	2 (0.8%)	36 (7.6%)
Hypothyroidism	23 (9.6%)	1 (0.4%)	24 (5.1%)
Hyperthyroidism	9 (3.8%)	1 (0.4%)	10 (2.1%)
Adrenal insufficiency	4 (1.7%)	0	4 (0.8%)
Autoimmune thyroiditis	1 (0.4%)	0	1 (0.2%)
Hyperparathyroidism	1 (0.4%)	0	1 (0.2%)
Hypophysitis	1 (0.4%)	0	1 (0.2%)
Thyroiditis	1 (0.4%)	0	1 (0.2%)
Hepatobiliary disorders	29 (12.1%)	7 (3.0%)	36 (7.6%)
Hypertransaminasaemia	10 (4.2%)	5 (2.1%)	15 (3.2%)
Hepatic function abnormal	6 (2.5%)	1 (0.4%)	7 (1.5%)
Hepatotoxicity	3 (1.3%)	0	3 (0.6%)
Autoimmune hepatitis	2 (0.8%)	0	2 (0.4%)
Hepatic cytolysis	2 (0.8%)	0	2 (0.4%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Hepatitis	2 (0.8%)	0	2 (0.4%)
Cholecystitis	1 (0.4%)	0	1 (0.2%)
Cholelithiasis	1 (0.4%)	0	1 (0.2%)
Hepatic cirrhosis	1 (0.4%)	0	1 (0.2%)
Hepatic pain	0	1 (0.4%)	1 (0.2%)
Hepatic steatosis	1 (0.4%)	0	1 (0.2%)
Hyperbilirubinaemia	1 (0.4%)	0	1 (0.2%)
Immune-mediated hepatitis	1 (0.4%)	0	1 (0.2%)
Cardiac disorders	17 (7.1%)	14 (5.9%)	31 (6.5%)
Sinus tachycardia	3 (1.3%)	3 (1.3%)	6 (1.3%)
Tachycardia	3 (1.3%)	3 (1.3%)	6 (1.3%)
Palpitations	3 (1.3%)	2 (0.8%)	5 (1.1%)
Atrial fibrillation	1 (0.4%)	3 (1.3%)	4 (0.8%)
Angina pectoris	1 (0.4%)	2 (0.8%)	3 (0.6%)
Bradycardia	2 (0.8%)	0	2 (0.4%)
Acute myocardial infarction	0	1 (0.4%)	1 (0.2%)
Arrhythmia	0	1 (0.4%)	1 (0.2%)
Bundle branch block left	1 (0.4%)	0	1 (0.2%)
Bundle branch block right	1 (0.4%)	0	1 (0.2%)
Cardiomyopathy	1 (0.4%)	0	1 (0.2%)
Diastolic dysfunction	1 (0.4%)	0	1 (0.2%)
Myocarditis	1 (0.4%)	0	1 (0.2%)
Pericardial effusion	1 (0.4%)	0	1 (0.2%)
Supraventricular tachycardia	1 (0.4%)	0	1 (0.2%)
Reproductive system and breast disorders	19 (7.9%)	6 (2.5%)	25 (5.3%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Pelvic pain	4 (1.7%)	3 (1.3%)	7 (1.5%)
Penile pain	2 (0.8%)	2 (0.8%)	4 (0.8%)
Balanoposthitis	2 (0.8%)	0	2 (0.4%)
Penile erythema	2 (0.8%)	0	2 (0.4%)
Vaginal discharge	2 (0.8%)	0	2 (0.4%)
Vaginal haemorrhage	1 (0.4%)	1 (0.4%)	2 (0.4%)
Atrophic vulvovaginitis	1 (0.4%)	0	1 (0.2%)
Nipple pain	1 (0.4%)	0	1 (0.2%)
Oedema genital	1 (0.4%)	0	1 (0.2%)
Prostatic obstruction	1 (0.4%)	0	1 (0.2%)
Pruritus genital	1 (0.4%)	0	1 (0.2%)
Scrotal pain	1 (0.4%)	0	1 (0.2%)
Testicular pain	1 (0.4%)	0	1 (0.2%)
Vaginal erosion	1 (0.4%)	0	1 (0.2%)
Vulvovaginal dryness	1 (0.4%)	0	1 (0.2%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	11 (4.6%)	5 (2.1%)	16 (3.4%)
Cancer pain	2 (0.8%)	3 (1.3%)	5 (1.1%)
Seborrhoeic keratosis	4 (1.7%)	0	4 (0.8%)
Acrochordon	1 (0.4%)	0	1 (0.2%)
Angiofibroma	1 (0.4%)	0	1 (0.2%)
Fibrous histiocytoma	1 (0.4%)	0	1 (0.2%)
Large intestine benign neoplasm	1 (0.4%)	0	1 (0.2%)
Skin papilloma	1 (0.4%)	0	1 (0.2%)
Tumour associated fever	0	1 (0.4%)	1 (0.2%)
Tumour pain	0	1 (0.4%)	1 (0.2%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Immune system disorders	5 (2.1%)	2 (0.8%)	7 (1.5%)
Contrast media allergy	1 (0.4%)	2 (0.8%)	3 (0.6%)
Seasonal allergy	2 (0.8%)	0	2 (0.4%)
Drug hypersensitivity	1 (0.4%)	0	1 (0.2%)
Hypersensitivity	1 (0.4%)	0	1 (0.2%)
Product issues	1 (0.4%)	3 (1.3%)	4 (0.8%)
Device occlusion	0	2 (0.8%)	2 (0.4%)
Device kink	0	1 (0.4%)	1 (0.2%)
Thrombosis in device	1 (0.4%)	0	1 (0.2%)
Congenital, familial and genetic disorders	3 (1.3%)	0	3 (0.6%)
Dermoid cyst	1 (0.4%)	0	1 (0.2%)
Dolichocolon	1 (0.4%)	0	1 (0.2%)
Hydrocele	1 (0.4%)	0	1 (0.2%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Overall	198 (98.5%)	190 (96.4%)	388 (97.5%)
Gastrointestinal disorders	150 (74.6%)	125 (63.5%)	275 (69.1%)
Constipation	49 (24.4%)	70 (35.5%)	119 (29.9%)
Nausea	55 (27.4%)	55 (27.9%)	110 (27.6%)
Diarrhoea	77 (38.3%)	27 (13.7%)	104 (26.1%)
Vomiting	27 (13.4%)	26 (13.2%)	53 (13.3%)
Abdominal pain	22 (10.9%)	5 (2.5%)	27 (6.8%)
Stomatitis	12 (6.0%)	11 (5.6%)	23 (5.8%)
Dyspepsia	13 (6.5%)	6 (3.0%)	19 (4.8%)
Dry mouth	17 (8.5%)	1 (0.5%)	18 (4.5%)
Abdominal distension	10 (5.0%)	2 (1.0%)	12 (3.0%)
Gastrooesophageal reflux disease	6 (3.0%)	6 (3.0%)	12 (3.0%)
Abdominal pain upper	5 (2.5%)	5 (2.5%)	10 (2.5%)
Dysphagia	7 (3.5%)	0	7 (1.8%)
Mouth ulceration	5 (2.5%)	1 (0.5%)	6 (1.5%)
Abdominal pain lower	1 (0.5%)	4 (2.0%)	5 (1.3%)
Haemorrhoids	4 (2.0%)	1 (0.5%)	5 (1.3%)
Gastritis	3 (1.5%)	1 (0.5%)	4 (1.0%)
Toothache	3 (1.5%)	1 (0.5%)	4 (1.0%)
Abdominal discomfort	1 (0.5%)	2 (1.0%)	3 (0.8%)
Aphthous ulcer	2 (1.0%)	0	2 (0.5%)
Cheilitis	2 (1.0%)	0	2 (0.5%)
Colitis	2 (1.0%)	0	2 (0.5%)
Eructation	1 (0.5%)	1 (0.5%)	2 (0.5%)
Faeces discoloured	0	2 (1.0%)	2 (0.5%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Haematochezia	2 (1.0%)	0	2 (0.5%)
Haemorrhoidal haemorrhage	2 (1.0%)	0	2 (0.5%)
Melaena	1 (0.5%)	1 (0.5%)	2 (0.5%)
Oesophagitis	1 (0.5%)	1 (0.5%)	2 (0.5%)
Paraesthesia oral	2 (1.0%)	0	2 (0.5%)
Aerophagia	1 (0.5%)	0	1 (0.3%)
Anal eczema	1 (0.5%)	0	1 (0.3%)
Anal fissure	1 (0.5%)	0	1 (0.3%)
Anal haemorrhage	1 (0.5%)	0	1 (0.3%)
Anal incontinence	0	1 (0.5%)	1 (0.3%)
Defaecation urgency	1 (0.5%)	0	1 (0.3%)
Dental caries	1 (0.5%)	0	1 (0.3%)
Faecaloma	1 (0.5%)	0	1 (0.3%)
Flatulence	0	1 (0.5%)	1 (0.3%)
Gastric ulcer	1 (0.5%)	0	1 (0.3%)
Gastritis erosive	1 (0.5%)	0	1 (0.3%)
Gingival bleeding	0	1 (0.5%)	1 (0.3%)
Gingival pain	0	1 (0.5%)	1 (0.3%)
Glossitis	1 (0.5%)	0	1 (0.3%)
Haematemesis	1 (0.5%)	0	1 (0.3%)
Hypoaesthesia oral	1 (0.5%)	0	1 (0.3%)
Inguinal hernia	1 (0.5%)	0	1 (0.3%)
Large intestinal obstruction	1 (0.5%)	0	1 (0.3%)
Leukoplakia oral	0	1 (0.5%)	1 (0.3%)
Lip dry	1 (0.5%)	0	1 (0.3%)

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Table 302.1.2000.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Mouth haemorrhage	0	1 (0.5%)	1 (0.3%)
Odynophagia	1 (0.5%)	0	1 (0.3%)
Oral lichen planus	1 (0.5%)	0	1 (0.3%)
Pancreatitis acute	0	1 (0.5%)	1 (0.3%)
Proctalgia	1 (0.5%)	0	1 (0.3%)
Proctitis	1 (0.5%)	0	1 (0.3%)
Rectal ulcer haemorrhage	1 (0.5%)	0	1 (0.3%)
Thrombosis mesenteric vessel	1 (0.5%)	0	1 (0.3%)
General disorders and administration site conditions	132 (65.7%)	131 (66.5%)	263 (66.1%)
Fatigue	73 (36.3%)	67 (34.0%)	140 (35.2%)
Asthenia	34 (16.9%)	40 (20.3%)	74 (18.6%)
Pyrexia	35 (17.4%)	32 (16.2%)	67 (16.8%)
Oedema peripheral	31 (15.4%)	26 (13.2%)	57 (14.3%)
Chills	7 (3.5%)	6 (3.0%)	13 (3.3%)
Malaise	6 (3.0%)	5 (2.5%)	11 (2.8%)
Gait disturbance	9 (4.5%)	0	9 (2.3%)
Non-cardiac chest pain	1 (0.5%)	5 (2.5%)	6 (1.5%)
Pain	3 (1.5%)	3 (1.5%)	6 (1.5%)
Discomfort	0	3 (1.5%)	3 (0.8%)
Administration site extravasation	1 (0.5%)	1 (0.5%)	2 (0.5%)
Face oedema	0	2 (1.0%)	2 (0.5%)
General physical health deterioration	0	2 (1.0%)	2 (0.5%)
Infusion site extravasation	2 (1.0%)	0	2 (0.5%)
Infusion site pain	1 (0.5%)	1 (0.5%)	2 (0.5%)
Peripheral swelling	2 (1.0%)	0	2 (0.5%)

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Table 302.1.2000.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Catheter site granuloma	0	1 (0.5%)	1 (0.3%)
Catheter site pain	0	1 (0.5%)	1 (0.3%)
Chest discomfort	1 (0.5%)	0	1 (0.3%)
Feeling cold	1 (0.5%)	0	1 (0.3%)
Generalised oedema	1 (0.5%)	0	1 (0.3%)
Injection site reaction	1 (0.5%)	0	1 (0.3%)
Physical deconditioning	0	1 (0.5%)	1 (0.3%)
Blood and lymphatic system disorders	74 (36.8%)	148 (75.1%)	222 (55.8%)
Anaemia	58 (28.9%)	119 (60.4%)	177 (44.5%)
Thrombocytopenia	8 (4.0%)	72 (36.5%)	80 (20.1%)
Neutropenia	14 (7.0%)	64 (32.5%)	78 (19.6%)
Leukopenia	8 (4.0%)	20 (10.2%)	28 (7.0%)
Lymphopenia	3 (1.5%)	8 (4.1%)	11 (2.8%)
Eosinophilia	6 (3.0%)	0	6 (1.5%)
Thrombocytosis	2 (1.0%)	4 (2.0%)	6 (1.5%)
Leukocytosis	3 (1.5%)	2 (1.0%)	5 (1.3%)
Disseminated intravascular coagulation	0	1 (0.5%)	1 (0.3%)
Febrile neutropenia	1 (0.5%)	0	1 (0.3%)
Haematotoxicity	0	1 (0.5%)	1 (0.3%)
Haemolytic anaemia	0	1 (0.5%)	1 (0.3%)
Haemorrhagic diathesis	0	1 (0.5%)	1 (0.3%)
Hyperfibrinogenaemia	0	1 (0.5%)	1 (0.3%)
Iron deficiency anaemia	0	1 (0.5%)	1 (0.3%)
Neutrophilia	0	1 (0.5%)	1 (0.3%)
Thrombocytopenic purpura	0	1 (0.5%)	1 (0.3%)

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Table 302.1.2000.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Skin and subcutaneous tissue disorders	157 (78.1%)	49 (24.9%)	206 (51.8%)
Pruritus	76 (37.8%)	16 (8.1%)	92 (23.1%)
Rash maculo-papular	68 (33.8%)	6 (3.0%)	74 (18.6%)
Alopecia	60 (29.9%)	11 (5.6%)	71 (17.8%)
Dry skin	37 (18.4%)	2 (1.0%)	39 (9.8%)
Rash macular	17 (8.5%)	4 (2.0%)	21 (5.3%)
Eczema	17 (8.5%)	2 (1.0%)	19 (4.8%)
Rash papular	12 (6.0%)	2 (1.0%)	14 (3.5%)
Dermatitis	10 (5.0%)	1 (0.5%)	11 (2.8%)
Erythema	5 (2.5%)	2 (1.0%)	7 (1.8%)
Skin hyperpigmentation	7 (3.5%)	0	7 (1.8%)
Urticaria	4 (2.0%)	2 (1.0%)	6 (1.5%)
Palmar-plantar erythrodysaesthesia syndrome	4 (2.0%)	1 (0.5%)	5 (1.3%)
Rash erythematous	3 (1.5%)	2 (1.0%)	5 (1.3%)
Dermatitis acneiform	3 (1.5%)	1 (0.5%)	4 (1.0%)
Dermatitis bullous	3 (1.5%)	1 (0.5%)	4 (1.0%)
Rash	2 (1.0%)	2 (1.0%)	4 (1.0%)
Skin exfoliation	4 (2.0%)	0	4 (1.0%)
Acne	3 (1.5%)	0	3 (0.8%)
Blister	3 (1.5%)	0	3 (0.8%)
Decubitus ulcer	2 (1.0%)	1 (0.5%)	3 (0.8%)
Lichen planus	3 (1.5%)	0	3 (0.8%)
Night sweats	2 (1.0%)	1 (0.5%)	3 (0.8%)
Purpura	2 (1.0%)	1 (0.5%)	3 (0.8%)
Skin toxicity	3 (1.5%)	0	3 (0.8%)

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Table 302.1.2000.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Skin ulcer	3 (1.5%)	0	3 (0.8%)
Vitiligo	3 (1.5%)	0	3 (0.8%)
Erythema multiforme	2 (1.0%)	0	2 (0.5%)
Hyperhidrosis	2 (1.0%)	0	2 (0.5%)
Madarosis	2 (1.0%)	0	2 (0.5%)
Pemphigoid	2 (1.0%)	0	2 (0.5%)
Rash pruritic	1 (0.5%)	1 (0.5%)	2 (0.5%)
Rash vesicular	2 (1.0%)	0	2 (0.5%)
Skin hypopigmentation	2 (1.0%)	0	2 (0.5%)
Acquired porokeratosis	1 (0.5%)	0	1 (0.3%)
Dermal cyst	1 (0.5%)	0	1 (0.3%)
Dermatitis contact	1 (0.5%)	0	1 (0.3%)
Dermatitis exfoliative	1 (0.5%)	0	1 (0.3%)
Ecchymosis	0	1 (0.5%)	1 (0.3%)
Intertrigo	1 (0.5%)	0	1 (0.3%)
Lentigo	1 (0.5%)	0	1 (0.3%)
Leukoderma	1 (0.5%)	0	1 (0.3%)
Lichenoid keratosis	1 (0.5%)	0	1 (0.3%)
Lipohypertrophy	0	1 (0.5%)	1 (0.3%)
Melanosis	1 (0.5%)	0	1 (0.3%)
Nail ridging	0	1 (0.5%)	1 (0.3%)
Nail toxicity	1 (0.5%)	0	1 (0.3%)
Onychoclasis	0	1 (0.5%)	1 (0.3%)
Onychomadesis	0	1 (0.5%)	1 (0.3%)
Papule	1 (0.5%)	0	1 (0.3%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Petechiae	0	1 (0.5%)	1 (0.3%)
Pseudocellulitis	0	1 (0.5%)	1 (0.3%)
Scab	1 (0.5%)	0	1 (0.3%)
Seborrhoeic dermatitis	1 (0.5%)	0	1 (0.3%)
Skin atrophy	1 (0.5%)	0	1 (0.3%)
Skin burning sensation	1 (0.5%)	0	1 (0.3%)
Skin discolouration	1 (0.5%)	0	1 (0.3%)
Skin disorder	1 (0.5%)	0	1 (0.3%)
Skin erosion	1 (0.5%)	0	1 (0.3%)
Skin induration	0	1 (0.5%)	1 (0.3%)
Skin lesion	1 (0.5%)	0	1 (0.3%)
Stasis dermatitis	1 (0.5%)	0	1 (0.3%)
Toxic skin eruption	1 (0.5%)	0	1 (0.3%)
Metabolism and nutrition disorders	117 (58.2%)	83 (42.1%)	200 (50.3%)
Decreased appetite	72 (35.8%)	50 (25.4%)	122 (30.7%)
Hyperglycaemia	27 (13.4%)	4 (2.0%)	31 (7.8%)
Hyponatraemia	20 (10.0%)	9 (4.6%)	29 (7.3%)
Hypophosphataemia	19 (9.5%)	9 (4.6%)	28 (7.0%)
Hypokalaemia	19 (9.5%)	8 (4.1%)	27 (6.8%)
Hyperkalaemia	8 (4.0%)	12 (6.1%)	20 (5.0%)
Hypocalcaemia	8 (4.0%)	11 (5.6%)	19 (4.8%)
Hypomagnesaemia	10 (5.0%)	7 (3.6%)	17 (4.3%)
Hypoalbuminaemia	10 (5.0%)	6 (3.0%)	16 (4.0%)
Dehydration	11 (5.5%)	3 (1.5%)	14 (3.5%)
Hypercalcaemia	7 (3.5%)	3 (1.5%)	10 (2.5%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Hypercreatininaemia	3 (1.5%)	0	3 (0.8%)
Hyperuricaemia	1 (0.5%)	2 (1.0%)	3 (0.8%)
Metabolic acidosis	2 (1.0%)	1 (0.5%)	3 (0.8%)
Type 2 diabetes mellitus	1 (0.5%)	2 (1.0%)	3 (0.8%)
Cachexia	1 (0.5%)	1 (0.5%)	2 (0.5%)
Diabetes mellitus	2 (1.0%)	0	2 (0.5%)
Gout	2 (1.0%)	0	2 (0.5%)
Hyperamylasaemia	2 (1.0%)	0	2 (0.5%)
Hyperlipasaemia	2 (1.0%)	0	2 (0.5%)
Hypoglycaemia	2 (1.0%)	0	2 (0.5%)
Hypozincaemia	2 (1.0%)	0	2 (0.5%)
Malnutrition	0	2 (1.0%)	2 (0.5%)
Polydipsia	1 (0.5%)	1 (0.5%)	2 (0.5%)
Hypercholesterolaemia	1 (0.5%)	0	1 (0.3%)
Hypermagnesaemia	0	1 (0.5%)	1 (0.3%)
Hypernatraemia	0	1 (0.5%)	1 (0.3%)
Hyperphosphataemia	1 (0.5%)	0	1 (0.3%)
Hypertriglyceridaemia	1 (0.5%)	0	1 (0.3%)
Hypochloraemia	1 (0.5%)	0	1 (0.3%)
Impaired fasting glucose	1 (0.5%)	0	1 (0.3%)
Type 1 diabetes mellitus	1 (0.5%)	0	1 (0.3%)
Vitamin D deficiency	0	1 (0.5%)	1 (0.3%)
Investigations	108 (53.7%)	86 (43.7%)	194 (48.7%)
Weight decreased	72 (35.8%)	15 (7.6%)	87 (21.9%)
Blood creatinine increased	27 (13.4%)	23 (11.7%)	50 (12.6%)

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Table 302.1.2000.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Alanine aminotransferase increased	27 (13.4%)	19 (9.6%)	46 (11.6%)
Aspartate aminotransferase increased	22 (10.9%)	17 (8.6%)	39 (9.8%)
Platelet count decreased	3 (1.5%)	29 (14.7%)	32 (8.0%)
Neutrophil count decreased	5 (2.5%)	19 (9.6%)	24 (6.0%)
Blood alkaline phosphatase increased	10 (5.0%)	8 (4.1%)	18 (4.5%)
Blood lactate dehydrogenase increased	6 (3.0%)	9 (4.6%)	15 (3.8%)
White blood cell count decreased	4 (2.0%)	9 (4.6%)	13 (3.3%)
Lymphocyte count decreased	8 (4.0%)	3 (1.5%)	11 (2.8%)
Weight increased	6 (3.0%)	2 (1.0%)	8 (2.0%)
Amylase increased	2 (1.0%)	4 (2.0%)	6 (1.5%)
Gamma-glutamyltransferase increased	2 (1.0%)	4 (2.0%)	6 (1.5%)
Lipase increased	3 (1.5%)	2 (1.0%)	5 (1.3%)
Blood bilirubin increased	3 (1.5%)	1 (0.5%)	4 (1.0%)
Blood bicarbonate decreased	3 (1.5%)	0	3 (0.8%)
Blood urea increased	0	3 (1.5%)	3 (0.8%)
Blood thyroid stimulating hormone increased	2 (1.0%)	0	2 (0.5%)
Apolipoprotein B increased	1 (0.5%)	0	1 (0.3%)
Blood cholesterol increased	1 (0.5%)	0	1 (0.3%)
Blood creatine phosphokinase increased	1 (0.5%)	0	1 (0.3%)
Blood glucose increased	1 (0.5%)	0	1 (0.3%)
Blood lactate dehydrogenase	1 (0.5%)	0	1 (0.3%)
Blood magnesium decreased	0	1 (0.5%)	1 (0.3%)
Blood phosphorus decreased	0	1 (0.5%)	1 (0.3%)
Blood potassium decreased	1 (0.5%)	0	1 (0.3%)
Blood triglycerides increased	1 (0.5%)	0	1 (0.3%)

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Table 302.1.2000.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
False positive investigation result	0	1 (0.5%)	1 (0.3%)
Glomerular filtration rate decreased	0	1 (0.5%)	1 (0.3%)
International normalised ratio increased	0	1 (0.5%)	1 (0.3%)
Platelet count increased	0	1 (0.5%)	1 (0.3%)
Respiratory rate decreased	1 (0.5%)	0	1 (0.3%)
SARS-CoV-2 test positive	1 (0.5%)	0	1 (0.3%)
Waist circumference increased	1 (0.5%)	0	1 (0.3%)
White blood cell count increased	0	1 (0.5%)	1 (0.3%)
Nervous system disorders	140 (69.7%)	46 (23.4%)	186 (46.7%)
Peripheral sensory neuropathy	101 (50.2%)	10 (5.1%)	111 (27.9%)
Dysgeusia	46 (22.9%)	9 (4.6%)	55 (13.8%)
Dizziness	12 (6.0%)	16 (8.1%)	28 (7.0%)
Headache	14 (7.0%)	10 (5.1%)	24 (6.0%)
Paraesthesia	12 (6.0%)	2 (1.0%)	14 (3.5%)
Peripheral motor neuropathy	9 (4.5%)	0	9 (2.3%)
Peripheral sensorimotor neuropathy	6 (3.0%)	0	6 (1.5%)
Hypoaesthesia	5 (2.5%)	0	5 (1.3%)
Taste disorder	4 (2.0%)	1 (0.5%)	5 (1.3%)
Peroneal nerve palsy	3 (1.5%)	0	3 (0.8%)
Somnolence	2 (1.0%)	1 (0.5%)	3 (0.8%)
Cerebrovascular accident	2 (1.0%)	0	2 (0.5%)
Hypogeusia	2 (1.0%)	0	2 (0.5%)
Neuralgia	2 (1.0%)	0	2 (0.5%)
Tremor	1 (0.5%)	1 (0.5%)	2 (0.5%)
Ageusia	1 (0.5%)	0	1 (0.3%)

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Table 302.1.2000.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Anosmia	1 (0.5%)	0	1 (0.3%)
Balance disorder	1 (0.5%)	0	1 (0.3%)
Burning sensation	0	1 (0.5%)	1 (0.3%)
Carotid arteriosclerosis	1 (0.5%)	0	1 (0.3%)
Cognitive disorder	1 (0.5%)	0	1 (0.3%)
Dementia	1 (0.5%)	0	1 (0.3%)
Disturbance in attention	1 (0.5%)	0	1 (0.3%)
Dizziness postural	0	1 (0.5%)	1 (0.3%)
Dysarthria	1 (0.5%)	0	1 (0.3%)
Embolic stroke	0	1 (0.5%)	1 (0.3%)
Hypergeusia	0	1 (0.5%)	1 (0.3%)
Lethargy	0	1 (0.5%)	1 (0.3%)
Migraine	1 (0.5%)	0	1 (0.3%)
Neuropathy peripheral	0	1 (0.5%)	1 (0.3%)
Pseudoparalysis	1 (0.5%)	0	1 (0.3%)
Restless legs syndrome	1 (0.5%)	0	1 (0.3%)
Infections and infestations	103 (51.2%)	57 (28.9%)	160 (40.2%)
Urinary tract infection	40 (19.9%)	29 (14.7%)	69 (17.3%)
COVID-19	17 (8.5%)	8 (4.1%)	25 (6.3%)
Oral candidiasis	9 (4.5%)	2 (1.0%)	11 (2.8%)
Pneumonia	9 (4.5%)	2 (1.0%)	11 (2.8%)
Conjunctivitis	9 (4.5%)	0	9 (2.3%)
Respiratory tract infection	4 (2.0%)	2 (1.0%)	6 (1.5%)
Bronchitis	4 (2.0%)	1 (0.5%)	5 (1.3%)
Cellulitis	4 (2.0%)	1 (0.5%)	5 (1.3%)

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Table 302.1.2000.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Skin infection	3 (1.5%)	2 (1.0%)	5 (1.3%)
Upper respiratory tract infection	4 (2.0%)	1 (0.5%)	5 (1.3%)
Nasopharyngitis	3 (1.5%)	1 (0.5%)	4 (1.0%)
Rhinitis	4 (2.0%)	0	4 (1.0%)
Cystitis	1 (0.5%)	2 (1.0%)	3 (0.8%)
Gastroenteritis	3 (1.5%)	0	3 (0.8%)
Influenza	2 (1.0%)	1 (0.5%)	3 (0.8%)
Pharyngitis	3 (1.5%)	0	3 (0.8%)
Pyelonephritis acute	1 (0.5%)	2 (1.0%)	3 (0.8%)
Bacteraemia	0	2 (1.0%)	2 (0.5%)
Bronchitis viral	1 (0.5%)	1 (0.5%)	2 (0.5%)
Clostridium difficile colitis	2 (1.0%)	0	2 (0.5%)
Eye infection	2 (1.0%)	0	2 (0.5%)
Pyelonephritis	2 (1.0%)	0	2 (0.5%)
Rash pustular	2 (1.0%)	0	2 (0.5%)
Skin candida	1 (0.5%)	1 (0.5%)	2 (0.5%)
Tinea pedis	2 (1.0%)	0	2 (0.5%)
Abdominal infection	0	1 (0.5%)	1 (0.3%)
Bronchopulmonary aspergillosis	1 (0.5%)	0	1 (0.3%)
Campylobacter gastroenteritis	1 (0.5%)	0	1 (0.3%)
Campylobacter infection	1 (0.5%)	0	1 (0.3%)
Candida infection	1 (0.5%)	0	1 (0.3%)
COVID-19 pneumonia	1 (0.5%)	0	1 (0.3%)
Cystitis escherichia	0	1 (0.5%)	1 (0.3%)
Cytomegalovirus colitis	1 (0.5%)	0	1 (0.3%)

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MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Device related infection	1 (0.5%)	0	1 (0.3%)
Enterobacter bacteraemia	0	1 (0.5%)	1 (0.3%)
Enterocolitis infectious	1 (0.5%)	0	1 (0.3%)
Folliculitis	0	1 (0.5%)	1 (0.3%)
Fungal foot infection	1 (0.5%)	0	1 (0.3%)
Gastritis viral	1 (0.5%)	0	1 (0.3%)
Gastroenteritis viral	1 (0.5%)	0	1 (0.3%)
Gingivitis	1 (0.5%)	0	1 (0.3%)
Herpes simplex	1 (0.5%)	0	1 (0.3%)
Herpes zoster	1 (0.5%)	0	1 (0.3%)
Intestinal fistula infection	1 (0.5%)	0	1 (0.3%)
Mumps	0	1 (0.5%)	1 (0.3%)
Nail infection	1 (0.5%)	0	1 (0.3%)
Oesophageal candidiasis	0	1 (0.5%)	1 (0.3%)
Oral herpes	1 (0.5%)	0	1 (0.3%)
Paronychia	0	1 (0.5%)	1 (0.3%)
Penile infection	1 (0.5%)	0	1 (0.3%)
Peritonsillar abscess	0	1 (0.5%)	1 (0.3%)
Pharyngitis streptococcal	1 (0.5%)	0	1 (0.3%)
Pyuria	1 (0.5%)	0	1 (0.3%)
Respiratory tract infection bacterial	0	1 (0.5%)	1 (0.3%)
Salmonellosis	1 (0.5%)	0	1 (0.3%)
Sinusitis	1 (0.5%)	0	1 (0.3%)
Stitch abscess	1 (0.5%)	0	1 (0.3%)
Subcutaneous abscess	1 (0.5%)	0	1 (0.3%)

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MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Tonsillitis	0	1 (0.5%)	1 (0.3%)
Urinary tract infection bacterial	1 (0.5%)	0	1 (0.3%)
Urosepsis	0	1 (0.5%)	1 (0.3%)
Viral infection	0	1 (0.5%)	1 (0.3%)
Respiratory, thoracic and mediastinal disorders	77 (38.3%)	55 (27.9%)	132 (33.2%)
Dyspnoea	27 (13.4%)	24 (12.2%)	51 (12.8%)
Cough	28 (13.9%)	10 (5.1%)	38 (9.5%)
Epistaxis	5 (2.5%)	8 (4.1%)	13 (3.3%)
Hiccups	6 (3.0%)	7 (3.6%)	13 (3.3%)
Pneumonitis	11 (5.5%)	0	11 (2.8%)
Dysphonia	9 (4.5%)	0	9 (2.3%)
Productive cough	6 (3.0%)	2 (1.0%)	8 (2.0%)
Pleural effusion	5 (2.5%)	2 (1.0%)	7 (1.8%)
Rhinorrhoea	7 (3.5%)	0	7 (1.8%)
Dyspnoea exertional	1 (0.5%)	3 (1.5%)	4 (1.0%)
Nasal congestion	4 (2.0%)	0	4 (1.0%)
Oropharyngeal pain	2 (1.0%)	2 (1.0%)	4 (1.0%)
Immune-mediated lung disease	3 (1.5%)	0	3 (0.8%)
Pneumothorax	2 (1.0%)	1 (0.5%)	3 (0.8%)
Pulmonary embolism	0	3 (1.5%)	3 (0.8%)
Wheezing	2 (1.0%)	1 (0.5%)	3 (0.8%)
Chronic obstructive pulmonary disease	1 (0.5%)	1 (0.5%)	2 (0.5%)
Hypoxia	2 (1.0%)	0	2 (0.5%)
Tachypnoea	2 (1.0%)	0	2 (0.5%)
Throat irritation	2 (1.0%)	0	2 (0.5%)

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MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Asthma	0	1 (0.5%)	1 (0.3%)
Autoimmune lung disease	1 (0.5%)	0	1 (0.3%)
Bronchospasm	0	1 (0.5%)	1 (0.3%)
Catarrh	1 (0.5%)	0	1 (0.3%)
Emphysema	1 (0.5%)	0	1 (0.3%)
Haemoptysis	0	1 (0.5%)	1 (0.3%)
Interstitial lung disease	1 (0.5%)	0	1 (0.3%)
Lung opacity	1 (0.5%)	0	1 (0.3%)
Nasal dryness	1 (0.5%)	0	1 (0.3%)
Oropharyngeal discomfort	1 (0.5%)	0	1 (0.3%)
Pharyngeal erythema	1 (0.5%)	0	1 (0.3%)
Rales	0	1 (0.5%)	1 (0.3%)
Respiratory acidosis	0	1 (0.5%)	1 (0.3%)
Respiratory disorder	1 (0.5%)	0	1 (0.3%)
Rhinitis allergic	1 (0.5%)	0	1 (0.3%)
Sinus pain	1 (0.5%)	0	1 (0.3%)
Sneezing	0	1 (0.5%)	1 (0.3%)
Throat clearing	0	1 (0.5%)	1 (0.3%)
Upper-airway cough syndrome	1 (0.5%)	0	1 (0.3%)
Musculoskeletal and connective tissue disorders	76 (37.8%)	51 (25.9%)	127 (31.9%)
Arthralgia	21 (10.4%)	10 (5.1%)	31 (7.8%)
Back pain	16 (8.0%)	12 (6.1%)	28 (7.0%)
Pain in extremity	11 (5.5%)	8 (4.1%)	19 (4.8%)
Muscular weakness	15 (7.5%)	3 (1.5%)	18 (4.5%)
Myalgia	9 (4.5%)	4 (2.0%)	13 (3.3%)

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MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Flank pain	7 (3.5%)	0	7 (1.8%)
Arthritis	3 (1.5%)	3 (1.5%)	6 (1.5%)
Muscle spasms	5 (2.5%)	1 (0.5%)	6 (1.5%)
Musculoskeletal chest pain	3 (1.5%)	3 (1.5%)	6 (1.5%)
Groin pain	2 (1.0%)	3 (1.5%)	5 (1.3%)
Bone pain	1 (0.5%)	3 (1.5%)	4 (1.0%)
Musculoskeletal pain	4 (2.0%)	0	4 (1.0%)
Spinal pain	1 (0.5%)	3 (1.5%)	4 (1.0%)
Neck pain	0	3 (1.5%)	3 (0.8%)
Bursitis	2 (1.0%)	0	2 (0.5%)
Immune-mediated arthritis	2 (1.0%)	0	2 (0.5%)
Joint swelling	2 (1.0%)	0	2 (0.5%)
Musculoskeletal discomfort	1 (0.5%)	1 (0.5%)	2 (0.5%)
Osteoarthritis	1 (0.5%)	1 (0.5%)	2 (0.5%)
Pathological fracture	1 (0.5%)	1 (0.5%)	2 (0.5%)
Pubic pain	1 (0.5%)	1 (0.5%)	2 (0.5%)
Intervertebral disc degeneration	0	1 (0.5%)	1 (0.3%)
Joint range of motion decreased	1 (0.5%)	0	1 (0.3%)
Muscle contracture	0	1 (0.5%)	1 (0.3%)
Myositis	1 (0.5%)	0	1 (0.3%)
Osteopenia	1 (0.5%)	0	1 (0.3%)
Osteoporotic fracture	1 (0.5%)	0	1 (0.3%)
Rhabdomyolysis	1 (0.5%)	0	1 (0.3%)
Sacral pain	1 (0.5%)	0	1 (0.3%)
Renal and urinary disorders	52 (25.9%)	40 (20.3%)	92 (23.1%)

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MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Haematuria	23 (11.4%)	18 (9.1%)	41 (10.3%)
Dysuria	8 (4.0%)	5 (2.5%)	13 (3.3%)
Acute kidney injury	5 (2.5%)	4 (2.0%)	9 (2.3%)
Pollakiuria	5 (2.5%)	2 (1.0%)	7 (1.8%)
Proteinuria	4 (2.0%)	3 (1.5%)	7 (1.8%)
Renal impairment	3 (1.5%)	3 (1.5%)	6 (1.5%)
Hydronephrosis	1 (0.5%)	4 (2.0%)	5 (1.3%)
Bladder spasm	0	4 (2.0%)	4 (1.0%)
Chromaturia	1 (0.5%)	1 (0.5%)	2 (0.5%)
Immune-mediated nephritis	2 (1.0%)	0	2 (0.5%)
Leukocyturia	1 (0.5%)	1 (0.5%)	2 (0.5%)
Nocturia	2 (1.0%)	0	2 (0.5%)
Renal failure	1 (0.5%)	1 (0.5%)	2 (0.5%)
Urinary retention	0	2 (1.0%)	2 (0.5%)
Urine odour abnormal	2 (1.0%)	0	2 (0.5%)
Azotaemia	1 (0.5%)	0	1 (0.3%)
Bladder irritation	1 (0.5%)	0	1 (0.3%)
Chronic kidney disease	1 (0.5%)	0	1 (0.3%)
Costovertebral angle tenderness	0	1 (0.5%)	1 (0.3%)
Cystitis noninfective	1 (0.5%)	0	1 (0.3%)
Hypertonic bladder	1 (0.5%)	0	1 (0.3%)
Nephroangiosclerosis	1 (0.5%)	0	1 (0.3%)
Nephropathy	0	1 (0.5%)	1 (0.3%)
Polyuria	1 (0.5%)	0	1 (0.3%)
Renal pain	0	1 (0.5%)	1 (0.3%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Renal tubular necrosis	1 (0.5%)	0	1 (0.3%)
Strangury	0	1 (0.5%)	1 (0.3%)
Tubulointerstitial nephritis	1 (0.5%)	0	1 (0.3%)
Ureteric obstruction	1 (0.5%)	0	1 (0.3%)
Urinary incontinence	1 (0.5%)	0	1 (0.3%)
Urinary tract obstruction	1 (0.5%)	0	1 (0.3%)
Urine flow decreased	1 (0.5%)	0	1 (0.3%)
Urogenital fistula	1 (0.5%)	0	1 (0.3%)
Eye disorders	64 (31.8%)	12 (6.1%)	76 (19.1%)
Dry eye	21 (10.4%)	2 (1.0%)	23 (5.8%)
Cataract	12 (6.0%)	0	12 (3.0%)
Lacrimation increased	11 (5.5%)	1 (0.5%)	12 (3.0%)
Vision blurred	10 (5.0%)	1 (0.5%)	11 (2.8%)
Eye pain	3 (1.5%)	1 (0.5%)	4 (1.0%)
Eye pruritus	3 (1.5%)	0	3 (0.8%)
Blepharitis	2 (1.0%)	0	2 (0.5%)
Conjunctival haemorrhage	2 (1.0%)	0	2 (0.5%)
Conjunctivitis allergic	2 (1.0%)	0	2 (0.5%)
Epiretinal membrane	2 (1.0%)	0	2 (0.5%)
Eye discharge	2 (1.0%)	0	2 (0.5%)
Keratitis	2 (1.0%)	0	2 (0.5%)
Meibomian gland dysfunction	2 (1.0%)	0	2 (0.5%)
Photophobia	1 (0.5%)	1 (0.5%)	2 (0.5%)
Punctate keratitis	2 (1.0%)	0	2 (0.5%)
Visual acuity reduced	1 (0.5%)	1 (0.5%)	2 (0.5%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Visual impairment	1 (0.5%)	1 (0.5%)	2 (0.5%)
Xerophthalmia	2 (1.0%)	0	2 (0.5%)
Angle closure glaucoma	0	1 (0.5%)	1 (0.3%)
Arteriosclerotic retinopathy	1 (0.5%)	0	1 (0.3%)
Conjunctival cyst	1 (0.5%)	0	1 (0.3%)
Conjunctival hyperaemia	1 (0.5%)	0	1 (0.3%)
Corneal degeneration	1 (0.5%)	0	1 (0.3%)
Corneal erosion	1 (0.5%)	0	1 (0.3%)
Dacryostenosis acquired	1 (0.5%)	0	1 (0.3%)
Erythema of eyelid	1 (0.5%)	0	1 (0.3%)
Exfoliation glaucoma	1 (0.5%)	0	1 (0.3%)
Exophthalmos	1 (0.5%)	0	1 (0.3%)
Eye irritation	0	1 (0.5%)	1 (0.3%)
Eye oedema	0	1 (0.5%)	1 (0.3%)
Keratoconus	1 (0.5%)	0	1 (0.3%)
Macular oedema	1 (0.5%)	0	1 (0.3%)
Normal tension glaucoma	1 (0.5%)	0	1 (0.3%)
Ocular discomfort	0	1 (0.5%)	1 (0.3%)
Ocular hyperaemia	1 (0.5%)	0	1 (0.3%)
Periorbital oedema	0	1 (0.5%)	1 (0.3%)
Posterior capsule opacification	1 (0.5%)	0	1 (0.3%)
Presbyopia	1 (0.5%)	0	1 (0.3%)
Scleritis	1 (0.5%)	0	1 (0.3%)
Psychiatric disorders	35 (17.4%)	20 (10.2%)	55 (13.8%)
Insomnia	23 (11.4%)	10 (5.1%)	33 (8.3%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Anxiety	9 (4.5%)	3 (1.5%)	12 (3.0%)
Depression	6 (3.0%)	2 (1.0%)	8 (2.0%)
Confusional state	2 (1.0%)	3 (1.5%)	5 (1.3%)
Delirium	4 (2.0%)	0	4 (1.0%)
Affect lability	0	2 (1.0%)	2 (0.5%)
Agitation	1 (0.5%)	0	1 (0.3%)
Emotional distress	0	1 (0.5%)	1 (0.3%)
Hallucination	1 (0.5%)	0	1 (0.3%)
Mental status changes	0	1 (0.5%)	1 (0.3%)
Panic attack	1 (0.5%)	0	1 (0.3%)
Vascular disorders	26 (12.9%)	25 (12.7%)	51 (12.8%)
Hypotension	8 (4.0%)	1 (0.5%)	9 (2.3%)
Hypertension	5 (2.5%)	3 (1.5%)	8 (2.0%)
Thrombophlebitis	1 (0.5%)	6 (3.0%)	7 (1.8%)
Hot flush	2 (1.0%)	3 (1.5%)	5 (1.3%)
Haematoma	2 (1.0%)	2 (1.0%)	4 (1.0%)
Deep vein thrombosis	2 (1.0%)	1 (0.5%)	3 (0.8%)
Superficial vein thrombosis	1 (0.5%)	2 (1.0%)	3 (0.8%)
Flushing	1 (0.5%)	1 (0.5%)	2 (0.5%)
Lymphoedema	0	2 (1.0%)	2 (0.5%)
Orthostatic hypotension	1 (0.5%)	1 (0.5%)	2 (0.5%)
Peripheral venous disease	1 (0.5%)	1 (0.5%)	2 (0.5%)
Phlebitis	0	2 (1.0%)	2 (0.5%)
Aortic dilatation	1 (0.5%)	0	1 (0.3%)
Peripheral coldness	1 (0.5%)	0	1 (0.3%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Peripheral embolism	1 (0.5%)	0	1 (0.3%)
Post thrombotic syndrome	0	1 (0.5%)	1 (0.3%)
Raynaud's phenomenon	1 (0.5%)	0	1 (0.3%)
Vascular pain	0	1 (0.5%)	1 (0.3%)
Injury, poisoning and procedural complications	25 (12.4%)	20 (10.2%)	45 (11.3%)
Fall	10 (5.0%)	5 (2.5%)	15 (3.8%)
Skin abrasion	6 (3.0%)	1 (0.5%)	7 (1.8%)
Contusion	3 (1.5%)	2 (1.0%)	5 (1.3%)
Infusion related reaction	1 (0.5%)	3 (1.5%)	4 (1.0%)
Urinary tract stoma complication	0	3 (1.5%)	3 (0.8%)
Radius fracture	2 (1.0%)	0	2 (0.5%)
Skin laceration	2 (1.0%)	0	2 (0.5%)
Tendon rupture	2 (1.0%)	0	2 (0.5%)
Thermal burn	2 (1.0%)	0	2 (0.5%)
Wound dehiscence	0	2 (1.0%)	2 (0.5%)
Wrist fracture	1 (0.5%)	1 (0.5%)	2 (0.5%)
Ankle fracture	1 (0.5%)	0	1 (0.3%)
Corneal abrasion	1 (0.5%)	0	1 (0.3%)
Foot fracture	1 (0.5%)	0	1 (0.3%)
Genital injury	1 (0.5%)	0	1 (0.3%)
Ligament sprain	1 (0.5%)	0	1 (0.3%)
Lumbar vertebral fracture	1 (0.5%)	0	1 (0.3%)
Post procedural haemorrhage	0	1 (0.5%)	1 (0.3%)
Rib fracture	1 (0.5%)	0	1 (0.3%)
Shoulder fracture	1 (0.5%)	0	1 (0.3%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Stoma site haemorrhage	0	1 (0.5%)	1 (0.3%)
Toxicity to various agents	0	1 (0.5%)	1 (0.3%)
Transfusion reaction	0	1 (0.5%)	1 (0.3%)
Urostomy complication	1 (0.5%)	0	1 (0.3%)
Endocrine disorders	35 (17.4%)	3 (1.5%)	38 (9.5%)
Hypothyroidism	22 (10.9%)	2 (1.0%)	24 (6.0%)
Hyperthyroidism	11 (5.5%)	1 (0.5%)	12 (3.0%)
Adrenal insufficiency	3 (1.5%)	0	3 (0.8%)
Hypophysitis	2 (1.0%)	0	2 (0.5%)
Central hypothyroidism	1 (0.5%)	0	1 (0.3%)
Immune-mediated hypothyroidism	1 (0.5%)	0	1 (0.3%)
Thyroiditis	1 (0.5%)	0	1 (0.3%)
Hepatobiliary disorders	28 (13.9%)	10 (5.1%)	38 (9.5%)
Hypertransaminasaemia	10 (5.0%)	6 (3.0%)	16 (4.0%)
Hepatic function abnormal	3 (1.5%)	2 (1.0%)	5 (1.3%)
Hyperbilirubinaemia	2 (1.0%)	2 (1.0%)	4 (1.0%)
Drug-induced liver injury	1 (0.5%)	2 (1.0%)	3 (0.8%)
Autoimmune hepatitis	2 (1.0%)	0	2 (0.5%)
Hepatotoxicity	2 (1.0%)	0	2 (0.5%)
Immune-mediated hepatitis	2 (1.0%)	0	2 (0.5%)
Biliary colic	1 (0.5%)	0	1 (0.3%)
Biliary dilatation	1 (0.5%)	0	1 (0.3%)
Cholangitis sclerosing	1 (0.5%)	0	1 (0.3%)
Cholecystitis	1 (0.5%)	0	1 (0.3%)
Gallbladder disorder	1 (0.5%)	0	1 (0.3%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Hepatic pain	1 (0.5%)	0	1 (0.3%)
Hepatic steatosis	1 (0.5%)	0	1 (0.3%)
Hepatitis	1 (0.5%)	0	1 (0.3%)
Cardiac disorders	12 (6.0%)	10 (5.1%)	22 (5.5%)
Atrial fibrillation	3 (1.5%)	3 (1.5%)	6 (1.5%)
Palpitations	2 (1.0%)	2 (1.0%)	4 (1.0%)
Cardiac failure	2 (1.0%)	0	2 (0.5%)
Tachycardia	1 (0.5%)	1 (0.5%)	2 (0.5%)
Ventricular tachycardia	1 (0.5%)	1 (0.5%)	2 (0.5%)
Angina pectoris	0	1 (0.5%)	1 (0.3%)
Aortic valve disease	0	1 (0.5%)	1 (0.3%)
Atrial flutter	0	1 (0.5%)	1 (0.3%)
Atrial thrombosis	1 (0.5%)	0	1 (0.3%)
Bundle branch block right	1 (0.5%)	0	1 (0.3%)
Cardiac discomfort	1 (0.5%)	0	1 (0.3%)
Cardiac flutter	0	1 (0.5%)	1 (0.3%)
Myocarditis	1 (0.5%)	0	1 (0.3%)
Sinus tachycardia	1 (0.5%)	0	1 (0.3%)
Ventricular extrasystoles	1 (0.5%)	0	1 (0.3%)
Reproductive system and breast disorders	9 (4.5%)	6 (3.0%)	15 (3.8%)
Pelvic pain	5 (2.5%)	0	5 (1.3%)
Breast pain	0	1 (0.5%)	1 (0.3%)
Erectile dysfunction	1 (0.5%)	0	1 (0.3%)
Genital burning sensation	0	1 (0.5%)	1 (0.3%)
Genital paraesthesia	1 (0.5%)	0	1 (0.3%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Ovarian vein thrombosis	0	1 (0.5%)	1 (0.3%)
Penile erythema	0	1 (0.5%)	1 (0.3%)
Prostatitis	0	1 (0.5%)	1 (0.3%)
Testicular pain	0	1 (0.5%)	1 (0.3%)
Vaginal prolapse	1 (0.5%)	0	1 (0.3%)
Vulval eczema	1 (0.5%)	0	1 (0.3%)
Vulvovaginal dryness	1 (0.5%)	0	1 (0.3%)
Ear and labyrinth disorders	3 (1.5%)	7 (3.6%)	10 (2.5%)
Tinnitus	1 (0.5%)	2 (1.0%)	3 (0.8%)
Vertigo	0	3 (1.5%)	3 (0.8%)
Hypoacusis	1 (0.5%)	1 (0.5%)	2 (0.5%)
Eustachian tube disorder	0	1 (0.5%)	1 (0.3%)
Otorrhoea	1 (0.5%)	0	1 (0.3%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	8 (4.0%)	1 (0.5%)	9 (2.3%)
Cancer pain	5 (2.5%)	0	5 (1.3%)
Monoclonal gammopathy	1 (0.5%)	0	1 (0.3%)
Neuroma	1 (0.5%)	0	1 (0.3%)
Pancreatic cystadenoma	1 (0.5%)	0	1 (0.3%)
Tumour pain	0	1 (0.5%)	1 (0.3%)
Immune system disorders	4 (2.0%)	0	4 (1.0%)
Contrast media allergy	2 (1.0%)	0	2 (0.5%)
Drug hypersensitivity	1 (0.5%)	0	1 (0.3%)
Seasonal allergy	1 (0.5%)	0	1 (0.3%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.3.1: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Overall	164 (68.6%)	175 (74.2%)	339 (71.4%)
Blood and lymphatic system disorders	17 (7.1%)	110 (46.6%)	127 (26.7%)
Anaemia	5 (2.1%)	68 (28.8%)	73 (15.4%)
Neutropenia	8 (3.3%)	52 (22.0%)	60 (12.6%)
Thrombocytopenia	2 (0.8%)	28 (11.9%)	30 (6.3%)
Leukopenia	2 (0.8%)	7 (3.0%)	9 (1.9%)
Febrile neutropenia	3 (1.3%)	4 (1.7%)	7 (1.5%)
Anaemia of malignant disease	1 (0.4%)	0	1 (0.2%)
Lymphopenia	0	1 (0.4%)	1 (0.2%)
Pancytopenia	0	1 (0.4%)	1 (0.2%)
Infections and infestations	28 (11.7%)	39 (16.5%)	67 (14.1%)
Urinary tract infection	8 (3.3%)	19 (8.1%)	27 (5.7%)
Sepsis	2 (0.8%)	6 (2.5%)	8 (1.7%)
COVID-19 pneumonia	3 (1.3%)	2 (0.8%)	5 (1.1%)
Pneumonia	3 (1.3%)	2 (0.8%)	5 (1.1%)
COVID-19	1 (0.4%)	2 (0.8%)	3 (0.6%)
Device related infection	1 (0.4%)	2 (0.8%)	3 (0.6%)
Urosepsis	1 (0.4%)	2 (0.8%)	3 (0.6%)
Kidney infection	1 (0.4%)	1 (0.4%)	2 (0.4%)
Pyelonephritis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Abdominal abscess	0	1 (0.4%)	1 (0.2%)
Cellulitis	1 (0.4%)	0	1 (0.2%)
Diverticulitis	1 (0.4%)	0	1 (0.2%)
Escherichia urinary tract infection	0	1 (0.4%)	1 (0.2%)
Infectious pleural effusion	1 (0.4%)	0	1 (0.2%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.3.1: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Neutropenic sepsis	0	1 (0.4%)	1 (0.2%)
Oesophageal candidiasis	1 (0.4%)	0	1 (0.2%)
Parotitis	1 (0.4%)	0	1 (0.2%)
Pelvic infection	1 (0.4%)	0	1 (0.2%)
Perineal abscess	0	1 (0.4%)	1 (0.2%)
Pneumonia haemophilus	0	1 (0.4%)	1 (0.2%)
Rash pustular	1 (0.4%)	0	1 (0.2%)
Respiratory syncytial virus infection	0	1 (0.4%)	1 (0.2%)
Respiratory tract infection	1 (0.4%)	0	1 (0.2%)
Urinary tract infection bacterial	0	1 (0.4%)	1 (0.2%)
Urinary tract infection pseudomonal	0	1 (0.4%)	1 (0.2%)
Wound infection	0	1 (0.4%)	1 (0.2%)
Investigations	33 (13.8%)	34 (14.4%)	67 (14.1%)
Neutrophil count decreased	4 (1.7%)	21 (8.9%)	25 (5.3%)
Platelet count decreased	0	12 (5.1%)	12 (2.5%)
Weight decreased	8 (3.3%)	1 (0.4%)	9 (1.9%)
Lipase increased	8 (3.3%)	0	8 (1.7%)
Alanine aminotransferase increased	6 (2.5%)	1 (0.4%)	7 (1.5%)
White blood cell count decreased	1 (0.4%)	6 (2.5%)	7 (1.5%)
Aspartate aminotransferase increased	5 (2.1%)	0	5 (1.1%)
Amylase increased	3 (1.3%)	0	3 (0.6%)
Blood creatine phosphokinase increased	3 (1.3%)	0	3 (0.6%)
Gamma-glutamyltransferase increased	3 (1.3%)	0	3 (0.6%)
Blood creatinine increased	0	2 (0.8%)	2 (0.4%)
Blood bilirubin increased	1 (0.4%)	0	1 (0.2%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.3.1: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Electrocardiogram QT prolonged	1 (0.4%)	0	1 (0.2%)
Troponin I increased	1 (0.4%)	0	1 (0.2%)
Urine output decreased	1 (0.4%)	0	1 (0.2%)
Metabolism and nutrition disorders	41 (17.2%)	25 (10.6%)	66 (13.9%)
Hyperglycaemia	20 (8.4%)	2 (0.8%)	22 (4.6%)
Hyponatraemia	7 (2.9%)	8 (3.4%)	15 (3.2%)
Decreased appetite	5 (2.1%)	3 (1.3%)	8 (1.7%)
Hypophosphataemia	4 (1.7%)	3 (1.3%)	7 (1.5%)
Dehydration	1 (0.4%)	5 (2.1%)	6 (1.3%)
Hypokalaemia	3 (1.3%)	2 (0.8%)	5 (1.1%)
Diabetes mellitus	2 (0.8%)	1 (0.4%)	3 (0.6%)
Hypomagnesaemia	1 (0.4%)	2 (0.8%)	3 (0.6%)
Hypercalcaemia	2 (0.8%)	0	2 (0.4%)
Hyperkalaemia	0	2 (0.8%)	2 (0.4%)
Hyperlipasaemia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Hyperamylasaemia	0	1 (0.4%)	1 (0.2%)
Hypercreatininaemia	1 (0.4%)	0	1 (0.2%)
Hypoalbuminaemia	1 (0.4%)	0	1 (0.2%)
Hypocalcaemia	0	1 (0.4%)	1 (0.2%)
Hypochloraemia	0	1 (0.4%)	1 (0.2%)
Hypoglycaemia	1 (0.4%)	0	1 (0.2%)
Hypoproteinaemia	0	1 (0.4%)	1 (0.2%)
Hypovolaemia	1 (0.4%)	0	1 (0.2%)
Metabolic acidosis	1 (0.4%)	0	1 (0.2%)
Tumour lysis syndrome	1 (0.4%)	0	1 (0.2%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.3.1: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Type 2 diabetes mellitus	1 (0.4%)	0	1 (0.2%)
Gastrointestinal disorders	29 (12.1%)	17 (7.2%)	46 (9.7%)
Nausea	4 (1.7%)	9 (3.8%)	13 (2.7%)
Diarrhoea	10 (4.2%)	2 (0.8%)	12 (2.5%)
Vomiting	4 (1.7%)	5 (2.1%)	9 (1.9%)
Colitis	5 (2.1%)	0	5 (1.1%)
Abdominal pain	2 (0.8%)	2 (0.8%)	4 (0.8%)
Pancreatitis	3 (1.3%)	0	3 (0.6%)
Immune-mediated enterocolitis	2 (0.8%)	0	2 (0.4%)
Colonic fistula	1 (0.4%)	0	1 (0.2%)
Constipation	0	1 (0.4%)	1 (0.2%)
Dental caries	0	1 (0.4%)	1 (0.2%)
Duodenal stenosis	1 (0.4%)	0	1 (0.2%)
Dyspepsia	1 (0.4%)	0	1 (0.2%)
Enterovesical fistula	1 (0.4%)	0	1 (0.2%)
Gastric ulcer	1 (0.4%)	0	1 (0.2%)
Hernial eventration	1 (0.4%)	0	1 (0.2%)
Inguinal hernia	1 (0.4%)	0	1 (0.2%)
Intestinal obstruction	1 (0.4%)	0	1 (0.2%)
Large intestine perforation	1 (0.4%)	0	1 (0.2%)
Obstructive pancreatitis	0	1 (0.4%)	1 (0.2%)
Small intestinal obstruction	1 (0.4%)	0	1 (0.2%)
Skin and subcutaneous tissue disorders	39 (16.3%)	0	39 (8.2%)
Rash maculo-papular	16 (6.7%)	0	16 (3.4%)
Rash macular	7 (2.9%)	0	7 (1.5%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.3.1: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Dermatitis bullous	3 (1.3%)	0	3 (0.6%)
Eczema	3 (1.3%)	0	3 (0.6%)
Rash papular	3 (1.3%)	0	3 (0.6%)
Lichenoid keratosis	2 (0.8%)	0	2 (0.4%)
Alopecia	1 (0.4%)	0	1 (0.2%)
Dermatitis	1 (0.4%)	0	1 (0.2%)
Dermatitis exfoliative generalised	1 (0.4%)	0	1 (0.2%)
Dry skin	1 (0.4%)	0	1 (0.2%)
Erythema	1 (0.4%)	0	1 (0.2%)
Rash erythematous	1 (0.4%)	0	1 (0.2%)
Rash morbilliform	1 (0.4%)	0	1 (0.2%)
SJS-TEN overlap	1 (0.4%)	0	1 (0.2%)
Toxic epidermal necrolysis	1 (0.4%)	0	1 (0.2%)
Toxic erythema of chemotherapy	1 (0.4%)	0	1 (0.2%)
General disorders and administration site conditions	13 (5.4%)	24 (10.2%)	37 (7.8%)
Fatigue	6 (2.5%)	12 (5.1%)	18 (3.8%)
Asthenia	5 (2.1%)	6 (2.5%)	11 (2.3%)
General physical health deterioration	1 (0.4%)	2 (0.8%)	3 (0.6%)
Pyrexia	1 (0.4%)	2 (0.8%)	3 (0.6%)
Chills	0	1 (0.4%)	1 (0.2%)
Malaise	0	1 (0.4%)	1 (0.2%)
Multiple organ dysfunction syndrome	0	1 (0.4%)	1 (0.2%)
Non-cardiac chest pain	0	1 (0.4%)	1 (0.2%)
Oedema peripheral	0	1 (0.4%)	1 (0.2%)
Respiratory, thoracic and mediastinal disorders	24 (10.0%)	13 (5.5%)	37 (7.8%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.3.1: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Pulmonary embolism	5 (2.1%)	10 (4.2%)	15 (3.2%)
Pneumonitis	5 (2.1%)	1 (0.4%)	6 (1.3%)
Dyspnoea	4 (1.7%)	1 (0.4%)	5 (1.1%)
Immune-mediated lung disease	4 (1.7%)	0	4 (0.8%)
Interstitial lung disease	3 (1.3%)	0	3 (0.6%)
Respiratory failure	2 (0.8%)	0	2 (0.4%)
Acute pulmonary oedema	1 (0.4%)	0	1 (0.2%)
Acute respiratory failure	1 (0.4%)	0	1 (0.2%)
Aspiration	1 (0.4%)	0	1 (0.2%)
Cough	0	1 (0.4%)	1 (0.2%)
Haemoptysis	1 (0.4%)	0	1 (0.2%)
Hypoxia	1 (0.4%)	0	1 (0.2%)
Organising pneumonia	1 (0.4%)	0	1 (0.2%)
Pulmonary oedema	0	1 (0.4%)	1 (0.2%)
Respiratory distress	1 (0.4%)	0	1 (0.2%)
Renal and urinary disorders	16 (6.7%)	16 (6.8%)	32 (6.7%)
Acute kidney injury	8 (3.3%)	6 (2.5%)	14 (2.9%)
Haematuria	2 (0.8%)	6 (2.5%)	8 (1.7%)
Hydronephrosis	2 (0.8%)	2 (0.8%)	4 (0.8%)
Urinary retention	2 (0.8%)	2 (0.8%)	4 (0.8%)
Renal impairment	1 (0.4%)	1 (0.4%)	2 (0.4%)
Calculus bladder	1 (0.4%)	0	1 (0.2%)
Chronic kidney disease	0	1 (0.4%)	1 (0.2%)
Immune-mediated nephritis	1 (0.4%)	0	1 (0.2%)
Postrenal failure	1 (0.4%)	0	1 (0.2%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.3.1: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Urinary tract obstruction	1 (0.4%)	0	1 (0.2%)
Nervous system disorders	23 (9.6%)	5 (2.1%)	28 (5.9%)
Peripheral sensory neuropathy	6 (2.5%)	0	6 (1.3%)
Peripheral sensorimotor neuropathy	5 (2.1%)	0	5 (1.1%)
Syncope	3 (1.3%)	2 (0.8%)	5 (1.1%)
Peripheral motor neuropathy	3 (1.3%)	0	3 (0.6%)
Cerebral infarction	0	2 (0.8%)	2 (0.4%)
Ageusia	1 (0.4%)	0	1 (0.2%)
Cerebral haemorrhage	1 (0.4%)	0	1 (0.2%)
Chronic inflammatory demyelinating polyradiculoneuropathy	1 (0.4%)	0	1 (0.2%)
Diabetic hyperglycaemic coma	1 (0.4%)	0	1 (0.2%)
Headache	0	1 (0.4%)	1 (0.2%)
Immune-mediated encephalitis	1 (0.4%)	0	1 (0.2%)
Neurotoxicity	1 (0.4%)	0	1 (0.2%)
Musculoskeletal and connective tissue disorders	10 (4.2%)	8 (3.4%)	18 (3.8%)
Back pain	4 (1.7%)	1 (0.4%)	5 (1.1%)
Pain in extremity	1 (0.4%)	2 (0.8%)	3 (0.6%)
Bone pain	0	2 (0.8%)	2 (0.4%)
Muscular weakness	2 (0.8%)	0	2 (0.4%)
Myositis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Arthropathy	1 (0.4%)	0	1 (0.2%)
Gouty arthritis	1 (0.4%)	0	1 (0.2%)
Mobility decreased	0	1 (0.4%)	1 (0.2%)
Myalgia	0	1 (0.4%)	1 (0.2%)
Pathological fracture	0	1 (0.4%)	1 (0.2%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.3.1: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Rhabdomyolysis	0	1 (0.4%)	1 (0.2%)
Vascular disorders	9 (3.8%)	8 (3.4%)	17 (3.6%)
Hypertension	5 (2.1%)	5 (2.1%)	10 (2.1%)
Hypotension	2 (0.8%)	2 (0.8%)	4 (0.8%)
Deep vein thrombosis	0	1 (0.4%)	1 (0.2%)
Lymphoedema	1 (0.4%)	0	1 (0.2%)
Peripheral arterial occlusive disease	1 (0.4%)	0	1 (0.2%)
Cardiac disorders	6 (2.5%)	9 (3.8%)	15 (3.2%)
Atrial fibrillation	0	3 (1.3%)	3 (0.6%)
Cardiac arrest	2 (0.8%)	0	2 (0.4%)
Acute coronary syndrome	1 (0.4%)	0	1 (0.2%)
Acute myocardial infarction	0	1 (0.4%)	1 (0.2%)
Acute right ventricular failure	0	1 (0.4%)	1 (0.2%)
Angina pectoris	0	1 (0.4%)	1 (0.2%)
Atrioventricular block complete	1 (0.4%)	0	1 (0.2%)
Cardio-respiratory arrest	1 (0.4%)	0	1 (0.2%)
Cardiogenic shock	0	1 (0.4%)	1 (0.2%)
Myocardial infarction	0	1 (0.4%)	1 (0.2%)
Pericardial effusion	0	1 (0.4%)	1 (0.2%)
Supraventricular tachycardia	0	1 (0.4%)	1 (0.2%)
Tachycardia	1 (0.4%)	0	1 (0.2%)
Hepatobiliary disorders	9 (3.8%)	1 (0.4%)	10 (2.1%)
Cholecystitis	2 (0.8%)	0	2 (0.4%)
Hepatotoxicity	2 (0.8%)	0	2 (0.4%)
Immune-mediated hepatitis	2 (0.8%)	0	2 (0.4%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.3.1: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Autoimmune hepatitis	1 (0.4%)	0	1 (0.2%)
Hepatitis	1 (0.4%)	0	1 (0.2%)
Hepatitis toxic	0	1 (0.4%)	1 (0.2%)
Hypertransaminasaemia	1 (0.4%)	0	1 (0.2%)
Injury, poisoning and procedural complications	6 (2.5%)	3 (1.3%)	9 (1.9%)
Urinary tract stoma complication	3 (1.3%)	1 (0.4%)	4 (0.8%)
Heat stroke	1 (0.4%)	0	1 (0.2%)
Skin laceration	1 (0.4%)	0	1 (0.2%)
Spinal fracture	1 (0.4%)	0	1 (0.2%)
Tibia fracture	0	1 (0.4%)	1 (0.2%)
Toxicity to various agents	0	1 (0.4%)	1 (0.2%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (1.3%)	2 (0.8%)	5 (1.1%)
Burkitt's lymphoma	1 (0.4%)	0	1 (0.2%)
Cancer pain	1 (0.4%)	0	1 (0.2%)
Metastases to central nervous system	0	1 (0.4%)	1 (0.2%)
Tumour pain	0	1 (0.4%)	1 (0.2%)
Tumour rupture	1 (0.4%)	0	1 (0.2%)
Reproductive system and breast disorders	2 (0.8%)	2 (0.8%)	4 (0.8%)
Pelvic pain	1 (0.4%)	1 (0.4%)	2 (0.4%)
Penile pain	1 (0.4%)	0	1 (0.2%)
Prostatitis	1 (0.4%)	0	1 (0.2%)
Vaginal haemorrhage	0	1 (0.4%)	1 (0.2%)
Eye disorders	3 (1.3%)	0	3 (0.6%)
Cataract	2 (0.8%)	0	2 (0.4%)
Retinopathy hypertensive	1 (0.4%)	0	1 (0.2%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.3.1: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Endocrine disorders	2 (0.8%)	0	2 (0.4%)
Adrenal insufficiency	1 (0.4%)	0	1 (0.2%)
Hypothyroidism	1 (0.4%)	0	1 (0.2%)
Psychiatric disorders	2 (0.8%)	0	2 (0.4%)
Anxiety	1 (0.4%)	0	1 (0.2%)
Confusional state	1 (0.4%)	0	1 (0.2%)
Ear and labyrinth disorders	1 (0.4%)	0	1 (0.2%)
Vertigo	1 (0.4%)	0	1 (0.2%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.3.2: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Overall	157 (78.1%)	166 (84.3%)	323 (81.2%)
Blood and lymphatic system disorders	43 (21.4%)	135 (68.5%)	178 (44.7%)
Anaemia	26 (12.9%)	80 (40.6%)	106 (26.6%)
Neutropenia	14 (7.0%)	78 (39.6%)	92 (23.1%)
Thrombocytopenia	2 (1.0%)	59 (29.9%)	61 (15.3%)
Leukopenia	2 (1.0%)	13 (6.6%)	15 (3.8%)
Febrile neutropenia	1 (0.5%)	10 (5.1%)	11 (2.8%)
Pancytopenia	0	4 (2.0%)	4 (1.0%)
Leukocytosis	2 (1.0%)	0	2 (0.5%)
Haemolytic anaemia	0	1 (0.5%)	1 (0.3%)
Immune thrombocytopenia	1 (0.5%)	0	1 (0.3%)
Myelosuppression	0	1 (0.5%)	1 (0.3%)
Infections and infestations	49 (24.4%)	36 (18.3%)	85 (21.4%)
Urinary tract infection	14 (7.0%)	16 (8.1%)	30 (7.5%)
Pyelonephritis	4 (2.0%)	6 (3.0%)	10 (2.5%)
Pneumonia	7 (3.5%)	2 (1.0%)	9 (2.3%)
Sepsis	6 (3.0%)	2 (1.0%)	8 (2.0%)
COVID-19	4 (2.0%)	1 (0.5%)	5 (1.3%)
Pneumonia aspiration	4 (2.0%)	0	4 (1.0%)
Pyelonephritis acute	1 (0.5%)	2 (1.0%)	3 (0.8%)
Respiratory tract infection	0	3 (1.5%)	3 (0.8%)
Septic shock	3 (1.5%)	0	3 (0.8%)
Urosepsis	1 (0.5%)	2 (1.0%)	3 (0.8%)
Clostridium difficile infection	2 (1.0%)	0	2 (0.5%)
COVID-19 pneumonia	1 (0.5%)	1 (0.5%)	2 (0.5%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.3.2: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Cystitis	2 (1.0%)	0	2 (0.5%)
Neutropenic sepsis	1 (0.5%)	1 (0.5%)	2 (0.5%)
Peritonitis	0	2 (1.0%)	2 (0.5%)
Campylobacter gastroenteritis	1 (0.5%)	0	1 (0.3%)
Cellulitis	1 (0.5%)	0	1 (0.3%)
Cytomegalovirus colitis	1 (0.5%)	0	1 (0.3%)
Device related infection	1 (0.5%)	0	1 (0.3%)
Diverticulitis	0	1 (0.5%)	1 (0.3%)
Enterocolitis infectious	1 (0.5%)	0	1 (0.3%)
Herpes simplex	1 (0.5%)	0	1 (0.3%)
Infectious pleural effusion	1 (0.5%)	0	1 (0.3%)
Klebsiella sepsis	0	1 (0.5%)	1 (0.3%)
Respiratory syncytial virus infection	0	1 (0.5%)	1 (0.3%)
Skin infection	1 (0.5%)	0	1 (0.3%)
Metabolism and nutrition disorders	45 (22.4%)	21 (10.7%)	66 (16.6%)
Hyponatraemia	15 (7.5%)	7 (3.6%)	22 (5.5%)
Hyperglycaemia	12 (6.0%)	1 (0.5%)	13 (3.3%)
Decreased appetite	3 (1.5%)	5 (2.5%)	8 (2.0%)
Hypokalaemia	5 (2.5%)	2 (1.0%)	7 (1.8%)
Hypophosphataemia	5 (2.5%)	2 (1.0%)	7 (1.8%)
Hyperkalaemia	1 (0.5%)	4 (2.0%)	5 (1.3%)
Dehydration	3 (1.5%)	1 (0.5%)	4 (1.0%)
Hypocalcaemia	3 (1.5%)	0	3 (0.8%)
Hypomagnesaemia	2 (1.0%)	0	2 (0.5%)
Type 2 diabetes mellitus	2 (1.0%)	0	2 (0.5%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.3.2: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Diabetes mellitus	1 (0.5%)	0	1 (0.3%)
Failure to thrive	0	1 (0.5%)	1 (0.3%)
Hyperamylasaemia	1 (0.5%)	0	1 (0.3%)
Hypercalcaemia	0	1 (0.5%)	1 (0.3%)
Hyperlipasaemia	1 (0.5%)	0	1 (0.3%)
Hypoalbuminaemia	1 (0.5%)	0	1 (0.3%)
Hypochloraemia	1 (0.5%)	0	1 (0.3%)
Lactic acidosis	0	1 (0.5%)	1 (0.3%)
Type 1 diabetes mellitus	1 (0.5%)	0	1 (0.3%)
Investigations	29 (14.4%)	36 (18.3%)	65 (16.3%)
Neutrophil count decreased	7 (3.5%)	19 (9.6%)	26 (6.5%)
Platelet count decreased	0	17 (8.6%)	17 (4.3%)
Weight decreased	8 (4.0%)	0	8 (2.0%)
White blood cell count decreased	0	7 (3.6%)	7 (1.8%)
Alanine aminotransferase increased	3 (1.5%)	2 (1.0%)	5 (1.3%)
Aspartate aminotransferase increased	3 (1.5%)	1 (0.5%)	4 (1.0%)
Lymphocyte count decreased	3 (1.5%)	1 (0.5%)	4 (1.0%)
Amylase increased	2 (1.0%)	0	2 (0.5%)
Blood alkaline phosphatase increased	2 (1.0%)	0	2 (0.5%)
Gamma-glutamyltransferase increased	2 (1.0%)	0	2 (0.5%)
Blood bilirubin increased	1 (0.5%)	0	1 (0.3%)
Blood creatinine increased	0	1 (0.5%)	1 (0.3%)
Blood lactic acid increased	1 (0.5%)	0	1 (0.3%)
C-reactive protein increased	0	1 (0.5%)	1 (0.3%)
Electrocardiogram QT prolonged	1 (0.5%)	0	1 (0.3%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.3.2: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
False positive investigation result	0	1 (0.5%)	1 (0.3%)
International normalised ratio increased	1 (0.5%)	0	1 (0.3%)
Lipase increased	1 (0.5%)	0	1 (0.3%)
Prothrombin time prolonged	1 (0.5%)	0	1 (0.3%)
Weight increased	1 (0.5%)	0	1 (0.3%)
General disorders and administration site conditions	24 (11.9%)	23 (11.7%)	47 (11.8%)
Fatigue	11 (5.5%)	8 (4.1%)	19 (4.8%)
Asthenia	5 (2.5%)	5 (2.5%)	10 (2.5%)
General physical health deterioration	0	6 (3.0%)	6 (1.5%)
Pyrexia	2 (1.0%)	3 (1.5%)	5 (1.3%)
Gait disturbance	2 (1.0%)	0	2 (0.5%)
Malaise	0	2 (1.0%)	2 (0.5%)
Multiple organ dysfunction syndrome	1 (0.5%)	1 (0.5%)	2 (0.5%)
Condition aggravated	1 (0.5%)	0	1 (0.3%)
Death	1 (0.5%)	0	1 (0.3%)
Non-cardiac chest pain	0	1 (0.5%)	1 (0.3%)
Pain	1 (0.5%)	0	1 (0.3%)
Performance status decreased	1 (0.5%)	0	1 (0.3%)
Sudden death	1 (0.5%)	0	1 (0.3%)
Gastrointestinal disorders	27 (13.4%)	16 (8.1%)	43 (10.8%)
Diarrhoea	11 (5.5%)	4 (2.0%)	15 (3.8%)
Nausea	3 (1.5%)	3 (1.5%)	6 (1.5%)
Abdominal pain	4 (2.0%)	1 (0.5%)	5 (1.3%)
Vomiting	2 (1.0%)	2 (1.0%)	4 (1.0%)
Constipation	0	2 (1.0%)	2 (0.5%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.3.2: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Intestinal obstruction	1 (0.5%)	1 (0.5%)	2 (0.5%)
Pancreatitis acute	1 (0.5%)	1 (0.5%)	2 (0.5%)
Anal incontinence	0	1 (0.5%)	1 (0.3%)
Colitis ulcerative	1 (0.5%)	0	1 (0.3%)
Duodenal ulcer	1 (0.5%)	0	1 (0.3%)
Dyspepsia	0	1 (0.5%)	1 (0.3%)
Enterovesical fistula	1 (0.5%)	0	1 (0.3%)
Gastric haemorrhage	0	1 (0.5%)	1 (0.3%)
Gastrointestinal haemorrhage	1 (0.5%)	0	1 (0.3%)
Haematemesis	0	1 (0.5%)	1 (0.3%)
Haemorrhoidal haemorrhage	0	1 (0.5%)	1 (0.3%)
Large intestinal ulcer haemorrhage	1 (0.5%)	0	1 (0.3%)
Malignant gastrointestinal obstruction	1 (0.5%)	0	1 (0.3%)
Rectal haemorrhage	1 (0.5%)	0	1 (0.3%)
Small intestinal perforation	0	1 (0.5%)	1 (0.3%)
Stomatitis	1 (0.5%)	0	1 (0.3%)
Skin and subcutaneous tissue disorders	39 (19.4%)	2 (1.0%)	41 (10.3%)
Rash maculo-papular	20 (10.0%)	0	20 (5.0%)
Pruritus	5 (2.5%)	0	5 (1.3%)
Rash papular	3 (1.5%)	0	3 (0.8%)
Alopecia	1 (0.5%)	1 (0.5%)	2 (0.5%)
Dermatitis	2 (1.0%)	0	2 (0.5%)
Pemphigoid	2 (1.0%)	0	2 (0.5%)
Toxic epidermal necrolysis	2 (1.0%)	0	2 (0.5%)
Acute generalised exanthematous pustulosis	0	1 (0.5%)	1 (0.3%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.3.2: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Blister	1 (0.5%)	0	1 (0.3%)
Dermatitis exfoliative	1 (0.5%)	0	1 (0.3%)
Eczema	1 (0.5%)	0	1 (0.3%)
Papule	1 (0.5%)	0	1 (0.3%)
Rash erythematous	1 (0.5%)	0	1 (0.3%)
Rash macular	1 (0.5%)	0	1 (0.3%)
Rash morbilliform	1 (0.5%)	0	1 (0.3%)
Rash pruritic	1 (0.5%)	0	1 (0.3%)
Vitiligo	1 (0.5%)	0	1 (0.3%)
Renal and urinary disorders	25 (12.4%)	15 (7.6%)	40 (10.1%)
Acute kidney injury	14 (7.0%)	4 (2.0%)	18 (4.5%)
Haematuria	5 (2.5%)	4 (2.0%)	9 (2.3%)
Renal impairment	3 (1.5%)	2 (1.0%)	5 (1.3%)
Chronic kidney disease	1 (0.5%)	3 (1.5%)	4 (1.0%)
Renal failure	3 (1.5%)	1 (0.5%)	4 (1.0%)
Hydronephrosis	1 (0.5%)	1 (0.5%)	2 (0.5%)
Proteinuria	1 (0.5%)	1 (0.5%)	2 (0.5%)
Urinary tract obstruction	1 (0.5%)	1 (0.5%)	2 (0.5%)
Urinoma	0	1 (0.5%)	1 (0.3%)
Respiratory, thoracic and mediastinal disorders	16 (8.0%)	16 (8.1%)	32 (8.0%)
Pulmonary embolism	9 (4.5%)	7 (3.6%)	16 (4.0%)
Dyspnoea	2 (1.0%)	4 (2.0%)	6 (1.5%)
Chronic obstructive pulmonary disease	0	3 (1.5%)	3 (0.8%)
Acute respiratory failure	2 (1.0%)	0	2 (0.5%)
Hypoxia	2 (1.0%)	0	2 (0.5%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.3.2: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Pneumonitis	2 (1.0%)	0	2 (0.5%)
Respiratory failure	1 (0.5%)	1 (0.5%)	2 (0.5%)
Alveolitis	0	1 (0.5%)	1 (0.3%)
Haemoptysis	0	1 (0.5%)	1 (0.3%)
Immune-mediated lung disease	1 (0.5%)	0	1 (0.3%)
Interstitial lung disease	1 (0.5%)	0	1 (0.3%)
Pleural effusion	0	1 (0.5%)	1 (0.3%)
Pneumothorax	0	1 (0.5%)	1 (0.3%)
Nervous system disorders	20 (10.0%)	4 (2.0%)	24 (6.0%)
Peripheral sensory neuropathy	11 (5.5%)	0	11 (2.8%)
Peripheral sensorimotor neuropathy	3 (1.5%)	0	3 (0.8%)
Syncope	1 (0.5%)	2 (1.0%)	3 (0.8%)
Cerebrovascular accident	1 (0.5%)	1 (0.5%)	2 (0.5%)
Dizziness	1 (0.5%)	1 (0.5%)	2 (0.5%)
Hypoaesthesia	1 (0.5%)	0	1 (0.3%)
Immune-mediated neuropathy	1 (0.5%)	0	1 (0.3%)
Nervous system disorder	1 (0.5%)	0	1 (0.3%)
Peripheral motor neuropathy	1 (0.5%)	0	1 (0.3%)
Seizure	1 (0.5%)	0	1 (0.3%)
Hepatobiliary disorders	8 (4.0%)	7 (3.6%)	15 (3.8%)
Hypertransaminasaemia	1 (0.5%)	4 (2.0%)	5 (1.3%)
Hepatic function abnormal	0	3 (1.5%)	3 (0.8%)
Hepatitis	2 (1.0%)	0	2 (0.5%)
Immune-mediated hepatitis	2 (1.0%)	0	2 (0.5%)
Cholangitis sclerosing	1 (0.5%)	0	1 (0.3%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.3.2: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Immune-mediated hepatic disorder	1 (0.5%)	0	1 (0.3%)
Portal vein thrombosis	1 (0.5%)	0	1 (0.3%)
Cardiac disorders	8 (4.0%)	4 (2.0%)	12 (3.0%)
Acute myocardial infarction	2 (1.0%)	2 (1.0%)	4 (1.0%)
Cardiac failure	3 (1.5%)	0	3 (0.8%)
Angina pectoris	0	1 (0.5%)	1 (0.3%)
Atrial fibrillation	0	1 (0.5%)	1 (0.3%)
Cardiac arrest	0	1 (0.5%)	1 (0.3%)
Cardio-respiratory arrest	1 (0.5%)	0	1 (0.3%)
Immune-mediated myocarditis	1 (0.5%)	0	1 (0.3%)
Myocardial infarction	1 (0.5%)	0	1 (0.3%)
Myocardial ischaemia	0	1 (0.5%)	1 (0.3%)
Stress cardiomyopathy	0	1 (0.5%)	1 (0.3%)
Ventricular tachycardia	1 (0.5%)	0	1 (0.3%)
Musculoskeletal and connective tissue disorders	6 (3.0%)	4 (2.0%)	10 (2.5%)
Arthralgia	2 (1.0%)	0	2 (0.5%)
Muscular weakness	2 (1.0%)	0	2 (0.5%)
Pain in extremity	0	2 (1.0%)	2 (0.5%)
Arthritis	1 (0.5%)	0	1 (0.3%)
Back pain	0	1 (0.5%)	1 (0.3%)
Musculoskeletal pain	1 (0.5%)	0	1 (0.3%)
Pathological fracture	0	1 (0.5%)	1 (0.3%)
Vascular disorders	5 (2.5%)	4 (2.0%)	9 (2.3%)
Deep vein thrombosis	0	2 (1.0%)	2 (0.5%)
Aortic aneurysm rupture	1 (0.5%)	0	1 (0.3%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.3.2: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Hypertension	0	1 (0.5%)	1 (0.3%)
Hypertensive crisis	1 (0.5%)	0	1 (0.3%)
Hypotension	1 (0.5%)	0	1 (0.3%)
Iliac artery occlusion	1 (0.5%)	0	1 (0.3%)
Orthostatic hypotension	1 (0.5%)	0	1 (0.3%)
Shock	0	1 (0.5%)	1 (0.3%)
Injury, poisoning and procedural complications	2 (1.0%)	3 (1.5%)	5 (1.3%)
Femur fracture	2 (1.0%)	1 (0.5%)	3 (0.8%)
Infusion related reaction	0	1 (0.5%)	1 (0.3%)
Urinary tract stoma complication	0	1 (0.5%)	1 (0.3%)
Psychiatric disorders	4 (2.0%)	1 (0.5%)	5 (1.3%)
Delirium	2 (1.0%)	0	2 (0.5%)
Affect lability	0	1 (0.5%)	1 (0.3%)
Confusional state	1 (0.5%)	0	1 (0.3%)
Insomnia	1 (0.5%)	0	1 (0.3%)
Endocrine disorders	3 (1.5%)	1 (0.5%)	4 (1.0%)
Adrenal insufficiency	1 (0.5%)	0	1 (0.3%)
Hypercalcaemia of malignancy	0	1 (0.5%)	1 (0.3%)
Hyperthyroidism	1 (0.5%)	0	1 (0.3%)
Hypothyroidism	1 (0.5%)	0	1 (0.3%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.5%)	3 (1.5%)	4 (1.0%)
Cancer pain	0	2 (1.0%)	2 (0.5%)
Chronic lymphocytic leukaemia	1 (0.5%)	0	1 (0.3%)
Tumour pain	0	1 (0.5%)	1 (0.3%)
Reproductive system and breast disorders	0	2 (1.0%)	2 (0.5%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.3.2: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Prostatitis	0	1 (0.5%)	1 (0.3%)
Vaginal haemorrhage	0	1 (0.5%)	1 (0.3%)
Immune system disorders	1 (0.5%)	0	1 (0.3%)
Sarcoidosis	1 (0.5%)	0	1 (0.3%)
Product issues	0	1 (0.5%)	1 (0.3%)
Device occlusion	0	1 (0.5%)	1 (0.3%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.4.1: Frequency Summary of Treatment Emergent Serious Adverse Events - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Overall	107 (44.8%)	83 (35.2%)	190 (40.0%)
Infections and infestations	24 (10.0%)	39 (16.5%)	63 (13.3%)
Urinary tract infection	4 (1.7%)	17 (7.2%)	21 (4.4%)
Sepsis	2 (0.8%)	6 (2.5%)	8 (1.7%)
COVID-19	2 (0.8%)	4 (1.7%)	6 (1.3%)
Pneumonia	3 (1.3%)	3 (1.3%)	6 (1.3%)
COVID-19 pneumonia	3 (1.3%)	2 (0.8%)	5 (1.1%)
Device related infection	1 (0.4%)	2 (0.8%)	3 (0.6%)
Urosepsis	1 (0.4%)	2 (0.8%)	3 (0.6%)
Pyelonephritis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Respiratory tract infection	1 (0.4%)	1 (0.4%)	2 (0.4%)
Abdominal abscess	0	1 (0.4%)	1 (0.2%)
Bacteraemia	1 (0.4%)	0	1 (0.2%)
Cellulitis	1 (0.4%)	0	1 (0.2%)
Diverticulitis	1 (0.4%)	0	1 (0.2%)
Escherichia infection	0	1 (0.4%)	1 (0.2%)
Infectious pleural effusion	1 (0.4%)	0	1 (0.2%)
Kidney infection	0	1 (0.4%)	1 (0.2%)
Neutropenic sepsis	0	1 (0.4%)	1 (0.2%)
Oesophageal candidiasis	1 (0.4%)	0	1 (0.2%)
Pelvic infection	1 (0.4%)	0	1 (0.2%)
Perineal abscess	0	1 (0.4%)	1 (0.2%)
Pneumonia haemophilus	0	1 (0.4%)	1 (0.2%)
Respiratory syncytial virus infection	0	1 (0.4%)	1 (0.2%)
Staphylococcal bacteraemia	1 (0.4%)	0	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.4.1: Frequency Summary of Treatment Emergent Serious Adverse Events - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Urinary tract infection bacterial	0	1 (0.4%)	1 (0.2%)
Urinary tract infection pseudomonal	0	1 (0.4%)	1 (0.2%)
Urinary tract infection staphylococcal	1 (0.4%)	0	1 (0.2%)
Wound infection	0	1 (0.4%)	1 (0.2%)
Renal and urinary disorders	18 (7.5%)	17 (7.2%)	35 (7.4%)
Acute kidney injury	9 (3.8%)	7 (3.0%)	16 (3.4%)
Haematuria	2 (0.8%)	7 (3.0%)	9 (1.9%)
Hydronephrosis	2 (0.8%)	2 (0.8%)	4 (0.8%)
Urinary retention	2 (0.8%)	2 (0.8%)	4 (0.8%)
Calculus bladder	2 (0.8%)	0	2 (0.4%)
Renal impairment	1 (0.4%)	1 (0.4%)	2 (0.4%)
Immune-mediated nephritis	1 (0.4%)	0	1 (0.2%)
Postrenal failure	1 (0.4%)	0	1 (0.2%)
Urinary tract obstruction	1 (0.4%)	0	1 (0.2%)
Gastrointestinal disorders	24 (10.0%)	6 (2.5%)	30 (6.3%)
Diarrhoea	7 (2.9%)	0	7 (1.5%)
Abdominal pain	4 (1.7%)	1 (0.4%)	5 (1.1%)
Nausea	2 (0.8%)	3 (1.3%)	5 (1.1%)
Vomiting	3 (1.3%)	1 (0.4%)	4 (0.8%)
Colitis	3 (1.3%)	0	3 (0.6%)
Immune-mediated enterocolitis	3 (1.3%)	0	3 (0.6%)
Gastric ulcer	1 (0.4%)	1 (0.4%)	2 (0.4%)
Pancreatitis	2 (0.8%)	0	2 (0.4%)
Ascites	1 (0.4%)	0	1 (0.2%)
Colonic fistula	1 (0.4%)	0	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.4.1: Frequency Summary of Treatment Emergent Serious Adverse Events - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Duodenal stenosis	1 (0.4%)	0	1 (0.2%)
Duodenitis	0	1 (0.4%)	1 (0.2%)
Dyspepsia	1 (0.4%)	0	1 (0.2%)
Enterovesical fistula	1 (0.4%)	0	1 (0.2%)
Inguinal hernia	1 (0.4%)	0	1 (0.2%)
Intestinal obstruction	1 (0.4%)	0	1 (0.2%)
Large intestine perforation	1 (0.4%)	0	1 (0.2%)
Obstructive pancreatitis	0	1 (0.4%)	1 (0.2%)
Small intestinal obstruction	1 (0.4%)	0	1 (0.2%)
Respiratory, thoracic and mediastinal disorders	25 (10.5%)	4 (1.7%)	29 (6.1%)
Pneumonitis	7 (2.9%)	0	7 (1.5%)
Pulmonary embolism	4 (1.7%)	2 (0.8%)	6 (1.3%)
Dyspnoea	3 (1.3%)	1 (0.4%)	4 (0.8%)
Immune-mediated lung disease	4 (1.7%)	0	4 (0.8%)
Interstitial lung disease	3 (1.3%)	0	3 (0.6%)
Acute respiratory failure	1 (0.4%)	0	1 (0.2%)
Aspiration	1 (0.4%)	0	1 (0.2%)
Cough	0	1 (0.4%)	1 (0.2%)
Haemoptysis	1 (0.4%)	0	1 (0.2%)
Hypoxia	1 (0.4%)	0	1 (0.2%)
Organising pneumonia	1 (0.4%)	0	1 (0.2%)
Pharyngeal dyskinesia	1 (0.4%)	0	1 (0.2%)
Respiratory distress	1 (0.4%)	0	1 (0.2%)
Respiratory failure	1 (0.4%)	0	1 (0.2%)
Metabolism and nutrition disorders	14 (5.9%)	10 (4.2%)	24 (5.1%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.4.1: Frequency Summary of Treatment Emergent Serious Adverse Events - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Decreased appetite	5 (2.1%)	0	5 (1.1%)
Dehydration	1 (0.4%)	4 (1.7%)	5 (1.1%)
Hyponatraemia	2 (0.8%)	3 (1.3%)	5 (1.1%)
Hyperglycaemia	4 (1.7%)	0	4 (0.8%)
Diabetes mellitus	1 (0.4%)	1 (0.4%)	2 (0.4%)
Hypocalcaemia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Hypercreatininaemia	1 (0.4%)	0	1 (0.2%)
Hyperkalaemia	0	1 (0.4%)	1 (0.2%)
Hypokalaemia	1 (0.4%)	0	1 (0.2%)
Hypomagnesaemia	1 (0.4%)	0	1 (0.2%)
Hypophosphataemia	1 (0.4%)	0	1 (0.2%)
Hypovolaemia	1 (0.4%)	0	1 (0.2%)
Metabolic acidosis	1 (0.4%)	0	1 (0.2%)
Blood and lymphatic system disorders	5 (2.1%)	16 (6.8%)	21 (4.4%)
Anaemia	0	10 (4.2%)	10 (2.1%)
Febrile neutropenia	3 (1.3%)	3 (1.3%)	6 (1.3%)
Thrombocytopenia	0	5 (2.1%)	5 (1.1%)
Neutropenia	0	3 (1.3%)	3 (0.6%)
Anaemia of malignant disease	1 (0.4%)	0	1 (0.2%)
Leukopenia	1 (0.4%)	0	1 (0.2%)
Cardiac disorders	7 (2.9%)	10 (4.2%)	17 (3.6%)
Atrial fibrillation	0	3 (1.3%)	3 (0.6%)
Cardiac arrest	2 (0.8%)	0	2 (0.4%)
Acute coronary syndrome	1 (0.4%)	0	1 (0.2%)
Acute myocardial infarction	0	1 (0.4%)	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.4.1: Frequency Summary of Treatment Emergent Serious Adverse Events - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Acute right ventricular failure	0	1 (0.4%)	1 (0.2%)
Angina pectoris	0	1 (0.4%)	1 (0.2%)
Atrioventricular block complete	1 (0.4%)	0	1 (0.2%)
Cardio-respiratory arrest	1 (0.4%)	0	1 (0.2%)
Cardiogenic shock	0	1 (0.4%)	1 (0.2%)
Myocardial infarction	0	1 (0.4%)	1 (0.2%)
Myocarditis	1 (0.4%)	0	1 (0.2%)
Pericardial effusion	0	1 (0.4%)	1 (0.2%)
Sinus tachycardia	0	1 (0.4%)	1 (0.2%)
Supraventricular tachycardia	0	1 (0.4%)	1 (0.2%)
Tachycardia	1 (0.4%)	0	1 (0.2%)
General disorders and administration site conditions	8 (3.3%)	8 (3.4%)	16 (3.4%)
Pyrexia	3 (1.3%)	3 (1.3%)	6 (1.3%)
Fatigue	2 (0.8%)	2 (0.8%)	4 (0.8%)
Asthenia	2 (0.8%)	1 (0.4%)	3 (0.6%)
General physical health deterioration	1 (0.4%)	0	1 (0.2%)
Malaise	0	1 (0.4%)	1 (0.2%)
Oedema peripheral	0	1 (0.4%)	1 (0.2%)
Skin and subcutaneous tissue disorders	15 (6.3%)	0	15 (3.2%)
Dermatitis bullous	3 (1.3%)	0	3 (0.6%)
Rash macular	2 (0.8%)	0	2 (0.4%)
Rash maculo-papular	2 (0.8%)	0	2 (0.4%)
Dermatitis	1 (0.4%)	0	1 (0.2%)
Dermatitis exfoliative generalised	1 (0.4%)	0	1 (0.2%)
Eczema	1 (0.4%)	0	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.4.1: Frequency Summary of Treatment Emergent Serious Adverse Events - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Rash	1 (0.4%)	0	1 (0.2%)
Rash morbilliform	1 (0.4%)	0	1 (0.2%)
SJS-TEN overlap	1 (0.4%)	0	1 (0.2%)
Toxic epidermal necrolysis	1 (0.4%)	0	1 (0.2%)
Toxic erythema of chemotherapy	1 (0.4%)	0	1 (0.2%)
Nervous system disorders	11 (4.6%)	3 (1.3%)	14 (2.9%)
Syncope	2 (0.8%)	2 (0.8%)	4 (0.8%)
Cerebral haemorrhage	1 (0.4%)	0	1 (0.2%)
Cerebral infarction	0	1 (0.4%)	1 (0.2%)
Chronic inflammatory demyelinating polyradiculoneuropathy	1 (0.4%)	0	1 (0.2%)
Diabetic hyperglycaemic coma	1 (0.4%)	0	1 (0.2%)
Immune-mediated encephalitis	1 (0.4%)	0	1 (0.2%)
Optic neuritis	1 (0.4%)	0	1 (0.2%)
Partial seizures	1 (0.4%)	0	1 (0.2%)
Peripheral sensorimotor neuropathy	1 (0.4%)	0	1 (0.2%)
Peripheral sensory neuropathy	1 (0.4%)	0	1 (0.2%)
Seizure	1 (0.4%)	0	1 (0.2%)
Musculoskeletal and connective tissue disorders	5 (2.1%)	6 (2.5%)	11 (2.3%)
Back pain	3 (1.3%)	1 (0.4%)	4 (0.8%)
Bone lesion	1 (0.4%)	0	1 (0.2%)
Bone pain	0	1 (0.4%)	1 (0.2%)
Mobility decreased	0	1 (0.4%)	1 (0.2%)
Muscular weakness	1 (0.4%)	0	1 (0.2%)
Myositis	0	1 (0.4%)	1 (0.2%)
Pathological fracture	0	1 (0.4%)	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.4.1: Frequency Summary of Treatment Emergent Serious Adverse Events - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Rhabdomyolysis	0	1 (0.4%)	1 (0.2%)
Injury, poisoning and procedural complications	4 (1.7%)	5 (2.1%)	9 (1.9%)
Urinary tract stoma complication	3 (1.3%)	2 (0.8%)	5 (1.1%)
Heat stroke	1 (0.4%)	0	1 (0.2%)
Sternal fracture	0	1 (0.4%)	1 (0.2%)
Tibia fracture	0	1 (0.4%)	1 (0.2%)
Toxicity to various agents	0	1 (0.4%)	1 (0.2%)
Investigations	5 (2.1%)	4 (1.7%)	9 (1.9%)
Platelet count decreased	0	3 (1.3%)	3 (0.6%)
Aspartate aminotransferase increased	2 (0.8%)	0	2 (0.4%)
Alanine aminotransferase increased	1 (0.4%)	0	1 (0.2%)
Blood bilirubin increased	1 (0.4%)	0	1 (0.2%)
Blood creatinine increased	0	1 (0.4%)	1 (0.2%)
Lipase increased	1 (0.4%)	0	1 (0.2%)
Neutrophil count decreased	1 (0.4%)	0	1 (0.2%)
Oxygen saturation decreased	1 (0.4%)	0	1 (0.2%)
Vascular disorders	2 (0.8%)	5 (2.1%)	7 (1.5%)
Deep vein thrombosis	0	3 (1.3%)	3 (0.6%)
Hypotension	1 (0.4%)	1 (0.4%)	2 (0.4%)
Lymphocele	0	1 (0.4%)	1 (0.2%)
Lymphoedema	1 (0.4%)	0	1 (0.2%)
Hepatobiliary disorders	6 (2.5%)	0	6 (1.3%)
Cholecystitis	3 (1.3%)	0	3 (0.6%)
Autoimmune hepatitis	1 (0.4%)	0	1 (0.2%)
Hepatotoxicity	1 (0.4%)	0	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.4.1: Frequency Summary of Treatment Emergent Serious Adverse Events - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Immune-mediated hepatitis	1 (0.4%)	0	1 (0.2%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (1.3%)	1 (0.4%)	4 (0.8%)
Burkitt's lymphoma	1 (0.4%)	0	1 (0.2%)
Cancer pain	1 (0.4%)	0	1 (0.2%)
Metastases to central nervous system	0	1 (0.4%)	1 (0.2%)
Tumour rupture	1 (0.4%)	0	1 (0.2%)
Psychiatric disorders	3 (1.3%)	0	3 (0.6%)
Confusional state	2 (0.8%)	0	2 (0.4%)
Anxiety	1 (0.4%)	0	1 (0.2%)
Disorientation	1 (0.4%)	0	1 (0.2%)
Reproductive system and breast disorders	1 (0.4%)	1 (0.4%)	2 (0.4%)
Prostatitis	1 (0.4%)	0	1 (0.2%)
Vaginal haemorrhage	0	1 (0.4%)	1 (0.2%)
Ear and labyrinth disorders	1 (0.4%)	0	1 (0.2%)
Vertigo	1 (0.4%)	0	1 (0.2%)
Endocrine disorders	1 (0.4%)	0	1 (0.2%)
Adrenal insufficiency	1 (0.4%)	0	1 (0.2%)
Eye disorders	1 (0.4%)	0	1 (0.2%)
Keratitis	1 (0.4%)	0	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.4.2: Frequency Summary of Treatment Emergent Serious Adverse Events - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Overall	113 (56.2%)	86 (43.7%)	199 (50.0%)
Infections and infestations	46 (22.9%)	34 (17.3%)	80 (20.1%)
Urinary tract infection	12 (6.0%)	14 (7.1%)	26 (6.5%)
Pneumonia	7 (3.5%)	2 (1.0%)	9 (2.3%)
Pyelonephritis	3 (1.5%)	5 (2.5%)	8 (2.0%)
COVID-19	6 (3.0%)	1 (0.5%)	7 (1.8%)
Sepsis	5 (2.5%)	2 (1.0%)	7 (1.8%)
Urosepsis	1 (0.5%)	3 (1.5%)	4 (1.0%)
COVID-19 pneumonia	2 (1.0%)	1 (0.5%)	3 (0.8%)
Pneumonia aspiration	3 (1.5%)	0	3 (0.8%)
Septic shock	3 (1.5%)	0	3 (0.8%)
Device related infection	2 (1.0%)	0	2 (0.5%)
Neutropenic sepsis	1 (0.5%)	1 (0.5%)	2 (0.5%)
Peritonitis	0	2 (1.0%)	2 (0.5%)
Pyelonephritis acute	1 (0.5%)	1 (0.5%)	2 (0.5%)
Respiratory tract infection	0	2 (1.0%)	2 (0.5%)
Skin infection	1 (0.5%)	1 (0.5%)	2 (0.5%)
Campylobacter gastroenteritis	1 (0.5%)	0	1 (0.3%)
Cellulitis	1 (0.5%)	0	1 (0.3%)
Clostridium difficile infection	1 (0.5%)	0	1 (0.3%)
Cystitis	1 (0.5%)	0	1 (0.3%)
Cytomegalovirus colitis	1 (0.5%)	0	1 (0.3%)
Diverticulitis	0	1 (0.5%)	1 (0.3%)
Enterocolitis infectious	1 (0.5%)	0	1 (0.3%)
Infectious pleural effusion	1 (0.5%)	0	1 (0.3%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.4.2: Frequency Summary of Treatment Emergent Serious Adverse Events - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Klebsiella sepsis	0	1 (0.5%)	1 (0.3%)
Respiratory syncytial virus infection	0	1 (0.5%)	1 (0.3%)
Gastrointestinal disorders	23 (11.4%)	11 (5.6%)	34 (8.5%)
Diarrhoea	7 (3.5%)	2 (1.0%)	9 (2.3%)
Abdominal pain	4 (2.0%)	1 (0.5%)	5 (1.3%)
Nausea	2 (1.0%)	1 (0.5%)	3 (0.8%)
Vomiting	2 (1.0%)	1 (0.5%)	3 (0.8%)
Intestinal obstruction	1 (0.5%)	1 (0.5%)	2 (0.5%)
Pancreatitis acute	1 (0.5%)	1 (0.5%)	2 (0.5%)
Colitis ulcerative	1 (0.5%)	0	1 (0.3%)
Constipation	0	1 (0.5%)	1 (0.3%)
Duodenal ulcer	1 (0.5%)	0	1 (0.3%)
Enterovesical fistula	1 (0.5%)	0	1 (0.3%)
Faeces discoloured	0	1 (0.5%)	1 (0.3%)
Gastric haemorrhage	0	1 (0.5%)	1 (0.3%)
Gastrointestinal haemorrhage	1 (0.5%)	0	1 (0.3%)
Haemorrhoidal haemorrhage	0	1 (0.5%)	1 (0.3%)
Large intestinal ulcer haemorrhage	1 (0.5%)	0	1 (0.3%)
Malignant gastrointestinal obstruction	1 (0.5%)	0	1 (0.3%)
Mouth ulceration	1 (0.5%)	0	1 (0.3%)
Oesophagitis	1 (0.5%)	0	1 (0.3%)
Rectal haemorrhage	1 (0.5%)	0	1 (0.3%)
Rectal ulcer haemorrhage	1 (0.5%)	0	1 (0.3%)
Small intestinal perforation	0	1 (0.5%)	1 (0.3%)
Blood and lymphatic system disorders	6 (3.0%)	26 (13.2%)	32 (8.0%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.4.2: Frequency Summary of Treatment Emergent Serious Adverse Events - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Anaemia	3 (1.5%)	7 (3.6%)	10 (2.5%)
Febrile neutropenia	1 (0.5%)	9 (4.6%)	10 (2.5%)
Thrombocytopenia	0	8 (4.1%)	8 (2.0%)
Neutropenia	1 (0.5%)	4 (2.0%)	5 (1.3%)
Pancytopenia	0	3 (1.5%)	3 (0.8%)
Immune thrombocytopenia	1 (0.5%)	0	1 (0.3%)
Renal and urinary disorders	21 (10.4%)	11 (5.6%)	32 (8.0%)
Acute kidney injury	14 (7.0%)	4 (2.0%)	18 (4.5%)
Haematuria	5 (2.5%)	3 (1.5%)	8 (2.0%)
Renal failure	2 (1.0%)	0	2 (0.5%)
Chronic kidney disease	0	1 (0.5%)	1 (0.3%)
Immune-mediated nephritis	1 (0.5%)	0	1 (0.3%)
Urinary retention	0	1 (0.5%)	1 (0.3%)
Urinary tract obstruction	0	1 (0.5%)	1 (0.3%)
Urinoma	0	1 (0.5%)	1 (0.3%)
General disorders and administration site conditions	13 (6.5%)	18 (9.1%)	31 (7.8%)
Pyrexia	6 (3.0%)	7 (3.6%)	13 (3.3%)
General physical health deterioration	0	7 (3.6%)	7 (1.8%)
Asthenia	1 (0.5%)	3 (1.5%)	4 (1.0%)
Fatigue	1 (0.5%)	1 (0.5%)	2 (0.5%)
Multiple organ dysfunction syndrome	1 (0.5%)	1 (0.5%)	2 (0.5%)
Condition aggravated	1 (0.5%)	0	1 (0.3%)
Death	1 (0.5%)	0	1 (0.3%)
Non-cardiac chest pain	0	1 (0.5%)	1 (0.3%)
Performance status decreased	1 (0.5%)	0	1 (0.3%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.4.2: Frequency Summary of Treatment Emergent Serious Adverse Events - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Sudden death	1 (0.5%)	0	1 (0.3%)
Respiratory, thoracic and mediastinal disorders	13 (6.5%)	11 (5.6%)	24 (6.0%)
Pulmonary embolism	3 (1.5%)	4 (2.0%)	7 (1.8%)
Dyspnoea	1 (0.5%)	3 (1.5%)	4 (1.0%)
Acute respiratory failure	2 (1.0%)	0	2 (0.5%)
Chronic obstructive pulmonary disease	0	2 (1.0%)	2 (0.5%)
Hypoxia	2 (1.0%)	0	2 (0.5%)
Pleural effusion	1 (0.5%)	1 (0.5%)	2 (0.5%)
Pneumonitis	2 (1.0%)	0	2 (0.5%)
Pneumothorax	0	2 (1.0%)	2 (0.5%)
Haemoptysis	0	1 (0.5%)	1 (0.3%)
Immune-mediated lung disease	1 (0.5%)	0	1 (0.3%)
Interstitial lung disease	1 (0.5%)	0	1 (0.3%)
Lung opacity	1 (0.5%)	0	1 (0.3%)
Respiratory failure	1 (0.5%)	0	1 (0.3%)
Metabolism and nutrition disorders	13 (6.5%)	5 (2.5%)	18 (4.5%)
Hyponatraemia	3 (1.5%)	2 (1.0%)	5 (1.3%)
Decreased appetite	3 (1.5%)	0	3 (0.8%)
Dehydration	2 (1.0%)	1 (0.5%)	3 (0.8%)
Hyperglycaemia	2 (1.0%)	0	2 (0.5%)
Failure to thrive	0	1 (0.5%)	1 (0.3%)
Hyperkalaemia	0	1 (0.5%)	1 (0.3%)
Hypoalbuminaemia	1 (0.5%)	0	1 (0.3%)
Hypocalcaemia	1 (0.5%)	0	1 (0.3%)
Type 2 diabetes mellitus	1 (0.5%)	0	1 (0.3%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.4.2: Frequency Summary of Treatment Emergent Serious Adverse Events - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Cardiac disorders	9 (4.5%)	3 (1.5%)	12 (3.0%)
Acute myocardial infarction	2 (1.0%)	1 (0.5%)	3 (0.8%)
Cardiac failure	3 (1.5%)	0	3 (0.8%)
Angina pectoris	0	1 (0.5%)	1 (0.3%)
Atrial fibrillation	0	1 (0.5%)	1 (0.3%)
Cardiac arrest	0	1 (0.5%)	1 (0.3%)
Cardio-respiratory arrest	1 (0.5%)	0	1 (0.3%)
Immune-mediated myocarditis	1 (0.5%)	0	1 (0.3%)
Myocardial infarction	1 (0.5%)	0	1 (0.3%)
Myocarditis	1 (0.5%)	0	1 (0.3%)
Stress cardiomyopathy	0	1 (0.5%)	1 (0.3%)
Ventricular tachycardia	1 (0.5%)	0	1 (0.3%)
Skin and subcutaneous tissue disorders	11 (5.5%)	1 (0.5%)	12 (3.0%)
Rash maculo-papular	5 (2.5%)	0	5 (1.3%)
Toxic epidermal necrolysis	2 (1.0%)	0	2 (0.5%)
Acute generalised exanthematous pustulosis	0	1 (0.5%)	1 (0.3%)
Dermatitis	1 (0.5%)	0	1 (0.3%)
Dermatitis exfoliative	1 (0.5%)	0	1 (0.3%)
Rash erythematous	1 (0.5%)	0	1 (0.3%)
Rash morbilliform	1 (0.5%)	0	1 (0.3%)
Investigations	7 (3.5%)	2 (1.0%)	9 (2.3%)
Alanine aminotransferase increased	4 (2.0%)	0	4 (1.0%)
Aspartate aminotransferase increased	3 (1.5%)	0	3 (0.8%)
Blood creatinine increased	2 (1.0%)	1 (0.5%)	3 (0.8%)
Platelet count decreased	0	1 (0.5%)	1 (0.3%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.4.2: Frequency Summary of Treatment Emergent Serious Adverse Events - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Prothrombin time prolonged	1 (0.5%)	0	1 (0.3%)
Weight decreased	1 (0.5%)	0	1 (0.3%)
Hepatobiliary disorders	7 (3.5%)	1 (0.5%)	8 (2.0%)
Hepatitis	2 (1.0%)	0	2 (0.5%)
Hepatotoxicity	2 (1.0%)	0	2 (0.5%)
Immune-mediated hepatitis	2 (1.0%)	0	2 (0.5%)
Cholangitis sclerosing	1 (0.5%)	0	1 (0.3%)
Hepatic function abnormal	0	1 (0.5%)	1 (0.3%)
Nervous system disorders	7 (3.5%)	1 (0.5%)	8 (2.0%)
Cerebrovascular accident	2 (1.0%)	1 (0.5%)	3 (0.8%)
Peripheral motor neuropathy	2 (1.0%)	0	2 (0.5%)
Immune-mediated neuropathy	1 (0.5%)	0	1 (0.3%)
Nervous system disorder	1 (0.5%)	0	1 (0.3%)
Peripheral sensorimotor neuropathy	1 (0.5%)	0	1 (0.3%)
Seizure	1 (0.5%)	0	1 (0.3%)
Vascular disorders	4 (2.0%)	2 (1.0%)	6 (1.5%)
Aortic aneurysm rupture	1 (0.5%)	0	1 (0.3%)
Deep vein thrombosis	0	1 (0.5%)	1 (0.3%)
Hypotension	1 (0.5%)	0	1 (0.3%)
Iliac artery occlusion	1 (0.5%)	0	1 (0.3%)
Orthostatic hypotension	1 (0.5%)	0	1 (0.3%)
Shock	0	1 (0.5%)	1 (0.3%)
Musculoskeletal and connective tissue disorders	2 (1.0%)	3 (1.5%)	5 (1.3%)
Pain in extremity	1 (0.5%)	1 (0.5%)	2 (0.5%)
Arthralgia	1 (0.5%)	0	1 (0.3%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.4.2: Frequency Summary of Treatment Emergent Serious Adverse Events - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Back pain	0	1 (0.5%)	1 (0.3%)
Pathological fracture	0	1 (0.5%)	1 (0.3%)
Injury, poisoning and procedural complications	2 (1.0%)	2 (1.0%)	4 (1.0%)
Femur fracture	2 (1.0%)	0	2 (0.5%)
Infusion related reaction	0	1 (0.5%)	1 (0.3%)
Urinary tract stoma complication	0	1 (0.5%)	1 (0.3%)
Endocrine disorders	2 (1.0%)	1 (0.5%)	3 (0.8%)
Adrenal insufficiency	1 (0.5%)	0	1 (0.3%)
Hypercalcaemia of malignancy	0	1 (0.5%)	1 (0.3%)
Hypothyroidism	1 (0.5%)	0	1 (0.3%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.5%)	2 (1.0%)	3 (0.8%)
Cancer pain	0	2 (1.0%)	2 (0.5%)
Chronic lymphocytic leukaemia	1 (0.5%)	0	1 (0.3%)
Psychiatric disorders	1 (0.5%)	1 (0.5%)	2 (0.5%)
Confusional state	0	1 (0.5%)	1 (0.3%)
Delirium	1 (0.5%)	0	1 (0.3%)
Ear and labyrinth disorders	0	1 (0.5%)	1 (0.3%)
Vertigo	0	1 (0.5%)	1 (0.3%)
Immune system disorders	1 (0.5%)	0	1 (0.3%)
Sarcoidosis	1 (0.5%)	0	1 (0.3%)
Reproductive system and breast disorders	0	1 (0.5%)	1 (0.3%)
Vaginal haemorrhage	0	1 (0.5%)	1 (0.3%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.5.1: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Overall	92 (38.5%)	58 (24.6%)	150 (31.6%)
Nervous system disorders	44 (18.4%)	1 (0.4%)	45 (9.5%)
Peripheral sensory neuropathy	29 (12.1%)	1 (0.4%)	30 (6.3%)
Paraesthesia	4 (1.7%)	0	4 (0.8%)
Peripheral motor neuropathy	3 (1.3%)	0	3 (0.6%)
Peripheral sensorimotor neuropathy	3 (1.3%)	0	3 (0.6%)
Cerebral haemorrhage	1 (0.4%)	0	1 (0.2%)
Chronic inflammatory demyelinating polyradiculoneuropathy	1 (0.4%)	0	1 (0.2%)
Diabetic hyperglycaemic coma	1 (0.4%)	0	1 (0.2%)
Neurotoxicity	1 (0.4%)	0	1 (0.2%)
Seizure	1 (0.4%)	0	1 (0.2%)
Renal and urinary disorders	2 (0.8%)	19 (8.1%)	21 (4.4%)
Acute kidney injury	1 (0.4%)	10 (4.2%)	11 (2.3%)
Chronic kidney disease	0	3 (1.3%)	3 (0.6%)
Renal failure	0	2 (0.8%)	2 (0.4%)
Renal impairment	0	2 (0.8%)	2 (0.4%)
Haematuria	0	1 (0.4%)	1 (0.2%)
Immune-mediated nephritis	1 (0.4%)	0	1 (0.2%)
Nephropathy	0	1 (0.4%)	1 (0.2%)
Skin and subcutaneous tissue disorders	17 (7.1%)	0	17 (3.6%)
Rash maculo-papular	4 (1.7%)	0	4 (0.8%)
Rash macular	3 (1.3%)	0	3 (0.6%)
Dermatitis exfoliative generalised	2 (0.8%)	0	2 (0.4%)
Dermatitis	1 (0.4%)	0	1 (0.2%)
Dermatitis bullous	1 (0.4%)	0	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.5.1: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Drug eruption	1 (0.4%)	0	1 (0.2%)
Erythema	1 (0.4%)	0	1 (0.2%)
Lichenoid keratosis	1 (0.4%)	0	1 (0.2%)
Pemphigoid	1 (0.4%)	0	1 (0.2%)
Psoriasis	1 (0.4%)	0	1 (0.2%)
Toxic epidermal necrolysis	1 (0.4%)	0	1 (0.2%)
Investigations	3 (1.3%)	11 (4.7%)	14 (2.9%)
Blood creatinine increased	0	8 (3.4%)	8 (1.7%)
Aspartate aminotransferase increased	2 (0.8%)	0	2 (0.4%)
Platelet count decreased	0	2 (0.8%)	2 (0.4%)
Alanine aminotransferase increased	1 (0.4%)	0	1 (0.2%)
Creatinine renal clearance decreased	0	1 (0.4%)	1 (0.2%)
Respiratory, thoracic and mediastinal disorders	13 (5.4%)	0	13 (2.7%)
Pneumonitis	5 (2.1%)	0	5 (1.1%)
Immune-mediated lung disease	4 (1.7%)	0	4 (0.8%)
Interstitial lung disease	2 (0.8%)	0	2 (0.4%)
Acute respiratory failure	1 (0.4%)	0	1 (0.2%)
Organising pneumonia	1 (0.4%)	0	1 (0.2%)
Blood and lymphatic system disorders	1 (0.4%)	11 (4.7%)	12 (2.5%)
Anaemia	1 (0.4%)	7 (3.0%)	8 (1.7%)
Neutropenia	0	2 (0.8%)	2 (0.4%)
Febrile neutropenia	0	1 (0.4%)	1 (0.2%)
Thrombocytopenia	0	1 (0.4%)	1 (0.2%)
Gastrointestinal disorders	5 (2.1%)	4 (1.7%)	9 (1.9%)
Diarrhoea	3 (1.3%)	1 (0.4%)	4 (0.8%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.5.1: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Nausea	0	3 (1.3%)	3 (0.6%)
Colitis	1 (0.4%)	0	1 (0.2%)
Pancreatitis chronic	1 (0.4%)	0	1 (0.2%)
General disorders and administration site conditions	2 (0.8%)	5 (2.1%)	7 (1.5%)
Fatigue	1 (0.4%)	5 (2.1%)	6 (1.3%)
Asthenia	1 (0.4%)	0	1 (0.2%)
Hepatobiliary disorders	7 (2.9%)	0	7 (1.5%)
Immune-mediated hepatitis	2 (0.8%)	0	2 (0.4%)
Autoimmune hepatitis	1 (0.4%)	0	1 (0.2%)
Hepatitis	1 (0.4%)	0	1 (0.2%)
Hepatotoxicity	1 (0.4%)	0	1 (0.2%)
Hyperbilirubinaemia	1 (0.4%)	0	1 (0.2%)
Hypertransaminasaemia	1 (0.4%)	0	1 (0.2%)
Cardiac disorders	1 (0.4%)	3 (1.3%)	4 (0.8%)
Acute right ventricular failure	0	1 (0.4%)	1 (0.2%)
Atrial fibrillation	0	1 (0.4%)	1 (0.2%)
Myocardial infarction	0	1 (0.4%)	1 (0.2%)
Myocarditis	1 (0.4%)	0	1 (0.2%)
Infections and infestations	2 (0.8%)	2 (0.8%)	4 (0.8%)
Infectious pleural effusion	1 (0.4%)	0	1 (0.2%)
Neutropenic sepsis	0	1 (0.4%)	1 (0.2%)
Pneumonia	1 (0.4%)	0	1 (0.2%)
Wound infection	0	1 (0.4%)	1 (0.2%)
Ear and labyrinth disorders	0	3 (1.3%)	3 (0.6%)
Hypoacusis	0	1 (0.4%)	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.5.1: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Analysis Set mSAF 1

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Ototoxicity	0	1 (0.4%)	1 (0.2%)
Tinnitus	0	1 (0.4%)	1 (0.2%)
Metabolism and nutrition disorders	0	2 (0.8%)	2 (0.4%)
Dehydration	0	1 (0.4%)	1 (0.2%)
Hyponatraemia	0	1 (0.4%)	1 (0.2%)
Musculoskeletal and connective tissue disorders	2 (0.8%)	0	2 (0.4%)
Arthropathy	1 (0.4%)	0	1 (0.2%)
Gouty arthritis	1 (0.4%)	0	1 (0.2%)
Endocrine disorders	1 (0.4%)	0	1 (0.2%)
Hypophysitis	1 (0.4%)	0	1 (0.2%)
Eye disorders	1 (0.4%)	0	1 (0.2%)
Keratitis	1 (0.4%)	0	1 (0.2%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.4%)	0	1 (0.2%)
Burkitt's lymphoma	1 (0.4%)	0	1 (0.2%)
Vascular disorders	0	1 (0.4%)	1 (0.2%)
Deep vein thrombosis	0	1 (0.4%)	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.5.2: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Overall	83 (41.3%)	35 (17.8%)	118 (29.6%)
Nervous system disorders	27 (13.4%)	1 (0.5%)	28 (7.0%)
Peripheral sensory neuropathy	20 (10.0%)	0	20 (5.0%)
Paraesthesia	2 (1.0%)	0	2 (0.5%)
Cerebrovascular accident	0	1 (0.5%)	1 (0.3%)
Dysgeusia	1 (0.5%)	0	1 (0.3%)
Hypoaesthesia	1 (0.5%)	0	1 (0.3%)
Nervous system disorder	1 (0.5%)	0	1 (0.3%)
Neuralgia	1 (0.5%)	0	1 (0.3%)
Peripheral sensorimotor neuropathy	1 (0.5%)	0	1 (0.3%)
Blood and lymphatic system disorders	3 (1.5%)	18 (9.1%)	21 (5.3%)
Anaemia	1 (0.5%)	5 (2.5%)	6 (1.5%)
Thrombocytopenia	1 (0.5%)	5 (2.5%)	6 (1.5%)
Neutropenia	0	5 (2.5%)	5 (1.3%)
Febrile neutropenia	0	2 (1.0%)	2 (0.5%)
Immune thrombocytopenia	1 (0.5%)	0	1 (0.3%)
Pancytopenia	0	1 (0.5%)	1 (0.3%)
Skin and subcutaneous tissue disorders	13 (6.5%)	1 (0.5%)	14 (3.5%)
Rash maculo-papular	3 (1.5%)	0	3 (0.8%)
Toxic epidermal necrolysis	2 (1.0%)	0	2 (0.5%)
Acute generalised exanthematous pustulosis	0	1 (0.5%)	1 (0.3%)
Eczema	1 (0.5%)	0	1 (0.3%)
Lichen planus	1 (0.5%)	0	1 (0.3%)
Papule	1 (0.5%)	0	1 (0.3%)
Pruritus	1 (0.5%)	0	1 (0.3%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.5.2: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Rash macular	1 (0.5%)	0	1 (0.3%)
Rash morbilliform	1 (0.5%)	0	1 (0.3%)
Rash vesicular	1 (0.5%)	0	1 (0.3%)
Skin hyperpigmentation	1 (0.5%)	0	1 (0.3%)
Respiratory, thoracic and mediastinal disorders	9 (4.5%)	2 (1.0%)	11 (2.8%)
Pneumonitis	4 (2.0%)	0	4 (1.0%)
Immune-mediated lung disease	2 (1.0%)	0	2 (0.5%)
Autoimmune lung disease	1 (0.5%)	0	1 (0.3%)
Haemoptysis	0	1 (0.5%)	1 (0.3%)
Interstitial lung disease	1 (0.5%)	0	1 (0.3%)
Pulmonary embolism	0	1 (0.5%)	1 (0.3%)
Respiratory failure	1 (0.5%)	0	1 (0.3%)
General disorders and administration site conditions	7 (3.5%)	3 (1.5%)	10 (2.5%)
Asthenia	3 (1.5%)	0	3 (0.8%)
Fatigue	1 (0.5%)	1 (0.5%)	2 (0.5%)
General physical health deterioration	0	2 (1.0%)	2 (0.5%)
Multiple organ dysfunction syndrome	1 (0.5%)	0	1 (0.3%)
Performance status decreased	1 (0.5%)	0	1 (0.3%)
Sudden death	1 (0.5%)	0	1 (0.3%)
Renal and urinary disorders	9 (4.5%)	0	9 (2.3%)
Acute kidney injury	4 (2.0%)	0	4 (1.0%)
Renal failure	2 (1.0%)	0	2 (0.5%)
Chronic kidney disease	1 (0.5%)	0	1 (0.3%)
Immune-mediated nephritis	1 (0.5%)	0	1 (0.3%)
Proteinuria	1 (0.5%)	0	1 (0.3%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.5.2: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Infections and infestations	5 (2.5%)	3 (1.5%)	8 (2.0%)
Sepsis	1 (0.5%)	1 (0.5%)	2 (0.5%)
COVID-19	1 (0.5%)	0	1 (0.3%)
Cystitis	0	1 (0.5%)	1 (0.3%)
Peritonitis	0	1 (0.5%)	1 (0.3%)
Pneumonia	1 (0.5%)	0	1 (0.3%)
Pneumonia aspiration	1 (0.5%)	0	1 (0.3%)
Septic shock	1 (0.5%)	0	1 (0.3%)
Cardiac disorders	4 (2.0%)	1 (0.5%)	5 (1.3%)
Acute myocardial infarction	1 (0.5%)	0	1 (0.3%)
Cardiac arrest	0	1 (0.5%)	1 (0.3%)
Cardiac failure	1 (0.5%)	0	1 (0.3%)
Cardio-respiratory arrest	1 (0.5%)	0	1 (0.3%)
Myocarditis	1 (0.5%)	0	1 (0.3%)
Gastrointestinal disorders	5 (2.5%)	0	5 (1.3%)
Diarrhoea	2 (1.0%)	0	2 (0.5%)
Colitis ulcerative	1 (0.5%)	0	1 (0.3%)
Nausea	1 (0.5%)	0	1 (0.3%)
Paraesthesia oral	1 (0.5%)	0	1 (0.3%)
Investigations	3 (1.5%)	2 (1.0%)	5 (1.3%)
Alanine aminotransferase increased	2 (1.0%)	0	2 (0.5%)
Aspartate aminotransferase increased	1 (0.5%)	1 (0.5%)	2 (0.5%)
Neutrophil count decreased	0	1 (0.5%)	1 (0.3%)
Hepatobiliary disorders	2 (1.0%)	1 (0.5%)	3 (0.8%)
Autoimmune hepatitis	1 (0.5%)	0	1 (0.3%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.5.2: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Analysis Set mSAF 2

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Cholangitis sclerosing	1 (0.5%)	0	1 (0.3%)
Hypertransaminasaemia	0	1 (0.5%)	1 (0.3%)
Vascular disorders	2 (1.0%)	1 (0.5%)	3 (0.8%)
Iliac artery occlusion	1 (0.5%)	0	1 (0.3%)
Orthostatic hypotension	1 (0.5%)	0	1 (0.3%)
Shock	0	1 (0.5%)	1 (0.3%)
Metabolism and nutrition disorders	1 (0.5%)	1 (0.5%)	2 (0.5%)
Decreased appetite	0	1 (0.5%)	1 (0.3%)
Hyponatraemia	1 (0.5%)	0	1 (0.3%)
Musculoskeletal and connective tissue disorders	2 (1.0%)	0	2 (0.5%)
Arthralgia	1 (0.5%)	0	1 (0.3%)
Musculoskeletal pain	1 (0.5%)	0	1 (0.3%)
Ear and labyrinth disorders	0	1 (0.5%)	1 (0.3%)
Tinnitus	0	1 (0.5%)	1 (0.3%)
Immune system disorders	1 (0.5%)	0	1 (0.3%)
Sarcoidosis	1 (0.5%)	0	1 (0.3%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.6.1: Summary of Duration of Observation Time for any TEAE - Analysis Set mSAF 1

	EV+Pembro (N=239)	**Plat+Gem (N=236)**
Duration of observation period (months)		
n	239	236
Mean (SD)	12.61 (6.162)	5.15 (1.296)
Median	11.60	5.59
Q1 - Q3	7.69 - 16.10	4.90 - 5.91
Range	1.1 - 28.7	1.0 - 8.3

Abbreviations: DCO=data cut-off; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation; TEAE=treatment emergent adverse event.
Note: Observation time is defined as the time from first dose until DCO, study treatment discontinuation + 90 days in the intervention arm, study treatment discontinuation + 30 days in the control arm or death, whichever occured first and stopped the collection of endpoint data.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2000.6.2: Summary of Duration of Observation Time for any TEAE - Analysis Set mSAF 2

	EV+Pembro (N=201)	**Plat+Gem (N=197)**
Duration of observation period (months)		
n	201	197
Mean (SD)	12.12 (6.379)	4.86 (1.613)
Median	11.30	5.39
Q1 - Q3	7.66 - 16.26	3.81 - 5.91
Range	0.3 - 31.9	0.2 - 9.1

Abbreviations: DCO=data cut-off; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation; TEAE=treatment emergent adverse event.
Note: Observation time is defined as the time from first dose until DCO, study treatment discontinuation + 90 days in the intervention arm, study treatment discontinuation + 30 days in the control arm or death, whichever occured first and stopped the collection of endpoint data.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Overall	239 (100.0%)	234 (99.2%)	473 (99.6%)
Gastrointestinal disorders	179 (74.9%)	184 (78.0%)	363 (76.4%)
Nausea	61 (25.5%)	120 (50.8%)	181 (38.1%)
Constipation	67 (28.0%)	76 (32.2%)	143 (30.1%)
Diarrhoea	89 (37.2%)	40 (16.9%)	129 (27.2%)
Vomiting	24 (10.0%)	42 (17.8%)	66 (13.9%)
Abdominal pain	27 (11.3%)	21 (8.9%)	48 (10.1%)
Stomatitis	27 (11.3%)	16 (6.8%)	43 (9.1%)
Dry mouth	24 (10.0%)	6 (2.5%)	30 (6.3%)
Dyspepsia	13 (5.4%)	11 (4.7%)	24 (5.1%)
Gastrooesophageal reflux disease	12 (5.0%)	9 (3.8%)	21 (4.4%)
Abdominal pain upper	12 (5.0%)	7 (3.0%)	19 (4.0%)
Haemorrhoids	10 (4.2%)	2 (0.8%)	12 (2.5%)
Colitis	7 (2.9%)	0	7 (1.5%)
Dysphagia	4 (1.7%)	2 (0.8%)	6 (1.3%)
Gastritis	4 (1.7%)	2 (0.8%)	6 (1.3%)
Abdominal discomfort	3 (1.3%)	2 (0.8%)	5 (1.1%)
Mouth ulceration	3 (1.3%)	2 (0.8%)	5 (1.1%)
Abdominal pain lower	1 (0.4%)	3 (1.3%)	4 (0.8%)
Ascites	3 (1.3%)	1 (0.4%)	4 (0.8%)
Flatulence	3 (1.3%)	1 (0.4%)	4 (0.8%)
Inguinal hernia	3 (1.3%)	1 (0.4%)	4 (0.8%)
Gastric ulcer	2 (0.8%)	1 (0.4%)	3 (0.6%)
Immune-mediated enterocolitis	3 (1.3%)	0	3 (0.6%)
Oral dysaesthesia	2 (0.8%)	1 (0.4%)	3 (0.6%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Pancreatitis	3 (1.3%)	0	3 (0.6%)
Toothache	2 (0.8%)	1 (0.4%)	3 (0.6%)
Abdominal distension	2 (0.8%)	0	2 (0.4%)
Dental caries	1 (0.4%)	1 (0.4%)	2 (0.4%)
Faeces soft	2 (0.8%)	0	2 (0.4%)
Haemorrhoidal haemorrhage	2 (0.8%)	0	2 (0.4%)
Oral pain	1 (0.4%)	1 (0.4%)	2 (0.4%)
Paraesthesia oral	1 (0.4%)	1 (0.4%)	2 (0.4%)
Proctalgia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Rectal haemorrhage	2 (0.8%)	0	2 (0.4%)
Abdominal rigidity	0	1 (0.4%)	1 (0.2%)
Anal erythema	1 (0.4%)	0	1 (0.2%)
Anal pruritus	1 (0.4%)	0	1 (0.2%)
Angular cheilitis	1 (0.4%)	0	1 (0.2%)
Autoimmune pancreatitis	1 (0.4%)	0	1 (0.2%)
Colonic fistula	1 (0.4%)	0	1 (0.2%)
Defaecation urgency	1 (0.4%)	0	1 (0.2%)
Duodenal stenosis	1 (0.4%)	0	1 (0.2%)
Duodenitis	0	1 (0.4%)	1 (0.2%)
Enterovesical fistula	1 (0.4%)	0	1 (0.2%)
Epigastric discomfort	0	1 (0.4%)	1 (0.2%)
Gingival bleeding	1 (0.4%)	0	1 (0.2%)
Haematochezia	0	1 (0.4%)	1 (0.2%)
Haemorrhagic erosive gastritis	1 (0.4%)	0	1 (0.2%)
Hernial eventration	1 (0.4%)	0	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Hypoaesthesia oral	1 (0.4%)	0	1 (0.2%)
Ileal ulcer	1 (0.4%)	0	1 (0.2%)
Ileus	1 (0.4%)	0	1 (0.2%)
Intestinal obstruction	1 (0.4%)	0	1 (0.2%)
Large intestine perforation	1 (0.4%)	0	1 (0.2%)
Lip dry	1 (0.4%)	0	1 (0.2%)
Lip ulceration	1 (0.4%)	0	1 (0.2%)
Melaena	0	1 (0.4%)	1 (0.2%)
Obstructive pancreatitis	0	1 (0.4%)	1 (0.2%)
Odynophagia	1 (0.4%)	0	1 (0.2%)
Oesophageal stenosis	1 (0.4%)	0	1 (0.2%)
Oral blood blister	1 (0.4%)	0	1 (0.2%)
Oral verrucous hyperplasia	1 (0.4%)	0	1 (0.2%)
Pancreatitis chronic	1 (0.4%)	0	1 (0.2%)
Periodontal disease	1 (0.4%)	0	1 (0.2%)
Rectal tenesmus	0	1 (0.4%)	1 (0.2%)
Regurgitation	0	1 (0.4%)	1 (0.2%)
Salivary gland calculus	1 (0.4%)	0	1 (0.2%)
Small intestinal obstruction	1 (0.4%)	0	1 (0.2%)
General disorders and administration site conditions	159 (66.5%)	167 (70.8%)	326 (68.6%)
Fatigue	79 (33.1%)	101 (42.8%)	180 (37.9%)
Asthenia	43 (18.0%)	45 (19.1%)	88 (18.5%)
Pyrexia	41 (17.2%)	32 (13.6%)	73 (15.4%)
Oedema peripheral	29 (12.1%)	22 (9.3%)	51 (10.7%)
Malaise	8 (3.3%)	5 (2.1%)	13 (2.7%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Chills	7 (2.9%)	3 (1.3%)	10 (2.1%)
Non-cardiac chest pain	4 (1.7%)	5 (2.1%)	9 (1.9%)
Pain	3 (1.3%)	6 (2.5%)	9 (1.9%)
Gait disturbance	8 (3.3%)	0	8 (1.7%)
Infusion site extravasation	5 (2.1%)	0	5 (1.1%)
Peripheral swelling	3 (1.3%)	2 (0.8%)	5 (1.1%)
Chest discomfort	2 (0.8%)	2 (0.8%)	4 (0.8%)
General physical health deterioration	2 (0.8%)	2 (0.8%)	4 (0.8%)
Catheter site pain	2 (0.8%)	0	2 (0.4%)
Chest pain	2 (0.8%)	0	2 (0.4%)
Infusion site pain	0	2 (0.8%)	2 (0.4%)
Injection site reaction	0	2 (0.8%)	2 (0.4%)
Temperature intolerance	2 (0.8%)	0	2 (0.4%)
Catheter site erosion	1 (0.4%)	0	1 (0.2%)
Catheter site haematoma	0	1 (0.4%)	1 (0.2%)
Catheter site inflammation	0	1 (0.4%)	1 (0.2%)
Catheter site irritation	1 (0.4%)	0	1 (0.2%)
Catheter site pruritus	1 (0.4%)	0	1 (0.2%)
Catheter site related reaction	1 (0.4%)	0	1 (0.2%)
Catheter site swelling	0	1 (0.4%)	1 (0.2%)
Face oedema	0	1 (0.4%)	1 (0.2%)
Generalised oedema	0	1 (0.4%)	1 (0.2%)
Hyperthermia	1 (0.4%)	0	1 (0.2%)
Impaired healing	0	1 (0.4%)	1 (0.2%)
Influenza like illness	1 (0.4%)	0	1 (0.2%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Infusion site reaction	0	1 (0.4%)	1 (0.2%)
Localised oedema	1 (0.4%)	0	1 (0.2%)
Multiple organ dysfunction syndrome	0	1 (0.4%)	1 (0.2%)
Oedema	0	1 (0.4%)	1 (0.2%)
Suprapubic pain	0	1 (0.4%)	1 (0.2%)
Swelling face	1 (0.4%)	0	1 (0.2%)
Nervous system disorders	187 (78.2%)	96 (40.7%)	283 (59.6%)
Peripheral sensory neuropathy	127 (53.1%)	34 (14.4%)	161 (33.9%)
Dysgeusia	47 (19.7%)	28 (11.9%)	75 (15.8%)
Dizziness	24 (10.0%)	26 (11.0%)	50 (10.5%)
Headache	19 (7.9%)	16 (6.8%)	35 (7.4%)
Paraesthesia	24 (10.0%)	6 (2.5%)	30 (6.3%)
Hypoaesthesia	12 (5.0%)	1 (0.4%)	13 (2.7%)
Peripheral motor neuropathy	11 (4.6%)	1 (0.4%)	12 (2.5%)
Taste disorder	10 (4.2%)	2 (0.8%)	12 (2.5%)
Peripheral sensorimotor neuropathy	10 (4.2%)	1 (0.4%)	11 (2.3%)
Ageusia	8 (3.3%)	0	8 (1.7%)
Lethargy	2 (0.8%)	6 (2.5%)	8 (1.7%)
Syncope	5 (2.1%)	3 (1.3%)	8 (1.7%)
Anosmia	7 (2.9%)	0	7 (1.5%)
Hypogeusia	3 (1.3%)	3 (1.3%)	6 (1.3%)
Tremor	4 (1.7%)	2 (0.8%)	6 (1.3%)
Balance disorder	4 (1.7%)	1 (0.4%)	5 (1.1%)
Neurotoxicity	5 (2.1%)	0	5 (1.1%)
Somnolence	1 (0.4%)	3 (1.3%)	4 (0.8%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Dysaesthesia	2 (0.8%)	1 (0.4%)	3 (0.6%)
Cerebral infarction	0	2 (0.8%)	2 (0.4%)
Optic neuritis	2 (0.8%)	0	2 (0.4%)
Altered state of consciousness	1 (0.4%)	0	1 (0.2%)
Amnesia	0	1 (0.4%)	1 (0.2%)
Amputation stump pain	1 (0.4%)	0	1 (0.2%)
Aphasia	1 (0.4%)	0	1 (0.2%)
Brain fog	0	1 (0.4%)	1 (0.2%)
Burning sensation	0	1 (0.4%)	1 (0.2%)
Cerebral haemorrhage	1 (0.4%)	0	1 (0.2%)
Chronic inflammatory demyelinating polyradiculoneuropathy	1 (0.4%)	0	1 (0.2%)
Diabetic hyperglycaemic coma	1 (0.4%)	0	1 (0.2%)
Disturbance in attention	0	1 (0.4%)	1 (0.2%)
Dizziness postural	1 (0.4%)	0	1 (0.2%)
Dyskinesia	1 (0.4%)	0	1 (0.2%)
Epilepsy	0	1 (0.4%)	1 (0.2%)
Immune-mediated encephalitis	1 (0.4%)	0	1 (0.2%)
Intercostal neuralgia	0	1 (0.4%)	1 (0.2%)
Loss of consciousness	1 (0.4%)	0	1 (0.2%)
Lumbar radiculopathy	1 (0.4%)	0	1 (0.2%)
Memory impairment	0	1 (0.4%)	1 (0.2%)
Metabolic encephalopathy	0	1 (0.4%)	1 (0.2%)
Neuralgia	1 (0.4%)	0	1 (0.2%)
Partial seizures	1 (0.4%)	0	1 (0.2%)
Presyncope	0	1 (0.4%)	1 (0.2%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Pronator teres syndrome	1 (0.4%)	0	1 (0.2%)
Radiculopathy	0	1 (0.4%)	1 (0.2%)
Seizure	1 (0.4%)	0	1 (0.2%)
Senile dementia	1 (0.4%)	0	1 (0.2%)
Ulnar nerve palsy	1 (0.4%)	0	1 (0.2%)
Skin and subcutaneous tissue disorders	204 (85.4%)	61 (25.8%)	265 (55.8%)
Pruritus	105 (43.9%)	13 (5.5%)	118 (24.8%)
Alopecia	91 (38.1%)	22 (9.3%)	113 (23.8%)
Rash maculo-papular	76 (31.8%)	9 (3.8%)	85 (17.9%)
Dry skin	39 (16.3%)	4 (1.7%)	43 (9.1%)
Rash macular	27 (11.3%)	2 (0.8%)	29 (6.1%)
Rash papular	21 (8.8%)	1 (0.4%)	22 (4.6%)
Skin hyperpigmentation	17 (7.1%)	0	17 (3.6%)
Erythema	12 (5.0%)	3 (1.3%)	15 (3.2%)
Dermatitis bullous	14 (5.9%)	0	14 (2.9%)
Eczema	12 (5.0%)	2 (0.8%)	14 (2.9%)
Rash erythematous	12 (5.0%)	2 (0.8%)	14 (2.9%)
Dermatitis	13 (5.4%)	0	13 (2.7%)
Hyperhidrosis	7 (2.9%)	4 (1.7%)	11 (2.3%)
Blister	10 (4.2%)	0	10 (2.1%)
Skin ulcer	9 (3.8%)	1 (0.4%)	10 (2.1%)
Dermatitis acneiform	7 (2.9%)	2 (0.8%)	9 (1.9%)
Rash	8 (3.3%)	1 (0.4%)	9 (1.9%)
Skin exfoliation	8 (3.3%)	0	8 (1.7%)
Night sweats	3 (1.3%)	4 (1.7%)	7 (1.5%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Rash pruritic	5 (2.1%)	1 (0.4%)	6 (1.3%)
Rash vesicular	5 (2.1%)	0	5 (1.1%)
Erythema multiforme	3 (1.3%)	1 (0.4%)	4 (0.8%)
Skin discolouration	4 (1.7%)	0	4 (0.8%)
Skin hypopigmentation	4 (1.7%)	0	4 (0.8%)
Toxic skin eruption	4 (1.7%)	0	4 (0.8%)
Urticaria	4 (1.7%)	0	4 (0.8%)
Dermal cyst	3 (1.3%)	0	3 (0.6%)
Dermatitis exfoliative generalised	3 (1.3%)	0	3 (0.6%)
Onycholysis	3 (1.3%)	0	3 (0.6%)
Psoriasis	3 (1.3%)	0	3 (0.6%)
Vitiligo	3 (1.3%)	0	3 (0.6%)
Dermatitis contact	2 (0.8%)	0	2 (0.4%)
Hyperkeratosis	2 (0.8%)	0	2 (0.4%)
Lichenoid keratosis	2 (0.8%)	0	2 (0.4%)
Nail dystrophy	2 (0.8%)	0	2 (0.4%)
Onychoclasis	2 (0.8%)	0	2 (0.4%)
Onychomadesis	2 (0.8%)	0	2 (0.4%)
Palmar-plantar erythrodysaesthesia syndrome	2 (0.8%)	0	2 (0.4%)
Purpura	2 (0.8%)	0	2 (0.4%)
Skin plaque	2 (0.8%)	0	2 (0.4%)
Toxic erythema of chemotherapy	2 (0.8%)	0	2 (0.4%)
Acne	1 (0.4%)	0	1 (0.2%)
Actinic keratosis	1 (0.4%)	0	1 (0.2%)
Angiolymphoid hyperplasia with eosinophilia	1 (0.4%)	0	1 (0.2%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Anhidrosis	1 (0.4%)	0	1 (0.2%)
Brow ptosis	0	1 (0.4%)	1 (0.2%)
Cellulite	1 (0.4%)	0	1 (0.2%)
Cutaneous vasculitis	1 (0.4%)	0	1 (0.2%)
Dermatitis psoriasiform	1 (0.4%)	0	1 (0.2%)
Dermatomyositis	1 (0.4%)	0	1 (0.2%)
Drug eruption	1 (0.4%)	0	1 (0.2%)
Dyshidrotic eczema	1 (0.4%)	0	1 (0.2%)
Hair colour changes	0	1 (0.4%)	1 (0.2%)
Hand dermatitis	1 (0.4%)	0	1 (0.2%)
Lentigo	1 (0.4%)	0	1 (0.2%)
Lichen sclerosus	1 (0.4%)	0	1 (0.2%)
Madarosis	1 (0.4%)	0	1 (0.2%)
Nail discolouration	1 (0.4%)	0	1 (0.2%)
Nail discomfort	1 (0.4%)	0	1 (0.2%)
Nail toxicity	1 (0.4%)	0	1 (0.2%)
Pain of skin	1 (0.4%)	0	1 (0.2%)
Papule	0	1 (0.4%)	1 (0.2%)
Paradoxical psoriasis	1 (0.4%)	0	1 (0.2%)
Pemphigoid	1 (0.4%)	0	1 (0.2%)
Penile ulceration	1 (0.4%)	0	1 (0.2%)
Petechiae	0	1 (0.4%)	1 (0.2%)
Plantar erythema	1 (0.4%)	0	1 (0.2%)
Rash morbilliform	1 (0.4%)	0	1 (0.2%)
Seborrhoeic dermatitis	1 (0.4%)	0	1 (0.2%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Sensitive skin	1 (0.4%)	0	1 (0.2%)
SJS-TEN overlap	1 (0.4%)	0	1 (0.2%)
Skin depigmentation	1 (0.4%)	0	1 (0.2%)
Skin fissures	1 (0.4%)	0	1 (0.2%)
Skin fragility	1 (0.4%)	0	1 (0.2%)
Skin haemorrhage	0	1 (0.4%)	1 (0.2%)
Skin irritation	1 (0.4%)	0	1 (0.2%)
Skin toxicity	1 (0.4%)	0	1 (0.2%)
Subcutaneous emphysema	1 (0.4%)	0	1 (0.2%)
Symmetrical drug-related intertriginous and flexural exanthema	1 (0.4%)	0	1 (0.2%)
Toxic epidermal necrolysis	1 (0.4%)	0	1 (0.2%)
Xeroderma	1 (0.4%)	0	1 (0.2%)
Investigations	134 (56.1%)	107 (45.3%)	241 (50.7%)
Weight decreased	73 (30.5%)	23 (9.7%)	96 (20.2%)
Alanine aminotransferase increased	49 (20.5%)	13 (5.5%)	62 (13.1%)
Aspartate aminotransferase increased	47 (19.7%)	10 (4.2%)	57 (12.0%)
Blood creatinine increased	12 (5.0%)	27 (11.4%)	39 (8.2%)
Neutrophil count decreased	7 (2.9%)	32 (13.6%)	39 (8.2%)
Platelet count decreased	1 (0.4%)	30 (12.7%)	31 (6.5%)
Blood alkaline phosphatase increased	12 (5.0%)	8 (3.4%)	20 (4.2%)
Lipase increased	17 (7.1%)	0	17 (3.6%)
White blood cell count decreased	1 (0.4%)	14 (5.9%)	15 (3.2%)
Weight increased	6 (2.5%)	8 (3.4%)	14 (2.9%)
Gamma-glutamyltransferase increased	8 (3.3%)	2 (0.8%)	10 (2.1%)
Amylase increased	7 (2.9%)	2 (0.8%)	9 (1.9%)

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Table 302.1.2001.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Blood lactate dehydrogenase increased	7 (2.9%)	1 (0.4%)	8 (1.7%)
Blood creatine phosphokinase increased	7 (2.9%)	0	7 (1.5%)
Blood bilirubin increased	5 (2.1%)	1 (0.4%)	6 (1.3%)
Lymphocyte count decreased	2 (0.8%)	1 (0.4%)	3 (0.6%)
Neutrophil count increased	2 (0.8%)	1 (0.4%)	3 (0.6%)
Blood bicarbonate decreased	2 (0.8%)	0	2 (0.4%)
Blood glucose increased	2 (0.8%)	0	2 (0.4%)
Blood thyroid stimulating hormone increased	2 (0.8%)	0	2 (0.4%)
C-reactive protein increased	1 (0.4%)	1 (0.4%)	2 (0.4%)
Creatinine renal clearance decreased	0	2 (0.8%)	2 (0.4%)
Troponin I increased	2 (0.8%)	0	2 (0.4%)
Apolipoprotein A-I increased	1 (0.4%)	0	1 (0.2%)
Basophil count increased	1 (0.4%)	0	1 (0.2%)
Blood albumin decreased	1 (0.4%)	0	1 (0.2%)
Blood creatine increased	1 (0.4%)	0	1 (0.2%)
Blood potassium increased	0	1 (0.4%)	1 (0.2%)
Blood triglycerides increased	1 (0.4%)	0	1 (0.2%)
Blood urea increased	1 (0.4%)	0	1 (0.2%)
Body temperature increased	1 (0.4%)	0	1 (0.2%)
Electrocardiogram QT prolonged	1 (0.4%)	0	1 (0.2%)
Glomerular filtration rate decreased	0	1 (0.4%)	1 (0.2%)
Glycosylated haemoglobin increased	1 (0.4%)	0	1 (0.2%)
International normalised ratio increased	1 (0.4%)	0	1 (0.2%)
Lymph node palpable	0	1 (0.4%)	1 (0.2%)
Nitrite urine present	1 (0.4%)	0	1 (0.2%)

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Table 302.1.2001.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Oxygen saturation decreased	1 (0.4%)	0	1 (0.2%)
SARS-CoV-2 test positive	1 (0.4%)	0	1 (0.2%)
Thyroxine increased	1 (0.4%)	0	1 (0.2%)
Urine output decreased	1 (0.4%)	0	1 (0.2%)
White blood cell count increased	1 (0.4%)	0	1 (0.2%)
Metabolism and nutrition disorders	132 (55.2%)	109 (46.2%)	241 (50.7%)
Decreased appetite	72 (30.1%)	59 (25.0%)	131 (27.6%)
Hyperglycaemia	44 (18.4%)	6 (2.5%)	50 (10.5%)
Hypokalaemia	16 (6.7%)	16 (6.8%)	32 (6.7%)
Hyponatraemia	12 (5.0%)	19 (8.1%)	31 (6.5%)
Hypomagnesaemia	9 (3.8%)	20 (8.5%)	29 (6.1%)
Dehydration	7 (2.9%)	9 (3.8%)	16 (3.4%)
Hypophosphataemia	9 (3.8%)	7 (3.0%)	16 (3.4%)
Hyperkalaemia	5 (2.1%)	7 (3.0%)	12 (2.5%)
Hypocalcaemia	7 (2.9%)	5 (2.1%)	12 (2.5%)
Hypercalcaemia	6 (2.5%)	3 (1.3%)	9 (1.9%)
Hyperuricaemia	7 (2.9%)	0	7 (1.5%)
Hypoalbuminaemia	5 (2.1%)	2 (0.8%)	7 (1.5%)
Diabetes mellitus	4 (1.7%)	2 (0.8%)	6 (1.3%)
Hyperamylasaemia	2 (0.8%)	2 (0.8%)	4 (0.8%)
Hypercreatininaemia	3 (1.3%)	1 (0.4%)	4 (0.8%)
Hyperlipasaemia	2 (0.8%)	2 (0.8%)	4 (0.8%)
Hyperphosphataemia	4 (1.7%)	0	4 (0.8%)
Hypoglycaemia	3 (1.3%)	1 (0.4%)	4 (0.8%)
Gout	2 (0.8%)	1 (0.4%)	3 (0.6%)

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Table 302.1.2001.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Hypercholesterolaemia	3 (1.3%)	0	3 (0.6%)
Type 2 diabetes mellitus	3 (1.3%)	0	3 (0.6%)
Glucose tolerance impaired	2 (0.8%)	0	2 (0.4%)
Hyperlipidaemia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Hypochloraemia	0	2 (0.8%)	2 (0.4%)
Metabolic acidosis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Alkalosis	0	1 (0.4%)	1 (0.2%)
Cachexia	1 (0.4%)	0	1 (0.2%)
Dyslipidaemia	1 (0.4%)	0	1 (0.2%)
Electrolyte imbalance	0	1 (0.4%)	1 (0.2%)
Folate deficiency	0	1 (0.4%)	1 (0.2%)
Hypertriglyceridaemia	1 (0.4%)	0	1 (0.2%)
Hypoproteinaemia	0	1 (0.4%)	1 (0.2%)
Hypovolaemia	1 (0.4%)	0	1 (0.2%)
Lactic acidosis	1 (0.4%)	0	1 (0.2%)
Malnutrition	1 (0.4%)	0	1 (0.2%)
Tumour lysis syndrome	1 (0.4%)	0	1 (0.2%)
Vitamin B12 deficiency	1 (0.4%)	0	1 (0.2%)
Vitamin D deficiency	1 (0.4%)	0	1 (0.2%)
Blood and lymphatic system disorders	69 (28.9%)	170 (72.0%)	239 (50.3%)
Anaemia	41 (17.2%)	132 (55.9%)	173 (36.4%)
Neutropenia	21 (8.8%)	86 (36.4%)	107 (22.5%)
Thrombocytopenia	9 (3.8%)	57 (24.2%)	66 (13.9%)
Leukopenia	9 (3.8%)	26 (11.0%)	35 (7.4%)
Febrile neutropenia	3 (1.3%)	4 (1.7%)	7 (1.5%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Lymphopenia	2 (0.8%)	5 (2.1%)	7 (1.5%)
Leukocytosis	4 (1.7%)	1 (0.4%)	5 (1.1%)
Pancytopenia	0	4 (1.7%)	4 (0.8%)
Thrombocytosis	2 (0.8%)	2 (0.8%)	4 (0.8%)
Eosinophilia	2 (0.8%)	0	2 (0.4%)
Anaemia of malignant disease	1 (0.4%)	0	1 (0.2%)
Haemolytic anaemia	1 (0.4%)	0	1 (0.2%)
Lymphadenitis	0	1 (0.4%)	1 (0.2%)
Lymphadenopathy	0	1 (0.4%)	1 (0.2%)
Neutrophilia	0	1 (0.4%)	1 (0.2%)
Platelet toxicity	0	1 (0.4%)	1 (0.2%)
Splenomegaly	1 (0.4%)	0	1 (0.2%)
Infections and infestations	145 (60.7%)	85 (36.0%)	230 (48.4%)
Urinary tract infection	43 (18.0%)	44 (18.6%)	87 (18.3%)
COVID-19	43 (18.0%)	12 (5.1%)	55 (11.6%)
Conjunctivitis	18 (7.5%)	0	18 (3.8%)
Pneumonia	12 (5.0%)	4 (1.7%)	16 (3.4%)
Oral candidiasis	9 (3.8%)	4 (1.7%)	13 (2.7%)
Upper respiratory tract infection	11 (4.6%)	1 (0.4%)	12 (2.5%)
Cellulitis	7 (2.9%)	1 (0.4%)	8 (1.7%)
Sepsis	2 (0.8%)	6 (2.5%)	8 (1.7%)
COVID-19 pneumonia	4 (1.7%)	2 (0.8%)	6 (1.3%)
Folliculitis	5 (2.1%)	1 (0.4%)	6 (1.3%)
Bronchitis	5 (2.1%)	0	5 (1.1%)
Cystitis	2 (0.8%)	3 (1.3%)	5 (1.1%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Nasopharyngitis	4 (1.7%)	1 (0.4%)	5 (1.1%)
Respiratory tract infection	4 (1.7%)	1 (0.4%)	5 (1.1%)
Rhinitis	5 (2.1%)	0	5 (1.1%)
Skin infection	4 (1.7%)	1 (0.4%)	5 (1.1%)
Fungal skin infection	3 (1.3%)	1 (0.4%)	4 (0.8%)
Herpes zoster	4 (1.7%)	0	4 (0.8%)
Bacteriuria	1 (0.4%)	2 (0.8%)	3 (0.6%)
Device related infection	1 (0.4%)	2 (0.8%)	3 (0.6%)
Gingivitis	2 (0.8%)	1 (0.4%)	3 (0.6%)
Lower respiratory tract infection	2 (0.8%)	1 (0.4%)	3 (0.6%)
Pharyngitis	2 (0.8%)	1 (0.4%)	3 (0.6%)
Rash pustular	2 (0.8%)	1 (0.4%)	3 (0.6%)
Urosepsis	1 (0.4%)	2 (0.8%)	3 (0.6%)
Wound infection	1 (0.4%)	2 (0.8%)	3 (0.6%)
Bacteraemia	2 (0.8%)	0	2 (0.4%)
Influenza	2 (0.8%)	0	2 (0.4%)
Kidney infection	1 (0.4%)	1 (0.4%)	2 (0.4%)
Oral herpes	1 (0.4%)	1 (0.4%)	2 (0.4%)
Pneumonia bacterial	2 (0.8%)	0	2 (0.4%)
Pyelonephritis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Pyelonephritis chronic	0	2 (0.8%)	2 (0.4%)
Pyuria	1 (0.4%)	1 (0.4%)	2 (0.4%)
Sinusitis	2 (0.8%)	0	2 (0.4%)
Tinea cruris	1 (0.4%)	1 (0.4%)	2 (0.4%)
Abdominal abscess	0	1 (0.4%)	1 (0.2%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Abdominal sepsis	1 (0.4%)	0	1 (0.2%)
Body tinea	1 (0.4%)	0	1 (0.2%)
Candida infection	1 (0.4%)	0	1 (0.2%)
Catheter site infection	1 (0.4%)	0	1 (0.2%)
Clostridium difficile infection	1 (0.4%)	0	1 (0.2%)
Diverticulitis	1 (0.4%)	0	1 (0.2%)
Ear infection	1 (0.4%)	0	1 (0.2%)
Epididymitis	0	1 (0.4%)	1 (0.2%)
Erysipelas	1 (0.4%)	0	1 (0.2%)
Escherichia infection	0	1 (0.4%)	1 (0.2%)
Escherichia urinary tract infection	0	1 (0.4%)	1 (0.2%)
Eyelid infection	1 (0.4%)	0	1 (0.2%)
Fungal foot infection	1 (0.4%)	0	1 (0.2%)
Furuncle	0	1 (0.4%)	1 (0.2%)
Gastroenteritis viral	1 (0.4%)	0	1 (0.2%)
Groin abscess	0	1 (0.4%)	1 (0.2%)
Herpes dermatitis	1 (0.4%)	0	1 (0.2%)
Hordeolum	0	1 (0.4%)	1 (0.2%)
Infectious pleural effusion	1 (0.4%)	0	1 (0.2%)
Injection site infection	0	1 (0.4%)	1 (0.2%)
Klebsiella urinary tract infection	1 (0.4%)	0	1 (0.2%)
Laryngopharyngitis	1 (0.4%)	0	1 (0.2%)
Lip infection	1 (0.4%)	0	1 (0.2%)
Localised infection	1 (0.4%)	0	1 (0.2%)
Lung abscess	1 (0.4%)	0	1 (0.2%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Neutropenic sepsis	0	1 (0.4%)	1 (0.2%)
Oesophageal candidiasis	1 (0.4%)	0	1 (0.2%)
Onychomycosis	1 (0.4%)	0	1 (0.2%)
Oral fungal infection	1 (0.4%)	0	1 (0.2%)
Parotitis	1 (0.4%)	0	1 (0.2%)
Pelvic infection	1 (0.4%)	0	1 (0.2%)
Penile infection	1 (0.4%)	0	1 (0.2%)
Perineal abscess	0	1 (0.4%)	1 (0.2%)
Periodontitis	1 (0.4%)	0	1 (0.2%)
Pharyngitis streptococcal	1 (0.4%)	0	1 (0.2%)
Pneumocystis jirovecii pneumonia	1 (0.4%)	0	1 (0.2%)
Pneumonia haemophilus	0	1 (0.4%)	1 (0.2%)
Postoperative wound infection	1 (0.4%)	0	1 (0.2%)
Respiratory syncytial virus infection	0	1 (0.4%)	1 (0.2%)
Skin bacterial infection	1 (0.4%)	0	1 (0.2%)
Skin candida	0	1 (0.4%)	1 (0.2%)
Soft tissue infection	0	1 (0.4%)	1 (0.2%)
Staphylococcal bacteraemia	1 (0.4%)	0	1 (0.2%)
Subcutaneous abscess	1 (0.4%)	0	1 (0.2%)
Tinea pedis	1 (0.4%)	0	1 (0.2%)
Tonsillitis	0	1 (0.4%)	1 (0.2%)
Tooth abscess	1 (0.4%)	0	1 (0.2%)
Urinary tract infection bacterial	0	1 (0.4%)	1 (0.2%)
Urinary tract infection enterococcal	0	1 (0.4%)	1 (0.2%)
Urinary tract infection pseudomonal	0	1 (0.4%)	1 (0.2%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Urinary tract infection staphylococcal	1 (0.4%)	0	1 (0.2%)
Viral infection	0	1 (0.4%)	1 (0.2%)
Viral upper respiratory tract infection	0	1 (0.4%)	1 (0.2%)
Vulvitis	0	1 (0.4%)	1 (0.2%)
Respiratory, thoracic and mediastinal disorders	100 (41.8%)	83 (35.2%)	183 (38.5%)
Dyspnoea	29 (12.1%)	24 (10.2%)	53 (11.2%)
Cough	26 (10.9%)	13 (5.5%)	39 (8.2%)
Hiccups	7 (2.9%)	22 (9.3%)	29 (6.1%)
Epistaxis	6 (2.5%)	19 (8.1%)	25 (5.3%)
Pulmonary embolism	8 (3.3%)	15 (6.4%)	23 (4.8%)
Pneumonitis	17 (7.1%)	1 (0.4%)	18 (3.8%)
Dysphonia	13 (5.4%)	4 (1.7%)	17 (3.6%)
Rhinorrhoea	8 (3.3%)	6 (2.5%)	14 (2.9%)
Nasal congestion	9 (3.8%)	1 (0.4%)	10 (2.1%)
Oropharyngeal pain	5 (2.1%)	4 (1.7%)	9 (1.9%)
Productive cough	3 (1.3%)	4 (1.7%)	7 (1.5%)
Dyspnoea exertional	3 (1.3%)	2 (0.8%)	5 (1.1%)
Immune-mediated lung disease	4 (1.7%)	0	4 (0.8%)
Interstitial lung disease	4 (1.7%)	0	4 (0.8%)
Aphonia	2 (0.8%)	1 (0.4%)	3 (0.6%)
Upper-airway cough syndrome	3 (1.3%)	0	3 (0.6%)
Chronic obstructive pulmonary disease	1 (0.4%)	1 (0.4%)	2 (0.4%)
Haemoptysis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Hypoxia	2 (0.8%)	0	2 (0.4%)
Nasal dryness	2 (0.8%)	0	2 (0.4%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Painful respiration	1 (0.4%)	1 (0.4%)	2 (0.4%)
Pleural effusion	1 (0.4%)	1 (0.4%)	2 (0.4%)
Pneumothorax	2 (0.8%)	0	2 (0.4%)
Respiratory failure	2 (0.8%)	0	2 (0.4%)
Rhinitis allergic	2 (0.8%)	0	2 (0.4%)
Acute pulmonary oedema	1 (0.4%)	0	1 (0.2%)
Acute respiratory failure	1 (0.4%)	0	1 (0.2%)
Aspiration	1 (0.4%)	0	1 (0.2%)
Catarrh	0	1 (0.4%)	1 (0.2%)
Dry throat	1 (0.4%)	0	1 (0.2%)
Laryngeal haemorrhage	0	1 (0.4%)	1 (0.2%)
Laryngeal inflammation	0	1 (0.4%)	1 (0.2%)
Lung disorder	1 (0.4%)	0	1 (0.2%)
Nasal polyps	1 (0.4%)	0	1 (0.2%)
Nocturnal dyspnoea	1 (0.4%)	0	1 (0.2%)
Organising pneumonia	1 (0.4%)	0	1 (0.2%)
Orthopnoea	1 (0.4%)	0	1 (0.2%)
Pharyngeal dyskinesia	1 (0.4%)	0	1 (0.2%)
Pharyngeal inflammation	1 (0.4%)	0	1 (0.2%)
Pleuritic pain	1 (0.4%)	0	1 (0.2%)
Pulmonary fibrosis	1 (0.4%)	0	1 (0.2%)
Pulmonary oedema	0	1 (0.4%)	1 (0.2%)
Pulmonary pain	0	1 (0.4%)	1 (0.2%)
Pulmonary toxicity	1 (0.4%)	0	1 (0.2%)
Respiratory distress	1 (0.4%)	0	1 (0.2%)

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Table 302.1.2001.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Sinus congestion	1 (0.4%)	0	1 (0.2%)
Musculoskeletal and connective tissue disorders	108 (45.2%)	68 (28.8%)	176 (37.1%)
Back pain	37 (15.5%)	21 (8.9%)	58 (12.2%)
Arthralgia	36 (15.1%)	11 (4.7%)	47 (9.9%)
Pain in extremity	21 (8.8%)	15 (6.4%)	36 (7.6%)
Myalgia	17 (7.1%)	7 (3.0%)	24 (5.1%)
Muscular weakness	13 (5.4%)	4 (1.7%)	17 (3.6%)
Flank pain	7 (2.9%)	7 (3.0%)	14 (2.9%)
Bone pain	4 (1.7%)	7 (3.0%)	11 (2.3%)
Muscle spasms	9 (3.8%)	1 (0.4%)	10 (2.1%)
Musculoskeletal chest pain	5 (2.1%)	1 (0.4%)	6 (1.3%)
Musculoskeletal discomfort	3 (1.3%)	3 (1.3%)	6 (1.3%)
Neck pain	4 (1.7%)	2 (0.8%)	6 (1.3%)
Arthritis	4 (1.7%)	1 (0.4%)	5 (1.1%)
Gouty arthritis	3 (1.3%)	0	3 (0.6%)
Limb discomfort	2 (0.8%)	1 (0.4%)	3 (0.6%)
Musculoskeletal pain	3 (1.3%)	0	3 (0.6%)
Musculoskeletal stiffness	2 (0.8%)	1 (0.4%)	3 (0.6%)
Joint stiffness	1 (0.4%)	1 (0.4%)	2 (0.4%)
Myositis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Osteopenia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Pain in jaw	0	2 (0.8%)	2 (0.4%)
Tendon pain	0	2 (0.8%)	2 (0.4%)
Arthropathy	1 (0.4%)	0	1 (0.2%)
Bone lesion	1 (0.4%)	0	1 (0.2%)

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Table 302.1.2001.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Groin pain	0	1 (0.4%)	1 (0.2%)
Hypercreatinaemia	0	1 (0.4%)	1 (0.2%)
Joint range of motion decreased	1 (0.4%)	0	1 (0.2%)
Mobility decreased	0	1 (0.4%)	1 (0.2%)
Osteoarthritis	1 (0.4%)	0	1 (0.2%)
Osteoporosis	1 (0.4%)	0	1 (0.2%)
Pathological fracture	0	1 (0.4%)	1 (0.2%)
Rhabdomyolysis	0	1 (0.4%)	1 (0.2%)
Sjogren's syndrome	1 (0.4%)	0	1 (0.2%)
Renal and urinary disorders	74 (31.0%)	76 (32.2%)	150 (31.6%)
Haematuria	31 (13.0%)	20 (8.5%)	51 (10.7%)
Acute kidney injury	11 (4.6%)	25 (10.6%)	36 (7.6%)
Dysuria	13 (5.4%)	8 (3.4%)	21 (4.4%)
Urinary retention	8 (3.3%)	9 (3.8%)	17 (3.6%)
Pollakiuria	8 (3.3%)	6 (2.5%)	14 (2.9%)
Renal impairment	4 (1.7%)	5 (2.1%)	9 (1.9%)
Renal failure	2 (0.8%)	5 (2.1%)	7 (1.5%)
Hydronephrosis	4 (1.7%)	2 (0.8%)	6 (1.3%)
Chronic kidney disease	1 (0.4%)	4 (1.7%)	5 (1.1%)
Leukocyturia	3 (1.3%)	2 (0.8%)	5 (1.1%)
Nocturia	1 (0.4%)	4 (1.7%)	5 (1.1%)
Urinary tract pain	2 (0.8%)	3 (1.3%)	5 (1.1%)
Chromaturia	4 (1.7%)	0	4 (0.8%)
Bladder spasm	3 (1.3%)	0	3 (0.6%)
Proteinuria	2 (0.8%)	1 (0.4%)	3 (0.6%)

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Table 302.1.2001.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Bladder pain	2 (0.8%)	0	2 (0.4%)
Calculus bladder	2 (0.8%)	0	2 (0.4%)
Micturition urgency	1 (0.4%)	1 (0.4%)	2 (0.4%)
Polyuria	1 (0.4%)	1 (0.4%)	2 (0.4%)
Urinary incontinence	2 (0.8%)	0	2 (0.4%)
Calculus urinary	1 (0.4%)	0	1 (0.2%)
Cystitis noninfective	0	1 (0.4%)	1 (0.2%)
Immune-mediated nephritis	1 (0.4%)	0	1 (0.2%)
Nephropathy	0	1 (0.4%)	1 (0.2%)
Oliguria	1 (0.4%)	0	1 (0.2%)
Postrenal failure	1 (0.4%)	0	1 (0.2%)
Prerenal failure	0	1 (0.4%)	1 (0.2%)
Renal colic	0	1 (0.4%)	1 (0.2%)
Renal pain	0	1 (0.4%)	1 (0.2%)
Stress urinary incontinence	1 (0.4%)	0	1 (0.2%)
Urethral stenosis	1 (0.4%)	0	1 (0.2%)
Urinary hesitation	0	1 (0.4%)	1 (0.2%)
Urinary tract obstruction	1 (0.4%)	0	1 (0.2%)
Urine abnormality	0	1 (0.4%)	1 (0.2%)
Urine odour abnormal	1 (0.4%)	0	1 (0.2%)
Eye disorders	88 (36.8%)	14 (5.9%)	102 (21.5%)
Dry eye	29 (12.1%)	3 (1.3%)	32 (6.7%)
Lacrimation increased	25 (10.5%)	1 (0.4%)	26 (5.5%)
Vision blurred	16 (6.7%)	4 (1.7%)	20 (4.2%)
Cataract	10 (4.2%)	1 (0.4%)	11 (2.3%)

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Table 302.1.2001.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Blepharitis	6 (2.5%)	0	6 (1.3%)
Eye irritation	5 (2.1%)	0	5 (1.1%)
Keratitis	4 (1.7%)	0	4 (0.8%)
Visual acuity reduced	4 (1.7%)	0	4 (0.8%)
Vitreous floaters	2 (0.8%)	2 (0.8%)	4 (0.8%)
Xerophthalmia	4 (1.7%)	0	4 (0.8%)
Eye pruritus	3 (1.3%)	0	3 (0.6%)
Conjunctivitis allergic	2 (0.8%)	0	2 (0.4%)
Eye discharge	2 (0.8%)	0	2 (0.4%)
Eye pain	2 (0.8%)	0	2 (0.4%)
Eyelids pruritus	1 (0.4%)	1 (0.4%)	2 (0.4%)
Photopsia	0	2 (0.8%)	2 (0.4%)
Visual impairment	2 (0.8%)	0	2 (0.4%)
Asthenopia	1 (0.4%)	0	1 (0.2%)
Conjunctival haemorrhage	0	1 (0.4%)	1 (0.2%)
Conjunctival irritation	1 (0.4%)	0	1 (0.2%)
Corneal erosion	1 (0.4%)	0	1 (0.2%)
Corneal toxicity	1 (0.4%)	0	1 (0.2%)
Diplopia	1 (0.4%)	0	1 (0.2%)
Eczema eyelids	1 (0.4%)	0	1 (0.2%)
Entropion	1 (0.4%)	0	1 (0.2%)
Exposure keratitis	1 (0.4%)	0	1 (0.2%)
Meibomianitis	1 (0.4%)	0	1 (0.2%)
Myopia	1 (0.4%)	0	1 (0.2%)
Ocular hyperaemia	1 (0.4%)	0	1 (0.2%)

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Table 302.1.2001.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Periorbital oedema	0	1 (0.4%)	1 (0.2%)
Photophobia	1 (0.4%)	0	1 (0.2%)
Pinguecula	1 (0.4%)	0	1 (0.2%)
Retinal degeneration	1 (0.4%)	0	1 (0.2%)
Retinal detachment	1 (0.4%)	0	1 (0.2%)
Retinal tear	1 (0.4%)	0	1 (0.2%)
Retinopathy hypertensive	1 (0.4%)	0	1 (0.2%)
Uveitis	1 (0.4%)	0	1 (0.2%)
Vitreous haemorrhage	1 (0.4%)	0	1 (0.2%)
Vascular disorders	38 (15.9%)	46 (19.5%)	84 (17.7%)
Hypertension	13 (5.4%)	17 (7.2%)	30 (6.3%)
Hypotension	7 (2.9%)	6 (2.5%)	13 (2.7%)
Deep vein thrombosis	2 (0.8%)	8 (3.4%)	10 (2.1%)
Hot flush	5 (2.1%)	0	5 (1.1%)
Phlebitis	0	5 (2.1%)	5 (1.1%)
Superficial vein thrombosis	0	5 (2.1%)	5 (1.1%)
Thrombophlebitis	1 (0.4%)	4 (1.7%)	5 (1.1%)
Flushing	2 (0.8%)	1 (0.4%)	3 (0.6%)
Lymphoedema	2 (0.8%)	1 (0.4%)	3 (0.6%)
Orthostatic hypotension	2 (0.8%)	1 (0.4%)	3 (0.6%)
Peripheral embolism	0	3 (1.3%)	3 (0.6%)
Capillary fragility	1 (0.4%)	0	1 (0.2%)
Intermittent claudication	1 (0.4%)	0	1 (0.2%)
Lymphocele	0	1 (0.4%)	1 (0.2%)
Pallor	1 (0.4%)	0	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Pelvic venous thrombosis	1 (0.4%)	0	1 (0.2%)
Peripheral arterial occlusive disease	1 (0.4%)	0	1 (0.2%)
Phlebosclerosis	0	1 (0.4%)	1 (0.2%)
Vascular pain	1 (0.4%)	0	1 (0.2%)
Venous thrombosis	0	1 (0.4%)	1 (0.2%)
Psychiatric disorders	39 (16.3%)	24 (10.2%)	63 (13.3%)
Insomnia	22 (9.2%)	14 (5.9%)	36 (7.6%)
Anxiety	10 (4.2%)	3 (1.3%)	13 (2.7%)
Depression	5 (2.1%)	5 (2.1%)	10 (2.1%)
Delirium	4 (1.7%)	0	4 (0.8%)
Confusional state	3 (1.3%)	0	3 (0.6%)
Disorientation	1 (0.4%)	1 (0.4%)	2 (0.4%)
Affective disorder	1 (0.4%)	0	1 (0.2%)
Agitation	1 (0.4%)	0	1 (0.2%)
Depressed mood	0	1 (0.4%)	1 (0.2%)
Dysphemia	0	1 (0.4%)	1 (0.2%)
Emotional distress	0	1 (0.4%)	1 (0.2%)
Hallucination, auditory	1 (0.4%)	0	1 (0.2%)
Initial insomnia	1 (0.4%)	0	1 (0.2%)
Mixed anxiety and depressive disorder	1 (0.4%)	0	1 (0.2%)
Sleep disorder	1 (0.4%)	0	1 (0.2%)
Suicidal ideation	1 (0.4%)	0	1 (0.2%)
Ear and labyrinth disorders	17 (7.1%)	33 (14.0%)	50 (10.5%)
Tinnitus	5 (2.1%)	27 (11.4%)	32 (6.7%)
Hypoacusis	2 (0.8%)	3 (1.3%)	5 (1.1%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Vertigo	5 (2.1%)	0	5 (1.1%)
Ear discomfort	1 (0.4%)	1 (0.4%)	2 (0.4%)
Ear pain	2 (0.8%)	0	2 (0.4%)
Ototoxicity	0	2 (0.8%)	2 (0.4%)
Presbyacusis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Deafness	0	1 (0.4%)	1 (0.2%)
Vestibular disorder	1 (0.4%)	0	1 (0.2%)
Injury, poisoning and procedural complications	34 (14.2%)	16 (6.8%)	50 (10.5%)
Fall	11 (4.6%)	3 (1.3%)	14 (2.9%)
Urinary tract stoma complication	5 (2.1%)	2 (0.8%)	7 (1.5%)
Contusion	3 (1.3%)	1 (0.4%)	4 (0.8%)
Infusion related reaction	2 (0.8%)	2 (0.8%)	4 (0.8%)
Skin laceration	3 (1.3%)	1 (0.4%)	4 (0.8%)
Skin abrasion	2 (0.8%)	1 (0.4%)	3 (0.6%)
Thermal burn	1 (0.4%)	1 (0.4%)	2 (0.4%)
Eschar	1 (0.4%)	0	1 (0.2%)
Eye contusion	1 (0.4%)	0	1 (0.2%)
Fibula fracture	1 (0.4%)	0	1 (0.2%)
Foot fracture	1 (0.4%)	0	1 (0.2%)
Heat stroke	1 (0.4%)	0	1 (0.2%)
Ligament sprain	0	1 (0.4%)	1 (0.2%)
Limb traumatic amputation	1 (0.4%)	0	1 (0.2%)
Muscle rupture	0	1 (0.4%)	1 (0.2%)
Overdose	1 (0.4%)	0	1 (0.2%)
Penis injury	1 (0.4%)	0	1 (0.2%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Post vaccination fever	1 (0.4%)	0	1 (0.2%)
Procedural pain	1 (0.4%)	0	1 (0.2%)
Spinal fracture	1 (0.4%)	0	1 (0.2%)
Sternal fracture	0	1 (0.4%)	1 (0.2%)
Stoma site pain	0	1 (0.4%)	1 (0.2%)
Subcutaneous haematoma	0	1 (0.4%)	1 (0.2%)
Tibia fracture	0	1 (0.4%)	1 (0.2%)
Toxicity to various agents	0	1 (0.4%)	1 (0.2%)
Urinary tract procedural complication	1 (0.4%)	0	1 (0.2%)
Urostomy complication	0	1 (0.4%)	1 (0.2%)
Wound dehiscence	1 (0.4%)	0	1 (0.2%)
Cardiac disorders	22 (9.2%)	20 (8.5%)	42 (8.8%)
Atrial fibrillation	1 (0.4%)	5 (2.1%)	6 (1.3%)
Sinus tachycardia	3 (1.3%)	3 (1.3%)	6 (1.3%)
Tachycardia	3 (1.3%)	3 (1.3%)	6 (1.3%)
Palpitations	3 (1.3%)	2 (0.8%)	5 (1.1%)
Angina pectoris	1 (0.4%)	2 (0.8%)	3 (0.6%)
Bradycardia	2 (0.8%)	0	2 (0.4%)
Cardiac arrest	2 (0.8%)	0	2 (0.4%)
Pericardial effusion	1 (0.4%)	1 (0.4%)	2 (0.4%)
Supraventricular tachycardia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Acute coronary syndrome	1 (0.4%)	0	1 (0.2%)
Acute myocardial infarction	0	1 (0.4%)	1 (0.2%)
Acute right ventricular failure	0	1 (0.4%)	1 (0.2%)
Arrhythmia	0	1 (0.4%)	1 (0.2%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Atrioventricular block complete	1 (0.4%)	0	1 (0.2%)
Bundle branch block left	1 (0.4%)	0	1 (0.2%)
Bundle branch block right	1 (0.4%)	0	1 (0.2%)
Cardio-respiratory arrest	1 (0.4%)	0	1 (0.2%)
Cardiogenic shock	0	1 (0.4%)	1 (0.2%)
Cardiomyopathy	1 (0.4%)	0	1 (0.2%)
Diastolic dysfunction	1 (0.4%)	0	1 (0.2%)
Myocardial infarction	0	1 (0.4%)	1 (0.2%)
Myocarditis	1 (0.4%)	0	1 (0.2%)
Hepatobiliary disorders	32 (13.4%)	8 (3.4%)	40 (8.4%)
Hypertransaminasaemia	10 (4.2%)	5 (2.1%)	15 (3.2%)
Hepatic function abnormal	6 (2.5%)	1 (0.4%)	7 (1.5%)
Autoimmune hepatitis	3 (1.3%)	0	3 (0.6%)
Cholecystitis	3 (1.3%)	0	3 (0.6%)
Hepatotoxicity	3 (1.3%)	0	3 (0.6%)
Hepatic cytolysis	2 (0.8%)	0	2 (0.4%)
Hepatitis	2 (0.8%)	0	2 (0.4%)
Immune-mediated hepatitis	2 (0.8%)	0	2 (0.4%)
Cholelithiasis	1 (0.4%)	0	1 (0.2%)
Hepatic cirrhosis	1 (0.4%)	0	1 (0.2%)
Hepatic pain	0	1 (0.4%)	1 (0.2%)
Hepatic steatosis	1 (0.4%)	0	1 (0.2%)
Hepatitis toxic	0	1 (0.4%)	1 (0.2%)
Hyperbilirubinaemia	1 (0.4%)	0	1 (0.2%)
Endocrine disorders	35 (14.6%)	2 (0.8%)	37 (7.8%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Hypothyroidism	23 (9.6%)	1 (0.4%)	24 (5.1%)
Hyperthyroidism	9 (3.8%)	1 (0.4%)	10 (2.1%)
Adrenal insufficiency	4 (1.7%)	0	4 (0.8%)
Autoimmune thyroiditis	1 (0.4%)	0	1 (0.2%)
Hyperparathyroidism	1 (0.4%)	0	1 (0.2%)
Hypophysitis	1 (0.4%)	0	1 (0.2%)
Inappropriate antidiuretic hormone secretion	1 (0.4%)	0	1 (0.2%)
Thyroiditis	1 (0.4%)	0	1 (0.2%)
Reproductive system and breast disorders	19 (7.9%)	6 (2.5%)	25 (5.3%)
Pelvic pain	4 (1.7%)	3 (1.3%)	7 (1.5%)
Penile pain	2 (0.8%)	2 (0.8%)	4 (0.8%)
Balanoposthitis	2 (0.8%)	0	2 (0.4%)
Penile erythema	2 (0.8%)	0	2 (0.4%)
Vaginal discharge	2 (0.8%)	0	2 (0.4%)
Vaginal haemorrhage	1 (0.4%)	1 (0.4%)	2 (0.4%)
Atrophic vulvovaginitis	1 (0.4%)	0	1 (0.2%)
Nipple pain	1 (0.4%)	0	1 (0.2%)
Oedema genital	1 (0.4%)	0	1 (0.2%)
Prostatic obstruction	1 (0.4%)	0	1 (0.2%)
Prostatitis	1 (0.4%)	0	1 (0.2%)
Pruritus genital	1 (0.4%)	0	1 (0.2%)
Scrotal pain	1 (0.4%)	0	1 (0.2%)
Testicular pain	1 (0.4%)	0	1 (0.2%)
Vaginal erosion	1 (0.4%)	0	1 (0.2%)
Vulvovaginal dryness	1 (0.4%)	0	1 (0.2%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	13 (5.4%)	7 (3.0%)	20 (4.2%)
Cancer pain	2 (0.8%)	3 (1.3%)	5 (1.1%)
Seborrhoeic keratosis	4 (1.7%)	0	4 (0.8%)
Tumour pain	0	2 (0.8%)	2 (0.4%)
Acrochordon	1 (0.4%)	0	1 (0.2%)
Angiofibroma	1 (0.4%)	0	1 (0.2%)
Burkitt's lymphoma	1 (0.4%)	0	1 (0.2%)
Fibrous histiocytoma	1 (0.4%)	0	1 (0.2%)
Large intestine benign neoplasm	1 (0.4%)	0	1 (0.2%)
Metastases to central nervous system	0	1 (0.4%)	1 (0.2%)
Skin papilloma	1 (0.4%)	0	1 (0.2%)
Tumour associated fever	0	1 (0.4%)	1 (0.2%)
Tumour rupture	1 (0.4%)	0	1 (0.2%)
Immune system disorders	5 (2.1%)	2 (0.8%)	7 (1.5%)
Contrast media allergy	1 (0.4%)	2 (0.8%)	3 (0.6%)
Seasonal allergy	2 (0.8%)	0	2 (0.4%)
Drug hypersensitivity	1 (0.4%)	0	1 (0.2%)
Hypersensitivity	1 (0.4%)	0	1 (0.2%)
Product issues	1 (0.4%)	3 (1.3%)	4 (0.8%)
Device occlusion	0	2 (0.8%)	2 (0.4%)
Device kink	0	1 (0.4%)	1 (0.2%)
Thrombosis in device	1 (0.4%)	0	1 (0.2%)
Congenital, familial and genetic disorders	3 (1.3%)	0	3 (0.6%)
Dermoid cyst	1 (0.4%)	0	1 (0.2%)
Dolichocolon	1 (0.4%)	0	1 (0.2%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.1: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Hydrocele	1 (0.4%)	0	1 (0.2%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Overall	200 (99.5%)	193 (98.0%)	393 (98.7%)
Gastrointestinal disorders	151 (75.1%)	129 (65.5%)	280 (70.4%)
Constipation	49 (24.4%)	71 (36.0%)	120 (30.2%)
Nausea	55 (27.4%)	58 (29.4%)	113 (28.4%)
Diarrhoea	77 (38.3%)	29 (14.7%)	106 (26.6%)
Vomiting	27 (13.4%)	27 (13.7%)	54 (13.6%)
Abdominal pain	24 (11.9%)	6 (3.0%)	30 (7.5%)
Stomatitis	12 (6.0%)	11 (5.6%)	23 (5.8%)
Dyspepsia	13 (6.5%)	7 (3.6%)	20 (5.0%)
Dry mouth	17 (8.5%)	1 (0.5%)	18 (4.5%)
Abdominal distension	10 (5.0%)	2 (1.0%)	12 (3.0%)
Gastrooesophageal reflux disease	6 (3.0%)	6 (3.0%)	12 (3.0%)
Abdominal pain upper	5 (2.5%)	5 (2.5%)	10 (2.5%)
Dysphagia	7 (3.5%)	0	7 (1.8%)
Mouth ulceration	5 (2.5%)	1 (0.5%)	6 (1.5%)
Abdominal pain lower	1 (0.5%)	4 (2.0%)	5 (1.3%)
Haemorrhoids	4 (2.0%)	1 (0.5%)	5 (1.3%)
Gastritis	3 (1.5%)	1 (0.5%)	4 (1.0%)
Toothache	3 (1.5%)	1 (0.5%)	4 (1.0%)
Abdominal discomfort	1 (0.5%)	2 (1.0%)	3 (0.8%)
Haemorrhoidal haemorrhage	2 (1.0%)	1 (0.5%)	3 (0.8%)
Aphthous ulcer	2 (1.0%)	0	2 (0.5%)
Cheilitis	2 (1.0%)	0	2 (0.5%)
Colitis	2 (1.0%)	0	2 (0.5%)
Eructation	1 (0.5%)	1 (0.5%)	2 (0.5%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Faeces discoloured	0	2 (1.0%)	2 (0.5%)
Haematemesis	1 (0.5%)	1 (0.5%)	2 (0.5%)
Haematochezia	2 (1.0%)	0	2 (0.5%)
Intestinal obstruction	1 (0.5%)	1 (0.5%)	2 (0.5%)
Melaena	1 (0.5%)	1 (0.5%)	2 (0.5%)
Oesophagitis	1 (0.5%)	1 (0.5%)	2 (0.5%)
Pancreatitis acute	1 (0.5%)	1 (0.5%)	2 (0.5%)
Paraesthesia oral	2 (1.0%)	0	2 (0.5%)
Aerophagia	1 (0.5%)	0	1 (0.3%)
Anal eczema	1 (0.5%)	0	1 (0.3%)
Anal fissure	1 (0.5%)	0	1 (0.3%)
Anal haemorrhage	1 (0.5%)	0	1 (0.3%)
Anal incontinence	0	1 (0.5%)	1 (0.3%)
Autoimmune colitis	1 (0.5%)	0	1 (0.3%)
Colitis microscopic	1 (0.5%)	0	1 (0.3%)
Colitis ulcerative	1 (0.5%)	0	1 (0.3%)
Defaecation urgency	1 (0.5%)	0	1 (0.3%)
Dental caries	1 (0.5%)	0	1 (0.3%)
Duodenal ulcer	1 (0.5%)	0	1 (0.3%)
Enterovesical fistula	1 (0.5%)	0	1 (0.3%)
Faecaloma	1 (0.5%)	0	1 (0.3%)
Flatulence	0	1 (0.5%)	1 (0.3%)
Gastric haemorrhage	0	1 (0.5%)	1 (0.3%)
Gastric ulcer	1 (0.5%)	0	1 (0.3%)
Gastritis erosive	1 (0.5%)	0	1 (0.3%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
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Table 302.1.2001.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Gastrointestinal haemorrhage	1 (0.5%)	0	1 (0.3%)
Gingival bleeding	0	1 (0.5%)	1 (0.3%)
Gingival pain	0	1 (0.5%)	1 (0.3%)
Glossitis	1 (0.5%)	0	1 (0.3%)
Hypoaesthesia oral	1 (0.5%)	0	1 (0.3%)
Inguinal hernia	1 (0.5%)	0	1 (0.3%)
Large intestinal obstruction	1 (0.5%)	0	1 (0.3%)
Large intestinal ulcer haemorrhage	1 (0.5%)	0	1 (0.3%)
Leukoplakia oral	0	1 (0.5%)	1 (0.3%)
Lip dry	1 (0.5%)	0	1 (0.3%)
Malignant gastrointestinal obstruction	1 (0.5%)	0	1 (0.3%)
Mouth haemorrhage	0	1 (0.5%)	1 (0.3%)
Odynophagia	1 (0.5%)	0	1 (0.3%)
Oral lichen planus	1 (0.5%)	0	1 (0.3%)
Proctalgia	1 (0.5%)	0	1 (0.3%)
Proctitis	1 (0.5%)	0	1 (0.3%)
Rectal haemorrhage	1 (0.5%)	0	1 (0.3%)
Rectal ulcer haemorrhage	1 (0.5%)	0	1 (0.3%)
Small intestinal perforation	0	1 (0.5%)	1 (0.3%)
Thrombosis mesenteric vessel	1 (0.5%)	0	1 (0.3%)
General disorders and administration site conditions	136 (67.7%)	136 (69.0%)	272 (68.3%)
Fatigue	76 (37.8%)	69 (35.0%)	145 (36.4%)
Asthenia	34 (16.9%)	43 (21.8%)	77 (19.3%)
Pyrexia	36 (17.9%)	35 (17.8%)	71 (17.8%)
Oedema peripheral	31 (15.4%)	26 (13.2%)	57 (14.3%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
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Table 302.1.2001.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Chills	7 (3.5%)	6 (3.0%)	13 (3.3%)
Malaise	6 (3.0%)	6 (3.0%)	12 (3.0%)
Gait disturbance	9 (4.5%)	0	9 (2.3%)
General physical health deterioration	0	8 (4.1%)	8 (2.0%)
Pain	4 (2.0%)	3 (1.5%)	7 (1.8%)
Non-cardiac chest pain	1 (0.5%)	5 (2.5%)	6 (1.5%)
Discomfort	0	3 (1.5%)	3 (0.8%)
Administration site extravasation	1 (0.5%)	1 (0.5%)	2 (0.5%)
Face oedema	0	2 (1.0%)	2 (0.5%)
Infusion site extravasation	2 (1.0%)	0	2 (0.5%)
Infusion site pain	1 (0.5%)	1 (0.5%)	2 (0.5%)
Multiple organ dysfunction syndrome	1 (0.5%)	1 (0.5%)	2 (0.5%)
Peripheral swelling	2 (1.0%)	0	2 (0.5%)
Catheter site granuloma	0	1 (0.5%)	1 (0.3%)
Catheter site pain	0	1 (0.5%)	1 (0.3%)
Chest discomfort	1 (0.5%)	0	1 (0.3%)
Condition aggravated	1 (0.5%)	0	1 (0.3%)
Death	1 (0.5%)	0	1 (0.3%)
Feeling cold	1 (0.5%)	0	1 (0.3%)
Generalised oedema	1 (0.5%)	0	1 (0.3%)
Injection site reaction	1 (0.5%)	0	1 (0.3%)
Performance status decreased	1 (0.5%)	0	1 (0.3%)
Physical deconditioning	0	1 (0.5%)	1 (0.3%)
Sudden death	1 (0.5%)	0	1 (0.3%)
Blood and lymphatic system disorders	88 (43.8%)	170 (86.3%)	258 (64.8%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Anaemia	67 (33.3%)	135 (68.5%)	202 (50.8%)
Neutropenia	22 (10.9%)	95 (48.2%)	117 (29.4%)
Thrombocytopenia	10 (5.0%)	96 (48.7%)	106 (26.6%)
Leukopenia	8 (4.0%)	21 (10.7%)	29 (7.3%)
Febrile neutropenia	1 (0.5%)	10 (5.1%)	11 (2.8%)
Lymphopenia	3 (1.5%)	8 (4.1%)	11 (2.8%)
Leukocytosis	5 (2.5%)	2 (1.0%)	7 (1.8%)
Eosinophilia	6 (3.0%)	0	6 (1.5%)
Thrombocytosis	2 (1.0%)	4 (2.0%)	6 (1.5%)
Pancytopenia	0	4 (2.0%)	4 (1.0%)
Disseminated intravascular coagulation	0	1 (0.5%)	1 (0.3%)
Haematotoxicity	0	1 (0.5%)	1 (0.3%)
Haemolytic anaemia	0	1 (0.5%)	1 (0.3%)
Haemorrhagic diathesis	0	1 (0.5%)	1 (0.3%)
Hyperfibrinogenaemia	0	1 (0.5%)	1 (0.3%)
Immune thrombocytopenia	1 (0.5%)	0	1 (0.3%)
Iron deficiency anaemia	0	1 (0.5%)	1 (0.3%)
Myelosuppression	0	1 (0.5%)	1 (0.3%)
Neutrophilia	0	1 (0.5%)	1 (0.3%)
Thrombocytopenic purpura	0	1 (0.5%)	1 (0.3%)
Skin and subcutaneous tissue disorders	163 (81.1%)	51 (25.9%)	214 (53.8%)
Pruritus	77 (38.3%)	16 (8.1%)	93 (23.4%)
Rash maculo-papular	70 (34.8%)	6 (3.0%)	76 (19.1%)
Alopecia	61 (30.3%)	12 (6.1%)	73 (18.3%)
Dry skin	37 (18.4%)	2 (1.0%)	39 (9.8%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Rash macular	18 (9.0%)	4 (2.0%)	22 (5.5%)
Eczema	17 (8.5%)	2 (1.0%)	19 (4.8%)
Rash papular	13 (6.5%)	2 (1.0%)	15 (3.8%)
Dermatitis	10 (5.0%)	1 (0.5%)	11 (2.8%)
Erythema	6 (3.0%)	2 (1.0%)	8 (2.0%)
Skin hyperpigmentation	7 (3.5%)	0	7 (1.8%)
Urticaria	4 (2.0%)	2 (1.0%)	6 (1.5%)
Palmar-plantar erythrodysaesthesia syndrome	4 (2.0%)	1 (0.5%)	5 (1.3%)
Rash erythematous	3 (1.5%)	2 (1.0%)	5 (1.3%)
Dermatitis acneiform	3 (1.5%)	1 (0.5%)	4 (1.0%)
Dermatitis bullous	3 (1.5%)	1 (0.5%)	4 (1.0%)
Rash	2 (1.0%)	2 (1.0%)	4 (1.0%)
Skin exfoliation	4 (2.0%)	0	4 (1.0%)
Acne	3 (1.5%)	0	3 (0.8%)
Blister	3 (1.5%)	0	3 (0.8%)
Decubitus ulcer	2 (1.0%)	1 (0.5%)	3 (0.8%)
Lichen planus	3 (1.5%)	0	3 (0.8%)
Night sweats	2 (1.0%)	1 (0.5%)	3 (0.8%)
Purpura	2 (1.0%)	1 (0.5%)	3 (0.8%)
Rash pruritic	2 (1.0%)	1 (0.5%)	3 (0.8%)
Skin toxicity	3 (1.5%)	0	3 (0.8%)
Skin ulcer	3 (1.5%)	0	3 (0.8%)
Vitiligo	3 (1.5%)	0	3 (0.8%)
Erythema multiforme	2 (1.0%)	0	2 (0.5%)
Hyperhidrosis	2 (1.0%)	0	2 (0.5%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Madarosis	2 (1.0%)	0	2 (0.5%)
Pemphigoid	2 (1.0%)	0	2 (0.5%)
Rash vesicular	2 (1.0%)	0	2 (0.5%)
Skin hypopigmentation	2 (1.0%)	0	2 (0.5%)
Toxic epidermal necrolysis	2 (1.0%)	0	2 (0.5%)
Acquired porokeratosis	1 (0.5%)	0	1 (0.3%)
Acute generalised exanthematous pustulosis	0	1 (0.5%)	1 (0.3%)
Dermal cyst	1 (0.5%)	0	1 (0.3%)
Dermatitis contact	1 (0.5%)	0	1 (0.3%)
Dermatitis exfoliative	1 (0.5%)	0	1 (0.3%)
Ecchymosis	0	1 (0.5%)	1 (0.3%)
Intertrigo	1 (0.5%)	0	1 (0.3%)
Lentigo	1 (0.5%)	0	1 (0.3%)
Leukoderma	1 (0.5%)	0	1 (0.3%)
Lichenoid keratosis	1 (0.5%)	0	1 (0.3%)
Lipohypertrophy	0	1 (0.5%)	1 (0.3%)
Melanosis	1 (0.5%)	0	1 (0.3%)
Nail ridging	0	1 (0.5%)	1 (0.3%)
Nail toxicity	1 (0.5%)	0	1 (0.3%)
Onychoclasis	0	1 (0.5%)	1 (0.3%)
Onychomadesis	0	1 (0.5%)	1 (0.3%)
Papule	1 (0.5%)	0	1 (0.3%)
Petechiae	0	1 (0.5%)	1 (0.3%)
Pseudocellulitis	0	1 (0.5%)	1 (0.3%)
Rash morbilliform	1 (0.5%)	0	1 (0.3%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Scab	1 (0.5%)	0	1 (0.3%)
Seborrhoeic dermatitis	1 (0.5%)	0	1 (0.3%)
Skin atrophy	1 (0.5%)	0	1 (0.3%)
Skin burning sensation	1 (0.5%)	0	1 (0.3%)
Skin discolouration	1 (0.5%)	0	1 (0.3%)
Skin disorder	1 (0.5%)	0	1 (0.3%)
Skin erosion	1 (0.5%)	0	1 (0.3%)
Skin induration	0	1 (0.5%)	1 (0.3%)
Skin lesion	1 (0.5%)	0	1 (0.3%)
Stasis dermatitis	1 (0.5%)	0	1 (0.3%)
Toxic skin eruption	1 (0.5%)	0	1 (0.3%)
Metabolism and nutrition disorders	122 (60.7%)	86 (43.7%)	208 (52.3%)
Decreased appetite	73 (36.3%)	53 (26.9%)	126 (31.7%)
Hyponatraemia	28 (13.9%)	11 (5.6%)	39 (9.8%)
Hyperglycaemia	28 (13.9%)	5 (2.5%)	33 (8.3%)
Hypophosphataemia	22 (10.9%)	10 (5.1%)	32 (8.0%)
Hypokalaemia	20 (10.0%)	9 (4.6%)	29 (7.3%)
Hyperkalaemia	8 (4.0%)	14 (7.1%)	22 (5.5%)
Hypocalcaemia	9 (4.5%)	11 (5.6%)	20 (5.0%)
Hypoalbuminaemia	11 (5.5%)	6 (3.0%)	17 (4.3%)
Hypomagnesaemia	10 (5.0%)	7 (3.6%)	17 (4.3%)
Dehydration	12 (6.0%)	4 (2.0%)	16 (4.0%)
Hypercalcaemia	7 (3.5%)	4 (2.0%)	11 (2.8%)
Type 2 diabetes mellitus	2 (1.0%)	2 (1.0%)	4 (1.0%)
Diabetes mellitus	3 (1.5%)	0	3 (0.8%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Hypercreatininaemia	3 (1.5%)	0	3 (0.8%)
Hyperuricaemia	1 (0.5%)	2 (1.0%)	3 (0.8%)
Metabolic acidosis	2 (1.0%)	1 (0.5%)	3 (0.8%)
Cachexia	1 (0.5%)	1 (0.5%)	2 (0.5%)
Gout	2 (1.0%)	0	2 (0.5%)
Hyperamylasaemia	2 (1.0%)	0	2 (0.5%)
Hyperlipasaemia	2 (1.0%)	0	2 (0.5%)
Hypoglycaemia	2 (1.0%)	0	2 (0.5%)
Hypozincaemia	2 (1.0%)	0	2 (0.5%)
Malnutrition	0	2 (1.0%)	2 (0.5%)
Polydipsia	1 (0.5%)	1 (0.5%)	2 (0.5%)
Failure to thrive	0	1 (0.5%)	1 (0.3%)
Hypercholesterolaemia	1 (0.5%)	0	1 (0.3%)
Hypermagnesaemia	0	1 (0.5%)	1 (0.3%)
Hypernatraemia	0	1 (0.5%)	1 (0.3%)
Hyperphosphataemia	1 (0.5%)	0	1 (0.3%)
Hypertriglyceridaemia	1 (0.5%)	0	1 (0.3%)
Hypochloraemia	1 (0.5%)	0	1 (0.3%)
Impaired fasting glucose	1 (0.5%)	0	1 (0.3%)
Lactic acidosis	0	1 (0.5%)	1 (0.3%)
Type 1 diabetes mellitus	1 (0.5%)	0	1 (0.3%)
Vitamin D deficiency	0	1 (0.5%)	1 (0.3%)
Investigations	111 (55.2%)	87 (44.2%)	198 (49.7%)
Weight decreased	72 (35.8%)	15 (7.6%)	87 (21.9%)
Blood creatinine increased	27 (13.4%)	23 (11.7%)	50 (12.6%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Alanine aminotransferase increased	27 (13.4%)	20 (10.2%)	47 (11.8%)
Aspartate aminotransferase increased	22 (10.9%)	17 (8.6%)	39 (9.8%)
Platelet count decreased	3 (1.5%)	34 (17.3%)	37 (9.3%)
Neutrophil count decreased	9 (4.5%)	24 (12.2%)	33 (8.3%)
Blood alkaline phosphatase increased	10 (5.0%)	8 (4.1%)	18 (4.5%)
Blood lactate dehydrogenase increased	6 (3.0%)	9 (4.6%)	15 (3.8%)
White blood cell count decreased	4 (2.0%)	11 (5.6%)	15 (3.8%)
Lymphocyte count decreased	8 (4.0%)	3 (1.5%)	11 (2.8%)
Weight increased	6 (3.0%)	2 (1.0%)	8 (2.0%)
Gamma-glutamyltransferase increased	3 (1.5%)	4 (2.0%)	7 (1.8%)
Amylase increased	2 (1.0%)	4 (2.0%)	6 (1.5%)
Lipase increased	3 (1.5%)	2 (1.0%)	5 (1.3%)
Blood bilirubin increased	3 (1.5%)	1 (0.5%)	4 (1.0%)
Blood bicarbonate decreased	3 (1.5%)	0	3 (0.8%)
Blood urea increased	0	3 (1.5%)	3 (0.8%)
Blood thyroid stimulating hormone increased	2 (1.0%)	0	2 (0.5%)
International normalised ratio increased	1 (0.5%)	1 (0.5%)	2 (0.5%)
Apolipoprotein B increased	1 (0.5%)	0	1 (0.3%)
Blood cholesterol increased	1 (0.5%)	0	1 (0.3%)
Blood creatine phosphokinase increased	1 (0.5%)	0	1 (0.3%)
Blood glucose increased	1 (0.5%)	0	1 (0.3%)
Blood lactate dehydrogenase	1 (0.5%)	0	1 (0.3%)
Blood lactic acid increased	1 (0.5%)	0	1 (0.3%)
Blood magnesium decreased	0	1 (0.5%)	1 (0.3%)
Blood phosphorus decreased	0	1 (0.5%)	1 (0.3%)

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Table 302.1.2001.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Blood potassium decreased	1 (0.5%)	0	1 (0.3%)
Blood triglycerides increased	1 (0.5%)	0	1 (0.3%)
C-reactive protein increased	0	1 (0.5%)	1 (0.3%)
Electrocardiogram QT prolonged	1 (0.5%)	0	1 (0.3%)
False positive investigation result	0	1 (0.5%)	1 (0.3%)
Glomerular filtration rate decreased	0	1 (0.5%)	1 (0.3%)
Nitrite urine present	1 (0.5%)	0	1 (0.3%)
Platelet count increased	0	1 (0.5%)	1 (0.3%)
Prothrombin time prolonged	1 (0.5%)	0	1 (0.3%)
Respiratory rate decreased	1 (0.5%)	0	1 (0.3%)
SARS-CoV-2 test positive	1 (0.5%)	0	1 (0.3%)
Waist circumference increased	1 (0.5%)	0	1 (0.3%)
White blood cell count increased	0	1 (0.5%)	1 (0.3%)
Infections and infestations	120 (59.7%)	75 (38.1%)	195 (49.0%)
Urinary tract infection	48 (23.9%)	39 (19.8%)	87 (21.9%)
COVID-19	20 (10.0%)	9 (4.6%)	29 (7.3%)
Pneumonia	15 (7.5%)	3 (1.5%)	18 (4.5%)
Oral candidiasis	9 (4.5%)	2 (1.0%)	11 (2.8%)
Pyelonephritis	5 (2.5%)	6 (3.0%)	11 (2.8%)
Conjunctivitis	9 (4.5%)	0	9 (2.3%)
Respiratory tract infection	4 (2.0%)	4 (2.0%)	8 (2.0%)
Sepsis	6 (3.0%)	2 (1.0%)	8 (2.0%)
Skin infection	4 (2.0%)	2 (1.0%)	6 (1.5%)
Bronchitis	4 (2.0%)	1 (0.5%)	5 (1.3%)
Cellulitis	4 (2.0%)	1 (0.5%)	5 (1.3%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Cystitis	3 (1.5%)	2 (1.0%)	5 (1.3%)
Upper respiratory tract infection	4 (2.0%)	1 (0.5%)	5 (1.3%)
Nasopharyngitis	3 (1.5%)	1 (0.5%)	4 (1.0%)
Pneumonia aspiration	4 (2.0%)	0	4 (1.0%)
Rhinitis	4 (2.0%)	0	4 (1.0%)
Urosepsis	1 (0.5%)	3 (1.5%)	4 (1.0%)
COVID-19 pneumonia	2 (1.0%)	1 (0.5%)	3 (0.8%)
Gastroenteritis	3 (1.5%)	0	3 (0.8%)
Influenza	2 (1.0%)	1 (0.5%)	3 (0.8%)
Pharyngitis	3 (1.5%)	0	3 (0.8%)
Pyelonephritis acute	1 (0.5%)	2 (1.0%)	3 (0.8%)
Septic shock	3 (1.5%)	0	3 (0.8%)
Bacteraemia	0	2 (1.0%)	2 (0.5%)
Bronchitis viral	1 (0.5%)	1 (0.5%)	2 (0.5%)
Clostridium difficile colitis	2 (1.0%)	0	2 (0.5%)
Clostridium difficile infection	2 (1.0%)	0	2 (0.5%)
Cytomegalovirus colitis	2 (1.0%)	0	2 (0.5%)
Device related infection	2 (1.0%)	0	2 (0.5%)
Eye infection	2 (1.0%)	0	2 (0.5%)
Neutropenic sepsis	1 (0.5%)	1 (0.5%)	2 (0.5%)
Peritonitis	0	2 (1.0%)	2 (0.5%)
Rash pustular	2 (1.0%)	0	2 (0.5%)
Skin candida	1 (0.5%)	1 (0.5%)	2 (0.5%)
Tinea pedis	2 (1.0%)	0	2 (0.5%)
Abdominal infection	0	1 (0.5%)	1 (0.3%)

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Table 302.1.2001.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Bronchopulmonary aspergillosis	1 (0.5%)	0	1 (0.3%)
Campylobacter gastroenteritis	1 (0.5%)	0	1 (0.3%)
Campylobacter infection	1 (0.5%)	0	1 (0.3%)
Candida infection	1 (0.5%)	0	1 (0.3%)
Cystitis escherichia	0	1 (0.5%)	1 (0.3%)
Diverticulitis	0	1 (0.5%)	1 (0.3%)
Enterobacter bacteraemia	0	1 (0.5%)	1 (0.3%)
Enterocolitis infectious	1 (0.5%)	0	1 (0.3%)
Folliculitis	0	1 (0.5%)	1 (0.3%)
Fungal foot infection	1 (0.5%)	0	1 (0.3%)
Gastritis viral	1 (0.5%)	0	1 (0.3%)
Gastroenteritis viral	1 (0.5%)	0	1 (0.3%)
Gingivitis	1 (0.5%)	0	1 (0.3%)
Herpes simplex	1 (0.5%)	0	1 (0.3%)
Herpes zoster	1 (0.5%)	0	1 (0.3%)
Infectious pleural effusion	1 (0.5%)	0	1 (0.3%)
Intestinal fistula infection	1 (0.5%)	0	1 (0.3%)
Klebsiella sepsis	0	1 (0.5%)	1 (0.3%)
Mumps	0	1 (0.5%)	1 (0.3%)
Nail infection	1 (0.5%)	0	1 (0.3%)
Oesophageal candidiasis	0	1 (0.5%)	1 (0.3%)
Oral herpes	1 (0.5%)	0	1 (0.3%)
Paronychia	0	1 (0.5%)	1 (0.3%)
Penile infection	1 (0.5%)	0	1 (0.3%)
Peritonsillar abscess	0	1 (0.5%)	1 (0.3%)

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Table 302.1.2001.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Pharyngitis streptococcal	1 (0.5%)	0	1 (0.3%)
Pyuria	1 (0.5%)	0	1 (0.3%)
Respiratory syncytial virus infection	0	1 (0.5%)	1 (0.3%)
Respiratory tract infection bacterial	0	1 (0.5%)	1 (0.3%)
Salmonellosis	1 (0.5%)	0	1 (0.3%)
Sinusitis	1 (0.5%)	0	1 (0.3%)
Stitch abscess	1 (0.5%)	0	1 (0.3%)
Subcutaneous abscess	1 (0.5%)	0	1 (0.3%)
Tonsillitis	0	1 (0.5%)	1 (0.3%)
Urinary tract infection bacterial	1 (0.5%)	0	1 (0.3%)
Viral infection	0	1 (0.5%)	1 (0.3%)
Nervous system disorders	143 (71.1%)	48 (24.4%)	191 (48.0%)
Peripheral sensory neuropathy	103 (51.2%)	10 (5.1%)	113 (28.4%)
Dysgeusia	46 (22.9%)	9 (4.6%)	55 (13.8%)
Dizziness	12 (6.0%)	17 (8.6%)	29 (7.3%)
Headache	14 (7.0%)	10 (5.1%)	24 (6.0%)
Paraesthesia	12 (6.0%)	2 (1.0%)	14 (3.5%)
Peripheral motor neuropathy	10 (5.0%)	0	10 (2.5%)
Peripheral sensorimotor neuropathy	7 (3.5%)	0	7 (1.8%)
Hypoaesthesia	5 (2.5%)	0	5 (1.3%)
Taste disorder	4 (2.0%)	1 (0.5%)	5 (1.3%)
Cerebrovascular accident	2 (1.0%)	1 (0.5%)	3 (0.8%)
Peroneal nerve palsy	3 (1.5%)	0	3 (0.8%)
Somnolence	2 (1.0%)	1 (0.5%)	3 (0.8%)
Syncope	1 (0.5%)	2 (1.0%)	3 (0.8%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Hypogeusia	2 (1.0%)	0	2 (0.5%)
Neuralgia	2 (1.0%)	0	2 (0.5%)
Tremor	1 (0.5%)	1 (0.5%)	2 (0.5%)
Ageusia	1 (0.5%)	0	1 (0.3%)
Anosmia	1 (0.5%)	0	1 (0.3%)
Balance disorder	1 (0.5%)	0	1 (0.3%)
Burning sensation	0	1 (0.5%)	1 (0.3%)
Carotid arteriosclerosis	1 (0.5%)	0	1 (0.3%)
Cognitive disorder	1 (0.5%)	0	1 (0.3%)
Dementia	1 (0.5%)	0	1 (0.3%)
Disturbance in attention	1 (0.5%)	0	1 (0.3%)
Dizziness postural	0	1 (0.5%)	1 (0.3%)
Dysarthria	1 (0.5%)	0	1 (0.3%)
Embolic stroke	0	1 (0.5%)	1 (0.3%)
Hypergeusia	0	1 (0.5%)	1 (0.3%)
Immune-mediated neuropathy	1 (0.5%)	0	1 (0.3%)
Lethargy	0	1 (0.5%)	1 (0.3%)
Migraine	1 (0.5%)	0	1 (0.3%)
Nervous system disorder	1 (0.5%)	0	1 (0.3%)
Neuropathy peripheral	0	1 (0.5%)	1 (0.3%)
Pseudoparalysis	1 (0.5%)	0	1 (0.3%)
Restless legs syndrome	1 (0.5%)	0	1 (0.3%)
Seizure	1 (0.5%)	0	1 (0.3%)
Respiratory, thoracic and mediastinal disorders	82 (40.8%)	61 (31.0%)	143 (35.9%)
Dyspnoea	29 (14.4%)	27 (13.7%)	56 (14.1%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Cough	28 (13.9%)	10 (5.1%)	38 (9.5%)
Pulmonary embolism	9 (4.5%)	9 (4.6%)	18 (4.5%)
Epistaxis	5 (2.5%)	8 (4.1%)	13 (3.3%)
Hiccups	6 (3.0%)	7 (3.6%)	13 (3.3%)
Pneumonitis	12 (6.0%)	0	12 (3.0%)
Dysphonia	9 (4.5%)	0	9 (2.3%)
Pleural effusion	5 (2.5%)	3 (1.5%)	8 (2.0%)
Productive cough	6 (3.0%)	2 (1.0%)	8 (2.0%)
Rhinorrhoea	7 (3.5%)	0	7 (1.8%)
Chronic obstructive pulmonary disease	1 (0.5%)	3 (1.5%)	4 (1.0%)
Dyspnoea exertional	1 (0.5%)	3 (1.5%)	4 (1.0%)
Nasal congestion	4 (2.0%)	0	4 (1.0%)
Oropharyngeal pain	2 (1.0%)	2 (1.0%)	4 (1.0%)
Pneumothorax	2 (1.0%)	2 (1.0%)	4 (1.0%)
Hypoxia	3 (1.5%)	0	3 (0.8%)
Immune-mediated lung disease	3 (1.5%)	0	3 (0.8%)
Wheezing	2 (1.0%)	1 (0.5%)	3 (0.8%)
Acute respiratory failure	2 (1.0%)	0	2 (0.5%)
Haemoptysis	0	2 (1.0%)	2 (0.5%)
Respiratory failure	1 (0.5%)	1 (0.5%)	2 (0.5%)
Tachypnoea	2 (1.0%)	0	2 (0.5%)
Throat irritation	2 (1.0%)	0	2 (0.5%)
Alveolitis	0	1 (0.5%)	1 (0.3%)
Asthma	0	1 (0.5%)	1 (0.3%)
Autoimmune lung disease	1 (0.5%)	0	1 (0.3%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Bronchospasm	0	1 (0.5%)	1 (0.3%)
Catarrh	1 (0.5%)	0	1 (0.3%)
Emphysema	1 (0.5%)	0	1 (0.3%)
Interstitial lung disease	1 (0.5%)	0	1 (0.3%)
Lung opacity	1 (0.5%)	0	1 (0.3%)
Nasal dryness	1 (0.5%)	0	1 (0.3%)
Oropharyngeal discomfort	1 (0.5%)	0	1 (0.3%)
Pharyngeal erythema	1 (0.5%)	0	1 (0.3%)
Rales	0	1 (0.5%)	1 (0.3%)
Respiratory acidosis	0	1 (0.5%)	1 (0.3%)
Respiratory disorder	1 (0.5%)	0	1 (0.3%)
Rhinitis allergic	1 (0.5%)	0	1 (0.3%)
Sinus pain	1 (0.5%)	0	1 (0.3%)
Sneezing	0	1 (0.5%)	1 (0.3%)
Throat clearing	0	1 (0.5%)	1 (0.3%)
Upper-airway cough syndrome	1 (0.5%)	0	1 (0.3%)
Musculoskeletal and connective tissue disorders	78 (38.8%)	53 (26.9%)	131 (32.9%)
Arthralgia	22 (10.9%)	10 (5.1%)	32 (8.0%)
Back pain	16 (8.0%)	13 (6.6%)	29 (7.3%)
Pain in extremity	11 (5.5%)	9 (4.6%)	20 (5.0%)
Muscular weakness	16 (8.0%)	3 (1.5%)	19 (4.8%)
Myalgia	9 (4.5%)	4 (2.0%)	13 (3.3%)
Flank pain	7 (3.5%)	0	7 (1.8%)
Arthritis	3 (1.5%)	3 (1.5%)	6 (1.5%)
Muscle spasms	5 (2.5%)	1 (0.5%)	6 (1.5%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Musculoskeletal chest pain	3 (1.5%)	3 (1.5%)	6 (1.5%)
Groin pain	2 (1.0%)	3 (1.5%)	5 (1.3%)
Bone pain	1 (0.5%)	3 (1.5%)	4 (1.0%)
Musculoskeletal pain	4 (2.0%)	0	4 (1.0%)
Spinal pain	1 (0.5%)	3 (1.5%)	4 (1.0%)
Neck pain	0	3 (1.5%)	3 (0.8%)
Bursitis	2 (1.0%)	0	2 (0.5%)
Immune-mediated arthritis	2 (1.0%)	0	2 (0.5%)
Joint swelling	2 (1.0%)	0	2 (0.5%)
Musculoskeletal discomfort	1 (0.5%)	1 (0.5%)	2 (0.5%)
Osteoarthritis	1 (0.5%)	1 (0.5%)	2 (0.5%)
Pathological fracture	1 (0.5%)	1 (0.5%)	2 (0.5%)
Pubic pain	1 (0.5%)	1 (0.5%)	2 (0.5%)
Intervertebral disc degeneration	0	1 (0.5%)	1 (0.3%)
Joint range of motion decreased	1 (0.5%)	0	1 (0.3%)
Muscle contracture	0	1 (0.5%)	1 (0.3%)
Myositis	1 (0.5%)	0	1 (0.3%)
Osteopenia	1 (0.5%)	0	1 (0.3%)
Osteoporotic fracture	1 (0.5%)	0	1 (0.3%)
Rhabdomyolysis	1 (0.5%)	0	1 (0.3%)
Sacral pain	1 (0.5%)	0	1 (0.3%)
Renal and urinary disorders	69 (34.3%)	49 (24.9%)	118 (29.6%)
Haematuria	27 (13.4%)	19 (9.6%)	46 (11.6%)
Acute kidney injury	16 (8.0%)	8 (4.1%)	24 (6.0%)
Dysuria	8 (4.0%)	5 (2.5%)	13 (3.3%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Proteinuria	5 (2.5%)	4 (2.0%)	9 (2.3%)
Renal impairment	5 (2.5%)	4 (2.0%)	9 (2.3%)
Hydronephrosis	3 (1.5%)	5 (2.5%)	8 (2.0%)
Pollakiuria	5 (2.5%)	2 (1.0%)	7 (1.8%)
Renal failure	4 (2.0%)	2 (1.0%)	6 (1.5%)
Bladder spasm	0	4 (2.0%)	4 (1.0%)
Chronic kidney disease	1 (0.5%)	3 (1.5%)	4 (1.0%)
Urinary tract obstruction	2 (1.0%)	1 (0.5%)	3 (0.8%)
Chromaturia	1 (0.5%)	1 (0.5%)	2 (0.5%)
Immune-mediated nephritis	2 (1.0%)	0	2 (0.5%)
Leukocyturia	1 (0.5%)	1 (0.5%)	2 (0.5%)
Nocturia	2 (1.0%)	0	2 (0.5%)
Urinary retention	0	2 (1.0%)	2 (0.5%)
Urine odour abnormal	2 (1.0%)	0	2 (0.5%)
Azotaemia	1 (0.5%)	0	1 (0.3%)
Bladder irritation	1 (0.5%)	0	1 (0.3%)
Costovertebral angle tenderness	0	1 (0.5%)	1 (0.3%)
Cystitis noninfective	1 (0.5%)	0	1 (0.3%)
Hypertonic bladder	1 (0.5%)	0	1 (0.3%)
Nephroangiosclerosis	1 (0.5%)	0	1 (0.3%)
Nephropathy	0	1 (0.5%)	1 (0.3%)
Polyuria	1 (0.5%)	0	1 (0.3%)
Renal pain	0	1 (0.5%)	1 (0.3%)
Renal tubular necrosis	1 (0.5%)	0	1 (0.3%)
Strangury	0	1 (0.5%)	1 (0.3%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Tubulointerstitial nephritis	1 (0.5%)	0	1 (0.3%)
Ureteric obstruction	1 (0.5%)	0	1 (0.3%)
Urinary incontinence	1 (0.5%)	0	1 (0.3%)
Urine flow decreased	1 (0.5%)	0	1 (0.3%)
Urinoma	0	1 (0.5%)	1 (0.3%)
Urogenital fistula	1 (0.5%)	0	1 (0.3%)
Eye disorders	64 (31.8%)	12 (6.1%)	76 (19.1%)
Dry eye	21 (10.4%)	2 (1.0%)	23 (5.8%)
Cataract	12 (6.0%)	0	12 (3.0%)
Lacrimation increased	11 (5.5%)	1 (0.5%)	12 (3.0%)
Vision blurred	10 (5.0%)	1 (0.5%)	11 (2.8%)
Eye pain	3 (1.5%)	1 (0.5%)	4 (1.0%)
Eye pruritus	3 (1.5%)	0	3 (0.8%)
Blepharitis	2 (1.0%)	0	2 (0.5%)
Conjunctival haemorrhage	2 (1.0%)	0	2 (0.5%)
Conjunctivitis allergic	2 (1.0%)	0	2 (0.5%)
Epiretinal membrane	2 (1.0%)	0	2 (0.5%)
Eye discharge	2 (1.0%)	0	2 (0.5%)
Keratitis	2 (1.0%)	0	2 (0.5%)
Meibomian gland dysfunction	2 (1.0%)	0	2 (0.5%)
Photophobia	1 (0.5%)	1 (0.5%)	2 (0.5%)
Punctate keratitis	2 (1.0%)	0	2 (0.5%)
Visual acuity reduced	1 (0.5%)	1 (0.5%)	2 (0.5%)
Visual impairment	1 (0.5%)	1 (0.5%)	2 (0.5%)
Xerophthalmia	2 (1.0%)	0	2 (0.5%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Angle closure glaucoma	0	1 (0.5%)	1 (0.3%)
Arteriosclerotic retinopathy	1 (0.5%)	0	1 (0.3%)
Conjunctival cyst	1 (0.5%)	0	1 (0.3%)
Conjunctival hyperaemia	1 (0.5%)	0	1 (0.3%)
Corneal degeneration	1 (0.5%)	0	1 (0.3%)
Corneal erosion	1 (0.5%)	0	1 (0.3%)
Dacryostenosis acquired	1 (0.5%)	0	1 (0.3%)
Erythema of eyelid	1 (0.5%)	0	1 (0.3%)
Exfoliation glaucoma	1 (0.5%)	0	1 (0.3%)
Exophthalmos	1 (0.5%)	0	1 (0.3%)
Eye irritation	0	1 (0.5%)	1 (0.3%)
Eye oedema	0	1 (0.5%)	1 (0.3%)
Keratoconus	1 (0.5%)	0	1 (0.3%)
Macular oedema	1 (0.5%)	0	1 (0.3%)
Normal tension glaucoma	1 (0.5%)	0	1 (0.3%)
Ocular discomfort	0	1 (0.5%)	1 (0.3%)
Ocular hyperaemia	1 (0.5%)	0	1 (0.3%)
Periorbital oedema	0	1 (0.5%)	1 (0.3%)
Posterior capsule opacification	1 (0.5%)	0	1 (0.3%)
Presbyopia	1 (0.5%)	0	1 (0.3%)
Scleritis	1 (0.5%)	0	1 (0.3%)
Psychiatric disorders	37 (18.4%)	20 (10.2%)	57 (14.3%)
Insomnia	23 (11.4%)	10 (5.1%)	33 (8.3%)
Anxiety	9 (4.5%)	3 (1.5%)	12 (3.0%)
Depression	6 (3.0%)	2 (1.0%)	8 (2.0%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
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Table 302.1.2001.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Confusional state	3 (1.5%)	3 (1.5%)	6 (1.5%)
Delirium	5 (2.5%)	0	5 (1.3%)
Affect lability	0	2 (1.0%)	2 (0.5%)
Agitation	1 (0.5%)	0	1 (0.3%)
Emotional distress	0	1 (0.5%)	1 (0.3%)
Hallucination	1 (0.5%)	0	1 (0.3%)
Mental status changes	0	1 (0.5%)	1 (0.3%)
Panic attack	1 (0.5%)	0	1 (0.3%)
Vascular disorders	30 (14.9%)	27 (13.7%)	57 (14.3%)
Hypotension	9 (4.5%)	1 (0.5%)	10 (2.5%)
Hypertension	5 (2.5%)	4 (2.0%)	9 (2.3%)
Thrombophlebitis	1 (0.5%)	6 (3.0%)	7 (1.8%)
Deep vein thrombosis	2 (1.0%)	3 (1.5%)	5 (1.3%)
Hot flush	2 (1.0%)	3 (1.5%)	5 (1.3%)
Haematoma	2 (1.0%)	2 (1.0%)	4 (1.0%)
Orthostatic hypotension	2 (1.0%)	1 (0.5%)	3 (0.8%)
Superficial vein thrombosis	1 (0.5%)	2 (1.0%)	3 (0.8%)
Flushing	1 (0.5%)	1 (0.5%)	2 (0.5%)
Lymphoedema	0	2 (1.0%)	2 (0.5%)
Peripheral venous disease	1 (0.5%)	1 (0.5%)	2 (0.5%)
Phlebitis	0	2 (1.0%)	2 (0.5%)
Aortic aneurysm rupture	1 (0.5%)	0	1 (0.3%)
Aortic dilatation	1 (0.5%)	0	1 (0.3%)
Hypertensive crisis	1 (0.5%)	0	1 (0.3%)
Iliac artery occlusion	1 (0.5%)	0	1 (0.3%)

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Table 302.1.2001.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Peripheral coldness	1 (0.5%)	0	1 (0.3%)
Peripheral embolism	1 (0.5%)	0	1 (0.3%)
Post thrombotic syndrome	0	1 (0.5%)	1 (0.3%)
Raynaud's phenomenon	1 (0.5%)	0	1 (0.3%)
Shock	0	1 (0.5%)	1 (0.3%)
Vascular pain	0	1 (0.5%)	1 (0.3%)
Injury, poisoning and procedural complications	27 (13.4%)	22 (11.2%)	49 (12.3%)
Fall	10 (5.0%)	5 (2.5%)	15 (3.8%)
Skin abrasion	6 (3.0%)	1 (0.5%)	7 (1.8%)
Contusion	3 (1.5%)	2 (1.0%)	5 (1.3%)
Infusion related reaction	1 (0.5%)	4 (2.0%)	5 (1.3%)
Femur fracture	2 (1.0%)	1 (0.5%)	3 (0.8%)
Urinary tract stoma complication	0	3 (1.5%)	3 (0.8%)
Radius fracture	2 (1.0%)	0	2 (0.5%)
Skin laceration	2 (1.0%)	0	2 (0.5%)
Tendon rupture	2 (1.0%)	0	2 (0.5%)
Thermal burn	2 (1.0%)	0	2 (0.5%)
Wound dehiscence	0	2 (1.0%)	2 (0.5%)
Wrist fracture	1 (0.5%)	1 (0.5%)	2 (0.5%)
Ankle fracture	1 (0.5%)	0	1 (0.3%)
Corneal abrasion	1 (0.5%)	0	1 (0.3%)
Foot fracture	1 (0.5%)	0	1 (0.3%)
Genital injury	1 (0.5%)	0	1 (0.3%)
Ligament sprain	1 (0.5%)	0	1 (0.3%)
Lumbar vertebral fracture	1 (0.5%)	0	1 (0.3%)

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Table 302.1.2001.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Post procedural haemorrhage	0	1 (0.5%)	1 (0.3%)
Rib fracture	1 (0.5%)	0	1 (0.3%)
Shoulder fracture	1 (0.5%)	0	1 (0.3%)
Stoma site haemorrhage	0	1 (0.5%)	1 (0.3%)
Toxicity to various agents	0	1 (0.5%)	1 (0.3%)
Transfusion reaction	0	1 (0.5%)	1 (0.3%)
Urostomy complication	1 (0.5%)	0	1 (0.3%)
Hepatobiliary disorders	32 (15.9%)	13 (6.6%)	45 (11.3%)
Hypertransaminasaemia	10 (5.0%)	8 (4.1%)	18 (4.5%)
Hepatic function abnormal	3 (1.5%)	3 (1.5%)	6 (1.5%)
Hyperbilirubinaemia	2 (1.0%)	2 (1.0%)	4 (1.0%)
Drug-induced liver injury	1 (0.5%)	2 (1.0%)	3 (0.8%)
Hepatitis	3 (1.5%)	0	3 (0.8%)
Autoimmune hepatitis	2 (1.0%)	0	2 (0.5%)
Hepatotoxicity	2 (1.0%)	0	2 (0.5%)
Immune-mediated hepatitis	2 (1.0%)	0	2 (0.5%)
Biliary colic	1 (0.5%)	0	1 (0.3%)
Biliary dilatation	1 (0.5%)	0	1 (0.3%)
Cholangitis sclerosing	1 (0.5%)	0	1 (0.3%)
Cholecystitis	1 (0.5%)	0	1 (0.3%)
Gallbladder disorder	1 (0.5%)	0	1 (0.3%)
Hepatic pain	1 (0.5%)	0	1 (0.3%)
Hepatic steatosis	1 (0.5%)	0	1 (0.3%)
Immune-mediated hepatic disorder	1 (0.5%)	0	1 (0.3%)
Portal vein thrombosis	1 (0.5%)	0	1 (0.3%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Endocrine disorders	36 (17.9%)	4 (2.0%)	40 (10.1%)
Hypothyroidism	23 (11.4%)	2 (1.0%)	25 (6.3%)
Hyperthyroidism	11 (5.5%)	1 (0.5%)	12 (3.0%)
Adrenal insufficiency	3 (1.5%)	0	3 (0.8%)
Hypophysitis	2 (1.0%)	0	2 (0.5%)
Central hypothyroidism	1 (0.5%)	0	1 (0.3%)
Hypercalcaemia of malignancy	0	1 (0.5%)	1 (0.3%)
Immune-mediated hypothyroidism	1 (0.5%)	0	1 (0.3%)
Thyroiditis	1 (0.5%)	0	1 (0.3%)
Cardiac disorders	17 (8.5%)	13 (6.6%)	30 (7.5%)
Atrial fibrillation	3 (1.5%)	4 (2.0%)	7 (1.8%)
Acute myocardial infarction	2 (1.0%)	2 (1.0%)	4 (1.0%)
Palpitations	2 (1.0%)	2 (1.0%)	4 (1.0%)
Cardiac failure	3 (1.5%)	0	3 (0.8%)
Tachycardia	1 (0.5%)	1 (0.5%)	2 (0.5%)
Ventricular tachycardia	1 (0.5%)	1 (0.5%)	2 (0.5%)
Angina pectoris	0	1 (0.5%)	1 (0.3%)
Aortic valve disease	0	1 (0.5%)	1 (0.3%)
Atrial flutter	0	1 (0.5%)	1 (0.3%)
Atrial thrombosis	1 (0.5%)	0	1 (0.3%)
Bundle branch block right	1 (0.5%)	0	1 (0.3%)
Cardiac arrest	0	1 (0.5%)	1 (0.3%)
Cardiac discomfort	1 (0.5%)	0	1 (0.3%)
Cardiac flutter	0	1 (0.5%)	1 (0.3%)
Cardio-respiratory arrest	1 (0.5%)	0	1 (0.3%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Immune-mediated myocarditis	1 (0.5%)	0	1 (0.3%)
Myocardial infarction	1 (0.5%)	0	1 (0.3%)
Myocardial ischaemia	0	1 (0.5%)	1 (0.3%)
Myocarditis	1 (0.5%)	0	1 (0.3%)
Sinus tachycardia	1 (0.5%)	0	1 (0.3%)
Stress cardiomyopathy	0	1 (0.5%)	1 (0.3%)
Ventricular extrasystoles	1 (0.5%)	0	1 (0.3%)
Reproductive system and breast disorders	9 (4.5%)	7 (3.6%)	16 (4.0%)
Pelvic pain	5 (2.5%)	0	5 (1.3%)
Breast pain	0	1 (0.5%)	1 (0.3%)
Erectile dysfunction	1 (0.5%)	0	1 (0.3%)
Genital burning sensation	0	1 (0.5%)	1 (0.3%)
Genital paraesthesia	1 (0.5%)	0	1 (0.3%)
Ovarian vein thrombosis	0	1 (0.5%)	1 (0.3%)
Penile erythema	0	1 (0.5%)	1 (0.3%)
Prostatitis	0	1 (0.5%)	1 (0.3%)
Testicular pain	0	1 (0.5%)	1 (0.3%)
Vaginal haemorrhage	0	1 (0.5%)	1 (0.3%)
Vaginal prolapse	1 (0.5%)	0	1 (0.3%)
Vulval eczema	1 (0.5%)	0	1 (0.3%)
Vulvovaginal dryness	1 (0.5%)	0	1 (0.3%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	9 (4.5%)	4 (2.0%)	13 (3.3%)
Cancer pain	5 (2.5%)	2 (1.0%)	7 (1.8%)
Tumour pain	0	2 (1.0%)	2 (0.5%)
Chronic lymphocytic leukaemia	1 (0.5%)	0	1 (0.3%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.1.2: Frequency Summary of Treatment Emergent Adverse Events - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Monoclonal gammopathy	1 (0.5%)	0	1 (0.3%)
Neuroma	1 (0.5%)	0	1 (0.3%)
Pancreatic cystadenoma	1 (0.5%)	0	1 (0.3%)
Ear and labyrinth disorders	3 (1.5%)	7 (3.6%)	10 (2.5%)
Tinnitus	1 (0.5%)	2 (1.0%)	3 (0.8%)
Vertigo	0	3 (1.5%)	3 (0.8%)
Hypoacusis	1 (0.5%)	1 (0.5%)	2 (0.5%)
Eustachian tube disorder	0	1 (0.5%)	1 (0.3%)
Otorrhoea	1 (0.5%)	0	1 (0.3%)
Immune system disorders	5 (2.5%)	0	5 (1.3%)
Contrast media allergy	2 (1.0%)	0	2 (0.5%)
Drug hypersensitivity	1 (0.5%)	0	1 (0.3%)
Sarcoidosis	1 (0.5%)	0	1 (0.3%)
Seasonal allergy	1 (0.5%)	0	1 (0.3%)
Product issues	0	1 (0.5%)	1 (0.3%)
Device occlusion	0	1 (0.5%)	1 (0.3%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Overall	239 (100.0%)	233 (98.7%)	472 (99.4%)
Gastrointestinal disorders	178 (74.5%)	181 (76.7%)	359 (75.6%)
Nausea	60 (25.1%)	117 (49.6%)	177 (37.3%)
Constipation	67 (28.0%)	75 (31.8%)	142 (29.9%)
Diarrhoea	88 (36.8%)	40 (16.9%)	128 (26.9%)
Vomiting	22 (9.2%)	39 (16.5%)	61 (12.8%)
Abdominal pain	25 (10.5%)	19 (8.1%)	44 (9.3%)
Stomatitis	27 (11.3%)	16 (6.8%)	43 (9.1%)
Dry mouth	24 (10.0%)	6 (2.5%)	30 (6.3%)
Dyspepsia	13 (5.4%)	11 (4.7%)	24 (5.1%)
Gastrooesophageal reflux disease	12 (5.0%)	9 (3.8%)	21 (4.4%)
Abdominal pain upper	12 (5.0%)	7 (3.0%)	19 (4.0%)
Haemorrhoids	10 (4.2%)	2 (0.8%)	12 (2.5%)
Dysphagia	4 (1.7%)	2 (0.8%)	6 (1.3%)
Gastritis	4 (1.7%)	2 (0.8%)	6 (1.3%)
Abdominal discomfort	3 (1.3%)	2 (0.8%)	5 (1.1%)
Colitis	5 (2.1%)	0	5 (1.1%)
Mouth ulceration	3 (1.3%)	2 (0.8%)	5 (1.1%)
Abdominal pain lower	1 (0.4%)	3 (1.3%)	4 (0.8%)
Ascites	3 (1.3%)	1 (0.4%)	4 (0.8%)
Flatulence	3 (1.3%)	1 (0.4%)	4 (0.8%)
Inguinal hernia	3 (1.3%)	1 (0.4%)	4 (0.8%)
Immune-mediated enterocolitis	3 (1.3%)	0	3 (0.6%)
Oral dysaesthesia	2 (0.8%)	1 (0.4%)	3 (0.6%)
Toothache	2 (0.8%)	1 (0.4%)	3 (0.6%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Abdominal distension	2 (0.8%)	0	2 (0.4%)
Faeces soft	2 (0.8%)	0	2 (0.4%)
Gastric ulcer	1 (0.4%)	1 (0.4%)	2 (0.4%)
Haemorrhoidal haemorrhage	2 (0.8%)	0	2 (0.4%)
Oral pain	1 (0.4%)	1 (0.4%)	2 (0.4%)
Paraesthesia oral	1 (0.4%)	1 (0.4%)	2 (0.4%)
Proctalgia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Rectal haemorrhage	2 (0.8%)	0	2 (0.4%)
Abdominal rigidity	0	1 (0.4%)	1 (0.2%)
Anal erythema	1 (0.4%)	0	1 (0.2%)
Anal pruritus	1 (0.4%)	0	1 (0.2%)
Angular cheilitis	1 (0.4%)	0	1 (0.2%)
Autoimmune pancreatitis	1 (0.4%)	0	1 (0.2%)
Defaecation urgency	1 (0.4%)	0	1 (0.2%)
Dental caries	1 (0.4%)	0	1 (0.2%)
Duodenitis	0	1 (0.4%)	1 (0.2%)
Epigastric discomfort	0	1 (0.4%)	1 (0.2%)
Gingival bleeding	1 (0.4%)	0	1 (0.2%)
Haematochezia	0	1 (0.4%)	1 (0.2%)
Haemorrhagic erosive gastritis	1 (0.4%)	0	1 (0.2%)
Hypoaesthesia oral	1 (0.4%)	0	1 (0.2%)
Ileal ulcer	1 (0.4%)	0	1 (0.2%)
Ileus	1 (0.4%)	0	1 (0.2%)
Lip dry	1 (0.4%)	0	1 (0.2%)
Lip ulceration	1 (0.4%)	0	1 (0.2%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Melaena	0	1 (0.4%)	1 (0.2%)
Odynophagia	1 (0.4%)	0	1 (0.2%)
Oesophageal stenosis	1 (0.4%)	0	1 (0.2%)
Oral blood blister	1 (0.4%)	0	1 (0.2%)
Oral verrucous hyperplasia	1 (0.4%)	0	1 (0.2%)
Pancreatitis chronic	1 (0.4%)	0	1 (0.2%)
Periodontal disease	1 (0.4%)	0	1 (0.2%)
Rectal tenesmus	0	1 (0.4%)	1 (0.2%)
Regurgitation	0	1 (0.4%)	1 (0.2%)
Salivary gland calculus	1 (0.4%)	0	1 (0.2%)
Small intestinal obstruction	1 (0.4%)	0	1 (0.2%)
General disorders and administration site conditions	157 (65.7%)	163 (69.1%)	320 (67.4%)
Fatigue	76 (31.8%)	97 (41.1%)	173 (36.4%)
Asthenia	41 (17.2%)	41 (17.4%)	82 (17.3%)
Pyrexia	41 (17.2%)	32 (13.6%)	73 (15.4%)
Oedema peripheral	29 (12.1%)	21 (8.9%)	50 (10.5%)
Malaise	8 (3.3%)	5 (2.1%)	13 (2.7%)
Chills	7 (2.9%)	2 (0.8%)	9 (1.9%)
Pain	3 (1.3%)	6 (2.5%)	9 (1.9%)
Gait disturbance	8 (3.3%)	0	8 (1.7%)
Non-cardiac chest pain	4 (1.7%)	4 (1.7%)	8 (1.7%)
Infusion site extravasation	5 (2.1%)	0	5 (1.1%)
Peripheral swelling	3 (1.3%)	2 (0.8%)	5 (1.1%)
Chest discomfort	2 (0.8%)	2 (0.8%)	4 (0.8%)
Catheter site pain	2 (0.8%)	0	2 (0.4%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Chest pain	2 (0.8%)	0	2 (0.4%)
General physical health deterioration	1 (0.4%)	1 (0.4%)	2 (0.4%)
Infusion site pain	0	2 (0.8%)	2 (0.4%)
Injection site reaction	0	2 (0.8%)	2 (0.4%)
Temperature intolerance	2 (0.8%)	0	2 (0.4%)
Catheter site erosion	1 (0.4%)	0	1 (0.2%)
Catheter site haematoma	0	1 (0.4%)	1 (0.2%)
Catheter site inflammation	0	1 (0.4%)	1 (0.2%)
Catheter site irritation	1 (0.4%)	0	1 (0.2%)
Catheter site pruritus	1 (0.4%)	0	1 (0.2%)
Catheter site related reaction	1 (0.4%)	0	1 (0.2%)
Catheter site swelling	0	1 (0.4%)	1 (0.2%)
Face oedema	0	1 (0.4%)	1 (0.2%)
Generalised oedema	0	1 (0.4%)	1 (0.2%)
Hyperthermia	1 (0.4%)	0	1 (0.2%)
Impaired healing	0	1 (0.4%)	1 (0.2%)
Influenza like illness	1 (0.4%)	0	1 (0.2%)
Infusion site reaction	0	1 (0.4%)	1 (0.2%)
Localised oedema	1 (0.4%)	0	1 (0.2%)
Oedema	0	1 (0.4%)	1 (0.2%)
Suprapubic pain	0	1 (0.4%)	1 (0.2%)
Swelling face	1 (0.4%)	0	1 (0.2%)
Nervous system disorders	183 (76.6%)	93 (39.4%)	276 (58.1%)
Peripheral sensory neuropathy	127 (53.1%)	34 (14.4%)	161 (33.9%)
Dysgeusia	47 (19.7%)	28 (11.9%)	75 (15.8%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Dizziness	24 (10.0%)	26 (11.0%)	50 (10.5%)
Headache	19 (7.9%)	15 (6.4%)	34 (7.2%)
Paraesthesia	24 (10.0%)	6 (2.5%)	30 (6.3%)
Hypoaesthesia	12 (5.0%)	1 (0.4%)	13 (2.7%)
Taste disorder	10 (4.2%)	2 (0.8%)	12 (2.5%)
Peripheral motor neuropathy	9 (3.8%)	1 (0.4%)	10 (2.1%)
Peripheral sensorimotor neuropathy	9 (3.8%)	1 (0.4%)	10 (2.1%)
Ageusia	8 (3.3%)	0	8 (1.7%)
Lethargy	2 (0.8%)	6 (2.5%)	8 (1.7%)
Anosmia	7 (2.9%)	0	7 (1.5%)
Hypogeusia	3 (1.3%)	3 (1.3%)	6 (1.3%)
Tremor	4 (1.7%)	2 (0.8%)	6 (1.3%)
Balance disorder	4 (1.7%)	1 (0.4%)	5 (1.1%)
Neurotoxicity	5 (2.1%)	0	5 (1.1%)
Syncope	4 (1.7%)	1 (0.4%)	5 (1.1%)
Somnolence	1 (0.4%)	3 (1.3%)	4 (0.8%)
Dysaesthesia	2 (0.8%)	1 (0.4%)	3 (0.6%)
Optic neuritis	2 (0.8%)	0	2 (0.4%)
Altered state of consciousness	1 (0.4%)	0	1 (0.2%)
Amnesia	0	1 (0.4%)	1 (0.2%)
Amputation stump pain	1 (0.4%)	0	1 (0.2%)
Aphasia	1 (0.4%)	0	1 (0.2%)
Brain fog	0	1 (0.4%)	1 (0.2%)
Burning sensation	0	1 (0.4%)	1 (0.2%)
Cerebral infarction	0	1 (0.4%)	1 (0.2%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Disturbance in attention	0	1 (0.4%)	1 (0.2%)
Dizziness postural	1 (0.4%)	0	1 (0.2%)
Dyskinesia	1 (0.4%)	0	1 (0.2%)
Epilepsy	0	1 (0.4%)	1 (0.2%)
Immune-mediated encephalitis	1 (0.4%)	0	1 (0.2%)
Intercostal neuralgia	0	1 (0.4%)	1 (0.2%)
Loss of consciousness	1 (0.4%)	0	1 (0.2%)
Lumbar radiculopathy	1 (0.4%)	0	1 (0.2%)
Memory impairment	0	1 (0.4%)	1 (0.2%)
Metabolic encephalopathy	0	1 (0.4%)	1 (0.2%)
Neuralgia	1 (0.4%)	0	1 (0.2%)
Partial seizures	1 (0.4%)	0	1 (0.2%)
Presyncope	0	1 (0.4%)	1 (0.2%)
Pronator teres syndrome	1 (0.4%)	0	1 (0.2%)
Radiculopathy	0	1 (0.4%)	1 (0.2%)
Seizure	1 (0.4%)	0	1 (0.2%)
Senile dementia	1 (0.4%)	0	1 (0.2%)
Ulnar nerve palsy	1 (0.4%)	0	1 (0.2%)
Skin and subcutaneous tissue disorders	203 (84.9%)	61 (25.8%)	264 (55.6%)
Pruritus	105 (43.9%)	13 (5.5%)	118 (24.8%)
Alopecia	90 (37.7%)	22 (9.3%)	112 (23.6%)
Rash maculo-papular	74 (31.0%)	9 (3.8%)	83 (17.5%)
Dry skin	39 (16.3%)	4 (1.7%)	43 (9.1%)
Rash macular	27 (11.3%)	2 (0.8%)	29 (6.1%)
Rash papular	21 (8.8%)	1 (0.4%)	22 (4.6%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Skin hyperpigmentation	17 (7.1%)	0	17 (3.6%)
Erythema	12 (5.0%)	3 (1.3%)	15 (3.2%)
Eczema	12 (5.0%)	2 (0.8%)	14 (2.9%)
Dermatitis	13 (5.4%)	0	13 (2.7%)
Dermatitis bullous	13 (5.4%)	0	13 (2.7%)
Rash erythematous	11 (4.6%)	2 (0.8%)	13 (2.7%)
Hyperhidrosis	7 (2.9%)	4 (1.7%)	11 (2.3%)
Blister	10 (4.2%)	0	10 (2.1%)
Skin ulcer	9 (3.8%)	1 (0.4%)	10 (2.1%)
Dermatitis acneiform	7 (2.9%)	2 (0.8%)	9 (1.9%)
Rash	8 (3.3%)	1 (0.4%)	9 (1.9%)
Skin exfoliation	8 (3.3%)	0	8 (1.7%)
Night sweats	3 (1.3%)	4 (1.7%)	7 (1.5%)
Rash pruritic	5 (2.1%)	1 (0.4%)	6 (1.3%)
Rash vesicular	5 (2.1%)	0	5 (1.1%)
Erythema multiforme	3 (1.3%)	1 (0.4%)	4 (0.8%)
Skin discolouration	4 (1.7%)	0	4 (0.8%)
Skin hypopigmentation	4 (1.7%)	0	4 (0.8%)
Toxic skin eruption	4 (1.7%)	0	4 (0.8%)
Urticaria	4 (1.7%)	0	4 (0.8%)
Dermal cyst	3 (1.3%)	0	3 (0.6%)
Onycholysis	3 (1.3%)	0	3 (0.6%)
Psoriasis	3 (1.3%)	0	3 (0.6%)
Vitiligo	3 (1.3%)	0	3 (0.6%)
Dermatitis contact	2 (0.8%)	0	2 (0.4%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Dermatitis exfoliative generalised	2 (0.8%)	0	2 (0.4%)
Hyperkeratosis	2 (0.8%)	0	2 (0.4%)
Lichenoid keratosis	2 (0.8%)	0	2 (0.4%)
Nail dystrophy	2 (0.8%)	0	2 (0.4%)
Onychoclasis	2 (0.8%)	0	2 (0.4%)
Onychomadesis	2 (0.8%)	0	2 (0.4%)
Palmar-plantar erythrodysaesthesia syndrome	2 (0.8%)	0	2 (0.4%)
Purpura	2 (0.8%)	0	2 (0.4%)
Skin plaque	2 (0.8%)	0	2 (0.4%)
Toxic erythema of chemotherapy	2 (0.8%)	0	2 (0.4%)
Acne	1 (0.4%)	0	1 (0.2%)
Actinic keratosis	1 (0.4%)	0	1 (0.2%)
Angiolymphoid hyperplasia with eosinophilia	1 (0.4%)	0	1 (0.2%)
Anhidrosis	1 (0.4%)	0	1 (0.2%)
Brow ptosis	0	1 (0.4%)	1 (0.2%)
Cellulite	1 (0.4%)	0	1 (0.2%)
Cutaneous vasculitis	1 (0.4%)	0	1 (0.2%)
Dermatitis psoriasiform	1 (0.4%)	0	1 (0.2%)
Dermatomyositis	1 (0.4%)	0	1 (0.2%)
Drug eruption	1 (0.4%)	0	1 (0.2%)
Dyshidrotic eczema	1 (0.4%)	0	1 (0.2%)
Hair colour changes	0	1 (0.4%)	1 (0.2%)
Hand dermatitis	1 (0.4%)	0	1 (0.2%)
Lentigo	1 (0.4%)	0	1 (0.2%)
Lichen sclerosus	1 (0.4%)	0	1 (0.2%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Madarosis	1 (0.4%)	0	1 (0.2%)
Nail discolouration	1 (0.4%)	0	1 (0.2%)
Nail discomfort	1 (0.4%)	0	1 (0.2%)
Nail toxicity	1 (0.4%)	0	1 (0.2%)
Pain of skin	1 (0.4%)	0	1 (0.2%)
Papule	0	1 (0.4%)	1 (0.2%)
Paradoxical psoriasis	1 (0.4%)	0	1 (0.2%)
Pemphigoid	1 (0.4%)	0	1 (0.2%)
Penile ulceration	1 (0.4%)	0	1 (0.2%)
Petechiae	0	1 (0.4%)	1 (0.2%)
Plantar erythema	1 (0.4%)	0	1 (0.2%)
Seborrhoeic dermatitis	1 (0.4%)	0	1 (0.2%)
Sensitive skin	1 (0.4%)	0	1 (0.2%)
Skin depigmentation	1 (0.4%)	0	1 (0.2%)
Skin fissures	1 (0.4%)	0	1 (0.2%)
Skin fragility	1 (0.4%)	0	1 (0.2%)
Skin haemorrhage	0	1 (0.4%)	1 (0.2%)
Skin irritation	1 (0.4%)	0	1 (0.2%)
Skin toxicity	1 (0.4%)	0	1 (0.2%)
Subcutaneous emphysema	1 (0.4%)	0	1 (0.2%)
Symmetrical drug-related intertriginous and flexural exanthema	1 (0.4%)	0	1 (0.2%)
Toxic epidermal necrolysis	1 (0.4%)	0	1 (0.2%)
Xeroderma	1 (0.4%)	0	1 (0.2%)
Metabolism and nutrition disorders	128 (53.6%)	104 (44.1%)	232 (48.8%)
Decreased appetite	72 (30.1%)	58 (24.6%)	130 (27.4%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Hyperglycaemia	38 (15.9%)	4 (1.7%)	42 (8.8%)
Hypokalaemia	15 (6.3%)	16 (6.8%)	31 (6.5%)
Hypomagnesaemia	8 (3.3%)	19 (8.1%)	27 (5.7%)
Hyponatraemia	10 (4.2%)	16 (6.8%)	26 (5.5%)
Hypophosphataemia	9 (3.8%)	5 (2.1%)	14 (2.9%)
Hyperkalaemia	5 (2.1%)	7 (3.0%)	12 (2.5%)
Dehydration	6 (2.5%)	5 (2.1%)	11 (2.3%)
Hypocalcaemia	7 (2.9%)	4 (1.7%)	11 (2.3%)
Hypercalcaemia	5 (2.1%)	3 (1.3%)	8 (1.7%)
Hyperuricaemia	7 (2.9%)	0	7 (1.5%)
Hypoalbuminaemia	4 (1.7%)	2 (0.8%)	6 (1.3%)
Diabetes mellitus	3 (1.3%)	2 (0.8%)	5 (1.1%)
Hyperphosphataemia	4 (1.7%)	0	4 (0.8%)
Gout	2 (0.8%)	1 (0.4%)	3 (0.6%)
Hyperamylasaemia	2 (0.8%)	1 (0.4%)	3 (0.6%)
Hypercholesterolaemia	3 (1.3%)	0	3 (0.6%)
Hypercreatininaemia	2 (0.8%)	1 (0.4%)	3 (0.6%)
Hyperlipasaemia	2 (0.8%)	1 (0.4%)	3 (0.6%)
Hypoglycaemia	2 (0.8%)	1 (0.4%)	3 (0.6%)
Type 2 diabetes mellitus	3 (1.3%)	0	3 (0.6%)
Glucose tolerance impaired	2 (0.8%)	0	2 (0.4%)
Hyperlipidaemia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Hypochloraemia	0	2 (0.8%)	2 (0.4%)
Metabolic acidosis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Alkalosis	0	1 (0.4%)	1 (0.2%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
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Table 302.1.2001.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Cachexia	1 (0.4%)	0	1 (0.2%)
Dyslipidaemia	1 (0.4%)	0	1 (0.2%)
Electrolyte imbalance	0	1 (0.4%)	1 (0.2%)
Folate deficiency	0	1 (0.4%)	1 (0.2%)
Hypertriglyceridaemia	1 (0.4%)	0	1 (0.2%)
Lactic acidosis	1 (0.4%)	0	1 (0.2%)
Malnutrition	1 (0.4%)	0	1 (0.2%)
Vitamin B12 deficiency	1 (0.4%)	0	1 (0.2%)
Vitamin D deficiency	1 (0.4%)	0	1 (0.2%)
Investigations	128 (53.6%)	102 (43.2%)	230 (48.4%)
Weight decreased	72 (30.1%)	22 (9.3%)	94 (19.8%)
Alanine aminotransferase increased	49 (20.5%)	12 (5.1%)	61 (12.8%)
Aspartate aminotransferase increased	47 (19.7%)	10 (4.2%)	57 (12.0%)
Blood creatinine increased	12 (5.0%)	27 (11.4%)	39 (8.2%)
Platelet count decreased	1 (0.4%)	25 (10.6%)	26 (5.5%)
Neutrophil count decreased	3 (1.3%)	21 (8.9%)	24 (5.1%)
Blood alkaline phosphatase increased	12 (5.0%)	8 (3.4%)	20 (4.2%)
White blood cell count decreased	1 (0.4%)	14 (5.9%)	15 (3.2%)
Weight increased	6 (2.5%)	8 (3.4%)	14 (2.9%)
Lipase increased	13 (5.4%)	0	13 (2.7%)
Amylase increased	6 (2.5%)	2 (0.8%)	8 (1.7%)
Blood lactate dehydrogenase increased	7 (2.9%)	1 (0.4%)	8 (1.7%)
Blood creatine phosphokinase increased	7 (2.9%)	0	7 (1.5%)
Gamma-glutamyltransferase increased	5 (2.1%)	2 (0.8%)	7 (1.5%)
Blood bilirubin increased	5 (2.1%)	1 (0.4%)	6 (1.3%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Lymphocyte count decreased	2 (0.8%)	1 (0.4%)	3 (0.6%)
Neutrophil count increased	2 (0.8%)	1 (0.4%)	3 (0.6%)
Blood bicarbonate decreased	2 (0.8%)	0	2 (0.4%)
Blood glucose increased	2 (0.8%)	0	2 (0.4%)
Blood thyroid stimulating hormone increased	2 (0.8%)	0	2 (0.4%)
C-reactive protein increased	1 (0.4%)	1 (0.4%)	2 (0.4%)
Creatinine renal clearance decreased	0	2 (0.8%)	2 (0.4%)
Apolipoprotein A-I increased	1 (0.4%)	0	1 (0.2%)
Basophil count increased	1 (0.4%)	0	1 (0.2%)
Blood albumin decreased	1 (0.4%)	0	1 (0.2%)
Blood creatine increased	1 (0.4%)	0	1 (0.2%)
Blood potassium increased	0	1 (0.4%)	1 (0.2%)
Blood triglycerides increased	1 (0.4%)	0	1 (0.2%)
Blood urea increased	1 (0.4%)	0	1 (0.2%)
Body temperature increased	1 (0.4%)	0	1 (0.2%)
Electrocardiogram QT prolonged	1 (0.4%)	0	1 (0.2%)
Glomerular filtration rate decreased	0	1 (0.4%)	1 (0.2%)
Glycosylated haemoglobin increased	1 (0.4%)	0	1 (0.2%)
International normalised ratio increased	1 (0.4%)	0	1 (0.2%)
Lymph node palpable	0	1 (0.4%)	1 (0.2%)
Nitrite urine present	1 (0.4%)	0	1 (0.2%)
Oxygen saturation decreased	1 (0.4%)	0	1 (0.2%)
SARS-CoV-2 test positive	1 (0.4%)	0	1 (0.2%)
Thyroxine increased	1 (0.4%)	0	1 (0.2%)
Troponin I increased	1 (0.4%)	0	1 (0.2%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
White blood cell count increased	1 (0.4%)	0	1 (0.2%)
Blood and lymphatic system disorders	62 (25.9%)	157 (66.5%)	219 (46.1%)
Anaemia	39 (16.3%)	123 (52.1%)	162 (34.1%)
Neutropenia	16 (6.7%)	69 (29.2%)	85 (17.9%)
Thrombocytopenia	8 (3.3%)	48 (20.3%)	56 (11.8%)
Leukopenia	8 (3.3%)	23 (9.7%)	31 (6.5%)
Lymphopenia	2 (0.8%)	5 (2.1%)	7 (1.5%)
Leukocytosis	4 (1.7%)	1 (0.4%)	5 (1.1%)
Thrombocytosis	2 (0.8%)	2 (0.8%)	4 (0.8%)
Pancytopenia	0	3 (1.3%)	3 (0.6%)
Eosinophilia	2 (0.8%)	0	2 (0.4%)
Anaemia of malignant disease	1 (0.4%)	0	1 (0.2%)
Haemolytic anaemia	1 (0.4%)	0	1 (0.2%)
Lymphadenitis	0	1 (0.4%)	1 (0.2%)
Lymphadenopathy	0	1 (0.4%)	1 (0.2%)
Neutrophilia	0	1 (0.4%)	1 (0.2%)
Platelet toxicity	0	1 (0.4%)	1 (0.2%)
Splenomegaly	1 (0.4%)	0	1 (0.2%)
Infections and infestations	139 (58.2%)	67 (28.4%)	206 (43.4%)
Urinary tract infection	37 (15.5%)	34 (14.4%)	71 (14.9%)
COVID-19	43 (18.0%)	10 (4.2%)	53 (11.2%)
Conjunctivitis	18 (7.5%)	0	18 (3.8%)
Pneumonia	11 (4.6%)	3 (1.3%)	14 (2.9%)
Oral candidiasis	9 (3.8%)	4 (1.7%)	13 (2.7%)
Upper respiratory tract infection	11 (4.6%)	1 (0.4%)	12 (2.5%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Cellulitis	7 (2.9%)	1 (0.4%)	8 (1.7%)
Folliculitis	5 (2.1%)	1 (0.4%)	6 (1.3%)
Bronchitis	5 (2.1%)	0	5 (1.1%)
Cystitis	2 (0.8%)	3 (1.3%)	5 (1.1%)
Nasopharyngitis	4 (1.7%)	1 (0.4%)	5 (1.1%)
Rhinitis	5 (2.1%)	0	5 (1.1%)
Skin infection	4 (1.7%)	1 (0.4%)	5 (1.1%)
Fungal skin infection	3 (1.3%)	1 (0.4%)	4 (0.8%)
Herpes zoster	4 (1.7%)	0	4 (0.8%)
Respiratory tract infection	3 (1.3%)	1 (0.4%)	4 (0.8%)
Bacteriuria	1 (0.4%)	2 (0.8%)	3 (0.6%)
Gingivitis	2 (0.8%)	1 (0.4%)	3 (0.6%)
Lower respiratory tract infection	2 (0.8%)	1 (0.4%)	3 (0.6%)
Pharyngitis	2 (0.8%)	1 (0.4%)	3 (0.6%)
Rash pustular	2 (0.8%)	1 (0.4%)	3 (0.6%)
Wound infection	1 (0.4%)	2 (0.8%)	3 (0.6%)
Bacteraemia	2 (0.8%)	0	2 (0.4%)
COVID-19 pneumonia	2 (0.8%)	0	2 (0.4%)
Influenza	2 (0.8%)	0	2 (0.4%)
Oral herpes	1 (0.4%)	1 (0.4%)	2 (0.4%)
Pneumonia bacterial	2 (0.8%)	0	2 (0.4%)
Pyelonephritis chronic	0	2 (0.8%)	2 (0.4%)
Pyuria	1 (0.4%)	1 (0.4%)	2 (0.4%)
Sinusitis	2 (0.8%)	0	2 (0.4%)
Tinea cruris	1 (0.4%)	1 (0.4%)	2 (0.4%)

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Table 302.1.2001.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Abdominal sepsis	1 (0.4%)	0	1 (0.2%)
Body tinea	1 (0.4%)	0	1 (0.2%)
Candida infection	1 (0.4%)	0	1 (0.2%)
Catheter site infection	1 (0.4%)	0	1 (0.2%)
Clostridium difficile infection	1 (0.4%)	0	1 (0.2%)
Device related infection	0	1 (0.4%)	1 (0.2%)
Diverticulitis	1 (0.4%)	0	1 (0.2%)
Ear infection	1 (0.4%)	0	1 (0.2%)
Epididymitis	0	1 (0.4%)	1 (0.2%)
Erysipelas	1 (0.4%)	0	1 (0.2%)
Escherichia infection	0	1 (0.4%)	1 (0.2%)
Eyelid infection	1 (0.4%)	0	1 (0.2%)
Fungal foot infection	1 (0.4%)	0	1 (0.2%)
Furuncle	0	1 (0.4%)	1 (0.2%)
Gastroenteritis viral	1 (0.4%)	0	1 (0.2%)
Groin abscess	0	1 (0.4%)	1 (0.2%)
Herpes dermatitis	1 (0.4%)	0	1 (0.2%)
Hordeolum	0	1 (0.4%)	1 (0.2%)
Injection site infection	0	1 (0.4%)	1 (0.2%)
Klebsiella urinary tract infection	1 (0.4%)	0	1 (0.2%)
Laryngopharyngitis	1 (0.4%)	0	1 (0.2%)
Lip infection	1 (0.4%)	0	1 (0.2%)
Localised infection	1 (0.4%)	0	1 (0.2%)
Lung abscess	1 (0.4%)	0	1 (0.2%)
Oesophageal candidiasis	1 (0.4%)	0	1 (0.2%)

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Table 302.1.2001.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Onychomycosis	1 (0.4%)	0	1 (0.2%)
Oral fungal infection	1 (0.4%)	0	1 (0.2%)
Penile infection	1 (0.4%)	0	1 (0.2%)
Periodontitis	1 (0.4%)	0	1 (0.2%)
Pharyngitis streptococcal	1 (0.4%)	0	1 (0.2%)
Pneumocystis jirovecii pneumonia	1 (0.4%)	0	1 (0.2%)
Postoperative wound infection	1 (0.4%)	0	1 (0.2%)
Pyelonephritis	1 (0.4%)	0	1 (0.2%)
Skin bacterial infection	1 (0.4%)	0	1 (0.2%)
Skin candida	0	1 (0.4%)	1 (0.2%)
Soft tissue infection	0	1 (0.4%)	1 (0.2%)
Staphylococcal bacteraemia	1 (0.4%)	0	1 (0.2%)
Subcutaneous abscess	1 (0.4%)	0	1 (0.2%)
Tinea pedis	1 (0.4%)	0	1 (0.2%)
Tonsillitis	0	1 (0.4%)	1 (0.2%)
Tooth abscess	1 (0.4%)	0	1 (0.2%)
Urinary tract infection enterococcal	0	1 (0.4%)	1 (0.2%)
Urinary tract infection staphylococcal	1 (0.4%)	0	1 (0.2%)
Urosepsis	1 (0.4%)	0	1 (0.2%)
Viral infection	0	1 (0.4%)	1 (0.2%)
Viral upper respiratory tract infection	0	1 (0.4%)	1 (0.2%)
Vulvitis	0	1 (0.4%)	1 (0.2%)
Respiratory, thoracic and mediastinal disorders	96 (40.2%)	77 (32.6%)	173 (36.4%)
Dyspnoea	29 (12.1%)	23 (9.7%)	52 (10.9%)
Cough	26 (10.9%)	12 (5.1%)	38 (8.0%)

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Table 302.1.2001.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Hiccups	7 (2.9%)	22 (9.3%)	29 (6.1%)
Epistaxis	6 (2.5%)	19 (8.1%)	25 (5.3%)
Dysphonia	13 (5.4%)	4 (1.7%)	17 (3.6%)
Pneumonitis	16 (6.7%)	0	16 (3.4%)
Rhinorrhoea	8 (3.3%)	6 (2.5%)	14 (2.9%)
Nasal congestion	9 (3.8%)	1 (0.4%)	10 (2.1%)
Pulmonary embolism	3 (1.3%)	7 (3.0%)	10 (2.1%)
Oropharyngeal pain	5 (2.1%)	4 (1.7%)	9 (1.9%)
Productive cough	3 (1.3%)	4 (1.7%)	7 (1.5%)
Dyspnoea exertional	3 (1.3%)	2 (0.8%)	5 (1.1%)
Aphonia	2 (0.8%)	1 (0.4%)	3 (0.6%)
Interstitial lung disease	3 (1.3%)	0	3 (0.6%)
Upper-airway cough syndrome	3 (1.3%)	0	3 (0.6%)
Chronic obstructive pulmonary disease	1 (0.4%)	1 (0.4%)	2 (0.4%)
Immune-mediated lung disease	2 (0.8%)	0	2 (0.4%)
Nasal dryness	2 (0.8%)	0	2 (0.4%)
Painful respiration	1 (0.4%)	1 (0.4%)	2 (0.4%)
Pleural effusion	1 (0.4%)	1 (0.4%)	2 (0.4%)
Pneumothorax	2 (0.8%)	0	2 (0.4%)
Rhinitis allergic	2 (0.8%)	0	2 (0.4%)
Catarrh	0	1 (0.4%)	1 (0.2%)
Dry throat	1 (0.4%)	0	1 (0.2%)
Haemoptysis	0	1 (0.4%)	1 (0.2%)
Hypoxia	1 (0.4%)	0	1 (0.2%)
Laryngeal haemorrhage	0	1 (0.4%)	1 (0.2%)

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Table 302.1.2001.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Laryngeal inflammation	0	1 (0.4%)	1 (0.2%)
Lung disorder	1 (0.4%)	0	1 (0.2%)
Nasal polyps	1 (0.4%)	0	1 (0.2%)
Nocturnal dyspnoea	1 (0.4%)	0	1 (0.2%)
Organising pneumonia	1 (0.4%)	0	1 (0.2%)
Orthopnoea	1 (0.4%)	0	1 (0.2%)
Pharyngeal dyskinesia	1 (0.4%)	0	1 (0.2%)
Pharyngeal inflammation	1 (0.4%)	0	1 (0.2%)
Pleuritic pain	1 (0.4%)	0	1 (0.2%)
Pulmonary fibrosis	1 (0.4%)	0	1 (0.2%)
Pulmonary pain	0	1 (0.4%)	1 (0.2%)
Pulmonary toxicity	1 (0.4%)	0	1 (0.2%)
Sinus congestion	1 (0.4%)	0	1 (0.2%)
Musculoskeletal and connective tissue disorders	106 (44.4%)	63 (26.7%)	169 (35.6%)
Back pain	36 (15.1%)	21 (8.9%)	57 (12.0%)
Arthralgia	36 (15.1%)	11 (4.7%)	47 (9.9%)
Pain in extremity	20 (8.4%)	14 (5.9%)	34 (7.2%)
Myalgia	17 (7.1%)	6 (2.5%)	23 (4.8%)
Muscular weakness	11 (4.6%)	4 (1.7%)	15 (3.2%)
Flank pain	7 (2.9%)	7 (3.0%)	14 (2.9%)
Bone pain	4 (1.7%)	6 (2.5%)	10 (2.1%)
Muscle spasms	9 (3.8%)	1 (0.4%)	10 (2.1%)
Musculoskeletal chest pain	5 (2.1%)	1 (0.4%)	6 (1.3%)
Musculoskeletal discomfort	3 (1.3%)	3 (1.3%)	6 (1.3%)
Neck pain	4 (1.7%)	2 (0.8%)	6 (1.3%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Arthritis	4 (1.7%)	1 (0.4%)	5 (1.1%)
Gouty arthritis	3 (1.3%)	0	3 (0.6%)
Limb discomfort	2 (0.8%)	1 (0.4%)	3 (0.6%)
Musculoskeletal pain	3 (1.3%)	0	3 (0.6%)
Musculoskeletal stiffness	2 (0.8%)	1 (0.4%)	3 (0.6%)
Joint stiffness	1 (0.4%)	1 (0.4%)	2 (0.4%)
Osteopenia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Pain in jaw	0	2 (0.8%)	2 (0.4%)
Tendon pain	0	2 (0.8%)	2 (0.4%)
Arthropathy	1 (0.4%)	0	1 (0.2%)
Bone lesion	1 (0.4%)	0	1 (0.2%)
Groin pain	0	1 (0.4%)	1 (0.2%)
Hypercreatinaemia	0	1 (0.4%)	1 (0.2%)
Joint range of motion decreased	1 (0.4%)	0	1 (0.2%)
Myositis	1 (0.4%)	0	1 (0.2%)
Osteoarthritis	1 (0.4%)	0	1 (0.2%)
Osteoporosis	1 (0.4%)	0	1 (0.2%)
Sjogren's syndrome	1 (0.4%)	0	1 (0.2%)
Renal and urinary disorders	66 (27.6%)	72 (30.5%)	138 (29.1%)
Haematuria	29 (12.1%)	17 (7.2%)	46 (9.7%)
Acute kidney injury	5 (2.1%)	21 (8.9%)	26 (5.5%)
Dysuria	13 (5.4%)	8 (3.4%)	21 (4.4%)
Pollakiuria	8 (3.3%)	6 (2.5%)	14 (2.9%)
Urinary retention	6 (2.5%)	7 (3.0%)	13 (2.7%)
Renal failure	2 (0.8%)	5 (2.1%)	7 (1.5%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Renal impairment	3 (1.3%)	4 (1.7%)	7 (1.5%)
Leukocyturia	3 (1.3%)	2 (0.8%)	5 (1.1%)
Nocturia	1 (0.4%)	4 (1.7%)	5 (1.1%)
Urinary tract pain	2 (0.8%)	3 (1.3%)	5 (1.1%)
Chromaturia	4 (1.7%)	0	4 (0.8%)
Chronic kidney disease	1 (0.4%)	3 (1.3%)	4 (0.8%)
Bladder spasm	3 (1.3%)	0	3 (0.6%)
Hydronephrosis	2 (0.8%)	1 (0.4%)	3 (0.6%)
Proteinuria	2 (0.8%)	1 (0.4%)	3 (0.6%)
Bladder pain	2 (0.8%)	0	2 (0.4%)
Micturition urgency	1 (0.4%)	1 (0.4%)	2 (0.4%)
Polyuria	1 (0.4%)	1 (0.4%)	2 (0.4%)
Urinary incontinence	2 (0.8%)	0	2 (0.4%)
Calculus bladder	1 (0.4%)	0	1 (0.2%)
Calculus urinary	1 (0.4%)	0	1 (0.2%)
Cystitis noninfective	0	1 (0.4%)	1 (0.2%)
Nephropathy	0	1 (0.4%)	1 (0.2%)
Oliguria	1 (0.4%)	0	1 (0.2%)
Prerenal failure	0	1 (0.4%)	1 (0.2%)
Renal colic	0	1 (0.4%)	1 (0.2%)
Renal pain	0	1 (0.4%)	1 (0.2%)
Stress urinary incontinence	1 (0.4%)	0	1 (0.2%)
Urethral stenosis	1 (0.4%)	0	1 (0.2%)
Urinary hesitation	0	1 (0.4%)	1 (0.2%)
Urine abnormality	0	1 (0.4%)	1 (0.2%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Urine odour abnormal	1 (0.4%)	0	1 (0.2%)
Eye disorders	87 (36.4%)	14 (5.9%)	101 (21.3%)
Dry eye	29 (12.1%)	3 (1.3%)	32 (6.7%)
Lacrimation increased	25 (10.5%)	1 (0.4%)	26 (5.5%)
Vision blurred	16 (6.7%)	4 (1.7%)	20 (4.2%)
Cataract	8 (3.3%)	1 (0.4%)	9 (1.9%)
Blepharitis	6 (2.5%)	0	6 (1.3%)
Eye irritation	5 (2.1%)	0	5 (1.1%)
Keratitis	4 (1.7%)	0	4 (0.8%)
Visual acuity reduced	4 (1.7%)	0	4 (0.8%)
Vitreous floaters	2 (0.8%)	2 (0.8%)	4 (0.8%)
Xerophthalmia	4 (1.7%)	0	4 (0.8%)
Eye pruritus	3 (1.3%)	0	3 (0.6%)
Conjunctivitis allergic	2 (0.8%)	0	2 (0.4%)
Eye discharge	2 (0.8%)	0	2 (0.4%)
Eye pain	2 (0.8%)	0	2 (0.4%)
Eyelids pruritus	1 (0.4%)	1 (0.4%)	2 (0.4%)
Photopsia	0	2 (0.8%)	2 (0.4%)
Visual impairment	2 (0.8%)	0	2 (0.4%)
Asthenopia	1 (0.4%)	0	1 (0.2%)
Conjunctival haemorrhage	0	1 (0.4%)	1 (0.2%)
Conjunctival irritation	1 (0.4%)	0	1 (0.2%)
Corneal erosion	1 (0.4%)	0	1 (0.2%)
Corneal toxicity	1 (0.4%)	0	1 (0.2%)
Diplopia	1 (0.4%)	0	1 (0.2%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Eczema eyelids	1 (0.4%)	0	1 (0.2%)
Entropion	1 (0.4%)	0	1 (0.2%)
Exposure keratitis	1 (0.4%)	0	1 (0.2%)
Meibomianitis	1 (0.4%)	0	1 (0.2%)
Myopia	1 (0.4%)	0	1 (0.2%)
Ocular hyperaemia	1 (0.4%)	0	1 (0.2%)
Periorbital oedema	0	1 (0.4%)	1 (0.2%)
Photophobia	1 (0.4%)	0	1 (0.2%)
Pinguecula	1 (0.4%)	0	1 (0.2%)
Retinal degeneration	1 (0.4%)	0	1 (0.2%)
Retinal detachment	1 (0.4%)	0	1 (0.2%)
Retinal tear	1 (0.4%)	0	1 (0.2%)
Uveitis	1 (0.4%)	0	1 (0.2%)
Vitreous haemorrhage	1 (0.4%)	0	1 (0.2%)
Vascular disorders	31 (13.0%)	44 (18.6%)	75 (15.8%)
Hypertension	9 (3.8%)	13 (5.5%)	22 (4.6%)
Hypotension	5 (2.1%)	6 (2.5%)	11 (2.3%)
Deep vein thrombosis	2 (0.8%)	8 (3.4%)	10 (2.1%)
Hot flush	5 (2.1%)	0	5 (1.1%)
Phlebitis	0	5 (2.1%)	5 (1.1%)
Superficial vein thrombosis	0	5 (2.1%)	5 (1.1%)
Thrombophlebitis	1 (0.4%)	4 (1.7%)	5 (1.1%)
Flushing	2 (0.8%)	1 (0.4%)	3 (0.6%)
Orthostatic hypotension	2 (0.8%)	1 (0.4%)	3 (0.6%)
Peripheral embolism	0	3 (1.3%)	3 (0.6%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Lymphoedema	1 (0.4%)	1 (0.4%)	2 (0.4%)
Capillary fragility	1 (0.4%)	0	1 (0.2%)
Intermittent claudication	1 (0.4%)	0	1 (0.2%)
Lymphocele	0	1 (0.4%)	1 (0.2%)
Pallor	1 (0.4%)	0	1 (0.2%)
Pelvic venous thrombosis	1 (0.4%)	0	1 (0.2%)
Peripheral arterial occlusive disease	1 (0.4%)	0	1 (0.2%)
Phlebosclerosis	0	1 (0.4%)	1 (0.2%)
Vascular pain	1 (0.4%)	0	1 (0.2%)
Venous thrombosis	0	1 (0.4%)	1 (0.2%)
Psychiatric disorders	38 (15.9%)	24 (10.2%)	62 (13.1%)
Insomnia	22 (9.2%)	14 (5.9%)	36 (7.6%)
Anxiety	10 (4.2%)	3 (1.3%)	13 (2.7%)
Depression	5 (2.1%)	5 (2.1%)	10 (2.1%)
Delirium	4 (1.7%)	0	4 (0.8%)
Confusional state	2 (0.8%)	0	2 (0.4%)
Disorientation	1 (0.4%)	1 (0.4%)	2 (0.4%)
Affective disorder	1 (0.4%)	0	1 (0.2%)
Agitation	1 (0.4%)	0	1 (0.2%)
Depressed mood	0	1 (0.4%)	1 (0.2%)
Dysphemia	0	1 (0.4%)	1 (0.2%)
Emotional distress	0	1 (0.4%)	1 (0.2%)
Hallucination, auditory	1 (0.4%)	0	1 (0.2%)
Initial insomnia	1 (0.4%)	0	1 (0.2%)
Mixed anxiety and depressive disorder	1 (0.4%)	0	1 (0.2%)

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Table 302.1.2001.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Sleep disorder	1 (0.4%)	0	1 (0.2%)
Suicidal ideation	1 (0.4%)	0	1 (0.2%)
Ear and labyrinth disorders	16 (6.7%)	33 (14.0%)	49 (10.3%)
Tinnitus	5 (2.1%)	27 (11.4%)	32 (6.7%)
Hypoacusis	2 (0.8%)	3 (1.3%)	5 (1.1%)
Vertigo	4 (1.7%)	0	4 (0.8%)
Ear discomfort	1 (0.4%)	1 (0.4%)	2 (0.4%)
Ear pain	2 (0.8%)	0	2 (0.4%)
Ototoxicity	0	2 (0.8%)	2 (0.4%)
Presbyacusis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Deafness	0	1 (0.4%)	1 (0.2%)
Vestibular disorder	1 (0.4%)	0	1 (0.2%)
Injury, poisoning and procedural complications	30 (12.6%)	13 (5.5%)	43 (9.1%)
Fall	11 (4.6%)	3 (1.3%)	14 (2.9%)
Contusion	3 (1.3%)	1 (0.4%)	4 (0.8%)
Infusion related reaction	2 (0.8%)	2 (0.8%)	4 (0.8%)
Skin laceration	3 (1.3%)	1 (0.4%)	4 (0.8%)
Skin abrasion	2 (0.8%)	1 (0.4%)	3 (0.6%)
Urinary tract stoma complication	2 (0.8%)	1 (0.4%)	3 (0.6%)
Thermal burn	1 (0.4%)	1 (0.4%)	2 (0.4%)
Eschar	1 (0.4%)	0	1 (0.2%)
Eye contusion	1 (0.4%)	0	1 (0.2%)
Fibula fracture	1 (0.4%)	0	1 (0.2%)
Foot fracture	1 (0.4%)	0	1 (0.2%)
Ligament sprain	0	1 (0.4%)	1 (0.2%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Limb traumatic amputation	1 (0.4%)	0	1 (0.2%)
Muscle rupture	0	1 (0.4%)	1 (0.2%)
Overdose	1 (0.4%)	0	1 (0.2%)
Penis injury	1 (0.4%)	0	1 (0.2%)
Post vaccination fever	1 (0.4%)	0	1 (0.2%)
Procedural pain	1 (0.4%)	0	1 (0.2%)
Sternal fracture	0	1 (0.4%)	1 (0.2%)
Stoma site pain	0	1 (0.4%)	1 (0.2%)
Subcutaneous haematoma	0	1 (0.4%)	1 (0.2%)
Urinary tract procedural complication	1 (0.4%)	0	1 (0.2%)
Urostomy complication	0	1 (0.4%)	1 (0.2%)
Wound dehiscence	1 (0.4%)	0	1 (0.2%)
Endocrine disorders	35 (14.6%)	2 (0.8%)	37 (7.8%)
Hypothyroidism	23 (9.6%)	1 (0.4%)	24 (5.1%)
Hyperthyroidism	9 (3.8%)	1 (0.4%)	10 (2.1%)
Adrenal insufficiency	4 (1.7%)	0	4 (0.8%)
Autoimmune thyroiditis	1 (0.4%)	0	1 (0.2%)
Hyperparathyroidism	1 (0.4%)	0	1 (0.2%)
Hypophysitis	1 (0.4%)	0	1 (0.2%)
Inappropriate antidiuretic hormone secretion	1 (0.4%)	0	1 (0.2%)
Thyroiditis	1 (0.4%)	0	1 (0.2%)
Hepatobiliary disorders	29 (12.1%)	7 (3.0%)	36 (7.6%)
Hypertransaminasaemia	10 (4.2%)	5 (2.1%)	15 (3.2%)
Hepatic function abnormal	6 (2.5%)	1 (0.4%)	7 (1.5%)
Hepatotoxicity	3 (1.3%)	0	3 (0.6%)

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Table 302.1.2001.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Autoimmune hepatitis	2 (0.8%)	0	2 (0.4%)
Hepatic cytolysis	2 (0.8%)	0	2 (0.4%)
Hepatitis	2 (0.8%)	0	2 (0.4%)
Cholecystitis	1 (0.4%)	0	1 (0.2%)
Cholelithiasis	1 (0.4%)	0	1 (0.2%)
Hepatic cirrhosis	1 (0.4%)	0	1 (0.2%)
Hepatic pain	0	1 (0.4%)	1 (0.2%)
Hepatic steatosis	1 (0.4%)	0	1 (0.2%)
Hyperbilirubinaemia	1 (0.4%)	0	1 (0.2%)
Immune-mediated hepatitis	1 (0.4%)	0	1 (0.2%)
Cardiac disorders	17 (7.1%)	14 (5.9%)	31 (6.5%)
Sinus tachycardia	3 (1.3%)	3 (1.3%)	6 (1.3%)
Tachycardia	3 (1.3%)	3 (1.3%)	6 (1.3%)
Palpitations	3 (1.3%)	2 (0.8%)	5 (1.1%)
Atrial fibrillation	1 (0.4%)	3 (1.3%)	4 (0.8%)
Angina pectoris	1 (0.4%)	2 (0.8%)	3 (0.6%)
Bradycardia	2 (0.8%)	0	2 (0.4%)
Acute myocardial infarction	0	1 (0.4%)	1 (0.2%)
Arrhythmia	0	1 (0.4%)	1 (0.2%)
Bundle branch block left	1 (0.4%)	0	1 (0.2%)
Bundle branch block right	1 (0.4%)	0	1 (0.2%)
Cardiomyopathy	1 (0.4%)	0	1 (0.2%)
Diastolic dysfunction	1 (0.4%)	0	1 (0.2%)
Myocarditis	1 (0.4%)	0	1 (0.2%)
Pericardial effusion	1 (0.4%)	0	1 (0.2%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Supraventricular tachycardia	1 (0.4%)	0	1 (0.2%)
Reproductive system and breast disorders	19 (7.9%)	6 (2.5%)	25 (5.3%)
Pelvic pain	4 (1.7%)	3 (1.3%)	7 (1.5%)
Penile pain	2 (0.8%)	2 (0.8%)	4 (0.8%)
Balanoposthitis	2 (0.8%)	0	2 (0.4%)
Penile erythema	2 (0.8%)	0	2 (0.4%)
Vaginal discharge	2 (0.8%)	0	2 (0.4%)
Vaginal haemorrhage	1 (0.4%)	1 (0.4%)	2 (0.4%)
Atrophic vulvovaginitis	1 (0.4%)	0	1 (0.2%)
Nipple pain	1 (0.4%)	0	1 (0.2%)
Oedema genital	1 (0.4%)	0	1 (0.2%)
Prostatic obstruction	1 (0.4%)	0	1 (0.2%)
Pruritus genital	1 (0.4%)	0	1 (0.2%)
Scrotal pain	1 (0.4%)	0	1 (0.2%)
Testicular pain	1 (0.4%)	0	1 (0.2%)
Vaginal erosion	1 (0.4%)	0	1 (0.2%)
Vulvovaginal dryness	1 (0.4%)	0	1 (0.2%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	11 (4.6%)	5 (2.1%)	16 (3.4%)
Cancer pain	2 (0.8%)	3 (1.3%)	5 (1.1%)
Seborrhoeic keratosis	4 (1.7%)	0	4 (0.8%)
Acrochordon	1 (0.4%)	0	1 (0.2%)
Angiofibroma	1 (0.4%)	0	1 (0.2%)
Fibrous histiocytoma	1 (0.4%)	0	1 (0.2%)
Large intestine benign neoplasm	1 (0.4%)	0	1 (0.2%)
Skin papilloma	1 (0.4%)	0	1 (0.2%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
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Table 302.1.2001.2.1: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Tumour associated fever	0	1 (0.4%)	1 (0.2%)
Tumour pain	0	1 (0.4%)	1 (0.2%)
Immune system disorders	5 (2.1%)	2 (0.8%)	7 (1.5%)
Contrast media allergy	1 (0.4%)	2 (0.8%)	3 (0.6%)
Seasonal allergy	2 (0.8%)	0	2 (0.4%)
Drug hypersensitivity	1 (0.4%)	0	1 (0.2%)
Hypersensitivity	1 (0.4%)	0	1 (0.2%)
Product issues	1 (0.4%)	3 (1.3%)	4 (0.8%)
Device occlusion	0	2 (0.8%)	2 (0.4%)
Device kink	0	1 (0.4%)	1 (0.2%)
Thrombosis in device	1 (0.4%)	0	1 (0.2%)
Congenital, familial and genetic disorders	3 (1.3%)	0	3 (0.6%)
Dermoid cyst	1 (0.4%)	0	1 (0.2%)
Dolichocolon	1 (0.4%)	0	1 (0.2%)
Hydrocele	1 (0.4%)	0	1 (0.2%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Overall	198 (98.5%)	190 (96.4%)	388 (97.5%)
Gastrointestinal disorders	150 (74.6%)	125 (63.5%)	275 (69.1%)
Constipation	49 (24.4%)	70 (35.5%)	119 (29.9%)
Nausea	55 (27.4%)	55 (27.9%)	110 (27.6%)
Diarrhoea	77 (38.3%)	27 (13.7%)	104 (26.1%)
Vomiting	27 (13.4%)	26 (13.2%)	53 (13.3%)
Abdominal pain	22 (10.9%)	5 (2.5%)	27 (6.8%)
Stomatitis	12 (6.0%)	11 (5.6%)	23 (5.8%)
Dyspepsia	13 (6.5%)	6 (3.0%)	19 (4.8%)
Dry mouth	17 (8.5%)	1 (0.5%)	18 (4.5%)
Abdominal distension	10 (5.0%)	2 (1.0%)	12 (3.0%)
Gastrooesophageal reflux disease	6 (3.0%)	6 (3.0%)	12 (3.0%)
Abdominal pain upper	5 (2.5%)	5 (2.5%)	10 (2.5%)
Dysphagia	7 (3.5%)	0	7 (1.8%)
Mouth ulceration	5 (2.5%)	1 (0.5%)	6 (1.5%)
Abdominal pain lower	1 (0.5%)	4 (2.0%)	5 (1.3%)
Haemorrhoids	4 (2.0%)	1 (0.5%)	5 (1.3%)
Gastritis	3 (1.5%)	1 (0.5%)	4 (1.0%)
Toothache	3 (1.5%)	1 (0.5%)	4 (1.0%)
Abdominal discomfort	1 (0.5%)	2 (1.0%)	3 (0.8%)
Aphthous ulcer	2 (1.0%)	0	2 (0.5%)
Cheilitis	2 (1.0%)	0	2 (0.5%)
Colitis	2 (1.0%)	0	2 (0.5%)
Eructation	1 (0.5%)	1 (0.5%)	2 (0.5%)
Faeces discoloured	0	2 (1.0%)	2 (0.5%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Haematochezia	2 (1.0%)	0	2 (0.5%)
Haemorrhoidal haemorrhage	2 (1.0%)	0	2 (0.5%)
Melaena	1 (0.5%)	1 (0.5%)	2 (0.5%)
Oesophagitis	1 (0.5%)	1 (0.5%)	2 (0.5%)
Paraesthesia oral	2 (1.0%)	0	2 (0.5%)
Aerophagia	1 (0.5%)	0	1 (0.3%)
Anal eczema	1 (0.5%)	0	1 (0.3%)
Anal fissure	1 (0.5%)	0	1 (0.3%)
Anal haemorrhage	1 (0.5%)	0	1 (0.3%)
Anal incontinence	0	1 (0.5%)	1 (0.3%)
Autoimmune colitis	1 (0.5%)	0	1 (0.3%)
Colitis microscopic	1 (0.5%)	0	1 (0.3%)
Defaecation urgency	1 (0.5%)	0	1 (0.3%)
Dental caries	1 (0.5%)	0	1 (0.3%)
Faecaloma	1 (0.5%)	0	1 (0.3%)
Flatulence	0	1 (0.5%)	1 (0.3%)
Gastric ulcer	1 (0.5%)	0	1 (0.3%)
Gastritis erosive	1 (0.5%)	0	1 (0.3%)
Gingival bleeding	0	1 (0.5%)	1 (0.3%)
Gingival pain	0	1 (0.5%)	1 (0.3%)
Glossitis	1 (0.5%)	0	1 (0.3%)
Haematemesis	1 (0.5%)	0	1 (0.3%)
Hypoaesthesia oral	1 (0.5%)	0	1 (0.3%)
Inguinal hernia	1 (0.5%)	0	1 (0.3%)
Large intestinal obstruction	1 (0.5%)	0	1 (0.3%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Leukoplakia oral	0	1 (0.5%)	1 (0.3%)
Lip dry	1 (0.5%)	0	1 (0.3%)
Mouth haemorrhage	0	1 (0.5%)	1 (0.3%)
Odynophagia	1 (0.5%)	0	1 (0.3%)
Oral lichen planus	1 (0.5%)	0	1 (0.3%)
Pancreatitis acute	0	1 (0.5%)	1 (0.3%)
Proctalgia	1 (0.5%)	0	1 (0.3%)
Proctitis	1 (0.5%)	0	1 (0.3%)
Rectal ulcer haemorrhage	1 (0.5%)	0	1 (0.3%)
Thrombosis mesenteric vessel	1 (0.5%)	0	1 (0.3%)
General disorders and administration site conditions	132 (65.7%)	131 (66.5%)	263 (66.1%)
Fatigue	73 (36.3%)	67 (34.0%)	140 (35.2%)
Asthenia	34 (16.9%)	40 (20.3%)	74 (18.6%)
Pyrexia	35 (17.4%)	32 (16.2%)	67 (16.8%)
Oedema peripheral	31 (15.4%)	26 (13.2%)	57 (14.3%)
Chills	7 (3.5%)	6 (3.0%)	13 (3.3%)
Malaise	6 (3.0%)	5 (2.5%)	11 (2.8%)
Gait disturbance	9 (4.5%)	0	9 (2.3%)
Non-cardiac chest pain	1 (0.5%)	5 (2.5%)	6 (1.5%)
Pain	3 (1.5%)	3 (1.5%)	6 (1.5%)
Discomfort	0	3 (1.5%)	3 (0.8%)
Administration site extravasation	1 (0.5%)	1 (0.5%)	2 (0.5%)
Face oedema	0	2 (1.0%)	2 (0.5%)
General physical health deterioration	0	2 (1.0%)	2 (0.5%)
Infusion site extravasation	2 (1.0%)	0	2 (0.5%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Infusion site pain	1 (0.5%)	1 (0.5%)	2 (0.5%)
Peripheral swelling	2 (1.0%)	0	2 (0.5%)
Catheter site granuloma	0	1 (0.5%)	1 (0.3%)
Catheter site pain	0	1 (0.5%)	1 (0.3%)
Chest discomfort	1 (0.5%)	0	1 (0.3%)
Feeling cold	1 (0.5%)	0	1 (0.3%)
Generalised oedema	1 (0.5%)	0	1 (0.3%)
Injection site reaction	1 (0.5%)	0	1 (0.3%)
Physical deconditioning	0	1 (0.5%)	1 (0.3%)
Blood and lymphatic system disorders	74 (36.8%)	148 (75.1%)	222 (55.8%)
Anaemia	58 (28.9%)	119 (60.4%)	177 (44.5%)
Thrombocytopenia	8 (4.0%)	72 (36.5%)	80 (20.1%)
Neutropenia	14 (7.0%)	64 (32.5%)	78 (19.6%)
Leukopenia	8 (4.0%)	20 (10.2%)	28 (7.0%)
Lymphopenia	3 (1.5%)	8 (4.1%)	11 (2.8%)
Eosinophilia	6 (3.0%)	0	6 (1.5%)
Thrombocytosis	2 (1.0%)	4 (2.0%)	6 (1.5%)
Leukocytosis	3 (1.5%)	2 (1.0%)	5 (1.3%)
Disseminated intravascular coagulation	0	1 (0.5%)	1 (0.3%)
Febrile neutropenia	1 (0.5%)	0	1 (0.3%)
Haematotoxicity	0	1 (0.5%)	1 (0.3%)
Haemolytic anaemia	0	1 (0.5%)	1 (0.3%)
Haemorrhagic diathesis	0	1 (0.5%)	1 (0.3%)
Hyperfibrinogenaemia	0	1 (0.5%)	1 (0.3%)
Iron deficiency anaemia	0	1 (0.5%)	1 (0.3%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Neutrophilia	0	1 (0.5%)	1 (0.3%)
Thrombocytopenic purpura	0	1 (0.5%)	1 (0.3%)
Skin and subcutaneous tissue disorders	158 (78.6%)	49 (24.9%)	207 (52.0%)
Pruritus	76 (37.8%)	16 (8.1%)	92 (23.1%)
Rash maculo-papular	68 (33.8%)	6 (3.0%)	74 (18.6%)
Alopecia	60 (29.9%)	11 (5.6%)	71 (17.8%)
Dry skin	37 (18.4%)	2 (1.0%)	39 (9.8%)
Rash macular	18 (9.0%)	4 (2.0%)	22 (5.5%)
Eczema	17 (8.5%)	2 (1.0%)	19 (4.8%)
Rash papular	12 (6.0%)	2 (1.0%)	14 (3.5%)
Dermatitis	10 (5.0%)	1 (0.5%)	11 (2.8%)
Erythema	6 (3.0%)	2 (1.0%)	8 (2.0%)
Skin hyperpigmentation	7 (3.5%)	0	7 (1.8%)
Urticaria	4 (2.0%)	2 (1.0%)	6 (1.5%)
Palmar-plantar erythrodysaesthesia syndrome	4 (2.0%)	1 (0.5%)	5 (1.3%)
Rash erythematous	3 (1.5%)	2 (1.0%)	5 (1.3%)
Dermatitis acneiform	3 (1.5%)	1 (0.5%)	4 (1.0%)
Dermatitis bullous	3 (1.5%)	1 (0.5%)	4 (1.0%)
Rash	2 (1.0%)	2 (1.0%)	4 (1.0%)
Skin exfoliation	4 (2.0%)	0	4 (1.0%)
Acne	3 (1.5%)	0	3 (0.8%)
Blister	3 (1.5%)	0	3 (0.8%)
Decubitus ulcer	2 (1.0%)	1 (0.5%)	3 (0.8%)
Lichen planus	3 (1.5%)	0	3 (0.8%)
Night sweats	2 (1.0%)	1 (0.5%)	3 (0.8%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Purpura	2 (1.0%)	1 (0.5%)	3 (0.8%)
Skin toxicity	3 (1.5%)	0	3 (0.8%)
Skin ulcer	3 (1.5%)	0	3 (0.8%)
Vitiligo	3 (1.5%)	0	3 (0.8%)
Erythema multiforme	2 (1.0%)	0	2 (0.5%)
Hyperhidrosis	2 (1.0%)	0	2 (0.5%)
Madarosis	2 (1.0%)	0	2 (0.5%)
Pemphigoid	2 (1.0%)	0	2 (0.5%)
Rash pruritic	1 (0.5%)	1 (0.5%)	2 (0.5%)
Rash vesicular	2 (1.0%)	0	2 (0.5%)
Skin hypopigmentation	2 (1.0%)	0	2 (0.5%)
Acquired porokeratosis	1 (0.5%)	0	1 (0.3%)
Dermal cyst	1 (0.5%)	0	1 (0.3%)
Dermatitis contact	1 (0.5%)	0	1 (0.3%)
Dermatitis exfoliative	1 (0.5%)	0	1 (0.3%)
Ecchymosis	0	1 (0.5%)	1 (0.3%)
Intertrigo	1 (0.5%)	0	1 (0.3%)
Lentigo	1 (0.5%)	0	1 (0.3%)
Leukoderma	1 (0.5%)	0	1 (0.3%)
Lichenoid keratosis	1 (0.5%)	0	1 (0.3%)
Lipohypertrophy	0	1 (0.5%)	1 (0.3%)
Melanosis	1 (0.5%)	0	1 (0.3%)
Nail ridging	0	1 (0.5%)	1 (0.3%)
Nail toxicity	1 (0.5%)	0	1 (0.3%)
Onychoclasis	0	1 (0.5%)	1 (0.3%)

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Table 302.1.2001.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Onychomadesis	0	1 (0.5%)	1 (0.3%)
Papule	1 (0.5%)	0	1 (0.3%)
Petechiae	0	1 (0.5%)	1 (0.3%)
Pseudocellulitis	0	1 (0.5%)	1 (0.3%)
Scab	1 (0.5%)	0	1 (0.3%)
Seborrhoeic dermatitis	1 (0.5%)	0	1 (0.3%)
Skin atrophy	1 (0.5%)	0	1 (0.3%)
Skin burning sensation	1 (0.5%)	0	1 (0.3%)
Skin discolouration	1 (0.5%)	0	1 (0.3%)
Skin disorder	1 (0.5%)	0	1 (0.3%)
Skin erosion	1 (0.5%)	0	1 (0.3%)
Skin induration	0	1 (0.5%)	1 (0.3%)
Skin lesion	1 (0.5%)	0	1 (0.3%)
Stasis dermatitis	1 (0.5%)	0	1 (0.3%)
Toxic skin eruption	1 (0.5%)	0	1 (0.3%)
Metabolism and nutrition disorders	117 (58.2%)	83 (42.1%)	200 (50.3%)
Decreased appetite	72 (35.8%)	50 (25.4%)	122 (30.7%)
Hyperglycaemia	27 (13.4%)	4 (2.0%)	31 (7.8%)
Hyponatraemia	20 (10.0%)	9 (4.6%)	29 (7.3%)
Hypophosphataemia	19 (9.5%)	9 (4.6%)	28 (7.0%)
Hypokalaemia	19 (9.5%)	8 (4.1%)	27 (6.8%)
Hyperkalaemia	8 (4.0%)	12 (6.1%)	20 (5.0%)
Hypocalcaemia	8 (4.0%)	11 (5.6%)	19 (4.8%)
Hypomagnesaemia	10 (5.0%)	7 (3.6%)	17 (4.3%)
Hypoalbuminaemia	10 (5.0%)	6 (3.0%)	16 (4.0%)

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Table 302.1.2001.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Dehydration	11 (5.5%)	3 (1.5%)	14 (3.5%)
Hypercalcaemia	7 (3.5%)	3 (1.5%)	10 (2.5%)
Hypercreatininaemia	3 (1.5%)	0	3 (0.8%)
Hyperuricaemia	1 (0.5%)	2 (1.0%)	3 (0.8%)
Metabolic acidosis	2 (1.0%)	1 (0.5%)	3 (0.8%)
Type 2 diabetes mellitus	1 (0.5%)	2 (1.0%)	3 (0.8%)
Cachexia	1 (0.5%)	1 (0.5%)	2 (0.5%)
Diabetes mellitus	2 (1.0%)	0	2 (0.5%)
Gout	2 (1.0%)	0	2 (0.5%)
Hyperamylasaemia	2 (1.0%)	0	2 (0.5%)
Hyperlipasaemia	2 (1.0%)	0	2 (0.5%)
Hypoglycaemia	2 (1.0%)	0	2 (0.5%)
Hypozincaemia	2 (1.0%)	0	2 (0.5%)
Malnutrition	0	2 (1.0%)	2 (0.5%)
Polydipsia	1 (0.5%)	1 (0.5%)	2 (0.5%)
Hypercholesterolaemia	1 (0.5%)	0	1 (0.3%)
Hypermagnesaemia	0	1 (0.5%)	1 (0.3%)
Hypernatraemia	0	1 (0.5%)	1 (0.3%)
Hyperphosphataemia	1 (0.5%)	0	1 (0.3%)
Hypertriglyceridaemia	1 (0.5%)	0	1 (0.3%)
Hypochloraemia	1 (0.5%)	0	1 (0.3%)
Impaired fasting glucose	1 (0.5%)	0	1 (0.3%)
Type 1 diabetes mellitus	1 (0.5%)	0	1 (0.3%)
Vitamin D deficiency	0	1 (0.5%)	1 (0.3%)
Investigations	108 (53.7%)	86 (43.7%)	194 (48.7%)

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Table 302.1.2001.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Weight decreased	72 (35.8%)	15 (7.6%)	87 (21.9%)
Blood creatinine increased	27 (13.4%)	23 (11.7%)	50 (12.6%)
Alanine aminotransferase increased	27 (13.4%)	19 (9.6%)	46 (11.6%)
Aspartate aminotransferase increased	22 (10.9%)	17 (8.6%)	39 (9.8%)
Platelet count decreased	3 (1.5%)	29 (14.7%)	32 (8.0%)
Neutrophil count decreased	5 (2.5%)	19 (9.6%)	24 (6.0%)
Blood alkaline phosphatase increased	10 (5.0%)	8 (4.1%)	18 (4.5%)
Blood lactate dehydrogenase increased	6 (3.0%)	9 (4.6%)	15 (3.8%)
White blood cell count decreased	4 (2.0%)	9 (4.6%)	13 (3.3%)
Lymphocyte count decreased	8 (4.0%)	3 (1.5%)	11 (2.8%)
Weight increased	6 (3.0%)	2 (1.0%)	8 (2.0%)
Amylase increased	2 (1.0%)	4 (2.0%)	6 (1.5%)
Gamma-glutamyltransferase increased	2 (1.0%)	4 (2.0%)	6 (1.5%)
Lipase increased	3 (1.5%)	2 (1.0%)	5 (1.3%)
Blood bilirubin increased	3 (1.5%)	1 (0.5%)	4 (1.0%)
Blood bicarbonate decreased	3 (1.5%)	0	3 (0.8%)
Blood urea increased	0	3 (1.5%)	3 (0.8%)
Blood thyroid stimulating hormone increased	2 (1.0%)	0	2 (0.5%)
Apolipoprotein B increased	1 (0.5%)	0	1 (0.3%)
Blood cholesterol increased	1 (0.5%)	0	1 (0.3%)
Blood creatine phosphokinase increased	1 (0.5%)	0	1 (0.3%)
Blood glucose increased	1 (0.5%)	0	1 (0.3%)
Blood lactate dehydrogenase	1 (0.5%)	0	1 (0.3%)
Blood magnesium decreased	0	1 (0.5%)	1 (0.3%)
Blood phosphorus decreased	0	1 (0.5%)	1 (0.3%)

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Table 302.1.2001.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Blood potassium decreased	1 (0.5%)	0	1 (0.3%)
Blood triglycerides increased	1 (0.5%)	0	1 (0.3%)
False positive investigation result	0	1 (0.5%)	1 (0.3%)
Glomerular filtration rate decreased	0	1 (0.5%)	1 (0.3%)
International normalised ratio increased	0	1 (0.5%)	1 (0.3%)
Nitrite urine present	1 (0.5%)	0	1 (0.3%)
Platelet count increased	0	1 (0.5%)	1 (0.3%)
Respiratory rate decreased	1 (0.5%)	0	1 (0.3%)
SARS-CoV-2 test positive	1 (0.5%)	0	1 (0.3%)
Waist circumference increased	1 (0.5%)	0	1 (0.3%)
White blood cell count increased	0	1 (0.5%)	1 (0.3%)
Nervous system disorders	140 (69.7%)	46 (23.4%)	186 (46.7%)
Peripheral sensory neuropathy	101 (50.2%)	10 (5.1%)	111 (27.9%)
Dysgeusia	46 (22.9%)	9 (4.6%)	55 (13.8%)
Dizziness	12 (6.0%)	16 (8.1%)	28 (7.0%)
Headache	14 (7.0%)	10 (5.1%)	24 (6.0%)
Paraesthesia	12 (6.0%)	2 (1.0%)	14 (3.5%)
Peripheral motor neuropathy	9 (4.5%)	0	9 (2.3%)
Peripheral sensorimotor neuropathy	6 (3.0%)	0	6 (1.5%)
Hypoaesthesia	5 (2.5%)	0	5 (1.3%)
Taste disorder	4 (2.0%)	1 (0.5%)	5 (1.3%)
Peroneal nerve palsy	3 (1.5%)	0	3 (0.8%)
Somnolence	2 (1.0%)	1 (0.5%)	3 (0.8%)
Cerebrovascular accident	2 (1.0%)	0	2 (0.5%)
Hypogeusia	2 (1.0%)	0	2 (0.5%)

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Table 302.1.2001.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Neuralgia	2 (1.0%)	0	2 (0.5%)
Tremor	1 (0.5%)	1 (0.5%)	2 (0.5%)
Ageusia	1 (0.5%)	0	1 (0.3%)
Anosmia	1 (0.5%)	0	1 (0.3%)
Balance disorder	1 (0.5%)	0	1 (0.3%)
Burning sensation	0	1 (0.5%)	1 (0.3%)
Carotid arteriosclerosis	1 (0.5%)	0	1 (0.3%)
Cognitive disorder	1 (0.5%)	0	1 (0.3%)
Dementia	1 (0.5%)	0	1 (0.3%)
Disturbance in attention	1 (0.5%)	0	1 (0.3%)
Dizziness postural	0	1 (0.5%)	1 (0.3%)
Dysarthria	1 (0.5%)	0	1 (0.3%)
Embolic stroke	0	1 (0.5%)	1 (0.3%)
Hypergeusia	0	1 (0.5%)	1 (0.3%)
Lethargy	0	1 (0.5%)	1 (0.3%)
Migraine	1 (0.5%)	0	1 (0.3%)
Neuropathy peripheral	0	1 (0.5%)	1 (0.3%)
Pseudoparalysis	1 (0.5%)	0	1 (0.3%)
Restless legs syndrome	1 (0.5%)	0	1 (0.3%)
Infections and infestations	103 (51.2%)	57 (28.9%)	160 (40.2%)
Urinary tract infection	40 (19.9%)	29 (14.7%)	69 (17.3%)
COVID-19	17 (8.5%)	8 (4.1%)	25 (6.3%)
Oral candidiasis	9 (4.5%)	2 (1.0%)	11 (2.8%)
Pneumonia	9 (4.5%)	2 (1.0%)	11 (2.8%)
Conjunctivitis	9 (4.5%)	0	9 (2.3%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Respiratory tract infection	4 (2.0%)	2 (1.0%)	6 (1.5%)
Bronchitis	4 (2.0%)	1 (0.5%)	5 (1.3%)
Cellulitis	4 (2.0%)	1 (0.5%)	5 (1.3%)
Skin infection	3 (1.5%)	2 (1.0%)	5 (1.3%)
Upper respiratory tract infection	4 (2.0%)	1 (0.5%)	5 (1.3%)
Nasopharyngitis	3 (1.5%)	1 (0.5%)	4 (1.0%)
Rhinitis	4 (2.0%)	0	4 (1.0%)
Cystitis	1 (0.5%)	2 (1.0%)	3 (0.8%)
Gastroenteritis	3 (1.5%)	0	3 (0.8%)
Influenza	2 (1.0%)	1 (0.5%)	3 (0.8%)
Pharyngitis	3 (1.5%)	0	3 (0.8%)
Pyelonephritis acute	1 (0.5%)	2 (1.0%)	3 (0.8%)
Bacteraemia	0	2 (1.0%)	2 (0.5%)
Bronchitis viral	1 (0.5%)	1 (0.5%)	2 (0.5%)
Clostridium difficile colitis	2 (1.0%)	0	2 (0.5%)
Eye infection	2 (1.0%)	0	2 (0.5%)
Pyelonephritis	2 (1.0%)	0	2 (0.5%)
Rash pustular	2 (1.0%)	0	2 (0.5%)
Skin candida	1 (0.5%)	1 (0.5%)	2 (0.5%)
Tinea pedis	2 (1.0%)	0	2 (0.5%)
Abdominal infection	0	1 (0.5%)	1 (0.3%)
Bronchopulmonary aspergillosis	1 (0.5%)	0	1 (0.3%)
Campylobacter gastroenteritis	1 (0.5%)	0	1 (0.3%)
Campylobacter infection	1 (0.5%)	0	1 (0.3%)
Candida infection	1 (0.5%)	0	1 (0.3%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
COVID-19 pneumonia	1 (0.5%)	0	1 (0.3%)
Cystitis escherichia	0	1 (0.5%)	1 (0.3%)
Cytomegalovirus colitis	1 (0.5%)	0	1 (0.3%)
Device related infection	1 (0.5%)	0	1 (0.3%)
Enterobacter bacteraemia	0	1 (0.5%)	1 (0.3%)
Enterocolitis infectious	1 (0.5%)	0	1 (0.3%)
Folliculitis	0	1 (0.5%)	1 (0.3%)
Fungal foot infection	1 (0.5%)	0	1 (0.3%)
Gastritis viral	1 (0.5%)	0	1 (0.3%)
Gastroenteritis viral	1 (0.5%)	0	1 (0.3%)
Gingivitis	1 (0.5%)	0	1 (0.3%)
Herpes simplex	1 (0.5%)	0	1 (0.3%)
Herpes zoster	1 (0.5%)	0	1 (0.3%)
Intestinal fistula infection	1 (0.5%)	0	1 (0.3%)
Mumps	0	1 (0.5%)	1 (0.3%)
Nail infection	1 (0.5%)	0	1 (0.3%)
Oesophageal candidiasis	0	1 (0.5%)	1 (0.3%)
Oral herpes	1 (0.5%)	0	1 (0.3%)
Paronychia	0	1 (0.5%)	1 (0.3%)
Penile infection	1 (0.5%)	0	1 (0.3%)
Peritonsillar abscess	0	1 (0.5%)	1 (0.3%)
Pharyngitis streptococcal	1 (0.5%)	0	1 (0.3%)
Pyuria	1 (0.5%)	0	1 (0.3%)
Respiratory tract infection bacterial	0	1 (0.5%)	1 (0.3%)
Salmonellosis	1 (0.5%)	0	1 (0.3%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Sinusitis	1 (0.5%)	0	1 (0.3%)
Stitch abscess	1 (0.5%)	0	1 (0.3%)
Subcutaneous abscess	1 (0.5%)	0	1 (0.3%)
Tonsillitis	0	1 (0.5%)	1 (0.3%)
Urinary tract infection bacterial	1 (0.5%)	0	1 (0.3%)
Urosepsis	0	1 (0.5%)	1 (0.3%)
Viral infection	0	1 (0.5%)	1 (0.3%)
Respiratory, thoracic and mediastinal disorders	77 (38.3%)	55 (27.9%)	132 (33.2%)
Dyspnoea	27 (13.4%)	24 (12.2%)	51 (12.8%)
Cough	28 (13.9%)	10 (5.1%)	38 (9.5%)
Epistaxis	5 (2.5%)	8 (4.1%)	13 (3.3%)
Hiccups	6 (3.0%)	7 (3.6%)	13 (3.3%)
Pneumonitis	11 (5.5%)	0	11 (2.8%)
Dysphonia	9 (4.5%)	0	9 (2.3%)
Productive cough	6 (3.0%)	2 (1.0%)	8 (2.0%)
Pleural effusion	5 (2.5%)	2 (1.0%)	7 (1.8%)
Rhinorrhoea	7 (3.5%)	0	7 (1.8%)
Dyspnoea exertional	1 (0.5%)	3 (1.5%)	4 (1.0%)
Nasal congestion	4 (2.0%)	0	4 (1.0%)
Oropharyngeal pain	2 (1.0%)	2 (1.0%)	4 (1.0%)
Immune-mediated lung disease	3 (1.5%)	0	3 (0.8%)
Pneumothorax	2 (1.0%)	1 (0.5%)	3 (0.8%)
Pulmonary embolism	0	3 (1.5%)	3 (0.8%)
Wheezing	2 (1.0%)	1 (0.5%)	3 (0.8%)
Chronic obstructive pulmonary disease	1 (0.5%)	1 (0.5%)	2 (0.5%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Hypoxia	2 (1.0%)	0	2 (0.5%)
Tachypnoea	2 (1.0%)	0	2 (0.5%)
Throat irritation	2 (1.0%)	0	2 (0.5%)
Acute respiratory failure	1 (0.5%)	0	1 (0.3%)
Asthma	0	1 (0.5%)	1 (0.3%)
Autoimmune lung disease	1 (0.5%)	0	1 (0.3%)
Bronchospasm	0	1 (0.5%)	1 (0.3%)
Catarrh	1 (0.5%)	0	1 (0.3%)
Emphysema	1 (0.5%)	0	1 (0.3%)
Haemoptysis	0	1 (0.5%)	1 (0.3%)
Interstitial lung disease	1 (0.5%)	0	1 (0.3%)
Lung opacity	1 (0.5%)	0	1 (0.3%)
Nasal dryness	1 (0.5%)	0	1 (0.3%)
Oropharyngeal discomfort	1 (0.5%)	0	1 (0.3%)
Pharyngeal erythema	1 (0.5%)	0	1 (0.3%)
Rales	0	1 (0.5%)	1 (0.3%)
Respiratory acidosis	0	1 (0.5%)	1 (0.3%)
Respiratory disorder	1 (0.5%)	0	1 (0.3%)
Rhinitis allergic	1 (0.5%)	0	1 (0.3%)
Sinus pain	1 (0.5%)	0	1 (0.3%)
Sneezing	0	1 (0.5%)	1 (0.3%)
Throat clearing	0	1 (0.5%)	1 (0.3%)
Upper-airway cough syndrome	1 (0.5%)	0	1 (0.3%)
Musculoskeletal and connective tissue disorders	76 (37.8%)	51 (25.9%)	127 (31.9%)
Arthralgia	21 (10.4%)	10 (5.1%)	31 (7.8%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
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Table 302.1.2001.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Back pain	16 (8.0%)	12 (6.1%)	28 (7.0%)
Pain in extremity	11 (5.5%)	8 (4.1%)	19 (4.8%)
Muscular weakness	15 (7.5%)	3 (1.5%)	18 (4.5%)
Myalgia	9 (4.5%)	4 (2.0%)	13 (3.3%)
Flank pain	7 (3.5%)	0	7 (1.8%)
Arthritis	3 (1.5%)	3 (1.5%)	6 (1.5%)
Muscle spasms	5 (2.5%)	1 (0.5%)	6 (1.5%)
Musculoskeletal chest pain	3 (1.5%)	3 (1.5%)	6 (1.5%)
Groin pain	2 (1.0%)	3 (1.5%)	5 (1.3%)
Bone pain	1 (0.5%)	3 (1.5%)	4 (1.0%)
Musculoskeletal pain	4 (2.0%)	0	4 (1.0%)
Spinal pain	1 (0.5%)	3 (1.5%)	4 (1.0%)
Neck pain	0	3 (1.5%)	3 (0.8%)
Bursitis	2 (1.0%)	0	2 (0.5%)
Immune-mediated arthritis	2 (1.0%)	0	2 (0.5%)
Joint swelling	2 (1.0%)	0	2 (0.5%)
Musculoskeletal discomfort	1 (0.5%)	1 (0.5%)	2 (0.5%)
Osteoarthritis	1 (0.5%)	1 (0.5%)	2 (0.5%)
Pathological fracture	1 (0.5%)	1 (0.5%)	2 (0.5%)
Pubic pain	1 (0.5%)	1 (0.5%)	2 (0.5%)
Intervertebral disc degeneration	0	1 (0.5%)	1 (0.3%)
Joint range of motion decreased	1 (0.5%)	0	1 (0.3%)
Muscle contracture	0	1 (0.5%)	1 (0.3%)
Myositis	1 (0.5%)	0	1 (0.3%)
Osteopenia	1 (0.5%)	0	1 (0.3%)

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Table 302.1.2001.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Osteoporotic fracture	1 (0.5%)	0	1 (0.3%)
Rhabdomyolysis	1 (0.5%)	0	1 (0.3%)
Sacral pain	1 (0.5%)	0	1 (0.3%)
Renal and urinary disorders	53 (26.4%)	40 (20.3%)	93 (23.4%)
Haematuria	23 (11.4%)	18 (9.1%)	41 (10.3%)
Dysuria	8 (4.0%)	5 (2.5%)	13 (3.3%)
Acute kidney injury	6 (3.0%)	4 (2.0%)	10 (2.5%)
Pollakiuria	5 (2.5%)	2 (1.0%)	7 (1.8%)
Proteinuria	4 (2.0%)	3 (1.5%)	7 (1.8%)
Renal impairment	3 (1.5%)	3 (1.5%)	6 (1.5%)
Hydronephrosis	1 (0.5%)	4 (2.0%)	5 (1.3%)
Bladder spasm	0	4 (2.0%)	4 (1.0%)
Renal failure	2 (1.0%)	1 (0.5%)	3 (0.8%)
Chromaturia	1 (0.5%)	1 (0.5%)	2 (0.5%)
Immune-mediated nephritis	2 (1.0%)	0	2 (0.5%)
Leukocyturia	1 (0.5%)	1 (0.5%)	2 (0.5%)
Nocturia	2 (1.0%)	0	2 (0.5%)
Urinary retention	0	2 (1.0%)	2 (0.5%)
Urine odour abnormal	2 (1.0%)	0	2 (0.5%)
Azotaemia	1 (0.5%)	0	1 (0.3%)
Bladder irritation	1 (0.5%)	0	1 (0.3%)
Chronic kidney disease	1 (0.5%)	0	1 (0.3%)
Costovertebral angle tenderness	0	1 (0.5%)	1 (0.3%)
Cystitis noninfective	1 (0.5%)	0	1 (0.3%)
Hypertonic bladder	1 (0.5%)	0	1 (0.3%)

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Table 302.1.2001.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Nephroangiosclerosis	1 (0.5%)	0	1 (0.3%)
Nephropathy	0	1 (0.5%)	1 (0.3%)
Polyuria	1 (0.5%)	0	1 (0.3%)
Renal pain	0	1 (0.5%)	1 (0.3%)
Renal tubular necrosis	1 (0.5%)	0	1 (0.3%)
Strangury	0	1 (0.5%)	1 (0.3%)
Tubulointerstitial nephritis	1 (0.5%)	0	1 (0.3%)
Ureteric obstruction	1 (0.5%)	0	1 (0.3%)
Urinary incontinence	1 (0.5%)	0	1 (0.3%)
Urinary tract obstruction	1 (0.5%)	0	1 (0.3%)
Urine flow decreased	1 (0.5%)	0	1 (0.3%)
Urogenital fistula	1 (0.5%)	0	1 (0.3%)
Eye disorders	64 (31.8%)	12 (6.1%)	76 (19.1%)
Dry eye	21 (10.4%)	2 (1.0%)	23 (5.8%)
Cataract	12 (6.0%)	0	12 (3.0%)
Lacrimation increased	11 (5.5%)	1 (0.5%)	12 (3.0%)
Vision blurred	10 (5.0%)	1 (0.5%)	11 (2.8%)
Eye pain	3 (1.5%)	1 (0.5%)	4 (1.0%)
Eye pruritus	3 (1.5%)	0	3 (0.8%)
Blepharitis	2 (1.0%)	0	2 (0.5%)
Conjunctival haemorrhage	2 (1.0%)	0	2 (0.5%)
Conjunctivitis allergic	2 (1.0%)	0	2 (0.5%)
Epiretinal membrane	2 (1.0%)	0	2 (0.5%)
Eye discharge	2 (1.0%)	0	2 (0.5%)
Keratitis	2 (1.0%)	0	2 (0.5%)

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Table 302.1.2001.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Meibomian gland dysfunction	2 (1.0%)	0	2 (0.5%)
Photophobia	1 (0.5%)	1 (0.5%)	2 (0.5%)
Punctate keratitis	2 (1.0%)	0	2 (0.5%)
Visual acuity reduced	1 (0.5%)	1 (0.5%)	2 (0.5%)
Visual impairment	1 (0.5%)	1 (0.5%)	2 (0.5%)
Xerophthalmia	2 (1.0%)	0	2 (0.5%)
Angle closure glaucoma	0	1 (0.5%)	1 (0.3%)
Arteriosclerotic retinopathy	1 (0.5%)	0	1 (0.3%)
Conjunctival cyst	1 (0.5%)	0	1 (0.3%)
Conjunctival hyperaemia	1 (0.5%)	0	1 (0.3%)
Corneal degeneration	1 (0.5%)	0	1 (0.3%)
Corneal erosion	1 (0.5%)	0	1 (0.3%)
Dacryostenosis acquired	1 (0.5%)	0	1 (0.3%)
Erythema of eyelid	1 (0.5%)	0	1 (0.3%)
Exfoliation glaucoma	1 (0.5%)	0	1 (0.3%)
Exophthalmos	1 (0.5%)	0	1 (0.3%)
Eye irritation	0	1 (0.5%)	1 (0.3%)
Eye oedema	0	1 (0.5%)	1 (0.3%)
Keratoconus	1 (0.5%)	0	1 (0.3%)
Macular oedema	1 (0.5%)	0	1 (0.3%)
Normal tension glaucoma	1 (0.5%)	0	1 (0.3%)
Ocular discomfort	0	1 (0.5%)	1 (0.3%)
Ocular hyperaemia	1 (0.5%)	0	1 (0.3%)
Periorbital oedema	0	1 (0.5%)	1 (0.3%)
Posterior capsule opacification	1 (0.5%)	0	1 (0.3%)

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Table 302.1.2001.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Presbyopia	1 (0.5%)	0	1 (0.3%)
Scleritis	1 (0.5%)	0	1 (0.3%)
Psychiatric disorders	35 (17.4%)	20 (10.2%)	55 (13.8%)
Insomnia	23 (11.4%)	10 (5.1%)	33 (8.3%)
Anxiety	9 (4.5%)	3 (1.5%)	12 (3.0%)
Depression	6 (3.0%)	2 (1.0%)	8 (2.0%)
Confusional state	2 (1.0%)	3 (1.5%)	5 (1.3%)
Delirium	4 (2.0%)	0	4 (1.0%)
Affect lability	0	2 (1.0%)	2 (0.5%)
Agitation	1 (0.5%)	0	1 (0.3%)
Emotional distress	0	1 (0.5%)	1 (0.3%)
Hallucination	1 (0.5%)	0	1 (0.3%)
Mental status changes	0	1 (0.5%)	1 (0.3%)
Panic attack	1 (0.5%)	0	1 (0.3%)
Vascular disorders	26 (12.9%)	25 (12.7%)	51 (12.8%)
Hypotension	8 (4.0%)	1 (0.5%)	9 (2.3%)
Hypertension	5 (2.5%)	3 (1.5%)	8 (2.0%)
Thrombophlebitis	1 (0.5%)	6 (3.0%)	7 (1.8%)
Hot flush	2 (1.0%)	3 (1.5%)	5 (1.3%)
Haematoma	2 (1.0%)	2 (1.0%)	4 (1.0%)
Deep vein thrombosis	2 (1.0%)	1 (0.5%)	3 (0.8%)
Superficial vein thrombosis	1 (0.5%)	2 (1.0%)	3 (0.8%)
Flushing	1 (0.5%)	1 (0.5%)	2 (0.5%)
Lymphoedema	0	2 (1.0%)	2 (0.5%)
Orthostatic hypotension	1 (0.5%)	1 (0.5%)	2 (0.5%)

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Table 302.1.2001.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Peripheral venous disease	1 (0.5%)	1 (0.5%)	2 (0.5%)
Phlebitis	0	2 (1.0%)	2 (0.5%)
Aortic dilatation	1 (0.5%)	0	1 (0.3%)
Peripheral coldness	1 (0.5%)	0	1 (0.3%)
Peripheral embolism	1 (0.5%)	0	1 (0.3%)
Post thrombotic syndrome	0	1 (0.5%)	1 (0.3%)
Raynaud's phenomenon	1 (0.5%)	0	1 (0.3%)
Vascular pain	0	1 (0.5%)	1 (0.3%)
Injury, poisoning and procedural complications	25 (12.4%)	20 (10.2%)	45 (11.3%)
Fall	10 (5.0%)	5 (2.5%)	15 (3.8%)
Skin abrasion	6 (3.0%)	1 (0.5%)	7 (1.8%)
Contusion	3 (1.5%)	2 (1.0%)	5 (1.3%)
Infusion related reaction	1 (0.5%)	3 (1.5%)	4 (1.0%)
Urinary tract stoma complication	0	3 (1.5%)	3 (0.8%)
Radius fracture	2 (1.0%)	0	2 (0.5%)
Skin laceration	2 (1.0%)	0	2 (0.5%)
Tendon rupture	2 (1.0%)	0	2 (0.5%)
Thermal burn	2 (1.0%)	0	2 (0.5%)
Wound dehiscence	0	2 (1.0%)	2 (0.5%)
Wrist fracture	1 (0.5%)	1 (0.5%)	2 (0.5%)
Ankle fracture	1 (0.5%)	0	1 (0.3%)
Corneal abrasion	1 (0.5%)	0	1 (0.3%)
Foot fracture	1 (0.5%)	0	1 (0.3%)
Genital injury	1 (0.5%)	0	1 (0.3%)
Ligament sprain	1 (0.5%)	0	1 (0.3%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Lumbar vertebral fracture	1 (0.5%)	0	1 (0.3%)
Post procedural haemorrhage	0	1 (0.5%)	1 (0.3%)
Rib fracture	1 (0.5%)	0	1 (0.3%)
Shoulder fracture	1 (0.5%)	0	1 (0.3%)
Stoma site haemorrhage	0	1 (0.5%)	1 (0.3%)
Toxicity to various agents	0	1 (0.5%)	1 (0.3%)
Transfusion reaction	0	1 (0.5%)	1 (0.3%)
Urostomy complication	1 (0.5%)	0	1 (0.3%)
Endocrine disorders	35 (17.4%)	3 (1.5%)	38 (9.5%)
Hypothyroidism	22 (10.9%)	2 (1.0%)	24 (6.0%)
Hyperthyroidism	11 (5.5%)	1 (0.5%)	12 (3.0%)
Adrenal insufficiency	3 (1.5%)	0	3 (0.8%)
Hypophysitis	2 (1.0%)	0	2 (0.5%)
Central hypothyroidism	1 (0.5%)	0	1 (0.3%)
Immune-mediated hypothyroidism	1 (0.5%)	0	1 (0.3%)
Thyroiditis	1 (0.5%)	0	1 (0.3%)
Hepatobiliary disorders	28 (13.9%)	10 (5.1%)	38 (9.5%)
Hypertransaminasaemia	10 (5.0%)	6 (3.0%)	16 (4.0%)
Hepatic function abnormal	3 (1.5%)	2 (1.0%)	5 (1.3%)
Hyperbilirubinaemia	2 (1.0%)	2 (1.0%)	4 (1.0%)
Drug-induced liver injury	1 (0.5%)	2 (1.0%)	3 (0.8%)
Autoimmune hepatitis	2 (1.0%)	0	2 (0.5%)
Hepatotoxicity	2 (1.0%)	0	2 (0.5%)
Immune-mediated hepatitis	2 (1.0%)	0	2 (0.5%)
Biliary colic	1 (0.5%)	0	1 (0.3%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Biliary dilatation	1 (0.5%)	0	1 (0.3%)
Cholangitis sclerosing	1 (0.5%)	0	1 (0.3%)
Cholecystitis	1 (0.5%)	0	1 (0.3%)
Gallbladder disorder	1 (0.5%)	0	1 (0.3%)
Hepatic pain	1 (0.5%)	0	1 (0.3%)
Hepatic steatosis	1 (0.5%)	0	1 (0.3%)
Hepatitis	1 (0.5%)	0	1 (0.3%)
Cardiac disorders	12 (6.0%)	10 (5.1%)	22 (5.5%)
Atrial fibrillation	3 (1.5%)	3 (1.5%)	6 (1.5%)
Palpitations	2 (1.0%)	2 (1.0%)	4 (1.0%)
Cardiac failure	2 (1.0%)	0	2 (0.5%)
Tachycardia	1 (0.5%)	1 (0.5%)	2 (0.5%)
Ventricular tachycardia	1 (0.5%)	1 (0.5%)	2 (0.5%)
Angina pectoris	0	1 (0.5%)	1 (0.3%)
Aortic valve disease	0	1 (0.5%)	1 (0.3%)
Atrial flutter	0	1 (0.5%)	1 (0.3%)
Atrial thrombosis	1 (0.5%)	0	1 (0.3%)
Bundle branch block right	1 (0.5%)	0	1 (0.3%)
Cardiac discomfort	1 (0.5%)	0	1 (0.3%)
Cardiac flutter	0	1 (0.5%)	1 (0.3%)
Myocarditis	1 (0.5%)	0	1 (0.3%)
Sinus tachycardia	1 (0.5%)	0	1 (0.3%)
Ventricular extrasystoles	1 (0.5%)	0	1 (0.3%)
Reproductive system and breast disorders	9 (4.5%)	6 (3.0%)	15 (3.8%)
Pelvic pain	5 (2.5%)	0	5 (1.3%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Breast pain	0	1 (0.5%)	1 (0.3%)
Erectile dysfunction	1 (0.5%)	0	1 (0.3%)
Genital burning sensation	0	1 (0.5%)	1 (0.3%)
Genital paraesthesia	1 (0.5%)	0	1 (0.3%)
Ovarian vein thrombosis	0	1 (0.5%)	1 (0.3%)
Penile erythema	0	1 (0.5%)	1 (0.3%)
Prostatitis	0	1 (0.5%)	1 (0.3%)
Testicular pain	0	1 (0.5%)	1 (0.3%)
Vaginal prolapse	1 (0.5%)	0	1 (0.3%)
Vulval eczema	1 (0.5%)	0	1 (0.3%)
Vulvovaginal dryness	1 (0.5%)	0	1 (0.3%)
Ear and labyrinth disorders	3 (1.5%)	7 (3.6%)	10 (2.5%)
Tinnitus	1 (0.5%)	2 (1.0%)	3 (0.8%)
Vertigo	0	3 (1.5%)	3 (0.8%)
Hypoacusis	1 (0.5%)	1 (0.5%)	2 (0.5%)
Eustachian tube disorder	0	1 (0.5%)	1 (0.3%)
Otorrhoea	1 (0.5%)	0	1 (0.3%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	8 (4.0%)	1 (0.5%)	9 (2.3%)
Cancer pain	5 (2.5%)	0	5 (1.3%)
Monoclonal gammopathy	1 (0.5%)	0	1 (0.3%)
Neuroma	1 (0.5%)	0	1 (0.3%)
Pancreatic cystadenoma	1 (0.5%)	0	1 (0.3%)
Tumour pain	0	1 (0.5%)	1 (0.3%)
Immune system disorders	4 (2.0%)	0	4 (1.0%)
Contrast media allergy	2 (1.0%)	0	2 (0.5%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.2.2: Frequency Summary of Non-Severe Treatment Emergent Adverse Events (CTCAE Grade <3) - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Drug hypersensitivity	1 (0.5%)	0	1 (0.3%)
Seasonal allergy	1 (0.5%)	0	1 (0.3%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.3.1: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Overall	165 (69.0%)	175 (74.2%)	340 (71.6%)
Blood and lymphatic system disorders	17 (7.1%)	110 (46.6%)	127 (26.7%)
Anaemia	5 (2.1%)	68 (28.8%)	73 (15.4%)
Neutropenia	8 (3.3%)	52 (22.0%)	60 (12.6%)
Thrombocytopenia	2 (0.8%)	28 (11.9%)	30 (6.3%)
Leukopenia	2 (0.8%)	7 (3.0%)	9 (1.9%)
Febrile neutropenia	3 (1.3%)	4 (1.7%)	7 (1.5%)
Anaemia of malignant disease	1 (0.4%)	0	1 (0.2%)
Lymphopenia	0	1 (0.4%)	1 (0.2%)
Pancytopenia	0	1 (0.4%)	1 (0.2%)
Infections and infestations	28 (11.7%)	39 (16.5%)	67 (14.1%)
Urinary tract infection	8 (3.3%)	19 (8.1%)	27 (5.7%)
Sepsis	2 (0.8%)	6 (2.5%)	8 (1.7%)
COVID-19 pneumonia	3 (1.3%)	2 (0.8%)	5 (1.1%)
Pneumonia	3 (1.3%)	2 (0.8%)	5 (1.1%)
COVID-19	1 (0.4%)	2 (0.8%)	3 (0.6%)
Device related infection	1 (0.4%)	2 (0.8%)	3 (0.6%)
Urosepsis	1 (0.4%)	2 (0.8%)	3 (0.6%)
Kidney infection	1 (0.4%)	1 (0.4%)	2 (0.4%)
Pyelonephritis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Abdominal abscess	0	1 (0.4%)	1 (0.2%)
Cellulitis	1 (0.4%)	0	1 (0.2%)
Diverticulitis	1 (0.4%)	0	1 (0.2%)
Escherichia urinary tract infection	0	1 (0.4%)	1 (0.2%)
Infectious pleural effusion	1 (0.4%)	0	1 (0.2%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.3.1: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Neutropenic sepsis	0	1 (0.4%)	1 (0.2%)
Oesophageal candidiasis	1 (0.4%)	0	1 (0.2%)
Parotitis	1 (0.4%)	0	1 (0.2%)
Pelvic infection	1 (0.4%)	0	1 (0.2%)
Perineal abscess	0	1 (0.4%)	1 (0.2%)
Pneumonia haemophilus	0	1 (0.4%)	1 (0.2%)
Rash pustular	1 (0.4%)	0	1 (0.2%)
Respiratory syncytial virus infection	0	1 (0.4%)	1 (0.2%)
Respiratory tract infection	1 (0.4%)	0	1 (0.2%)
Urinary tract infection bacterial	0	1 (0.4%)	1 (0.2%)
Urinary tract infection pseudomonal	0	1 (0.4%)	1 (0.2%)
Wound infection	0	1 (0.4%)	1 (0.2%)
Investigations	33 (13.8%)	34 (14.4%)	67 (14.1%)
Neutrophil count decreased	4 (1.7%)	21 (8.9%)	25 (5.3%)
Platelet count decreased	0	12 (5.1%)	12 (2.5%)
Weight decreased	8 (3.3%)	1 (0.4%)	9 (1.9%)
Lipase increased	8 (3.3%)	0	8 (1.7%)
Alanine aminotransferase increased	6 (2.5%)	1 (0.4%)	7 (1.5%)
White blood cell count decreased	1 (0.4%)	6 (2.5%)	7 (1.5%)
Aspartate aminotransferase increased	5 (2.1%)	0	5 (1.1%)
Amylase increased	3 (1.3%)	0	3 (0.6%)
Blood creatine phosphokinase increased	3 (1.3%)	0	3 (0.6%)
Gamma-glutamyltransferase increased	3 (1.3%)	0	3 (0.6%)
Blood creatinine increased	0	2 (0.8%)	2 (0.4%)
Blood bilirubin increased	1 (0.4%)	0	1 (0.2%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.3.1: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Electrocardiogram QT prolonged	1 (0.4%)	0	1 (0.2%)
Troponin I increased	1 (0.4%)	0	1 (0.2%)
Urine output decreased	1 (0.4%)	0	1 (0.2%)
Metabolism and nutrition disorders	41 (17.2%)	25 (10.6%)	66 (13.9%)
Hyperglycaemia	20 (8.4%)	2 (0.8%)	22 (4.6%)
Hyponatraemia	7 (2.9%)	8 (3.4%)	15 (3.2%)
Decreased appetite	5 (2.1%)	3 (1.3%)	8 (1.7%)
Hypophosphataemia	4 (1.7%)	3 (1.3%)	7 (1.5%)
Dehydration	1 (0.4%)	5 (2.1%)	6 (1.3%)
Hypokalaemia	3 (1.3%)	2 (0.8%)	5 (1.1%)
Diabetes mellitus	2 (0.8%)	1 (0.4%)	3 (0.6%)
Hypomagnesaemia	1 (0.4%)	2 (0.8%)	3 (0.6%)
Hypercalcaemia	2 (0.8%)	0	2 (0.4%)
Hyperkalaemia	0	2 (0.8%)	2 (0.4%)
Hyperlipasaemia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Hyperamylasaemia	0	1 (0.4%)	1 (0.2%)
Hypercreatininaemia	1 (0.4%)	0	1 (0.2%)
Hypoalbuminaemia	1 (0.4%)	0	1 (0.2%)
Hypocalcaemia	0	1 (0.4%)	1 (0.2%)
Hypochloraemia	0	1 (0.4%)	1 (0.2%)
Hypoglycaemia	1 (0.4%)	0	1 (0.2%)
Hypoproteinaemia	0	1 (0.4%)	1 (0.2%)
Hypovolaemia	1 (0.4%)	0	1 (0.2%)
Metabolic acidosis	1 (0.4%)	0	1 (0.2%)
Tumour lysis syndrome	1 (0.4%)	0	1 (0.2%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.3.1: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Type 2 diabetes mellitus	1 (0.4%)	0	1 (0.2%)
Gastrointestinal disorders	29 (12.1%)	17 (7.2%)	46 (9.7%)
Nausea	4 (1.7%)	9 (3.8%)	13 (2.7%)
Diarrhoea	10 (4.2%)	2 (0.8%)	12 (2.5%)
Vomiting	4 (1.7%)	5 (2.1%)	9 (1.9%)
Colitis	5 (2.1%)	0	5 (1.1%)
Abdominal pain	2 (0.8%)	2 (0.8%)	4 (0.8%)
Pancreatitis	3 (1.3%)	0	3 (0.6%)
Immune-mediated enterocolitis	2 (0.8%)	0	2 (0.4%)
Colonic fistula	1 (0.4%)	0	1 (0.2%)
Constipation	0	1 (0.4%)	1 (0.2%)
Dental caries	0	1 (0.4%)	1 (0.2%)
Duodenal stenosis	1 (0.4%)	0	1 (0.2%)
Dyspepsia	1 (0.4%)	0	1 (0.2%)
Enterovesical fistula	1 (0.4%)	0	1 (0.2%)
Gastric ulcer	1 (0.4%)	0	1 (0.2%)
Hernial eventration	1 (0.4%)	0	1 (0.2%)
Inguinal hernia	1 (0.4%)	0	1 (0.2%)
Intestinal obstruction	1 (0.4%)	0	1 (0.2%)
Large intestine perforation	1 (0.4%)	0	1 (0.2%)
Obstructive pancreatitis	0	1 (0.4%)	1 (0.2%)
Small intestinal obstruction	1 (0.4%)	0	1 (0.2%)
Skin and subcutaneous tissue disorders	39 (16.3%)	0	39 (8.2%)
Rash maculo-papular	16 (6.7%)	0	16 (3.4%)
Rash macular	7 (2.9%)	0	7 (1.5%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.3.1: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Dermatitis bullous	3 (1.3%)	0	3 (0.6%)
Eczema	3 (1.3%)	0	3 (0.6%)
Rash papular	3 (1.3%)	0	3 (0.6%)
Lichenoid keratosis	2 (0.8%)	0	2 (0.4%)
Alopecia	1 (0.4%)	0	1 (0.2%)
Dermatitis	1 (0.4%)	0	1 (0.2%)
Dermatitis exfoliative generalised	1 (0.4%)	0	1 (0.2%)
Dry skin	1 (0.4%)	0	1 (0.2%)
Erythema	1 (0.4%)	0	1 (0.2%)
Rash erythematous	1 (0.4%)	0	1 (0.2%)
Rash morbilliform	1 (0.4%)	0	1 (0.2%)
SJS-TEN overlap	1 (0.4%)	0	1 (0.2%)
Toxic epidermal necrolysis	1 (0.4%)	0	1 (0.2%)
Toxic erythema of chemotherapy	1 (0.4%)	0	1 (0.2%)
General disorders and administration site conditions	13 (5.4%)	24 (10.2%)	37 (7.8%)
Fatigue	6 (2.5%)	12 (5.1%)	18 (3.8%)
Asthenia	5 (2.1%)	6 (2.5%)	11 (2.3%)
General physical health deterioration	1 (0.4%)	2 (0.8%)	3 (0.6%)
Pyrexia	1 (0.4%)	2 (0.8%)	3 (0.6%)
Chills	0	1 (0.4%)	1 (0.2%)
Malaise	0	1 (0.4%)	1 (0.2%)
Multiple organ dysfunction syndrome	0	1 (0.4%)	1 (0.2%)
Non-cardiac chest pain	0	1 (0.4%)	1 (0.2%)
Oedema peripheral	0	1 (0.4%)	1 (0.2%)
Respiratory, thoracic and mediastinal disorders	24 (10.0%)	13 (5.5%)	37 (7.8%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.3.1: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Pulmonary embolism	5 (2.1%)	10 (4.2%)	15 (3.2%)
Pneumonitis	5 (2.1%)	1 (0.4%)	6 (1.3%)
Dyspnoea	4 (1.7%)	1 (0.4%)	5 (1.1%)
Immune-mediated lung disease	4 (1.7%)	0	4 (0.8%)
Interstitial lung disease	3 (1.3%)	0	3 (0.6%)
Respiratory failure	2 (0.8%)	0	2 (0.4%)
Acute pulmonary oedema	1 (0.4%)	0	1 (0.2%)
Acute respiratory failure	1 (0.4%)	0	1 (0.2%)
Aspiration	1 (0.4%)	0	1 (0.2%)
Cough	0	1 (0.4%)	1 (0.2%)
Haemoptysis	1 (0.4%)	0	1 (0.2%)
Hypoxia	1 (0.4%)	0	1 (0.2%)
Organising pneumonia	1 (0.4%)	0	1 (0.2%)
Pulmonary oedema	0	1 (0.4%)	1 (0.2%)
Respiratory distress	1 (0.4%)	0	1 (0.2%)
Renal and urinary disorders	16 (6.7%)	16 (6.8%)	32 (6.7%)
Acute kidney injury	8 (3.3%)	6 (2.5%)	14 (2.9%)
Haematuria	2 (0.8%)	6 (2.5%)	8 (1.7%)
Hydronephrosis	2 (0.8%)	2 (0.8%)	4 (0.8%)
Urinary retention	2 (0.8%)	2 (0.8%)	4 (0.8%)
Renal impairment	1 (0.4%)	1 (0.4%)	2 (0.4%)
Calculus bladder	1 (0.4%)	0	1 (0.2%)
Chronic kidney disease	0	1 (0.4%)	1 (0.2%)
Immune-mediated nephritis	1 (0.4%)	0	1 (0.2%)
Postrenal failure	1 (0.4%)	0	1 (0.2%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.3.1: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Urinary tract obstruction	1 (0.4%)	0	1 (0.2%)
Nervous system disorders	24 (10.0%)	5 (2.1%)	29 (6.1%)
Peripheral sensory neuropathy	7 (2.9%)	0	7 (1.5%)
Peripheral sensorimotor neuropathy	5 (2.1%)	0	5 (1.1%)
Syncope	3 (1.3%)	2 (0.8%)	5 (1.1%)
Peripheral motor neuropathy	3 (1.3%)	0	3 (0.6%)
Cerebral infarction	0	2 (0.8%)	2 (0.4%)
Ageusia	1 (0.4%)	0	1 (0.2%)
Cerebral haemorrhage	1 (0.4%)	0	1 (0.2%)
Chronic inflammatory demyelinating polyradiculoneuropathy	1 (0.4%)	0	1 (0.2%)
Diabetic hyperglycaemic coma	1 (0.4%)	0	1 (0.2%)
Headache	0	1 (0.4%)	1 (0.2%)
Immune-mediated encephalitis	1 (0.4%)	0	1 (0.2%)
Neurotoxicity	1 (0.4%)	0	1 (0.2%)
Musculoskeletal and connective tissue disorders	10 (4.2%)	8 (3.4%)	18 (3.8%)
Back pain	4 (1.7%)	1 (0.4%)	5 (1.1%)
Pain in extremity	1 (0.4%)	2 (0.8%)	3 (0.6%)
Bone pain	0	2 (0.8%)	2 (0.4%)
Muscular weakness	2 (0.8%)	0	2 (0.4%)
Myositis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Arthropathy	1 (0.4%)	0	1 (0.2%)
Gouty arthritis	1 (0.4%)	0	1 (0.2%)
Mobility decreased	0	1 (0.4%)	1 (0.2%)
Myalgia	0	1 (0.4%)	1 (0.2%)
Pathological fracture	0	1 (0.4%)	1 (0.2%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.3.1: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Rhabdomyolysis	0	1 (0.4%)	1 (0.2%)
Vascular disorders	9 (3.8%)	8 (3.4%)	17 (3.6%)
Hypertension	5 (2.1%)	5 (2.1%)	10 (2.1%)
Hypotension	2 (0.8%)	2 (0.8%)	4 (0.8%)
Deep vein thrombosis	0	1 (0.4%)	1 (0.2%)
Lymphoedema	1 (0.4%)	0	1 (0.2%)
Peripheral arterial occlusive disease	1 (0.4%)	0	1 (0.2%)
Cardiac disorders	6 (2.5%)	9 (3.8%)	15 (3.2%)
Atrial fibrillation	0	3 (1.3%)	3 (0.6%)
Cardiac arrest	2 (0.8%)	0	2 (0.4%)
Acute coronary syndrome	1 (0.4%)	0	1 (0.2%)
Acute myocardial infarction	0	1 (0.4%)	1 (0.2%)
Acute right ventricular failure	0	1 (0.4%)	1 (0.2%)
Angina pectoris	0	1 (0.4%)	1 (0.2%)
Atrioventricular block complete	1 (0.4%)	0	1 (0.2%)
Cardio-respiratory arrest	1 (0.4%)	0	1 (0.2%)
Cardiogenic shock	0	1 (0.4%)	1 (0.2%)
Myocardial infarction	0	1 (0.4%)	1 (0.2%)
Pericardial effusion	0	1 (0.4%)	1 (0.2%)
Supraventricular tachycardia	0	1 (0.4%)	1 (0.2%)
Tachycardia	1 (0.4%)	0	1 (0.2%)
Hepatobiliary disorders	9 (3.8%)	1 (0.4%)	10 (2.1%)
Cholecystitis	2 (0.8%)	0	2 (0.4%)
Hepatotoxicity	2 (0.8%)	0	2 (0.4%)
Immune-mediated hepatitis	2 (0.8%)	0	2 (0.4%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.3.1: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Autoimmune hepatitis	1 (0.4%)	0	1 (0.2%)
Hepatitis	1 (0.4%)	0	1 (0.2%)
Hepatitis toxic	0	1 (0.4%)	1 (0.2%)
Hypertransaminasaemia	1 (0.4%)	0	1 (0.2%)
Injury, poisoning and procedural complications	6 (2.5%)	3 (1.3%)	9 (1.9%)
Urinary tract stoma complication	3 (1.3%)	1 (0.4%)	4 (0.8%)
Heat stroke	1 (0.4%)	0	1 (0.2%)
Skin laceration	1 (0.4%)	0	1 (0.2%)
Spinal fracture	1 (0.4%)	0	1 (0.2%)
Tibia fracture	0	1 (0.4%)	1 (0.2%)
Toxicity to various agents	0	1 (0.4%)	1 (0.2%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (1.3%)	2 (0.8%)	5 (1.1%)
Burkitt's lymphoma	1 (0.4%)	0	1 (0.2%)
Cancer pain	1 (0.4%)	0	1 (0.2%)
Metastases to central nervous system	0	1 (0.4%)	1 (0.2%)
Tumour pain	0	1 (0.4%)	1 (0.2%)
Tumour rupture	1 (0.4%)	0	1 (0.2%)
Reproductive system and breast disorders	2 (0.8%)	2 (0.8%)	4 (0.8%)
Pelvic pain	1 (0.4%)	1 (0.4%)	2 (0.4%)
Penile pain	1 (0.4%)	0	1 (0.2%)
Prostatitis	1 (0.4%)	0	1 (0.2%)
Vaginal haemorrhage	0	1 (0.4%)	1 (0.2%)
Endocrine disorders	3 (1.3%)	0	3 (0.6%)
Adrenal insufficiency	1 (0.4%)	0	1 (0.2%)
Hypothyroidism	1 (0.4%)	0	1 (0.2%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.3.1: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Inappropriate antidiuretic hormone secretion	1 (0.4%)	0	1 (0.2%)
Eye disorders	3 (1.3%)	0	3 (0.6%)
Cataract	2 (0.8%)	0	2 (0.4%)
Retinopathy hypertensive	1 (0.4%)	0	1 (0.2%)
Psychiatric disorders	2 (0.8%)	0	2 (0.4%)
Anxiety	1 (0.4%)	0	1 (0.2%)
Confusional state	1 (0.4%)	0	1 (0.2%)
Ear and labyrinth disorders	1 (0.4%)	0	1 (0.2%)
Vertigo	1 (0.4%)	0	1 (0.2%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.3.2: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Overall	158 (78.6%)	166 (84.3%)	324 (81.4%)
Blood and lymphatic system disorders	44 (21.9%)	135 (68.5%)	179 (45.0%)
Anaemia	27 (13.4%)	80 (40.6%)	107 (26.9%)
Neutropenia	14 (7.0%)	78 (39.6%)	92 (23.1%)
Thrombocytopenia	2 (1.0%)	59 (29.9%)	61 (15.3%)
Leukopenia	2 (1.0%)	13 (6.6%)	15 (3.8%)
Febrile neutropenia	1 (0.5%)	10 (5.1%)	11 (2.8%)
Pancytopenia	0	4 (2.0%)	4 (1.0%)
Leukocytosis	2 (1.0%)	0	2 (0.5%)
Haemolytic anaemia	0	1 (0.5%)	1 (0.3%)
Immune thrombocytopenia	1 (0.5%)	0	1 (0.3%)
Myelosuppression	0	1 (0.5%)	1 (0.3%)
Infections and infestations	49 (24.4%)	36 (18.3%)	85 (21.4%)
Urinary tract infection	14 (7.0%)	16 (8.1%)	30 (7.5%)
Pyelonephritis	4 (2.0%)	6 (3.0%)	10 (2.5%)
Pneumonia	7 (3.5%)	2 (1.0%)	9 (2.3%)
Sepsis	6 (3.0%)	2 (1.0%)	8 (2.0%)
COVID-19	4 (2.0%)	1 (0.5%)	5 (1.3%)
Pneumonia aspiration	4 (2.0%)	0	4 (1.0%)
Pyelonephritis acute	1 (0.5%)	2 (1.0%)	3 (0.8%)
Respiratory tract infection	0	3 (1.5%)	3 (0.8%)
Septic shock	3 (1.5%)	0	3 (0.8%)
Urosepsis	1 (0.5%)	2 (1.0%)	3 (0.8%)
Clostridium difficile infection	2 (1.0%)	0	2 (0.5%)
COVID-19 pneumonia	1 (0.5%)	1 (0.5%)	2 (0.5%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.3.2: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Cystitis	2 (1.0%)	0	2 (0.5%)
Neutropenic sepsis	1 (0.5%)	1 (0.5%)	2 (0.5%)
Peritonitis	0	2 (1.0%)	2 (0.5%)
Campylobacter gastroenteritis	1 (0.5%)	0	1 (0.3%)
Cellulitis	1 (0.5%)	0	1 (0.3%)
Cytomegalovirus colitis	1 (0.5%)	0	1 (0.3%)
Device related infection	1 (0.5%)	0	1 (0.3%)
Diverticulitis	0	1 (0.5%)	1 (0.3%)
Enterocolitis infectious	1 (0.5%)	0	1 (0.3%)
Herpes simplex	1 (0.5%)	0	1 (0.3%)
Infectious pleural effusion	1 (0.5%)	0	1 (0.3%)
Klebsiella sepsis	0	1 (0.5%)	1 (0.3%)
Respiratory syncytial virus infection	0	1 (0.5%)	1 (0.3%)
Skin infection	1 (0.5%)	0	1 (0.3%)
Metabolism and nutrition disorders	45 (22.4%)	21 (10.7%)	66 (16.6%)
Hyponatraemia	15 (7.5%)	7 (3.6%)	22 (5.5%)
Hyperglycaemia	12 (6.0%)	1 (0.5%)	13 (3.3%)
Decreased appetite	3 (1.5%)	5 (2.5%)	8 (2.0%)
Hypokalaemia	5 (2.5%)	2 (1.0%)	7 (1.8%)
Hypophosphataemia	5 (2.5%)	2 (1.0%)	7 (1.8%)
Hyperkalaemia	1 (0.5%)	4 (2.0%)	5 (1.3%)
Dehydration	3 (1.5%)	1 (0.5%)	4 (1.0%)
Hypocalcaemia	3 (1.5%)	0	3 (0.8%)
Hypomagnesaemia	2 (1.0%)	0	2 (0.5%)
Type 2 diabetes mellitus	2 (1.0%)	0	2 (0.5%)

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ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.3.2: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Diabetes mellitus	1 (0.5%)	0	1 (0.3%)
Failure to thrive	0	1 (0.5%)	1 (0.3%)
Hyperamylasaemia	1 (0.5%)	0	1 (0.3%)
Hypercalcaemia	0	1 (0.5%)	1 (0.3%)
Hyperlipasaemia	1 (0.5%)	0	1 (0.3%)
Hypoalbuminaemia	1 (0.5%)	0	1 (0.3%)
Hypochloraemia	1 (0.5%)	0	1 (0.3%)
Lactic acidosis	0	1 (0.5%)	1 (0.3%)
Type 1 diabetes mellitus	1 (0.5%)	0	1 (0.3%)
Investigations	29 (14.4%)	36 (18.3%)	65 (16.3%)
Neutrophil count decreased	7 (3.5%)	19 (9.6%)	26 (6.5%)
Platelet count decreased	0	17 (8.6%)	17 (4.3%)
Weight decreased	8 (4.0%)	0	8 (2.0%)
White blood cell count decreased	0	7 (3.6%)	7 (1.8%)
Alanine aminotransferase increased	3 (1.5%)	2 (1.0%)	5 (1.3%)
Aspartate aminotransferase increased	3 (1.5%)	1 (0.5%)	4 (1.0%)
Lymphocyte count decreased	3 (1.5%)	1 (0.5%)	4 (1.0%)
Amylase increased	2 (1.0%)	0	2 (0.5%)
Blood alkaline phosphatase increased	2 (1.0%)	0	2 (0.5%)
Gamma-glutamyltransferase increased	2 (1.0%)	0	2 (0.5%)
Blood bilirubin increased	1 (0.5%)	0	1 (0.3%)
Blood creatinine increased	0	1 (0.5%)	1 (0.3%)
Blood lactic acid increased	1 (0.5%)	0	1 (0.3%)
C-reactive protein increased	0	1 (0.5%)	1 (0.3%)
Electrocardiogram QT prolonged	1 (0.5%)	0	1 (0.3%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
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Table 302.1.2001.3.2: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
False positive investigation result	0	1 (0.5%)	1 (0.3%)
International normalised ratio increased	1 (0.5%)	0	1 (0.3%)
Lipase increased	1 (0.5%)	0	1 (0.3%)
Prothrombin time prolonged	1 (0.5%)	0	1 (0.3%)
Weight increased	1 (0.5%)	0	1 (0.3%)
General disorders and administration site conditions	25 (12.4%)	23 (11.7%)	48 (12.1%)
Fatigue	11 (5.5%)	8 (4.1%)	19 (4.8%)
Asthenia	6 (3.0%)	5 (2.5%)	11 (2.8%)
General physical health deterioration	0	6 (3.0%)	6 (1.5%)
Pyrexia	2 (1.0%)	3 (1.5%)	5 (1.3%)
Gait disturbance	2 (1.0%)	0	2 (0.5%)
Malaise	0	2 (1.0%)	2 (0.5%)
Multiple organ dysfunction syndrome	1 (0.5%)	1 (0.5%)	2 (0.5%)
Condition aggravated	1 (0.5%)	0	1 (0.3%)
Death	1 (0.5%)	0	1 (0.3%)
Non-cardiac chest pain	0	1 (0.5%)	1 (0.3%)
Pain	1 (0.5%)	0	1 (0.3%)
Performance status decreased	1 (0.5%)	0	1 (0.3%)
Sudden death	1 (0.5%)	0	1 (0.3%)
Gastrointestinal disorders	27 (13.4%)	16 (8.1%)	43 (10.8%)
Diarrhoea	11 (5.5%)	4 (2.0%)	15 (3.8%)
Nausea	3 (1.5%)	3 (1.5%)	6 (1.5%)
Abdominal pain	4 (2.0%)	1 (0.5%)	5 (1.3%)
Vomiting	2 (1.0%)	2 (1.0%)	4 (1.0%)
Constipation	0	2 (1.0%)	2 (0.5%)

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Table 302.1.2001.3.2: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Intestinal obstruction	1 (0.5%)	1 (0.5%)	2 (0.5%)
Pancreatitis acute	1 (0.5%)	1 (0.5%)	2 (0.5%)
Anal incontinence	0	1 (0.5%)	1 (0.3%)
Colitis ulcerative	1 (0.5%)	0	1 (0.3%)
Duodenal ulcer	1 (0.5%)	0	1 (0.3%)
Dyspepsia	0	1 (0.5%)	1 (0.3%)
Enterovesical fistula	1 (0.5%)	0	1 (0.3%)
Gastric haemorrhage	0	1 (0.5%)	1 (0.3%)
Gastrointestinal haemorrhage	1 (0.5%)	0	1 (0.3%)
Haematemesis	0	1 (0.5%)	1 (0.3%)
Haemorrhoidal haemorrhage	0	1 (0.5%)	1 (0.3%)
Large intestinal ulcer haemorrhage	1 (0.5%)	0	1 (0.3%)
Malignant gastrointestinal obstruction	1 (0.5%)	0	1 (0.3%)
Rectal haemorrhage	1 (0.5%)	0	1 (0.3%)
Small intestinal perforation	0	1 (0.5%)	1 (0.3%)
Stomatitis	1 (0.5%)	0	1 (0.3%)
Skin and subcutaneous tissue disorders	40 (19.9%)	2 (1.0%)	42 (10.6%)
Rash maculo-papular	21 (10.4%)	0	21 (5.3%)
Pruritus	5 (2.5%)	0	5 (1.3%)
Rash papular	3 (1.5%)	0	3 (0.8%)
Alopecia	1 (0.5%)	1 (0.5%)	2 (0.5%)
Dermatitis	2 (1.0%)	0	2 (0.5%)
Pemphigoid	2 (1.0%)	0	2 (0.5%)
Toxic epidermal necrolysis	2 (1.0%)	0	2 (0.5%)
Acute generalised exanthematous pustulosis	0	1 (0.5%)	1 (0.3%)

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Table 302.1.2001.3.2: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Blister	1 (0.5%)	0	1 (0.3%)
Dermatitis exfoliative	1 (0.5%)	0	1 (0.3%)
Eczema	1 (0.5%)	0	1 (0.3%)
Papule	1 (0.5%)	0	1 (0.3%)
Rash erythematous	1 (0.5%)	0	1 (0.3%)
Rash macular	1 (0.5%)	0	1 (0.3%)
Rash morbilliform	1 (0.5%)	0	1 (0.3%)
Rash pruritic	1 (0.5%)	0	1 (0.3%)
Vitiligo	1 (0.5%)	0	1 (0.3%)
Renal and urinary disorders	25 (12.4%)	15 (7.6%)	40 (10.1%)
Acute kidney injury	14 (7.0%)	4 (2.0%)	18 (4.5%)
Haematuria	5 (2.5%)	4 (2.0%)	9 (2.3%)
Renal impairment	3 (1.5%)	2 (1.0%)	5 (1.3%)
Chronic kidney disease	1 (0.5%)	3 (1.5%)	4 (1.0%)
Renal failure	3 (1.5%)	1 (0.5%)	4 (1.0%)
Hydronephrosis	2 (1.0%)	1 (0.5%)	3 (0.8%)
Proteinuria	1 (0.5%)	1 (0.5%)	2 (0.5%)
Urinary tract obstruction	1 (0.5%)	1 (0.5%)	2 (0.5%)
Urinoma	0	1 (0.5%)	1 (0.3%)
Respiratory, thoracic and mediastinal disorders	16 (8.0%)	16 (8.1%)	32 (8.0%)
Pulmonary embolism	9 (4.5%)	7 (3.6%)	16 (4.0%)
Dyspnoea	2 (1.0%)	4 (2.0%)	6 (1.5%)
Chronic obstructive pulmonary disease	0	3 (1.5%)	3 (0.8%)
Acute respiratory failure	2 (1.0%)	0	2 (0.5%)
Hypoxia	2 (1.0%)	0	2 (0.5%)

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Table 302.1.2001.3.2: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Pneumonitis	2 (1.0%)	0	2 (0.5%)
Respiratory failure	1 (0.5%)	1 (0.5%)	2 (0.5%)
Alveolitis	0	1 (0.5%)	1 (0.3%)
Haemoptysis	0	1 (0.5%)	1 (0.3%)
Immune-mediated lung disease	1 (0.5%)	0	1 (0.3%)
Interstitial lung disease	1 (0.5%)	0	1 (0.3%)
Pleural effusion	0	1 (0.5%)	1 (0.3%)
Pneumothorax	0	1 (0.5%)	1 (0.3%)
Nervous system disorders	20 (10.0%)	4 (2.0%)	24 (6.0%)
Peripheral sensory neuropathy	11 (5.5%)	0	11 (2.8%)
Peripheral sensorimotor neuropathy	3 (1.5%)	0	3 (0.8%)
Syncope	1 (0.5%)	2 (1.0%)	3 (0.8%)
Cerebrovascular accident	1 (0.5%)	1 (0.5%)	2 (0.5%)
Dizziness	1 (0.5%)	1 (0.5%)	2 (0.5%)
Hypoaesthesia	1 (0.5%)	0	1 (0.3%)
Immune-mediated neuropathy	1 (0.5%)	0	1 (0.3%)
Nervous system disorder	1 (0.5%)	0	1 (0.3%)
Peripheral motor neuropathy	1 (0.5%)	0	1 (0.3%)
Seizure	1 (0.5%)	0	1 (0.3%)
Hepatobiliary disorders	8 (4.0%)	7 (3.6%)	15 (3.8%)
Hypertransaminasaemia	1 (0.5%)	4 (2.0%)	5 (1.3%)
Hepatic function abnormal	0	3 (1.5%)	3 (0.8%)
Hepatitis	2 (1.0%)	0	2 (0.5%)
Immune-mediated hepatitis	2 (1.0%)	0	2 (0.5%)
Cholangitis sclerosing	1 (0.5%)	0	1 (0.3%)

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Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.3.2: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Immune-mediated hepatic disorder	1 (0.5%)	0	1 (0.3%)
Portal vein thrombosis	1 (0.5%)	0	1 (0.3%)
Cardiac disorders	8 (4.0%)	4 (2.0%)	12 (3.0%)
Acute myocardial infarction	2 (1.0%)	2 (1.0%)	4 (1.0%)
Cardiac failure	3 (1.5%)	0	3 (0.8%)
Angina pectoris	0	1 (0.5%)	1 (0.3%)
Atrial fibrillation	0	1 (0.5%)	1 (0.3%)
Cardiac arrest	0	1 (0.5%)	1 (0.3%)
Cardio-respiratory arrest	1 (0.5%)	0	1 (0.3%)
Immune-mediated myocarditis	1 (0.5%)	0	1 (0.3%)
Myocardial infarction	1 (0.5%)	0	1 (0.3%)
Myocardial ischaemia	0	1 (0.5%)	1 (0.3%)
Stress cardiomyopathy	0	1 (0.5%)	1 (0.3%)
Ventricular tachycardia	1 (0.5%)	0	1 (0.3%)
Musculoskeletal and connective tissue disorders	6 (3.0%)	4 (2.0%)	10 (2.5%)
Arthralgia	2 (1.0%)	0	2 (0.5%)
Muscular weakness	2 (1.0%)	0	2 (0.5%)
Pain in extremity	0	2 (1.0%)	2 (0.5%)
Arthritis	1 (0.5%)	0	1 (0.3%)
Back pain	0	1 (0.5%)	1 (0.3%)
Musculoskeletal pain	1 (0.5%)	0	1 (0.3%)
Pathological fracture	0	1 (0.5%)	1 (0.3%)
Vascular disorders	5 (2.5%)	4 (2.0%)	9 (2.3%)
Deep vein thrombosis	0	2 (1.0%)	2 (0.5%)
Aortic aneurysm rupture	1 (0.5%)	0	1 (0.3%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.3.2: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Hypertension	0	1 (0.5%)	1 (0.3%)
Hypertensive crisis	1 (0.5%)	0	1 (0.3%)
Hypotension	1 (0.5%)	0	1 (0.3%)
Iliac artery occlusion	1 (0.5%)	0	1 (0.3%)
Orthostatic hypotension	1 (0.5%)	0	1 (0.3%)
Shock	0	1 (0.5%)	1 (0.3%)
Injury, poisoning and procedural complications	2 (1.0%)	3 (1.5%)	5 (1.3%)
Femur fracture	2 (1.0%)	1 (0.5%)	3 (0.8%)
Infusion related reaction	0	1 (0.5%)	1 (0.3%)
Urinary tract stoma complication	0	1 (0.5%)	1 (0.3%)
Psychiatric disorders	4 (2.0%)	1 (0.5%)	5 (1.3%)
Delirium	2 (1.0%)	0	2 (0.5%)
Affect lability	0	1 (0.5%)	1 (0.3%)
Confusional state	1 (0.5%)	0	1 (0.3%)
Insomnia	1 (0.5%)	0	1 (0.3%)
Endocrine disorders	3 (1.5%)	1 (0.5%)	4 (1.0%)
Adrenal insufficiency	1 (0.5%)	0	1 (0.3%)
Hypercalcaemia of malignancy	0	1 (0.5%)	1 (0.3%)
Hyperthyroidism	1 (0.5%)	0	1 (0.3%)
Hypothyroidism	1 (0.5%)	0	1 (0.3%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.5%)	3 (1.5%)	4 (1.0%)
Cancer pain	0	2 (1.0%)	2 (0.5%)
Chronic lymphocytic leukaemia	1 (0.5%)	0	1 (0.3%)
Tumour pain	0	1 (0.5%)	1 (0.3%)
Reproductive system and breast disorders	0	2 (1.0%)	2 (0.5%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.3.2: Frequency Summary of Severe Treatment Emergent Adverse Events (CTCAE Grade >=3) - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Prostatitis	0	1 (0.5%)	1 (0.3%)
Vaginal haemorrhage	0	1 (0.5%)	1 (0.3%)
Immune system disorders	1 (0.5%)	0	1 (0.3%)
Sarcoidosis	1 (0.5%)	0	1 (0.3%)
Product issues	0	1 (0.5%)	1 (0.3%)
Device occlusion	0	1 (0.5%)	1 (0.3%)

Abbreviations: CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.4.1: Frequency Summary of Treatment Emergent Serious Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Overall	107 (44.8%)	83 (35.2%)	190 (40.0%)
Infections and infestations	24 (10.0%)	39 (16.5%)	63 (13.3%)
Urinary tract infection	4 (1.7%)	17 (7.2%)	21 (4.4%)
Sepsis	2 (0.8%)	6 (2.5%)	8 (1.7%)
COVID-19	2 (0.8%)	4 (1.7%)	6 (1.3%)
Pneumonia	3 (1.3%)	3 (1.3%)	6 (1.3%)
COVID-19 pneumonia	3 (1.3%)	2 (0.8%)	5 (1.1%)
Device related infection	1 (0.4%)	2 (0.8%)	3 (0.6%)
Urosepsis	1 (0.4%)	2 (0.8%)	3 (0.6%)
Pyelonephritis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Respiratory tract infection	1 (0.4%)	1 (0.4%)	2 (0.4%)
Abdominal abscess	0	1 (0.4%)	1 (0.2%)
Bacteraemia	1 (0.4%)	0	1 (0.2%)
Cellulitis	1 (0.4%)	0	1 (0.2%)
Diverticulitis	1 (0.4%)	0	1 (0.2%)
Escherichia infection	0	1 (0.4%)	1 (0.2%)
Infectious pleural effusion	1 (0.4%)	0	1 (0.2%)
Kidney infection	0	1 (0.4%)	1 (0.2%)
Neutropenic sepsis	0	1 (0.4%)	1 (0.2%)
Oesophageal candidiasis	1 (0.4%)	0	1 (0.2%)
Pelvic infection	1 (0.4%)	0	1 (0.2%)
Perineal abscess	0	1 (0.4%)	1 (0.2%)
Pneumonia haemophilus	0	1 (0.4%)	1 (0.2%)
Respiratory syncytial virus infection	0	1 (0.4%)	1 (0.2%)
Staphylococcal bacteraemia	1 (0.4%)	0	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.4.1: Frequency Summary of Treatment Emergent Serious Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Urinary tract infection bacterial	0	1 (0.4%)	1 (0.2%)
Urinary tract infection pseudomonal	0	1 (0.4%)	1 (0.2%)
Urinary tract infection staphylococcal	1 (0.4%)	0	1 (0.2%)
Wound infection	0	1 (0.4%)	1 (0.2%)
Renal and urinary disorders	18 (7.5%)	17 (7.2%)	35 (7.4%)
Acute kidney injury	9 (3.8%)	7 (3.0%)	16 (3.4%)
Haematuria	2 (0.8%)	7 (3.0%)	9 (1.9%)
Hydronephrosis	2 (0.8%)	2 (0.8%)	4 (0.8%)
Urinary retention	2 (0.8%)	2 (0.8%)	4 (0.8%)
Calculus bladder	2 (0.8%)	0	2 (0.4%)
Renal impairment	1 (0.4%)	1 (0.4%)	2 (0.4%)
Immune-mediated nephritis	1 (0.4%)	0	1 (0.2%)
Postrenal failure	1 (0.4%)	0	1 (0.2%)
Urinary tract obstruction	1 (0.4%)	0	1 (0.2%)
Gastrointestinal disorders	24 (10.0%)	6 (2.5%)	30 (6.3%)
Diarrhoea	7 (2.9%)	0	7 (1.5%)
Abdominal pain	4 (1.7%)	1 (0.4%)	5 (1.1%)
Nausea	2 (0.8%)	3 (1.3%)	5 (1.1%)
Vomiting	3 (1.3%)	1 (0.4%)	4 (0.8%)
Colitis	3 (1.3%)	0	3 (0.6%)
Immune-mediated enterocolitis	3 (1.3%)	0	3 (0.6%)
Gastric ulcer	1 (0.4%)	1 (0.4%)	2 (0.4%)
Pancreatitis	2 (0.8%)	0	2 (0.4%)
Ascites	1 (0.4%)	0	1 (0.2%)
Colonic fistula	1 (0.4%)	0	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.4.1: Frequency Summary of Treatment Emergent Serious Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Duodenal stenosis	1 (0.4%)	0	1 (0.2%)
Duodenitis	0	1 (0.4%)	1 (0.2%)
Dyspepsia	1 (0.4%)	0	1 (0.2%)
Enterovesical fistula	1 (0.4%)	0	1 (0.2%)
Inguinal hernia	1 (0.4%)	0	1 (0.2%)
Intestinal obstruction	1 (0.4%)	0	1 (0.2%)
Large intestine perforation	1 (0.4%)	0	1 (0.2%)
Obstructive pancreatitis	0	1 (0.4%)	1 (0.2%)
Small intestinal obstruction	1 (0.4%)	0	1 (0.2%)
Respiratory, thoracic and mediastinal disorders	25 (10.5%)	4 (1.7%)	29 (6.1%)
Pneumonitis	7 (2.9%)	0	7 (1.5%)
Pulmonary embolism	4 (1.7%)	2 (0.8%)	6 (1.3%)
Dyspnoea	3 (1.3%)	1 (0.4%)	4 (0.8%)
Immune-mediated lung disease	4 (1.7%)	0	4 (0.8%)
Interstitial lung disease	3 (1.3%)	0	3 (0.6%)
Acute respiratory failure	1 (0.4%)	0	1 (0.2%)
Aspiration	1 (0.4%)	0	1 (0.2%)
Cough	0	1 (0.4%)	1 (0.2%)
Haemoptysis	1 (0.4%)	0	1 (0.2%)
Hypoxia	1 (0.4%)	0	1 (0.2%)
Organising pneumonia	1 (0.4%)	0	1 (0.2%)
Pharyngeal dyskinesia	1 (0.4%)	0	1 (0.2%)
Respiratory distress	1 (0.4%)	0	1 (0.2%)
Respiratory failure	1 (0.4%)	0	1 (0.2%)
Metabolism and nutrition disorders	14 (5.9%)	10 (4.2%)	24 (5.1%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.4.1: Frequency Summary of Treatment Emergent Serious Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Decreased appetite	5 (2.1%)	0	5 (1.1%)
Dehydration	1 (0.4%)	4 (1.7%)	5 (1.1%)
Hyponatraemia	2 (0.8%)	3 (1.3%)	5 (1.1%)
Hyperglycaemia	4 (1.7%)	0	4 (0.8%)
Diabetes mellitus	1 (0.4%)	1 (0.4%)	2 (0.4%)
Hypocalcaemia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Hypercreatininaemia	1 (0.4%)	0	1 (0.2%)
Hyperkalaemia	0	1 (0.4%)	1 (0.2%)
Hypokalaemia	1 (0.4%)	0	1 (0.2%)
Hypomagnesaemia	1 (0.4%)	0	1 (0.2%)
Hypophosphataemia	1 (0.4%)	0	1 (0.2%)
Hypovolaemia	1 (0.4%)	0	1 (0.2%)
Metabolic acidosis	1 (0.4%)	0	1 (0.2%)
Blood and lymphatic system disorders	5 (2.1%)	16 (6.8%)	21 (4.4%)
Anaemia	0	10 (4.2%)	10 (2.1%)
Febrile neutropenia	3 (1.3%)	3 (1.3%)	6 (1.3%)
Thrombocytopenia	0	5 (2.1%)	5 (1.1%)
Neutropenia	0	3 (1.3%)	3 (0.6%)
Anaemia of malignant disease	1 (0.4%)	0	1 (0.2%)
Leukopenia	1 (0.4%)	0	1 (0.2%)
Cardiac disorders	7 (2.9%)	10 (4.2%)	17 (3.6%)
Atrial fibrillation	0	3 (1.3%)	3 (0.6%)
Cardiac arrest	2 (0.8%)	0	2 (0.4%)
Acute coronary syndrome	1 (0.4%)	0	1 (0.2%)
Acute myocardial infarction	0	1 (0.4%)	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.4.1: Frequency Summary of Treatment Emergent Serious Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Acute right ventricular failure	0	1 (0.4%)	1 (0.2%)
Angina pectoris	0	1 (0.4%)	1 (0.2%)
Atrioventricular block complete	1 (0.4%)	0	1 (0.2%)
Cardio-respiratory arrest	1 (0.4%)	0	1 (0.2%)
Cardiogenic shock	0	1 (0.4%)	1 (0.2%)
Myocardial infarction	0	1 (0.4%)	1 (0.2%)
Myocarditis	1 (0.4%)	0	1 (0.2%)
Pericardial effusion	0	1 (0.4%)	1 (0.2%)
Sinus tachycardia	0	1 (0.4%)	1 (0.2%)
Supraventricular tachycardia	0	1 (0.4%)	1 (0.2%)
Tachycardia	1 (0.4%)	0	1 (0.2%)
General disorders and administration site conditions	8 (3.3%)	8 (3.4%)	16 (3.4%)
Pyrexia	3 (1.3%)	3 (1.3%)	6 (1.3%)
Fatigue	2 (0.8%)	2 (0.8%)	4 (0.8%)
Asthenia	2 (0.8%)	1 (0.4%)	3 (0.6%)
General physical health deterioration	1 (0.4%)	0	1 (0.2%)
Malaise	0	1 (0.4%)	1 (0.2%)
Oedema peripheral	0	1 (0.4%)	1 (0.2%)
Skin and subcutaneous tissue disorders	15 (6.3%)	0	15 (3.2%)
Dermatitis bullous	3 (1.3%)	0	3 (0.6%)
Rash macular	2 (0.8%)	0	2 (0.4%)
Rash maculo-papular	2 (0.8%)	0	2 (0.4%)
Dermatitis	1 (0.4%)	0	1 (0.2%)
Dermatitis exfoliative generalised	1 (0.4%)	0	1 (0.2%)
Eczema	1 (0.4%)	0	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.4.1: Frequency Summary of Treatment Emergent Serious Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Rash	1 (0.4%)	0	1 (0.2%)
Rash morbilliform	1 (0.4%)	0	1 (0.2%)
SJS-TEN overlap	1 (0.4%)	0	1 (0.2%)
Toxic epidermal necrolysis	1 (0.4%)	0	1 (0.2%)
Toxic erythema of chemotherapy	1 (0.4%)	0	1 (0.2%)
Nervous system disorders	11 (4.6%)	3 (1.3%)	14 (2.9%)
Syncope	2 (0.8%)	2 (0.8%)	4 (0.8%)
Cerebral haemorrhage	1 (0.4%)	0	1 (0.2%)
Cerebral infarction	0	1 (0.4%)	1 (0.2%)
Chronic inflammatory demyelinating polyradiculoneuropathy	1 (0.4%)	0	1 (0.2%)
Diabetic hyperglycaemic coma	1 (0.4%)	0	1 (0.2%)
Immune-mediated encephalitis	1 (0.4%)	0	1 (0.2%)
Optic neuritis	1 (0.4%)	0	1 (0.2%)
Partial seizures	1 (0.4%)	0	1 (0.2%)
Peripheral sensorimotor neuropathy	1 (0.4%)	0	1 (0.2%)
Peripheral sensory neuropathy	1 (0.4%)	0	1 (0.2%)
Seizure	1 (0.4%)	0	1 (0.2%)
Musculoskeletal and connective tissue disorders	5 (2.1%)	6 (2.5%)	11 (2.3%)
Back pain	3 (1.3%)	1 (0.4%)	4 (0.8%)
Bone lesion	1 (0.4%)	0	1 (0.2%)
Bone pain	0	1 (0.4%)	1 (0.2%)
Mobility decreased	0	1 (0.4%)	1 (0.2%)
Muscular weakness	1 (0.4%)	0	1 (0.2%)
Myositis	0	1 (0.4%)	1 (0.2%)
Pathological fracture	0	1 (0.4%)	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.4.1: Frequency Summary of Treatment Emergent Serious Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Rhabdomyolysis	0	1 (0.4%)	1 (0.2%)
Injury, poisoning and procedural complications	4 (1.7%)	5 (2.1%)	9 (1.9%)
Urinary tract stoma complication	3 (1.3%)	2 (0.8%)	5 (1.1%)
Heat stroke	1 (0.4%)	0	1 (0.2%)
Sternal fracture	0	1 (0.4%)	1 (0.2%)
Tibia fracture	0	1 (0.4%)	1 (0.2%)
Toxicity to various agents	0	1 (0.4%)	1 (0.2%)
Investigations	5 (2.1%)	4 (1.7%)	9 (1.9%)
Platelet count decreased	0	3 (1.3%)	3 (0.6%)
Aspartate aminotransferase increased	2 (0.8%)	0	2 (0.4%)
Alanine aminotransferase increased	1 (0.4%)	0	1 (0.2%)
Blood bilirubin increased	1 (0.4%)	0	1 (0.2%)
Blood creatinine increased	0	1 (0.4%)	1 (0.2%)
Lipase increased	1 (0.4%)	0	1 (0.2%)
Neutrophil count decreased	1 (0.4%)	0	1 (0.2%)
Oxygen saturation decreased	1 (0.4%)	0	1 (0.2%)
Vascular disorders	2 (0.8%)	5 (2.1%)	7 (1.5%)
Deep vein thrombosis	0	3 (1.3%)	3 (0.6%)
Hypotension	1 (0.4%)	1 (0.4%)	2 (0.4%)
Lymphocele	0	1 (0.4%)	1 (0.2%)
Lymphoedema	1 (0.4%)	0	1 (0.2%)
Hepatobiliary disorders	6 (2.5%)	0	6 (1.3%)
Cholecystitis	3 (1.3%)	0	3 (0.6%)
Autoimmune hepatitis	1 (0.4%)	0	1 (0.2%)
Hepatotoxicity	1 (0.4%)	0	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.4.1: Frequency Summary of Treatment Emergent Serious Adverse Events - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Immune-mediated hepatitis	1 (0.4%)	0	1 (0.2%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (1.3%)	1 (0.4%)	4 (0.8%)
Burkitt's lymphoma	1 (0.4%)	0	1 (0.2%)
Cancer pain	1 (0.4%)	0	1 (0.2%)
Metastases to central nervous system	0	1 (0.4%)	1 (0.2%)
Tumour rupture	1 (0.4%)	0	1 (0.2%)
Psychiatric disorders	3 (1.3%)	0	3 (0.6%)
Confusional state	2 (0.8%)	0	2 (0.4%)
Anxiety	1 (0.4%)	0	1 (0.2%)
Disorientation	1 (0.4%)	0	1 (0.2%)
Endocrine disorders	2 (0.8%)	0	2 (0.4%)
Adrenal insufficiency	1 (0.4%)	0	1 (0.2%)
Inappropriate antidiuretic hormone secretion	1 (0.4%)	0	1 (0.2%)
Reproductive system and breast disorders	1 (0.4%)	1 (0.4%)	2 (0.4%)
Prostatitis	1 (0.4%)	0	1 (0.2%)
Vaginal haemorrhage	0	1 (0.4%)	1 (0.2%)
Ear and labyrinth disorders	1 (0.4%)	0	1 (0.2%)
Vertigo	1 (0.4%)	0	1 (0.2%)
Eye disorders	1 (0.4%)	0	1 (0.2%)
Keratitis	1 (0.4%)	0	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.4.2: Frequency Summary of Treatment Emergent Serious Adverse Events - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Overall	113 (56.2%)	86 (43.7%)	199 (50.0%)
Infections and infestations	46 (22.9%)	34 (17.3%)	80 (20.1%)
Urinary tract infection	12 (6.0%)	14 (7.1%)	26 (6.5%)
Pneumonia	7 (3.5%)	2 (1.0%)	9 (2.3%)
Pyelonephritis	3 (1.5%)	5 (2.5%)	8 (2.0%)
COVID-19	6 (3.0%)	1 (0.5%)	7 (1.8%)
Sepsis	5 (2.5%)	2 (1.0%)	7 (1.8%)
Urosepsis	1 (0.5%)	3 (1.5%)	4 (1.0%)
COVID-19 pneumonia	2 (1.0%)	1 (0.5%)	3 (0.8%)
Pneumonia aspiration	3 (1.5%)	0	3 (0.8%)
Septic shock	3 (1.5%)	0	3 (0.8%)
Device related infection	2 (1.0%)	0	2 (0.5%)
Neutropenic sepsis	1 (0.5%)	1 (0.5%)	2 (0.5%)
Peritonitis	0	2 (1.0%)	2 (0.5%)
Pyelonephritis acute	1 (0.5%)	1 (0.5%)	2 (0.5%)
Respiratory tract infection	0	2 (1.0%)	2 (0.5%)
Skin infection	1 (0.5%)	1 (0.5%)	2 (0.5%)
Campylobacter gastroenteritis	1 (0.5%)	0	1 (0.3%)
Cellulitis	1 (0.5%)	0	1 (0.3%)
Clostridium difficile infection	1 (0.5%)	0	1 (0.3%)
Cystitis	1 (0.5%)	0	1 (0.3%)
Cytomegalovirus colitis	1 (0.5%)	0	1 (0.3%)
Diverticulitis	0	1 (0.5%)	1 (0.3%)
Enterocolitis infectious	1 (0.5%)	0	1 (0.3%)
Infectious pleural effusion	1 (0.5%)	0	1 (0.3%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.4.2: Frequency Summary of Treatment Emergent Serious Adverse Events - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Klebsiella sepsis	0	1 (0.5%)	1 (0.3%)
Respiratory syncytial virus infection	0	1 (0.5%)	1 (0.3%)
Gastrointestinal disorders	23 (11.4%)	11 (5.6%)	34 (8.5%)
Diarrhoea	7 (3.5%)	2 (1.0%)	9 (2.3%)
Abdominal pain	4 (2.0%)	1 (0.5%)	5 (1.3%)
Nausea	2 (1.0%)	1 (0.5%)	3 (0.8%)
Vomiting	2 (1.0%)	1 (0.5%)	3 (0.8%)
Intestinal obstruction	1 (0.5%)	1 (0.5%)	2 (0.5%)
Pancreatitis acute	1 (0.5%)	1 (0.5%)	2 (0.5%)
Colitis ulcerative	1 (0.5%)	0	1 (0.3%)
Constipation	0	1 (0.5%)	1 (0.3%)
Duodenal ulcer	1 (0.5%)	0	1 (0.3%)
Enterovesical fistula	1 (0.5%)	0	1 (0.3%)
Faeces discoloured	0	1 (0.5%)	1 (0.3%)
Gastric haemorrhage	0	1 (0.5%)	1 (0.3%)
Gastrointestinal haemorrhage	1 (0.5%)	0	1 (0.3%)
Haemorrhoidal haemorrhage	0	1 (0.5%)	1 (0.3%)
Large intestinal ulcer haemorrhage	1 (0.5%)	0	1 (0.3%)
Malignant gastrointestinal obstruction	1 (0.5%)	0	1 (0.3%)
Mouth ulceration	1 (0.5%)	0	1 (0.3%)
Oesophagitis	1 (0.5%)	0	1 (0.3%)
Rectal haemorrhage	1 (0.5%)	0	1 (0.3%)
Rectal ulcer haemorrhage	1 (0.5%)	0	1 (0.3%)
Small intestinal perforation	0	1 (0.5%)	1 (0.3%)
Blood and lymphatic system disorders	6 (3.0%)	26 (13.2%)	32 (8.0%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.4.2: Frequency Summary of Treatment Emergent Serious Adverse Events - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Anaemia	3 (1.5%)	7 (3.6%)	10 (2.5%)
Febrile neutropenia	1 (0.5%)	9 (4.6%)	10 (2.5%)
Thrombocytopenia	0	8 (4.1%)	8 (2.0%)
Neutropenia	1 (0.5%)	4 (2.0%)	5 (1.3%)
Pancytopenia	0	3 (1.5%)	3 (0.8%)
Immune thrombocytopenia	1 (0.5%)	0	1 (0.3%)
Renal and urinary disorders	21 (10.4%)	11 (5.6%)	32 (8.0%)
Acute kidney injury	14 (7.0%)	4 (2.0%)	18 (4.5%)
Haematuria	5 (2.5%)	3 (1.5%)	8 (2.0%)
Renal failure	2 (1.0%)	0	2 (0.5%)
Chronic kidney disease	0	1 (0.5%)	1 (0.3%)
Immune-mediated nephritis	1 (0.5%)	0	1 (0.3%)
Urinary retention	0	1 (0.5%)	1 (0.3%)
Urinary tract obstruction	0	1 (0.5%)	1 (0.3%)
Urinoma	0	1 (0.5%)	1 (0.3%)
General disorders and administration site conditions	13 (6.5%)	18 (9.1%)	31 (7.8%)
Pyrexia	6 (3.0%)	7 (3.6%)	13 (3.3%)
General physical health deterioration	0	7 (3.6%)	7 (1.8%)
Asthenia	1 (0.5%)	3 (1.5%)	4 (1.0%)
Fatigue	1 (0.5%)	1 (0.5%)	2 (0.5%)
Multiple organ dysfunction syndrome	1 (0.5%)	1 (0.5%)	2 (0.5%)
Condition aggravated	1 (0.5%)	0	1 (0.3%)
Death	1 (0.5%)	0	1 (0.3%)
Non-cardiac chest pain	0	1 (0.5%)	1 (0.3%)
Performance status decreased	1 (0.5%)	0	1 (0.3%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.4.2: Frequency Summary of Treatment Emergent Serious Adverse Events - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Sudden death	1 (0.5%)	0	1 (0.3%)
Respiratory, thoracic and mediastinal disorders	13 (6.5%)	11 (5.6%)	24 (6.0%)
Pulmonary embolism	3 (1.5%)	4 (2.0%)	7 (1.8%)
Dyspnoea	1 (0.5%)	3 (1.5%)	4 (1.0%)
Acute respiratory failure	2 (1.0%)	0	2 (0.5%)
Chronic obstructive pulmonary disease	0	2 (1.0%)	2 (0.5%)
Hypoxia	2 (1.0%)	0	2 (0.5%)
Pleural effusion	1 (0.5%)	1 (0.5%)	2 (0.5%)
Pneumonitis	2 (1.0%)	0	2 (0.5%)
Pneumothorax	0	2 (1.0%)	2 (0.5%)
Haemoptysis	0	1 (0.5%)	1 (0.3%)
Immune-mediated lung disease	1 (0.5%)	0	1 (0.3%)
Interstitial lung disease	1 (0.5%)	0	1 (0.3%)
Lung opacity	1 (0.5%)	0	1 (0.3%)
Respiratory failure	1 (0.5%)	0	1 (0.3%)
Metabolism and nutrition disorders	13 (6.5%)	5 (2.5%)	18 (4.5%)
Hyponatraemia	3 (1.5%)	2 (1.0%)	5 (1.3%)
Decreased appetite	3 (1.5%)	0	3 (0.8%)
Dehydration	2 (1.0%)	1 (0.5%)	3 (0.8%)
Hyperglycaemia	2 (1.0%)	0	2 (0.5%)
Failure to thrive	0	1 (0.5%)	1 (0.3%)
Hyperkalaemia	0	1 (0.5%)	1 (0.3%)
Hypoalbuminaemia	1 (0.5%)	0	1 (0.3%)
Hypocalcaemia	1 (0.5%)	0	1 (0.3%)
Type 2 diabetes mellitus	1 (0.5%)	0	1 (0.3%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.4.2: Frequency Summary of Treatment Emergent Serious Adverse Events - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Cardiac disorders	9 (4.5%)	3 (1.5%)	12 (3.0%)
Acute myocardial infarction	2 (1.0%)	1 (0.5%)	3 (0.8%)
Cardiac failure	3 (1.5%)	0	3 (0.8%)
Angina pectoris	0	1 (0.5%)	1 (0.3%)
Atrial fibrillation	0	1 (0.5%)	1 (0.3%)
Cardiac arrest	0	1 (0.5%)	1 (0.3%)
Cardio-respiratory arrest	1 (0.5%)	0	1 (0.3%)
Immune-mediated myocarditis	1 (0.5%)	0	1 (0.3%)
Myocardial infarction	1 (0.5%)	0	1 (0.3%)
Myocarditis	1 (0.5%)	0	1 (0.3%)
Stress cardiomyopathy	0	1 (0.5%)	1 (0.3%)
Ventricular tachycardia	1 (0.5%)	0	1 (0.3%)
Skin and subcutaneous tissue disorders	11 (5.5%)	1 (0.5%)	12 (3.0%)
Rash maculo-papular	5 (2.5%)	0	5 (1.3%)
Toxic epidermal necrolysis	2 (1.0%)	0	2 (0.5%)
Acute generalised exanthematous pustulosis	0	1 (0.5%)	1 (0.3%)
Dermatitis	1 (0.5%)	0	1 (0.3%)
Dermatitis exfoliative	1 (0.5%)	0	1 (0.3%)
Rash erythematous	1 (0.5%)	0	1 (0.3%)
Rash morbilliform	1 (0.5%)	0	1 (0.3%)
Investigations	7 (3.5%)	2 (1.0%)	9 (2.3%)
Alanine aminotransferase increased	4 (2.0%)	0	4 (1.0%)
Aspartate aminotransferase increased	3 (1.5%)	0	3 (0.8%)
Blood creatinine increased	2 (1.0%)	1 (0.5%)	3 (0.8%)
Platelet count decreased	0	1 (0.5%)	1 (0.3%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.4.2: Frequency Summary of Treatment Emergent Serious Adverse Events - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Prothrombin time prolonged	1 (0.5%)	0	1 (0.3%)
Weight decreased	1 (0.5%)	0	1 (0.3%)
Hepatobiliary disorders	7 (3.5%)	1 (0.5%)	8 (2.0%)
Hepatitis	2 (1.0%)	0	2 (0.5%)
Hepatotoxicity	2 (1.0%)	0	2 (0.5%)
Immune-mediated hepatitis	2 (1.0%)	0	2 (0.5%)
Cholangitis sclerosing	1 (0.5%)	0	1 (0.3%)
Hepatic function abnormal	0	1 (0.5%)	1 (0.3%)
Nervous system disorders	7 (3.5%)	1 (0.5%)	8 (2.0%)
Cerebrovascular accident	2 (1.0%)	1 (0.5%)	3 (0.8%)
Peripheral motor neuropathy	2 (1.0%)	0	2 (0.5%)
Immune-mediated neuropathy	1 (0.5%)	0	1 (0.3%)
Nervous system disorder	1 (0.5%)	0	1 (0.3%)
Peripheral sensorimotor neuropathy	1 (0.5%)	0	1 (0.3%)
Seizure	1 (0.5%)	0	1 (0.3%)
Vascular disorders	4 (2.0%)	2 (1.0%)	6 (1.5%)
Aortic aneurysm rupture	1 (0.5%)	0	1 (0.3%)
Deep vein thrombosis	0	1 (0.5%)	1 (0.3%)
Hypotension	1 (0.5%)	0	1 (0.3%)
Iliac artery occlusion	1 (0.5%)	0	1 (0.3%)
Orthostatic hypotension	1 (0.5%)	0	1 (0.3%)
Shock	0	1 (0.5%)	1 (0.3%)
Musculoskeletal and connective tissue disorders	2 (1.0%)	3 (1.5%)	5 (1.3%)
Pain in extremity	1 (0.5%)	1 (0.5%)	2 (0.5%)
Arthralgia	1 (0.5%)	0	1 (0.3%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.4.2: Frequency Summary of Treatment Emergent Serious Adverse Events - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Back pain	0	1 (0.5%)	1 (0.3%)
Pathological fracture	0	1 (0.5%)	1 (0.3%)
Injury, poisoning and procedural complications	2 (1.0%)	2 (1.0%)	4 (1.0%)
Femur fracture	2 (1.0%)	0	2 (0.5%)
Infusion related reaction	0	1 (0.5%)	1 (0.3%)
Urinary tract stoma complication	0	1 (0.5%)	1 (0.3%)
Endocrine disorders	2 (1.0%)	1 (0.5%)	3 (0.8%)
Adrenal insufficiency	1 (0.5%)	0	1 (0.3%)
Hypercalcaemia of malignancy	0	1 (0.5%)	1 (0.3%)
Hypothyroidism	1 (0.5%)	0	1 (0.3%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.5%)	2 (1.0%)	3 (0.8%)
Cancer pain	0	2 (1.0%)	2 (0.5%)
Chronic lymphocytic leukaemia	1 (0.5%)	0	1 (0.3%)
Psychiatric disorders	1 (0.5%)	1 (0.5%)	2 (0.5%)
Confusional state	0	1 (0.5%)	1 (0.3%)
Delirium	1 (0.5%)	0	1 (0.3%)
Ear and labyrinth disorders	0	1 (0.5%)	1 (0.3%)
Vertigo	0	1 (0.5%)	1 (0.3%)
Immune system disorders	1 (0.5%)	0	1 (0.3%)
Sarcoidosis	1 (0.5%)	0	1 (0.3%)
Reproductive system and breast disorders	0	1 (0.5%)	1 (0.3%)
Vaginal haemorrhage	0	1 (0.5%)	1 (0.3%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.5.1: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Overall	93 (38.9%)	58 (24.6%)	151 (31.8%)
Nervous system disorders	44 (18.4%)	1 (0.4%)	45 (9.5%)
Peripheral sensory neuropathy	29 (12.1%)	1 (0.4%)	30 (6.3%)
Paraesthesia	4 (1.7%)	0	4 (0.8%)
Peripheral motor neuropathy	3 (1.3%)	0	3 (0.6%)
Peripheral sensorimotor neuropathy	3 (1.3%)	0	3 (0.6%)
Cerebral haemorrhage	1 (0.4%)	0	1 (0.2%)
Chronic inflammatory demyelinating polyradiculoneuropathy	1 (0.4%)	0	1 (0.2%)
Diabetic hyperglycaemic coma	1 (0.4%)	0	1 (0.2%)
Neurotoxicity	1 (0.4%)	0	1 (0.2%)
Seizure	1 (0.4%)	0	1 (0.2%)
Renal and urinary disorders	2 (0.8%)	19 (8.1%)	21 (4.4%)
Acute kidney injury	1 (0.4%)	10 (4.2%)	11 (2.3%)
Chronic kidney disease	0	3 (1.3%)	3 (0.6%)
Renal failure	0	2 (0.8%)	2 (0.4%)
Renal impairment	0	2 (0.8%)	2 (0.4%)
Haematuria	0	1 (0.4%)	1 (0.2%)
Immune-mediated nephritis	1 (0.4%)	0	1 (0.2%)
Nephropathy	0	1 (0.4%)	1 (0.2%)
Skin and subcutaneous tissue disorders	17 (7.1%)	0	17 (3.6%)
Rash maculo-papular	4 (1.7%)	0	4 (0.8%)
Rash macular	3 (1.3%)	0	3 (0.6%)
Dermatitis exfoliative generalised	2 (0.8%)	0	2 (0.4%)
Dermatitis	1 (0.4%)	0	1 (0.2%)
Dermatitis bullous	1 (0.4%)	0	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.5.1: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Drug eruption	1 (0.4%)	0	1 (0.2%)
Erythema	1 (0.4%)	0	1 (0.2%)
Lichenoid keratosis	1 (0.4%)	0	1 (0.2%)
Pemphigoid	1 (0.4%)	0	1 (0.2%)
Psoriasis	1 (0.4%)	0	1 (0.2%)
Toxic epidermal necrolysis	1 (0.4%)	0	1 (0.2%)
Investigations	3 (1.3%)	11 (4.7%)	14 (2.9%)
Blood creatinine increased	0	8 (3.4%)	8 (1.7%)
Aspartate aminotransferase increased	2 (0.8%)	0	2 (0.4%)
Platelet count decreased	0	2 (0.8%)	2 (0.4%)
Alanine aminotransferase increased	1 (0.4%)	0	1 (0.2%)
Creatinine renal clearance decreased	0	1 (0.4%)	1 (0.2%)
Respiratory, thoracic and mediastinal disorders	14 (5.9%)	0	14 (2.9%)
Pneumonitis	6 (2.5%)	0	6 (1.3%)
Immune-mediated lung disease	4 (1.7%)	0	4 (0.8%)
Interstitial lung disease	2 (0.8%)	0	2 (0.4%)
Acute respiratory failure	1 (0.4%)	0	1 (0.2%)
Organising pneumonia	1 (0.4%)	0	1 (0.2%)
Blood and lymphatic system disorders	1 (0.4%)	11 (4.7%)	12 (2.5%)
Anaemia	1 (0.4%)	7 (3.0%)	8 (1.7%)
Neutropenia	0	2 (0.8%)	2 (0.4%)
Febrile neutropenia	0	1 (0.4%)	1 (0.2%)
Thrombocytopenia	0	1 (0.4%)	1 (0.2%)
Gastrointestinal disorders	5 (2.1%)	4 (1.7%)	9 (1.9%)
Diarrhoea	3 (1.3%)	1 (0.4%)	4 (0.8%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.5.1: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Nausea	0	3 (1.3%)	3 (0.6%)
Colitis	1 (0.4%)	0	1 (0.2%)
Pancreatitis chronic	1 (0.4%)	0	1 (0.2%)
General disorders and administration site conditions	2 (0.8%)	5 (2.1%)	7 (1.5%)
Fatigue	1 (0.4%)	5 (2.1%)	6 (1.3%)
Asthenia	1 (0.4%)	0	1 (0.2%)
Hepatobiliary disorders	7 (2.9%)	0	7 (1.5%)
Immune-mediated hepatitis	2 (0.8%)	0	2 (0.4%)
Autoimmune hepatitis	1 (0.4%)	0	1 (0.2%)
Hepatitis	1 (0.4%)	0	1 (0.2%)
Hepatotoxicity	1 (0.4%)	0	1 (0.2%)
Hyperbilirubinaemia	1 (0.4%)	0	1 (0.2%)
Hypertransaminasaemia	1 (0.4%)	0	1 (0.2%)
Cardiac disorders	1 (0.4%)	3 (1.3%)	4 (0.8%)
Acute right ventricular failure	0	1 (0.4%)	1 (0.2%)
Atrial fibrillation	0	1 (0.4%)	1 (0.2%)
Myocardial infarction	0	1 (0.4%)	1 (0.2%)
Myocarditis	1 (0.4%)	0	1 (0.2%)
Infections and infestations	2 (0.8%)	2 (0.8%)	4 (0.8%)
Infectious pleural effusion	1 (0.4%)	0	1 (0.2%)
Neutropenic sepsis	0	1 (0.4%)	1 (0.2%)
Pneumonia	1 (0.4%)	0	1 (0.2%)
Wound infection	0	1 (0.4%)	1 (0.2%)
Ear and labyrinth disorders	0	3 (1.3%)	3 (0.6%)
Hypoacusis	0	1 (0.4%)	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.5.1: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Analysis Set mSAF 1 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=239)	Plat+Gem (N=236)	Total (N=475)
Ototoxicity	0	1 (0.4%)	1 (0.2%)
Tinnitus	0	1 (0.4%)	1 (0.2%)
Metabolism and nutrition disorders	0	2 (0.8%)	2 (0.4%)
Dehydration	0	1 (0.4%)	1 (0.2%)
Hyponatraemia	0	1 (0.4%)	1 (0.2%)
Musculoskeletal and connective tissue disorders	2 (0.8%)	0	2 (0.4%)
Arthropathy	1 (0.4%)	0	1 (0.2%)
Gouty arthritis	1 (0.4%)	0	1 (0.2%)
Endocrine disorders	1 (0.4%)	0	1 (0.2%)
Hypophysitis	1 (0.4%)	0	1 (0.2%)
Eye disorders	1 (0.4%)	0	1 (0.2%)
Keratitis	1 (0.4%)	0	1 (0.2%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.4%)	0	1 (0.2%)
Burkitt's lymphoma	1 (0.4%)	0	1 (0.2%)
Vascular disorders	0	1 (0.4%)	1 (0.2%)
Deep vein thrombosis	0	1 (0.4%)	1 (0.2%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.5.2: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Overall	84 (41.8%)	35 (17.8%)	119 (29.9%)
Nervous system disorders	28 (13.9%)	1 (0.5%)	29 (7.3%)
Peripheral sensory neuropathy	20 (10.0%)	0	20 (5.0%)
Paraesthesia	2 (1.0%)	0	2 (0.5%)
Peripheral sensorimotor neuropathy	2 (1.0%)	0	2 (0.5%)
Cerebrovascular accident	0	1 (0.5%)	1 (0.3%)
Dysgeusia	1 (0.5%)	0	1 (0.3%)
Hypoaesthesia	1 (0.5%)	0	1 (0.3%)
Nervous system disorder	1 (0.5%)	0	1 (0.3%)
Neuralgia	1 (0.5%)	0	1 (0.3%)
Blood and lymphatic system disorders	3 (1.5%)	18 (9.1%)	21 (5.3%)
Anaemia	1 (0.5%)	5 (2.5%)	6 (1.5%)
Thrombocytopenia	1 (0.5%)	5 (2.5%)	6 (1.5%)
Neutropenia	0	5 (2.5%)	5 (1.3%)
Febrile neutropenia	0	2 (1.0%)	2 (0.5%)
Immune thrombocytopenia	1 (0.5%)	0	1 (0.3%)
Pancytopenia	0	1 (0.5%)	1 (0.3%)
Skin and subcutaneous tissue disorders	13 (6.5%)	1 (0.5%)	14 (3.5%)
Rash maculo-papular	3 (1.5%)	0	3 (0.8%)
Toxic epidermal necrolysis	2 (1.0%)	0	2 (0.5%)
Acute generalised exanthematous pustulosis	0	1 (0.5%)	1 (0.3%)
Eczema	1 (0.5%)	0	1 (0.3%)
Lichen planus	1 (0.5%)	0	1 (0.3%)
Papule	1 (0.5%)	0	1 (0.3%)
Pruritus	1 (0.5%)	0	1 (0.3%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.5.2: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Rash macular	1 (0.5%)	0	1 (0.3%)
Rash morbilliform	1 (0.5%)	0	1 (0.3%)
Rash vesicular	1 (0.5%)	0	1 (0.3%)
Skin hyperpigmentation	1 (0.5%)	0	1 (0.3%)
Respiratory, thoracic and mediastinal disorders	9 (4.5%)	2 (1.0%)	11 (2.8%)
Pneumonitis	4 (2.0%)	0	4 (1.0%)
Immune-mediated lung disease	2 (1.0%)	0	2 (0.5%)
Autoimmune lung disease	1 (0.5%)	0	1 (0.3%)
Haemoptysis	0	1 (0.5%)	1 (0.3%)
Interstitial lung disease	1 (0.5%)	0	1 (0.3%)
Pulmonary embolism	0	1 (0.5%)	1 (0.3%)
Respiratory failure	1 (0.5%)	0	1 (0.3%)
General disorders and administration site conditions	7 (3.5%)	3 (1.5%)	10 (2.5%)
Asthenia	3 (1.5%)	0	3 (0.8%)
Fatigue	1 (0.5%)	1 (0.5%)	2 (0.5%)
General physical health deterioration	0	2 (1.0%)	2 (0.5%)
Multiple organ dysfunction syndrome	1 (0.5%)	0	1 (0.3%)
Performance status decreased	1 (0.5%)	0	1 (0.3%)
Sudden death	1 (0.5%)	0	1 (0.3%)
Renal and urinary disorders	9 (4.5%)	0	9 (2.3%)
Acute kidney injury	4 (2.0%)	0	4 (1.0%)
Renal failure	2 (1.0%)	0	2 (0.5%)
Chronic kidney disease	1 (0.5%)	0	1 (0.3%)
Immune-mediated nephritis	1 (0.5%)	0	1 (0.3%)
Proteinuria	1 (0.5%)	0	1 (0.3%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.5.2: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Infections and infestations	5 (2.5%)	3 (1.5%)	8 (2.0%)
Sepsis	1 (0.5%)	1 (0.5%)	2 (0.5%)
COVID-19	1 (0.5%)	0	1 (0.3%)
Cystitis	0	1 (0.5%)	1 (0.3%)
Peritonitis	0	1 (0.5%)	1 (0.3%)
Pneumonia	1 (0.5%)	0	1 (0.3%)
Pneumonia aspiration	1 (0.5%)	0	1 (0.3%)
Septic shock	1 (0.5%)	0	1 (0.3%)
Cardiac disorders	4 (2.0%)	1 (0.5%)	5 (1.3%)
Acute myocardial infarction	1 (0.5%)	0	1 (0.3%)
Cardiac arrest	0	1 (0.5%)	1 (0.3%)
Cardiac failure	1 (0.5%)	0	1 (0.3%)
Cardio-respiratory arrest	1 (0.5%)	0	1 (0.3%)
Myocarditis	1 (0.5%)	0	1 (0.3%)
Gastrointestinal disorders	5 (2.5%)	0	5 (1.3%)
Diarrhoea	2 (1.0%)	0	2 (0.5%)
Colitis ulcerative	1 (0.5%)	0	1 (0.3%)
Nausea	1 (0.5%)	0	1 (0.3%)
Paraesthesia oral	1 (0.5%)	0	1 (0.3%)
Investigations	3 (1.5%)	2 (1.0%)	5 (1.3%)
Alanine aminotransferase increased	2 (1.0%)	0	2 (0.5%)
Aspartate aminotransferase increased	1 (0.5%)	1 (0.5%)	2 (0.5%)
Neutrophil count decreased	0	1 (0.5%)	1 (0.3%)
Hepatobiliary disorders	2 (1.0%)	1 (0.5%)	3 (0.8%)
Autoimmune hepatitis	1 (0.5%)	0	1 (0.3%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.5.2: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Analysis Set mSAF 2 - Sensitivity Analysis

MedDRA SOC and PT	EV+Pembro (N=201)	Plat+Gem (N=197)	Total (N=398)
Cholangitis sclerosing	1 (0.5%)	0	1 (0.3%)
Hypertransaminasaemia	0	1 (0.5%)	1 (0.3%)
Vascular disorders	2 (1.0%)	1 (0.5%)	3 (0.8%)
Iliac artery occlusion	1 (0.5%)	0	1 (0.3%)
Orthostatic hypotension	1 (0.5%)	0	1 (0.3%)
Shock	0	1 (0.5%)	1 (0.3%)
Metabolism and nutrition disorders	1 (0.5%)	1 (0.5%)	2 (0.5%)
Decreased appetite	0	1 (0.5%)	1 (0.3%)
Hyponatraemia	1 (0.5%)	0	1 (0.3%)
Musculoskeletal and connective tissue disorders	2 (1.0%)	0	2 (0.5%)
Arthralgia	1 (0.5%)	0	1 (0.3%)
Musculoskeletal pain	1 (0.5%)	0	1 (0.3%)
Ear and labyrinth disorders	0	1 (0.5%)	1 (0.3%)
Tinnitus	0	1 (0.5%)	1 (0.3%)
Immune system disorders	1 (0.5%)	0	1 (0.3%)
Sarcoidosis	1 (0.5%)	0	1 (0.3%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; MedDRA=medical dictionary for regulatory activities; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; SOC=system organ class.
Note: Data are sorted by descending number of subjects in Total group for System Organ Class and Preferred Term.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.6.1: Summary of Duration of Observation Time for any TEAE - Analysis Set mSAF 1 - Sensitivity Analysis

	EV+Pembro (N=239)	**Plat+Gem (N=236)**
Duration of observation period (months)		
n	239	236
Mean (SD)	15.34 (6.978)	13.64 (7.343)
Median	14.55	12.68
Q1 - Q3	10.55 - 20.53	8.31 - 18.17
Range	1.0 - 37.7	0.1 - 36.6

Abbreviations: DCO=data cut-off; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation; TEAE=treatment emergent adverse event.
Note: Observation time for the sensitivity analysis of safety is defined as the time from randomization until DCO, study discontinuation/loss to follow-up or death, whichever occured first and stopped the collection of endpoint data.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2001.6.2: Summary of Duration of Observation Time for any TEAE - Analysis Set mSAF 2 - Sensitivity Analysis

	EV+Pembro (N=201)	**Plat+Gem (N=197)**
Duration of observation period (months)		
n	201	197
Mean (SD)	14.23 (7.116)	11.43 (6.380)
Median	14.06	11.04
Q1 - Q3	9.86 - 19.84	6.64 - 15.47
Range	0.3 - 32.0	0.3 - 32.3

Abbreviations: DCO=data cut-off; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; n=number of patients with non-missing values; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; Q1=first quartile; Q3=third quartile; SD=standard deviation; TEAE=treatment emergent adverse event.
Note: Observation time for the sensitivity analysis of safety is defined as the time from randomization until DCO, study discontinuation/loss to follow-up or death, whichever occured first and stopped the collection of endpoint data.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.1.1.1: Summary and Results of TEAEs - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	239 (100.0%)	234 (99.2%)	
Number of patients censored	0 (0.0%)	2 (0.8%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	2.1 [0.8, 4.5]	0.5 [0.0, 2.5]	
Month 6	0.4 [0.0, 2.2]	NC [NC, NC]	
Month 9	0.0 [NC, NC]	NC [NC, NC]	
Month 12	0.0 [NC, NC]	NC [NC, NC]	
Month 18	0.0 [NC, NC]	NC [NC, NC]	
Month 24	0.0 [NC, NC]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	0.2 [0.2, 0.2]	0.1 [0.1, 0.2]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.832 [0.694, 0.998]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0527

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAE=treatment-emergent adverse event.
Note: The analysis was conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.1.1.2: Summary and Results of TEAEs by Subgroups - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	47 (100.0)	0.2 [0.1, 0.3]	47	46 (97.9)	0.2 [0.1, 0.3]	1.039 [0.691, 1.563]	0.7643	0.2310
Absent	192	192 (100.0)	0.2 [0.2, 0.2]	189	188 (99.5)	0.1 [0.1, 0.2]	0.781 [0.637, 0.959]	0.0188	
Age									
< 65 years	105	105 (100.0)	0.2 [0.2, 0.3]	102	101 (99.0)	0.1 [0.1, 0.2]	0.741 [0.560, 0.981]	0.0361	0.2180
>= 65 years	134	134 (100.0)	0.2 [0.2, 0.2]	134	133 (99.3)	0.1 [0.1, 0.2]	0.937 [0.736, 1.192]	0.6124	
Region									
Europe	97	97 (100.0)	0.2 [0.2, 0.3]	101	100 (99.0)	0.2 [0.1, 0.2]	0.823 [0.620, 1.092]	0.1919	0.2237
North America	57	57 (100.0)	0.1 [0.1, 0.2]	51	51 (100.0)	0.1 [0.1, 0.1]	0.626 [0.423, 0.928]	0.0183	
Rest of World	85	85 (100.0)	0.2 [0.2, 0.3]	84	83 (98.8)	0.1 [0.1, 0.2]	0.904 [0.665, 1.228]	0.5306	
Sex									
Male	197	197 (100.0)	0.2 [0.2, 0.3]	181	179 (98.9)	0.1 [0.1, 0.2]	0.859 [0.700, 1.053]	0.1570	0.6267
Female	42	42 (100.0)	0.2 [0.1, 0.2]	55	55 (100.0)	0.1 [0.1, 0.2]	0.837 [0.557, 1.257]	0.4064	
Metastases at Baseline									
Visceral metastases	169	169 (100.0)	0.2 [0.2, 0.2]	157	156 (99.4)	0.1 [0.1, 0.2]	0.905 [0.727, 1.127]	0.3975	0.1015
Lymph node only	60	60 (100.0)	0.2 [0.2, 0.3]	65	64 (98.5)	0.1 [0.1, 0.1]	0.614 [0.426, 0.886]	0.0086	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAE=treatment-emergent adverse event.
Note: The analysis was conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.2.1.1: Summary and Results of Non-Severe TEAEs (CTCAE Grade < 3) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	239 (100.0%)	233 (98.7%)	
Number of patients censored	0 (0.0%)	3 (1.3%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	2.5 [1.0, 5.1]	1.0 [0.2, 3.2]	
Month 6	0.4 [0.0, 2.2]	NC [NC, NC]	
Month 9	0.0 [NC, NC]	NC [NC, NC]	
Month 12	0.0 [NC, NC]	NC [NC, NC]	
Month 18	0.0 [NC, NC]	NC [NC, NC]	
Month 24	0.0 [NC, NC]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	0.2 [0.2, 0.2]	0.1 [0.1, 0.2]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.884 [0.737, 1.060]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1928

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAE=treatment-emergent adverse event.
Note: The analysis was conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.2.1.2: Summary and Results of Non-Severe TEAEs (CTCAE Grade < 3) by Subgroups - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	47 (100.0)	0.2 [0.1, 0.3]	47	46 (97.9)	0.2 [0.1, 0.3]	1.071 [0.710, 1.614]	0.6763	0.2572
Absent	192	192 (100.0)	0.2 [0.2, 0.3]	189	187 (98.9)	0.1 [0.1, 0.2]	0.838 [0.684, 1.027]	0.0887	
Age									
< 65 years	105	105 (100.0)	0.2 [0.2, 0.3]	102	100 (98.0)	0.1 [0.1, 0.2]	0.810 [0.613, 1.069]	0.1349	0.3470
>= 65 years	134	134 (100.0)	0.2 [0.2, 0.2]	134	133 (99.3)	0.1 [0.1, 0.2]	0.970 [0.762, 1.234]	0.8018	
Region									
Europe	97	97 (100.0)	0.2 [0.2, 0.3]	101	100 (99.0)	0.2 [0.2, 0.3]	0.896 [0.675, 1.190]	0.4577	0.2741
North America	57	57 (100.0)	0.1 [0.1, 0.2]	51	51 (100.0)	0.1 [0.1, 0.1]	0.677 [0.459, 0.998]	0.0466	
Rest of World	85	85 (100.0)	0.2 [0.2, 0.3]	84	82 (97.6)	0.1 [0.1, 0.2]	0.942 [0.695, 1.278]	0.7103	
Sex									
Male	197	197 (100.0)	0.2 [0.2, 0.3]	181	178 (98.3)	0.2 [0.1, 0.2]	0.921 [0.751, 1.129]	0.4477	0.5157
Female	42	42 (100.0)	0.2 [0.1, 0.2]	55	55 (100.0)	0.1 [0.1, 0.2]	0.862 [0.574, 1.294]	0.4814	
Metastases at Baseline									
Visceral metastases	169	169 (100.0)	0.2 [0.2, 0.2]	157	156 (99.4)	0.2 [0.1, 0.2]	0.950 [0.763, 1.183]	0.6591	0.0813
Lymph node only	60	60 (100.0)	0.2 [0.2, 0.3]	65	64 (98.5)	0.1 [0.1, 0.2]	0.624 [0.432, 0.900]	0.0109	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAE=treatment-emergent adverse event.
Note: The analysis was conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.3.1.1: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	164 (68.6%)	175 (74.2%)	
Number of patients censored	75 (31.4%)	61 (25.8%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	56.2 [49.6, 62.2]	32.1 [26.2, 38.2]	
Month 6	44.8 [38.3, 51.1]	NC [NC, NC]	
Month 9	35.6 [29.3, 42.0]	NC [NC, NC]	
Month 12	29.2 [23.0, 35.7]	NC [NC, NC]	
Month 18	23.0 [16.5, 30.2]	NC [NC, NC]	
Month 24	19.2 [11.2, 28.8]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	4.2 [3.0, 6.1]	1.4 [1.0, 1.8]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.514 [0.408, 0.649]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAE=treatment-emergent adverse event.
Note: The analysis was conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.3.1.2: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) by Subgroups - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	35 (74.5)	1.8 [1.1, 3.8]	47	33 (70.2)	1.6 [0.5, 2.3]	0.775 [0.471, 1.278]	0.3242	0.0797
Absent	192	129 (67.2)	5.1 [3.3, 6.9]	189	142 (75.1)	1.4 [1.0, 1.9]	0.462 [0.355, 0.601]	<.0001	
Age									
< 65 years	105	62 (59.0)	6.1 [4.2, 12.4]	102	69 (67.6)	1.6 [1.3, 2.3]	0.447 [0.305, 0.655]	<.0001	0.2908
>= 65 years	134	102 (76.1)	2.7 [1.8, 4.4]	134	106 (79.1)	1.2 [0.7, 1.6]	0.565 [0.422, 0.757]	0.0001	
Region									
Europe	97	63 (64.9)	4.4 [2.7, 7.7]	101	73 (72.3)	1.4 [0.9, 2.1]	0.507 [0.353, 0.730]	0.0002	0.9382
North America	57	41 (71.9)	3.4 [1.3, 6.9]	51	40 (78.4)	1.6 [0.7, 2.1]	0.488 [0.302, 0.788]	0.0029	
Rest of World	85	60 (70.6)	4.2 [1.7, 7.5]	84	62 (73.8)	1.3 [0.7, 2.3]	0.548 [0.372, 0.808]	0.0023	
Sex									
Male	197	135 (68.5)	4.4 [3.0, 6.2]	181	131 (72.4)	1.4 [1.0, 2.1]	0.516 [0.397, 0.671]	<.0001	0.7981
Female	42	29 (69.0)	3.8 [1.1, 8.1]	55	44 (80.0)	1.4 [0.7, 2.1]	0.525 [0.317, 0.868]	0.0104	
Metastases at Baseline									
Visceral metastases	169	122 (72.2)	3.4 [2.1, 5.9]	157	118 (75.2)	1.3 [0.9, 1.8]	0.554 [0.421, 0.728]	<.0001	0.4729
Lymph node only	60	37 (61.7)	6.0 [3.1, 11.4]	65	46 (70.8)	1.7 [1.0, 2.3]	0.441 [0.272, 0.713]	0.0006	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAE=treatment-emergent adverse event.
Note: The analysis was conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.4.1.1: Summary and Results of TESAEs - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	107 (44.8%)	83 (35.2%)	
Number of patients censored	132 (55.2%)	153 (64.8%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	72.8 [66.7, 78.0]	71.1 [64.7, 76.5]	
Month 6	62.9 [56.4, 68.8]	62.4 [55.3, 68.6]	
Month 9	57.9 [51.2, 64.0]	NC [NC, NC]	
Month 12	54.1 [47.1, 60.5]	NC [NC, NC]	
Month 18	48.9 [40.8, 56.5]	NC [NC, NC]	
Month 24	48.9 [40.8, 56.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	18.0 [9.5, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.910 [0.670, 1.234]
Log-rank test			
Two-sided unstratified log-rank p-value			0.5433

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAE=treatment-emergent serious adverse event.
Note: The analysis was conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.4.1.2: Summary and Results of TESAEs by Subgroups - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	27 (57.4)	5.8 [1.3, NC]	47	12 (25.5)	NC [NC, NC]	1.906 [0.942, 3.854]	0.0672	0.0116
Absent	192	80 (41.7)	NC [11.4, NC]	189	71 (37.6)	NC [NC, NC]	0.744 [0.527, 1.049]	0.0904	
Age									
< 65 years	105	35 (33.3)	NC [18.0, NC]	102	29 (28.4)	NC [NC, NC]	0.833 [0.491, 1.412]	0.4978	0.5935
>= 65 years	134	72 (53.7)	8.2 [4.8, 17.2]	134	54 (40.3)	NC [4.4, NC]	0.951 [0.654, 1.383]	0.7923	
Region									
Europe	97	37 (38.1)	NC [17.2, NC]	101	36 (35.6)	NC [NC, NC]	0.848 [0.526, 1.368]	0.4993	0.4334
North America	57	27 (47.4)	16.1 [5.8, NC]	51	20 (39.2)	NC [2.9, NC]	0.850 [0.457, 1.580]	0.6071	
Rest of World	85	43 (50.6)	11.3 [6.2, NC]	84	27 (32.1)	NC [4.8, NC]	1.037 [0.618, 1.742]	0.8884	
Sex									
Male	197	89 (45.2)	18.0 [9.4, NC]	181	62 (34.3)	NC [NC, NC]	0.925 [0.656, 1.306]	0.6599	0.7319
Female	42	18 (42.9)	NC [5.4, NC]	55	21 (38.2)	NC [3.9, NC]	0.853 [0.435, 1.674]	0.6406	
Metastases at Baseline									
Visceral metastases	169	85 (50.3)	10.0 [6.9, NC]	157	51 (32.5)	NC [NC, NC]	1.062 [0.733, 1.540]	0.7495	0.0285
Lymph node only	60	19 (31.7)	NC [18.0, NC]	65	26 (40.0)	NC [3.9, NC]	0.668 [0.365, 1.221]	0.1872	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAE=treatment-emergent serious adverse event.
Note: The analysis was conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.5.1.1: Summary and Results of First Treatment Discontinuation of Any Study Drugs due to TEAEs - Analysis Set mSAF 1

	EV+Pembro (N= 239)	**Plat+Gem (N= 236)**	**EV+Pembro vs. Plat+Gem**
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	92 (38.5%)	58 (24.6%)	
Number of patients censored	147 (61.5%)	178 (75.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	88.3 [83.4, 91.8]	78.9 [73.0, 83.7]	
Month 6	75.1 [68.7, 80.3]	73.9 [67.6, 79.2]	
Month 9	61.1 [53.8, 67.6]	NC [NC, NC]	
Month 12	54.7 [46.9, 61.9]	NC [NC, NC]	
Month 18	48.1 [39.2, 56.4]	NC [NC, NC]	
Month 24	45.1 [35.0, 54.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	14.5 [11.3, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.700 [0.477, 1.027]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0678

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAE=treatment-emergent adverse event.
Note: The analysis was conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.5.1.1.1: Frequency of Patients with TEAEs leading to First Treatment Discontinuation for each Drug - Analysis Set mSAF 1

	EV+Pembro (N=239)	Plat+Gem (N=236)
Number of patients at risk	239 (100.0%)	236 (100.0%)
Number of patients with events	92 (38.5%)	58 (24.6%)
Carboplatin	0 (0.0%)	3 (1.3%)
Cisplatin	0 (0.0%)	54 (22.9%)
Enfortumab Vedotin	78 (32.6%)	0 (0.0%)
Gemcitabine	0 (0.0%)	24 (10.2%)
Pembrolizumab	53 (22.2%)	0 (0.0%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAE=treatment-emergent adverse event.
Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.5.1.2: Summary and Results of First Treatment Discontinuation of Any Study Drugs due to TEAEs by Subgroups - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	16 (34.0)	14.2 [6.8, NC]	47	9 (19.1)	NC [NC, NC]	0.563 [0.197, 1.612]	0.2785	0.4945
Absent	192	76 (39.6)	16.2 [10.1, NC]	189	49 (25.9)	NC [NC, NC]	0.721 [0.477, 1.089]	0.1189	
Age									
< 65 years	105	31 (29.5)	NC [14.2, NC]	102	16 (15.7)	NC [NC, NC]	0.652 [0.307, 1.385]	0.2609	0.6068
>= 65 years	134	61 (45.5)	9.2 [6.6, NC]	134	42 (31.3)	NC [NC, NC]	0.704 [0.450, 1.100]	0.1223	
Region									
Europe	97	46 (47.4)	9.7 [7.2, 14.2]	101	29 (28.7)	NC [NC, NC]	0.722 [0.419, 1.243]	0.2375	0.8487
North America	57	23 (40.4)	12.0 [6.7, NC]	51	15 (29.4)	NC [NC, NC]	0.492 [0.215, 1.124]	0.0859	
Rest of World	85	23 (27.1)	NC [19.3, NC]	84	14 (16.7)	NC [NC, NC]	0.867 [0.414, 1.816]	0.7035	
Sex									
Male	197	79 (40.1)	14.5 [9.2, NC]	181	44 (24.3)	NC [NC, NC]	0.718 [0.467, 1.103]	0.1296	0.4465
Female	42	13 (31.0)	NC [9.7, NC]	55	14 (25.5)	NC [NC, NC]	0.605 [0.247, 1.483]	0.2676	
Metastases at Baseline									
Visceral metastases	169	56 (33.1)	NC [12.2, NC]	157	37 (23.6)	NC [NC, NC]	0.671 [0.415, 1.084]	0.1023	0.2839
Lymph node only	60	33 (55.0)	9.7 [6.6, 14.5]	65	17 (26.2)	NC [NC, NC]	0.864 [0.435, 1.720]	0.6787	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAE=treatment-emergent adverse event.
Note: The analysis was conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.6.1.1: Summary and Results of TEAEs - Blood and lymphatic system disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	69 (28.9%)	170 (72.0%)	
Number of patients censored	170 (71.1%)	66 (28.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	80.3 [74.6, 84.9]	31.0 [25.1, 37.2]	
Month 6	74.8 [68.6, 80.0]	NC [NC, NC]	
Month 9	71.9 [65.4, 77.4]	NC [NC, NC]	
Month 12	67.9 [60.6, 74.2]	NC [NC, NC]	
Month 18	63.7 [55.2, 71.1]	NC [NC, NC]	
Month 24	63.7 [55.2, 71.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	1.2 [1.0, 1.6]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.186 [0.136, 0.253]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.6.1.2: Summary and Results of TEAEs by Subgroups - Blood and lymphatic system disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	16 (34.0)	15.6 [6.2, NC]	47	35 (74.5)	1.2 [0.5, 2.3]	0.215 [0.112, 0.415]	<.0001	0.4512
Absent	192	53 (27.6)	NC [NC, NC]	189	135 (71.4)	1.2 [1.0, 1.7]	0.179 [0.126, 0.255]	<.0001	
Age									
< 65 years	105	22 (21.0)	NC [NC, NC]	102	69 (67.6)	1.3 [1.0, 2.1]	0.148 [0.086, 0.255]	<.0001	0.1474
>= 65 years	134	47 (35.1)	NC [12.6, NC]	134	101 (75.4)	1.2 [0.7, 2.0]	0.210 [0.143, 0.308]	<.0001	
Region									
Europe	97	36 (37.1)	15.6 [11.8, NC]	101	77 (76.2)	1.2 [0.8, 1.9]	0.210 [0.134, 0.329]	<.0001	0.0385
North America	57	4 (7.0)	NC [NC, NC]	51	31 (60.8)	2.3 [0.8, NC]	0.057 [0.017, 0.187]	<.0001	
Rest of World	85	29 (34.1)	NC [12.0, NC]	84	62 (73.8)	1.1 [0.5, 1.4]	0.229 [0.143, 0.368]	<.0001	
Sex									
Male	197	61 (31.0)	NC [NC, NC]	181	126 (69.6)	1.2 [1.0, 2.1]	0.222 [0.159, 0.309]	<.0001	0.0648
Female	42	8 (19.0)	NC [NC, NC]	55	44 (80.0)	1.2 [0.5, 2.1]	0.068 [0.026, 0.180]	<.0001	
Metastases at Baseline									
Visceral metastases	169	48 (28.4)	NC [NC, NC]	157	112 (71.3)	1.2 [0.9, 1.9]	0.190 [0.131, 0.277]	<.0001	0.5983
Lymph node only	60	15 (25.0)	NC [NC, NC]	65	47 (72.3)	1.2 [0.9, 2.1]	0.153 [0.080, 0.291]	<.0001	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.7.1.1: Summary and Results of TEAEs - Anaemia (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	41 (17.2%)	132 (55.9%)	
Number of patients censored	198 (82.8%)	104 (44.1%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	88.0 [83.1, 91.5]	48.4 [41.7, 54.8]	
Month 6	84.9 [79.5, 89.0]	NC [NC, NC]	
Month 9	83.8 [78.2, 88.1]	NC [NC, NC]	
Month 12	81.9 [75.6, 86.6]	NC [NC, NC]	
Month 18	77.6 [69.5, 83.8]	NC [NC, NC]	
Month 24	77.6 [69.5, 83.8]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	2.8 [2.3, 3.5]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.173 [0.117, 0.254]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.7.1.2: Summary and Results of TEAEs by Subgroups - Anaemia (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	13 (27.7)	NC [15.6, NC]	47	23 (48.9)	4.2 [2.1, NC]	0.372 [0.178, 0.778]	0.0063	0.0108
Absent	192	28 (14.6)	NC [NC, NC]	189	109 (57.7)	2.8 [2.2, 3.5]	0.136 [0.086, 0.216]	<.0001	
Age									
< 65 years	105	13 (12.4)	NC [NC, NC]	102	51 (50.0)	3.5 [2.3, NC]	0.167 [0.087, 0.320]	<.0001	0.4212
>= 65 years	134	28 (20.9)	NC [NC, NC]	134	81 (60.4)	2.8 [2.1, 3.1]	0.173 [0.107, 0.280]	<.0001	
Region									
Europe	97	21 (21.6)	NC [15.6, NC]	101	60 (59.4)	3.0 [2.1, 3.9]	0.172 [0.097, 0.306]	<.0001	0.1892
North America	57	3 (5.3)	NC [NC, NC]	51	24 (47.1)	NC [2.2, NC]	0.059 [0.014, 0.248]	<.0001	
Rest of World	85	17 (20.0)	NC [NC, NC]	84	48 (57.1)	2.6 [1.8, NC]	0.247 [0.140, 0.435]	<.0001	
Sex									
Male	197	36 (18.3)	NC [NC, NC]	181	97 (53.6)	3.0 [2.3, 5.1]	0.194 [0.127, 0.296]	<.0001	0.2228
Female	42	5 (11.9)	NC [NC, NC]	55	35 (63.6)	2.3 [1.7, 3.9]	0.103 [0.036, 0.291]	<.0001	
Metastases at Baseline									
Visceral metastases	169	30 (17.8)	NC [NC, NC]	157	85 (54.1)	3.0 [2.3, 4.9]	0.194 [0.124, 0.305]	<.0001	0.2920
Lymph node only	60	7 (11.7)	NC [NC, NC]	65	37 (56.9)	2.9 [2.1, NC]	0.114 [0.047, 0.278]	<.0001	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.8.1.1: Summary and Results of TEAEs - Leukopenia (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	9 (3.8%)	26 (11.0%)	
Number of patients censored	230 (96.2%)	210 (89.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.4 [94.3, 98.8]	88.8 [84.0, 92.3]	
Month 6	97.4 [94.3, 98.8]	88.8 [84.0, 92.3]	
Month 9	96.7 [93.2, 98.5]	NC [NC, NC]	
Month 12	94.6 [89.2, 97.3]	NC [NC, NC]	
Month 18	94.6 [89.2, 97.3]	NC [NC, NC]	
Month 24	94.6 [89.2, 97.3]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.215 [0.089, 0.523]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0002

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.8.1.2: Summary and Results of TEAEs by Subgroups - Leukopenia (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	2 (4.3)	NC [NC, NC]	47	6 (12.8)	NC [NC, NC]	0.319 [0.064, 1.583]	0.1403	0.9011
Absent	192	7 (3.6)	NC [NC, NC]	189	20 (10.6)	NC [NC, NC]	0.185 [0.063, 0.542]	0.0006	
Age									
< 65 years	105	4 (3.8)	NC [NC, NC]	102	12 (11.8)	NC [NC, NC]	0.153 [0.034, 0.685]	0.0047	0.8704
>= 65 years	134	5 (3.7)	NC [NC, NC]	134	14 (10.4)	NC [NC, NC]	0.270 [0.089, 0.820]	0.0134	
Region									
Europe	97	2 (2.1)	NC [NC, NC]	101	10 (9.9)	NC [NC, NC]	0.199 [0.043, 0.906]	0.0202	NC
North America	57	0 (0.0)	NC [NC, NC]	51	4 (7.8)	NC [NC, NC]	NC [NC, NC]	0.0319	
Rest of World	85	7 (8.2)	NC [NC, NC]	84	12 (14.3)	NC [NC, NC]	0.307 [0.099, 0.951]	0.0305	
Sex									
Male	197	7 (3.6)	NC [NC, NC]	181	22 (12.2)	NC [NC, NC]	0.235 [0.095, 0.580]	0.0006	0.4276
Female	42	2 (4.8)	NC [NC, NC]	55	4 (7.3)	NC [NC, NC]	0.000 [0.000, NC]	0.0763	
Metastases at Baseline									
Visceral metastases	169	9 (5.3)	NC [NC, NC]	157	17 (10.8)	NC [NC, NC]	0.310 [0.122, 0.785]	0.0092	NC
Lymph node only	60	0 (0.0)	NC [NC, NC]	65	6 (9.2)	NC [NC, NC]	NC [NC, NC]	0.0160	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.9.1.1: Summary and Results of TEAEs - Neutropenia (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	21 (8.8%)	86 (36.4%)	
Number of patients censored	218 (91.2%)	150 (63.6%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	93.2 [89.1, 95.8]	64.3 [57.7, 70.2]	
Month 6	91.1 [86.4, 94.2]	62.1 [55.4, 68.1]	
Month 9	91.1 [86.4, 94.2]	NC [NC, NC]	
Month 12	89.9 [84.7, 93.5]	NC [NC, NC]	
Month 18	89.9 [84.7, 93.5]	NC [NC, NC]	
Month 24	89.9 [84.7, 93.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.169 [0.103, 0.279]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.9.1.2: Summary and Results of TEAEs by Subgroups - Neutropenia (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	4 (8.5)	NC [NC, NC]	47	22 (46.8)	NC [2.1, NC]	0.142 [0.049, 0.412]	<.0001	0.5742
Absent	192	17 (8.9)	NC [NC, NC]	189	64 (33.9)	NC [NC, NC]	0.179 [0.101, 0.316]	<.0001	
Age									
< 65 years	105	4 (3.8)	NC [NC, NC]	102	37 (36.3)	NC [NC, NC]	0.063 [0.019, 0.204]	<.0001	0.0428
>= 65 years	134	17 (12.7)	NC [NC, NC]	134	49 (36.6)	NC [NC, NC]	0.253 [0.143, 0.447]	<.0001	
Region									
Europe	97	11 (11.3)	NC [NC, NC]	101	40 (39.6)	NC [3.1, NC]	0.195 [0.096, 0.393]	<.0001	NC
North America	57	0 (0.0)	NC [NC, NC]	51	14 (27.5)	NC [NC, NC]	NC [NC, NC]	<.0001	
Rest of World	85	10 (11.8)	NC [NC, NC]	84	32 (38.1)	NC [3.5, NC]	0.221 [0.105, 0.464]	<.0001	
Sex									
Male	197	21 (10.7)	NC [NC, NC]	181	67 (37.0)	NC [NC, NC]	0.201 [0.120, 0.335]	<.0001	NC
Female	42	0 (0.0)	NC [NC, NC]	55	19 (34.5)	NC [NC, NC]	NC [NC, NC]	<.0001	
Metastases at Baseline									
Visceral metastases	169	16 (9.5)	NC [NC, NC]	157	58 (36.9)	NC [NC, NC]	0.172 [0.095, 0.311]	<.0001	0.6923
Lymph node only	60	4 (6.7)	NC [NC, NC]	65	21 (32.3)	NC [NC, NC]	0.166 [0.057, 0.483]	0.0002	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.10.1.1: Summary and Results of TEAEs - Thrombocytopenia (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	9 (3.8%)	57 (24.2%)	
Number of patients censored	230 (96.2%)	179 (75.8%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	99.5 [96.8, 99.9]	78.0 [72.0, 82.8]	
Month 6	97.0 [93.4, 98.6]	74.5 [68.2, 79.8]	
Month 9	95.7 [91.5, 97.8]	NC [NC, NC]	
Month 12	95.7 [91.5, 97.8]	NC [NC, NC]	
Month 18	93.5 [86.1, 97.1]	NC [NC, NC]	
Month 24	93.5 [86.1, 97.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.078 [0.033, 0.184]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.10.1.2: Summary and Results of TEAEs by Subgroups - Thrombocytopenia (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	2 (4.3)	NC [NC, NC]	47	12 (25.5)	NC [NC, NC]	0.000 [0.000, NC]	0.0003	0.7998
Absent	192	7 (3.6)	NC [NC, NC]	189	45 (23.8)	NC [NC, NC]	0.094 [0.039, 0.226]	<.0001	
Age									
< 65 years	105	5 (4.8)	NC [NC, NC]	102	13 (12.7)	NC [NC, NC]	0.169 [0.046, 0.626]	0.0029	0.0503
>= 65 years	134	4 (3.0)	NC [NC, NC]	134	44 (32.8)	NC [NC, NC]	0.050 [0.015, 0.162]	<.0001	
Region									
Europe	97	5 (5.2)	NC [NC, NC]	101	27 (26.7)	NC [NC, NC]	0.088 [0.026, 0.296]	<.0001	0.8036
North America	57	1 (1.8)	NC [NC, NC]	51	9 (17.6)	NC [NC, NC]	0.084 [0.011, 0.662]	0.0028	
Rest of World	85	3 (3.5)	NC [NC, NC]	84	21 (25.0)	NC [NC, NC]	0.067 [0.015, 0.294]	<.0001	
Sex									
Male	197	7 (3.6)	NC [NC, NC]	181	42 (23.2)	NC [NC, NC]	0.086 [0.034, 0.221]	<.0001	0.8565
Female	42	2 (4.8)	NC [NC, NC]	55	15 (27.3)	NC [NC, NC]	0.056 [0.007, 0.450]	0.0004	
Metastases at Baseline									
Visceral metastases	169	4 (2.4)	NC [NC, NC]	157	40 (25.5)	NC [NC, NC]	0.017 [0.002, 0.127]	<.0001	0.1245
Lymph node only	60	4 (6.7)	NC [NC, NC]	65	14 (21.5)	NC [NC, NC]	0.228 [0.071, 0.727]	0.0069	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.11.1.1: Summary and Results of TEAEs - Cardiac disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	22 (9.2%)	20 (8.5%)	
Number of patients censored	217 (90.8%)	216 (91.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	94.0 [90.0, 96.4]	92.0 [87.6, 94.9]	
Month 6	92.4 [88.0, 95.2]	90.9 [86.2, 94.0]	
Month 9	91.0 [86.1, 94.2]	NC [NC, NC]	
Month 12	90.1 [84.9, 93.6]	NC [NC, NC]	
Month 18	88.9 [83.0, 92.9]	NC [NC, NC]	
Month 24	88.9 [83.0, 92.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [25.5, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.756 [0.391, 1.463]
Log-rank test			
Two-sided unstratified log-rank p-value			0.4047

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.12.1.1: Summary and Results of TEAEs - Ear and labyrinth disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	17 (7.1%)	33 (14.0%)	
Number of patients censored	222 (92.9%)	203 (86.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.3 [95.6, 99.4]	87.3 [82.3, 91.0]	
Month 6	96.1 [92.3, 98.1]	85.1 [79.6, 89.2]	
Month 9	93.4 [88.6, 96.3]	NC [NC, NC]	
Month 12	90.6 [84.5, 94.4]	NC [NC, NC]	
Month 18	89.4 [82.6, 93.6]	NC [NC, NC]	
Month 24	86.9 [77.9, 92.4]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.171 [0.074, 0.396]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.12.1.2: Summary and Results of TEAEs by Subgroups - Ear and labyrinth disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	2 (4.3)	NC [NC, NC]	47	5 (10.6)	NC [NC, NC]	0.000 [0.000, NC]	0.0221	0.9643
Absent	192	15 (7.8)	NC [NC, NC]	189	28 (14.8)	NC [NC, NC]	0.198 [0.084, 0.467]	<.0001	
Age									
< 65 years	105	5 (4.8)	NC [NC, NC]	102	20 (19.6)	NC [NC, NC]	0.086 [0.020, 0.370]	<.0001	0.0195
>= 65 years	134	12 (9.0)	NC [NC, NC]	134	13 (9.7)	NC [NC, NC]	0.301 [0.102, 0.891]	0.0220	
Region									
Europe	97	2 (2.1)	NC [NC, NC]	101	11 (10.9)	NC [NC, NC]	0.030 [0.002, 0.425]	0.0008	0.3870
North America	57	11 (19.3)	NC [12.9, NC]	51	16 (31.4)	NC [NC, NC]	0.225 [0.082, 0.616]	0.0015	
Rest of World	85	4 (4.7)	NC [NC, NC]	84	6 (7.1)	NC [NC, NC]	0.160 [0.019, 1.332]	0.0523	
Sex									
Male	197	13 (6.6)	NC [NC, NC]	181	24 (13.3)	NC [NC, NC]	0.178 [0.069, 0.459]	<.0001	0.8053
Female	42	4 (9.5)	NC [NC, NC]	55	9 (16.4)	NC [NC, NC]	0.161 [0.026, 0.989]	0.0283	
Metastases at Baseline									
Visceral metastases	169	10 (5.9)	NC [NC, NC]	157	25 (15.9)	NC [NC, NC]	0.140 [0.051, 0.387]	<.0001	0.3775
Lymph node only	60	5 (8.3)	NC [NC, NC]	65	7 (10.8)	NC [NC, NC]	0.000 [0.000, NC]	0.0092	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.13.1.1: Summary and Results of TEAEs - Tinnitus (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	5 (2.1%)	27 (11.4%)	
Number of patients censored	234 (97.9%)	209 (88.6%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	99.1 [96.6, 99.8]	89.5 [84.8, 92.9]	
Month 6	97.5 [93.9, 98.9]	87.8 [82.7, 91.5]	
Month 9	97.5 [93.9, 98.9]	NC [NC, NC]	
Month 12	97.5 [93.9, 98.9]	NC [NC, NC]	
Month 18	97.5 [93.9, 98.9]	NC [NC, NC]	
Month 24	97.5 [93.9, 98.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.113 [0.038, 0.337]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.13.1.2: Summary and Results of TEAEs by Subgroups - Tinnitus (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	0 (0.0)	NC [NC, NC]	47	5 (10.6)	NC [NC, NC]	NC [NC, NC]	0.0221	NC
Absent	192	5 (2.6)	NC [NC, NC]	189	22 (11.6)	NC [NC, NC]	0.136 [0.044, 0.415]	<.0001	
Age									
< 65 years	105	1 (1.0)	NC [NC, NC]	102	17 (16.7)	NC [NC, NC]	0.052 [0.007, 0.388]	<.0001	0.0894
>= 65 years	134	4 (3.0)	NC [NC, NC]	134	10 (7.5)	NC [NC, NC]	0.209 [0.052, 0.846]	0.0172	
Region									
Europe	97	1 (1.0)	NC [NC, NC]	101	6 (5.9)	NC [NC, NC]	0.043 [0.002, 0.855]	0.0144	0.9923
North America	57	3 (5.3)	NC [NC, NC]	51	15 (29.4)	NC [NC, NC]	0.094 [0.021, 0.413]	<.0001	
Rest of World	85	1 (1.2)	NC [NC, NC]	84	6 (7.1)	NC [NC, NC]	0.160 [0.019, 1.332]	0.0523	
Sex									
Male	197	3 (1.5)	NC [NC, NC]	181	21 (11.6)	NC [NC, NC]	0.088 [0.023, 0.337]	<.0001	0.2476
Female	42	2 (4.8)	NC [NC, NC]	55	6 (10.9)	NC [NC, NC]	0.239 [0.035, 1.628]	0.1186	
Metastases at Baseline									
Visceral metastases	169	4 (2.4)	NC [NC, NC]	157	22 (14.0)	NC [NC, NC]	0.087 [0.023, 0.319]	<.0001	NC
Lymph node only	60	0 (0.0)	NC [NC, NC]	65	5 (7.7)	NC [NC, NC]	NC [NC, NC]	0.0291	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.14.1.1: Summary and Results of TEAEs - Endocrine disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	34 (14.2%)	2 (0.8%)	
Number of patients censored	205 (85.8%)	234 (99.2%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	93.4 [89.2, 96.0]	99.6 [97.0, 99.9]	
Month 6	87.2 [81.8, 91.0]	99.1 [96.3, 99.8]	
Month 9	84.6 [78.6, 88.9]	NC [NC, NC]	
Month 12	82.6 [76.0, 87.5]	NC [NC, NC]	
Month 18	82.6 [76.0, 87.5]	NC [NC, NC]	
Month 24	79.8 [70.8, 86.3]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			12.371 [2.934, 52.158]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.14.1.2: Summary and Results of TEAEs by Subgroups - Endocrine disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	7 (14.9)	NC [NC, NC]	47	1 (2.1)	NC [NC, NC]	5.336 [0.623, 45.685]	0.0866	0.4298
Absent	192	27 (14.1)	NC [NC, NC]	189	1 (0.5)	NC [NC, NC]	19.263 [2.588, 143.38]	<.0001	
Age									
< 65 years	105	12 (11.4)	NC [NC, NC]	102	2 (2.0)	NC [NC, NC]	4.389 [0.948, 20.316]	0.0384	NC
>= 65 years	134	22 (16.4)	NC [NC, NC]	134	0 (0.0)	NC [NC, NC]	NC [NC, NC]	<.0001	
Region									
Europe	97	13 (13.4)	NC [NC, NC]	101	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0011	NC
North America	57	8 (14.0)	NC [NC, NC]	51	1 (2.0)	NC [NC, NC]	4.873 [0.586, 40.506]	0.1064	
Rest of World	85	13 (15.3)	NC [NC, NC]	84	1 (1.2)	NC [NC, NC]	8.874 [1.125, 70.012]	0.0122	
Sex									
Male	197	24 (12.2)	NC [NC, NC]	181	2 (1.1)	NC [NC, NC]	7.537 [1.742, 32.606]	0.0015	NC
Female	42	10 (23.8)	NC [NC, NC]	55	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0008	
Metastases at Baseline									
Visceral metastases	169	23 (13.6)	NC [NC, NC]	157	1 (0.6)	NC [NC, NC]	14.805 [1.969, 111.34]	0.0005	0.4561
Lymph node only	60	7 (11.7)	NC [NC, NC]	65	1 (1.5)	NC [NC, NC]	5.363 [0.627, 45.907]	0.0855	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.15.1.1: Summary and Results of TEAEs - Hyperthyroidism (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	9 (3.8%)	1 (0.4%)	
Number of patients censored	230 (96.2%)	235 (99.6%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.8 [94.7, 99.1]	100.0 [100.0, 100.0]	
Month 6	96.7 [93.2, 98.4]	99.5 [96.5, 99.9]	
Month 9	95.5 [91.4, 97.6]	NC [NC, NC]	
Month 12	95.5 [91.4, 97.6]	NC [NC, NC]	
Month 18	95.5 [91.4, 97.6]	NC [NC, NC]	
Month 24	95.5 [91.4, 97.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			6.030 [0.733, 49.607]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0577

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.16.1.1: Summary and Results of TEAEs - Hypothyroidism (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	23 (9.6%)	1 (0.4%)	
Number of patients censored	216 (90.4%)	235 (99.6%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.9 [93.6, 98.5]	99.6 [97.0, 99.9]	
Month 6	90.7 [85.8, 94.0]	99.6 [97.0, 99.9]	
Month 9	89.3 [84.0, 92.9]	NC [NC, NC]	
Month 12	88.2 [82.3, 92.2]	NC [NC, NC]	
Month 18	88.2 [82.3, 92.2]	NC [NC, NC]	
Month 24	85.5 [76.8, 91.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			16.738 [2.235, 125.34]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0002

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.16.1.2: Summary and Results of TEAEs by Subgroups - Hypothyroidism (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	4 (8.5)	NC [NC, NC]	47	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0793	NC
Absent	192	19 (9.9)	NC [NC, NC]	189	1 (0.5)	NC [NC, NC]	13.515 [1.784, 102.39]	0.0010	
Age									
< 65 years	105	7 (6.7)	NC [NC, NC]	102	1 (1.0)	NC [NC, NC]	4.744 [0.556, 40.473]	0.1166	NC
>= 65 years	134	16 (11.9)	NC [NC, NC]	134	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0005	
Region									
Europe	97	11 (11.3)	NC [NC, NC]	101	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0022	NC
North America	57	4 (7.0)	NC [NC, NC]	51	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0996	
Rest of World	85	8 (9.4)	NC [NC, NC]	84	1 (1.2)	NC [NC, NC]	4.763 [0.556, 40.772]	0.1157	
Sex									
Male	197	18 (9.1)	NC [NC, NC]	181	1 (0.6)	NC [NC, NC]	12.000 [1.577, 91.338]	0.0022	NC
Female	42	5 (11.9)	NC [NC, NC]	55	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0257	
Metastases at Baseline									
Visceral metastases	169	15 (8.9)	NC [NC, NC]	157	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0013	NC
Lymph node only	60	5 (8.3)	NC [NC, NC]	65	1 (1.5)	NC [NC, NC]	3.163 [0.331, 30.237]	0.2916	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.17.1.1: Summary and Results of TEAEs - Eye disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	88 (36.8%)	14 (5.9%)	
Number of patients censored	151 (63.2%)	222 (94.1%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	78.8 [72.9, 83.5]	93.7 [89.6, 96.2]	
Month 6	66.4 [59.5, 72.3]	93.7 [89.6, 96.2]	
Month 9	60.4 [53.1, 66.9]	NC [NC, NC]	
Month 12	59.6 [52.2, 66.2]	NC [NC, NC]	
Month 18	53.0 [43.7, 61.5]	NC [NC, NC]	
Month 24	49.9 [39.3, 59.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	19.7 [12.7, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			5.300 [2.984, 9.412]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.17.1.2: Summary and Results of TEAEs by Subgroups - Eye disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	23 (48.9)	5.1 [3.9, NC]	47	2 (4.3)	NC [NC, NC]	12.067 [2.813, 51.773]	<.0001	0.1888
Absent	192	65 (33.9)	NC [17.8, NC]	189	12 (6.3)	NC [NC, NC]	4.364 [2.324, 8.194]	<.0001	
Age									
< 65 years	105	37 (35.2)	NC [8.4, NC]	102	6 (5.9)	NC [NC, NC]	4.888 [2.025, 11.798]	<.0001	0.8518
>= 65 years	134	51 (38.1)	17.8 [9.3, NC]	134	8 (6.0)	NC [NC, NC]	5.626 [2.638, 11.995]	<.0001	
Region									
Europe	97	39 (40.2)	16.3 [6.7, NC]	101	2 (2.0)	NC [NC, NC]	15.975 [3.805, 67.068]	<.0001	0.1129
North America	57	34 (59.6)	3.9 [2.8, 5.4]	51	9 (17.6)	NC [NC, NC]	3.902 [1.862, 8.177]	0.0001	
Rest of World	85	15 (17.6)	NC [NC, NC]	84	3 (3.6)	NC [NC, NC]	2.975 [0.807, 10.970]	0.0857	
Sex									
Male	197	74 (37.6)	19.7 [12.2, NC]	181	11 (6.1)	NC [NC, NC]	5.107 [2.676, 9.745]	<.0001	0.9900
Female	42	14 (33.3)	NC [4.9, NC]	55	3 (5.5)	NC [NC, NC]	5.922 [1.689, 20.763]	0.0016	
Metastases at Baseline									
Visceral metastases	169	63 (37.3)	NC [8.2, NC]	157	9 (5.7)	NC [NC, NC]	5.704 [2.807, 11.589]	<.0001	0.5163
Lymph node only	60	21 (35.0)	17.8 [8.4, NC]	65	5 (7.7)	NC [NC, NC]	3.455 [1.257, 9.501]	0.0105	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.18.1.1: Summary and Results of TEAEs - Cataract (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	10 (4.2%)	1 (0.4%)	
Number of patients censored	229 (95.8%)	235 (99.6%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	99.6 [96.9, 99.9]	99.6 [97.0, 99.9]	
Month 6	98.5 [95.5, 99.5]	99.6 [97.0, 99.9]	
Month 9	97.1 [92.9, 98.8]	NC [NC, NC]	
Month 12	96.3 [91.7, 98.3]	NC [NC, NC]	
Month 18	89.5 [79.7, 94.7]	NC [NC, NC]	
Month 24	89.5 [79.7, 94.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			2.773 [0.288, 26.684]
Log-rank test			
Two-sided unstratified log-rank p-value			0.3566

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.19.1.1: Summary and Results of TEAEs - Dry eye (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	29 (12.1%)	3 (1.3%)	
Number of patients censored	210 (87.9%)	233 (98.7%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	92.6 [88.3, 95.3]	98.7 [96.1, 99.6]	
Month 6	89.5 [84.6, 92.9]	98.7 [96.1, 99.6]	
Month 9	86.9 [81.3, 90.9]	NC [NC, NC]	
Month 12	86.1 [80.3, 90.3]	NC [NC, NC]	
Month 18	84.6 [77.9, 89.4]	NC [NC, NC]	
Month 24	84.6 [77.9, 89.4]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			7.431 [2.230, 24.766]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.19.1.2: Summary and Results of TEAEs by Subgroups - Dry eye (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	8 (17.0)	NC [NC, NC]	47	1 (2.1)	NC [NC, NC]	7.012 [0.860, 57.194]	0.0344	0.9216
Absent	192	21 (10.9)	NC [NC, NC]	189	2 (1.1)	NC [NC, NC]	7.830 [1.801, 34.040]	0.0011	
Age									
< 65 years	105	16 (15.2)	NC [NC, NC]	102	1 (1.0)	NC [NC, NC]	12.567 [1.642, 96.205]	0.0017	0.4825
>= 65 years	134	13 (9.7)	NC [NC, NC]	134	2 (1.5)	NC [NC, NC]	4.823 [1.056, 22.015]	0.0246	
Region									
Europe	97	11 (11.3)	NC [NC, NC]	101	1 (1.0)	NC [NC, NC]	7.722 [0.963, 61.916]	0.0231	0.7629
North America	57	13 (22.8)	NC [NC, NC]	51	1 (2.0)	NC [NC, NC]	11.363 [1.477, 87.411]	0.0032	
Rest of World	85	5 (5.9)	NC [NC, NC]	84	1 (1.2)	NC [NC, NC]	2.939 [0.308, 28.013]	0.3263	
Sex									
Male	197	23 (11.7)	NC [NC, NC]	181	0 (0.0)	NC [NC, NC]	NC [NC, NC]	<.0001	NC
Female	42	6 (14.3)	NC [NC, NC]	55	3 (5.5)	NC [NC, NC]	2.317 [0.574, 9.350]	0.2243	
Metastases at Baseline									
Visceral metastases	169	21 (12.4)	NC [NC, NC]	157	2 (1.3)	NC [NC, NC]	7.658 [1.767, 33.192]	0.0013	0.8325
Lymph node only	60	7 (11.7)	NC [NC, NC]	65	1 (1.5)	NC [NC, NC]	5.339 [0.624, 45.697]	0.0865	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.20.1.1: Summary and Results of TEAEs - Lacrimation increased (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	25 (10.5%)	1 (0.4%)	
Number of patients censored	214 (89.5%)	235 (99.6%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	93.9 [89.9, 96.3]	99.5 [96.8, 99.9]	
Month 6	91.7 [87.2, 94.7]	99.5 [96.8, 99.9]	
Month 9	87.7 [82.0, 91.7]	NC [NC, NC]	
Month 12	86.5 [80.3, 90.9]	NC [NC, NC]	
Month 18	86.5 [80.3, 90.9]	NC [NC, NC]	
Month 24	86.5 [80.3, 90.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			16.265 [2.163, 122.29]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0002

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.20.1.2: Summary and Results of TEAEs by Subgroups - Lacrimation increased (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	4 (8.5)	NC [NC, NC]	47	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1474	NC
Absent	192	21 (10.9)	NC [NC, NC]	189	1 (0.5)	NC [NC, NC]	14.026 [1.849, 106.37]	0.0008	
Age									
< 65 years	105	7 (6.7)	NC [NC, NC]	102	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0457	NC
>= 65 years	134	18 (13.4)	NC [NC, NC]	134	1 (0.7)	NC [NC, NC]	12.455 [1.626, 95.411]	0.0019	
Region									
Europe	97	16 (16.5)	NC [NC, NC]	101	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0009	NC
North America	57	6 (10.5)	NC [NC, NC]	51	1 (2.0)	NC [NC, NC]	3.590 [0.402, 32.029]	0.2215	
Rest of World	85	3 (3.5)	NC [NC, NC]	84	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1726	
Sex									
Male	197	23 (11.7)	NC [NC, NC]	181	1 (0.6)	NC [NC, NC]	15.095 [2.006, 113.59]	0.0004	NC
Female	42	2 (4.8)	NC [NC, NC]	55	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.7277	
Metastases at Baseline									
Visceral metastases	169	17 (10.1)	NC [NC, NC]	157	1 (0.6)	NC [NC, NC]	9.406 [1.206, 73.355]	0.0091	NC
Lymph node only	60	6 (10.0)	NC [NC, NC]	65	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0194	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.21.1.1: Summary and Results of TEAEs - Vision blurred (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	16 (6.7%)	4 (1.7%)	
Number of patients censored	223 (93.3%)	232 (98.3%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.0 [93.7, 98.5]	98.2 [95.3, 99.3]	
Month 6	93.8 [89.6, 96.4]	98.2 [95.3, 99.3]	
Month 9	91.9 [87.1, 95.0]	NC [NC, NC]	
Month 12	91.9 [87.1, 95.0]	NC [NC, NC]	
Month 18	91.9 [87.1, 95.0]	NC [NC, NC]	
Month 24	91.9 [87.1, 95.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			2.840 [0.919, 8.779]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0584

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.22.1.1: Summary and Results of TEAEs - Gastrointestinal disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	179 (74.9%)	184 (78.0%)	
Number of patients censored	60 (25.1%)	52 (22.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	39.3 [33.0, 45.5]	26.1 [20.6, 32.0]	
Month 6	33.1 [27.0, 39.2]	19.2 [14.0, 24.9]	
Month 9	24.6 [19.0, 30.6]	NC [NC, NC]	
Month 12	22.5 [17.0, 28.6]	NC [NC, NC]	
Month 18	19.1 [13.5, 25.6]	NC [NC, NC]	
Month 24	17.4 [11.5, 24.3]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	1.1 [0.7, 1.9]	0.5 [0.3, 0.8]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.649 [0.524, 0.803]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.22.1.2: Summary and Results of TEAEs by Subgroups - Gastrointestinal disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	39 (83.0)	0.7 [0.3, 1.2]	47	34 (72.3)	0.8 [0.3, 2.3]	1.107 [0.694, 1.765]	0.6565	0.0225
Absent	192	140 (72.9)	1.3 [0.8, 2.7]	189	150 (79.4)	0.5 [0.2, 0.8]	0.565 [0.444, 0.720]	<.0001	
Age									
< 65 years	105	72 (68.6)	2.1 [0.7, 6.5]	102	79 (77.5)	0.3 [0.1, 0.8]	0.548 [0.392, 0.768]	0.0004	0.1249
>= 65 years	134	107 (79.9)	0.9 [0.6, 1.3]	134	105 (78.4)	0.6 [0.3, 1.0]	0.745 [0.564, 0.984]	0.0391	
Region									
Europe	97	68 (70.1)	1.1 [0.8, 3.7]	101	83 (82.2)	0.6 [0.3, 0.8]	0.554 [0.397, 0.774]	0.0005	0.2822
North America	57	49 (86.0)	0.4 [0.2, 0.8]	51	43 (84.3)	0.2 [0.1, 0.3]	0.841 [0.555, 1.273]	0.4332	
Rest of World	85	62 (72.9)	2.3 [0.8, 6.4]	84	58 (69.0)	1.1 [0.2, 2.5]	0.632 [0.431, 0.925]	0.0190	
Sex									
Male	197	148 (75.1)	1.1 [0.7, 1.9]	181	137 (75.7)	0.6 [0.3, 1.0]	0.696 [0.547, 0.886]	0.0034	0.2822
Female	42	31 (73.8)	1.1 [0.6, 4.9]	55	47 (85.5)	0.2 [0.1, 0.7]	0.512 [0.318, 0.825]	0.0055	
Metastases at Baseline									
Visceral metastases	169	128 (75.7)	1.1 [0.7, 2.0]	157	118 (75.2)	0.6 [0.3, 1.0]	0.701 [0.541, 0.909]	0.0078	0.1016
Lymph node only	60	42 (70.0)	1.1 [0.6, 2.7]	65	56 (86.2)	0.3 [0.1, 1.0]	0.520 [0.343, 0.788]	0.0018	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.23.1.1: Summary and Results of TEAEs - Abdominal pain (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	27 (11.3%)	21 (8.9%)	
Number of patients censored	212 (88.7%)	215 (91.1%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	92.8 [88.6, 95.5]	92.7 [88.5, 95.4]	
Month 6	90.3 [85.6, 93.5]	90.5 [85.7, 93.7]	
Month 9	88.3 [83.0, 92.0]	NC [NC, NC]	
Month 12	88.3 [83.0, 92.0]	NC [NC, NC]	
Month 18	87.1 [81.1, 91.2]	NC [NC, NC]	
Month 24	84.1 [74.8, 90.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.997 [0.548, 1.815]
Log-rank test			
Two-sided unstratified log-rank p-value			0.9925

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.24.1.1: Summary and Results of TEAEs - Abdominal pain upper (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	12 (5.0%)	7 (3.0%)	
Number of patients censored	227 (95.0%)	229 (97.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.2 [92.8, 98.0]	97.7 [94.7, 99.1]	
Month 6	95.7 [92.1, 97.7]	96.5 [92.8, 98.4]	
Month 9	95.7 [92.1, 97.7]	NC [NC, NC]	
Month 12	93.8 [88.9, 96.6]	NC [NC, NC]	
Month 18	93.8 [88.9, 96.6]	NC [NC, NC]	
Month 24	93.8 [88.9, 96.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.386 [0.527, 3.643]
Log-rank test			
Two-sided unstratified log-rank p-value			0.5054

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.25.1.1: Summary and Results of TEAEs - Constipation (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	67 (28.0%)	76 (32.2%)	
Number of patients censored	172 (72.0%)	160 (67.8%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	83.8 [78.4, 87.9]	70.7 [64.3, 76.1]	
Month 6	77.8 [71.7, 82.7]	66.4 [59.8, 72.2]	
Month 9	71.7 [64.9, 77.4]	NC [NC, NC]	
Month 12	69.0 [61.8, 75.2]	NC [NC, NC]	
Month 18	66.6 [58.7, 73.3]	NC [NC, NC]	
Month 24	64.1 [55.0, 71.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [24.8, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.555 [0.387, 0.795]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0012

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.25.1.2: Summary and Results of TEAEs by Subgroups - Constipation (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	10 (21.3)	24.8 [NC, NC]	47	10 (21.3)	NC [NC, NC]	0.738 [0.291, 1.870]	0.5237	0.5598
Absent	192	57 (29.7)	NC [NC, NC]	189	66 (34.9)	NC [NC, NC]	0.523 [0.354, 0.773]	0.0010	
Age									
< 65 years	105	23 (21.9)	24.8 [24.8, NC]	102	30 (29.4)	NC [NC, NC]	0.404 [0.216, 0.758]	0.0035	0.3422
>= 65 years	134	44 (32.8)	NC [13.9, NC]	134	46 (34.3)	NC [NC, NC]	0.654 [0.420, 1.017]	0.0583	
Region									
Europe	97	21 (21.6)	NC [24.8, NC]	101	30 (29.7)	NC [NC, NC]	0.435 [0.231, 0.818]	0.0080	0.7286
North America	57	22 (38.6)	NC [5.1, NC]	51	21 (41.2)	NC [1.2, NC]	0.744 [0.401, 1.381]	0.3523	
Rest of World	85	24 (28.2)	NC [19.3, NC]	84	25 (29.8)	NC [NC, NC]	0.506 [0.267, 0.961]	0.0345	
Sex									
Male	197	55 (27.9)	NC [24.8, NC]	181	57 (31.5)	NC [NC, NC]	0.577 [0.386, 0.863]	0.0068	0.8526
Female	42	12 (28.6)	NC [8.1, NC]	55	19 (34.5)	NC [3.9, NC]	0.477 [0.209, 1.090]	0.0728	
Metastases at Baseline									
Visceral metastases	169	44 (26.0)	24.8 [19.3, NC]	157	46 (29.3)	NC [NC, NC]	0.558 [0.355, 0.879]	0.0108	0.5034
Lymph node only	60	19 (31.7)	NC [NC, NC]	65	27 (41.5)	NC [3.1, NC]	0.524 [0.280, 0.980]	0.0393	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.26.1.1: Summary and Results of TEAEs - Diarrhoea (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	89 (37.2%)	40 (16.9%)	
Number of patients censored	150 (62.8%)	196 (83.1%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	72.1 [65.9, 77.4]	86.2 [81.1, 90.1]	
Month 6	66.0 [59.4, 71.8]	82.0 [76.2, 86.5]	
Month 9	62.7 [55.9, 68.7]	NC [NC, NC]	
Month 12	62.0 [55.2, 68.1]	NC [NC, NC]	
Month 18	57.3 [49.0, 64.8]	NC [NC, NC]	
Month 24	54.8 [45.4, 63.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [16.4, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.904 [1.295, 2.799]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0009

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.26.1.2: Summary and Results of TEAEs by Subgroups - Diarrhoea (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	18 (38.3)	15.9 [6.0, NC]	47	3 (6.4)	NC [NC, NC]	5.606 [1.617, 19.434]	0.0022	0.0409
Absent	192	71 (37.0)	NC [20.0, NC]	189	37 (19.6)	NC [NC, NC]	1.601 [1.061, 2.415]	0.0234	
Age									
< 65 years	105	35 (33.3)	NC [20.0, NC]	102	16 (15.7)	NC [NC, NC]	1.622 [0.870, 3.023]	0.1226	0.7796
>= 65 years	134	54 (40.3)	NC [6.5, NC]	134	24 (17.9)	NC [NC, NC]	2.108 [1.290, 3.444]	0.0023	
Region									
Europe	97	32 (33.0)	NC [20.0, NC]	101	17 (16.8)	NC [NC, NC]	1.841 [1.009, 3.359]	0.0433	0.8423
North America	57	29 (50.9)	7.0 [1.5, NC]	51	13 (25.5)	NC [NC, NC]	1.727 [0.874, 3.410]	0.1116	
Rest of World	85	28 (32.9)	NC [NC, NC]	84	10 (11.9)	NC [NC, NC]	2.194 [1.041, 4.625]	0.0340	
Sex									
Male	197	80 (40.6)	NC [13.7, NC]	181	31 (17.1)	NC [NC, NC]	2.019 [1.315, 3.100]	0.0010	0.2129
Female	42	9 (21.4)	NC [NC, NC]	55	9 (16.4)	NC [NC, NC]	1.321 [0.524, 3.330]	0.5531	
Metastases at Baseline									
Visceral metastases	169	61 (36.1)	NC [15.9, NC]	157	24 (15.3)	NC [NC, NC]	2.072 [1.275, 3.366]	0.0026	0.7214
Lymph node only	60	23 (38.3)	20.0 [6.7, NC]	65	12 (18.5)	NC [NC, NC]	1.624 [0.778, 3.389]	0.1910	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.27.1.1: Summary and Results of TEAEs - Dry mouth (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	24 (10.0%)	6 (2.5%)	
Number of patients censored	215 (90.0%)	230 (97.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	93.9 [89.9, 96.3]	97.4 [94.2, 98.8]	
Month 6	91.3 [86.7, 94.4]	97.4 [94.2, 98.8]	
Month 9	90.0 [85.0, 93.4]	NC [NC, NC]	
Month 12	89.2 [84.0, 92.8]	NC [NC, NC]	
Month 18	86.8 [80.3, 91.3]	NC [NC, NC]	
Month 24	86.8 [80.3, 91.3]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			3.109 [1.242, 7.784]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0106

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.27.1.2: Summary and Results of TEAEs by Subgroups - Dry mouth (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	2 (4.3)	NC [NC, NC]	47	2 (4.3)	NC [NC, NC]	0.989 [0.139, 7.027]	0.9915	0.1534
Absent	192	22 (11.5)	NC [NC, NC]	189	4 (2.1)	NC [NC, NC]	4.155 [1.398, 12.348]	0.0053	
Age									
< 65 years	105	8 (7.6)	NC [NC, NC]	102	2 (2.0)	NC [NC, NC]	3.370 [0.700, 16.226]	0.1072	0.9431
>= 65 years	134	16 (11.9)	NC [NC, NC]	134	4 (3.0)	NC [NC, NC]	2.984 [0.962, 9.254]	0.0467	
Region									
Europe	97	9 (9.3)	NC [NC, NC]	101	3 (3.0)	NC [NC, NC]	2.806 [0.744, 10.576]	0.1115	0.9014
North America	57	11 (19.3)	NC [NC, NC]	51	2 (3.9)	NC [NC, NC]	3.509 [0.744, 16.540]	0.0902	
Rest of World	85	4 (4.7)	NC [NC, NC]	84	1 (1.2)	NC [NC, NC]	2.910 [0.303, 27.975]	0.3323	
Sex									
Male	197	19 (9.6)	NC [NC, NC]	181	6 (3.3)	NC [NC, NC]	2.422 [0.948, 6.189]	0.0563	NC
Female	42	5 (11.9)	NC [NC, NC]	55	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0504	
Metastases at Baseline									
Visceral metastases	169	14 (8.3)	NC [NC, NC]	157	6 (3.8)	NC [NC, NC]	1.661 [0.614, 4.492]	0.3120	NC
Lymph node only	60	9 (15.0)	NC [NC, NC]	65	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0052	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.28.1.1: Summary and Results of TEAEs - Dyspepsia (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	13 (5.4%)	11 (4.7%)	
Number of patients censored	226 (94.6%)	225 (95.3%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	95.8 [92.3, 97.7]	95.3 [91.6, 97.4]	
Month 6	94.7 [90.9, 97.0]	95.3 [91.6, 97.4]	
Month 9	94.7 [90.9, 97.0]	NC [NC, NC]	
Month 12	94.7 [90.9, 97.0]	NC [NC, NC]	
Month 18	94.7 [90.9, 97.0]	NC [NC, NC]	
Month 24	91.6 [81.7, 96.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.057 [0.466, 2.396]
Log-rank test			
Two-sided unstratified log-rank p-value			0.8935

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.29.1.1: Summary and Results of TEAEs - Gastrooesophageal reflux disease (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	**Plat+Gem (N= 236)**	**EV+Pembro vs. Plat+Gem**
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	12 (5.0%)	9 (3.8%)	
Number of patients censored	227 (95.0%)	227 (96.2%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.6 [93.3, 98.3]	96.5 [93.2, 98.3]	
Month 6	95.0 [91.0, 97.2]	96.0 [92.5, 97.9]	
Month 9	95.0 [91.0, 97.2]	NC [NC, NC]	
Month 12	93.9 [89.3, 96.6]	NC [NC, NC]	
Month 18	93.9 [89.3, 96.6]	NC [NC, NC]	
Month 24	93.9 [89.3, 96.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.079 [0.440, 2.650]
Log-rank test			
Two-sided unstratified log-rank p-value			0.8670

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.30.1.1: Summary and Results of TEAEs - Haemorrhoids (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	10 (4.2%)	2 (0.8%)	
Number of patients censored	229 (95.8%)	234 (99.2%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.7 [96.1, 99.6]	99.1 [96.6, 99.8]	
Month 6	98.3 [95.4, 99.3]	99.1 [96.6, 99.8]	
Month 9	95.6 [91.2, 97.8]	NC [NC, NC]	
Month 12	93.6 [88.0, 96.6]	NC [NC, NC]	
Month 18	93.6 [88.0, 96.6]	NC [NC, NC]	
Month 24	93.6 [88.0, 96.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.956 [0.358, 10.676]
Log-rank test			
Two-sided unstratified log-rank p-value			0.4300

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.31.1.1: Summary and Results of TEAEs - Nausea (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	61 (25.5%)	120 (50.8%)	
Number of patients censored	178 (74.5%)	116 (49.2%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	78.1 [72.3, 82.8]	51.1 [44.4, 57.4]	
Month 6	76.5 [70.4, 81.4]	47.2 [40.4, 53.6]	
Month 9	73.2 [66.8, 78.6]	NC [NC, NC]	
Month 12	73.2 [66.8, 78.6]	NC [NC, NC]	
Month 18	73.2 [66.8, 78.6]	NC [NC, NC]	
Month 24	68.9 [57.8, 77.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	3.3 [2.1, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.355 [0.257, 0.491]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.31.1.2: Summary and Results of TEAEs by Subgroups - Nausea (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	16 (34.0)	22.1 [7.5, NC]	47	18 (38.3)	NC [2.9, NC]	0.708 [0.348, 1.441]	0.3366	0.0125
Absent	192	45 (23.4)	NC [NC, NC]	189	102 (54.0)	2.4 [1.4, NC]	0.301 [0.209, 0.433]	<.0001	
Age									
< 65 years	105	23 (21.9)	NC [22.1, NC]	102	61 (59.8)	2.3 [0.8, 3.8]	0.244 [0.147, 0.405]	<.0001	0.0410
>= 65 years	134	38 (28.4)	NC [NC, NC]	134	59 (44.0)	NC [2.1, NC]	0.479 [0.313, 0.733]	0.0005	
Region									
Europe	97	25 (25.8)	NC [22.1, NC]	101	55 (54.5)	2.9 [1.4, NC]	0.333 [0.203, 0.546]	<.0001	0.9394
North America	57	22 (38.6)	NC [6.0, NC]	51	34 (66.7)	0.9 [0.2, 3.0]	0.352 [0.199, 0.625]	0.0002	
Rest of World	85	14 (16.5)	NC [NC, NC]	84	31 (36.9)	NC [3.6, NC]	0.358 [0.187, 0.685]	0.0012	
Sex									
Male	197	47 (23.9)	NC [NC, NC]	181	83 (45.9)	NC [2.5, NC]	0.382 [0.263, 0.555]	<.0001	0.5763
Female	42	14 (33.3)	NC [8.9, NC]	55	37 (67.3)	0.9 [0.2, 2.5]	0.311 [0.162, 0.598]	0.0002	
Metastases at Baseline									
Visceral metastases	169	43 (25.4)	NC [22.1, NC]	157	73 (46.5)	NC [2.3, NC]	0.389 [0.261, 0.579]	<.0001	0.1290
Lymph node only	60	13 (21.7)	NC [NC, NC]	65	40 (61.5)	1.7 [0.8, 3.5]	0.250 [0.133, 0.469]	<.0001	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.32.1.1: Summary and Results of TEAEs - Stomatitis (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	27 (11.3%)	16 (6.8%)	
Number of patients censored	212 (88.7%)	220 (93.2%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	92.8 [88.6, 95.4]	93.4 [89.3, 96.0]	
Month 6	90.7 [86.0, 93.8]	92.2 [87.1, 95.3]	
Month 9	88.7 [83.4, 92.3]	NC [NC, NC]	
Month 12	86.7 [80.7, 91.0]	NC [NC, NC]	
Month 18	85.5 [79.0, 90.2]	NC [NC, NC]	
Month 24	85.5 [79.0, 90.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.207 [0.625, 2.327]
Log-rank test			
Two-sided unstratified log-rank p-value			0.5742

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.33.1.1: Summary and Results of TEAEs - Vomiting (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	24 (10.0%)	42 (17.8%)	
Number of patients censored	215 (90.0%)	194 (82.2%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	91.8 [87.5, 94.7]	83.4 [77.9, 87.6]	
Month 6	90.8 [86.3, 93.9]	81.1 [75.3, 85.7]	
Month 9	90.8 [86.3, 93.9]	NC [NC, NC]	
Month 12	90.0 [85.1, 93.4]	NC [NC, NC]	
Month 18	88.1 [81.5, 92.5]	NC [NC, NC]	
Month 24	83.5 [70.1, 91.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.445 [0.262, 0.755]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0021

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.33.1.2: Summary and Results of TEAEs by Subgroups - Vomiting (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	8 (17.0)	22.1 [16.1, NC]	47	7 (14.9)	NC [NC, NC]	0.706 [0.224, 2.225]	0.5517	0.0715
Absent	192	16 (8.3)	NC [NC, NC]	189	35 (18.5)	NC [NC, NC]	0.397 [0.218, 0.723]	0.0018	
Age									
< 65 years	105	11 (10.5)	NC [22.1, NC]	102	28 (27.5)	NC [NC, NC]	0.277 [0.131, 0.588]	0.0003	0.0571
>= 65 years	134	13 (9.7)	NC [NC, NC]	134	14 (10.4)	NC [NC, NC]	0.778 [0.356, 1.704]	0.5294	
Region									
Europe	97	6 (6.2)	NC [NC, NC]	101	21 (20.8)	NC [NC, NC]	0.228 [0.086, 0.605]	0.0012	0.1940
North America	57	10 (17.5)	NC [16.1, NC]	51	11 (21.6)	NC [NC, NC]	0.588 [0.236, 1.462]	0.2493	
Rest of World	85	8 (9.4)	NC [NC, NC]	84	10 (11.9)	NC [NC, NC]	0.703 [0.272, 1.814]	0.4644	
Sex									
Male	197	18 (9.1)	NC [NC, NC]	181	26 (14.4)	NC [NC, NC]	0.474 [0.249, 0.903]	0.0203	0.6429
Female	42	6 (14.3)	NC [NC, NC]	55	16 (29.1)	NC [NC, NC]	0.450 [0.176, 1.151]	0.0872	
Metastases at Baseline									
Visceral metastases	169	16 (9.5)	NC [NC, NC]	157	29 (18.5)	NC [NC, NC]	0.387 [0.201, 0.744]	0.0031	0.8021
Lymph node only	60	6 (10.0)	NC [NC, NC]	65	11 (16.9)	NC [NC, NC]	0.490 [0.174, 1.378]	0.1679	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.34.1.1: Summary and Results of TEAEs - General disorders and administration site conditions (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	159 (66.5%)	167 (70.8%)	
Number of patients censored	80 (33.5%)	69 (29.2%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	47.6 [41.1, 53.9]	33.7 [27.6, 39.8]	
Month 6	40.8 [34.4, 47.1]	26.9 [21.2, 32.9]	
Month 9	36.8 [30.4, 43.2]	NC [NC, NC]	
Month 12	31.5 [25.0, 38.2]	NC [NC, NC]	
Month 18	24.6 [17.5, 32.4]	NC [NC, NC]	
Month 24	18.2 [9.9, 28.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	2.6 [1.2, 5.3]	1.0 [0.8, 1.6]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.683 [0.544, 0.859]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0010

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.34.1.2: Summary and Results of TEAEs by Subgroups - General disorders and administration site conditions (SOC) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	37 (78.7)	1.0 [0.5, 2.9]	47	33 (70.2)	1.2 [0.5, 3.5]	0.950 [0.584, 1.547]	0.8366	0.0666
Absent	192	122 (63.5)	3.0 [1.4, 7.2]	189	134 (70.9)	1.0 [0.8, 1.5]	0.627 [0.484, 0.813]	0.0004	
Age									
< 65 years	105	62 (59.0)	5.7 [2.0, 13.8]	102	67 (65.7)	1.9 [0.9, 3.2]	0.603 [0.417, 0.873]	0.0065	0.4342
>= 65 years	134	97 (72.4)	1.2 [0.7, 2.8]	134	100 (74.6)	0.9 [0.5, 1.1]	0.743 [0.556, 0.995]	0.0444	
Region									
Europe	97	68 (70.1)	1.4 [0.8, 2.9]	101	84 (83.2)	0.8 [0.4, 1.4]	0.612 [0.439, 0.852]	0.0033	0.5273
North America	57	46 (80.7)	0.8 [0.2, 1.5]	51	40 (78.4)	0.7 [0.2, 1.0]	0.810 [0.520, 1.263]	0.3358	
Rest of World	85	45 (52.9)	10.7 [4.4, 19.3]	84	43 (51.2)	3.5 [1.1, NC]	0.669 [0.424, 1.056]	0.0817	
Sex									
Male	197	134 (68.0)	2.5 [1.2, 4.8]	181	125 (69.1)	1.3 [0.9, 2.1]	0.740 [0.573, 0.956]	0.0200	0.0980
Female	42	25 (59.5)	2.9 [0.7, NC]	55	42 (76.4)	0.5 [0.3, 1.4]	0.504 [0.298, 0.854]	0.0093	
Metastases at Baseline									
Visceral metastases	169	113 (66.9)	2.8 [0.8, 5.7]	157	108 (68.8)	1.1 [0.8, 1.9]	0.722 [0.546, 0.955]	0.0209	0.2681
Lymph node only	60	39 (65.0)	2.6 [1.1, 9.0]	65	49 (75.4)	0.9 [0.5, 1.8]	0.586 [0.378, 0.910]	0.0159	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.35.1.1: Summary and Results of TEAEs - Asthenia (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	43 (18.0%)	45 (19.1%)	
Number of patients censored	196 (82.0%)	191 (80.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	87.6 [82.6, 91.2]	84.9 [79.5, 88.9]	
Month 6	85.7 [80.4, 89.6]	79.5 [73.5, 84.3]	
Month 9	83.8 [78.2, 88.1]	NC [NC, NC]	
Month 12	79.8 [72.9, 85.1]	NC [NC, NC]	
Month 18	74.9 [66.0, 81.8]	NC [NC, NC]	
Month 24	74.9 [66.0, 81.8]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.692 [0.442, 1.085]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1067

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.36.1.1: Summary and Results of TEAEs - Chills (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	7 (2.9%)	3 (1.3%)	
Number of patients censored	232 (97.1%)	233 (98.7%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.5 [94.5, 98.9]	98.7 [95.9, 99.6]	
Month 6	97.5 [94.5, 98.9]	98.7 [95.9, 99.6]	
Month 9	96.9 [93.5, 98.5]	NC [NC, NC]	
Month 12	96.9 [93.5, 98.5]	NC [NC, NC]	
Month 18	96.9 [93.5, 98.5]	NC [NC, NC]	
Month 24	96.9 [93.5, 98.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.996 [0.500, 7.968]
Log-rank test			
Two-sided unstratified log-rank p-value			0.3186

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.37.1.1: Summary and Results of TEAEs - Fatigue (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	79 (33.1%)	101 (42.8%)	
Number of patients censored	160 (66.9%)	135 (57.2%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	76.3 [70.4, 81.3]	59.0 [52.3, 65.1]	
Month 6	71.6 [65.2, 77.1]	55.8 [49.0, 62.0]	
Month 9	65.9 [58.9, 71.9]	NC [NC, NC]	
Month 12	65.1 [58.1, 71.3]	NC [NC, NC]	
Month 18	60.3 [51.6, 67.9]	NC [NC, NC]	
Month 24	57.4 [47.3, 66.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [19.3, NC]	NC [3.5, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.526 [0.384, 0.722]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.37.1.2: Summary and Results of TEAEs by Subgroups - Fatigue (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	19 (40.4)	15.8 [5.6, NC]	47	18 (38.3)	NC [3.5, NC]	0.830 [0.421, 1.639]	0.5939	0.0840
Absent	192	60 (31.3)	NC [19.3, NC]	189	83 (43.9)	NC [3.0, NC]	0.470 [0.328, 0.673]	<.0001	
Age									
< 65 years	105	31 (29.5)	NC [16.3, NC]	102	41 (40.2)	NC [3.3, NC]	0.431 [0.257, 0.724]	0.0011	0.5130
>= 65 years	134	48 (35.8)	NC [19.3, NC]	134	60 (44.8)	NC [2.4, NC]	0.601 [0.403, 0.897]	0.0118	
Region									
Europe	97	25 (25.8)	NC [NC, NC]	101	45 (44.6)	NC [3.0, NC]	0.434 [0.261, 0.723]	0.0010	0.3085
North America	57	33 (57.9)	5.3 [1.0, 8.8]	51	34 (66.7)	1.0 [0.3, 2.1]	0.600 [0.361, 0.997]	0.0456	
Rest of World	85	21 (24.7)	NC [19.3, NC]	84	22 (26.2)	NC [NC, NC]	0.507 [0.255, 1.008]	0.0486	
Sex									
Male	197	66 (33.5)	NC [19.3, NC]	181	70 (38.7)	NC [NC, NC]	0.615 [0.430, 0.879]	0.0072	0.1235
Female	42	13 (31.0)	NC [8.8, NC]	55	31 (56.4)	2.0 [0.7, NC]	0.316 [0.150, 0.666]	0.0014	
Metastases at Baseline									
Visceral metastases	169	66 (39.1)	19.3 [13.1, NC]	157	64 (40.8)	NC [4.2, NC]	0.676 [0.467, 0.978]	0.0365	0.0003
Lymph node only	60	8 (13.3)	NC [NC, NC]	65	32 (49.2)	3.4 [1.0, NC]	0.175 [0.077, 0.398]	<.0001	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.38.1.1: Summary and Results of TEAEs - Malaise (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	8 (3.3%)	5 (2.1%)	
Number of patients censored	231 (96.7%)	231 (97.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.3 [95.6, 99.4]	97.8 [94.8, 99.1]	
Month 6	96.3 [92.6, 98.1]	97.8 [94.8, 99.1]	
Month 9	96.3 [92.6, 98.1]	NC [NC, NC]	
Month 12	96.3 [92.6, 98.1]	NC [NC, NC]	
Month 18	96.3 [92.6, 98.1]	NC [NC, NC]	
Month 24	96.3 [92.6, 98.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.360 [0.433, 4.272]
Log-rank test			
Two-sided unstratified log-rank p-value			0.5968

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.39.1.1: Summary and Results of TEAEs - Oedema peripheral (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	29 (12.1%)	22 (9.3%)	
Number of patients censored	210 (87.9%)	214 (90.7%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	91.4 [87.0, 94.4]	92.5 [88.2, 95.3]	
Month 6	90.4 [85.7, 93.6]	90.0 [85.2, 93.3]	
Month 9	88.4 [83.2, 92.1]	NC [NC, NC]	
Month 12	86.5 [80.5, 90.7]	NC [NC, NC]	
Month 18	84.1 [77.1, 89.1]	NC [NC, NC]	
Month 24	84.1 [77.1, 89.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.988 [0.547, 1.783]
Log-rank test			
Two-sided unstratified log-rank p-value			0.9674

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.40.1.1: Summary and Results of TEAEs - Pyrexia (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	41 (17.2%)	32 (13.6%)	
Number of patients censored	198 (82.8%)	204 (86.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	88.2 [83.4, 91.7]	86.8 [81.7, 90.6]	
Month 6	85.6 [80.3, 89.6]	85.7 [80.4, 89.7]	
Month 9	83.1 [77.3, 87.5]	NC [NC, NC]	
Month 12	81.5 [75.3, 86.3]	NC [NC, NC]	
Month 18	81.5 [75.3, 86.3]	NC [NC, NC]	
Month 24	76.0 [65.7, 83.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.958 [0.585, 1.568]
Log-rank test			
Two-sided unstratified log-rank p-value			0.8578

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.41.1.1: Summary and Results of TEAEs - Hepatobiliary disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	32 (13.4%)	8 (3.4%)	
Number of patients censored	207 (86.6%)	228 (96.6%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	88.5 [83.6, 91.9]	96.6 [93.2, 98.3]	
Month 6	87.9 [83.0, 91.5]	96.6 [93.2, 98.3]	
Month 9	85.8 [80.3, 89.9]	NC [NC, NC]	
Month 12	84.7 [78.7, 89.1]	NC [NC, NC]	
Month 18	84.7 [78.7, 89.1]	NC [NC, NC]	
Month 24	84.7 [78.7, 89.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			3.460 [1.575, 7.599]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0010

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.41.1.2: Summary and Results of TEAEs by Subgroups - Hepatobiliary disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	5 (10.6)	NC [NC, NC]	47	2 (4.3)	NC [NC, NC]	2.531 [0.491, 13.047]	0.2502	0.5584
Absent	192	27 (14.1)	NC [NC, NC]	189	6 (3.2)	NC [NC, NC]	3.769 [1.532, 9.270]	0.0019	
Age									
< 65 years	105	10 (9.5)	NC [NC, NC]	102	1 (1.0)	NC [NC, NC]	9.046 [1.146, 71.407]	0.0112	0.3221
>= 65 years	134	22 (16.4)	NC [NC, NC]	134	7 (5.2)	NC [NC, NC]	2.682 [1.125, 6.391]	0.0205	
Region									
Europe	97	18 (18.6)	NC [NC, NC]	101	5 (5.0)	NC [NC, NC]	3.137 [1.138, 8.650]	0.0196	NC
North America	57	6 (10.5)	NC [NC, NC]	51	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0170	
Rest of World	85	8 (9.4)	NC [NC, NC]	84	3 (3.6)	NC [NC, NC]	2.288 [0.592, 8.846]	0.2180	
Sex									
Male	197	24 (12.2)	NC [NC, NC]	181	6 (3.3)	NC [NC, NC]	3.021 [1.211, 7.536]	0.0127	0.6663
Female	42	8 (19.0)	NC [NC, NC]	55	2 (3.6)	NC [NC, NC]	5.431 [1.153, 25.584]	0.0163	
Metastases at Baseline									
Visceral metastases	169	24 (14.2)	NC [NC, NC]	157	5 (3.2)	NC [NC, NC]	4.004 [1.510, 10.619]	0.0026	0.9474
Lymph node only	60	8 (13.3)	NC [NC, NC]	65	2 (3.1)	NC [NC, NC]	3.490 [0.717, 16.981]	0.0995	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.42.1.1: Summary and Results of TEAEs - Hypertransaminasaemia (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	10 (4.2%)	5 (2.1%)	
Number of patients censored	229 (95.8%)	231 (97.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.2 [92.8, 98.0]	97.8 [94.8, 99.1]	
Month 6	96.2 [92.8, 98.0]	97.8 [94.8, 99.1]	
Month 9	95.5 [91.7, 97.6]	NC [NC, NC]	
Month 12	95.5 [91.7, 97.6]	NC [NC, NC]	
Month 18	95.5 [91.7, 97.6]	NC [NC, NC]	
Month 24	95.5 [91.7, 97.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.778 [0.596, 5.306]
Log-rank test			
Two-sided unstratified log-rank p-value			0.2953

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.43.1.1: Summary and Results of TEAEs - Infections and infestations (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	145 (60.7%)	85 (36.0%)	
Number of patients censored	94 (39.3%)	151 (64.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	61.3 [54.8, 67.2]	69.4 [63.0, 74.9]	
Month 6	44.9 [38.2, 51.3]	61.7 [54.8, 67.8]	
Month 9	37.4 [30.7, 44.0]	NC [NC, NC]	
Month 12	34.2 [27.5, 41.0]	NC [NC, NC]	
Month 18	29.7 [22.3, 37.5]	NC [NC, NC]	
Month 24	29.7 [22.3, 37.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	5.0 [3.7, 6.3]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.370 [1.037, 1.812]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0260

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.43.1.2: Summary and Results of TEAEs by Subgroups - Infections and infestations (SOC) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	33 (70.2)	4.6 [2.1, 6.1]	47	16 (34.0)	NC [4.4, NC]	1.581 [0.843, 2.965]	0.1503	0.2556
Absent	192	112 (58.3)	5.0 [3.6, 8.3]	189	69 (36.5)	NC [NC, NC]	1.323 [0.969, 1.807]	0.0763	
Age									
< 65 years	105	64 (61.0)	6.1 [3.8, 8.4]	102	33 (32.4)	NC [NC, NC]	1.318 [0.842, 2.062]	0.2250	0.6574
>= 65 years	134	81 (60.4)	4.1 [3.0, 5.6]	134	52 (38.8)	NC [4.4, NC]	1.415 [0.990, 2.023]	0.0554	
Region									
Europe	97	57 (58.8)	4.9 [3.0, 7.8]	101	44 (43.6)	NC [3.4, NC]	1.096 [0.729, 1.650]	0.6561	0.2178
North America	57	43 (75.4)	3.6 [2.0, 5.3]	51	17 (33.3)	NC [4.2, NC]	1.765 [0.985, 3.164]	0.0528	
Rest of World	85	45 (52.9)	7.6 [4.1, NC]	84	24 (28.6)	NC [NC, NC]	1.525 [0.908, 2.562]	0.1075	
Sex									
Male	197	117 (59.4)	4.9 [3.6, 6.5]	181	64 (35.4)	NC [NC, NC]	1.365 [0.996, 1.871]	0.0514	0.6438
Female	42	28 (66.7)	5.4 [1.9, 9.2]	55	21 (38.2)	NC [3.7, NC]	1.398 [0.756, 2.588]	0.2835	
Metastases at Baseline									
Visceral metastases	169	103 (60.9)	5.0 [3.6, 6.5]	157	53 (33.8)	NC [NC, NC]	1.468 [1.040, 2.073]	0.0278	0.2298
Lymph node only	60	37 (61.7)	5.0 [2.1, 12.5]	65	29 (44.6)	NC [3.3, NC]	1.032 [0.618, 1.725]	0.9035	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.44.1.1: Summary and Results of TEAEs - COVID-19 (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	43 (18.0%)	12 (5.1%)	
Number of patients censored	196 (82.0%)	224 (94.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	92.3 [87.9, 95.2]	95.6 [92.0, 97.6]	
Month 6	88.6 [83.5, 92.3]	94.5 [90.4, 96.8]	
Month 9	82.5 [76.1, 87.4]	NC [NC, NC]	
Month 12	77.1 [69.5, 83.0]	NC [NC, NC]	
Month 18	70.2 [60.1, 78.2]	NC [NC, NC]	
Month 24	70.2 [60.1, 78.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.720 [0.852, 3.470]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1257

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.45.1.1: Summary and Results of TEAEs - Conjunctivitis (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	18 (7.5%)	0 (0.0%)	
Number of patients censored	221 (92.5%)	236 (100.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.1 [92.6, 97.9]	100.0 [100.0, 100.0]	
Month 6	92.8 [88.4, 95.6]	100.0 [100.0, 100.0]	
Month 9	92.8 [88.4, 95.6]	NC [NC, NC]	
Month 12	92.0 [87.1, 95.1]	NC [NC, NC]	
Month 18	90.7 [85.0, 94.3]	NC [NC, NC]	
Month 24	87.7 [78.1, 93.3]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			NC [NC, NC]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0008

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.45.1.2: Summary and Results of TEAEs by Subgroups - Conjunctivitis (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	3 (6.4)	NC [NC, NC]	47	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1021	NC
Absent	192	15 (7.8)	NC [NC, NC]	189	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0030	
Age									
< 65 years	105	6 (5.7)	NC [NC, NC]	102	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0470	NC
>= 65 years	134	12 (9.0)	NC [NC, NC]	134	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0064	
Region									
Europe	97	10 (10.3)	NC [NC, NC]	101	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0065	NC
North America	57	5 (8.8)	NC [19.4, NC]	51	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0991	
Rest of World	85	3 (3.5)	NC [NC, NC]	84	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.2442	
Sex									
Male	197	15 (7.6)	NC [NC, NC]	181	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0031	NC
Female	42	3 (7.1)	NC [NC, NC]	55	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1043	
Metastases at Baseline									
Visceral metastases	169	14 (8.3)	NC [NC, NC]	157	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0047	NC
Lymph node only	60	4 (6.7)	NC [NC, NC]	65	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0742	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.46.1.1: Summary and Results of TEAEs - Oral candidiasis (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	9 (3.8%)	4 (1.7%)	
Number of patients censored	230 (96.2%)	232 (98.3%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.9 [95.0, 99.1]	98.3 [95.5, 99.3]	
Month 6	96.9 [93.5, 98.5]	98.3 [95.5, 99.3]	
Month 9	96.3 [92.6, 98.1]	NC [NC, NC]	
Month 12	96.3 [92.6, 98.1]	NC [NC, NC]	
Month 18	94.8 [89.3, 97.5]	NC [NC, NC]	
Month 24	94.8 [89.3, 97.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.523 [0.435, 5.333]
Log-rank test			
Two-sided unstratified log-rank p-value			0.5077

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.47.1.1: Summary and Results of TEAEs - Pneumonia (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	12 (5.0%)	4 (1.7%)	
Number of patients censored	227 (95.0%)	232 (98.3%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.2 [95.3, 99.3]	98.3 [95.4, 99.3]	
Month 6	96.1 [92.3, 98.0]	98.3 [95.4, 99.3]	
Month 9	95.4 [91.2, 97.6]	NC [NC, NC]	
Month 12	95.4 [91.2, 97.6]	NC [NC, NC]	
Month 18	95.4 [91.2, 97.6]	NC [NC, NC]	
Month 24	89.6 [77.6, 95.4]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	26.7 [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.488 [0.428, 5.178]
Log-rank test			
Two-sided unstratified log-rank p-value			0.5293

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.48.1.1: Summary and Results of TEAEs - Upper respiratory tract infection (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	11 (4.6%)	1 (0.4%)	
Number of patients censored	228 (95.4%)	235 (99.6%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.2 [95.3, 99.3]	100.0 [100.0, 100.0]	
Month 6	96.6 [93.0, 98.4]	99.5 [96.3, 99.9]	
Month 9	95.4 [91.2, 97.6]	NC [NC, NC]	
Month 12	94.3 [89.3, 97.0]	NC [NC, NC]	
Month 18	92.2 [84.6, 96.1]	NC [NC, NC]	
Month 24	92.2 [84.6, 96.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			5.773 [0.697, 47.830]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0660

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.49.1.1: Summary and Results of TEAEs - Urinary tract infection (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	43 (18.0%)	44 (18.6%)	
Number of patients censored	196 (82.0%)	192 (81.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	88.9 [84.1, 92.3]	83.9 [78.4, 88.0]	
Month 6	83.3 [77.6, 87.6]	78.0 [69.9, 84.2]	
Month 9	80.8 [74.8, 85.6]	NC [NC, NC]	
Month 12	80.1 [73.9, 85.0]	NC [NC, NC]	
Month 18	78.4 [71.3, 84.0]	NC [NC, NC]	
Month 24	78.4 [71.3, 84.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.719 [0.460, 1.122]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1448

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.50.1.1: Summary and Results of TEAEs - Injury, poisoning and procedural complications (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	34 (14.2%)	16 (6.8%)	
Number of patients censored	205 (85.8%)	220 (93.2%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	93.5 [89.4, 96.0]	93.6 [89.4, 96.2]	
Month 6	90.4 [85.7, 93.7]	92.6 [88.1, 95.4]	
Month 9	85.7 [79.8, 90.0]	NC [NC, NC]	
Month 12	83.6 [76.9, 88.5]	NC [NC, NC]	
Month 18	78.6 [69.5, 85.2]	NC [NC, NC]	
Month 24	75.9 [65.4, 83.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.209 [0.627, 2.332]
Log-rank test			
Two-sided unstratified log-rank p-value			0.5708

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.51.1.1: Summary and Results of TEAEs - Fall (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	11 (4.6%)	3 (1.3%)	
Number of patients censored	228 (95.4%)	233 (98.7%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.3 [95.4, 99.3]	98.5 [95.5, 99.5]	
Month 6	97.2 [93.8, 98.7]	98.5 [95.5, 99.5]	
Month 9	95.2 [90.8, 97.5]	NC [NC, NC]	
Month 12	94.0 [88.7, 96.9]	NC [NC, NC]	
Month 18	94.0 [88.7, 96.9]	NC [NC, NC]	
Month 24	91.3 [82.2, 95.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.639 [0.394, 6.817]
Log-rank test			
Two-sided unstratified log-rank p-value			0.4929

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.52.1.1: Summary and Results of TEAEs - Investigations (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	**Plat+Gem (N= 236)**	**EV+Pembro vs. Plat+Gem**
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	134 (56.1%)	107 (45.3%)	
Number of patients censored	105 (43.9%)	129 (54.7%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	61.8 [55.2, 67.6]	59.0 [52.3, 65.0]	
Month 6	47.1 [40.3, 53.6]	50.9 [43.5, 57.8]	
Month 9	43.3 [36.5, 50.0]	NC [NC, NC]	
Month 12	39.3 [32.2, 46.2]	NC [NC, NC]	
Month 18	33.1 [24.9, 41.5]	NC [NC, NC]	
Month 24	33.1 [24.9, 41.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	5.2 [3.6, 8.9]	NC [3.7, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.961 [0.738, 1.252]
Log-rank test			
Two-sided unstratified log-rank p-value			0.7781

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.53.1.1: Summary and Results of TEAEs - Alanine aminotransferase increased (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	49 (20.5%)	13 (5.5%)	
Number of patients censored	190 (79.5%)	223 (94.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	84.0 [78.7, 88.1]	94.5 [90.7, 96.7]	
Month 6	80.8 [75.0, 85.3]	94.5 [90.7, 96.7]	
Month 9	80.0 [74.0, 84.7]	NC [NC, NC]	
Month 12	76.8 [69.9, 82.4]	NC [NC, NC]	
Month 18	76.8 [69.9, 82.4]	NC [NC, NC]	
Month 24	73.7 [64.2, 81.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			3.288 [1.765, 6.124]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.53.1.2: Summary and Results of TEAEs by Subgroups - Alanine aminotransferase increased (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	8 (17.0)	NC [NC, NC]	47	3 (6.4)	NC [NC, NC]	2.453 [0.634, 9.488]	0.1787	0.6523
Absent	192	41 (21.4)	NC [NC, NC]	189	10 (5.3)	NC [NC, NC]	3.528 [1.747, 7.125]	0.0002	
Age									
< 65 years	105	26 (24.8)	NC [NC, NC]	102	4 (3.9)	NC [NC, NC]	5.663 [1.950, 16.444]	0.0003	0.1526
>= 65 years	134	23 (17.2)	NC [NC, NC]	134	9 (6.7)	NC [NC, NC]	2.251 [1.026, 4.936]	0.0373	
Region									
Europe	97	19 (19.6)	NC [19.8, NC]	101	8 (7.9)	NC [NC, NC]	1.752 [0.736, 4.172]	0.2005	0.2960
North America	57	4 (7.0)	NC [NC, NC]	51	1 (2.0)	NC [NC, NC]	3.443 [0.384, 30.845]	0.2393	
Rest of World	85	26 (30.6)	NC [NC, NC]	84	4 (4.8)	NC [NC, NC]	6.868 [2.384, 19.788]	<.0001	
Sex									
Male	197	41 (20.8)	NC [NC, NC]	181	12 (6.6)	NC [NC, NC]	2.642 [1.368, 5.102]	0.0027	0.2652
Female	42	8 (19.0)	NC [NC, NC]	55	1 (1.8)	NC [NC, NC]	11.322 [1.415, 90.559]	0.0038	
Metastases at Baseline									
Visceral metastases	169	34 (20.1)	NC [NC, NC]	157	9 (5.7)	NC [NC, NC]	2.855 [1.343, 6.072]	0.0044	0.5667
Lymph node only	60	9 (15.0)	NC [NC, NC]	65	4 (6.2)	NC [NC, NC]	2.420 [0.745, 7.858]	0.1282	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.54.1.1: Summary and Results of TEAEs - Aspartate aminotransferase increased (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	47 (19.7%)	10 (4.2%)	
Number of patients censored	192 (80.3%)	226 (95.8%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	83.9 [78.6, 88.0]	95.7 [92.1, 97.6]	
Month 6	81.2 [75.5, 85.8]	95.7 [92.1, 97.6]	
Month 9	79.0 [72.8, 83.9]	NC [NC, NC]	
Month 12	78.1 [71.6, 83.2]	NC [NC, NC]	
Month 18	78.1 [71.6, 83.2]	NC [NC, NC]	
Month 24	78.1 [71.6, 83.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			4.217 [2.113, 8.417]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.54.1.2: Summary and Results of TEAEs by Subgroups - Aspartate aminotransferase increased (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	10 (21.3)	NC [NC, NC]	47	3 (6.4)	NC [NC, NC]	3.593 [0.989, 13.061]	0.0376	0.6279
Absent	192	37 (19.3)	NC [NC, NC]	189	7 (3.7)	NC [NC, NC]	4.492 [1.979, 10.200]	<.0001	
Age									
< 65 years	105	23 (21.9)	NC [NC, NC]	102	4 (3.9)	NC [NC, NC]	5.364 [1.839, 15.642]	0.0006	0.6017
>= 65 years	134	24 (17.9)	NC [NC, NC]	134	6 (4.5)	NC [NC, NC]	3.452 [1.389, 8.577]	0.0046	
Region									
Europe	97	18 (18.6)	NC [NC, NC]	101	7 (6.9)	NC [NC, NC]	2.133 [0.865, 5.261]	0.0931	NC
North America	57	5 (8.8)	NC [NC, NC]	51	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0486	
Rest of World	85	24 (28.2)	NC [NC, NC]	84	3 (3.6)	NC [NC, NC]	8.169 [2.446, 27.283]	<.0001	
Sex									
Male	197	41 (20.8)	NC [NC, NC]	181	8 (4.4)	NC [NC, NC]	4.142 [1.922, 8.925]	<.0001	0.8623
Female	42	6 (14.3)	NC [NC, NC]	55	2 (3.6)	NC [NC, NC]	4.199 [0.847, 20.808]	0.0563	
Metastases at Baseline									
Visceral metastases	169	31 (18.3)	NC [NC, NC]	157	7 (4.5)	NC [NC, NC]	3.660 [1.593, 8.412]	0.0011	0.7597
Lymph node only	60	10 (16.7)	NC [NC, NC]	65	2 (3.1)	NC [NC, NC]	4.982 [1.076, 23.062]	0.0227	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.55.1.1: Summary and Results of TEAEs - Blood alkaline phosphatase increased (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	12 (5.0%)	8 (3.4%)	
Number of patients censored	227 (95.0%)	228 (96.6%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.1 [93.9, 98.6]	97.4 [94.2, 98.8]	
Month 6	95.5 [91.8, 97.6]	96.3 [92.7, 98.1]	
Month 9	94.2 [89.8, 96.7]	NC [NC, NC]	
Month 12	94.2 [89.8, 96.7]	NC [NC, NC]	
Month 18	94.2 [89.8, 96.7]	NC [NC, NC]	
Month 24	94.2 [89.8, 96.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.121 [0.435, 2.886]
Log-rank test			
Two-sided unstratified log-rank p-value			0.8123

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.56.1.1: Summary and Results of TEAEs - Blood creatinine increased (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	12 (5.0%)	27 (11.4%)	
Number of patients censored	227 (95.0%)	209 (88.6%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.9 [95.0, 99.1]	89.6 [84.8, 92.9]	
Month 6	95.8 [92.1, 97.8]	88.0 [82.9, 91.6]	
Month 9	95.8 [92.1, 97.8]	NC [NC, NC]	
Month 12	93.2 [88.0, 96.2]	NC [NC, NC]	
Month 18	93.2 [88.0, 96.2]	NC [NC, NC]	
Month 24	93.2 [88.0, 96.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.281 [0.129, 0.612]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0007

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.56.1.2: Summary and Results of TEAEs by Subgroups - Blood creatinine increased (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	3 (6.4)	NC [NC, NC]	47	5 (10.6)	NC [NC, NC]	0.401 [0.078, 2.066]	0.2579	0.5234
Absent	192	9 (4.7)	NC [NC, NC]	189	22 (11.6)	NC [NC, NC]	0.257 [0.106, 0.622]	0.0012	
Age									
< 65 years	105	4 (3.8)	NC [NC, NC]	102	14 (13.7)	NC [NC, NC]	0.129 [0.029, 0.567]	0.0013	0.2460
>= 65 years	134	8 (6.0)	NC [NC, NC]	134	13 (9.7)	NC [NC, NC]	0.453 [0.175, 1.173]	0.0944	
Region									
Europe	97	2 (2.1)	NC [NC, NC]	101	10 (9.9)	NC [NC, NC]	0.202 [0.044, 0.921]	0.0218	0.0620
North America	57	2 (3.5)	NC [NC, NC]	51	10 (19.6)	NC [NC, NC]	0.000 [0.000, NC]	0.0004	
Rest of World	85	8 (9.4)	NC [NC, NC]	84	7 (8.3)	NC [NC, NC]	0.811 [0.272, 2.414]	0.7058	
Sex									
Male	197	10 (5.1)	NC [NC, NC]	181	21 (11.6)	NC [NC, NC]	0.292 [0.126, 0.679]	0.0024	0.9602
Female	42	2 (4.8)	NC [NC, NC]	55	6 (10.9)	NC [NC, NC]	0.210 [0.025, 1.741]	0.1101	
Metastases at Baseline									
Visceral metastases	169	10 (5.9)	NC [NC, NC]	157	18 (11.5)	NC [NC, NC]	0.348 [0.147, 0.824]	0.0121	0.5222
Lymph node only	60	2 (3.3)	NC [NC, NC]	65	7 (10.8)	NC [NC, NC]	0.147 [0.018, 1.196]	0.0376	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.57.1.1: Summary and Results of TEAEs - Gamma-glutamyltransferase increased (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	8 (3.3%)	2 (0.8%)	
Number of patients censored	231 (96.7%)	234 (99.2%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.3 [95.6, 99.4]	99.6 [97.0, 99.9]	
Month 6	96.8 [93.4, 98.5]	99.0 [96.0, 99.8]	
Month 9	96.2 [92.4, 98.1]	NC [NC, NC]	
Month 12	96.2 [92.4, 98.1]	NC [NC, NC]	
Month 18	96.2 [92.4, 98.1]	NC [NC, NC]	
Month 24	96.2 [92.4, 98.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			3.327 [0.691, 16.019]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1116

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.58.1.1: Summary and Results of TEAEs - Lipase increased (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	17 (7.1%)	0 (0.0%)	
Number of patients censored	222 (92.9%)	236 (100.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	95.6 [92.0, 97.6]	100.0 [100.0, 100.0]	
Month 6	94.0 [89.9, 96.5]	100.0 [100.0, 100.0]	
Month 9	92.6 [87.9, 95.5]	NC [NC, NC]	
Month 12	91.9 [86.9, 95.0]	NC [NC, NC]	
Month 18	89.4 [81.5, 94.1]	NC [NC, NC]	
Month 24	89.4 [81.5, 94.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			NC [NC, NC]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0010

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.58.1.2: Summary and Results of TEAEs by Subgroups - Lipase increased (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	3 (6.4)	NC [NC, NC]	47	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1500	NC
Absent	192	14 (7.3)	NC [NC, NC]	189	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0029	
Age									
< 65 years	105	7 (6.7)	NC [NC, NC]	102	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0159	NC
>= 65 years	134	10 (7.5)	NC [NC, NC]	134	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0248	
Region									
Europe	97	12 (12.4)	NC [NC, NC]	101	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0010	NC
North America	57	1 (1.8)	NC [NC, NC]	51	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.3447	
Rest of World	85	4 (4.7)	NC [NC, NC]	84	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.7024	
Sex									
Male	197	17 (8.6)	NC [NC, NC]	181	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0015	NC
Female	42	0 (0.0)	NC [NC, NC]	55	0 (0.0)	NC [NC, NC]	NC [NC, NC]	NC	
Metastases at Baseline									
Visceral metastases	169	13 (7.7)	NC [NC, NC]	157	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0037	NC
Lymph node only	60	3 (5.0)	NC [NC, NC]	65	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1468	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.59.1.1: Summary and Results of TEAEs - Neutrophil count decreased (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	7 (2.9%)	32 (13.6%)	
Number of patients censored	232 (97.1%)	204 (86.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.9 [95.0, 99.1]	89.1 [84.3, 92.5]	
Month 6	97.4 [94.2, 98.8]	85.2 [79.6, 89.3]	
Month 9	96.7 [93.1, 98.4]	NC [NC, NC]	
Month 12	96.7 [93.1, 98.4]	NC [NC, NC]	
Month 18	96.7 [93.1, 98.4]	NC [NC, NC]	
Month 24	96.7 [93.1, 98.4]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.169 [0.071, 0.404]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.59.1.2: Summary and Results of TEAEs by Subgroups - Neutrophil count decreased (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	1 (2.1)	NC [NC, NC]	47	6 (12.8)	NC [NC, NC]	0.161 [0.019, 1.339]	0.0531	0.8391
Absent	192	6 (3.1)	NC [NC, NC]	189	26 (13.8)	NC [NC, NC]	0.169 [0.065, 0.441]	<.0001	
Age									
< 65 years	105	2 (1.9)	NC [NC, NC]	102	15 (14.7)	NC [NC, NC]	0.118 [0.027, 0.515]	0.0006	0.3703
>= 65 years	134	5 (3.7)	NC [NC, NC]	134	17 (12.7)	NC [NC, NC]	0.215 [0.072, 0.640]	0.0024	
Region									
Europe	97	3 (3.1)	NC [NC, NC]	101	10 (9.9)	NC [NC, NC]	0.299 [0.082, 1.086]	0.0514	NC
North America	57	0 (0.0)	NC [NC, NC]	51	9 (17.6)	NC [NC, NC]	NC [NC, NC]	0.0007	
Rest of World	85	4 (4.7)	NC [NC, NC]	84	13 (15.5)	NC [NC, NC]	0.203 [0.058, 0.712]	0.0058	
Sex									
Male	197	5 (2.5)	NC [NC, NC]	181	25 (13.8)	NC [NC, NC]	0.169 [0.065, 0.442]	<.0001	0.4580
Female	42	2 (4.8)	NC [NC, NC]	55	7 (12.7)	NC [NC, NC]	0.162 [0.020, 1.322]	0.0523	
Metastases at Baseline									
Visceral metastases	169	4 (2.4)	NC [NC, NC]	157	21 (13.4)	NC [NC, NC]	0.124 [0.037, 0.416]	<.0001	0.8348
Lymph node only	60	2 (3.3)	NC [NC, NC]	65	10 (15.4)	NC [NC, NC]	0.186 [0.041, 0.850]	0.0150	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.60.1.1: Summary and Results of TEAEs - Platelet count decreased (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	1 (0.4%)	30 (12.7%)	
Number of patients censored	238 (99.6%)	206 (87.3%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	100.0 [100.0, 100.0]	88.7 [83.9, 92.2]	
Month 6	100.0 [100.0, 100.0]	85.3 [78.7, 89.9]	
Month 9	100.0 [100.0, 100.0]	NC [NC, NC]	
Month 12	99.2 [94.6, 99.9]	NC [NC, NC]	
Month 18	99.2 [94.6, 99.9]	NC [NC, NC]	
Month 24	99.2 [94.6, 99.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.000 [0.000, NC]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.60.1.2: Summary and Results of TEAEs by Subgroups - Platelet count decreased (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	0 (0.0)	NC [NC, NC]	47	6 (12.8)	NC [NC, NC]	NC [NC, NC]	0.0125	NC
Absent	192	1 (0.5)	NC [NC, NC]	189	24 (12.7)	NC [NC, NC]	0.000 [0.000, NC]	<.0001	
Age									
< 65 years	105	1 (1.0)	NC [NC, NC]	102	12 (11.8)	NC [NC, NC]	0.000 [0.000, NC]	0.0003	NC
>= 65 years	134	0 (0.0)	NC [NC, NC]	134	18 (13.4)	NC [NC, NC]	NC [NC, NC]	<.0001	
Region									
Europe	97	0 (0.0)	NC [NC, NC]	101	11 (10.9)	NC [NC, NC]	NC [NC, NC]	0.0005	NC
North America	57	0 (0.0)	NC [NC, NC]	51	10 (19.6)	NC [NC, NC]	NC [NC, NC]	0.0004	
Rest of World	85	1 (1.2)	NC [NC, NC]	84	9 (10.7)	NC [NC, NC]	0.000 [0.000, NC]	0.0017	
Sex									
Male	197	1 (0.5)	NC [NC, NC]	181	23 (12.7)	NC [NC, NC]	0.000 [0.000, NC]	<.0001	NC
Female	42	0 (0.0)	NC [NC, NC]	55	7 (12.7)	NC [NC, NC]	NC [NC, NC]	0.0164	
Metastases at Baseline									
Visceral metastases	169	1 (0.6)	NC [NC, NC]	157	19 (12.1)	NC [NC, NC]	0.000 [0.000, NC]	<.0001	NC
Lymph node only	60	0 (0.0)	NC [NC, NC]	65	10 (15.4)	NC [NC, NC]	NC [NC, NC]	0.0013	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.61.1.1: Summary and Results of TEAEs - Weight decreased (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	73 (30.5%)	23 (9.7%)	
Number of patients censored	166 (69.5%)	213 (90.3%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	83.4 [77.9, 87.6]	91.8 [87.4, 94.7]	
Month 6	70.5 [63.9, 76.2]	88.1 [82.0, 92.3]	
Month 9	67.5 [60.6, 73.4]	NC [NC, NC]	
Month 12	66.6 [59.5, 72.7]	NC [NC, NC]	
Month 18	62.9 [54.3, 70.3]	NC [NC, NC]	
Month 24	57.2 [43.3, 68.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [22.5, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			2.709 [1.679, 4.372]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.61.1.2: Summary and Results of TEAEs by Subgroups - Weight decreased (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	17 (36.2)	NC [4.4, NC]	47	8 (17.0)	NC [NC, NC]	1.935 [0.820, 4.565]	0.1256	0.4211
Absent	192	56 (29.2)	NC [22.5, NC]	189	15 (7.9)	NC [NC, NC]	3.099 [1.733, 5.540]	<.0001	
Age									
< 65 years	105	25 (23.8)	NC [NC, NC]	102	5 (4.9)	NC [NC, NC]	4.198 [1.584, 11.127]	0.0017	0.3106
>= 65 years	134	48 (35.8)	22.5 [14.3, NC]	134	18 (13.4)	NC [NC, NC]	2.314 [1.329, 4.028]	0.0023	
Region									
Europe	97	28 (28.9)	NC [17.4, NC]	101	12 (11.9)	NC [NC, NC]	1.853 [0.916, 3.748]	0.0812	0.5477
North America	57	18 (31.6)	NC [NC, NC]	51	5 (9.8)	NC [NC, NC]	3.166 [1.167, 8.586]	0.0169	
Rest of World	85	27 (31.8)	NC [NC, NC]	84	6 (7.1)	NC [NC, NC]	4.053 [1.654, 9.932]	0.0009	
Sex									
Male	197	62 (31.5)	NC [22.5, NC]	181	19 (10.5)	NC [NC, NC]	2.552 [1.508, 4.316]	0.0003	0.7783
Female	42	11 (26.2)	NC [NC, NC]	55	4 (7.3)	NC [NC, NC]	3.286 [1.032, 10.461]	0.0329	
Metastases at Baseline									
Visceral metastases	169	47 (27.8)	NC [NC, NC]	157	18 (11.5)	NC [NC, NC]	2.065 [1.184, 3.600]	0.0089	0.2578
Lymph node only	60	21 (35.0)	22.5 [6.5, NC]	65	5 (7.7)	NC [NC, NC]	3.812 [1.406, 10.333]	0.0048	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.62.1.1: Summary and Results of TEAEs - Weight increased (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	6 (2.5%)	8 (3.4%)	
Number of patients censored	233 (97.5%)	228 (96.6%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	99.1 [96.5, 99.8]	97.7 [94.6, 99.1]	
Month 6	98.6 [95.7, 99.5]	96.1 [92.4, 98.1]	
Month 9	97.9 [94.4, 99.2]	NC [NC, NC]	
Month 12	97.9 [94.4, 99.2]	NC [NC, NC]	
Month 18	95.2 [88.7, 98.0]	NC [NC, NC]	
Month 24	95.2 [88.7, 98.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.351 [0.093, 1.323]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1058

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.63.1.1: Summary and Results of TEAEs - White blood cell count decreased (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	1 (0.4%)	14 (5.9%)	
Number of patients censored	238 (99.6%)	222 (94.1%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	99.6 [97.1, 99.9]	94.0 [90.0, 96.4]	
Month 6	99.6 [97.1, 99.9]	94.0 [90.0, 96.4]	
Month 9	99.6 [97.1, 99.9]	NC [NC, NC]	
Month 12	99.6 [97.1, 99.9]	NC [NC, NC]	
Month 18	99.6 [97.1, 99.9]	NC [NC, NC]	
Month 24	99.6 [97.1, 99.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.068 [0.009, 0.520]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0006

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.63.1.2: Summary and Results of TEAEs by Subgroups - White blood cell count decreased (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	1 (2.1)	NC [NC, NC]	47	2 (4.3)	NC [NC, NC]	0.508 [0.046, 5.599]	0.5712	NC
Absent	192	0 (0.0)	NC [NC, NC]	189	12 (6.3)	NC [NC, NC]	NC [NC, NC]	0.0004	
Age									
< 65 years	105	0 (0.0)		102	7 (6.9)				
>= 65 years	134	1 (0.7)		134	7 (5.2)				
Region									
Europe	97	0 (0.0)	NC [NC, NC]	101	2 (2.0)	NC [NC, NC]	NC [NC, NC]	0.1647	NC
North America	57	0 (0.0)	NC [NC, NC]	51	3 (5.9)	NC [NC, NC]	NC [NC, NC]	0.0647	
Rest of World	85	1 (1.2)	NC [NC, NC]	84	9 (10.7)	NC [NC, NC]	0.104 [0.013, 0.818]	0.0082	
Sex									
Male	197	1 (0.5)	NC [NC, NC]	181	11 (6.1)	NC [NC, NC]	0.081 [0.010, 0.627]	0.0020	NC
Female	42	0 (0.0)	NC [NC, NC]	55	3 (5.5)	NC [NC, NC]	NC [NC, NC]	0.1257	
Metastases at Baseline									
Visceral metastases	169	1 (0.6)		157	8 (5.1)				
Lymph node only	60	0 (0.0)		65	5 (7.7)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.64.1.1: Summary and Results of TEAEs - Metabolism and nutrition disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	132 (55.2%)	109 (46.2%)	
Number of patients censored	107 (44.8%)	127 (53.8%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	57.4 [50.8, 63.4]	55.1 [48.4, 61.3]	
Month 6	50.6 [43.9, 56.8]	52.4 [45.7, 58.7]	
Month 9	46.9 [40.1, 53.4]	NC [NC, NC]	
Month 12	42.5 [35.5, 49.2]	NC [NC, NC]	
Month 18	36.5 [28.4, 44.6]	NC [NC, NC]	
Month 24	33.9 [25.0, 42.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	6.4 [3.5, 10.8]	NC [2.8, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.985 [0.756, 1.282]
Log-rank test			
Two-sided unstratified log-rank p-value			0.9066

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.65.1.1: Summary and Results of TEAEs - Decreased appetite (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	72 (30.1%)	59 (25.0%)	
Number of patients censored	167 (69.9%)	177 (75.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	77.5 [71.6, 82.3]	75.7 [69.6, 80.7]	
Month 6	71.3 [64.9, 76.8]	74.0 [67.7, 79.2]	
Month 9	69.5 [62.8, 75.2]	NC [NC, NC]	
Month 12	67.9 [61.1, 73.8]	NC [NC, NC]	
Month 18	66.4 [59.0, 72.8]	NC [NC, NC]	
Month 24	60.9 [47.6, 71.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [23.2, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.989 [0.692, 1.415]
Log-rank test			
Two-sided unstratified log-rank p-value			0.9544

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.66.1.1: Summary and Results of TEAEs - Dehydration (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	7 (2.9%)	9 (3.8%)	
Number of patients censored	232 (97.1%)	227 (96.2%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.2 [95.4, 99.3]	97.0 [93.9, 98.6]	
Month 6	97.2 [93.8, 98.7]	95.8 [92.0, 97.8]	
Month 9	96.5 [92.8, 98.3]	NC [NC, NC]	
Month 12	96.5 [92.8, 98.3]	NC [NC, NC]	
Month 18	96.5 [92.8, 98.3]	NC [NC, NC]	
Month 24	96.5 [92.8, 98.3]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.572 [0.200, 1.631]
Log-rank test			
Two-sided unstratified log-rank p-value			0.2902

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.67.1.1: Summary and Results of TEAEs - Hyperglycaemia (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	44 (18.4%)	6 (2.5%)	
Number of patients censored	195 (81.6%)	230 (97.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	86.0 [80.9, 89.9]	97.4 [94.3, 98.8]	
Month 6	83.5 [78.0, 87.7]	97.4 [94.3, 98.8]	
Month 9	82.1 [76.3, 86.6]	NC [NC, NC]	
Month 12	81.2 [75.2, 85.9]	NC [NC, NC]	
Month 18	75.7 [66.8, 82.6]	NC [NC, NC]	
Month 24	75.7 [66.8, 82.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			6.458 [2.727, 15.294]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.67.1.2: Summary and Results of TEAEs by Subgroups - Hyperglycaemia (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	8 (17.0)	NC [NC, NC]	47	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0095	NC
Absent	192	36 (18.8)	NC [NC, NC]	189	6 (3.2)	NC [NC, NC]	5.320 [2.218, 12.763]	<.0001	
Age									
< 65 years	105	21 (20.0)	NC [NC, NC]	102	5 (4.9)	NC [NC, NC]	3.388 [1.246, 9.214]	0.0111	0.1157
>= 65 years	134	23 (17.2)	NC [NC, NC]	134	1 (0.7)	NC [NC, NC]	21.719 [2.919, 161.59]	<.0001	
Region									
Europe	97	19 (19.6)	NC [NC, NC]	101	4 (4.0)	NC [NC, NC]	4.522 [1.511, 13.528]	0.0031	0.5252
North America	57	6 (10.5)	NC [NC, NC]	51	1 (2.0)	NC [NC, NC]	5.546 [0.668, 46.050]	0.0734	
Rest of World	85	19 (22.4)	NC [NC, NC]	84	1 (1.2)	NC [NC, NC]	15.634 [2.068, 118.21]	0.0004	
Sex									
Male	197	38 (19.3)	NC [NC, NC]	181	4 (2.2)	NC [NC, NC]	7.750 [2.739, 21.928]	<.0001	0.4152
Female	42	6 (14.3)	NC [NC, NC]	55	2 (3.6)	NC [NC, NC]	3.651 [0.726, 18.369]	0.0936	
Metastases at Baseline									
Visceral metastases	169	27 (16.0)	NC [NC, NC]	157	3 (1.9)	NC [NC, NC]	7.285 [2.184, 24.305]	0.0002	0.5033
Lymph node only	60	13 (21.7)	NC [NC, NC]	65	3 (4.6)	NC [NC, NC]	4.315 [1.204, 15.472]	0.0144	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.68.1.1: Summary and Results of TEAEs - Hyperkalaemia (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	5 (2.1%)	7 (3.0%)	
Number of patients censored	234 (97.9%)	229 (97.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	99.2 [96.7, 99.8]	96.8 [93.3, 98.5]	
Month 6	98.6 [95.7, 99.6]	96.8 [93.3, 98.5]	
Month 9	97.9 [94.3, 99.2]	NC [NC, NC]	
Month 12	97.9 [94.3, 99.2]	NC [NC, NC]	
Month 18	95.7 [87.2, 98.6]	NC [NC, NC]	
Month 24	95.7 [87.2, 98.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.352 [0.088, 1.407]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1237

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.69.1.1: Summary and Results of TEAEs - Hypocalcaemia (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	7 (2.9%)	5 (2.1%)	
Number of patients censored	232 (97.1%)	231 (97.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.3 [95.5, 99.4]	98.3 [95.4, 99.3]	
Month 6	98.3 [95.5, 99.4]	97.7 [94.6, 99.0]	
Month 9	97.6 [94.1, 99.0]	NC [NC, NC]	
Month 12	96.8 [92.8, 98.6]	NC [NC, NC]	
Month 18	96.8 [92.8, 98.6]	NC [NC, NC]	
Month 24	93.7 [82.7, 97.8]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.780 [0.209, 2.904]
Log-rank test			
Two-sided unstratified log-rank p-value			0.7099

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.70.1.1: Summary and Results of TEAEs - Hypokalaemia (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	16 (6.7%)	16 (6.8%)	
Number of patients censored	223 (93.3%)	220 (93.2%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	94.9 [91.1, 97.1]	93.9 [90.0, 96.4]	
Month 6	93.9 [89.9, 96.4]	92.8 [88.4, 95.5]	
Month 9	93.9 [89.9, 96.4]	NC [NC, NC]	
Month 12	93.1 [88.7, 95.8]	NC [NC, NC]	
Month 18	91.4 [85.1, 95.1]	NC [NC, NC]	
Month 24	91.4 [85.1, 95.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.839 [0.409, 1.718]
Log-rank test			
Two-sided unstratified log-rank p-value			0.6307

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.71.1.1: Summary and Results of TEAEs - Hypomagnesaemia (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	9 (3.8%)	20 (8.5%)	
Number of patients censored	230 (96.2%)	216 (91.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.6 [93.2, 98.3]	92.5 [88.2, 95.3]	
Month 6	96.6 [93.2, 98.3]	90.9 [86.2, 94.1]	
Month 9	96.6 [93.2, 98.3]	NC [NC, NC]	
Month 12	96.6 [93.2, 98.3]	NC [NC, NC]	
Month 18	95.0 [89.3, 97.7]	NC [NC, NC]	
Month 24	95.0 [89.3, 97.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.381 [0.168, 0.864]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0164

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.71.1.2: Summary and Results of TEAEs by Subgroups - Hypomagnesaemia (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	3 (6.4)	NC [14.6, NC]	47	3 (6.4)	NC [NC, NC]	0.676 [0.113, 4.045]	0.6686	0.2278
Absent	192	6 (3.1)	NC [NC, NC]	189	17 (9.0)	NC [NC, NC]	0.330 [0.130, 0.836]	0.0139	
Age									
< 65 years	105	5 (4.8)	NC [NC, NC]	102	8 (7.8)	NC [NC, NC]	0.468 [0.141, 1.555]	0.2046	0.4763
>= 65 years	134	4 (3.0)	NC [NC, NC]	134	12 (9.0)	NC [NC, NC]	0.320 [0.103, 0.992]	0.0373	
Region									
Europe	97	3 (3.1)	NC [NC, NC]	101	7 (6.9)	NC [NC, NC]	0.291 [0.060, 1.400]	0.1010	0.6498
North America	57	4 (7.0)	NC [NC, NC]	51	11 (21.6)	NC [NC, NC]	0.296 [0.094, 0.931]	0.0271	
Rest of World	85	2 (2.4)	NC [NC, NC]	84	2 (2.4)	NC [NC, NC]	0.969 [0.136, 6.880]	0.9749	
Sex									
Male	197	9 (4.6)	NC [NC, NC]	181	15 (8.3)	NC [NC, NC]	0.473 [0.201, 1.117]	0.0805	NC
Female	42	0 (0.0)	NC [NC, NC]	55	5 (9.1)	NC [NC, NC]	NC [NC, NC]	0.0472	
Metastases at Baseline									
Visceral metastases	169	7 (4.1)	NC [NC, NC]	157	11 (7.0)	NC [NC, NC]	0.494 [0.183, 1.337]	0.1567	0.2265
Lymph node only	60	1 (1.7)	NC [NC, NC]	65	7 (10.8)	NC [NC, NC]	0.144 [0.018, 1.171]	0.0350	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.72.1.1: Summary and Results of TEAEs - Hyponatraemia (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	12 (5.0%)	19 (8.1%)	
Number of patients censored	227 (95.0%)	217 (91.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	95.8 [92.3, 97.7]	92.2 [87.9, 95.0]	
Month 6	95.8 [92.3, 97.7]	91.7 [87.3, 94.6]	
Month 9	95.1 [91.2, 97.3]	NC [NC, NC]	
Month 12	95.1 [91.2, 97.3]	NC [NC, NC]	
Month 18	95.1 [91.2, 97.3]	NC [NC, NC]	
Month 24	95.1 [91.2, 97.3]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.512 [0.238, 1.101]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0806

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.73.1.1: Summary and Results of TEAEs - Hypophosphataemia (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	9 (3.8%)	7 (3.0%)	
Number of patients censored	230 (96.2%)	229 (97.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.2 [92.8, 98.0]	97.4 [94.4, 98.8]	
Month 6	96.2 [92.8, 98.0]	96.9 [93.6, 98.5]	
Month 9	96.2 [92.8, 98.0]	NC [NC, NC]	
Month 12	96.2 [92.8, 98.0]	NC [NC, NC]	
Month 18	96.2 [92.8, 98.0]	NC [NC, NC]	
Month 24	96.2 [92.8, 98.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.266 [0.471, 3.399]
Log-rank test			
Two-sided unstratified log-rank p-value			0.6405

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.74.1.1: Summary and Results of TEAEs - Musculoskeletal and connective tissue disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	**Plat+Gem (N= 236)**	**EV+Pembro vs. Plat+Gem**
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	108 (45.2%)	68 (28.8%)	
Number of patients censored	131 (54.8%)	168 (71.2%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	71.4 [65.2, 76.8]	72.7 [66.4, 78.0]	
Month 6	60.4 [53.6, 66.5]	69.8 [63.3, 75.4]	
Month 9	55.5 [48.4, 62.0]	NC [NC, NC]	
Month 12	51.2 [43.8, 58.2]	NC [NC, NC]	
Month 18	44.9 [36.4, 53.0]	NC [NC, NC]	
Month 24	42.3 [32.9, 51.3]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	12.3 [7.3, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.204 [0.875, 1.657]
Log-rank test			
Two-sided unstratified log-rank p-value			0.2523

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.75.1.1: Summary and Results of TEAEs - Arthralgia (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	36 (15.1%)	11 (4.7%)	
Number of patients censored	203 (84.9%)	225 (95.3%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	90.6 [86.1, 93.7]	95.6 [91.9, 97.6]	
Month 6	87.6 [82.5, 91.3]	95.0 [91.1, 97.2]	
Month 9	85.7 [80.2, 89.8]	NC [NC, NC]	
Month 12	84.0 [78.1, 88.5]	NC [NC, NC]	
Month 18	80.8 [72.9, 86.5]	NC [NC, NC]	
Month 24	77.5 [67.0, 85.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			2.405 [1.191, 4.856]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0116

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.75.1.2: Summary and Results of TEAEs by Subgroups - Arthralgia (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	8 (17.0)	NC [NC, NC]	47	1 (2.1)	NC [NC, NC]	6.368 [0.767, 52.883]	0.0489	0.2756
Absent	192	28 (14.6)	NC [NC, NC]	189	10 (5.3)	NC [NC, NC]	2.002 [0.940, 4.265]	0.0663	
Age									
< 65 years	105	16 (15.2)	NC [NC, NC]	102	4 (3.9)	NC [NC, NC]	2.726 [0.869, 8.551]	0.0733	0.6952
>= 65 years	134	20 (14.9)	NC [NC, NC]	134	7 (5.2)	NC [NC, NC]	2.210 [0.905, 5.396]	0.0739	
Region									
Europe	97	14 (14.4)	NC [20.2, NC]	101	6 (5.9)	NC [NC, NC]	1.641 [0.591, 4.552]	0.3367	0.6854
North America	57	18 (31.6)	NC [10.1, NC]	51	4 (7.8)	NC [NC, NC]	3.307 [1.088, 10.053]	0.0254	
Rest of World	85	4 (4.7)	NC [NC, NC]	84	1 (1.2)	NC [NC, NC]	3.060 [0.322, 29.060]	0.3070	
Sex									
Male	197	31 (15.7)	NC [NC, NC]	181	9 (5.0)	NC [NC, NC]	2.314 [1.068, 5.013]	0.0285	0.9875
Female	42	5 (11.9)	NC [NC, NC]	55	2 (3.6)	NC [NC, NC]	2.670 [0.492, 14.497]	0.2371	
Metastases at Baseline									
Visceral metastases	169	26 (15.4)	NC [NC, NC]	157	9 (5.7)	NC [NC, NC]	2.007 [0.908, 4.435]	0.0790	0.6143
Lymph node only	60	8 (13.3)	NC [NC, NC]	65	2 (3.1)	NC [NC, NC]	3.356 [0.687, 16.402]	0.1131	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.76.1.1: Summary and Results of TEAEs - Back pain (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	37 (15.5%)	21 (8.9%)	
Number of patients censored	202 (84.5%)	215 (91.1%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	91.0 [86.5, 94.0]	90.9 [86.3, 94.0]	
Month 6	86.9 [81.6, 90.7]	90.9 [86.3, 94.0]	
Month 9	85.6 [80.1, 89.7]	NC [NC, NC]	
Month 12	81.6 [74.8, 86.8]	NC [NC, NC]	
Month 18	78.8 [70.8, 84.8]	NC [NC, NC]	
Month 24	78.8 [70.8, 84.8]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.259 [0.714, 2.220]
Log-rank test			
Two-sided unstratified log-rank p-value			0.4252

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.77.1.1: Summary and Results of TEAEs - Bone pain (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	4 (1.7%)	7 (3.0%)	
Number of patients censored	235 (98.3%)	229 (97.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	99.2 [96.7, 99.8]	97.0 [93.7, 98.5]	
Month 6	98.7 [95.9, 99.6]	97.0 [93.7, 98.5]	
Month 9	98.7 [95.9, 99.6]	NC [NC, NC]	
Month 12	97.7 [93.6, 99.2]	NC [NC, NC]	
Month 18	97.7 [93.6, 99.2]	NC [NC, NC]	
Month 24	97.7 [93.6, 99.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.418 [0.108, 1.617]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1920

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.78.1.1: Summary and Results of TEAEs - Flank pain (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	7 (2.9%)	7 (3.0%)	
Number of patients censored	232 (97.1%)	229 (97.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	99.2 [96.7, 99.8]	97.0 [93.7, 98.5]	
Month 6	97.6 [94.3, 99.0]	97.0 [93.7, 98.5]	
Month 9	96.9 [93.0, 98.6]	NC [NC, NC]	
Month 12	95.9 [91.4, 98.1]	NC [NC, NC]	
Month 18	95.9 [91.4, 98.1]	NC [NC, NC]	
Month 24	95.9 [91.4, 98.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.566 [0.169, 1.889]
Log-rank test			
Two-sided unstratified log-rank p-value			0.3484

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.79.1.1: Summary and Results of TEAEs - Muscle spasms (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	9 (3.8%)	1 (0.4%)	
Number of patients censored	230 (96.2%)	235 (99.6%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	99.1 [96.5, 99.8]	99.6 [96.9, 99.9]	
Month 6	98.0 [94.6, 99.2]	99.6 [96.9, 99.9]	
Month 9	96.0 [91.7, 98.1]	NC [NC, NC]	
Month 12	95.2 [90.6, 97.6]	NC [NC, NC]	
Month 18	95.2 [90.6, 97.6]	NC [NC, NC]	
Month 24	91.9 [81.1, 96.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			2.061 [0.194, 21.938]
Log-rank test			
Two-sided unstratified log-rank p-value			0.5411

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.80.1.1: Summary and Results of TEAEs - Muscular weakness (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	13 (5.4%)	4 (1.7%)	
Number of patients censored	226 (94.6%)	232 (98.3%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.2 [95.4, 99.3]	98.7 [96.1, 99.6]	
Month 6	93.8 [89.3, 96.4]	98.0 [94.7, 99.3]	
Month 9	93.2 [88.4, 96.0]	NC [NC, NC]	
Month 12	93.2 [88.4, 96.0]	NC [NC, NC]	
Month 18	93.2 [88.4, 96.0]	NC [NC, NC]	
Month 24	93.2 [88.4, 96.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.518 [0.444, 5.191]
Log-rank test			
Two-sided unstratified log-rank p-value			0.5028

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
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Table 302.1.2002.81.1.1: Summary and Results of TEAEs - Myalgia (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	17 (7.1%)	7 (3.0%)	
Number of patients censored	222 (92.9%)	229 (97.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	95.7 [92.2, 97.7]	97.0 [93.8, 98.5]	
Month 6	93.7 [89.5, 96.2]	97.0 [93.8, 98.5]	
Month 9	93.7 [89.5, 96.2]	NC [NC, NC]	
Month 12	93.7 [89.5, 96.2]	NC [NC, NC]	
Month 18	89.8 [83.0, 94.0]	NC [NC, NC]	
Month 24	89.8 [83.0, 94.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.877 [0.755, 4.666]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1681

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
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Table 302.1.2002.82.1.1: Summary and Results of TEAEs - Pain in extremity (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	21 (8.8%)	15 (6.4%)	
Number of patients censored	218 (91.2%)	221 (93.6%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.9 [93.6, 98.5]	93.8 [89.8, 96.3]	
Month 6	94.9 [90.9, 97.1]	93.3 [89.1, 95.9]	
Month 9	91.5 [86.3, 94.8]	NC [NC, NC]	
Month 12	88.8 [82.7, 92.9]	NC [NC, NC]	
Month 18	85.3 [76.8, 90.9]	NC [NC, NC]	
Month 24	85.3 [76.8, 90.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.690 [0.317, 1.501]
Log-rank test			
Two-sided unstratified log-rank p-value			0.3472

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
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Table 302.1.2002.83.1.1: Summary and Results of TEAEs - Neoplasms benign, malignant and unspecified (incl cysts and polyps) (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	13 (5.4%)	7 (3.0%)	
Number of patients censored	226 (94.6%)	229 (97.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.7 [96.0, 99.6]	97.0 [93.8, 98.6]	
Month 6	95.5 [91.5, 97.6]	97.0 [93.8, 98.6]	
Month 9	94.2 [89.6, 96.8]	NC [NC, NC]	
Month 12	93.1 [87.9, 96.1]	NC [NC, NC]	
Month 18	90.9 [83.1, 95.2]	NC [NC, NC]	
Month 24	90.9 [83.1, 95.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.871 [0.303, 2.500]
Log-rank test			
Two-sided unstratified log-rank p-value			0.7978

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
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Table 302.1.2002.84.1.1: Summary and Results of TEAEs - Nervous system disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	186 (77.8%)	96 (40.7%)	
Number of patients censored	53 (22.2%)	140 (59.3%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	48.4 [41.7, 54.7]	63.5 [56.8, 69.4]	
Month 6	23.7 [18.0, 29.9]	54.9 [47.0, 62.1]	
Month 9	11.9 [7.5, 17.5]	NC [NC, NC]	
Month 12	11.9 [7.5, 17.5]	NC [NC, NC]	
Month 18	3.4 [0.4, 12.2]	NC [NC, NC]	
Month 24	NC [NC, NC]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	2.6 [2.1, 3.3]	NC [5.1, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.826 [1.417, 2.353]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
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Table 302.1.2002.84.1.2: Summary and Results of TEAEs by Subgroups - Nervous system disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	29 (61.7)	3.3 [2.0, 5.4]	47	21 (44.7)	NC [2.1, NC]	1.498 [0.844, 2.657]	0.1662	0.3996
Absent	192	157 (81.8)	2.4 [2.0, 3.2]	189	75 (39.7)	NC [5.1, NC]	1.899 [1.430, 2.522]	<.0001	
Age									
< 65 years	105	80 (76.2)	3.1 [2.1, 3.9]	102	39 (38.2)	NC [5.1, NC]	1.760 [1.183, 2.618]	0.0047	0.6387
>= 65 years	134	106 (79.1)	2.2 [1.6, 3.4]	134	57 (42.5)	NC [3.2, NC]	1.888 [1.358, 2.626]	0.0001	
Region									
Europe	97	76 (78.4)	2.4 [1.8, 3.1]	101	39 (38.6)	NC [3.9, NC]	2.196 [1.476, 3.266]	<.0001	0.0905
North America	57	49 (86.0)	1.5 [0.7, 3.0]	51	33 (64.7)	1.3 [0.7, 3.1]	1.049 [0.661, 1.665]	0.8406	
Rest of World	85	61 (71.8)	4.0 [3.1, 4.8]	84	24 (28.6)	NC [5.1, NC]	2.274 [1.400, 3.695]	0.0007	
Sex									
Male	197	152 (77.2)	2.5 [2.1, 3.2]	181	72 (39.8)	NC [4.1, NC]	1.914 [1.434, 2.554]	<.0001	0.4896
Female	42	34 (81.0)	3.1 [1.4, 4.7]	55	24 (43.6)	NC [1.5, NC]	1.544 [0.900, 2.649]	0.1118	
Metastases at Baseline									
Visceral metastases	169	129 (76.3)	2.7 [2.0, 3.4]	157	67 (42.7)	NC [3.2, NC]	1.686 [1.245, 2.282]	0.0006	0.6695
Lymph node only	60	48 (80.0)	2.5 [1.4, 3.5]	65	25 (38.5)	NC [3.9, NC]	2.002 [1.208, 3.316]	0.0060	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
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Table 302.1.2002.85.1.1: Summary and Results of TEAEs - Dizziness (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	24 (10.0%)	26 (11.0%)	
Number of patients censored	215 (90.0%)	210 (89.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	92.8 [88.6, 95.4]	90.0 [85.4, 93.3]	
Month 6	91.2 [86.7, 94.3]	88.4 [83.4, 92.0]	
Month 9	89.1 [83.9, 92.7]	NC [NC, NC]	
Month 12	88.3 [82.9, 92.1]	NC [NC, NC]	
Month 18	88.3 [82.9, 92.1]	NC [NC, NC]	
Month 24	88.3 [82.9, 92.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.736 [0.411, 1.318]
Log-rank test			
Two-sided unstratified log-rank p-value			0.3009

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
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Table 302.1.2002.86.1.1: Summary and Results of TEAEs - Dysgeusia (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	47 (19.7%)	28 (11.9%)	
Number of patients censored	192 (80.3%)	208 (88.1%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	86.7 [81.6, 90.5]	89.0 [84.1, 92.4]	
Month 6	79.9 [73.8, 84.7]	87.3 [82.1, 91.1]	
Month 9	77.9 [71.6, 83.0]	NC [NC, NC]	
Month 12	77.9 [71.6, 83.0]	NC [NC, NC]	
Month 18	77.9 [71.6, 83.0]	NC [NC, NC]	
Month 24	77.9 [71.6, 83.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.433 [0.887, 2.316]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1395

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
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Table 302.1.2002.87.1.1: Summary and Results of TEAEs - Headache (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	19 (7.9%)	16 (6.8%)	
Number of patients censored	220 (92.1%)	220 (93.2%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	94.9 [91.1, 97.1]	93.9 [89.8, 96.3]	
Month 6	93.3 [89.1, 95.9]	92.7 [88.4, 95.5]	
Month 9	92.0 [87.4, 95.0]	NC [NC, NC]	
Month 12	91.0 [85.7, 94.3]	NC [NC, NC]	
Month 18	91.0 [85.7, 94.3]	NC [NC, NC]	
Month 24	87.5 [77.0, 93.4]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.891 [0.440, 1.805]
Log-rank test			
Two-sided unstratified log-rank p-value			0.7494

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
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Table 302.1.2002.88.1.1: Summary and Results of TEAEs - Hypoaesthesia (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	12 (5.0%)	1 (0.4%)	
Number of patients censored	227 (95.0%)	235 (99.6%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.8 [94.9, 99.1]	99.5 [96.8, 99.9]	
Month 6	96.3 [92.7, 98.1]	99.5 [96.8, 99.9]	
Month 9	95.1 [91.0, 97.4]	NC [NC, NC]	
Month 12	95.1 [91.0, 97.4]	NC [NC, NC]	
Month 18	92.0 [85.0, 95.9]	NC [NC, NC]	
Month 24	92.0 [85.0, 95.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			7.380 [0.921, 59.116]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0274

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
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Table 302.1.2002.88.1.2: Summary and Results of TEAEs by Subgroups - Hypoaesthesia (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	3 (6.4)	NC [NC, NC]	47	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0796	NC
Absent	192	9 (4.7)	NC [NC, NC]	189	1 (0.5)	NC [NC, NC]	4.318 [0.503, 37.074]	0.1470	
Age									
< 65 years	105	4 (3.8)		102	1 (1.0)				
>= 65 years	134	8 (6.0)		134	0 (0.0)				
Region									
Europe	97	2 (2.1)		101	0 (0.0)				
North America	57	2 (3.5)		51	0 (0.0)				
Rest of World	85	8 (9.4)		84	1 (1.2)				
Sex									
Male	197	7 (3.6)		181	1 (0.6)				
Female	42	5 (11.9)		55	0 (0.0)				
Metastases at Baseline									
Visceral metastases	169	8 (4.7)		157	0 (0.0)				
Lymph node only	60	4 (6.7)		65	1 (1.5)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.89.1.1: Summary and Results of TEAEs - Paraesthesia (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	24 (10.0%)	6 (2.5%)	
Number of patients censored	215 (90.0%)	230 (97.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	95.5 [91.9, 97.6]	98.2 [95.3, 99.3]	
Month 6	90.9 [86.0, 94.1]	97.1 [93.7, 98.7]	
Month 9	90.3 [85.3, 93.6]	NC [NC, NC]	
Month 12	88.3 [82.5, 92.3]	NC [NC, NC]	
Month 18	85.5 [78.3, 90.5]	NC [NC, NC]	
Month 24	85.5 [78.3, 90.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			2.680 [1.057, 6.794]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0308

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.89.1.2: Summary and Results of TEAEs by Subgroups - Paraesthesia (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	6 (12.8)	NC [11.4, NC]	47	2 (4.3)	NC [NC, NC]	1.160 [0.176, 7.637]	0.8771	0.8150
Absent	192	18 (9.4)	NC [NC, NC]	189	4 (2.1)	NC [NC, NC]	3.448 [1.142, 10.407]	0.0194	
Age									
< 65 years	105	10 (9.5)	NC [NC, NC]	102	4 (3.9)	NC [NC, NC]	1.769 [0.530, 5.906]	0.3474	0.2375
>= 65 years	134	14 (10.4)	NC [NC, NC]	134	2 (1.5)	NC [NC, NC]	4.560 [0.988, 21.037]	0.0328	
Region									
Europe	97	15 (15.5)	NC [NC, NC]	101	2 (2.0)	NC [NC, NC]	6.423 [1.440, 28.655]	0.0051	0.0401
North America	57	8 (14.0)	NC [NC, NC]	51	1 (2.0)	NC [NC, NC]	4.015 [0.463, 34.845]	0.1735	
Rest of World	85	1 (1.2)	NC [NC, NC]	84	3 (3.6)	NC [NC, NC]	0.000 [0.000, NC]	0.0740	
Sex									
Male	197	21 (10.7)	NC [NC, NC]	181	4 (2.2)	NC [NC, NC]	3.492 [1.166, 10.454]	0.0172	0.3858
Female	42	3 (7.1)	NC [NC, NC]	55	2 (3.6)	NC [NC, NC]	0.776 [0.086, 6.992]	0.8207	
Metastases at Baseline									
Visceral metastases	169	18 (10.7)	NC [NC, NC]	157	3 (1.9)	NC [NC, NC]	3.833 [1.092, 13.455]	0.0241	0.9439
Lymph node only	60	6 (10.0)	NC [NC, NC]	65	1 (1.5)	NC [NC, NC]	4.298 [0.482, 38.343]	0.1542	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.90.1.1: Summary and Results of TEAEs - Peripheral motor neuropathy (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	11 (4.6%)	1 (0.4%)	
Number of patients censored	228 (95.4%)	235 (99.6%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	100.0 [100.0, 100.0]	99.5 [96.8, 99.9]	
Month 6	97.3 [93.7, 98.9]	99.5 [96.8, 99.9]	
Month 9	94.7 [90.0, 97.2]	NC [NC, NC]	
Month 12	92.6 [86.8, 96.0]	NC [NC, NC]	
Month 18	92.6 [86.8, 96.0]	NC [NC, NC]	
Month 24	92.6 [86.8, 96.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			2.459 [0.261, 23.192]
Log-rank test			
Two-sided unstratified log-rank p-value			0.4192

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.91.1.1: Summary and Results of TEAEs - Peripheral sensorimotor neuropathy (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	10 (4.2%)	1 (0.4%)	
Number of patients censored	229 (95.8%)	235 (99.6%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.8 [94.7, 99.1]	99.6 [96.9, 99.9]	
Month 6	96.7 [93.2, 98.4]	99.6 [96.9, 99.9]	
Month 9	95.3 [91.2, 97.6]	NC [NC, NC]	
Month 12	95.3 [91.2, 97.6]	NC [NC, NC]	
Month 18	93.9 [88.1, 96.9]	NC [NC, NC]	
Month 24	93.9 [88.1, 96.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			5.919 [0.715, 49.005]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0613

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.92.1.1: Summary and Results of TEAEs - Peripheral sensory neuropathy (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	126 (52.7%)	34 (14.4%)	
Number of patients censored	113 (47.3%)	202 (85.6%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	76.6 [70.5, 81.6]	90.6 [86.0, 93.8]	
Month 6	52.5 [45.3, 59.1]	81.2 [72.9, 87.1]	
Month 9	39.4 [32.0, 46.8]	NC [NC, NC]	
Month 12	39.4 [32.0, 46.8]	NC [NC, NC]	
Month 18	30.1 [21.6, 39.0]	NC [NC, NC]	
Month 24	23.3 [14.4, 33.3]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	6.4 [5.3, 8.1]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			2.826 [1.906, 4.191]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.92.1.2: Summary and Results of TEAEs by Subgroups - Peripheral sensory neuropathy (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	18 (38.3)	8.4 [4.4, NC]	47	6 (12.8)	NC [NC, NC]	2.956 [1.149, 7.608]	0.0188	0.9558
Absent	192	108 (56.3)	6.4 [4.9, 7.8]	189	28 (14.8)	NC [NC, NC]	2.791 [1.809, 4.308]	<.0001	
Age									
< 65 years	105	56 (53.3)	6.6 [5.3, 13.2]	102	17 (16.7)	NC [NC, NC]	2.256 [1.273, 3.997]	0.0042	0.4414
>= 65 years	134	70 (52.2)	6.0 [4.4, 8.5]	134	17 (12.7)	NC [NC, NC]	3.420 [1.980, 5.907]	<.0001	
Region									
Europe	97	50 (51.5)	6.4 [4.2, 8.8]	101	10 (9.9)	NC [NC, NC]	4.591 [2.283, 9.234]	<.0001	0.2797
North America	57	37 (64.9)	5.3 [3.3, 5.7]	51	13 (25.5)	NC [NC, NC]	1.708 [0.874, 3.338]	0.1139	
Rest of World	85	39 (45.9)	13.2 [5.6, NC]	84	11 (13.1)	NC [NC, NC]	2.490 [1.238, 5.009]	0.0082	
Sex									
Male	197	105 (53.3)	6.0 [4.9, 6.9]	181	27 (14.9)	NC [NC, NC]	2.758 [1.777, 4.282]	<.0001	0.9648
Female	42	21 (50.0)	8.1 [3.7, 19.9]	55	7 (12.7)	NC [NC, NC]	2.944 [1.200, 7.222]	0.0134	
Metastases at Baseline									
Visceral metastases	169	86 (50.9)	6.2 [5.1, 8.5]	157	26 (16.6)	NC [NC, NC]	2.305 [1.458, 3.642]	0.0002	0.3962
Lymph node only	60	34 (56.7)	7.2 [4.2, 14.5]	65	8 (12.3)	NC [NC, NC]	3.329 [1.483, 7.475]	0.0020	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.93.1.1: Summary and Results of TEAEs - Taste disorder (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	10 (4.2%)	2 (0.8%)	
Number of patients censored	229 (95.8%)	234 (99.2%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	95.7 [92.2, 97.7]	99.1 [96.5, 99.8]	
Month 6	95.7 [92.2, 97.7]	99.1 [96.5, 99.8]	
Month 9	95.7 [92.2, 97.7]	NC [NC, NC]	
Month 12	95.7 [92.2, 97.7]	NC [NC, NC]	
Month 18	95.7 [92.2, 97.7]	NC [NC, NC]	
Month 24	95.7 [92.2, 97.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			5.008 [1.097, 22.855]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0207

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.93.1.2: Summary and Results of TEAEs by Subgroups - Taste disorder (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	3 (6.4)		47	0 (0.0)				
Absent	192	7 (3.6)		189	2 (1.1)				
Age									
< 65 years	105	2 (1.9)	NC [NC, NC]	102	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1624	NC
>= 65 years	134	8 (6.0)	NC [NC, NC]	134	2 (1.5)	NC [NC, NC]	4.068 [0.864, 19.159]	0.0541	
Region									
Europe	97	1 (1.0)		101	1 (1.0)				
North America	57	3 (5.3)		51	1 (2.0)				
Rest of World	85	6 (7.1)		84	0 (0.0)				
Sex									
Male	197	9 (4.6)	NC [NC, NC]	181	1 (0.6)	NC [NC, NC]	8.394 [1.064, 66.258]	0.0155	0.2928
Female	42	1 (2.4)	NC [NC, NC]	55	1 (1.8)	NC [NC, NC]	1.358 [0.085, 21.714]	0.8280	
Metastases at Baseline									
Visceral metastases	169	7 (4.1)		157	1 (0.6)				
Lymph node only	60	2 (3.3)		65	0 (0.0)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.94.1.1: Summary and Results of TEAEs - Psychiatric disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	39 (16.3%)	24 (10.2%)	
Number of patients censored	200 (83.7%)	212 (89.8%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	88.5 [83.6, 91.9]	91.0 [86.5, 94.0]	
Month 6	85.3 [79.9, 89.3]	89.0 [84.0, 92.6]	
Month 9	84.0 [78.4, 88.3]	NC [NC, NC]	
Month 12	83.1 [77.2, 87.6]	NC [NC, NC]	
Month 18	80.4 [73.3, 85.9]	NC [NC, NC]	
Month 24	76.0 [63.7, 84.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.239 [0.727, 2.111]
Log-rank test			
Two-sided unstratified log-rank p-value			0.4306

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.95.1.1: Summary and Results of TEAEs - Anxiety (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	10 (4.2%)	3 (1.3%)	
Number of patients censored	229 (95.8%)	233 (98.7%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.8 [94.9, 99.1]	98.6 [95.8, 99.6]	
Month 6	96.2 [92.5, 98.1]	98.6 [95.8, 99.6]	
Month 9	96.2 [92.5, 98.1]	NC [NC, NC]	
Month 12	95.3 [91.0, 97.6]	NC [NC, NC]	
Month 18	93.7 [87.6, 96.9]	NC [NC, NC]	
Month 24	93.7 [87.6, 96.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.992 [0.505, 7.865]
Log-rank test			
Two-sided unstratified log-rank p-value			0.3160

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.96.1.1: Summary and Results of TEAEs - Depression (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	5 (2.1%)	5 (2.1%)	
Number of patients censored	234 (97.9%)	231 (97.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	99.6 [97.1, 99.9]	98.7 [96.0, 99.6]	
Month 6	99.0 [96.1, 99.8]	97.4 [93.9, 98.9]	
Month 9	98.4 [95.1, 99.5]	NC [NC, NC]	
Month 12	96.5 [91.3, 98.6]	NC [NC, NC]	
Month 18	96.5 [91.3, 98.6]	NC [NC, NC]	
Month 24	96.5 [91.3, 98.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.236 [0.038, 1.472]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0991

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.97.1.1: Summary and Results of TEAEs - Insomnia (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	22 (9.2%)	14 (5.9%)	
Number of patients censored	217 (90.8%)	222 (94.1%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	92.7 [88.5, 95.4]	94.9 [91.2, 97.1]	
Month 6	91.1 [86.5, 94.2]	93.6 [89.4, 96.2]	
Month 9	90.4 [85.6, 93.7]	NC [NC, NC]	
Month 12	90.4 [85.6, 93.7]	NC [NC, NC]	
Month 18	89.2 [83.7, 93.0]	NC [NC, NC]	
Month 24	89.2 [83.7, 93.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.315 [0.660, 2.620]
Log-rank test			
Two-sided unstratified log-rank p-value			0.4357

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.98.1.1: Summary and Results of TEAEs - Renal and urinary disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	74 (31.0%)	76 (32.2%)	
Number of patients censored	165 (69.0%)	160 (67.8%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	78.7 [72.9, 83.4]	71.2 [64.9, 76.7]	
Month 6	74.0 [67.6, 79.2]	66.1 [59.5, 72.0]	
Month 9	68.1 [61.1, 74.1]	NC [NC, NC]	
Month 12	64.4 [56.9, 71.0]	NC [NC, NC]	
Month 18	63.3 [55.5, 70.1]	NC [NC, NC]	
Month 24	59.1 [47.8, 68.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [22.1, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.696 [0.493, 0.983]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0381

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.98.1.2: Summary and Results of TEAEs by Subgroups - Renal and urinary disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	14 (29.8)	NC [11.5, NC]	47	15 (31.9)	NC [NC, NC]	0.773 [0.356, 1.677]	0.5132	0.8562
Absent	192	60 (31.3)	NC [22.1, NC]	189	61 (32.3)	NC [NC, NC]	0.678 [0.461, 0.998]	0.0473	
Age									
< 65 years	105	27 (25.7)	NC [NC, NC]	102	26 (25.5)	NC [NC, NC]	0.823 [0.467, 1.450]	0.4967	0.8020
>= 65 years	134	47 (35.1)	22.1 [11.0, NC]	134	50 (37.3)	NC [NC, NC]	0.628 [0.406, 0.972]	0.0351	
Region									
Europe	97	33 (34.0)	NC [10.6, NC]	101	39 (38.6)	NC [4.4, NC]	0.722 [0.443, 1.176]	0.1875	0.9784
North America	57	20 (35.1)	22.1 [22.1, NC]	51	18 (35.3)	NC [3.6, NC]	0.833 [0.430, 1.614]	0.5856	
Rest of World	85	21 (24.7)	NC [NC, NC]	84	19 (22.6)	NC [NC, NC]	0.542 [0.260, 1.131]	0.0974	
Sex									
Male	197	62 (31.5)	NC [NC, NC]	181	60 (33.1)	NC [NC, NC]	0.713 [0.489, 1.041]	0.0789	0.9555
Female	42	12 (28.6)	22.1 [11.0, 22.1]	55	16 (29.1)	NC [NC, NC]	0.574 [0.242, 1.361]	0.1997	
Metastases at Baseline									
Visceral metastases	169	48 (28.4)	NC [22.1, NC]	157	50 (31.8)	NC [NC, NC]	0.623 [0.405, 0.959]	0.0299	0.7615
Lymph node only	60	21 (35.0)	NC [6.9, NC]	65	23 (35.4)	NC [3.2, NC]	0.740 [0.393, 1.391]	0.3467	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.99.1.1: Summary and Results of TEAEs - Acute kidney injury (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	11 (4.6%)	25 (10.6%)	
Number of patients censored	228 (95.4%)	211 (89.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.5 [94.4, 98.8]	91.6 [87.1, 94.5]	
Month 6	96.4 [92.8, 98.2]	88.5 [83.5, 92.1]	
Month 9	94.4 [89.9, 96.9]	NC [NC, NC]	
Month 12	94.4 [89.9, 96.9]	NC [NC, NC]	
Month 18	94.4 [89.9, 96.9]	NC [NC, NC]	
Month 24	94.4 [89.9, 96.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.269 [0.117, 0.616]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0009

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.99.1.2: Summary and Results of TEAEs by Subgroups - Acute kidney injury (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	3 (6.4)	NC [NC, NC]	47	2 (4.3)	NC [NC, NC]	1.052 [0.148, 7.469]	0.9599	0.0973
Absent	192	8 (4.2)	NC [NC, NC]	189	23 (12.2)	NC [NC, NC]	0.201 [0.076, 0.528]	0.0003	
Age									
< 65 years	105	7 (6.7)	NC [NC, NC]	102	9 (8.8)	NC [NC, NC]	0.533 [0.178, 1.589]	0.2511	0.1277
>= 65 years	134	4 (3.0)	NC [NC, NC]	134	16 (11.9)	NC [NC, NC]	0.127 [0.032, 0.503]	0.0006	
Region									
Europe	97	3 (3.1)	NC [NC, NC]	101	9 (8.9)	NC [NC, NC]	0.233 [0.052, 1.032]	0.0375	0.3946
North America	57	3 (5.3)	NC [NC, NC]	51	10 (19.6)	NC [NC, NC]	0.162 [0.035, 0.740]	0.0074	
Rest of World	85	5 (5.9)	NC [NC, NC]	84	6 (7.1)	NC [NC, NC]	0.487 [0.122, 1.946]	0.2985	
Sex									
Male	197	10 (5.1)	NC [NC, NC]	181	19 (10.5)	NC [NC, NC]	0.280 [0.113, 0.695]	0.0035	0.4686
Female	42	1 (2.4)	NC [NC, NC]	55	6 (10.9)	NC [NC, NC]	0.212 [0.025, 1.758]	0.1125	
Metastases at Baseline									
Visceral metastases	169	9 (5.3)	NC [NC, NC]	157	17 (10.8)	NC [NC, NC]	0.265 [0.098, 0.715]	0.0049	0.3694
Lymph node only	60	1 (1.7)	NC [NC, NC]	65	6 (9.2)	NC [NC, NC]	0.172 [0.021, 1.427]	0.0643	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.100.1.1: Summary and Results of TEAEs - Dysuria (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	13 (5.4%)	8 (3.4%)	
Number of patients censored	226 (94.6%)	228 (96.6%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.8 [94.9, 99.1]	96.9 [93.7, 98.5]	
Month 6	97.3 [94.0, 98.8]	96.4 [92.8, 98.2]	
Month 9	94.7 [90.2, 97.1]	NC [NC, NC]	
Month 12	92.9 [87.5, 96.0]	NC [NC, NC]	
Month 18	91.0 [83.9, 95.1]	NC [NC, NC]	
Month 24	91.0 [83.9, 95.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.640 [0.216, 1.893]
Log-rank test			
Two-sided unstratified log-rank p-value			0.4163

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.101.1.1: Summary and Results of TEAEs - Haematuria (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	31 (13.0%)	20 (8.5%)	
Number of patients censored	208 (87.0%)	216 (91.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	92.8 [88.6, 95.4]	92.5 [88.2, 95.3]	
Month 6	89.1 [84.2, 92.6]	91.0 [86.3, 94.1]	
Month 9	87.3 [81.9, 91.1]	NC [NC, NC]	
Month 12	85.3 [79.2, 89.7]	NC [NC, NC]	
Month 18	84.1 [77.5, 88.9]	NC [NC, NC]	
Month 24	79.5 [66.7, 87.8]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.088 [0.596, 1.985]
Log-rank test			
Two-sided unstratified log-rank p-value			0.7832

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.102.1.1: Summary and Results of TEAEs - Pollakiuria (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	8 (3.3%)	6 (2.5%)	
Number of patients censored	231 (96.7%)	230 (97.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.4 [94.3, 98.8]	98.7 [96.1, 99.6]	
Month 6	96.9 [93.5, 98.5]	97.0 [93.4, 98.7]	
Month 9	96.9 [93.5, 98.5]	NC [NC, NC]	
Month 12	96.9 [93.5, 98.5]	NC [NC, NC]	
Month 18	96.9 [93.5, 98.5]	NC [NC, NC]	
Month 24	93.7 [83.0, 97.8]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.985 [0.321, 3.018]
Log-rank test			
Two-sided unstratified log-rank p-value			0.9775

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.103.1.1: Summary and Results of TEAEs - Urinary retention (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	8 (3.3%)	9 (3.8%)	
Number of patients censored	231 (96.7%)	227 (96.2%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.9 [95.0, 99.1]	96.5 [93.1, 98.2]	
Month 6	97.4 [94.2, 98.8]	95.9 [92.3, 97.9]	
Month 9	96.7 [93.1, 98.4]	NC [NC, NC]	
Month 12	95.9 [91.8, 98.0]	NC [NC, NC]	
Month 18	95.9 [91.8, 98.0]	NC [NC, NC]	
Month 24	95.9 [91.8, 98.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.648 [0.230, 1.820]
Log-rank test			
Two-sided unstratified log-rank p-value			0.4065

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.104.1.1: Summary and Results of TEAEs - Reproductive system and breast disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	19 (7.9%)	6 (2.5%)	
Number of patients censored	220 (92.1%)	230 (97.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.6 [93.2, 98.3]	98.7 [96.0, 99.6]	
Month 6	93.3 [88.8, 96.0]	97.0 [93.4, 98.7]	
Month 9	91.8 [86.8, 95.0]	NC [NC, NC]	
Month 12	91.1 [85.8, 94.4]	NC [NC, NC]	
Month 18	89.7 [83.6, 93.6]	NC [NC, NC]	
Month 24	82.8 [63.5, 92.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.493 [0.544, 4.101]
Log-rank test			
Two-sided unstratified log-rank p-value			0.4341

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.105.1.1: Summary and Results of TEAEs - Respiratory, thoracic and mediastinal disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	**Plat+Gem (N= 236)**	**EV+Pembro vs. Plat+Gem**
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	100 (41.8%)	83 (35.2%)	
Number of patients censored	139 (58.2%)	153 (64.8%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	73.8 [67.7, 79.0]	66.6 [60.1, 72.3]	
Month 6	61.7 [54.8, 67.8]	63.3 [56.6, 69.3]	
Month 9	56.3 [49.1, 62.9]	NC [NC, NC]	
Month 12	53.9 [46.5, 60.7]	NC [NC, NC]	
Month 18	49.1 [40.4, 57.2]	NC [NC, NC]	
Month 24	46.4 [36.6, 55.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	17.3 [8.7, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.839 [0.617, 1.140]
Log-rank test			
Two-sided unstratified log-rank p-value			0.2649

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.106.1.1: Summary and Results of TEAEs - Cough (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	26 (10.9%)	13 (5.5%)	
Number of patients censored	213 (89.1%)	223 (94.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	93.0 [88.9, 95.7]	94.7 [90.9, 97.0]	
Month 6	90.8 [86.1, 94.0]	94.2 [90.3, 96.6]	
Month 9	87.2 [81.4, 91.3]	NC [NC, NC]	
Month 12	86.4 [80.3, 90.6]	NC [NC, NC]	
Month 18	86.4 [80.3, 90.6]	NC [NC, NC]	
Month 24	86.4 [80.3, 90.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.368 [0.671, 2.788]
Log-rank test			
Two-sided unstratified log-rank p-value			0.3866

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.107.1.1: Summary and Results of TEAEs - Dysphonia (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	13 (5.4%)	4 (1.7%)	
Number of patients censored	226 (94.6%)	232 (98.3%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.2 [95.4, 99.3]	98.7 [96.1, 99.6]	
Month 6	95.6 [91.7, 97.7]	98.2 [95.1, 99.3]	
Month 9	94.3 [89.9, 96.8]	NC [NC, NC]	
Month 12	92.3 [86.8, 95.6]	NC [NC, NC]	
Month 18	92.3 [86.8, 95.6]	NC [NC, NC]	
Month 24	92.3 [86.8, 95.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.866 [0.563, 6.183]
Log-rank test			
Two-sided unstratified log-rank p-value			0.2997

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.108.1.1: Summary and Results of TEAEs - Dyspnoea (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	29 (12.1%)	24 (10.2%)	
Number of patients censored	210 (87.9%)	212 (89.8%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	92.4 [88.2, 95.1]	91.2 [86.7, 94.2]	
Month 6	90.2 [85.4, 93.5]	89.1 [84.1, 92.6]	
Month 9	88.4 [83.2, 92.0]	NC [NC, NC]	
Month 12	88.4 [83.2, 92.0]	NC [NC, NC]	
Month 18	80.9 [71.1, 87.6]	NC [NC, NC]	
Month 24	80.9 [71.1, 87.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.820 [0.455, 1.479]
Log-rank test			
Two-sided unstratified log-rank p-value			0.5089

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.109.1.1: Summary and Results of TEAEs - Epistaxis (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	6 (2.5%)	19 (8.1%)	
Number of patients censored	233 (97.5%)	217 (91.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.7 [96.1, 99.6]	93.9 [89.9, 96.3]	
Month 6	97.7 [94.6, 99.0]	91.3 [86.7, 94.4]	
Month 9	97.7 [94.6, 99.0]	NC [NC, NC]	
Month 12	97.7 [94.6, 99.0]	NC [NC, NC]	
Month 18	96.4 [91.2, 98.5]	NC [NC, NC]	
Month 24	96.4 [91.2, 98.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.237 [0.088, 0.636]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0019

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.109.1.2: Summary and Results of TEAEs by Subgroups - Epistaxis (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	1 (2.1)	NC [NC, NC]	47	2 (4.3)	NC [NC, NC]	0.000 [0.000, NC]	0.1550	0.6261
Absent	192	5 (2.6)	NC [NC, NC]	189	17 (9.0)	NC [NC, NC]	0.259 [0.095, 0.706]	0.0045	
Age									
< 65 years	105	1 (1.0)	NC [NC, NC]	102	10 (9.8)	NC [NC, NC]	0.000 [0.000, NC]	0.0010	0.1207
>= 65 years	134	5 (3.7)	NC [NC, NC]	134	9 (6.7)	NC [NC, NC]	0.496 [0.165, 1.491]	0.2032	
Region									
Europe	97	3 (3.1)	NC [NC, NC]	101	10 (9.9)	NC [NC, NC]	0.182 [0.040, 0.836]	0.0140	NC
North America	57	3 (5.3)	NC [NC, NC]	51	8 (15.7)	NC [NC, NC]	0.315 [0.083, 1.187]	0.0716	
Rest of World	85	0 (0.0)	NC [NC, NC]	84	1 (1.2)	NC [NC, NC]	NC [NC, NC]	0.3144	
Sex									
Male	197	3 (1.5)	NC [NC, NC]	181	14 (7.7)	NC [NC, NC]	0.174 [0.050, 0.608]	0.0020	0.1341
Female	42	3 (7.1)	NC [NC, NC]	55	5 (9.1)	NC [NC, NC]	0.530 [0.103, 2.731]	0.4399	
Metastases at Baseline									
Visceral metastases	169	4 (2.4)	NC [NC, NC]	157	12 (7.6)	NC [NC, NC]	0.225 [0.063, 0.797]	0.0114	0.9564
Lymph node only	60	2 (3.3)	NC [NC, NC]	65	7 (10.8)	NC [NC, NC]	0.255 [0.052, 1.239]	0.0682	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.110.1.1: Summary and Results of TEAEs - Hiccups (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	7 (2.9%)	22 (9.3%)	
Number of patients censored	232 (97.1%)	214 (90.7%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.3 [95.5, 99.3]	90.7 [86.2, 93.8]	
Month 6	97.2 [93.9, 98.8]	90.7 [86.2, 93.8]	
Month 9	96.6 [92.8, 98.4]	NC [NC, NC]	
Month 12	96.6 [92.8, 98.4]	NC [NC, NC]	
Month 18	96.6 [92.8, 98.4]	NC [NC, NC]	
Month 24	96.6 [92.8, 98.4]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.236 [0.094, 0.588]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0008

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.110.1.2: Summary and Results of TEAEs by Subgroups - Hiccups (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	1 (2.1)	NC [NC, NC]	47	4 (8.5)	NC [NC, NC]	0.241 [0.027, 2.155]	0.1670	0.8588
Absent	192	6 (3.1)	NC [NC, NC]	189	18 (9.5)	NC [NC, NC]	0.235 [0.086, 0.643]	0.0023	
Age									
< 65 years	105	2 (1.9)	NC [NC, NC]	102	11 (10.8)	NC [NC, NC]	0.166 [0.037, 0.750]	0.0079	0.3076
>= 65 years	134	5 (3.7)	NC [NC, NC]	134	11 (8.2)	NC [NC, NC]	0.303 [0.094, 0.976]	0.0355	
Region									
Europe	97	3 (3.1)	NC [NC, NC]	101	2 (2.0)	NC [NC, NC]	0.691 [0.086, 5.539]	0.7271	0.1169
North America	57	2 (3.5)	NC [NC, NC]	51	10 (19.6)	NC [NC, NC]	0.160 [0.035, 0.732]	0.0070	
Rest of World	85	2 (2.4)	NC [NC, NC]	84	10 (11.9)	NC [NC, NC]	0.186 [0.041, 0.847]	0.0149	
Sex									
Male	197	7 (3.6)	NC [NC, NC]	181	22 (12.2)	NC [NC, NC]	0.214 [0.086, 0.536]	0.0003	NC
Female	42	0 (0.0)	NC [NC, NC]	55	0 (0.0)	NC [NC, NC]	NC [NC, NC]	NC	
Metastases at Baseline									
Visceral metastases	169	5 (3.0)	NC [NC, NC]	157	13 (8.3)	NC [NC, NC]	0.304 [0.106, 0.870]	0.0194	0.3891
Lymph node only	60	1 (1.7)	NC [NC, NC]	65	8 (12.3)	NC [NC, NC]	0.000 [0.000, NC]	0.0052	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.111.1.1: Summary and Results of TEAEs - Nasal congestion (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	9 (3.8%)	1 (0.4%)	
Number of patients censored	230 (96.2%)	235 (99.6%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.7 [96.1, 99.6]	99.5 [96.8, 99.9]	
Month 6	98.1 [95.1, 99.3]	99.5 [96.8, 99.9]	
Month 9	97.4 [93.8, 98.9]	NC [NC, NC]	
Month 12	95.7 [90.9, 98.0]	NC [NC, NC]	
Month 18	94.4 [88.6, 97.3]	NC [NC, NC]	
Month 24	91.4 [80.9, 96.3]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			3.006 [0.315, 28.698]
Log-rank test			
Two-sided unstratified log-rank p-value			0.3155

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.112.1.1: Summary and Results of TEAEs - Pneumonitis (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	17 (7.1%)	1 (0.4%)	
Number of patients censored	222 (92.9%)	235 (99.6%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.2 [95.3, 99.3]	99.5 [96.8, 99.9]	
Month 6	93.6 [89.2, 96.2]	99.5 [96.8, 99.9]	
Month 9	91.5 [86.5, 94.8]	NC [NC, NC]	
Month 12	90.8 [85.4, 94.2]	NC [NC, NC]	
Month 18	90.8 [85.4, 94.2]	NC [NC, NC]	
Month 24	90.8 [85.4, 94.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			10.288 [1.334, 79.335]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0057

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.112.1.2: Summary and Results of TEAEs by Subgroups - Pneumonitis (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	2 (4.3)	NC [NC, NC]	47	1 (2.1)	NC [NC, NC]	1.676 [0.148, 19.040]	0.6738	NC
Absent	192	15 (7.8)	NC [NC, NC]	189	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0034	
Age									
< 65 years	105	7 (6.7)	NC [NC, NC]	102	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0549	NC
>= 65 years	134	10 (7.5)	NC [NC, NC]	134	1 (0.7)	NC [NC, NC]	6.637 [0.826, 53.358]	0.0408	
Region									
Europe	97	1 (1.0)	NC [NC, NC]	101	1 (1.0)	NC [NC, NC]	0.000 [0.000, NC]	0.3334	NC
North America	57	3 (5.3)	NC [NC, NC]	51	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.2030	
Rest of World	85	13 (15.3)	NC [NC, NC]	84	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0039	
Sex									
Male	197	15 (7.6)	NC [NC, NC]	181	1 (0.6)	NC [NC, NC]	7.844 [1.000, 61.504]	0.0206	NC
Female	42	2 (4.8)	NC [NC, NC]	55	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1220	
Metastases at Baseline									
Visceral metastases	169	14 (8.3)	NC [NC, NC]	157	1 (0.6)	NC [NC, NC]	9.401 [1.212, 72.890]	0.0090	NC
Lymph node only	60	2 (3.3)	NC [NC, NC]	65	0 (0.0)	NC [NC, NC]	NC [NC, NC]	NC	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.113.1.1: Summary and Results of TEAEs - Pulmonary embolism (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	8 (3.3%)	15 (6.4%)	
Number of patients censored	231 (96.7%)	221 (93.6%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.3 [95.5, 99.3]	94.6 [90.7, 96.9]	
Month 6	97.2 [93.9, 98.7]	92.8 [88.3, 95.6]	
Month 9	96.6 [93.0, 98.4]	NC [NC, NC]	
Month 12	96.6 [93.0, 98.4]	NC [NC, NC]	
Month 18	96.6 [93.0, 98.4]	NC [NC, NC]	
Month 24	92.2 [77.0, 97.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.379 [0.148, 0.971]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0359

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.113.1.2: Summary and Results of TEAEs by Subgroups - Pulmonary embolism (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	1 (2.1)	NC [21.0, NC]	47	3 (6.4)	NC [NC, NC]	0.000 [0.000, NC]	0.0870	0.7369
Absent	192	7 (3.6)	NC [NC, NC]	189	12 (6.3)	NC [NC, NC]	0.467 [0.176, 1.235]	0.1163	
Age									
< 65 years	105	3 (2.9)	NC [21.0, NC]	102	10 (9.8)	NC [NC, NC]	0.183 [0.040, 0.837]	0.0139	0.1848
>= 65 years	134	5 (3.7)	NC [NC, NC]	134	5 (3.7)	NC [NC, NC]	0.779 [0.210, 2.891]	0.7086	
Region									
Europe	97	2 (2.1)	NC [NC, NC]	101	7 (6.9)	NC [NC, NC]	0.284 [0.059, 1.369]	0.0942	0.6220
North America	57	4 (7.0)	NC [21.0, NC]	51	6 (11.8)	NC [NC, NC]	0.301 [0.061, 1.490]	0.1187	
Rest of World	85	2 (2.4)	NC [NC, NC]	84	2 (2.4)	NC [NC, NC]	0.912 [0.128, 6.482]	0.9270	
Sex									
Male	197	7 (3.6)	NC [NC, NC]	181	14 (7.7)	NC [NC, NC]	0.311 [0.113, 0.860]	0.0174	0.4356
Female	42	1 (2.4)	NC [NC, NC]	55	1 (1.8)	NC [NC, NC]	1.210 [0.076, 19.384]	0.8928	
Metastases at Baseline									
Visceral metastases	169	6 (3.6)	NC [NC, NC]	157	9 (5.7)	NC [NC, NC]	0.396 [0.122, 1.277]	0.1082	0.7024
Lymph node only	60	2 (3.3)	NC [NC, NC]	65	5 (7.7)	NC [NC, NC]	0.417 [0.081, 2.151]	0.2808	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.114.1.1: Summary and Results of TEAEs - Rhinorrhoea (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	8 (3.3%)	6 (2.5%)	
Number of patients censored	231 (96.7%)	230 (97.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.7 [96.0, 99.6]	97.8 [94.8, 99.1]	
Month 6	97.2 [93.9, 98.7]	97.3 [94.1, 98.8]	
Month 9	95.8 [91.7, 97.9]	NC [NC, NC]	
Month 12	95.8 [91.7, 97.9]	NC [NC, NC]	
Month 18	95.8 [91.7, 97.9]	NC [NC, NC]	
Month 24	95.8 [91.7, 97.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.944 [0.304, 2.929]
Log-rank test			
Two-sided unstratified log-rank p-value			0.9204

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.115.1.1: Summary and Results of TEAEs - Skin and subcutaneous tissue disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	204 (85.4%)	61 (25.8%)	
Number of patients censored	35 (14.6%)	175 (74.2%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	19.6 [14.7, 25.1]	76.2 [70.2, 81.2]	
Month 6	14.1 [9.6, 19.3]	72.8 [66.3, 78.2]	
Month 9	8.9 [5.1, 14.1]	NC [NC, NC]	
Month 12	7.6 [3.9, 12.9]	NC [NC, NC]	
Month 18	7.6 [3.9, 12.9]	NC [NC, NC]	
Month 24	NC [NC, NC]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	0.5 [0.4, 0.6]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			5.896 [4.404, 7.894]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.115.1.2: Summary and Results of TEAEs by Subgroups - Skin and subcutaneous tissue disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	37 (78.7)	0.6 [0.4, 2.0]	47	9 (19.1)	NC [NC, NC]	7.093 [3.391, 14.836]	<.0001	0.6084
Absent	192	167 (87.0)	0.5 [0.4, 0.6]	189	52 (27.5)	NC [NC, NC]	5.717 [4.159, 7.860]	<.0001	
Age									
< 65 years	105	89 (84.8)	0.5 [0.5, 0.8]	102	22 (21.6)	NC [NC, NC]	7.253 [4.505, 11.676]	<.0001	0.3760
>= 65 years	134	115 (85.8)	0.5 [0.4, 0.6]	134	39 (29.1)	NC [NC, NC]	5.154 [3.558, 7.465]	<.0001	
Region									
Europe	97	75 (77.3)	0.7 [0.5, 2.1]	101	21 (20.8)	NC [NC, NC]	5.437 [3.323, 8.895]	<.0001	0.1775
North America	57	49 (86.0)	0.5 [0.4, 0.7]	51	19 (37.3)	NC [3.4, NC]	4.474 [2.587, 7.738]	<.0001	
Rest of World	85	80 (94.1)	0.4 [0.3, 0.5]	84	21 (25.0)	NC [NC, NC]	8.422 [5.143, 13.791]	<.0001	
Sex									
Male	197	170 (86.3)	0.5 [0.5, 0.7]	181	43 (23.8)	NC [NC, NC]	6.592 [4.688, 9.270]	<.0001	0.4184
Female	42	34 (81.0)	0.4 [0.3, 0.5]	55	18 (32.7)	NC [NC, NC]	4.351 [2.417, 7.834]	<.0001	
Metastases at Baseline									
Visceral metastases	169	141 (83.4)	0.5 [0.5, 0.7]	157	45 (28.7)	NC [NC, NC]	5.142 [3.653, 7.236]	<.0001	0.2348
Lymph node only	60	53 (88.3)	0.4 [0.3, 0.7]	65	15 (23.1)	NC [NC, NC]	6.757 [3.762, 12.134]	<.0001	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.116.1.1: Summary and Results of TEAEs - Alopecia (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	91 (38.1%)	22 (9.3%)	
Number of patients censored	148 (61.9%)	214 (90.7%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	66.5 [60.1, 72.2]	91.2 [86.7, 94.3]	
Month 6	62.4 [55.7, 68.4]	90.1 [85.3, 93.4]	
Month 9	59.8 [52.9, 66.0]	NC [NC, NC]	
Month 12	58.9 [51.8, 65.2]	NC [NC, NC]	
Month 18	58.9 [51.8, 65.2]	NC [NC, NC]	
Month 24	58.9 [51.8, 65.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			4.418 [2.764, 7.062]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.116.1.2: Summary and Results of TEAEs by Subgroups - Alopecia (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	14 (29.8)	NC [NC, NC]	47	5 (10.6)	NC [NC, NC]	3.152 [1.134, 8.763]	0.0206	0.4185
Absent	192	77 (40.1)	NC [9.9, NC]	189	17 (9.0)	NC [NC, NC]	4.785 [2.818, 8.124]	<.0001	
Age									
< 65 years	105	38 (36.2)	NC [9.9, NC]	102	11 (10.8)	NC [NC, NC]	3.379 [1.712, 6.667]	0.0002	0.3891
>= 65 years	134	53 (39.6)	NC [6.2, NC]	134	11 (8.2)	NC [NC, NC]	5.472 [2.851, 10.503]	<.0001	
Region									
Europe	97	28 (28.9)	NC [NC, NC]	101	6 (5.9)	NC [NC, NC]	4.815 [1.974, 11.741]	0.0001	0.3426
North America	57	28 (49.1)	5.5 [2.4, NC]	51	4 (7.8)	NC [NC, NC]	7.596 [2.653, 21.745]	<.0001	
Rest of World	85	35 (41.2)	NC [4.3, NC]	84	12 (14.3)	NC [NC, NC]	3.123 [1.613, 6.046]	0.0004	
Sex									
Male	197	67 (34.0)	NC [NC, NC]	181	12 (6.6)	NC [NC, NC]	5.442 [2.932, 10.099]	<.0001	0.4210
Female	42	24 (57.1)	2.1 [1.3, NC]	55	10 (18.2)	NC [NC, NC]	3.771 [1.791, 7.937]	0.0002	
Metastases at Baseline									
Visceral metastases	169	59 (34.9)	NC [NC, NC]	157	19 (12.1)	NC [NC, NC]	3.029 [1.798, 5.103]	<.0001	0.0692
Lymph node only	60	26 (43.3)	NC [3.0, NC]	65	3 (4.6)	NC [NC, NC]	10.423 [3.136, 34.640]	<.0001	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.117.1.1: Summary and Results of TEAEs - Blister (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	10 (4.2%)	0 (0.0%)	
Number of patients censored	229 (95.8%)	236 (100.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.2 [95.3, 99.3]	100.0 [100.0, 100.0]	
Month 6	96.5 [92.8, 98.3]	100.0 [100.0, 100.0]	
Month 9	95.3 [91.1, 97.5]	NC [NC, NC]	
Month 12	95.3 [91.1, 97.5]	NC [NC, NC]	
Month 18	95.3 [91.1, 97.5]	NC [NC, NC]	
Month 24	88.5 [66.2, 96.4]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			NC [NC, NC]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0436

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.117.1.2: Summary and Results of TEAEs by Subgroups - Blister (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	3 (6.4)		47	0 (0.0)				
Absent	192	7 (3.6)		189	0 (0.0)				
Age									
< 65 years	105	6 (5.7)		102	0 (0.0)				
>= 65 years	134	4 (3.0)		134	0 (0.0)				
Region									
Europe	97	4 (4.1)		101	0 (0.0)				
North America	57	2 (3.5)		51	0 (0.0)				
Rest of World	85	4 (4.7)		84	0 (0.0)				
Sex									
Male	197	10 (5.1)	NC [NC, NC]	181	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0526	NC
Female	42	0 (0.0)	NC [NC, NC]	55	0 (0.0)	NC [NC, NC]	NC [NC, NC]	NC	
Metastases at Baseline									
Visceral metastases	169	6 (3.6)		157	0 (0.0)				
Lymph node only	60	3 (5.0)		65	0 (0.0)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.118.1.1: Summary and Results of TEAEs - Dermatitis (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	13 (5.4%)	0 (0.0%)	
Number of patients censored	226 (94.6%)	236 (100.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.1 [92.6, 97.9]	100.0 [100.0, 100.0]	
Month 6	95.5 [91.8, 97.6]	100.0 [100.0, 100.0]	
Month 9	94.2 [89.9, 96.7]	NC [NC, NC]	
Month 12	94.2 [89.9, 96.7]	NC [NC, NC]	
Month 18	92.5 [86.4, 95.9]	NC [NC, NC]	
Month 24	92.5 [86.4, 95.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			NC [NC, NC]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0026

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.118.1.2: Summary and Results of TEAEs by Subgroups - Dermatitis (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	0 (0.0)	NC [NC, NC]	47	0 (0.0)	NC [NC, NC]	NC [NC, NC]	NC	NC
Absent	192	13 (6.8)	NC [NC, NC]	189	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0027	
Age									
< 65 years	105	5 (4.8)		102	0 (0.0)				
>= 65 years	134	8 (6.0)		134	0 (0.0)				
Region									
Europe	97	5 (5.2)		101	0 (0.0)				
North America	57	2 (3.5)		51	0 (0.0)				
Rest of World	85	6 (7.1)		84	0 (0.0)				
Sex									
Male	197	9 (4.6)		181	0 (0.0)				
Female	42	4 (9.5)		55	0 (0.0)				
Metastases at Baseline									
Visceral metastases	169	8 (4.7)		157	0 (0.0)				
Lymph node only	60	5 (8.3)		65	0 (0.0)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.119.1.1: Summary and Results of TEAEs - Dermatitis bullous (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	14 (5.9%)	0 (0.0%)	
Number of patients censored	225 (94.1%)	236 (100.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.9 [93.7, 98.5]	100.0 [100.0, 100.0]	
Month 6	94.3 [90.1, 96.7]	100.0 [100.0, 100.0]	
Month 9	93.6 [89.2, 96.3]	NC [NC, NC]	
Month 12	93.6 [89.2, 96.3]	NC [NC, NC]	
Month 18	92.4 [87.1, 95.6]	NC [NC, NC]	
Month 24	92.4 [87.1, 95.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			NC [NC, NC]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0017

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
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Table 302.1.2002.119.1.2: Summary and Results of TEAEs by Subgroups - Dermatitis bullous (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	3 (6.4)	NC [NC, NC]	47	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1420	NC
Absent	192	11 (5.7)	NC [NC, NC]	189	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0053	
Age									
< 65 years	105	6 (5.7)		102	0 (0.0)				
>= 65 years	134	8 (6.0)		134	0 (0.0)				
Region									
Europe	97	5 (5.2)		101	0 (0.0)				
North America	57	4 (7.0)		51	0 (0.0)				
Rest of World	85	5 (5.9)		84	0 (0.0)				
Sex									
Male	197	13 (6.6)	NC [NC, NC]	181	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0039	NC
Female	42	1 (2.4)	NC [NC, NC]	55	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.2689	
Metastases at Baseline									
Visceral metastases	169	9 (5.3)		157	0 (0.0)				
Lymph node only	60	5 (8.3)		65	0 (0.0)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.120.1.1: Summary and Results of TEAEs - Dry skin (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	39 (16.3%)	4 (1.7%)	
Number of patients censored	200 (83.7%)	232 (98.3%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	90.1 [85.5, 93.3]	99.1 [96.5, 99.8]	
Month 6	84.4 [78.8, 88.6]	98.0 [94.8, 99.3]	
Month 9	81.6 [75.4, 86.4]	NC [NC, NC]	
Month 12	80.5 [74.0, 85.6]	NC [NC, NC]	
Month 18	80.5 [74.0, 85.6]	NC [NC, NC]	
Month 24	80.5 [74.0, 85.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			8.382 [2.970, 23.654]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
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Table 302.1.2002.120.1.2: Summary and Results of TEAEs by Subgroups - Dry skin (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	5 (10.6)	NC [NC, NC]	47	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0807	NC
Absent	192	34 (17.7)	NC [NC, NC]	189	4 (2.1)	NC [NC, NC]	7.537 [2.655, 21.392]	<.0001	
Age									
< 65 years	105	14 (13.3)	NC [NC, NC]	102	1 (1.0)	NC [NC, NC]	12.122 [1.580, 93.004]	0.0022	0.7037
>= 65 years	134	25 (18.7)	NC [NC, NC]	134	3 (2.2)	NC [NC, NC]	7.151 [2.131, 23.999]	0.0002	
Region									
Europe	97	15 (15.5)	NC [NC, NC]	101	1 (1.0)	NC [NC, NC]	13.720 [1.793, 104.98]	0.0010	0.8032
North America	57	15 (26.3)	NC [NC, NC]	51	2 (3.9)	NC [NC, NC]	6.092 [1.374, 27.010]	0.0066	
Rest of World	85	9 (10.6)	NC [NC, NC]	84	1 (1.2)	NC [NC, NC]	7.352 [0.912, 59.250]	0.0284	
Sex									
Male	197	35 (17.8)	NC [NC, NC]	181	4 (2.2)	NC [NC, NC]	7.079 [2.492, 20.105]	<.0001	NC
Female	42	4 (9.5)	NC [NC, NC]	55	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0458	
Metastases at Baseline									
Visceral metastases	169	28 (16.6)	NC [NC, NC]	157	2 (1.3)	NC [NC, NC]	11.554 [2.731, 48.873]	<.0001	0.2787
Lymph node only	60	8 (13.3)	NC [NC, NC]	65	2 (3.1)	NC [NC, NC]	3.834 [0.796, 18.457]	0.0713	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.121.1.1: Summary and Results of TEAEs - Eczema (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	12 (5.0%)	2 (0.8%)	
Number of patients censored	227 (95.0%)	234 (99.2%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.2 [92.8, 98.0]	99.1 [96.6, 99.8]	
Month 6	95.2 [91.4, 97.3]	99.1 [96.6, 99.8]	
Month 9	94.5 [90.5, 96.9]	NC [NC, NC]	
Month 12	94.5 [90.5, 96.9]	NC [NC, NC]	
Month 18	94.5 [90.5, 96.9]	NC [NC, NC]	
Month 24	94.5 [90.5, 96.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			5.436 [1.205, 24.519]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0133

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.121.1.2: Summary and Results of TEAEs by Subgroups - Eczema (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	3 (6.4)	NC [NC, NC]	47	1 (2.1)	NC [NC, NC]	3.049 [0.317, 29.317]	0.3095	0.5067
Absent	192	9 (4.7)	NC [NC, NC]	189	1 (0.5)	NC [NC, NC]	7.892 [0.987, 63.092]	0.0208	
Age									
< 65 years	105	6 (5.7)		102	0 (0.0)				
>= 65 years	134	6 (4.5)		134	2 (1.5)				
Region									
Europe	97	3 (3.1)		101	0 (0.0)				
North America	57	1 (1.8)		51	1 (2.0)				
Rest of World	85	8 (9.4)		84	1 (1.2)				
Sex									
Male	197	8 (4.1)	NC [NC, NC]	181	2 (1.1)	NC [NC, NC]	3.162 [0.657, 15.223]	0.1295	NC
Female	42	4 (9.5)	NC [NC, NC]	55	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0197	
Metastases at Baseline									
Visceral metastases	169	8 (4.7)	NC [NC, NC]	157	2 (1.3)	NC [NC, NC]	3.209 [0.666, 15.451]	0.1241	NC
Lymph node only	60	4 (6.7)	NC [NC, NC]	65	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0350	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
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Table 302.1.2002.122.1.1: Summary and Results of TEAEs - Erythema (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	12 (5.0%)	3 (1.3%)	
Number of patients censored	227 (95.0%)	233 (98.7%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	95.8 [92.3, 97.7]	98.7 [96.1, 99.6]	
Month 6	95.8 [92.3, 97.7]	98.7 [96.1, 99.6]	
Month 9	94.5 [90.5, 96.9]	NC [NC, NC]	
Month 12	94.5 [90.5, 96.9]	NC [NC, NC]	
Month 18	94.5 [90.5, 96.9]	NC [NC, NC]	
Month 24	94.5 [90.5, 96.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			3.332 [0.918, 12.100]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0522

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
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Table 302.1.2002.123.1.1: Summary and Results of TEAEs - Hyperhidrosis (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	7 (2.9%)	4 (1.7%)	
Number of patients censored	232 (97.1%)	232 (98.3%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.8 [94.8, 99.1]	98.3 [95.5, 99.4]	
Month 6	97.3 [94.1, 98.8]	98.3 [95.5, 99.4]	
Month 9	96.7 [93.2, 98.4]	NC [NC, NC]	
Month 12	96.7 [93.2, 98.4]	NC [NC, NC]	
Month 18	96.7 [93.2, 98.4]	NC [NC, NC]	
Month 24	96.7 [93.2, 98.4]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.478 [0.418, 5.229]
Log-rank test			
Two-sided unstratified log-rank p-value			0.5419

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
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Table 302.1.2002.124.1.1: Summary and Results of TEAEs - Pruritus (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	105 (43.9%)	13 (5.5%)	
Number of patients censored	134 (56.1%)	223 (94.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	60.3 [53.7, 66.3]	96.2 [92.7, 98.0]	
Month 6	58.1 [51.4, 64.3]	93.9 [89.6, 96.4]	
Month 9	54.2 [47.2, 60.6]	NC [NC, NC]	
Month 12	52.2 [44.9, 58.9]	NC [NC, NC]	
Month 18	52.2 [44.9, 58.9]	NC [NC, NC]	
Month 24	52.2 [44.9, 58.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [7.2, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			9.225 [5.167, 16.472]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
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Table 302.1.2002.124.1.2: Summary and Results of TEAEs by Subgroups - Pruritus (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	17 (36.2)	NC [7.2, NC]	47	1 (2.1)	NC [NC, NC]	16.668 [2.191, 126.83]	0.0002	0.4379
Absent	192	88 (45.8)	NC [4.1, NC]	189	12 (6.3)	NC [NC, NC]	8.613 [4.697, 15.793]	<.0001	
Age									
< 65 years	105	48 (45.7)	NC [2.8, NC]	102	7 (6.9)	NC [NC, NC]	8.422 [3.799, 18.672]	<.0001	0.6102
>= 65 years	134	57 (42.5)	NC [6.8, NC]	134	6 (4.5)	NC [NC, NC]	10.171 [4.359, 23.734]	<.0001	
Region									
Europe	97	41 (42.3)	NC [3.1, NC]	101	3 (3.0)	NC [NC, NC]	16.653 [5.137, 53.986]	<.0001	0.4635
North America	57	23 (40.4)	NC [2.1, NC]	51	3 (5.9)	NC [NC, NC]	8.148 [2.435, 27.268]	<.0001	
Rest of World	85	41 (48.2)	10.4 [2.8, NC]	84	7 (8.3)	NC [NC, NC]	6.466 [2.876, 14.536]	<.0001	
Sex									
Male	197	90 (45.7)	NC [4.1, NC]	181	10 (5.5)	NC [NC, NC]	9.713 [5.037, 18.730]	<.0001	0.7269
Female	42	15 (35.7)	NC [6.2, NC]	55	3 (5.5)	NC [NC, NC]	6.809 [1.940, 23.896]	0.0005	
Metastases at Baseline									
Visceral metastases	169	71 (42.0)	NC [7.2, NC]	157	11 (7.0)	NC [NC, NC]	6.833 [3.605, 12.952]	<.0001	0.0902
Lymph node only	60	30 (50.0)	7.7 [1.2, NC]	65	1 (1.5)	NC [NC, NC]	40.402 [5.492, 297.23]	<.0001	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.125.1.1: Summary and Results of TEAEs - Rash erythematous (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	12 (5.0%)	2 (0.8%)	
Number of patients censored	227 (95.0%)	234 (99.2%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	95.8 [92.3, 97.7]	99.2 [96.7, 99.8]	
Month 6	94.8 [90.9, 97.0]	99.2 [96.7, 99.8]	
Month 9	94.8 [90.9, 97.0]	NC [NC, NC]	
Month 12	94.8 [90.9, 97.0]	NC [NC, NC]	
Month 18	94.8 [90.9, 97.0]	NC [NC, NC]	
Month 24	94.8 [90.9, 97.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			5.939 [1.330, 26.532]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0079

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.125.1.2: Summary and Results of TEAEs by Subgroups - Rash erythematous (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	2 (4.3)	NC [NC, NC]	47	1 (2.1)	NC [NC, NC]	2.034 [0.184, 22.445]	0.5537	0.3226
Absent	192	10 (5.2)	NC [NC, NC]	189	1 (0.5)	NC [NC, NC]	9.831 [1.258, 76.809]	0.0073	
Age									
< 65 years	105	8 (7.6)		102	0 (0.0)				
>= 65 years	134	4 (3.0)		134	2 (1.5)				
Region									
Europe	97	5 (5.2)		101	2 (2.0)				
North America	57	2 (3.5)		51	0 (0.0)				
Rest of World	85	5 (5.9)		84	0 (0.0)				
Sex									
Male	197	11 (5.6)	NC [NC, NC]	181	2 (1.1)	NC [NC, NC]	5.051 [1.120, 22.784]	0.0190	NC
Female	42	1 (2.4)	NC [NC, NC]	55	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.2525	
Metastases at Baseline									
Visceral metastases	169	7 (4.1)		157	1 (0.6)				
Lymph node only	60	3 (5.0)		65	1 (1.5)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.126.1.1: Summary and Results of TEAEs - Rash macular (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	27 (11.3%)	2 (0.8%)	
Number of patients censored	212 (88.7%)	234 (99.2%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	92.0 [87.8, 94.8]	99.1 [96.6, 99.8]	
Month 6	90.4 [85.8, 93.6]	99.1 [96.6, 99.8]	
Month 9	89.8 [84.9, 93.1]	NC [NC, NC]	
Month 12	88.8 [83.6, 92.5]	NC [NC, NC]	
Month 18	83.5 [74.8, 89.5]	NC [NC, NC]	
Month 24	83.5 [74.8, 89.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			10.497 [2.460, 44.790]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.126.1.2: Summary and Results of TEAEs by Subgroups - Rash macular (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	5 (10.6)	NC [NC, NC]	47	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0223	NC
Absent	192	22 (11.5)	NC [NC, NC]	189	2 (1.1)	NC [NC, NC]	7.843 [1.802, 34.140]	0.0012	
Age									
< 65 years	105	14 (13.3)	NC [NC, NC]	102	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0009	NC
>= 65 years	134	13 (9.7)	NC [NC, NC]	134	2 (1.5)	NC [NC, NC]	4.946 [1.082, 22.611]	0.0225	
Region									
Europe	97	13 (13.4)	NC [NC, NC]	101	1 (1.0)	NC [NC, NC]	10.422 [1.332, 81.560]	0.0055	NC
North America	57	6 (10.5)	NC [15.3, NC]	51	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0551	
Rest of World	85	8 (9.4)	NC [NC, NC]	84	1 (1.2)	NC [NC, NC]	7.077 [0.871, 57.524]	0.0327	
Sex									
Male	197	23 (11.7)	NC [NC, NC]	181	1 (0.6)	NC [NC, NC]	15.613 [2.078, 117.32]	0.0003	0.3812
Female	42	4 (9.5)	NC [NC, NC]	55	1 (1.8)	NC [NC, NC]	5.536 [0.619, 49.546]	0.0847	
Metastases at Baseline									
Visceral metastases	169	22 (13.0)	NC [NC, NC]	157	2 (1.3)	NC [NC, NC]	8.257 [1.909, 35.722]	0.0007	NC
Lymph node only	60	5 (8.3)	NC [NC, NC]	65	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0530	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.127.1.1: Summary and Results of TEAEs - Rash maculo-papular (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	76 (31.8%)	9 (3.8%)	
Number of patients censored	163 (68.2%)	227 (96.2%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	77.0 [71.1, 81.9]	96.6 [93.3, 98.3]	
Month 6	70.5 [63.9, 76.1]	96.1 [92.6, 97.9]	
Month 9	67.1 [60.2, 73.1]	NC [NC, NC]	
Month 12	65.3 [58.1, 71.6]	NC [NC, NC]	
Month 18	62.5 [54.5, 69.5]	NC [NC, NC]	
Month 24	59.0 [48.7, 68.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [20.6, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			7.420 [3.688, 14.930]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.127.1.2: Summary and Results of TEAEs by Subgroups - Rash maculo-papular (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	16 (34.0)	NC [6.8, NC]	47	2 (4.3)	NC [NC, NC]	5.936 [1.321, 26.684]	0.0087	0.9958
Absent	192	60 (31.3)	NC [20.6, NC]	189	7 (3.7)	NC [NC, NC]	7.876 [3.575, 17.354]	<.0001	
Age									
< 65 years	105	29 (27.6)	NC [NC, NC]	102	4 (3.9)	NC [NC, NC]	5.367 [1.850, 15.571]	0.0006	0.5727
>= 65 years	134	47 (35.1)	NC [14.9, NC]	134	5 (3.7)	NC [NC, NC]	9.285 [3.664, 23.528]	<.0001	
Region									
Europe	97	17 (17.5)	NC [NC, NC]	101	3 (3.0)	NC [NC, NC]	4.208 [1.190, 14.883]	0.0155	0.5982
North America	57	30 (52.6)	5.2 [2.7, NC]	51	4 (7.8)	NC [NC, NC]	7.029 [2.453, 20.143]	<.0001	
Rest of World	85	29 (34.1)	NC [20.6, NC]	84	2 (2.4)	NC [NC, NC]	13.121 [3.099, 55.556]	<.0001	
Sex									
Male	197	60 (30.5)	NC [NC, NC]	181	6 (3.3)	NC [NC, NC]	8.312 [3.563, 19.390]	<.0001	0.7469
Female	42	16 (38.1)	20.6 [6.4, NC]	55	3 (5.5)	NC [NC, NC]	5.822 [1.648, 20.562]	0.0020	
Metastases at Baseline									
Visceral metastases	169	53 (31.4)	NC [20.6, NC]	157	5 (3.2)	NC [NC, NC]	8.378 [3.313, 21.185]	<.0001	0.3630
Lymph node only	60	19 (31.7)	NC [NC, NC]	65	4 (6.2)	NC [NC, NC]	5.076 [1.708, 15.084]	0.0011	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.128.1.1: Summary and Results of TEAEs - Rash papular (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	21 (8.8%)	1 (0.4%)	
Number of patients censored	218 (91.2%)	235 (99.6%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	95.3 [91.6, 97.4]	99.6 [97.0, 99.9]	
Month 6	94.2 [90.3, 96.6]	99.6 [97.0, 99.9]	
Month 9	90.8 [85.6, 94.2]	NC [NC, NC]	
Month 12	90.0 [84.5, 93.6]	NC [NC, NC]	
Month 18	86.6 [78.8, 91.7]	NC [NC, NC]	
Month 24	86.6 [78.8, 91.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			12.867 [1.683, 98.351]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0014

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.128.1.2: Summary and Results of TEAEs by Subgroups - Rash papular (PT) - Analysis Set mSAF 1

Subgroup	EV+Pembro N	EV+Pembro n (%)	EV+Pembro KME [95% CI](a)	Plat+Gem N	Plat+Gem n (%)	Plat+Gem KME [95% CI](a)	EV+Pembro vs. Plat+Gem HR [95% CI](b)	Log-rank p-value(c)	Test for Interaction p-value(d)
Liver Metastases									
Present	47	3 (6.4)	NC [NC, NC]	47	0 (0.0)	NC [NC, NC]	NC [NC, NC]	NC	NC
Absent	192	18 (9.4)	NC [NC, NC]	189	1 (0.5)	NC [NC, NC]	12.794 [1.674, 97.801]	0.0015	
Age									
< 65 years	105	11 (10.5)	NC [NC, NC]	102	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0093	NC
>= 65 years	134	10 (7.5)	NC [NC, NC]	134	1 (0.7)	NC [NC, NC]	6.055 [0.729, 50.272]	0.0572	
Region									
Europe	97	8 (8.2)	NC [NC, NC]	101	1 (1.0)	NC [NC, NC]	3.162 [0.329, 30.398]	0.2924	NC
North America	57	1 (1.8)	NC [NC, NC]	51	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.3442	
Rest of World	85	12 (14.1)	NC [NC, NC]	84	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0027	
Sex									
Male	197	16 (8.1)	NC [NC, NC]	181	1 (0.6)	NC [NC, NC]	8.157 [1.033, 64.396]	0.0175	NC
Female	42	5 (11.9)	NC [NC, NC]	55	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0200	
Metastases at Baseline									
Visceral metastases	169	14 (8.3)	NC [NC, NC]	157	1 (0.6)	NC [NC, NC]	7.377 [0.922, 58.998]	0.0269	NC
Lymph node only	60	6 (10.0)	NC [NC, NC]	65	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0352	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.129.1.1: Summary and Results of TEAEs - Skin hyperpigmentation (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	17 (7.1%)	0 (0.0%)	
Number of patients censored	222 (92.9%)	236 (100.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.8 [94.9, 99.1]	100.0 [100.0, 100.0]	
Month 6	96.3 [92.8, 98.2]	100.0 [100.0, 100.0]	
Month 9	93.8 [89.2, 96.4]	NC [NC, NC]	
Month 12	91.9 [86.3, 95.3]	NC [NC, NC]	
Month 18	86.0 [76.2, 91.9]	NC [NC, NC]	
Month 24	86.0 [76.2, 91.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			NC [NC, NC]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0054

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.129.1.2: Summary and Results of TEAEs by Subgroups - Skin hyperpigmentation (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	4 (8.5)	NC [NC, NC]	47	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.3010	NC
Absent	192	13 (6.8)	NC [NC, NC]	189	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0101	
Age									
< 65 years	105	9 (8.6)		102	0 (0.0)				
>= 65 years	134	8 (6.0)		134	0 (0.0)				
Region									
Europe	97	6 (6.2)		101	0 (0.0)				
North America	57	7 (12.3)		51	0 (0.0)				
Rest of World	85	4 (4.7)		84	0 (0.0)				
Sex									
Male	197	13 (6.6)	NC [NC, NC]	181	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0359	NC
Female	42	4 (9.5)	NC [NC, NC]	55	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0440	
Metastases at Baseline									
Visceral metastases	169	14 (8.3)	NC [NC, NC]	157	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0197	NC
Lymph node only	60	3 (5.0)	NC [NC, NC]	65	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1392	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.130.1.1: Summary and Results of TEAEs - Skin ulcer (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	9 (3.8%)	1 (0.4%)	
Number of patients censored	230 (96.2%)	235 (99.6%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.8 [94.7, 99.1]	99.6 [97.0, 99.9]	
Month 6	96.2 [92.6, 98.1]	99.6 [97.0, 99.9]	
Month 9	95.6 [91.7, 97.7]	NC [NC, NC]	
Month 12	95.6 [91.7, 97.7]	NC [NC, NC]	
Month 18	95.6 [91.7, 97.7]	NC [NC, NC]	
Month 24	95.6 [91.7, 97.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			7.243 [0.901, 58.195]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0296

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.130.1.2: Summary and Results of TEAEs by Subgroups - Skin ulcer (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	3 (6.4)		47	1 (2.1)				
Absent	192	6 (3.1)		189	0 (0.0)				
Age									
< 65 years	105	2 (1.9)		102	0 (0.0)				
>= 65 years	134	7 (5.2)		134	1 (0.7)				
Region									
Europe	97	3 (3.1)		101	0 (0.0)				
North America	57	3 (5.3)		51	1 (2.0)				
Rest of World	85	3 (3.5)		84	0 (0.0)				
Sex									
Male	197	9 (4.6)	NC [NC, NC]	181	1 (0.6)	NC [NC, NC]	6.702 [0.834, 53.837]	0.0387	NC
Female	42	0 (0.0)	NC [NC, NC]	55	0 (0.0)	NC [NC, NC]	NC [NC, NC]	NC	
Metastases at Baseline									
Visceral metastases	169	6 (3.6)		157	1 (0.6)				
Lymph node only	60	2 (3.3)		65	0 (0.0)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.131.1.1: Summary and Results of TEAEs - Vascular disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	38 (15.9%)	46 (19.5%)	
Number of patients censored	201 (84.1%)	190 (80.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	91.1 [86.7, 94.1]	82.4 [76.8, 86.8]	
Month 6	88.1 [83.0, 91.7]	79.2 [73.2, 84.0]	
Month 9	85.4 [79.8, 89.6]	NC [NC, NC]	
Month 12	81.7 [75.0, 86.8]	NC [NC, NC]	
Month 18	78.0 [70.1, 84.1]	NC [NC, NC]	
Month 24	78.0 [70.1, 84.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.531 [0.328, 0.858]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0085

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.131.1.2: Summary and Results of TEAEs by Subgroups - Vascular disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	8 (17.0)	NC [NC, NC]	47	7 (14.9)	NC [NC, NC]	0.881 [0.298, 2.604]	0.8188	0.3162
Absent	192	30 (15.6)	NC [NC, NC]	189	39 (20.6)	NC [NC, NC]	0.467 [0.272, 0.802]	0.0046	
Age									
< 65 years	105	14 (13.3)	NC [NC, NC]	102	17 (16.7)	NC [NC, NC]	0.504 [0.226, 1.123]	0.0868	0.8602
>= 65 years	134	24 (17.9)	NC [NC, NC]	134	29 (21.6)	NC [NC, NC]	0.546 [0.300, 0.994]	0.0444	
Region									
Europe	97	14 (14.4)	NC [NC, NC]	101	16 (15.8)	NC [NC, NC]	0.633 [0.287, 1.396]	0.2532	0.1822
North America	57	11 (19.3)	NC [14.1, NC]	51	19 (37.3)	NC [3.0, NC]	0.238 [0.095, 0.597]	0.0009	
Rest of World	85	13 (15.3)	NC [NC, NC]	84	11 (13.1)	NC [NC, NC]	0.898 [0.381, 2.116]	0.8050	
Sex									
Male	197	35 (17.8)	NC [NC, NC]	181	36 (19.9)	NC [NC, NC]	0.554 [0.328, 0.934]	0.0244	0.2305
Female	42	3 (7.1)	NC [NC, NC]	55	10 (18.2)	NC [NC, NC]	0.386 [0.106, 1.404]	0.1339	
Metastases at Baseline									
Visceral metastases	169	30 (17.8)	NC [NC, NC]	157	30 (19.1)	NC [NC, NC]	0.534 [0.298, 0.957]	0.0320	0.1610
Lymph node only	60	6 (10.0)	NC [NC, NC]	65	14 (21.5)	NC [NC, NC]	0.439 [0.168, 1.143]	0.0828	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.132.1.1: Summary and Results of TEAEs - Deep vein thrombosis (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	2 (0.8%)	8 (3.4%)	
Number of patients censored	237 (99.2%)	228 (96.6%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	100.0 [100.0, 100.0]	96.9 [93.5, 98.5]	
Month 6	99.5 [96.5, 99.9]	96.3 [92.8, 98.2]	
Month 9	99.5 [96.5, 99.9]	NC [NC, NC]	
Month 12	98.7 [94.5, 99.7]	NC [NC, NC]	
Month 18	98.7 [94.5, 99.7]	NC [NC, NC]	
Month 24	98.7 [94.5, 99.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.118 [0.015, 0.947]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0157

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.132.1.2: Summary and Results of TEAEs by Subgroups - Deep vein thrombosis (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	0 (0.0)		47	2 (4.3)				
Absent	192	2 (1.0)		189	6 (3.2)				
Age									
< 65 years	105	1 (1.0)		102	4 (3.9)				
>= 65 years	134	1 (0.7)		134	4 (3.0)				
Region									
Europe	97	0 (0.0)		101	1 (1.0)				
North America	57	1 (1.8)		51	2 (3.9)				
Rest of World	85	1 (1.2)		84	5 (6.0)				
Sex									
Male	197	2 (1.0)		181	5 (2.8)				
Female	42	0 (0.0)		55	3 (5.5)				
Metastases at Baseline									
Visceral metastases	169	1 (0.6)		157	5 (3.2)				
Lymph node only	60	0 (0.0)		65	3 (4.6)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.133.1.1: Summary and Results of TEAEs - Hypertension (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	13 (5.4%)	17 (7.2%)	
Number of patients censored	226 (94.6%)	219 (92.8%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.6 [93.3, 98.3]	94.2 [90.2, 96.6]	
Month 6	95.6 [92.0, 97.6]	92.0 [87.5, 95.0]	
Month 9	95.0 [91.0, 97.2]	NC [NC, NC]	
Month 12	93.9 [89.1, 96.6]	NC [NC, NC]	
Month 18	92.4 [86.3, 95.9]	NC [NC, NC]	
Month 24	92.4 [86.3, 95.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.565 [0.259, 1.234]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1464

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.134.1.1: Summary and Results of TEAEs - Hypotension (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	7 (2.9%)	6 (2.5%)	
Number of patients censored	232 (97.1%)	230 (97.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.3 [95.5, 99.3]	97.4 [94.2, 98.8]	
Month 6	97.7 [94.5, 99.0]	97.4 [94.2, 98.8]	
Month 9	97.1 [93.5, 98.7]	NC [NC, NC]	
Month 12	97.1 [93.5, 98.7]	NC [NC, NC]	
Month 18	95.8 [90.6, 98.1]	NC [NC, NC]	
Month 24	95.8 [90.6, 98.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.661 [0.189, 2.314]
Log-rank test			
Two-sided unstratified log-rank p-value			0.5139

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.135.1.1: Summary and Results of TESAEs - Blood and lymphatic system disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	5 (2.1%)	16 (6.8%)	
Number of patients censored	234 (97.9%)	220 (93.2%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.7 [96.1, 99.6]	94.6 [90.6, 96.9]	
Month 6	98.7 [96.1, 99.6]	91.5 [85.7, 95.0]	
Month 9	98.1 [94.9, 99.3]	NC [NC, NC]	
Month 12	97.1 [92.7, 98.9]	NC [NC, NC]	
Month 18	97.1 [92.7, 98.9]	NC [NC, NC]	
Month 24	97.1 [92.7, 98.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.159 [0.046, 0.551]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0009

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.135.1.2: Summary and Results of TESAEs by Subgroups - Blood and lymphatic system disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	1 (2.1)	NC [NC, NC]	47	0 (0.0)	NC [NC, NC]	NC [NC, NC]	NC	NC
Absent	192	4 (2.1)	NC [NC, NC]	189	16 (8.5)	NC [NC, NC]	0.155 [0.045, 0.539]	0.0008	
Age									
< 65 years	105	2 (1.9)	NC [NC, NC]	102	6 (5.9)	NC [NC, NC]	0.000 [0.000, NC]	0.0103	0.9296
>= 65 years	134	3 (2.2)	NC [NC, NC]	134	10 (7.5)	NC [NC, NC]	0.249 [0.068, 0.920]	0.0247	
Region									
Europe	97	1 (1.0)	NC [NC, NC]	101	4 (4.0)	NC [NC, NC]	0.191 [0.021, 1.761]	0.1059	NC
North America	57	0 (0.0)	NC [NC, NC]	51	1 (2.0)	NC [NC, NC]	NC [NC, NC]	0.2857	
Rest of World	85	4 (4.7)	NC [NC, NC]	84	11 (13.1)	NC [NC, NC]	0.164 [0.036, 0.740]	0.0073	
Sex									
Male	197	3 (1.5)	NC [NC, NC]	181	12 (6.6)	NC [NC, NC]	0.195 [0.055, 0.700]	0.0054	0.3428
Female	42	2 (4.8)	NC [NC, NC]	55	4 (7.3)	NC [NC, NC]	0.000 [0.000, NC]	0.0646	
Metastases at Baseline									
Visceral metastases	169	5 (3.0)	NC [NC, NC]	157	10 (6.4)	NC [NC, NC]	0.239 [0.065, 0.880]	0.0199	NC
Lymph node only	60	0 (0.0)	NC [NC, NC]	65	5 (7.7)	NC [NC, NC]	NC [NC, NC]	0.0209	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.136.1.1: Summary and Results of TESAEs - Anaemia (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	0 (0.0%)	10 (4.2%)	
Number of patients censored	239 (100.0%)	226 (95.8%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	100.0 [100.0, 100.0]	96.3 [92.8, 98.1]	
Month 6	100.0 [100.0, 100.0]	94.3 [88.6, 97.2]	
Month 9	100.0 [100.0, 100.0]	NC [NC, NC]	
Month 12	100.0 [100.0, 100.0]	NC [NC, NC]	
Month 18	100.0 [100.0, 100.0]	NC [NC, NC]	
Month 24	100.0 [100.0, 100.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			NC [NC, NC]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0004

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.136.1.2: Summary and Results of TESAEs by Subgroups - Anaemia (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	0 (0.0)	NC [NC, NC]	47	0 (0.0)	NC [NC, NC]	NC [NC, NC]	NC	NC
Absent	192	0 (0.0)	NC [NC, NC]	189	10 (5.3)	NC [NC, NC]	NC [NC, NC]	0.0004	
Age									
< 65 years	105	0 (0.0)		102	3 (2.9)				
>= 65 years	134	0 (0.0)		134	7 (5.2)				
Region									
Europe	97	0 (0.0)		101	4 (4.0)				
North America	57	0 (0.0)		51	1 (2.0)				
Rest of World	85	0 (0.0)		84	5 (6.0)				
Sex									
Male	197	0 (0.0)		181	9 (5.0)				
Female	42	0 (0.0)		55	1 (1.8)				
Metastases at Baseline									
Visceral metastases	169	0 (0.0)		157	6 (3.8)				
Lymph node only	60	0 (0.0)		65	3 (4.6)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.137.1.1: Summary and Results of TESAEs - Cardiac disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	7 (2.9%)	10 (4.2%)	
Number of patients censored	232 (97.1%)	226 (95.8%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.9 [95.0, 99.1]	95.5 [91.8, 97.6]	
Month 6	97.9 [95.0, 99.1]	95.5 [91.8, 97.6]	
Month 9	97.3 [94.0, 98.8]	NC [NC, NC]	
Month 12	97.3 [94.0, 98.8]	NC [NC, NC]	
Month 18	97.3 [94.0, 98.8]	NC [NC, NC]	
Month 24	97.3 [94.0, 98.8]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [25.5, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.469 [0.160, 1.372]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1568

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.138.1.1: Summary and Results of TESAEs - Gastrointestinal disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	24 (10.0%)	6 (2.5%)	
Number of patients censored	215 (90.0%)	230 (97.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	93.3 [89.2, 95.8]	98.7 [96.1, 99.6]	
Month 6	91.0 [86.5, 94.0]	95.0 [85.4, 98.3]	
Month 9	91.0 [86.5, 94.0]	NC [NC, NC]	
Month 12	91.0 [86.5, 94.0]	NC [NC, NC]	
Month 18	85.9 [77.5, 91.3]	NC [NC, NC]	
Month 24	85.9 [77.5, 91.3]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			3.216 [1.294, 7.991]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0078

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.138.1.2: Summary and Results of TESAEs by Subgroups - Gastrointestinal disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	10 (21.3)	NC [16.1, NC]	47	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0018	NC
Absent	192	14 (7.3)	NC [NC, NC]	189	6 (3.2)	NC [NC, NC]	1.716 [0.638, 4.611]	0.2786	
Age									
< 65 years	105	9 (8.6)	NC [NC, NC]	102	2 (2.0)	NC [NC, NC]	3.297 [0.685, 15.873]	0.1149	0.9127
>= 65 years	134	15 (11.2)	NC [NC, NC]	134	4 (3.0)	NC [NC, NC]	3.169 [1.037, 9.681]	0.0326	
Region									
Europe	97	10 (10.3)	NC [NC, NC]	101	3 (3.0)	NC [NC, NC]	3.054 [0.826, 11.284]	0.0779	0.6224
North America	57	9 (15.8)	NC [16.1, NC]	51	1 (2.0)	NC [NC, NC]	7.233 [0.905, 57.837]	0.0289	
Rest of World	85	5 (5.9)	NC [NC, NC]	84	2 (2.4)	NC [NC, NC]	1.477 [0.261, 8.349]	0.6573	
Sex									
Male	197	21 (10.7)	NC [NC, NC]	181	3 (1.7)	NC [NC, NC]	5.384 [1.589, 18.240]	0.0024	0.1213
Female	42	3 (7.1)	NC [NC, NC]	55	3 (5.5)	NC [NC, NC]	0.852 [0.142, 5.101]	0.8608	
Metastases at Baseline									
Visceral metastases	169	20 (11.8)	NC [NC, NC]	157	3 (1.9)	NC [NC, NC]	5.453 [1.606, 18.515]	0.0022	0.0741
Lymph node only	60	3 (5.0)	NC [NC, NC]	65	3 (4.6)	NC [5.0, NC]	0.465 [0.071, 3.065]	0.4173	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.139.1.1: Summary and Results of TESAEs - General disorders and administration site conditions (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	8 (3.3%)	8 (3.4%)	
Number of patients censored	231 (96.7%)	228 (96.6%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.9 [95.0, 99.1]	97.4 [94.2, 98.8]	
Month 6	97.0 [93.7, 98.5]	96.3 [92.6, 98.1]	
Month 9	96.3 [92.8, 98.2]	NC [NC, NC]	
Month 12	96.3 [92.8, 98.2]	NC [NC, NC]	
Month 18	96.3 [92.8, 98.2]	NC [NC, NC]	
Month 24	96.3 [92.8, 98.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.807 [0.292, 2.227]
Log-rank test			
Two-sided unstratified log-rank p-value			0.6785

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.140.1.1: Summary and Results of TESAEs - Infections and infestations (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	24 (10.0%)	39 (16.5%)	
Number of patients censored	215 (90.0%)	197 (83.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	93.7 [89.8, 96.2]	87.8 [82.8, 91.4]	
Month 6	90.8 [86.3, 93.9]	80.9 [74.4, 85.9]	
Month 9	90.2 [85.5, 93.5]	NC [NC, NC]	
Month 12	90.2 [85.5, 93.5]	NC [NC, NC]	
Month 18	89.2 [83.9, 92.8]	NC [NC, NC]	
Month 24	86.4 [77.8, 91.8]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.427 [0.247, 0.738]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0017

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.140.1.2: Summary and Results of TESAEs by Subgroups - Infections and infestations (SOC) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	6 (12.8)	NC [NC, NC]	47	7 (14.9)	NC [NC, NC]	0.551 [0.166, 1.833]	0.3248	0.4202
Absent	192	18 (9.4)	NC [NC, NC]	189	32 (16.9)	NC [NC, NC]	0.400 [0.216, 0.741]	0.0026	
Age									
< 65 years	105	7 (6.7)	NC [NC, NC]	102	15 (14.7)	NC [NC, NC]	0.291 [0.106, 0.796]	0.0106	0.4102
>= 65 years	134	17 (12.7)	NC [NC, NC]	134	24 (17.9)	NC [NC, NC]	0.516 [0.267, 0.998]	0.0454	
Region									
Europe	97	11 (11.3)	NC [NC, NC]	101	21 (20.8)	NC [NC, NC]	0.413 [0.191, 0.894]	0.0207	0.6532
North America	57	5 (8.8)	NC [NC, NC]	51	9 (17.6)	NC [NC, NC]	0.357 [0.110, 1.161]	0.0737	
Rest of World	85	8 (9.4)	NC [NC, NC]	84	9 (10.7)	NC [NC, NC]	0.544 [0.192, 1.543]	0.2452	
Sex									
Male	197	19 (9.6)	NC [NC, NC]	181	30 (16.6)	NC [NC, NC]	0.372 [0.198, 0.700]	0.0014	0.6331
Female	42	5 (11.9)	NC [NC, NC]	55	9 (16.4)	NC [NC, NC]	0.717 [0.240, 2.142]	0.5532	
Metastases at Baseline									
Visceral metastases	169	16 (9.5)	NC [NC, NC]	157	25 (15.9)	NC [NC, NC]	0.437 [0.224, 0.854]	0.0128	0.9427
Lymph node only	60	7 (11.7)	NC [NC, NC]	65	12 (18.5)	NC [NC, NC]	0.381 [0.133, 1.089]	0.0618	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.141.1.1: Summary and Results of TESAEs - Urinary tract infection (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	4 (1.7%)	17 (7.2%)	
Number of patients censored	235 (98.3%)	219 (92.8%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	99.2 [96.7, 99.8]	94.7 [90.9, 97.0]	
Month 6	98.7 [95.9, 99.6]	92.0 [86.8, 95.2]	
Month 9	98.0 [94.7, 99.3]	NC [NC, NC]	
Month 12	98.0 [94.7, 99.3]	NC [NC, NC]	
Month 18	98.0 [94.7, 99.3]	NC [NC, NC]	
Month 24	98.0 [94.7, 99.3]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	6.1 [6.1, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.106 [0.026, 0.435]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0002

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.141.1.2: Summary and Results of TESAEs by Subgroups - Urinary tract infection (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	2 (4.3)	NC [NC, NC]	47	4 (8.5)	NC [NC, NC]	0.467 [0.085, 2.553]	0.3681	0.2445
Absent	192	2 (1.0)	NC [NC, NC]	189	13 (6.9)	6.1 [6.1, NC]	0.024 [0.002, 0.313]	0.0001	
Age									
< 65 years	105	2 (1.9)	NC [NC, NC]	102	4 (3.9)	6.1 [6.1, NC]	0.068 [0.003, 1.316]	0.0473	0.3061
>= 65 years	134	2 (1.5)	NC [NC, NC]	134	13 (9.7)	NC [NC, NC]	0.125 [0.028, 0.558]	0.0013	
Region									
Europe	97	1 (1.0)	NC [NC, NC]	101	9 (8.9)	NC [NC, NC]	0.107 [0.013, 0.842]	0.0095	NC
North America	57	0 (0.0)	NC [NC, NC]	51	3 (5.9)	NC [NC, NC]	NC [NC, NC]	0.0632	
Rest of World	85	3 (3.5)	NC [NC, NC]	84	5 (6.0)	6.1 [NC, NC]	0.164 [0.022, 1.227]	0.0508	
Sex									
Male	197	3 (1.5)	NC [NC, NC]	181	11 (6.1)	NC [NC, NC]	0.140 [0.031, 0.636]	0.0031	0.9312
Female	42	1 (2.4)	NC [NC, NC]	55	6 (10.9)	6.1 [6.1, NC]	0.092 [0.007, 1.128]	0.0385	
Metastases at Baseline									
Visceral metastases	169	4 (2.4)	NC [NC, NC]	157	11 (7.0)	NC [NC, NC]	0.235 [0.066, 0.844]	0.0156	NC
Lymph node only	60	0 (0.0)	NC [NC, NC]	65	6 (9.2)	6.1 [NC, NC]	NC [NC, NC]	0.0009	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.142.1.1: Summary and Results of TESAEs - Metabolism and nutrition disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	14 (5.9%)	10 (4.2%)	
Number of patients censored	225 (94.1%)	226 (95.8%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.2 [92.9, 98.0]	97.0 [93.8, 98.6]	
Month 6	93.9 [90.0, 96.4]	95.2 [91.2, 97.4]	
Month 9	93.9 [90.0, 96.4]	NC [NC, NC]	
Month 12	93.9 [90.0, 96.4]	NC [NC, NC]	
Month 18	93.9 [90.0, 96.4]	NC [NC, NC]	
Month 24	93.9 [90.0, 96.4]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.303 [0.579, 2.936]
Log-rank test			
Two-sided unstratified log-rank p-value			0.5214

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.143.1.1: Summary and Results of TESAEs - Musculoskeletal and connective tissue disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	5 (2.1%)	6 (2.5%)	
Number of patients censored	234 (97.9%)	230 (97.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.7 [96.2, 99.6]	97.7 [94.6, 99.0]	
Month 6	97.7 [94.5, 99.0]	97.1 [93.7, 98.7]	
Month 9	97.7 [94.5, 99.0]	NC [NC, NC]	
Month 12	97.7 [94.5, 99.0]	NC [NC, NC]	
Month 18	97.7 [94.5, 99.0]	NC [NC, NC]	
Month 24	97.7 [94.5, 99.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.492 [0.128, 1.884]
Log-rank test			
Two-sided unstratified log-rank p-value			0.2916

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.144.1.1: Summary and Results of TESAEs - Nervous system disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	11 (4.6%)	3 (1.3%)	
Number of patients censored	228 (95.4%)	233 (98.7%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.7 [96.1, 99.6]	98.7 [96.1, 99.6]	
Month 6	96.7 [93.3, 98.4]	98.7 [96.1, 99.6]	
Month 9	95.6 [91.6, 97.7]	NC [NC, NC]	
Month 12	95.6 [91.6, 97.7]	NC [NC, NC]	
Month 18	93.5 [86.5, 97.0]	NC [NC, NC]	
Month 24	90.7 [80.2, 95.8]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.636 [0.404, 6.623]
Log-rank test			
Two-sided unstratified log-rank p-value			0.4864

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.145.1.1: Summary and Results of TESAEs - Renal and urinary disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	**Plat+Gem (N= 236)**	**EV+Pembro vs. Plat+Gem**
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	18 (7.5%)	17 (7.2%)	
Number of patients censored	221 (92.5%)	219 (92.8%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.6 [93.4, 98.3]	94.7 [90.9, 97.0]	
Month 6	94.3 [90.3, 96.6]	90.9 [84.8, 94.6]	
Month 9	92.5 [87.9, 95.3]	NC [NC, NC]	
Month 12	90.8 [85.5, 94.2]	NC [NC, NC]	
Month 18	90.8 [85.5, 94.2]	NC [NC, NC]	
Month 24	90.8 [85.5, 94.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.623 [0.297, 1.308]
Log-rank test			
Two-sided unstratified log-rank p-value			0.2074

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.146.1.1: Summary and Results of TESAEs - Acute kidney injury (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	9 (3.8%)	7 (3.0%)	
Number of patients censored	230 (96.2%)	229 (97.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.3 [95.6, 99.4]	97.0 [93.8, 98.6]	
Month 6	97.3 [94.1, 98.8]	97.0 [93.8, 98.6]	
Month 9	95.5 [91.4, 97.7]	NC [NC, NC]	
Month 12	95.5 [91.4, 97.7]	NC [NC, NC]	
Month 18	95.5 [91.4, 97.7]	NC [NC, NC]	
Month 24	95.5 [91.4, 97.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.690 [0.221, 2.161]
Log-rank test			
Two-sided unstratified log-rank p-value			0.5223

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.147.1.1: Summary and Results of TESAEs - Respiratory, thoracic and mediastinal disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	**Plat+Gem (N= 236)**	**EV+Pembro vs. Plat+Gem**
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	25 (10.5%)	4 (1.7%)	
Number of patients censored	214 (89.5%)	232 (98.3%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	94.5 [90.7, 96.8]	98.2 [95.3, 99.3]	
Month 6	91.6 [87.1, 94.6]	98.2 [95.3, 99.3]	
Month 9	89.8 [84.9, 93.2]	NC [NC, NC]	
Month 12	88.4 [83.1, 92.2]	NC [NC, NC]	
Month 18	88.4 [83.1, 92.2]	NC [NC, NC]	
Month 24	84.7 [74.2, 91.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			4.066 [1.373, 12.037]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0062

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.147.1.2: Summary and Results of TESAEs by Subgroups - Respiratory, thoracic and mediastinal disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	6 (12.8)	NC [21.0, NC]	47	1 (2.1)	NC [NC, NC]	3.663 [0.410, 32.724]	0.2153	0.9466
Absent	192	19 (9.9)	NC [NC, NC]	189	3 (1.6)	NC [NC, NC]	4.210 [1.207, 14.681]	0.0142	
Age									
< 65 years	105	8 (7.6)	NC [NC, NC]	102	2 (2.0)	NC [NC, NC]	1.893 [0.348, 10.311]	0.4529	0.4711
>= 65 years	134	17 (12.7)	NC [NC, NC]	134	2 (1.5)	NC [NC, NC]	6.265 [1.420, 27.648]	0.0057	
Region									
Europe	97	8 (8.2)	NC [NC, NC]	101	2 (2.0)	NC [NC, NC]	3.032 [0.615, 14.943]	0.1521	0.7720
North America	57	6 (10.5)	NC [21.0, NC]	51	1 (2.0)	NC [NC, NC]	3.647 [0.408, 32.628]	0.2151	
Rest of World	85	11 (12.9)	NC [NC, NC]	84	1 (1.2)	NC [NC, NC]	6.543 [0.811, 52.765]	0.0431	
Sex									
Male	197	22 (11.2)	NC [NC, NC]	181	3 (1.7)	NC [NC, NC]	4.076 [1.177, 14.118]	0.0165	0.7177
Female	42	3 (7.1)	NC [NC, NC]	55	1 (1.8)	NC [NC, NC]	3.992 [0.415, 38.381]	0.1947	
Metastases at Baseline									
Visceral metastases	169	19 (11.2)	NC [NC, NC]	157	3 (1.9)	NC [NC, NC]	3.720 [1.057, 13.092]	0.0282	0.9319
Lymph node only	60	5 (8.3)	NC [NC, NC]	65	1 (1.5)	NC [NC, NC]	4.256 [0.479, 37.788]	0.1578	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.148.1.1: Summary and Results of TESAEs - Skin and subcutaneous tissue disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	15 (6.3%)	0 (0.0%)	
Number of patients censored	224 (93.7%)	236 (100.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	95.8 [92.3, 97.7]	100.0 [100.0, 100.0]	
Month 6	94.2 [90.3, 96.6]	100.0 [100.0, 100.0]	
Month 9	93.7 [89.5, 96.2]	NC [NC, NC]	
Month 12	93.7 [89.5, 96.2]	NC [NC, NC]	
Month 18	92.5 [87.3, 95.6]	NC [NC, NC]	
Month 24	92.5 [87.3, 95.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			NC [NC, NC]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0011

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.148.1.2: Summary and Results of TESAEs by Subgroups - Skin and subcutaneous tissue disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	4 (8.5)	NC [NC, NC]	47	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1288	NC
Absent	192	11 (5.7)	NC [NC, NC]	189	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0037	
Age									
< 65 years	105	4 (3.8)	NC [NC, NC]	102	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0834	NC
>= 65 years	134	11 (8.2)	NC [NC, NC]	134	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0053	
Region									
Europe	97	5 (5.2)		101	0 (0.0)				
North America	57	3 (5.3)		51	0 (0.0)				
Rest of World	85	7 (8.2)		84	0 (0.0)				
Sex									
Male	197	12 (6.1)	NC [NC, NC]	181	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0044	NC
Female	42	3 (7.1)	NC [NC, NC]	55	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1171	
Metastases at Baseline									
Visceral metastases	169	10 (5.9)	NC [NC, NC]	157	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0117	NC
Lymph node only	60	5 (8.3)	NC [NC, NC]	65	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0384	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.149.1.1: Summary and Results of Severe TEAEs - Blood and lymphatic system disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	17 (7.1%)	110 (46.6%)	
Number of patients censored	222 (92.9%)	126 (53.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	95.7 [92.1, 97.7]	56.8 [50.0, 63.0]	
Month 6	94.2 [90.2, 96.6]	47.1 [38.2, 55.4]	
Month 9	93.5 [89.2, 96.1]	NC [NC, NC]	
Month 12	90.8 [85.2, 94.4]	NC [NC, NC]	
Month 18	90.8 [85.2, 94.4]	NC [NC, NC]	
Month 24	90.8 [85.2, 94.4]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	4.9 [3.0, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.082 [0.046, 0.147]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.149.1.2: Summary and Results of Severe TEAEs by Subgroups - Blood and lymphatic system disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	4 (8.5)	NC [NC, NC]	47	21 (44.7)	NC [2.3, NC]	0.112 [0.033, 0.375]	<.0001	0.4539
Absent	192	13 (6.8)	NC [NC, NC]	189	89 (47.1)	4.9 [2.9, NC]	0.076 [0.039, 0.147]	<.0001	
Age									
< 65 years	105	6 (5.7)	NC [NC, NC]	102	43 (42.2)	NC [3.0, NC]	0.052 [0.016, 0.167]	<.0001	0.7341
>= 65 years	134	11 (8.2)	NC [NC, NC]	134	67 (50.0)	3.7 [2.8, NC]	0.100 [0.051, 0.196]	<.0001	
Region									
Europe	97	9 (9.3)	NC [NC, NC]	101	46 (45.5)	4.9 [2.8, NC]	0.135 [0.063, 0.286]	<.0001	0.4491
North America	57	2 (3.5)	NC [NC, NC]	51	23 (45.1)	NC [2.3, NC]	0.028 [0.004, 0.211]	<.0001	
Rest of World	85	6 (7.1)	NC [NC, NC]	84	41 (48.8)	5.0 [2.6, NC]	0.065 [0.023, 0.184]	<.0001	
Sex									
Male	197	14 (7.1)	NC [NC, NC]	181	80 (44.2)	5.0 [3.2, NC]	0.107 [0.059, 0.194]	<.0001	0.6441
Female	42	3 (7.1)	NC [NC, NC]	55	30 (54.5)	3.0 [2.1, NC]	0.000 [0.000, NC]	<.0001	
Metastases at Baseline									
Visceral metastases	169	13 (7.7)	NC [NC, NC]	157	76 (48.4)	4.2 [2.8, NC]	0.080 [0.040, 0.159]	<.0001	0.6645
Lymph node only	60	3 (5.0)	NC [NC, NC]	65	28 (43.1)	5.0 [2.6, NC]	0.079 [0.024, 0.265]	<.0001	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.150.1.1: Summary and Results of Severe TEAEs - Anaemia (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	5 (2.1%)	68 (28.8%)	
Number of patients censored	234 (97.9%)	168 (71.2%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	99.2 [96.7, 99.8]	75.5 [69.3, 80.7]	
Month 6	98.7 [95.9, 99.6]	65.3 [56.6, 72.6]	
Month 9	98.7 [95.9, 99.6]	NC [NC, NC]	
Month 12	97.0 [92.7, 98.8]	NC [NC, NC]	
Month 18	97.0 [92.7, 98.8]	NC [NC, NC]	
Month 24	97.0 [92.7, 98.8]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.034 [0.011, 0.108]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.150.1.2: Summary and Results of Severe TEAEs by Subgroups - Anaemia (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	0 (0.0)	NC [NC, NC]	47	12 (25.5)	NC [NC, NC]	NC [NC, NC]	0.0002	NC
Absent	192	5 (2.6)	NC [NC, NC]	189	56 (29.6)	NC [NC, NC]	0.040 [0.012, 0.128]	<.0001	
Age									
< 65 years	105	2 (1.9)	NC [NC, NC]	102	26 (25.5)	NC [NC, NC]	0.032 [0.004, 0.239]	<.0001	0.9699
>= 65 years	134	3 (2.2)	NC [NC, NC]	134	42 (31.3)	NC [5.0, NC]	0.034 [0.008, 0.142]	<.0001	
Region									
Europe	97	4 (4.1)	NC [NC, NC]	101	30 (29.7)	NC [NC, NC]	0.084 [0.025, 0.275]	<.0001	NC
North America	57	1 (1.8)	NC [NC, NC]	51	17 (33.3)	NC [3.2, NC]	0.000 [0.000, NC]	<.0001	
Rest of World	85	0 (0.0)	NC [NC, NC]	84	21 (25.0)	NC [5.0, NC]	NC [NC, NC]	<.0001	
Sex									
Male	197	4 (2.0)	NC [NC, NC]	181	48 (26.5)	NC [NC, NC]	0.044 [0.014, 0.142]	<.0001	0.8715
Female	42	1 (2.4)	NC [NC, NC]	55	20 (36.4)	NC [3.9, NC]	0.000 [0.000, NC]	<.0001	
Metastases at Baseline									
Visceral metastases	169	4 (2.4)	NC [NC, NC]	157	45 (28.7)	NC [NC, NC]	0.034 [0.008, 0.139]	<.0001	0.7257
Lymph node only	60	1 (1.7)	NC [NC, NC]	65	19 (29.2)	NC [5.0, NC]	0.040 [0.005, 0.306]	<.0001	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.151.1.1: Summary and Results of Severe TEAEs - Neutropenia (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	8 (3.3%)	52 (22.0%)	
Number of patients censored	231 (96.7%)	184 (78.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.0 [93.7, 98.5]	80.4 [74.6, 85.0]	
Month 6	96.4 [93.0, 98.2]	76.7 [70.5, 81.7]	
Month 9	96.4 [93.0, 98.2]	NC [NC, NC]	
Month 12	96.4 [93.0, 98.2]	NC [NC, NC]	
Month 18	96.4 [93.0, 98.2]	NC [NC, NC]	
Month 24	96.4 [93.0, 98.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.132 [0.063, 0.278]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.151.1.2: Summary and Results of Severe TEAEs by Subgroups - Neutropenia (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	3 (6.4)	NC [NC, NC]	47	12 (25.5)	NC [NC, NC]	0.225 [0.063, 0.797]	0.0114	0.3437
Absent	192	5 (2.6)	NC [NC, NC]	189	40 (21.2)	NC [NC, NC]	0.107 [0.042, 0.272]	<.0001	
Age									
< 65 years	105	1 (1.0)	NC [NC, NC]	102	22 (21.6)	NC [NC, NC]	0.039 [0.005, 0.287]	<.0001	0.1337
>= 65 years	134	7 (5.2)	NC [NC, NC]	134	30 (22.4)	NC [NC, NC]	0.203 [0.089, 0.462]	<.0001	
Region									
Europe	97	5 (5.2)	NC [NC, NC]	101	22 (21.8)	NC [NC, NC]	0.208 [0.079, 0.550]	0.0005	NC
North America	57	0 (0.0)	NC [NC, NC]	51	8 (15.7)	NC [NC, NC]	NC [NC, NC]	0.0018	
Rest of World	85	3 (3.5)	NC [NC, NC]	84	22 (26.2)	NC [NC, NC]	0.115 [0.034, 0.383]	<.0001	
Sex									
Male	197	8 (4.1)	NC [NC, NC]	181	37 (20.4)	NC [NC, NC]	0.174 [0.081, 0.374]	<.0001	NC
Female	42	0 (0.0)	NC [NC, NC]	55	15 (27.3)	NC [NC, NC]	NC [NC, NC]	0.0002	
Metastases at Baseline									
Visceral metastases	169	6 (3.6)	NC [NC, NC]	157	37 (23.6)	NC [NC, NC]	0.131 [0.055, 0.310]	<.0001	0.6616
Lymph node only	60	2 (3.3)	NC [NC, NC]	65	10 (15.4)	NC [NC, NC]	0.195 [0.043, 0.891]	0.0189	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.152.1.1: Summary and Results of Severe TEAEs - Thrombocytopenia (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	2 (0.8%)	28 (11.9%)	
Number of patients censored	237 (99.2%)	208 (88.1%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	100.0 [100.0, 100.0]	90.4 [85.7, 93.6]	
Month 6	99.0 [96.1, 99.8]	87.0 [81.7, 90.9]	
Month 9	99.0 [96.1, 99.8]	NC [NC, NC]	
Month 12	99.0 [96.1, 99.8]	NC [NC, NC]	
Month 18	99.0 [96.1, 99.8]	NC [NC, NC]	
Month 24	99.0 [96.1, 99.8]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.064 [0.015, 0.269]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.152.1.2: Summary and Results of Severe TEAEs by Subgroups - Thrombocytopenia (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	0 (0.0)	NC [NC, NC]	47	6 (12.8)	NC [NC, NC]	NC [NC, NC]	0.0121	NC
Absent	192	2 (1.0)	NC [NC, NC]	189	22 (11.6)	NC [NC, NC]	0.080 [0.019, 0.339]	<.0001	
Age									
< 65 years	105	1 (1.0)	NC [NC, NC]	102	7 (6.9)	NC [NC, NC]	0.132 [0.016, 1.075]	0.0257	0.4479
>= 65 years	134	1 (0.7)	NC [NC, NC]	134	21 (15.7)	NC [NC, NC]	0.042 [0.006, 0.310]	<.0001	
Region									
Europe	97	1 (1.0)	NC [NC, NC]	101	12 (11.9)	NC [NC, NC]	0.079 [0.010, 0.611]	0.0017	NC
North America	57	1 (1.8)	NC [NC, NC]	51	5 (9.8)	NC [NC, NC]	0.156 [0.018, 1.342]	0.0523	
Rest of World	85	0 (0.0)	NC [NC, NC]	84	11 (13.1)	NC [NC, NC]	NC [NC, NC]	0.0005	
Sex									
Male	197	2 (1.0)	NC [NC, NC]	181	21 (11.6)	NC [NC, NC]	0.079 [0.018, 0.336]	<.0001	NC
Female	42	0 (0.0)	NC [NC, NC]	55	7 (12.7)	NC [NC, NC]	NC [NC, NC]	0.0170	
Metastases at Baseline									
Visceral metastases	169	0 (0.0)	NC [NC, NC]	157	21 (13.4)	NC [NC, NC]	NC [NC, NC]	<.0001	NC
Lymph node only	60	1 (1.7)	NC [NC, NC]	65	6 (9.2)	NC [NC, NC]	0.162 [0.020, 1.348]	0.0542	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.153.1.1: Summary and Results of Severe TEAEs - Cardiac disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	6 (2.5%)	9 (3.8%)	
Number of patients censored	233 (97.5%)	227 (96.2%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.8 [94.8, 99.1]	96.0 [92.4, 97.9]	
Month 6	97.8 [94.8, 99.1]	96.0 [92.4, 97.9]	
Month 9	97.8 [94.8, 99.1]	NC [NC, NC]	
Month 12	97.8 [94.8, 99.1]	NC [NC, NC]	
Month 18	97.8 [94.8, 99.1]	NC [NC, NC]	
Month 24	97.8 [94.8, 99.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [25.5, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.542 [0.182, 1.618]
Log-rank test			
Two-sided unstratified log-rank p-value			0.2650

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.154.1.1: Summary and Results of Severe TEAEs - Gastrointestinal disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	29 (12.1%)	17 (7.2%)	
Number of patients censored	210 (87.9%)	219 (92.8%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	92.3 [88.0, 95.1]	93.5 [89.4, 96.0]	
Month 6	89.3 [84.4, 92.7]	92.5 [88.1, 95.2]	
Month 9	88.7 [83.7, 92.2]	NC [NC, NC]	
Month 12	87.8 [82.5, 91.6]	NC [NC, NC]	
Month 18	82.7 [74.1, 88.7]	NC [NC, NC]	
Month 24	82.7 [74.1, 88.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.360 [0.731, 2.532]
Log-rank test			
Two-sided unstratified log-rank p-value			0.3286

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.155.1.1: Summary and Results of Severe TEAEs - Diarrhoea (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	10 (4.2%)	2 (0.8%)	
Number of patients censored	229 (95.8%)	234 (99.2%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.0 [93.8, 98.5]	99.1 [96.6, 99.8]	
Month 6	96.0 [92.3, 97.9]	99.1 [96.6, 99.8]	
Month 9	96.0 [92.3, 97.9]	NC [NC, NC]	
Month 12	95.0 [90.8, 97.4]	NC [NC, NC]	
Month 18	95.0 [90.8, 97.4]	NC [NC, NC]	
Month 24	95.0 [90.8, 97.4]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			4.341 [0.938, 20.100]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0403

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.155.1.2: Summary and Results of Severe TEAEs by Subgroups - Diarrhoea (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	3 (6.4)		47	0 (0.0)				
Absent	192	7 (3.6)		189	2 (1.1)				
Age									
< 65 years	105	4 (3.8)		102	1 (1.0)				
>= 65 years	134	6 (4.5)		134	1 (0.7)				
Region									
Europe	97	1 (1.0)		101	1 (1.0)				
North America	57	4 (7.0)		51	0 (0.0)				
Rest of World	85	5 (5.9)		84	1 (1.2)				
Sex									
Male	197	7 (3.6)		181	2 (1.1)				
Female	42	3 (7.1)		55	0 (0.0)				
Metastases at Baseline									
Visceral metastases	169	9 (5.3)	NC [NC, NC]	157	1 (0.6)	NC [NC, NC]	7.260 [0.908, 58.071]	0.0286	NC
Lymph node only	60	0 (0.0)	NC [NC, NC]	65	1 (1.5)	NC [NC, NC]	NC [NC, NC]	0.3411	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.156.1.1: Summary and Results of Severe TEAEs - Nausea (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	4 (1.7%)	9 (3.8%)	
Number of patients censored	235 (98.3%)	227 (96.2%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.3 [95.4, 99.3]	96.1 [92.7, 98.0]	
Month 6	98.3 [95.4, 99.3]	96.1 [92.7, 98.0]	
Month 9	98.3 [95.4, 99.3]	NC [NC, NC]	
Month 12	98.3 [95.4, 99.3]	NC [NC, NC]	
Month 18	98.3 [95.4, 99.3]	NC [NC, NC]	
Month 24	98.3 [95.4, 99.3]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.429 [0.132, 1.391]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1464

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.157.1.1: Summary and Results of Severe TEAEs - General disorders and administration site conditions (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	13 (5.4%)	24 (10.2%)	
Number of patients censored	226 (94.6%)	212 (89.8%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.4 [94.4, 98.8]	91.3 [86.8, 94.3]	
Month 6	96.4 [92.9, 98.2]	89.1 [84.2, 92.6]	
Month 9	94.4 [90.0, 96.9]	NC [NC, NC]	
Month 12	92.5 [87.1, 95.7]	NC [NC, NC]	
Month 18	92.5 [87.1, 95.7]	NC [NC, NC]	
Month 24	92.5 [87.1, 95.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.304 [0.137, 0.676]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0020

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.157.1.2: Summary and Results of Severe TEAEs by Subgroups - General disorders and administration site conditions (SOC) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	6 (12.8)	NC [NC, NC]	47	6 (12.8)	NC [NC, NC]	0.648 [0.183, 2.297]	0.5002	0.1182
Absent	192	7 (3.6)	NC [NC, NC]	189	18 (9.5)	NC [NC, NC]	0.197 [0.068, 0.576]	0.0010	
Age									
< 65 years	105	6 (5.7)	NC [NC, NC]	102	10 (9.8)	NC [NC, NC]	0.285 [0.081, 1.002]	0.0378	0.8600
>= 65 years	134	7 (5.2)	NC [NC, NC]	134	14 (10.4)	NC [NC, NC]	0.322 [0.115, 0.899]	0.0228	
Region									
Europe	97	3 (3.1)	NC [NC, NC]	101	15 (14.9)	NC [NC, NC]	0.066 [0.009, 0.497]	0.0004	0.1240
North America	57	4 (7.0)	NC [NC, NC]	51	3 (5.9)	NC [NC, NC]	0.597 [0.100, 3.571]	0.5674	
Rest of World	85	6 (7.1)	NC [NC, NC]	84	6 (7.1)	NC [NC, NC]	0.725 [0.220, 2.393]	0.5973	
Sex									
Male	197	11 (5.6)	NC [NC, NC]	181	17 (9.4)	NC [NC, NC]	0.343 [0.142, 0.831]	0.0130	0.5525
Female	42	2 (4.8)	NC [NC, NC]	55	7 (12.7)	NC [NC, NC]	0.181 [0.022, 1.472]	0.0721	
Metastases at Baseline									
Visceral metastases	169	11 (6.5)	NC [NC, NC]	157	17 (10.8)	NC [NC, NC]	0.311 [0.122, 0.788]	0.0092	NC
Lymph node only	60	0 (0.0)	NC [NC, NC]	65	6 (9.2)	NC [NC, NC]	NC [NC, NC]	0.0157	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.158.1.1: Summary and Results of Severe TEAEs - Asthenia (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	5 (2.1%)	6 (2.5%)	
Number of patients censored	234 (97.9%)	230 (97.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	99.1 [96.6, 99.8]	98.3 [95.5, 99.4]	
Month 6	98.6 [95.9, 99.6]	97.1 [93.7, 98.7]	
Month 9	97.9 [94.5, 99.2]	NC [NC, NC]	
Month 12	96.9 [92.1, 98.8]	NC [NC, NC]	
Month 18	96.9 [92.1, 98.8]	NC [NC, NC]	
Month 24	96.9 [92.1, 98.8]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.473 [0.118, 1.893]
Log-rank test			
Two-sided unstratified log-rank p-value			0.2790

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.159.1.1: Summary and Results of Severe TEAEs - Fatigue (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	6 (2.5%)	12 (5.1%)	
Number of patients censored	233 (97.5%)	224 (94.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.7 [96.1, 99.6]	95.5 [91.8, 97.6]	
Month 6	98.2 [95.2, 99.3]	94.3 [90.2, 96.8]	
Month 9	97.6 [94.3, 99.0]	NC [NC, NC]	
Month 12	96.7 [92.6, 98.6]	NC [NC, NC]	
Month 18	96.7 [92.6, 98.6]	NC [NC, NC]	
Month 24	96.7 [92.6, 98.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.299 [0.097, 0.925]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0267

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.159.1.2: Summary and Results of Severe TEAEs by Subgroups - Fatigue (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	2 (4.3)	NC [NC, NC]	47	2 (4.3)	NC [NC, NC]	1.011 [0.142, 7.178]	0.9912	0.3335
Absent	192	4 (2.1)	NC [NC, NC]	189	10 (5.3)	NC [NC, NC]	0.173 [0.039, 0.759]	0.0095	
Age									
< 65 years	105	3 (2.9)	NC [NC, NC]	102	5 (4.9)	NC [NC, NC]	0.387 [0.079, 1.905]	0.2270	0.7624
>= 65 years	134	3 (2.2)	NC [NC, NC]	134	7 (5.2)	NC [NC, NC]	0.244 [0.050, 1.195]	0.0605	
Region									
Europe	97	0 (0.0)		101	6 (5.9)				
North America	57	3 (5.3)		51	3 (5.9)				
Rest of World	85	3 (3.5)		84	3 (3.6)				
Sex									
Male	197	6 (3.0)	NC [NC, NC]	181	8 (4.4)	NC [NC, NC]	0.405 [0.121, 1.360]	0.1311	NC
Female	42	0 (0.0)	NC [NC, NC]	55	4 (7.3)	NC [NC, NC]	NC [NC, NC]	0.0763	
Metastases at Baseline									
Visceral metastases	169	4 (2.4)	NC [NC, NC]	157	8 (5.1)	NC [NC, NC]	0.227 [0.048, 1.070]	0.0402	NC
Lymph node only	60	0 (0.0)	NC [NC, NC]	65	4 (6.2)	NC [NC, NC]	NC [NC, NC]	0.0449	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.160.1.1: Summary and Results of Severe TEAEs - Hepatobiliary disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	9 (3.8%)	1 (0.4%)	
Number of patients censored	230 (96.2%)	235 (99.6%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.6 [93.2, 98.3]	99.6 [97.0, 99.9]	
Month 6	96.6 [93.2, 98.3]	99.6 [97.0, 99.9]	
Month 9	96.6 [93.2, 98.3]	NC [NC, NC]	
Month 12	95.4 [90.9, 97.7]	NC [NC, NC]	
Month 18	95.4 [90.9, 97.7]	NC [NC, NC]	
Month 24	95.4 [90.9, 97.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			7.954 [0.995, 63.592]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0201

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.160.1.2: Summary and Results of Severe TEAEs by Subgroups - Hepatobiliary disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	2 (4.3)		47	0 (0.0)				
Absent	192	7 (3.6)		189	1 (0.5)				
Age									
< 65 years	105	1 (1.0)		102	1 (1.0)				
>= 65 years	134	8 (6.0)		134	0 (0.0)				
Region									
Europe	97	4 (4.1)		101	0 (0.0)				
North America	57	3 (5.3)		51	0 (0.0)				
Rest of World	85	2 (2.4)		84	1 (1.2)				
Sex									
Male	197	6 (3.0)		181	1 (0.6)				
Female	42	3 (7.1)		55	0 (0.0)				
Metastases at Baseline									
Visceral metastases	169	9 (5.3)	NC [NC, NC]	157	1 (0.6)	NC [NC, NC]	7.531 [0.942, 60.210]	0.0248	NC
Lymph node only	60	0 (0.0)	NC [NC, NC]	65	0 (0.0)	NC [NC, NC]	NC [NC, NC]	NC	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.161.1.1: Summary and Results of Severe TEAEs - Infections and infestations (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	28 (11.7%)	39 (16.5%)	
Number of patients censored	211 (88.3%)	197 (83.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	93.2 [89.2, 95.8]	86.9 [81.8, 90.7]	
Month 6	88.7 [83.7, 92.3]	81.9 [75.9, 86.5]	
Month 9	88.1 [82.9, 91.7]	NC [NC, NC]	
Month 12	88.1 [82.9, 91.7]	NC [NC, NC]	
Month 18	87.0 [81.3, 91.0]	NC [NC, NC]	
Month 24	84.2 [75.4, 90.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.519 [0.309, 0.870]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0114

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.161.1.2: Summary and Results of Severe TEAEs by Subgroups - Infections and infestations (SOC) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	9 (19.1)	NC [NC, NC]	47	5 (10.6)	NC [NC, NC]	1.285 [0.408, 4.054]	0.6675	0.0332
Absent	192	19 (9.9)	NC [NC, NC]	189	34 (18.0)	NC [NC, NC]	0.408 [0.225, 0.742]	0.0024	
Age									
< 65 years	105	8 (7.6)	NC [NC, NC]	102	13 (12.7)	NC [NC, NC]	0.442 [0.175, 1.119]	0.0772	0.6448
>= 65 years	134	20 (14.9)	NC [NC, NC]	134	26 (19.4)	NC [NC, NC]	0.562 [0.302, 1.047]	0.0661	
Region									
Europe	97	10 (10.3)	NC [NC, NC]	101	21 (20.8)	NC [NC, NC]	0.381 [0.171, 0.850]	0.0145	0.4183
North America	57	8 (14.0)	NC [NC, NC]	51	9 (17.6)	NC [NC, NC]	0.576 [0.211, 1.574]	0.2751	
Rest of World	85	10 (11.8)	NC [NC, NC]	84	9 (10.7)	NC [NC, NC]	0.743 [0.282, 1.954]	0.5456	
Sex									
Male	197	21 (10.7)	NC [NC, NC]	181	29 (16.0)	NC [NC, NC]	0.483 [0.265, 0.878]	0.0147	0.5088
Female	42	7 (16.7)	NC [NC, NC]	55	10 (18.2)	NC [NC, NC]	0.698 [0.249, 1.956]	0.4926	
Metastases at Baseline									
Visceral metastases	169	18 (10.7)	NC [NC, NC]	157	26 (16.6)	NC [NC, NC]	0.469 [0.247, 0.890]	0.0179	0.9845
Lymph node only	60	7 (11.7)	NC [NC, NC]	65	11 (16.9)	NC [NC, NC]	0.448 [0.155, 1.289]	0.1266	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.162.1.1: Summary and Results of Severe TEAEs - Urinary tract infection (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	8 (3.3%)	19 (8.1%)	
Number of patients censored	231 (96.7%)	217 (91.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.9 [95.0, 99.1]	92.9 [88.7, 95.6]	
Month 6	96.3 [92.7, 98.1]	91.9 [87.5, 94.8]	
Month 9	96.3 [92.7, 98.1]	NC [NC, NC]	
Month 12	96.3 [92.7, 98.1]	NC [NC, NC]	
Month 18	96.3 [92.7, 98.1]	NC [NC, NC]	
Month 24	96.3 [92.7, 98.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	6.1 [6.1, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.317 [0.132, 0.761]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0068

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.162.1.2: Summary and Results of Severe TEAEs by Subgroups - Urinary tract infection (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	4 (8.5)	NC [NC, NC]	47	2 (4.3)	NC [NC, NC]	1.709 [0.307, 9.525]	0.5363	0.0259
Absent	192	4 (2.1)	NC [NC, NC]	189	17 (9.0)	6.1 [6.1, NC]	0.161 [0.048, 0.537]	0.0008	
Age									
< 65 years	105	3 (2.9)	NC [NC, NC]	102	3 (2.9)	6.1 [6.1, NC]	0.511 [0.083, 3.135]	0.4618	0.2243
>= 65 years	134	5 (3.7)	NC [NC, NC]	134	16 (11.9)	NC [NC, NC]	0.277 [0.101, 0.761]	0.0078	
Region									
Europe	97	2 (2.1)	NC [NC, NC]	101	10 (9.9)	NC [NC, NC]	0.203 [0.044, 0.926]	0.0223	0.2332
North America	57	1 (1.8)	NC [NC, NC]	51	4 (7.8)	NC [NC, NC]	0.153 [0.016, 1.470]	0.0678	
Rest of World	85	5 (5.9)	NC [NC, NC]	84	5 (6.0)	6.1 [NC, NC]	0.656 [0.172, 2.501]	0.5347	
Sex									
Male	197	6 (3.0)	NC [NC, NC]	181	12 (6.6)	NC [NC, NC]	0.416 [0.155, 1.114]	0.0719	0.8471
Female	42	2 (4.8)	NC [NC, NC]	55	7 (12.7)	6.1 [6.1, NC]	0.191 [0.032, 1.143]	0.0516	
Metastases at Baseline									
Visceral metastases	169	6 (3.6)	NC [NC, NC]	157	13 (8.3)	NC [NC, NC]	0.359 [0.134, 0.963]	0.0342	0.4488
Lymph node only	60	1 (1.7)	NC [NC, NC]	65	6 (9.2)	6.1 [NC, NC]	0.055 [0.003, 0.882]	0.0177	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.163.1.1: Summary and Results of Severe TEAEs - Investigations (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	33 (13.8%)	34 (14.4%)	
Number of patients censored	206 (86.2%)	202 (85.6%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	92.8 [88.7, 95.5]	88.3 [83.5, 91.9]	
Month 6	90.8 [86.2, 93.9]	83.3 [76.6, 88.2]	
Month 9	87.5 [82.0, 91.4]	NC [NC, NC]	
Month 12	82.0 [74.9, 87.2]	NC [NC, NC]	
Month 18	80.8 [73.3, 86.4]	NC [NC, NC]	
Month 24	80.8 [73.3, 86.4]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.556 [0.322, 0.959]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0322

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.163.1.2: Summary and Results of Severe TEAEs by Subgroups - Investigations (SOC) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	9 (19.1)	NC [10.8, NC]	47	8 (17.0)	NC [NC, NC]	0.583 [0.191, 1.784]	0.3388	0.5650
Absent	192	24 (12.5)	NC [NC, NC]	189	26 (13.8)	NC [NC, NC]	0.547 [0.293, 1.023]	0.0549	
Age									
< 65 years	105	12 (11.4)	NC [NC, NC]	102	10 (9.8)	NC [NC, NC]	0.647 [0.246, 1.700]	0.3733	0.6248
>= 65 years	134	21 (15.7)	NC [NC, NC]	134	24 (17.9)	NC [NC, NC]	0.519 [0.268, 1.007]	0.0483	
Region									
Europe	97	15 (15.5)	NC [NC, NC]	101	12 (11.9)	NC [NC, NC]	0.785 [0.338, 1.825]	0.5711	0.1872
North America	57	3 (5.3)	NC [NC, NC]	51	8 (15.7)	NC [NC, NC]	0.101 [0.013, 0.807]	0.0077	
Rest of World	85	15 (17.6)	NC [NC, NC]	84	14 (16.7)	NC [NC, NC]	0.663 [0.295, 1.490]	0.3162	
Sex									
Male	197	29 (14.7)	NC [NC, NC]	181	28 (15.5)	NC [NC, NC]	0.567 [0.316, 1.018]	0.0536	0.9079
Female	42	4 (9.5)	NC [NC, NC]	55	6 (10.9)	NC [NC, NC]	0.396 [0.080, 1.968]	0.2409	
Metastases at Baseline									
Visceral metastases	169	24 (14.2)	NC [NC, NC]	157	25 (15.9)	NC [NC, NC]	0.546 [0.291, 1.026]	0.0559	0.9682
Lymph node only	60	7 (11.7)	NC [NC, NC]	65	8 (12.3)	NC [NC, NC]	0.475 [0.143, 1.580]	0.2139	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.164.1.1: Summary and Results of Severe TEAEs - Neutrophil count decreased (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	4 (1.7%)	21 (8.9%)	
Number of patients censored	235 (98.3%)	215 (91.1%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.7 [96.2, 99.6]	93.1 [88.9, 95.7]	
Month 6	98.2 [95.3, 99.3]	90.2 [85.3, 93.5]	
Month 9	98.2 [95.3, 99.3]	NC [NC, NC]	
Month 12	98.2 [95.3, 99.3]	NC [NC, NC]	
Month 18	98.2 [95.3, 99.3]	NC [NC, NC]	
Month 24	98.2 [95.3, 99.3]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.175 [0.060, 0.509]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0003

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.164.1.2: Summary and Results of Severe TEAEs by Subgroups - Neutrophil count decreased (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	0 (0.0)	NC [NC, NC]	47	4 (8.5)	NC [NC, NC]	NC [NC, NC]	0.0431	NC
Absent	192	4 (2.1)	NC [NC, NC]	189	17 (9.0)	NC [NC, NC]	0.212 [0.071, 0.629]	0.0021	
Age									
< 65 years	105	2 (1.9)	NC [NC, NC]	102	8 (7.8)	NC [NC, NC]	0.229 [0.049, 1.081]	0.0420	0.6613
>= 65 years	134	2 (1.5)	NC [NC, NC]	134	13 (9.7)	NC [NC, NC]	0.142 [0.032, 0.629]	0.0027	
Region									
Europe	97	2 (2.1)	NC [NC, NC]	101	7 (6.9)	NC [NC, NC]	0.284 [0.059, 1.366]	0.0936	NC
North America	57	0 (0.0)	NC [NC, NC]	51	5 (9.8)	NC [NC, NC]	NC [NC, NC]	0.0138	
Rest of World	85	2 (2.4)	NC [NC, NC]	84	9 (10.7)	NC [NC, NC]	0.201 [0.044, 0.933]	0.0230	
Sex									
Male	197	3 (1.5)	NC [NC, NC]	181	16 (8.8)	NC [NC, NC]	0.162 [0.047, 0.555]	0.0009	0.7569
Female	42	1 (2.4)	NC [NC, NC]	55	5 (9.1)	NC [NC, NC]	0.233 [0.027, 2.001]	0.1480	
Metastases at Baseline									
Visceral metastases	169	2 (1.2)	NC [NC, NC]	157	14 (8.9)	NC [NC, NC]	0.127 [0.029, 0.557]	0.0012	0.3613
Lymph node only	60	2 (3.3)	NC [NC, NC]	65	6 (9.2)	NC [NC, NC]	0.317 [0.064, 1.571]	0.1375	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.165.1.1: Summary and Results of Severe TEAEs - Platelet count decreased (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	0 (0.0%)	12 (5.1%)	
Number of patients censored	239 (100.0%)	224 (94.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	100.0 [100.0, 100.0]	96.9 [93.7, 98.5]	
Month 6	100.0 [100.0, 100.0]	93.1 [87.1, 96.3]	
Month 9	100.0 [100.0, 100.0]	NC [NC, NC]	
Month 12	100.0 [100.0, 100.0]	NC [NC, NC]	
Month 18	100.0 [100.0, 100.0]	NC [NC, NC]	
Month 24	100.0 [100.0, 100.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			NC [NC, NC]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0002

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.165.1.2: Summary and Results of Severe TEAEs by Subgroups - Platelet count decreased (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	0 (0.0)		47	3 (6.4)				
Absent	192	0 (0.0)		189	9 (4.8)				
Age									
< 65 years	105	0 (0.0)	NC [NC, NC]	102	1 (1.0)	NC [NC, NC]	NC [NC, NC]	0.2885	NC
>= 65 years	134	0 (0.0)	NC [NC, NC]	134	11 (8.2)	NC [NC, NC]	NC [NC, NC]	0.0003	
Region									
Europe	97	0 (0.0)		101	4 (4.0)				
North America	57	0 (0.0)		51	4 (7.8)				
Rest of World	85	0 (0.0)		84	4 (4.8)				
Sex									
Male	197	0 (0.0)	NC [NC, NC]	181	10 (5.5)	NC [NC, NC]	NC [NC, NC]	0.0003	NC
Female	42	0 (0.0)	NC [NC, NC]	55	2 (3.6)	NC [NC, NC]	NC [NC, NC]	0.1947	
Metastases at Baseline									
Visceral metastases	169	0 (0.0)		157	7 (4.5)				
Lymph node only	60	0 (0.0)		65	4 (6.2)				

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.166.1.1: Summary and Results of Severe TEAEs - Metabolism and nutrition disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	41 (17.2%)	25 (10.6%)	
Number of patients censored	198 (82.8%)	211 (89.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	87.2 [82.2, 90.9]	90.5 [85.9, 93.6]	
Month 6	83.6 [78.1, 87.9]	88.8 [83.8, 92.3]	
Month 9	83.6 [78.1, 87.9]	NC [NC, NC]	
Month 12	81.8 [75.7, 86.5]	NC [NC, NC]	
Month 18	79.0 [71.5, 84.7]	NC [NC, NC]	
Month 24	79.0 [71.5, 84.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.375 [0.823, 2.299]
Log-rank test			
Two-sided unstratified log-rank p-value			0.2225

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.167.1.1: Summary and Results of Severe TEAEs - Hyperglycaemia (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	20 (8.4%)	2 (0.8%)	
Number of patients censored	219 (91.6%)	234 (99.2%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	94.0 [90.1, 96.4]	99.1 [96.6, 99.8]	
Month 6	93.0 [88.8, 95.7]	99.1 [96.6, 99.8]	
Month 9	93.0 [88.8, 95.7]	NC [NC, NC]	
Month 12	90.9 [85.5, 94.4]	NC [NC, NC]	
Month 18	87.9 [80.4, 92.6]	NC [NC, NC]	
Month 24	87.9 [80.4, 92.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			7.697 [1.765, 33.568]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0013

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.167.1.2: Summary and Results of Severe TEAEs by Subgroups - Hyperglycaemia (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	4 (8.5)	NC [NC, NC]	47	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.2428	NC
Absent	192	16 (8.3)	NC [NC, NC]	189	2 (1.1)	NC [NC, NC]	7.048 [1.602, 31.012]	0.0026	
Age									
< 65 years	105	13 (12.4)	NC [NC, NC]	102	2 (2.0)	NC [NC, NC]	4.191 [0.899, 19.545]	0.0477	NC
>= 65 years	134	7 (5.2)	NC [NC, NC]	134	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0084	
Region									
Europe	97	7 (7.2)	NC [NC, NC]	101	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0113	NC
North America	57	3 (5.3)	NC [NC, NC]	51	1 (2.0)	NC [NC, NC]	2.740 [0.285, 26.339]	0.3627	
Rest of World	85	10 (11.8)	NC [NC, NC]	84	1 (1.2)	NC [NC, NC]	6.303 [0.768, 51.732]	0.0501	
Sex									
Male	197	15 (7.6)	NC [NC, NC]	181	2 (1.1)	NC [NC, NC]	5.587 [1.251, 24.959]	0.0110	NC
Female	42	5 (11.9)	NC [NC, NC]	55	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0388	
Metastases at Baseline									
Visceral metastases	169	15 (8.9)	NC [NC, NC]	157	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0019	NC
Lymph node only	60	5 (8.3)	NC [NC, NC]	65	2 (3.1)	NC [NC, NC]	2.798 [0.543, 14.421]	0.1990	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.168.1.1: Summary and Results of Severe TEAEs - Hyponatraemia (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	7 (2.9%)	8 (3.4%)	
Number of patients censored	232 (97.1%)	228 (96.6%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.1 [93.9, 98.6]	96.5 [93.2, 98.2]	
Month 6	97.1 [93.9, 98.6]	96.5 [93.2, 98.2]	
Month 9	97.1 [93.9, 98.6]	NC [NC, NC]	
Month 12	97.1 [93.9, 98.6]	NC [NC, NC]	
Month 18	97.1 [93.9, 98.6]	NC [NC, NC]	
Month 24	97.1 [93.9, 98.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.865 [0.314, 2.386]
Log-rank test			
Two-sided unstratified log-rank p-value			0.7792

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.169.1.1: Summary and Results of Severe TEAEs - Musculoskeletal and connective tissue disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	10 (4.2%)	8 (3.4%)	
Number of patients censored	229 (95.8%)	228 (96.6%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.9 [95.0, 99.1]	96.8 [93.4, 98.5]	
Month 6	96.7 [93.2, 98.4]	96.2 [92.6, 98.1]	
Month 9	96.1 [92.2, 98.0]	NC [NC, NC]	
Month 12	95.3 [91.0, 97.6]	NC [NC, NC]	
Month 18	94.2 [89.0, 97.0]	NC [NC, NC]	
Month 24	94.2 [89.0, 97.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.627 [0.209, 1.880]
Log-rank test			
Two-sided unstratified log-rank p-value			0.4002

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.170.1.1: Summary and Results of Severe TEAEs - Nervous system disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	23 (9.6%)	5 (2.1%)	
Number of patients censored	216 (90.4%)	231 (97.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.7 [96.0, 99.6]	97.8 [94.9, 99.1]	
Month 6	93.9 [89.5, 96.5]	97.8 [94.9, 99.1]	
Month 9	90.8 [85.5, 94.2]	NC [NC, NC]	
Month 12	89.7 [84.0, 93.5]	NC [NC, NC]	
Month 18	84.9 [76.3, 90.6]	NC [NC, NC]	
Month 24	78.1 [64.3, 87.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.597 [0.535, 4.765]
Log-rank test			
Two-sided unstratified log-rank p-value			0.3978

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.171.1.1: Summary and Results of Severe TEAEs - Renal and urinary disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	16 (6.7%)	16 (6.8%)	
Number of patients censored	223 (93.3%)	220 (93.2%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.5 [93.2, 98.3]	94.7 [90.8, 96.9]	
Month 6	94.0 [89.8, 96.5]	91.5 [85.5, 95.0]	
Month 9	92.0 [87.2, 95.1]	NC [NC, NC]	
Month 12	92.0 [87.2, 95.1]	NC [NC, NC]	
Month 18	92.0 [87.2, 95.1]	NC [NC, NC]	
Month 24	92.0 [87.2, 95.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.690 [0.326, 1.461]
Log-rank test			
Two-sided unstratified log-rank p-value			0.3304

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.172.1.1: Summary and Results of Severe TEAEs - Acute kidney injury (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	8 (3.3%)	6 (2.5%)	
Number of patients censored	231 (96.7%)	230 (97.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.3 [95.5, 99.4]	97.4 [94.3, 98.8]	
Month 6	97.2 [93.8, 98.7]	97.4 [94.3, 98.8]	
Month 9	95.9 [91.9, 98.0]	NC [NC, NC]	
Month 12	95.9 [91.9, 98.0]	NC [NC, NC]	
Month 18	95.9 [91.9, 98.0]	NC [NC, NC]	
Month 24	95.9 [91.9, 98.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.823 [0.253, 2.680]
Log-rank test			
Two-sided unstratified log-rank p-value			0.7458

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.173.1.1: Summary and Results of Severe TEAEs - Respiratory, thoracic and mediastinal disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	**Plat+Gem (N= 236)**	**EV+Pembro vs. Plat+Gem**
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	24 (10.0%)	13 (5.5%)	
Number of patients censored	215 (90.0%)	223 (94.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	95.2 [91.5, 97.3]	94.2 [90.1, 96.6]	
Month 6	92.2 [87.6, 95.1]	94.2 [90.1, 96.6]	
Month 9	89.7 [84.6, 93.2]	NC [NC, NC]	
Month 12	88.2 [82.6, 92.1]	NC [NC, NC]	
Month 18	88.2 [82.6, 92.1]	NC [NC, NC]	
Month 24	84.2 [72.8, 91.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.134 [0.546, 2.358]
Log-rank test			
Two-sided unstratified log-rank p-value			0.7349

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.174.1.1: Summary and Results of Severe TEAEs - Pulmonary embolism (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	5 (2.1%)	10 (4.2%)	
Number of patients censored	234 (97.9%)	226 (95.8%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	99.1 [96.6, 99.8]	95.5 [91.8, 97.6]	
Month 6	98.6 [95.8, 99.6]	95.5 [91.8, 97.6]	
Month 9	98.0 [94.8, 99.3]	NC [NC, NC]	
Month 12	98.0 [94.8, 99.3]	NC [NC, NC]	
Month 18	98.0 [94.8, 99.3]	NC [NC, NC]	
Month 24	93.6 [76.3, 98.4]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.296 [0.083, 1.052]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0463

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.174.1.2: Summary and Results of Severe TEAEs by Subgroups - Pulmonary embolism (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	1 (2.1)	NC [21.0, NC]	47	2 (4.3)	NC [NC, NC]	0.000 [0.000, NC]	0.1648	0.8929
Absent	192	4 (2.1)	NC [NC, NC]	189	8 (4.2)	NC [NC, NC]	0.366 [0.099, 1.348]	0.1163	
Age									
< 65 years	105	3 (2.9)		102	6 (5.9)				
>= 65 years	134	2 (1.5)		134	4 (3.0)				
Region									
Europe	97	1 (1.0)		101	3 (3.0)				
North America	57	3 (5.3)		51	5 (9.8)				
Rest of World	85	1 (1.2)		84	2 (2.4)				
Sex									
Male	197	5 (2.5)	NC [NC, NC]	181	10 (5.5)	NC [NC, NC]	0.269 [0.075, 0.968]	0.0313	NC
Female	42	0 (0.0)	NC [NC, NC]	55	0 (0.0)	NC [NC, NC]	NC [NC, NC]	NC	
Metastases at Baseline									
Visceral metastases	169	4 (2.4)	NC [NC, NC]	157	6 (3.8)	NC [NC, NC]	0.306 [0.063, 1.485]	0.1206	0.6531
Lymph node only	60	1 (1.7)	NC [NC, NC]	65	3 (4.6)	NC [NC, NC]	0.358 [0.037, 3.439]	0.3523	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.175.1.1: Summary and Results of Severe TEAEs - Skin and subcutaneous tissue disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	39 (16.3%)	0 (0.0%)	
Number of patients censored	200 (83.7%)	236 (100.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	90.1 [85.5, 93.3]	100.0 [100.0, 100.0]	
Month 6	86.9 [81.7, 90.8]	100.0 [100.0, 100.0]	
Month 9	84.5 [78.8, 88.8]	NC [NC, NC]	
Month 12	82.2 [75.9, 87.0]	NC [NC, NC]	
Month 18	77.8 [69.7, 84.0]	NC [NC, NC]	
Month 24	77.8 [69.7, 84.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			NC [NC, NC]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.175.1.2: Summary and Results of Severe TEAEs by Subgroups - Skin and subcutaneous tissue disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	6 (12.8)	NC [NC, NC]	47	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0220	NC
Absent	192	33 (17.2)	NC [NC, NC]	189	0 (0.0)	NC [NC, NC]	NC [NC, NC]	<.0001	
Age									
< 65 years	105	15 (14.3)	NC [NC, NC]	102	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0017	NC
>= 65 years	134	24 (17.9)	NC [NC, NC]	134	0 (0.0)	NC [NC, NC]	NC [NC, NC]	<.0001	
Region									
Europe	97	14 (14.4)	NC [NC, NC]	101	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0027	NC
North America	57	7 (12.3)	NC [NC, NC]	51	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0553	
Rest of World	85	18 (21.2)	NC [NC, NC]	84	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0001	
Sex									
Male	197	34 (17.3)	NC [NC, NC]	181	0 (0.0)	NC [NC, NC]	NC [NC, NC]	<.0001	NC
Female	42	5 (11.9)	NC [NC, NC]	55	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0273	
Metastases at Baseline									
Visceral metastases	169	28 (16.6)	NC [NC, NC]	157	0 (0.0)	NC [NC, NC]	NC [NC, NC]	<.0001	NC
Lymph node only	60	11 (18.3)	NC [NC, NC]	65	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0156	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.176.1.1: Summary and Results of Severe TEAEs - Rash maculo-papular (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	16 (6.7%)	0 (0.0%)	
Number of patients censored	223 (93.3%)	236 (100.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	95.7 [92.2, 97.7]	100.0 [100.0, 100.0]	
Month 6	95.2 [91.5, 97.3]	100.0 [100.0, 100.0]	
Month 9	94.0 [89.8, 96.5]	NC [NC, NC]	
Month 12	93.2 [88.7, 96.0]	NC [NC, NC]	
Month 18	90.3 [83.4, 94.4]	NC [NC, NC]	
Month 24	90.3 [83.4, 94.4]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			NC [NC, NC]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0010

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.176.1.2: Summary and Results of Severe TEAEs by Subgroups - Rash maculo-papular (PT) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	2 (4.3)	NC [NC, NC]	47	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1551	NC
Absent	192	14 (7.3)	NC [NC, NC]	189	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0030	
Age									
< 65 years	105	4 (3.8)	NC [NC, NC]	102	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1659	NC
>= 65 years	134	12 (9.0)	NC [NC, NC]	134	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0026	
Region									
Europe	97	3 (3.1)		101	0 (0.0)				
North America	57	5 (8.8)		51	0 (0.0)				
Rest of World	85	8 (9.4)		84	0 (0.0)				
Sex									
Male	197	14 (7.1)	NC [NC, NC]	181	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0024	NC
Female	42	2 (4.8)	NC [NC, NC]	55	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.2538	
Metastases at Baseline									
Visceral metastases	169	13 (7.7)	NC [NC, NC]	157	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0037	NC
Lymph node only	60	3 (5.0)	NC [NC, NC]	65	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1394	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.177.1.1: Summary and Results of Severe TEAEs - Vascular disorders (SOC) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	9 (3.8%)	8 (3.4%)	
Number of patients censored	230 (96.2%)	228 (96.6%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.3 [95.5, 99.4]	96.9 [93.6, 98.5]	
Month 6	97.8 [94.8, 99.1]	96.4 [92.9, 98.2]	
Month 9	96.5 [92.6, 98.3]	NC [NC, NC]	
Month 12	95.6 [91.3, 97.9]	NC [NC, NC]	
Month 18	94.2 [88.3, 97.2]	NC [NC, NC]	
Month 24	94.2 [88.3, 97.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.603 [0.197, 1.845]
Log-rank test			
Two-sided unstratified log-rank p-value			0.3708

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.178.1.1: Summary and Results of Severe TEAEs - Hypertension (PT) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	5 (2.1%)	5 (2.1%)	
Number of patients censored	234 (97.9%)	231 (97.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	99.1 [96.6, 99.8]	98.2 [95.2, 99.3]	
Month 6	98.6 [95.9, 99.6]	97.7 [94.5, 99.0]	
Month 9	98.0 [94.7, 99.3]	NC [NC, NC]	
Month 12	98.0 [94.7, 99.3]	NC [NC, NC]	
Month 18	96.5 [90.8, 98.7]	NC [NC, NC]	
Month 24	96.5 [90.8, 98.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.580 [0.138, 2.425]
Log-rank test			
Two-sided unstratified log-rank p-value			0.4495

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.179.1.1: Summary and Results of TEAESI - Immune related and infusion reactions - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	104 (43.5%)	10 (4.2%)	
Number of patients censored	135 (56.5%)	226 (95.8%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	75.9 [69.9, 80.9]	96.4 [92.9, 98.2]	
Month 6	61.6 [54.7, 67.7]	95.4 [91.6, 97.5]	
Month 9	54.2 [47.0, 60.8]	NC [NC, NC]	
Month 12	51.8 [44.5, 58.7]	NC [NC, NC]	
Month 18	48.1 [40.1, 55.7]	NC [NC, NC]	
Month 24	45.9 [37.2, 54.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	12.6 [7.2, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			8.888 [4.607, 17.145]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.179.1.2: Summary and Results of TEAESI by Subgroups - Immune related and infusion reactions - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	18 (38.3)	NC [4.2, NC]	47	2 (4.3)	NC [NC, NC]	9.669 [2.222, 42.087]	0.0002	0.9942
Absent	192	86 (44.8)	12.6 [7.0, NC]	189	8 (4.2)	NC [NC, NC]	8.628 [4.139, 17.984]	<.0001	
Age									
< 65 years	105	37 (35.2)	NC [12.6, NC]	102	5 (4.9)	NC [NC, NC]	6.223 [2.412, 16.058]	<.0001	0.2727
>= 65 years	134	67 (50.0)	7.7 [4.8, 18.9]	134	5 (3.7)	NC [NC, NC]	11.661 [4.655, 29.210]	<.0001	
Region									
Europe	97	38 (39.2)	18.9 [7.0, NC]	101	4 (4.0)	NC [NC, NC]	8.922 [3.148, 25.285]	<.0001	0.1772
North America	57	27 (47.4)	9.4 [3.9, NC]	51	5 (9.8)	NC [NC, NC]	4.254 [1.600, 11.306]	0.0016	
Rest of World	85	39 (45.9)	12.6 [6.4, NC]	84	1 (1.2)	NC [NC, NC]	31.416 [4.280, 230.61]	<.0001	
Sex									
Male	197	86 (43.7)	12.6 [7.0, NC]	181	7 (3.9)	NC [NC, NC]	9.566 [4.388, 20.850]	<.0001	0.6833
Female	42	18 (42.9)	NC [4.2, NC]	55	3 (5.5)	NC [NC, NC]	7.398 [2.140, 25.583]	0.0002	
Metastases at Baseline									
Visceral metastases	169	75 (44.4)	9.4 [6.1, NC]	157	7 (4.5)	NC [NC, NC]	8.680 [3.963, 19.010]	<.0001	0.6890
Lymph node only	60	23 (38.3)	NC [7.2, NC]	65	3 (4.6)	NC [NC, NC]	6.769 [1.986, 23.067]	0.0004	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.180.1.1: Summary and Results of TEAESI - Peripheral neuropathy - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	162 (67.8%)	43 (18.2%)	
Number of patients censored	77 (32.2%)	193 (81.8%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	66.0 [59.4, 71.8]	87.1 [81.9, 90.9]	
Month 6	36.1 [29.4, 42.8]	77.3 [69.2, 83.5]	
Month 9	21.5 [15.6, 28.1]	NC [NC, NC]	
Month 12	21.5 [15.6, 28.1]	NC [NC, NC]	
Month 18	7.7 [2.3, 17.7]	NC [NC, NC]	
Month 24	7.7 [2.3, 17.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	4.4 [3.5, 5.1]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			3.297 [2.330, 4.666]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.180.1.2: Summary and Results of TEAESI by Subgroups - Peripheral neuropathy - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	24 (51.1)	4.4 [3.3, 8.4]	47	10 (21.3)	NC [NC, NC]	2.630 [1.238, 5.589]	0.0092	0.3155
Absent	192	138 (71.9)	4.2 [3.4, 5.1]	189	33 (17.5)	NC [NC, NC]	3.483 [2.352, 5.159]	<.0001	
Age									
< 65 years	105	73 (69.5)	4.5 [3.4, 5.6]	102	22 (21.6)	NC [NC, NC]	2.617 [1.593, 4.300]	<.0001	0.1767
>= 65 years	134	89 (66.4)	4.2 [3.3, 5.4]	134	21 (15.7)	NC [NC, NC]	4.031 [2.474, 6.569]	<.0001	
Region									
Europe	97	66 (68.0)	3.8 [3.1, 5.1]	101	14 (13.9)	NC [NC, NC]	5.081 [2.813, 9.177]	<.0001	0.1742
North America	57	45 (78.9)	3.3 [2.4, 5.3]	51	14 (27.5)	NC [NC, NC]	2.281 [1.219, 4.269]	0.0081	
Rest of World	85	51 (60.0)	5.6 [4.2, 8.8]	84	15 (17.9)	NC [NC, NC]	2.627 [1.442, 4.786]	0.0011	
Sex									
Male	197	134 (68.0)	4.3 [3.4, 5.1]	181	34 (18.8)	NC [NC, NC]	3.215 [2.179, 4.742]	<.0001	0.9869
Female	42	28 (66.7)	4.5 [3.3, 8.1]	55	9 (16.4)	NC [NC, NC]	3.423 [1.568, 7.475]	0.0010	
Metastases at Baseline									
Visceral metastases	169	112 (66.3)	4.4 [3.5, 5.4]	157	31 (19.7)	NC [NC, NC]	2.921 [1.937, 4.407]	<.0001	0.4050
Lymph node only	60	43 (71.7)	4.2 [3.1, 6.2]	65	10 (15.4)	NC [NC, NC]	3.909 [1.909, 8.003]	<.0001	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.181.1.1: Summary and Results of TEAESI - Ocular disorders - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	79 (33.1%)	8 (3.4%)	
Number of patients censored	160 (66.9%)	228 (96.6%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	80.1 [74.3, 84.7]	96.4 [93.0, 98.2]	
Month 6	69.7 [63.0, 75.4]	96.4 [93.0, 98.2]	
Month 9	65.1 [58.0, 71.3]	NC [NC, NC]	
Month 12	64.3 [57.1, 70.6]	NC [NC, NC]	
Month 18	56.7 [47.4, 65.0]	NC [NC, NC]	
Month 24	56.7 [47.4, 65.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [17.8, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			8.237 [3.944, 17.199]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.181.1.2: Summary and Results of TEAESI by Subgroups - Ocular disorders - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	21 (44.7)	6.0 [4.3, NC]	47	1 (2.1)	NC [NC, NC]	21.786 [2.911, 163.07]	<.0001	0.2860
Absent	192	58 (30.2)	NC [NC, NC]	189	7 (3.7)	NC [NC, NC]	6.586 [2.966, 14.622]	<.0001	
Age									
< 65 years	105	31 (29.5)	NC [NC, NC]	102	2 (2.0)	NC [NC, NC]	10.911 [2.562, 46.472]	<.0001	0.5104
>= 65 years	134	48 (35.8)	NC [12.6, NC]	134	6 (4.5)	NC [NC, NC]	7.439 [3.156, 17.532]	<.0001	
Region									
Europe	97	32 (33.0)	NC [12.3, NC]	101	2 (2.0)	NC [NC, NC]	13.156 [3.106, 55.722]	<.0001	0.5446
North America	57	31 (54.4)	4.4 [3.0, NC]	51	5 (9.8)	NC [NC, NC]	6.262 [2.417, 16.223]	<.0001	
Rest of World	85	16 (18.8)	NC [NC, NC]	84	1 (1.2)	NC [NC, NC]	9.659 [1.240, 75.247]	0.0082	
Sex									
Male	197	63 (32.0)	NC [17.8, NC]	181	5 (2.8)	NC [NC, NC]	9.715 [3.870, 24.392]	<.0001	0.5268
Female	42	16 (38.1)	NC [4.9, NC]	55	3 (5.5)	NC [NC, NC]	6.012 [1.724, 20.973]	0.0014	
Metastases at Baseline									
Visceral metastases	169	59 (34.9)	NC [12.6, NC]	157	3 (1.9)	NC [NC, NC]	15.645 [4.869, 50.271]	<.0001	0.0303
Lymph node only	60	17 (28.3)	NC [17.8, NC]	65	5 (7.7)	NC [NC, NC]	2.989 [1.065, 8.384]	0.0289	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.182.1.1: Summary and Results of TEAESI - Hyperglycemia - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	53 (22.2%)	8 (3.4%)	
Number of patients censored	186 (77.8%)	228 (96.6%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	83.5 [78.1, 87.7]	96.5 [93.0, 98.2]	
Month 6	80.4 [74.6, 85.0]	96.5 [93.0, 98.2]	
Month 9	77.6 [71.4, 82.7]	NC [NC, NC]	
Month 12	76.8 [70.3, 82.0]	NC [NC, NC]	
Month 18	71.3 [62.3, 78.5]	NC [NC, NC]	
Month 24	71.3 [62.3, 78.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			5.722 [2.691, 12.165]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.182.1.2: Summary and Results of TEAESI by Subgroups - Hyperglycemia - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	9 (19.1)	NC [NC, NC]	47	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0094	NC
Absent	192	44 (22.9)	NC [NC, NC]	189	8 (4.2)	NC [NC, NC]	4.860 [2.262, 10.443]	<.0001	
Age									
< 65 years	105	23 (21.9)	NC [NC, NC]	102	6 (5.9)	NC [NC, NC]	3.004 [1.189, 7.591]	0.0146	0.0887
>= 65 years	134	30 (22.4)	NC [NC, NC]	134	2 (1.5)	NC [NC, NC]	13.861 [3.288, 58.430]	<.0001	
Region									
Europe	97	23 (23.7)	NC [NC, NC]	101	4 (4.0)	NC [NC, NC]	5.473 [1.862, 16.090]	0.0005	0.9256
North America	57	6 (10.5)	NC [NC, NC]	51	1 (2.0)	NC [NC, NC]	5.546 [0.668, 46.050]	0.0734	
Rest of World	85	24 (28.2)	NC [NC, NC]	84	3 (3.6)	NC [NC, NC]	6.415 [1.892, 21.752]	0.0006	
Sex									
Male	197	45 (22.8)	NC [NC, NC]	181	6 (3.3)	NC [NC, NC]	5.885 [2.479, 13.970]	<.0001	0.7831
Female	42	8 (19.0)	NC [NC, NC]	55	2 (3.6)	NC [NC, NC]	5.158 [1.085, 24.515]	0.0219	
Metastases at Baseline									
Visceral metastases	169	32 (18.9)	NC [NC, NC]	157	4 (2.5)	NC [NC, NC]	6.252 [2.179, 17.940]	<.0001	0.8425
Lymph node only	60	17 (28.3)	NC [16.8, NC]	65	3 (4.6)	NC [NC, NC]	5.700 [1.637, 19.840]	0.0020	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.183.1.1: Summary and Results of TEAESI - Skin reactions - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	165 (69.0%)	38 (16.1%)	
Number of patients censored	74 (31.0%)	198 (83.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	42.4 [35.9, 48.6]	84.4 [79.1, 88.5]	
Month 6	28.7 [22.7, 35.1]	82.7 [76.6, 87.3]	
Month 9	25.6 [19.6, 32.1]	NC [NC, NC]	
Month 12	22.9 [16.6, 29.8]	NC [NC, NC]	
Month 18	22.9 [16.6, 29.8]	NC [NC, NC]	
Month 24	22.9 [16.6, 29.8]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	2.0 [1.0, 3.0]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			5.608 [3.928, 8.006]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.183.1.2: Summary and Results of TEAESI by Subgroups - Skin reactions - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	33 (70.2)	2.3 [0.5, 5.0]	47	8 (17.0)	NC [NC, NC]	5.044 [2.313, 10.999]	<.0001	0.8709
Absent	192	132 (68.8)	1.8 [1.0, 3.0]	189	30 (15.9)	NC [NC, NC]	5.786 [3.878, 8.631]	<.0001	
Age									
< 65 years	105	72 (68.6)	2.6 [1.4, 4.5]	102	8 (7.8)	NC [NC, NC]	10.807 [5.177, 22.563]	<.0001	0.0228
>= 65 years	134	93 (69.4)	1.2 [0.5, 2.3]	134	30 (22.4)	NC [NC, NC]	4.265 [2.816, 6.460]	<.0001	
Region									
Europe	97	62 (63.9)	3.3 [1.6, 5.0]	101	16 (15.8)	NC [NC, NC]	4.666 [2.673, 8.144]	<.0001	0.6513
North America	57	39 (68.4)	1.6 [0.5, 3.9]	51	9 (17.6)	NC [NC, NC]	5.285 [2.545, 10.976]	<.0001	
Rest of World	85	64 (75.3)	1.0 [0.5, 2.0]	84	13 (15.5)	NC [NC, NC]	6.956 [3.813, 12.688]	<.0001	
Sex									
Male	197	134 (68.0)	2.3 [1.4, 3.7]	181	30 (16.6)	NC [NC, NC]	5.154 [3.456, 7.686]	<.0001	0.2827
Female	42	31 (73.8)	0.5 [0.4, 2.0]	55	8 (14.5)	NC [NC, NC]	7.869 [3.576, 17.315]	<.0001	
Metastases at Baseline									
Visceral metastases	169	111 (65.7)	2.6 [1.4, 3.9]	157	28 (17.8)	NC [NC, NC]	4.623 [3.044, 7.021]	<.0001	0.1284
Lymph node only	60	46 (76.7)	0.7 [0.4, 2.2]	65	9 (13.8)	NC [NC, NC]	8.037 [3.903, 16.549]	<.0001	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.184.1.1: Summary and Results of TEAESI - Infusion related reactions (IRR) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	**Plat+Gem (N= 236)**	**EV+Pembro vs. Plat+Gem**
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	8 (3.3%)	4 (1.7%)	
Number of patients censored	231 (96.7%)	232 (98.3%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	99.2 [96.7, 99.8]	98.6 [95.8, 99.6]	
Month 6	98.1 [94.9, 99.3]	98.1 [95.0, 99.3]	
Month 9	97.4 [93.8, 98.9]	NC [NC, NC]	
Month 12	96.6 [92.5, 98.5]	NC [NC, NC]	
Month 18	93.0 [84.5, 96.9]	NC [NC, NC]	
Month 24	93.0 [84.5, 96.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.743 [0.171, 3.235]
Log-rank test			
Two-sided unstratified log-rank p-value			0.6914

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.184.1.2: Summary and Results of TEAESI by Subgroups - Infusion related reactions (IRR) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	1 (2.1)	NC [14.9, NC]	47	1 (2.1)	NC [NC, NC]	0.000 [0.000, NC]	0.3300	0.6913
Absent	192	7 (3.6)	NC [NC, NC]	189	3 (1.6)	NC [NC, NC]	0.982 [0.202, 4.768]	0.9817	
Age									
< 65 years	105	4 (3.8)		102	3 (2.9)				
>= 65 years	134	4 (3.0)		134	1 (0.7)				
Region									
Europe	97	1 (1.0)		101	1 (1.0)				
North America	57	6 (10.5)		51	3 (5.9)				
Rest of World	85	1 (1.2)		84	0 (0.0)				
Sex									
Male	197	6 (3.0)	NC [NC, NC]	181	4 (2.2)	NC [NC, NC]	0.687 [0.157, 3.001]	0.6158	NC
Female	42	2 (4.8)	NC [14.9, NC]	55	0 (0.0)	NC [NC, NC]	NC [NC, NC]	NC	
Metastases at Baseline									
Visceral metastases	169	6 (3.6)	NC [NC, NC]	157	4 (2.5)	NC [NC, NC]	0.701 [0.161, 3.053]	0.6339	NC
Lymph node only	60	1 (1.7)	NC [NC, NC]	65	0 (0.0)	NC [NC, NC]	NC [NC, NC]	NC	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.185.1.1: Summary and Results of Non-Severe TEAESI (CTCAE Grade < 3) - Immune related and infusion reactions - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	84 (35.1%)	7 (3.0%)	
Number of patients censored	155 (64.9%)	229 (97.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	82.7 [77.1, 87.0]	97.8 [94.7, 99.1]	
Month 6	68.9 [62.2, 74.7]	96.8 [93.3, 98.4]	
Month 9	62.5 [55.3, 68.9]	NC [NC, NC]	
Month 12	59.9 [52.3, 66.6]	NC [NC, NC]	
Month 18	55.0 [46.1, 63.1]	NC [NC, NC]	
Month 24	52.8 [43.1, 61.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [16.6, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			9.285 [4.251, 20.281]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.185.1.2: Summary and Results of Non-Severe TEAESI (CTCAE Grade < 3) by Subgroups - Immune related and infusion reactions - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	15 (31.9)	NC [6.4, NC]	47	1 (2.1)	NC [NC, NC]	14.296 [1.866, 109.54]	0.0007	0.6809
Absent	192	69 (35.9)	NC [12.6, NC]	189	6 (3.2)	NC [NC, NC]	8.422 [3.610, 19.648]	<.0001	
Age									
< 65 years	105	30 (28.6)	NC [NC, NC]	102	5 (4.9)	NC [NC, NC]	5.262 [2.017, 13.729]	0.0001	0.0658
>= 65 years	134	54 (40.3)	17.6 [7.2, NC]	134	2 (1.5)	NC [NC, NC]	19.322 [4.656, 80.189]	<.0001	
Region									
Europe	97	31 (32.0)	NC [17.6, NC]	101	2 (2.0)	NC [NC, NC]	13.409 [3.167, 56.761]	<.0001	0.1500
North America	57	20 (35.1)	NC [6.2, NC]	51	4 (7.8)	NC [NC, NC]	4.024 [1.350, 11.991]	0.0069	
Rest of World	85	33 (38.8)	NC [8.7, NC]	84	1 (1.2)	NC [NC, NC]	21.802 [2.936, 161.88]	<.0001	
Sex									
Male	197	69 (35.0)	NC [16.6, NC]	181	6 (3.3)	NC [NC, NC]	7.885 [3.379, 18.401]	<.0001	0.5194
Female	42	15 (35.7)	NC [7.7, NC]	55	1 (1.8)	NC [NC, NC]	18.320 [2.392, 140.28]	0.0001	
Metastases at Baseline									
Visceral metastases	169	61 (36.1)	NC [11.6, NC]	157	5 (3.2)	NC [NC, NC]	8.747 [3.471, 22.039]	<.0001	0.7453
Lymph node only	60	17 (28.3)	NC [18.9, NC]	65	2 (3.1)	NC [NC, NC]	6.983 [1.567, 31.128]	0.0031	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.186.1.1: Summary and Results of Non-Severe TEAESI (CTCAE Grade < 3) - Peripheral neuropathy - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	160 (66.9%)	43 (18.2%)	
Number of patients censored	79 (33.1%)	193 (81.8%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	66.4 [59.8, 72.1]	87.1 [81.9, 90.9]	
Month 6	36.9 [30.1, 43.6]	77.3 [69.2, 83.5]	
Month 9	22.0 [15.9, 28.7]	NC [NC, NC]	
Month 12	22.0 [15.9, 28.7]	NC [NC, NC]	
Month 18	7.9 [2.3, 18.1]	NC [NC, NC]	
Month 24	7.9 [2.3, 18.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	4.4 [3.5, 5.3]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			3.266 [2.307, 4.624]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.186.1.2: Summary and Results of Non-Severe TEAESI (CTCAE Grade < 3) by Subgroups - Peripheral neuropathy - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	23 (48.9)	4.5 [3.3, NC]	47	10 (21.3)	NC [NC, NC]	2.517 [1.177, 5.381]	0.0139	0.2764
Absent	192	137 (71.4)	4.2 [3.4, 5.1]	189	33 (17.5)	NC [NC, NC]	3.478 [2.348, 5.152]	<.0001	
Age									
< 65 years	105	72 (68.6)	4.6 [3.4, 5.6]	102	22 (21.6)	NC [NC, NC]	2.570 [1.562, 4.228]	0.0001	0.1747
>= 65 years	134	88 (65.7)	4.2 [3.3, 5.4]	134	21 (15.7)	NC [NC, NC]	4.022 [2.468, 6.555]	<.0001	
Region									
Europe	97	66 (68.0)	3.8 [3.1, 5.1]	101	14 (13.9)	NC [NC, NC]	5.081 [2.813, 9.177]	<.0001	0.1527
North America	57	43 (75.4)	3.3 [2.4, 5.3]	51	14 (27.5)	NC [NC, NC]	2.211 [1.178, 4.151]	0.0113	
Rest of World	85	51 (60.0)	5.6 [4.2, 8.8]	84	15 (17.9)	NC [NC, NC]	2.627 [1.442, 4.786]	0.0011	
Sex									
Male	197	132 (67.0)	4.4 [3.4, 5.3]	181	34 (18.8)	NC [NC, NC]	3.179 [2.154, 4.692]	<.0001	0.9829
Female	42	28 (66.7)	4.5 [3.3, 8.1]	55	9 (16.4)	NC [NC, NC]	3.423 [1.568, 7.475]	0.0010	
Metastases at Baseline									
Visceral metastases	169	110 (65.1)	4.4 [3.6, 5.4]	157	31 (19.7)	NC [NC, NC]	2.882 [1.909, 4.351]	<.0001	0.3772
Lymph node only	60	43 (71.7)	4.2 [3.1, 6.2]	65	10 (15.4)	NC [NC, NC]	3.909 [1.909, 8.003]	<.0001	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.187.1.1: Summary and Results of Non-Severe TEAESI (CTCAE Grade < 3) - Ocular disorders - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	79 (33.1%)	8 (3.4%)	
Number of patients censored	160 (66.9%)	228 (96.6%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	80.1 [74.3, 84.7]	96.4 [93.0, 98.2]	
Month 6	69.7 [63.0, 75.4]	96.4 [93.0, 98.2]	
Month 9	65.1 [58.0, 71.3]	NC [NC, NC]	
Month 12	64.3 [57.1, 70.6]	NC [NC, NC]	
Month 18	56.7 [47.4, 65.0]	NC [NC, NC]	
Month 24	56.7 [47.4, 65.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [17.8, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			8.237 [3.944, 17.199]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.187.1.2: Summary and Results of Non-Severe TEAESI (CTCAE Grade < 3) by Subgroups - Ocular disorders - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	21 (44.7)	6.0 [4.3, NC]	47	1 (2.1)	NC [NC, NC]	21.786 [2.911, 163.07]	<.0001	0.2860
Absent	192	58 (30.2)	NC [NC, NC]	189	7 (3.7)	NC [NC, NC]	6.586 [2.966, 14.622]	<.0001	
Age									
< 65 years	105	31 (29.5)	NC [NC, NC]	102	2 (2.0)	NC [NC, NC]	10.911 [2.562, 46.472]	<.0001	0.5104
>= 65 years	134	48 (35.8)	NC [12.6, NC]	134	6 (4.5)	NC [NC, NC]	7.439 [3.156, 17.532]	<.0001	
Region									
Europe	97	32 (33.0)	NC [12.3, NC]	101	2 (2.0)	NC [NC, NC]	13.156 [3.106, 55.722]	<.0001	0.5446
North America	57	31 (54.4)	4.4 [3.0, NC]	51	5 (9.8)	NC [NC, NC]	6.262 [2.417, 16.223]	<.0001	
Rest of World	85	16 (18.8)	NC [NC, NC]	84	1 (1.2)	NC [NC, NC]	9.659 [1.240, 75.247]	0.0082	
Sex									
Male	197	63 (32.0)	NC [17.8, NC]	181	5 (2.8)	NC [NC, NC]	9.715 [3.870, 24.392]	<.0001	0.5268
Female	42	16 (38.1)	NC [4.9, NC]	55	3 (5.5)	NC [NC, NC]	6.012 [1.724, 20.973]	0.0014	
Metastases at Baseline									
Visceral metastases	169	59 (34.9)	NC [12.6, NC]	157	3 (1.9)	NC [NC, NC]	15.645 [4.869, 50.271]	<.0001	0.0303
Lymph node only	60	17 (28.3)	NC [17.8, NC]	65	5 (7.7)	NC [NC, NC]	2.989 [1.065, 8.384]	0.0289	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.188.1.1: Summary and Results of Non-Severe TEAESI (CTCAE Grade < 3) - Hyperglycemia - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	46 (19.2%)	6 (2.5%)	
Number of patients censored	193 (80.8%)	230 (97.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	87.3 [82.3, 90.9]	97.3 [94.1, 98.8]	
Month 6	83.7 [78.2, 87.9]	97.3 [94.1, 98.8]	
Month 9	80.9 [74.8, 85.7]	NC [NC, NC]	
Month 12	80.0 [73.7, 85.0]	NC [NC, NC]	
Month 18	74.5 [65.4, 81.5]	NC [NC, NC]	
Month 24	68.3 [52.3, 79.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			6.116 [2.577, 14.516]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.188.1.2: Summary and Results of Non-Severe TEAESI (CTCAE Grade < 3) by Subgroups - Hyperglycemia - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	8 (17.0)	NC [NC, NC]	47	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0097	NC
Absent	192	38 (19.8)	NC [23.0, NC]	189	6 (3.2)	NC [NC, NC]	4.972 [2.066, 11.965]	<.0001	
Age									
< 65 years	105	19 (18.1)	NC [NC, NC]	102	4 (3.9)	NC [NC, NC]	3.229 [1.055, 9.884]	0.0300	0.2045
>= 65 years	134	27 (20.1)	NC [23.0, NC]	134	2 (1.5)	NC [NC, NC]	11.944 [2.814, 50.701]	<.0001	
Region									
Europe	97	18 (18.6)	NC [NC, NC]	101	4 (4.0)	NC [NC, NC]	4.215 [1.399, 12.702]	0.0054	NC
North America	57	6 (10.5)	NC [23.0, NC]	51	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0328	
Rest of World	85	22 (25.9)	NC [NC, NC]	84	2 (2.4)	NC [NC, NC]	7.962 [1.830, 34.638]	0.0011	
Sex									
Male	197	39 (19.8)	NC [NC, NC]	181	4 (2.2)	NC [NC, NC]	7.009 [2.466, 19.921]	<.0001	0.5166
Female	42	7 (16.7)	NC [NC, NC]	55	2 (3.6)	NC [NC, NC]	4.408 [0.904, 21.497]	0.0456	
Metastases at Baseline									
Visceral metastases	169	27 (16.0)	NC [NC, NC]	157	4 (2.5)	NC [NC, NC]	4.901 [1.678, 14.312]	0.0013	0.4027
Lymph node only	60	15 (25.0)	NC [16.8, NC]	65	1 (1.5)	NC [NC, NC]	13.303 [1.726, 102.54]	0.0012	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.189.1.1: Summary and Results of Non-Severe TEAESI (CTCAE Grade < 3) - Skin reactions - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	164 (68.6%)	38 (16.1%)	
Number of patients censored	75 (31.4%)	198 (83.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	43.3 [36.8, 49.5]	84.4 [79.1, 88.5]	
Month 6	29.2 [23.1, 35.6]	82.7 [76.6, 87.3]	
Month 9	26.1 [20.0, 32.6]	NC [NC, NC]	
Month 12	23.5 [17.2, 30.4]	NC [NC, NC]	
Month 18	23.5 [17.2, 30.4]	NC [NC, NC]	
Month 24	23.5 [17.2, 30.4]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	2.0 [1.1, 3.0]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			5.530 [3.873, 7.897]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.189.1.2: Summary and Results of Non-Severe TEAESI (CTCAE Grade < 3) by Subgroups - Skin reactions - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	33 (70.2)	2.3 [0.5, 5.0]	47	8 (17.0)	NC [NC, NC]	5.044 [2.313, 10.999]	<.0001	0.9147
Absent	192	131 (68.2)	2.0 [1.0, 3.0]	189	30 (15.9)	NC [NC, NC]	5.684 [3.809, 8.481]	<.0001	
Age									
< 65 years	105	71 (67.6)	2.6 [1.4, 4.6]	102	8 (7.8)	NC [NC, NC]	10.538 [5.045, 22.013]	<.0001	0.0244
>= 65 years	134	93 (69.4)	1.3 [0.6, 2.3]	134	30 (22.4)	NC [NC, NC]	4.233 [2.795, 6.411]	<.0001	
Region									
Europe	97	61 (62.9)	3.4 [1.6, 5.1]	101	16 (15.8)	NC [NC, NC]	4.546 [2.602, 7.945]	<.0001	0.6456
North America	57	39 (68.4)	1.6 [0.6, 3.9]	51	9 (17.6)	NC [NC, NC]	5.274 [2.539, 10.952]	<.0001	
Rest of World	85	64 (75.3)	1.1 [0.5, 2.2]	84	13 (15.5)	NC [NC, NC]	6.915 [3.791, 12.614]	<.0001	
Sex									
Male	197	133 (67.5)	2.4 [1.4, 3.7]	181	30 (16.6)	NC [NC, NC]	5.064 [3.395, 7.555]	<.0001	0.2550
Female	42	31 (73.8)	0.5 [0.4, 2.0]	55	8 (14.5)	NC [NC, NC]	7.869 [3.576, 17.315]	<.0001	
Metastases at Baseline									
Visceral metastases	169	110 (65.1)	2.5 [1.4, 3.9]	157	28 (17.8)	NC [NC, NC]	4.539 [2.987, 6.896]	<.0001	0.1231
Lymph node only	60	46 (76.7)	0.7 [0.4, 2.2]	65	9 (13.8)	NC [NC, NC]	8.001 [3.886, 16.475]	<.0001	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.190.1.1: Summary and Results of Non-Severe TEAESI (CTCAE Grade < 3) - Infusion related reactions (IRR) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	8 (3.3%)	4 (1.7%)	
Number of patients censored	231 (96.7%)	232 (98.3%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	99.2 [96.7, 99.8]	98.6 [95.8, 99.6]	
Month 6	98.1 [94.9, 99.3]	98.1 [95.0, 99.3]	
Month 9	97.4 [93.8, 98.9]	NC [NC, NC]	
Month 12	96.6 [92.5, 98.5]	NC [NC, NC]	
Month 18	93.0 [84.5, 96.9]	NC [NC, NC]	
Month 24	93.0 [84.5, 96.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.743 [0.171, 3.235]
Log-rank test			
Two-sided unstratified log-rank p-value			0.6914

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.190.1.2: Summary and Results of Non-Severe TEAESI (CTCAE Grade < 3) by Subgroups - Infusion related reactions (IRR) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	1 (2.1)	NC [14.9, NC]	47	1 (2.1)	NC [NC, NC]	0.000 [0.000, NC]	0.3300	0.6913
Absent	192	7 (3.6)	NC [NC, NC]	189	3 (1.6)	NC [NC, NC]	0.982 [0.202, 4.768]	0.9817	
Age									
< 65 years	105	4 (3.8)		102	3 (2.9)				
>= 65 years	134	4 (3.0)		134	1 (0.7)				
Region									
Europe	97	1 (1.0)		101	1 (1.0)				
North America	57	6 (10.5)		51	3 (5.9)				
Rest of World	85	1 (1.2)		84	0 (0.0)				
Sex									
Male	197	6 (3.0)	NC [NC, NC]	181	4 (2.2)	NC [NC, NC]	0.687 [0.157, 3.001]	0.6158	NC
Female	42	2 (4.8)	NC [14.9, NC]	55	0 (0.0)	NC [NC, NC]	NC [NC, NC]	NC	
Metastases at Baseline									
Visceral metastases	169	6 (3.6)	NC [NC, NC]	157	4 (2.5)	NC [NC, NC]	0.701 [0.161, 3.053]	0.6339	NC
Lymph node only	60	1 (1.7)	NC [NC, NC]	65	0 (0.0)	NC [NC, NC]	NC [NC, NC]	NC	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.191.1.1: Summary and Results of Severe TEAESI (CTCAE Grade >= 3) - Immune related and infusion reactions - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	49 (20.5%)	3 (1.3%)	
Number of patients censored	190 (79.5%)	233 (98.7%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	88.4 [83.5, 91.9]	98.6 [95.7, 99.6]	
Month 6	84.4 [78.9, 88.5]	98.6 [95.7, 99.6]	
Month 9	80.1 [73.9, 85.0]	NC [NC, NC]	
Month 12	77.1 [70.4, 82.5]	NC [NC, NC]	
Month 18	73.3 [65.3, 79.7]	NC [NC, NC]	
Month 24	73.3 [65.3, 79.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			11.074 [3.396, 36.108]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.191.1.2: Summary and Results of Severe TEAESI (CTCAE Grade >= 3) by Subgroups - Immune related and infusion reactions - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	9 (19.1)	NC [NC, NC]	47	1 (2.1)	NC [NC, NC]	7.705 [0.950, 62.490]	0.0241	0.5910
Absent	192	40 (20.8)	NC [NC, NC]	189	2 (1.1)	NC [NC, NC]	12.764 [3.029, 53.790]	<.0001	
Age									
< 65 years	105	14 (13.3)	NC [NC, NC]	102	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0053	NC
>= 65 years	134	35 (26.1)	NC [NC, NC]	134	3 (2.2)	NC [NC, NC]	8.628 [2.604, 28.581]	<.0001	
Region									
Europe	97	16 (16.5)	NC [NC, NC]	101	2 (2.0)	NC [NC, NC]	6.366 [1.427, 28.405]	0.0054	NC
North America	57	16 (28.1)	NC [12.6, NC]	51	1 (2.0)	NC [NC, NC]	8.755 [1.109, 69.127]	0.0129	
Rest of World	85	17 (20.0)	NC [NC, NC]	84	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0008	
Sex									
Male	197	43 (21.8)	NC [NC, NC]	181	1 (0.6)	NC [NC, NC]	27.032 [3.682, 198.48]	<.0001	0.0738
Female	42	6 (14.3)	NC [NC, NC]	55	2 (3.6)	NC [NC, NC]	2.749 [0.508, 14.865]	0.2217	
Metastases at Baseline									
Visceral metastases	169	39 (23.1)	NC [NC, NC]	157	2 (1.3)	NC [NC, NC]	12.181 [2.886, 51.414]	<.0001	0.5049
Lymph node only	60	8 (13.3)	NC [NC, NC]	65	1 (1.5)	NC [NC, NC]	6.389 [0.770, 52.985]	0.0484	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.192.1.1: Summary and Results of Severe TEAESI (CTCAE Grade >= 3) - Peripheral neuropathy - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	17 (7.1%)	0 (0.0%)	
Number of patients censored	222 (92.9%)	236 (100.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	99.6 [97.1, 99.9]	100.0 [100.0, 100.0]	
Month 6	95.2 [91.0, 97.5]	100.0 [100.0, 100.0]	
Month 9	92.8 [87.8, 95.8]	NC [NC, NC]	
Month 12	91.7 [86.2, 95.1]	NC [NC, NC]	
Month 18	89.1 [82.1, 93.5]	NC [NC, NC]	
Month 24	85.0 [72.6, 92.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			NC [NC, NC]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0512

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.192.1.2: Summary and Results of Severe TEAESI (CTCAE Grade >= 3) by Subgroups - Peripheral neuropathy - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	3 (6.4)	NC [NC, NC]	47	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.3154	NC
Absent	192	14 (7.3)	NC [NC, NC]	189	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0987	
Age									
< 65 years	105	8 (7.6)		102	0 (0.0)				
>= 65 years	134	9 (6.7)		134	0 (0.0)				
Region									
Europe	97	5 (5.2)		101	0 (0.0)				
North America	57	7 (12.3)		51	0 (0.0)				
Rest of World	85	5 (5.9)		84	0 (0.0)				
Sex									
Male	197	16 (8.1)	NC [NC, NC]	181	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0605	NC
Female	42	1 (2.4)	NC [NC, NC]	55	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.7630	
Metastases at Baseline									
Visceral metastases	169	12 (7.1)	NC [NC, NC]	157	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1000	NC
Lymph node only	60	4 (6.7)	NC [NC, NC]	65	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.8282	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.193.1.1: Summary and Results of Severe TEAESI (CTCAE Grade >= 3) - Ocular disorders - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	0 (0.0%)	0 (0.0%)	
Number of patients censored	239 (100.0%)	236 (100.0%)	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.193.1.2: Summary and Results of Severe TEAESI (CTCAE Grade >= 3) by Subgroups - Ocular disorders - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	0 (0.0)		47	0 (0.0)				
Absent	192	0 (0.0)		189	0 (0.0)				
Age									
< 65 years	105	0 (0.0)		102	0 (0.0)				
>= 65 years	134	0 (0.0)		134	0 (0.0)				
Region									
Europe	97	0 (0.0)		101	0 (0.0)				
North America	57	0 (0.0)		51	0 (0.0)				
Rest of World	85	0 (0.0)		84	0 (0.0)		NC [NC, NC]		
Sex									
Male	197	0 (0.0)		181	0 (0.0)				
Female	42	0 (0.0)		55	0 (0.0)				
Metastases at Baseline									
Visceral metastases	169	0 (0.0)		157	0 (0.0)				
Lymph node only	60	0 (0.0)		65	0 (0.0)				

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.194.1.1: Summary and Results of Severe TEAESI (CTCAE Grade >= 3) - Hyperglycemia - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	23 (9.6%)	3 (1.3%)	
Number of patients censored	216 (90.4%)	233 (98.7%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	93.2 [89.1, 95.8]	99.1 [96.6, 99.8]	
Month 6	91.6 [87.0, 94.5]	98.6 [95.7, 99.5]	
Month 9	91.6 [87.0, 94.5]	NC [NC, NC]	
Month 12	89.5 [84.0, 93.2]	NC [NC, NC]	
Month 18	86.5 [79.1, 91.5]	NC [NC, NC]	
Month 24	86.5 [79.1, 91.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			5.831 [1.714, 19.835]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0014

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.194.1.2: Summary and Results of Severe TEAESI (CTCAE Grade >= 3) by Subgroups - Hyperglycemia - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	5 (10.6)	NC [11.6, NC]	47	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.2392	NC
Absent	192	18 (9.4)	NC [NC, NC]	189	3 (1.6)	NC [NC, NC]	5.378 [1.567, 18.458]	0.0027	
Age									
< 65 years	105	13 (12.4)	NC [NC, NC]	102	2 (2.0)	NC [NC, NC]	4.191 [0.899, 19.545]	0.0477	0.7007
>= 65 years	134	10 (7.5)	NC [NC, NC]	134	1 (0.7)	NC [NC, NC]	9.090 [1.152, 71.715]	0.0110	
Region									
Europe	97	10 (10.3)	NC [NC, NC]	101	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0033	NC
North America	57	3 (5.3)	NC [NC, NC]	51	1 (2.0)	NC [NC, NC]	2.740 [0.285, 26.339]	0.3627	
Rest of World	85	10 (11.8)	NC [NC, NC]	84	2 (2.4)	NC [NC, NC]	3.159 [0.648, 15.389]	0.1334	
Sex									
Male	197	17 (8.6)	NC [NC, NC]	181	3 (1.7)	NC [NC, NC]	4.041 [1.152, 14.172]	0.0182	NC
Female	42	6 (14.3)	NC [NC, NC]	55	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0172	
Metastases at Baseline									
Visceral metastases	169	17 (10.1)	NC [NC, NC]	157	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0011	NC
Lymph node only	60	6 (10.0)	NC [NC, NC]	65	2 (3.1)	NC [NC, NC]	3.397 [0.686, 16.832]	0.1116	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.195.1.1: Summary and Results of Severe TEAESI (CTCAE Grade >= 3) - Skin reactions - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	36 (15.1%)	0 (0.0%)	
Number of patients censored	203 (84.9%)	236 (100.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	90.6 [86.0, 93.7]	100.0 [100.0, 100.0]	
Month 6	87.9 [82.8, 91.6]	100.0 [100.0, 100.0]	
Month 9	86.1 [80.6, 90.1]	NC [NC, NC]	
Month 12	83.7 [77.6, 88.3]	NC [NC, NC]	
Month 18	79.4 [71.4, 85.4]	NC [NC, NC]	
Month 24	79.4 [71.4, 85.4]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			NC [NC, NC]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.195.1.2: Summary and Results of Severe TEAESI (CTCAE Grade >= 3) by Subgroups - Skin reactions - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	5 (10.6)	NC [NC, NC]	47	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0431	NC
Absent	192	31 (16.1)	NC [NC, NC]	189	0 (0.0)	NC [NC, NC]	NC [NC, NC]	<.0001	
Age									
< 65 years	105	13 (12.4)	NC [NC, NC]	102	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0030	NC
>= 65 years	134	23 (17.2)	NC [NC, NC]	134	0 (0.0)	NC [NC, NC]	NC [NC, NC]	<.0001	
Region									
Europe	97	11 (11.3)	NC [NC, NC]	101	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0065	NC
North America	57	7 (12.3)	NC [NC, NC]	51	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0553	
Rest of World	85	18 (21.2)	NC [NC, NC]	84	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0001	
Sex									
Male	197	31 (15.7)	NC [NC, NC]	181	0 (0.0)	NC [NC, NC]	NC [NC, NC]	<.0001	NC
Female	42	5 (11.9)	NC [NC, NC]	55	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0273	
Metastases at Baseline									
Visceral metastases	169	27 (16.0)	NC [NC, NC]	157	0 (0.0)	NC [NC, NC]	NC [NC, NC]	<.0001	NC
Lymph node only	60	9 (15.0)	NC [NC, NC]	65	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0194	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.196.1.1: Summary and Results of Severe TEAESI (CTCAE Grade >= 3) - Infusion related reactions (IRR) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	0 (0.0%)	0 (0.0%)	
Number of patients censored	239 (100.0%)	236 (100.0%)	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.196.1.2: Summary and Results of Severe TEAESI (CTCAE Grade >= 3) by Subgroups - Infusion related reactions (IRR) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	0 (0.0)		47	0 (0.0)				
Absent	192	0 (0.0)		189	0 (0.0)				
Age									
< 65 years	105	0 (0.0)		102	0 (0.0)				
>= 65 years	134	0 (0.0)		134	0 (0.0)				
Region									
Europe	97	0 (0.0)		101	0 (0.0)				
North America	57	0 (0.0)		51	0 (0.0)				
Rest of World	85	0 (0.0)		84	0 (0.0)		NC [NC, NC]		
Sex									
Male	197	0 (0.0)		181	0 (0.0)				
Female	42	0 (0.0)		55	0 (0.0)				
Metastases at Baseline									
Visceral metastases	169	0 (0.0)		157	0 (0.0)				
Lymph node only	60	0 (0.0)		65	0 (0.0)				

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.197.1.1: Summary and Results of TESAESI - Immune related and infusion reactions - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	34 (14.2%)	2 (0.8%)	
Number of patients censored	205 (85.8%)	234 (99.2%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	92.4 [88.2, 95.1]	99.1 [96.3, 99.8]	
Month 6	89.1 [84.2, 92.5]	99.1 [96.3, 99.8]	
Month 9	86.2 [80.7, 90.2]	NC [NC, NC]	
Month 12	84.0 [78.1, 88.5]	NC [NC, NC]	
Month 18	82.9 [76.6, 87.7]	NC [NC, NC]	
Month 24	82.9 [76.6, 87.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			11.075 [2.614, 46.916]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAESI=treatment-emergent serious adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.197.1.2: Summary and Results of TESAESI by Subgroups - Immune related and infusion reactions - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	9 (19.1)	NC [NC, NC]	47	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0052	NC
Absent	192	25 (13.0)	NC [NC, NC]	189	2 (1.1)	NC [NC, NC]	7.284 [1.673, 31.711]	0.0020	
Age									
< 65 years	105	9 (8.6)	NC [NC, NC]	102	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0294	NC
>= 65 years	134	25 (18.7)	NC [NC, NC]	134	2 (1.5)	NC [NC, NC]	8.749 [2.034, 37.638]	0.0005	
Region									
Europe	97	11 (11.3)	NC [NC, NC]	101	1 (1.0)	NC [NC, NC]	9.059 [1.148, 71.514]	0.0111	NC
North America	57	8 (14.0)	NC [NC, NC]	51	1 (2.0)	NC [NC, NC]	5.604 [0.675, 46.534]	0.0717	
Rest of World	85	15 (17.6)	NC [NC, NC]	84	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0074	
Sex									
Male	197	31 (15.7)	NC [NC, NC]	181	0 (0.0)	NC [NC, NC]	NC [NC, NC]	<.0001	NC
Female	42	3 (7.1)	NC [NC, NC]	55	2 (3.6)	NC [NC, NC]	1.381 [0.208, 9.184]	0.7372	
Metastases at Baseline									
Visceral metastases	169	26 (15.4)	NC [NC, NC]	157	1 (0.6)	NC [NC, NC]	14.153 [1.876, 106.77]	0.0007	0.3618
Lymph node only	60	6 (10.0)	NC [NC, NC]	65	1 (1.5)	NC [NC, NC]	6.197 [0.746, 51.461]	0.0532	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAESI=treatment-emergent serious adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.198.1.1: Summary and Results of TESAESI - Peripheral neuropathy - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	3 (1.3%)	0 (0.0%)	
Number of patients censored	236 (98.7%)	236 (100.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	99.6 [97.0, 99.9]	100.0 [100.0, 100.0]	
Month 6	98.5 [95.5, 99.5]	100.0 [100.0, 100.0]	
Month 9	98.5 [95.5, 99.5]	NC [NC, NC]	
Month 12	98.5 [95.5, 99.5]	NC [NC, NC]	
Month 18	98.5 [95.5, 99.5]	NC [NC, NC]	
Month 24	98.5 [95.5, 99.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			NC [NC, NC]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1950

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAESI=treatment-emergent serious adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.198.1.2: Summary and Results of TESAESI by Subgroups - Peripheral neuropathy - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	1 (2.1)		47	0 (0.0)				
Absent	192	2 (1.0)		189	0 (0.0)				
Age									
< 65 years	105	1 (1.0)		102	0 (0.0)				
>= 65 years	134	2 (1.5)		134	0 (0.0)				
Region									
Europe	97	0 (0.0)		101	0 (0.0)				
North America	57	1 (1.8)		51	0 (0.0)				
Rest of World	85	2 (2.4)		84	0 (0.0)				
Sex									
Male	197	2 (1.0)		181	0 (0.0)				
Female	42	1 (2.4)		55	0 (0.0)				
Metastases at Baseline									
Visceral metastases	169	3 (1.8)		157	0 (0.0)				
Lymph node only	60	0 (0.0)		65	0 (0.0)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAESI=treatment-emergent serious adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.199.1.1: Summary and Results of TESAESI - Ocular disorders - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	1 (0.4%)	0 (0.0%)	
Number of patients censored	238 (99.6%)	236 (100.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	99.6 [97.0, 99.9]	100.0 [100.0, 100.0]	
Month 6	99.6 [97.0, 99.9]	100.0 [100.0, 100.0]	
Month 9	99.6 [97.0, 99.9]	NC [NC, NC]	
Month 12	99.6 [97.0, 99.9]	NC [NC, NC]	
Month 18	99.6 [97.0, 99.9]	NC [NC, NC]	
Month 24	99.6 [97.0, 99.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			NC [NC, NC]
Log-rank test			
Two-sided unstratified log-rank p-value			0.3288

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAESI=treatment-emergent serious adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.199.1.2: Summary and Results of TESAESI by Subgroups - Ocular disorders - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	0 (0.0)		47	0 (0.0)				
Absent	192	1 (0.5)		189	0 (0.0)				
Age									
< 65 years	105	0 (0.0)		102	0 (0.0)				
>= 65 years	134	1 (0.7)		134	0 (0.0)				
Region									
Europe	97	0 (0.0)		101	0 (0.0)				
North America	57	0 (0.0)		51	0 (0.0)				
Rest of World	85	1 (1.2)		84	0 (0.0)				
Sex									
Male	197	1 (0.5)		181	0 (0.0)				
Female	42	0 (0.0)		55	0 (0.0)				
Metastases at Baseline									
Visceral metastases	169	1 (0.6)		157	0 (0.0)				
Lymph node only	60	0 (0.0)		65	0 (0.0)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAESI=treatment-emergent serious adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.200.1.1: Summary and Results of TESAESI - Hyperglycemia - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	6 (2.5%)	1 (0.4%)	
Number of patients censored	233 (97.5%)	235 (99.6%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.7 [96.2, 99.6]	100.0 [100.0, 100.0]	
Month 6	97.4 [94.2, 98.8]	99.4 [95.7, 99.9]	
Month 9	97.4 [94.2, 98.8]	NC [NC, NC]	
Month 12	97.4 [94.2, 98.8]	NC [NC, NC]	
Month 18	97.4 [94.2, 98.8]	NC [NC, NC]	
Month 24	97.4 [94.2, 98.8]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			5.403 [0.650, 44.901]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0796

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAESI=treatment-emergent serious adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.200.1.2: Summary and Results of TESAESI by Subgroups - Hyperglycemia - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	N	n (%)	KME [95% CI](a)	N	n (%)	KME [95% CI](a)	HR [95% CI](b)	Log-rank p-value(c)	Test for Interaction p-value(d)
Liver Metastases									
Present	47	0 (0.0)		47	0 (0.0)				
Absent	192	6 (3.1)		189	1 (0.5)				
Age									
< 65 years	105	2 (1.9)		102	0 (0.0)				
>= 65 years	134	4 (3.0)		134	1 (0.7)				
Region									
Europe	97	3 (3.1)		101	0 (0.0)				
North America	57	0 (0.0)		51	0 (0.0)				
Rest of World	85	3 (3.5)		84	1 (1.2)				
Sex									
Male	197	5 (2.5)		181	1 (0.6)				
Female	42	1 (2.4)		55	0 (0.0)				
Metastases at Baseline									
Visceral metastases	169	4 (2.4)		157	0 (0.0)				
Lymph node only	60	2 (3.3)		65	0 (0.0)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAESI=treatment-emergent serious adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.201.1.1: Summary and Results of TESAESI - Skin reactions - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	15 (6.3%)	0 (0.0%)	
Number of patients censored	224 (93.7%)	236 (100.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	95.8 [92.3, 97.7]	100.0 [100.0, 100.0]	
Month 6	94.2 [90.3, 96.6]	100.0 [100.0, 100.0]	
Month 9	93.7 [89.5, 96.2]	NC [NC, NC]	
Month 12	93.7 [89.5, 96.2]	NC [NC, NC]	
Month 18	92.5 [87.3, 95.6]	NC [NC, NC]	
Month 24	92.5 [87.3, 95.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			NC [NC, NC]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0011

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAESI=treatment-emergent serious adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.201.1.2: Summary and Results of TESAESI by Subgroups - Skin reactions - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	4 (8.5)	NC [NC, NC]	47	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1288	NC
Absent	192	11 (5.7)	NC [NC, NC]	189	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0037	
Age									
< 65 years	105	4 (3.8)	NC [NC, NC]	102	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0834	NC
>= 65 years	134	11 (8.2)	NC [NC, NC]	134	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0053	
Region									
Europe	97	5 (5.2)		101	0 (0.0)				
North America	57	3 (5.3)		51	0 (0.0)				
Rest of World	85	7 (8.2)		84	0 (0.0)				
Sex									
Male	197	12 (6.1)	NC [NC, NC]	181	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0044	NC
Female	42	3 (7.1)	NC [NC, NC]	55	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1171	
Metastases at Baseline									
Visceral metastases	169	10 (5.9)	NC [NC, NC]	157	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0117	NC
Lymph node only	60	5 (8.3)	NC [NC, NC]	65	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0384	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAESI=treatment-emergent serious adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.202.1.1: Summary and Results of TESAESI - Infusion related reactions (IRR) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	0 (0.0%)	0 (0.0%)	
Number of patients censored	239 (100.0%)	236 (100.0%)	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAESI=treatment-emergent serious adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.202.1.2: Summary and Results of TESAESI by Subgroups - Infusion related reactions (IRR) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	0 (0.0)		47	0 (0.0)				
Absent	192	0 (0.0)		189	0 (0.0)				
Age									
< 65 years	105	0 (0.0)		102	0 (0.0)				
>= 65 years	134	0 (0.0)		134	0 (0.0)				
Region									
Europe	97	0 (0.0)		101	0 (0.0)				
North America	57	0 (0.0)		51	0 (0.0)				
Rest of World	85	0 (0.0)		84	0 (0.0)		NC [NC, NC]		
Sex									
Male	197	0 (0.0)		181	0 (0.0)				
Female	42	0 (0.0)		55	0 (0.0)				
Metastases at Baseline									
Visceral metastases	169	0 (0.0)		157	0 (0.0)				
Lymph node only	60	0 (0.0)		65	0 (0.0)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAESI=treatment-emergent serious adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.203.1.1: Summary and Results of TEAESI leading to discontinuation from study medication - Immune related and infusion reactions - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	26 (10.9%)	0 (0.0%)	
Number of patients censored	213 (89.1%)	236 (100.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	94.8 [91.0, 97.0]	100.0 [100.0, 100.0]	
Month 6	92.3 [87.9, 95.2]	100.0 [100.0, 100.0]	
Month 9	88.5 [83.1, 92.3]	NC [NC, NC]	
Month 12	87.0 [81.2, 91.1]	NC [NC, NC]	
Month 18	85.6 [79.0, 90.3]	NC [NC, NC]	
Month 24	85.6 [79.0, 90.3]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			NC [NC, NC]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.203.1.2: Summary and Results of TEAESI leading to discontinuation from study medication by Subgroups - Immune related and infusion reactions - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	5 (10.6)	NC [NC, NC]	47	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1152	NC
Absent	192	21 (10.9)	NC [NC, NC]	189	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0003	
Age									
< 65 years	105	7 (6.7)	NC [NC, NC]	102	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0882	NC
>= 65 years	134	19 (14.2)	NC [NC, NC]	134	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0004	
Region									
Europe	97	11 (11.3)	NC [NC, NC]	101	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0068	NC
North America	57	6 (10.5)	NC [NC, NC]	51	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0335	
Rest of World	85	9 (10.6)	NC [NC, NC]	84	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0583	
Sex									
Male	197	23 (11.7)	NC [NC, NC]	181	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0004	NC
Female	42	3 (7.1)	NC [NC, NC]	55	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1072	
Metastases at Baseline									
Visceral metastases	169	17 (10.1)	NC [NC, NC]	157	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0052	NC
Lymph node only	60	8 (13.3)	NC [NC, NC]	65	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0062	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.204.1.1: Summary and Results of TEAESI leading to discontinuation from study medication - Peripheral neuropathy - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	40 (16.7%)	1 (0.4%)	
Number of patients censored	199 (83.3%)	235 (99.6%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	99.1 [96.3, 99.8]	99.5 [96.8, 99.9]	
Month 6	91.0 [85.8, 94.3]	99.5 [96.8, 99.9]	
Month 9	83.1 [76.5, 88.0]	NC [NC, NC]	
Month 12	77.5 [69.7, 83.6]	NC [NC, NC]	
Month 18	69.9 [59.9, 77.9]	NC [NC, NC]	
Month 24	69.9 [59.9, 77.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			9.795 [1.271, 75.469]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0075

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.204.1.2: Summary and Results of TEAESI leading to discontinuation from study medication by Subgroups - Peripheral neuropathy - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	6 (12.8)	NC [12.2, NC]	47	1 (2.1)	NC [NC, NC]	0.927 [0.058, 14.924]	0.9571	NC
Absent	192	34 (17.7)	NC [NC, NC]	189	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0037	
Age									
< 65 years	105	16 (15.2)	NC [NC, NC]	102	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0999	NC
>= 65 years	134	24 (17.9)	NC [NC, NC]	134	1 (0.7)	NC [NC, NC]	6.971 [0.877, 55.401]	0.0338	
Region									
Europe	97	23 (23.7)	NC [12.4, NC]	101	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0078	NC
North America	57	11 (19.3)	NC [12.0, NC]	51	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.2173	
Rest of World	85	6 (7.1)	NC [NC, NC]	84	1 (1.2)	NC [NC, NC]	1.507 [0.139, 16.307]	0.7344	
Sex									
Male	197	35 (17.8)	NC [NC, NC]	181	1 (0.6)	NC [NC, NC]	8.289 [1.066, 64.445]	0.0163	NC
Female	42	5 (11.9)	NC [14.2, NC]	55	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.3039	
Metastases at Baseline									
Visceral metastases	169	24 (14.2)	NC [NC, NC]	157	1 (0.6)	NC [NC, NC]	6.499 [0.818, 51.631]	0.0427	NC
Lymph node only	60	14 (23.3)	NC [12.0, NC]	65	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0859	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.205.1.1: Summary and Results of TEAESI leading to discontinuation from study medication - Ocular disorders - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	1 (0.4%)	0 (0.0%)	
Number of patients censored	238 (99.6%)	236 (100.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	99.6 [96.9, 99.9]	100.0 [100.0, 100.0]	
Month 6	99.6 [96.9, 99.9]	100.0 [100.0, 100.0]	
Month 9	99.6 [96.9, 99.9]	NC [NC, NC]	
Month 12	99.6 [96.9, 99.9]	NC [NC, NC]	
Month 18	99.6 [96.9, 99.9]	NC [NC, NC]	
Month 24	99.6 [96.9, 99.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			NC [NC, NC]
Log-rank test			
Two-sided unstratified log-rank p-value			0.3205

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.205.1.2: Summary and Results of TEAESI leading to discontinuation from study medication by Subgroups - Ocular disorders - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	0 (0.0)		47	0 (0.0)				
Absent	192	1 (0.5)		189	0 (0.0)				
Age									
< 65 years	105	0 (0.0)		102	0 (0.0)				
>= 65 years	134	1 (0.7)		134	0 (0.0)				
Region									
Europe	97	0 (0.0)		101	0 (0.0)				
North America	57	0 (0.0)		51	0 (0.0)				
Rest of World	85	1 (1.2)		84	0 (0.0)				
Sex									
Male	197	1 (0.5)		181	0 (0.0)				
Female	42	0 (0.0)		55	0 (0.0)				
Metastases at Baseline									
Visceral metastases	169	1 (0.6)		157	0 (0.0)				
Lymph node only	60	0 (0.0)		65	0 (0.0)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.206.1.1: Summary and Results of TEAESI leading to discontinuation from study medication - Hyperglycemia - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	1 (0.4%)	0 (0.0%)	
Number of patients censored	238 (99.6%)	236 (100.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	99.6 [97.0, 99.9]	100.0 [100.0, 100.0]	
Month 6	99.6 [97.0, 99.9]	100.0 [100.0, 100.0]	
Month 9	99.6 [97.0, 99.9]	NC [NC, NC]	
Month 12	99.6 [97.0, 99.9]	NC [NC, NC]	
Month 18	99.6 [97.0, 99.9]	NC [NC, NC]	
Month 24	99.6 [97.0, 99.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			NC [NC, NC]
Log-rank test			
Two-sided unstratified log-rank p-value			0.3246

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.206.1.2: Summary and Results of TEAESI leading to discontinuation from study medication by Subgroups - Hyperglycemia - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	0 (0.0)		47	0 (0.0)				
Absent	192	1 (0.5)		189	0 (0.0)				
Age									
< 65 years	105	1 (1.0)		102	0 (0.0)				
>= 65 years	134	0 (0.0)		134	0 (0.0)				
Region									
Europe	97	1 (1.0)		101	0 (0.0)				
North America	57	0 (0.0)		51	0 (0.0)				
Rest of World	85	0 (0.0)		84	0 (0.0)		NC [NC, NC]		
Sex									
Male	197	1 (0.5)		181	0 (0.0)				
Female	42	0 (0.0)		55	0 (0.0)				
Metastases at Baseline									
Visceral metastases	169	1 (0.6)		157	0 (0.0)				
Lymph node only	60	0 (0.0)		65	0 (0.0)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.207.1.1: Summary and Results of TEAESI leading to discontinuation from study medication - Skin reactions - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	15 (6.3%)	0 (0.0%)	
Number of patients censored	224 (93.7%)	236 (100.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.5 [93.2, 98.3]	100.0 [100.0, 100.0]	
Month 6	95.6 [91.9, 97.6]	100.0 [100.0, 100.0]	
Month 9	92.9 [88.1, 95.8]	NC [NC, NC]	
Month 12	92.1 [87.1, 95.3]	NC [NC, NC]	
Month 18	92.1 [87.1, 95.3]	NC [NC, NC]	
Month 24	92.1 [87.1, 95.3]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			NC [NC, NC]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0019

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.207.1.2: Summary and Results of TEAESI leading to discontinuation from study medication by Subgroups - Skin reactions - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	5 (10.6)	NC [NC, NC]	47	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1494	NC
Absent	192	10 (5.2)	NC [NC, NC]	189	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0058	
Age									
< 65 years	105	5 (4.8)	NC [NC, NC]	102	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0859	NC
>= 65 years	134	10 (7.5)	NC [NC, NC]	134	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0090	
Region									
Europe	97	8 (8.2)		101	0 (0.0)				
North America	57	3 (5.3)		51	0 (0.0)				
Rest of World	85	4 (4.7)		84	0 (0.0)				
Sex									
Male	197	11 (5.6)	NC [NC, NC]	181	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0069	NC
Female	42	4 (9.5)	NC [NC, NC]	55	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1317	
Metastases at Baseline									
Visceral metastases	169	9 (5.3)		157	0 (0.0)				
Lymph node only	60	6 (10.0)		65	0 (0.0)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.208.1.1: Summary and Results of TEAESI leading to discontinuation from study medication - Infusion related reactions (IRR) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	0 (0.0%)	0 (0.0%)	
Number of patients censored	239 (100.0%)	236 (100.0%)	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.208.1.2: Summary and Results of TEAESI leading to discontinuation from study medication by Subgroups - Infusion related reactions (IRR) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	0 (0.0)		47	0 (0.0)				
Absent	192	0 (0.0)		189	0 (0.0)				
Age									
< 65 years	105	0 (0.0)		102	0 (0.0)				
>= 65 years	134	0 (0.0)		134	0 (0.0)				
Region									
Europe	97	0 (0.0)		101	0 (0.0)				
North America	57	0 (0.0)		51	0 (0.0)				
Rest of World	85	0 (0.0)		84	0 (0.0)		NC [NC, NC]		
Sex									
Male	197	0 (0.0)		181	0 (0.0)				
Female	42	0 (0.0)		55	0 (0.0)				
Metastases at Baseline									
Visceral metastases	169	0 (0.0)		157	0 (0.0)				
Lymph node only	60	0 (0.0)		65	0 (0.0)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.209.1.1: Summary and Results of TEAESI leading to death - Immune related and infusion reactions - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	1 (0.4%)	0 (0.0%)	
Number of patients censored	238 (99.6%)	236 (100.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	100.0 [100.0, 100.0]	100.0 [100.0, 100.0]	
Month 6	99.5 [96.6, 99.9]	100.0 [100.0, 100.0]	
Month 9	99.5 [96.6, 99.9]	NC [NC, NC]	
Month 12	99.5 [96.6, 99.9]	NC [NC, NC]	
Month 18	99.5 [96.6, 99.9]	NC [NC, NC]	
Month 24	99.5 [96.6, 99.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			NC [NC, NC]
Log-rank test			
Two-sided unstratified log-rank p-value			0.3308

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.209.1.2: Summary and Results of TEAESI leading to death by Subgroups - Immune related and infusion reactions - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	0 (0.0)		47	0 (0.0)				
Absent	192	1 (0.5)		189	0 (0.0)				
Age									
< 65 years	105	0 (0.0)		102	0 (0.0)				
>= 65 years	134	1 (0.7)		134	0 (0.0)				
Region									
Europe	97	0 (0.0)		101	0 (0.0)				
North America	57	1 (1.8)		51	0 (0.0)				
Rest of World	85	0 (0.0)		84	0 (0.0)		NC [NC, NC]		
Sex									
Male	197	1 (0.5)		181	0 (0.0)				
Female	42	0 (0.0)		55	0 (0.0)				
Metastases at Baseline									
Visceral metastases	169	1 (0.6)		157	0 (0.0)				
Lymph node only	60	0 (0.0)		65	0 (0.0)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.210.1.1: Summary and Results of TEAESI leading to death - Peripheral neuropathy - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	0 (0.0%)	0 (0.0%)	
Number of patients censored	239 (100.0%)	236 (100.0%)	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.210.1.2: Summary and Results of TEAESI leading to death by Subgroups - Peripheral neuropathy - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	0 (0.0)		47	0 (0.0)				
Absent	192	0 (0.0)		189	0 (0.0)				
Age									
< 65 years	105	0 (0.0)		102	0 (0.0)				
>= 65 years	134	0 (0.0)		134	0 (0.0)				
Region									
Europe	97	0 (0.0)		101	0 (0.0)				
North America	57	0 (0.0)		51	0 (0.0)				
Rest of World	85	0 (0.0)		84	0 (0.0)		NC [NC, NC]		
Sex									
Male	197	0 (0.0)		181	0 (0.0)				
Female	42	0 (0.0)		55	0 (0.0)				
Metastases at Baseline									
Visceral metastases	169	0 (0.0)		157	0 (0.0)				
Lymph node only	60	0 (0.0)		65	0 (0.0)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.211.1.1: Summary and Results of TEAESI leading to death - Ocular disorders - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	0 (0.0%)	0 (0.0%)	
Number of patients censored	239 (100.0%)	236 (100.0%)	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.211.1.2: Summary and Results of TEAESI leading to death by Subgroups - Ocular disorders - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	0 (0.0)		47	0 (0.0)				
Absent	192	0 (0.0)		189	0 (0.0)				
Age									
< 65 years	105	0 (0.0)		102	0 (0.0)				
>= 65 years	134	0 (0.0)		134	0 (0.0)				
Region									
Europe	97	0 (0.0)		101	0 (0.0)				
North America	57	0 (0.0)		51	0 (0.0)				
Rest of World	85	0 (0.0)		84	0 (0.0)		NC [NC, NC]		
Sex									
Male	197	0 (0.0)		181	0 (0.0)				
Female	42	0 (0.0)		55	0 (0.0)				
Metastases at Baseline									
Visceral metastases	169	0 (0.0)		157	0 (0.0)				
Lymph node only	60	0 (0.0)		65	0 (0.0)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.212.1.1: Summary and Results of TEAESI leading to death - Hyperglycemia - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	0 (0.0%)	0 (0.0%)	
Number of patients censored	239 (100.0%)	236 (100.0%)	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.212.1.2: Summary and Results of TEAESI leading to death by Subgroups - Hyperglycemia - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	0 (0.0)		47	0 (0.0)				
Absent	192	0 (0.0)		189	0 (0.0)				
Age									
< 65 years	105	0 (0.0)		102	0 (0.0)				
>= 65 years	134	0 (0.0)		134	0 (0.0)				
Region									
Europe	97	0 (0.0)		101	0 (0.0)				
North America	57	0 (0.0)		51	0 (0.0)				
Rest of World	85	0 (0.0)		84	0 (0.0)		NC [NC, NC]		
Sex									
Male	197	0 (0.0)		181	0 (0.0)				
Female	42	0 (0.0)		55	0 (0.0)				
Metastases at Baseline									
Visceral metastases	169	0 (0.0)		157	0 (0.0)				
Lymph node only	60	0 (0.0)		65	0 (0.0)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.213.1.1: Summary and Results of TEAESI leading to death - Skin reactions - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	0 (0.0%)	0 (0.0%)	
Number of patients censored	239 (100.0%)	236 (100.0%)	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.213.1.2: Summary and Results of TEAESI leading to death by Subgroups - Skin reactions - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	0 (0.0)		47	0 (0.0)				
Absent	192	0 (0.0)		189	0 (0.0)				
Age									
< 65 years	105	0 (0.0)		102	0 (0.0)				
>= 65 years	134	0 (0.0)		134	0 (0.0)				
Region									
Europe	97	0 (0.0)		101	0 (0.0)				
North America	57	0 (0.0)		51	0 (0.0)				
Rest of World	85	0 (0.0)		84	0 (0.0)		NC [NC, NC]		
Sex									
Male	197	0 (0.0)		181	0 (0.0)				
Female	42	0 (0.0)		55	0 (0.0)				
Metastases at Baseline									
Visceral metastases	169	0 (0.0)		157	0 (0.0)				
Lymph node only	60	0 (0.0)		65	0 (0.0)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.214.1.1: Summary and Results of TEAESI leading to death - Infusion related reactions (IRR) - Analysis Set mSAF 1

	EV+Pembro (N= 239)	Plat+Gem (N= 236)	EV+Pembro vs. Plat+Gem
Number of patients at risk	239 (100.0%)	236 (100.0%)	
Number of patients with events	0 (0.0%)	0 (0.0%)	
Number of patients censored	239 (100.0%)	236 (100.0%)	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.214.1.2: Summary and Results of TEAESI leading to death by Subgroups - Infusion related reactions (IRR) - Analysis Set mSAF 1

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	47	0 (0.0)		47	0 (0.0)				
Absent	192	0 (0.0)		189	0 (0.0)				
Age									
< 65 years	105	0 (0.0)		102	0 (0.0)				
>= 65 years	134	0 (0.0)		134	0 (0.0)				
Region									
Europe	97	0 (0.0)		101	0 (0.0)				
North America	57	0 (0.0)		51	0 (0.0)				
Rest of World	85	0 (0.0)		84	0 (0.0)		NC [NC, NC]		
Sex									
Male	197	0 (0.0)		181	0 (0.0)				
Female	42	0 (0.0)		55	0 (0.0)				
Metastases at Baseline									
Visceral metastases	169	0 (0.0)		157	0 (0.0)				
Lymph node only	60	0 (0.0)		65	0 (0.0)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.1.2.1: Summary and Results of TEAEs - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	200 (99.5%)	193 (98.0%)	
Number of patients censored	1 (0.5%)	4 (2.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	2.5 [0.9, 5.4]	1.2 [0.2, 3.8]	
Month 6	2.0 [0.7, 4.7]	NC [NC, NC]	
Month 9	0.7 [0.1, 3.2]	NC [NC, NC]	
Month 12	0.7 [0.1, 3.2]	NC [NC, NC]	
Month 18	0.0 [NC, NC]	NC [NC, NC]	
Month 24	0.0 [NC, NC]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	0.3 [0.2, 0.3]	0.2 [0.1, 0.2]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.817 [0.669, 0.997]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0570

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAE=treatment-emergent adverse event.
Note: The analysis was conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.1.2.2: Summary and Results of TEAEs by Subgroups - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	50 (100.0)	0.2 [0.2, 0.3]	49	48 (98.0)	0.2 [0.1, 0.3]	0.835 [0.559, 1.245]	0.4170	0.8845
Absent	151	150 (99.3)	0.3 [0.2, 0.3]	148	145 (98.0)	0.2 [0.1, 0.2]	0.817 [0.649, 1.028]	0.0943	
Age									
< 65 years	39	39 (100.0)	0.3 [0.2, 0.4]	28	27 (96.4)	0.2 [0.1, 0.3]	0.832 [0.504, 1.371]	0.4937	0.9719
>= 65 years	162	161 (99.4)	0.2 [0.2, 0.3]	169	166 (98.2)	0.2 [0.1, 0.2]	0.829 [0.667, 1.031]	0.1056	
Region									
Europe	73	72 (98.6)	0.3 [0.2, 0.3]	94	92 (97.9)	0.2 [0.2, 0.2]	0.750 [0.549, 1.026]	0.0807	0.8325
North America	46	46 (100.0)	0.2 [0.1, 0.3]	33	32 (97.0)	0.1 [0.1, 0.2]	0.876 [0.549, 1.398]	0.5999	
Rest of World	82	82 (100.0)	0.3 [0.2, 0.3]	70	69 (98.6)	0.2 [0.1, 0.3]	0.798 [0.577, 1.104]	0.2159	
Sex									
Male	145	144 (99.3)	0.3 [0.2, 0.3]	148	144 (97.3)	0.2 [0.2, 0.3]	0.881 [0.698, 1.112]	0.3313	0.0845
Female	56	56 (100.0)	0.2 [0.1, 0.3]	49	49 (100.0)	0.1 [0.1, 0.2]	0.564 [0.379, 0.841]	0.0048	
Metastases at Baseline									
Visceral metastases	147	146 (99.3)	0.2 [0.2, 0.3]	152	150 (98.7)	0.2 [0.1, 0.2]	0.842 [0.669, 1.059]	0.1572	0.9856
Lymph node only	43	43 (100.0)	0.3 [0.2, 0.3]	37	35 (94.6)	0.2 [0.1, 0.3]	0.850 [0.543, 1.332]	0.5225	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAE=treatment-emergent adverse event.
Note: The analysis was conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.2.2.1: Summary and Results of Non-Severe TEAEs (CTCAE Grade < 3) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	198 (98.5%)	190 (96.4%)	
Number of patients censored	3 (1.5%)	7 (3.6%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	2.8 [1.1, 6.0]	1.2 [0.2, 3.9]	
Month 6	2.3 [0.8, 5.3]	NC [NC, NC]	
Month 9	0.8 [0.1, 3.6]	NC [NC, NC]	
Month 12	0.8 [0.1, 3.6]	NC [NC, NC]	
Month 18	0.0 [NC, NC]	NC [NC, NC]	
Month 24	0.0 [NC, NC]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	0.3 [0.2, 0.3]	0.2 [0.2, 0.3]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.889 [0.727, 1.085]
Log-rank test			
Two-sided unstratified log-rank p-value			0.2669

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAE=treatment-emergent adverse event.
Note: The analysis was conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.2.2.2: Summary and Results of Non-Severe TEAEs (CTCAE Grade < 3) by Subgroups - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	48 (96.0)	0.3 [0.2, 0.3]	49	47 (95.9)	0.2 [0.1, 0.3]	0.841 [0.560, 1.262]	0.4348	0.8607
Absent	151	150 (99.3)	0.3 [0.2, 0.3]	148	143 (96.6)	0.2 [0.2, 0.3]	0.907 [0.720, 1.142]	0.4154	
Age									
< 65 years	39	39 (100.0)	0.3 [0.2, 0.4]	28	27 (96.4)	0.2 [0.1, 0.4]	0.891 [0.540, 1.469]	0.6481	0.9326
>= 65 years	162	159 (98.1)	0.3 [0.2, 0.3]	169	163 (96.4)	0.2 [0.2, 0.3]	0.902 [0.724, 1.122]	0.3723	
Region									
Europe	73	72 (98.6)	0.3 [0.2, 0.3]	94	90 (95.7)	0.2 [0.2, 0.3]	0.896 [0.656, 1.224]	0.5364	0.9647
North America	46	44 (95.7)	0.2 [0.2, 0.3]	33	31 (93.9)	0.1 [0.1, 0.3]	0.914 [0.570, 1.466]	0.7005	
Rest of World	82	82 (100.0)	0.3 [0.2, 0.3]	70	69 (98.6)	0.3 [0.2, 0.3]	0.845 [0.611, 1.169]	0.3548	
Sex									
Male	145	142 (97.9)	0.3 [0.2, 0.3]	148	142 (95.9)	0.3 [0.2, 0.3]	0.949 [0.751, 1.199]	0.6927	0.1225
Female	56	56 (100.0)	0.2 [0.2, 0.3]	49	48 (98.0)	0.1 [0.1, 0.2]	0.641 [0.432, 0.952]	0.0290	
Metastases at Baseline									
Visceral metastases	147	144 (98.0)	0.3 [0.2, 0.3]	152	147 (96.7)	0.2 [0.2, 0.3]	0.915 [0.726, 1.153]	0.4504	0.9459
Lymph node only	43	43 (100.0)	0.3 [0.2, 0.3]	37	35 (94.6)	0.2 [0.1, 0.3]	0.912 [0.582, 1.431]	0.7786	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAE=treatment-emergent adverse event.
Note: The analysis was conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.3.2.1: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	157 (78.1%)	166 (84.3%)	
Number of patients censored	44 (21.9%)	31 (15.7%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	46.7 [39.7, 53.4]	17.4 [12.3, 23.1]	
Month 6	34.7 [28.1, 41.3]	NC [NC, NC]	
Month 9	25.8 [19.7, 32.2]	NC [NC, NC]	
Month 12	20.8 [15.1, 27.2]	NC [NC, NC]	
Month 18	16.9 [11.0, 23.9]	NC [NC, NC]	
Month 24	12.7 [6.7, 20.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	2.6 [2.0, 4.0]	0.7 [0.5, 0.9]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.459 [0.362, 0.582]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAE=treatment-emergent adverse event.
Note: The analysis was conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.3.2.2: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) by Subgroups - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	43 (86.0)	1.0 [0.7, 2.5]	49	42 (85.7)	0.5 [0.5, 0.9]	0.567 [0.359, 0.895]	0.0146	0.5925
Absent	151	114 (75.5)	3.3 [2.1, 4.6]	148	124 (83.8)	0.8 [0.6, 1.0]	0.425 [0.322, 0.562]	<.0001	
Age									
< 65 years	39	26 (66.7)	6.9 [2.1, 10.5]	28	21 (75.0)	1.4 [0.5, 3.0]	0.414 [0.219, 0.782]	0.0060	0.6677
>= 65 years	162	131 (80.9)	2.2 [1.4, 3.0]	169	145 (85.8)	0.7 [0.5, 0.9]	0.475 [0.368, 0.614]	<.0001	
Region									
Europe	73	54 (74.0)	3.5 [1.8, 5.7]	94	79 (84.0)	0.7 [0.5, 1.0]	0.401 [0.274, 0.585]	<.0001	0.0571
North America	46	40 (87.0)	0.8 [0.5, 2.0]	33	25 (75.8)	0.7 [0.5, 1.8]	0.861 [0.510, 1.454]	0.5873	
Rest of World	82	63 (76.8)	3.2 [2.1, 5.7]	70	62 (88.6)	0.7 [0.5, 1.0]	0.368 [0.250, 0.543]	<.0001	
Sex									
Male	145	117 (80.7)	2.3 [1.4, 3.5]	148	123 (83.1)	0.7 [0.5, 1.0]	0.521 [0.396, 0.686]	<.0001	0.0775
Female	56	40 (71.4)	3.9 [2.1, 6.0]	49	43 (87.8)	0.7 [0.5, 0.9]	0.301 [0.185, 0.487]	<.0001	
Metastases at Baseline									
Visceral metastases	147	118 (80.3)	2.1 [1.4, 3.5]	152	130 (85.5)	0.7 [0.5, 0.8]	0.479 [0.365, 0.627]	<.0001	0.9887
Lymph node only	43	31 (72.1)	4.1 [1.4, 8.9]	37	29 (78.4)	1.0 [0.6, 1.5]	0.460 [0.264, 0.803]	0.0051	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAE=treatment-emergent adverse event.
Note: The analysis was conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.4.2.1: Summary and Results of TESAEs - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	113 (56.2%)	86 (43.7%)	
Number of patients censored	88 (43.8%)	111 (56.3%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	64.1 [57.0, 70.3]	60.2 [52.8, 66.8]	
Month 6	54.0 [46.7, 60.7]	NC [NC, NC]	
Month 9	46.5 [39.3, 53.4]	NC [NC, NC]	
Month 12	43.7 [36.4, 50.8]	NC [NC, NC]	
Month 18	40.6 [33.1, 48.0]	NC [NC, NC]	
Month 24	35.8 [26.9, 44.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	7.9 [5.3, 12.9]	5.4 [4.2, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.870 [0.644, 1.176]
Log-rank test			
Two-sided unstratified log-rank p-value			0.3646

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAE=treatment-emergent serious adverse event.
Note: The analysis was conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.4.2.2: Summary and Results of TESAEs by Subgroups - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	34 (68.0)	4.5 [1.8, 7.0]	49	24 (49.0)	4.4 [1.9, NC]	1.010 [0.577, 1.767]	0.9729	0.4145
Absent	151	79 (52.3)	9.1 [5.6, NC]	148	62 (41.9)	5.4 [4.2, NC]	0.820 [0.574, 1.173]	0.2766	
Age									
< 65 years	39	18 (46.2)	18.7 [6.1, NC]	28	11 (39.3)	5.4 [4.2, NC]	0.557 [0.238, 1.304]	0.1742	0.5469
>= 65 years	162	95 (58.6)	6.2 [3.7, 11.1]	169	75 (44.4)	NC [3.3, NC]	0.960 [0.696, 1.323]	0.7986	
Region									
Europe	73	45 (61.6)	6.9 [4.0, 11.1]	94	42 (44.7)	5.1 [2.5, NC]	0.828 [0.522, 1.313]	0.4233	0.7834
North America	46	27 (58.7)	6.1 [1.1, NC]	33	14 (42.4)	NC [1.7, NC]	1.044 [0.531, 2.054]	0.9067	
Rest of World	82	41 (50.0)	13.1 [5.3, NC]	70	30 (42.9)	5.4 [3.7, NC]	0.825 [0.500, 1.362]	0.4501	
Sex									
Male	145	87 (60.0)	6.2 [3.9, 11.1]	148	65 (43.9)	5.4 [4.2, NC]	0.980 [0.695, 1.382]	0.9045	0.1803
Female	56	26 (46.4)	NC [5.6, NC]	49	21 (42.9)	NC [1.7, NC]	0.633 [0.339, 1.182]	0.1491	
Metastases at Baseline									
Visceral metastases	147	87 (59.2)	6.2 [3.9, 9.1]	152	70 (46.1)	5.1 [2.8, NC]	0.883 [0.629, 1.240]	0.4710	0.7434
Lymph node only	43	22 (51.2)	11.1 [4.0, NC]	37	14 (37.8)	NC [1.5, NC]	0.848 [0.417, 1.728]	0.6523	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAE=treatment-emergent serious adverse event.
Note: The analysis was conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.5.2.1: Summary and Results of First Treatment Discontinuation of Any Study Drugs due to TEAEs - Analysis Set mSAF 2

	EV+Pembro (N= 201)	**Plat+Gem (N= 197)**	**EV+Pembro vs. Plat+Gem**
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	83 (41.3%)	35 (17.8%)	
Number of patients censored	118 (58.7%)	162 (82.2%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	84.3 [78.4, 88.7]	86.6 [80.8, 90.8]	
Month 6	71.5 [64.5, 77.4]	76.6 [65.3, 84.6]	
Month 9	62.3 [54.6, 69.2]	NC [NC, NC]	
Month 12	53.1 [44.6, 60.9]	NC [NC, NC]	
Month 18	42.9 [31.8, 53.5]	NC [NC, NC]	
Month 24	37.5 [24.1, 50.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	14.0 [10.3, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.302 [0.847, 2.002]
Log-rank test			
Two-sided unstratified log-rank p-value			0.2277

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAE=treatment-emergent adverse event.
Note: The analysis was conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.5.2.1.1: Frequency of Patients with TEAEs leading to First Treatment Discontinuation for each Drug - Analysis Set mSAF 2

	EV+Pembro (N=201)	**Plat+Gem (N=197)**
Number of patients at risk	201 (100.0%)	197 (100.0%)
Number of patients with events	83 (41.3%)	35 (17.8%)
Carboplatin	0 (0.0%)	34 (17.3%)
Cisplatin	0 (0.0%)	0 (0.0%)
Enfortumab Vedotin	69 (34.3%)	0 (0.0%)
Gemcitabine	0 (0.0%)	35 (17.8%)
Pembrolizumab	49 (24.4%)	0 (0.0%)

Abbreviations: EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAE=treatment-emergent adverse event.
Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.5.2.2: Summary and Results of First Treatment Discontinuation of Any Study Drugs due to TEAEs by Subgroups - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	19 (38.0)	17.1 [7.2, NC]	49	10 (20.4)	NC [NC, NC]	1.219 [0.530, 2.800]	0.6407	0.5249
Absent	151	64 (42.4)	13.7 [9.7, NC]	148	25 (16.9)	NC [NC, NC]	1.355 [0.820, 2.239]	0.2348	
Age									
< 65 years	39	21 (53.8)	13.7 [8.9, 20.4]	28	4 (14.3)	NC [NC, NC]	1.923 [0.608, 6.084]	0.2583	0.3680
>= 65 years	162	62 (38.3)	14.0 [10.3, NC]	169	31 (18.3)	NC [NC, NC]	1.209 [0.757, 1.930]	0.4270	
Region									
Europe	73	35 (47.9)	11.1 [7.9, 17.1]	94	18 (19.1)	NC [NC, NC]	1.438 [0.770, 2.682]	0.2514	0.8401
North America	46	20 (43.5)	11.8 [5.1, NC]	33	7 (21.2)	NC [NC, NC]	1.329 [0.539, 3.279]	0.5364	
Rest of World	82	28 (34.1)	NC [10.3, NC]	70	10 (14.3)	NC [5.4, NC]	1.119 [0.501, 2.502]	0.7865	
Sex									
Male	145	62 (42.8)	13.7 [9.7, NC]	148	25 (16.9)	NC [NC, NC]	1.538 [0.932, 2.540]	0.0900	0.2407
Female	56	21 (37.5)	20.4 [8.9, NC]	49	10 (20.4)	NC [NC, NC]	0.784 [0.336, 1.826]	0.5717	
Metastases at Baseline									
Visceral metastases	147	56 (38.1)	17.1 [9.8, NC]	152	24 (15.8)	NC [NC, NC]	1.527 [0.915, 2.550]	0.1029	0.5924
Lymph node only	43	25 (58.1)	10.3 [5.3, 14.0]	37	11 (29.7)	NC [5.4, NC]	0.829 [0.373, 1.844]	0.6457	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAE=treatment-emergent adverse event.
Note: The analysis was conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.6.2.1: Summary and Results of TEAEs - Blood and lymphatic system disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	88 (43.8%)	170 (86.3%)	
Number of patients censored	113 (56.2%)	27 (13.7%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	67.9 [60.8, 74.0]	12.0 [7.7, 17.3]	
Month 6	63.1 [55.7, 69.6]	NC [NC, NC]	
Month 9	59.3 [51.7, 66.2]	NC [NC, NC]	
Month 12	52.3 [43.9, 60.0]	NC [NC, NC]	
Month 18	42.9 [33.2, 52.3]	NC [NC, NC]	
Month 24	42.9 [33.2, 52.3]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	13.4 [9.2, NC]	0.5 [0.5, 0.7]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.184 [0.137, 0.245]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.6.2.2: Summary and Results of TEAEs by Subgroups - Blood and lymphatic system disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	22 (44.0)	10.1 [2.1, NC]	49	40 (81.6)	0.5 [0.4, 0.7]	0.277 [0.160, 0.477]	<.0001	0.3572
Absent	151	66 (43.7)	13.8 [10.1, NC]	148	130 (87.8)	0.5 [0.5, 0.7]	0.159 [0.113, 0.223]	<.0001	
Age									
< 65 years	39	13 (33.3)	NC [9.0, NC]	28	22 (78.6)	0.9 [0.4, 1.5]	0.156 [0.069, 0.355]	<.0001	0.6895
>= 65 years	162	75 (46.3)	11.5 [7.2, 17.5]	169	148 (87.6)	0.5 [0.5, 0.7]	0.189 [0.138, 0.258]	<.0001	
Region									
Europe	73	35 (47.9)	10.1 [4.2, NC]	94	84 (89.4)	0.5 [0.5, 0.7]	0.185 [0.118, 0.290]	<.0001	0.9553
North America	46	14 (30.4)	NC [NC, NC]	33	24 (72.7)	0.9 [0.5, 1.6]	0.222 [0.112, 0.439]	<.0001	
Rest of World	82	39 (47.6)	12.1 [6.2, 17.5]	70	62 (88.6)	0.5 [0.5, 0.7]	0.177 [0.111, 0.280]	<.0001	
Sex									
Male	145	66 (45.5)	10.7 [6.5, NC]	148	127 (85.8)	0.5 [0.5, 0.8]	0.207 [0.149, 0.288]	<.0001	0.0938
Female	56	22 (39.3)	17.5 [8.9, NC]	49	43 (87.8)	0.5 [0.5, 0.7]	0.136 [0.073, 0.251]	<.0001	
Metastases at Baseline									
Visceral metastases	147	60 (40.8)	15.1 [10.1, NC]	152	128 (84.2)	0.5 [0.5, 0.7]	0.188 [0.134, 0.264]	<.0001	0.8258
Lymph node only	43	21 (48.8)	10.1 [2.4, NC]	37	35 (94.6)	0.7 [0.5, 1.0]	0.180 [0.097, 0.334]	<.0001	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.7.2.1: Summary and Results of TEAEs - Anaemia (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	67 (33.3%)	135 (68.5%)	
Number of patients censored	134 (66.7%)	62 (31.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	76.5 [69.8, 81.9]	30.7 [24.1, 37.6]	
Month 6	69.8 [62.5, 75.9]	NC [NC, NC]	
Month 9	67.6 [60.1, 74.0]	NC [NC, NC]	
Month 12	63.5 [55.3, 70.5]	NC [NC, NC]	
Month 18	56.1 [45.8, 65.2]	NC [NC, NC]	
Month 24	56.1 [45.8, 65.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [15.4, NC]	1.4 [1.0, 1.6]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.247 [0.180, 0.340]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.7.2.2: Summary and Results of TEAEs by Subgroups - Anaemia (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	17 (34.0)	NC [4.9, NC]	49	31 (63.3)	1.4 [0.7, 2.7]	0.359 [0.195, 0.661]	0.0006	0.3918
Absent	151	50 (33.1)	NC [15.4, NC]	148	104 (70.3)	1.4 [1.0, 1.6]	0.218 [0.150, 0.317]	<.0001	
Age									
< 65 years	39	8 (20.5)	NC [NC, NC]	28	18 (64.3)	1.5 [0.7, NC]	0.173 [0.068, 0.438]	<.0001	0.2243
>= 65 years	162	59 (36.4)	17.5 [12.1, NC]	169	117 (69.2)	1.4 [1.0, 1.6]	0.264 [0.188, 0.371]	<.0001	
Region									
Europe	73	29 (39.7)	13.8 [7.6, NC]	94	68 (72.3)	1.4 [1.0, 2.3]	0.266 [0.163, 0.433]	<.0001	0.7083
North America	46	11 (23.9)	NC [NC, NC]	33	17 (51.5)	2.1 [0.7, NC]	0.294 [0.136, 0.635]	0.0010	
Rest of World	82	27 (32.9)	NC [15.4, NC]	70	50 (71.4)	1.2 [0.9, 1.5]	0.226 [0.136, 0.377]	<.0001	
Sex									
Male	145	49 (33.8)	NC [13.8, NC]	148	100 (67.6)	1.4 [1.0, 2.1]	0.270 [0.187, 0.390]	<.0001	0.2879
Female	56	18 (32.1)	NC [15.4, NC]	49	35 (71.4)	1.1 [0.5, 1.5]	0.197 [0.104, 0.372]	<.0001	
Metastases at Baseline									
Visceral metastases	147	44 (29.9)	NC [17.5, NC]	152	106 (69.7)	1.2 [1.0, 1.6]	0.225 [0.155, 0.327]	<.0001	0.1547
Lymph node only	43	17 (39.5)	NC [5.5, NC]	37	23 (62.2)	1.4 [1.1, NC]	0.359 [0.181, 0.713]	0.0024	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.8.2.1: Summary and Results of TEAEs - Febrile neutropenia (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	1 (0.5%)	10 (5.1%)	
Number of patients censored	200 (99.5%)	187 (94.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	99.5 [96.5, 99.9]	94.9 [90.3, 97.3]	
Month 6	99.5 [96.5, 99.9]	93.9 [88.9, 96.7]	
Month 9	99.5 [96.5, 99.9]	NC [NC, NC]	
Month 12	99.5 [96.5, 99.9]	NC [NC, NC]	
Month 18	99.5 [96.5, 99.9]	NC [NC, NC]	
Month 24	99.5 [96.5, 99.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.090 [0.011, 0.701]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0038

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.8.2.2: Summary and Results of TEAEs by Subgroups - Febrile neutropenia (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	1 (2.0)		49	6 (12.2)				
Absent	151	0 (0.0)		148	4 (2.7)				
Age									
< 65 years	39	0 (0.0)	NC [NC, NC]	28	1 (3.6)	NC [NC, NC]	NC [NC, NC]	0.2379	NC
>= 65 years	162	1 (0.6)	NC [NC, NC]	169	9 (5.3)	NC [NC, NC]	0.105 [0.013, 0.828]	0.0088	
Region									
Europe	73	1 (1.4)		94	8 (8.5)				
North America	46	0 (0.0)		33	0 (0.0)				
Rest of World	82	0 (0.0)		70	2 (2.9)				
Sex									
Male	145	1 (0.7)		148	7 (4.7)				
Female	56	0 (0.0)		49	3 (6.1)				
Metastases at Baseline									
Visceral metastases	147	1 (0.7)	NC [NC, NC]	152	9 (5.9)	NC [NC, NC]	0.105 [0.013, 0.829]	0.0089	NC
Lymph node only	43	0 (0.0)	NC [NC, NC]	37	1 (2.7)	NC [NC, NC]	NC [NC, NC]	0.2810	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.9.2.1: Summary and Results of TEAEs - Leukopenia (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	8 (4.0%)	21 (10.7%)	
Number of patients censored	193 (96.0%)	176 (89.3%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.4 [93.8, 98.9]	89.0 [83.6, 92.7]	
Month 6	97.4 [93.8, 98.9]	89.0 [83.6, 92.7]	
Month 9	95.8 [91.3, 98.0]	NC [NC, NC]	
Month 12	94.7 [89.2, 97.4]	NC [NC, NC]	
Month 18	94.7 [89.2, 97.4]	NC [NC, NC]	
Month 24	94.7 [89.2, 97.4]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.222 [0.084, 0.585]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0009

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.9.2.2: Summary and Results of TEAEs by Subgroups - Leukopenia (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	1 (2.0)	NC [NC, NC]	49	5 (10.2)	NC [NC, NC]	0.195 [0.023, 1.672]	0.0968	0.5991
Absent	151	7 (4.6)	NC [NC, NC]	148	16 (10.8)	NC [NC, NC]	0.231 [0.078, 0.683]	0.0040	
Age									
< 65 years	39	2 (5.1)	NC [NC, NC]	28	1 (3.6)	NC [NC, NC]	0.734 [0.046, 11.734]	0.8261	0.2516
>= 65 years	162	6 (3.7)	NC [NC, NC]	169	20 (11.8)	NC [NC, NC]	0.195 [0.067, 0.572]	0.0009	
Region									
Europe	73	1 (1.4)	NC [NC, NC]	94	6 (6.4)	NC [NC, NC]	0.209 [0.025, 1.738]	0.1094	NC
North America	46	0 (0.0)	NC [NC, NC]	33	1 (3.0)	NC [NC, NC]	NC [NC, NC]	0.2232	
Rest of World	82	7 (8.5)	NC [NC, NC]	70	14 (20.0)	NC [NC, NC]	0.220 [0.072, 0.668]	0.0034	
Sex									
Male	145	5 (3.4)	NC [NC, NC]	148	16 (10.8)	NC [NC, NC]	0.244 [0.081, 0.729]	0.0062	0.6248
Female	56	3 (5.4)	NC [NC, NC]	49	5 (10.2)	NC [NC, NC]	0.161 [0.019, 1.378]	0.0565	
Metastases at Baseline									
Visceral metastases	147	6 (4.1)	NC [NC, NC]	152	18 (11.8)	NC [NC, NC]	0.271 [0.101, 0.729]	0.0056	0.8683
Lymph node only	43	1 (2.3)	NC [NC, NC]	37	2 (5.4)	NC [NC, NC]	0.107 [0.005, 2.558]	0.1412	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.10.2.1: Summary and Results of TEAEs - Lymphopenia (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	3 (1.5%)	8 (4.1%)	
Number of patients censored	198 (98.5%)	189 (95.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	99.0 [95.9, 99.7]	96.4 [92.5, 98.3]	
Month 6	99.0 [95.9, 99.7]	95.7 [91.5, 97.8]	
Month 9	99.0 [95.9, 99.7]	NC [NC, NC]	
Month 12	99.0 [95.9, 99.7]	NC [NC, NC]	
Month 18	99.0 [95.9, 99.7]	NC [NC, NC]	
Month 24	95.4 [80.1, 99.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.237 [0.050, 1.116]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0475

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.10.2.2: Summary and Results of TEAEs by Subgroups - Lymphopenia (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	0 (0.0)	NC [NC, NC]	49	1 (2.0)	NC [NC, NC]	NC [NC, NC]	0.3124	NC
Absent	151	3 (2.0)	NC [NC, NC]	148	7 (4.7)	NC [NC, NC]	0.267 [0.056, 1.288]	0.0774	
Age									
< 65 years	39	1 (2.6)	NC [NC, NC]	28	0 (0.0)	NC [NC, NC]	NC [NC, NC]	NC	NC
>= 65 years	162	2 (1.2)	NC [NC, NC]	169	8 (4.7)	NC [NC, NC]	0.250 [0.053, 1.180]	0.0583	
Region									
Europe	73	0 (0.0)		94	0 (0.0)				
North America	46	2 (4.3)		33	1 (3.0)				
Rest of World	82	1 (1.2)		70	7 (10.0)				
Sex									
Male	145	3 (2.1)		148	5 (3.4)				
Female	56	0 (0.0)		49	3 (6.1)				
Metastases at Baseline									
Visceral metastases	147	3 (2.0)	NC [NC, NC]	152	7 (4.6)	NC [NC, NC]	0.286 [0.059, 1.376]	0.0957	NC
Lymph node only	43	0 (0.0)	NC [NC, NC]	37	1 (2.7)	NC [NC, NC]	NC [NC, NC]	0.2810	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.11.2.1: Summary and Results of TEAEs - Neutropenia (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	22 (10.9%)	95 (48.2%)	
Number of patients censored	179 (89.1%)	102 (51.8%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	93.0 [88.3, 95.9]	52.9 [45.4, 59.8]	
Month 6	90.6 [85.2, 94.0]	48.0 [40.3, 55.3]	
Month 9	89.9 [84.3, 93.5]	NC [NC, NC]	
Month 12	87.8 [81.4, 92.1]	NC [NC, NC]	
Month 18	84.3 [75.8, 90.0]	NC [NC, NC]	
Month 24	84.3 [75.8, 90.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	3.6 [1.8, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.120 [0.071, 0.202]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.11.2.2: Summary and Results of TEAEs by Subgroups - Neutropenia (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	6 (12.0)	NC [NC, NC]	49	20 (40.8)	NC [1.8, NC]	0.191 [0.072, 0.513]	0.0003	0.2985
Absent	151	16 (10.6)	NC [NC, NC]	148	75 (50.7)	3.0 [1.5, NC]	0.104 [0.056, 0.192]	<.0001	
Age									
< 65 years	39	3 (7.7)	NC [NC, NC]	28	12 (42.9)	NC [1.8, NC]	0.043 [0.006, 0.333]	<.0001	0.6972
>= 65 years	162	19 (11.7)	NC [NC, NC]	169	83 (49.1)	3.6 [1.6, NC]	0.137 [0.080, 0.234]	<.0001	
Region									
Europe	73	7 (9.6)	NC [NC, NC]	94	45 (47.9)	3.6 [1.6, NC]	0.118 [0.050, 0.278]	<.0001	0.3378
North America	46	1 (2.2)	NC [NC, NC]	33	12 (36.4)	NC [1.6, NC]	0.045 [0.006, 0.344]	<.0001	
Rest of World	82	14 (17.1)	NC [NC, NC]	70	38 (54.3)	2.1 [0.9, NC]	0.145 [0.072, 0.294]	<.0001	
Sex									
Male	145	17 (11.7)	NC [NC, NC]	148	67 (45.3)	NC [1.8, NC]	0.142 [0.078, 0.259]	<.0001	0.1835
Female	56	5 (8.9)	NC [NC, NC]	49	28 (57.1)	1.6 [0.7, NC]	0.074 [0.026, 0.213]	<.0001	
Metastases at Baseline									
Visceral metastases	147	17 (11.6)	NC [NC, NC]	152	68 (44.7)	NC [1.9, NC]	0.153 [0.086, 0.273]	<.0001	0.1519
Lymph node only	43	3 (7.0)	NC [NC, NC]	37	22 (59.5)	1.6 [1.0, NC]	0.047 [0.011, 0.202]	<.0001	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.12.2.1: Summary and Results of TEAEs - Thrombocytopenia (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	10 (5.0%)	96 (48.7%)	
Number of patients censored	191 (95.0%)	101 (51.3%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.3 [92.4, 98.2]	51.1 [43.7, 58.1]	
Month 6	95.7 [91.5, 97.8]	NC [NC, NC]	
Month 9	95.0 [90.5, 97.4]	NC [NC, NC]	
Month 12	93.8 [88.4, 96.7]	NC [NC, NC]	
Month 18	93.8 [88.4, 96.7]	NC [NC, NC]	
Month 24	93.8 [88.4, 96.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	3.2 [2.1, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.058 [0.028, 0.120]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.12.2.2: Summary and Results of TEAEs by Subgroups - Thrombocytopenia (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	3 (6.0)	NC [NC, NC]	49	21 (42.9)	NC [1.1, NC]	0.112 [0.033, 0.378]	<.0001	0.4655
Absent	151	7 (4.6)	NC [NC, NC]	148	75 (50.7)	3.0 [1.9, NC]	0.045 [0.018, 0.112]	<.0001	
Age									
< 65 years	39	1 (2.6)	NC [NC, NC]	28	13 (46.4)	NC [1.2, NC]	0.043 [0.006, 0.327]	<.0001	0.5492
>= 65 years	162	9 (5.6)	NC [NC, NC]	169	83 (49.1)	3.2 [1.9, NC]	0.062 [0.029, 0.135]	<.0001	
Region									
Europe	73	6 (8.2)	NC [NC, NC]	94	47 (50.0)	2.8 [1.3, NC]	0.116 [0.049, 0.272]	<.0001	NC
North America	46	0 (0.0)	NC [NC, NC]	33	11 (33.3)	NC [2.8, NC]	NC [NC, NC]	<.0001	
Rest of World	82	4 (4.9)	NC [NC, NC]	70	38 (54.3)	2.8 [1.4, NC]	0.031 [0.007, 0.130]	<.0001	
Sex									
Male	145	9 (6.2)	NC [NC, NC]	148	74 (50.0)	3.0 [1.8, NC]	0.069 [0.032, 0.150]	<.0001	0.2750
Female	56	1 (1.8)	NC [NC, NC]	49	22 (44.9)	NC [1.4, NC]	0.029 [0.004, 0.219]	<.0001	
Metastases at Baseline									
Visceral metastases	147	7 (4.8)	NC [NC, NC]	152	69 (45.4)	NC [2.1, NC]	0.056 [0.023, 0.139]	<.0001	0.9274
Lymph node only	43	3 (7.0)	NC [NC, NC]	37	22 (59.5)	2.8 [1.4, NC]	0.076 [0.023, 0.257]	<.0001	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.13.2.1: Summary and Results of TEAEs - Cardiac disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	17 (8.5%)	13 (6.6%)	
Number of patients censored	184 (91.5%)	184 (93.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	93.8 [89.4, 96.4]	92.8 [88.0, 95.8]	
Month 6	92.1 [87.2, 95.2]	92.8 [88.0, 95.8]	
Month 9	91.3 [86.0, 94.6]	NC [NC, NC]	
Month 12	91.3 [86.0, 94.6]	NC [NC, NC]	
Month 18	91.3 [86.0, 94.6]	NC [NC, NC]	
Month 24	87.1 [74.9, 93.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.077 [0.512, 2.266]
Log-rank test			
Two-sided unstratified log-rank p-value			0.8438

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.14.2.1: Summary and Results of TEAEs - Ear and labyrinth disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	3 (1.5%)	7 (3.6%)	
Number of patients censored	198 (98.5%)	190 (96.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	99.0 [96.1, 99.7]	98.3 [94.6, 99.4]	
Month 6	98.3 [94.8, 99.5]	94.6 [88.8, 97.5]	
Month 9	98.3 [94.8, 99.5]	NC [NC, NC]	
Month 12	98.3 [94.8, 99.5]	NC [NC, NC]	
Month 18	98.3 [94.8, 99.5]	NC [NC, NC]	
Month 24	98.3 [94.8, 99.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.297 [0.074, 1.197]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0718

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.15.2.1: Summary and Results of TEAEs - Endocrine disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	36 (17.9%)	4 (2.0%)	
Number of patients censored	165 (82.1%)	193 (98.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	91.4 [86.3, 94.6]	98.3 [94.7, 99.4]	
Month 6	85.7 [79.6, 90.2]	97.6 [93.8, 99.1]	
Month 9	81.1 [74.1, 86.4]	NC [NC, NC]	
Month 12	77.4 [69.3, 83.7]	NC [NC, NC]	
Month 18	74.2 [65.0, 81.3]	NC [NC, NC]	
Month 24	74.2 [65.0, 81.3]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			5.473 [1.897, 15.792]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0004

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.15.2.2: Summary and Results of TEAEs by Subgroups - Endocrine disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	5 (10.0)	NC [13.1, NC]	49	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.3367	NC
Absent	151	31 (20.5)	NC [NC, NC]	148	4 (2.7)	NC [NC, NC]	5.274 [1.822, 15.264]	0.0006	
Age									
< 65 years	39	7 (17.9)	NC [NC, NC]	28	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1379	NC
>= 65 years	162	29 (17.9)	NC [NC, NC]	169	4 (2.4)	NC [NC, NC]	5.041 [1.726, 14.723]	0.0010	
Region									
Europe	73	14 (19.2)	NC [NC, NC]	94	1 (1.1)	NC [NC, NC]	11.285 [1.429, 89.095]	0.0040	NC
North America	46	5 (10.9)	NC [13.1, NC]	33	3 (9.1)	NC [NC, NC]	0.433 [0.072, 2.595]	0.3452	
Rest of World	82	17 (20.7)	NC [NC, NC]	70	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0017	
Sex									
Male	145	25 (17.2)	NC [NC, NC]	148	2 (1.4)	NC [NC, NC]	7.898 [1.813, 34.410]	0.0011	0.2799
Female	56	11 (19.6)	NC [NC, NC]	49	2 (4.1)	NC [NC, NC]	2.749 [0.582, 12.978]	0.1833	
Metastases at Baseline									
Visceral metastases	147	23 (15.6)	NC [NC, NC]	152	2 (1.3)	NC [NC, NC]	7.387 [1.688, 32.332]	0.0019	0.3250
Lymph node only	43	10 (23.3)	NC [NC, NC]	37	2 (5.4)	NC [NC, NC]	2.578 [0.532, 12.499]	0.2224	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.16.2.1: Summary and Results of TEAEs - Hyperthyroidism (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	11 (5.5%)	1 (0.5%)	
Number of patients censored	190 (94.5%)	196 (99.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.4 [93.8, 98.9]	100.0 [100.0, 100.0]	
Month 6	95.4 [90.9, 97.7]	99.3 [95.4, 99.9]	
Month 9	95.4 [90.9, 97.7]	NC [NC, NC]	
Month 12	94.4 [89.2, 97.1]	NC [NC, NC]	
Month 18	91.2 [83.5, 95.4]	NC [NC, NC]	
Month 24	91.2 [83.5, 95.4]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			6.105 [0.748, 49.830]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0549

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.17.2.1: Summary and Results of TEAEs - Hypothyroidism (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	23 (11.4%)	2 (1.0%)	
Number of patients censored	178 (88.6%)	195 (99.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.2 [92.2, 98.2]	98.9 [95.6, 99.7]	
Month 6	91.2 [85.7, 94.6]	98.9 [95.6, 99.7]	
Month 9	88.0 [81.8, 92.3]	NC [NC, NC]	
Month 12	84.2 [76.4, 89.6]	NC [NC, NC]	
Month 18	82.6 [74.1, 88.5]	NC [NC, NC]	
Month 24	82.6 [74.1, 88.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			5.894 [1.335, 26.018]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0081

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.17.2.2: Summary and Results of TEAEs by Subgroups - Hypothyroidism (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	3 (6.0)	NC [NC, NC]	49	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.3367	NC
Absent	151	20 (13.2)	NC [NC, NC]	148	2 (1.4)	NC [NC, NC]	5.463 [1.229, 24.276]	0.0124	
Age									
< 65 years	39	4 (10.3)	NC [NC, NC]	28	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.3486	NC
>= 65 years	162	19 (11.7)	NC [NC, NC]	169	2 (1.2)	NC [NC, NC]	5.622 [1.261, 25.061]	0.0109	
Region									
Europe	73	8 (11.0)	NC [NC, NC]	94	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0190	NC
North America	46	3 (6.5)	NC [NC, NC]	33	2 (6.1)	NC [NC, NC]	0.653 [0.092, 4.638]	0.6679	
Rest of World	82	12 (14.6)	NC [NC, NC]	70	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0333	
Sex									
Male	145	19 (13.1)	NC [NC, NC]	148	1 (0.7)	NC [NC, NC]	8.798 [1.122, 68.963]	0.0130	0.2015
Female	56	4 (7.1)	NC [NC, NC]	49	1 (2.0)	NC [NC, NC]	2.725 [0.304, 24.432]	0.3505	
Metastases at Baseline									
Visceral metastases	147	12 (8.2)	NC [NC, NC]	152	1 (0.7)	NC [NC, NC]	5.901 [0.714, 48.794]	0.0622	0.6801
Lymph node only	43	8 (18.6)	NC [NC, NC]	37	1 (2.7)	NC [NC, NC]	3.743 [0.443, 31.600]	0.1930	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.18.2.1: Summary and Results of TEAEs - Eye disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	64 (31.8%)	12 (6.1%)	
Number of patients censored	137 (68.2%)	185 (93.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	80.5 [74.0, 85.6]	95.5 [91.3, 97.8]	
Month 6	70.9 [63.5, 77.1]	92.4 [86.9, 95.7]	
Month 9	64.6 [56.5, 71.5]	NC [NC, NC]	
Month 12	64.6 [56.5, 71.5]	NC [NC, NC]	
Month 18	53.4 [41.4, 64.0]	NC [NC, NC]	
Month 24	53.4 [41.4, 64.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [16.6, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			3.851 [2.043, 7.261]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.18.2.2: Summary and Results of TEAEs by Subgroups - Eye disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	11 (22.0)	17.5 [17.5, NC]	49	2 (4.1)	NC [NC, NC]	3.455 [0.718, 16.620]	0.0999	0.9827
Absent	151	53 (35.1)	NC [13.1, NC]	148	10 (6.8)	NC [NC, NC]	3.973 [1.987, 7.945]	<.0001	
Age									
< 65 years	39	15 (38.5)	NC [7.4, NC]	28	1 (3.6)	NC [NC, NC]	5.937 [0.741, 47.555]	0.0569	0.4433
>= 65 years	162	49 (30.2)	NC [15.0, NC]	169	11 (6.5)	NC [NC, NC]	3.704 [1.898, 7.229]	<.0001	
Region									
Europe	73	23 (31.5)	17.5 [8.6, NC]	94	7 (7.4)	NC [NC, NC]	2.984 [1.236, 7.203]	0.0108	0.8115
North America	46	17 (37.0)	NC [3.9, NC]	33	2 (6.1)	NC [NC, NC]	5.041 [1.145, 22.186]	0.0172	
Rest of World	82	24 (29.3)	NC [15.0, NC]	70	3 (4.3)	NC [NC, NC]	4.612 [1.344, 15.826]	0.0076	
Sex									
Male	145	45 (31.0)	NC [13.1, NC]	148	9 (6.1)	NC [NC, NC]	4.274 [2.056, 8.888]	<.0001	0.8423
Female	56	19 (33.9)	16.6 [8.6, NC]	49	3 (6.1)	NC [NC, NC]	2.848 [0.799, 10.157]	0.0920	
Metastases at Baseline									
Visceral metastases	147	44 (29.9)	NC [15.0, NC]	152	9 (5.9)	NC [NC, NC]	3.644 [1.734, 7.655]	0.0003	0.6641
Lymph node only	43	17 (39.5)	NC [5.4, NC]	37	2 (5.4)	NC [NC, NC]	5.619 [1.270, 24.856]	0.0103	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.19.2.1: Summary and Results of TEAEs - Cataract (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	12 (6.0%)	0 (0.0%)	
Number of patients censored	189 (94.0%)	197 (100.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	99.5 [96.4, 99.9]	100.0 [100.0, 100.0]	
Month 6	97.5 [93.5, 99.1]	100.0 [100.0, 100.0]	
Month 9	96.7 [92.1, 98.6]	NC [NC, NC]	
Month 12	93.3 [86.7, 96.7]	NC [NC, NC]	
Month 18	89.2 [78.9, 94.6]	NC [NC, NC]	
Month 24	79.8 [60.7, 90.3]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			NC [NC, NC]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1262

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.20.2.1: Summary and Results of TEAEs - Dry eye (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	21 (10.4%)	2 (1.0%)	
Number of patients censored	180 (89.6%)	195 (99.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	92.4 [87.5, 95.5]	98.9 [95.9, 99.7]	
Month 6	89.8 [84.2, 93.5]	98.9 [95.9, 99.7]	
Month 9	89.8 [84.2, 93.5]	NC [NC, NC]	
Month 12	88.6 [82.4, 92.7]	NC [NC, NC]	
Month 18	85.1 [76.8, 90.6]	NC [NC, NC]	
Month 24	85.1 [76.8, 90.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			7.670 [1.763, 33.369]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0014

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.20.2.2: Summary and Results of TEAEs by Subgroups - Dry eye (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	5 (10.0)	NC [14.8, NC]	49	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1427	NC
Absent	151	16 (10.6)	NC [NC, NC]	148	2 (1.4)	NC [NC, NC]	6.597 [1.498, 29.046]	0.0040	
Age									
< 65 years	39	4 (10.3)	NC [NC, NC]	28	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1229	NC
>= 65 years	162	17 (10.5)	NC [NC, NC]	169	2 (1.2)	NC [NC, NC]	6.488 [1.462, 28.787]	0.0047	
Region									
Europe	73	5 (6.8)		94	2 (2.1)				
North America	46	8 (17.4)		33	0 (0.0)				
Rest of World	82	8 (9.8)		70	0 (0.0)				
Sex									
Male	145	17 (11.7)	NC [NC, NC]	148	1 (0.7)	NC [NC, NC]	14.628 [1.923, 111.26]	0.0006	0.2362
Female	56	4 (7.1)	NC [NC, NC]	49	1 (2.0)	NC [NC, NC]	1.613 [0.146, 17.847]	0.6939	
Metastases at Baseline									
Visceral metastases	147	13 (8.8)	NC [NC, NC]	152	1 (0.7)	NC [NC, NC]	8.403 [1.054, 66.978]	0.0163	0.4838
Lymph node only	43	6 (14.0)	NC [NC, NC]	37	1 (2.7)	NC [NC, NC]	4.549 [0.544, 38.031]	0.1252	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.21.2.1: Summary and Results of TEAEs - Lacrimation increased (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	11 (5.5%)	1 (0.5%)	
Number of patients censored	190 (94.5%)	196 (99.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.8 [94.2, 99.2]	100.0 [100.0, 100.0]	
Month 6	95.2 [90.6, 97.6]	99.2 [94.5, 99.9]	
Month 9	92.8 [87.2, 96.0]	NC [NC, NC]	
Month 12	92.8 [87.2, 96.0]	NC [NC, NC]	
Month 18	92.8 [87.2, 96.0]	NC [NC, NC]	
Month 24	92.8 [87.2, 96.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			5.821 [0.716, 47.290]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0631

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.22.2.1: Summary and Results of TEAEs - Vision blurred (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	10 (5.0%)	1 (0.5%)	
Number of patients censored	191 (95.0%)	196 (99.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.9 [95.8, 99.7]	99.5 [96.3, 99.9]	
Month 6	96.5 [92.5, 98.4]	99.5 [96.3, 99.9]	
Month 9	94.9 [89.9, 97.4]	NC [NC, NC]	
Month 12	93.7 [87.9, 96.8]	NC [NC, NC]	
Month 18	90.5 [79.7, 95.7]	NC [NC, NC]	
Month 24	90.5 [79.7, 95.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			5.286 [0.636, 43.925]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0846

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.23.2.1: Summary and Results of TEAEs - Gastrointestinal disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	151 (75.1%)	129 (65.5%)	
Number of patients censored	50 (24.9%)	68 (34.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	36.4 [29.7, 43.1]	33.0 [26.2, 39.9]	
Month 6	29.6 [23.3, 36.2]	NC [NC, NC]	
Month 9	25.2 [19.1, 31.6]	NC [NC, NC]	
Month 12	21.1 [15.3, 27.6]	NC [NC, NC]	
Month 18	18.5 [11.8, 26.2]	NC [NC, NC]	
Month 24	18.5 [11.8, 26.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	1.2 [0.7, 1.8]	0.8 [0.6, 1.5]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.898 [0.705, 1.144]
Log-rank test			
Two-sided unstratified log-rank p-value			0.3916

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.24.2.1: Summary and Results of TEAEs - Abdominal distension (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	10 (5.0%)	2 (1.0%)	
Number of patients censored	191 (95.0%)	195 (99.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.4 [93.9, 98.9]	98.8 [95.4, 99.7]	
Month 6	95.5 [91.1, 97.7]	98.8 [95.4, 99.7]	
Month 9	94.7 [90.0, 97.2]	NC [NC, NC]	
Month 12	94.7 [90.0, 97.2]	NC [NC, NC]	
Month 18	93.0 [86.3, 96.5]	NC [NC, NC]	
Month 24	93.0 [86.3, 96.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			3.219 [0.670, 15.469]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1232

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.25.2.1: Summary and Results of TEAEs - Abdominal pain (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	24 (11.9%)	6 (3.0%)	
Number of patients censored	177 (88.1%)	191 (97.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	91.8 [86.9, 94.9]	96.6 [92.5, 98.5]	
Month 6	90.5 [85.2, 93.9]	96.6 [92.5, 98.5]	
Month 9	87.9 [81.8, 92.0]	NC [NC, NC]	
Month 12	85.6 [78.6, 90.5]	NC [NC, NC]	
Month 18	84.2 [76.6, 89.5]	NC [NC, NC]	
Month 24	84.2 [76.6, 89.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			2.792 [1.102, 7.072]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0239

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.25.2.2: Summary and Results of TEAEs by Subgroups - Abdominal pain (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	11 (22.0)	NC [NC, NC]	49	1 (2.0)	NC [NC, NC]	11.323 [1.449, 88.487]	0.0035	0.1579
Absent	151	13 (8.6)	NC [NC, NC]	148	5 (3.4)	NC [NC, NC]	1.330 [0.428, 4.136]	0.6206	
Age									
< 65 years	39	7 (17.9)	NC [NC, NC]	28	1 (3.6)	NC [NC, NC]	3.140 [0.353, 27.916]	0.2793	0.7553
>= 65 years	162	17 (10.5)	NC [NC, NC]	169	5 (3.0)	NC [NC, NC]	2.689 [0.959, 7.540]	0.0506	
Region									
Europe	73	14 (19.2)	NC [NC, NC]	94	4 (4.3)	NC [NC, NC]	3.704 [1.183, 11.596]	0.0163	NC
North America	46	6 (13.0)	NC [NC, NC]	33	2 (6.1)	NC [NC, NC]	1.005 [0.168, 6.016]	0.9956	
Rest of World	82	4 (4.9)	NC [NC, NC]	70	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1031	
Sex									
Male	145	18 (12.4)	NC [NC, NC]	148	4 (2.7)	NC [NC, NC]	3.274 [1.061, 10.103]	0.0292	0.4909
Female	56	6 (10.7)	NC [NC, NC]	49	2 (4.1)	NC [NC, NC]	1.842 [0.352, 9.641]	0.4625	
Metastases at Baseline									
Visceral metastases	147	18 (12.2)	NC [NC, NC]	152	5 (3.3)	NC [NC, NC]	2.814 [1.007, 7.868]	0.0396	NC
Lymph node only	43	5 (11.6)	NC [NC, NC]	37	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1552	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.26.2.1: Summary and Results of TEAEs - Abdominal pain upper (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	**Plat+Gem (N= 197)**	**EV+Pembro vs. Plat+Gem**
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	5 (2.5%)	5 (2.5%)	
Number of patients censored	196 (97.5%)	192 (97.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.5 [95.4, 99.5]	97.8 [94.2, 99.2]	
Month 6	97.9 [94.5, 99.2]	95.3 [85.9, 98.5]	
Month 9	97.9 [94.5, 99.2]	NC [NC, NC]	
Month 12	96.7 [91.7, 98.7]	NC [NC, NC]	
Month 18	96.7 [91.7, 98.7]	NC [NC, NC]	
Month 24	96.7 [91.7, 98.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.668 [0.175, 2.549]
Log-rank test			
Two-sided unstratified log-rank p-value			0.5521

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.27.2.1: Summary and Results of TEAEs - Constipation (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	49 (24.4%)	71 (36.0%)	
Number of patients censored	152 (75.6%)	126 (64.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	81.1 [74.8, 86.0]	62.7 [55.3, 69.3]	
Month 6	79.3 [72.7, 84.4]	62.0 [54.5, 68.6]	
Month 9	76.2 [69.1, 81.8]	NC [NC, NC]	
Month 12	75.2 [67.9, 81.0]	NC [NC, NC]	
Month 18	68.9 [58.7, 77.1]	NC [NC, NC]	
Month 24	65.6 [53.7, 75.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [24.5, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.449 [0.303, 0.663]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.27.2.2: Summary and Results of TEAEs by Subgroups - Constipation (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	12 (24.0)	NC [9.5, NC]	49	20 (40.8)	NC [1.3, NC]	0.430 [0.201, 0.919]	0.0255	0.7715
Absent	151	37 (24.5)	24.5 [24.5, NC]	148	51 (34.5)	NC [NC, NC]	0.458 [0.290, 0.723]	0.0006	
Age									
< 65 years	39	11 (28.2)	NC [16.4, NC]	28	11 (39.3)	NC [1.1, NC]	0.436 [0.175, 1.086]	0.0671	0.9460
>= 65 years	162	38 (23.5)	24.5 [19.1, NC]	169	60 (35.5)	NC [NC, NC]	0.450 [0.291, 0.695]	0.0002	
Region									
Europe	73	19 (26.0)	NC [19.1, NC]	94	38 (40.4)	NC [1.9, NC]	0.439 [0.245, 0.788]	0.0046	0.6580
North America	46	15 (32.6)	16.4 [13.0, NC]	33	12 (36.4)	NC [1.6, NC]	0.569 [0.251, 1.291]	0.1723	
Rest of World	82	15 (18.3)	NC [NC, NC]	70	21 (30.0)	NC [NC, NC]	0.408 [0.201, 0.831]	0.0109	
Sex									
Male	145	40 (27.6)	24.5 [19.1, NC]	148	51 (34.5)	NC [NC, NC]	0.558 [0.359, 0.869]	0.0090	0.0514
Female	56	9 (16.1)	NC [16.4, NC]	49	20 (40.8)	NC [1.5, NC]	0.217 [0.091, 0.515]	0.0001	
Metastases at Baseline									
Visceral metastases	147	36 (24.5)	NC [NC, NC]	152	51 (33.6)	NC [NC, NC]	0.517 [0.329, 0.811]	0.0036	0.3271
Lymph node only	43	9 (20.9)	24.5 [16.4, 24.5]	37	16 (43.2)	NC [1.5, NC]	0.258 [0.101, 0.664]	0.0025	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.28.2.1: Summary and Results of TEAEs - Diarrhoea (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	77 (38.3%)	29 (14.7%)	
Number of patients censored	124 (61.7%)	168 (85.3%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	71.5 [64.6, 77.3]	85.9 [80.0, 90.2]	
Month 6	64.6 [57.3, 71.1]	83.9 [77.5, 88.5]	
Month 9	60.5 [52.9, 67.3]	NC [NC, NC]	
Month 12	56.4 [48.3, 63.8]	NC [NC, NC]	
Month 18	56.4 [48.3, 63.8]	NC [NC, NC]	
Month 24	56.4 [48.3, 63.8]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [11.1, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			2.298 [1.482, 3.563]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.28.2.2: Summary and Results of TEAEs by Subgroups - Diarrhoea (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	23 (46.0)	6.3 [1.8, NC]	49	6 (12.2)	NC [NC, NC]	3.763 [1.507, 9.397]	0.0024	0.2295
Absent	151	54 (35.8)	NC [NC, NC]	148	23 (15.5)	NC [NC, NC]	1.951 [1.179, 3.228]	0.0082	
Age									
< 65 years	39	19 (48.7)	11.1 [2.7, NC]	28	4 (14.3)	NC [NC, NC]	2.587 [0.846, 7.917]	0.0842	0.5850
>= 65 years	162	58 (35.8)	NC [NC, NC]	169	25 (14.8)	NC [NC, NC]	2.236 [1.385, 3.609]	0.0007	
Region									
Europe	73	33 (45.2)	11.1 [4.4, NC]	94	17 (18.1)	NC [NC, NC]	2.246 [1.225, 4.118]	0.0074	0.8605
North America	46	22 (47.8)	5.5 [1.2, NC]	33	7 (21.2)	NC [NC, NC]	2.159 [0.907, 5.139]	0.0751	
Rest of World	82	22 (26.8)	NC [NC, NC]	70	5 (7.1)	NC [NC, NC]	2.995 [1.109, 8.083]	0.0230	
Sex									
Male	145	52 (35.9)	NC [11.1, NC]	148	24 (16.2)	NC [NC, NC]	1.864 [1.127, 3.083]	0.0139	0.2172
Female	56	25 (44.6)	NC [3.9, NC]	49	5 (10.2)	NC [NC, NC]	4.162 [1.581, 10.958]	0.0017	
Metastases at Baseline									
Visceral metastases	147	57 (38.8)	NC [9.4, NC]	152	21 (13.8)	NC [NC, NC]	2.562 [1.533, 4.280]	0.0002	0.3421
Lymph node only	43	16 (37.2)	NC [6.6, NC]	37	7 (18.9)	NC [NC, NC]	1.547 [0.621, 3.853]	0.3484	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.29.2.1: Summary and Results of TEAEs - Dry mouth (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	17 (8.5%)	1 (0.5%)	
Number of patients censored	184 (91.5%)	196 (99.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	93.7 [89.2, 96.4]	99.5 [96.2, 99.9]	
Month 6	91.9 [86.8, 95.0]	99.5 [96.2, 99.9]	
Month 9	91.9 [86.8, 95.0]	NC [NC, NC]	
Month 12	91.0 [85.5, 94.4]	NC [NC, NC]	
Month 18	89.4 [82.9, 93.6]	NC [NC, NC]	
Month 24	89.4 [82.9, 93.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			13.714 [1.804, 104.25]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0009

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.29.2.2: Summary and Results of TEAEs by Subgroups - Dry mouth (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	5 (10.0)	NC [NC, NC]	49	1 (2.0)	NC [NC, NC]	5.322 [0.622, 45.562]	0.0875	NC
Absent	151	12 (7.9)	NC [NC, NC]	148	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0035	
Age									
< 65 years	39	4 (10.3)	NC [NC, NC]	28	1 (3.6)	NC [NC, NC]	2.235 [0.232, 21.507]	0.4744	NC
>= 65 years	162	13 (8.0)	NC [NC, NC]	169	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0007	
Region									
Europe	73	7 (9.6)		94	1 (1.1)				
North America	46	9 (19.6)		33	0 (0.0)				
Rest of World	82	1 (1.2)		70	0 (0.0)				
Sex									
Male	145	13 (9.0)	NC [NC, NC]	148	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0012	NC
Female	56	4 (7.1)	NC [NC, NC]	49	1 (2.0)	NC [NC, NC]	3.046 [0.340, 27.275]	0.2946	
Metastases at Baseline									
Visceral metastases	147	12 (8.2)	NC [NC, NC]	152	1 (0.7)	NC [NC, NC]	10.495 [1.344, 81.956]	0.0052	NC
Lymph node only	43	5 (11.6)	NC [NC, NC]	37	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0688	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.30.2.1: Summary and Results of TEAEs - Dyspepsia (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	13 (6.5%)	7 (3.6%)	
Number of patients censored	188 (93.5%)	190 (96.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	95.2 [91.0, 97.5]	96.1 [92.1, 98.1]	
Month 6	95.2 [91.0, 97.5]	96.1 [92.1, 98.1]	
Month 9	95.2 [91.0, 97.5]	NC [NC, NC]	
Month 12	91.6 [85.0, 95.4]	NC [NC, NC]	
Month 18	89.1 [80.0, 94.3]	NC [NC, NC]	
Month 24	89.1 [80.0, 94.3]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.251 [0.466, 3.361]
Log-rank test			
Two-sided unstratified log-rank p-value			0.6557

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.31.2.1: Summary and Results of TEAEs - Gastrooesophageal reflux disease (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	**Plat+Gem (N= 197)**	**EV+Pembro vs. Plat+Gem**
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	6 (3.0%)	6 (3.0%)	
Number of patients censored	195 (97.0%)	191 (97.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.4 [93.9, 98.9]	97.3 [93.7, 98.9]	
Month 6	97.4 [93.9, 98.9]	96.7 [92.8, 98.5]	
Month 9	97.4 [93.9, 98.9]	NC [NC, NC]	
Month 12	97.4 [93.9, 98.9]	NC [NC, NC]	
Month 18	97.4 [93.9, 98.9]	NC [NC, NC]	
Month 24	93.7 [80.0, 98.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.810 [0.247, 2.654]
Log-rank test			
Two-sided unstratified log-rank p-value			0.7265

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.32.2.1: Summary and Results of TEAEs - Nausea (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	55 (27.4%)	58 (29.4%)	
Number of patients censored	146 (72.6%)	139 (70.6%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	75.4 [68.6, 80.8]	69.7 [62.6, 75.8]	
Month 6	74.1 [67.3, 79.7]	69.1 [61.8, 75.2]	
Month 9	71.9 [64.7, 77.8]	NC [NC, NC]	
Month 12	70.7 [63.3, 76.9]	NC [NC, NC]	
Month 18	67.4 [57.3, 75.5]	NC [NC, NC]	
Month 24	67.4 [57.3, 75.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.781 [0.535, 1.141]
Log-rank test			
Two-sided unstratified log-rank p-value			0.2028

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.33.2.1: Summary and Results of TEAEs - Stomatitis (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	12 (6.0%)	11 (5.6%)	
Number of patients censored	189 (94.0%)	186 (94.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	95.9 [91.9, 97.9]	94.0 [89.5, 96.7]	
Month 6	94.6 [90.3, 97.1]	94.0 [89.5, 96.7]	
Month 9	94.6 [90.3, 97.1]	NC [NC, NC]	
Month 12	92.3 [86.2, 95.7]	NC [NC, NC]	
Month 18	92.3 [86.2, 95.7]	NC [NC, NC]	
Month 24	92.3 [86.2, 95.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.850 [0.360, 2.003]
Log-rank test			
Two-sided unstratified log-rank p-value			0.7092

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.34.2.1: Summary and Results of TEAEs - Vomiting (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	27 (13.4%)	27 (13.7%)	
Number of patients censored	174 (86.6%)	170 (86.3%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	90.1 [85.0, 93.6]	86.0 [80.1, 90.3]	
Month 6	87.6 [82.0, 91.6]	85.2 [79.0, 89.6]	
Month 9	86.1 [80.1, 90.5]	NC [NC, NC]	
Month 12	83.9 [77.0, 88.9]	NC [NC, NC]	
Month 18	83.9 [77.0, 88.9]	NC [NC, NC]	
Month 24	83.9 [77.0, 88.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.769 [0.441, 1.344]
Log-rank test			
Two-sided unstratified log-rank p-value			0.3567

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.35.2.1: Summary and Results of TEAEs - General disorders and administration site conditions (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	136 (67.7%)	136 (69.0%)	
Number of patients censored	65 (32.3%)	61 (31.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	48.0 [40.8, 54.8]	31.4 [24.7, 38.2]	
Month 6	40.6 [33.5, 47.6]	24.8 [17.0, 33.3]	
Month 9	30.8 [24.0, 37.9]	NC [NC, NC]	
Month 12	23.3 [16.5, 30.9]	NC [NC, NC]	
Month 18	23.3 [16.5, 30.9]	NC [NC, NC]	
Month 24	19.5 [11.2, 29.4]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	2.6 [1.5, 4.9]	1.0 [0.7, 1.4]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.635 [0.494, 0.817]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0004

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.35.2.2: Summary and Results of TEAEs by Subgroups - General disorders and administration site conditions (SOC) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	39 (78.0)	1.2 [0.7, 2.8]	49	37 (75.5)	0.8 [0.6, 1.3]	0.770 [0.483, 1.228]	0.2690	0.3141
Absent	151	97 (64.2)	4.7 [2.2, 6.5]	148	99 (66.9)	1.1 [0.6, 1.6]	0.595 [0.442, 0.803]	0.0006	
Age									
< 65 years	39	26 (66.7)	4.7 [1.0, 8.6]	28	17 (60.7)	1.6 [0.7, NC]	0.792 [0.411, 1.524]	0.4836	0.3966
>= 65 years	162	110 (67.9)	2.6 [1.5, 4.8]	169	119 (70.4)	0.8 [0.5, 1.3]	0.616 [0.469, 0.810]	0.0005	
Region									
Europe	73	59 (80.8)	1.2 [0.6, 2.4]	94	77 (81.9)	0.7 [0.4, 1.0]	0.667 [0.466, 0.953]	0.0254	0.2745
North America	46	37 (80.4)	1.0 [0.4, 2.2]	33	23 (69.7)	0.7 [0.3, 2.4]	0.927 [0.546, 1.576]	0.8028	
Rest of World	82	40 (48.8)	10.3 [6.0, NC]	70	36 (51.4)	3.2 [1.1, NC]	0.510 [0.310, 0.839]	0.0070	
Sex									
Male	145	100 (69.0)	2.4 [1.4, 5.0]	148	98 (66.2)	1.2 [0.7, 1.5]	0.719 [0.536, 0.965]	0.0270	0.1043
Female	56	36 (64.3)	4.4 [1.2, 7.4]	49	38 (77.6)	0.7 [0.3, 1.6]	0.422 [0.257, 0.690]	0.0004	
Metastases at Baseline									
Visceral metastases	147	101 (68.7)	2.2 [1.4, 4.8]	152	105 (69.1)	1.0 [0.7, 1.4]	0.666 [0.500, 0.888]	0.0052	0.6628
Lymph node only	43	28 (65.1)	4.7 [0.5, 7.4]	37	25 (67.6)	0.5 [0.2, 2.9]	0.573 [0.322, 1.018]	0.0565	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.36.2.1: Summary and Results of TEAEs - Asthenia (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	34 (16.9%)	43 (21.8%)	
Number of patients censored	167 (83.1%)	154 (78.2%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	88.7 [83.3, 92.4]	79.5 [72.9, 84.7]	
Month 6	84.9 [78.9, 89.4]	68.8 [50.7, 81.3]	
Month 9	81.8 [75.1, 86.9]	NC [NC, NC]	
Month 12	79.6 [72.3, 85.2]	NC [NC, NC]	
Month 18	79.6 [72.3, 85.2]	NC [NC, NC]	
Month 24	79.6 [72.3, 85.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.556 [0.344, 0.900]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0153

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.36.2.2: Summary and Results of TEAEs by Subgroups - Asthenia (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	8 (16.0)	NC [NC, NC]	49	11 (22.4)	NC [NC, NC]	0.633 [0.251, 1.599]	0.3292	0.9308
Absent	151	26 (17.2)	NC [NC, NC]	148	32 (21.6)	NC [NC, NC]	0.528 [0.300, 0.928]	0.0240	
Age									
< 65 years	39	6 (15.4)	NC [NC, NC]	28	5 (17.9)	NC [5.4, NC]	0.488 [0.125, 1.905]	0.2926	0.7985
>= 65 years	162	28 (17.3)	NC [NC, NC]	169	38 (22.5)	NC [NC, NC]	0.572 [0.342, 0.956]	0.0306	
Region									
Europe	73	27 (37.0)	NC [6.5, NC]	94	30 (31.9)	NC [5.4, NC]	0.968 [0.566, 1.655]	0.9048	NC
North America	46	0 (0.0)	NC [NC, NC]	33	2 (6.1)	NC [NC, NC]	NC [NC, NC]	0.0757	
Rest of World	82	7 (8.5)	NC [NC, NC]	70	11 (15.7)	NC [NC, NC]	0.226 [0.065, 0.788]	0.0110	
Sex									
Male	145	26 (17.9)	NC [NC, NC]	148	31 (20.9)	NC [5.4, NC]	0.619 [0.354, 1.084]	0.0905	0.3143
Female	56	8 (14.3)	NC [NC, NC]	49	12 (24.5)	NC [NC, NC]	0.404 [0.158, 1.035]	0.0510	
Metastases at Baseline									
Visceral metastases	147	24 (16.3)	NC [NC, NC]	152	32 (21.1)	NC [NC, NC]	0.576 [0.329, 1.009]	0.0509	0.9343
Lymph node only	43	8 (18.6)	NC [NC, NC]	37	8 (21.6)	5.4 [5.4, NC]	0.613 [0.216, 1.739]	0.3538	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.37.2.1: Summary and Results of TEAEs - Chills (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	7 (3.5%)	6 (3.0%)	
Number of patients censored	194 (96.5%)	191 (97.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.5 [94.1, 98.9]	97.4 [93.8, 98.9]	
Month 6	96.9 [93.2, 98.6]	96.4 [92.0, 98.4]	
Month 9	96.2 [92.0, 98.2]	NC [NC, NC]	
Month 12	96.2 [92.0, 98.2]	NC [NC, NC]	
Month 18	96.2 [92.0, 98.2]	NC [NC, NC]	
Month 24	96.2 [92.0, 98.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.942 [0.304, 2.920]
Log-rank test			
Two-sided unstratified log-rank p-value			0.9169

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.38.2.1: Summary and Results of TEAEs - Fatigue (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	76 (37.8%)	69 (35.0%)	
Number of patients censored	125 (62.2%)	128 (65.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	72.7 [65.8, 78.4]	65.3 [58.0, 71.7]	
Month 6	65.9 [58.5, 72.3]	61.6 [53.2, 69.0]	
Month 9	61.5 [53.9, 68.3]	NC [NC, NC]	
Month 12	56.2 [47.8, 63.8]	NC [NC, NC]	
Month 18	56.2 [47.8, 63.8]	NC [NC, NC]	
Month 24	52.5 [41.7, 62.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [10.6, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.784 [0.557, 1.104]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1645

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.39.2.1: Summary and Results of TEAEs - Malaise (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	6 (3.0%)	6 (3.0%)	
Number of patients censored	195 (97.0%)	191 (97.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.4 [95.0, 99.5]	98.0 [94.7, 99.2]	
Month 6	97.0 [93.0, 98.8]	96.4 [91.9, 98.4]	
Month 9	97.0 [93.0, 98.8]	NC [NC, NC]	
Month 12	95.9 [90.7, 98.2]	NC [NC, NC]	
Month 18	95.9 [90.7, 98.2]	NC [NC, NC]	
Month 24	95.9 [90.7, 98.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.602 [0.171, 2.117]
Log-rank test			
Two-sided unstratified log-rank p-value			0.4248

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.40.2.1: Summary and Results of TEAEs - Oedema peripheral (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	31 (15.4%)	26 (13.2%)	
Number of patients censored	170 (84.6%)	171 (86.8%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	90.0 [84.7, 93.5]	86.6 [80.6, 90.8]	
Month 6	87.5 [81.7, 91.5]	85.1 [78.8, 89.7]	
Month 9	82.9 [76.2, 87.9]	NC [NC, NC]	
Month 12	80.6 [73.1, 86.2]	NC [NC, NC]	
Month 18	80.6 [73.1, 86.2]	NC [NC, NC]	
Month 24	80.6 [73.1, 86.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.782 [0.445, 1.374]
Log-rank test			
Two-sided unstratified log-rank p-value			0.3918

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.41.2.1: Summary and Results of TEAEs - Pyrexia (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	36 (17.9%)	35 (17.8%)	
Number of patients censored	165 (82.1%)	162 (82.2%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	84.8 [78.9, 89.2]	84.4 [78.3, 88.9]	
Month 6	83.5 [77.3, 88.1]	78.9 [71.1, 84.8]	
Month 9	81.2 [74.6, 86.3]	NC [NC, NC]	
Month 12	78.8 [71.4, 84.5]	NC [NC, NC]	
Month 18	78.8 [71.4, 84.5]	NC [NC, NC]	
Month 24	78.8 [71.4, 84.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.797 [0.490, 1.299]
Log-rank test			
Two-sided unstratified log-rank p-value			0.3616

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.42.2.1: Summary and Results of TEAEs - Hepatobiliary disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	32 (15.9%)	13 (6.6%)	
Number of patients censored	169 (84.1%)	184 (93.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	86.5 [80.8, 90.6]	93.7 [89.2, 96.4]	
Month 6	84.0 [77.9, 88.6]	93.1 [88.4, 95.9]	
Month 9	84.0 [77.9, 88.6]	NC [NC, NC]	
Month 12	83.0 [76.5, 87.8]	NC [NC, NC]	
Month 18	81.5 [74.2, 86.8]	NC [NC, NC]	
Month 24	81.5 [74.2, 86.8]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			2.127 [1.104, 4.097]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0209

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.42.2.2: Summary and Results of TEAEs by Subgroups - Hepatobiliary disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	4 (8.0)	NC [NC, NC]	49	5 (10.2)	NC [NC, NC]	0.779 [0.209, 2.902]	0.7111	0.0616
Absent	151	28 (18.5)	NC [NC, NC]	148	8 (5.4)	NC [NC, NC]	2.963 [1.335, 6.578]	0.0051	
Age									
< 65 years	39	8 (20.5)	NC [NC, NC]	28	1 (3.6)	NC [NC, NC]	4.720 [0.576, 38.674]	0.1115	0.3432
>= 65 years	162	24 (14.8)	NC [NC, NC]	169	12 (7.1)	NC [NC, NC]	1.896 [0.939, 3.829]	0.0693	
Region									
Europe	73	15 (20.5)	NC [NC, NC]	94	8 (8.5)	NC [NC, NC]	2.106 [0.875, 5.068]	0.0888	0.9310
North America	46	3 (6.5)	NC [NC, NC]	33	1 (3.0)	NC [NC, NC]	1.331 [0.121, 14.687]	0.8146	
Rest of World	82	14 (17.1)	NC [NC, NC]	70	4 (5.7)	NC [NC, NC]	2.917 [0.954, 8.913]	0.0496	
Sex									
Male	145	26 (17.9)	NC [NC, NC]	148	11 (7.4)	NC [NC, NC]	2.092 [1.018, 4.300]	0.0402	0.9894
Female	56	6 (10.7)	NC [NC, NC]	49	2 (4.1)	NC [NC, NC]	2.394 [0.483, 11.868]	0.2699	
Metastases at Baseline									
Visceral metastases	147	25 (17.0)	NC [NC, NC]	152	10 (6.6)	NC [NC, NC]	2.295 [1.089, 4.837]	0.0247	0.5701
Lymph node only	43	6 (14.0)	NC [NC, NC]	37	3 (8.1)	NC [NC, NC]	1.681 [0.420, 6.721]	0.4577	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.43.2.1: Summary and Results of TEAEs - Hypertransaminasaemia (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	10 (5.0%)	8 (4.1%)	
Number of patients censored	191 (95.0%)	189 (95.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	95.9 [92.0, 97.9]	96.3 [92.4, 98.2]	
Month 6	95.2 [91.0, 97.5]	95.6 [91.4, 97.8]	
Month 9	95.2 [91.0, 97.5]	NC [NC, NC]	
Month 12	94.2 [89.1, 96.9]	NC [NC, NC]	
Month 18	94.2 [89.1, 96.9]	NC [NC, NC]	
Month 24	94.2 [89.1, 96.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.985 [0.372, 2.606]
Log-rank test			
Two-sided unstratified log-rank p-value			0.9728

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.44.2.1: Summary and Results of TEAEs - Infections and infestations (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	120 (59.7%)	75 (38.1%)	
Number of patients censored	81 (40.3%)	122 (61.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	61.4 [54.1, 67.8]	63.5 [56.1, 70.0]	
Month 6	49.2 [41.8, 56.2]	NC [NC, NC]	
Month 9	40.6 [33.2, 47.8]	NC [NC, NC]	
Month 12	35.3 [27.9, 42.8]	NC [NC, NC]	
Month 18	30.8 [23.3, 38.7]	NC [NC, NC]	
Month 24	24.7 [13.4, 37.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	5.6 [3.6, 7.6]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.124 [0.828, 1.525]
Log-rank test			
Two-sided unstratified log-rank p-value			0.4497

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.45.2.1: Summary and Results of TEAEs - COVID-19 (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	20 (10.0%)	9 (4.6%)	
Number of patients censored	181 (90.0%)	188 (95.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.3 [92.4, 98.2]	96.0 [91.8, 98.1]	
Month 6	91.8 [86.5, 95.1]	93.7 [87.2, 96.9]	
Month 9	90.4 [84.7, 94.0]	NC [NC, NC]	
Month 12	88.0 [81.2, 92.5]	NC [NC, NC]	
Month 18	84.1 [74.8, 90.2]	NC [NC, NC]	
Month 24	84.1 [74.8, 90.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.187 [0.502, 2.809]
Log-rank test			
Two-sided unstratified log-rank p-value			0.6959

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.46.2.1: Summary and Results of TEAEs - Oral candidiasis (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	9 (4.5%)	2 (1.0%)	
Number of patients censored	192 (95.5%)	195 (99.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.8 [93.0, 98.5]	98.9 [95.9, 99.7]	
Month 6	94.9 [90.4, 97.3]	98.9 [95.9, 99.7]	
Month 9	94.9 [90.4, 97.3]	NC [NC, NC]	
Month 12	94.9 [90.4, 97.3]	NC [NC, NC]	
Month 18	94.9 [90.4, 97.3]	NC [NC, NC]	
Month 24	94.9 [90.4, 97.3]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			3.791 [0.807, 17.810]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0697

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.47.2.1: Summary and Results of TEAEs - Pneumonia (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	15 (7.5%)	3 (1.5%)	
Number of patients censored	186 (92.5%)	194 (98.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.2 [93.5, 98.8]	98.9 [95.8, 99.7]	
Month 6	94.8 [90.3, 97.3]	98.3 [94.7, 99.4]	
Month 9	91.0 [85.1, 94.6]	NC [NC, NC]	
Month 12	89.8 [83.3, 93.8]	NC [NC, NC]	
Month 18	89.8 [83.3, 93.8]	NC [NC, NC]	
Month 24	89.8 [83.3, 93.8]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			2.611 [0.703, 9.696]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1371

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.48.2.1: Summary and Results of TEAEs - Pyelonephritis (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	5 (2.5%)	6 (3.0%)	
Number of patients censored	196 (97.5%)	191 (97.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.5 [95.4, 99.5]	97.0 [93.0, 98.8]	
Month 6	97.8 [94.1, 99.2]	96.1 [91.3, 98.3]	
Month 9	97.1 [93.0, 98.8]	NC [NC, NC]	
Month 12	97.1 [93.0, 98.8]	NC [NC, NC]	
Month 18	97.1 [93.0, 98.8]	NC [NC, NC]	
Month 24	97.1 [93.0, 98.8]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.477 [0.123, 1.851]
Log-rank test			
Two-sided unstratified log-rank p-value			0.2745

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.49.2.1: Summary and Results of TEAEs - Urinary tract infection (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	48 (23.9%)	39 (19.8%)	
Number of patients censored	153 (76.1%)	158 (80.2%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	87.8 [82.2, 91.7]	81.4 [74.9, 86.4]	
Month 6	80.3 [73.5, 85.5]	77.8 [70.8, 83.3]	
Month 9	75.9 [68.6, 81.7]	NC [NC, NC]	
Month 12	71.2 [63.1, 77.8]	NC [NC, NC]	
Month 18	68.5 [59.8, 75.7]	NC [NC, NC]	
Month 24	68.5 [59.8, 75.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.728 [0.458, 1.157]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1777

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.50.2.1: Summary and Results of TEAEs - Injury, poisoning and procedural complications (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	27 (13.4%)	22 (11.2%)	
Number of patients censored	174 (86.6%)	175 (88.8%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	94.5 [90.1, 97.0]	90.7 [85.5, 94.1]	
Month 6	91.3 [85.9, 94.7]	85.5 [78.0, 90.7]	
Month 9	86.2 [79.4, 90.9]	NC [NC, NC]	
Month 12	82.9 [75.1, 88.4]	NC [NC, NC]	
Month 18	76.8 [66.2, 84.5]	NC [NC, NC]	
Month 24	76.8 [66.2, 84.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.507 [0.257, 1.000]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0461

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.50.2.2: Summary and Results of TEAEs by Subgroups - Injury, poisoning and procedural complications (SOC) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	5 (10.0)	NC [NC, NC]	49	8 (16.3)	NC [NC, NC]	0.403 [0.119, 1.363]	0.1311	0.2431
Absent	151	22 (14.6)	NC [NC, NC]	148	14 (9.5)	NC [NC, NC]	0.569 [0.250, 1.293]	0.1728	
Age									
< 65 years	39	7 (17.9)	NC [15.8, NC]	28	3 (10.7)	NC [NC, NC]	0.237 [0.025, 2.277]	0.1745	0.6989
>= 65 years	162	20 (12.3)	NC [NC, NC]	169	19 (11.2)	NC [NC, NC]	0.567 [0.277, 1.159]	0.1153	
Region									
Europe	73	6 (8.2)	NC [NC, NC]	94	11 (11.7)	NC [NC, NC]	0.307 [0.085, 1.110]	0.0570	0.3529
North America	46	11 (23.9)	NC [9.5, NC]	33	4 (12.1)	NC [NC, NC]	0.891 [0.249, 3.190]	0.8596	
Rest of World	82	10 (12.2)	NC [NC, NC]	70	7 (10.0)	NC [NC, NC]	0.423 [0.130, 1.378]	0.1419	
Sex									
Male	145	18 (12.4)	NC [NC, NC]	148	13 (8.8)	NC [NC, NC]	0.665 [0.289, 1.534]	0.3370	0.2582
Female	56	9 (16.1)	NC [NC, NC]	49	9 (18.4)	NC [NC, NC]	0.281 [0.084, 0.943]	0.0290	
Metastases at Baseline									
Visceral metastases	147	15 (10.2)	NC [NC, NC]	152	14 (9.2)	NC [NC, NC]	0.636 [0.280, 1.443]	0.2748	0.9790
Lymph node only	43	9 (20.9)	NC [15.8, NC]	37	6 (16.2)	NC [5.0, NC]	0.332 [0.081, 1.360]	0.1083	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.51.2.1: Summary and Results of TEAEs - Fall (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	10 (5.0%)	5 (2.5%)	
Number of patients censored	191 (95.0%)	192 (97.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	99.5 [96.5, 99.9]	98.4 [95.0, 99.5]	
Month 6	96.8 [92.4, 98.6]	96.7 [92.1, 98.7]	
Month 9	95.1 [90.0, 97.7]	NC [NC, NC]	
Month 12	93.1 [87.0, 96.4]	NC [NC, NC]	
Month 18	91.4 [83.8, 95.5]	NC [NC, NC]	
Month 24	91.4 [83.8, 95.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.441 [0.109, 1.785]
Log-rank test			
Two-sided unstratified log-rank p-value			0.2410

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.52.2.1: Summary and Results of TEAEs - Investigations (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	111 (55.2%)	87 (44.2%)	
Number of patients censored	90 (44.8%)	110 (55.8%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	59.1 [51.7, 65.8]	55.4 [47.9, 62.3]	
Month 6	45.0 [37.5, 52.2]	52.3 [44.6, 59.4]	
Month 9	39.4 [31.9, 46.9]	NC [NC, NC]	
Month 12	37.0 [29.2, 44.7]	NC [NC, NC]	
Month 18	33.4 [25.1, 41.9]	NC [NC, NC]	
Month 24	33.4 [25.1, 41.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	4.3 [3.4, 7.0]	NC [2.6, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.946 [0.709, 1.263]
Log-rank test			
Two-sided unstratified log-rank p-value			0.7186

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.53.2.1: Summary and Results of TEAEs - Alanine aminotransferase increased (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	27 (13.4%)	20 (10.2%)	
Number of patients censored	174 (86.6%)	177 (89.8%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	91.1 [86.0, 94.4]	89.9 [84.6, 93.4]	
Month 6	86.5 [80.5, 90.8]	89.2 [83.7, 92.9]	
Month 9	85.1 [78.7, 89.6]	NC [NC, NC]	
Month 12	84.1 [77.5, 88.9]	NC [NC, NC]	
Month 18	84.1 [77.5, 88.9]	NC [NC, NC]	
Month 24	84.1 [77.5, 88.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.984 [0.535, 1.809]
Log-rank test			
Two-sided unstratified log-rank p-value			0.9601

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.54.2.1: Summary and Results of TEAEs - Aspartate aminotransferase increased (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	22 (10.9%)	17 (8.6%)	
Number of patients censored	179 (89.1%)	180 (91.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	91.6 [86.7, 94.8]	91.4 [86.2, 94.6]	
Month 6	87.8 [81.9, 91.8]	90.7 [85.4, 94.1]	
Month 9	87.8 [81.9, 91.8]	NC [NC, NC]	
Month 12	87.8 [81.9, 91.8]	NC [NC, NC]	
Month 18	87.8 [81.9, 91.8]	NC [NC, NC]	
Month 24	87.8 [81.9, 91.8]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.065 [0.555, 2.043]
Log-rank test			
Two-sided unstratified log-rank p-value			0.8489

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.55.2.1: Summary and Results of TEAEs - Blood alkaline phosphatase increased (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	10 (5.0%)	8 (4.1%)	
Number of patients censored	191 (95.0%)	189 (95.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.9 [93.1, 98.6]	95.6 [91.4, 97.8]	
Month 6	95.7 [91.5, 97.8]	95.6 [91.4, 97.8]	
Month 9	95.7 [91.5, 97.8]	NC [NC, NC]	
Month 12	95.7 [91.5, 97.8]	NC [NC, NC]	
Month 18	92.9 [86.2, 96.4]	NC [NC, NC]	
Month 24	92.9 [86.2, 96.4]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.950 [0.356, 2.533]
Log-rank test			
Two-sided unstratified log-rank p-value			0.9189

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.56.2.1: Summary and Results of TEAEs - Blood creatinine increased (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	27 (13.4%)	23 (11.7%)	
Number of patients censored	174 (86.6%)	174 (88.3%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	92.6 [87.8, 95.5]	88.8 [83.2, 92.7]	
Month 6	90.2 [84.8, 93.7]	86.5 [80.3, 90.9]	
Month 9	88.6 [82.8, 92.6]	NC [NC, NC]	
Month 12	85.1 [77.9, 90.2]	NC [NC, NC]	
Month 18	78.0 [67.6, 85.4]	NC [NC, NC]	
Month 24	78.0 [67.6, 85.4]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.706 [0.381, 1.310]
Log-rank test			
Two-sided unstratified log-rank p-value			0.2674

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.57.2.1: Summary and Results of TEAEs - Blood lactate dehydrogenase increased (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	6 (3.0%)	9 (4.6%)	
Number of patients censored	195 (97.0%)	188 (95.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.4 [93.8, 98.9]	94.9 [90.4, 97.3]	
Month 6	96.8 [93.0, 98.5]	94.9 [90.4, 97.3]	
Month 9	96.8 [93.0, 98.5]	NC [NC, NC]	
Month 12	96.8 [93.0, 98.5]	NC [NC, NC]	
Month 18	96.8 [93.0, 98.5]	NC [NC, NC]	
Month 24	96.8 [93.0, 98.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.628 [0.223, 1.765]
Log-rank test			
Two-sided unstratified log-rank p-value			0.3733

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.58.2.1: Summary and Results of TEAEs - Lymphocyte count decreased (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	8 (4.0%)	3 (1.5%)	
Number of patients censored	193 (96.0%)	194 (98.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.9 [93.2, 98.6]	99.0 [96.0, 99.7]	
Month 6	95.7 [91.6, 97.8]	98.2 [94.3, 99.4]	
Month 9	95.7 [91.6, 97.8]	NC [NC, NC]	
Month 12	95.7 [91.6, 97.8]	NC [NC, NC]	
Month 18	95.7 [91.6, 97.8]	NC [NC, NC]	
Month 24	95.7 [91.6, 97.8]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			2.494 [0.661, 9.406]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1625

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.59.2.1: Summary and Results of TEAEs - Neutrophil count decreased (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	9 (4.5%)	24 (12.2%)	
Number of patients censored	192 (95.5%)	173 (87.8%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.2 [92.2, 98.2]	87.0 [81.2, 91.1]	
Month 6	95.6 [91.4, 97.8]	87.0 [81.2, 91.1]	
Month 9	95.6 [91.4, 97.8]	NC [NC, NC]	
Month 12	94.6 [89.8, 97.2]	NC [NC, NC]	
Month 18	94.6 [89.8, 97.2]	NC [NC, NC]	
Month 24	94.6 [89.8, 97.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.303 [0.136, 0.673]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0019

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.59.2.2: Summary and Results of TEAEs by Subgroups - Neutrophil count decreased (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	1 (2.0)	NC [NC, NC]	49	6 (12.2)	NC [NC, NC]	0.158 [0.019, 1.312]	0.0500	0.4419
Absent	151	8 (5.3)	NC [NC, NC]	148	18 (12.2)	NC [NC, NC]	0.347 [0.145, 0.832]	0.0131	
Age									
< 65 years	39	2 (5.1)	NC [NC, NC]	28	4 (14.3)	NC [NC, NC]	0.173 [0.019, 1.546]	0.0757	0.9548
>= 65 years	162	7 (4.3)	NC [NC, NC]	169	20 (11.8)	NC [NC, NC]	0.337 [0.142, 0.796]	0.0094	
Region									
Europe	73	2 (2.7)	NC [NC, NC]	94	11 (11.7)	NC [NC, NC]	0.221 [0.049, 0.996]	0.0310	0.6507
North America	46	2 (4.3)	NC [NC, NC]	33	5 (15.2)	NC [NC, NC]	0.245 [0.047, 1.262]	0.0682	
Rest of World	82	5 (6.1)	NC [NC, NC]	70	8 (11.4)	NC [NC, NC]	0.405 [0.122, 1.345]	0.1278	
Sex									
Male	145	7 (4.8)	NC [NC, NC]	148	20 (13.5)	NC [NC, NC]	0.287 [0.115, 0.714]	0.0043	0.8599
Female	56	2 (3.6)	NC [NC, NC]	49	4 (8.2)	NC [NC, NC]	0.376 [0.069, 2.054]	0.2395	
Metastases at Baseline									
Visceral metastases	147	6 (4.1)	NC [NC, NC]	152	19 (12.5)	NC [NC, NC]	0.252 [0.094, 0.674]	0.0030	0.4589
Lymph node only	43	3 (7.0)	NC [NC, NC]	37	4 (10.8)	NC [NC, NC]	0.608 [0.136, 2.717]	0.5063	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.60.2.1: Summary and Results of TEAEs - Platelet count decreased (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	3 (1.5%)	34 (17.3%)	
Number of patients censored	198 (98.5%)	163 (82.7%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	99.4 [96.1, 99.9]	83.0 [76.8, 87.7]	
Month 6	99.4 [96.1, 99.9]	81.4 [74.9, 86.4]	
Month 9	99.4 [96.1, 99.9]	NC [NC, NC]	
Month 12	99.4 [96.1, 99.9]	NC [NC, NC]	
Month 18	95.2 [83.8, 98.6]	NC [NC, NC]	
Month 24	95.2 [83.8, 98.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.026 [0.004, 0.187]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.60.2.2: Summary and Results of TEAEs by Subgroups - Platelet count decreased (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	0 (0.0)	NC [NC, NC]	49	14 (28.6)	NC [NC, NC]	NC [NC, NC]	<.0001	NC
Absent	151	3 (2.0)	NC [NC, NC]	148	20 (13.5)	NC [NC, NC]	0.044 [0.006, 0.325]	<.0001	
Age									
< 65 years	39	1 (2.6)	NC [NC, NC]	28	4 (14.3)	NC [NC, NC]	0.000 [0.000, NC]	0.0152	0.7476
>= 65 years	162	2 (1.2)	NC [NC, NC]	169	30 (17.8)	NC [NC, NC]	0.031 [0.004, 0.225]	<.0001	
Region									
Europe	73	1 (1.4)	NC [NC, NC]	94	14 (14.9)	NC [NC, NC]	0.000 [0.000, NC]	0.0006	0.9318
North America	46	1 (2.2)	NC [NC, NC]	33	7 (21.2)	NC [NC, NC]	0.083 [0.010, 0.675]	0.0031	
Rest of World	82	1 (1.2)	NC [NC, NC]	70	13 (18.6)	NC [NC, NC]	0.000 [0.000, NC]	<.0001	
Sex									
Male	145	2 (1.4)	NC [NC, NC]	148	25 (16.9)	NC [NC, NC]	0.037 [0.005, 0.273]	<.0001	0.9999
Female	56	1 (1.8)	NC [NC, NC]	49	9 (18.4)	NC [NC, NC]	0.000 [0.000, NC]	0.0006	
Metastases at Baseline									
Visceral metastases	147	2 (1.4)	NC [NC, NC]	152	31 (20.4)	NC [NC, NC]	0.030 [0.004, 0.217]	<.0001	NC
Lymph node only	43	0 (0.0)	NC [NC, NC]	37	2 (5.4)	NC [NC, NC]	NC [NC, NC]	0.0920	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.61.2.1: Summary and Results of TEAEs - Weight decreased (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	72 (35.8%)	15 (7.6%)	
Number of patients censored	129 (64.2%)	182 (92.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	76.2 [69.3, 81.8]	92.2 [87.2, 95.3]	
Month 6	66.8 [59.2, 73.3]	91.5 [86.3, 94.8]	
Month 9	60.3 [52.2, 67.5]	NC [NC, NC]	
Month 12	57.0 [48.4, 64.7]	NC [NC, NC]	
Month 18	53.3 [43.6, 62.0]	NC [NC, NC]	
Month 24	49.7 [38.4, 60.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	18.7 [10.6, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			3.736 [2.113, 6.604]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.61.2.2: Summary and Results of TEAEs by Subgroups - Weight decreased (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	18 (36.0)	NC [3.0, NC]	49	9 (18.4)	NC [NC, NC]	1.830 [0.817, 4.102]	0.1362	0.0100
Absent	151	54 (35.8)	18.7 [10.6, NC]	148	6 (4.1)	NC [NC, NC]	6.555 [2.775, 15.486]	<.0001	
Age									
< 65 years	39	8 (20.5)	NC [NC, NC]	28	2 (7.1)	NC [NC, NC]	2.243 [0.455, 11.066]	0.3083	0.4128
>= 65 years	162	64 (39.5)	16.7 [7.9, NC]	169	13 (7.7)	NC [NC, NC]	4.103 [2.228, 7.554]	<.0001	
Region									
Europe	73	24 (32.9)	18.7 [11.7, NC]	94	7 (7.4)	NC [NC, NC]	2.970 [1.230, 7.173]	0.0112	0.3516
North America	46	20 (43.5)	7.9 [3.0, NC]	33	1 (3.0)	NC [NC, NC]	13.320 [1.773, 100.07]	0.0010	
Rest of World	82	28 (34.1)	NC [8.5, NC]	70	7 (10.0)	NC [NC, NC]	2.737 [1.171, 6.397]	0.0154	
Sex									
Male	145	51 (35.2)	18.7 [9.7, NC]	148	13 (8.8)	NC [NC, NC]	3.396 [1.817, 6.349]	<.0001	0.4079
Female	56	21 (37.5)	NC [7.2, NC]	49	2 (4.1)	NC [NC, NC]	6.004 [1.379, 26.131]	0.0066	
Metastases at Baseline									
Visceral metastases	147	50 (34.0)	NC [8.5, NC]	152	13 (8.6)	NC [NC, NC]	3.618 [1.945, 6.728]	<.0001	NC
Lymph node only	43	15 (34.9)	18.7 [9.7, NC]	37	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0102	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.62.2.1: Summary and Results of TEAEs - White blood cell count decreased (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	4 (2.0%)	11 (5.6%)	
Number of patients censored	197 (98.0%)	186 (94.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.4 [95.0, 99.5]	94.1 [89.6, 96.7]	
Month 6	97.7 [93.8, 99.1]	94.1 [89.6, 96.7]	
Month 9	97.7 [93.8, 99.1]	NC [NC, NC]	
Month 12	97.7 [93.8, 99.1]	NC [NC, NC]	
Month 18	97.7 [93.8, 99.1]	NC [NC, NC]	
Month 24	97.7 [93.8, 99.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.264 [0.076, 0.921]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0253

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.62.2.2: Summary and Results of TEAEs by Subgroups - White blood cell count decreased (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	0 (0.0)	NC [NC, NC]	49	3 (6.1)	NC [NC, NC]	NC [NC, NC]	0.0832	NC
Absent	151	4 (2.6)	NC [NC, NC]	148	8 (5.4)	NC [NC, NC]	0.358 [0.098, 1.312]	0.1067	
Age									
< 65 years	39	0 (0.0)	NC [NC, NC]	28	3 (10.7)	NC [NC, NC]	NC [NC, NC]	0.0377	NC
>= 65 years	162	4 (2.5)	NC [NC, NC]	169	8 (4.7)	NC [NC, NC]	0.384 [0.104, 1.420]	0.1373	
Region									
Europe	73	0 (0.0)		94	5 (5.3)				
North America	46	2 (4.3)		33	2 (6.1)				
Rest of World	82	2 (2.4)		70	4 (5.7)				
Sex									
Male	145	4 (2.8)	NC [NC, NC]	148	11 (7.4)	NC [NC, NC]	0.281 [0.081, 0.969]	0.0327	NC
Female	56	0 (0.0)	NC [NC, NC]	49	0 (0.0)	NC [NC, NC]	NC [NC, NC]	NC	
Metastases at Baseline									
Visceral metastases	147	3 (2.0)	NC [NC, NC]	152	7 (4.6)	NC [NC, NC]	0.300 [0.065, 1.379]	0.1027	NC
Lymph node only	43	0 (0.0)	NC [NC, NC]	37	3 (8.1)	NC [NC, NC]	NC [NC, NC]	0.0478	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.63.2.1: Summary and Results of TEAEs - Metabolism and nutrition disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	122 (60.7%)	86 (43.7%)	
Number of patients censored	79 (39.3%)	111 (56.3%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	42.5 [35.4, 49.4]	57.7 [50.2, 64.5]	
Month 6	39.1 [32.1, 45.9]	52.7 [45.0, 59.9]	
Month 9	38.4 [31.5, 45.3]	NC [NC, NC]	
Month 12	36.7 [29.7, 43.7]	NC [NC, NC]	
Month 18	36.7 [29.7, 43.7]	NC [NC, NC]	
Month 24	34.1 [26.0, 42.3]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	2.0 [1.4, 2.8]	NC [3.1, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.428 [1.081, 1.886]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0113

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.63.2.2: Summary and Results of TEAEs by Subgroups - Metabolism and nutrition disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	27 (54.0)	2.3 [1.4, NC]	49	17 (34.7)	NC [3.3, NC]	1.593 [0.864, 2.939]	0.1283	0.6567
Absent	151	95 (62.9)	1.9 [1.1, 2.8]	148	69 (46.6)	4.6 [2.4, NC]	1.384 [1.013, 1.892]	0.0408	
Age									
< 65 years	39	20 (51.3)	9.0 [1.1, NC]	28	10 (35.7)	NC [2.1, NC]	1.574 [0.731, 3.388]	0.2451	0.9188
>= 65 years	162	102 (63.0)	1.9 [1.2, 2.6]	169	76 (45.0)	NC [2.8, NC]	1.438 [1.066, 1.940]	0.0161	
Region									
Europe	73	44 (60.3)	2.0 [1.3, 18.2]	94	46 (48.9)	4.6 [2.2, NC]	1.219 [0.802, 1.853]	0.3550	0.4501
North America	46	33 (71.7)	0.7 [0.5, 1.8]	33	14 (42.4)	NC [0.4, NC]	1.765 [0.937, 3.322]	0.0698	
Rest of World	82	45 (54.9)	3.3 [1.9, NC]	70	26 (37.1)	NC [3.3, NC]	1.465 [0.901, 2.380]	0.1166	
Sex									
Male	145	93 (64.1)	1.9 [1.2, 2.8]	148	57 (38.5)	NC [4.6, NC]	1.906 [1.366, 2.660]	0.0001	0.0006
Female	56	29 (51.8)	2.4 [1.1, NC]	49	29 (59.2)	1.2 [0.4, NC]	0.685 [0.408, 1.149]	0.1487	
Metastases at Baseline									
Visceral metastases	147	89 (60.5)	2.0 [1.3, 2.8]	152	68 (44.7)	NC [2.4, NC]	1.391 [1.012, 1.913]	0.0402	0.7000
Lymph node only	43	25 (58.1)	1.6 [1.0, NC]	37	17 (45.9)	4.6 [1.1, NC]	1.213 [0.651, 2.260]	0.5410	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.64.2.1: Summary and Results of TEAEs - Decreased appetite (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	73 (36.3%)	53 (26.9%)	
Number of patients censored	128 (63.7%)	144 (73.1%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	64.7 [57.5, 71.1]	72.8 [65.7, 78.6]	
Month 6	62.3 [54.9, 68.9]	71.2 [64.0, 77.3]	
Month 9	61.0 [53.5, 67.6]	NC [NC, NC]	
Month 12	61.0 [53.5, 67.6]	NC [NC, NC]	
Month 18	61.0 [53.5, 67.6]	NC [NC, NC]	
Month 24	61.0 [53.5, 67.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.272 [0.891, 1.815]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1828

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.65.2.1: Summary and Results of TEAEs - Dehydration (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	12 (6.0%)	4 (2.0%)	
Number of patients censored	189 (94.0%)	193 (98.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	95.8 [91.8, 97.9]	98.4 [95.1, 99.5]	
Month 6	94.6 [90.2, 97.1]	97.7 [94.0, 99.1]	
Month 9	94.6 [90.2, 97.1]	NC [NC, NC]	
Month 12	94.6 [90.2, 97.1]	NC [NC, NC]	
Month 18	93.2 [87.5, 96.4]	NC [NC, NC]	
Month 24	89.9 [79.0, 95.3]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			2.367 [0.742, 7.548]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1333

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.66.2.1: Summary and Results of TEAEs - Hypercalcaemia (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	7 (3.5%)	4 (2.0%)	
Number of patients censored	194 (96.5%)	193 (98.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.5 [94.1, 98.9]	98.3 [94.9, 99.5]	
Month 6	97.5 [94.1, 98.9]	97.4 [93.1, 99.1]	
Month 9	96.0 [91.8, 98.1]	NC [NC, NC]	
Month 12	96.0 [91.8, 98.1]	NC [NC, NC]	
Month 18	96.0 [91.8, 98.1]	NC [NC, NC]	
Month 24	96.0 [91.8, 98.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.186 [0.319, 4.412]
Log-rank test			
Two-sided unstratified log-rank p-value			0.7985

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.67.2.1: Summary and Results of TEAEs - Hyperglycaemia (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	28 (13.9%)	5 (2.5%)	
Number of patients censored	173 (86.1%)	192 (97.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	88.8 [83.5, 92.5]	97.9 [94.4, 99.2]	
Month 6	86.4 [80.7, 90.6]	97.1 [93.1, 98.8]	
Month 9	84.8 [78.6, 89.3]	NC [NC, NC]	
Month 12	84.8 [78.6, 89.3]	NC [NC, NC]	
Month 18	84.8 [78.6, 89.3]	NC [NC, NC]	
Month 24	84.8 [78.6, 89.3]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			5.219 [2.004, 13.592]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0002

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.67.2.2: Summary and Results of TEAEs by Subgroups - Hyperglycaemia (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	5 (10.0)	NC [NC, NC]	49	1 (2.0)	NC [NC, NC]	4.151 [0.464, 37.153]	0.1671	0.9144
Absent	151	23 (15.2)	NC [NC, NC]	148	4 (2.7)	NC [NC, NC]	5.492 [1.892, 15.937]	0.0004	
Age									
< 65 years	39	4 (10.3)	NC [NC, NC]	28	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0802	NC
>= 65 years	162	24 (14.8)	NC [NC, NC]	169	5 (3.0)	NC [NC, NC]	4.647 [1.759, 12.275]	0.0006	
Region									
Europe	73	8 (11.0)	NC [NC, NC]	94	2 (2.1)	NC [NC, NC]	4.695 [0.976, 22.576]	0.0335	0.9952
North America	46	8 (17.4)	NC [NC, NC]	33	1 (3.0)	NC [NC, NC]	5.596 [0.700, 44.772]	0.0662	
Rest of World	82	12 (14.6)	NC [NC, NC]	70	2 (2.9)	NC [NC, NC]	4.843 [1.073, 21.862]	0.0232	
Sex									
Male	145	26 (17.9)	NC [NC, NC]	148	4 (2.7)	NC [NC, NC]	6.505 [2.257, 18.743]	<.0001	0.2697
Female	56	2 (3.6)	NC [NC, NC]	49	1 (2.0)	NC [NC, NC]	1.696 [0.154, 18.708]	0.6615	
Metastases at Baseline									
Visceral metastases	147	20 (13.6)	NC [NC, NC]	152	4 (2.6)	NC [NC, NC]	5.117 [1.740, 15.042]	0.0009	0.9871
Lymph node only	43	6 (14.0)	NC [NC, NC]	37	1 (2.7)	NC [NC, NC]	5.125 [0.617, 42.594]	0.0918	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.68.2.1: Summary and Results of TEAEs - Hyperkalaemia (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	8 (4.0%)	14 (7.1%)	
Number of patients censored	193 (96.0%)	183 (92.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.3 [92.4, 98.2]	92.3 [87.4, 95.4]	
Month 6	95.7 [91.5, 97.8]	92.3 [87.4, 95.4]	
Month 9	95.7 [91.5, 97.8]	NC [NC, NC]	
Month 12	95.7 [91.5, 97.8]	NC [NC, NC]	
Month 18	95.7 [91.5, 97.8]	NC [NC, NC]	
Month 24	95.7 [91.5, 97.8]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.532 [0.223, 1.269]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1479

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.69.2.1: Summary and Results of TEAEs - Hypoalbuminaemia (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	11 (5.5%)	6 (3.0%)	
Number of patients censored	190 (94.5%)	191 (97.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	94.7 [90.4, 97.1]	96.8 [93.0, 98.5]	
Month 6	94.1 [89.6, 96.7]	96.8 [93.0, 98.5]	
Month 9	94.1 [89.6, 96.7]	NC [NC, NC]	
Month 12	94.1 [89.6, 96.7]	NC [NC, NC]	
Month 18	94.1 [89.6, 96.7]	NC [NC, NC]	
Month 24	94.1 [89.6, 96.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.778 [0.657, 4.809]
Log-rank test			
Two-sided unstratified log-rank p-value			0.2503

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.70.2.1: Summary and Results of TEAEs - Hypocalcaemia (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	9 (4.5%)	11 (5.6%)	
Number of patients censored	192 (95.5%)	186 (94.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.9 [93.1, 98.6]	94.4 [89.8, 97.0]	
Month 6	96.3 [92.3, 98.2]	93.7 [88.9, 96.5]	
Month 9	94.6 [89.8, 97.2]	NC [NC, NC]	
Month 12	94.6 [89.8, 97.2]	NC [NC, NC]	
Month 18	94.6 [89.8, 97.2]	NC [NC, NC]	
Month 24	94.6 [89.8, 97.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.600 [0.233, 1.542]
Log-rank test			
Two-sided unstratified log-rank p-value			0.2834

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.71.2.1: Summary and Results of TEAEs - Hypokalaemia (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	20 (10.0%)	9 (4.6%)	
Number of patients censored	181 (90.0%)	188 (95.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	92.2 [87.3, 95.2]	96.0 [91.7, 98.1]	
Month 6	90.9 [85.7, 94.3]	94.0 [88.6, 96.9]	
Month 9	88.4 [82.4, 92.4]	NC [NC, NC]	
Month 12	88.4 [82.4, 92.4]	NC [NC, NC]	
Month 18	88.4 [82.4, 92.4]	NC [NC, NC]	
Month 24	88.4 [82.4, 92.4]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.731 [0.770, 3.893]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1788

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.72.2.1: Summary and Results of TEAEs - Hypomagnesaemia (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	10 (5.0%)	7 (3.6%)	
Number of patients censored	191 (95.0%)	190 (96.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	95.9 [91.9, 97.9]	96.0 [91.7, 98.1]	
Month 6	95.3 [91.1, 97.5]	96.0 [91.7, 98.1]	
Month 9	95.3 [91.1, 97.5]	NC [NC, NC]	
Month 12	94.3 [89.6, 97.0]	NC [NC, NC]	
Month 18	94.3 [89.6, 97.0]	NC [NC, NC]	
Month 24	94.3 [89.6, 97.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.213 [0.451, 3.260]
Log-rank test			
Two-sided unstratified log-rank p-value			0.7017

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.73.2.1: Summary and Results of TEAEs - Hyponatraemia (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	28 (13.9%)	11 (5.6%)	
Number of patients censored	173 (86.1%)	186 (94.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	88.4 [82.9, 92.2]	95.3 [91.1, 97.5]	
Month 6	85.9 [80.0, 90.2]	93.5 [88.3, 96.4]	
Month 9	85.1 [78.9, 89.6]	NC [NC, NC]	
Month 12	85.1 [78.9, 89.6]	NC [NC, NC]	
Month 18	83.5 [76.5, 88.6]	NC [NC, NC]	
Month 24	83.5 [76.5, 88.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			2.172 [1.071, 4.408]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0276

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.73.2.2: Summary and Results of TEAEs by Subgroups - Hyponatraemia (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	2 (4.0)	NC [NC, NC]	49	2 (4.1)	NC [NC, NC]	0.891 [0.124, 6.405]	0.9086	0.3439
Absent	151	26 (17.2)	NC [NC, NC]	148	9 (6.1)	NC [NC, NC]	2.444 [1.134, 5.271]	0.0185	
Age									
< 65 years	39	1 (2.6)	NC [NC, NC]	28	1 (3.6)	NC [NC, NC]	0.727 [0.045, 11.617]	0.8206	0.3503
>= 65 years	162	27 (16.7)	NC [NC, NC]	169	10 (5.9)	NC [NC, NC]	2.427 [1.162, 5.068]	0.0149	
Region									
Europe	73	8 (11.0)	NC [NC, NC]	94	2 (2.1)	NC [NC, NC]	5.157 [1.095, 24.297]	0.0207	0.4091
North America	46	11 (23.9)	NC [14.0, NC]	33	5 (15.2)	NC [NC, NC]	1.162 [0.389, 3.470]	0.7904	
Rest of World	82	9 (11.0)	NC [NC, NC]	70	4 (5.7)	NC [NC, NC]	1.626 [0.493, 5.369]	0.4204	
Sex									
Male	145	25 (17.2)	NC [NC, NC]	148	7 (4.7)	NC [NC, NC]	3.378 [1.447, 7.886]	0.0028	0.0271
Female	56	3 (5.4)	NC [NC, NC]	49	4 (8.2)	NC [NC, NC]	0.508 [0.110, 2.343]	0.3789	
Metastases at Baseline									
Visceral metastases	147	20 (13.6)	NC [NC, NC]	152	10 (6.6)	NC [NC, NC]	1.886 [0.875, 4.064]	0.0999	0.4538
Lymph node only	43	6 (14.0)	NC [NC, NC]	37	1 (2.7)	NC [NC, NC]	4.072 [0.475, 34.867]	0.1648	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.74.2.1: Summary and Results of TEAEs - Hypophosphataemia (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	22 (10.9%)	10 (5.1%)	
Number of patients censored	179 (89.1%)	187 (94.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	91.9 [87.1, 95.0]	95.1 [90.8, 97.4]	
Month 6	91.3 [86.4, 94.5]	94.2 [89.4, 96.9]	
Month 9	89.0 [83.4, 92.8]	NC [NC, NC]	
Month 12	88.0 [81.9, 92.1]	NC [NC, NC]	
Month 18	86.4 [79.4, 91.2]	NC [NC, NC]	
Month 24	86.4 [79.4, 91.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.652 [0.757, 3.607]
Log-rank test			
Two-sided unstratified log-rank p-value			0.2037

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.75.2.1: Summary and Results of TEAEs - Musculoskeletal and connective tissue disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	78 (38.8%)	53 (26.9%)	
Number of patients censored	123 (61.2%)	144 (73.1%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	76.3 [69.6, 81.8]	73.0 [65.9, 78.9]	
Month 6	65.7 [58.2, 72.2]	67.5 [58.0, 75.3]	
Month 9	61.1 [53.2, 68.0]	NC [NC, NC]	
Month 12	56.1 [47.7, 63.7]	NC [NC, NC]	
Month 18	49.8 [39.6, 59.2]	NC [NC, NC]	
Month 24	38.1 [21.7, 54.3]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	16.3 [9.9, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.982 [0.676, 1.426]
Log-rank test			
Two-sided unstratified log-rank p-value			0.9228

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.76.2.1: Summary and Results of TEAEs - Arthralgia (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	22 (10.9%)	10 (5.1%)	
Number of patients censored	179 (89.1%)	187 (94.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	95.8 [91.7, 97.9]	95.4 [91.0, 97.7]	
Month 6	93.4 [88.6, 96.2]	93.7 [88.4, 96.6]	
Month 9	89.3 [83.2, 93.3]	NC [NC, NC]	
Month 12	88.2 [81.7, 92.6]	NC [NC, NC]	
Month 18	81.6 [70.7, 88.7]	NC [NC, NC]	
Month 24	76.5 [60.7, 86.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.083 [0.468, 2.504]
Log-rank test			
Two-sided unstratified log-rank p-value			0.8522

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.77.2.1: Summary and Results of TEAEs - Back pain (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	16 (8.0%)	13 (6.6%)	
Number of patients censored	185 (92.0%)	184 (93.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	94.8 [90.6, 97.2]	92.8 [88.0, 95.8]	
Month 6	92.3 [87.4, 95.4]	92.8 [88.0, 95.8]	
Month 9	92.3 [87.4, 95.4]	NC [NC, NC]	
Month 12	90.1 [83.8, 94.0]	NC [NC, NC]	
Month 18	90.1 [83.8, 94.0]	NC [NC, NC]	
Month 24	90.1 [83.8, 94.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.944 [0.438, 2.033]
Log-rank test			
Two-sided unstratified log-rank p-value			0.8821

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.78.2.1: Summary and Results of TEAEs - Muscular weakness (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	16 (8.0%)	3 (1.5%)	
Number of patients censored	185 (92.0%)	194 (98.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	95.6 [91.4, 97.8]	98.4 [95.2, 99.5]	
Month 6	92.3 [87.1, 95.5]	98.4 [95.2, 99.5]	
Month 9	90.7 [85.0, 94.3]	NC [NC, NC]	
Month 12	90.7 [85.0, 94.3]	NC [NC, NC]	
Month 18	90.7 [85.0, 94.3]	NC [NC, NC]	
Month 24	90.7 [85.0, 94.3]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	26.2 [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			3.241 [0.904, 11.623]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0569

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.79.2.1: Summary and Results of TEAEs - Myalgia (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	9 (4.5%)	4 (2.0%)	
Number of patients censored	192 (95.5%)	193 (98.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.4 [93.8, 98.9]	97.9 [94.4, 99.2]	
Month 6	96.7 [92.8, 98.5]	97.9 [94.4, 99.2]	
Month 9	95.8 [91.2, 98.0]	NC [NC, NC]	
Month 12	95.8 [91.2, 98.0]	NC [NC, NC]	
Month 18	92.7 [85.4, 96.5]	NC [NC, NC]	
Month 24	92.7 [85.4, 96.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.275 [0.352, 4.621]
Log-rank test			
Two-sided unstratified log-rank p-value			0.7106

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.80.2.1: Summary and Results of TEAEs - Pain in extremity (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	11 (5.5%)	9 (4.6%)	
Number of patients censored	190 (94.5%)	188 (95.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.4 [92.6, 98.3]	95.5 [91.2, 97.7]	
Month 6	95.8 [91.7, 97.9]	94.6 [89.6, 97.2]	
Month 9	94.1 [89.2, 96.8]	NC [NC, NC]	
Month 12	94.1 [89.2, 96.8]	NC [NC, NC]	
Month 18	94.1 [89.2, 96.8]	NC [NC, NC]	
Month 24	87.8 [68.1, 95.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.835 [0.322, 2.162]
Log-rank test			
Two-sided unstratified log-rank p-value			0.7095

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.81.2.1: Summary and Results of TEAEs - Neoplasms benign, malignant and unspecified (incl cysts and polyps) (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	**Plat+Gem (N= 197)**	**EV+Pembro vs. Plat+Gem**
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	9 (4.5%)	4 (2.0%)	
Number of patients censored	192 (95.5%)	193 (98.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	99.0 [96.0, 99.7]	98.2 [94.6, 99.4]	
Month 6	98.3 [94.9, 99.5]	97.5 [93.4, 99.1]	
Month 9	96.6 [91.9, 98.6]	NC [NC, NC]	
Month 12	94.2 [87.7, 97.3]	NC [NC, NC]	
Month 18	90.9 [82.2, 95.5]	NC [NC, NC]	
Month 24	90.9 [82.2, 95.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.661 [0.148, 2.964]
Log-rank test			
Two-sided unstratified log-rank p-value			0.5858

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.82.2.1: Summary and Results of TEAEs - Nervous system disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	143 (71.1%)	48 (24.4%)	
Number of patients censored	58 (28.9%)	149 (75.6%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	54.2 [46.7, 61.2]	77.4 [70.7, 82.8]	
Month 6	29.6 [22.8, 36.8]	65.8 [49.9, 77.7]	
Month 9	18.9 [12.8, 25.9]	NC [NC, NC]	
Month 12	15.1 [9.3, 22.2]	NC [NC, NC]	
Month 18	8.3 [3.4, 15.9]	NC [NC, NC]	
Month 24	NC [NC, NC]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	3.4 [2.8, 3.7]	NC [5.4, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			2.692 [1.922, 3.769]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.82.2.2: Summary and Results of TEAEs by Subgroups - Nervous system disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	30 (60.0)	3.3 [2.3, 4.6]	49	14 (28.6)	NC [NC, NC]	1.982 [1.041, 3.774]	0.0340	0.1439
Absent	151	113 (74.8)	3.4 [2.8, 4.1]	148	34 (23.0)	NC [5.4, NC]	2.970 [1.999, 4.412]	<.0001	
Age									
< 65 years	39	27 (69.2)	3.7 [2.8, 5.1]	28	9 (32.1)	NC [3.7, NC]	2.020 [0.932, 4.379]	0.0692	0.2870
>= 65 years	162	116 (71.6)	3.3 [2.7, 3.7]	169	39 (23.1)	NC [5.4, NC]	2.854 [1.963, 4.150]	<.0001	
Region									
Europe	73	54 (74.0)	2.8 [2.5, 3.7]	94	26 (27.7)	NC [NC, NC]	2.625 [1.621, 4.250]	<.0001	0.2535
North America	46	33 (71.7)	2.3 [1.4, 3.5]	33	12 (36.4)	NC [2.3, NC]	1.903 [0.968, 3.745]	0.0580	
Rest of World	82	56 (68.3)	4.5 [3.3, 5.7]	70	10 (14.3)	NC [5.4, NC]	3.792 [1.898, 7.578]	<.0001	
Sex									
Male	145	101 (69.7)	3.3 [2.6, 3.7]	148	36 (24.3)	NC [5.4, NC]	2.938 [1.987, 4.343]	<.0001	0.4821
Female	56	42 (75.0)	3.7 [2.8, 6.5]	49	12 (24.5)	NC [NC, NC]	2.155 [1.110, 4.187]	0.0202	
Metastases at Baseline									
Visceral metastases	147	100 (68.0)	3.4 [2.7, 4.4]	152	34 (22.4)	NC [NC, NC]	2.838 [1.903, 4.232]	<.0001	0.8218
Lymph node only	43	34 (79.1)	3.4 [2.1, 4.1]	37	10 (27.0)	5.4 [4.9, NC]	3.049 [1.479, 6.284]	0.0015	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.83.2.1: Summary and Results of TEAEs - Dizziness (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	12 (6.0%)	17 (8.6%)	
Number of patients censored	189 (94.0%)	180 (91.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	95.7 [91.6, 97.8]	91.2 [85.9, 94.5]	
Month 6	94.5 [90.0, 97.0]	90.4 [85.0, 94.0]	
Month 9	94.5 [90.0, 97.0]	NC [NC, NC]	
Month 12	92.0 [85.8, 95.6]	NC [NC, NC]	
Month 18	92.0 [85.8, 95.6]	NC [NC, NC]	
Month 24	92.0 [85.8, 95.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.534 [0.244, 1.166]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1098

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.84.2.1: Summary and Results of TEAEs - Dysgeusia (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	46 (22.9%)	9 (4.6%)	
Number of patients censored	155 (77.1%)	188 (95.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	79.7 [73.2, 84.8]	95.7 [91.6, 97.8]	
Month 6	76.6 [69.8, 82.1]	94.9 [90.2, 97.3]	
Month 9	74.3 [67.0, 80.1]	NC [NC, NC]	
Month 12	74.3 [67.0, 80.1]	NC [NC, NC]	
Month 18	74.3 [67.0, 80.1]	NC [NC, NC]	
Month 24	74.3 [67.0, 80.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			4.827 [2.350, 9.916]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.84.2.2: Summary and Results of TEAEs by Subgroups - Dysgeusia (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	9 (18.0)	NC [NC, NC]	49	3 (6.1)	NC [NC, NC]	2.681 [0.711, 10.109]	0.1296	0.3405
Absent	151	37 (24.5)	NC [NC, NC]	148	6 (4.1)	NC [NC, NC]	5.922 [2.487, 14.100]	<.0001	
Age									
< 65 years	39	10 (25.6)	NC [NC, NC]	28	2 (7.1)	NC [NC, NC]	3.054 [0.652, 14.307]	0.1362	0.6403
>= 65 years	162	36 (22.2)	NC [NC, NC]	169	7 (4.1)	NC [NC, NC]	5.354 [2.373, 12.077]	<.0001	
Region									
Europe	73	12 (16.4)	NC [NC, NC]	94	5 (5.3)	NC [NC, NC]	3.215 [1.133, 9.126]	0.0203	0.5200
North America	46	22 (47.8)	3.5 [1.9, NC]	33	3 (9.1)	NC [NC, NC]	5.490 [1.629, 18.508]	0.0020	
Rest of World	82	12 (14.6)	NC [NC, NC]	70	1 (1.4)	NC [NC, NC]	8.969 [1.148, 70.061]	0.0112	
Sex									
Male	145	35 (24.1)	NC [NC, NC]	148	7 (4.7)	NC [NC, NC]	5.138 [2.268, 11.639]	<.0001	0.7911
Female	56	11 (19.6)	NC [NC, NC]	49	2 (4.1)	NC [NC, NC]	4.090 [0.896, 18.669]	0.0489	
Metastases at Baseline									
Visceral metastases	147	33 (22.4)	NC [NC, NC]	152	6 (3.9)	NC [NC, NC]	5.623 [2.346, 13.478]	<.0001	0.9558
Lymph node only	43	13 (30.2)	NC [7.2, NC]	37	2 (5.4)	NC [NC, NC]	5.272 [1.171, 23.735]	0.0155	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.85.2.1: Summary and Results of TEAEs - Headache (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	14 (7.0%)	10 (5.1%)	
Number of patients censored	187 (93.0%)	187 (94.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	95.4 [91.4, 97.6]	96.2 [92.3, 98.2]	
Month 6	94.2 [89.7, 96.8]	93.5 [88.0, 96.5]	
Month 9	93.4 [88.5, 96.2]	NC [NC, NC]	
Month 12	93.4 [88.5, 96.2]	NC [NC, NC]	
Month 18	89.9 [82.0, 94.4]	NC [NC, NC]	
Month 24	89.9 [82.0, 94.4]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.012 [0.429, 2.387]
Log-rank test			
Two-sided unstratified log-rank p-value			0.9777

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.86.2.1: Summary and Results of TEAEs - Paraesthesia (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	12 (6.0%)	2 (1.0%)	
Number of patients censored	189 (94.0%)	195 (99.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.1 [92.0, 98.1]	98.9 [95.5, 99.7]	
Month 6	94.1 [89.3, 96.8]	98.9 [95.5, 99.7]	
Month 9	93.3 [88.1, 96.2]	NC [NC, NC]	
Month 12	92.1 [86.1, 95.5]	NC [NC, NC]	
Month 18	92.1 [86.1, 95.5]	NC [NC, NC]	
Month 24	92.1 [86.1, 95.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			3.925 [0.843, 18.272]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0606

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.87.2.1: Summary and Results of TEAEs - Peripheral motor neuropathy (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	10 (5.0%)	0 (0.0%)	
Number of patients censored	191 (95.0%)	197 (100.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.9 [95.8, 99.7]	100.0 [100.0, 100.0]	
Month 6	97.6 [93.6, 99.1]	100.0 [100.0, 100.0]	
Month 9	94.7 [89.6, 97.3]	NC [NC, NC]	
Month 12	93.4 [87.3, 96.6]	NC [NC, NC]	
Month 18	91.9 [84.9, 95.8]	NC [NC, NC]	
Month 24	91.9 [84.9, 95.8]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			NC [NC, NC]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1171

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.88.2.1: Summary and Results of TEAEs - Peripheral sensory neuropathy (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	103 (51.2%)	10 (5.1%)	
Number of patients censored	98 (48.8%)	187 (94.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	79.5 [72.8, 84.7]	95.9 [91.7, 98.0]	
Month 6	52.4 [44.4, 59.8]	92.7 [86.0, 96.3]	
Month 9	40.4 [32.3, 48.3]	NC [NC, NC]	
Month 12	35.3 [27.2, 43.4]	NC [NC, NC]	
Month 18	25.8 [16.0, 36.7]	NC [NC, NC]	
Month 24	NC [NC, NC]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	6.5 [5.1, 8.3]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			7.376 [3.808, 14.286]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.88.2.2: Summary and Results of TEAEs by Subgroups - Peripheral sensory neuropathy (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	22 (44.0)	6.0 [3.7, NC]	49	3 (6.1)	NC [NC, NC]	5.722 [1.678, 19.511]	0.0016	0.5397
Absent	151	81 (53.6)	6.5 [5.1, 8.3]	148	7 (4.7)	NC [NC, NC]	8.026 [3.657, 17.614]	<.0001	
Age									
< 65 years	39	22 (56.4)	5.8 [3.7, 14.9]	28	3 (10.7)	NC [NC, NC]	4.269 [1.241, 14.680]	0.0121	0.3026
>= 65 years	162	81 (50.0)	6.7 [5.1, 8.3]	169	7 (4.1)	NC [NC, NC]	8.688 [3.962, 19.049]	<.0001	
Region									
Europe	73	38 (52.1)	6.0 [3.7, 15.0]	94	5 (5.3)	NC [NC, NC]	8.780 [3.408, 22.622]	<.0001	0.4202
North America	46	23 (50.0)	6.9 [3.8, 9.8]	33	3 (9.1)	NC [NC, NC]	3.386 [0.984, 11.649]	0.0398	
Rest of World	82	42 (51.2)	6.5 [5.1, 14.9]	70	2 (2.9)	NC [NC, NC]	10.965 [2.606, 46.140]	<.0001	
Sex									
Male	145	72 (49.7)	6.0 [4.6, 8.3]	148	7 (4.7)	NC [NC, NC]	8.695 [3.952, 19.128]	<.0001	0.5071
Female	56	31 (55.4)	6.9 [4.6, 9.7]	49	3 (6.1)	NC [NC, NC]	4.731 [1.404, 15.944]	0.0057	
Metastases at Baseline									
Visceral metastases	147	72 (49.0)	6.7 [5.6, 9.7]	152	5 (3.3)	NC [NC, NC]	10.166 [4.047, 25.539]	<.0001	0.7543
Lymph node only	43	24 (55.8)	4.9 [3.6, 17.4]	37	2 (5.4)	NC [NC, NC]	9.890 [2.314, 42.266]	0.0001	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.89.2.1: Summary and Results of TEAEs - Psychiatric disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	37 (18.4%)	20 (10.2%)	
Number of patients censored	164 (81.6%)	177 (89.8%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	86.6 [80.9, 90.7]	90.1 [84.7, 93.6]	
Month 6	82.8 [76.5, 87.5]	88.3 [82.3, 92.4]	
Month 9	81.3 [74.8, 86.3]	NC [NC, NC]	
Month 12	81.3 [74.8, 86.3]	NC [NC, NC]	
Month 18	76.9 [68.5, 83.3]	NC [NC, NC]	
Month 24	76.9 [68.5, 83.3]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.433 [0.814, 2.522]
Log-rank test			
Two-sided unstratified log-rank p-value			0.2105

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.90.2.1: Summary and Results of TEAEs - Anxiety (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	9 (4.5%)	3 (1.5%)	
Number of patients censored	192 (95.5%)	194 (98.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.9 [93.2, 98.6]	98.4 [95.2, 99.5]	
Month 6	95.5 [91.2, 97.7]	98.4 [95.2, 99.5]	
Month 9	95.5 [91.2, 97.7]	NC [NC, NC]	
Month 12	95.5 [91.2, 97.7]	NC [NC, NC]	
Month 18	93.7 [87.1, 97.0]	NC [NC, NC]	
Month 24	93.7 [87.1, 97.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			2.071 [0.529, 8.104]
Log-rank test			
Two-sided unstratified log-rank p-value			0.2854

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.91.2.1: Summary and Results of TEAEs - Insomnia (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	23 (11.4%)	10 (5.1%)	
Number of patients censored	178 (88.6%)	187 (94.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	90.7 [85.6, 94.0]	95.0 [90.6, 97.4]	
Month 6	89.3 [83.9, 93.0]	94.2 [89.4, 96.9]	
Month 9	88.5 [82.9, 92.4]	NC [NC, NC]	
Month 12	88.5 [82.9, 92.4]	NC [NC, NC]	
Month 18	85.6 [78.3, 90.6]	NC [NC, NC]	
Month 24	85.6 [78.3, 90.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.872 [0.873, 4.017]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1019

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.92.2.1: Summary and Results of TEAEs - Renal and urinary disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	69 (34.3%)	49 (24.9%)	
Number of patients censored	132 (65.7%)	148 (75.1%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	78.5 [72.0, 83.6]	74.6 [67.6, 80.4]	
Month 6	73.0 [66.0, 78.8]	72.4 [65.0, 78.4]	
Month 9	68.1 [60.6, 74.5]	NC [NC, NC]	
Month 12	65.1 [57.2, 72.0]	NC [NC, NC]	
Month 18	54.7 [44.7, 63.7]	NC [NC, NC]	
Month 24	41.0 [17.7, 63.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	23.5 [14.5, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.901 [0.604, 1.344]
Log-rank test			
Two-sided unstratified log-rank p-value			0.6102

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.93.2.1: Summary and Results of TEAEs - Acute kidney injury (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	16 (8.0%)	8 (4.1%)	
Number of patients censored	185 (92.0%)	189 (95.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	93.9 [89.5, 96.5]	95.5 [91.1, 97.7]	
Month 6	92.1 [87.2, 95.2]	95.5 [91.1, 97.7]	
Month 9	92.1 [87.2, 95.2]	NC [NC, NC]	
Month 12	92.1 [87.2, 95.2]	NC [NC, NC]	
Month 18	90.4 [84.0, 94.4]	NC [NC, NC]	
Month 24	90.4 [84.0, 94.4]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.775 [0.752, 4.190]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1847

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.94.2.1: Summary and Results of TEAEs - Dysuria (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	8 (4.0%)	5 (2.5%)	
Number of patients censored	193 (96.0%)	192 (97.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.4 [94.0, 98.9]	97.8 [94.3, 99.2]	
Month 6	96.8 [93.1, 98.6]	96.9 [92.5, 98.7]	
Month 9	96.8 [93.1, 98.6]	NC [NC, NC]	
Month 12	96.8 [93.1, 98.6]	NC [NC, NC]	
Month 18	92.0 [81.3, 96.7]	NC [NC, NC]	
Month 24	92.0 [81.3, 96.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.108 [0.337, 3.639]
Log-rank test			
Two-sided unstratified log-rank p-value			0.8662

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.95.2.1: Summary and Results of TEAEs - Haematuria (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	27 (13.4%)	19 (9.6%)	
Number of patients censored	174 (86.6%)	178 (90.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	94.8 [90.5, 97.2]	90.8 [85.6, 94.2]	
Month 6	92.2 [87.1, 95.3]	60.0 [8.6, 89.9]	
Month 9	87.4 [81.0, 91.8]	NC [NC, NC]	
Month 12	86.5 [79.7, 91.1]	NC [NC, NC]	
Month 18	78.3 [68.1, 85.6]	NC [NC, NC]	
Month 24	62.7 [29.2, 83.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [23.5, NC]	NC [5.8, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.547 [0.263, 1.138]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1011

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.96.2.1: Summary and Results of TEAEs - Reproductive system and breast disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	9 (4.5%)	7 (3.6%)	
Number of patients censored	192 (95.5%)	190 (96.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.4 [95.0, 99.5]	96.2 [92.1, 98.2]	
Month 6	97.8 [94.2, 99.2]	96.2 [92.1, 98.2]	
Month 9	95.4 [90.4, 97.8]	NC [NC, NC]	
Month 12	95.4 [90.4, 97.8]	NC [NC, NC]	
Month 18	92.2 [84.5, 96.2]	NC [NC, NC]	
Month 24	92.2 [84.5, 96.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.543 [0.161, 1.834]
Log-rank test			
Two-sided unstratified log-rank p-value			0.3183

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.97.2.1: Summary and Results of TEAEs - Respiratory, thoracic and mediastinal disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	82 (40.8%)	61 (31.0%)	
Number of patients censored	119 (59.2%)	136 (69.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	70.7 [63.7, 76.6]	73.0 [66.0, 78.9]	
Month 6	62.0 [54.4, 68.7]	51.0 [31.5, 67.5]	
Month 9	59.0 [51.3, 65.9]	NC [NC, NC]	
Month 12	56.0 [48.0, 63.3]	NC [NC, NC]	
Month 18	48.2 [38.6, 57.1]	NC [NC, NC]	
Month 24	48.2 [38.6, 57.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	16.4 [10.3, NC]	NC [5.4, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.941 [0.662, 1.336]
Log-rank test			
Two-sided unstratified log-rank p-value			0.7314

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.98.2.1: Summary and Results of TEAEs - Cough (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	28 (13.9%)	10 (5.1%)	
Number of patients censored	173 (86.1%)	187 (94.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	92.7 [87.9, 95.6]	96.2 [92.1, 98.2]	
Month 6	88.3 [82.6, 92.3]	94.0 [89.0, 96.8]	
Month 9	86.9 [80.8, 91.1]	NC [NC, NC]	
Month 12	86.9 [80.8, 91.1]	NC [NC, NC]	
Month 18	79.8 [70.1, 86.7]	NC [NC, NC]	
Month 24	76.5 [64.5, 84.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.849 [0.866, 3.950]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1066

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.99.2.1: Summary and Results of TEAEs - Dyspnoea (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	29 (14.4%)	27 (13.7%)	
Number of patients censored	172 (85.6%)	170 (86.3%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	89.5 [84.2, 93.1]	88.0 [82.3, 92.0]	
Month 6	84.9 [78.7, 89.5]	73.4 [51.3, 86.6]	
Month 9	84.1 [77.8, 88.8]	NC [NC, NC]	
Month 12	84.1 [77.8, 88.8]	NC [NC, NC]	
Month 18	82.4 [75.0, 87.8]	NC [NC, NC]	
Month 24	82.4 [75.0, 87.8]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.767 [0.441, 1.336]
Log-rank test			
Two-sided unstratified log-rank p-value			0.3476

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.100.2.1: Summary and Results of TEAEs - Epistaxis (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	5 (2.5%)	8 (4.1%)	
Number of patients censored	196 (97.5%)	189 (95.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.5 [95.3, 99.5]	95.6 [91.5, 97.8]	
Month 6	97.2 [93.4, 98.8]	95.6 [91.5, 97.8]	
Month 9	97.2 [93.4, 98.8]	NC [NC, NC]	
Month 12	97.2 [93.4, 98.8]	NC [NC, NC]	
Month 18	97.2 [93.4, 98.8]	NC [NC, NC]	
Month 24	97.2 [93.4, 98.8]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.547 [0.177, 1.688]
Log-rank test			
Two-sided unstratified log-rank p-value			0.2873

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.101.2.1: Summary and Results of TEAEs - Hiccups (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	6 (3.0%)	7 (3.6%)	
Number of patients censored	195 (97.0%)	190 (96.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.2 [93.5, 98.8]	96.9 [93.3, 98.6]	
Month 6	96.5 [92.4, 98.4]	96.2 [92.2, 98.2]	
Month 9	96.5 [92.4, 98.4]	NC [NC, NC]	
Month 12	96.5 [92.4, 98.4]	NC [NC, NC]	
Month 18	96.5 [92.4, 98.4]	NC [NC, NC]	
Month 24	96.5 [92.4, 98.4]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.681 [0.218, 2.132]
Log-rank test			
Two-sided unstratified log-rank p-value			0.5070

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.102.2.1: Summary and Results of TEAEs - Pneumonitis (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	12 (6.0%)	0 (0.0%)	
Number of patients censored	189 (94.0%)	197 (100.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.8 [93.0, 98.5]	100.0 [100.0, 100.0]	
Month 6	95.5 [91.2, 97.7]	100.0 [100.0, 100.0]	
Month 9	94.0 [89.1, 96.8]	NC [NC, NC]	
Month 12	93.0 [87.4, 96.1]	NC [NC, NC]	
Month 18	91.2 [84.1, 95.2]	NC [NC, NC]	
Month 24	91.2 [84.1, 95.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			NC [NC, NC]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0069

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.102.2.2: Summary and Results of TEAEs by Subgroups - Pneumonitis (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	2 (4.0)	NC [NC, NC]	49	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.3002	NC
Absent	151	10 (6.6)	NC [NC, NC]	148	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0121	
Age									
< 65 years	39	0 (0.0)	NC [NC, NC]	28	0 (0.0)	NC [NC, NC]	NC [NC, NC]	NC	NC
>= 65 years	162	12 (7.4)	NC [NC, NC]	169	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0056	
Region									
Europe	73	4 (5.5)		94	0 (0.0)				
North America	46	3 (6.5)		33	0 (0.0)				
Rest of World	82	5 (6.1)		70	0 (0.0)				
Sex									
Male	145	9 (6.2)		148	0 (0.0)				
Female	56	3 (5.4)		49	0 (0.0)				
Metastases at Baseline									
Visceral metastases	147	9 (6.1)		152	0 (0.0)				
Lymph node only	43	3 (7.0)		37	0 (0.0)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.103.2.1: Summary and Results of TEAEs - Pulmonary embolism (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	9 (4.5%)	9 (4.6%)	
Number of patients censored	192 (95.5%)	188 (95.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.8 [94.4, 99.2]	95.4 [91.0, 97.7]	
Month 6	95.4 [90.9, 97.7]	94.6 [89.8, 97.2]	
Month 9	95.4 [90.9, 97.7]	NC [NC, NC]	
Month 12	95.4 [90.9, 97.7]	NC [NC, NC]	
Month 18	94.1 [88.4, 97.0]	NC [NC, NC]	
Month 24	94.1 [88.4, 97.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.709 [0.266, 1.890]
Log-rank test			
Two-sided unstratified log-rank p-value			0.4897

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.104.2.1: Summary and Results of TEAEs - Skin and subcutaneous tissue disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	162 (80.6%)	51 (25.9%)	
Number of patients censored	39 (19.4%)	146 (74.1%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	23.4 [17.6, 29.7]	72.7 [65.6, 78.5]	
Month 6	16.2 [11.1, 22.3]	72.7 [65.6, 78.5]	
Month 9	15.4 [10.3, 21.4]	NC [NC, NC]	
Month 12	12.0 [6.8, 18.7]	NC [NC, NC]	
Month 18	12.0 [6.8, 18.7]	NC [NC, NC]	
Month 24	NC [NC, NC]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	0.6 [0.5, 0.7]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			4.951 [3.599, 6.812]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.104.2.2: Summary and Results of TEAEs by Subgroups - Skin and subcutaneous tissue disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	38 (76.0)	0.8 [0.5, 1.7]	49	18 (36.7)	NC [2.5, NC]	2.866 [1.619, 5.072]	0.0002	0.0320
Absent	151	124 (82.1)	0.5 [0.4, 0.7]	148	33 (22.3)	NC [NC, NC]	6.040 [4.094, 8.912]	<.0001	
Age									
< 65 years	39	27 (69.2)	0.8 [0.3, 4.7]	28	6 (21.4)	NC [NC, NC]	4.568 [1.864, 11.194]	0.0003	0.9650
>= 65 years	162	135 (83.3)	0.5 [0.4, 0.7]	169	45 (26.6)	NC [NC, NC]	5.147 [3.656, 7.246]	<.0001	
Region									
Europe	73	57 (78.1)	1.0 [0.5, 1.4]	94	19 (20.2)	NC [NC, NC]	5.624 [3.327, 9.508]	<.0001	0.7796
North America	46	42 (91.3)	0.5 [0.3, 0.7]	33	12 (36.4)	NC [2.3, NC]	5.909 [3.005, 11.617]	<.0001	
Rest of World	82	63 (76.8)	0.5 [0.4, 0.8]	70	20 (28.6)	NC [NC, NC]	3.927 [2.361, 6.533]	<.0001	
Sex									
Male	145	116 (80.0)	0.7 [0.5, 0.8]	148	34 (23.0)	NC [NC, NC]	5.632 [3.820, 8.305]	<.0001	0.1835
Female	56	46 (82.1)	0.4 [0.3, 0.7]	49	17 (34.7)	NC [2.1, NC]	3.551 [2.027, 6.220]	<.0001	
Metastases at Baseline									
Visceral metastases	147	114 (77.6)	0.5 [0.4, 0.7]	152	42 (27.6)	NC [NC, NC]	4.313 [3.016, 6.169]	<.0001	0.1356
Lymph node only	43	38 (88.4)	0.5 [0.4, 0.9]	37	7 (18.9)	NC [NC, NC]	10.311 [4.525, 23.494]	<.0001	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.105.2.1: Summary and Results of TEAEs - Alopecia (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	61 (30.3%)	12 (6.1%)	
Number of patients censored	140 (69.7%)	185 (93.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	73.7 [66.8, 79.4]	94.0 [89.4, 96.6]	
Month 6	69.9 [62.6, 76.0]	93.2 [88.3, 96.1]	
Month 9	66.8 [59.3, 73.3]	NC [NC, NC]	
Month 12	66.8 [59.3, 73.3]	NC [NC, NC]	
Month 18	65.5 [57.5, 72.3]	NC [NC, NC]	
Month 24	65.5 [57.5, 72.3]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			4.912 [2.630, 9.172]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.105.2.2: Summary and Results of TEAEs by Subgroups - Alopecia (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	9 (18.0)	NC [NC, NC]	49	5 (10.2)	NC [NC, NC]	1.430 [0.454, 4.507]	0.5442	0.0311
Absent	151	52 (34.4)	NC [NC, NC]	148	7 (4.7)	NC [NC, NC]	7.481 [3.385, 16.533]	<.0001	
Age									
< 65 years	39	11 (28.2)	NC [NC, NC]	28	2 (7.1)	NC [NC, NC]	3.420 [0.742, 15.772]	0.0938	0.6876
>= 65 years	162	50 (30.9)	NC [NC, NC]	169	10 (5.9)	NC [NC, NC]	5.263 [2.655, 10.433]	<.0001	
Region									
Europe	73	14 (19.2)	NC [NC, NC]	94	4 (4.3)	NC [NC, NC]	3.762 [1.211, 11.686]	0.0140	0.9083
North America	46	17 (37.0)	NC [2.5, NC]	33	3 (9.1)	NC [NC, NC]	4.257 [1.239, 14.627]	0.0123	
Rest of World	82	30 (36.6)	NC [6.8, NC]	70	5 (7.1)	NC [NC, NC]	5.364 [2.065, 13.931]	0.0001	
Sex									
Male	145	38 (26.2)	NC [NC, NC]	148	4 (2.7)	NC [NC, NC]	9.393 [3.324, 26.542]	<.0001	0.0304
Female	56	23 (41.1)	NC [2.5, NC]	49	8 (16.3)	NC [NC, NC]	2.448 [1.092, 5.489]	0.0243	
Metastases at Baseline									
Visceral metastases	147	40 (27.2)	NC [NC, NC]	152	11 (7.2)	NC [NC, NC]	3.907 [1.996, 7.649]	<.0001	NC
Lymph node only	43	17 (39.5)	NC [5.3, NC]	37	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0003	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.106.2.1: Summary and Results of TEAEs - Dermatitis (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	10 (5.0%)	1 (0.5%)	
Number of patients censored	191 (95.0%)	196 (99.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	95.8 [91.8, 97.9]	99.5 [96.4, 99.9]	
Month 6	94.6 [90.1, 97.1]	99.5 [96.4, 99.9]	
Month 9	94.6 [90.1, 97.1]	NC [NC, NC]	
Month 12	94.6 [90.1, 97.1]	NC [NC, NC]	
Month 18	94.6 [90.1, 97.1]	NC [NC, NC]	
Month 24	94.6 [90.1, 97.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			9.412 [1.204, 73.590]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0090

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.106.2.2: Summary and Results of TEAEs by Subgroups - Dermatitis (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	2 (4.0)		49	1 (2.0)				
Absent	151	8 (5.3)		148	0 (0.0)				
Age									
< 65 years	39	0 (0.0)	NC [NC, NC]	28	0 (0.0)	NC [NC, NC]	NC [NC, NC]	NC	NC
>= 65 years	162	10 (6.2)	NC [NC, NC]	169	1 (0.6)	NC [NC, NC]	10.008 [1.280, 78.269]	0.0067	
Region									
Europe	73	4 (5.5)		94	1 (1.1)				
North America	46	1 (2.2)		33	0 (0.0)				
Rest of World	82	5 (6.1)		70	0 (0.0)				
Sex									
Male	145	4 (2.8)		148	1 (0.7)				
Female	56	6 (10.7)		49	0 (0.0)				
Metastases at Baseline									
Visceral metastases	147	5 (3.4)		152	1 (0.7)				
Lymph node only	43	2 (4.7)		37	0 (0.0)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.107.2.1: Summary and Results of TEAEs - Dry skin (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	37 (18.4%)	2 (1.0%)	
Number of patients censored	164 (81.6%)	195 (99.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	88.2 [82.6, 92.1]	98.9 [95.8, 99.7]	
Month 6	82.5 [76.0, 87.4]	98.9 [95.8, 99.7]	
Month 9	81.0 [74.2, 86.1]	NC [NC, NC]	
Month 12	78.6 [71.0, 84.4]	NC [NC, NC]	
Month 18	74.3 [64.5, 81.8]	NC [NC, NC]	
Month 24	74.3 [64.5, 81.8]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			14.367 [3.434, 60.107]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.107.2.2: Summary and Results of TEAEs by Subgroups - Dry skin (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	3 (6.0)	NC [NC, NC]	49	1 (2.0)	NC [NC, NC]	1.920 [0.193, 19.096]	0.5717	0.1081
Absent	151	34 (22.5)	NC [NC, NC]	148	1 (0.7)	NC [NC, NC]	26.988 [3.669, 198.51]	<.0001	
Age									
< 65 years	39	8 (20.5)	NC [NC, NC]	28	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0200	NC
>= 65 years	162	29 (17.9)	NC [NC, NC]	169	2 (1.2)	NC [NC, NC]	11.462 [2.701, 48.634]	<.0001	
Region									
Europe	73	16 (21.9)	NC [NC, NC]	94	1 (1.1)	NC [NC, NC]	18.191 [2.401, 137.83]	<.0001	NC
North America	46	13 (28.3)	NC [9.3, NC]	33	1 (3.0)	NC [NC, NC]	6.994 [0.895, 54.651]	0.0307	
Rest of World	82	8 (9.8)	NC [NC, NC]	70	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0338	
Sex									
Male	145	28 (19.3)	NC [NC, NC]	148	2 (1.4)	NC [NC, NC]	11.685 [2.750, 49.649]	<.0001	NC
Female	56	9 (16.1)	NC [NC, NC]	49	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0190	
Metastases at Baseline									
Visceral metastases	147	21 (14.3)	NC [NC, NC]	152	1 (0.7)	NC [NC, NC]	17.858 [2.381, 133.96]	0.0001	0.6968
Lymph node only	43	14 (32.6)	NC [13.0, NC]	37	1 (2.7)	NC [NC, NC]	9.713 [1.258, 75.000]	0.0075	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.108.2.1: Summary and Results of TEAEs - Eczema (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	17 (8.5%)	2 (1.0%)	
Number of patients censored	184 (91.5%)	195 (99.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	93.9 [89.4, 96.5]	98.8 [95.4, 99.7]	
Month 6	91.9 [86.9, 95.1]	98.8 [95.4, 99.7]	
Month 9	91.2 [86.0, 94.5]	NC [NC, NC]	
Month 12	91.2 [86.0, 94.5]	NC [NC, NC]	
Month 18	89.4 [82.6, 93.7]	NC [NC, NC]	
Month 24	89.4 [82.6, 93.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			6.812 [1.549, 29.962]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0033

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.108.2.2: Summary and Results of TEAEs by Subgroups - Eczema (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	3 (6.0)	NC [14.3, NC]	49	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1594	NC
Absent	151	14 (9.3)	NC [NC, NC]	148	2 (1.4)	NC [NC, NC]	5.804 [1.301, 25.896]	0.0091	
Age									
< 65 years	39	5 (12.8)	NC [NC, NC]	28	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0797	NC
>= 65 years	162	12 (7.4)	NC [NC, NC]	169	2 (1.2)	NC [NC, NC]	4.981 [1.090, 22.761]	0.0215	
Region									
Europe	73	10 (13.7)	NC [NC, NC]	94	2 (2.1)	NC [NC, NC]	5.229 [1.110, 24.628]	0.0195	NC
North America	46	0 (0.0)	NC [NC, NC]	33	0 (0.0)	NC [NC, NC]	NC [NC, NC]	NC	
Rest of World	82	7 (8.5)	NC [NC, NC]	70	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0229	
Sex									
Male	145	12 (8.3)	NC [NC, NC]	148	2 (1.4)	NC [NC, NC]	4.718 [1.022, 21.793]	0.0287	NC
Female	56	5 (8.9)	NC [NC, NC]	49	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0482	
Metastases at Baseline									
Visceral metastases	147	11 (7.5)	NC [NC, NC]	152	1 (0.7)	NC [NC, NC]	8.901 [1.126, 70.337]	0.0121	0.5946
Lymph node only	43	6 (14.0)	NC [NC, NC]	37	1 (2.7)	NC [NC, NC]	4.523 [0.530, 38.593]	0.1304	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.109.2.1: Summary and Results of TEAEs - Pruritus (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	77 (38.3%)	16 (8.1%)	
Number of patients censored	124 (61.7%)	181 (91.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	66.8 [59.7, 73.0]	91.7 [86.8, 94.8]	
Month 6	62.0 [54.6, 68.6]	91.7 [86.8, 94.8]	
Month 9	60.3 [52.7, 67.1]	NC [NC, NC]	
Month 12	59.1 [51.2, 66.1]	NC [NC, NC]	
Month 18	57.7 [49.5, 65.0]	NC [NC, NC]	
Month 24	54.5 [44.5, 63.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [12.0, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			4.926 [2.862, 8.481]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.109.2.2: Summary and Results of TEAEs by Subgroups - Pruritus (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	15 (30.0)	NC [5.4, NC]	49	4 (8.2)	NC [NC, NC]	3.155 [1.020, 9.761]	0.0362	0.5723
Absent	151	62 (41.1)	NC [7.7, NC]	148	12 (8.1)	NC [NC, NC]	5.492 [2.947, 10.235]	<.0001	
Age									
< 65 years	39	14 (35.9)	NC [5.4, NC]	28	2 (7.1)	NC [NC, NC]	5.124 [1.151, 22.803]	0.0171	0.9378
>= 65 years	162	63 (38.9)	NC [11.2, NC]	169	14 (8.3)	NC [NC, NC]	4.930 [2.748, 8.842]	<.0001	
Region									
Europe	73	25 (34.2)	NC [11.2, NC]	94	5 (5.3)	NC [NC, NC]	6.174 [2.336, 16.320]	<.0001	0.4428
North America	46	23 (50.0)	5.1 [0.6, NC]	33	3 (9.1)	NC [NC, NC]	6.392 [1.909, 21.398]	0.0005	
Rest of World	82	29 (35.4)	NC [18.7, NC]	70	8 (11.4)	NC [NC, NC]	3.197 [1.450, 7.049]	0.0024	
Sex									
Male	145	55 (37.9)	NC [11.2, NC]	148	10 (6.8)	NC [NC, NC]	5.735 [2.904, 11.326]	<.0001	0.3332
Female	56	22 (39.3)	NC [1.1, NC]	49	6 (12.2)	NC [NC, NC]	3.620 [1.462, 8.960]	0.0030	
Metastases at Baseline									
Visceral metastases	147	51 (34.7)	NC [18.7, NC]	152	14 (9.2)	NC [NC, NC]	3.698 [2.030, 6.737]	<.0001	0.0825
Lymph node only	43	24 (55.8)	1.8 [0.6, NC]	37	1 (2.7)	NC [NC, NC]	28.883 [3.901, 213.83]	<.0001	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.110.2.1: Summary and Results of TEAEs - Rash macular (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	17 (8.5%)	4 (2.0%)	
Number of patients censored	184 (91.5%)	193 (98.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	94.9 [90.7, 97.2]	97.9 [94.6, 99.2]	
Month 6	93.7 [89.1, 96.4]	97.9 [94.6, 99.2]	
Month 9	92.8 [87.8, 95.8]	NC [NC, NC]	
Month 12	91.9 [86.4, 95.2]	NC [NC, NC]	
Month 18	87.6 [79.9, 92.6]	NC [NC, NC]	
Month 24	87.6 [79.9, 92.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			2.882 [0.928, 8.943]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0550

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.111.2.1: Summary and Results of TEAEs - Rash maculo-papular (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	70 (34.8%)	6 (3.0%)	
Number of patients censored	131 (65.2%)	191 (97.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	71.2 [64.2, 77.0]	96.9 [93.3, 98.6]	
Month 6	66.1 [58.8, 72.4]	96.9 [93.3, 98.6]	
Month 9	61.4 [53.7, 68.3]	NC [NC, NC]	
Month 12	61.4 [53.7, 68.3]	NC [NC, NC]	
Month 18	61.4 [53.7, 68.3]	NC [NC, NC]	
Month 24	61.4 [53.7, 68.3]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			11.395 [4.930, 26.338]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.111.2.2: Summary and Results of TEAEs by Subgroups - Rash maculo-papular (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	19 (38.0)	NC [2.1, NC]	49	3 (6.1)	NC [NC, NC]	6.838 [2.008, 23.285]	0.0004	0.2849
Absent	151	51 (33.8)	NC [NC, NC]	148	3 (2.0)	NC [NC, NC]	15.994 [4.971, 51.466]	<.0001	
Age									
< 65 years	39	8 (20.5)	NC [NC, NC]	28	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0314	NC
>= 65 years	162	62 (38.3)	NC [8.7, NC]	169	6 (3.6)	NC [NC, NC]	11.123 [4.793, 25.814]	<.0001	
Region									
Europe	73	16 (21.9)	NC [NC, NC]	94	0 (0.0)	NC [NC, NC]	NC [NC, NC]	<.0001	NC
North America	46	30 (65.2)	1.4 [0.6, 3.5]	33	0 (0.0)	NC [NC, NC]	NC [NC, NC]	<.0001	
Rest of World	82	24 (29.3)	NC [NC, NC]	70	6 (8.6)	NC [NC, NC]	3.112 [1.260, 7.691]	0.0095	
Sex									
Male	145	54 (37.2)	NC [8.7, NC]	148	4 (2.7)	NC [NC, NC]	14.677 [5.298, 40.663]	<.0001	0.3587
Female	56	16 (28.6)	NC [NC, NC]	49	2 (4.1)	NC [NC, NC]	5.693 [1.284, 25.243]	0.0097	
Metastases at Baseline									
Visceral metastases	147	53 (36.1)	NC [8.7, NC]	152	6 (3.9)	NC [NC, NC]	8.815 [3.766, 20.633]	<.0001	NC
Lymph node only	43	14 (32.6)	NC [NC, NC]	37	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0002	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.112.2.1: Summary and Results of TEAEs - Rash papular (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	13 (6.5%)	2 (1.0%)	
Number of patients censored	188 (93.5%)	195 (99.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	95.5 [91.5, 97.6]	98.9 [95.8, 99.7]	
Month 6	95.5 [91.5, 97.6]	98.9 [95.8, 99.7]	
Month 9	94.7 [90.3, 97.1]	NC [NC, NC]	
Month 12	92.3 [86.2, 95.8]	NC [NC, NC]	
Month 18	92.3 [86.2, 95.8]	NC [NC, NC]	
Month 24	86.6 [69.1, 94.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			4.482 [0.969, 20.737]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0355

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.112.2.2: Summary and Results of TEAEs by Subgroups - Rash papular (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	1 (2.0)	NC [NC, NC]	49	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.3222	NC
Absent	151	12 (7.9)	NC [NC, NC]	148	2 (1.4)	NC [NC, NC]	3.963 [0.842, 18.651]	0.0599	
Age									
< 65 years	39	2 (5.1)	NC [NC, NC]	28	1 (3.6)	NC [NC, NC]	0.747 [0.047, 11.954]	0.8362	0.1528
>= 65 years	162	11 (6.8)	NC [20.9, NC]	169	1 (0.6)	NC [NC, NC]	8.494 [1.062, 67.910]	0.0154	
Region									
Europe	73	2 (2.7)	NC [NC, NC]	94	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1070	NC
North America	46	3 (6.5)	NC [20.9, NC]	33	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.2431	
Rest of World	82	8 (9.8)	NC [NC, NC]	70	2 (2.9)	NC [NC, NC]	2.206 [0.428, 11.369]	0.3327	
Sex									
Male	145	8 (5.5)	NC [NC, NC]	148	2 (1.4)	NC [NC, NC]	3.108 [0.627, 15.396]	0.1431	NC
Female	56	5 (8.9)	NC [20.9, NC]	49	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1032	
Metastases at Baseline									
Visceral metastases	147	8 (5.4)	NC [NC, NC]	152	2 (1.3)	NC [NC, NC]	3.682 [0.765, 17.723]	0.0814	NC
Lymph node only	43	3 (7.0)	NC [NC, NC]	37	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1852	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.113.2.1: Summary and Results of TEAEs - Vascular disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	30 (14.9%)	27 (13.7%)	
Number of patients censored	171 (85.1%)	170 (86.3%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	92.5 [87.7, 95.5]	86.7 [80.8, 90.9]	
Month 6	86.2 [80.0, 90.5]	84.4 [78.0, 89.1]	
Month 9	84.6 [78.2, 89.3]	NC [NC, NC]	
Month 12	83.6 [76.8, 88.6]	NC [NC, NC]	
Month 18	77.5 [67.1, 85.0]	NC [NC, NC]	
Month 24	77.5 [67.1, 85.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.700 [0.400, 1.227]
Log-rank test			
Two-sided unstratified log-rank p-value			0.2106

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.114.2.1: Summary and Results of TEAEs - Hypotension (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	9 (4.5%)	1 (0.5%)	
Number of patients censored	192 (95.5%)	196 (99.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.3 [93.7, 98.9]	99.4 [95.8, 99.9]	
Month 6	96.7 [92.8, 98.5]	99.4 [95.8, 99.9]	
Month 9	96.0 [91.8, 98.1]	NC [NC, NC]	
Month 12	96.0 [91.8, 98.1]	NC [NC, NC]	
Month 18	92.9 [85.5, 96.6]	NC [NC, NC]	
Month 24	92.9 [85.5, 96.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			5.545 [0.667, 46.071]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0743

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.115.2.1: Summary and Results of TESAEs - Blood and lymphatic system disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	6 (3.0%)	26 (13.2%)	
Number of patients censored	195 (97.0%)	171 (86.8%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	99.0 [95.9, 99.7]	88.3 [82.6, 92.2]	
Month 6	98.4 [95.1, 99.5]	42.4 [1.3, 84.3]	
Month 9	97.6 [93.5, 99.1]	NC [NC, NC]	
Month 12	95.5 [89.8, 98.0]	NC [NC, NC]	
Month 18	95.5 [89.8, 98.0]	NC [NC, NC]	
Month 24	95.5 [89.8, 98.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	5.8 [5.8, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.069 [0.018, 0.263]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.115.2.2: Summary and Results of TESAEs by Subgroups - Blood and lymphatic system disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	2 (4.0)	NC [NC, NC]	49	10 (20.4)	NC [NC, NC]	0.167 [0.036, 0.766]	0.0090	0.9262
Absent	151	4 (2.6)	NC [NC, NC]	148	16 (10.8)	5.8 [5.8, NC]	0.023 [0.002, 0.250]	<.0001	
Age									
< 65 years	39	2 (5.1)	NC [NC, NC]	28	1 (3.6)	NC [NC, NC]	0.000 [0.000, NC]	0.2379	0.1153
>= 65 years	162	4 (2.5)	NC [NC, NC]	169	25 (14.8)	5.8 [NC, NC]	0.072 [0.018, 0.285]	<.0001	
Region									
Europe	73	4 (5.5)	NC [NC, NC]	94	16 (17.0)	NC [NC, NC]	0.064 [0.008, 0.482]	0.0004	0.7256
North America	46	1 (2.2)	NC [NC, NC]	33	3 (9.1)	NC [NC, NC]	0.193 [0.020, 1.866]	0.1133	
Rest of World	82	1 (1.2)	NC [NC, NC]	70	7 (10.0)	5.8 [NC, NC]	0.036 [0.002, 0.580]	0.0034	
Sex									
Male	145	5 (3.4)	NC [NC, NC]	148	21 (14.2)	5.8 [5.8, NC]	0.091 [0.024, 0.352]	<.0001	0.6470
Female	56	1 (1.8)	NC [NC, NC]	49	5 (10.2)	NC [NC, NC]	0.000 [0.000, NC]	0.0142	
Metastases at Baseline									
Visceral metastases	147	3 (2.0)	NC [NC, NC]	152	23 (15.1)	5.8 [NC, NC]	0.080 [0.020, 0.318]	<.0001	0.2088
Lymph node only	43	2 (4.7)	NC [NC, NC]	37	3 (8.1)	NC [NC, NC]	0.000 [0.000, NC]	0.0381	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.116.2.1: Summary and Results of TESAEs - Anaemia (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	3 (1.5%)	7 (3.6%)	
Number of patients censored	198 (98.5%)	190 (96.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	100.0 [100.0, 100.0]	96.5 [92.3, 98.4]	
Month 6	99.4 [95.9, 99.9]	64.3 [6.7, 93.1]	
Month 9	99.4 [95.9, 99.9]	NC [NC, NC]	
Month 12	97.3 [91.7, 99.2]	NC [NC, NC]	
Month 18	97.3 [91.7, 99.2]	NC [NC, NC]	
Month 24	97.3 [91.7, 99.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [5.8, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.041 [0.003, 0.608]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0045

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.116.2.2: Summary and Results of TESAEs by Subgroups - Anaemia (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	1 (2.0)		49	2 (4.1)				
Absent	151	2 (1.3)		148	5 (3.4)				
Age									
< 65 years	39	1 (2.6)		28	0 (0.0)				
>= 65 years	162	2 (1.2)		169	7 (4.1)				
Region									
Europe	73	2 (2.7)		94	3 (3.2)				
North America	46	1 (2.2)		33	1 (3.0)				
Rest of World	82	0 (0.0)		70	3 (4.3)				
Sex									
Male	145	3 (2.1)	NC [NC, NC]	148	7 (4.7)	NC [5.8, NC]	0.049 [0.004, 0.657]	0.0063	NC
Female	56	0 (0.0)	NC [NC, NC]	49	0 (0.0)	NC [NC, NC]	NC [NC, NC]	NC	
Metastases at Baseline									
Visceral metastases	147	1 (0.7)		152	7 (4.6)				
Lymph node only	43	1 (2.3)		37	0 (0.0)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.117.2.1: Summary and Results of TESAEs - Febrile neutropenia (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	1 (0.5%)	9 (4.6%)	
Number of patients censored	200 (99.5%)	188 (95.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	99.5 [96.5, 99.9]	95.4 [90.9, 97.7]	
Month 6	99.5 [96.5, 99.9]	94.4 [89.4, 97.1]	
Month 9	99.5 [96.5, 99.9]	NC [NC, NC]	
Month 12	99.5 [96.5, 99.9]	NC [NC, NC]	
Month 18	99.5 [96.5, 99.9]	NC [NC, NC]	
Month 24	99.5 [96.5, 99.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.096 [0.012, 0.759]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0058

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.117.2.2: Summary and Results of TESAEs by Subgroups - Febrile neutropenia (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	1 (2.0)		49	6 (12.2)				
Absent	151	0 (0.0)		148	3 (2.0)				
Age									
< 65 years	39	0 (0.0)		28	1 (3.6)				
>= 65 years	162	1 (0.6)		169	8 (4.7)				
Region									
Europe	73	1 (1.4)		94	7 (7.4)				
North America	46	0 (0.0)		33	0 (0.0)				
Rest of World	82	0 (0.0)		70	2 (2.9)				
Sex									
Male	145	1 (0.7)		148	6 (4.1)				
Female	56	0 (0.0)		49	3 (6.1)				
Metastases at Baseline									
Visceral metastases	147	1 (0.7)		152	8 (5.3)				
Lymph node only	43	0 (0.0)		37	1 (2.7)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.118.2.1: Summary and Results of TESAEs - Cardiac disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	9 (4.5%)	3 (1.5%)	
Number of patients censored	192 (95.5%)	194 (98.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	95.9 [92.0, 97.9]	98.4 [95.0, 99.5]	
Month 6	95.9 [92.0, 97.9]	98.4 [95.0, 99.5]	
Month 9	95.9 [92.0, 97.9]	NC [NC, NC]	
Month 12	95.9 [92.0, 97.9]	NC [NC, NC]	
Month 18	95.9 [92.0, 97.9]	NC [NC, NC]	
Month 24	92.1 [79.3, 97.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			2.575 [0.683, 9.709]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1471

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.119.2.1: Summary and Results of TESAEs - Gastrointestinal disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	**Plat+Gem (N= 197)**	**EV+Pembro vs. Plat+Gem**
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	23 (11.4%)	11 (5.6%)	
Number of patients censored	178 (88.6%)	186 (94.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	93.4 [88.8, 96.1]	93.8 [89.1, 96.5]	
Month 6	90.9 [85.8, 94.3]	93.8 [89.1, 96.5]	
Month 9	89.5 [83.9, 93.2]	NC [NC, NC]	
Month 12	87.5 [81.1, 91.8]	NC [NC, NC]	
Month 18	86.1 [79.1, 90.9]	NC [NC, NC]	
Month 24	83.0 [73.0, 89.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.329 [0.616, 2.867]
Log-rank test			
Two-sided unstratified log-rank p-value			0.4668

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.120.2.1: Summary and Results of TESAEs - General disorders and administration site conditions (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	**Plat+Gem (N= 197)**	**EV+Pembro vs. Plat+Gem**
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	13 (6.5%)	18 (9.1%)	
Number of patients censored	188 (93.5%)	179 (90.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	94.9 [90.7, 97.2]	90.9 [85.7, 94.2]	
Month 6	94.3 [90.0, 96.8]	90.2 [84.9, 93.7]	
Month 9	93.7 [89.1, 96.4]	NC [NC, NC]	
Month 12	93.7 [89.1, 96.4]	NC [NC, NC]	
Month 18	93.7 [89.1, 96.4]	NC [NC, NC]	
Month 24	90.4 [80.3, 95.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.567 [0.267, 1.200]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1327

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.121.2.1: Summary and Results of TESAEs - Pyrexia (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	6 (3.0%)	7 (3.6%)	
Number of patients censored	195 (97.0%)	190 (96.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.9 [93.2, 98.6]	96.3 [92.3, 98.2]	
Month 6	96.9 [93.2, 98.6]	96.3 [92.3, 98.2]	
Month 9	96.9 [93.2, 98.6]	NC [NC, NC]	
Month 12	96.9 [93.2, 98.6]	NC [NC, NC]	
Month 18	96.9 [93.2, 98.6]	NC [NC, NC]	
Month 24	96.9 [93.2, 98.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.810 [0.272, 2.412]
Log-rank test			
Two-sided unstratified log-rank p-value			0.7047

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.122.2.1: Summary and Results of TESAEs - Infections and infestations (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	46 (22.9%)	34 (17.3%)	
Number of patients censored	155 (77.1%)	163 (82.7%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	86.8 [81.2, 90.8]	83.7 [77.5, 88.4]	
Month 6	83.2 [77.1, 87.9]	80.5 [73.6, 85.8]	
Month 9	76.6 [69.5, 82.2]	NC [NC, NC]	
Month 12	73.9 [66.3, 80.0]	NC [NC, NC]	
Month 18	73.9 [66.3, 80.0]	NC [NC, NC]	
Month 24	68.9 [56.1, 78.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.783 [0.480, 1.278]
Log-rank test			
Two-sided unstratified log-rank p-value			0.3273

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.123.2.1: Summary and Results of TESAEs - Urinary tract infection (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	12 (6.0%)	14 (7.1%)	
Number of patients censored	189 (94.0%)	183 (92.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.9 [93.3, 98.6]	94.1 [89.5, 96.7]	
Month 6	95.7 [91.5, 97.8]	91.8 [86.4, 95.1]	
Month 9	94.3 [89.5, 96.9]	NC [NC, NC]	
Month 12	92.6 [87.1, 95.8]	NC [NC, NC]	
Month 18	92.6 [87.1, 95.8]	NC [NC, NC]	
Month 24	92.6 [87.1, 95.8]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.455 [0.187, 1.110]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0763

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.124.2.1: Summary and Results of TESAEs - Metabolism and nutrition disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	13 (6.5%)	5 (2.5%)	
Number of patients censored	188 (93.5%)	192 (97.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	94.8 [90.6, 97.2]	97.8 [94.2, 99.2]	
Month 6	93.7 [89.2, 96.4]	96.8 [92.2, 98.7]	
Month 9	93.0 [88.3, 95.9]	NC [NC, NC]	
Month 12	93.0 [88.3, 95.9]	NC [NC, NC]	
Month 18	93.0 [88.3, 95.9]	NC [NC, NC]	
Month 24	93.0 [88.3, 95.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			2.184 [0.769, 6.206]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1324

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.125.2.1: Summary and Results of TESAEs - Renal and urinary disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	21 (10.4%)	11 (5.6%)	
Number of patients censored	180 (89.6%)	186 (94.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	93.4 [89.0, 96.1]	95.6 [91.4, 97.8]	
Month 6	91.1 [86.0, 94.4]	46.9 [0.9, 88.5]	
Month 9	91.1 [86.0, 94.4]	NC [NC, NC]	
Month 12	91.1 [86.0, 94.4]	NC [NC, NC]	
Month 18	86.6 [78.7, 91.7]	NC [NC, NC]	
Month 24	83.5 [72.8, 90.3]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	5.8 [5.8, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.176 [0.535, 2.586]
Log-rank test			
Two-sided unstratified log-rank p-value			0.6855

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.126.2.1: Summary and Results of TESAEs - Acute kidney injury (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	14 (7.0%)	4 (2.0%)	
Number of patients censored	187 (93.0%)	193 (98.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	94.9 [90.8, 97.2]	97.7 [94.0, 99.1]	
Month 6	93.2 [88.6, 96.0]	97.7 [94.0, 99.1]	
Month 9	93.2 [88.6, 96.0]	NC [NC, NC]	
Month 12	93.2 [88.6, 96.0]	NC [NC, NC]	
Month 18	91.7 [85.5, 95.3]	NC [NC, NC]	
Month 24	91.7 [85.5, 95.3]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			2.996 [0.975, 9.203]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0441

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.126.2.2: Summary and Results of TESAEs by Subgroups - Acute kidney injury (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	6 (12.0)	NC [NC, NC]	49	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0217	NC
Absent	151	8 (5.3)	NC [NC, NC]	148	4 (2.7)	NC [NC, NC]	1.752 [0.526, 5.833]	0.3544	
Age									
< 65 years	39	1 (2.6)	NC [NC, NC]	28	1 (3.6)	NC [NC, NC]	0.705 [0.044, 11.273]	0.8038	0.2286
>= 65 years	162	13 (8.0)	NC [NC, NC]	169	3 (1.8)	NC [NC, NC]	3.875 [1.092, 13.758]	0.0240	
Region									
Europe	73	4 (5.5)	NC [NC, NC]	94	1 (1.1)	NC [NC, NC]	3.457 [0.358, 33.412]	0.2541	NC
North America	46	7 (15.2)	NC [NC, NC]	33	3 (9.1)	NC [NC, NC]	1.639 [0.424, 6.342]	0.4694	
Rest of World	82	3 (3.7)	NC [NC, NC]	70	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1485	
Sex									
Male	145	14 (9.7)	NC [NC, NC]	148	4 (2.7)	NC [NC, NC]	3.209 [1.045, 9.852]	0.0312	NC
Female	56	0 (0.0)	NC [NC, NC]	49	0 (0.0)	NC [NC, NC]	NC [NC, NC]	NC	
Metastases at Baseline									
Visceral metastases	147	12 (8.2)	NC [NC, NC]	152	4 (2.6)	NC [NC, NC]	2.729 [0.868, 8.582]	0.0735	NC
Lymph node only	43	2 (4.7)	NC [NC, NC]	37	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.2351	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.127.2.1: Summary and Results of TESAEs - Respiratory, thoracic and mediastinal disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	13 (6.5%)	11 (5.6%)	
Number of patients censored	188 (93.5%)	186 (94.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.4 [92.6, 98.3]	95.7 [91.6, 97.8]	
Month 6	94.7 [90.3, 97.1]	88.0 [72.8, 95.0]	
Month 9	92.5 [87.3, 95.6]	NC [NC, NC]	
Month 12	92.5 [87.3, 95.6]	NC [NC, NC]	
Month 18	92.5 [87.3, 95.6]	NC [NC, NC]	
Month 24	92.5 [87.3, 95.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.668 [0.275, 1.622]
Log-rank test			
Two-sided unstratified log-rank p-value			0.3704

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.128.2.1: Summary and Results of TESAEs - Skin and subcutaneous tissue disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	11 (5.5%)	1 (0.5%)	
Number of patients censored	190 (94.5%)	196 (99.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	94.8 [90.6, 97.2]	99.5 [96.4, 99.9]	
Month 6	94.8 [90.6, 97.2]	99.5 [96.4, 99.9]	
Month 9	94.8 [90.6, 97.2]	NC [NC, NC]	
Month 12	93.8 [88.7, 96.6]	NC [NC, NC]	
Month 18	93.8 [88.7, 96.6]	NC [NC, NC]	
Month 24	93.8 [88.7, 96.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			9.562 [1.224, 74.704]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0083

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.128.2.2: Summary and Results of TESAEs by Subgroups - Skin and subcutaneous tissue disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	4 (8.0)		49	0 (0.0)				
Absent	151	7 (4.6)		148	1 (0.7)				
Age									
< 65 years	39	1 (2.6)	NC [NC, NC]	28	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.4019	NC
>= 65 years	162	10 (6.2)	NC [NC, NC]	169	1 (0.6)	NC [NC, NC]	9.137 [1.157, 72.135]	0.0107	
Region									
Europe	73	6 (8.2)		94	0 (0.0)				
North America	46	1 (2.2)		33	0 (0.0)				
Rest of World	82	4 (4.9)		70	1 (1.4)				
Sex									
Male	145	9 (6.2)	NC [NC, NC]	148	1 (0.7)	NC [NC, NC]	8.046 [1.006, 64.343]	0.0192	NC
Female	56	2 (3.6)	NC [NC, NC]	49	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.2015	
Metastases at Baseline									
Visceral metastases	147	9 (6.1)	NC [NC, NC]	152	1 (0.7)	NC [NC, NC]	7.989 [0.999, 63.889]	0.0197	NC
Lymph node only	43	2 (4.7)	NC [NC, NC]	37	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1843	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.129.2.1: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) - Blood and lymphatic system disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	43 (21.4%)	135 (68.5%)	
Number of patients censored	158 (78.6%)	62 (31.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	85.7 [79.9, 90.0]	29.4 [22.9, 36.2]	
Month 6	80.8 [74.3, 85.9]	NC [NC, NC]	
Month 9	79.3 [72.5, 84.6]	NC [NC, NC]	
Month 12	75.3 [67.6, 81.4]	NC [NC, NC]	
Month 18	71.1 [61.2, 78.9]	NC [NC, NC]	
Month 24	71.1 [61.2, 78.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	1.3 [1.0, 1.6]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.138 [0.094, 0.202]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.129.2.2: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) by Subgroups - Blood and lymphatic system disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	17 (34.0)	NC [5.5, NC]	49	32 (65.3)	1.3 [0.6, 2.1]	0.265 [0.140, 0.502]	<.0001	0.0193
Absent	151	26 (17.2)	NC [NC, NC]	148	103 (69.6)	1.3 [1.0, 1.8]	0.101 [0.062, 0.166]	<.0001	
Age									
< 65 years	39	8 (20.5)	NC [NC, NC]	28	15 (53.6)	3.0 [1.2, NC]	0.142 [0.047, 0.430]	<.0001	0.4065
>= 65 years	162	35 (21.6)	NC [NC, NC]	169	120 (71.0)	1.2 [1.0, 1.5]	0.137 [0.091, 0.207]	<.0001	
Region									
Europe	73	19 (26.0)	NC [NC, NC]	94	65 (69.1)	1.1 [0.9, 1.6]	0.154 [0.086, 0.277]	<.0001	0.7810
North America	46	8 (17.4)	NC [NC, NC]	33	19 (57.6)	2.1 [0.7, NC]	0.187 [0.081, 0.433]	<.0001	
Rest of World	82	16 (19.5)	NC [NC, NC]	70	51 (72.9)	1.4 [1.0, 1.9]	0.110 [0.057, 0.211]	<.0001	
Sex									
Male	145	34 (23.4)	NC [NC, NC]	148	96 (64.9)	1.6 [1.2, 2.1]	0.180 [0.117, 0.277]	<.0001	0.0233
Female	56	9 (16.1)	NC [17.5, NC]	49	39 (79.6)	0.9 [0.7, 1.2]	0.056 [0.023, 0.137]	<.0001	
Metastases at Baseline									
Visceral metastases	147	35 (23.8)	NC [NC, NC]	152	101 (66.4)	1.3 [0.9, 1.8]	0.174 [0.114, 0.264]	<.0001	0.1229
Lymph node only	43	5 (11.6)	NC [NC, NC]	37	27 (73.0)	1.5 [1.0, 2.8]	0.056 [0.017, 0.186]	<.0001	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.130.2.1: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) - Anaemia (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	26 (12.9%)	80 (40.6%)	
Number of patients censored	175 (87.1%)	117 (59.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	91.6 [86.6, 94.8]	59.7 [52.1, 66.6]	
Month 6	87.8 [82.0, 91.8]	54.9 [47.1, 62.1]	
Month 9	87.8 [82.0, 91.8]	0.0 [NC, NC]	
Month 12	84.7 [77.9, 89.6]	0.0 [NC, NC]	
Month 18	81.8 [72.2, 88.3]	0.0 [NC, NC]	
Month 24	81.8 [72.2, 88.3]	0.0 [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	6.5 [3.3, 6.5]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.183 [0.112, 0.299]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.130.2.2: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) by Subgroups - Anaemia (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	12 (24.0)	NC [NC, NC]	49	22 (44.9)	NC [1.9, NC]	0.382 [0.182, 0.805]	0.0085	0.0517
Absent	151	14 (9.3)	NC [NC, NC]	148	58 (39.2)	6.5 [3.4, 6.5]	0.117 [0.059, 0.231]	<.0001	
Age									
< 65 years	39	4 (10.3)	NC [NC, NC]	28	9 (32.1)	6.5 [3.3, 6.5]	0.166 [0.040, 0.689]	0.0056	0.8981
>= 65 years	162	22 (13.6)	NC [NC, NC]	169	71 (42.0)	NC [2.8, NC]	0.188 [0.112, 0.318]	<.0001	
Region									
Europe	73	12 (16.4)	NC [NC, NC]	94	44 (46.8)	3.4 [2.6, 6.5]	0.166 [0.077, 0.356]	<.0001	0.5927
North America	46	7 (15.2)	NC [NC, NC]	33	11 (33.3)	NC [2.1, NC]	0.349 [0.135, 0.906]	0.0239	
Rest of World	82	7 (8.5)	NC [NC, NC]	70	25 (35.7)	NC [3.5, NC]	0.140 [0.055, 0.356]	<.0001	
Sex									
Male	145	19 (13.1)	NC [NC, NC]	148	58 (39.2)	6.5 [3.3, 6.5]	0.204 [0.114, 0.363]	<.0001	0.4279
Female	56	7 (12.5)	NC [NC, NC]	49	22 (44.9)	3.5 [1.9, NC]	0.136 [0.053, 0.349]	<.0001	
Metastases at Baseline									
Visceral metastases	147	21 (14.3)	NC [NC, NC]	152	64 (42.1)	NC [2.8, NC]	0.210 [0.123, 0.356]	<.0001	0.5976
Lymph node only	43	3 (7.0)	NC [NC, NC]	37	12 (32.4)	6.5 [3.3, 6.5]	0.081 [0.015, 0.433]	0.0003	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.131.2.1: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) - Febrile neutropenia (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	1 (0.5%)	10 (5.1%)	
Number of patients censored	200 (99.5%)	187 (94.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	99.5 [96.5, 99.9]	94.9 [90.3, 97.3]	
Month 6	99.5 [96.5, 99.9]	93.9 [88.9, 96.7]	
Month 9	99.5 [96.5, 99.9]	NC [NC, NC]	
Month 12	99.5 [96.5, 99.9]	NC [NC, NC]	
Month 18	99.5 [96.5, 99.9]	NC [NC, NC]	
Month 24	99.5 [96.5, 99.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.090 [0.011, 0.701]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0038

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.131.2.2: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) by Subgroups - Febrile neutropenia (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	1 (2.0)		49	6 (12.2)				
Absent	151	0 (0.0)		148	4 (2.7)				
Age									
< 65 years	39	0 (0.0)	NC [NC, NC]	28	1 (3.6)	NC [NC, NC]	NC [NC, NC]	0.2379	NC
>= 65 years	162	1 (0.6)	NC [NC, NC]	169	9 (5.3)	NC [NC, NC]	0.105 [0.013, 0.828]	0.0088	
Region									
Europe	73	1 (1.4)		94	8 (8.5)				
North America	46	0 (0.0)		33	0 (0.0)				
Rest of World	82	0 (0.0)		70	2 (2.9)				
Sex									
Male	145	1 (0.7)		148	7 (4.7)				
Female	56	0 (0.0)		49	3 (6.1)				
Metastases at Baseline									
Visceral metastases	147	1 (0.7)	NC [NC, NC]	152	9 (5.9)	NC [NC, NC]	0.105 [0.013, 0.829]	0.0089	NC
Lymph node only	43	0 (0.0)	NC [NC, NC]	37	1 (2.7)	NC [NC, NC]	NC [NC, NC]	0.2810	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.132.2.1: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) - Leukopenia (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	2 (1.0%)	13 (6.6%)	
Number of patients censored	199 (99.0%)	184 (93.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.9 [95.8, 99.7]	94.1 [89.5, 96.7]	
Month 6	98.9 [95.8, 99.7]	92.7 [87.8, 95.7]	
Month 9	98.9 [95.8, 99.7]	NC [NC, NC]	
Month 12	98.9 [95.8, 99.7]	NC [NC, NC]	
Month 18	98.9 [95.8, 99.7]	NC [NC, NC]	
Month 24	98.9 [95.8, 99.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.144 [0.032, 0.638]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0030

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.132.2.2: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) by Subgroups - Leukopenia (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	0 (0.0)	NC [NC, NC]	49	3 (6.1)	NC [NC, NC]	NC [NC, NC]	0.0806	NC
Absent	151	2 (1.3)	NC [NC, NC]	148	10 (6.8)	NC [NC, NC]	0.185 [0.040, 0.843]	0.0143	
Age									
< 65 years	39	1 (2.6)	NC [NC, NC]	28	1 (3.6)	NC [NC, NC]	0.734 [0.046, 11.734]	0.8261	0.2177
>= 65 years	162	1 (0.6)	NC [NC, NC]	169	12 (7.1)	NC [NC, NC]	0.082 [0.011, 0.630]	0.0021	
Region									
Europe	73	0 (0.0)	NC [NC, NC]	94	3 (3.2)	NC [NC, NC]	NC [NC, NC]	0.1082	NC
North America	46	0 (0.0)	NC [NC, NC]	33	0 (0.0)	NC [NC, NC]	NC [NC, NC]	NC	
Rest of World	82	2 (2.4)	NC [NC, NC]	70	10 (14.3)	NC [NC, NC]	0.164 [0.036, 0.747]	0.0076	
Sex									
Male	145	2 (1.4)	NC [NC, NC]	148	11 (7.4)	NC [NC, NC]	0.182 [0.040, 0.823]	0.0127	NC
Female	56	0 (0.0)	NC [NC, NC]	49	2 (4.1)	NC [NC, NC]	NC [NC, NC]	0.1260	
Metastases at Baseline									
Visceral metastases	147	2 (1.4)	NC [NC, NC]	152	11 (7.2)	NC [NC, NC]	0.180 [0.040, 0.814]	0.0121	NC
Lymph node only	43	0 (0.0)	NC [NC, NC]	37	1 (2.7)	NC [NC, NC]	NC [NC, NC]	0.2664	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.133.2.1: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) - Neutropenia (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	14 (7.0%)	78 (39.6%)	
Number of patients censored	187 (93.0%)	119 (60.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	95.1 [90.9, 97.4]	62.6 [55.1, 69.1]	
Month 6	93.9 [89.2, 96.6]	56.6 [48.8, 63.7]	
Month 9	93.2 [88.2, 96.1]	NC [NC, NC]	
Month 12	92.0 [86.4, 95.4]	NC [NC, NC]	
Month 18	90.5 [83.7, 94.5]	NC [NC, NC]	
Month 24	90.5 [83.7, 94.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [3.4, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.100 [0.053, 0.189]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.133.2.2: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) by Subgroups - Neutropenia (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	4 (8.0)	NC [NC, NC]	49	19 (38.8)	NC [3.1, NC]	0.115 [0.034, 0.391]	<.0001	0.6141
Absent	151	10 (6.6)	NC [NC, NC]	148	59 (39.9)	NC [3.2, NC]	0.096 [0.045, 0.202]	<.0001	
Age									
< 65 years	39	3 (7.7)	NC [NC, NC]	28	11 (39.3)	NC [1.9, NC]	0.039 [0.005, 0.316]	<.0001	0.8400
>= 65 years	162	11 (6.8)	NC [NC, NC]	169	67 (39.6)	NC [3.4, NC]	0.117 [0.060, 0.229]	<.0001	
Region									
Europe	73	4 (5.5)	NC [NC, NC]	94	35 (37.2)	NC [3.2, NC]	0.111 [0.039, 0.312]	<.0001	0.6658
North America	46	1 (2.2)	NC [NC, NC]	33	9 (27.3)	NC [3.0, NC]	0.063 [0.008, 0.501]	0.0004	
Rest of World	82	9 (11.0)	NC [NC, NC]	70	34 (48.6)	3.7 [1.8, NC]	0.103 [0.043, 0.250]	<.0001	
Sex									
Male	145	13 (9.0)	NC [NC, NC]	148	53 (35.8)	NC [NC, NC]	0.146 [0.074, 0.290]	<.0001	0.0361
Female	56	1 (1.8)	NC [NC, NC]	49	25 (51.0)	2.1 [1.0, NC]	0.023 [0.003, 0.168]	<.0001	
Metastases at Baseline									
Visceral metastases	147	13 (8.8)	NC [NC, NC]	152	58 (38.2)	NC [3.4, NC]	0.141 [0.073, 0.272]	<.0001	NC
Lymph node only	43	0 (0.0)	NC [NC, NC]	37	15 (40.5)	NC [1.6, NC]	NC [NC, NC]	<.0001	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.134.2.1: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) - Thrombocytopenia (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	2 (1.0%)	59 (29.9%)	
Number of patients censored	199 (99.0%)	138 (70.1%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	99.4 [96.1, 99.9]	73.0 [66.0, 78.8]	
Month 6	98.8 [95.3, 99.7]	66.8 [59.1, 73.4]	
Month 9	98.8 [95.3, 99.7]	NC [NC, NC]	
Month 12	98.8 [95.3, 99.7]	NC [NC, NC]	
Month 18	98.8 [95.3, 99.7]	NC [NC, NC]	
Month 24	98.8 [95.3, 99.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.026 [0.006, 0.108]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.134.2.2: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) by Subgroups - Thrombocytopenia (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	1 (2.0)	NC [NC, NC]	49	16 (32.7)	NC [4.4, NC]	0.048 [0.006, 0.366]	<.0001	0.4969
Absent	151	1 (0.7)	NC [NC, NC]	148	43 (29.1)	NC [NC, NC]	0.018 [0.003, 0.132]	<.0001	
Age									
< 65 years	39	0 (0.0)	NC [NC, NC]	28	6 (21.4)	NC [NC, NC]	NC [NC, NC]	0.0025	NC
>= 65 years	162	2 (1.2)	NC [NC, NC]	169	53 (31.4)	NC [NC, NC]	0.031 [0.007, 0.125]	<.0001	
Region									
Europe	73	2 (2.7)	NC [NC, NC]	94	34 (36.2)	NC [4.4, NC]	0.057 [0.014, 0.237]	<.0001	NC
North America	46	0 (0.0)	NC [NC, NC]	33	9 (27.3)	NC [3.9, NC]	NC [NC, NC]	<.0001	
Rest of World	82	0 (0.0)	NC [NC, NC]	70	16 (22.9)	NC [NC, NC]	NC [NC, NC]	<.0001	
Sex									
Male	145	2 (1.4)	NC [NC, NC]	148	46 (31.1)	NC [NC, NC]	0.035 [0.009, 0.146]	<.0001	NC
Female	56	0 (0.0)	NC [NC, NC]	49	13 (26.5)	NC [NC, NC]	NC [NC, NC]	<.0001	
Metastases at Baseline									
Visceral metastases	147	1 (0.7)	NC [NC, NC]	152	45 (29.6)	NC [NC, NC]	0.018 [0.003, 0.134]	<.0001	0.4314
Lymph node only	43	1 (2.3)	NC [NC, NC]	37	12 (32.4)	NC [3.7, NC]	0.058 [0.007, 0.444]	0.0002	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.135.2.1: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) - Cardiac disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	8 (4.0%)	4 (2.0%)	
Number of patients censored	193 (96.0%)	193 (98.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.4 [92.6, 98.3]	97.9 [94.4, 99.2]	
Month 6	96.4 [92.6, 98.3]	97.9 [94.4, 99.2]	
Month 9	96.4 [92.6, 98.3]	NC [NC, NC]	
Month 12	96.4 [92.6, 98.3]	NC [NC, NC]	
Month 18	96.4 [92.6, 98.3]	NC [NC, NC]	
Month 24	92.0 [77.0, 97.4]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.697 [0.497, 5.797]
Log-rank test			
Two-sided unstratified log-rank p-value			0.3932

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.136.2.1: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) - Gastrointestinal disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	**Plat+Gem (N= 197)**	**EV+Pembro vs. Plat+Gem**
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	27 (13.4%)	16 (8.1%)	
Number of patients censored	174 (86.6%)	181 (91.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	92.8 [88.1, 95.7]	91.7 [86.7, 94.9]	
Month 6	89.0 [83.4, 92.8]	90.8 [85.2, 94.3]	
Month 9	86.7 [80.5, 91.0]	NC [NC, NC]	
Month 12	84.4 [77.4, 89.4]	NC [NC, NC]	
Month 18	82.9 [75.2, 88.4]	NC [NC, NC]	
Month 24	79.5 [68.5, 87.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.084 [0.557, 2.109]
Log-rank test			
Two-sided unstratified log-rank p-value			0.8122

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.137.2.1: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) - Diarrhoea (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	11 (5.5%)	4 (2.0%)	
Number of patients censored	190 (94.5%)	193 (98.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.4 [92.5, 98.3]	97.9 [94.4, 99.2]	
Month 6	95.1 [90.9, 97.5]	97.9 [94.4, 99.2]	
Month 9	93.7 [88.8, 96.5]	NC [NC, NC]	
Month 12	93.7 [88.8, 96.5]	NC [NC, NC]	
Month 18	93.7 [88.8, 96.5]	NC [NC, NC]	
Month 24	93.7 [88.8, 96.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			2.130 [0.656, 6.918]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1973

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.138.2.1: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) - General disorders and administration site conditions (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	24 (11.9%)	23 (11.7%)	
Number of patients censored	177 (88.1%)	174 (88.3%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	92.3 [87.5, 95.3]	89.8 [84.5, 93.4]	
Month 6	91.7 [86.7, 94.8]	87.1 [81.2, 91.3]	
Month 9	88.6 [82.7, 92.5]	NC [NC, NC]	
Month 12	86.3 [79.5, 91.0]	NC [NC, NC]	
Month 18	86.3 [79.5, 91.0]	NC [NC, NC]	
Month 24	79.7 [67.0, 87.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.655 [0.346, 1.239]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1897

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.139.2.1: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) - Asthenia (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	5 (2.5%)	5 (2.5%)	
Number of patients censored	196 (97.5%)	192 (97.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	99.0 [95.9, 99.7]	97.8 [94.1, 99.2]	
Month 6	98.4 [95.0, 99.5]	97.0 [92.9, 98.8]	
Month 9	98.4 [95.0, 99.5]	NC [NC, NC]	
Month 12	97.2 [92.3, 99.0]	NC [NC, NC]	
Month 18	97.2 [92.3, 99.0]	NC [NC, NC]	
Month 24	93.9 [81.3, 98.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.544 [0.130, 2.282]
Log-rank test			
Two-sided unstratified log-rank p-value			0.3981

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.140.2.1: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) - Fatigue (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	11 (5.5%)	8 (4.1%)	
Number of patients censored	190 (94.5%)	189 (95.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.3 [92.4, 98.2]	96.7 [92.8, 98.5]	
Month 6	96.3 [92.4, 98.2]	95.3 [90.7, 97.6]	
Month 9	94.0 [89.0, 96.8]	NC [NC, NC]	
Month 12	92.8 [87.1, 96.1]	NC [NC, NC]	
Month 18	92.8 [87.1, 96.1]	NC [NC, NC]	
Month 24	92.8 [87.1, 96.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.838 [0.305, 2.304]
Log-rank test			
Two-sided unstratified log-rank p-value			0.7322

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.141.2.1: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) - Hepatobiliary disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	8 (4.0%)	7 (3.6%)	
Number of patients censored	193 (96.0%)	190 (96.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.4 [93.8, 98.9]	96.3 [92.3, 98.2]	
Month 6	96.1 [92.0, 98.1]	96.3 [92.3, 98.2]	
Month 9	96.1 [92.0, 98.1]	NC [NC, NC]	
Month 12	96.1 [92.0, 98.1]	NC [NC, NC]	
Month 18	94.6 [88.5, 97.5]	NC [NC, NC]	
Month 24	94.6 [88.5, 97.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.890 [0.309, 2.563]
Log-rank test			
Two-sided unstratified log-rank p-value			0.8290

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.142.2.1: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) - Infections and infestations (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	**Plat+Gem (N= 197)**	**EV+Pembro vs. Plat+Gem**
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	49 (24.4%)	36 (18.3%)	
Number of patients censored	152 (75.6%)	161 (81.7%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	85.6 [79.9, 89.9]	82.6 [76.2, 87.4]	
Month 6	81.3 [74.8, 86.2]	79.3 [72.3, 84.7]	
Month 9	74.2 [66.8, 80.2]	NC [NC, NC]	
Month 12	71.3 [63.5, 77.8]	NC [NC, NC]	
Month 18	71.3 [63.5, 77.8]	NC [NC, NC]	
Month 24	65.4 [50.8, 76.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.820 [0.510, 1.317]
Log-rank test			
Two-sided unstratified log-rank p-value			0.4133

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.143.2.1: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) - Pyelonephritis (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	4 (2.0%)	6 (3.0%)	
Number of patients censored	197 (98.0%)	191 (97.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	99.0 [95.9, 99.7]	97.0 [93.0, 98.8]	
Month 6	98.3 [94.6, 99.4]	96.1 [91.3, 98.3]	
Month 9	97.5 [93.5, 99.1]	NC [NC, NC]	
Month 12	97.5 [93.5, 99.1]	NC [NC, NC]	
Month 18	97.5 [93.5, 99.1]	NC [NC, NC]	
Month 24	97.5 [93.5, 99.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.323 [0.070, 1.492]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1300

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.144.2.1: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) - Urinary tract infection (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	**Plat+Gem (N= 197)**	**EV+Pembro vs. Plat+Gem**
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	14 (7.0%)	16 (8.1%)	
Number of patients censored	187 (93.0%)	181 (91.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.4 [92.6, 98.3]	92.9 [88.0, 95.8]	
Month 6	94.5 [90.0, 97.0]	90.4 [84.7, 94.1]	
Month 9	93.0 [87.9, 96.0]	NC [NC, NC]	
Month 12	91.2 [85.3, 94.8]	NC [NC, NC]	
Month 18	91.2 [85.3, 94.8]	NC [NC, NC]	
Month 24	91.2 [85.3, 94.8]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.522 [0.233, 1.169]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1080

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.145.2.1: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) - Investigations (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	29 (14.4%)	36 (18.3%)	
Number of patients censored	172 (85.6%)	161 (81.7%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	91.1 [86.0, 94.3]	82.1 [75.8, 87.0]	
Month 6	87.2 [81.4, 91.4]	79.6 [72.7, 84.9]	
Month 9	84.9 [78.5, 89.6]	NC [NC, NC]	
Month 12	82.7 [75.5, 87.9]	NC [NC, NC]	
Month 18	80.9 [72.9, 86.8]	NC [NC, NC]	
Month 24	80.9 [72.9, 86.8]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.516 [0.303, 0.878]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0136

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.145.2.2: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) by Subgroups - Investigations (SOC) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	8 (16.0)	NC [14.5, NC]	49	12 (24.5)	NC [NC, NC]	0.291 [0.093, 0.906]	0.0238	0.6578
Absent	151	21 (13.9)	NC [NC, NC]	148	24 (16.2)	NC [NC, NC]	0.627 [0.339, 1.158]	0.1361	
Age									
< 65 years	39	7 (17.9)	NC [NC, NC]	28	5 (17.9)	NC [NC, NC]	0.651 [0.191, 2.223]	0.5003	0.6476
>= 65 years	162	22 (13.6)	NC [NC, NC]	169	31 (18.3)	NC [NC, NC]	0.486 [0.268, 0.883]	0.0160	
Region									
Europe	73	11 (15.1)	NC [NC, NC]	94	16 (17.0)	NC [NC, NC]	0.522 [0.217, 1.258]	0.1424	0.8282
North America	46	5 (10.9)	NC [NC, NC]	33	6 (18.2)	NC [NC, NC]	0.480 [0.143, 1.607]	0.2259	
Rest of World	82	13 (15.9)	NC [NC, NC]	70	14 (20.0)	NC [NC, NC]	0.501 [0.221, 1.137]	0.0939	
Sex									
Male	145	22 (15.2)	NC [NC, NC]	148	32 (21.6)	NC [NC, NC]	0.494 [0.275, 0.889]	0.0170	0.2820
Female	56	7 (12.5)	NC [NC, NC]	49	4 (8.2)	NC [NC, NC]	0.735 [0.189, 2.860]	0.6564	
Metastases at Baseline									
Visceral metastases	147	21 (14.3)	NC [NC, NC]	152	31 (20.4)	NC [NC, NC]	0.431 [0.233, 0.799]	0.0062	0.0957
Lymph node only	43	8 (18.6)	NC [NC, NC]	37	3 (8.1)	NC [NC, NC]	1.759 [0.449, 6.893]	0.4145	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.146.2.1: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) - Neutrophil count decreased (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	**Plat+Gem (N= 197)**	**EV+Pembro vs. Plat+Gem**
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	7 (3.5%)	19 (9.6%)	
Number of patients censored	194 (96.5%)	178 (90.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.7 [92.9, 98.5]	90.8 [85.6, 94.2]	
Month 6	96.7 [92.9, 98.5]	89.2 [83.5, 93.0]	
Month 9	96.7 [92.9, 98.5]	NC [NC, NC]	
Month 12	95.8 [91.1, 98.0]	NC [NC, NC]	
Month 18	95.8 [91.1, 98.0]	NC [NC, NC]	
Month 24	95.8 [91.1, 98.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.287 [0.114, 0.718]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0045

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.146.2.2: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) by Subgroups - Neutrophil count decreased (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	1 (2.0)	NC [NC, NC]	49	5 (10.2)	NC [NC, NC]	0.181 [0.021, 1.559]	0.0806	0.5708
Absent	151	6 (4.0)	NC [NC, NC]	148	14 (9.5)	NC [NC, NC]	0.323 [0.116, 0.897]	0.0224	
Age									
< 65 years	39	2 (5.1)	NC [NC, NC]	28	2 (7.1)	NC [NC, NC]	0.355 [0.032, 3.919]	0.3772	0.4467
>= 65 years	162	5 (3.1)	NC [NC, NC]	169	17 (10.1)	NC [NC, NC]	0.280 [0.103, 0.760]	0.0077	
Region									
Europe	73	2 (2.7)	NC [NC, NC]	94	8 (8.5)	NC [NC, NC]	0.298 [0.063, 1.403]	0.1041	NC
North America	46	0 (0.0)	NC [NC, NC]	33	5 (15.2)	NC [NC, NC]	NC [NC, NC]	0.0038	
Rest of World	82	5 (6.1)	NC [NC, NC]	70	6 (8.6)	NC [NC, NC]	0.548 [0.155, 1.941]	0.3444	
Sex									
Male	145	5 (3.4)	NC [NC, NC]	148	16 (10.8)	NC [NC, NC]	0.241 [0.080, 0.720]	0.0057	0.6093
Female	56	2 (3.6)	NC [NC, NC]	49	3 (6.1)	NC [NC, NC]	0.506 [0.084, 3.035]	0.4476	
Metastases at Baseline									
Visceral metastases	147	4 (2.7)	NC [NC, NC]	152	16 (10.5)	NC [NC, NC]	0.178 [0.052, 0.610]	0.0020	0.1320
Lymph node only	43	3 (7.0)	NC [NC, NC]	37	2 (5.4)	NC [NC, NC]	1.237 [0.207, 7.402]	0.8196	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.147.2.1: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) - Platelet count decreased (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	0 (0.0%)	17 (8.6%)	
Number of patients censored	201 (100.0%)	180 (91.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	100.0 [100.0, 100.0]	91.4 [86.4, 94.7]	
Month 6	100.0 [100.0, 100.0]	90.5 [85.0, 94.0]	
Month 9	100.0 [100.0, 100.0]	NC [NC, NC]	
Month 12	100.0 [100.0, 100.0]	NC [NC, NC]	
Month 18	100.0 [100.0, 100.0]	NC [NC, NC]	
Month 24	100.0 [100.0, 100.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			NC [NC, NC]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.147.2.2: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) by Subgroups - Platelet count decreased (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	0 (0.0)	NC [NC, NC]	49	6 (12.2)	NC [NC, NC]	NC [NC, NC]	0.0127	NC
Absent	151	0 (0.0)	NC [NC, NC]	148	11 (7.4)	NC [NC, NC]	NC [NC, NC]	0.0004	
Age									
< 65 years	39	0 (0.0)	NC [NC, NC]	28	2 (7.1)	NC [NC, NC]	NC [NC, NC]	0.0965	NC
>= 65 years	162	0 (0.0)	NC [NC, NC]	169	15 (8.9)	NC [NC, NC]	NC [NC, NC]	<.0001	
Region									
Europe	73	0 (0.0)		94	6 (6.4)				
North America	46	0 (0.0)		33	3 (9.1)				
Rest of World	82	0 (0.0)		70	8 (11.4)				
Sex									
Male	145	0 (0.0)	NC [NC, NC]	148	15 (10.1)	NC [NC, NC]	NC [NC, NC]	<.0001	NC
Female	56	0 (0.0)	NC [NC, NC]	49	2 (4.1)	NC [NC, NC]	NC [NC, NC]	0.1281	
Metastases at Baseline									
Visceral metastases	147	0 (0.0)	NC [NC, NC]	152	15 (9.9)	NC [NC, NC]	NC [NC, NC]	<.0001	NC
Lymph node only	43	0 (0.0)	NC [NC, NC]	37	1 (2.7)	NC [NC, NC]	NC [NC, NC]	0.1904	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.148.2.1: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) - Metabolism and nutrition disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	45 (22.4%)	21 (10.7%)	
Number of patients censored	156 (77.6%)	176 (89.3%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	81.5 [75.2, 86.3]	89.6 [84.1, 93.2]	
Month 6	80.3 [74.0, 85.3]	87.6 [81.5, 91.9]	
Month 9	75.8 [68.7, 81.5]	NC [NC, NC]	
Month 12	75.8 [68.7, 81.5]	NC [NC, NC]	
Month 18	74.2 [66.5, 80.4]	NC [NC, NC]	
Month 24	74.2 [66.5, 80.4]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.791 [1.051, 3.052]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0301

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.148.2.2: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) by Subgroups - Metabolism and nutrition disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	10 (20.0)	NC [14.3, NC]	49	4 (8.2)	NC [NC, NC]	1.966 [0.591, 6.544]	0.2622	0.6803
Absent	151	35 (23.2)	NC [NC, NC]	148	17 (11.5)	NC [NC, NC]	1.735 [0.957, 3.144]	0.0667	
Age									
< 65 years	39	6 (15.4)	NC [NC, NC]	28	2 (7.1)	NC [NC, NC]	1.879 [0.367, 9.631]	0.4437	0.9856
>= 65 years	162	39 (24.1)	NC [NC, NC]	169	19 (11.2)	NC [NC, NC]	1.820 [1.035, 3.202]	0.0353	
Region									
Europe	73	13 (17.8)	NC [NC, NC]	94	7 (7.4)	NC [NC, NC]	1.986 [0.770, 5.124]	0.1483	0.2344
North America	46	12 (26.1)	NC [NC, NC]	33	8 (24.2)	NC [4.6, NC]	0.819 [0.323, 2.078]	0.6611	
Rest of World	82	20 (24.4)	NC [NC, NC]	70	6 (8.6)	NC [NC, NC]	2.552 [1.006, 6.473]	0.0409	
Sex									
Male	145	37 (25.5)	NC [NC, NC]	148	13 (8.8)	NC [NC, NC]	2.465 [1.286, 4.727]	0.0050	0.0222
Female	56	8 (14.3)	NC [NC, NC]	49	8 (16.3)	NC [NC, NC]	0.810 [0.304, 2.160]	0.6734	
Metastases at Baseline									
Visceral metastases	147	35 (23.8)	NC [NC, NC]	152	17 (11.2)	NC [NC, NC]	1.801 [0.990, 3.279]	0.0514	0.9077
Lymph node only	43	7 (16.3)	NC [NC, NC]	37	3 (8.1)	NC [NC, NC]	1.979 [0.511, 7.660]	0.3133	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.149.2.1: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) - Hyperglycaemia (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	**Plat+Gem (N= 197)**	**EV+Pembro vs. Plat+Gem**
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	12 (6.0%)	1 (0.5%)	
Number of patients censored	189 (94.0%)	196 (99.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	94.9 [90.6, 97.2]	99.5 [96.4, 99.9]	
Month 6	94.3 [89.9, 96.8]	99.5 [96.4, 99.9]	
Month 9	93.4 [88.7, 96.3]	NC [NC, NC]	
Month 12	93.4 [88.7, 96.3]	NC [NC, NC]	
Month 18	93.4 [88.7, 96.3]	NC [NC, NC]	
Month 24	93.4 [88.7, 96.3]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			10.706 [1.382, 82.920]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0045

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.149.2.2: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) by Subgroups - Hyperglycaemia (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	3 (6.0)		49	1 (2.0)				
Absent	151	9 (6.0)		148	0 (0.0)				
Age									
< 65 years	39	1 (2.6)	NC [NC, NC]	28	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.3968	NC
>= 65 years	162	11 (6.8)	NC [NC, NC]	169	1 (0.6)	NC [NC, NC]	10.306 [1.319, 80.522]	0.0057	
Region									
Europe	73	4 (5.5)		94	1 (1.1)				
North America	46	3 (6.5)		33	0 (0.0)				
Rest of World	82	5 (6.1)		70	0 (0.0)				
Sex									
Male	145	11 (7.6)	NC [NC, NC]	148	1 (0.7)	NC [NC, NC]	10.364 [1.327, 80.944]	0.0056	NC
Female	56	1 (1.8)	NC [NC, NC]	49	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.4120	
Metastases at Baseline									
Visceral metastases	147	10 (6.8)	NC [NC, NC]	152	1 (0.7)	NC [NC, NC]	9.335 [1.183, 73.684]	0.0097	NC
Lymph node only	43	1 (2.3)	NC [NC, NC]	37	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.3536	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.150.2.1: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) - Hyponatraemia (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	15 (7.5%)	7 (3.6%)	
Number of patients censored	186 (92.5%)	190 (96.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	94.2 [89.8, 96.8]	96.8 [93.0, 98.5]	
Month 6	93.0 [88.2, 95.9]	95.8 [91.1, 98.0]	
Month 9	92.1 [87.0, 95.3]	NC [NC, NC]	
Month 12	92.1 [87.0, 95.3]	NC [NC, NC]	
Month 18	90.5 [83.9, 94.5]	NC [NC, NC]	
Month 24	90.5 [83.9, 94.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.684 [0.670, 4.237]
Log-rank test			
Two-sided unstratified log-rank p-value			0.2627

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.151.2.1: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) - Musculoskeletal and connective tissue disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	6 (3.0%)	4 (2.0%)	
Number of patients censored	195 (97.0%)	193 (98.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	99.0 [95.9, 99.7]	98.3 [94.9, 99.5]	
Month 6	97.7 [93.8, 99.1]	97.6 [93.7, 99.1]	
Month 9	96.9 [92.8, 98.7]	NC [NC, NC]	
Month 12	96.9 [92.8, 98.7]	NC [NC, NC]	
Month 18	95.3 [88.9, 98.1]	NC [NC, NC]	
Month 24	95.3 [88.9, 98.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.746 [0.178, 3.122]
Log-rank test			
Two-sided unstratified log-rank p-value			0.6879

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.152.2.1: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) - Nervous system disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	20 (10.0%)	4 (2.0%)	
Number of patients censored	181 (90.0%)	193 (98.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.7 [94.1, 99.1]	98.3 [94.7, 99.4]	
Month 6	93.2 [88.0, 96.2]	93.1 [72.4, 98.4]	
Month 9	88.2 [81.6, 92.6]	NC [NC, NC]	
Month 12	87.0 [79.8, 91.7]	NC [NC, NC]	
Month 18	83.3 [74.0, 89.5]	NC [NC, NC]	
Month 24	83.3 [74.0, 89.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.427 [0.421, 4.832]
Log-rank test			
Two-sided unstratified log-rank p-value			0.5664

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.153.2.1: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) - Peripheral sensory neuropathy (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	11 (5.5%)	0 (0.0%)	
Number of patients censored	190 (94.5%)	197 (100.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.9 [95.5, 99.7]	100.0 [100.0, 100.0]	
Month 6	97.5 [93.4, 99.1]	100.0 [100.0, 100.0]	
Month 9	93.2 [87.2, 96.4]	NC [NC, NC]	
Month 12	91.9 [85.2, 95.6]	NC [NC, NC]	
Month 18	89.5 [80.5, 94.5]	NC [NC, NC]	
Month 24	89.5 [80.5, 94.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			NC [NC, NC]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1630

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.154.2.1: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) - Renal and urinary disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	**Plat+Gem (N= 197)**	**EV+Pembro vs. Plat+Gem**
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	25 (12.4%)	15 (7.6%)	
Number of patients censored	176 (87.6%)	182 (92.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	92.3 [87.6, 95.3]	93.3 [88.5, 96.2]	
Month 6	89.9 [84.6, 93.5]	90.8 [85.0, 94.4]	
Month 9	89.1 [83.6, 92.9]	NC [NC, NC]	
Month 12	88.0 [81.8, 92.1]	NC [NC, NC]	
Month 18	83.2 [74.7, 89.1]	NC [NC, NC]	
Month 24	80.0 [68.9, 87.6]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			1.124 [0.567, 2.230]
Log-rank test			
Two-sided unstratified log-rank p-value			0.7358

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.155.2.1: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) - Acute kidney injury (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	14 (7.0%)	4 (2.0%)	
Number of patients censored	187 (93.0%)	193 (98.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	94.9 [90.7, 97.2]	97.7 [94.0, 99.1]	
Month 6	93.1 [88.4, 96.0]	97.7 [94.0, 99.1]	
Month 9	93.1 [88.4, 96.0]	NC [NC, NC]	
Month 12	93.1 [88.4, 96.0]	NC [NC, NC]	
Month 18	91.4 [85.1, 95.2]	NC [NC, NC]	
Month 24	91.4 [85.1, 95.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			3.048 [0.993, 9.358]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0405

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.155.2.2: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) by Subgroups - Acute kidney injury (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	5 (10.0)	NC [NC, NC]	49	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0409	NC
Absent	151	9 (6.0)	NC [NC, NC]	148	4 (2.7)	NC [NC, NC]	2.039 [0.627, 6.633]	0.2264	
Age									
< 65 years	39	1 (2.6)	NC [NC, NC]	28	1 (3.6)	NC [NC, NC]	0.705 [0.044, 11.273]	0.8038	0.2271
>= 65 years	162	13 (8.0)	NC [NC, NC]	169	3 (1.8)	NC [NC, NC]	3.955 [1.114, 14.035]	0.0216	
Region									
Europe	73	4 (5.5)	NC [NC, NC]	94	1 (1.1)	NC [NC, NC]	3.546 [0.367, 34.244]	0.2430	NC
North America	46	7 (15.2)	NC [NC, NC]	33	3 (9.1)	NC [NC, NC]	1.672 [0.432, 6.467]	0.4526	
Rest of World	82	3 (3.7)	NC [NC, NC]	70	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1399	
Sex									
Male	145	14 (9.7)	NC [NC, NC]	148	4 (2.7)	NC [NC, NC]	3.275 [1.067, 10.054]	0.0281	NC
Female	56	0 (0.0)	NC [NC, NC]	49	0 (0.0)	NC [NC, NC]	NC [NC, NC]	NC	
Metastases at Baseline									
Visceral metastases	147	12 (8.2)	NC [NC, NC]	152	4 (2.6)	NC [NC, NC]	2.773 [0.882, 8.717]	0.0686	NC
Lymph node only	43	2 (4.7)	NC [NC, NC]	37	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.2292	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.156.2.1: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) - Respiratory, thoracic and mediastinal disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	**Plat+Gem (N= 197)**	**EV+Pembro vs. Plat+Gem**
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	16 (8.0%)	16 (8.1%)	
Number of patients censored	185 (92.0%)	181 (91.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.3 [92.5, 98.2]	93.0 [88.3, 95.9]	
Month 6	93.3 [88.5, 96.2]	85.6 [71.6, 93.0]	
Month 9	90.9 [85.2, 94.5]	NC [NC, NC]	
Month 12	90.9 [85.2, 94.5]	NC [NC, NC]	
Month 18	89.6 [83.3, 93.7]	NC [NC, NC]	
Month 24	89.6 [83.3, 93.7]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.595 [0.277, 1.277]
Log-rank test			
Two-sided unstratified log-rank p-value			0.1779

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.157.2.1: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) - Pulmonary embolism (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	**Plat+Gem (N= 197)**	**EV+Pembro vs. Plat+Gem**
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	9 (4.5%)	7 (3.6%)	
Number of patients censored	192 (95.5%)	190 (96.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.8 [94.4, 99.2]	96.7 [92.7, 98.5]	
Month 6	95.4 [90.9, 97.7]	95.9 [91.4, 98.0]	
Month 9	95.4 [90.9, 97.7]	NC [NC, NC]	
Month 12	95.4 [90.9, 97.7]	NC [NC, NC]	
Month 18	94.1 [88.4, 97.0]	NC [NC, NC]	
Month 24	94.1 [88.4, 97.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.915 [0.323, 2.593]
Log-rank test			
Two-sided unstratified log-rank p-value			0.8662

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.158.2.1: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) - Skin and subcutaneous tissue disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	39 (19.4%)	2 (1.0%)	
Number of patients censored	162 (80.6%)	195 (99.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	86.0 [80.2, 90.2]	99.0 [95.9, 99.7]	
Month 6	82.8 [76.6, 87.6]	99.0 [95.9, 99.7]	
Month 9	80.6 [73.9, 85.7]	NC [NC, NC]	
Month 12	77.3 [69.7, 83.3]	NC [NC, NC]	
Month 18	74.6 [65.0, 81.9]	NC [NC, NC]	
Month 24	74.6 [65.0, 81.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			15.277 [3.655, 63.843]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.158.2.2: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) by Subgroups - Skin and subcutaneous tissue disorders (SOC) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	10 (20.0)	NC [NC, NC]	49	1 (2.0)	NC [NC, NC]	9.639 [1.225, 75.820]	0.0085	0.4990
Absent	151	29 (19.2)	NC [NC, NC]	148	1 (0.7)	NC [NC, NC]	20.861 [2.807, 155.03]	<.0001	
Age									
< 65 years	39	6 (15.4)	NC [NC, NC]	28	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.2168	NC
>= 65 years	162	33 (20.4)	NC [NC, NC]	169	2 (1.2)	NC [NC, NC]	15.189 [3.622, 63.696]	<.0001	
Region									
Europe	73	12 (16.4)	NC [NC, NC]	94	1 (1.1)	NC [NC, NC]	13.573 [1.738, 106.00]	0.0012	NC
North America	46	10 (21.7)	NC [17.2, NC]	33	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0142	
Rest of World	82	17 (20.7)	NC [NC, NC]	70	1 (1.4)	NC [NC, NC]	10.167 [1.323, 78.123]	0.0059	
Sex									
Male	145	28 (19.3)	NC [NC, NC]	148	1 (0.7)	NC [NC, NC]	23.136 [3.117, 171.75]	<.0001	0.4300
Female	56	11 (19.6)	NC [NC, NC]	49	1 (2.0)	NC [NC, NC]	7.102 [0.897, 56.224]	0.0303	
Metastases at Baseline									
Visceral metastases	147	31 (21.1)	NC [NC, NC]	152	2 (1.3)	NC [NC, NC]	13.201 [3.125, 55.769]	<.0001	NC
Lymph node only	43	6 (14.0)	NC [NC, NC]	37	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0443	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.159.2.1: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) - Rash maculo-papular (PT) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	20 (10.0%)	0 (0.0%)	
Number of patients censored	181 (90.0%)	197 (100.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	92.3 [87.5, 95.3]	100.0 [100.0, 100.0]	
Month 6	91.1 [86.0, 94.4]	100.0 [100.0, 100.0]	
Month 9	89.5 [83.9, 93.2]	NC [NC, NC]	
Month 12	88.5 [82.4, 92.5]	NC [NC, NC]	
Month 18	88.5 [82.4, 92.5]	NC [NC, NC]	
Month 24	88.5 [82.4, 92.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			NC [NC, NC]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.159.2.2: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) by Subgroups - Rash maculo-papular (PT) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	5 (10.0)	NC [NC, NC]	49	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0273	NC
Absent	151	15 (9.9)	NC [NC, NC]	148	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0006	
Age									
< 65 years	39	3 (7.7)	NC [NC, NC]	28	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.2203	NC
>= 65 years	162	17 (10.5)	NC [NC, NC]	169	0 (0.0)	NC [NC, NC]	NC [NC, NC]	<.0001	
Region									
Europe	73	6 (8.2)		94	0 (0.0)				
North America	46	8 (17.4)		33	0 (0.0)				
Rest of World	82	6 (7.3)		70	0 (0.0)				
Sex									
Male	145	14 (9.7)	NC [NC, NC]	148	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0004	NC
Female	56	6 (10.7)	NC [NC, NC]	49	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0463	
Metastases at Baseline									
Visceral metastases	147	17 (11.6)	NC [NC, NC]	152	0 (0.0)	NC [NC, NC]	NC [NC, NC]	<.0001	NC
Lymph node only	43	2 (4.7)	NC [NC, NC]	37	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.3479	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.160.2.1: Summary and Results of TEAESI - Immune related and infusion reactions - Analysis Set mSAF 2

	EV+Pembro (N= 201)	**Plat+Gem (N= 197)**	**EV+Pembro vs. Plat+Gem**
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	89 (44.3%)	11 (5.6%)	
Number of patients censored	112 (55.7%)	186 (94.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	71.8 [64.8, 77.6]	95.2 [91.0, 97.5]	
Month 6	60.7 [53.1, 67.5]	93.7 [88.8, 96.5]	
Month 9	52.4 [44.4, 59.8]	NC [NC, NC]	
Month 12	48.9 [40.5, 56.7]	NC [NC, NC]	
Month 18	43.8 [34.3, 52.8]	NC [NC, NC]	
Month 24	43.8 [34.3, 52.8]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	11.5 [6.9, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			6.403 [3.385, 12.111]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.160.2.2: Summary and Results of TEAESI by Subgroups - Immune related and infusion reactions - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	16 (32.0)	NC [6.2, NC]	49	2 (4.1)	NC [NC, NC]	5.369 [1.182, 24.394]	0.0149	0.9384
Absent	151	73 (48.3)	8.7 [5.7, NC]	148	9 (6.1)	NC [NC, NC]	6.641 [3.287, 13.417]	<.0001	
Age									
< 65 years	39	12 (30.8)	NC [6.9, NC]	28	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0122	NC
>= 65 years	162	77 (47.5)	8.3 [5.7, 16.3]	169	11 (6.5)	NC [NC, NC]	6.019 [3.162, 11.459]	<.0001	
Region									
Europe	73	35 (47.9)	8.1 [5.7, NC]	94	4 (4.3)	NC [NC, NC]	8.541 [2.965, 24.599]	<.0001	0.2102
North America	46	19 (41.3)	13.1 [5.1, NC]	33	4 (12.1)	NC [NC, NC]	2.642 [0.874, 7.987]	0.0725	
Rest of World	82	35 (42.7)	13.1 [4.9, NC]	70	3 (4.3)	NC [NC, NC]	8.443 [2.568, 27.754]	<.0001	
Sex									
Male	145	68 (46.9)	10.3 [5.8, 16.3]	148	7 (4.7)	NC [NC, NC]	8.327 [3.780, 18.345]	<.0001	0.1661
Female	56	21 (37.5)	NC [6.2, NC]	49	4 (8.2)	NC [NC, NC]	3.255 [1.087, 9.745]	0.0254	
Metastases at Baseline									
Visceral metastases	147	61 (41.5)	13.1 [6.2, NC]	152	8 (5.3)	NC [NC, NC]	6.417 [3.030, 13.590]	<.0001	0.8283
Lymph node only	43	23 (53.5)	8.0 [3.1, NC]	37	3 (8.1)	NC [NC, NC]	5.622 [1.654, 19.109]	0.0018	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.161.2.1: Summary and Results of TEAESI - Peripheral neuropathy - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	131 (65.2%)	17 (8.6%)	
Number of patients censored	70 (34.8%)	180 (91.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	68.0 [60.7, 74.3]	92.2 [87.1, 95.3]	
Month 6	35.4 [28.1, 42.9]	88.9 [82.0, 93.3]	
Month 9	23.9 [17.2, 31.3]	NC [NC, NC]	
Month 12	19.4 [12.9, 26.8]	NC [NC, NC]	
Month 18	6.8 [0.9, 21.4]	NC [NC, NC]	
Month 24	NC [NC, NC]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	4.5 [3.7, 5.1]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			6.412 [3.833, 10.726]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.161.2.2: Summary and Results of TEAESI by Subgroups - Peripheral neuropathy - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	26 (52.0)	4.6 [3.5, 6.0]	49	6 (12.2)	NC [NC, NC]	3.609 [1.457, 8.943]	0.0031	0.1344
Absent	151	105 (69.5)	4.4 [3.6, 5.6]	148	11 (7.4)	NC [NC, NC]	7.917 [4.211, 14.886]	<.0001	
Age									
< 65 years	39	27 (69.2)	4.1 [3.7, 6.0]	28	5 (17.9)	NC [NC, NC]	3.519 [1.324, 9.349]	0.0073	0.1205
>= 65 years	162	104 (64.2)	4.5 [3.5, 5.6]	169	12 (7.1)	NC [NC, NC]	7.591 [4.133, 13.939]	<.0001	
Region									
Europe	73	50 (68.5)	3.7 [3.2, 4.6]	94	9 (9.6)	NC [NC, NC]	7.303 [3.546, 15.040]	<.0001	0.3400
North America	46	29 (63.0)	3.8 [2.5, 5.6]	33	5 (15.2)	NC [NC, NC]	3.673 [1.399, 9.641]	0.0046	
Rest of World	82	52 (63.4)	5.6 [4.5, 6.5]	70	3 (4.3)	NC [NC, NC]	9.731 [2.988, 31.692]	<.0001	
Sex									
Male	145	96 (66.2)	3.8 [3.5, 5.1]	148	11 (7.4)	NC [NC, NC]	8.704 [4.622, 16.390]	<.0001	0.0649
Female	56	35 (62.5)	5.8 [3.7, 7.8]	49	6 (12.2)	NC [NC, NC]	2.988 [1.220, 7.317]	0.0118	
Metastases at Baseline									
Visceral metastases	147	92 (62.6)	4.6 [3.7, 5.7]	152	11 (7.2)	NC [NC, NC]	7.145 [3.780, 13.504]	<.0001	0.8339
Lymph node only	43	31 (72.1)	3.7 [2.8, 4.9]	37	3 (8.1)	NC [NC, NC]	9.729 [2.943, 32.161]	<.0001	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.162.2.1: Summary and Results of TEAESI - Ocular disorders - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	49 (24.4%)	8 (4.1%)	
Number of patients censored	152 (75.6%)	189 (95.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	85.0 [78.9, 89.4]	96.7 [92.8, 98.5]	
Month 6	78.0 [71.0, 83.4]	95.1 [90.4, 97.6]	
Month 9	73.9 [66.4, 80.0]	NC [NC, NC]	
Month 12	71.5 [63.4, 78.1]	NC [NC, NC]	
Month 18	65.1 [54.2, 74.0]	NC [NC, NC]	
Month 24	65.1 [54.2, 74.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			4.361 [2.028, 9.381]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.162.2.2: Summary and Results of TEAESI by Subgroups - Ocular disorders - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	8 (16.0)	NC [17.5, NC]	49	2 (4.1)	NC [NC, NC]	2.505 [0.487, 12.897]	0.2558	0.5537
Absent	151	41 (27.2)	NC [NC, NC]	148	6 (4.1)	NC [NC, NC]	5.034 [2.101, 12.062]	<.0001	
Age									
< 65 years	39	10 (25.6)	NC [17.5, NC]	28	1 (3.6)	NC [NC, NC]	4.237 [0.506, 35.492]	0.1469	0.8525
>= 65 years	162	39 (24.1)	NC [NC, NC]	169	7 (4.1)	NC [NC, NC]	4.483 [1.972, 10.193]	<.0001	
Region									
Europe	73	19 (26.0)	NC [17.5, NC]	94	5 (5.3)	NC [NC, NC]	3.580 [1.298, 9.876]	0.0086	0.6803
North America	46	14 (30.4)	NC [8.1, NC]	33	2 (6.1)	NC [NC, NC]	3.434 [0.752, 15.679]	0.0902	
Rest of World	82	16 (19.5)	NC [NC, NC]	70	1 (1.4)	NC [NC, NC]	10.122 [1.311, 78.119]	0.0061	
Sex									
Male	145	35 (24.1)	NC [NC, NC]	148	6 (4.1)	NC [NC, NC]	4.706 [1.939, 11.421]	0.0002	0.8730
Female	56	14 (25.0)	NC [15.0, NC]	49	2 (4.1)	NC [NC, NC]	3.435 [0.748, 15.784]	0.0918	
Metastases at Baseline									
Visceral metastases	147	29 (19.7)	NC [NC, NC]	152	7 (4.6)	NC [NC, NC]	2.793 [1.175, 6.635]	0.0152	0.2367
Lymph node only	43	17 (39.5)	NC [4.9, NC]	37	1 (2.7)	NC [NC, NC]	12.346 [1.625, 93.798]	0.0019	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.163.2.1: Summary and Results of TEAESI - Hyperglycemia - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	32 (15.9%)	7 (3.6%)	
Number of patients censored	169 (84.1%)	190 (96.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	87.8 [82.4, 91.7]	96.7 [92.9, 98.5]	
Month 6	84.8 [78.9, 89.2]	96.0 [91.7, 98.1]	
Month 9	82.4 [75.9, 87.3]	NC [NC, NC]	
Month 12	82.4 [75.9, 87.3]	NC [NC, NC]	
Month 18	82.4 [75.9, 87.3]	NC [NC, NC]	
Month 24	82.4 [75.9, 87.3]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			4.110 [1.799, 9.389]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0003

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.163.2.2: Summary and Results of TEAESI by Subgroups - Hyperglycemia - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	5 (10.0)	NC [NC, NC]	49	1 (2.0)	NC [NC, NC]	4.151 [0.464, 37.153]	0.1671	0.9264
Absent	151	27 (17.9)	NC [NC, NC]	148	6 (4.1)	NC [NC, NC]	4.111 [1.685, 10.031]	0.0008	
Age									
< 65 years	39	6 (15.4)	NC [NC, NC]	28	1 (3.6)	NC [NC, NC]	3.969 [0.465, 33.859]	0.1740	0.9902
>= 65 years	162	26 (16.0)	NC [NC, NC]	169	6 (3.6)	NC [NC, NC]	4.141 [1.690, 10.147]	0.0007	
Region									
Europe	73	9 (12.3)	NC [NC, NC]	94	4 (4.3)	NC [NC, NC]	2.701 [0.814, 8.957]	0.0906	0.6579
North America	46	8 (17.4)	NC [NC, NC]	33	1 (3.0)	NC [NC, NC]	5.596 [0.700, 44.772]	0.0662	
Rest of World	82	15 (18.3)	NC [NC, NC]	70	2 (2.9)	NC [NC, NC]	5.515 [1.241, 24.511]	0.0117	
Sex									
Male	145	29 (20.0)	NC [NC, NC]	148	6 (4.1)	NC [NC, NC]	4.744 [1.953, 11.524]	0.0002	0.5259
Female	56	3 (5.4)	NC [NC, NC]	49	1 (2.0)	NC [NC, NC]	2.050 [0.206, 20.391]	0.5307	
Metastases at Baseline									
Visceral metastases	147	23 (15.6)	NC [NC, NC]	152	6 (3.9)	NC [NC, NC]	3.693 [1.488, 9.163]	0.0026	0.7253
Lymph node only	43	7 (16.3)	NC [NC, NC]	37	1 (2.7)	NC [NC, NC]	6.065 [0.746, 49.335]	0.0546	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.164.2.1: Summary and Results of TEAESI - Skin reactions - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	139 (69.2%)	30 (15.2%)	
Number of patients censored	62 (30.8%)	167 (84.8%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	41.4 [34.4, 48.3]	84.2 [78.2, 88.7]	
Month 6	33.3 [26.6, 40.2]	84.2 [78.2, 88.7]	
Month 9	26.2 [19.5, 33.4]	NC [NC, NC]	
Month 12	21.5 [14.4, 29.4]	NC [NC, NC]	
Month 18	19.8 [12.8, 27.9]	NC [NC, NC]	
Month 24	NC [NC, NC]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	1.4 [0.8, 2.6]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			5.566 [3.735, 8.296]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.164.2.2: Summary and Results of TEAESI by Subgroups - Skin reactions - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	33 (66.0)	1.7 [0.8, 4.9]	49	8 (16.3)	NC [NC, NC]	4.802 [2.185, 10.551]	<.0001	0.7550
Absent	151	106 (70.2)	1.2 [0.7, 3.0]	148	22 (14.9)	NC [NC, NC]	5.819 [3.661, 9.250]	<.0001	
Age									
< 65 years	39	24 (61.5)	4.2 [0.7, 8.6]	28	4 (14.3)	NC [NC, NC]	4.353 [1.482, 12.780]	0.0035	0.7842
>= 65 years	162	115 (71.0)	1.2 [0.7, 1.8]	169	26 (15.4)	NC [NC, NC]	5.915 [3.849, 9.090]	<.0001	
Region									
Europe	73	44 (60.3)	4.0 [1.4, 8.7]	94	14 (14.9)	NC [NC, NC]	4.250 [2.297, 7.862]	<.0001	0.1413
North America	46	37 (80.4)	0.7 [0.5, 1.7]	33	2 (6.1)	NC [NC, NC]	20.700 [4.948, 86.597]	<.0001	
Rest of World	82	58 (70.7)	1.2 [0.5, 3.0]	70	14 (20.0)	NC [NC, NC]	4.374 [2.428, 7.883]	<.0001	
Sex									
Male	145	98 (67.6)	1.3 [0.8, 2.6]	148	20 (13.5)	NC [NC, NC]	6.391 [3.932, 10.388]	<.0001	0.3493
Female	56	41 (73.2)	1.7 [0.5, 4.0]	49	10 (20.4)	NC [NC, NC]	3.856 [1.912, 7.777]	<.0001	
Metastases at Baseline									
Visceral metastases	147	98 (66.7)	1.7 [0.8, 3.5]	152	23 (15.1)	NC [NC, NC]	5.358 [3.387, 8.476]	<.0001	0.2946
Lymph node only	43	33 (76.7)	1.0 [0.5, 1.4]	37	4 (10.8)	NC [NC, NC]	10.997 [3.860, 31.332]	<.0001	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.165.2.1: Summary and Results of TEAESI - Infusion related reactions (IRR) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	**Plat+Gem (N= 197)**	**EV+Pembro vs. Plat+Gem**
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	5 (2.5%)	5 (2.5%)	
Number of patients censored	196 (97.5%)	192 (97.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.0 [94.7, 99.2]	97.9 [94.5, 99.2]	
Month 6	98.0 [94.7, 99.2]	97.0 [92.7, 98.8]	
Month 9	98.0 [94.7, 99.2]	NC [NC, NC]	
Month 12	98.0 [94.7, 99.2]	NC [NC, NC]	
Month 18	98.0 [94.7, 99.2]	NC [NC, NC]	
Month 24	93.5 [76.3, 98.4]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.757 [0.203, 2.825]
Log-rank test			
Two-sided unstratified log-rank p-value			0.6761

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.165.2.2: Summary and Results of TEAESI by Subgroups - Infusion related reactions (IRR) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	0 (0.0)		49	1 (2.0)				
Absent	151	5 (3.3)		148	4 (2.7)				
Age									
< 65 years	39	2 (5.1)		28	1 (3.6)				
>= 65 years	162	3 (1.9)		169	4 (2.4)				
Region									
Europe	73	1 (1.4)		94	3 (3.2)				
North America	46	2 (4.3)		33	2 (6.1)				
Rest of World	82	2 (2.4)		70	0 (0.0)				
Sex									
Male	145	4 (2.8)		148	2 (1.4)				
Female	56	1 (1.8)		49	3 (6.1)				
Metastases at Baseline									
Visceral metastases	147	4 (2.7)		152	4 (2.6)				
Lymph node only	43	1 (2.3)		37	1 (2.7)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.166.2.1: Summary and Results of Non-Severe TEAESI (CTCAE Grade < 3) - Immune related and infusion reactions - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	70 (34.8%)	10 (5.1%)	
Number of patients censored	131 (65.2%)	187 (94.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	79.9 [73.4, 85.0]	95.2 [91.0, 97.5]	
Month 6	70.4 [63.0, 76.6]	94.6 [90.1, 97.0]	
Month 9	63.6 [55.6, 70.5]	NC [NC, NC]	
Month 12	59.1 [50.5, 66.8]	NC [NC, NC]	
Month 18	52.1 [41.9, 61.4]	NC [NC, NC]	
Month 24	52.1 [41.9, 61.4]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [13.1, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			4.762 [2.409, 9.414]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.166.2.2: Summary and Results of Non-Severe TEAESI (CTCAE Grade < 3) by Subgroups - Immune related and infusion reactions - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	12 (24.0)	NC [13.1, NC]	49	1 (2.0)	NC [NC, NC]	6.162 [0.742, 51.165]	0.0542	0.5859
Absent	151	58 (38.4)	16.3 [10.3, NC]	148	9 (6.1)	NC [NC, NC]	4.632 [2.255, 9.516]	<.0001	
Age									
< 65 years	39	9 (23.1)	NC [NC, NC]	28	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0329	NC
>= 65 years	162	61 (37.7)	14.5 [9.0, NC]	169	10 (5.9)	NC [NC, NC]	4.406 [2.209, 8.788]	<.0001	
Region									
Europe	73	30 (41.1)	14.5 [8.0, NC]	94	4 (4.3)	NC [NC, NC]	6.863 [2.347, 20.072]	<.0001	0.0431
North America	46	11 (23.9)	NC [13.1, NC]	33	4 (12.1)	NC [NC, NC]	1.009 [0.285, 3.576]	0.9900	
Rest of World	82	29 (35.4)	NC [10.3, NC]	70	2 (2.9)	NC [NC, NC]	9.273 [2.178, 39.482]	0.0002	
Sex									
Male	145	54 (37.2)	14.5 [10.3, NC]	148	7 (4.7)	NC [NC, NC]	5.504 [2.449, 12.370]	<.0001	0.3692
Female	56	16 (28.6)	NC [NC, NC]	49	3 (6.1)	NC [NC, NC]	3.123 [0.881, 11.078]	0.0627	
Metastases at Baseline									
Visceral metastases	147	44 (29.9)	NC [13.1, NC]	152	7 (4.6)	NC [NC, NC]	4.358 [1.909, 9.948]	0.0001	0.9814
Lymph node only	43	21 (48.8)	8.1 [4.1, NC]	37	3 (8.1)	NC [NC, NC]	4.785 [1.392, 16.451]	0.0061	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.167.2.1: Summary and Results of Non-Severe TEAESI (CTCAE Grade < 3) - Peripheral neuropathy - Analysis Set mSAF 2

	EV+Pembro (N= 201)	**Plat+Gem (N= 197)**	**EV+Pembro vs. Plat+Gem**
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	128 (63.7%)	17 (8.6%)	
Number of patients censored	73 (36.3%)	180 (91.4%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	68.6 [61.3, 74.8]	92.2 [87.1, 95.3]	
Month 6	37.3 [29.8, 44.8]	88.9 [82.0, 93.3]	
Month 9	25.5 [18.6, 33.1]	NC [NC, NC]	
Month 12	20.9 [14.1, 28.6]	NC [NC, NC]	
Month 18	10.2 [3.1, 22.2]	NC [NC, NC]	
Month 24	10.2 [3.1, 22.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	4.5 [3.7, 5.6]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			6.301 [3.765, 10.545]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.167.2.2: Summary and Results of Non-Severe TEAESI (CTCAE Grade < 3) by Subgroups - Peripheral neuropathy - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	25 (50.0)	4.6 [3.5, 6.8]	49	6 (12.2)	NC [NC, NC]	3.592 [1.448, 8.908]	0.0032	0.1285
Absent	151	103 (68.2)	4.5 [3.7, 5.6]	148	11 (7.4)	NC [NC, NC]	7.753 [4.121, 14.585]	<.0001	
Age									
< 65 years	39	27 (69.2)	4.1 [3.7, 6.0]	28	5 (17.9)	NC [NC, NC]	3.519 [1.324, 9.349]	0.0073	0.1443
>= 65 years	162	101 (62.3)	4.6 [3.6, 5.6]	169	12 (7.1)	NC [NC, NC]	7.430 [4.044, 13.654]	<.0001	
Region									
Europe	73	50 (68.5)	3.7 [3.2, 4.6]	94	9 (9.6)	NC [NC, NC]	7.303 [3.546, 15.040]	<.0001	0.3352
North America	46	28 (60.9)	3.8 [2.5, 5.6]	33	5 (15.2)	NC [NC, NC]	3.673 [1.399, 9.641]	0.0046	
Rest of World	82	50 (61.0)	5.7 [4.5, 6.7]	70	3 (4.3)	NC [NC, NC]	9.301 [2.851, 30.342]	<.0001	
Sex									
Male	145	93 (64.1)	3.9 [3.5, 5.1]	148	11 (7.4)	NC [NC, NC]	8.493 [4.507, 16.004]	<.0001	0.0827
Female	56	35 (62.5)	5.8 [3.7, 7.8]	49	6 (12.2)	NC [NC, NC]	2.988 [1.220, 7.317]	0.0118	
Metastases at Baseline									
Visceral metastases	147	91 (61.9)	4.6 [3.7, 5.8]	152	11 (7.2)	NC [NC, NC]	7.129 [3.771, 13.476]	<.0001	0.9044
Lymph node only	43	30 (69.8)	3.7 [2.8, 4.9]	37	3 (8.1)	NC [NC, NC]	9.729 [2.943, 32.161]	<.0001	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.168.2.1: Summary and Results of Non-Severe TEAESI (CTCAE Grade < 3) - Ocular disorders - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	49 (24.4%)	8 (4.1%)	
Number of patients censored	152 (75.6%)	189 (95.9%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	85.0 [78.9, 89.4]	96.7 [92.8, 98.5]	
Month 6	78.0 [71.0, 83.4]	95.1 [90.4, 97.6]	
Month 9	73.9 [66.4, 80.0]	NC [NC, NC]	
Month 12	71.5 [63.4, 78.1]	NC [NC, NC]	
Month 18	65.1 [54.2, 74.0]	NC [NC, NC]	
Month 24	65.1 [54.2, 74.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			4.361 [2.028, 9.381]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.168.2.2: Summary and Results of Non-Severe TEAESI (CTCAE Grade < 3) by Subgroups - Ocular disorders - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	8 (16.0)	NC [17.5, NC]	49	2 (4.1)	NC [NC, NC]	2.505 [0.487, 12.897]	0.2558	0.5537
Absent	151	41 (27.2)	NC [NC, NC]	148	6 (4.1)	NC [NC, NC]	5.034 [2.101, 12.062]	<.0001	
Age									
< 65 years	39	10 (25.6)	NC [17.5, NC]	28	1 (3.6)	NC [NC, NC]	4.237 [0.506, 35.492]	0.1469	0.8525
>= 65 years	162	39 (24.1)	NC [NC, NC]	169	7 (4.1)	NC [NC, NC]	4.483 [1.972, 10.193]	<.0001	
Region									
Europe	73	19 (26.0)	NC [17.5, NC]	94	5 (5.3)	NC [NC, NC]	3.580 [1.298, 9.876]	0.0086	0.6803
North America	46	14 (30.4)	NC [8.1, NC]	33	2 (6.1)	NC [NC, NC]	3.434 [0.752, 15.679]	0.0902	
Rest of World	82	16 (19.5)	NC [NC, NC]	70	1 (1.4)	NC [NC, NC]	10.122 [1.311, 78.119]	0.0061	
Sex									
Male	145	35 (24.1)	NC [NC, NC]	148	6 (4.1)	NC [NC, NC]	4.706 [1.939, 11.421]	0.0002	0.8730
Female	56	14 (25.0)	NC [15.0, NC]	49	2 (4.1)	NC [NC, NC]	3.435 [0.748, 15.784]	0.0918	
Metastases at Baseline									
Visceral metastases	147	29 (19.7)	NC [NC, NC]	152	7 (4.6)	NC [NC, NC]	2.793 [1.175, 6.635]	0.0152	0.2367
Lymph node only	43	17 (39.5)	NC [4.9, NC]	37	1 (2.7)	NC [NC, NC]	12.346 [1.625, 93.798]	0.0019	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.169.2.1: Summary and Results of Non-Severe TEAESI (CTCAE Grade < 3) - Hyperglycemia - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	30 (14.9%)	6 (3.0%)	
Number of patients censored	171 (85.1%)	191 (97.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	88.8 [83.5, 92.5]	97.3 [93.5, 98.8]	
Month 6	85.7 [79.8, 90.0]	96.5 [92.3, 98.4]	
Month 9	84.1 [77.8, 88.7]	NC [NC, NC]	
Month 12	82.8 [75.9, 87.8]	NC [NC, NC]	
Month 18	82.8 [75.9, 87.8]	NC [NC, NC]	
Month 24	82.8 [75.9, 87.8]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			4.353 [1.794, 10.561]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0004

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.169.2.2: Summary and Results of Non-Severe TEAESI (CTCAE Grade < 3) by Subgroups - Hyperglycemia - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	5 (10.0)	NC [NC, NC]	49	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0411	NC
Absent	151	25 (16.6)	NC [NC, NC]	148	6 (4.1)	NC [NC, NC]	3.664 [1.489, 9.015]	0.0025	
Age									
< 65 years	39	6 (15.4)	NC [NC, NC]	28	1 (3.6)	NC [NC, NC]	3.969 [0.465, 33.859]	0.1740	0.9265
>= 65 years	162	24 (14.8)	NC [NC, NC]	169	5 (3.0)	NC [NC, NC]	4.402 [1.662, 11.657]	0.0011	
Region									
Europe	73	8 (11.0)	NC [NC, NC]	94	3 (3.2)	NC [NC, NC]	3.149 [0.815, 12.161]	0.0790	0.8130
North America	46	7 (15.2)	NC [NC, NC]	33	1 (3.0)	NC [NC, NC]	4.848 [0.596, 39.427]	0.1010	
Rest of World	82	15 (18.3)	NC [NC, NC]	70	2 (2.9)	NC [NC, NC]	5.302 [1.191, 23.612]	0.0145	
Sex									
Male	145	27 (18.6)	NC [NC, NC]	148	5 (3.4)	NC [NC, NC]	5.126 [1.954, 13.444]	0.0002	0.4680
Female	56	3 (5.4)	NC [NC, NC]	49	1 (2.0)	NC [NC, NC]	2.050 [0.206, 20.391]	0.5307	
Metastases at Baseline									
Visceral metastases	147	22 (15.0)	NC [NC, NC]	152	5 (3.3)	NC [NC, NC]	4.199 [1.574, 11.207]	0.0019	0.9289
Lymph node only	43	6 (14.0)	NC [NC, NC]	37	1 (2.7)	NC [NC, NC]	5.079 [0.611, 42.214]	0.0939	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.170.2.1: Summary and Results of Non-Severe TEAESI (CTCAE Grade < 3) - Skin reactions - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	135 (67.2%)	29 (14.7%)	
Number of patients censored	66 (32.8%)	168 (85.3%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	42.7 [35.6, 49.6]	84.7 [78.7, 89.1]	
Month 6	34.5 [27.6, 41.5]	84.7 [78.7, 89.1]	
Month 9	27.2 [20.4, 34.6]	NC [NC, NC]	
Month 12	24.2 [17.1, 32.0]	NC [NC, NC]	
Month 18	22.6 [15.4, 30.6]	NC [NC, NC]	
Month 24	NC [NC, NC]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	1.6 [1.0, 3.0]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			5.576 [3.718, 8.364]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.170.2.2: Summary and Results of Non-Severe TEAESI (CTCAE Grade < 3) by Subgroups - Skin reactions - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	33 (66.0)	1.7 [0.8, 4.9]	49	8 (16.3)	NC [NC, NC]	4.785 [2.178, 10.513]	<.0001	0.7501
Absent	151	102 (67.5)	1.4 [0.8, 3.0]	148	21 (14.2)	NC [NC, NC]	5.851 [3.643, 9.396]	<.0001	
Age									
< 65 years	39	23 (59.0)	4.2 [0.7, 8.6]	28	4 (14.3)	NC [NC, NC]	4.353 [1.482, 12.780]	0.0035	0.7361
>= 65 years	162	112 (69.1)	1.4 [0.8, 2.6]	169	25 (14.8)	NC [NC, NC]	5.915 [3.818, 9.162]	<.0001	
Region									
Europe	73	42 (57.5)	4.4 [1.6, 11.9]	94	14 (14.9)	NC [NC, NC]	3.947 [2.124, 7.336]	<.0001	0.1626
North America	46	36 (78.3)	0.9 [0.5, 2.1]	33	2 (6.1)	NC [NC, NC]	19.861 [4.742, 83.176]	<.0001	
Rest of World	82	57 (69.5)	1.2 [0.5, 3.0]	70	13 (18.6)	NC [NC, NC]	4.754 [2.591, 8.721]	<.0001	
Sex									
Male	145	95 (65.5)	1.4 [1.0, 3.0]	148	19 (12.8)	NC [NC, NC]	6.557 [3.988, 10.781]	<.0001	0.2793
Female	56	40 (71.4)	2.2 [0.5, 4.4]	49	10 (20.4)	NC [NC, NC]	3.683 [1.822, 7.442]	<.0001	
Metastases at Baseline									
Visceral metastases	147	96 (65.3)	2.1 [1.0, 3.7]	152	22 (14.5)	NC [NC, NC]	5.434 [3.403, 8.677]	<.0001	0.3358
Lymph node only	43	32 (74.4)	1.1 [0.5, 1.4]	37	4 (10.8)	NC [NC, NC]	10.479 [3.670, 29.919]	<.0001	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.171.2.1: Summary and Results of Non-Severe TEAESI (CTCAE Grade < 3) - Infusion related reactions (IRR) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	5 (2.5%)	5 (2.5%)	
Number of patients censored	196 (97.5%)	192 (97.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.0 [94.7, 99.2]	97.9 [94.5, 99.2]	
Month 6	98.0 [94.7, 99.2]	97.0 [92.7, 98.8]	
Month 9	98.0 [94.7, 99.2]	NC [NC, NC]	
Month 12	98.0 [94.7, 99.2]	NC [NC, NC]	
Month 18	98.0 [94.7, 99.2]	NC [NC, NC]	
Month 24	93.5 [76.3, 98.4]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			0.757 [0.203, 2.825]
Log-rank test			
Two-sided unstratified log-rank p-value			0.6761

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.171.2.2: Summary and Results of Non-Severe TEAESI (CTCAE Grade < 3) by Subgroups - Infusion related reactions (IRR) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	0 (0.0)		49	1 (2.0)				
Absent	151	5 (3.3)		148	4 (2.7)				
Age									
< 65 years	39	2 (5.1)		28	1 (3.6)				
>= 65 years	162	3 (1.9)		169	4 (2.4)				
Region									
Europe	73	1 (1.4)		94	3 (3.2)				
North America	46	2 (4.3)		33	2 (6.1)				
Rest of World	82	2 (2.4)		70	0 (0.0)				
Sex									
Male	145	4 (2.8)		148	2 (1.4)				
Female	56	1 (1.8)		49	3 (6.1)				
Metastases at Baseline									
Visceral metastases	147	4 (2.7)		152	4 (2.6)				
Lymph node only	43	1 (2.3)		37	1 (2.7)				

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.172.2.1: Summary and Results of Severe TEAESI (CTCAE Grade >= 3) - Immune related and infusion reactions - Analysis Set mSAF 2

	EV+Pembro (N= 201)	**Plat+Gem (N= 197)**	**EV+Pembro vs. Plat+Gem**
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	42 (20.9%)	2 (1.0%)	
Number of patients censored	159 (79.1%)	195 (99.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	86.5 [80.8, 90.6]	99.4 [95.9, 99.9]	
Month 6	82.3 [76.0, 87.1]	98.5 [94.0, 99.6]	
Month 9	76.9 [69.6, 82.6]	NC [NC, NC]	
Month 12	76.9 [69.6, 82.6]	NC [NC, NC]	
Month 18	73.0 [63.7, 80.2]	NC [NC, NC]	
Month 24	73.0 [63.7, 80.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			15.919 [3.818, 66.378]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.172.2.2: Summary and Results of Severe TEAESI (CTCAE Grade >= 3) by Subgroups - Immune related and infusion reactions - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	9 (18.0)	NC [NC, NC]	49	1 (2.0)	NC [NC, NC]	8.103 [1.017, 64.559]	0.0188	0.3919
Absent	151	33 (21.9)	NC [NC, NC]	148	1 (0.7)	NC [NC, NC]	23.580 [3.189, 174.35]	<.0001	
Age									
< 65 years	39	6 (15.4)	NC [NC, NC]	28	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0832	NC
>= 65 years	162	36 (22.2)	NC [NC, NC]	169	2 (1.2)	NC [NC, NC]	14.862 [3.541, 62.373]	<.0001	
Region									
Europe	73	13 (17.8)	NC [NC, NC]	94	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0005	NC
North America	46	12 (26.1)	NC [17.2, NC]	33	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0089	
Rest of World	82	17 (20.7)	NC [NC, NC]	70	2 (2.9)	NC [NC, NC]	5.629 [1.275, 24.844]	0.0101	
Sex									
Male	145	33 (22.8)	NC [NC, NC]	148	1 (0.7)	NC [NC, NC]	27.039 [3.666, 199.44]	<.0001	0.2820
Female	56	9 (16.1)	NC [NC, NC]	49	1 (2.0)	NC [NC, NC]	5.286 [0.647, 43.171]	0.0817	
Metastases at Baseline									
Visceral metastases	147	34 (23.1)	NC [NC, NC]	152	2 (1.3)	NC [NC, NC]	14.902 [3.551, 62.537]	<.0001	NC
Lymph node only	43	6 (14.0)	NC [NC, NC]	37	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1135	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.173.2.1: Summary and Results of Severe TEAESI (CTCAE Grade >= 3) - Peripheral neuropathy - Analysis Set mSAF 2

	EV+Pembro (N= 201)	**Plat+Gem (N= 197)**	**EV+Pembro vs. Plat+Gem**
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	17 (8.5%)	0 (0.0%)	
Number of patients censored	184 (91.5%)	197 (100.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.4 [95.0, 99.5]	100.0 [100.0, 100.0]	
Month 6	94.4 [89.4, 97.1]	100.0 [100.0, 100.0]	
Month 9	89.4 [82.8, 93.5]	NC [NC, NC]	
Month 12	88.1 [81.0, 92.7]	NC [NC, NC]	
Month 18	85.8 [76.8, 91.5]	NC [NC, NC]	
Month 24	85.8 [76.8, 91.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			NC [NC, NC]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0407

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.173.2.2: Summary and Results of Severe TEAESI (CTCAE Grade >= 3) by Subgroups - Peripheral neuropathy - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	3 (6.0)	NC [15.5, NC]	49	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.7606	NC
Absent	151	14 (9.3)	NC [NC, NC]	148	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0434	
Age									
< 65 years	39	0 (0.0)	NC [NC, NC]	28	0 (0.0)	NC [NC, NC]	NC [NC, NC]	NC	NC
>= 65 years	162	17 (10.5)	NC [NC, NC]	169	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0378	
Region									
Europe	73	2 (2.7)	NC [NC, NC]	94	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.2485	NC
North America	46	5 (10.9)	NC [NC, NC]	33	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.4042	
Rest of World	82	10 (12.2)	NC [NC, NC]	70	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1856	
Sex									
Male	145	14 (9.7)	NC [NC, NC]	148	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0437	NC
Female	56	3 (5.4)	NC [NC, NC]	49	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.5505	
Metastases at Baseline									
Visceral metastases	147	11 (7.5)	NC [NC, NC]	152	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0818	NC
Lymph node only	43	5 (11.6)	NC [NC, NC]	37	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.5184	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.174.2.1: Summary and Results of Severe TEAESI (CTCAE Grade >= 3) - Ocular disorders - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	0 (0.0%)	0 (0.0%)	
Number of patients censored	201 (100.0%)	197 (100.0%)	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.174.2.2: Summary and Results of Severe TEAESI (CTCAE Grade >= 3) by Subgroups - Ocular disorders - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	0 (0.0)		49	0 (0.0)				
Absent	151	0 (0.0)		148	0 (0.0)				
Age									
< 65 years	39	0 (0.0)		28	0 (0.0)				
>= 65 years	162	0 (0.0)		169	0 (0.0)				
Region									
Europe	73	0 (0.0)		94	0 (0.0)				
North America	46	0 (0.0)		33	0 (0.0)				
Rest of World	82	0 (0.0)		70	0 (0.0)		NC [NC, NC]		
Sex									
Male	145	0 (0.0)		148	0 (0.0)				
Female	56	0 (0.0)		49	0 (0.0)				
Metastases at Baseline									
Visceral metastases	147	0 (0.0)		152	0 (0.0)				
Lymph node only	43	0 (0.0)		37	0 (0.0)				

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.175.2.1: Summary and Results of Severe TEAESI (CTCAE Grade >= 3) - Hyperglycemia - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	15 (7.5%)	1 (0.5%)	
Number of patients censored	186 (92.5%)	196 (99.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	93.8 [89.4, 96.4]	99.5 [96.4, 99.9]	
Month 6	93.2 [88.6, 96.0]	99.5 [96.4, 99.9]	
Month 9	91.6 [86.3, 94.9]	NC [NC, NC]	
Month 12	91.6 [86.3, 94.9]	NC [NC, NC]	
Month 18	91.6 [86.3, 94.9]	NC [NC, NC]	
Month 24	91.6 [86.3, 94.9]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			12.755 [1.669, 97.476]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0015

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.175.2.2: Summary and Results of Severe TEAESI (CTCAE Grade >= 3) by Subgroups - Hyperglycemia - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	3 (6.0)	NC [NC, NC]	49	1 (2.0)	NC [NC, NC]	1.925 [0.174, 21.257]	0.5863	NC
Absent	151	12 (7.9)	NC [NC, NC]	148	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0010	
Age									
< 65 years	39	1 (2.6)	NC [NC, NC]	28	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.3968	NC
>= 65 years	162	14 (8.6)	NC [NC, NC]	169	1 (0.6)	NC [NC, NC]	12.473 [1.622, 95.931]	0.0018	
Region									
Europe	73	6 (8.2)		94	1 (1.1)				
North America	46	3 (6.5)		33	0 (0.0)				
Rest of World	82	6 (7.3)		70	0 (0.0)				
Sex									
Male	145	14 (9.7)	NC [NC, NC]	148	1 (0.7)	NC [NC, NC]	12.578 [1.636, 96.699]	0.0017	NC
Female	56	1 (1.8)	NC [NC, NC]	49	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.4120	
Metastases at Baseline									
Visceral metastases	147	10 (6.8)	NC [NC, NC]	152	1 (0.7)	NC [NC, NC]	9.335 [1.183, 73.684]	0.0097	NC
Lymph node only	43	3 (7.0)	NC [NC, NC]	37	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1075	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.176.2.1: Summary and Results of Severe TEAESI (CTCAE Grade >= 3) - Skin reactions - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	35 (17.4%)	1 (0.5%)	
Number of patients censored	166 (82.6%)	196 (99.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	87.6 [82.1, 91.5]	99.5 [96.4, 99.9]	
Month 6	84.5 [78.4, 89.0]	99.5 [96.4, 99.9]	
Month 9	82.2 [75.7, 87.2]	NC [NC, NC]	
Month 12	79.8 [72.5, 85.4]	NC [NC, NC]	
Month 18	77.1 [67.7, 84.1]	NC [NC, NC]	
Month 24	77.1 [67.7, 84.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			27.793 [3.782, 204.28]
Log-rank test			
Two-sided unstratified log-rank p-value			<.0001

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.176.2.2: Summary and Results of Severe TEAESI (CTCAE Grade >= 3) by Subgroups - Skin reactions - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	8 (16.0)	NC [NC, NC]	49	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0041	NC
Absent	151	27 (17.9)	NC [NC, NC]	148	1 (0.7)	NC [NC, NC]	19.562 [2.626, 145.73]	<.0001	
Age									
< 65 years	39	6 (15.4)	NC [NC, NC]	28	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1396	NC
>= 65 years	162	29 (17.9)	NC [NC, NC]	169	1 (0.6)	NC [NC, NC]	26.609 [3.605, 196.40]	<.0001	
Region									
Europe	73	11 (15.1)	NC [NC, NC]	94	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0005	NC
North America	46	9 (19.6)	NC [17.2, NC]	33	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0155	
Rest of World	82	15 (18.3)	NC [NC, NC]	70	1 (1.4)	NC [NC, NC]	9.047 [1.168, 70.042]	0.0106	
Sex									
Male	145	24 (16.6)	NC [NC, NC]	148	1 (0.7)	NC [NC, NC]	20.186 [2.703, 150.77]	<.0001	NC
Female	56	11 (19.6)	NC [NC, NC]	49	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0079	
Metastases at Baseline									
Visceral metastases	147	28 (19.0)	NC [NC, NC]	152	1 (0.7)	NC [NC, NC]	24.475 [3.305, 181.22]	<.0001	NC
Lymph node only	43	5 (11.6)	NC [NC, NC]	37	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0728	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.177.2.1: Summary and Results of Severe TEAESI (CTCAE Grade >= 3) - Infusion related reactions (IRR) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	0 (0.0%)	0 (0.0%)	
Number of patients censored	201 (100.0%)	197 (100.0%)	

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.177.2.2: Summary and Results of Severe TEAESI (CTCAE Grade >= 3) by Subgroups - Infusion related reactions (IRR) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	0 (0.0)		49	0 (0.0)				
Absent	151	0 (0.0)		148	0 (0.0)				
Age									
< 65 years	39	0 (0.0)		28	0 (0.0)				
>= 65 years	162	0 (0.0)		169	0 (0.0)				
Region									
Europe	73	0 (0.0)		94	0 (0.0)				
North America	46	0 (0.0)		33	0 (0.0)				
Rest of World	82	0 (0.0)		70	0 (0.0)		NC [NC, NC]		
Sex									
Male	145	0 (0.0)		148	0 (0.0)				
Female	56	0 (0.0)		49	0 (0.0)				
Metastases at Baseline									
Visceral metastases	147	0 (0.0)		152	0 (0.0)				
Lymph node only	43	0 (0.0)		37	0 (0.0)				

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.178.2.1: Summary and Results of TESAESI - Immune related and infusion reactions - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	20 (10.0%)	2 (1.0%)	
Number of patients censored	181 (90.0%)	195 (99.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	93.8 [89.3, 96.4]	99.4 [95.9, 99.9]	
Month 6	91.5 [86.4, 94.7]	98.5 [94.0, 99.6]	
Month 9	89.2 [83.5, 93.0]	NC [NC, NC]	
Month 12	89.2 [83.5, 93.0]	NC [NC, NC]	
Month 18	87.9 [81.4, 92.2]	NC [NC, NC]	
Month 24	87.9 [81.4, 92.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			6.930 [1.584, 30.312]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0028

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAESI=treatment-emergent serious adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.178.2.2: Summary and Results of TESAESI by Subgroups - Immune related and infusion reactions - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	3 (6.0)	NC [NC, NC]	49	1 (2.0)	NC [NC, NC]	2.678 [0.277, 25.940]	0.3765	0.2793
Absent	151	17 (11.3)	NC [NC, NC]	148	1 (0.7)	NC [NC, NC]	11.113 [1.445, 85.438]	0.0036	
Age									
< 65 years	39	3 (7.7)	NC [NC, NC]	28	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1464	NC
>= 65 years	162	17 (10.5)	NC [NC, NC]	169	2 (1.2)	NC [NC, NC]	5.943 [1.330, 26.567]	0.0080	
Region									
Europe	73	8 (11.0)	NC [NC, NC]	94	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0057	NC
North America	46	1 (2.2)	NC [NC, NC]	33	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.4404	
Rest of World	82	11 (13.4)	NC [NC, NC]	70	2 (2.9)	NC [NC, NC]	3.108 [0.658, 14.681]	0.1316	
Sex									
Male	145	15 (10.3)	NC [NC, NC]	148	1 (0.7)	NC [NC, NC]	11.056 [1.427, 85.649]	0.0038	0.3631
Female	56	5 (8.9)	NC [NC, NC]	49	1 (2.0)	NC [NC, NC]	2.753 [0.306, 24.805]	0.3465	
Metastases at Baseline									
Visceral metastases	147	16 (10.9)	NC [NC, NC]	152	2 (1.3)	NC [NC, NC]	5.806 [1.299, 25.954]	0.0091	NC
Lymph node only	43	4 (9.3)	NC [NC, NC]	37	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1177	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAESI=treatment-emergent serious adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.179.2.1: Summary and Results of TESAESI - Peripheral neuropathy - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	3 (1.5%)	0 (0.0%)	
Number of patients censored	198 (98.5%)	197 (100.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	100.0 [100.0, 100.0]	100.0 [100.0, 100.0]	
Month 6	99.4 [96.0, 99.9]	100.0 [100.0, 100.0]	
Month 9	98.8 [95.1, 99.7]	NC [NC, NC]	
Month 12	98.8 [95.1, 99.7]	NC [NC, NC]	
Month 18	97.3 [91.1, 99.2]	NC [NC, NC]	
Month 24	97.3 [91.1, 99.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			NC [NC, NC]
Log-rank test			
Two-sided unstratified log-rank p-value			0.3848

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAESI=treatment-emergent serious adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.179.2.2: Summary and Results of TESAESI by Subgroups - Peripheral neuropathy - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	2 (4.0)		49	0 (0.0)				
Absent	151	1 (0.7)		148	0 (0.0)				
Age									
< 65 years	39	0 (0.0)		28	0 (0.0)				
>= 65 years	162	3 (1.9)		169	0 (0.0)				
Region									
Europe	73	1 (1.4)		94	0 (0.0)				
North America	46	1 (2.2)		33	0 (0.0)				
Rest of World	82	1 (1.2)		70	0 (0.0)				
Sex									
Male	145	3 (2.1)		148	0 (0.0)				
Female	56	0 (0.0)		49	0 (0.0)				
Metastases at Baseline									
Visceral metastases	147	3 (2.0)		152	0 (0.0)				
Lymph node only	43	0 (0.0)		37	0 (0.0)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAESI=treatment-emergent serious adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.180.2.1: Summary and Results of TESAESI - Ocular disorders - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	0 (0.0%)	0 (0.0%)	
Number of patients censored	201 (100.0%)	197 (100.0%)	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAESI=treatment-emergent serious adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.180.2.2: Summary and Results of TESAESI by Subgroups - Ocular disorders - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	0 (0.0)		49	0 (0.0)				
Absent	151	0 (0.0)		148	0 (0.0)				
Age									
< 65 years	39	0 (0.0)		28	0 (0.0)				
>= 65 years	162	0 (0.0)		169	0 (0.0)				
Region									
Europe	73	0 (0.0)		94	0 (0.0)				
North America	46	0 (0.0)		33	0 (0.0)				
Rest of World	82	0 (0.0)		70	0 (0.0)		NC [NC, NC]		
Sex									
Male	145	0 (0.0)		148	0 (0.0)				
Female	56	0 (0.0)		49	0 (0.0)				
Metastases at Baseline									
Visceral metastases	147	0 (0.0)		152	0 (0.0)				
Lymph node only	43	0 (0.0)		37	0 (0.0)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAESI=treatment-emergent serious adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.181.2.1: Summary and Results of TESAESI - Hyperglycemia - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	3 (1.5%)	0 (0.0%)	
Number of patients censored	198 (98.5%)	197 (100.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	99.0 [96.0, 99.7]	100.0 [100.0, 100.0]	
Month 6	98.4 [95.2, 99.5]	100.0 [100.0, 100.0]	
Month 9	98.4 [95.2, 99.5]	NC [NC, NC]	
Month 12	98.4 [95.2, 99.5]	NC [NC, NC]	
Month 18	98.4 [95.2, 99.5]	NC [NC, NC]	
Month 24	98.4 [95.2, 99.5]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			NC [NC, NC]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0970

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAESI=treatment-emergent serious adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.181.2.2: Summary and Results of TESAESI by Subgroups - Hyperglycemia - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	N	n (%)	KME [95% CI](a)	N	n (%)	KME [95% CI](a)	HR [95% CI](b)	Log-rank p-value(c)	Test for Interaction p-value(d)
Liver Metastases									
Present	50	0 (0.0)		49	0 (0.0)				
Absent	151	3 (2.0)		148	0 (0.0)				
Age									
< 65 years	39	0 (0.0)		28	0 (0.0)				
>= 65 years	162	3 (1.9)		169	0 (0.0)				
Region									
Europe	73	0 (0.0)		94	0 (0.0)				
North America	46	1 (2.2)		33	0 (0.0)				
Rest of World	82	2 (2.4)		70	0 (0.0)				
Sex									
Male	145	3 (2.1)		148	0 (0.0)				
Female	56	0 (0.0)		49	0 (0.0)				
Metastases at Baseline									
Visceral metastases	147	1 (0.7)		152	0 (0.0)				
Lymph node only	43	1 (2.3)		37	0 (0.0)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAESI=treatment-emergent serious adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.182.2.1: Summary and Results of TESAESI - Skin reactions - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	12 (6.0%)	1 (0.5%)	
Number of patients censored	189 (94.0%)	196 (99.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	94.3 [89.9, 96.8]	99.5 [96.4, 99.9]	
Month 6	94.3 [89.9, 96.8]	99.5 [96.4, 99.9]	
Month 9	94.3 [89.9, 96.8]	NC [NC, NC]	
Month 12	93.2 [88.1, 96.2]	NC [NC, NC]	
Month 18	93.2 [88.1, 96.2]	NC [NC, NC]	
Month 24	93.2 [88.1, 96.2]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			10.537 [1.360, 81.620]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0049

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAESI=treatment-emergent serious adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.182.2.2: Summary and Results of TESAESI by Subgroups - Skin reactions - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	4 (8.0)		49	0 (0.0)				
Absent	151	8 (5.3)		148	1 (0.7)				
Age									
< 65 years	39	1 (2.6)	NC [NC, NC]	28	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.4019	NC
>= 65 years	162	11 (6.8)	NC [NC, NC]	169	1 (0.6)	NC [NC, NC]	10.174 [1.302, 79.494]	0.0061	
Region									
Europe	73	6 (8.2)		94	0 (0.0)				
North America	46	1 (2.2)		33	0 (0.0)				
Rest of World	82	5 (6.1)		70	1 (1.4)				
Sex									
Male	145	9 (6.2)	NC [NC, NC]	148	1 (0.7)	NC [NC, NC]	8.046 [1.006, 64.343]	0.0192	NC
Female	56	3 (5.4)	NC [NC, NC]	49	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1181	
Metastases at Baseline									
Visceral metastases	147	10 (6.8)	NC [NC, NC]	152	1 (0.7)	NC [NC, NC]	9.023 [1.143, 71.227]	0.0113	NC
Lymph node only	43	2 (4.7)	NC [NC, NC]	37	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1843	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAESI=treatment-emergent serious adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.183.2.1: Summary and Results of TESAESI - Infusion related reactions (IRR) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	0 (0.0%)	0 (0.0%)	
Number of patients censored	201 (100.0%)	197 (100.0%)	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAESI=treatment-emergent serious adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.183.2.2: Summary and Results of TESAESI by Subgroups - Infusion related reactions (IRR) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	0 (0.0)		49	0 (0.0)				
Absent	151	0 (0.0)		148	0 (0.0)				
Age									
< 65 years	39	0 (0.0)		28	0 (0.0)				
>= 65 years	162	0 (0.0)		169	0 (0.0)				
Region									
Europe	73	0 (0.0)		94	0 (0.0)				
North America	46	0 (0.0)		33	0 (0.0)				
Rest of World	82	0 (0.0)		70	0 (0.0)		NC [NC, NC]		
Sex									
Male	145	0 (0.0)		148	0 (0.0)				
Female	56	0 (0.0)		49	0 (0.0)				
Metastases at Baseline									
Visceral metastases	147	0 (0.0)		152	0 (0.0)				
Lymph node only	43	0 (0.0)		37	0 (0.0)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAESI=treatment-emergent serious adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).
In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.184.2.1: Summary and Results of TEAESI leading to discontinuation from study medication - Immune related and infusion reactions - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	18 (9.0%)	0 (0.0%)	
Number of patients censored	183 (91.0%)	197 (100.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	96.8 [93.0, 98.6]	100.0 [100.0, 100.0]	
Month 6	92.5 [87.3, 95.6]	100.0 [100.0, 100.0]	
Month 9	89.2 [83.0, 93.2]	NC [NC, NC]	
Month 12	89.2 [83.0, 93.2]	NC [NC, NC]	
Month 18	86.8 [78.3, 92.1]	NC [NC, NC]	
Month 24	86.8 [78.3, 92.1]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			NC [NC, NC]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0015

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.184.2.2: Summary and Results of TEAESI leading to discontinuation from study medication by Subgroups - Immune related and infusion reactions - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	3 (6.0)	NC [NC, NC]	49	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1465	NC
Absent	151	15 (9.9)	NC [NC, NC]	148	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0048	
Age									
< 65 years	39	1 (2.6)	NC [NC, NC]	28	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.4410	NC
>= 65 years	162	17 (10.5)	NC [NC, NC]	169	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0018	
Region									
Europe	73	8 (11.0)		94	0 (0.0)				
North America	46	4 (8.7)		33	0 (0.0)				
Rest of World	82	6 (7.3)		70	0 (0.0)				
Sex									
Male	145	15 (10.3)	NC [NC, NC]	148	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0034	NC
Female	56	3 (5.4)	NC [NC, NC]	49	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1830	
Metastases at Baseline									
Visceral metastases	147	11 (7.5)	NC [NC, NC]	152	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0047	NC
Lymph node only	43	7 (16.3)	NC [NC, NC]	37	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1312	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.185.2.1: Summary and Results of TEAESI leading to discontinuation from study medication - Peripheral neuropathy - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	25 (12.4%)	0 (0.0%)	
Number of patients censored	176 (87.6%)	197 (100.0%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	98.3 [94.8, 99.4]	100.0 [100.0, 100.0]	
Month 6	94.5 [89.7, 97.1]	100.0 [100.0, 100.0]	
Month 9	87.8 [80.9, 92.3]	NC [NC, NC]	
Month 12	83.2 [75.0, 88.9]	NC [NC, NC]	
Month 18	73.1 [59.6, 82.8]	NC [NC, NC]	
Month 24	73.1 [59.6, 82.8]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			NC [NC, NC]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0124

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.185.2.2: Summary and Results of TEAESI leading to discontinuation from study medication by Subgroups - Peripheral neuropathy - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	6 (12.0)	NC [17.1, NC]	49	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1600	NC
Absent	151	19 (12.6)	NC [NC, NC]	148	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0344	
Age									
< 65 years	39	5 (12.8)	NC [17.3, NC]	28	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.4027	NC
>= 65 years	162	20 (12.3)	NC [NC, NC]	169	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0193	
Region									
Europe	73	13 (17.8)	NC [13.7, NC]	94	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0147	NC
North America	46	5 (10.9)	NC [11.8, NC]	33	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.4936	
Rest of World	82	7 (8.5)	NC [NC, NC]	70	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.3212	
Sex									
Male	145	19 (13.1)	NC [NC, NC]	148	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0102	NC
Female	56	6 (10.7)	NC [NC, NC]	49	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.6126	
Metastases at Baseline									
Visceral metastases	147	15 (10.2)	NC [NC, NC]	152	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.0586	NC
Lymph node only	43	9 (20.9)	NC [13.7, NC]	37	0 (0.0)	NC [NC, NC]	NC [NC, NC]	0.1897	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.186.2.1: Summary and Results of TEAESI leading to discontinuation from study medication - Ocular disorders - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	0 (0.0%)	0 (0.0%)	
Number of patients censored	201 (100.0%)	197 (100.0%)	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.186.2.2: Summary and Results of TEAESI leading to discontinuation from study medication by Subgroups - Ocular disorders - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	0 (0.0)		49	0 (0.0)				
Absent	151	0 (0.0)		148	0 (0.0)				
Age									
< 65 years	39	0 (0.0)		28	0 (0.0)				
>= 65 years	162	0 (0.0)		169	0 (0.0)				
Region									
Europe	73	0 (0.0)		94	0 (0.0)				
North America	46	0 (0.0)		33	0 (0.0)				
Rest of World	82	0 (0.0)		70	0 (0.0)		NC [NC, NC]		
Sex									
Male	145	0 (0.0)		148	0 (0.0)				
Female	56	0 (0.0)		49	0 (0.0)				
Metastases at Baseline									
Visceral metastases	147	0 (0.0)		152	0 (0.0)				
Lymph node only	43	0 (0.0)		37	0 (0.0)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.187.2.1: Summary and Results of TEAESI leading to discontinuation from study medication - Hyperglycemia - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	0 (0.0%)	0 (0.0%)	
Number of patients censored	201 (100.0%)	197 (100.0%)	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.187.2.2: Summary and Results of TEAESI leading to discontinuation from study medication by Subgroups - Hyperglycemia - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	0 (0.0)		49	0 (0.0)				
Absent	151	0 (0.0)		148	0 (0.0)				
Age									
< 65 years	39	0 (0.0)		28	0 (0.0)				
>= 65 years	162	0 (0.0)		169	0 (0.0)				
Region									
Europe	73	0 (0.0)		94	0 (0.0)				
North America	46	0 (0.0)		33	0 (0.0)				
Rest of World	82	0 (0.0)		70	0 (0.0)		NC [NC, NC]		
Sex									
Male	145	0 (0.0)		148	0 (0.0)				
Female	56	0 (0.0)		49	0 (0.0)				
Metastases at Baseline									
Visceral metastases	147	0 (0.0)		152	0 (0.0)				
Lymph node only	43	0 (0.0)		37	0 (0.0)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.188.2.1: Summary and Results of TEAESI leading to discontinuation from study medication - Skin reactions - Analysis Set mSAF 2

	EV+Pembro (N= 201)	**Plat+Gem (N= 197)**	**EV+Pembro vs. Plat+Gem**
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	9 (4.5%)	1 (0.5%)	
Number of patients censored	192 (95.5%)	196 (99.5%)	
Probability of being event-free (a) [95% CI] (b) at:			
Month 3	97.9 [94.6, 99.2]	99.5 [96.4, 99.9]	
Month 6	95.4 [91.0, 97.7]	99.5 [96.4, 99.9]	
Month 9	95.4 [91.0, 97.7]	NC [NC, NC]	
Month 12	94.2 [88.7, 97.0]	NC [NC, NC]	
Month 18	94.2 [88.7, 97.0]	NC [NC, NC]	
Month 24	94.2 [88.7, 97.0]	NC [NC, NC]	
Kaplan-Meier estimates of time to event (months)			
Median [95% CI] (c)	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Unstratified HR [95% CI]			6.123 [0.755, 49.685]
Log-rank test			
Two-sided unstratified log-rank p-value			0.0539

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.188.2.2: Summary and Results of TEAESI leading to discontinuation from study medication by Subgroups - Skin reactions - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	2 (4.0)		49	0 (0.0)				
Absent	151	7 (4.6)		148	1 (0.7)				
Age									
< 65 years	39	1 (2.6)		28	0 (0.0)				
>= 65 years	162	8 (4.9)		169	1 (0.6)				
Region									
Europe	73	3 (4.1)		94	0 (0.0)				
North America	46	2 (4.3)		33	0 (0.0)				
Rest of World	82	4 (4.9)		70	1 (1.4)				
Sex									
Male	145	6 (4.1)		148	1 (0.7)				
Female	56	3 (5.4)		49	0 (0.0)				
Metastases at Baseline									
Visceral metastases	147	7 (4.8)		152	1 (0.7)				
Lymph node only	43	2 (4.7)		37	0 (0.0)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.189.2.1: Summary and Results of TEAESI leading to discontinuation from study medication - Infusion related reactions (IRR) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	0 (0.0%)	0 (0.0%)	
Number of patients censored	201 (100.0%)	197 (100.0%)	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.189.2.2: Summary and Results of TEAESI leading to discontinuation from study medication by Subgroups - Infusion related reactions (IRR) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	0 (0.0)		49	0 (0.0)				
Absent	151	0 (0.0)		148	0 (0.0)				
Age									
< 65 years	39	0 (0.0)		28	0 (0.0)				
>= 65 years	162	0 (0.0)		169	0 (0.0)				
Region									
Europe	73	0 (0.0)		94	0 (0.0)				
North America	46	0 (0.0)		33	0 (0.0)				
Rest of World	82	0 (0.0)		70	0 (0.0)		NC [NC, NC]		
Sex									
Male	145	0 (0.0)		148	0 (0.0)				
Female	56	0 (0.0)		49	0 (0.0)				
Metastases at Baseline									
Visceral metastases	147	0 (0.0)		152	0 (0.0)				
Lymph node only	43	0 (0.0)		37	0 (0.0)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.190.2.1: Summary and Results of TEAESI leading to death - Immune related and infusion reactions - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	0 (0.0%)	0 (0.0%)	
Number of patients censored	201 (100.0%)	197 (100.0%)	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.190.2.2: Summary and Results of TEAESI leading to death by Subgroups - Immune related and infusion reactions - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	0 (0.0)		49	0 (0.0)				
Absent	151	0 (0.0)		148	0 (0.0)				
Age									
< 65 years	39	0 (0.0)		28	0 (0.0)				
>= 65 years	162	0 (0.0)		169	0 (0.0)				
Region									
Europe	73	0 (0.0)		94	0 (0.0)				
North America	46	0 (0.0)		33	0 (0.0)				
Rest of World	82	0 (0.0)		70	0 (0.0)		NC [NC, NC]		
Sex									
Male	145	0 (0.0)		148	0 (0.0)				
Female	56	0 (0.0)		49	0 (0.0)				
Metastases at Baseline									
Visceral metastases	147	0 (0.0)		152	0 (0.0)				
Lymph node only	43	0 (0.0)		37	0 (0.0)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.191.2.1: Summary and Results of TEAESI leading to death - Peripheral neuropathy - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	0 (0.0%)	0 (0.0%)	
Number of patients censored	201 (100.0%)	197 (100.0%)	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.191.2.2: Summary and Results of TEAESI leading to death by Subgroups - Peripheral neuropathy - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	0 (0.0)		49	0 (0.0)				
Absent	151	0 (0.0)		148	0 (0.0)				
Age									
< 65 years	39	0 (0.0)		28	0 (0.0)				
>= 65 years	162	0 (0.0)		169	0 (0.0)				
Region									
Europe	73	0 (0.0)		94	0 (0.0)				
North America	46	0 (0.0)		33	0 (0.0)				
Rest of World	82	0 (0.0)		70	0 (0.0)		NC [NC, NC]		
Sex									
Male	145	0 (0.0)		148	0 (0.0)				
Female	56	0 (0.0)		49	0 (0.0)				
Metastases at Baseline									
Visceral metastases	147	0 (0.0)		152	0 (0.0)				
Lymph node only	43	0 (0.0)		37	0 (0.0)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.192.2.1: Summary and Results of TEAESI leading to death - Ocular disorders - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	0 (0.0%)	0 (0.0%)	
Number of patients censored	201 (100.0%)	197 (100.0%)	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.192.2.2: Summary and Results of TEAESI leading to death by Subgroups - Ocular disorders - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	0 (0.0)		49	0 (0.0)				
Absent	151	0 (0.0)		148	0 (0.0)				
Age									
< 65 years	39	0 (0.0)		28	0 (0.0)				
>= 65 years	162	0 (0.0)		169	0 (0.0)				
Region									
Europe	73	0 (0.0)		94	0 (0.0)				
North America	46	0 (0.0)		33	0 (0.0)				
Rest of World	82	0 (0.0)		70	0 (0.0)		NC [NC, NC]		
Sex									
Male	145	0 (0.0)		148	0 (0.0)				
Female	56	0 (0.0)		49	0 (0.0)				
Metastases at Baseline									
Visceral metastases	147	0 (0.0)		152	0 (0.0)				
Lymph node only	43	0 (0.0)		37	0 (0.0)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.193.2.1: Summary and Results of TEAESI leading to death - Hyperglycemia - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	0 (0.0%)	0 (0.0%)	
Number of patients censored	201 (100.0%)	197 (100.0%)	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.193.2.2: Summary and Results of TEAESI leading to death by Subgroups - Hyperglycemia - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	0 (0.0)		49	0 (0.0)				
Absent	151	0 (0.0)		148	0 (0.0)				
Age									
< 65 years	39	0 (0.0)		28	0 (0.0)				
>= 65 years	162	0 (0.0)		169	0 (0.0)				
Region									
Europe	73	0 (0.0)		94	0 (0.0)				
North America	46	0 (0.0)		33	0 (0.0)				
Rest of World	82	0 (0.0)		70	0 (0.0)		NC [NC, NC]		
Sex									
Male	145	0 (0.0)		148	0 (0.0)				
Female	56	0 (0.0)		49	0 (0.0)				
Metastases at Baseline									
Visceral metastases	147	0 (0.0)		152	0 (0.0)				
Lymph node only	43	0 (0.0)		37	0 (0.0)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.194.2.1: Summary and Results of TEAESI leading to death - Skin reactions - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	0 (0.0%)	0 (0.0%)	
Number of patients censored	201 (100.0%)	197 (100.0%)	

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.194.2.2: Summary and Results of TEAESI leading to death by Subgroups - Skin reactions - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	0 (0.0)		49	0 (0.0)				
Absent	151	0 (0.0)		148	0 (0.0)				
Age									
< 65 years	39	0 (0.0)		28	0 (0.0)				
>= 65 years	162	0 (0.0)		169	0 (0.0)				
Region									
Europe	73	0 (0.0)		94	0 (0.0)				
North America	46	0 (0.0)		33	0 (0.0)				
Rest of World	82	0 (0.0)		70	0 (0.0)		NC [NC, NC]		
Sex									
Male	145	0 (0.0)		148	0 (0.0)				
Female	56	0 (0.0)		49	0 (0.0)				
Metastases at Baseline									
Visceral metastases	147	0 (0.0)		152	0 (0.0)				
Lymph node only	43	0 (0.0)		37	0 (0.0)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.195.2.1: Summary and Results of TEAESI leading to death - Infusion related reactions (IRR) - Analysis Set mSAF 2

	EV+Pembro (N= 201)	Plat+Gem (N= 197)	EV+Pembro vs. Plat+Gem
Number of patients at risk	201 (100.0%)	197 (100.0%)	
Number of patients with events	0 (0.0%)	0 (0.0%)	
Number of patients censored	201 (100.0%)	197 (100.0%)	

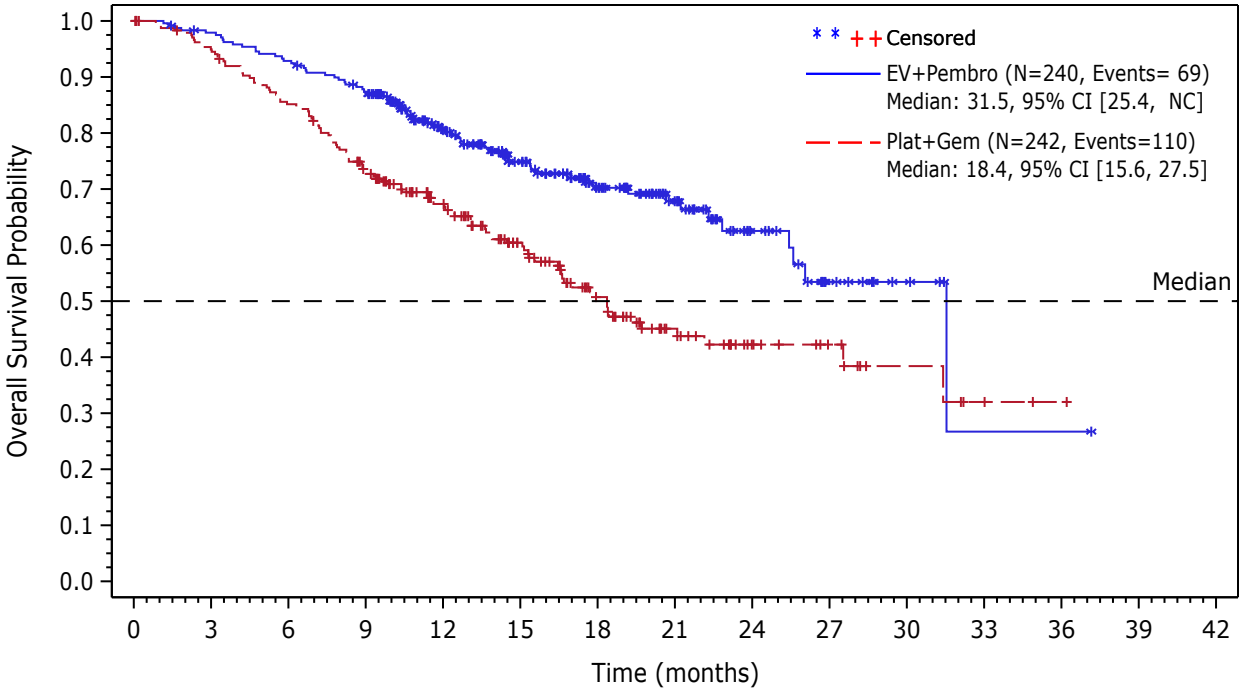
Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08AUG2023

Table 302.1.2002.195.2.2: Summary and Results of TEAESI leading to death by Subgroups - Infusion related reactions (IRR) - Analysis Set mSAF 2

	EV+Pembro			Plat+Gem			EV+Pembro vs. Plat+Gem		
Subgroup	**N**	**n (%)**	**KME [95% CI](a)**	**N**	**n (%)**	**KME [95% CI](a)**	**HR [95% CI](b)**	**Log-rank p-value(c)**	**Test for Interaction p-value(d)**
Liver Metastases									
Present	50	0 (0.0)		49	0 (0.0)				
Absent	151	0 (0.0)		148	0 (0.0)				
Age									
< 65 years	39	0 (0.0)		28	0 (0.0)				
>= 65 years	162	0 (0.0)		169	0 (0.0)				
Region									
Europe	73	0 (0.0)		94	0 (0.0)				
North America	46	0 (0.0)		33	0 (0.0)				
Rest of World	82	0 (0.0)		70	0 (0.0)		NC [NC, NC]		
Sex									
Male	145	0 (0.0)		148	0 (0.0)				
Female	56	0 (0.0)		49	0 (0.0)				
Metastases at Baseline									
Visceral metastases	147	0 (0.0)		152	0 (0.0)				
Lymph node only	43	0 (0.0)		37	0 (0.0)				

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mSAF=modified safety analysis set; N=number of patients; n=number of events; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.
Note: The analysis were conducted unstratified.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).
(a) Based on the Brookmeyer-Crowley Method; (b) Calculated from unstratified Cox proportional hazards model; (c) Based on 2-sided stratified log-rank test, unadjusted for multiplicity; (d) Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.1: Kaplan-Meier Plot of Overall Survival - Analysis Set mITT 1



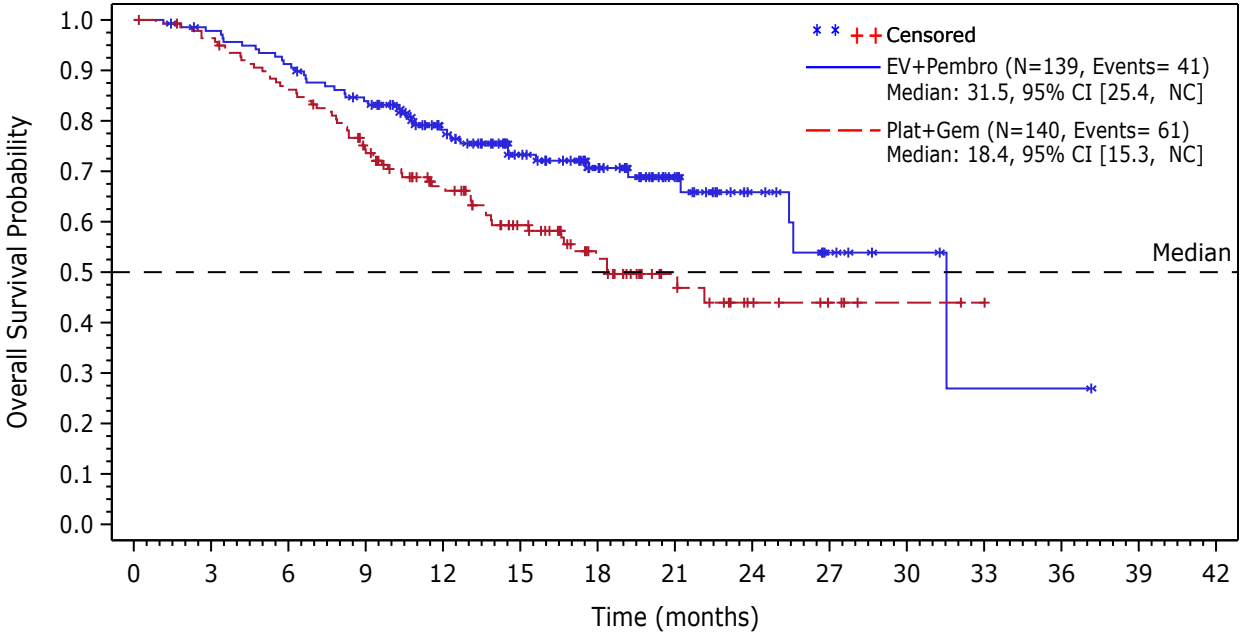
at Risk

1	240	233	221	206	150	112	78	49	24	11	5	1	1	0	0
2	242	224	200	167	125	90	58	34	18	12	6	3	1	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.1.1: Kaplan-Meier Plot of Overall Survival by PD-L1 Expression - Analysis Set mITT 1 PD-L1 Expression: High (CPS>=10)



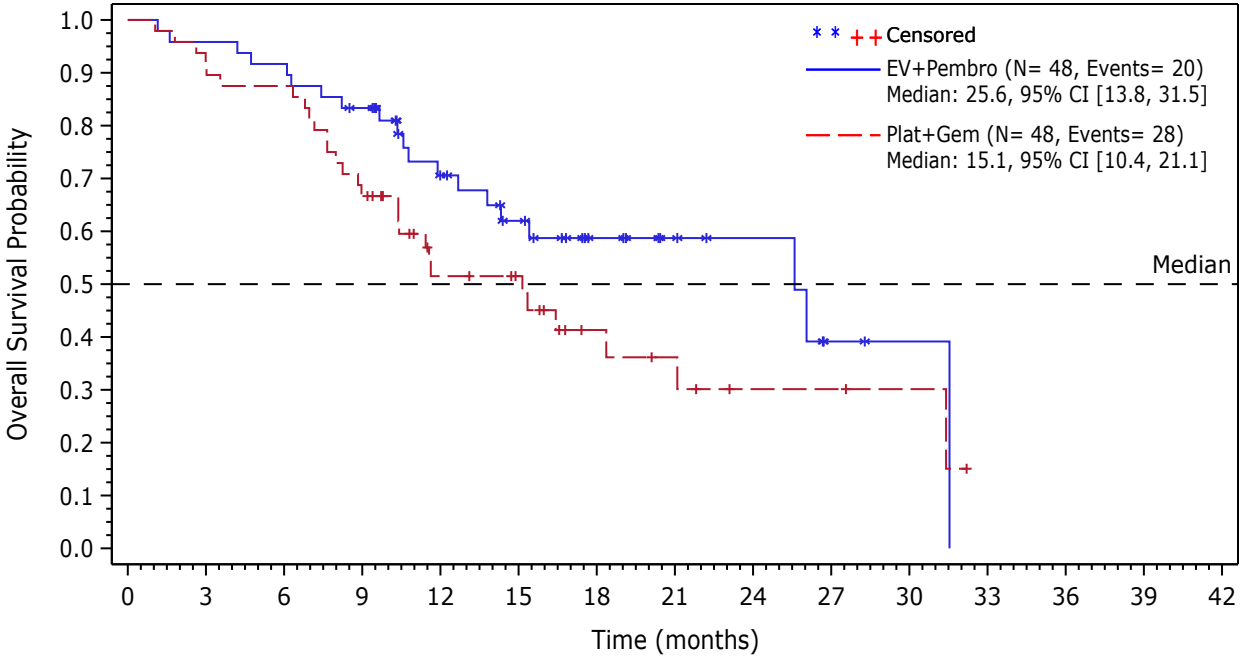
at Risk

1	139	134	125	113	87	64	47	26	13	6	3	1	1	0	0
2	140	133	118	98	74	54	35	18	9	5	2	1	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.1.2: Kaplan-Meier Plot of Overall Survival by Liver Metastases - Analysis Set mITT 1
Liver Metastases: Present



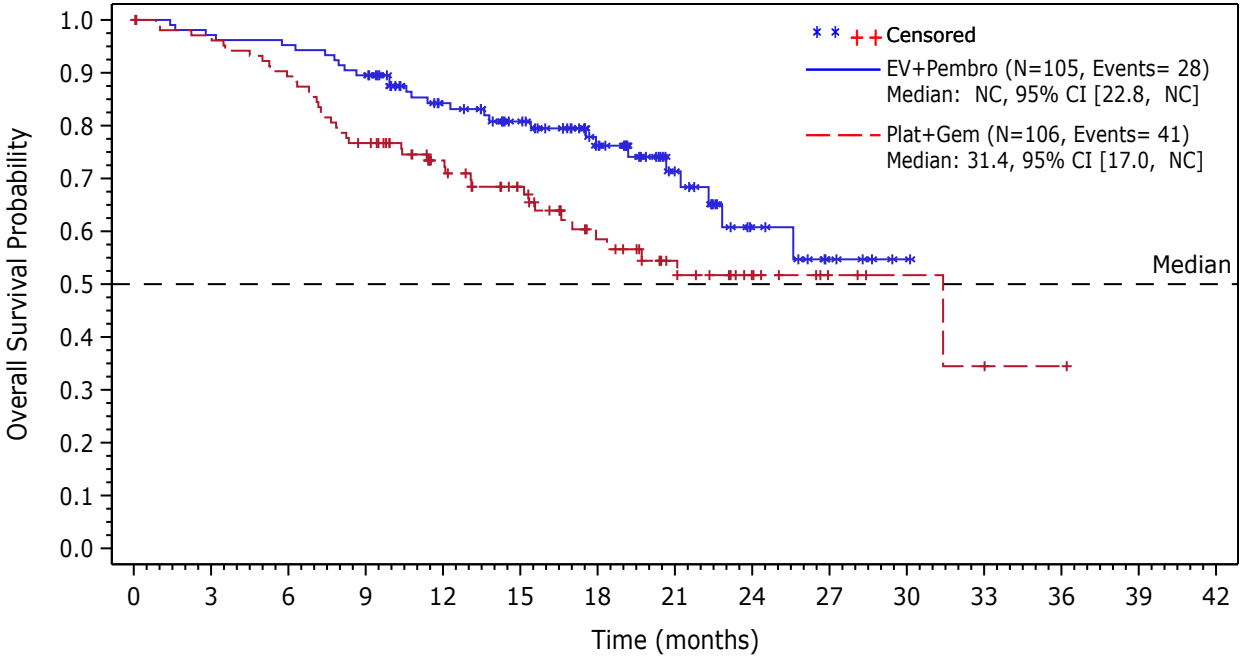
at Risk

1	48	46	44	39	26	20	12	8	6	2	1	0	0	0	0
2	48	44	42	32	19	16	8	6	3	3	2	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.1.3: Kaplan-Meier Plot of Overall Survival by Age - Analysis Set mITT 1
Age: < 65 years



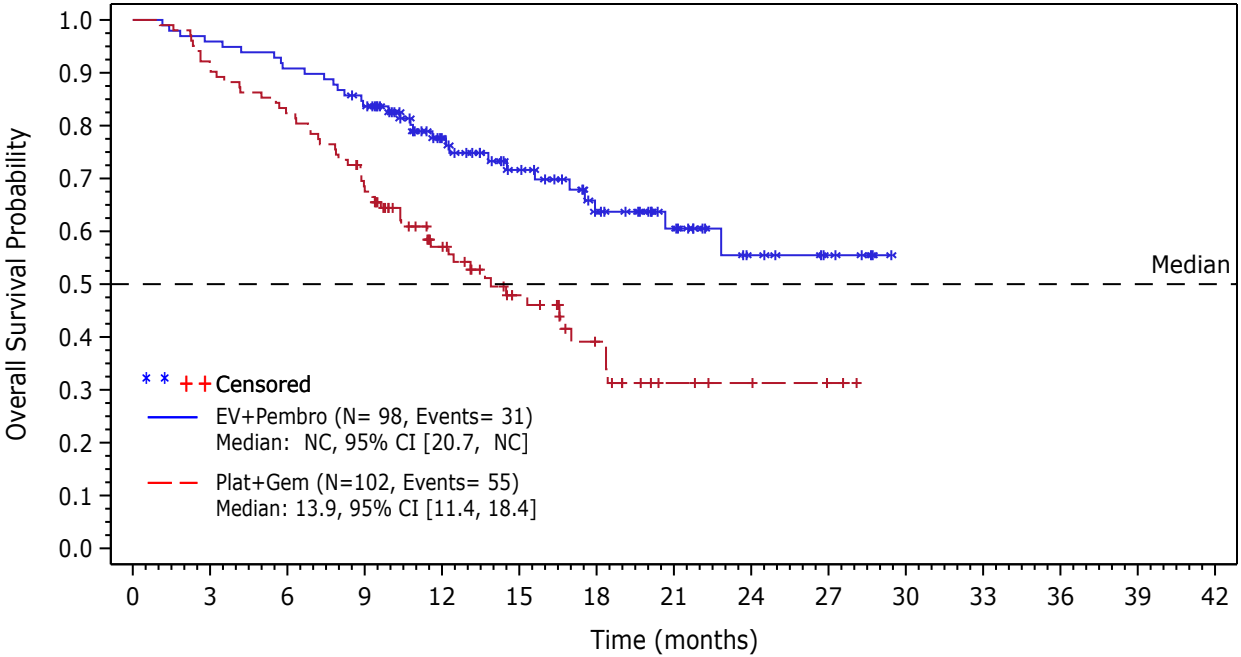
at Risk

1	105	102	100	94	75	64	45	24	11	5	1	0	0	0	0
2	106	100	92	78	60	47	31	20	11	5	3	2	1	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.1.4: Kaplan-Meier Plot of Overall Survival by Region - Analysis Set mITT 1
Region: Europe



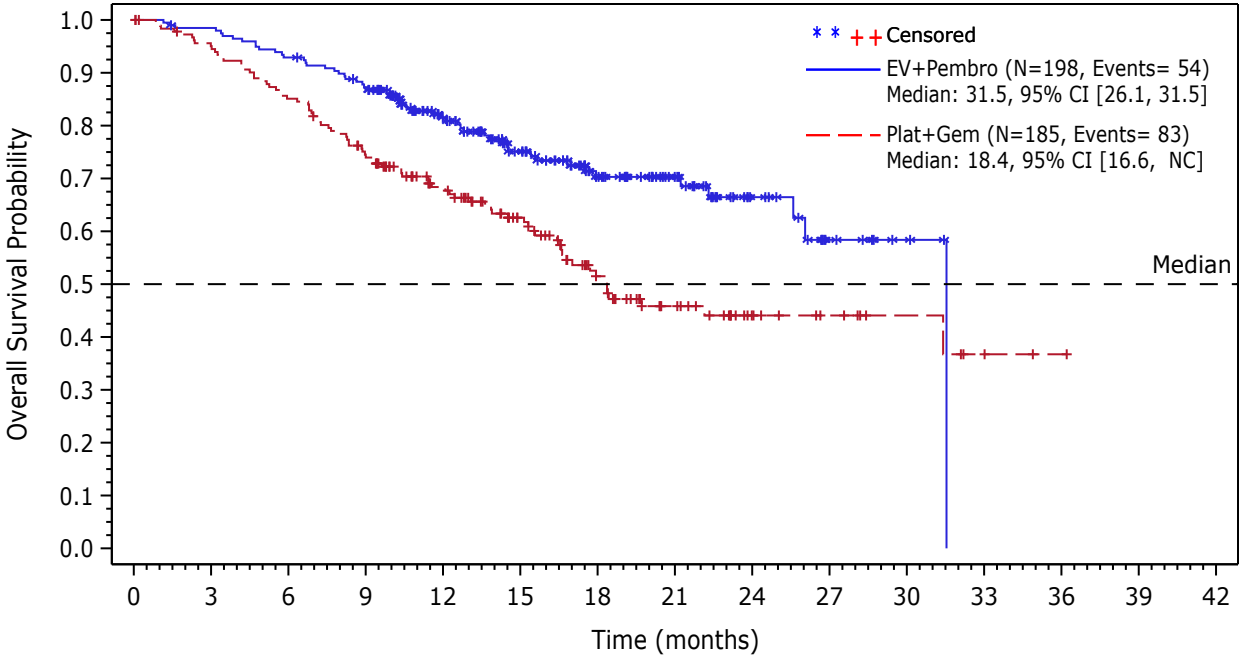
at Risk

1	98	94	89	81	56	42	29	19	9	5	0	0	0	0	0
2	102	93	84	68	42	26	15	6	4	2	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.1.5: Kaplan-Meier Plot of Overall Survival by Sex - Analysis Set mITT 1
Sex: Male



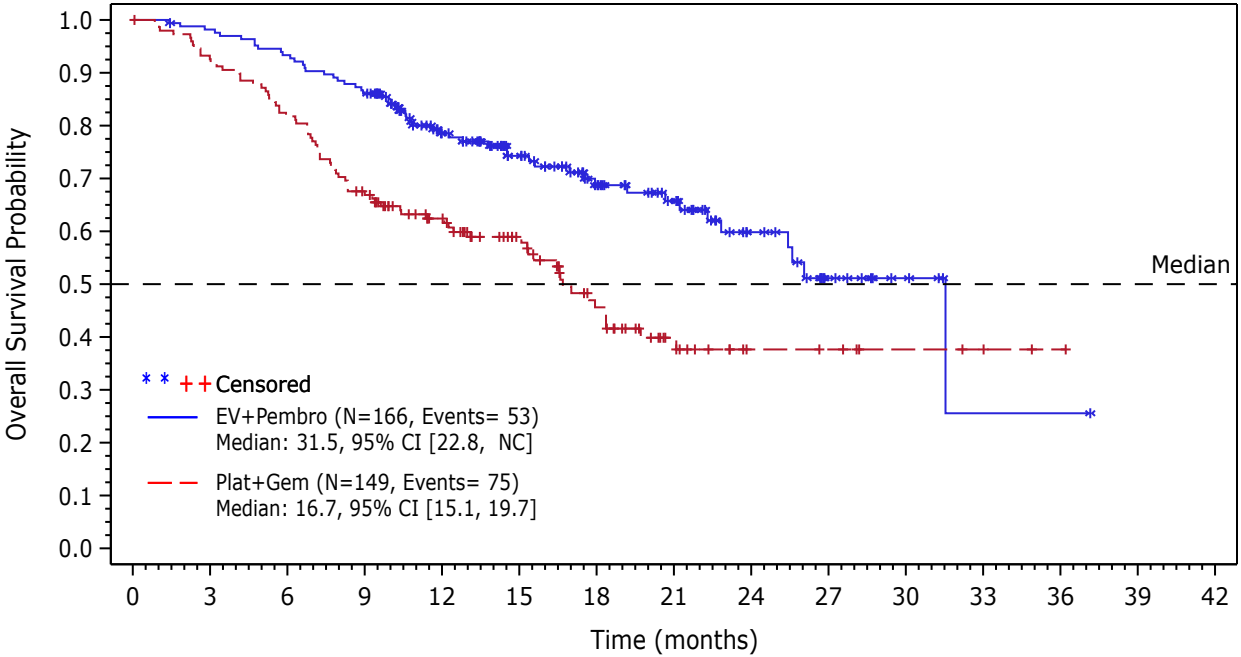
at Risk

1	198	194	183	170	126	94	63	42	20	8	3	0	0	0	0
2	185	172	154	132	101	75	48	30	15	10	6	3	1	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.1.6: Kaplan-Meier Plot of Overall Survival by Race - Analysis Set mITT 1
Race: White



at Risk

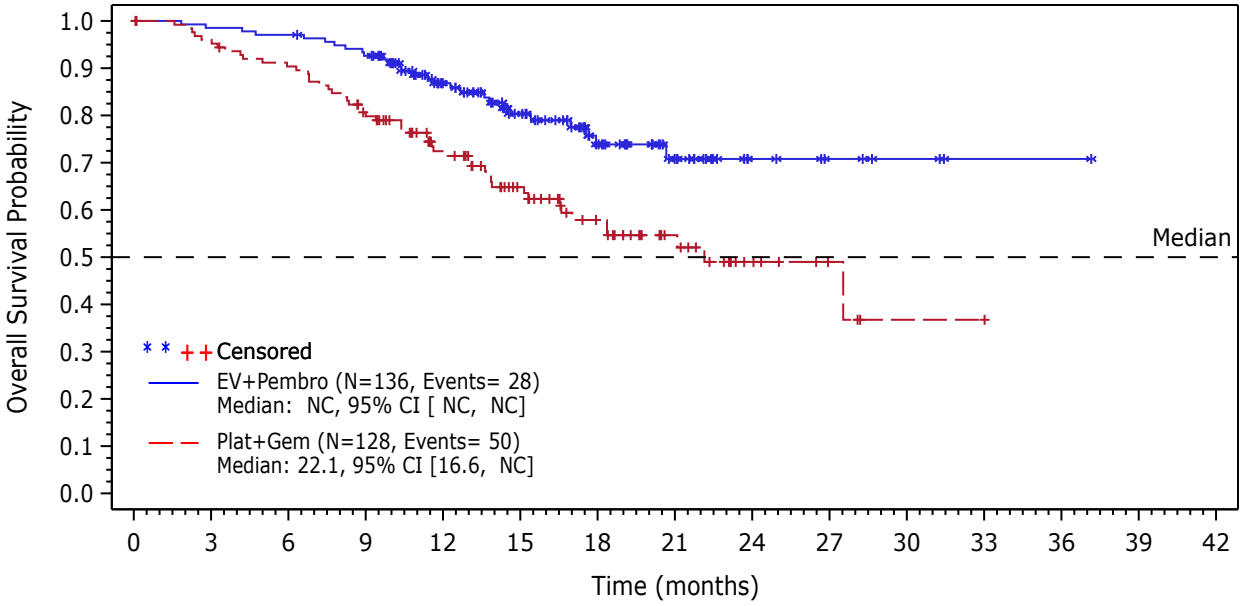
1	166	162	154	142	103	77	55	41	23	11	5	1	1	0	0
2	149	137	121	98	75	54	34	18	8	7	4	3	1	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.1.7: Kaplan-Meier Plot of Overall Survival by ECOG Status at Baseline - Analysis Set mITT 1

ECOG Status at Baseline: 0



at Risk

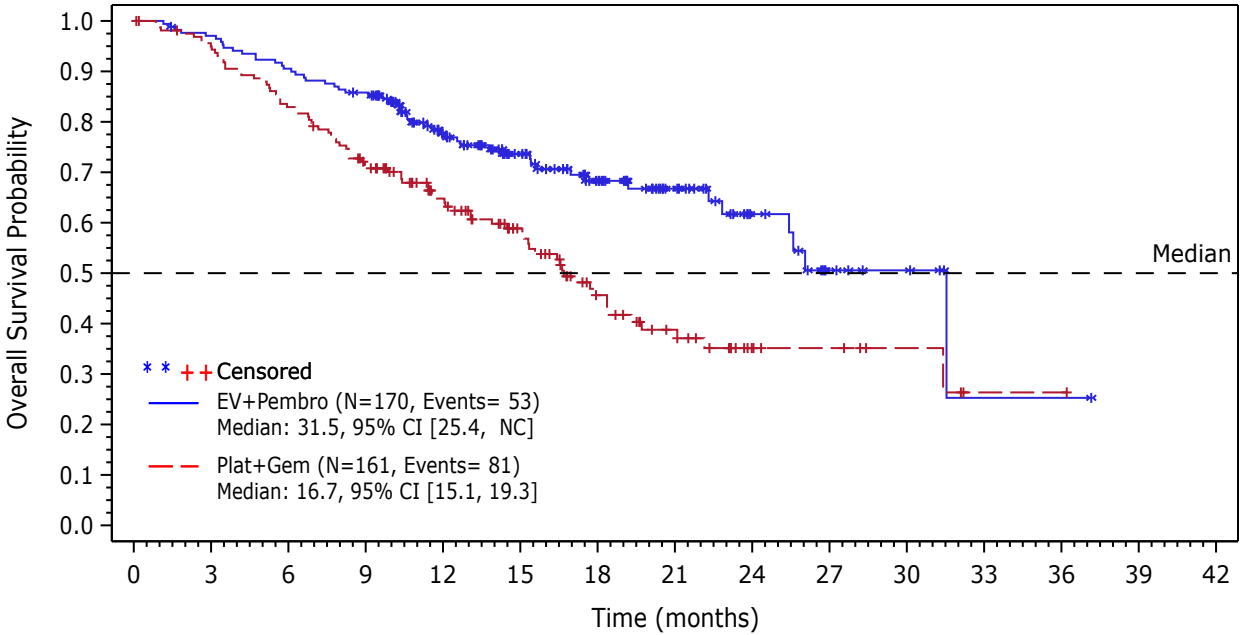
1	136	134	132	125	90	64	39	21	8	5	3	1	1	0	0
2	128	120	112	97	72	52	36	21	9	4	1	1	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.1.8: Kaplan-Meier Plot of Overall Survival by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Visceral metastases



at Risk

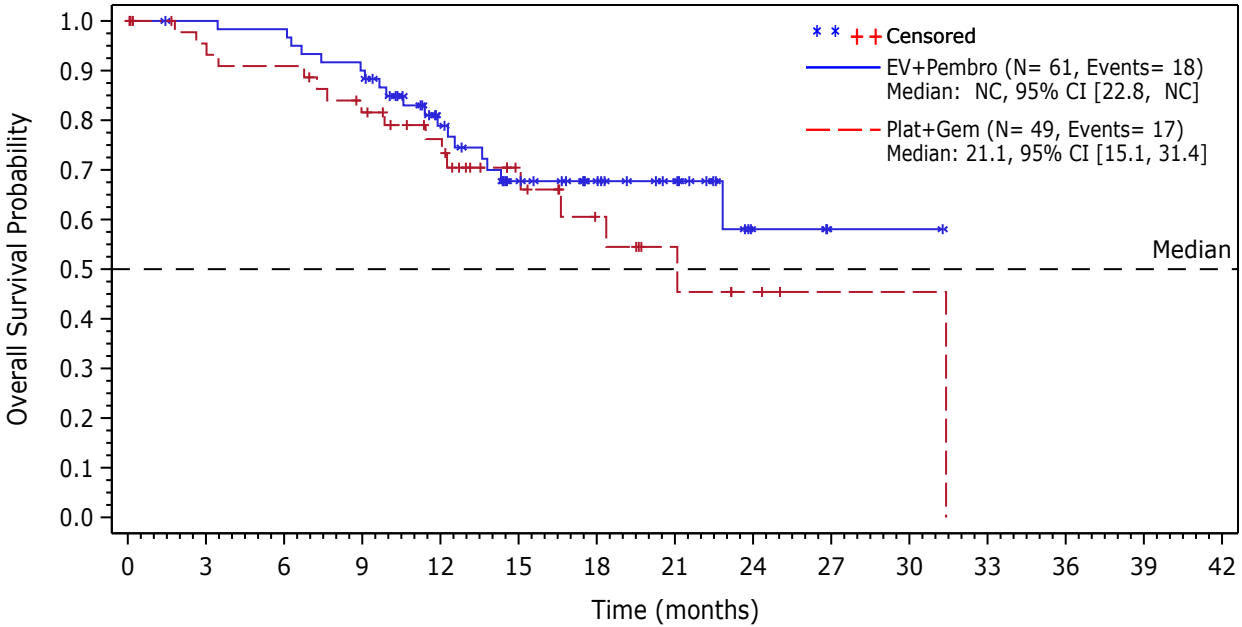
1	170	164	153	144	102	78	54	34	18	8	5	1	1	0	0
2	161	150	131	109	81	58	35	23	9	7	4	1	1	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.1.9: Kaplan-Meier Plot of Overall Survival by Primary Disease Site of Origin - Analysis Set mITT 1

Primary Disease Site of Origin: Upper tract



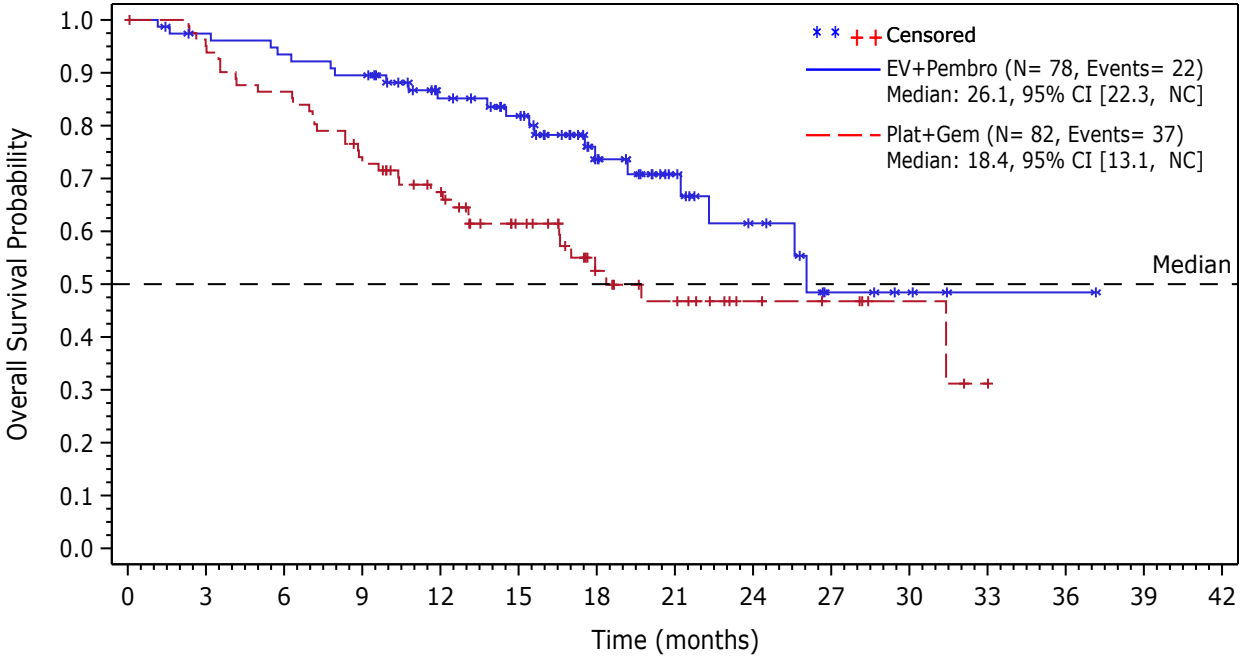
at Risk

1	61	60	59	54	37	26	19	13	3	1	1	0	0	0	0
2	49	42	40	34	27	16	10	6	3	1	1	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.1.10: Kaplan-Meier Plot of Overall Survival by Renal Function - Analysis Set mITT 1
Renal Function: Normal



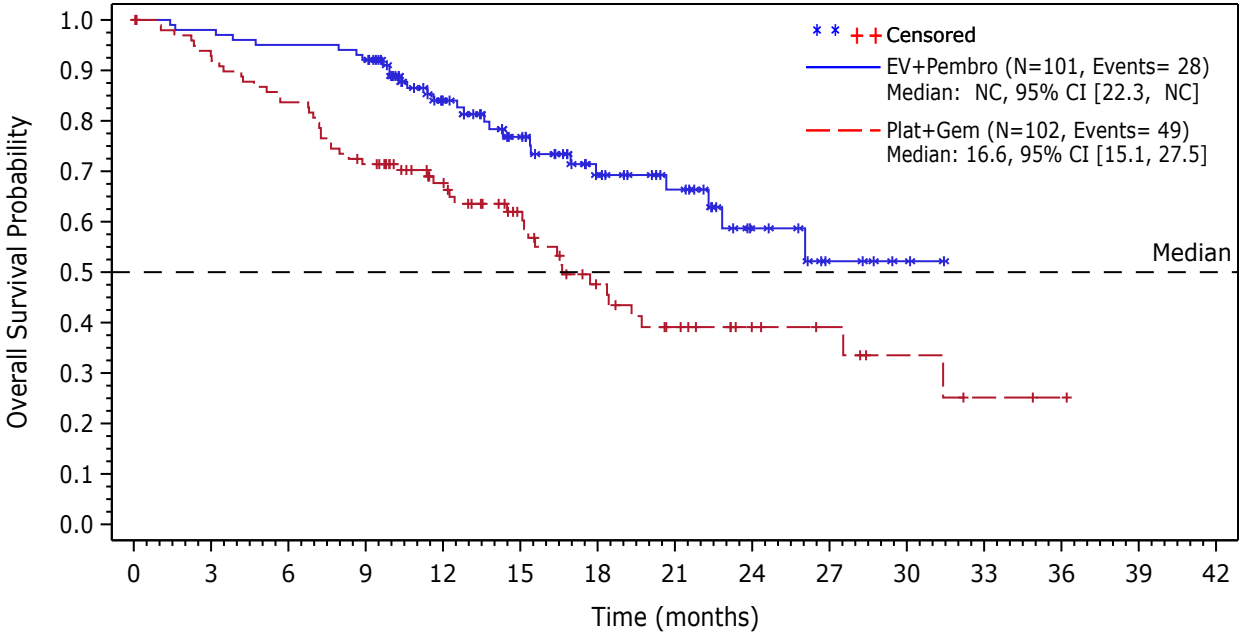
at Risk

1	78	74	71	68	55	48	30	18	11	5	3	1	1	0	0
2	82	77	70	59	48	34	20	15	8	6	3	1	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.1.1: Kaplan-Meier Plot of Overall Survival by PD-L1 Expression - Analysis Set mITT 1 PD-L1 Expression: Low (CPS<10)



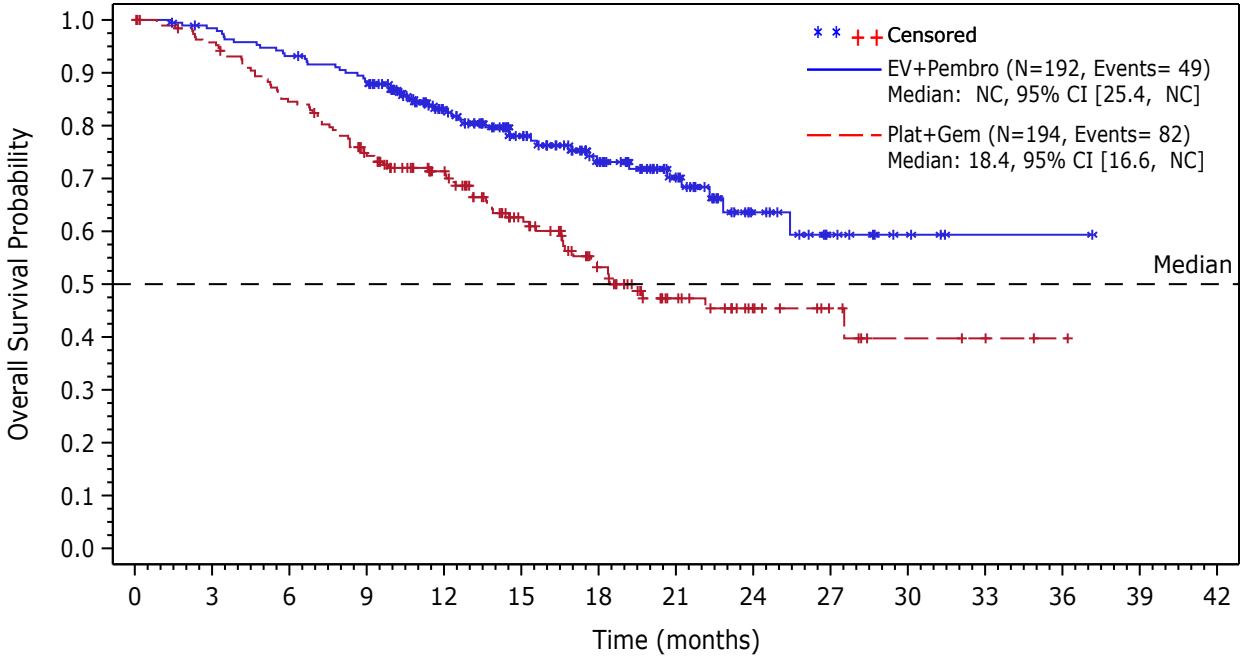
at Risk

1	101	99	96	93	63	48	31	23	11	5	2	0	0	0	0
2	102	91	82	69	51	36	23	16	9	7	4	2	1	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.1.2: Kaplan-Meier Plot of Overall Survival by Liver Metastases - Analysis Set mITT 1
Liver Metastases: Absent



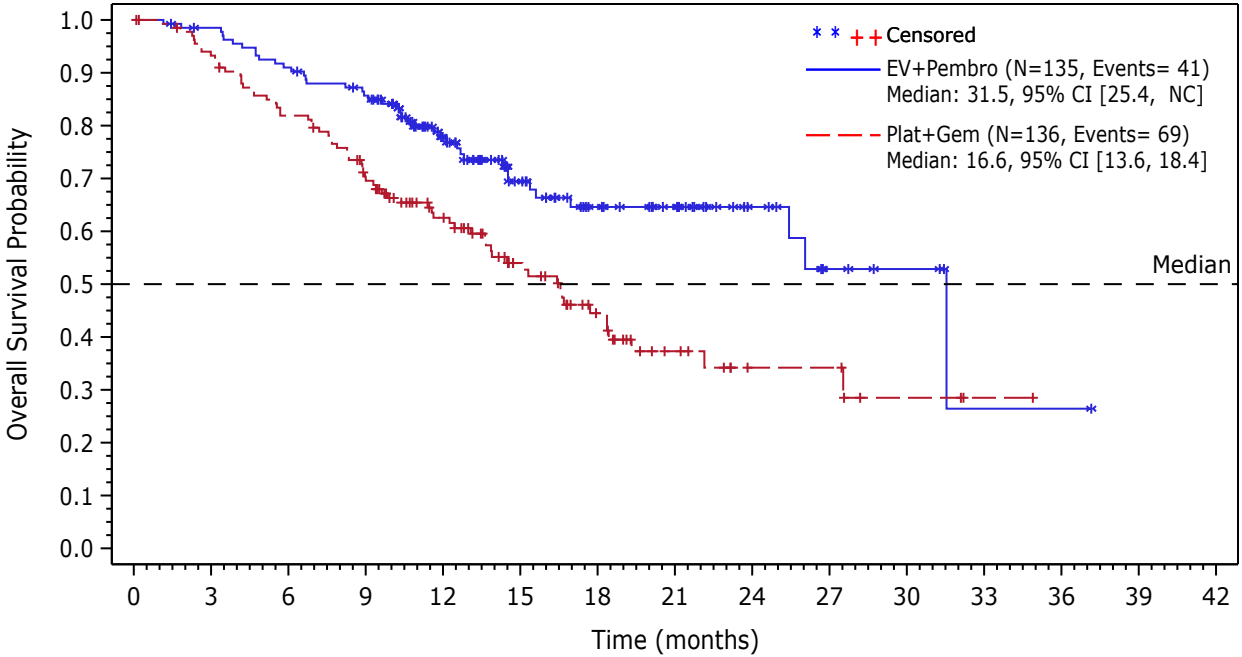
at Risk

1	192	187	177	167	124	92	66	41	18	9	4	1	1	0	0
2	194	180	158	135	106	74	50	28	15	9	4	3	1	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.1.3: Kaplan-Meier Plot of Overall Survival by Age - Analysis Set mITT 1
Age: >= 65 years



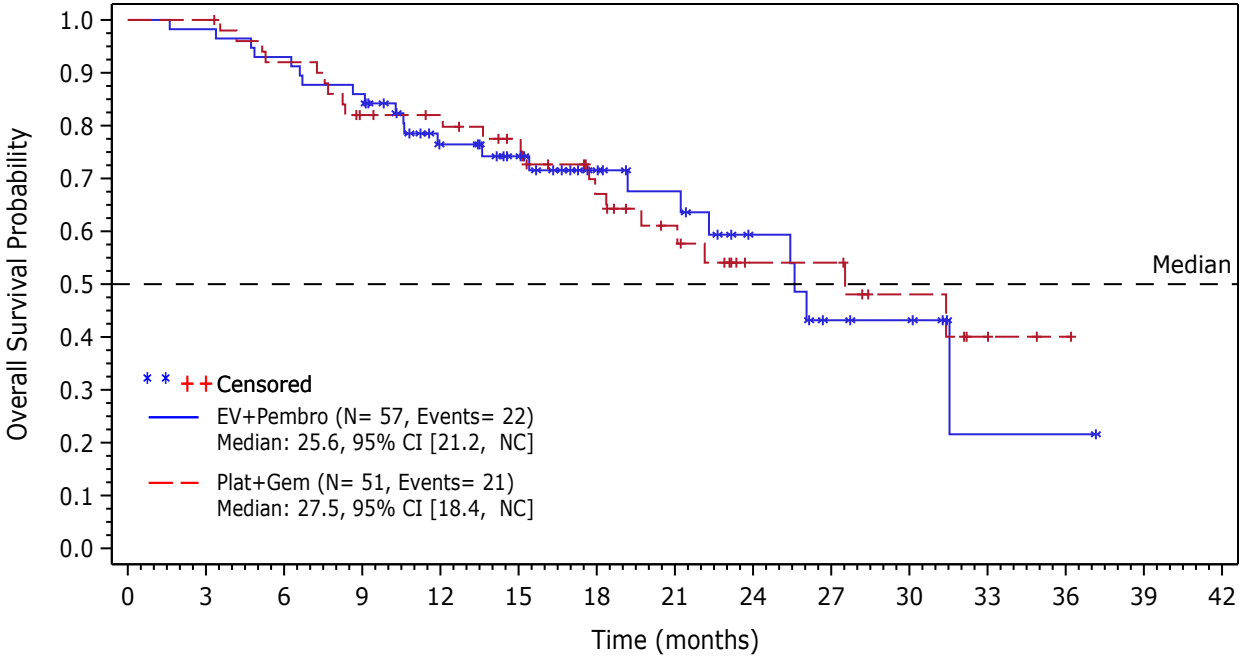
at Risk

1	135	131	121	112	75	48	33	25	13	6	4	1	1	0	0
2	136	124	108	89	65	43	27	14	7	7	3	1	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.1.4: Kaplan-Meier Plot of Overall Survival by Region - Analysis Set mITT 1
Region: North America



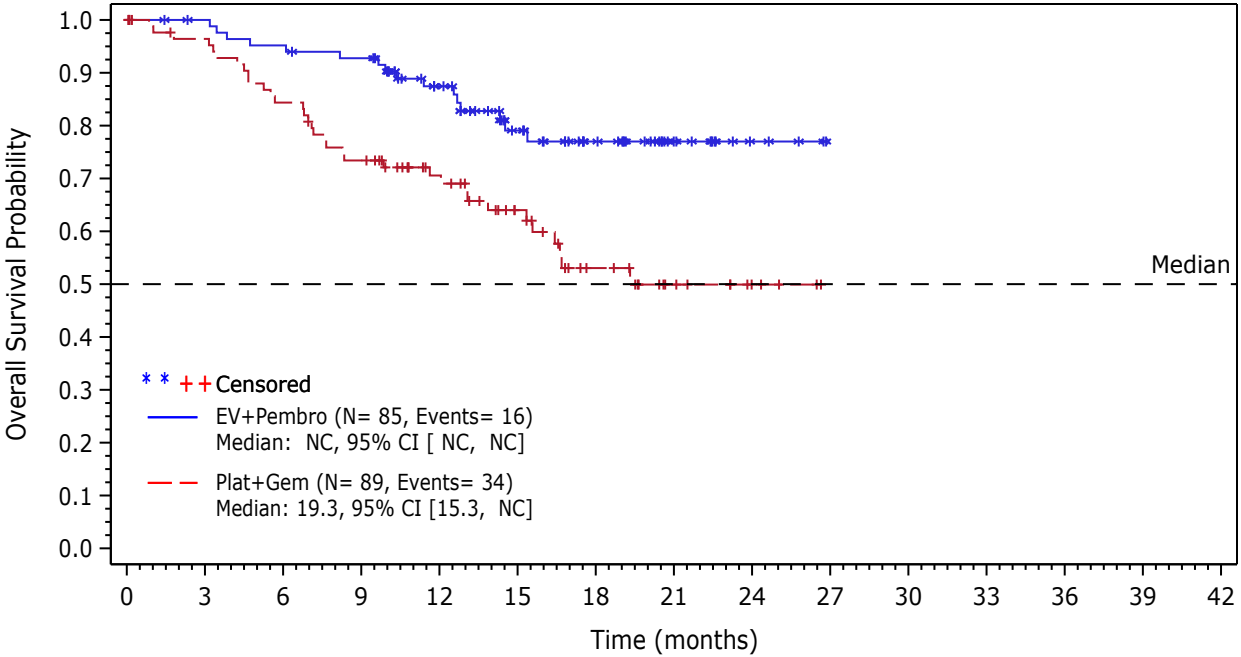
at Risk

1	57	56	53	49	36	30	21	17	11	6	5	1	1	0	0
2	51	51	46	39	37	32	24	18	10	10	6	3	1	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.1.4: Kaplan-Meier Plot of Overall Survival by Region - Analysis Set mITT 1
Region: Rest of World



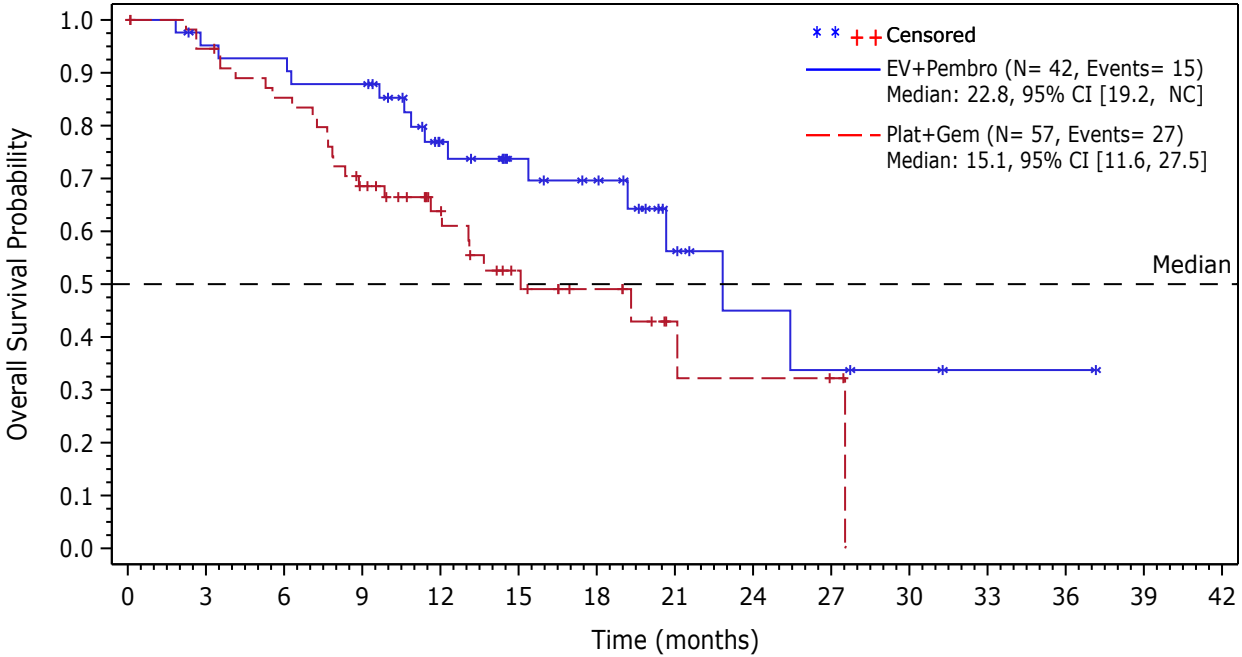
at Risk

1	85	83	79	76	58	40	28	13	4	0	0	0	0	0	0
2	89	80	70	60	46	32	19	10	4	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.1.5: Kaplan-Meier Plot of Overall Survival by Sex - Analysis Set mITT 1
Sex: Female



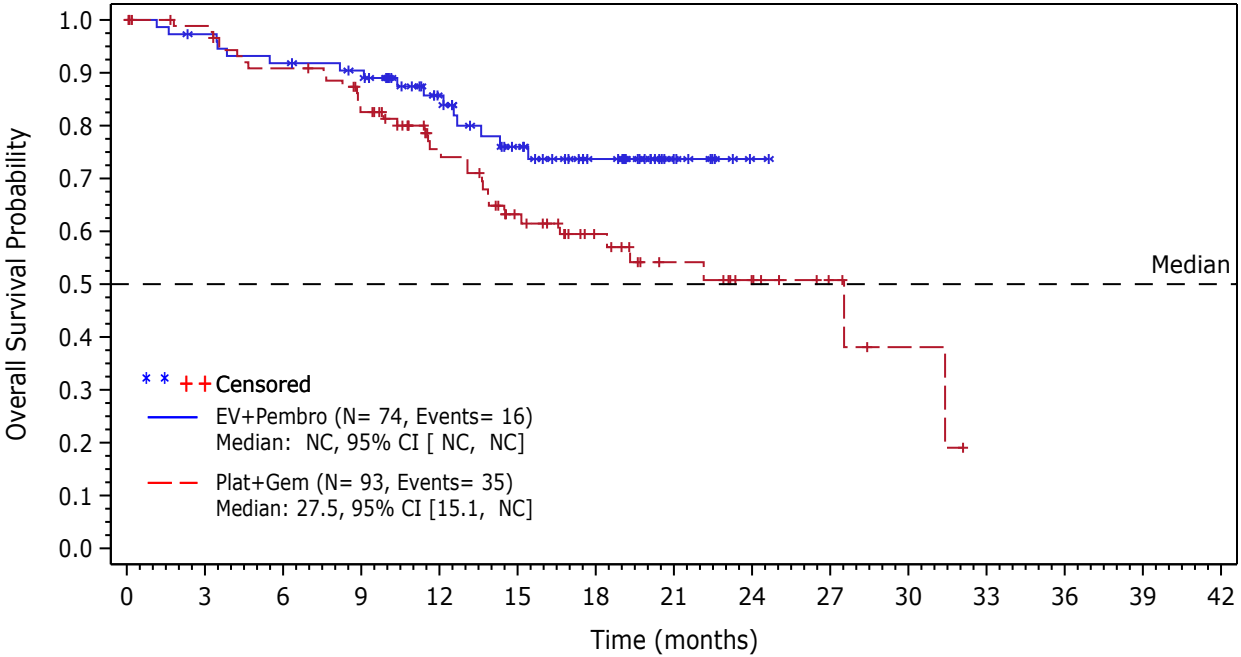
at Risk

1	42	39	38	36	24	18	15	7	4	3	2	1	1	0	0
2	57	52	46	35	24	15	10	4	3	2	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.1.6: Kaplan-Meier Plot of Overall Survival by Race - Analysis Set mITT 1
Race: Non-white



at Risk

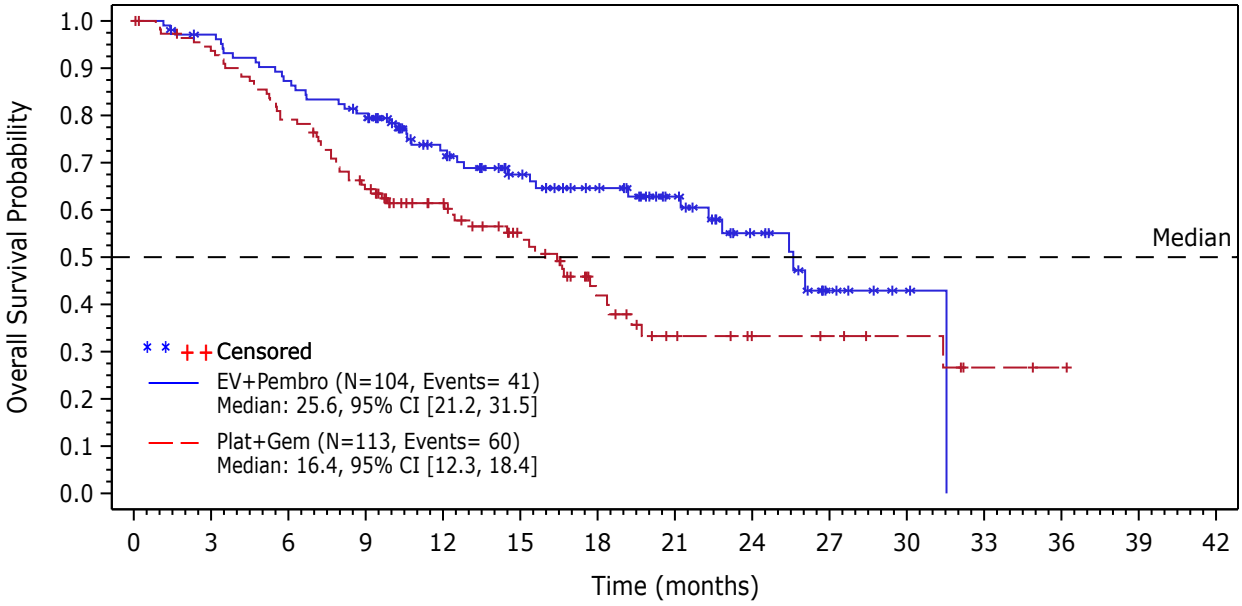
1	74	71	67	64	47	35	23	8	1	0	0	0	0	0	0
2	93	87	79	69	50	36	24	16	10	5	2	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.1.7: Kaplan-Meier Plot of Overall Survival by ECOG Status at Baseline - Analysis Set mITT 1

ECOG Status at Baseline: 1-2



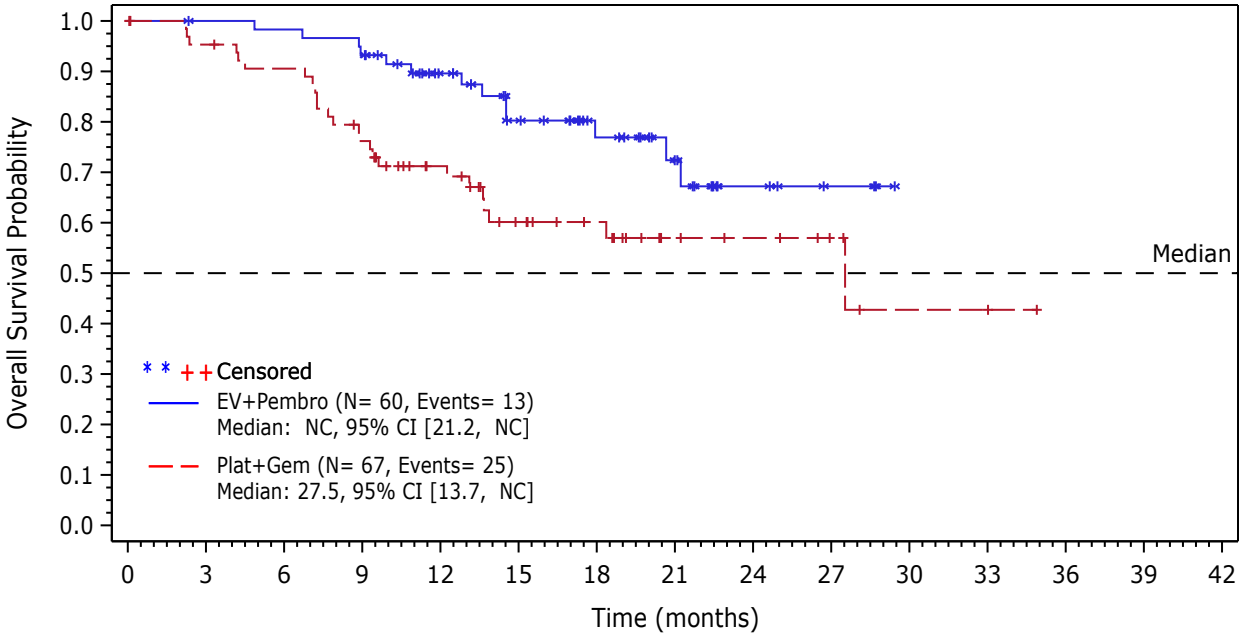
at Risk

1	104	99	89	81	60	48	39	28	16	6	2	0	0	0	0
2	113	103	87	69	52	37	21	12	8	7	5	2	1	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.1.8: Kaplan-Meier Plot of Overall Survival by Metastases at Baseline - Analysis Set mITT 1
Metastases at Baseline: Lymph node only



at Risk

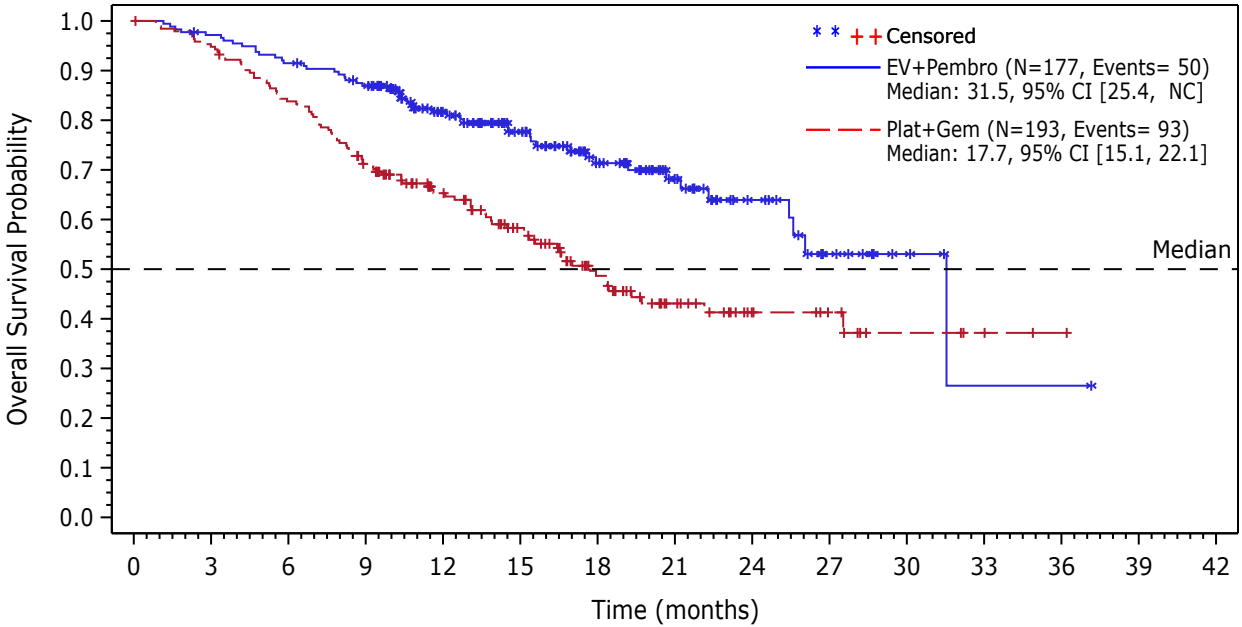
1	60	59	58	55	43	32	23	15	6	3	0	0	0	0	0
2	67	61	57	47	35	24	19	10	8	5	2	2	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.1.9: Kaplan-Meier Plot of Overall Survival by Primary Disease Site of Origin - Analysis Set mITT 1

Primary Disease Site of Origin: Lower tract



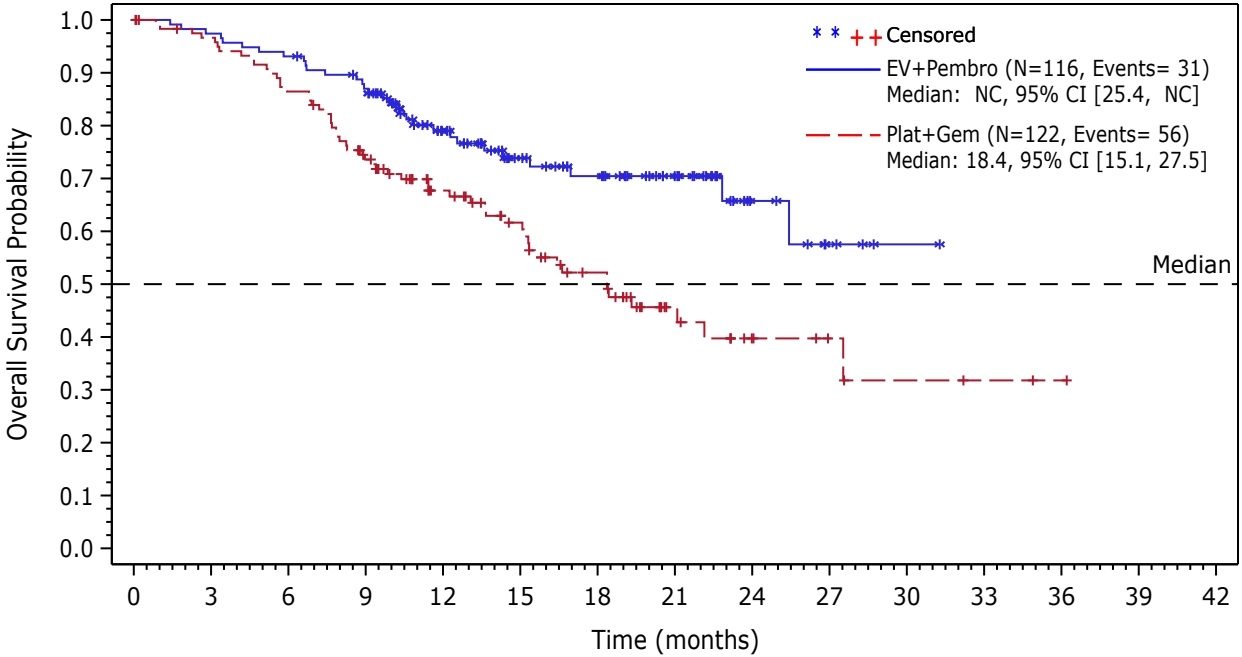
at Risk

1	177	171	161	151	112	85	59	36	21	10	4	1	1	0	0
2	193	182	160	133	98	74	48	28	15	11	5	3	1	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.1.10: Kaplan-Meier Plot of Overall Survival by Renal Function - Analysis Set mITT 1
Renal Function: Mild



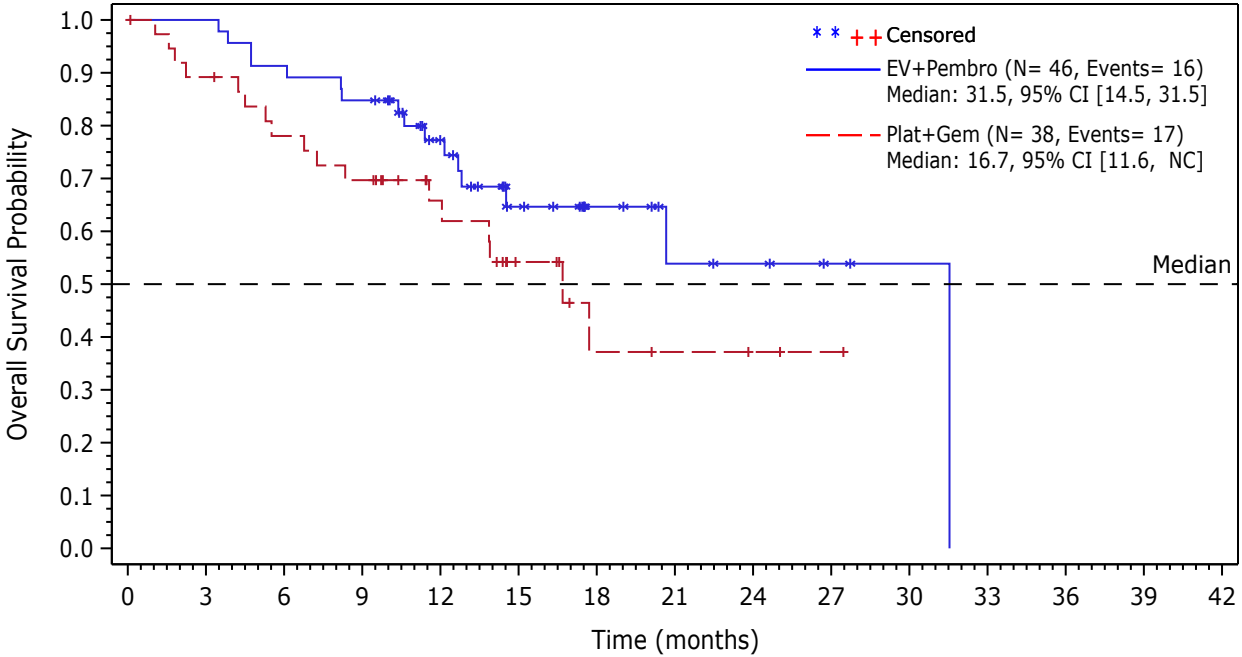
at Risk

1	116	113	108	99	68	48	39	26	9	4	1	0	0	0	0
2	122	114	102	83	60	47	34	16	8	5	3	2	1	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.1.10: Kaplan-Meier Plot of Overall Survival by Renal Function - Analysis Set mITT 1
Renal Function: Moderate



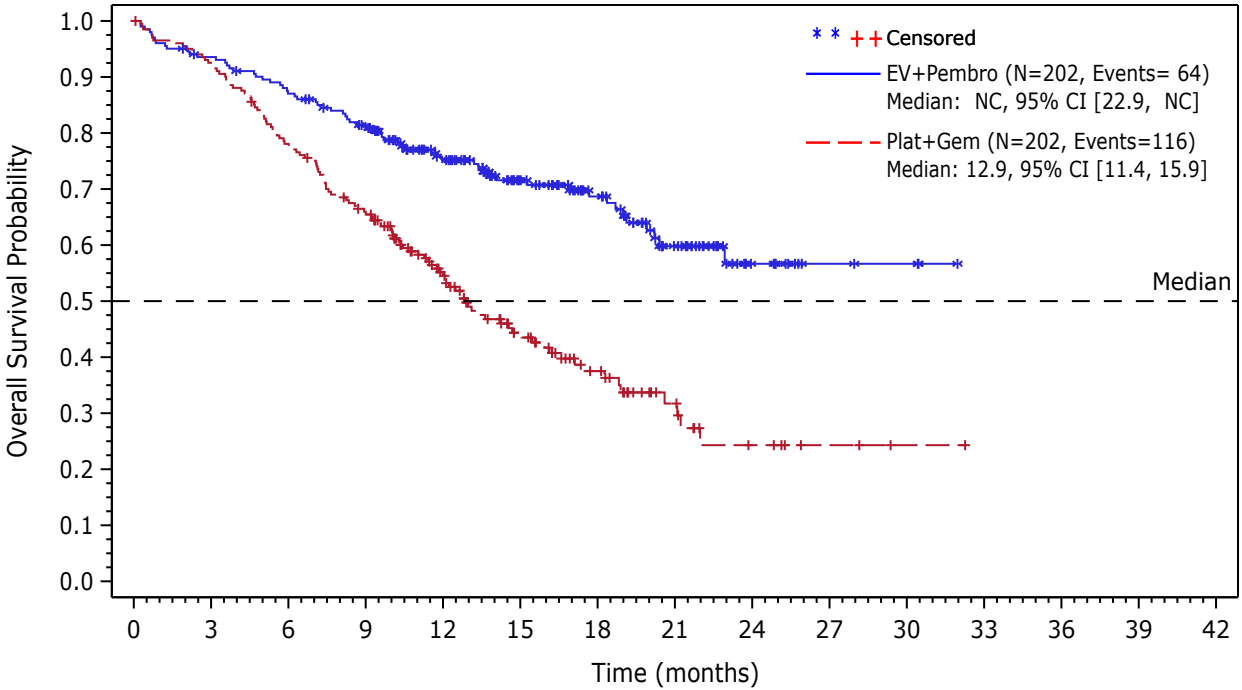
at Risk

1	46	46	42	39	27	16	9	5	4	2	1	0	0	0	0
2	38	33	28	25	17	9	4	3	2	1	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.2: Kaplan-Meier Plot of Overall Survival - Analysis Set mITT 2



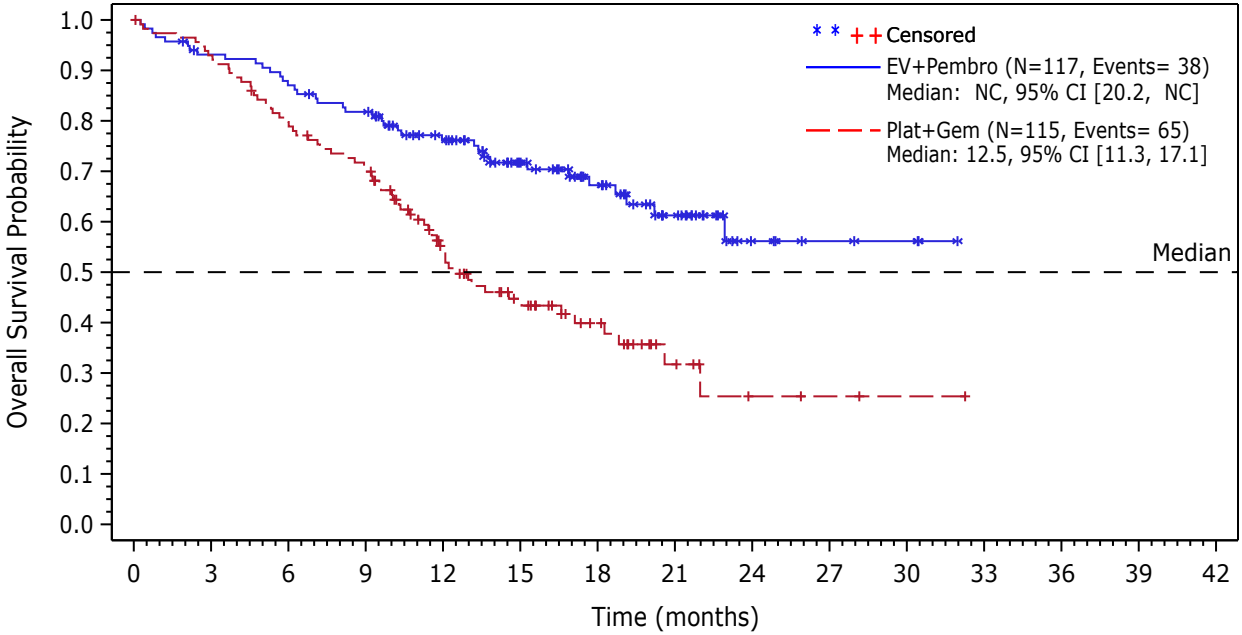
at Risk

1	202	187	173	157	120	86	63	36	12	4	3	0	0	0	0
2	202	186	156	129	84	52	32	16	7	3	1	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.2.1: Kaplan-Meier Plot of Overall Survival by PD-L1 Expression - Analysis Set mITT 2 PD-L1 Expression: High (CPS>=10)



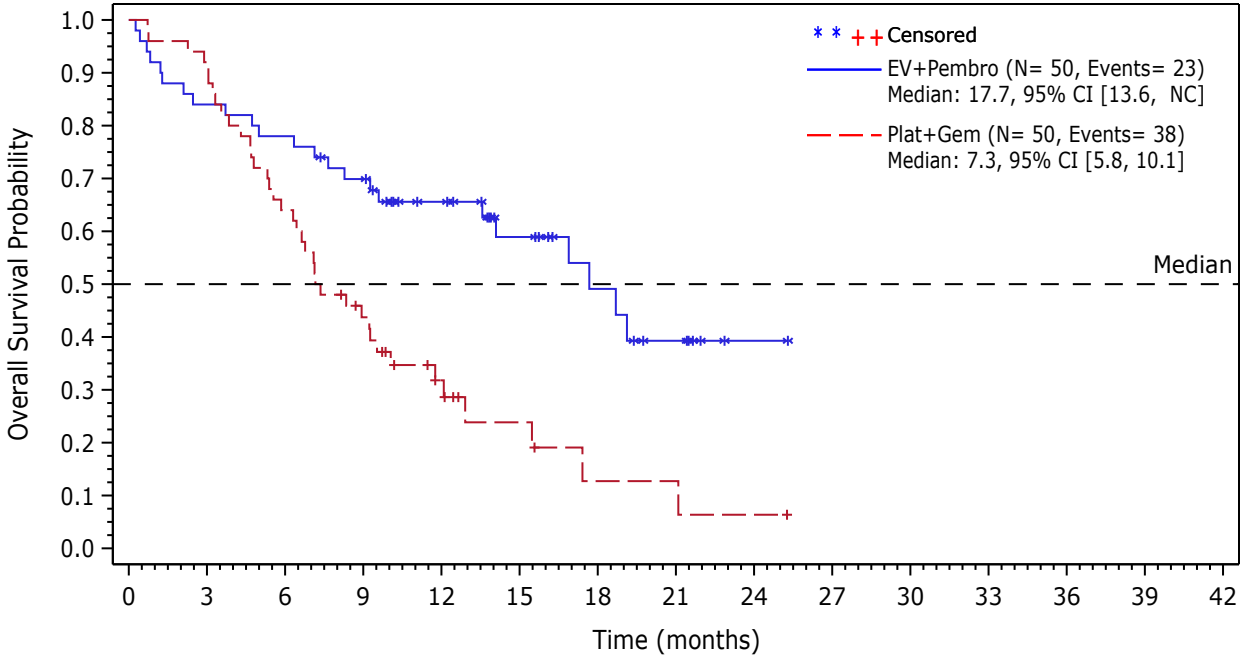
at Risk

1	117	107	100	93	76	56	40	24	7	4	3	0	0	0	0
2	115	106	90	79	49	33	20	8	3	2	1	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.2.2: Kaplan-Meier Plot of Overall Survival by Liver Metastases - Analysis Set mITT 2
Liver Metastases: Present



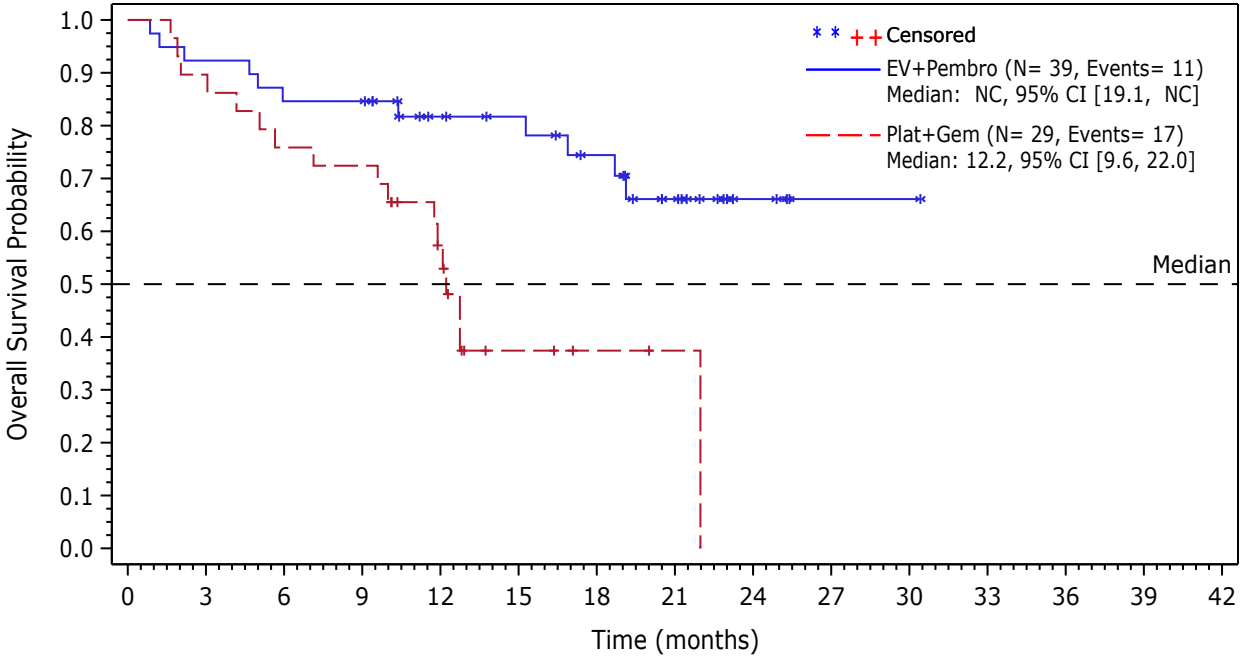
at Risk

1	50	42	39	34	25	16	10	6	1	0	0	0	0	0	0
2	50	46	32	20	10	5	2	2	1	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.2.3: Kaplan-Meier Plot of Overall Survival by Age - Analysis Set mITT 2
Age: < 65 years



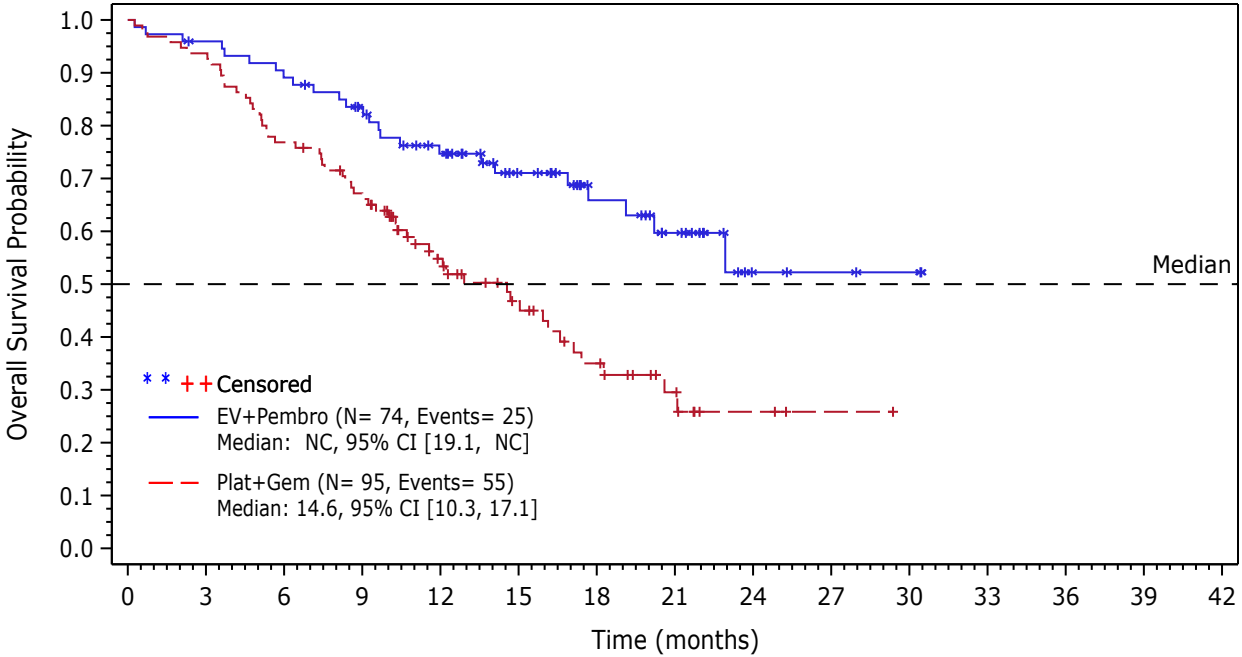
at Risk

1	39	36	33	33	25	23	19	12	4	1	1	0	0	0	0
2	29	26	22	21	13	4	2	1	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.2.4: Kaplan-Meier Plot of Overall Survival by Region - Analysis Set mITT 2
Region: Europe



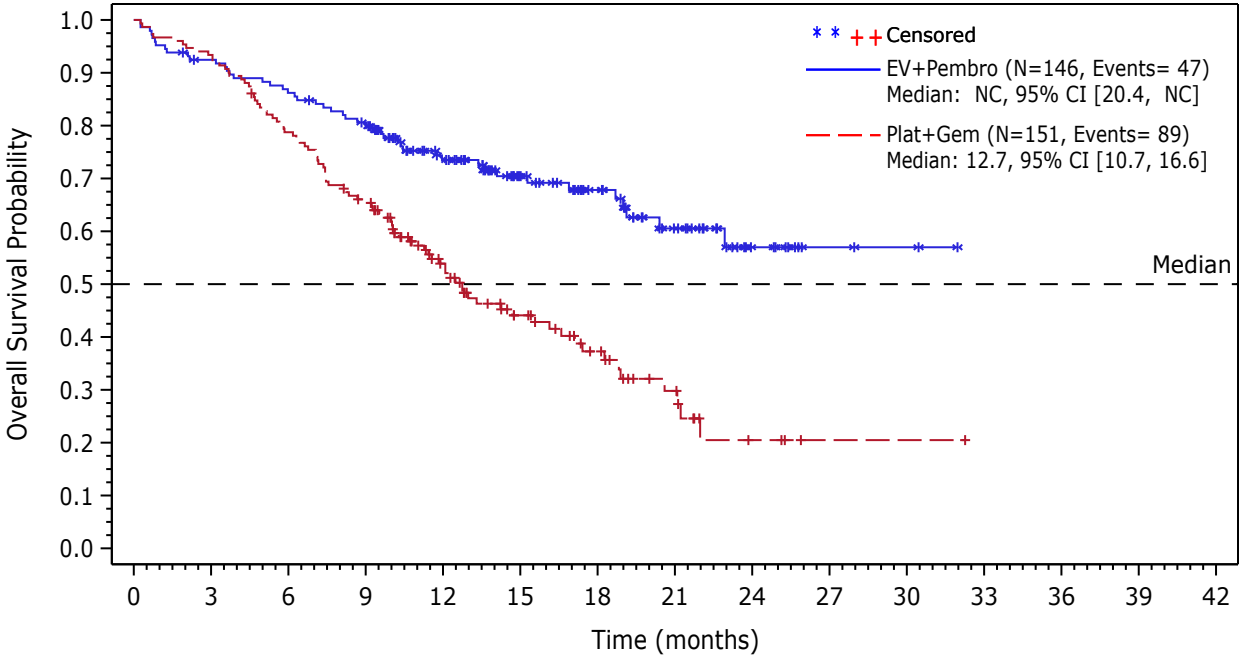
at Risk

1	74	70	65	58	48	35	23	15	4	3	2	0	0	0	0
2	95	89	73	62	38	26	17	9	3	1	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.2.5: Kaplan-Meier Plot of Overall Survival by Sex - Analysis Set mITT 2
Sex: Male



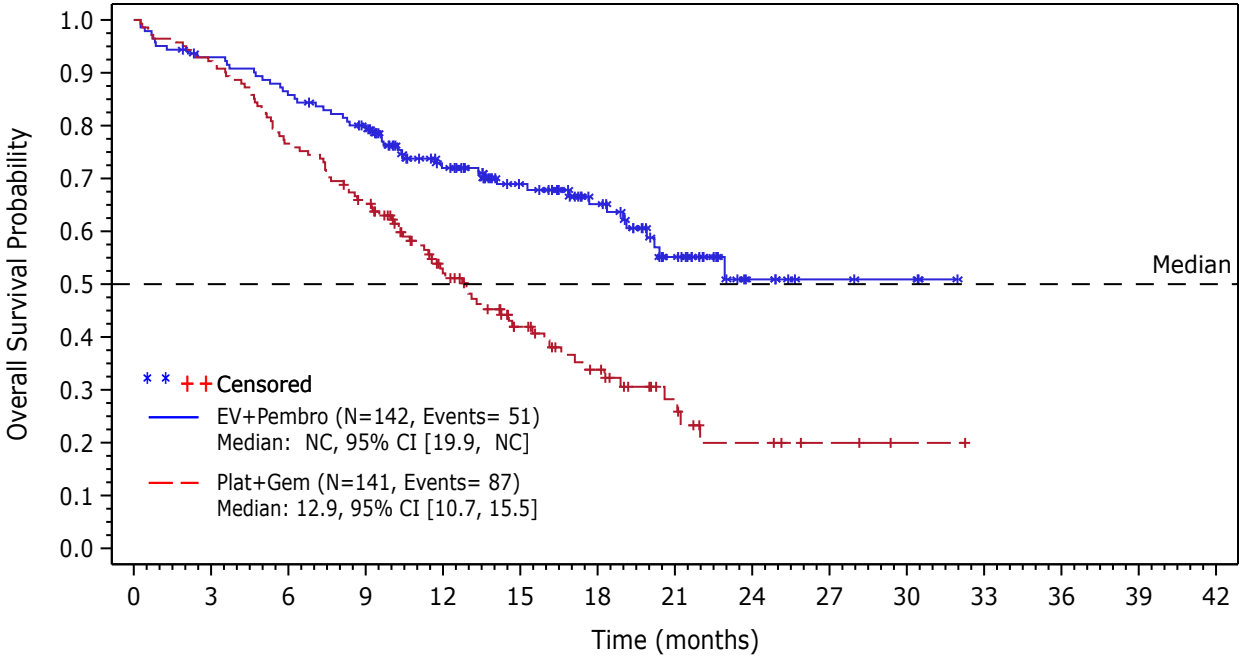
at Risk

1	146	133	124	114	84	58	43	26	10	3	2	0	0	0	0
2	151	141	118	96	60	37	24	13	4	1	1	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.2.6: Kaplan-Meier Plot of Overall Survival by Race - Analysis Set mITT 2
Race: White



at Risk

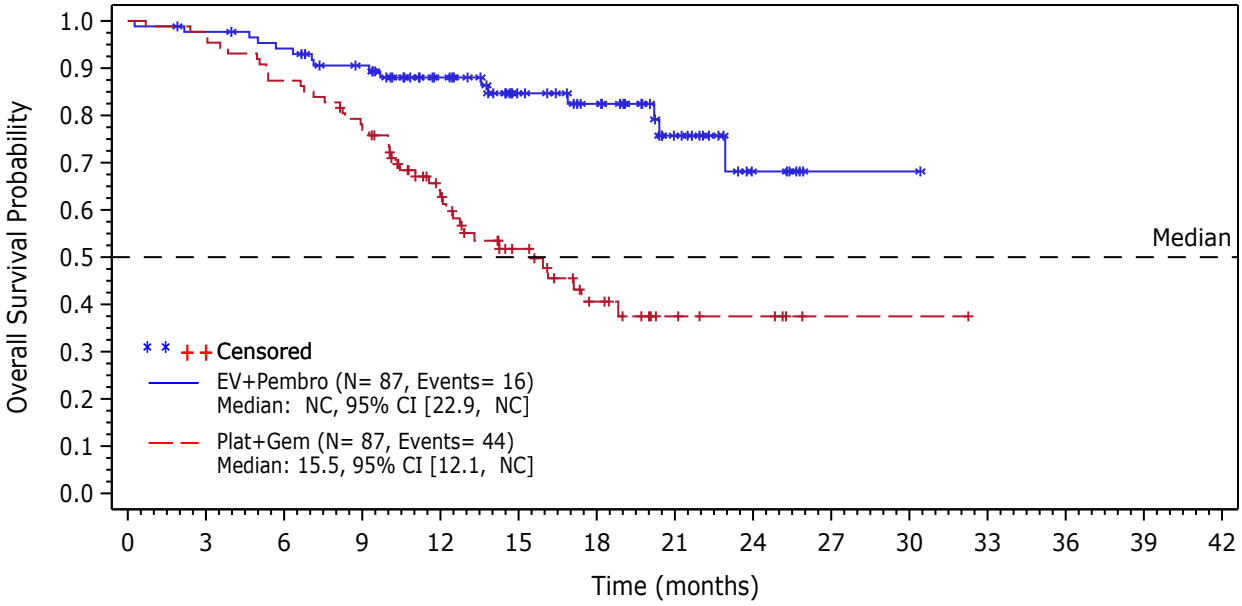
1	142	130	120	109	81	61	46	25	8	4	3	0	0	0	0
2	141	130	108	91	57	35	23	12	6	3	1	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.2.7: Kaplan-Meier Plot of Overall Survival by ECOG Status at Baseline - Analysis Set mITT 2

ECOG Status at Baseline: 0



at Risk

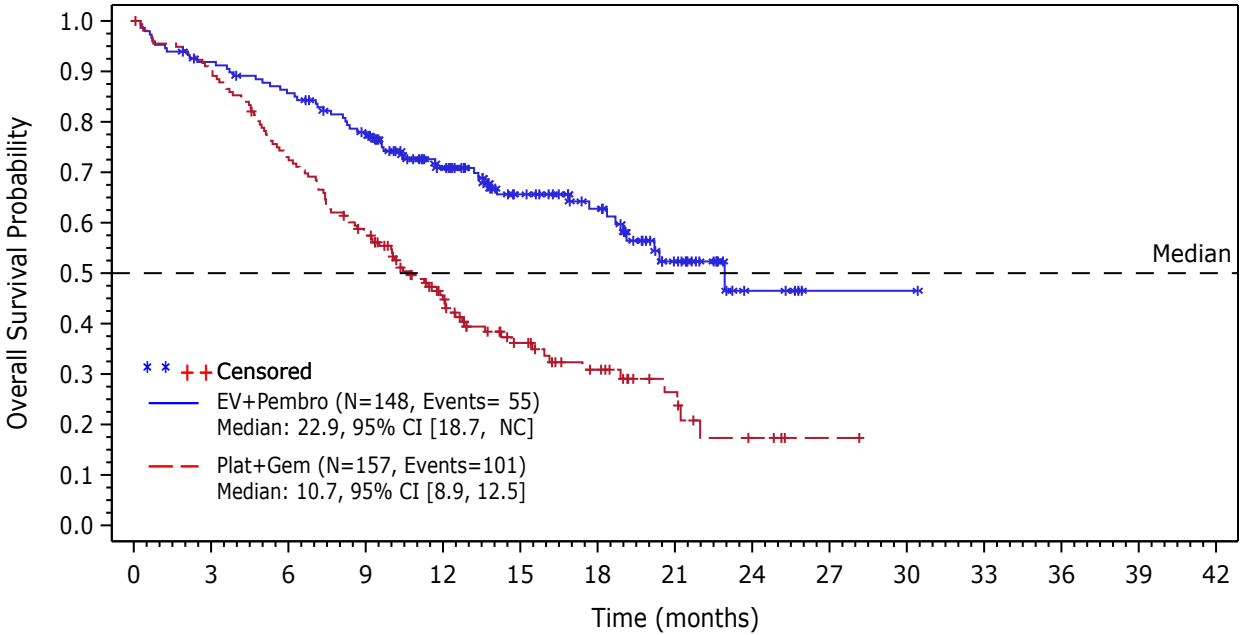
1	87	84	80	73	58	42	34	18	6	1	1	0	0	0	0
2	87	85	76	67	43	27	15	7	5	1	1	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.2.8: Kaplan-Meier Plot of Overall Survival by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Visceral metastases



at Risk

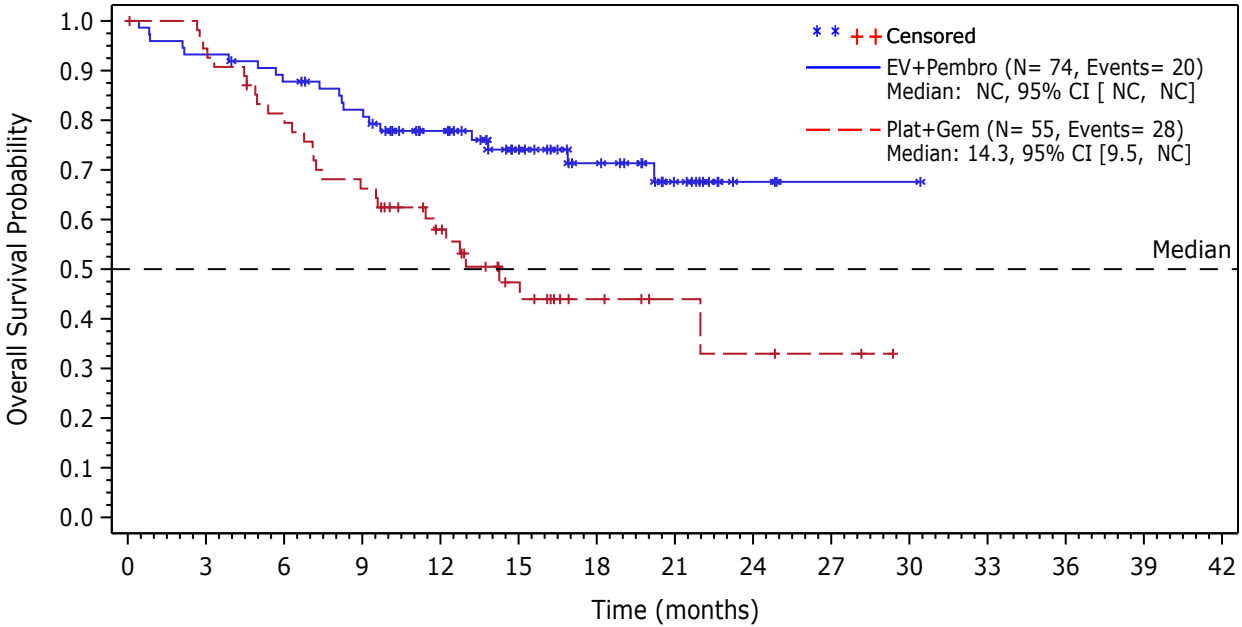
1	148	134	124	109	80	55	43	22	5	1	1	0	0	0	0
2	157	141	113	88	53	31	20	10	4	1	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.2.9: Kaplan-Meier Plot of Overall Survival by Primary Disease Site of Origin - Analysis Set mITT 2

Primary Disease Site of Origin: Upper tract



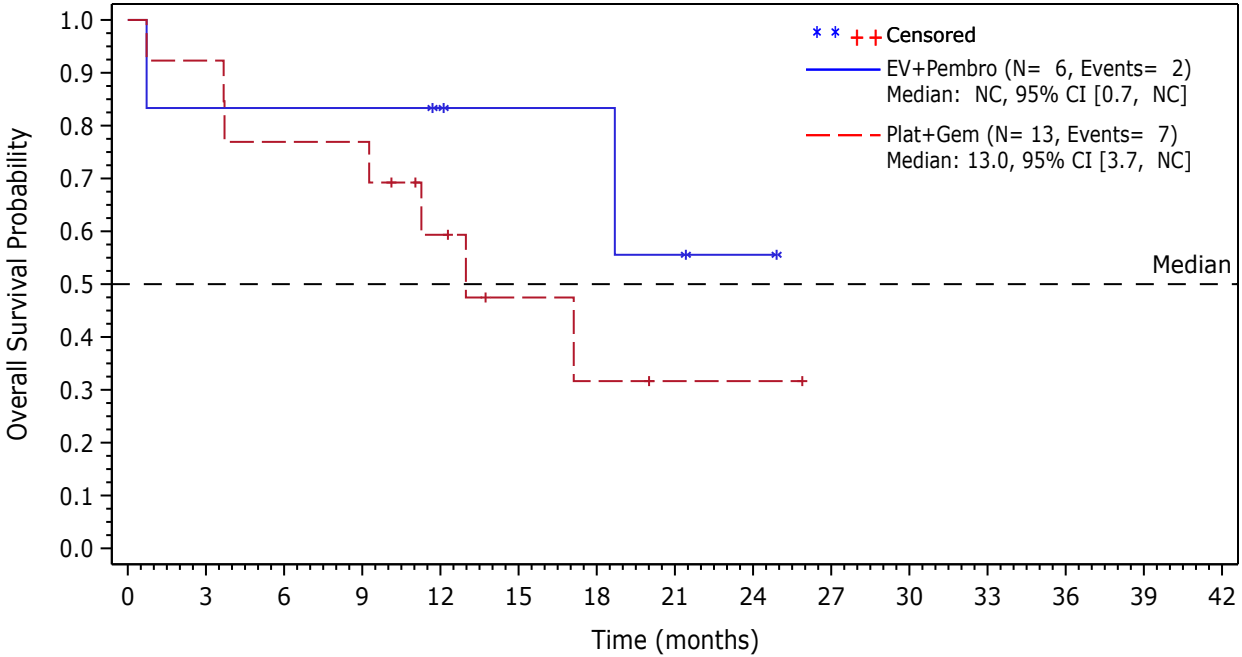
at Risk

1	74	69	64	58	47	34	24	12	3	1	1	0	0	0	0
2	55	51	43	35	25	14	7	4	3	2	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.2.10: Kaplan-Meier Plot of Overall Survival by Renal Function - Analysis Set mITT 2
Renal Function: Normal



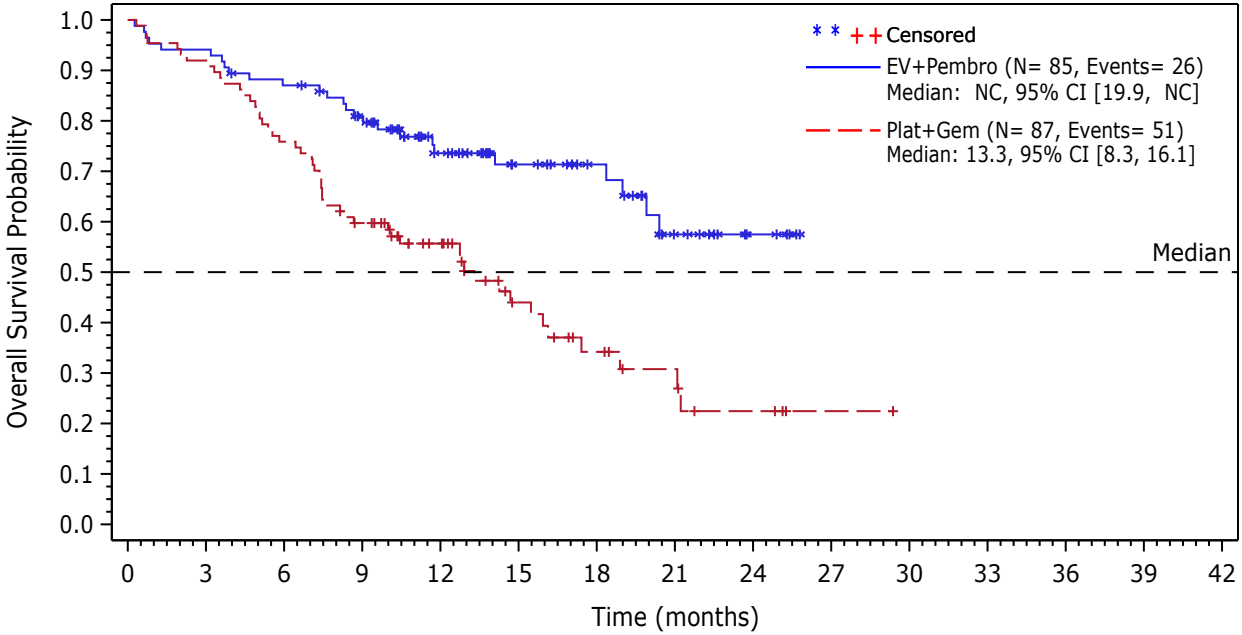
at Risk

1	6	5	5	5	4	3	3	2	1	0	0	0	0	0	0
2	13	12	10	10	6	3	2	1	1	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.2.1: Kaplan-Meier Plot of Overall Survival by PD-L1 Expression - Analysis Set mITT 2 PD-L1 Expression: Low (CPS<10)



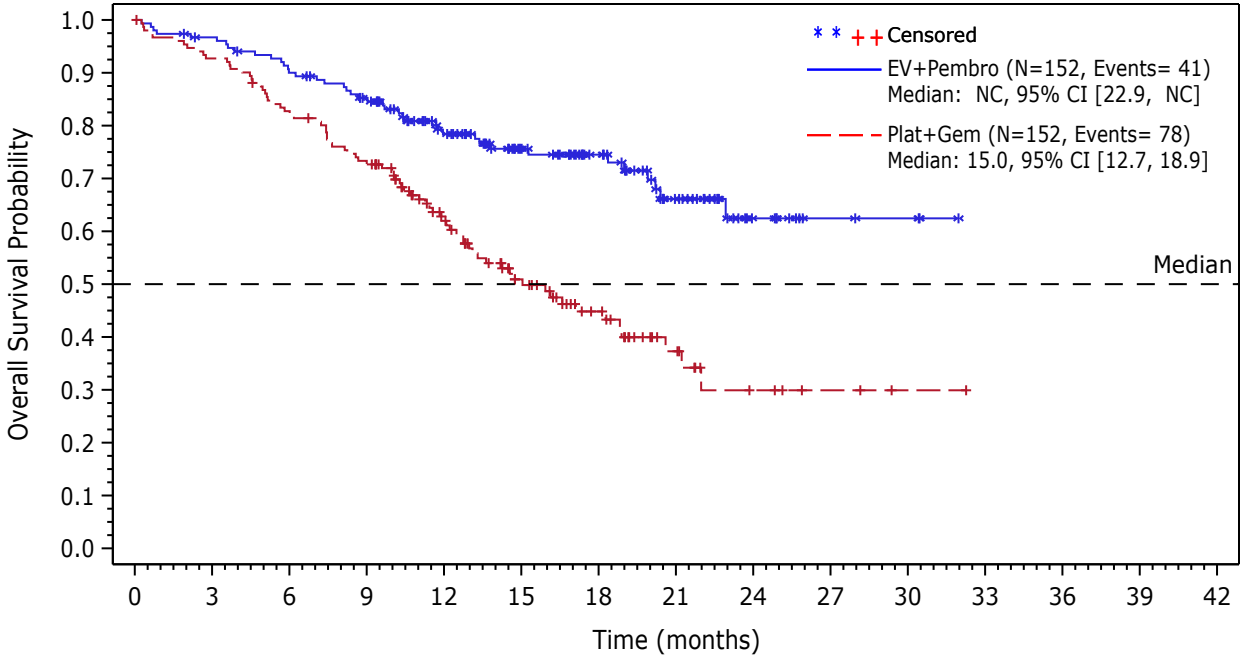
at Risk

1	85	80	73	64	44	30	23	12	5	0	0	0	0	0	0
2	87	80	66	50	35	19	12	8	4	1	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.2.2: Kaplan-Meier Plot of Overall Survival by Liver Metastases - Analysis Set mITT 2
Liver Metastases: Absent



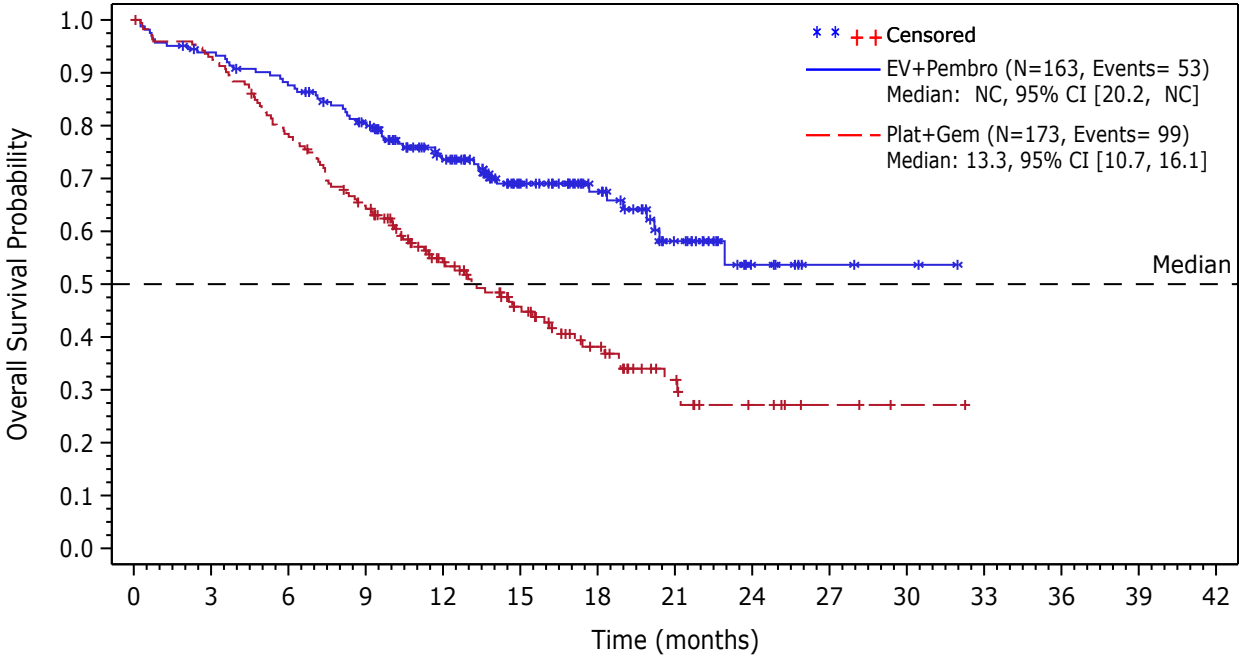
at Risk

1	152	145	134	123	95	70	53	30	11	4	3	0	0	0	0
2	152	140	124	109	74	47	30	14	6	3	1	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.2.3: Kaplan-Meier Plot of Overall Survival by Age - Analysis Set mITT 2
Age: >= 65 years



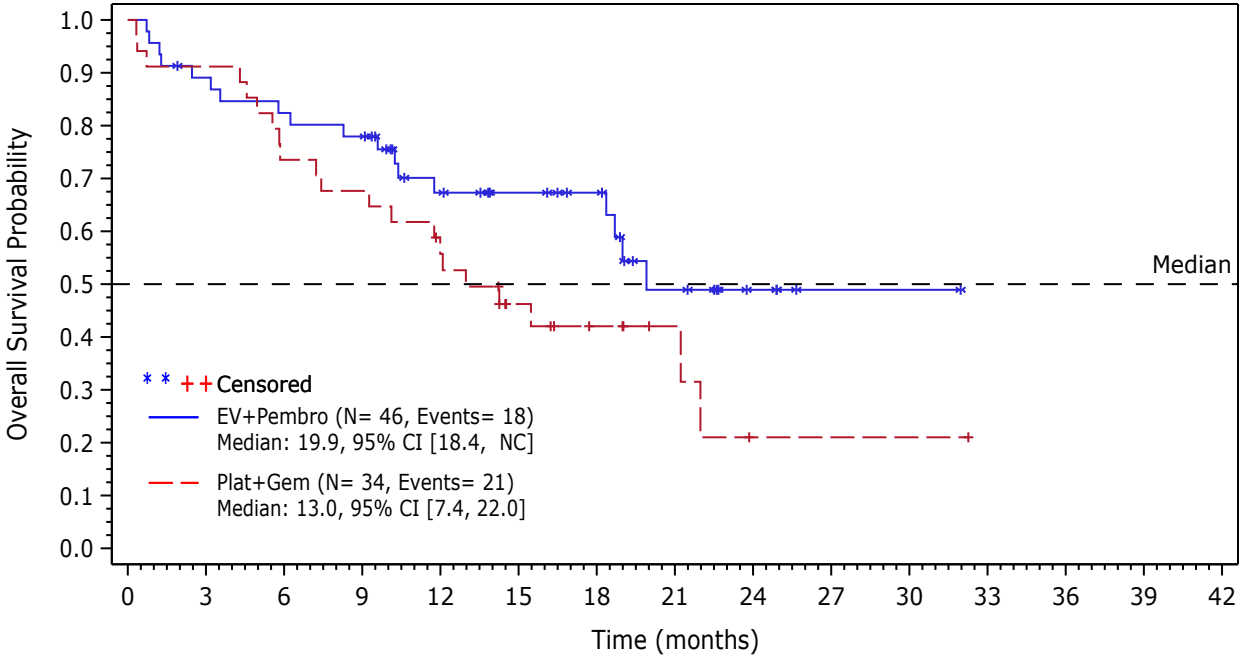
at Risk

1	163	151	140	124	95	63	44	24	8	3	2	0	0	0	0
2	173	160	134	108	71	48	30	15	7	3	1	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.2.4: Kaplan-Meier Plot of Overall Survival by Region - Analysis Set mITT 2
Region: North America



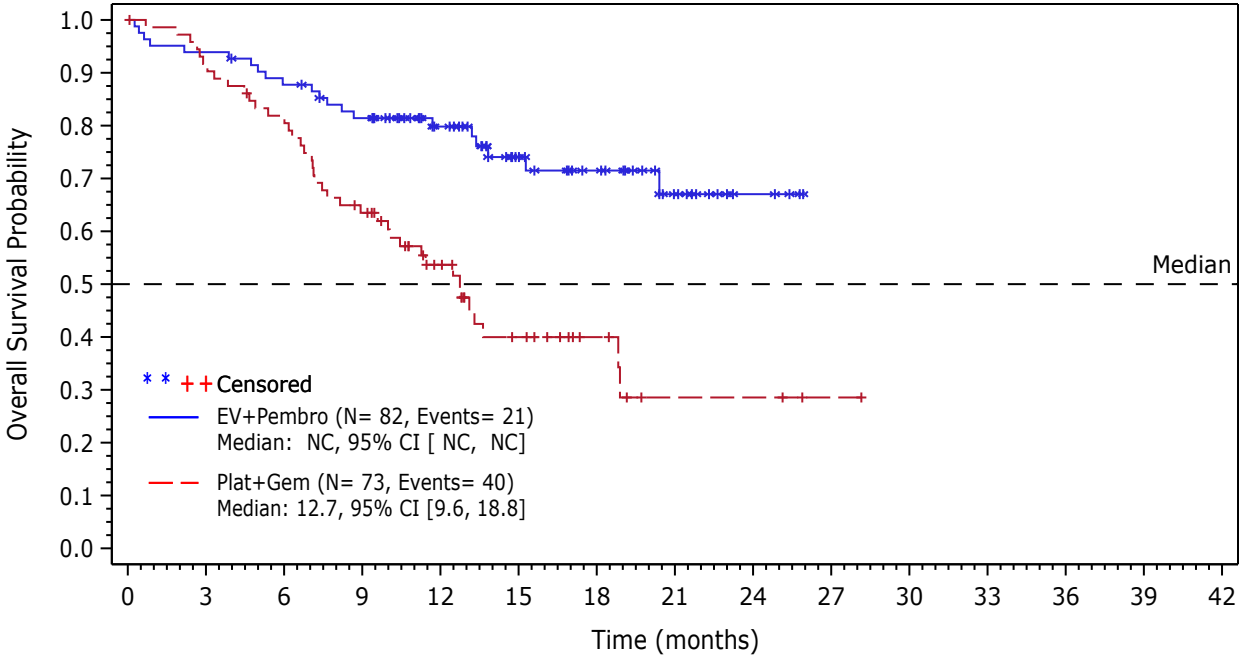
at Risk

1	46	40	37	35	24	20	17	9	4	1	1	0	0	0	0
2	34	31	25	23	18	11	7	4	1	1	1	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.2.4: Kaplan-Meier Plot of Overall Survival by Region - Analysis Set mITT 2
Region: Rest of World



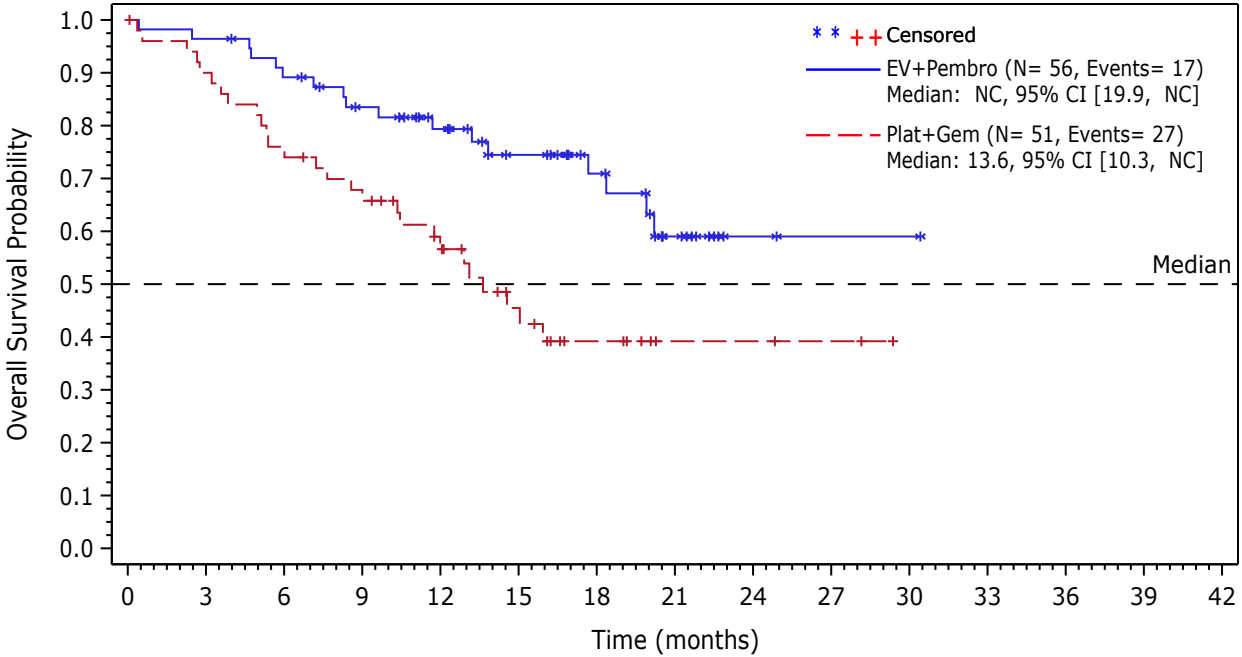
at Risk

1	82	77	71	64	48	31	23	12	4	0	0	0	0	0	0
2	73	66	58	44	28	15	8	3	3	1	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.2.5: Kaplan-Meier Plot of Overall Survival by Sex - Analysis Set mITT 2
Sex: Female



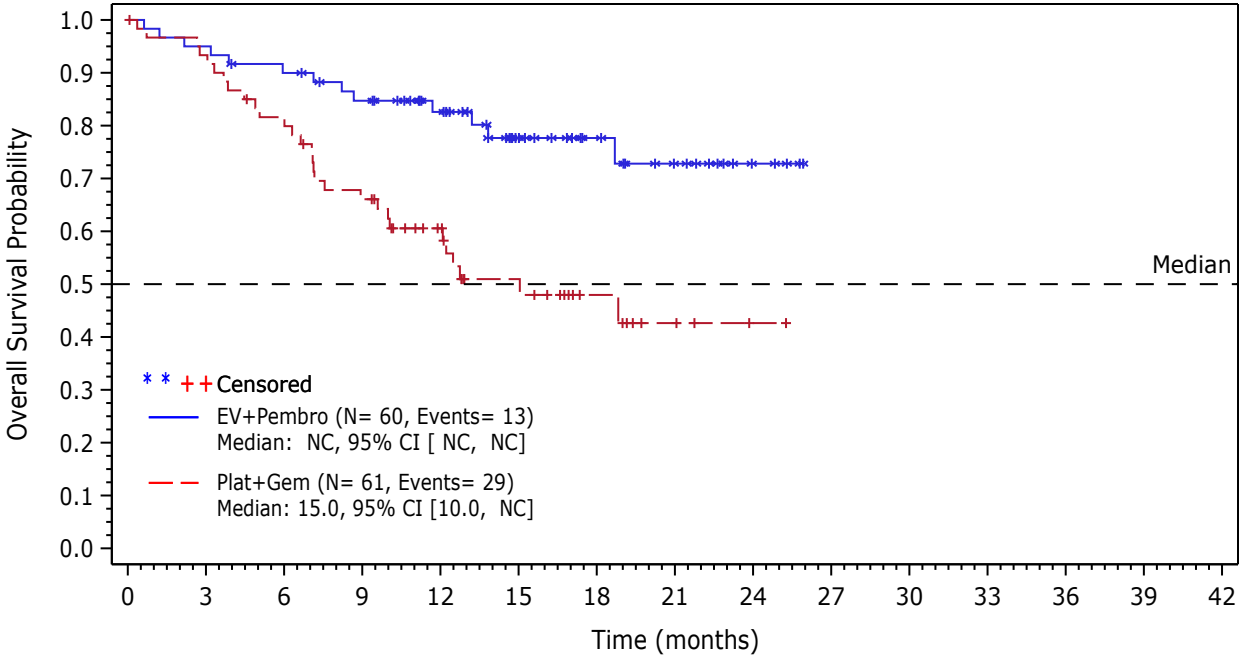
at Risk

1	56	54	49	43	36	28	20	10	2	1	1	0	0	0	0
2	51	45	38	33	24	15	8	3	3	2	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.2.6: Kaplan-Meier Plot of Overall Survival by Race - Analysis Set mITT 2
Race: Non-white



at Risk

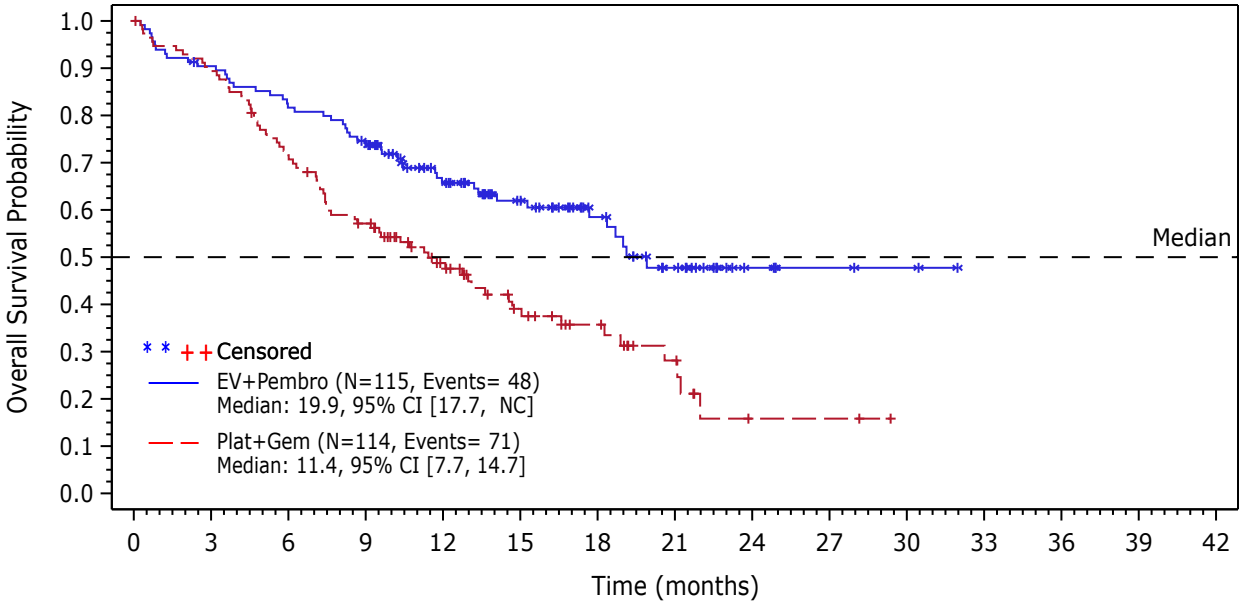
1	60	57	53	48	39	25	17	11	4	0	0	0	0	0	0
2	61	56	48	38	27	17	9	4	1	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.2.7: Kaplan-Meier Plot of Overall Survival by ECOG Status at Baseline - Analysis Set mITT 2

ECOG Status at Baseline: 1-2



at Risk

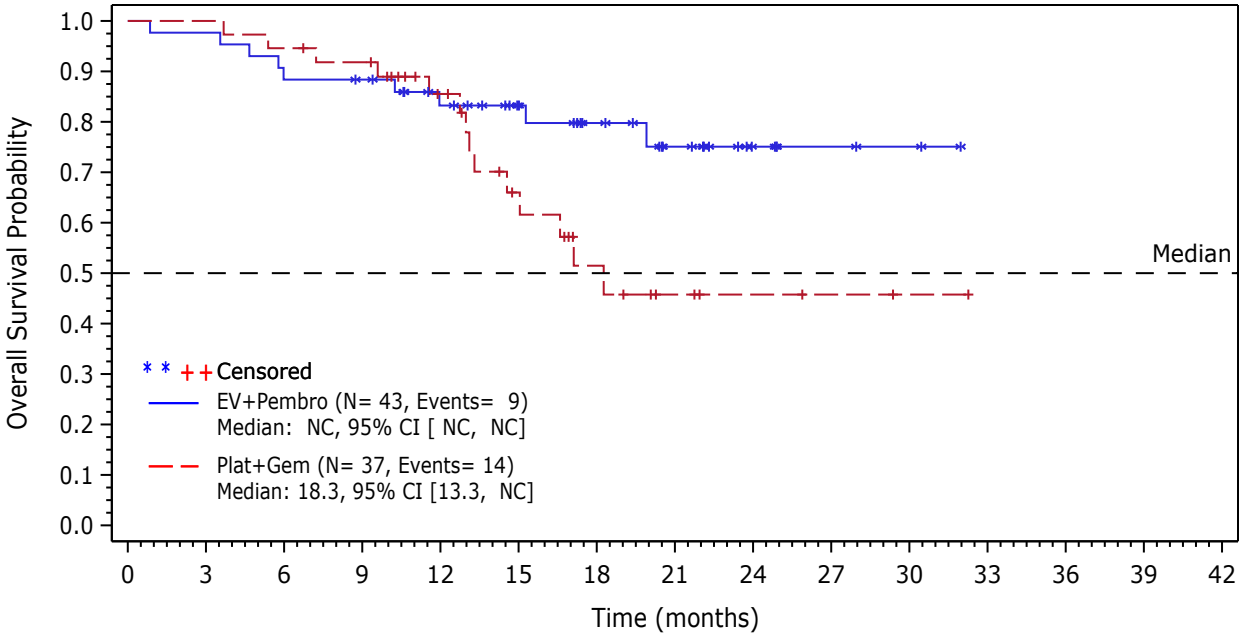
1	115	103	93	84	62	44	29	18	6	3	2	0	0	0	0
2	114	101	80	62	41	25	17	9	2	2	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.2.8: Kaplan-Meier Plot of Overall Survival by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Lymph node only



at Risk

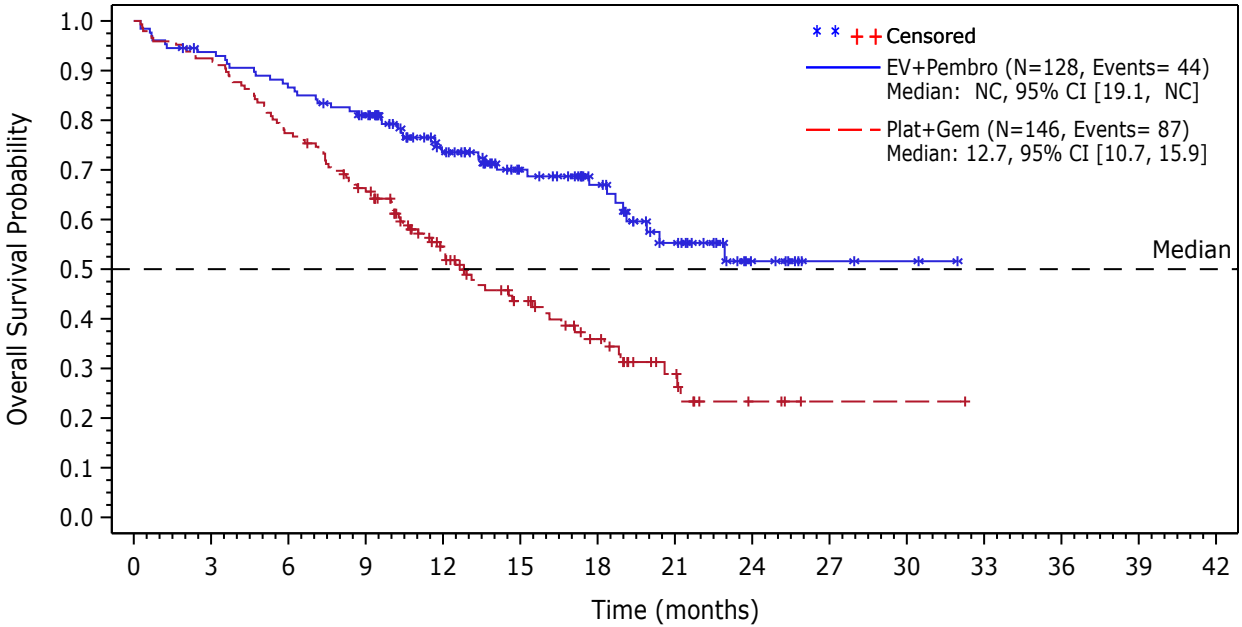
1	43	42	38	37	31	25	19	13	6	3	2	0	0	0	0
2	37	37	35	33	24	15	9	5	3	2	1	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.2.9: Kaplan-Meier Plot of Overall Survival by Primary Disease Site of Origin - Analysis Set mITT 2

Primary Disease Site of Origin: Lower tract



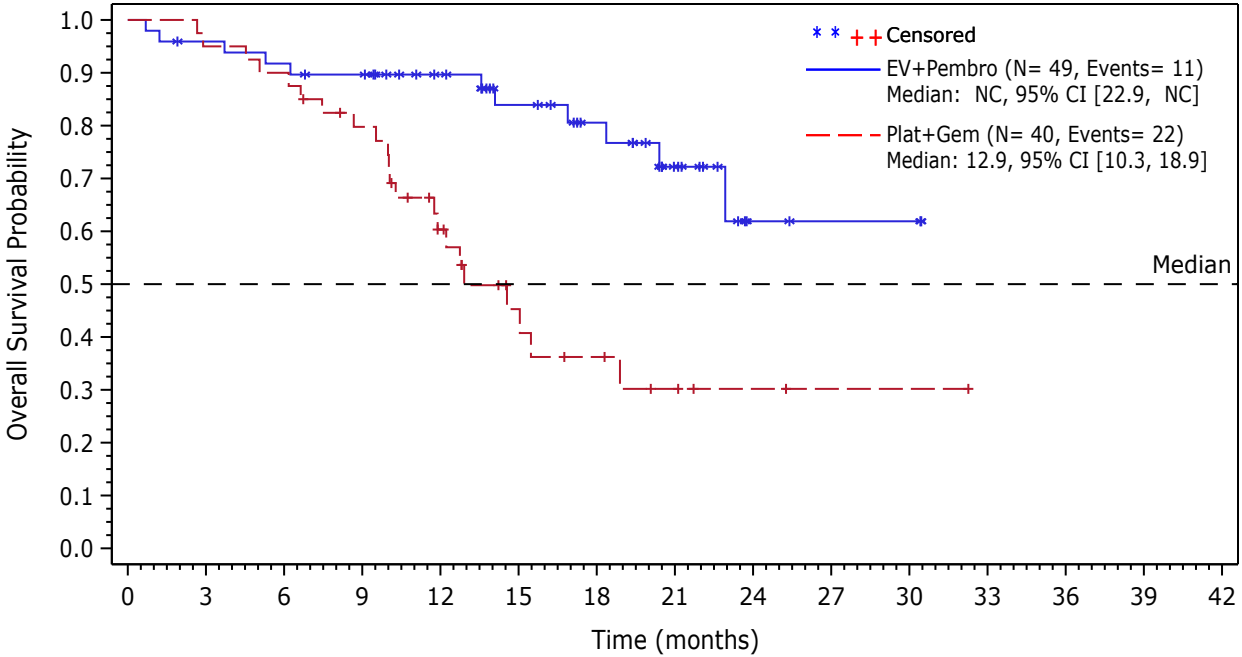
at Risk

1	128	118	109	99	73	52	39	24	9	3	2	0	0	0	0
2	146	135	113	94	59	38	25	12	4	1	1	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.2.10: Kaplan-Meier Plot of Overall Survival by Renal Function - Analysis Set mITT 2
Renal Function: Mild



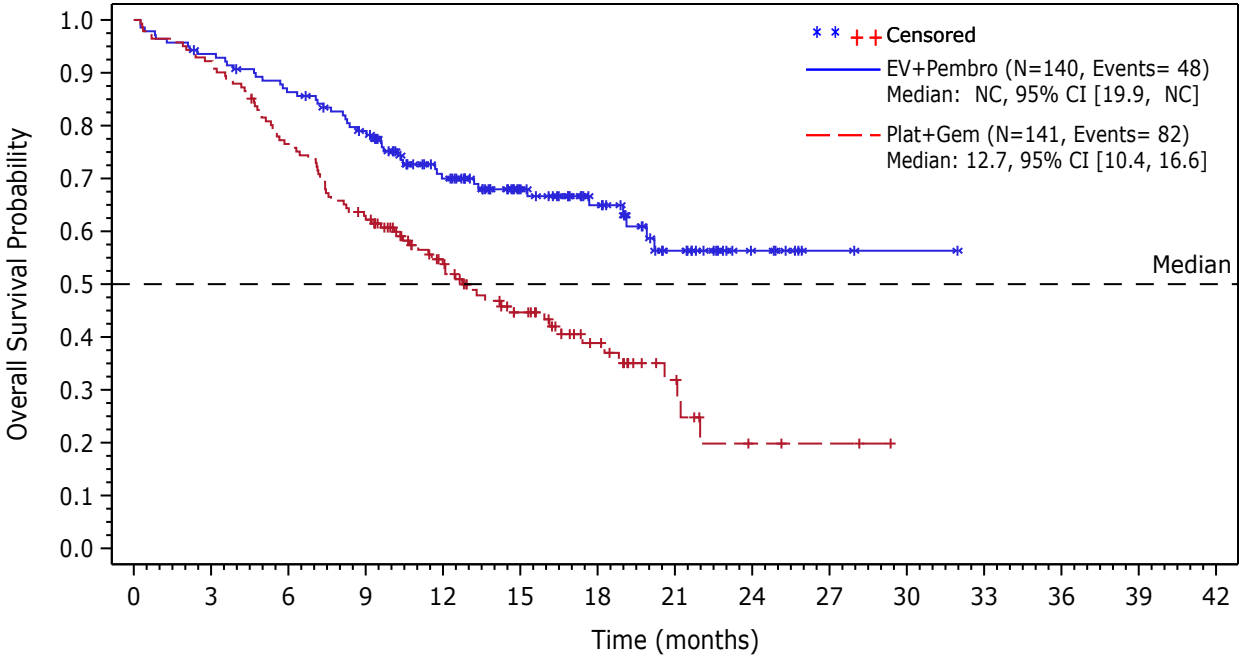
at Risk

1	49	46	44	42	35	27	21	12	3	2	2	0	0	0	0
2	40	38	36	30	19	10	7	4	2	1	1	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.2.10: Kaplan-Meier Plot of Overall Survival by Renal Function - Analysis Set mITT 2
Renal Function: Moderate



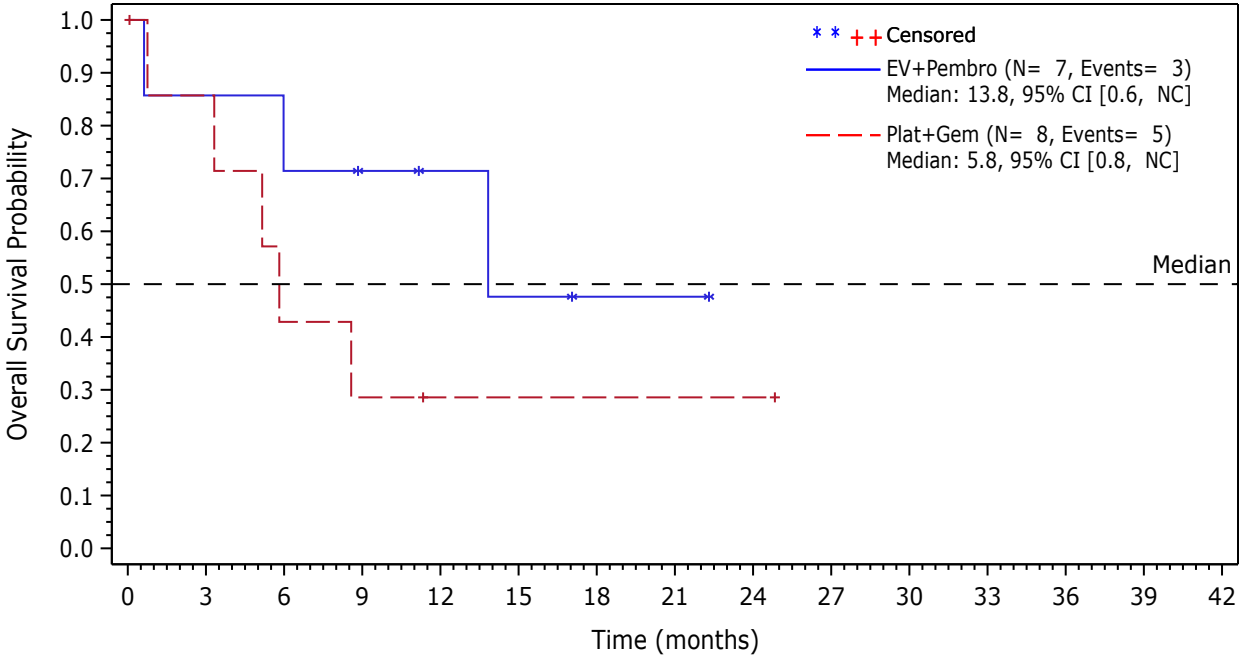
at Risk

1	140	130	119	106	78	54	38	21	8	2	1	0	0	0	0
2	141	130	107	87	58	38	22	10	3	2	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.1.2.10: Kaplan-Meier Plot of Overall Survival by Renal Function - Analysis Set mITT 2
Renal Function: Severe



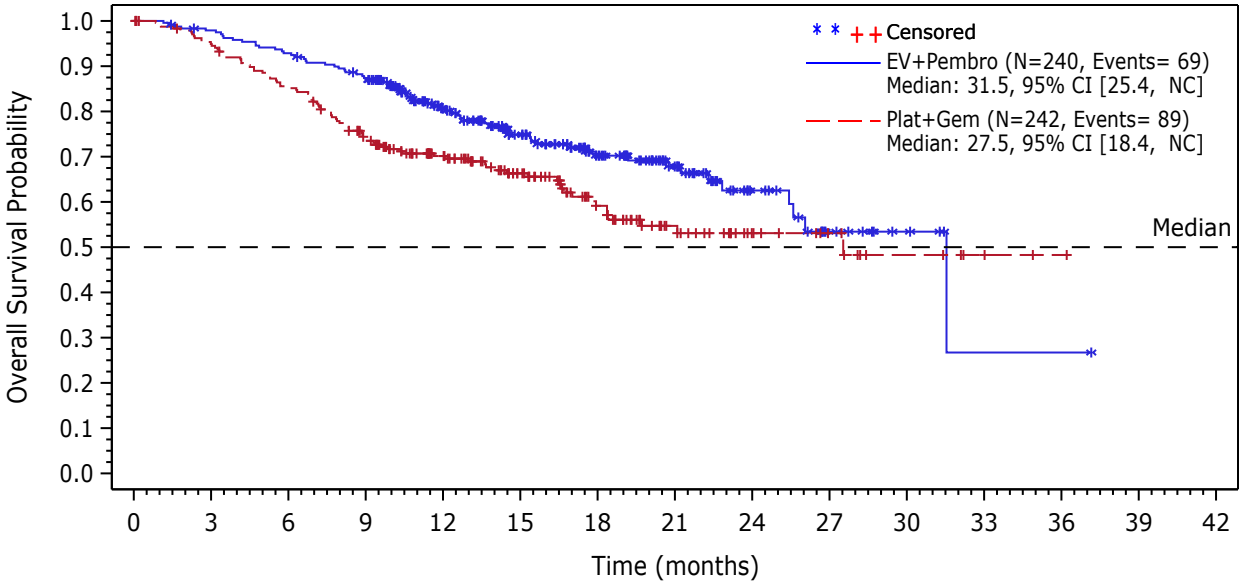
at Risk

1	7	6	5	4	3	2	1	1	0	0	0	0	0	0	0
2	8	6	3	2	1	1	1	1	1	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.1: Kaplan-Meier Plot of Overall Survival - Analysis Set mITT 1 - Sensitivity Analysis 1



at Risk

1	240	233	221	206	150	112	78	49	24	11	5	1	1	0	0
2	242	224	200	167	125	90	58	34	18	12	6	3	1	0	0

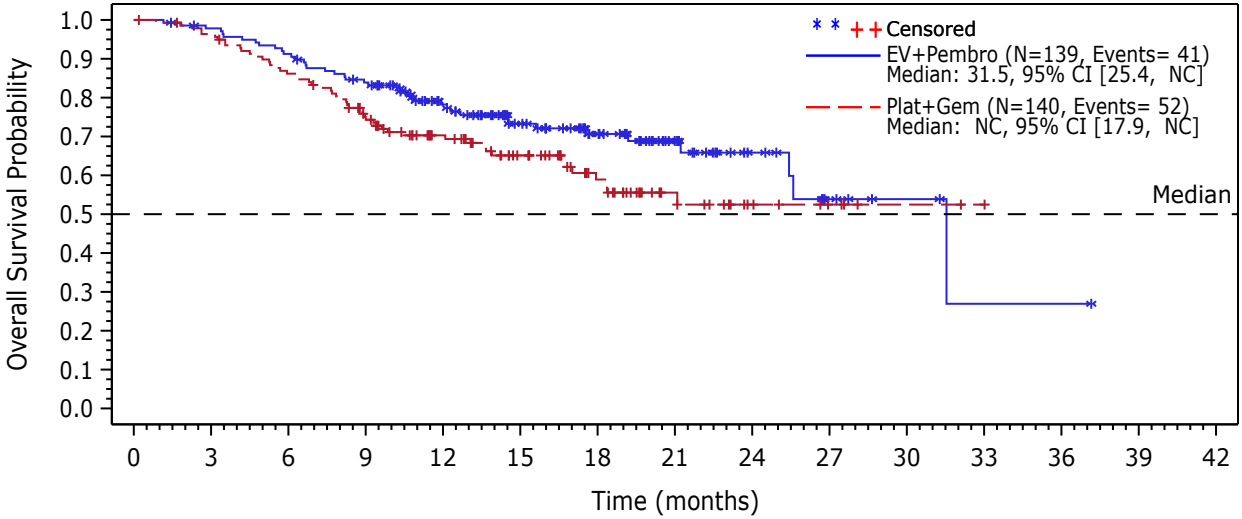
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.1.1: Kaplan-Meier Plot of Overall Survival by PD-L1 Expression - Analysis Set mITT 1 - Sensitivity Analysis 1

PD-L1 Expression: High (CPS>=10)



at Risk

1	139	134	125	113	87	64	47	26	13	6	3	1	1	0	0
2	140	133	118	98	74	54	35	18	9	5	2	1	0	0	0

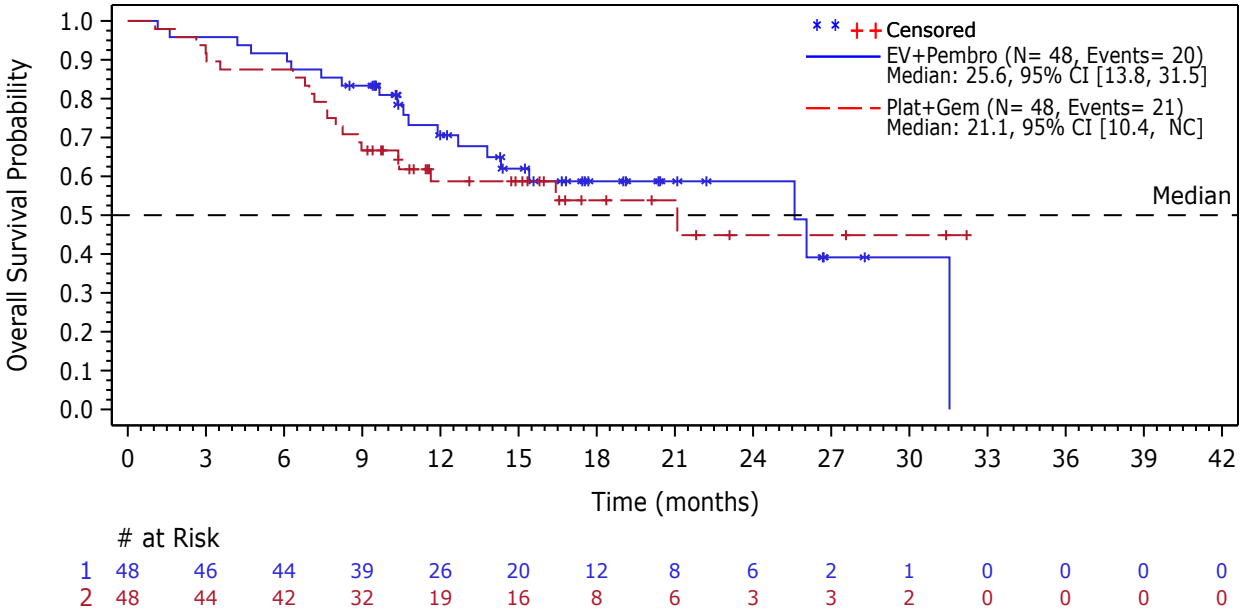
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.1.2: Kaplan-Meier Plot of Overall Survival by Liver Metastases - Analysis Set mITT 1 - Sensitivity Analysis 1

Liver Metastases: Present



at Risk

1	48	46	44	39	26	20	12	8	6	2	1	0	0	0	0
2	48	44	42	32	19	16	8	6	3	3	2	0	0	0	0

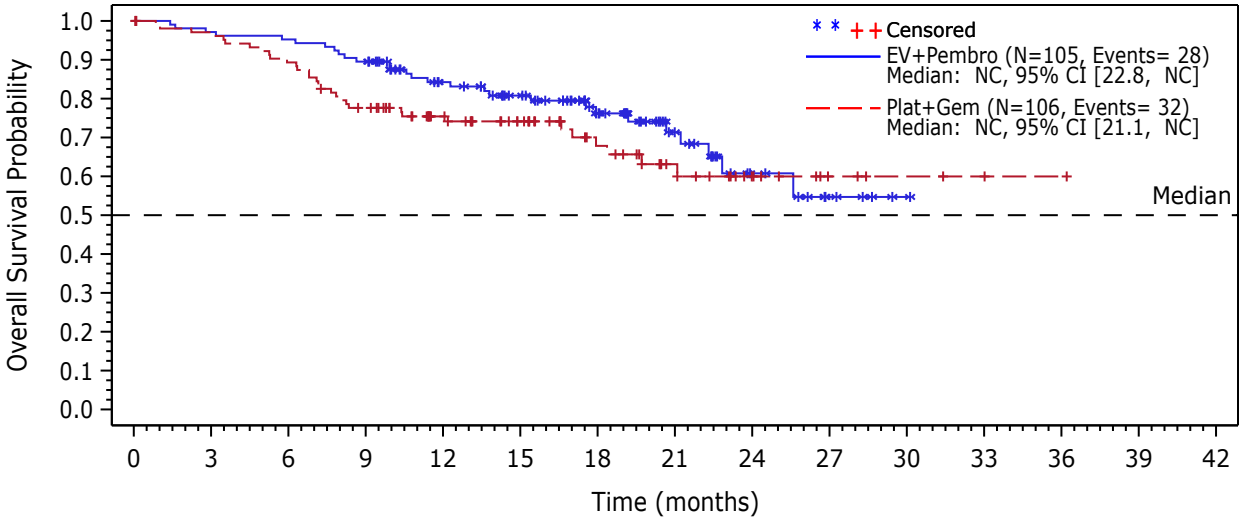
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.1.3: Kaplan-Meier Plot of Overall Survival by Age - Analysis Set mITT 1 - Sensitivity Analysis 1

Age: < 65 years



at Risk

1	105	102	100	94	75	64	45	24	11	5	1	0	0	0	0
2	106	100	92	78	60	47	31	20	11	5	3	2	1	0	0

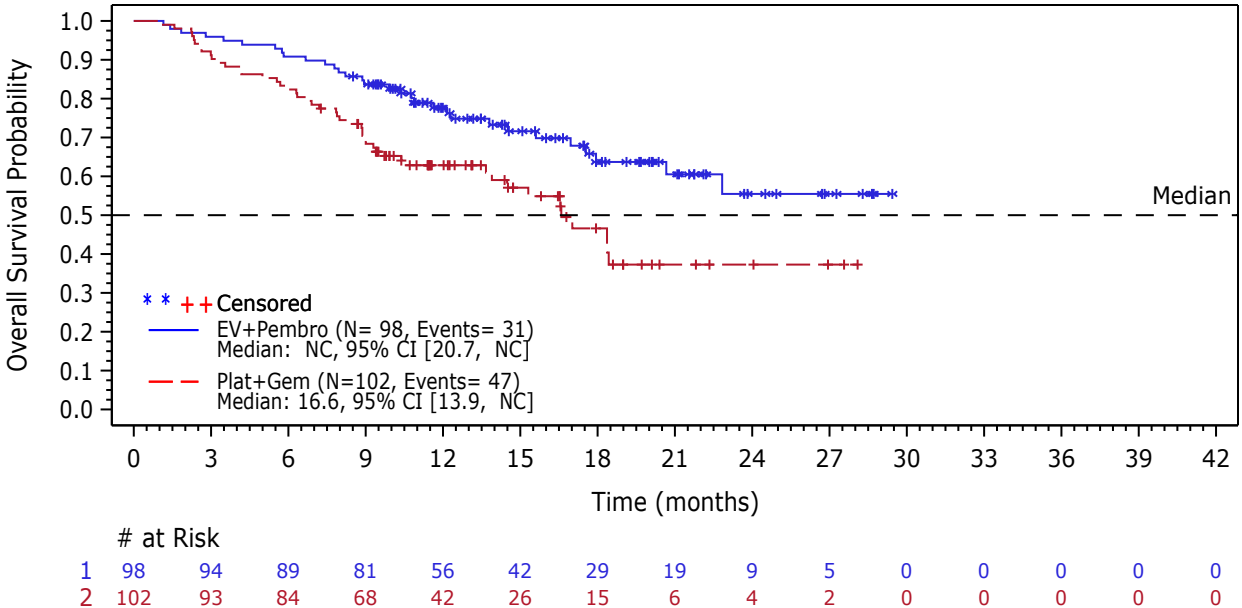
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.1.4: Kaplan-Meier Plot of Overall Survival by Region - Analysis Set mITT 1 - Sensitivity Analysis 1

Region: Europe



at Risk

1	98	94	89	81	56	42	29	19	9	5	0	0	0	0	0
2	102	93	84	68	42	26	15	6	4	2	0	0	0	0	0

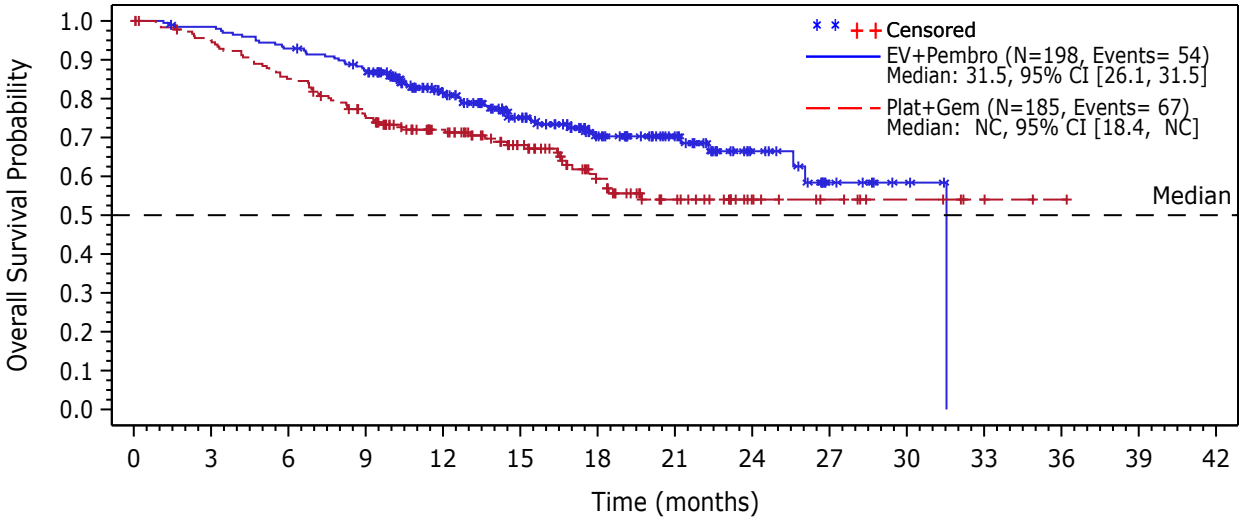
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.1.5: Kaplan-Meier Plot of Overall Survival by Sex - Analysis Set mITT 1 - Sensitivity Analysis 1

Sex: Male



at Risk

1	198	194	183	170	126	94	63	42	20	8	3	0	0	0	0
2	185	172	154	132	101	75	48	30	15	10	6	3	1	0	0

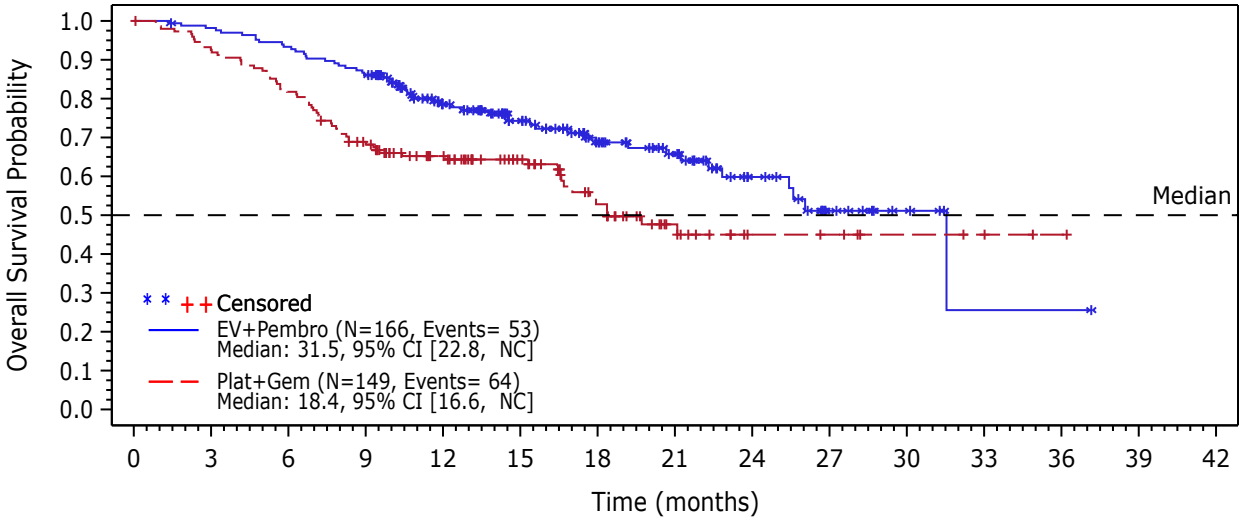
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.1.6: Kaplan-Meier Plot of Overall Survival by Race - Analysis Set mITT 1 - Sensitivity Analysis 1

Race: White



at Risk

1	166	162	154	142	103	77	55	41	23	11	5	1	1	0	0
2	149	137	121	98	75	54	34	18	8	7	4	3	1	0	0

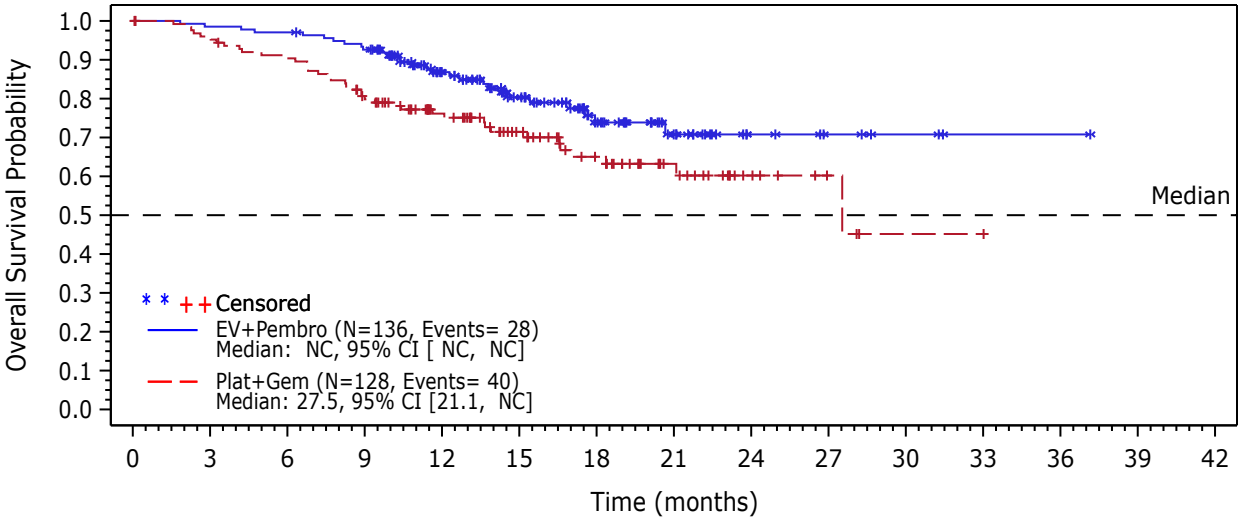
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.1.7: Kaplan-Meier Plot of Overall Survival by ECOG Status at Baseline - Analysis Set mITT 1 - Sensitivity Analysis 1

ECOG Status at Baseline: 0



at Risk

1	136	134	132	125	90	64	39	21	8	5	3	1	1	0	0
2	128	120	112	97	72	52	36	21	9	4	1	1	0	0	0

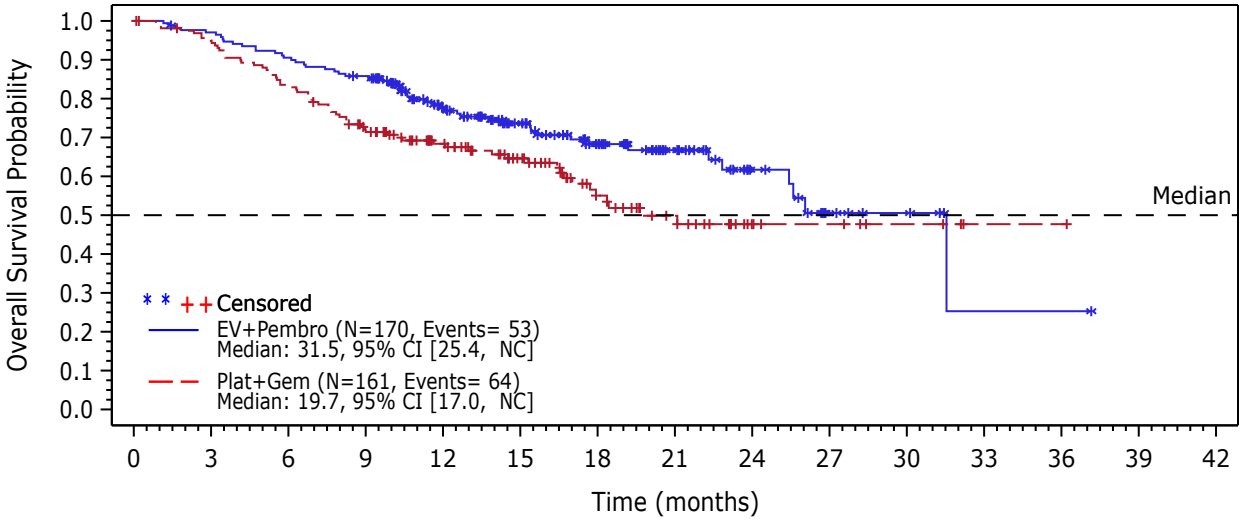
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.1.8: Kaplan-Meier Plot of Overall Survival by Metastases at Baseline - Analysis Set mITT 1 - Sensitivity Analysis 1

Metastases at Baseline: Visceral metastases



at Risk

1	170	164	153	144	102	78	54	34	18	8	5	1	1	0	0
2	161	150	131	109	81	58	35	23	9	7	4	1	1	0	0

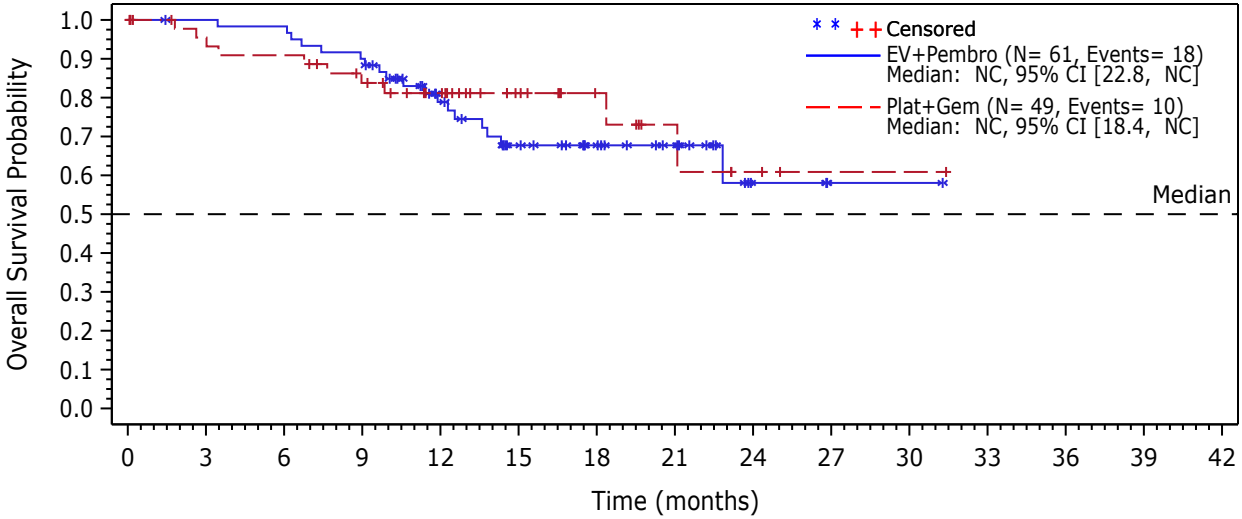
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.1.9: Kaplan-Meier Plot of Overall Survival by Primary Disease Site of Origin - Analysis Set mITT 1 - Sensitivity Analysis 1

Primary Disease Site of Origin: Upper tract



at Risk

1	61	60	59	54	37	26	19	13	3	1	1	0	0	0	0
2	49	42	40	34	27	16	10	6	3	1	1	0	0	0	0

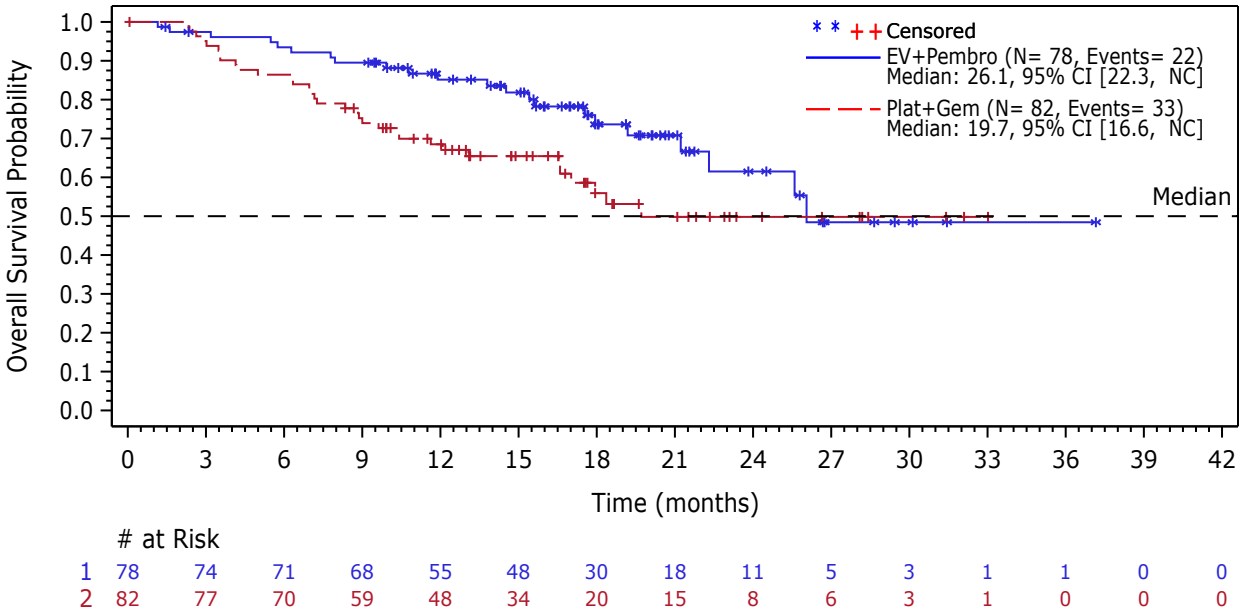
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.1.10: Kaplan-Meier Plot of Overall Survival by Renal Function - Analysis Set mITT 1 - Sensitivity Analysis 1

Renal Function: Normal



at Risk

1	78	74	71	68	55	48	30	18	11	5	3	1	1	0	0
2	82	77	70	59	48	34	20	15	8	6	3	1	0	0	0

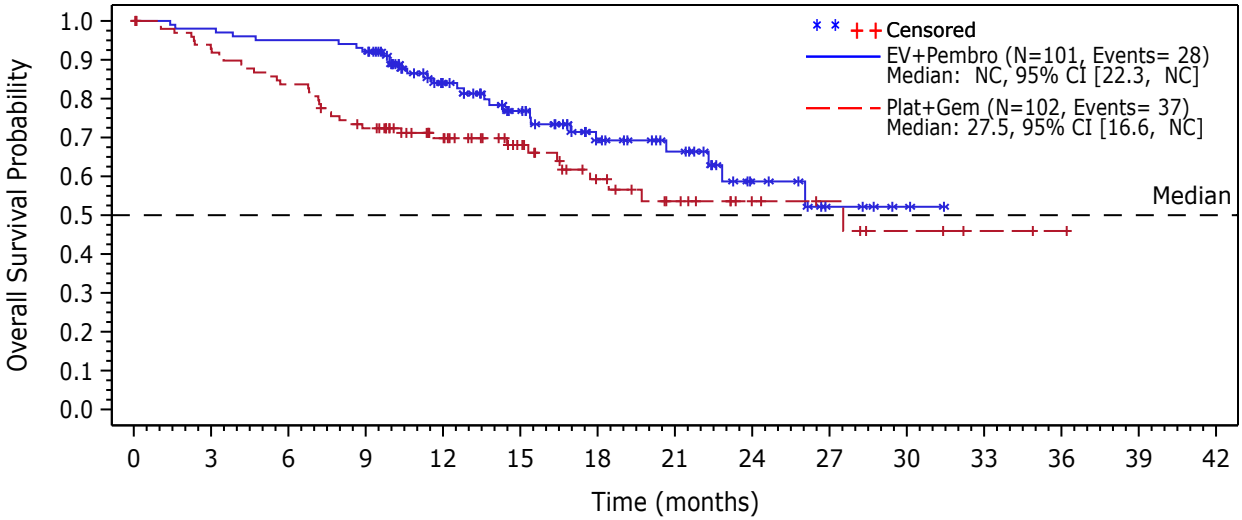
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.1.1: Kaplan-Meier Plot of Overall Survival by PD-L1 Expression - Analysis Set mITT 1 - Sensitivity Analysis 1

PD-L1 Expression: Low (CPS<10)



at Risk

1	101	99	96	93	63	48	31	23	11	5	2	0	0	0	0
2	102	91	82	69	51	36	23	16	9	7	4	2	1	0	0

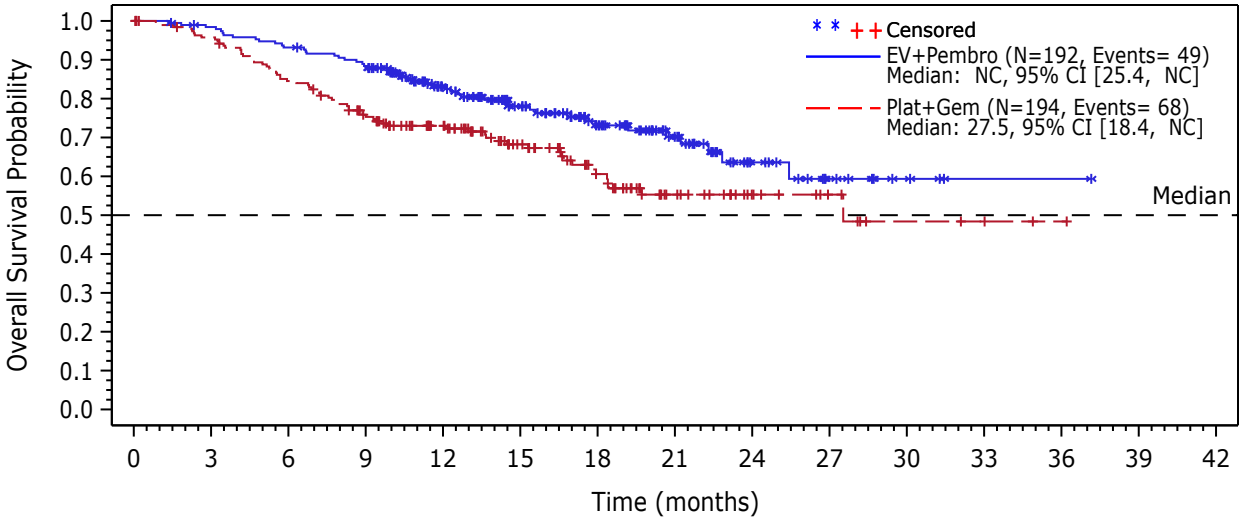
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.1.2: Kaplan-Meier Plot of Overall Survival by Liver Metastases - Analysis Set mITT 1 - Sensitivity Analysis 1

Liver Metastases: Absent



at Risk

1	192	187	177	167	124	92	66	41	18	9	4	1	1	0	0
2	194	180	158	135	106	74	50	28	15	9	4	3	1	0	0

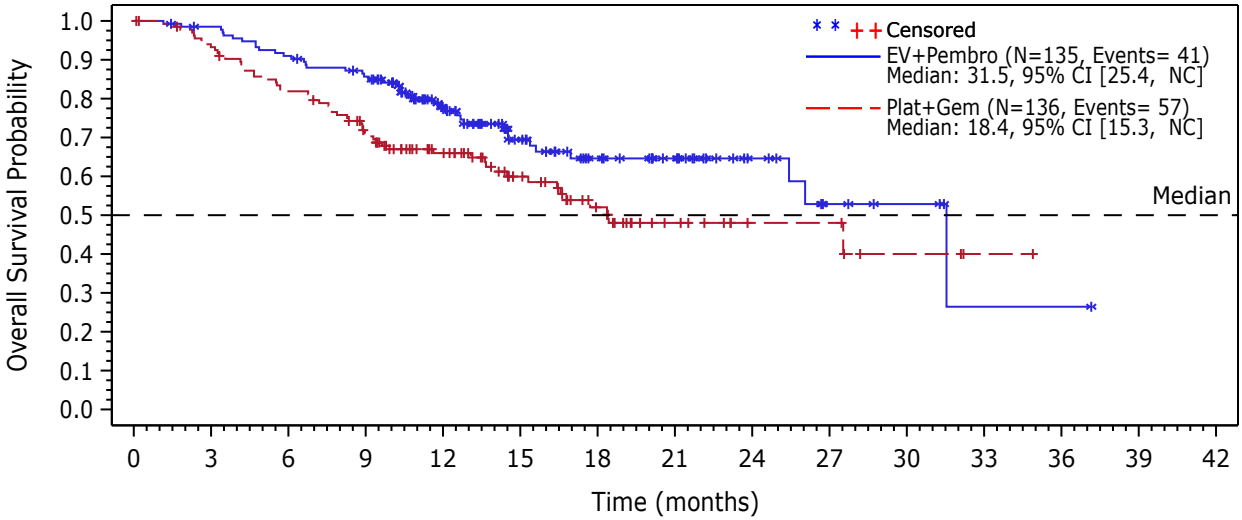
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.1.3: Kaplan-Meier Plot of Overall Survival by Age - Analysis Set mITT 1 - Sensitivity Analysis 1

Age: >= 65 years



at Risk

1	135	131	121	112	75	48	33	25	13	6	4	1	1	0	0
2	136	124	108	89	65	43	27	14	7	7	3	1	0	0	0

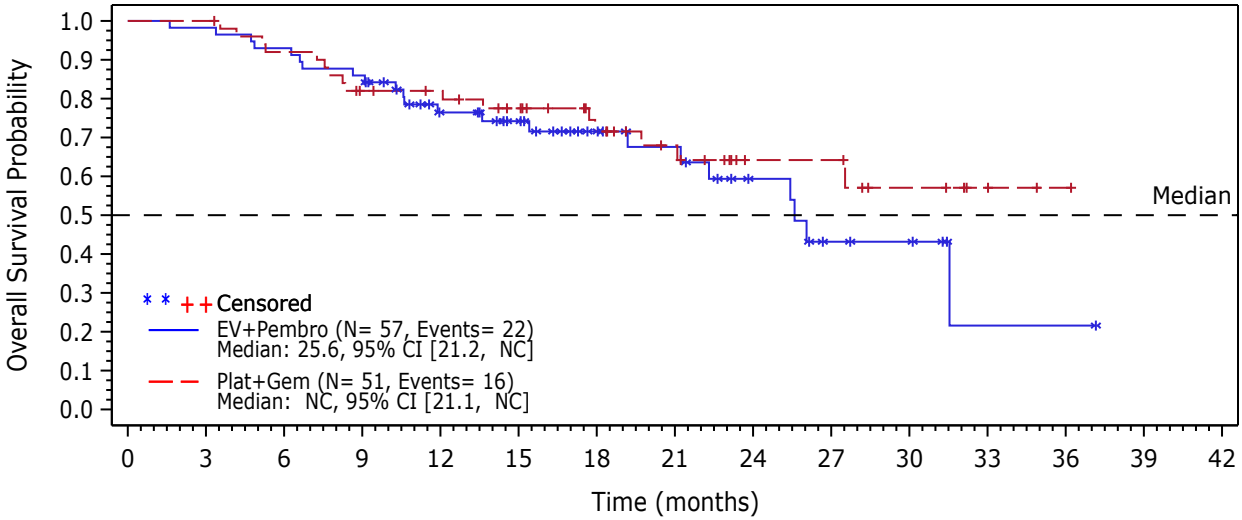
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.1.4: Kaplan-Meier Plot of Overall Survival by Region - Analysis Set mITT 1 - Sensitivity Analysis 1

Region: North America



at Risk

1	57	56	53	49	36	30	21	17	11	6	5	1	1	0	0
2	51	51	46	39	37	32	24	18	10	10	6	3	1	0	0

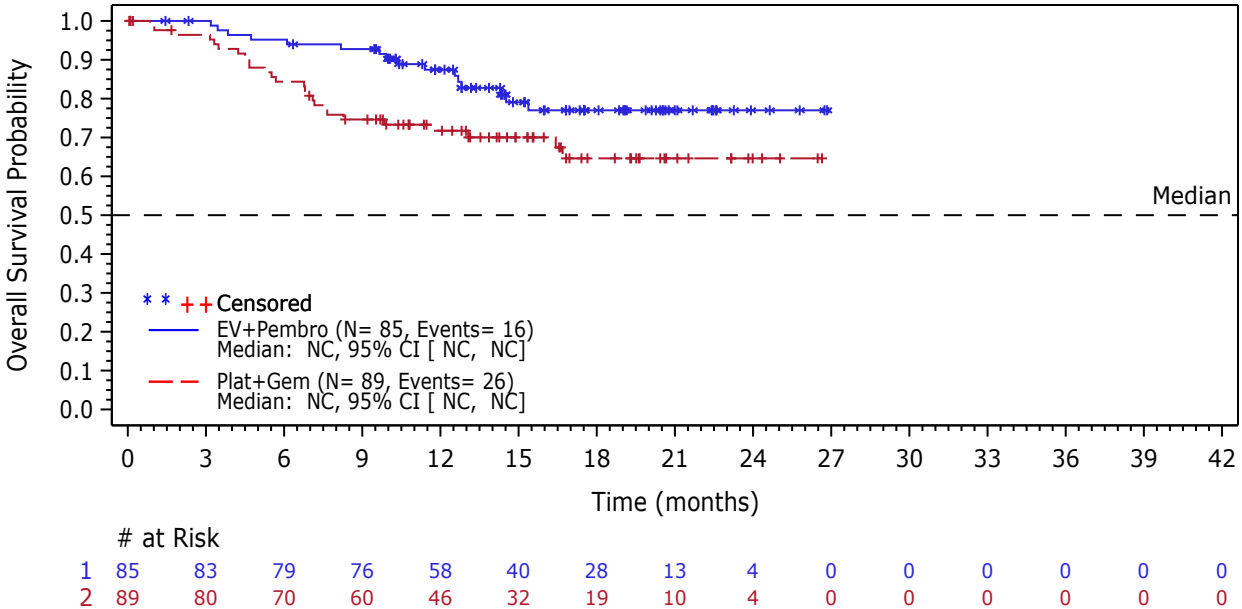
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.1.4: Kaplan-Meier Plot of Overall Survival by Region - Analysis Set mITT 1 - Sensitivity Analysis 1

Region: Rest of World



at Risk

1	85	83	79	76	58	40	28	13	4	0	0	0	0	0	0
2	89	80	70	60	46	32	19	10	4	0	0	0	0	0	0

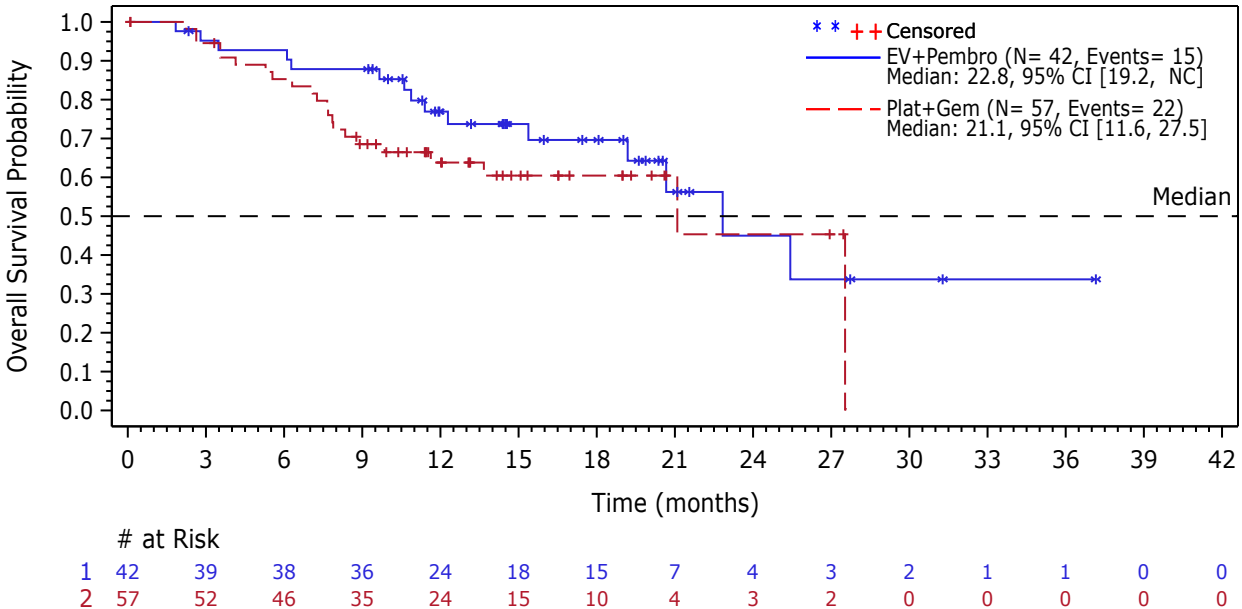
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.1.5: Kaplan-Meier Plot of Overall Survival by Sex - Analysis Set mITT 1 - Sensitivity Analysis 1

Sex: Female



at Risk

1	42	39	38	36	24	18	15	7	4	3	2	1	1	0	0
2	57	52	46	35	24	15	10	4	3	2	0	0	0	0	0

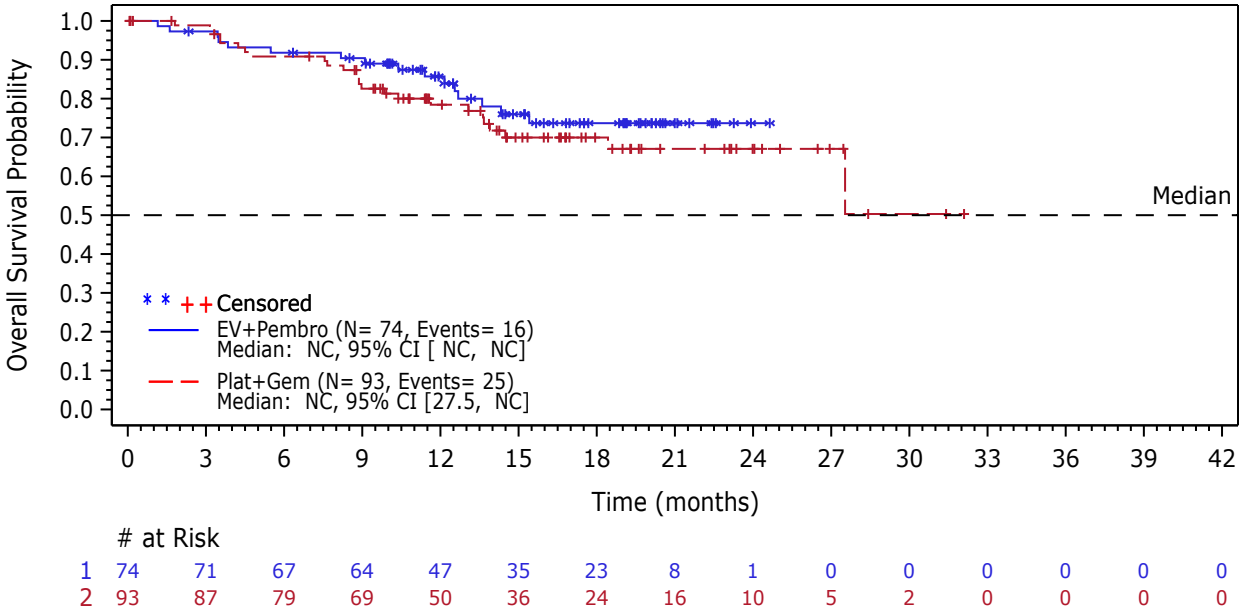
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.1.6: Kaplan-Meier Plot of Overall Survival by Race - Analysis Set mITT 1 - Sensitivity Analysis 1

Race: Non-white



at Risk

1	74	71	67	64	47	35	23	8	1	0	0	0	0	0	0
2	93	87	79	69	50	36	24	16	10	5	2	0	0	0	0

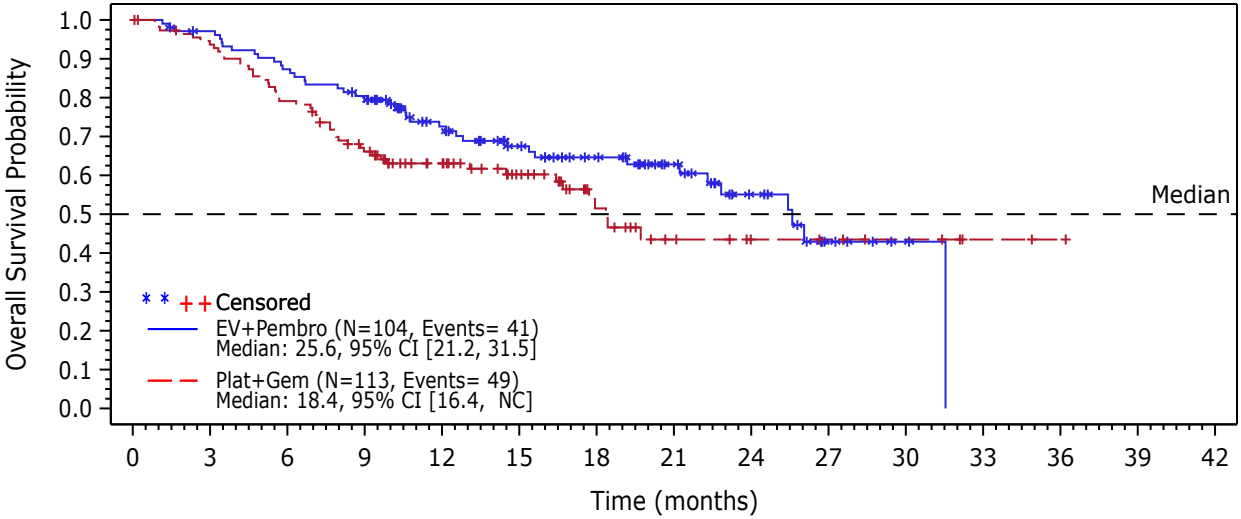
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.1.7: Kaplan-Meier Plot of Overall Survival by ECOG Status at Baseline - Analysis Set mITT 1 - Sensitivity Analysis 1

ECOG Status at Baseline: 1-2



at Risk

1	104	99	89	81	60	48	39	28	16	6	2	0	0	0	0
2	113	103	87	69	52	37	21	12	8	7	5	2	1	0	0

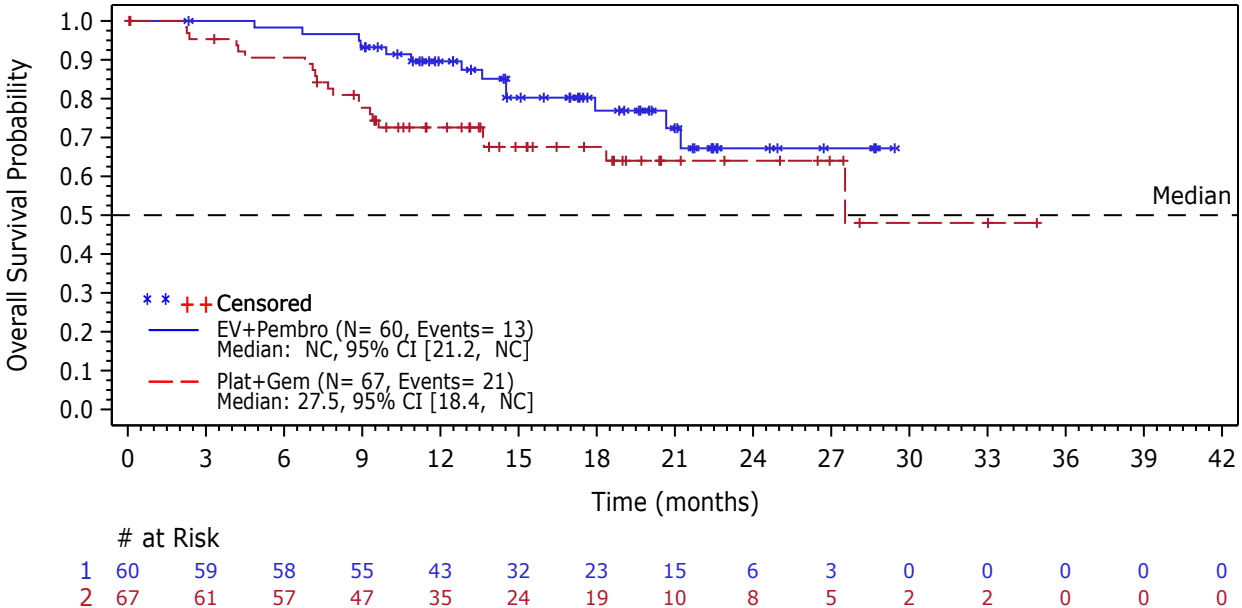
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.1.8: Kaplan-Meier Plot of Overall Survival by Metastases at Baseline - Analysis Set mITT 1 - Sensitivity Analysis 1

Metastases at Baseline: Lymph node only



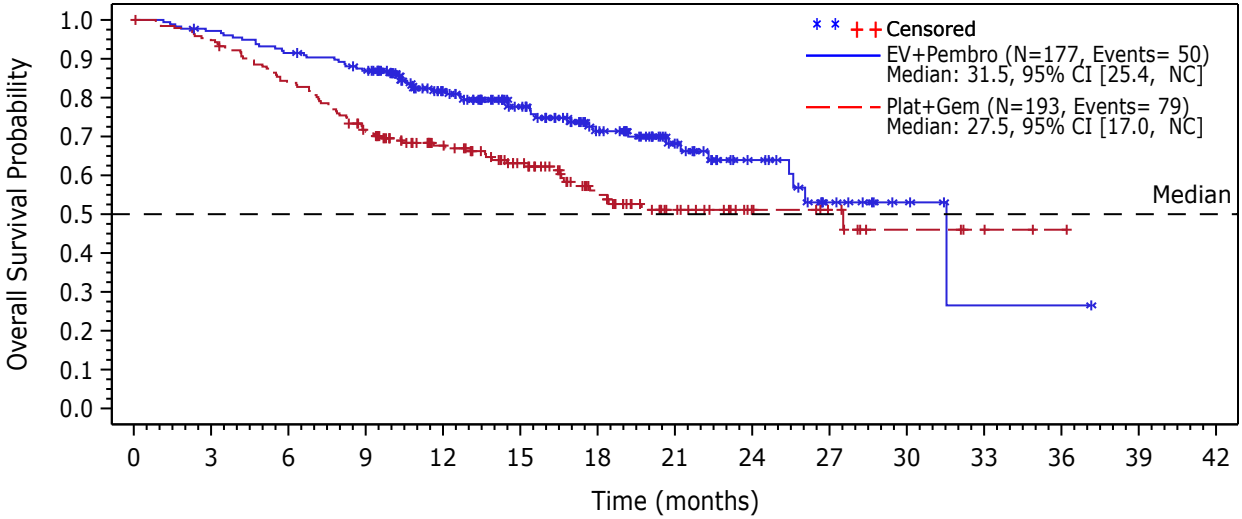
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.1.9: Kaplan-Meier Plot of Overall Survival by Primary Disease Site of Origin - Analysis Set mITT 1 - Sensitivity Analysis 1

Primary Disease Site of Origin: Lower tract



at Risk

1	177	171	161	151	112	85	59	36	21	10	4	1	1	0	0
2	193	182	160	133	98	74	48	28	15	11	5	3	1	0	0

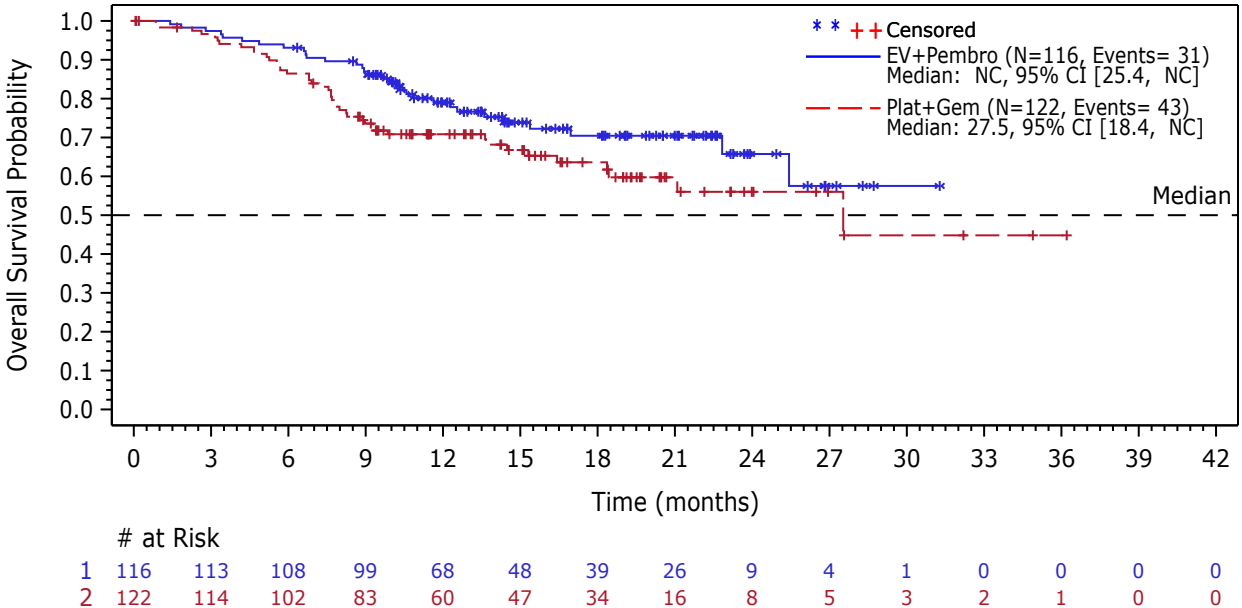
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.1.10: Kaplan-Meier Plot of Overall Survival by Renal Function - Analysis Set mITT 1 - Sensitivity Analysis 1

Renal Function: Mild



at Risk

1	116	113	108	99	68	48	39	26	9	4	1	0	0	0	0
2	122	114	102	83	60	47	34	16	8	5	3	2	1	0	0

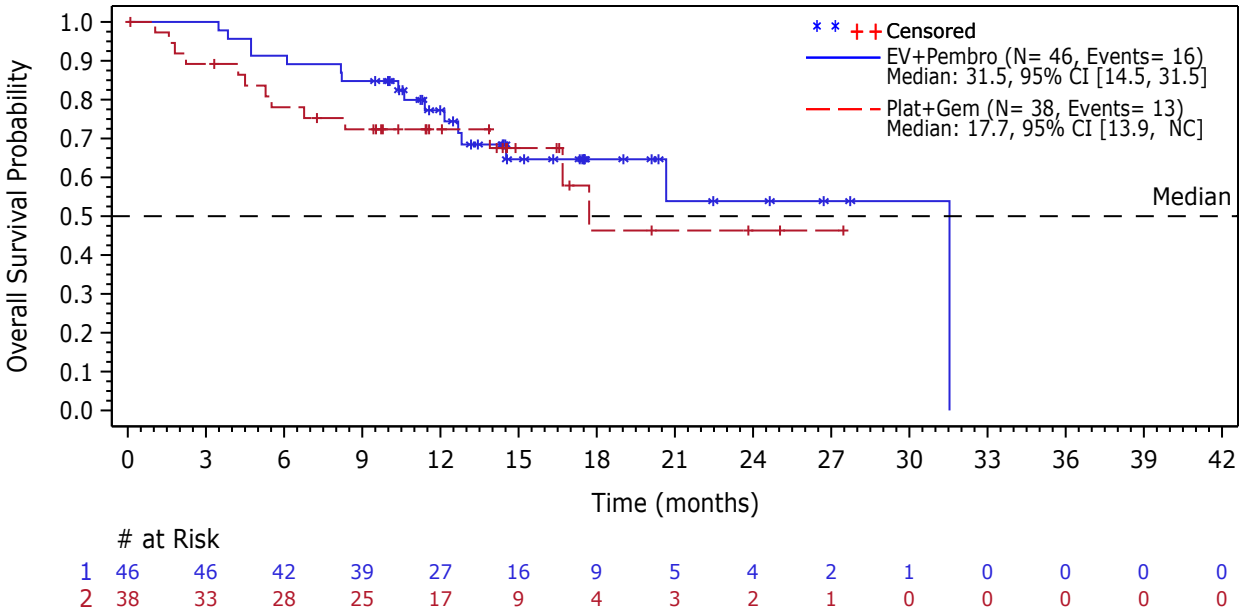
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.1.10: Kaplan-Meier Plot of Overall Survival by Renal Function - Analysis Set mITT 1 - Sensitivity Analysis 1

Renal Function: Moderate



at Risk

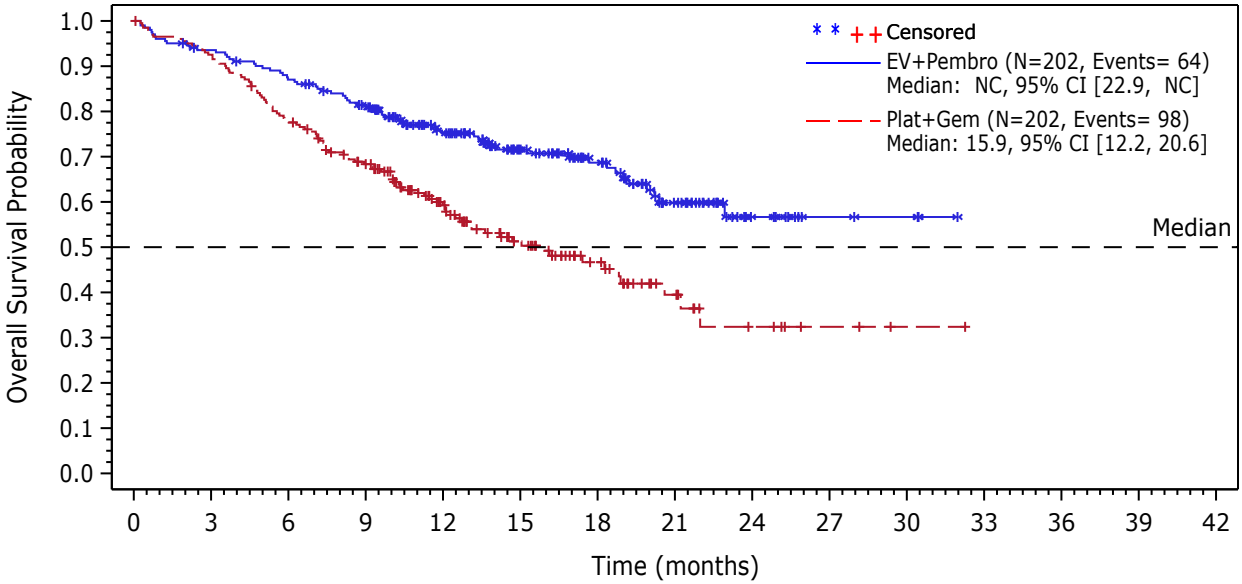
1	46	46	42	39	27	16	9	5	4	2	1	0	0	0	0
2	38	33	28	25	17	9	4	3	2	1	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.2: Kaplan-Meier Plot of Overall Survival - Analysis Set mITT 2 - Sensitivity Analysis 1



at Risk

1	202	187	173	157	120	86	63	36	12	4	3	0	0	0	0
2	202	186	156	129	84	52	32	16	7	3	1	0	0	0	0

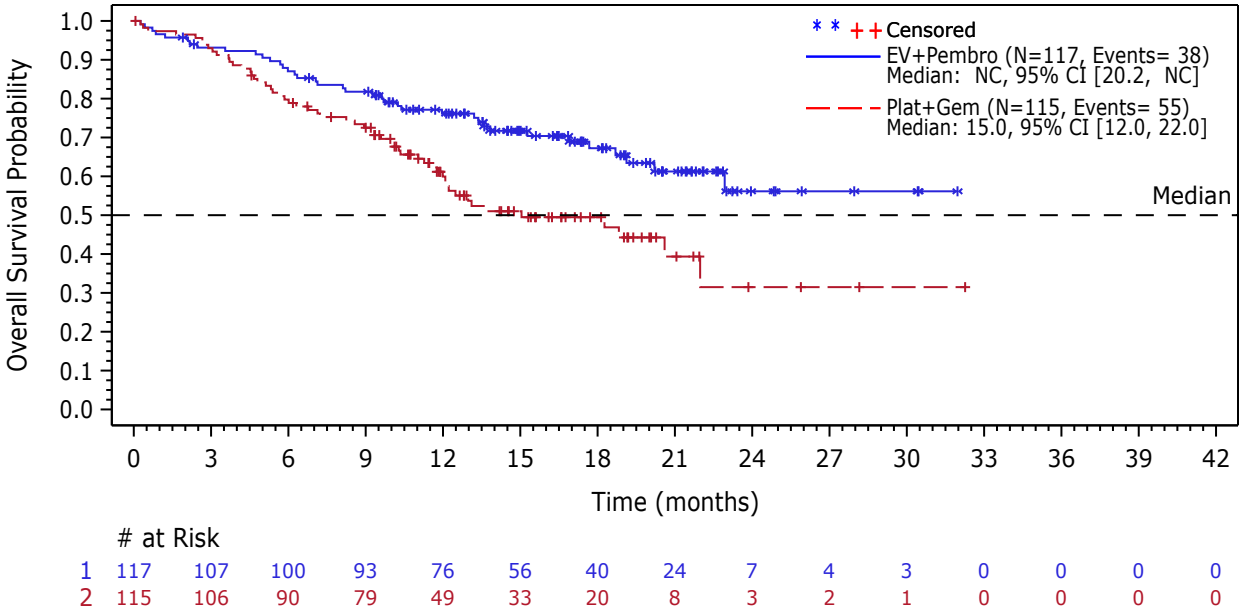
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.2.1: Kaplan-Meier Plot of Overall Survival by PD-L1 Expression - Analysis Set mITT 2 - Sensitivity Analysis 1

PD-L1 Expression: High (CPS>=10)



at Risk

1	117	107	100	93	76	56	40	24	7	4	3	0	0	0	0
2	115	106	90	79	49	33	20	8	3	2	1	0	0	0	0

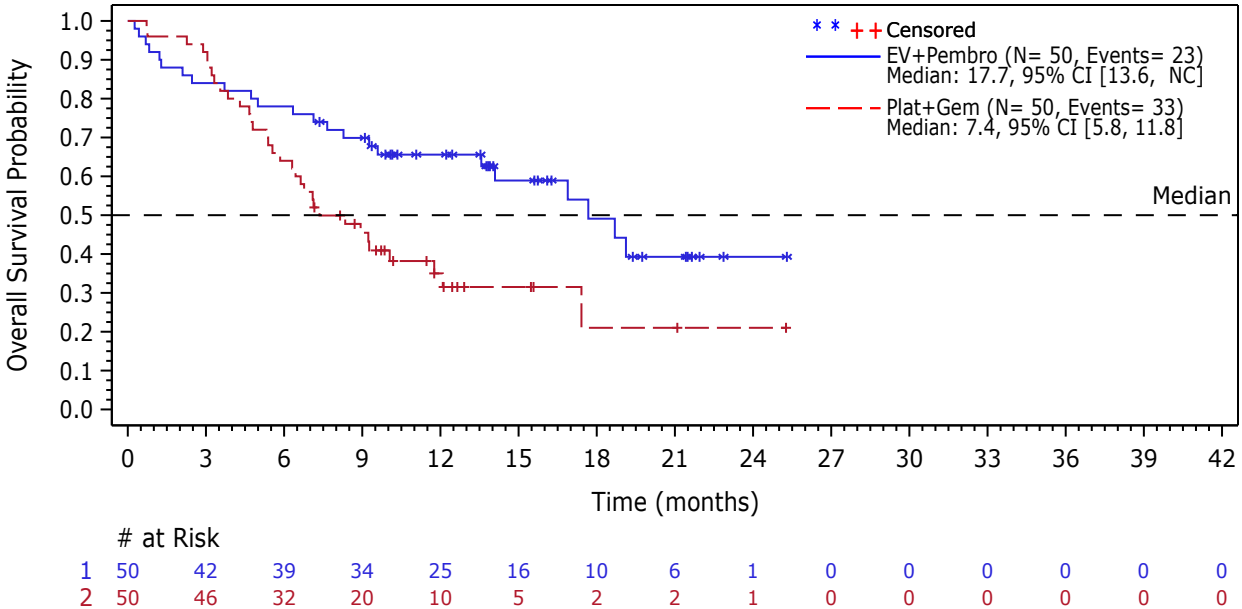
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.2.2: Kaplan-Meier Plot of Overall Survival by Liver Metastases - Analysis Set mITT 2 - Sensitivity Analysis 1

Liver Metastases: Present



at Risk

1	50	42	39	34	25	16	10	6	1	0	0	0	0	0	0
2	50	46	32	20	10	5	2	2	1	0	0	0	0	0	0

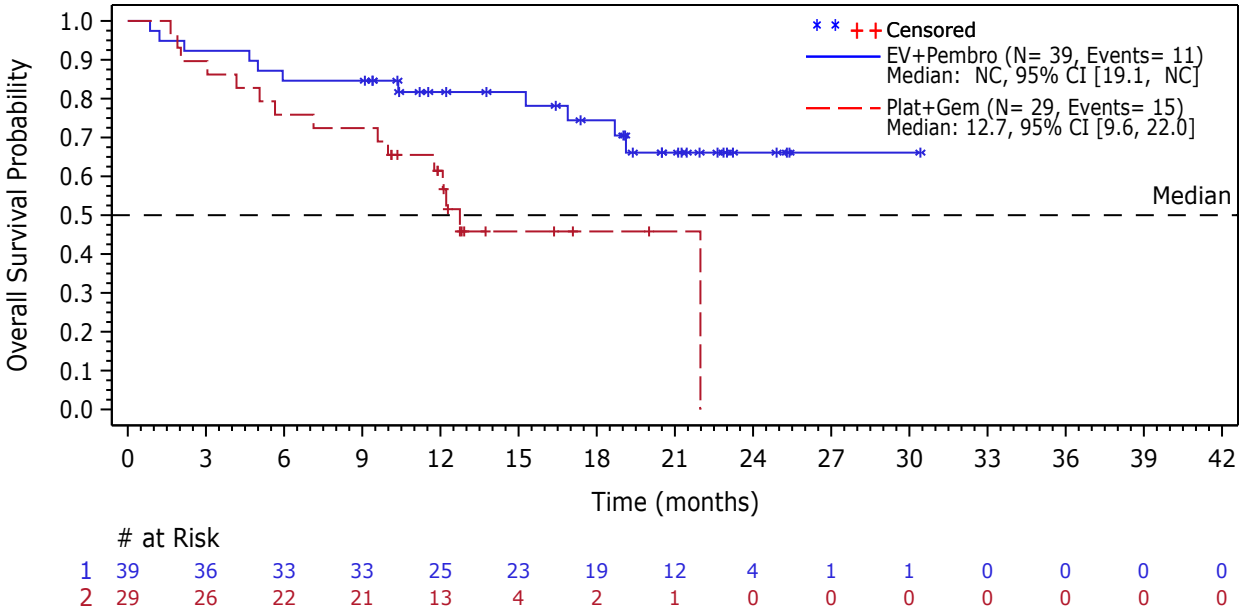
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.2.3: Kaplan-Meier Plot of Overall Survival by Age - Analysis Set mITT 2 - Sensitivity Analysis 1

Age: < 65 years



at Risk

1	39	36	33	33	25	23	19	12	4	1	1	0	0	0	0
2	29	26	22	21	13	4	2	1	0	0	0	0	0	0	0

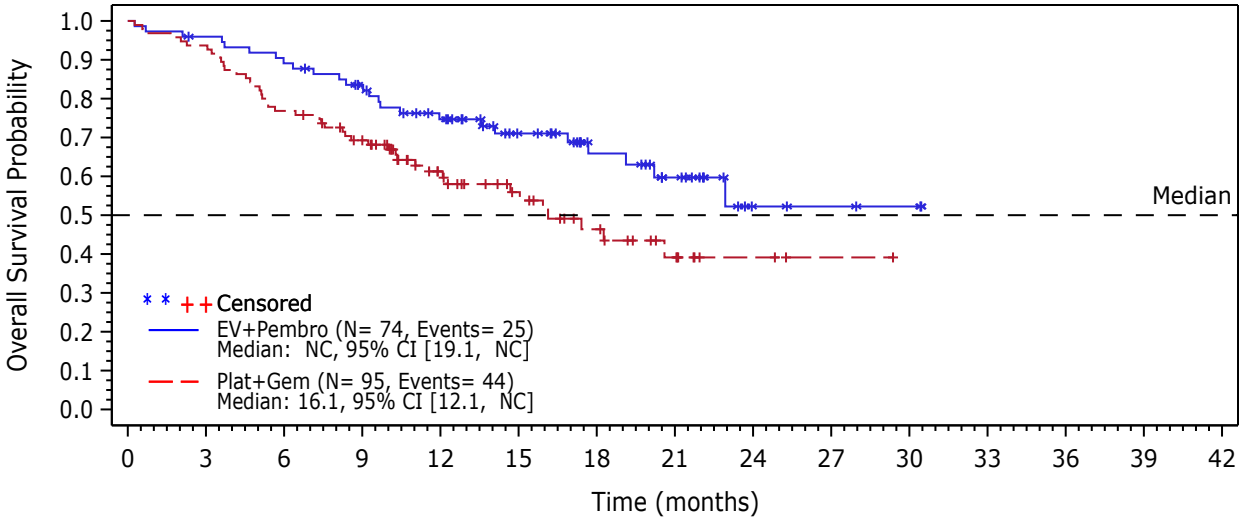
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.2.4: Kaplan-Meier Plot of Overall Survival by Region - Analysis Set mITT 2 - Sensitivity Analysis 1

Region: Europe



at Risk

1	74	70	65	58	48	35	23	15	4	3	2	0	0	0	0
2	95	89	73	62	38	26	17	9	3	1	0	0	0	0	0

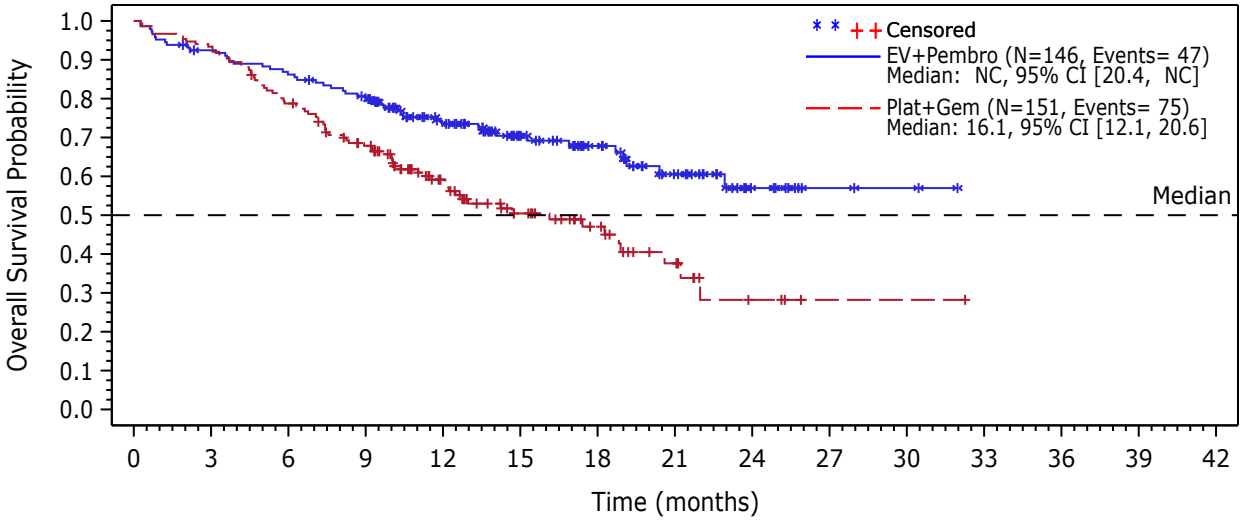
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.2.5: Kaplan-Meier Plot of Overall Survival by Sex - Analysis Set mITT 2 - Sensitivity Analysis 1

Sex: Male



at Risk

1	146	133	124	114	84	58	43	26	10	3	2	0	0	0	0
2	151	141	118	96	60	37	24	13	4	1	1	0	0	0	0

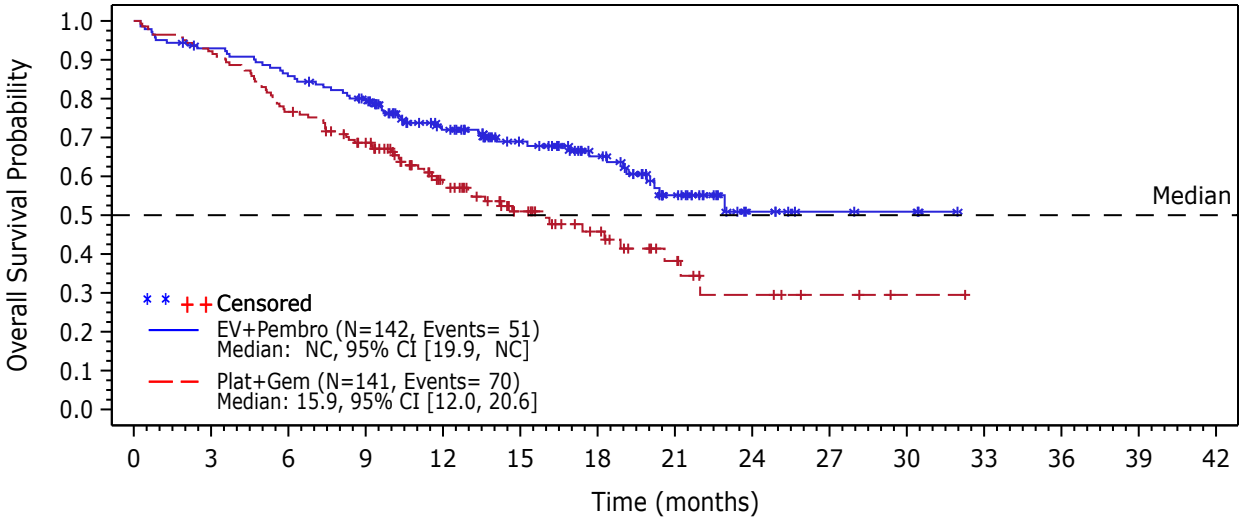
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.2.6: Kaplan-Meier Plot of Overall Survival by Race - Analysis Set mITT 2 - Sensitivity Analysis 1

Race: White



at Risk

1	142	130	120	109	81	61	46	25	8	4	3	0	0	0	0
2	141	130	108	91	57	35	23	12	6	3	1	0	0	0	0

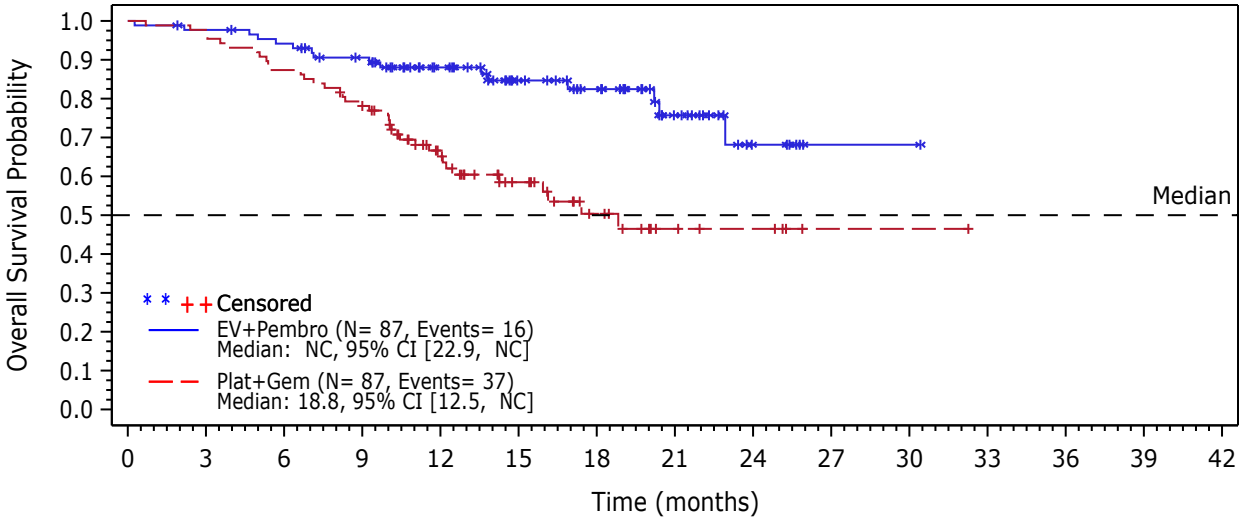
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.2.7: Kaplan-Meier Plot of Overall Survival by ECOG Status at Baseline - Analysis Set mITT 2 - Sensitivity Analysis 1

ECOG Status at Baseline: 0



at Risk

1	87	84	80	73	58	42	34	18	6	1	1	0	0	0	0
2	87	85	76	67	43	27	15	7	5	1	1	0	0	0	0

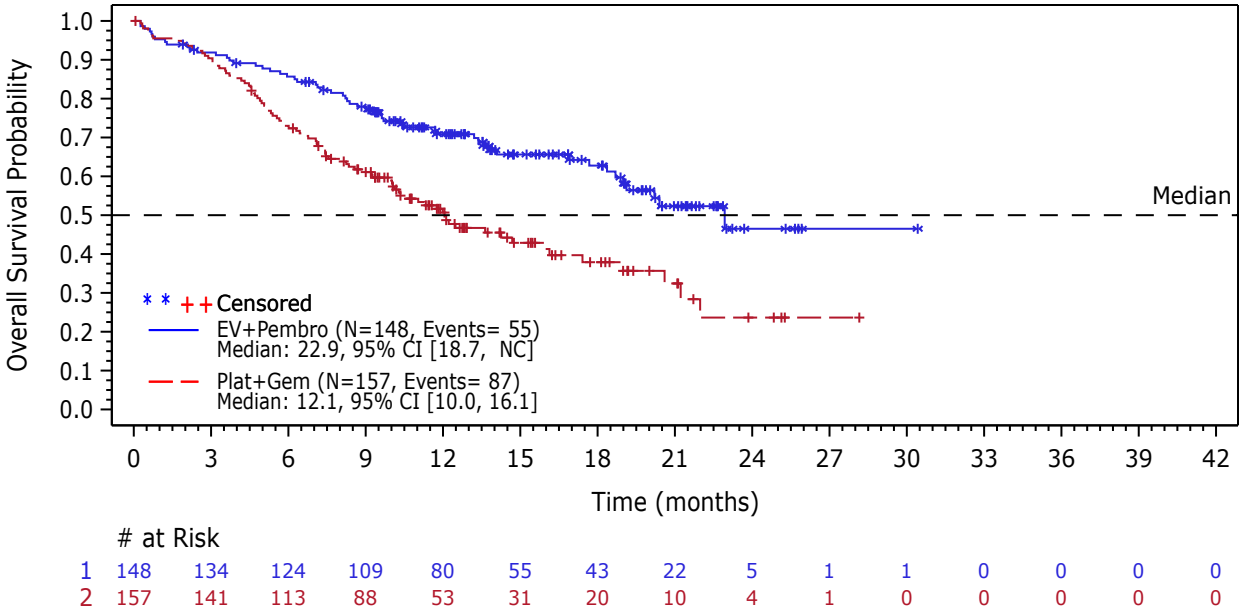
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.2.8: Kaplan-Meier Plot of Overall Survival by Metastases at Baseline - Analysis Set mITT 2 - Sensitivity Analysis 1

Metastases at Baseline: Visceral metastases



at Risk

1	148	134	124	109	80	55	43	22	5	1	1	0	0	0	0
2	157	141	113	88	53	31	20	10	4	1	0	0	0	0	0

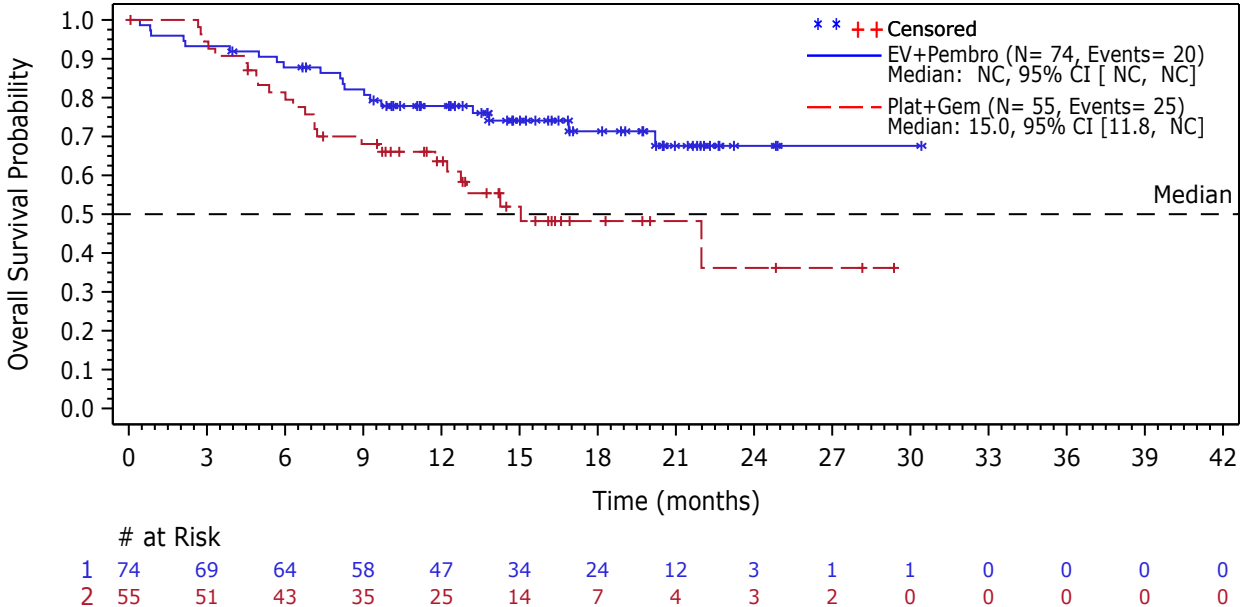
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.2.9: Kaplan-Meier Plot of Overall Survival by Primary Disease Site of Origin - Analysis Set mITT 2 - Sensitivity Analysis 1

Primary Disease Site of Origin: Upper tract



at Risk

1	74	69	64	58	47	34	24	12	3	1	1	0	0	0	0
2	55	51	43	35	25	14	7	4	3	2	0	0	0	0	0

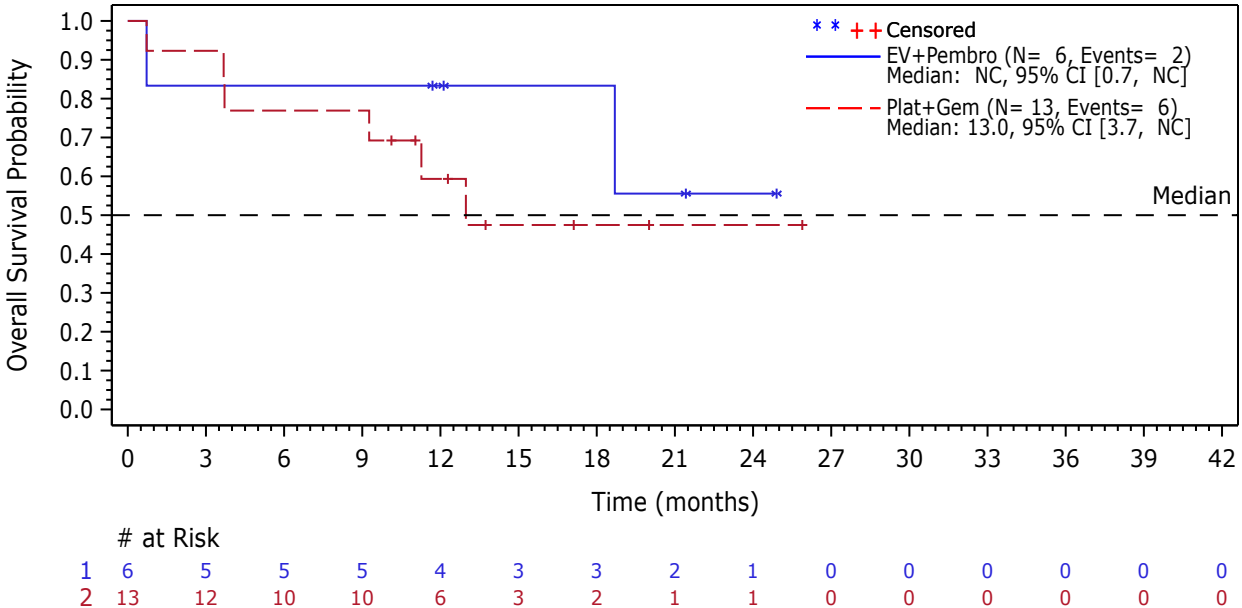
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.2.10: Kaplan-Meier Plot of Overall Survival by Renal Function - Analysis Set mITT 2 - Sensitivity Analysis 1

Renal Function: Normal



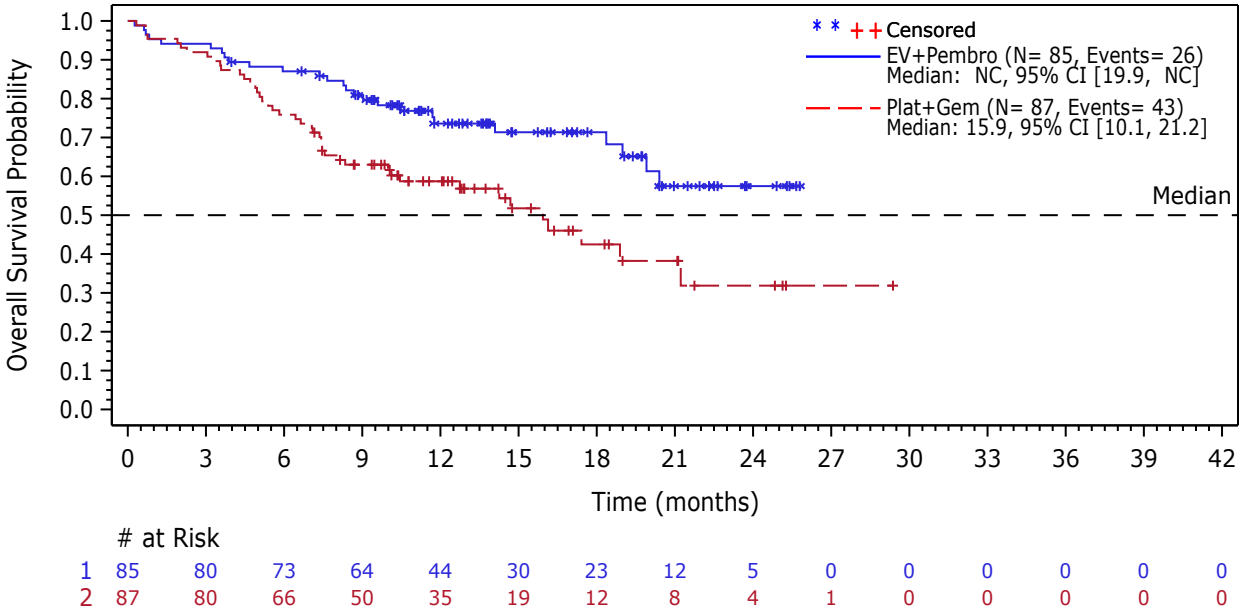
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.2.1: Kaplan-Meier Plot of Overall Survival by PD-L1 Expression - Analysis Set mITT 2 - Sensitivity Analysis 1

PD-L1 Expression: Low (CPS<10)



at Risk

1	85	80	73	64	44	30	23	12	5	0	0	0	0	0	0
2	87	80	66	50	35	19	12	8	4	1	0	0	0	0	0

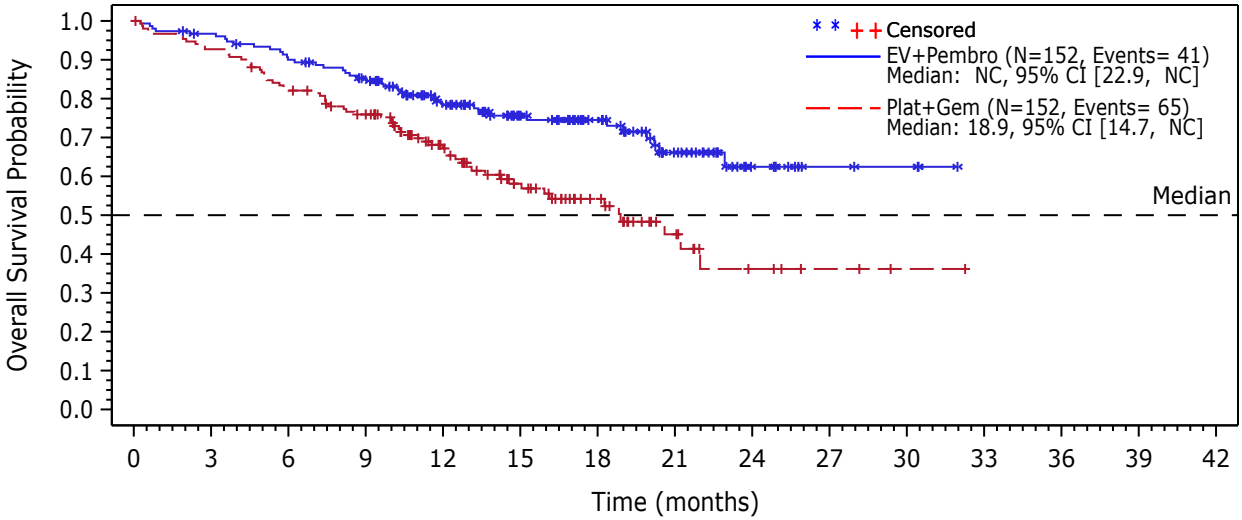
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.2.2: Kaplan-Meier Plot of Overall Survival by Liver Metastases - Analysis Set mITT 2 - Sensitivity Analysis 1

Liver Metastases: Absent



at Risk

1	152	145	134	123	95	70	53	30	11	4	3	0	0	0	0
2	152	140	124	109	74	47	30	14	6	3	1	0	0	0	0

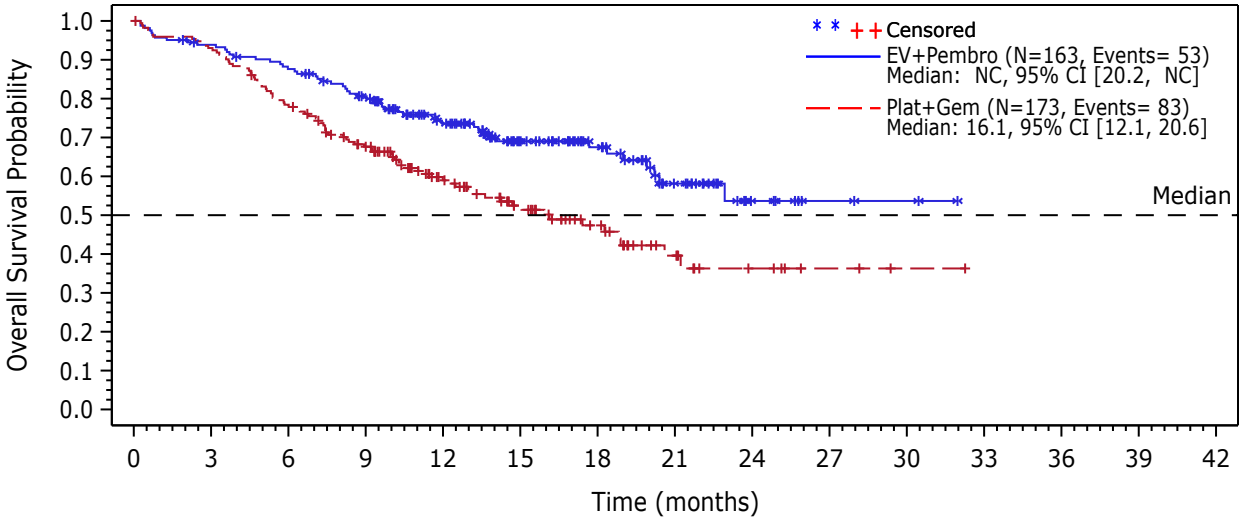
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.2.3: Kaplan-Meier Plot of Overall Survival by Age - Analysis Set mITT 2 - Sensitivity Analysis 1

Age: >= 65 years



at Risk

1	163	151	140	124	95	63	44	24	8	3	2	0	0	0	0
2	173	160	134	108	71	48	30	15	7	3	1	0	0	0	0

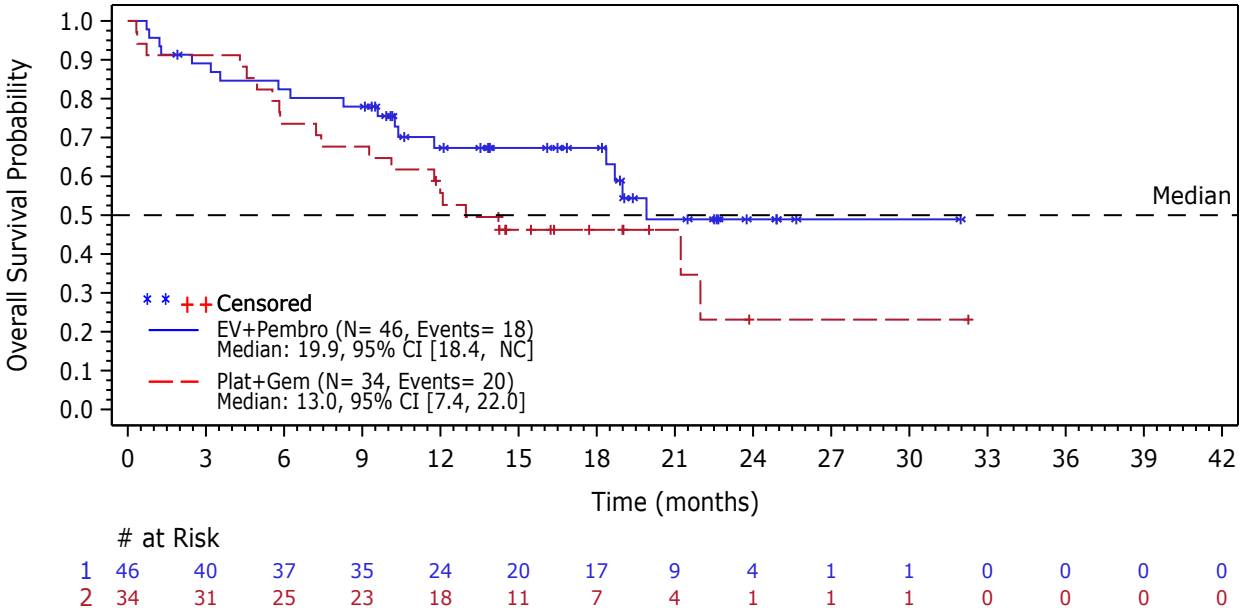
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.2.4: Kaplan-Meier Plot of Overall Survival by Region - Analysis Set mITT 2 - Sensitivity Analysis 1

Region: North America



at Risk

1	46	40	37	35	24	20	17	9	4	1	1	0	0	0	0
2	34	31	25	23	18	11	7	4	1	1	1	0	0	0	0

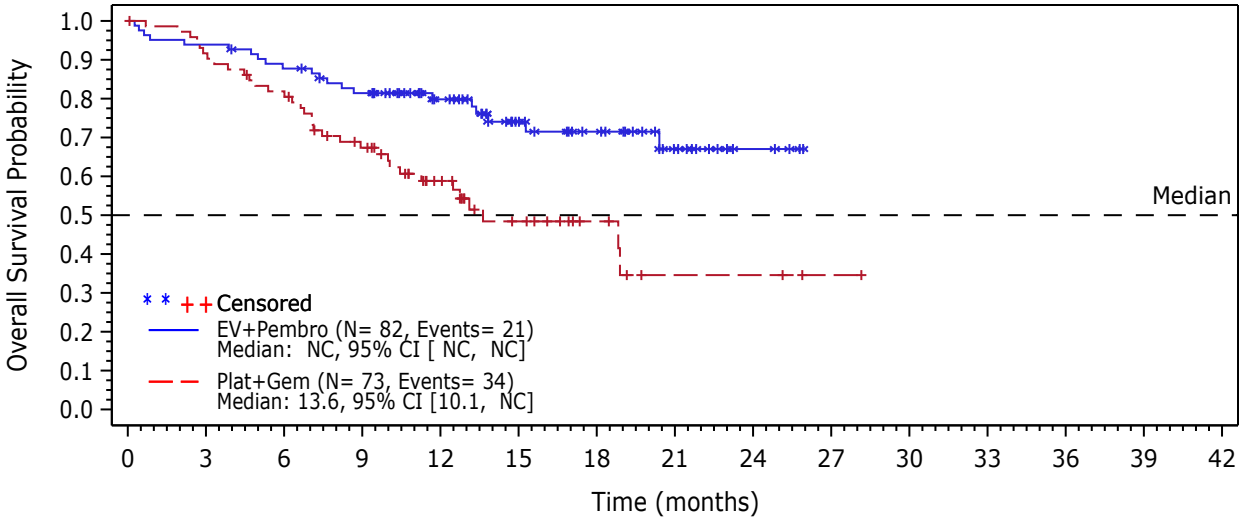
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.2.4: Kaplan-Meier Plot of Overall Survival by Region - Analysis Set mITT 2 - Sensitivity Analysis 1

Region: Rest of World



at Risk

1	82	77	71	64	48	31	23	12	4	0	0	0	0	0	0
2	73	66	58	44	28	15	8	3	3	1	0	0	0	0	0

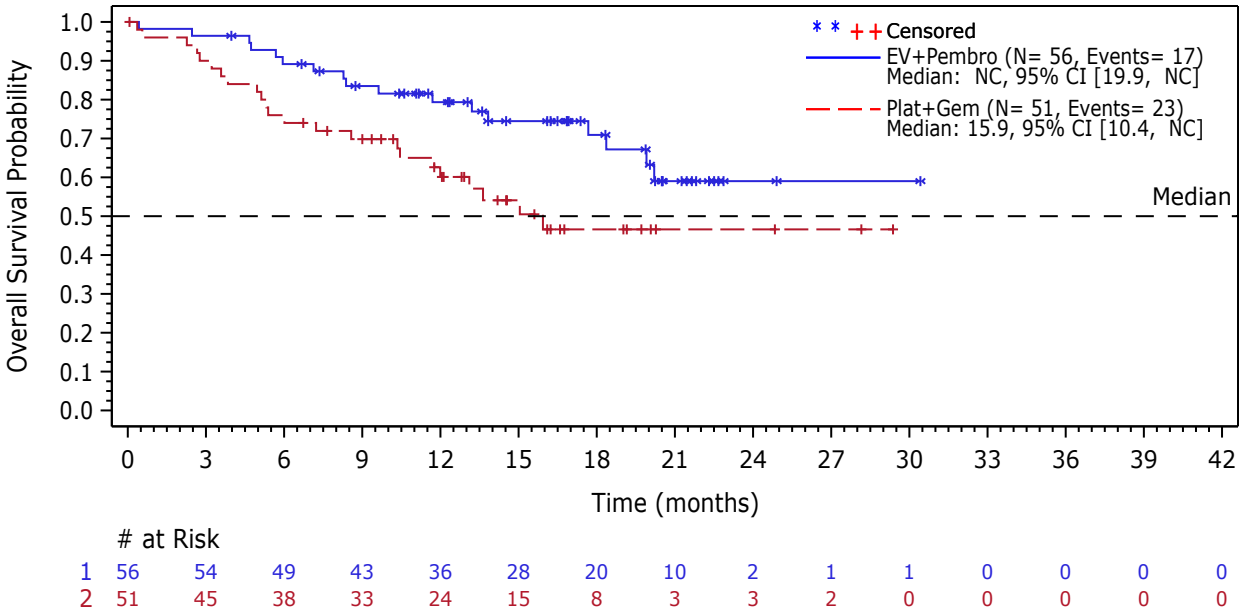
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.2.5: Kaplan-Meier Plot of Overall Survival by Sex - Analysis Set mITT 2 - Sensitivity Analysis 1

Sex: Female



at Risk

1	56	54	49	43	36	28	20	10	2	1	1	0	0	0	0
2	51	45	38	33	24	15	8	3	3	2	0	0	0	0	0

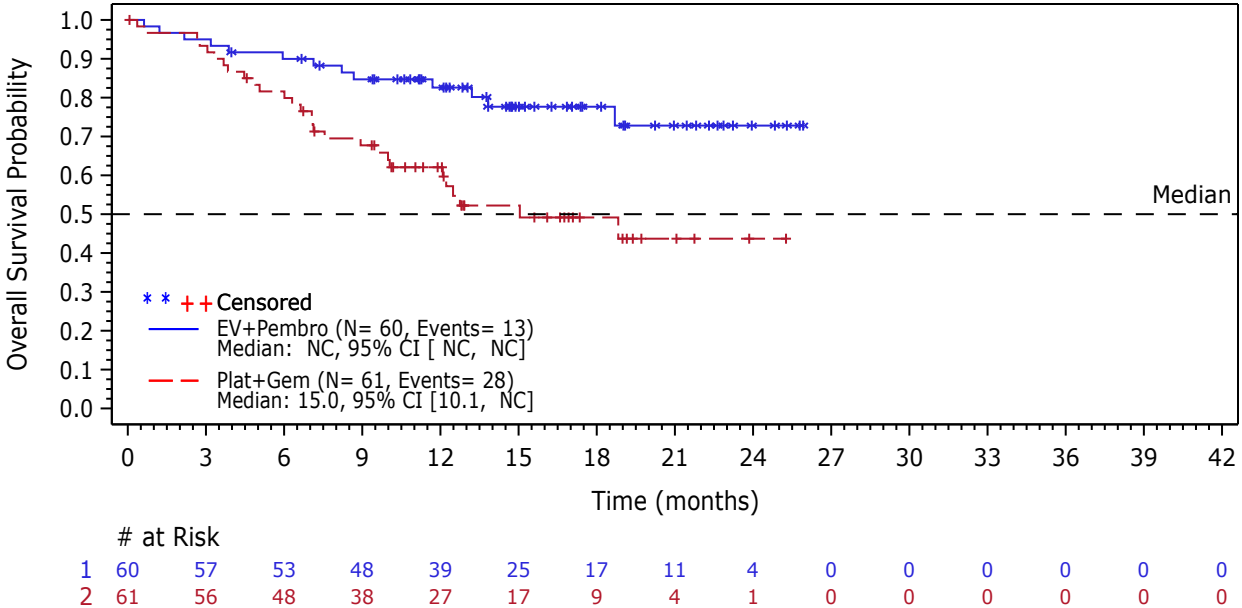
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.2.6: Kaplan-Meier Plot of Overall Survival by Race - Analysis Set mITT 2 - Sensitivity Analysis 1

Race: Non-white



at Risk

1	60	57	53	48	39	25	17	11	4	0	0	0	0	0	0
2	61	56	48	38	27	17	9	4	1	0	0	0	0	0	0

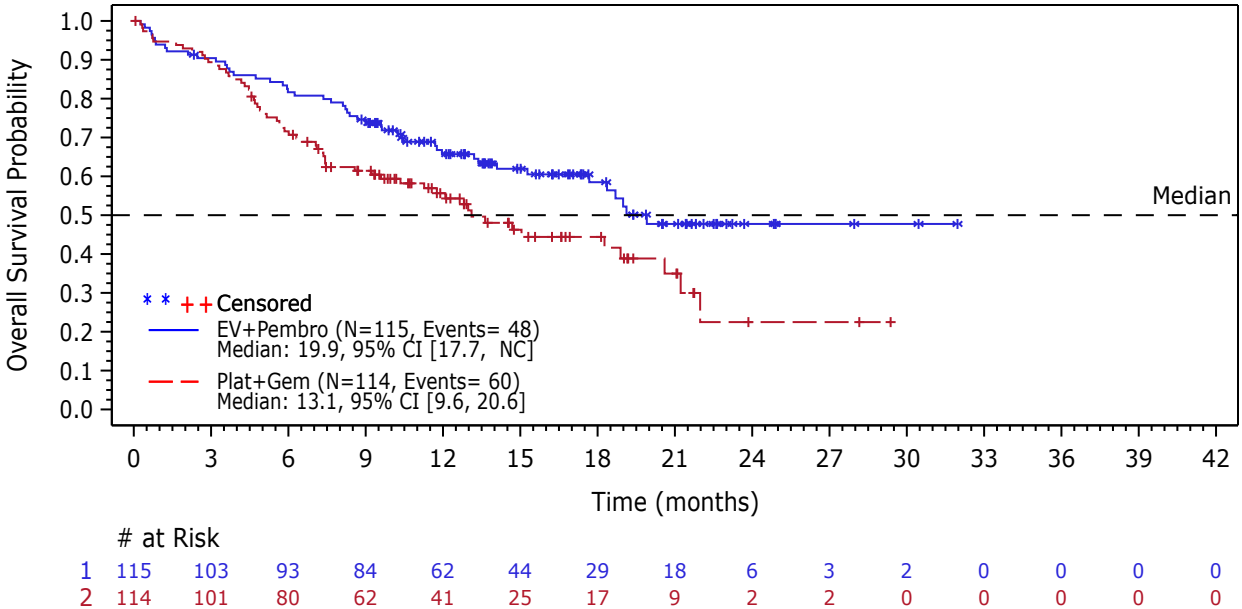
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.2.7: Kaplan-Meier Plot of Overall Survival by ECOG Status at Baseline - Analysis Set mITT 2 - Sensitivity Analysis 1

ECOG Status at Baseline: 1-2



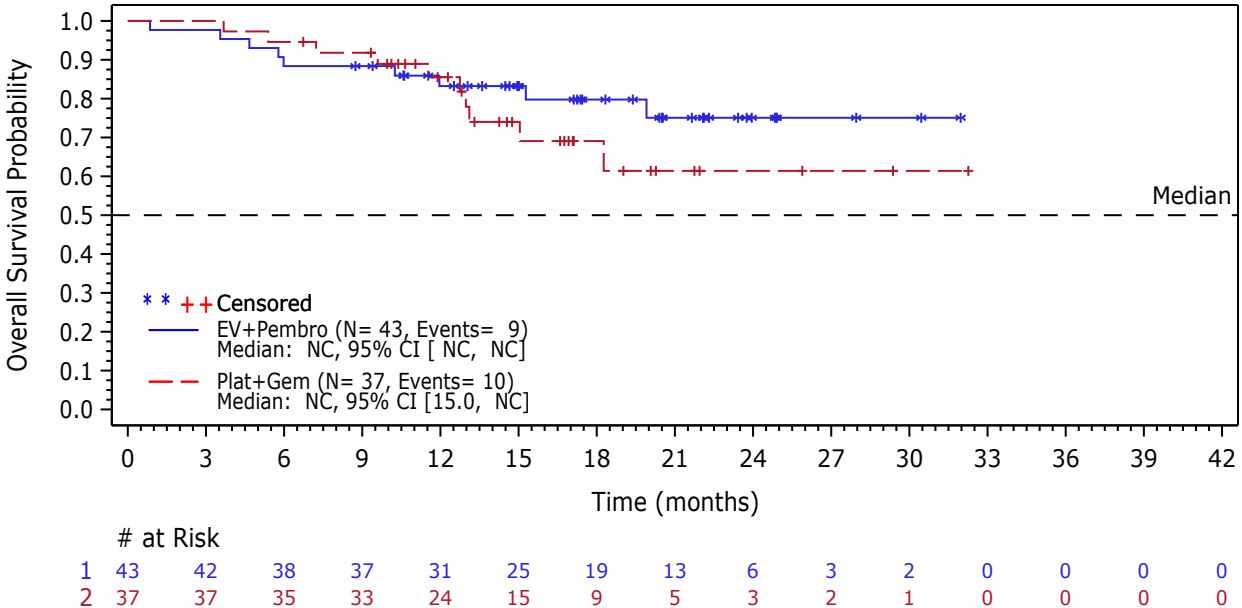
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.2.8: Kaplan-Meier Plot of Overall Survival by Metastases at Baseline - Analysis Set mITT 2 - Sensitivity Analysis 1

Metastases at Baseline: Lymph node only



at Risk

1	43	42	38	37	31	25	19	13	6	3	2	0	0	0	0
2	37	37	35	33	24	15	9	5	3	2	1	0	0	0	0

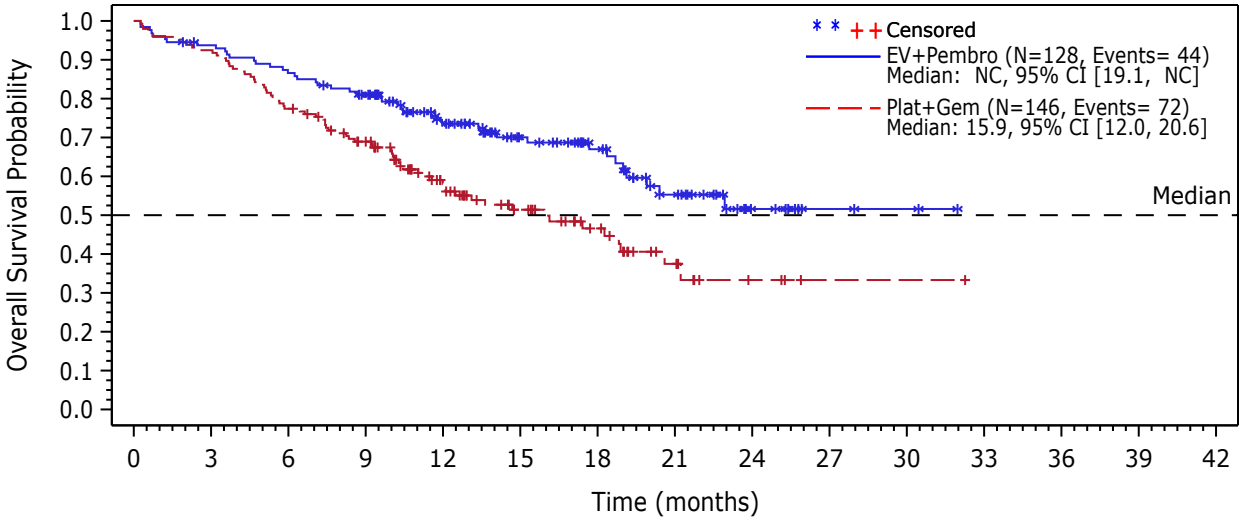
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.2.9: Kaplan-Meier Plot of Overall Survival by Primary Disease Site of Origin - Analysis Set mITT 2 - Sensitivity Analysis 1

Primary Disease Site of Origin: Lower tract



at Risk

1	128	118	109	99	73	52	39	24	9	3	2	0	0	0	0
2	146	135	113	94	59	38	25	12	4	1	1	0	0	0	0

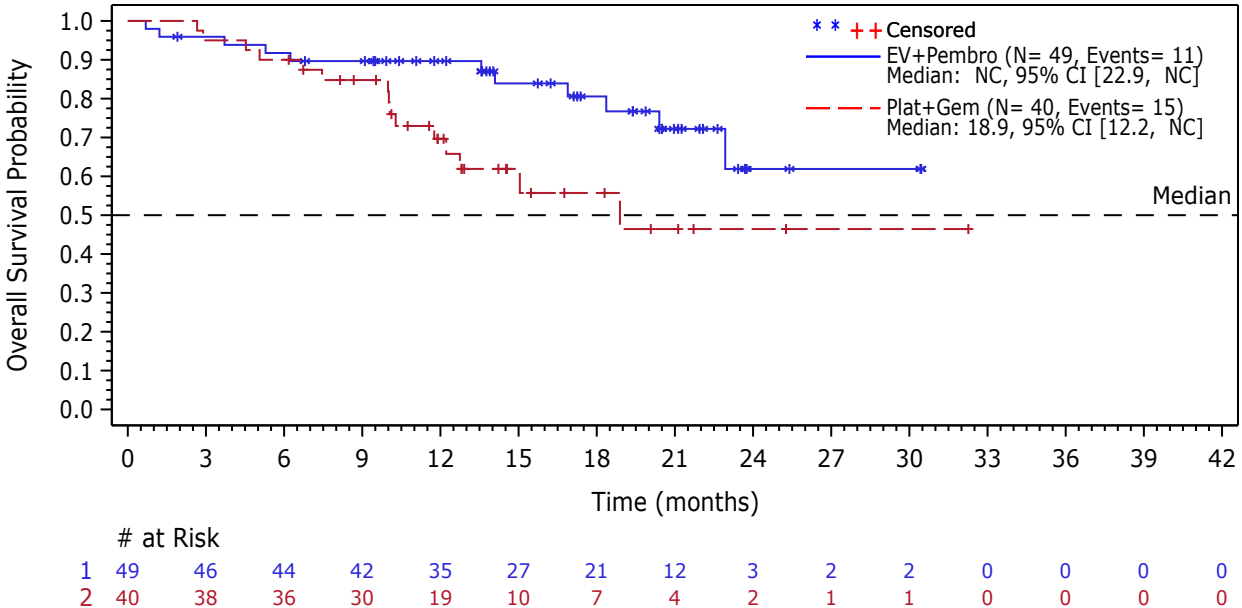
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.2.10: Kaplan-Meier Plot of Overall Survival by Renal Function - Analysis Set mITT 2 - Sensitivity Analysis 1

Renal Function: Mild



at Risk

1	49	46	44	42	35	27	21	12	3	2	2	0	0	0	0
2	40	38	36	30	19	10	7	4	2	1	1	0	0	0	0

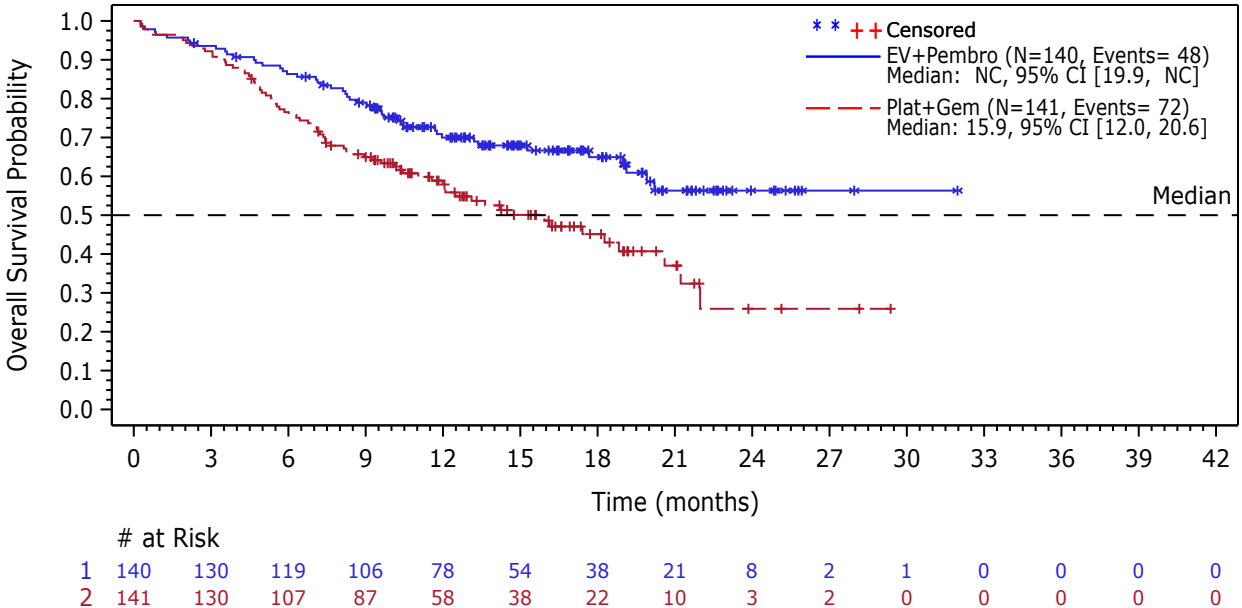
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.2.10: Kaplan-Meier Plot of Overall Survival by Renal Function - Analysis Set mITT 2 - Sensitivity Analysis 1

Renal Function: Moderate



at Risk

1	140	130	119	106	78	54	38	21	8	2	1	0	0	0	0
2	141	130	107	87	58	38	22	10	3	2	0	0	0	0	0

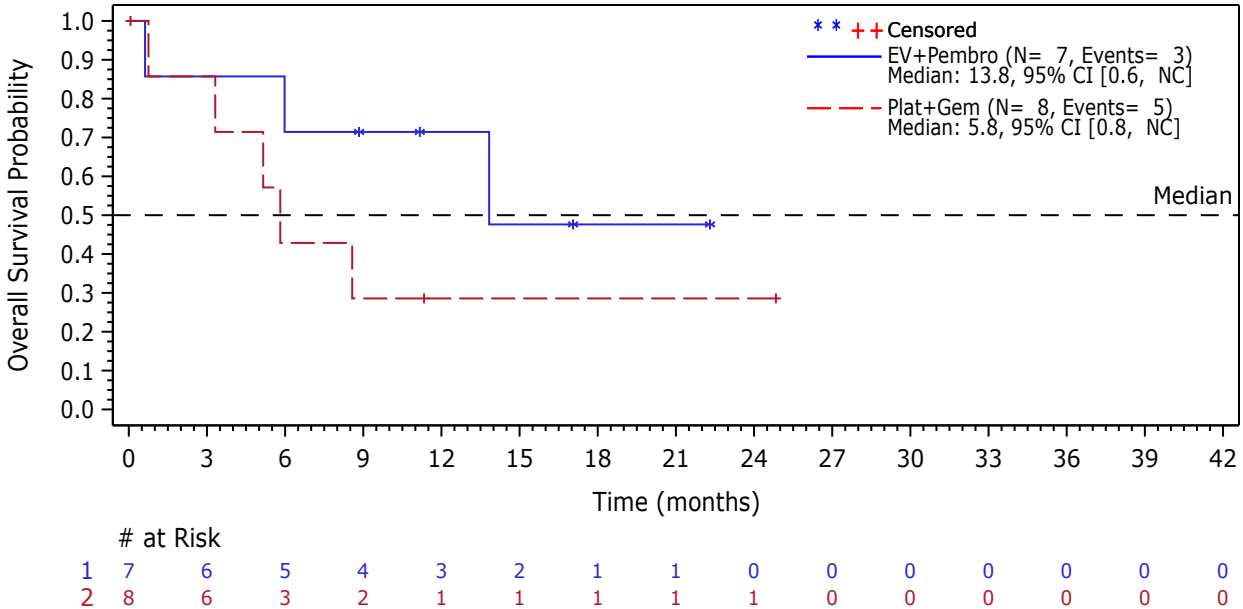
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.2.2.10: Kaplan-Meier Plot of Overall Survival by Renal Function - Analysis Set mITT 2 - Sensitivity Analysis 1

Renal Function: Severe

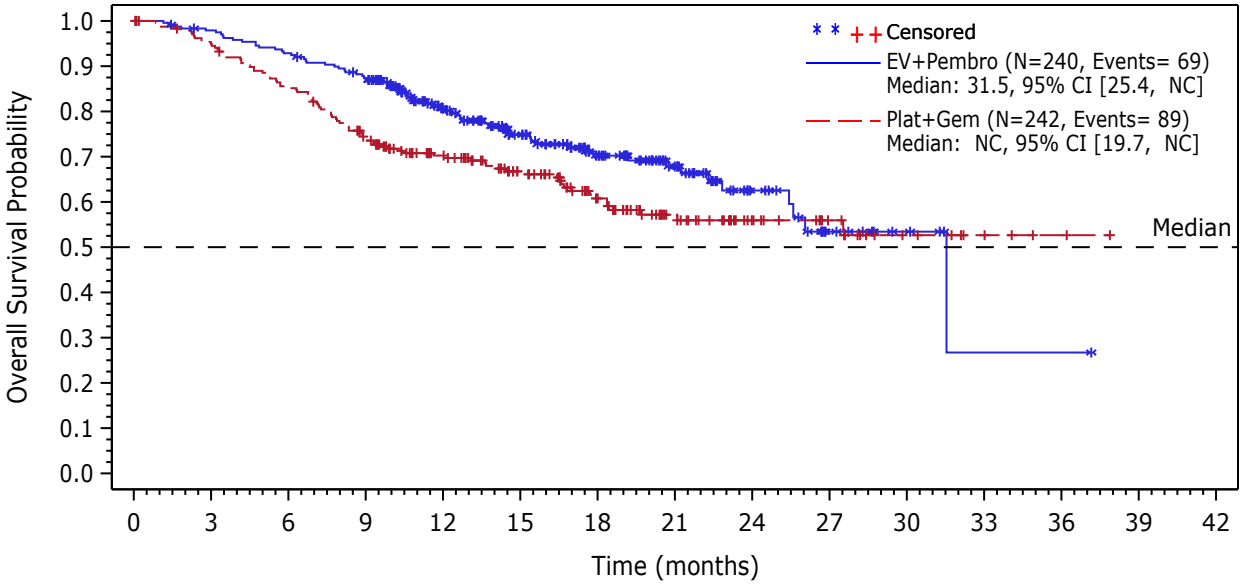


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of death.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.1: Kaplan-Meier Plot of Overall Survival - Analysis Set mITT 1 - Sensitivity Analysis 2



at Risk

1	240	233	221	206	150	112	78	49	24	11	5	1	1	0	0
2	242	224	200	169	131	102	73	46	27	18	9	5	2	0	0

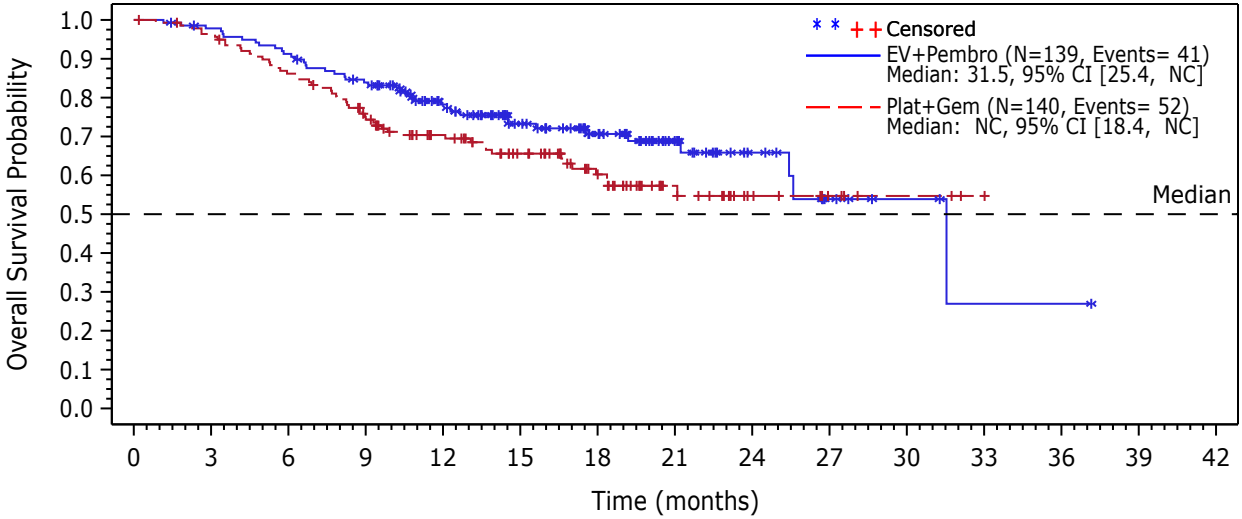
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.1.1: Kaplan-Meier Plot of Overall Survival by PD-L1 Expression - Analysis Set mITT 1 - Sensitivity Analysis 2

PD-L1 Expression: High (CPS>=10)



at Risk

1	139	134	125	113	87	64	47	26	13	6	3	1	1	0	0
2	140	133	118	99	78	61	42	22	11	6	3	1	0	0	0

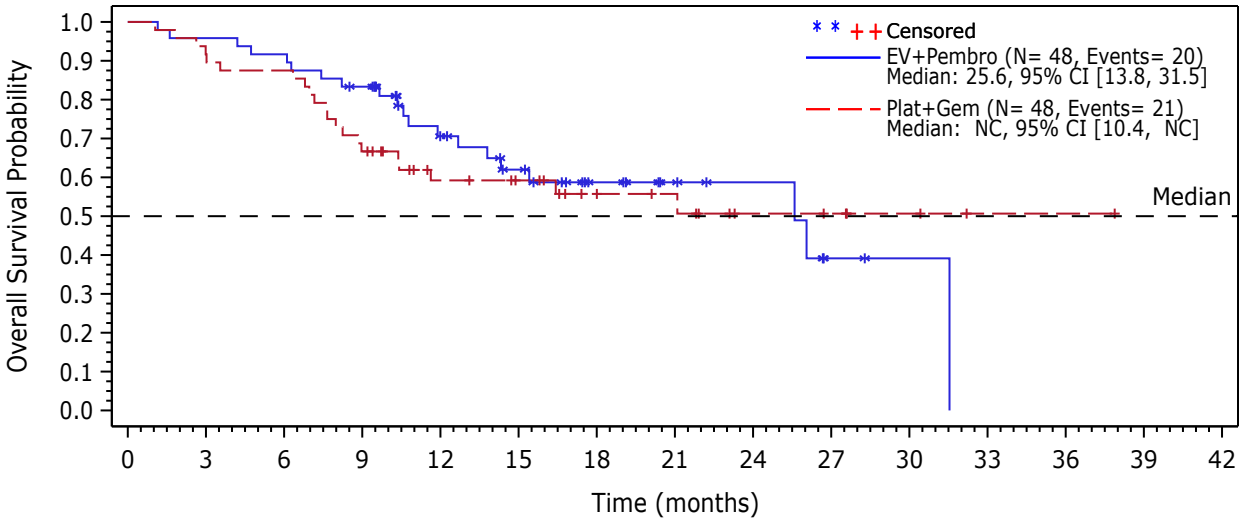
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.1.2: Kaplan-Meier Plot of Overall Survival by Liver Metastases - Analysis Set mITT 1 - Sensitivity Analysis 2

Liver Metastases: Present



at Risk

1	48	46	44	39	26	20	12	8	6	2	1	0	0	0	0
2	48	44	42	32	22	19	13	11	6	5	3	1	1	0	0

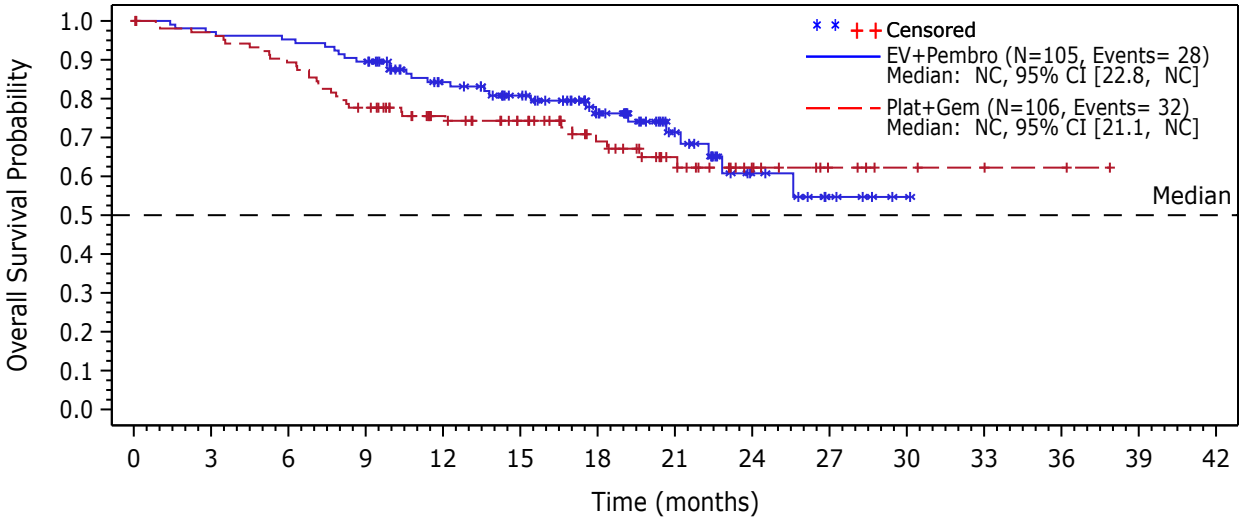
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.1.3: Kaplan-Meier Plot of Overall Survival by Age - Analysis Set mITT 1 - Sensitivity Analysis 2

Age: < 65 years



at Risk

1	105	102	100	94	75	64	45	24	11	5	1	0	0	0	0
2	106	100	92	79	62	52	37	24	13	7	4	3	2	0	0

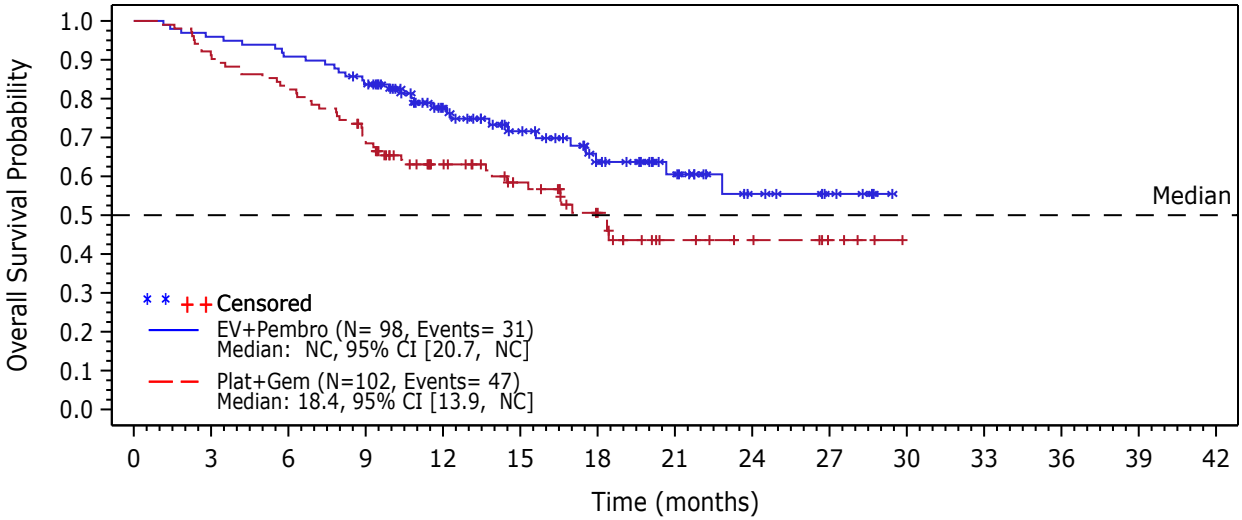
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.1.4: Kaplan-Meier Plot of Overall Survival by Region - Analysis Set mITT 1 - Sensitivity Analysis 2

Region: Europe



at Risk

1	98	94	89	81	56	42	29	19	9	5	0	0	0	0	0
2	102	93	84	69	47	34	23	11	8	4	0	0	0	0	0

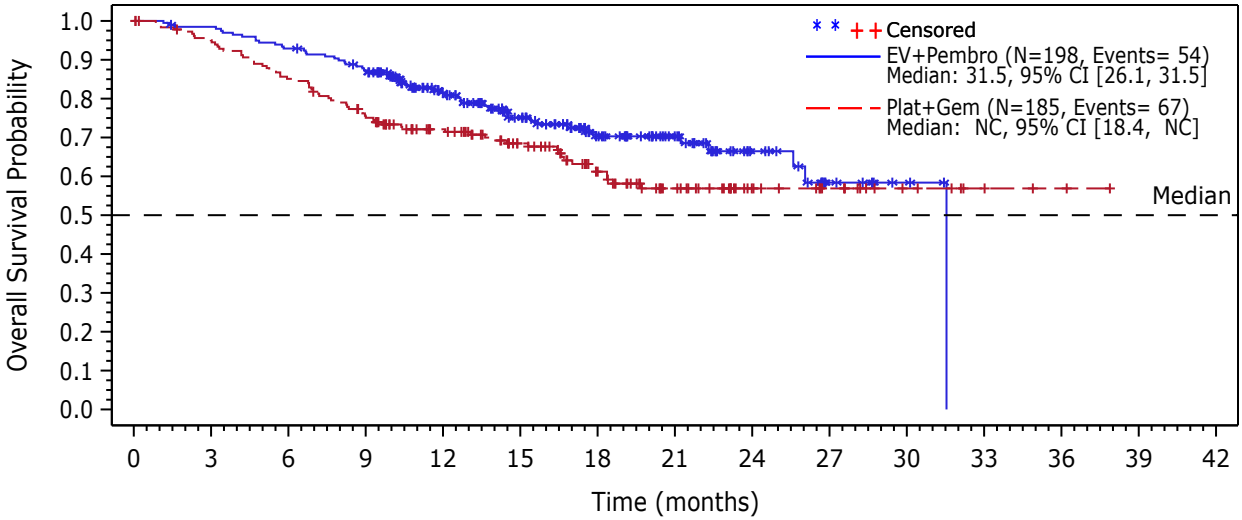
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.1.5: Kaplan-Meier Plot of Overall Survival by Sex - Analysis Set mITT 1 - Sensitivity Analysis 2

Sex: Male



at Risk

1	198	194	183	170	126	94	63	42	20	8	3	0	0	0	0
2	185	172	154	134	107	84	61	40	22	15	8	4	2	0	0

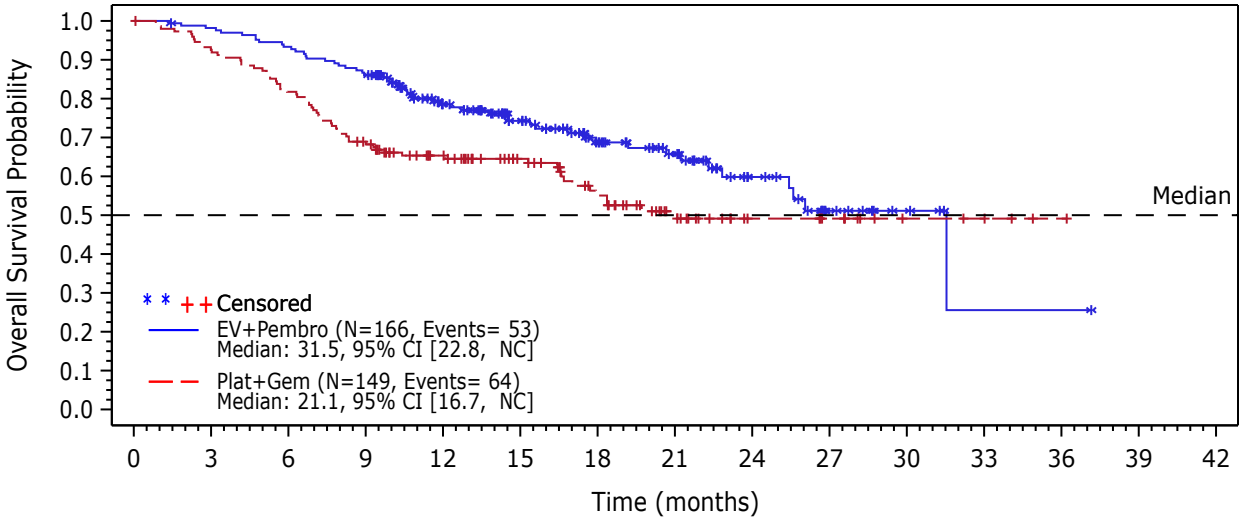
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.1.6: Kaplan-Meier Plot of Overall Survival by Race - Analysis Set mITT 1 - Sensitivity Analysis 2

Race: White



at Risk

1	166	162	154	142	103	77	55	41	23	11	5	1	1	0	0
2	149	137	121	100	79	61	44	27	14	11	5	4	1	0	0

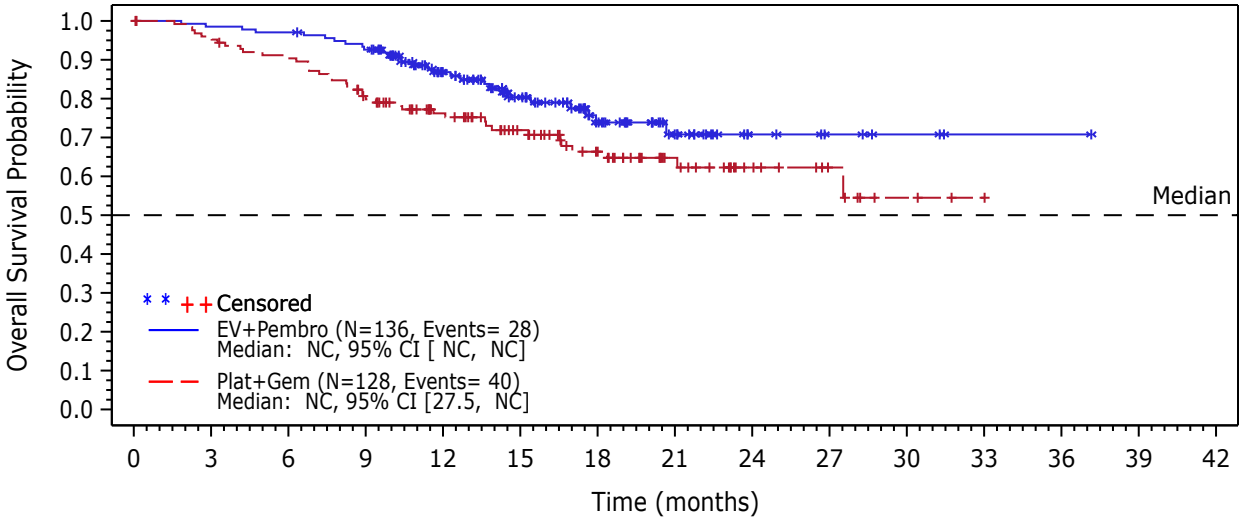
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.1.7: Kaplan-Meier Plot of Overall Survival by ECOG Status at Baseline - Analysis Set mITT 1 - Sensitivity Analysis 2

ECOG Status at Baseline: 0



at Risk

1	136	134	132	125	90	64	39	21	8	5	3	1	1	0	0
2	128	120	112	97	76	59	43	26	14	8	3	1	0	0	0

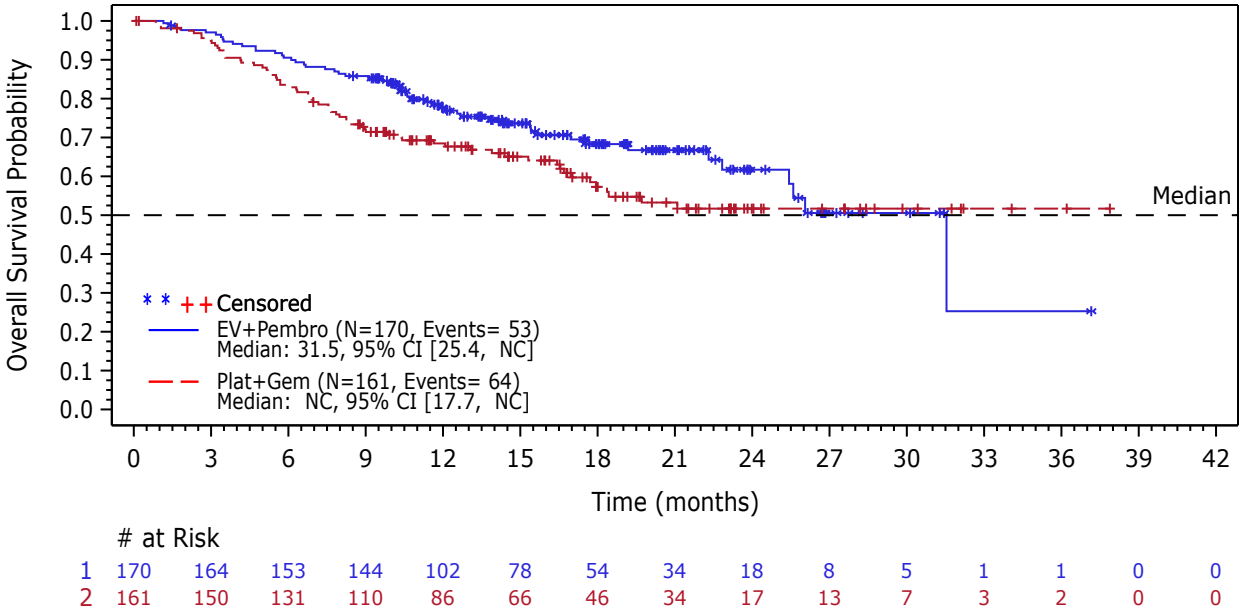
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.1.8: Kaplan-Meier Plot of Overall Survival by Metastases at Baseline - Analysis Set mITT 1 - Sensitivity Analysis 2

Metastases at Baseline: Visceral metastases



at Risk

1	170	164	153	144	102	78	54	34	18	8	5	1	1	0	0
2	161	150	131	110	86	66	46	34	17	13	7	3	2	0	0

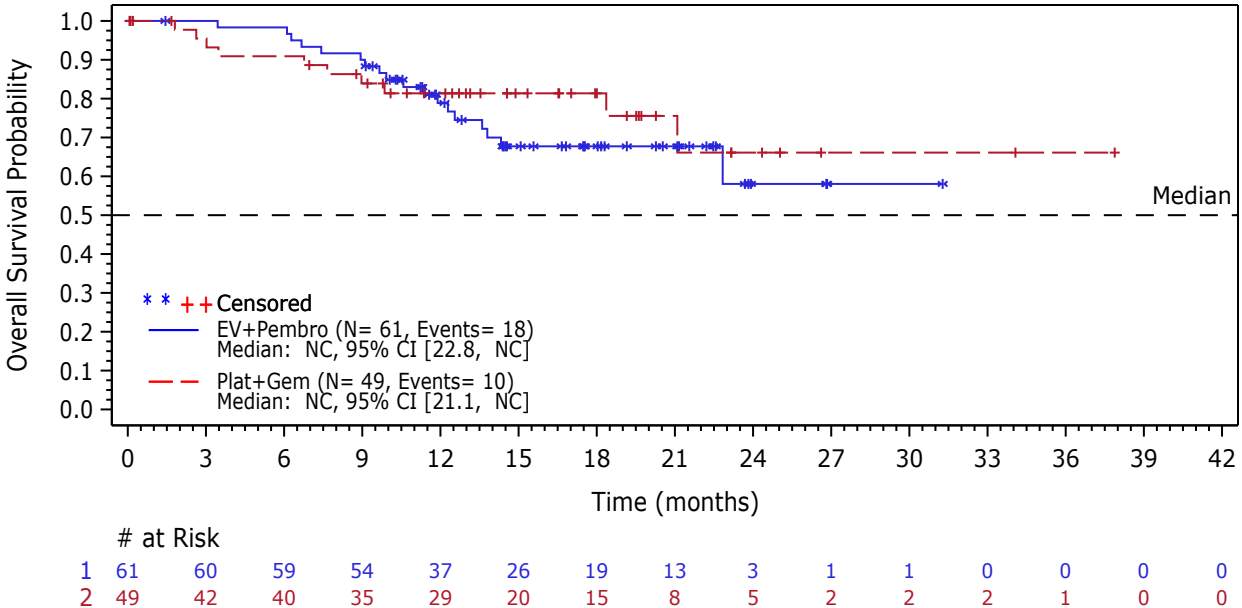
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.1.9: Kaplan-Meier Plot of Overall Survival by Primary Disease Site of Origin - Analysis Set mITT 1 - Sensitivity Analysis 2

Primary Disease Site of Origin: Upper tract



at Risk

1	61	60	59	54	37	26	19	13	3	1	1	0	0	0	0
2	49	42	40	35	29	20	15	8	5	2	2	2	1	0	0

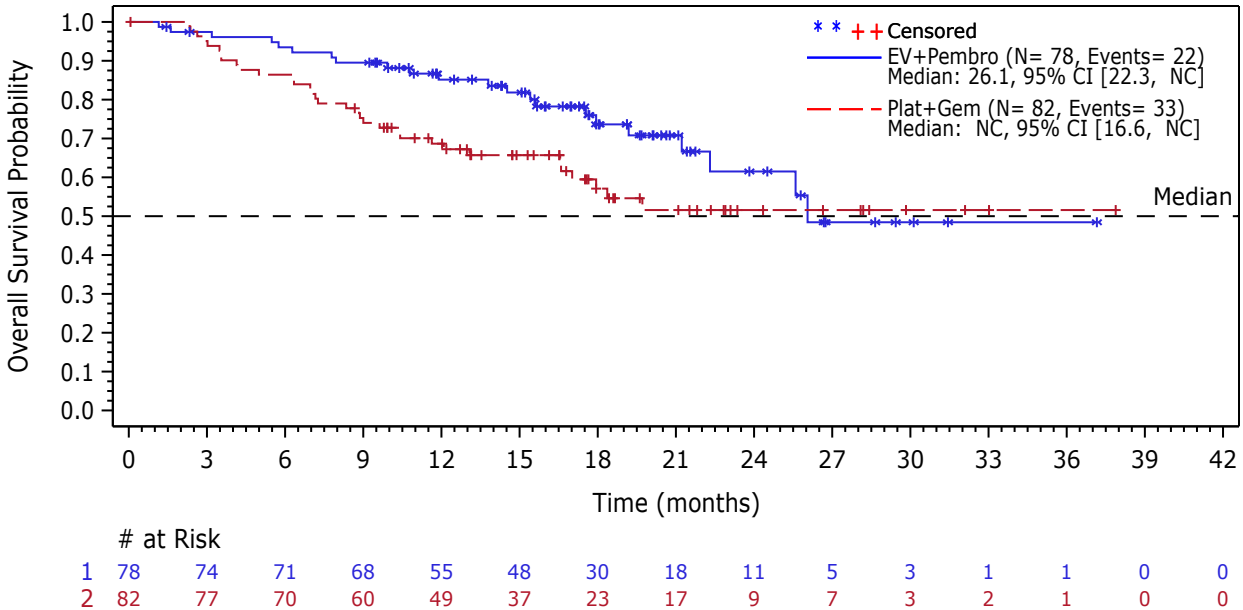
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.1.10: Kaplan-Meier Plot of Overall Survival by Renal Function - Analysis Set mITT 1 - Sensitivity Analysis 2

Renal Function: Normal



at Risk

1	78	74	71	68	55	48	30	18	11	5	3	1	1	0	0
2	82	77	70	60	49	37	23	17	9	7	3	2	1	0	0

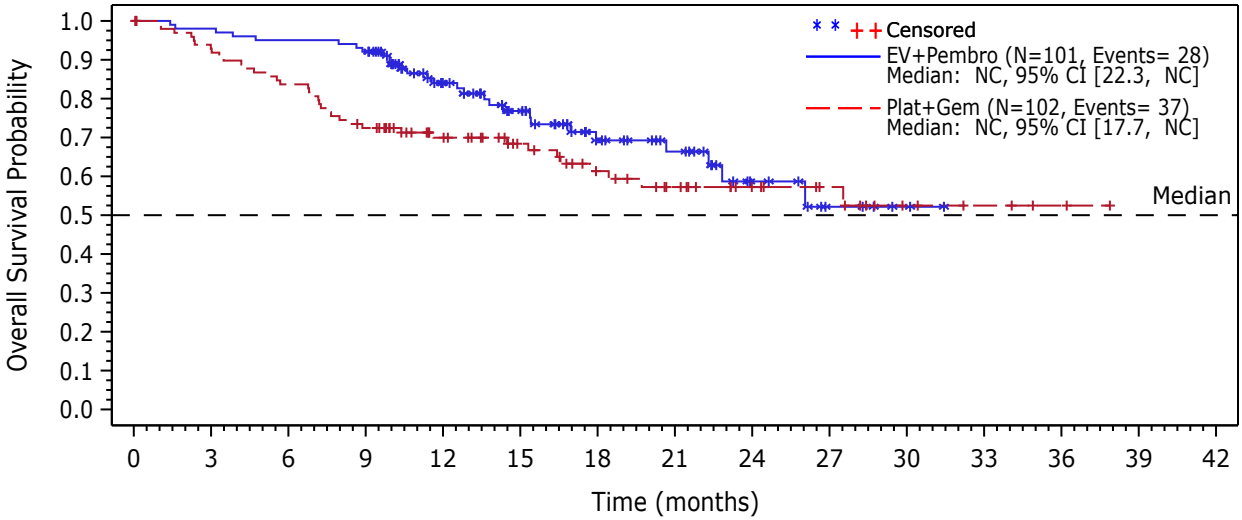
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.1.1: Kaplan-Meier Plot of Overall Survival by PD-L1 Expression - Analysis Set mITT 1 - Sensitivity Analysis 2

PD-L1 Expression: Low (CPS<10)



at Risk

1	101	99	96	93	63	48	31	23	11	5	2	0	0	0	0
2	102	91	82	70	53	41	31	24	16	12	6	4	2	0	0

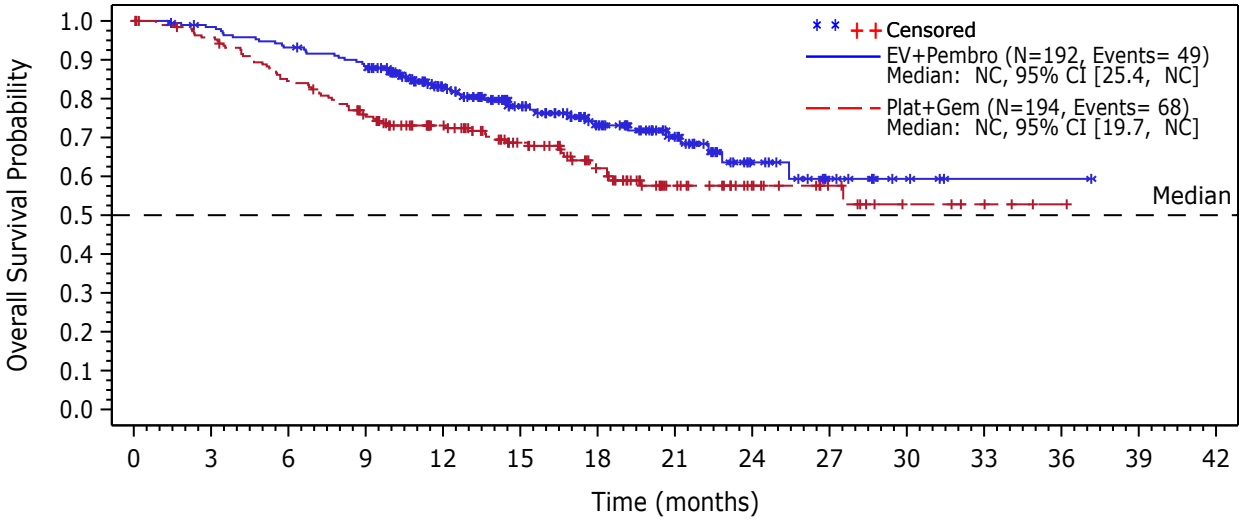
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.1.2: Kaplan-Meier Plot of Overall Survival by Liver Metastases - Analysis Set mITT 1 - Sensitivity Analysis 2

Liver Metastases: Absent



at Risk

1	192	187	177	167	124	92	66	41	18	9	4	1	1	0	0
2	194	180	158	137	109	83	60	35	21	13	6	4	1	0	0

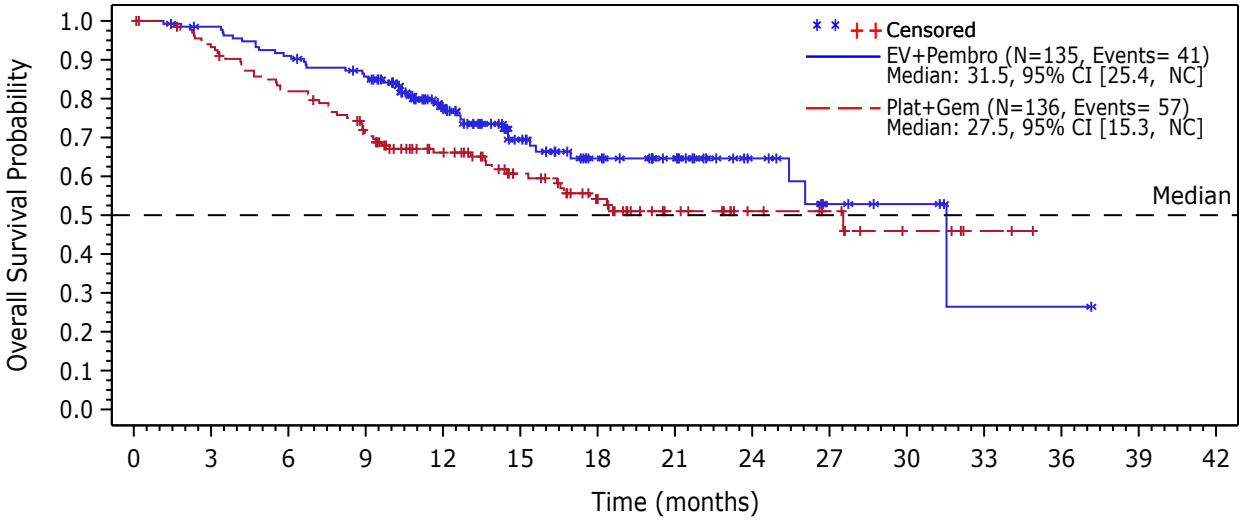
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.1.3: Kaplan-Meier Plot of Overall Survival by Age - Analysis Set mITT 1 - Sensitivity Analysis 2

Age: >= 65 years



at Risk

1	135	131	121	112	75	48	33	25	13	6	4	1	1	0	0
2	136	124	108	90	69	50	36	22	14	11	5	2	0	0	0

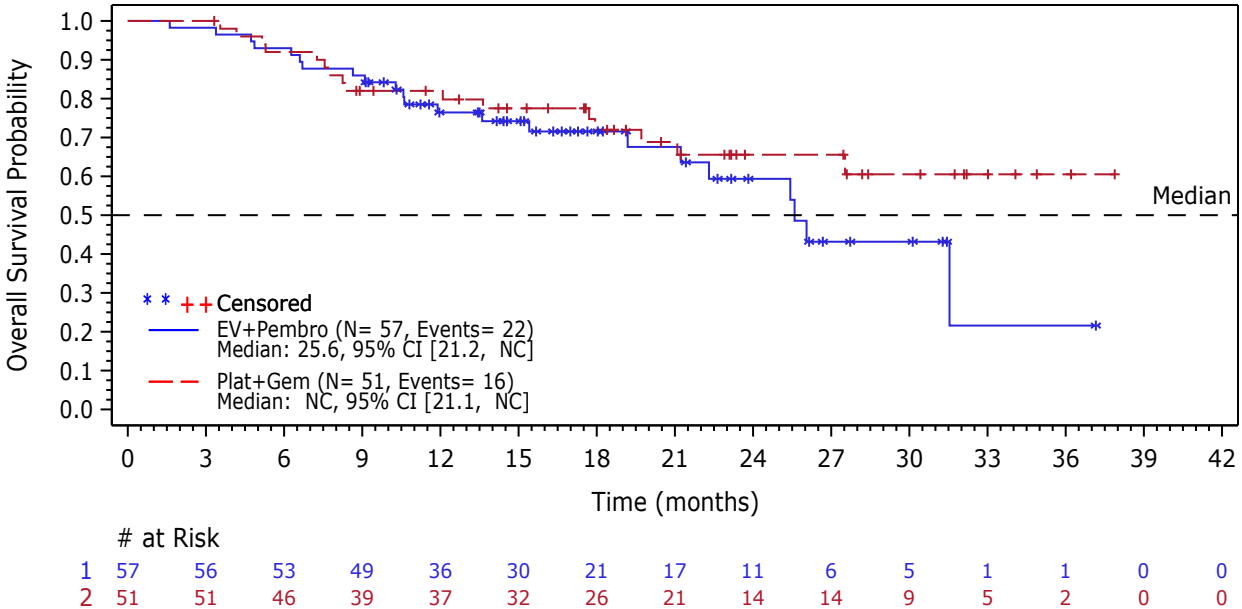
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.1.4: Kaplan-Meier Plot of Overall Survival by Region - Analysis Set mITT 1 - Sensitivity Analysis 2

Region: North America



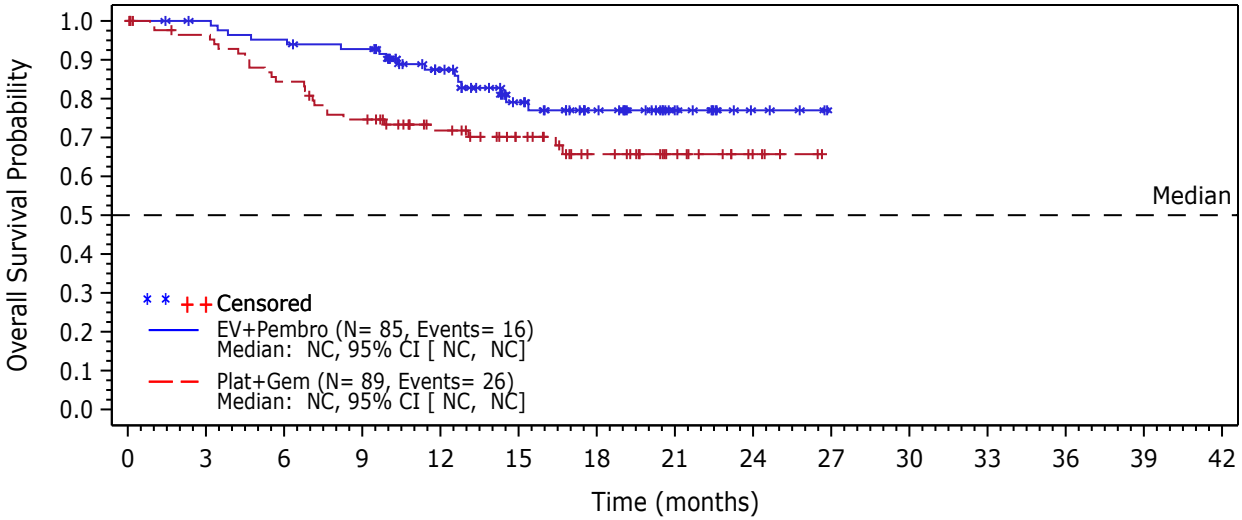
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.1.4: Kaplan-Meier Plot of Overall Survival by Region - Analysis Set mITT 1 - Sensitivity Analysis 2

Region: Rest of World



at Risk

1	85	83	79	76	58	40	28	13	4	0	0	0	0	0	0
2	89	80	70	61	47	36	24	14	5	0	0	0	0	0	0

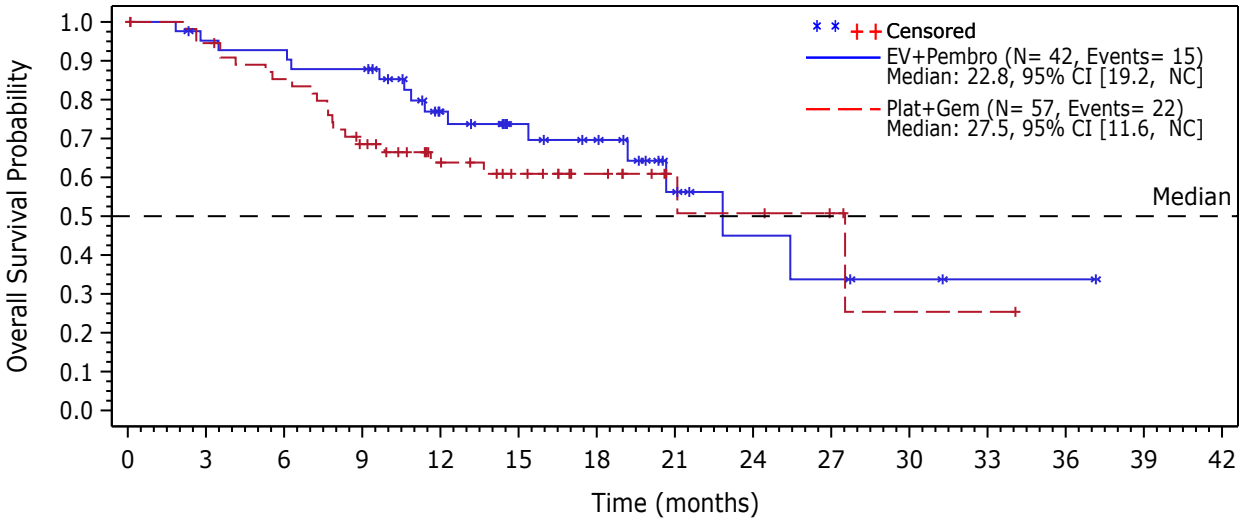
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.1.5: Kaplan-Meier Plot of Overall Survival by Sex - Analysis Set mITT 1 - Sensitivity Analysis 2

Sex: Female



at Risk

1	42	39	38	36	24	18	15	7	4	3	2	1	1	0	0
2	57	52	46	35	24	18	12	6	5	3	1	1	0	0	0

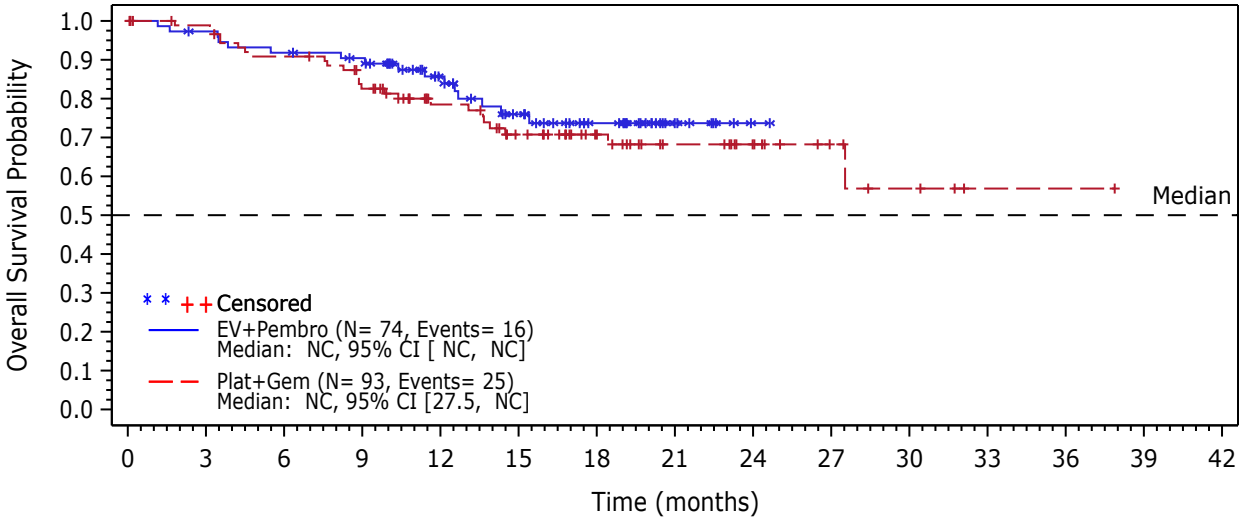
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.1.6: Kaplan-Meier Plot of Overall Survival by Race - Analysis Set mITT 1 - Sensitivity Analysis 2

Race: Non-white



at Risk

1	74	71	67	64	47	35	23	8	1	0	0	0	0	0	0
2	93	87	79	69	52	41	29	19	13	7	4	1	1	0	0

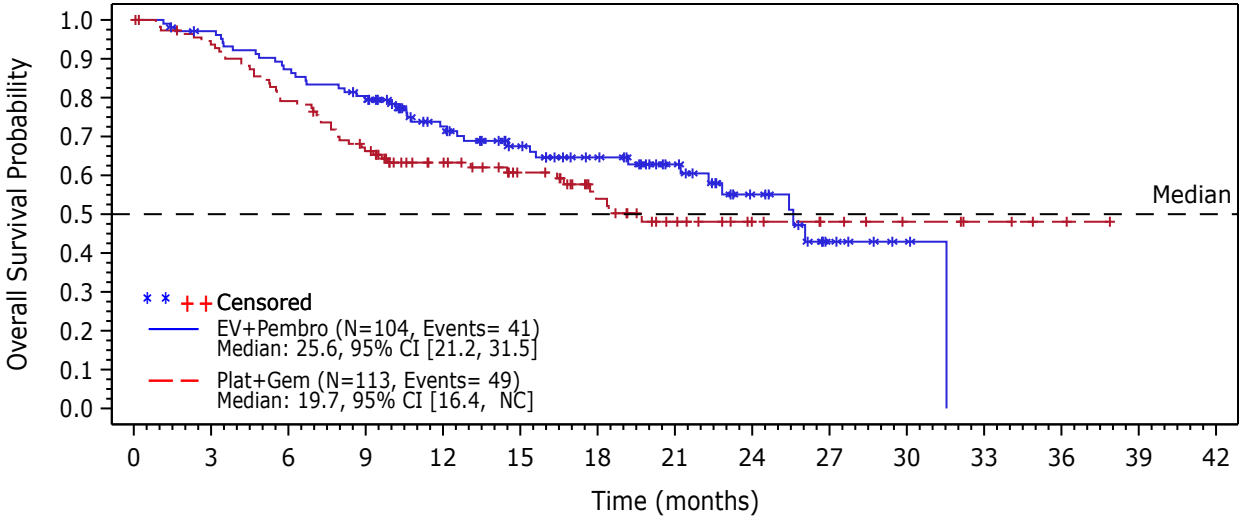
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.1.7: Kaplan-Meier Plot of Overall Survival by ECOG Status at Baseline - Analysis Set mITT 1 - Sensitivity Analysis 2

ECOG Status at Baseline: 1-2



at Risk

1	104	99	89	81	60	48	39	28	16	6	2	0	0	0	0
2	113	103	87	71	54	42	29	19	12	9	6	4	2	0	0

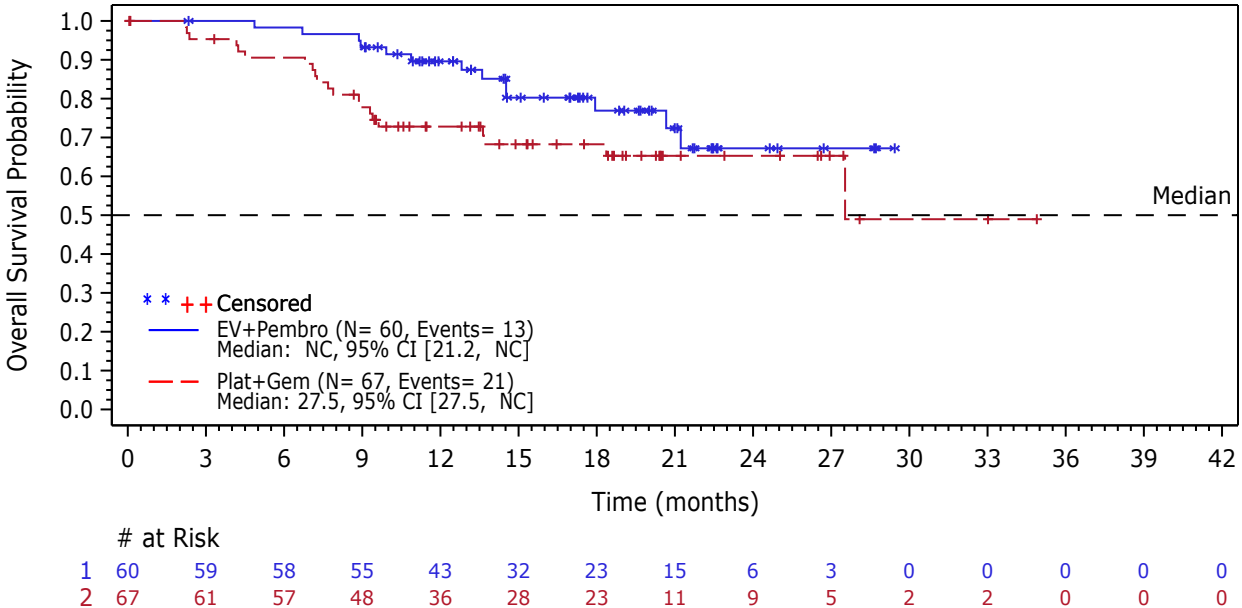
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.1.8: Kaplan-Meier Plot of Overall Survival by Metastases at Baseline - Analysis Set mITT 1 - Sensitivity Analysis 2

Metastases at Baseline: Lymph node only



at Risk

1	60	59	58	55	43	32	23	15	6	3	0	0	0	0	0
2	67	61	57	48	36	28	23	11	9	5	2	2	0	0	0

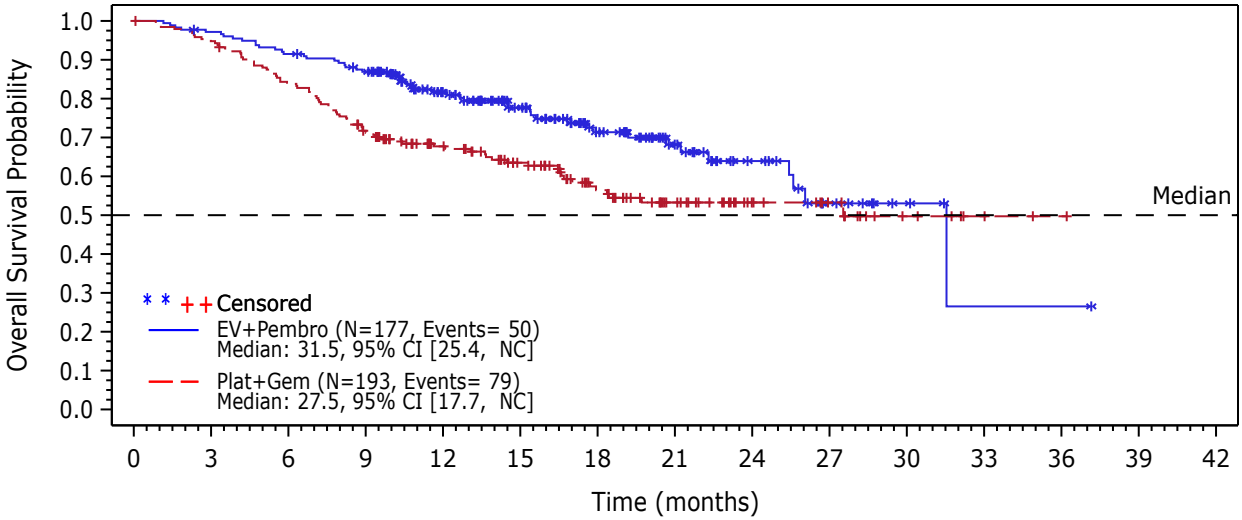
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.1.9: Kaplan-Meier Plot of Overall Survival by Primary Disease Site of Origin - Analysis Set mITT 1 - Sensitivity Analysis 2

Primary Disease Site of Origin: Lower tract



at Risk

1	177	171	161	151	112	85	59	36	21	10	4	1	1	0	0
2	193	182	160	134	102	82	58	38	22	16	7	3	1	0	0

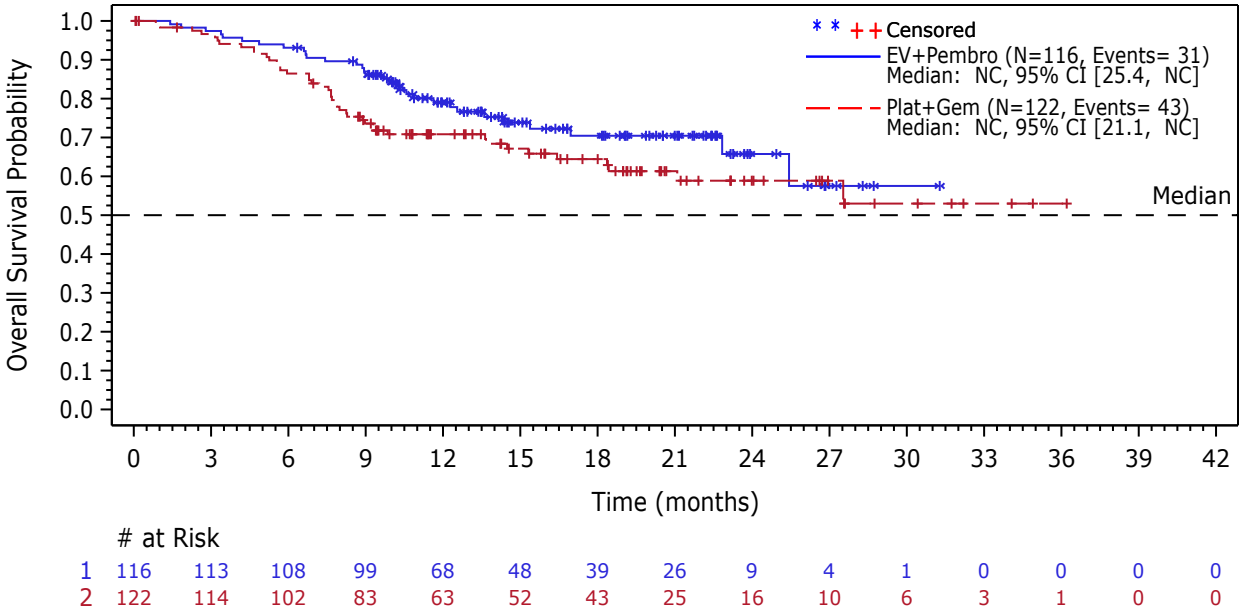
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.1.10: Kaplan-Meier Plot of Overall Survival by Renal Function - Analysis Set mITT 1 - Sensitivity Analysis 2

Renal Function: Mild



at Risk

1	116	113	108	99	68	48	39	26	9	4	1	0	0	0	0
2	122	114	102	83	63	52	43	25	16	10	6	3	1	0	0

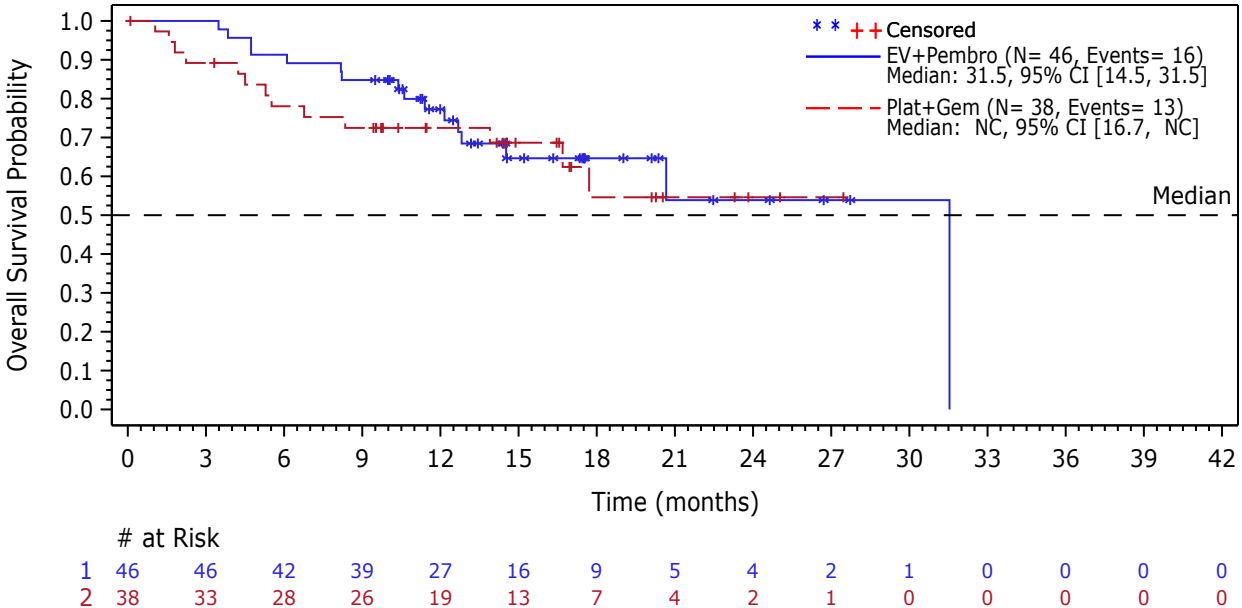
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.1.10: Kaplan-Meier Plot of Overall Survival by Renal Function - Analysis Set mITT 1 - Sensitivity Analysis 2

Renal Function: Moderate



at Risk

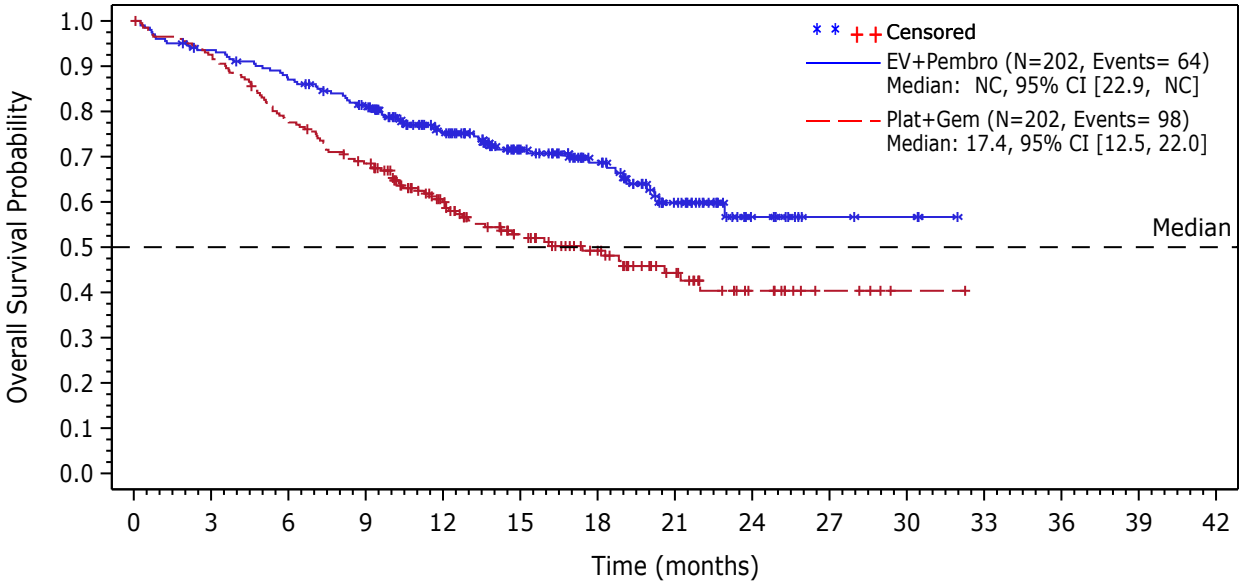
1	46	46	42	39	27	16	9	5	4	2	1	0	0	0	0
2	38	33	28	26	19	13	7	4	2	1	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.2: Kaplan-Meier Plot of Overall Survival - Analysis Set mITT 2 - Sensitivity Analysis 2



at Risk

1	202	187	173	157	120	86	63	36	12	4	3	0	0	0	0
2	202	186	156	134	93	64	47	28	13	5	1	0	0	0	0

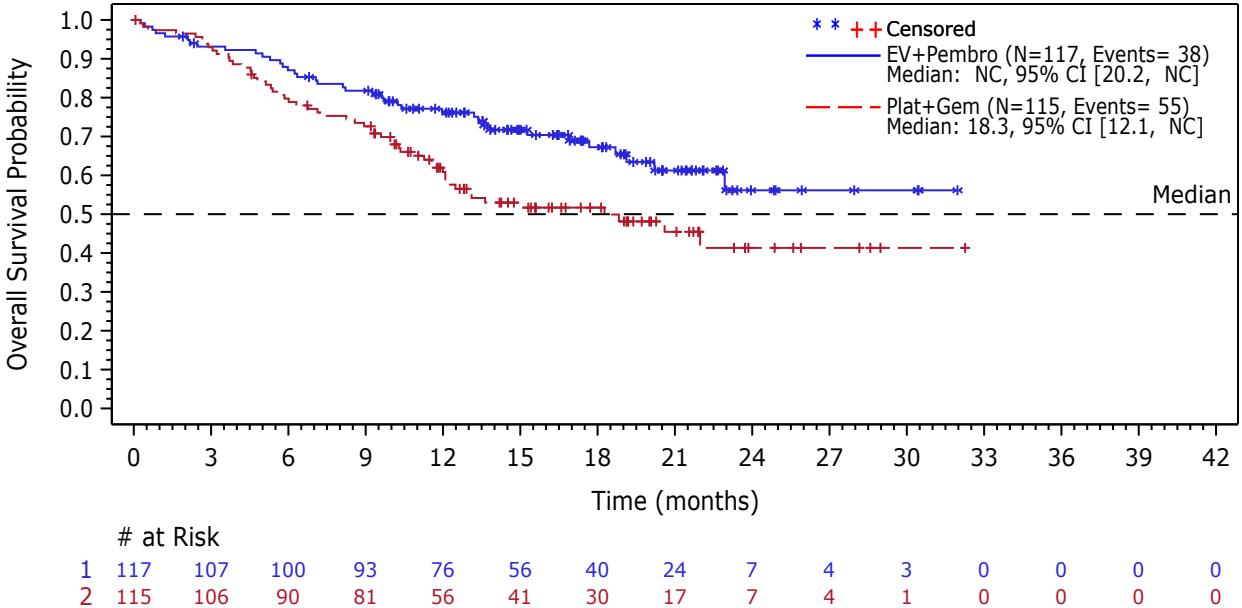
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.2.1: Kaplan-Meier Plot of Overall Survival by PD-L1 Expression - Analysis Set mITT 2 - Sensitivity Analysis 2

PD-L1 Expression: High (CPS>=10)



at Risk

1	117	107	100	93	76	56	40	24	7	4	3	0	0	0	0
2	115	106	90	81	56	41	30	17	7	4	1	0	0	0	0

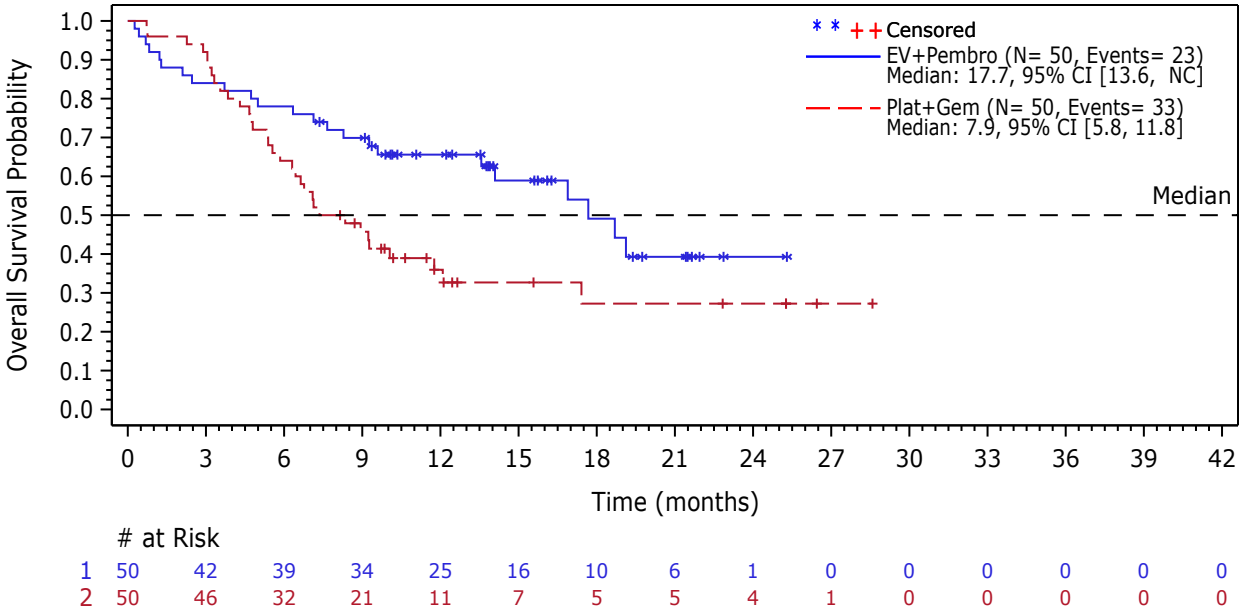
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.2.2: Kaplan-Meier Plot of Overall Survival by Liver Metastases - Analysis Set mITT 2 - Sensitivity Analysis 2

Liver Metastases: Present



at Risk

1	50	42	39	34	25	16	10	6	1	0	0	0	0	0	0
2	50	46	32	21	11	7	5	5	4	1	0	0	0	0	0

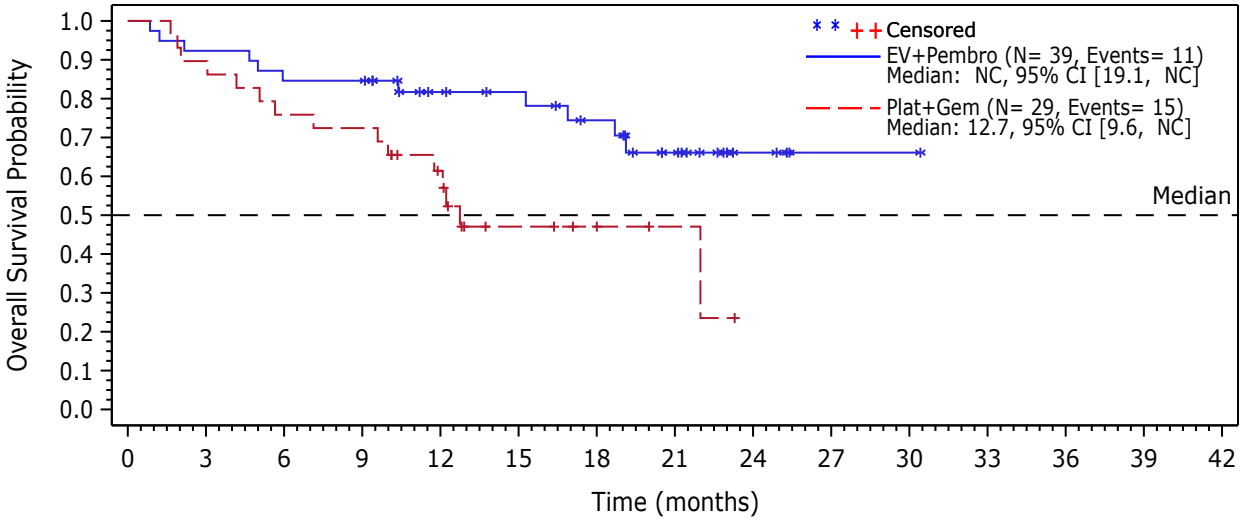
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.2.3: Kaplan-Meier Plot of Overall Survival by Age - Analysis Set mITT 2 - Sensitivity Analysis 2

Age: < 65 years



at Risk

1	39	36	33	33	25	23	19	12	4	1	1	0	0	0	0
2	29	26	22	21	14	6	4	2	0	0	0	0	0	0	0

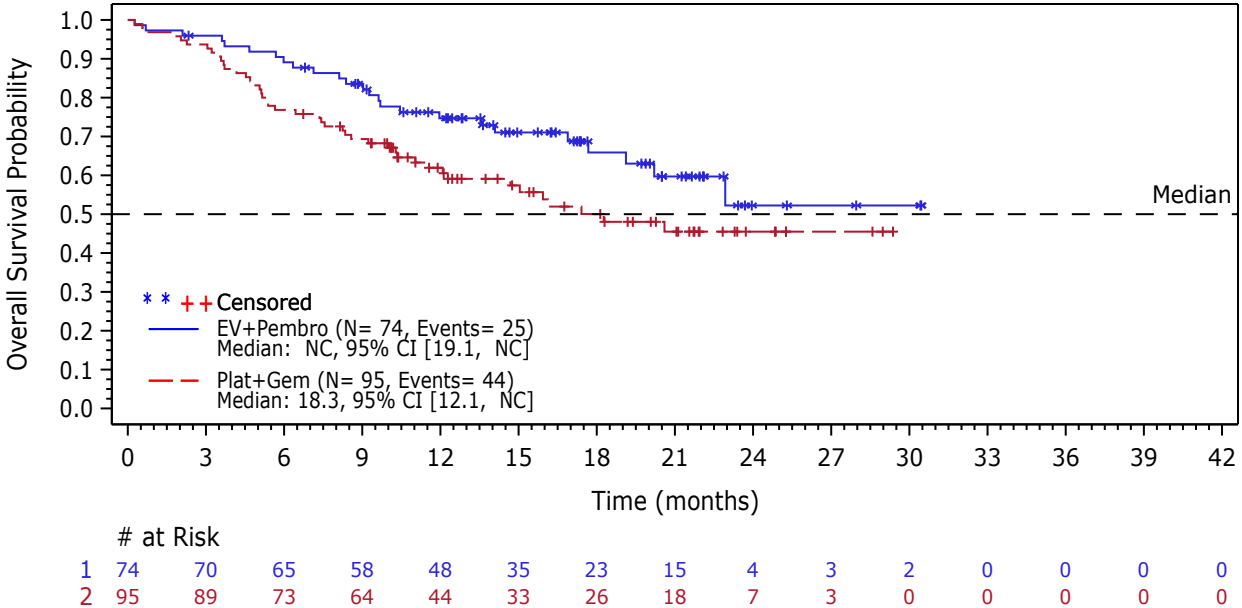
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.2.4: Kaplan-Meier Plot of Overall Survival by Region - Analysis Set mITT 2 - Sensitivity Analysis 2

Region: Europe



at Risk

1	74	70	65	58	48	35	23	15	4	3	2	0	0	0	0
2	95	89	73	64	44	33	26	18	7	3	0	0	0	0	0

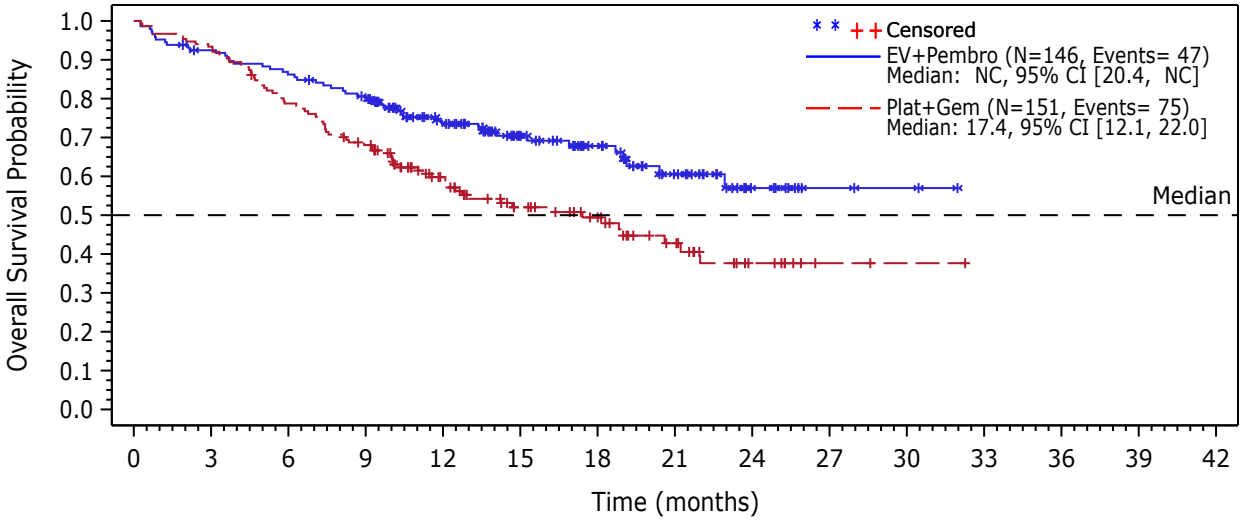
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.2.5: Kaplan-Meier Plot of Overall Survival by Sex - Analysis Set mITT 2 - Sensitivity Analysis 2

Sex: Male



at Risk

1	146	133	124	114	84	58	43	26	10	3	2	0	0	0	0
2	151	141	118	100	67	45	35	21	9	2	1	0	0	0	0

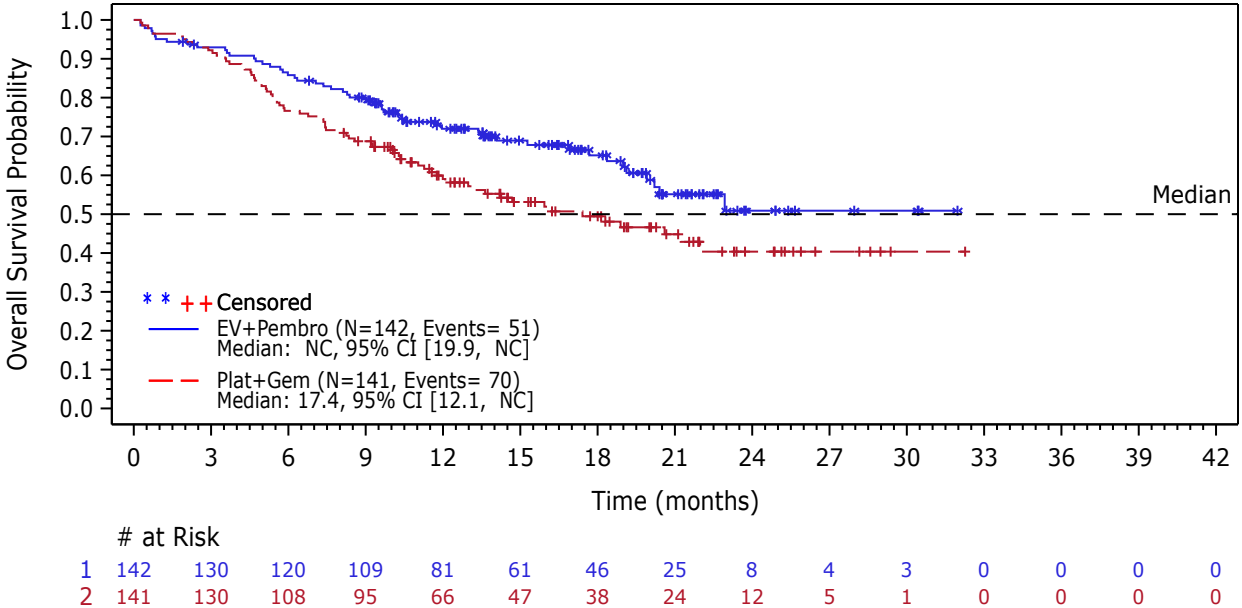
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.2.6: Kaplan-Meier Plot of Overall Survival by Race - Analysis Set mITT 2 - Sensitivity Analysis 2

Race: White



at Risk

1	142	130	120	109	81	61	46	25	8	4	3	0	0	0	0
2	141	130	108	95	66	47	38	24	12	5	1	0	0	0	0

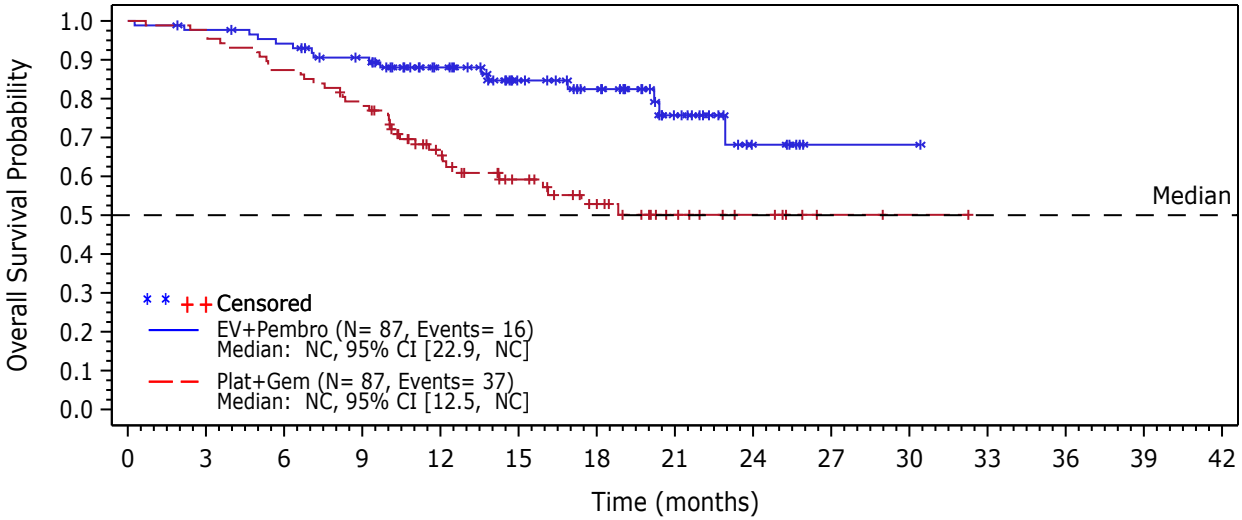
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.2.7: Kaplan-Meier Plot of Overall Survival by ECOG Status at Baseline - Analysis Set mITT 2 - Sensitivity Analysis 2

ECOG Status at Baseline: 0



at Risk

1	87	84	80	73	58	42	34	18	6	1	1	0	0	0	0
2	87	85	76	67	45	32	22	12	7	2	1	0	0	0	0

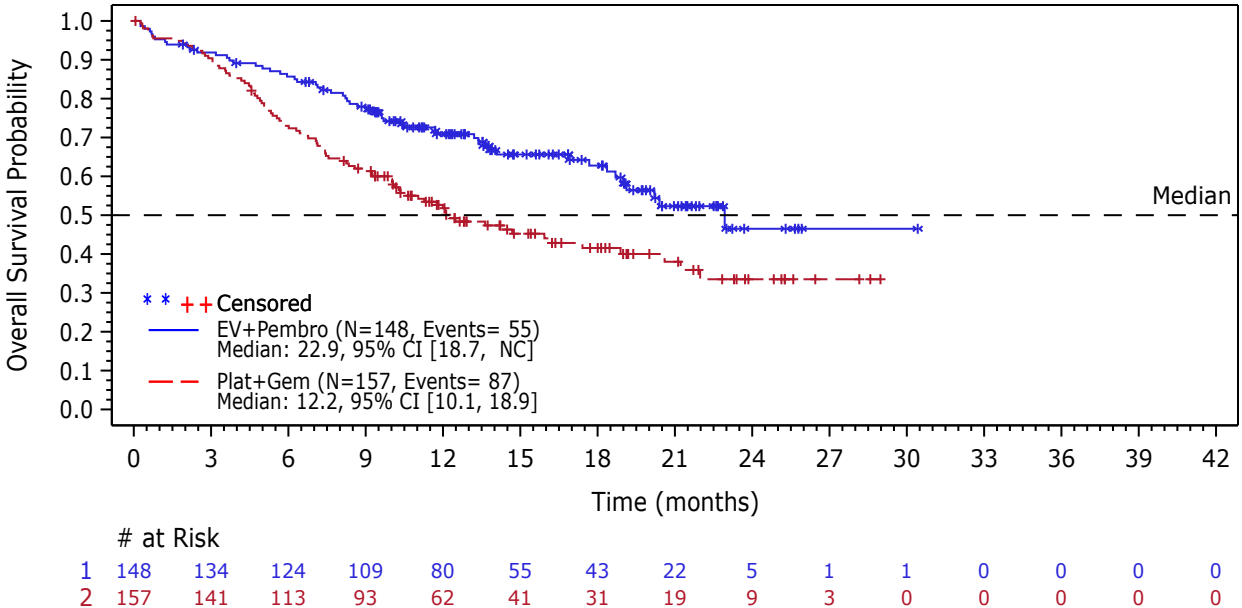
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.2.8: Kaplan-Meier Plot of Overall Survival by Metastases at Baseline - Analysis Set mITT 2 - Sensitivity Analysis 2

Metastases at Baseline: Visceral metastases



at Risk

1	148	134	124	109	80	55	43	22	5	1	1	0	0	0	0
2	157	141	113	93	62	41	31	19	9	3	0	0	0	0	0

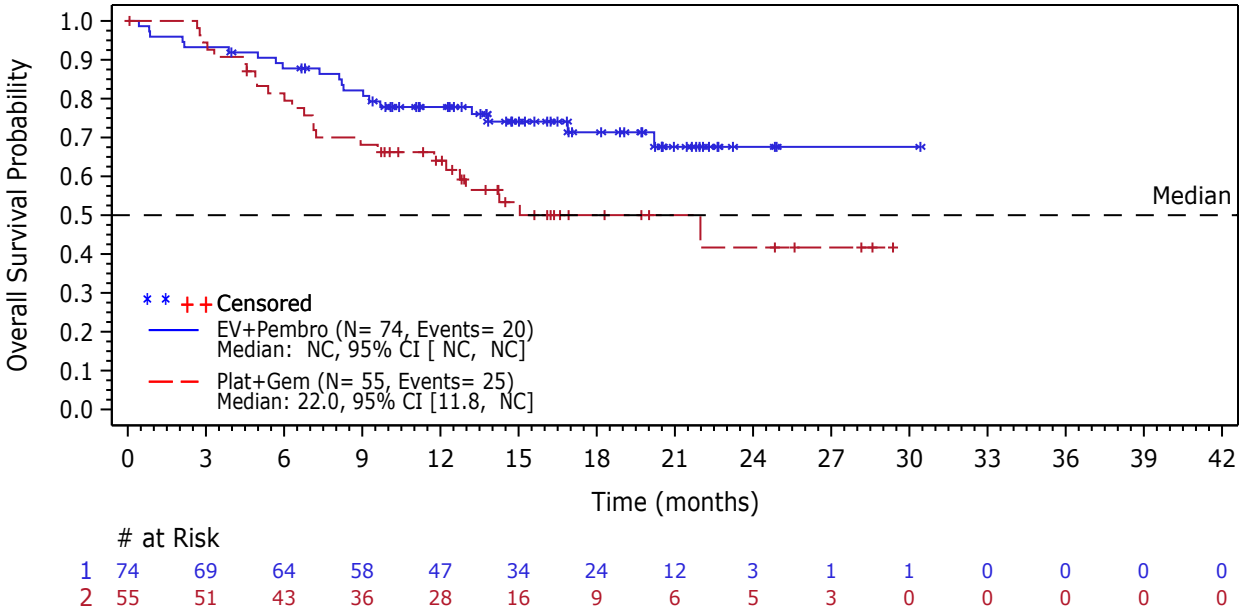
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.2.9: Kaplan-Meier Plot of Overall Survival by Primary Disease Site of Origin - Analysis Set mITT 2 - Sensitivity Analysis 2

Primary Disease Site of Origin: Upper tract



at Risk

1	74	69	64	58	47	34	24	12	3	1	1	0	0	0	0
2	55	51	43	36	28	16	9	6	5	3	0	0	0	0	0

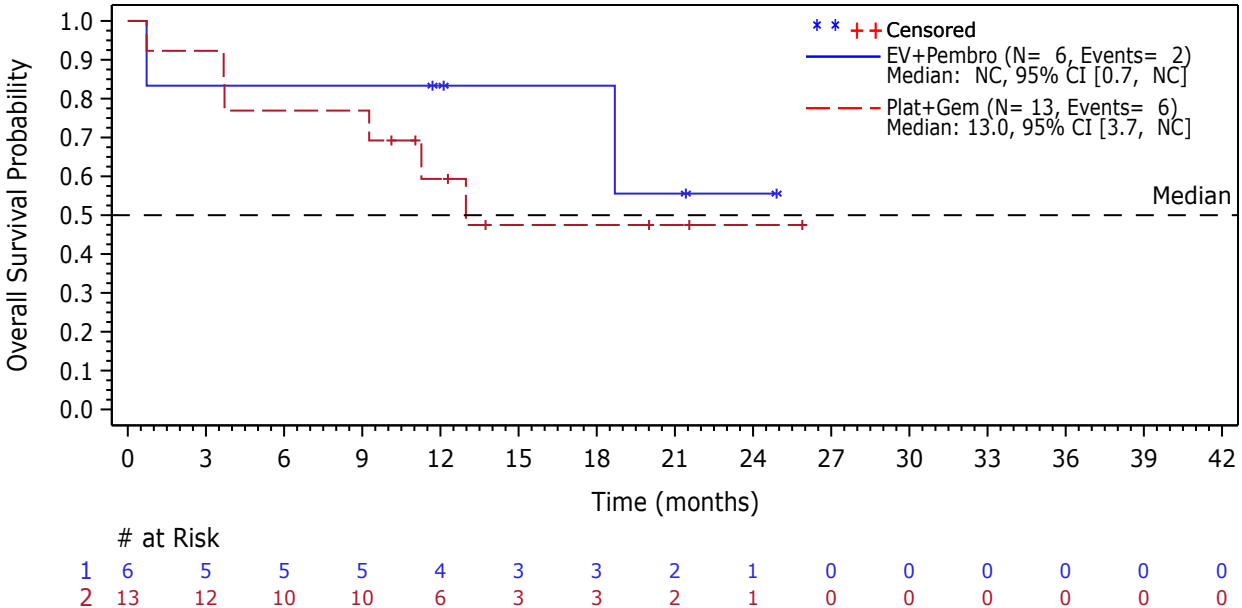
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.2.10: Kaplan-Meier Plot of Overall Survival by Renal Function - Analysis Set mITT 2 - Sensitivity Analysis 2

Renal Function: Normal



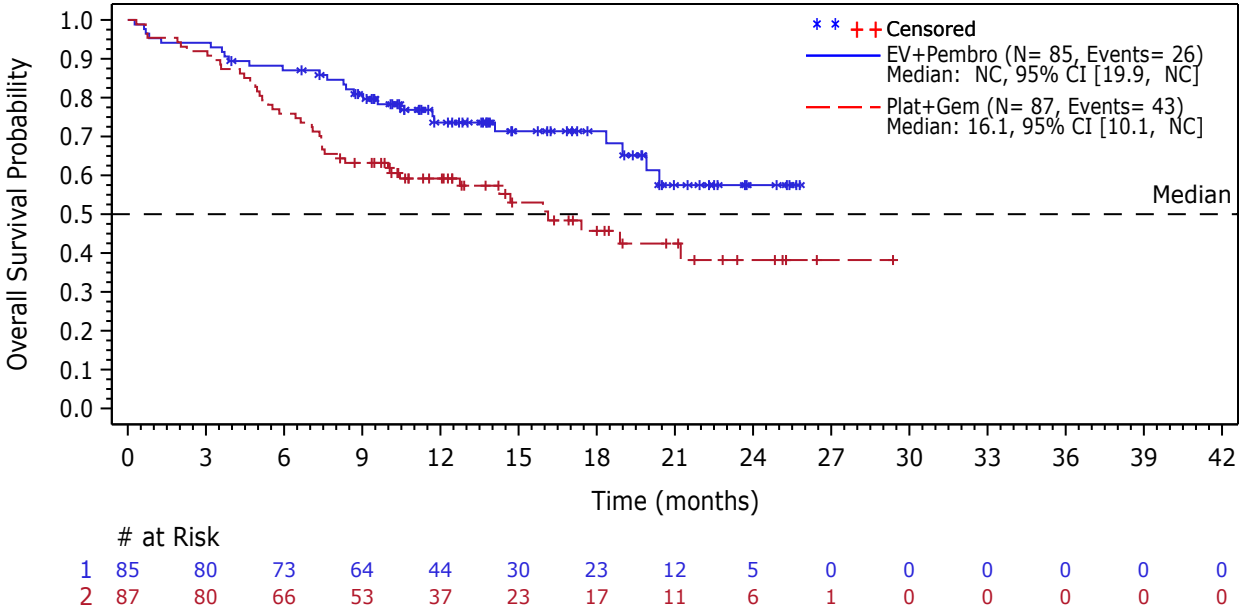
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.2.1: Kaplan-Meier Plot of Overall Survival by PD-L1 Expression - Analysis Set mITT 2 - Sensitivity Analysis 2

PD-L1 Expression: Low (CPS<10)



at Risk

1	85	80	73	64	44	30	23	12	5	0	0	0	0	0	0
2	87	80	66	53	37	23	17	11	6	1	0	0	0	0	0

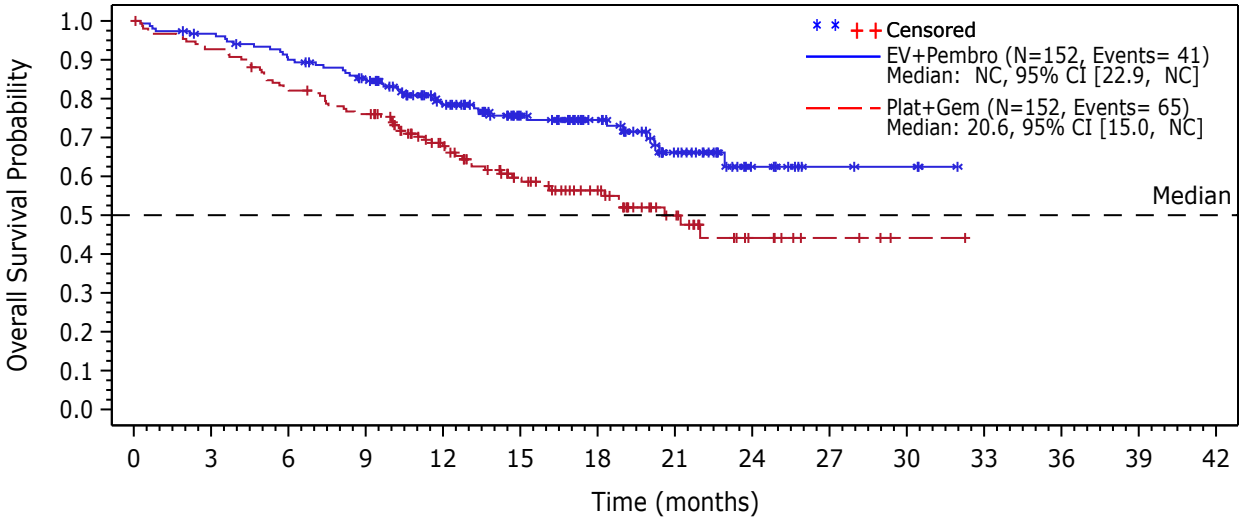
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.2.2: Kaplan-Meier Plot of Overall Survival by Liver Metastases - Analysis Set mITT 2 - Sensitivity Analysis 2

Liver Metastases: Absent



at Risk

1	152	145	134	123	95	70	53	30	11	4	3	0	0	0	0
2	152	140	124	113	82	57	42	23	9	4	1	0	0	0	0

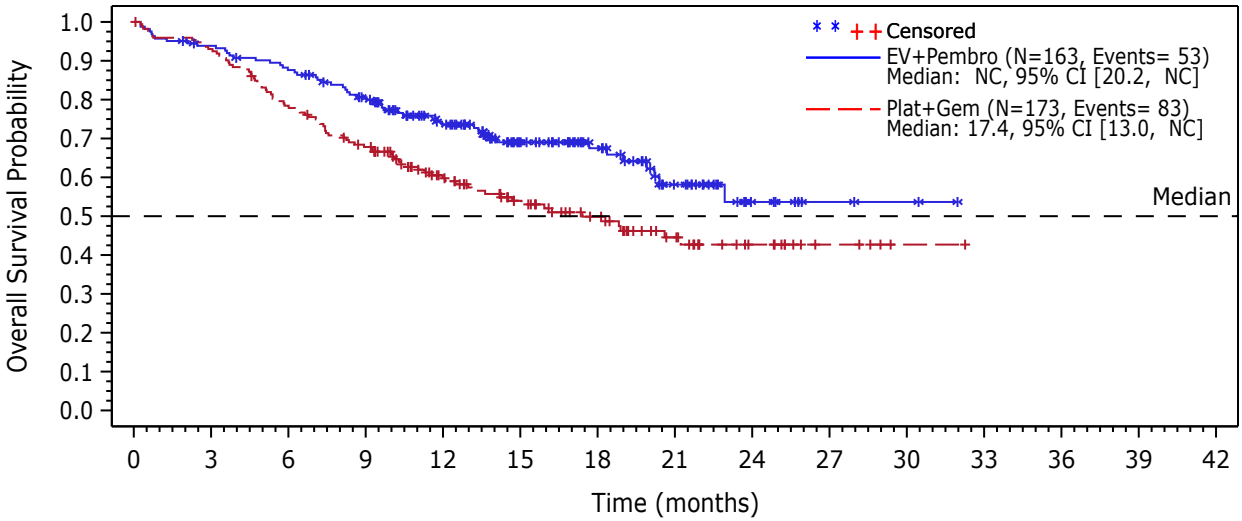
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.2.3: Kaplan-Meier Plot of Overall Survival by Age - Analysis Set mITT 2 - Sensitivity Analysis 2

Age: >= 65 years



at Risk

1	163	151	140	124	95	63	44	24	8	3	2	0	0	0	0
2	173	160	134	113	79	58	43	26	13	5	1	0	0	0	0

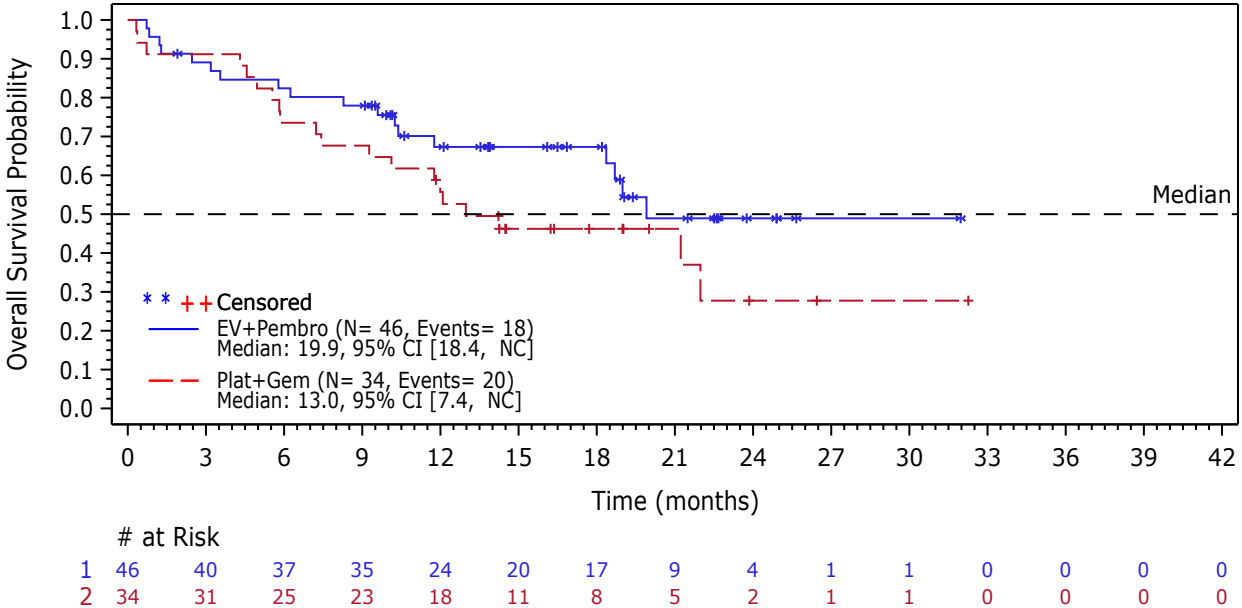
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.2.4: Kaplan-Meier Plot of Overall Survival by Region - Analysis Set mITT 2 - Sensitivity Analysis 2

Region: North America



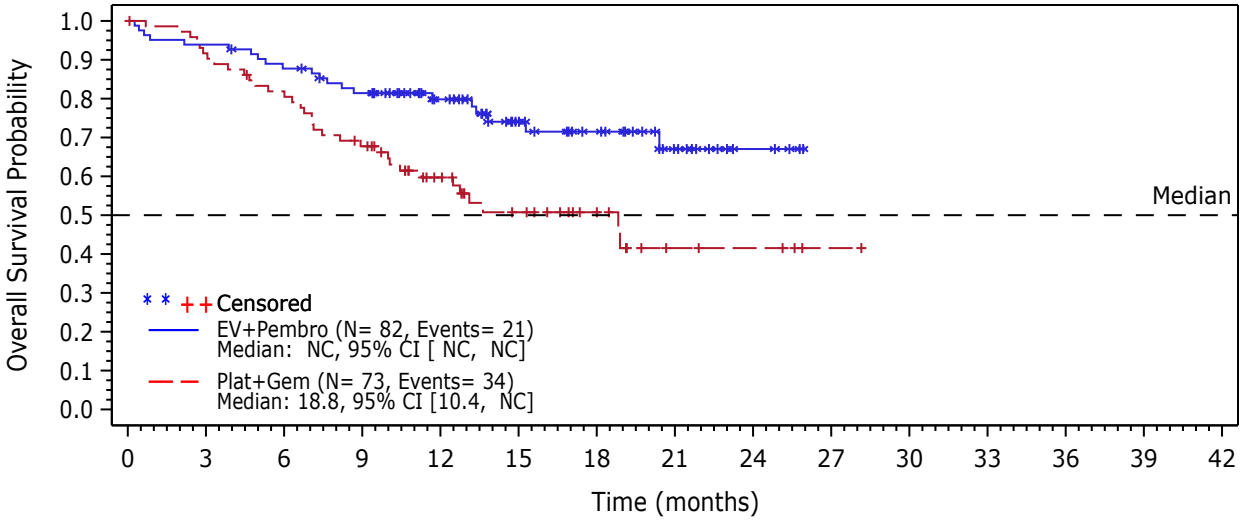
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.2.4: Kaplan-Meier Plot of Overall Survival by Region - Analysis Set mITT 2 - Sensitivity Analysis 2

Region: Rest of World



at Risk

1	82	77	71	64	48	31	23	12	4	0	0	0	0	0	0
2	73	66	58	47	31	20	13	5	4	1	0	0	0	0	0

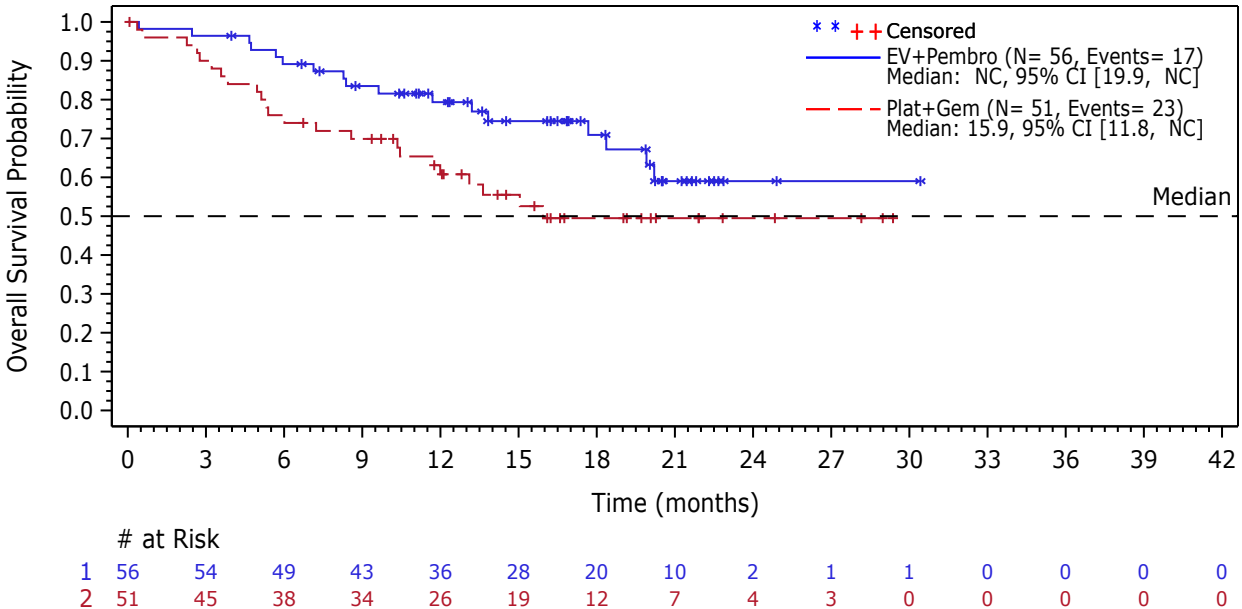
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.2.5: Kaplan-Meier Plot of Overall Survival by Sex - Analysis Set mITT 2 - Sensitivity Analysis 2

Sex: Female



at Risk

1	56	54	49	43	36	28	20	10	2	1	1	0	0	0	0
2	51	45	38	34	26	19	12	7	4	3	0	0	0	0	0

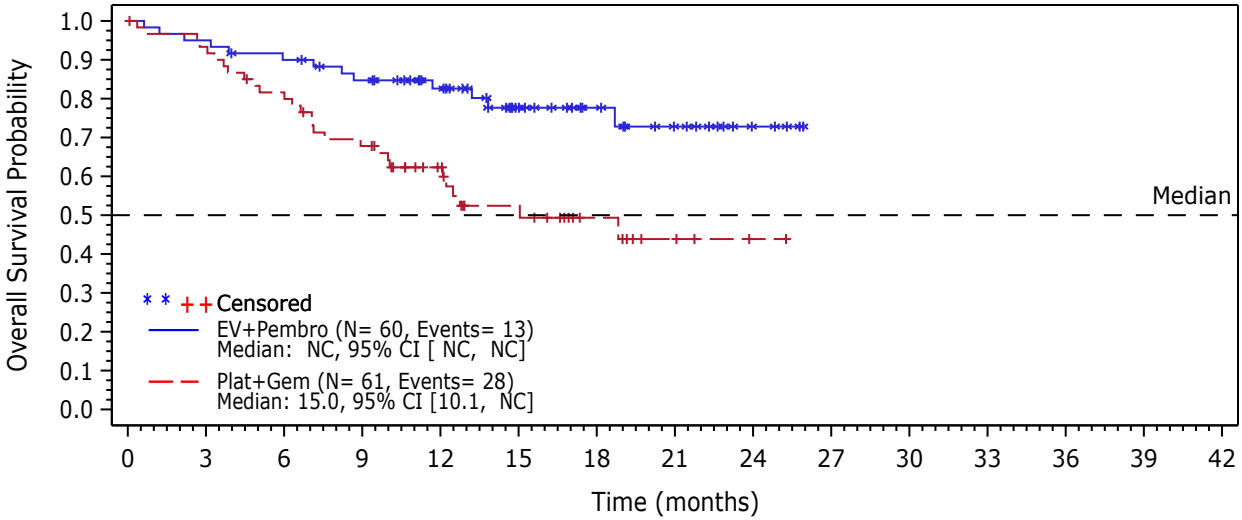
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.2.6: Kaplan-Meier Plot of Overall Survival by Race - Analysis Set mITT 2 - Sensitivity Analysis 2

Race: Non-white



at Risk

1	60	57	53	48	39	25	17	11	4	0	0	0	0	0	0
2	61	56	48	39	27	17	9	4	1	0	0	0	0	0	0

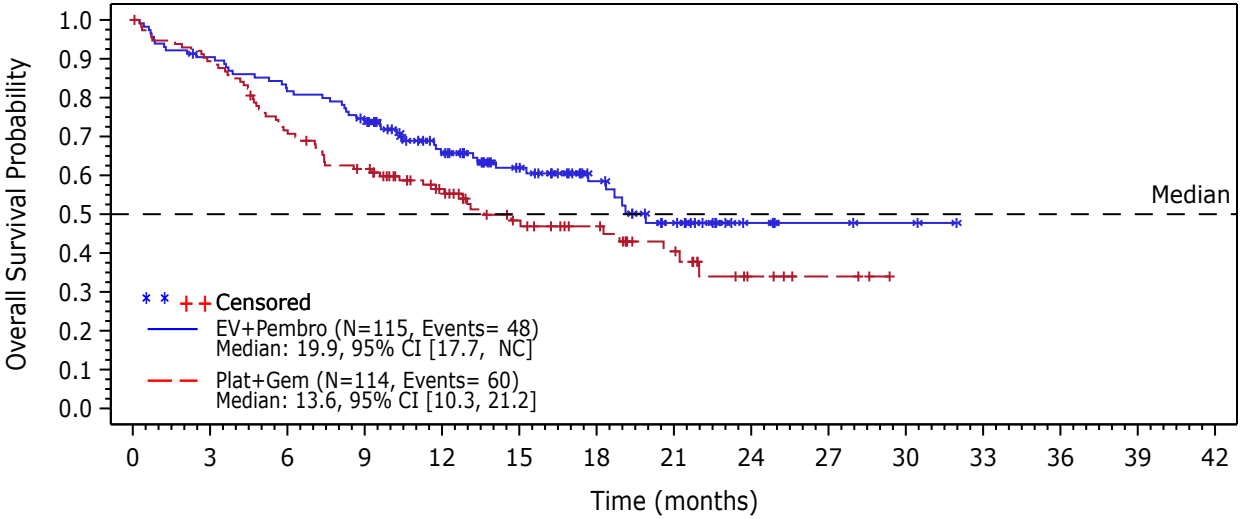
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.2.7: Kaplan-Meier Plot of Overall Survival by ECOG Status at Baseline - Analysis Set mITT 2 - Sensitivity Analysis 2

ECOG Status at Baseline: 1-2



at Risk

1	115	103	93	84	62	44	29	18	6	3	2	0	0	0	0
2	114	101	80	67	48	32	25	16	6	3	0	0	0	0	0

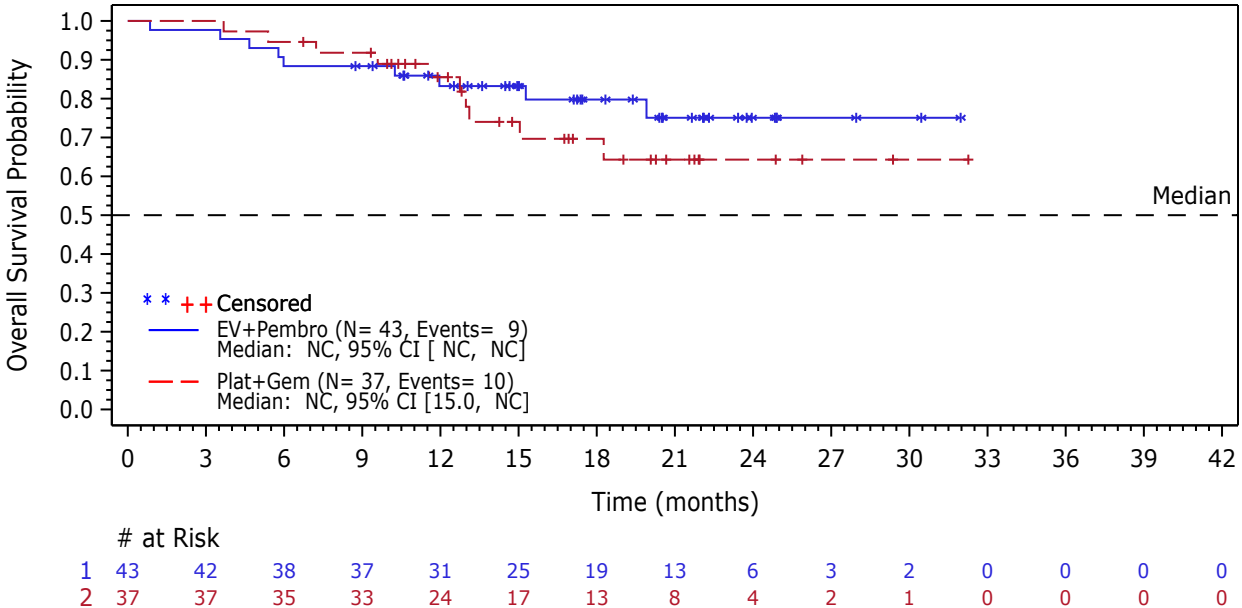
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.2.8: Kaplan-Meier Plot of Overall Survival by Metastases at Baseline - Analysis Set mITT 2 - Sensitivity Analysis 2

Metastases at Baseline: Lymph node only



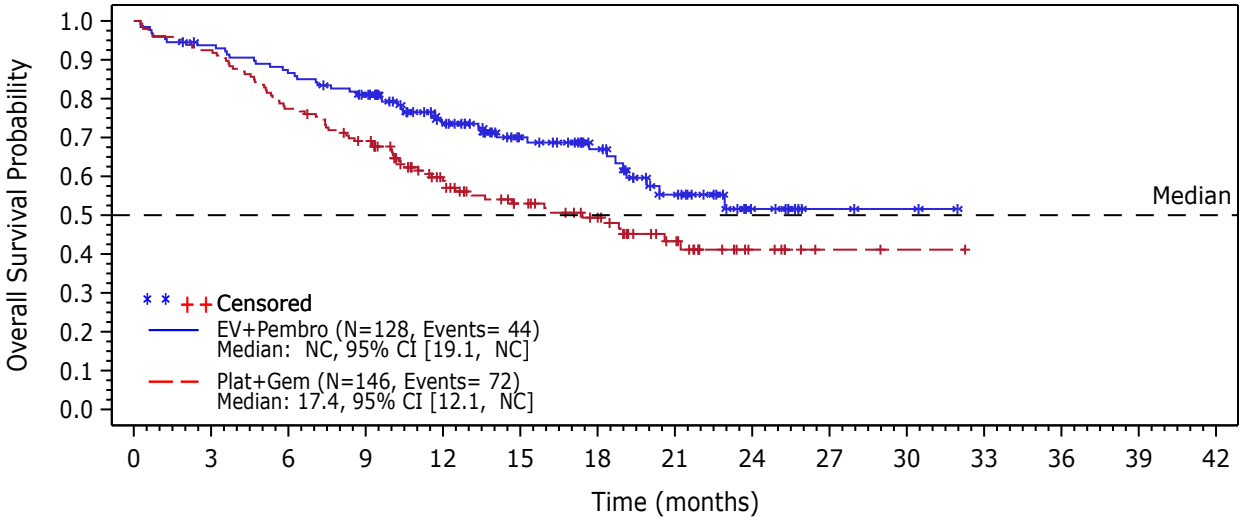
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.2.9: Kaplan-Meier Plot of Overall Survival by Primary Disease Site of Origin - Analysis Set mITT 2 - Sensitivity Analysis 2

Primary Disease Site of Origin: Lower tract



at Risk

1	128	118	109	99	73	52	39	24	9	3	2	0	0	0	0
2	146	135	113	98	65	48	38	22	8	2	1	0	0	0	0

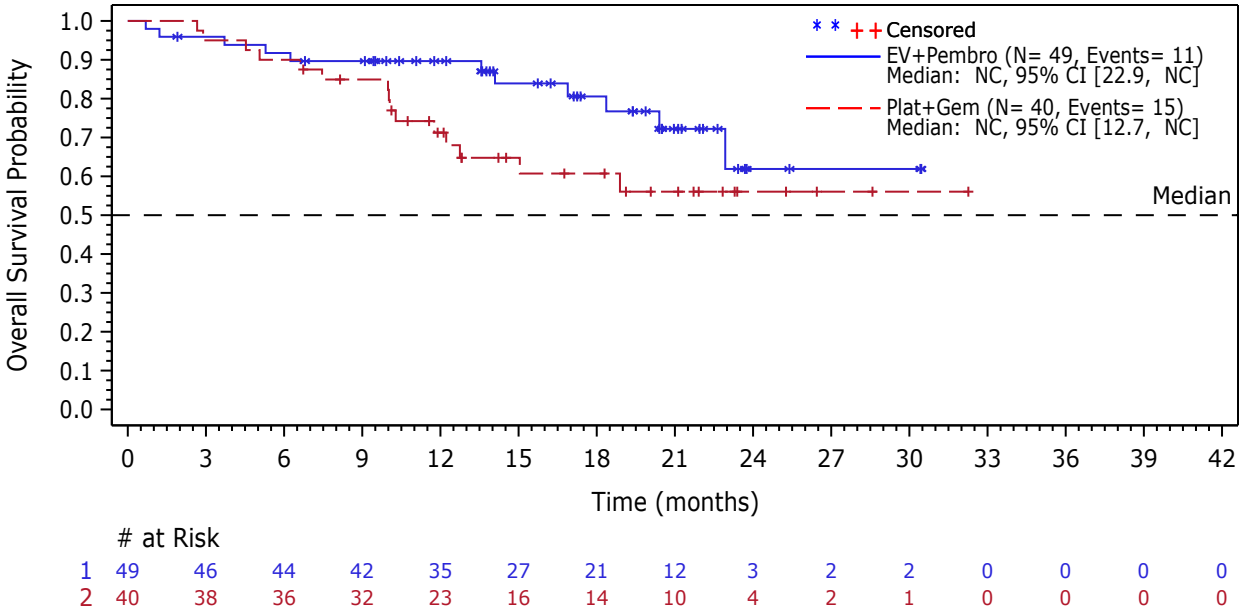
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.2.10: Kaplan-Meier Plot of Overall Survival by Renal Function - Analysis Set mITT 2 - Sensitivity Analysis 2

Renal Function: Mild



at Risk

1	49	46	44	42	35	27	21	12	3	2	2	0	0	0	0
2	40	38	36	32	23	16	14	10	4	2	1	0	0	0	0

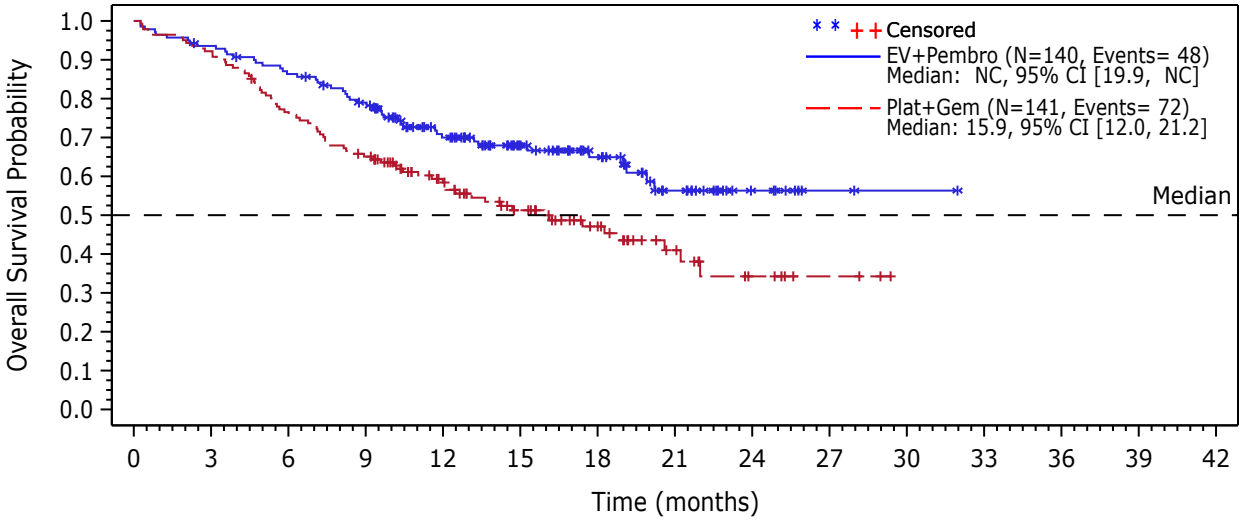
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.2.10: Kaplan-Meier Plot of Overall Survival by Renal Function - Analysis Set mITT 2 - Sensitivity Analysis 2

Renal Function: Moderate



at Risk

1	140	130	119	106	78	54	38	21	8	2	1	0	0	0	0
2	141	130	107	90	63	44	29	15	7	3	0	0	0	0	0

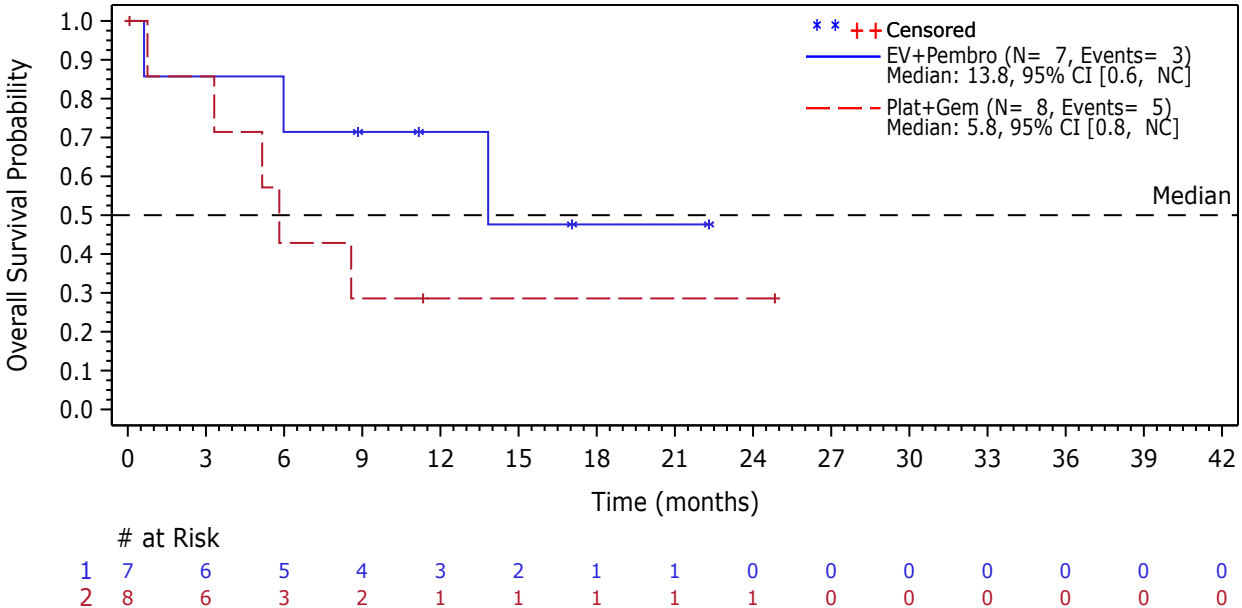
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.3.2.10: Kaplan-Meier Plot of Overall Survival by Renal Function - Analysis Set mITT 2 - Sensitivity Analysis 2

Renal Function: Severe

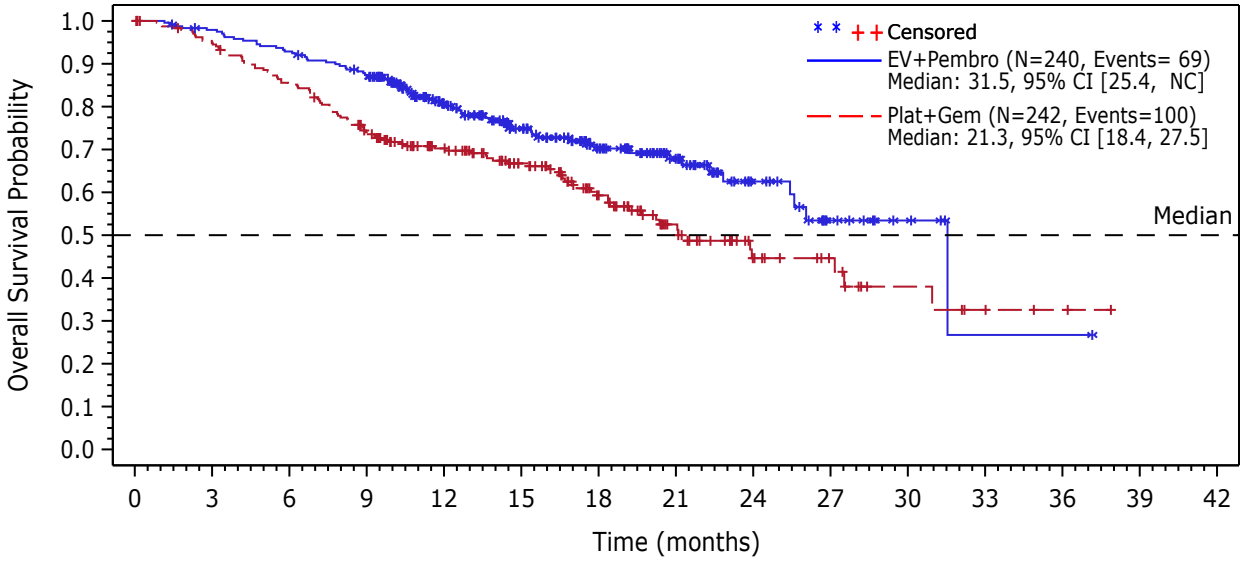


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were censored at date of data cutoff date.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.1: Kaplan-Meier Plot of Overall Survival - Analysis Set mITT 1 - Sensitivity Analysis 3



at Risk

1	240	233	221	206	150	112	78	49	24	11	5	1	1	0	0
2	242	224	200	169	131	102	71	42	21	14	7	4	2	0	0

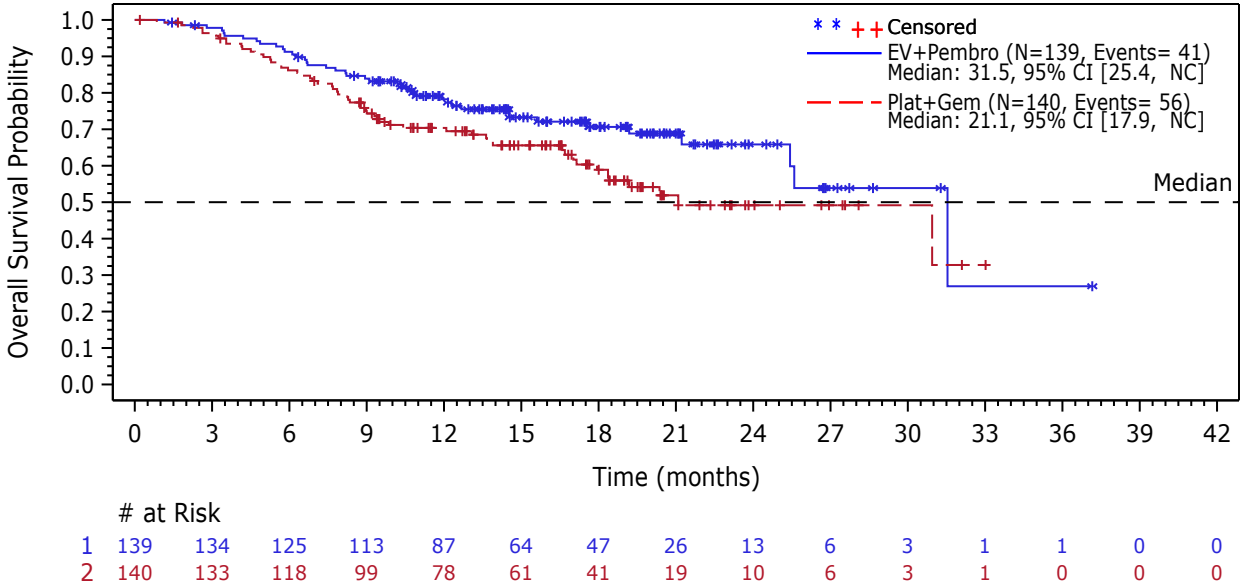
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (8.8 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.1.1: Kaplan-Meier Plot of Overall Survival by PD-L1 Expression - Analysis Set mITT 1 - Sensitivity Analysis 3

PD-L1 Expression: High (CPS>=10)



at Risk

1	139	134	125	113	87	64	47	26	13	6	3	1	1	0	0
2	140	133	118	99	78	61	41	19	10	6	3	1	0	0	0

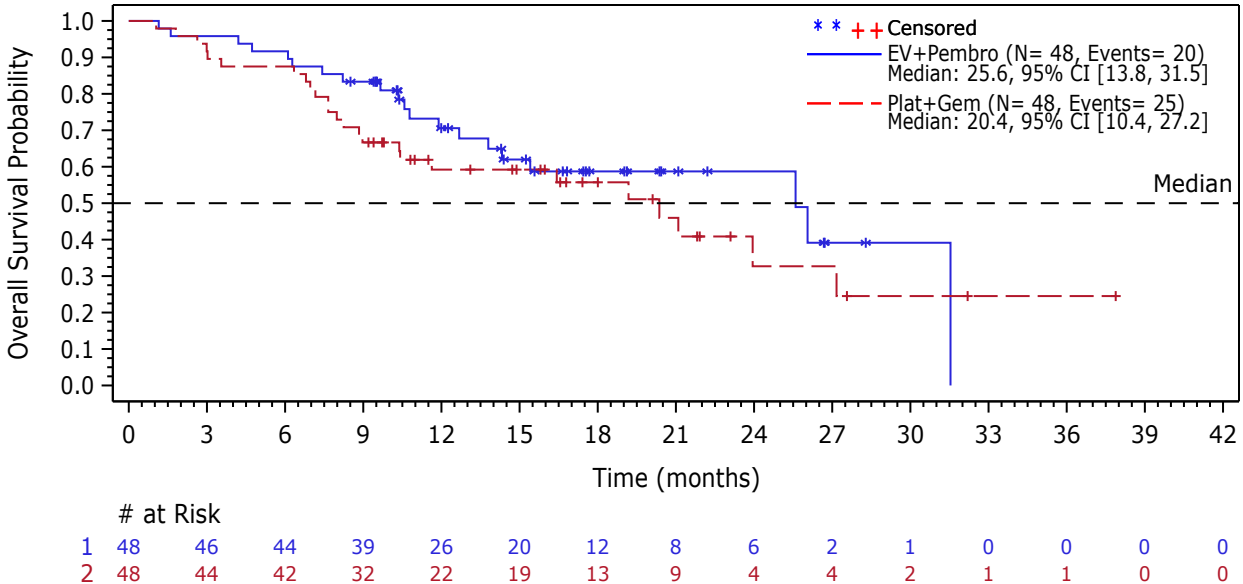
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (8.8 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.1.2: Kaplan-Meier Plot of Overall Survival by Liver Metastases - Analysis Set mITT 1 - Sensitivity Analysis 3

Liver Metastases: Present



at Risk

1	48	46	44	39	26	20	12	8	6	2	1	0	0	0	0
2	48	44	42	32	22	19	13	9	4	4	2	1	1	0	0

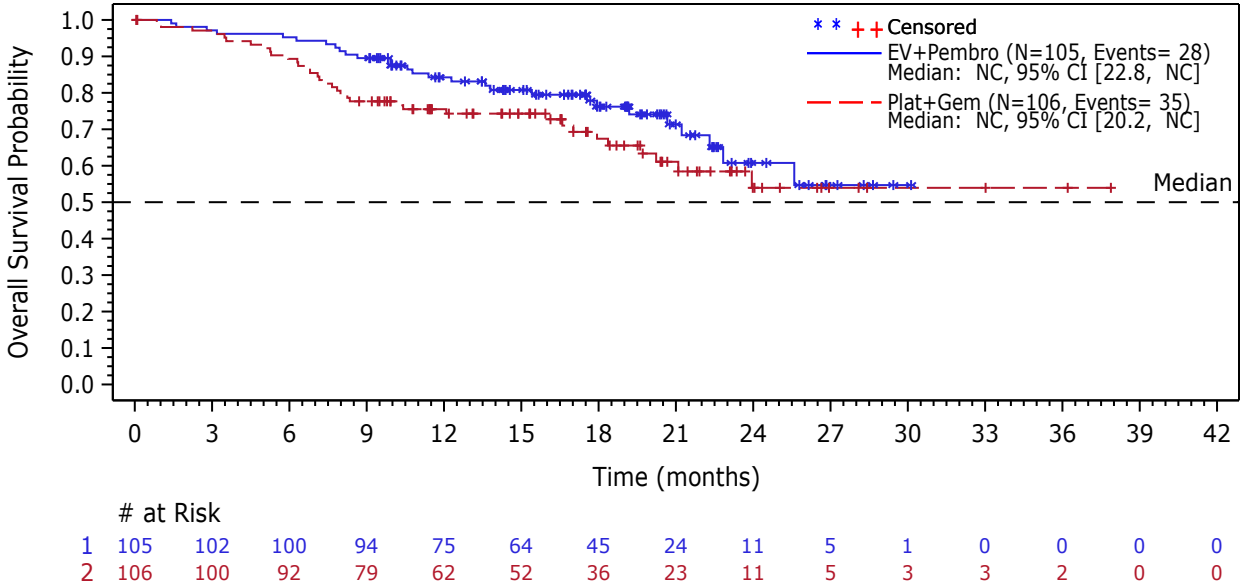
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (8.8 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.1.3: Kaplan-Meier Plot of Overall Survival by Age - Analysis Set mITT 1 - Sensitivity Analysis 3

Age: < 65 years



at Risk

1	105	102	100	94	75	64	45	24	11	5	1	0	0	0	0
2	106	100	92	79	62	52	36	23	11	5	3	3	2	0	0

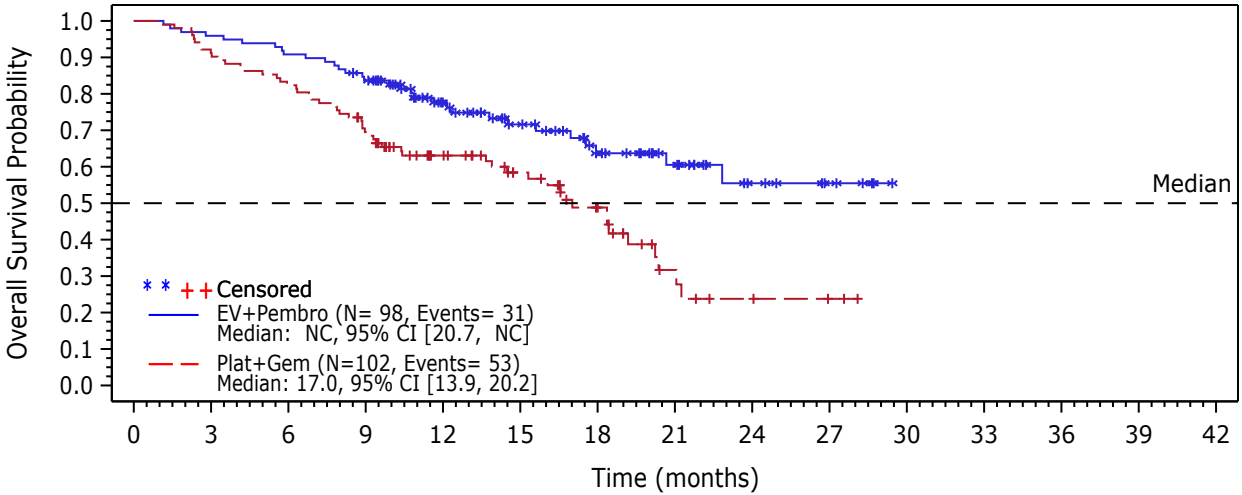
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (8.8 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.1.4: Kaplan-Meier Plot of Overall Survival by Region - Analysis Set mITT 1 - Sensitivity Analysis 3

Region: Europe



at Risk

1	98	94	89	81	56	42	29	19	9	5	0	0	0	0	0
2	102	93	84	69	47	34	22	8	4	2	0	0	0	0	0

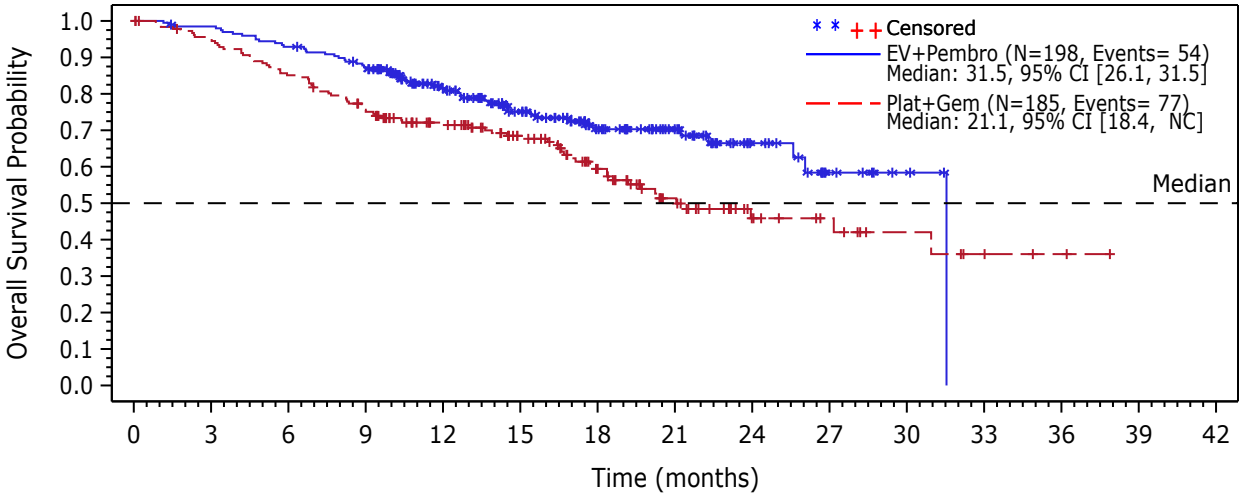
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (8.8 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.1.5: Kaplan-Meier Plot of Overall Survival by Sex - Analysis Set mITT 1 - Sensitivity Analysis 3

Sex: Male



at Risk

1	198	194	183	170	126	94	63	42	20	8	3	0	0	0	0
2	185	172	154	134	107	84	59	36	17	12	7	4	2	0	0

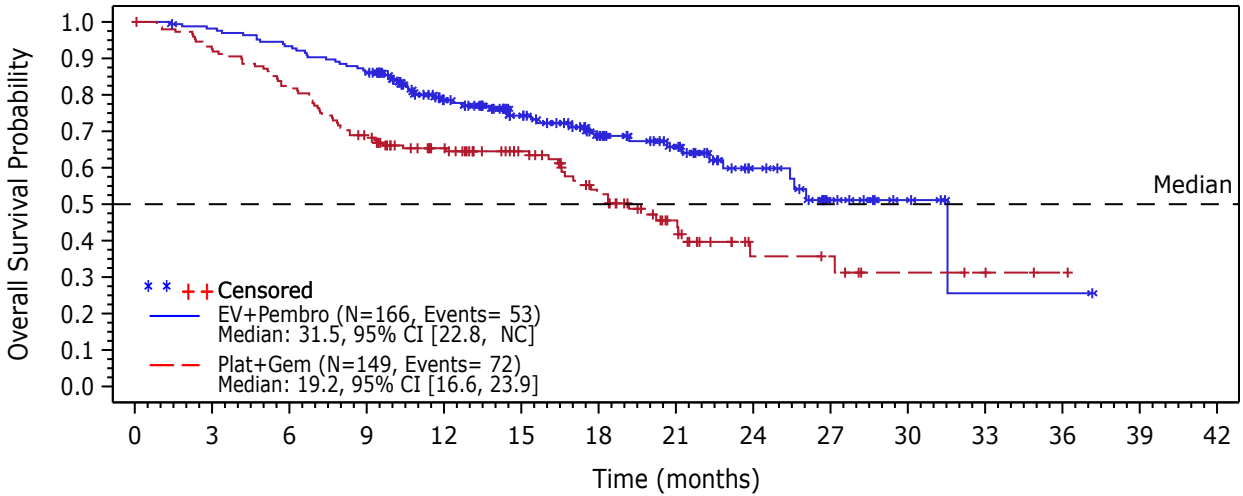
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (8.8 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.1.6: Kaplan-Meier Plot of Overall Survival by Race - Analysis Set mITT 1 - Sensitivity Analysis 3

Race: White



at Risk

1	166	162	154	142	103	77	55	41	23	11	5	1	1	0	0
2	149	137	121	100	79	61	42	24	9	8	4	3	1	0	0

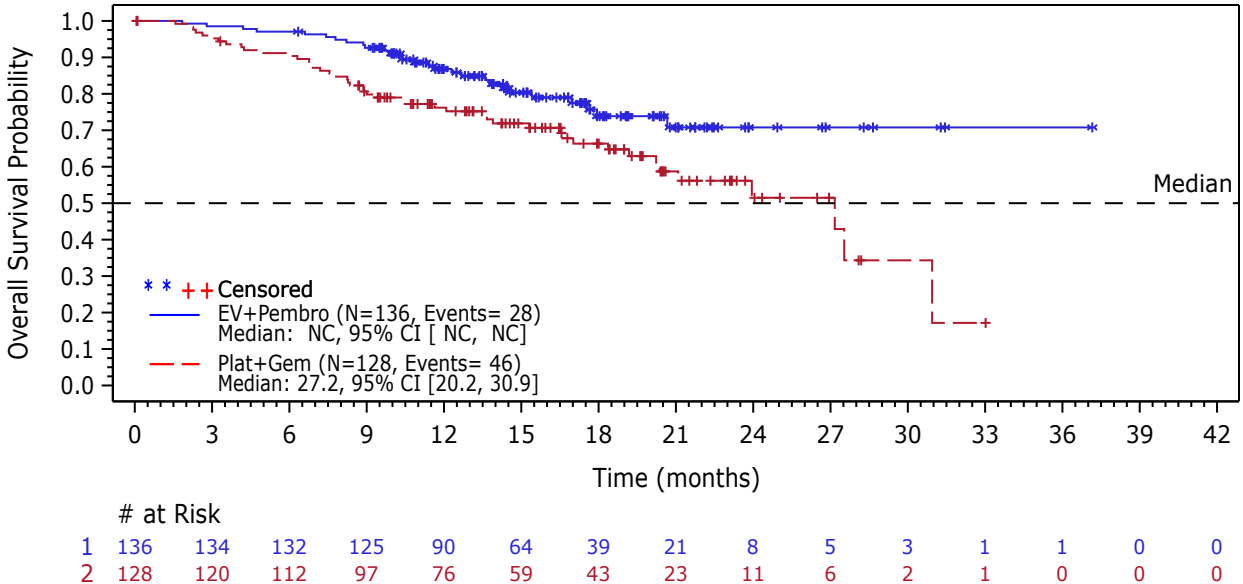
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (8.8 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.1.7: Kaplan-Meier Plot of Overall Survival by ECOG Status at Baseline - Analysis Set mITT 1 - Sensitivity Analysis 3

ECOG Status at Baseline: 0



at Risk

1	136	134	132	125	90	64	39	21	8	5	3	1	1	0	0
2	128	120	112	97	76	59	43	23	11	6	2	1	0	0	0

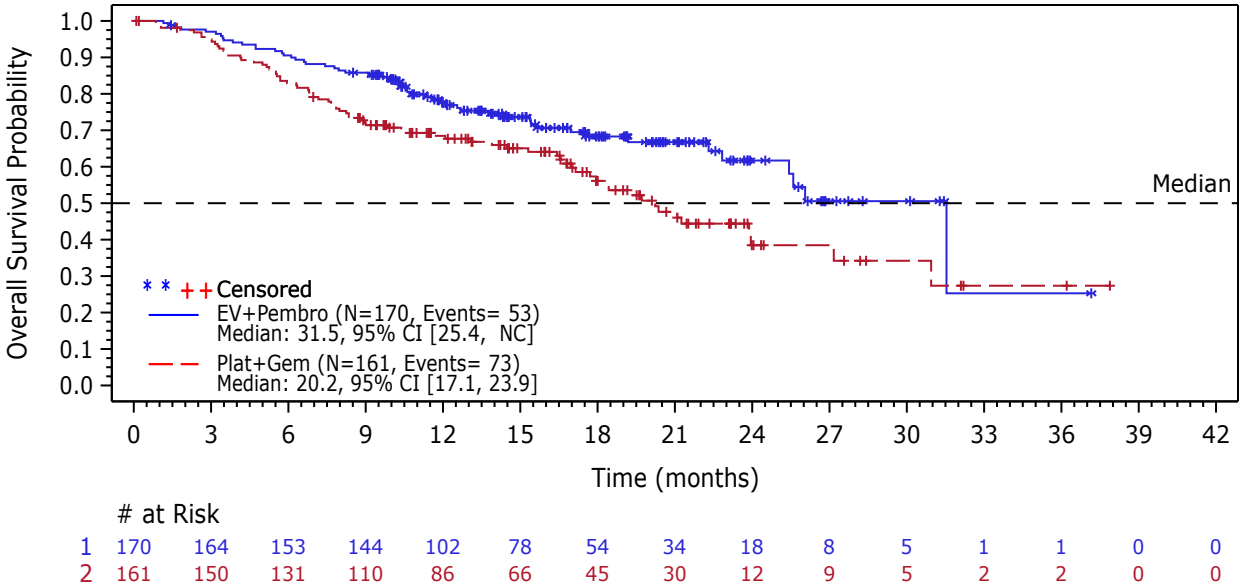
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (8.8 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.1.8: Kaplan-Meier Plot of Overall Survival by Metastases at Baseline - Analysis Set mITT 1 - Sensitivity Analysis 3

Metastases at Baseline: Visceral metastases



at Risk

1	170	164	153	144	102	78	54	34	18	8	5	1	1	0	0
2	161	150	131	110	86	66	45	30	12	9	5	2	2	0	0

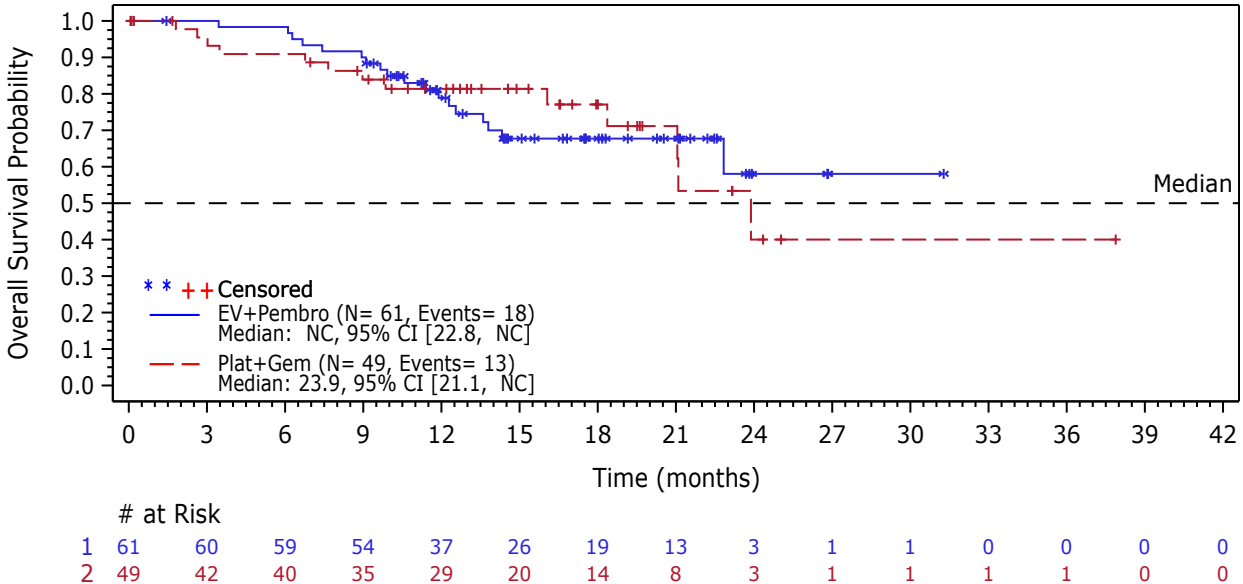
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (8.8 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.1.9: Kaplan-Meier Plot of Overall Survival by Primary Disease Site of Origin - Analysis Set mITT 1 - Sensitivity Analysis 3

Primary Disease Site of Origin: Upper tract



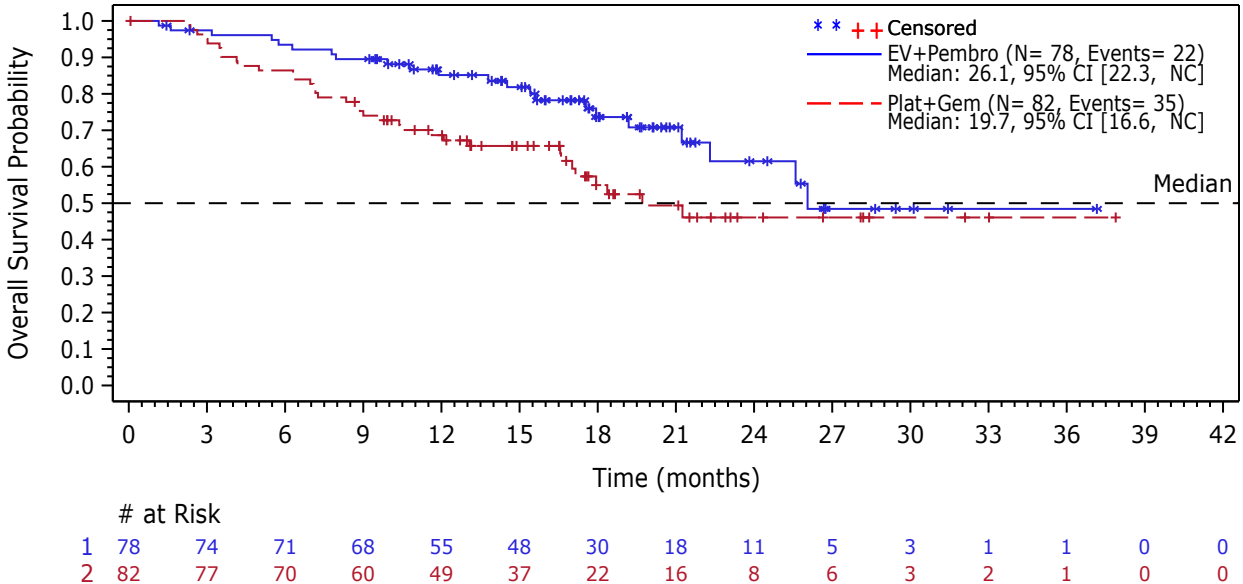
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (8.8 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.1.10: Kaplan-Meier Plot of Overall Survival by Renal Function - Analysis Set mITT 1 - Sensitivity Analysis 3

Renal Function: Normal



at Risk

1	78	74	71	68	55	48	30	18	11	5	3	1	1	0	0
2	82	77	70	60	49	37	22	16	8	6	3	2	1	0	0

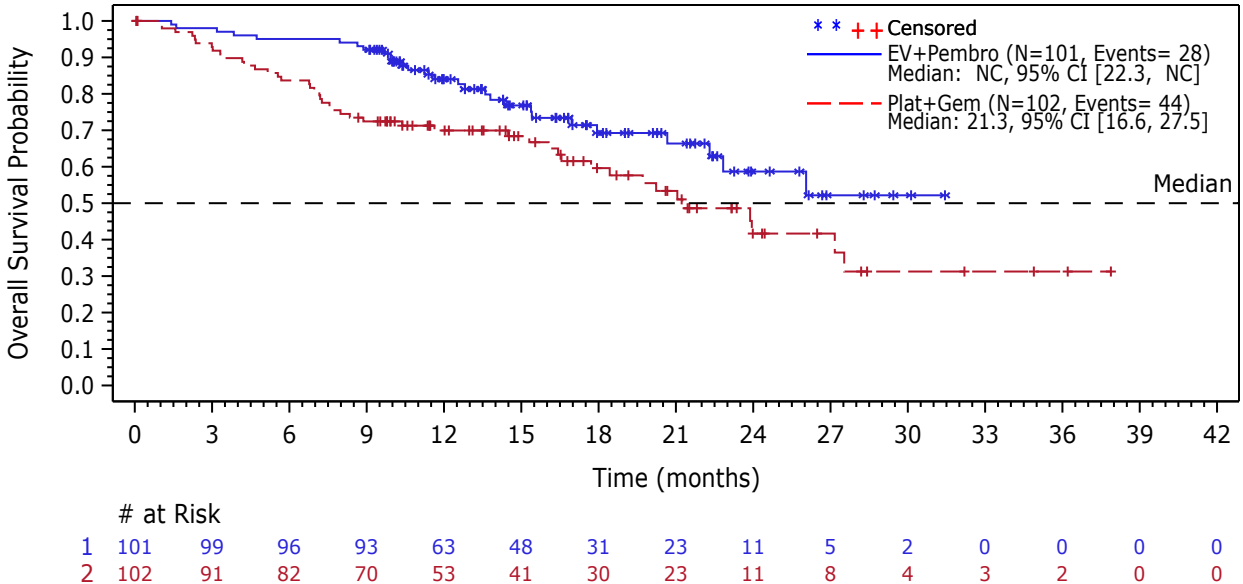
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (8.8 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.1.1: Kaplan-Meier Plot of Overall Survival by PD-L1 Expression - Analysis Set mITT 1 - Sensitivity Analysis 3

PD-L1 Expression: Low (CPS<10)



at Risk

1	101	99	96	93	63	48	31	23	11	5	2	0	0	0	0
2	102	91	82	70	53	41	30	23	11	8	4	3	2	0	0

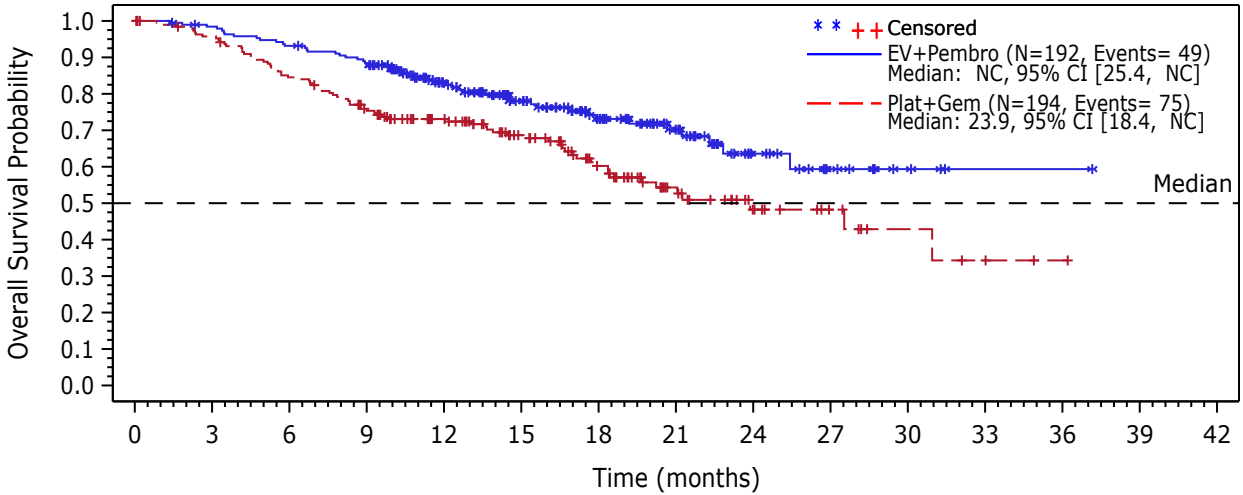
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (8.8 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.1.2: Kaplan-Meier Plot of Overall Survival by Liver Metastases - Analysis Set mITT 1 - Sensitivity Analysis 3

Liver Metastases: Absent



at Risk

1	192	187	177	167	124	92	66	41	18	9	4	1	1	0	0
2	194	180	158	137	109	83	58	33	17	10	5	3	1	0	0

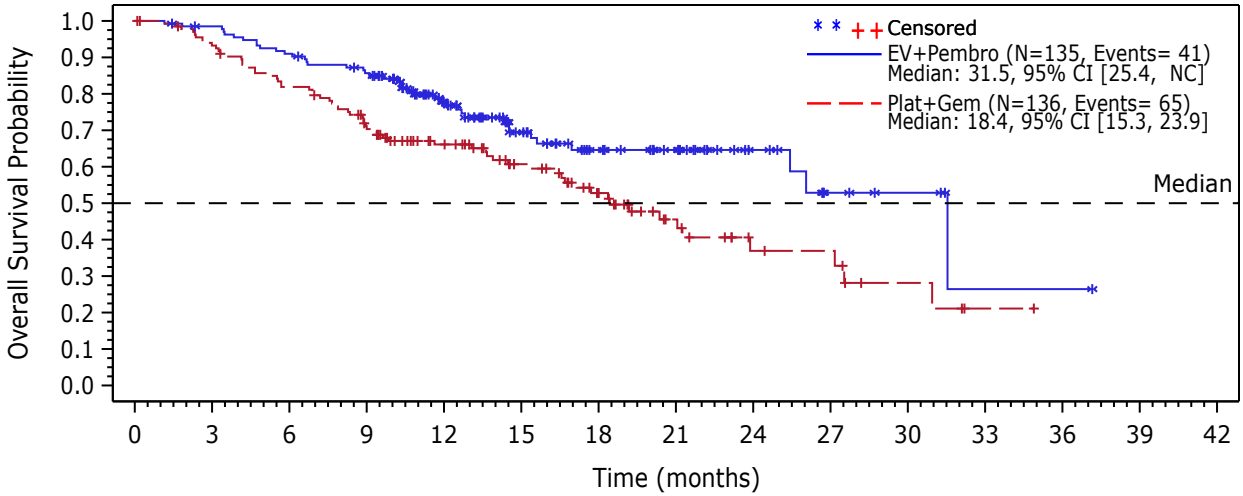
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (8.8 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.1.3: Kaplan-Meier Plot of Overall Survival by Age - Analysis Set mITT 1 - Sensitivity Analysis 3

Age: >= 65 years



at Risk

1	135	131	121	112	75	48	33	25	13	6	4	1	1	0	0
2	136	124	108	90	69	50	35	19	10	9	4	1	0	0	0

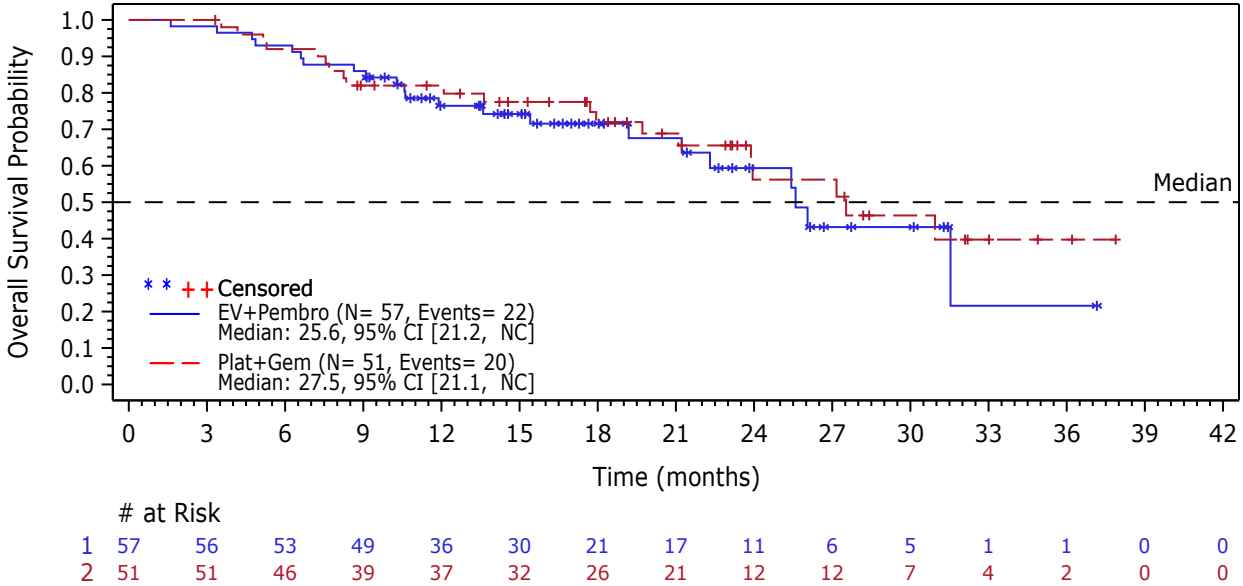
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (8.8 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.1.4: Kaplan-Meier Plot of Overall Survival by Region - Analysis Set mITT 1 - Sensitivity Analysis 3

Region: North America



at Risk

1	57	56	53	49	36	30	21	17	11	6	5	1	1	0	0
2	51	51	46	39	37	32	26	21	12	12	7	4	2	0	0

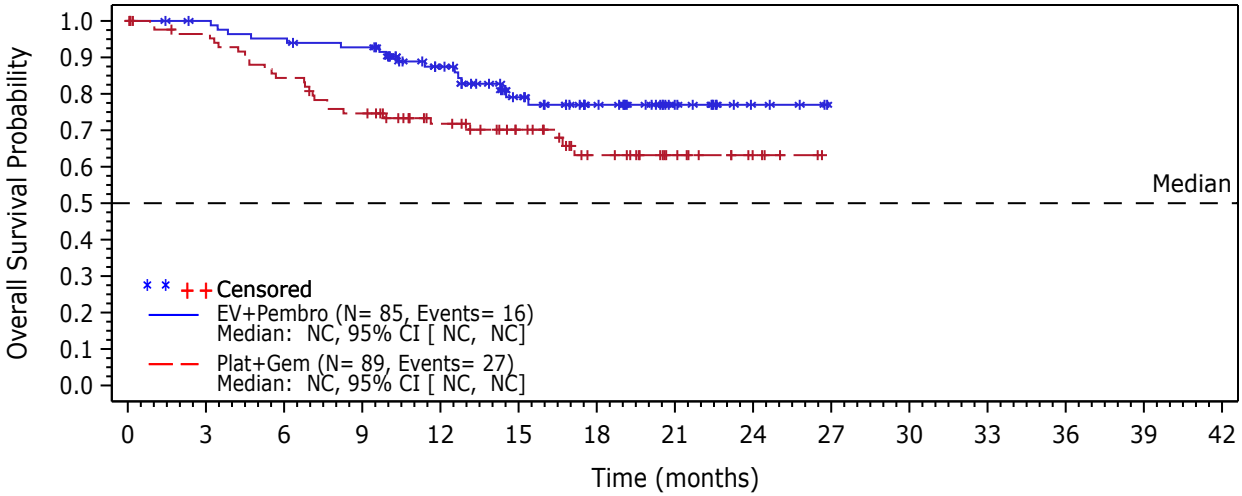
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (8.8 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.1.4: Kaplan-Meier Plot of Overall Survival by Region - Analysis Set mITT 1 - Sensitivity Analysis 3

Region: Rest of World



at Risk

1	85	83	79	76	58	40	28	13	4	0	0	0	0	0	0
2	89	80	70	61	47	36	23	13	5	0	0	0	0	0	0

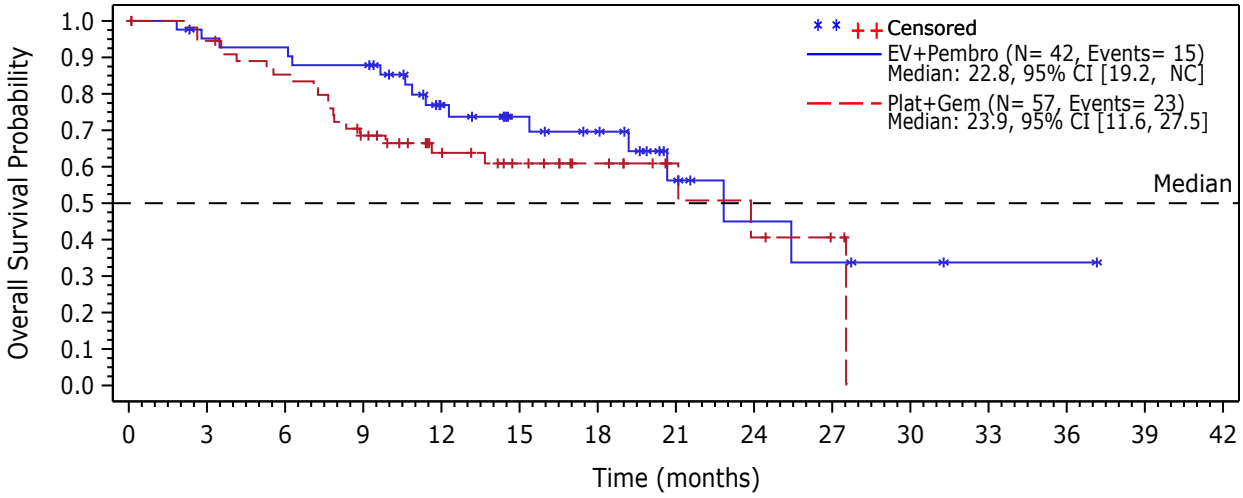
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (8.8 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.1.5: Kaplan-Meier Plot of Overall Survival by Sex - Analysis Set mITT 1 - Sensitivity Analysis 3

Sex: Female



at Risk

1	42	39	38	36	24	18	15	7	4	3	2	1	1	0	0
2	57	52	46	35	24	18	12	6	4	2	0	0	0	0	0

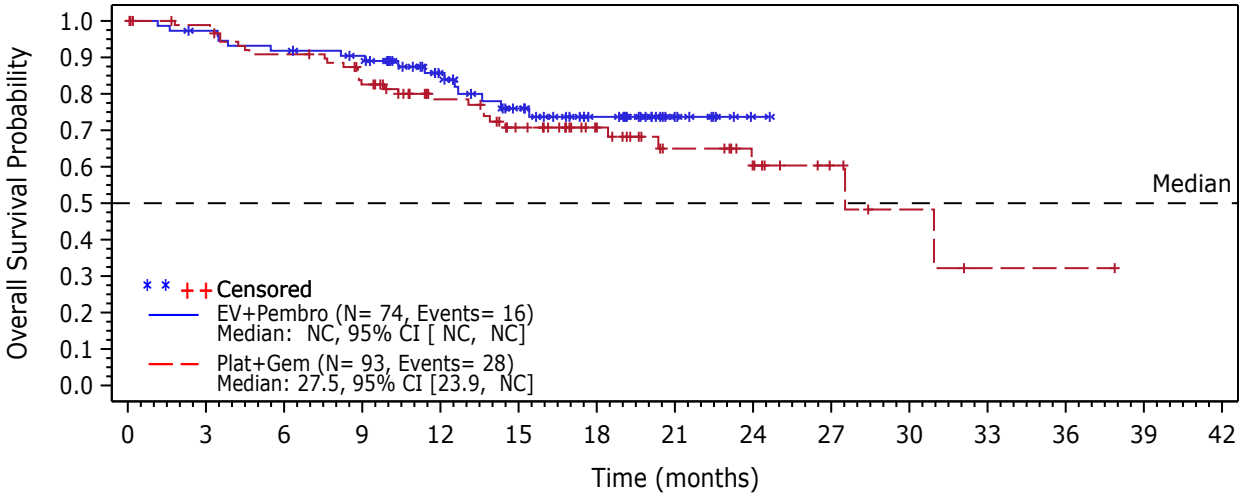
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (8.8 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.1.6: Kaplan-Meier Plot of Overall Survival by Race - Analysis Set mITT 1 - Sensitivity Analysis 3

Race: Non-white



at Risk

1	74	71	67	64	47	35	23	8	1	0	0	0	0	0	0
2	93	87	79	69	52	41	29	18	12	6	3	1	1	0	0

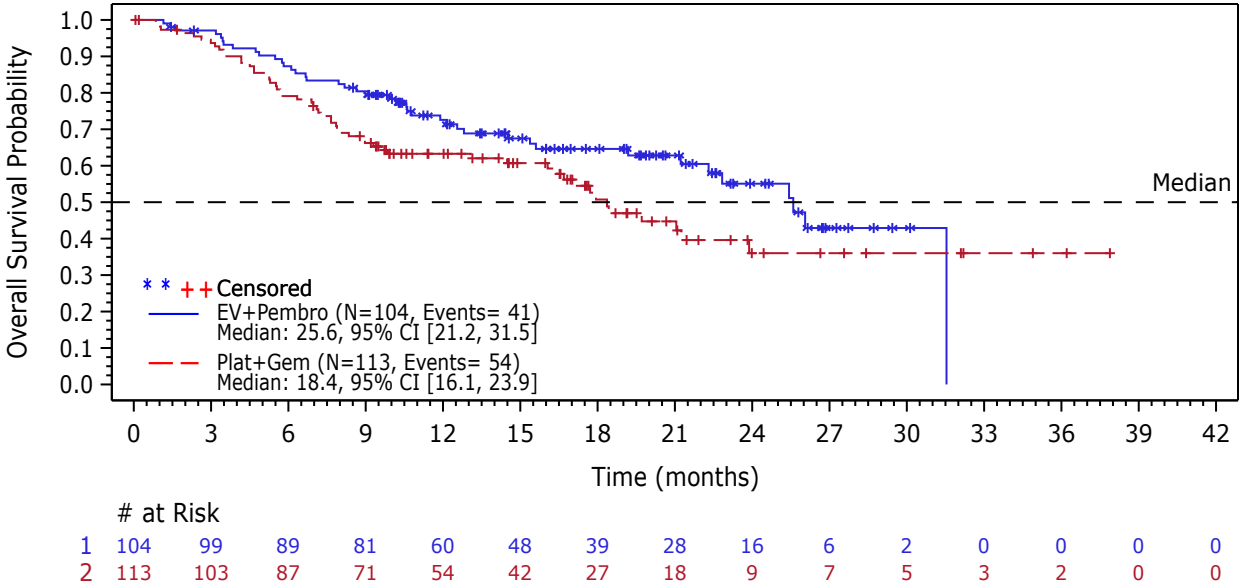
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (8.8 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.1.7: Kaplan-Meier Plot of Overall Survival by ECOG Status at Baseline - Analysis Set mITT 1 - Sensitivity Analysis 3

ECOG Status at Baseline: 1-2



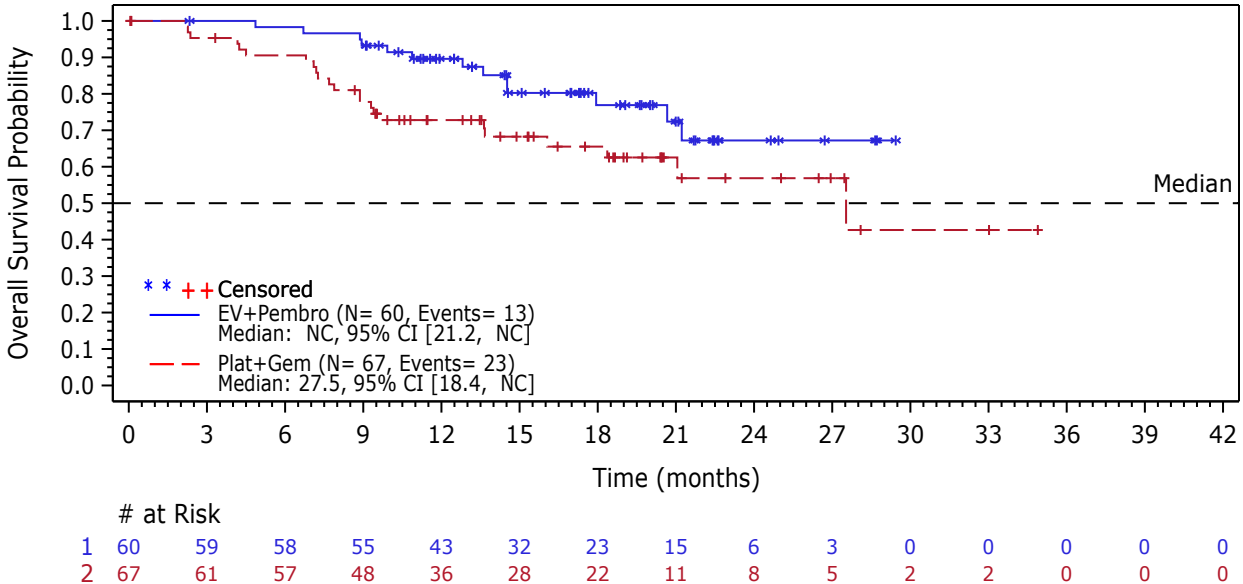
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (8.8 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.1.8: Kaplan-Meier Plot of Overall Survival by Metastases at Baseline - Analysis Set mITT 1 - Sensitivity Analysis 3

Metastases at Baseline: Lymph node only



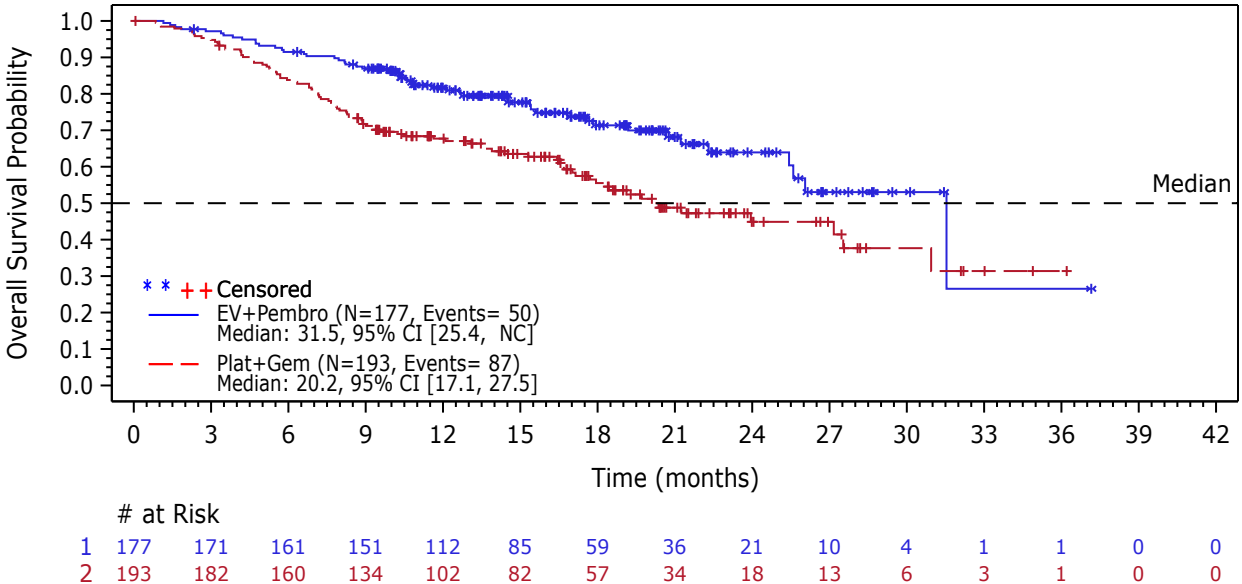
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (8.8 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.1.9: Kaplan-Meier Plot of Overall Survival by Primary Disease Site of Origin - Analysis Set mITT 1 - Sensitivity Analysis 3

Primary Disease Site of Origin: Lower tract



at Risk

1	177	171	161	151	112	85	59	36	21	10	4	1	1	0	0
2	193	182	160	134	102	82	57	34	18	13	6	3	1	0	0

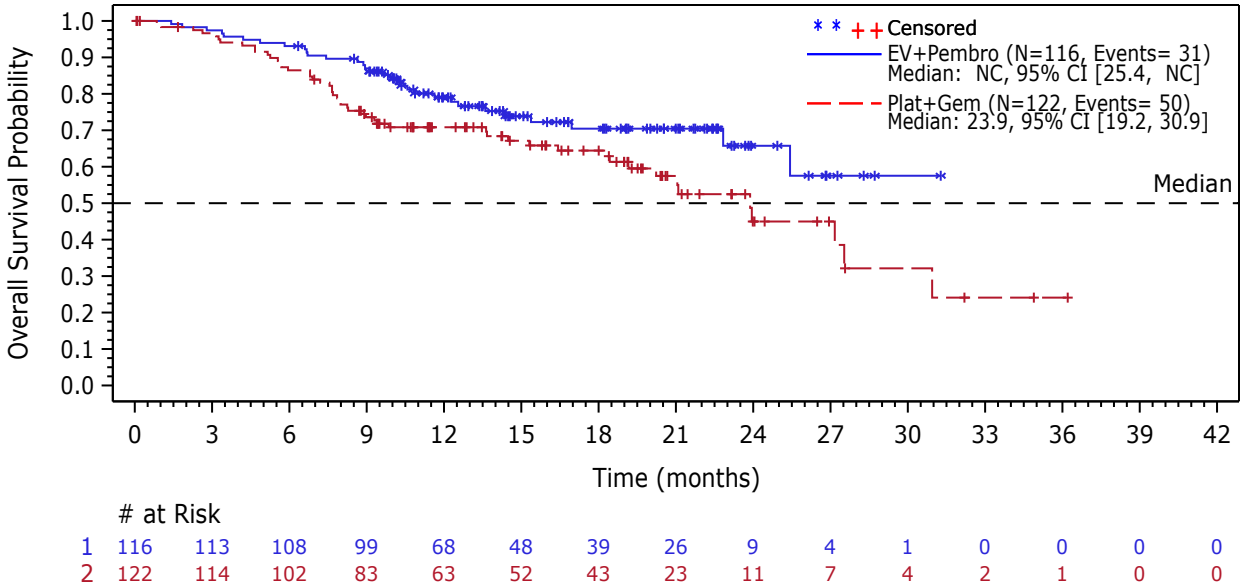
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (8.8 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.1.10: Kaplan-Meier Plot of Overall Survival by Renal Function - Analysis Set mITT 1 - Sensitivity Analysis 3

Renal Function: Mild



at Risk

1	116	113	108	99	68	48	39	26	9	4	1	0	0	0	0
2	122	114	102	83	63	52	43	23	11	7	4	2	1	0	0

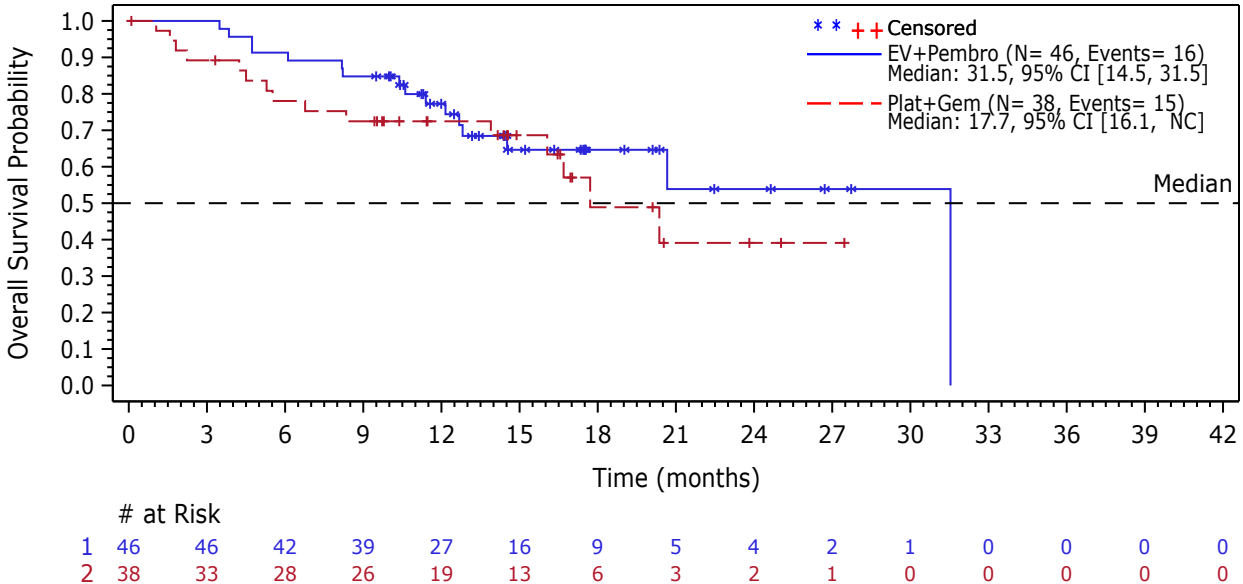
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (8.8 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.1.10: Kaplan-Meier Plot of Overall Survival by Renal Function - Analysis Set mITT 1 - Sensitivity Analysis 3

Renal Function: Moderate

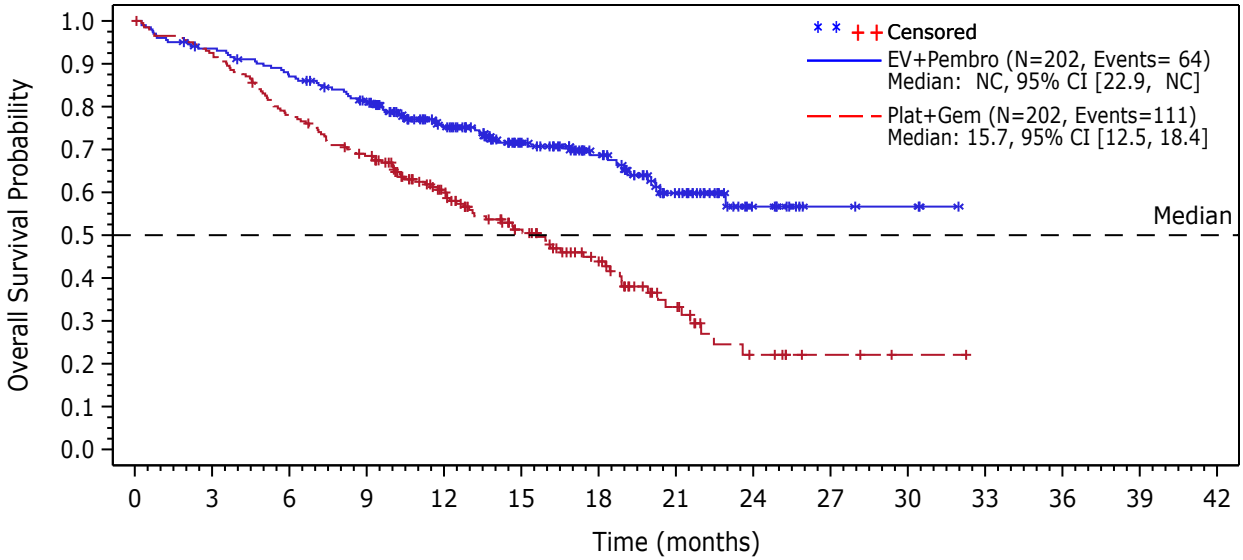


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (8.8 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.2: Kaplan-Meier Plot of Overall Survival - Analysis Set mITT 2 - Sensitivity Analysis 3



at Risk

1	202	187	173	157	120	86	63	36	12	4	3	0	0	0	0
2	202	186	156	134	93	62	41	20	8	3	1	0	0	0	0

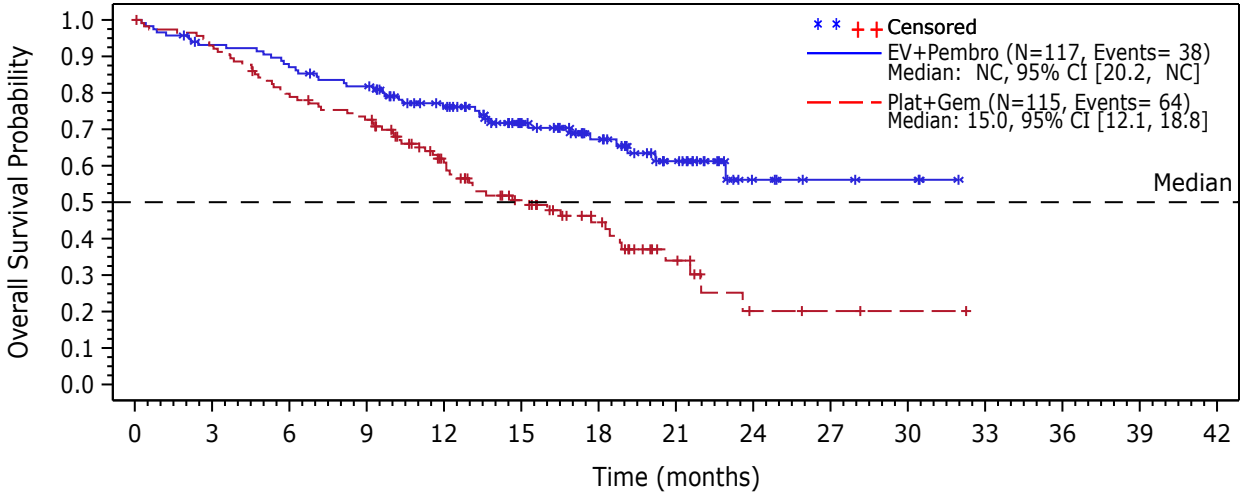
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (7.0 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.2.1: Kaplan-Meier Plot of Overall Survival by PD-L1 Expression - Analysis Set mITT 2 - Sensitivity Analysis 3

PD-L1 Expression: High (CPS>=10)



at Risk

1	117	107	100	93	76	56	40	24	7	4	3	0	0	0	0
2	115	106	90	81	56	39	25	11	3	2	1	0	0	0	0

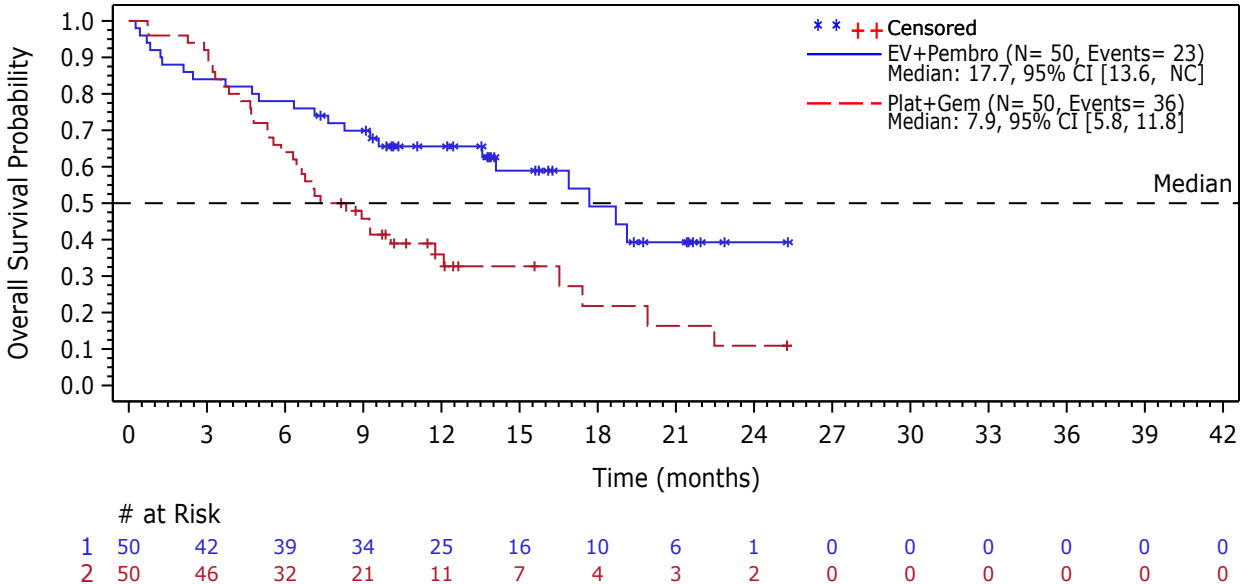
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (7.0 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.2.2: Kaplan-Meier Plot of Overall Survival by Liver Metastases - Analysis Set mITT 2 - Sensitivity Analysis 3

Liver Metastases: Present



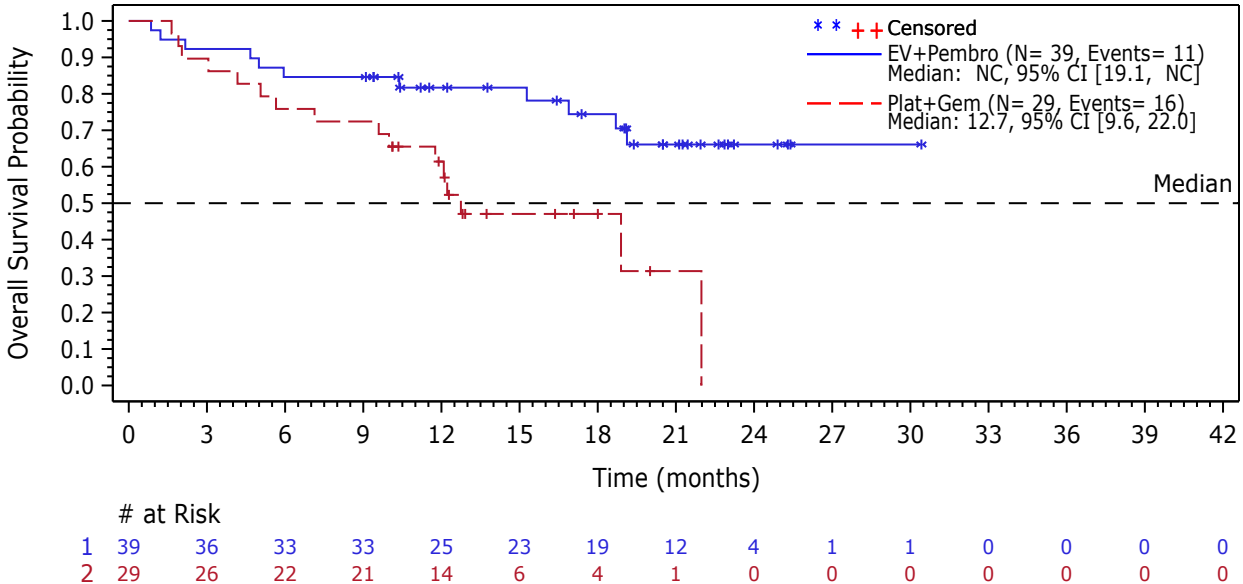
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (7.0 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.2.3: Kaplan-Meier Plot of Overall Survival by Age - Analysis Set mITT 2 - Sensitivity Analysis 3

Age: < 65 years



at Risk

1	39	36	33	33	25	23	19	12	4	1	1	0	0	0	0
2	29	26	22	21	14	6	4	1	0	0	0	0	0	0	0

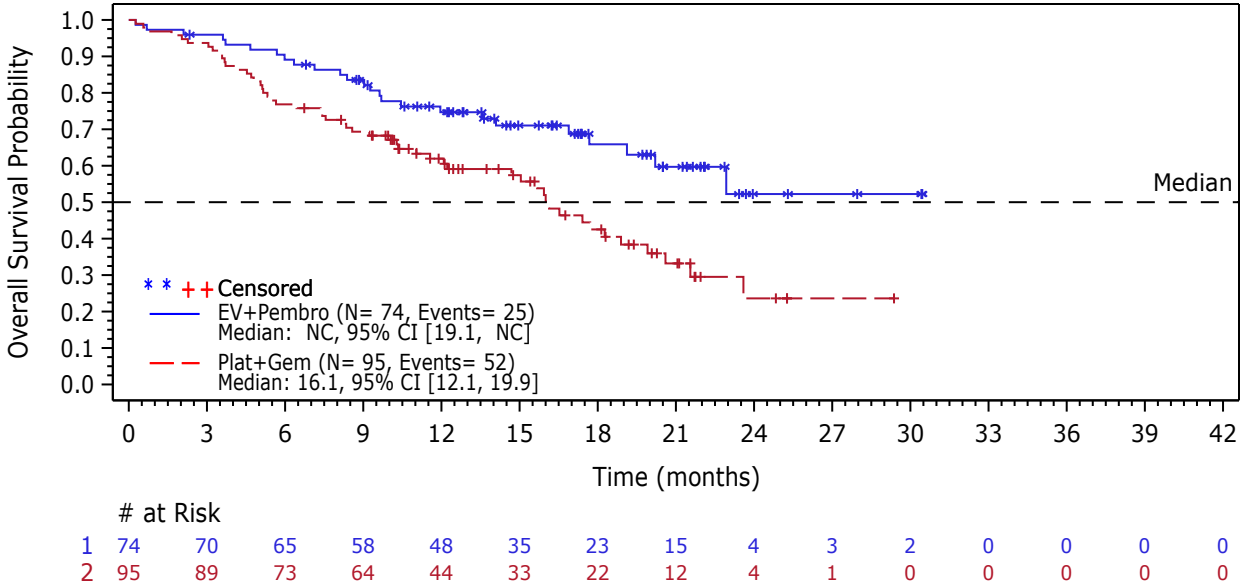
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (7.0 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.2.4: Kaplan-Meier Plot of Overall Survival by Region - Analysis Set mITT 2 - Sensitivity Analysis 3

Region: Europe



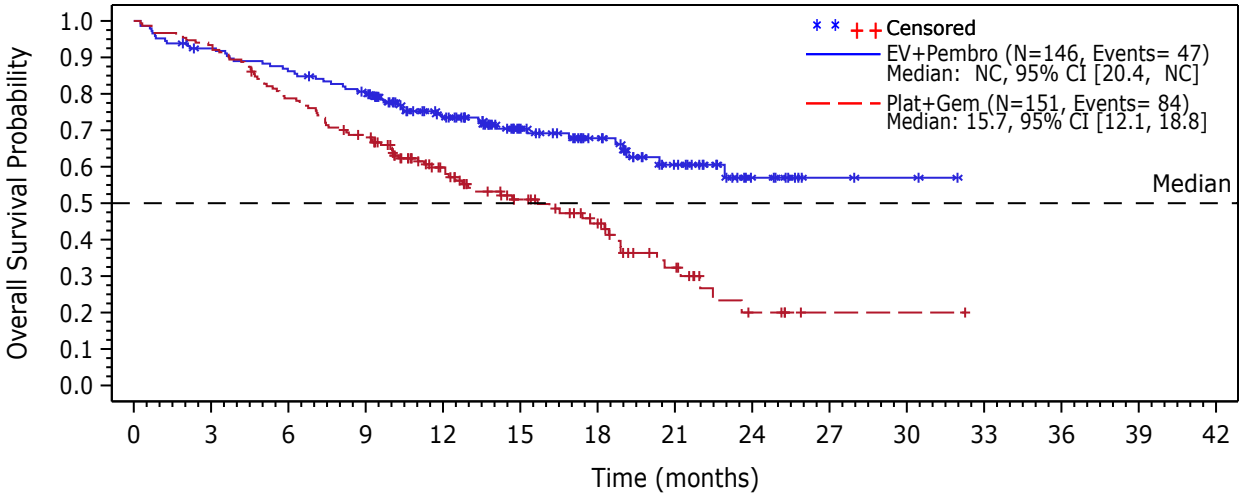
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (7.0 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.2.5: Kaplan-Meier Plot of Overall Survival by Sex - Analysis Set mITT 2 - Sensitivity Analysis 3

Sex: Male



at Risk

1	146	133	124	114	84	58	43	26	10	3	2	0	0	0	0
2	151	141	118	100	67	44	31	16	5	1	1	0	0	0	0

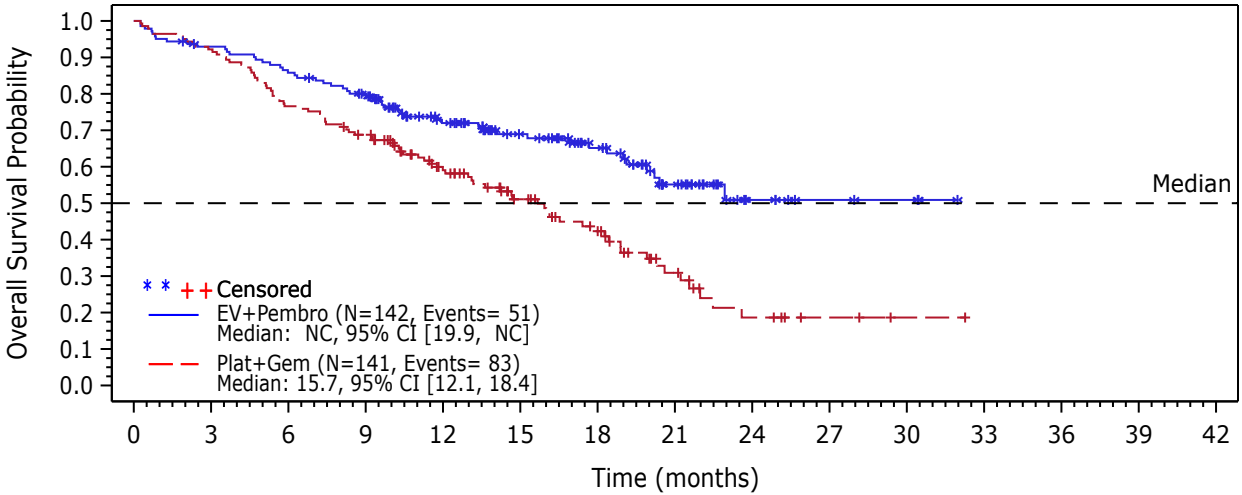
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (7.0 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.2.6: Kaplan-Meier Plot of Overall Survival by Race - Analysis Set mITT 2 - Sensitivity Analysis 3

Race: White



at Risk

1	142	130	120	109	81	61	46	25	8	4	3	0	0	0	0
2	141	130	108	95	66	45	32	16	7	3	1	0	0	0	0

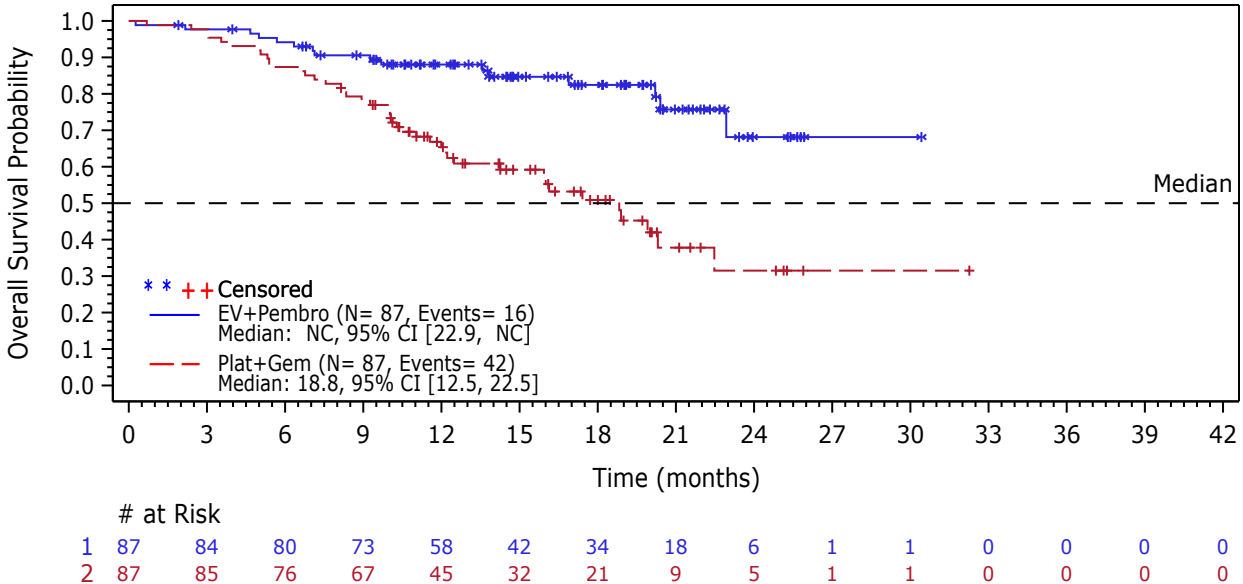
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (7.0 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.2.7: Kaplan-Meier Plot of Overall Survival by ECOG Status at Baseline - Analysis Set mITT 2 - Sensitivity Analysis 3

ECOG Status at Baseline: 0



at Risk

1	87	84	80	73	58	42	34	18	6	1	1	0	0	0	0
2	87	85	76	67	45	32	21	9	5	1	1	0	0	0	0

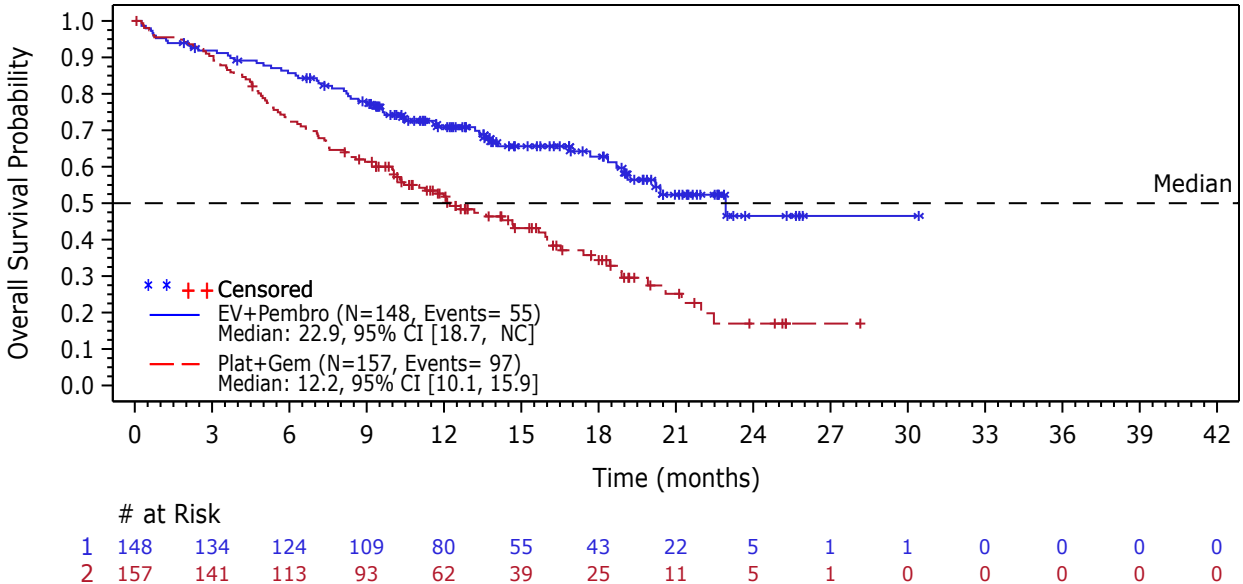
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (7.0 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.2.8: Kaplan-Meier Plot of Overall Survival by Metastases at Baseline - Analysis Set mITT 2 - Sensitivity Analysis 3

Metastases at Baseline: Visceral metastases



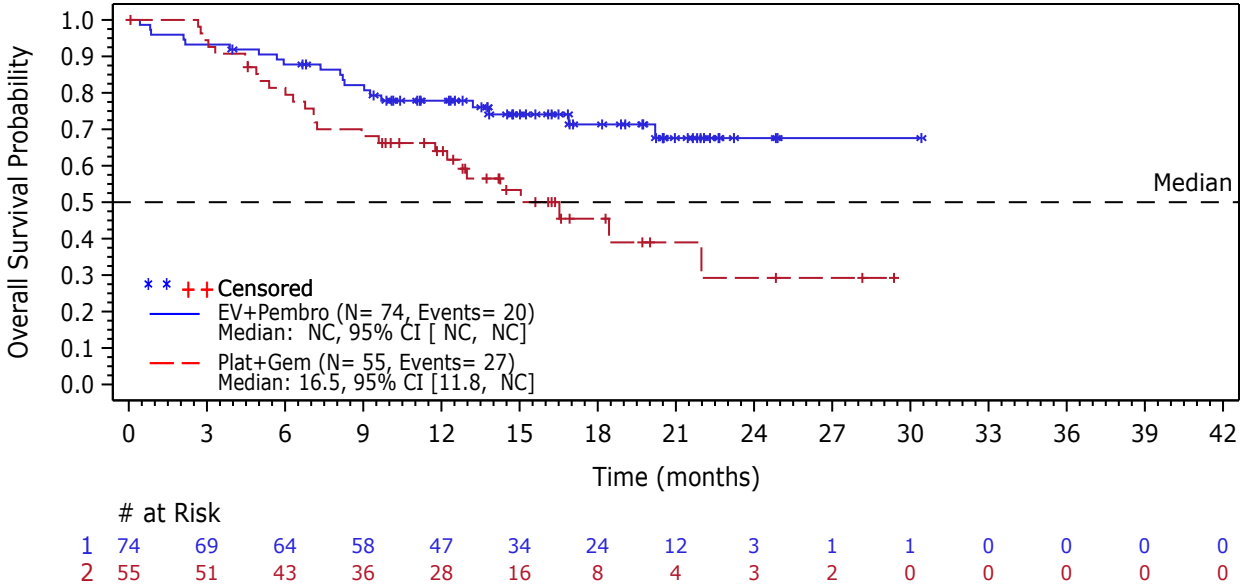
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (7.0 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.2.9: Kaplan-Meier Plot of Overall Survival by Primary Disease Site of Origin - Analysis Set mITT 2 - Sensitivity Analysis 3

Primary Disease Site of Origin: Upper tract



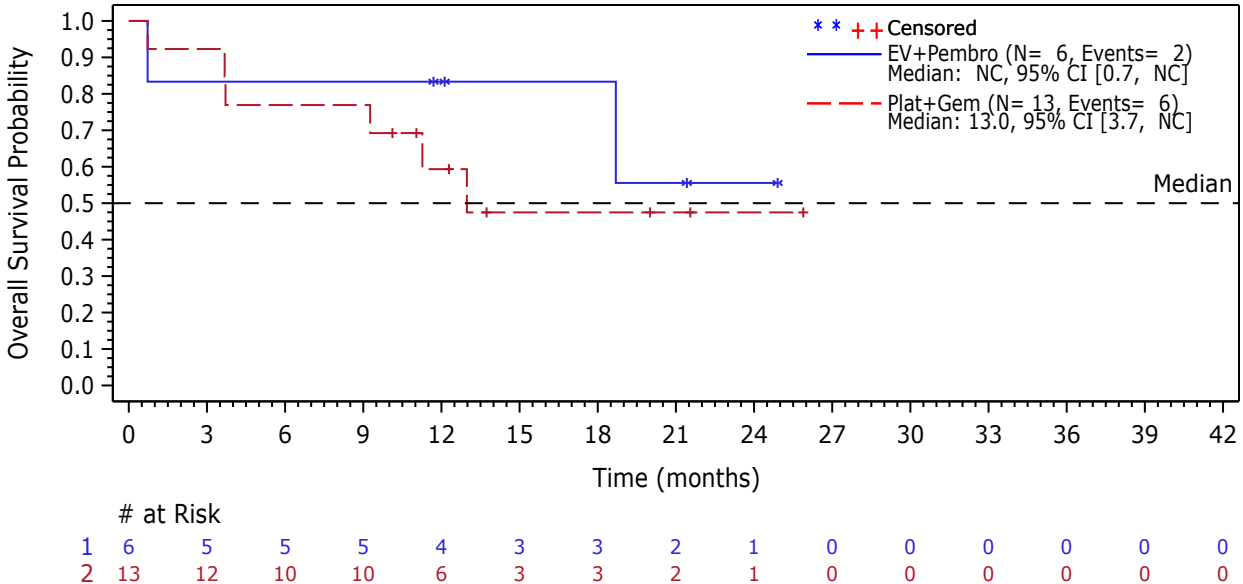
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (7.0 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.2.10: Kaplan-Meier Plot of Overall Survival by Renal Function - Analysis Set mITT 2 - Sensitivity Analysis 3

Renal Function: Normal



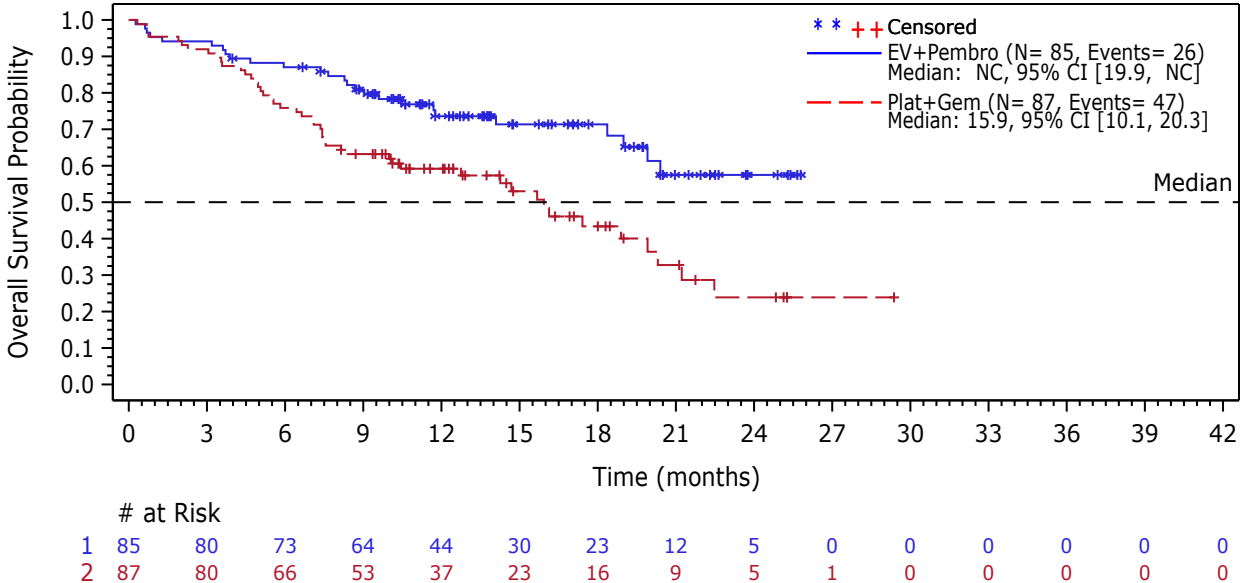
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (7.0 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.2.1: Kaplan-Meier Plot of Overall Survival by PD-L1 Expression - Analysis Set mITT 2 - Sensitivity Analysis 3

PD-L1 Expression: Low (CPS<10)



at Risk

1	85	80	73	64	44	30	23	12	5	0	0	0	0	0	0
2	87	80	66	53	37	23	16	9	5	1	0	0	0	0	0

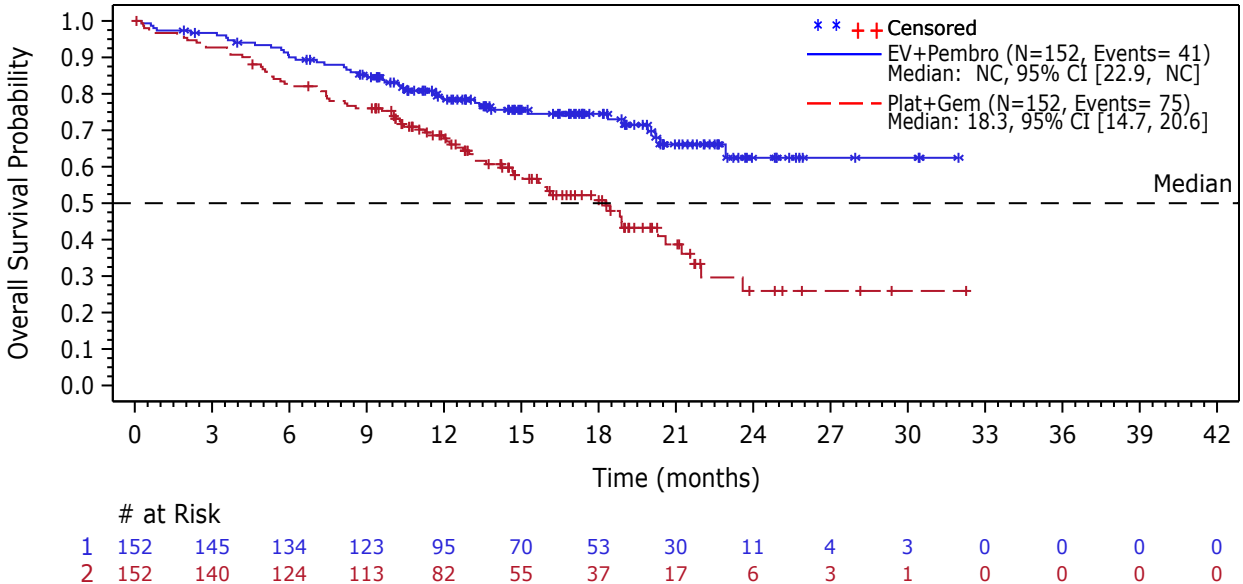
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (7.0 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.2.2: Kaplan-Meier Plot of Overall Survival by Liver Metastases - Analysis Set mITT 2 - Sensitivity Analysis 3

Liver Metastases: Absent



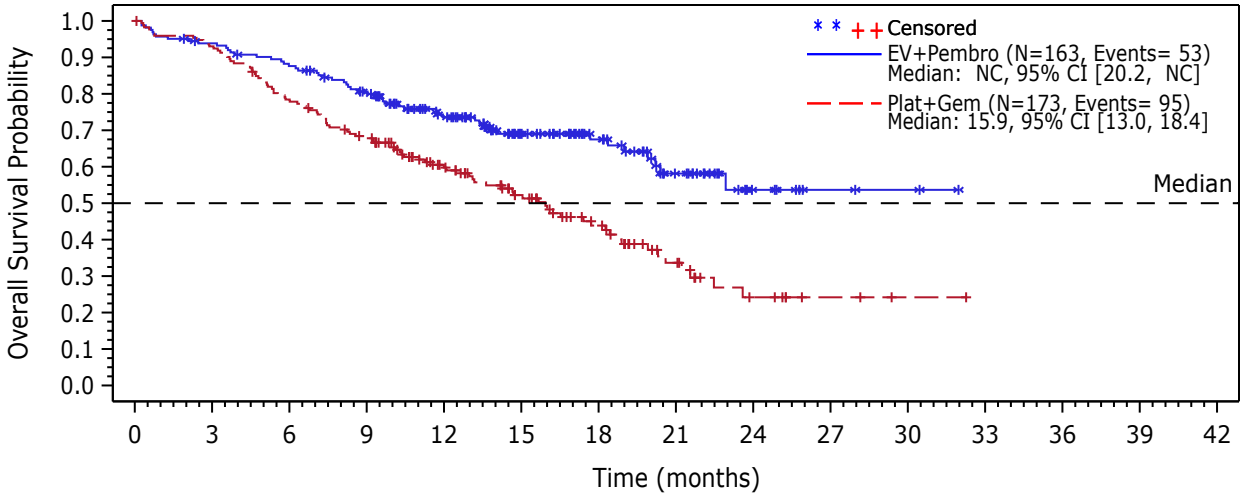
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (7.0 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.2.3: Kaplan-Meier Plot of Overall Survival by Age - Analysis Set mITT 2 - Sensitivity Analysis 3

Age: >= 65 years



at Risk

1	163	151	140	124	95	63	44	24	8	3	2	0	0	0	0
2	173	160	134	113	79	56	37	19	8	3	1	0	0	0	0

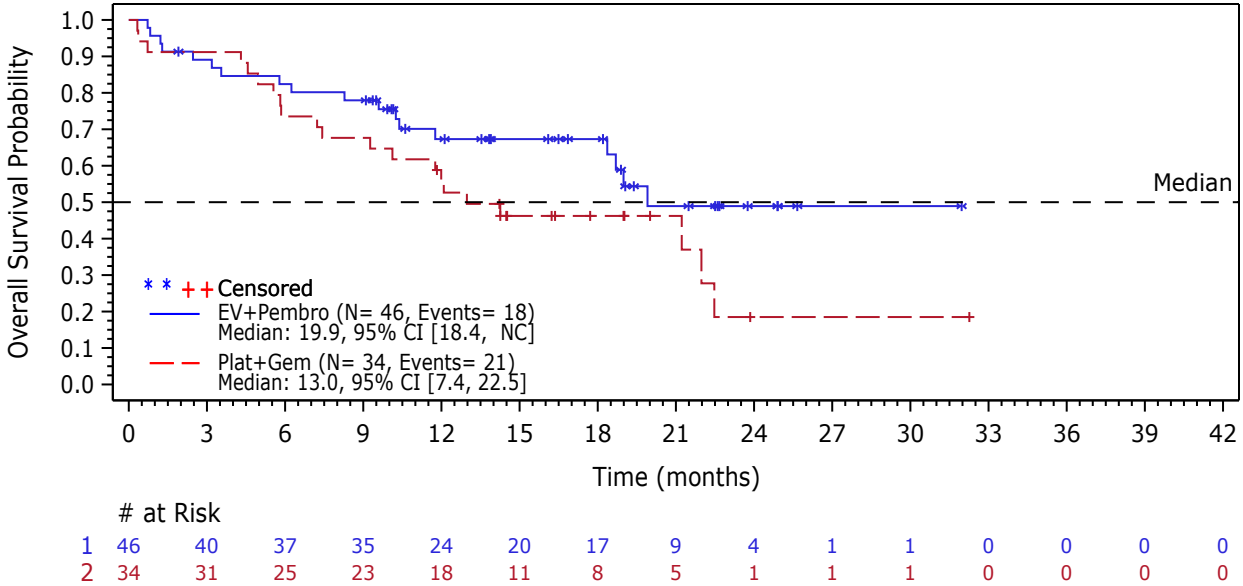
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (7.0 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.2.4: Kaplan-Meier Plot of Overall Survival by Region - Analysis Set mITT 2 - Sensitivity Analysis 3

Region: North America



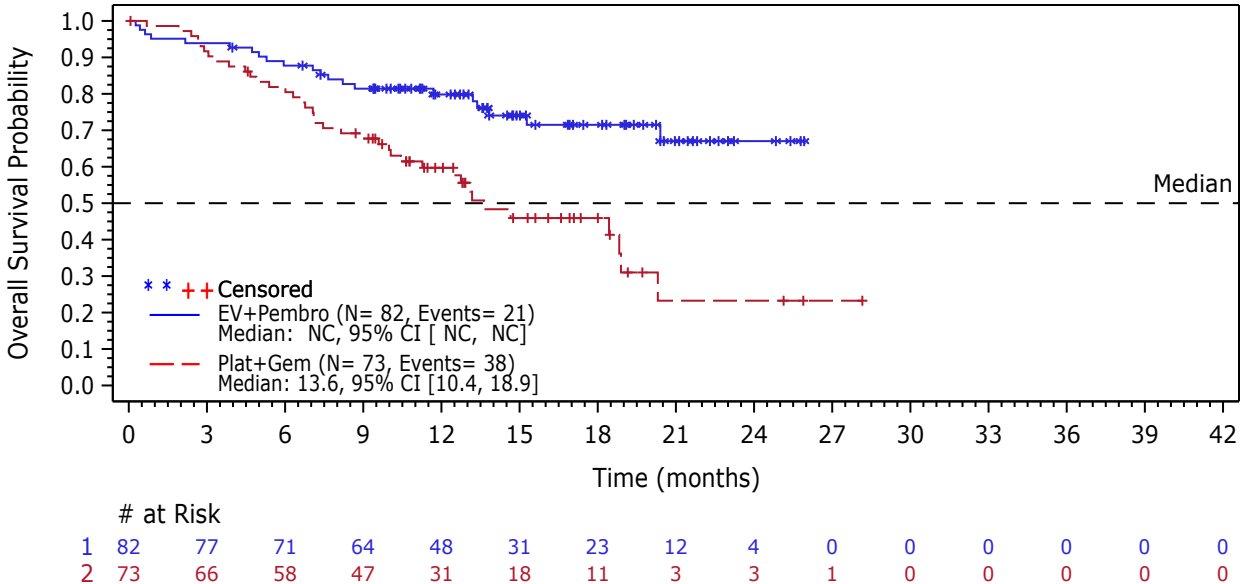
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (7.0 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.2.4: Kaplan-Meier Plot of Overall Survival by Region - Analysis Set mITT 2 - Sensitivity Analysis 3

Region: Rest of World



at Risk

1	82	77	71	64	48	31	23	12	4	0	0	0	0	0	0
2	73	66	58	47	31	18	11	3	3	1	0	0	0	0	0

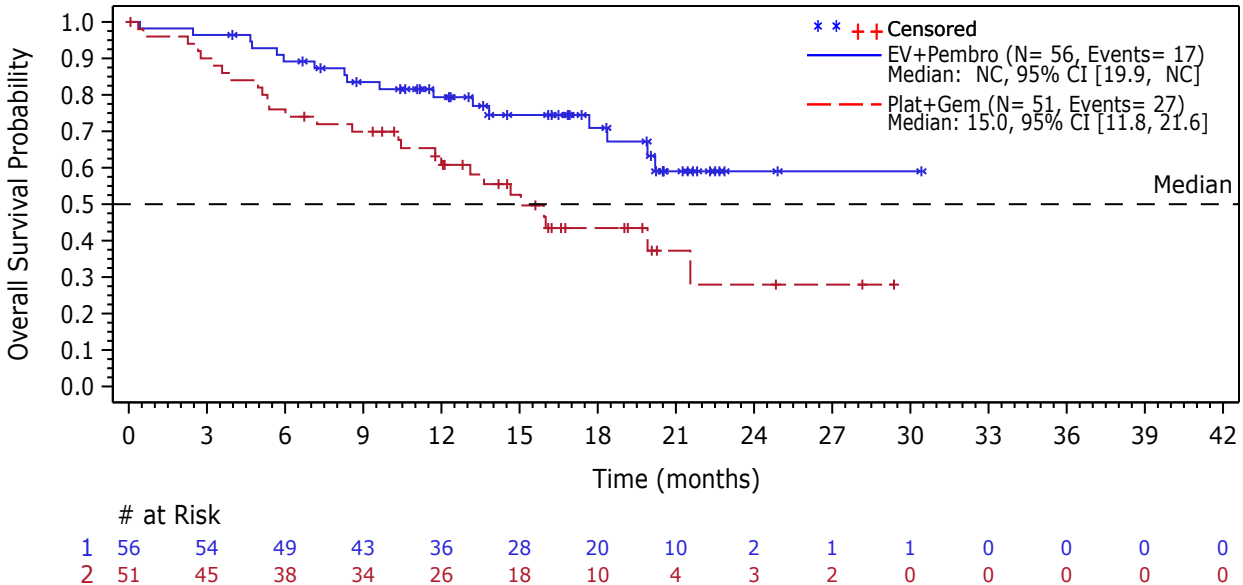
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (7.0 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.2.5: Kaplan-Meier Plot of Overall Survival by Sex - Analysis Set mITT 2 - Sensitivity Analysis 3

Sex: Female



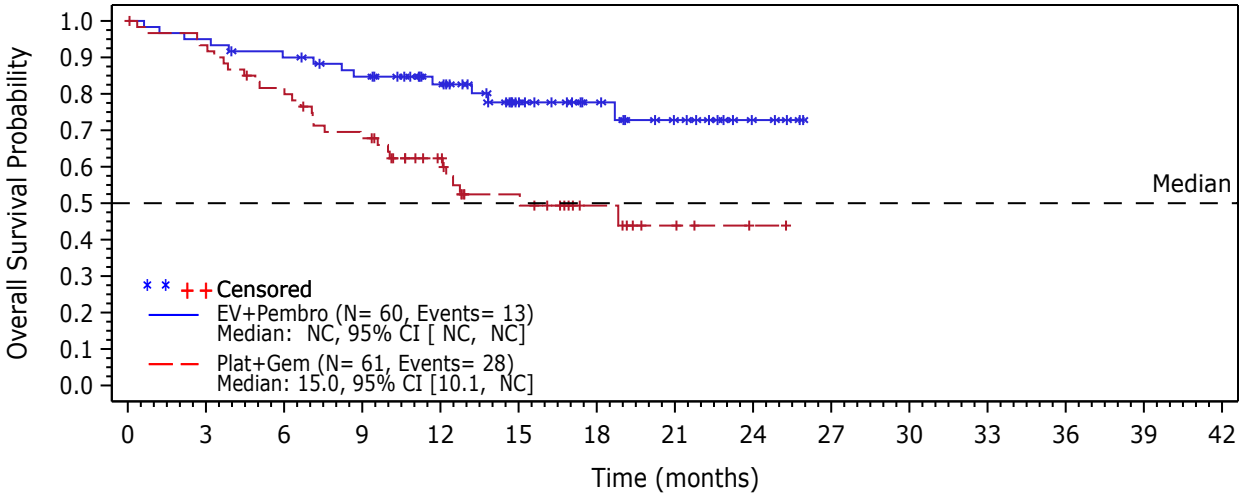
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (7.0 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.2.6: Kaplan-Meier Plot of Overall Survival by Race - Analysis Set mITT 2 - Sensitivity Analysis 3

Race: Non-white



at Risk

1	60	57	53	48	39	25	17	11	4	0	0	0	0	0	0
2	61	56	48	39	27	17	9	4	1	0	0	0	0	0	0

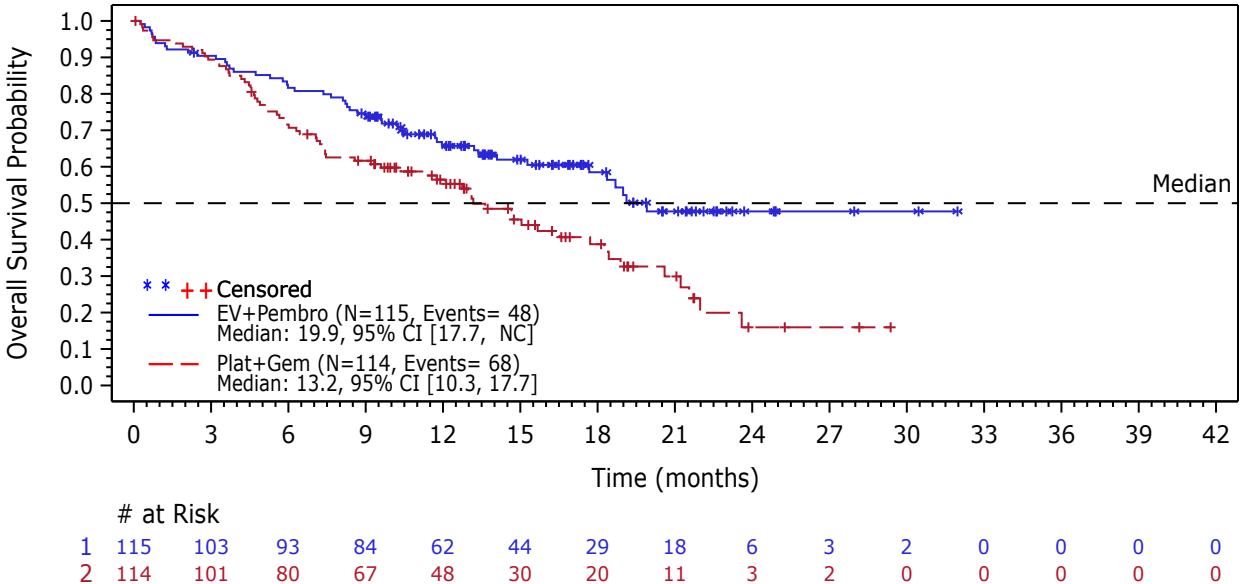
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (7.0 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.2.7: Kaplan-Meier Plot of Overall Survival by ECOG Status at Baseline - Analysis Set mITT 2 - Sensitivity Analysis 3

ECOG Status at Baseline: 1-2



at Risk

1	115	103	93	84	62	44	29	18	6	3	2	0	0	0	0
2	114	101	80	67	48	30	20	11	3	2	0	0	0	0	0

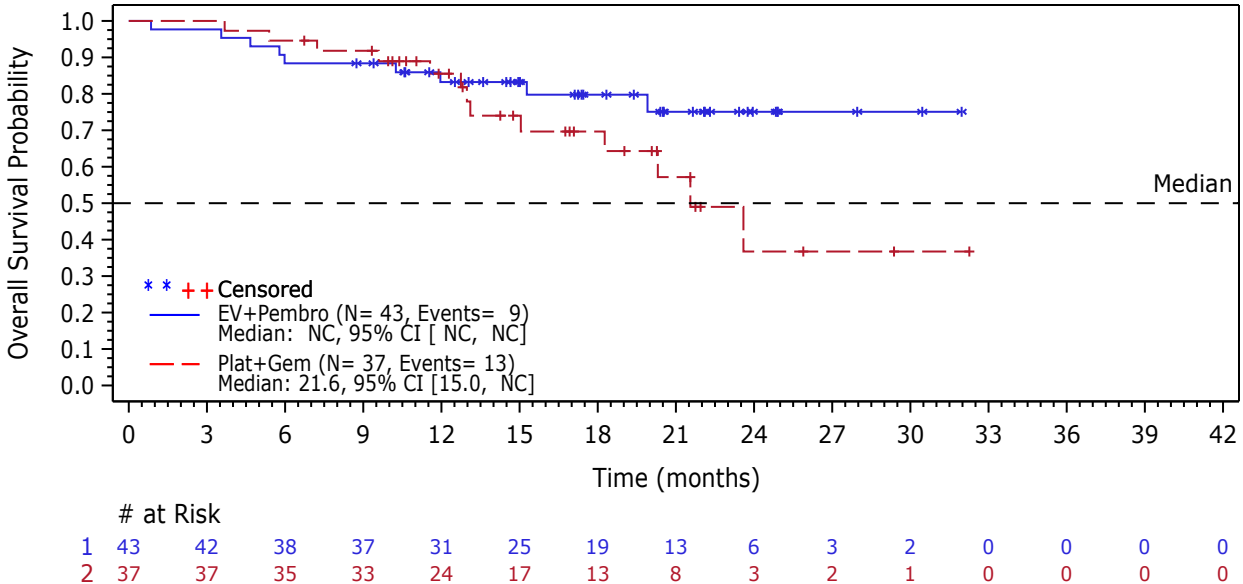
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (7.0 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.2.8: Kaplan-Meier Plot of Overall Survival by Metastases at Baseline - Analysis Set mITT 2 - Sensitivity Analysis 3

Metastases at Baseline: Lymph node only



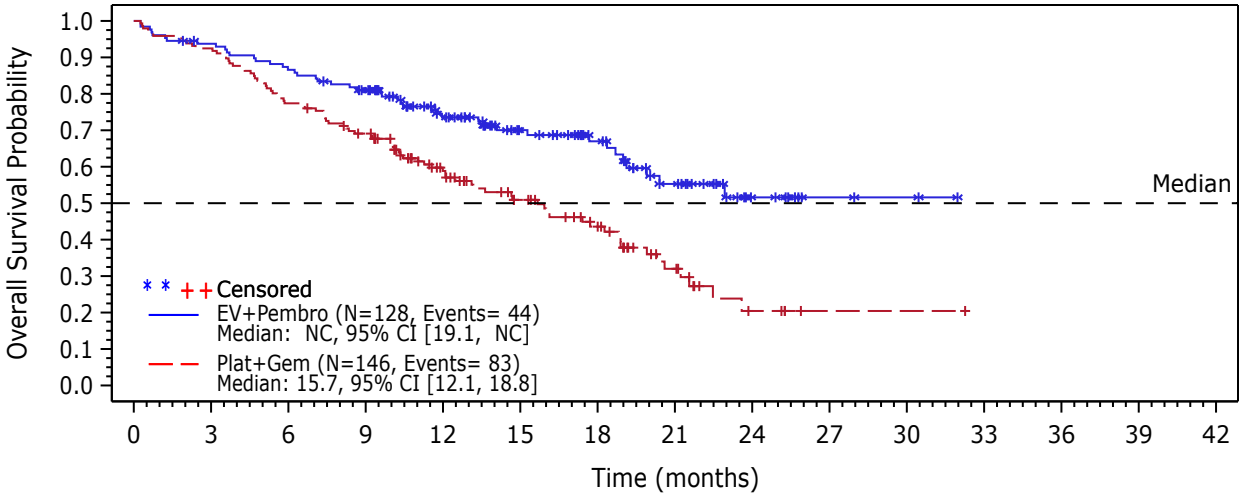
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (7.0 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.2.9: Kaplan-Meier Plot of Overall Survival by Primary Disease Site of Origin - Analysis Set mITT 2 - Sensitivity Analysis 3

Primary Disease Site of Origin: Lower tract



at Risk

1	128	118	109	99	73	52	39	24	9	3	2	0	0	0	0
2	146	135	113	98	65	46	33	16	5	1	1	0	0	0	0

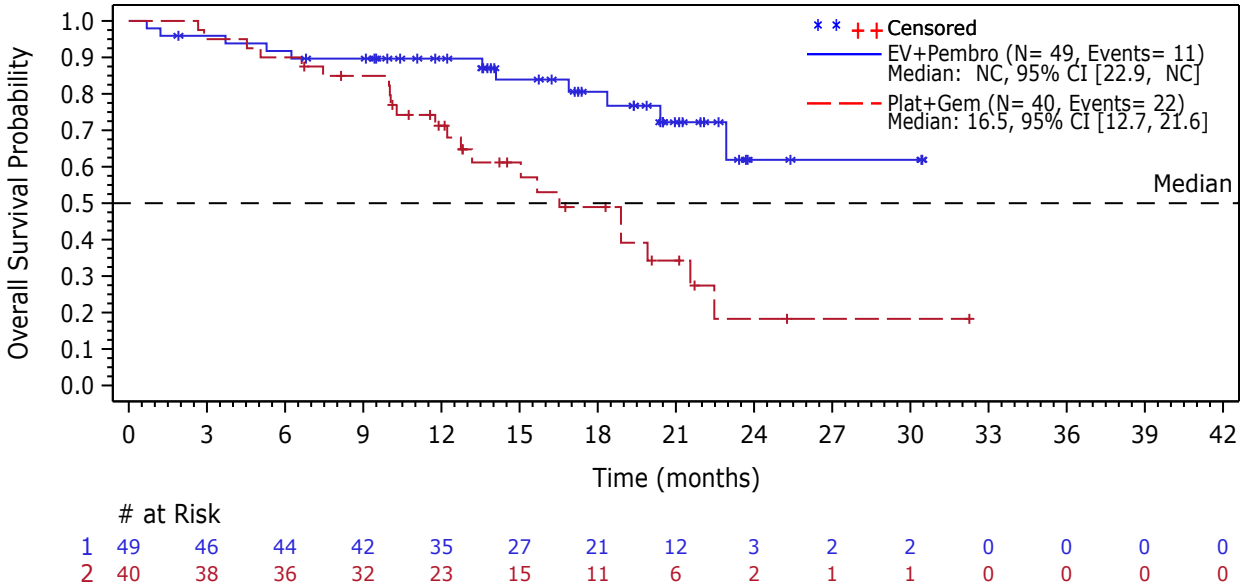
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (7.0 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.2.10: Kaplan-Meier Plot of Overall Survival by Renal Function - Analysis Set mITT 2 - Sensitivity Analysis 3

Renal Function: Mild



at Risk

1	49	46	44	42	35	27	21	12	3	2	2	0	0	0	0
2	40	38	36	32	23	15	11	6	2	1	1	0	0	0	0

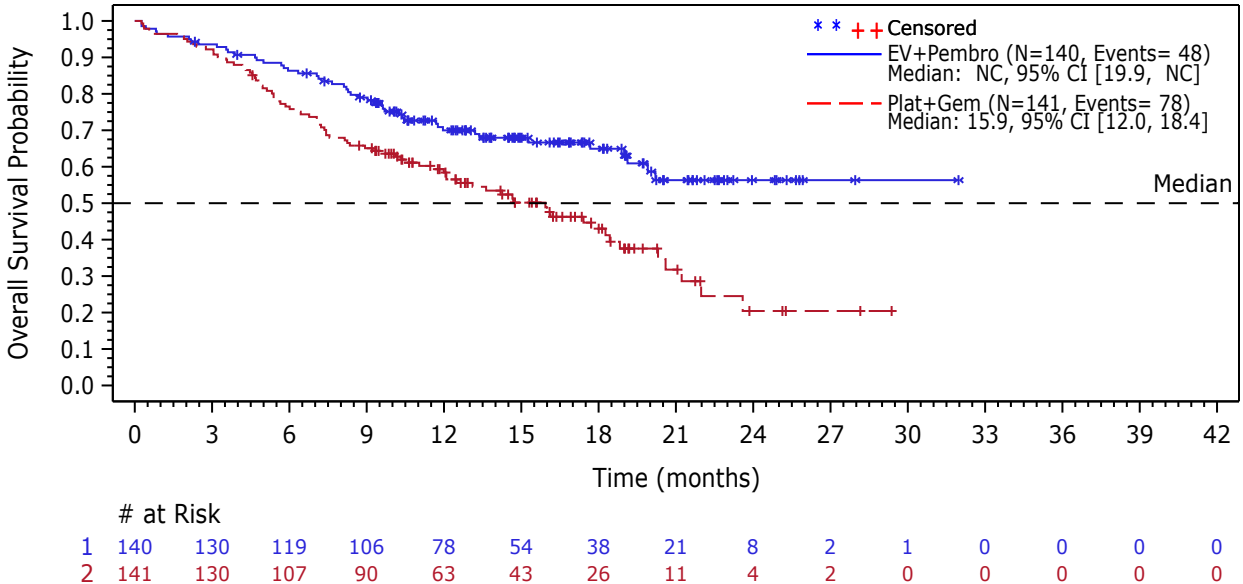
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (7.0 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.2.10: Kaplan-Meier Plot of Overall Survival by Renal Function - Analysis Set mITT 2 - Sensitivity Analysis 3

Renal Function: Moderate



at Risk

1	140	130	119	106	78	54	38	21	8	2	1	0	0	0	0
2	141	130	107	90	63	43	26	11	4	2	0	0	0	0	0

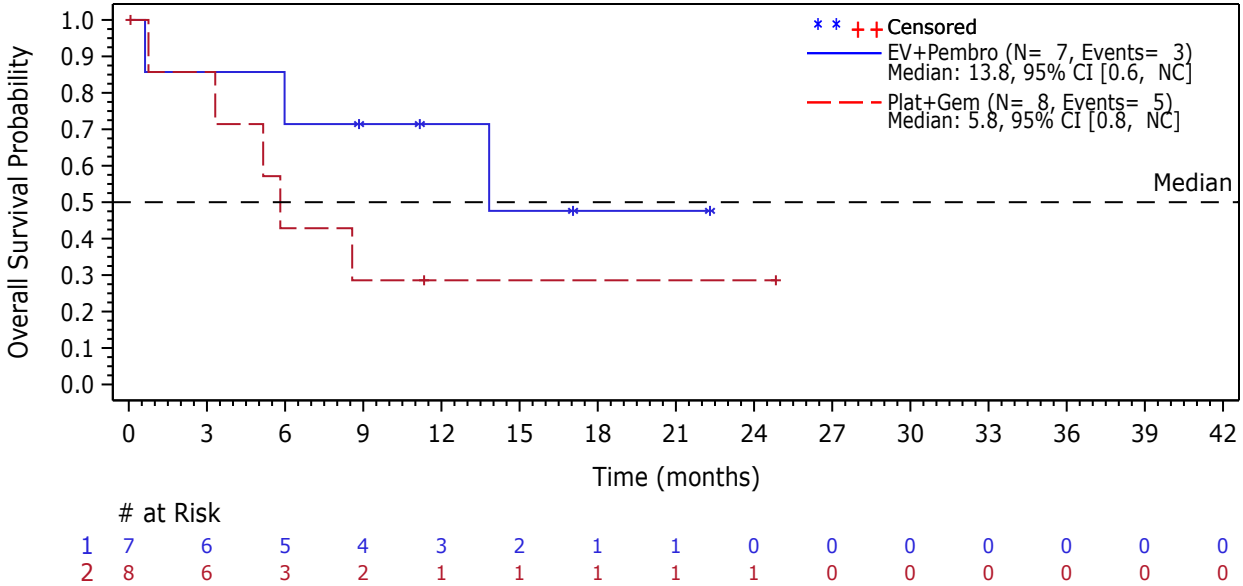
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (7.0 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.4.2.10: Kaplan-Meier Plot of Overall Survival by Renal Function - Analysis Set mITT 2 - Sensitivity Analysis 3

Renal Function: Severe

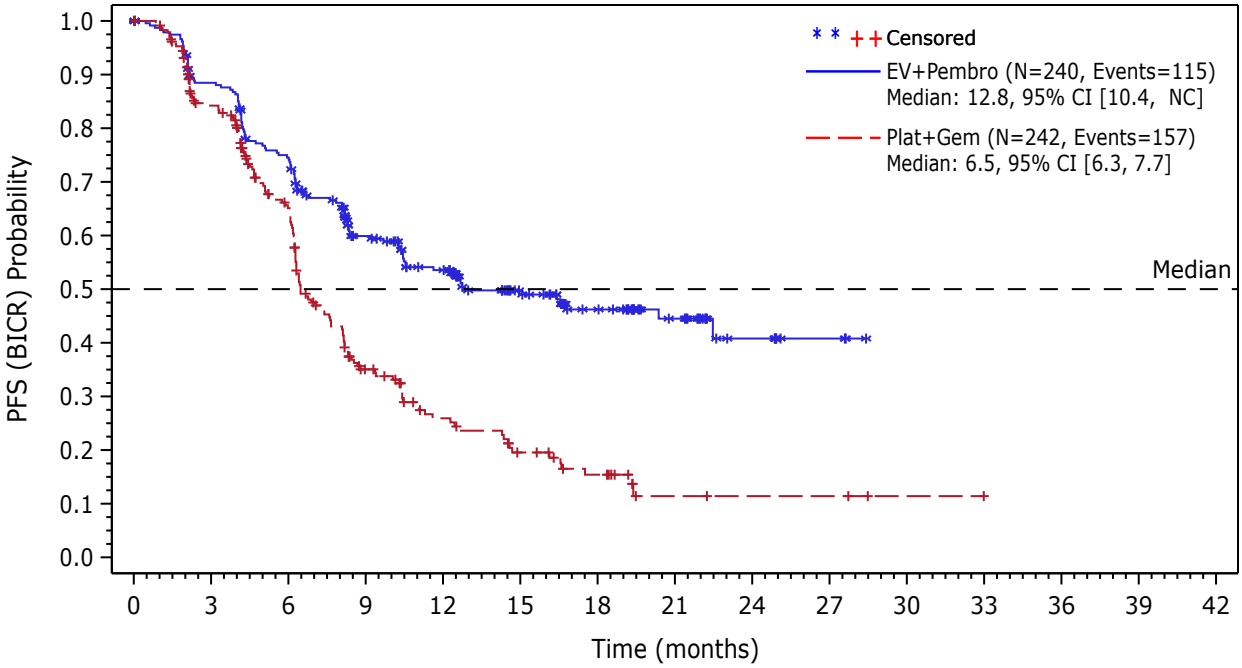


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; INV=investigator; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OS=overall survival; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Patients who died in platinum-based chemotherapy and completed at least 4 cycles of chemotherapy, had at least stable disease until end of treatment visit (INV) and had no progressive disease or died within 10 weeks after last dose of chemotherapy were imputed as having an event at date of death + avelumab OS advantage (7.0 months) or censored at data cutoff date if data cutoff date < date of death + avelumab OS advantage.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.1: Kaplan-Meier Plot of Progression-Free Survival (BICR) - Analysis Set mITT 1



at Risk

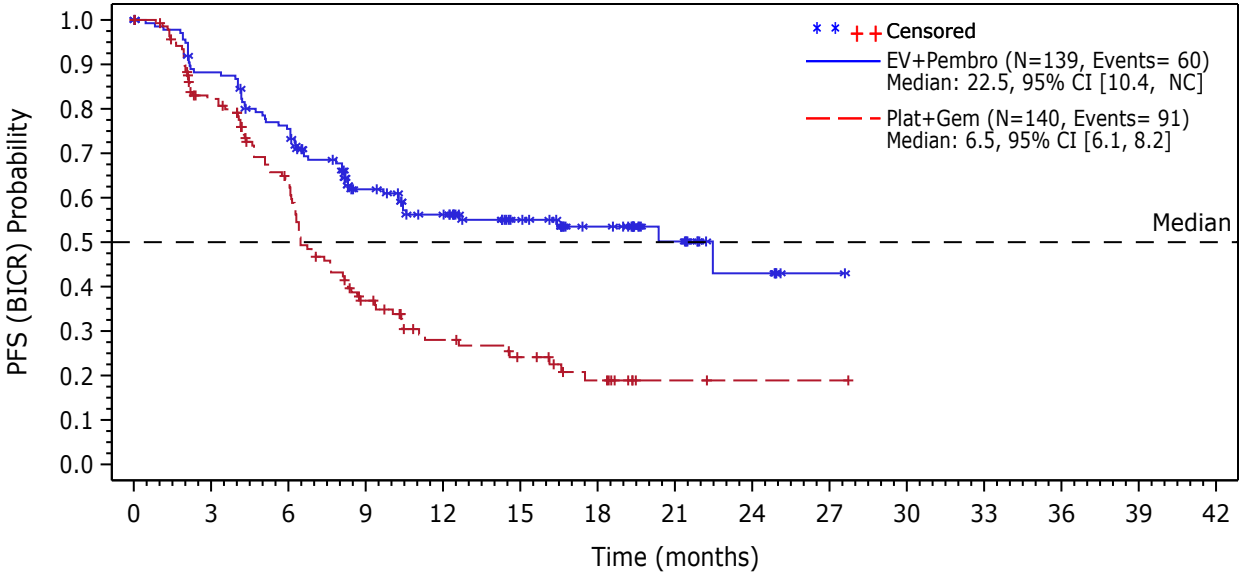
1	240	205	170	120	97	64	43	25	9	3	0	0	0	0	0
2	242	185	124	56	34	22	14	4	3	3	1	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.1.1: Kaplan-Meier Plot of Progression-Free Survival (BICR) by PD-L1 Expression - Analysis Set mITT 1

PD-L1 Expression: High (CPS>=10)



at Risk

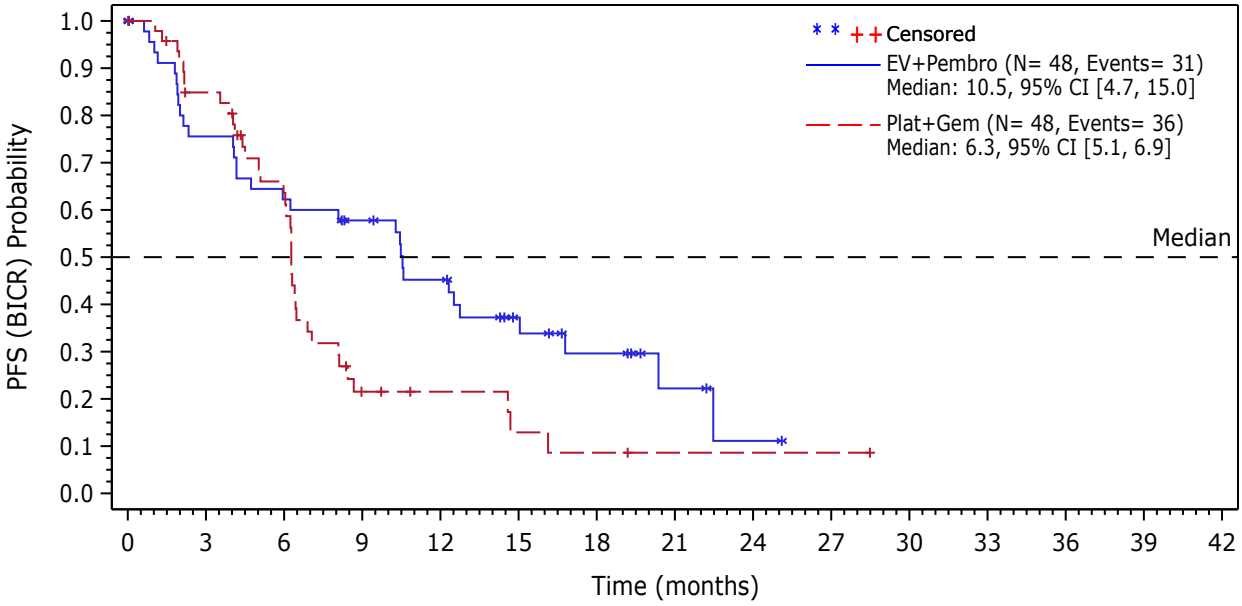
1	139	119	100	69	56	40	28	15	6	1	0	0	0	0	0
2	140	106	73	38	23	17	10	2	1	1	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.1.2: Kaplan-Meier Plot of Progression-Free Survival (BICR) by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Present



at Risk

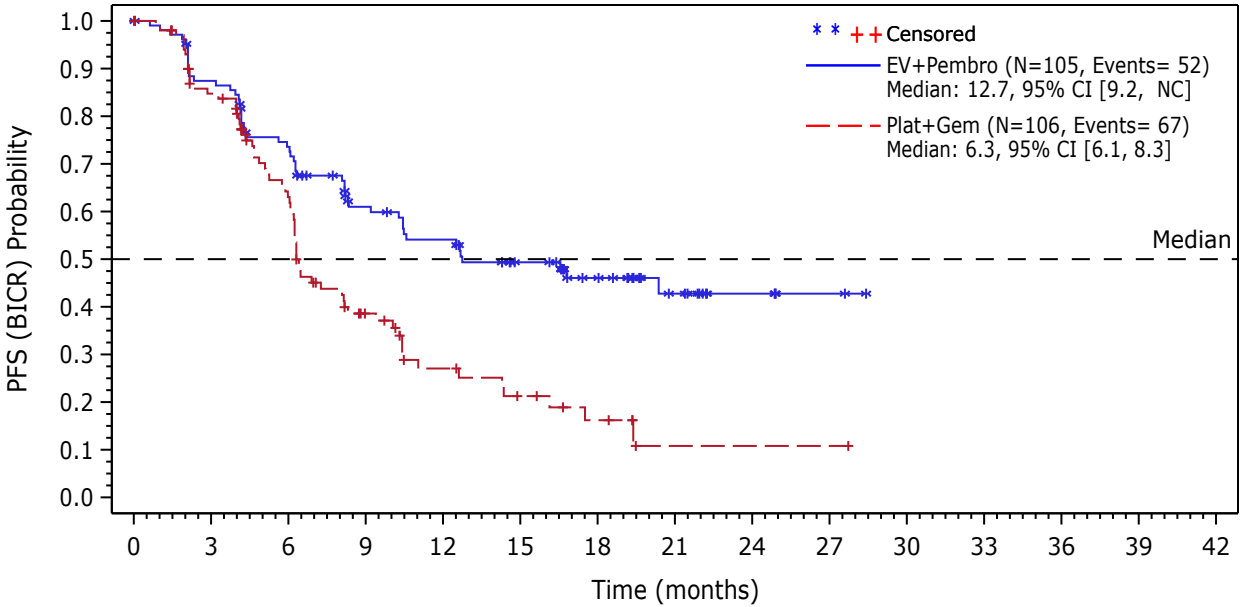
1	48	34	28	24	18	11	7	3	1	0	0	0	0	0	0
2	48	38	26	7	5	3	2	1	1	1	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.1.3: Kaplan-Meier Plot of Progression-Free Survival (BICR) by Age - Analysis Set mITT 1

Age: < 65 years



at Risk

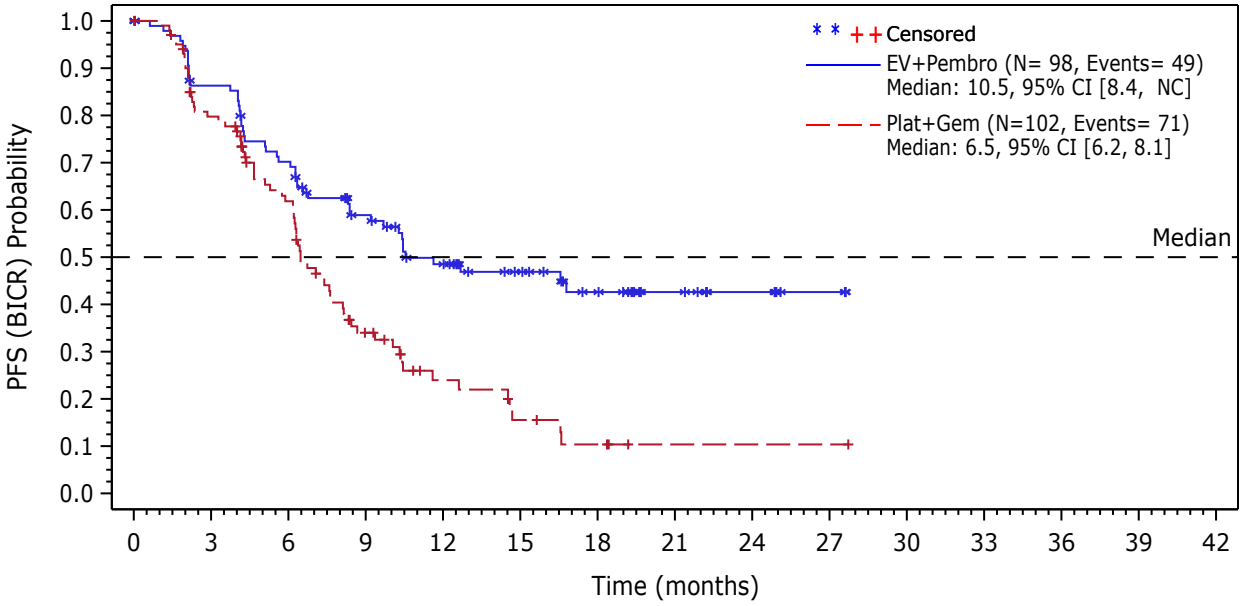
1	105	90	73	54	47	36	23	12	5	2	0	0	0	0	0
2	106	81	53	26	15	10	6	1	1	1	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.1.4: Kaplan-Meier Plot of Progression-Free Survival (BICR) by Region - Analysis Set mITT 1

Region: Europe



at Risk

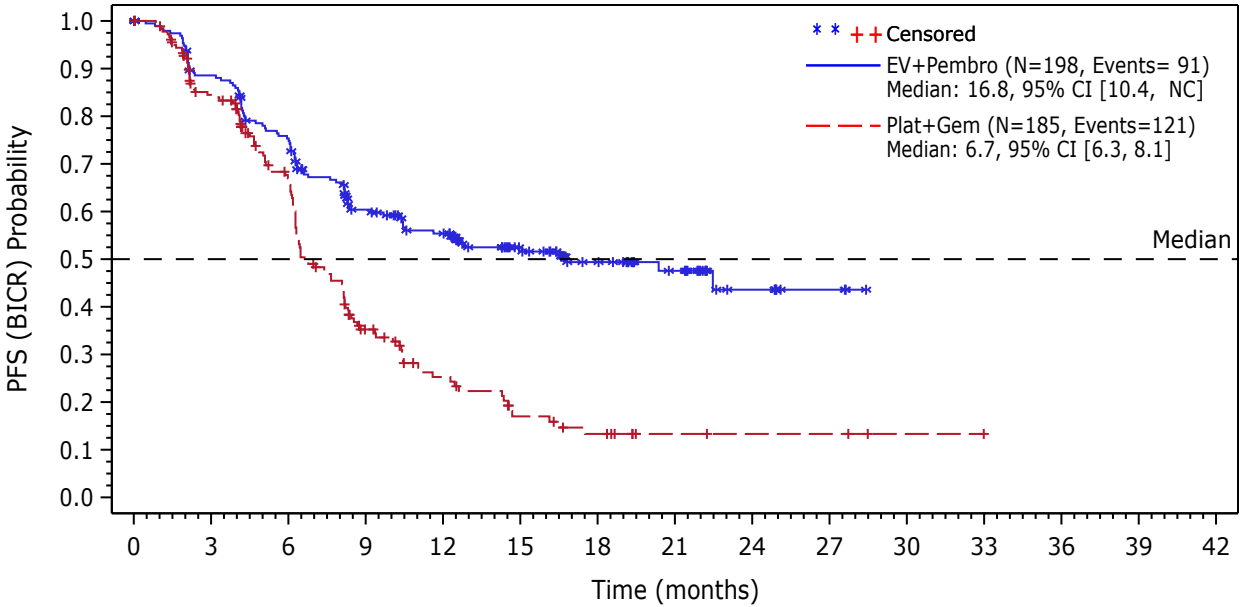
1	98	81	65	48	36	26	18	10	6	2	0	0	0	0	0
2	102	77	53	24	12	7	4	1	1	1	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.1.5: Kaplan-Meier Plot of Progression-Free Survival (BICR) by Sex - Analysis Set mITT 1

Sex: Male



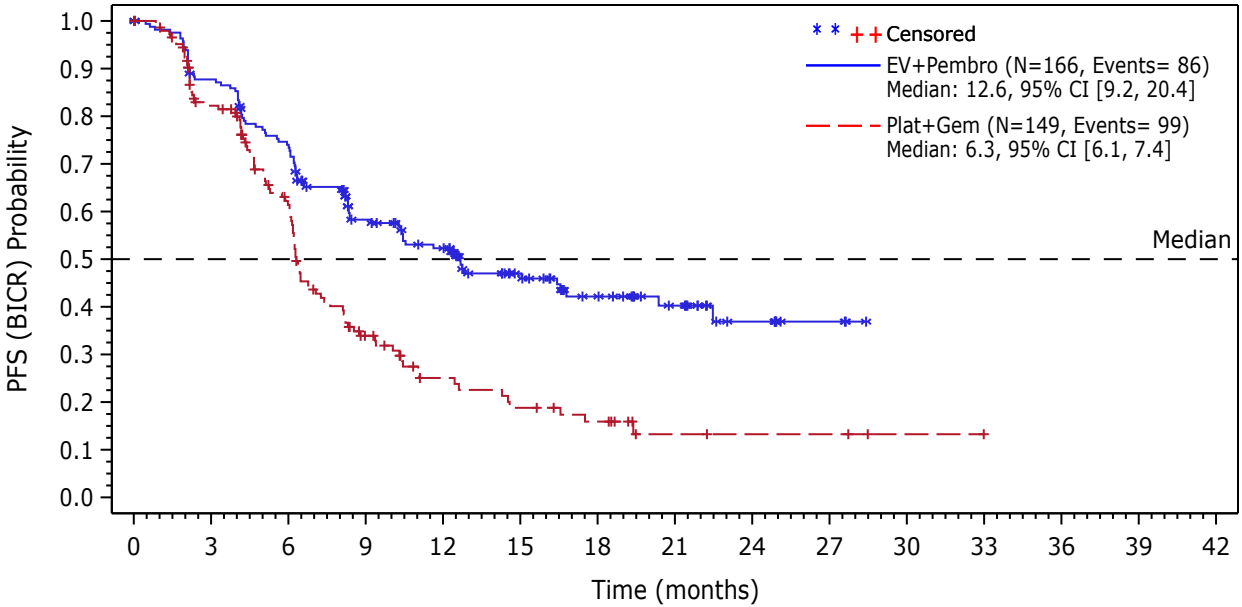
at Risk

1	198	169	141	102	86	59	39	25	9	3	0	0	0	0	0
2	185	142	97	43	26	15	10	4	3	3	1	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.1.6: Kaplan-Meier Plot of Progression-Free Survival (BICR) by Race - Analysis Set mITT 1
Race: White



at Risk

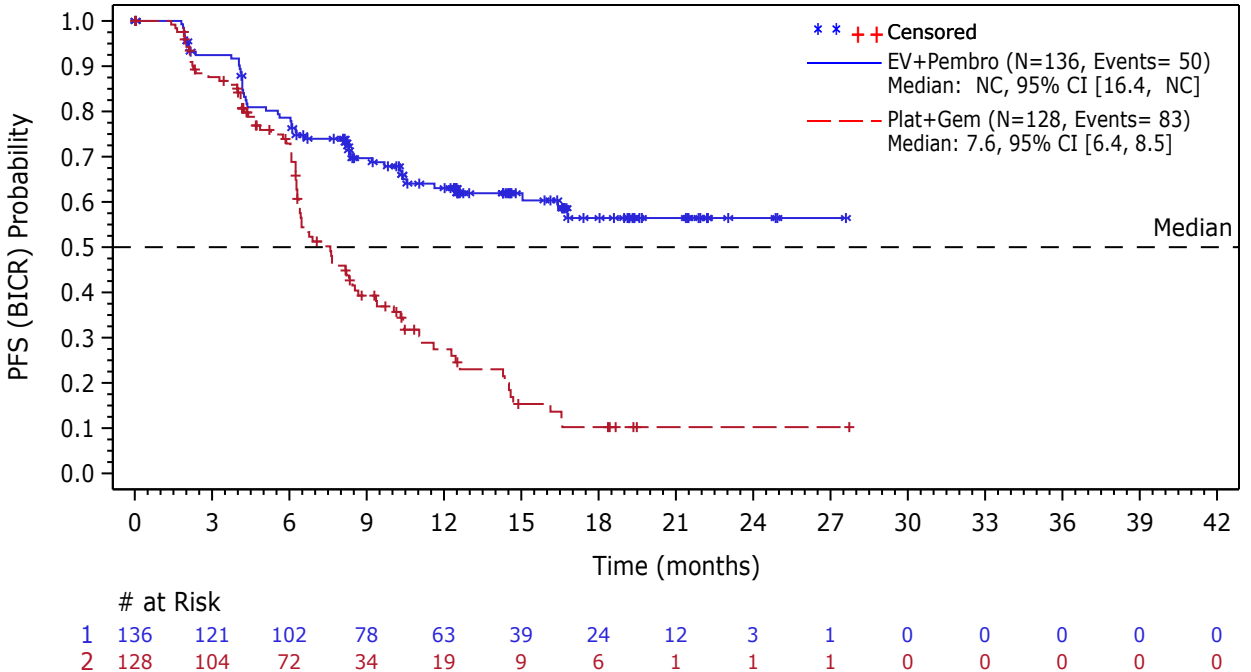
1	166	142	118	82	68	44	30	20	9	3	0	0	0	0	0
2	149	111	73	34	20	15	11	4	3	3	1	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.1.7: Kaplan-Meier Plot of Progression-Free Survival (BICR) by ECOG Status at Baseline - Analysis Set mITT 1

ECOG Status at Baseline: 0

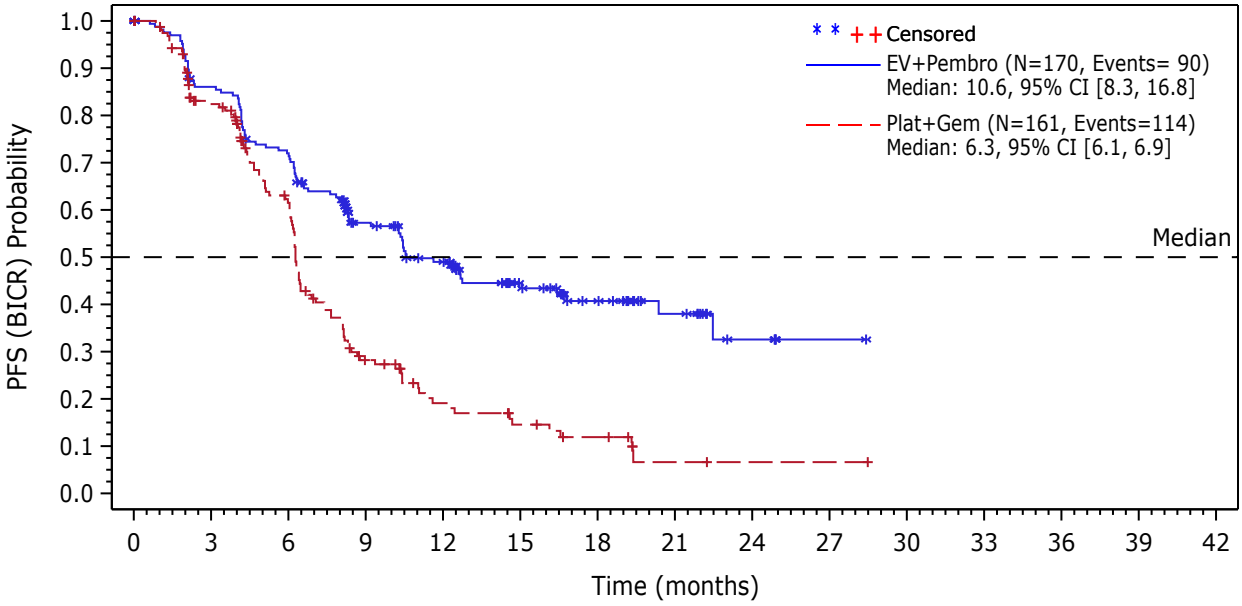


Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.1.8: Kaplan-Meier Plot of Progression-Free Survival (BICR) by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Visceral metastases



at Risk

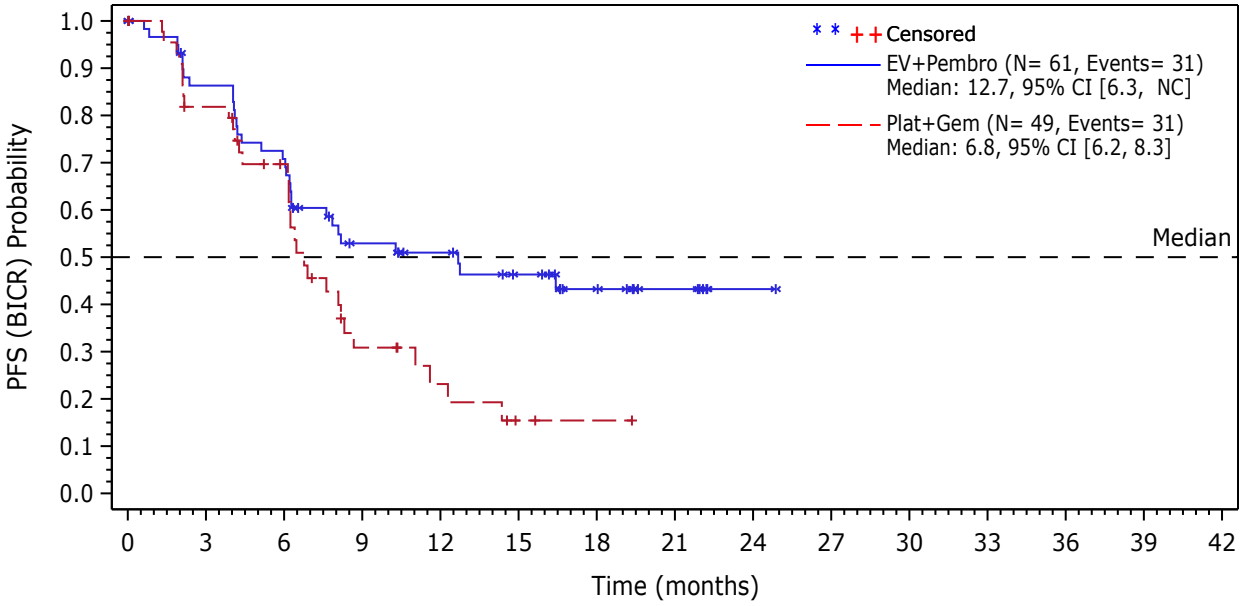
1	170	141	117	80	63	40	26	14	5	1	0	0	0	0	0
2	161	120	79	32	18	12	8	2	1	1	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.1.9: Kaplan-Meier Plot of Progression-Free Survival (BICR) by Primary Disease Site of Origin - Analysis Set mITT 1

Primary Disease Site of Origin: Upper tract



at Risk

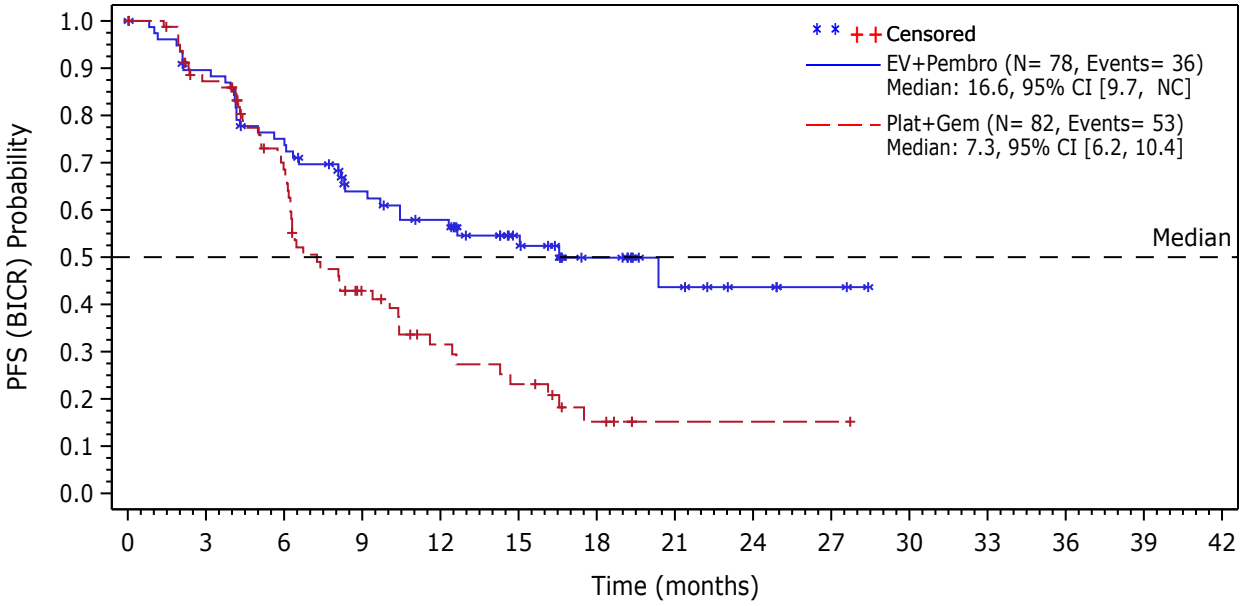
1	61	50	41	27	23	18	11	6	1	0	0	0	0	0	0
2	49	35	26	10	6	2	1	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.1.10: Kaplan-Meier Plot of Progression-Free Survival (BICR) by Renal Function - Analysis Set mITT 1

Renal Function: Normal



at Risk

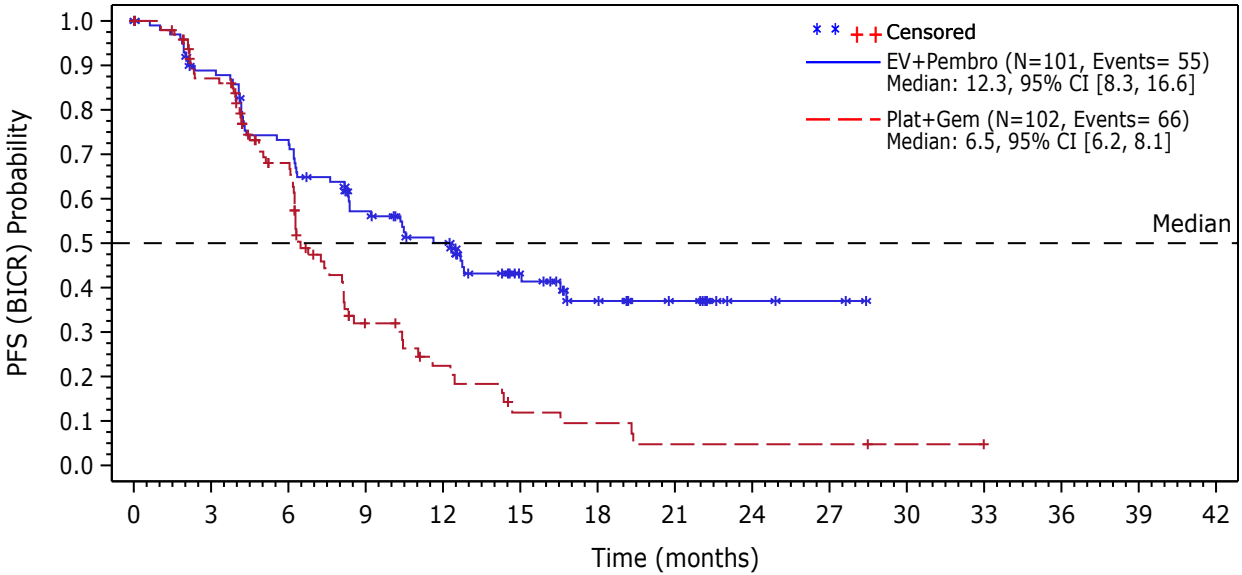
1	78	68	56	43	37	25	15	7	4	2	0	0	0	0	0
2	82	66	46	24	15	11	5	1	1	1	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.1.1: Kaplan-Meier Plot of Progression-Free Survival (BICR) by PD-L1 Expression - Analysis Set mITT 1

PD-L1 Expression: Low (CPS<10)



at Risk

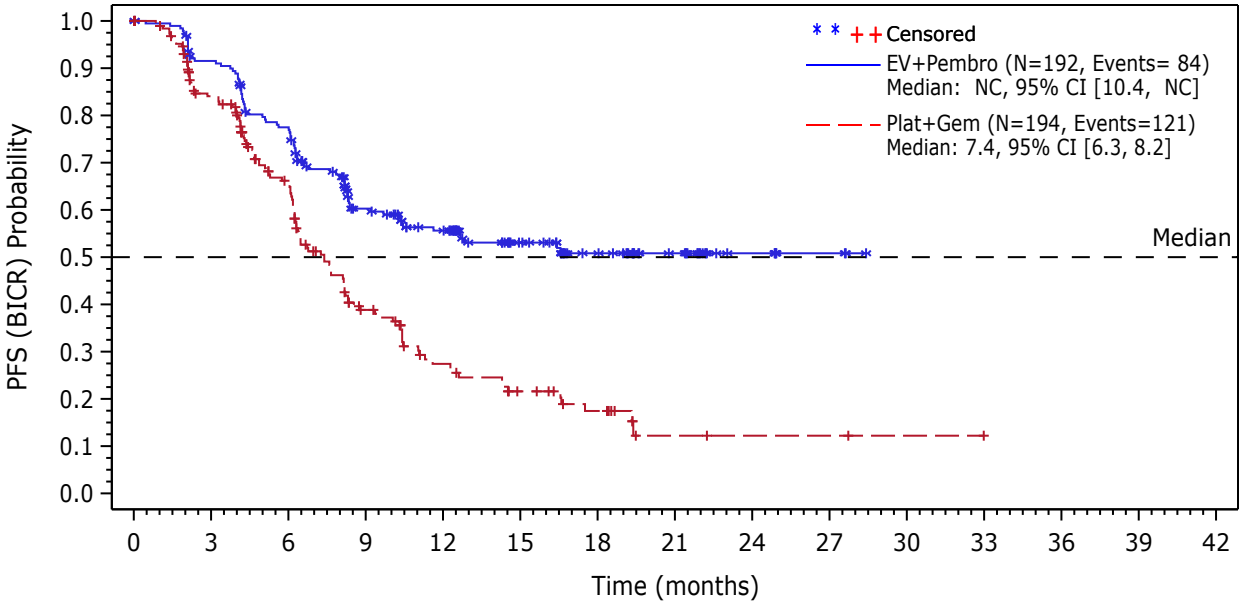
1	101	86	70	51	41	24	15	10	3	2	0	0	0	0	0
2	102	79	51	18	11	5	4	2	2	2	1	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.1.2: Kaplan-Meier Plot of Progression-Free Survival (BICR) by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Absent



at Risk

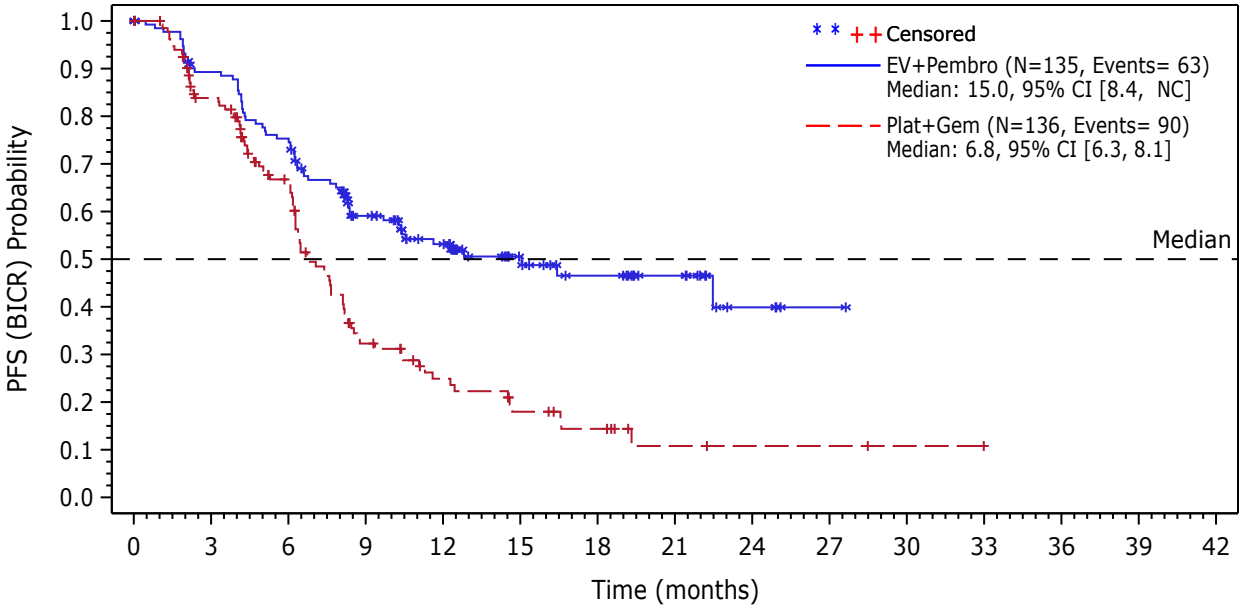
1	192	171	142	96	79	53	36	22	8	3	0	0	0	0	0
2	194	147	98	49	29	19	12	3	2	2	1	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.1.3: Kaplan-Meier Plot of Progression-Free Survival (BICR) by Age - Analysis Set mITT 1

Age: >= 65 years



at Risk

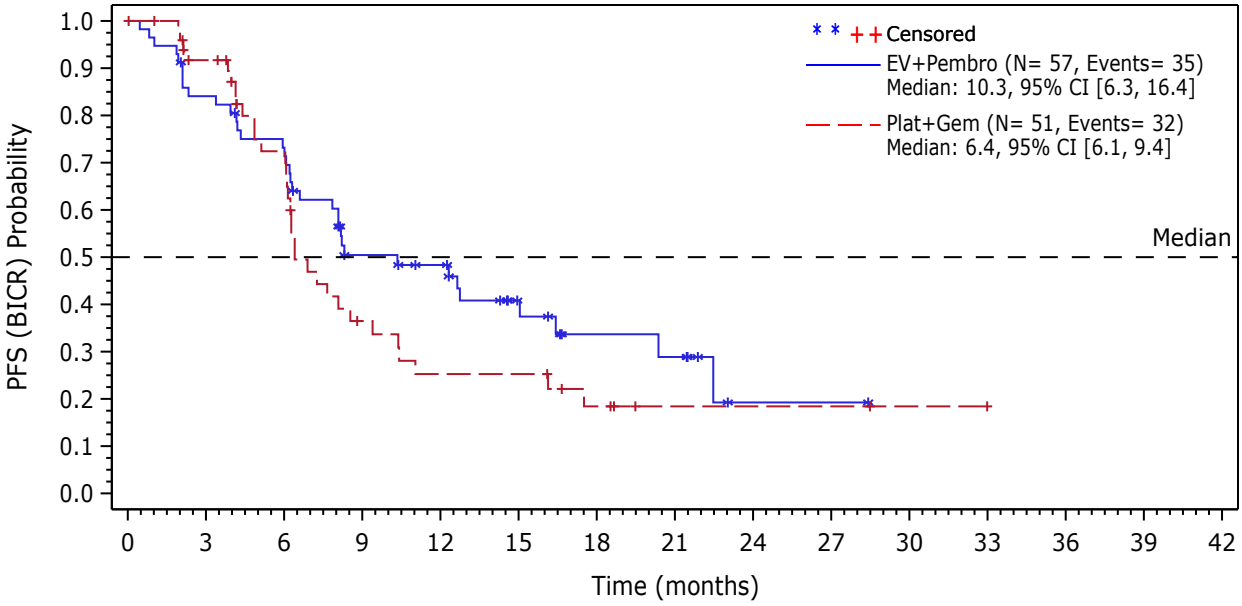
1	135	115	97	66	50	28	20	13	4	1	0	0	0	0	0
2	136	104	71	30	19	12	8	3	2	2	1	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.1.4: Kaplan-Meier Plot of Progression-Free Survival (BICR) by Region - Analysis Set mITT 1

Region: North America



at Risk

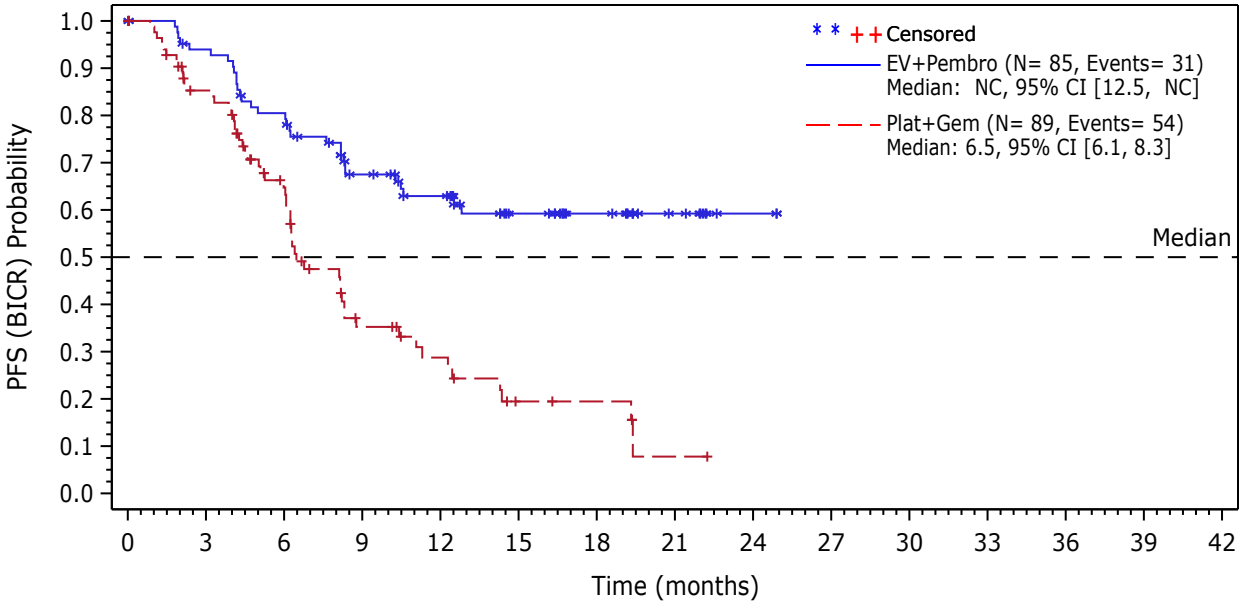
1	57	47	40	24	21	12	7	6	1	1	0	0	0	0	0
2	51	42	29	13	9	9	5	2	2	2	1	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.1.4: Kaplan-Meier Plot of Progression-Free Survival (BICR) by Region - Analysis Set mITT 1

Region: Rest of World



at Risk

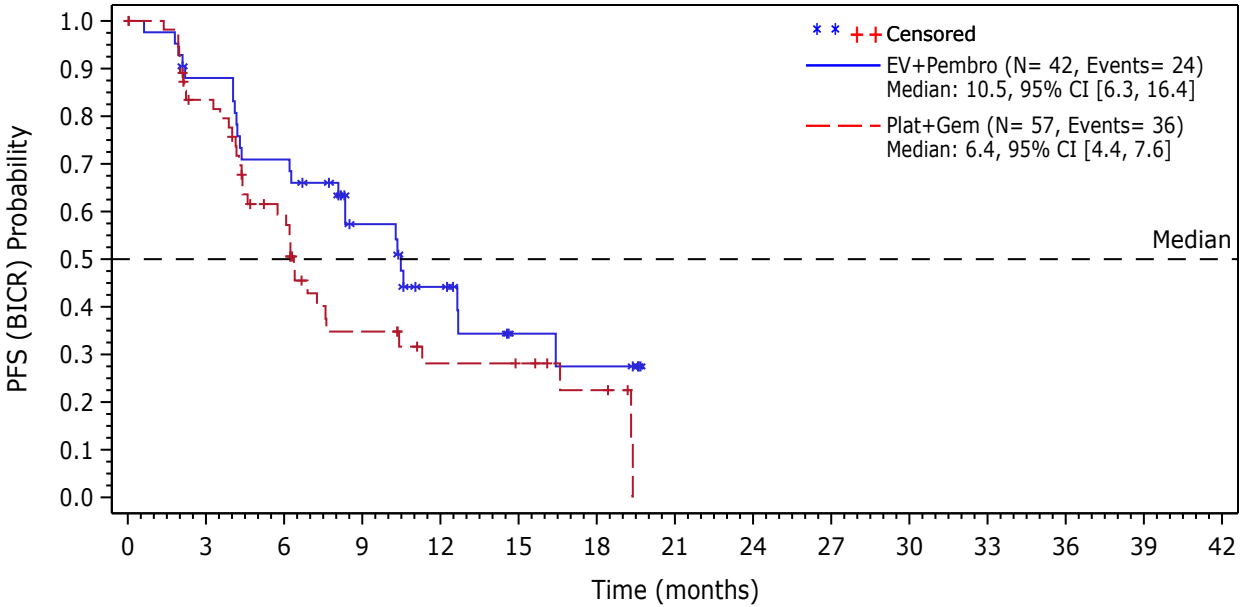
1	85	77	65	48	40	26	18	9	2	0	0	0	0	0	0
2	89	66	42	19	13	6	5	1	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.1.5: Kaplan-Meier Plot of Progression-Free Survival (BICR) by Sex - Analysis Set mITT 1

Sex: Female



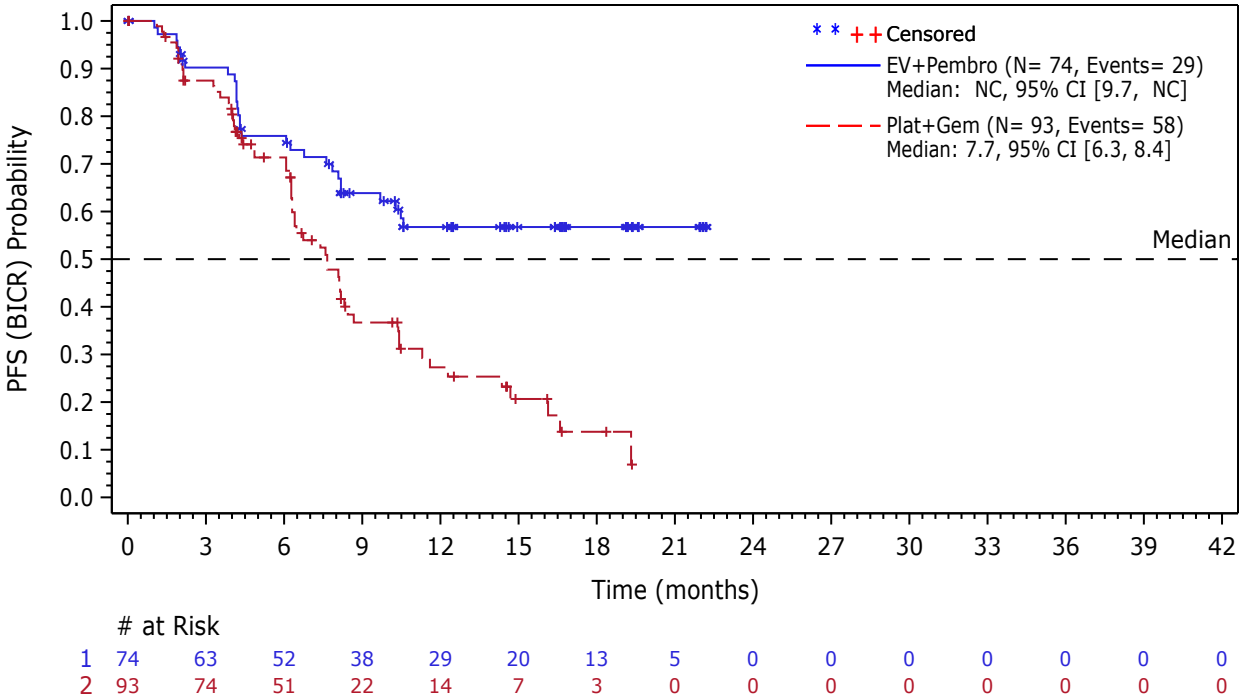
at Risk

1	42	36	29	18	11	5	4	0	0	0	0	0	0	0	0
2	57	43	27	13	8	7	4	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.1.6: Kaplan-Meier Plot of Progression-Free Survival (BICR) by Race - Analysis Set mITT 1
Race: Non-white

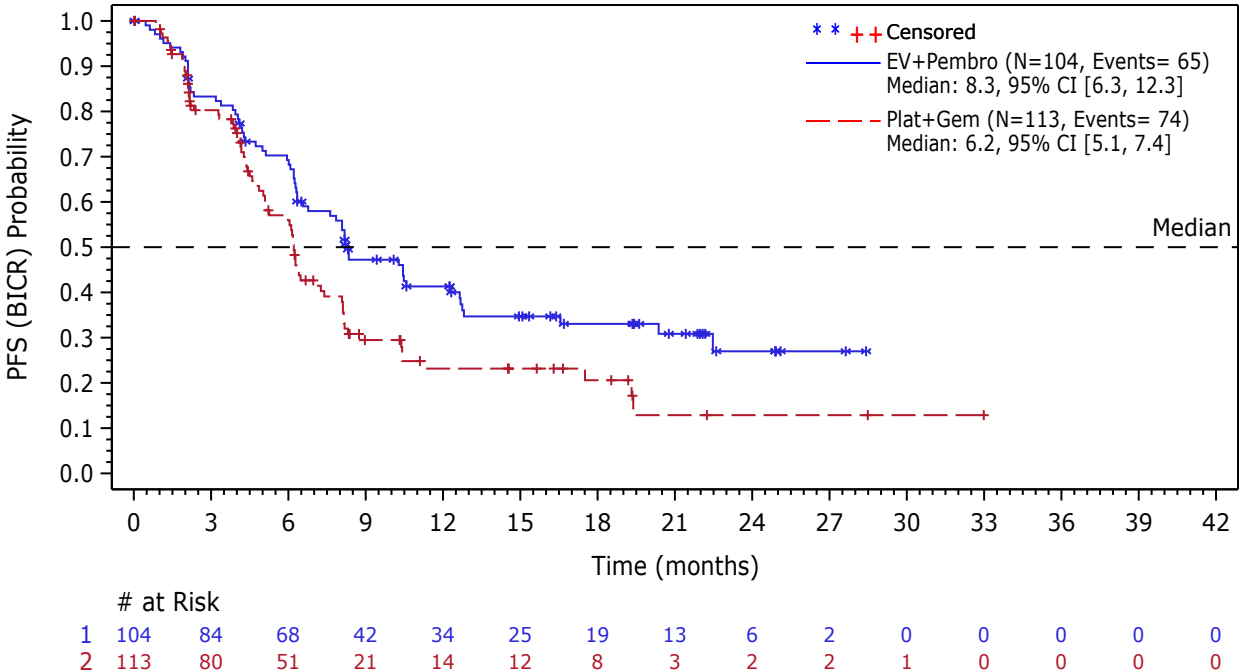


Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.1.7: Kaplan-Meier Plot of Progression-Free Survival (BICR) by ECOG Status at Baseline - Analysis Set mITT 1

ECOG Status at Baseline: 1-2

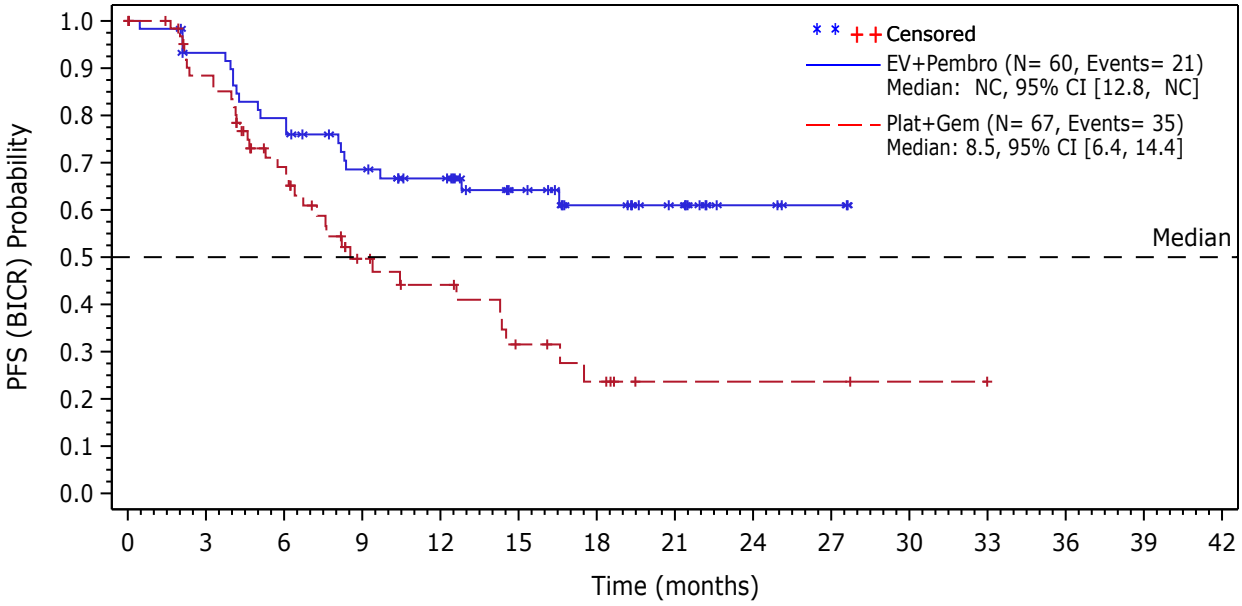


Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.1.8: Kaplan-Meier Plot of Progression-Free Survival (BICR) by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Lymph node only



at Risk

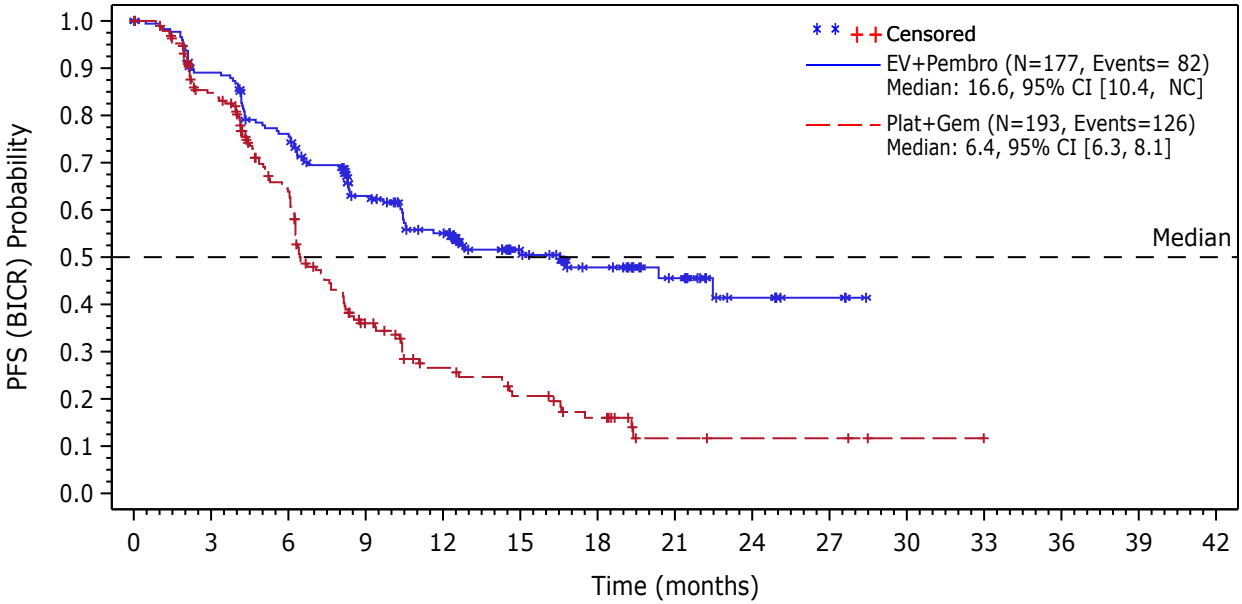
1	60	54	46	37	32	23	16	11	4	2	0	0	0	0	0
2	67	53	35	19	15	9	6	2	2	2	1	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.1.9: Kaplan-Meier Plot of Progression-Free Survival (BICR) by Primary Disease Site of Origin - Analysis Set mITT 1

Primary Disease Site of Origin: Lower tract



at Risk

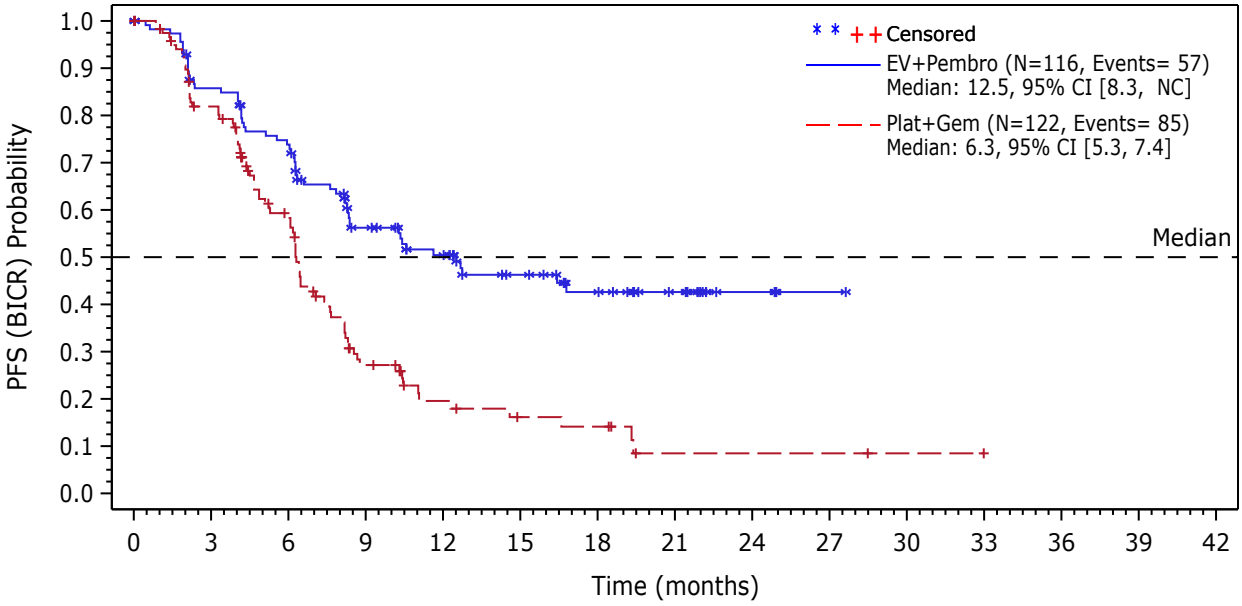
1	177	153	128	93	74	46	32	19	8	3	0	0	0	0	0
2	193	150	98	46	28	20	13	4	3	3	1	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.1.10: Kaplan-Meier Plot of Progression-Free Survival (BICR) by Renal Function - Analysis Set mITT 1

Renal Function: Mild



at Risk

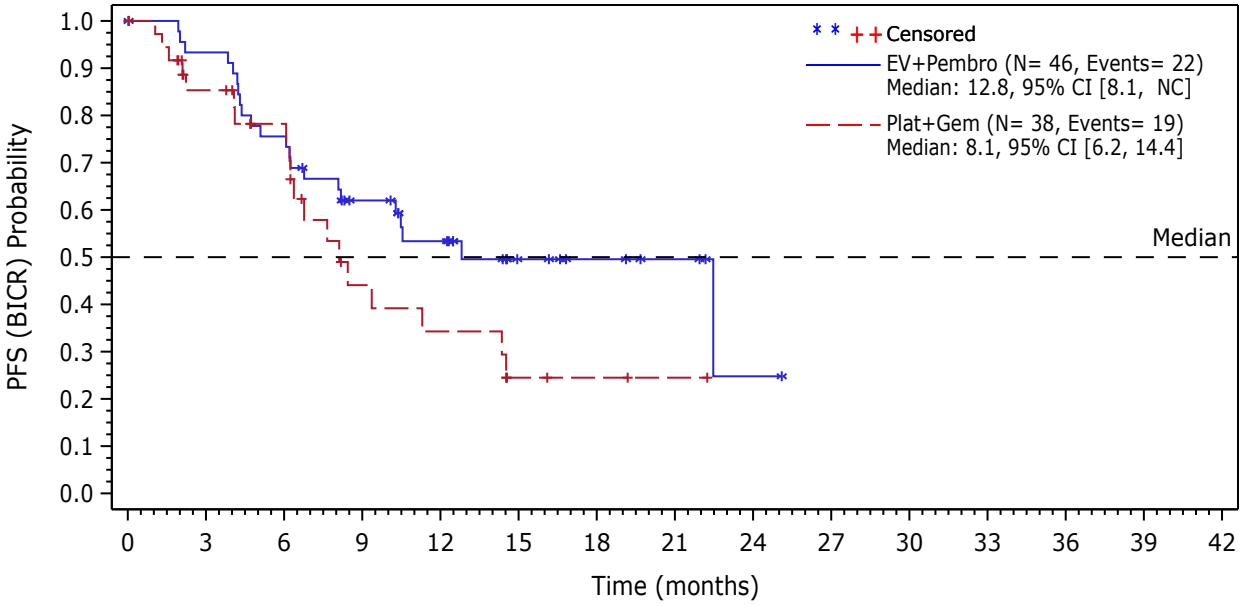
1	116	95	80	53	42	30	22	14	4	1	0	0	0	0	0
2	122	93	58	23	12	8	7	2	2	2	1	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.1.10: Kaplan-Meier Plot of Progression-Free Survival (BICR) by Renal Function - Analysis Set mITT 1

Renal Function: Moderate



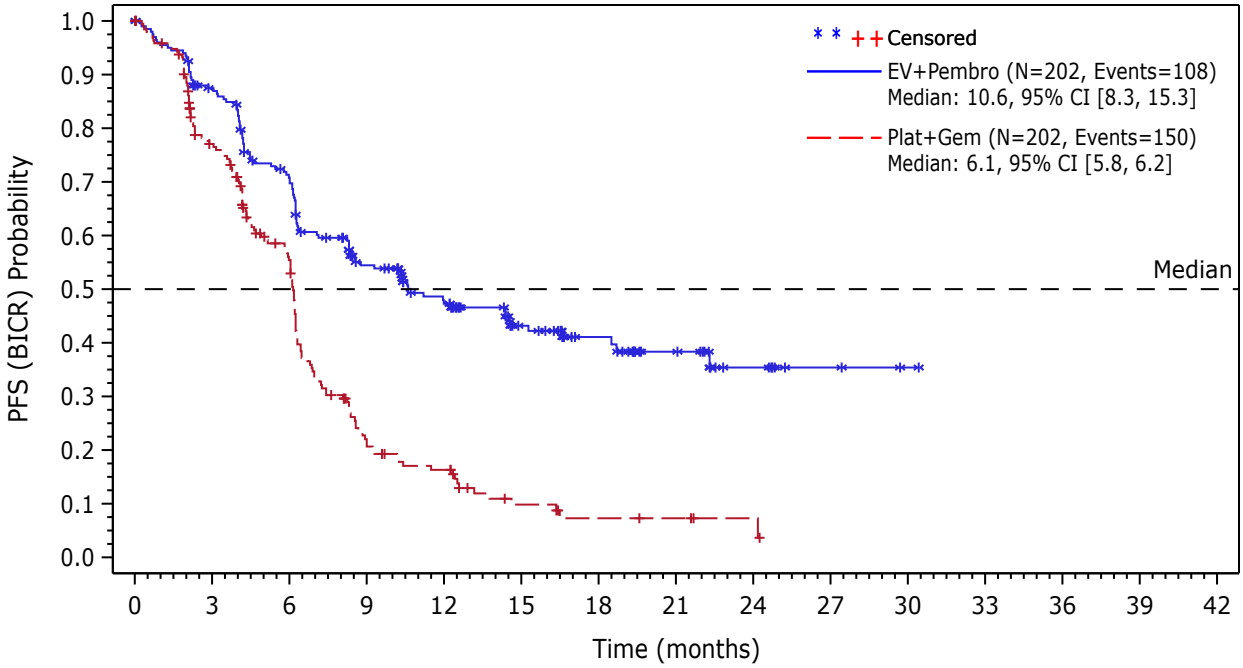
at Risk

1	46	42	34	24	18	9	6	4	1	0	0	0	0	0	0
2	38	26	20	9	7	3	2	1	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.2: Kaplan-Meier Plot of Progression-Free Survival (BICR) - Analysis Set mITT 2



at Risk

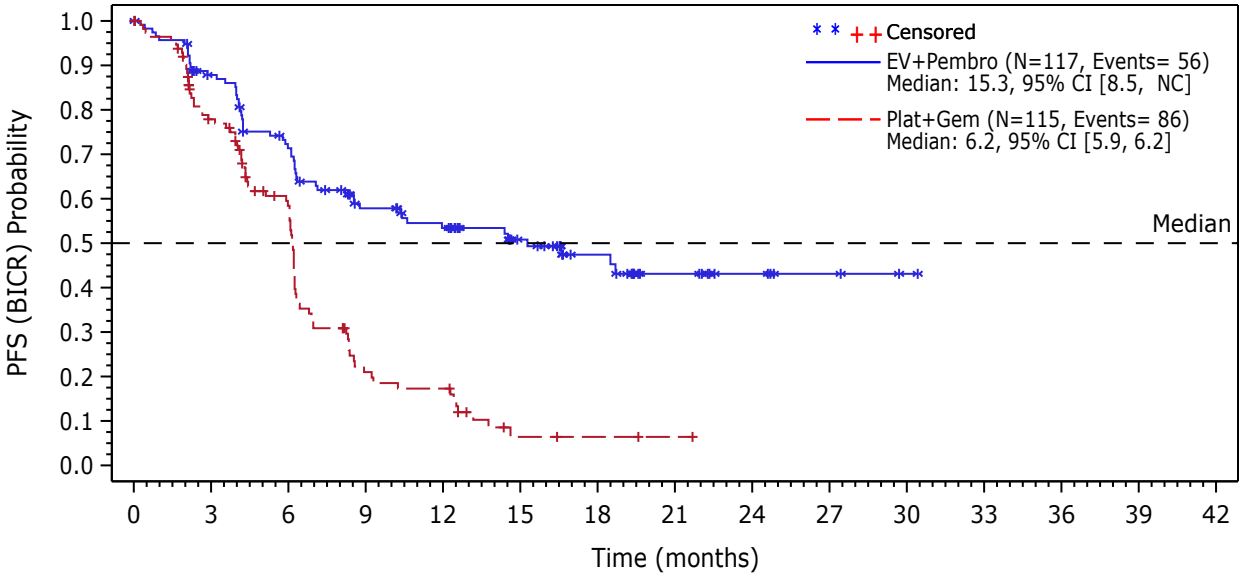
1	202	170	133	92	70	45	30	18	8	3	1	0	0	0	0
2	202	138	89	32	22	9	5	4	2	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.2.1: Kaplan-Meier Plot of Progression-Free Survival (BICR) by PD-L1 Expression - Analysis Set mITT 2

PD-L1 Expression: High (CPS>=10)



at Risk

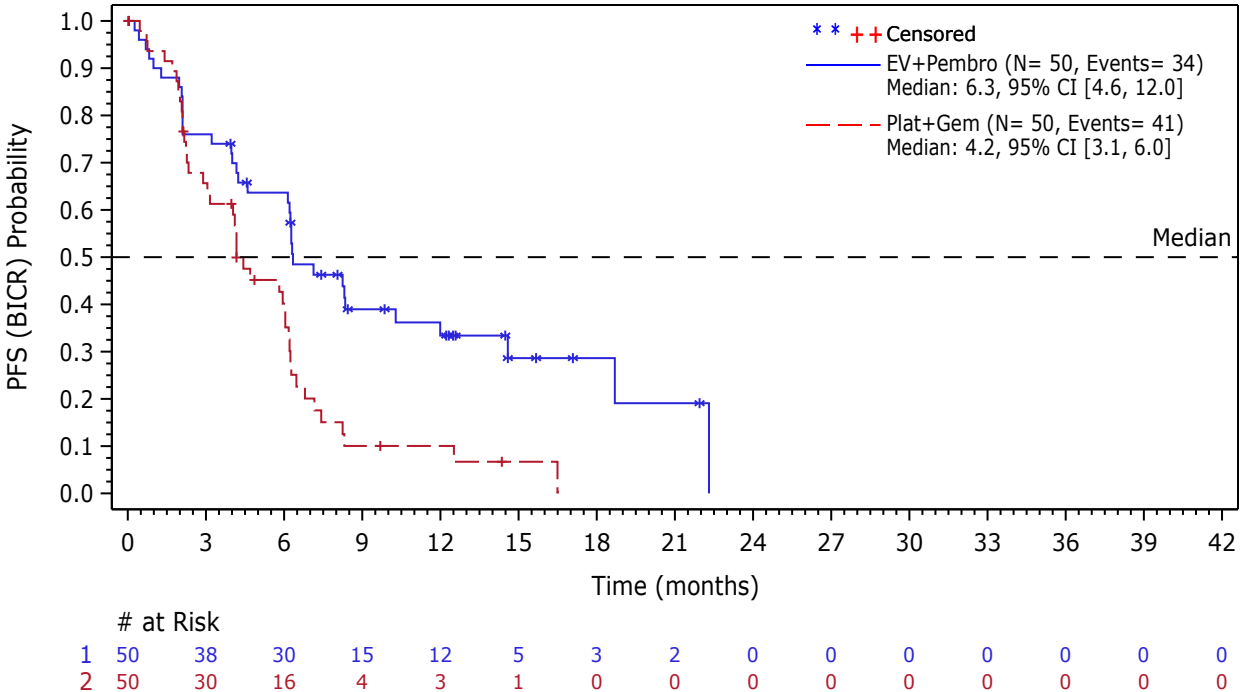
1	117	97	76	55	48	34	22	11	6	3	1	0	0	0	0
2	115	80	53	17	14	3	2	1	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.2.2: Kaplan-Meier Plot of Progression-Free Survival (BICR) by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Present

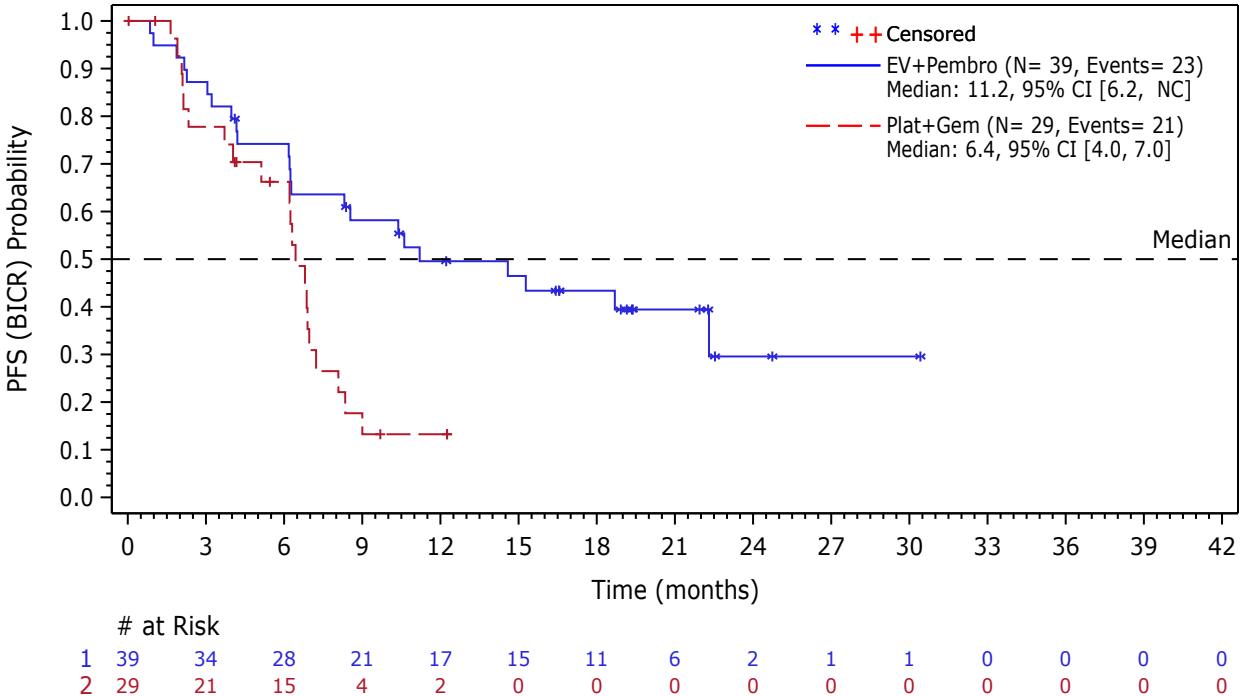


Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.2.3: Kaplan-Meier Plot of Progression-Free Survival (BICR) by Age - Analysis Set mITT 2

Age: < 65 years

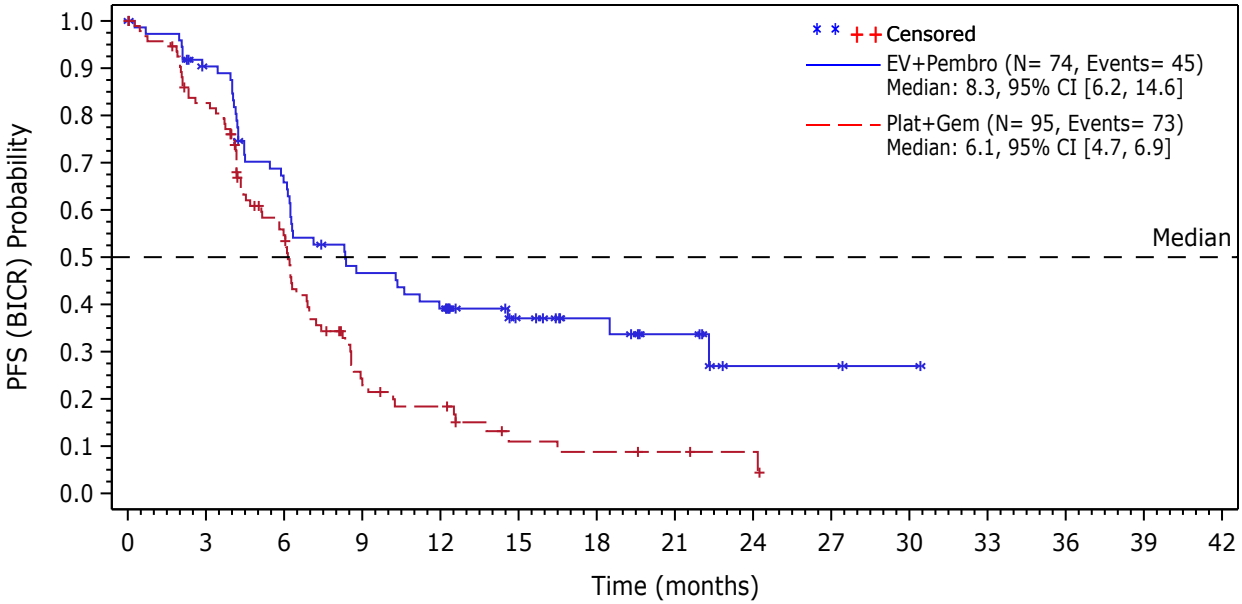


Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.2.4: Kaplan-Meier Plot of Progression-Free Survival (BICR) by Region - Analysis Set mITT 2

Region: Europe



at Risk

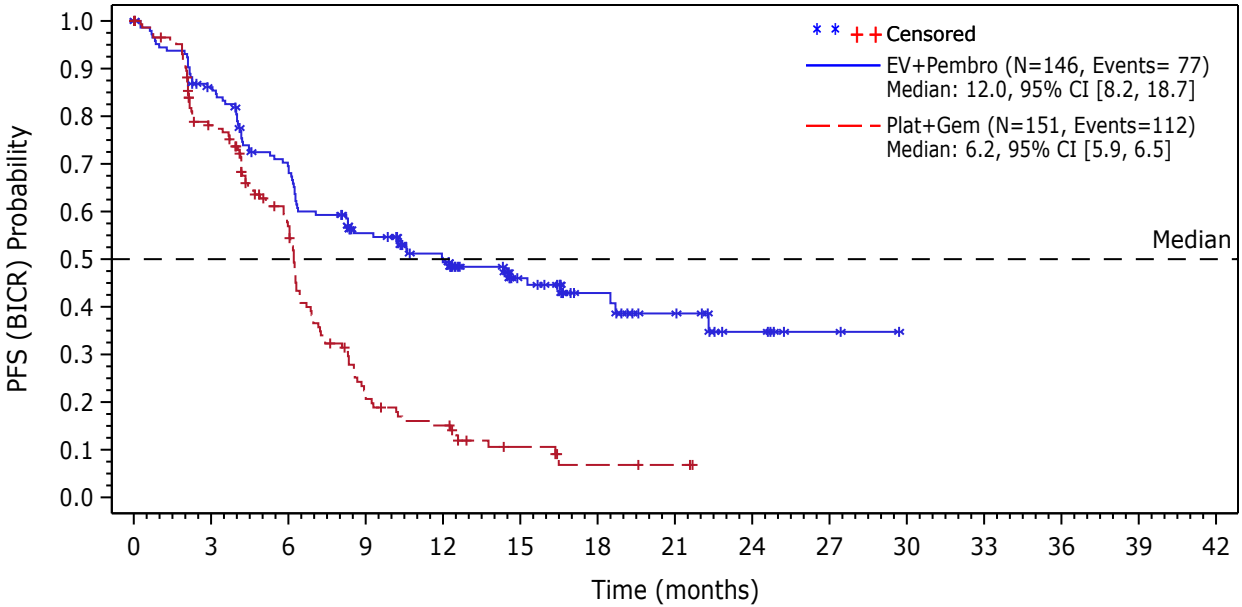
1	74	63	45	31	26	16	11	7	2	2	1	0	0	0	0
2	95	75	44	17	12	5	4	3	2	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.2.5: Kaplan-Meier Plot of Progression-Free Survival (BICR) by Sex - Analysis Set mITT 2

Sex: Male



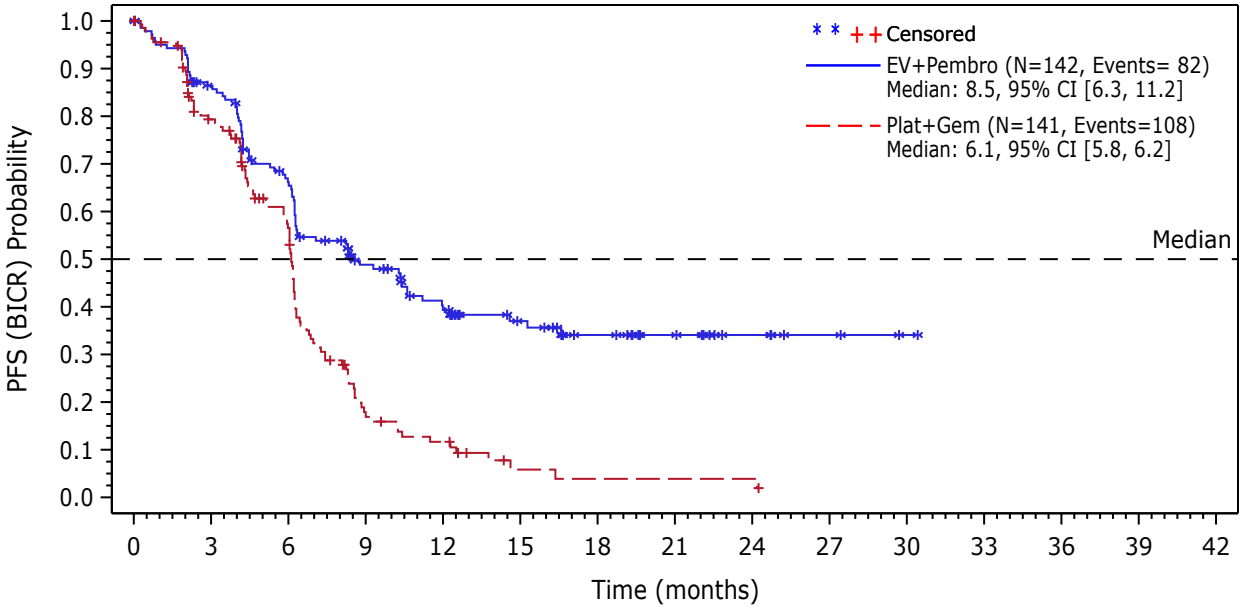
at Risk

1	146	121	95	69	54	33	20	13	6	2	0	0	0	0	0
2	151	106	68	25	16	7	3	2	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.2.6: Kaplan-Meier Plot of Progression-Free Survival (BICR) by Race - Analysis Set mITT 2
Race: White



at Risk

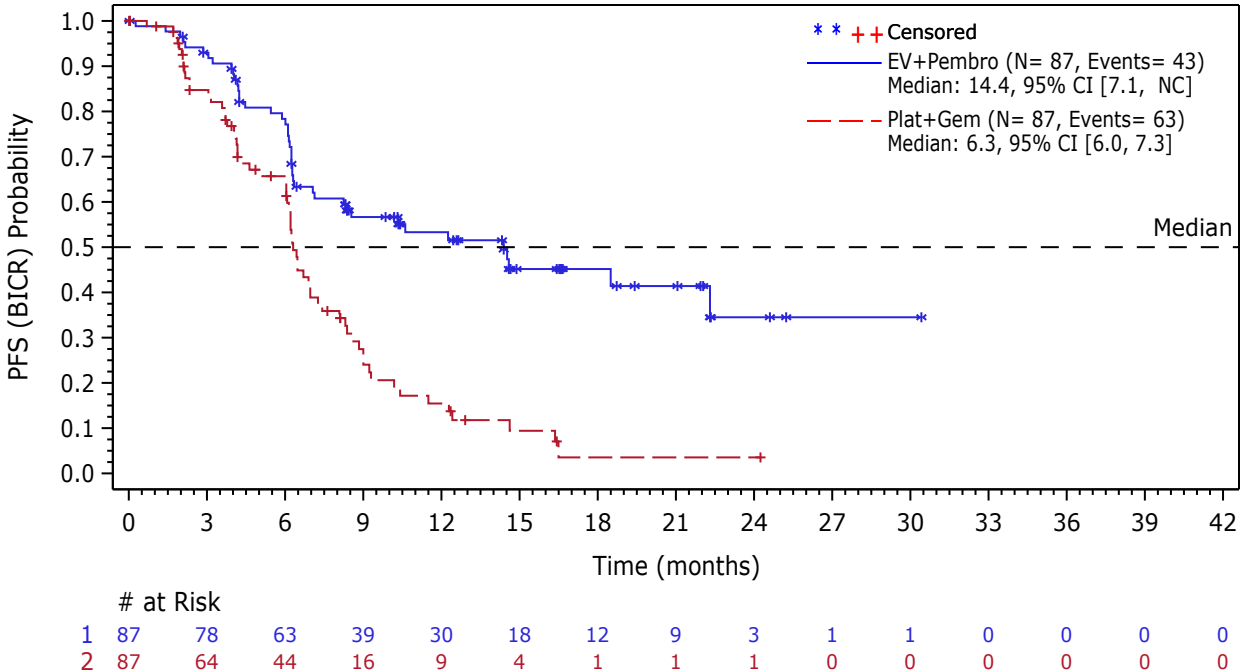
1	142	117	86	55	40	27	18	12	6	3	1	0	0	0	0
2	141	99	64	18	11	3	2	2	2	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.2.7: Kaplan-Meier Plot of Progression-Free Survival (BICR) by ECOG Status at Baseline - Analysis Set mITT 2

ECOG Status at Baseline: 0

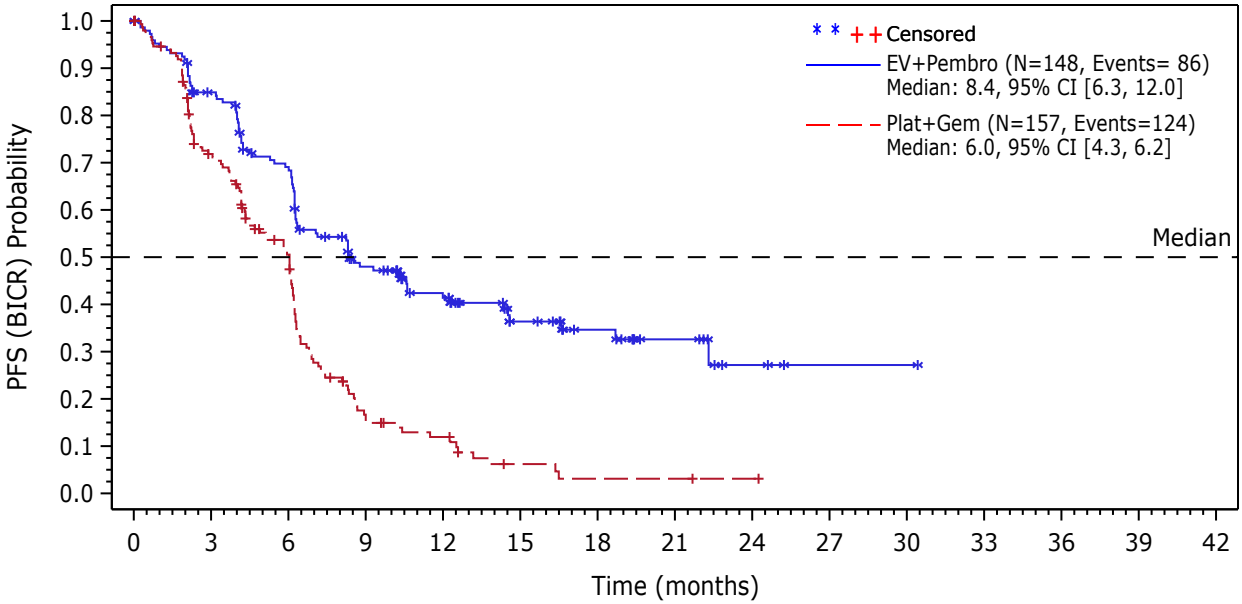


Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.2.8: Kaplan-Meier Plot of Progression-Free Survival (BICR) by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Visceral metastases



at Risk

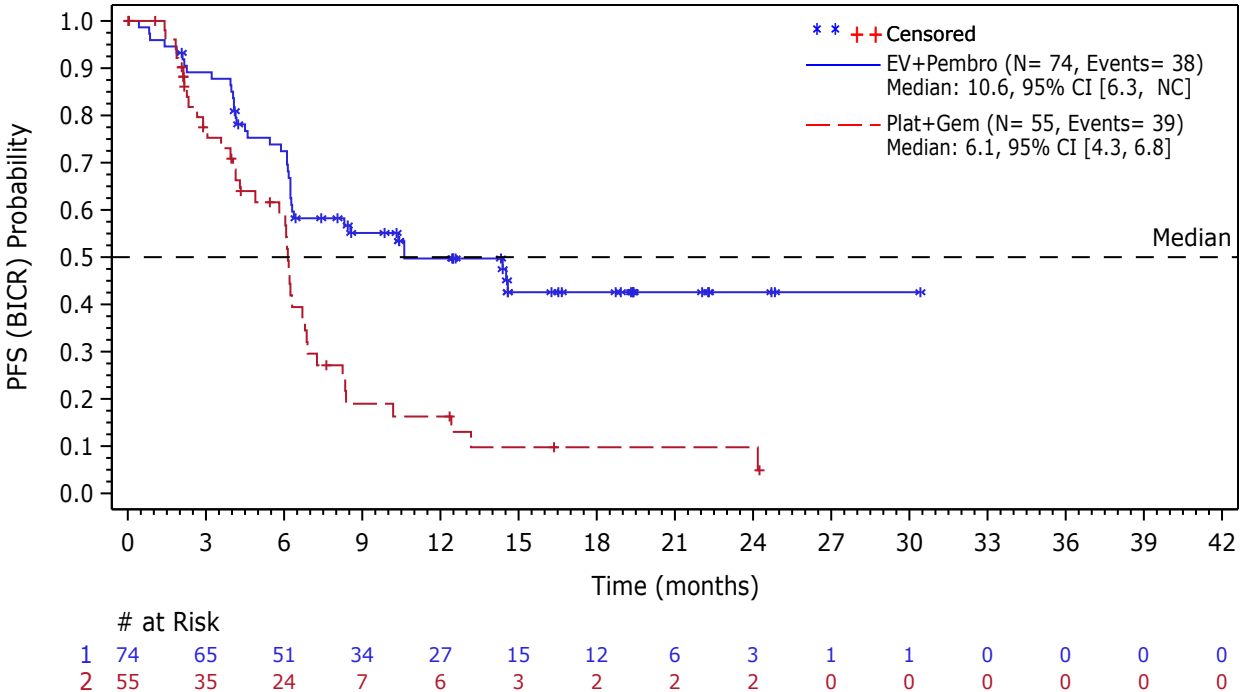
1	148	120	94	59	41	25	17	9	3	1	1	0	0	0	0
2	157	101	65	19	12	4	2	2	1	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.2.9: Kaplan-Meier Plot of Progression-Free Survival (BICR) by Primary Disease Site of Origin - Analysis Set mITT 2

Primary Disease Site of Origin: Upper tract



at Risk

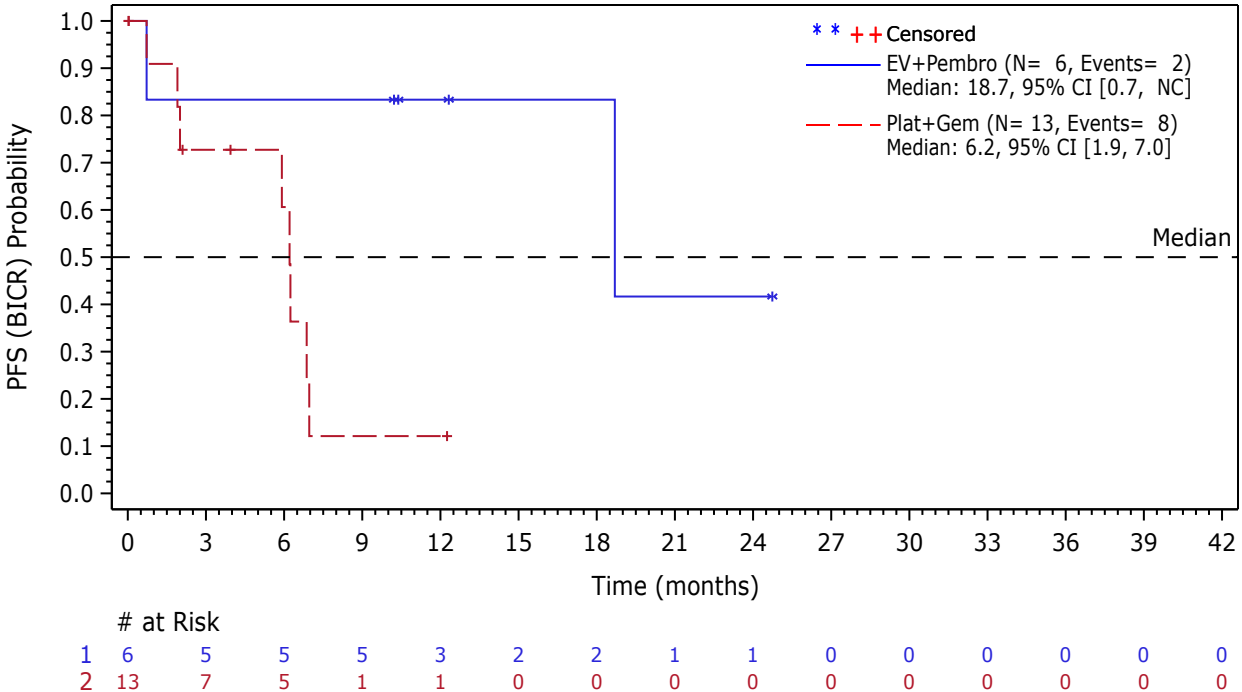
1	74	65	51	34	27	15	12	6	3	1	1	0	0	0	0
2	55	35	24	7	6	3	2	2	2	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.2.10: Kaplan-Meier Plot of Progression-Free Survival (BICR) by Renal Function - Analysis Set mITT 2

Renal Function: Normal

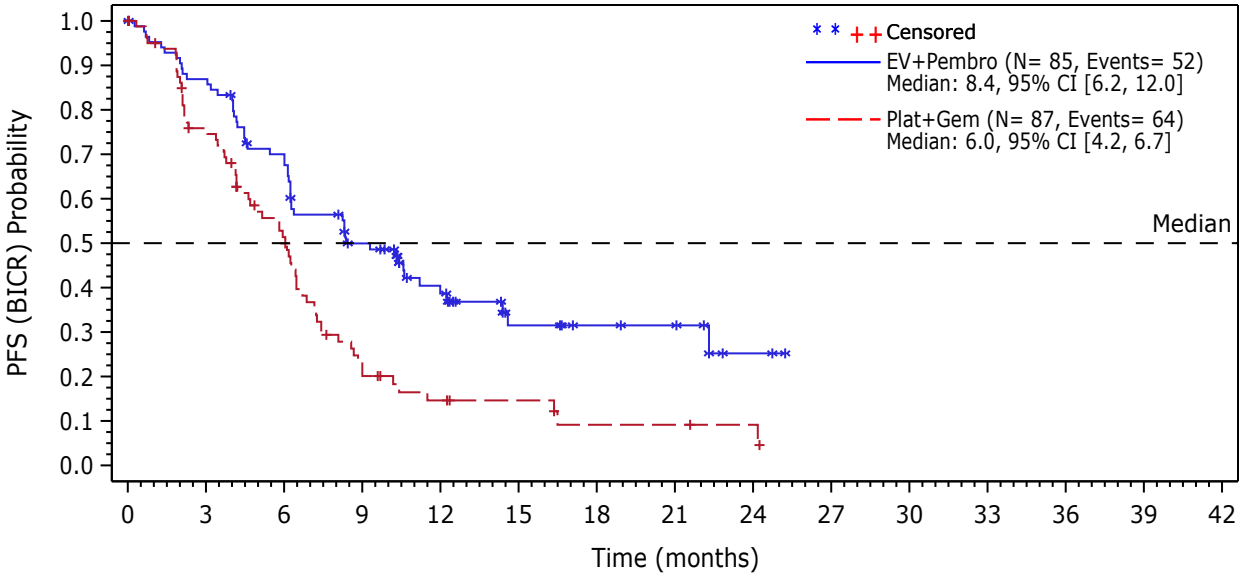


Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.2.1: Kaplan-Meier Plot of Progression-Free Survival (BICR) by PD-L1 Expression - Analysis Set mITT 2

PD-L1 Expression: Low (CPS<10)



at Risk

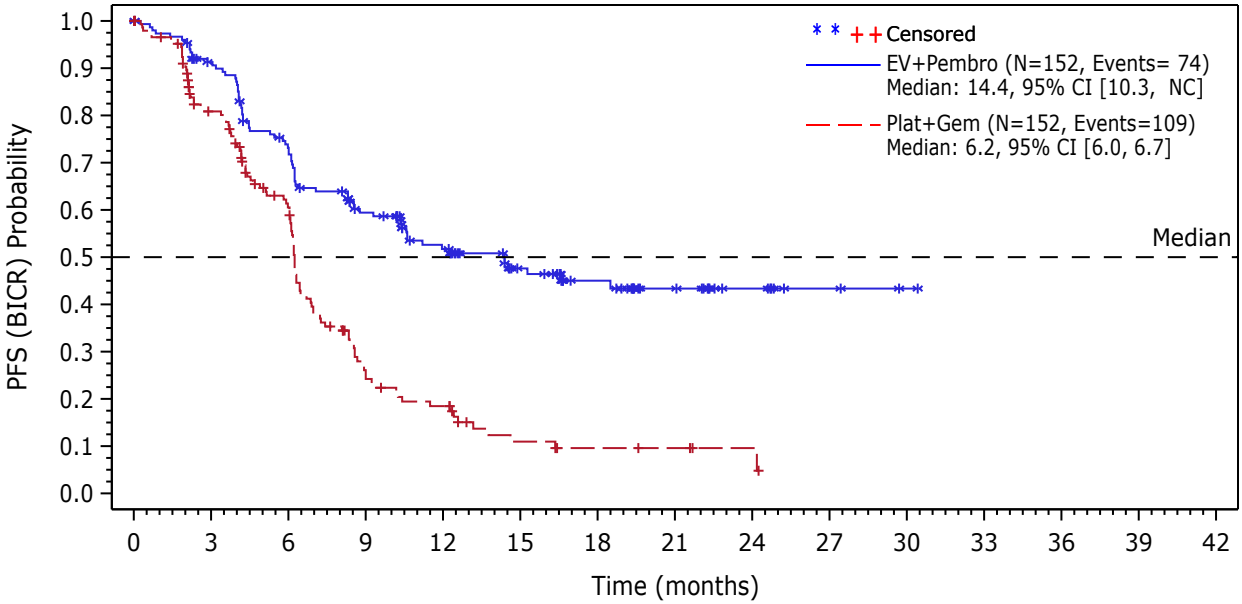
1	85	73	57	37	22	11	8	7	2	0	0	0	0	0	0
2	87	58	36	15	8	6	3	3	2	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.2.2: Kaplan-Meier Plot of Progression-Free Survival (BICR) by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Absent



at Risk

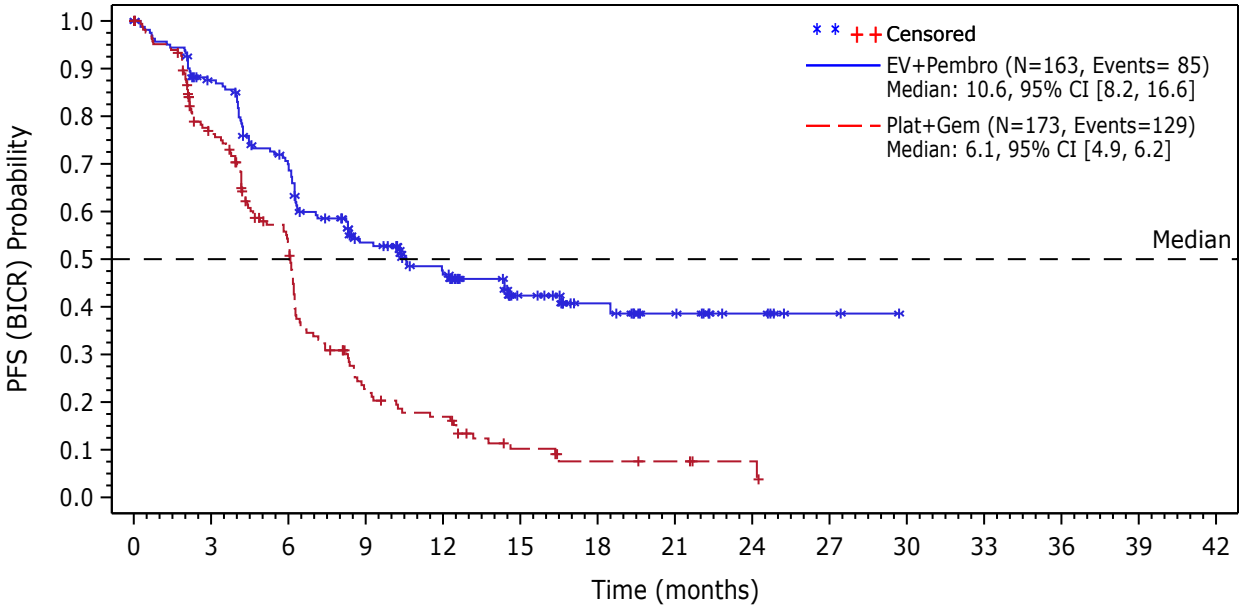
1	152	132	103	77	58	40	27	16	8	3	1	0	0	0	0
2	152	108	73	28	19	8	5	4	2	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.2.3: Kaplan-Meier Plot of Progression-Free Survival (BICR) by Age - Analysis Set mITT 2

Age: >= 65 years



at Risk

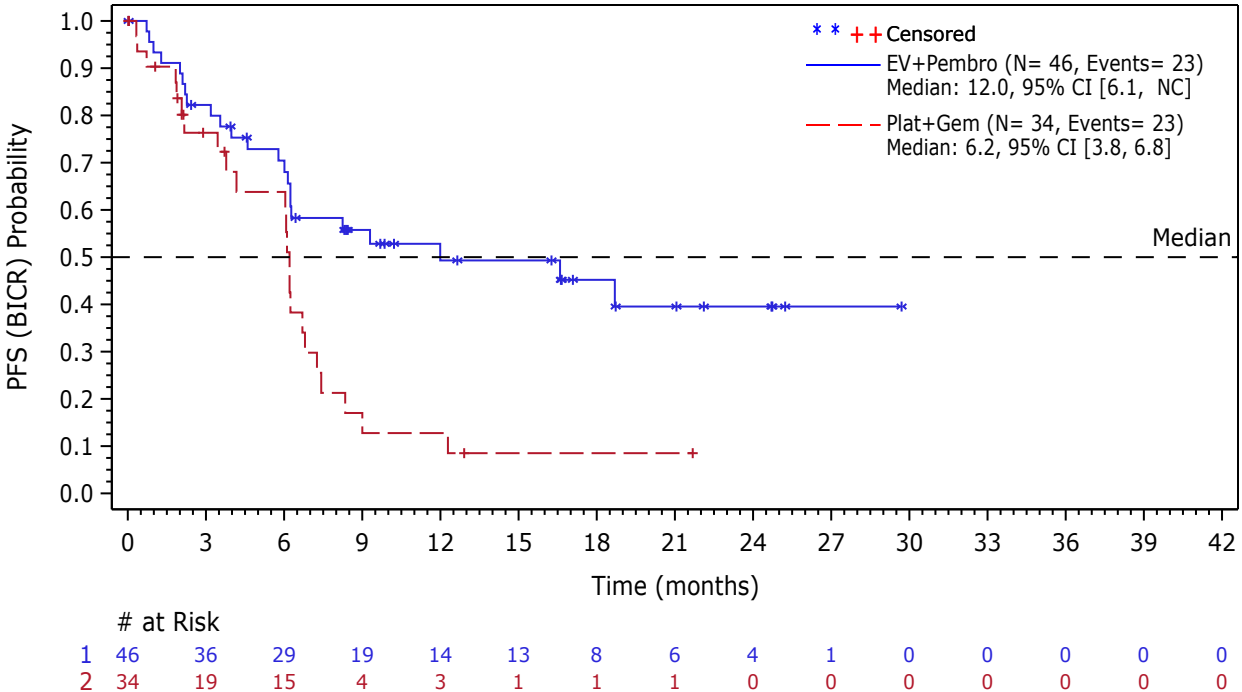
1	163	136	105	71	53	30	19	12	6	2	0	0	0	0	0
2	173	117	74	28	20	9	5	4	2	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.2.4: Kaplan-Meier Plot of Progression-Free Survival (BICR) by Region - Analysis Set mITT 2

Region: North America

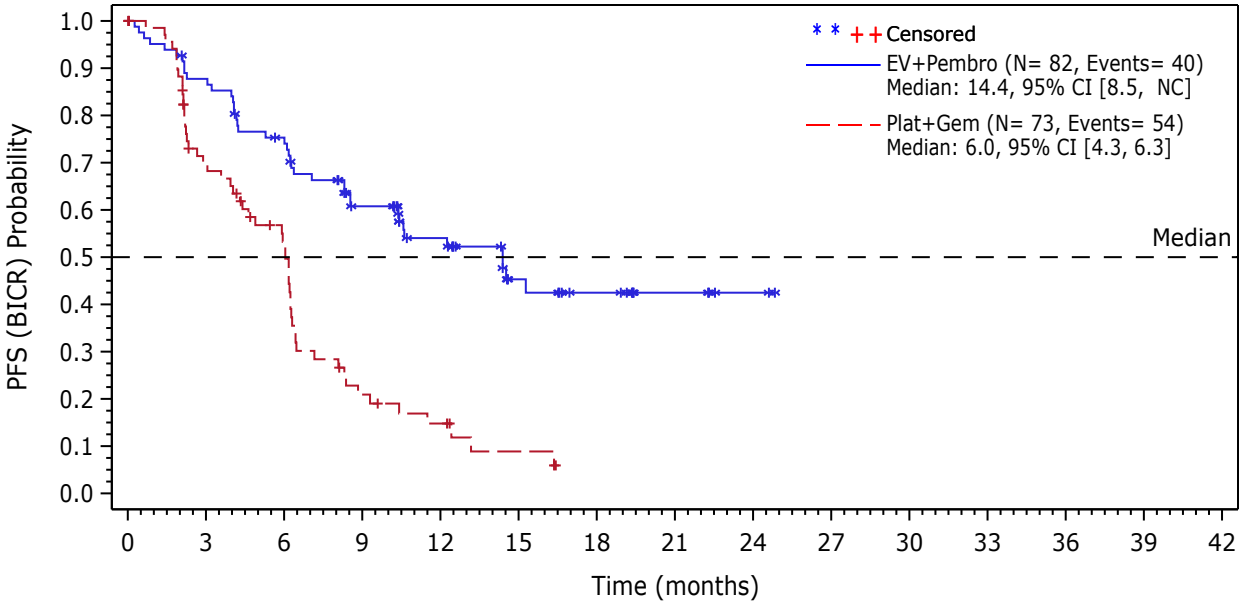


Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.2.4: Kaplan-Meier Plot of Progression-Free Survival (BICR) by Region - Analysis Set mITT 2

Region: Rest of World



at Risk

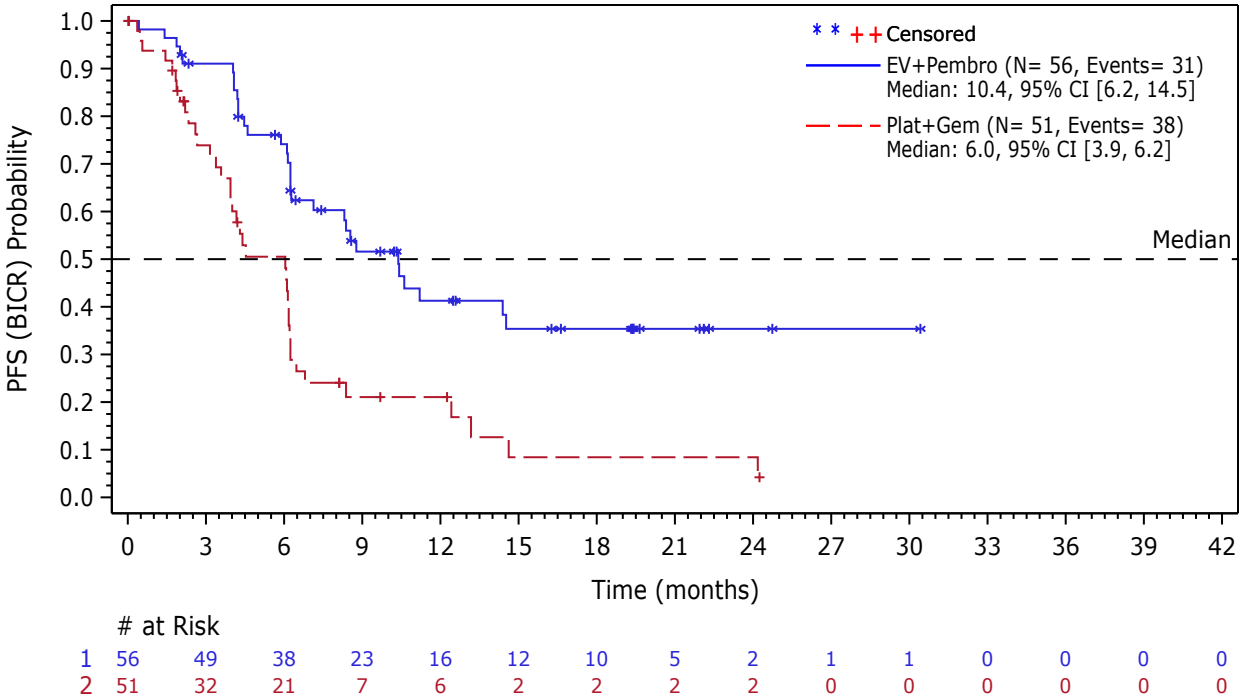
1	82	71	59	42	30	16	11	5	2	0	0	0	0	0	0
2	73	44	30	11	7	3	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.2.5: Kaplan-Meier Plot of Progression-Free Survival (BICR) by Sex - Analysis Set mITT 2

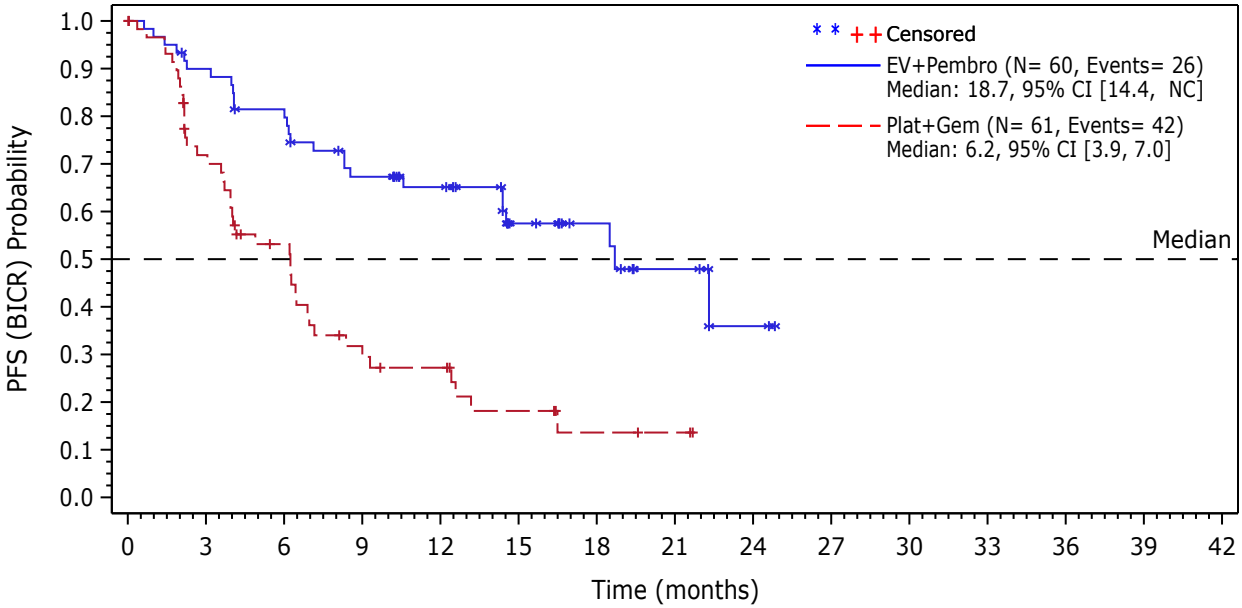
Sex: Female



Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.2.6: Kaplan-Meier Plot of Progression-Free Survival (BICR) by Race - Analysis Set mITT 2
Race: Non-white



at Risk

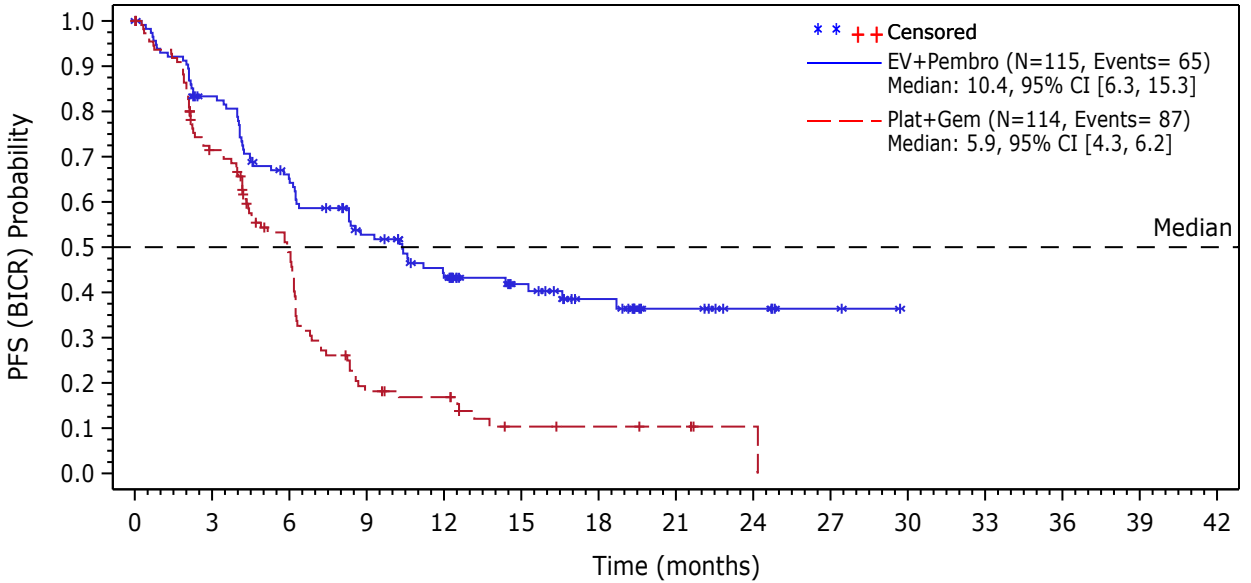
1	60	53	47	37	30	18	12	6	2	0	0	0	0	0	0
2	61	39	25	14	11	6	3	2	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.2.7: Kaplan-Meier Plot of Progression-Free Survival (BICR) by ECOG Status at Baseline - Analysis Set mITT 2

ECOG Status at Baseline: 1-2



at Risk

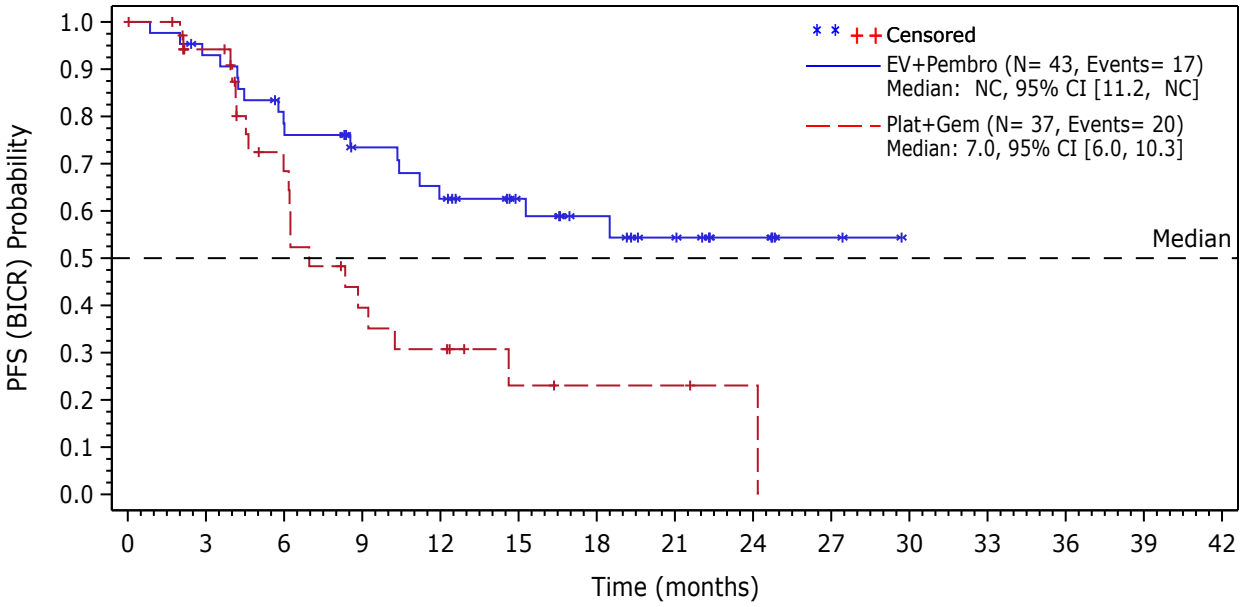
1	115	92	70	53	40	27	18	9	5	2	0	0	0	0	0
2	114	74	45	16	13	5	4	3	1	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.2.8: Kaplan-Meier Plot of Progression-Free Survival (BICR) by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Lymph node only



at Risk

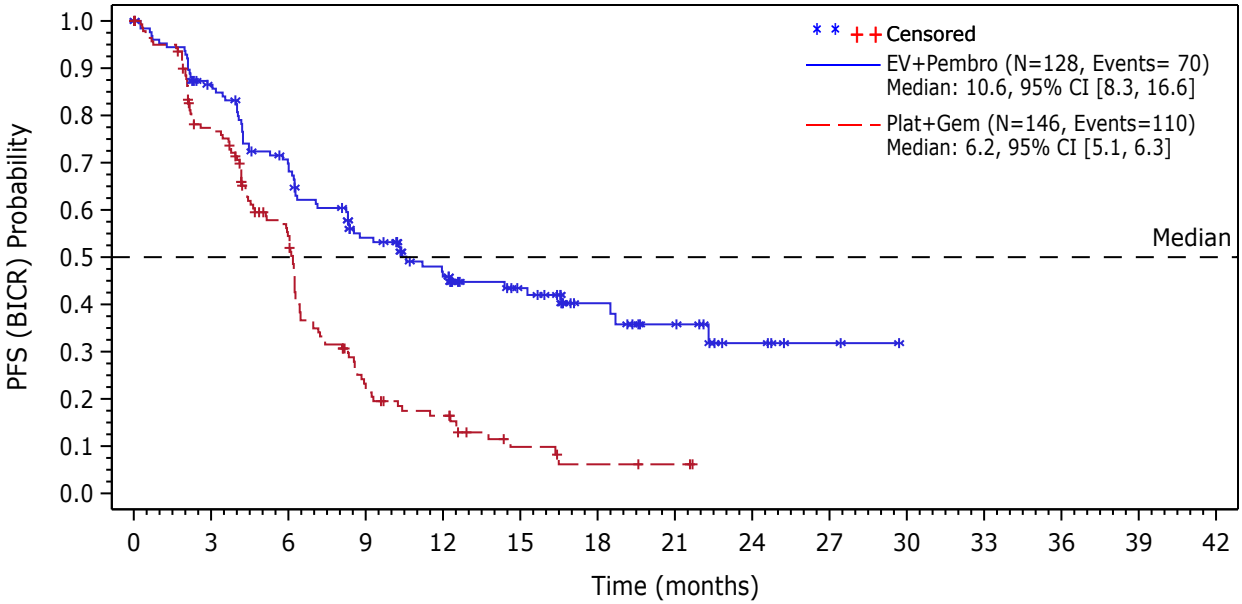
1	43	39	32	27	23	17	13	9	5	2	0	0	0	0	0
2	37	29	17	9	7	3	2	2	1	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.2.9: Kaplan-Meier Plot of Progression-Free Survival (BICR) by Primary Disease Site of Origin - Analysis Set mITT 2

Primary Disease Site of Origin: Lower tract



at Risk

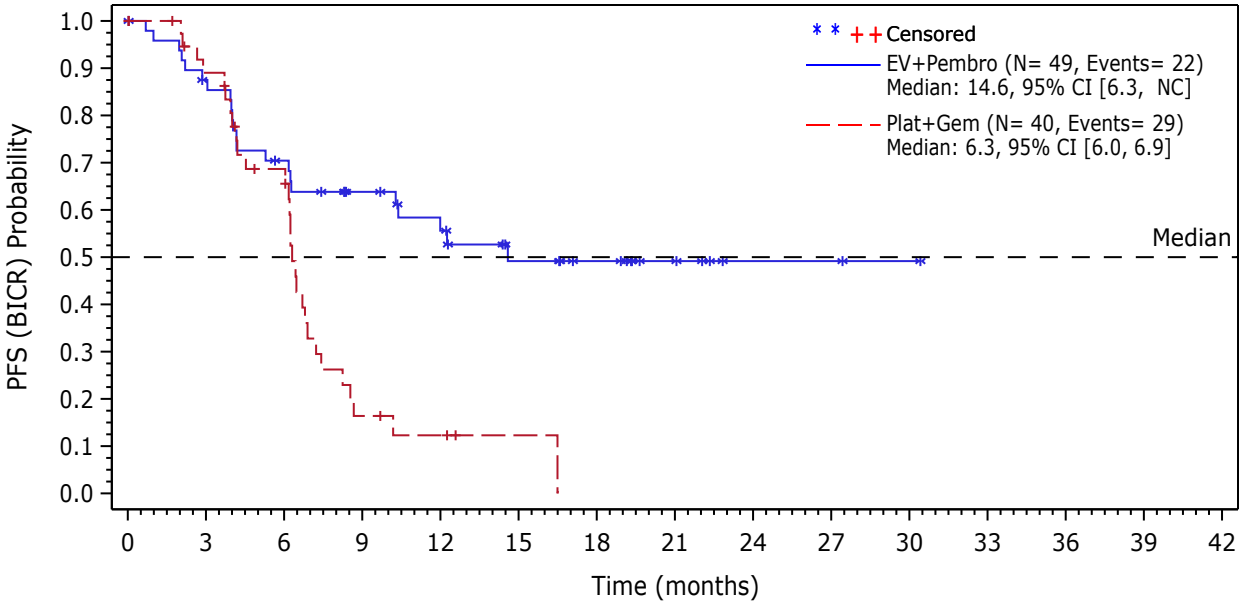
1	128	105	82	58	43	30	18	12	5	2	0	0	0	0	0
2	146	103	65	25	16	6	3	2	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.2.10: Kaplan-Meier Plot of Progression-Free Survival (BICR) by Renal Function - Analysis Set mITT 2

Renal Function: Mild



at Risk

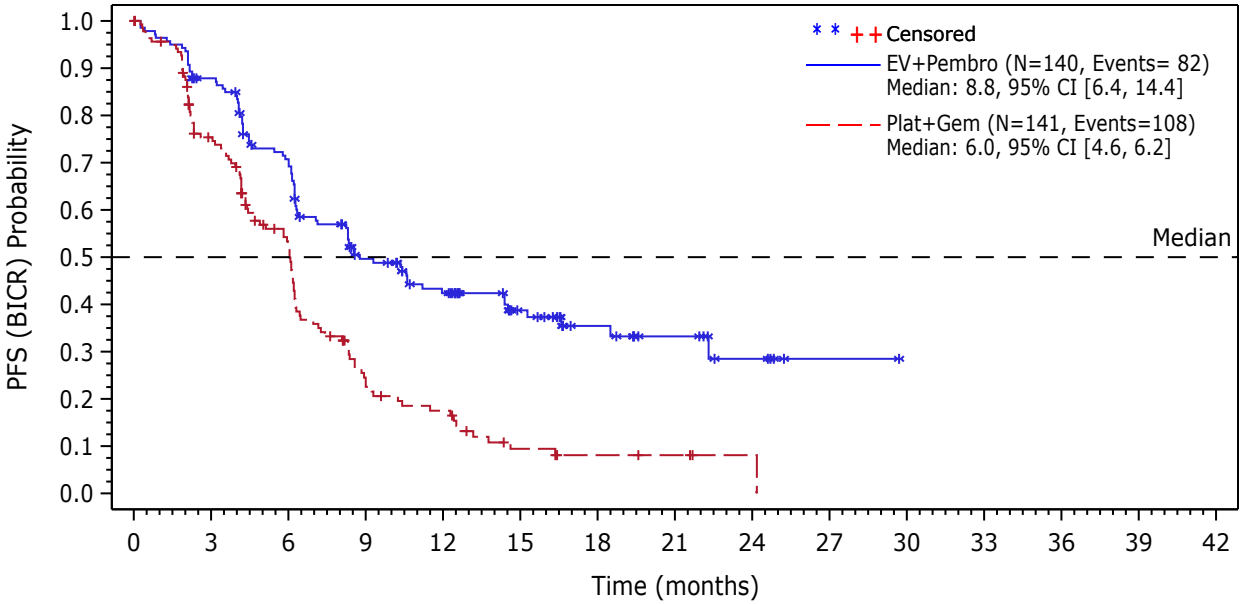
1	49	41	32	25	20	14	11	6	2	2	1	0	0	0	0
2	40	32	22	5	3	1	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.2.10: Kaplan-Meier Plot of Progression-Free Survival (BICR) by Renal Function - Analysis Set mITT 2

Renal Function: Moderate



at Risk

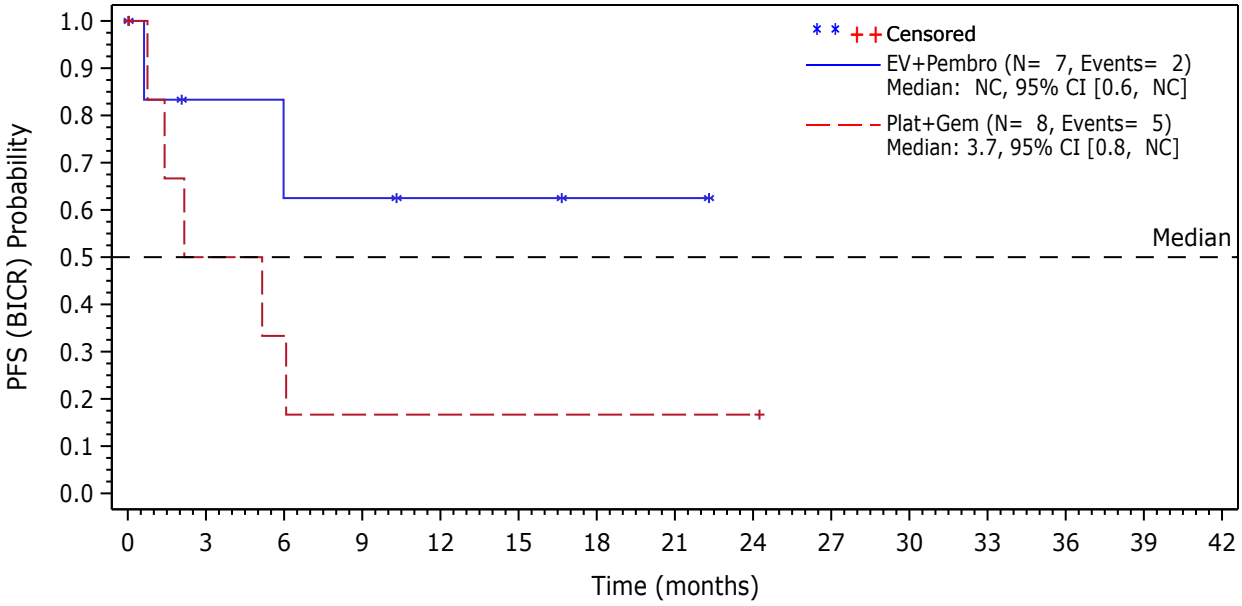
1	140	120	93	59	45	27	16	10	5	1	0	0	0	0	0
2	141	96	60	25	17	7	4	3	1	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.5.2.10: Kaplan-Meier Plot of Progression-Free Survival (BICR) by Renal Function - Analysis Set mITT 2

Renal Function: Severe



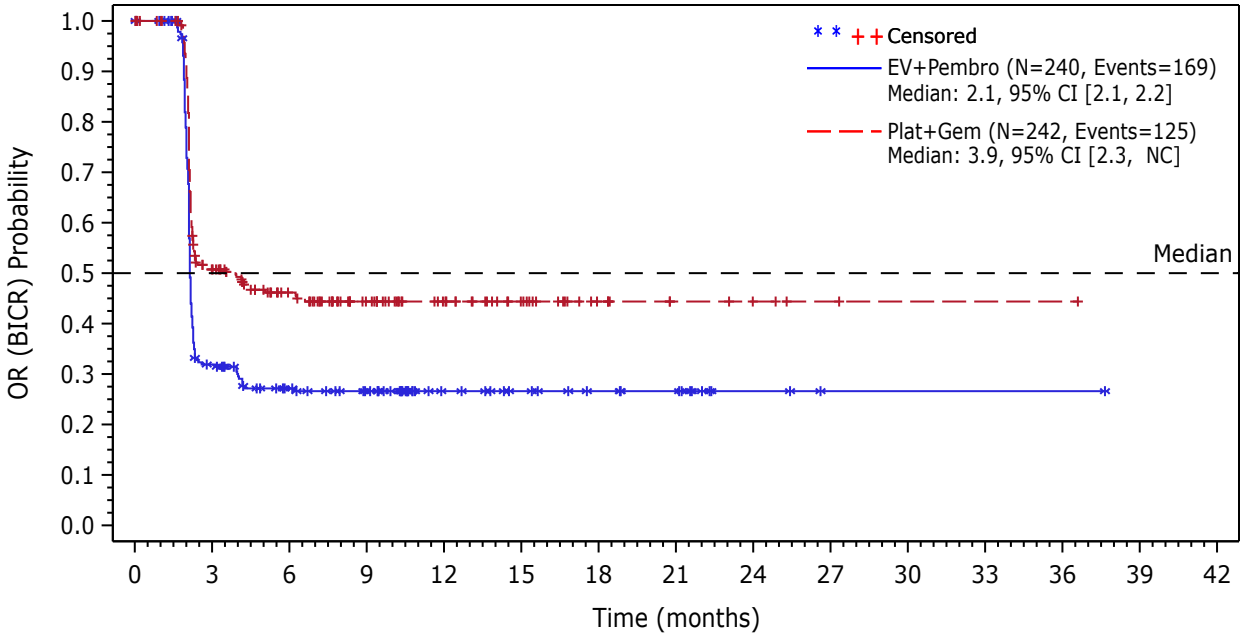
at Risk

1	7	4	3	3	2	2	1	1	0	0	0	0	0	0	0
2	8	3	2	1	1	1	1	1	1	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; PFS=progression-free survival; Plat=cisplatin or carboplatin.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.1: Kaplan-Meier Plot of Objective Response (BICR) - Analysis Set mITT 1



at Risk

1	240	72	51	42	21	16	12	10	3	1	1	1	1	0	0
2	242	110	78	53	36	23	11	6	4	2	1	1	1	0	0

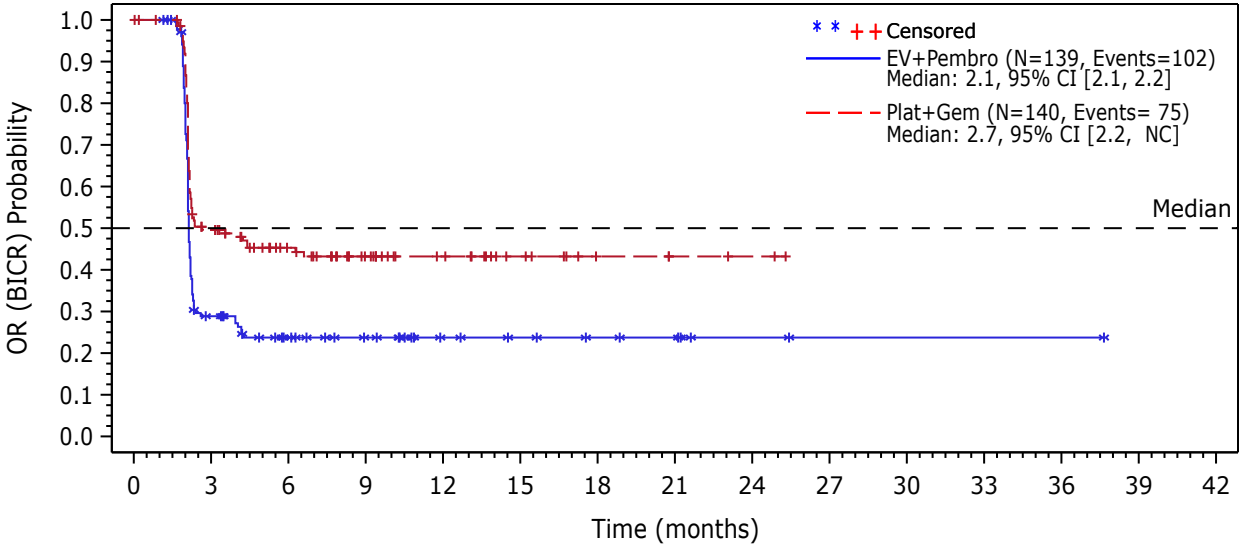
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.1.1: Kaplan-Meier Plot of Objective Response (BICR) by PD-L1 Expression - Analysis Set mITT 1

PD-L1 Expression: High (CPS>=10)



at Risk

1	139	37	23	17	10	8	6	5	2	1	1	1	1	0	0
2	140	64	44	29	19	11	5	3	2	0	0	0	0	0	0

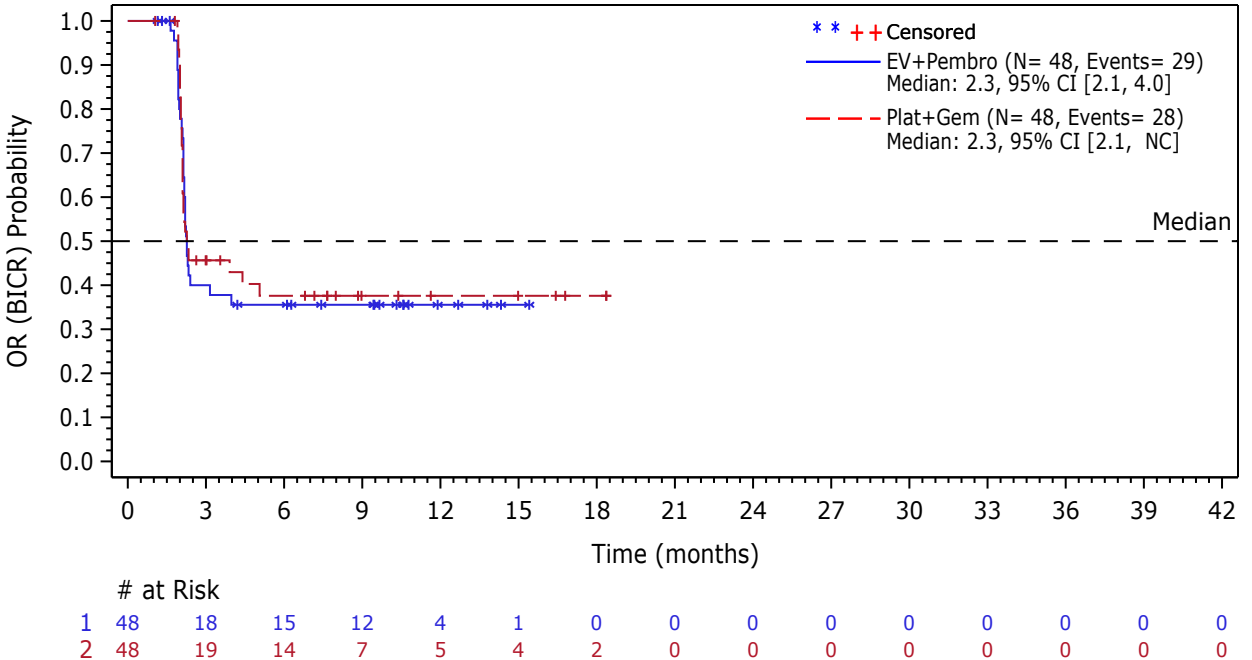
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.1.2: Kaplan-Meier Plot of Objective Response (BICR) by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Present

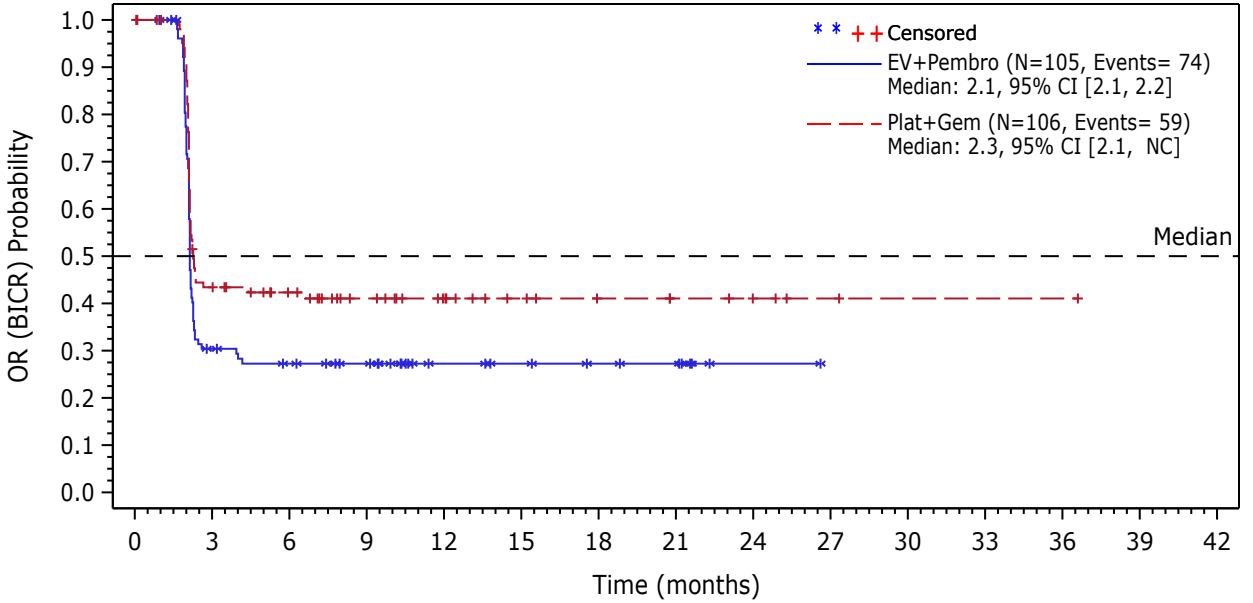


Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.1.3: Kaplan-Meier Plot of Objective Response (BICR) by Age - Analysis Set mITT 1
Age: < 65 years



at Risk

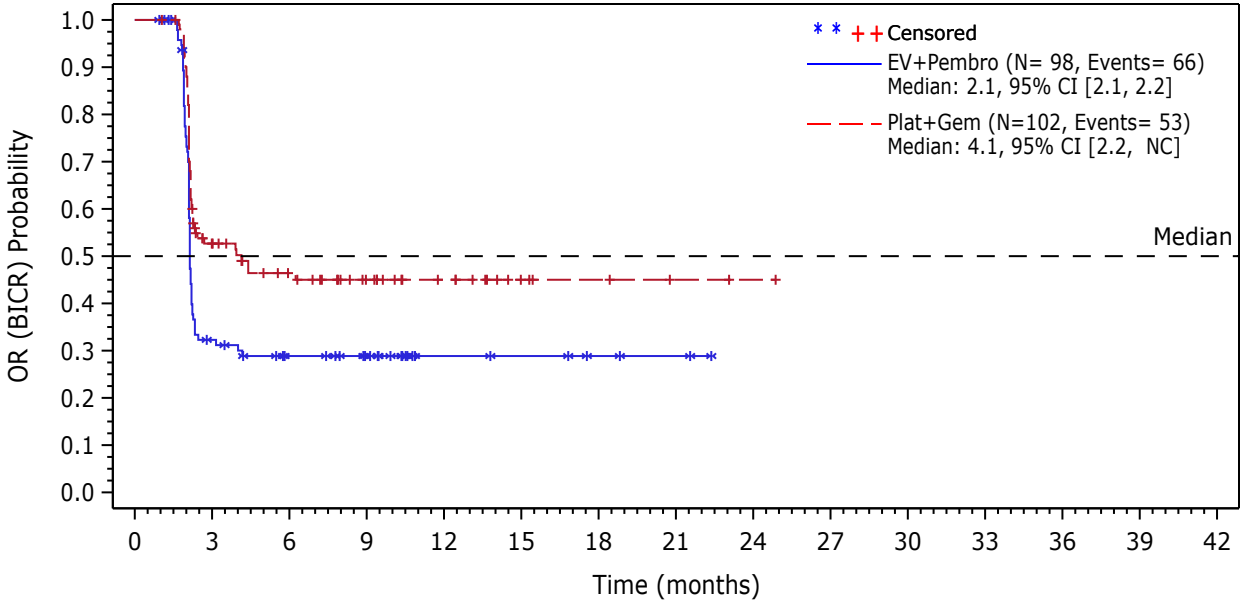
1	105	30	25	21	11	9	7	6	1	0	0	0	0	0	0
2	106	43	34	24	17	11	8	6	4	2	1	1	1	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.1.4: Kaplan-Meier Plot of Objective Response (BICR) by Region - Analysis Set mITT 1 Region: Europe



at Risk

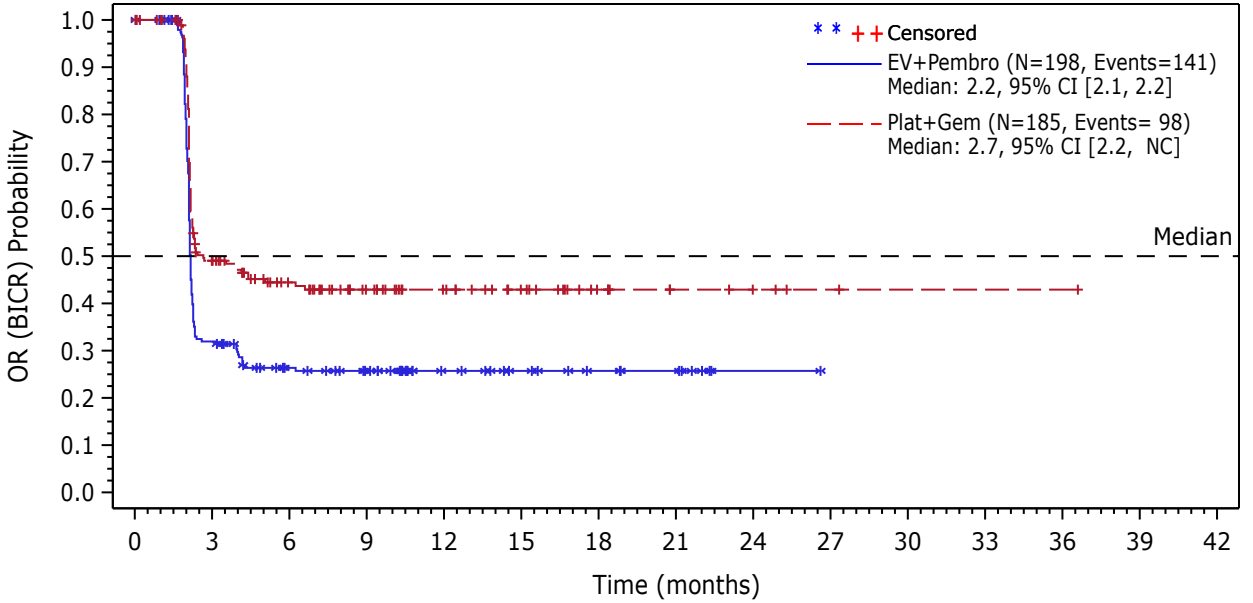
1	98	29	21	16	6	5	3	2	0	0	0	0	0	0	0
2	102	46	33	22	14	6	4	2	1	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.1.5: Kaplan-Meier Plot of Objective Response (BICR) by Sex - Analysis Set mITT 1
Sex: Male



at Risk

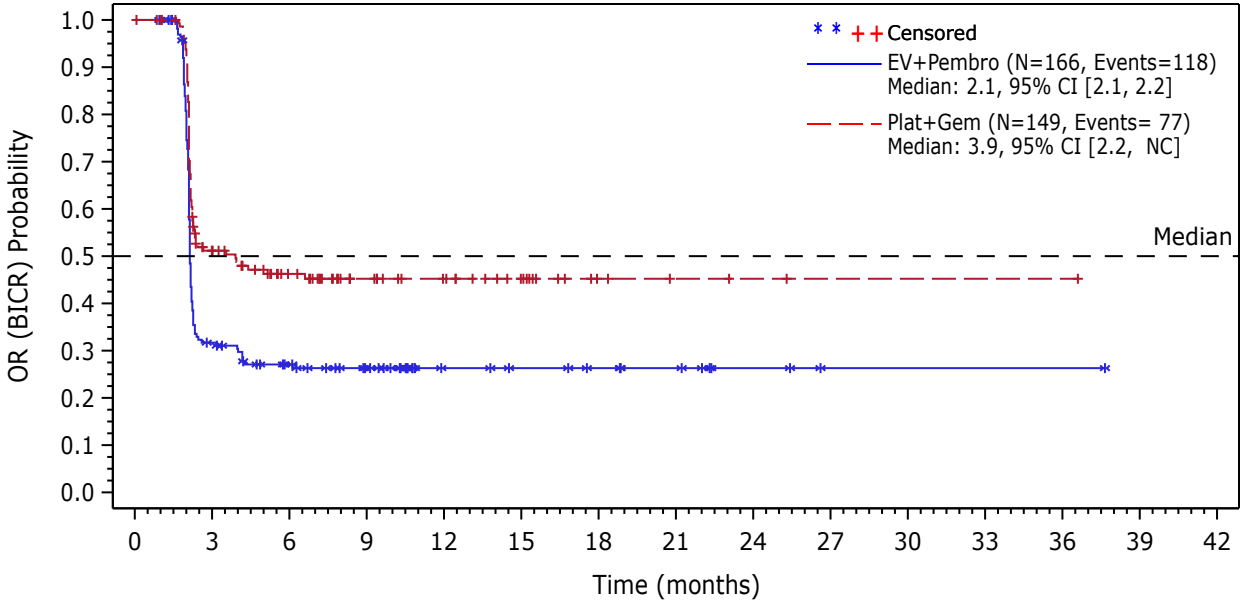
1	198	61	41	34	18	13	9	7	1	0	0	0	0	0	0
2	185	82	58	41	30	21	11	6	4	2	1	1	1	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.1.6: Kaplan-Meier Plot of Objective Response (BICR) by Race - Analysis Set mITT 1 Race: White



at Risk

1	166	50	36	27	13	11	9	7	3	1	1	1	1	0	0
2	149	67	46	29	22	14	5	3	2	1	1	1	1	0	0

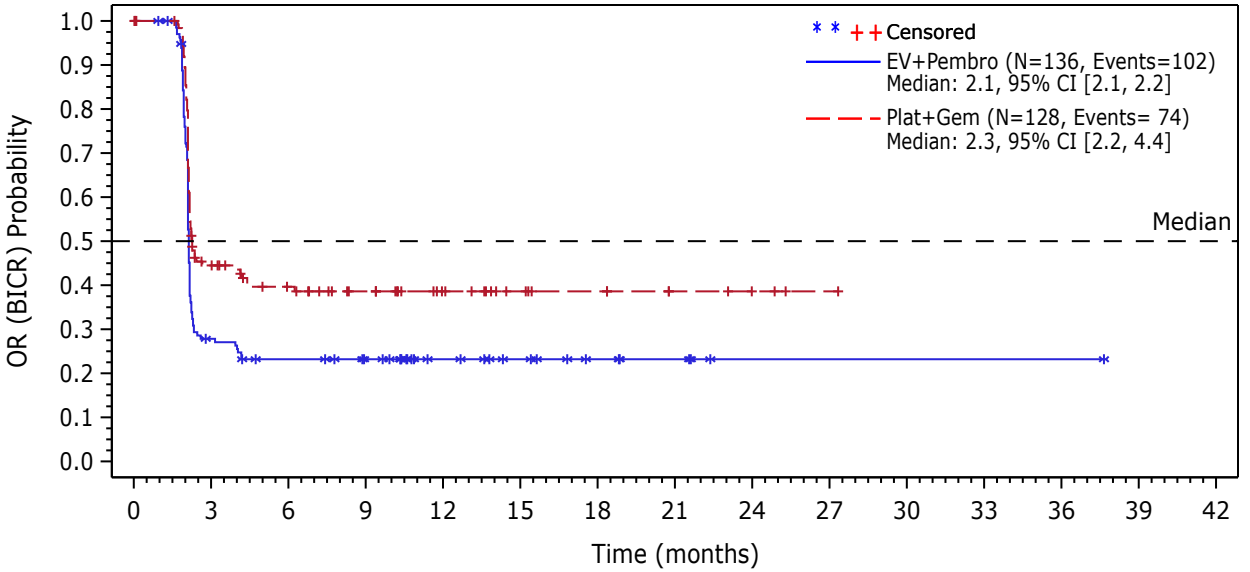
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.1.7: Kaplan-Meier Plot of Objective Response (BICR) by ECOG Status at Baseline - Analysis Set mITT 1

ECOG Status at Baseline: 0



at Risk

1	136	36	28	24	14	10	6	4	1	1	1	1	1	0	0
2	128	51	38	29	19	12	9	5	3	1	0	0	0	0	0

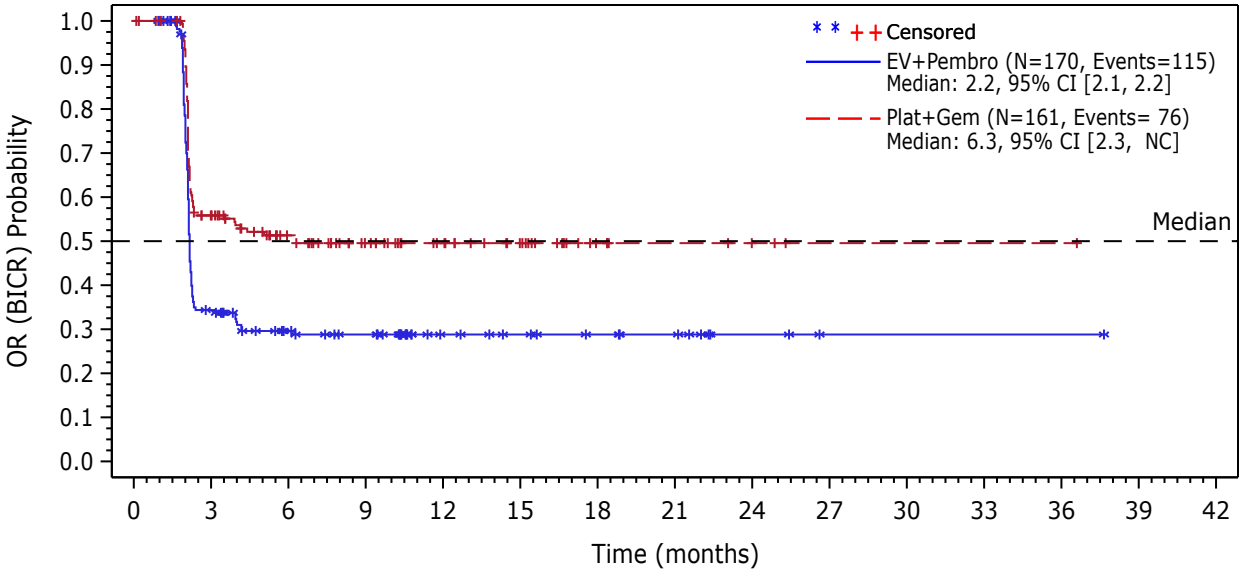
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.1.8: Kaplan-Meier Plot of Objective Response (BICR) by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Visceral metastases



at Risk

1	170	55	38	32	16	13	10	8	3	1	1	1	1	0	0
2	161	82	58	40	29	20	8	5	3	1	1	1	1	0	0

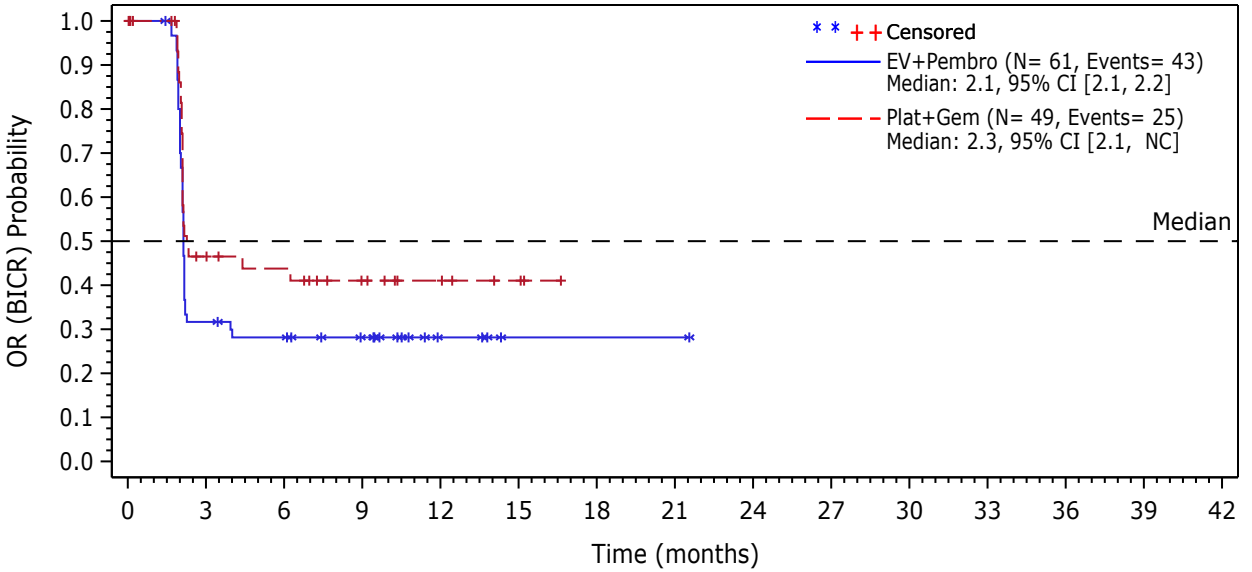
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.1.9: Kaplan-Meier Plot of Objective Response (BICR) by Primary Disease Site of Origin - Analysis Set mITT 1

Primary Disease Site of Origin: Upper tract



at Risk

1	61	19	16	12	4	1	1	1	0	0	0	0	0	0	0
2	49	19	16	10	6	3	0	0	0	0	0	0	0	0	0

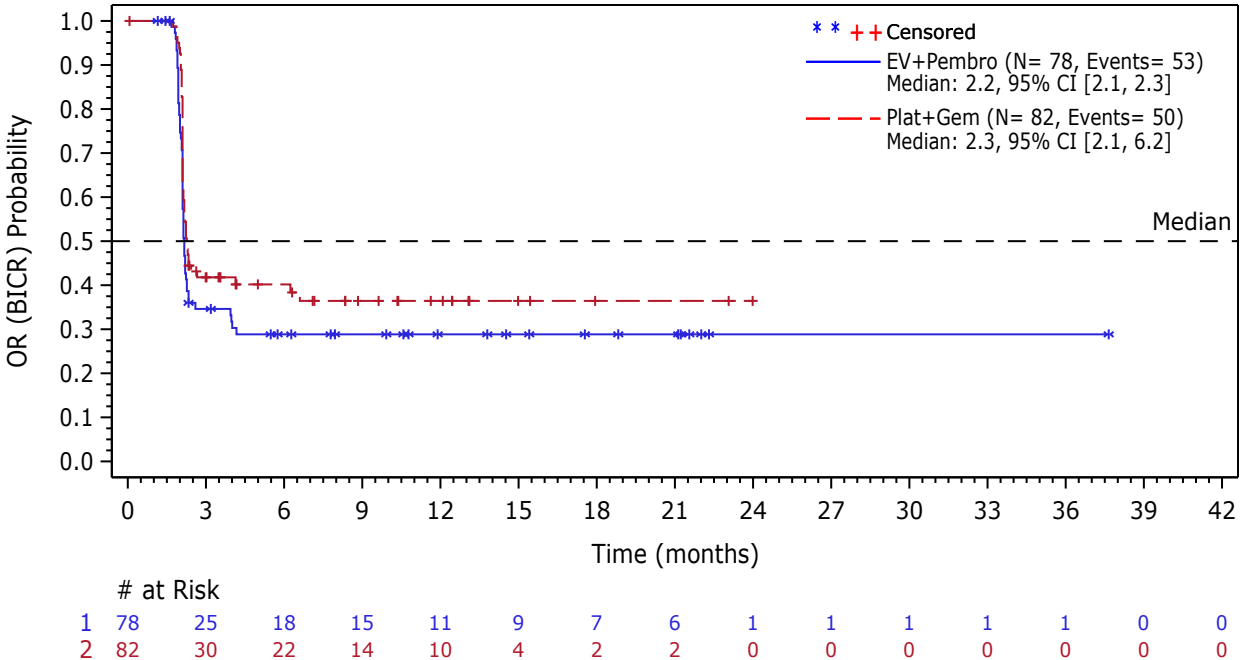
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.1.10: Kaplan-Meier Plot of Objective Response (BICR) by Renal Function - Analysis Set mITT 1

Renal Function: Normal



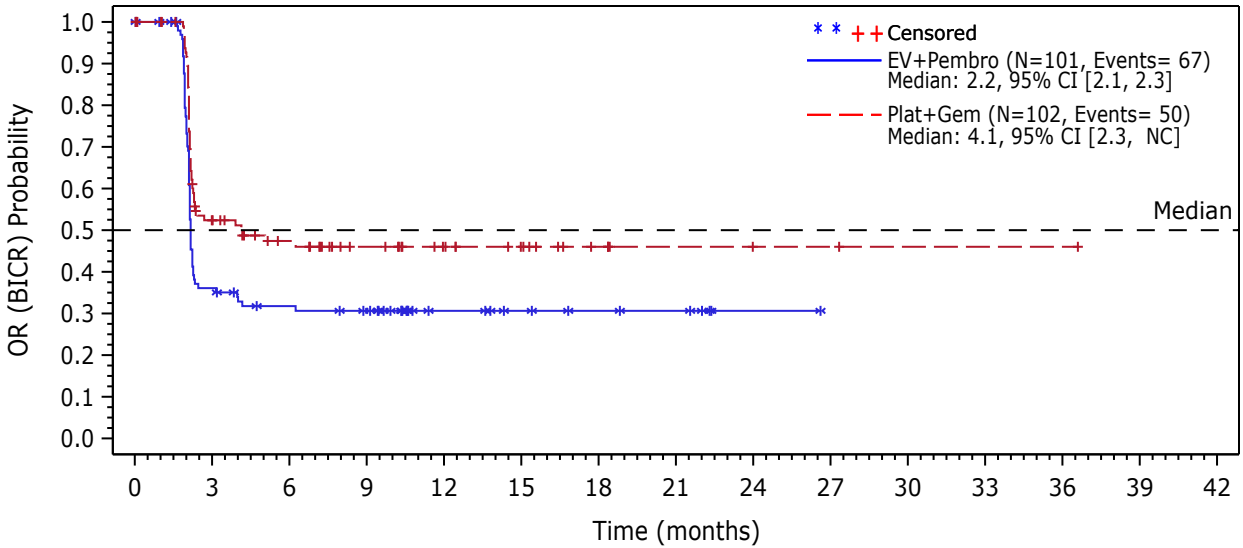
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.1.1: Kaplan-Meier Plot of Objective Response (BICR) by PD-L1 Expression - Analysis Set mITT 1

PD-L1 Expression: Low (CPS<10)



at Risk

1	101	35	28	25	11	8	6	5	1	0	0	0	0	0	0
2	102	46	34	24	17	12	6	3	2	2	1	1	1	0	0

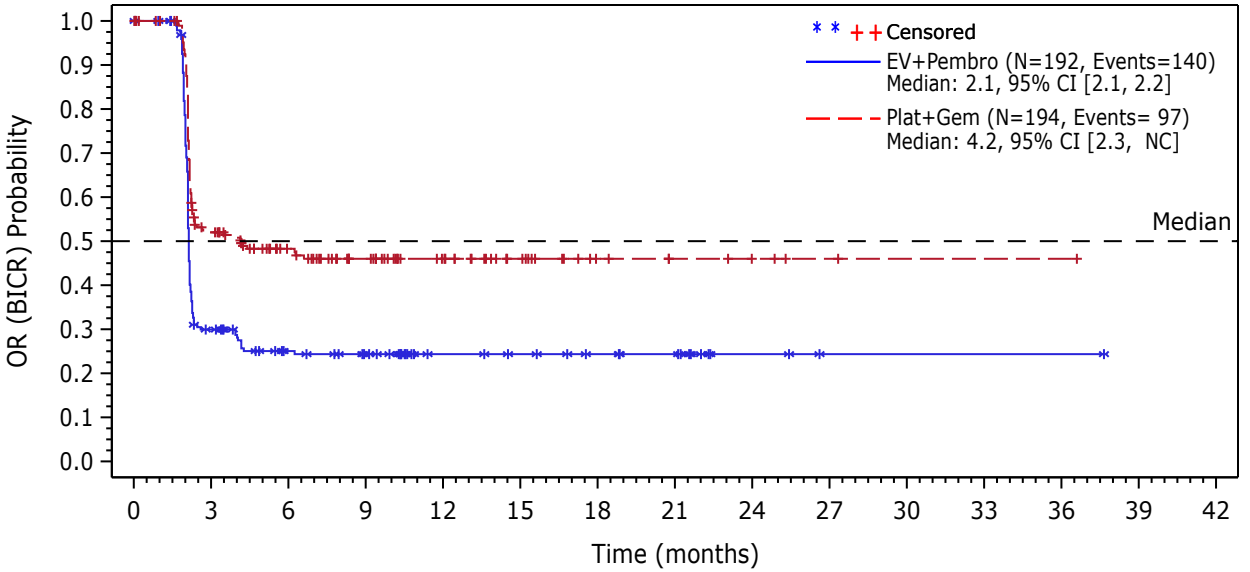
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.1.2: Kaplan-Meier Plot of Objective Response (BICR) by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Absent



at Risk

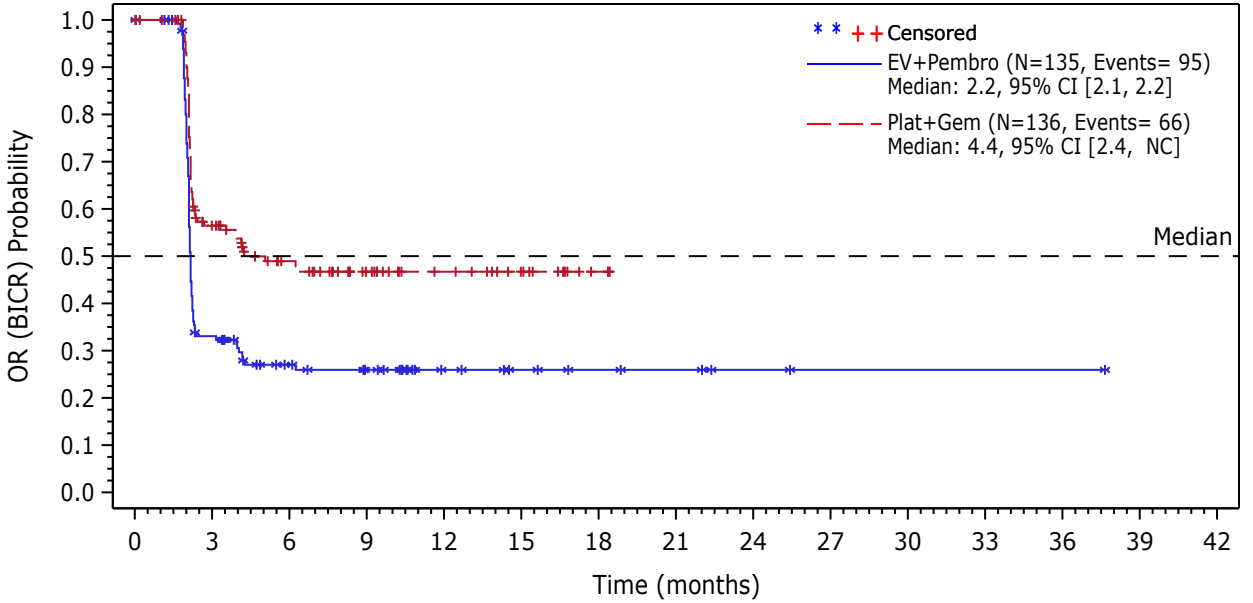
1	192	54	36	30	17	15	12	10	3	1	1	1	1	0	0
2	194	91	64	46	31	19	9	6	4	2	1	1	1	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.1.3: Kaplan-Meier Plot of Objective Response (BICR) by Age - Analysis Set mITT 1
Age: >= 65 years



at Risk

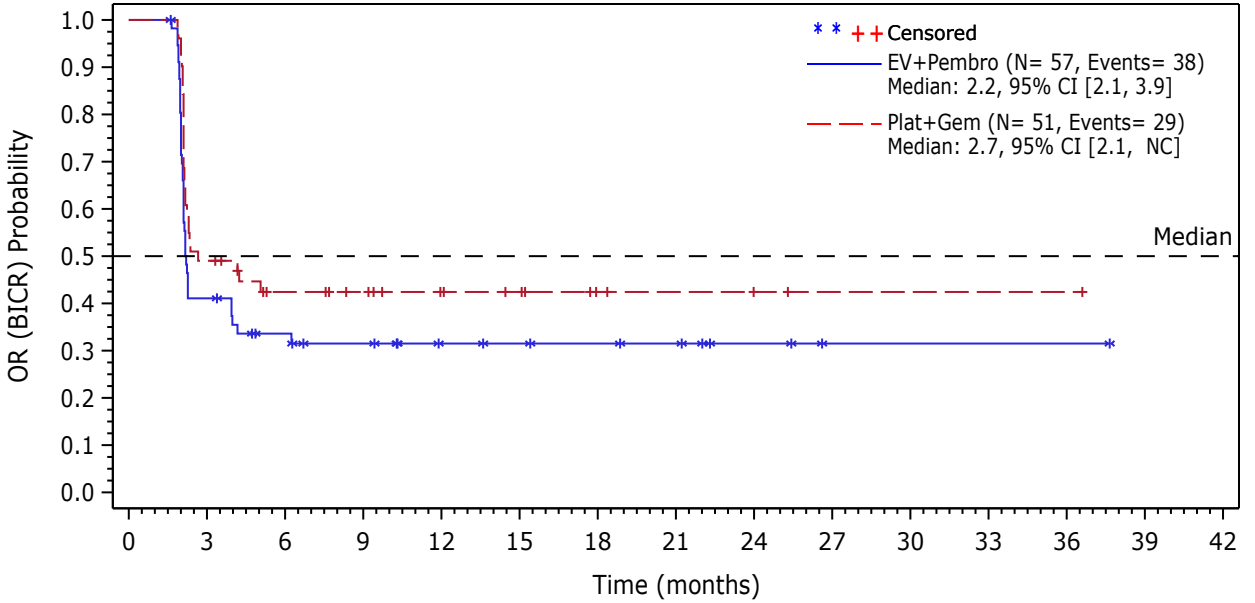
1	135	42	26	21	10	7	5	4	2	1	1	1	1	0	0
2	136	67	44	29	19	12	3	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.1.4: Kaplan-Meier Plot of Objective Response (BICR) by Region - Analysis Set mITT 1 Region: North America



at Risk

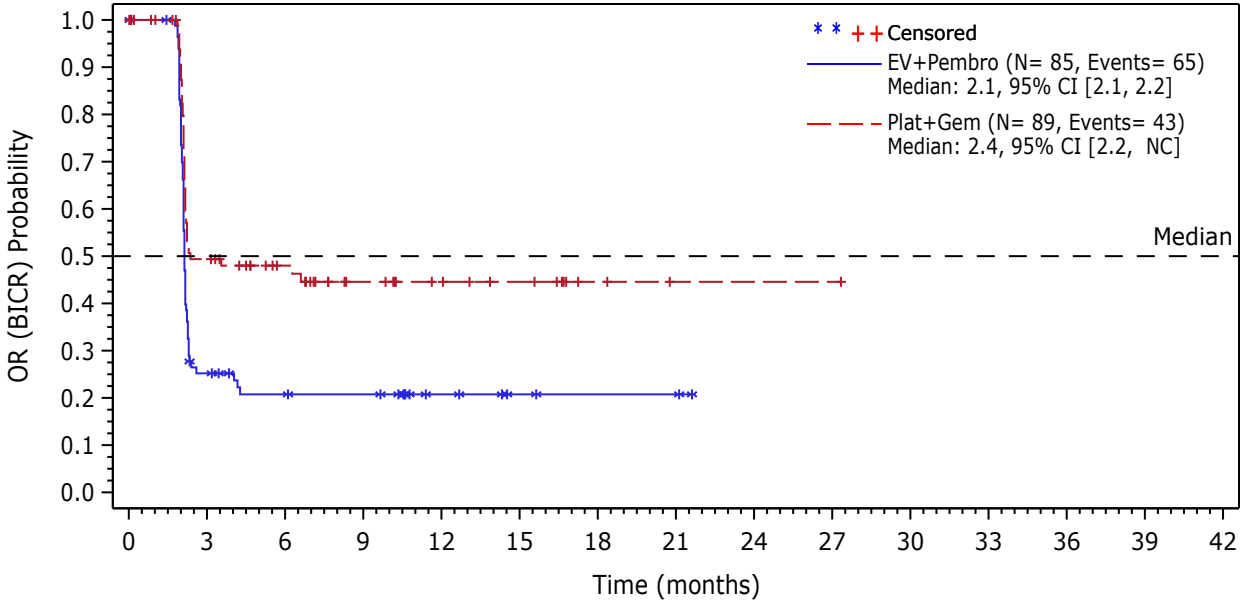
1	57	23	16	13	9	8	7	6	3	1	1	1	1	0	0
2	51	25	17	14	10	8	4	3	2	1	1	1	1	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.1.4: Kaplan-Meier Plot of Objective Response (BICR) by Region - Analysis Set mITT 1 Region: Rest of World



at Risk

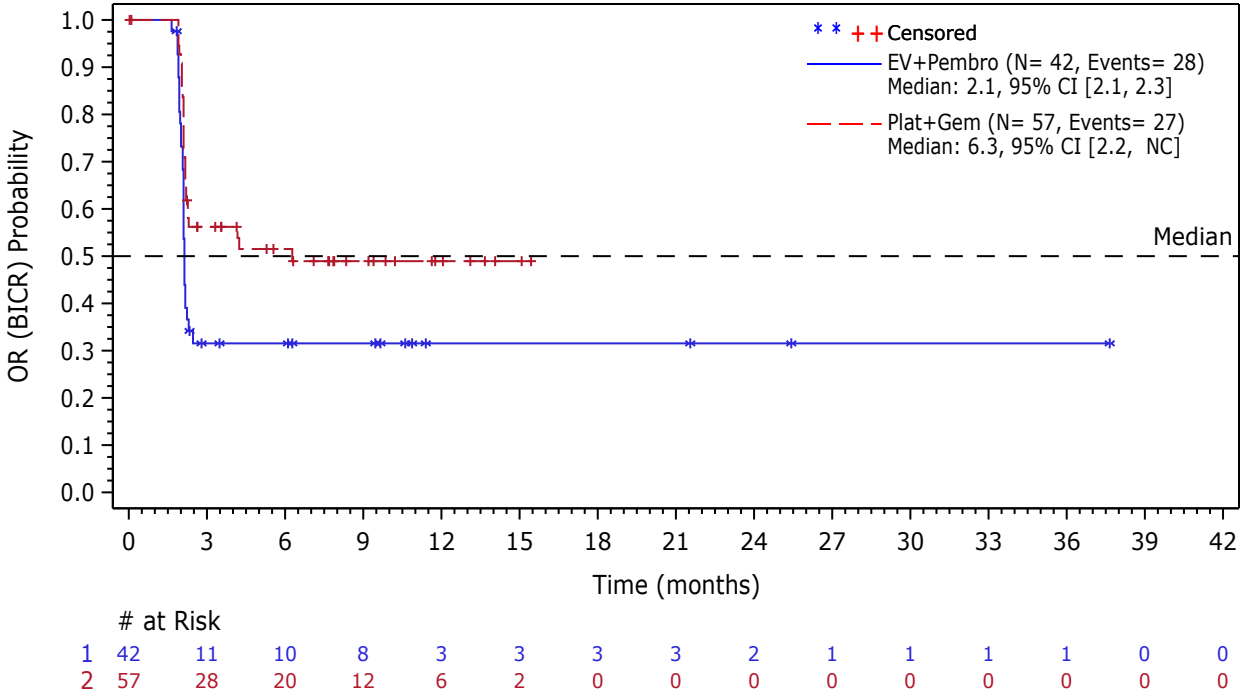
1	85	20	14	13	6	3	2	2	0	0	0	0	0	0	0
2	89	39	28	17	12	9	3	1	1	1	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.1.5: Kaplan-Meier Plot of Objective Response (BICR) by Sex - Analysis Set mITT 1
Sex: Female

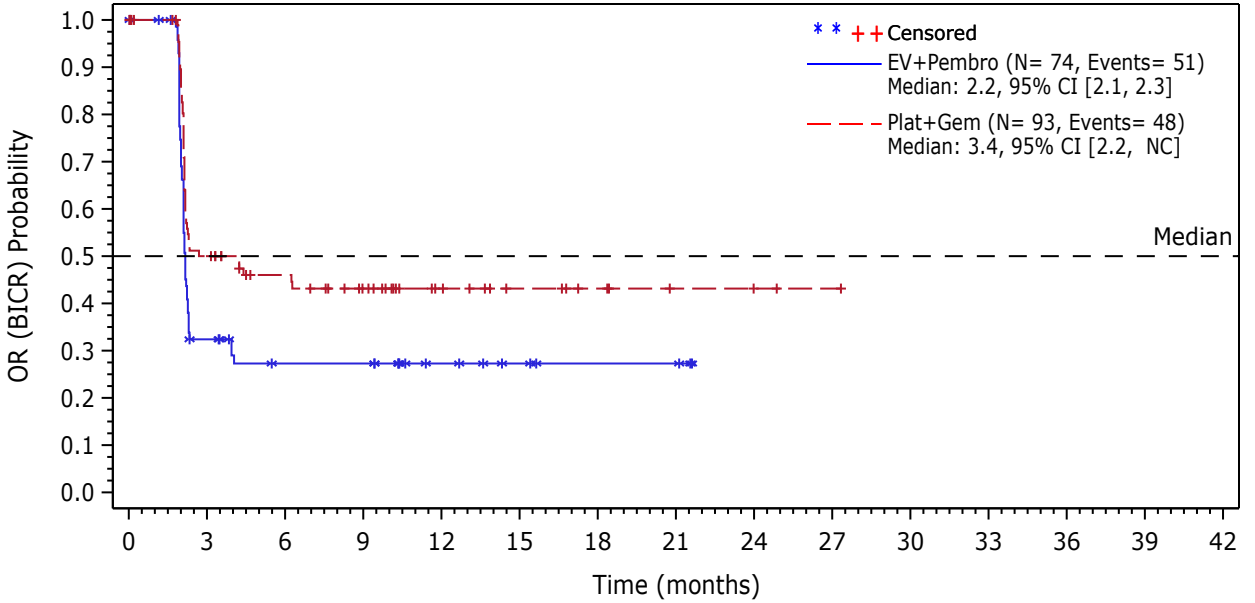


Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.1.6: Kaplan-Meier Plot of Objective Response (BICR) by Race - Analysis Set mITT 1
Race: Non-white



at Risk

1	74	22	15	15	8	5	3	3	0	0	0	0	0	0	0
2	93	43	32	24	14	9	6	3	2	1	0	0	0	0	0

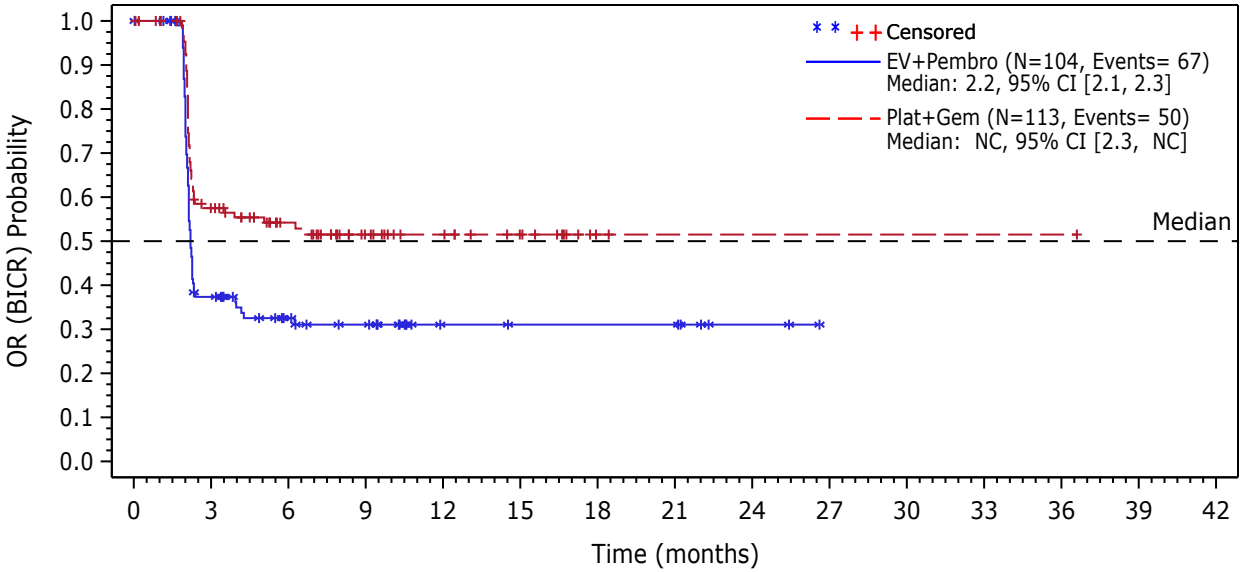
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.1.7: Kaplan-Meier Plot of Objective Response (BICR) by ECOG Status at Baseline - Analysis Set mITT 1

ECOG Status at Baseline: 1-2



at Risk

1	104	36	23	18	7	6	6	6	2	0	0	0	0	0	0
2	113	58	40	24	17	11	2	1	1	1	1	1	1	0	0

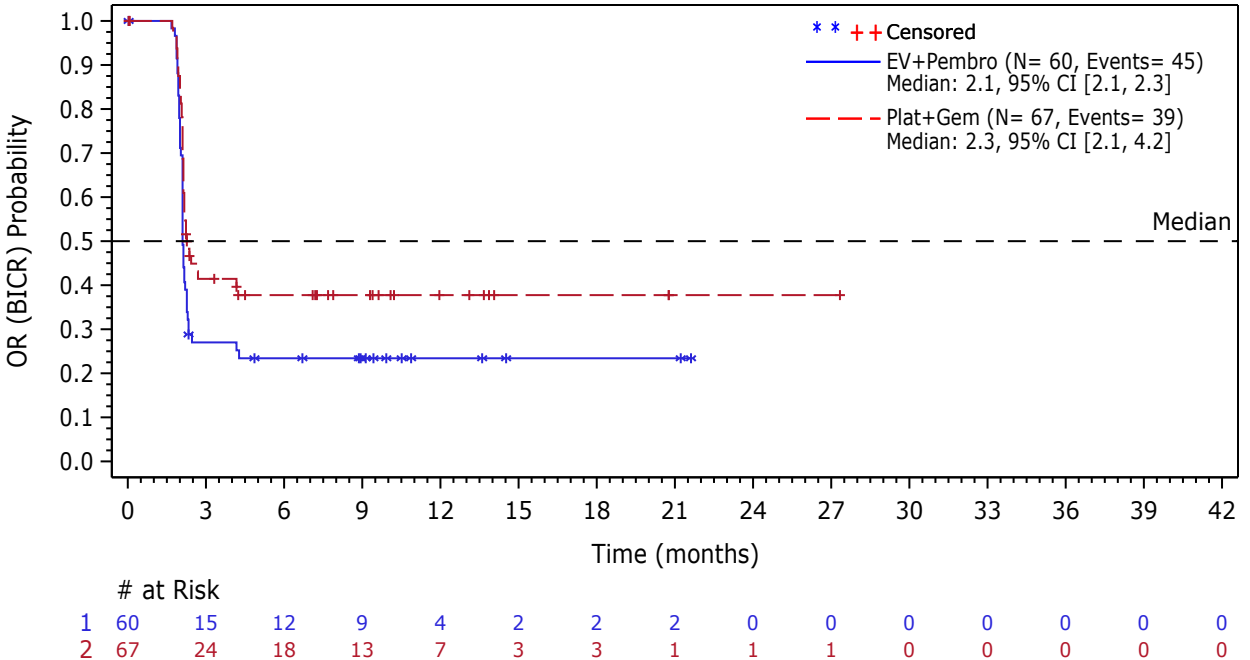
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.1.8: Kaplan-Meier Plot of Objective Response (BICR) by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Lymph node only



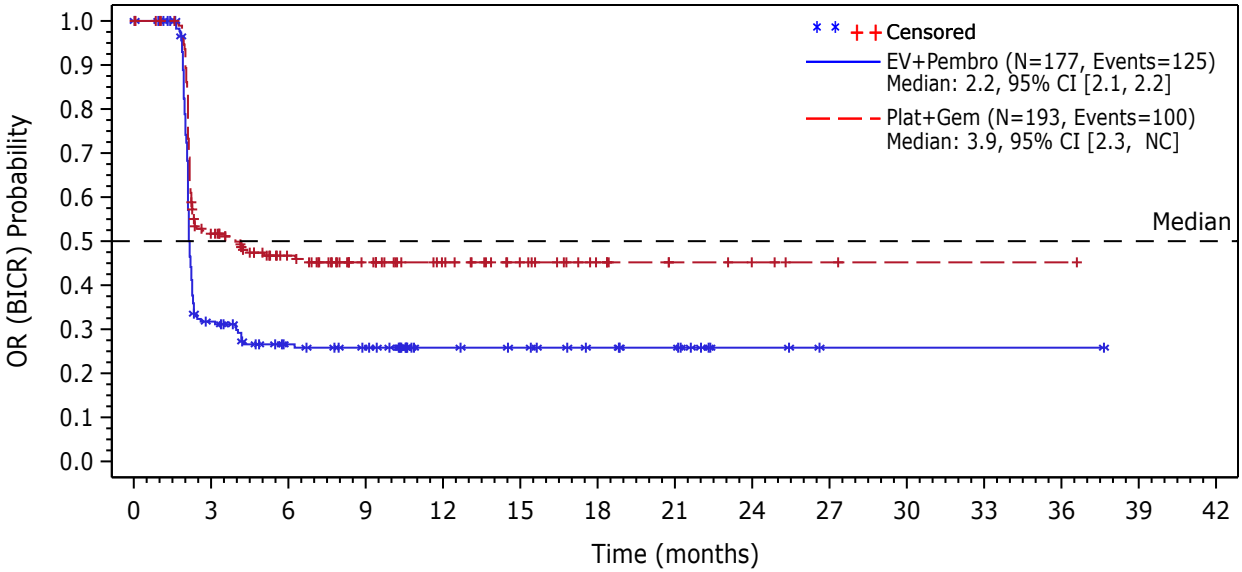
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.1.9: Kaplan-Meier Plot of Objective Response (BICR) by Primary Disease Site of Origin - Analysis Set mITT 1

Primary Disease Site of Origin: Lower tract



at Risk

1	177	52	35	30	17	15	11	9	3	1	1	1	1	0	0
2	193	91	62	43	30	20	11	6	4	2	1	1	1	0	0

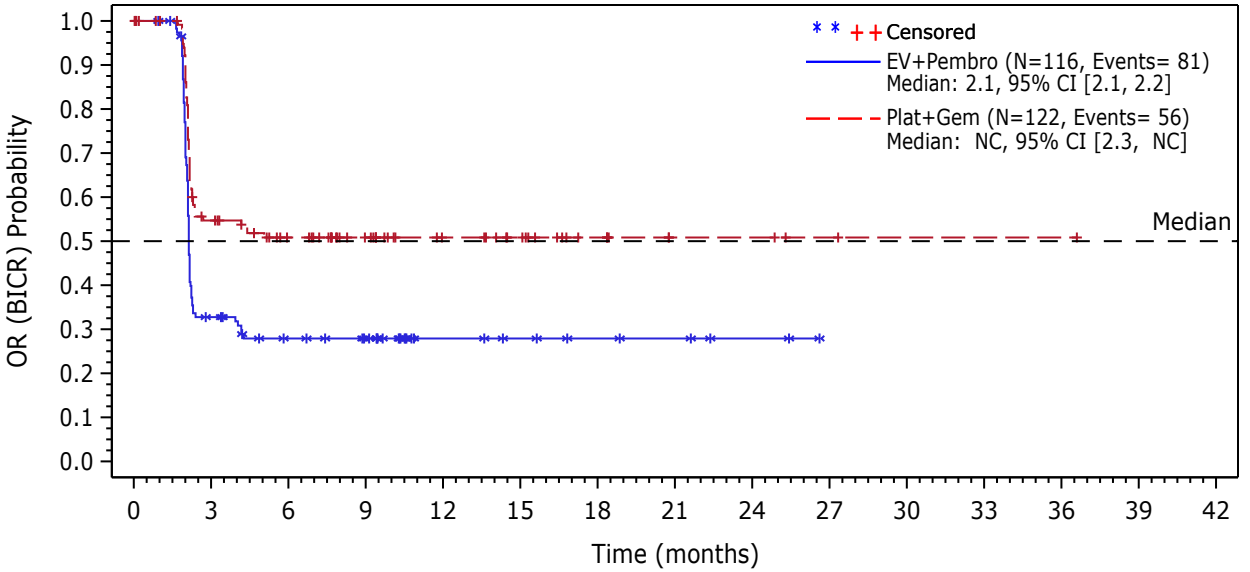
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.1.10: Kaplan-Meier Plot of Objective Response (BICR) by Renal Function - Analysis Set mITT 1

Renal Function: Mild



at Risk

1	116	36	26	22	9	7	5	4	2	0	0	0	0	0	0
2	122	61	46	33	22	17	9	4	4	2	1	1	1	0	0

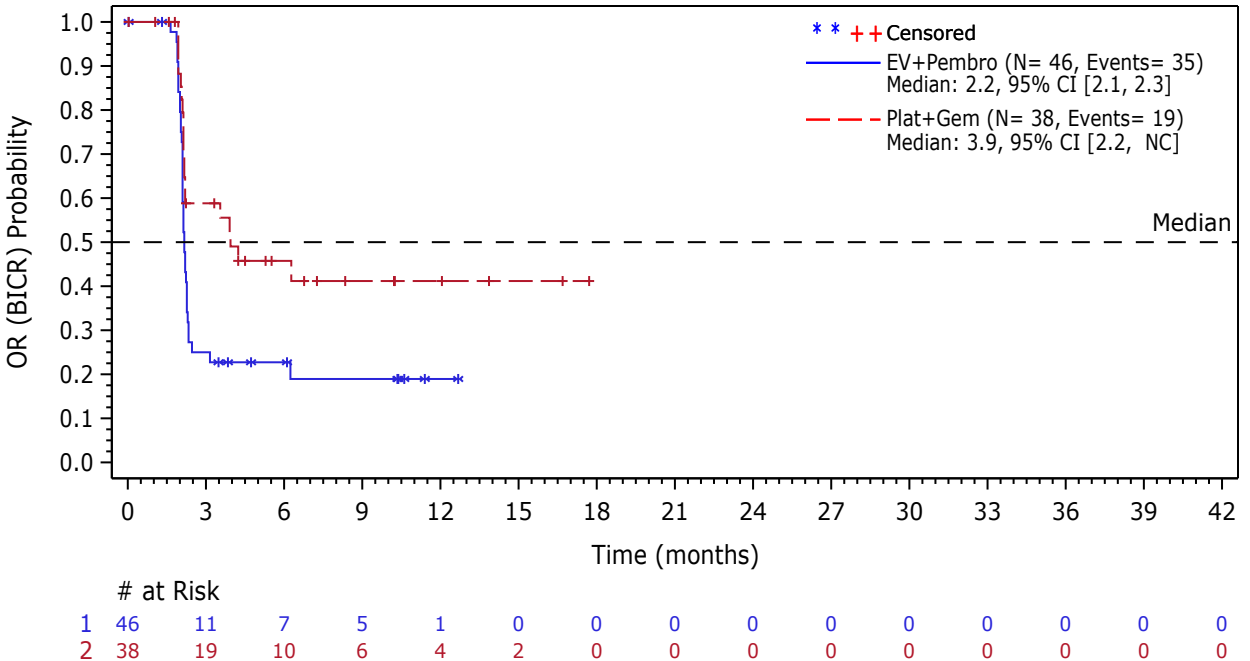
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.1.10: Kaplan-Meier Plot of Objective Response (BICR) by Renal Function - Analysis Set mITT 1

Renal Function: Moderate

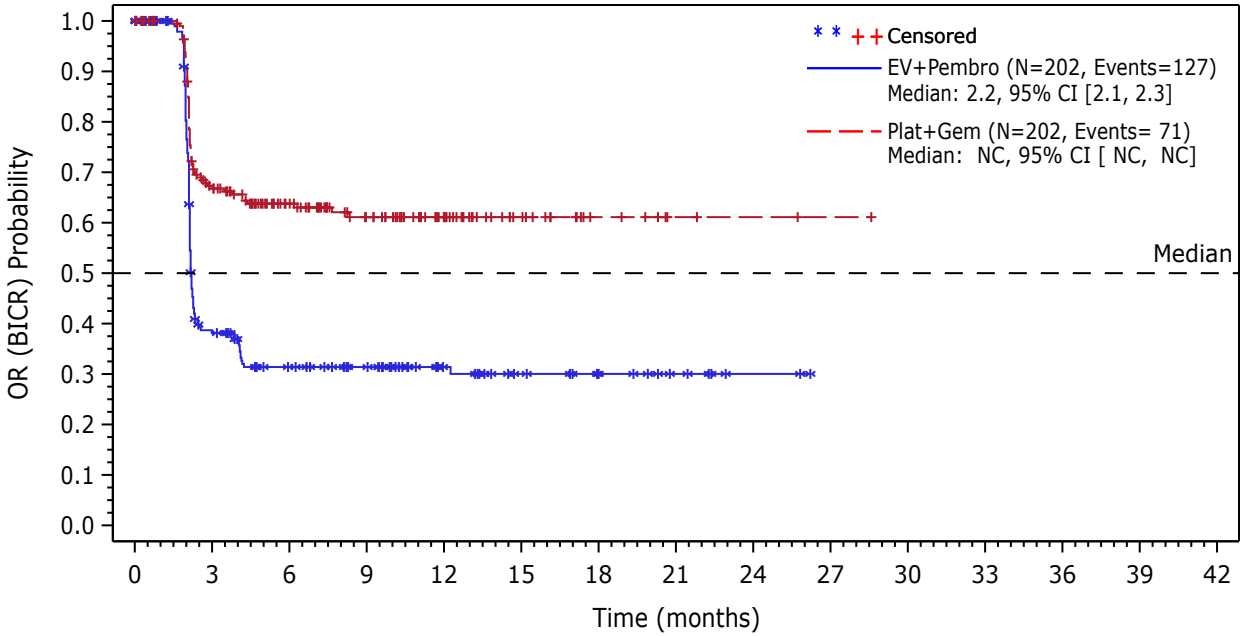


Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.2: Kaplan-Meier Plot of Objective Response (BICR) - Analysis Set mITT 2



at Risk

1	202	68	47	39	23	15	11	6	2	0	0	0	0	0	0
2	202	121	86	60	38	19	8	3	2	1	0	0	0	0	0

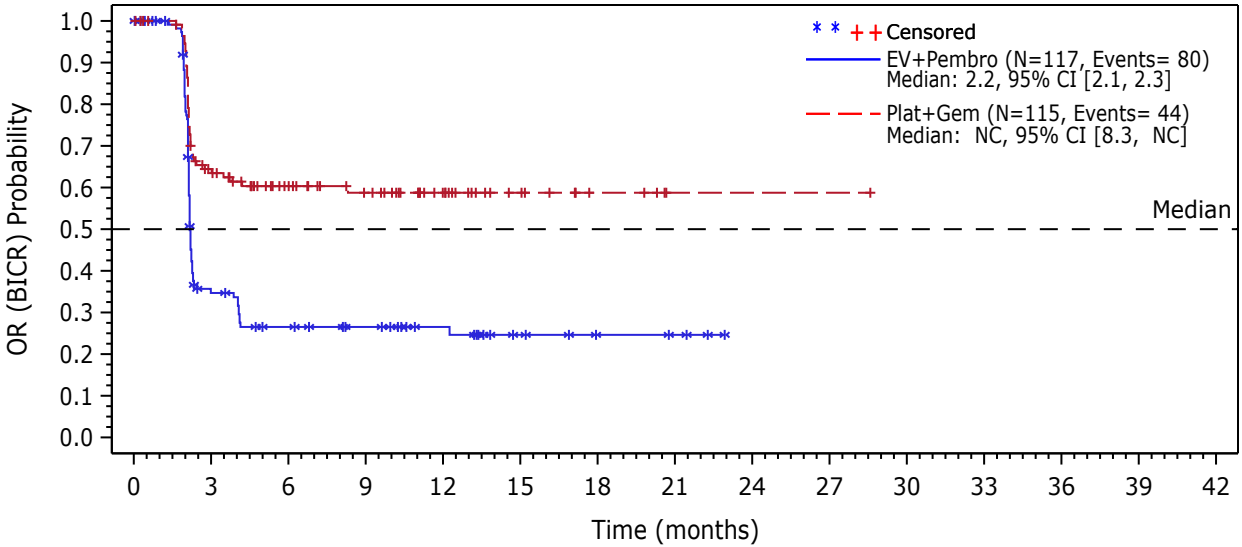
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.2.1: Kaplan-Meier Plot of Objective Response (BICR) by PD-L1 Expression - Analysis Set mITT 2

PD-L1 Expression: High (CPS>=10)



at Risk

1	117	35	24	20	14	7	4	3	0	0	0	0	0	0	0
2	115	66	46	36	22	11	5	1	1	1	0	0	0	0	0

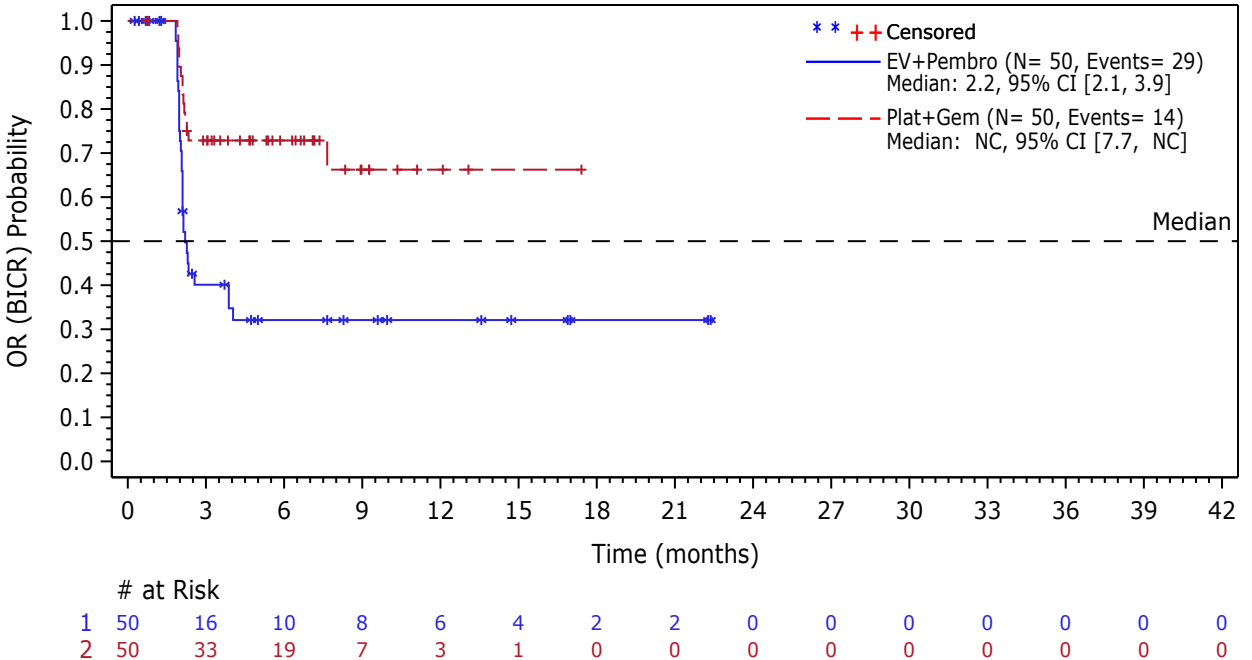
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.2.2: Kaplan-Meier Plot of Objective Response (BICR) by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Present

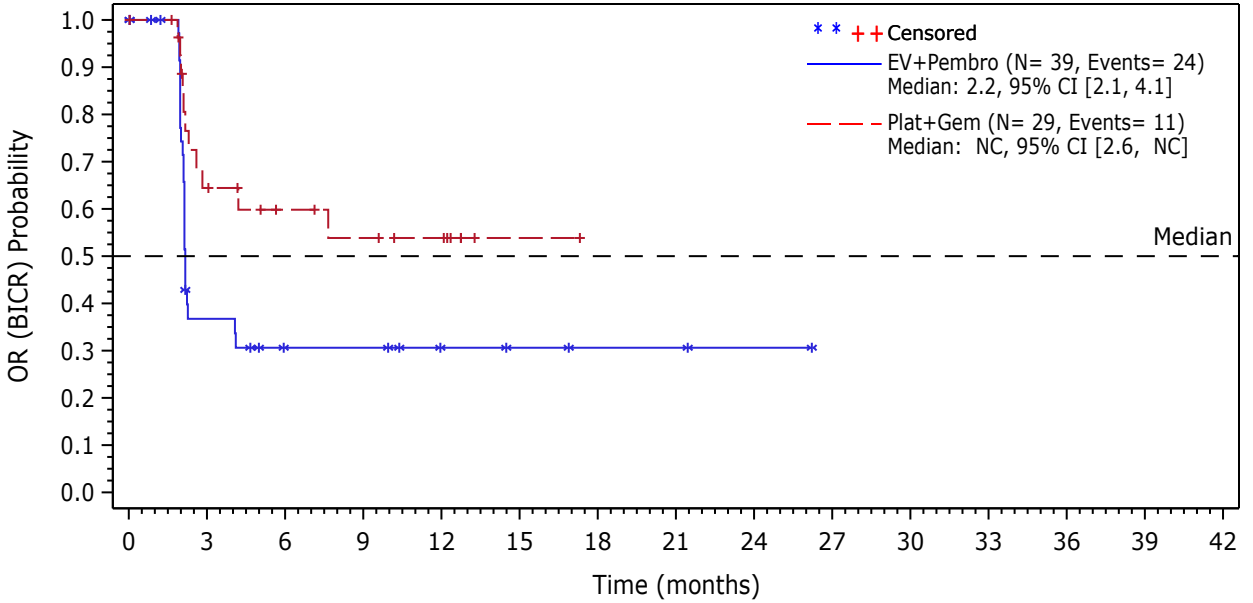


Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.2.3: Kaplan-Meier Plot of Objective Response (BICR) by Age - Analysis Set mITT 2
Age: < 65 years



at Risk

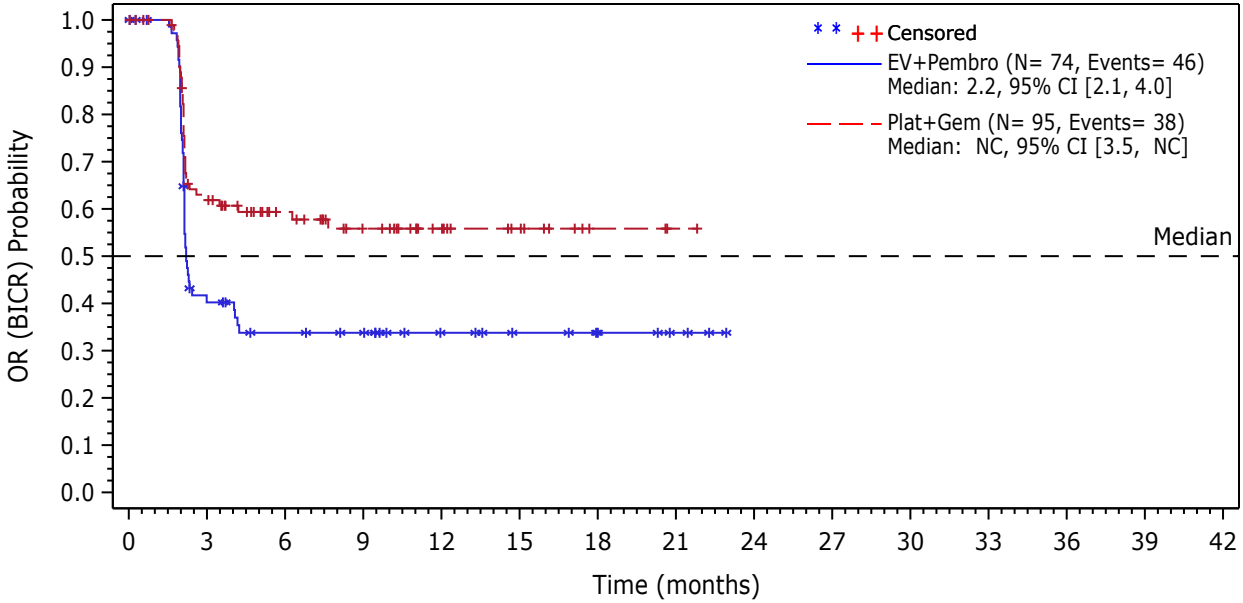
1	39	12	7	7	4	3	2	2	1	0	0	0	0	0	0
2	29	16	11	9	7	1	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.2.4: Kaplan-Meier Plot of Objective Response (BICR) by Region - Analysis Set mITT 2 Region: Europe



at Risk

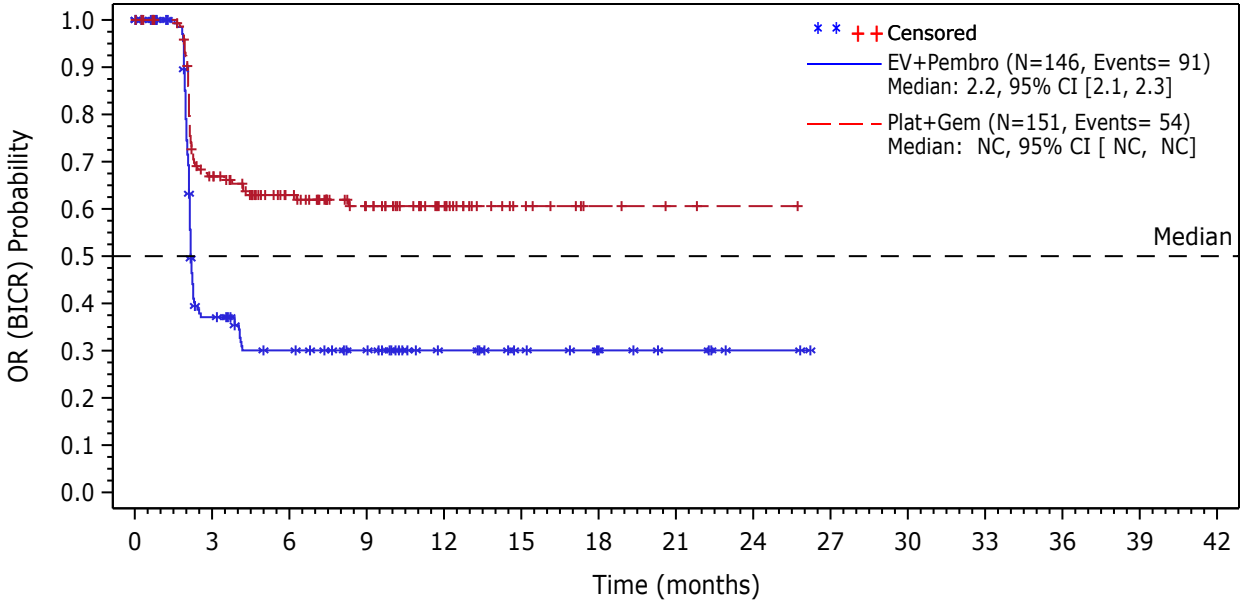
1	74	27	20	18	11	8	6	3	0	0	0	0	0	0	0
2	95	54	37	26	16	10	3	1	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.2.5: Kaplan-Meier Plot of Objective Response (BICR) by Sex - Analysis Set mITT 2
Sex: Male



at Risk

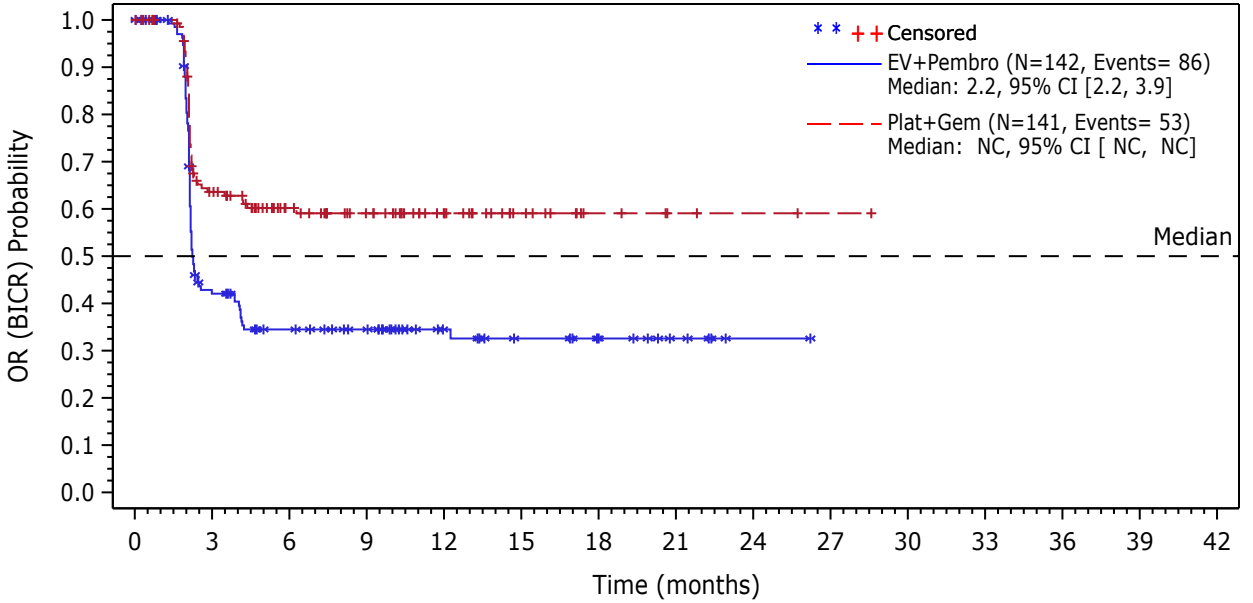
1	146	47	33	27	16	11	8	5	2	0	0	0	0	0	0
2	151	91	64	42	25	10	4	2	1	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.2.6: Kaplan-Meier Plot of Objective Response (BICR) by Race - Analysis Set mITT 2 Race: White



at Risk

1	142	53	38	32	18	13	10	5	1	0	0	0	0	0	0
2	141	80	55	41	26	14	6	3	2	1	0	0	0	0	0

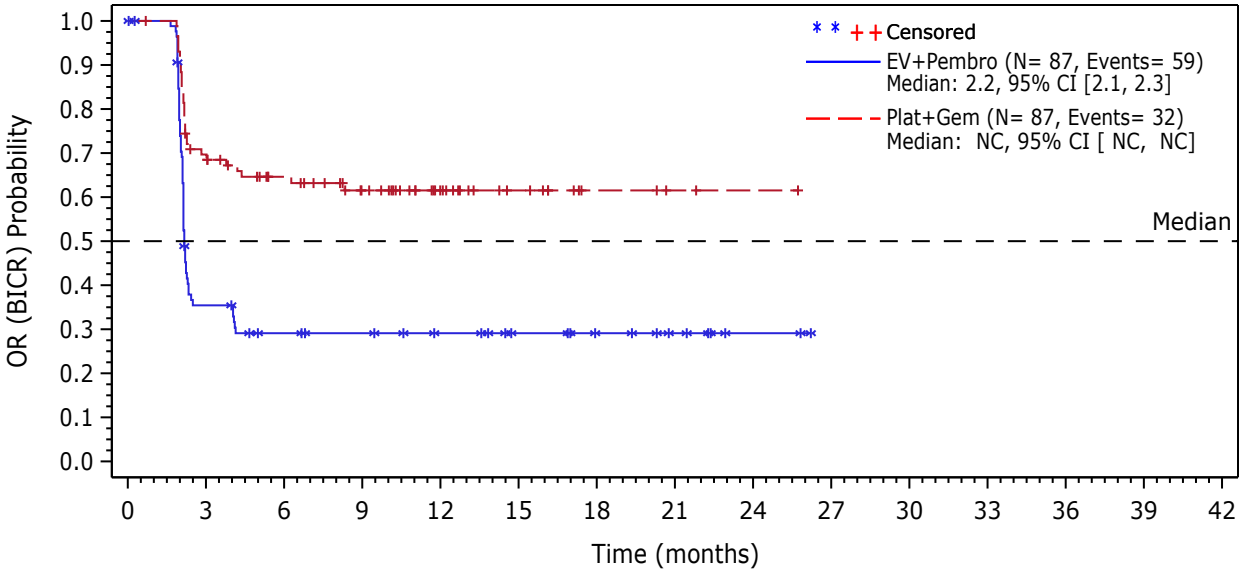
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.2.7: Kaplan-Meier Plot of Objective Response (BICR) by ECOG Status at Baseline - Analysis Set mITT 2

ECOG Status at Baseline: 0



at Risk

1	87	29	21	19	16	12	9	6	2	0	0	0	0	0	0
2	87	58	45	34	20	11	4	2	1	0	0	0	0	0	0

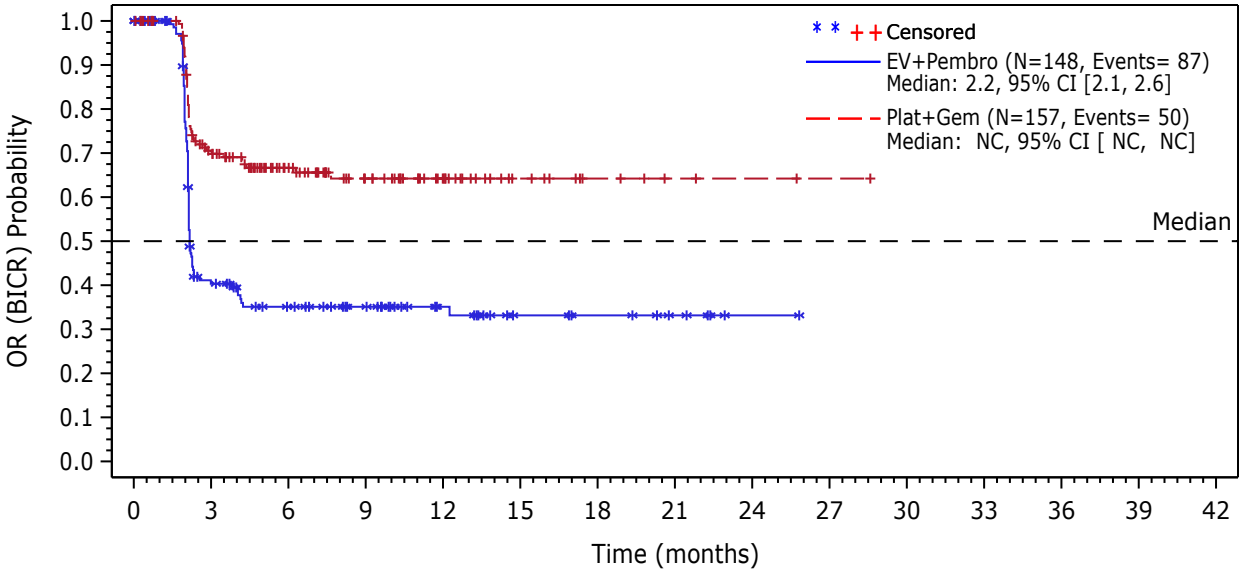
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.2.8: Kaplan-Meier Plot of Objective Response (BICR) by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Visceral metastases



at Risk

1	148	51	37	29	18	10	8	5	1	0	0	0	0	0	0
2	157	97	65	42	26	12	6	3	2	1	0	0	0	0	0

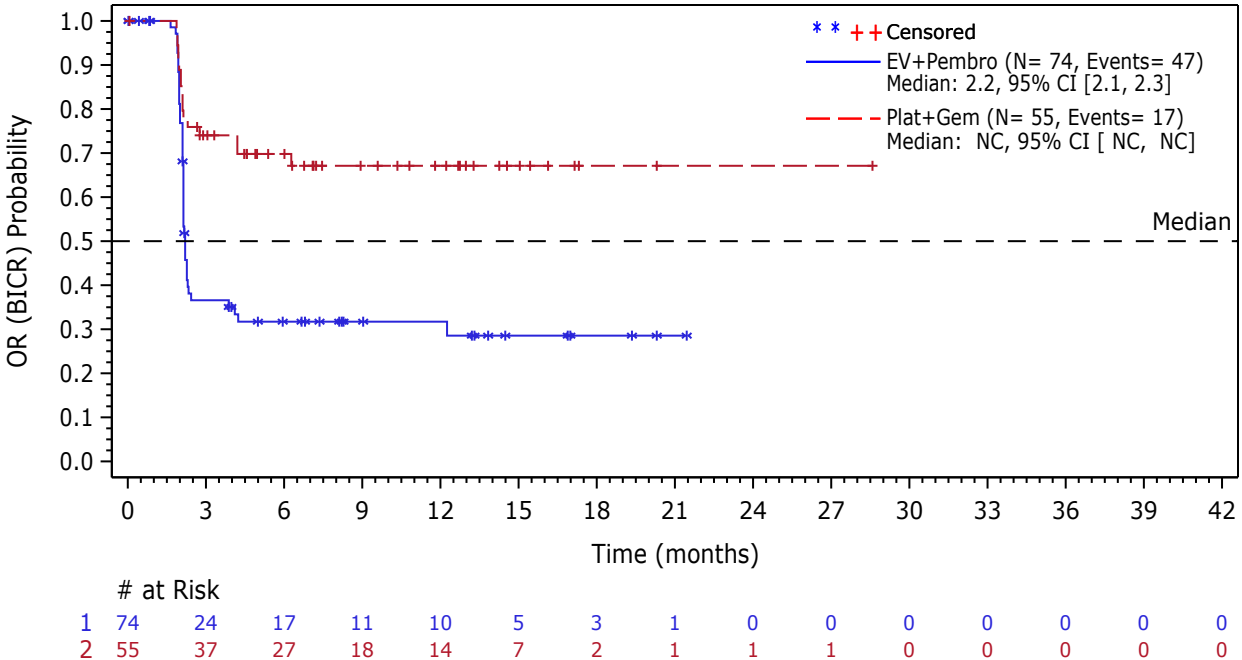
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.2.9: Kaplan-Meier Plot of Objective Response (BICR) by Primary Disease Site of Origin - Analysis Set mITT 2

Primary Disease Site of Origin: Upper tract



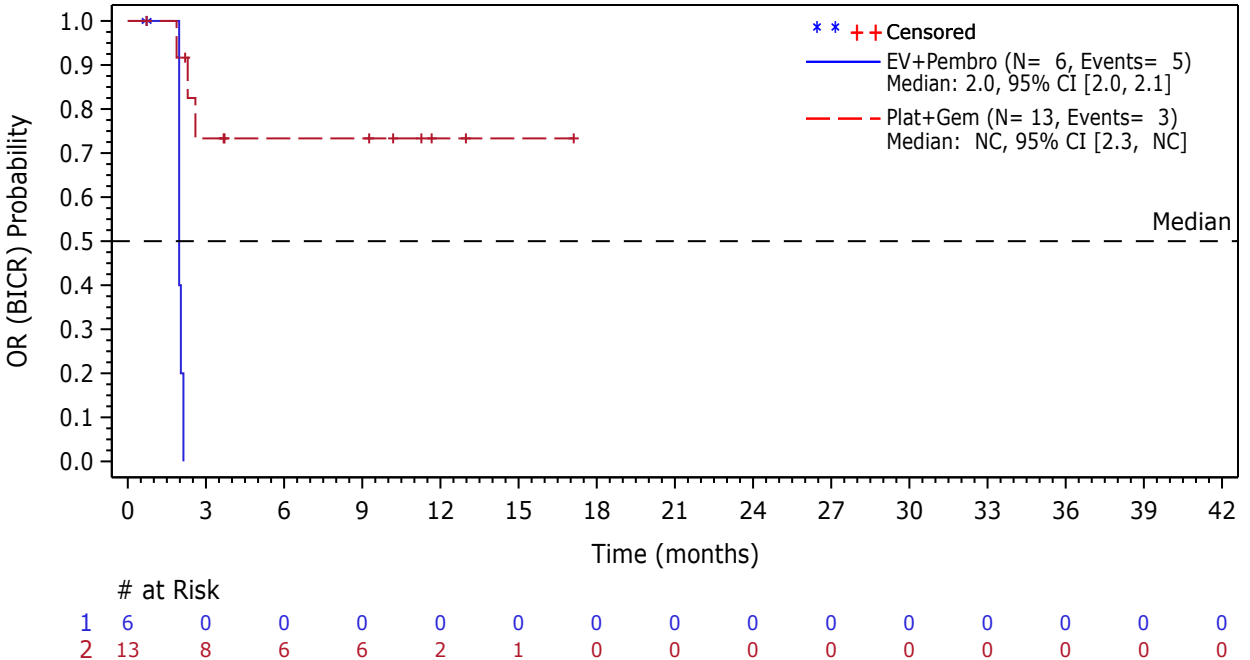
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.2.10: Kaplan-Meier Plot of Objective Response (BICR) by Renal Function - Analysis Set mITT 2

Renal Function: Normal



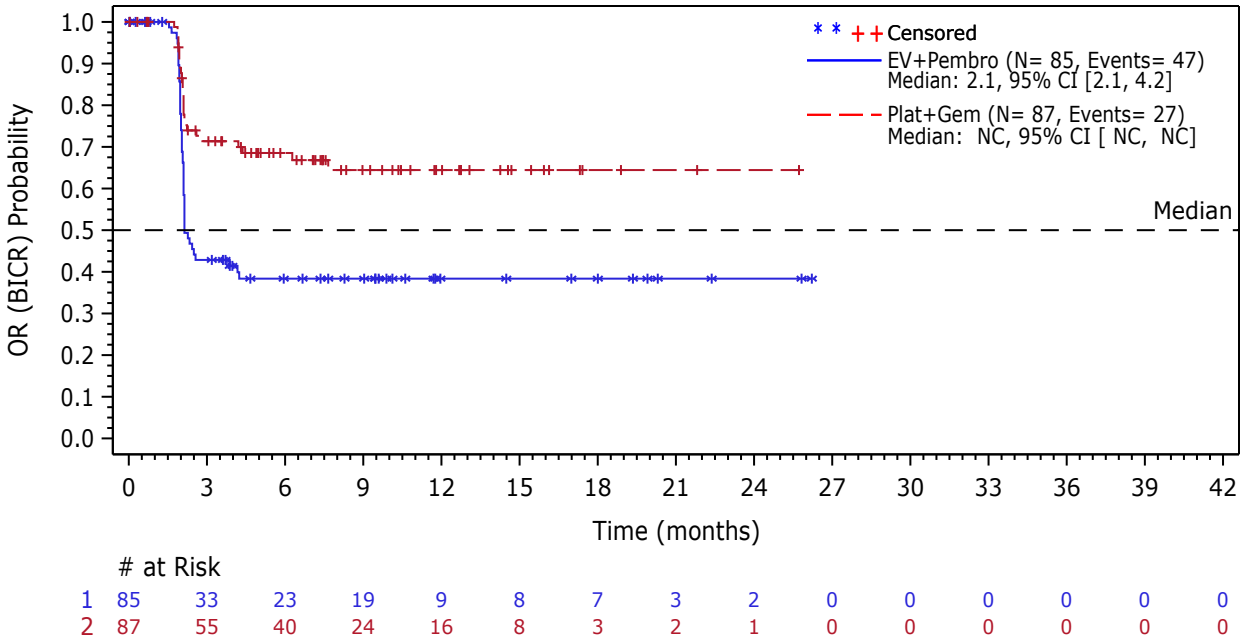
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.2.1: Kaplan-Meier Plot of Objective Response (BICR) by PD-L1 Expression - Analysis Set mITT 2

PD-L1 Expression: Low (CPS<10)



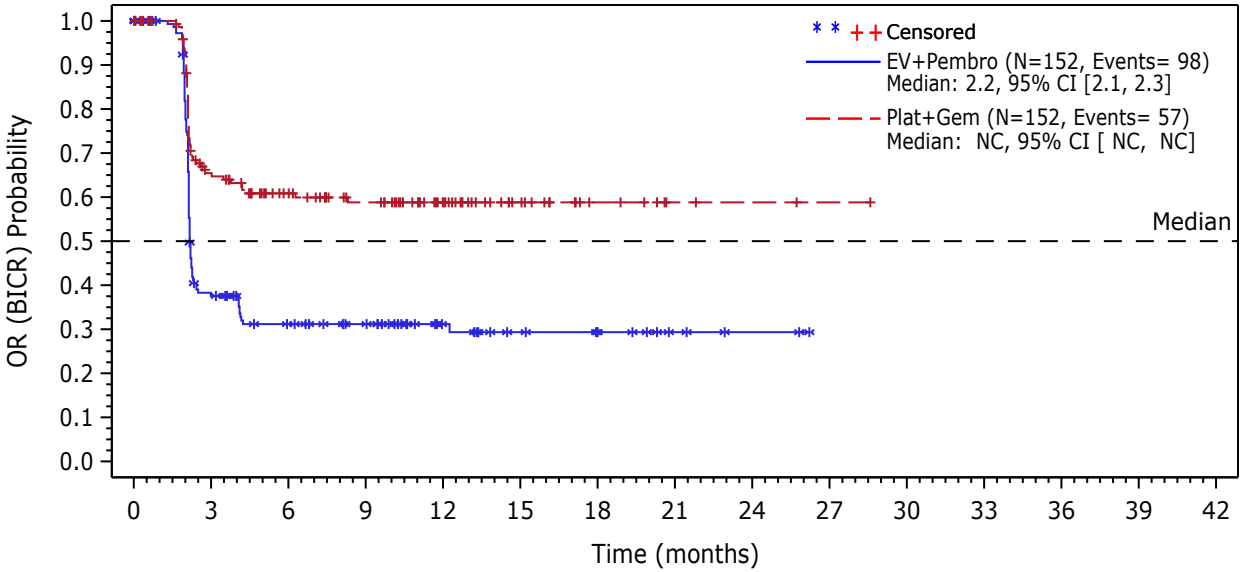
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.2.2: Kaplan-Meier Plot of Objective Response (BICR) by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Absent



at Risk

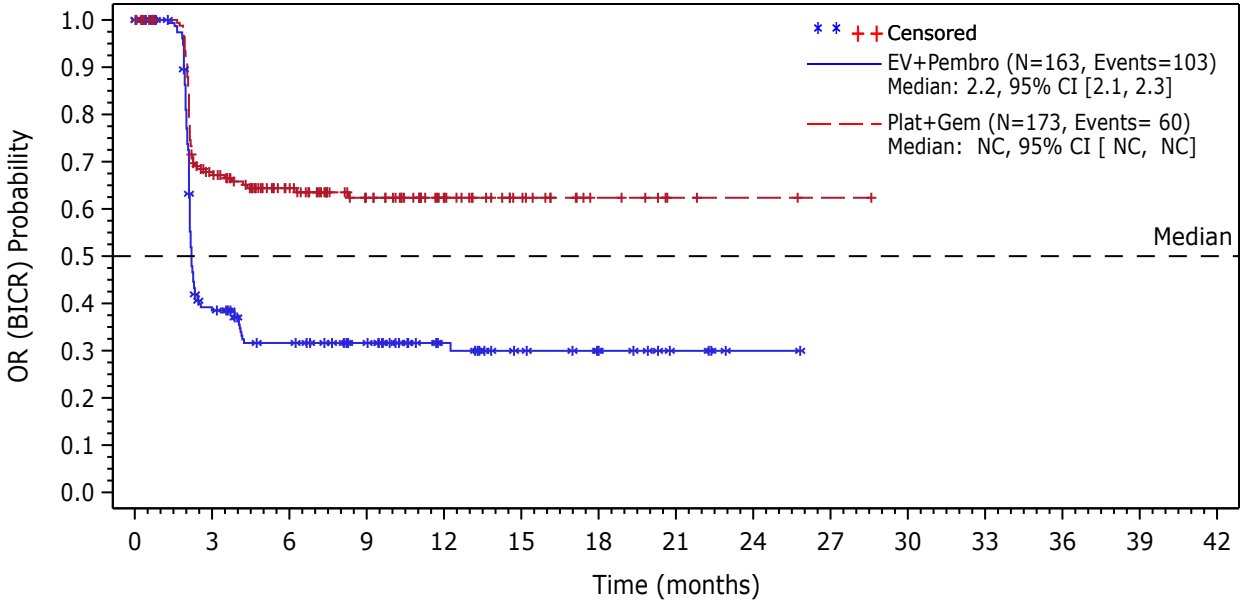
1	152	52	37	31	17	11	9	4	2	0	0	0	0	0	0
2	152	88	67	53	35	18	8	3	2	1	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.2.3: Kaplan-Meier Plot of Objective Response (BICR) by Age - Analysis Set mITT 2
Age: >= 65 years



at Risk

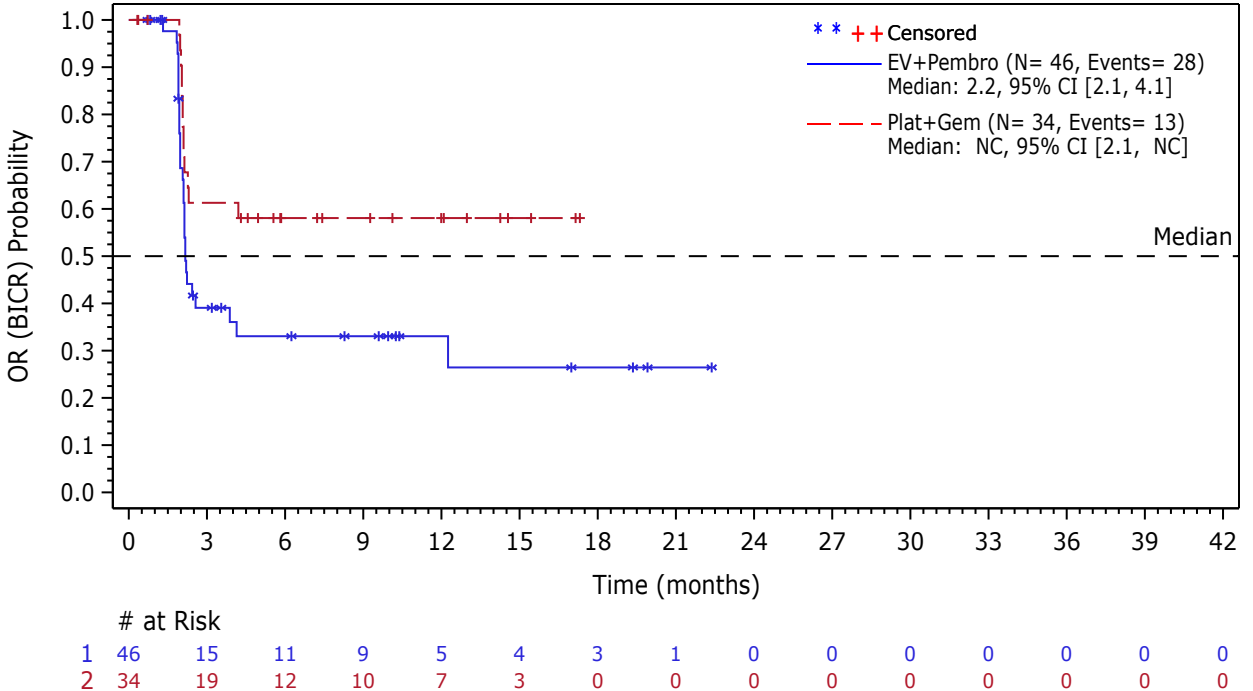
1	163	56	40	32	19	12	9	4	1	0	0	0	0	0	0
2	173	105	75	51	31	18	8	3	2	1	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.2.4: Kaplan-Meier Plot of Objective Response (BICR) by Region - Analysis Set mITT 2 Region: North America

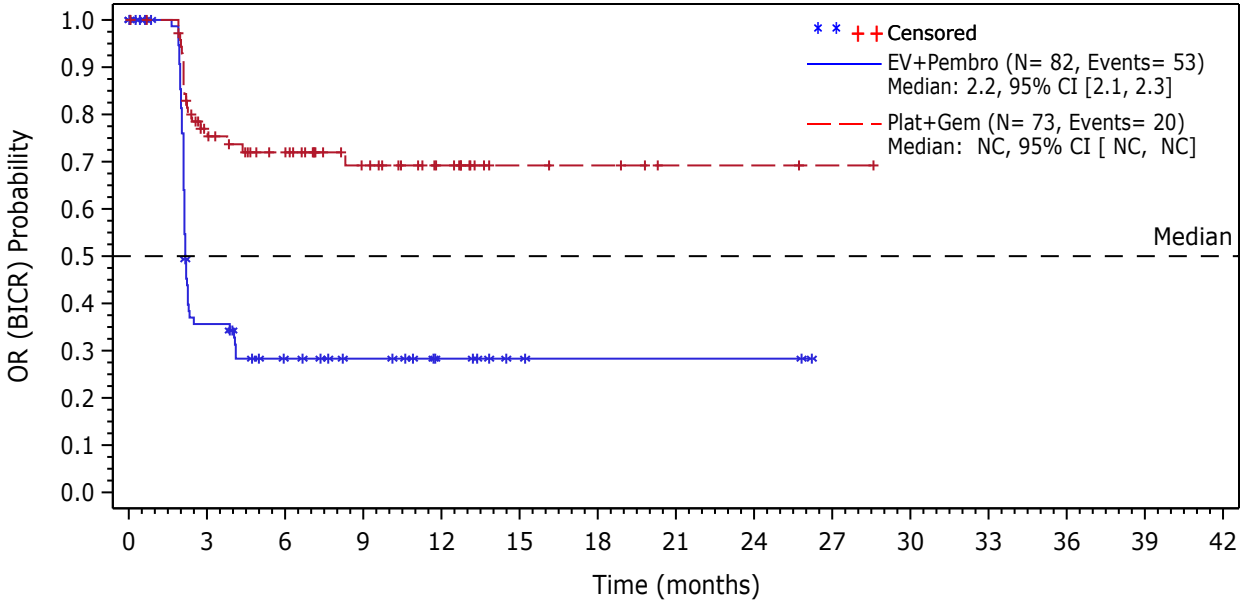


Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.2.4: Kaplan-Meier Plot of Objective Response (BICR) by Region - Analysis Set mITT 2 Region: Rest of World



at Risk

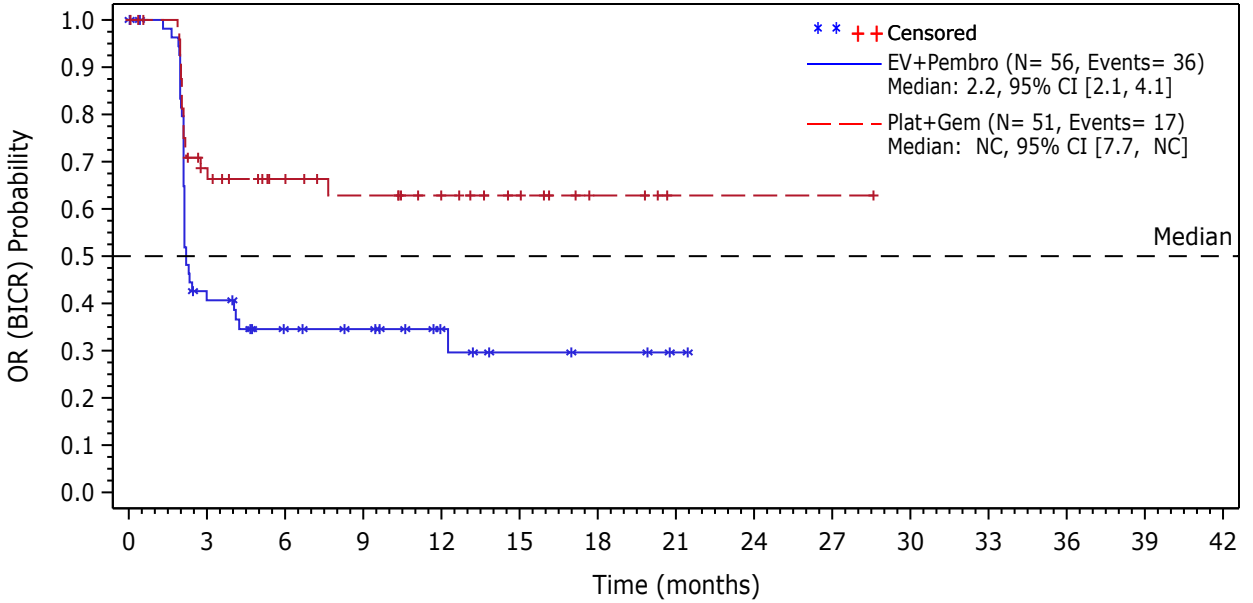
1	82	26	16	12	7	3	2	2	2	0	0	0	0	0	0
2	73	48	37	24	15	6	5	2	2	1	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.2.5: Kaplan-Meier Plot of Objective Response (BICR) by Sex - Analysis Set mITT 2
Sex: Female



at Risk

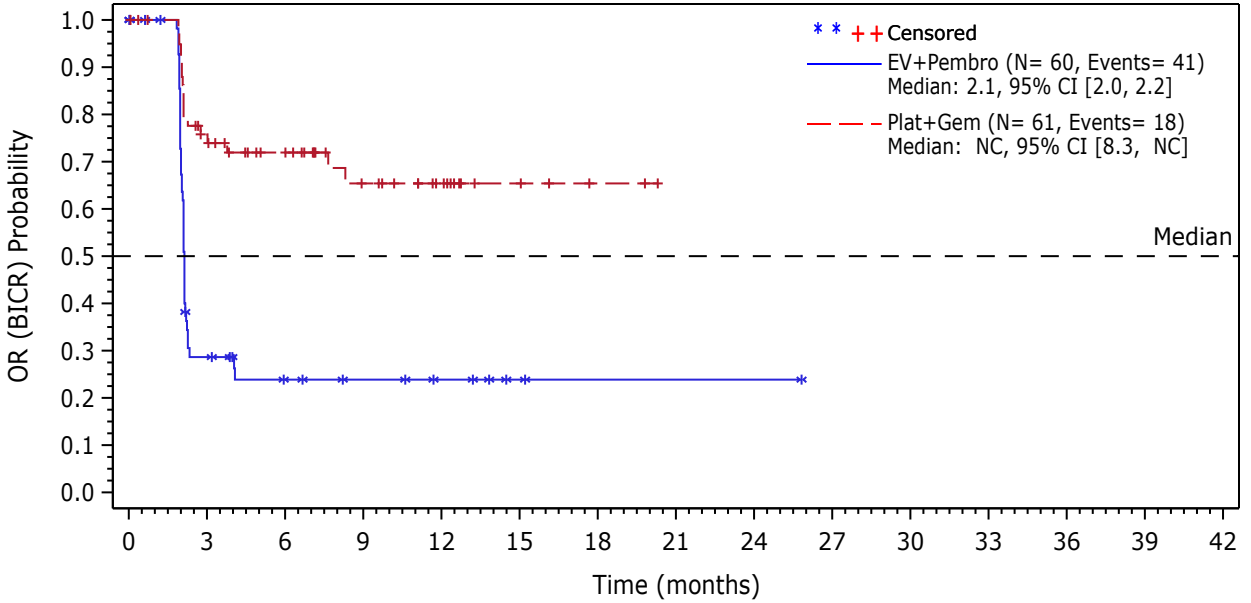
1	56	21	14	12	7	4	3	1	0	0	0	0	0	0	0
2	51	30	22	18	13	9	4	1	1	1	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.2.6: Kaplan-Meier Plot of Objective Response (BICR) by Race - Analysis Set mITT 2
Race: Non-white



at Risk

1	60	15	9	7	5	2	1	1	1	0	0	0	0	0	0
2	61	41	31	19	12	5	2	0	0	0	0	0	0	0	0

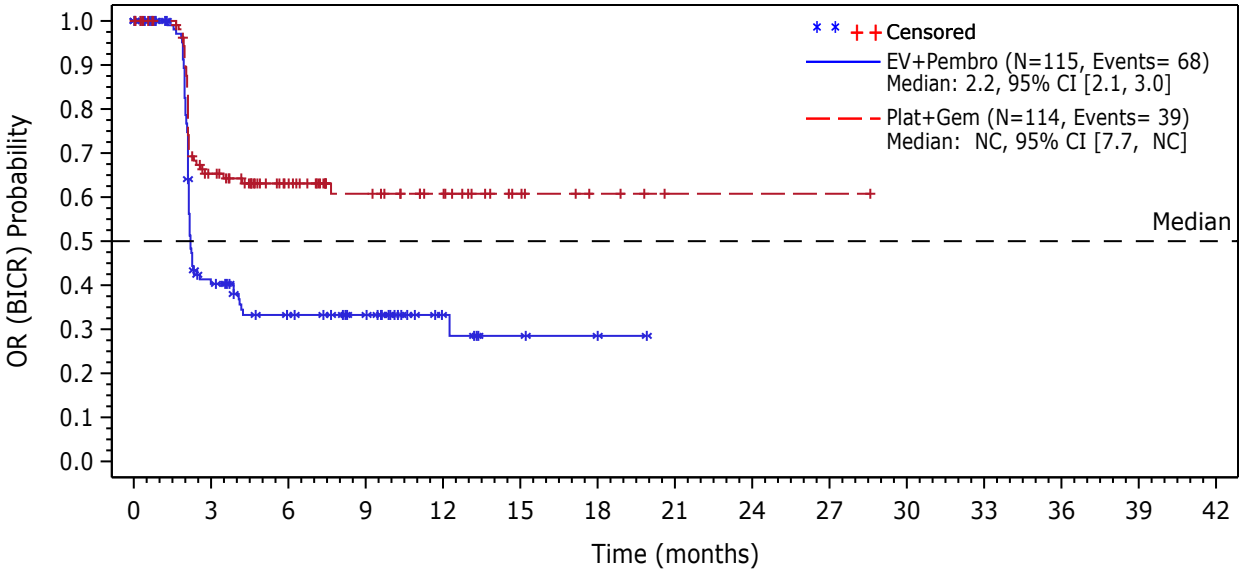
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.2.7: Kaplan-Meier Plot of Objective Response (BICR) by ECOG Status at Baseline - Analysis Set mITT 2

ECOG Status at Baseline: 1-2



at Risk

1	115	39	26	20	7	3	2	0	0	0	0	0	0	0	0
2	114	63	41	26	18	8	4	1	1	1	0	0	0	0	0

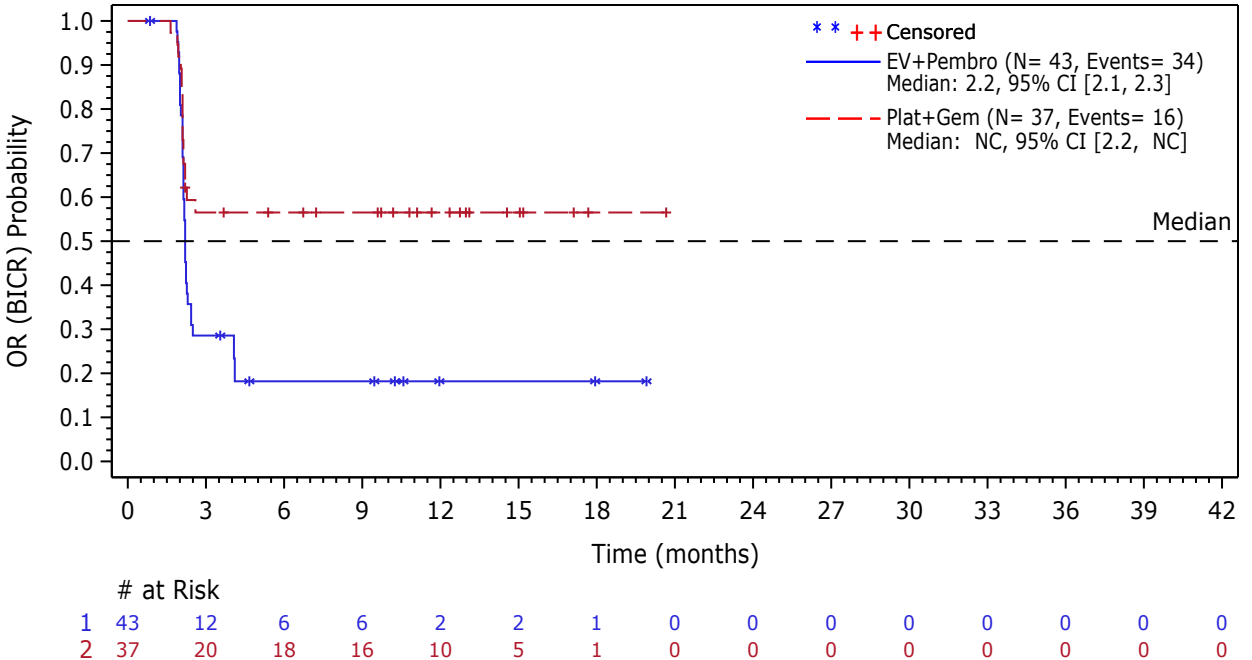
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.2.8: Kaplan-Meier Plot of Objective Response (BICR) by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Lymph node only



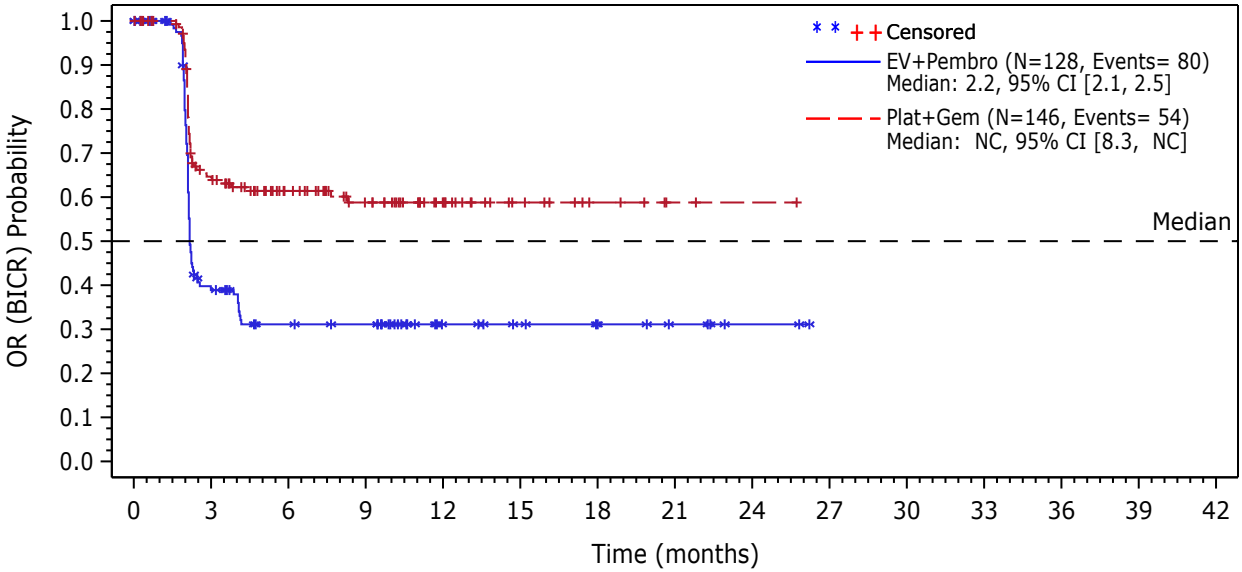
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.2.9: Kaplan-Meier Plot of Objective Response (BICR) by Primary Disease Site of Origin - Analysis Set mITT 2

Primary Disease Site of Origin: Lower tract



at Risk

1	128	44	30	28	13	10	8	5	2	0	0	0	0	0	0
2	146	84	59	42	24	12	6	2	1	0	0	0	0	0	0

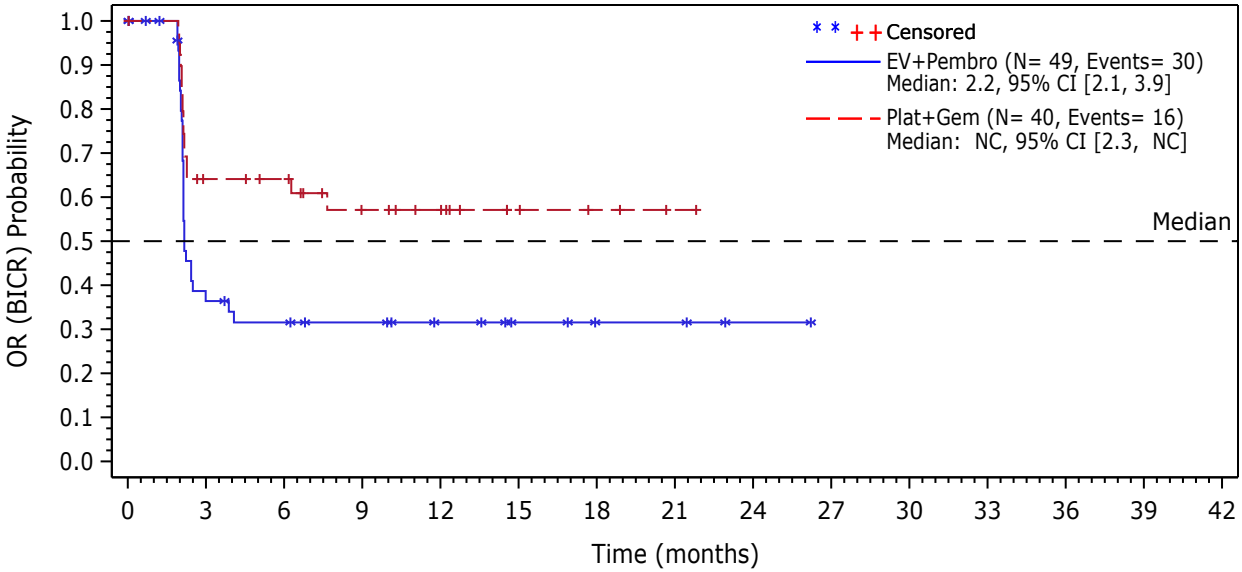
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.2.10: Kaplan-Meier Plot of Objective Response (BICR) by Renal Function - Analysis Set mITT 2

Renal Function: Mild



at Risk

1	49	16	13	11	8	5	3	3	1	0	0	0	0	0	0
2	40	23	21	14	11	5	3	1	0	0	0	0	0	0	0

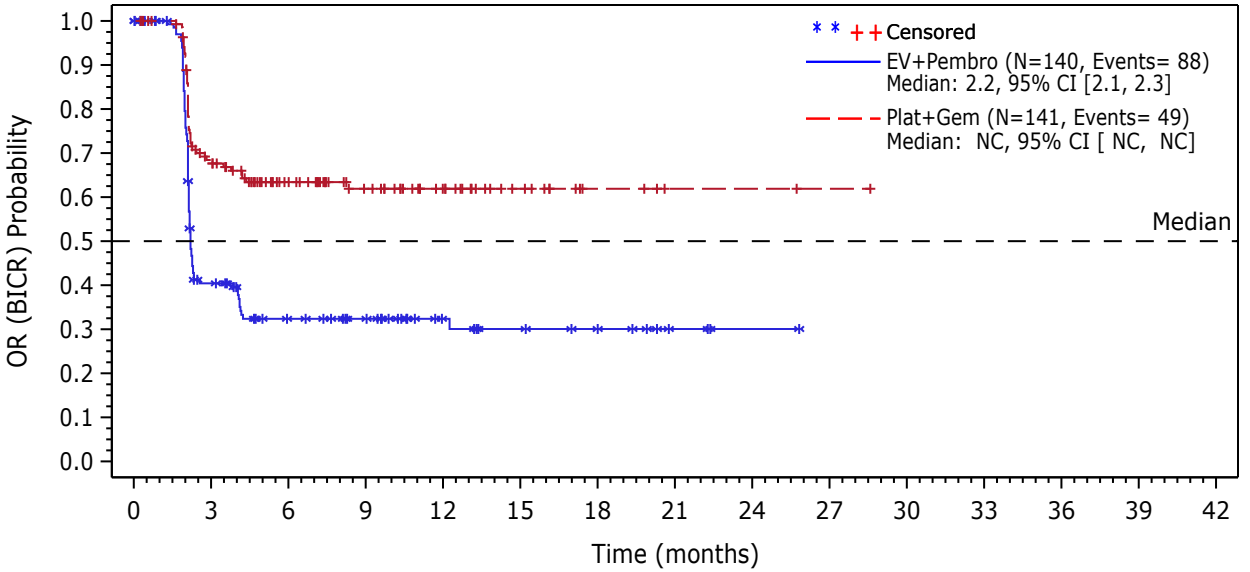
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.2.10: Kaplan-Meier Plot of Objective Response (BICR) by Renal Function - Analysis Set mITT 2

Renal Function: Moderate



at Risk

1	140	50	32	26	14	10	8	3	1	0	0	0	0	0	0
2	141	87	58	39	25	13	5	2	2	1	0	0	0	0	0

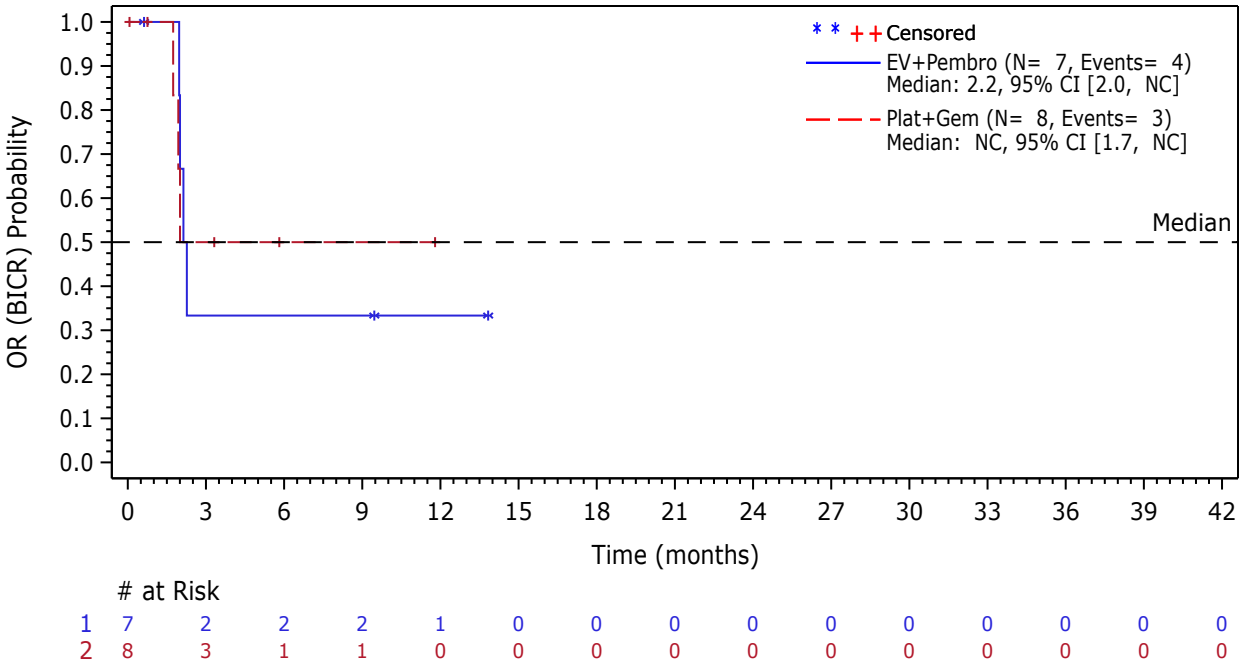
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.6.2.10: Kaplan-Meier Plot of Objective Response (BICR) by Renal Function - Analysis Set mITT 2

Renal Function: Severe

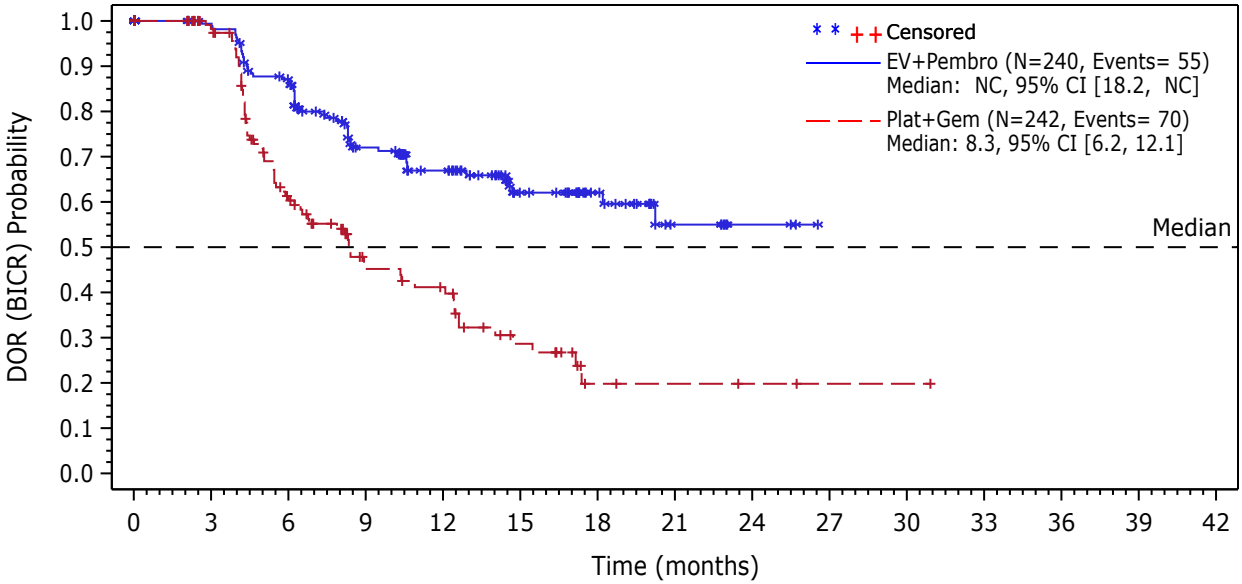


Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; OR=objective response; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Objective response was defined as complete or partial response that was subsequently confirmed.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.1: Kaplan-Meier Plot of Duration of Response (BICR) - Analysis Set mITT 1



at Risk

1	240	163	138	95	72	43	26	9	3	0	0	0	0	0	0
2	242	112	62	35	29	15	4	3	2	1	1	0	0	0	0

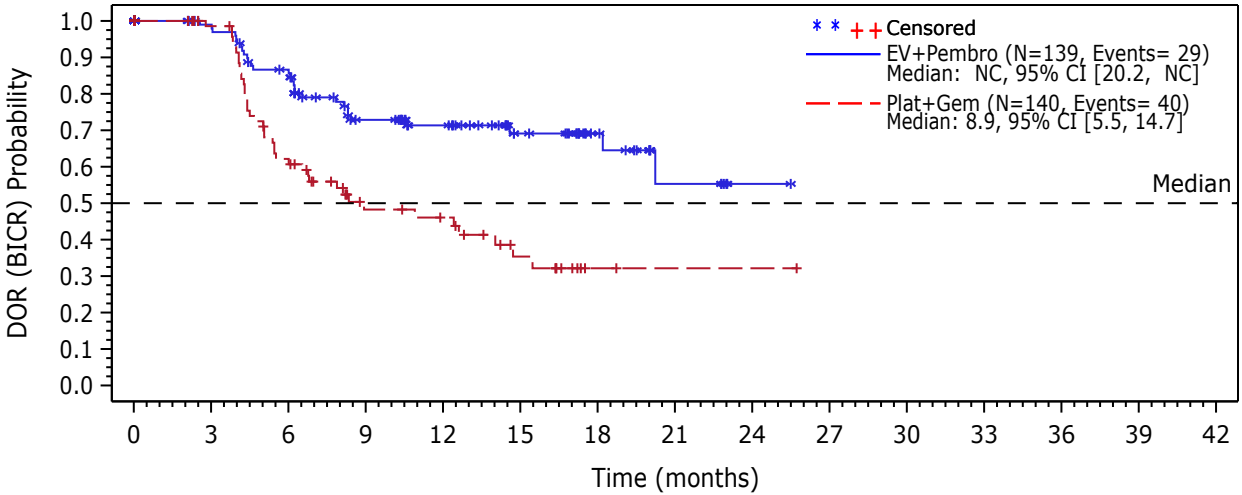
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.1.1: Kaplan-Meier Plot of Duration of Response (BICR) by PD-L1 Expression - Analysis Set mITT 1

PD-L1 Expression: High (CPS>=10)



at Risk

1	139	97	82	56	45	29	16	6	1	0	0	0	0	0	0
2	140	69	42	23	20	11	2	1	1	0	0	0	0	0	0

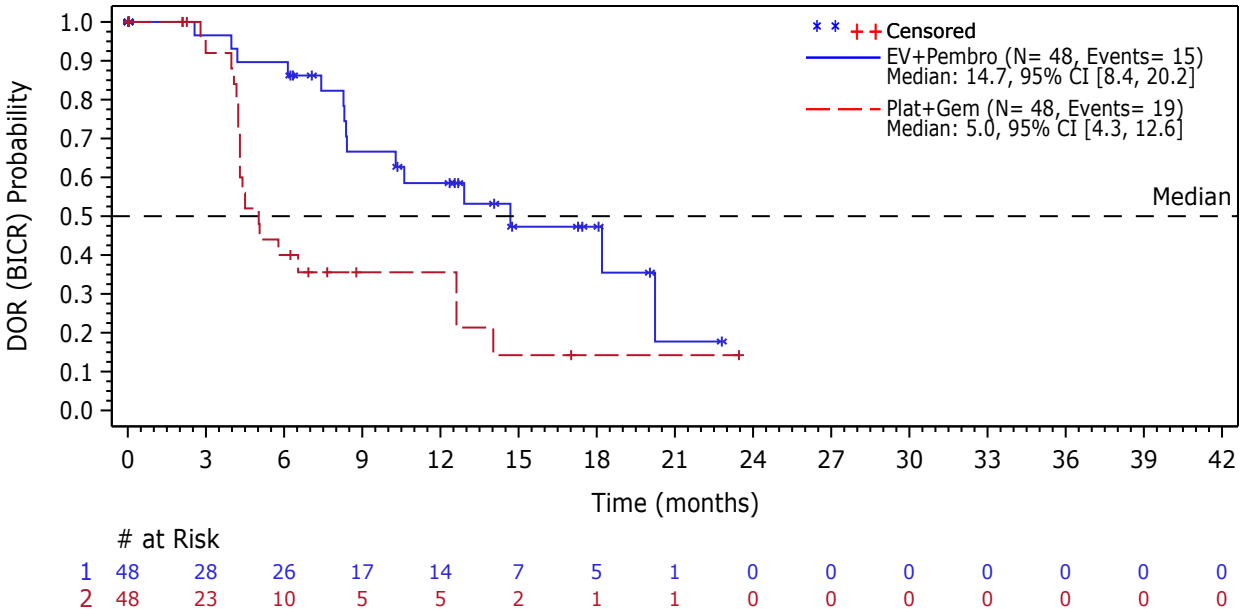
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.1.2: Kaplan-Meier Plot of Duration of Response (BICR) by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Present

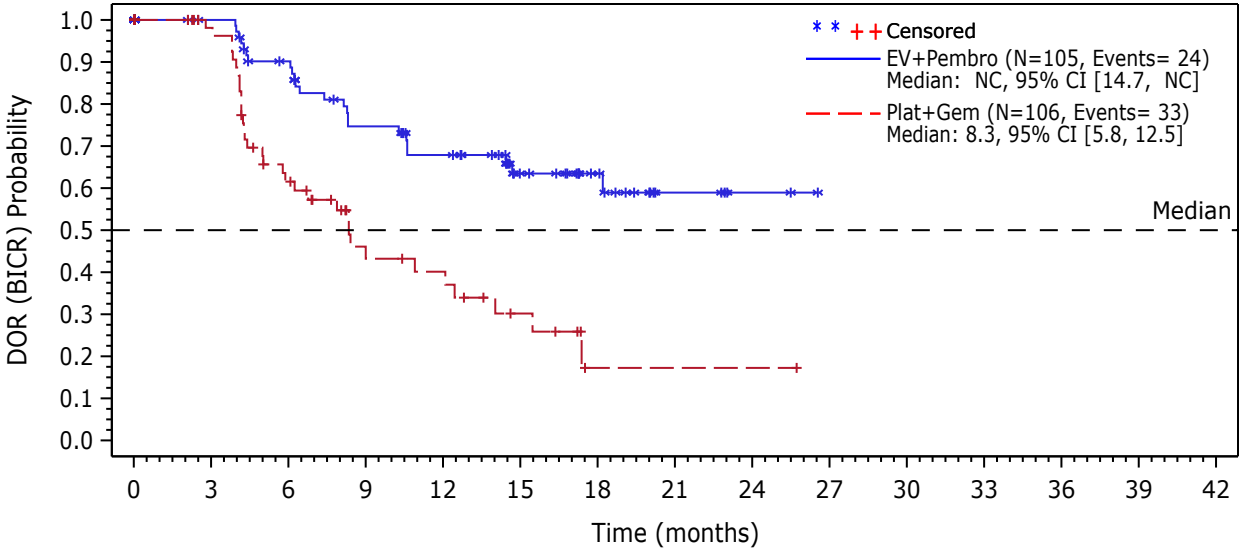


Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.1.3: Kaplan-Meier Plot of Duration of Response (BICR) by Age - Analysis Set mITT 1
Age: < 65 years



at Risk

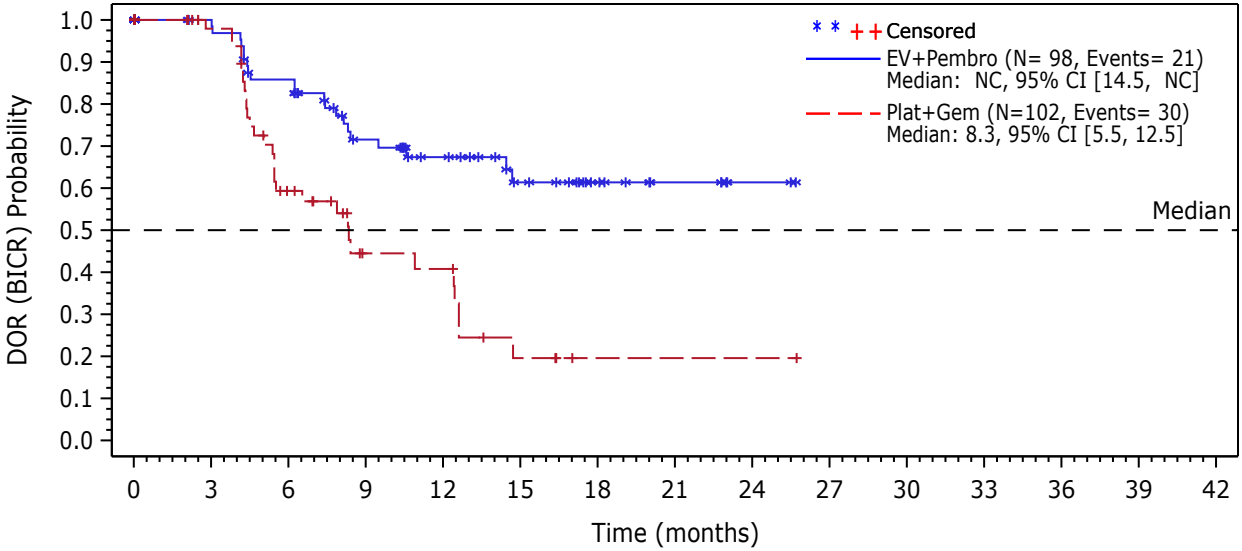
1	105	72	61	47	39	24	15	5	2	0	0	0	0	0	0
2	106	52	30	16	13	7	1	1	1	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.1.4: Kaplan-Meier Plot of Duration of Response (BICR) by Region - Analysis Set mITT 1 Region: Europe



at Risk

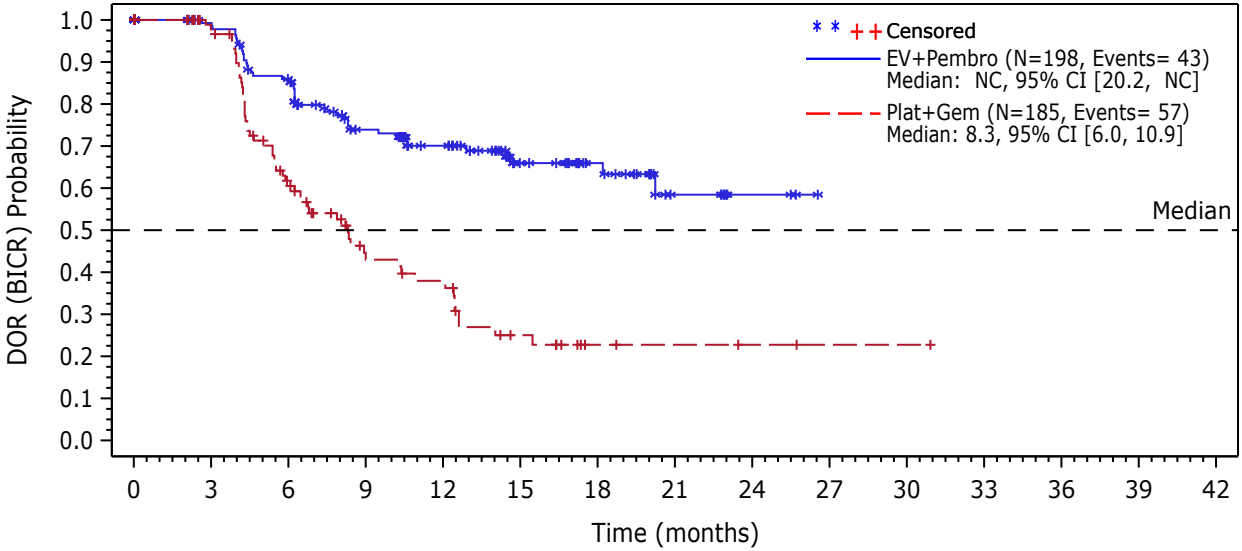
1	98	64	53	37	28	19	11	6	2	0	0	0	0	0	0
2	102	47	25	12	11	4	1	1	1	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.1.5: Kaplan-Meier Plot of Duration of Response (BICR) by Sex - Analysis Set mITT 1 Sex: Male



at Risk

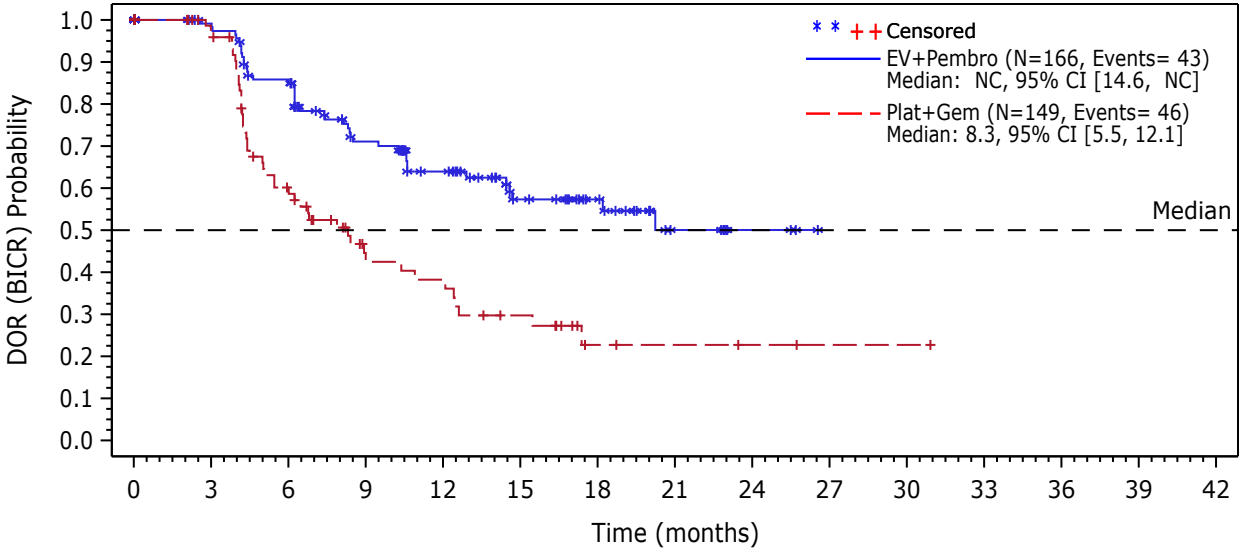
1	198	135	114	84	65	39	25	9	3	0	0	0	0	0	0
2	185	87	50	27	22	11	4	3	2	1	1	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.1.6: Kaplan-Meier Plot of Duration of Response (BICR) by Race - Analysis Set mITT 1 Race: White



at Risk

1	166	113	95	67	49	31	22	9	3	0	0	0	0	0	0
2	149	71	40	21	18	12	4	3	2	1	1	0	0	0	0

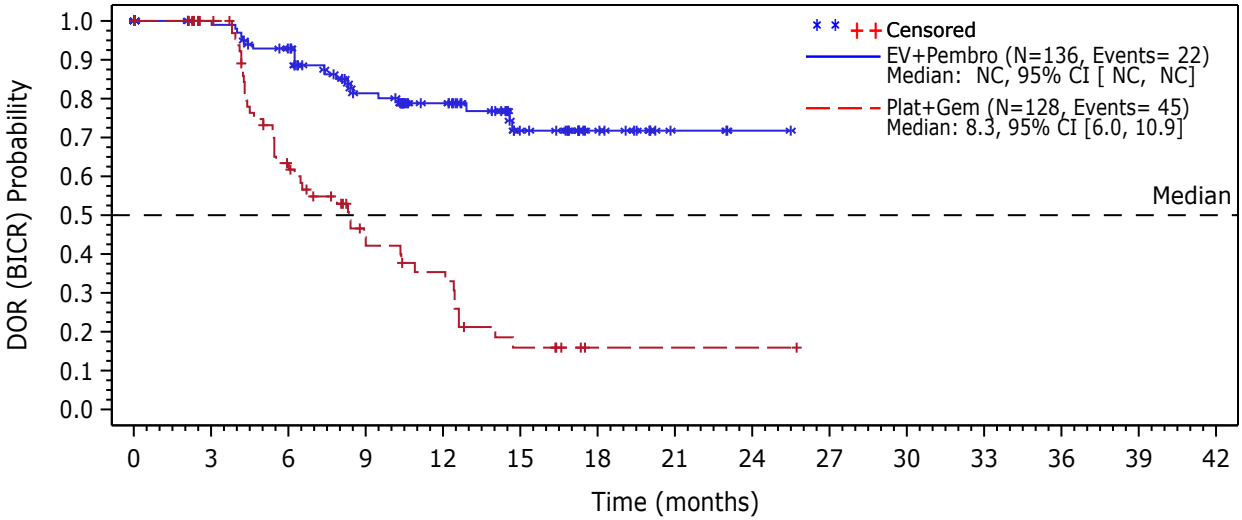
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.1.7: Kaplan-Meier Plot of Duration of Response (BICR) by ECOG Status at Baseline - Analysis Set mITT 1

ECOG Status at Baseline: 0



at Risk

1	136	99	88	64	47	25	13	3	1	0	0	0	0	0	0
2	128	66	38	20	15	6	1	1	1	0	0	0	0	0	0

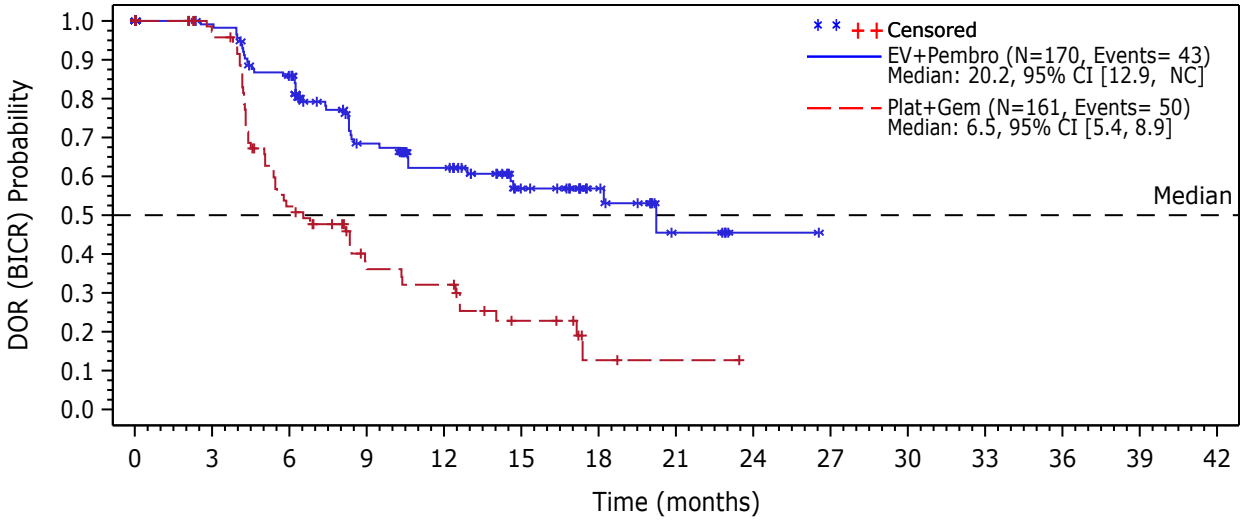
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.1.8: Kaplan-Meier Plot of Duration of Response (BICR) by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Visceral metastases



at Risk

1	170	113	95	62	46	27	16	5	1	0	0	0	0	0	0
2	161	69	35	19	16	8	2	1	0	0	0	0	0	0	0

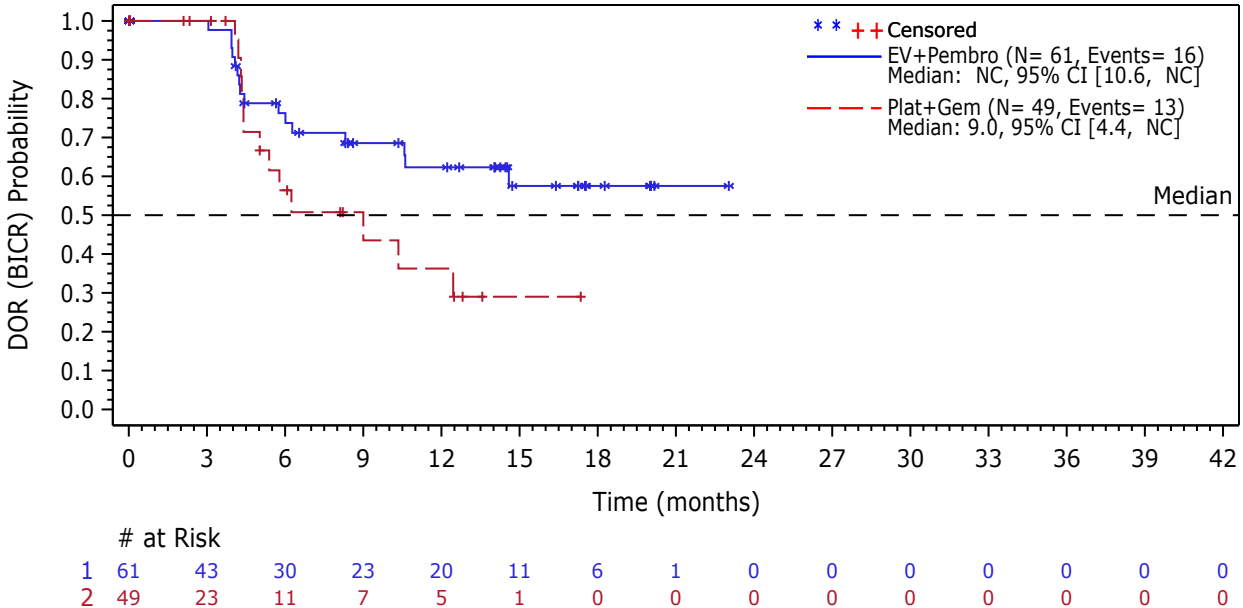
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.1.9: Kaplan-Meier Plot of Duration of Response (BICR) by Primary Disease Site of Origin - Analysis Set mITT 1

Primary Disease Site of Origin: Upper tract



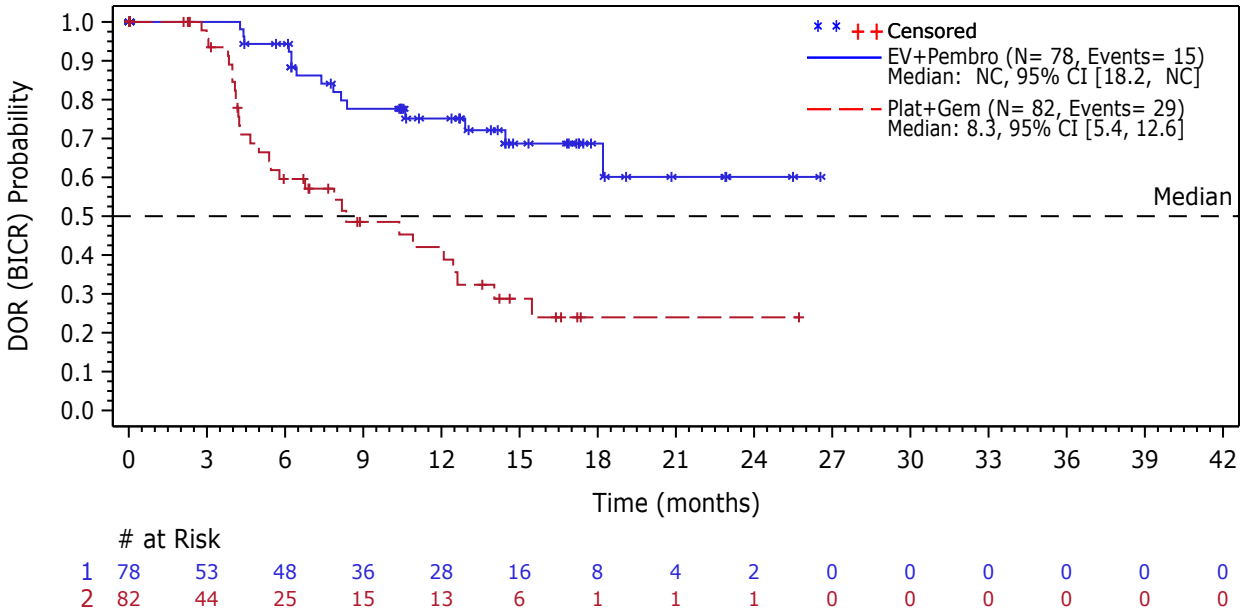
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.1.10: Kaplan-Meier Plot of Duration of Response (BICR) by Renal Function - Analysis Set mITT 1

Renal Function: Normal



at Risk

1	78	53	48	36	28	16	8	4	2	0	0	0	0	0	0
2	82	44	25	15	13	6	1	1	1	0	0	0	0	0	0

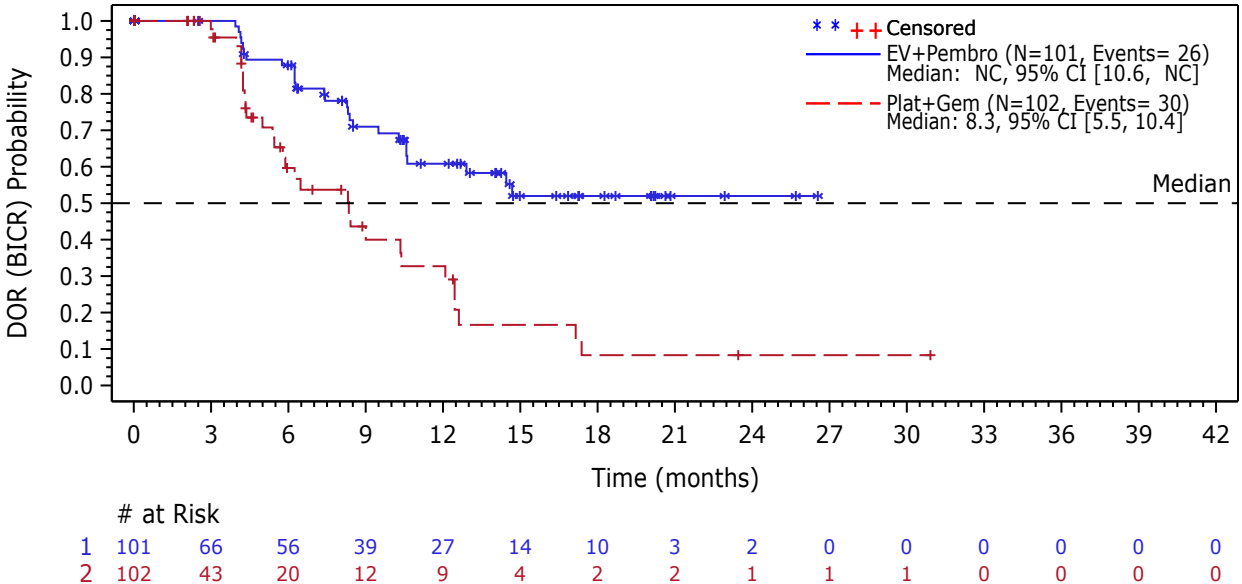
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.1.1: Kaplan-Meier Plot of Duration of Response (BICR) by PD-L1 Expression - Analysis Set mITT 1

PD-L1 Expression: Low (CPS<10)



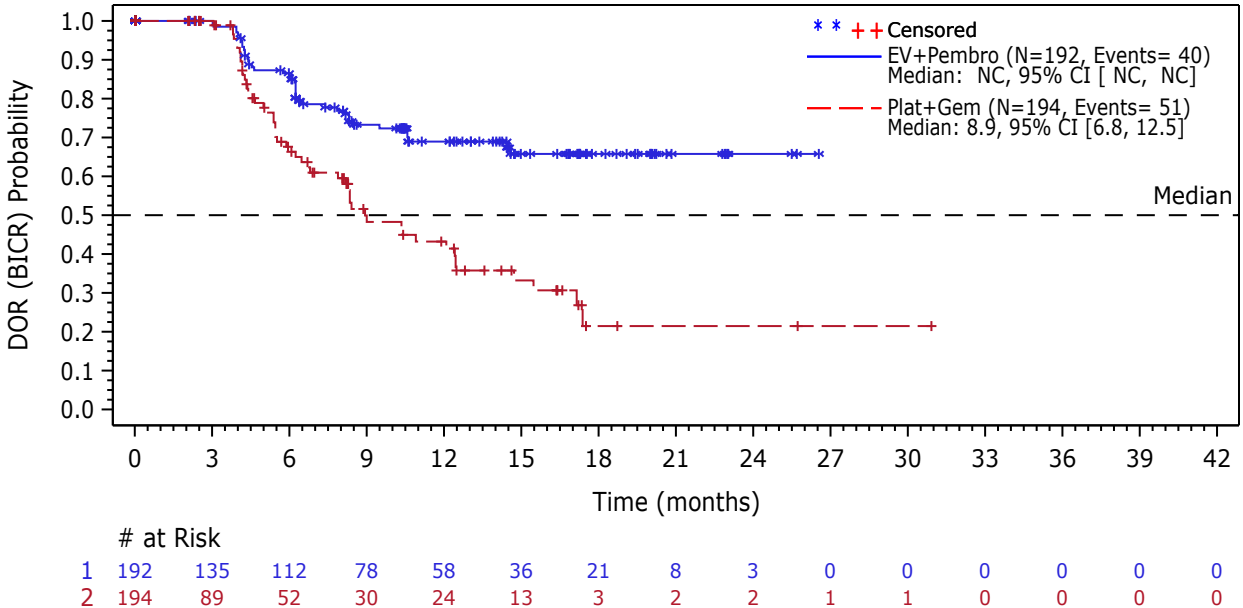
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.1.2: Kaplan-Meier Plot of Duration of Response (BICR) by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Absent



at Risk

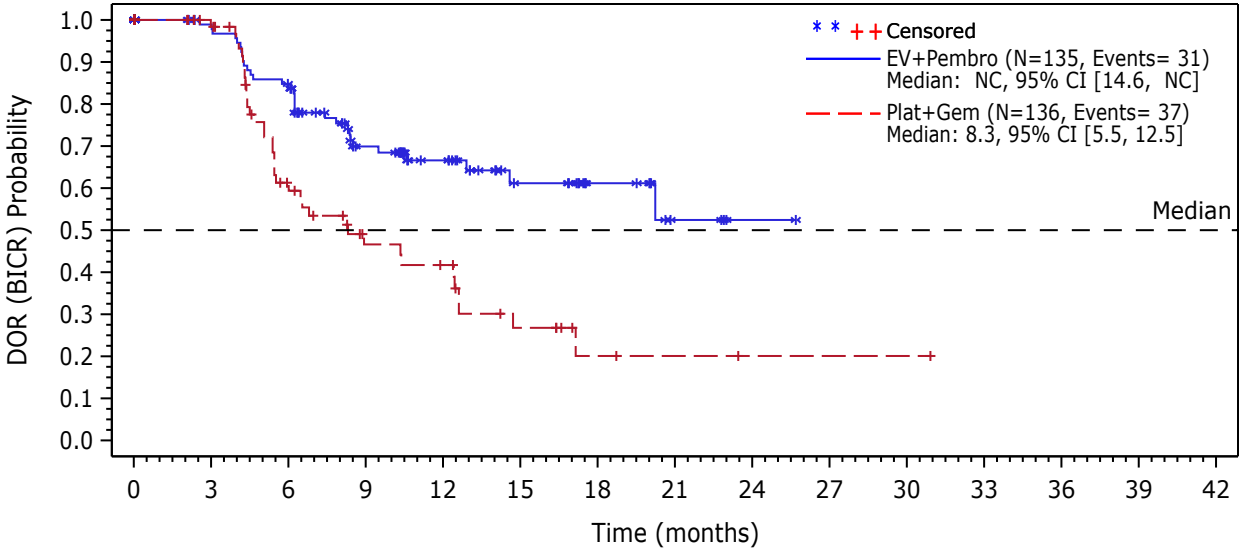
1	192	135	112	78	58	36	21	8	3	0	0	0	0	0	0
2	194	89	52	30	24	13	3	2	2	1	1	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.1.3: Kaplan-Meier Plot of Duration of Response (BICR) by Age - Analysis Set mITT 1
Age: >= 65 years



at Risk

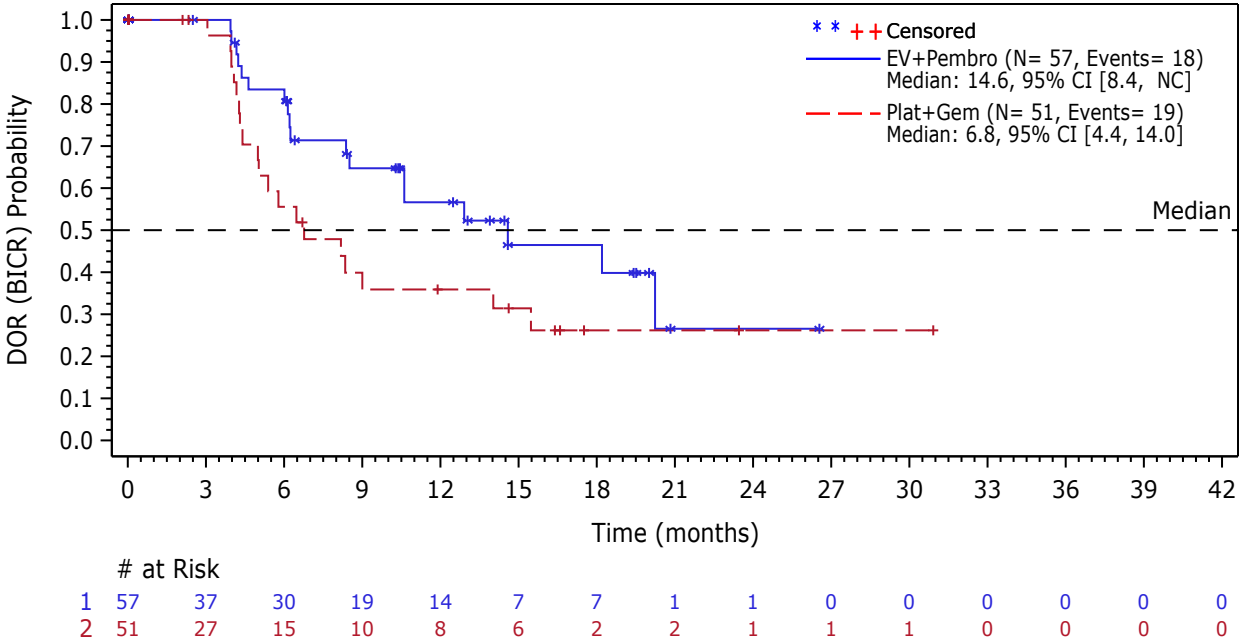
1	135	91	77	48	33	19	11	4	1	0	0	0	0	0	0
2	136	60	32	19	16	8	3	2	1	1	1	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.1.4: Kaplan-Meier Plot of Duration of Response (BICR) by Region - Analysis Set mITT 1 Region: North America

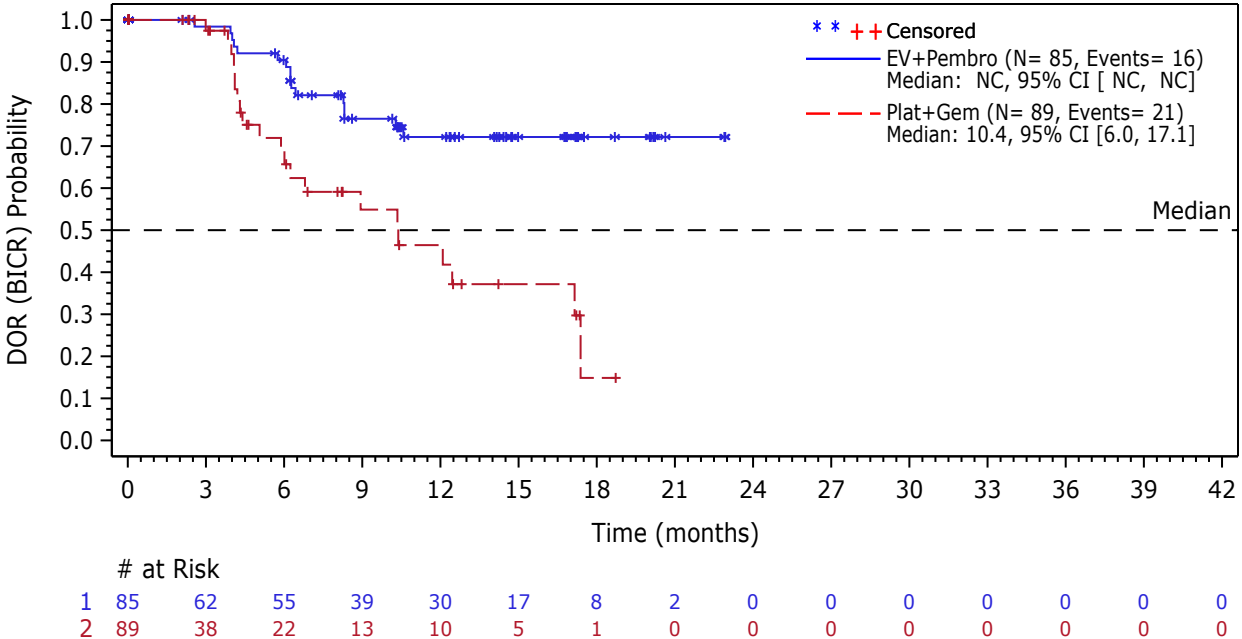


Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.1.4: Kaplan-Meier Plot of Duration of Response (BICR) by Region - Analysis Set mITT 1 Region: Rest of World



at Risk

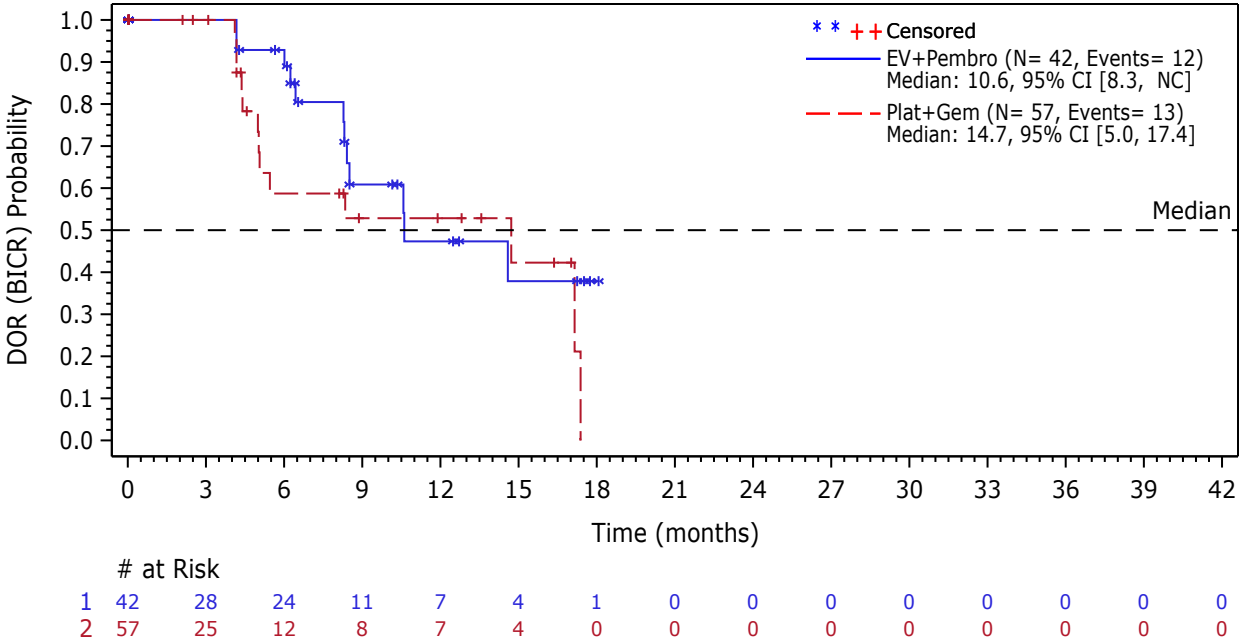
1	85	62	55	39	30	17	8	2	0	0	0	0	0	0	0
2	89	38	22	13	10	5	1	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.1.5: Kaplan-Meier Plot of Duration of Response (BICR) by Sex - Analysis Set mITT 1
Sex: Female



at Risk

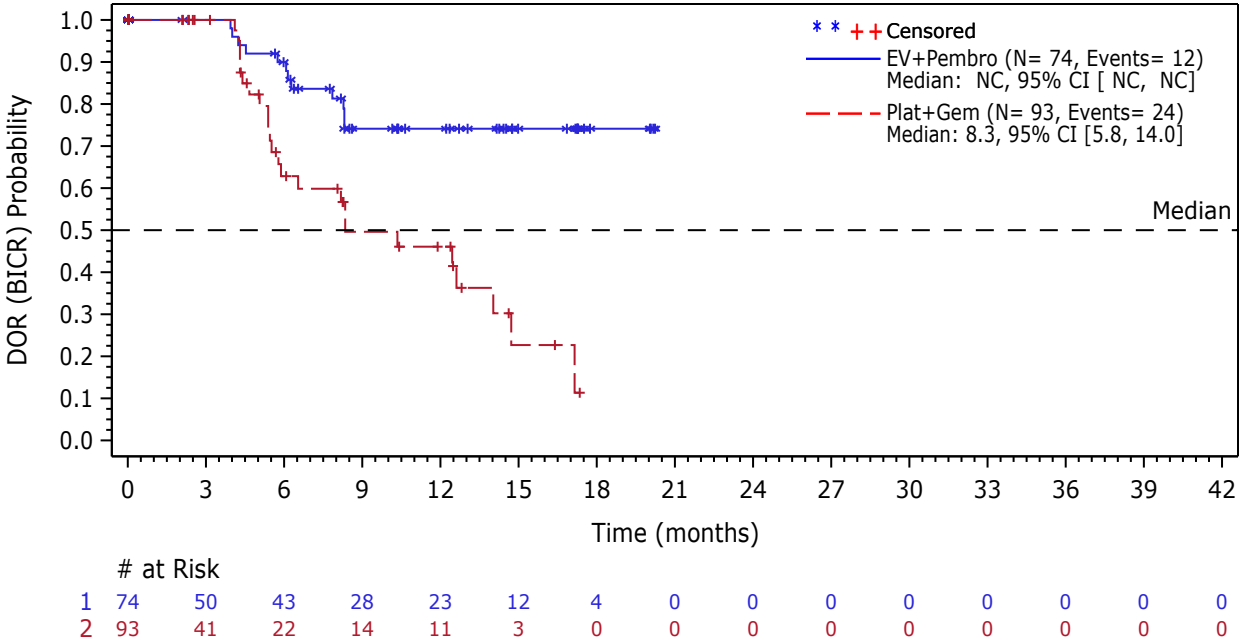
1	42	28	24	11	7	4	1	0	0	0	0	0	0	0	0
2	57	25	12	8	7	4	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.1.6: Kaplan-Meier Plot of Duration of Response (BICR) by Race - Analysis Set mITT 1 Race: Non-white



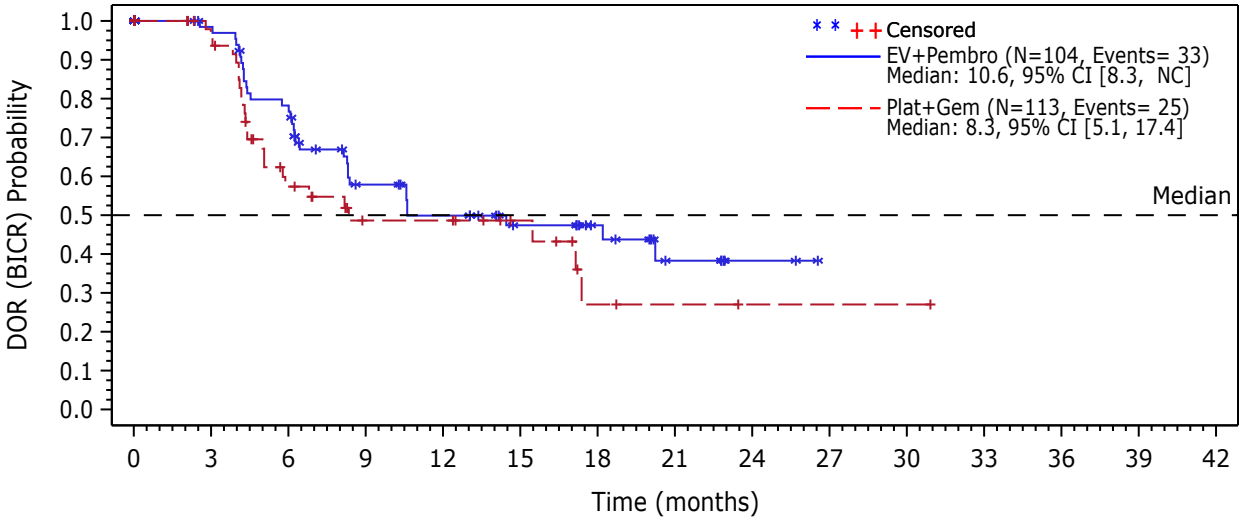
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.1.7: Kaplan-Meier Plot of Duration of Response (BICR) by ECOG Status at Baseline - Analysis Set mITT 1

ECOG Status at Baseline: 1-2



at Risk

1	104	64	50	31	25	18	13	6	2	0	0	0	0	0	0
2	113	45	23	14	14	9	3	2	1	1	1	0	0	0	0

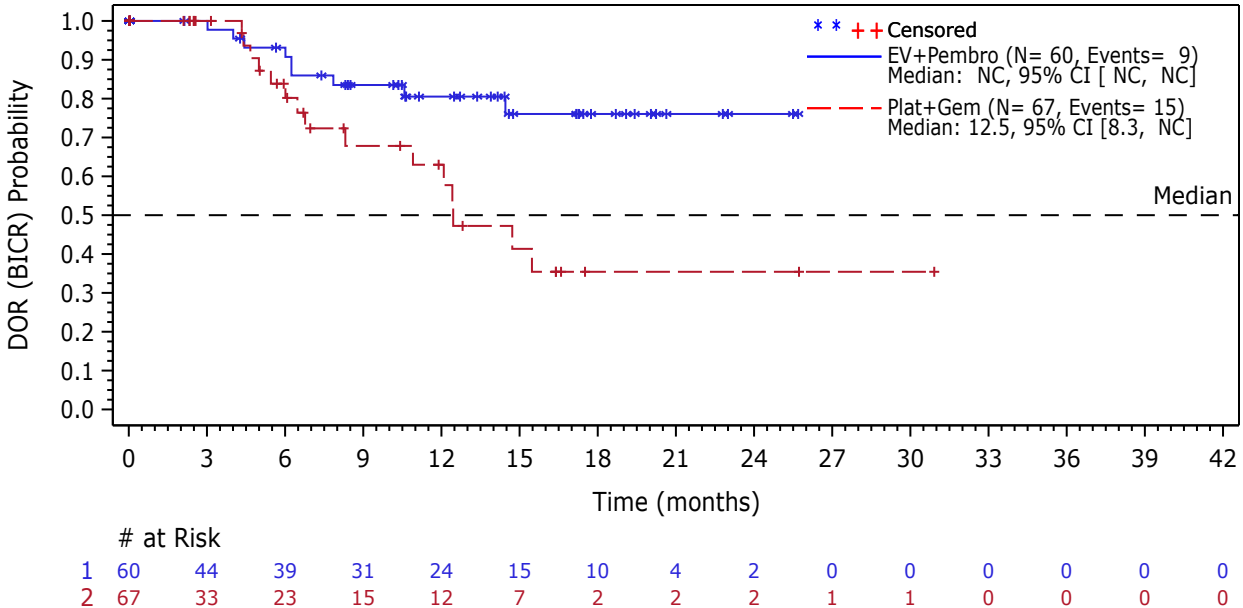
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.1.8: Kaplan-Meier Plot of Duration of Response (BICR) by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Lymph node only



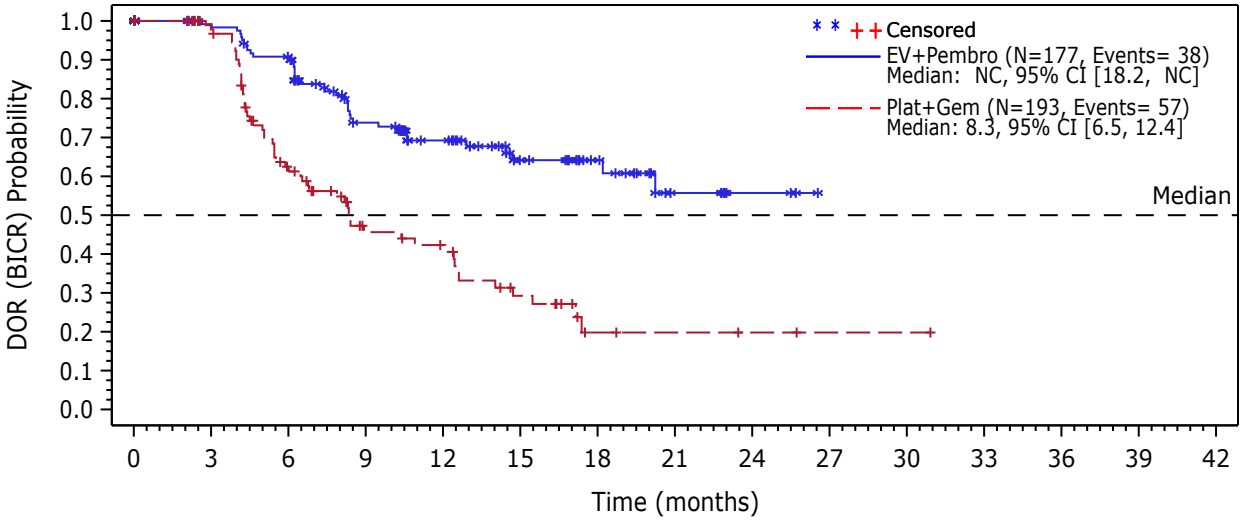
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.1.9: Kaplan-Meier Plot of Duration of Response (BICR) by Primary Disease Site of Origin - Analysis Set mITT 1

Primary Disease Site of Origin: Lower tract



at Risk

1	177	119	107	72	52	32	20	8	3	0	0	0	0	0	0
2	193	89	51	28	24	14	4	3	2	1	1	0	0	0	0

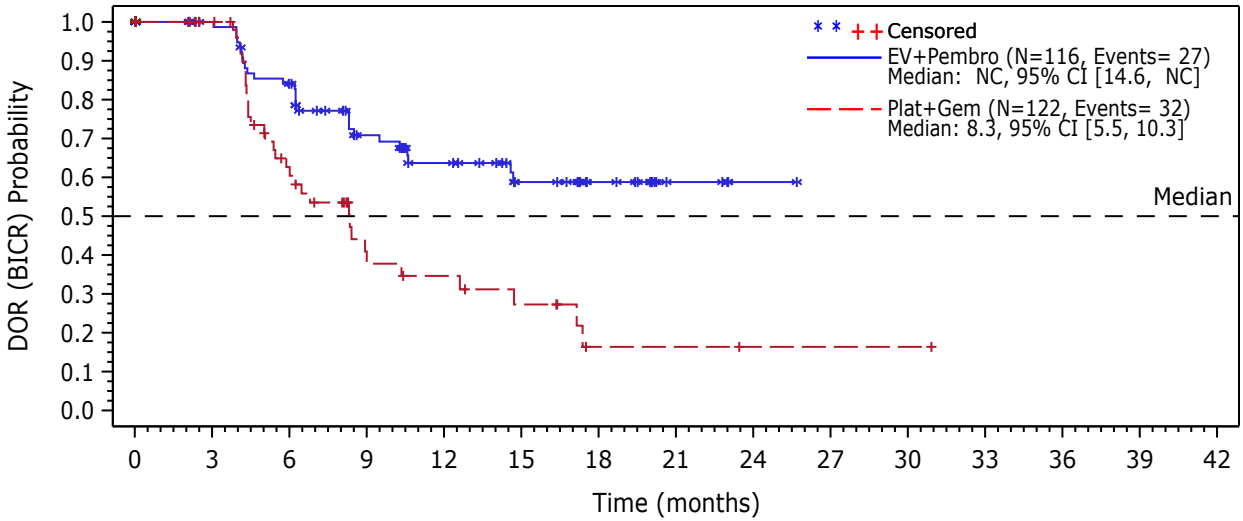
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.1.10: Kaplan-Meier Plot of Duration of Response (BICR) by Renal Function - Analysis Set mITT 1

Renal Function: Mild



at Risk

1	116	76	62	43	32	22	14	4	1	0	0	0	0	0	0
2	122	51	28	13	10	7	2	2	1	1	1	0	0	0	0

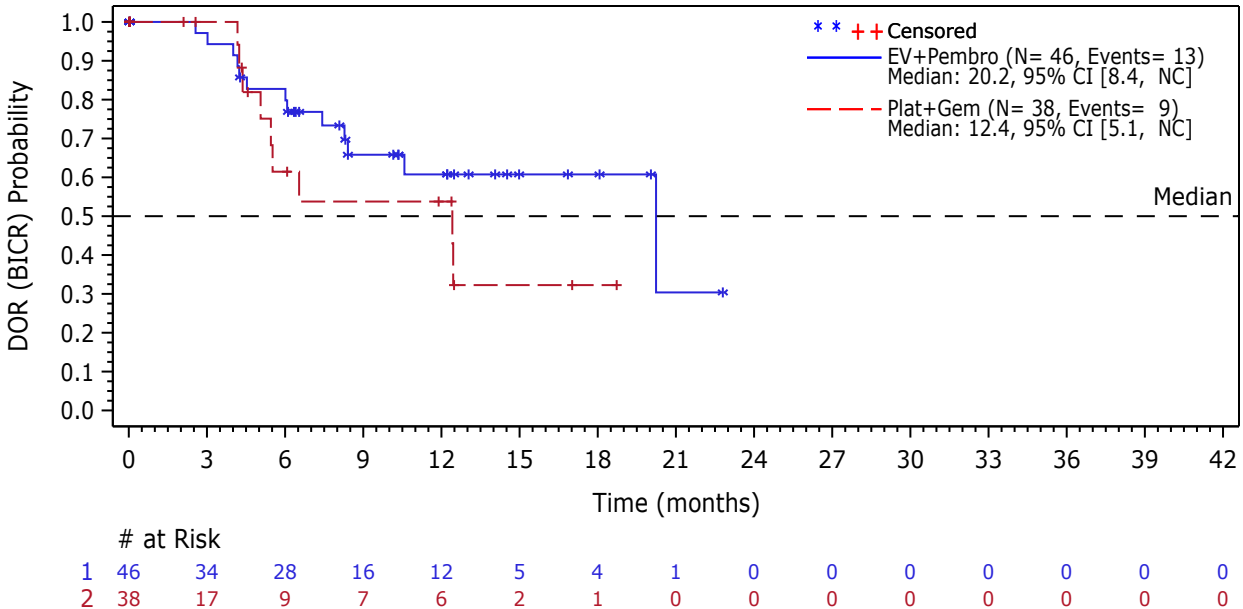
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.1.10: Kaplan-Meier Plot of Duration of Response (BICR) by Renal Function - Analysis Set mITT 1

Renal Function: Moderate

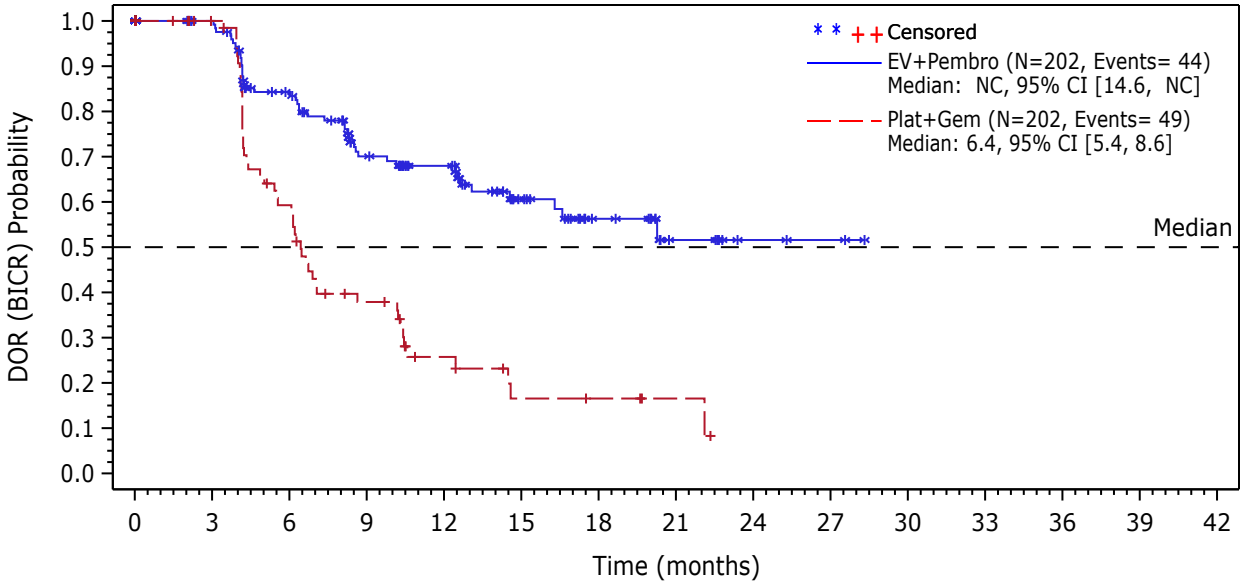


Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.2: Kaplan-Meier Plot of Duration of Response (BICR) - Analysis Set mITT 2



at Risk

1	202	123	95	68	53	31	18	8	3	2	0	0	0	0	0
2	202	65	37	21	10	5	4	2	0	0	0	0	0	0	0

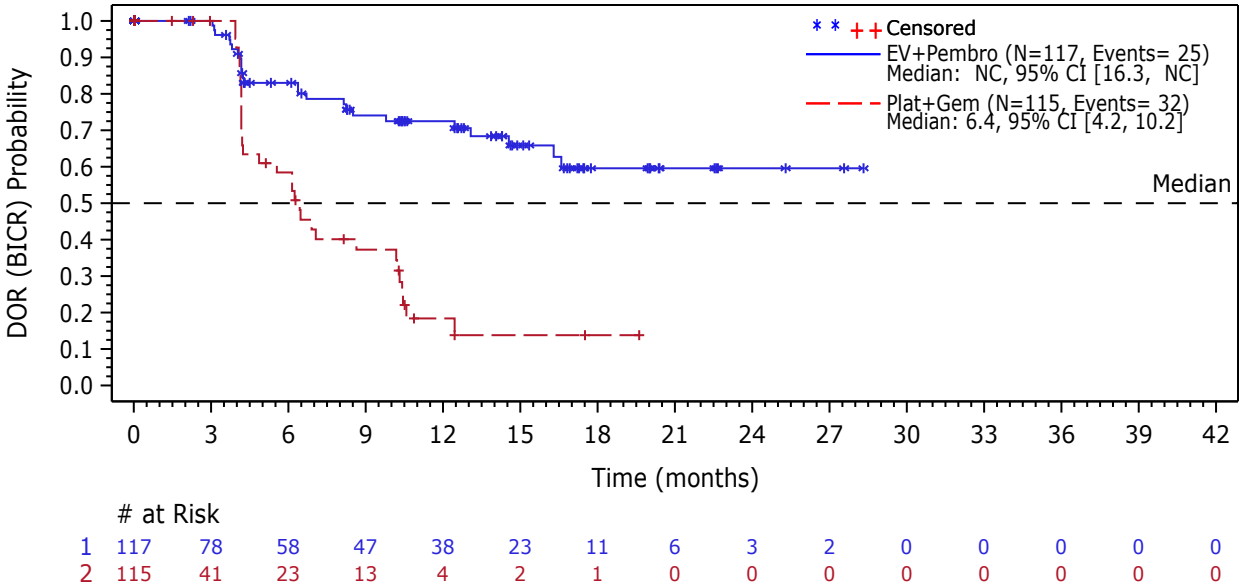
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.2.1: Kaplan-Meier Plot of Duration of Response (BICR) by PD-L1 Expression - Analysis Set mITT 2

PD-L1 Expression: High (CPS>=10)



at Risk

1	117	78	58	47	38	23	11	6	3	2	0	0	0	0	0
2	115	41	23	13	4	2	1	0	0	0	0	0	0	0	0

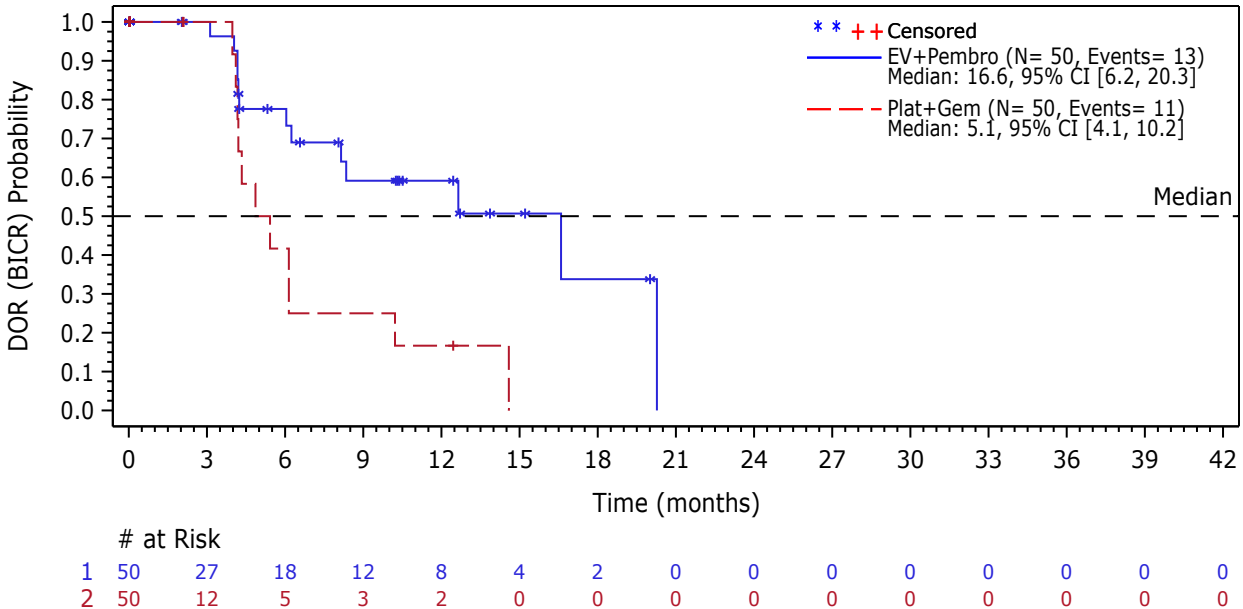
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.2.2: Kaplan-Meier Plot of Duration of Response (BICR) by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Present

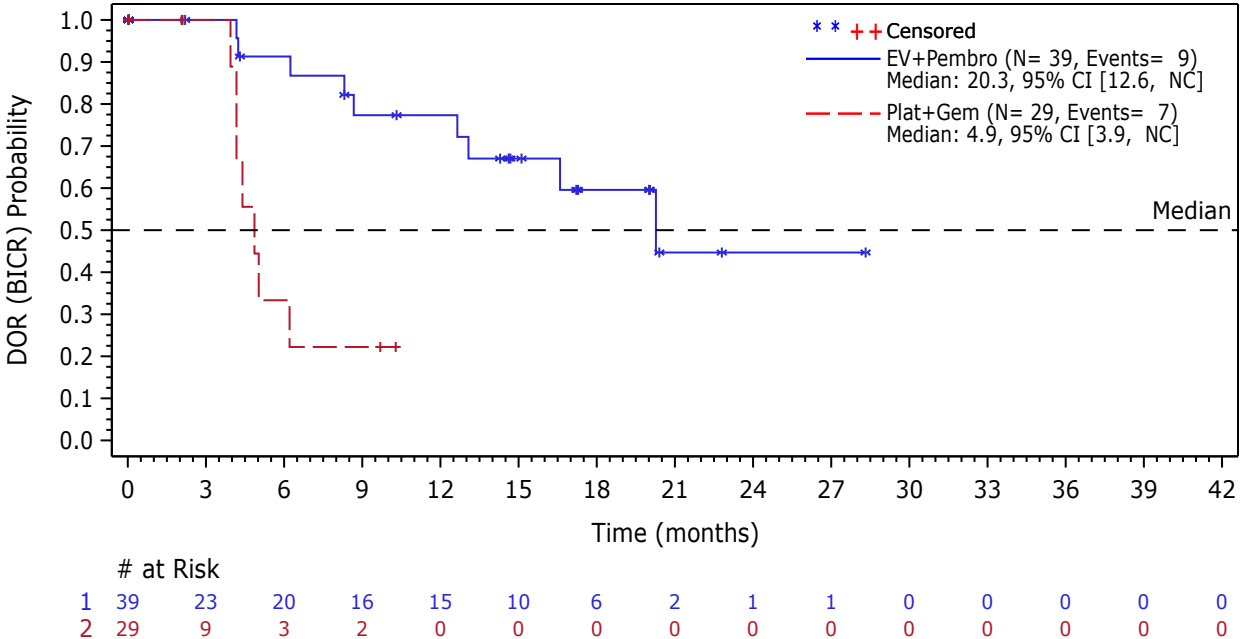


Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.2.3: Kaplan-Meier Plot of Duration of Response (BICR) by Age - Analysis Set mITT 2
Age: < 65 years



at Risk

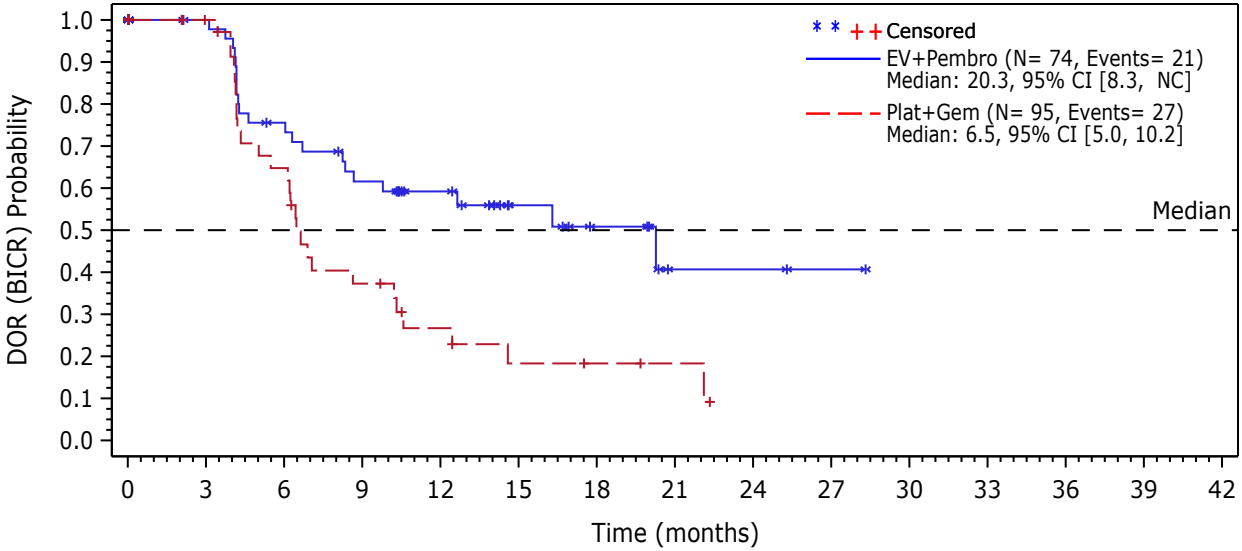
1	39	23	20	16	15	10	6	2	1	1	0	0	0	0	0
2	29	9	3	2	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.2.4: Kaplan-Meier Plot of Duration of Response (BICR) by Region - Analysis Set mITT 2 Region: Europe



at Risk

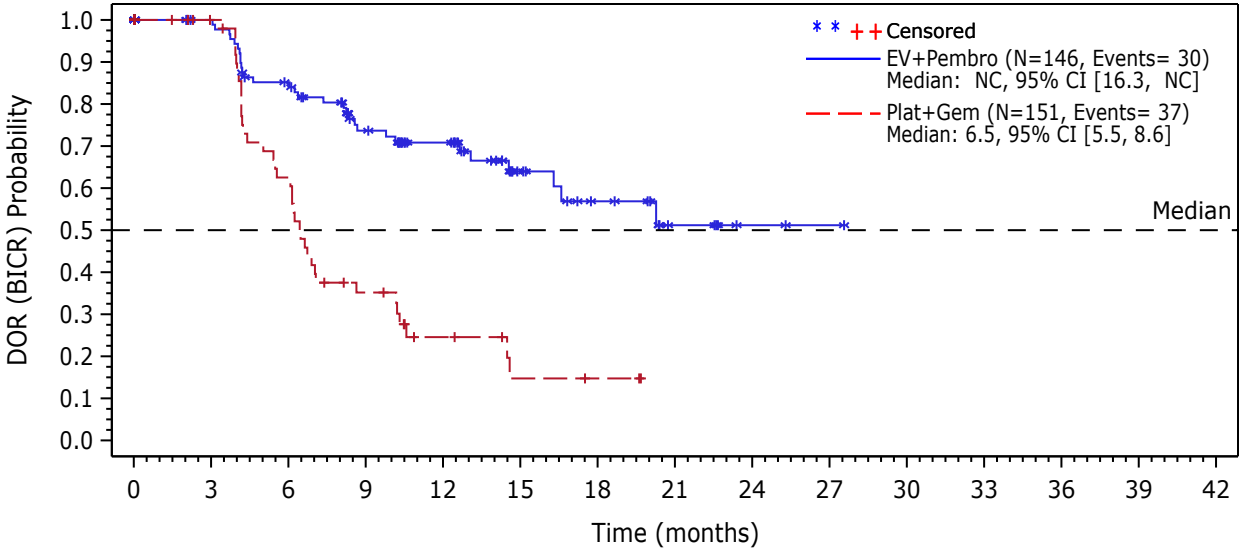
1	74	45	33	26	19	11	7	2	2	1	0	0	0	0	0
2	95	35	22	12	7	4	3	2	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.2.5: Kaplan-Meier Plot of Duration of Response (BICR) by Sex - Analysis Set mITT 2
Sex: Male



at Risk

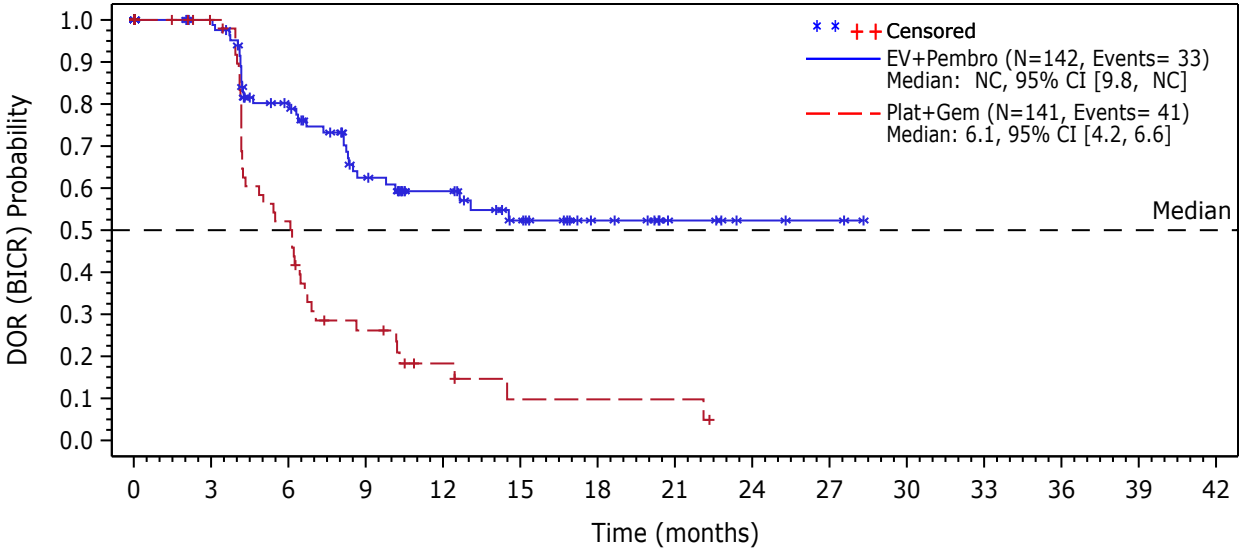
1	146	88	72	53	40	20	13	6	2	1	0	0	0	0	0
2	151	49	30	15	7	3	2	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.2.6: Kaplan-Meier Plot of Duration of Response (BICR) by Race - Analysis Set mITT 2 Race: White



at Risk

1	142	83	59	40	29	20	12	6	3	2	0	0	0	0	0
2	141	49	25	11	5	2	2	2	0	0	0	0	0	0	0

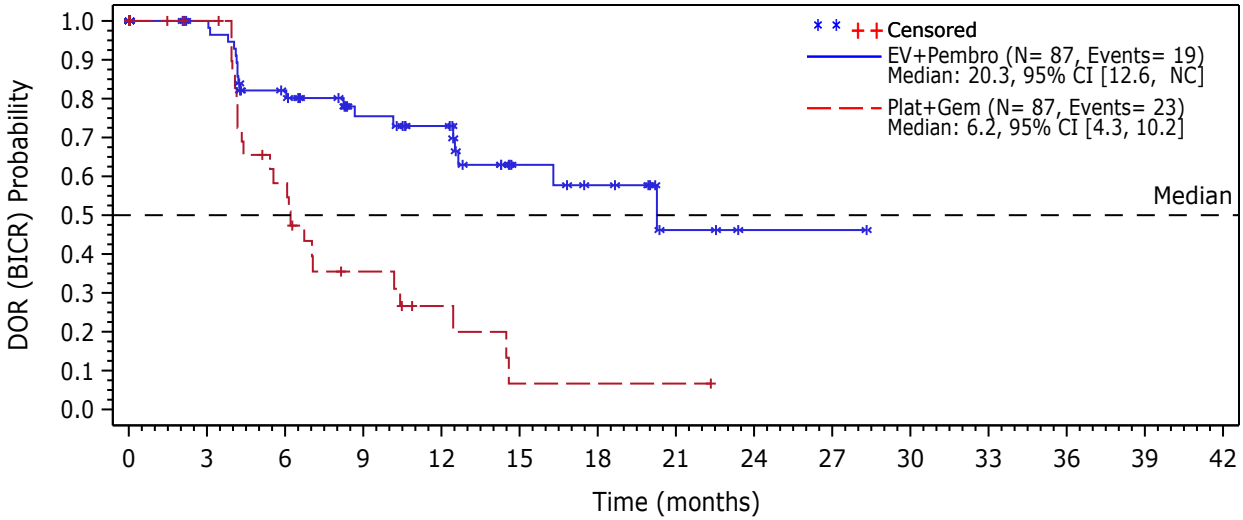
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.2.7: Kaplan-Meier Plot of Duration of Response (BICR) by ECOG Status at Baseline - Analysis Set mITT 2

ECOG Status at Baseline: 0



at Risk

1	87	56	42	30	25	12	9	3	1	1	0	0	0	0	0
2	87	30	16	8	4	1	1	1	0	0	0	0	0	0	0

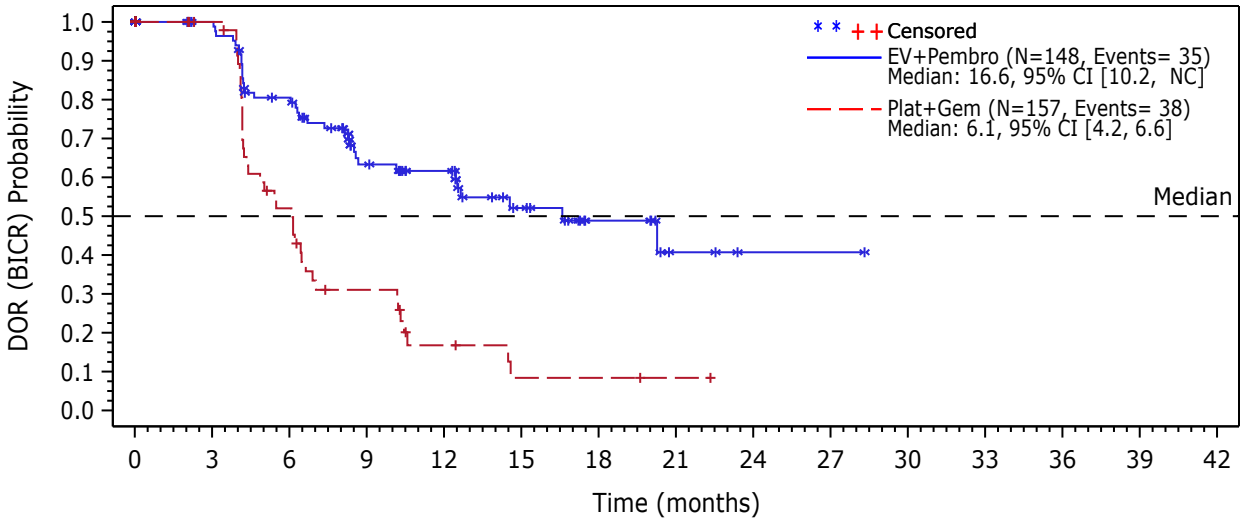
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.2.8: Kaplan-Meier Plot of Duration of Response (BICR) by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Visceral metastases



at Risk

1	148	83	63	39	31	18	9	3	1	1	0	0	0	0	0
2	157	47	23	12	5	2	2	1	0	0	0	0	0	0	0

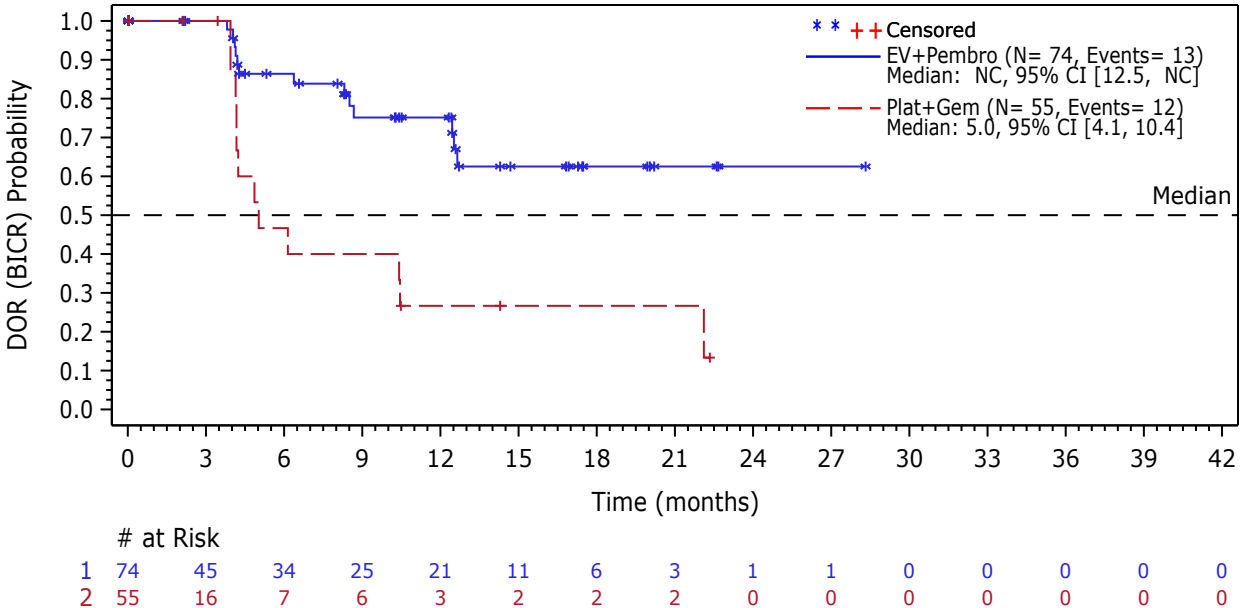
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.2.9: Kaplan-Meier Plot of Duration of Response (BICR) by Primary Disease Site of Origin - Analysis Set mITT 2

Primary Disease Site of Origin: Upper tract



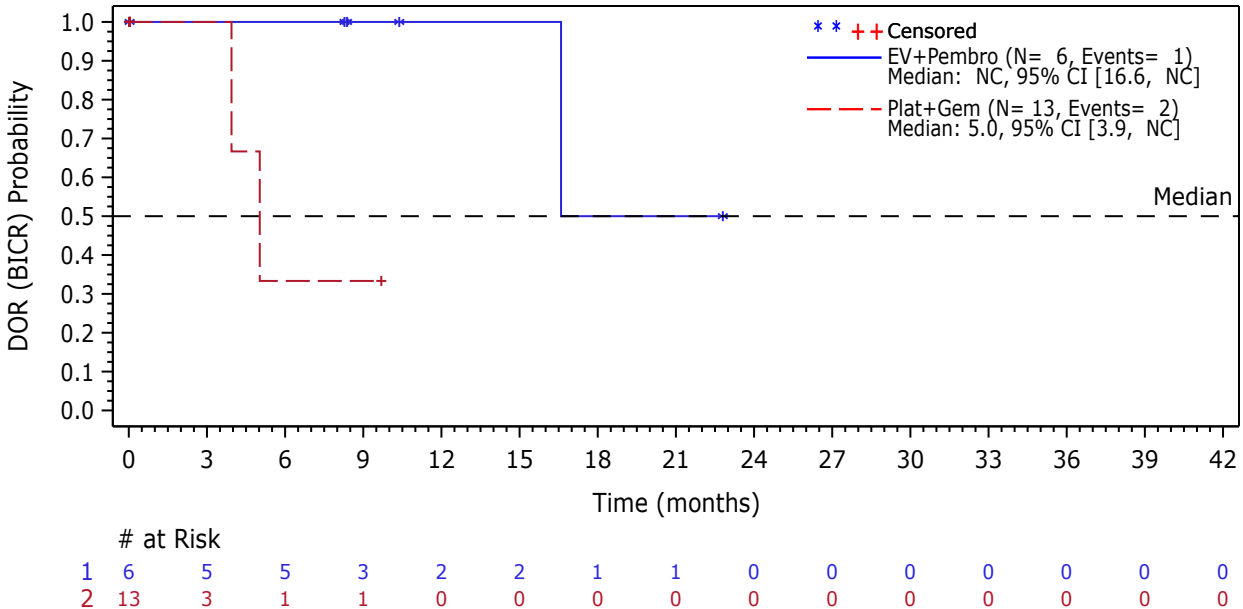
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.2.10: Kaplan-Meier Plot of Duration of Response (BICR) by Renal Function - Analysis Set mITT 2

Renal Function: Normal



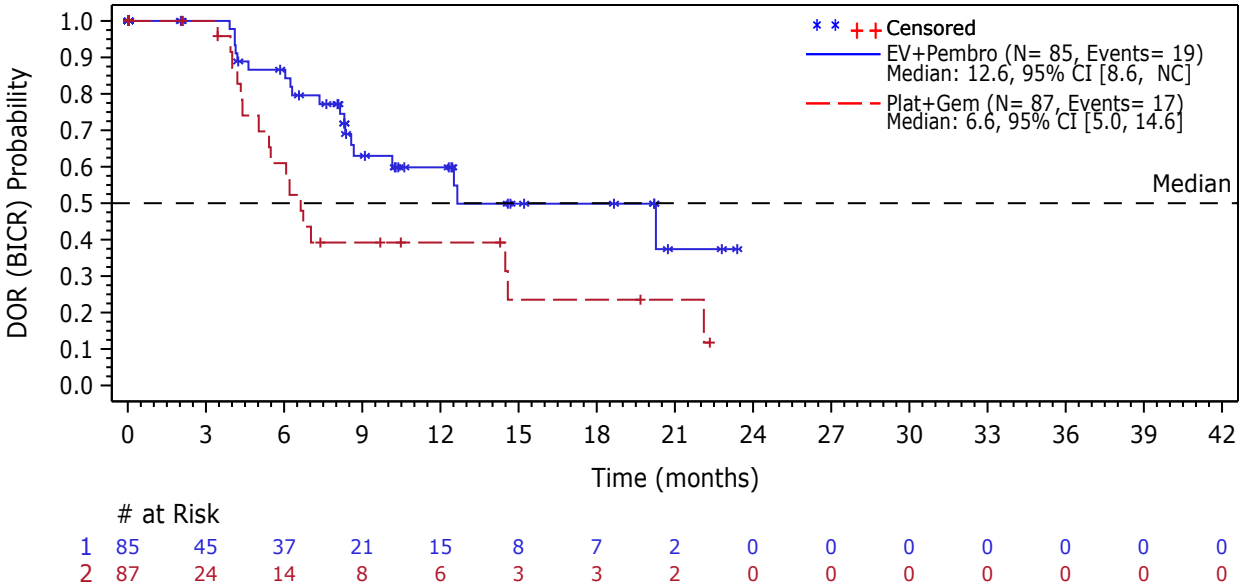
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.2.1: Kaplan-Meier Plot of Duration of Response (BICR) by PD-L1 Expression - Analysis Set mITT 2

PD-L1 Expression: Low (CPS<10)



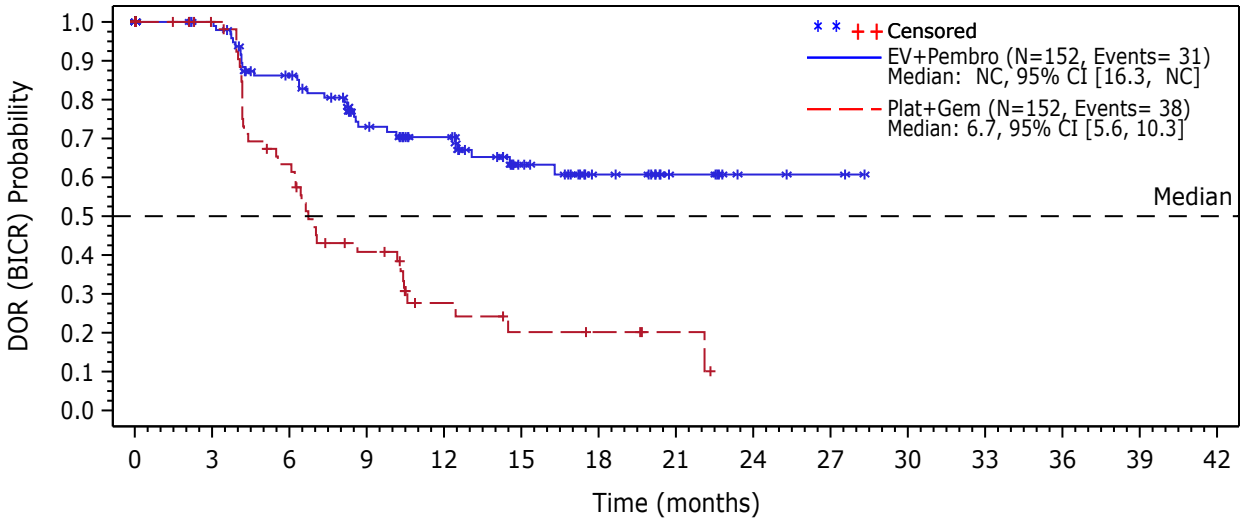
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.2.2: Kaplan-Meier Plot of Duration of Response (BICR) by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Absent



at Risk

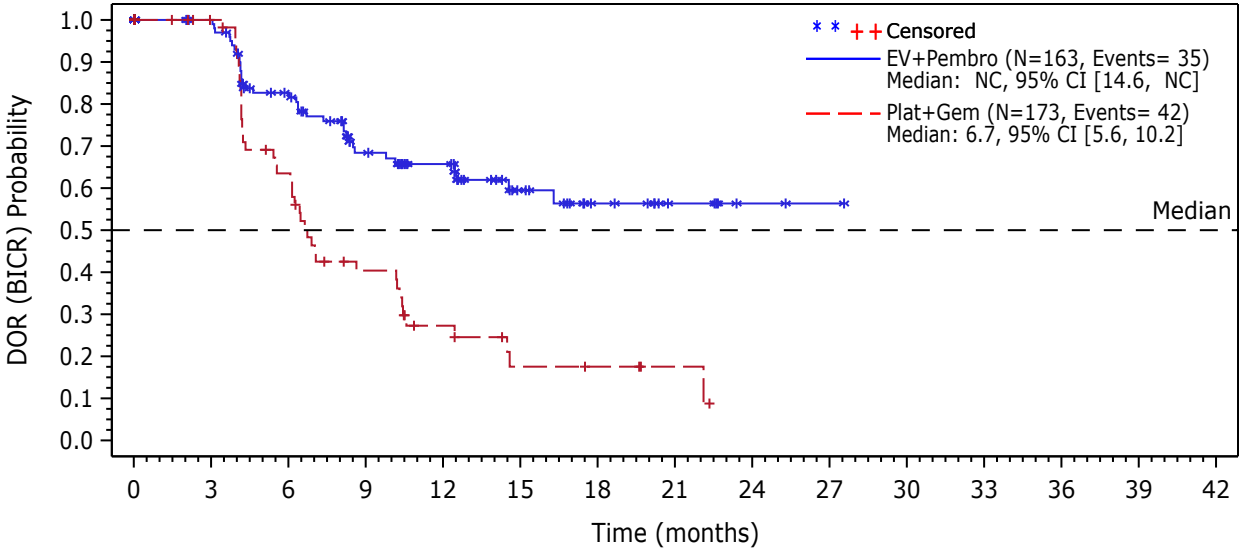
1	152	96	77	56	45	27	16	8	3	2	0	0	0	0	0
2	152	53	32	18	8	5	4	2	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.2.3: Kaplan-Meier Plot of Duration of Response (BICR) by Age - Analysis Set mITT 2
Age: >= 65 years



at Risk

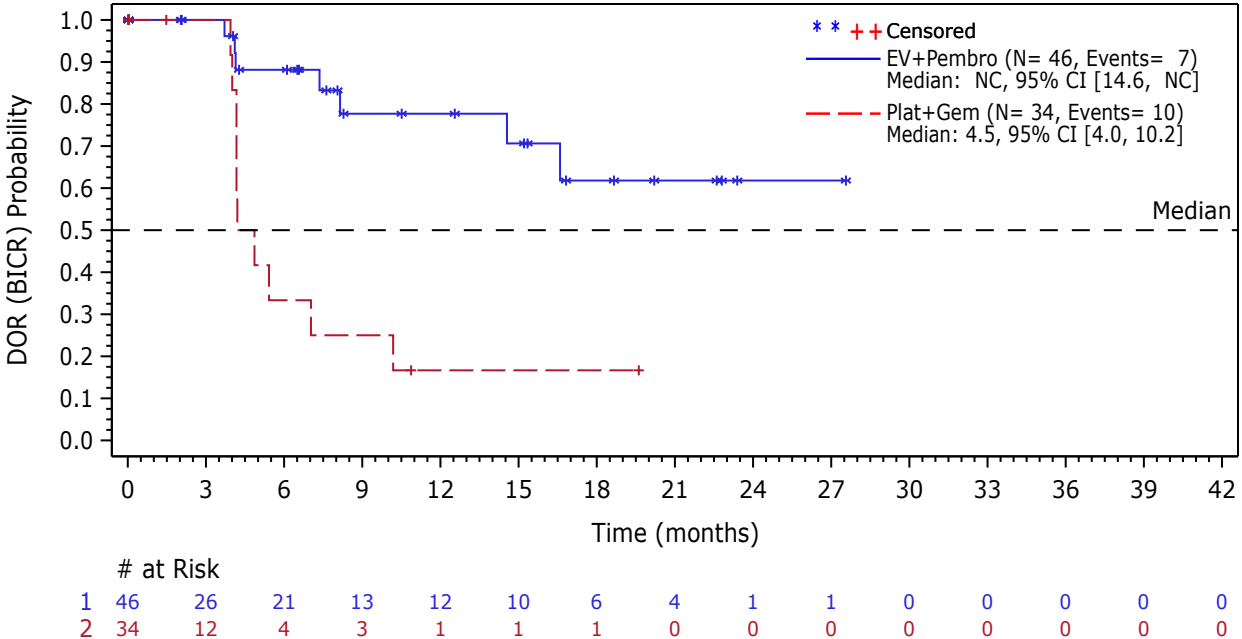
1	163	100	75	52	38	21	12	6	2	1	0	0	0	0	0
2	173	56	34	19	10	5	4	2	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.2.4: Kaplan-Meier Plot of Duration of Response (BICR) by Region - Analysis Set mITT 2 Region: North America

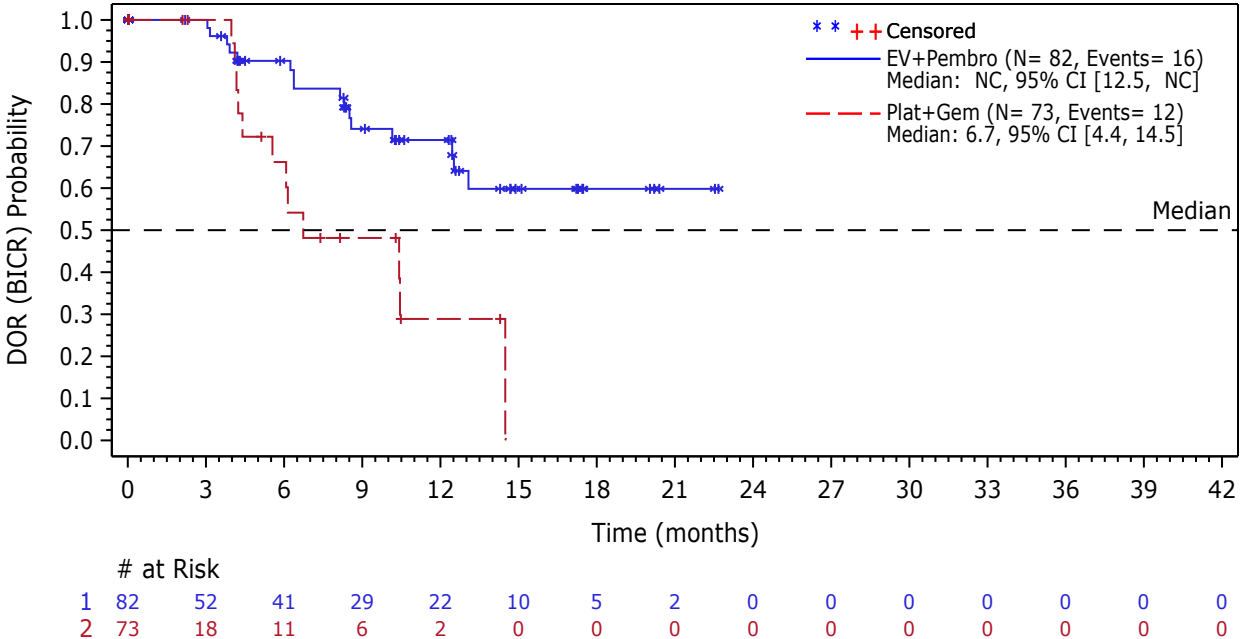


Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.2.4: Kaplan-Meier Plot of Duration of Response (BICR) by Region - Analysis Set mITT 2 Region: Rest of World

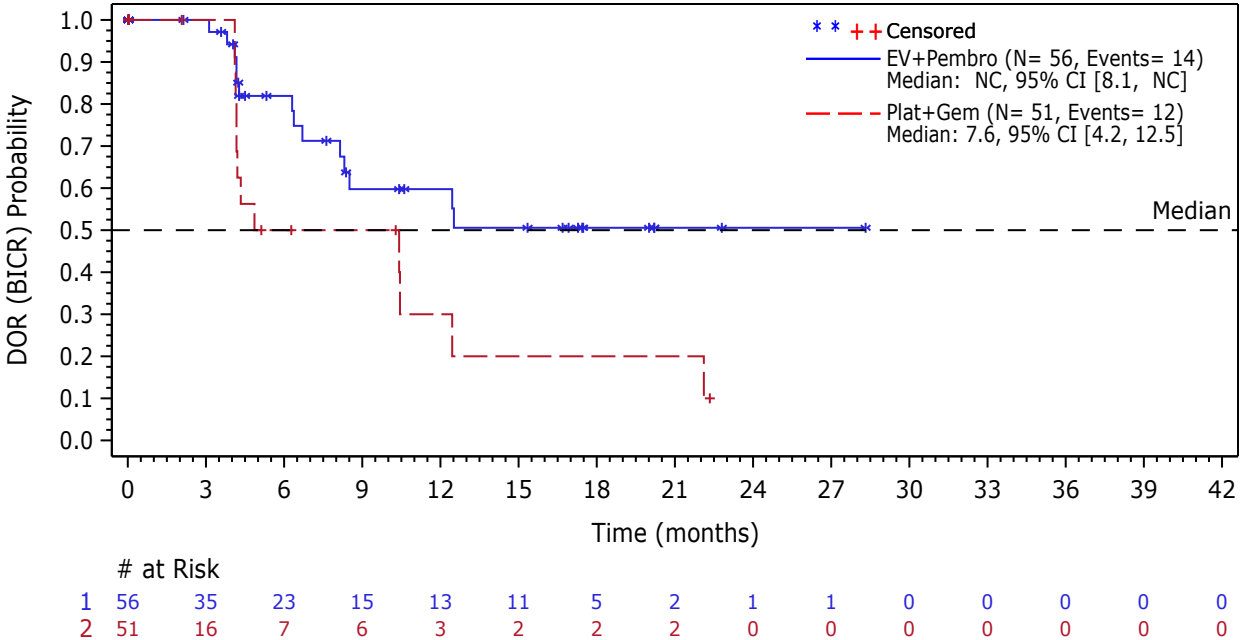


Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.2.5: Kaplan-Meier Plot of Duration of Response (BICR) by Sex - Analysis Set mITT 2
Sex: Female



at Risk

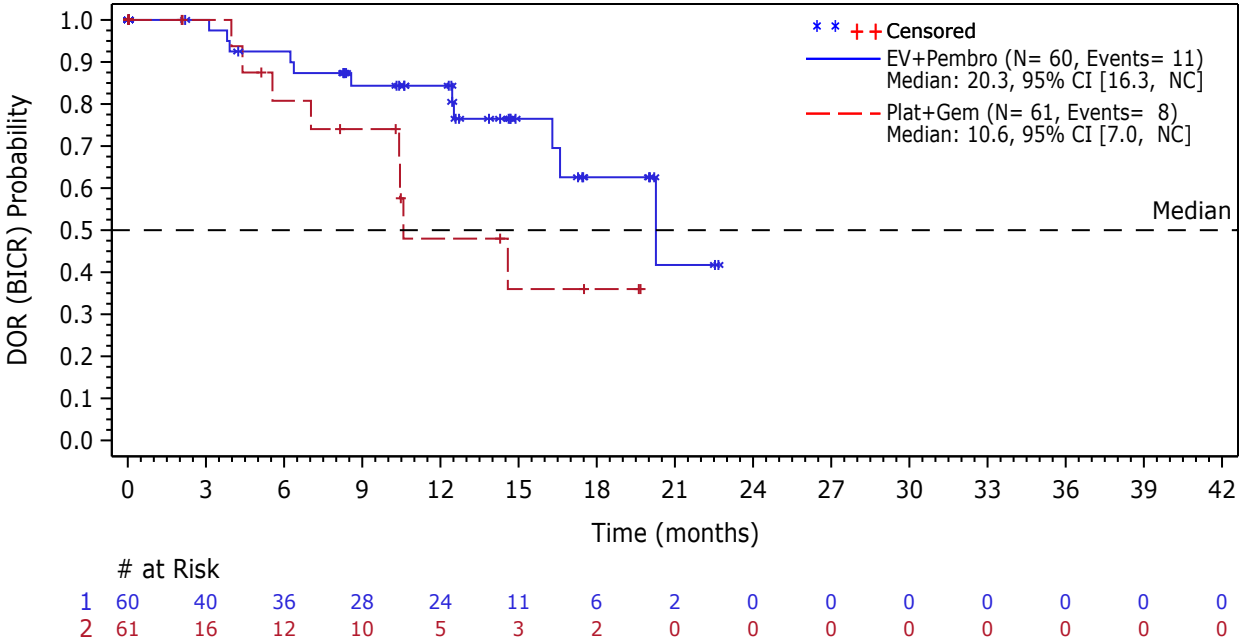
1	56	35	23	15	13	11	5	2	1	1	0	0	0	0	0
2	51	16	7	6	3	2	2	2	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.2.6: Kaplan-Meier Plot of Duration of Response (BICR) by Race - Analysis Set mITT 2 Race: Non-white



at Risk

1	60	40	36	28	24	11	6	2	0	0	0	0	0	0	0
2	61	16	12	10	5	3	2	0	0	0	0	0	0	0	0

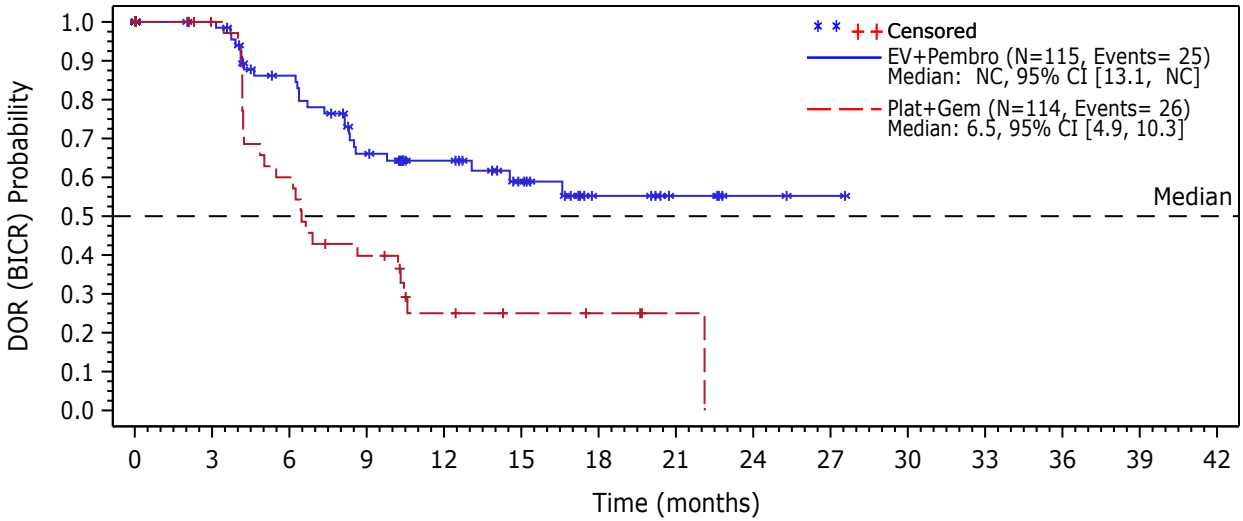
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.2.7: Kaplan-Meier Plot of Duration of Response (BICR) by ECOG Status at Baseline - Analysis Set mITT 2

ECOG Status at Baseline: 1-2



at Risk

1	115	67	53	38	28	19	9	5	2	1	0	0	0	0	0
2	114	35	21	13	6	4	3	1	0	0	0	0	0	0	0

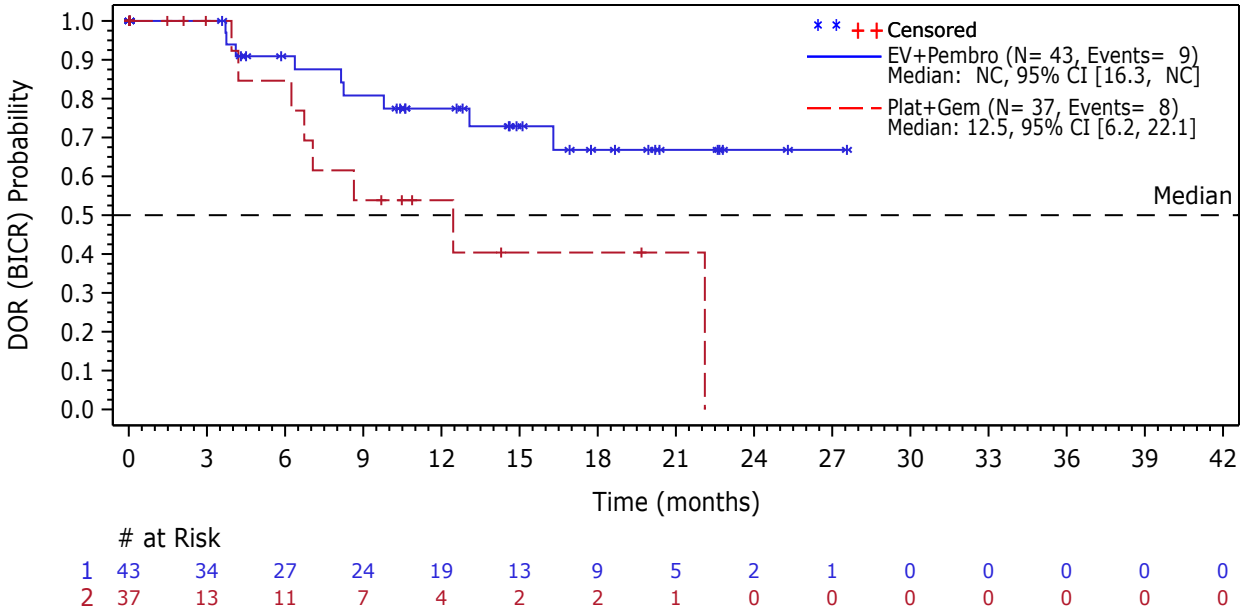
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.2.8: Kaplan-Meier Plot of Duration of Response (BICR) by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Lymph node only



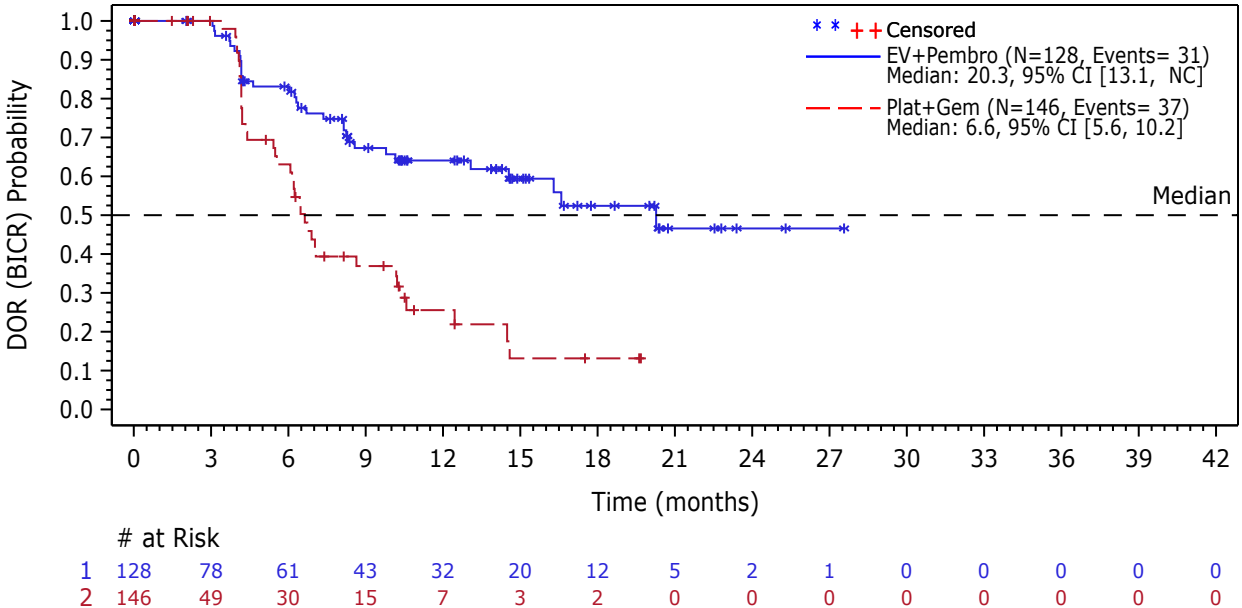
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.2.9: Kaplan-Meier Plot of Duration of Response (BICR) by Primary Disease Site of Origin - Analysis Set mITT 2

Primary Disease Site of Origin: Lower tract



at Risk

1	128	78	61	43	32	20	12	5	2	1	0	0	0	0	0
2	146	49	30	15	7	3	2	0	0	0	0	0	0	0	0

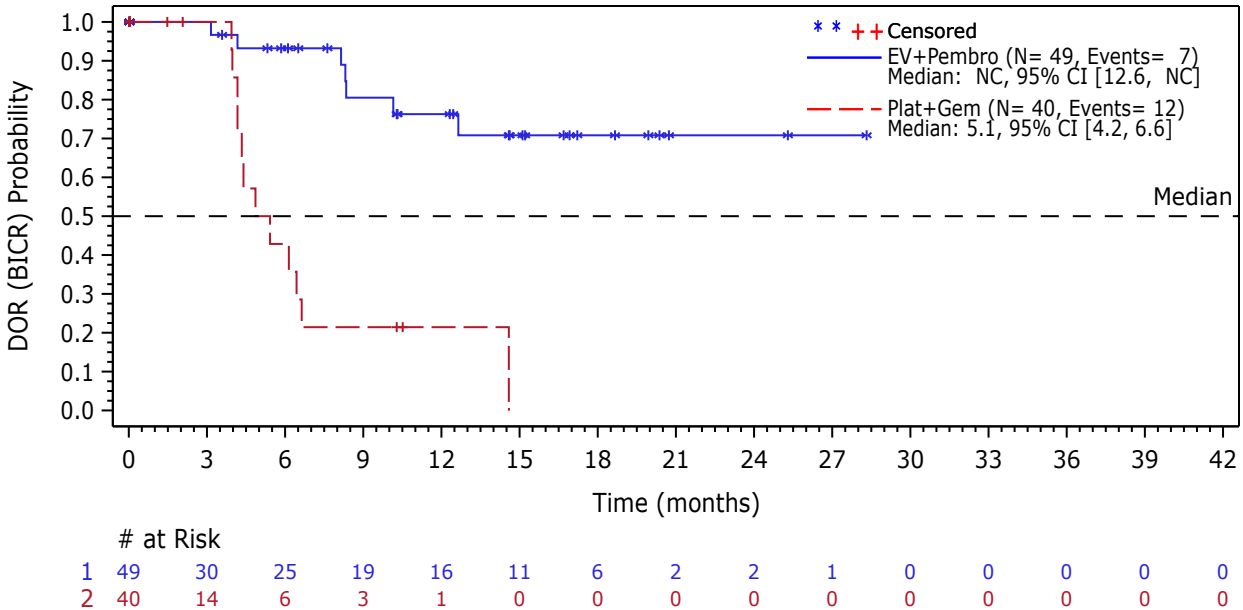
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.2.10: Kaplan-Meier Plot of Duration of Response (BICR) by Renal Function - Analysis Set mITT 2

Renal Function: Mild



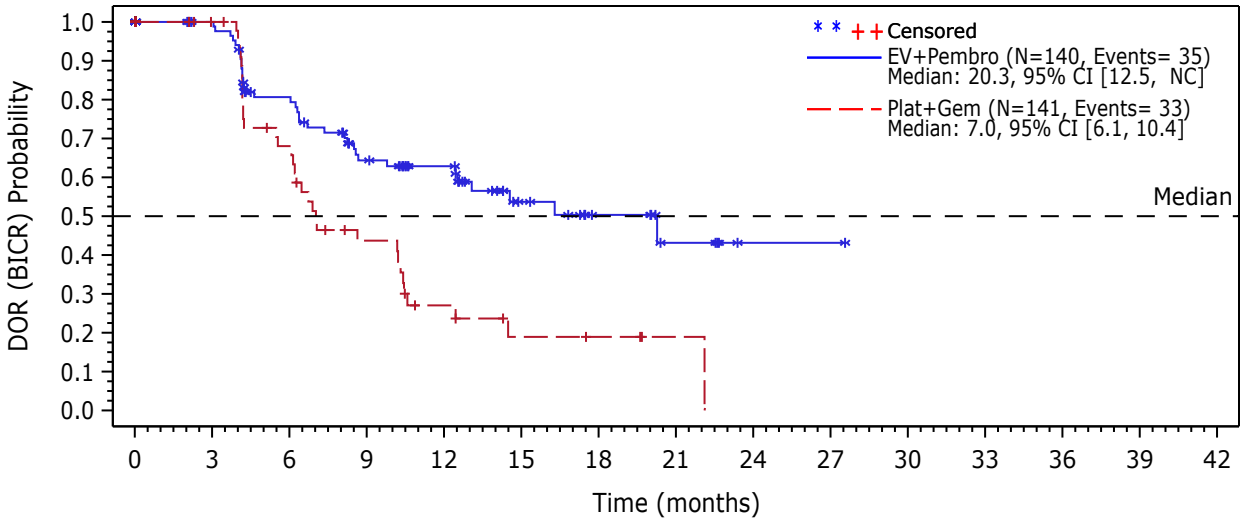
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.2.10: Kaplan-Meier Plot of Duration of Response (BICR) by Renal Function - Analysis Set mITT 2

Renal Function: Moderate



at Risk

1	140	84	62	44	33	17	10	5	1	1	0	0	0	0	0
2	141	45	29	16	8	4	3	1	0	0	0	0	0	0	0

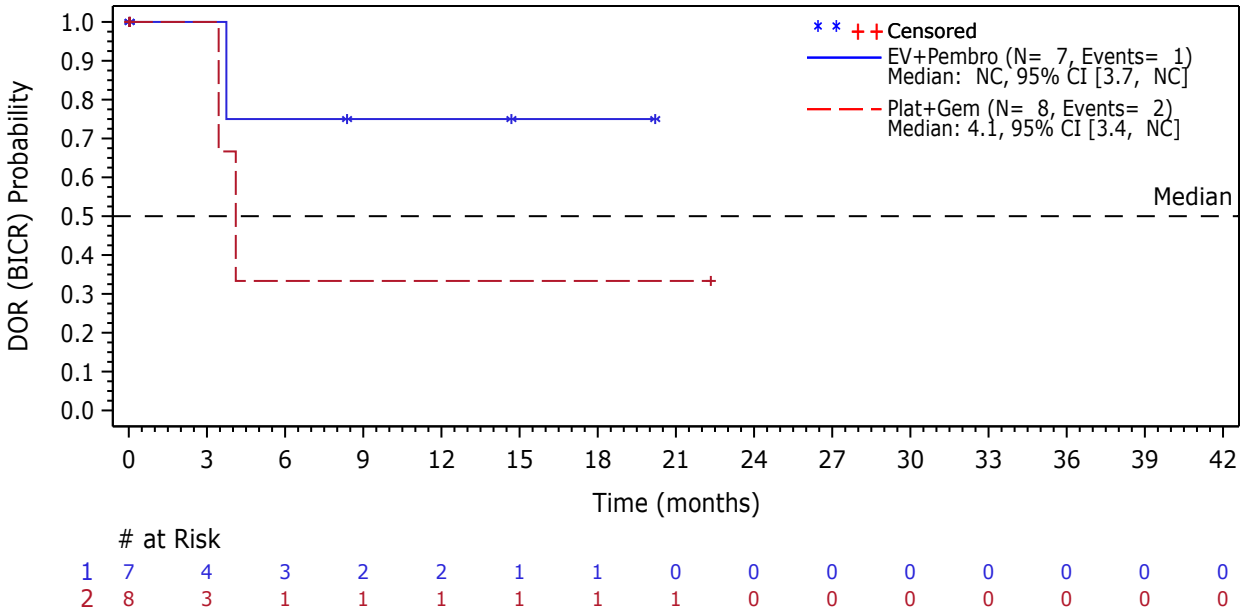
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.7.2.10: Kaplan-Meier Plot of Duration of Response (BICR) by Renal Function - Analysis Set mITT 2

Renal Function: Severe

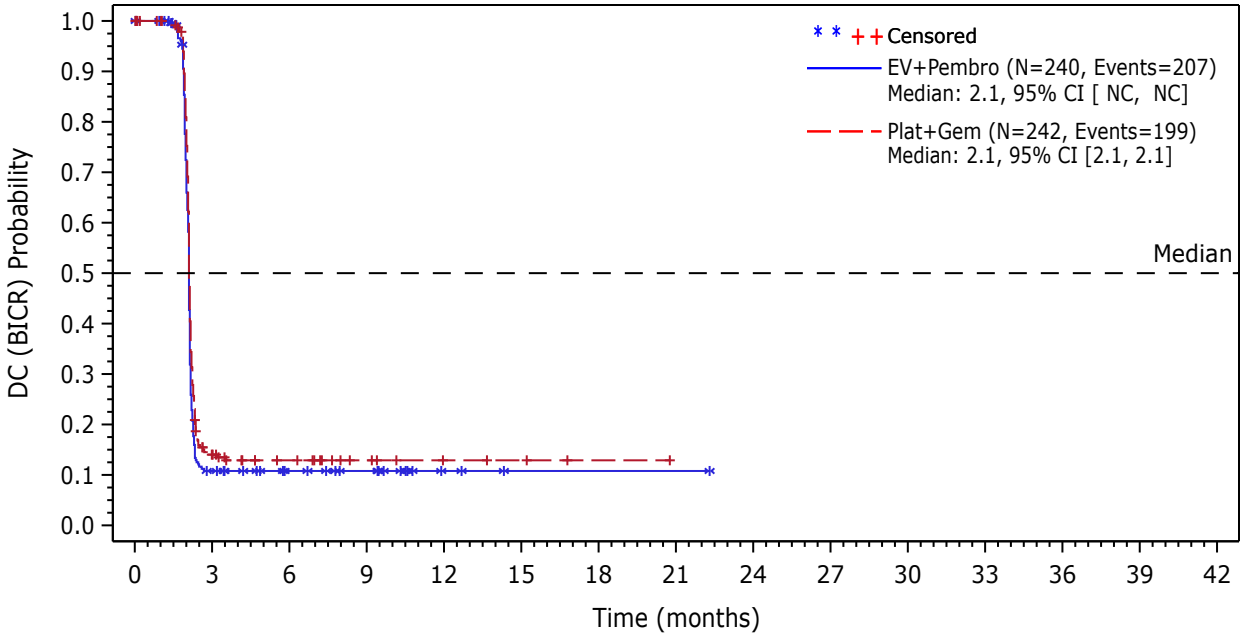


Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DOR=duration of response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD=progressive disease; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Duration of response is defined as the time from the first objective response (complete or partial response that is subsequently confirmed) to the first documented progressive disease per RECIST v1.1 or death from any cause, whichever occurs first.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.1: Kaplan-Meier Plot of Disease Control (BICR) - Analysis Set mITT 1



at Risk

1	240	24	16	12	3	1	1	1	0	0	0	0	0	0	0
2	242	28	16	8	4	3	1	0	0	0	0	0	0	0	0

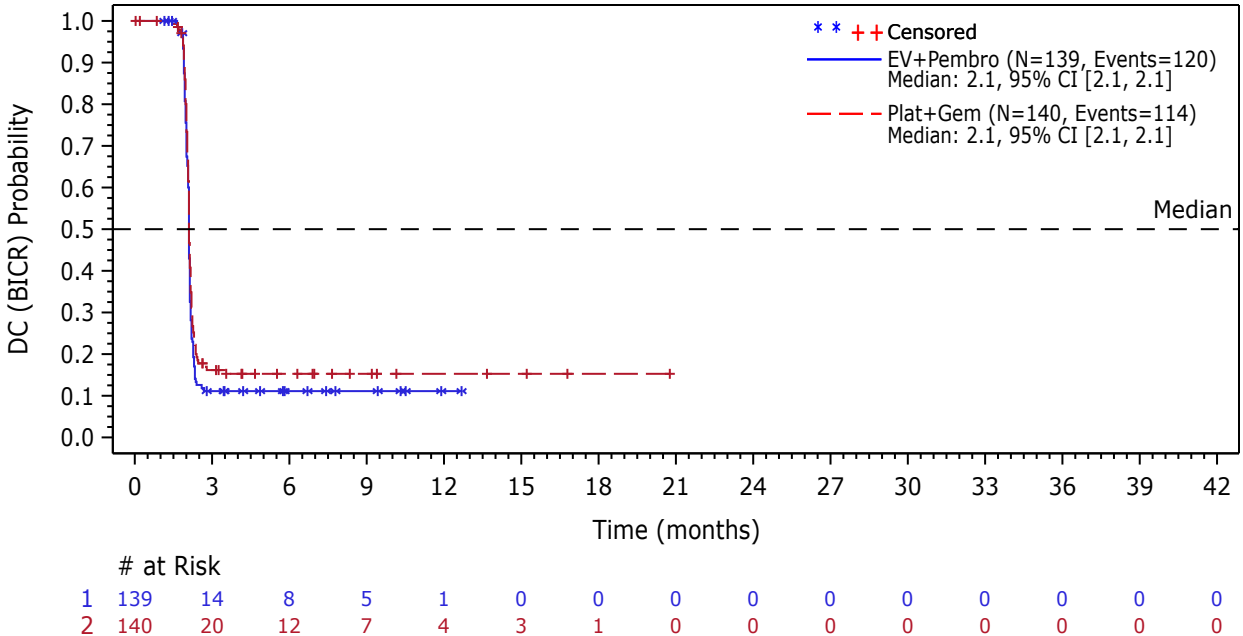
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.1.1: Kaplan-Meier Plot of Disease Control (BICR) by PD-L1 Expression - Analysis Set mITT 1

PD-L1 Expression: High (CPS>=10)



at Risk

1	139	14	8	5	1	0	0	0	0	0	0	0	0	0	0
2	140	20	12	7	4	3	1	0	0	0	0	0	0	0	0

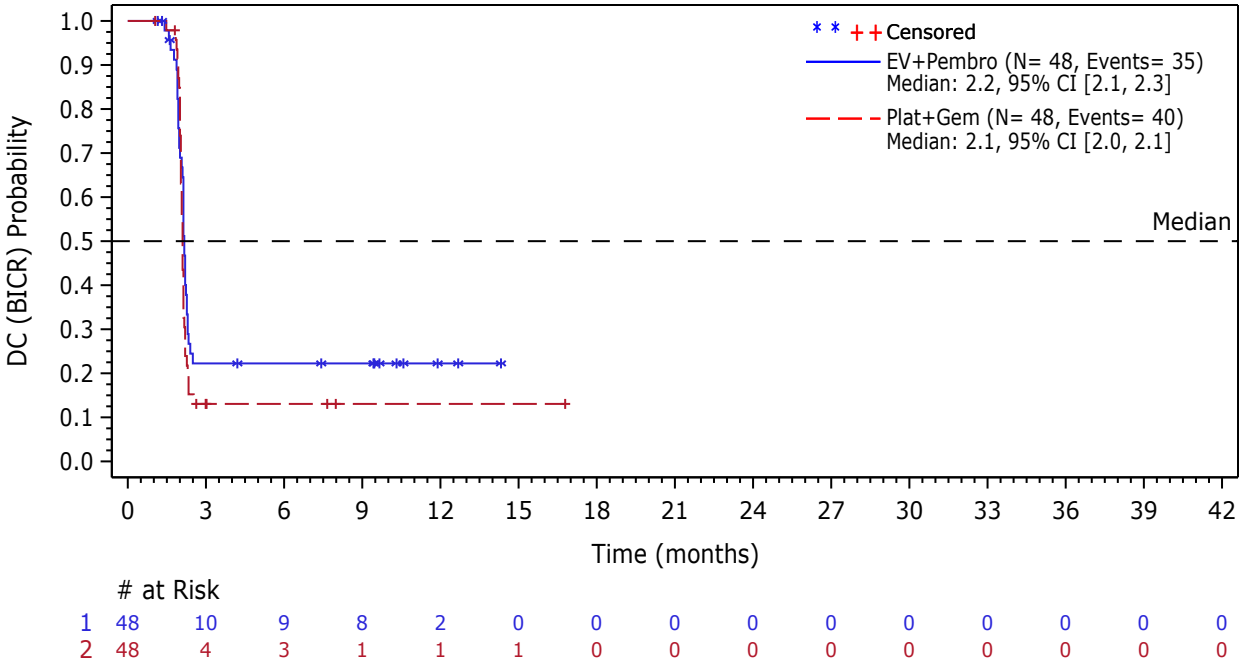
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.1.2: Kaplan-Meier Plot of Disease Control (BICR) by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Present

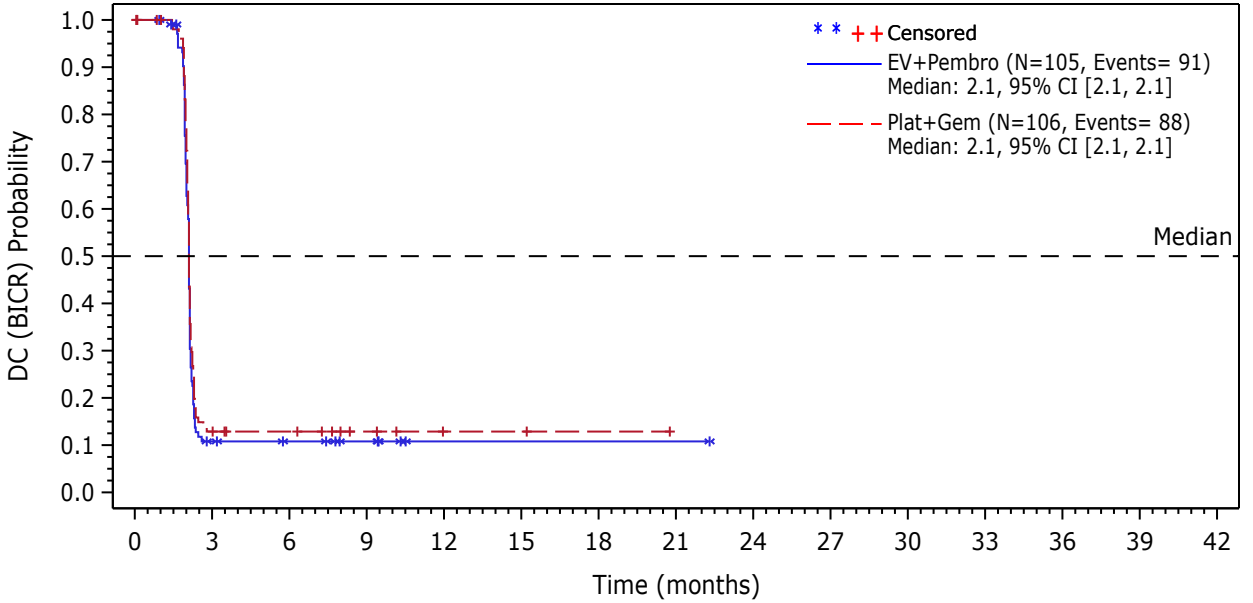


Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.1.3: Kaplan-Meier Plot of Disease Control (BICR) by Age - Analysis Set mITT 1
Age: < 65 years



at Risk

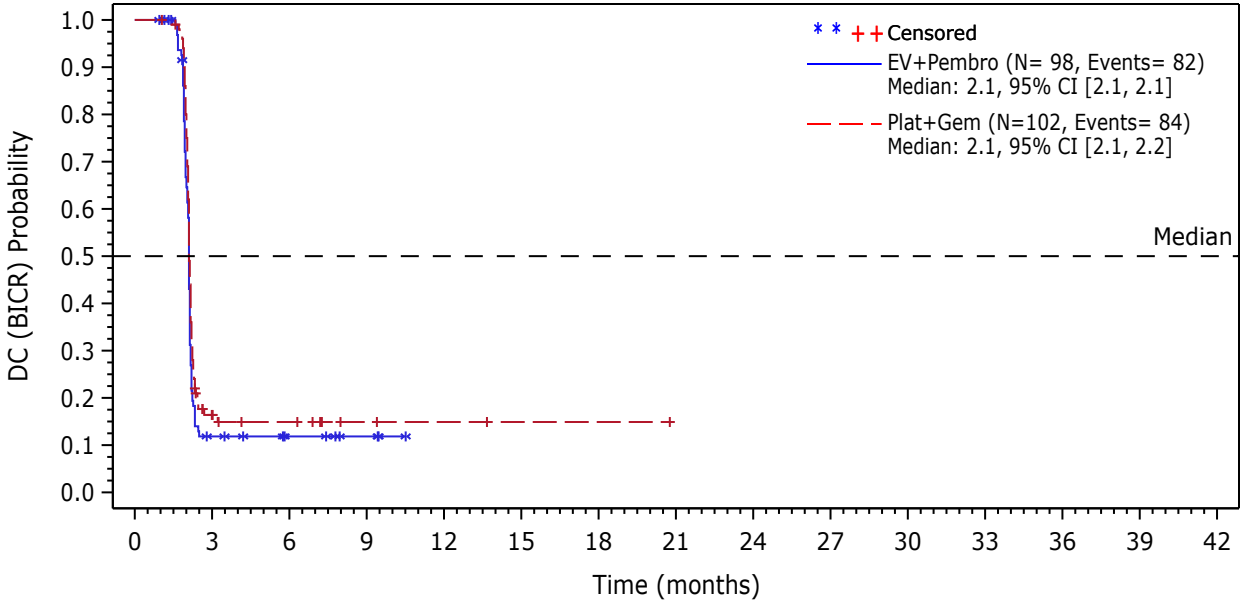
1	105	10	8	5	1	1	1	1	0	0	0	0	0	0	0
2	106	13	10	5	2	2	1	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.1.4: Kaplan-Meier Plot of Disease Control (BICR) by Region - Analysis Set mITT 1 Region: Europe



at Risk

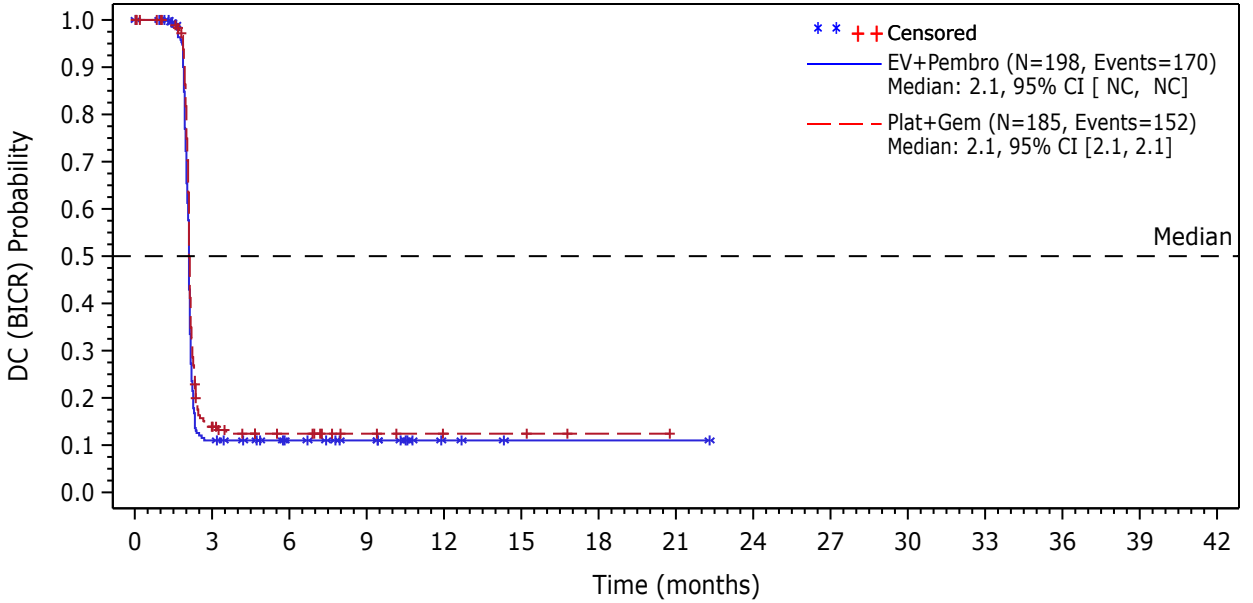
1	98	10	6	3	0	0	0	0	0	0	0	0	0	0	0
2	102	12	8	3	2	1	1	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.1.5: Kaplan-Meier Plot of Disease Control (BICR) by Sex - Analysis Set mITT 1
Sex: Male



at Risk

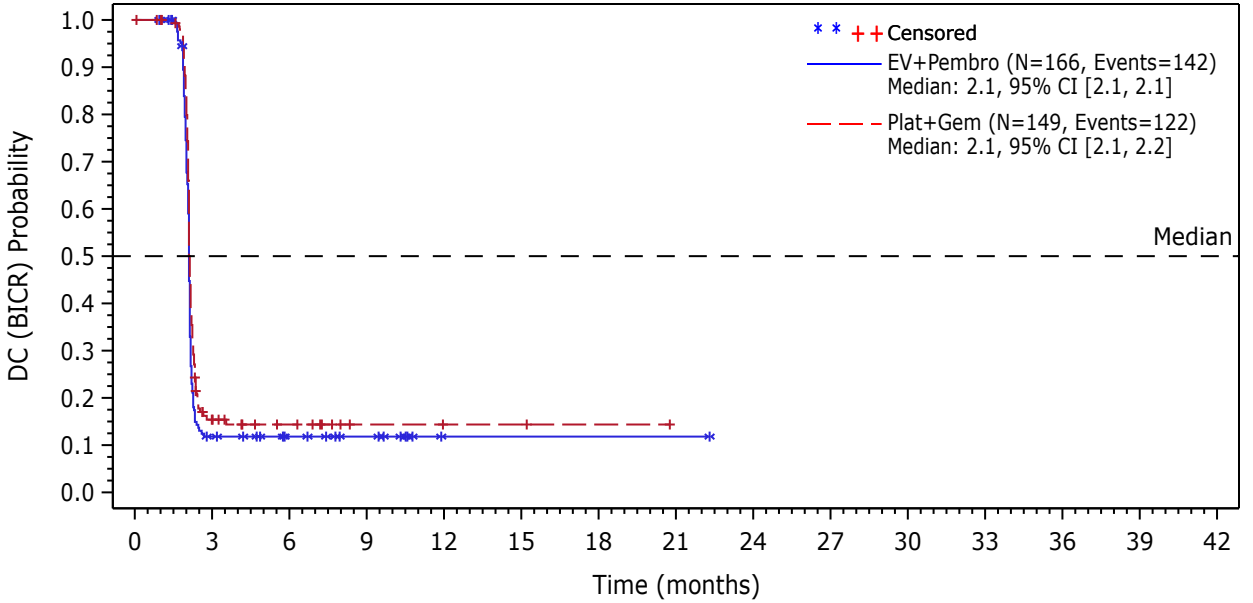
1	198	21	14	10	3	1	1	1	0	0	0	0	0	0	0
2	185	22	12	6	3	3	1	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.1.6: Kaplan-Meier Plot of Disease Control (BICR) by Race - Analysis Set mITT 1
Race: White



at Risk

1	166	18	12	8	1	1	1	1	0	0	0	0	0	0	0
2	149	18	10	3	2	2	1	0	0	0	0	0	0	0	0

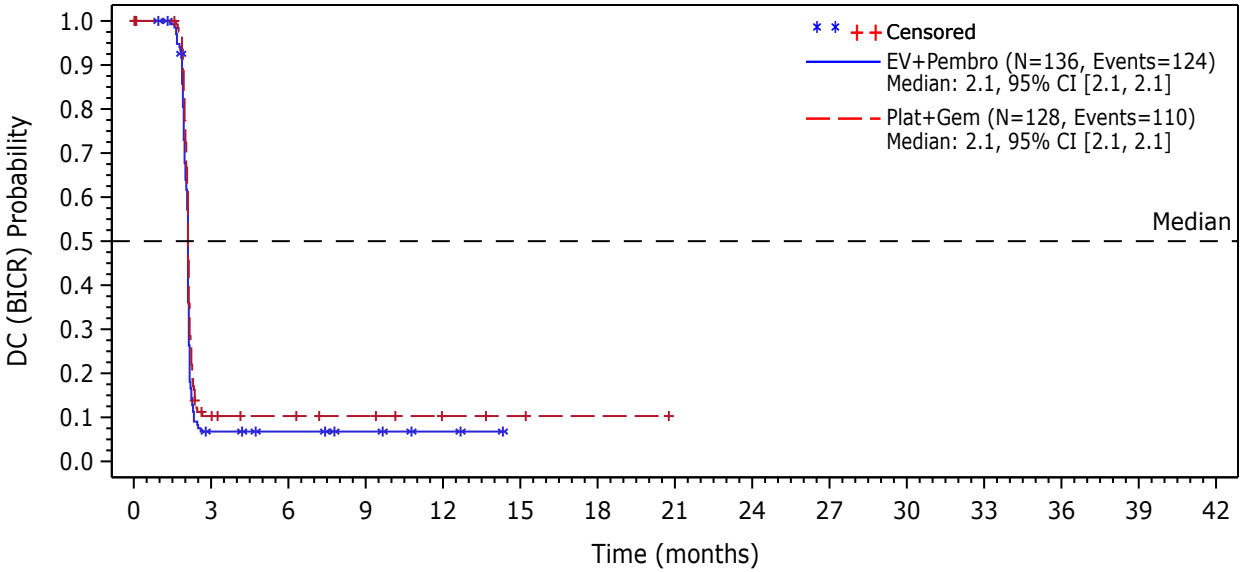
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.1.7: Kaplan-Meier Plot of Disease Control (BICR) by ECOG Status at Baseline - Analysis Set mITT 1

ECOG Status at Baseline: 0



at Risk

1	136	8	6	4	2	0	0	0	0	0	0	0	0	0	0
2	128	11	8	6	3	2	1	0	0	0	0	0	0	0	0

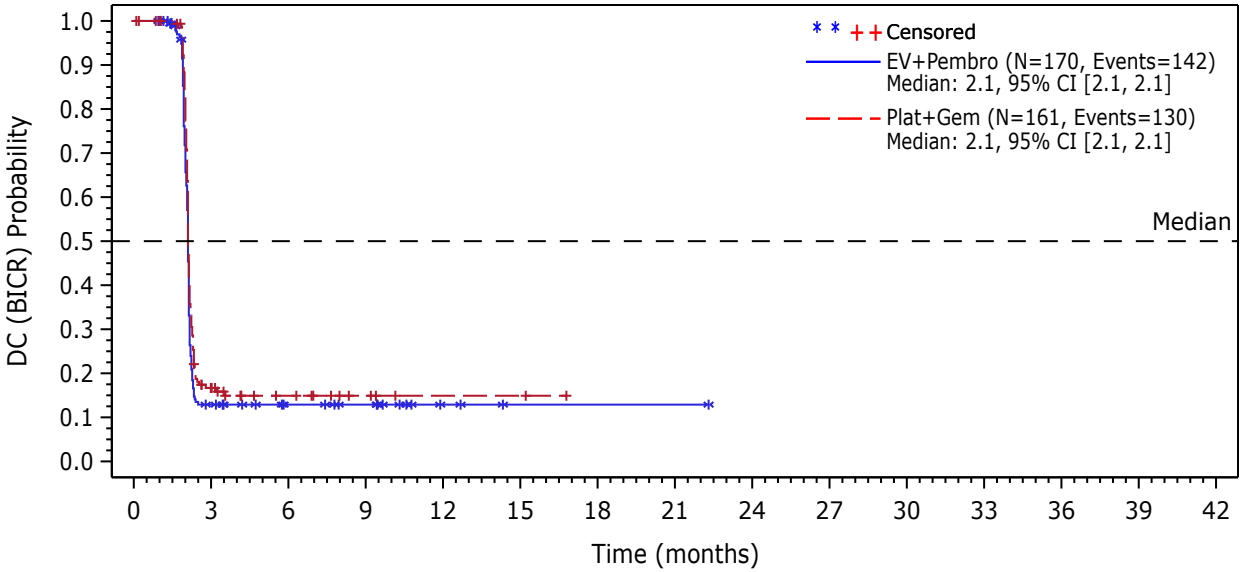
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.1.8: Kaplan-Meier Plot of Disease Control (BICR) by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Visceral metastases



# at Risk															
1	170	20	13	10	3	1	1	1	0	0	0	0	0	0	0
2	161	22	11	5	2	2	0	0	0	0	0	0	0	0	0

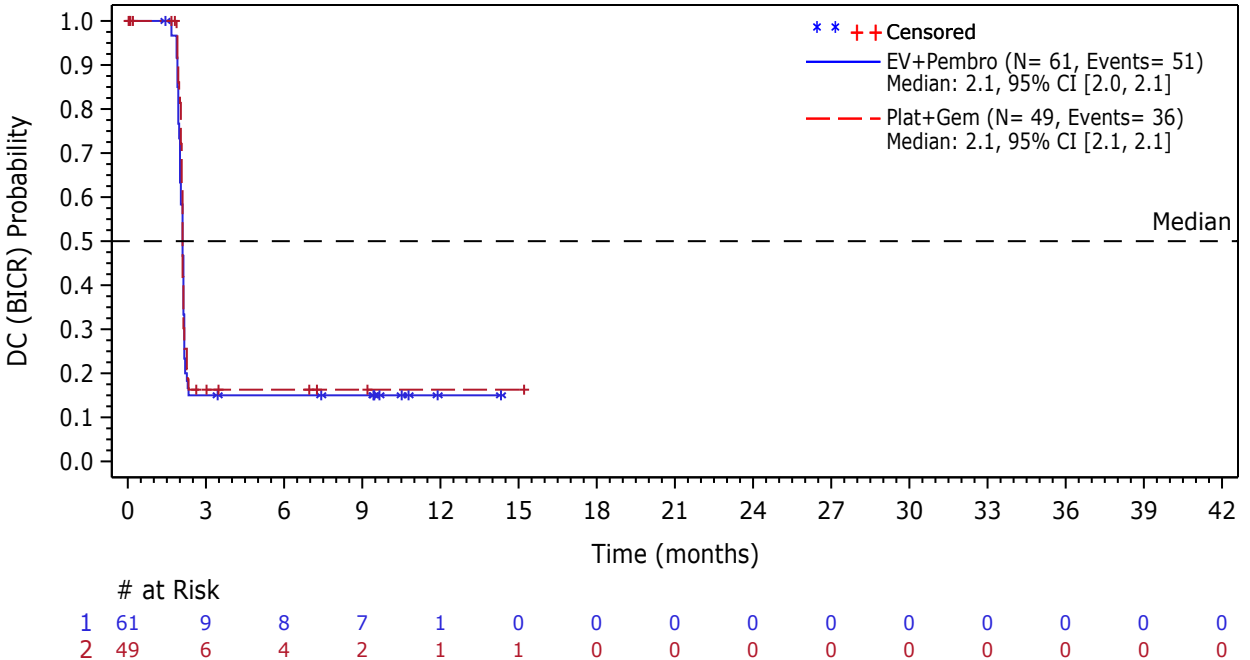
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.1.9: Kaplan-Meier Plot of Disease Control (BICR) by Primary Disease Site of Origin - Analysis Set mITT 1

Primary Disease Site of Origin: Upper tract



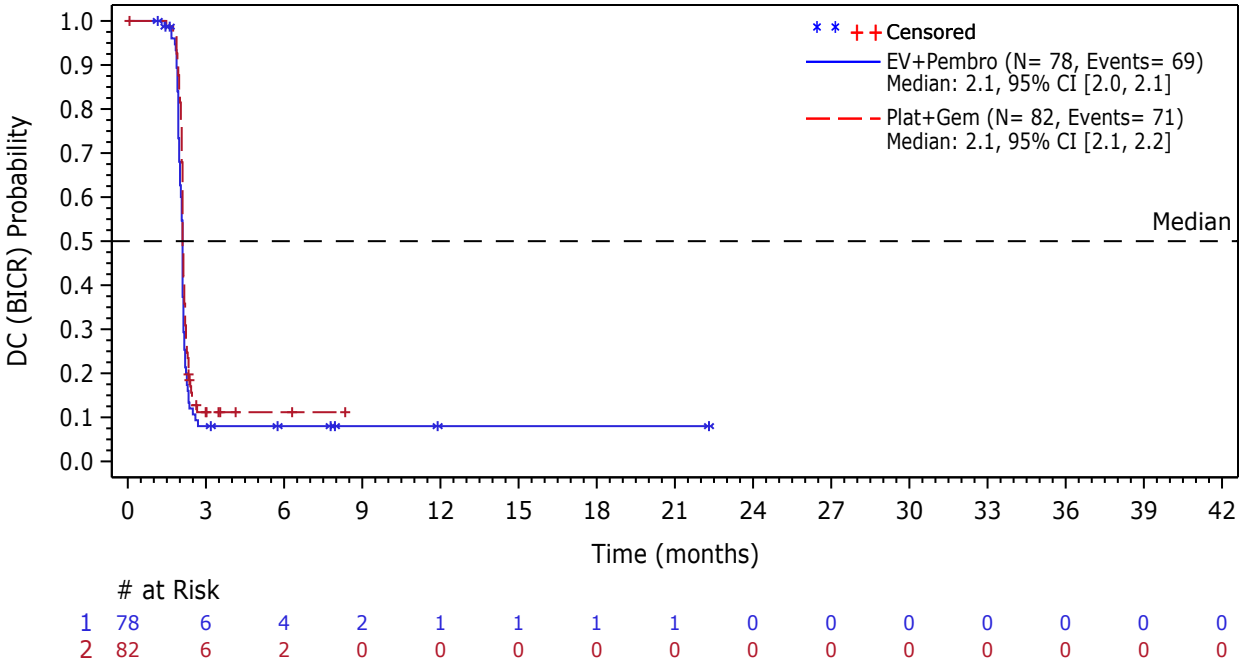
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.1.10: Kaplan-Meier Plot of Disease Control (BICR) by Renal Function - Analysis Set mITT 1

Renal Function: Normal



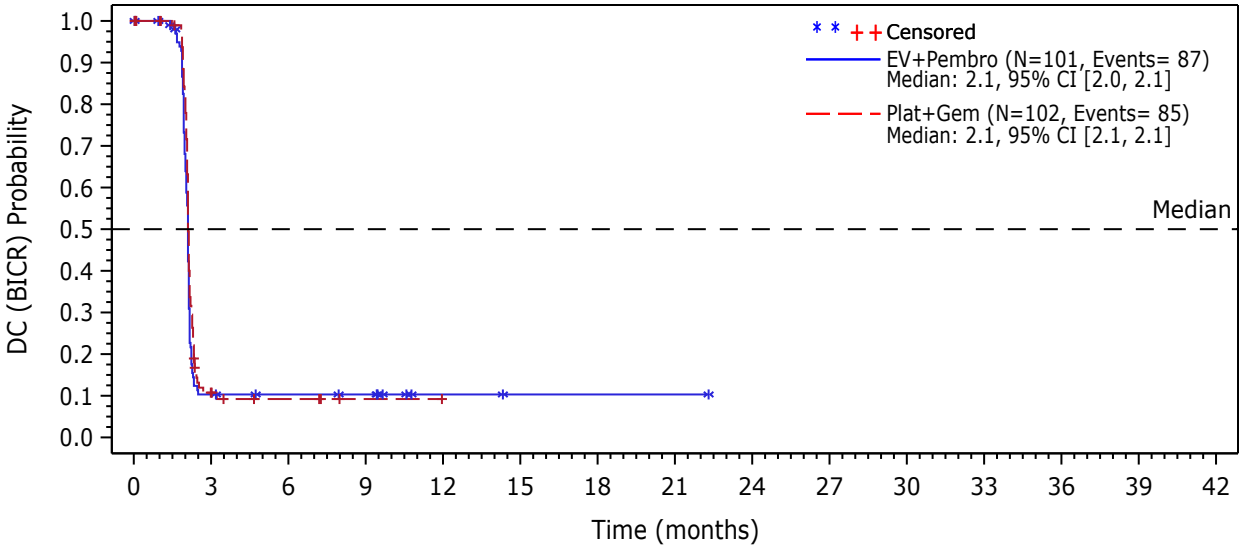
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.1.1: Kaplan-Meier Plot of Disease Control (BICR) by PD-L1 Expression - Analysis Set mITT 1

PD-L1 Expression: Low (CPS<10)



at Risk

1	101	10	8	7	2	1	1	1	0	0	0	0	0	0	0
2	102	8	4	1	0	0	0	0	0	0	0	0	0	0	0

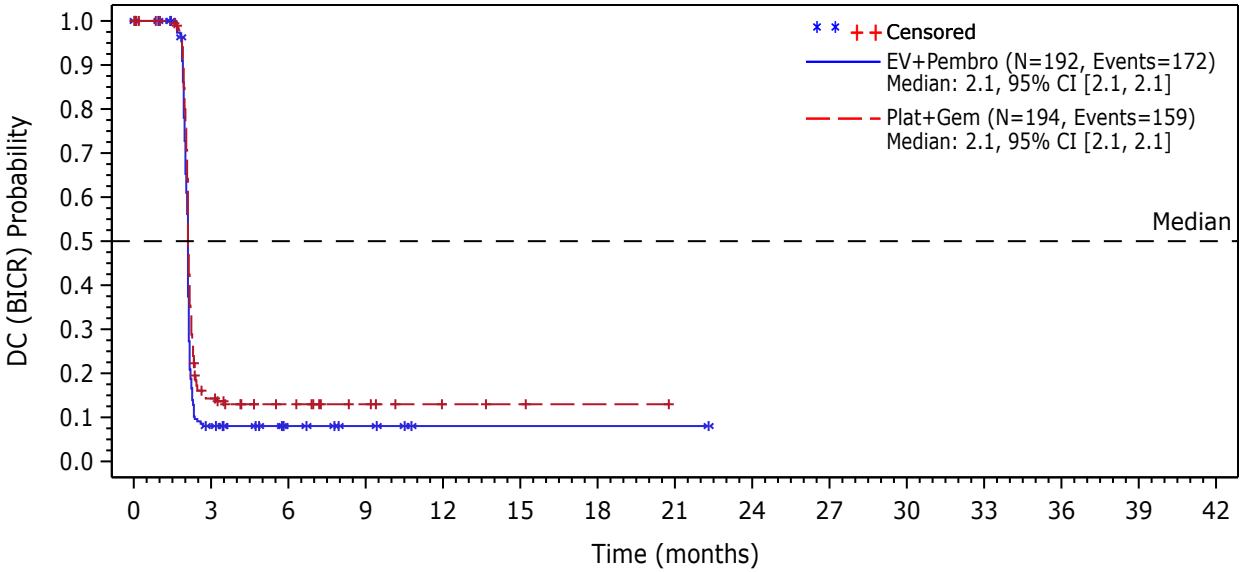
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.1.2: Kaplan-Meier Plot of Disease Control (BICR) by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Absent



at Risk

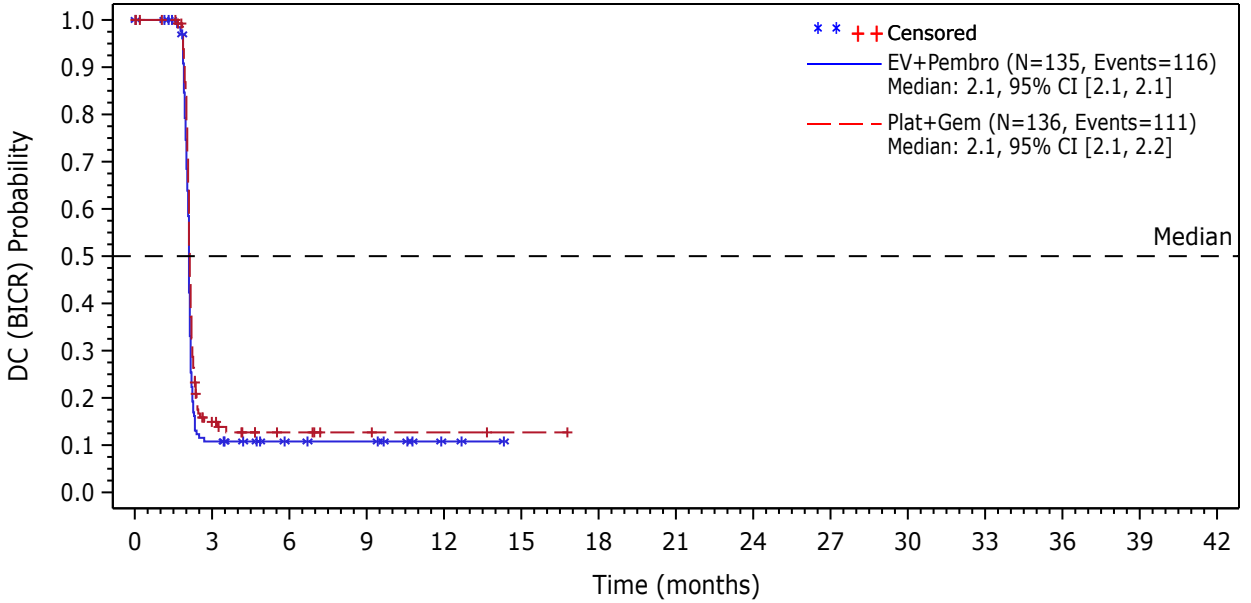
1	192	14	7	4	1	1	1	1	0	0	0	0	0	0	0
2	194	24	13	7	3	2	1	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.1.3: Kaplan-Meier Plot of Disease Control (BICR) by Age - Analysis Set mITT 1
Age: >= 65 years



at Risk

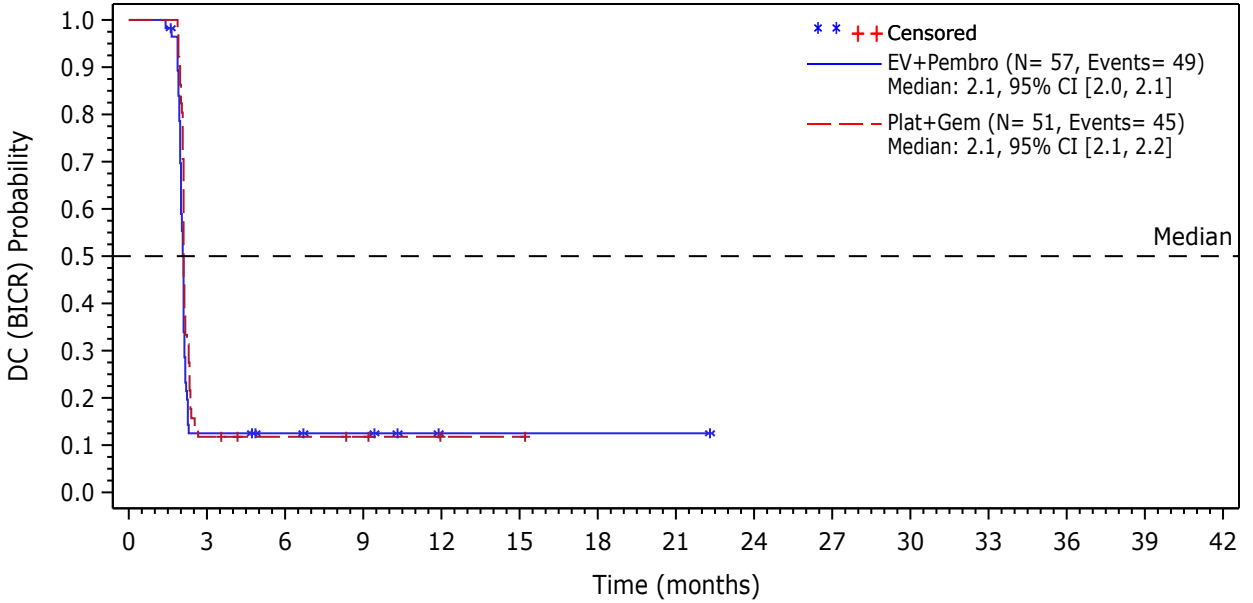
1	135	14	8	7	2	0	0	0	0	0	0	0	0	0	0
2	136	15	6	3	2	1	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.1.4: Kaplan-Meier Plot of Disease Control (BICR) by Region - Analysis Set mITT 1
Region: North America



at Risk

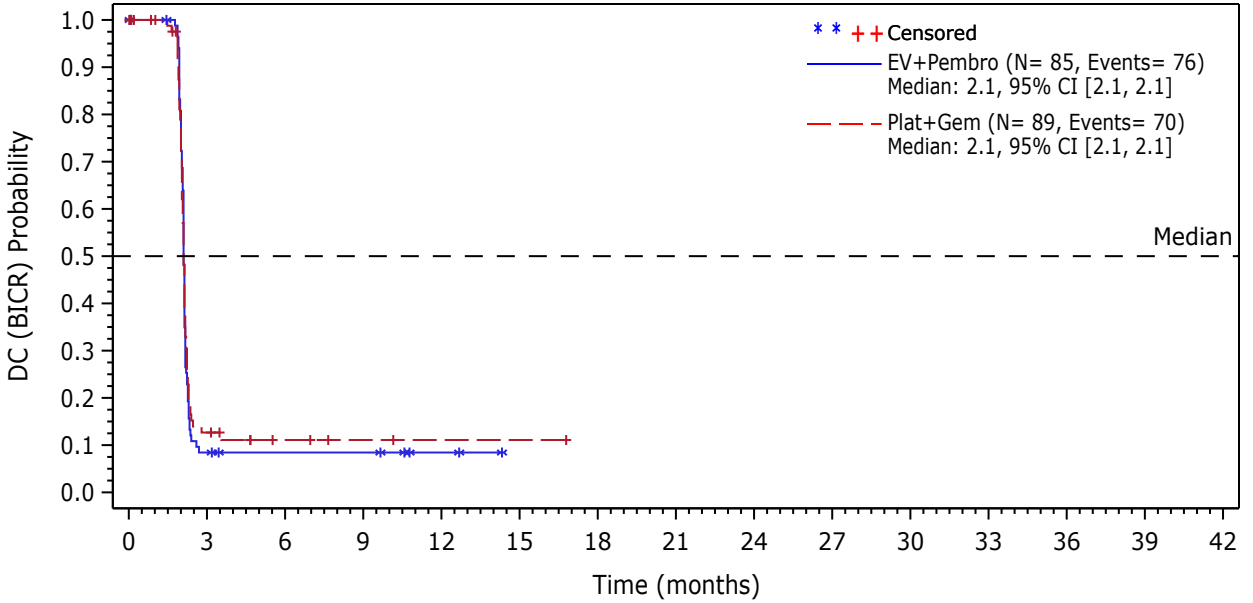
1	57	7	5	4	1	1	1	1	0	0	0	0	0	0	0
2	51	6	4	3	1	1	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.1.4: Kaplan-Meier Plot of Disease Control (BICR) by Region - Analysis Set mITT 1 Region: Rest of World



at Risk

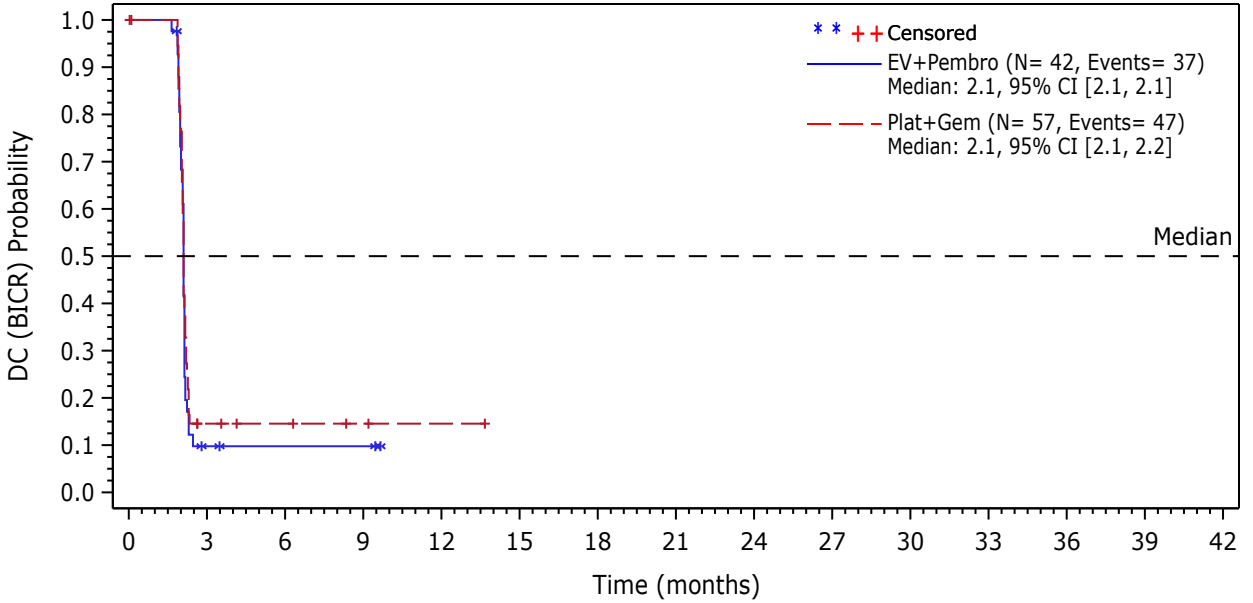
1	85	7	5	5	2	0	0	0	0	0	0	0	0	0	0
2	89	10	4	2	1	1	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.1.5: Kaplan-Meier Plot of Disease Control (BICR) by Sex - Analysis Set mITT 1
Sex: Female



at Risk

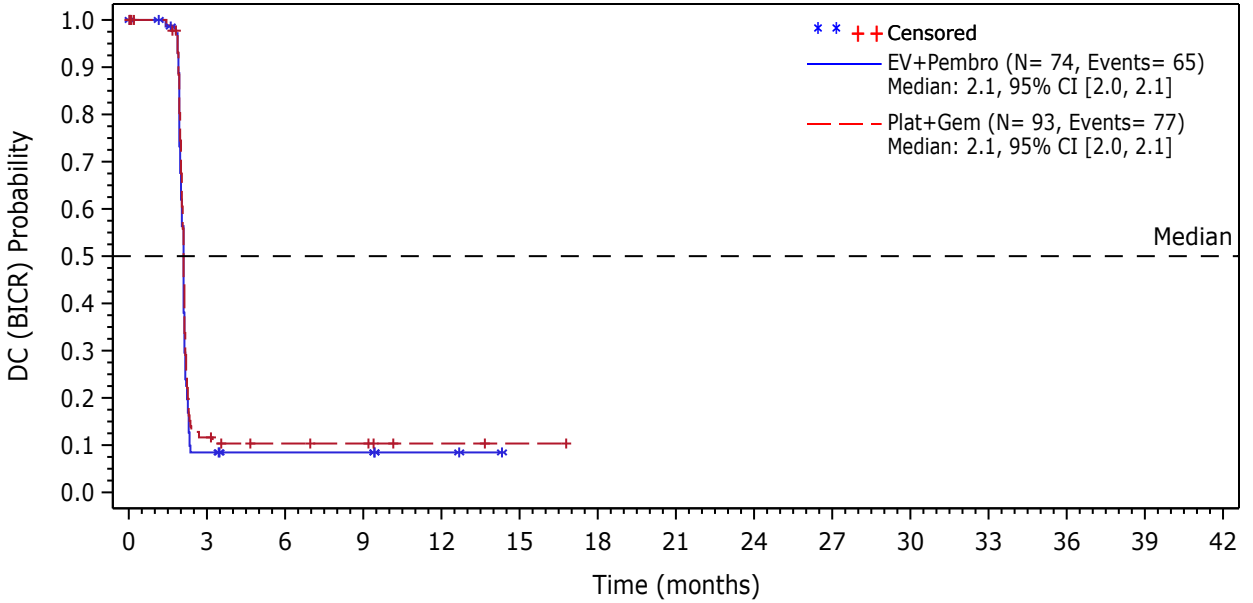
1	42	3	2	2	0	0	0	0	0	0	0	0	0	0	0
2	57	6	4	2	1	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.1.6: Kaplan-Meier Plot of Disease Control (BICR) by Race - Analysis Set mITT 1
Race: Non-white



at Risk

1	74	6	4	4	2	0	0	0	0	0	0	0	0	0	0
2	93	10	6	5	2	1	0	0	0	0	0	0	0	0	0

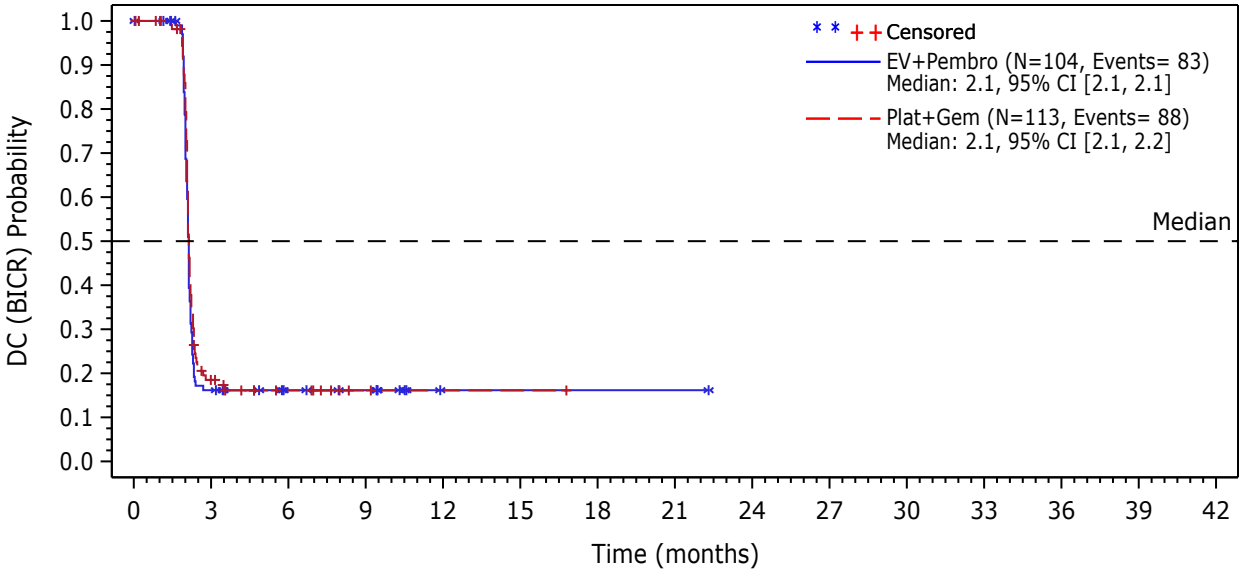
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.1.7: Kaplan-Meier Plot of Disease Control (BICR) by ECOG Status at Baseline - Analysis Set mITT 1

ECOG Status at Baseline: 1-2



at Risk

1	104	16	10	8	1	1	1	1	0	0	0	0	0	0	0
2	113	17	8	2	1	1	0	0	0	0	0	0	0	0	0

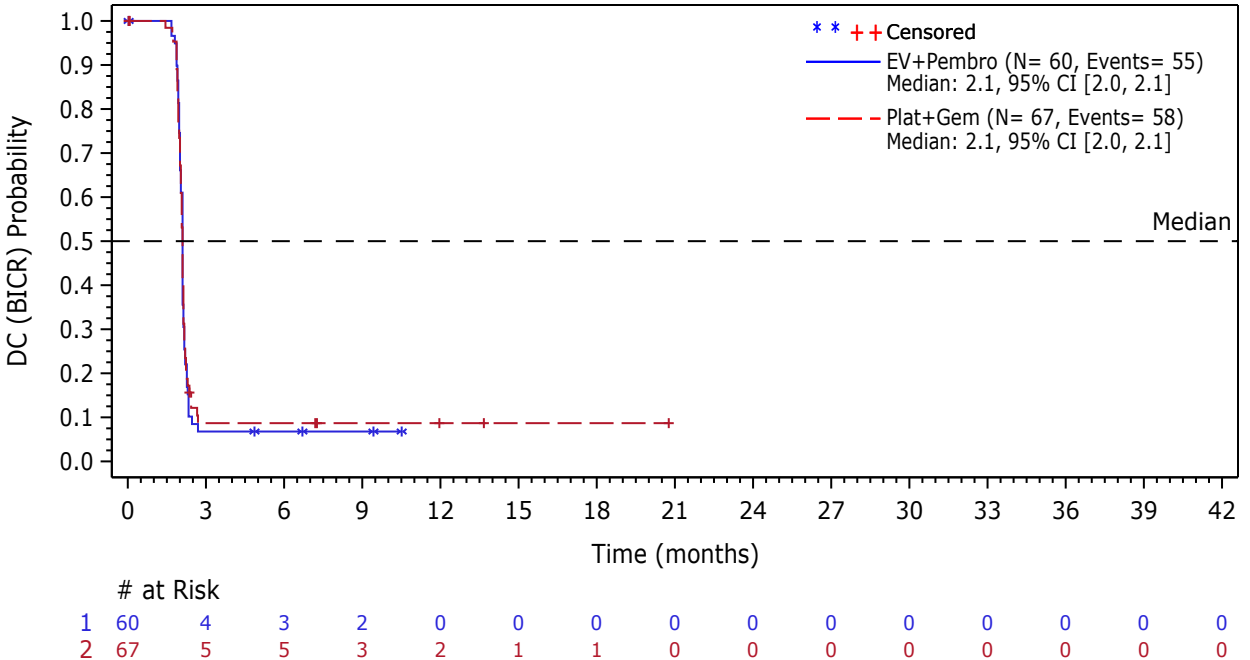
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.1.8: Kaplan-Meier Plot of Disease Control (BICR) by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Lymph node only



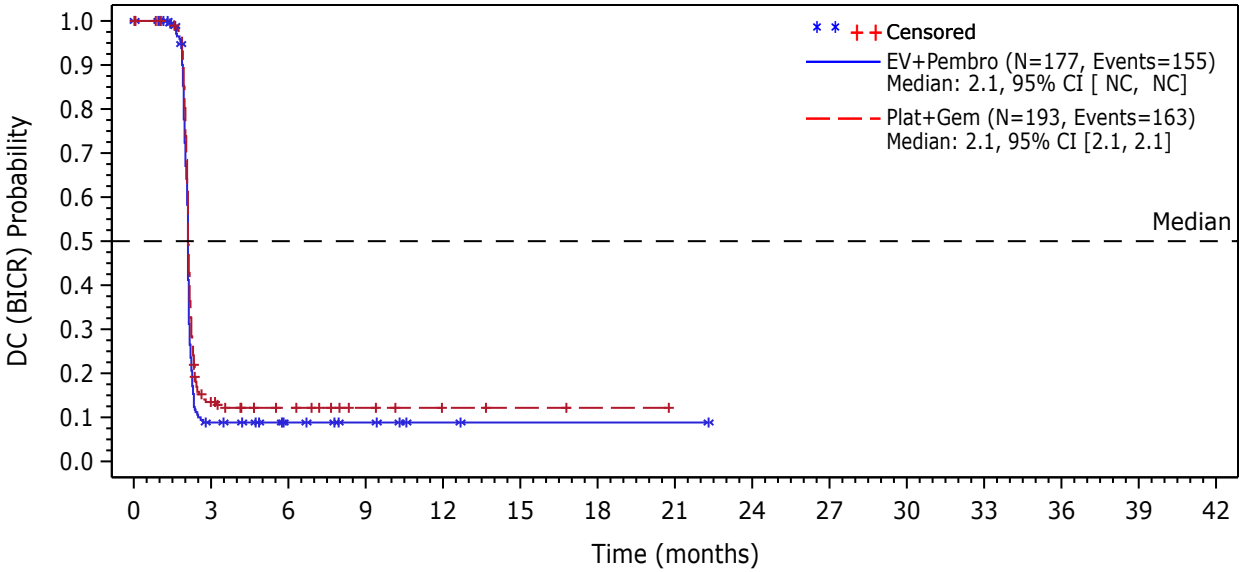
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.1.9: Kaplan-Meier Plot of Disease Control (BICR) by Primary Disease Site of Origin - Analysis Set mITT 1

Primary Disease Site of Origin: Lower tract



at Risk

1	177	14	8	5	2	1	1	1	0	0	0	0	0	0	0
2	193	22	12	6	3	2	1	0	0	0	0	0	0	0	0

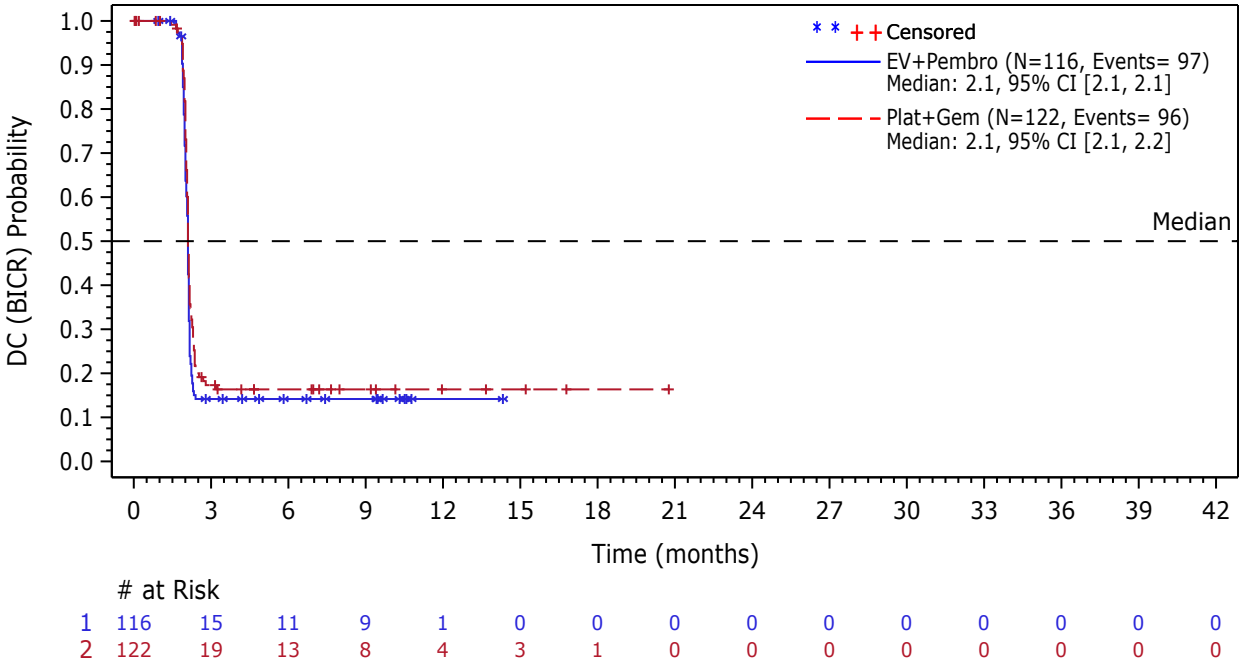
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.1.10: Kaplan-Meier Plot of Disease Control (BICR) by Renal Function - Analysis Set mITT 1

Renal Function: Mild



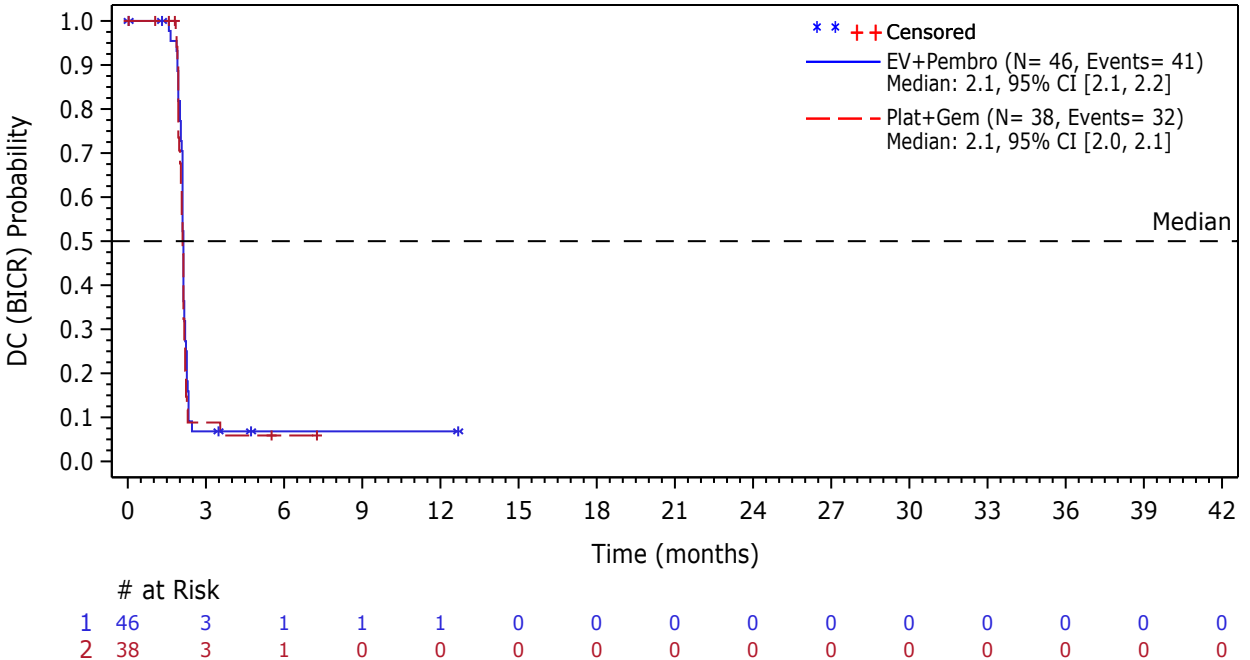
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.1.10: Kaplan-Meier Plot of Disease Control (BICR) by Renal Function - Analysis Set mITT 1

Renal Function: Moderate

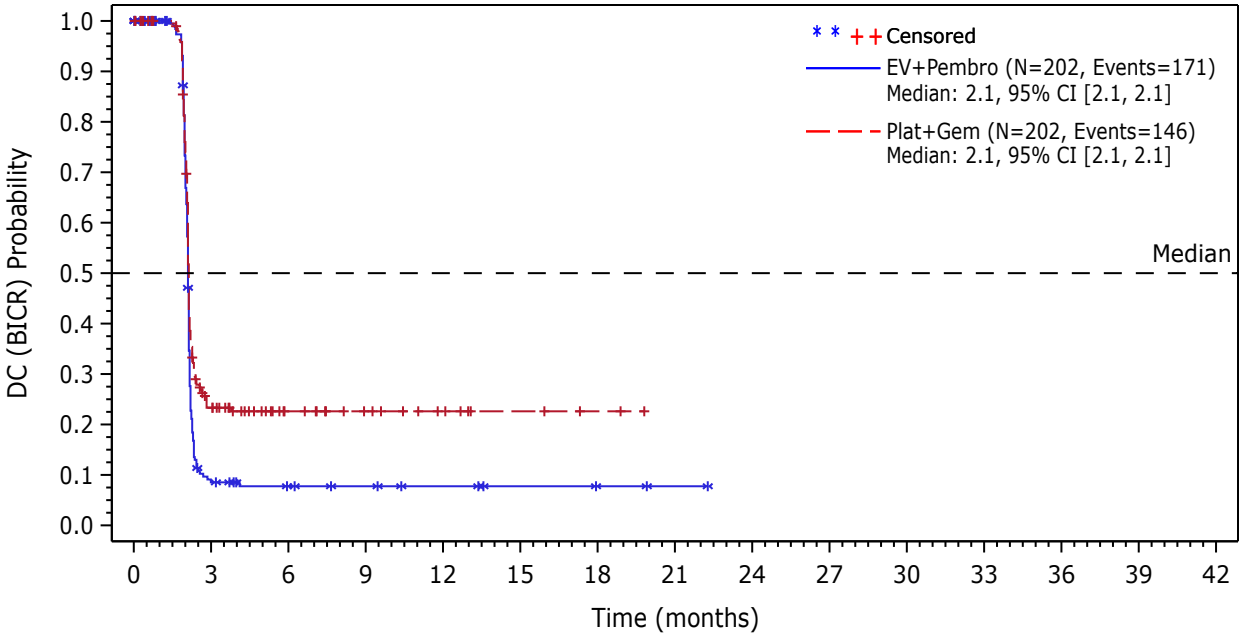


Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.2: Kaplan-Meier Plot of Disease Control (BICR) - Analysis Set mITT 2



at Risk

1	202	15	9	7	5	3	2	1	0	0	0	0	0	0	0
2	202	40	20	13	8	4	2	0	0	0	0	0	0	0	0

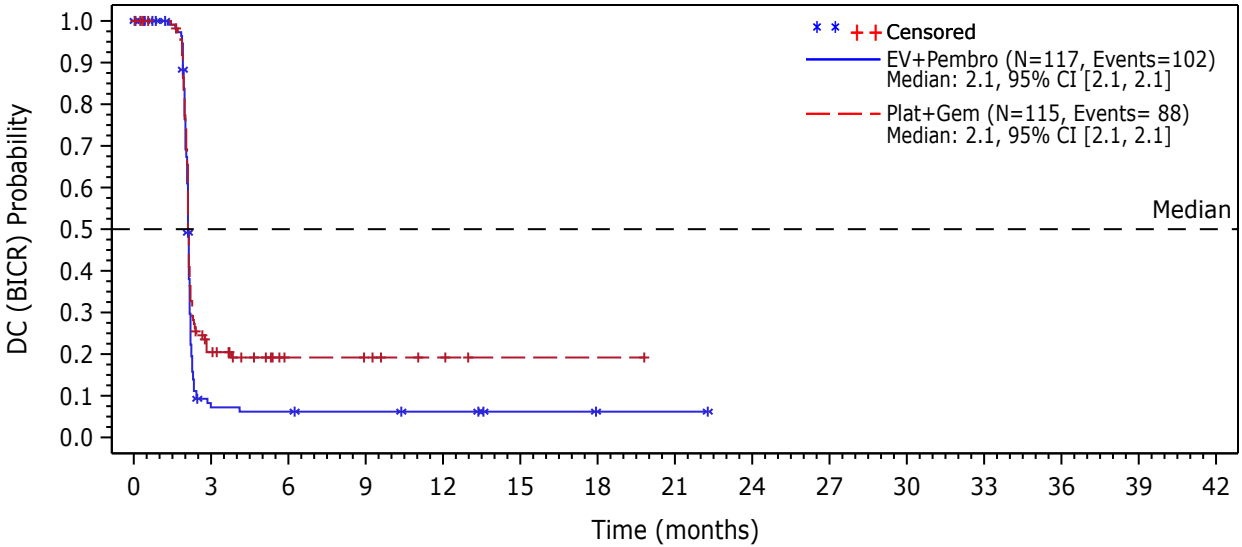
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.2.1: Kaplan-Meier Plot of Disease Control (BICR) by PD-L1 Expression - Analysis Set mITT 2

PD-L1 Expression: High (CPS>=10)



at Risk

1	117	7	6	5	4	2	1	1	0	0	0	0	0	0	0
2	115	20	7	6	3	1	1	0	0	0	0	0	0	0	0

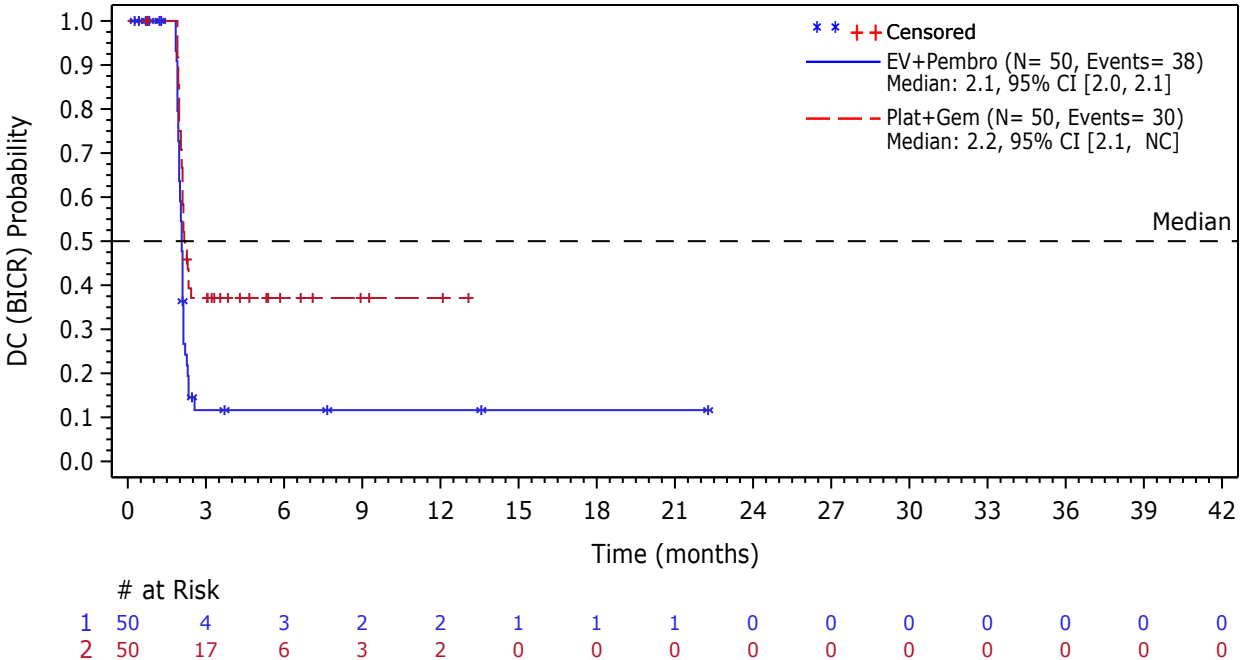
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.2.2: Kaplan-Meier Plot of Disease Control (BICR) by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Present

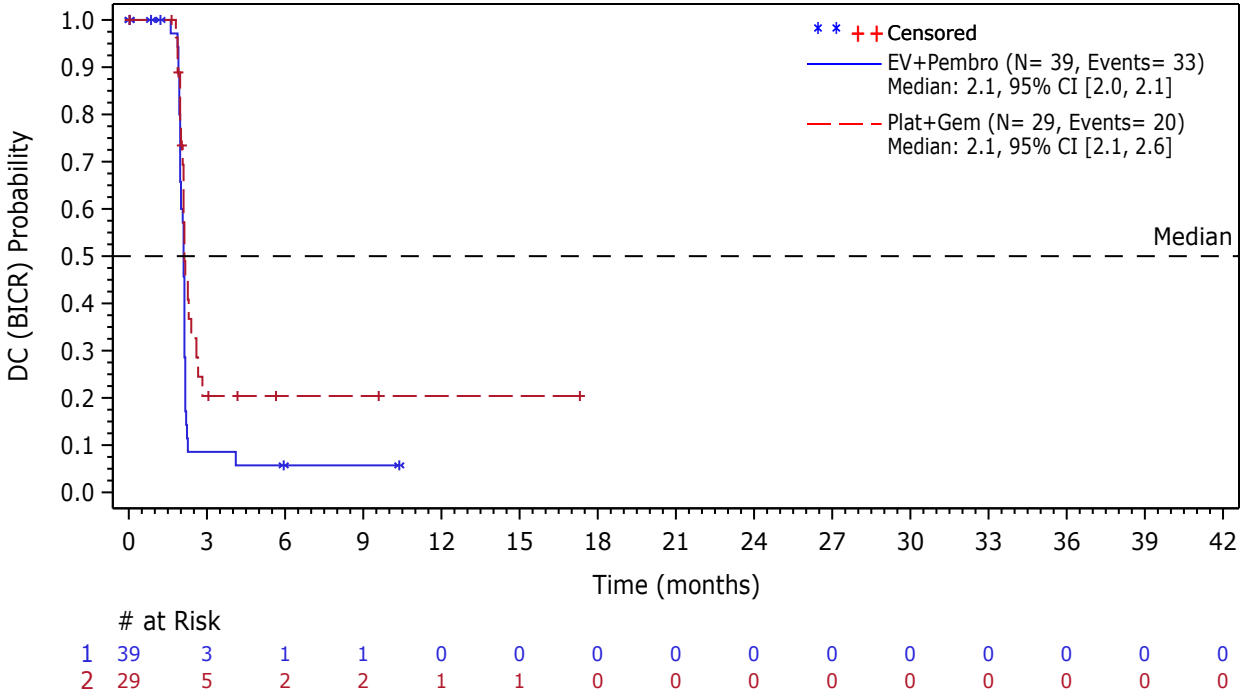


Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.2.3: Kaplan-Meier Plot of Disease Control (BICR) by Age - Analysis Set mITT 2
Age: < 65 years

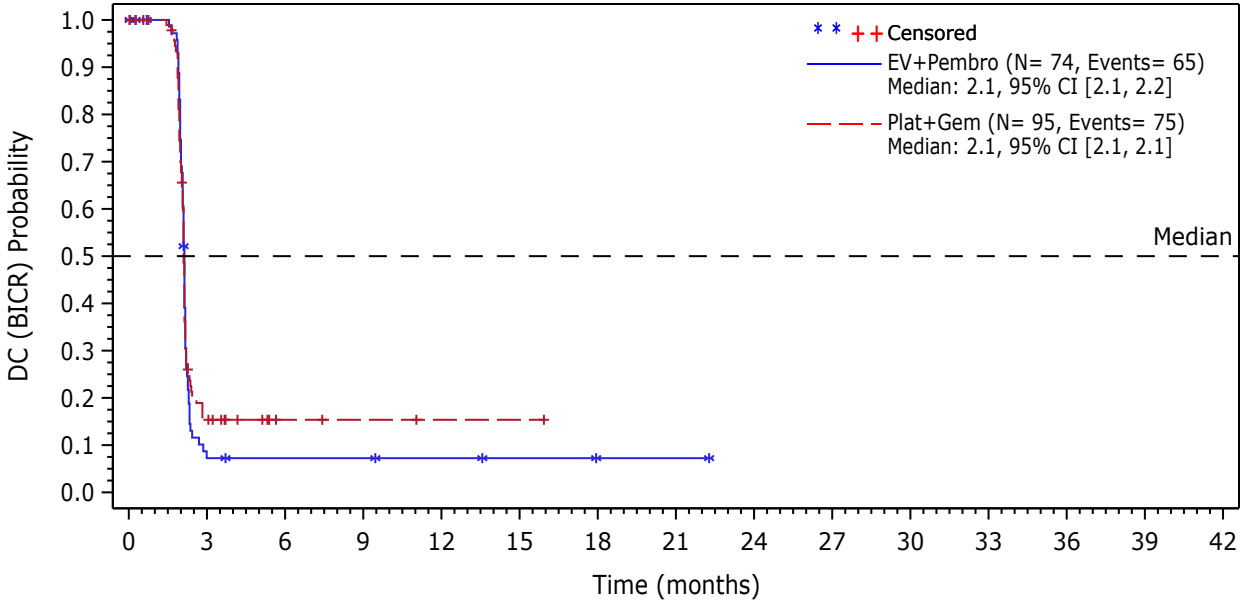


Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.2.4: Kaplan-Meier Plot of Disease Control (BICR) by Region - Analysis Set mITT 2 Region: Europe



at Risk

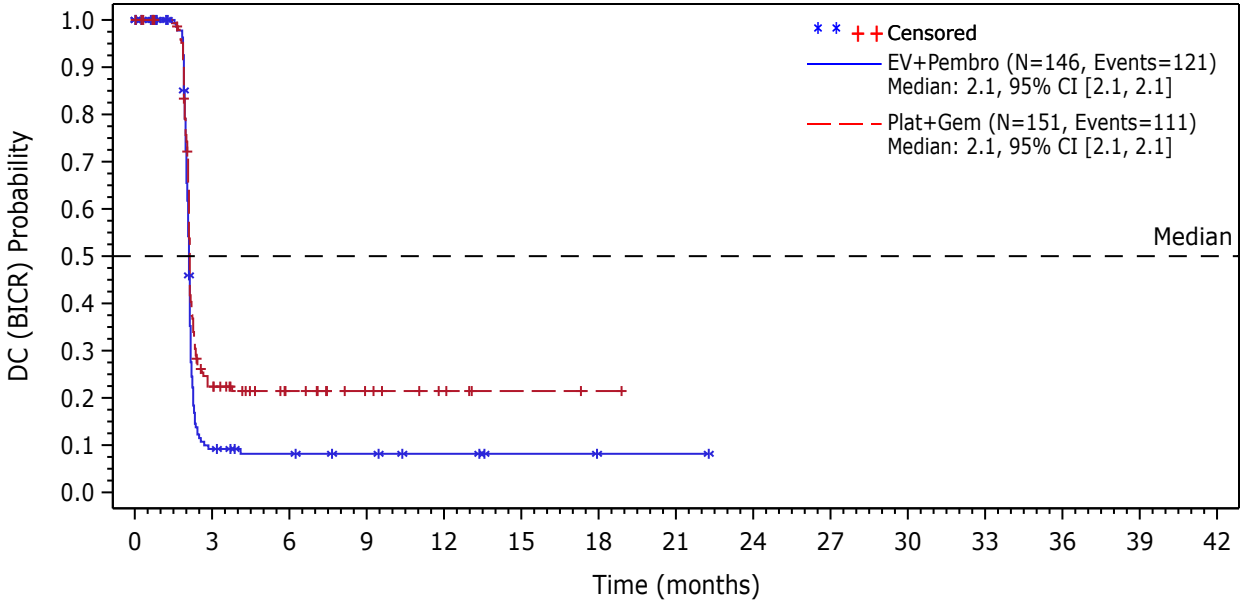
1	74	5	4	4	3	2	1	1	0	0	0	0	0	0	0
2	95	13	3	2	1	1	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.2.5: Kaplan-Meier Plot of Disease Control (BICR) by Sex - Analysis Set mITT 2
Sex: Male



at Risk

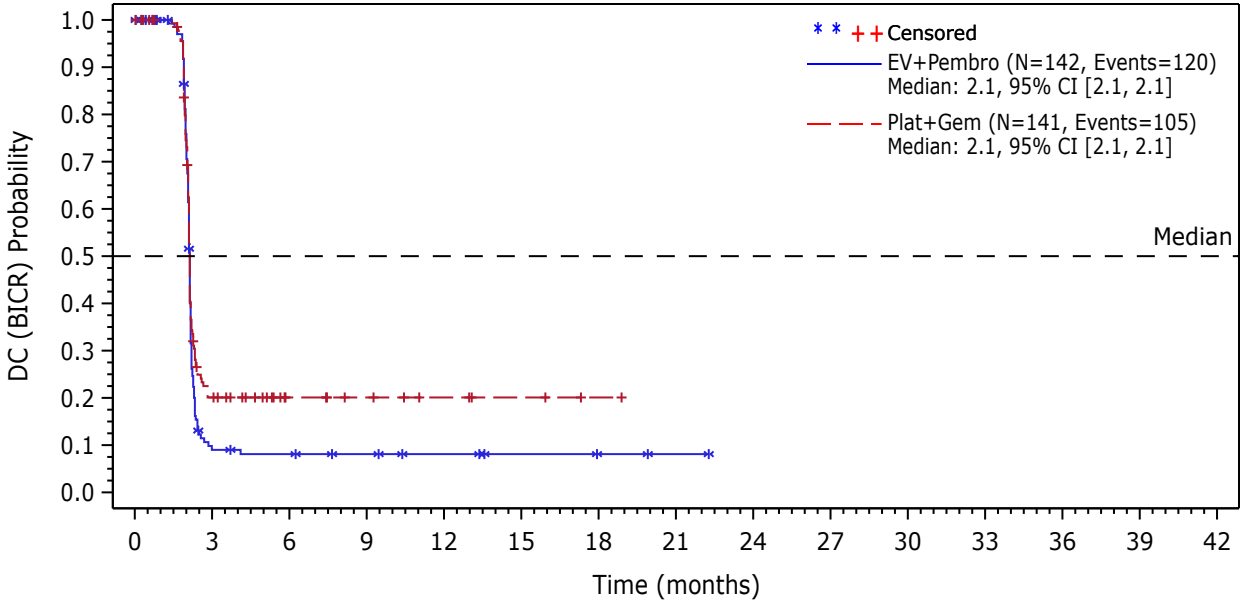
1	146	12	8	6	4	2	1	1	0	0	0	0	0	0	0
2	151	30	16	9	5	2	1	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.2.6: Kaplan-Meier Plot of Disease Control (BICR) by Race - Analysis Set mITT 2
Race: White



at Risk

1	142	11	9	7	5	3	2	1	0	0	0	0	0	0	0
2	141	25	11	8	5	3	1	0	0	0	0	0	0	0	0

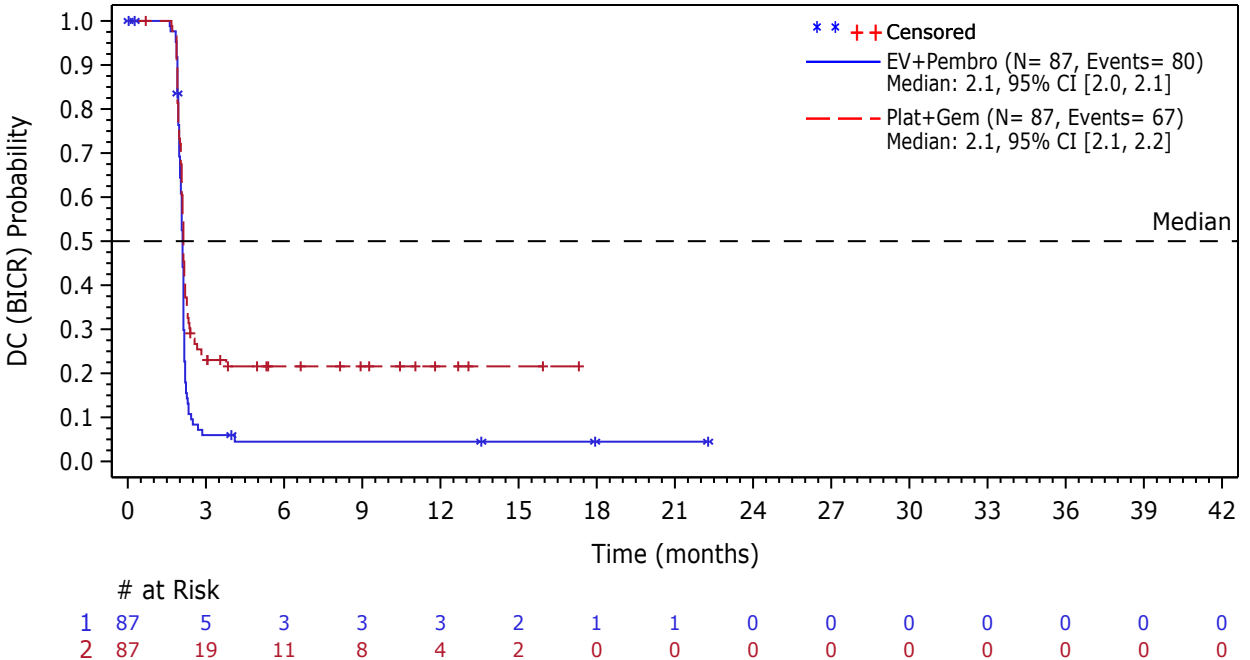
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.2.7: Kaplan-Meier Plot of Disease Control (BICR) by ECOG Status at Baseline - Analysis Set mITT 2

ECOG Status at Baseline: 0



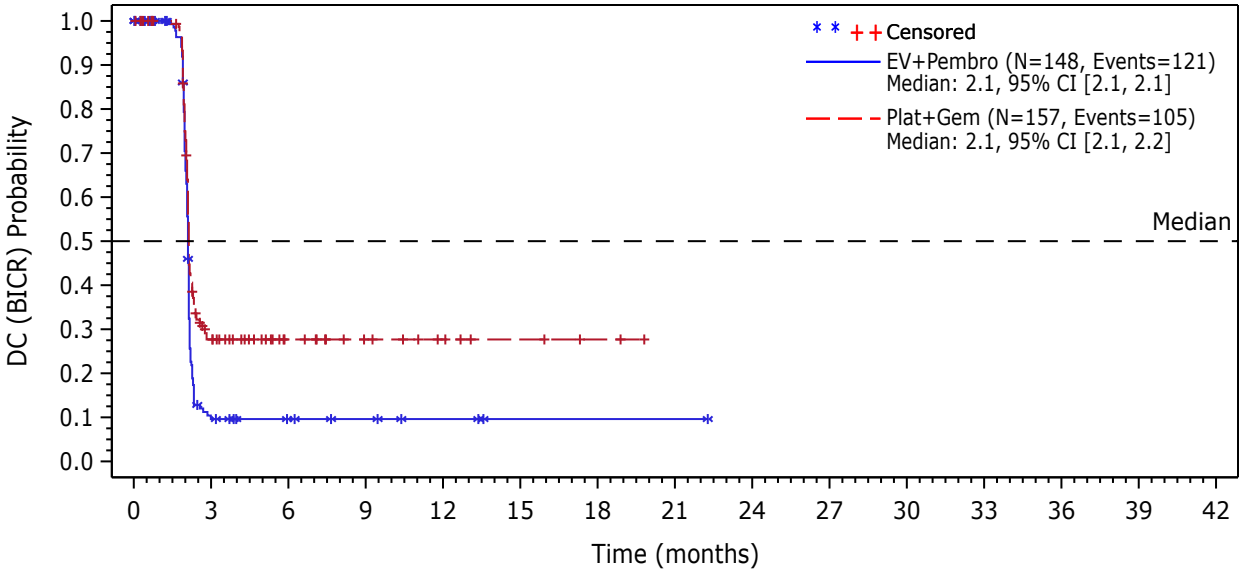
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.2.8: Kaplan-Meier Plot of Disease Control (BICR) by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Visceral metastases



at Risk

1	148	12	7	5	3	1	1	1	0	0	0	0	0	0	0
2	157	36	18	11	7	4	2	0	0	0	0	0	0	0	0

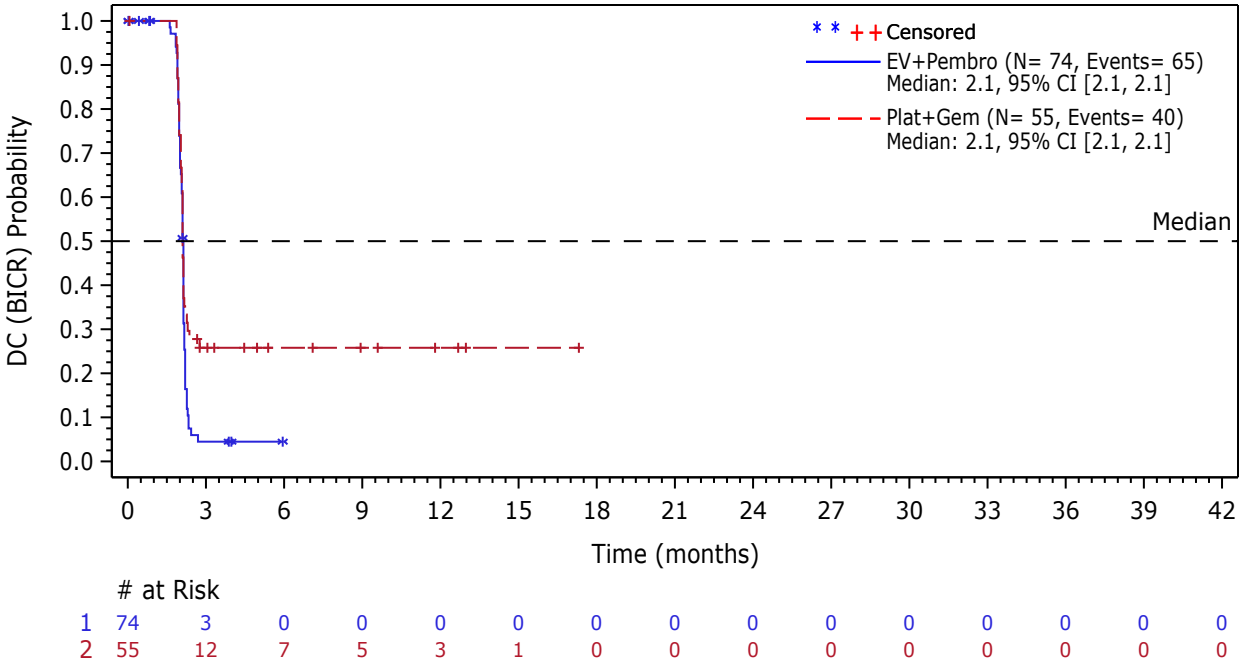
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.2.9: Kaplan-Meier Plot of Disease Control (BICR) by Primary Disease Site of Origin - Analysis Set mITT 2

Primary Disease Site of Origin: Upper tract



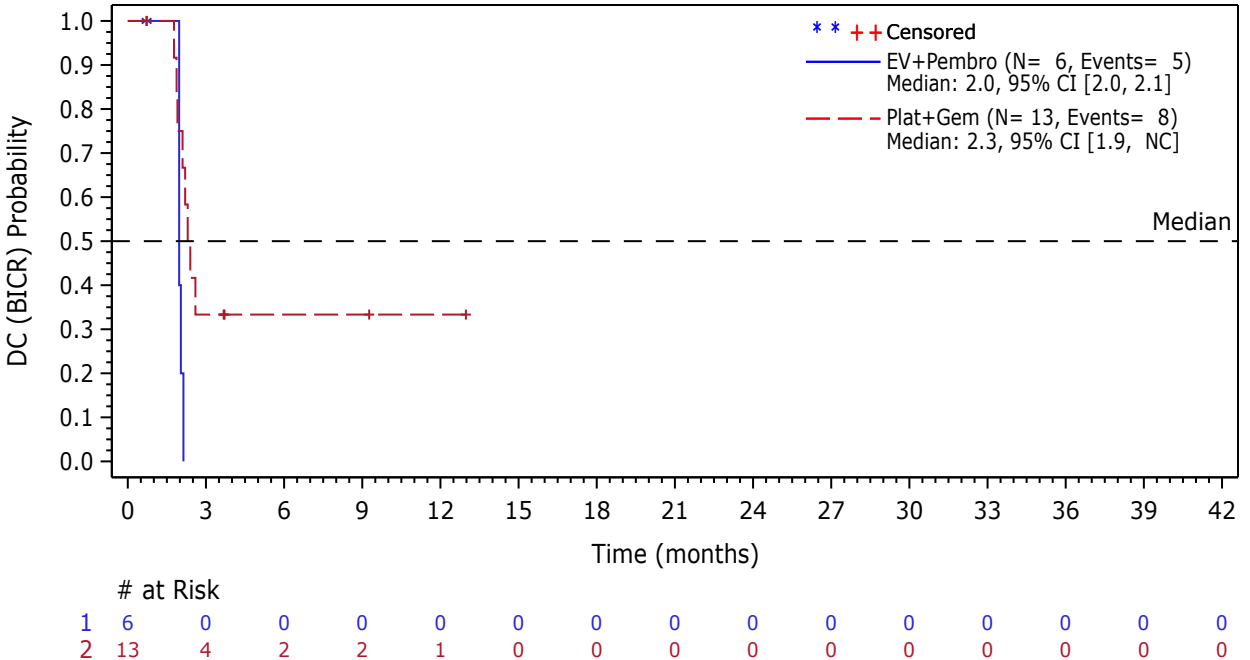
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.2.10: Kaplan-Meier Plot of Disease Control (BICR) by Renal Function - Analysis Set mITT 2

Renal Function: Normal



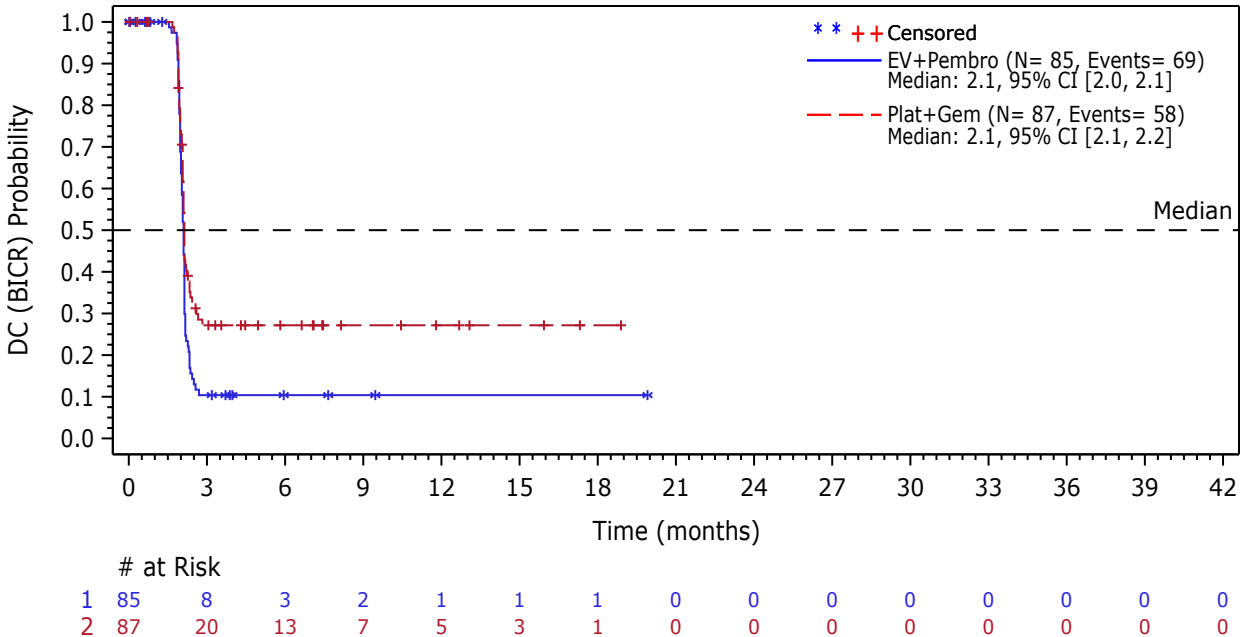
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.2.1: Kaplan-Meier Plot of Disease Control (BICR) by PD-L1 Expression - Analysis Set mITT 2

PD-L1 Expression: Low (CPS<10)



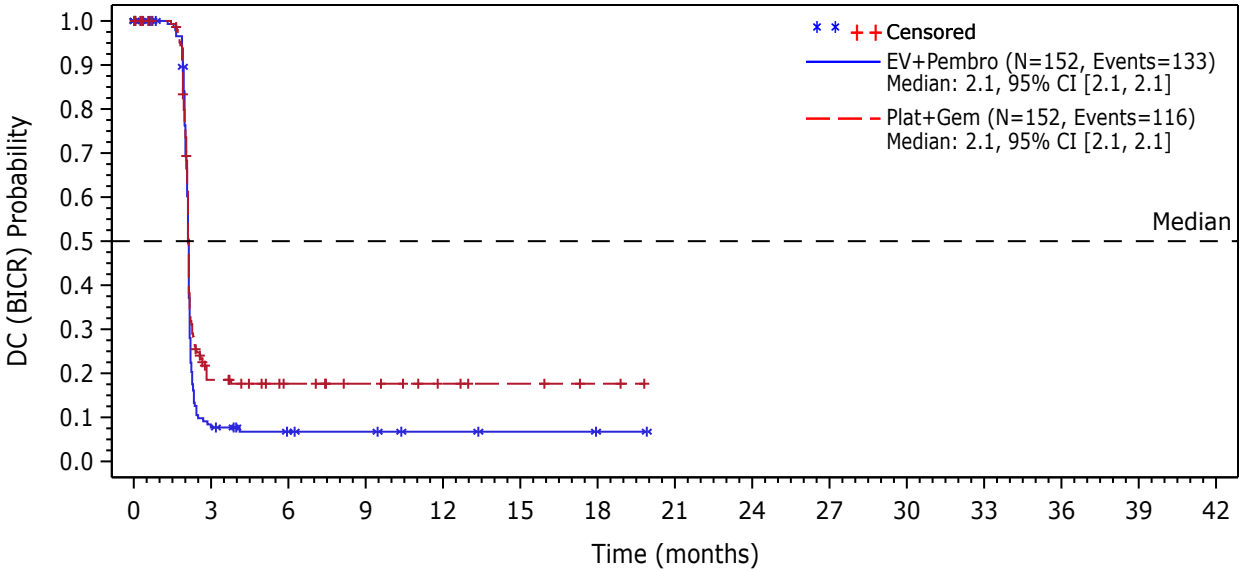
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.2.2: Kaplan-Meier Plot of Disease Control (BICR) by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Absent



at Risk

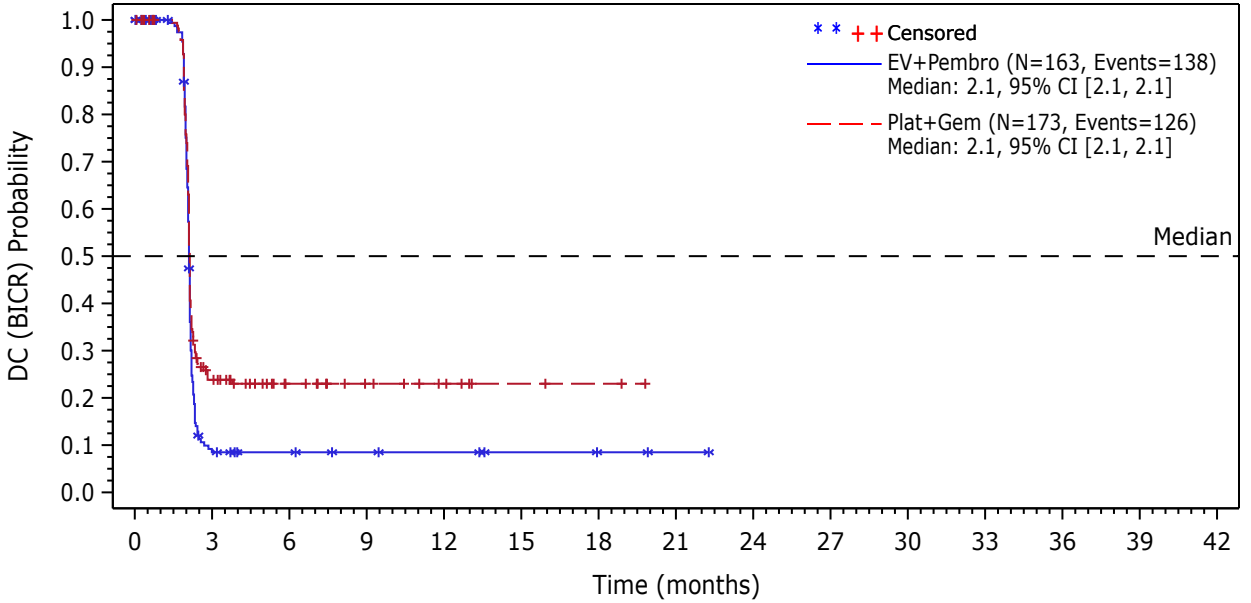
1	152	11	6	5	3	2	1	0	0	0	0	0	0	0	0
2	152	23	14	10	6	4	2	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.2.3: Kaplan-Meier Plot of Disease Control (BICR) by Age - Analysis Set mITT 2
Age: >= 65 years



at Risk

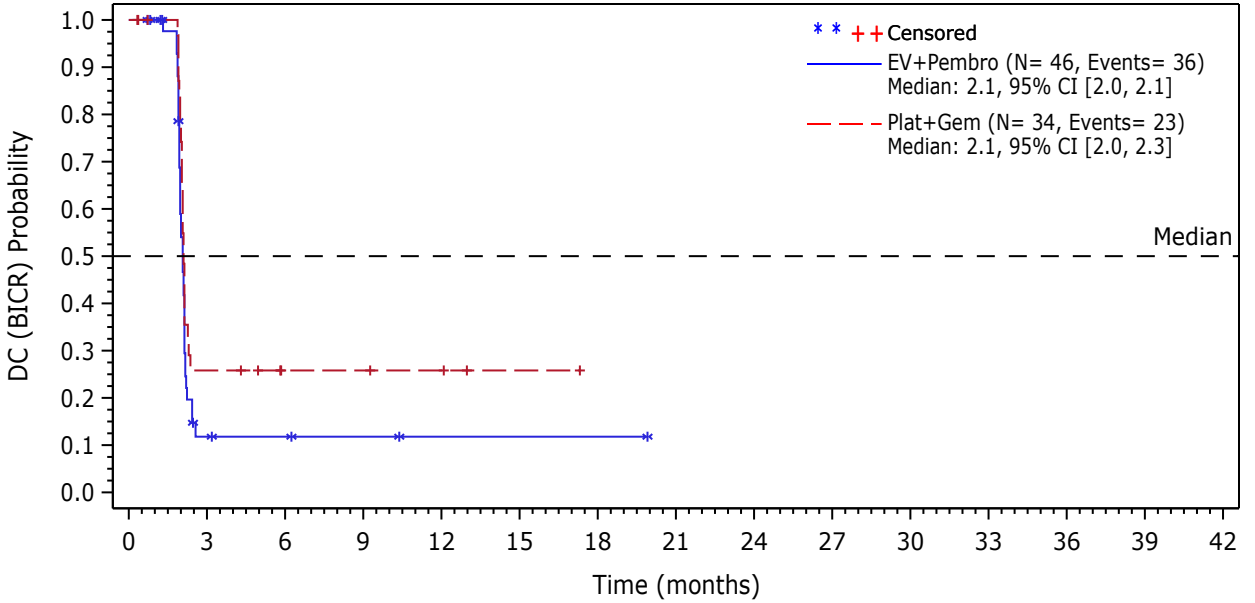
1	163	12	8	6	5	3	2	1	0	0	0	0	0	0	0
2	173	35	18	11	7	3	2	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.2.4: Kaplan-Meier Plot of Disease Control (BICR) by Region - Analysis Set mITT 2
Region: North America



at Risk

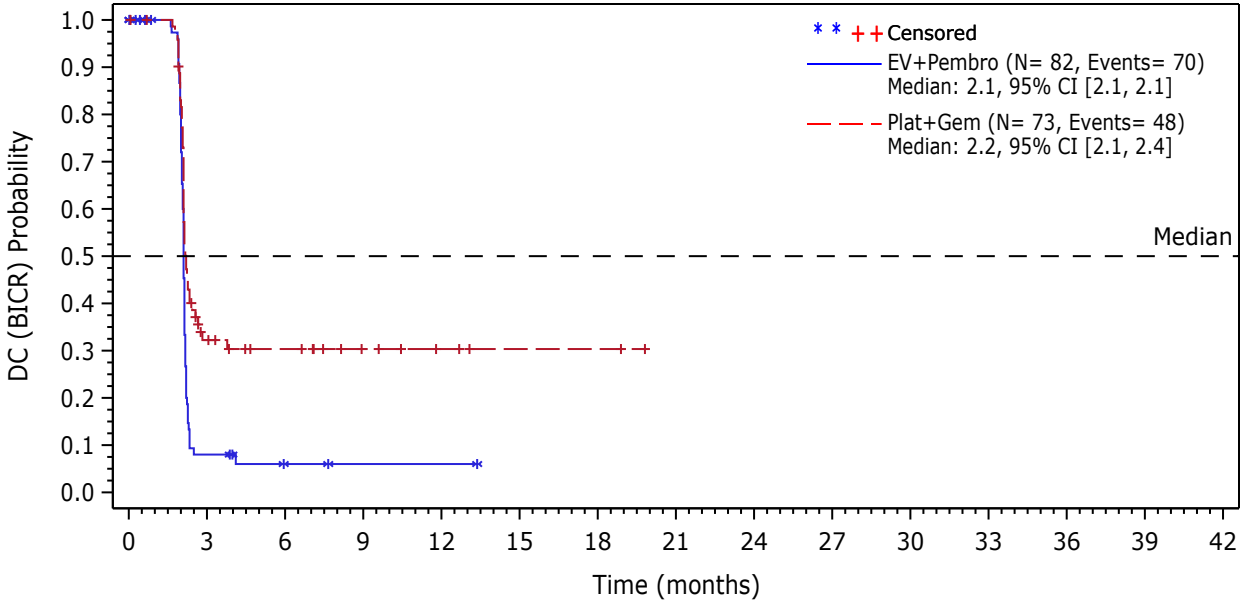
1	46	4	3	2	1	1	1	0	0	0	0	0	0	0	0
2	34	8	4	4	3	1	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.2.4: Kaplan-Meier Plot of Disease Control (BICR) by Region - Analysis Set mITT 2 Region: Rest of World



at Risk

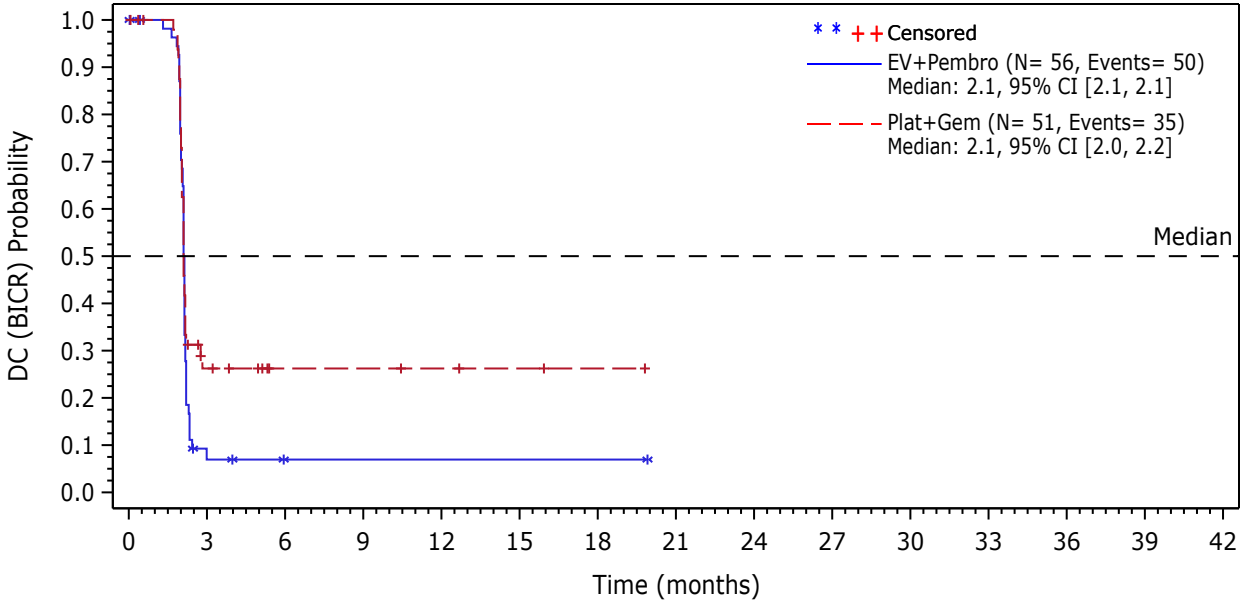
1	82	6	2	1	1	0	0	0	0	0	0	0	0	0	0
2	73	19	13	7	4	2	2	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.2.5: Kaplan-Meier Plot of Disease Control (BICR) by Sex - Analysis Set mITT 2
Sex: Female



at Risk

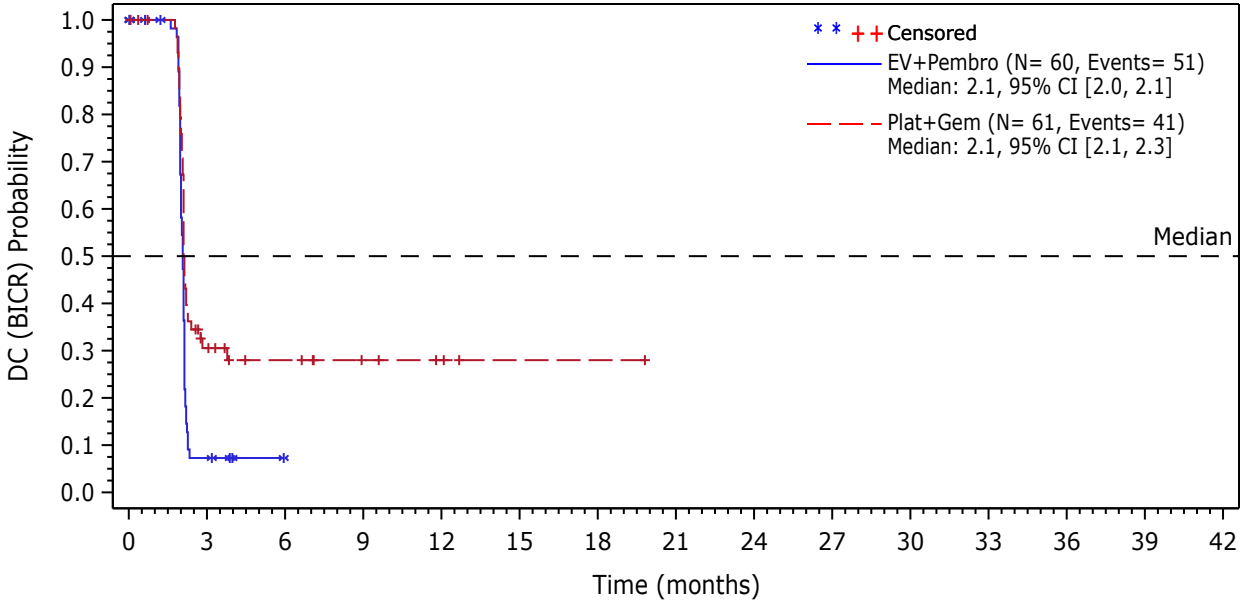
1	56	3	1	1	1	1	1	0	0	0	0	0	0	0	0
2	51	10	4	4	3	2	1	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.2.6: Kaplan-Meier Plot of Disease Control (BICR) by Race - Analysis Set mITT 2
Race: Non-white



at Risk

1	60	4	0	0	0	0	0	0	0	0	0	0	0	0	0
2	61	15	9	5	3	1	1	0	0	0	0	0	0	0	0

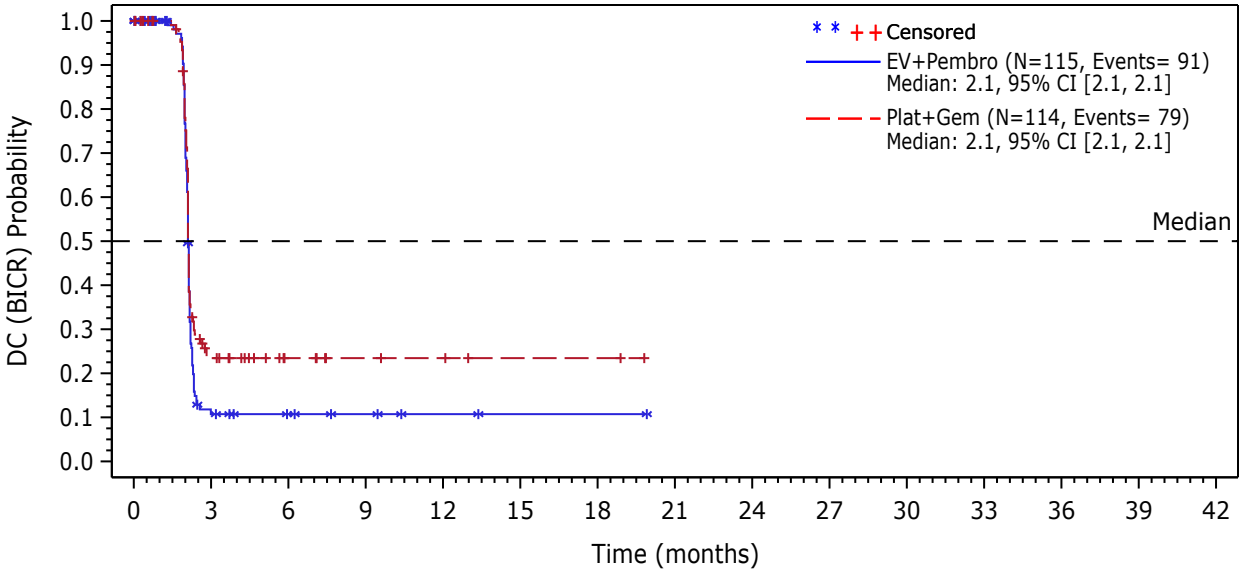
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.2.7: Kaplan-Meier Plot of Disease Control (BICR) by ECOG Status at Baseline - Analysis Set mITT 2

ECOG Status at Baseline: 1-2



at Risk

1	115	10	6	4	2	1	1	0	0	0	0	0	0	0	0
2	114	21	9	5	4	2	2	0	0	0	0	0	0	0	0

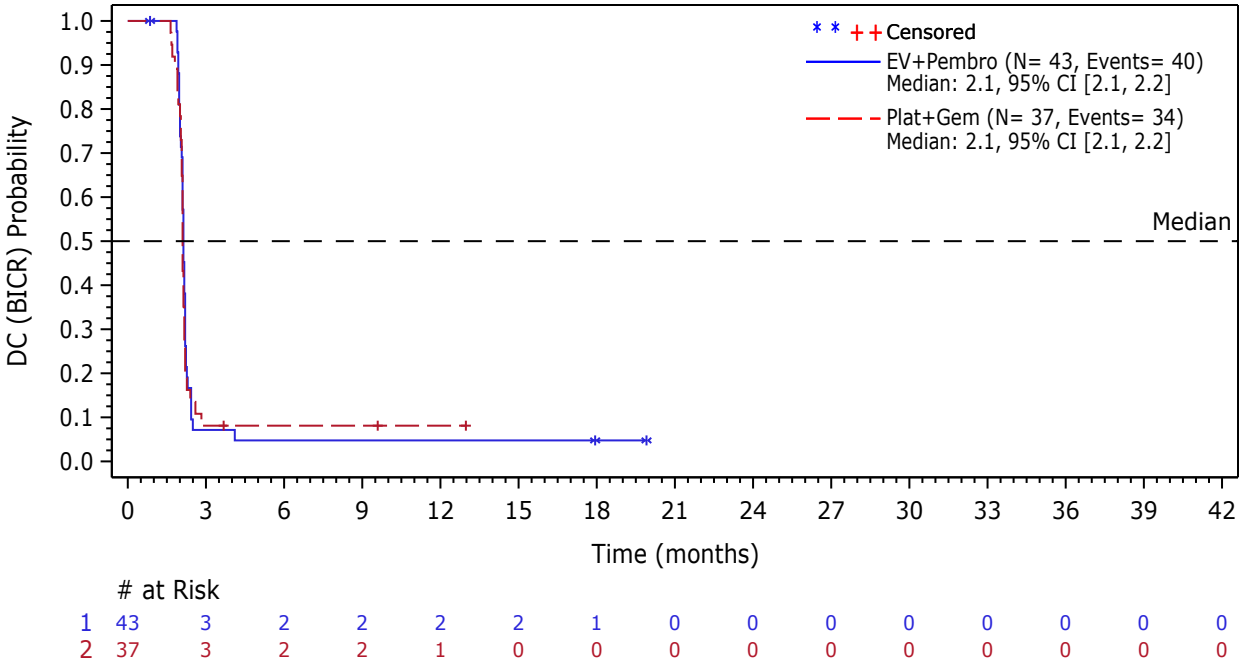
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.2.8: Kaplan-Meier Plot of Disease Control (BICR) by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Lymph node only



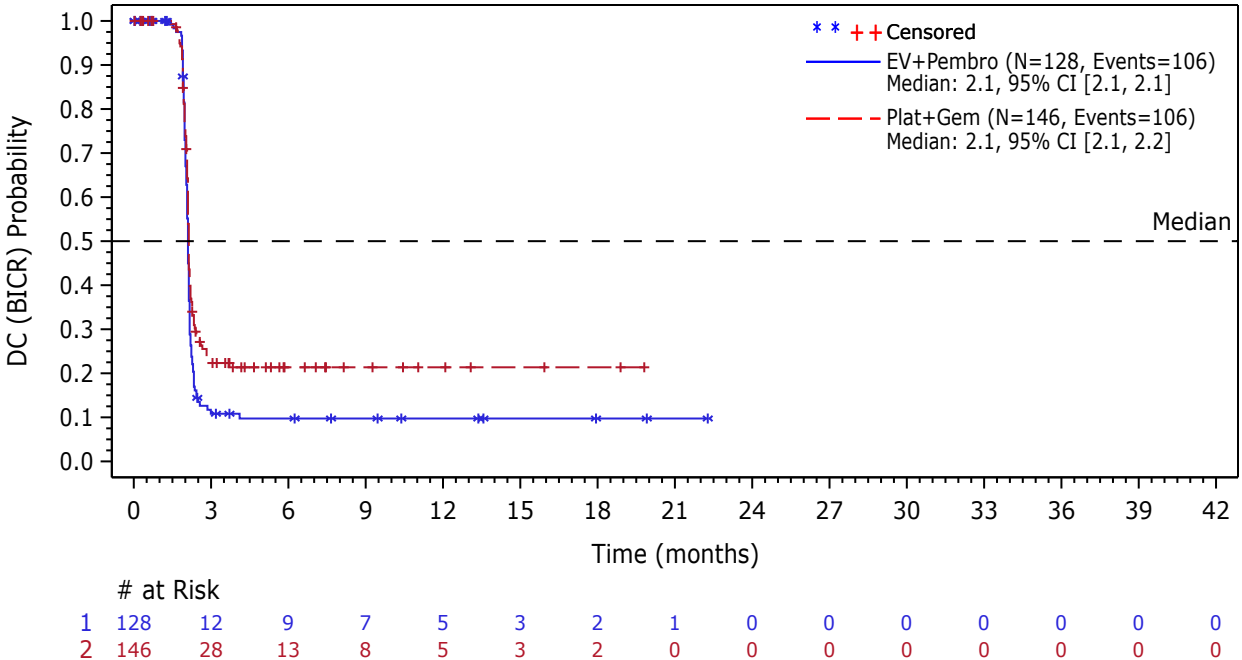
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.2.9: Kaplan-Meier Plot of Disease Control (BICR) by Primary Disease Site of Origin - Analysis Set mITT 2

Primary Disease Site of Origin: Lower tract



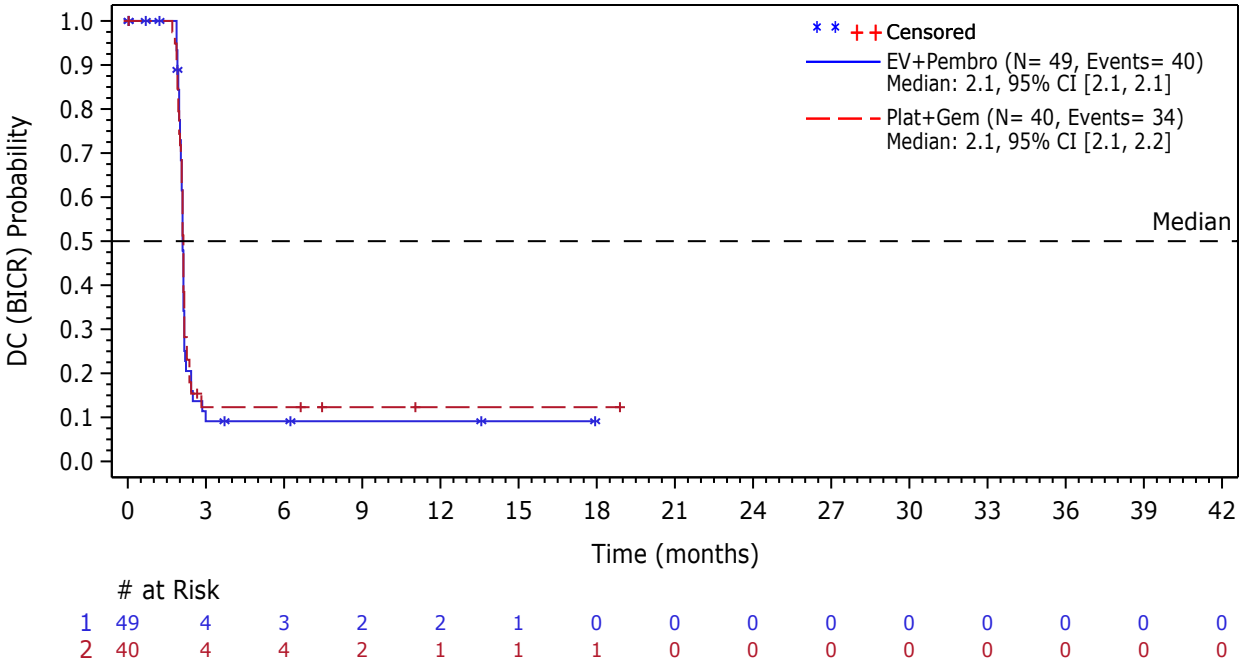
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.2.10: Kaplan-Meier Plot of Disease Control (BICR) by Renal Function - Analysis Set mITT 2

Renal Function: Mild



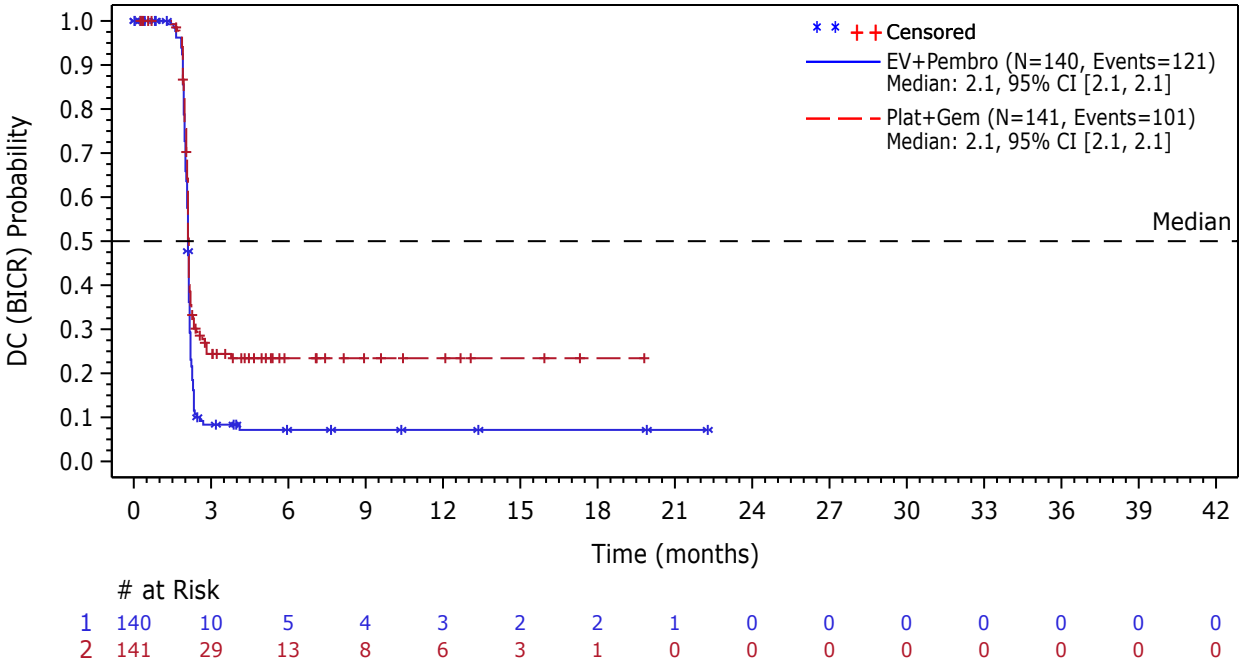
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.2.10: Kaplan-Meier Plot of Disease Control (BICR) by Renal Function - Analysis Set mITT 2

Renal Function: Moderate



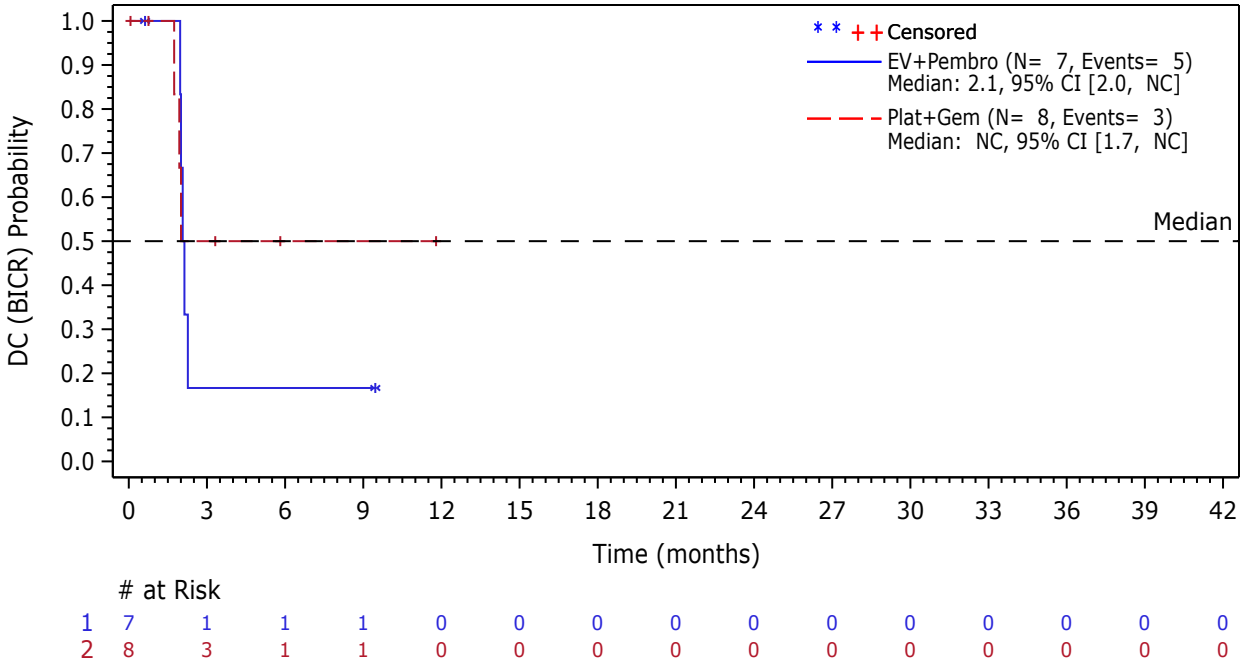
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.8.2.10: Kaplan-Meier Plot of Disease Control (BICR) by Renal Function - Analysis Set mITT 2

Renal Function: Severe

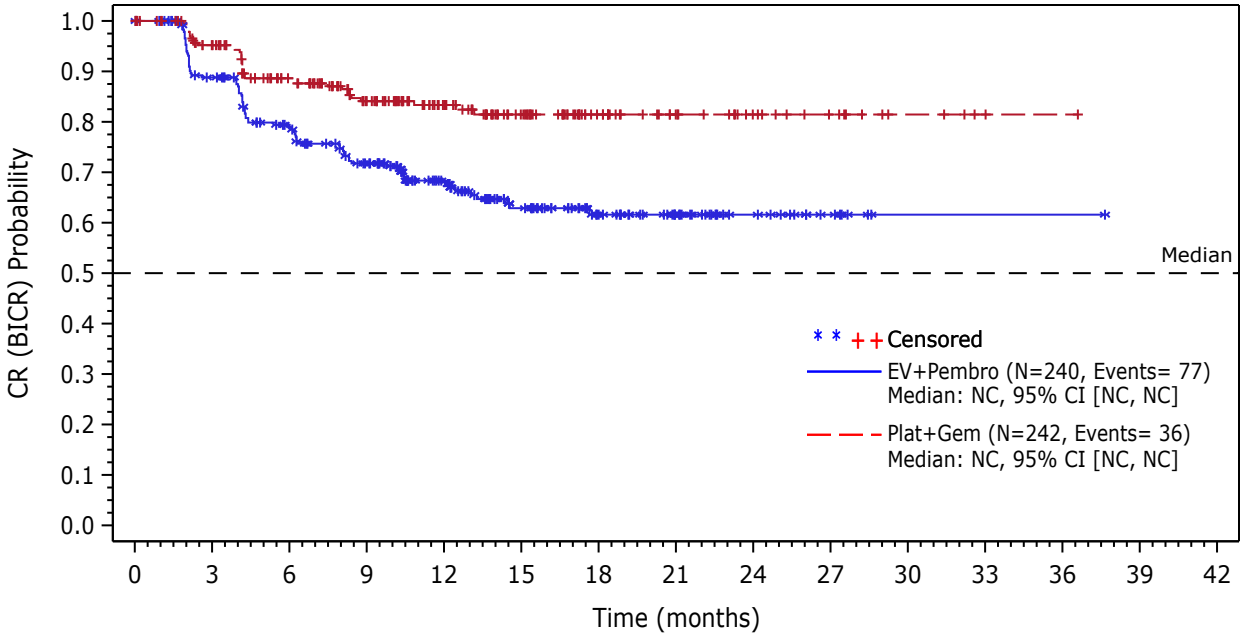


Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; DC=disease control; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Disease control was defined as first subsequently confirmed response (complete or partial response) or stable disease.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.1: Kaplan-Meier Plot of Complete Response (BICR) - Analysis Set mITT 1



at Risk

1	240	204	171	143	101	68	45	29	15	7	1	1	1	0	0
2	242	212	174	136	97	68	41	26	17	11	5	2	1	0	0

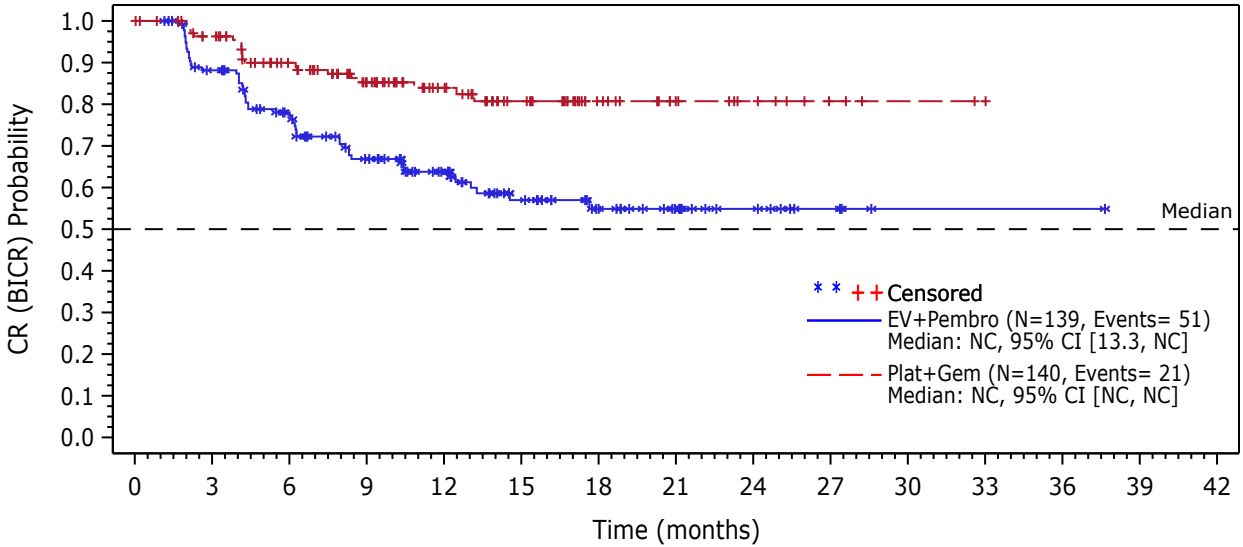
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.1.1: Kaplan-Meier Plot of Complete Response (BICR) by PD-L1 Expression - Analysis Set mITT 1

PD-L1 Expression: High (CPS>=10)



at Risk

1	139	117	95	73	55	35	24	15	9	4	1	1	1	0	0
2	140	127	104	81	57	39	22	13	9	4	2	1	0	0	0

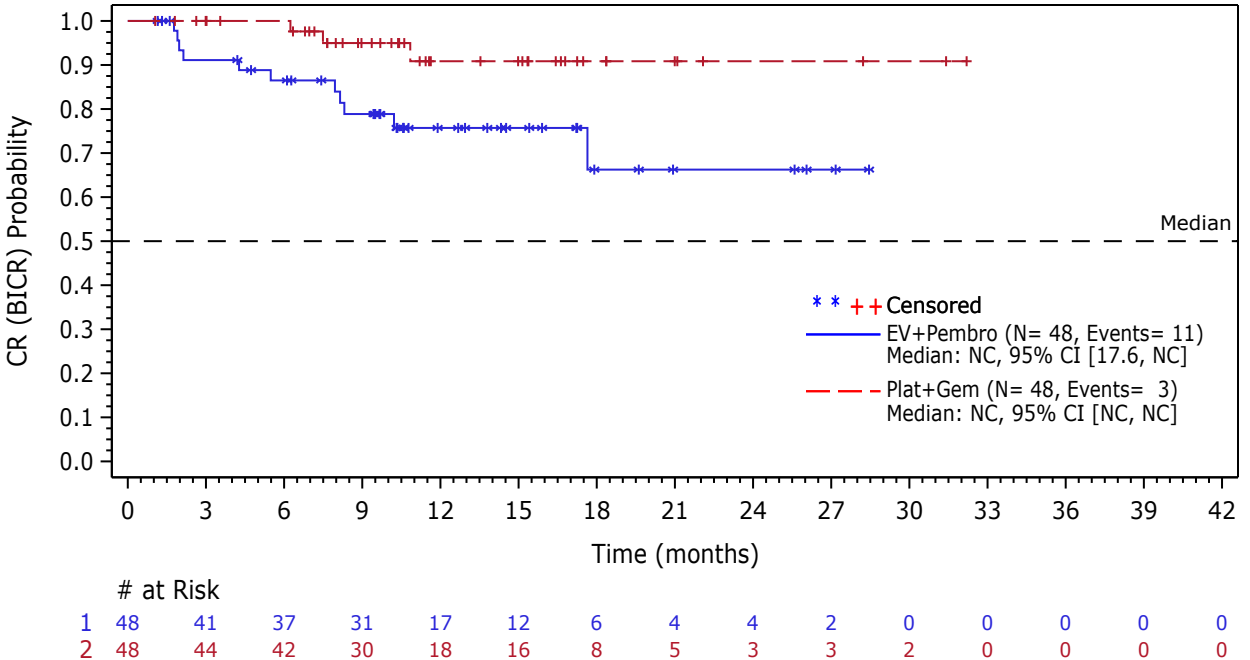
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.1.2: Kaplan-Meier Plot of Complete Response (BICR) by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Present

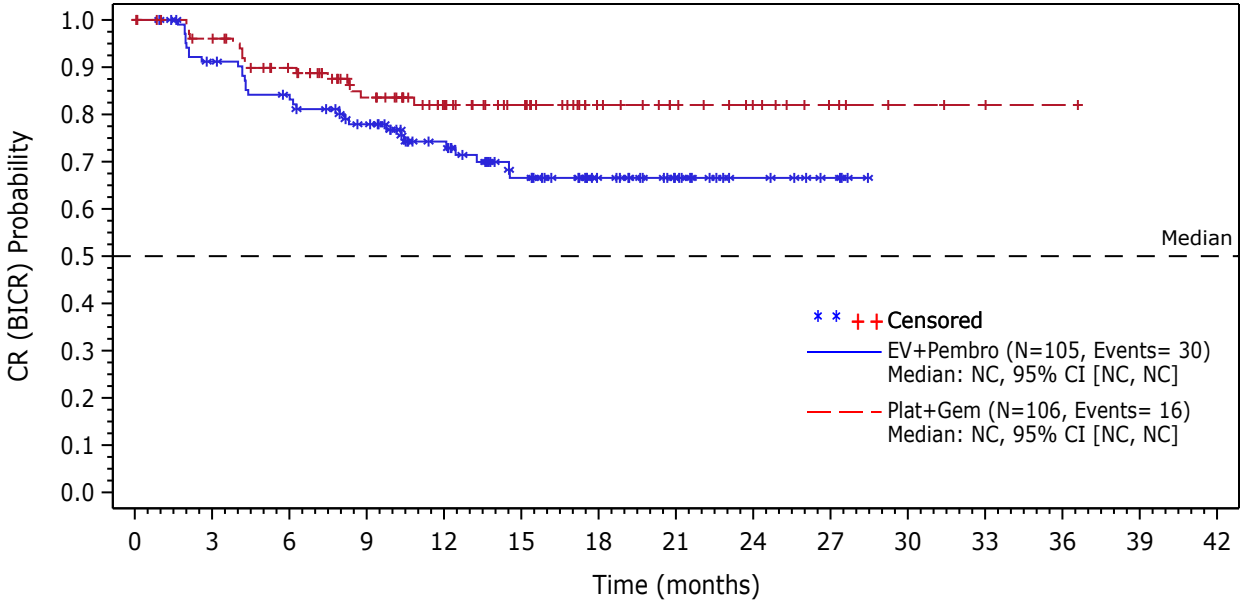


Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.1.3: Kaplan-Meier Plot of Complete Response (BICR) by Age - Analysis Set mITT 1
Age: < 65 years



at Risk

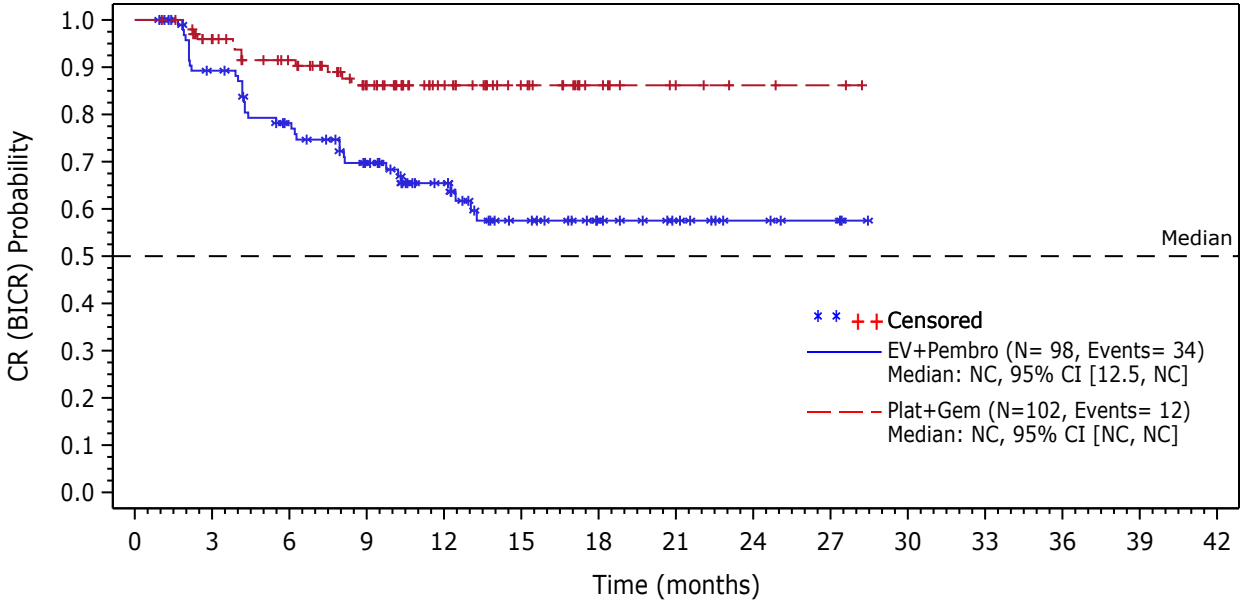
1	105	92	83	71	54	39	26	16	8	4	0	0	0	0	0
2	106	96	82	63	47	35	22	16	11	6	3	2	1	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.1.4: Kaplan-Meier Plot of Complete Response (BICR) by Region - Analysis Set mITT 1 Region: Europe



at Risk

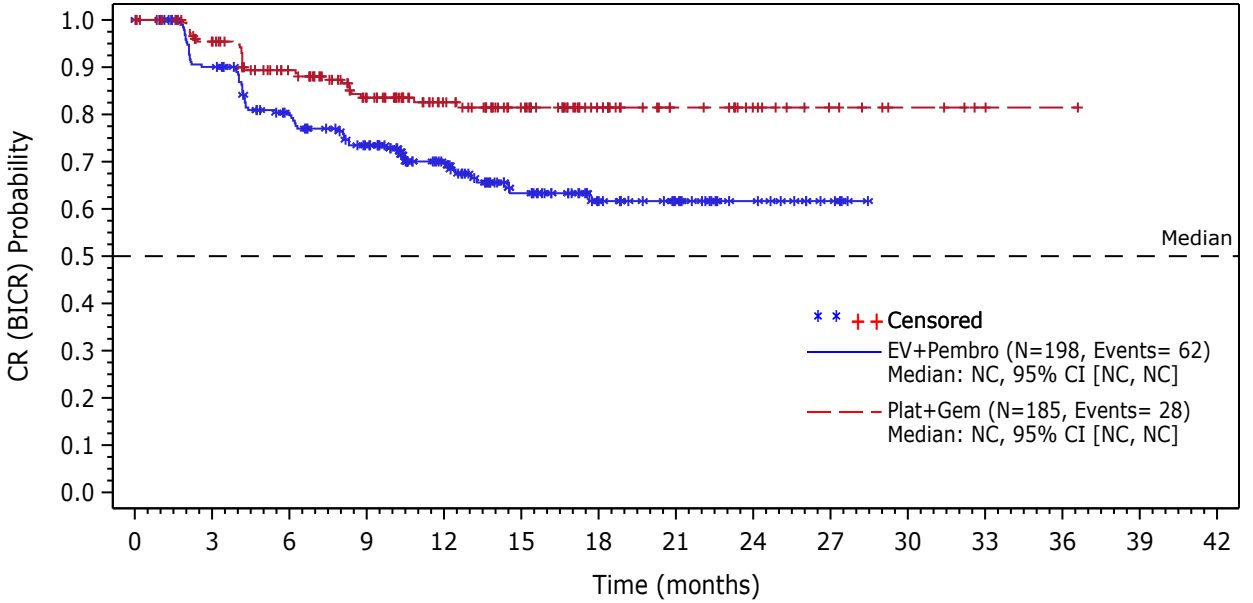
1	98	82	67	54	38	23	15	10	5	3	0	0	0	0	0
2	102	89	76	57	35	22	11	5	3	2	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.1.5: Kaplan-Meier Plot of Complete Response (BICR) by Sex - Analysis Set mITT 1
Sex: Male



at Risk

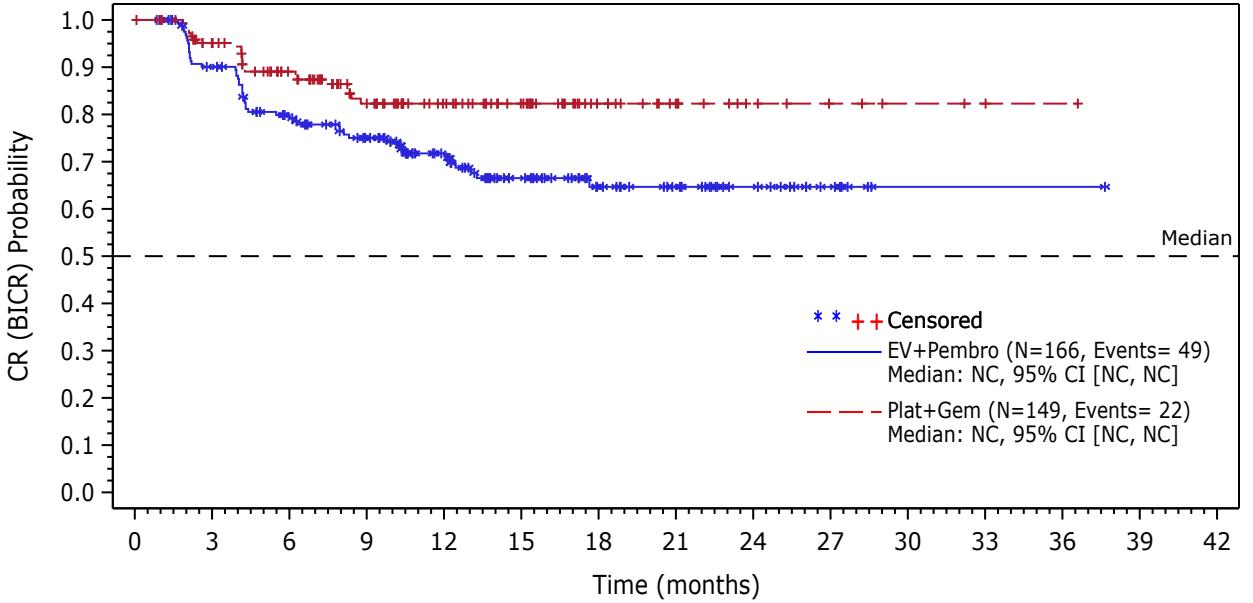
1	198	172	143	121	85	55	35	24	12	5	0	0	0	0	0
2	185	163	135	106	77	57	36	22	15	9	5	2	1	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.1.6: Kaplan-Meier Plot of Complete Response (BICR) by Race - Analysis Set mITT 1 Race: White



at Risk

1	166	144	120	102	73	50	33	25	15	7	1	1	1	0	0
2	149	130	106	78	57	42	23	14	8	5	3	2	1	0	0

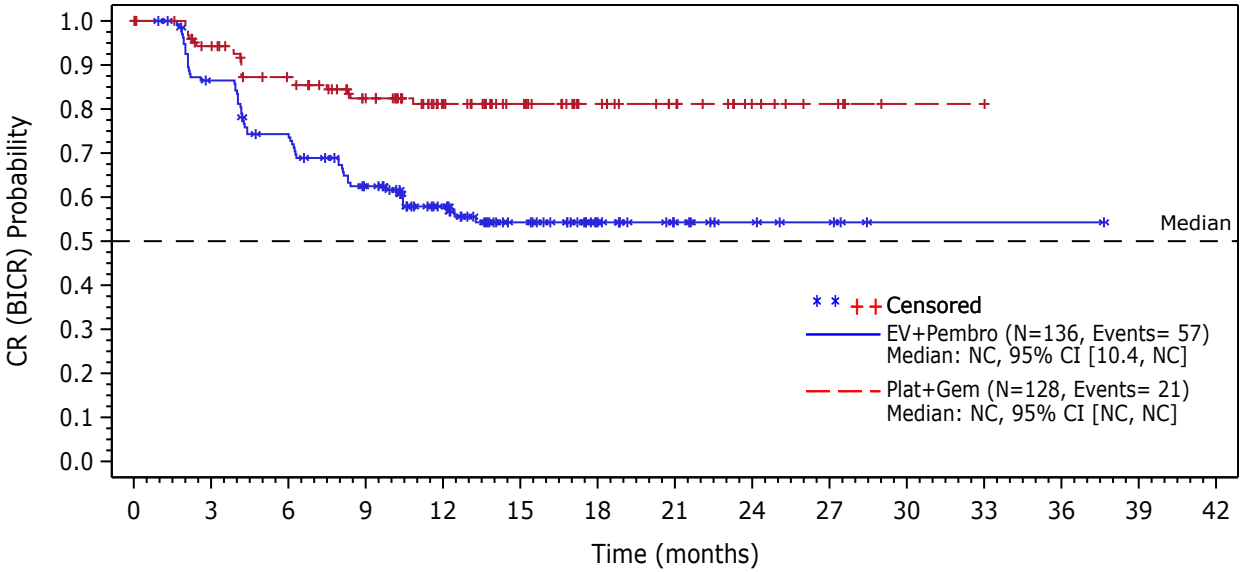
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.1.7: Kaplan-Meier Plot of Complete Response (BICR) by ECOG Status at Baseline - Analysis Set mITT 1

ECOG Status at Baseline: 0



at Risk

1	136	114	96	76	53	34	19	10	6	4	1	1	1	0	0
2	128	112	96	78	54	38	25	17	9	5	1	1	0	0	0

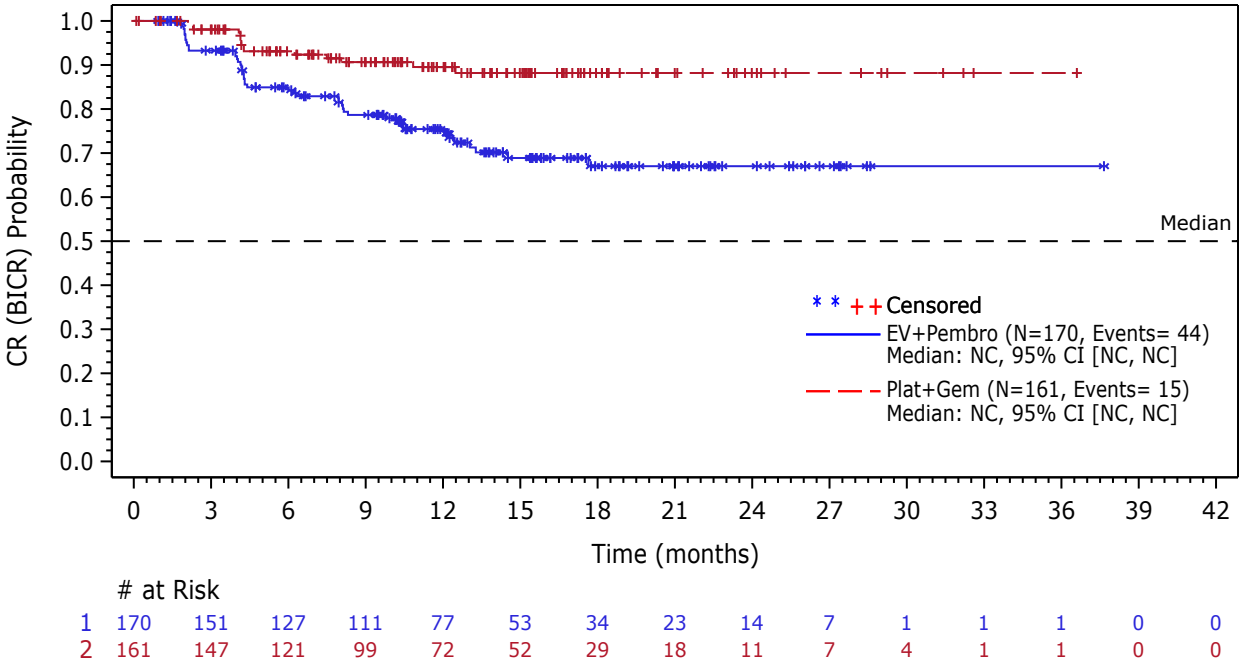
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.1.8: Kaplan-Meier Plot of Complete Response (BICR) by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Visceral metastases



at Risk

1	170	151	127	111	77	53	34	23	14	7	1	1	1	0	0
2	161	147	121	99	72	52	29	18	11	7	4	1	1	0	0

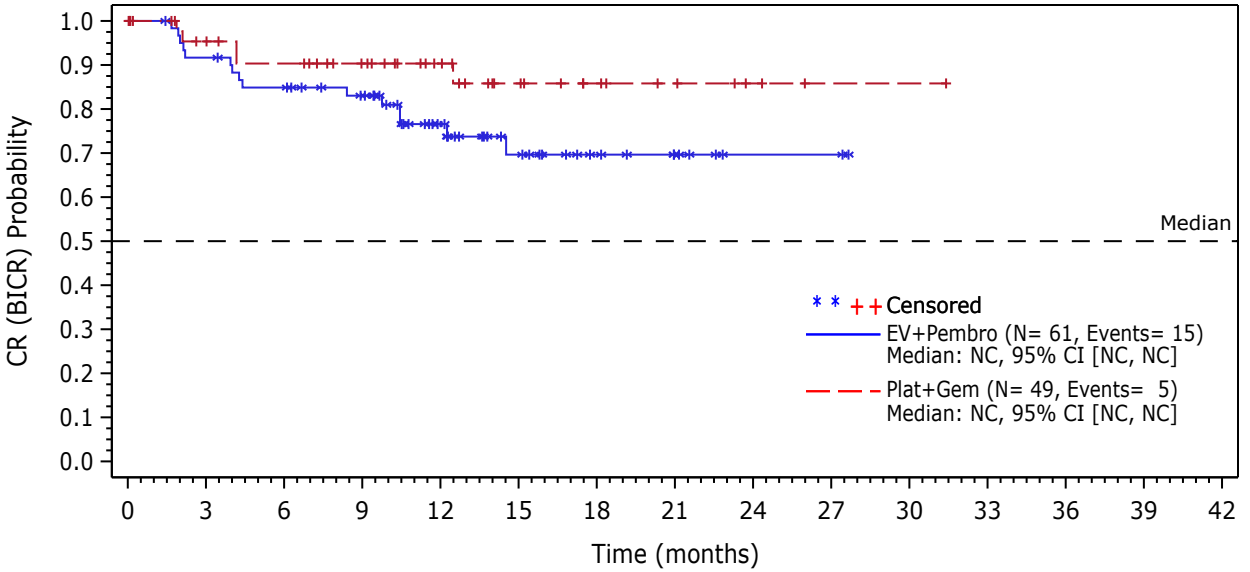
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.1.9: Kaplan-Meier Plot of Complete Response (BICR) by Primary Disease Site of Origin - Analysis Set mITT 1

Primary Disease Site of Origin: Upper tract



at Risk

1	61	55	50	44	28	17	10	6	2	2	0	0	0	0	0
2	49	40	36	30	22	14	9	6	3	1	1	0	0	0	0

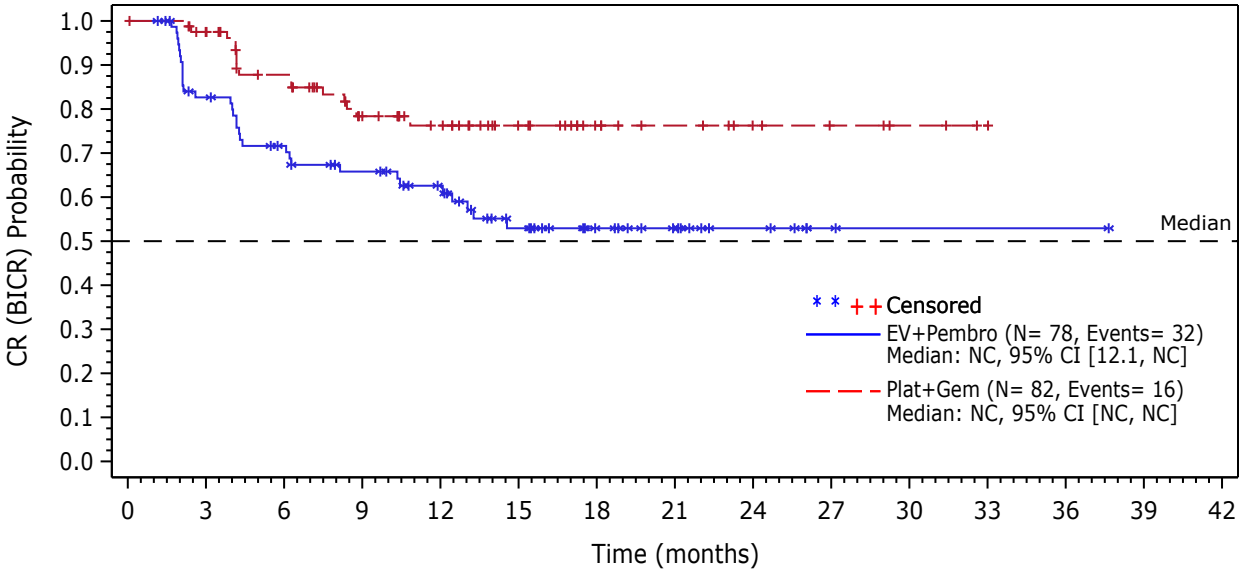
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.1.10: Kaplan-Meier Plot of Complete Response (BICR) by Renal Function - Analysis Set mITT 1

Renal Function: Normal



at Risk

1	78	61	50	43	36	24	16	11	6	2	1	1	1	0	0
2	82	75	61	45	35	24	15	11	7	5	3	1	0	0	0

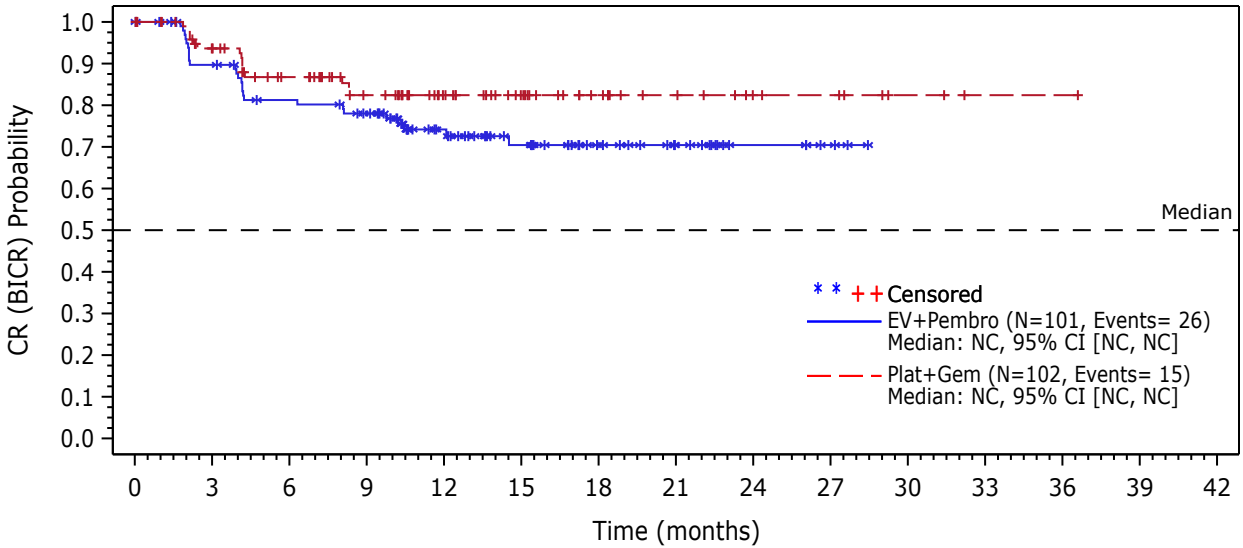
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.1.1: Kaplan-Meier Plot of Complete Response (BICR) by PD-L1 Expression - Analysis Set mITT 1

PD-L1 Expression: Low (CPS<10)



at Risk

1	101	87	76	70	46	33	21	14	6	3	0	0	0	0	0
2	102	85	70	55	40	29	19	13	8	7	3	1	1	0	0

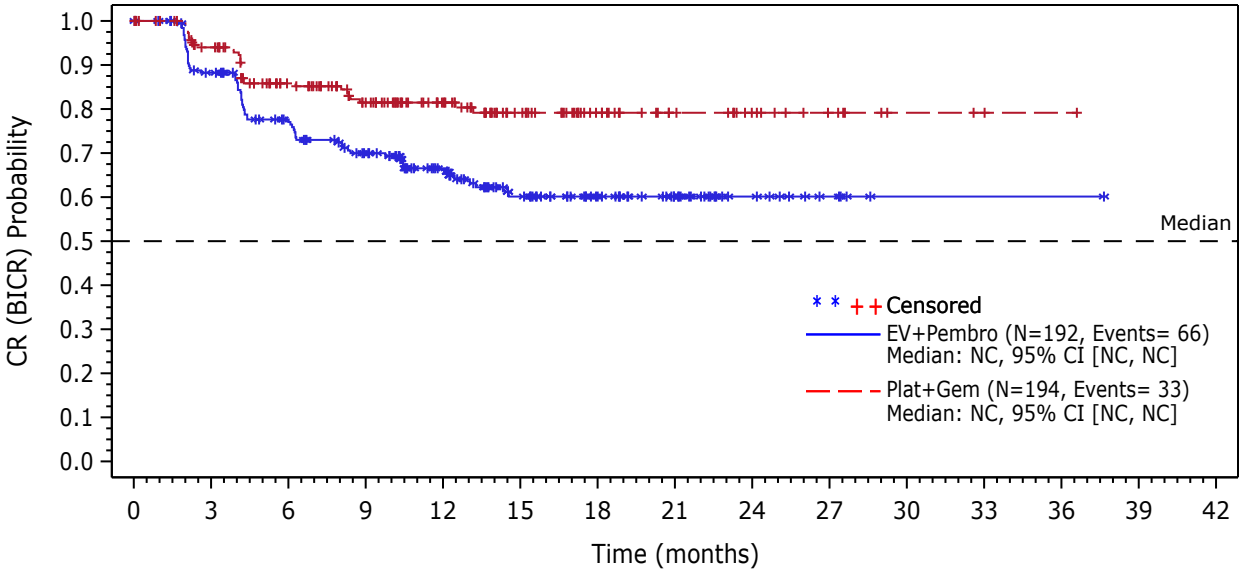
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.1.2: Kaplan-Meier Plot of Complete Response (BICR) by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Absent



at Risk

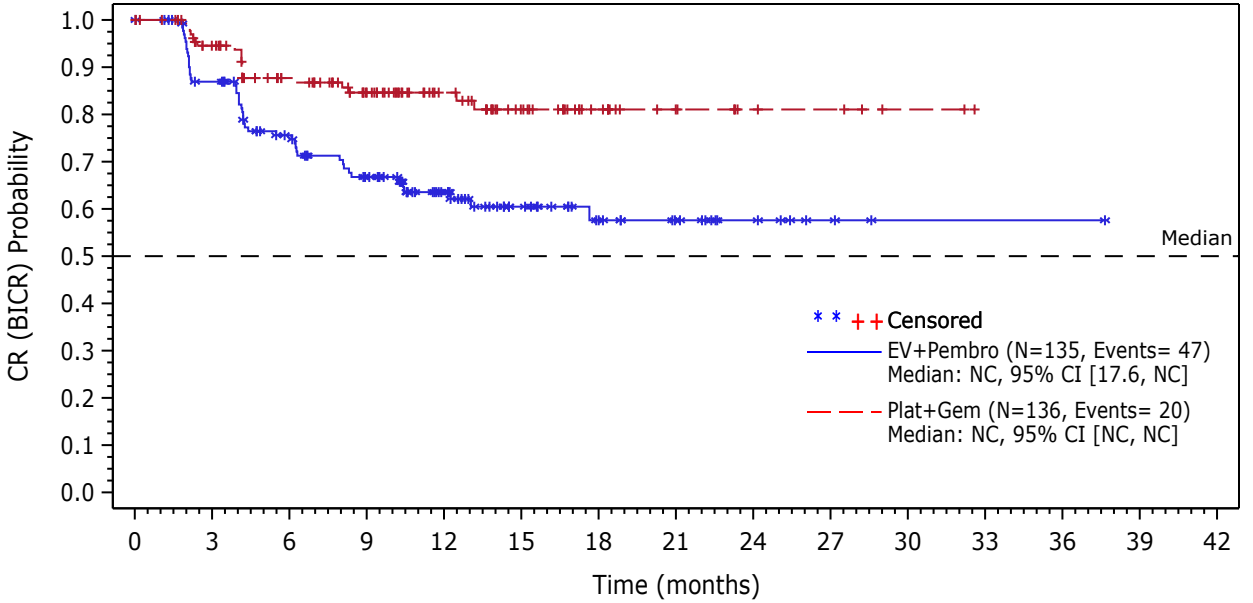
1	192	163	134	112	84	56	39	25	11	5	1	1	1	0	0
2	194	168	132	106	79	52	33	21	14	8	3	2	1	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.1.3: Kaplan-Meier Plot of Complete Response (BICR) by Age - Analysis Set mITT 1
Age: >= 65 years



at Risk

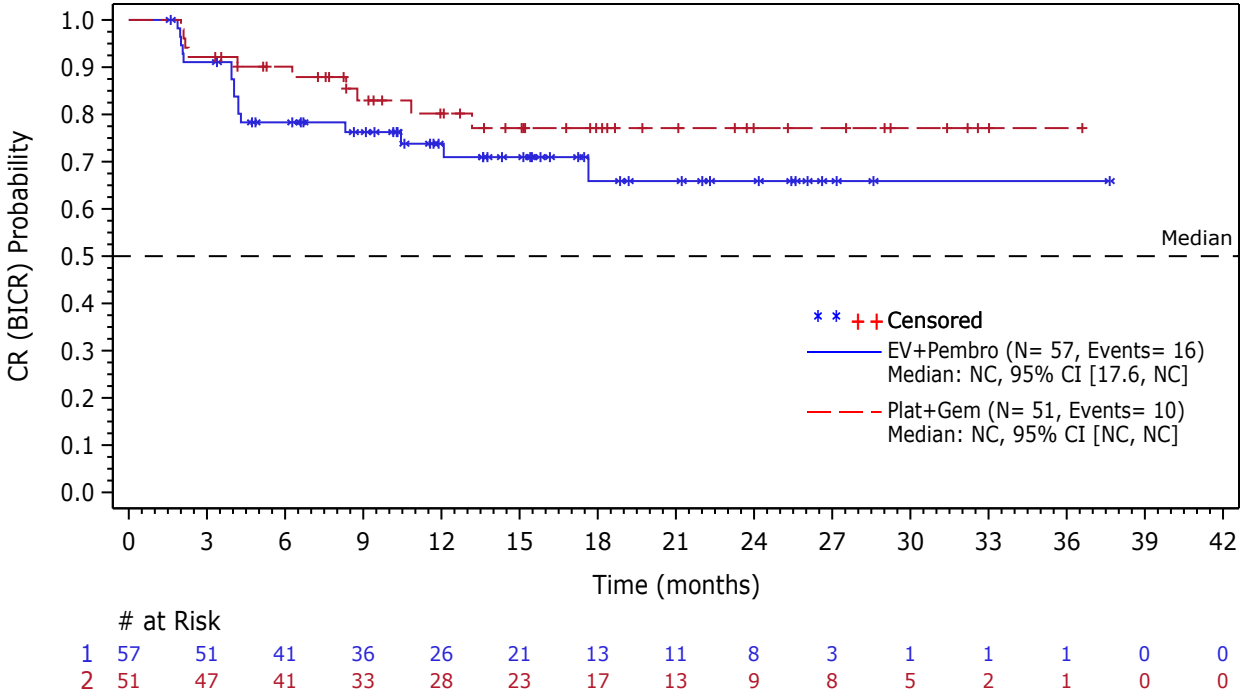
1	135	112	88	72	47	29	19	13	7	3	1	1	1	0	0
2	136	116	92	73	50	33	19	10	6	5	2	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.1.4: Kaplan-Meier Plot of Complete Response (BICR) by Region - Analysis Set mITT 1 Region: North America

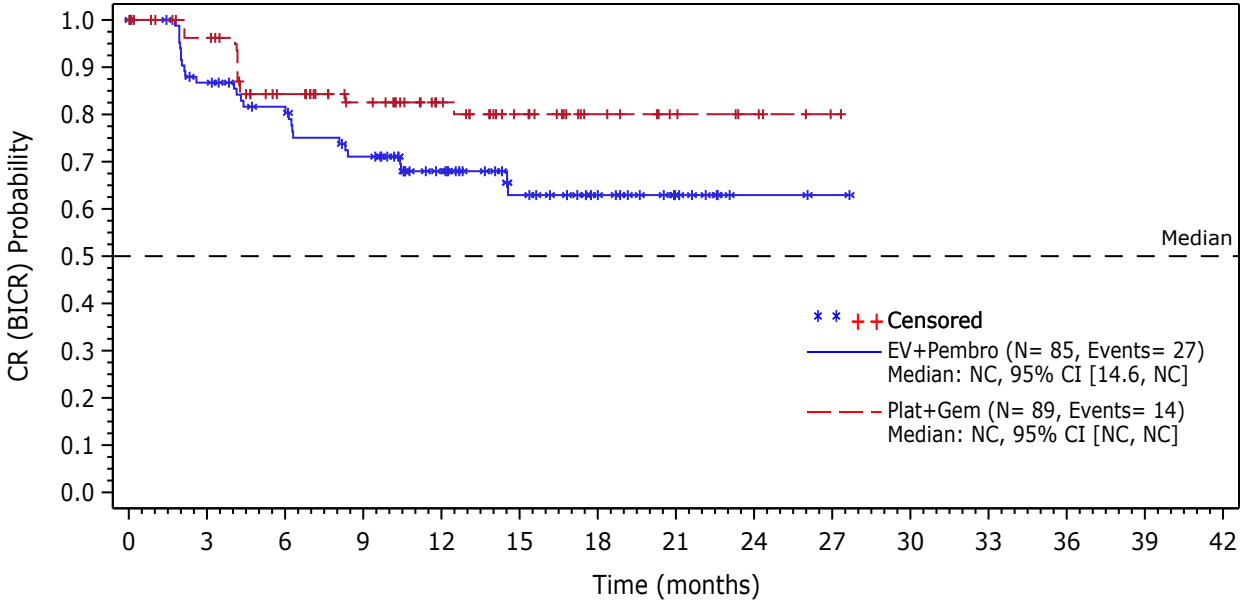


Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.1.4: Kaplan-Meier Plot of Complete Response (BICR) by Region - Analysis Set mITT 1 Region: Rest of World



at Risk

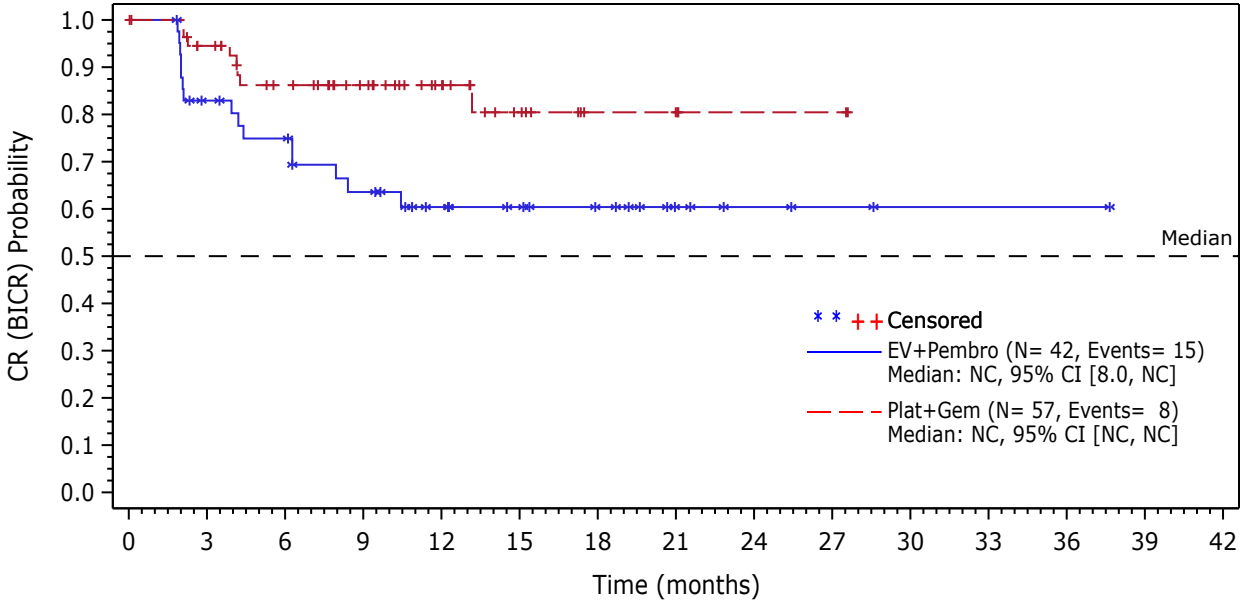
1	85	71	63	53	37	24	17	8	2	1	0	0	0	0	0
2	89	76	57	46	34	23	13	8	5	1	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.1.5: Kaplan-Meier Plot of Complete Response (BICR) by Sex - Analysis Set mITT 1
Sex: Female



at Risk

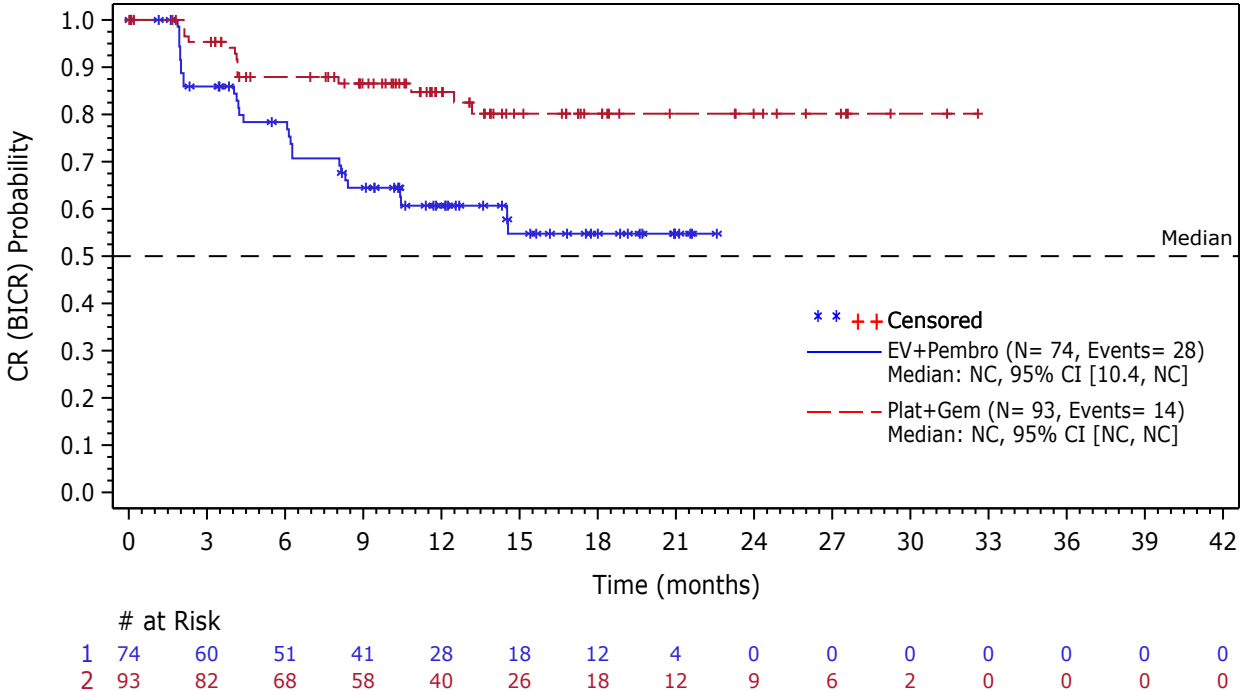
1	42	32	28	22	16	13	10	5	3	2	1	1	1	0	0
2	57	49	39	30	20	11	5	4	2	2	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.1.6: Kaplan-Meier Plot of Complete Response (BICR) by Race - Analysis Set mITT 1
Race: Non-white



at Risk

1	74	60	51	41	28	18	12	4	0	0	0	0	0	0	0
2	93	82	68	58	40	26	18	12	9	6	2	0	0	0	0

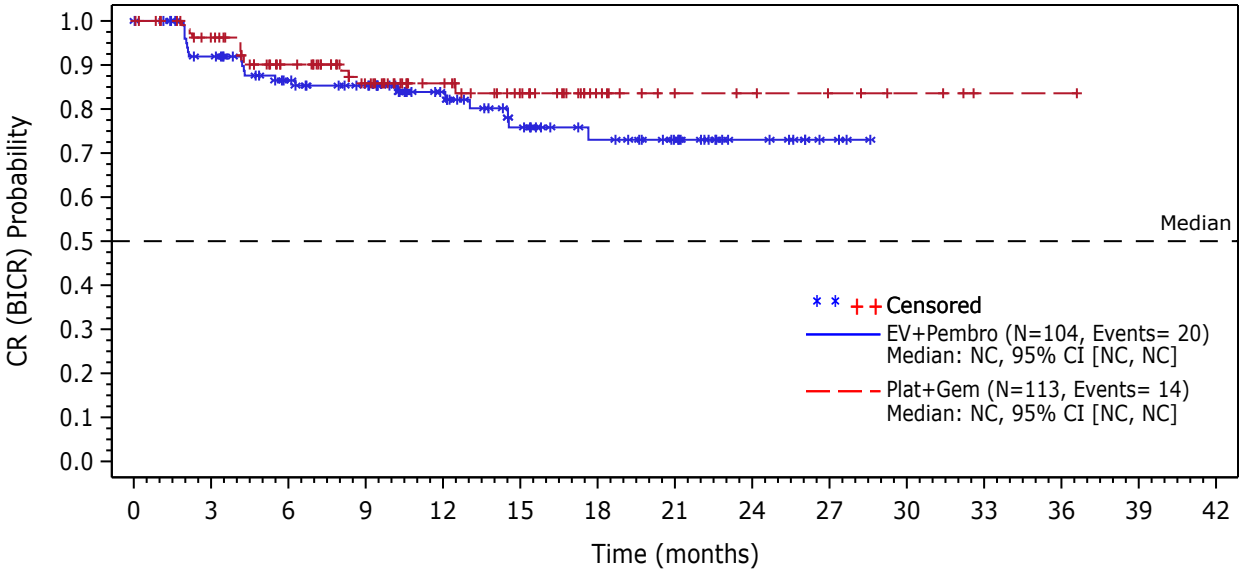
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.1.7: Kaplan-Meier Plot of Complete Response (BICR) by ECOG Status at Baseline - Analysis Set mITT 1

ECOG Status at Baseline: 1-2



at Risk

1	104	90	75	67	48	34	26	19	9	3	0	0	0	0	0
2	113	99	77	57	42	30	16	9	8	6	4	1	1	0	0

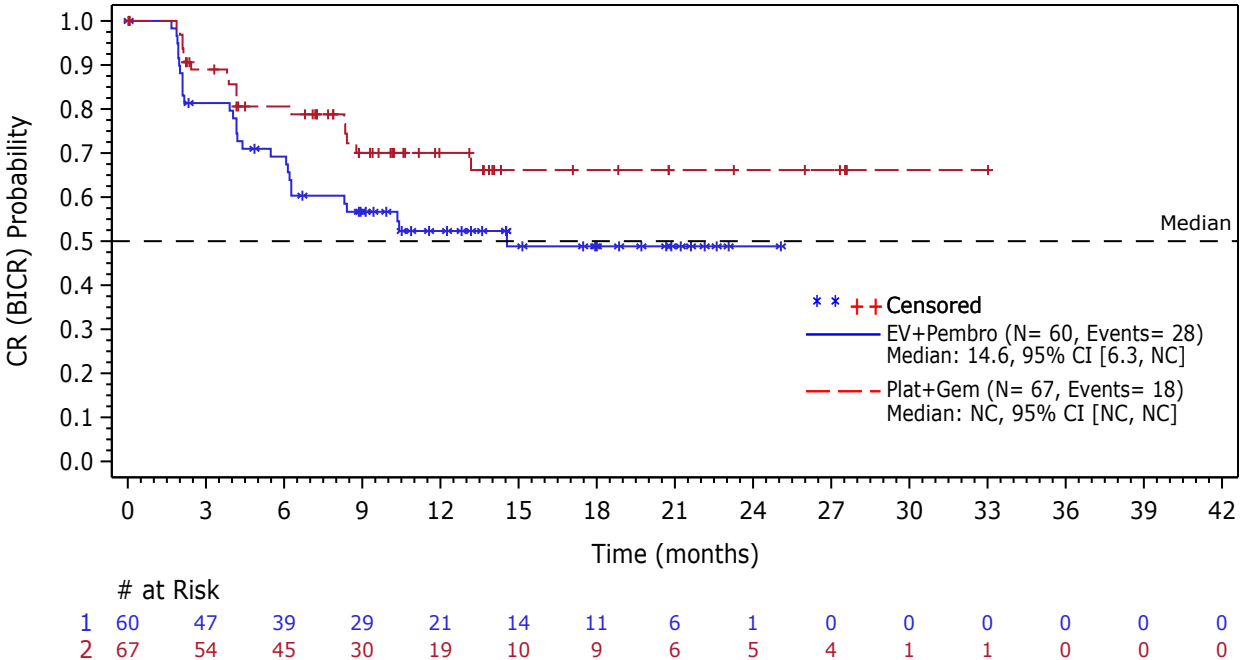
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.1.8: Kaplan-Meier Plot of Complete Response (BICR) by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Lymph node only



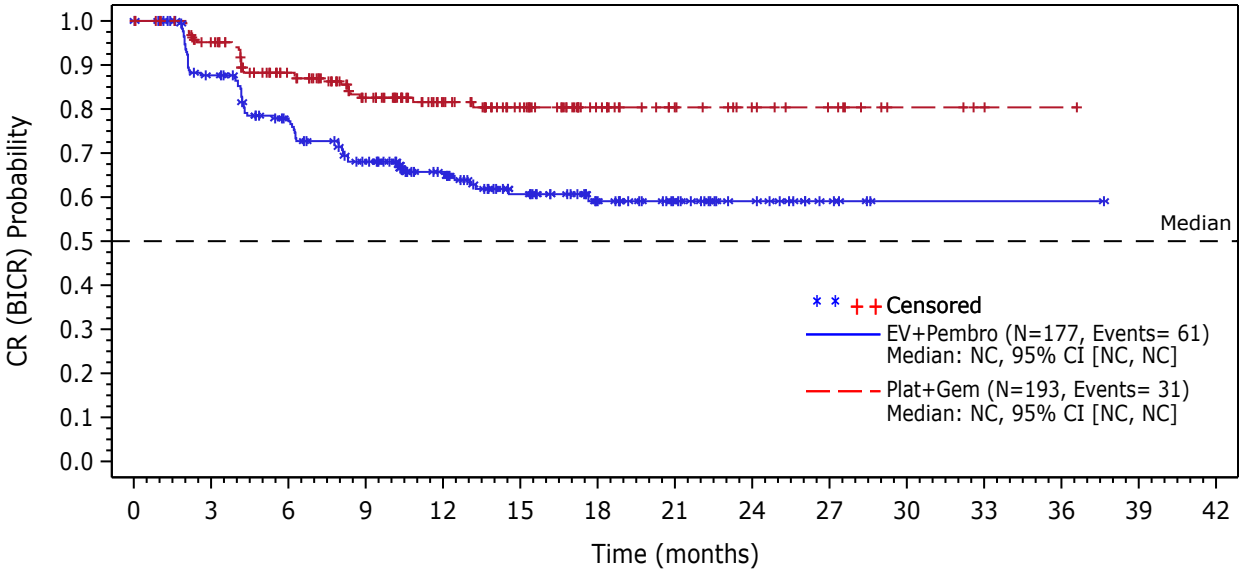
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.1.9: Kaplan-Meier Plot of Complete Response (BICR) by Primary Disease Site of Origin - Analysis Set mITT 1

Primary Disease Site of Origin: Lower tract



at Risk

1	177	147	121	99	73	51	35	23	13	5	1	1	1	0	0
2	193	172	138	106	75	54	32	20	14	10	4	2	1	0	0

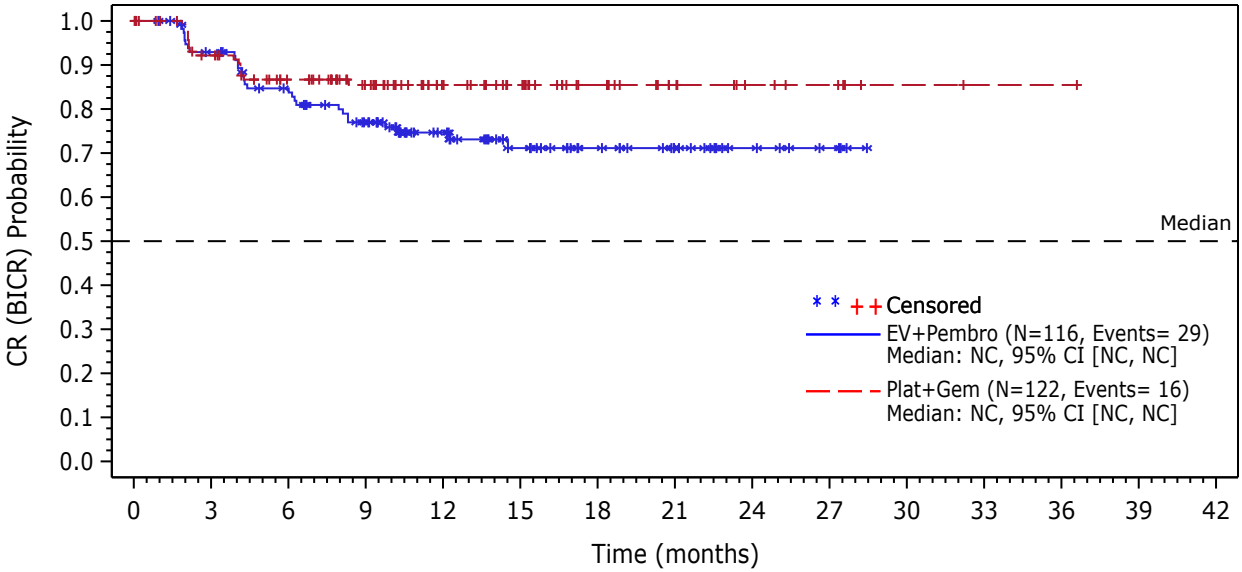
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.1.10: Kaplan-Meier Plot of Complete Response (BICR) by Renal Function - Analysis Set mITT 1

Renal Function: Mild



at Risk

1	116	104	90	75	50	35	25	17	8	4	0	0	0	0	0
2	122	104	86	68	46	35	23	13	8	6	2	1	1	0	0

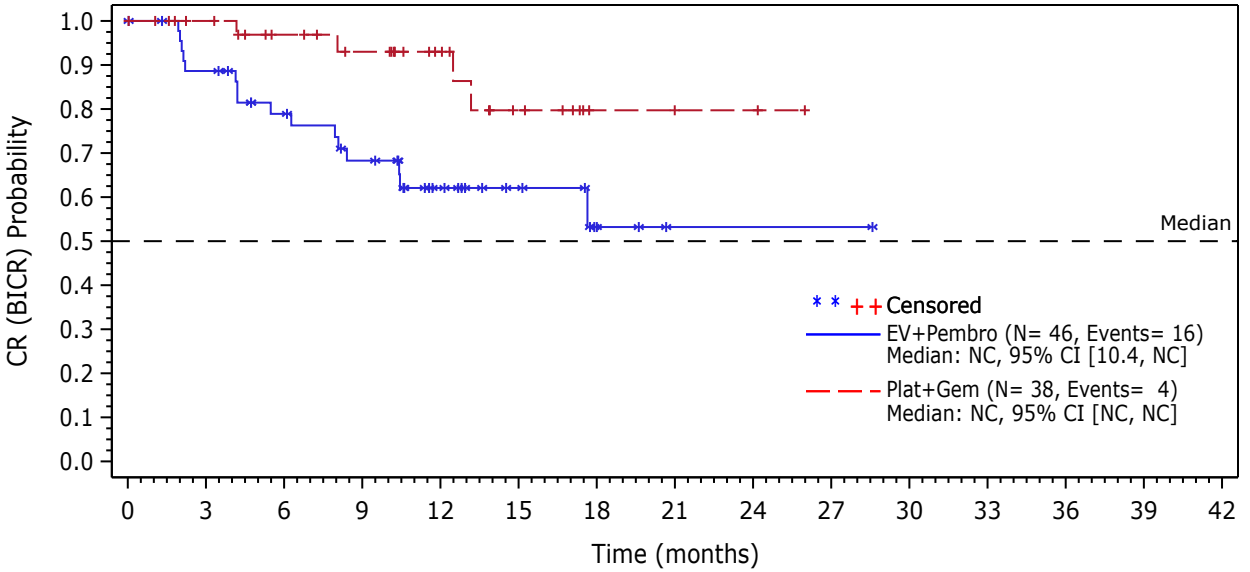
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.1.10: Kaplan-Meier Plot of Complete Response (BICR) by Renal Function - Analysis Set mITT 1

Renal Function: Moderate



at Risk

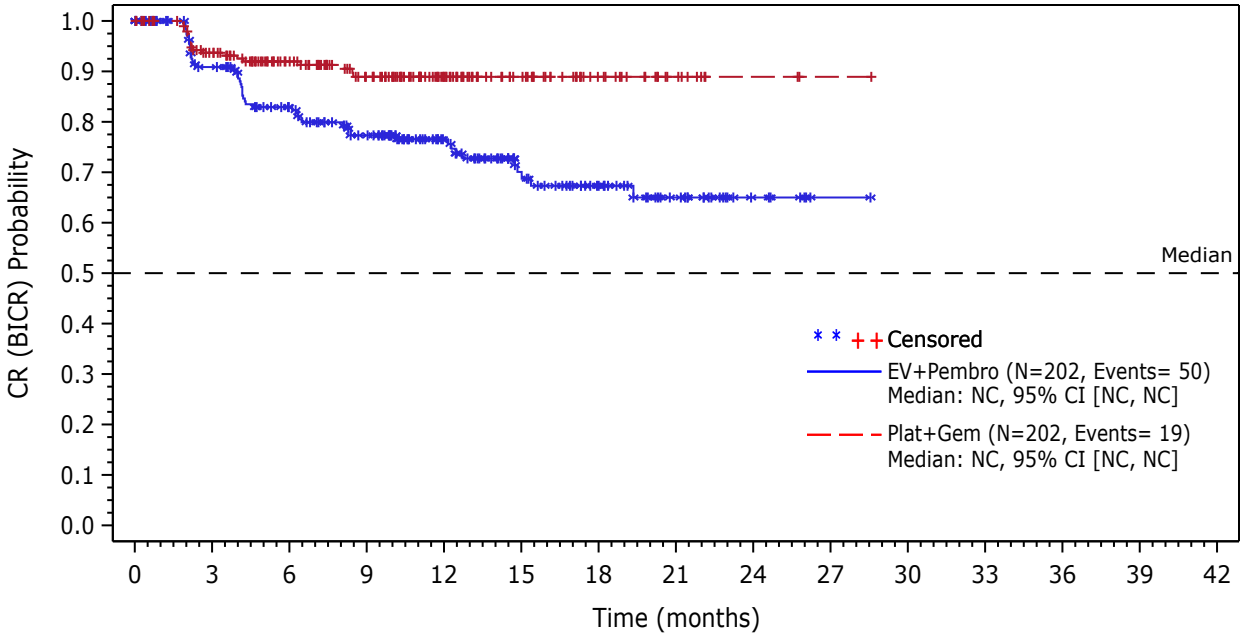
1	46	39	31	25	15	9	4	1	1	1	0	0	0	0	0
2	38	33	27	23	16	9	3	2	2	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.2: Kaplan-Meier Plot of Complete Response (BICR) - Analysis Set mITT 2



at Risk

1	202	166	139	116	82	52	36	21	7	1	0	0	0	0	0
2	202	171	138	108	70	43	23	10	3	1	0	0	0	0	0

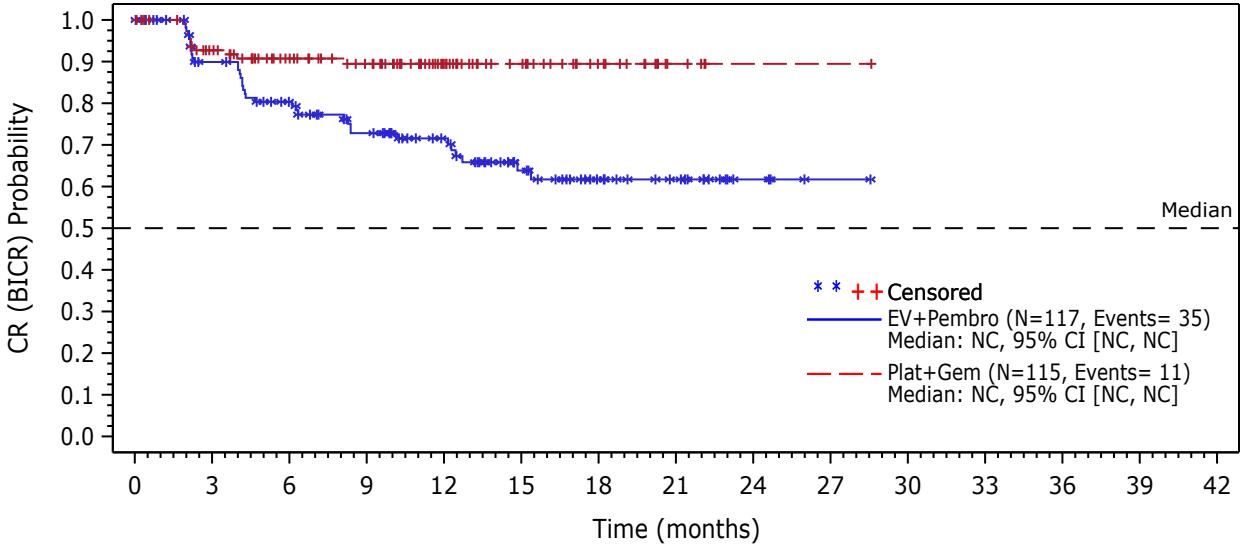
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.2.1: Kaplan-Meier Plot of Complete Response (BICR) by PD-L1 Expression - Analysis Set mITT 2

PD-L1 Expression: High (CPS>=10)



	# at Risk														
1	117	95	79	65	51	32	20	14	4	1	0	0	0	0	0
2	115	97	79	67	43	28	16	5	1	1	0	0	0	0	0

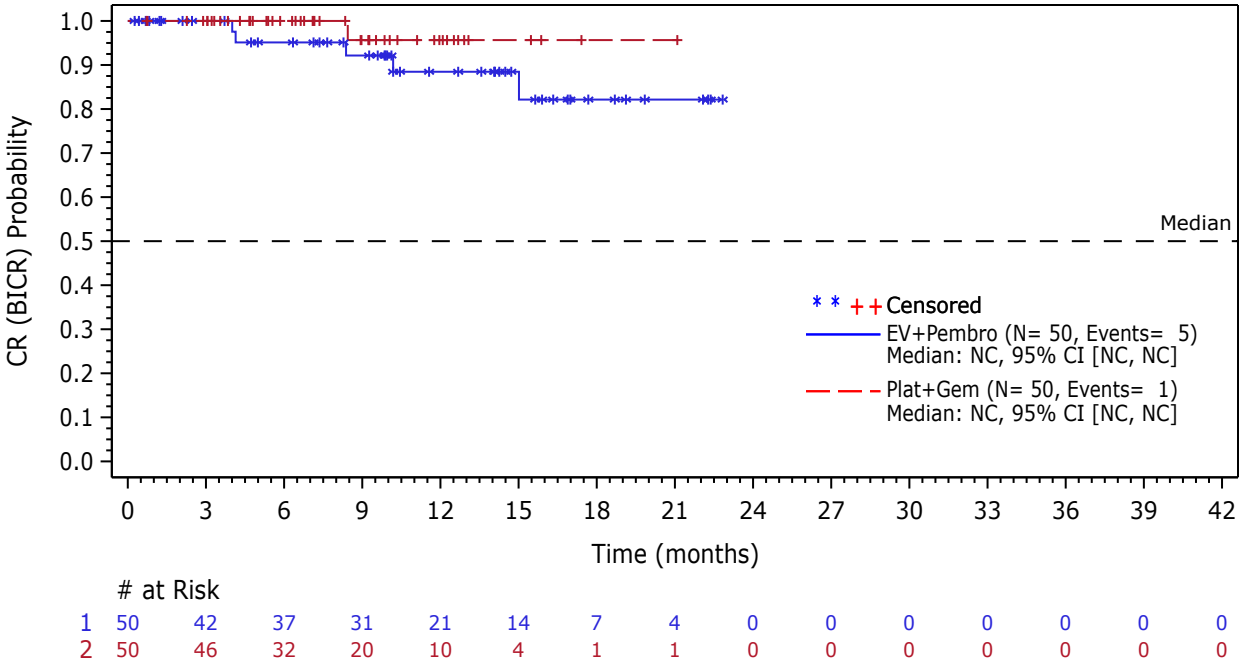
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.2.2: Kaplan-Meier Plot of Complete Response (BICR) by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Present

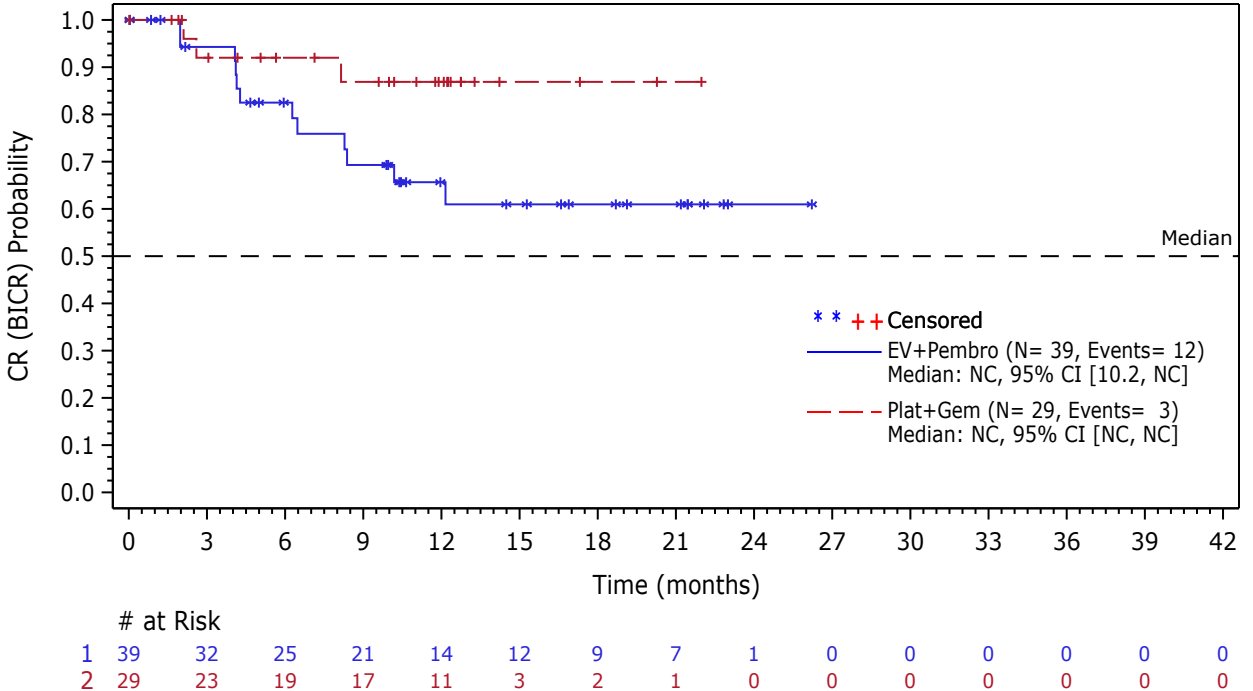


Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.2.3: Kaplan-Meier Plot of Complete Response (BICR) by Age - Analysis Set mITT 2
Age: < 65 years

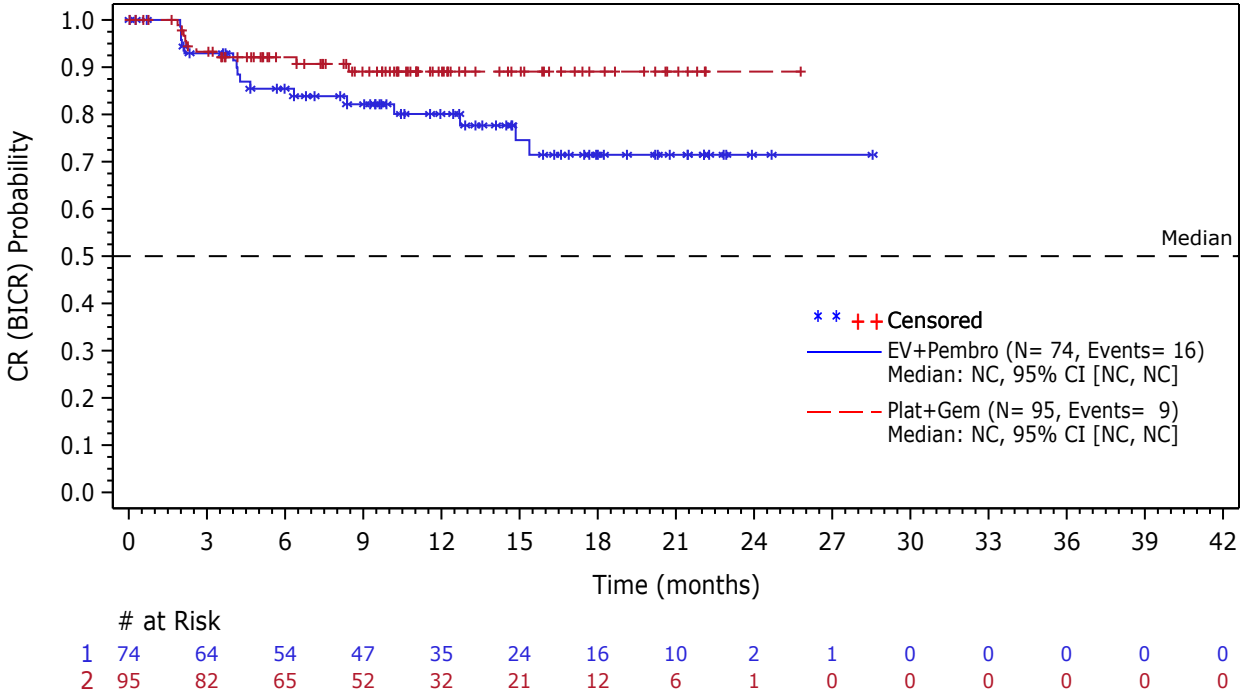


Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.2.4: Kaplan-Meier Plot of Complete Response (BICR) by Region - Analysis Set mITT 2 Region: Europe

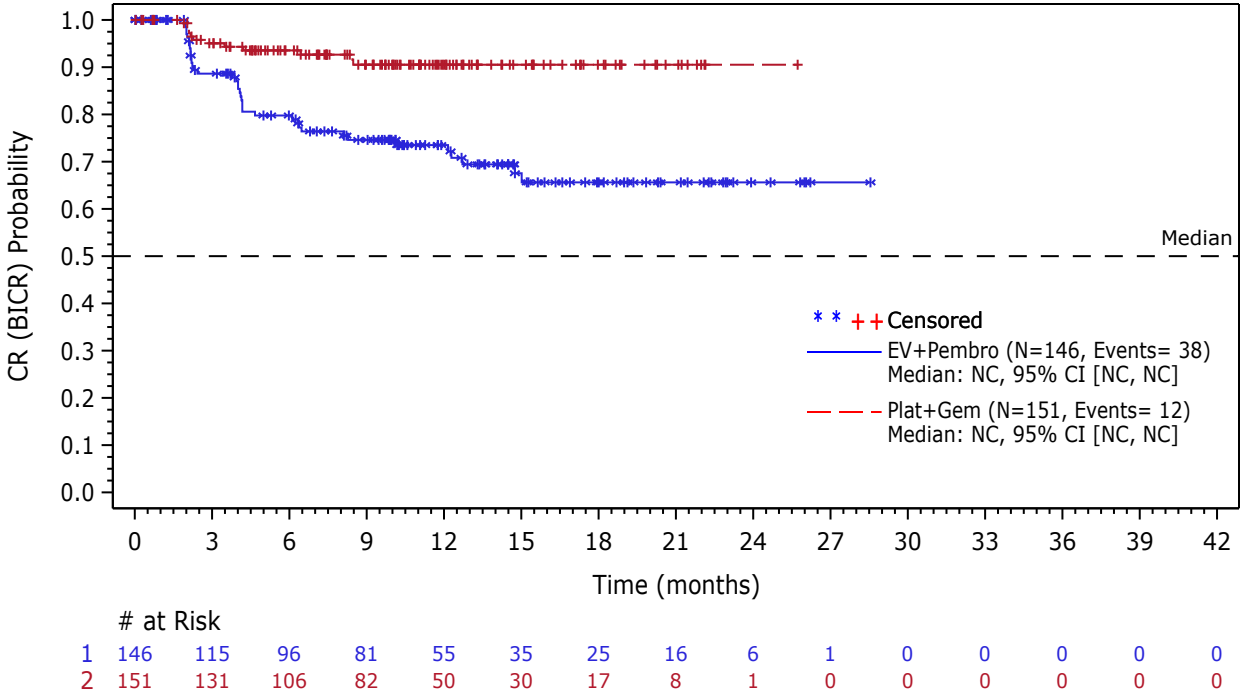


Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.2.5: Kaplan-Meier Plot of Complete Response (BICR) by Sex - Analysis Set mITT 2
Sex: Male



at Risk

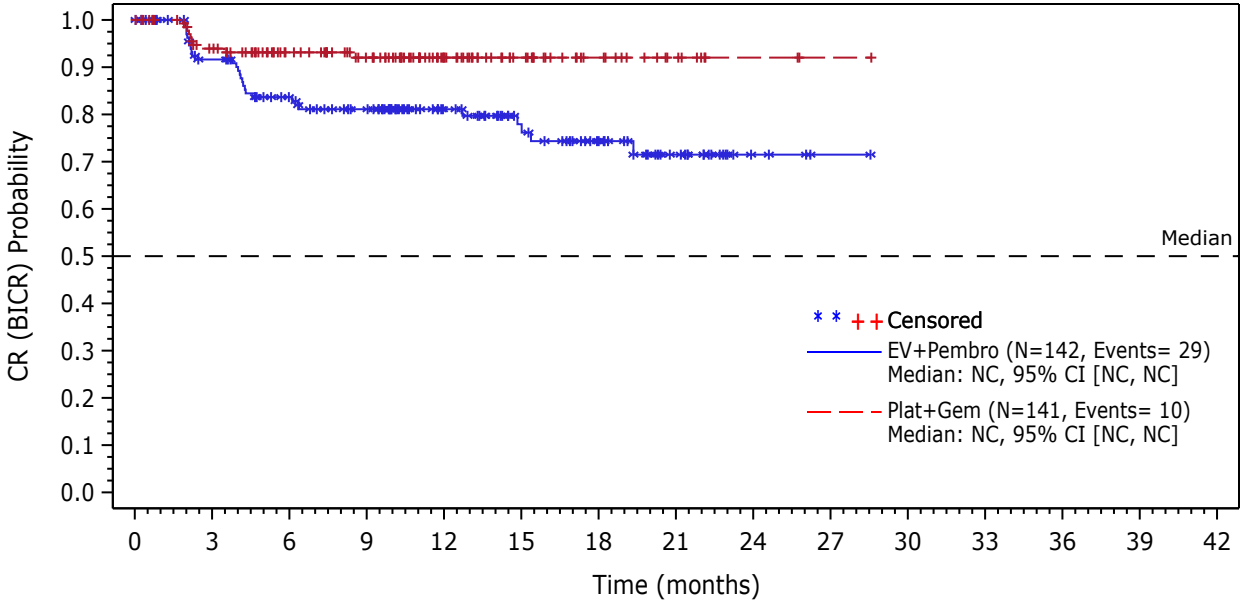
1	146	115	96	81	55	35	25	16	6	1	0	0	0	0	0
2	151	131	106	82	50	30	17	8	1	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.2.6: Kaplan-Meier Plot of Complete Response (BICR) by Race - Analysis Set mITT 2 Race: White



at Risk

1	142	118	99	87	60	44	32	18	4	1	0	0	0	0	0
2	141	120	97	80	51	32	18	9	3	1	0	0	0	0	0

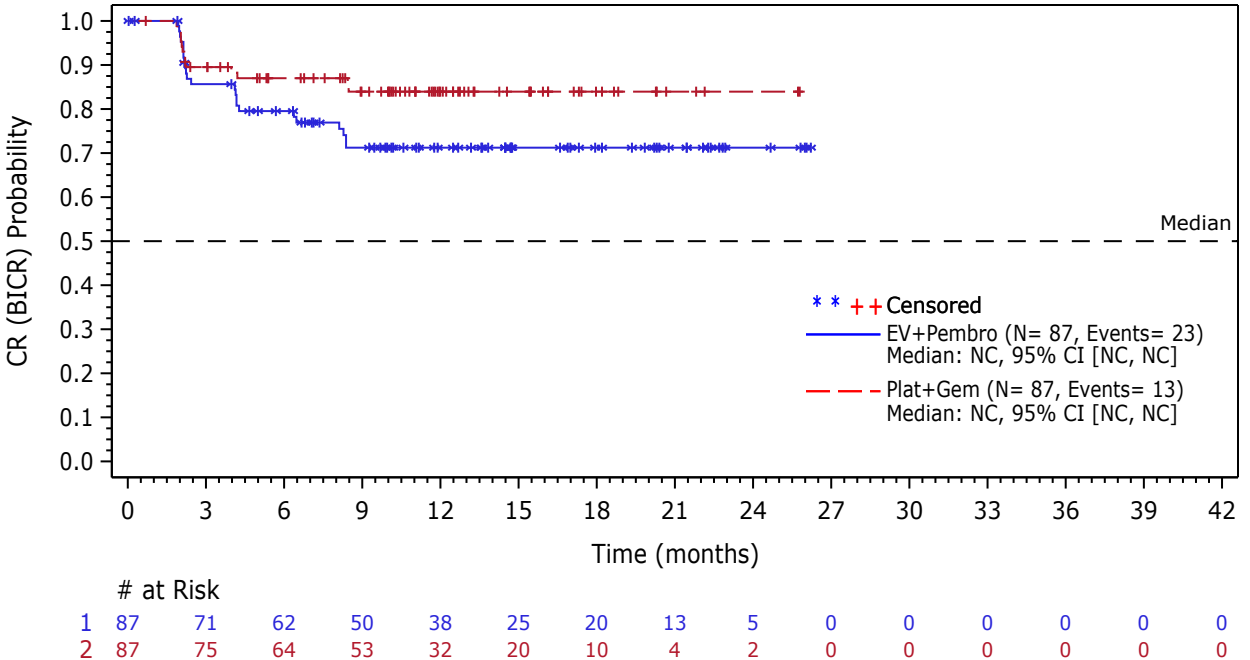
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.2.7: Kaplan-Meier Plot of Complete Response (BICR) by ECOG Status at Baseline - Analysis Set mITT 2

ECOG Status at Baseline: 0



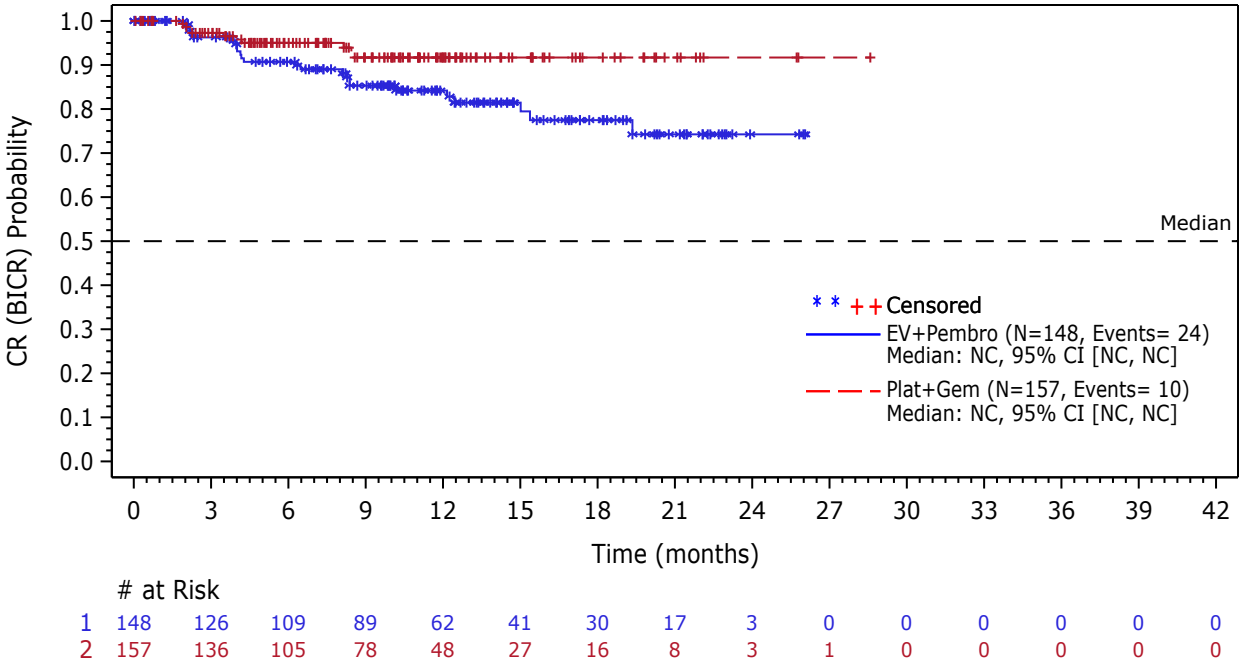
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.2.8: Kaplan-Meier Plot of Complete Response (BICR) by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Visceral metastases



at Risk

1	148	126	109	89	62	41	30	17	3	0	0	0	0	0	0
2	157	136	105	78	48	27	16	8	3	1	0	0	0	0	0

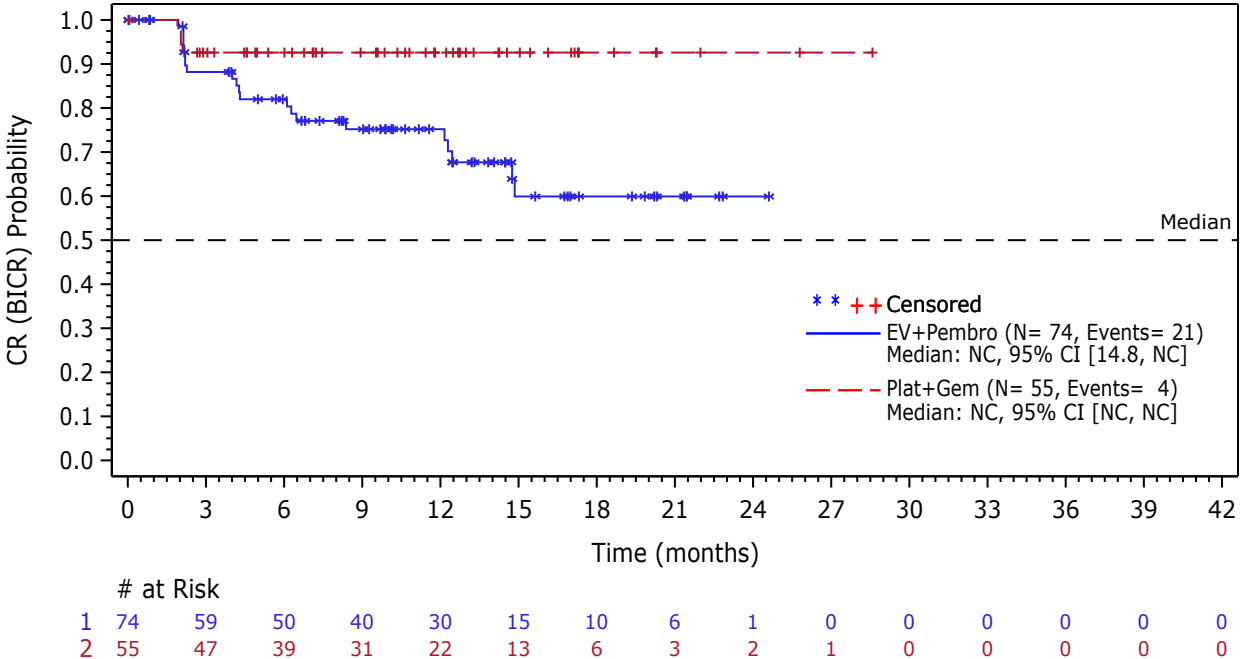
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.2.9: Kaplan-Meier Plot of Complete Response (BICR) by Primary Disease Site of Origin - Analysis Set mITT 2

Primary Disease Site of Origin: Upper tract



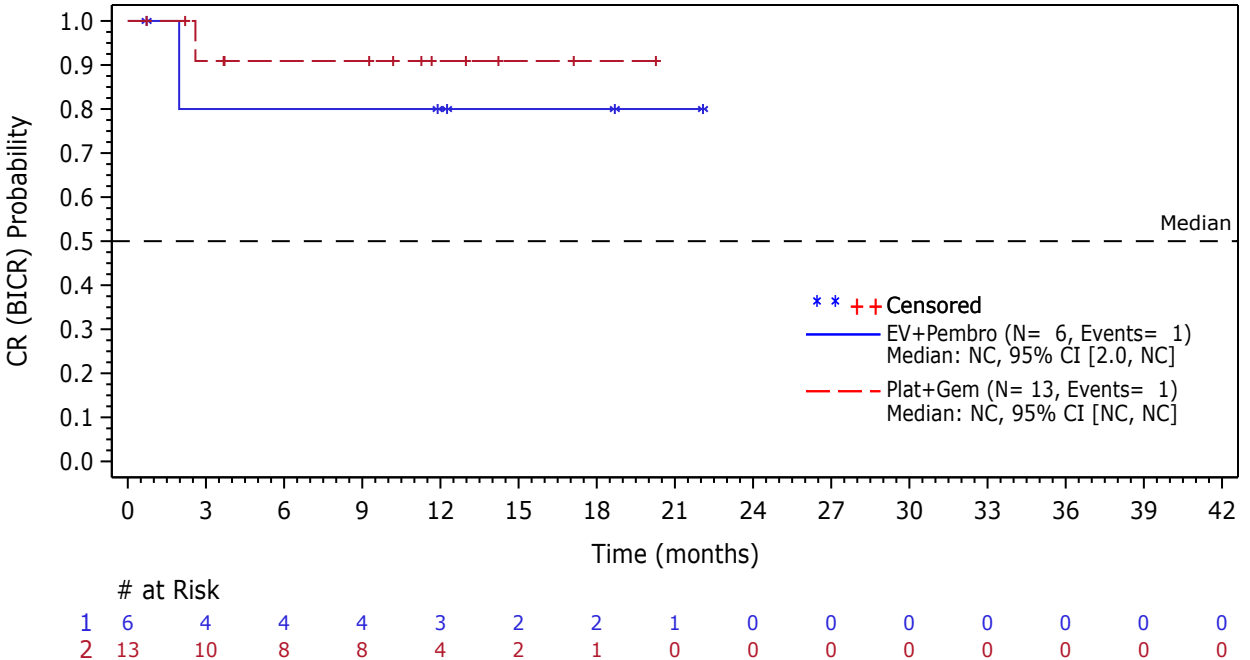
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.2.10: Kaplan-Meier Plot of Complete Response (BICR) by Renal Function - Analysis Set mITT 2

Renal Function: Normal



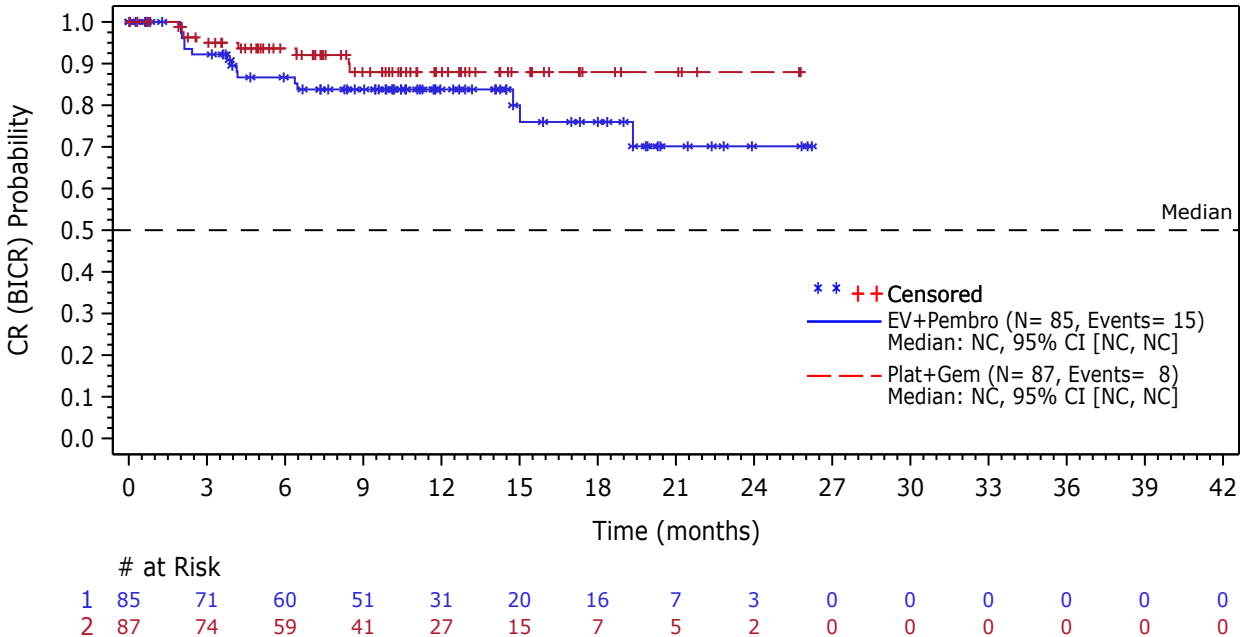
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.2.1: Kaplan-Meier Plot of Complete Response (BICR) by PD-L1 Expression - Analysis Set mITT 2

PD-L1 Expression: Low (CPS<10)



at Risk

1	85	71	60	51	31	20	16	7	3	0	0	0	0	0	0
2	87	74	59	41	27	15	7	5	2	0	0	0	0	0	0

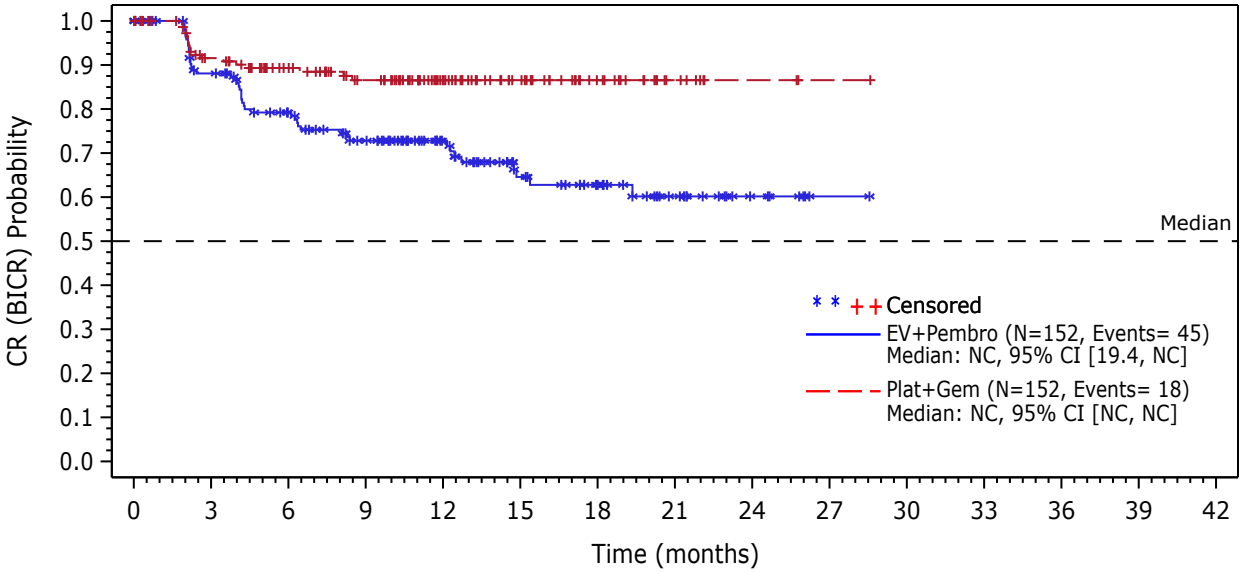
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CPS=combined positive score; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; PD-L1=programmed cell death ligand-1; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.2.2: Kaplan-Meier Plot of Complete Response (BICR) by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Absent



at Risk

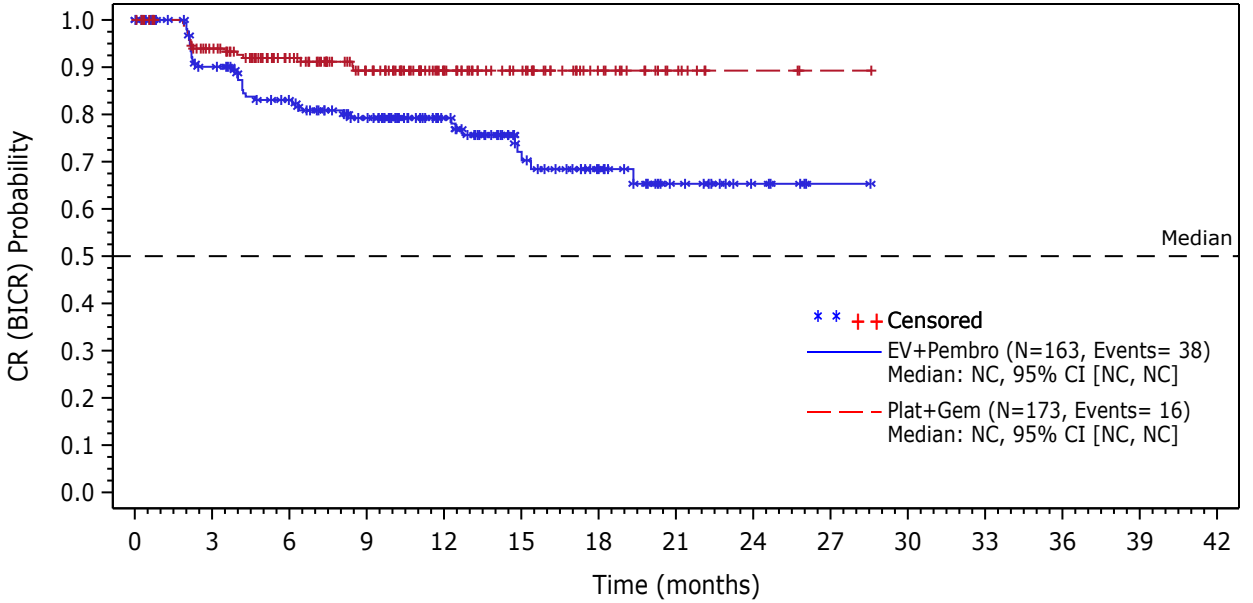
1	152	124	102	85	61	38	29	17	7	1	0	0	0	0	0
2	152	125	106	88	60	39	22	9	3	1	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.2.3: Kaplan-Meier Plot of Complete Response (BICR) by Age - Analysis Set mITT 2
Age: >= 65 years



at Risk

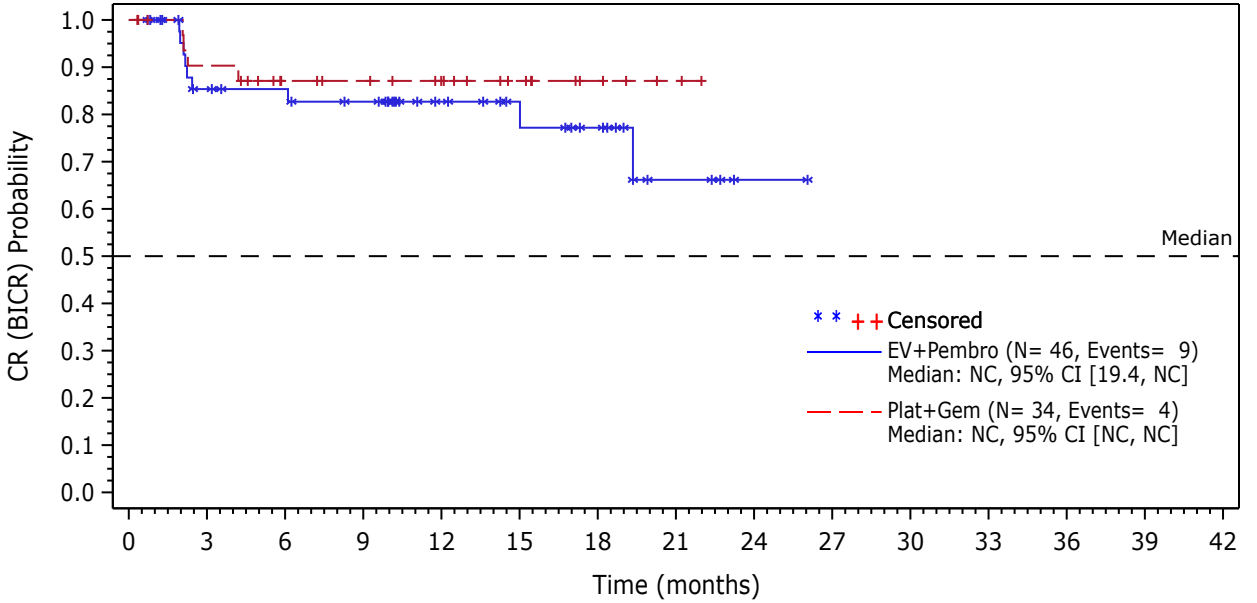
1	163	134	114	95	68	40	27	14	6	1	0	0	0	0	0
2	173	148	119	91	59	40	21	9	3	1	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.2.4: Kaplan-Meier Plot of Complete Response (BICR) by Region - Analysis Set mITT 2 Region: North America



at Risk

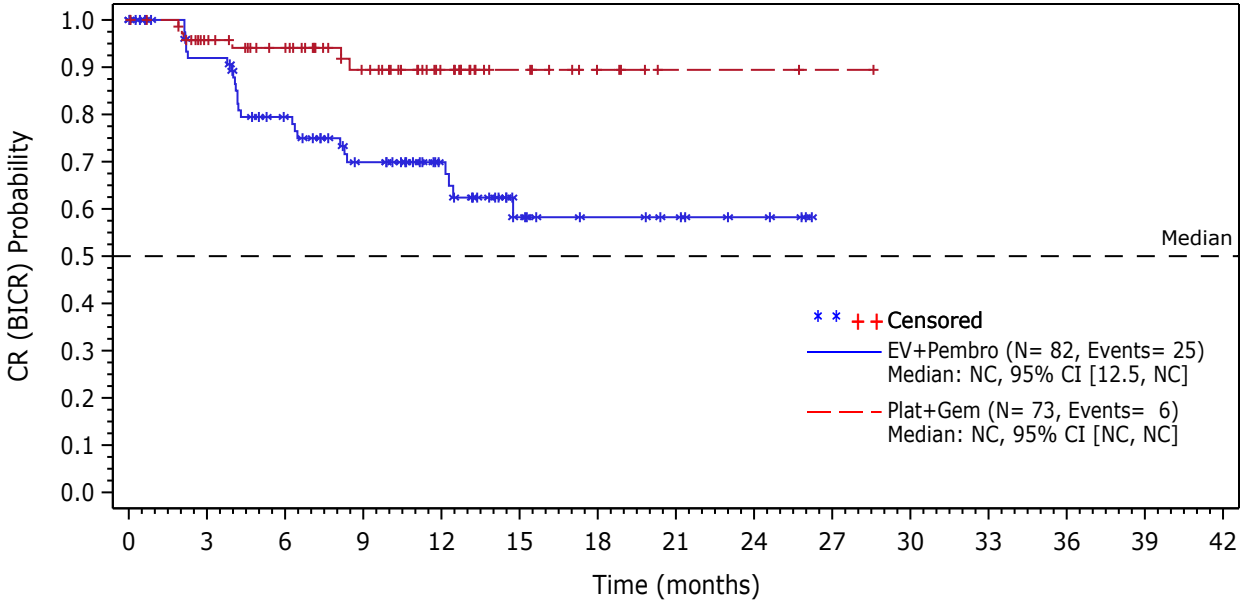
1	46	34	32	29	19	15	11	4	1	0	0	0	0	0	0
2	34	28	21	19	15	10	5	2	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.2.4: Kaplan-Meier Plot of Complete Response (BICR) by Region - Analysis Set mITT 2 Region: Rest of World



at Risk

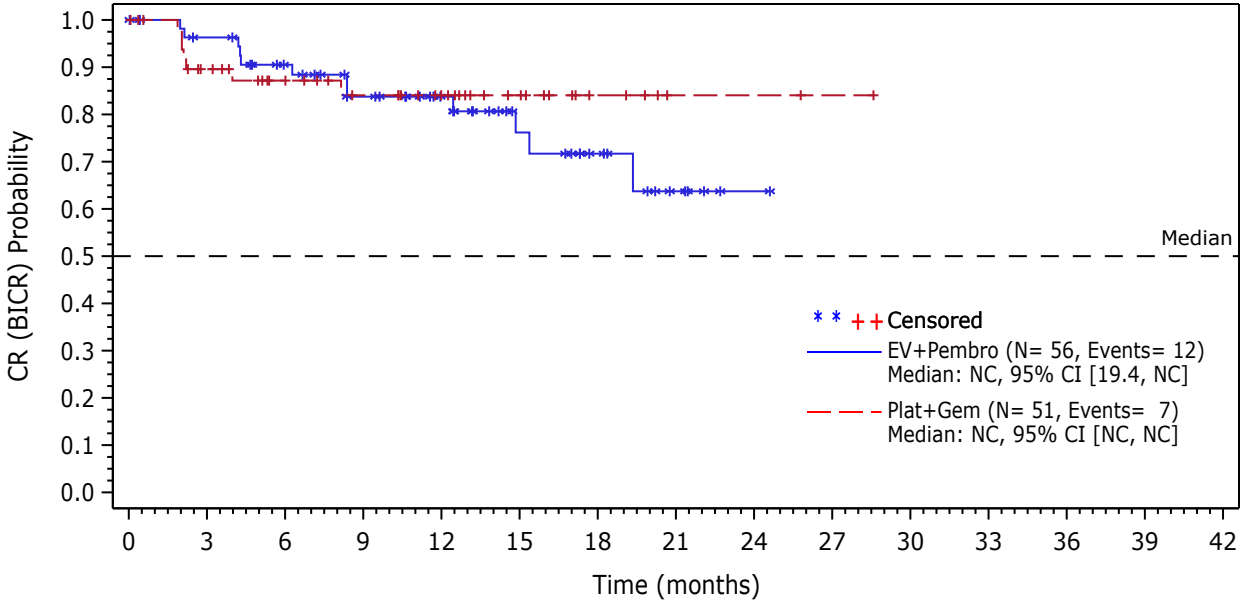
1	82	68	53	40	28	13	9	7	4	0	0	0	0	0	0
2	73	61	52	37	23	12	6	2	2	1	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.2.5: Kaplan-Meier Plot of Complete Response (BICR) by Sex - Analysis Set mITT 2
Sex: Female



at Risk

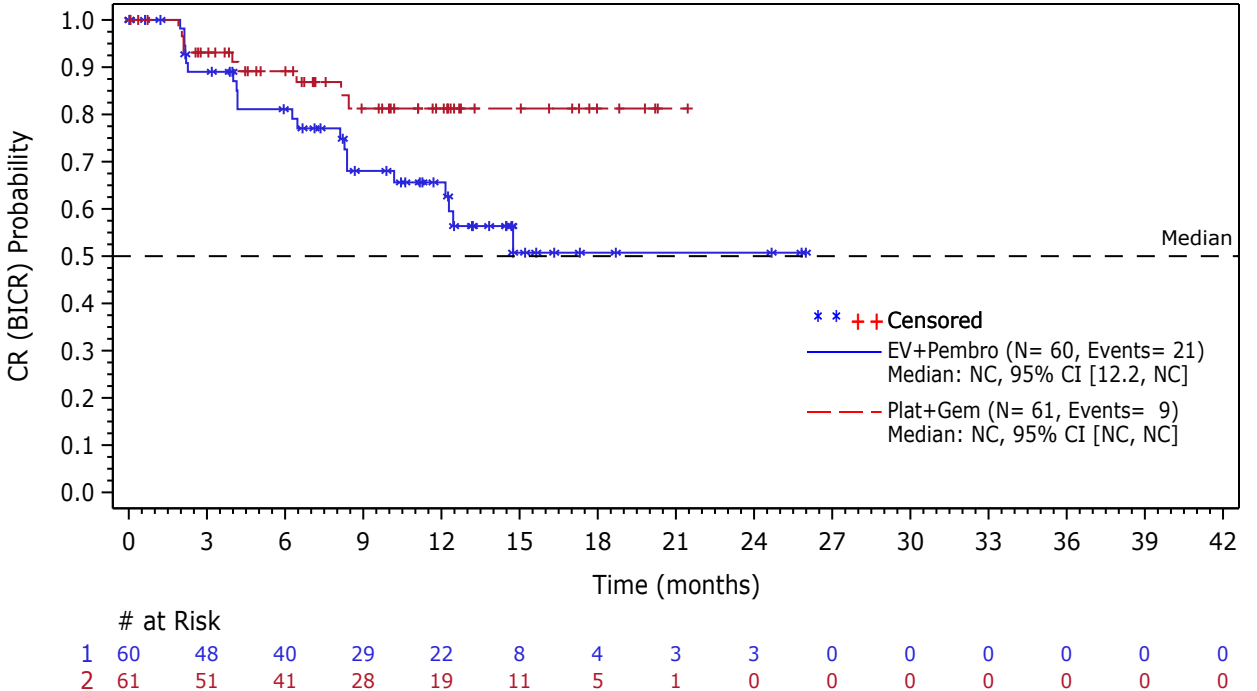
1	56	51	43	35	27	17	11	5	1	0	0	0	0	0	0
2	51	40	32	26	20	13	6	2	2	1	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.2.6: Kaplan-Meier Plot of Complete Response (BICR) by Race - Analysis Set mITT 2
Race: Non-white



at Risk

1	60	48	40	29	22	8	4	3	3	0	0	0	0	0	0
2	61	51	41	28	19	11	5	1	0	0	0	0	0	0	0

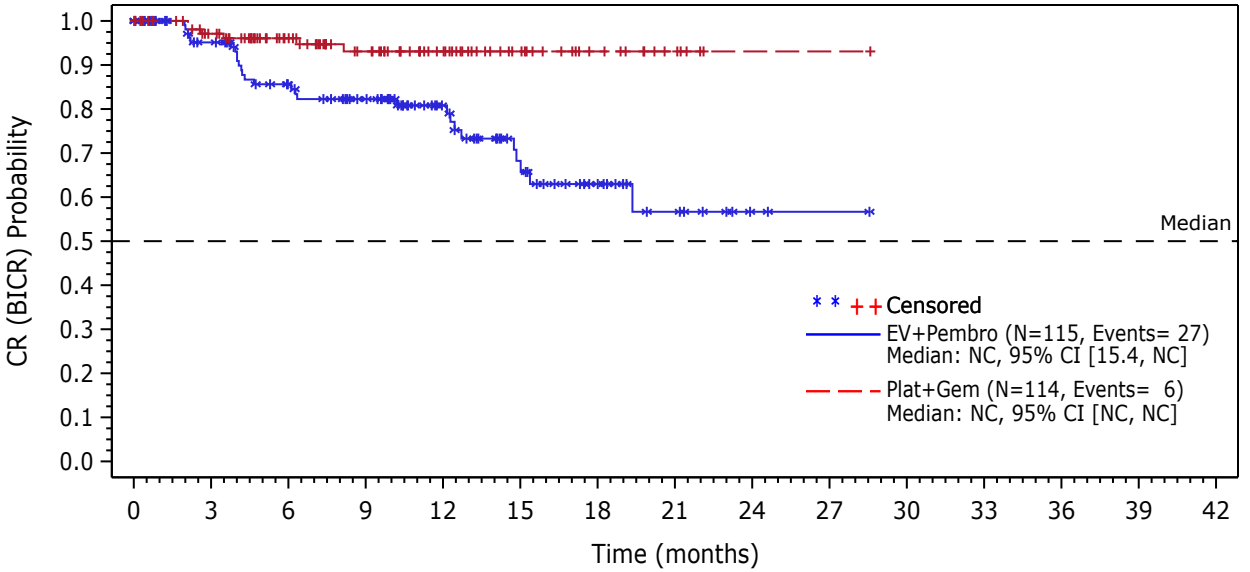
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.2.7: Kaplan-Meier Plot of Complete Response (BICR) by ECOG Status at Baseline - Analysis Set mITT 2

ECOG Status at Baseline: 1-2



at Risk

1	115	95	77	66	44	27	16	8	2	1	0	0	0	0	0
2	114	96	74	55	38	23	13	6	1	1	0	0	0	0	0

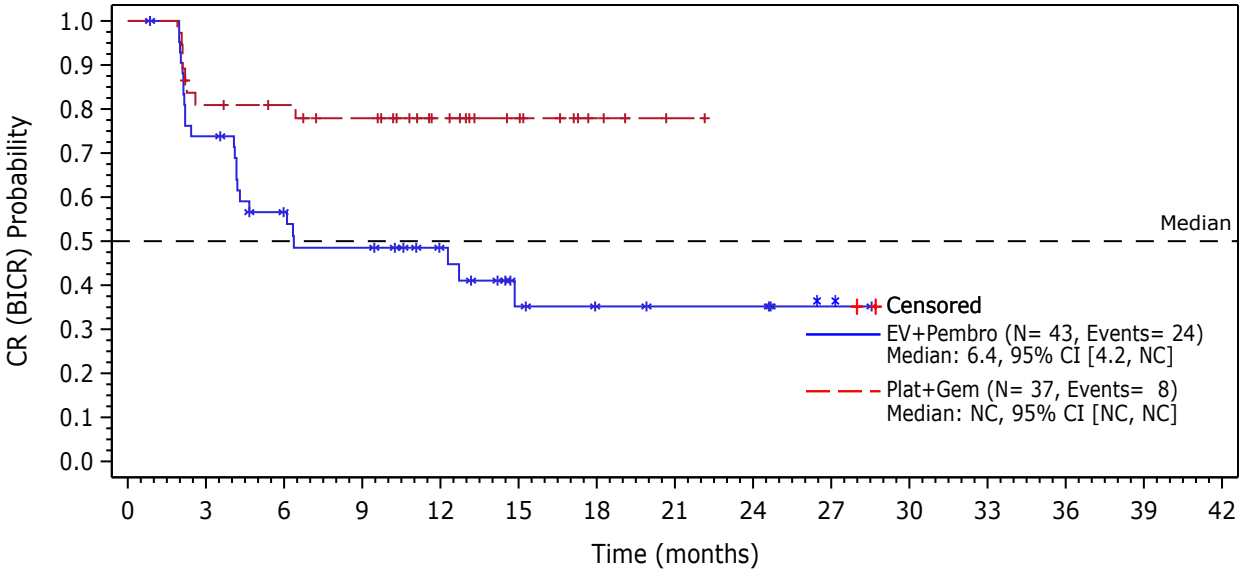
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; ECOG=Eastern Cooperative Oncology Group; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.2.8: Kaplan-Meier Plot of Complete Response (BICR) by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Lymph node only



at Risk

1	43	31	21	18	13	6	4	3	3	1	0	0	0	0	0
2	37	29	27	24	16	10	4	1	0	0	0	0	0	0	0

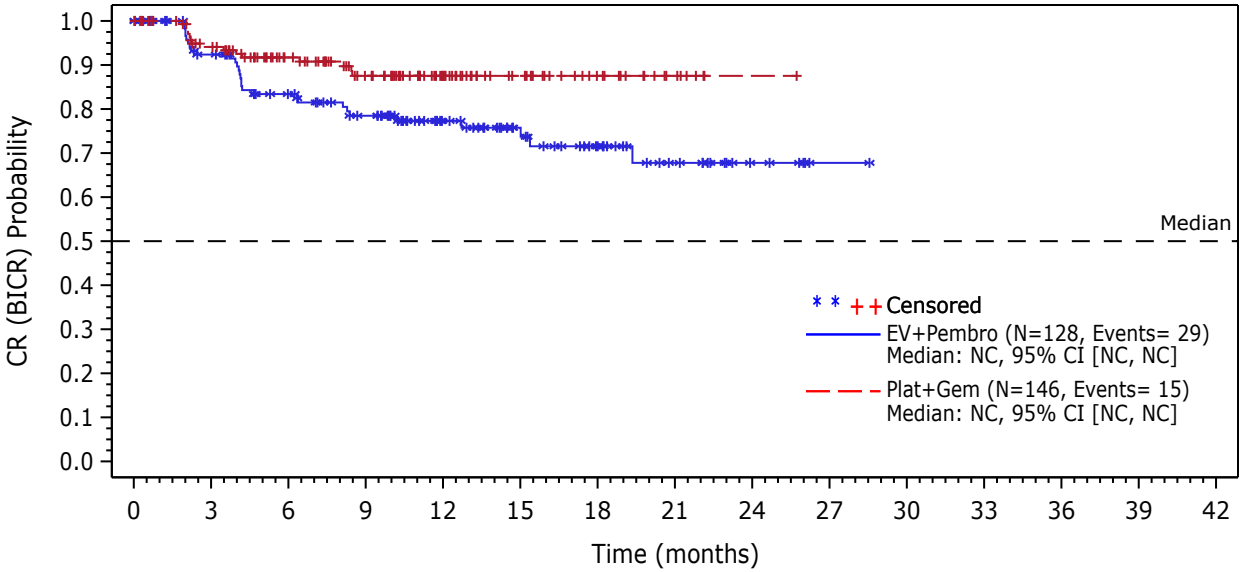
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.2.9: Kaplan-Meier Plot of Complete Response (BICR) by Primary Disease Site of Origin - Analysis Set mITT 2

Primary Disease Site of Origin: Lower tract



at Risk

1	128	107	89	76	52	37	26	15	6	1	0	0	0	0	0
2	146	124	99	77	48	30	17	7	1	0	0	0	0	0	0

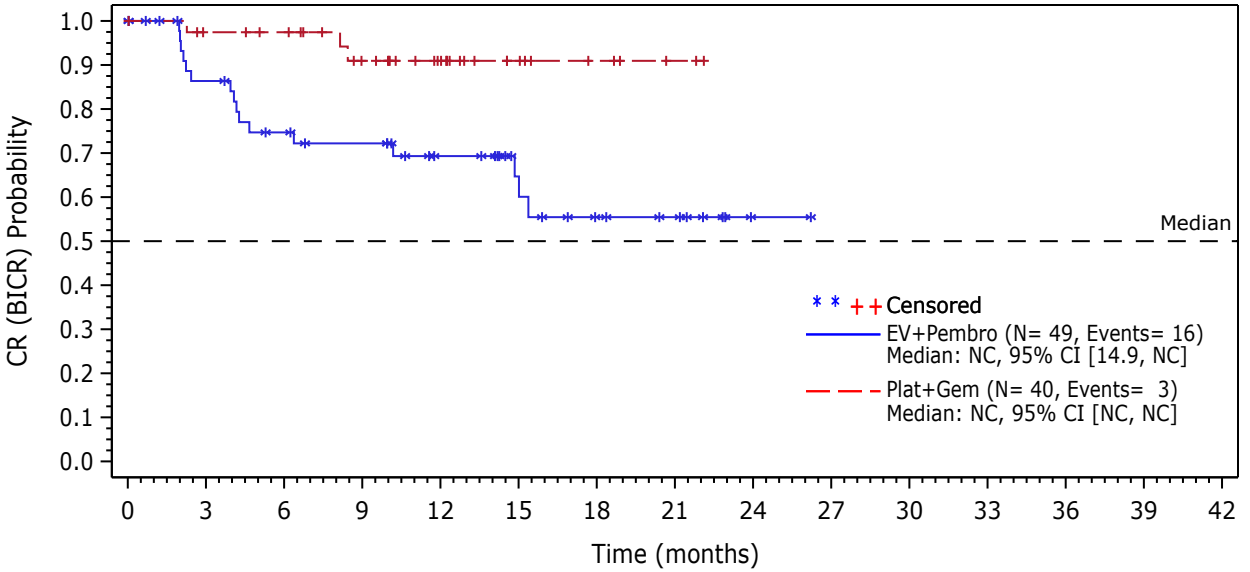
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.2.10: Kaplan-Meier Plot of Complete Response (BICR) by Renal Function - Analysis Set mITT 2

Renal Function: Mild



at Risk

1	49	38	31	28	21	14	9	7	1	0	0	0	0	0	0
2	40	36	34	26	18	9	5	2	0	0	0	0	0	0	0

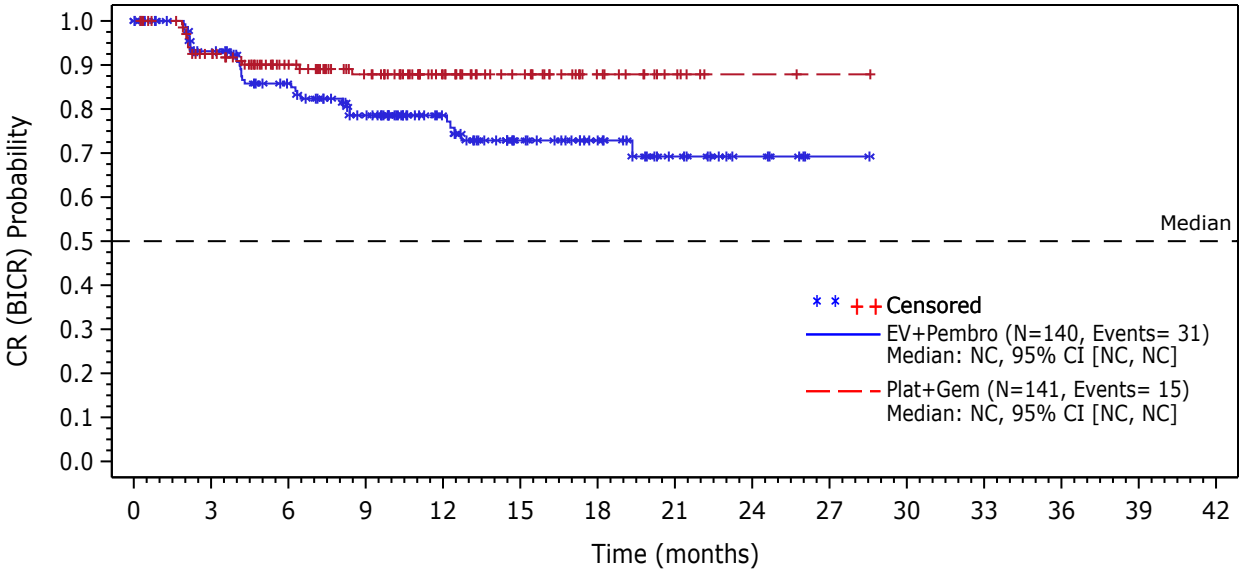
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.2.10: Kaplan-Meier Plot of Complete Response (BICR) by Renal Function - Analysis Set mITT 2

Renal Function: Moderate



at Risk

1	140	119	100	80	56	36	25	13	6	1	0	0	0	0	0
2	141	119	93	72	47	31	16	7	2	1	0	0	0	0	0

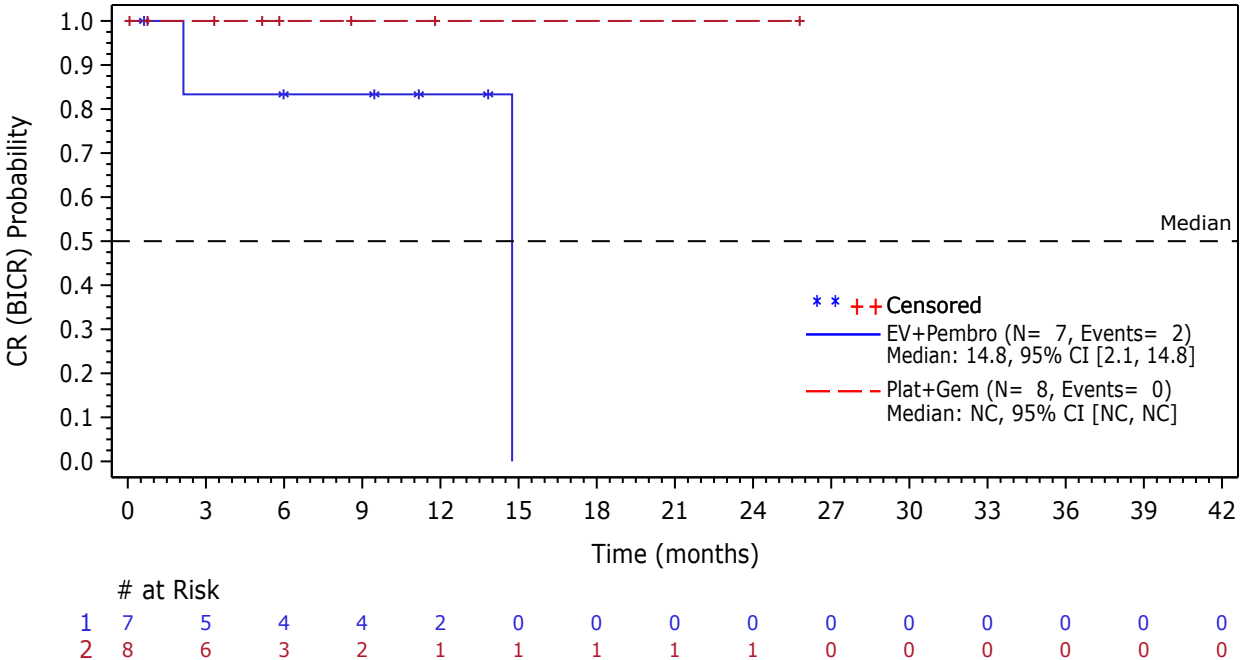
Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.1002.9.2.10: Kaplan-Meier Plot of Complete Response (BICR) by Renal Function - Analysis Set mITT 2

Renal Function: Severe

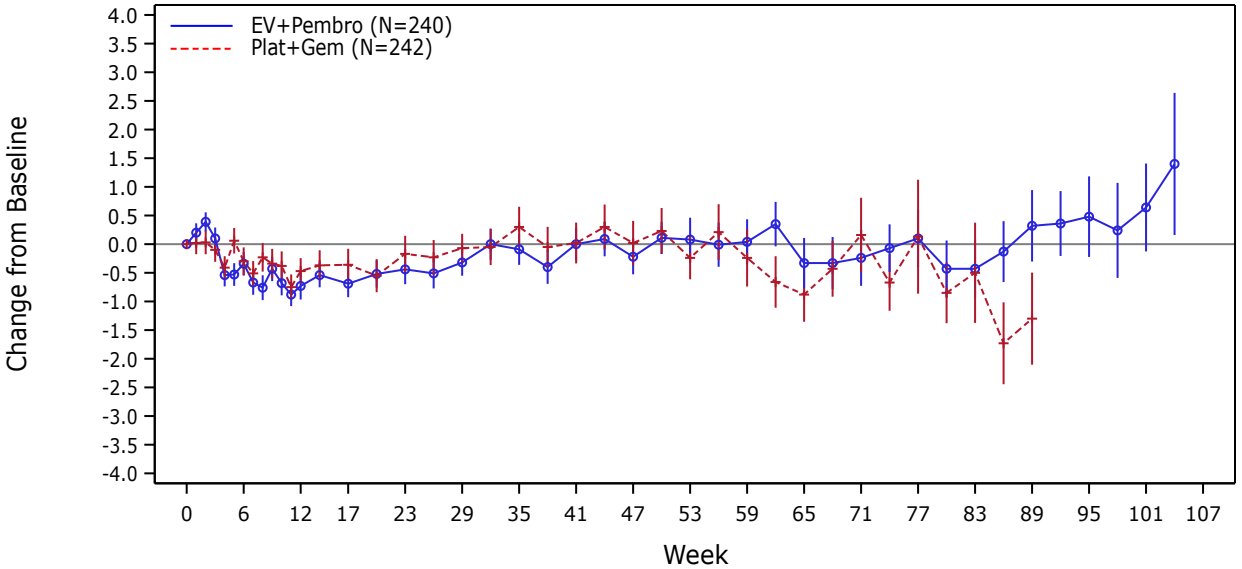


Abbreviations: # at Risk=number of patients at risk; BICR=blinded independent central review; CI=confidence interval; CR=complete response; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Complete response was defined as first confirmed complete response.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.4.1: BPI-SF - Plot of Mean Change from Baseline of Worst Pain in the last 24 hours - Analysis Set mITT 1



Number of subjects

EV+Pembro	209	172	172	163	151	146	122	119	94	74	68	54	49	42	35	31	21	14
Plat+Gem	190	151	140	133	98	87	70	57	50	42	33	26	19	15	12	10		

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

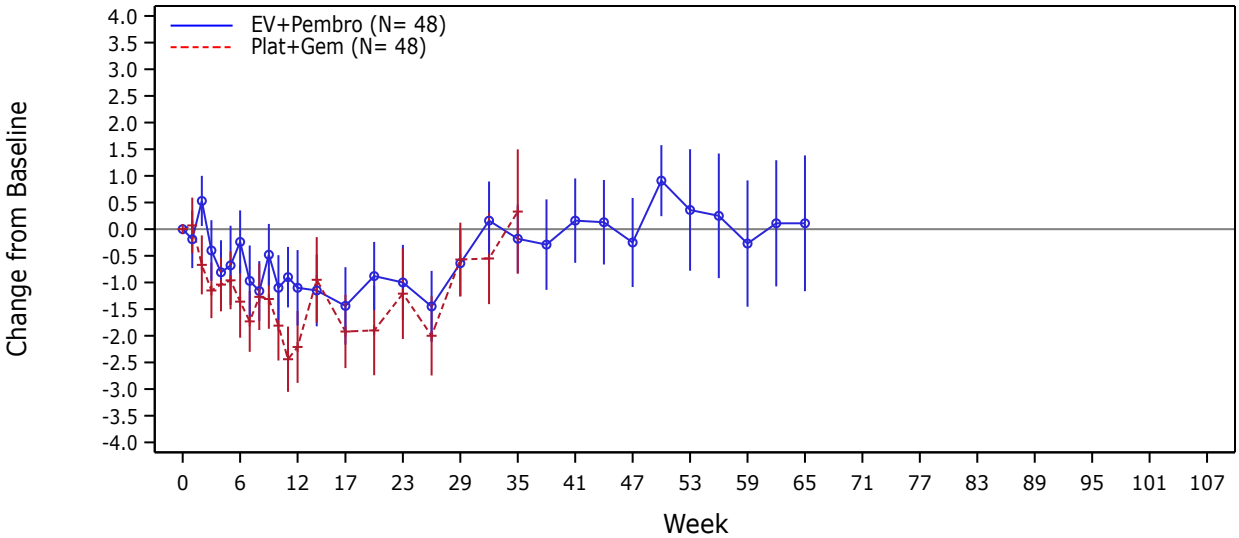
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.4.1.1: BPI-SF - Plot of Mean Change from Baseline of Worst Pain in the last 24 hours by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Present



Number of subjects

EV+Pembro	39	25	29	25	23	22	17	19	16	11	11	9
Plat+Gem	34	28	24	26	19	14	9					

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

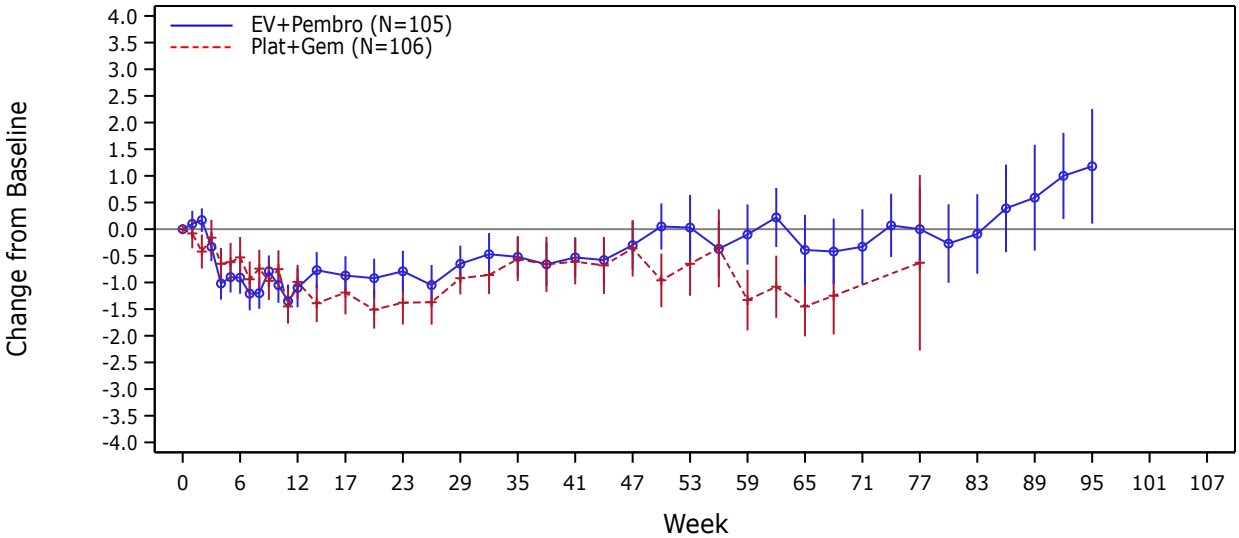
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.4.1.2: BPI-SF - Plot of Mean Change from Baseline of Worst Pain in the last 24 hours by Age - Analysis Set mITT 1

Age: < 65 years



Number of subjects

EV+Pembro	94	82	80	78	73	68	58	59	46	37	39	31	30	24	22	17	11
Plat+Gem	84	68	67	59	45	38	32	23	22	17	12	11		8			

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

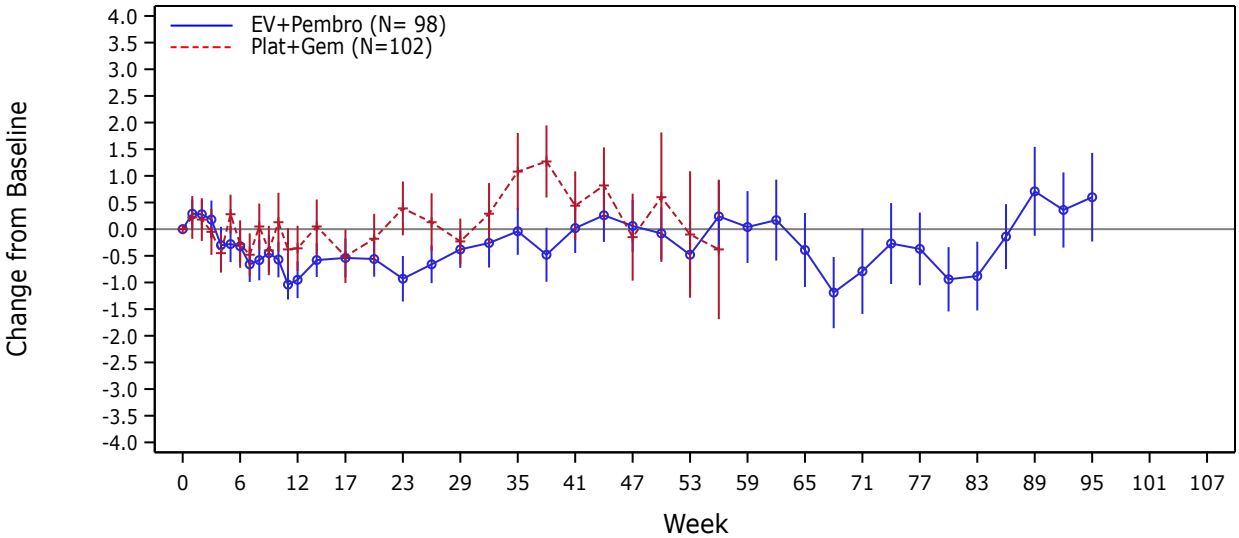
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.4.1.3: BPI-SF - Plot of Mean Change from Baseline of Worst Pain in the last 24 hours by Region - Analysis Set mITT 1

Region: Europe



Number of subjects

EV+Pembro	81	63	66	63	57	58	52	48	36	27	27	23	19	19	16	14	10
Plat+Gem	73	58	50	47	33	26	25	18	13	10							

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

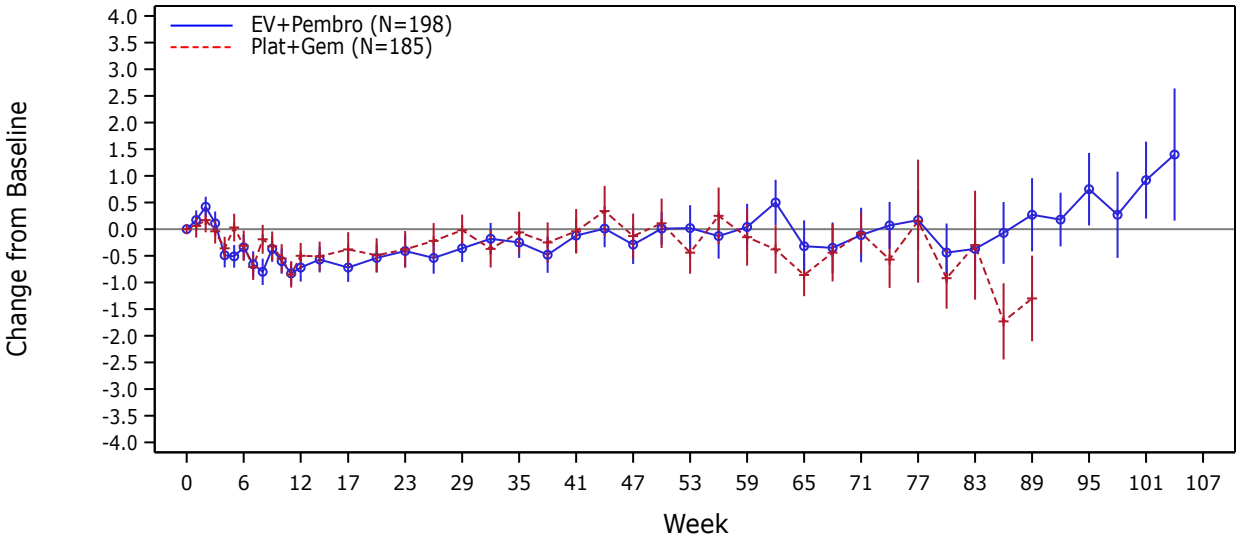
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.4.1.4: BPI-SF - Plot of Mean Change from Baseline of Worst Pain in the last 24 hours by Sex - Analysis Set mITT 1

Sex: Male



Number of subjects

EV+Pembro	173	140	141	131	122	121	100	94	75	59	54	47	45	36	30	26	20	12
Plat+Gem	148	116	110	104	79	66	53	45	39	34	27	21	14	13	10	10		

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

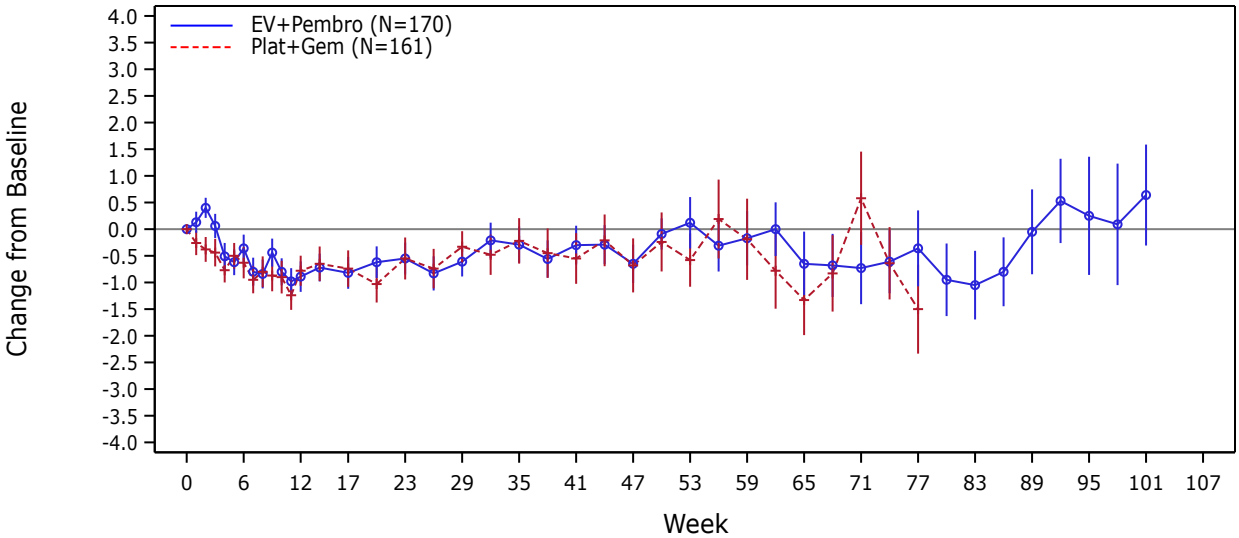
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.4.1.5: BPI-SF - Plot of Mean Change from Baseline of Worst Pain in the last 24 hours by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Visceral metastases



Number of subjects

EV+Pembro	149	115	121	112	103	99	79	81	63	50	47	34	30	25	22	20	12	11
Plat+Gem	131	104	93	91	69	60	45	33	31	24	21	18	12	10				

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

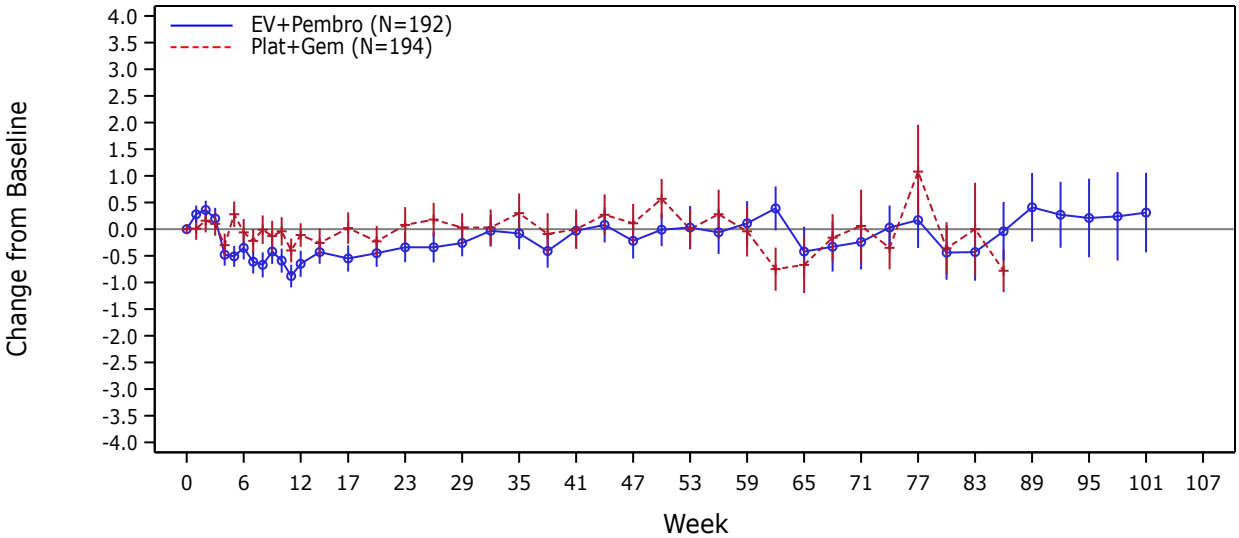
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.4.1.1: BPI-SF - Plot of Mean Change from Baseline of Worst Pain in the last 24 hours by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Absent



Number of subjects

EV+Pembro	170	147	143	138	128	124	105	100	78	63	57	45	42	36	30	27	19	13
Plat+Gem	156	123	116	107	79	73	61	54	45	37	28	21	18	13	10			

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

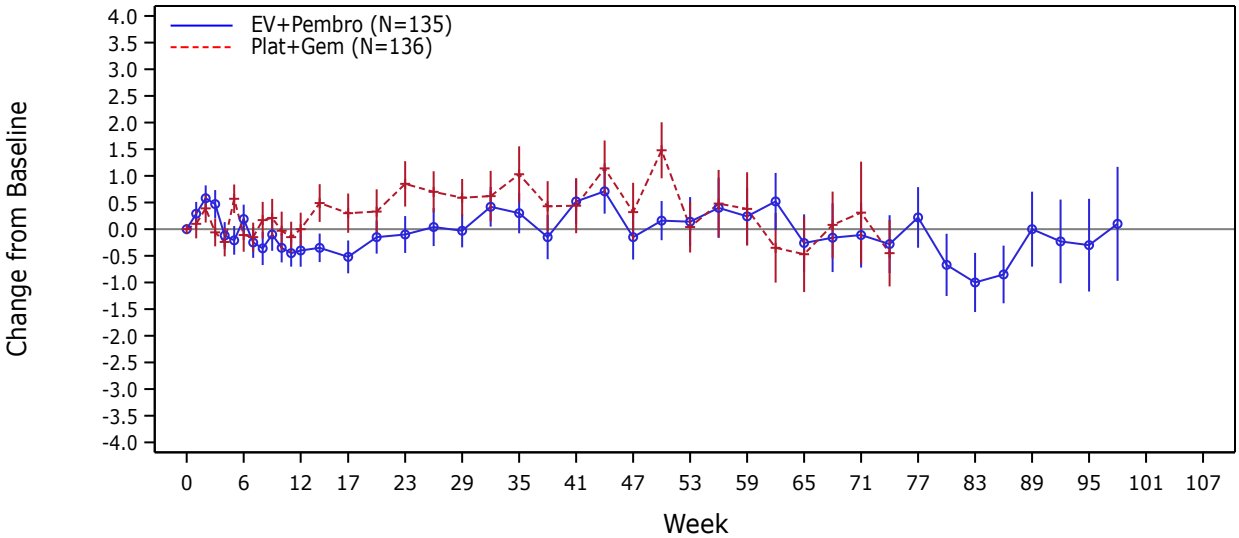
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.4.1.2: BPI-SF - Plot of Mean Change from Baseline of Worst Pain in the last 24 hours by Age - Analysis Set mITT 1

Age: >= 65 years



Number of subjects

EV+Pembro	115	90	92	85	78	78	64	60	48	37	29	23	19	18	13	14	10
Plat+Gem	106	83	73	74	53	49	38	34	28	25	21	15	13				

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

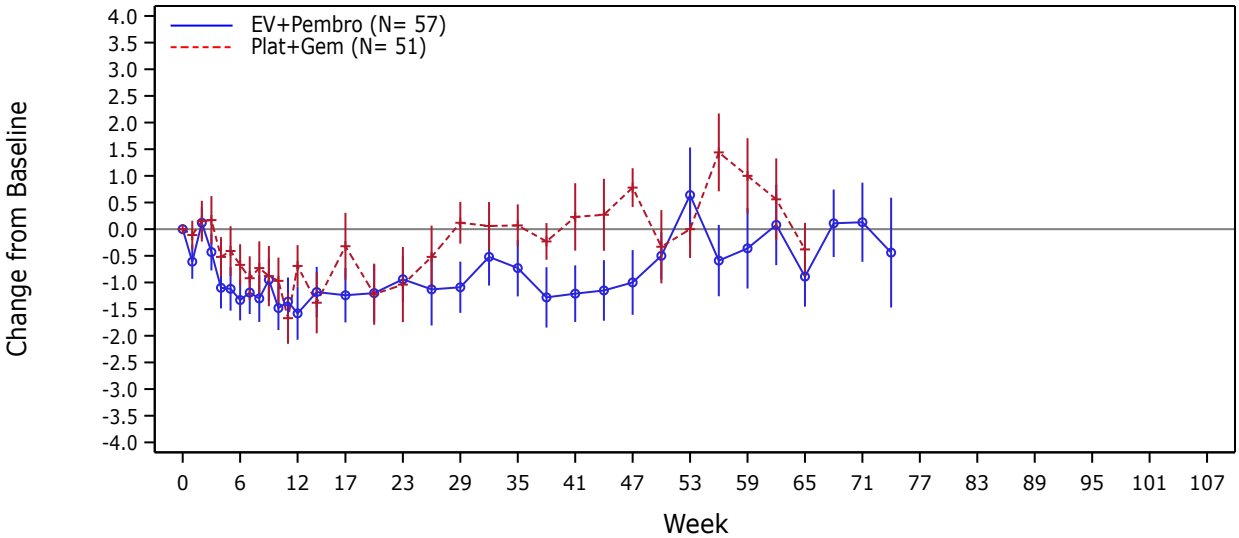
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.4.1.3: BPI-SF - Plot of Mean Change from Baseline of Worst Pain in the last 24 hours by Region - Analysis Set mITT 1

Region: North America



Number of subjects

EV+Pembro	48	39	40	37	35	34	30	24	23	14	14	9	8
Plat+Gem	42	30	32	31	23	25	15	13	9	11	9	8	

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

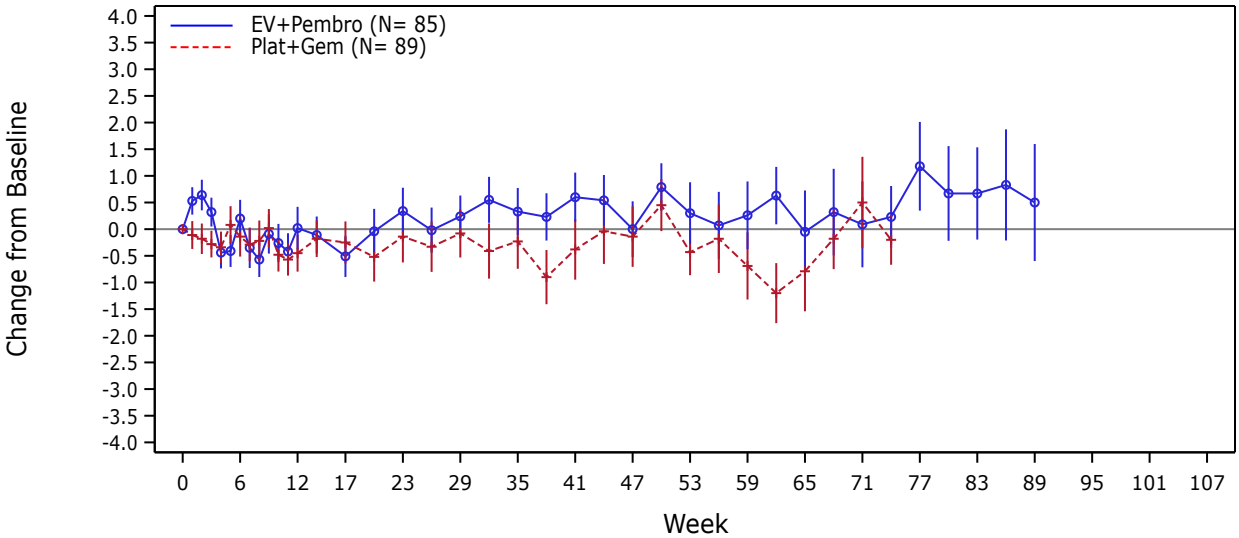
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.4.1.3: BPI-SF - Plot of Mean Change from Baseline of Worst Pain in the last 24 hours by Region - Analysis Set mITT 1

Region: Rest of World



Number of subjects

EV+Pembro	80	70	66	63	59	54	40	47	35	33	27	22	22	17	15	12
Plat+Gem	75	63	58	55	42	36	30	26	28	21	16	14	12			

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

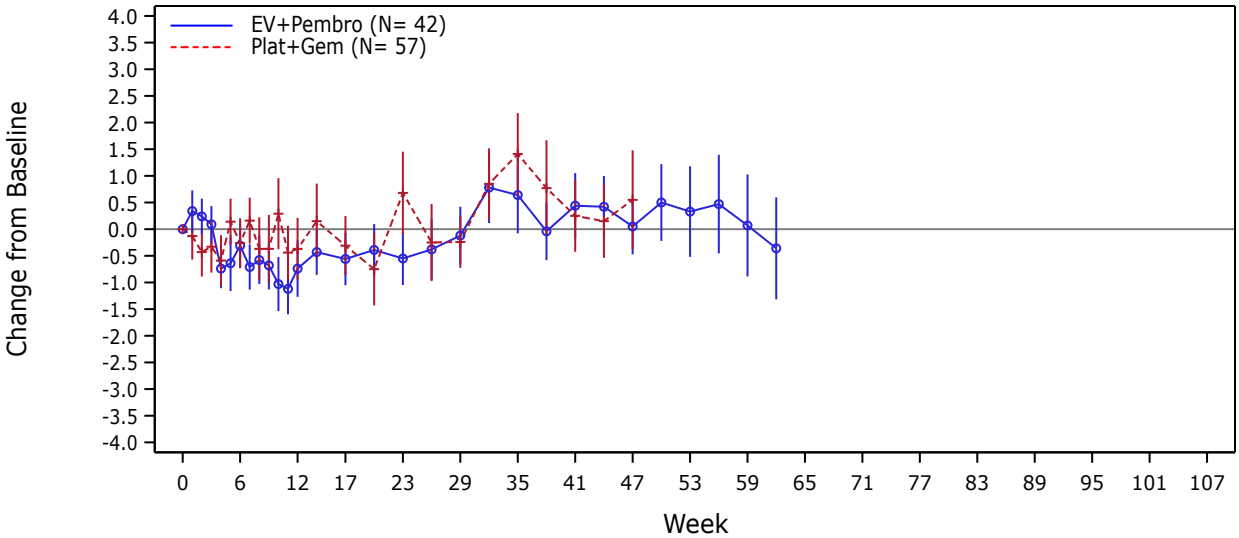
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.4.1.4: BPI-SF - Plot of Mean Change from Baseline of Worst Pain in the last 24 hours by Sex - Analysis Set mITT 1

Sex: Female



Number of subjects

EV+Pembro	36	32	31	32	29	25	22	25	19	15	14
Plat+Gem	42	35	30	29	19	21	17	12	11		

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

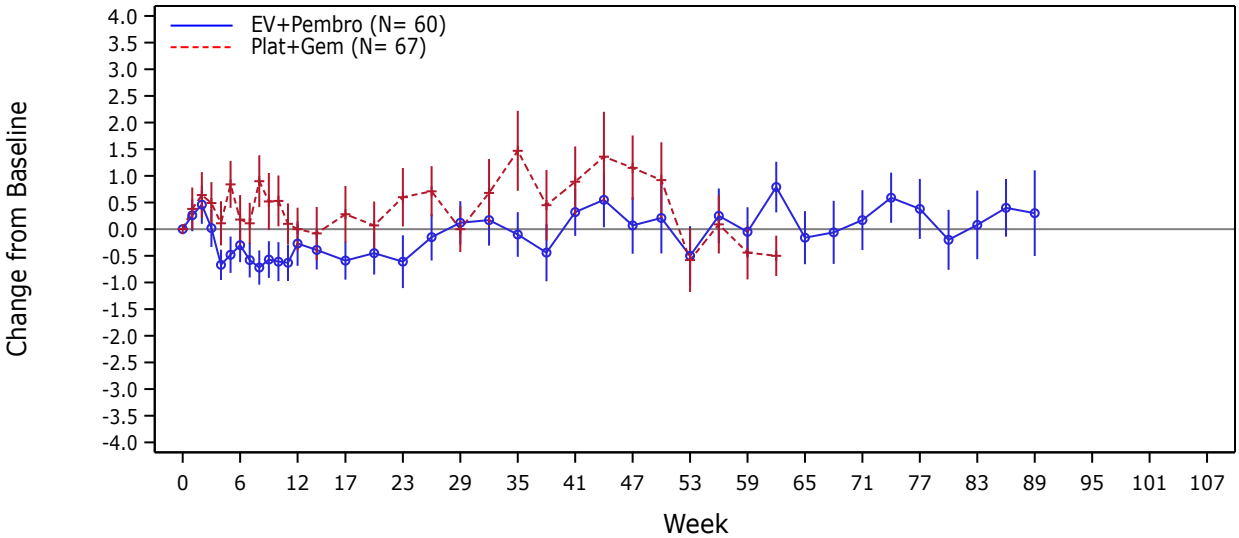
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.4.1.5: BPI-SF - Plot of Mean Change from Baseline of Worst Pain in the last 24 hours by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Lymph node only



Number of subjects

EV+Pembro	53	50	45	44	41	42	40	34	27	22	19	19	18	16	12	10
Plat+Gem	49	40	39	36	25	21	19	18	13	12	9					

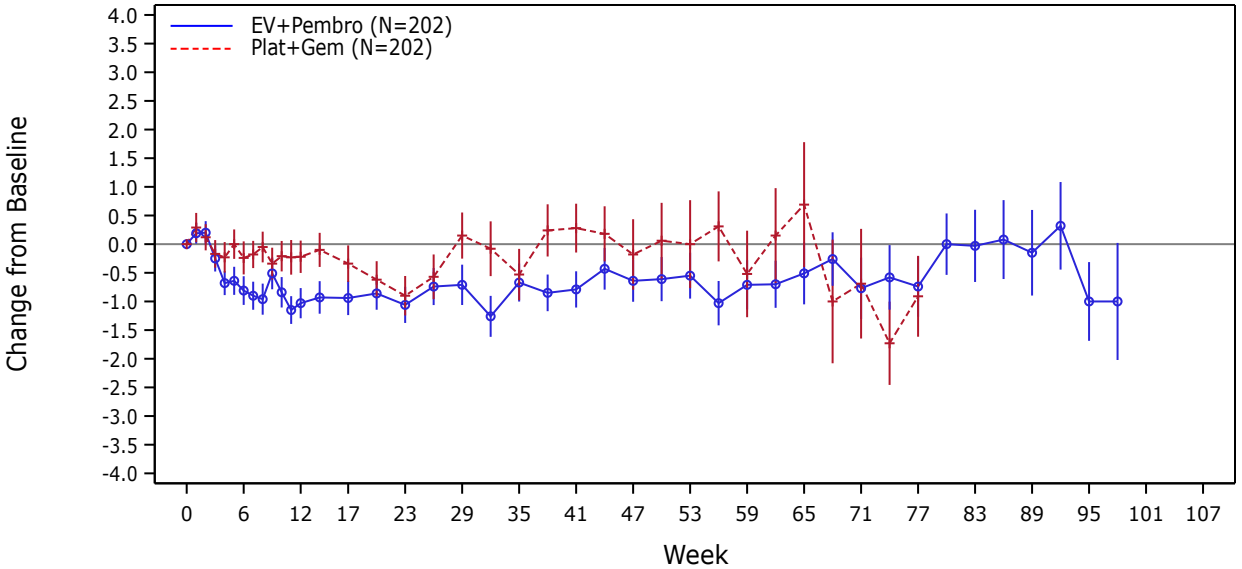
Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.4.2: BPI-SF - Plot of Mean Change from Baseline of Worst Pain in the last 24 hours - Analysis Set mITT 2



Number of subjects

EV+Pembro	166	128	123	114	100	95	88	87	72	66	59	41	39	34	30	20	14
Plat+Gem	168	131	116	108	81	71	57	47	39	28	21	16	13	11			

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

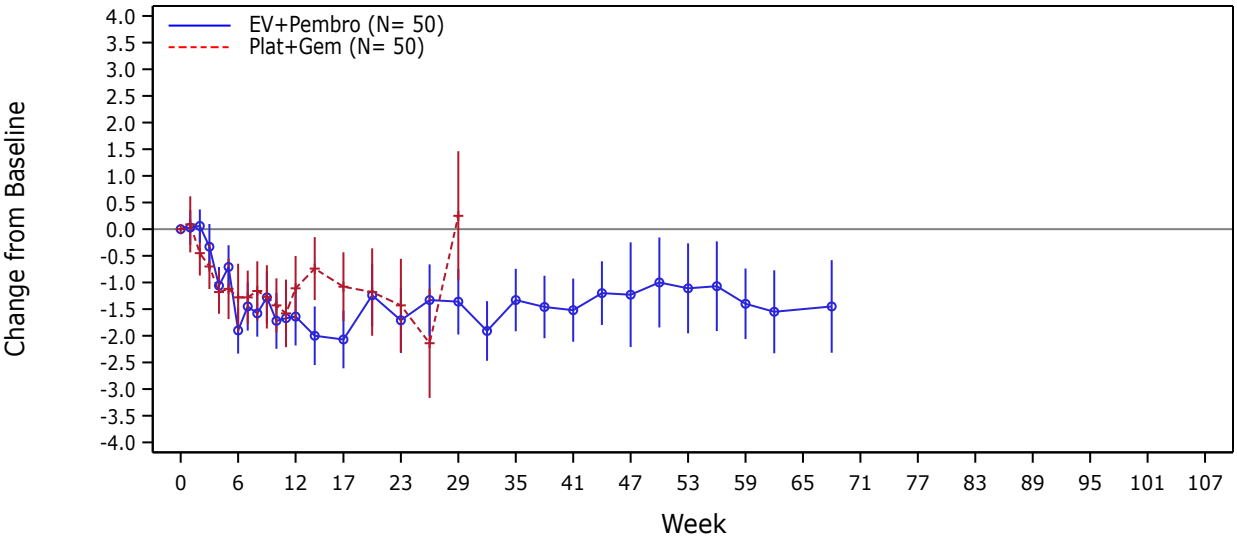
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.4.2.1: BPI-SF - Plot of Mean Change from Baseline of Worst Pain in the last 24 hours by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Present



Number of subjects

EV+Pembro	41	30	28	27	24	25	24	23	13	18	15
Plat+Gem	41	29	28	24	14	12					

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

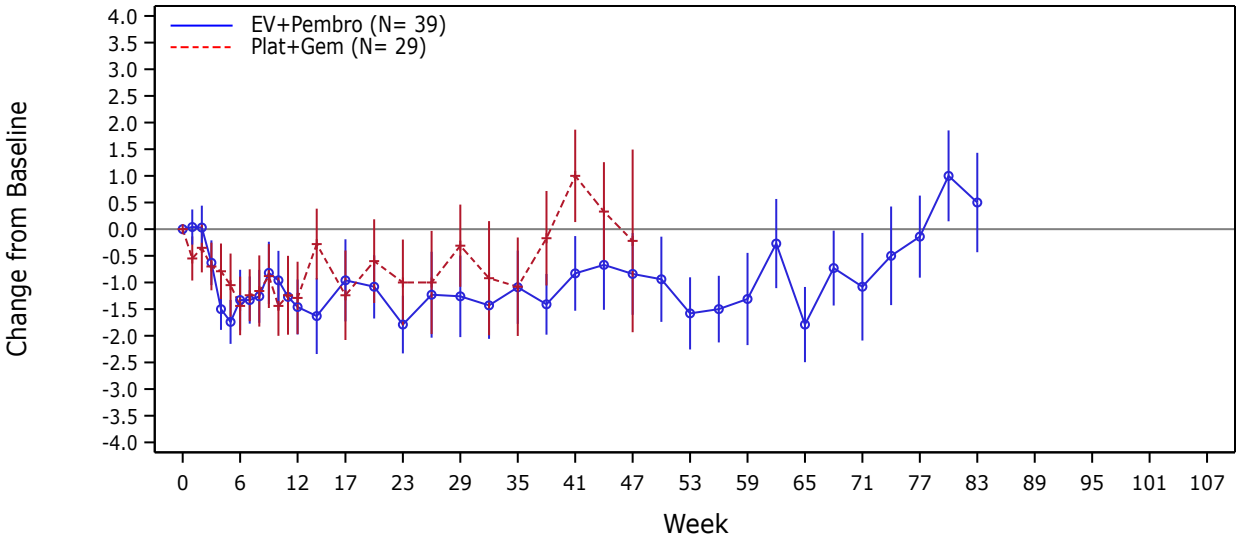
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.4.2.2: BPI-SF - Plot of Mean Change from Baseline of Worst Pain in the last 24 hours by Age - Analysis Set mITT 2

Age: < 65 years



Number of subjects

EV+Pembro	33	27	26	25	24	23	22	24	19	19	16	14	13	14	12
Plat+Gem	22	18	17	17	16	13	13	9	9						

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

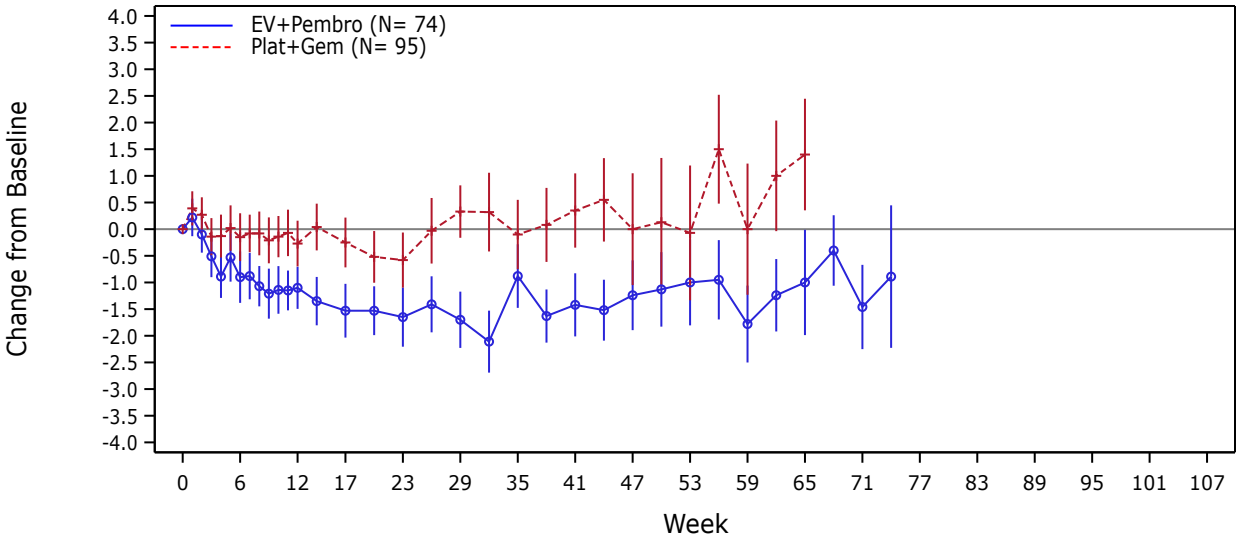
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.4.2.3: BPI-SF - Plot of Mean Change from Baseline of Worst Pain in the last 24 hours by Region - Analysis Set mITT 2

Region: Europe



Number of subjects

EV+Pembro	57	41	41	34	31	30	26	24	21	23	18	13	13
Plat+Gem	76	61	56	53	40	36	30	23	20	14	10	10	

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

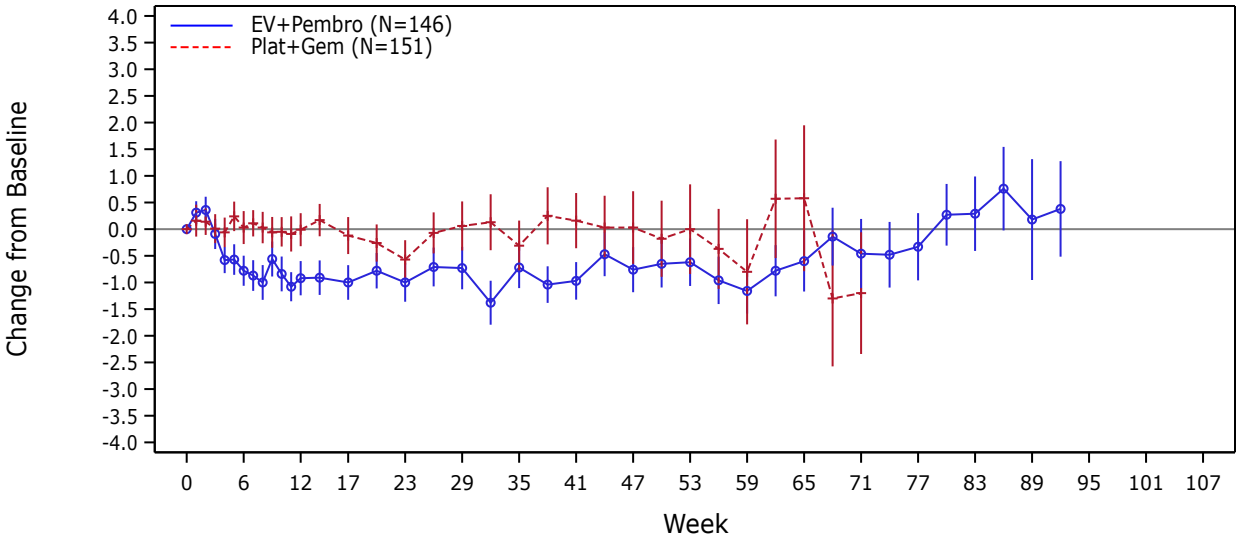
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.4.2.4: BPI-SF - Plot of Mean Change from Baseline of Worst Pain in the last 24 hours by Sex - Analysis Set mITT 2

Sex: Male



Number of subjects

EV+Pembro	123	95	89	86	76	73	68	66	51	50	44	30	28	24	21	11
Plat+Gem	126	98	89	84	63	53	45	37	29	20	15	12	10			

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

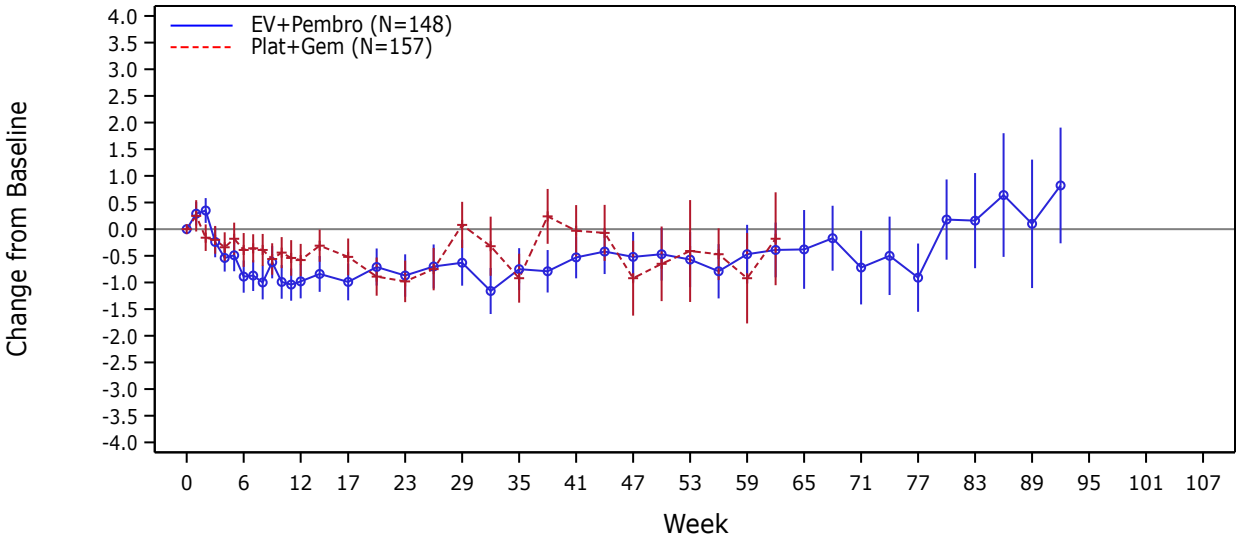
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.4.2.5: BPI-SF - Plot of Mean Change from Baseline of Worst Pain in the last 24 hours by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Visceral metastases



Number of subjects

EV+Pembro	121	91	86	81	71	64	63	60	48	44	38	24	25	23	19	10
Plat+Gem	130	98	85	82	59	50	37	31	26	17	12					

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

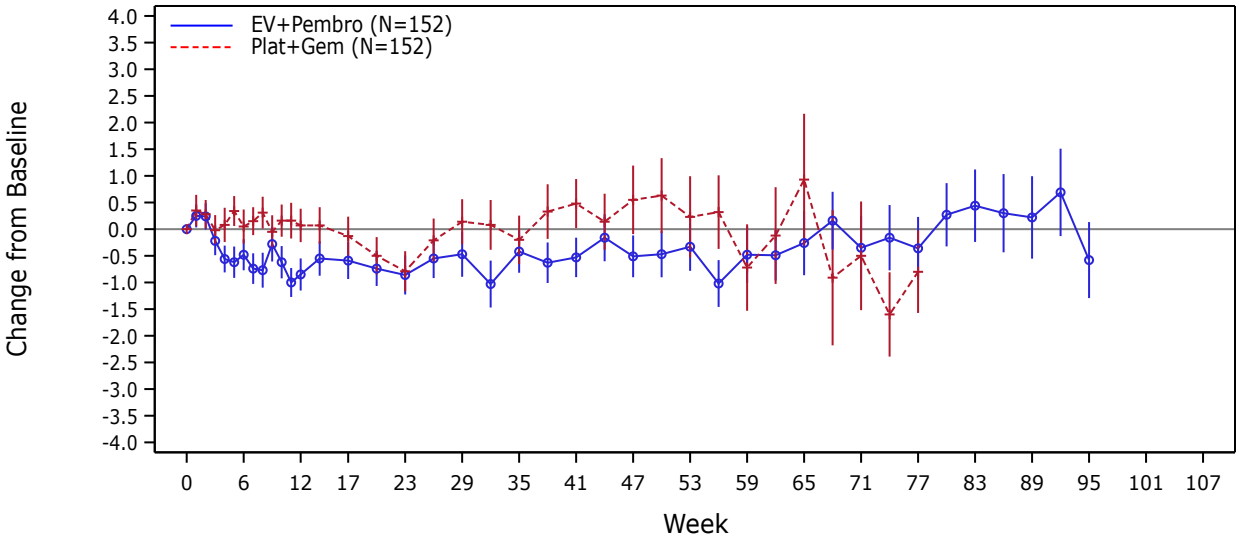
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.4.2.1: BPI-SF - Plot of Mean Change from Baseline of Worst Pain in the last 24 hours by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Absent



Number of subjects

EV+Pembro	125	98	95	87	76	70	64	64	59	48	44	34	31	28	25	18	12
Plat+Gem	127	102	88	84	67	59	49	40	31	22	18	14	12	10			

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

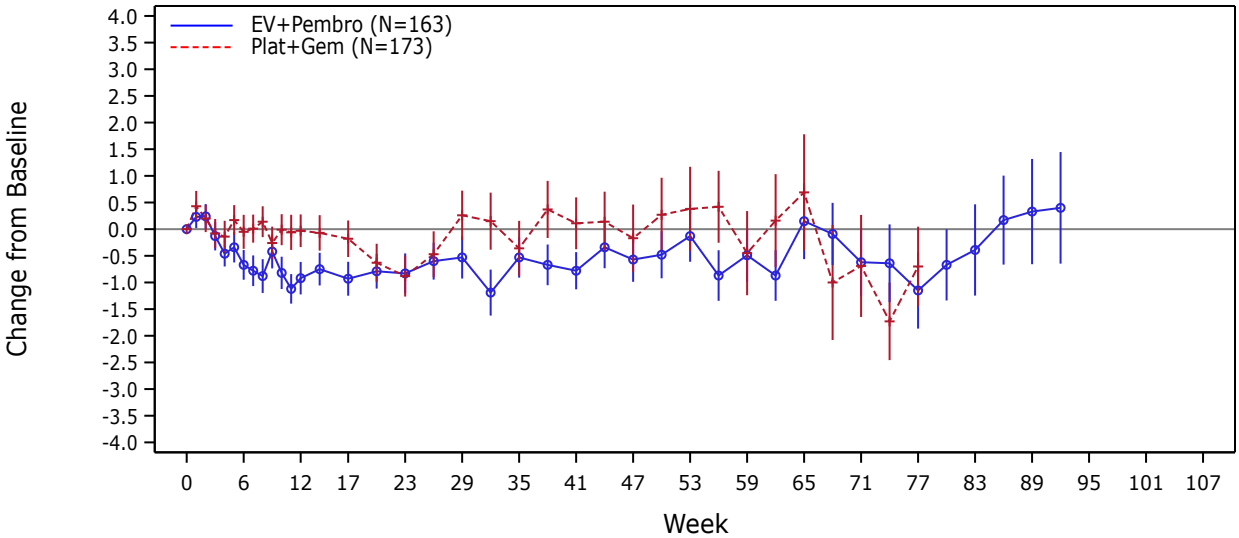
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.4.2.2: BPI-SF - Plot of Mean Change from Baseline of Worst Pain in the last 24 hours by Age - Analysis Set mITT 2

Age: >= 65 years



Number of subjects

EV+Pembro	133	101	97	89	76	72	66	63	53	47	43	27	26	20	18	12
Plat+Gem	146	113	99	91	65	58	44	38	30	24	20	16	13	10		

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

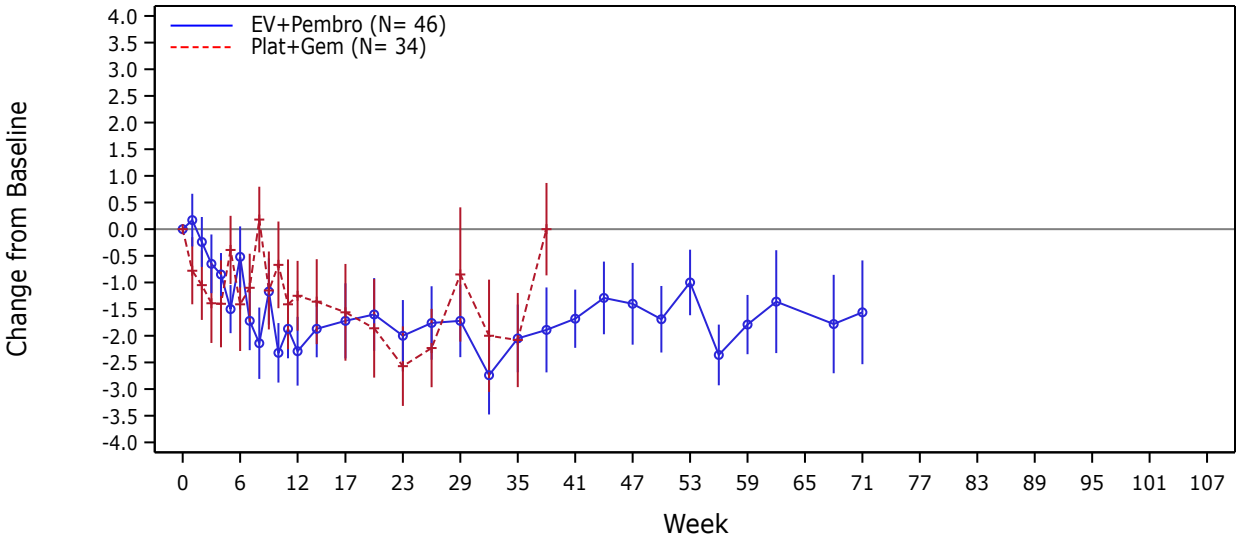
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.4.2.3: BPI-SF - Plot of Mean Change from Baseline of Worst Pain in the last 24 hours by Region - Analysis Set mITT 2

Region: North America



Number of subjects

EV+Pembro	35	25	24	25	19	18	20	19	15	12	14	9
Plat+Gem	28	17	16	18	14	13	12					

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

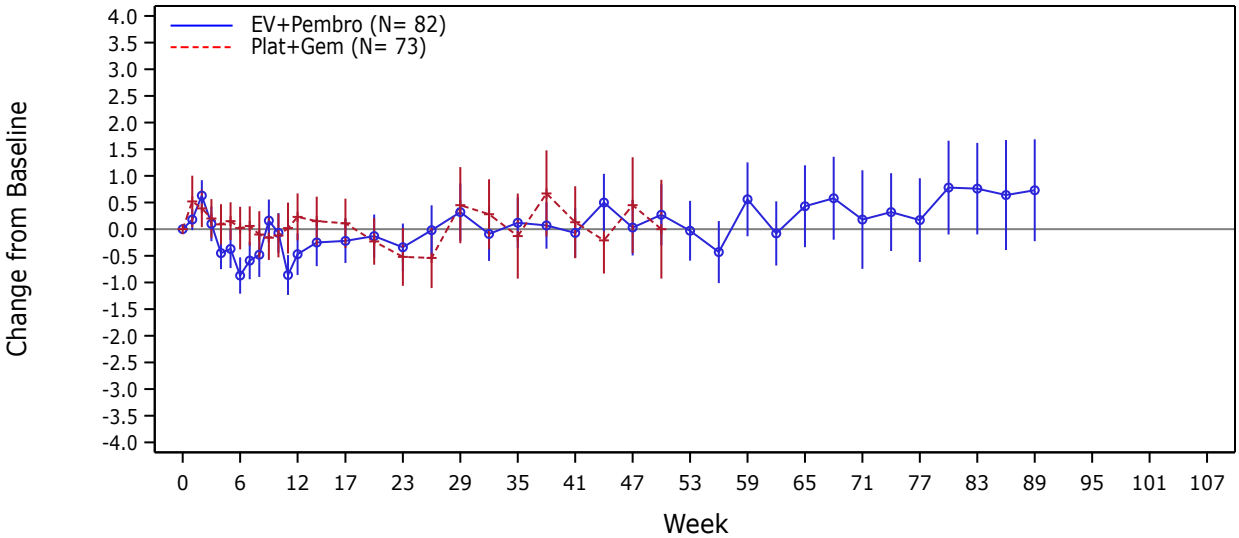
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.4.2.3: BPI-SF - Plot of Mean Change from Baseline of Worst Pain in the last 24 hours by Region - Analysis Set mITT 2

Region: Rest of World



Number of subjects

EV+Pembro	74	62	58	55	50	47	42	44	36	31	27	21	17	18	17	11
Plat+Gem	64	53	44	37	27	22	15	16	11							

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

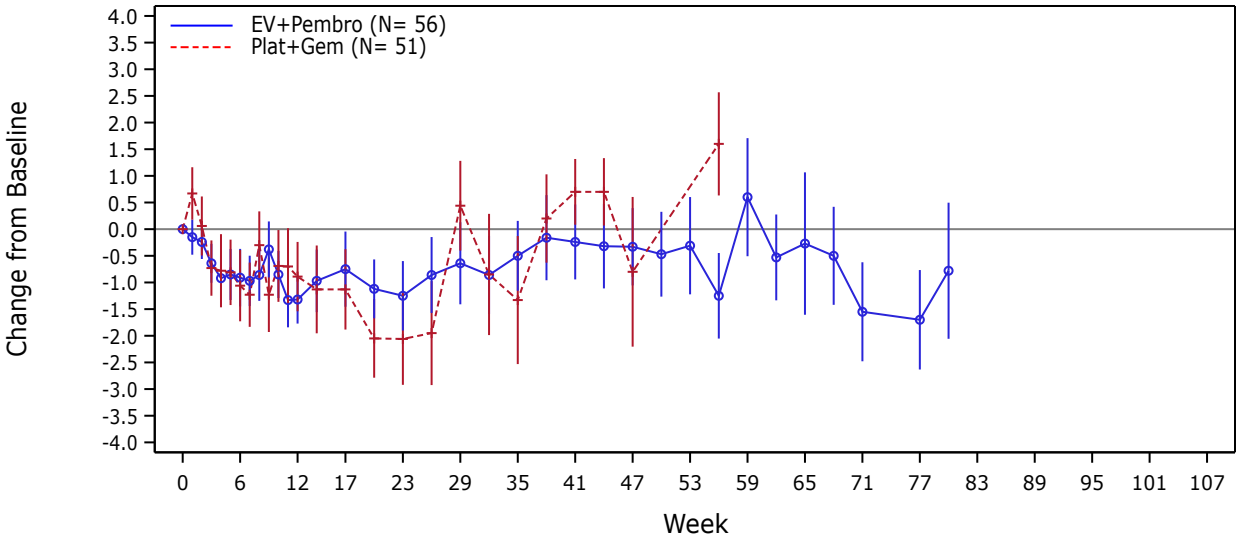
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.4.2.4: BPI-SF - Plot of Mean Change from Baseline of Worst Pain in the last 24 hours by Sex - Analysis Set mITT 2

Sex: Female



Number of subjects

EV+Pembro	43	33	34	28	24	22	20	21	21	16	15	11	11	10
Plat+Gem	42	33	27	24	18	18	12	10	10					

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

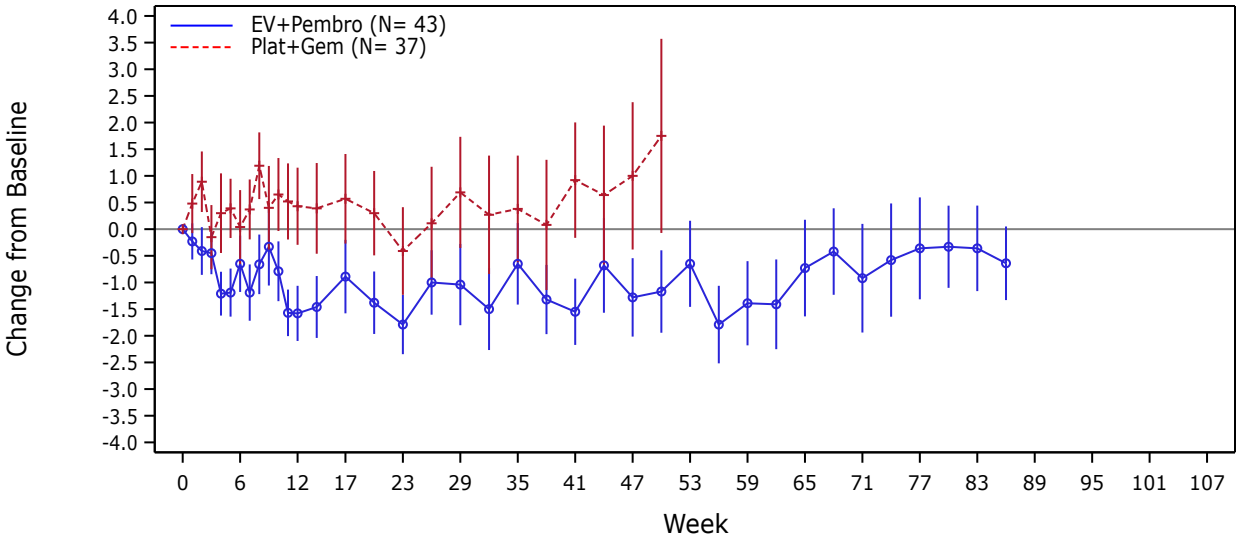
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.4.2.5: BPI-SF - Plot of Mean Change from Baseline of Worst Pain in the last 24 hours by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Lymph node only



Number of subjects

EV+Pembro	36	31	31	27	24	25	20	20	18	17	18	15	12	11	11
Plat+Gem	30	27	23	21	17	16	16	12	10						

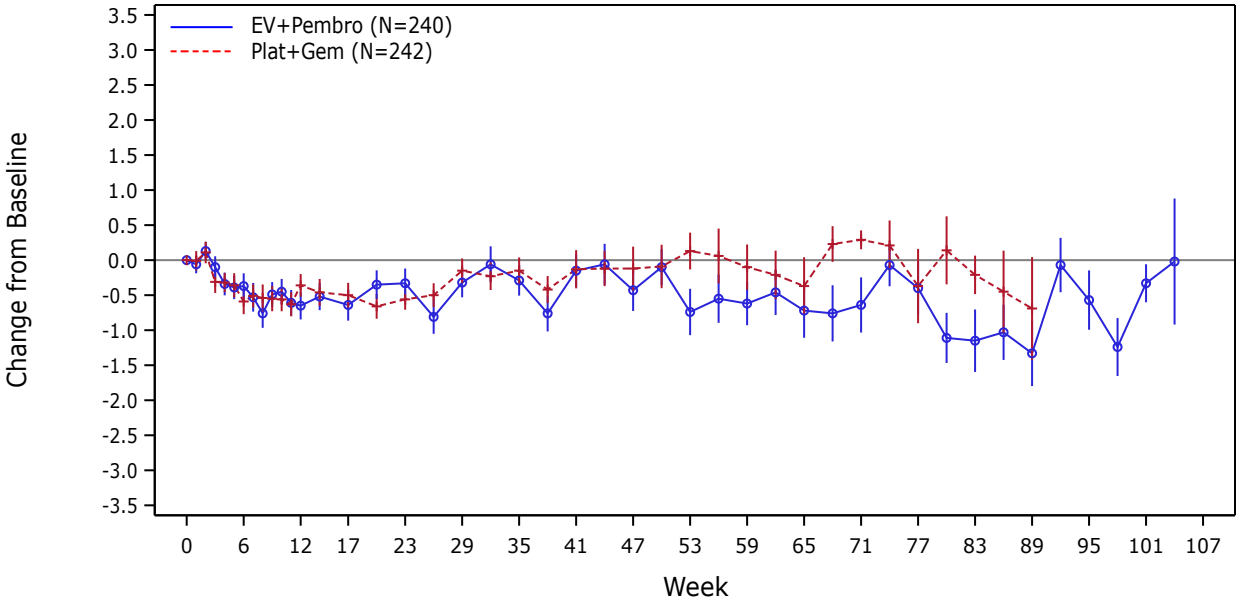
Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.5.1: BPI-SF - Plot of Mean Change from Baseline of Pain Severity - Analysis Set mITT 1



Number of subjects

EV+Pembro	209	150	147	136	127	123	100	100	81	61	57	47	41	33	28	23	15	12
Plat+Gem	190	132	127	113	81	71	58	48	43	38	29	22	16	13	11	10		

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

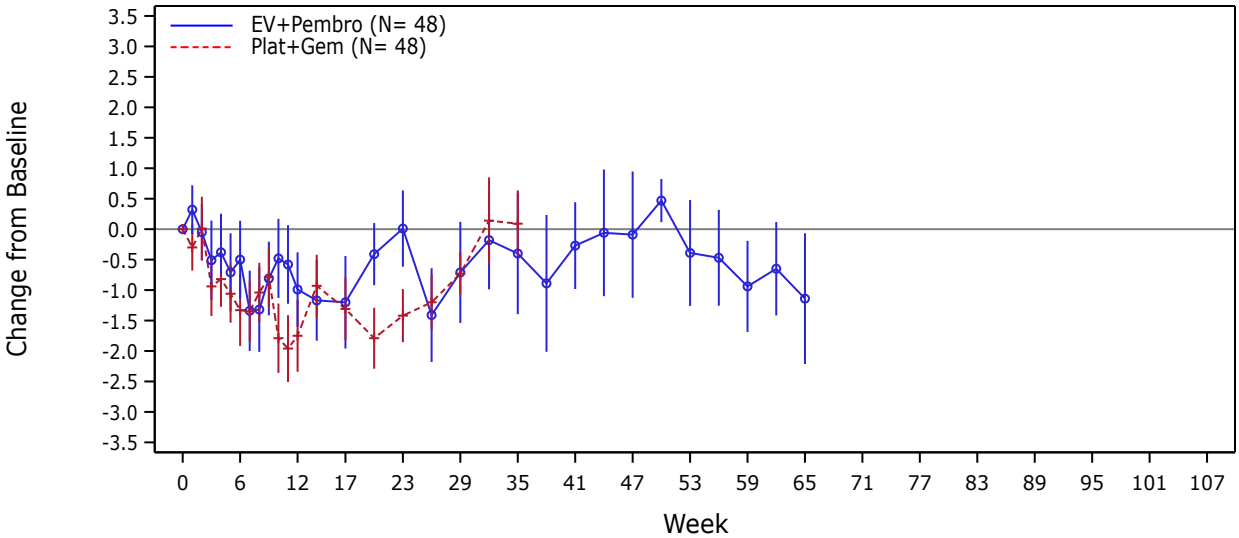
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.5.1.1: BPI-SF - Plot of Mean Change from Baseline of Pain Severity by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Present



Number of subjects

EV+Pembro	39	19	26	21	20	18	13	15	14	10	11	7
Plat+Gem	34	23	22	23	14	11	8					

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

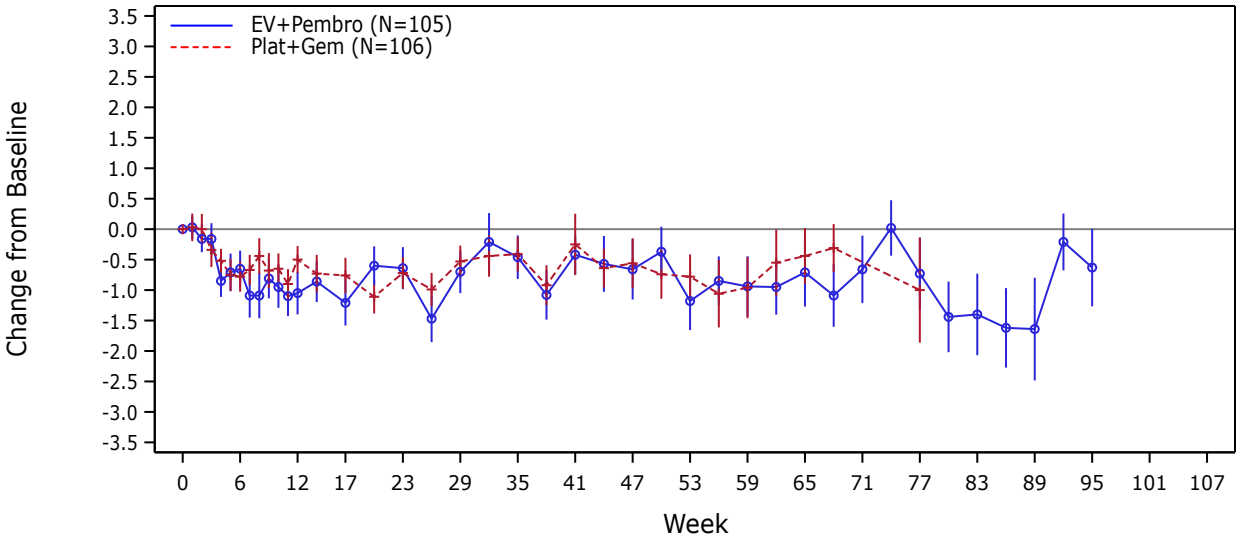
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.5.1.2: BPI-SF - Plot of Mean Change from Baseline of Pain Severity by Age - Analysis Set mITT 1

Age: < 65 years



Number of subjects

EV+Pembro	94	72	67	62	60	58	50	53	41	30	33	27	25	19	18	12	8
Plat+Gem	84	59	61	51	38	32	27	20	18	15	12	10		7			

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

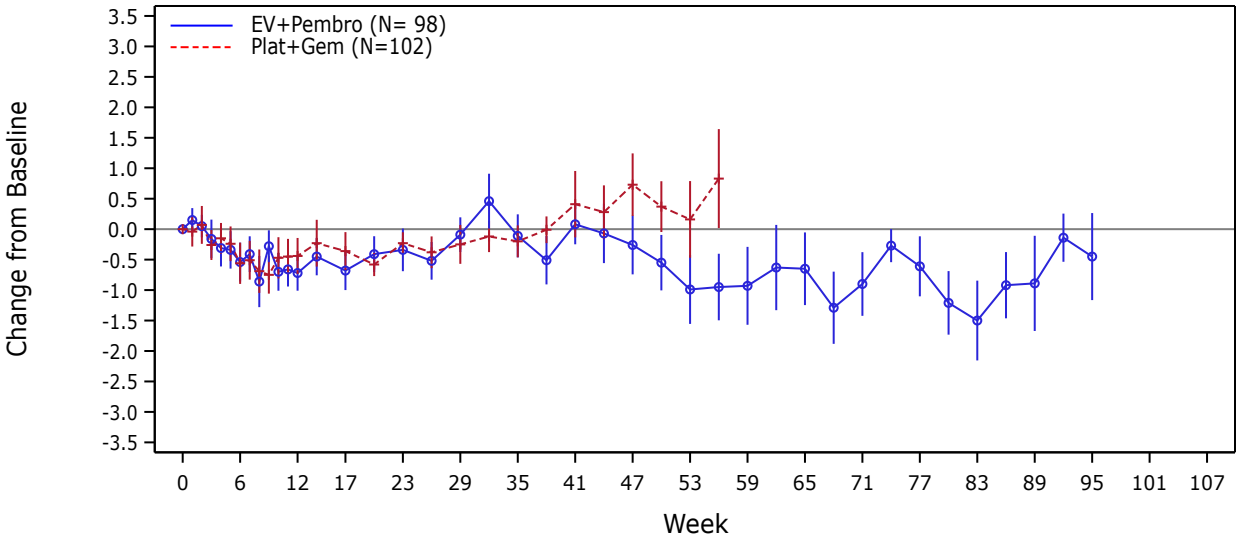
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.5.1.3: BPI-SF - Plot of Mean Change from Baseline of Pain Severity by Region - Analysis Set mITT 1

Region: Europe



Number of subjects

EV+Pembro	81	53	56	54	49	50	42	39	30	23	21	19	16	16	14	10	7
Plat+Gem	73	49	44	40	27	23	19	14	12	8							

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

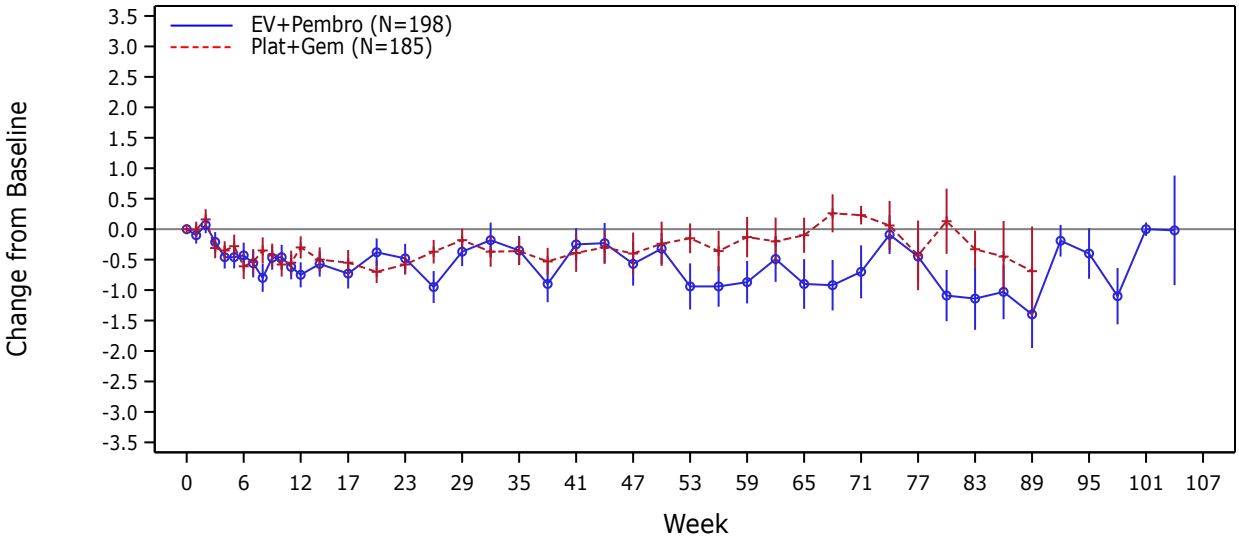
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.5.1.4: BPI-SF - Plot of Mean Change from Baseline of Pain Severity by Sex - Analysis Set mITT 1

Sex: Male



Number of subjects

EV+Pembro	173	121	120	111	101	103	84	79	64	48	45	40	37	28	24	19	14	10
Plat+Gem	148	99	101	87	66	53	44	38	35	31	25	20	13	12	9	10		

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

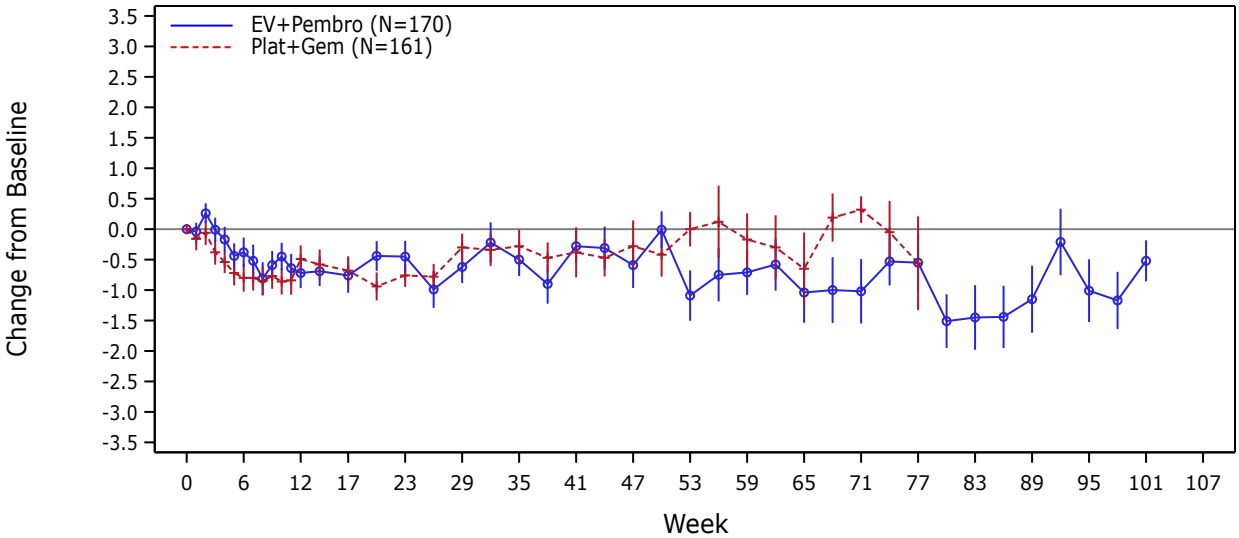
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.5.1.5: BPI-SF - Plot of Mean Change from Baseline of Pain Severity by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Visceral metastases



Number of subjects

EV+Pembro	149	98	107	93	90	85	65	71	59	42	42	31	28	22	20	17	10	9
Plat+Gem	131	92	85	79	57	50	39	28	28	23	18	15	9	9				

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

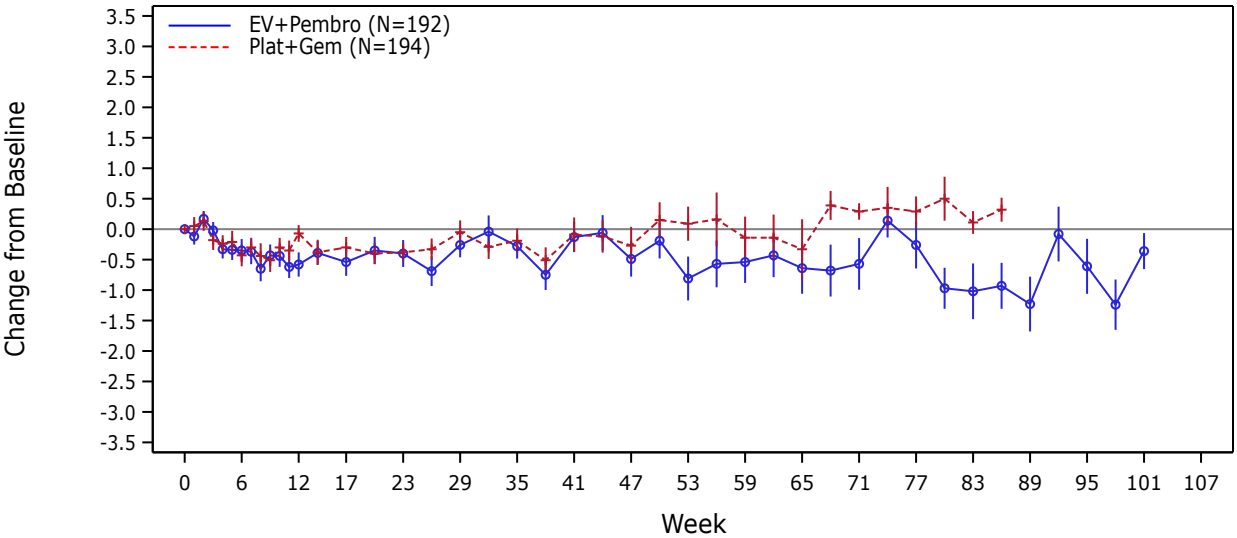
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.5.1.1: BPI-SF - Plot of Mean Change from Baseline of Pain Severity by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Absent



Number of subjects

EV+Pembro	170	131	121	115	107	105	87	85	67	51	46	40	34	27	24	19	14	11
Plat+Gem	156	109	105	90	67	60	50	46	39	33	25	18	16	11	9			

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

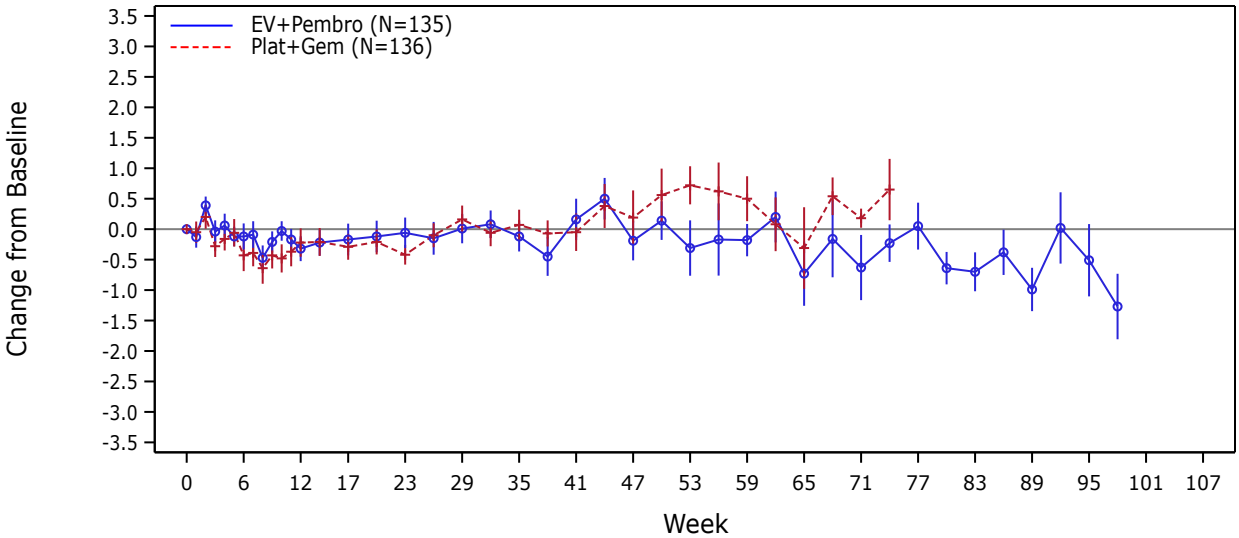
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.5.1.2: BPI-SF - Plot of Mean Change from Baseline of Pain Severity by Age - Analysis Set mITT 1

Age: >= 65 years



Number of subjects

EV+Pembro	115	78	80	74	67	65	50	47	40	31	24	20	16	14	10	11	7
Plat+Gem	106	73	66	62	43	39	31	28	25	23	17	12	11				

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

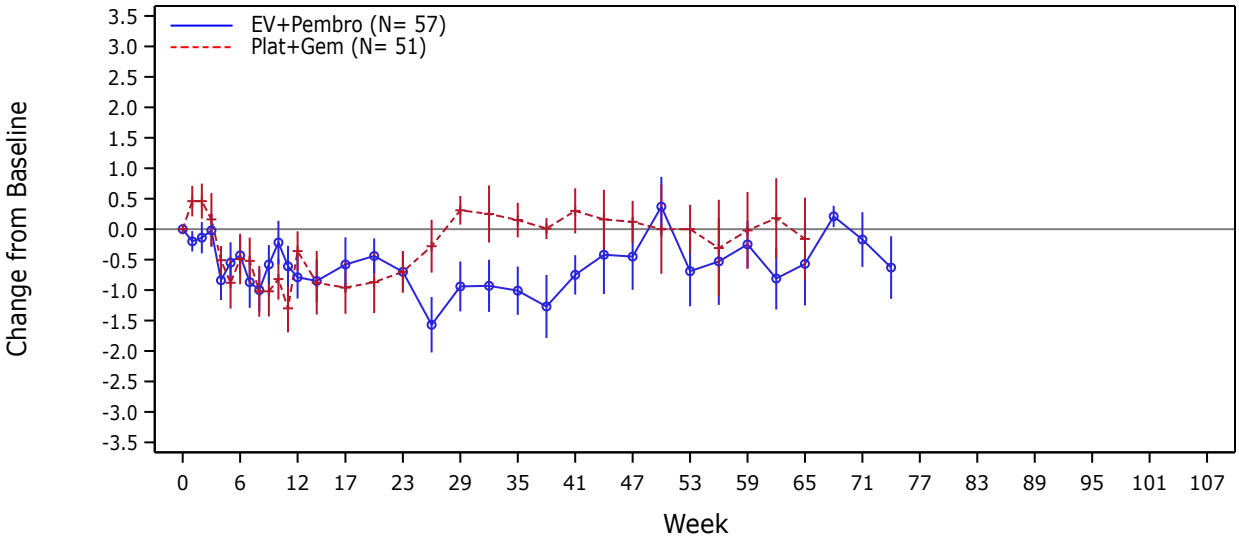
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.5.1.3: BPI-SF - Plot of Mean Change from Baseline of Pain Severity by Region - Analysis Set mITT 1

Region: North America



Number of subjects

EV+Pembro	48	34	35	30	31	32	26	23	22	11	12	9	6
Plat+Gem	42	27	28	24	19	17	13	12	7	10	7	7	

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

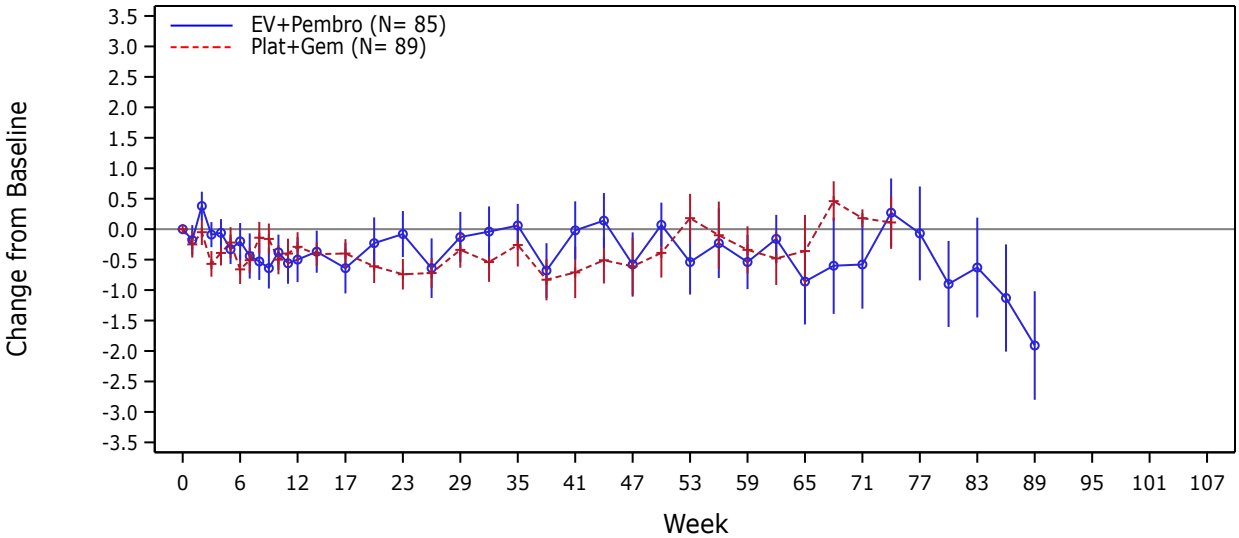
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.5.1.3: BPI-SF - Plot of Mean Change from Baseline of Pain Severity by Region - Analysis Set mITT 1

Region: Rest of World



Number of subjects

EV+Pembro	80	63	56	52	47	41	32	38	29	27	24	19	19	12	10	8
Plat+Gem	75	56	55	49	35	31	26	22	24	20	15	13	11			

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

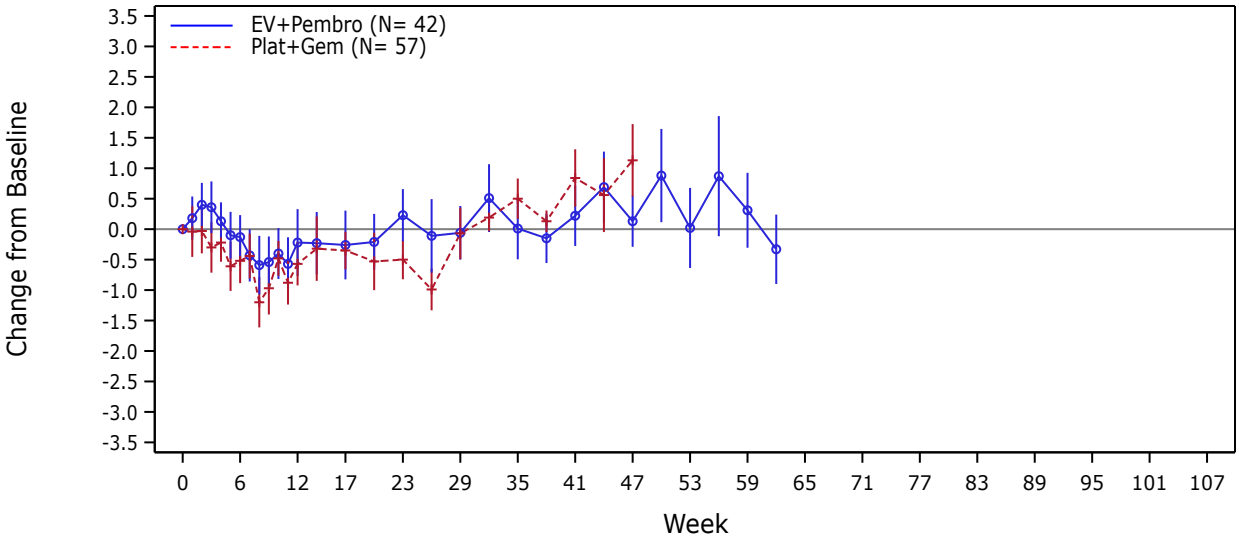
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.5.1.4: BPI-SF - Plot of Mean Change from Baseline of Pain Severity by Sex - Analysis Set mITT 1

Sex: Female



Number of subjects

EV+Pembro	36	29	27	25	26	20	16	21	17	13	12
Plat+Gem	42	33	26	26	15	18	14	10	8		

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

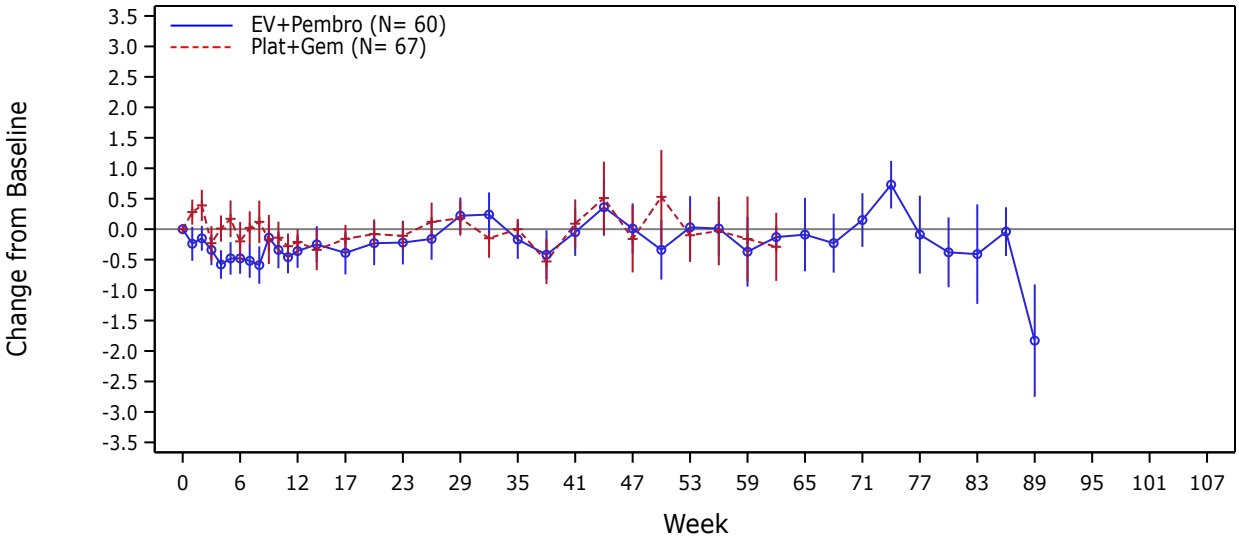
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.5.1.5: BPI-SF - Plot of Mean Change from Baseline of Pain Severity by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Lymph node only



Number of subjects

EV+Pembro	53	46	36	38	33	35	33	27	22	19	15	16	13	11	8	6
Plat+Gem	49	35	34	28	20	17	14	14	9	11	8					

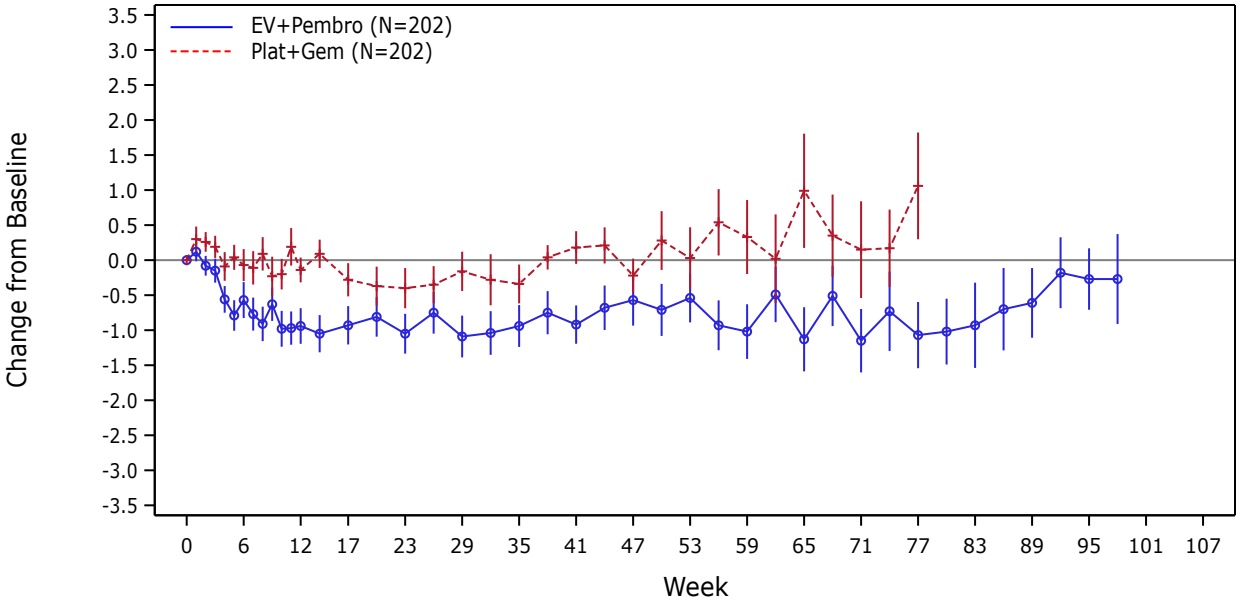
Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.5.2: BPI-SF - Plot of Mean Change from Baseline of Pain Severity - Analysis Set mITT 2



Number of subjects

EV+Pembro	166	110	104	96	85	76	71	70	59	54	49	31	33	28	24	17	14
Plat+Gem	168	114	100	91	76	62	51	42	33	24	18	13	12	10			

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

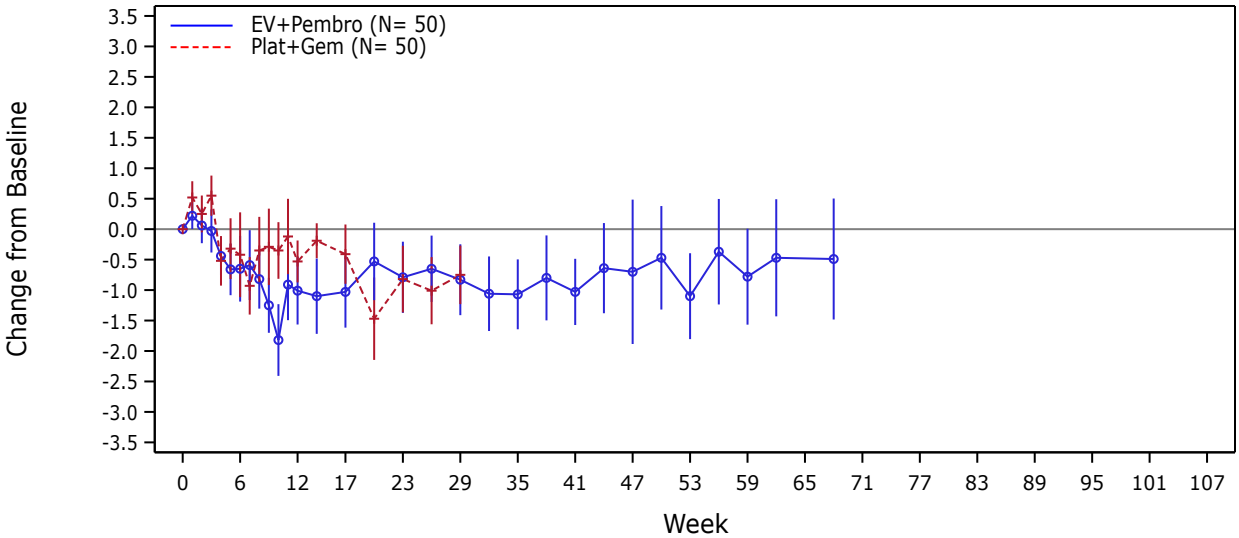
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.5.2.1: BPI-SF - Plot of Mean Change from Baseline of Pain Severity by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Present



Number of subjects

EV+Pembro	41	28	26	26	22	23	22	21	11	15	15
Plat+Gem	41	25	25	21	13	9					

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

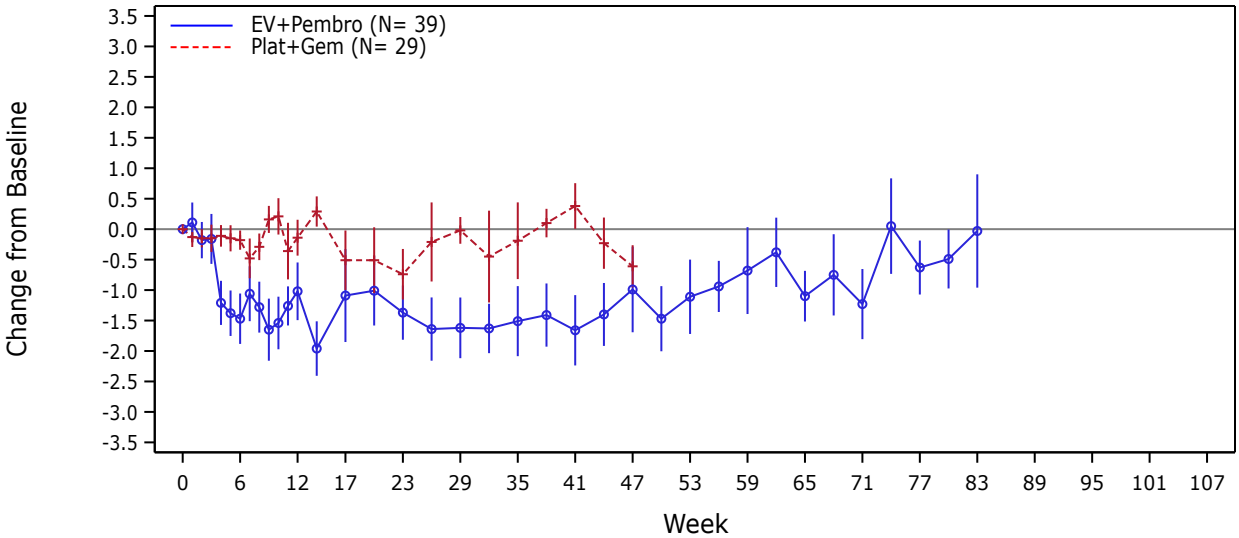
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.5.2.2: BPI-SF - Plot of Mean Change from Baseline of Pain Severity by Age - Analysis Set mITT 2

Age: < 65 years



Number of subjects

EV+Pembro	33	22	23	20	20	19	17	17	15	16	13	12	10	10	9
Plat+Gem	22	17	15	15	16	12	13	8	8						

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

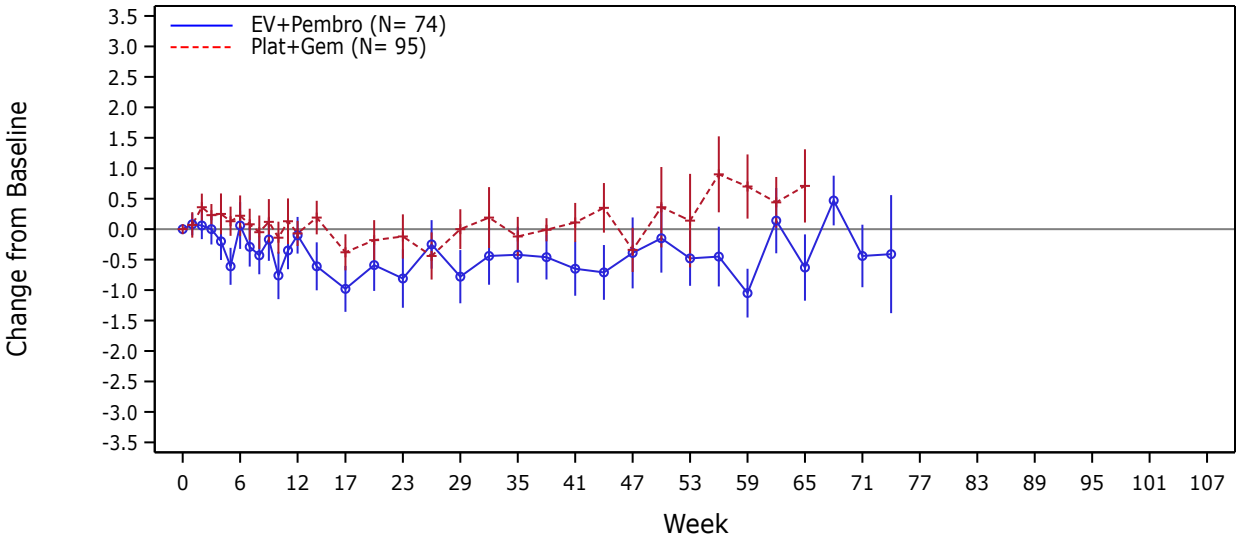
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.5.2.3: BPI-SF - Plot of Mean Change from Baseline of Pain Severity by Region - Analysis Set mITT 2

Region: Europe



Number of subjects

EV+Pembro	57	35	37	29	25	27	23	19	17	19	16	10	13
Plat+Gem	76	54	46	46	36	31	26	21	16	12	8	7	

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

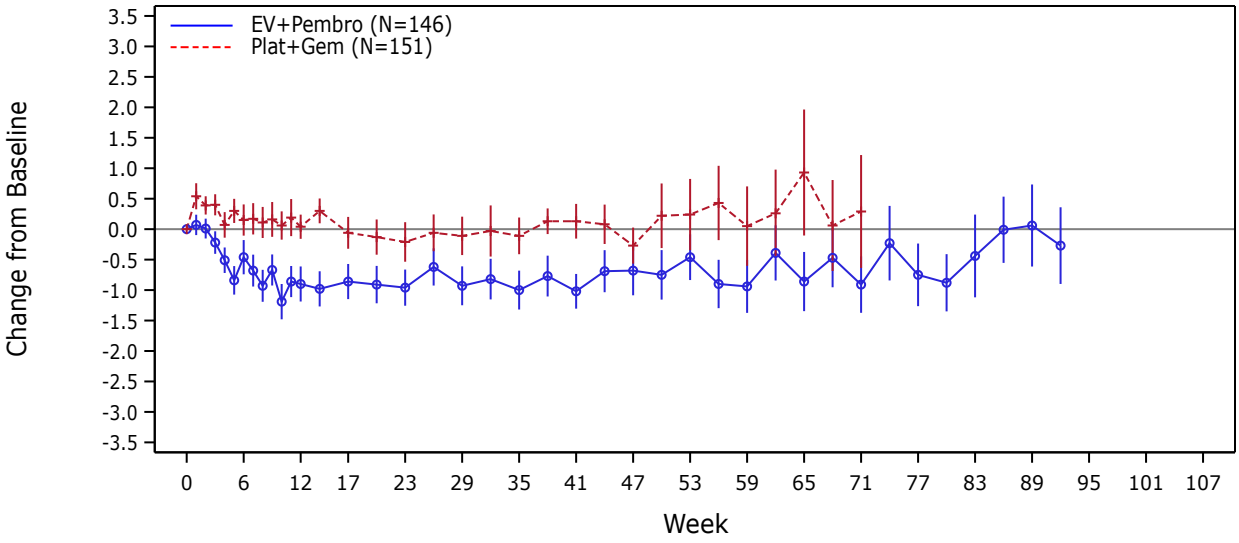
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.5.2.4: BPI-SF - Plot of Mean Change from Baseline of Pain Severity by Sex - Analysis Set mITT 2

Sex: Male



Number of subjects

EV+Pembro	123	83	78	74	66	59	58	57	44	43	39	23	23	18	17	9
Plat+Gem	126	85	75	69	58	44	39	32	24	17	13	10	9			

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

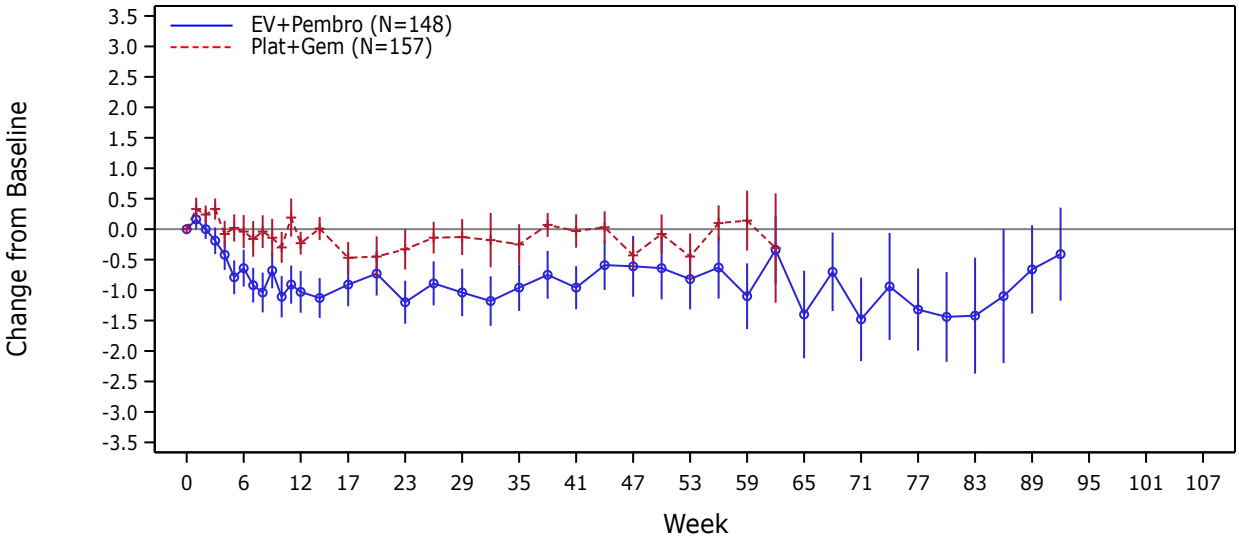
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.5.2.5: BPI-SF - Plot of Mean Change from Baseline of Pain Severity by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Visceral metastases



Number of subjects

EV+Pembro	121	82	72	69	61	52	52	49	38	34	30	18	20	18	14	8
Plat+Gem	130	87	76	69	56	43	34	28	23	15	11					

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

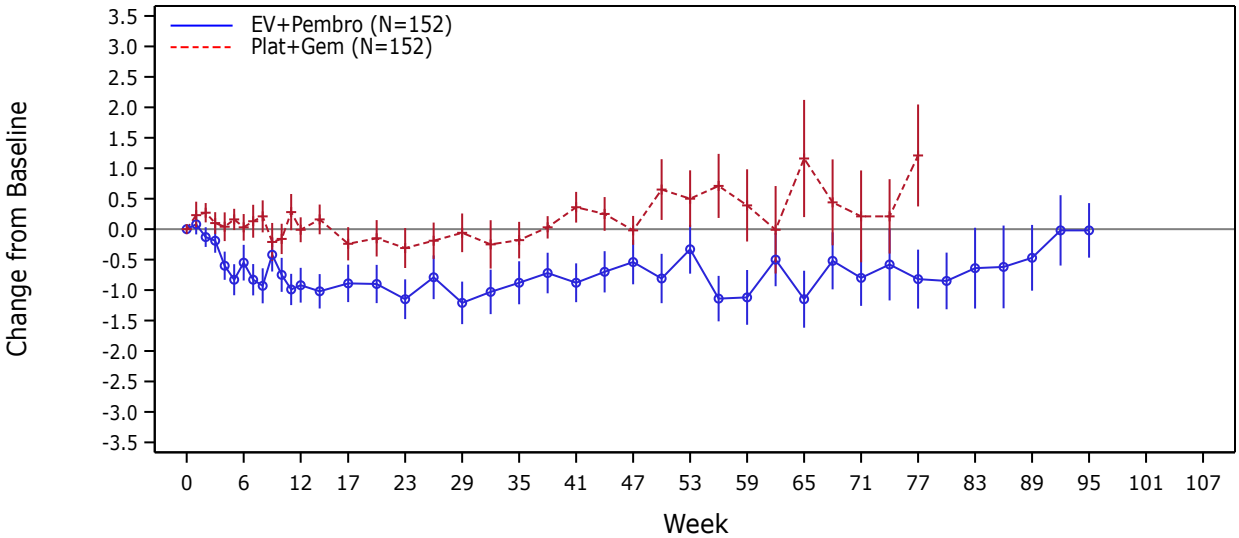
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.5.2.1: BPI-SF - Plot of Mean Change from Baseline of Pain Severity by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Absent



Number of subjects

EV+Pembro	125	82	78	70	63	53	49	49	48	39	34	24	26	23	19	15	12
Plat+Gem	127	89	75	70	63	53	44	35	26	19	16	11	11	9			

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

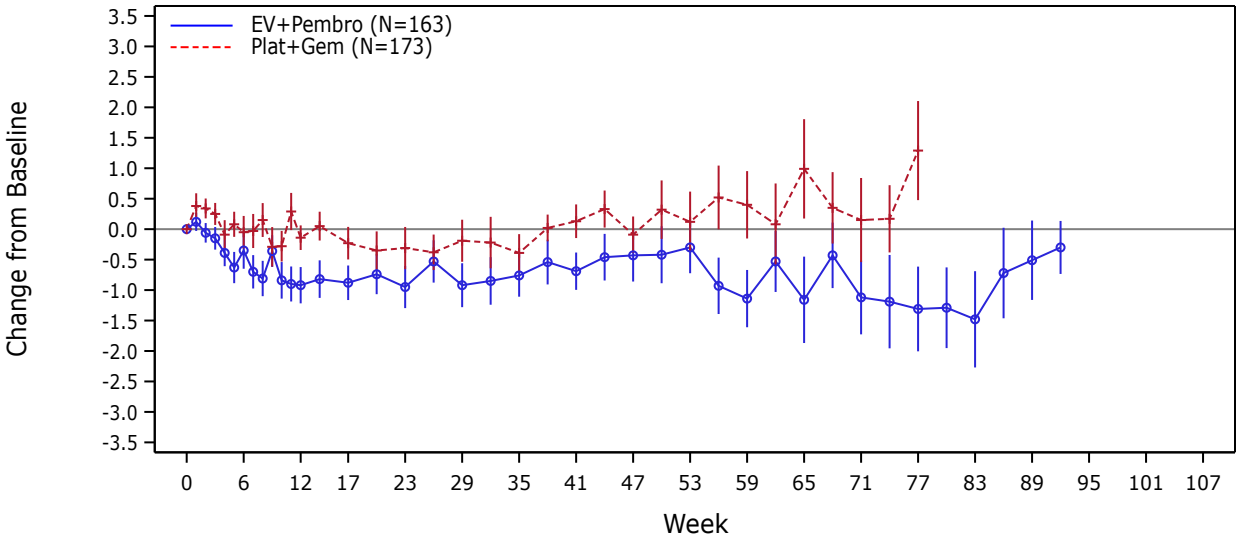
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.5.2.2: BPI-SF - Plot of Mean Change from Baseline of Pain Severity by Age - Analysis Set mITT 2

Age: >= 65 years



Number of subjects

EV+Pembro	133	88	81	76	65	57	54	53	44	38	36	19	23	18	15	10
Plat+Gem	146	97	85	76	60	50	38	34	25	20	17	13	12	9		

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

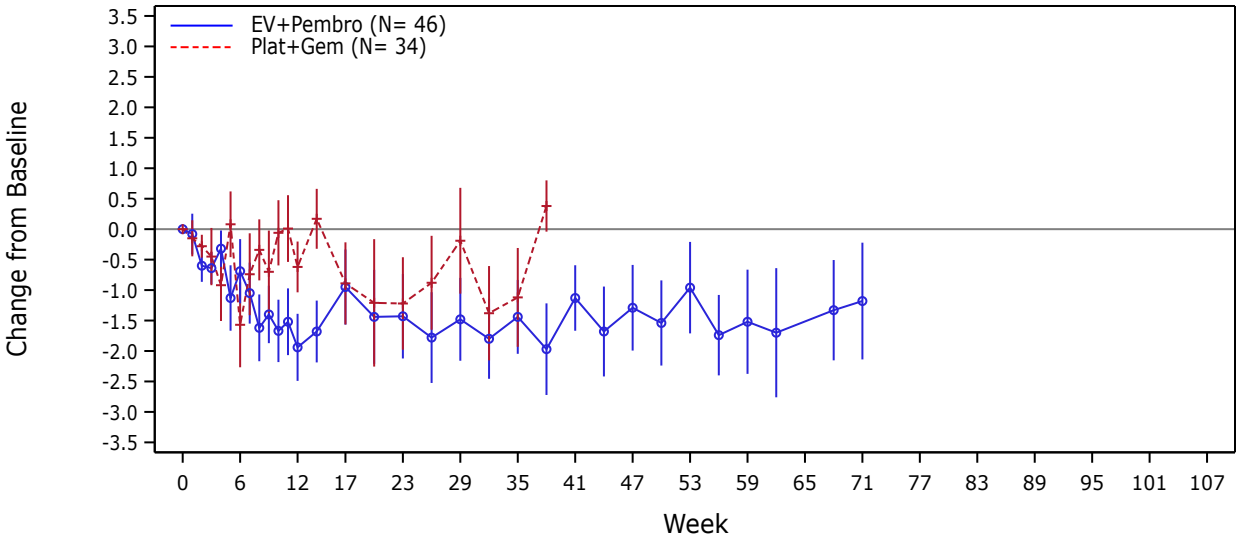
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.5.2.3: BPI-SF - Plot of Mean Change from Baseline of Pain Severity by Region - Analysis Set mITT 2

Region: North America



Number of subjects

EV+Pembro	35	24	23	24	19	16	20	18	14	11	14	8
Plat+Gem	28	15	14	15	14	11	11					

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

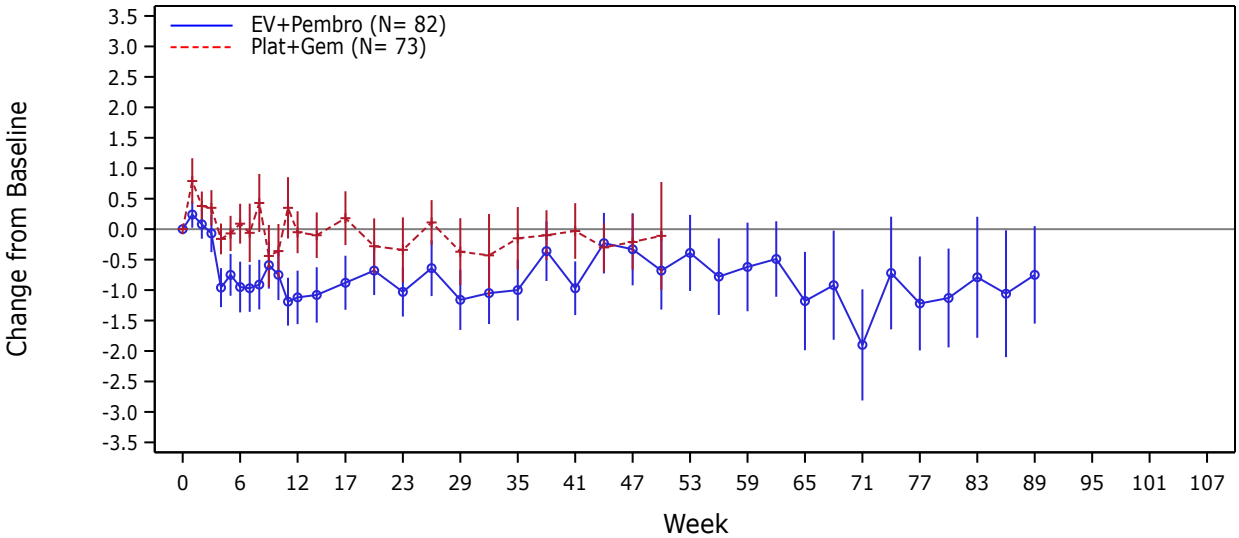
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.5.2.3: BPI-SF - Plot of Mean Change from Baseline of Pain Severity by Region - Analysis Set mITT 2

Region: Rest of World



Number of subjects

EV+Pembro	74	51	44	43	41	33	28	33	28	24	19	14	12	13	12	9
Plat+Gem	64	45	40	30	26	20	14	14	10							

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

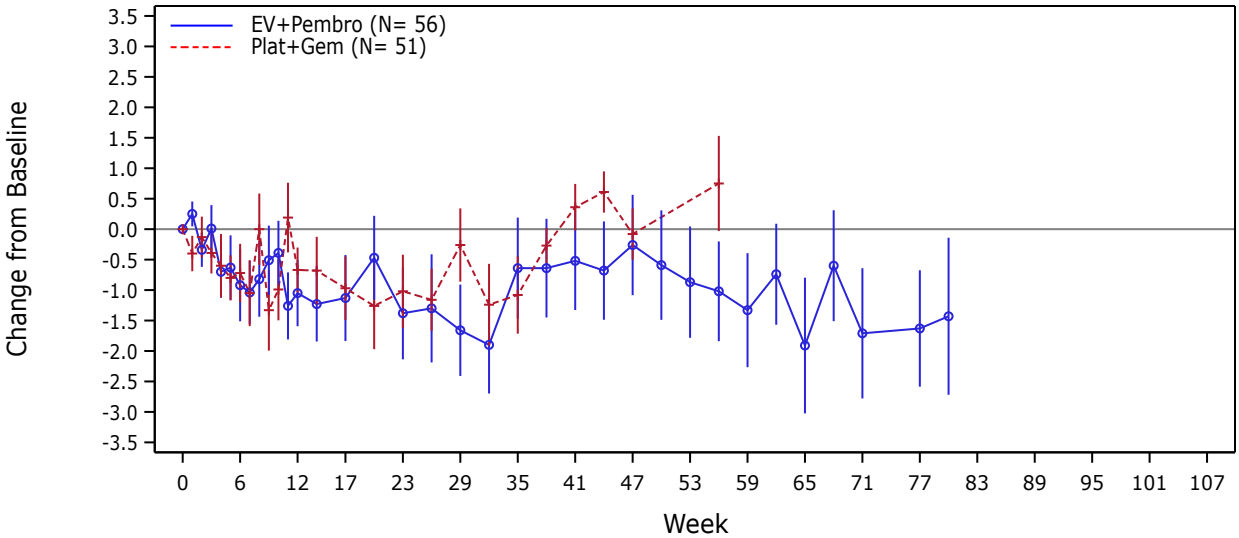
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.5.2.4: BPI-SF - Plot of Mean Change from Baseline of Pain Severity by Sex - Analysis Set mITT 2

Sex: Female



Number of subjects

EV+Pembro	43	27	26	22	19	17	13	13	15	11	10	8	10	10
Plat+Gem	42	29	25	22	18	18	12	10	9					

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

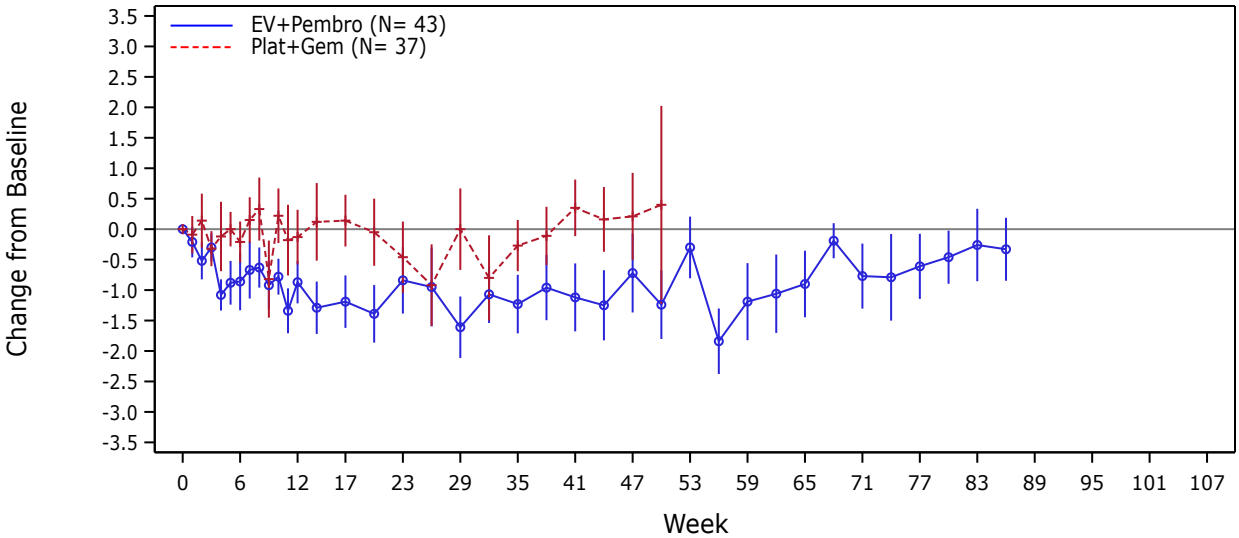
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.5.2.5: BPI-SF - Plot of Mean Change from Baseline of Pain Severity by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Lymph node only



Number of subjects

EV+Pembro	36	23	27	22	20	19	15	15	16	15	16	11	11	10	10
Plat+Gem	30	23	17	17	16	15	14	11	8						

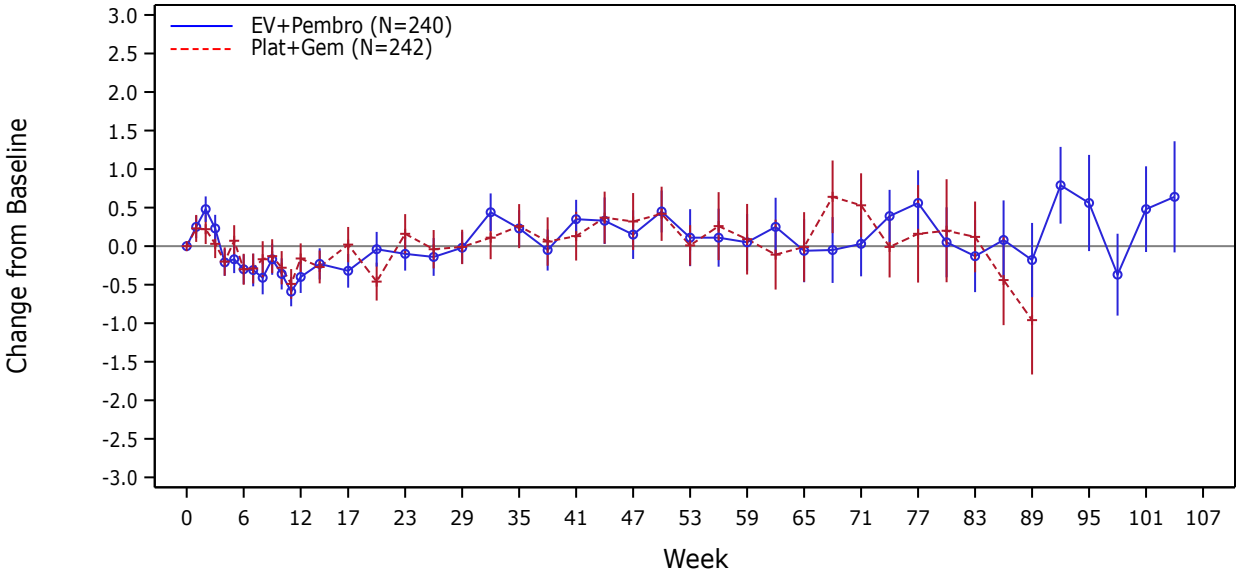
Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.6.1: BPI-SF - Plot of Mean Change from Baseline of Pain Interference - Analysis Set mITT 1



Number of subjects

EV+Pembro	209	172	172	163	151	146	122	119	94	74	68	54	49	42	35	31	21	14
Plat+Gem	190	151	140	133	98	87	70	57	50	42	33	26	19	15	12	10		

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

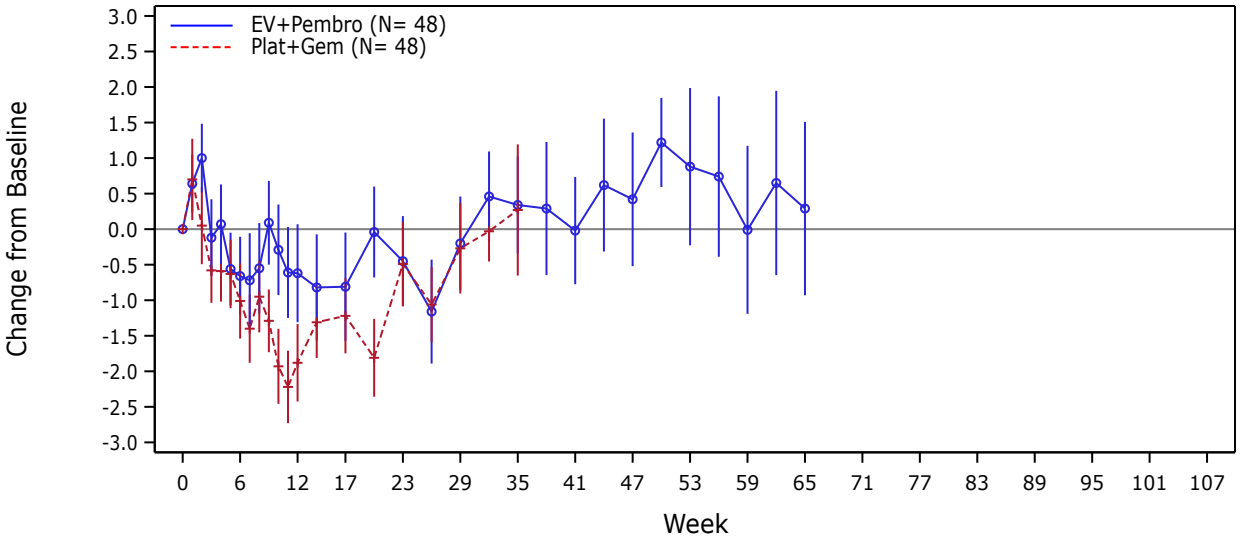
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.6.1.1: BPI-SF - Plot of Mean Change from Baseline of Pain Interference by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Present



Number of subjects

EV+Pembro	39	25	29	25	23	22	17	19	16	11	11	9
Plat+Gem	34	28	24	26	19	14	9					

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

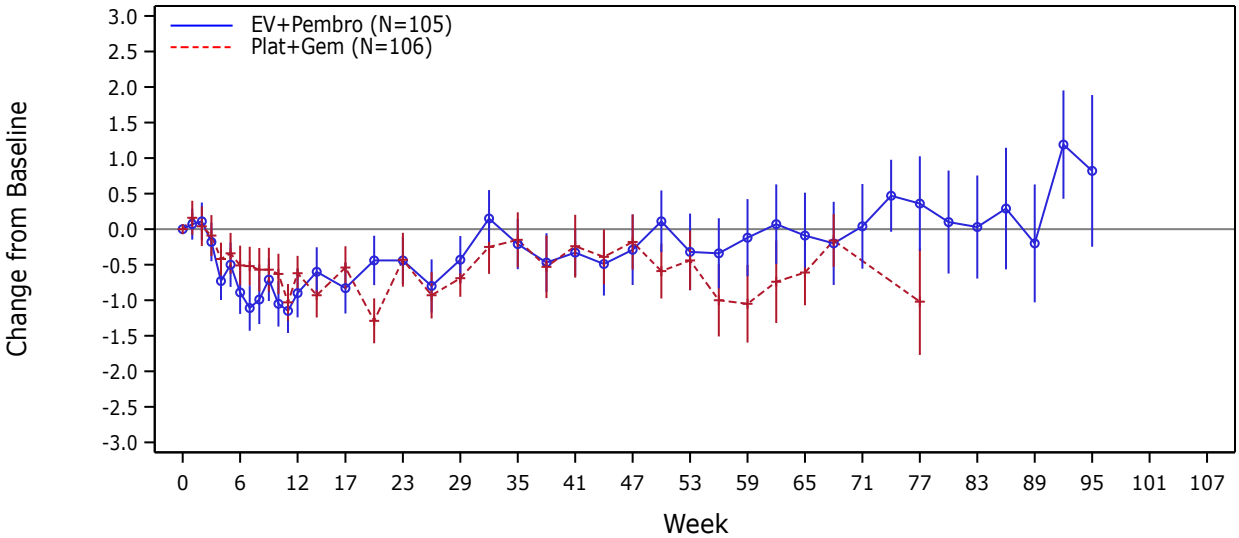
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.6.1.2: BPI-SF - Plot of Mean Change from Baseline of Pain Interference by Age - Analysis Set mITT 1

Age: < 65 years



Number of subjects

EV+Pembro	94	82	80	78	73	68	58	59	46	37	39	31	30	24	22	17	11
Plat+Gem	84	68	67	59	45	38	32	23	22	17	12	11		8			

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

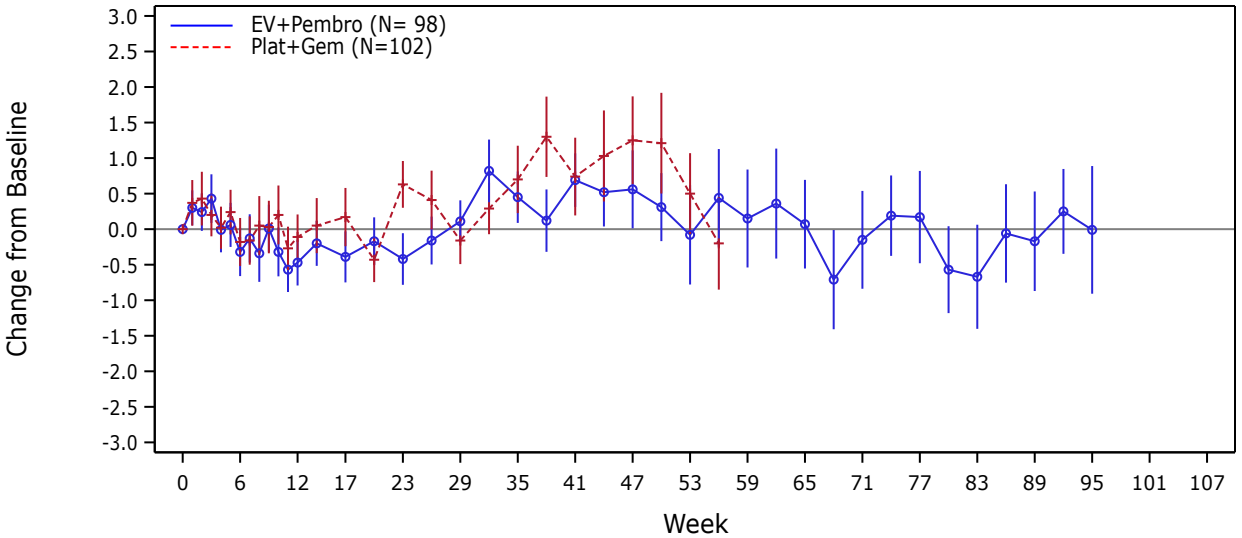
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.6.1.3: BPI-SF - Plot of Mean Change from Baseline of Pain Interference by Region - Analysis Set mITT 1

Region: Europe



Number of subjects

EV+Pembro	81	63	66	63	57	58	52	48	36	27	27	23	19	19	16	14	10
Plat+Gem	73	58	50	47	33	26	25	18	13	10							

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

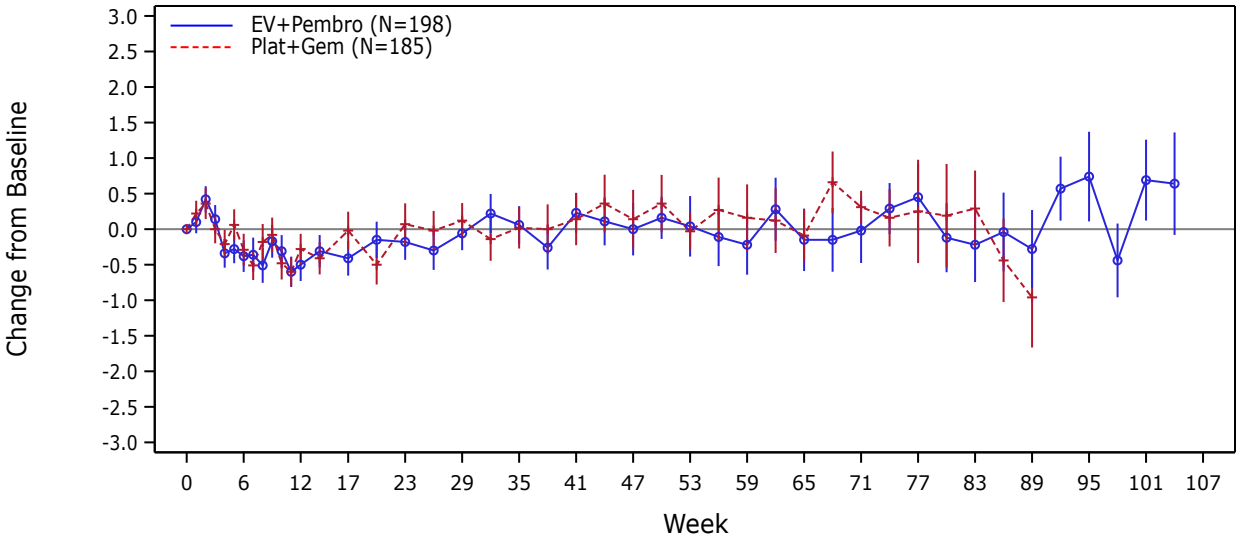
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.6.1.4: BPI-SF - Plot of Mean Change from Baseline of Pain Interference by Sex - Analysis Set mITT 1

Sex: Male



Number of subjects

EV+Pembro	173	140	141	131	122	121	100	94	75	59	54	47	45	36	30	26	20	12
Plat+Gem	148	116	110	104	79	66	53	45	39	34	27	21	14	13	10	10		

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

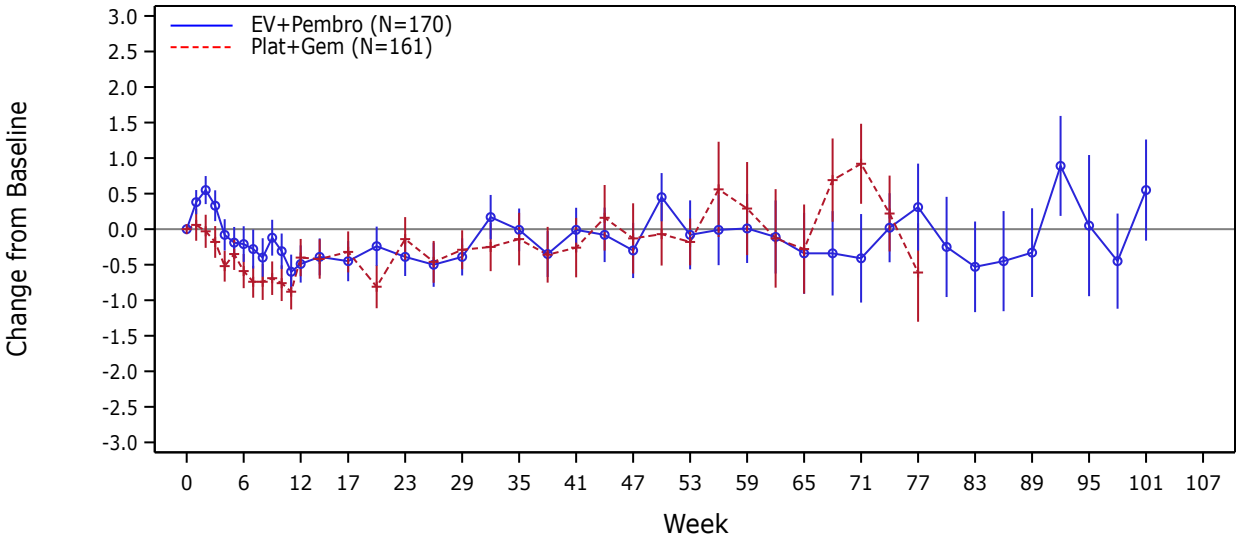
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.6.1.5: BPI-SF - Plot of Mean Change from Baseline of Pain Interference by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Visceral metastases



Number of subjects

EV+Pembro	149	115	121	112	103	99	79	81	63	50	47	34	30	25	22	20	12	11
Plat+Gem	131	104	93	91	69	60	45	33	31	24	21	18	12	10				

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

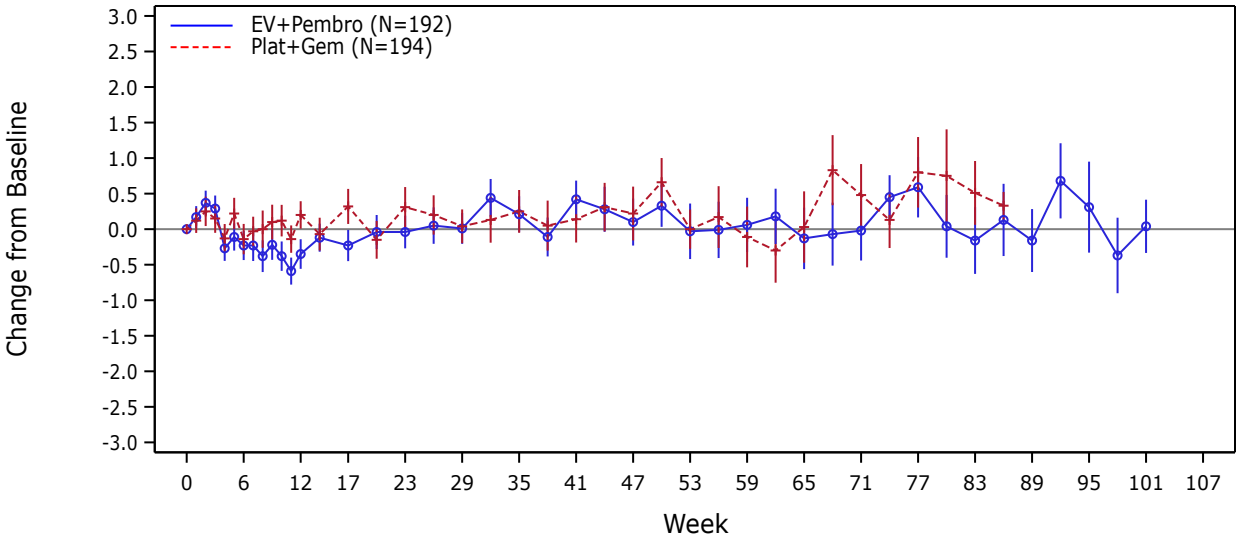
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.6.1.1: BPI-SF - Plot of Mean Change from Baseline of Pain Interference by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Absent



Number of subjects

EV+Pembro	170	147	143	138	128	124	105	100	78	63	57	45	42	36	30	27	19	13
Plat+Gem	156	123	116	107	79	73	61	54	45	37	28	21	18	13	10			

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

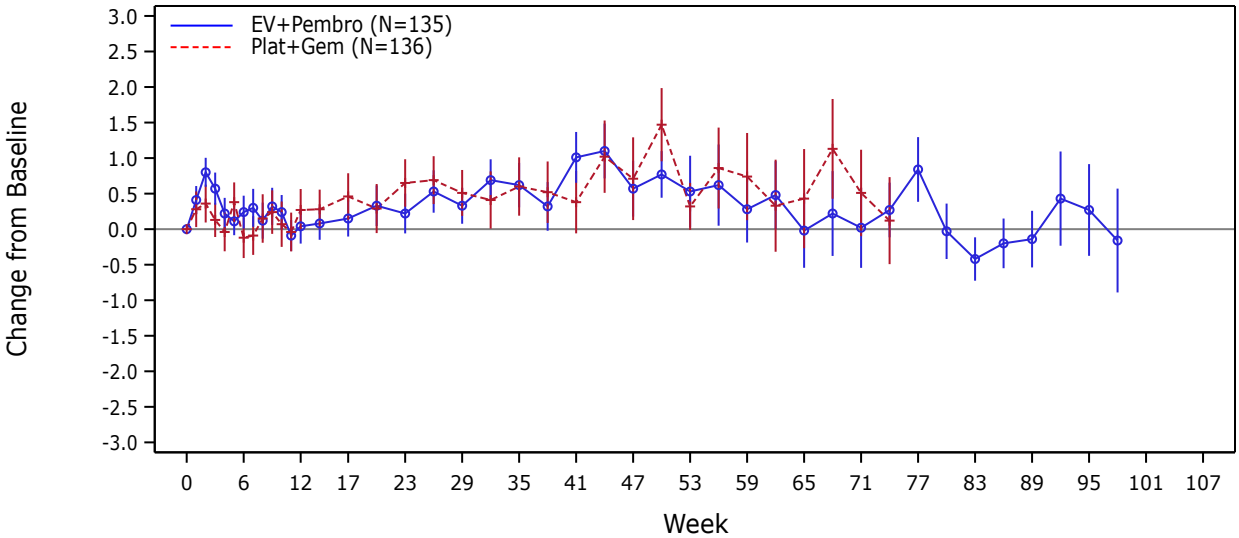
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.6.1.2: BPI-SF - Plot of Mean Change from Baseline of Pain Interference by Age - Analysis Set mITT 1

Age: >= 65 years



Number of subjects

EV+Pembro	115	90	92	85	78	78	64	60	48	37	29	23	19	18	13	14	10
Plat+Gem	106	83	73	74	53	49	38	34	28	25	21	15	13				

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

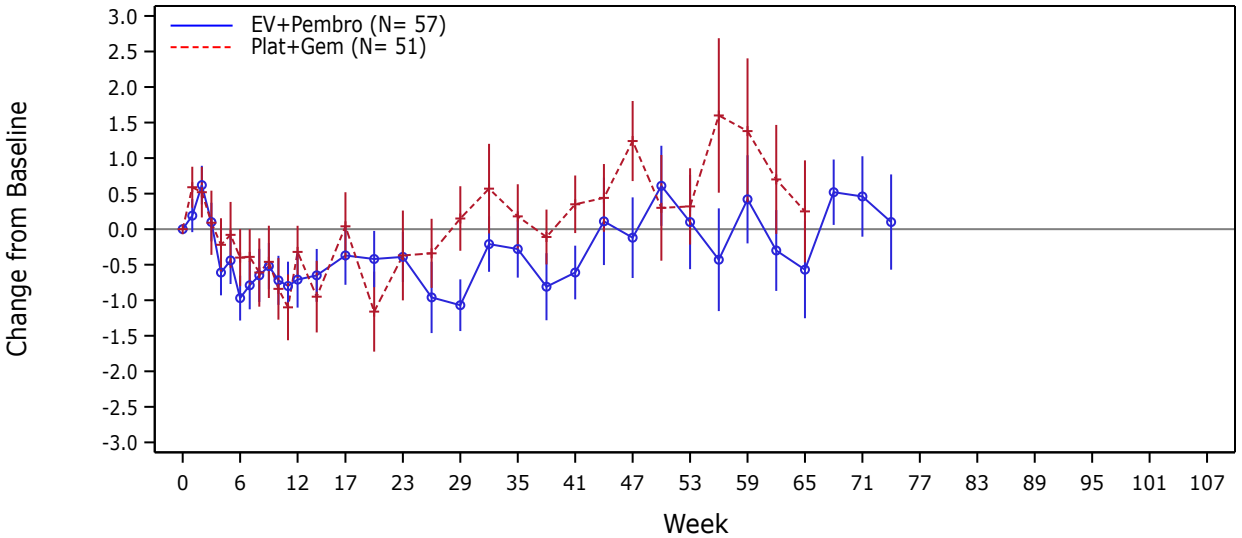
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.6.1.3: BPI-SF - Plot of Mean Change from Baseline of Pain Interference by Region - Analysis Set mITT 1

Region: North America



Number of subjects

EV+Pembro	48	39	40	37	35	34	30	24	23	14	14	9	8
Plat+Gem	42	30	32	31	23	25	15	13	9	11	9	8	

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

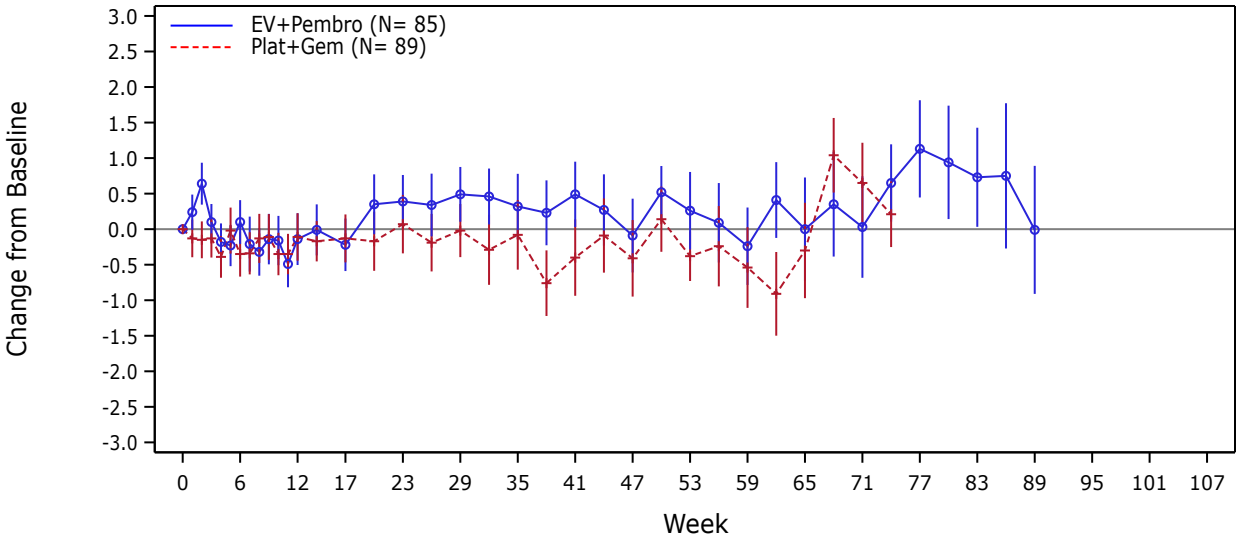
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.6.1.3: BPI-SF - Plot of Mean Change from Baseline of Pain Interference by Region - Analysis Set mITT 1

Region: Rest of World



Number of subjects

EV+Pembro	80	70	66	63	59	54	40	47	35	33	27	22	22	17	15	12
Plat+Gem	75	63	58	55	42	36	30	26	28	21	16	14	12			

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

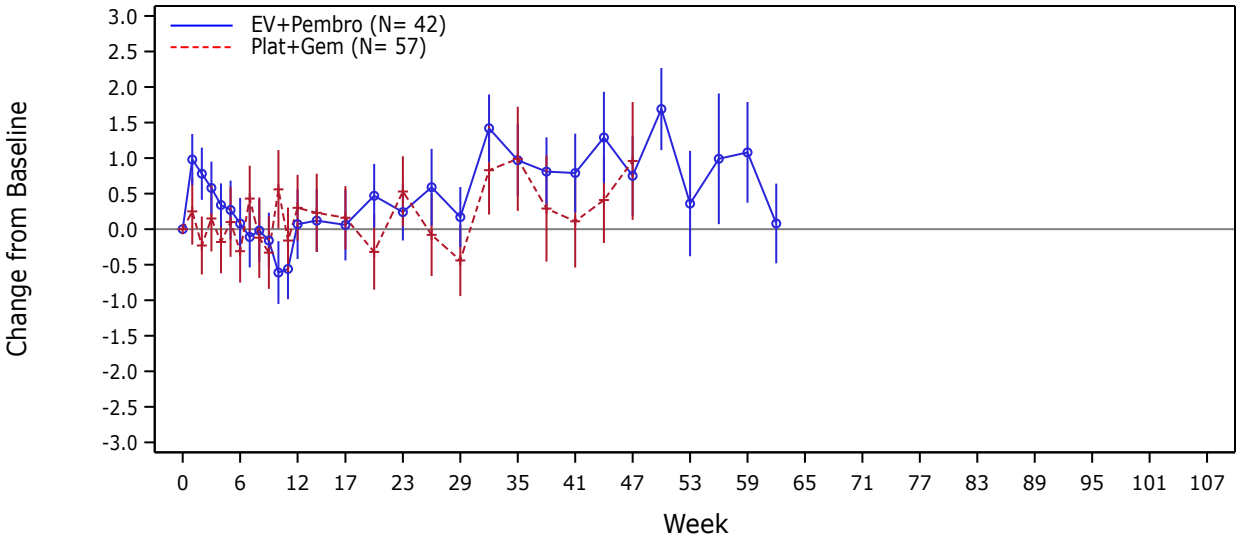
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.6.1.4: BPI-SF - Plot of Mean Change from Baseline of Pain Interference by Sex - Analysis Set mITT 1

Sex: Female



Number of subjects

EV+Pembro	36	32	31	32	29	25	22	25	19	15	14
Plat+Gem	42	35	30	29	19	21	17	12	11		

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

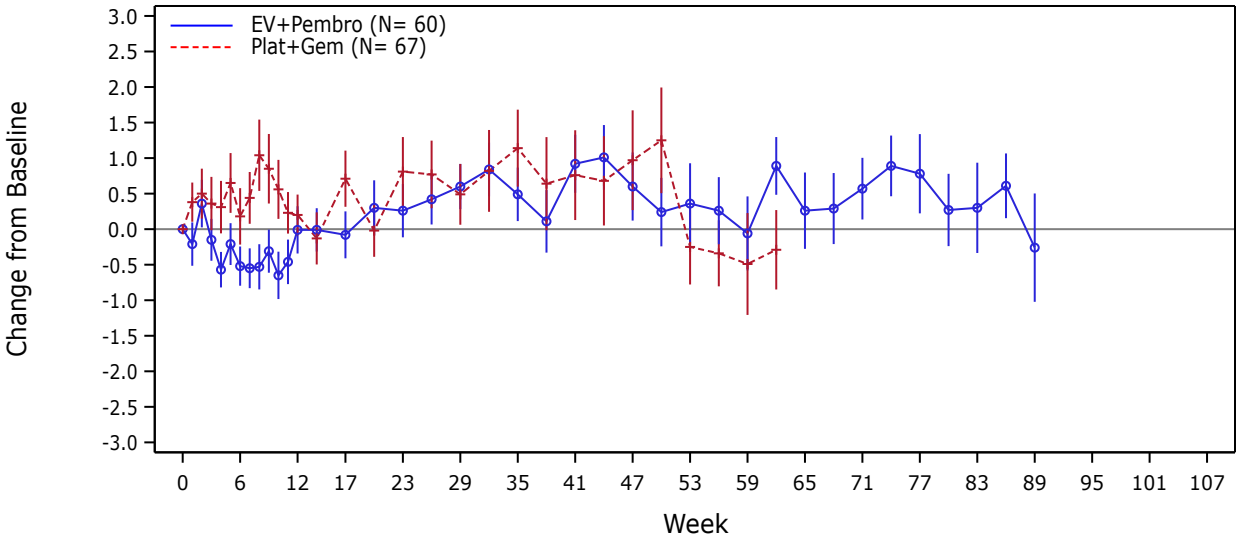
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.6.1.5: BPI-SF - Plot of Mean Change from Baseline of Pain Interference by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Lymph node only



Number of subjects

EV+Pembro	53	50	45	44	41	42	40	34	27	22	19	19	18	16	12	10
Plat+Gem	49	40	39	36	25	21	19	18	13	12	9					

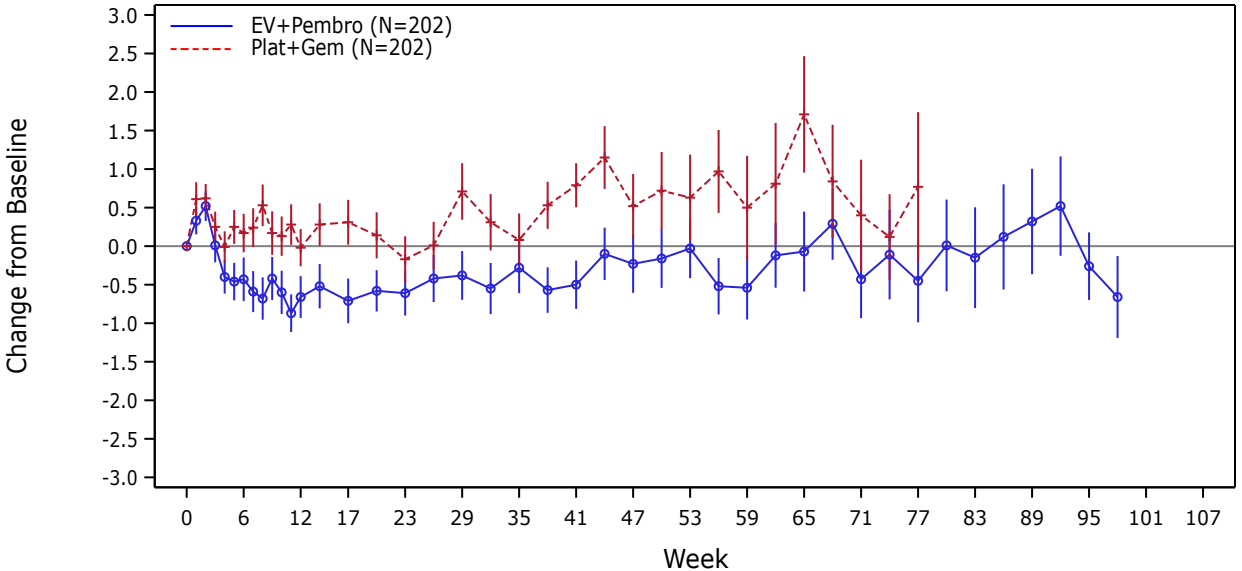
Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.6.2: BPI-SF - Plot of Mean Change from Baseline of Pain Interference - Analysis Set mITT 2



Number of subjects

EV+Pembro	166	128	123	114	100	95	88	87	72	66	59	41	39	34	30	20	14
Plat+Gem	168	131	116	108	81	71	57	47	39	28	21	16	13	11			

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

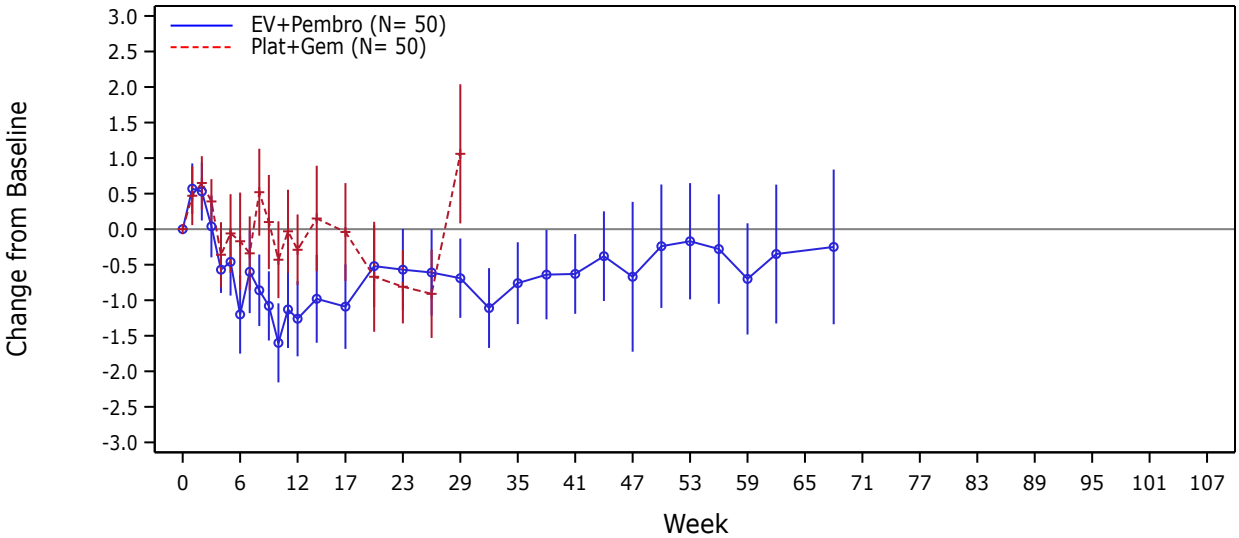
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.6.2.1: BPI-SF - Plot of Mean Change from Baseline of Pain Interference by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Present



Number of subjects

EV+Pembro	41	30	28	27	24	25	24	23	13	18	15
Plat+Gem	41	29	28	24	14	12					

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

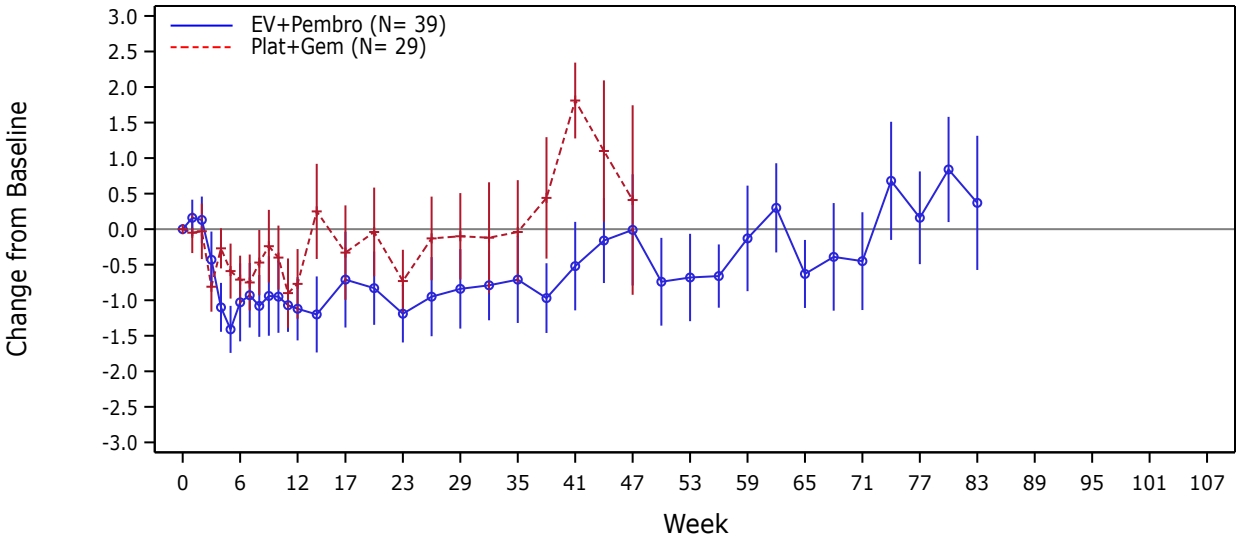
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.6.2.2: BPI-SF - Plot of Mean Change from Baseline of Pain Interference by Age - Analysis Set mITT 2

Age: < 65 years



Number of subjects

EV+Pembro	33	27	26	25	24	23	22	24	19	19	16	14	13	14	12
Plat+Gem	22	18	17	17	16	13	13	9	9						

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

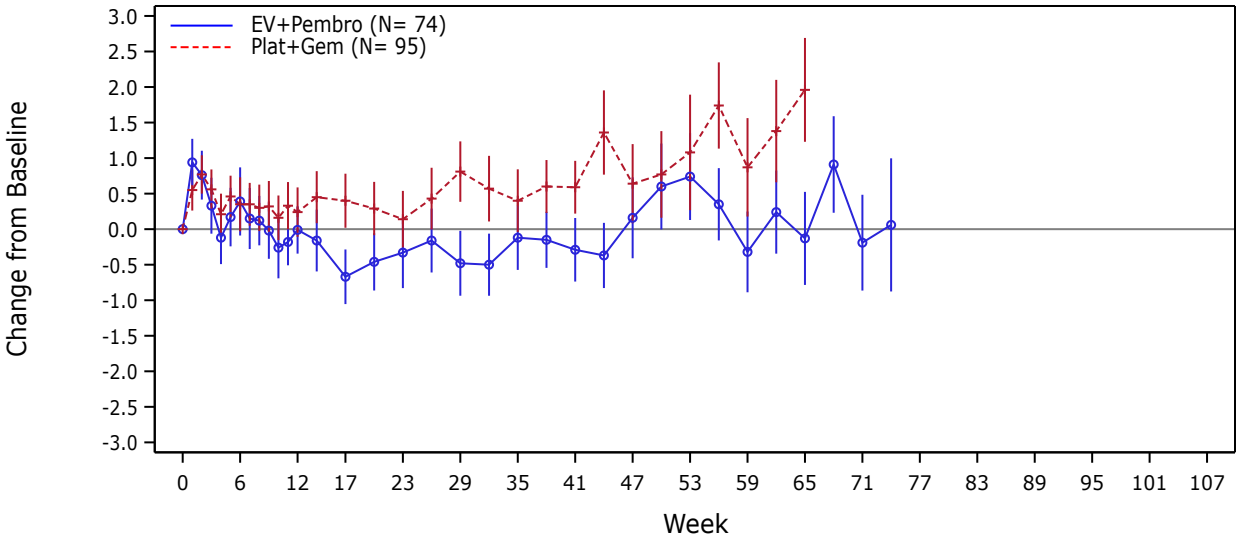
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.6.2.3: BPI-SF - Plot of Mean Change from Baseline of Pain Interference by Region - Analysis Set mITT 2

Region: Europe



Number of subjects

EV+Pembro	57	41	41	34	31	30	26	24	21	23	18	13	13
Plat+Gem	76	61	56	53	40	36	30	23	20	14	10	10	

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

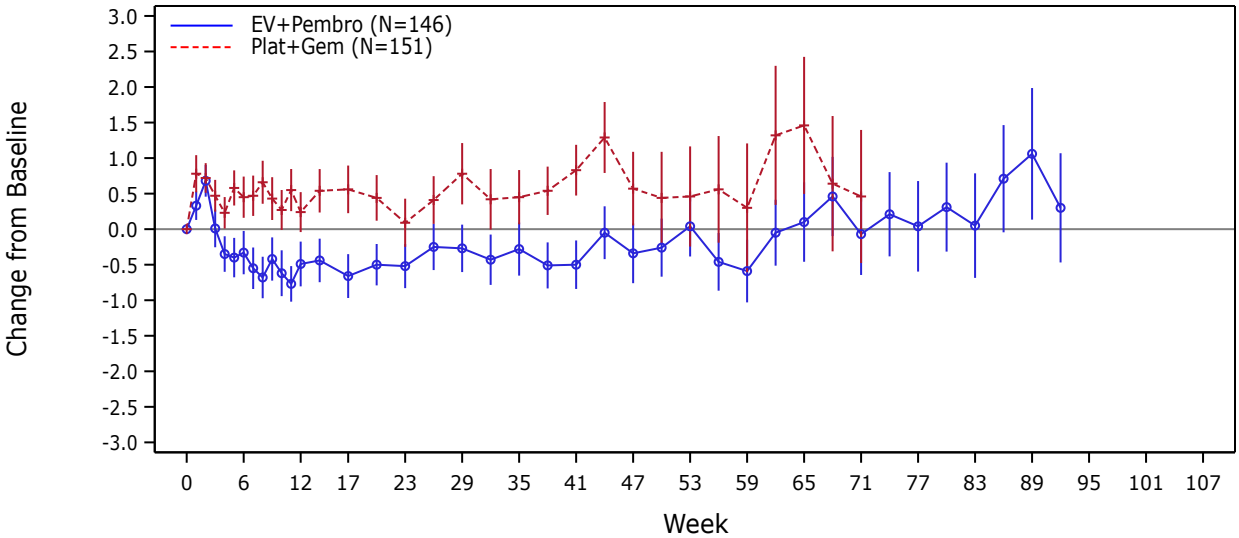
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.6.2.4: BPI-SF - Plot of Mean Change from Baseline of Pain Interference by Sex - Analysis Set mITT 2

Sex: Male



Number of subjects

EV+Pembro	123	95	89	86	76	73	68	66	51	50	44	30	28	24	21	11
Plat+Gem	126	98	89	84	63	53	45	37	29	20	15	12	10			

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

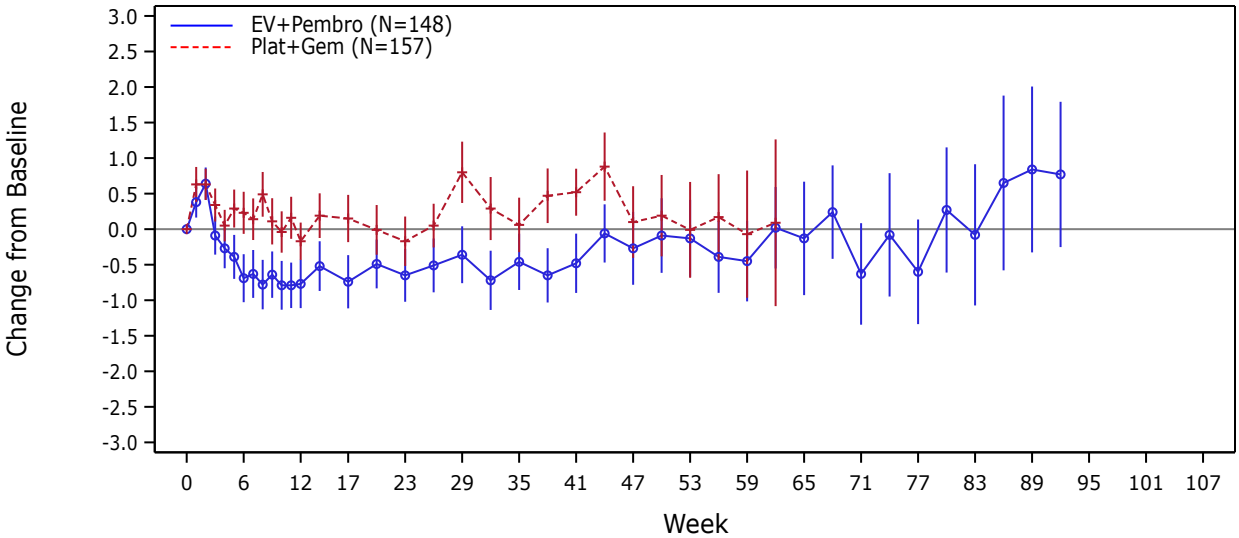
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.6.2.5: BPI-SF - Plot of Mean Change from Baseline of Pain Interference by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Visceral metastases



Number of subjects

EV+Pembro	121	91	86	81	71	64	63	60	48	44	38	24	25	23	19	10
Plat+Gem	130	98	85	82	59	50	37	31	26	17	12					

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

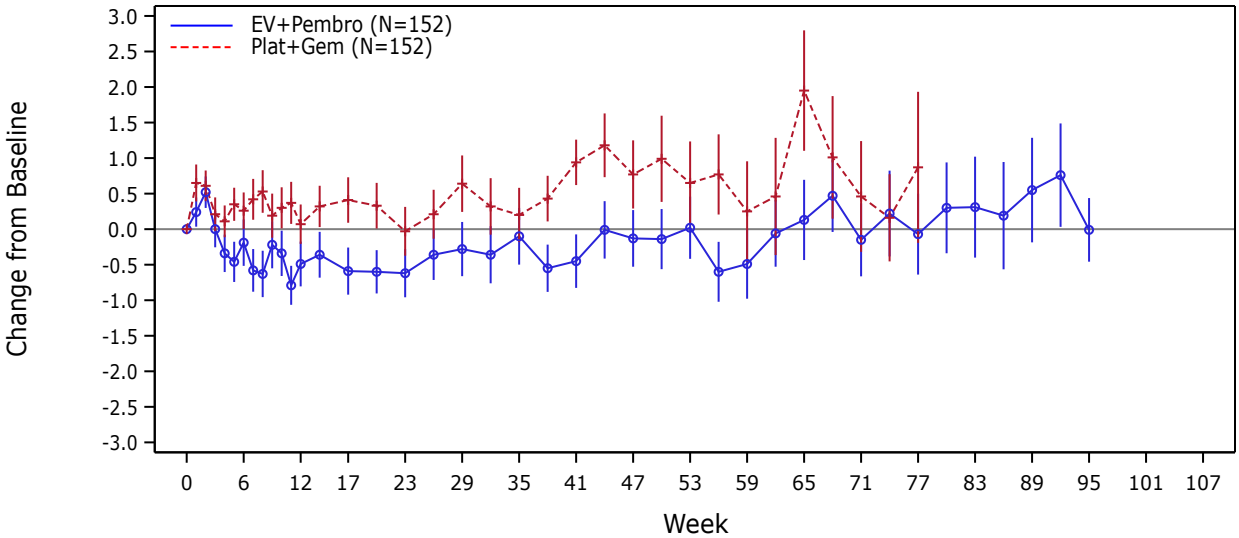
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.6.2.1: BPI-SF - Plot of Mean Change from Baseline of Pain Interference by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Absent



Number of subjects

EV+Pembro	125	98	95	87	76	70	64	64	59	48	44	34	31	28	25	18	12
Plat+Gem	127	102	88	84	67	59	49	40	31	22	18	14	12	10			

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

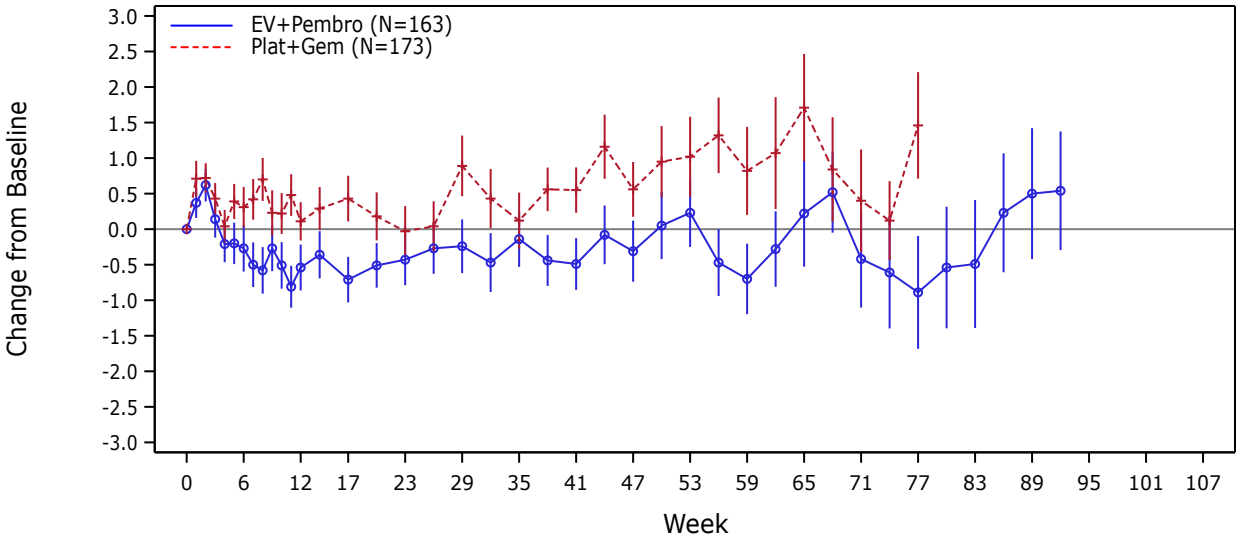
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.6.2.2: BPI-SF - Plot of Mean Change from Baseline of Pain Interference by Age - Analysis Set mITT 2

Age: >= 65 years



Number of subjects

EV+Pembro	133	101	97	89	76	72	66	63	53	47	43	27	26	20	18	12
Plat+Gem	146	113	99	91	65	58	44	38	30	24	20	16	13	10		

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

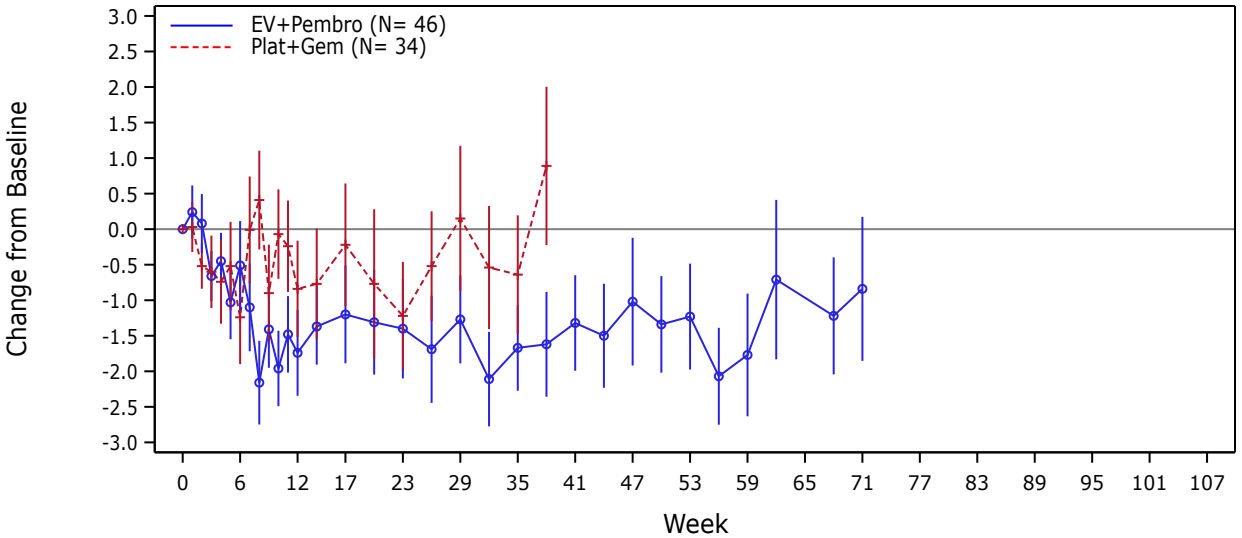
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.6.2.3: BPI-SF - Plot of Mean Change from Baseline of Pain Interference by Region - Analysis Set mITT 2

Region: North America



Number of subjects

EV+Pembro	35	25	24	25	19	18	20	19	15	12	14	9
Plat+Gem	28	17	16	18	14	13	12					

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

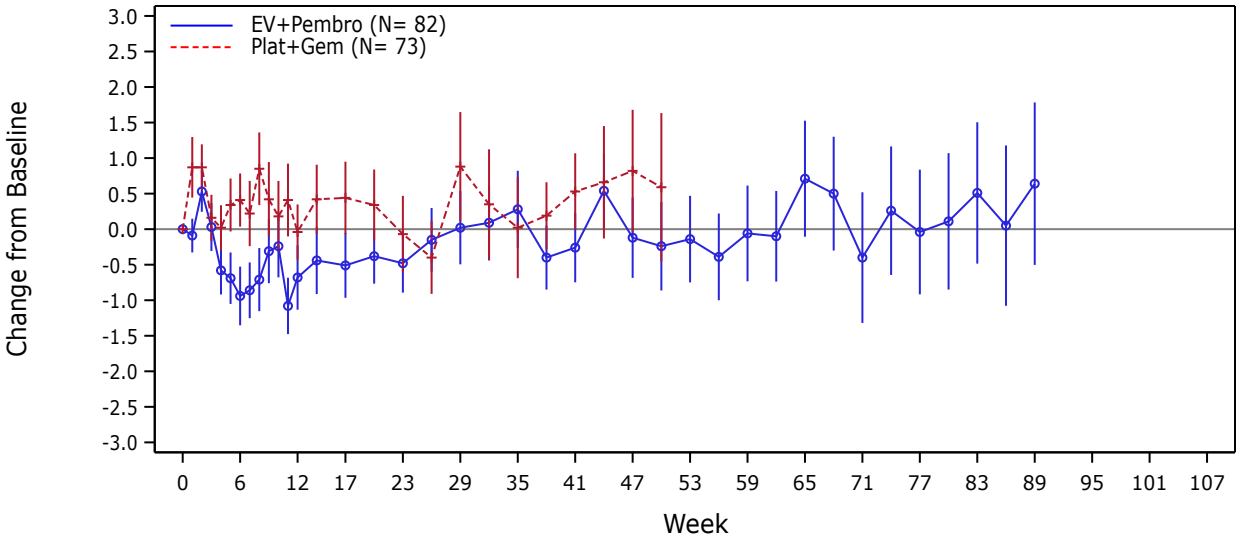
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.6.2.3: BPI-SF - Plot of Mean Change from Baseline of Pain Interference by Region - Analysis Set mITT 2

Region: Rest of World



Number of subjects

EV+Pembro	74	62	58	55	50	47	42	44	36	31	27	21	17	18	17	11
Plat+Gem	64	53	44	37	27	22	15	16	11							

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

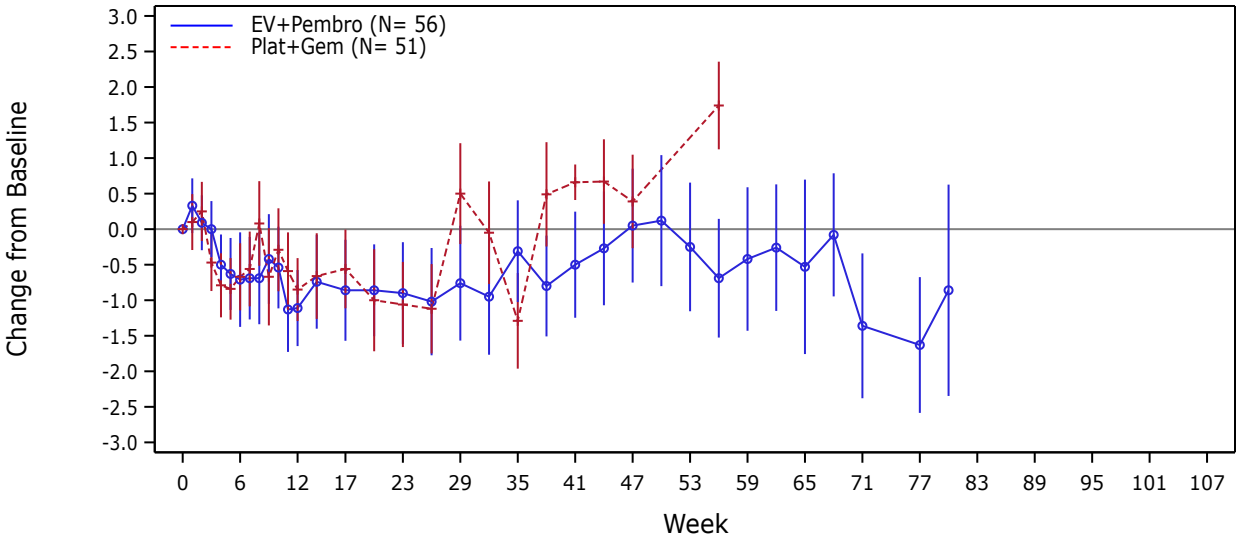
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.6.2.4: BPI-SF - Plot of Mean Change from Baseline of Pain Interference by Sex - Analysis Set mITT 2

Sex: Female



Number of subjects

EV+Pembro	43	33	34	28	24	22	20	21	21	16	15	11	11	10
Plat+Gem	42	33	27	24	18	18	12	10	10					

Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

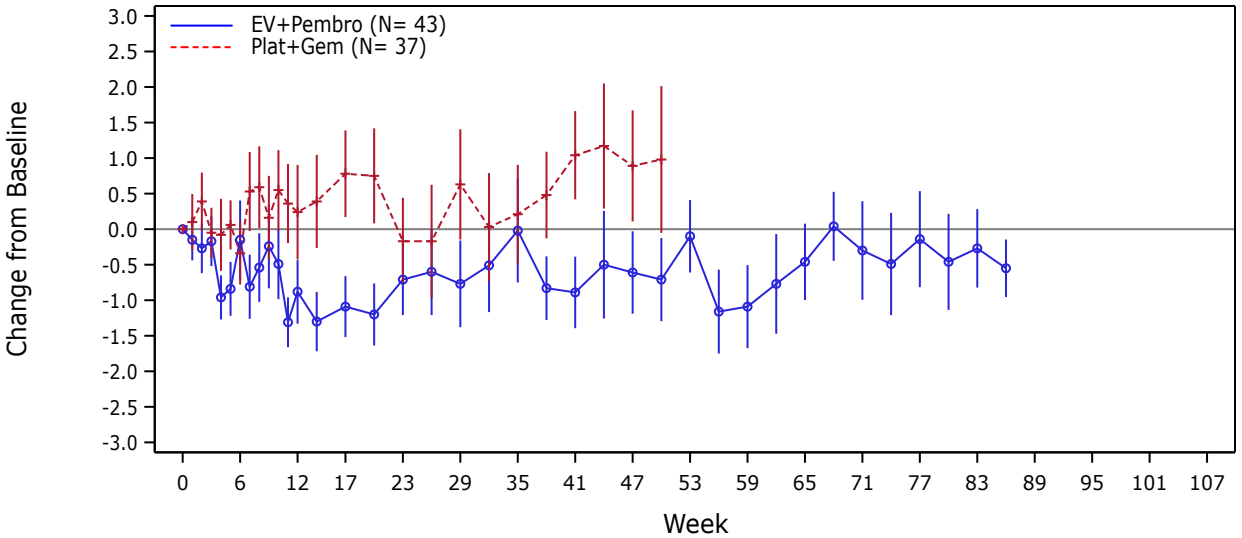
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.6.2.5: BPI-SF - Plot of Mean Change from Baseline of Pain Interference by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Lymph node only



Number of subjects

EV+Pembro	36	31	31	27	24	25	20	20	18	17	18	15	12	11	11
Plat+Gem	30	27	23	21	17	16	16	12	10						

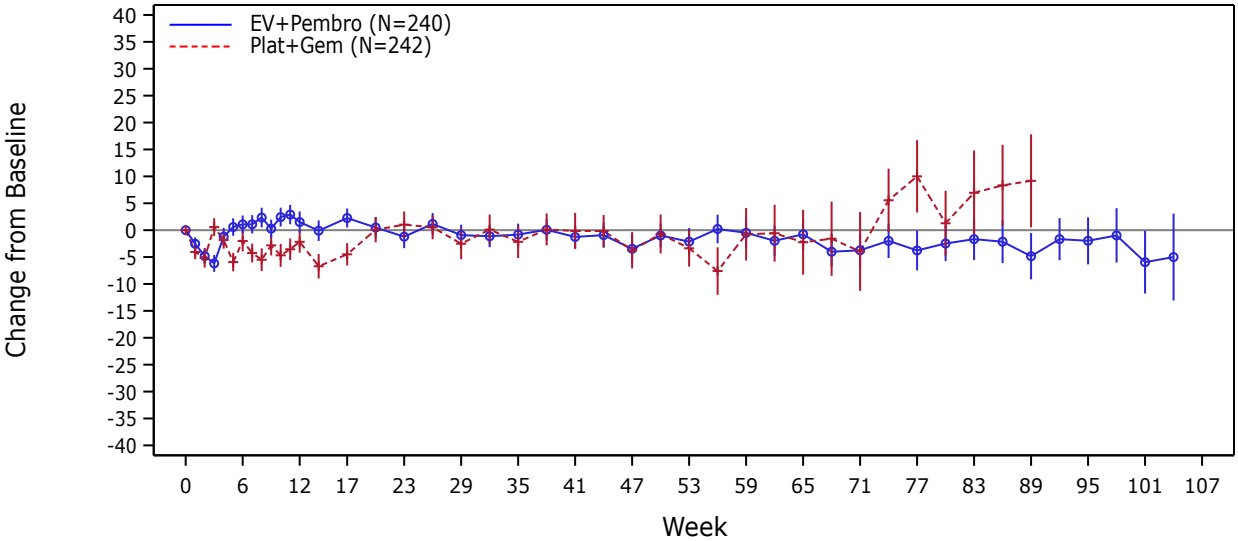
Abbreviations: BPI-SF=Brief Pain Inventory - Short Form; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.9.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Global Health Status/QoL - Analysis Set mITT 1



Number of subjects

EV+Pembro	206	170	171	162	151	145	122	119	94	74	68	54	49	42	35	31	21	14
Plat+Gem	188	149	138	130	97	86	69	56	49	42	33	26	19	15	12	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life.

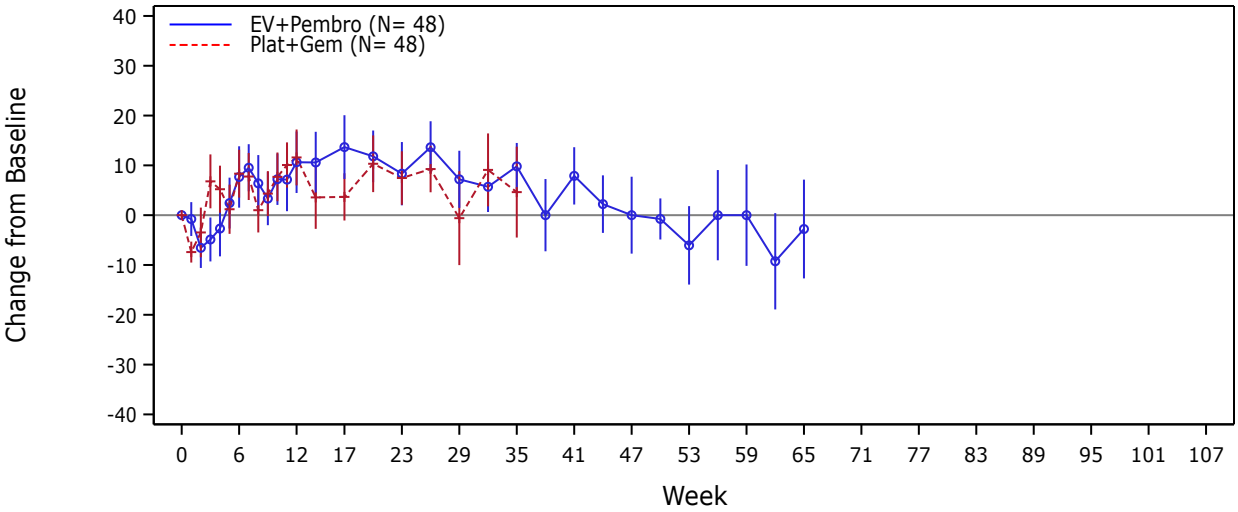
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.9.1.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Global Health Status/QoL by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Present



Number of subjects

EV+Pembro	39	25	29	25	23	22	17	19	16	11	11	9
Plat+Gem	33	27	23	25	19	14	9					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life.

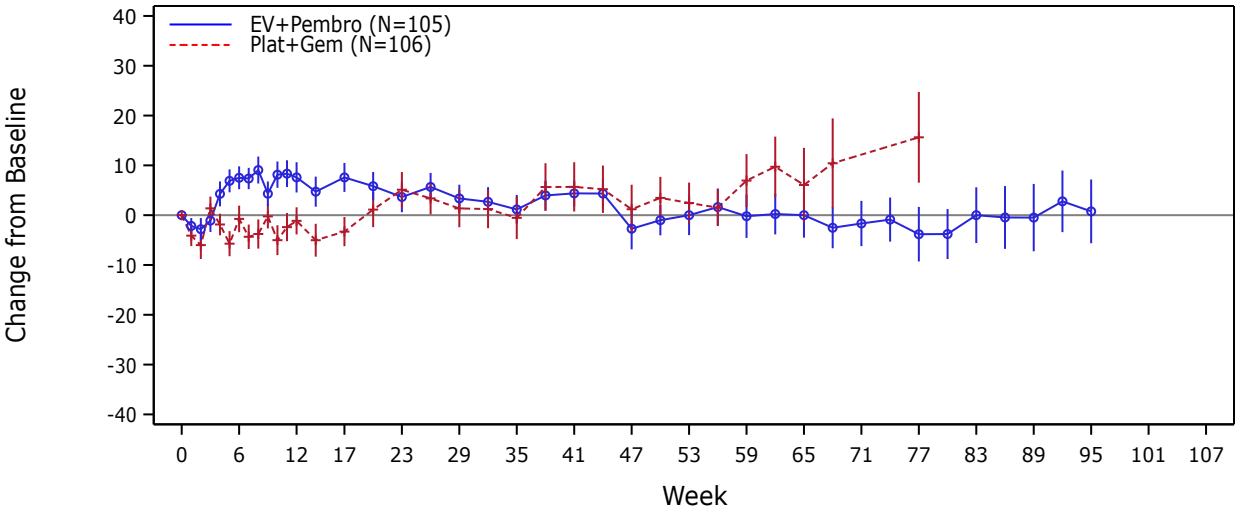
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.9.1.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Global Health Status/QoL by Age - Analysis Set mITT 1

Age: < 65 years



Number of subjects

EV+Pembro	92	81	79	77	73	67	58	59	46	37	39	31	30	24	22	17	11
Plat+Gem	83	67	66	58	44	37	31	22	21	17	12	11		8			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life.

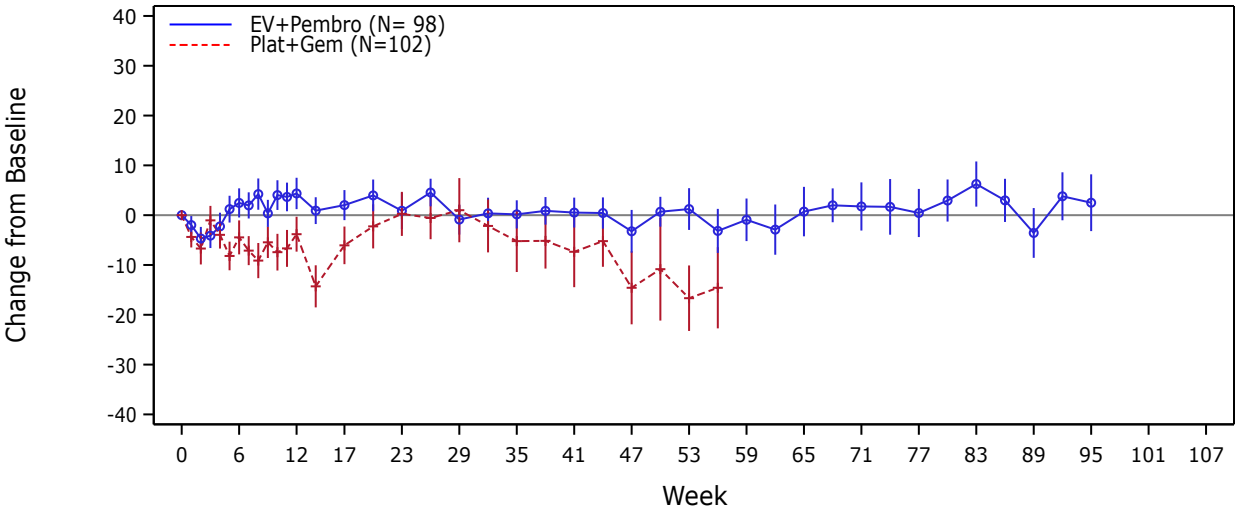
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.9.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Global Health Status/QoL by Region - Analysis Set mITT 1

Region: Europe



Number of subjects

EV+Pembro	79	61	65	62	57	57	52	48	36	27	27	23	19	19	16	14	10
Plat+Gem	71	56	48	44	32	25	24	17	12	10							

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life.

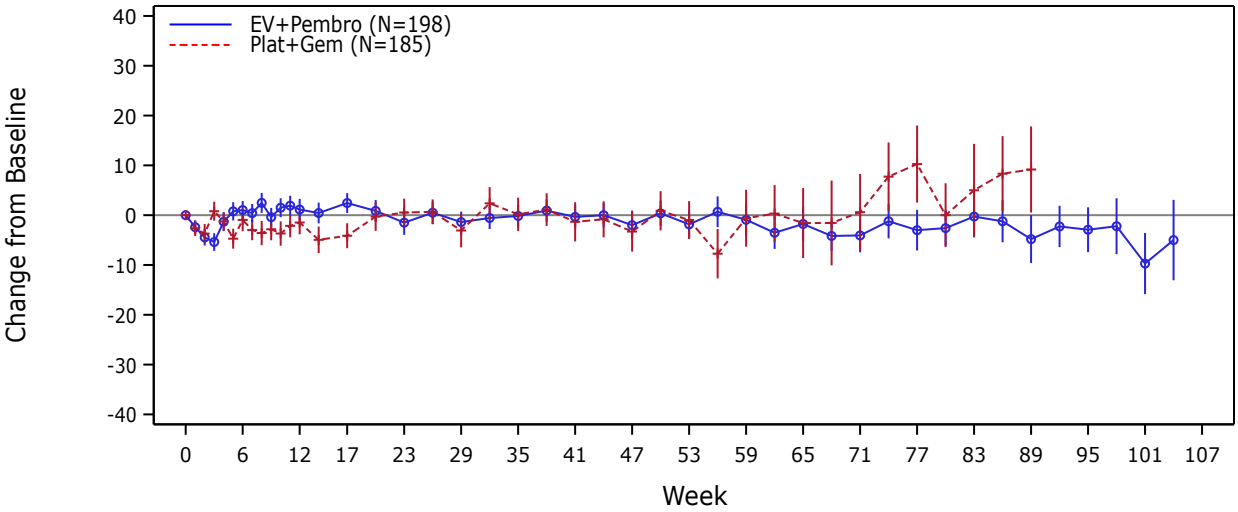
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.9.1.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Global Health Status/QoL by Sex - Analysis Set mITT 1

Sex: Male



Number of subjects

EV+Pembro	170	138	140	130	122	120	100	94	75	59	54	47	45	36	30	26	20	12
Plat+Gem	146	114	108	101	78	65	52	44	38	34	27	21	14	13	10	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life.

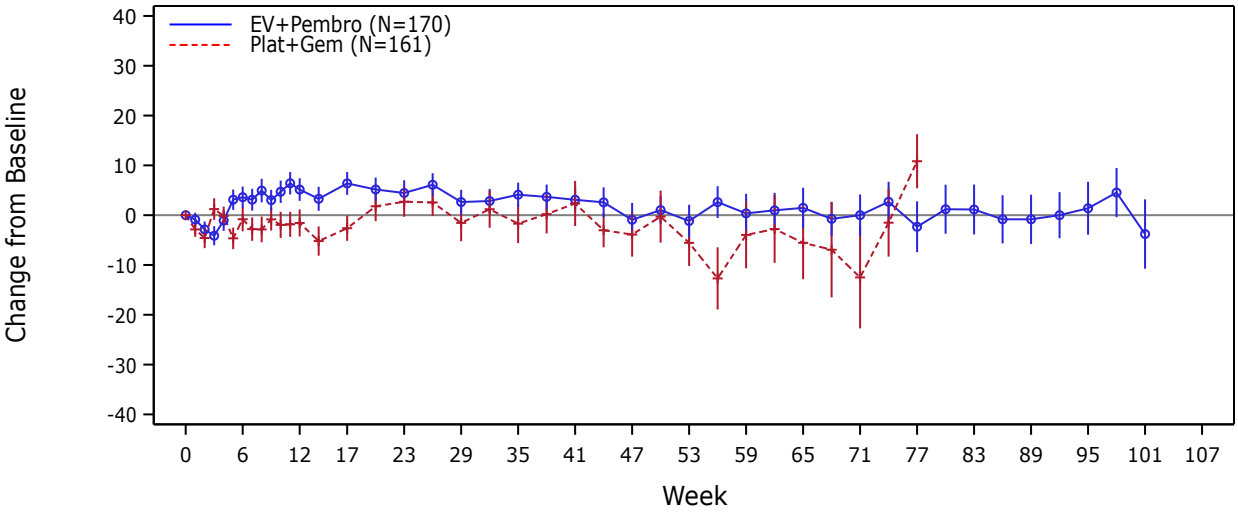
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.9.1.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Global Health Status/QoL by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Visceral metastases



Number of subjects

EV+Pembro	146	113	120	111	103	98	79	81	63	50	47	34	30	25	22	20	12	11
Plat+Gem	129	102	91	89	68	59	44	32	30	24	21	18	12	10				

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life.

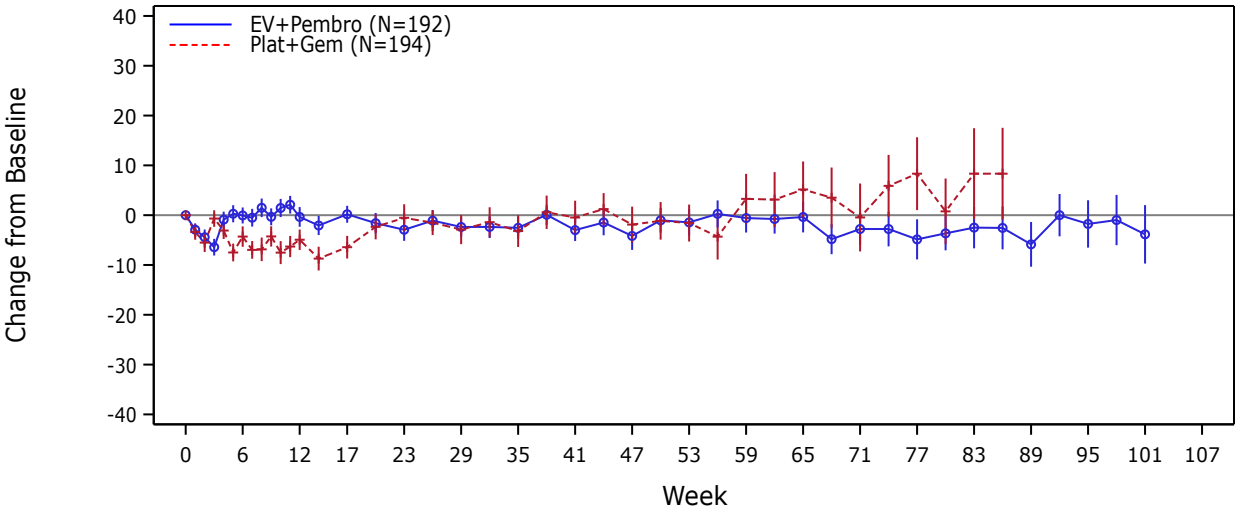
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.9.1.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Global Health Status/QoL by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Absent



Number of subjects

EV+Pembro	167	145	142	137	128	123	105	100	78	63	57	45	42	36	30	27	19	13
Plat+Gem	155	122	115	105	78	72	60	53	44	37	28	21	18	13	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life.

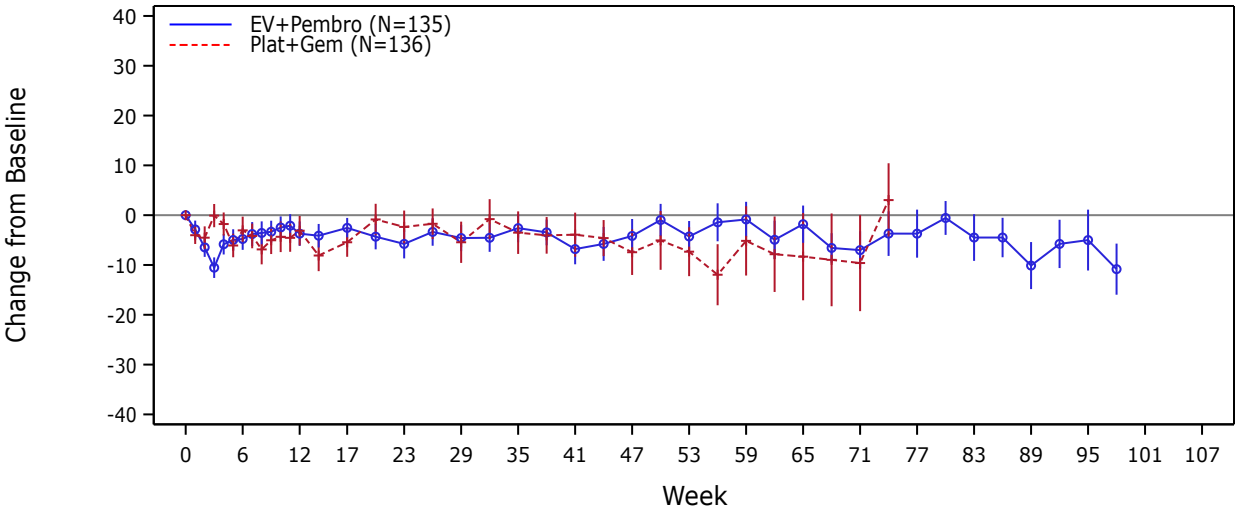
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.9.1.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Global Health Status/QoL by Age - Analysis Set mITT 1

Age: >= 65 years



Number of subjects

EV+Pembro	114	89	92	85	78	78	64	60	48	37	29	23	19	18	13	14	10
Plat+Gem	105	82	72	72	53	49	38	34	28	25	21	15	13				

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life.

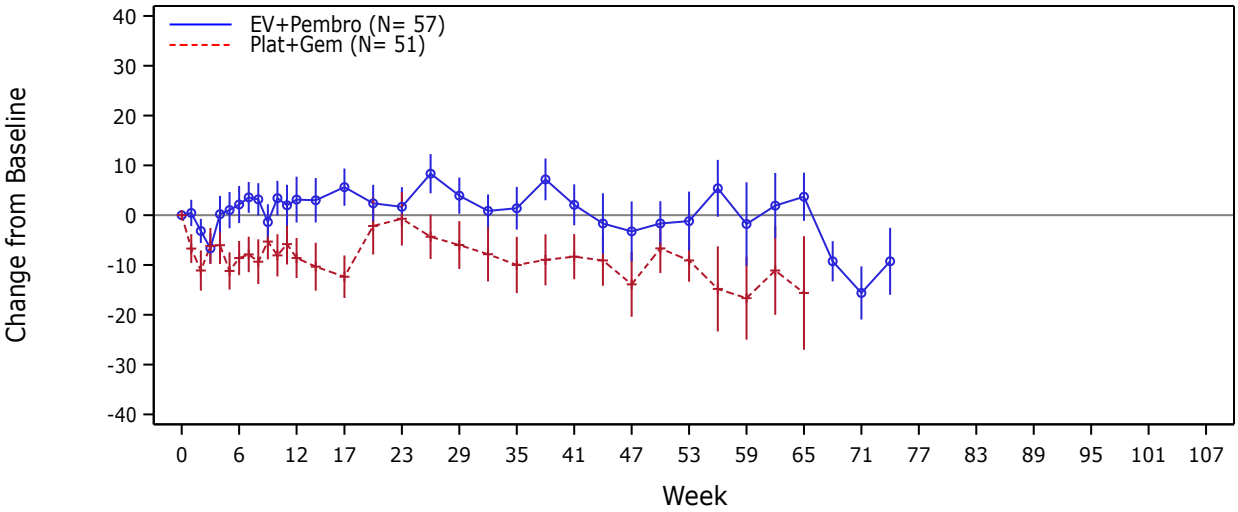
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.9.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Global Health Status/QoL by Region - Analysis Set mITT 1

Region: North America



Number of subjects

EV+Pembro	47	39	40	37	35	34	30	24	23	14	14	9	8
Plat+Gem	42	30	32	31	23	25	15	13	9	11	9	8	

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life.

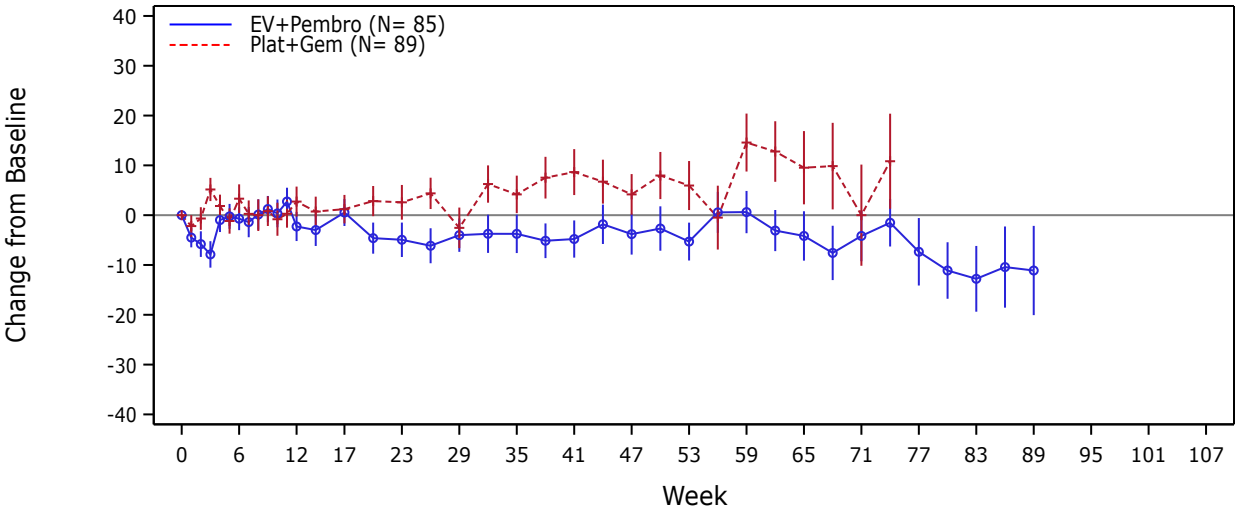
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.9.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Global Health Status/QoL by Region - Analysis Set mITT 1

Region: Rest of World



Number of subjects

EV+Pembro	80	70	66	63	59	54	40	47	35	33	27	22	22	17	15	12
Plat+Gem	75	63	58	55	42	36	30	26	28	21	16	14	12			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life.

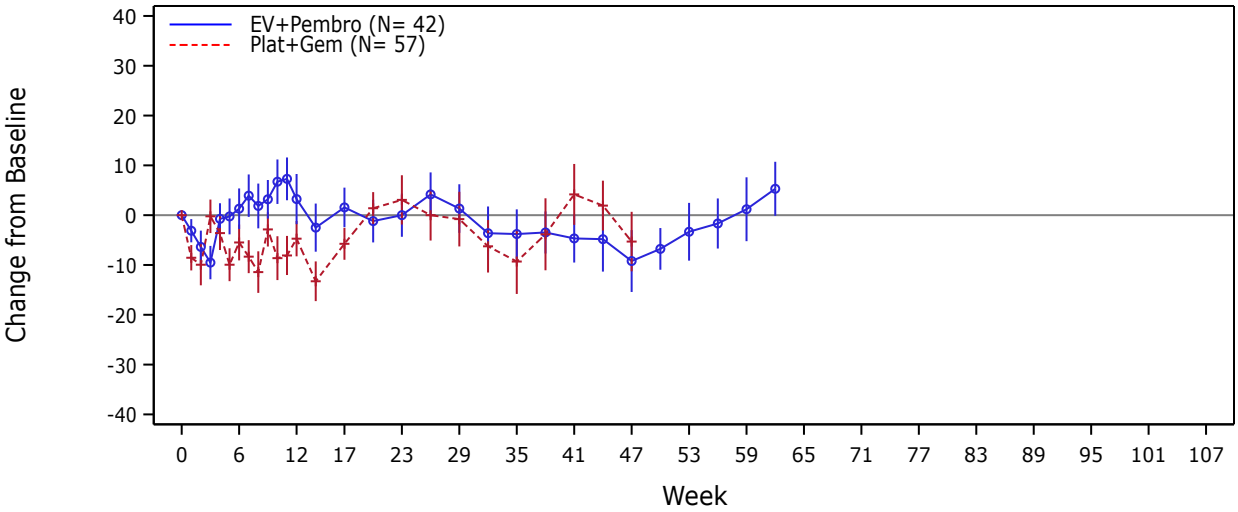
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.9.1.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Global Health Status/QoL by Sex - Analysis Set mITT 1

Sex: Female



Number of subjects

EV+Pembro	36	32	31	32	29	25	22	25	19	15	14
Plat+Gem	42	35	30	29	19	21	17	12	11		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life.

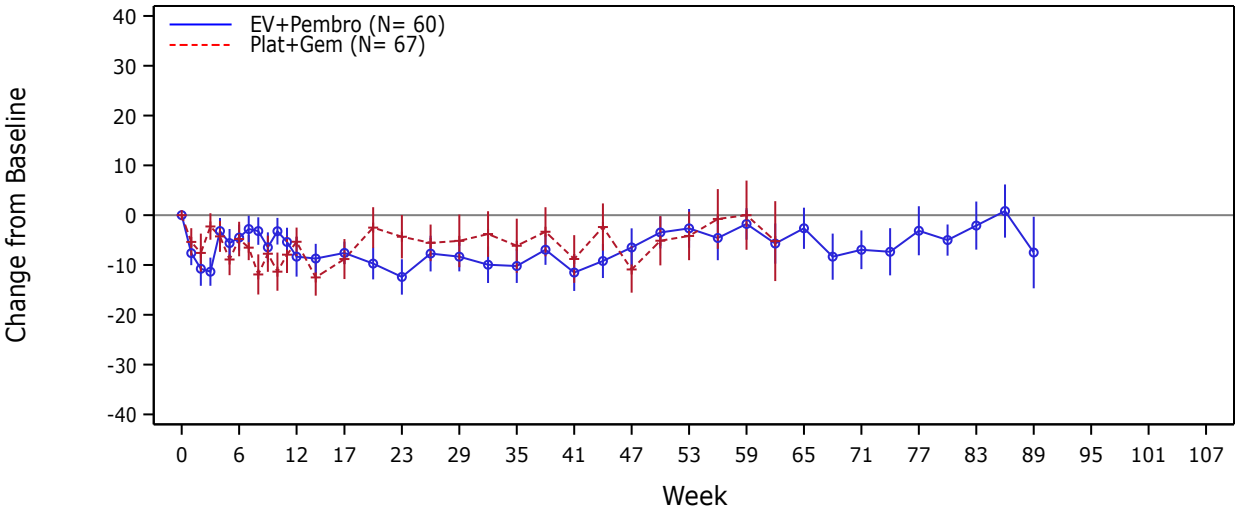
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.9.1.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Global Health Status/QoL by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Lymph node only



Number of subjects

EV+Pembro	53	50	45	44	41	42	40	34	27	22	19	19	18	16	12	10
Plat+Gem	49	40	39	35	25	21	19	18	13	12	9					

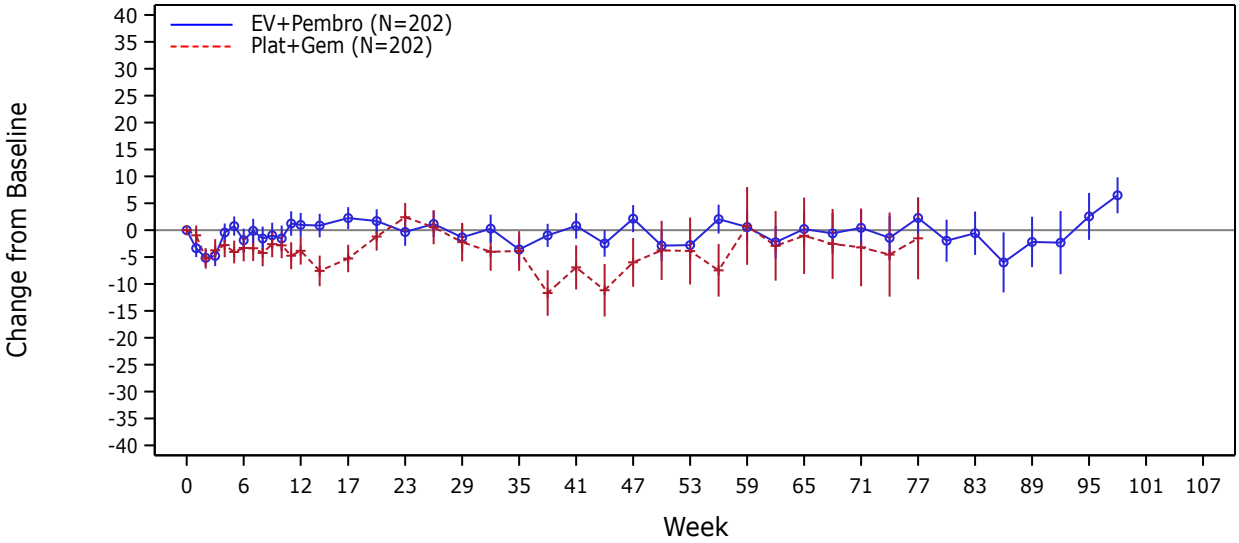
Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life.

Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.9.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Global Health Status/QoL - Analysis Set mITT 2



Number of subjects

EV+Pembro	160	124	119	111	97	93	86	84	70	63	57	40	38	33	29	19	13
Plat+Gem	165	131	115	106	80	71	56	47	39	28	21	16	13	11			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life.

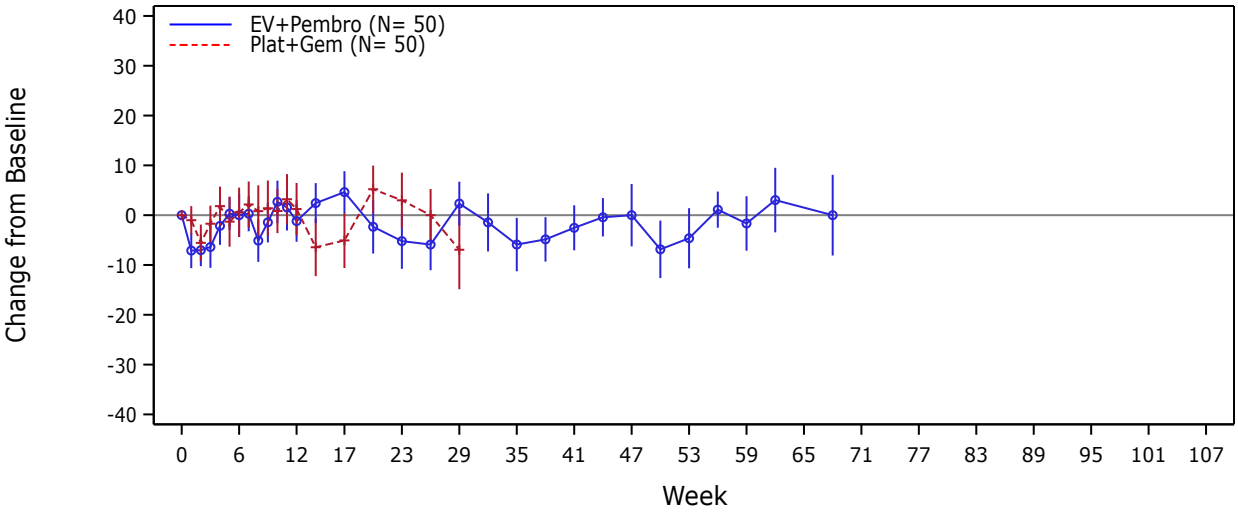
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.9.2.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Global Health Status/QoL by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Present



Number of subjects

EV+Pembro	40	30	28	27	24	25	24	23	13	18	15
Plat+Gem	40	29	27	23	14	12					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life.

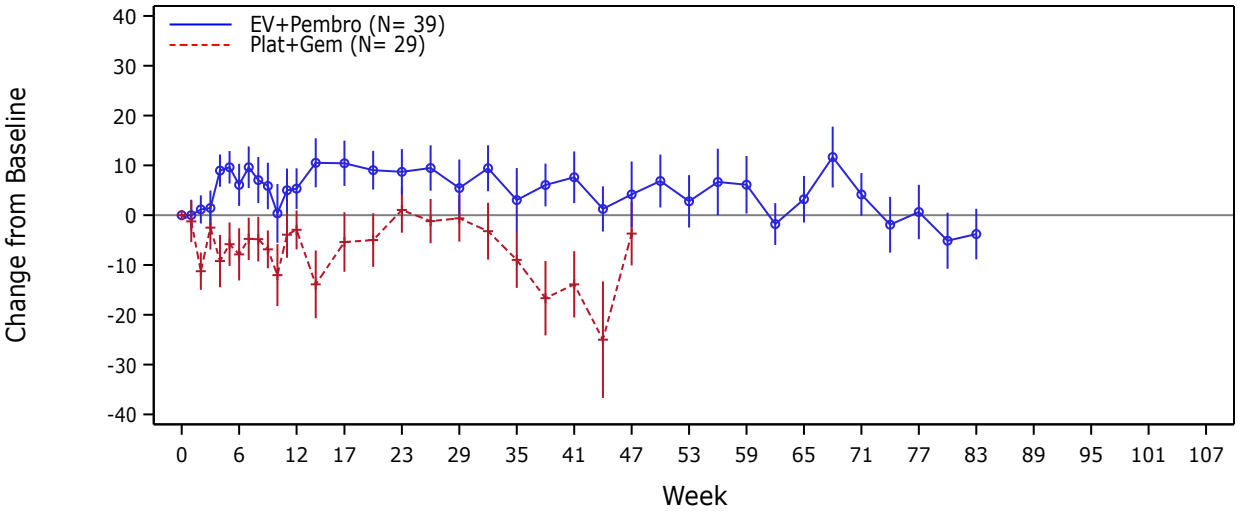
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.9.2.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Global Health Status/QoL by Age - Analysis Set mITT 2

Age: < 65 years



Number of subjects

EV+Pembro	32	26	25	24	23	23	22	23	18	18	15	13	12	13	11
Plat+Gem	22	18	17	17	16	13	13	9	9						

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life.

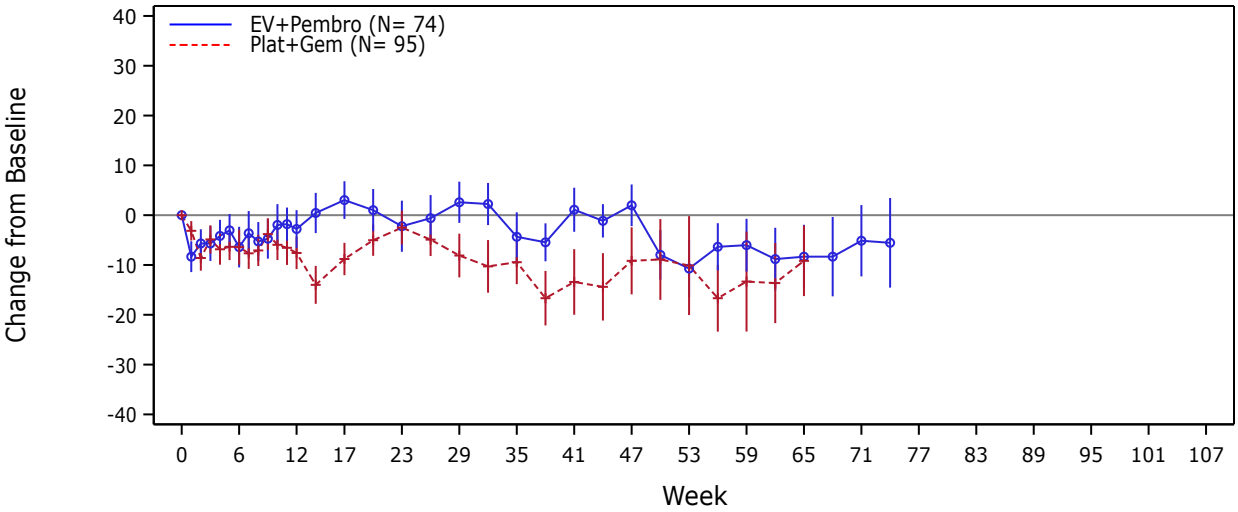
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.9.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Global Health Status/QoL by Region - Analysis Set mITT 2

Region: Europe



Number of subjects

EV+Pembro	53	39	39	33	30	29	25	23	21	21	18	13	13
Plat+Gem	75	61	56	53	40	36	30	23	20	14	10	10	

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life.

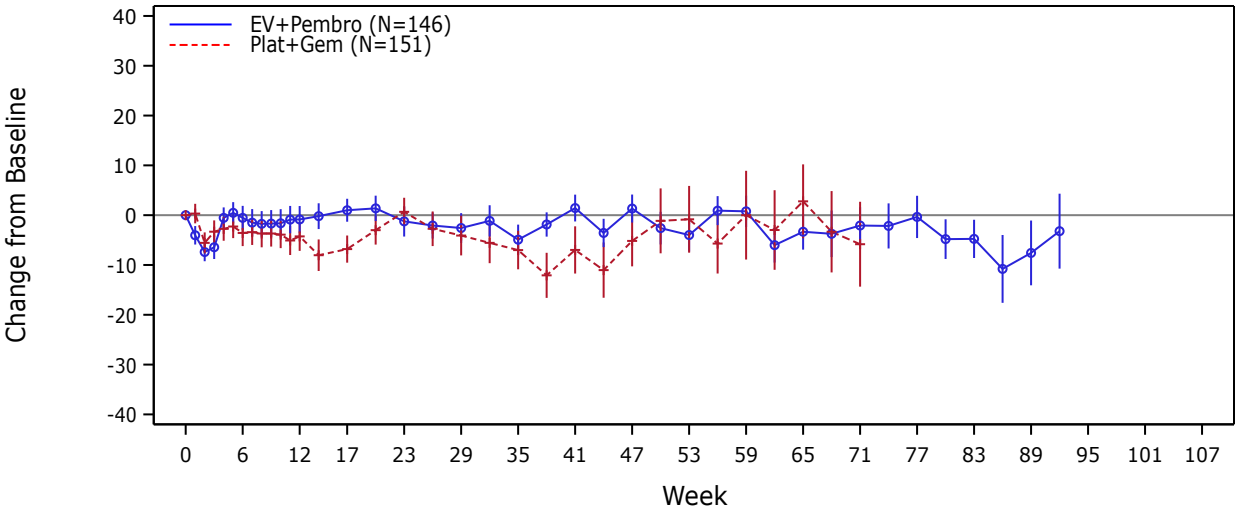
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.9.2.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Global Health Status/QoL by Sex - Analysis Set mITT 2

Sex: Male



Number of subjects

EV+Pembro	119	93	87	84	74	71	66	64	50	48	43	30	28	24	21	11
Plat+Gem	123	98	88	82	62	53	44	37	29	20	15	12	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life.

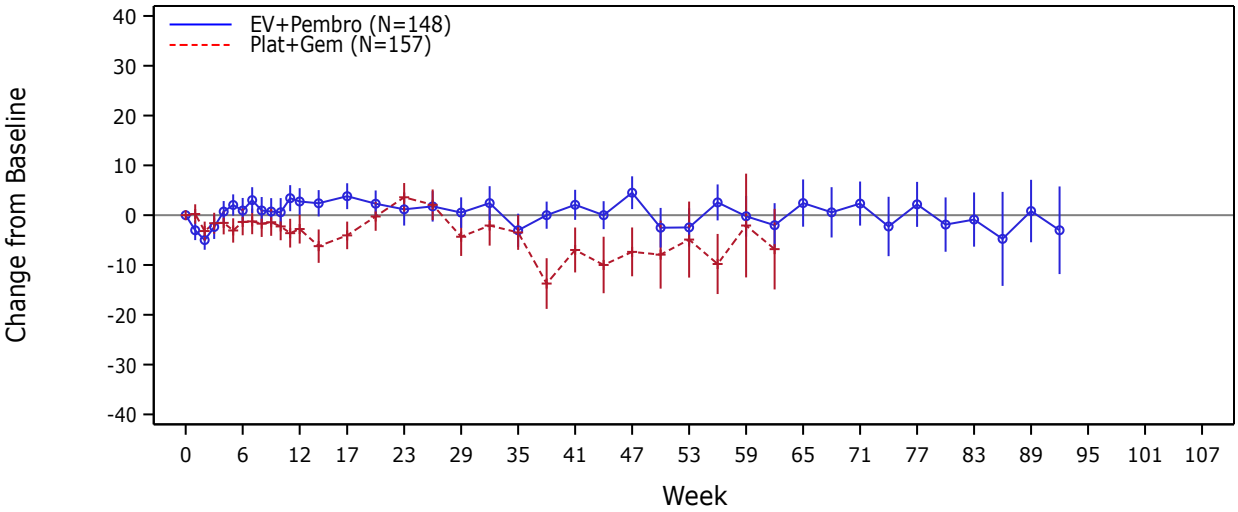
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.9.2.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Global Health Status/QoL by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Visceral metastases



Number of subjects

EV+Pembro	119	90	85	81	71	64	63	60	48	44	38	24	25	23	19	10
Plat+Gem	128	98	84	80	58	50	36	31	26	17	12					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life.

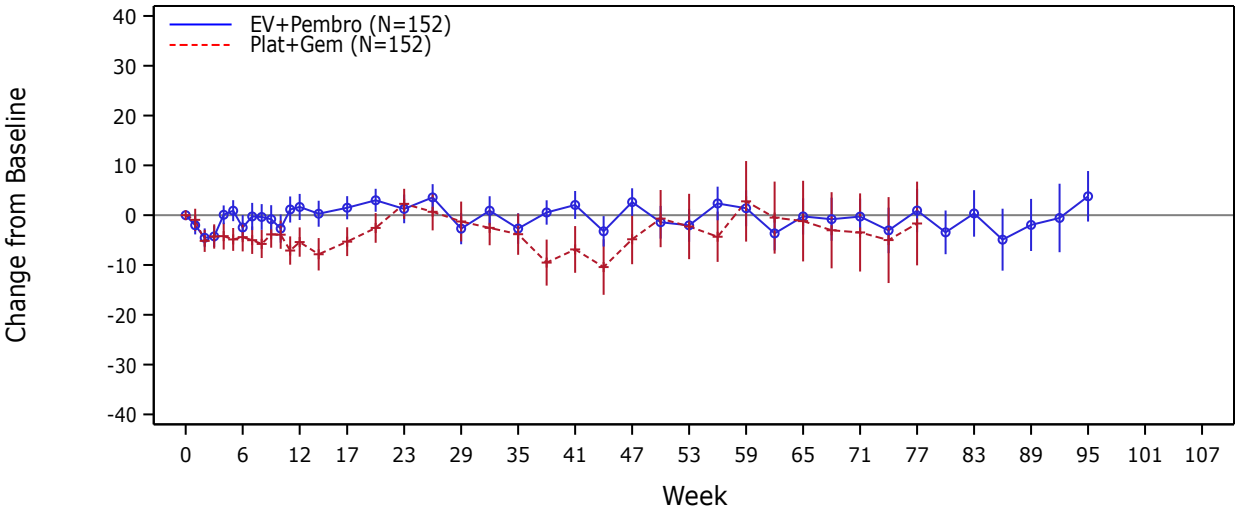
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.9.2.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Global Health Status/QoL by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Absent



Number of subjects

EV+Pembro	120	94	91	84	73	68	62	61	57	45	42	33	30	27	24	17	11
Plat+Gem	125	102	88	83	66	59	48	40	31	22	18	14	12	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life.

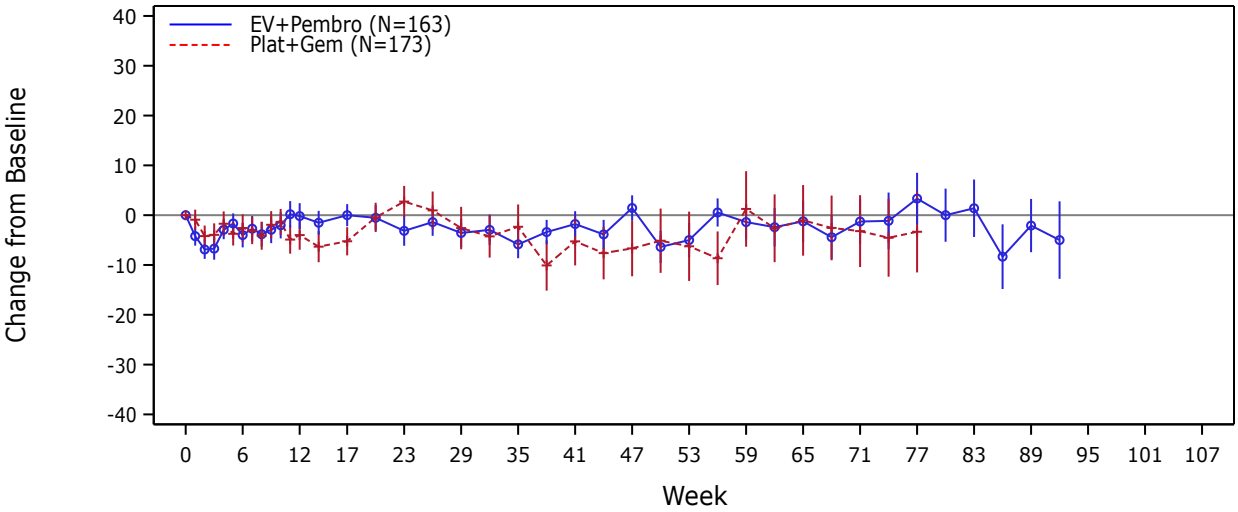
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.9.2.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Global Health Status/QoL by Age - Analysis Set mITT 2

Age: >= 65 years



Number of subjects

EV+Pembro	128	98	94	87	74	70	64	61	52	45	42	27	26	20	18	12
Plat+Gem	143	113	98	89	64	58	43	38	30	24	20	16	13	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life.

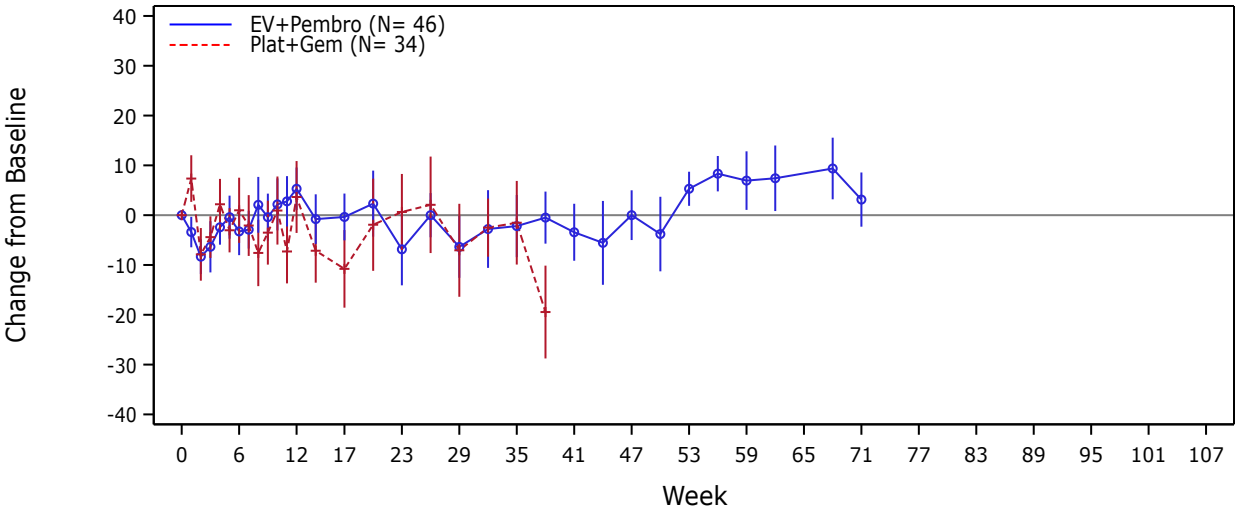
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.9.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Global Health Status/QoL by Region - Analysis Set mITT 2

Region: North America



Number of subjects

EV+Pembro	33	23	22	23	17	17	19	17	13	11	12	8
Plat+Gem	27	17	16	17	13	13	11					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life.

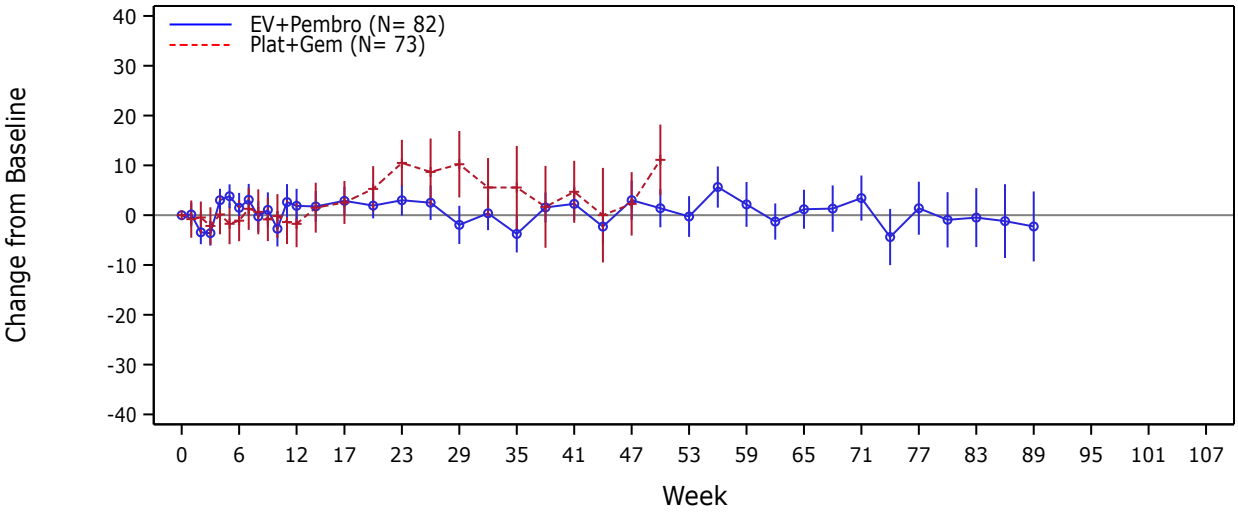
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.9.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Global Health Status/QoL by Region - Analysis Set mITT 2

Region: Rest of World



Number of subjects

EV+Pembro	74	62	58	55	50	47	42	44	36	31	27	21	17	18	17	11
Plat+Gem	63	53	43	36	27	22	15	16	11							

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life.

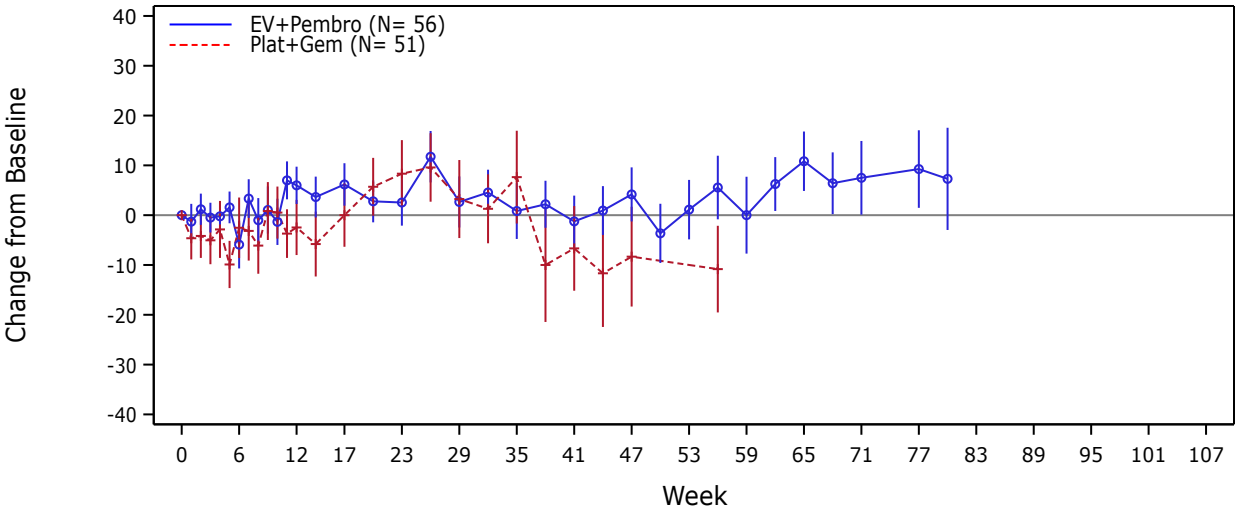
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.9.2.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Global Health Status/QoL by Sex - Analysis Set mITT 2

Sex: Female



Number of subjects

EV+Pembro	41	31	32	27	23	22	20	20	20	15	14	10	10	9
Plat+Gem	42	33	27	24	18	18	12	10	10					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life.

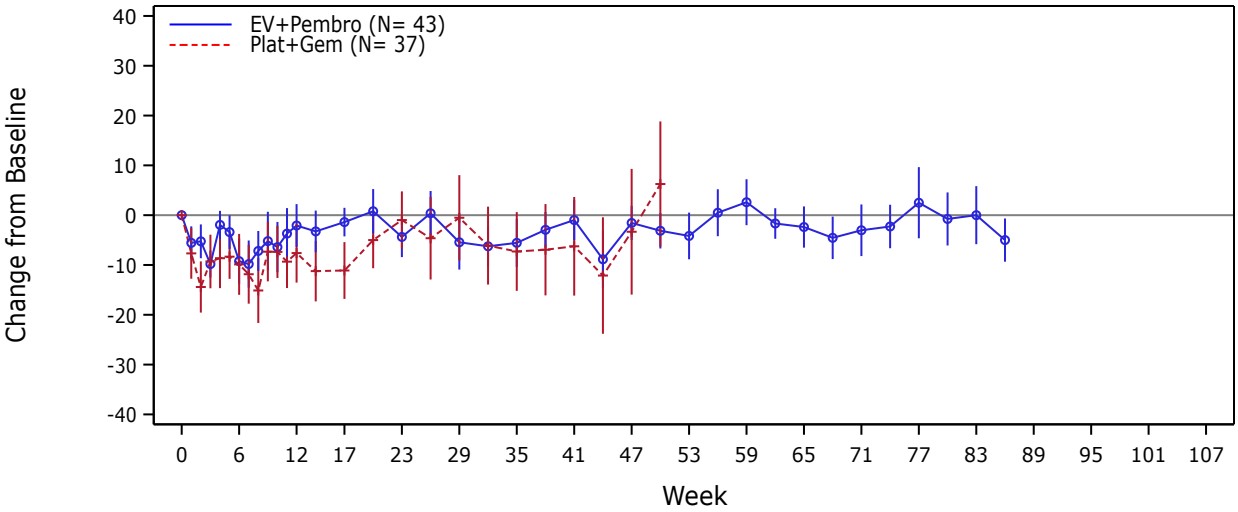
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.9.2.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Global Health Status/QoL by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Lymph node only



Number of subjects

EV+Pembro	33	28	28	24	21	23	18	17	16	14	16	14	11	10	10
Plat+Gem	29	27	23	21	17	16	16	12	10						

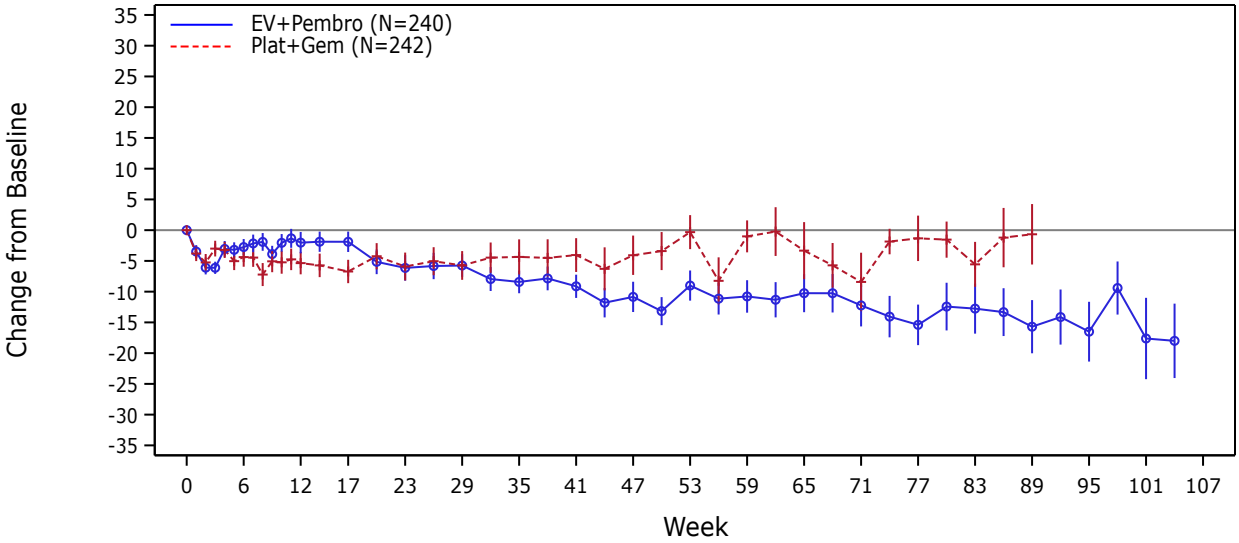
Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life.

Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.10.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Physical Functioning - Analysis Set mITT 1



Number of subjects

EV+Pembro	206	170	171	162	151	145	122	119	94	74	68	54	49	42	35	31	21	14
Plat+Gem	188	149	138	130	97	86	69	56	49	42	33	26	19	15	12	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

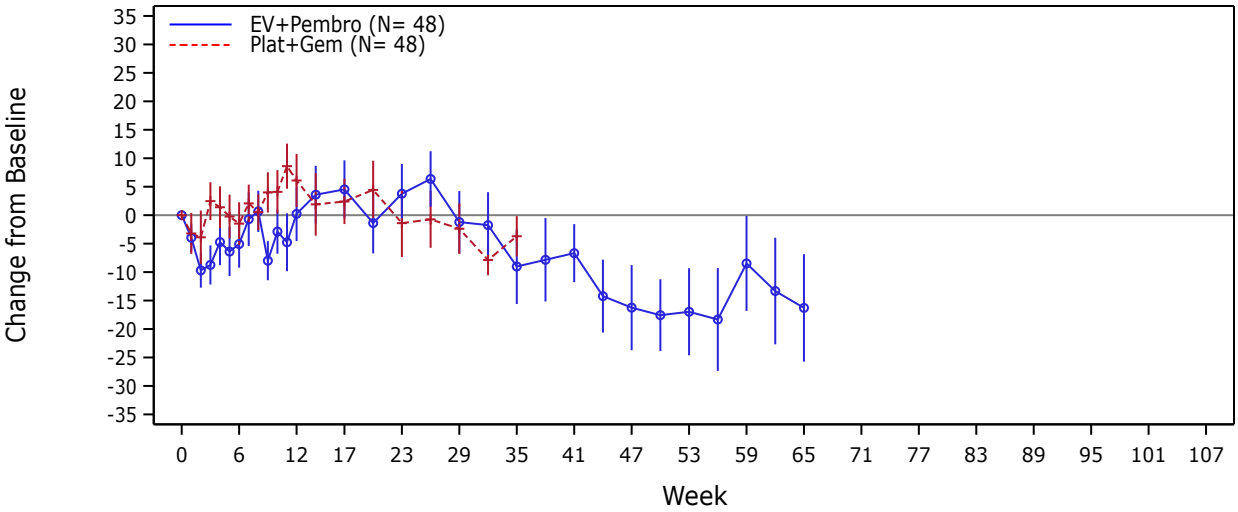
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.10.1.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Physical Functioning by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Present



Number of subjects

EV+Pembro	39	25	29	25	23	22	17	19	16	11	11	9
Plat+Gem	33	27	23	25	19	14	9					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

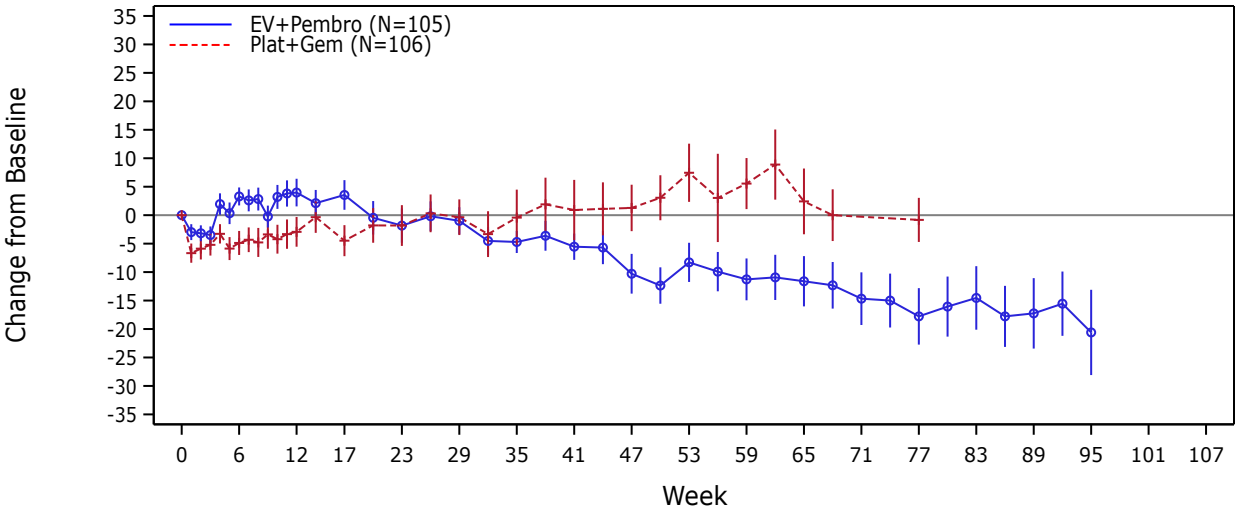
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.10.1.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Physical Functioning by Age - Analysis Set mITT 1

Age: < 65 years



Number of subjects

EV+Pembro	92	81	79	77	73	67	58	59	46	37	39	31	30	24	22	17	11
Plat+Gem	83	67	66	58	44	37	31	22	21	17	12	11		8			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

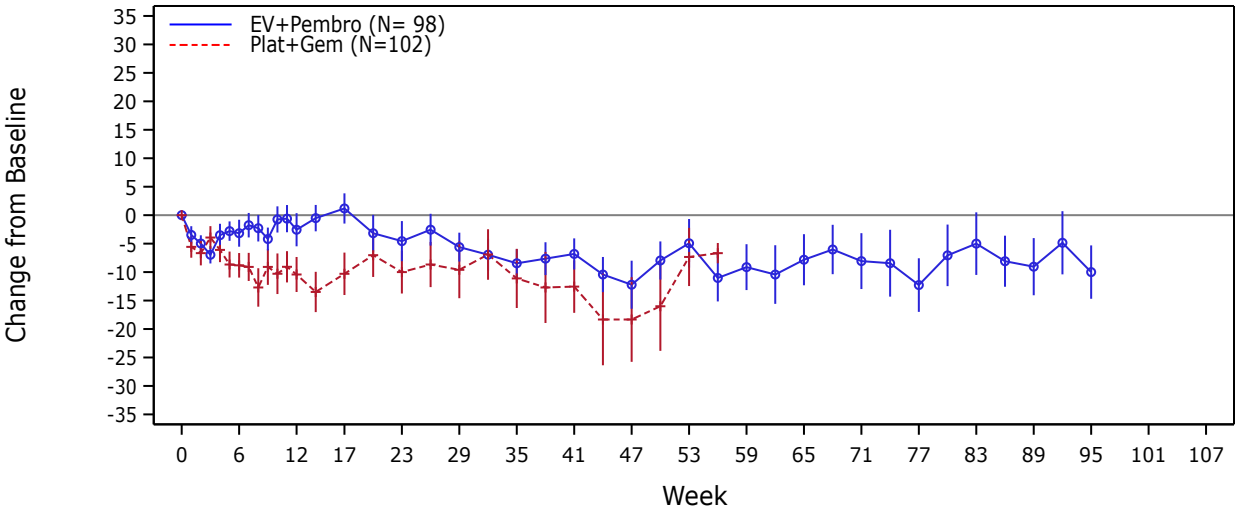
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.10.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Physical Functioning by Region - Analysis Set mITT 1

Region: Europe



Number of subjects

EV+Pembro	79	61	65	62	57	57	52	48	36	27	27	23	19	19	16	14	10
Plat+Gem	71	56	48	44	32	25	24	17	12	10							

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

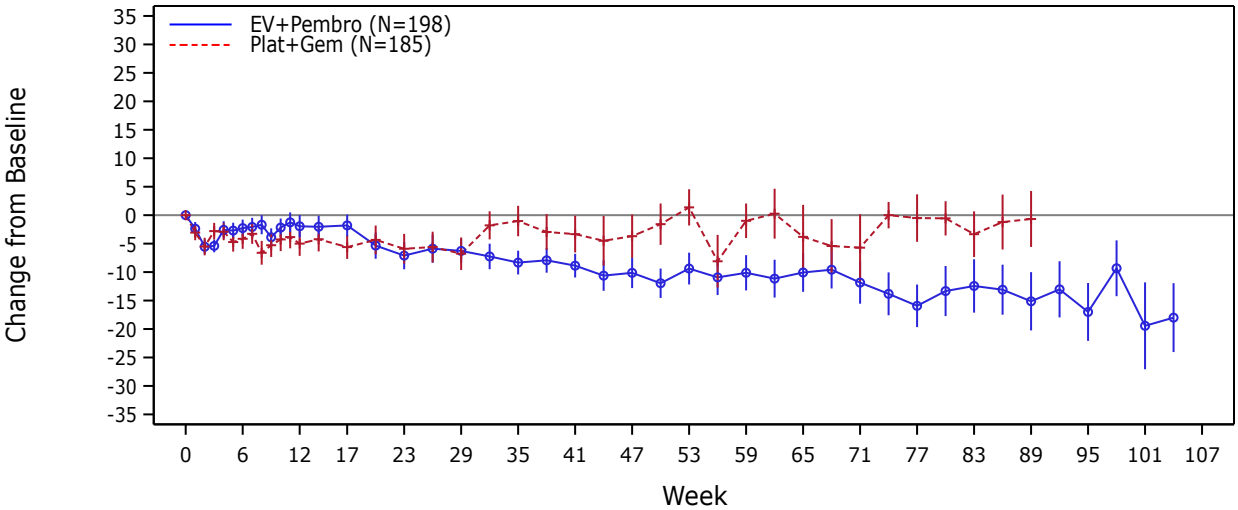
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.10.1.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Physical Functioning by Sex - Analysis Set mITT 1

Sex: Male



Number of subjects

EV+Pembro	170	138	140	130	122	120	100	94	75	59	54	47	45	36	30	26	20	12
Plat+Gem	146	114	108	101	78	65	52	44	38	34	27	21	14	13	10	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

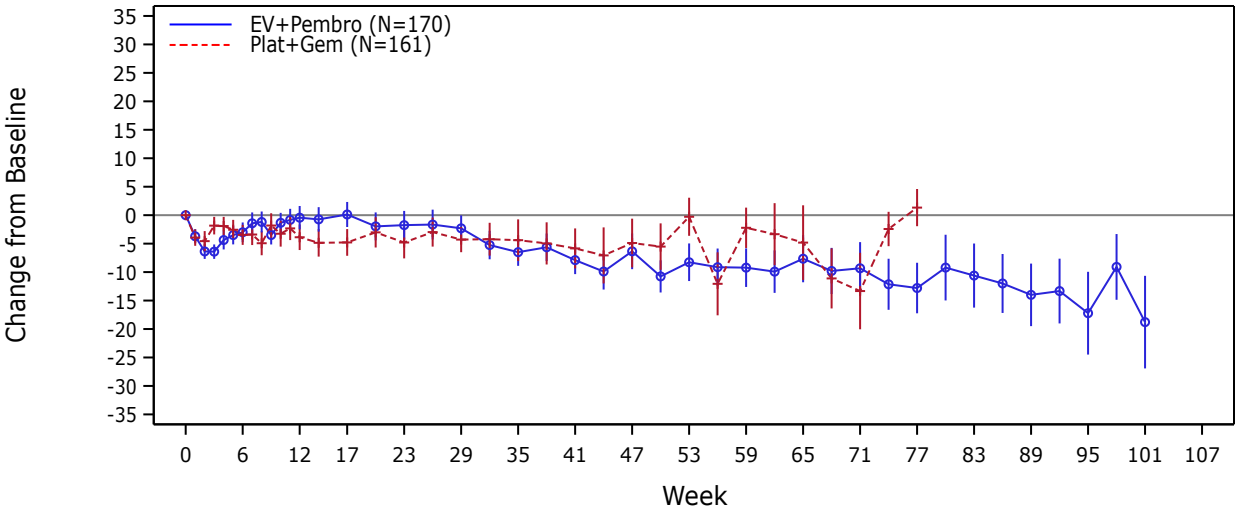
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.10.1.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Physical Functioning by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Visceral metastases



Number of subjects

EV+Pembro	146	113	120	111	103	98	79	81	63	50	47	34	30	25	22	20	12	11
Plat+Gem	129	102	91	89	68	59	44	32	30	24	21	18	12	10				

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

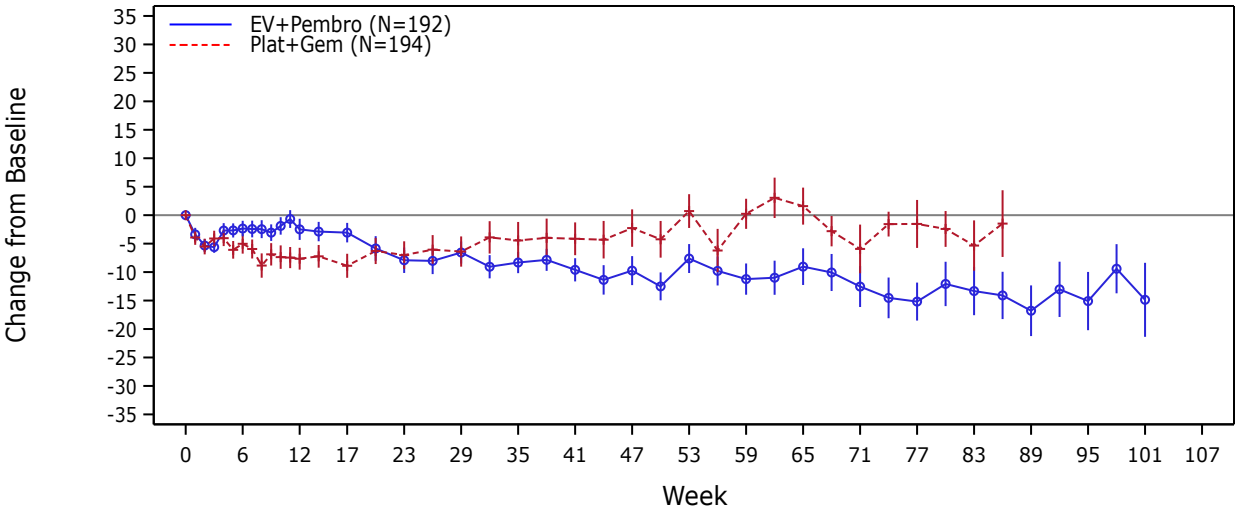
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.10.1.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Physical Functioning by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Absent



Number of subjects

EV+Pembro	167	145	142	137	128	123	105	100	78	63	57	45	42	36	30	27	19	13
Plat+Gem	155	122	115	105	78	72	60	53	44	37	28	21	18	13	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

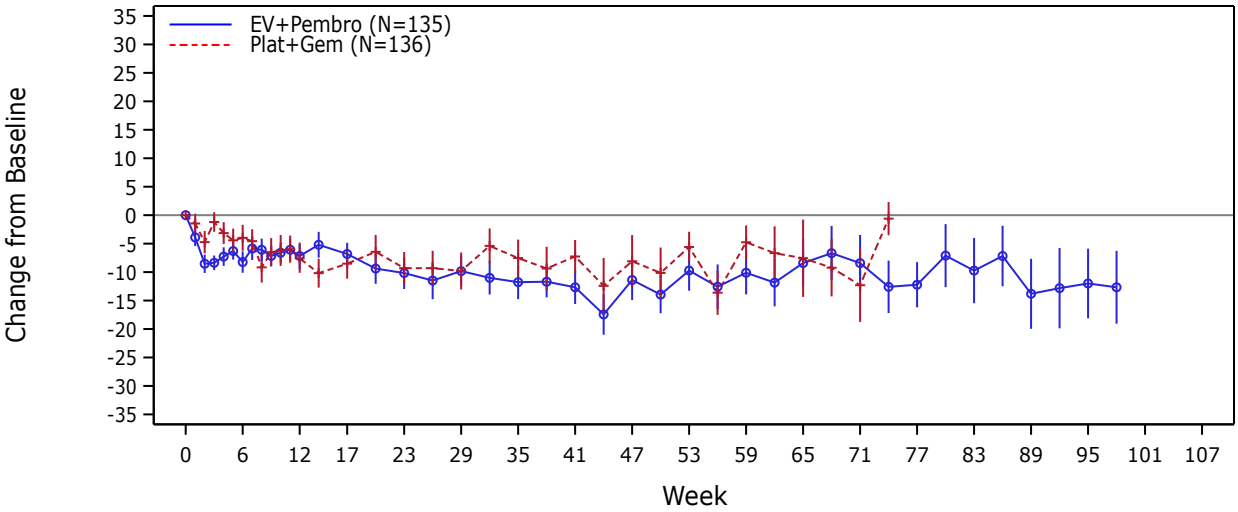
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.10.1.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Physical Functioning by Age - Analysis Set mITT 1

Age: >= 65 years



Number of subjects

EV+Pembro	114	89	92	85	78	78	64	60	48	37	29	23	19	18	13	14	10
Plat+Gem	105	82	72	72	53	49	38	34	28	25	21	15	13				

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

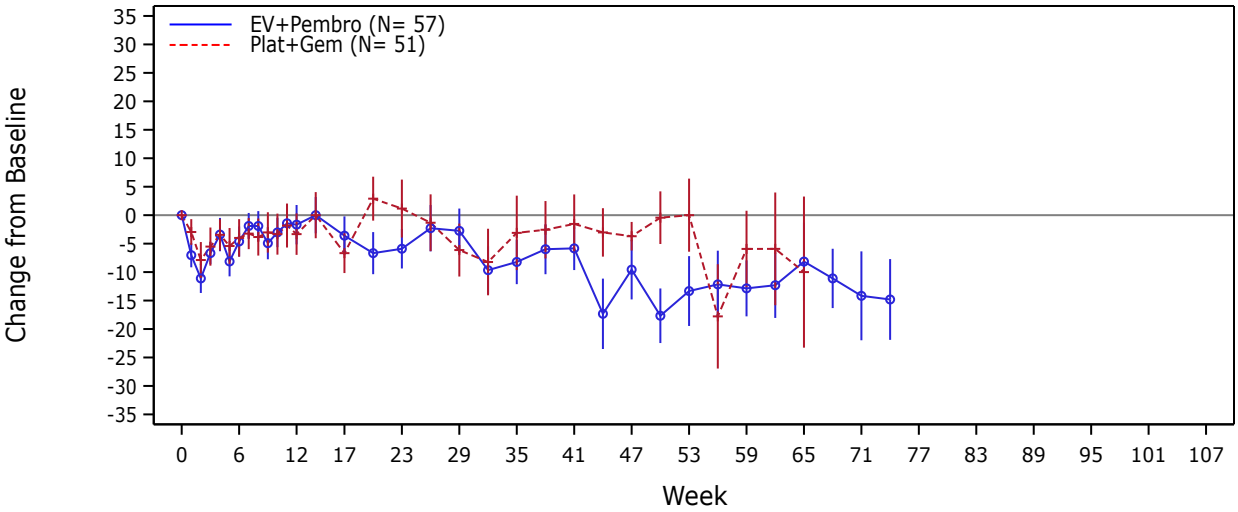
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.10.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Physical Functioning by Region - Analysis Set mITT 1

Region: North America



Number of subjects

EV+Pembro	47	39	40	37	35	34	30	24	23	14	14	9	8
Plat+Gem	42	30	32	31	23	25	15	13	9	11	9	8	

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

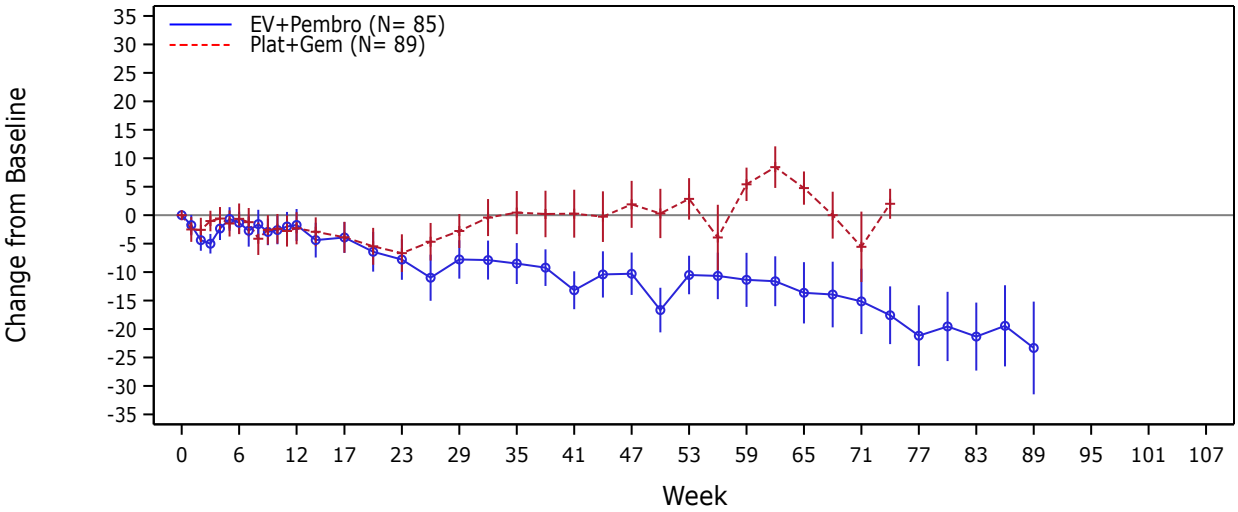
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.10.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Physical Functioning by Region - Analysis Set mITT 1

Region: Rest of World



Number of subjects

EV+Pembro	80	70	66	63	59	54	40	47	35	33	27	22	22	17	15	12
Plat+Gem	75	63	58	55	42	36	30	26	28	21	16	14	12			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

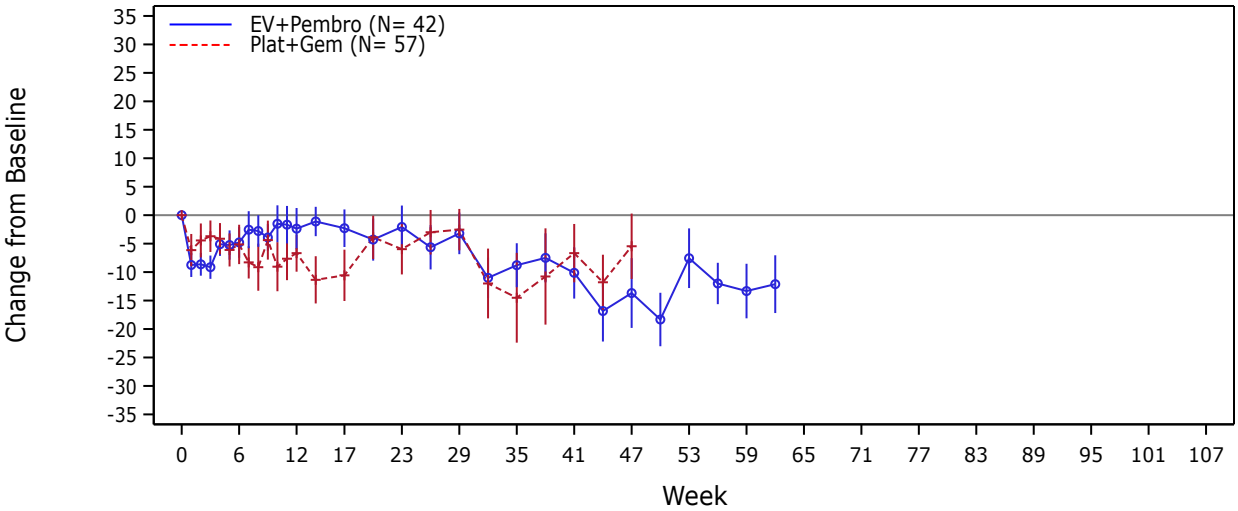
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.10.1.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Physical Functioning by Sex - Analysis Set mITT 1

Sex: Female



Number of subjects

EV+Pembro	36	32	31	32	29	25	22	25	19	15	14
Plat+Gem	42	35	30	29	19	21	17	12	11		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

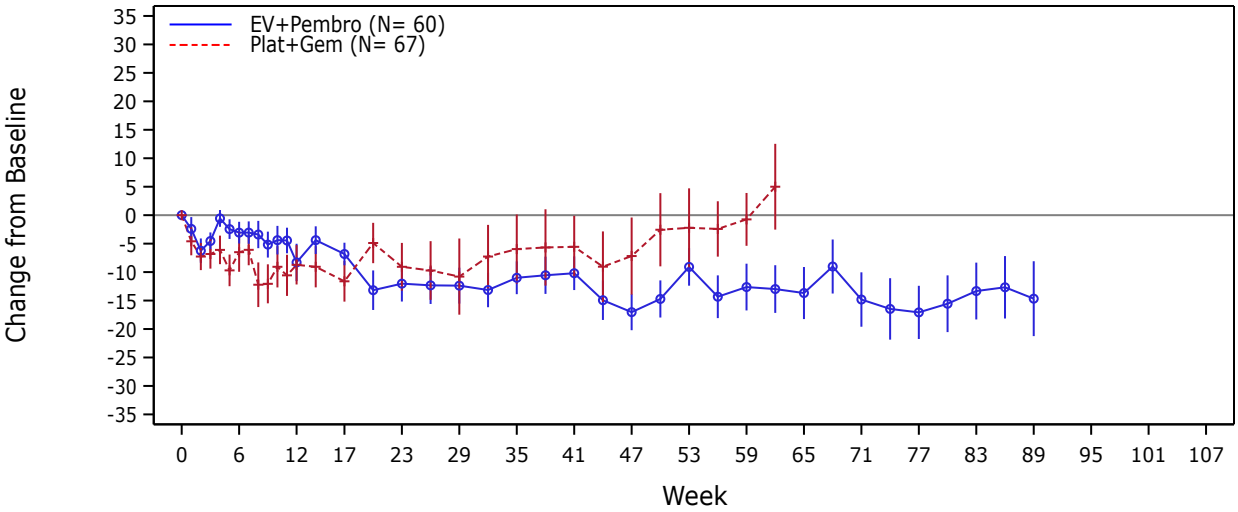
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.10.1.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Physical Functioning by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Lymph node only



Number of subjects

EV+Pembro	53	50	45	44	41	42	40	34	27	22	19	19	18	16	12	10
Plat+Gem	49	40	39	35	25	21	19	18	13	12	9					

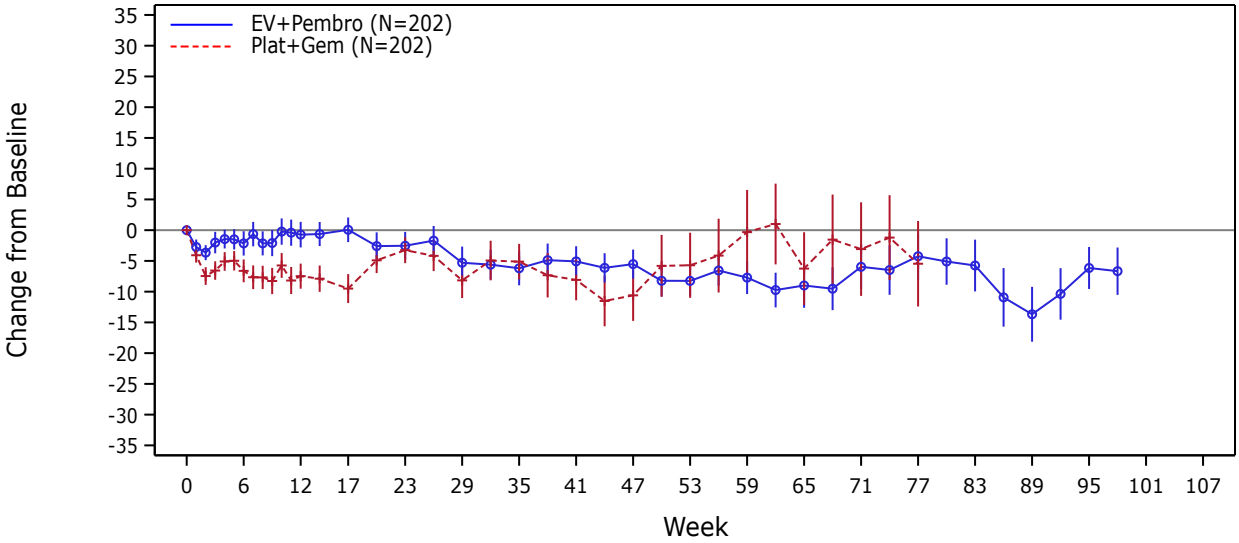
Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.10.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Physical Functioning - Analysis Set mITT 2



Number of subjects

EV+Pembro	160	124	119	111	97	93	86	84	70	63	57	40	38	33	29	19	13
Plat+Gem	165	131	115	106	80	71	56	47	39	28	21	16	13	11			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

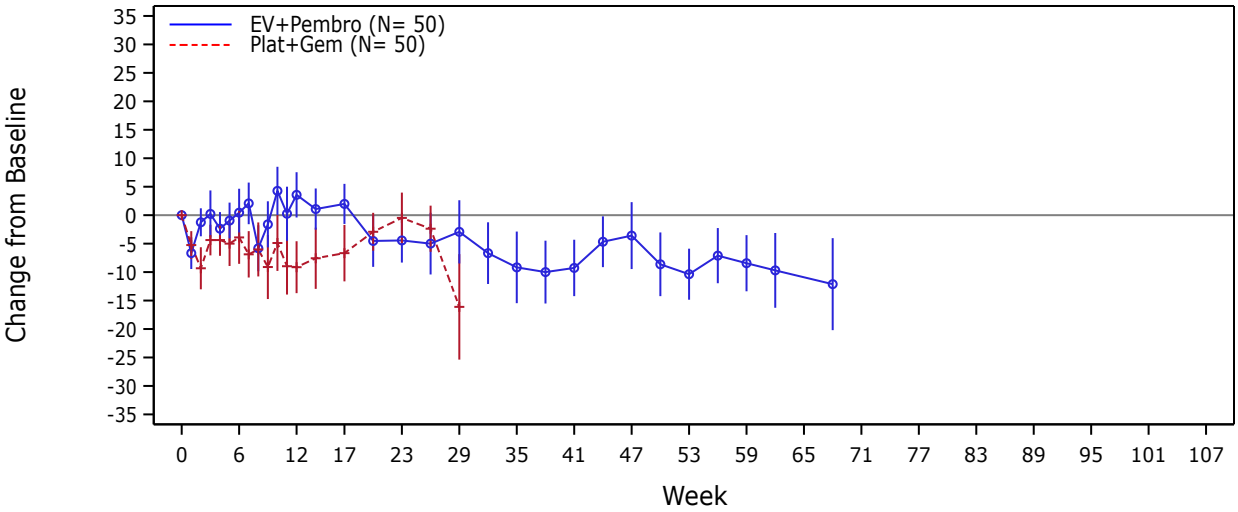
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.10.2.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Physical Functioning by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Present



Number of subjects

EV+Pembro	40	30	28	27	24	25	24	23	13	18	15
Plat+Gem	40	29	27	23	14	12					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

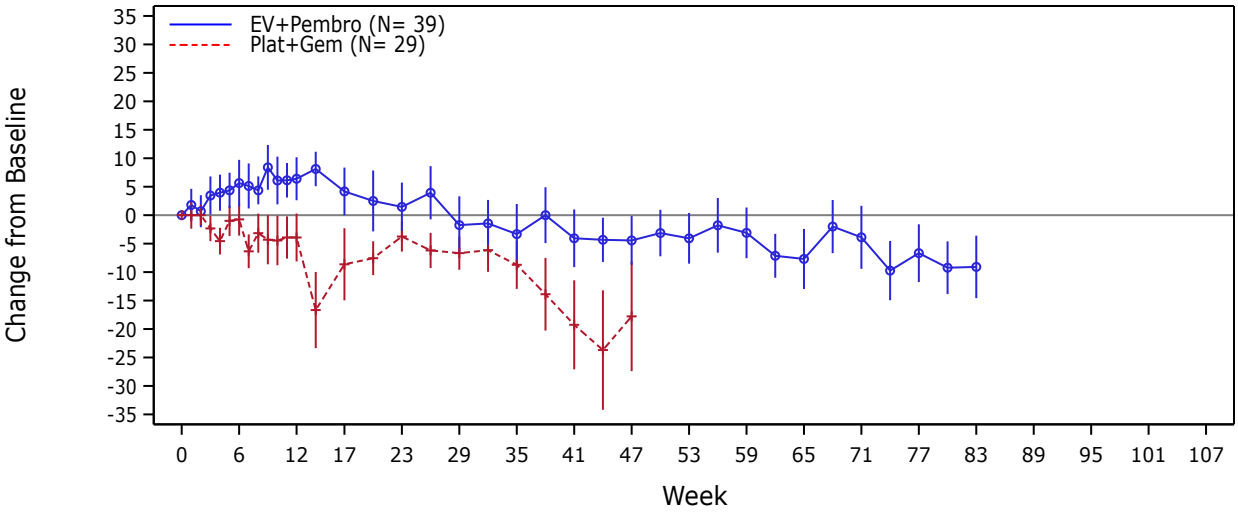
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.10.2.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Physical Functioning by Age - Analysis Set mITT 2

Age: < 65 years



Number of subjects

EV+Pembro	32	26	25	24	23	23	22	23	18	18	15	13	12	13	11
Plat+Gem	22	18	17	17	16	13	13	9	9						

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

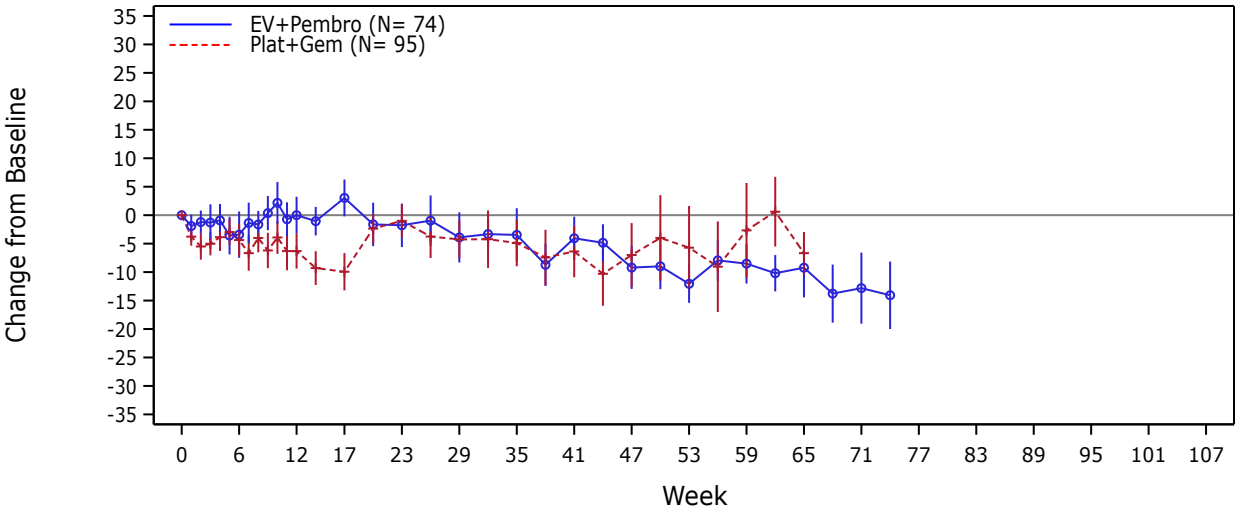
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.10.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Physical Functioning by Region - Analysis Set mITT 2

Region: Europe



Number of subjects

EV+Pembro	53	39	39	33	30	29	25	23	21	21	18	13	13
Plat+Gem	75	61	56	53	40	36	30	23	20	14	10	10	

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

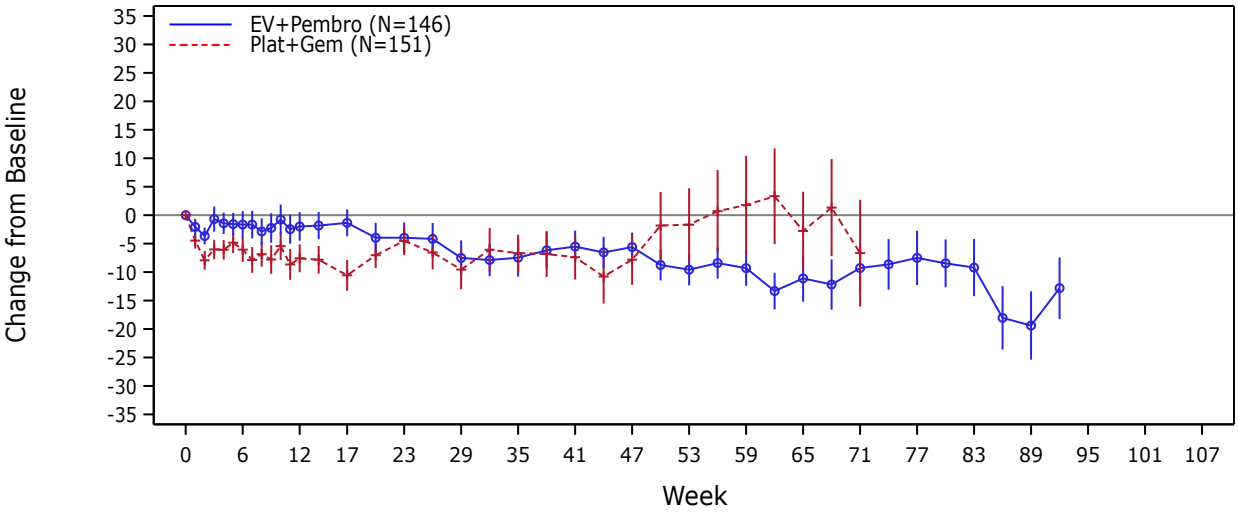
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.10.2.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Physical Functioning by Sex - Analysis Set mITT 2

Sex: Male



Number of subjects

EV+Pembro	119	93	87	84	74	71	66	64	50	48	43	30	28	24	21	11
Plat+Gem	123	98	88	82	62	53	44	37	29	20	15	12	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

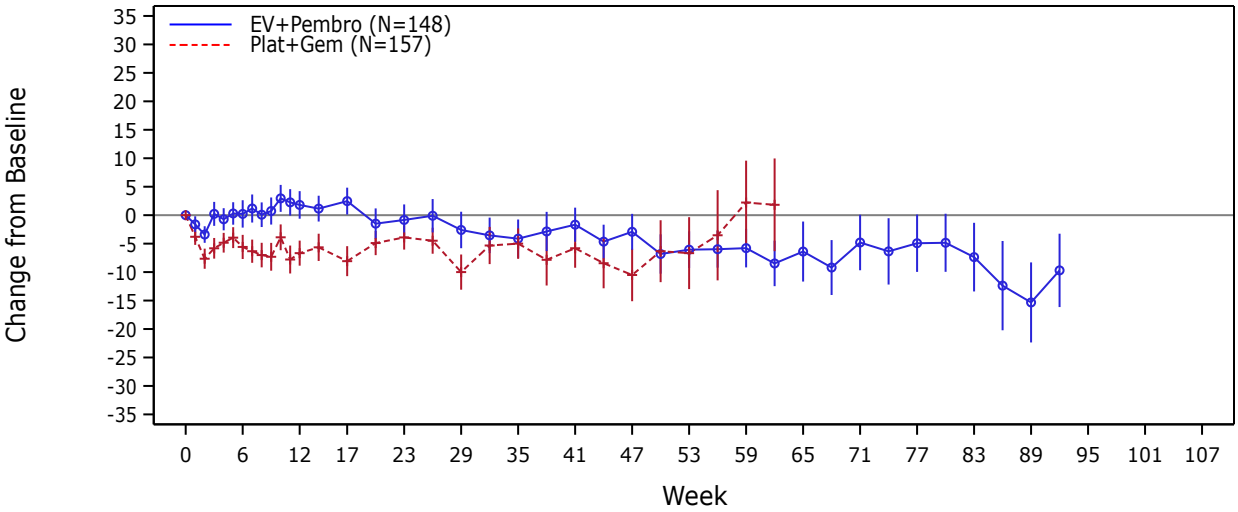
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.10.2.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Physical Functioning by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Visceral metastases



Number of subjects

EV+Pembro	119	90	85	81	71	64	63	60	48	44	38	24	25	23	19	10
Plat+Gem	128	98	84	80	58	50	36	31	26	17	12					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

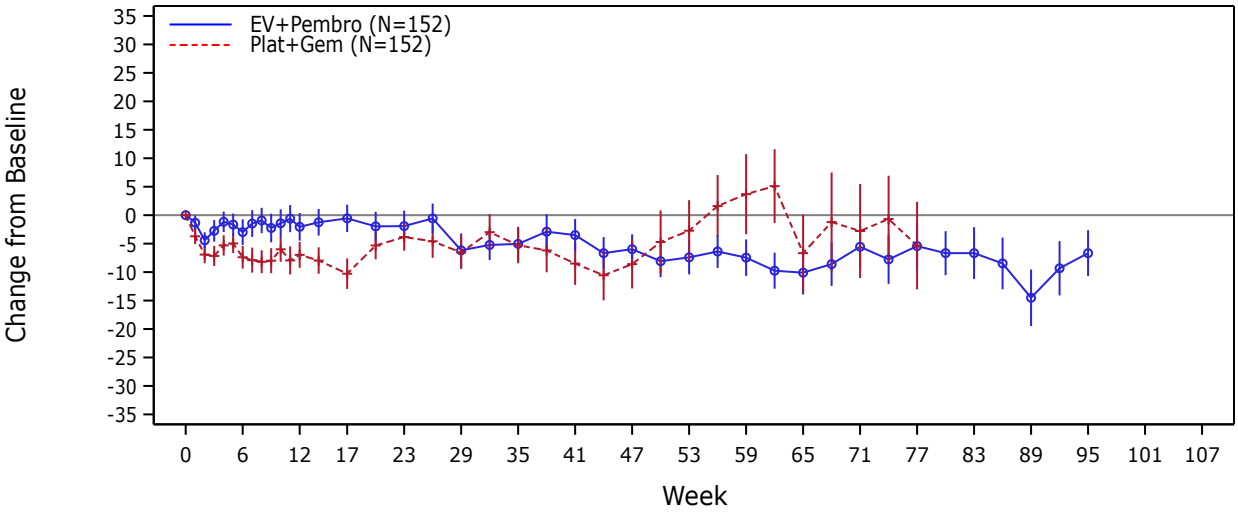
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.10.2.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Physical Functioning by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Absent



Number of subjects

EV+Pembro	120	94	91	84	73	68	62	61	57	45	42	33	30	27	24	17	11
Plat+Gem	125	102	88	83	66	59	48	40	31	22	18	14	12	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

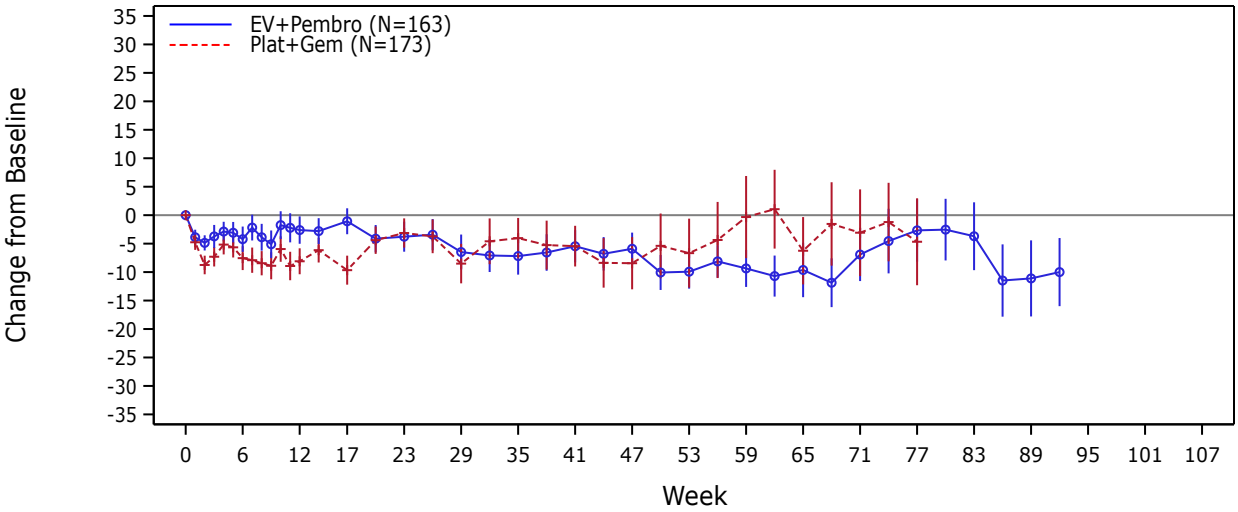
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.10.2.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Physical Functioning by Age - Analysis Set mITT 2

Age: >= 65 years



Number of subjects

EV+Pembro	128	98	94	87	74	70	64	61	52	45	42	27	26	20	18	12
Plat+Gem	143	113	98	89	64	58	43	38	30	24	20	16	13	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

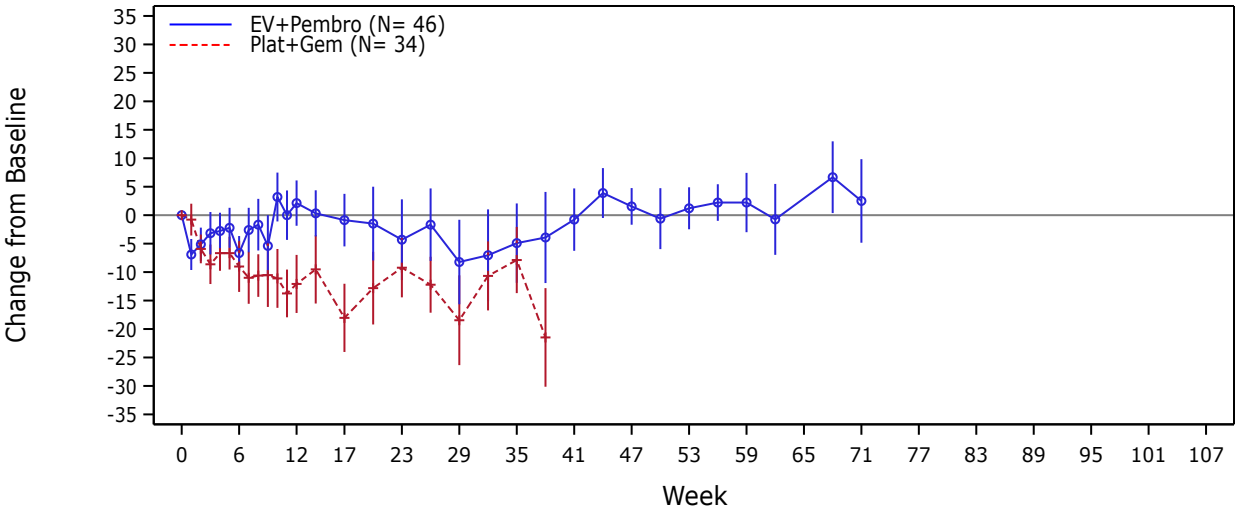
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.10.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Physical Functioning by Region - Analysis Set mITT 2

Region: North America



Number of subjects

EV+Pembro	33	23	22	23	17	17	19	17	13	11	12	8
Plat+Gem	27	17	16	17	13	13	11					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

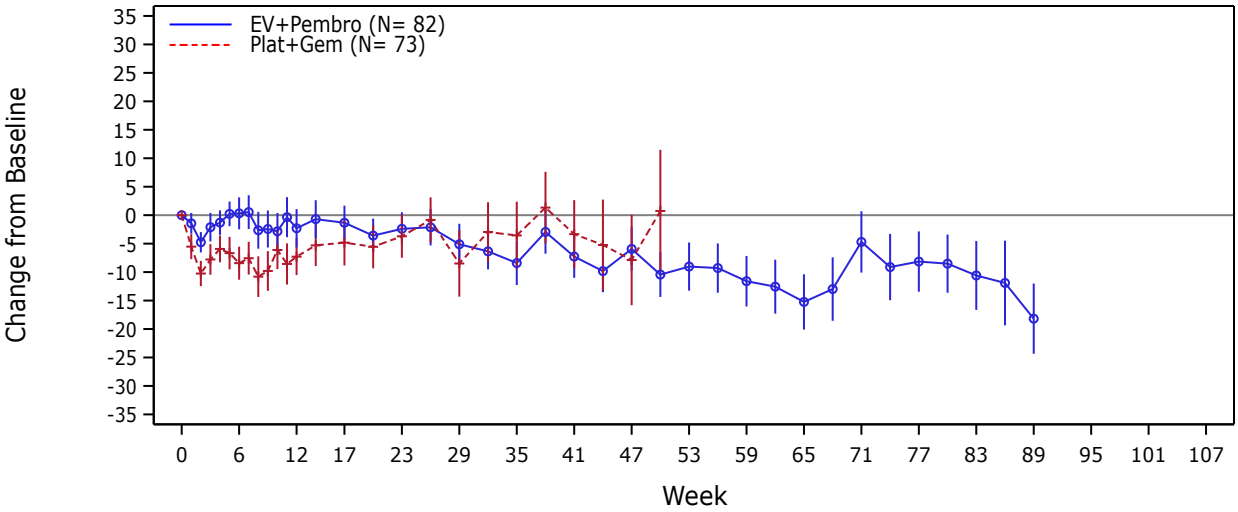
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.10.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Physical Functioning by Region - Analysis Set mITT 2

Region: Rest of World



Number of subjects

EV+Pembro	74	62	58	55	50	47	42	44	36	31	27	21	17	18	17	11
Plat+Gem	63	53	43	36	27	22	15	16	11							

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

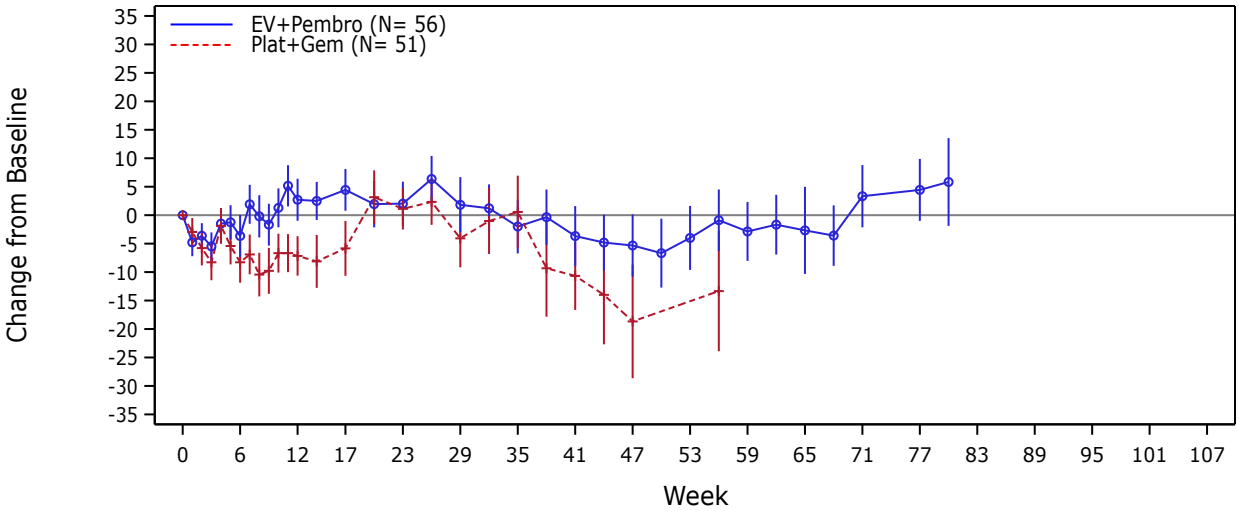
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.10.2.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Physical Functioning by Sex - Analysis Set mITT 2

Sex: Female



Number of subjects

EV+Pembro	41	31	32	27	23	22	20	20	20	15	14	10	10	9
Plat+Gem	42	33	27	24	18	18	12	10	10					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

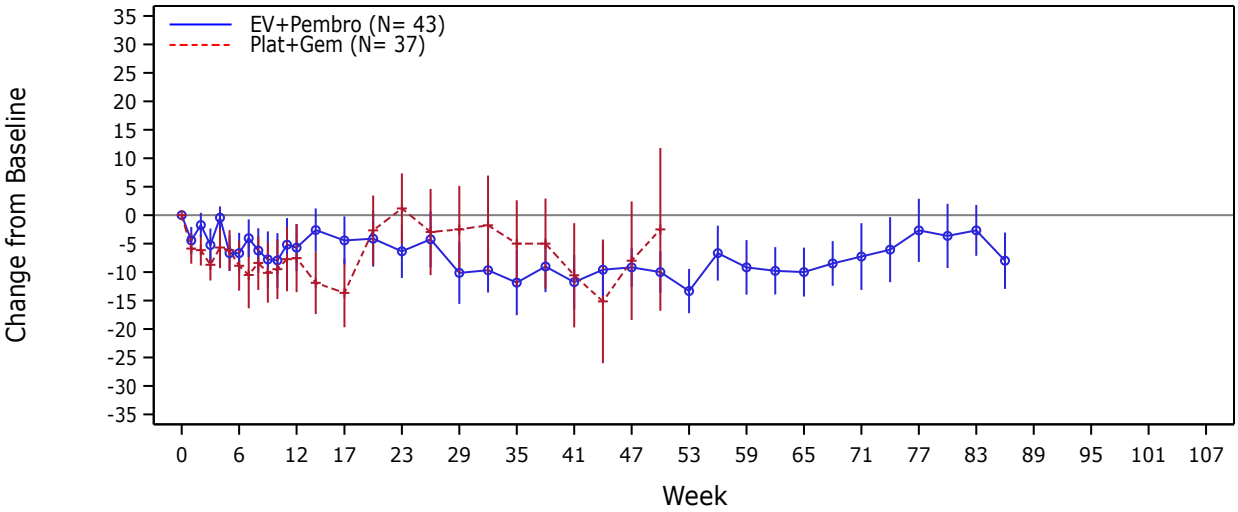
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.10.2.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Physical Functioning by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Lymph node only



Number of subjects

EV+Pembro	33	28	28	24	21	23	18	17	16	14	16	14	11	10	10
Plat+Gem	29	27	23	21	17	16	16	12	10						

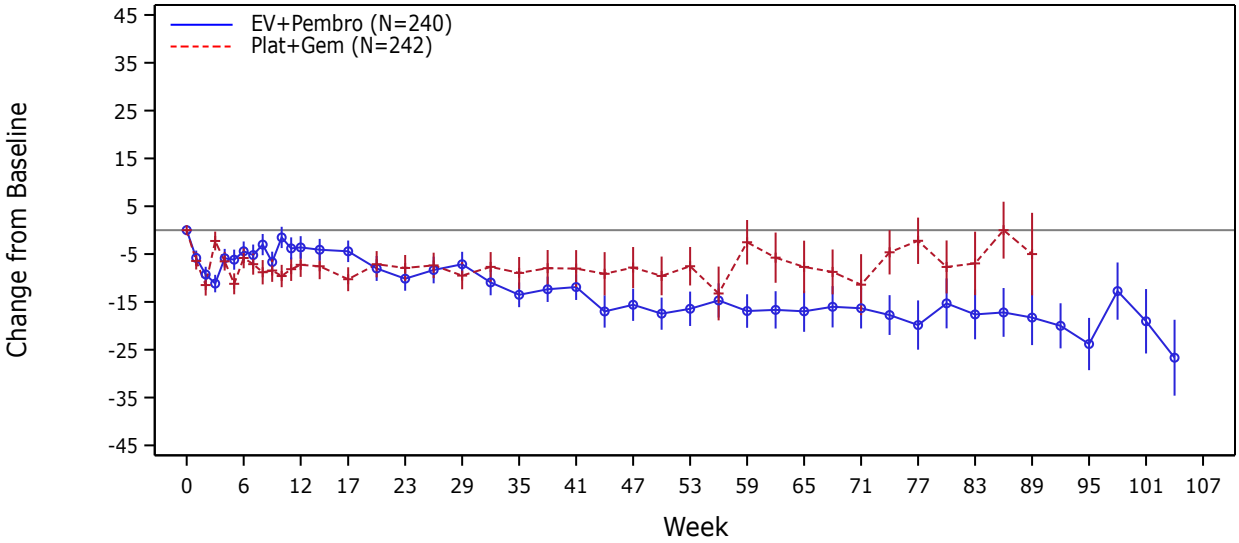
Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.11.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Role Functioning - Analysis Set mITT 1



Number of subjects

EV+Pembro	206	170	171	162	151	145	122	119	94	74	68	54	49	42	35	31	21	14
Plat+Gem	188	149	138	130	97	86	69	56	49	42	33	26	19	15	12	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

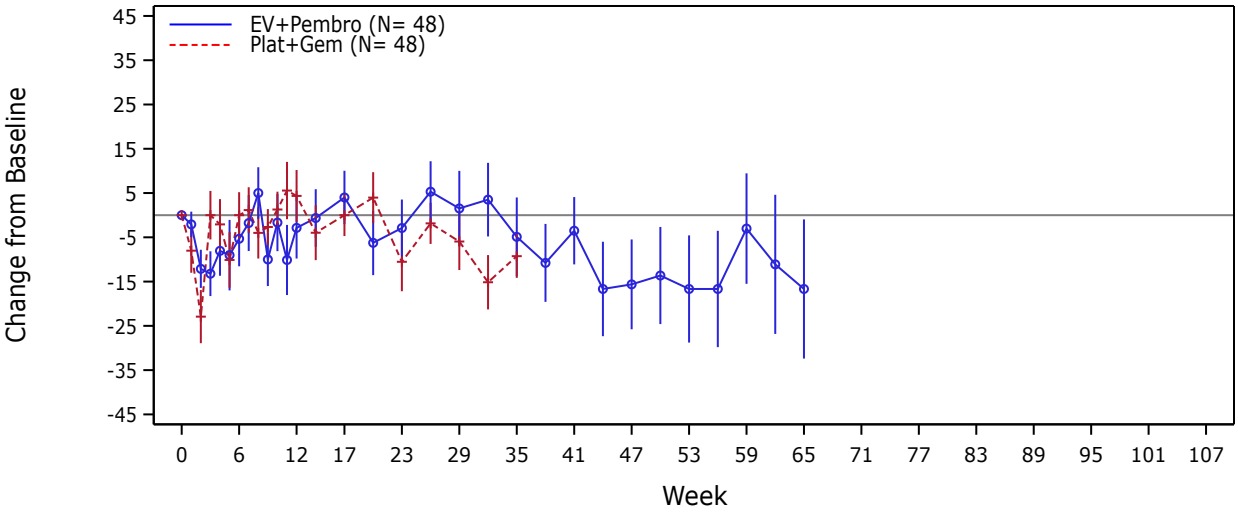
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.11.1.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Role Functioning by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Present



Number of subjects

EV+Pembro	39	25	29	25	23	22	17	19	16	11	11	9
Plat+Gem	33	27	23	25	19	14	9					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

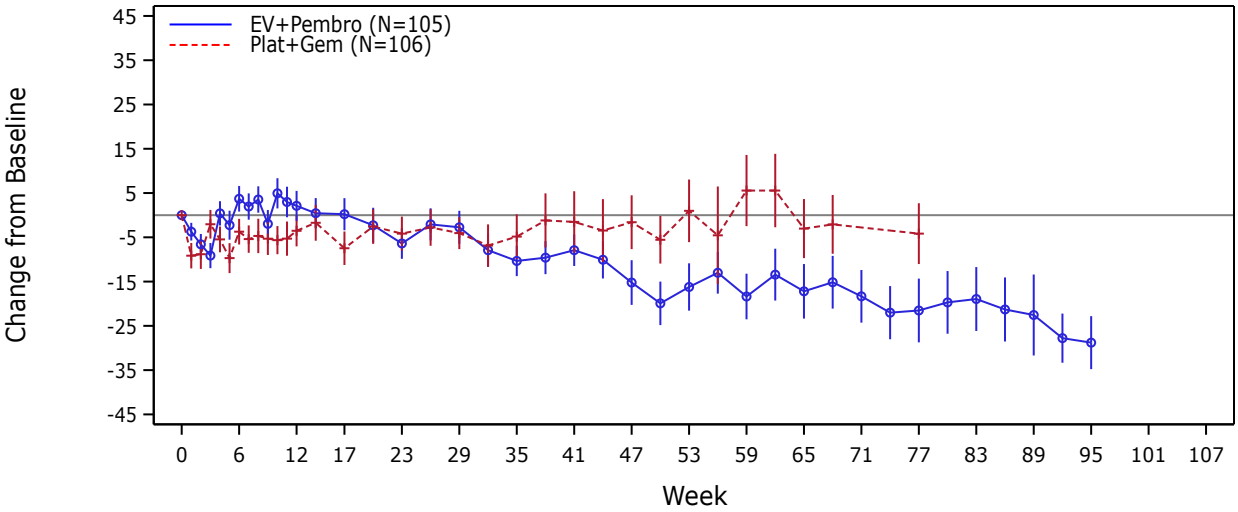
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.11.1.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Role Functioning by Age - Analysis Set mITT 1

Age: < 65 years



Number of subjects

EV+Pembro	92	81	79	77	73	67	58	59	46	37	39	31	30	24	22	17	11
Plat+Gem	83	67	66	58	44	37	31	22	21	17	12	11		8			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

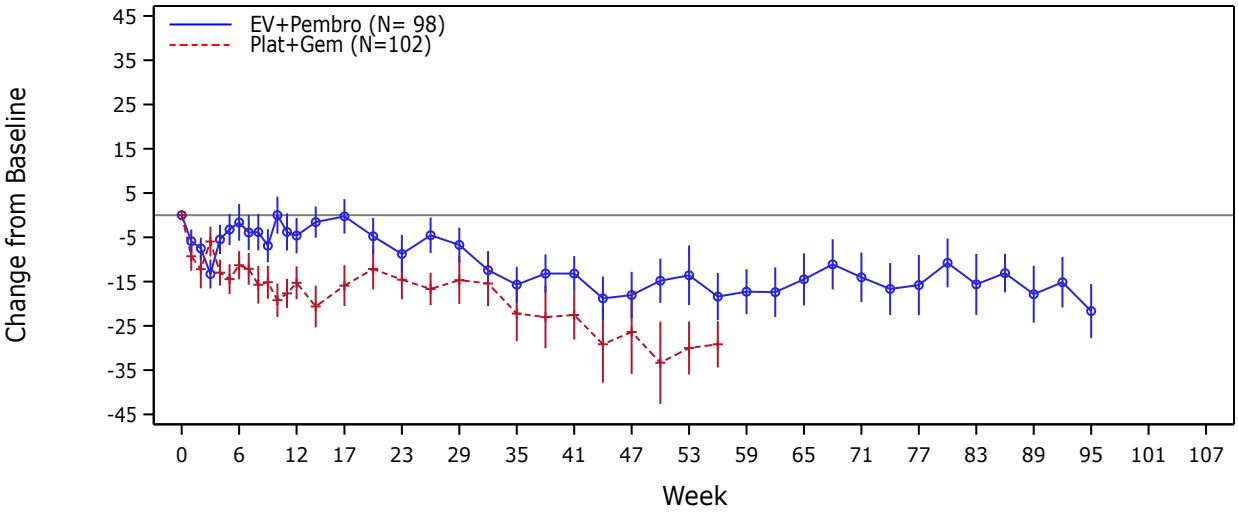
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.11.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Role Functioning by Region - Analysis Set mITT 1

Region: Europe



Number of subjects

EV+Pembro	79	61	65	62	57	57	52	48	36	27	27	23	19	19	16	14	10
Plat+Gem	71	56	48	44	32	25	24	17	12	10							

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

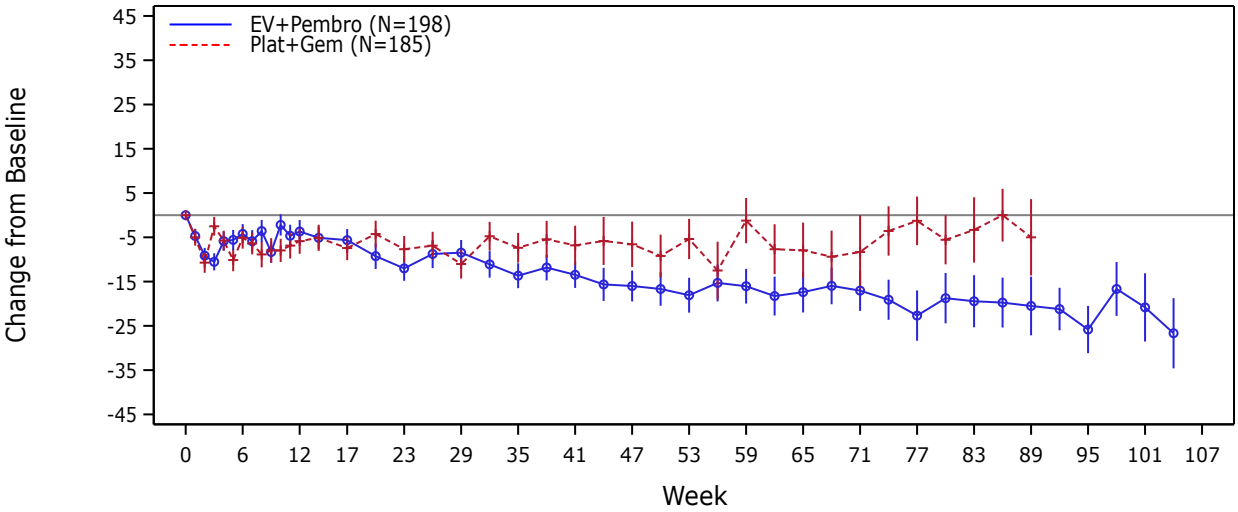
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.11.1.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Role Functioning by Sex - Analysis Set mITT 1

Sex: Male



Number of subjects

EV+Pembro	170	138	140	130	122	120	100	94	75	59	54	47	45	36	30	26	20	12
Plat+Gem	146	114	108	101	78	65	52	44	38	34	27	21	14	13	10	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

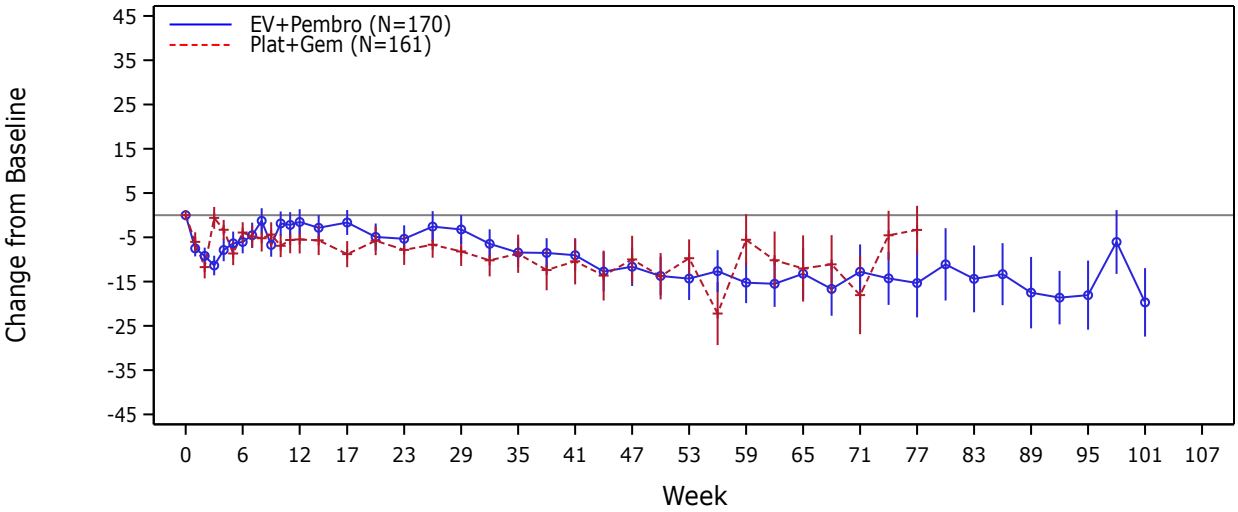
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.11.1.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Role Functioning by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Visceral metastases



Number of subjects

EV+Pembro	146	113	120	111	103	98	79	81	63	50	47	34	30	25	22	20	12	11
Plat+Gem	129	102	91	89	68	59	44	32	30	24	21	18	12	10				

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

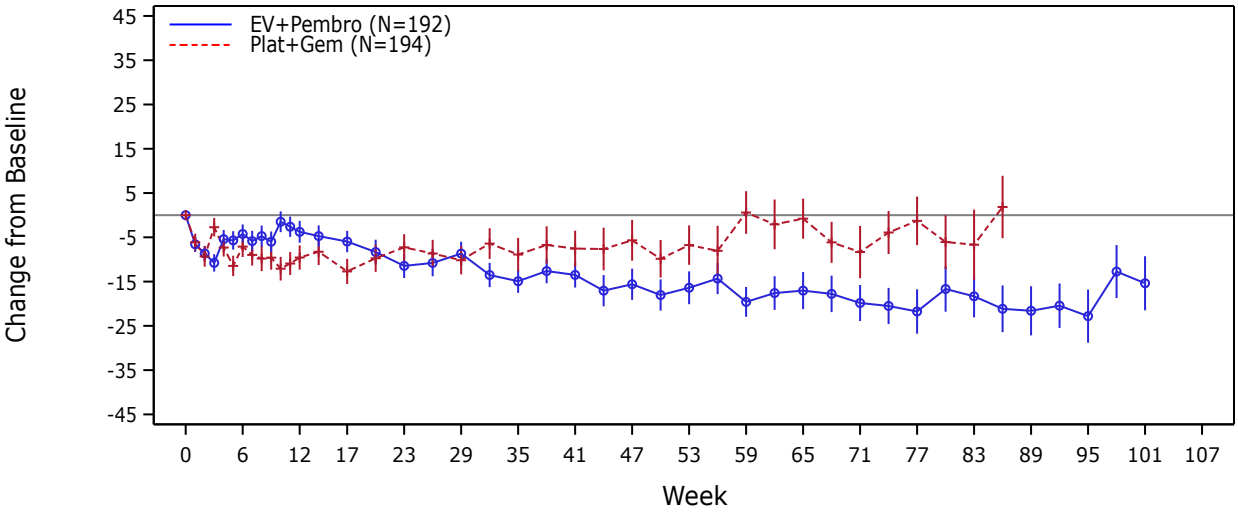
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.11.1.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Role Functioning by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Absent



Number of subjects

EV+Pembro	167	145	142	137	128	123	105	100	78	63	57	45	42	36	30	27	19	13
Plat+Gem	155	122	115	105	78	72	60	53	44	37	28	21	18	13	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

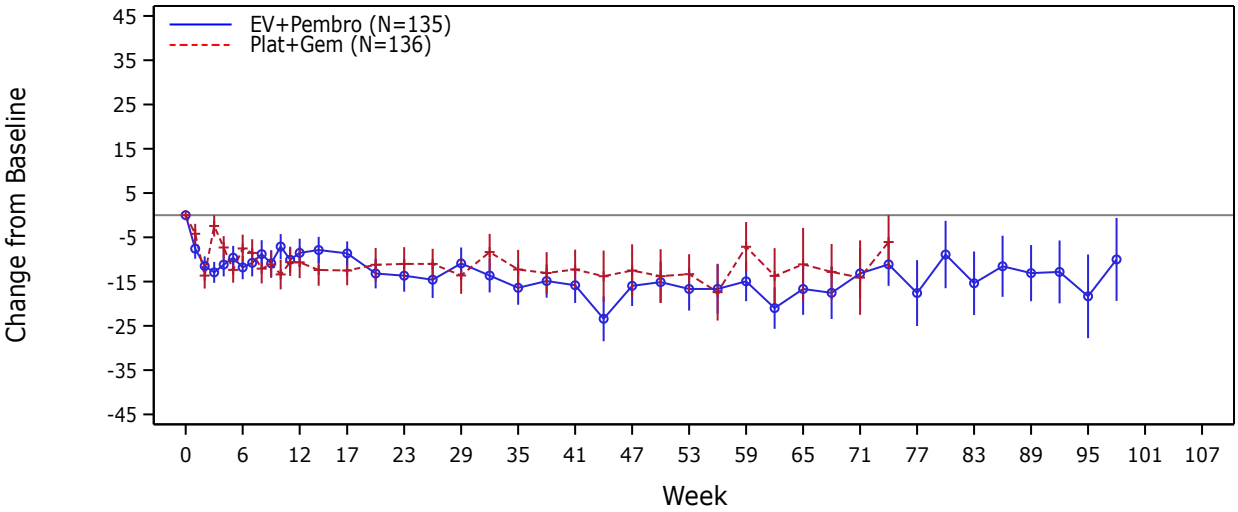
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.11.1.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Role Functioning by Age - Analysis Set mITT 1

Age: >= 65 years



Number of subjects

EV+Pembro	114	89	92	85	78	78	64	60	48	37	29	23	19	18	13	14	10
Plat+Gem	105	82	72	72	53	49	38	34	28	25	21	15	13				

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

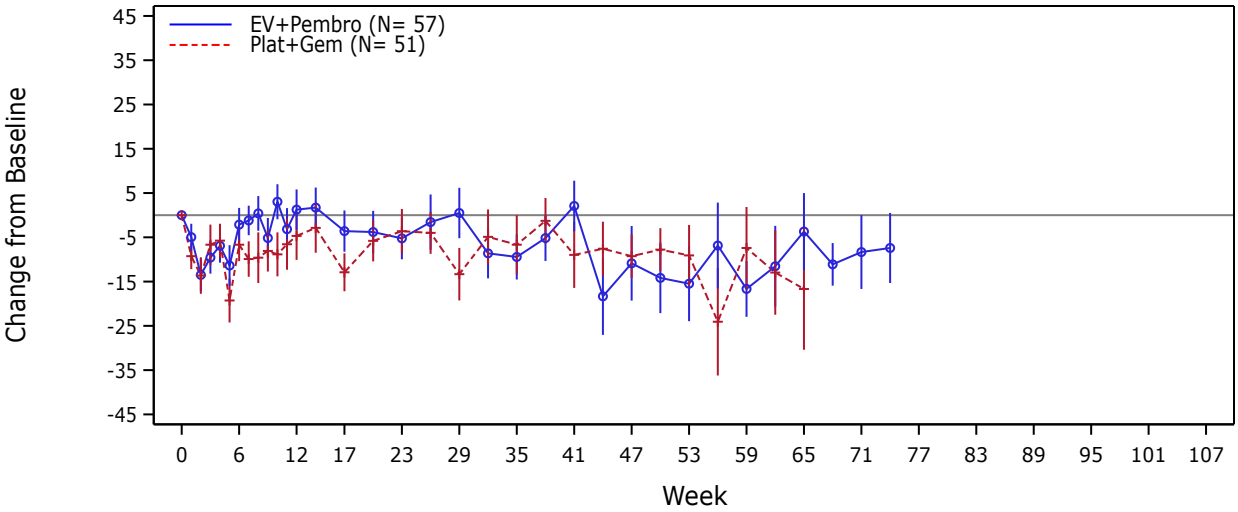
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.11.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Role Functioning by Region - Analysis Set mITT 1

Region: North America



Number of subjects

EV+Pembro	47	39	40	37	35	34	30	24	23	14	14	9	8
Plat+Gem	42	30	32	31	23	25	15	13	9	11	9	8	

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

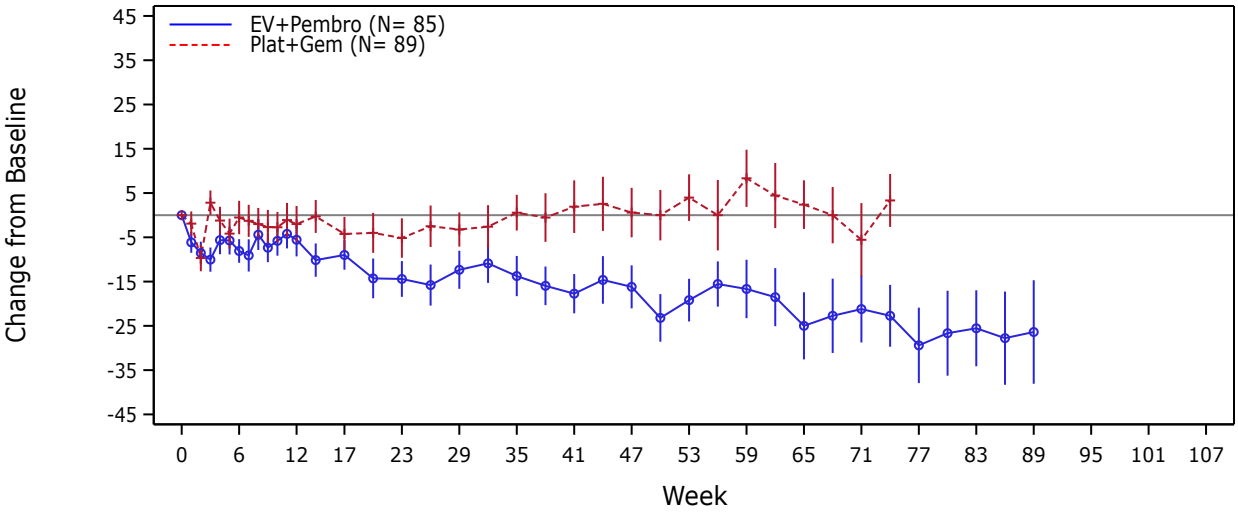
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.11.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Role Functioning by Region - Analysis Set mITT 1

Region: Rest of World



Number of subjects

EV+Pembro	80	70	66	63	59	54	40	47	35	33	27	22	22	17	15	12
Plat+Gem	75	63	58	55	42	36	30	26	28	21	16	14	12			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

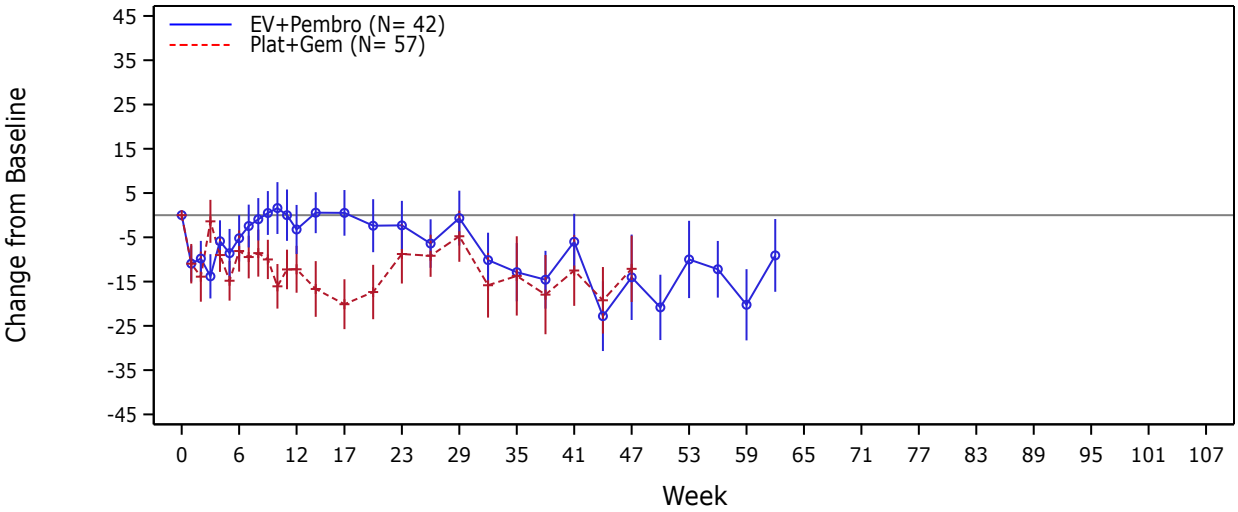
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.11.1.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Role Functioning by Sex - Analysis Set mITT 1

Sex: Female



Number of subjects

EV+Pembro	36	32	31	32	29	25	22	25	19	15	14
Plat+Gem	42	35	30	29	19	21	17	12	11		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

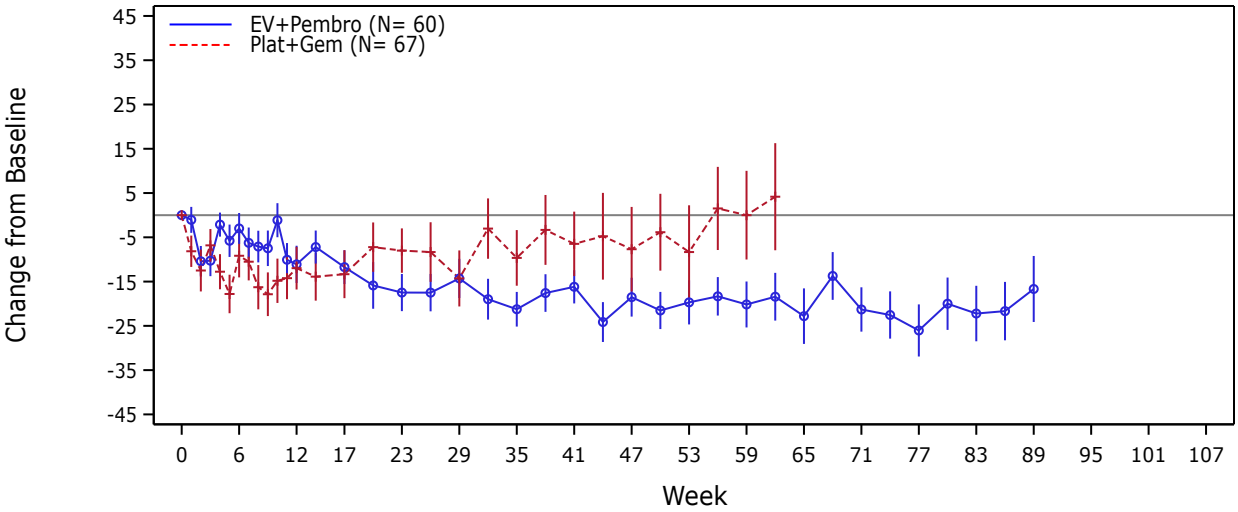
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.11.1.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Role Functioning by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Lymph node only



Number of subjects

EV+Pembro	53	50	45	44	41	42	40	34	27	22	19	19	18	16	12	10
Plat+Gem	49	40	39	35	25	21	19	18	13	12	9					

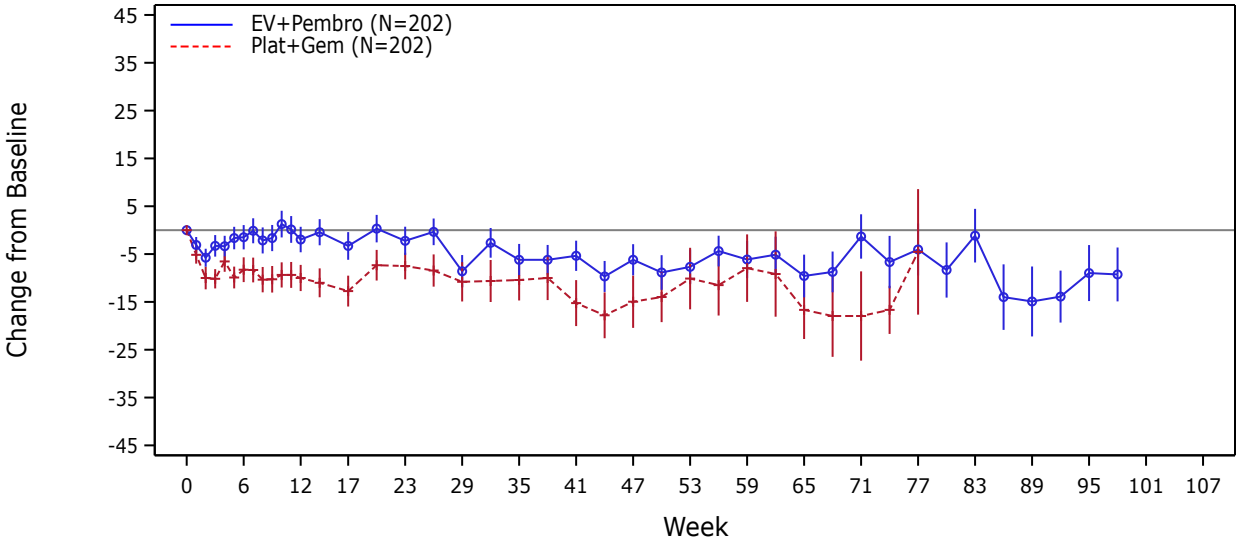
Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.11.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Role Functioning - Analysis Set mITT 2



Number of subjects

EV+Pembro	160	124	119	111	97	93	86	84	70	63	57	40	38	33	29	19	13
Plat+Gem	165	131	115	106	80	71	56	47	39	28	21	16	13	11			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

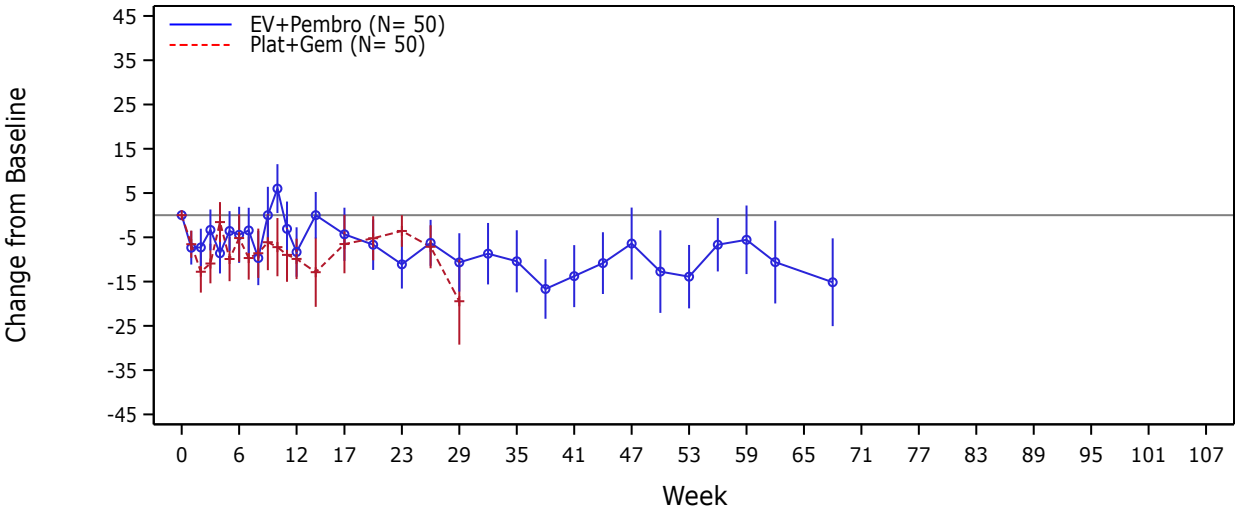
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.11.2.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Role Functioning by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Present



Number of subjects

EV+Pembro	40	30	28	27	24	25	24	23	13	18	15
Plat+Gem	40	29	27	23	14	12					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

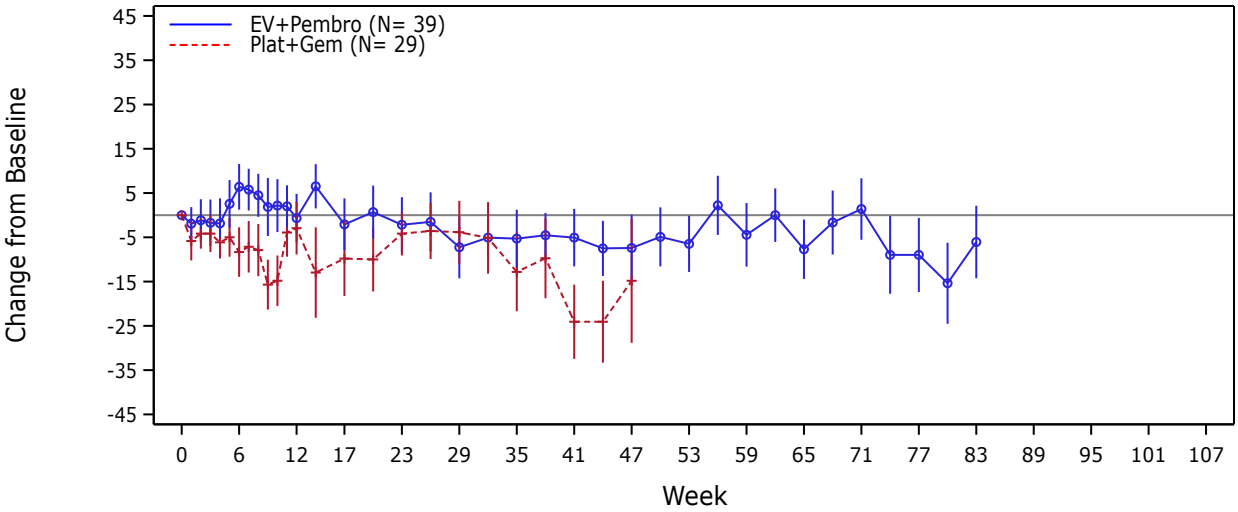
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.11.2.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Role Functioning by Age - Analysis Set mITT 2

Age: < 65 years



Number of subjects

EV+Pembro	32	26	25	24	23	23	22	23	18	18	15	13	12	13	11
Plat+Gem	22	18	17	17	16	13	13	9	9						

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

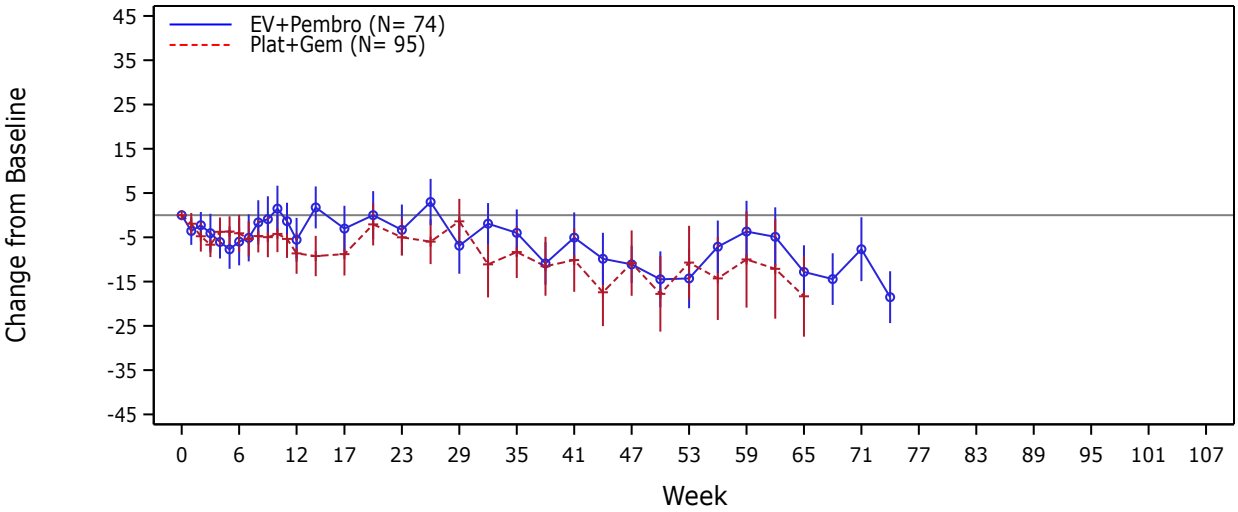
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.11.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Role Functioning by Region - Analysis Set mITT 2

Region: Europe



Number of subjects

EV+Pembro	53	39	39	33	30	29	25	23	21	21	18	13	13
Plat+Gem	75	61	56	53	40	36	30	23	20	14	10	10	

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

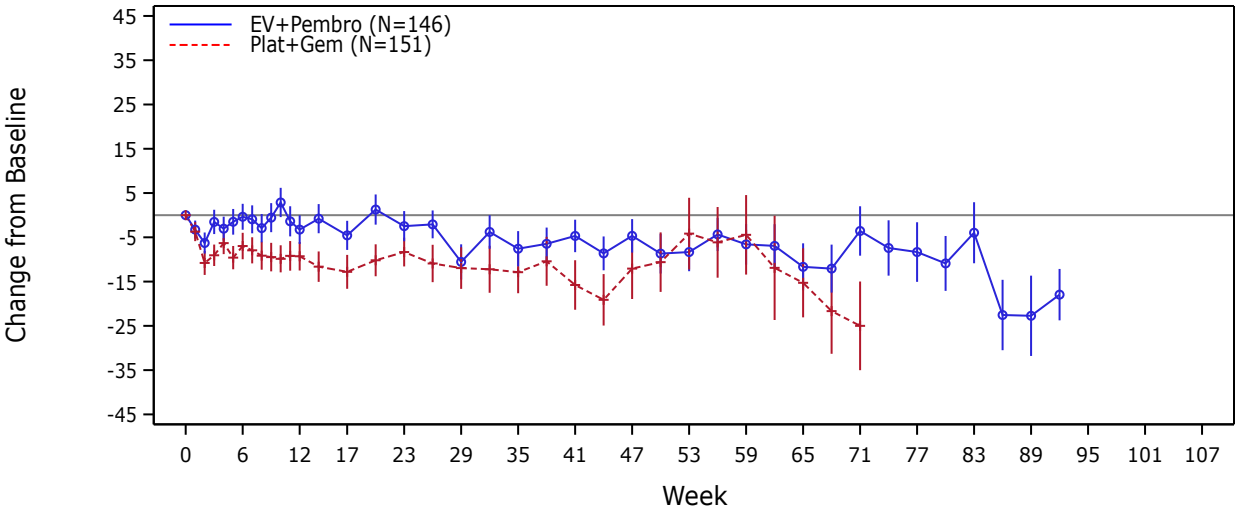
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.11.2.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Role Functioning by Sex - Analysis Set mITT 2

Sex: Male



Number of subjects

EV+Pembro	119	93	87	84	74	71	66	64	50	48	43	30	28	24	21	11
Plat+Gem	123	98	88	82	62	53	44	37	29	20	15	12	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

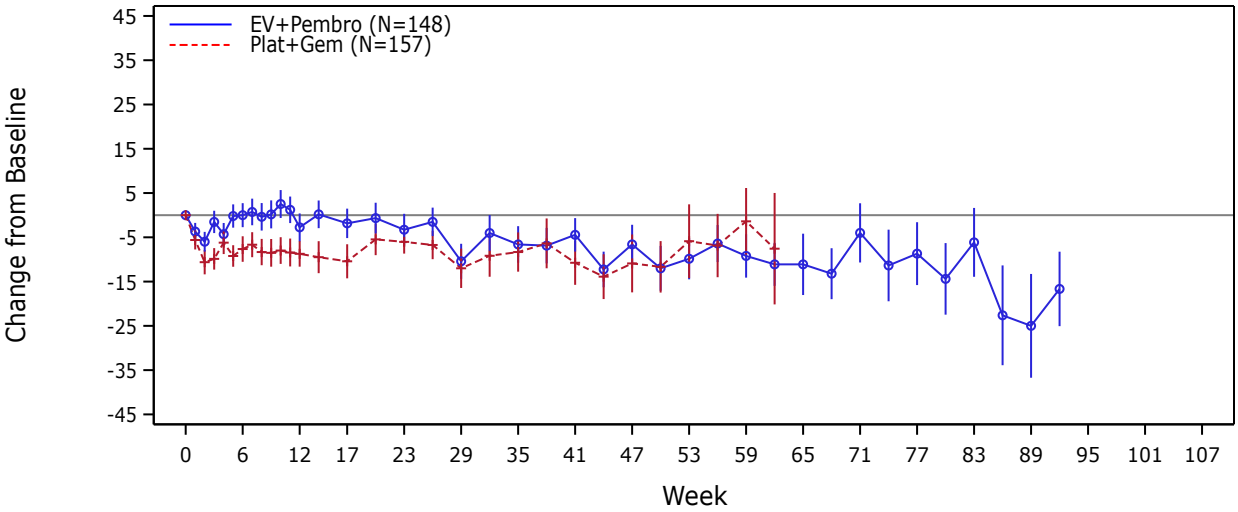
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.11.2.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Role Functioning by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Visceral metastases



Number of subjects

EV+Pembro	119	90	85	81	71	64	63	60	48	44	38	24	25	23	19	10
Plat+Gem	128	98	84	80	58	50	36	31	26	17	12					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

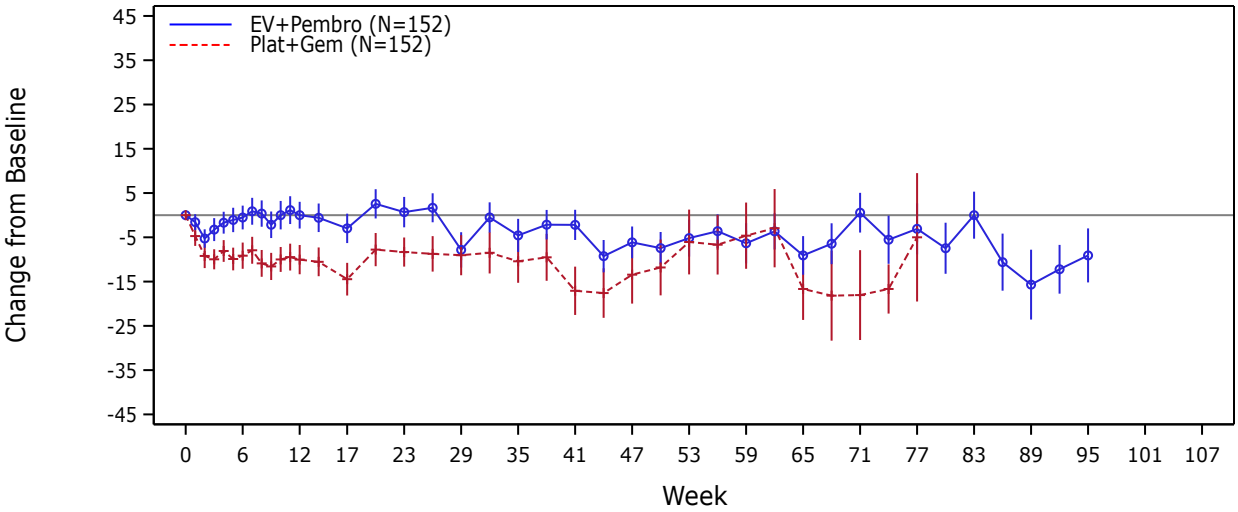
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.11.2.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Role Functioning by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Absent



Number of subjects

EV+Pembro	120	94	91	84	73	68	62	61	57	45	42	33	30	27	24	17	11
Plat+Gem	125	102	88	83	66	59	48	40	31	22	18	14	12	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

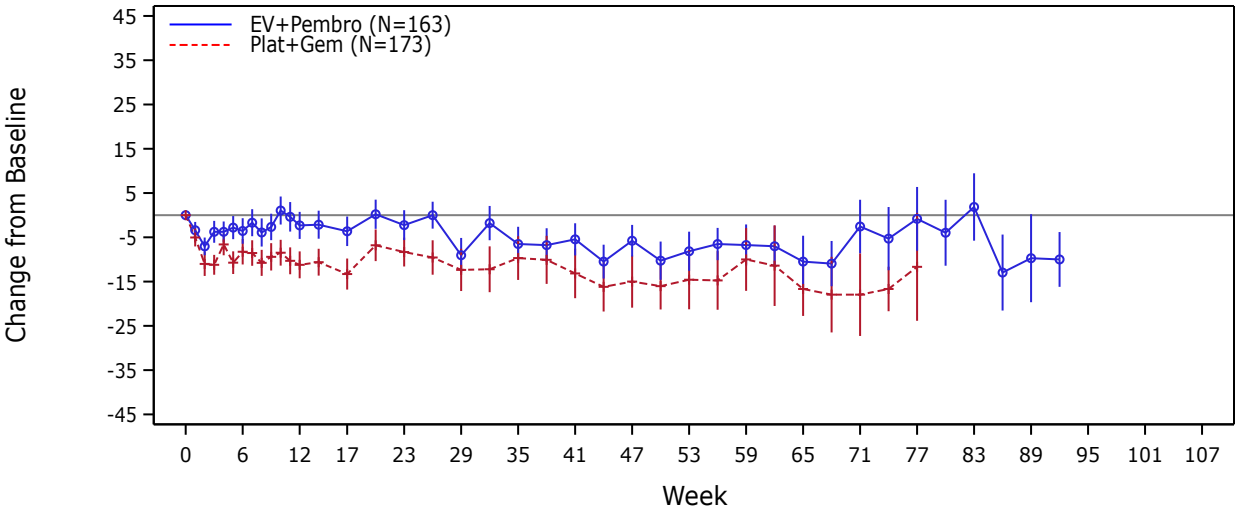
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.11.2.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Role Functioning by Age - Analysis Set mITT 2

Age: >= 65 years



Number of subjects

EV+Pembro	128	98	94	87	74	70	64	61	52	45	42	27	26	20	18	12
Plat+Gem	143	113	98	89	64	58	43	38	30	24	20	16	13	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

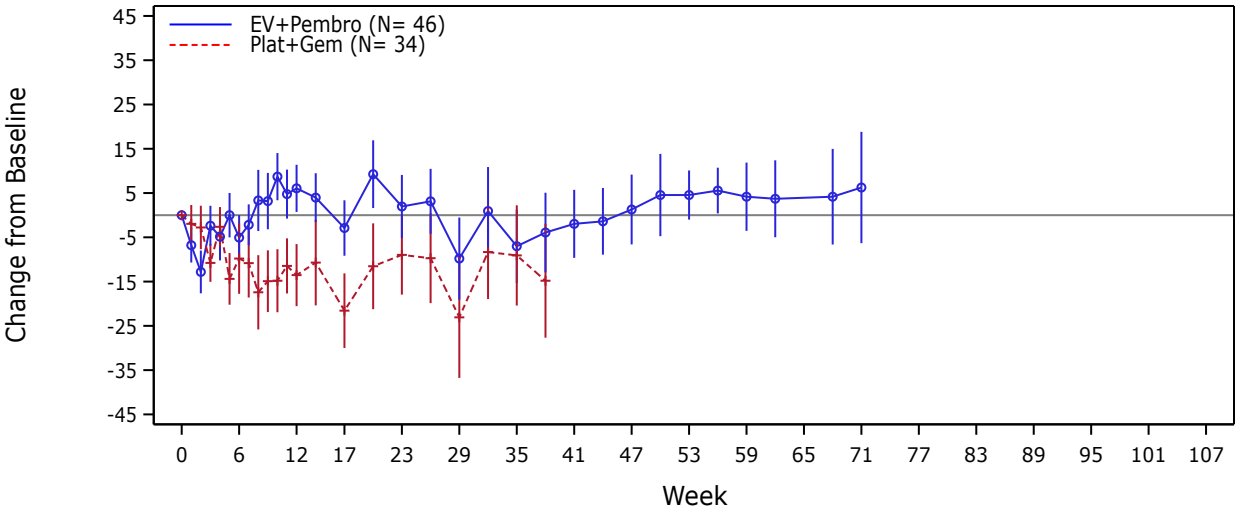
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.11.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Role Functioning by Region - Analysis Set mITT 2

Region: North America



Number of subjects

EV+Pembro	33	23	22	23	17	17	19	17	13	11	12	8
Plat+Gem	27	17	16	17	13	13	11					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

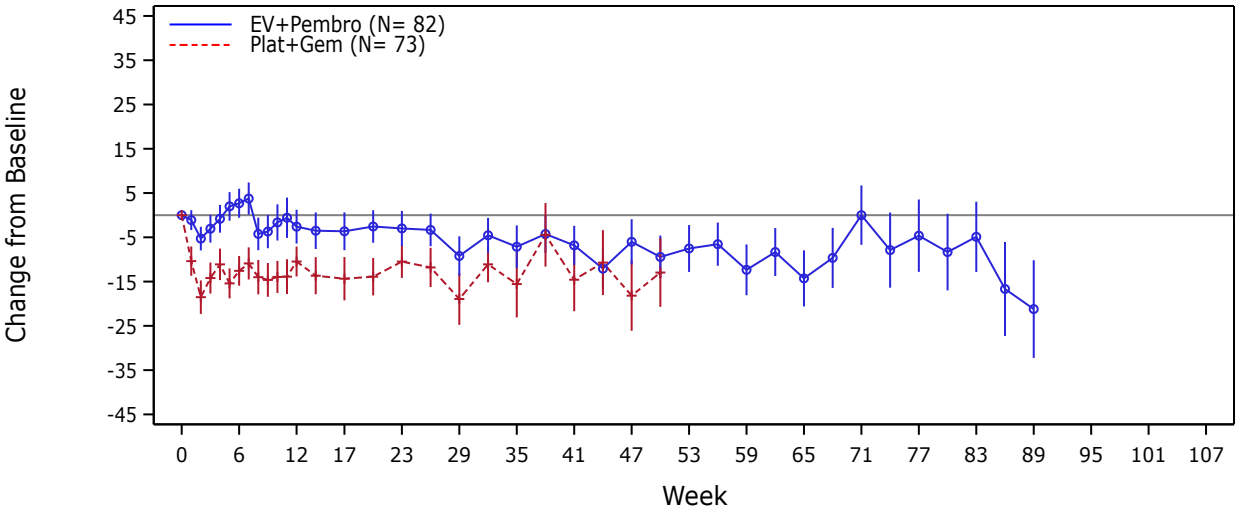
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.11.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Role Functioning by Region - Analysis Set mITT 2

Region: Rest of World



Number of subjects

EV+Pembro	74	62	58	55	50	47	42	44	36	31	27	21	17	18	17	11
Plat+Gem	63	53	43	36	27	22	15	16	11							

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

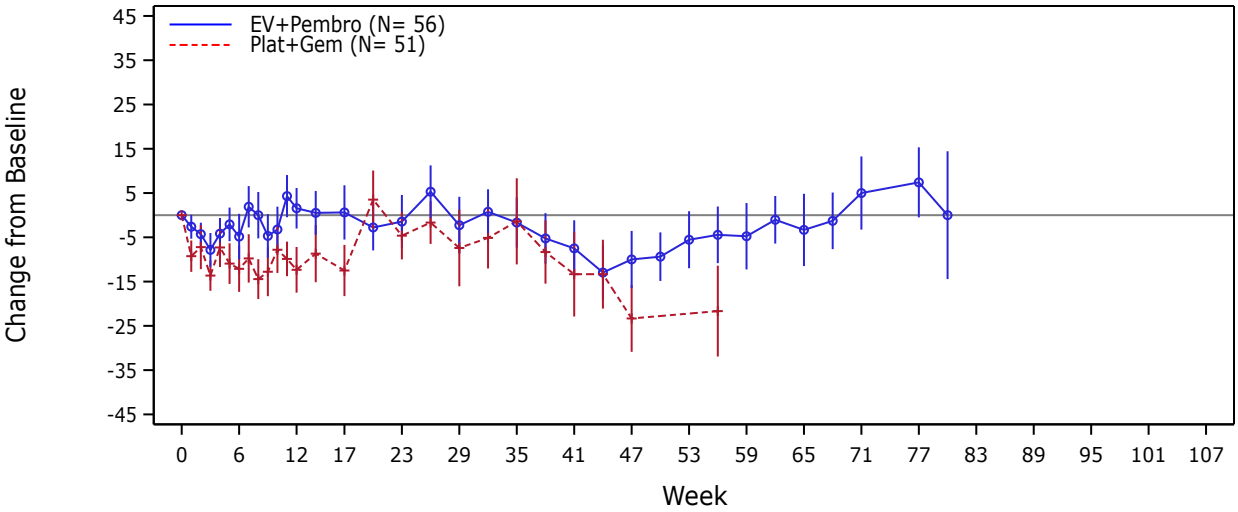
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.11.2.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Role Functioning by Sex - Analysis Set mITT 2

Sex: Female



Number of subjects

EV+Pembro	41	31	32	27	23	22	20	20	20	15	14	10	10	9
Plat+Gem	42	33	27	24	18	18	12	10	10					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

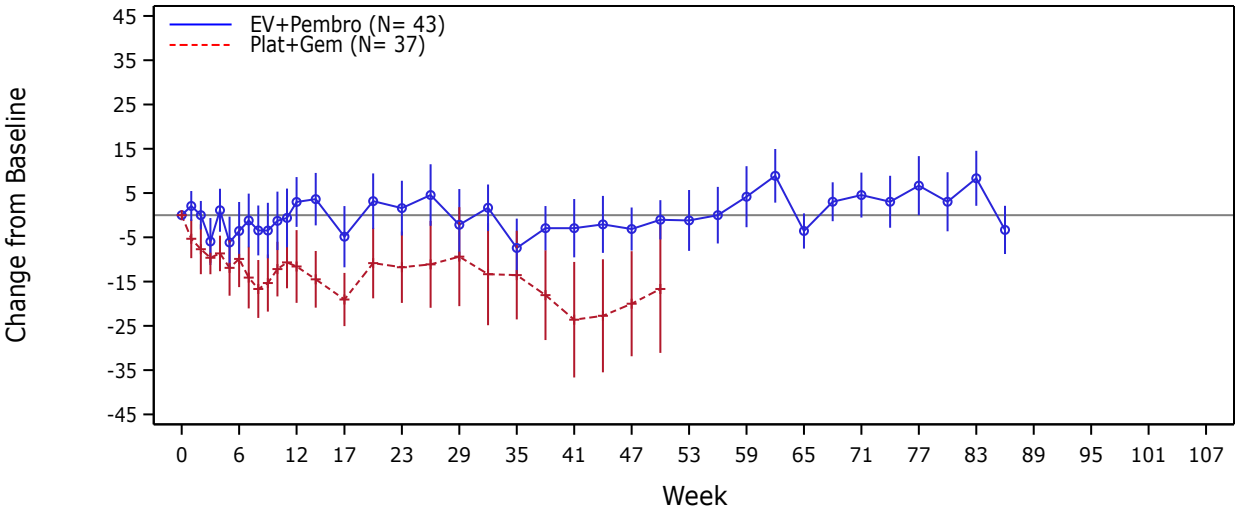
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.11.2.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Role Functioning by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Lymph node only



Number of subjects

EV+Pembro	33	28	28	24	21	23	18	17	16	14	16	14	11	10	10
Plat+Gem	29	27	23	21	17	16	16	12	10						

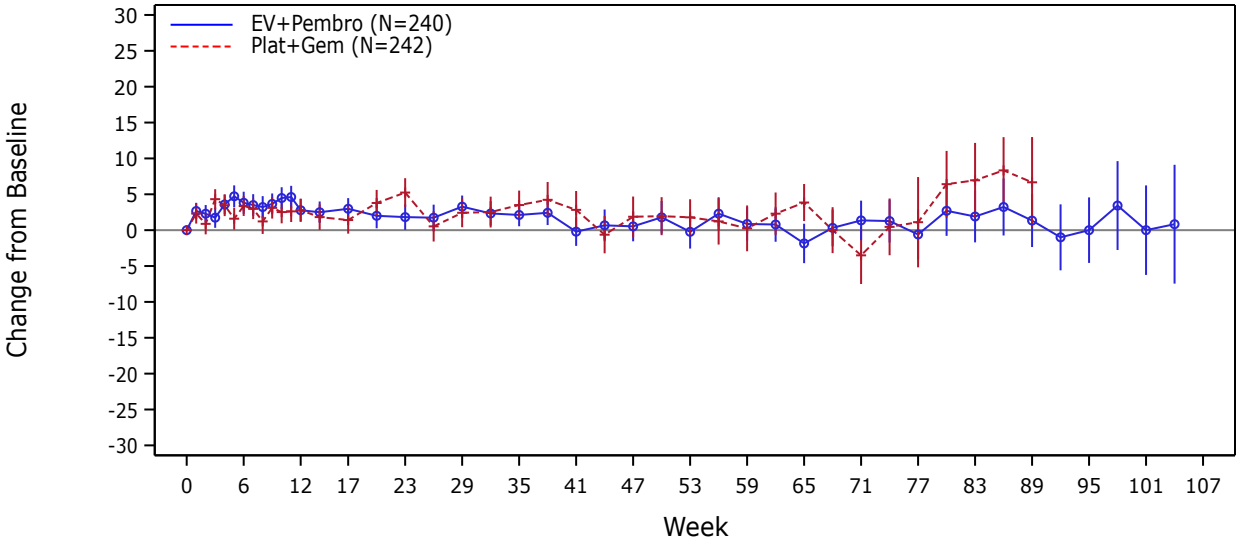
Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.12.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Emotional Functioning - Analysis Set mITT 1



Number of subjects

EV+Pembro	206	170	171	162	151	145	122	119	94	74	68	54	49	42	35	31	21	14
Plat+Gem	188	149	138	130	97	86	69	56	49	42	33	26	19	15	12	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

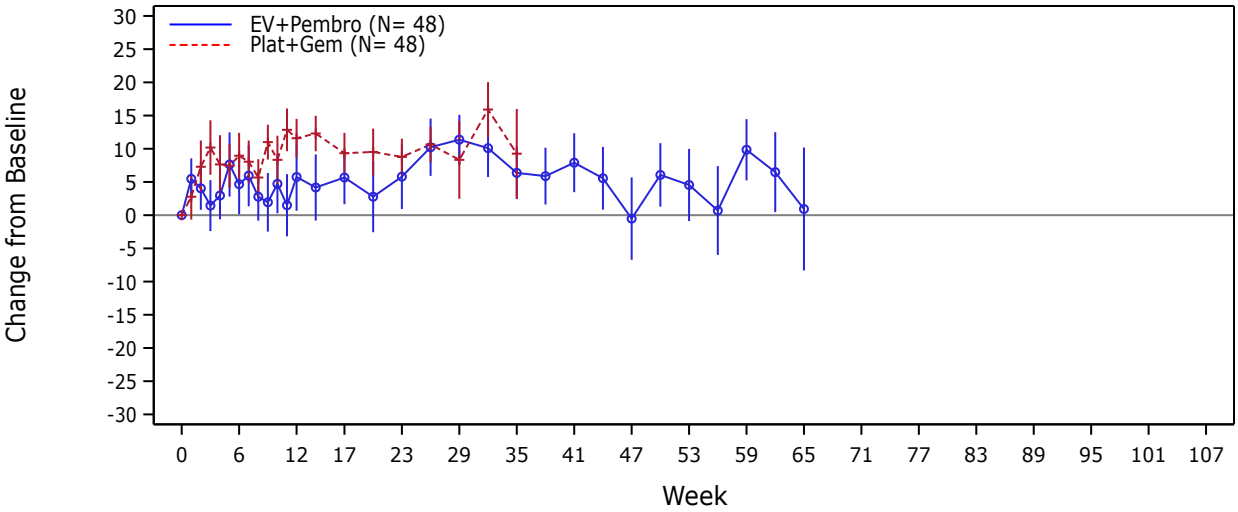
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.12.1.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Emotional Functioning by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Present



Number of subjects

EV+Pembro	39	25	29	25	23	22	17	19	16	11	11	9
Plat+Gem	33	27	23	25	19	14	9					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

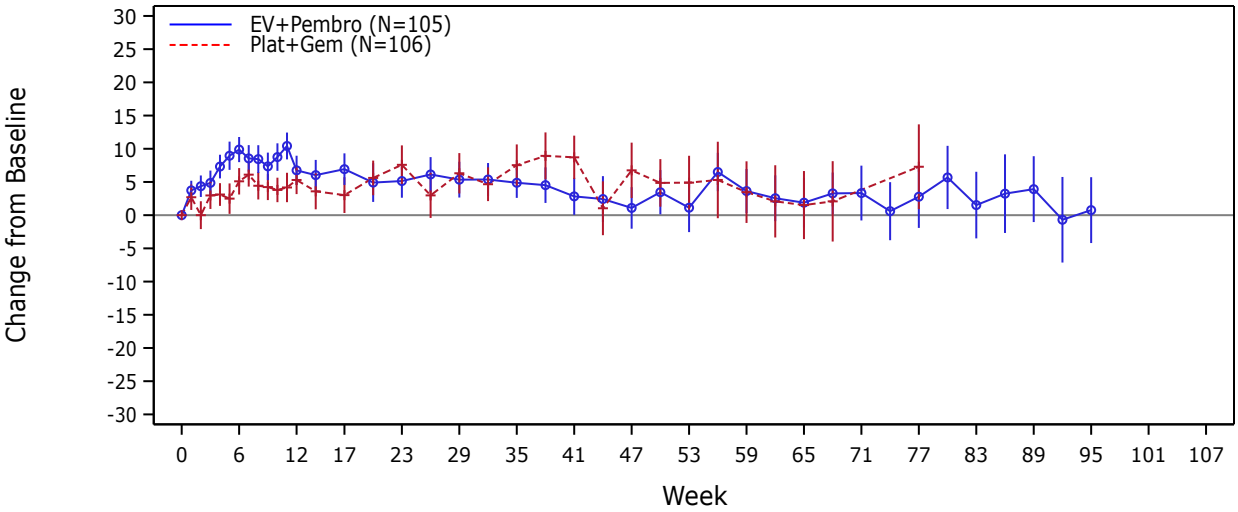
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.12.1.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Emotional Functioning by Age - Analysis Set mITT 1

Age: < 65 years



Number of subjects

EV+Pembro	92	81	79	77	73	67	58	59	46	37	39	31	30	24	22	17	11
Plat+Gem	83	67	66	58	44	37	31	22	21	17	12	11		8			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

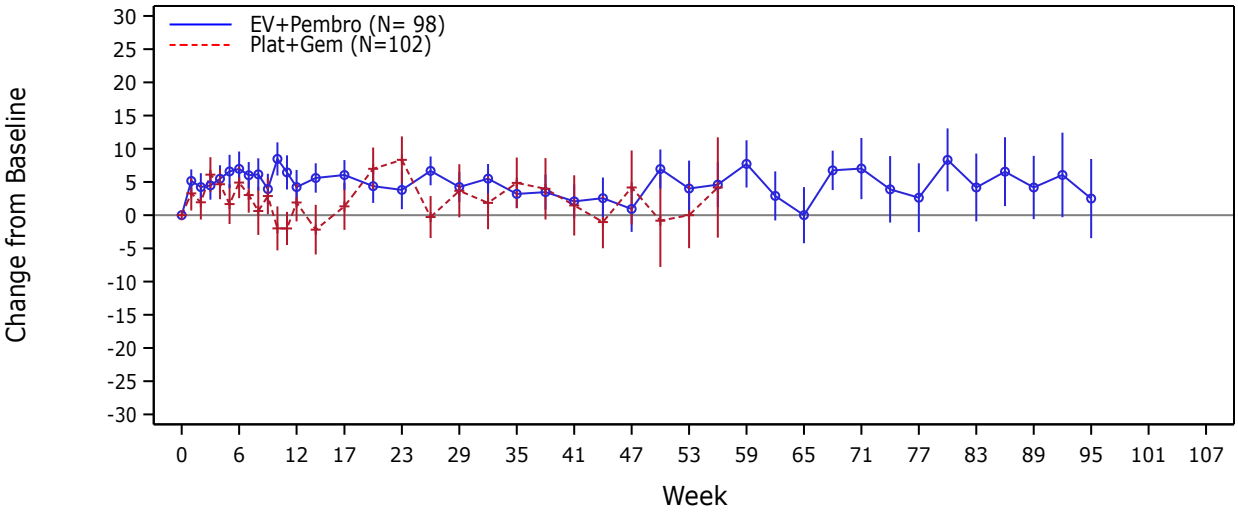
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.12.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Emotional Functioning by Region - Analysis Set mITT 1

Region: Europe



Number of subjects

EV+Pembro	79	61	65	62	57	57	52	48	36	27	27	23	19	19	16	14	10
Plat+Gem	71	56	48	44	32	25	24	17	12	10							

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

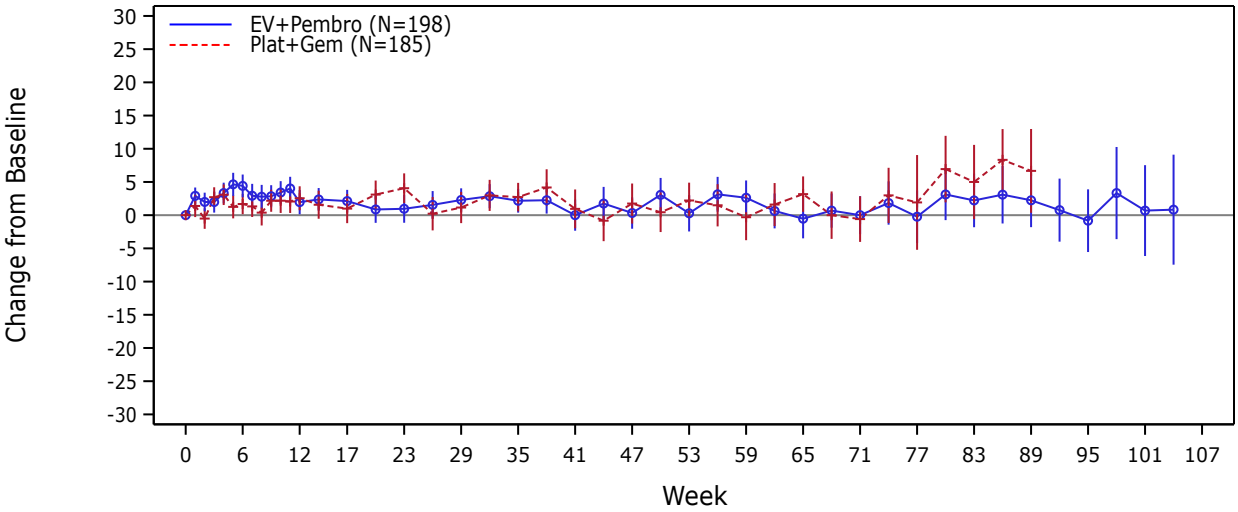
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.12.1.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Emotional Functioning by Sex - Analysis Set mITT 1

Sex: Male



Number of subjects

EV+Pembro	170	138	140	130	122	120	100	94	75	59	54	47	45	36	30	26	20	12
Plat+Gem	146	114	108	101	78	65	52	44	38	34	27	21	14	13	10	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

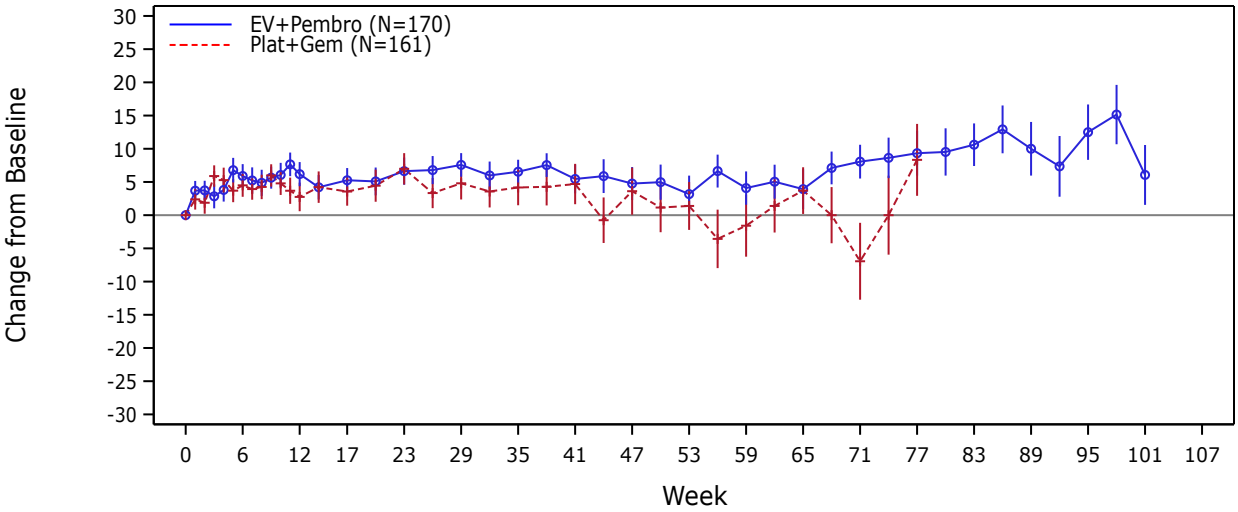
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.12.1.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Emotional Functioning by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Visceral metastases



Number of subjects

EV+Pembro	146	113	120	111	103	98	79	81	63	50	47	34	30	25	22	20	12	11
Plat+Gem	129	102	91	89	68	59	44	32	30	24	21	18	12	10				

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

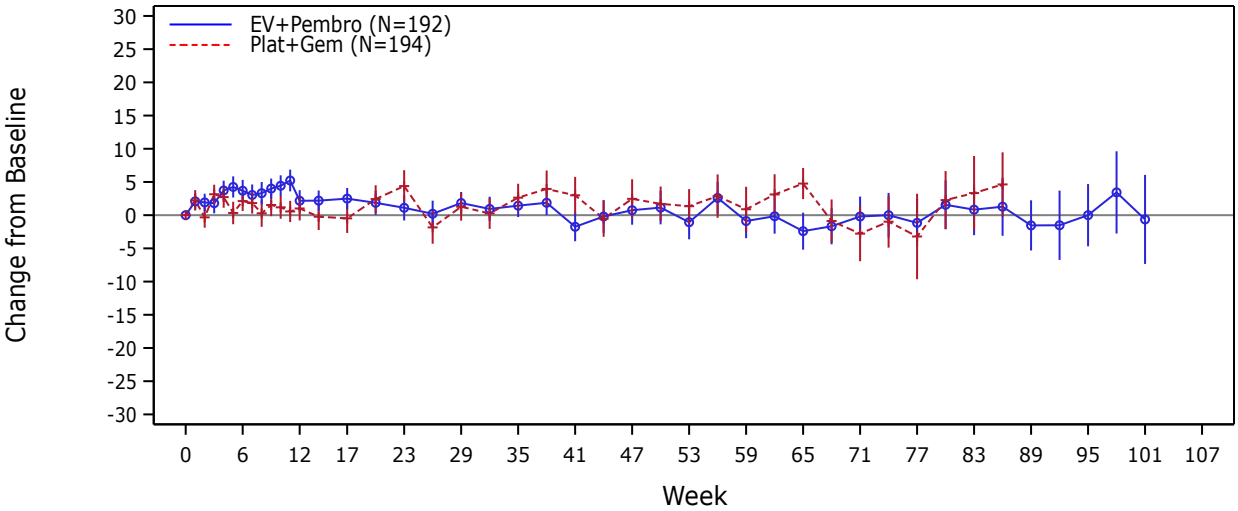
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.12.1.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Emotional Functioning by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Absent



Number of subjects

EV+Pembro	167	145	142	137	128	123	105	100	78	63	57	45	42	36	30	27	19	13
Plat+Gem	155	122	115	105	78	72	60	53	44	37	28	21	18	13	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

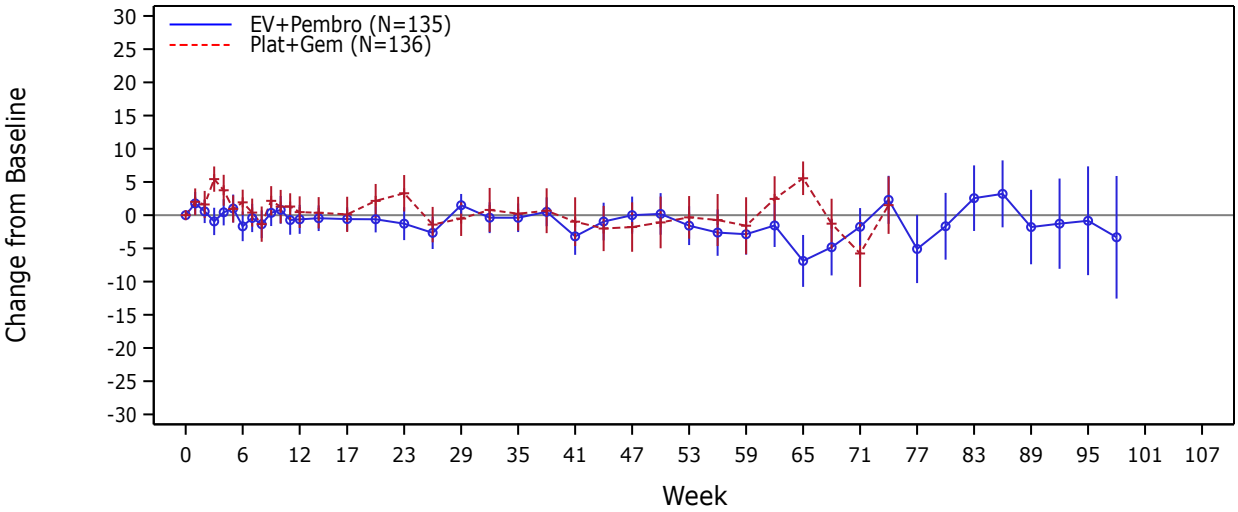
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.12.1.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Emotional Functioning by Age - Analysis Set mITT 1

Age: >= 65 years



Number of subjects

EV+Pembro	114	89	92	85	78	78	64	60	48	37	29	23	19	18	13	14	10
Plat+Gem	105	82	72	72	53	49	38	34	28	25	21	15	13				

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

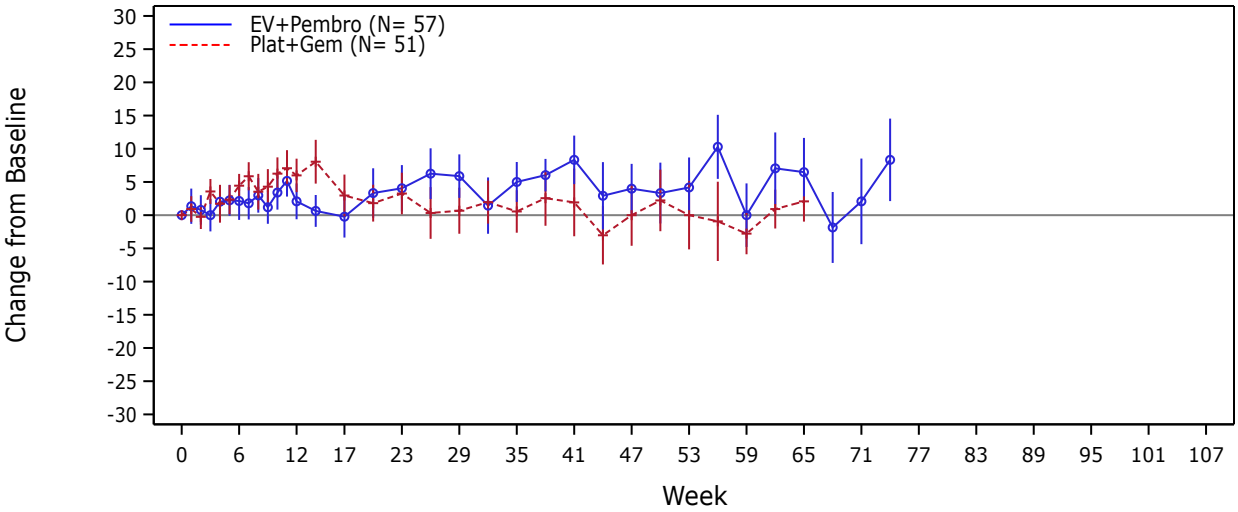
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.12.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Emotional Functioning by Region - Analysis Set mITT 1

Region: North America



Number of subjects

EV+Pembro	47	39	40	37	35	34	30	24	23	14	14	9	8
Plat+Gem	42	30	32	31	23	25	15	13	9	11	9	8	

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

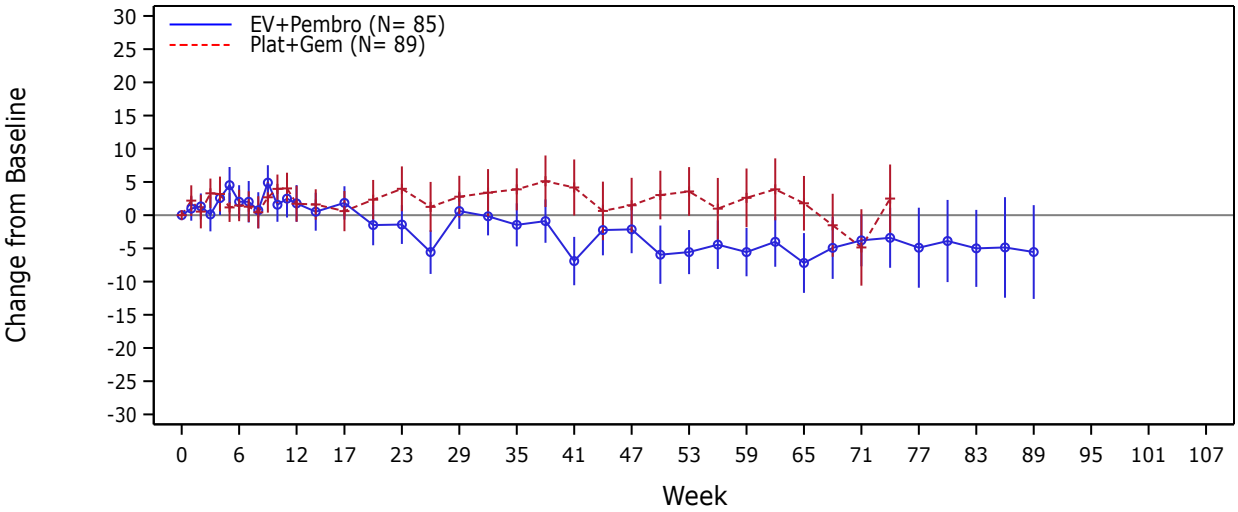
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.12.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Emotional Functioning by Region - Analysis Set mITT 1

Region: Rest of World



Number of subjects

EV+Pembro	80	70	66	63	59	54	40	47	35	33	27	22	22	17	15	12
Plat+Gem	75	63	58	55	42	36	30	26	28	21	16	14	12			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

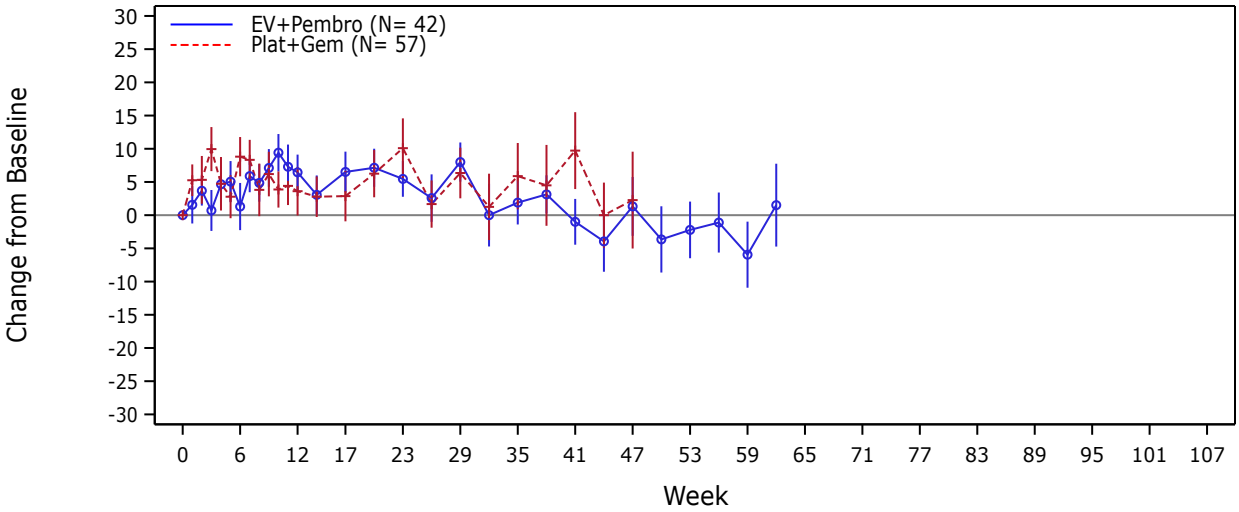
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.12.1.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Emotional Functioning by Sex - Analysis Set mITT 1

Sex: Female



Number of subjects

EV+Pembro	36	32	31	32	29	25	22	25	19	15	14
Plat+Gem	42	35	30	29	19	21	17	12	11		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

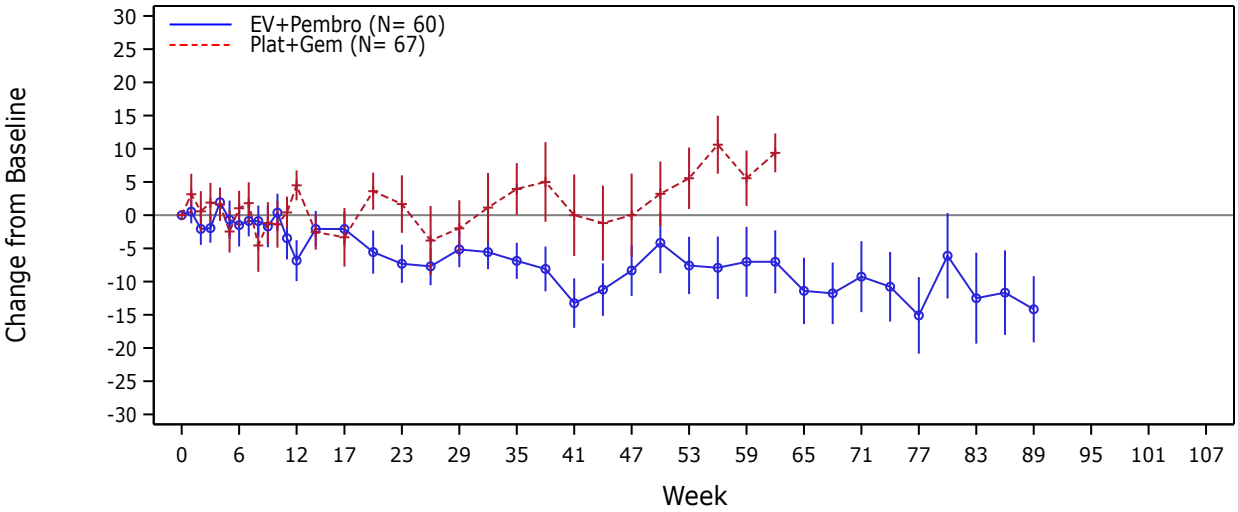
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.12.1.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Emotional Functioning by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Lymph node only



Number of subjects

EV+Pembro	53	50	45	44	41	42	40	34	27	22	19	19	18	16	12	10
Plat+Gem	49	40	39	35	25	21	19	18	13	12	9					

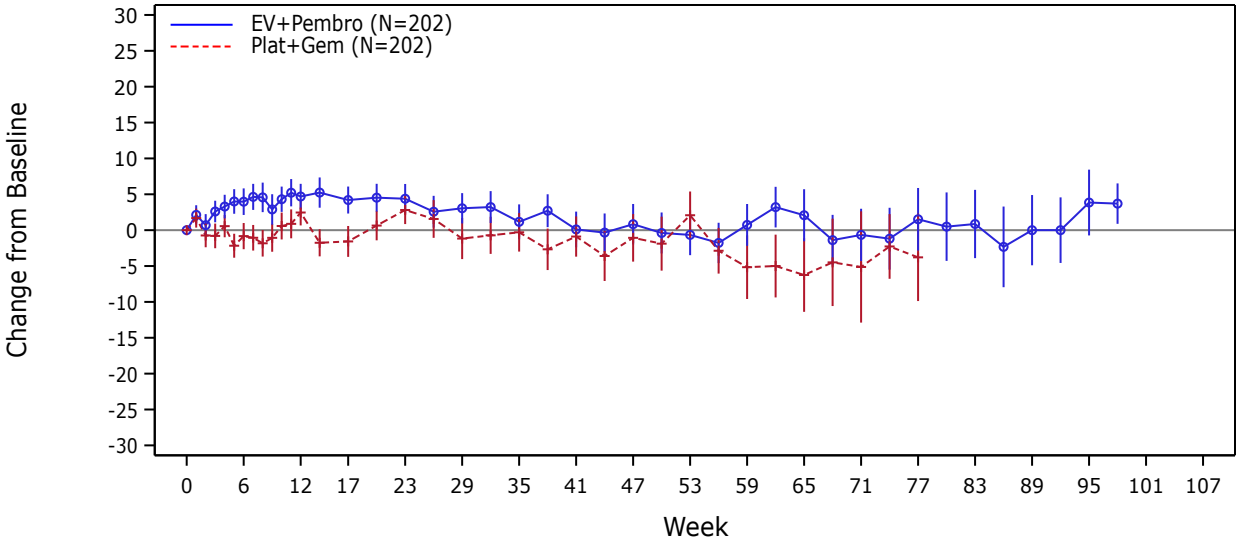
Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.12.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Emotional Functioning - Analysis Set mITT 2



Number of subjects

EV+Pembro	160	124	119	111	97	93	86	84	70	63	57	40	38	33	29	19	13
Plat+Gem	165	131	115	106	80	71	56	47	39	28	21	16	13	11			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

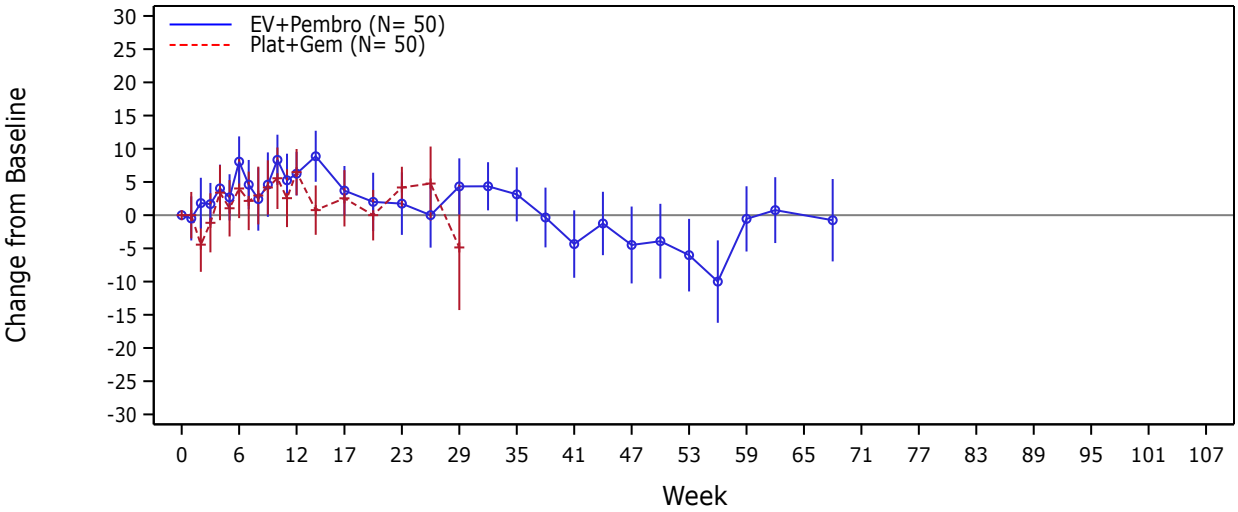
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.12.2.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Emotional Functioning by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Present



Number of subjects

EV+Pembro	40	30	28	27	24	25	24	23	13	18	15
Plat+Gem	40	29	27	23	14	12					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

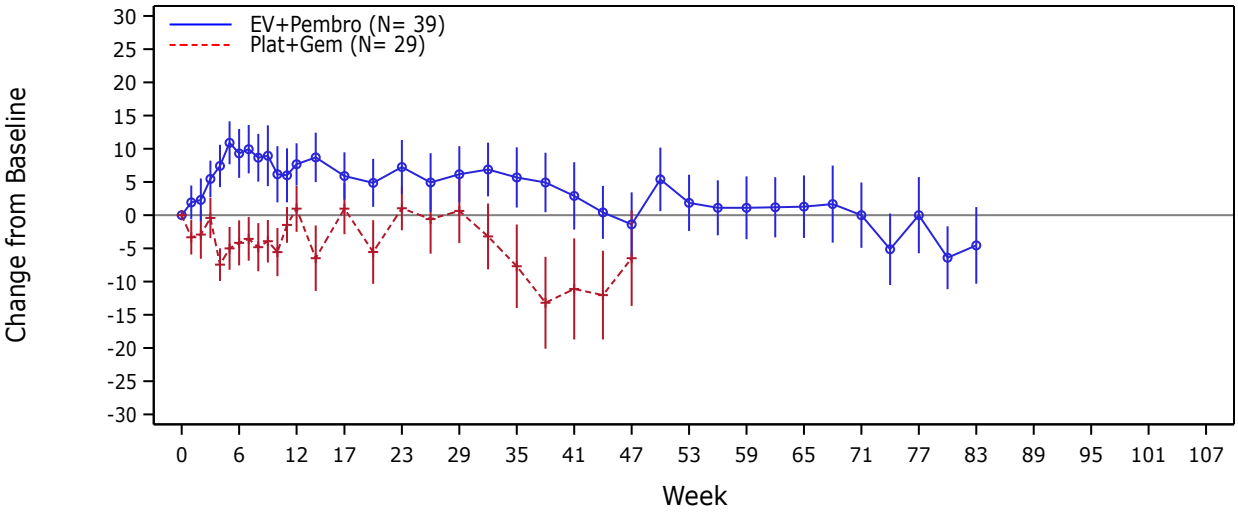
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.12.2.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Emotional Functioning by Age - Analysis Set mITT 2

Age: < 65 years



Number of subjects

EV+Pembro	32	26	25	24	23	23	22	23	18	18	15	13	12	13	11
Plat+Gem	22	18	17	17	16	13	13	9	9						

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

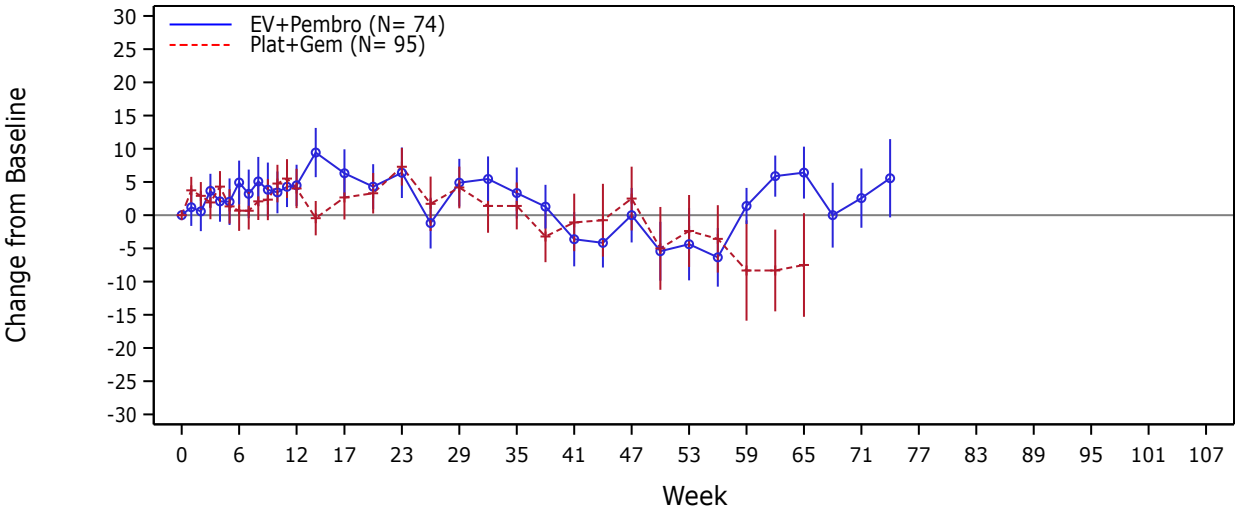
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.12.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Emotional Functioning by Region - Analysis Set mITT 2

Region: Europe



Number of subjects

EV+Pembro	53	39	39	33	30	29	25	23	21	21	18	13	13
Plat+Gem	75	61	56	53	40	36	30	23	20	14	10	10	

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

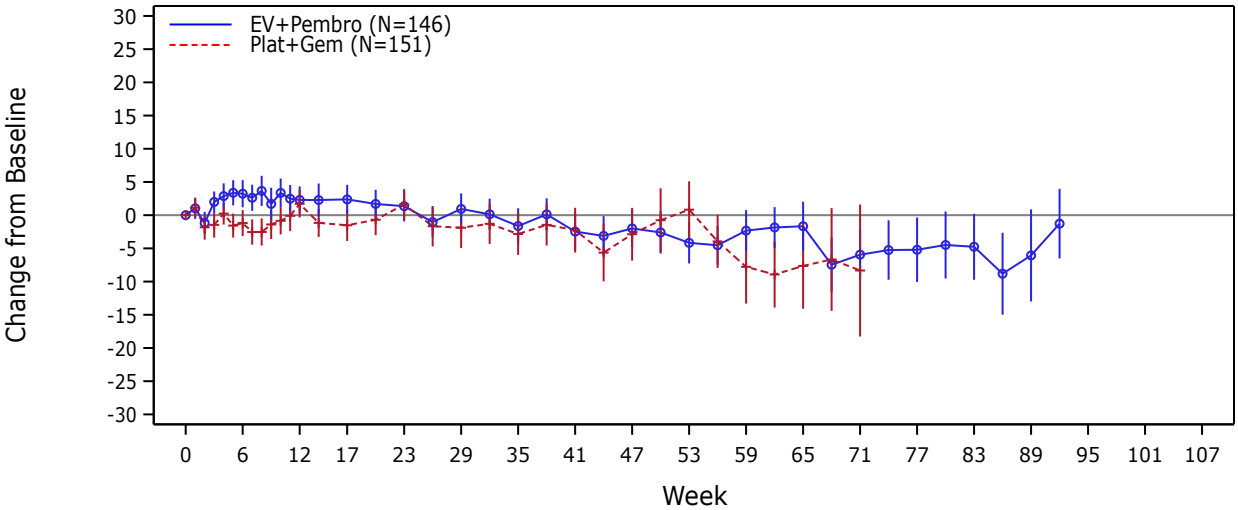
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.12.2.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Emotional Functioning by Sex - Analysis Set mITT 2

Sex: Male



Number of subjects

EV+Pembro	119	93	87	84	74	71	66	64	50	48	43	30	28	24	21	11
Plat+Gem	123	98	88	82	62	53	44	37	29	20	15	12	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

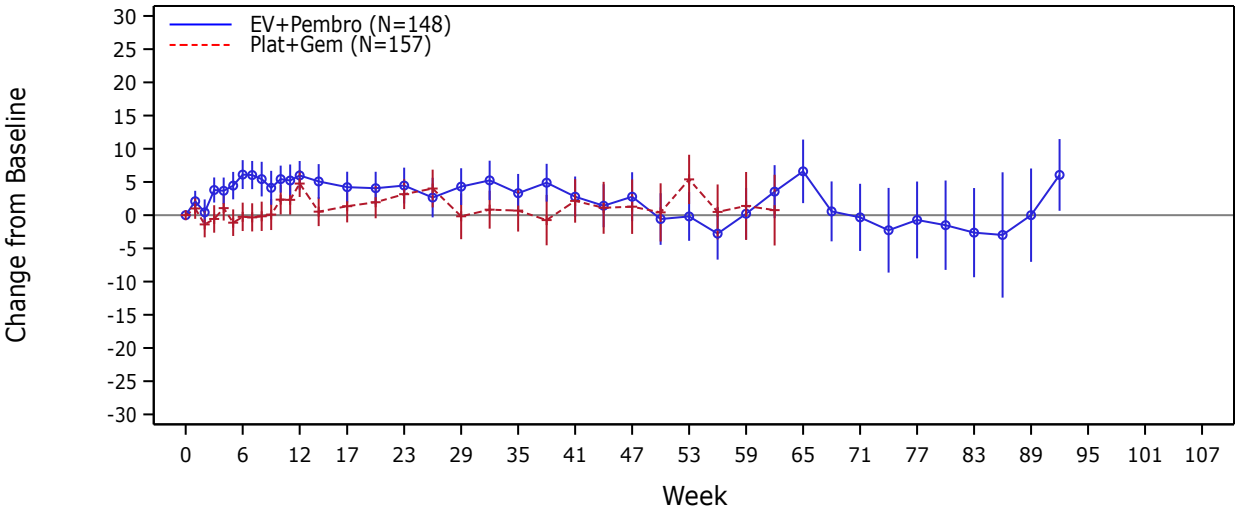
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.12.2.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Emotional Functioning by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Visceral metastases



Number of subjects

EV+Pembro	119	90	85	81	71	64	63	60	48	44	38	24	25	23	19	10
Plat+Gem	128	98	84	80	58	50	36	31	26	17	12					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

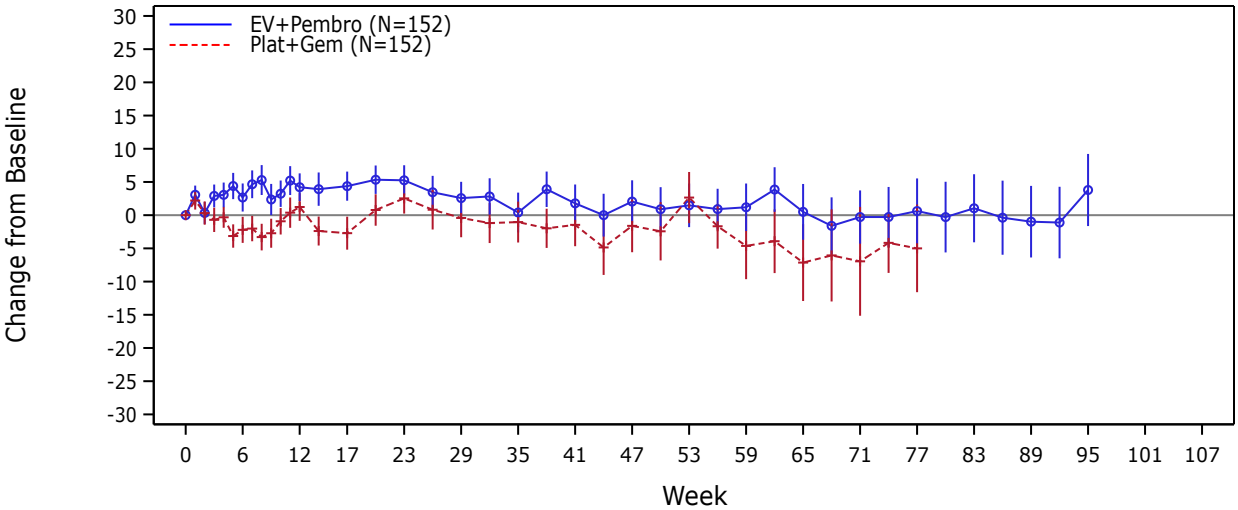
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.12.2.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Emotional Functioning by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Absent



Number of subjects

EV+Pembro	120	94	91	84	73	68	62	61	57	45	42	33	30	27	24	17	11
Plat+Gem	125	102	88	83	66	59	48	40	31	22	18	14	12	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

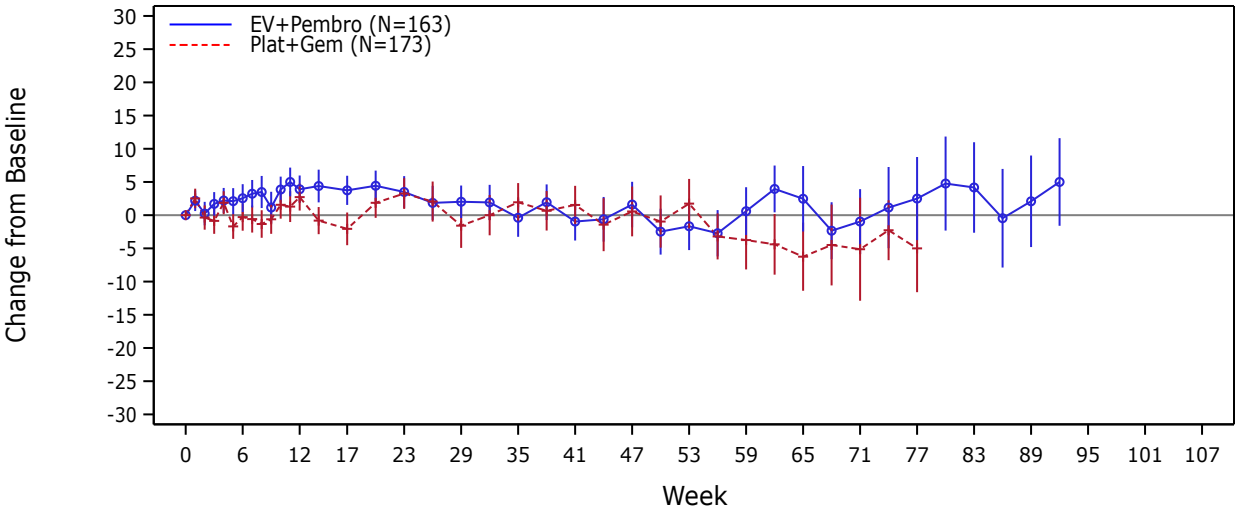
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.12.2.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Emotional Functioning by Age - Analysis Set mITT 2

Age: >= 65 years



Number of subjects

EV+Pembro	128	98	94	87	74	70	64	61	52	45	42	27	26	20	18	12
Plat+Gem	143	113	98	89	64	58	43	38	30	24	20	16	13	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

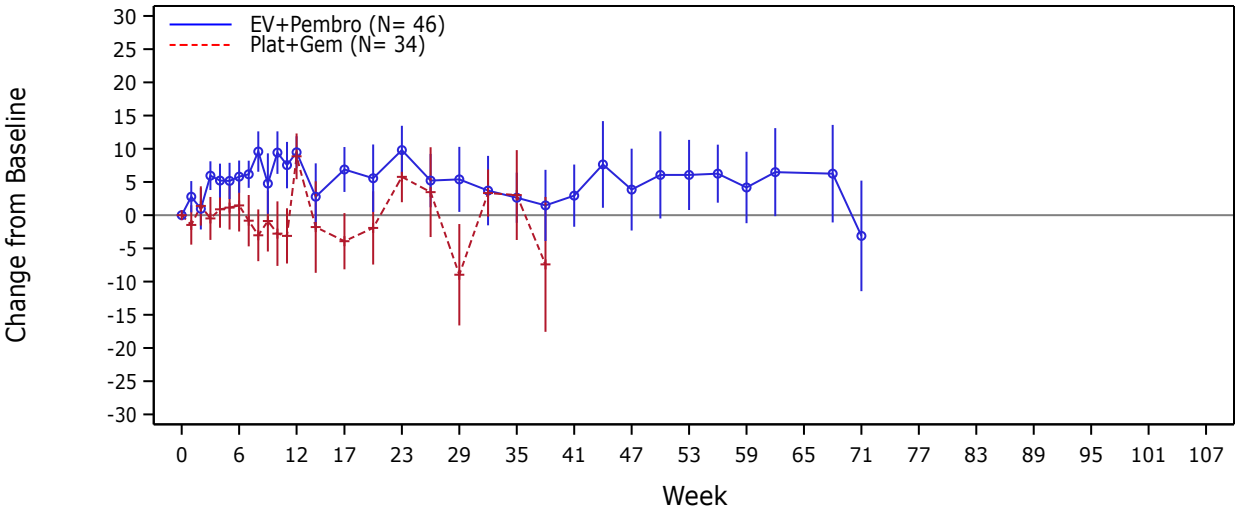
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.12.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Emotional Functioning by Region - Analysis Set mITT 2

Region: North America



Number of subjects

EV+Pembro	33	23	22	23	17	17	19	17	13	11	12	8
Plat+Gem	27	17	16	17	13	13	11					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

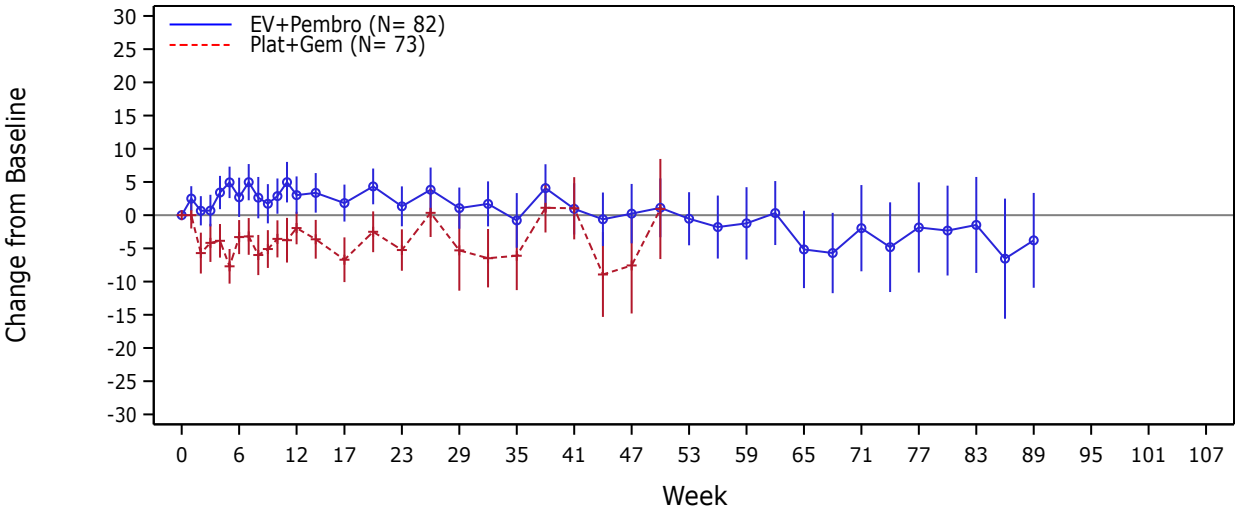
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.12.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Emotional Functioning by Region - Analysis Set mITT 2

Region: Rest of World



Number of subjects

EV+Pembro	74	62	58	55	50	47	42	44	36	31	27	21	17	18	17	11
Plat+Gem	63	53	43	36	27	22	15	16	11							

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

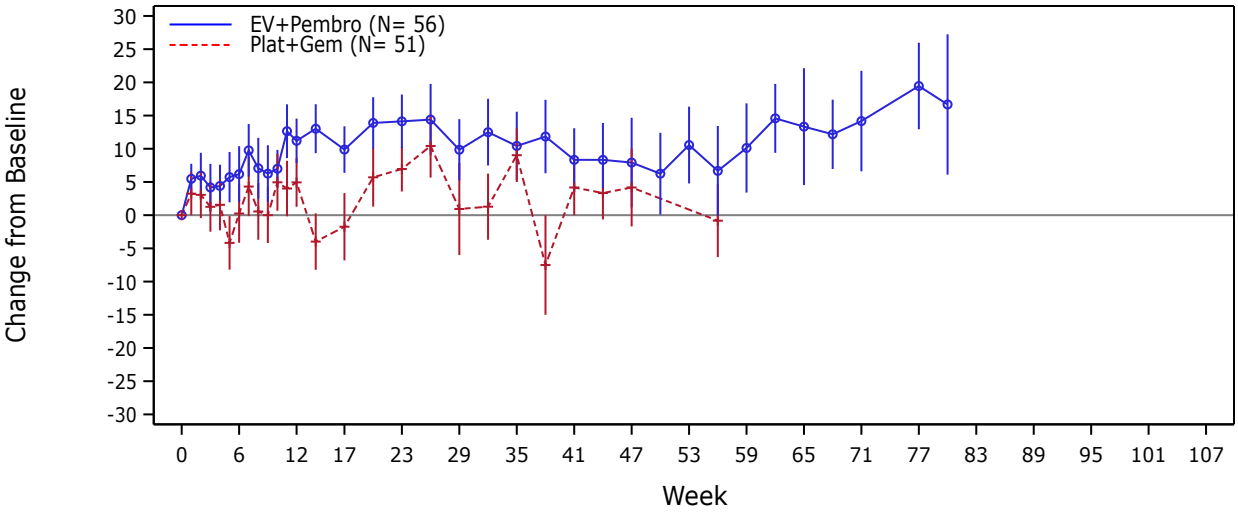
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.12.2.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Emotional Functioning by Sex - Analysis Set mITT 2

Sex: Female



Number of subjects

EV+Pembro	41	31	32	27	23	22	20	20	20	15	14	10	10	9
Plat+Gem	42	33	27	24	18	18	12	10	10					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

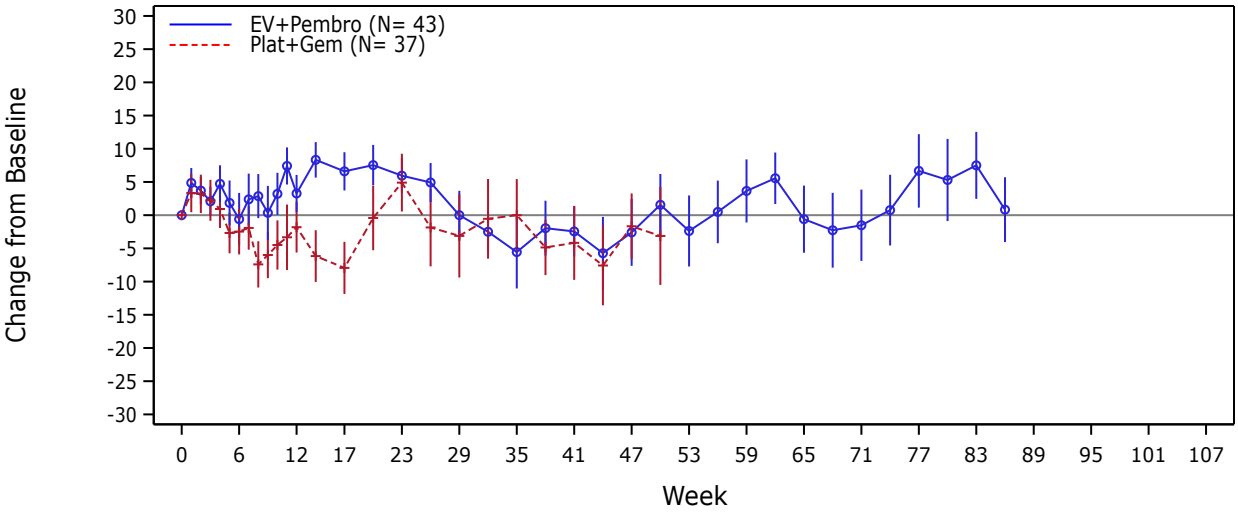
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.12.2.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Emotional Functioning by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Lymph node only



Number of subjects

EV+Pembro	33	28	28	24	21	23	18	17	16	14	16	14	11	10	10
Plat+Gem	29	27	23	21	17	16	16	12	10						

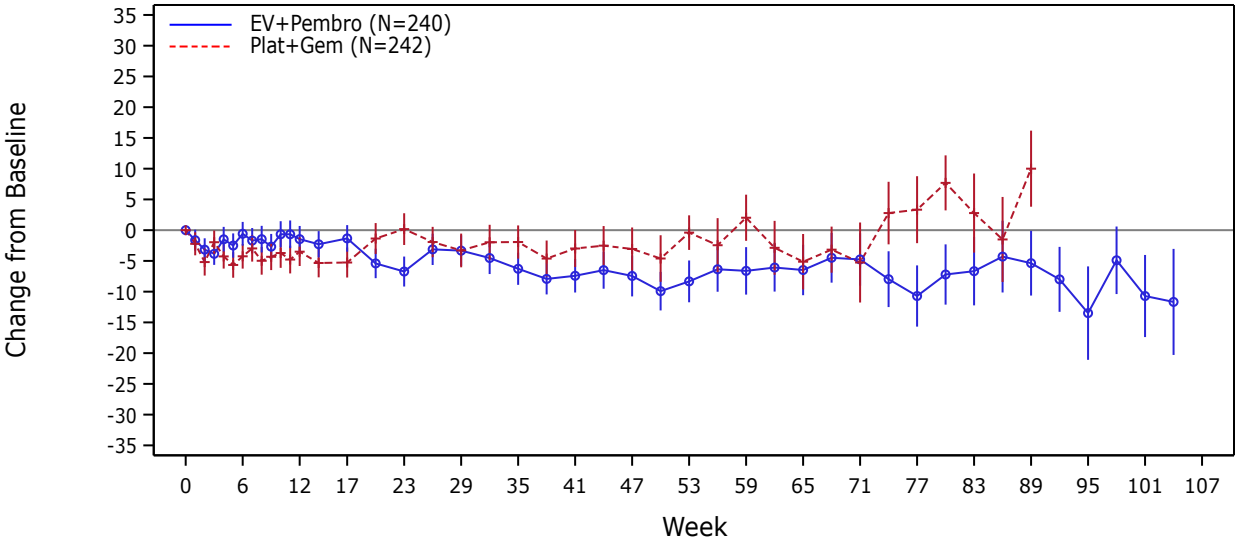
Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.13.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Social Functioning - Analysis Set mITT 1



Number of subjects

EV+Pembro	206	170	171	162	151	145	122	119	94	74	68	54	49	42	35	31	21	14
Plat+Gem	188	149	138	130	97	86	69	56	49	42	33	26	19	15	12	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

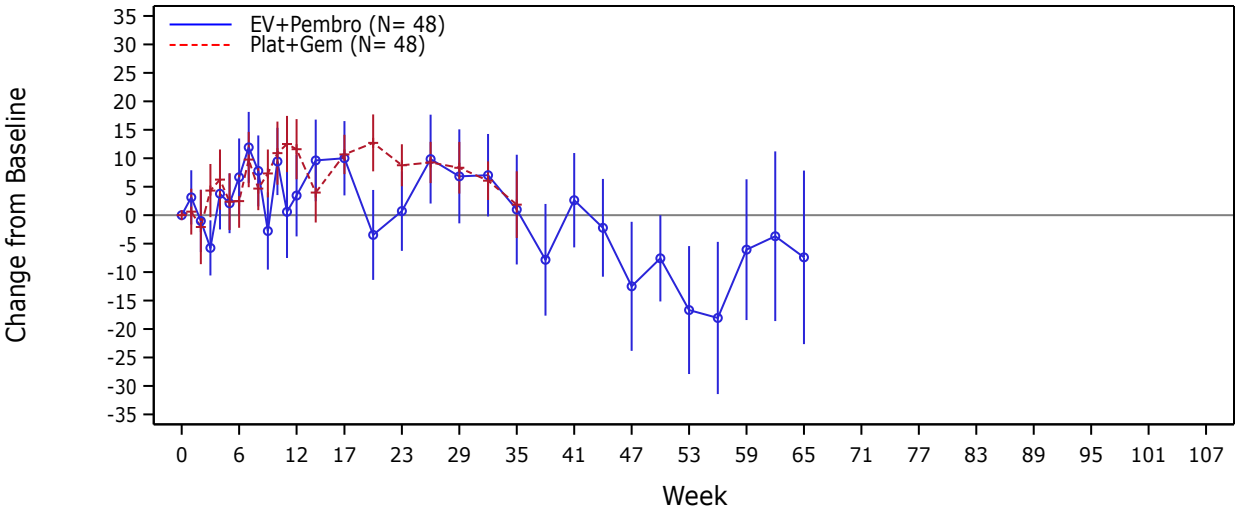
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.13.1.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Social Functioning by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Present



Number of subjects

EV+Pembro	39	25	29	25	23	22	17	19	16	11	11	9
Plat+Gem	33	27	23	25	19	14	9					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

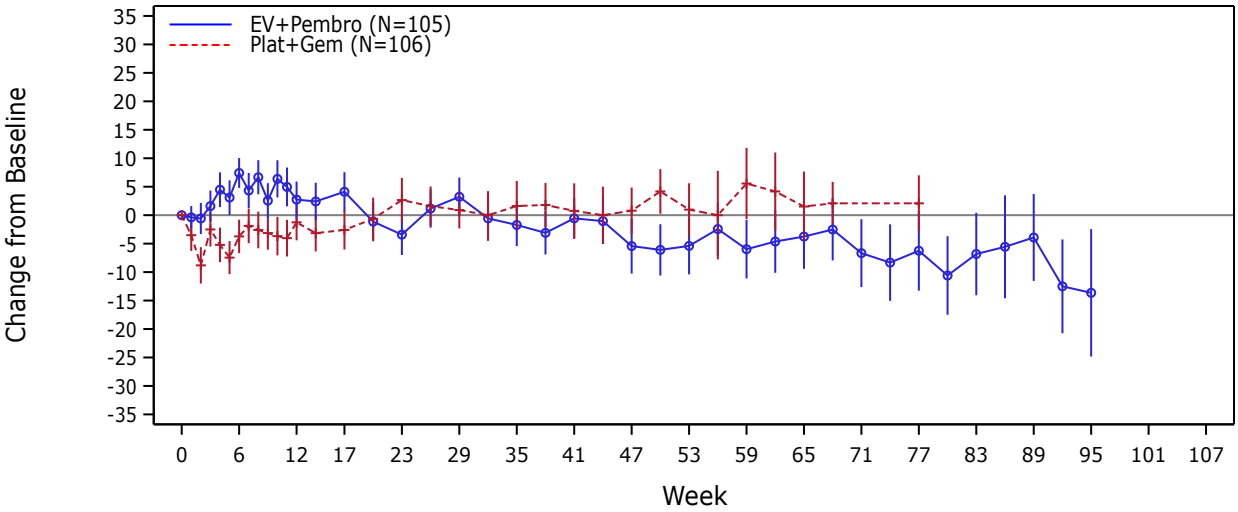
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.13.1.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Social Functioning by Age - Analysis Set mITT 1

Age: < 65 years



Number of subjects

EV+Pembro	92	81	79	77	73	67	58	59	46	37	39	31	30	24	22	17	11
Plat+Gem	83	67	66	58	44	37	31	22	21	17	12	11		8			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

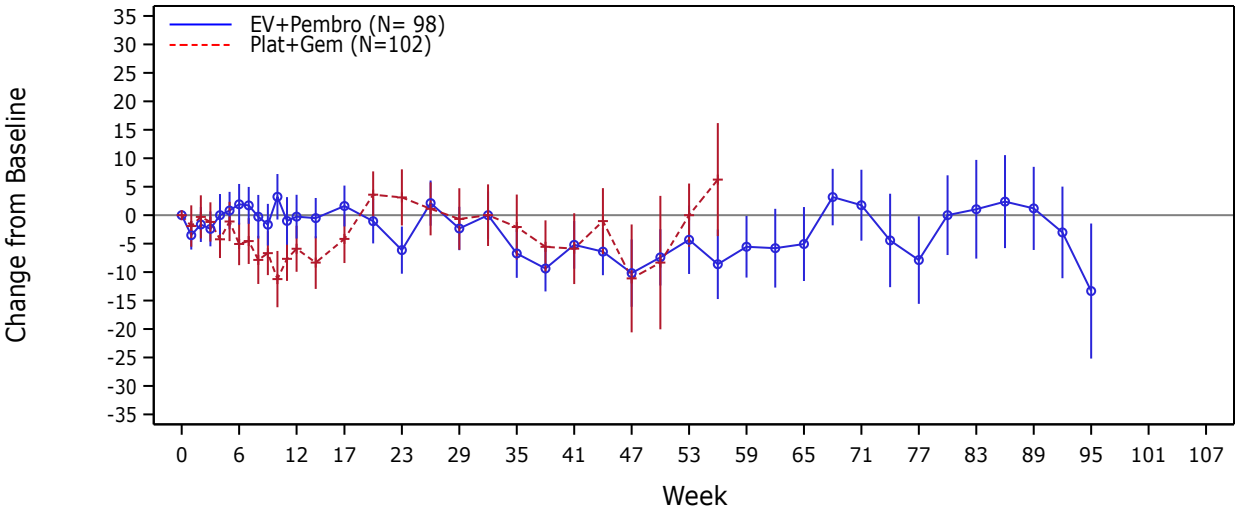
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.13.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Social Functioning by Region - Analysis Set mITT 1

Region: Europe



Number of subjects

EV+Pembro	79	61	65	62	57	57	52	48	36	27	27	23	19	19	16	14	10
Plat+Gem	71	56	48	44	32	25	24	17	12	10							

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

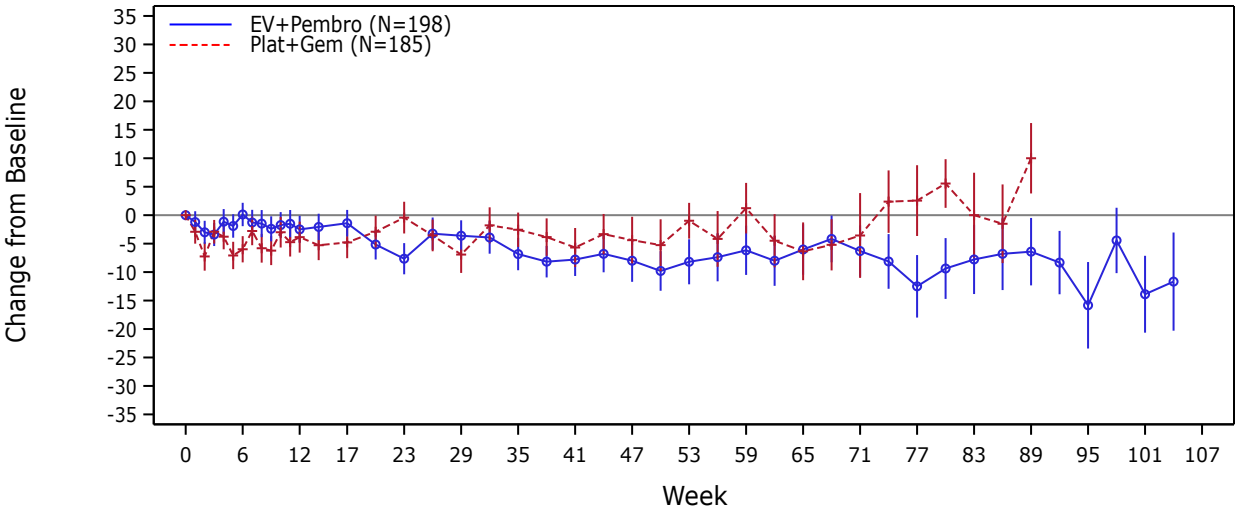
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.13.1.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Social Functioning by Sex - Analysis Set mITT 1

Sex: Male



Number of subjects

EV+Pembro	170	138	140	130	122	120	100	94	75	59	54	47	45	36	30	26	20	12
Plat+Gem	146	114	108	101	78	65	52	44	38	34	27	21	14	13	10	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

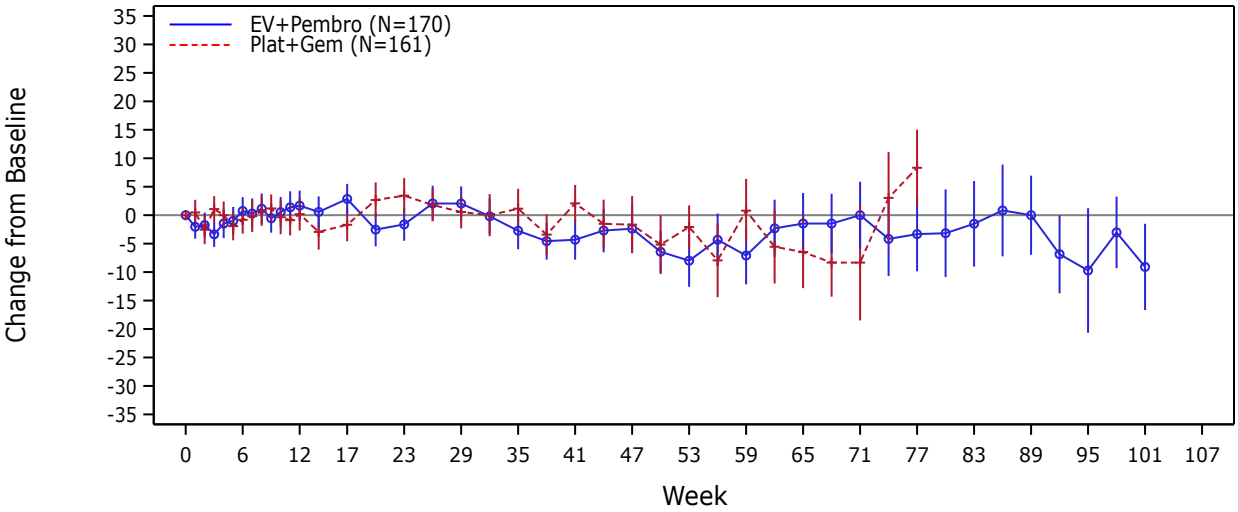
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.13.1.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Social Functioning by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Visceral metastases



Number of subjects

EV+Pembro	146	113	120	111	103	98	79	81	63	50	47	34	30	25	22	20	12	11
Plat+Gem	129	102	91	89	68	59	44	32	30	24	21	18	12	10				

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

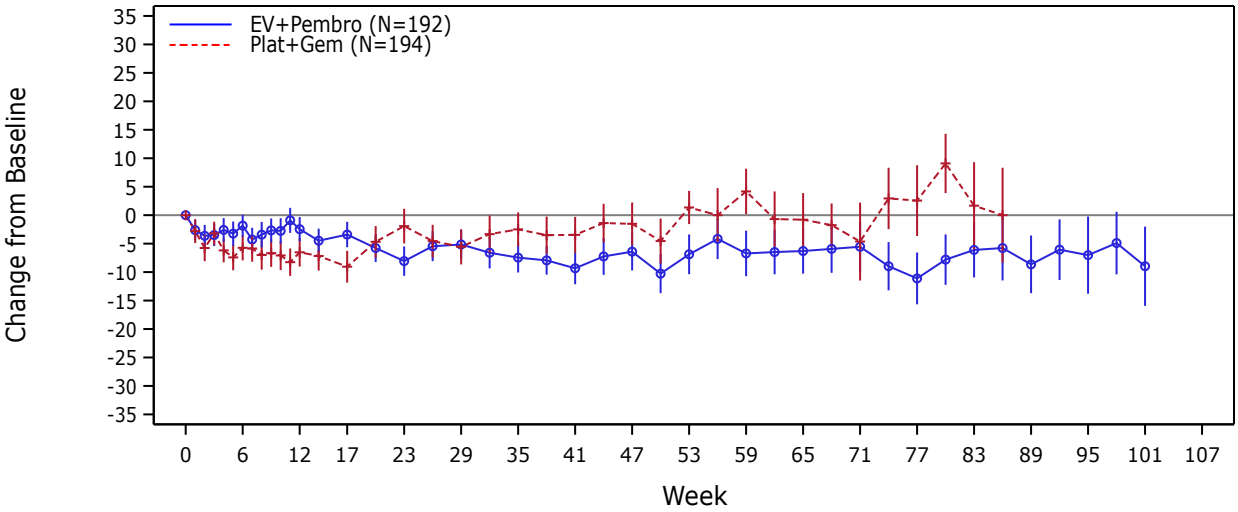
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.13.1.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Social Functioning by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Absent



Number of subjects

EV+Pembro	167	145	142	137	128	123	105	100	78	63	57	45	42	36	30	27	19	13
Plat+Gem	155	122	115	105	78	72	60	53	44	37	28	21	18	13	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

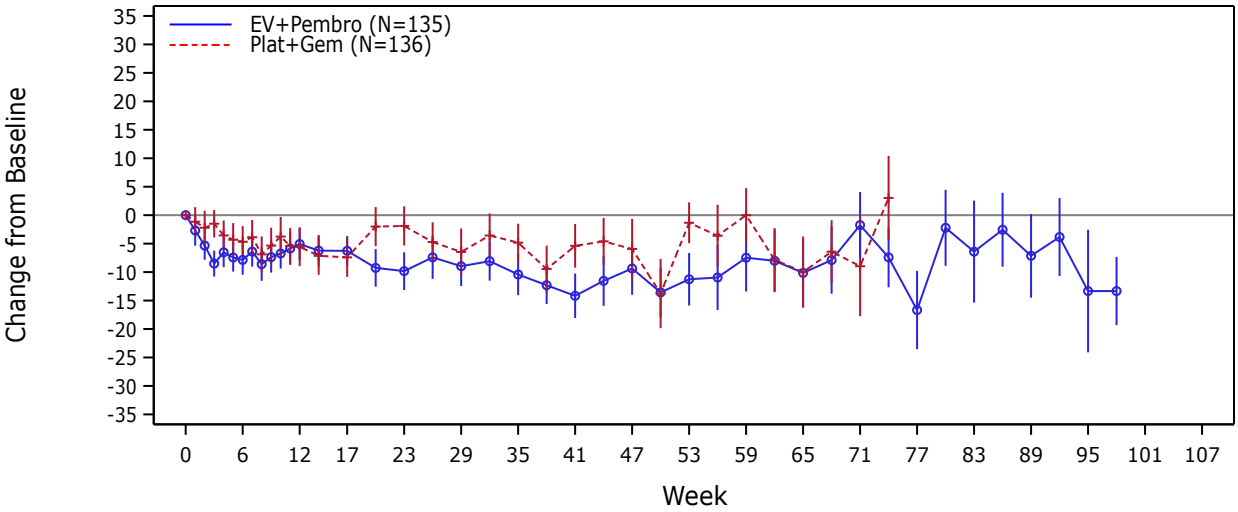
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.13.1.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Social Functioning by Age - Analysis Set mITT 1

Age: >= 65 years



Number of subjects

EV+Pembro	114	89	92	85	78	78	64	60	48	37	29	23	19	18	13	14	10
Plat+Gem	105	82	72	72	53	49	38	34	28	25	21	15	13				

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

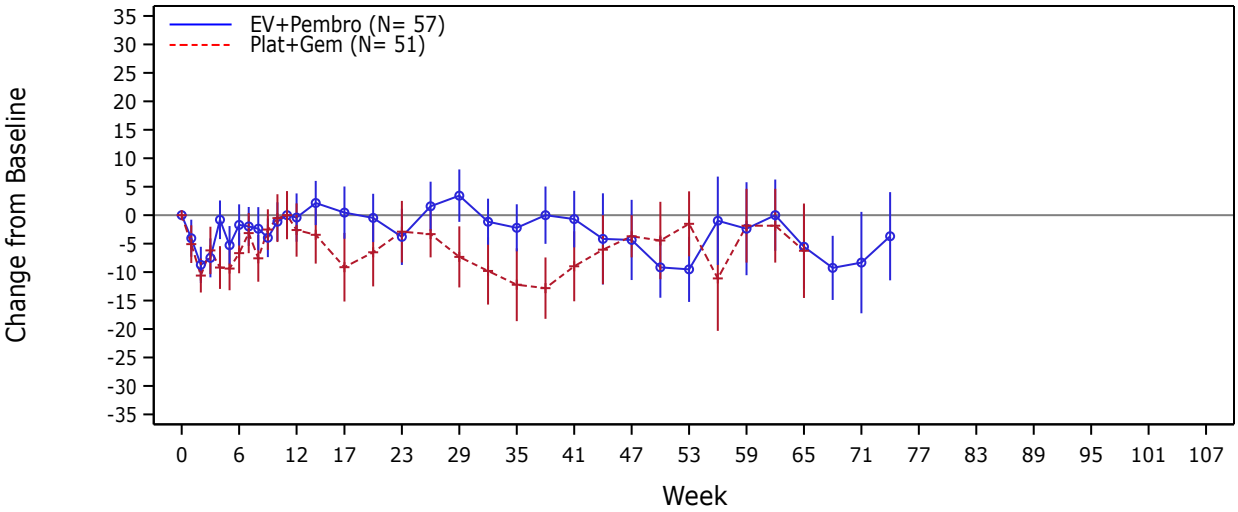
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.13.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Social Functioning by Region - Analysis Set mITT 1

Region: North America



Number of subjects

EV+Pembro	47	39	40	37	35	34	30	24	23	14	14	9	8
Plat+Gem	42	30	32	31	23	25	15	13	9	11	9	8	

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

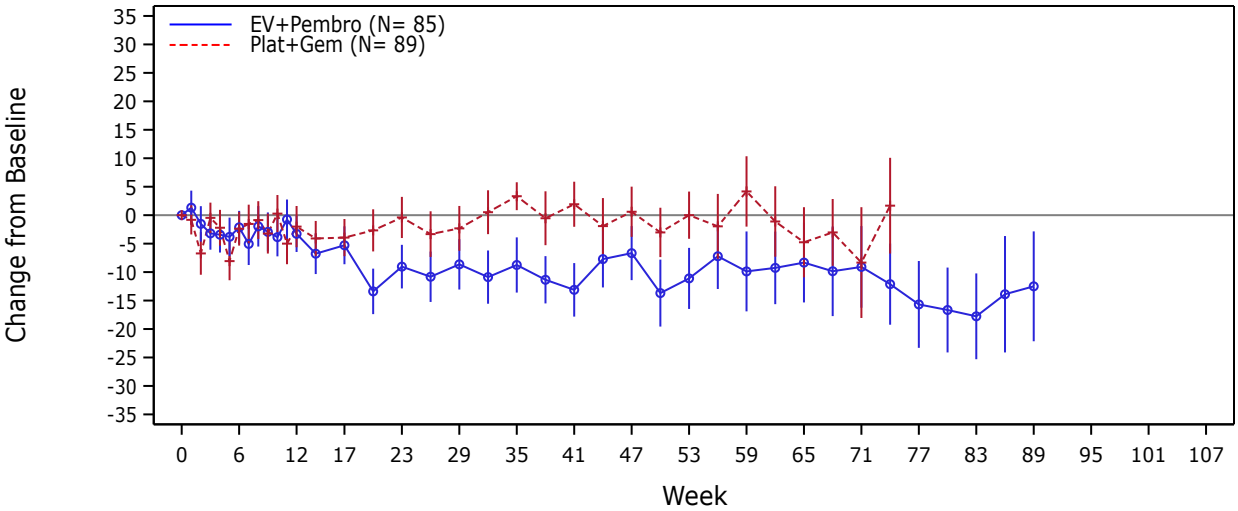
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.13.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Social Functioning by Region - Analysis Set mITT 1

Region: Rest of World



Number of subjects

EV+Pembro	80	70	66	63	59	54	40	47	35	33	27	22	22	17	15	12
Plat+Gem	75	63	58	55	42	36	30	26	28	21	16	14	12			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

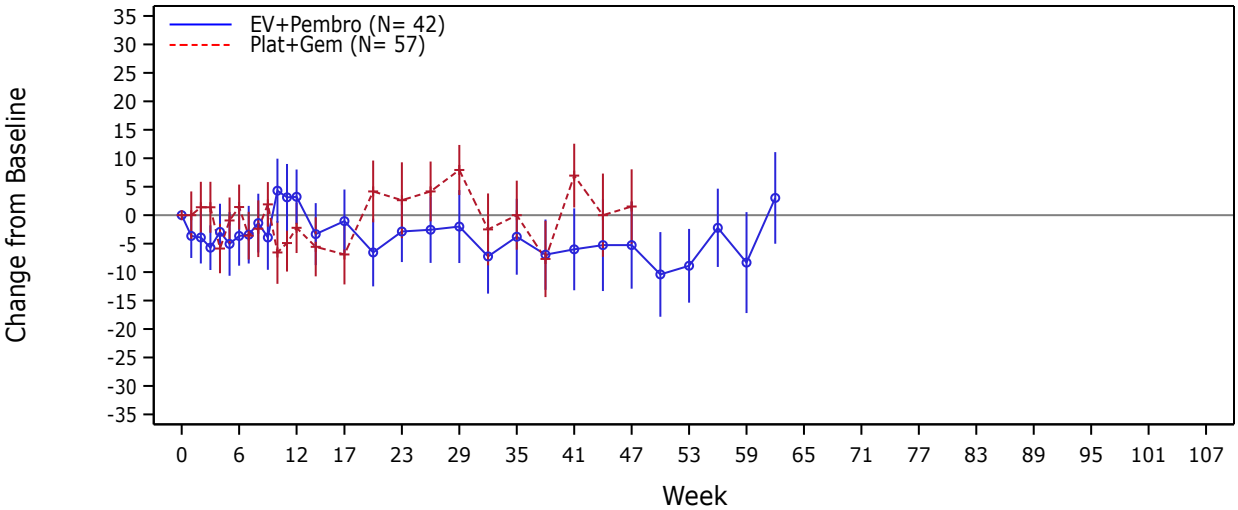
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.13.1.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Social Functioning by Sex - Analysis Set mITT 1

Sex: Female



Number of subjects

EV+Pembro	36	32	31	32	29	25	22	25	19	15	14
Plat+Gem	42	35	30	29	19	21	17	12	11		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

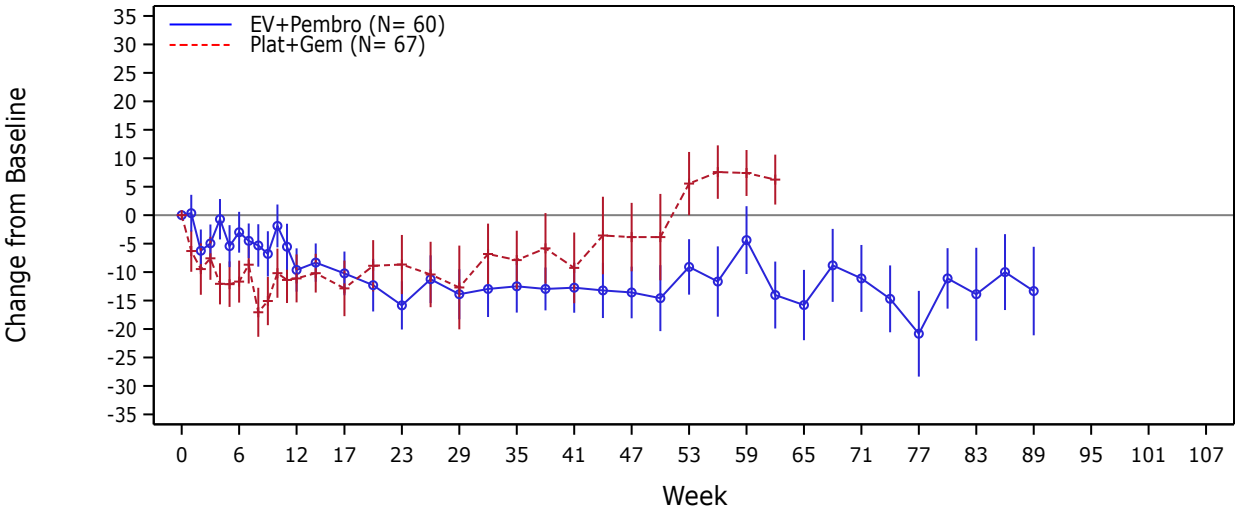
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.13.1.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Social Functioning by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Lymph node only



Number of subjects

EV+Pembro	53	50	45	44	41	42	40	34	27	22	19	19	18	16	12	10
Plat+Gem	49	40	39	35	25	21	19	18	13	12	9					

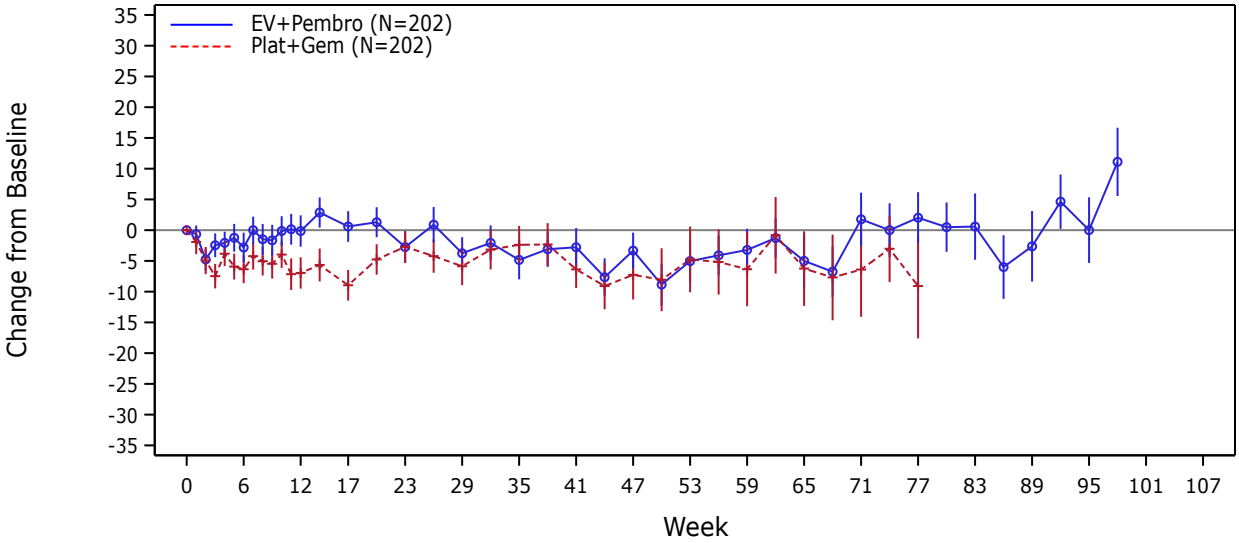
Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.13.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Social Functioning - Analysis Set mITT 2



Number of subjects

EV+Pembro	160	124	119	111	97	93	86	84	70	63	57	40	38	33	29	19	13
Plat+Gem	165	131	115	106	80	71	56	47	39	28	21	16	13	11			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

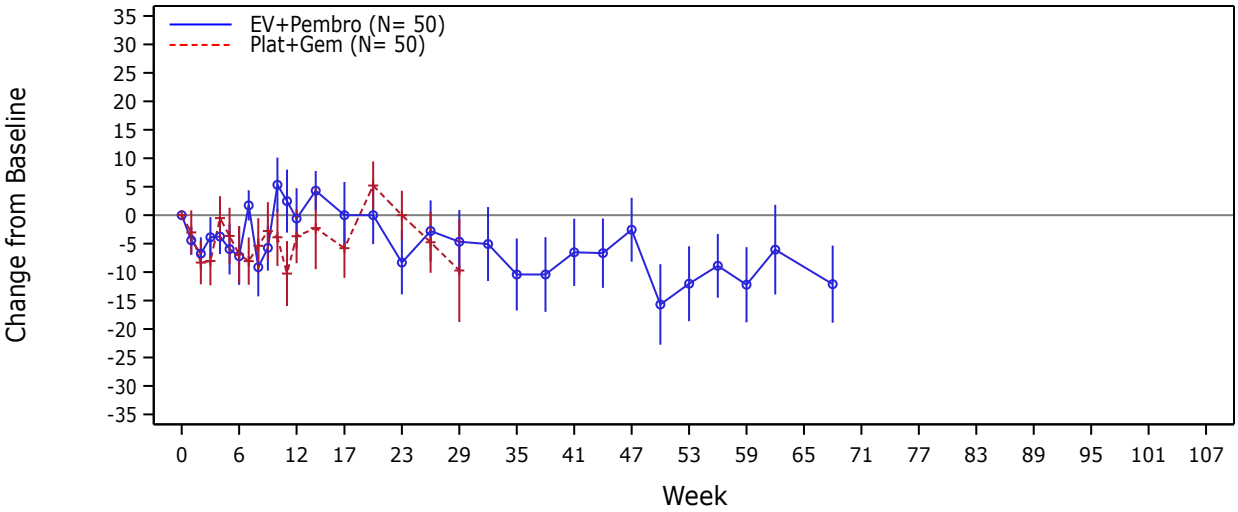
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.13.2.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Social Functioning by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Present



Number of subjects

EV+Pembro	40	30	28	27	24	25	24	23	13	18	15
Plat+Gem	40	29	27	23	14	12					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

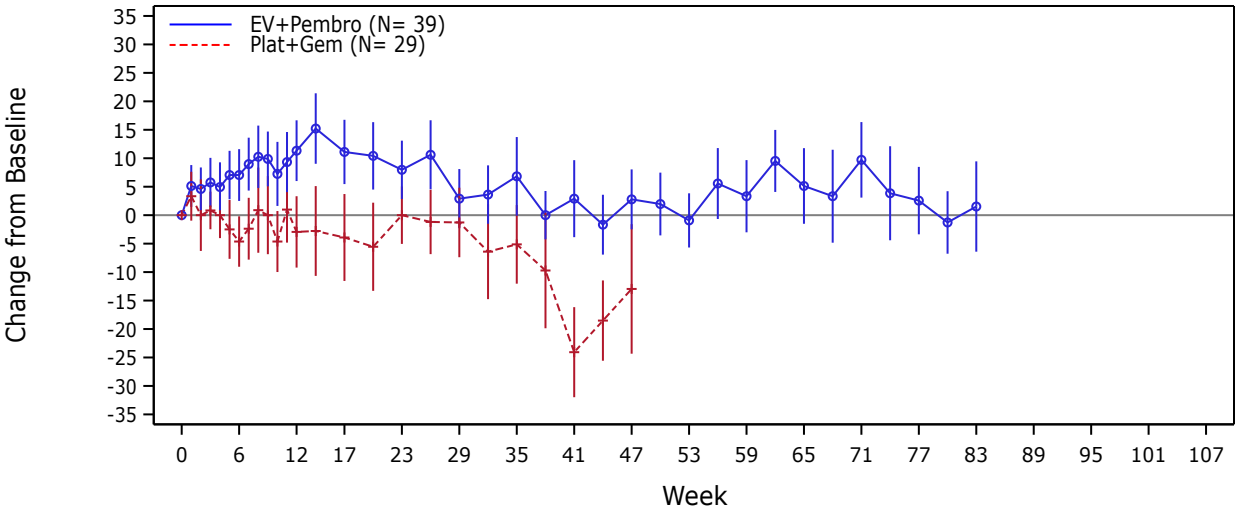
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.13.2.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Social Functioning by Age - Analysis Set mITT 2

Age: < 65 years



Number of subjects

EV+Pembro	32	26	25	24	23	23	22	23	18	18	15	13	12	13	11
Plat+Gem	22	18	17	17	16	13	13	9	9						

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

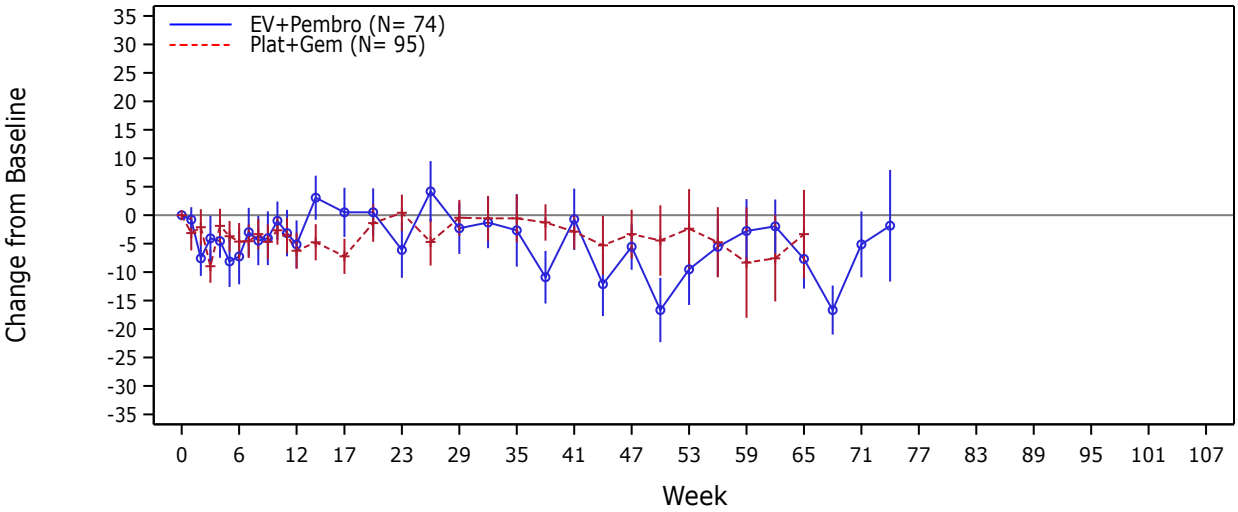
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.13.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Social Functioning by Region - Analysis Set mITT 2

Region: Europe



Number of subjects

EV+Pembro	53	39	39	33	30	29	25	23	21	21	18	13	13
Plat+Gem	75	61	56	53	40	36	30	23	20	14	10	10	

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

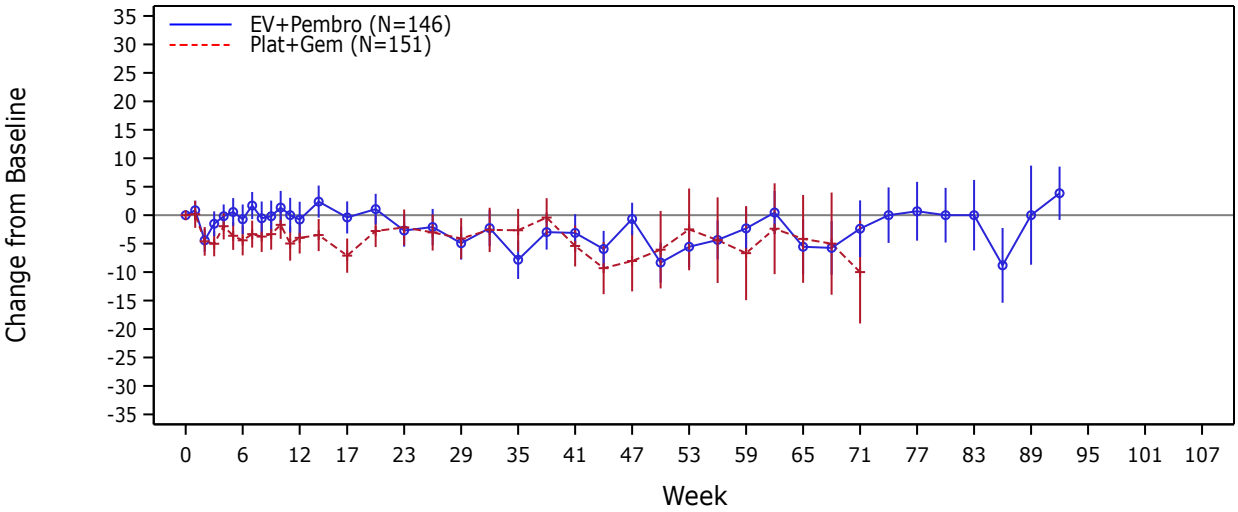
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.13.2.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Social Functioning by Sex - Analysis Set mITT 2

Sex: Male



Number of subjects

EV+Pembro	119	93	87	84	74	71	66	64	50	48	43	30	28	24	21	11
Plat+Gem	123	98	88	82	62	53	44	37	29	20	15	12	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

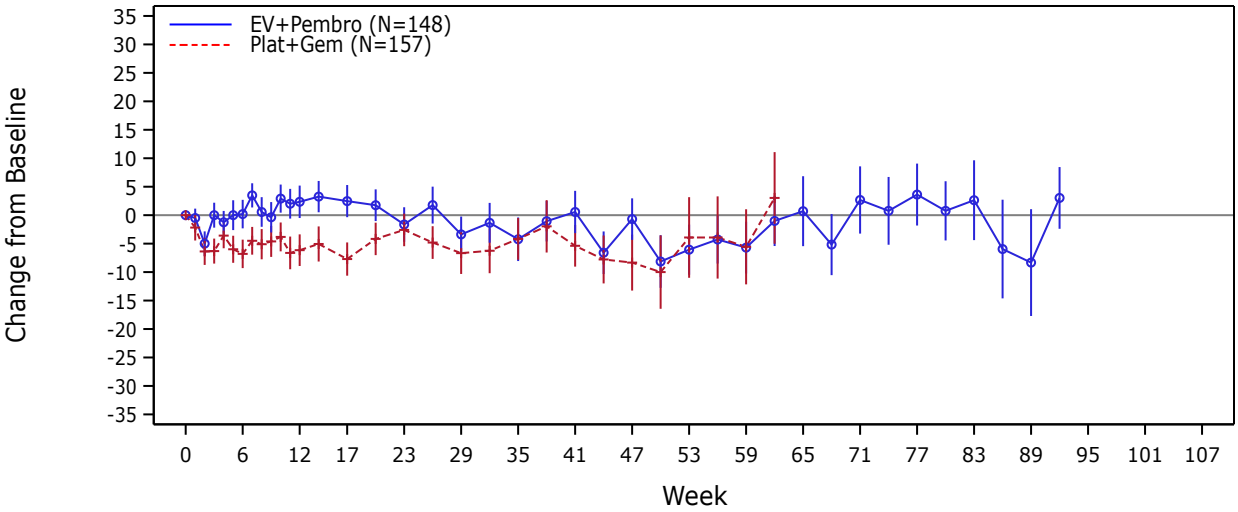
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.13.2.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Social Functioning by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Visceral metastases



Number of subjects

EV+Pembro	119	90	85	81	71	64	63	60	48	44	38	24	25	23	19	10
Plat+Gem	128	98	84	80	58	50	36	31	26	17	12					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

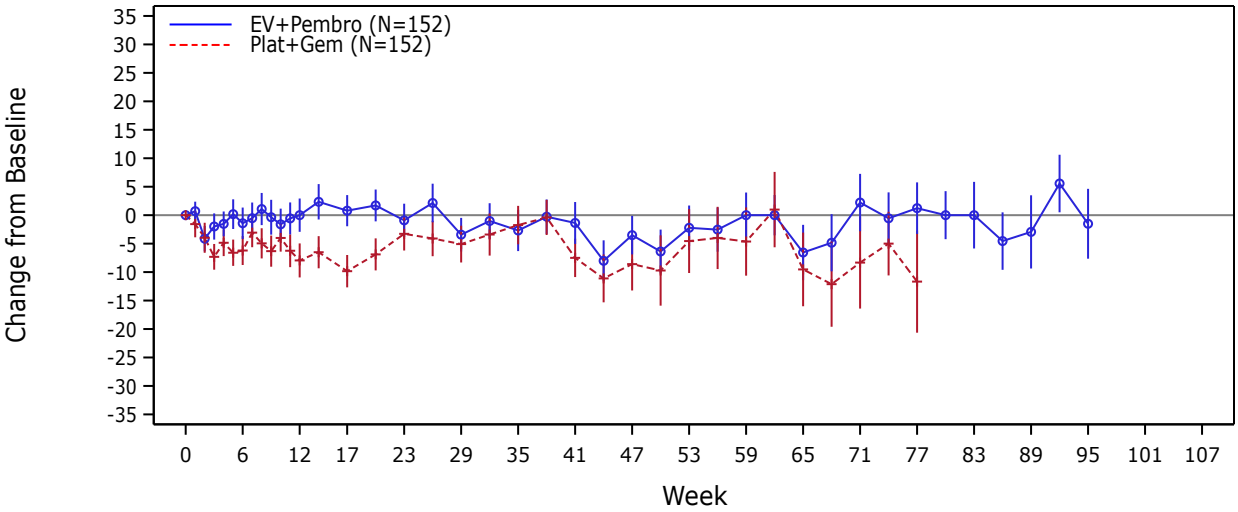
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.13.2.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Social Functioning by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Absent



Number of subjects

EV+Pembro	120	94	91	84	73	68	62	61	57	45	42	33	30	27	24	17	11
Plat+Gem	125	102	88	83	66	59	48	40	31	22	18	14	12	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

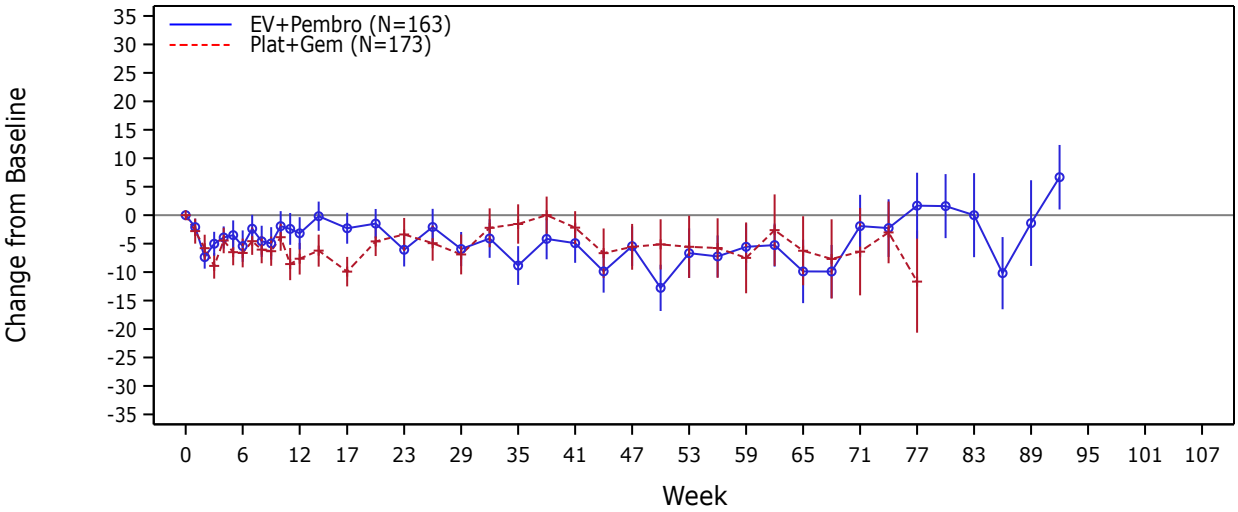
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.13.2.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Social Functioning by Age - Analysis Set mITT 2

Age: >= 65 years



Number of subjects

EV+Pembro	128	98	94	87	74	70	64	61	52	45	42	27	26	20	18	12
Plat+Gem	143	113	98	89	64	58	43	38	30	24	20	16	13	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

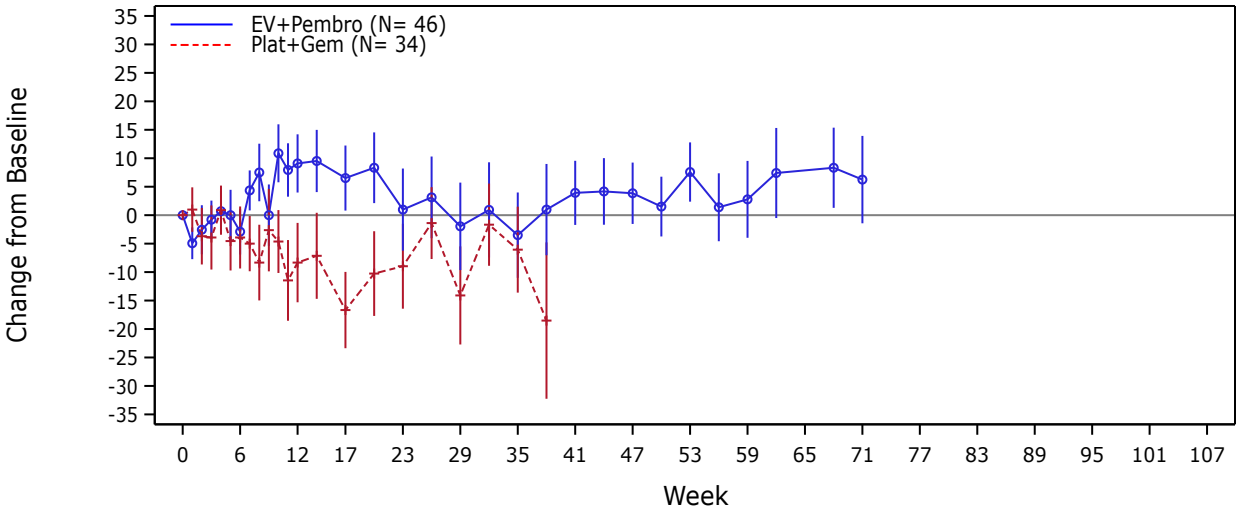
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.13.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Social Functioning by Region - Analysis Set mITT 2

Region: North America



Number of subjects

EV+Pembro	33	23	22	23	17	17	19	17	13	11	12	8
Plat+Gem	27	17	16	17	13	13	11					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

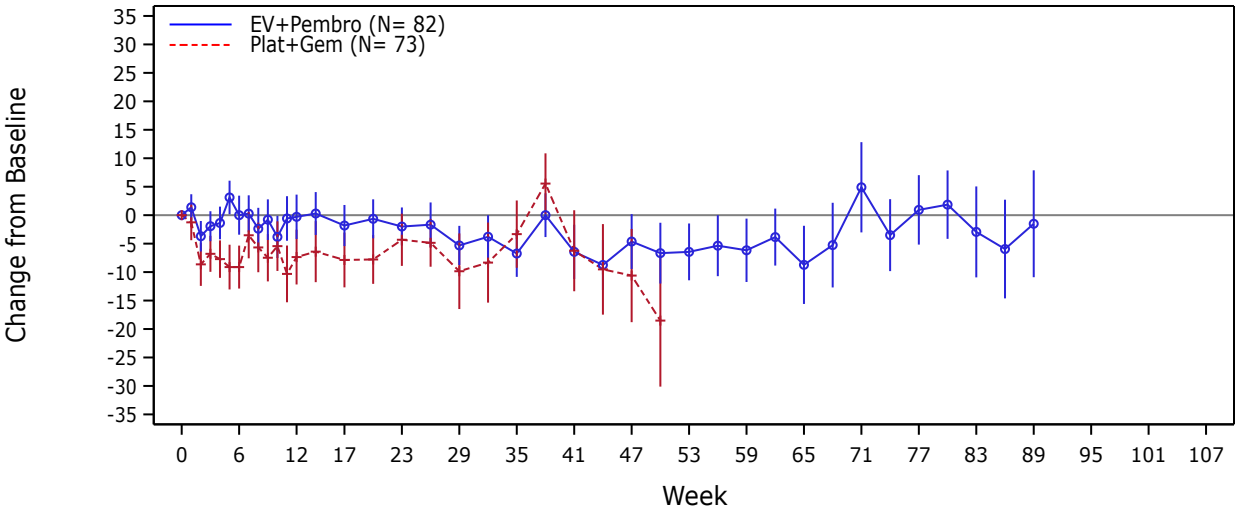
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.13.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Social Functioning by Region - Analysis Set mITT 2

Region: Rest of World



Number of subjects

EV+Pembro	74	62	58	55	50	47	42	44	36	31	27	21	17	18	17	11
Plat+Gem	63	53	43	36	27	22	15	16	11							

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

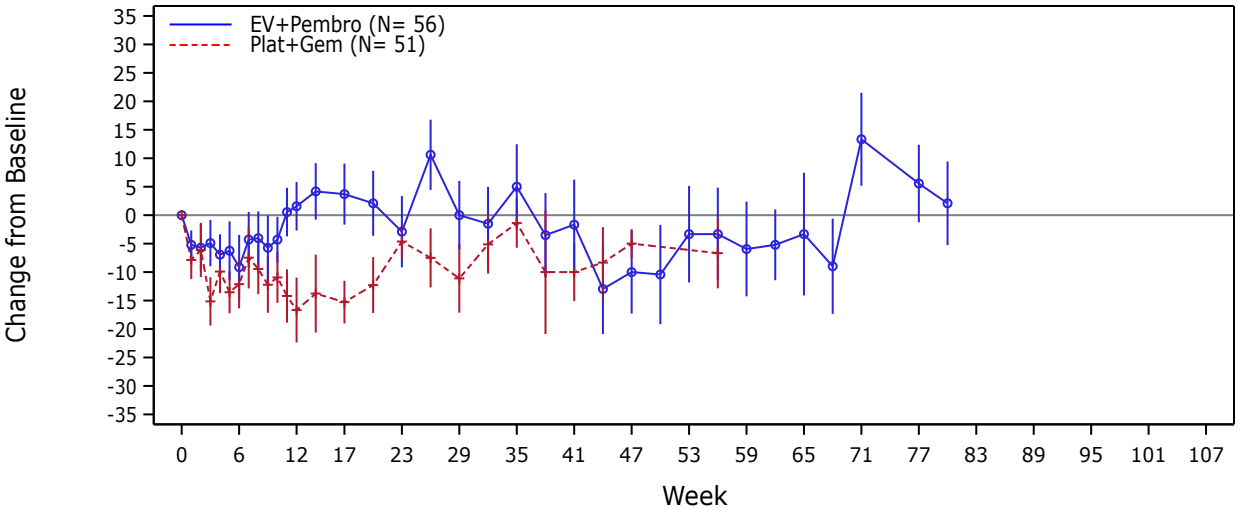
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.13.2.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Social Functioning by Sex - Analysis Set mITT 2

Sex: Female



Number of subjects

EV+Pembro	41	31	32	27	23	22	20	20	20	15	14	10	10	9
Plat+Gem	42	33	27	24	18	18	12	10	10					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

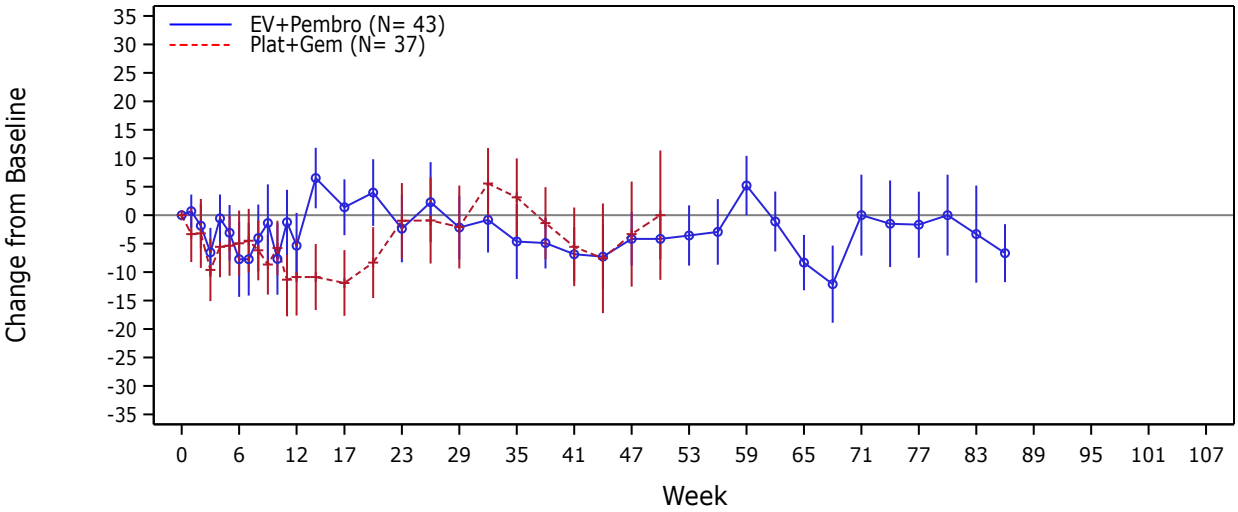
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.13.2.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Social Functioning by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Lymph node only



Number of subjects

EV+Pembro	33	28	28	24	21	23	18	17	16	14	16	14	11	10	10
Plat+Gem	29	27	23	21	17	16	16	12	10						

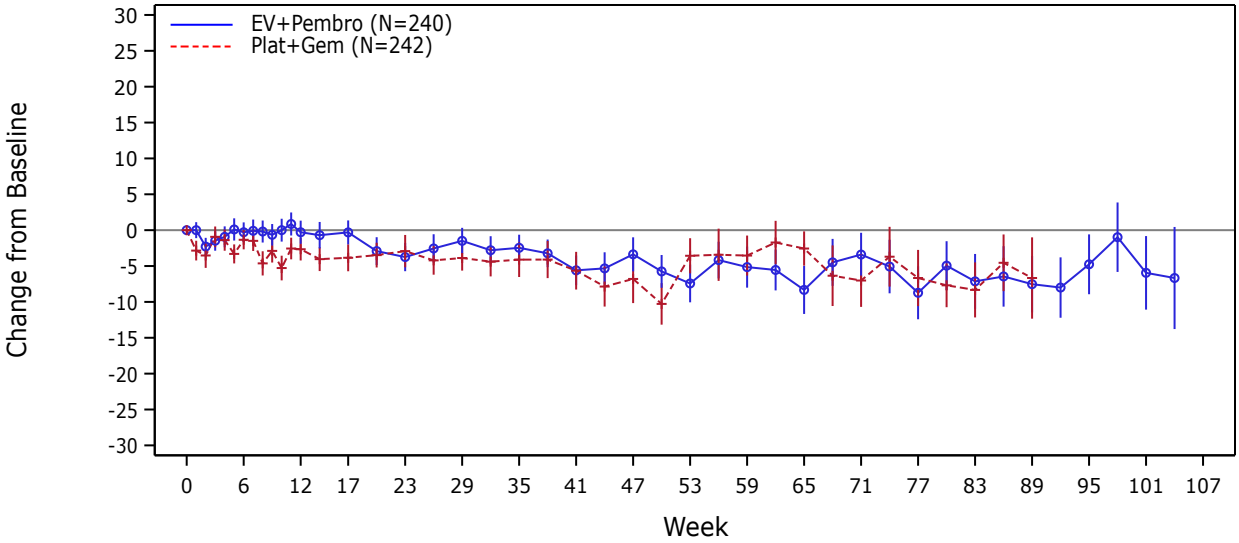
Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.14.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Cognitive Functioning - Analysis Set mITT 1



Number of subjects

EV+Pembro	206	170	171	162	151	145	122	119	94	74	68	54	49	42	35	31	21	14
Plat+Gem	188	149	138	130	97	86	69	56	49	42	33	26	19	15	12	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

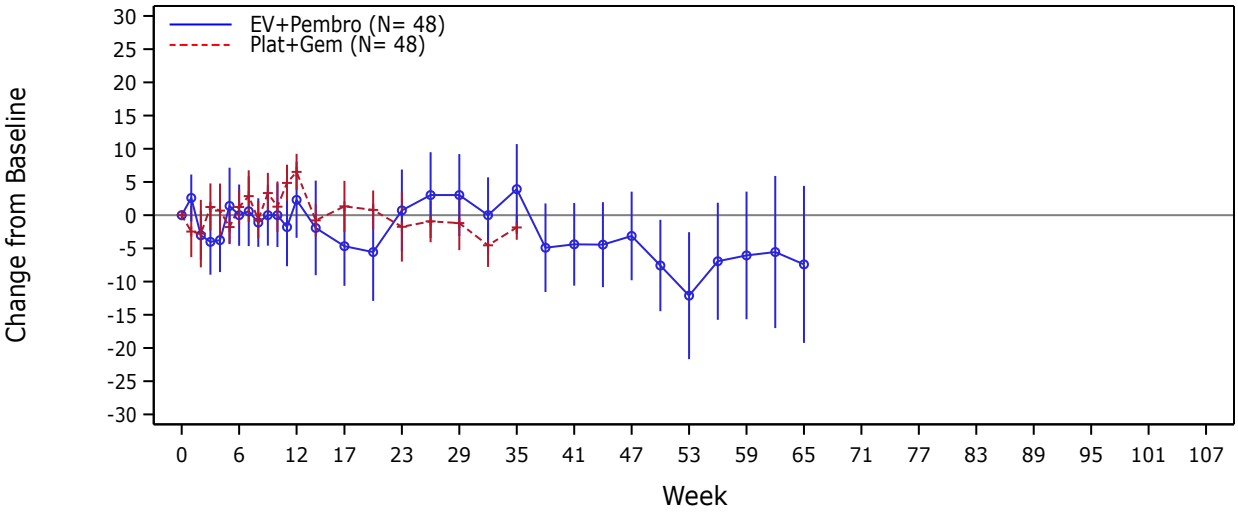
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.14.1.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Cognitive Functioning by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Present



Number of subjects

EV+Pembro	39	25	29	25	23	22	17	19	16	11	11	9
Plat+Gem	33	27	23	25	19	14	9					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

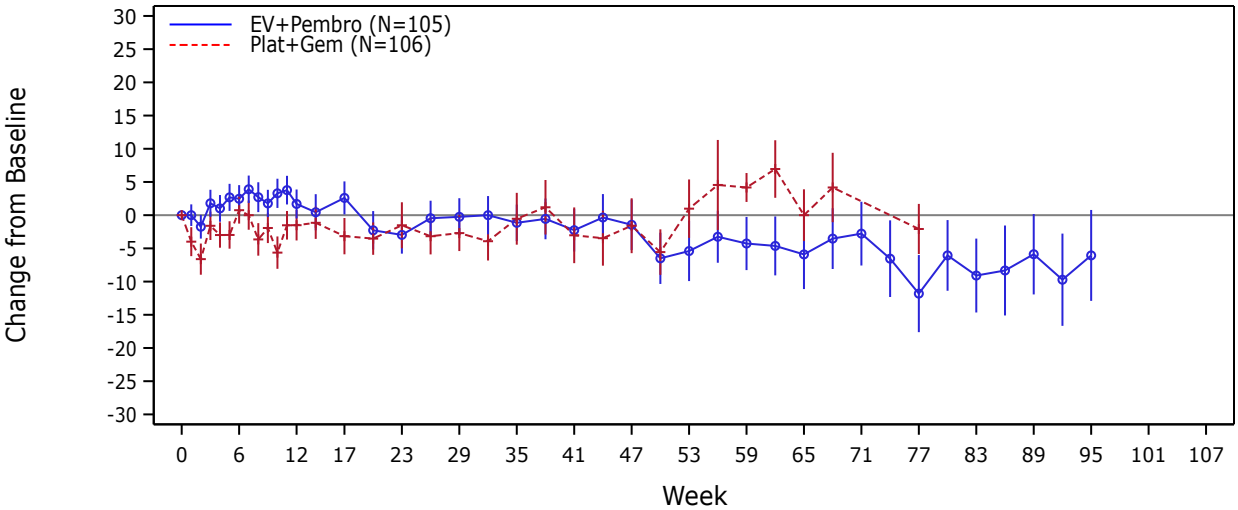
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.14.1.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Cognitive Functioning by Age - Analysis Set mITT 1

Age: < 65 years



Number of subjects

EV+Pembro	92	81	79	77	73	67	58	59	46	37	39	31	30	24	22	17	11
Plat+Gem	83	67	66	58	44	37	31	22	21	17	12	11		8			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

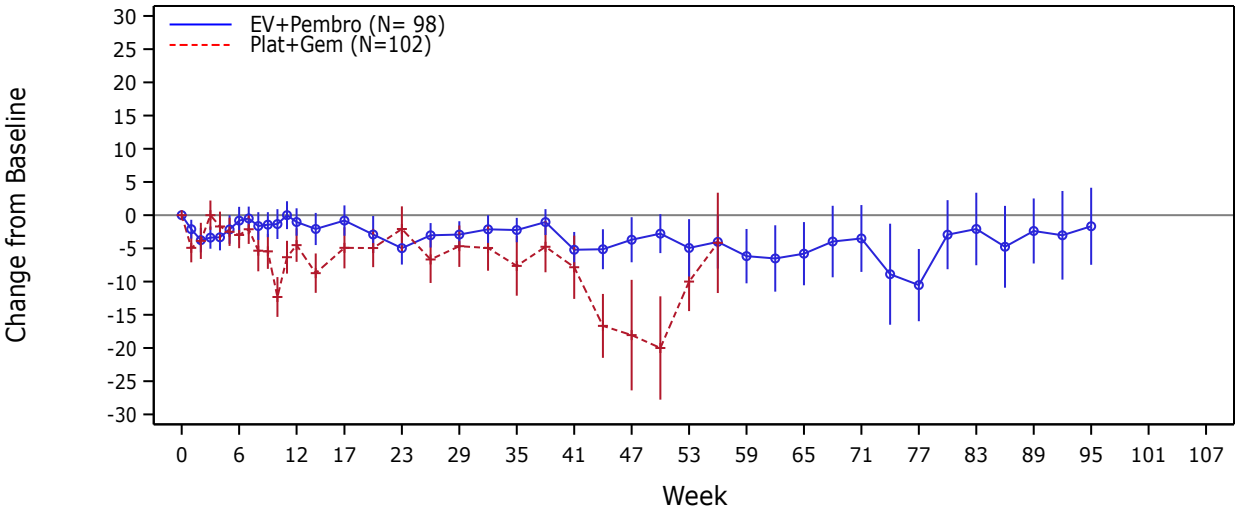
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.14.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Cognitive Functioning by Region - Analysis Set mITT 1

Region: Europe



Number of subjects

EV+Pembro	79	61	65	62	57	57	52	48	36	27	27	23	19	19	16	14	10
Plat+Gem	71	56	48	44	32	25	24	17	12	10							

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

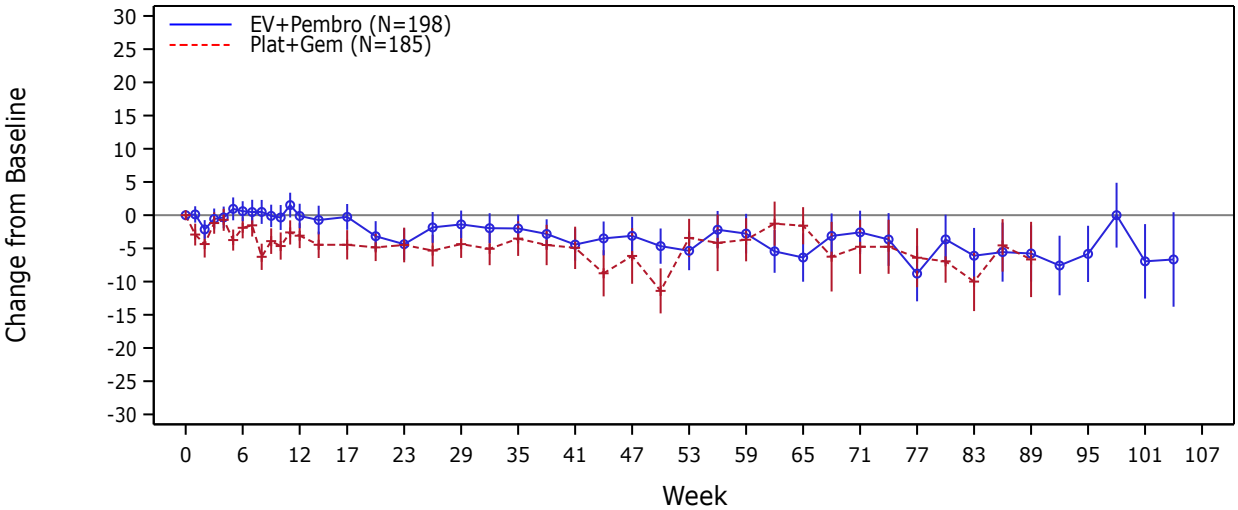
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.14.1.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Cognitive Functioning by Sex - Analysis Set mITT 1

Sex: Male



Number of subjects

EV+Pembro	170	138	140	130	122	120	100	94	75	59	54	47	45	36	30	26	20	12
Plat+Gem	146	114	108	101	78	65	52	44	38	34	27	21	14	13	10	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

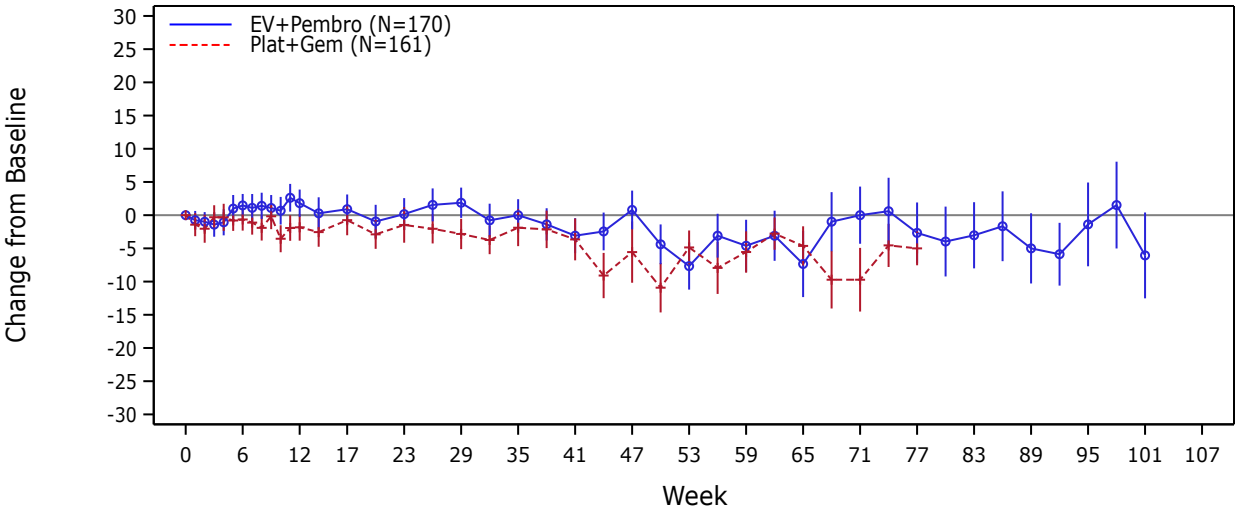
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.14.1.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Cognitive Functioning by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Visceral metastases



Number of subjects

EV+Pembro	146	113	120	111	103	98	79	81	63	50	47	34	30	25	22	20	12	11
Plat+Gem	129	102	91	89	68	59	44	32	30	24	21	18	12	10				

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

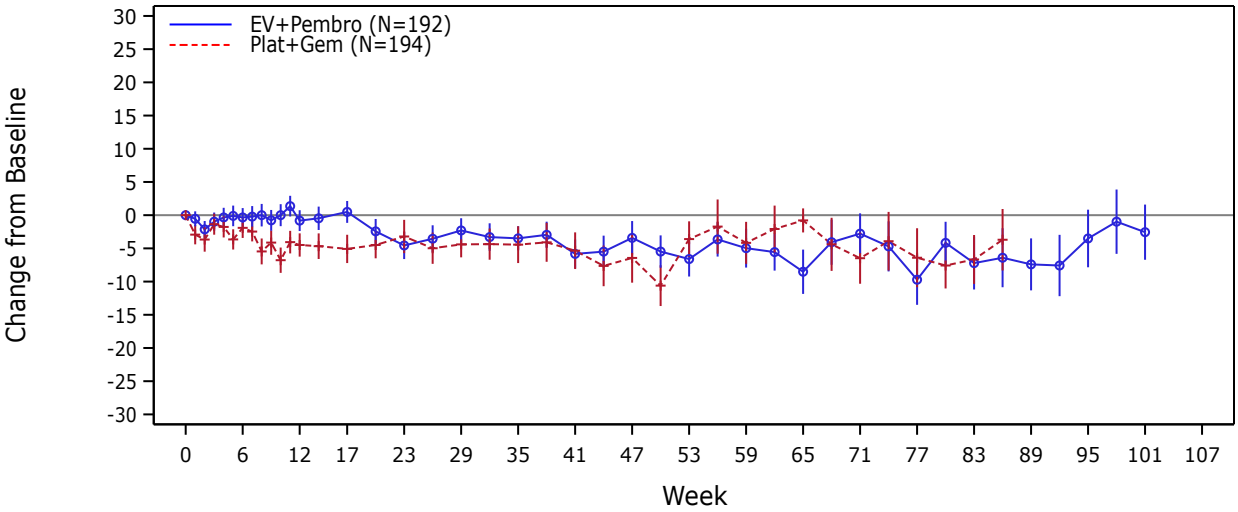
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.14.1.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Cognitive Functioning by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Absent



Number of subjects

EV+Pembro	167	145	142	137	128	123	105	100	78	63	57	45	42	36	30	27	19	13
Plat+Gem	155	122	115	105	78	72	60	53	44	37	28	21	18	13	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

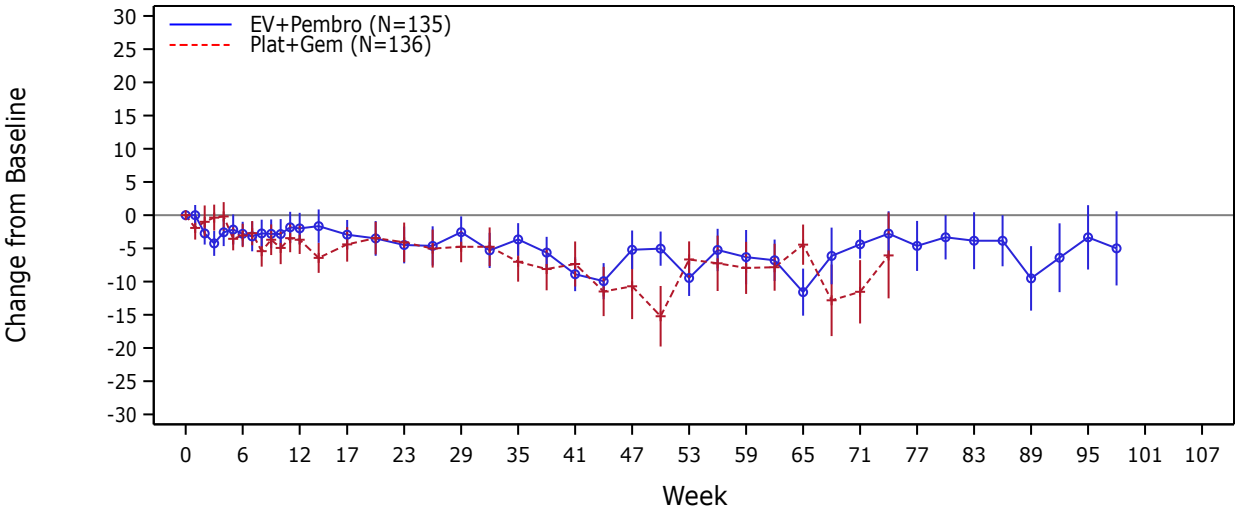
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.14.1.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Cognitive Functioning by Age - Analysis Set mITT 1

Age: >= 65 years



Number of subjects

EV+Pembro	114	89	92	85	78	78	64	60	48	37	29	23	19	18	13	14	10
Plat+Gem	105	82	72	72	53	49	38	34	28	25	21	15	13				

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

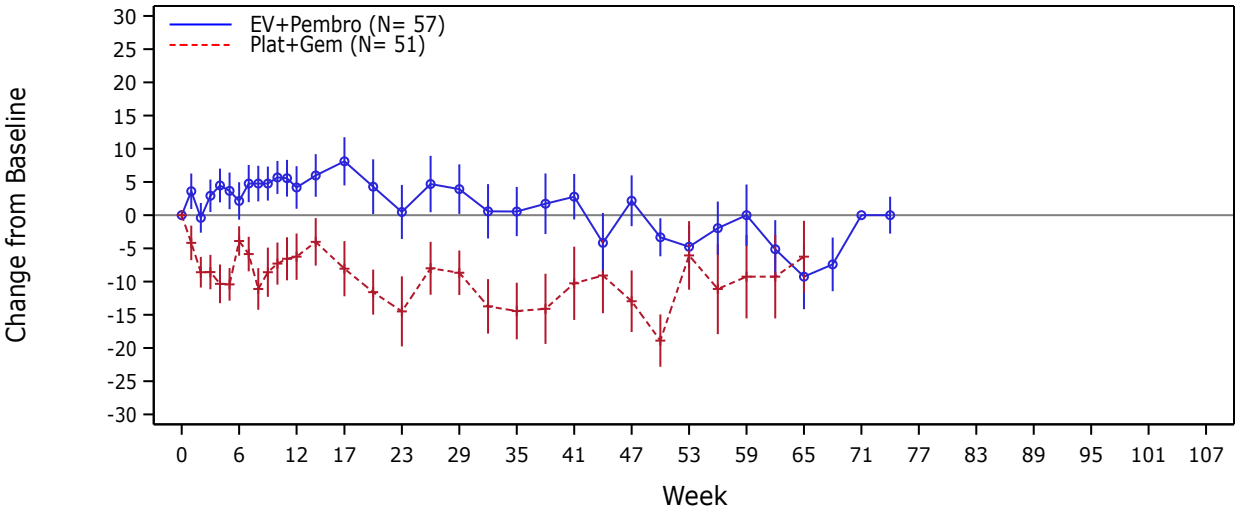
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.14.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Cognitive Functioning by Region - Analysis Set mITT 1

Region: North America



Number of subjects

EV+Pembro	47	39	40	37	35	34	30	24	23	14	14	9	8
Plat+Gem	42	30	32	31	23	25	15	13	9	11	9	8	

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

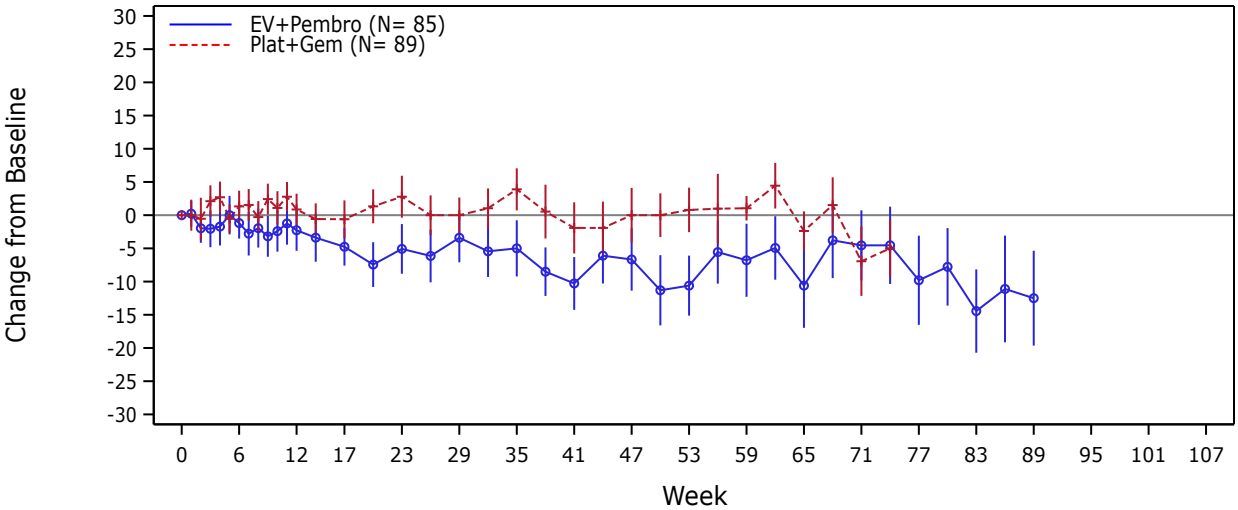
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.14.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Cognitive Functioning by Region - Analysis Set mITT 1

Region: Rest of World



Number of subjects

EV+Pembro	80	70	66	63	59	54	40	47	35	33	27	22	22	17	15	12
Plat+Gem	75	63	58	55	42	36	30	26	28	21	16	14	12			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

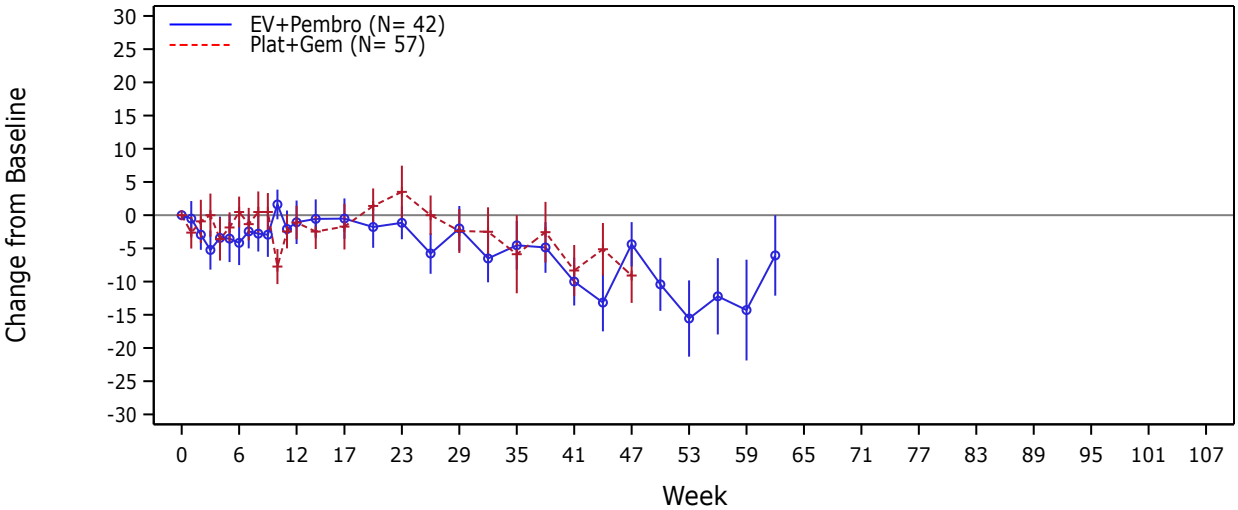
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.14.1.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Cognitive Functioning by Sex - Analysis Set mITT 1

Sex: Female



Number of subjects

EV+Pembro	36	32	31	32	29	25	22	25	19	15	14
Plat+Gem	42	35	30	29	19	21	17	12	11		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

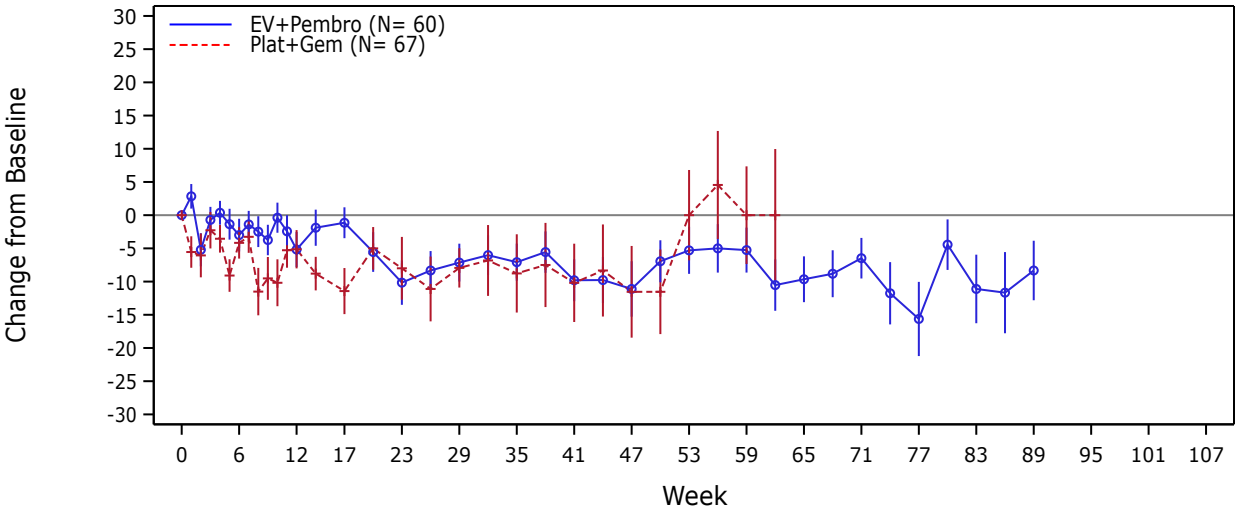
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.14.1.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Cognitive Functioning by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Lymph node only



Number of subjects

EV+Pembro	53	50	45	44	41	42	40	34	27	22	19	19	18	16	12	10
Plat+Gem	49	40	39	35	25	21	19	18	13	12	9					

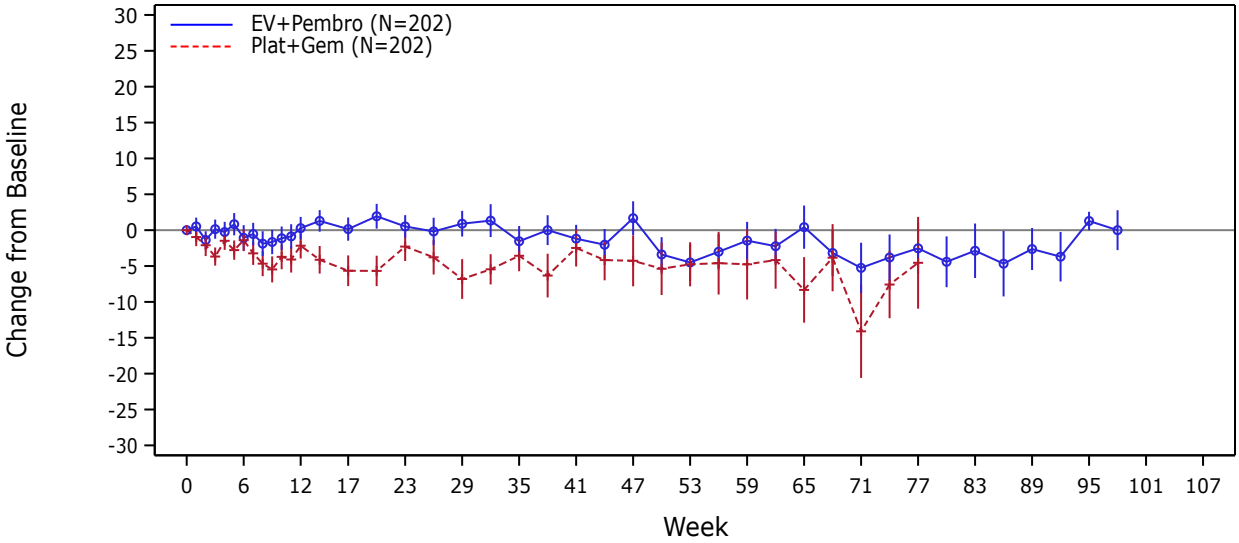
Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.14.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Cognitive Functioning - Analysis Set mITT 2



Number of subjects

EV+Pembro	160	124	119	111	97	93	86	84	70	63	57	40	38	33	29	19	13
Plat+Gem	165	131	115	106	80	71	56	47	39	28	21	16	13	11			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

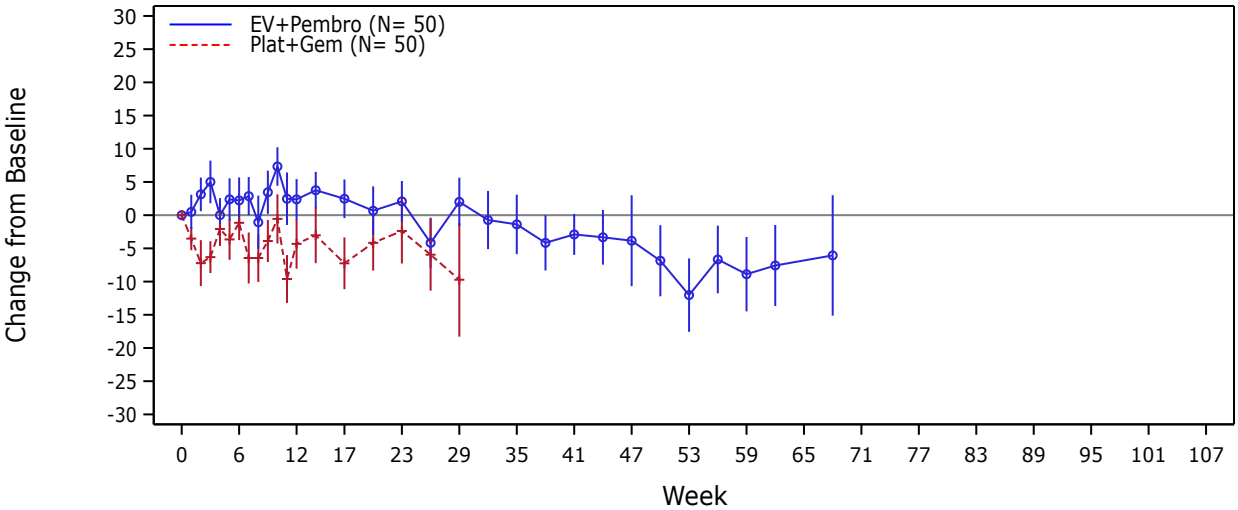
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.14.2.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Cognitive Functioning by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Present



Number of subjects

EV+Pembro	40	30	28	27	24	25	24	23	13	18	15
Plat+Gem	40	29	27	23	14	12					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

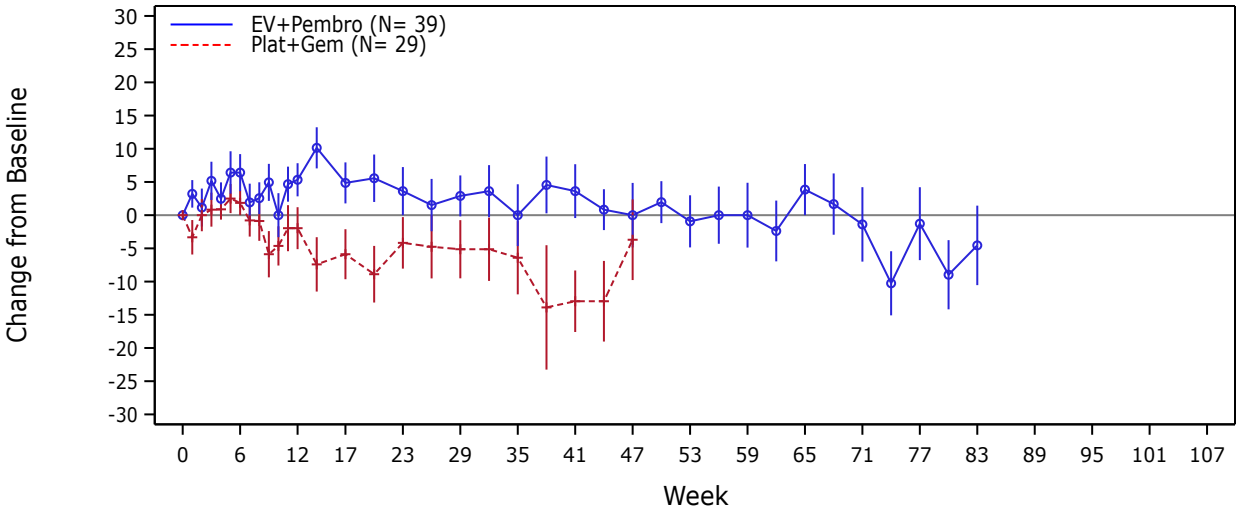
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.14.2.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Cognitive Functioning by Age - Analysis Set mITT 2

Age: < 65 years



Number of subjects

EV+Pembro	32	26	25	24	23	23	22	23	18	18	15	13	12	13	11
Plat+Gem	22	18	17	17	16	13	13	9	9						

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

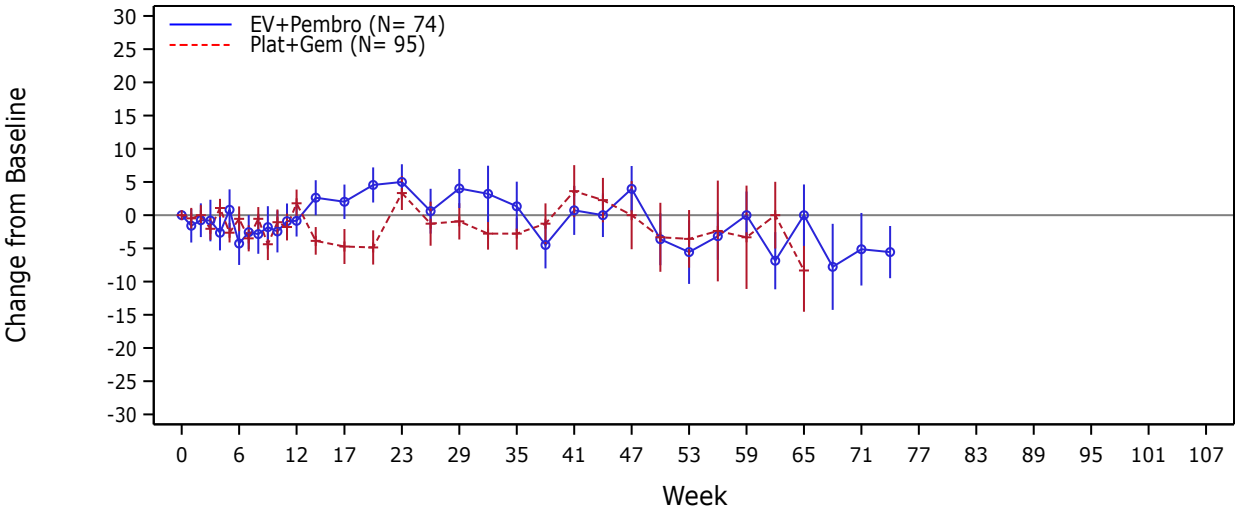
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.14.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Cognitive Functioning by Region - Analysis Set mITT 2

Region: Europe



Number of subjects

EV+Pembro	53	39	39	33	30	29	25	23	21	21	18	13	13
Plat+Gem	75	61	56	53	40	36	30	23	20	14	10	10	

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

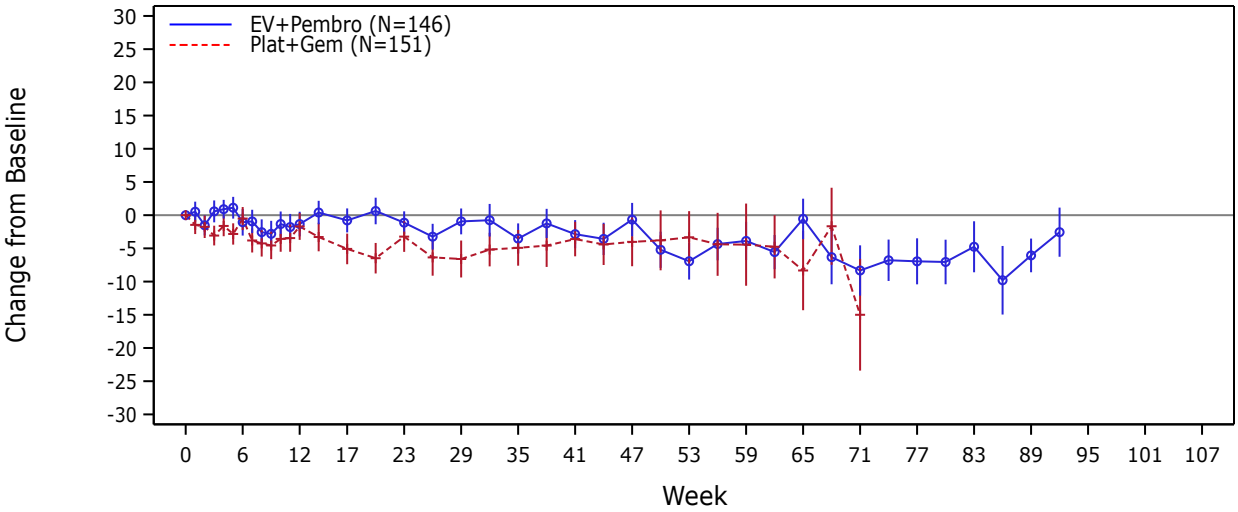
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.14.2.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Cognitive Functioning by Sex - Analysis Set mITT 2

Sex: Male



Number of subjects

EV+Pembro	119	93	87	84	74	71	66	64	50	48	43	30	28	24	21	11
Plat+Gem	123	98	88	82	62	53	44	37	29	20	15	12	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

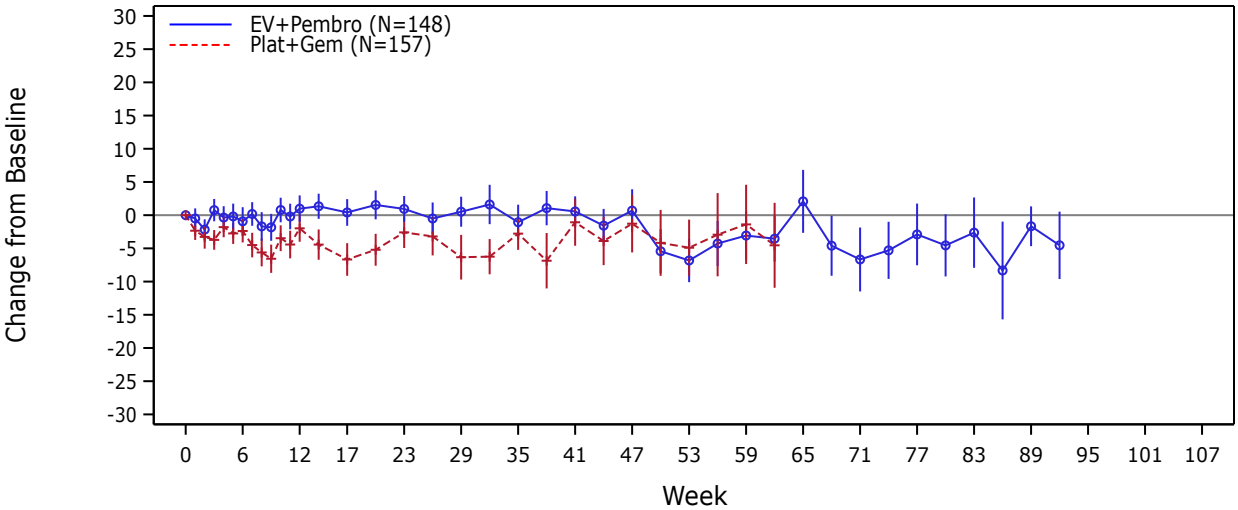
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.14.2.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Cognitive Functioning by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Visceral metastases



Number of subjects

EV+Pembro	119	90	85	81	71	64	63	60	48	44	38	24	25	23	19	10
Plat+Gem	128	98	84	80	58	50	36	31	26	17	12					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

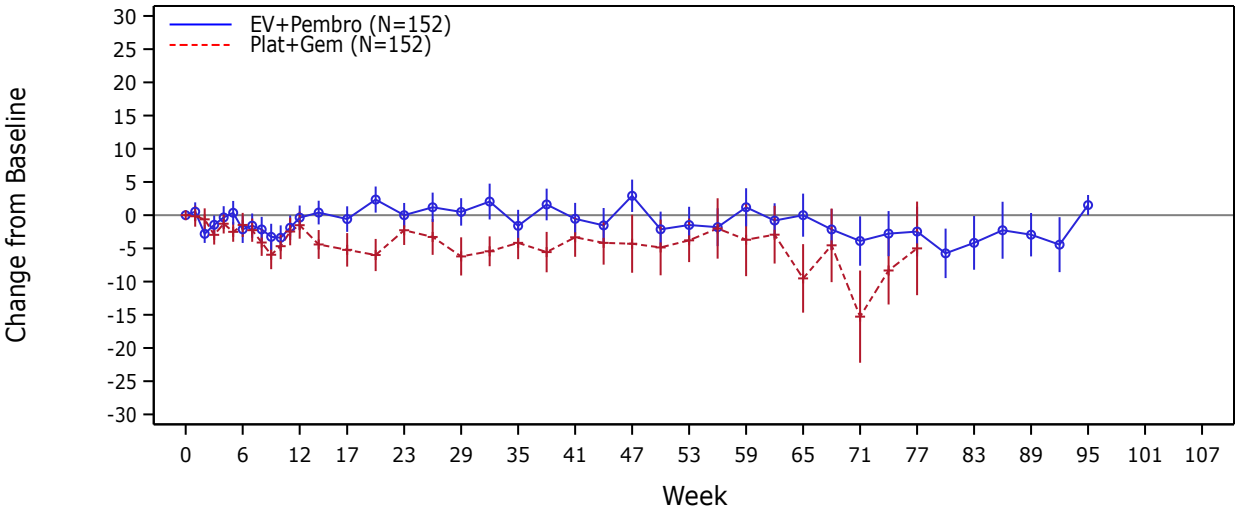
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.14.2.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Cognitive Functioning by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Absent



Number of subjects

EV+Pembro	120	94	91	84	73	68	62	61	57	45	42	33	30	27	24	17	11
Plat+Gem	125	102	88	83	66	59	48	40	31	22	18	14	12	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

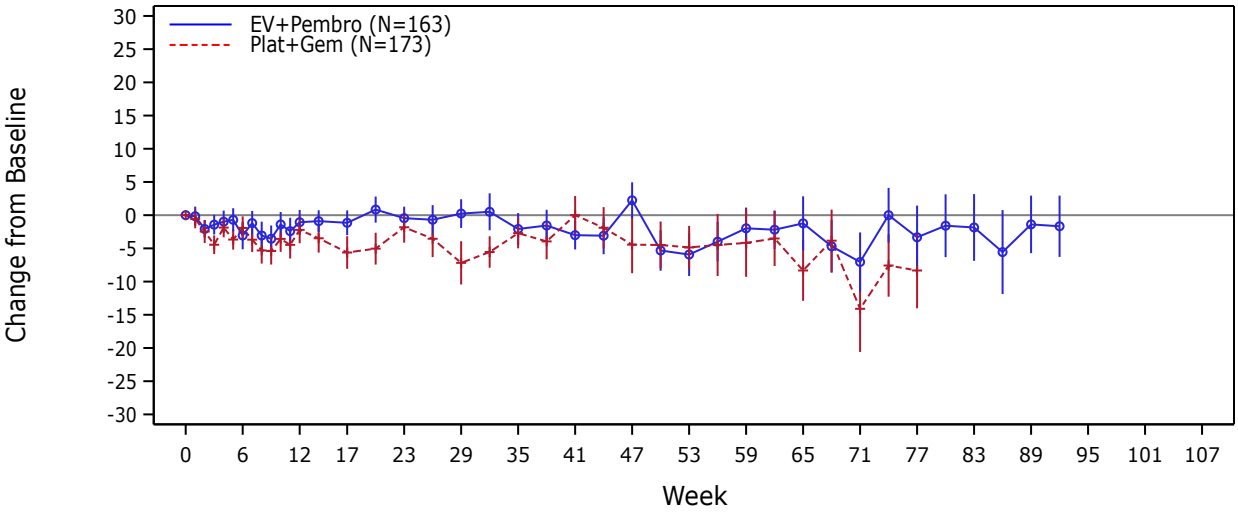
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.14.2.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Cognitive Functioning by Age - Analysis Set mITT 2

Age: >= 65 years



Number of subjects

EV+Pembro	128	98	94	87	74	70	64	61	52	45	42	27	26	20	18	12
Plat+Gem	143	113	98	89	64	58	43	38	30	24	20	16	13	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

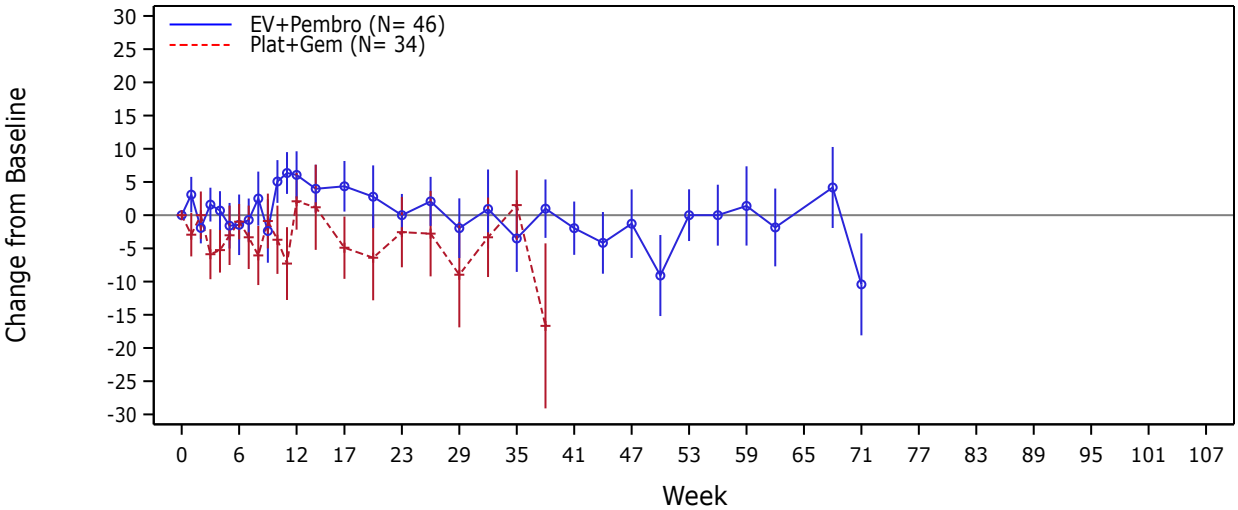
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.14.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Cognitive Functioning by Region - Analysis Set mITT 2

Region: North America



Number of subjects

EV+Pembro	33	23	22	23	17	17	19	17	13	11	12	8
Plat+Gem	27	17	16	17	13	13	11					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

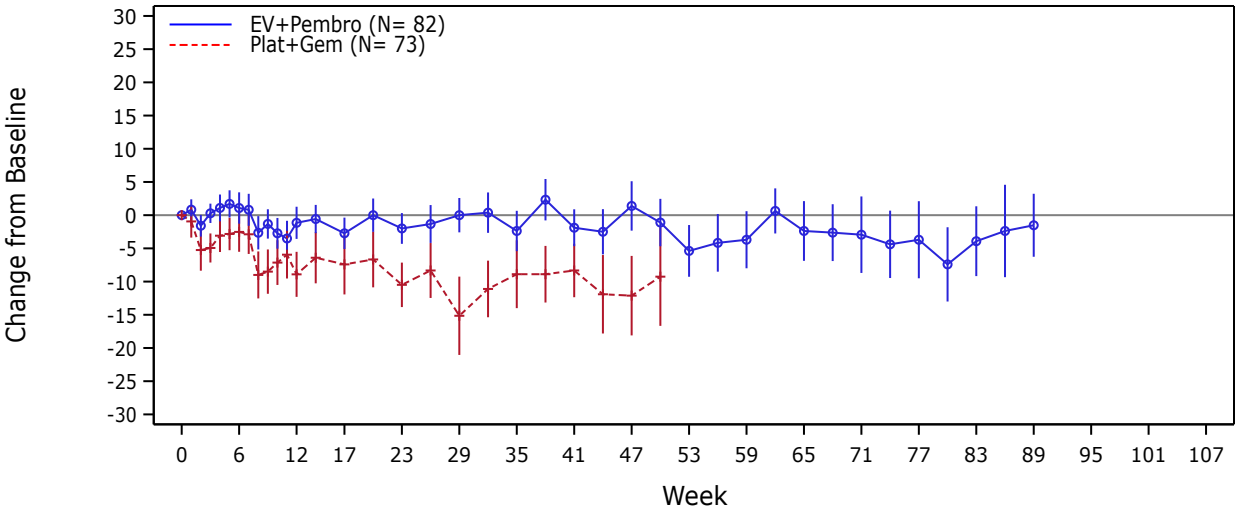
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.14.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Cognitive Functioning by Region - Analysis Set mITT 2

Region: Rest of World



Number of subjects

EV+Pembro	74	62	58	55	50	47	42	44	36	31	27	21	17	18	17	11
Plat+Gem	63	53	43	36	27	22	15	16	11							

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

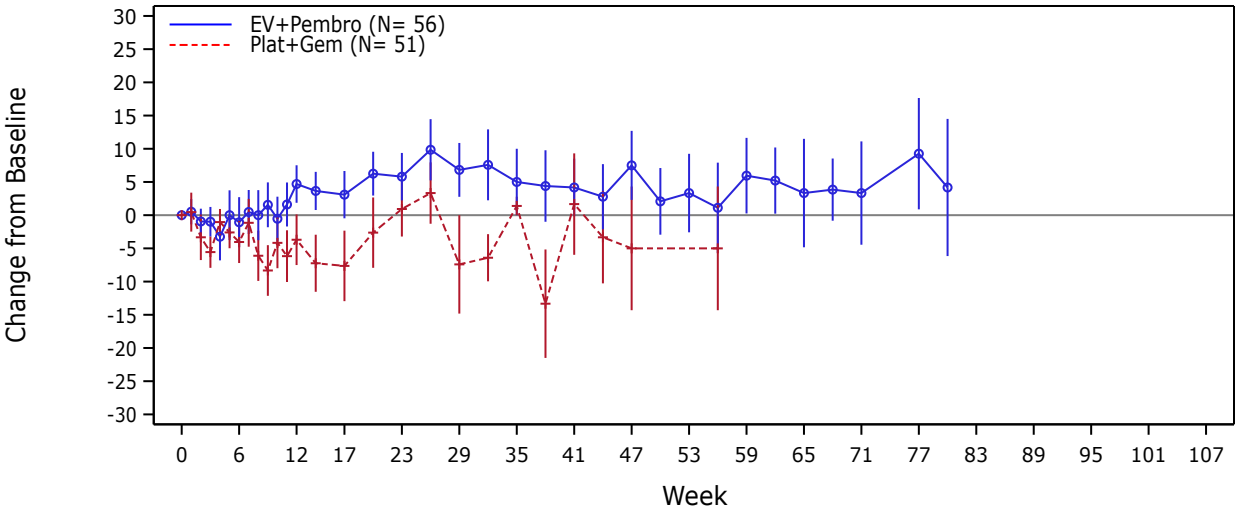
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.14.2.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Cognitive Functioning by Sex - Analysis Set mITT 2

Sex: Female



Number of subjects

EV+Pembro	41	31	32	27	23	22	20	20	20	15	14	10	10	9
Plat+Gem	42	33	27	24	18	18	12	10	10					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

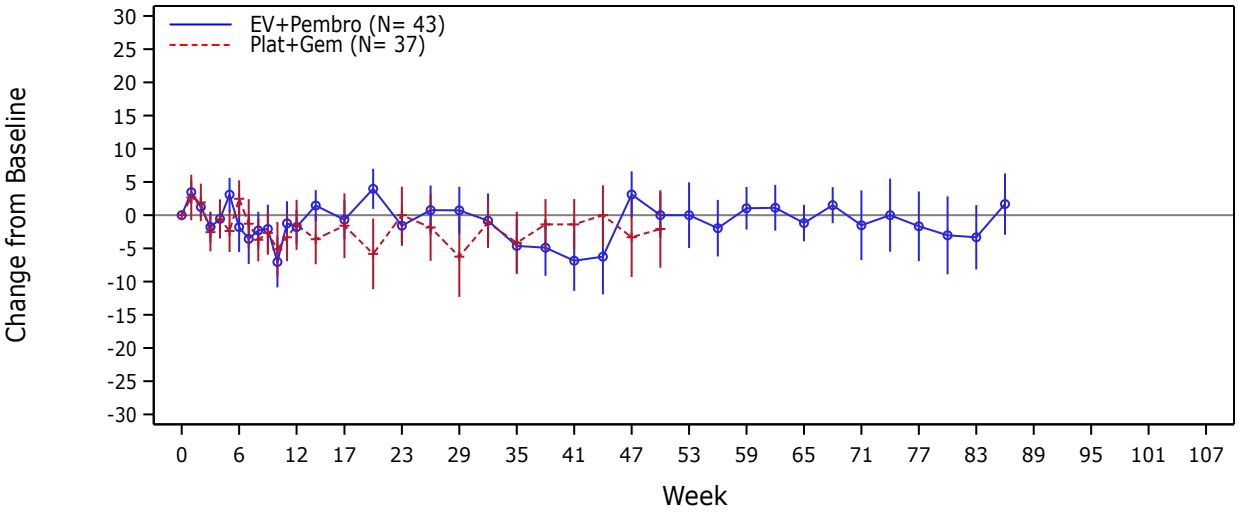
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.14.2.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Cognitive Functioning by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Lymph node only



Number of subjects

EV+Pembro	33	28	28	24	21	23	18	17	16	14	16	14	11	10	10
Plat+Gem	29	27	23	21	17	16	16	12	10						

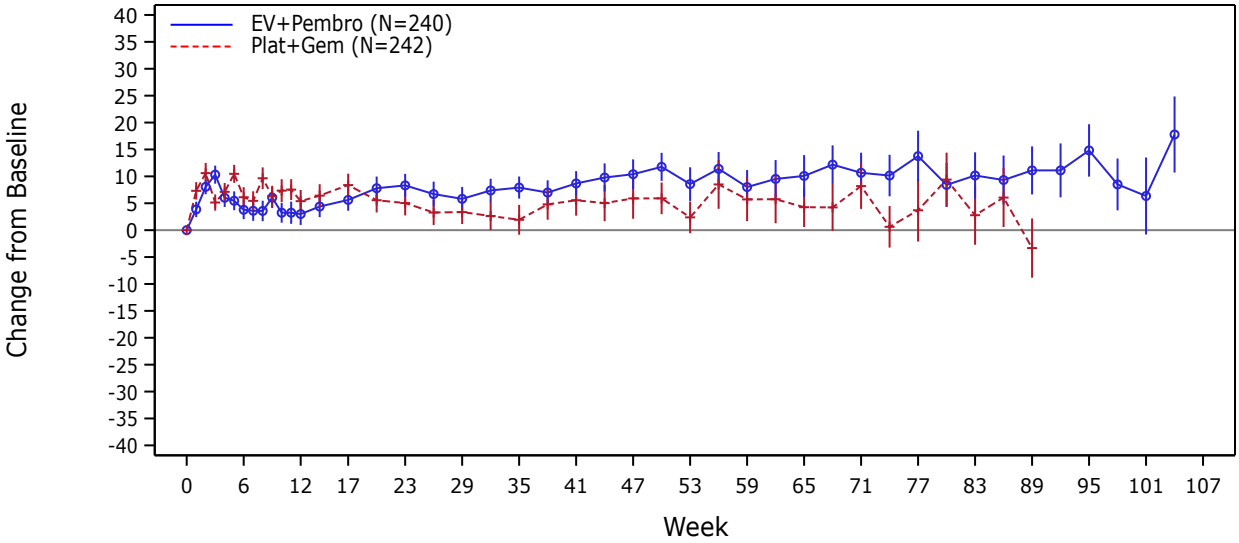
Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.15.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Fatigue - Analysis Set mITT 1



Number of subjects

EV+Pembro	206	170	171	162	151	145	122	119	94	74	68	54	49	42	35	31	21	14
Plat+Gem	188	149	138	130	97	86	69	56	49	42	33	26	19	15	12	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

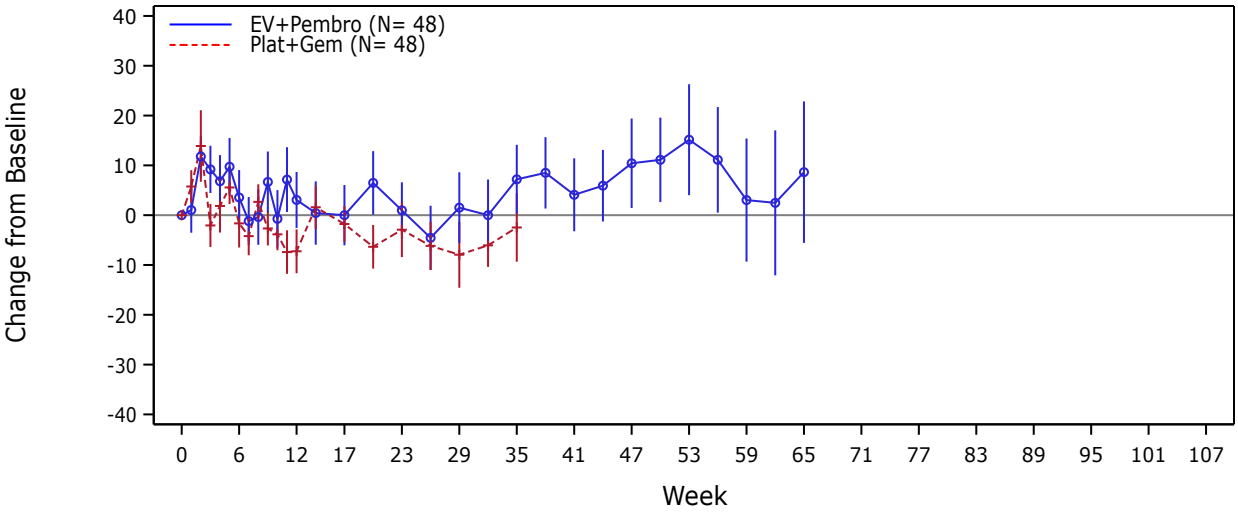
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.15.1.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Fatigue by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Present



Number of subjects

EV+Pembro	39	25	29	25	23	22	17	19	16	11	11	9
Plat+Gem	33	27	23	25	19	14	9					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

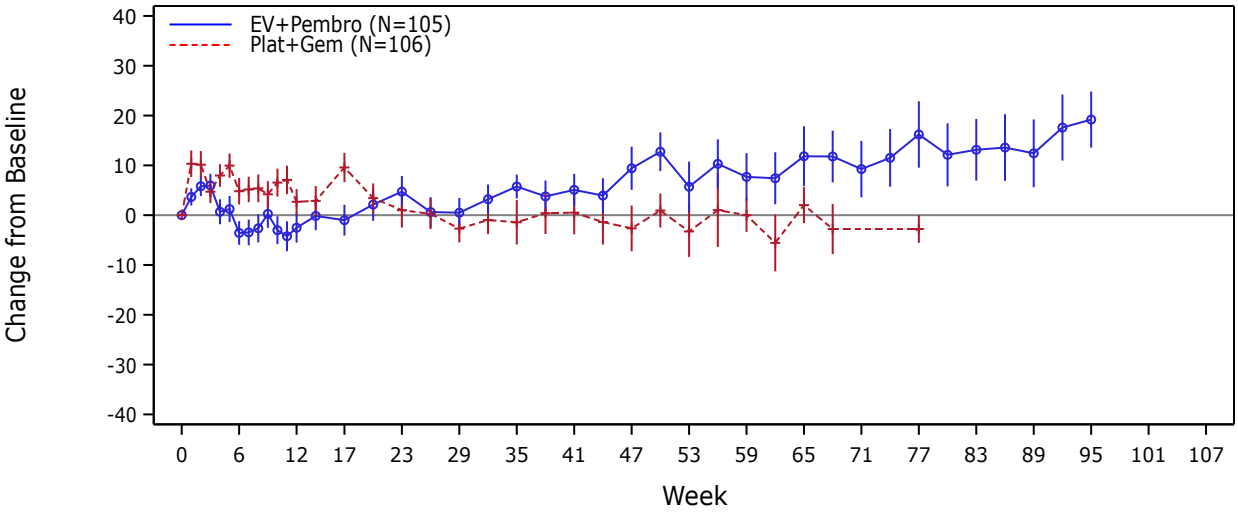
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.15.1.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Fatigue by Age - Analysis Set mITT 1

Age: < 65 years



Number of subjects

EV+Pembro	92	81	79	77	73	67	58	59	46	37	39	31	30	24	22	17	11
Plat+Gem	83	67	66	58	44	37	31	22	21	17	12	11		8			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

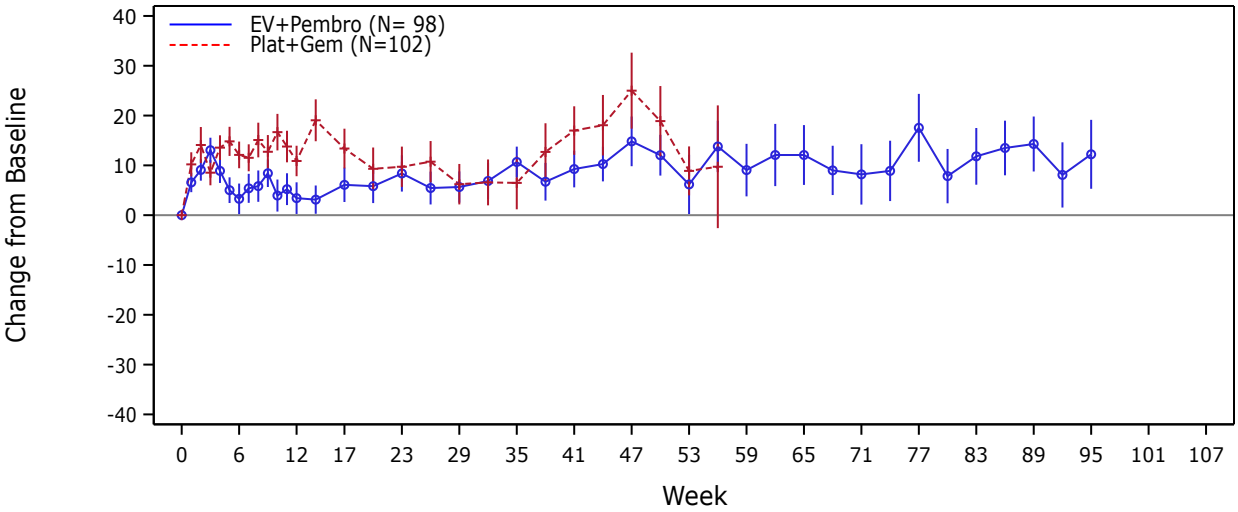
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.15.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Fatigue by Region - Analysis Set mITT 1

Region: Europe



Number of subjects

EV+Pembro	79	61	65	62	57	57	52	48	36	27	27	23	19	19	16	14	10
Plat+Gem	71	56	48	44	32	25	24	17	12	10							

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

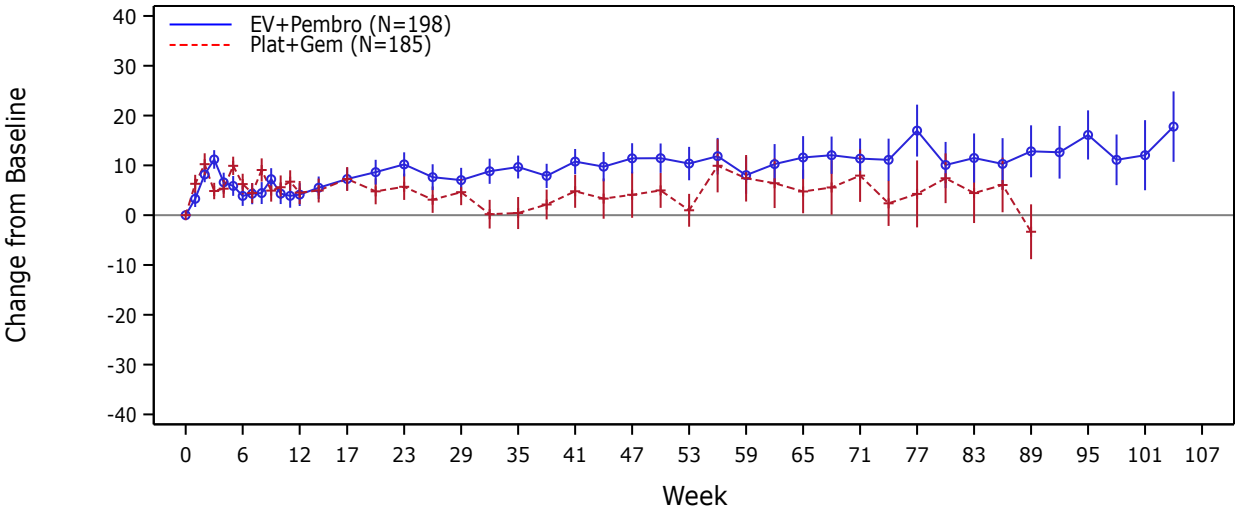
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.15.1.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Fatigue by Sex - Analysis Set mITT 1

Sex: Male



Number of subjects

EV+Pembro	170	138	140	130	122	120	100	94	75	59	54	47	45	36	30	26	20	12
Plat+Gem	146	114	108	101	78	65	52	44	38	34	27	21	14	13	10	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

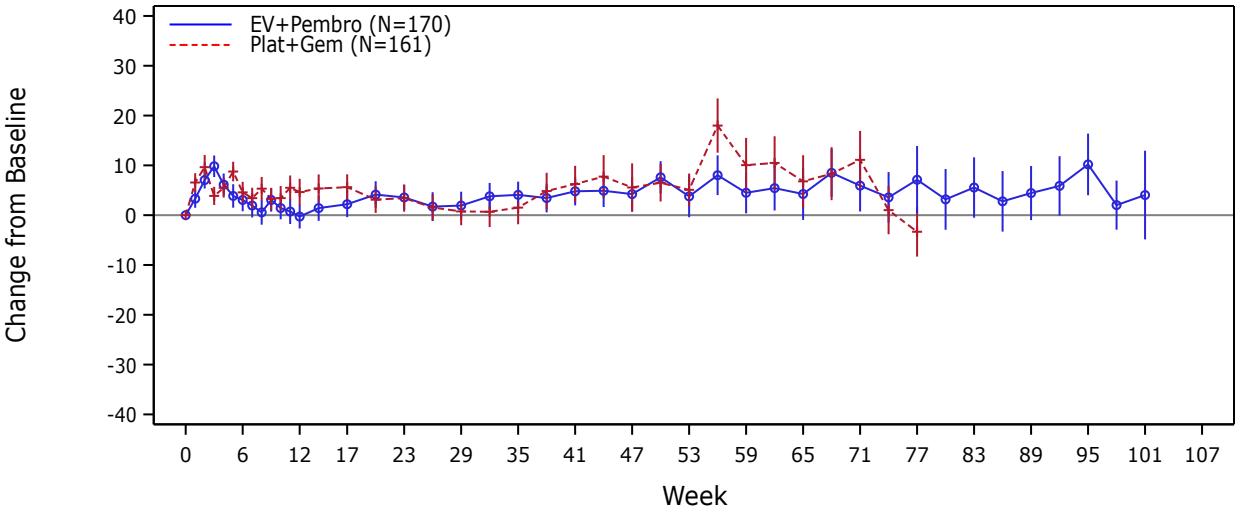
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.15.1.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Fatigue by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Visceral metastases



Number of subjects

EV+Pembro	146	113	120	111	103	98	79	81	63	50	47	34	30	25	22	20	12	11
Plat+Gem	129	102	91	89	68	59	44	32	30	24	21	18	12	10				

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

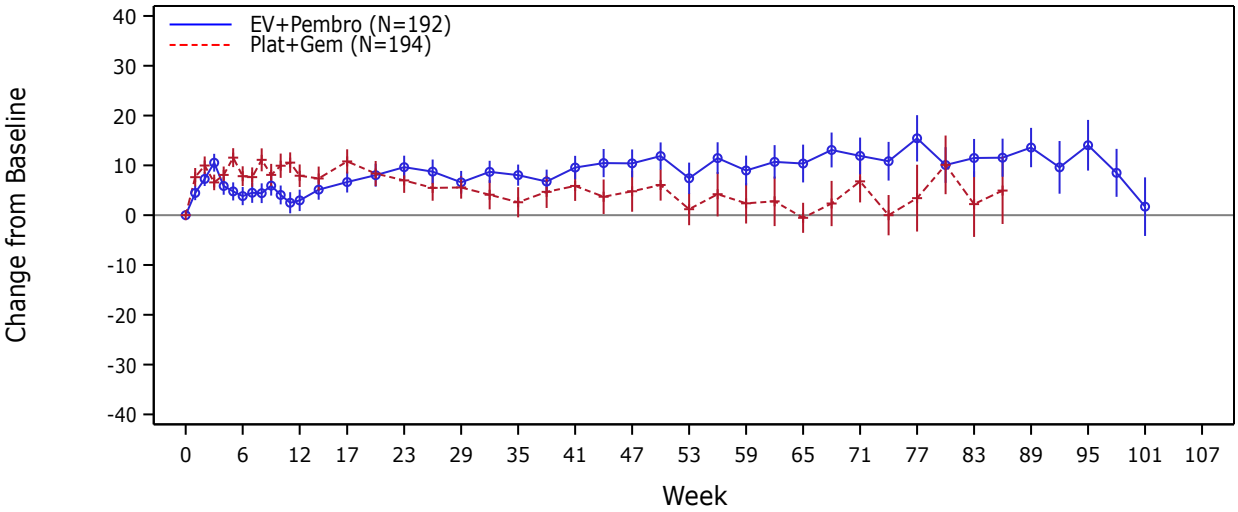
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.15.1.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Fatigue by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Absent



Number of subjects

EV+Pembro	167	145	142	137	128	123	105	100	78	63	57	45	42	36	30	27	19	13
Plat+Gem	155	122	115	105	78	72	60	53	44	37	28	21	18	13	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

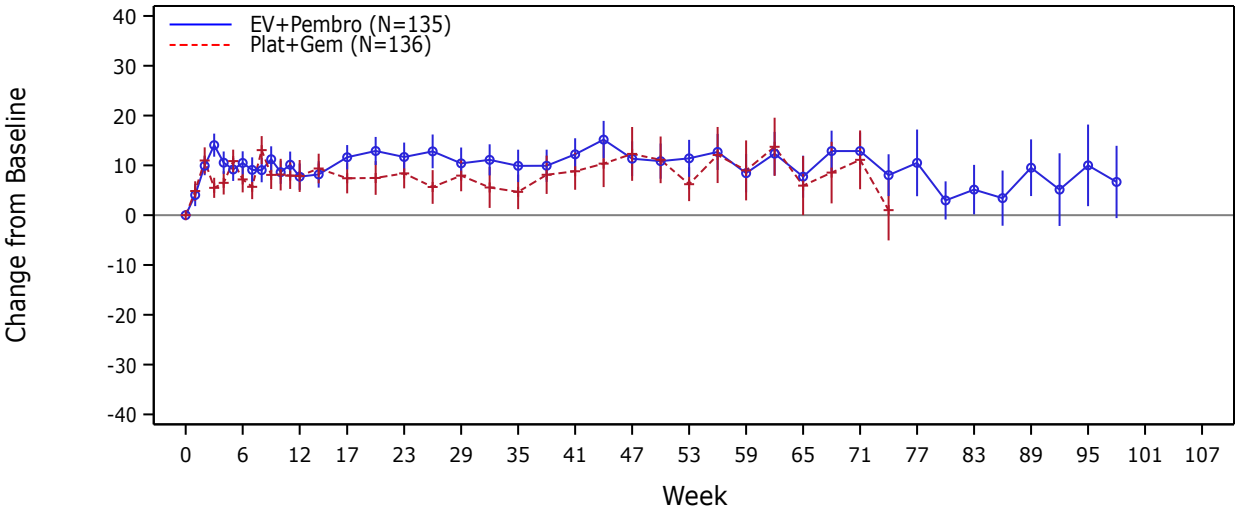
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.15.1.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Fatigue by Age - Analysis Set mITT 1

Age: >= 65 years



Number of subjects

EV+Pembro	114	89	92	85	78	78	64	60	48	37	29	23	19	18	13	14	10
Plat+Gem	105	82	72	72	53	49	38	34	28	25	21	15	13				

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

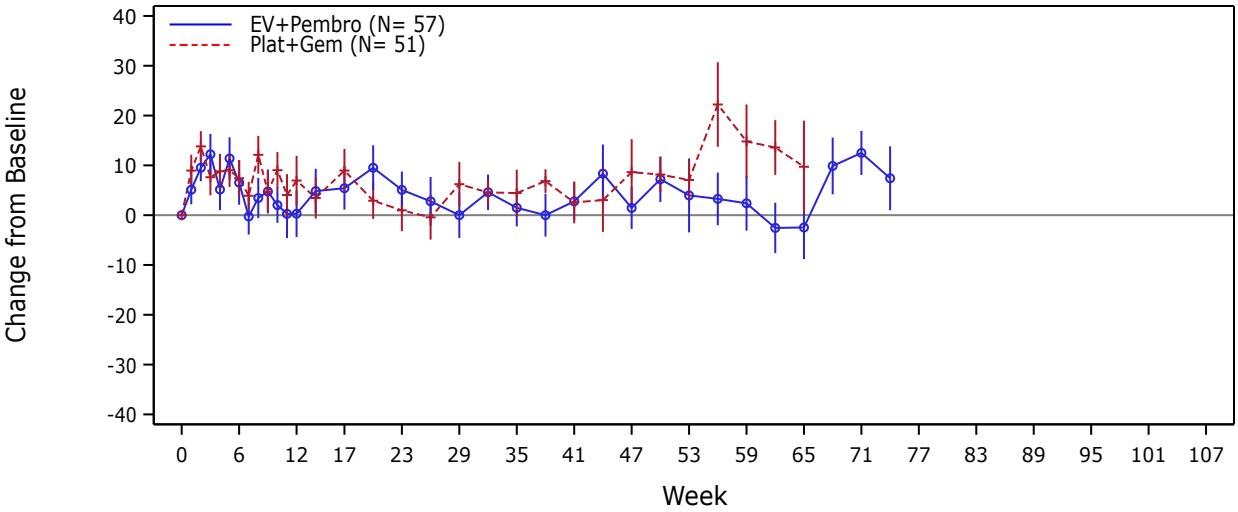
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.15.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Fatigue by Region - Analysis Set mITT 1

Region: North America



Number of subjects

EV+Pembro	47	39	40	37	35	34	30	24	23	14	14	9	8
Plat+Gem	42	30	32	31	23	25	15	13	9	11	9	8	

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

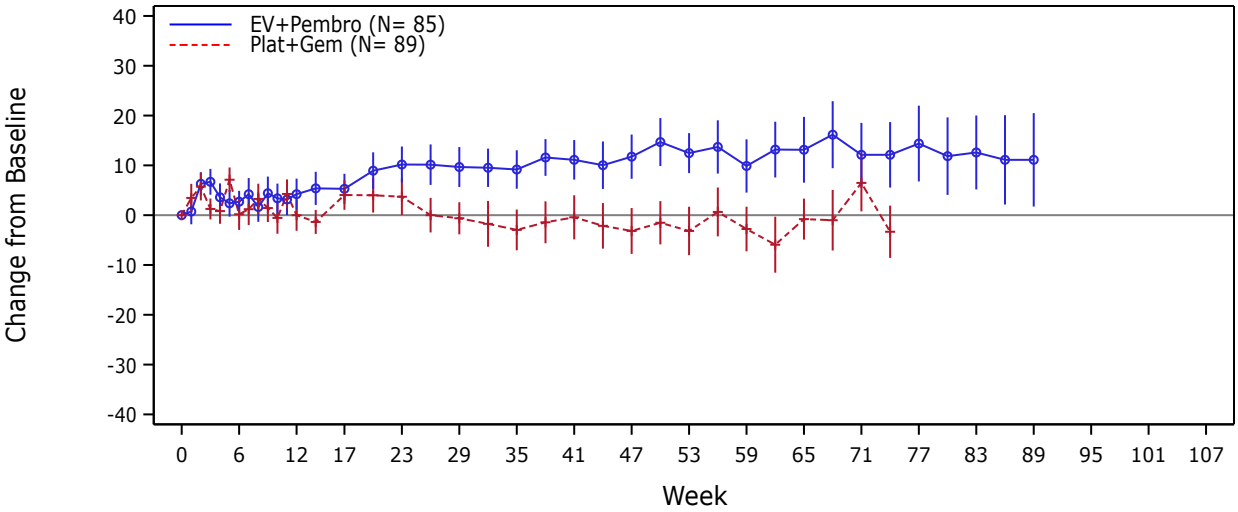
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.15.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Fatigue by Region - Analysis Set mITT 1

Region: Rest of World



Number of subjects

EV+Pembro	80	70	66	63	59	54	40	47	35	33	27	22	22	17	15	12
Plat+Gem	75	63	58	55	42	36	30	26	28	21	16	14	12			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

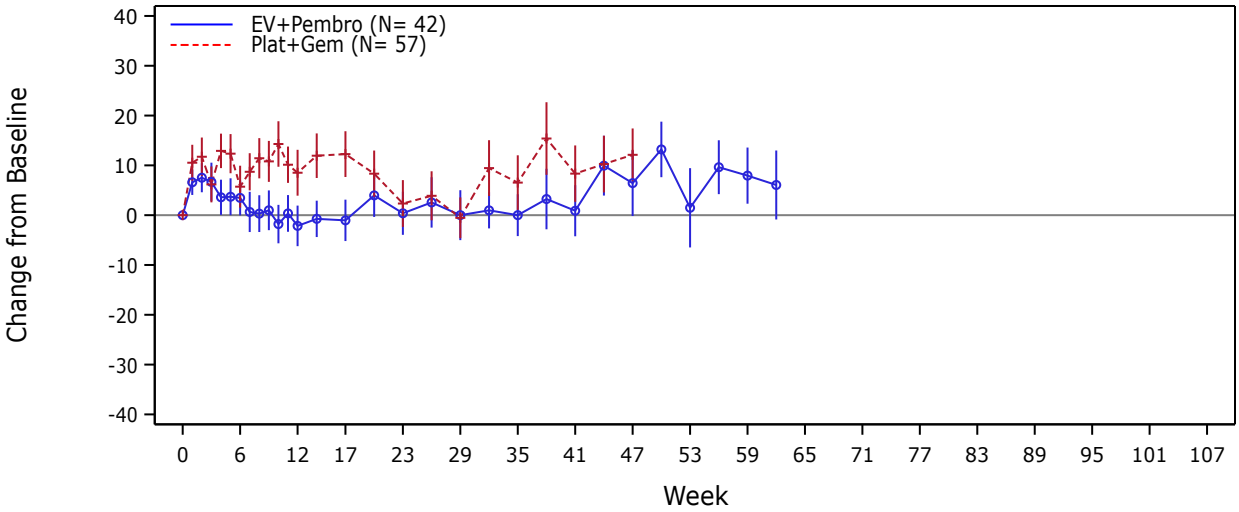
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.15.1.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Fatigue by Sex - Analysis Set mITT 1

Sex: Female



Number of subjects

EV+Pembro	36	32	31	32	29	25	22	25	19	15	14
Plat+Gem	42	35	30	29	19	21	17	12	11		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

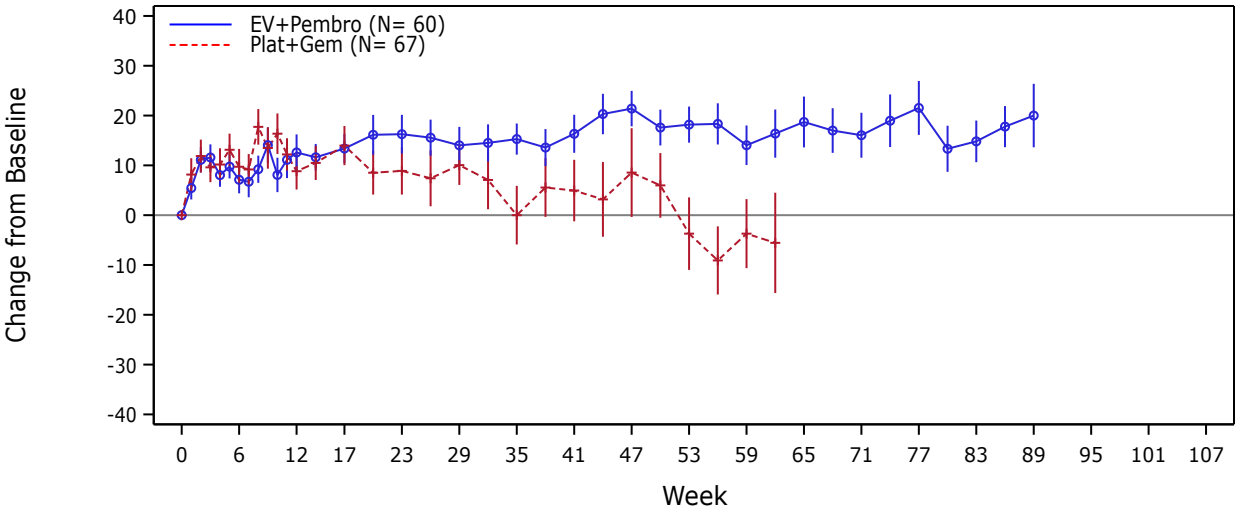
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.15.1.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Fatigue by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Lymph node only



Number of subjects

EV+Pembro	53	50	45	44	41	42	40	34	27	22	19	19	18	16	12	10
Plat+Gem	49	40	39	35	25	21	19	18	13	12	9					

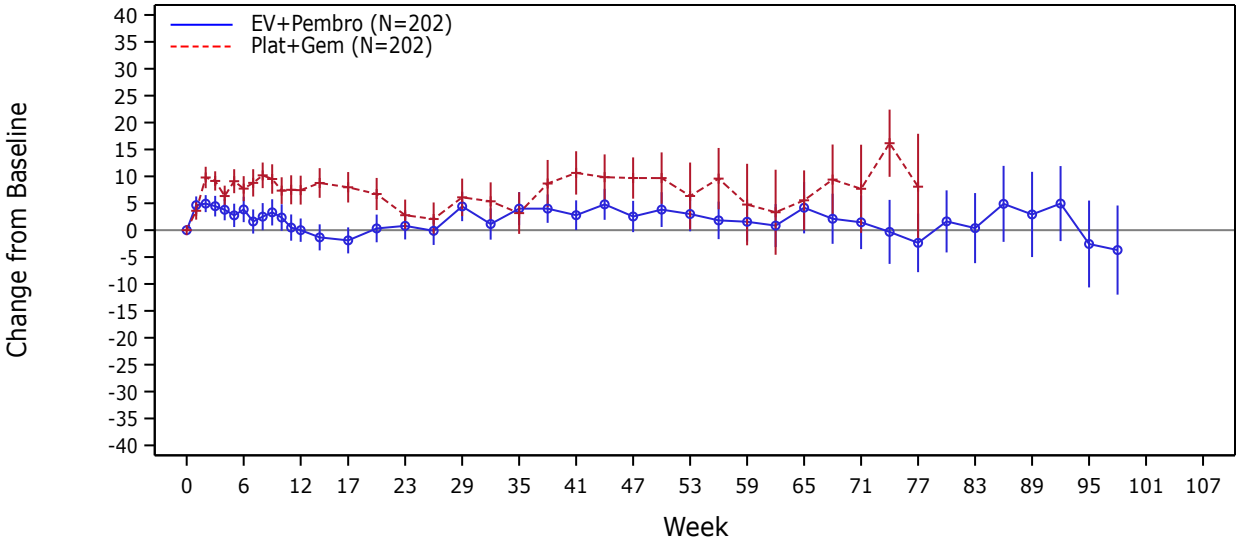
Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.15.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Fatigue - Analysis Set mITT 2



Number of subjects

EV+Pembro	160	124	119	111	97	93	86	84	70	63	57	40	38	33	29	19	13
Plat+Gem	165	131	115	106	80	71	56	47	39	28	21	16	13	11			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

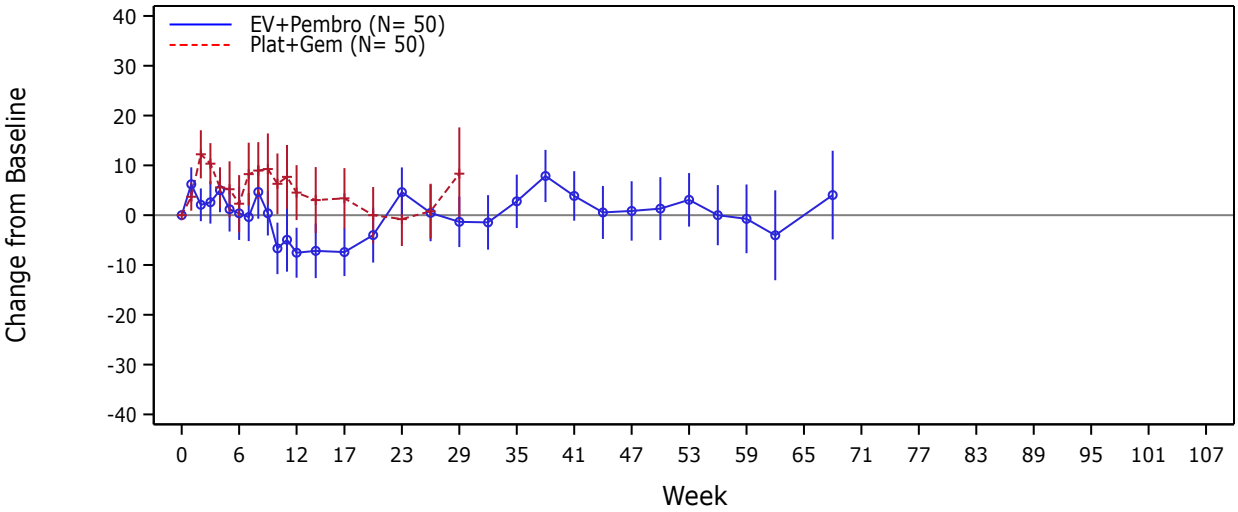
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.15.2.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Fatigue by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Present



Number of subjects

EV+Pembro	40	30	28	27	24	25	24	23	13	18	15
Plat+Gem	40	29	27	23	14	12					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

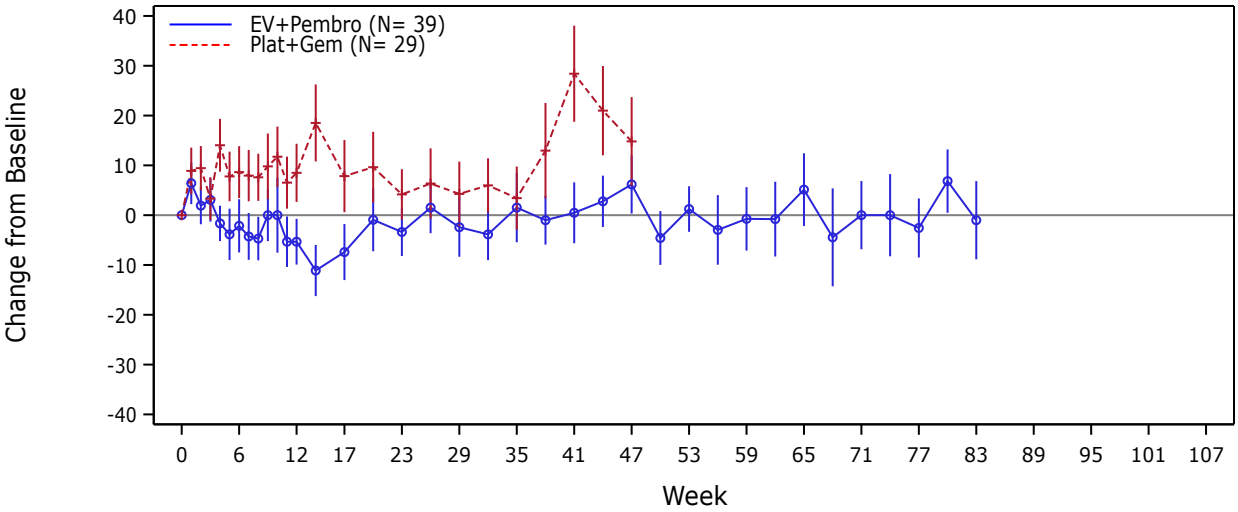
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.15.2.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Fatigue by Age - Analysis Set mITT 2

Age: < 65 years



Number of subjects

EV+Pembro	32	26	25	24	23	23	22	23	18	18	15	13	12	13	11
Plat+Gem	22	18	17	17	16	13	13	9	9						

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

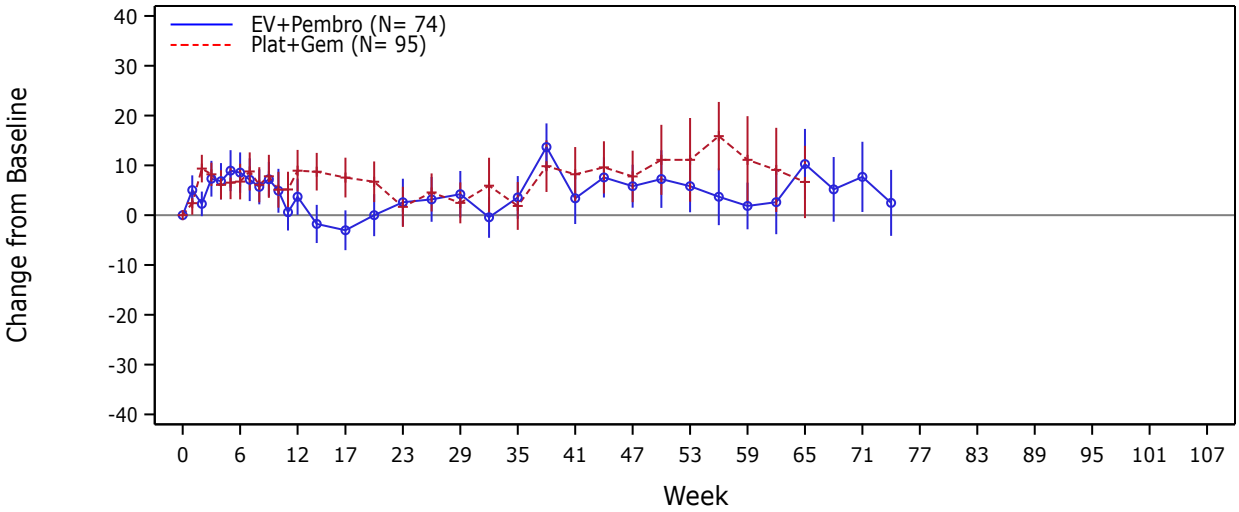
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.15.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Fatigue by Region - Analysis Set mITT 2

Region: Europe



Number of subjects

EV+Pembro	53	39	39	33	30	29	25	23	21	21	18	13	13
Plat+Gem	75	61	56	53	40	36	30	23	20	14	10	10	

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

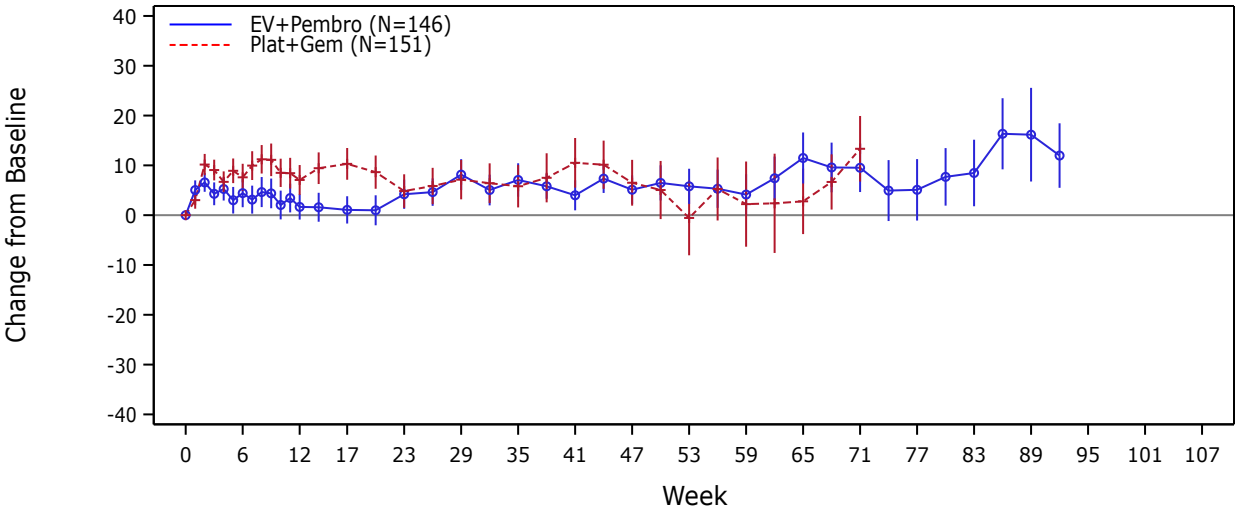
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.15.2.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Fatigue by Sex - Analysis Set mITT 2

Sex: Male



Number of subjects

EV+Pembro	119	93	87	84	74	71	66	64	50	48	43	30	28	24	21	11
Plat+Gem	123	98	88	82	62	53	44	37	29	20	15	12	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

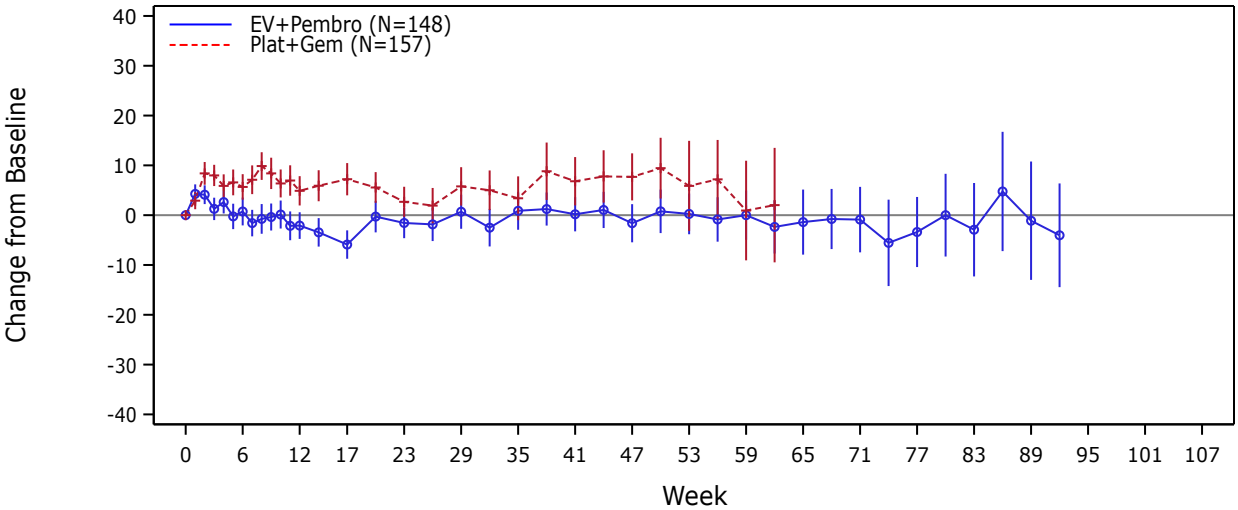
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.15.2.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Fatigue by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Visceral metastases



Number of subjects

EV+Pembro	119	90	85	81	71	64	63	60	48	44	38	24	25	23	19	10
Plat+Gem	128	98	84	80	58	50	36	31	26	17	12					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

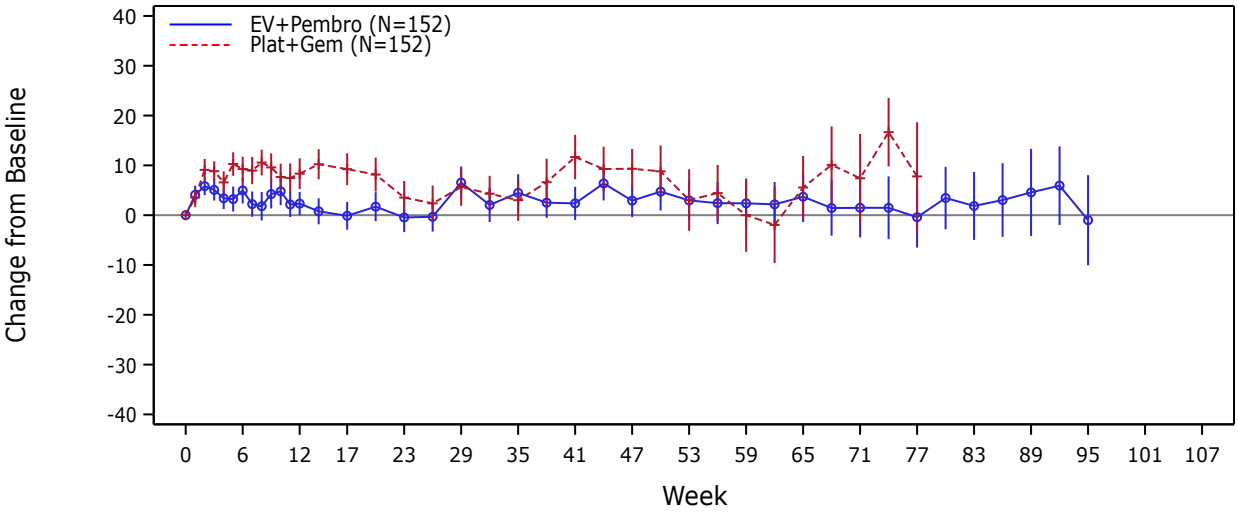
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.15.2.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Fatigue by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Absent



Number of subjects

EV+Pembro	120	94	91	84	73	68	62	61	57	45	42	33	30	27	24	17	11
Plat+Gem	125	102	88	83	66	59	48	40	31	22	18	14	12	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

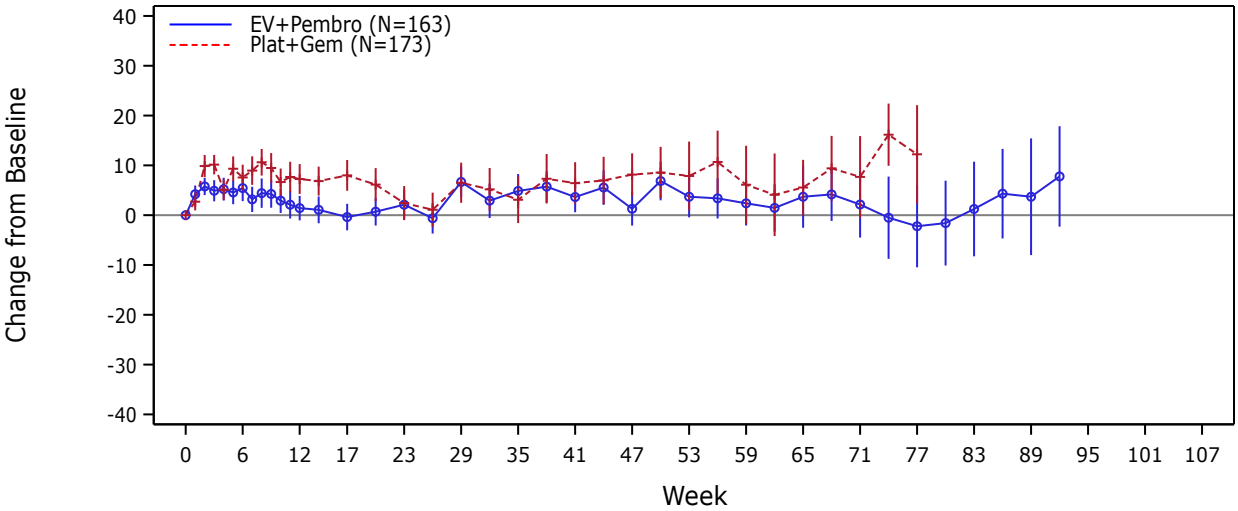
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.15.2.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Fatigue by Age - Analysis Set mITT 2

Age: >= 65 years



Number of subjects

EV+Pembro	128	98	94	87	74	70	64	61	52	45	42	27	26	20	18	12
Plat+Gem	143	113	98	89	64	58	43	38	30	24	20	16	13	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

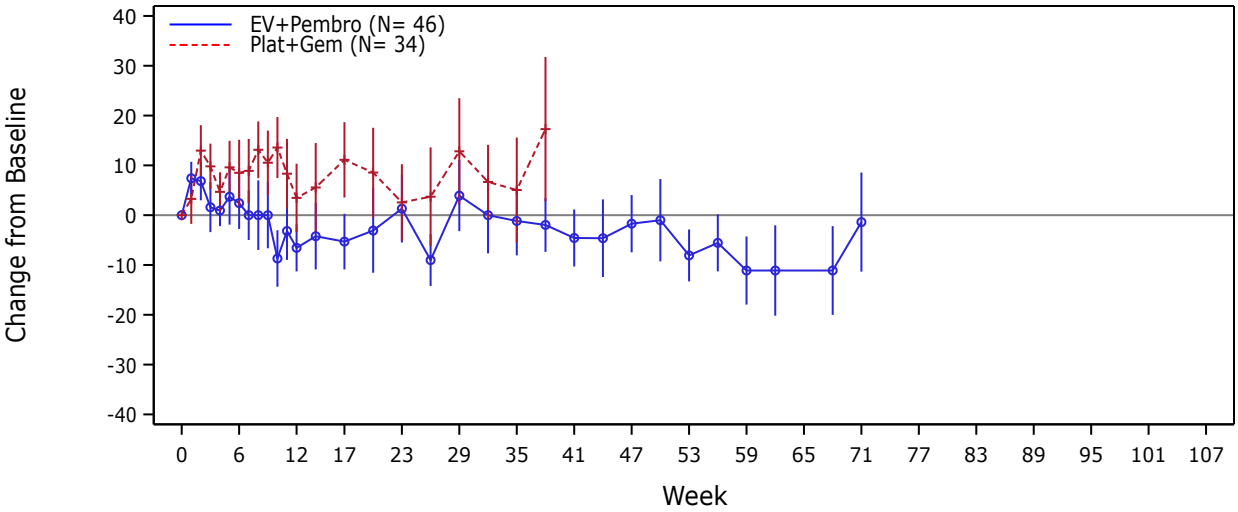
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.15.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Fatigue by Region - Analysis Set mITT 2

Region: North America



Number of subjects

EV+Pembro	33	23	22	23	17	17	19	17	13	11	12	8
Plat+Gem	27	17	16	17	13	13	11					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

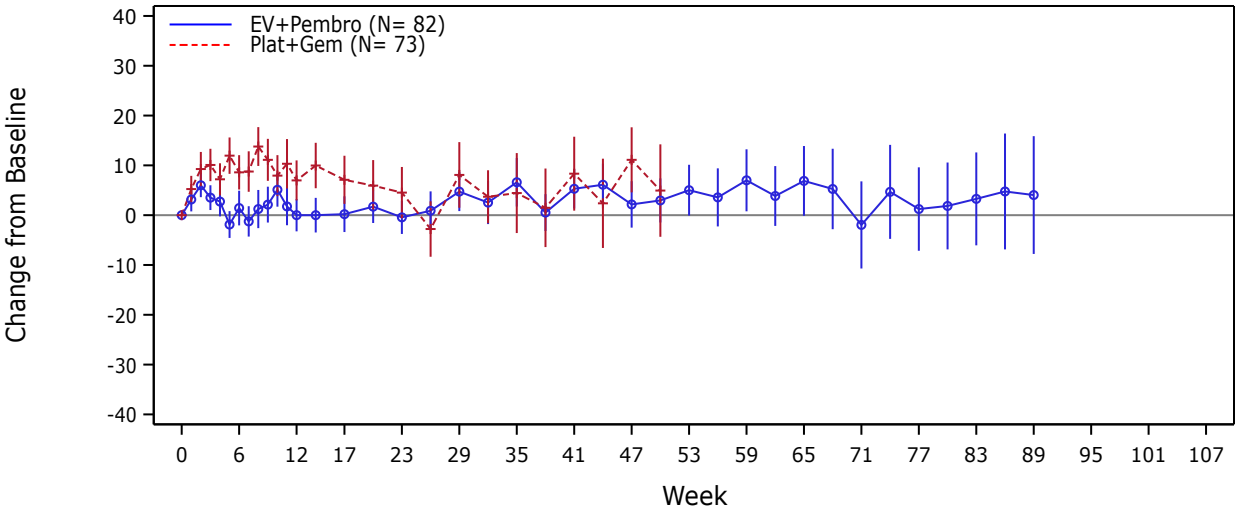
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.15.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Fatigue by Region - Analysis Set mITT 2

Region: Rest of World



Number of subjects

EV+Pembro	74	62	58	55	50	47	42	44	36	31	27	21	17	18	17	11
Plat+Gem	63	53	43	36	27	22	15	16	11							

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

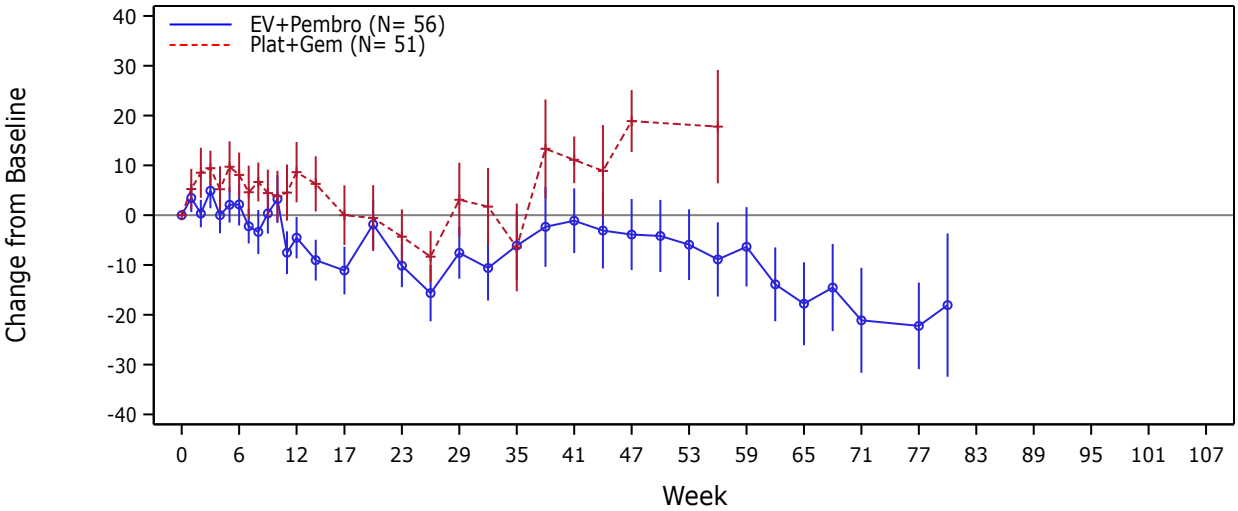
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.15.2.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Fatigue by Sex - Analysis Set mITT 2

Sex: Female



Number of subjects

EV+Pembro	41	31	32	27	23	22	20	20	20	15	14	10	10	9
Plat+Gem	42	33	27	24	18	18	12	10	10					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

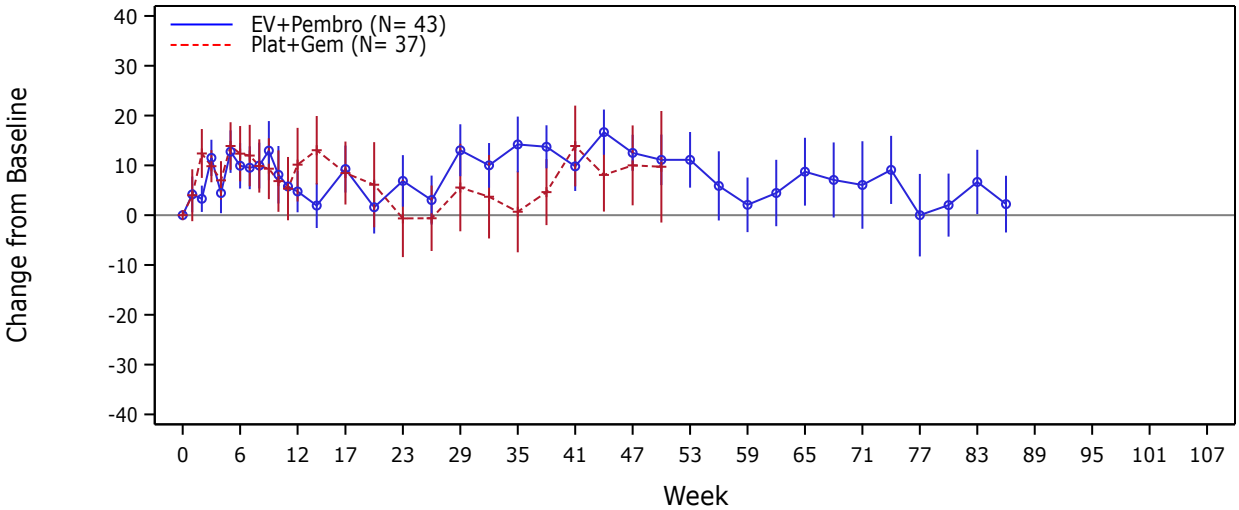
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.15.2.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Fatigue by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Lymph node only



Number of subjects

EV+Pembro	33	28	28	24	21	23	18	17	16	14	16	14	11	10	10
Plat+Gem	29	27	23	21	17	16	16	12	10						

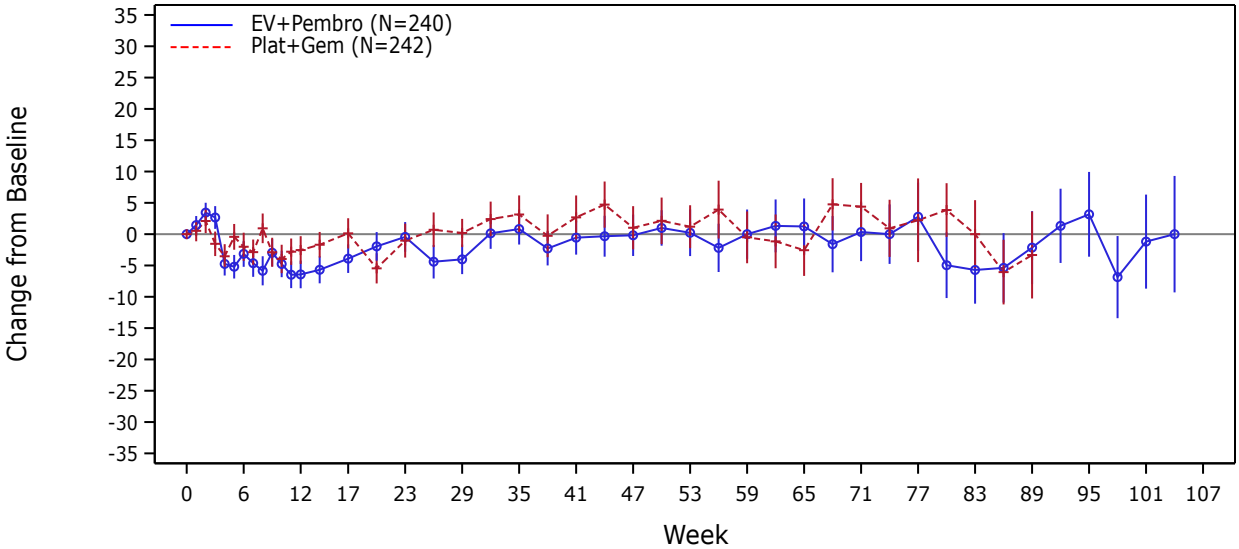
Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.16.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Pain - Analysis Set mITT 1



Number of subjects

EV+Pembro	206	170	171	162	151	145	122	119	94	74	68	54	49	42	35	31	21	14
Plat+Gem	188	149	138	130	97	86	69	56	49	42	33	26	19	15	12	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

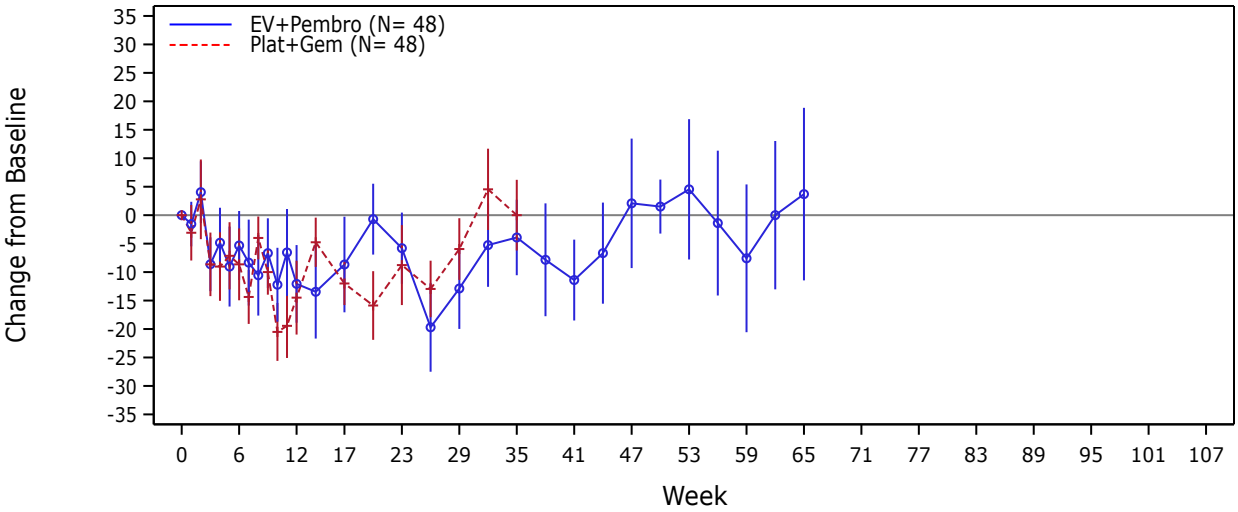
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.16.1.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Pain by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Present



Number of subjects

EV+Pembro	39	25	29	25	23	22	17	19	16	11	11	9
Plat+Gem	33	27	23	25	19	14	9					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

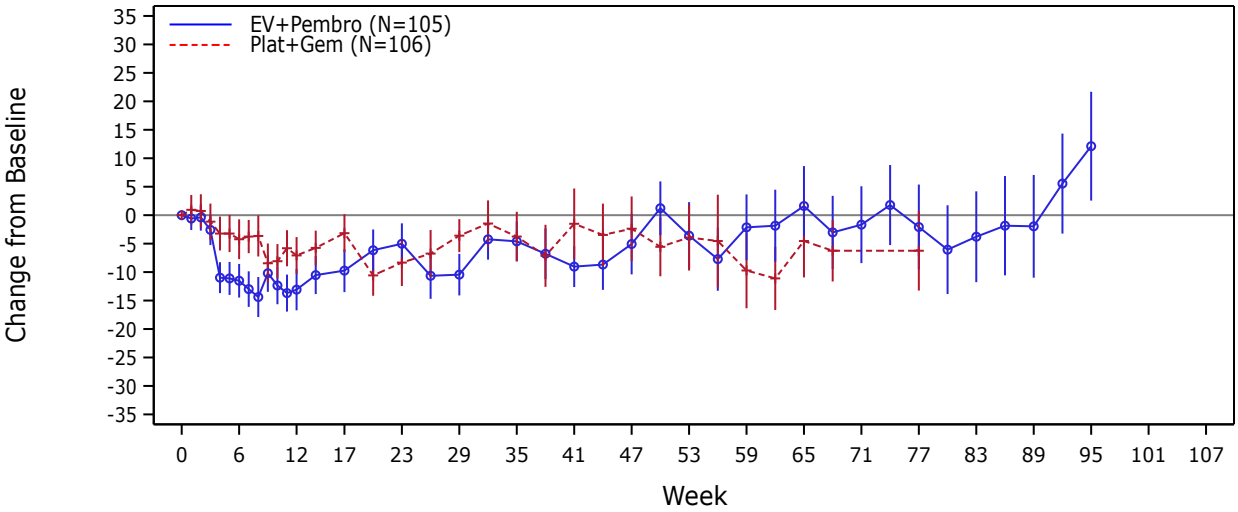
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.16.1.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Pain by Age - Analysis Set mITT 1

Age: < 65 years



Number of subjects

EV+Pembro	92	81	79	77	73	67	58	59	46	37	39	31	30	24	22	17	11
Plat+Gem	83	67	66	58	44	37	31	22	21	17	12	11		8			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

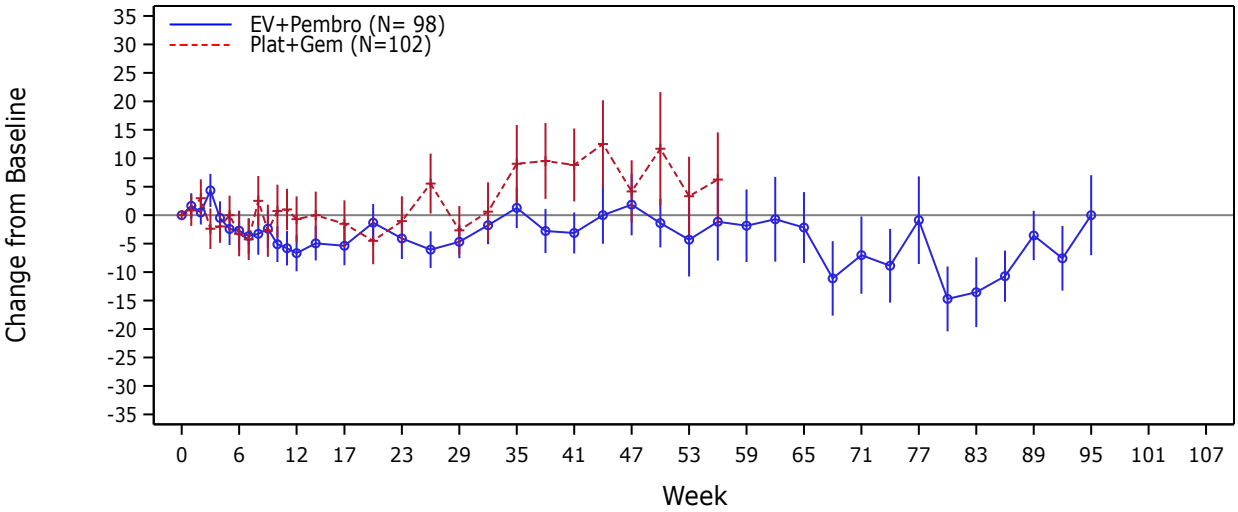
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.16.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Pain by Region - Analysis Set mITT 1

Region: Europe



Number of subjects

EV+Pembro	79	61	65	62	57	57	52	48	36	27	27	23	19	19	16	14	10
Plat+Gem	71	56	48	44	32	25	24	17	12	10							

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

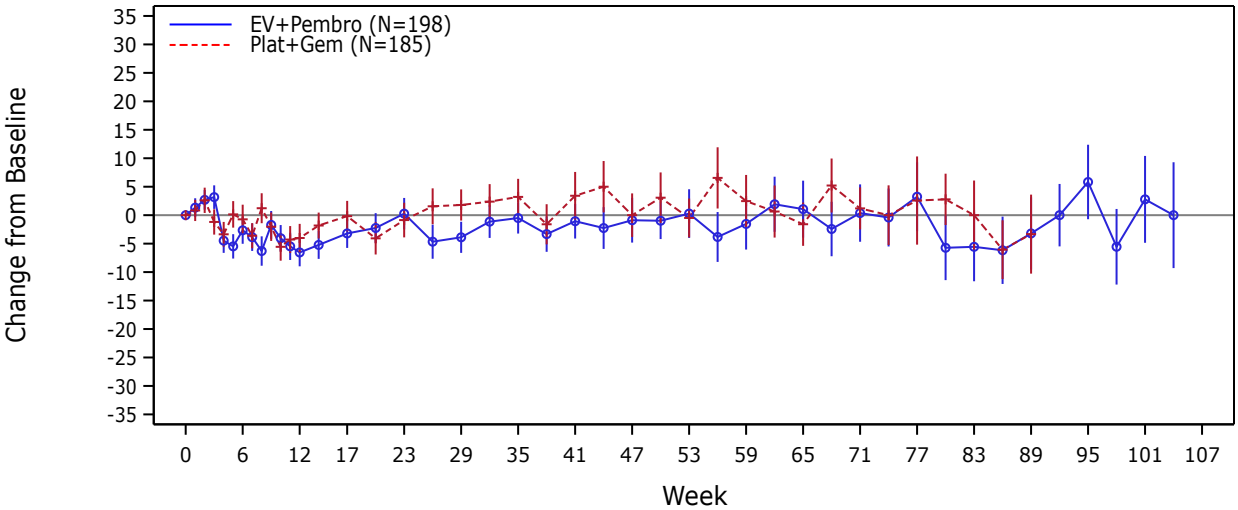
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.16.1.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Pain by Sex - Analysis Set mITT 1

Sex: Male



Number of subjects

EV+Pembro	170	138	140	130	122	120	100	94	75	59	54	47	45	36	30	26	20	12
Plat+Gem	146	114	108	101	78	65	52	44	38	34	27	21	14	13	10	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

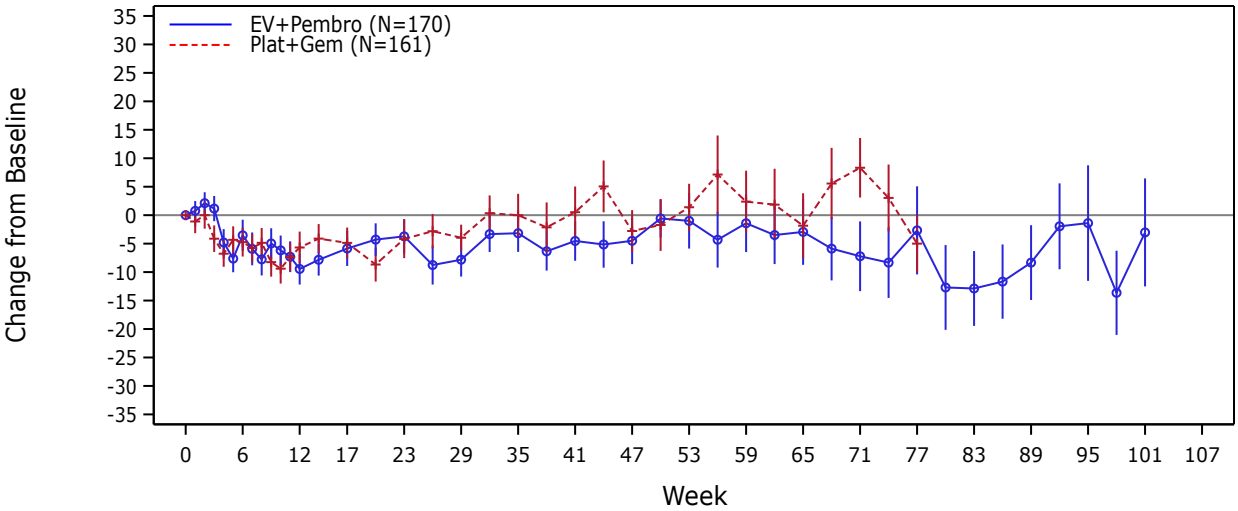
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.16.1.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Pain by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Visceral metastases



Number of subjects

EV+Pembro	146	113	120	111	103	98	79	81	63	50	47	34	30	25	22	20	12	11
Plat+Gem	129	102	91	89	68	59	44	32	30	24	21	18	12	10				

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

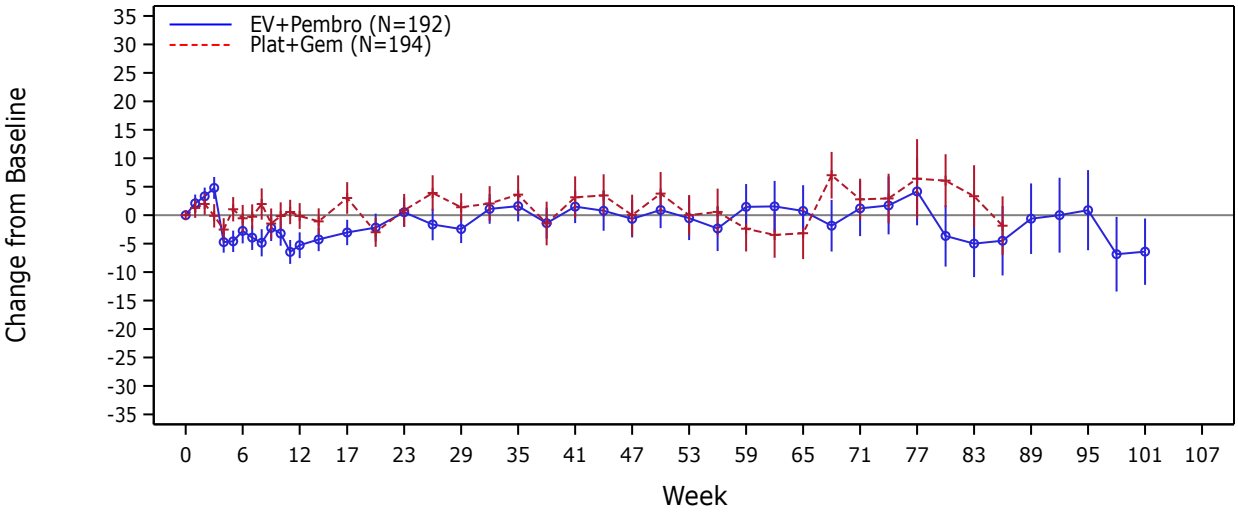
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.16.1.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Pain by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Absent



Number of subjects

EV+Pembro	167	145	142	137	128	123	105	100	78	63	57	45	42	36	30	27	19	13
Plat+Gem	155	122	115	105	78	72	60	53	44	37	28	21	18	13	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

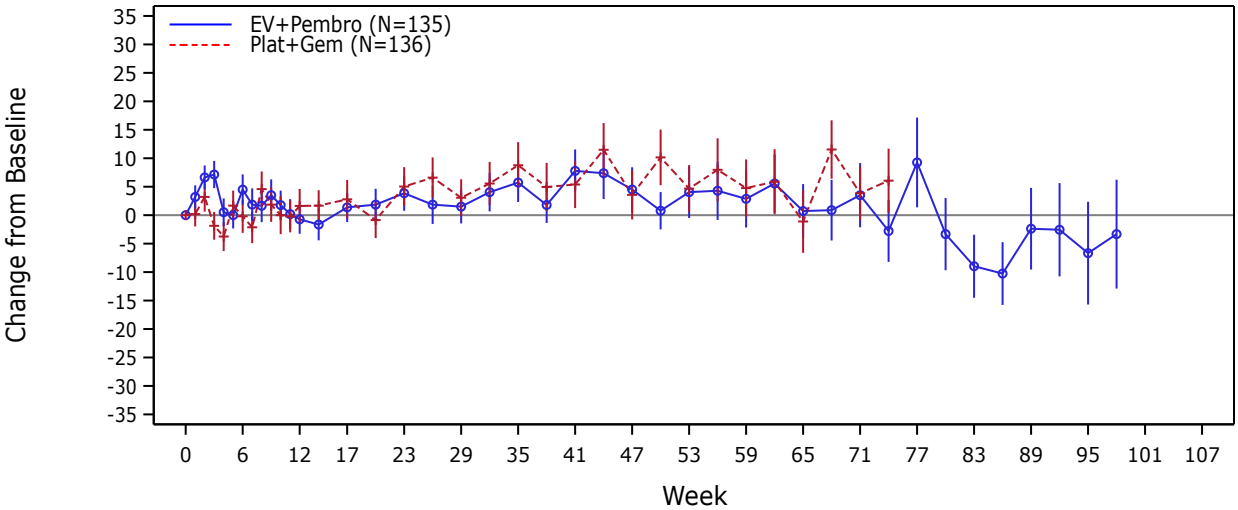
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.16.1.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Pain by Age - Analysis Set mITT 1

Age: >= 65 years



Number of subjects

EV+Pembro	114	89	92	85	78	78	64	60	48	37	29	23	19	18	13	14	10
Plat+Gem	105	82	72	72	53	49	38	34	28	25	21	15	13				

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

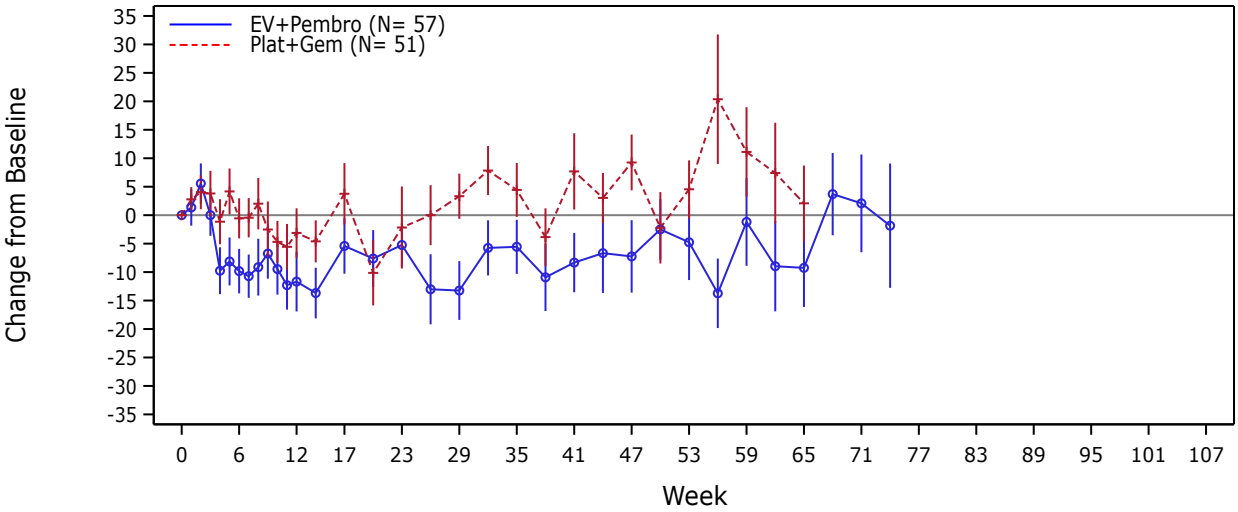
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.16.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Pain by Region - Analysis Set mITT 1

Region: North America



Number of subjects

EV+Pembro	47	39	40	37	35	34	30	24	23	14	14	9	8
Plat+Gem	42	30	32	31	23	25	15	13	9	11	9	8	

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

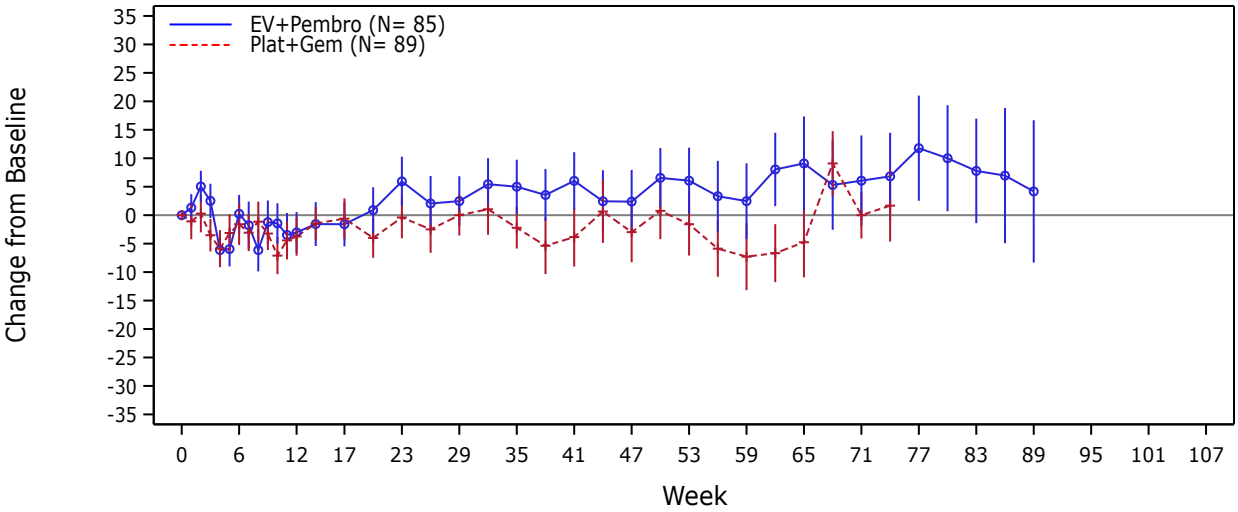
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.16.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Pain by Region - Analysis Set mITT 1

Region: Rest of World



Number of subjects

EV+Pembro	80	70	66	63	59	54	40	47	35	33	27	22	22	17	15	12
Plat+Gem	75	63	58	55	42	36	30	26	28	21	16	14	12			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

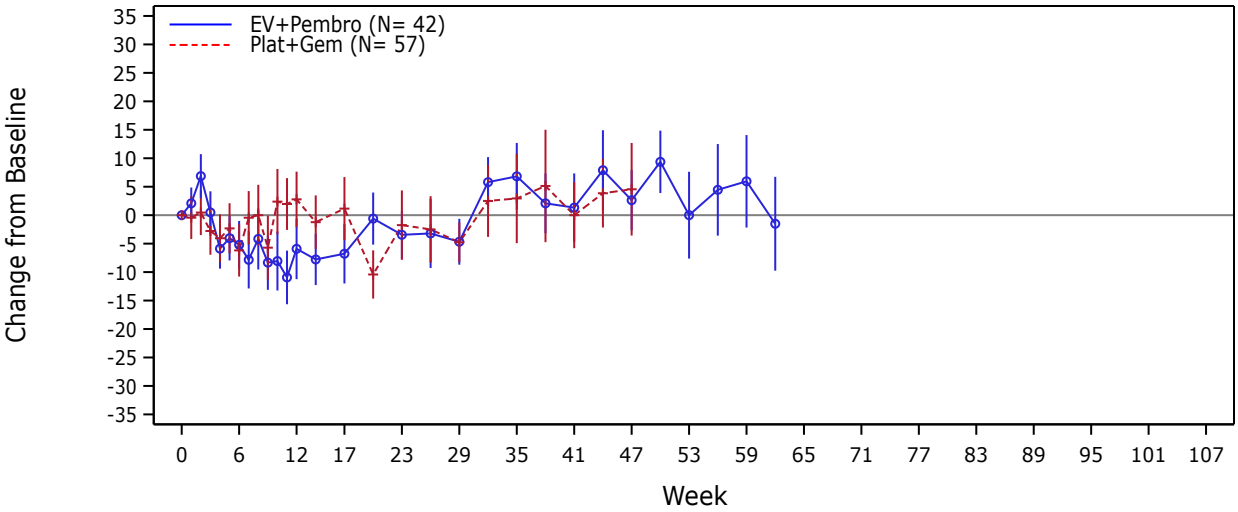
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.16.1.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Pain by Sex - Analysis Set mITT 1

Sex: Female



Number of subjects

EV+Pembro	36	32	31	32	29	25	22	25	19	15	14
Plat+Gem	42	35	30	29	19	21	17	12	11		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

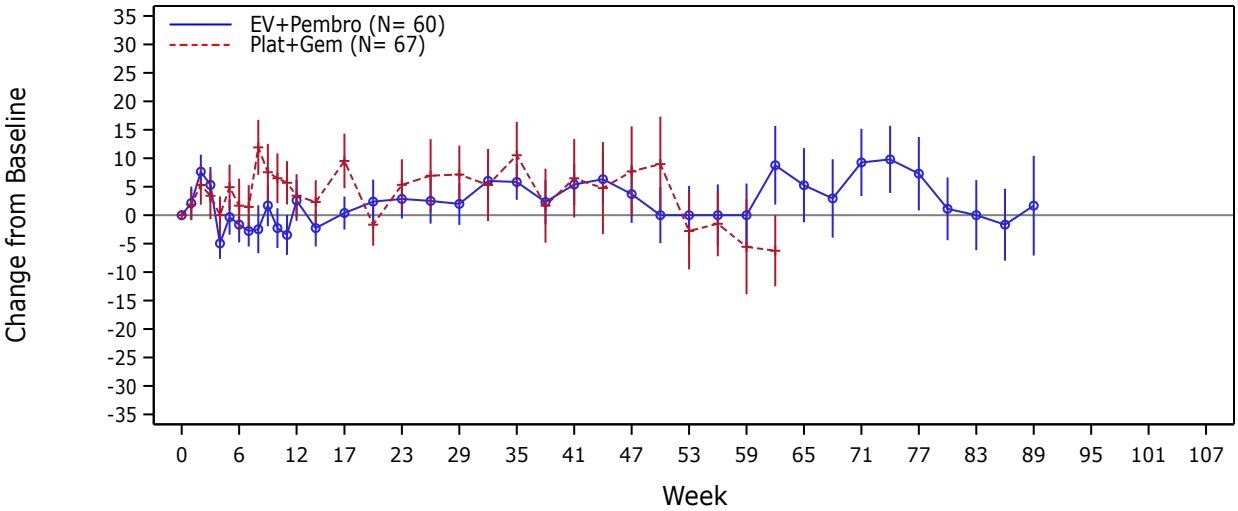
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.16.1.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Pain by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Lymph node only



Number of subjects

EV+Pembro	53	50	45	44	41	42	40	34	27	22	19	19	18	16	12	10
Plat+Gem	49	40	39	35	25	21	19	18	13	12	9					

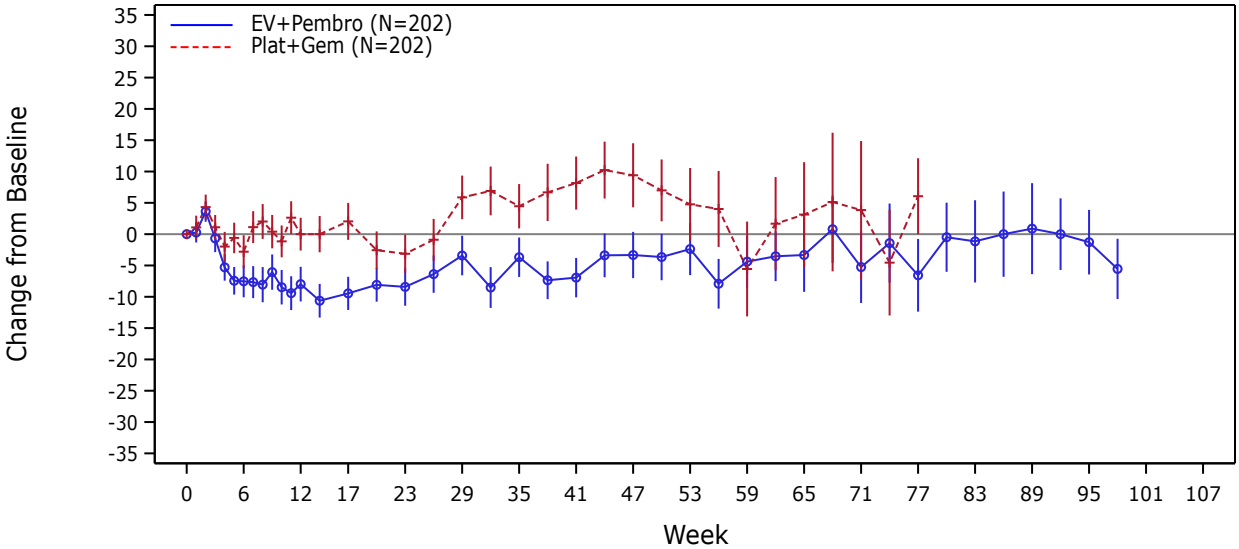
Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.16.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Pain - Analysis Set mITT 2



Number of subjects

EV+Pembro	160	124	119	111	97	93	86	84	70	63	57	40	38	33	29	19	13
Plat+Gem	165	131	115	106	80	71	56	47	39	28	21	16	13	11			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

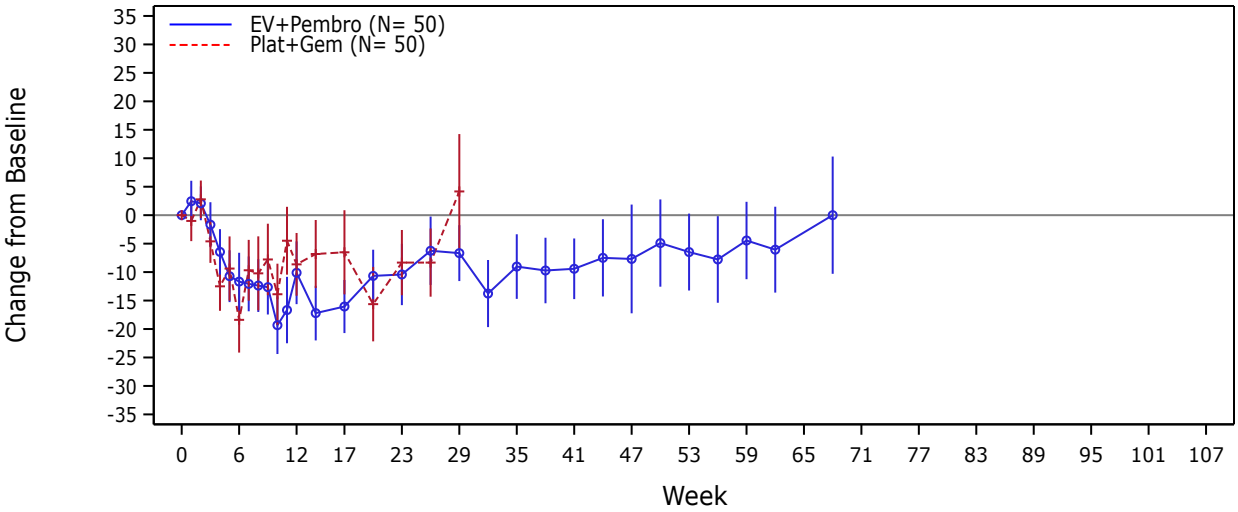
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.16.2.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Pain by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Present



Number of subjects

EV+Pembro	40	30	28	27	24	25	24	23	13	18	15
Plat+Gem	40	29	27	23	14	12					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

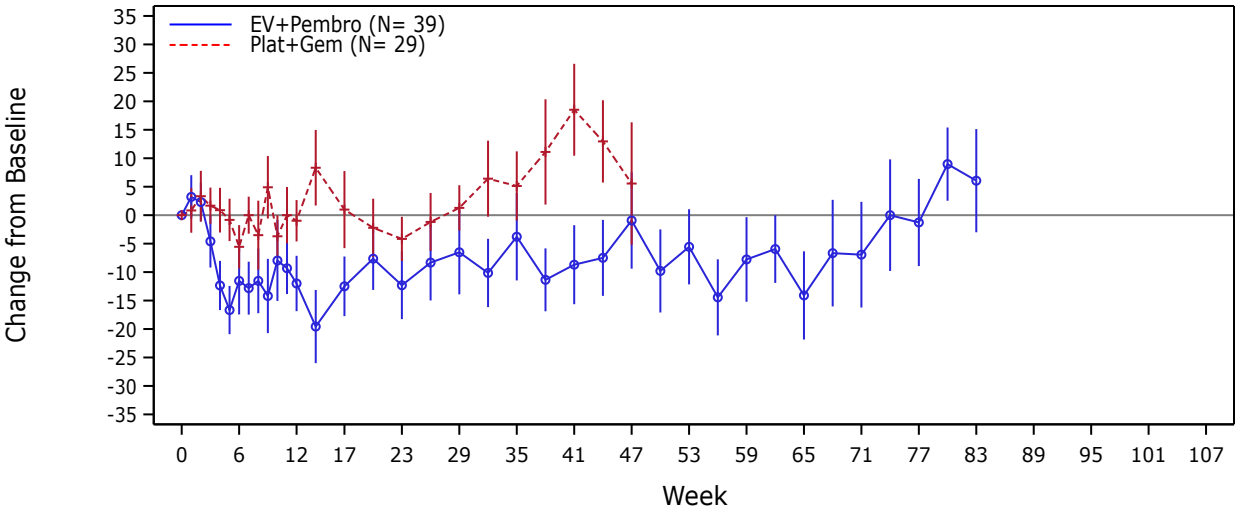
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.16.2.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Pain by Age - Analysis Set mITT 2

Age: < 65 years



Number of subjects

EV+Pembro	32	26	25	24	23	23	22	23	18	18	15	13	12	13	11
Plat+Gem	22	18	17	17	16	13	13	9	9						

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

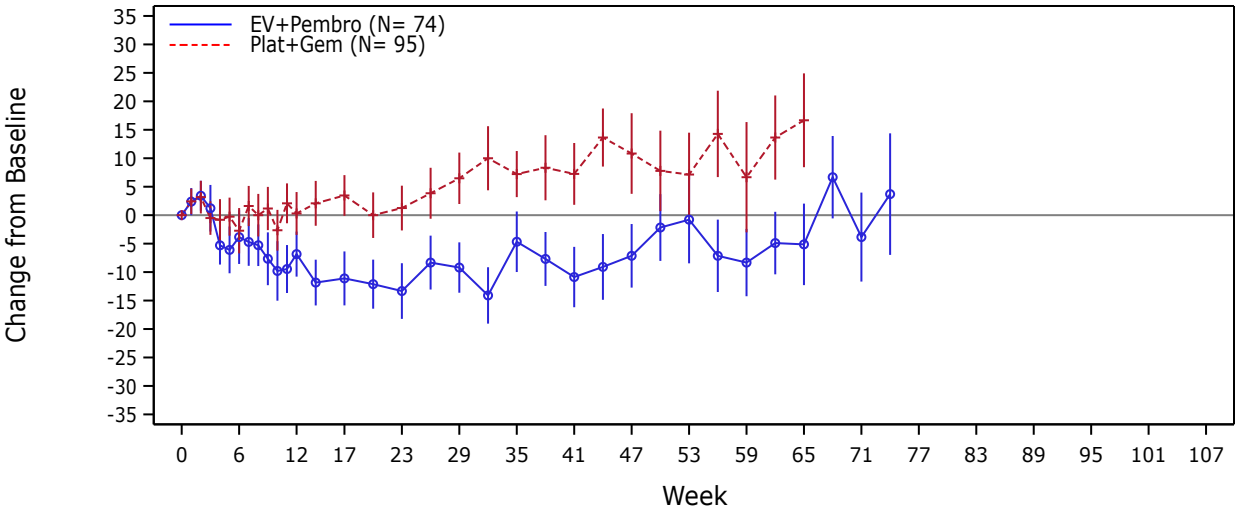
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.16.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Pain by Region - Analysis Set mITT 2

Region: Europe



Number of subjects

EV+Pembro	53	39	39	33	30	29	25	23	21	21	18	13	13
Plat+Gem	75	61	56	53	40	36	30	23	20	14	10	10	

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

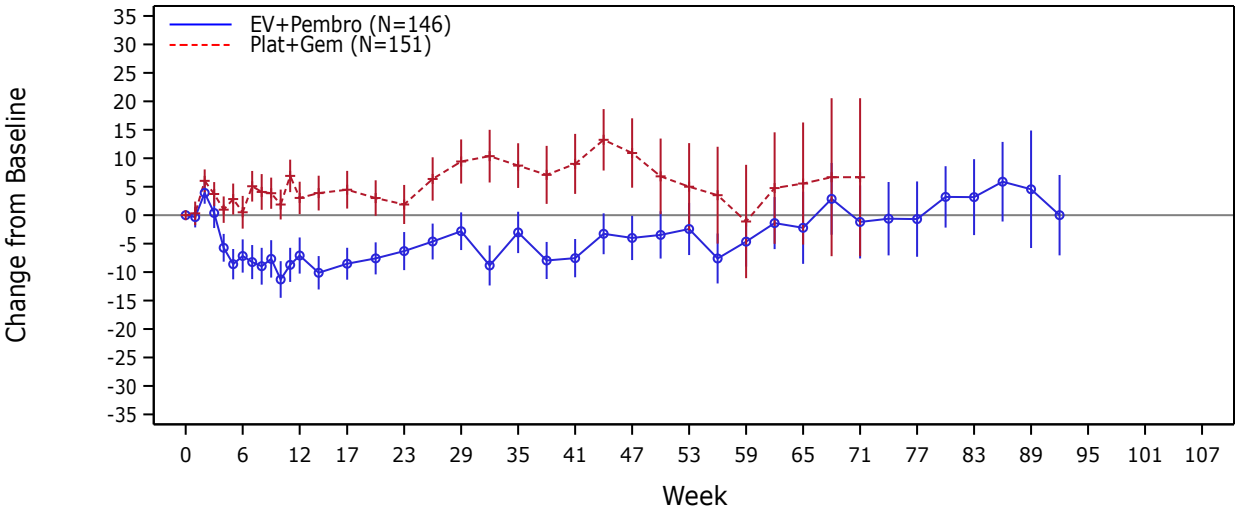
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.16.2.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Pain by Sex - Analysis Set mITT 2

Sex: Male



Number of subjects

EV+Pembro	119	93	87	84	74	71	66	64	50	48	43	30	28	24	21	11
Plat+Gem	123	98	88	82	62	53	44	37	29	20	15	12	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

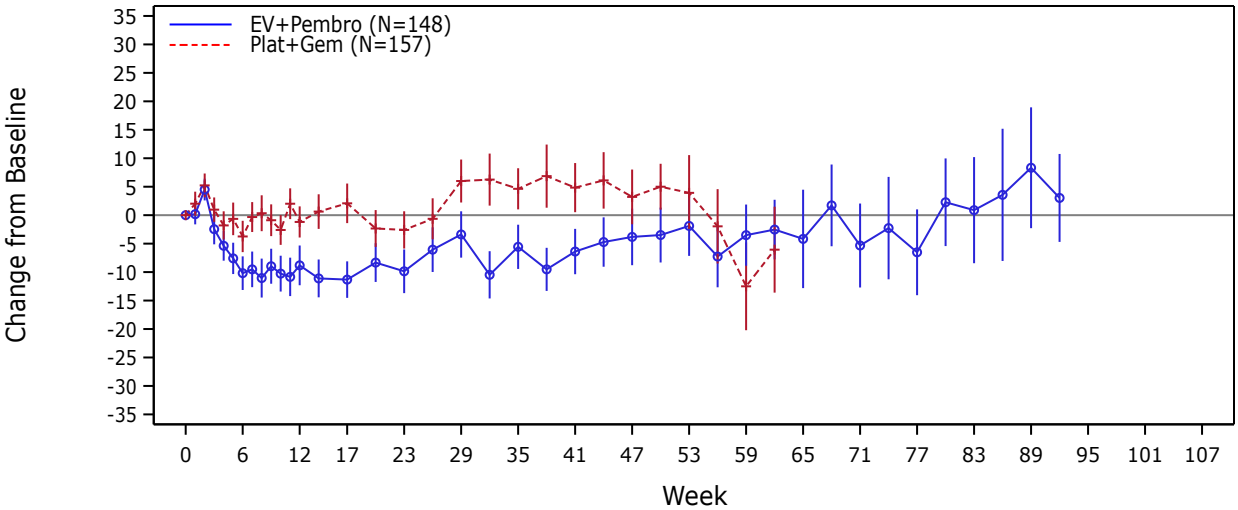
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.16.2.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Pain by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Visceral metastases



Number of subjects

EV+Pembro	119	90	85	81	71	64	63	60	48	44	38	24	25	23	19	10
Plat+Gem	128	98	84	80	58	50	36	31	26	17	12					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

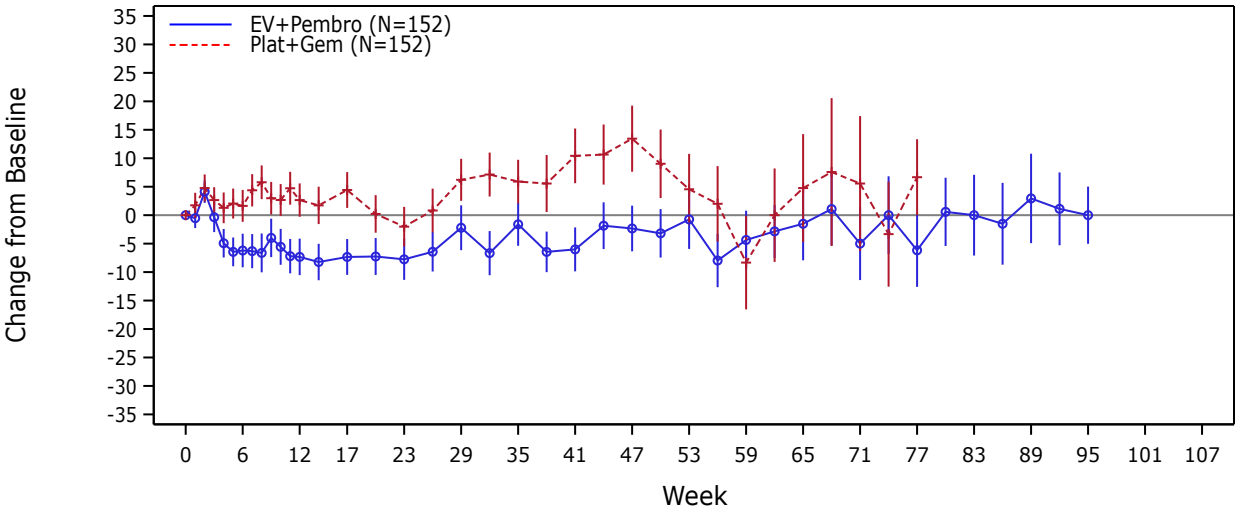
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.16.2.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Pain by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Absent



Number of subjects

EV+Pembro	120	94	91	84	73	68	62	61	57	45	42	33	30	27	24	17	11
Plat+Gem	125	102	88	83	66	59	48	40	31	22	18	14	12	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

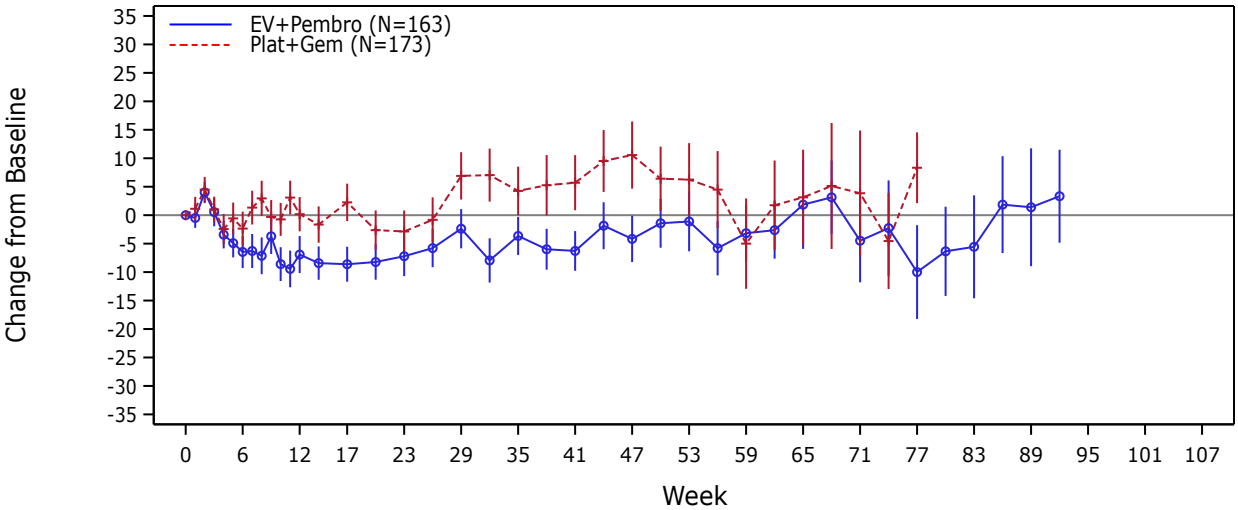
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.16.2.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Pain by Age - Analysis Set mITT 2

Age: >= 65 years



Number of subjects

EV+Pembro	128	98	94	87	74	70	64	61	52	45	42	27	26	20	18	12
Plat+Gem	143	113	98	89	64	58	43	38	30	24	20	16	13	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

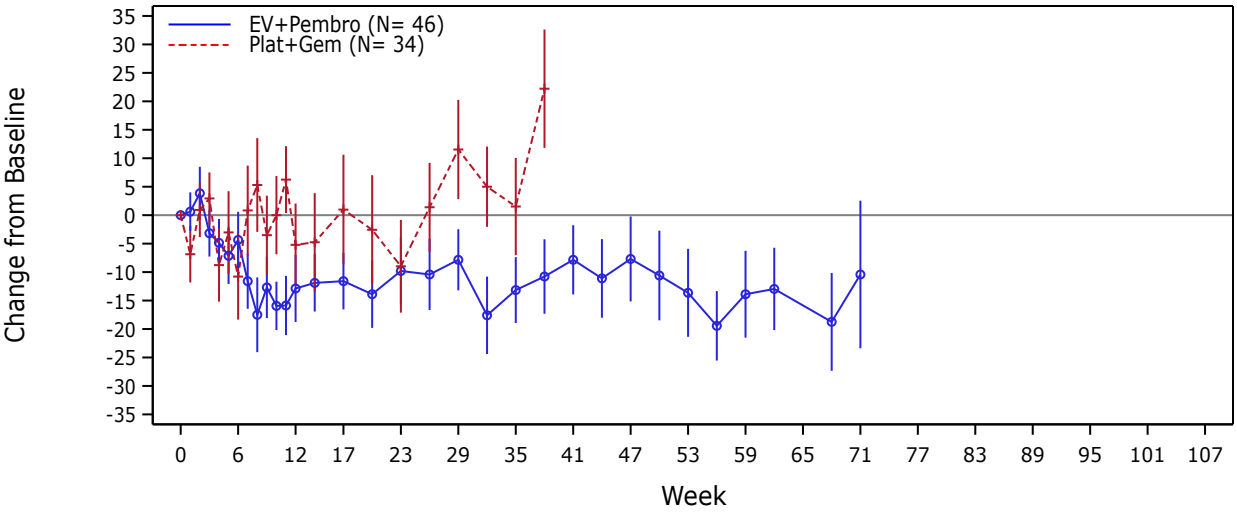
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.16.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Pain by Region - Analysis Set mITT 2

Region: North America



Number of subjects

EV+Pembro	33	23	22	23	17	17	19	17	13	11	12	8
Plat+Gem	27	17	16	17	13	13	11					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

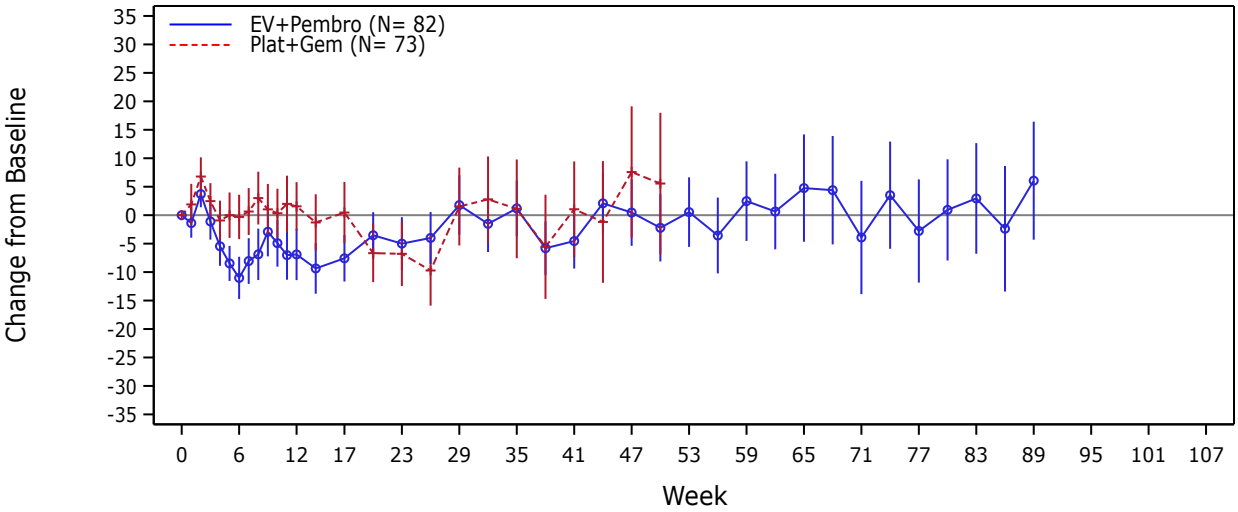
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.16.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Pain by Region - Analysis Set mITT 2

Region: Rest of World



Number of subjects

EV+Pembro	74	62	58	55	50	47	42	44	36	31	27	21	17	18	17	11
Plat+Gem	63	53	43	36	27	22	15	16	11							

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

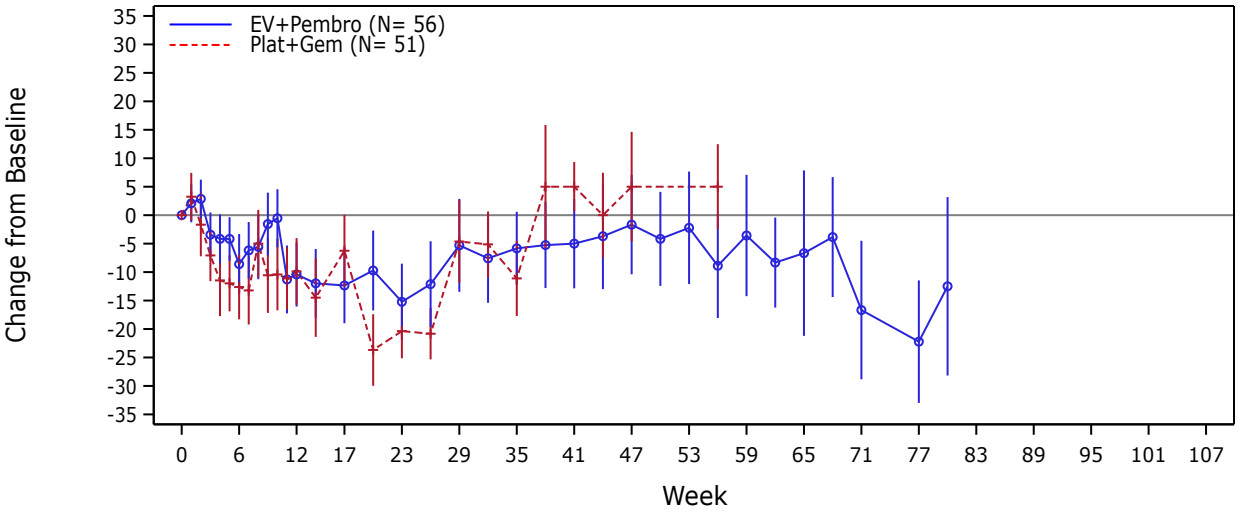
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.16.2.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Pain by Sex - Analysis Set mITT 2

Sex: Female



Number of subjects

EV+Pembro	41	31	32	27	23	22	20	20	20	15	14	10	10	9
Plat+Gem	42	33	27	24	18	18	12	10	10					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

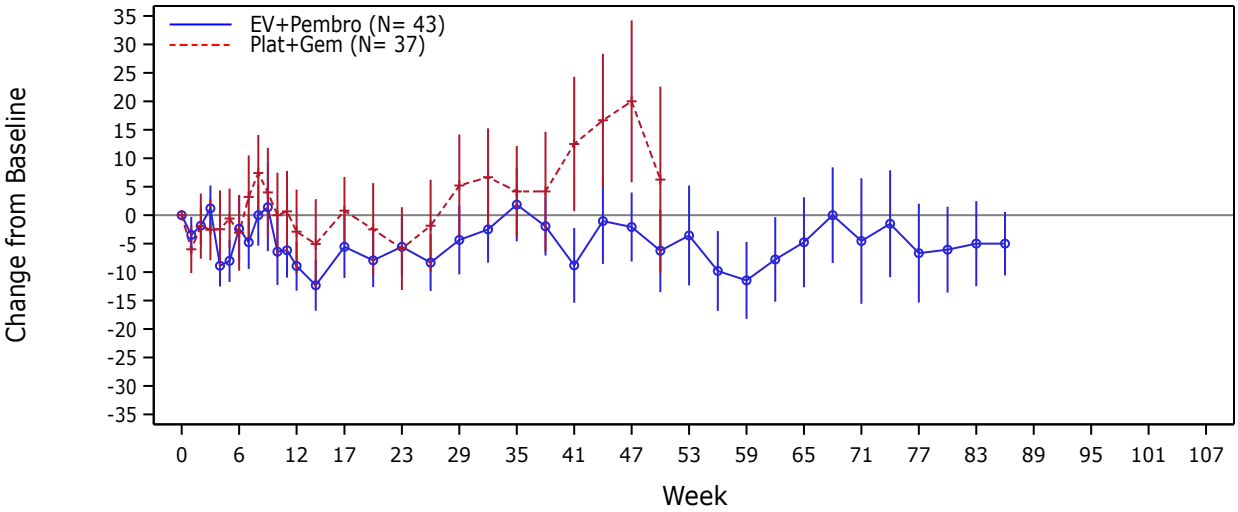
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.16.2.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Pain by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Lymph node only



Number of subjects

EV+Pembro	33	28	28	24	21	23	18	17	16	14	16	14	11	10	10
Plat+Gem	29	27	23	21	17	16	16	12	10						

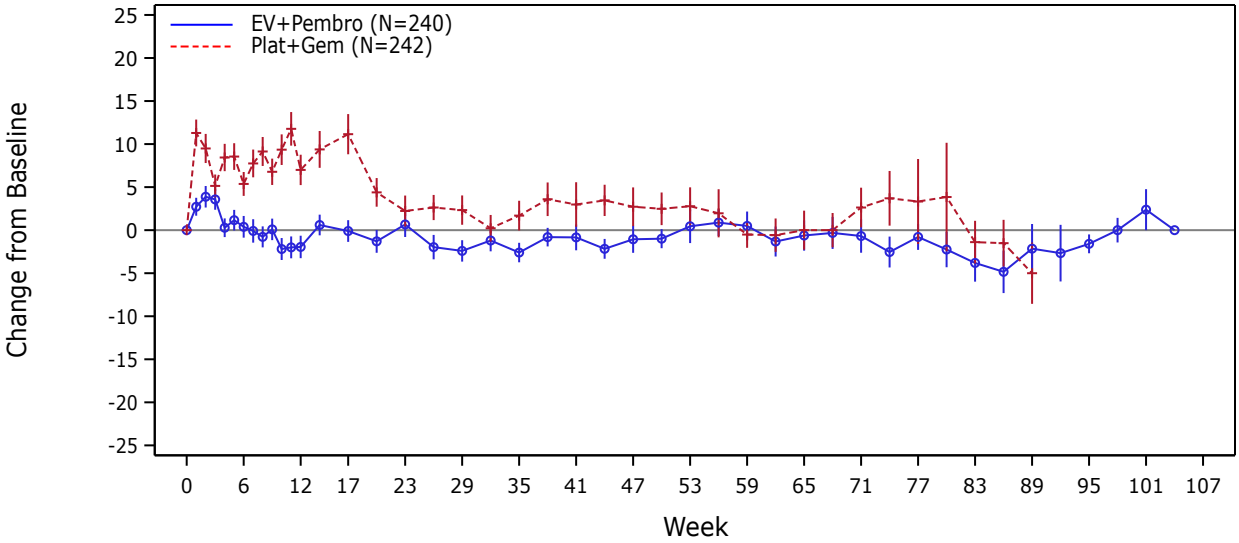
Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.17.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Nausea and Vomiting - Analysis Set mITT 1



Number of subjects

EV+Pembro	206	170	171	162	151	145	122	119	94	74	68	54	49	42	35	31	21	14
Plat+Gem	188	149	138	130	97	86	69	56	49	42	33	26	19	15	12	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

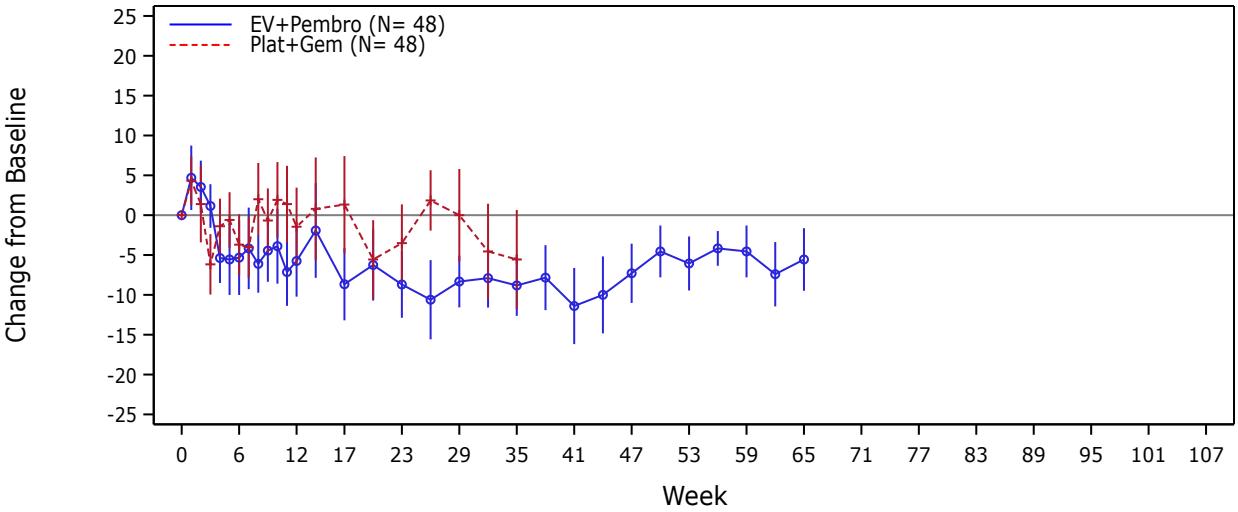
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.17.1.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Nausea and Vomiting by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Present



Number of subjects

EV+Pembro	39	25	29	25	23	22	17	19	16	11	11	9
Plat+Gem	33	27	23	25	19	14	9					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

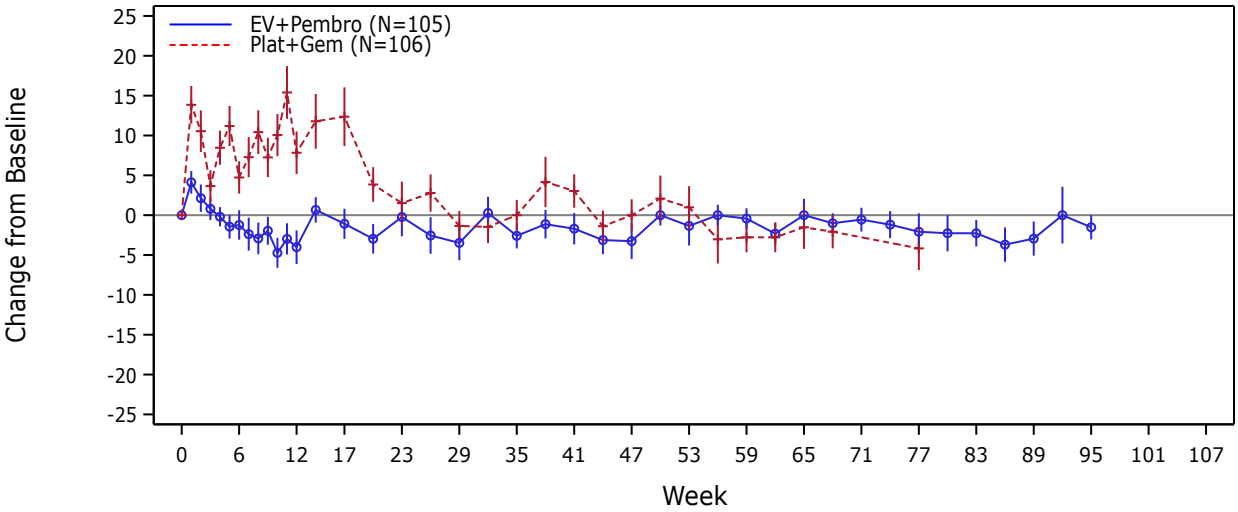
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.17.1.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Nausea and Vomiting by Age - Analysis Set mITT 1

Age: < 65 years



Number of subjects

EV+Pembro	92	81	79	77	73	67	58	59	46	37	39	31	30	24	22	17	11
Plat+Gem	83	67	66	58	44	37	31	22	21	17	12	11		8			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

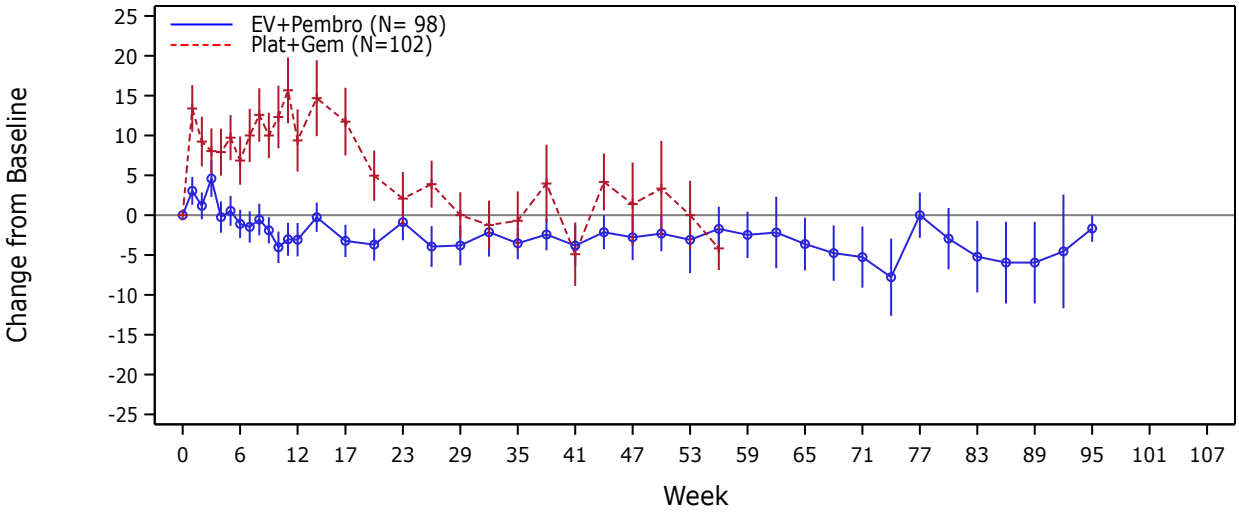
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.17.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Nausea and Vomiting by Region - Analysis Set mITT 1

Region: Europe



Number of subjects

EV+Pembro	79	61	65	62	57	57	52	48	36	27	27	23	19	19	16	14	10
Plat+Gem	71	56	48	44	32	25	24	17	12	10							

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

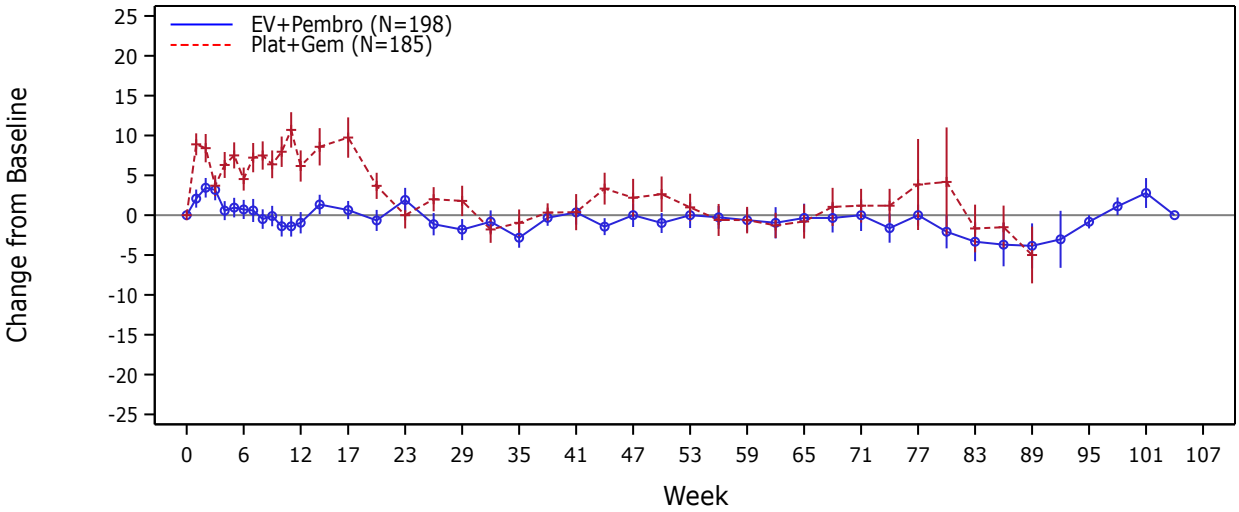
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.17.1.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Nausea and Vomiting by Sex - Analysis Set mITT 1

Sex: Male



Number of subjects

EV+Pembro	170	138	140	130	122	120	100	94	75	59	54	47	45	36	30	26	20	12
Plat+Gem	146	114	108	101	78	65	52	44	38	34	27	21	14	13	10	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

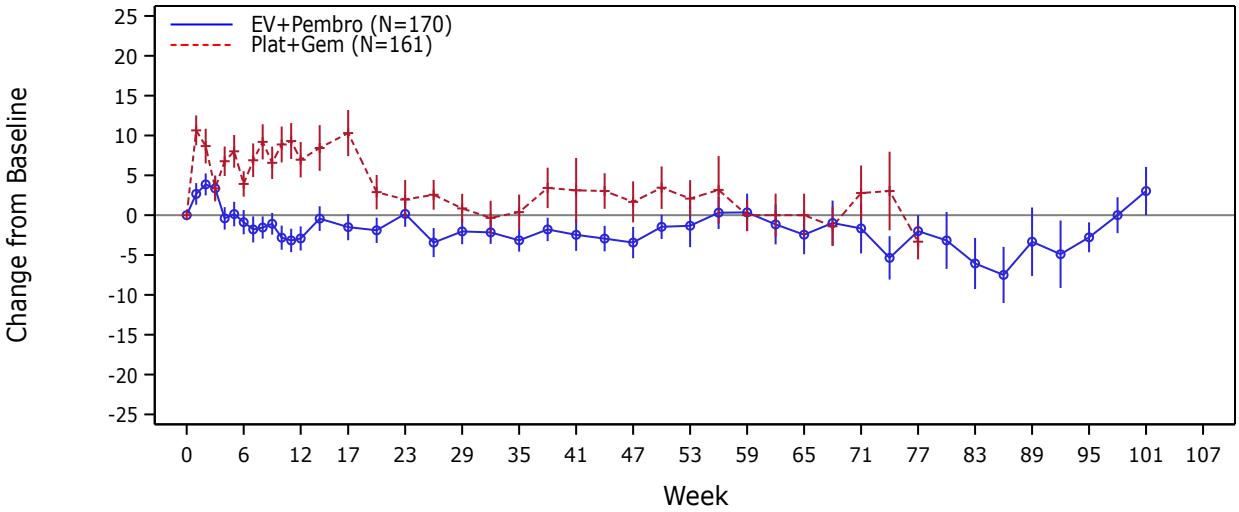
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.17.1.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Nausea and Vomiting by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Visceral metastases



Number of subjects

EV+Pembro	146	113	120	111	103	98	79	81	63	50	47	34	30	25	22	20	12	11
Plat+Gem	129	102	91	89	68	59	44	32	30	24	21	18	12	10				

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

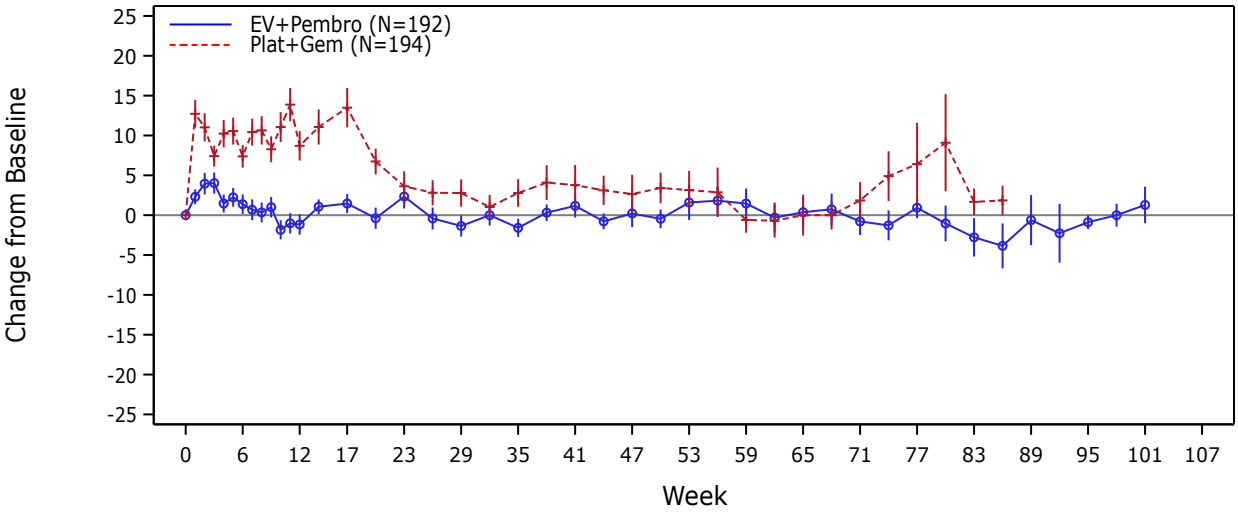
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.17.1.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Nausea and Vomiting by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Absent



Number of subjects

EV+Pembro	167	145	142	137	128	123	105	100	78	63	57	45	42	36	30	27	19	13
Plat+Gem	155	122	115	105	78	72	60	53	44	37	28	21	18	13	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

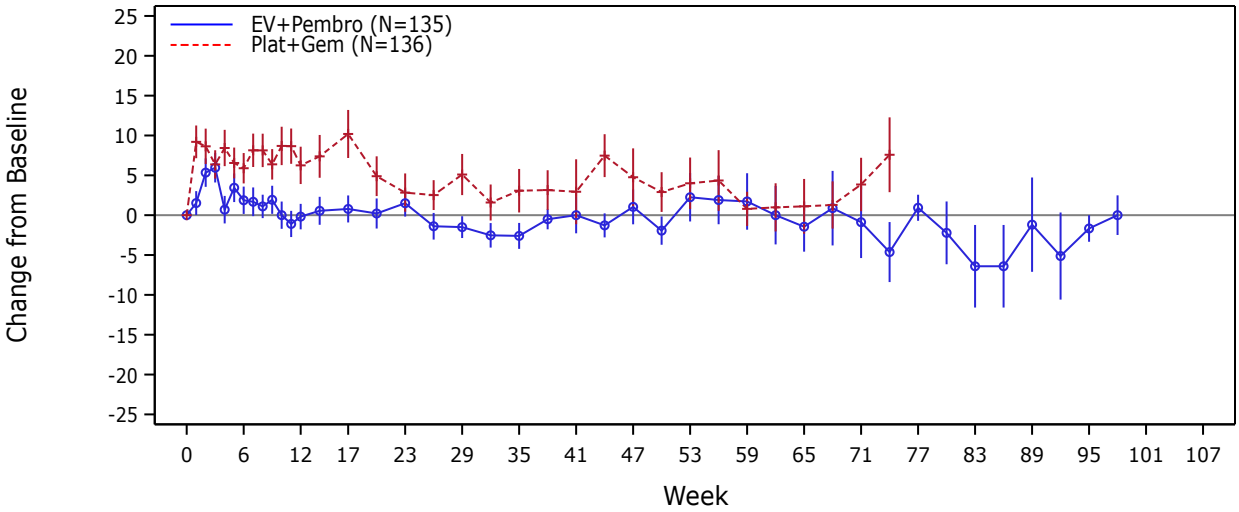
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.17.1.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Nausea and Vomiting by Age - Analysis Set mITT 1

Age: >= 65 years



Number of subjects

EV+Pembro	114	89	92	85	78	78	64	60	48	37	29	23	19	18	13	14	10
Plat+Gem	105	82	72	72	53	49	38	34	28	25	21	15	13				

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

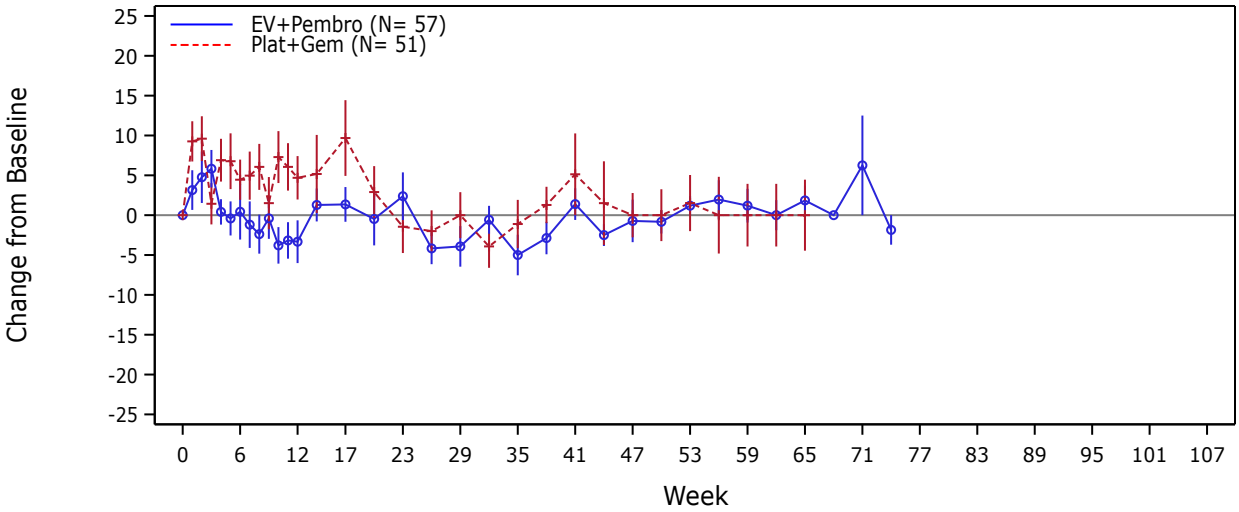
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.17.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Nausea and Vomiting by Region - Analysis Set mITT 1

Region: North America



Number of subjects

EV+Pembro	47	39	40	37	35	34	30	24	23	14	14	9	8
Plat+Gem	42	30	32	31	23	25	15	13	9	11	9	8	

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

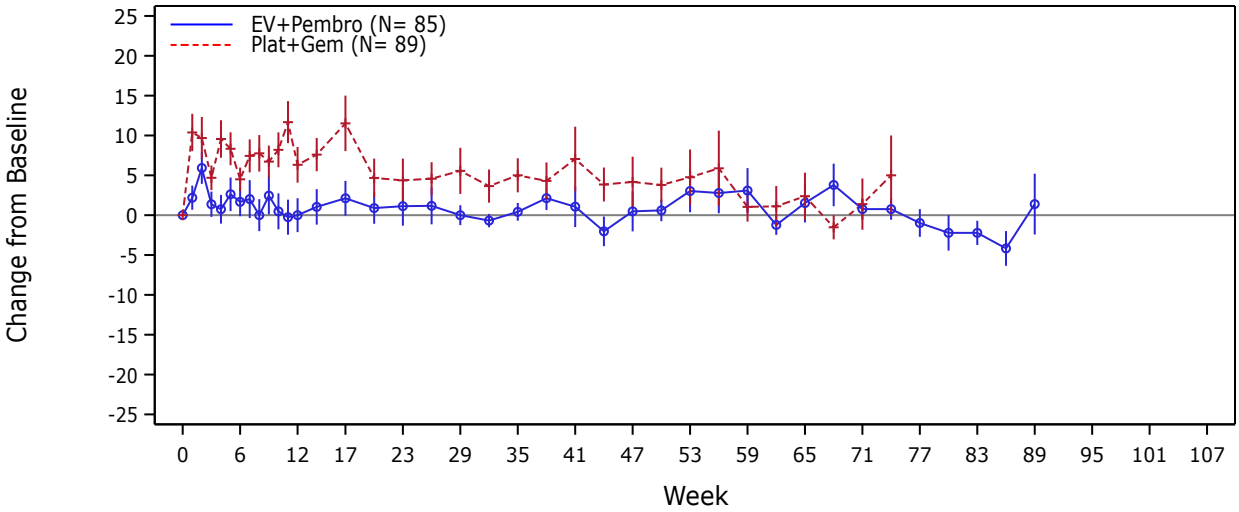
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.17.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Nausea and Vomiting by Region - Analysis Set mITT 1

Region: Rest of World



Number of subjects

EV+Pembro	80	70	66	63	59	54	40	47	35	33	27	22	22	17	15	12
Plat+Gem	75	63	58	55	42	36	30	26	28	21	16	14	12			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

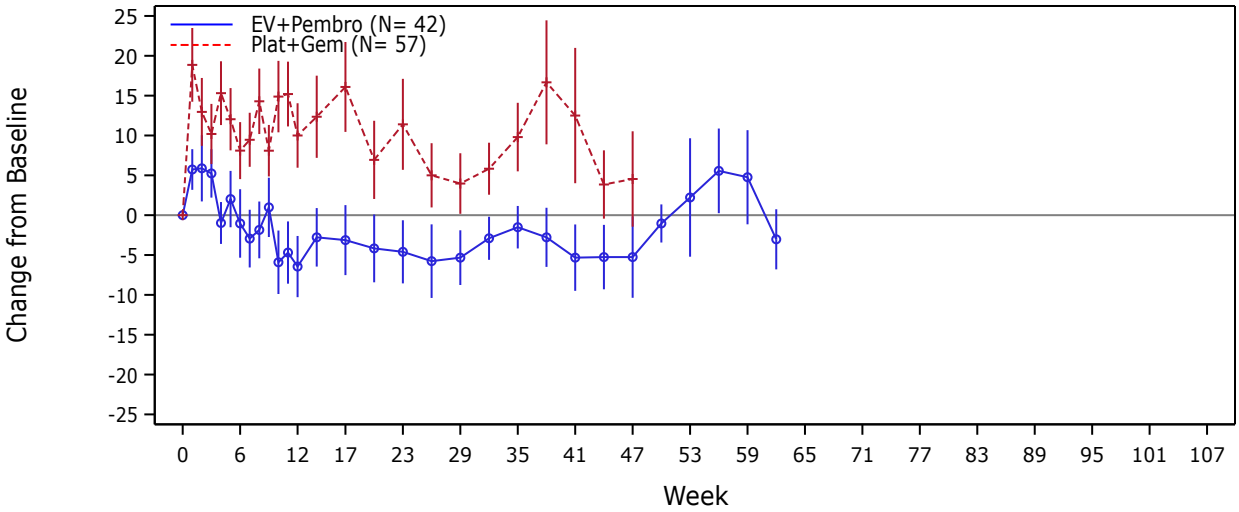
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.17.1.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Nausea and Vomiting by Sex - Analysis Set mITT 1

Sex: Female



Number of subjects

EV+Pembro	36	32	31	32	29	25	22	25	19	15	14
Plat+Gem	42	35	30	29	19	21	17	12	11		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

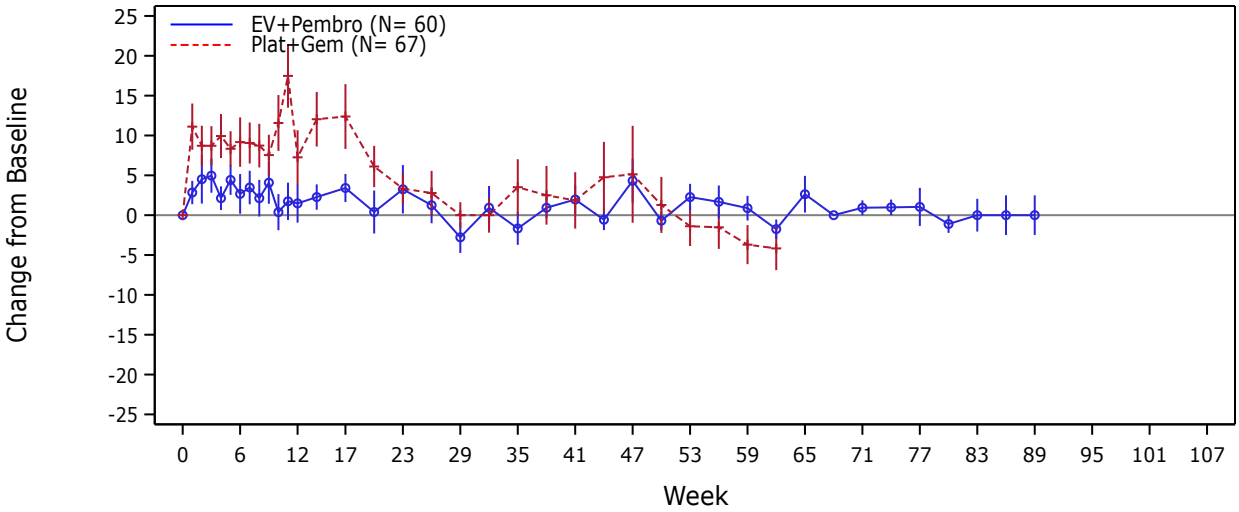
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.17.1.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Nausea and Vomiting by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Lymph node only



Number of subjects

EV+Pembro	53	50	45	44	41	42	40	34	27	22	19	19	18	16	12	10
Plat+Gem	49	40	39	35	25	21	19	18	13	12	9					

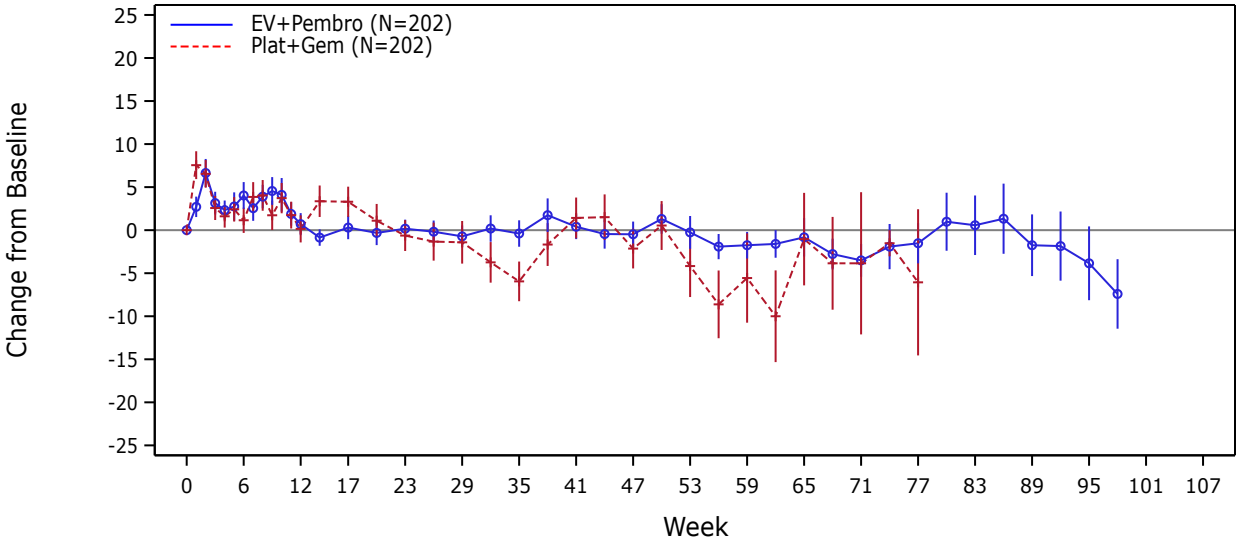
Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.17.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Nausea and Vomiting - Analysis Set mITT 2



Number of subjects

EV+Pembro	160	124	119	111	97	93	86	84	70	63	57	40	38	33	29	19	13
Plat+Gem	165	131	115	106	80	71	56	47	39	28	21	16	13	11			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

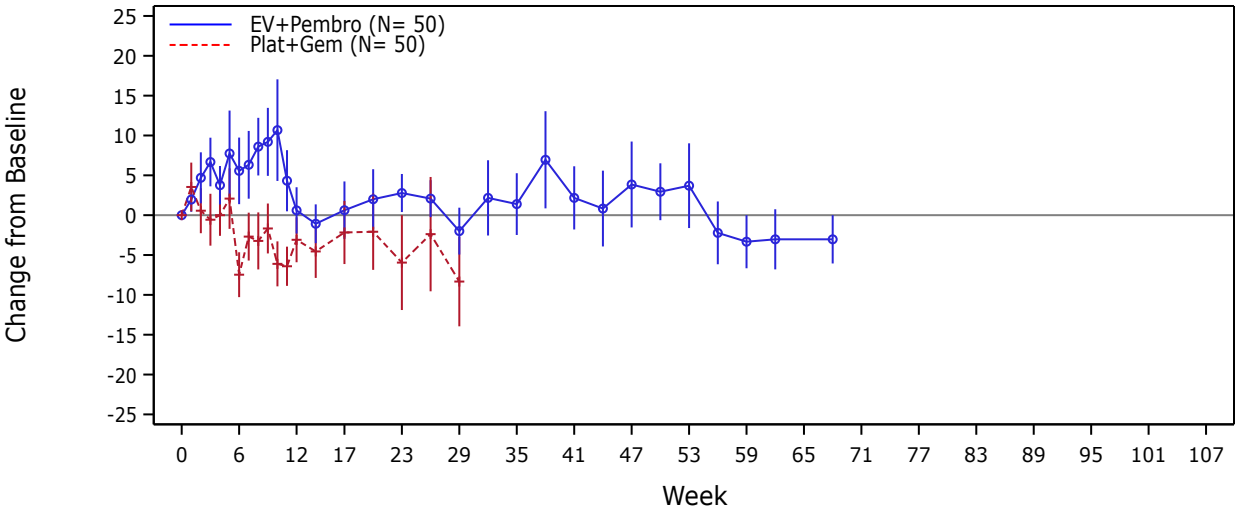
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.17.2.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Nausea and Vomiting by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Present



Number of subjects

EV+Pembro	40	30	28	27	24	25	24	23	13	18	15
Plat+Gem	40	29	27	23	14	12					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

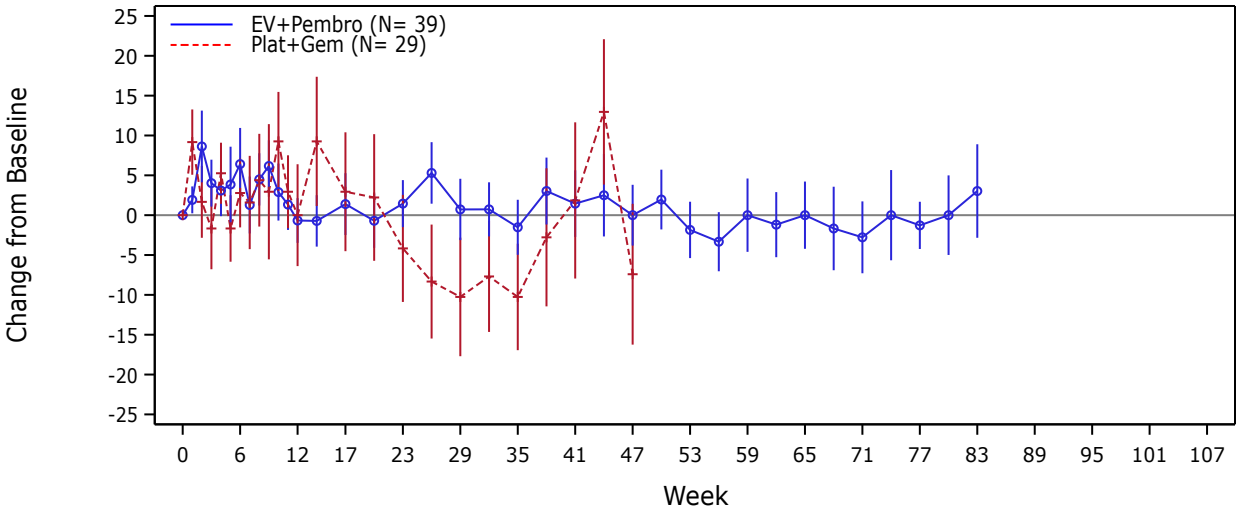
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.17.2.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Nausea and Vomiting by Age - Analysis Set mITT 2

Age: < 65 years



Number of subjects

EV+Pembro	32	26	25	24	23	23	22	23	18	18	15	13	12	13	11
Plat+Gem	22	18	17	17	16	13	13	9	9						

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

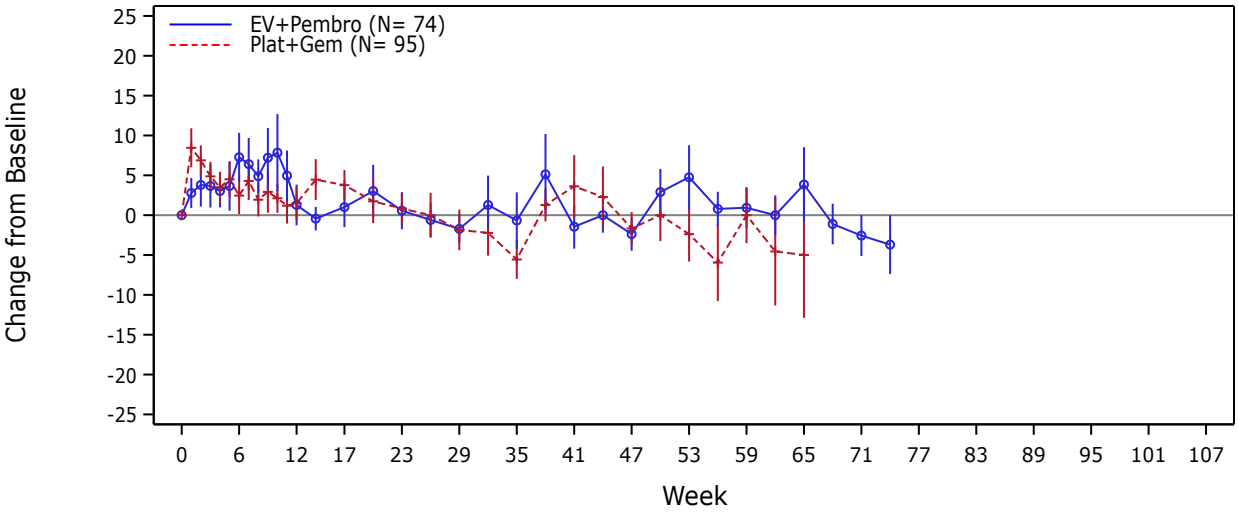
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.17.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Nausea and Vomiting by Region - Analysis Set mITT 2

Region: Europe



Number of subjects

EV+Pembro	53	39	39	33	30	29	25	23	21	21	18	13	13
Plat+Gem	75	61	56	53	40	36	30	23	20	14	10	10	

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

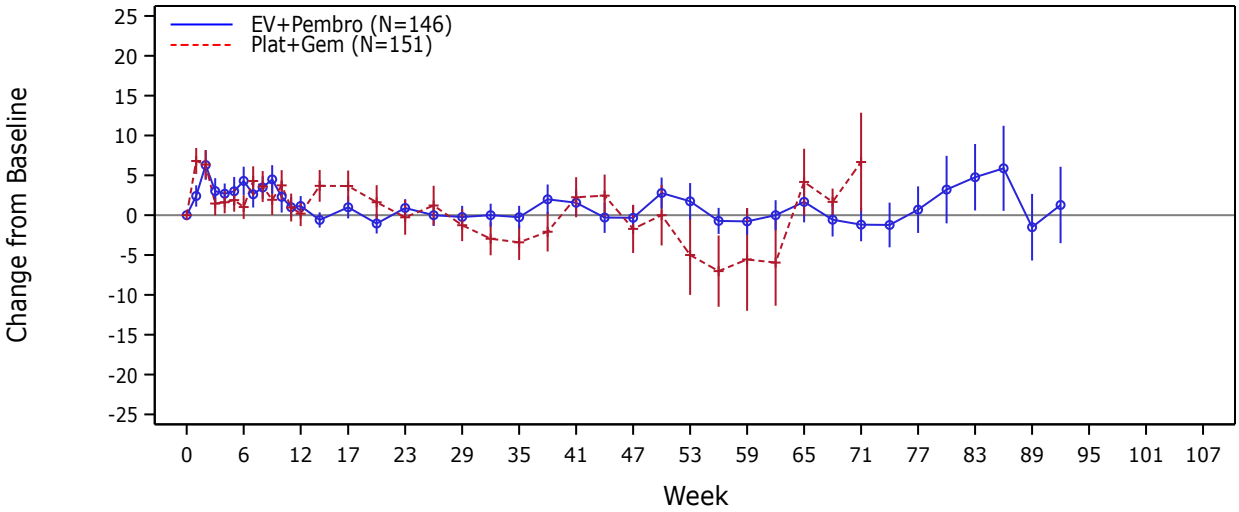
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.17.2.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Nausea and Vomiting by Sex - Analysis Set mITT 2

Sex: Male



Number of subjects

EV+Pembro	119	93	87	84	74	71	66	64	50	48	43	30	28	24	21	11
Plat+Gem	123	98	88	82	62	53	44	37	29	20	15	12	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

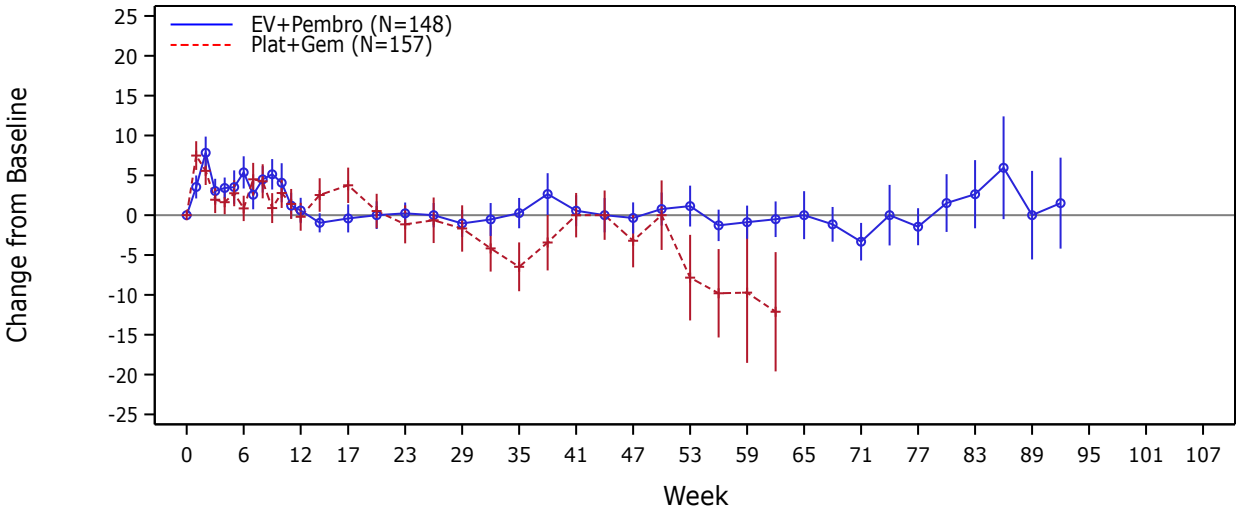
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.17.2.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Nausea and Vomiting by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Visceral metastases



Number of subjects

EV+Pembro	119	90	85	81	71	64	63	60	48	44	38	24	25	23	19	10
Plat+Gem	128	98	84	80	58	50	36	31	26	17	12					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

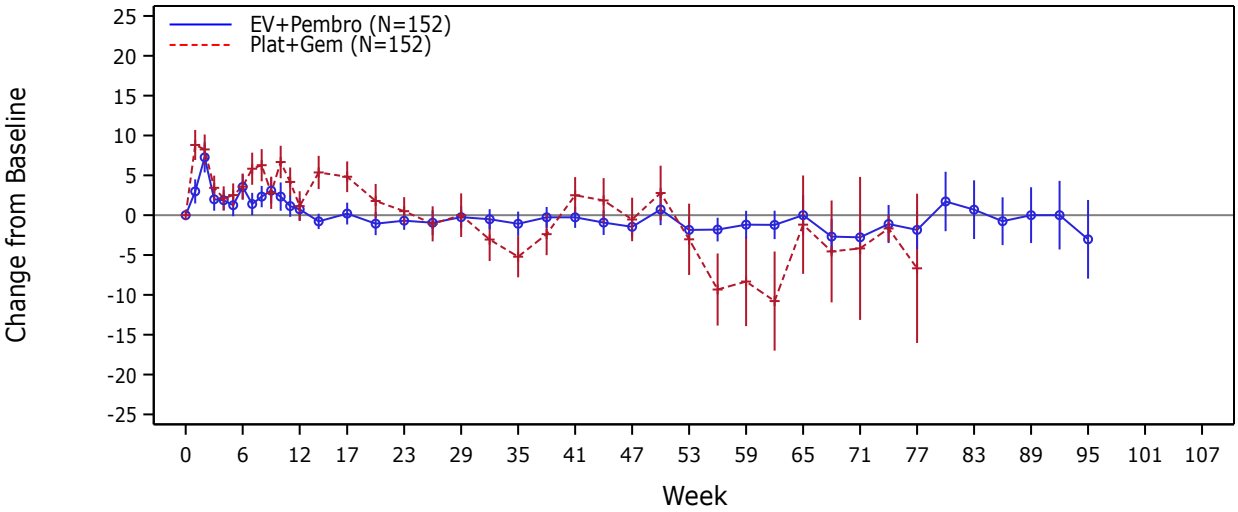
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.17.2.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Nausea and Vomiting by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Absent



Number of subjects

EV+Pembro	120	94	91	84	73	68	62	61	57	45	42	33	30	27	24	17	11
Plat+Gem	125	102	88	83	66	59	48	40	31	22	18	14	12	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

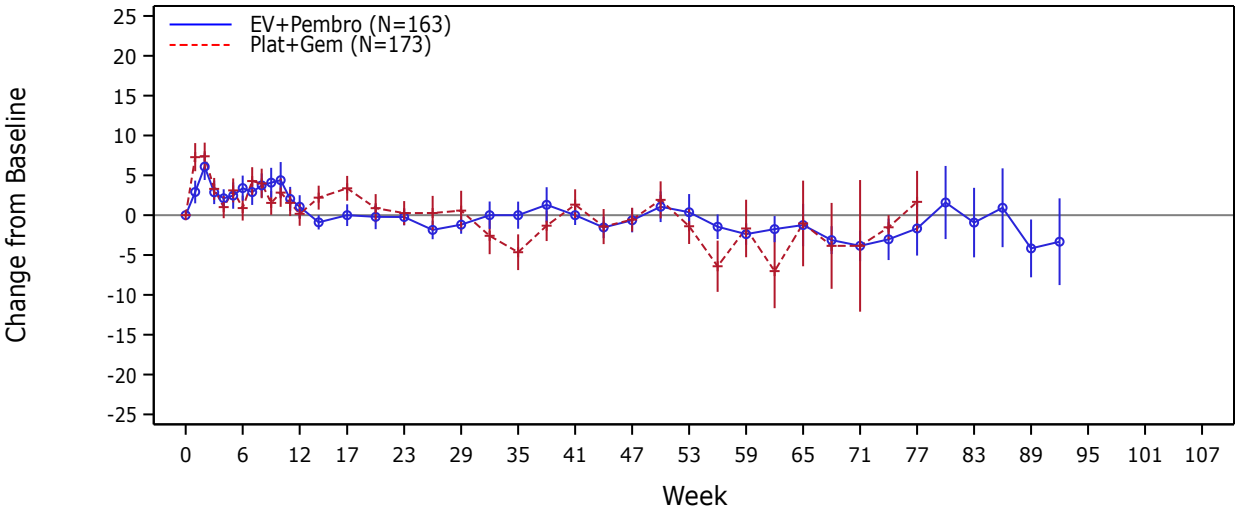
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.17.2.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Nausea and Vomiting by Age - Analysis Set mITT 2

Age: >= 65 years



Number of subjects

EV+Pembro	128	98	94	87	74	70	64	61	52	45	42	27	26	20	18	12
Plat+Gem	143	113	98	89	64	58	43	38	30	24	20	16	13	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

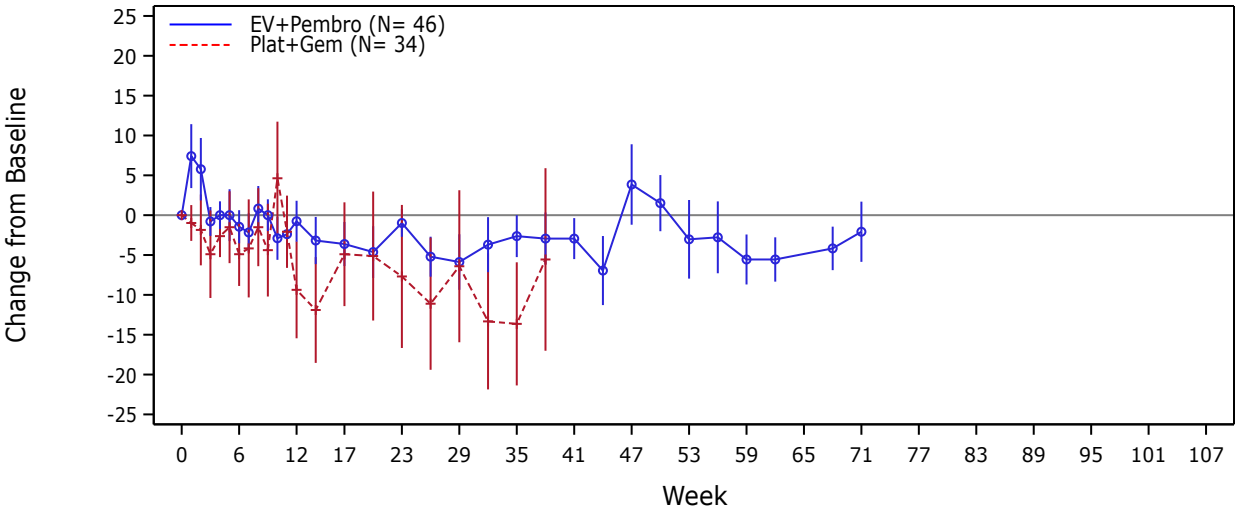
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.17.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Nausea and Vomiting by Region - Analysis Set mITT 2

Region: North America



Number of subjects

EV+Pembro	33	23	22	23	17	17	19	17	13	11	12	8
Plat+Gem	27	17	16	17	13	13	11					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

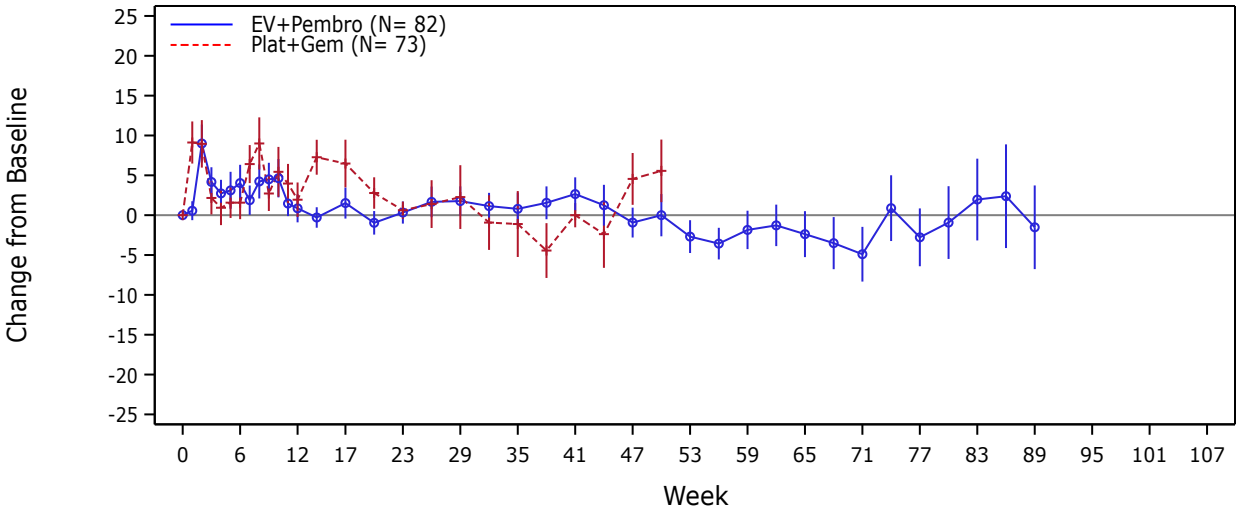
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.17.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Nausea and Vomiting by Region - Analysis Set mITT 2

Region: Rest of World



Number of subjects

EV+Pembro	74	62	58	55	50	47	42	44	36	31	27	21	17	18	17	11
Plat+Gem	63	53	43	36	27	22	15	16	11							

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

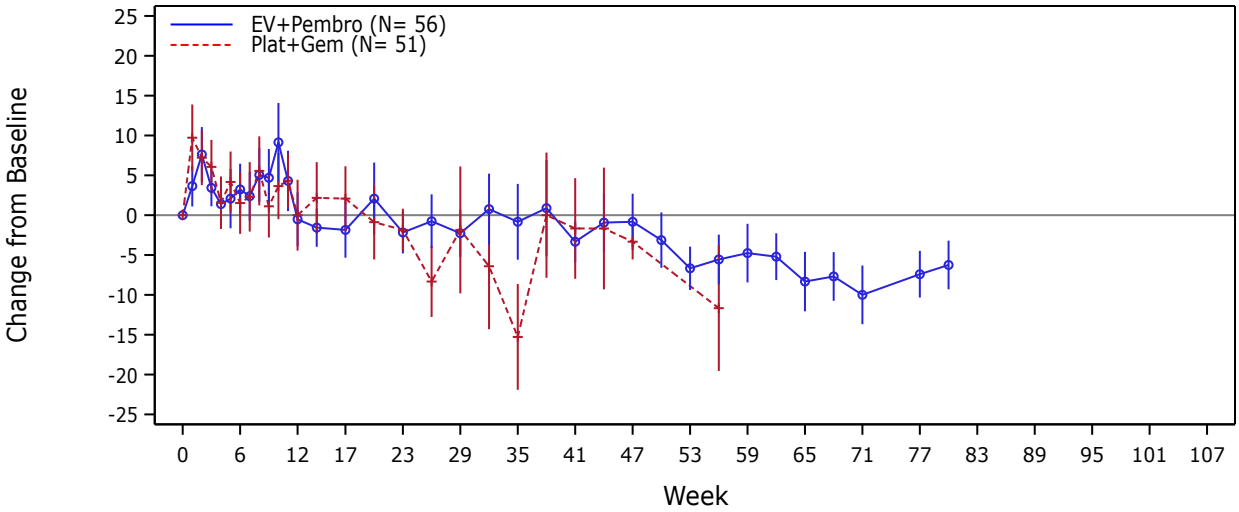
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.17.2.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Nausea and Vomiting by Sex - Analysis Set mITT 2

Sex: Female



Number of subjects

EV+Pembro	41	31	32	27	23	22	20	20	20	15	14	10	10	9
Plat+Gem	42	33	27	24	18	18	12	10	10					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

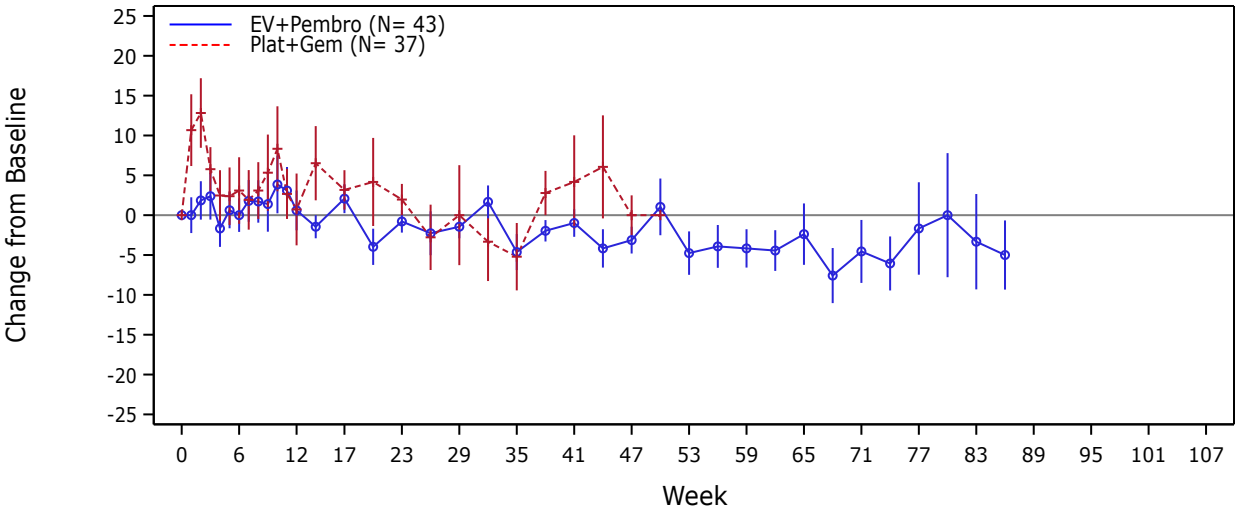
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.17.2.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Nausea and Vomiting by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Lymph node only



Number of subjects

EV+Pembro	33	28	28	24	21	23	18	17	16	14	16	14	11	10	10
Plat+Gem	29	27	23	21	17	16	16	12	10						

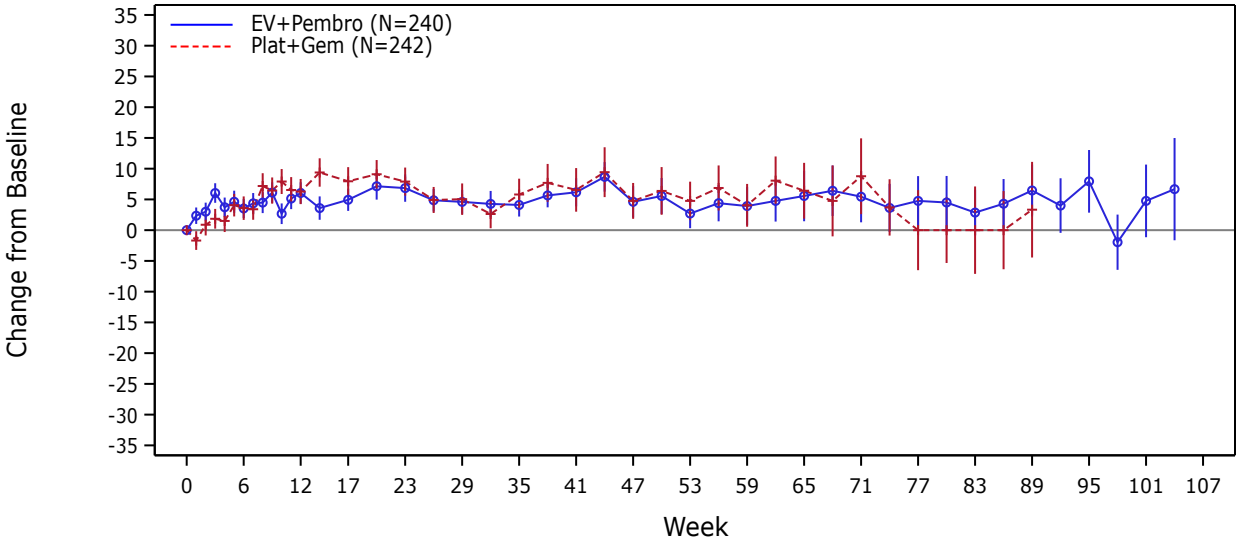
Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.18.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Shortness of Breath - Analysis Set mITT 1



Number of subjects

EV+Pembro	206	170	171	162	151	145	122	119	94	74	68	54	49	42	35	31	21	14
Plat+Gem	188	149	138	130	97	86	69	56	49	42	33	26	19	15	12	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

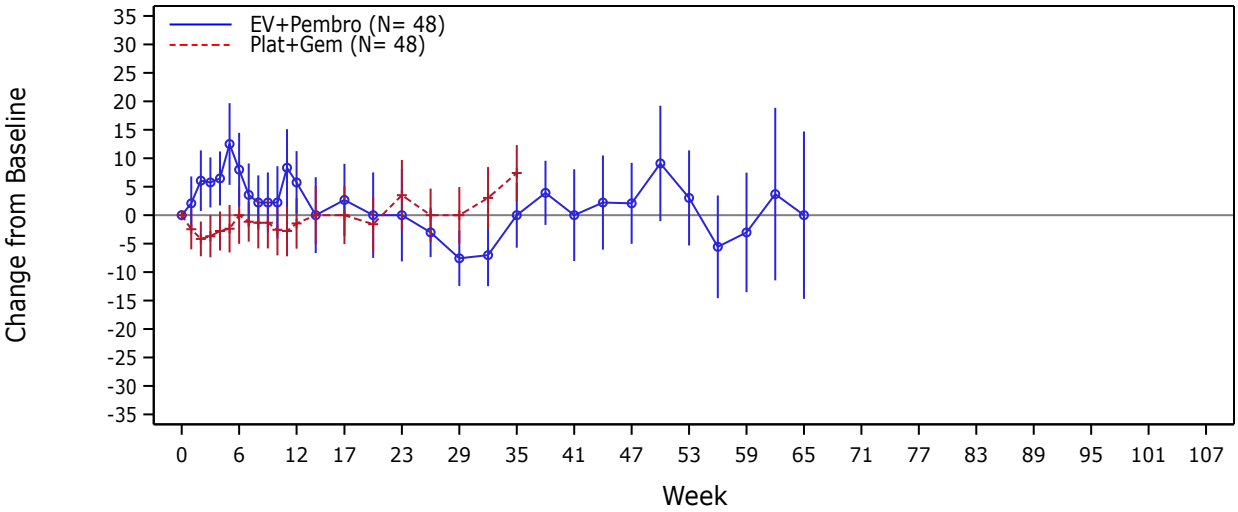
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.18.1.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Shortness of Breath by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Present



Number of subjects

EV+Pembro	39	25	29	25	23	22	17	19	16	11	11	9
Plat+Gem	33	27	23	25	19	14	9					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

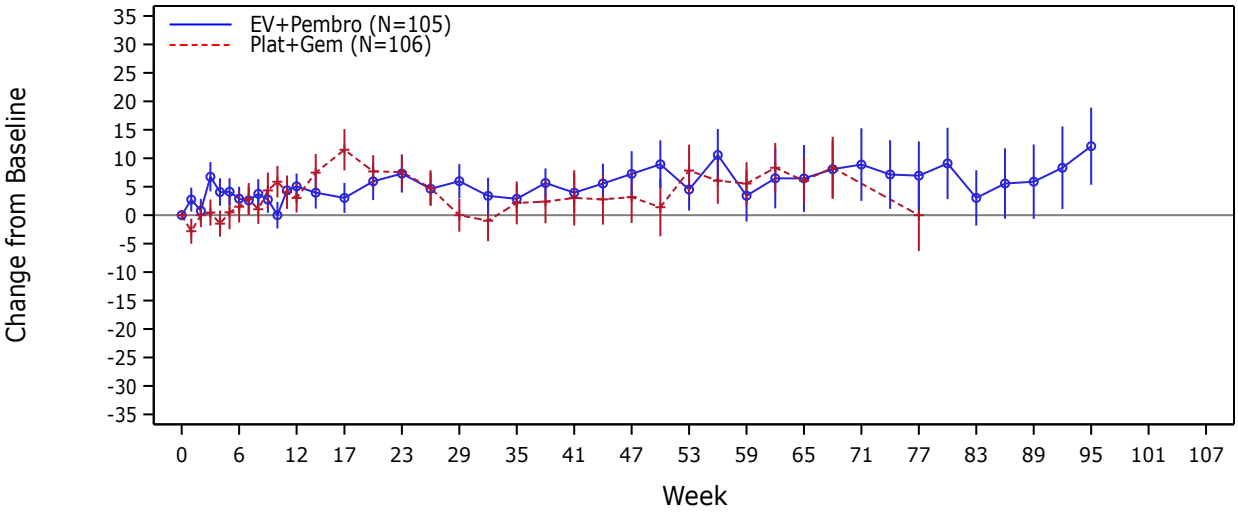
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.18.1.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Shortness of Breath by Age - Analysis Set mITT 1

Age: < 65 years



Number of subjects

EV+Pembro	92	81	79	77	73	67	58	59	46	37	39	31	30	24	22	17	11
Plat+Gem	83	67	66	58	44	37	31	22	21	17	12	11		8			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

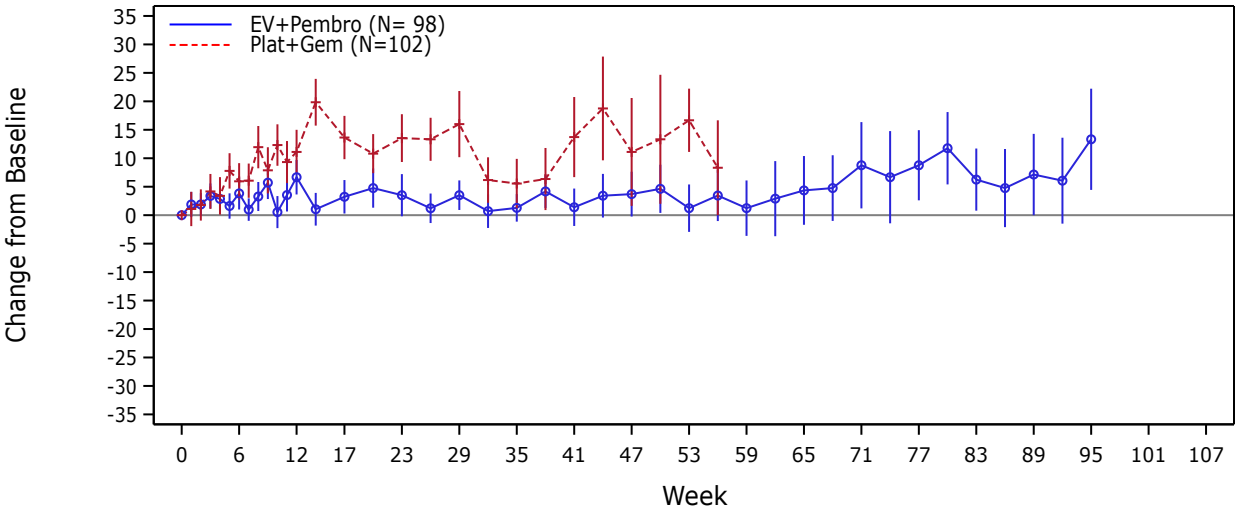
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.18.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Shortness of Breath by Region - Analysis Set mITT 1

Region: Europe



Number of subjects

EV+Pembro	79	61	65	62	57	57	52	48	36	27	27	23	19	19	16	14	10
Plat+Gem	71	56	48	44	32	25	24	17	12	10							

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

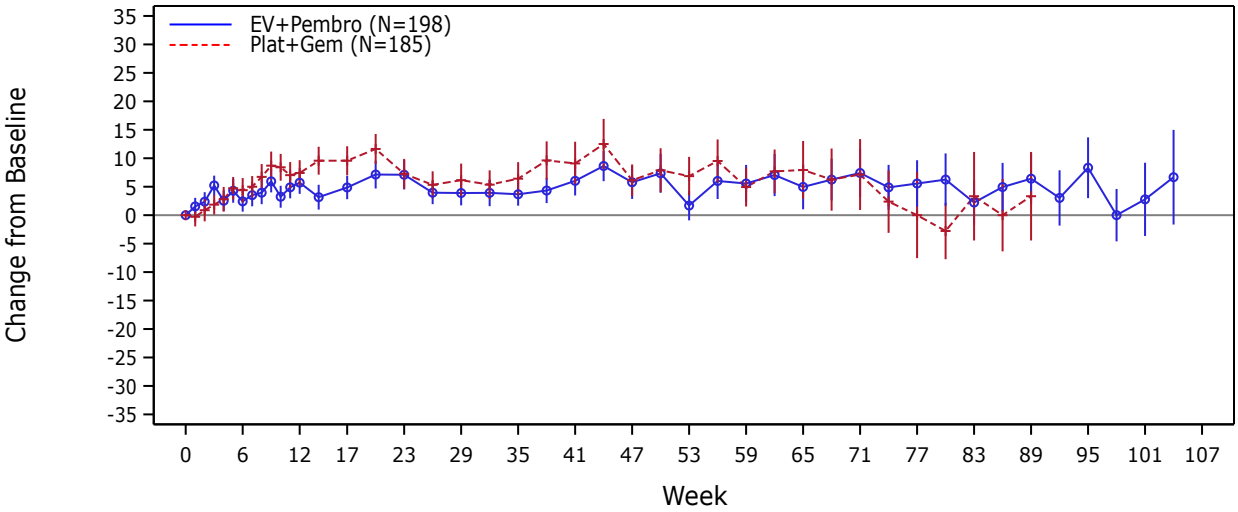
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.18.1.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Shortness of Breath by Sex - Analysis Set mITT 1

Sex: Male



Number of subjects

EV+Pembro	170	138	140	130	122	120	100	94	75	59	54	47	45	36	30	26	20	12
Plat+Gem	146	114	108	101	78	65	52	44	38	34	27	21	14	13	10	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

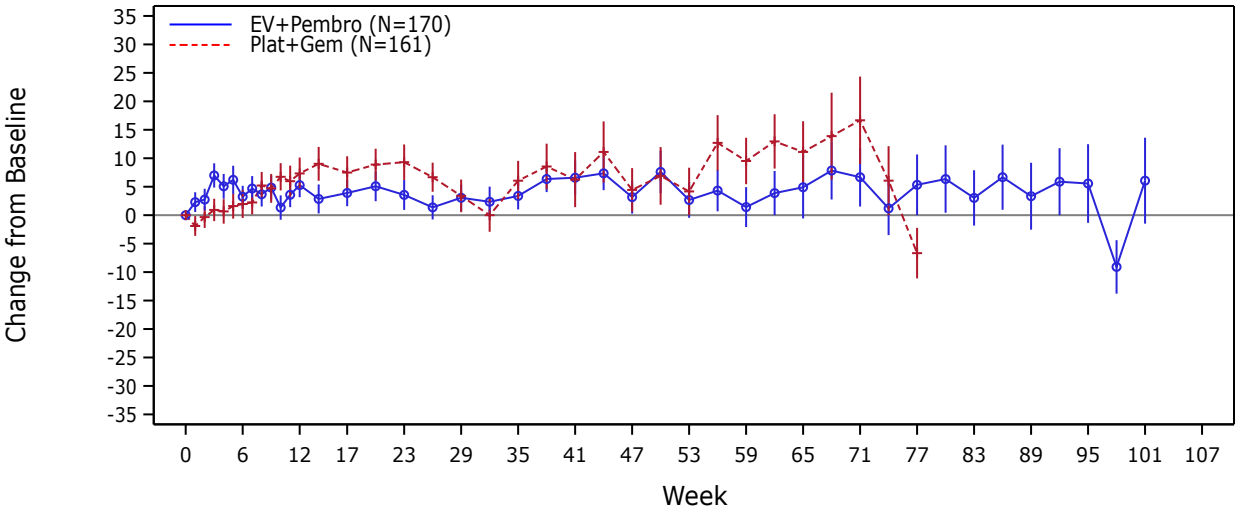
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.18.1.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Shortness of Breath by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Visceral metastases



Number of subjects

EV+Pembro	146	113	120	111	103	98	79	81	63	50	47	34	30	25	22	20	12	11
Plat+Gem	129	102	91	89	68	59	44	32	30	24	21	18	12	10				

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

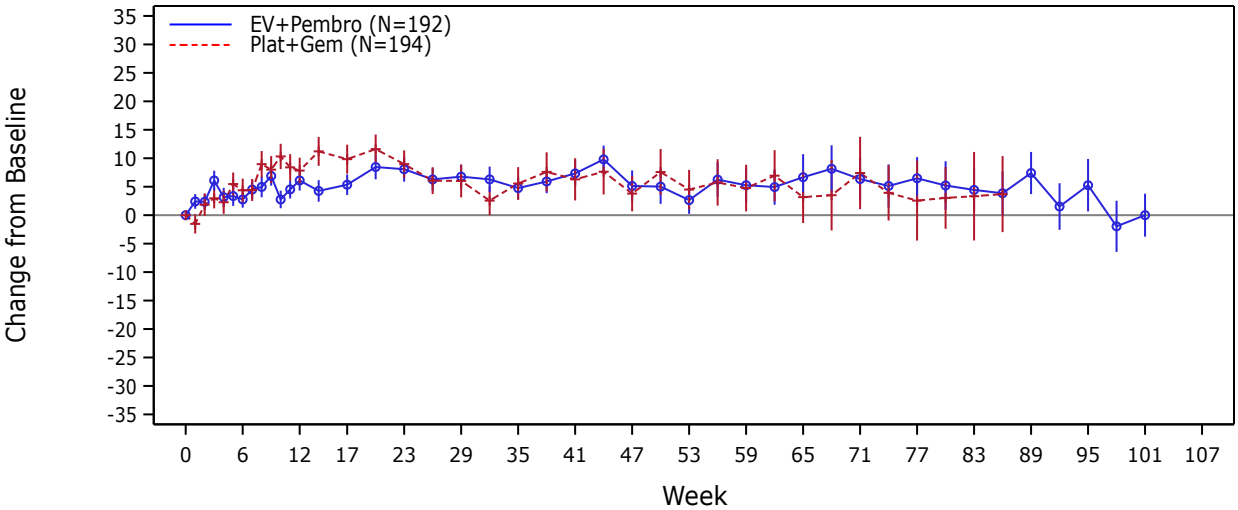
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.18.1.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Shortness of Breath by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Absent



Number of subjects

EV+Pembro	167	145	142	137	128	123	105	100	78	63	57	45	42	36	30	27	19	13
Plat+Gem	155	122	115	105	78	72	60	53	44	37	28	21	18	13	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

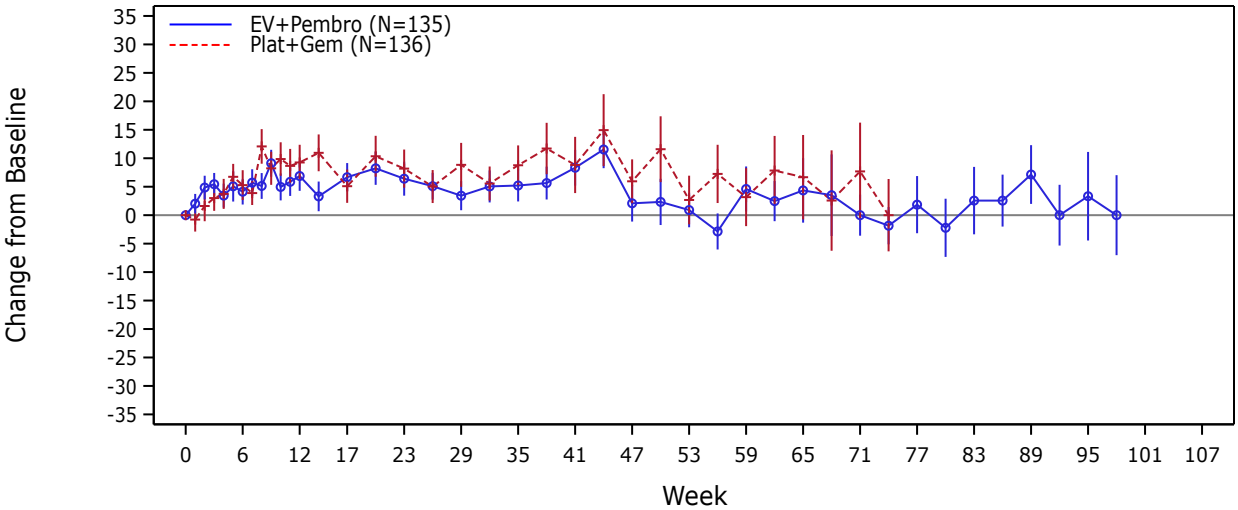
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.18.1.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Shortness of Breath by Age - Analysis Set mITT 1

Age: >= 65 years



Number of subjects

EV+Pembro	114	89	92	85	78	78	64	60	48	37	29	23	19	18	13	14	10
Plat+Gem	105	82	72	72	53	49	38	34	28	25	21	15	13				

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

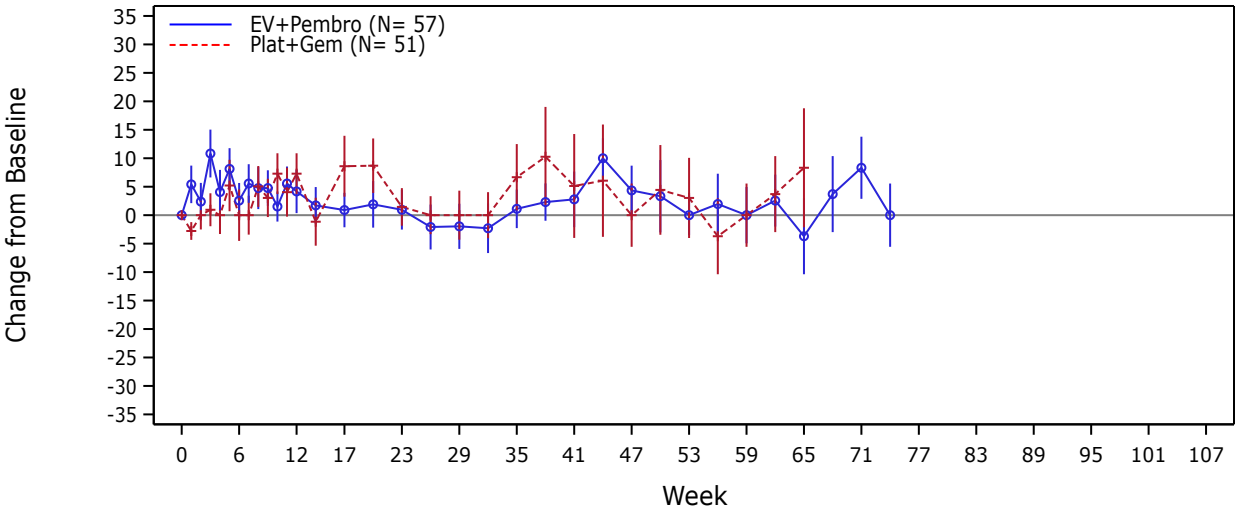
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.18.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Shortness of Breath by Region - Analysis Set mITT 1

Region: North America



Number of subjects

EV+Pembro	47	39	40	37	35	34	30	24	23	14	14	9	8
Plat+Gem	42	30	32	31	23	25	15	13	9	11	9	8	

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

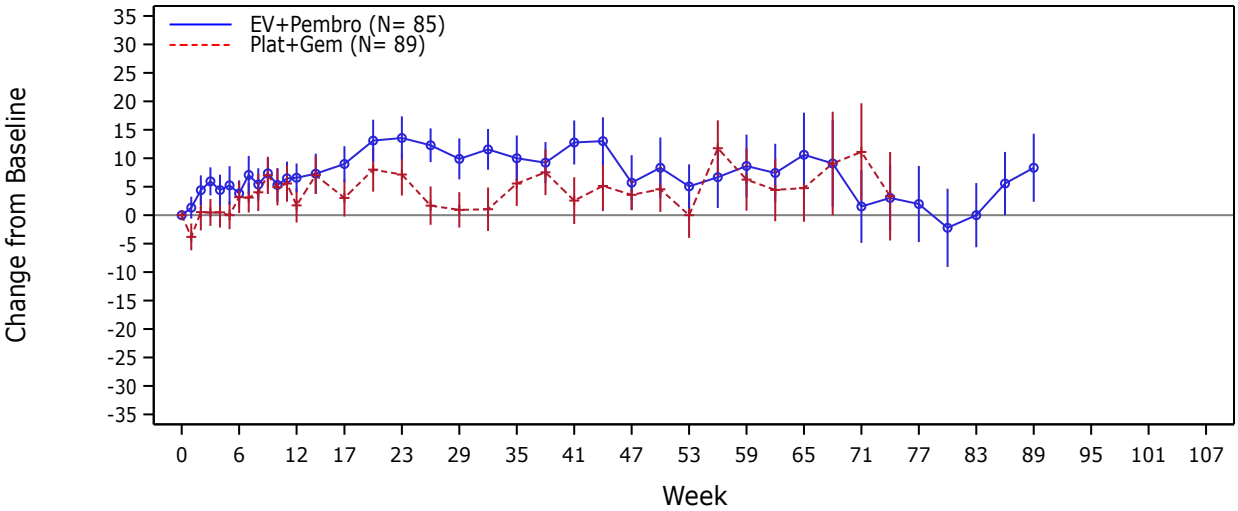
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.18.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Shortness of Breath by Region - Analysis Set mITT 1

Region: Rest of World



Number of subjects

EV+Pembro	80	70	66	63	59	54	40	47	35	33	27	22	22	17	15	12
Plat+Gem	75	63	58	55	42	36	30	26	28	21	16	14	12			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

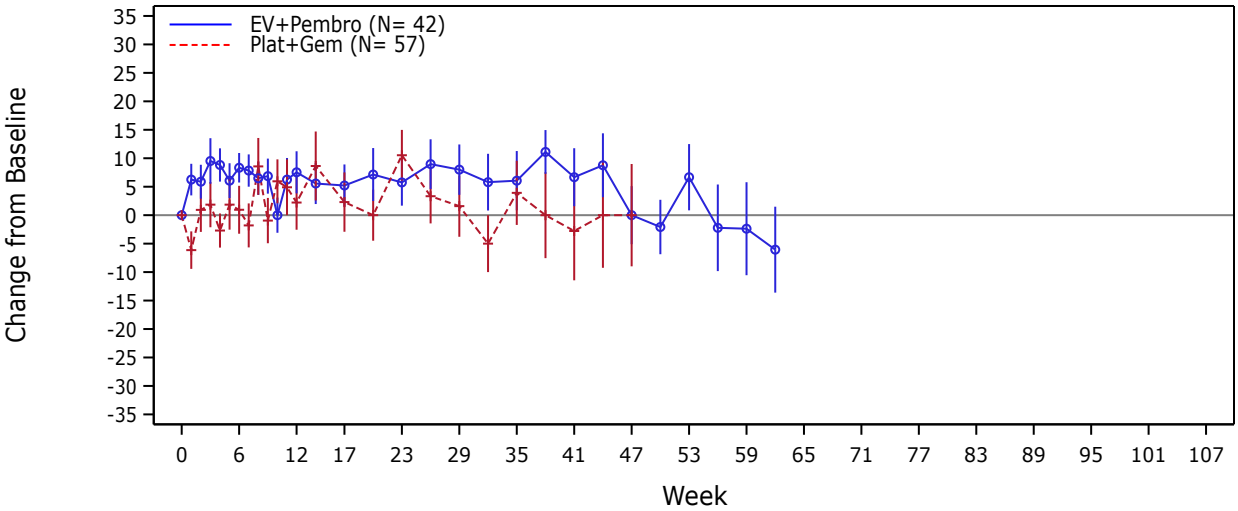
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.18.1.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Shortness of Breath by Sex - Analysis Set mITT 1

Sex: Female



Number of subjects

EV+Pembro	36	32	31	32	29	25	22	25	19	15	14
Plat+Gem	42	35	30	29	19	21	17	12	11		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

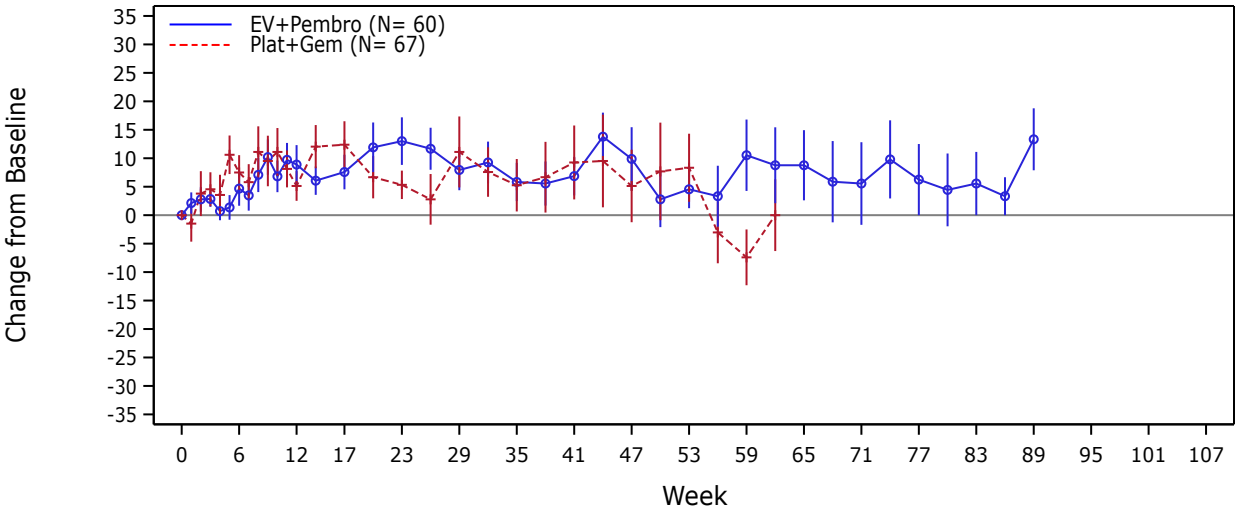
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.18.1.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Shortness of Breath by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Lymph node only



Number of subjects

EV+Pembro	53	50	45	44	41	42	40	34	27	22	19	19	18	16	12	10
Plat+Gem	49	40	39	35	25	21	19	18	13	12	9					

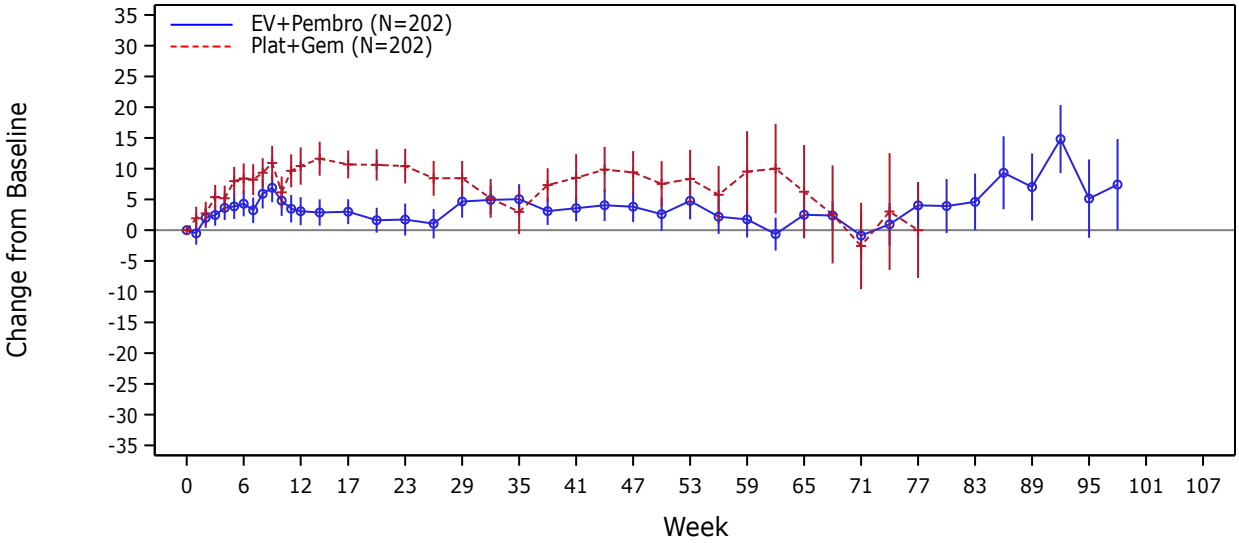
Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.18.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Shortness of Breath - Analysis Set mITT 2



Number of subjects

EV+Pembro	160	124	119	111	97	93	86	84	70	63	57	40	38	33	29	19	13
Plat+Gem	165	131	115	106	80	71	56	47	39	28	21	16	13	11			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

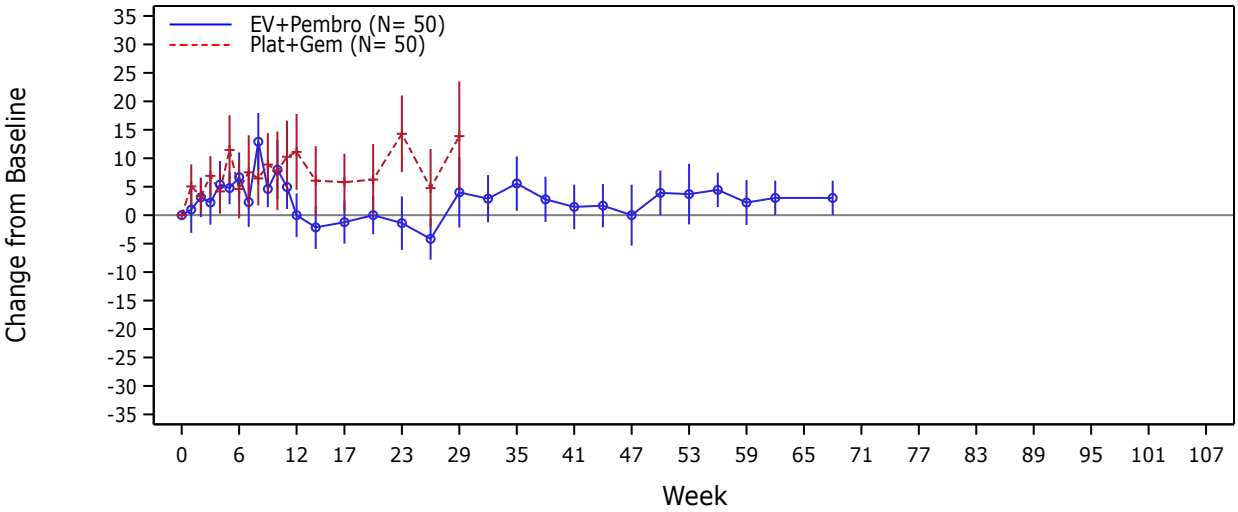
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.18.2.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Shortness of Breath by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Present



Number of subjects

EV+Pembro	40	30	28	27	24	25	24	23	13	18	15
Plat+Gem	40	29	27	23	14	12					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

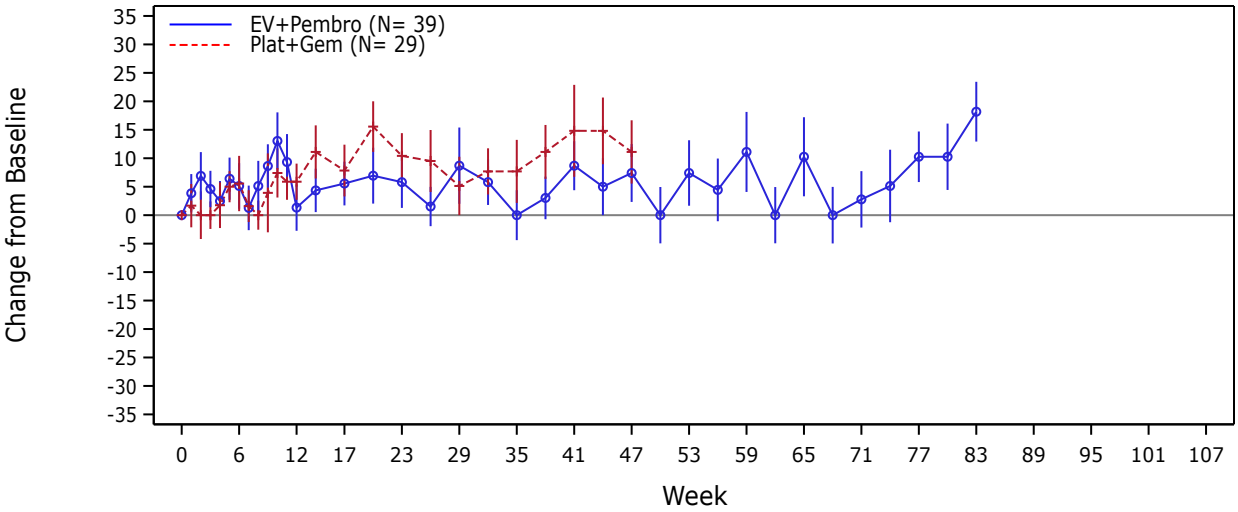
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.18.2.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Shortness of Breath by Age - Analysis Set mITT 2

Age: < 65 years



Number of subjects

EV+Pembro	32	26	25	24	23	23	22	23	18	18	15	13	12	13	11
Plat+Gem	22	18	17	17	16	13	13	9	9						

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

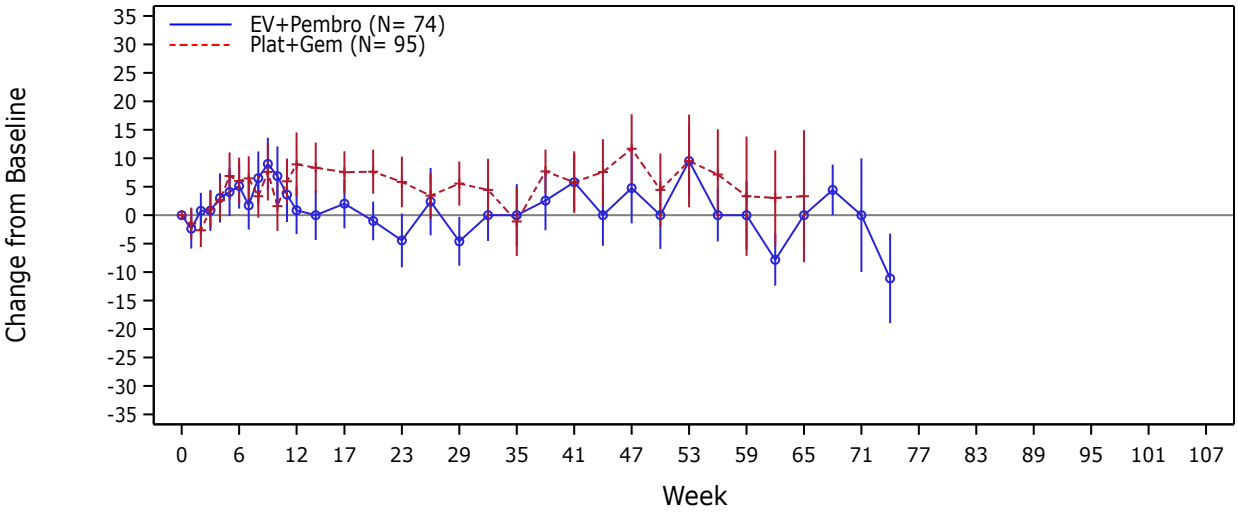
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.18.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Shortness of Breath by Region - Analysis Set mITT 2

Region: Europe



Number of subjects

EV+Pembro	53	39	39	33	30	29	25	23	21	21	18	13	13
Plat+Gem	75	61	56	53	40	36	30	23	20	14	10	10	

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

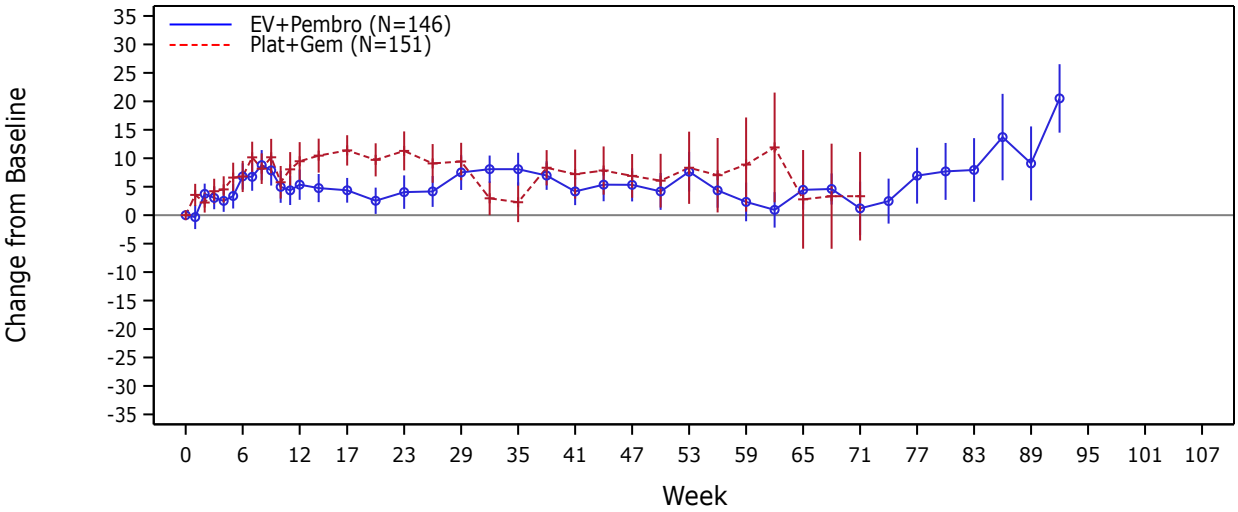
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.18.2.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Shortness of Breath by Sex - Analysis Set mITT 2

Sex: Male



Number of subjects

EV+Pembro	119	93	87	84	74	71	66	64	50	48	43	30	28	24	21	11
Plat+Gem	123	98	88	82	62	53	44	37	29	20	15	12	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

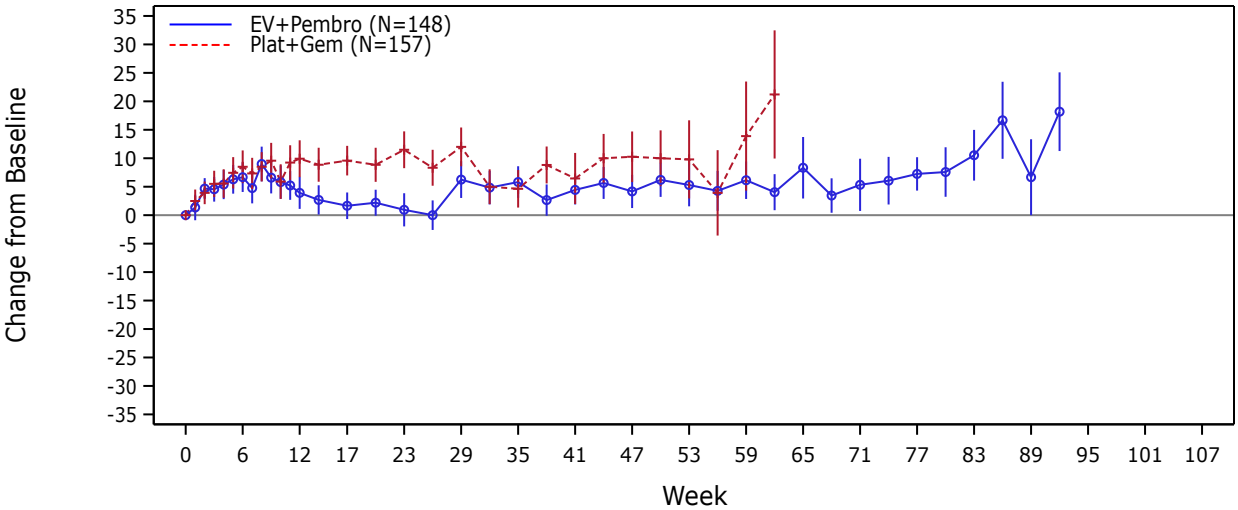
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.18.2.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Shortness of Breath by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Visceral metastases



Number of subjects

EV+Pembro	119	90	85	81	71	64	63	60	48	44	38	24	25	23	19	10
Plat+Gem	128	98	84	80	58	50	36	31	26	17	12					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

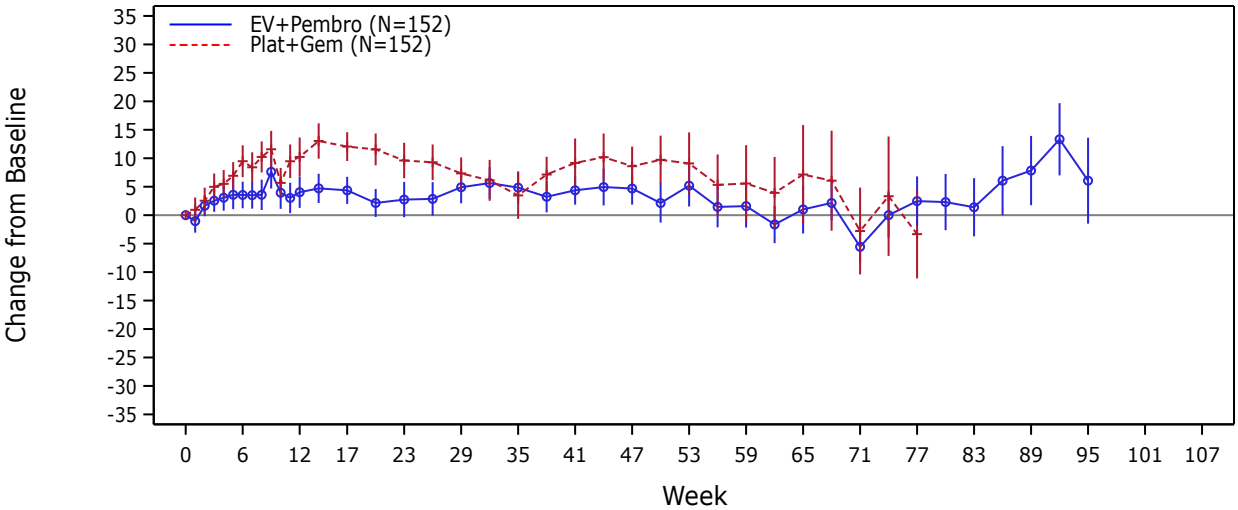
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.18.2.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Shortness of Breath by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Absent



Number of subjects

EV+Pembro	120	94	91	84	73	68	62	61	57	45	42	33	30	27	24	17	11
Plat+Gem	125	102	88	83	66	59	48	40	31	22	18	14	12	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

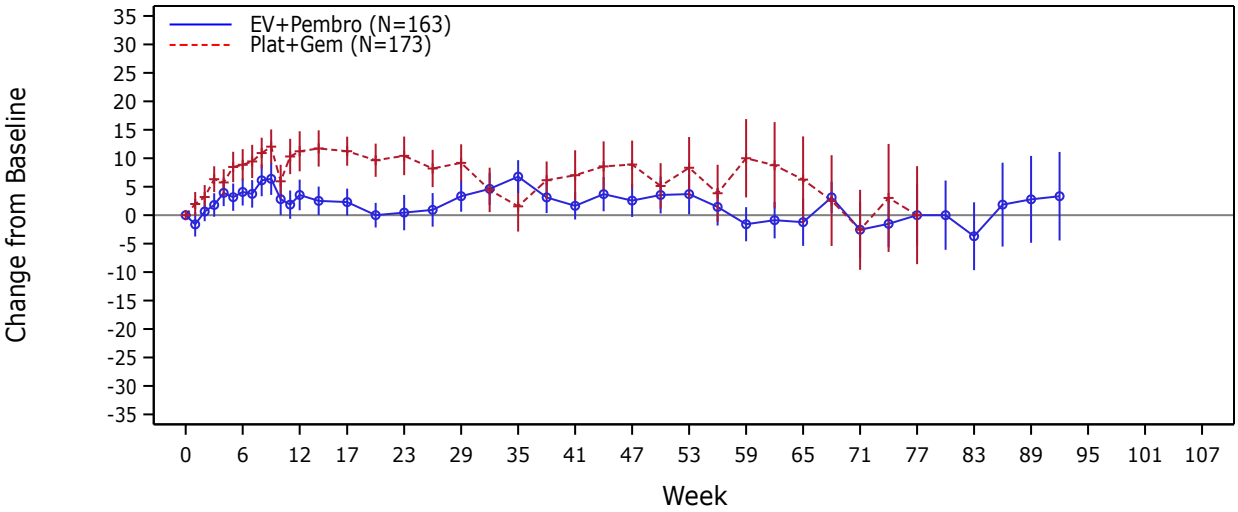
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.18.2.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Shortness of Breath by Age - Analysis Set mITT 2

Age: >= 65 years



Number of subjects

EV+Pembro	128	98	94	87	74	70	64	61	52	45	42	27	26	20	18	12
Plat+Gem	143	113	98	89	64	58	43	38	30	24	20	16	13	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

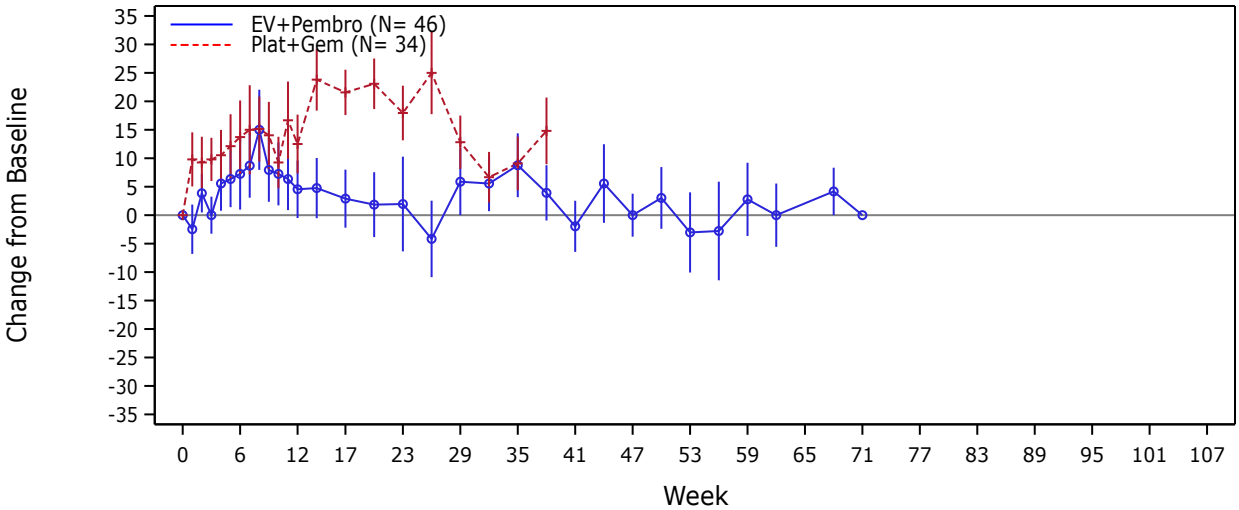
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.18.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Shortness of Breath by Region - Analysis Set mITT 2

Region: North America



Number of subjects

EV+Pembro	33	23	22	23	17	17	19	17	13	11	12	8
Plat+Gem	27	17	16	17	13	13	11					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

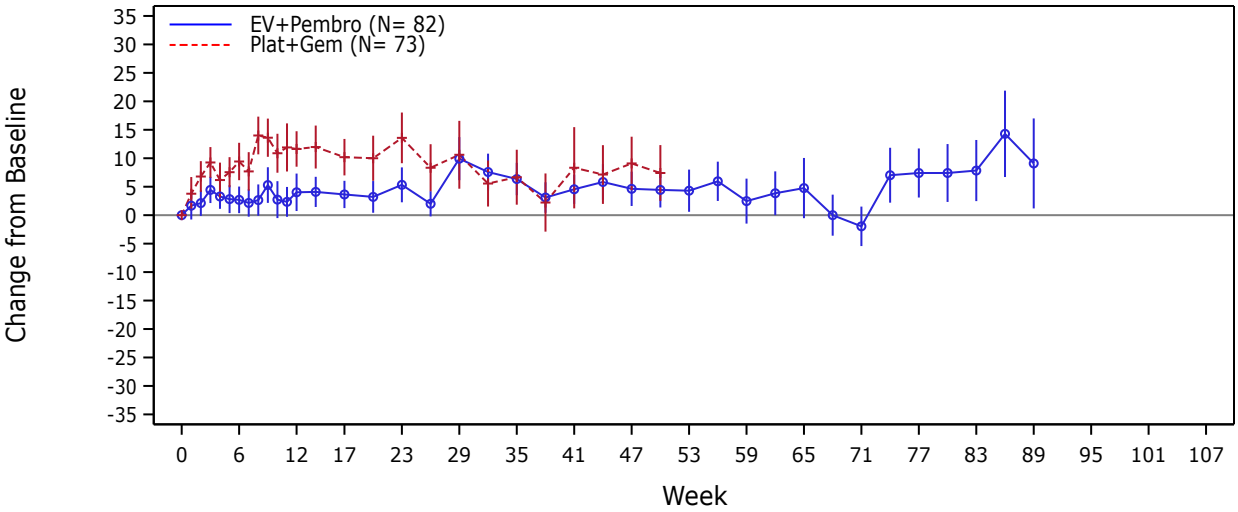
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.18.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Shortness of Breath by Region - Analysis Set mITT 2

Region: Rest of World



Number of subjects

EV+Pembro	74	62	58	55	50	47	42	44	36	31	27	21	17	18	17	11
Plat+Gem	63	53	43	36	27	22	15	16	11							

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

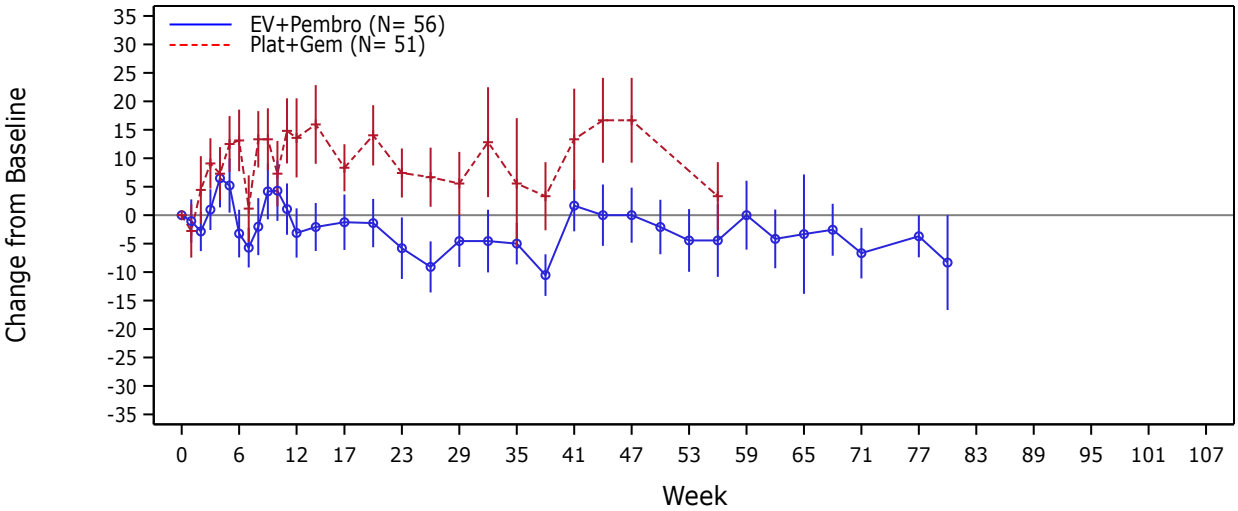
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.18.2.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Shortness of Breath by Sex - Analysis Set mITT 2

Sex: Female



Number of subjects

EV+Pembro	41	31	32	27	23	22	20	20	20	15	14	10	10	9
Plat+Gem	42	33	27	24	18	18	12	10	10					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

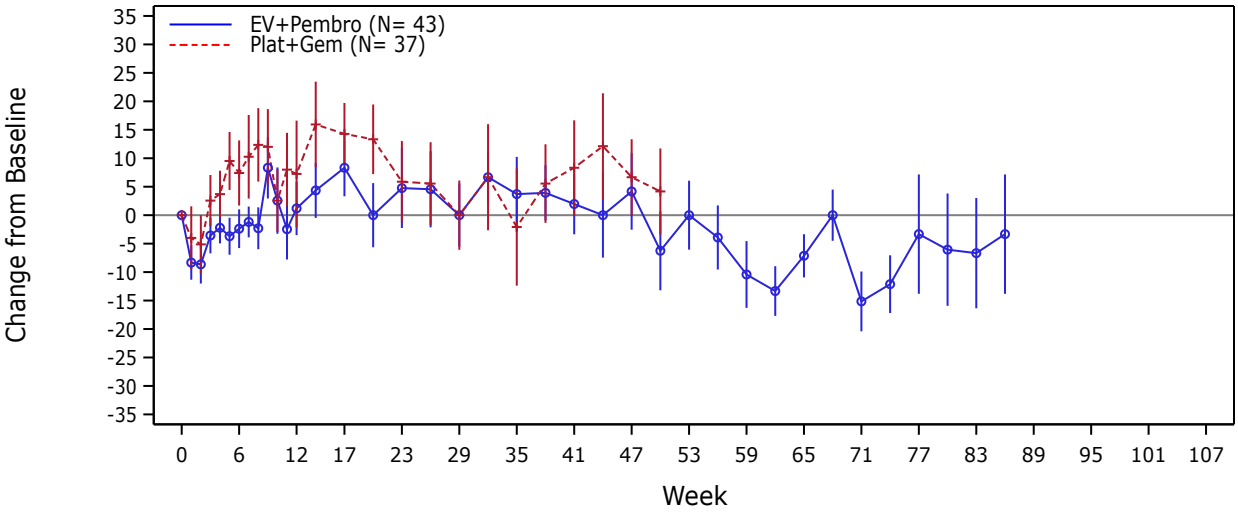
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.18.2.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Shortness of Breath by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Lymph node only



Number of subjects

EV+Pembro	33	28	28	24	21	23	18	17	16	14	16	14	11	10	10
Plat+Gem	29	27	23	21	17	16	16	12	10						

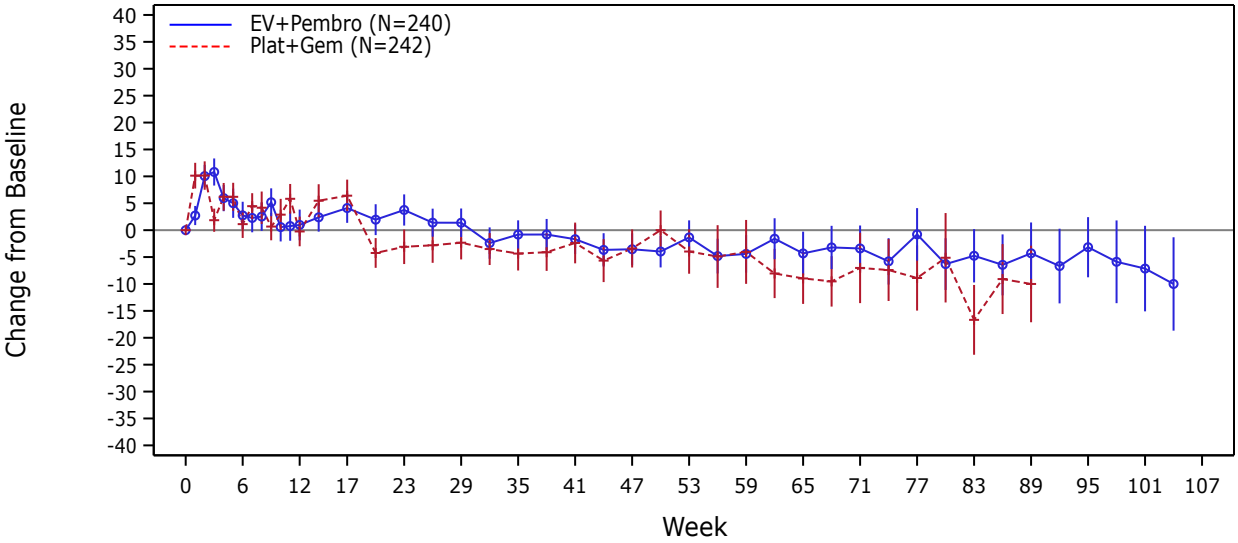
Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.19.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Loss of Appetite - Analysis Set mITT 1



Number of subjects

EV+Pembro	206	170	171	162	151	145	122	119	94	74	68	54	49	42	35	31	21	14
Plat+Gem	188	149	138	130	97	86	69	56	49	42	33	26	19	15	12	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

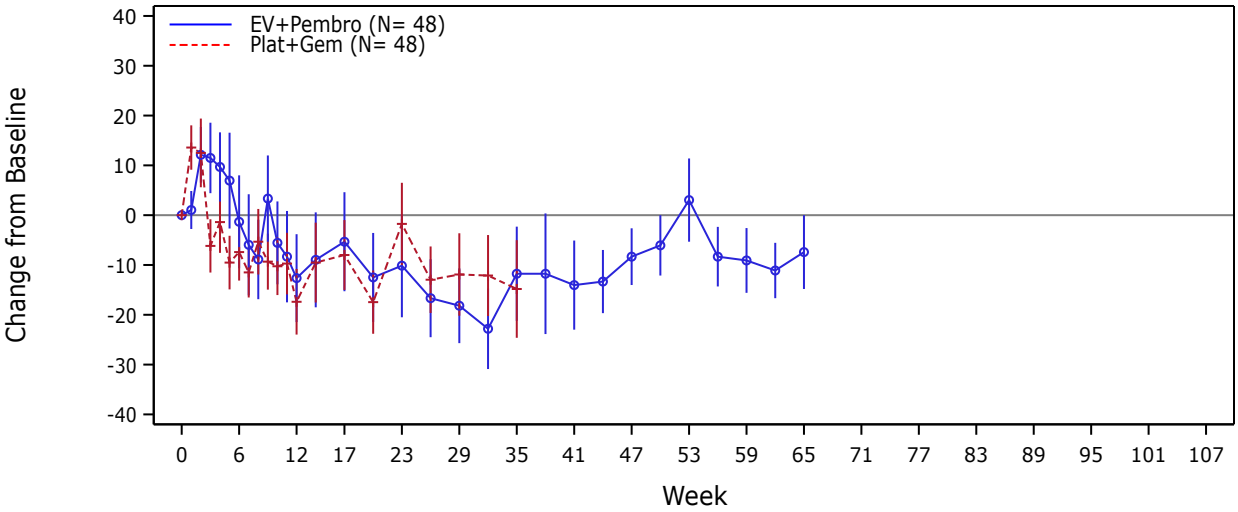
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.19.1.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Loss of Appetite by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Present



Number of subjects

EV+Pembro	39	25	29	25	23	22	17	19	16	11	11	9
Plat+Gem	33	27	23	25	19	14	9					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

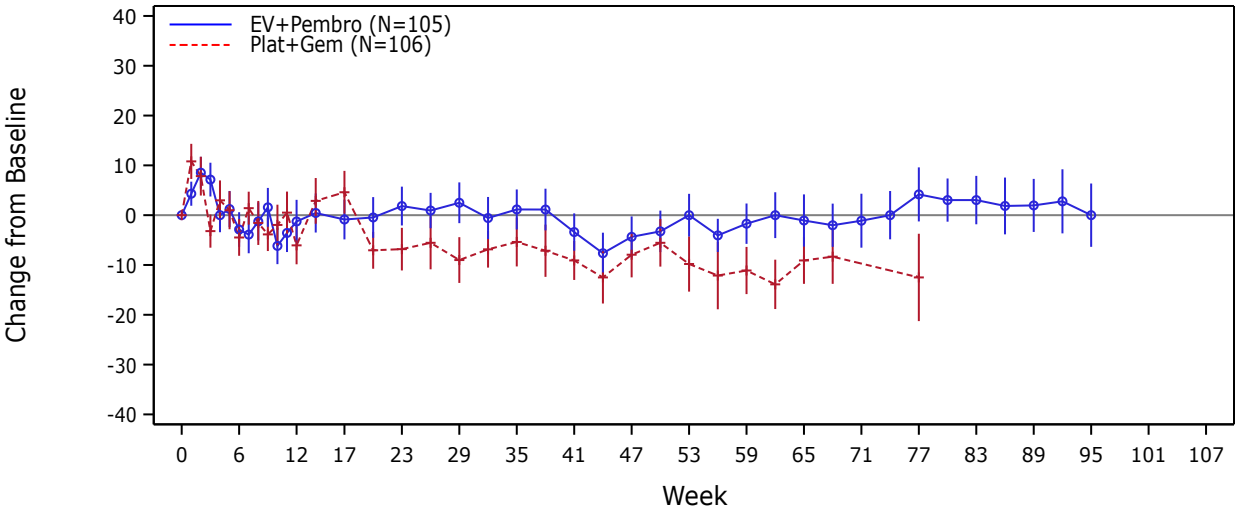
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.19.1.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Loss of Appetite by Age - Analysis Set mITT 1

Age: < 65 years



Number of subjects

EV+Pembro	92	81	79	77	73	67	58	59	46	37	39	31	30	24	22	17	11
Plat+Gem	83	67	66	58	44	37	31	22	21	17	12	11		8			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

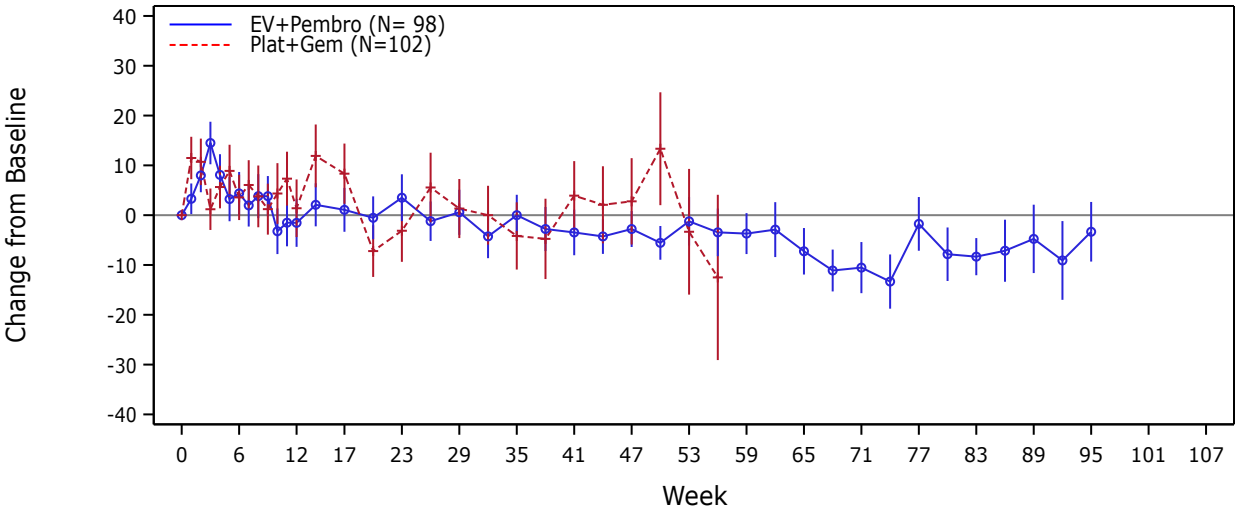
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.19.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Loss of Appetite by Region - Analysis Set mITT 1

Region: Europe



Number of subjects

EV+Pembro	79	61	65	62	57	57	52	48	36	27	27	23	19	19	16	14	10
Plat+Gem	71	56	48	44	32	25	24	17	12	10							

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

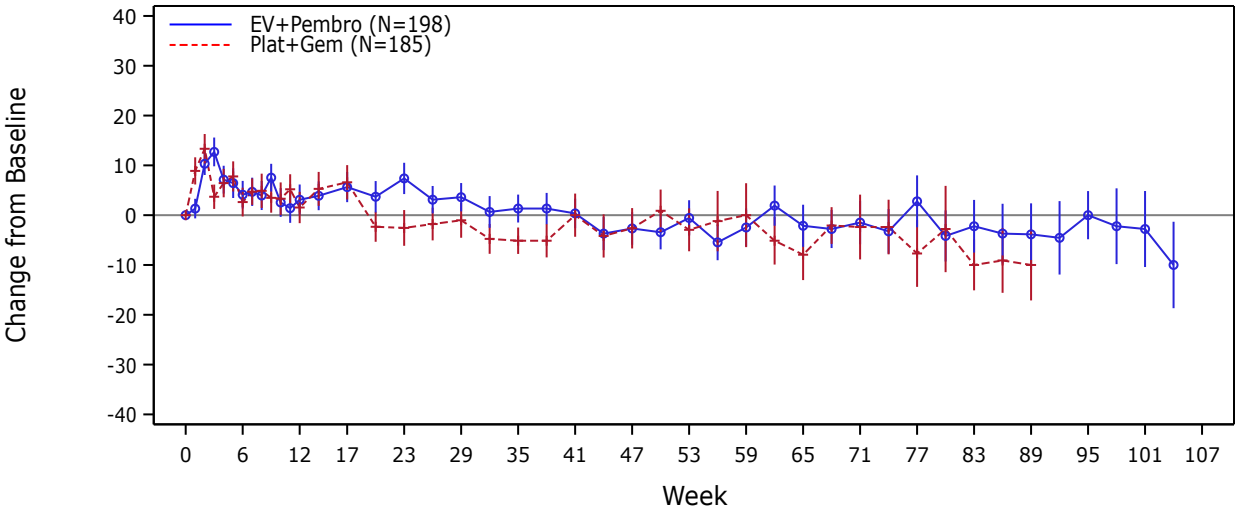
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.19.1.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Loss of Appetite by Sex - Analysis Set mITT 1

Sex: Male



Number of subjects

EV+Pembro	170	138	140	130	122	120	100	94	75	59	54	47	45	36	30	26	20	12
Plat+Gem	146	114	108	101	78	65	52	44	38	34	27	21	14	13	10	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

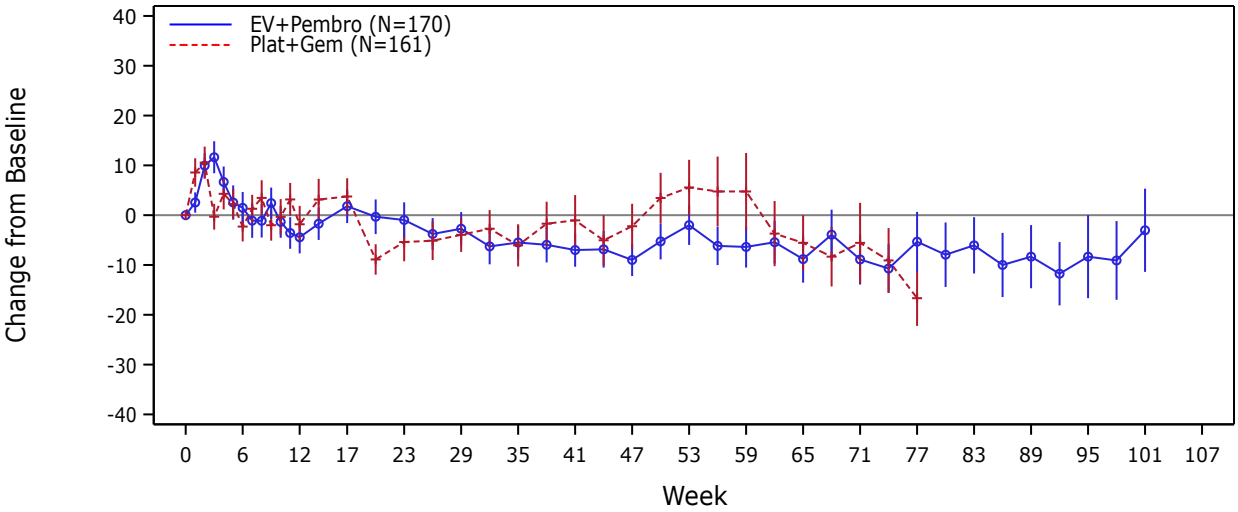
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.19.1.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Loss of Appetite by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Visceral metastases



Number of subjects

EV+Pembro	146	113	120	111	103	98	79	81	63	50	47	34	30	25	22	20	12	11
Plat+Gem	129	102	91	89	68	59	44	32	30	24	21	18	12	10				

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

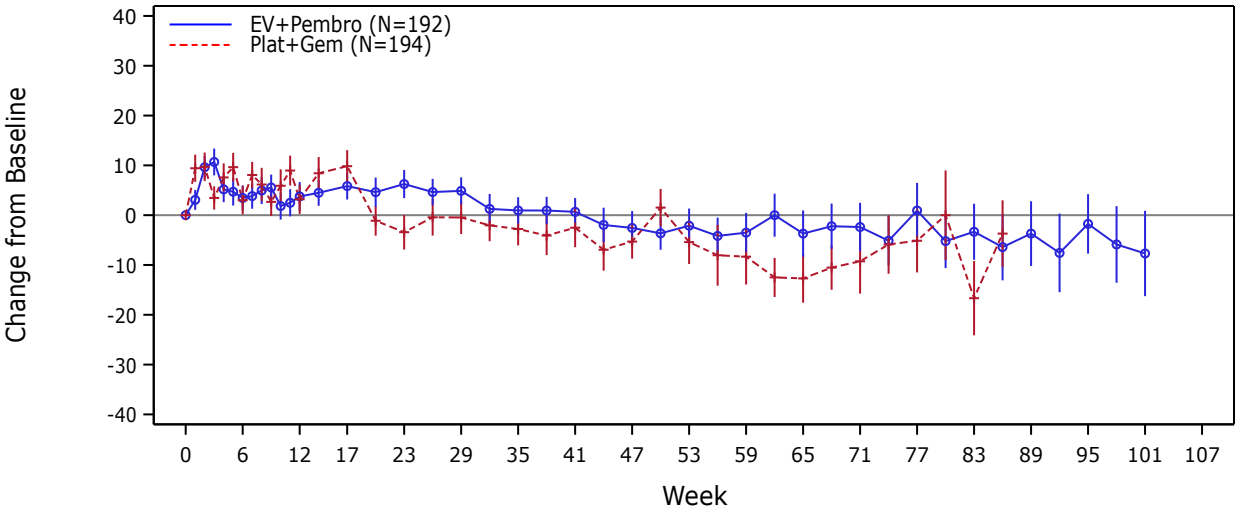
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.19.1.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Loss of Appetite by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Absent



Number of subjects

EV+Pembro	167	145	142	137	128	123	105	100	78	63	57	45	42	36	30	27	19	13
Plat+Gem	155	122	115	105	78	72	60	53	44	37	28	21	18	13	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

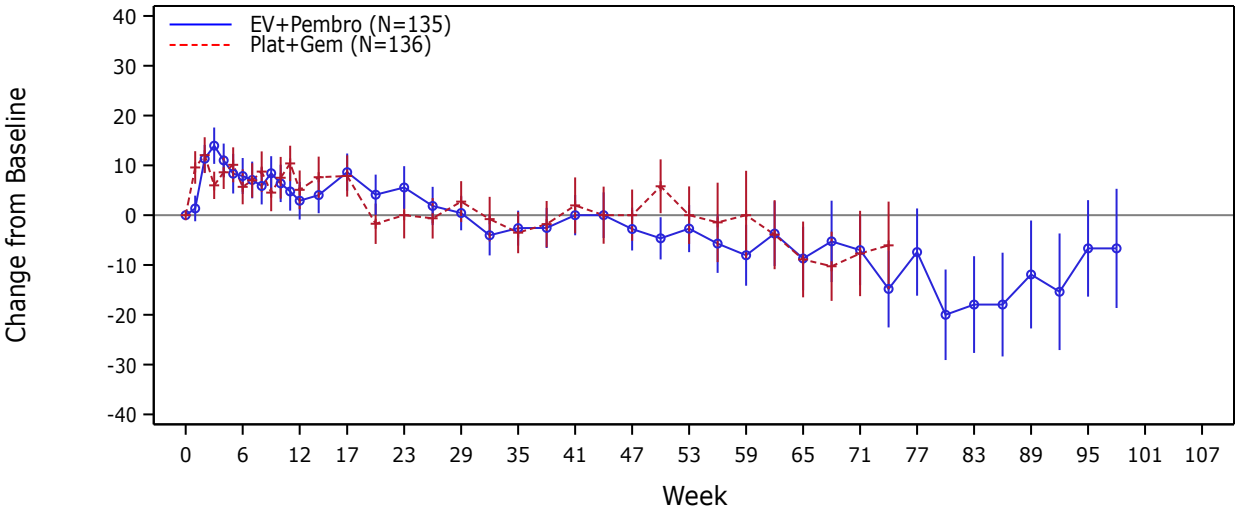
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.19.1.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Loss of Appetite by Age - Analysis Set mITT 1

Age: >= 65 years



Number of subjects

EV+Pembro	114	89	92	85	78	78	64	60	48	37	29	23	19	18	13	14	10
Plat+Gem	105	82	72	72	53	49	38	34	28	25	21	15	13				

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

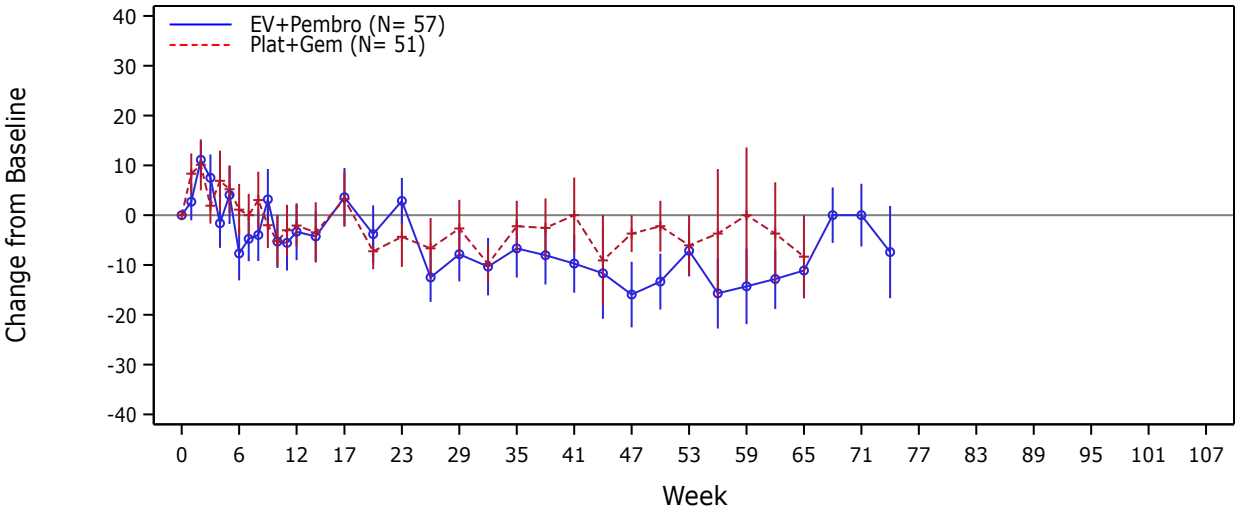
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.19.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Loss of Appetite by Region - Analysis Set mITT 1

Region: North America



Number of subjects

EV+Pembro	47	39	40	37	35	34	30	24	23	14	14	9	8
Plat+Gem	42	30	32	31	23	25	15	13	9	11	9	8	

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

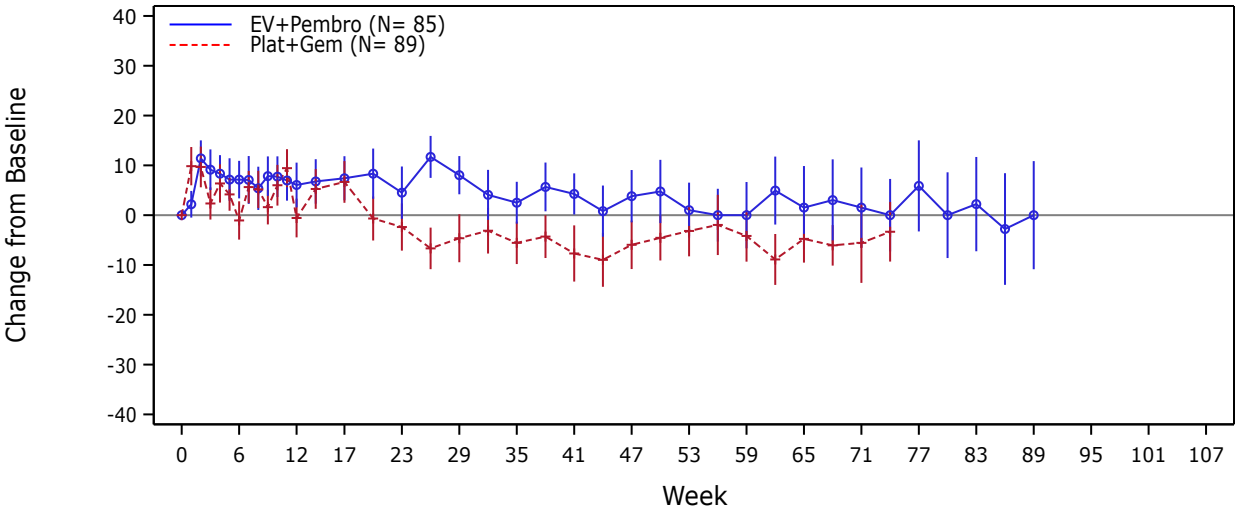
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.19.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Loss of Appetite by Region - Analysis Set mITT 1

Region: Rest of World



Number of subjects

EV+Pembro	80	70	66	63	59	54	40	47	35	33	27	22	22	17	15	12
Plat+Gem	75	63	58	55	42	36	30	26	28	21	16	14	12			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

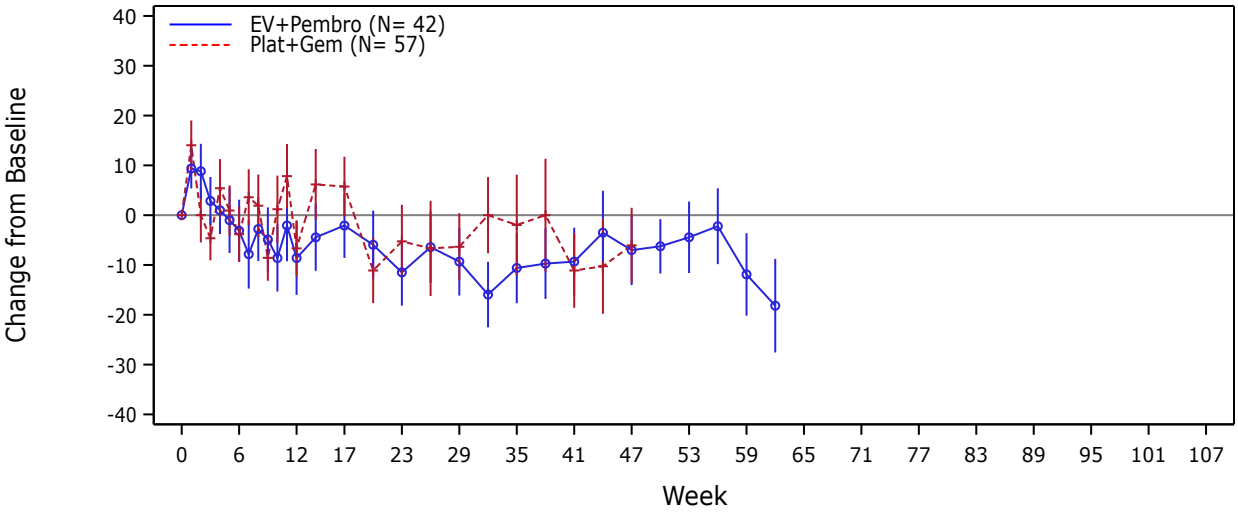
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.19.1.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Loss of Appetite by Sex - Analysis Set mITT 1

Sex: Female



Number of subjects

EV+Pembro	36	32	31	32	29	25	22	25	19	15	14
Plat+Gem	42	35	30	29	19	21	17	12	11		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

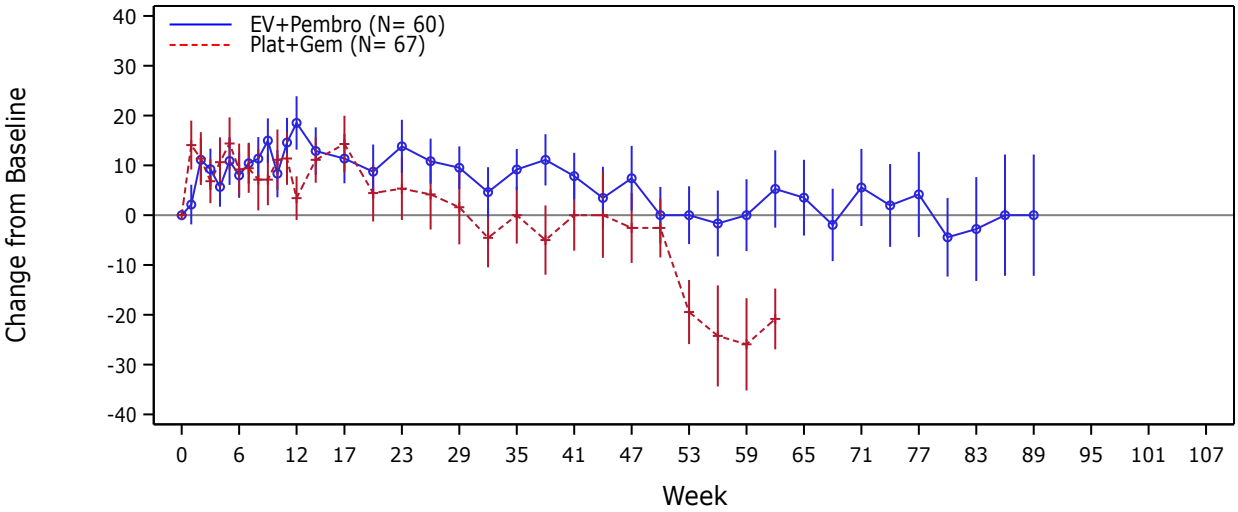
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.19.1.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Loss of Appetite by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Lymph node only



Number of subjects

EV+Pembro	53	50	45	44	41	42	40	34	27	22	19	19	18	16	12	10
Plat+Gem	49	40	39	35	25	21	19	18	13	12	9					

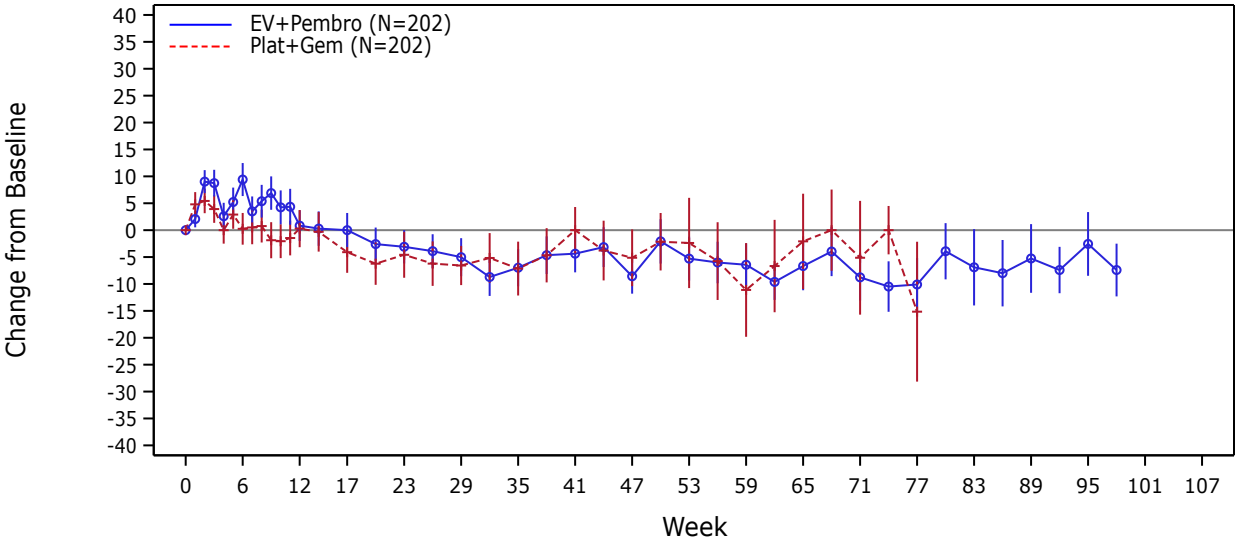
Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.19.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Loss of Appetite - Analysis Set mITT 2



Number of subjects

EV+Pembro	160	124	119	111	97	93	86	84	70	63	57	40	38	33	29	19	13
Plat+Gem	165	131	115	106	80	71	56	47	39	28	21	16	13	11			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

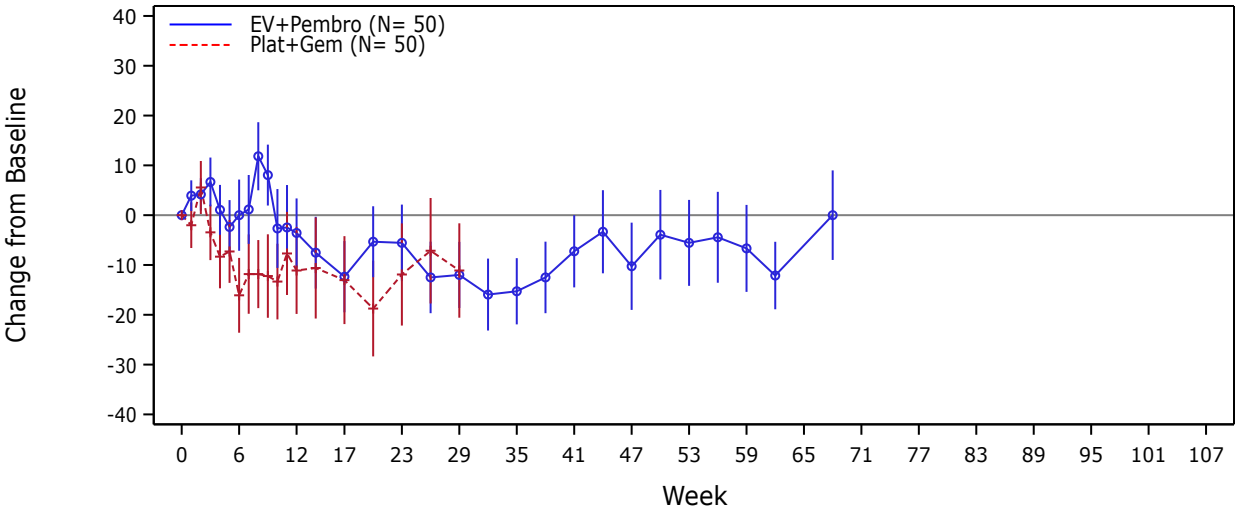
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.19.2.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Loss of Appetite by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Present



Number of subjects

EV+Pembro	40	30	28	27	24	25	24	23	13	18	15
Plat+Gem	40	29	27	23	14	12					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

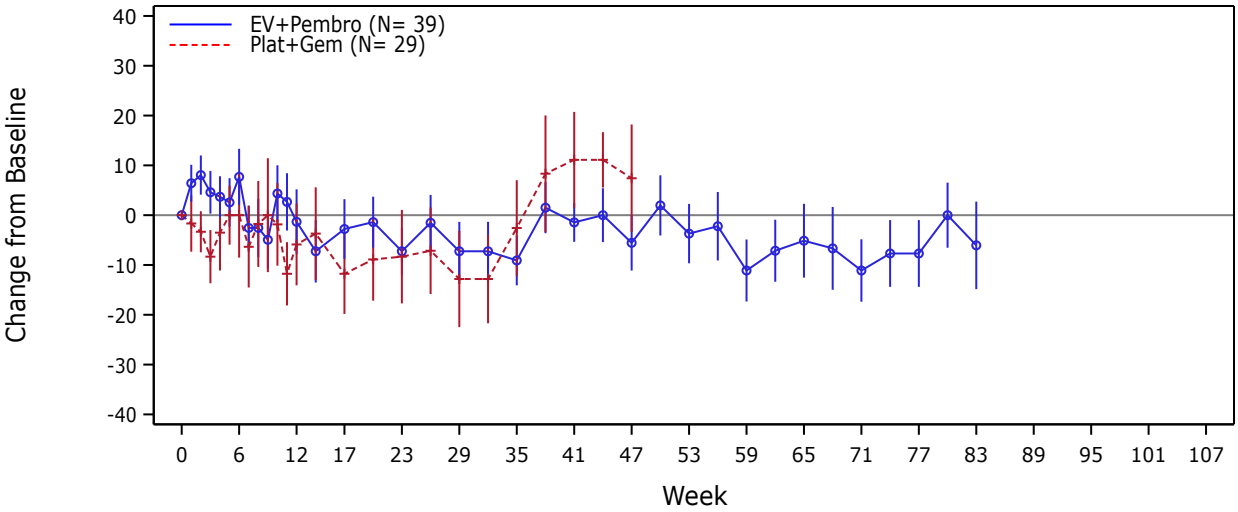
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.19.2.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Loss of Appetite by Age - Analysis Set mITT 2

Age: < 65 years



Number of subjects

EV+Pembro	32	26	25	24	23	23	22	23	18	18	15	13	12	13	11
Plat+Gem	22	18	17	17	16	13	13	9	9						

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

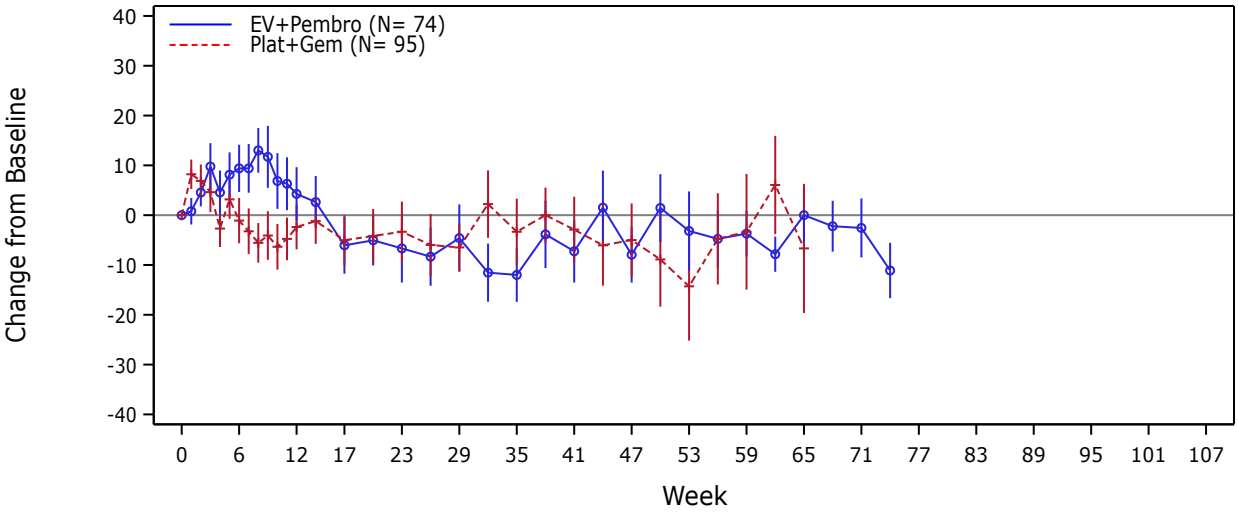
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.19.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Loss of Appetite by Region - Analysis Set mITT 2

Region: Europe



Number of subjects

EV+Pembro	53	39	39	33	30	29	25	23	21	21	18	13	13
Plat+Gem	75	61	56	53	40	36	30	23	20	14	10	10	

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

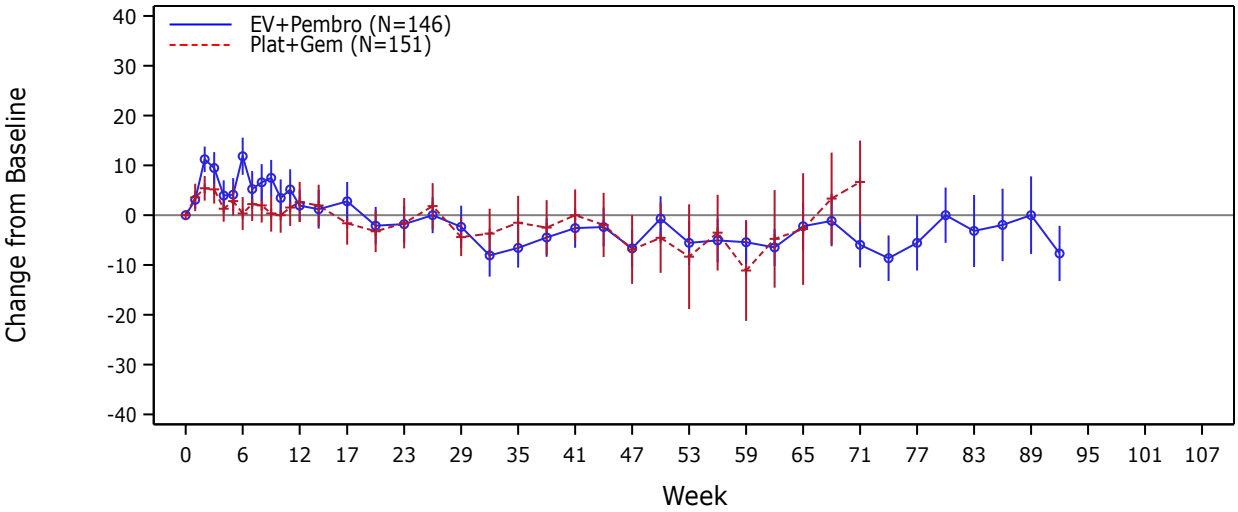
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.19.2.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Loss of Appetite by Sex - Analysis Set mITT 2

Sex: Male



Number of subjects

EV+Pembro	119	93	87	84	74	71	66	64	50	48	43	30	28	24	21	11
Plat+Gem	123	98	88	82	62	53	44	37	29	20	15	12	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

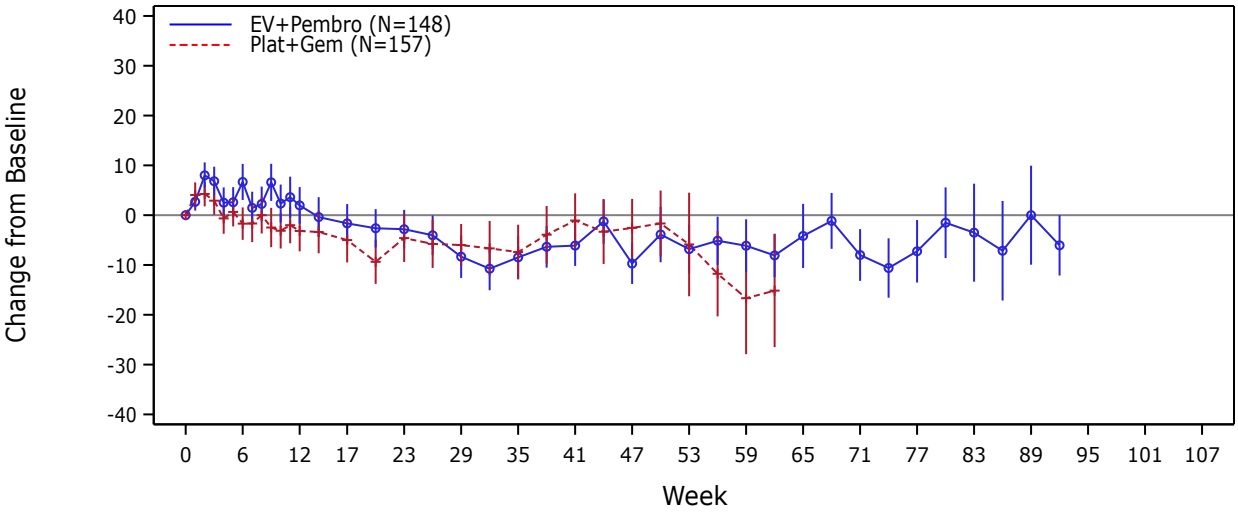
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.19.2.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Loss of Appetite by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Visceral metastases



Number of subjects

EV+Pembro	119	90	85	81	71	64	63	60	48	44	38	24	25	23	19	10
Plat+Gem	128	98	84	80	58	50	36	31	26	17	12					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

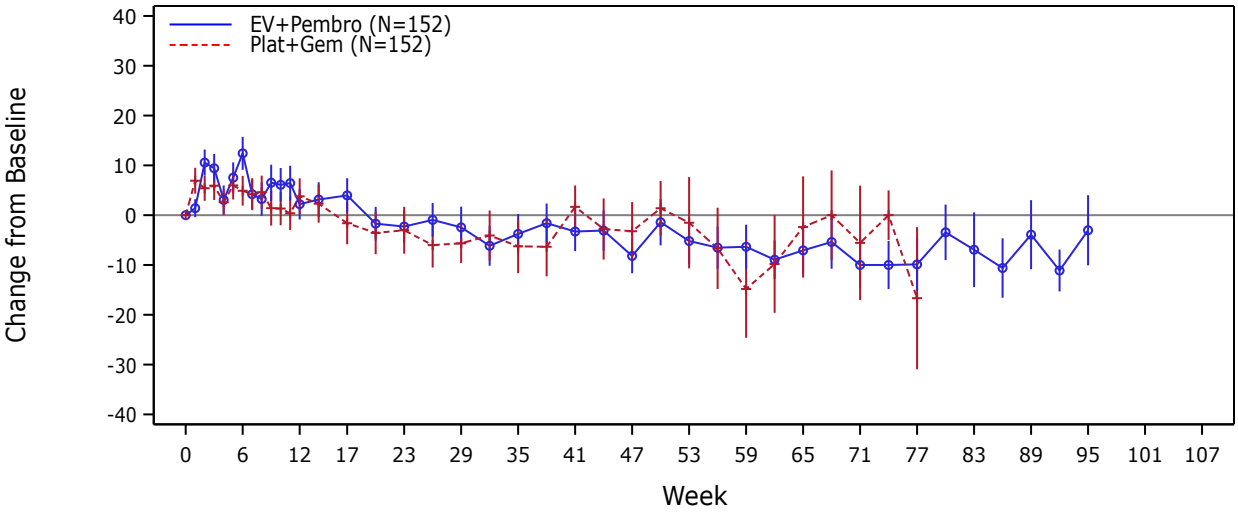
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.19.2.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Loss of Appetite by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Absent



Number of subjects

EV+Pembro	120	94	91	84	73	68	62	61	57	45	42	33	30	27	24	17	11
Plat+Gem	125	102	88	83	66	59	48	40	31	22	18	14	12	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

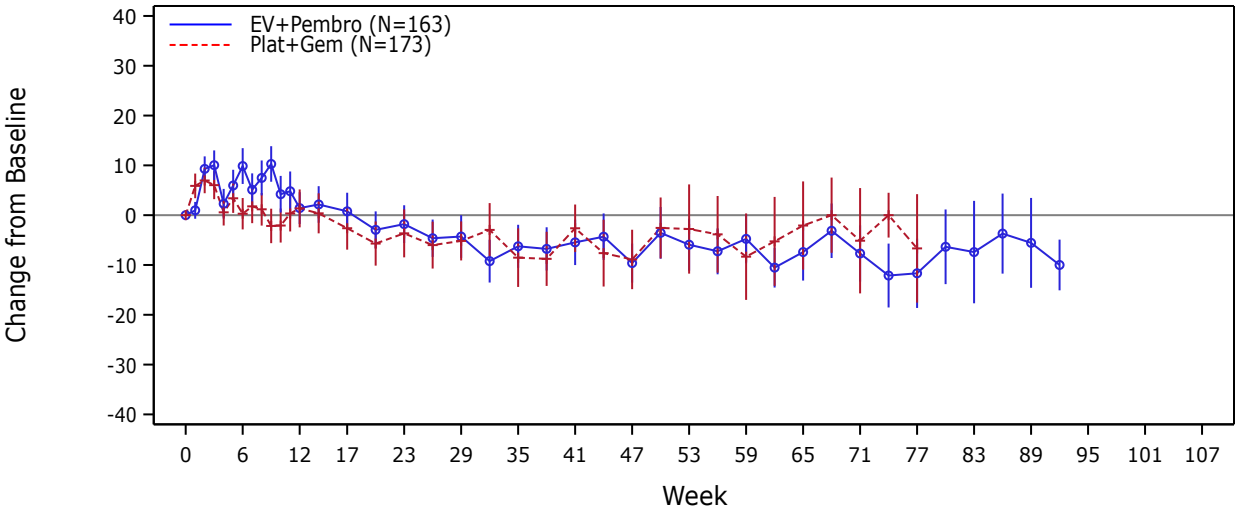
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.19.2.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Loss of Appetite by Age - Analysis Set mITT 2

Age: >= 65 years



Number of subjects

EV+Pembro	128	98	94	87	74	70	64	61	52	45	42	27	26	20	18	12
Plat+Gem	143	113	98	89	64	58	43	38	30	24	20	16	13	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

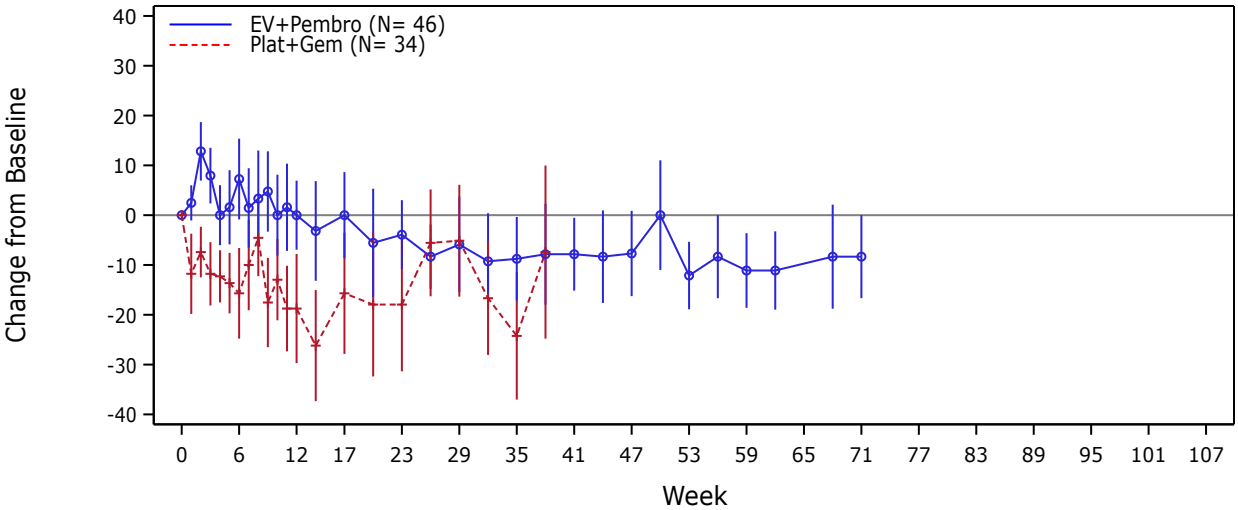
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.19.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Loss of Appetite by Region - Analysis Set mITT 2

Region: North America



Number of subjects

EV+Pembro	33	23	22	23	17	17	19	17	13	11	12	8
Plat+Gem	27	17	16	17	13	13	11					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

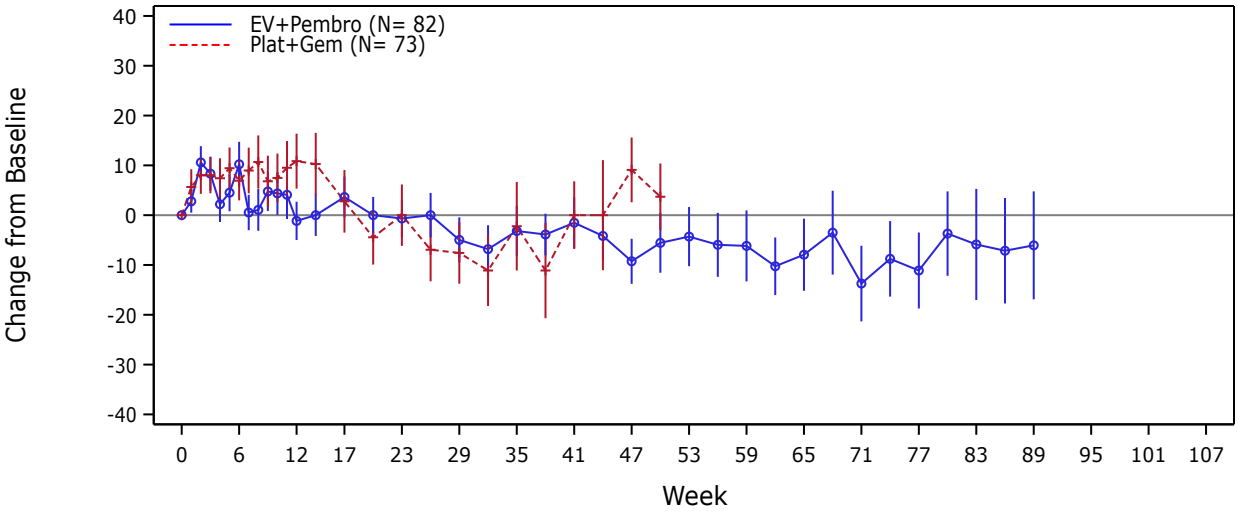
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.19.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Loss of Appetite by Region - Analysis Set mITT 2

Region: Rest of World



Number of subjects

EV+Pembro	74	62	58	55	50	47	42	44	36	31	27	21	17	18	17	11
Plat+Gem	63	53	43	36	27	22	15	16	11							

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

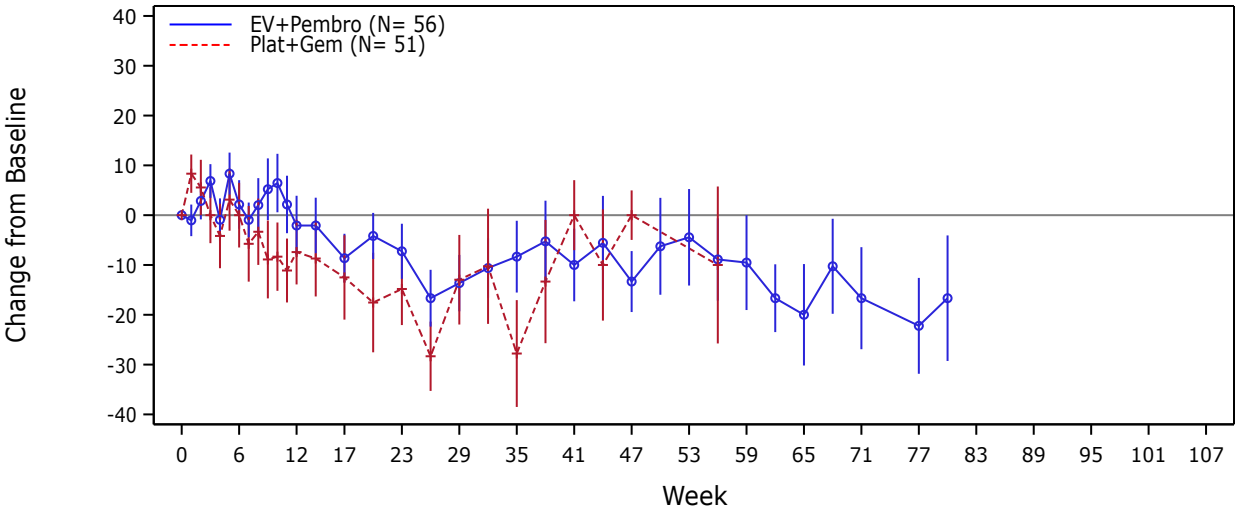
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.19.2.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Loss of Appetite by Sex - Analysis Set mITT 2

Sex: Female



Number of subjects

EV+Pembro	41	31	32	27	23	22	20	20	20	15	14	10	10	9
Plat+Gem	42	33	27	24	18	18	12	10	10					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

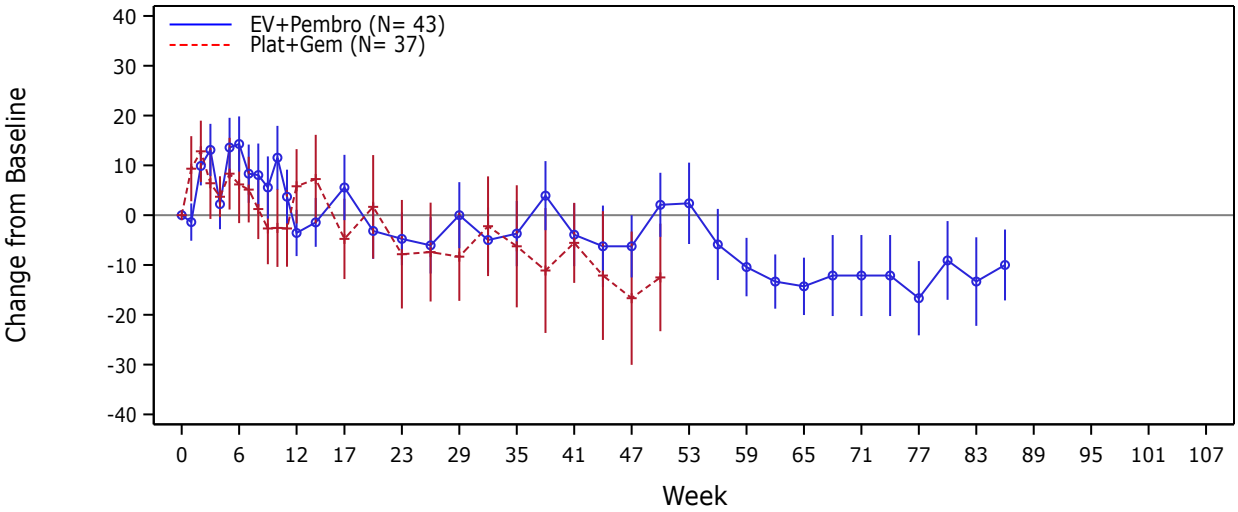
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.19.2.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Loss of Appetite by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Lymph node only



Number of subjects

EV+Pembro	33	28	28	24	21	23	18	17	16	14	16	14	11	10	10
Plat+Gem	29	27	23	21	17	16	16	12	10						

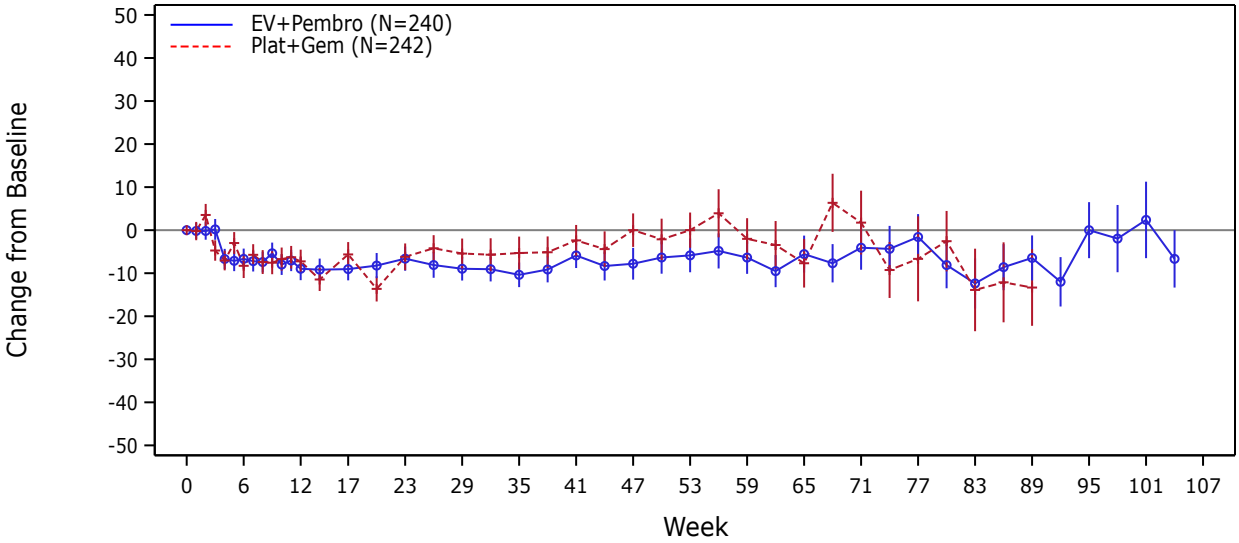
Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.20.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Sleep Disturbance - Analysis Set mITT 1



Number of subjects

EV+Pembro	206	170	171	162	151	145	122	119	94	74	68	54	49	42	35	31	21	14
Plat+Gem	188	149	138	130	97	86	69	56	49	42	33	26	19	15	12	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

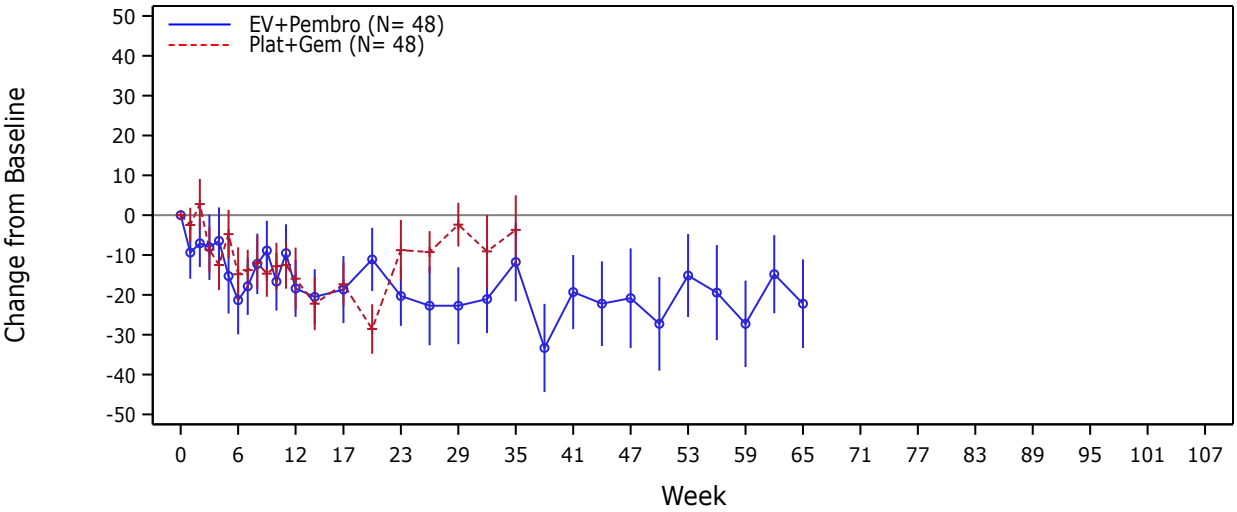
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.20.1.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Sleep Disturbance by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Present



Number of subjects

EV+Pembro	39	25	29	25	23	22	17	19	16	11	11	9
Plat+Gem	33	27	23	25	19	14	9					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

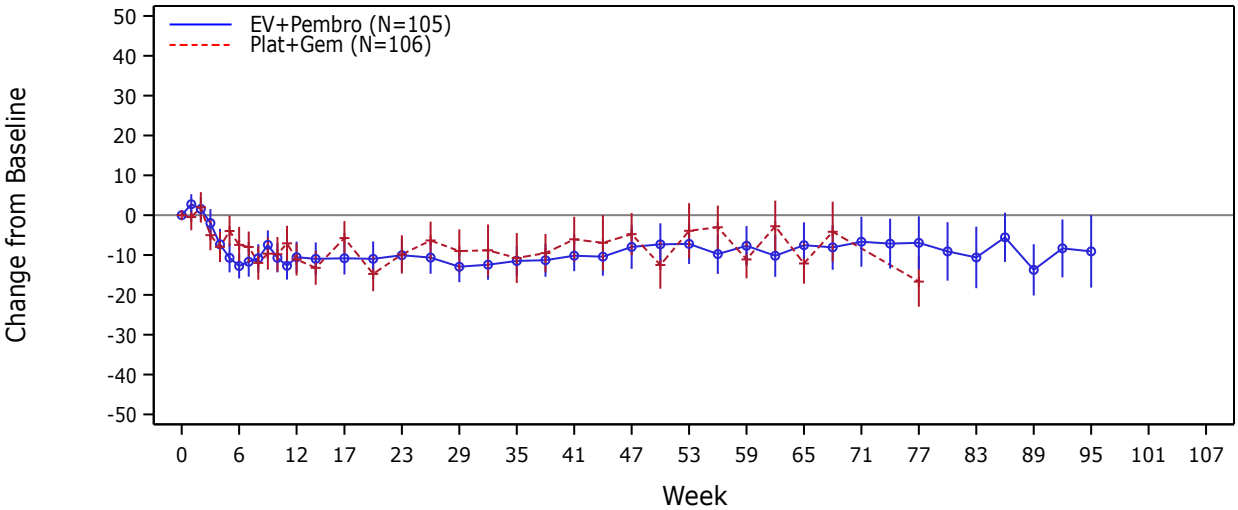
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.20.1.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Sleep Disturbance by Age - Analysis Set mITT 1

Age: < 65 years



Number of subjects

EV+Pembro	92	81	79	77	73	67	58	59	46	37	39	31	30	24	22	17	11
Plat+Gem	83	67	66	58	44	37	31	22	21	17	12	11		8			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

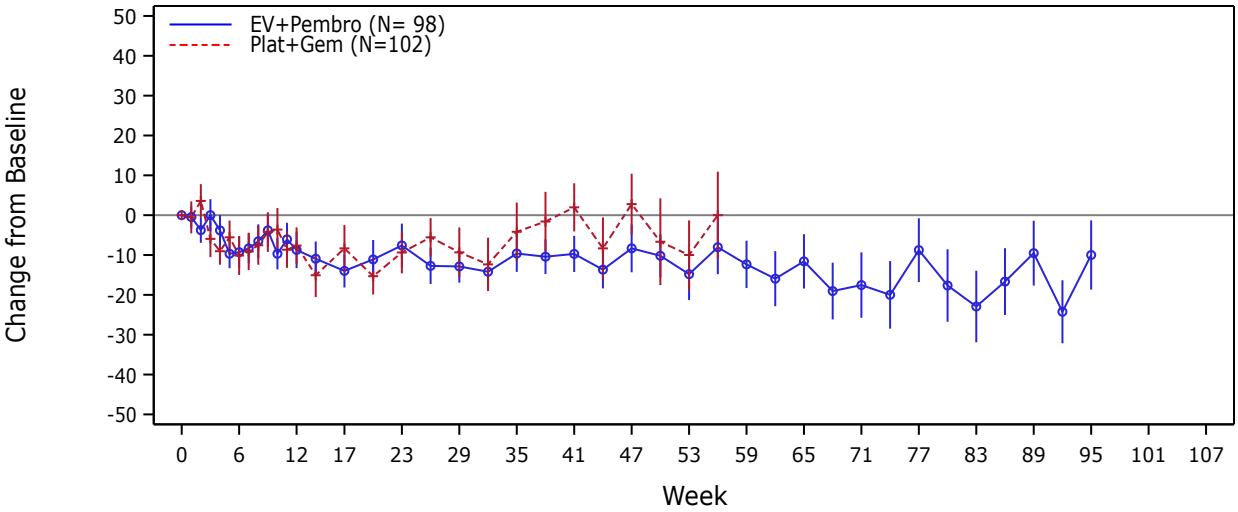
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.20.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Sleep Disturbance by Region - Analysis Set mITT 1

Region: Europe



Number of subjects

EV+Pembro	79	61	65	62	57	57	52	48	36	27	27	23	19	19	16	14	10
Plat+Gem	71	56	48	44	32	25	24	17	12	10							

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

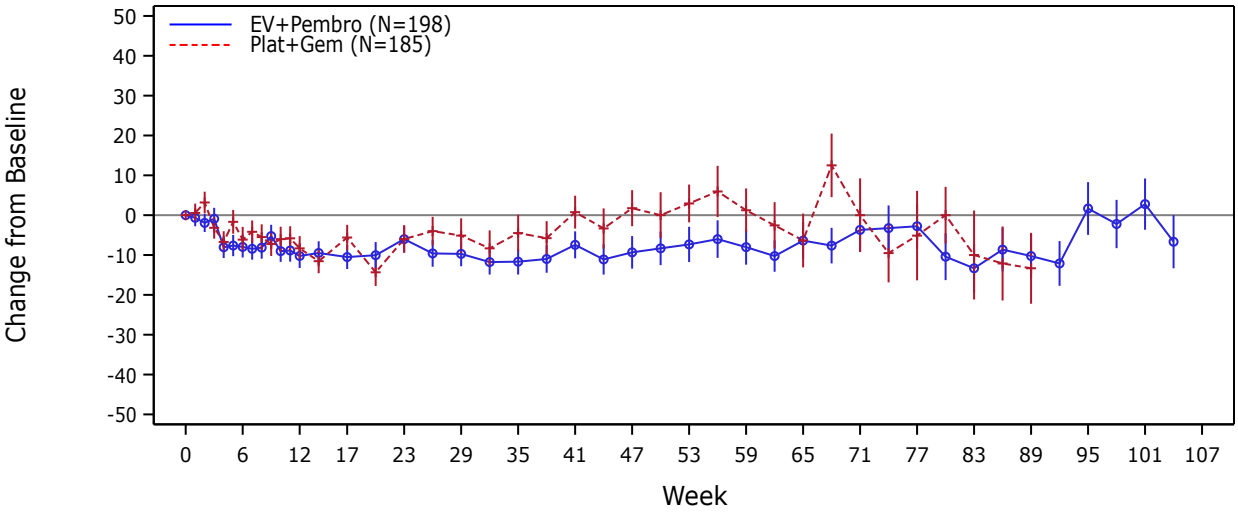
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.20.1.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Sleep Disturbance by Sex - Analysis Set mITT 1

Sex: Male



Number of subjects

EV+Pembro	170	138	140	130	122	120	100	94	75	59	54	47	45	36	30	26	20	12
Plat+Gem	146	114	108	101	78	65	52	44	38	34	27	21	14	13	10	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

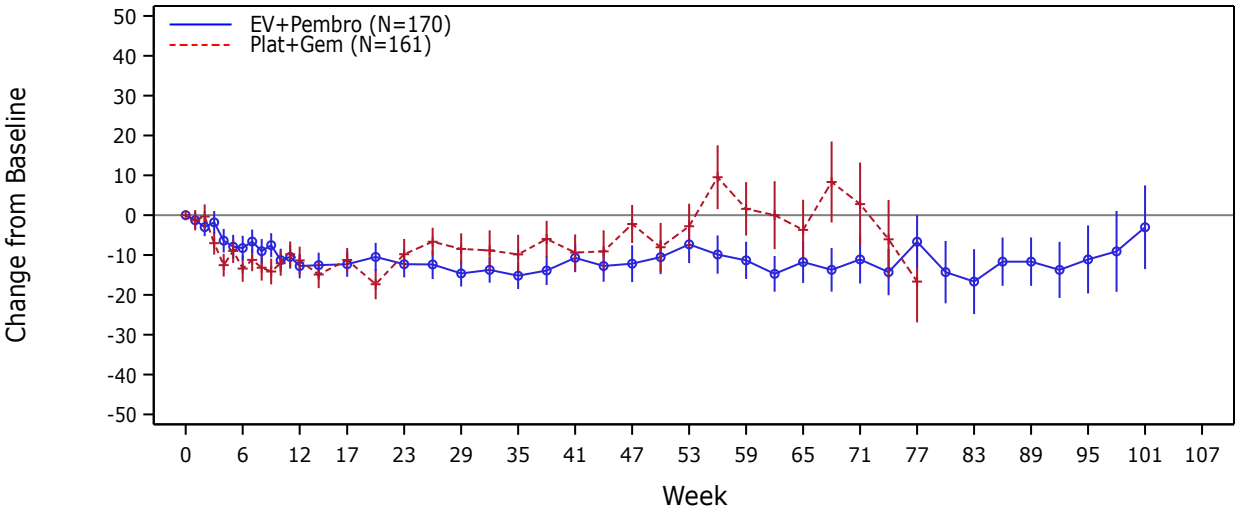
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.20.1.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Sleep Disturbance by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Visceral metastases



Number of subjects

EV+Pembro	146	113	120	111	103	98	79	81	63	50	47	34	30	25	22	20	12	11
Plat+Gem	129	102	91	89	68	59	44	32	30	24	21	18	12	10				

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

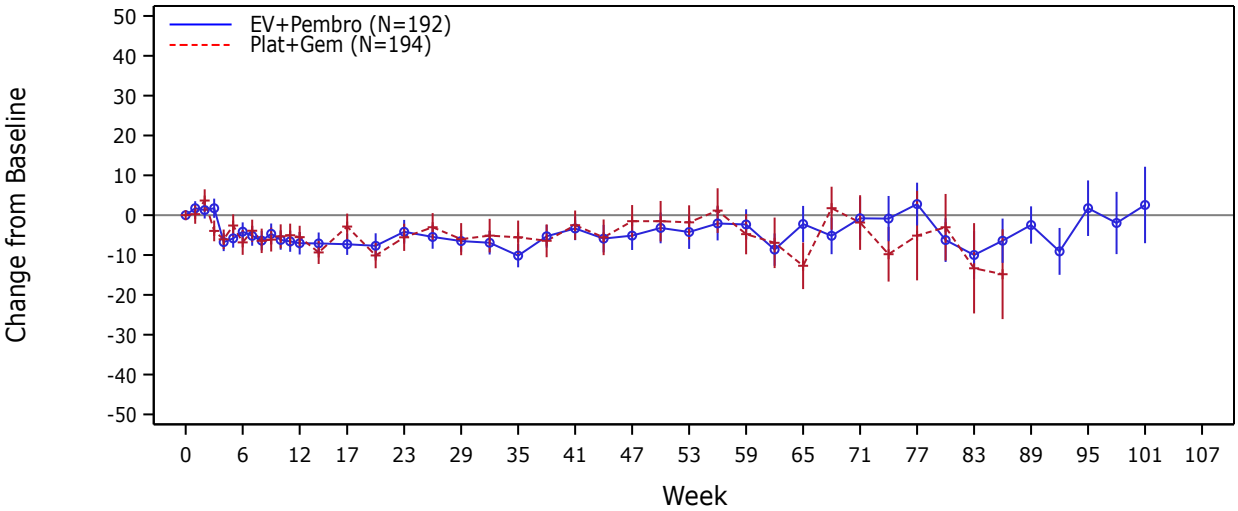
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.20.1.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Sleep Disturbance by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Absent



Number of subjects

EV+Pembro	167	145	142	137	128	123	105	100	78	63	57	45	42	36	30	27	19	13
Plat+Gem	155	122	115	105	78	72	60	53	44	37	28	21	18	13	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

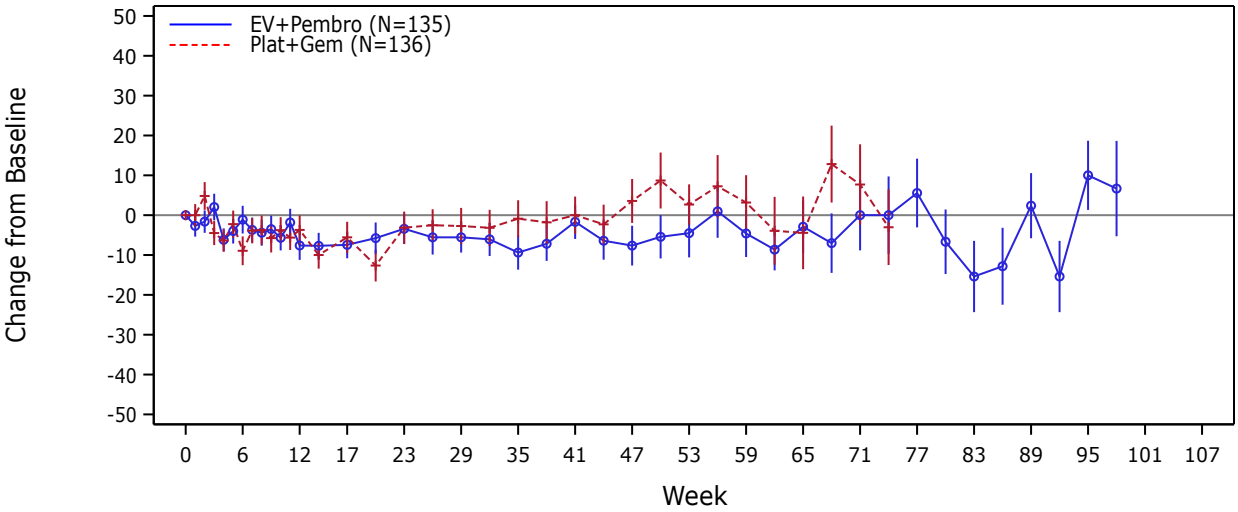
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.20.1.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Sleep Disturbance by Age - Analysis Set mITT 1

Age: >= 65 years



Number of subjects

EV+Pembro	114	89	92	85	78	78	64	60	48	37	29	23	19	18	13	14	10
Plat+Gem	105	82	72	72	53	49	38	34	28	25	21	15	13				

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

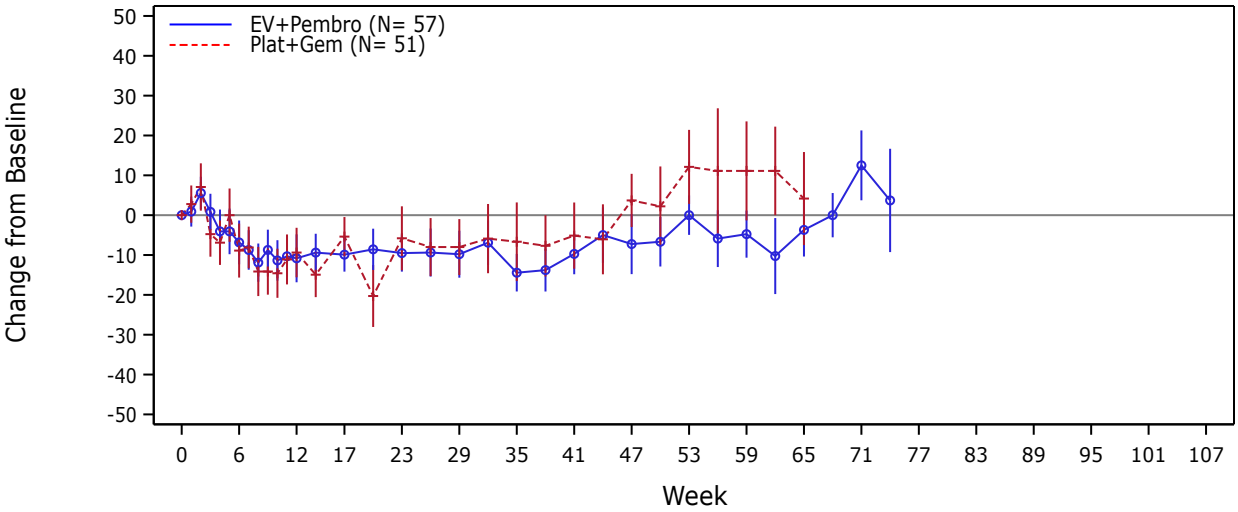
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.20.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Sleep Disturbance by Region - Analysis Set mITT 1

Region: North America



Number of subjects

EV+Pembro	47	39	40	37	35	34	30	24	23	14	14	9	8
Plat+Gem	42	30	32	31	23	25	15	13	9	11	9	8	

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

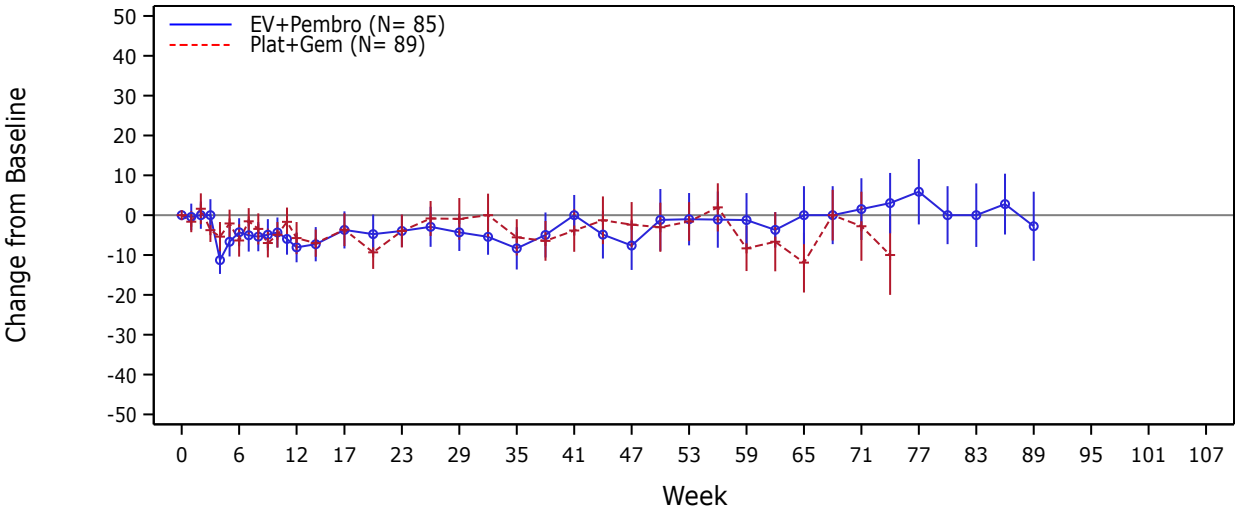
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.20.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Sleep Disturbance by Region - Analysis Set mITT 1

Region: Rest of World



Number of subjects

EV+Pembro	80	70	66	63	59	54	40	47	35	33	27	22	22	17	15	12
Plat+Gem	75	63	58	55	42	36	30	26	28	21	16	14	12			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

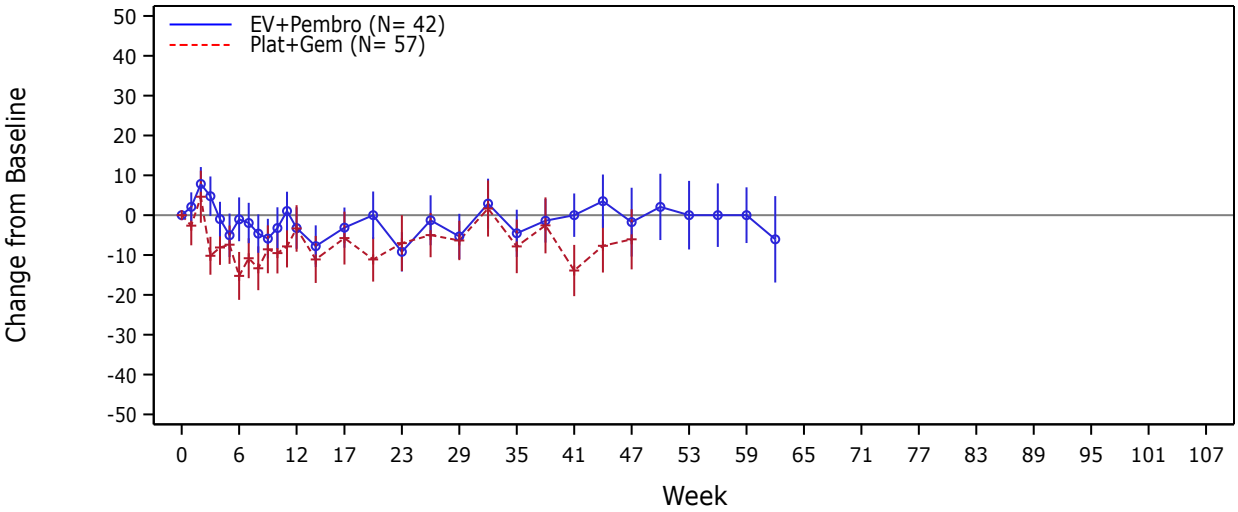
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.20.1.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Sleep Disturbance by Sex - Analysis Set mITT 1

Sex: Female



Number of subjects

EV+Pembro	36	32	31	32	29	25	22	25	19	15	14
Plat+Gem	42	35	30	29	19	21	17	12	11		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

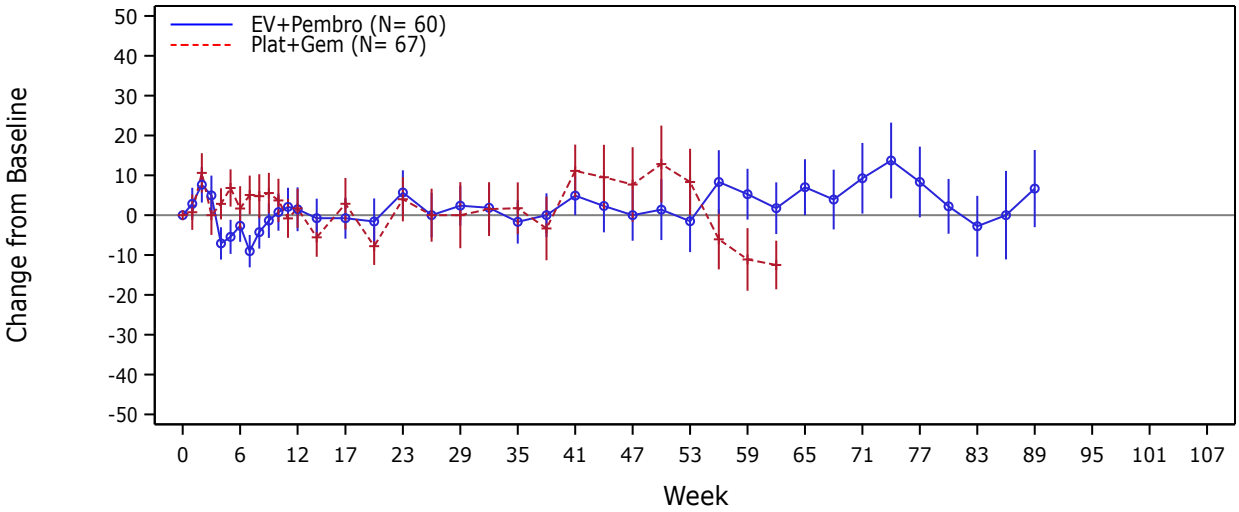
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.20.1.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Sleep Disturbance by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Lymph node only



Number of subjects

EV+Pembro	53	50	45	44	41	42	40	34	27	22	19	19	18	16	12	10
Plat+Gem	49	40	39	35	25	21	19	18	13	12	9					

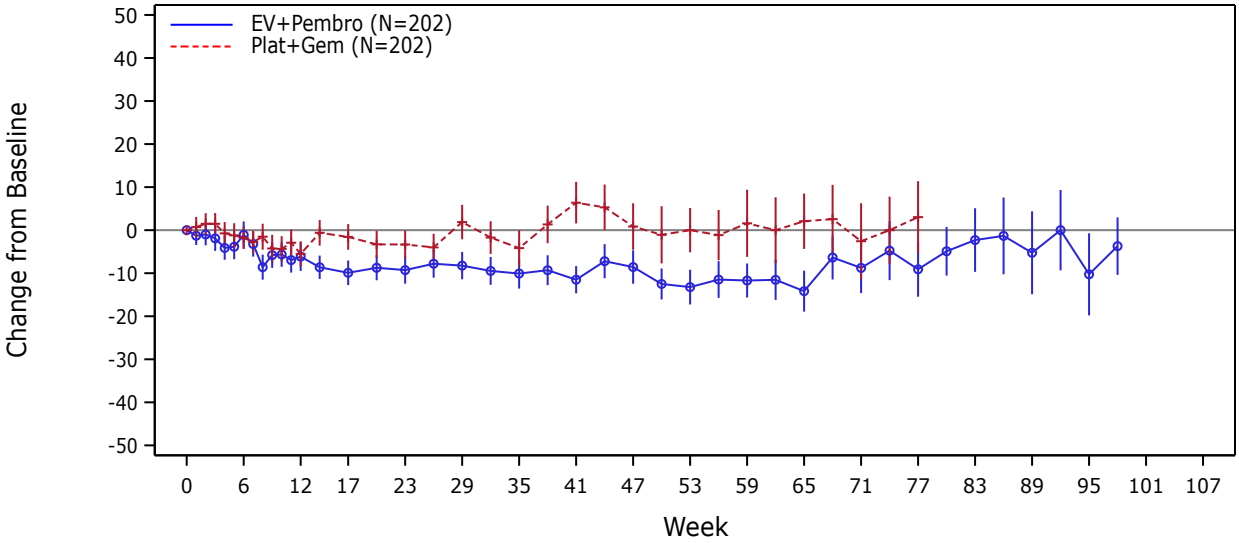
Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.20.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Sleep Disturbance - Analysis Set mITT 2



Number of subjects

EV+Pembro	160	124	119	111	97	93	86	84	70	63	57	40	38	33	29	19	13
Plat+Gem	165	131	115	106	80	71	56	47	39	28	21	16	13	11			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

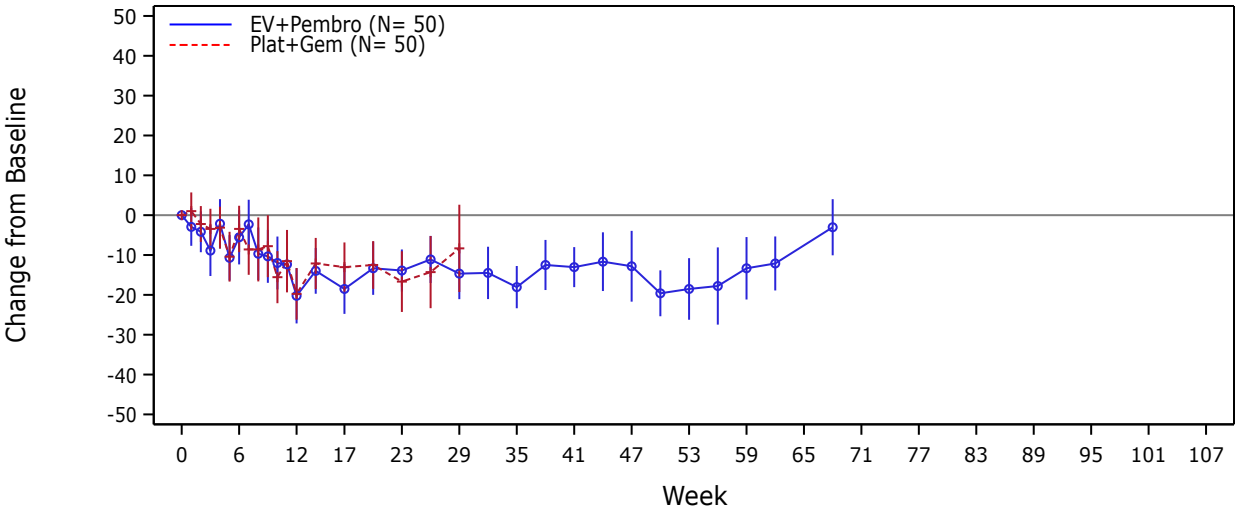
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.20.2.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Sleep Disturbance by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Present



Number of subjects

EV+Pembro	40	30	28	27	24	25	24	23	13	18	15
Plat+Gem	40	29	27	23	14	12					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

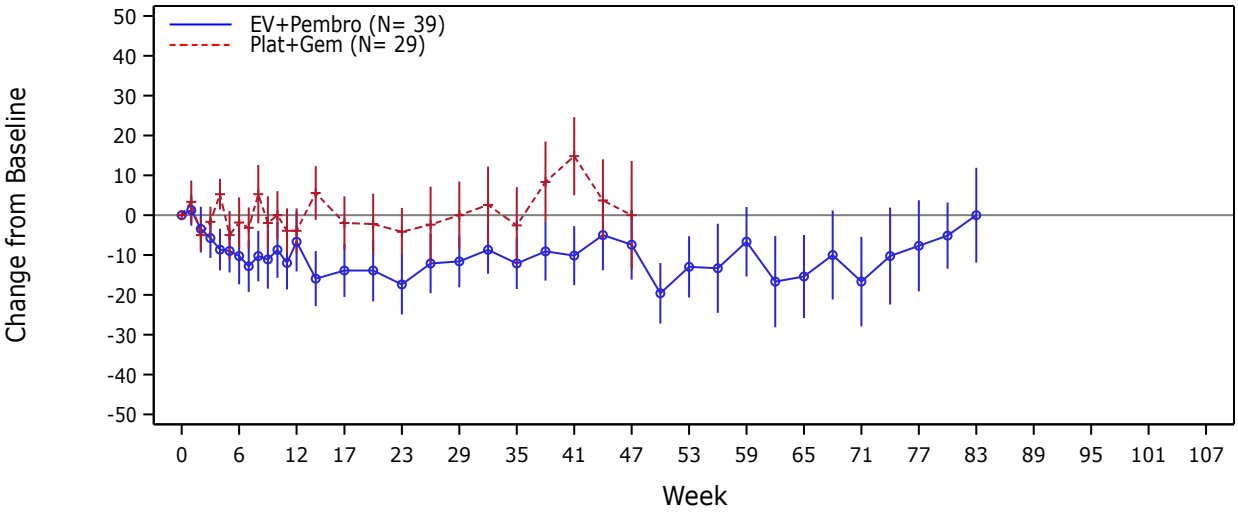
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.20.2.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Sleep Disturbance by Age - Analysis Set mITT 2

Age: < 65 years



Number of subjects

EV+Pembro	32	26	25	24	23	23	22	23	18	18	15	13	12	13	11
Plat+Gem	22	18	17	17	16	13	13	9	9						

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

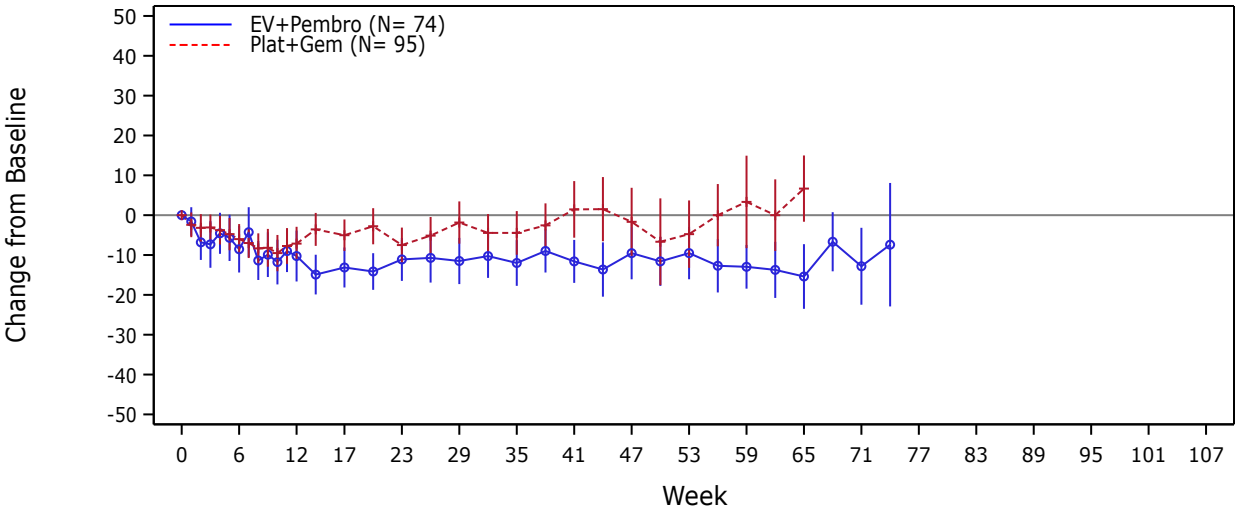
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.20.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Sleep Disturbance by Region - Analysis Set mITT 2

Region: Europe



Number of subjects

EV+Pembro	53	39	39	33	30	29	25	23	21	21	18	13	13
Plat+Gem	75	61	56	53	40	36	30	23	20	14	10	10	

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

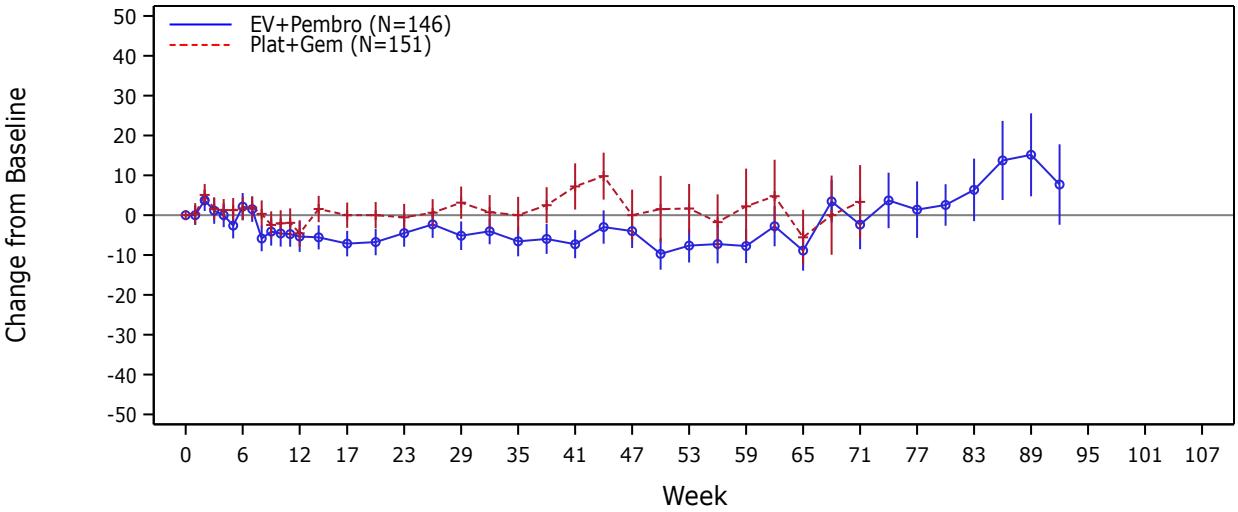
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.20.2.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Sleep Disturbance by Sex - Analysis Set mITT 2

Sex: Male



Number of subjects

EV+Pembro	119	93	87	84	74	71	66	64	50	48	43	30	28	24	21	11
Plat+Gem	123	98	88	82	62	53	44	37	29	20	15	12	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

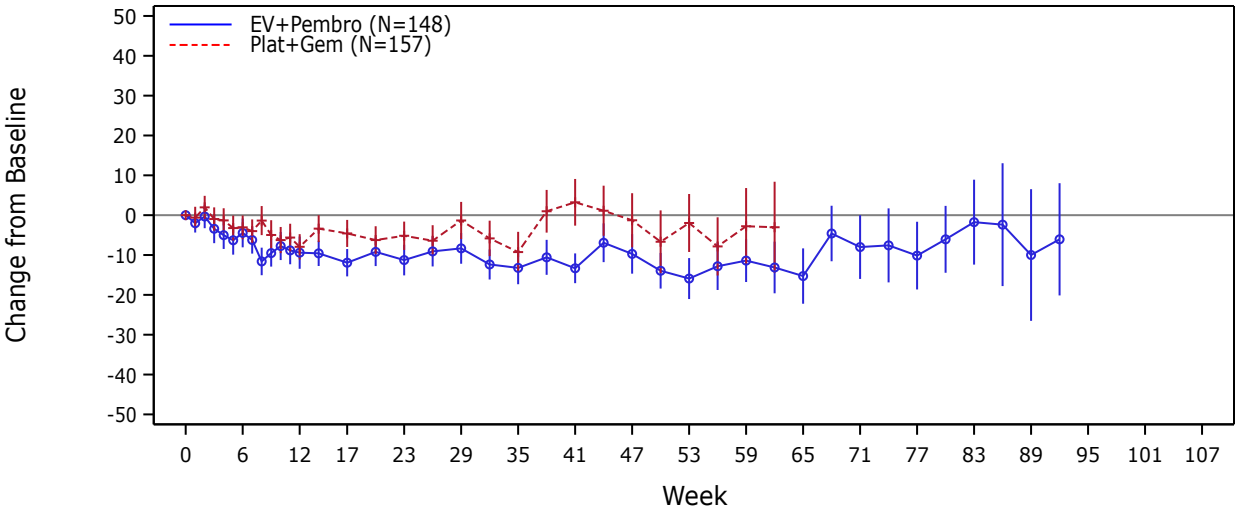
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.20.2.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Sleep Disturbance by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Visceral metastases



Number of subjects

EV+Pembro	119	90	85	81	71	64	63	60	48	44	38	24	25	23	19	10
Plat+Gem	128	98	84	80	58	50	36	31	26	17	12					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

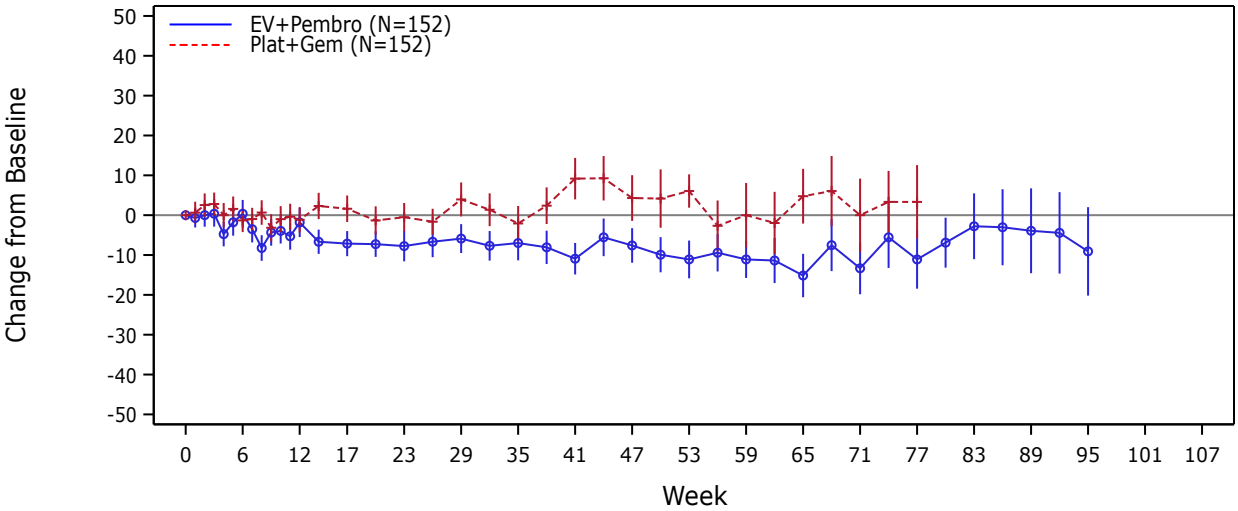
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.20.2.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Sleep Disturbance by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Absent



Number of subjects

EV+Pembro	120	94	91	84	73	68	62	61	57	45	42	33	30	27	24	17	11
Plat+Gem	125	102	88	83	66	59	48	40	31	22	18	14	12	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

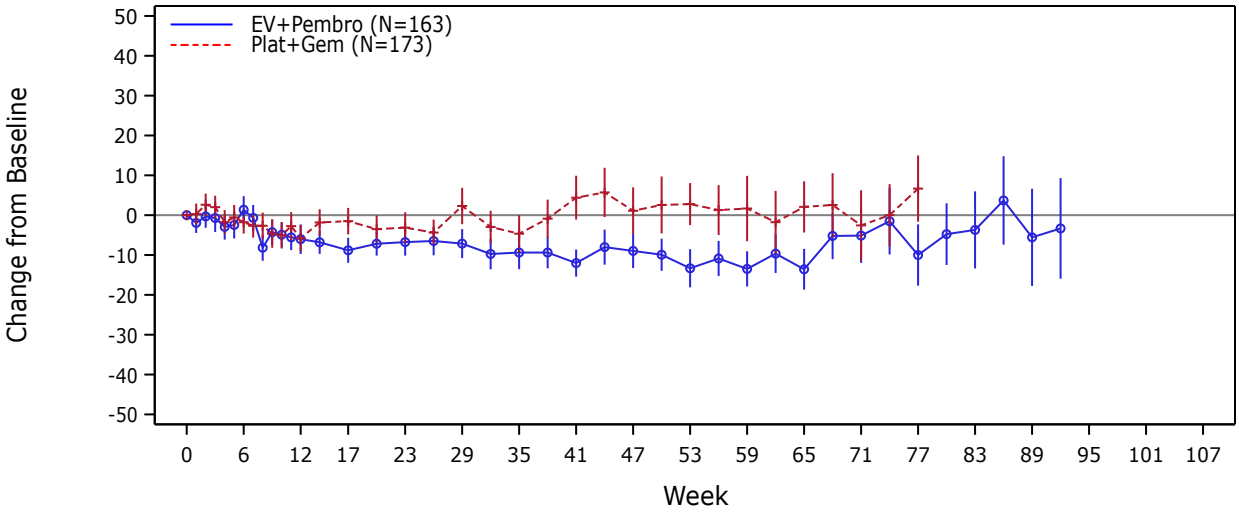
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.20.2.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Sleep Disturbance by Age - Analysis Set mITT 2

Age: >= 65 years



Number of subjects

EV+Pembro	128	98	94	87	74	70	64	61	52	45	42	27	26	20	18	12
Plat+Gem	143	113	98	89	64	58	43	38	30	24	20	16	13	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

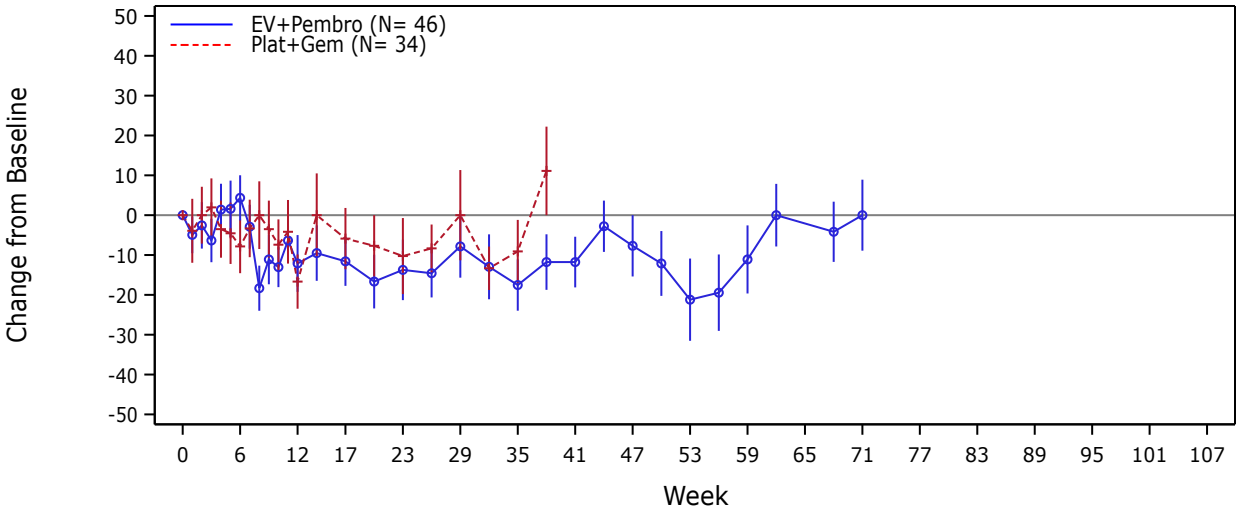
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.20.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Sleep Disturbance by Region - Analysis Set mITT 2

Region: North America



Number of subjects

EV+Pembro	33	23	22	23	17	17	19	17	13	11	12	8
Plat+Gem	27	17	16	17	13	13	11					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

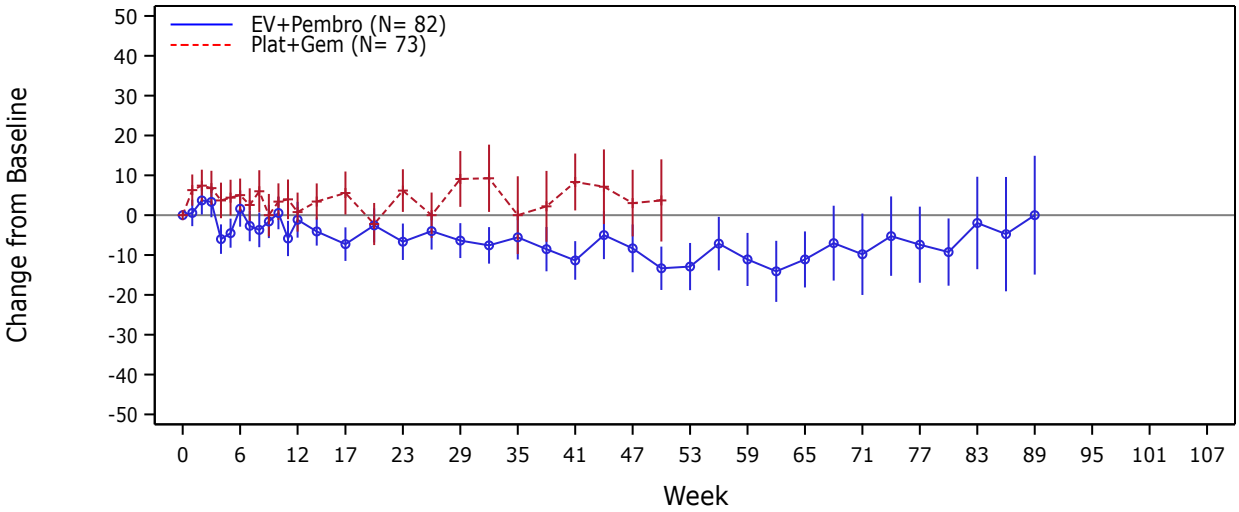
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.20.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Sleep Disturbance by Region - Analysis Set mITT 2

Region: Rest of World



Number of subjects

EV+Pembro	74	62	58	55	50	47	42	44	36	31	27	21	17	18	17	11
Plat+Gem	63	53	43	36	27	22	15	16	11							

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

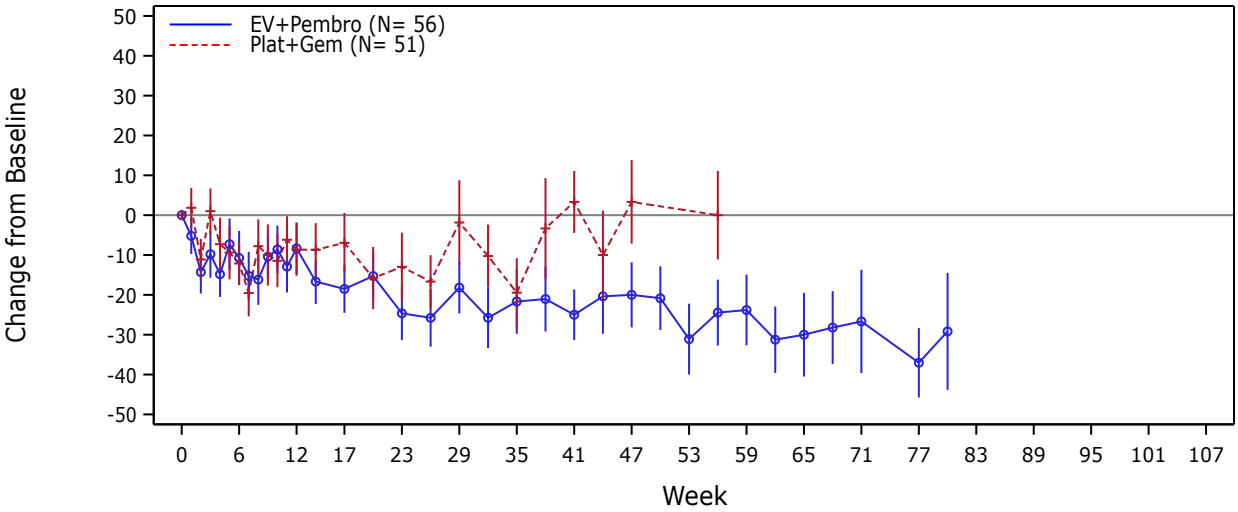
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.20.2.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Sleep Disturbance by Sex - Analysis Set mITT 2

Sex: Female



Number of subjects

EV+Pembro	41	31	32	27	23	22	20	20	20	15	14	10	10	9
Plat+Gem	42	33	27	24	18	18	12	10	10					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

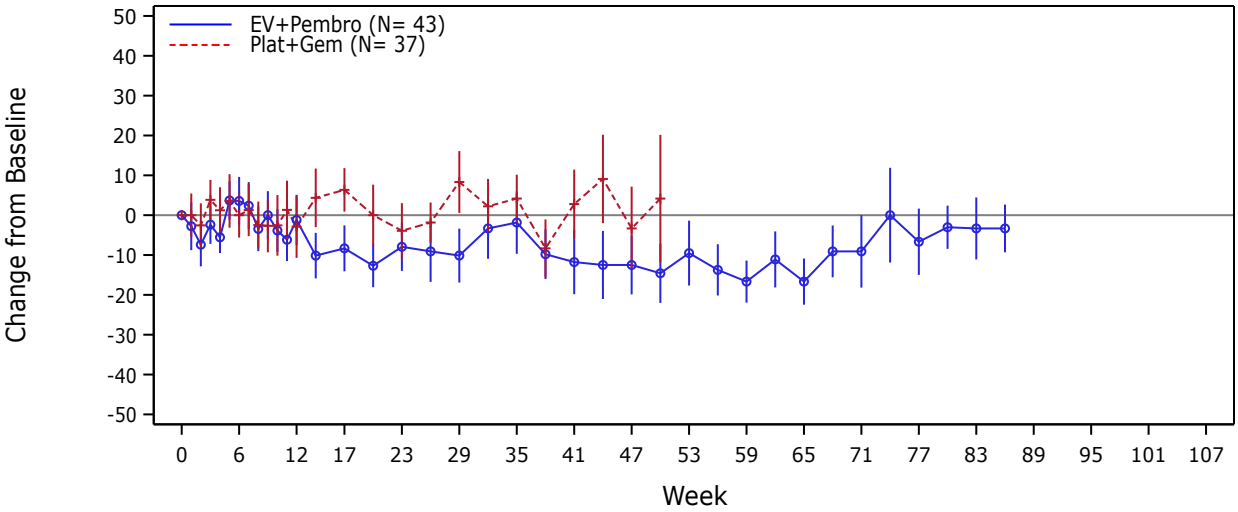
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.20.2.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Sleep Disturbance by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Lymph node only



Number of subjects

EV+Pembro	33	28	28	24	21	23	18	17	16	14	16	14	11	10	10
Plat+Gem	29	27	23	21	17	16	16	12	10						

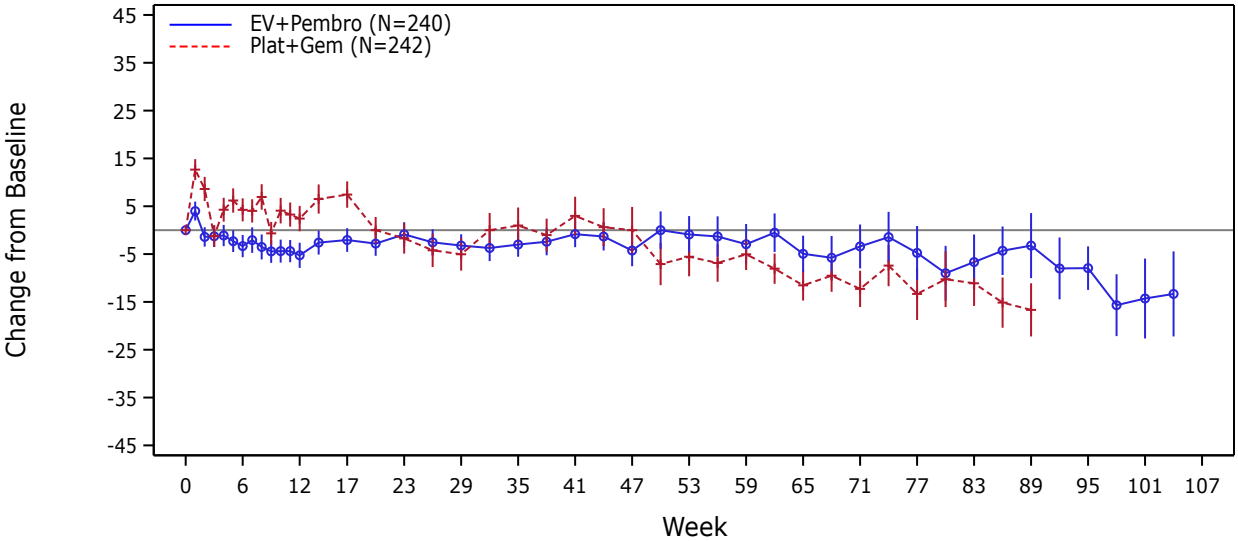
Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.21.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Constipation - Analysis Set mITT 1



Number of subjects

EV+Pembro	206	170	171	162	151	145	122	119	94	74	68	54	49	42	35	31	21	14
Plat+Gem	188	149	138	130	97	86	69	56	49	42	33	26	19	15	12	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

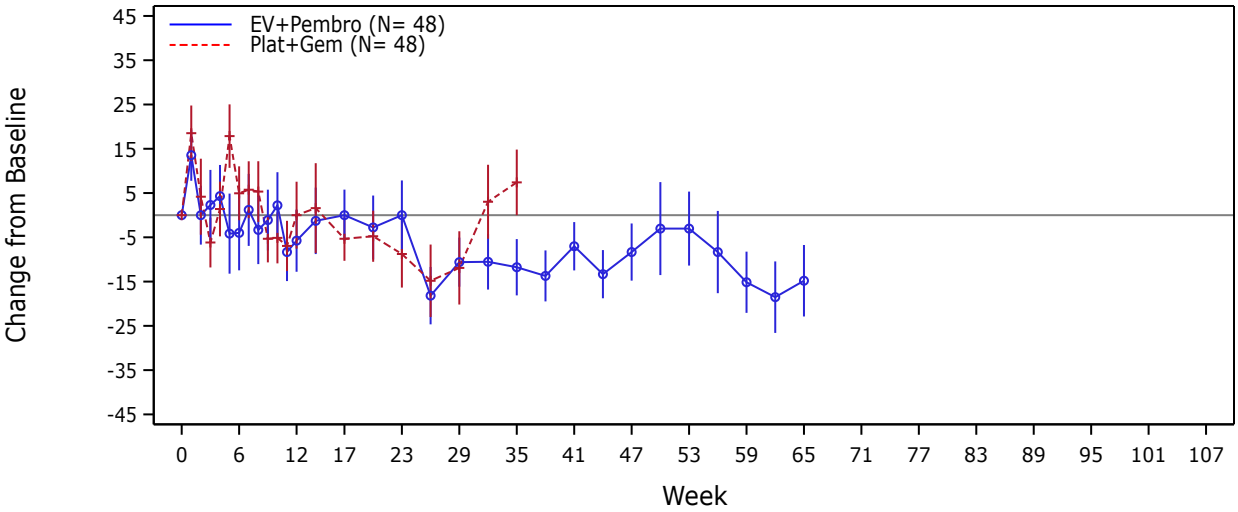
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.21.1.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Constipation by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Present



Number of subjects

EV+Pembro	39	25	29	25	23	22	17	19	16	11	11	9
Plat+Gem	33	27	23	25	19	14	9					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

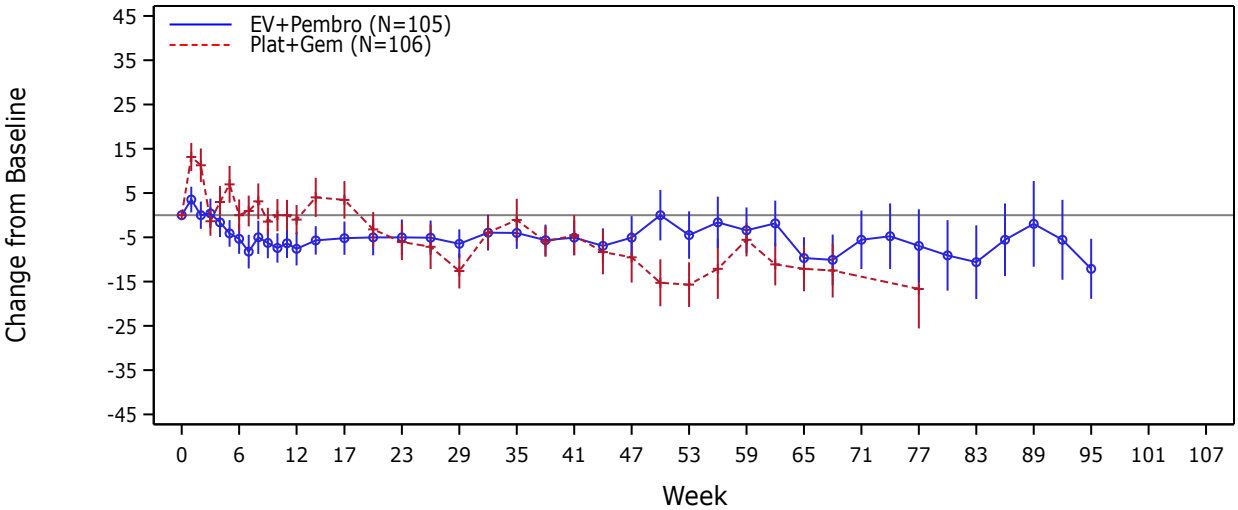
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.21.1.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Constipation by Age - Analysis Set mITT 1

Age: < 65 years



Number of subjects

EV+Pembro	92	81	79	77	73	67	58	59	46	37	39	31	30	24	22	17	11
Plat+Gem	83	67	66	58	44	37	31	22	21	17	12	11		8			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

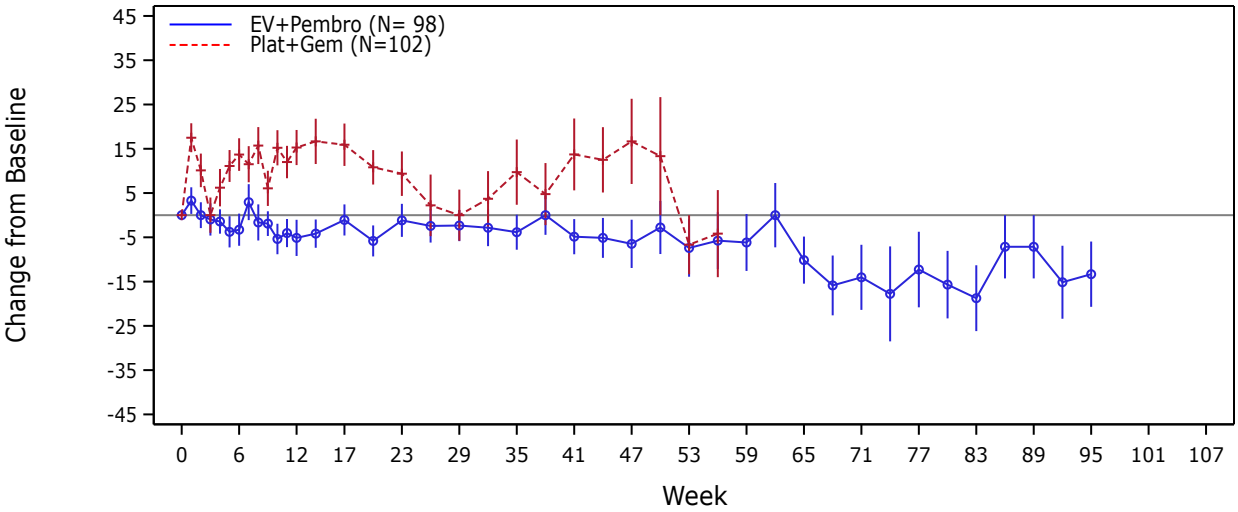
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.21.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Constipation by Region - Analysis Set mITT 1

Region: Europe



Number of subjects

EV+Pembro	79	61	65	62	57	57	52	48	36	27	27	23	19	19	16	14	10
Plat+Gem	71	56	48	44	32	25	24	17	12	10							

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

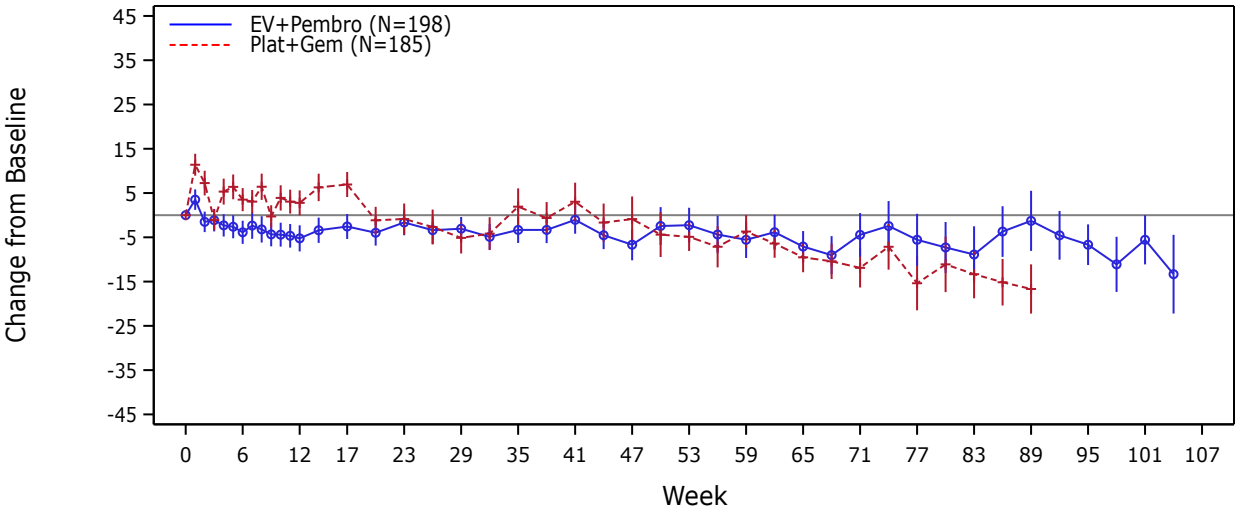
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.21.1.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Constipation by Sex - Analysis Set mITT 1

Sex: Male



Number of subjects

EV+Pembro	170	138	140	130	122	120	100	94	75	59	54	47	45	36	30	26	20	12
Plat+Gem	146	114	108	101	78	65	52	44	38	34	27	21	14	13	10	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

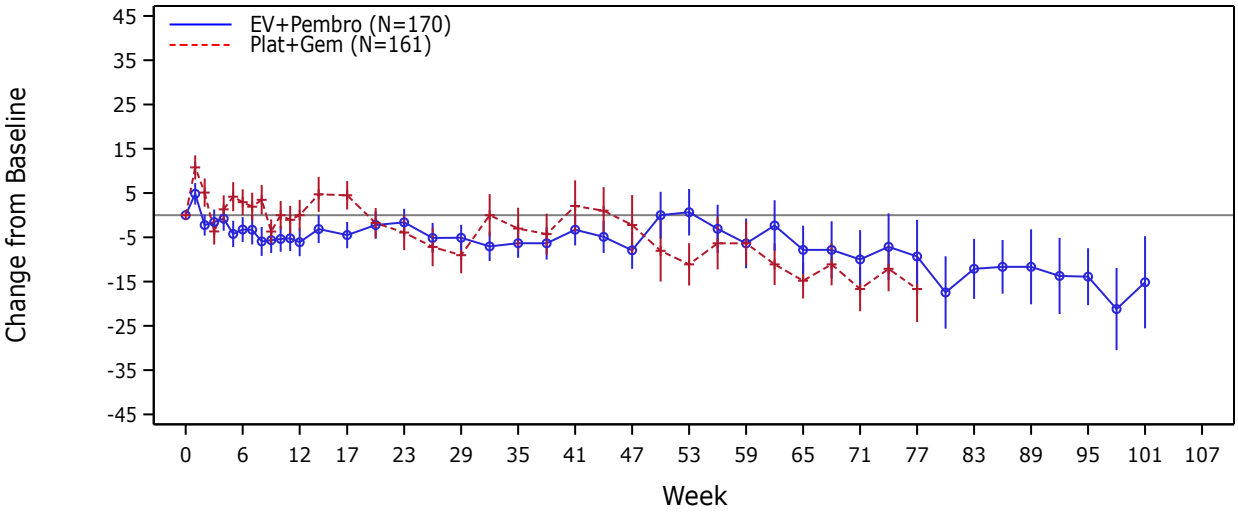
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.21.1.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Constipation by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Visceral metastases



Number of subjects

EV+Pembro	146	113	120	111	103	98	79	81	63	50	47	34	30	25	22	20	12	11
Plat+Gem	129	102	91	89	68	59	44	32	30	24	21	18	12	10				

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

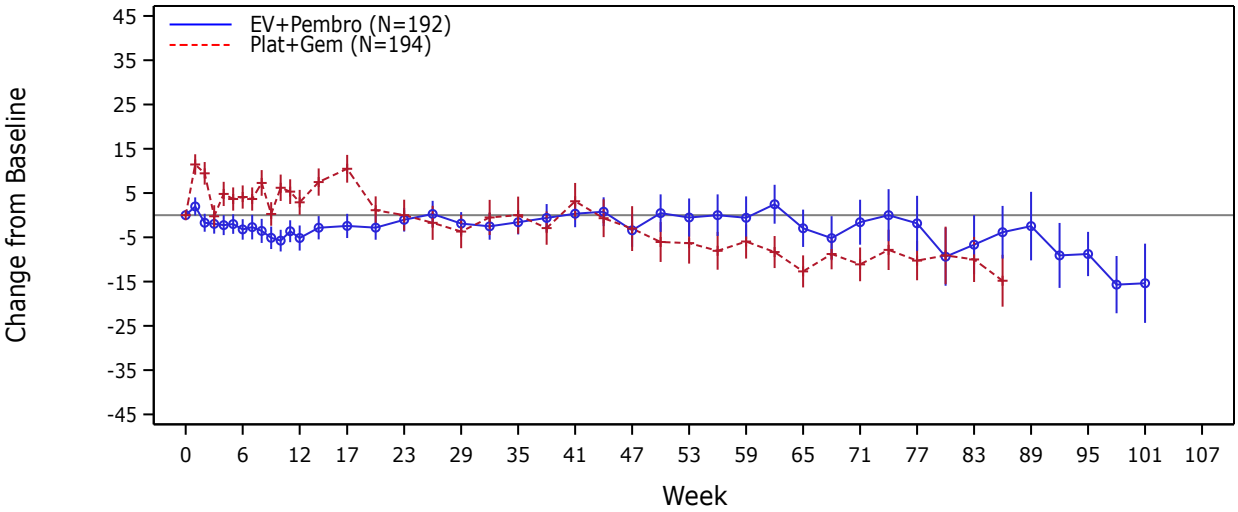
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.21.1.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Constipation by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Absent



Number of subjects

EV+Pembro	167	145	142	137	128	123	105	100	78	63	57	45	42	36	30	27	19	13
Plat+Gem	155	122	115	105	78	72	60	53	44	37	28	21	18	13	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

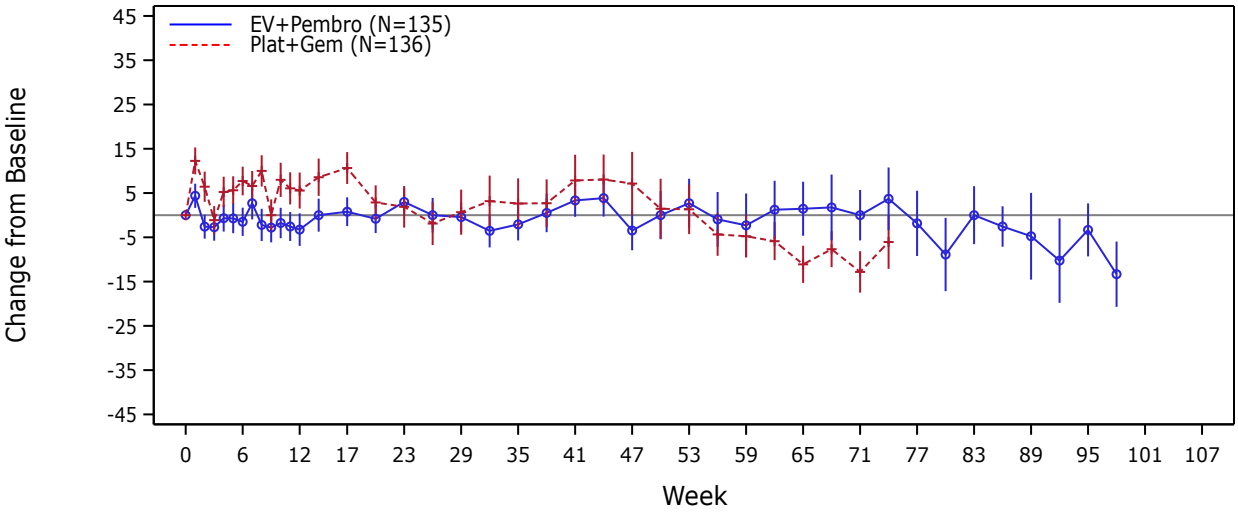
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.21.1.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Constipation by Age - Analysis Set mITT 1

Age: >= 65 years



Number of subjects

EV+Pembro	114	89	92	85	78	78	64	60	48	37	29	23	19	18	13	14	10
Plat+Gem	105	82	72	72	53	49	38	34	28	25	21	15	13				

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

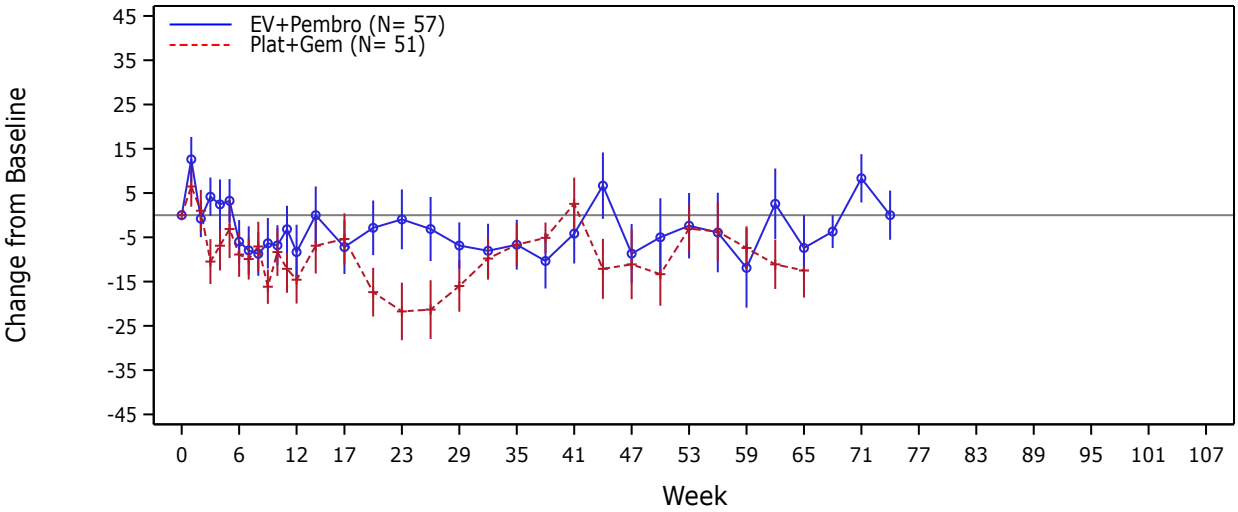
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.21.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Constipation by Region - Analysis Set mITT 1

Region: North America



Number of subjects

EV+Pembro	47	39	40	37	35	34	30	24	23	14	14	9	8
Plat+Gem	42	30	32	31	23	25	15	13	9	11	9	8	

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

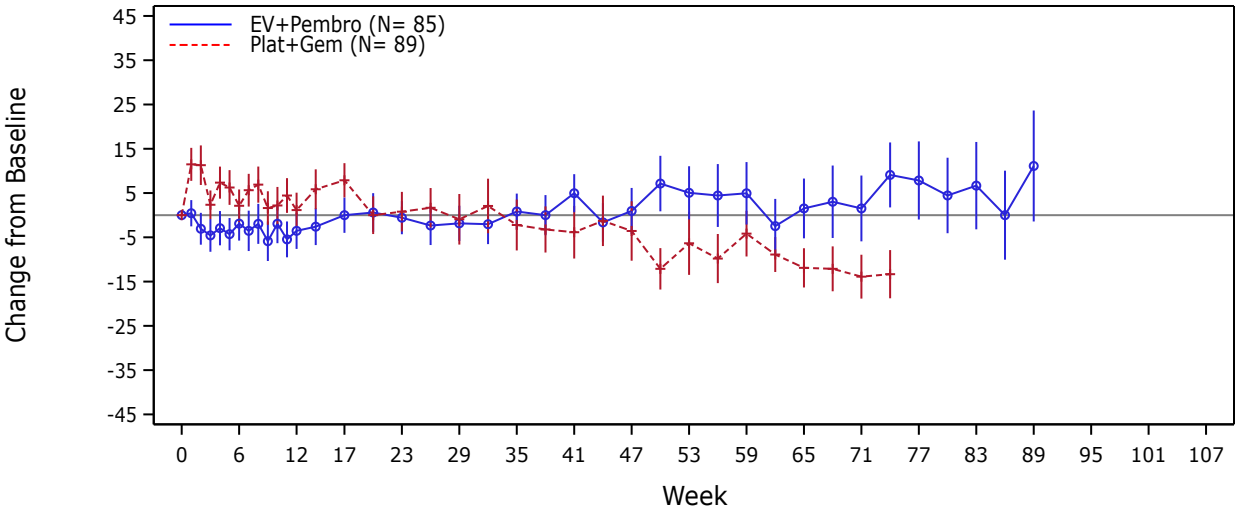
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.21.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Constipation by Region - Analysis Set mITT 1

Region: Rest of World



Number of subjects

EV+Pembro	80	70	66	63	59	54	40	47	35	33	27	22	22	17	15	12
Plat+Gem	75	63	58	55	42	36	30	26	28	21	16	14	12			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

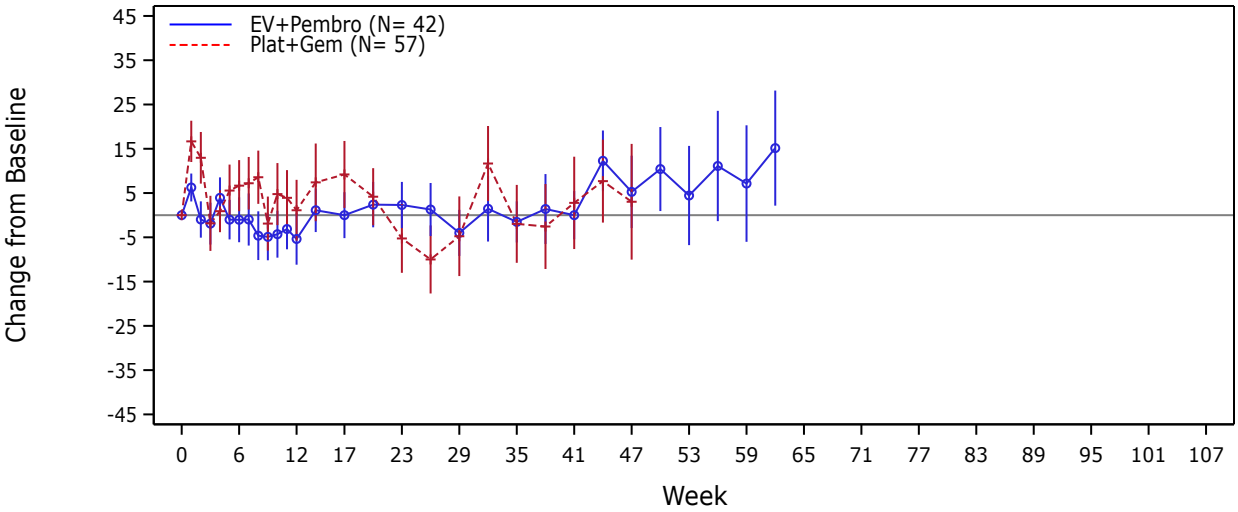
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.21.1.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Constipation by Sex - Analysis Set mITT 1

Sex: Female



Number of subjects

EV+Pembro	36	32	31	32	29	25	22	25	19	15	14
Plat+Gem	42	35	30	29	19	21	17	12	11		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

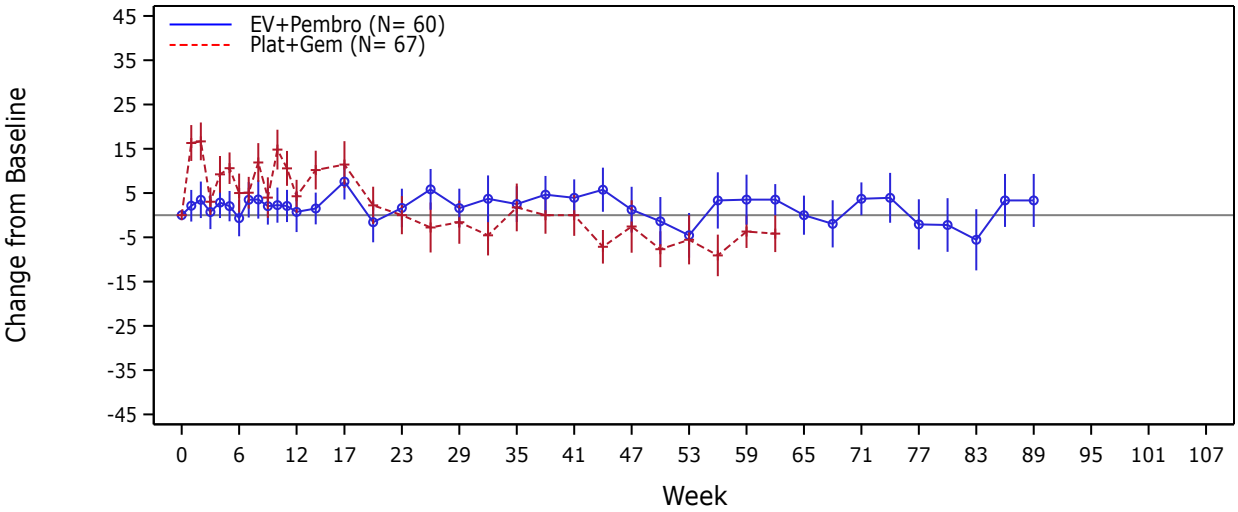
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.21.1.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Constipation by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Lymph node only



Number of subjects

EV+Pembro	53	50	45	44	41	42	40	34	27	22	19	19	18	16	12	10
Plat+Gem	49	40	39	35	25	21	19	18	13	12	9					

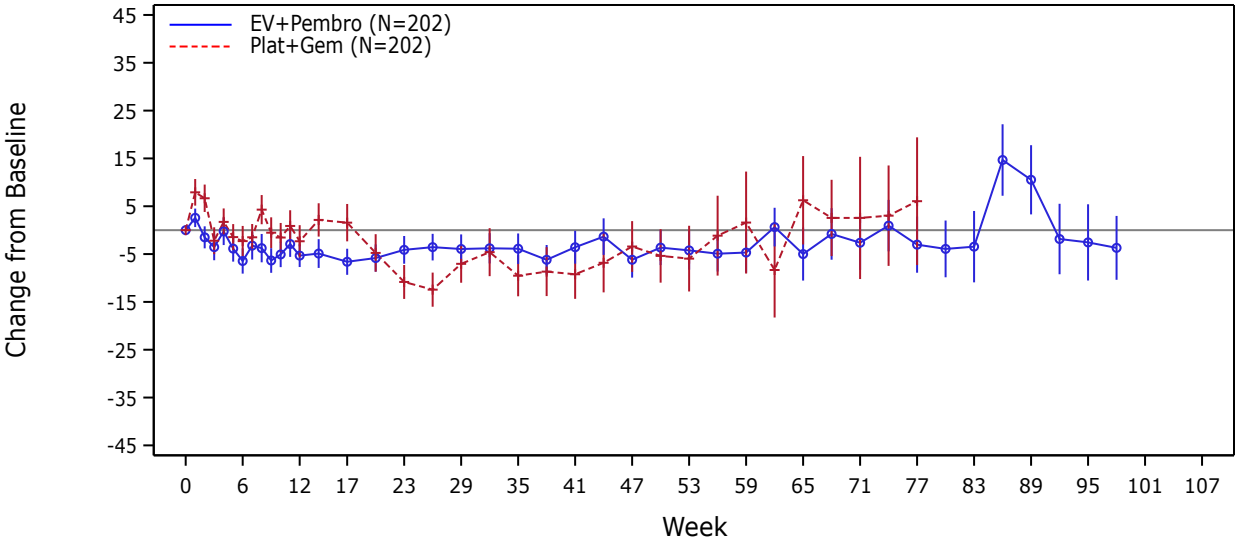
Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.21.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Constipation - Analysis Set mITT 2



Number of subjects

EV+Pembro	160	124	119	111	97	93	86	84	70	63	57	40	38	33	29	19	13
Plat+Gem	165	131	115	106	80	71	56	47	39	28	21	16	13	11			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

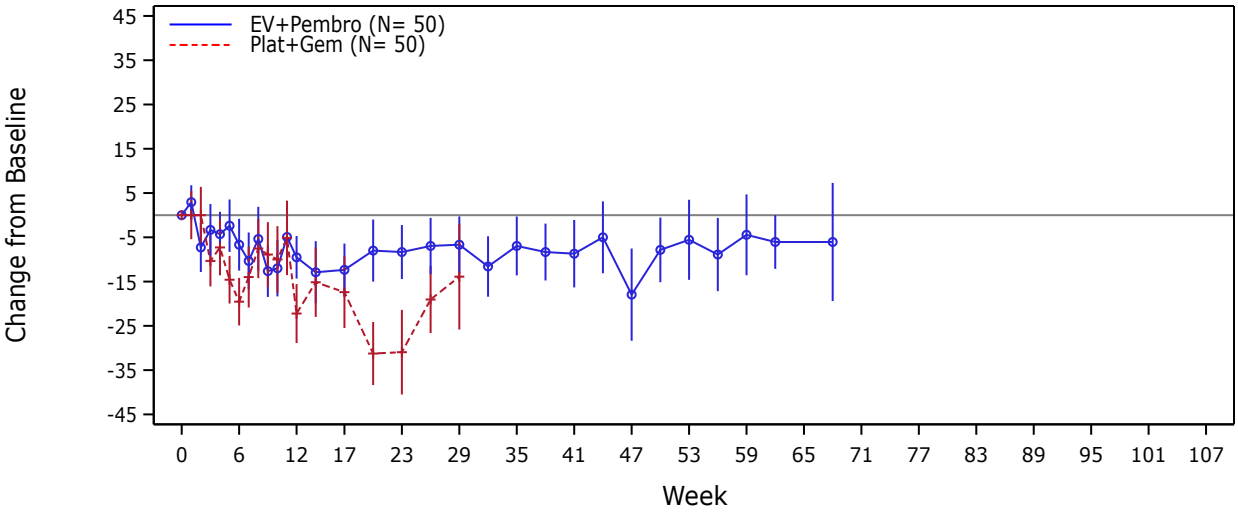
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.21.2.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Constipation by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Present



Number of subjects

EV+Pembro	40	30	28	27	24	25	24	23	13	18	15
Plat+Gem	40	29	27	23	14	12					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

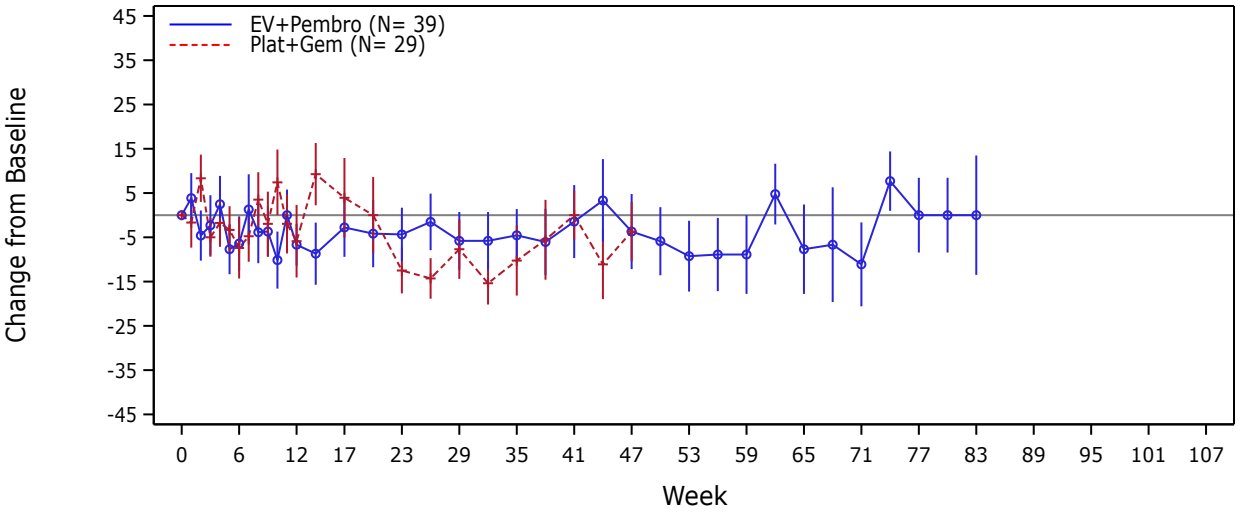
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.21.2.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Constipation by Age - Analysis Set mITT 2

Age: < 65 years



Number of subjects

EV+Pembro	32	26	25	24	23	23	22	23	18	18	15	13	12	13	11
Plat+Gem	22	18	17	17	16	13	13	9	9						

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

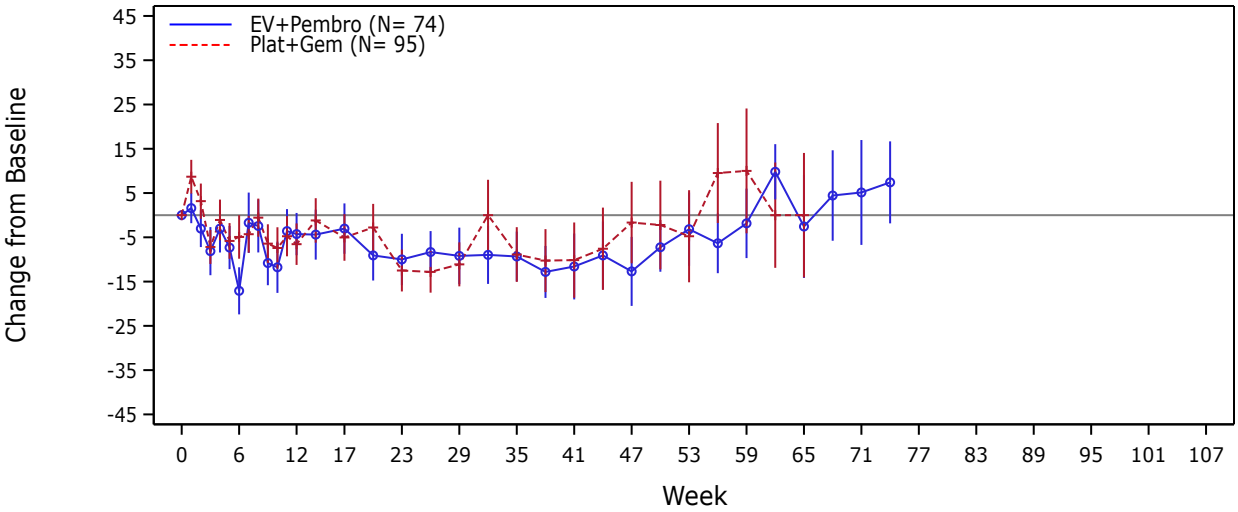
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.21.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Constipation by Region - Analysis Set mITT 2

Region: Europe



Number of subjects

EV+Pembro	53	39	39	33	30	29	25	23	21	21	18	13	13
Plat+Gem	75	61	56	53	40	36	30	23	20	14	10	10	

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

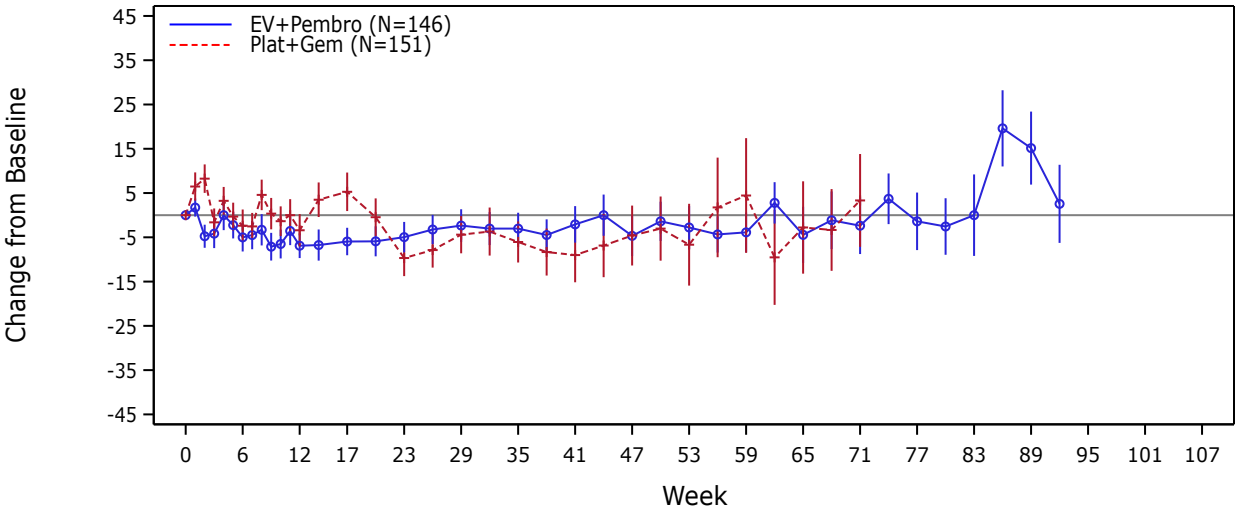
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.21.2.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Constipation by Sex - Analysis Set mITT 2

Sex: Male



Number of subjects

EV+Pembro	119	93	87	84	74	71	66	64	50	48	43	30	28	24	21	11
Plat+Gem	123	98	88	82	62	53	44	37	29	20	15	12	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

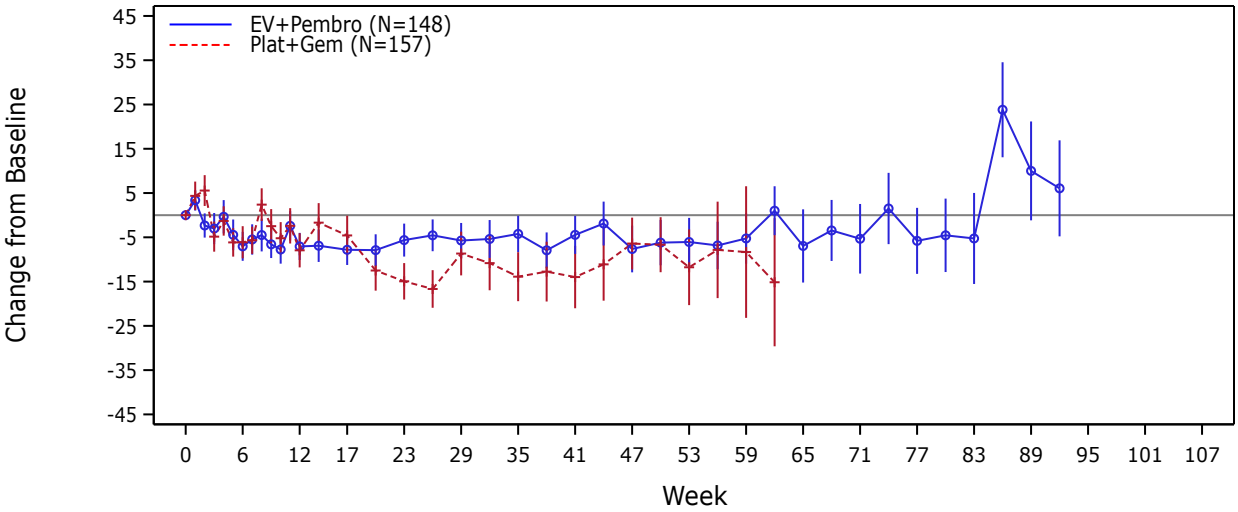
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.21.2.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Constipation by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Visceral metastases



Number of subjects

EV+Pembro	119	90	85	81	71	64	63	60	48	44	38	24	25	23	19	10
Plat+Gem	128	98	84	80	58	50	36	31	26	17	12					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

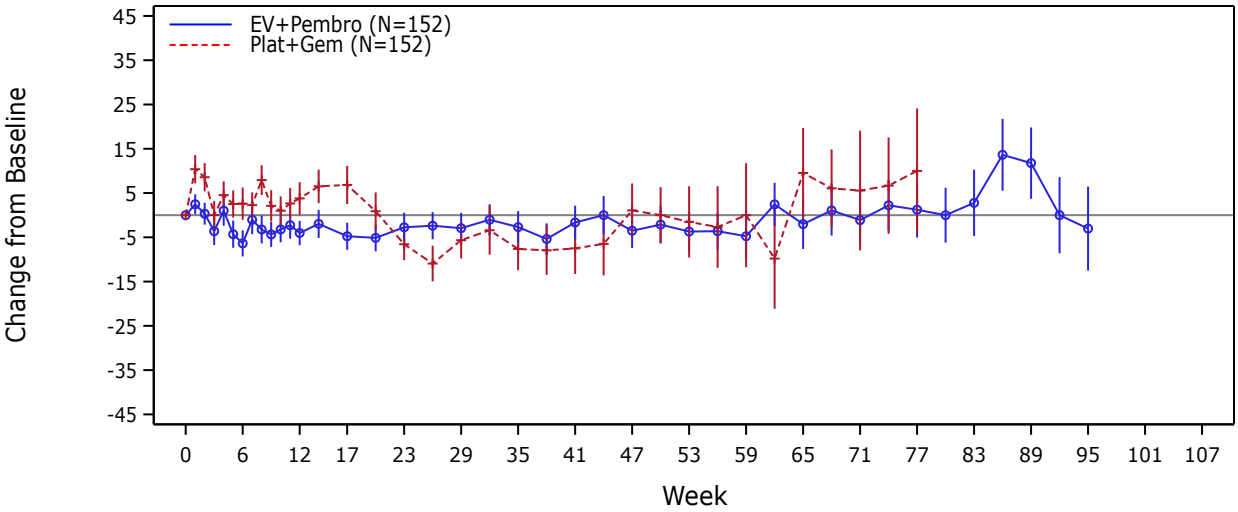
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.21.2.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Constipation by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Absent



Number of subjects

EV+Pembro	120	94	91	84	73	68	62	61	57	45	42	33	30	27	24	17	11
Plat+Gem	125	102	88	83	66	59	48	40	31	22	18	14	12	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

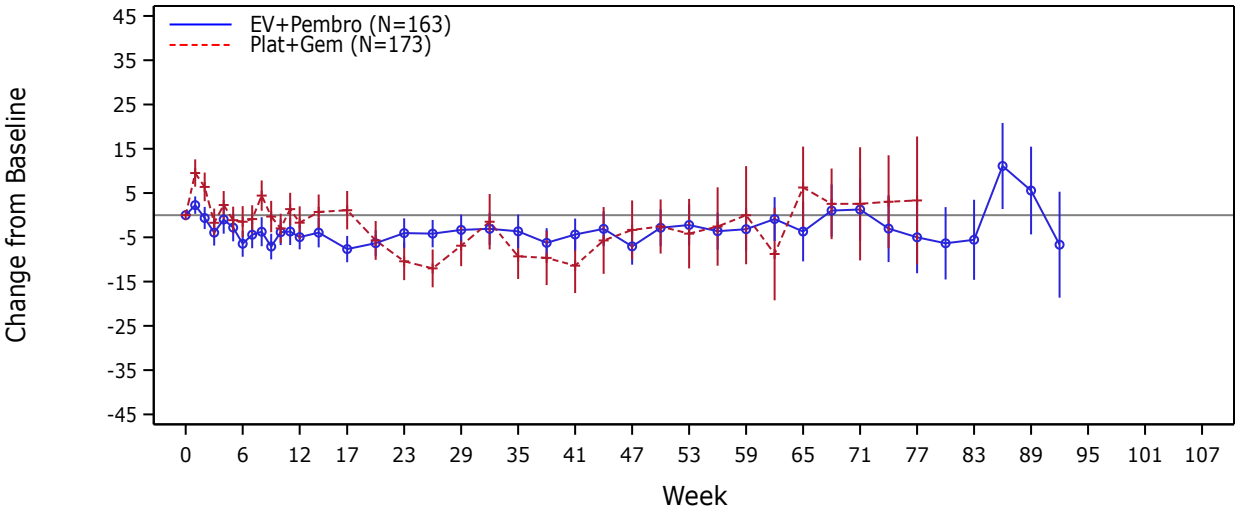
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.21.2.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Constipation by Age - Analysis Set mITT 2

Age: >= 65 years



Number of subjects

EV+Pembro	128	98	94	87	74	70	64	61	52	45	42	27	26	20	18	12
Plat+Gem	143	113	98	89	64	58	43	38	30	24	20	16	13	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

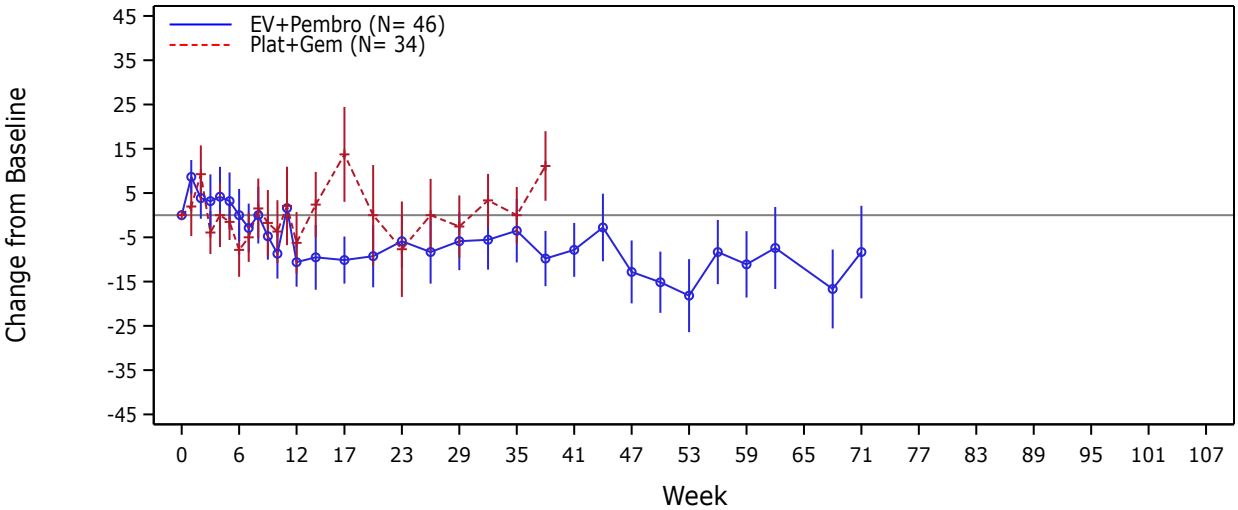
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.21.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Constipation by Region - Analysis Set mITT 2

Region: North America



Number of subjects

EV+Pembro	33	23	22	23	17	17	19	17	13	11	12	8
Plat+Gem	27	17	16	17	13	13	11					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

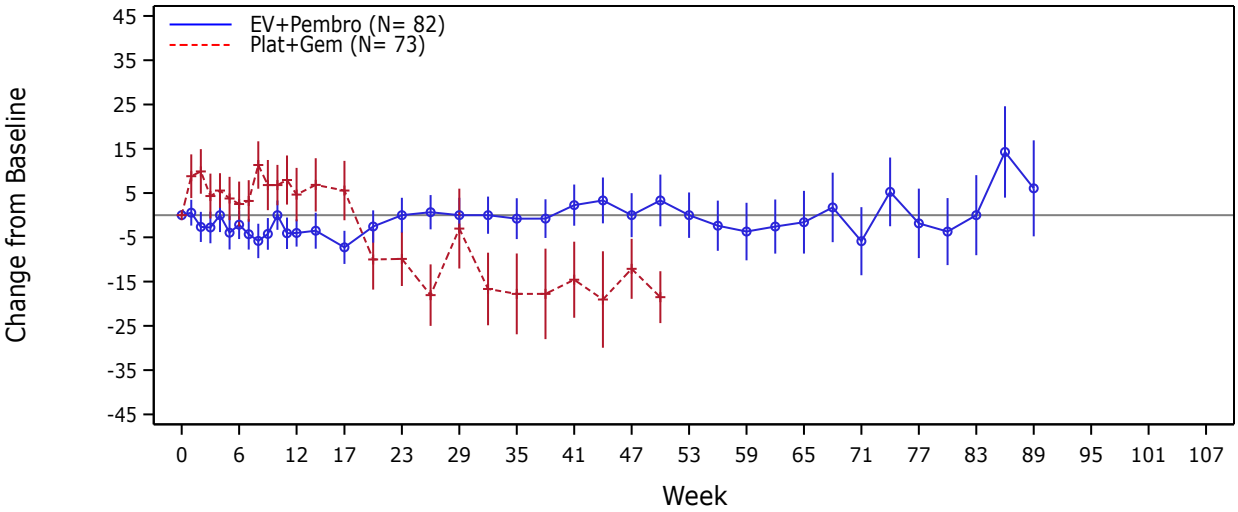
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.21.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Constipation by Region - Analysis Set mITT 2

Region: Rest of World



Number of subjects

EV+Pembro	74	62	58	55	50	47	42	44	36	31	27	21	17	18	17	11
Plat+Gem	63	53	43	36	27	22	15	16	11							

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

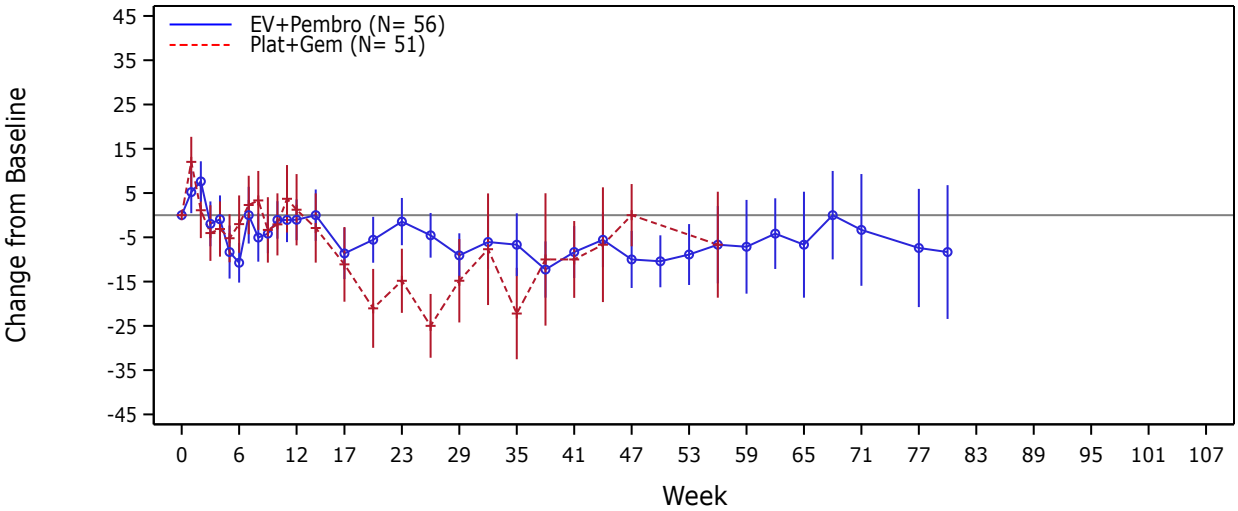
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.21.2.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Constipation by Sex - Analysis Set mITT 2

Sex: Female



Number of subjects

EV+Pembro	41	31	32	27	23	22	20	20	20	15	14	10	10	9
Plat+Gem	42	33	27	24	18	18	12	10	10					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

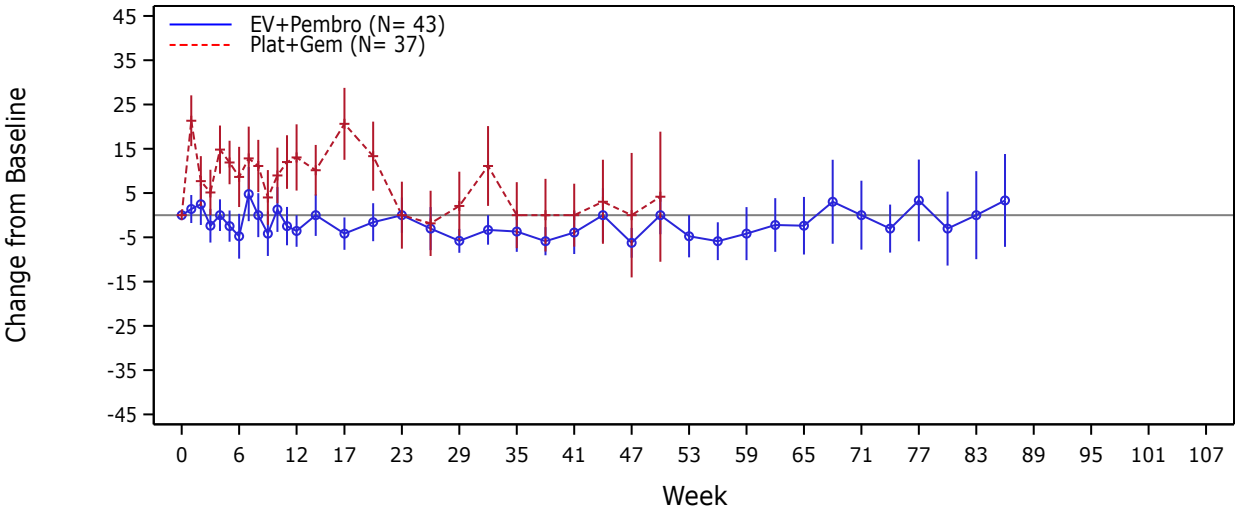
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.21.2.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Constipation by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Lymph node only



Number of subjects

EV+Pembro	33	28	28	24	21	23	18	17	16	14	16	14	11	10	10
Plat+Gem	29	27	23	21	17	16	16	12	10						

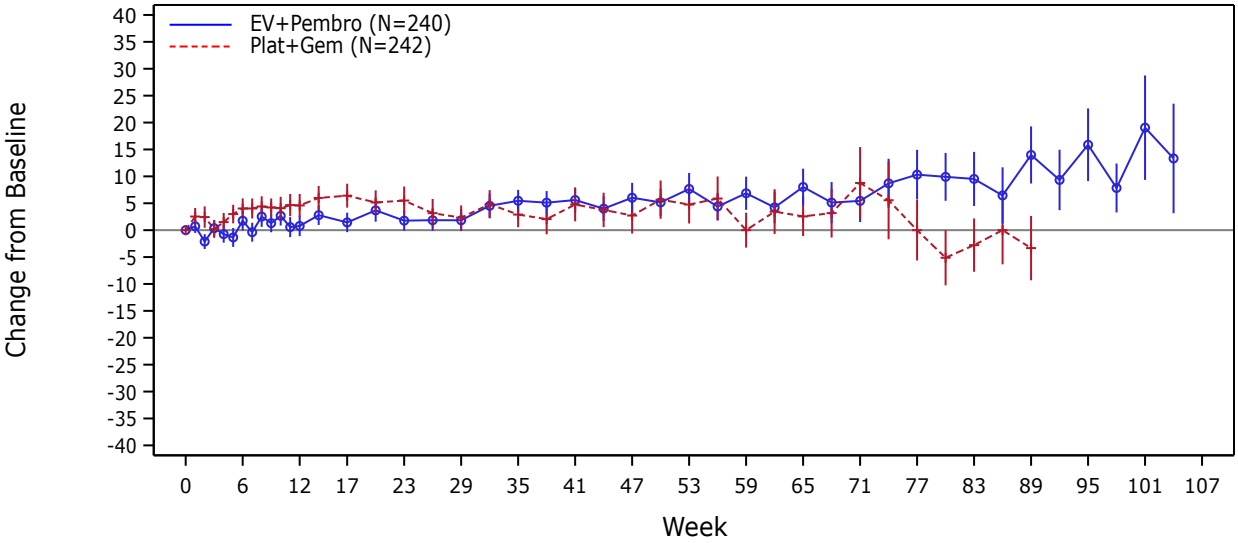
Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.22.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Financial Impact - Analysis Set mITT 1



Number of subjects

EV+Pembro	206	170	171	162	151	145	122	119	94	74	68	54	49	42	35	31	21	14
Plat+Gem	188	149	138	130	97	86	69	56	49	42	33	26	19	15	12	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

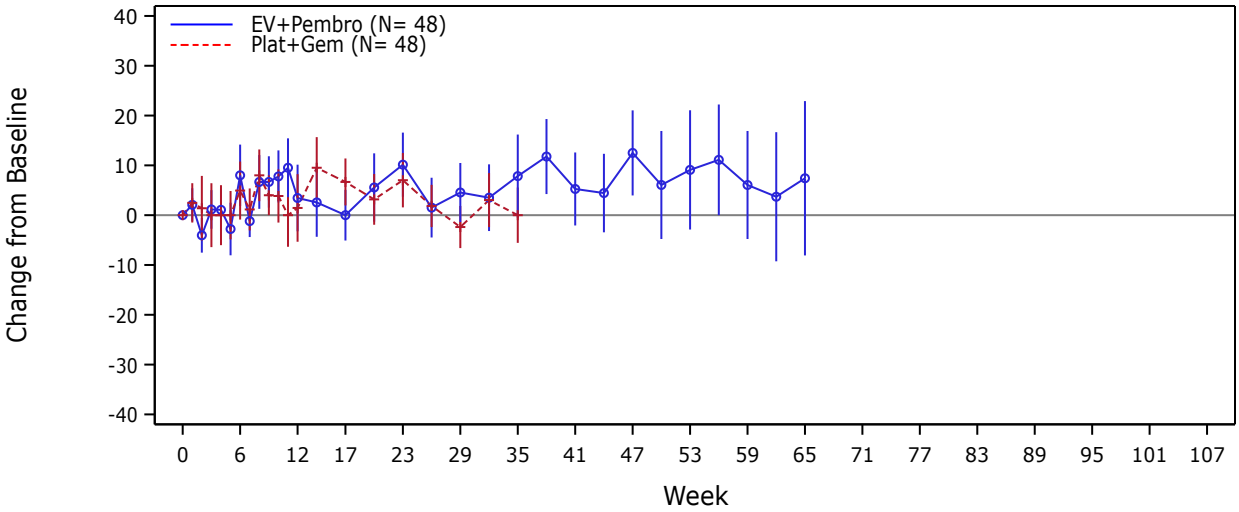
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.22.1.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Financial Impact by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Present



Number of subjects

EV+Pembro	39	25	29	25	23	22	17	19	16	11	11	9
Plat+Gem	33	27	23	25	19	14	9					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

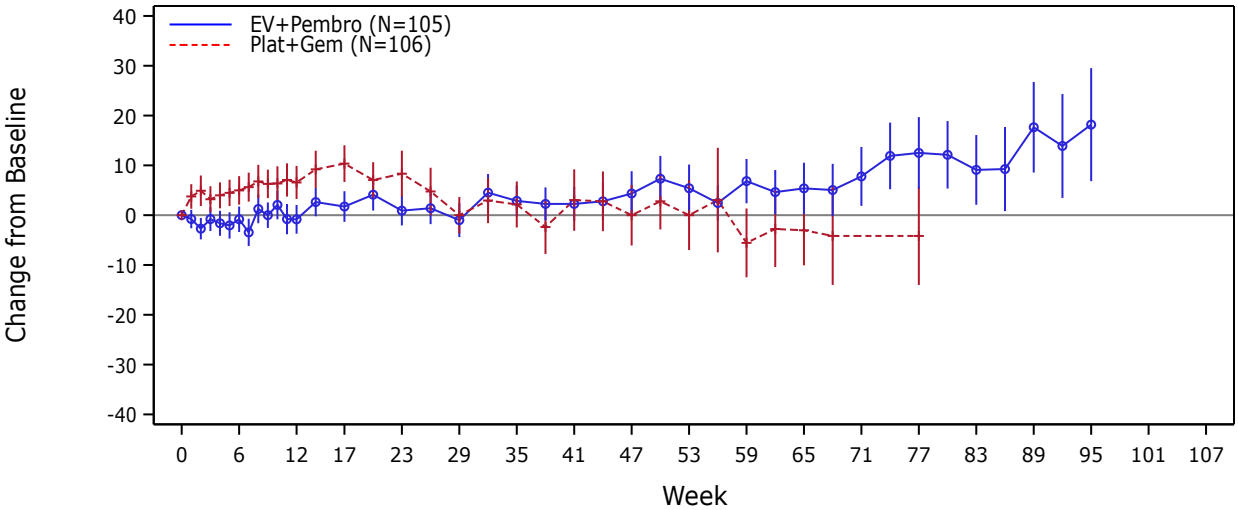
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.22.1.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Financial Impact by Age - Analysis Set mITT 1

Age: < 65 years



Number of subjects

EV+Pembro	92	81	79	77	73	67	58	59	46	37	39	31	30	24	22	17	11
Plat+Gem	83	67	66	58	44	37	31	22	21	17	12	11		8			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

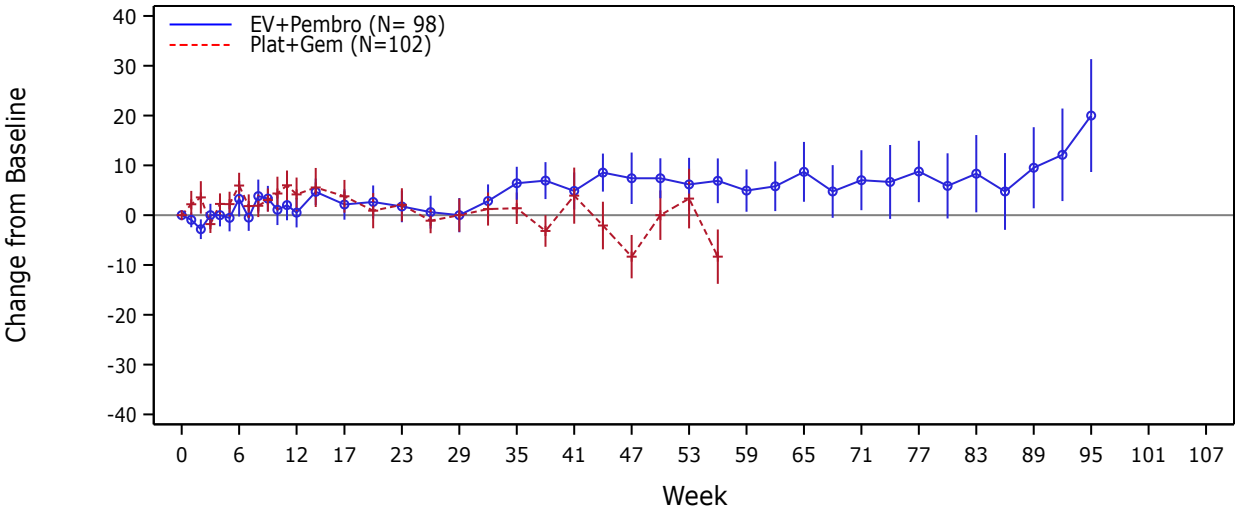
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.22.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Financial Impact by Region - Analysis Set mITT 1

Region: Europe



Number of subjects

EV+Pembro	79	61	65	62	57	57	52	48	36	27	27	23	19	19	16	14	10
Plat+Gem	71	56	48	44	32	25	24	17	12	10							

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

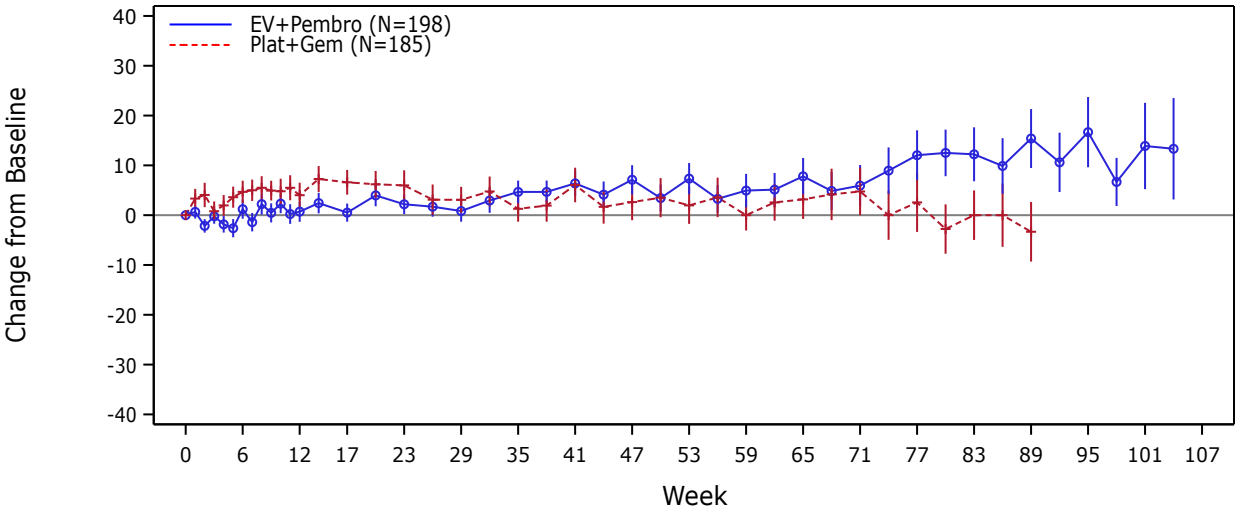
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.22.1.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Financial Impact by Sex - Analysis Set mITT 1

Sex: Male



Number of subjects

EV+Pembro	170	138	140	130	122	120	100	94	75	59	54	47	45	36	30	26	20	12
Plat+Gem	146	114	108	101	78	65	52	44	38	34	27	21	14	13	10	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

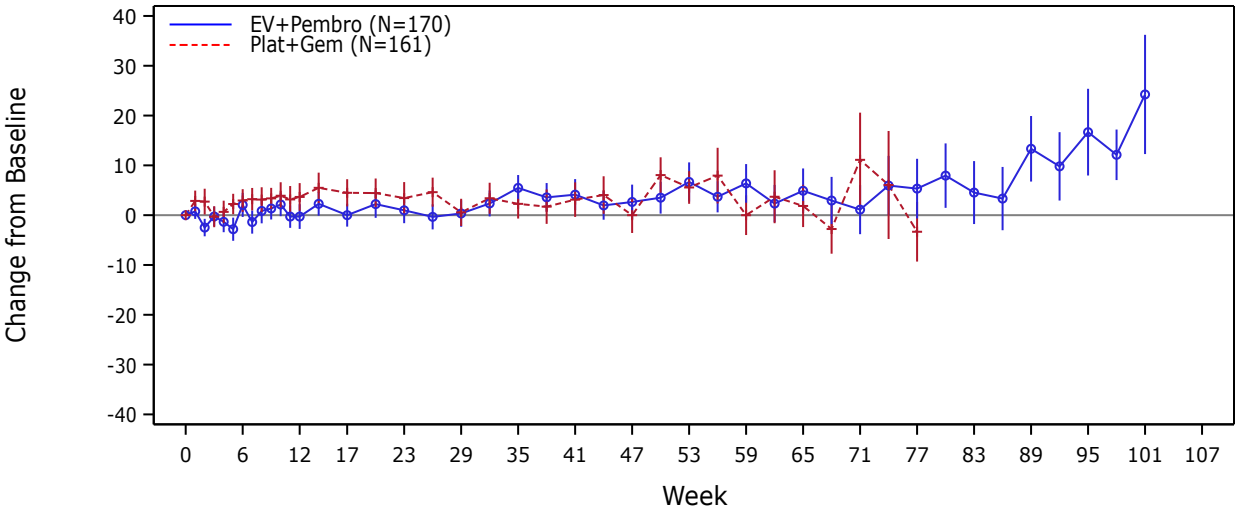
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.22.1.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Financial Impact by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Visceral metastases



Number of subjects

EV+Pembro	146	113	120	111	103	98	79	81	63	50	47	34	30	25	22	20	12	11
Plat+Gem	129	102	91	89	68	59	44	32	30	24	21	18	12	10				

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

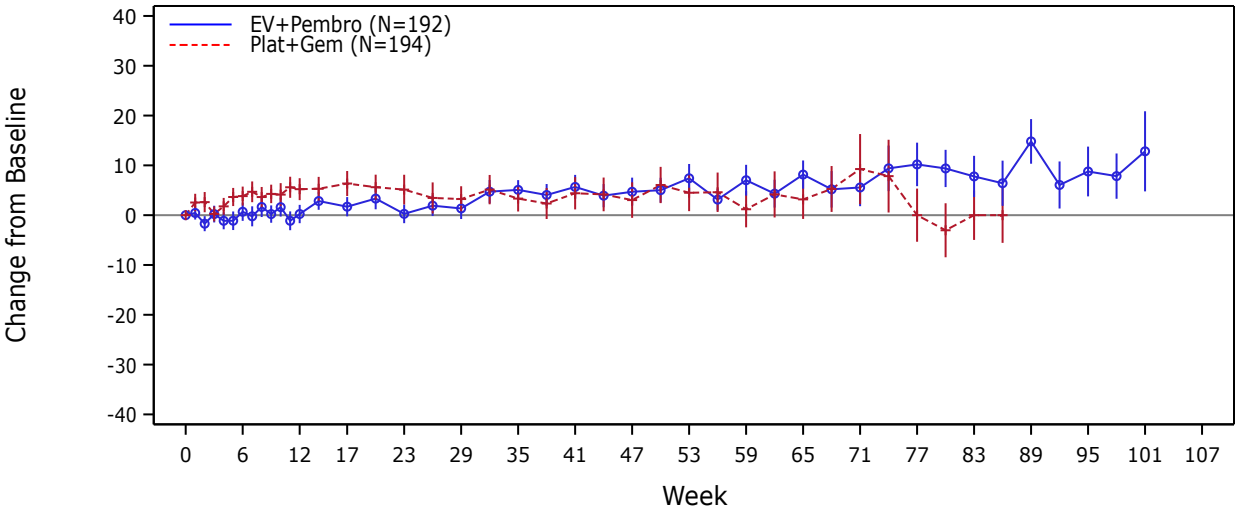
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.22.1.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Financial Impact by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Absent



Number of subjects

EV+Pembro	167	145	142	137	128	123	105	100	78	63	57	45	42	36	30	27	19	13
Plat+Gem	155	122	115	105	78	72	60	53	44	37	28	21	18	13	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

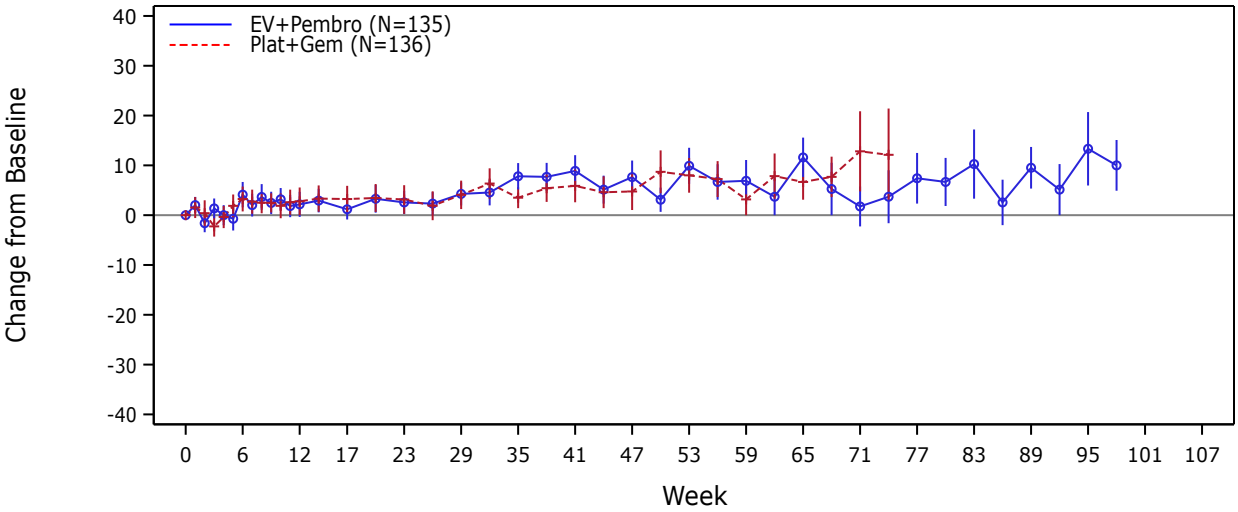
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.22.1.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Financial Impact by Age - Analysis Set mITT 1

Age: >= 65 years



Number of subjects

EV+Pembro	114	89	92	85	78	78	64	60	48	37	29	23	19	18	13	14	10
Plat+Gem	105	82	72	72	53	49	38	34	28	25	21	15	13				

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

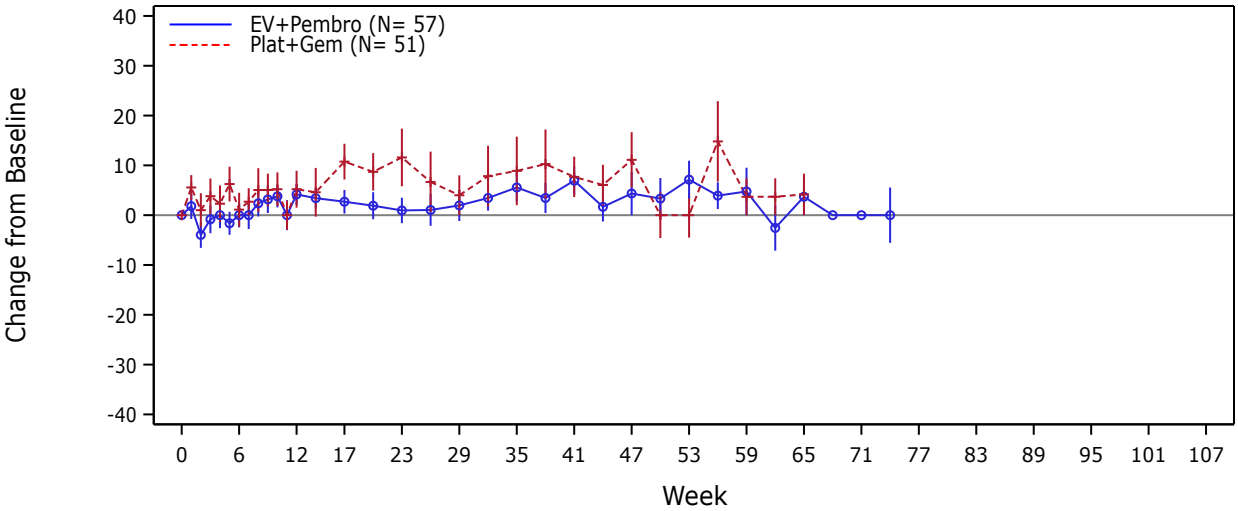
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.22.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Financial Impact by Region - Analysis Set mITT 1

Region: North America



Number of subjects

EV+Pembro	47	39	40	37	35	34	30	24	23	14	14	9	8
Plat+Gem	42	30	32	31	23	25	15	13	9	11	9	8	

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

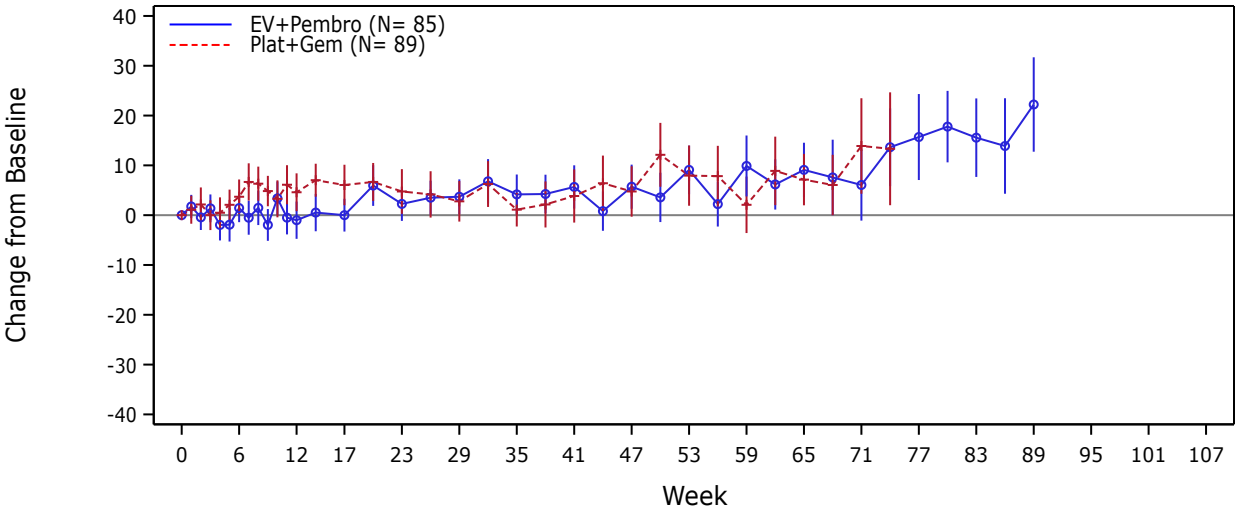
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.22.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Financial Impact by Region - Analysis Set mITT 1

Region: Rest of World



Number of subjects

EV+Pembro	80	70	66	63	59	54	40	47	35	33	27	22	22	17	15	12
Plat+Gem	75	63	58	55	42	36	30	26	28	21	16	14	12			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

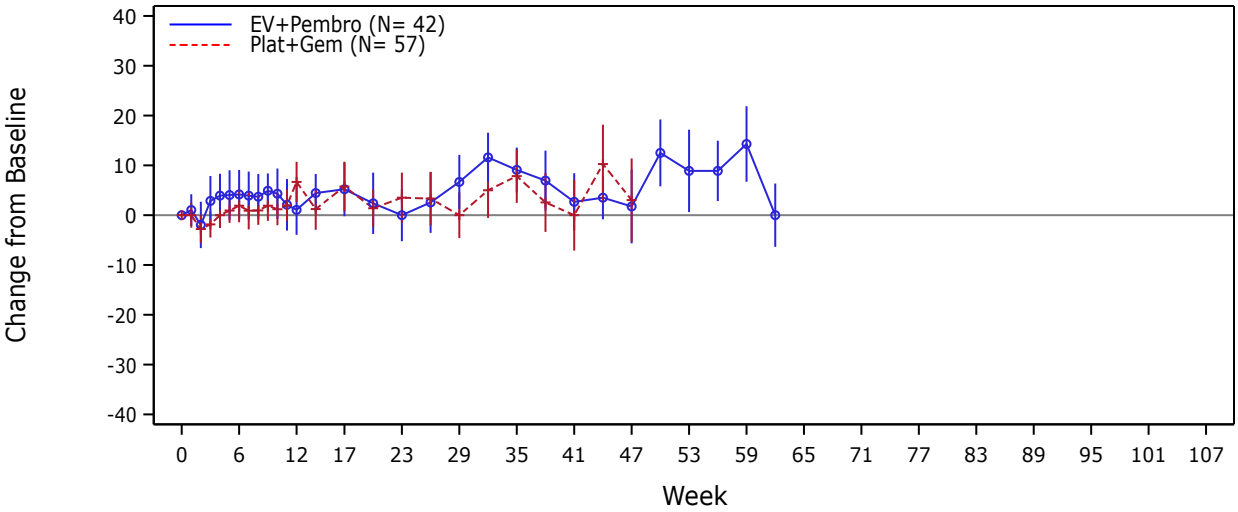
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.22.1.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Financial Impact by Sex - Analysis Set mITT 1

Sex: Female



Number of subjects

EV+Pembro	36	32	31	32	29	25	22	25	19	15	14
Plat+Gem	42	35	30	29	19	21	17	12	11		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

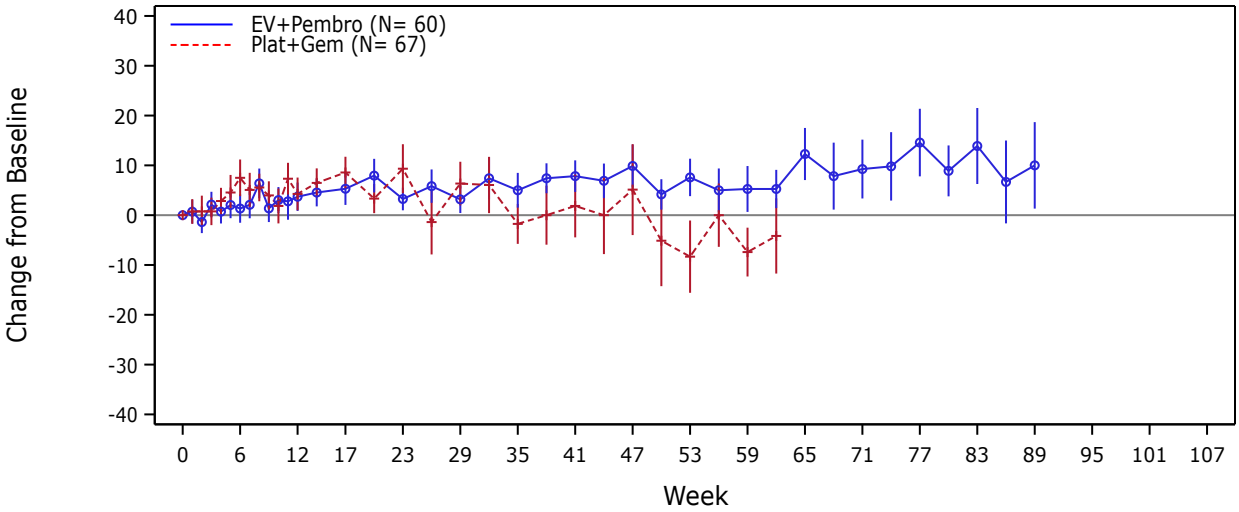
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.22.1.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Financial Impact by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Lymph node only



Number of subjects

EV+Pembro	53	50	45	44	41	42	40	34	27	22	19	19	18	16	12	10
Plat+Gem	49	40	39	35	25	21	19	18	13	12	9					

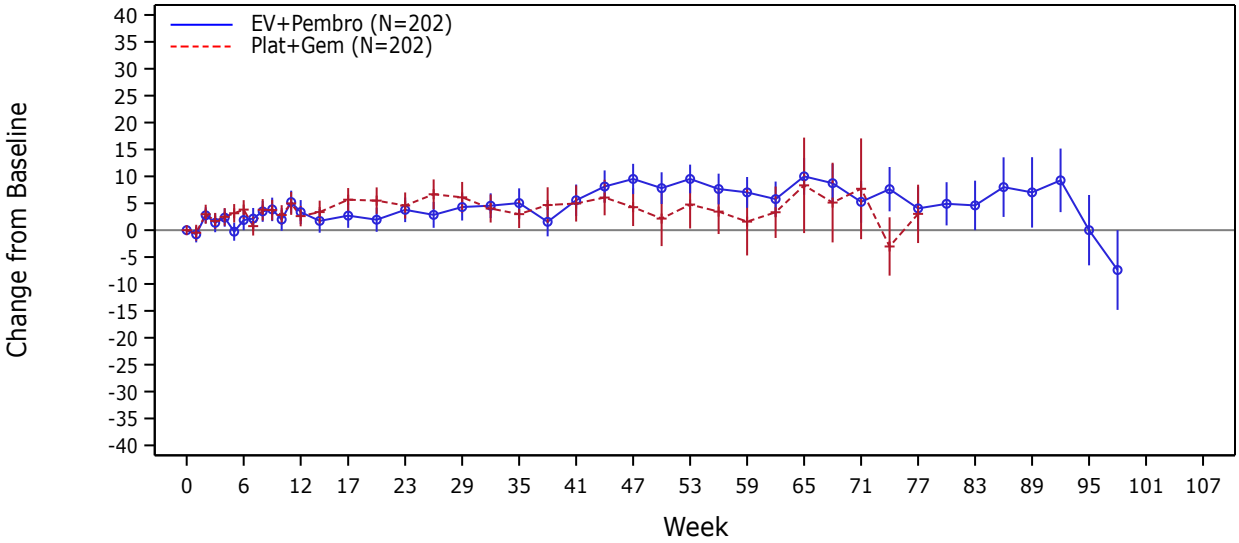
Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.22.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Financial Impact - Analysis Set mITT 2



Number of subjects

EV+Pembro	160	124	119	111	97	93	86	84	70	63	57	40	38	33	29	19	13
Plat+Gem	165	131	115	106	80	71	56	47	39	28	21	16	13	11			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

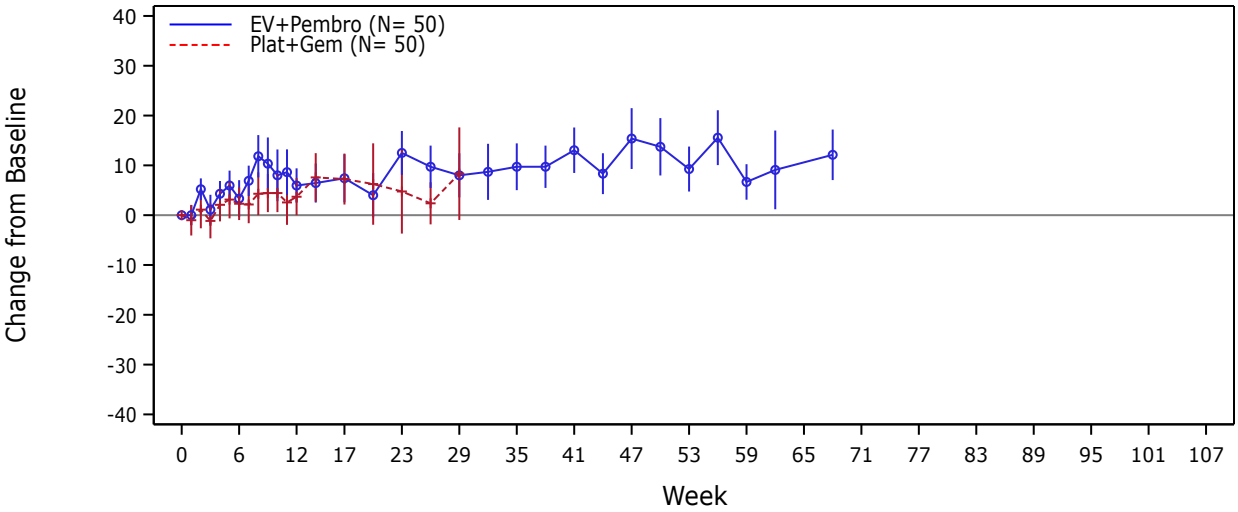
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.22.2.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Financial Impact by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Present



Number of subjects

EV+Pembro	40	30	28	27	24	25	24	23	13	18	15
Plat+Gem	40	29	27	23	14	12					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

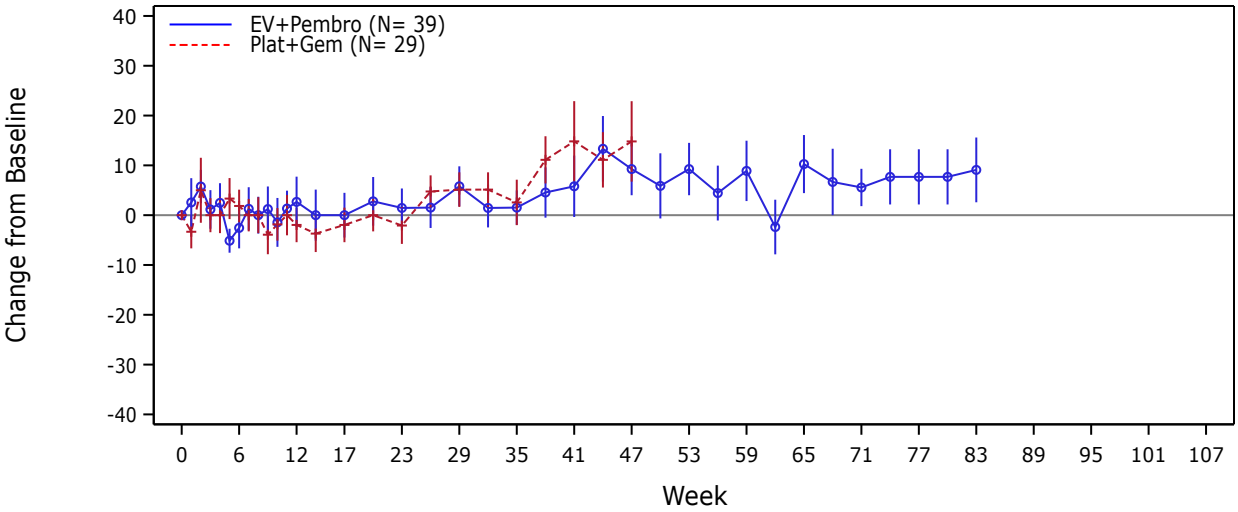
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.22.2.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Financial Impact by Age - Analysis Set mITT 2

Age: < 65 years



Number of subjects

EV+Pembro	32	26	25	24	23	23	22	23	18	18	15	13	12	13	11
Plat+Gem	22	18	17	17	16	13	13	9	9						

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

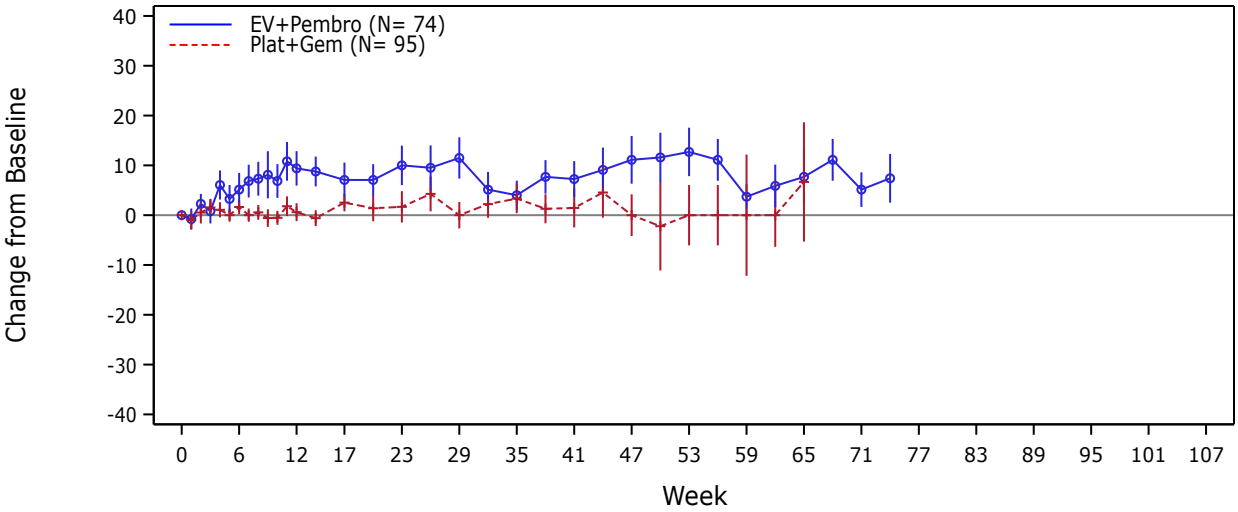
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.22.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Financial Impact by Region - Analysis Set mITT 2

Region: Europe



Number of subjects

EV+Pembro	53	39	39	33	30	29	25	23	21	21	18	13	13
Plat+Gem	75	61	56	53	40	36	30	23	20	14	10	10	

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

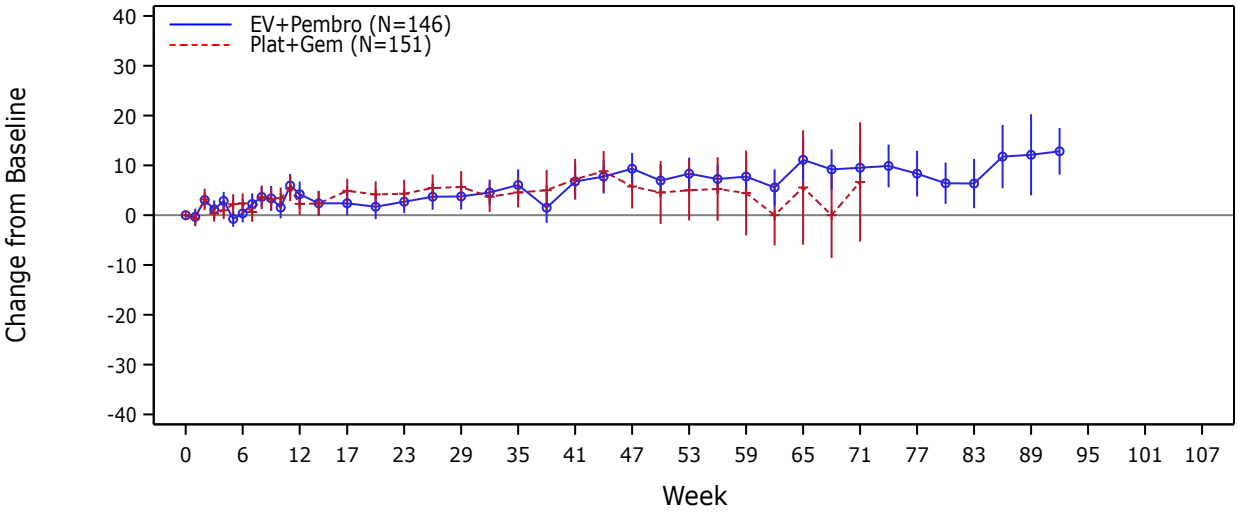
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.22.2.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Financial Impact by Sex - Analysis Set mITT 2

Sex: Male



Number of subjects

EV+Pembro	119	93	87	84	74	71	66	64	50	48	43	30	28	24	21	11
Plat+Gem	123	98	88	82	62	53	44	37	29	20	15	12	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

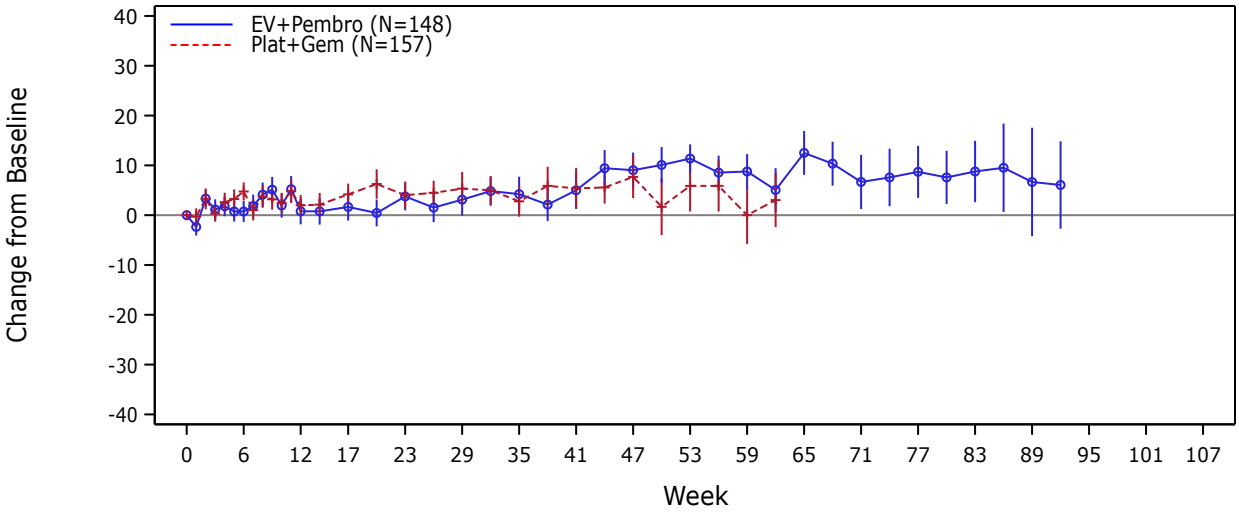
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.22.2.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Financial Impact by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Visceral metastases



Number of subjects

EV+Pembro	119	90	85	81	71	64	63	60	48	44	38	24	25	23	19	10
Plat+Gem	128	98	84	80	58	50	36	31	26	17	12					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

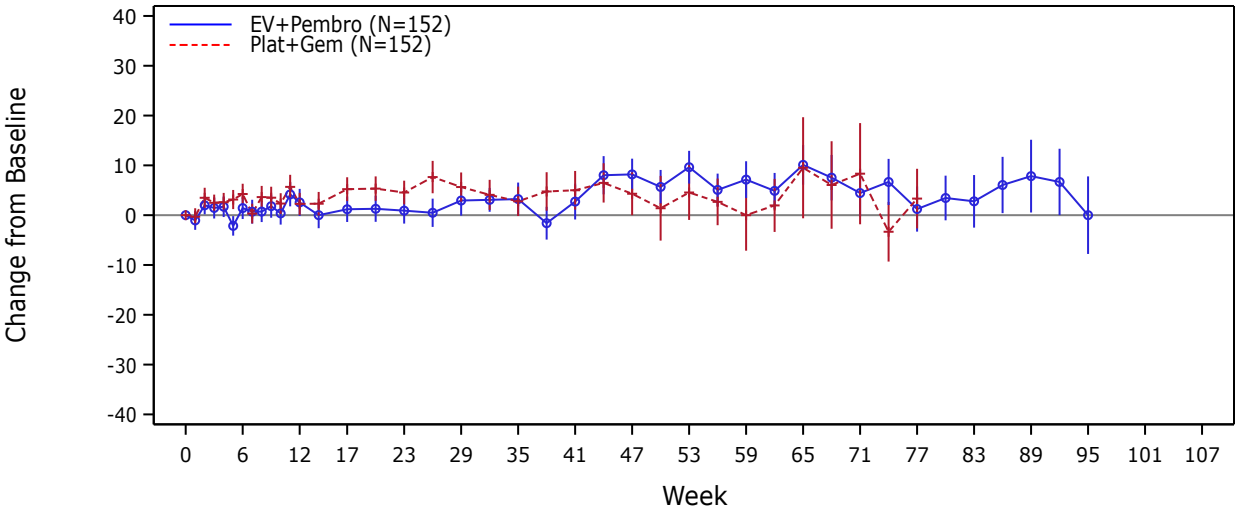
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.22.2.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Financial Impact by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Absent



Number of subjects

EV+Pembro	120	94	91	84	73	68	62	61	57	45	42	33	30	27	24	17	11
Plat+Gem	125	102	88	83	66	59	48	40	31	22	18	14	12	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

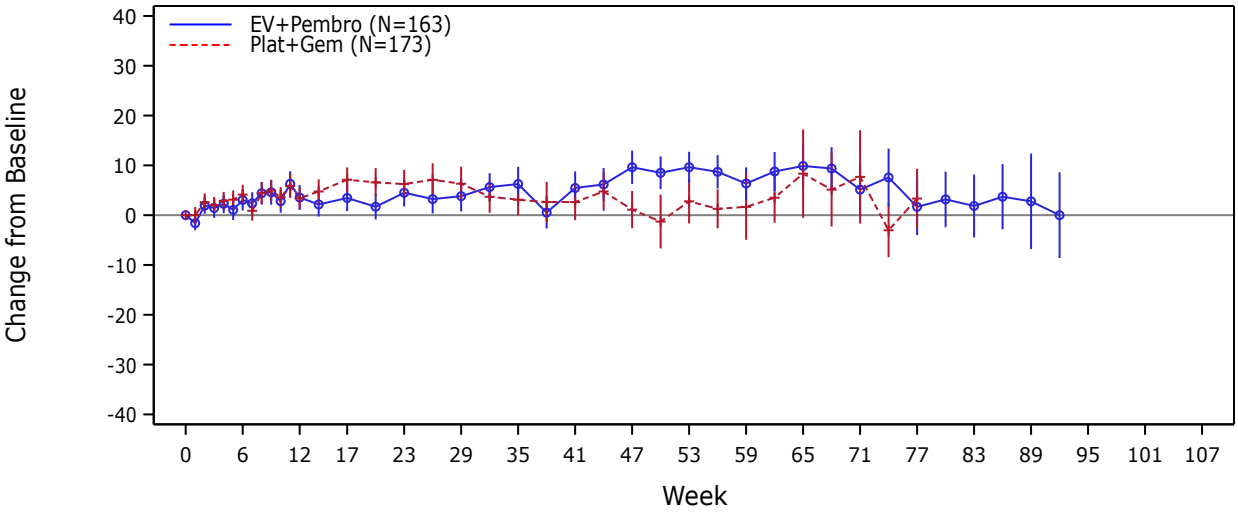
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.22.2.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Financial Impact by Age - Analysis Set mITT 2

Age: >= 65 years



Number of subjects

EV+Pembro	128	98	94	87	74	70	64	61	52	45	42	27	26	20	18	12
Plat+Gem	143	113	98	89	64	58	43	38	30	24	20	16	13	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

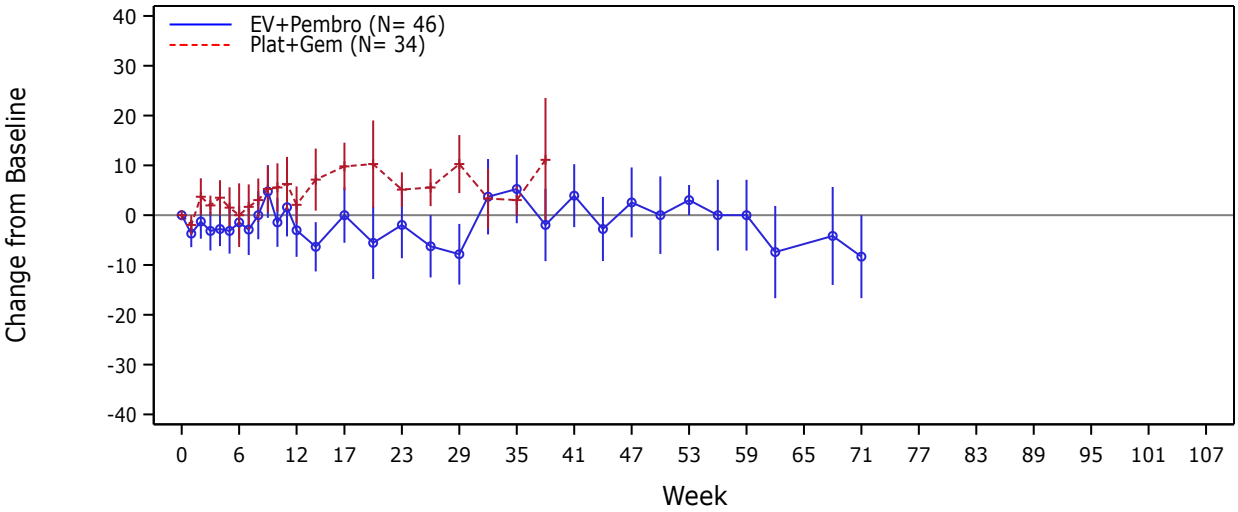
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.22.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Financial Impact by Region - Analysis Set mITT 2

Region: North America



Number of subjects

EV+Pembro	33	23	22	23	17	17	19	17	13	11	12	8
Plat+Gem	27	17	16	17	13	13	11					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

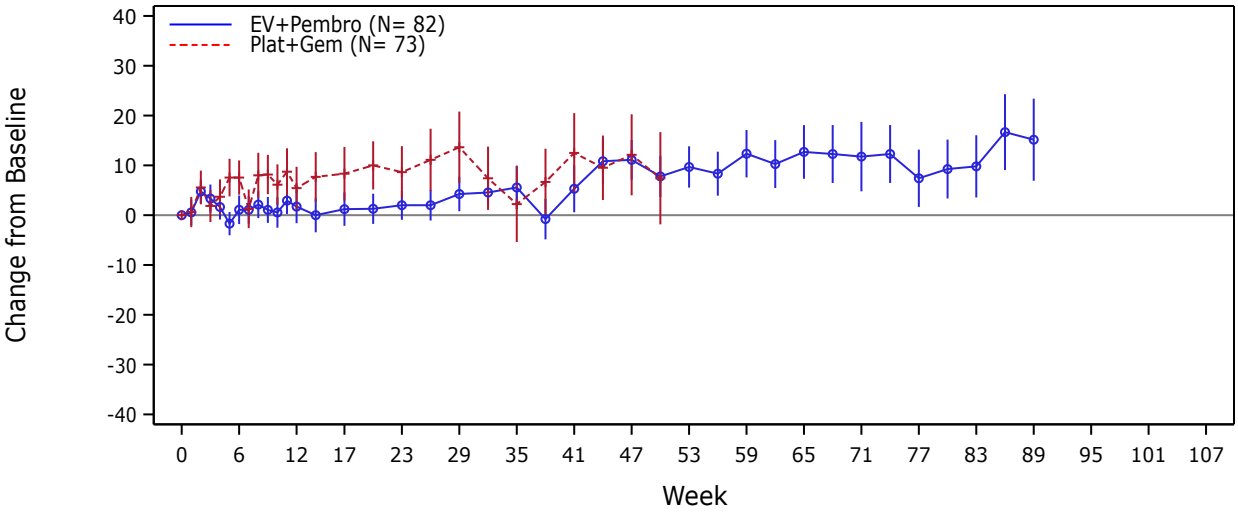
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.22.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Financial Impact by Region - Analysis Set mITT 2

Region: Rest of World



Number of subjects

EV+Pembro	74	62	58	55	50	47	42	44	36	31	27	21	17	18	17	11
Plat+Gem	63	53	43	36	27	22	15	16	11							

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

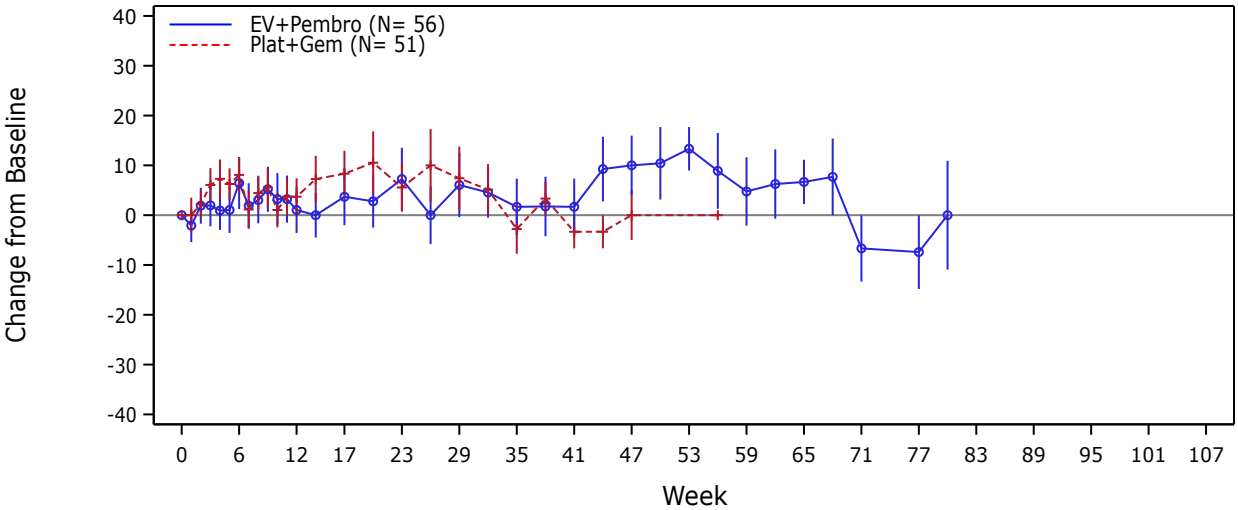
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.22.2.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Financial Impact by Sex - Analysis Set mITT 2

Sex: Female



Number of subjects

EV+Pembro	41	31	32	27	23	22	20	20	20	15	14	10	10	9
Plat+Gem	42	33	27	24	18	18	12	10	10					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

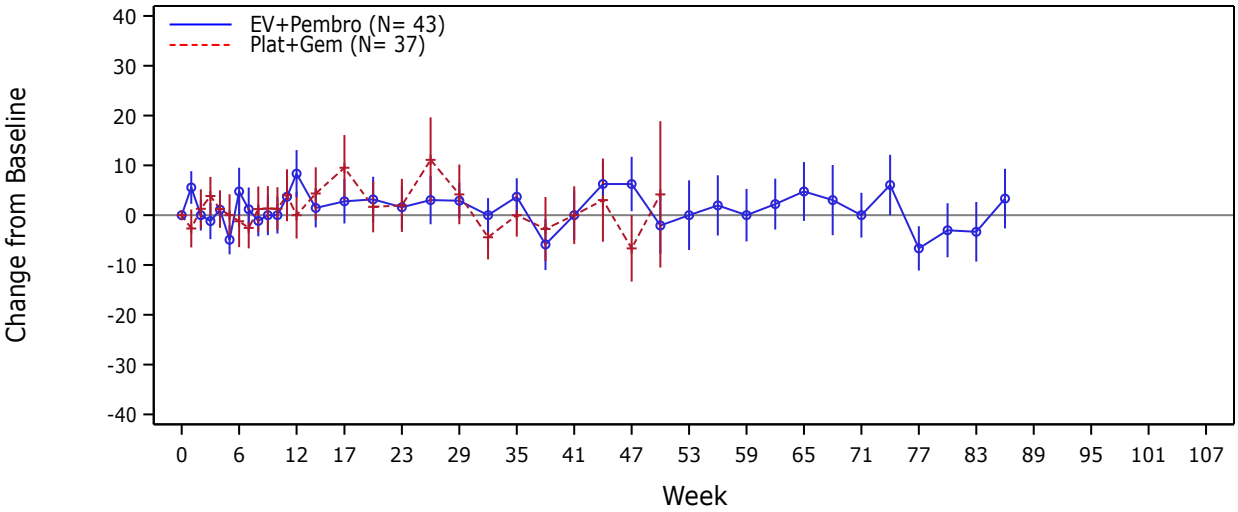
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.22.2.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Financial Impact by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Lymph node only



Number of subjects

EV+Pembro	33	28	28	24	21	23	18	17	16	14	16	14	11	10	10
Plat+Gem	29	27	23	21	17	16	16	12	10						

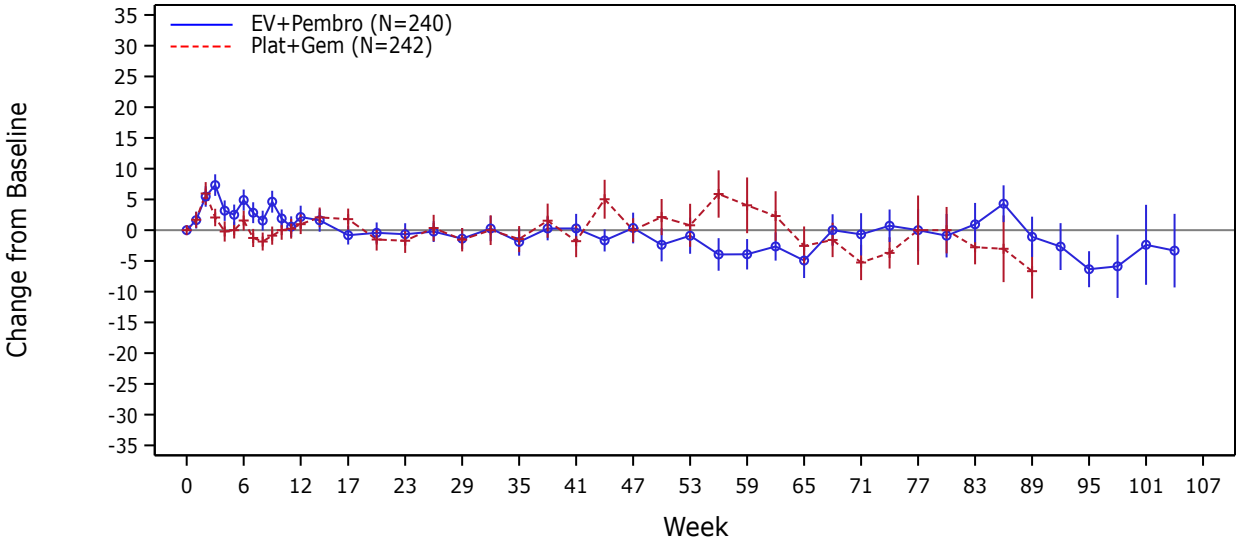
Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.23.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Diarrhea - Analysis Set mITT 1



Number of subjects

EV+Pembro	206	170	171	162	151	145	122	119	94	74	68	54	49	42	35	31	21	14
Plat+Gem	188	149	138	130	97	86	69	56	49	42	33	26	19	15	12	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

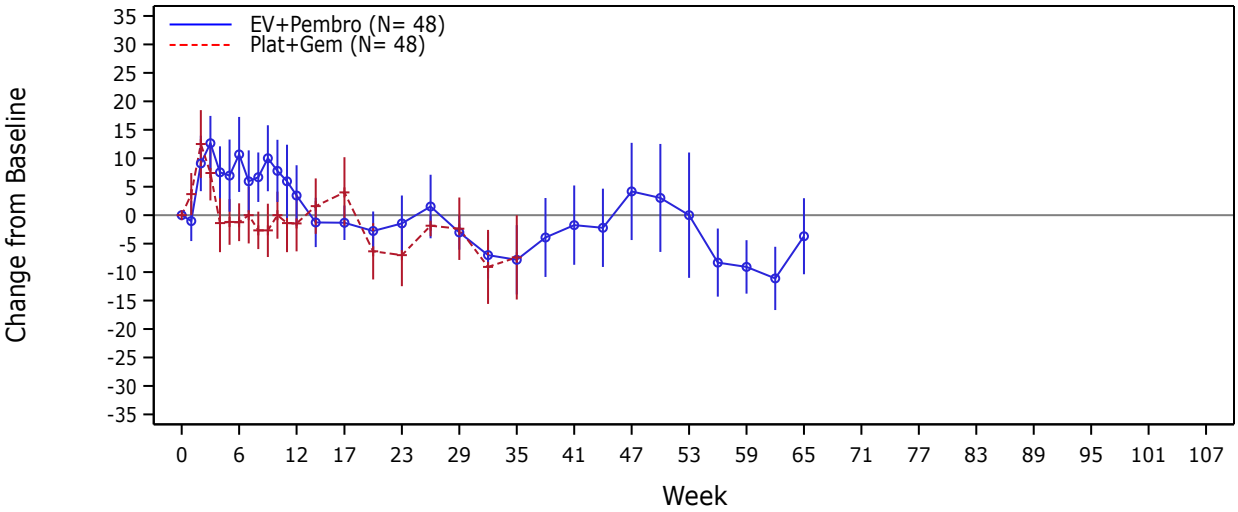
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.23.1.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Diarrhea by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Present



Number of subjects

EV+Pembro	39	25	29	25	23	22	17	19	16	11	11	9
Plat+Gem	33	27	23	25	19	14	9					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

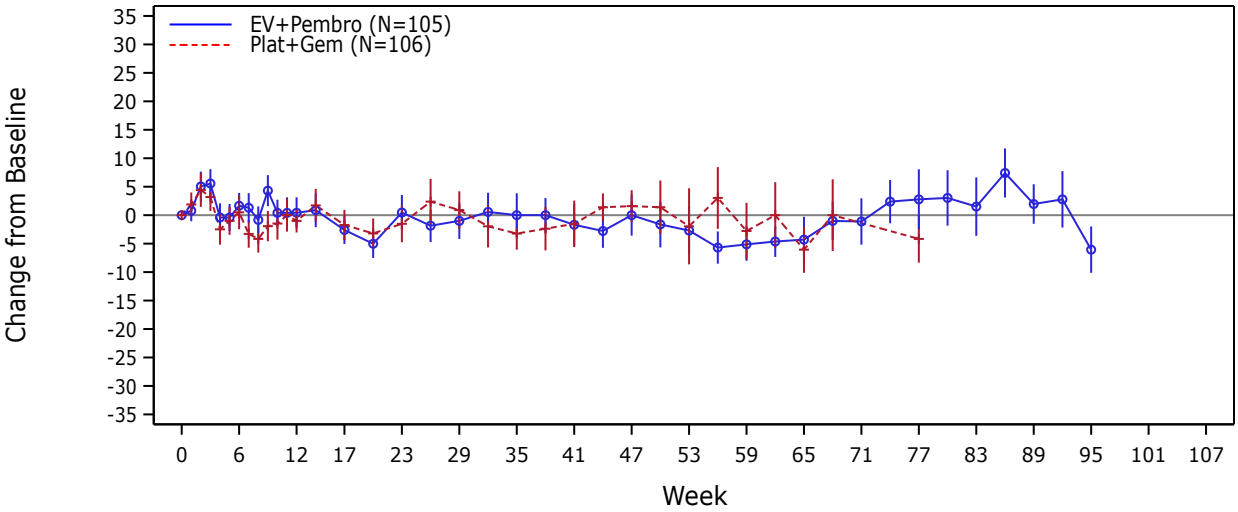
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.23.1.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Diarrhea by Age - Analysis Set mITT 1

Age: < 65 years



Number of subjects

EV+Pembro	92	81	79	77	73	67	58	59	46	37	39	31	30	24	22	17	11
Plat+Gem	83	67	66	58	44	37	31	22	21	17	12	11		8			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

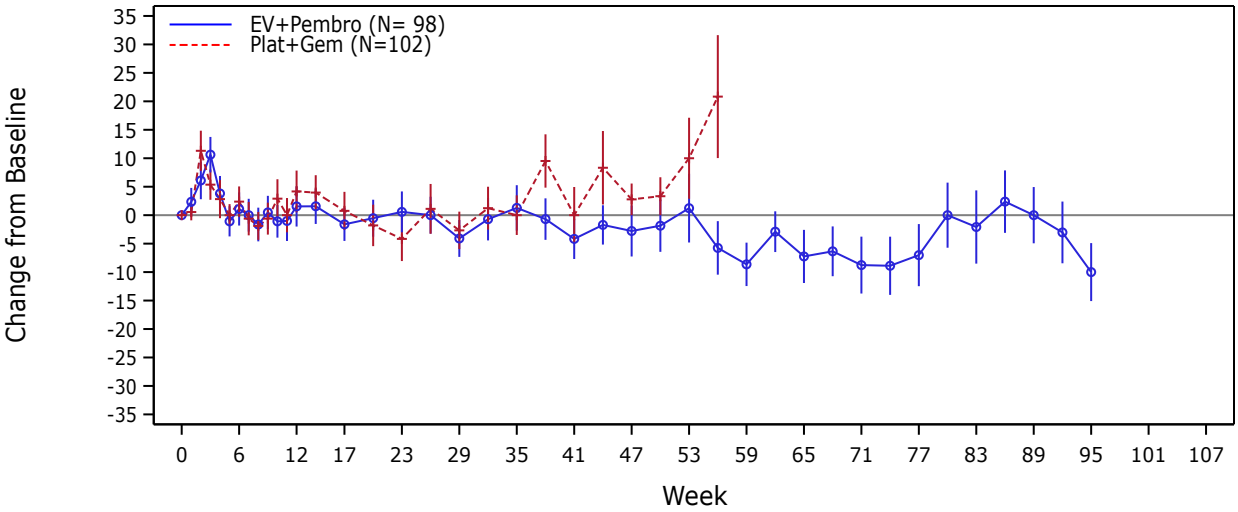
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.23.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Diarrhea by Region - Analysis Set mITT 1

Region: Europe



Number of subjects

EV+Pembro	79	61	65	62	57	57	52	48	36	27	27	23	19	19	16	14	10
Plat+Gem	71	56	48	44	32	25	24	17	12	10							

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

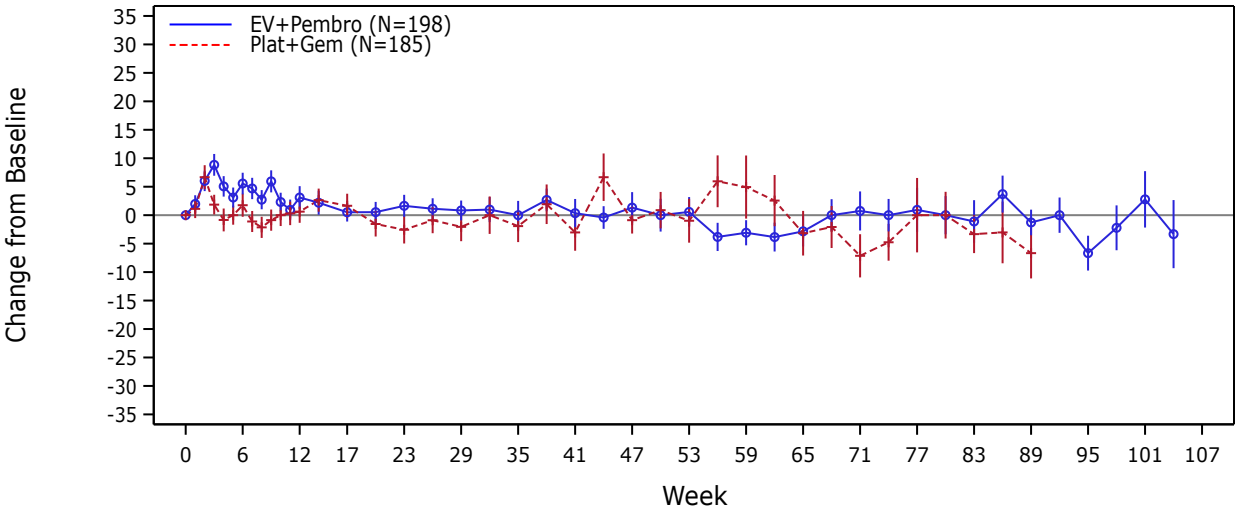
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.23.1.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Diarrhea by Sex - Analysis Set mITT 1

Sex: Male



Number of subjects

EV+Pembro	170	138	140	130	122	120	100	94	75	59	54	47	45	36	30	26	20	12
Plat+Gem	146	114	108	101	78	65	52	44	38	34	27	21	14	13	10	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

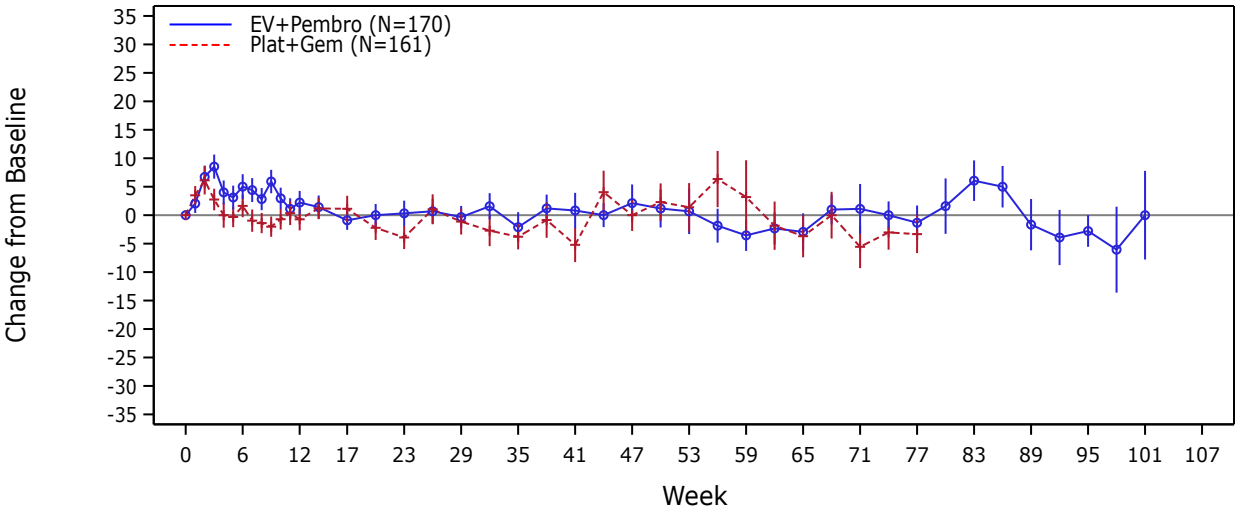
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.23.1.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Diarrhea by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Visceral metastases



Number of subjects

EV+Pembro	146	113	120	111	103	98	79	81	63	50	47	34	30	25	22	20	12	11
Plat+Gem	129	102	91	89	68	59	44	32	30	24	21	18	12	10				

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

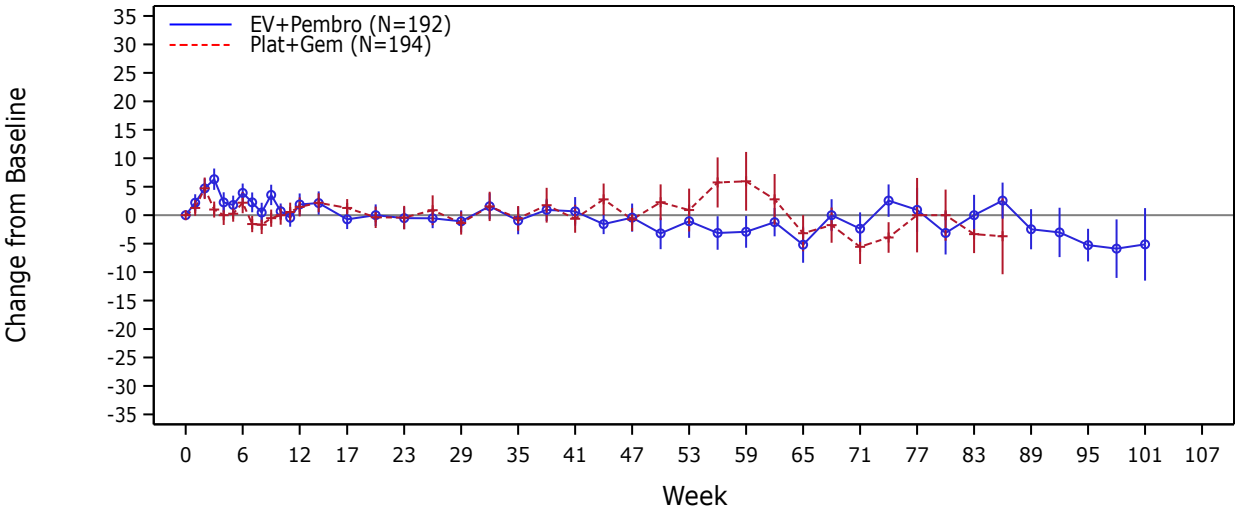
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.23.1.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Diarrhea by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Absent



Number of subjects

EV+Pembro	167	145	142	137	128	123	105	100	78	63	57	45	42	36	30	27	19	13
Plat+Gem	155	122	115	105	78	72	60	53	44	37	28	21	18	13	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

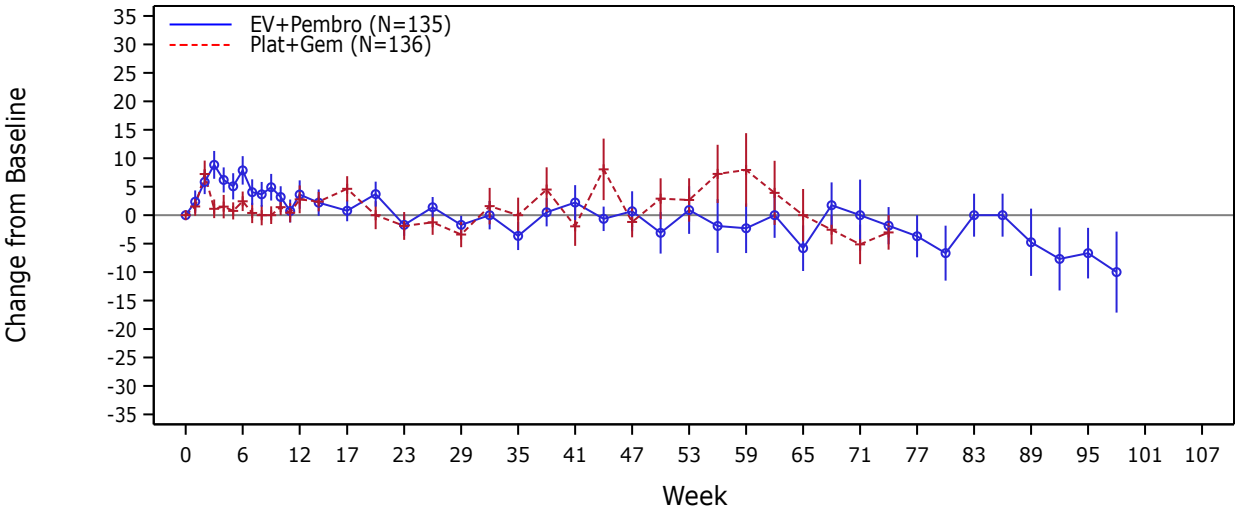
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.23.1.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Diarrhea by Age - Analysis Set mITT 1

Age: >= 65 years



Number of subjects

EV+Pembro	114	89	92	85	78	78	64	60	48	37	29	23	19	18	13	14	10
Plat+Gem	105	82	72	72	53	49	38	34	28	25	21	15	13				

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

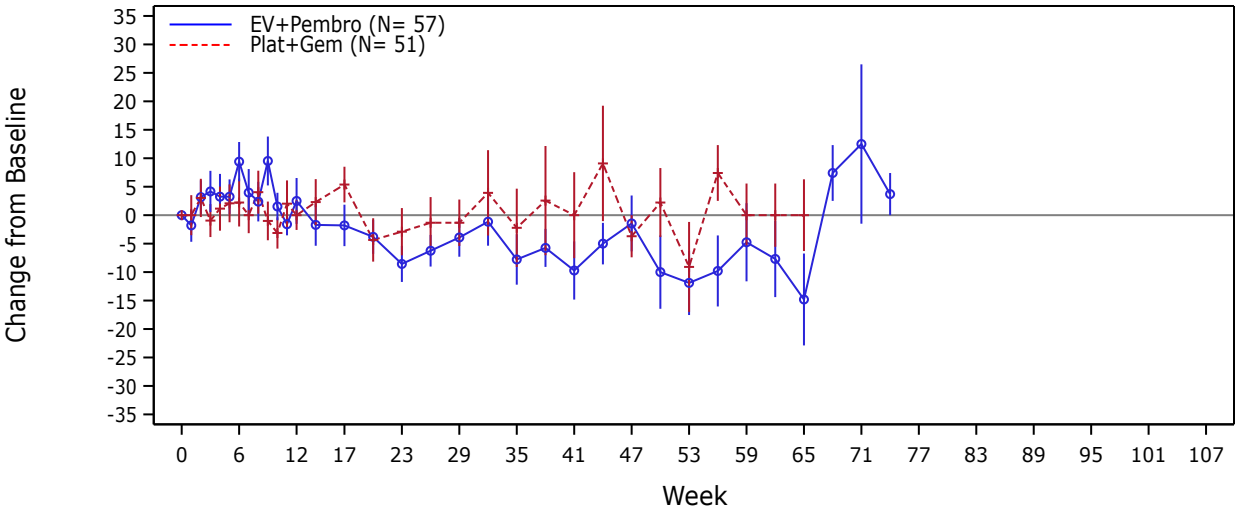
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.23.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Diarrhea by Region - Analysis Set mITT 1

Region: North America



Number of subjects

EV+Pembro	47	39	40	37	35	34	30	24	23	14	14	9	8
Plat+Gem	42	30	32	31	23	25	15	13	9	11	9	8	

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

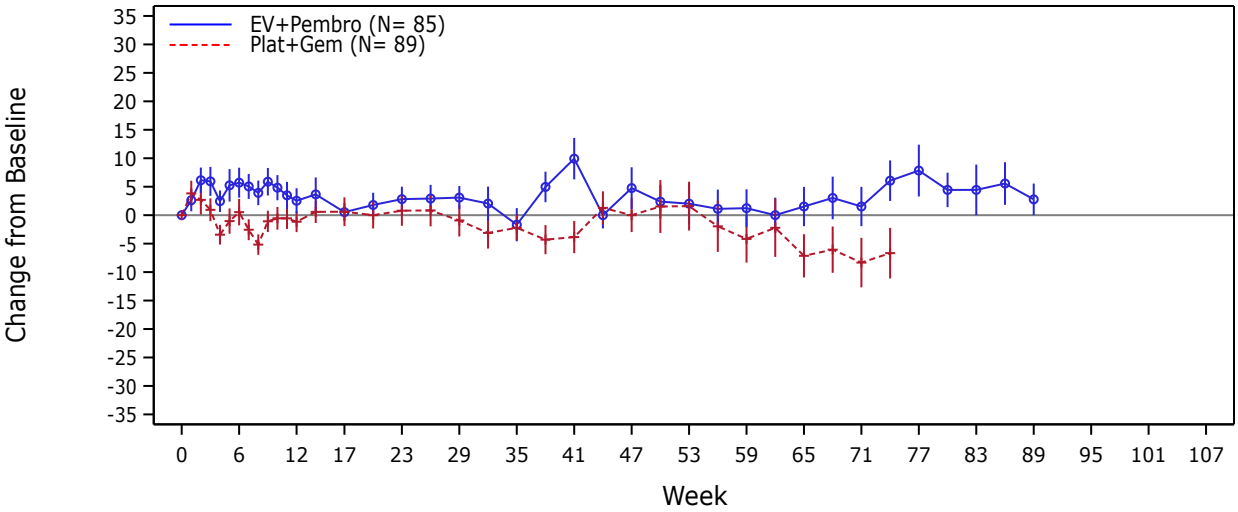
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.23.1.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Diarrhea by Region - Analysis Set mITT 1

Region: Rest of World



Number of subjects

EV+Pembro	80	70	66	63	59	54	40	47	35	33	27	22	22	17	15	12
Plat+Gem	75	63	58	55	42	36	30	26	28	21	16	14	12			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

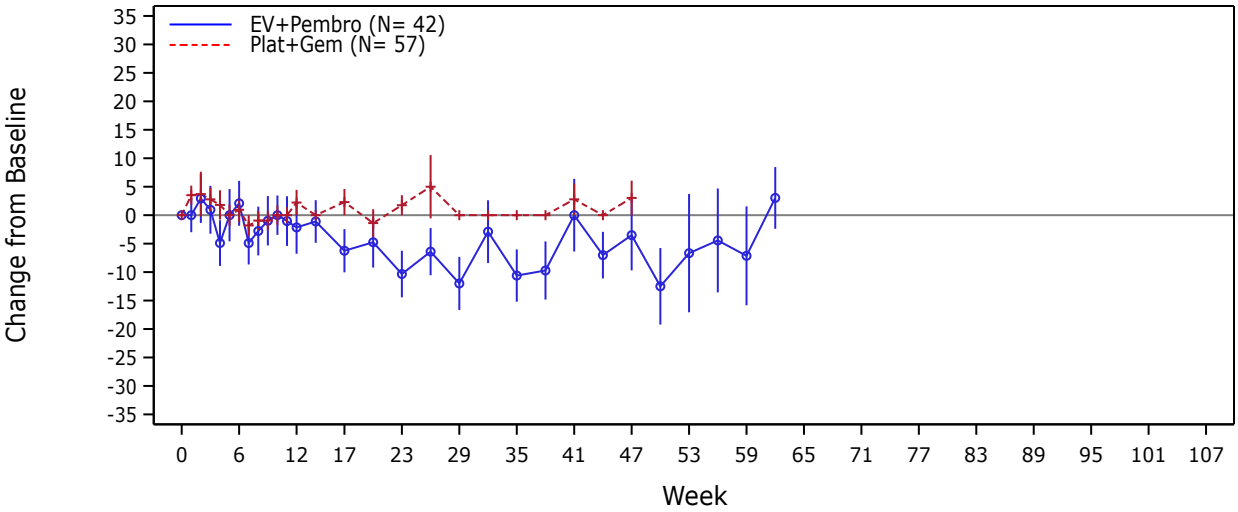
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.23.1.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Diarrhea by Sex - Analysis Set mITT 1

Sex: Female



Number of subjects

EV+Pembro	36	32	31	32	29	25	22	25	19	15	14
Plat+Gem	42	35	30	29	19	21	17	12	11		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

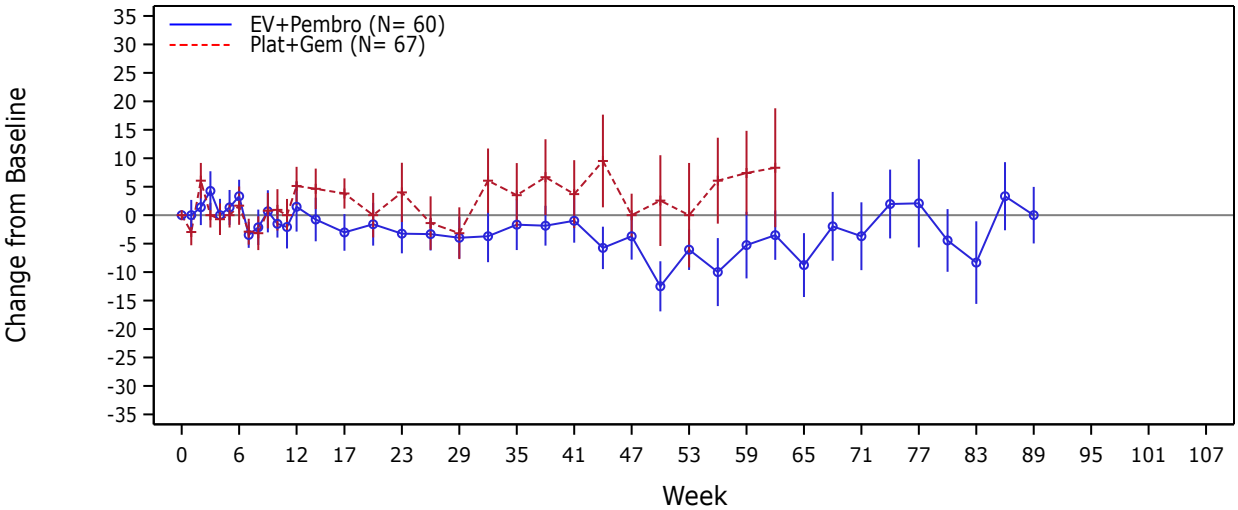
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.23.1.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Diarrhea by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Lymph node only



Number of subjects

EV+Pembro	53	50	45	44	41	42	40	34	27	22	19	19	18	16	12	10
Plat+Gem	49	40	39	35	25	21	19	18	13	12	9					

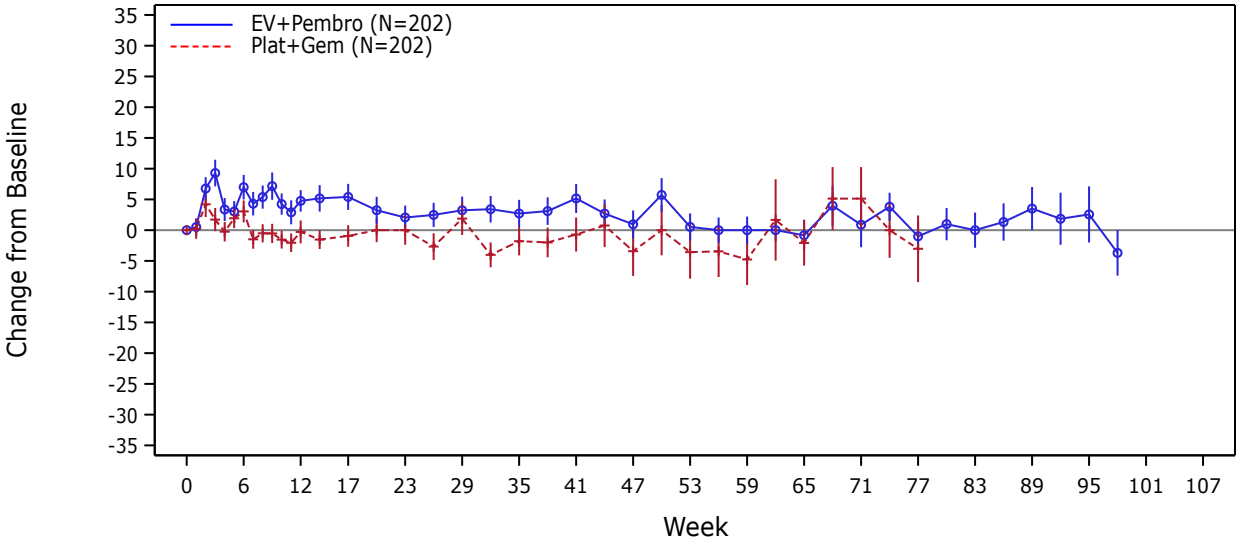
Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.23.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Diarrhea - Analysis Set mITT 2



Number of subjects

EV+Pembro	160	124	119	111	97	93	86	84	70	63	57	40	38	33	29	19	13
Plat+Gem	165	131	115	106	80	71	56	47	39	28	21	16	13	11			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

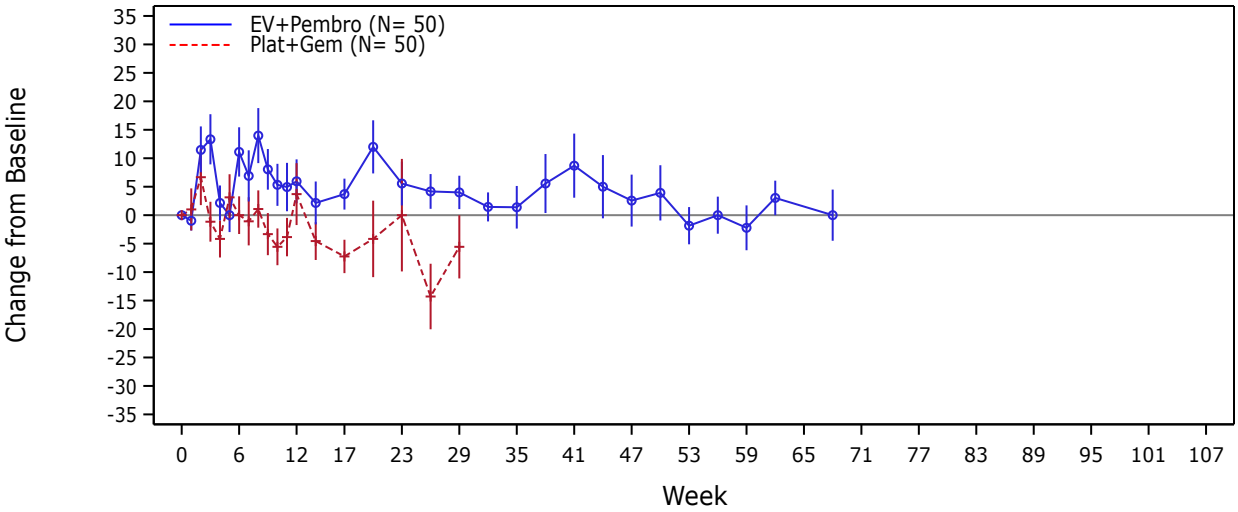
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.23.2.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Diarrhea by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Present



Number of subjects

EV+Pembro	40	30	28	27	24	25	24	23	13	18	15
Plat+Gem	40	29	27	23	14	12					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

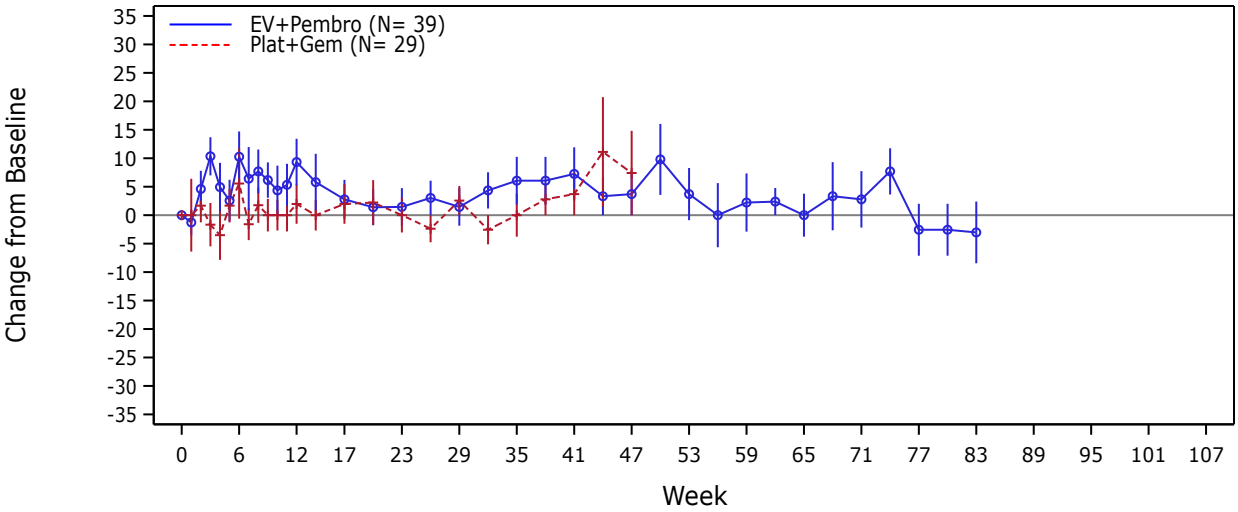
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.23.2.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Diarrhea by Age - Analysis Set mITT 2

Age: < 65 years



Number of subjects

EV+Pembro	32	26	25	24	23	23	22	23	18	18	15	13	12	13	11
Plat+Gem	22	18	17	17	16	13	13	9	9						

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

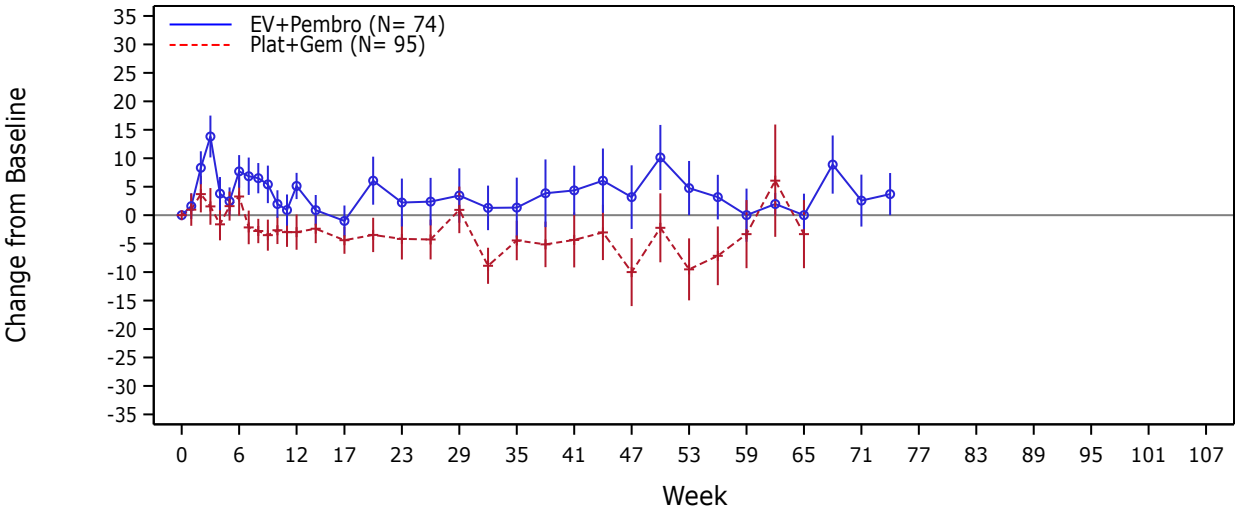
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.23.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Diarrhea by Region - Analysis Set mITT 2

Region: Europe



Number of subjects

EV+Pembro	53	39	39	33	30	29	25	23	21	21	18	13	13
Plat+Gem	75	61	56	53	40	36	30	23	20	14	10	10	

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

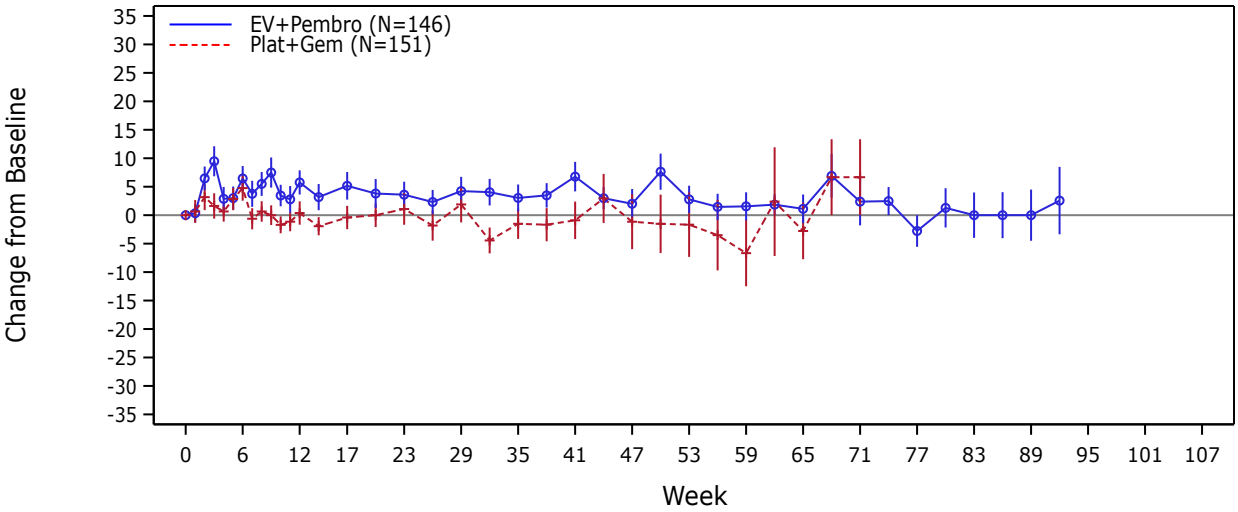
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.23.2.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Diarrhea by Sex - Analysis Set mITT 2

Sex: Male



Number of subjects

EV+Pembro	119	93	87	84	74	71	66	64	50	48	43	30	28	24	21	11
Plat+Gem	123	98	88	82	62	53	44	37	29	20	15	12	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

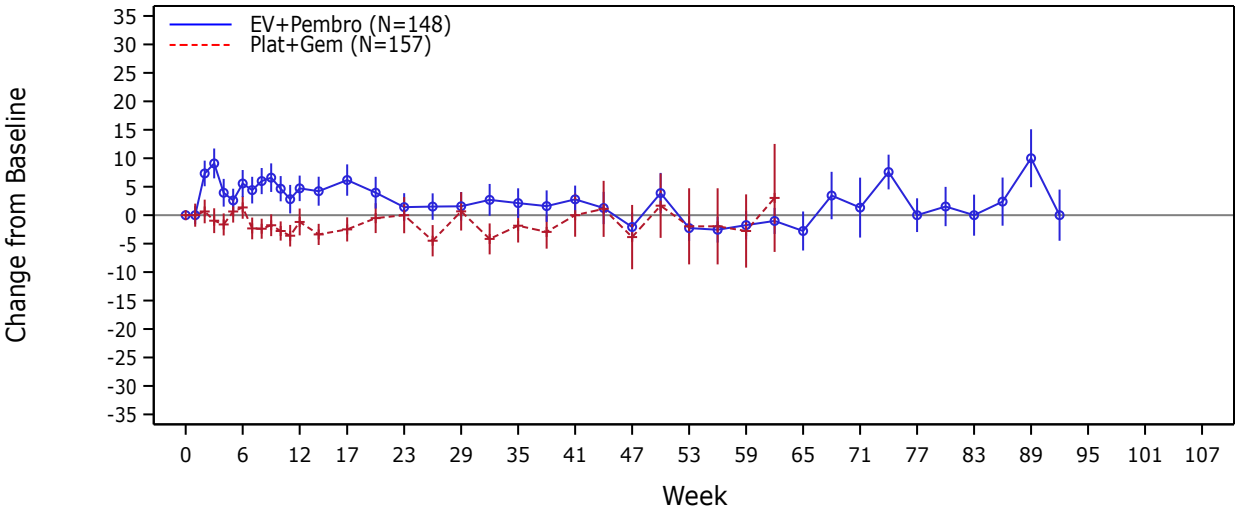
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.23.2.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Diarrhea by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Visceral metastases



Number of subjects

EV+Pembro	119	90	85	81	71	64	63	60	48	44	38	24	25	23	19	10
Plat+Gem	128	98	84	80	58	50	36	31	26	17	12					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

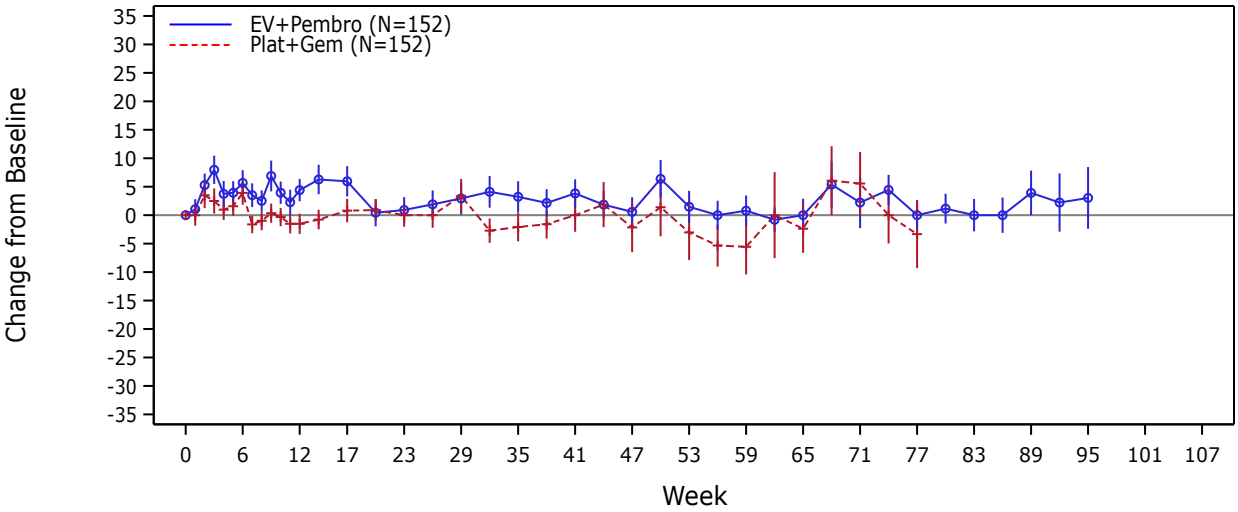
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.23.2.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Diarrhea by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Absent



Number of subjects

EV+Pembro	120	94	91	84	73	68	62	61	57	45	42	33	30	27	24	17	11
Plat+Gem	125	102	88	83	66	59	48	40	31	22	18	14	12	10			

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

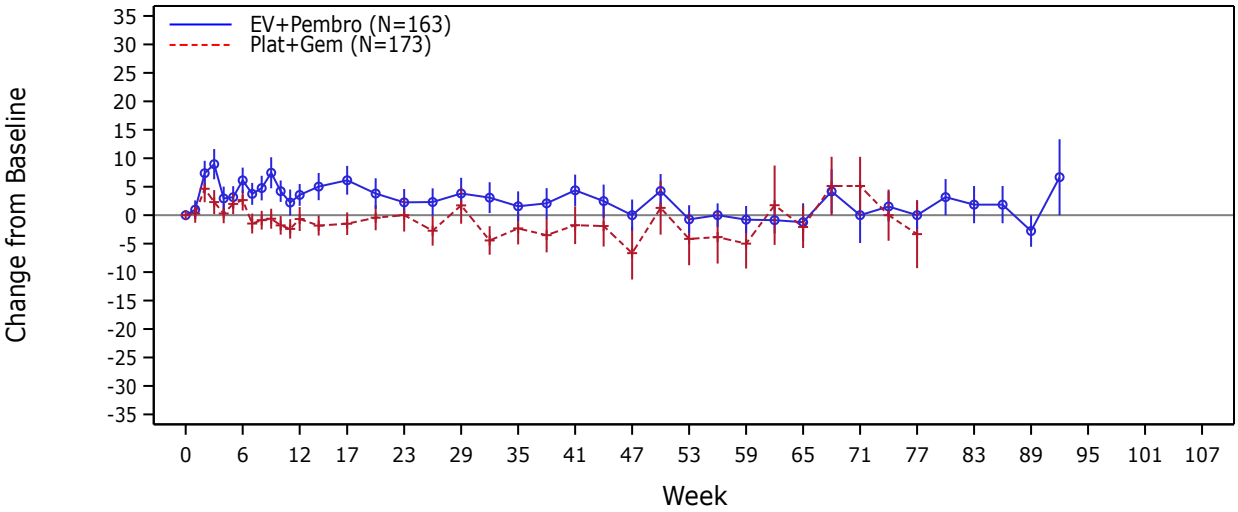
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.23.2.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Diarrhea by Age - Analysis Set mITT 2

Age: >= 65 years



Number of subjects

EV+Pembro	128	98	94	87	74	70	64	61	52	45	42	27	26	20	18	12
Plat+Gem	143	113	98	89	64	58	43	38	30	24	20	16	13	10		

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

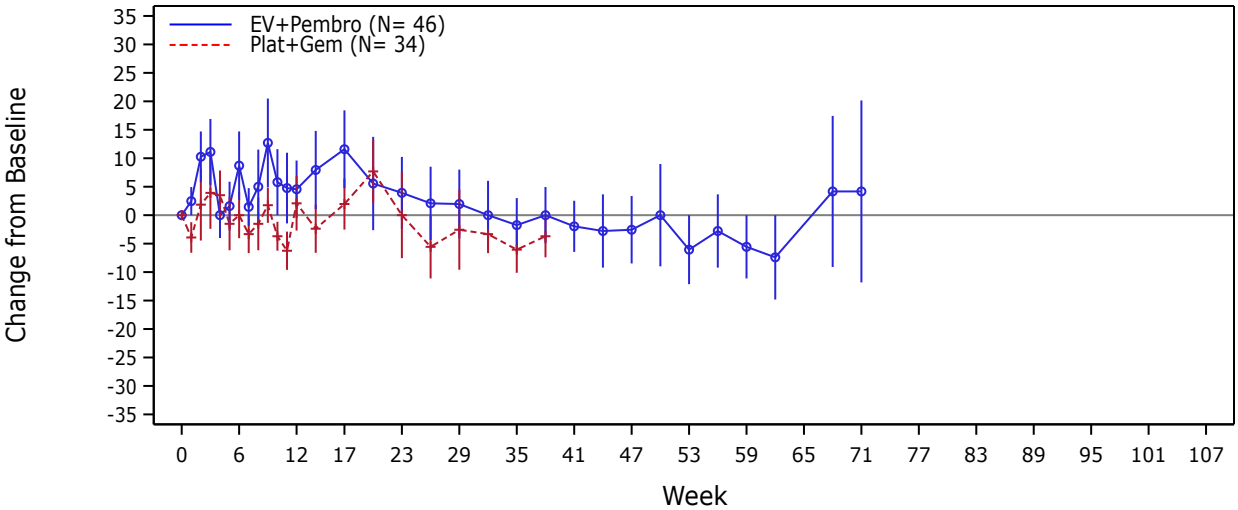
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.23.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Diarrhea by Region - Analysis Set mITT 2

Region: North America



Number of subjects

EV+Pembro	33	23	22	23	17	17	19	17	13	11	12	8
Plat+Gem	27	17	16	17	13	13	11					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

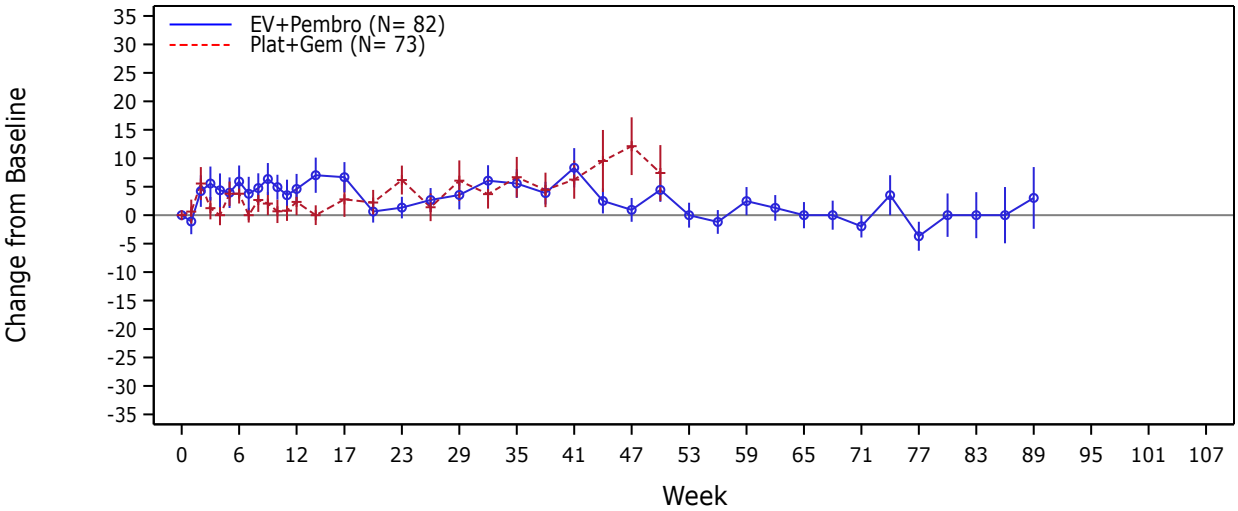
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.23.2.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Diarrhea by Region - Analysis Set mITT 2

Region: Rest of World



Number of subjects

EV+Pembro	74	62	58	55	50	47	42	44	36	31	27	21	17	18	17	11
Plat+Gem	63	53	43	36	27	22	15	16	11							

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

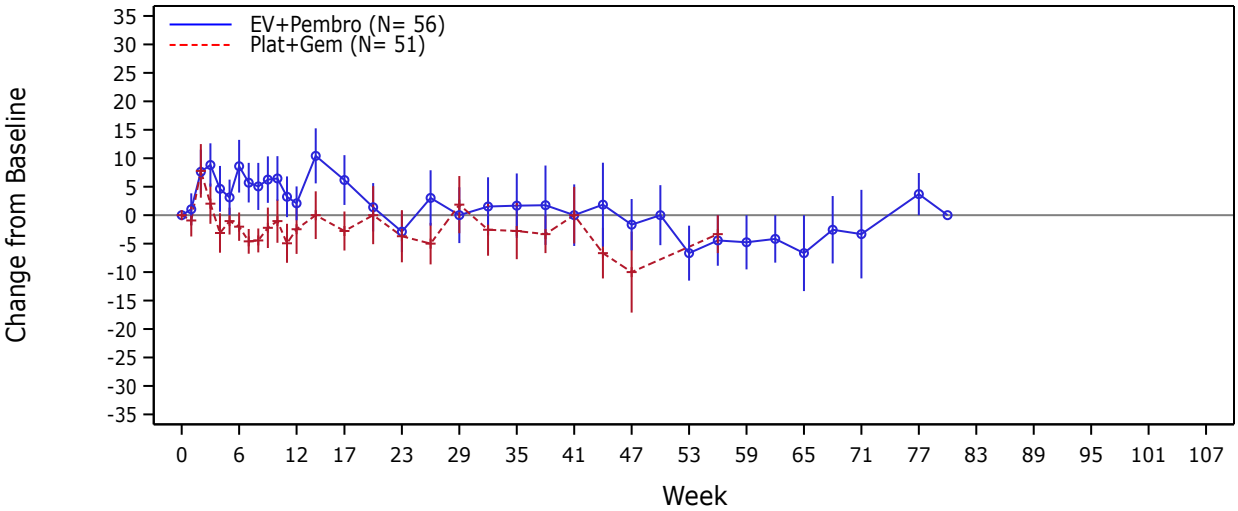
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.23.2.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Diarrhea by Sex - Analysis Set mITT 2

Sex: Female



Number of subjects

EV+Pembro	41	31	32	27	23	22	20	20	20	15	14	10	10	9
Plat+Gem	42	33	27	24	18	18	12	10	10					

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

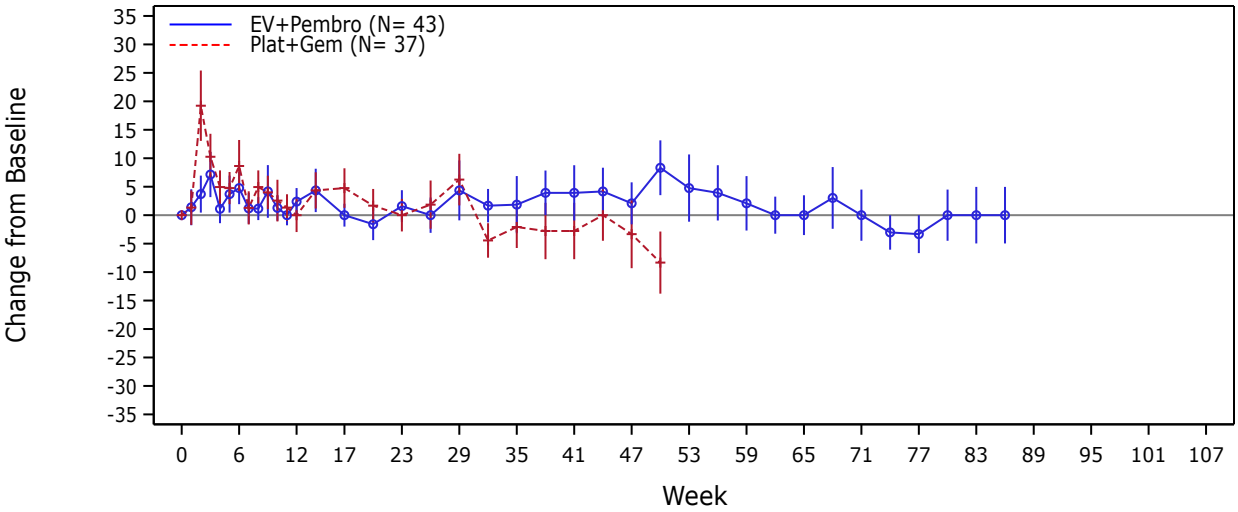
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.23.2.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Diarrhea by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Lymph node only



Number of subjects

EV+Pembro	33	28	28	24	21	23	18	17	16	14	16	14	11	10	10
Plat+Gem	29	27	23	21	17	16	16	12	10						

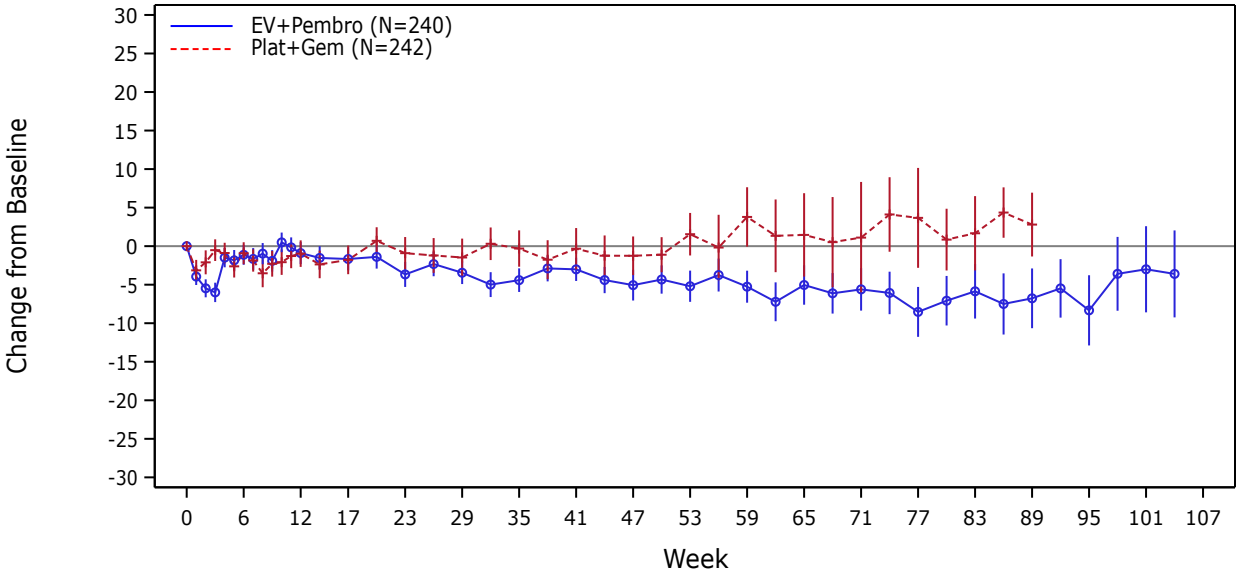
Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.24.1: EQ-5D-5L - Plot of Mean Change from Baseline of VAS Scale - Analysis Set mITT 1



Number of subjects

EV+Pembro	211	175	173	164	152	146	123	119	94	74	68	54	49	43	36	31	21	14
Plat+Gem	190	151	141	133	100	87	70	57	51	42	33	26	19	15	12	10		

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 levels; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; VAS=visual analogue scale.

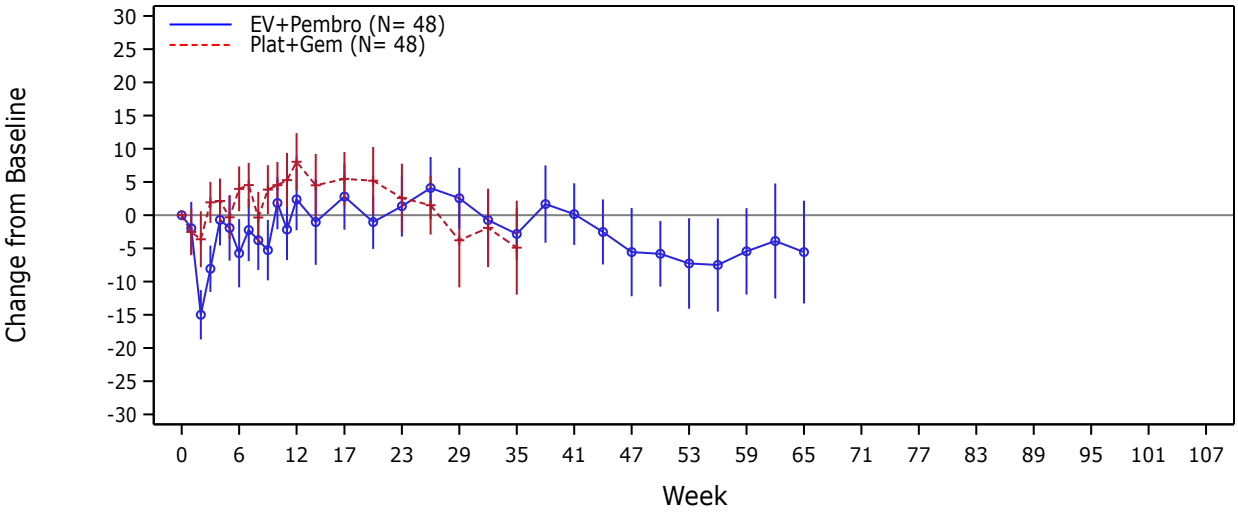
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.24.1.1: EQ-5D-5L - Plot of Mean Change from Baseline of VAS Scale by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Present



Number of subjects

EV+Pembro	39	26	29	25	23	22	18	19	16	11	11	9
Plat+Gem	34	28	24	26	19	14	9					

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 levels; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; VAS=visual analogue scale.

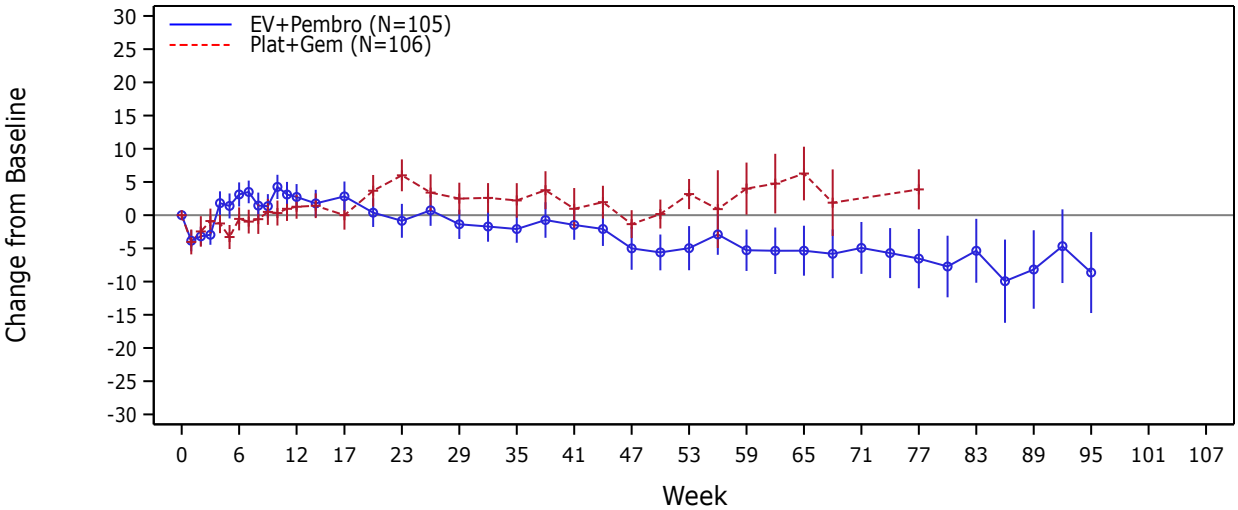
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.24.1.2: EQ-5D-5L - Plot of Mean Change from Baseline of VAS Scale by Age - Analysis Set mITT 1

Age: < 65 years



Number of subjects

EV+Pembro	94	83	80	78	73	68	58	59	46	37	39	31	30	24	22	17	11
Plat+Gem	84	68	67	59	45	38	32	23	23	17	12	11		8			

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 levels; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; VAS=visual analogue scale.

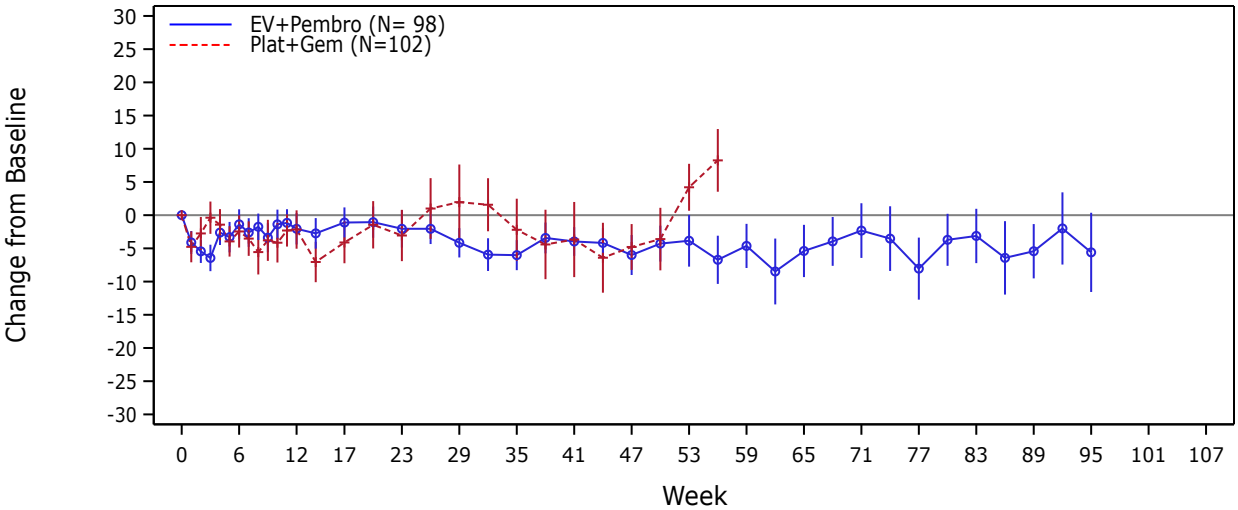
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.24.1.3: EQ-5D-5L - Plot of Mean Change from Baseline of VAS Scale by Region - Analysis Set mITT 1

Region: Europe



Number of subjects

EV+Pembro	81	64	66	63	57	58	53	48	36	27	27	23	19	19	16	14	10
Plat+Gem	73	58	50	47	34	26	25	18	14	10							

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 levels; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; VAS=visual analogue scale.

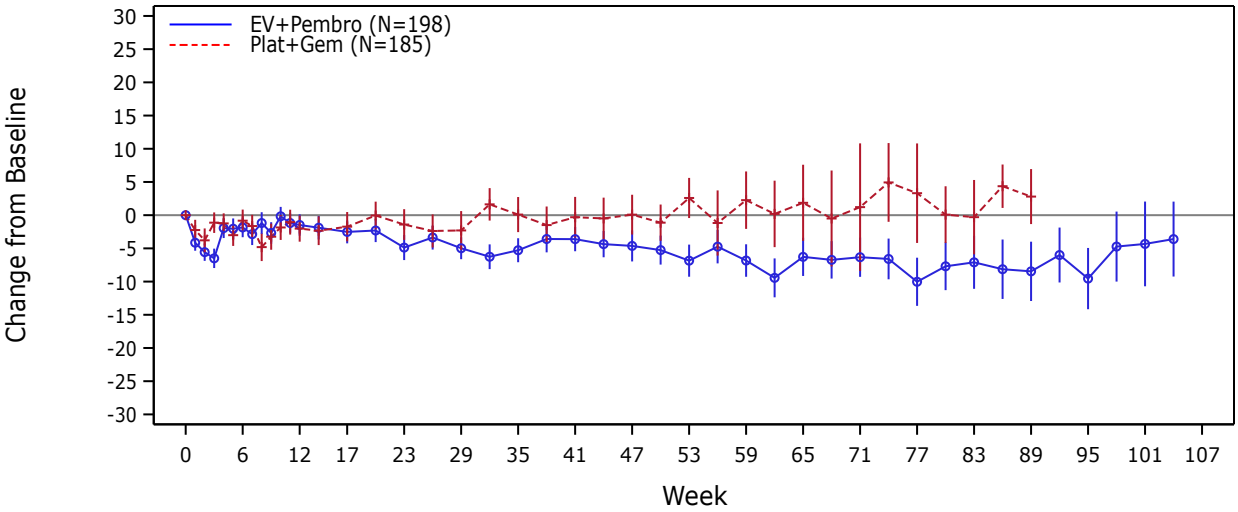
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.24.1.4: EQ-5D-5L - Plot of Mean Change from Baseline of VAS Scale by Sex - Analysis Set mITT 1

Sex: Male



Number of subjects

EV+Pembro	175	143	142	132	123	121	100	94	75	59	54	47	45	37	31	26	20	12
Plat+Gem	148	116	111	104	80	66	53	45	40	34	27	21	14	13	10	10		

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 levels; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; VAS=visual analogue scale.

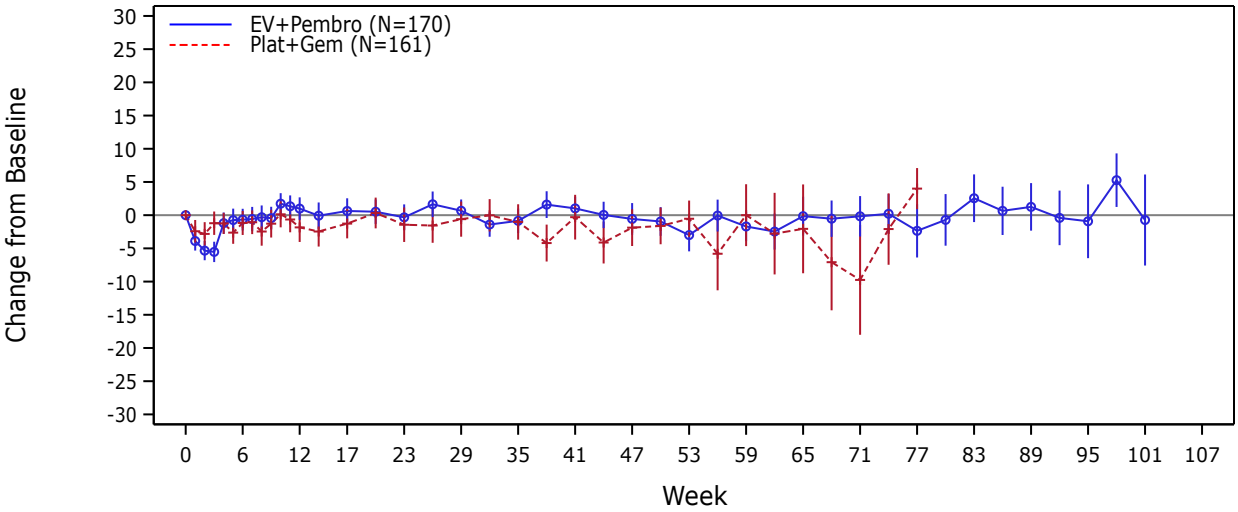
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.24.1.5: EQ-5D-5L - Plot of Mean Change from Baseline of VAS Scale by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Visceral metastases



Number of subjects

EV+Pembro	149	117	121	112	103	99	80	81	63	50	47	34	30	25	22	20	12	11
Plat+Gem	131	104	94	91	70	60	45	33	32	24	21	18	12	10				

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 levels; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; VAS=visual analogue scale.

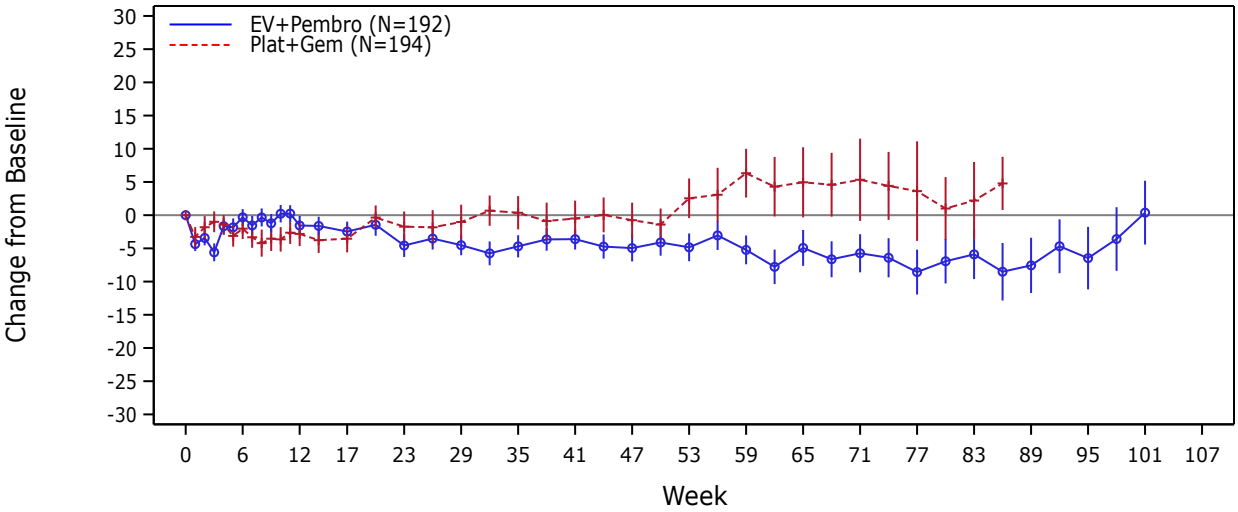
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.24.1.1: EQ-5D-5L - Plot of Mean Change from Baseline of VAS Scale by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Absent



Number of subjects

EV+Pembro	172	149	144	139	129	124	105	100	78	63	57	45	42	37	31	27	19	13
Plat+Gem	156	123	117	107	81	73	61	54	46	37	28	21	18	13	10			

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 levels; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; VAS=visual analogue scale.

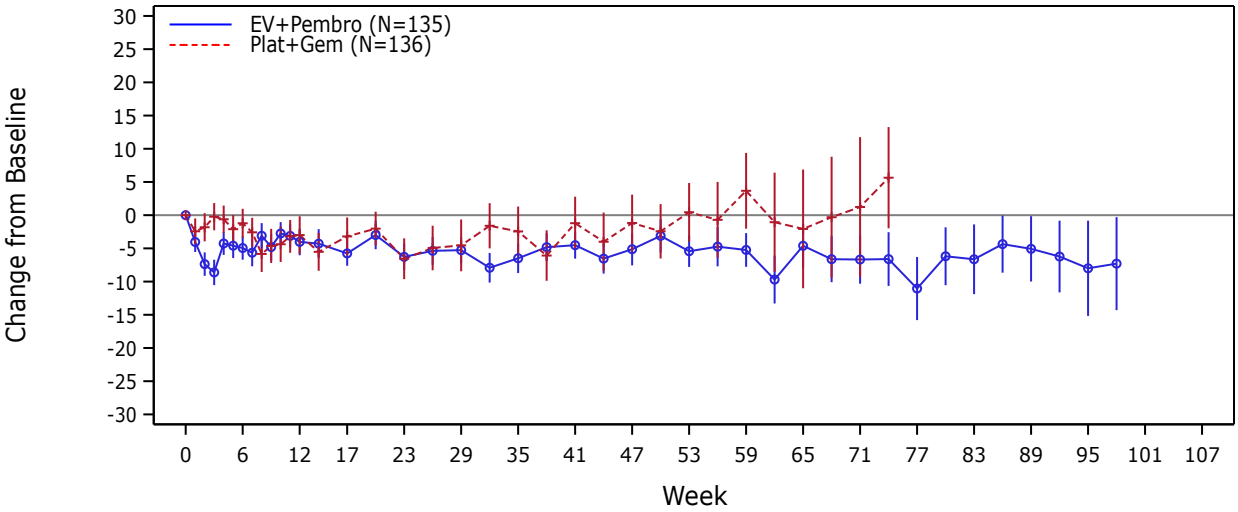
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.24.1.2: EQ-5D-5L - Plot of Mean Change from Baseline of VAS Scale by Age - Analysis Set mITT 1

Age: >= 65 years



Number of subjects

EV+Pembro	117	92	93	86	79	78	65	60	48	37	29	23	19	19	14	14	10
Plat+Gem	106	83	74	74	55	49	38	34	28	25	21	15	13				

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 levels; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; VAS=visual analogue scale.

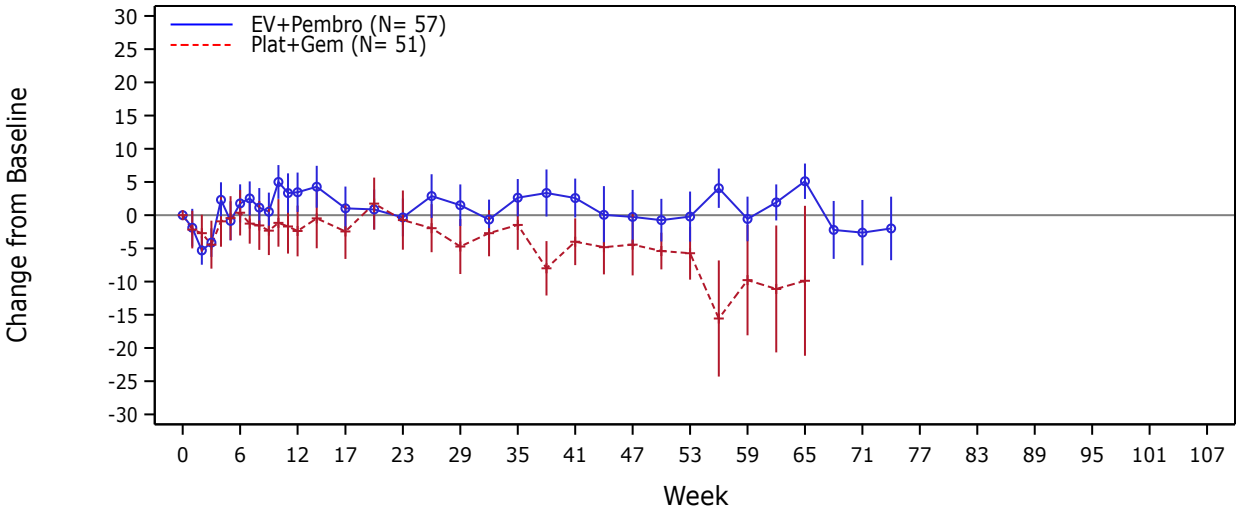
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.24.1.3: EQ-5D-5L - Plot of Mean Change from Baseline of VAS Scale by Region - Analysis Set mITT 1

Region: North America



Number of subjects

EV+Pembro	49	39	40	37	35	34	30	24	23	14	14	9	8
Plat+Gem	42	30	32	31	23	25	15	13	9	11	9	8	

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 levels; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; VAS=visual analogue scale.

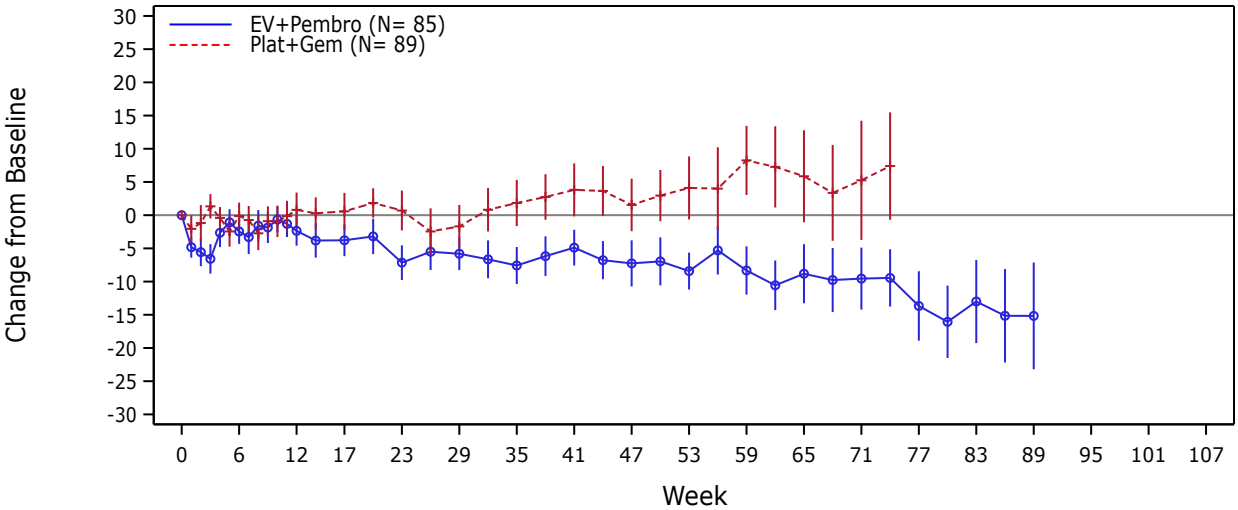
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.24.1.3: EQ-5D-5L - Plot of Mean Change from Baseline of VAS Scale by Region - Analysis Set mITT 1

Region: Rest of World



Number of subjects

EV+Pembro	81	72	67	64	60	54	40	47	35	33	27	22	22	18	16	12
Plat+Gem	75	63	59	55	43	36	30	26	28	21	16	14	12			

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 levels; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; VAS=visual analogue scale.

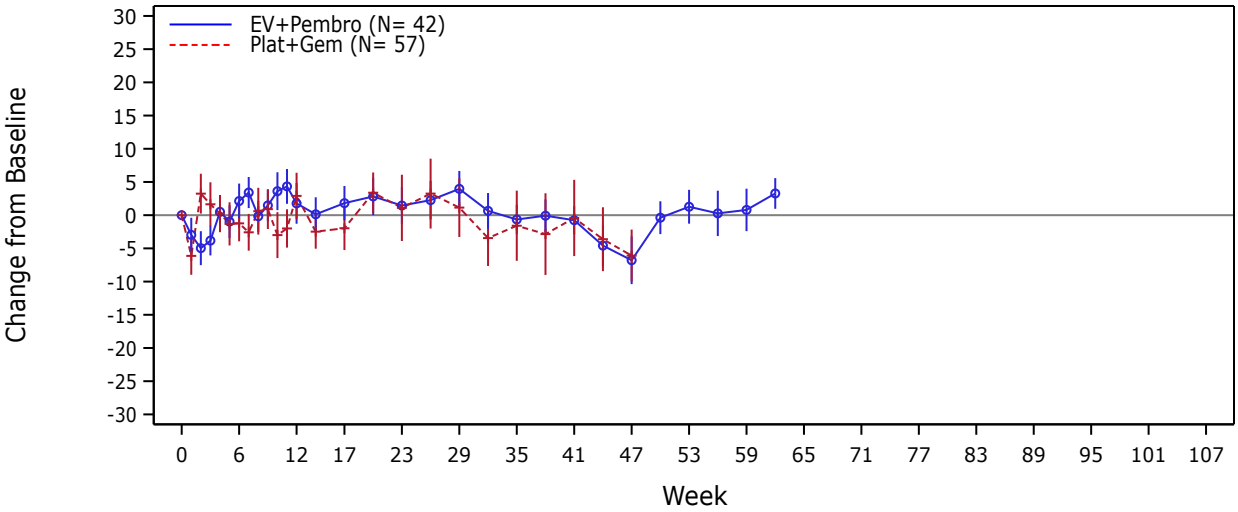
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.24.1.4: EQ-5D-5L - Plot of Mean Change from Baseline of VAS Scale by Sex - Analysis Set mITT 1

Sex: Female



Number of subjects

EV+Pembro	36	32	31	32	29	25	23	25	19	15	14
Plat+Gem	42	35	30	29	20	21	17	12	11		

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 levels; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; VAS=visual analogue scale.

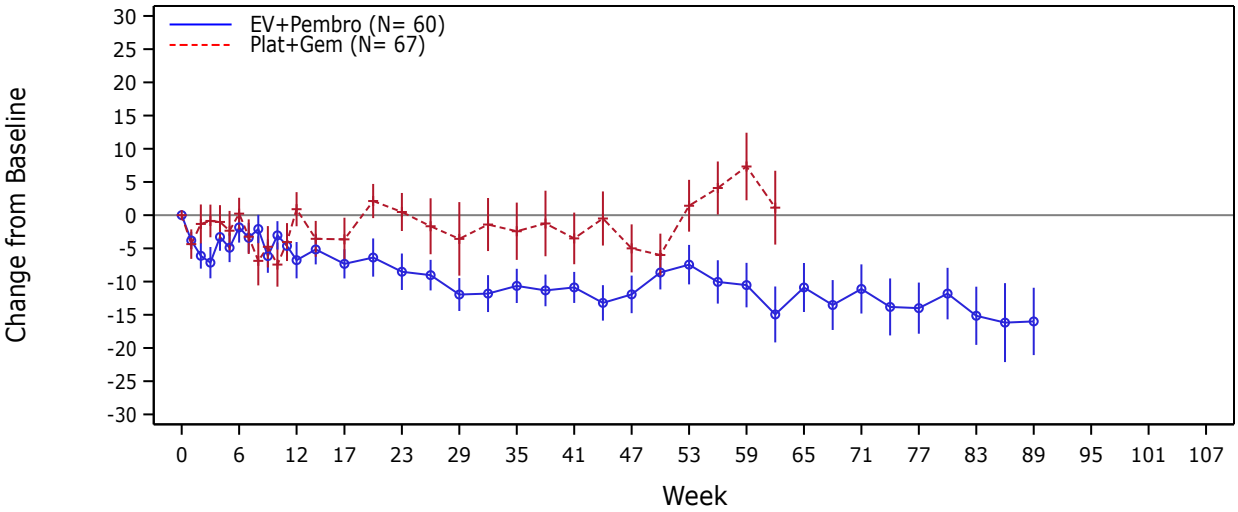
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.24.1.5: EQ-5D-5L - Plot of Mean Change from Baseline of VAS Scale by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Lymph node only



Number of subjects

EV+Pembro	55	51	46	45	42	42	40	34	27	22	19	19	18	17	13	10
Plat+Gem	49	40	39	36	25	21	19	18	13	12	9					

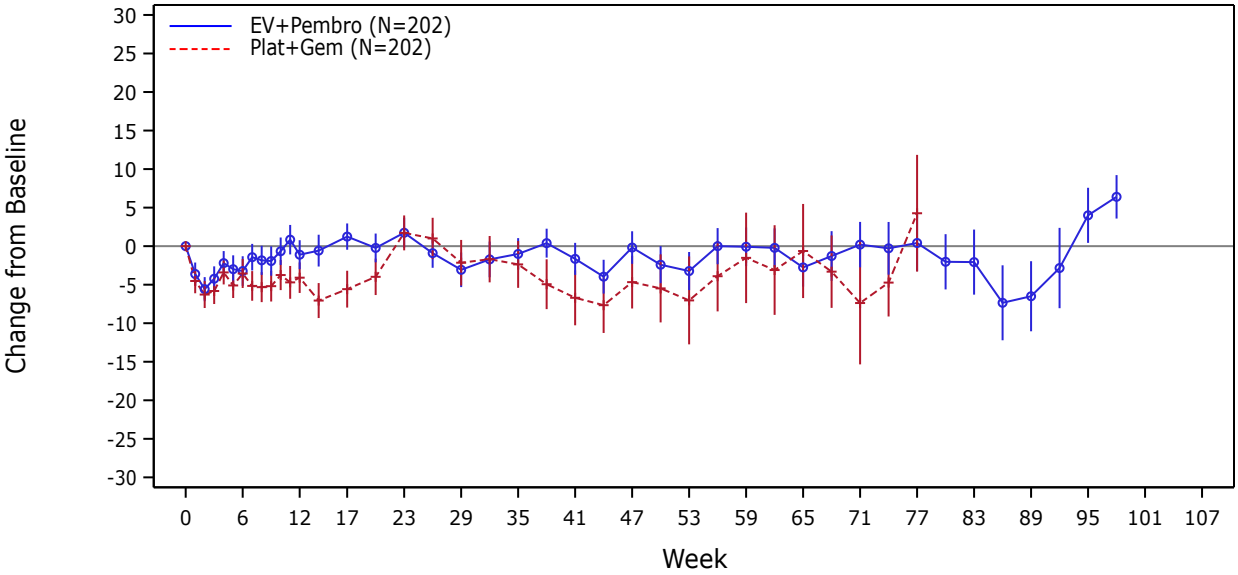
Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 levels; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; VAS=visual analogue scale.

Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.24.2: EQ-5D-5L - Plot of Mean Change from Baseline of VAS Scale - Analysis Set mITT 2



Number of subjects

EV+Pembro	166	130	123	115	100	96	88	88	72	66	59	41	40	34	30	20	14
Plat+Gem	168	131	116	108	82	71	57	47	39	28	21	16	13	11			

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 levels; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; VAS=visual analogue scale.

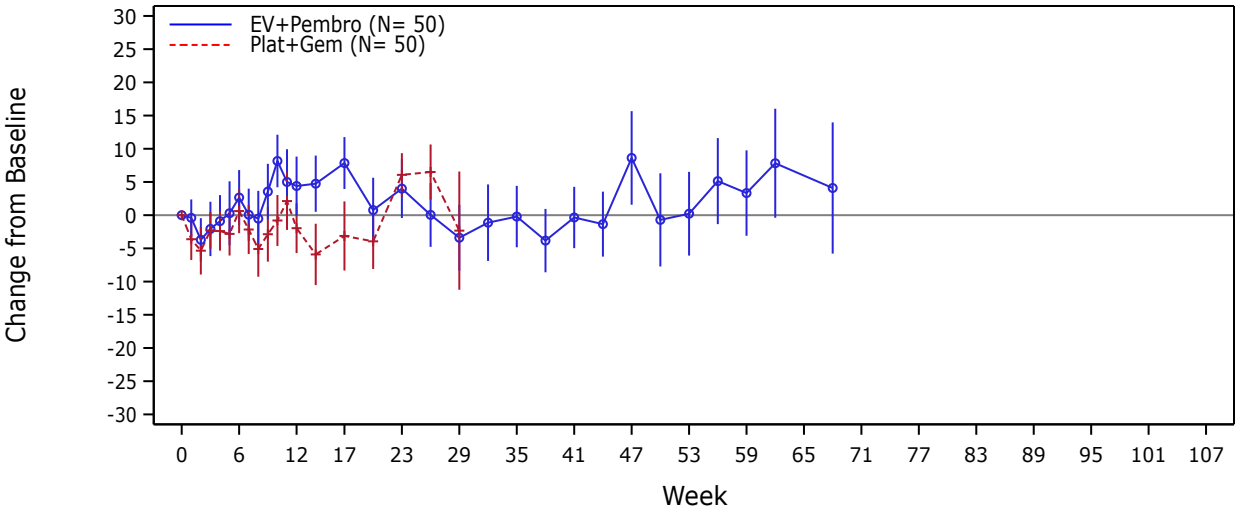
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.24.2.1: EQ-5D-5L - Plot of Mean Change from Baseline of VAS Scale by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Present



Number of subjects

EV+Pembro	41	31	28	27	24	25	24	23	13	18	15
Plat+Gem	41	29	28	24	14	12					

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 levels; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; VAS=visual analogue scale.

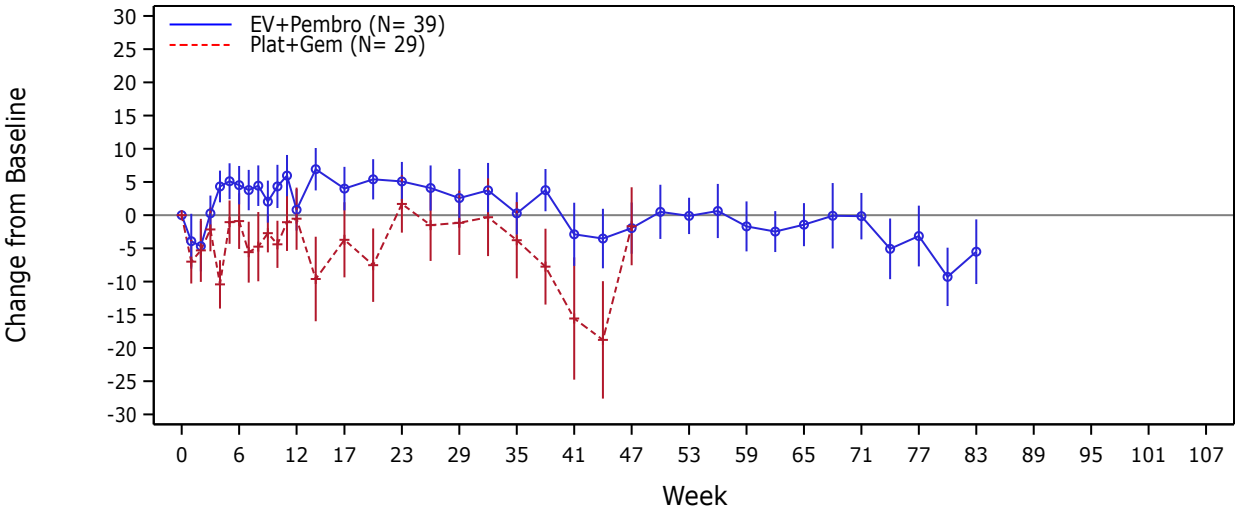
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.24.2.2: EQ-5D-5L - Plot of Mean Change from Baseline of VAS Scale by Age - Analysis Set mITT 2

Age: < 65 years



Number of subjects

EV+Pembro	33	27	26	25	24	23	22	24	19	19	16	14	13	14	12
Plat+Gem	22	18	17	17	16	13	13	9	9						

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 levels; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; VAS=visual analogue scale.

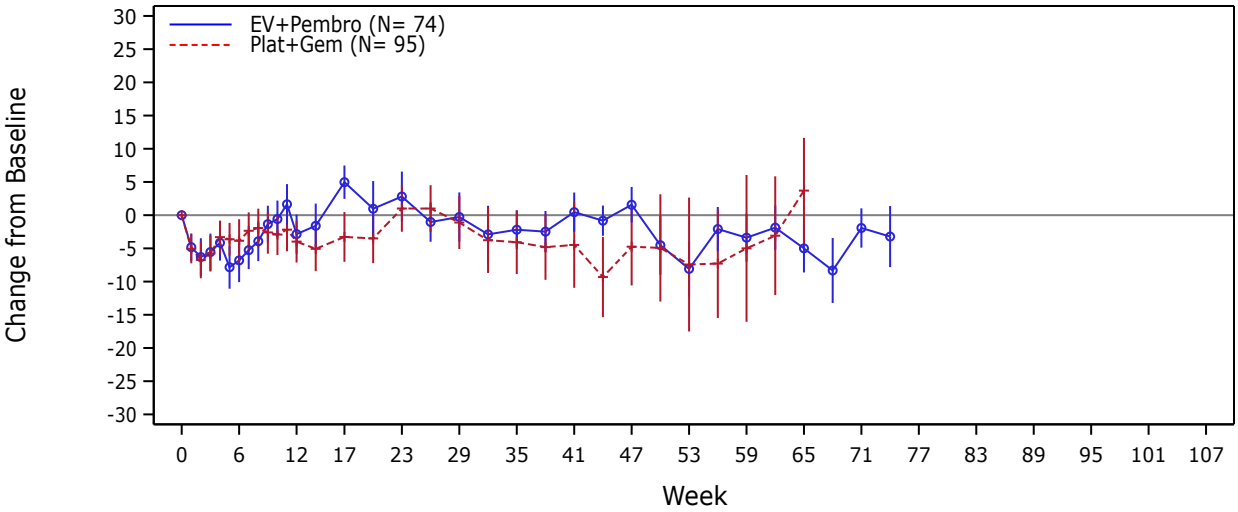
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.24.2.3: EQ-5D-5L - Plot of Mean Change from Baseline of VAS Scale by Region - Analysis Set mITT 2

Region: Europe



Number of subjects

EV+Pembro	57	42	41	34	31	30	26	24	21	23	18	13	14
Plat+Gem	76	61	56	53	41	36	30	23	20	14	10	10	

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 levels; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; VAS=visual analogue scale.

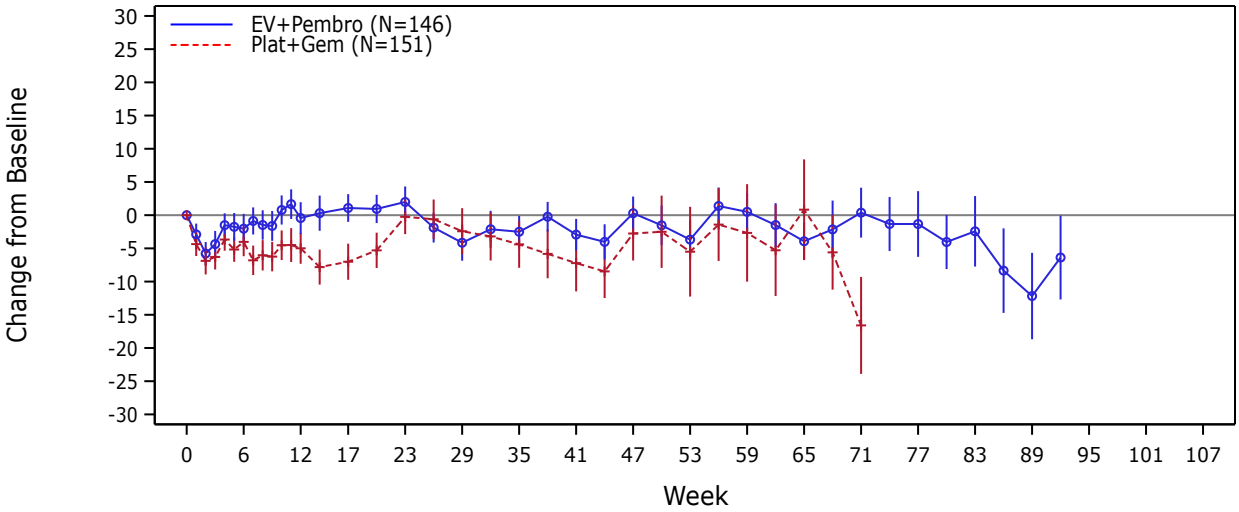
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.24.2.4: EQ-5D-5L - Plot of Mean Change from Baseline of VAS Scale by Sex - Analysis Set mITT 2

Sex: Male



Number of subjects

EV+Pembro	123	96	89	86	76	74	68	67	51	50	44	30	29	24	21	11
Plat+Gem	126	98	89	84	64	53	45	37	29	20	15	12	10			

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 levels; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; VAS=visual analogue scale.

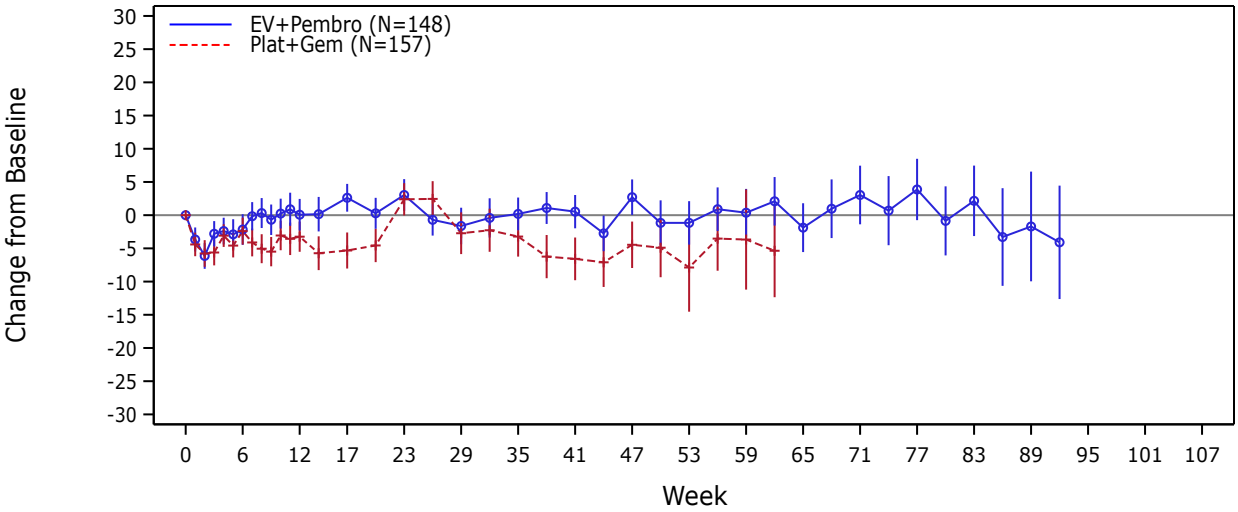
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.24.2.5: EQ-5D-5L - Plot of Mean Change from Baseline of VAS Scale by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Visceral metastases



Number of subjects

EV+Pembro	121	93	86	81	71	64	63	60	48	44	38	24	25	23	19	10
Plat+Gem	130	98	85	82	59	50	37	31	26	17	12					

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 levels; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; VAS=visual analogue scale.

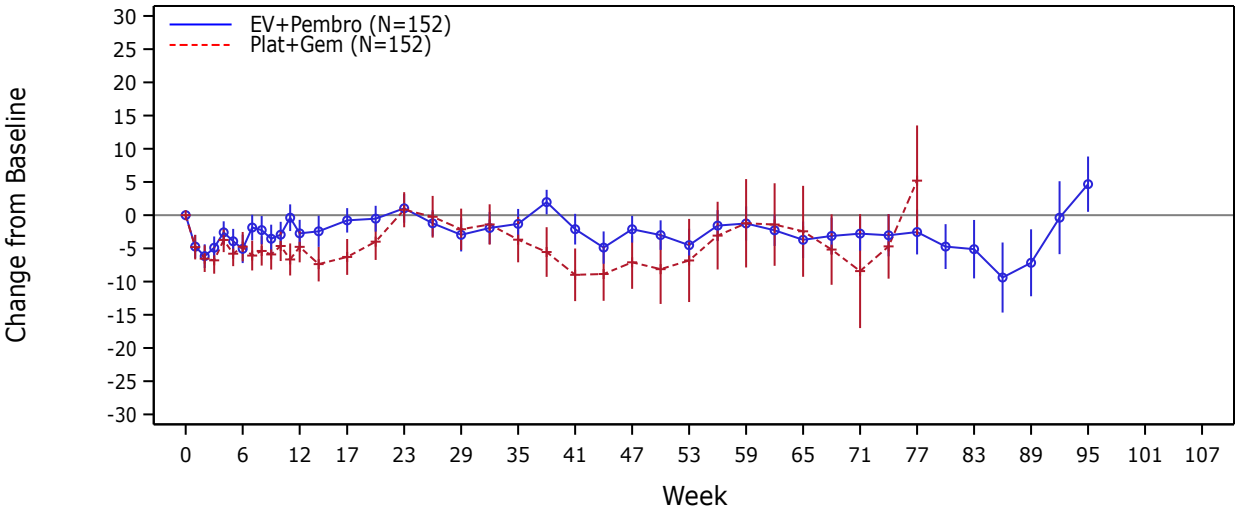
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.24.2.1: EQ-5D-5L - Plot of Mean Change from Baseline of VAS Scale by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Absent



Number of subjects

EV+Pembro	125	99	95	88	76	71	64	65	59	48	44	34	32	28	25	18	12
Plat+Gem	127	102	88	84	68	59	49	40	31	22	18	14	12	10			

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 levels; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; VAS=visual analogue scale.

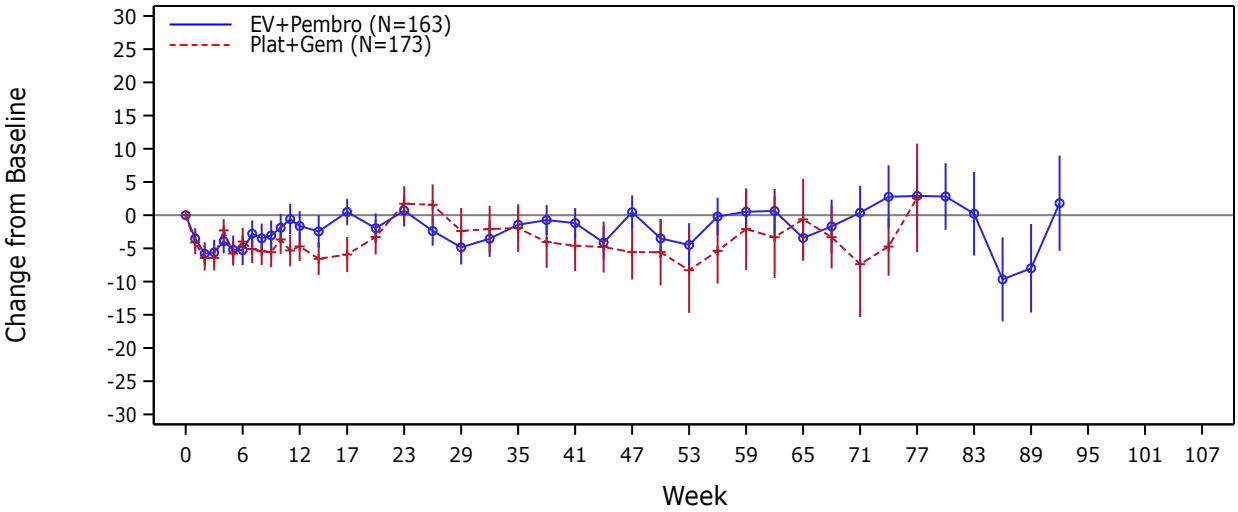
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.24.2.2: EQ-5D-5L - Plot of Mean Change from Baseline of VAS Scale by Age - Analysis Set mITT 2

Age: >= 65 years



Number of subjects

EV+Pembro	133	103	97	90	76	73	66	64	53	47	43	27	27	20	18	12
Plat+Gem	146	113	99	91	66	58	44	38	30	24	20	16	13	10		

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 levels; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; VAS=visual analogue scale.

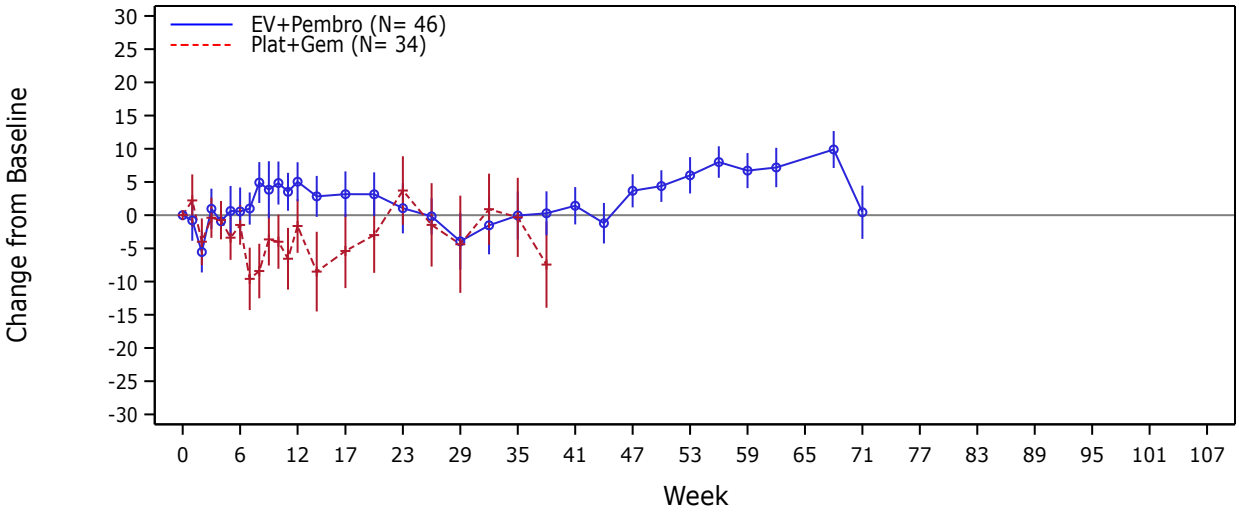
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.24.2.3: EQ-5D-5L - Plot of Mean Change from Baseline of VAS Scale by Region - Analysis Set mITT 2

Region: North America



Number of subjects

EV+Pembro	35	25	24	25	19	18	20	19	15	12	14	9
Plat+Gem	28	17	16	18	14	13	12					

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 levels; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; VAS=visual analogue scale.

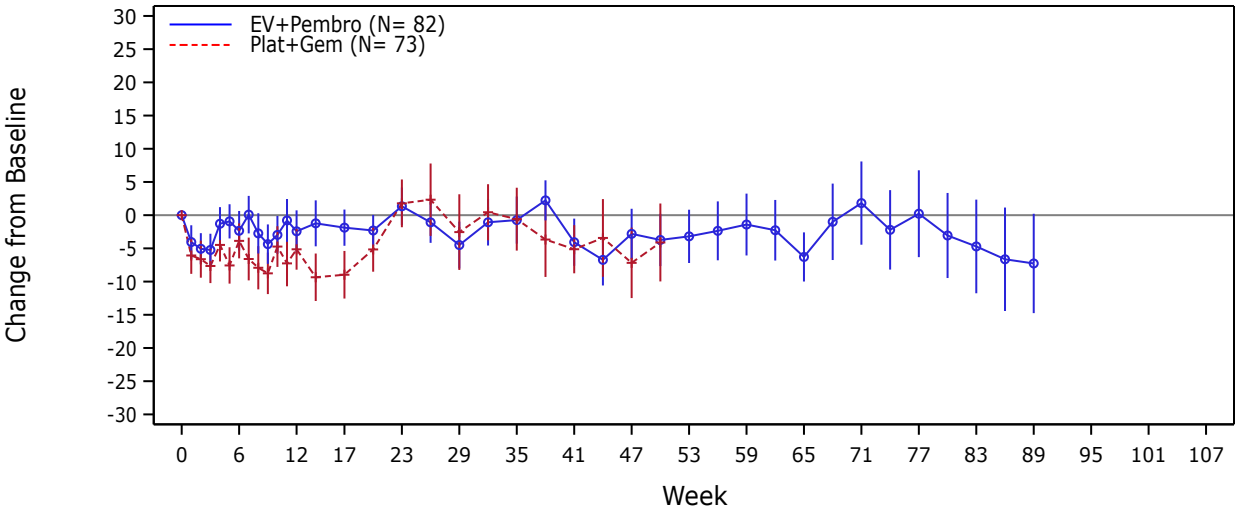
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.24.2.3: EQ-5D-5L - Plot of Mean Change from Baseline of VAS Scale by Region - Analysis Set mITT 2

Region: Rest of World



Number of subjects

EV+Pembro	74	63	58	56	50	48	42	45	36	31	27	21	17	18	17	11
Plat+Gem	64	53	44	37	27	22	15	16	11							

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 levels; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; VAS=visual analogue scale.

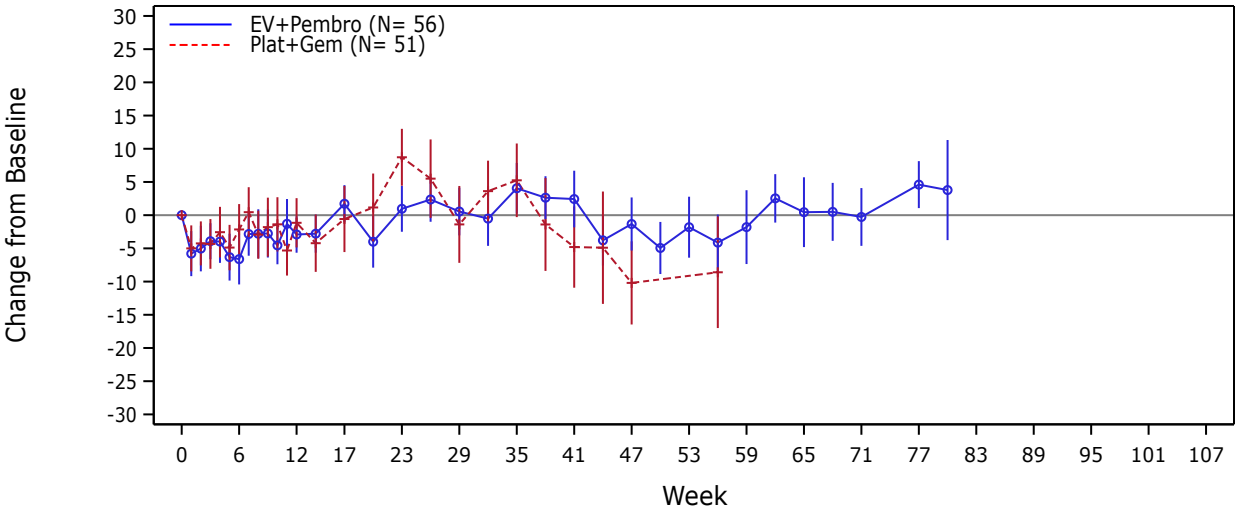
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.24.2.4: EQ-5D-5L - Plot of Mean Change from Baseline of VAS Scale by Sex - Analysis Set mITT 2

Sex: Female



Number of subjects

EV+Pembro	43	34	34	29	24	22	20	21	21	16	15	11	11	10
Plat+Gem	42	33	27	24	18	18	12	10	10					

Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 levels; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; VAS=visual analogue scale.

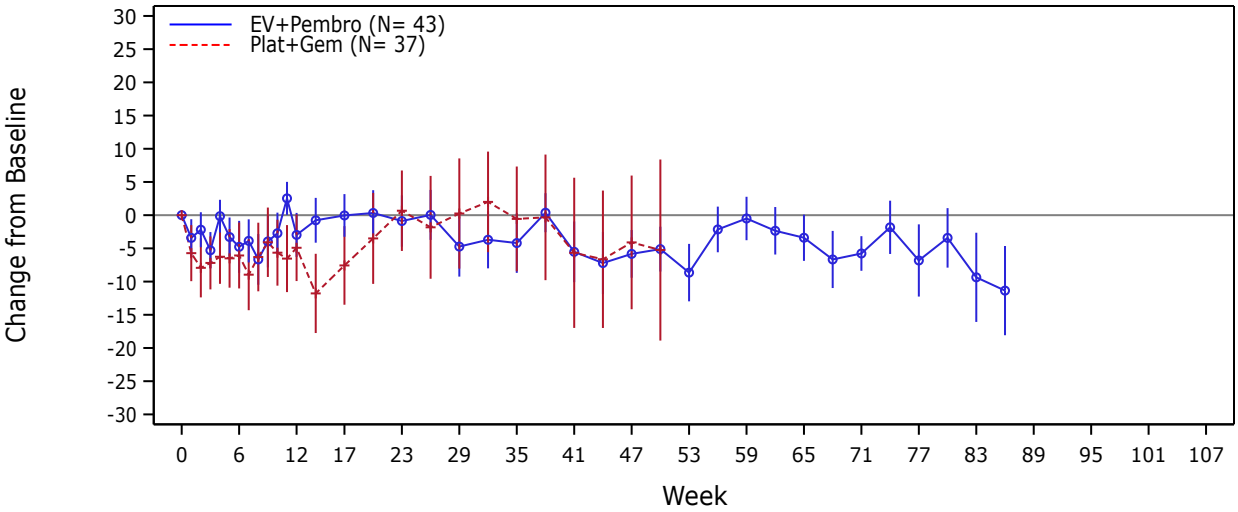
Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3002.24.2.5: EQ-5D-5L - Plot of Mean Change from Baseline of VAS Scale by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Lymph node only



Number of subjects

EV+Pembro	36	31	31	28	24	26	20	21	18	17	18	15	13	11	11
Plat+Gem	30	27	23	21	18	16	16	12	10						

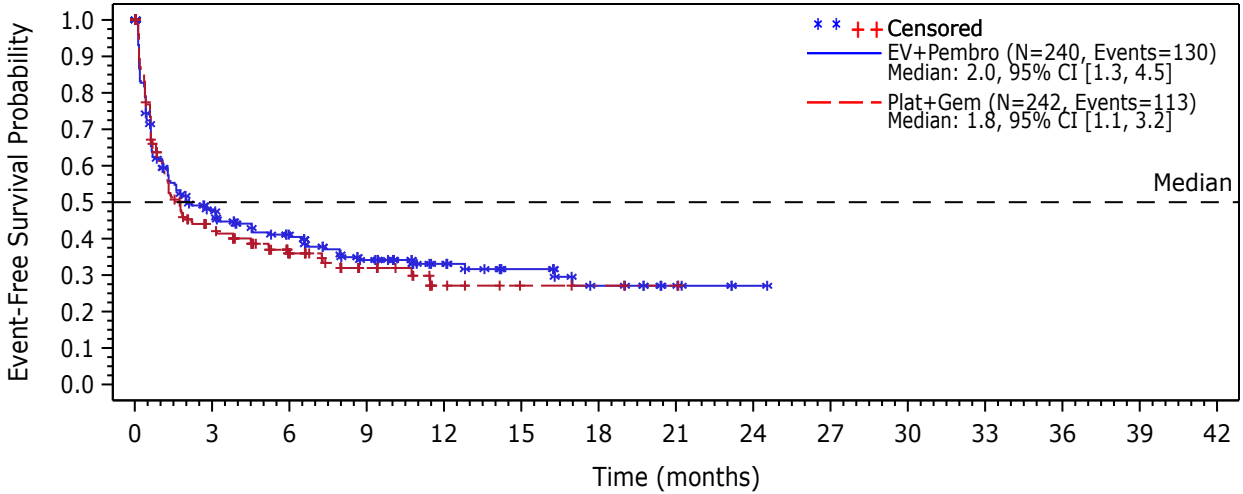
Abbreviations: EQ-5D-5L=European Quality of Life 5 dimensions 5 levels; EV=enfortumab vedotin; Gem=gemcitabine; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; VAS=visual analogue scale.

Note: Vertical bars indicate mean change from baseline +/- standard error and are only provided for the treatment arm at a visit if that arm has at least 10 subjects at that visit.

Baseline is the last available assessment on or before Cycle 1 Day 1.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.4.1: BPI-SF - Kaplan-Meier Plot of Time to first Deterioration of Worst Pain in the last 24 hours (MID=2) - Analysis Set mITT 1



at Risk

1	240	88	64	43	26	17	10	5	1	0	0	0	0	0	0
2	242	67	34	18	7	3	2	1	0	0	0	0	0	0	0

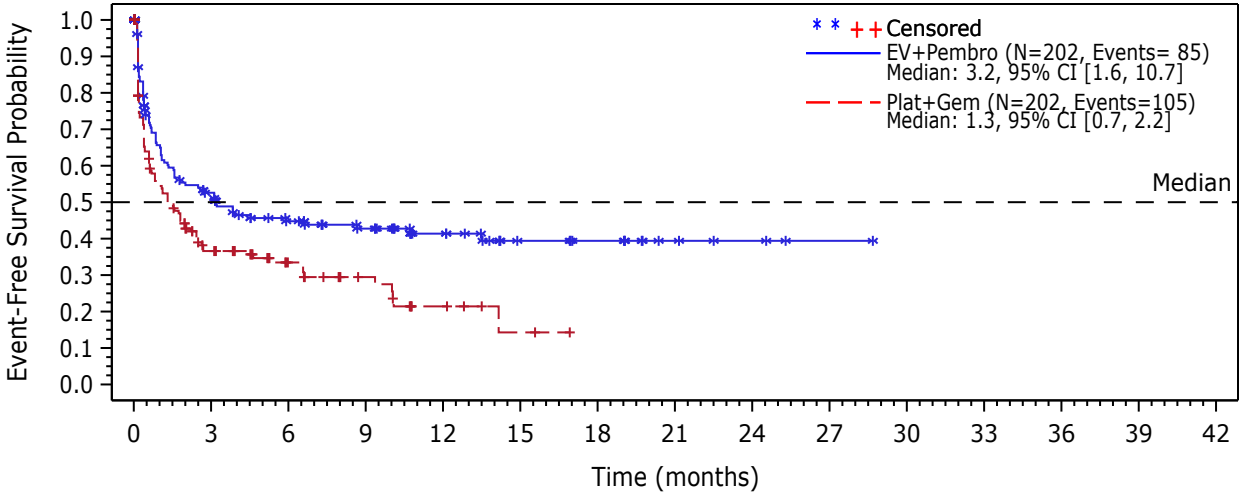
Abbreviations: # at Risk=number of patients at risk; BPI-SF=Brief Pain Inventory - Short Form; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=2 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.4.2: BPI-SF - Kaplan-Meier Plot of Time to first Deterioration of Worst Pain in the last 24 hours (MID=2) - Analysis Set mITT 2



at Risk

1	202	73	50	39	25	14	11	5	3	1	0	0	0	0	0
2	202	46	25	15	6	2	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BPI-SF=Brief Pain Inventory - Short Form; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

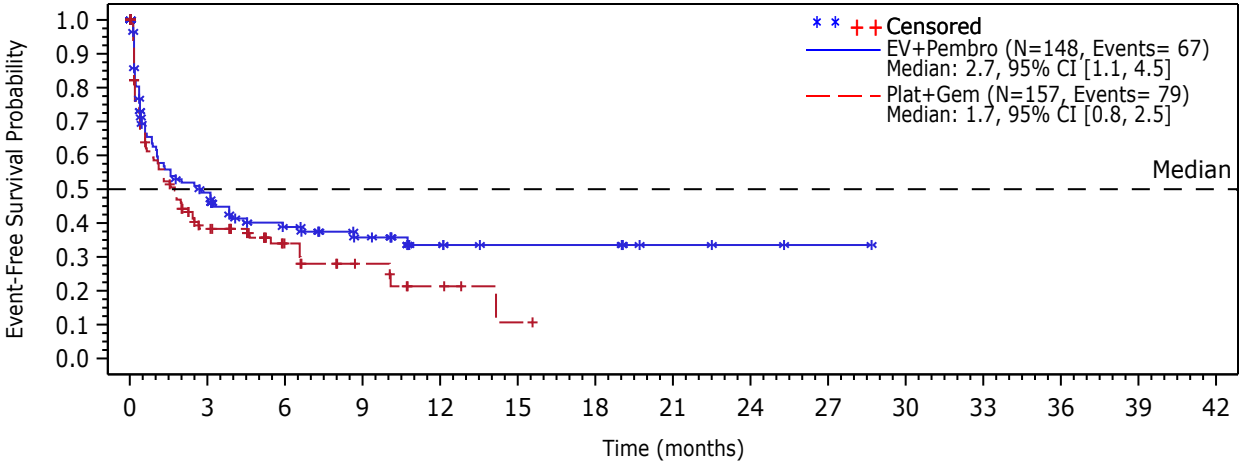
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=2 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.4.2.1: BPI-SF - Kaplan-Meier Plot of Time to first Deterioration of Worst Pain in the last 24 hours (MID=2) by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Visceral metastases



at Risk

1	148	49	29	20	10	7	7	3	2	1	0	0	0	0	0
2	157	37	17	9	4	1	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BPI-SF=Brief Pain Inventory - Short Form; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

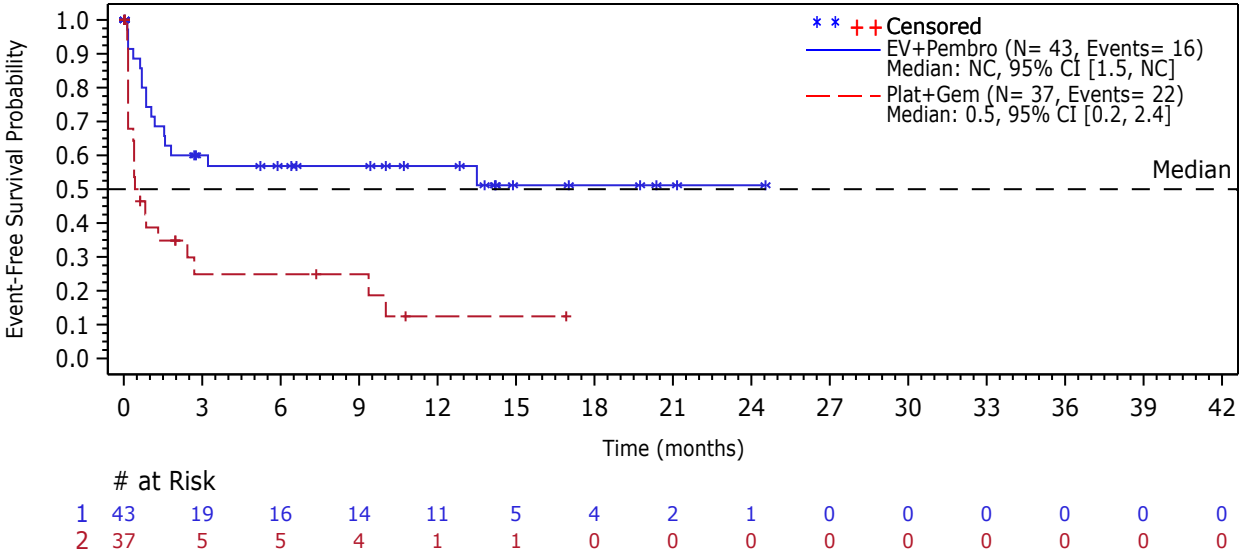
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=2 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.4.2.1: BPI-SF - Kaplan-Meier Plot of Time to first Deterioration of Worst Pain in the last 24 hours (MID=2) by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Lymph node only



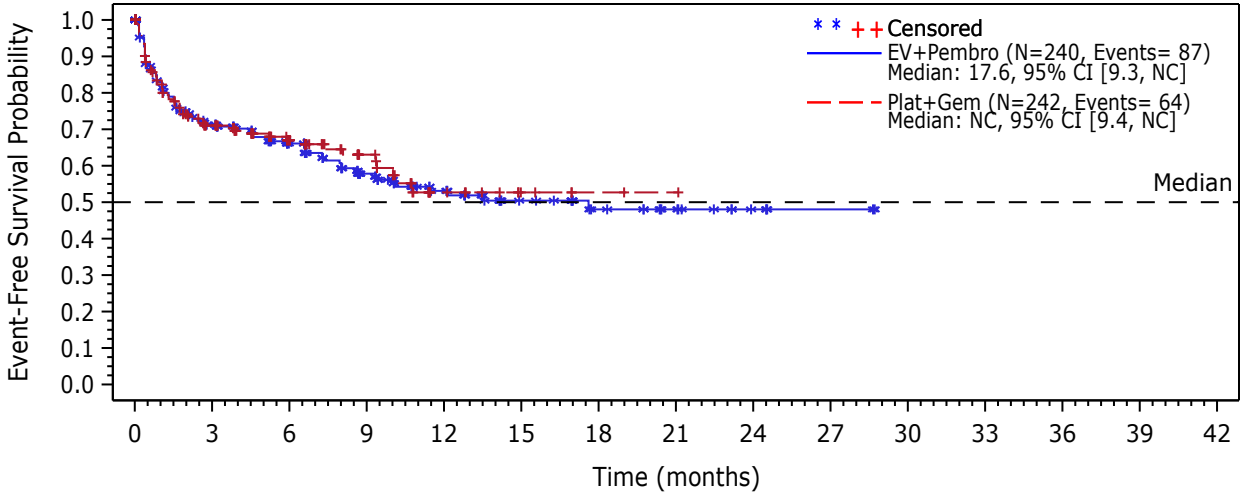
Abbreviations: # at Risk=number of patients at risk; BPI-SF=Brief Pain Inventory - Short Form; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=2 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.5.1: BPI-SF - Kaplan-Meier Plot of Time to first Deterioration of Pain Severity (MID=2) - Analysis Set mITT 1



at Risk

1	240	134	104	70	46	28	18	12	5	2	0	0	0	0	0
2	242	109	64	36	13	5	2	1	0	0	0	0	0	0	0

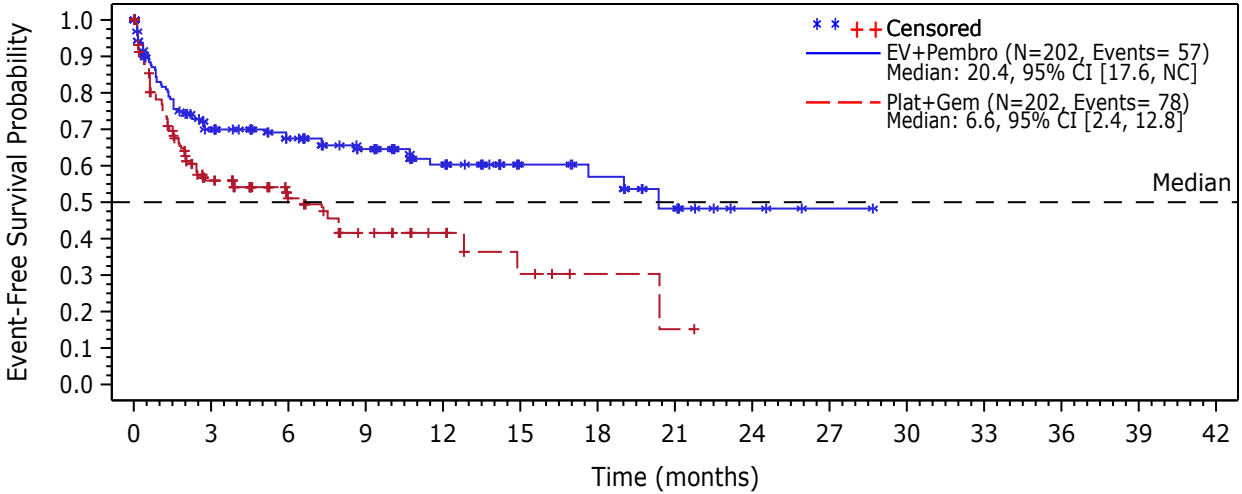
Abbreviations: # at Risk=number of patients at risk; BPI-SF=Brief Pain Inventory - Short Form; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=2 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.5.2: BPI-SF - Kaplan-Meier Plot of Time to first Deterioration of Pain Severity (MID=2) - Analysis Set mITT 2



at Risk

1	202	96	78	60	38	20	17	9	3	1	0	0	0	0	0
2	202	68	31	17	10	5	2	1	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BPI-SF=Brief Pain Inventory - Short Form; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

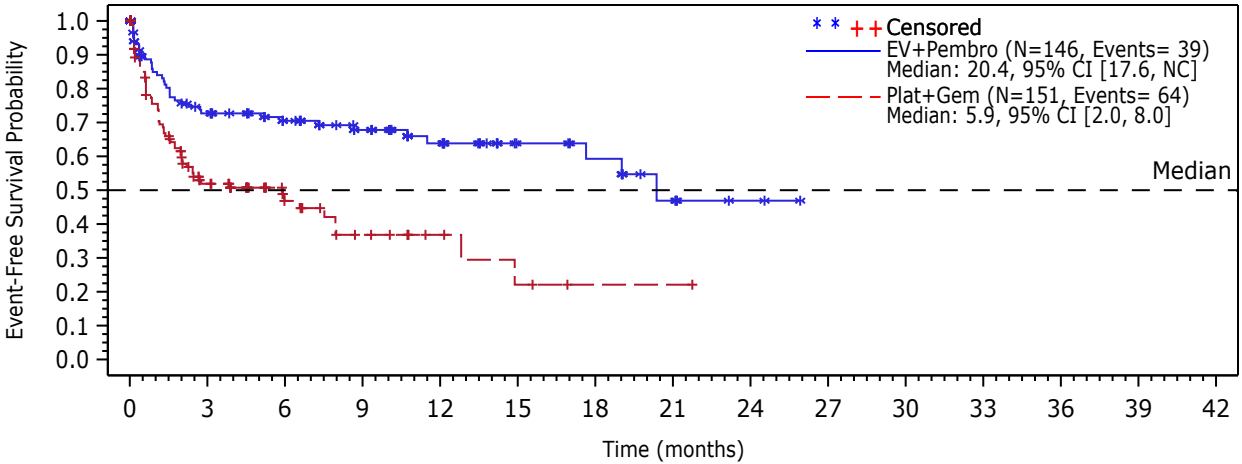
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=2 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.5.2.1: BPI-SF - Kaplan-Meier Plot of Time to first Deterioration of Pain Severity (MID=2) by Sex - Analysis Set mITT 2

Sex: Male



at Risk

1	146	75	60	45	30	16	13	6	2	0	0	0	0	0	0
2	151	49	22	12	6	3	1	1	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BPI-SF=Brief Pain Inventory - Short Form; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

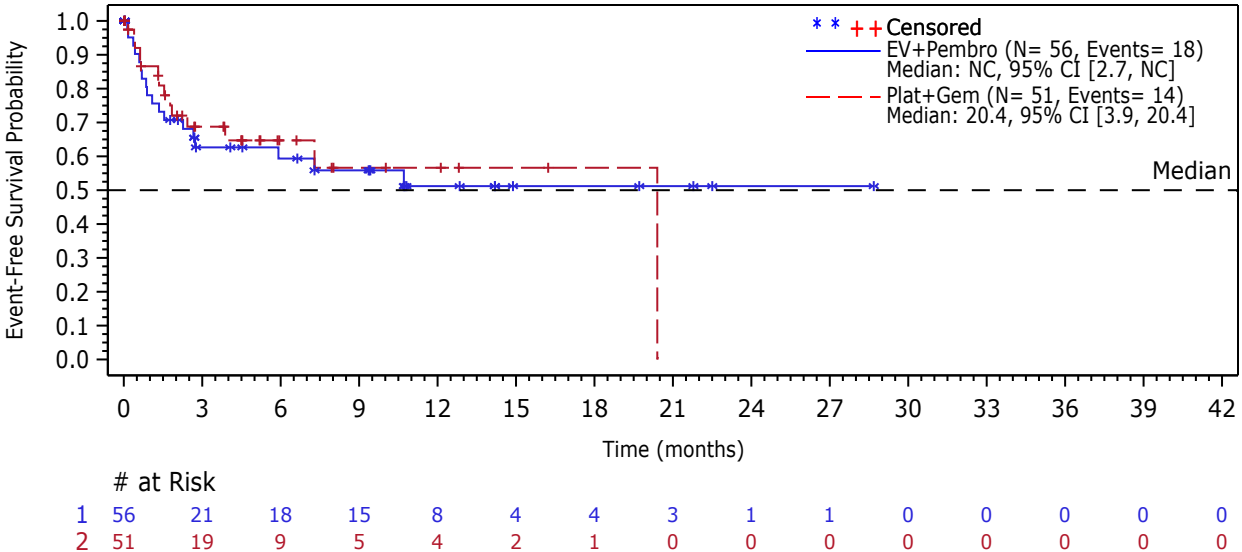
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=2 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.5.2.1: BPI-SF - Kaplan-Meier Plot of Time to first Deterioration of Pain Severity (MID=2) by Sex - Analysis Set mITT 2

Sex: Female



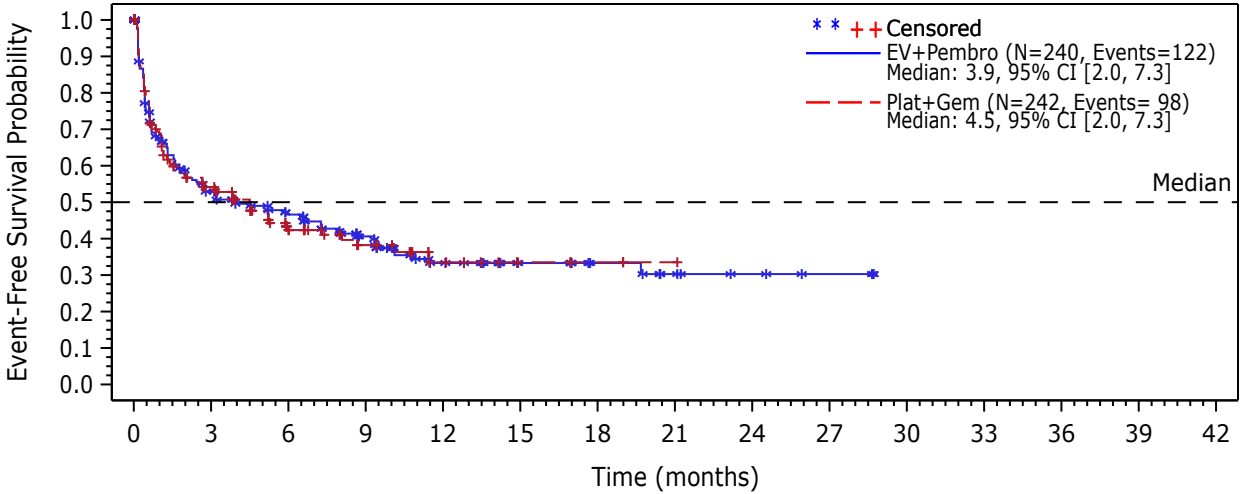
Abbreviations: # at Risk=number of patients at risk; BPI-SF=Brief Pain Inventory - Short Form; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=2 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.6.1: BPI-SF - Kaplan-Meier Plot of Time to first Deterioration of Pain Interference (MID=2) - Analysis Set mITT 1



at Risk

1	240	98	76	52	29	17	11	7	4	2	0	0	0	0	0
2	242	82	42	24	11	5	3	1	0	0	0	0	0	0	0

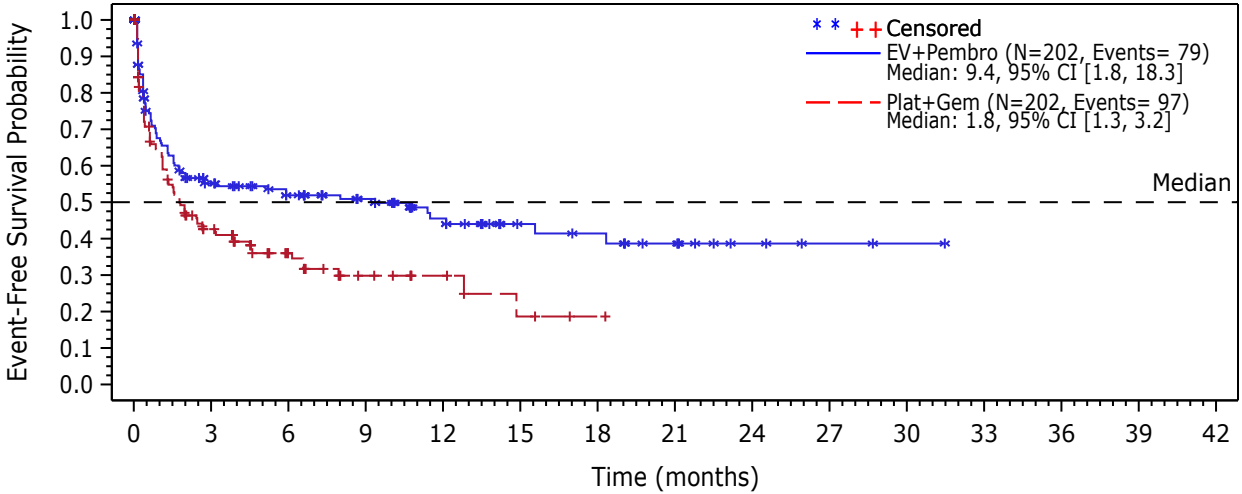
Abbreviations: # at Risk=number of patients at risk; BPI-SF=Brief Pain Inventory - Short Form; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=2 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.6.2: BPI-SF - Kaplan-Meier Plot of Time to first Deterioration of Pain Interference (MID=2) - Analysis Set mITT 2



at Risk

1	202	74	60	47	30	17	15	10	4	2	1	0	0	0	0
2	202	54	25	12	7	3	1	0	0	0	0	0	0	0	0

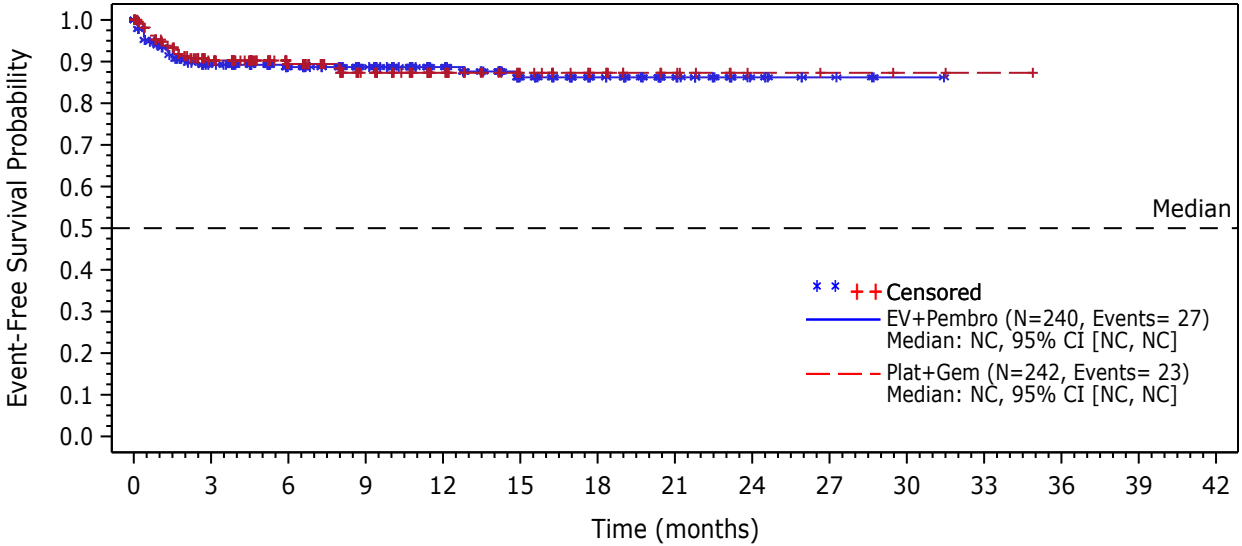
Abbreviations: # at Risk=number of patients at risk; BPI-SF=Brief Pain Inventory - Short Form; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=2 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.7.1: BPI-SF - Kaplan-Meier Plot of Time to Initiation of new Opioid medication for pain (MID=2) - Analysis Set mITT 1



at Risk

1	240	182	156	127	89	56	40	25	9	4	1	0	0	0	0
2	242	162	104	69	44	26	17	10	4	3	2	1	0	0	0

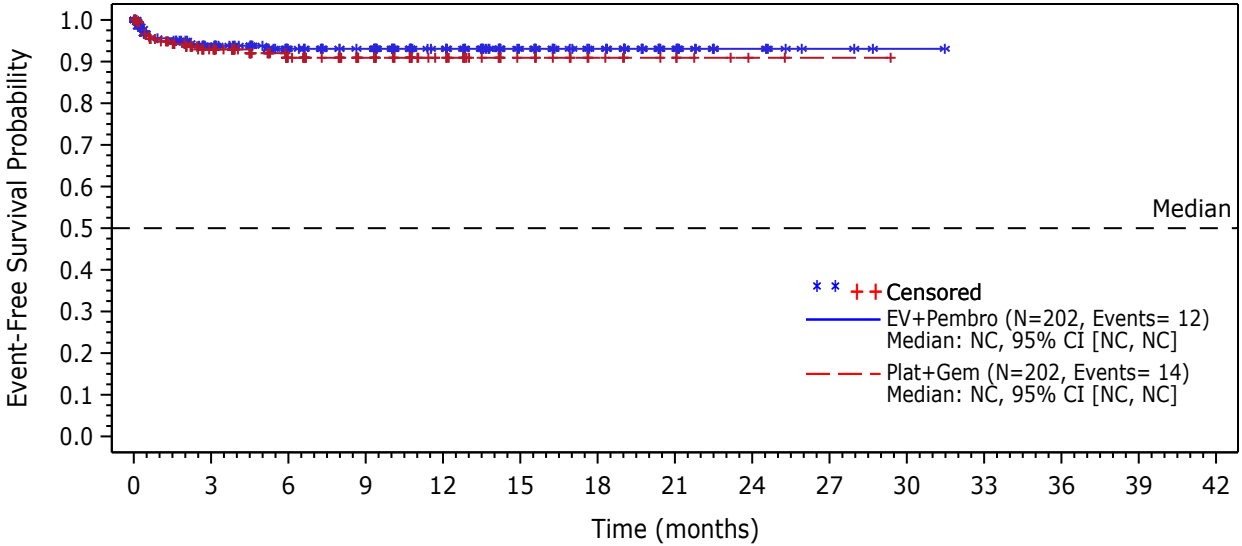
Abbreviations: # at Risk=number of patients at risk; BPI-SF=Brief Pain Inventory - Short Form; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Time to event is defined as time from randomization to the initiation of new opioid medication for pain. Censoring date is the date of last assessment for use of opioid medications for pain.

Patients with no baseline and/or no post-baseline assessments are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.7.2: BPI-SF - Kaplan-Meier Plot of Time to Initiation of new Opioid medication for pain (MID=2) - Analysis Set mITT 2



at Risk

1	202	147	115	103	77	50	36	19	8	3	1	0	0	0	0
2	202	128	77	55	33	18	11	7	2	1	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BPI-SF=Brief Pain Inventory - Short Form; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

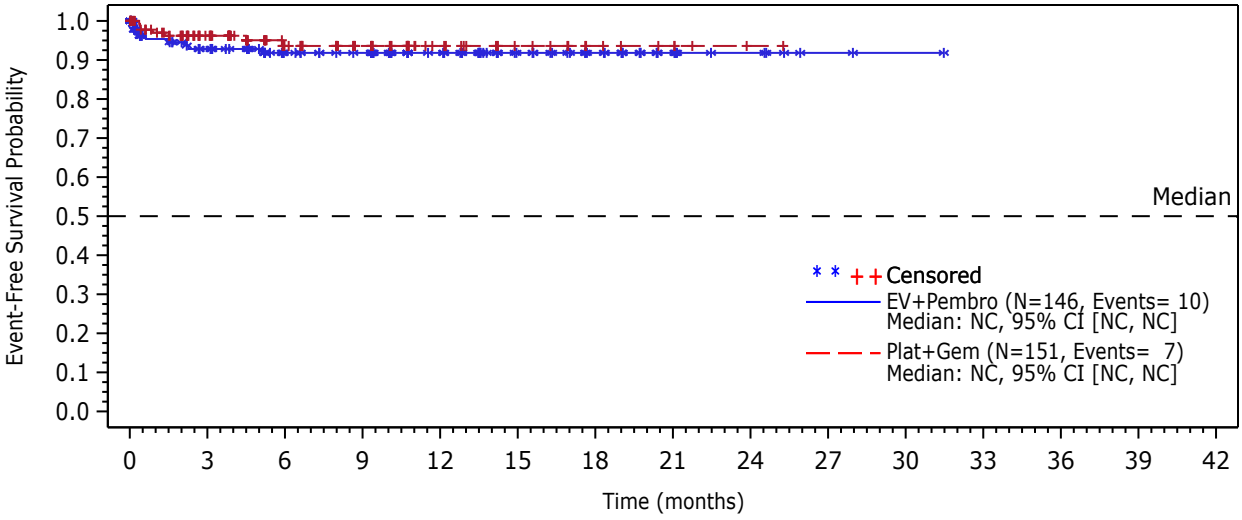
Note: Time to event is defined as time from randomization to the initiation of new opioid medication for pain. Censoring date is the date of last assessment for use of opioid medications for pain.

Patients with no baseline and/or no post-baseline assessments are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.7.2.1: BPI-SF - Kaplan-Meier Plot of Time to Initiation of new Opioid medication for pain (MID=2) by Sex - Analysis Set mITT 2

Sex: Male



at Risk

1	146	104	82	75	55	34	25	12	6	2	1	0	0	0	0
2	151	102	60	43	23	14	8	5	1	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BPI-SF=Brief Pain Inventory - Short Form; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

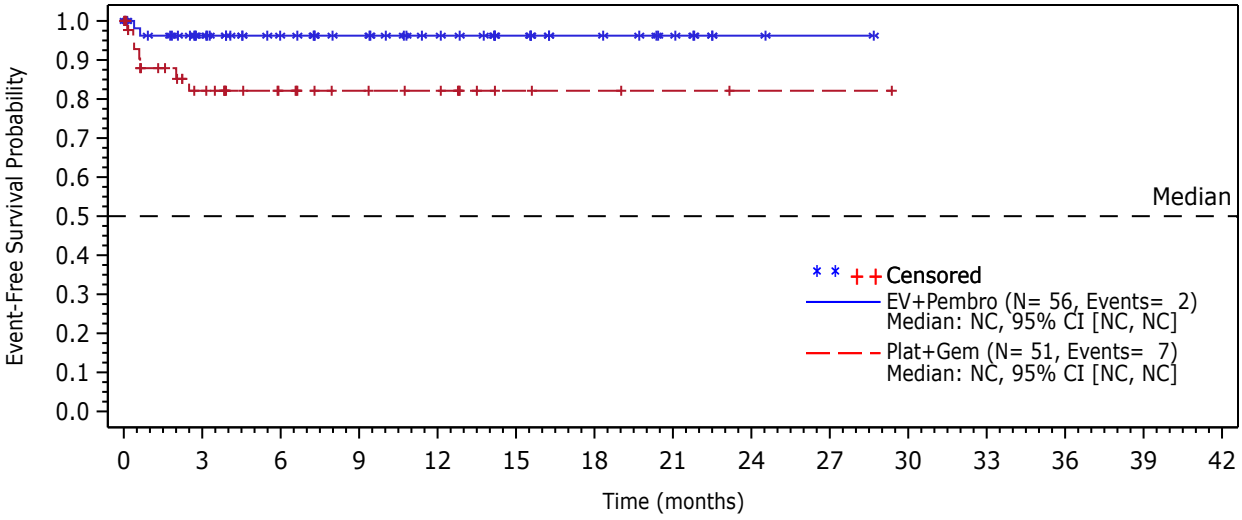
Note: Time to event is defined as time from randomization to the initiation of new opioid medication for pain. Censoring date is the date of last assessment for use of opioid medications for pain.

Patients with no baseline and/or no post-baseline assessments are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.7.2.1: BPI-SF - Kaplan-Meier Plot of Time to Initiation of new Opioid medication for pain (MID=2) by Sex - Analysis Set mITT 2

Sex: Female



at Risk

1	56	43	33	28	22	16	11	7	2	1	0	0	0	0	0
2	51	26	17	12	10	4	3	2	1	1	0	0	0	0	0

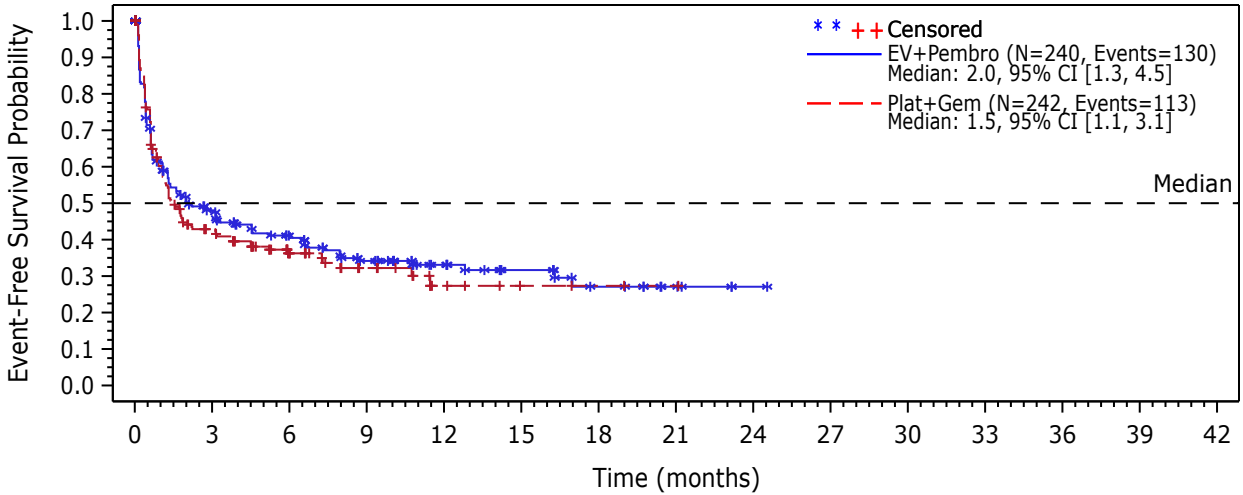
Abbreviations: # at Risk=number of patients at risk; BPI-SF=Brief Pain Inventory - Short Form; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Time to event is defined as time from randomization to the initiation of new opioid medication for pain. Censoring date is the date of last assessment for use of opioid medications for pain.

Patients with no baseline and/or no post-baseline assessments are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.8.1: BPI-SF - Kaplan-Meier Plot of Time to first Deterioration of Composite endpoint (MID=2) - Analysis Set mITT 1



at Risk

1	240	88	64	43	26	17	10	5	1	0	0	0	0	0	0
2	242	65	34	18	7	3	2	1	0	0	0	0	0	0	0

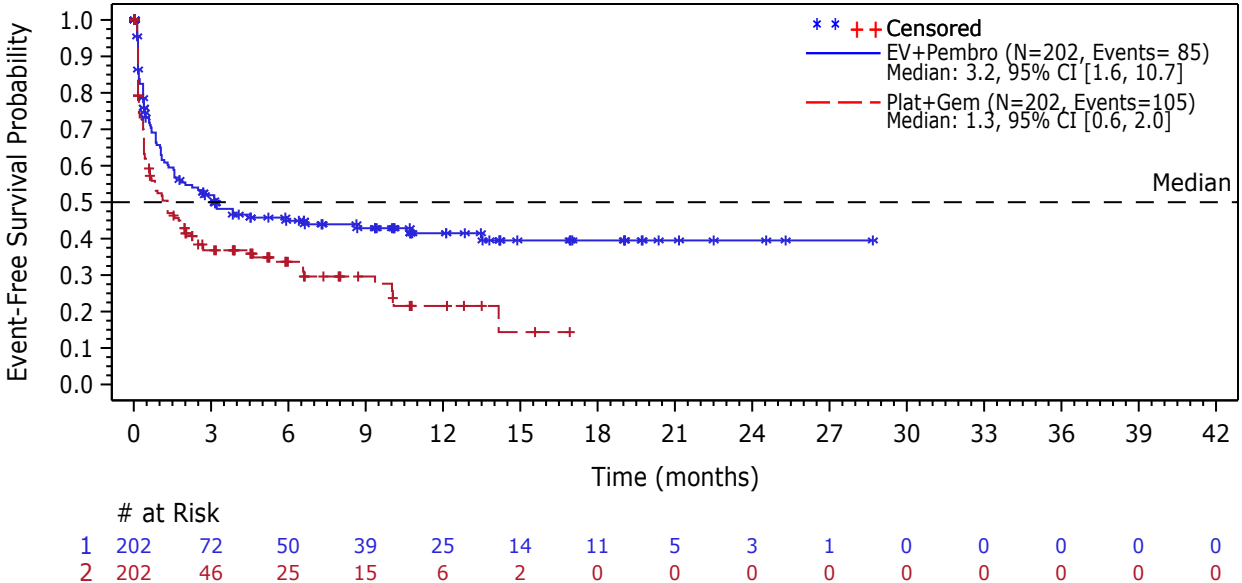
Abbreviations: # at Risk=number of patients at risk; BPI-SF=Brief Pain Inventory - Short Form; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=2 point increase or initiation of new opioid medication for pain before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.8.2: BPI-SF - Kaplan-Meier Plot of Time to first Deterioration of Composite endpoint (MID=2) - Analysis Set mITT 2



at Risk

1	202	72	50	39	25	14	11	5	3	1	0	0	0	0	0
2	202	46	25	15	6	2	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BPI-SF=Brief Pain Inventory - Short Form; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

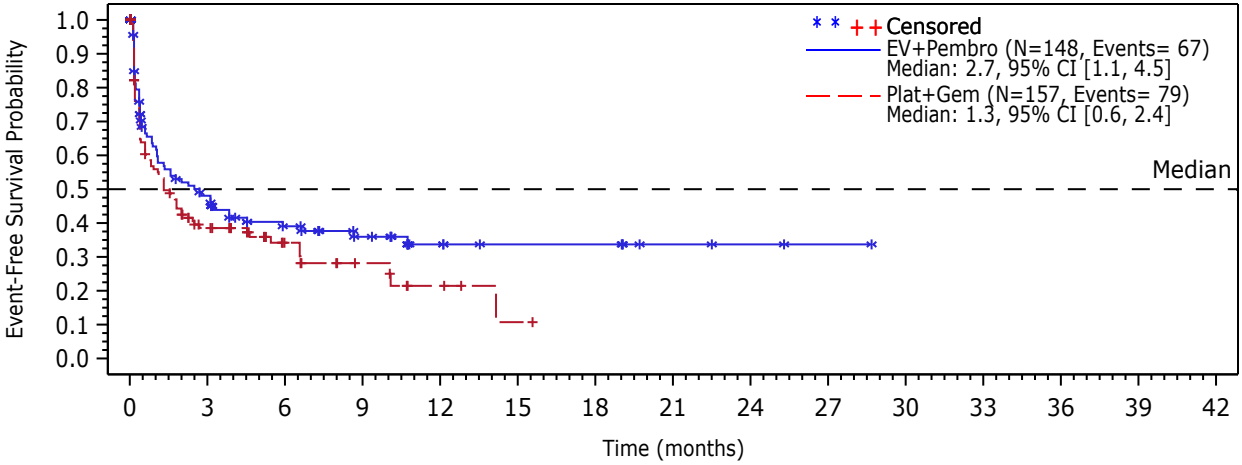
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=2 point increase or initiation of new opioid medication for pain before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.8.2.1: BPI-SF - Kaplan-Meier Plot of Time to first Deterioration of Composite endpoint (MID=2) by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Visceral metastases



at Risk

1	148	48	29	20	10	7	7	3	2	1	0	0	0	0	0
2	157	37	17	9	4	1	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; BPI-SF=Brief Pain Inventory - Short Form; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

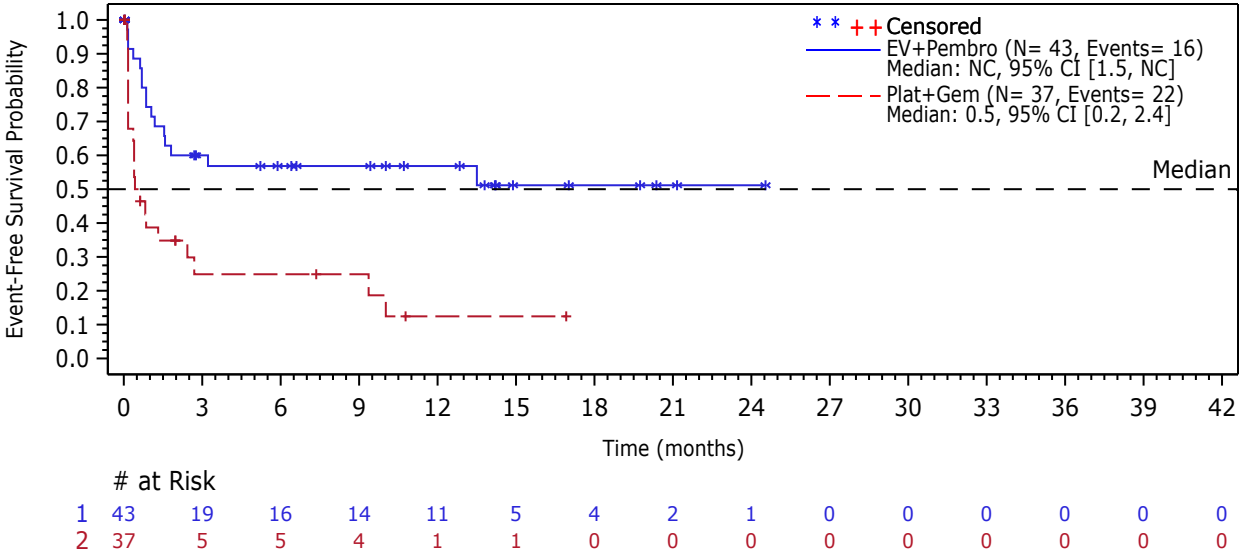
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=2 point increase or initiation of new opioid medication for pain before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.8.2.1: BPI-SF - Kaplan-Meier Plot of Time to first Deterioration of Composite endpoint (MID=2) by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Lymph node only



at Risk

1	43	19	16	14	11	5	4	2	1	0	0	0	0	0	0
2	37	5	5	4	1	1	0	0	0	0	0	0	0	0	0

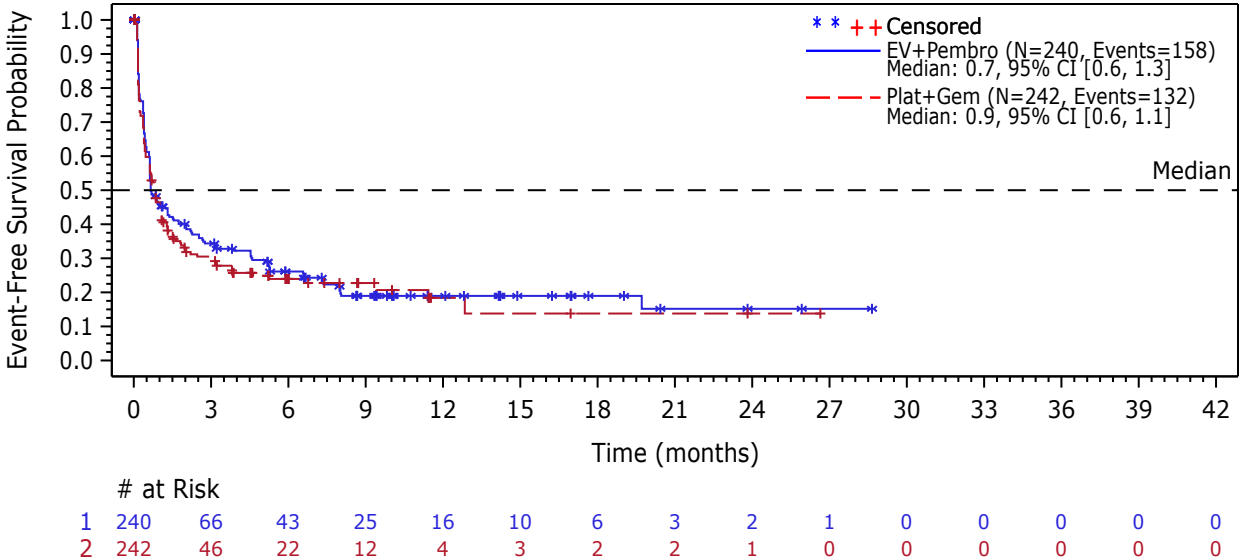
Abbreviations: # at Risk=number of patients at risk; BPI-SF=Brief Pain Inventory - Short Form; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=2 point increase or initiation of new opioid medication for pain before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.9.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Global Health Status/QoL (MID=10) - Analysis Set mITT 1



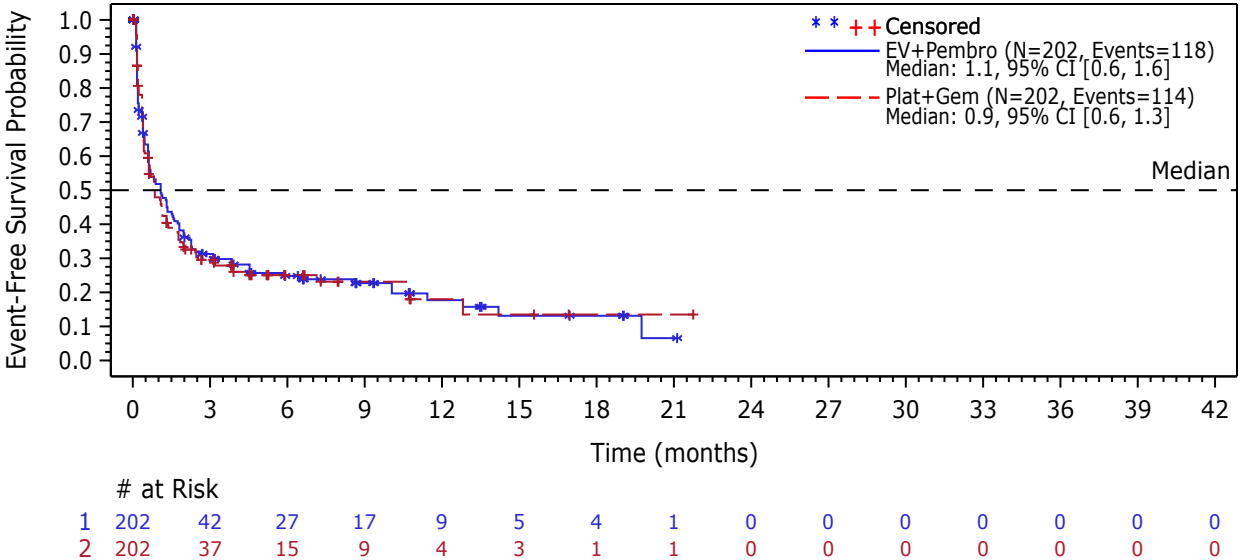
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.9.2: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Global Health Status/QoL (MID=10) - Analysis Set mITT 2



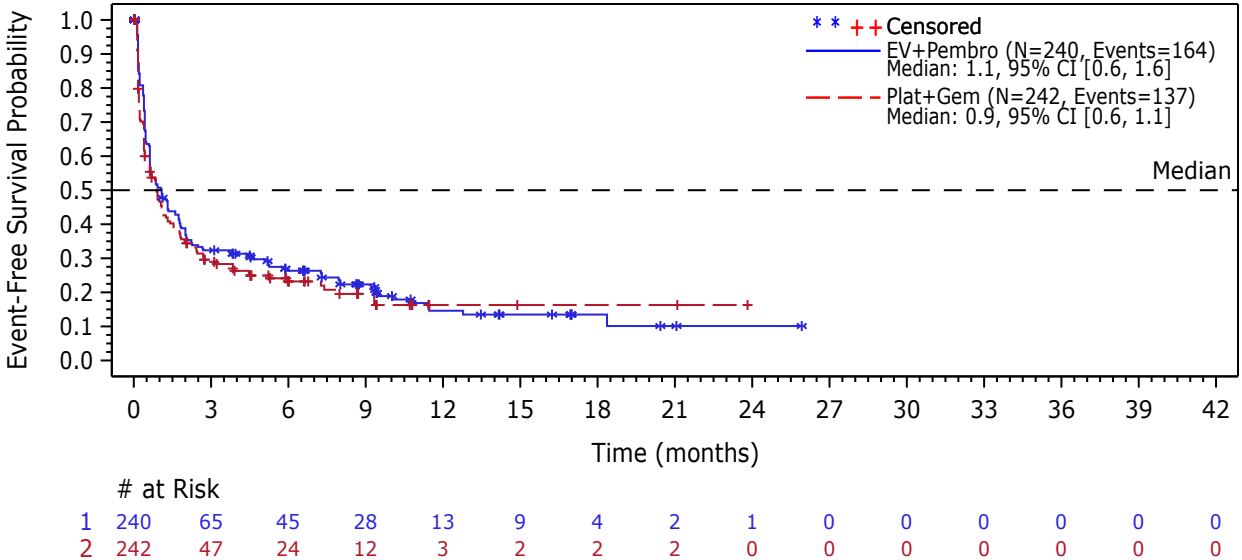
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; QoL=quality of life.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.10.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Physical Functioning (MID=10) - Analysis Set mITT 1



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

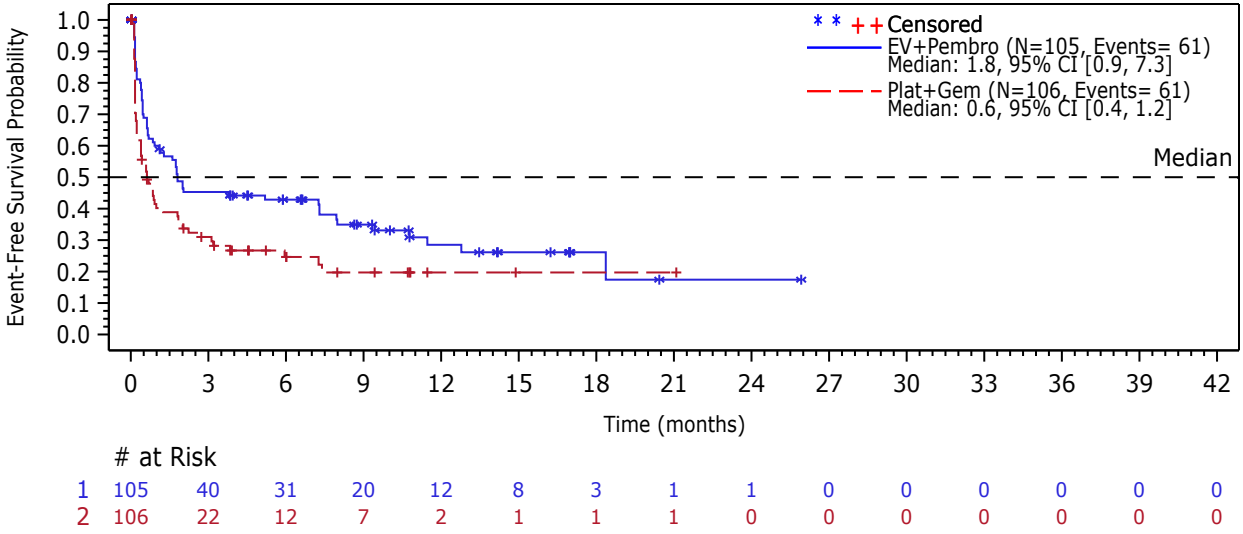
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.10.1.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Physical Functioning (MID=10) by Age - Analysis Set mITT 1

Age: < 65 years



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

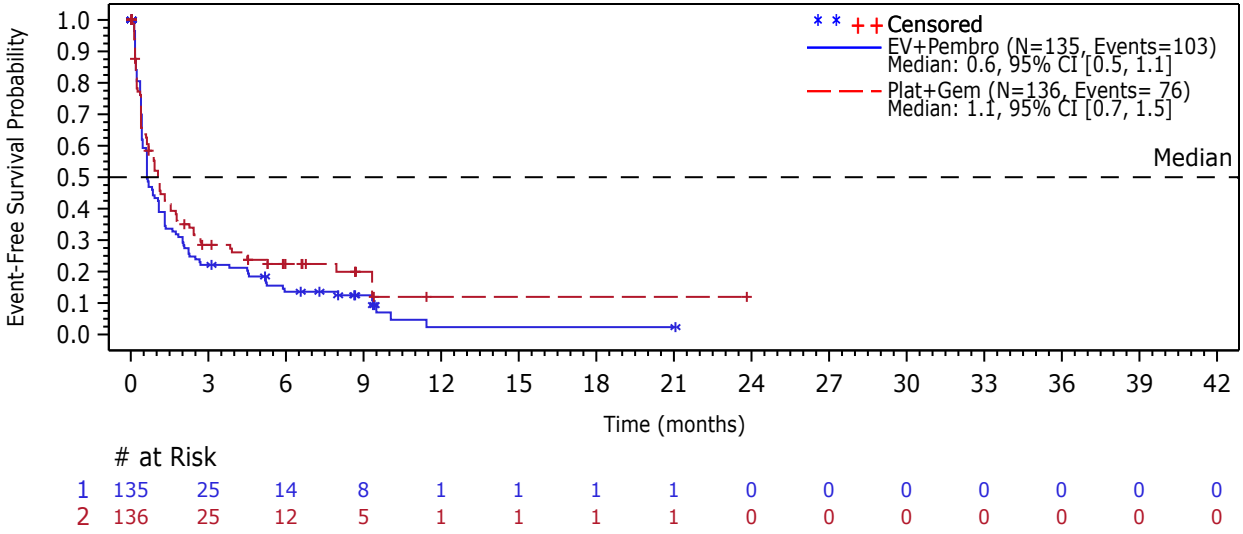
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.10.1.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Physical Functioning (MID=10) by Age - Analysis Set mITT 1

Age: >= 65 years



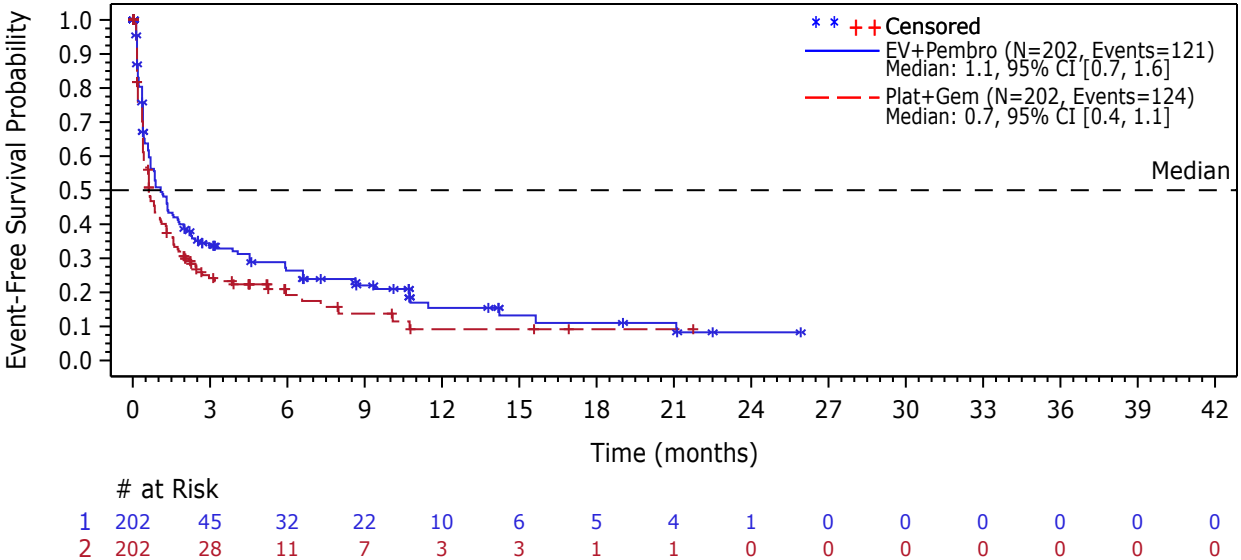
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.10.2: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Physical Functioning (MID=10) - Analysis Set mITT 2



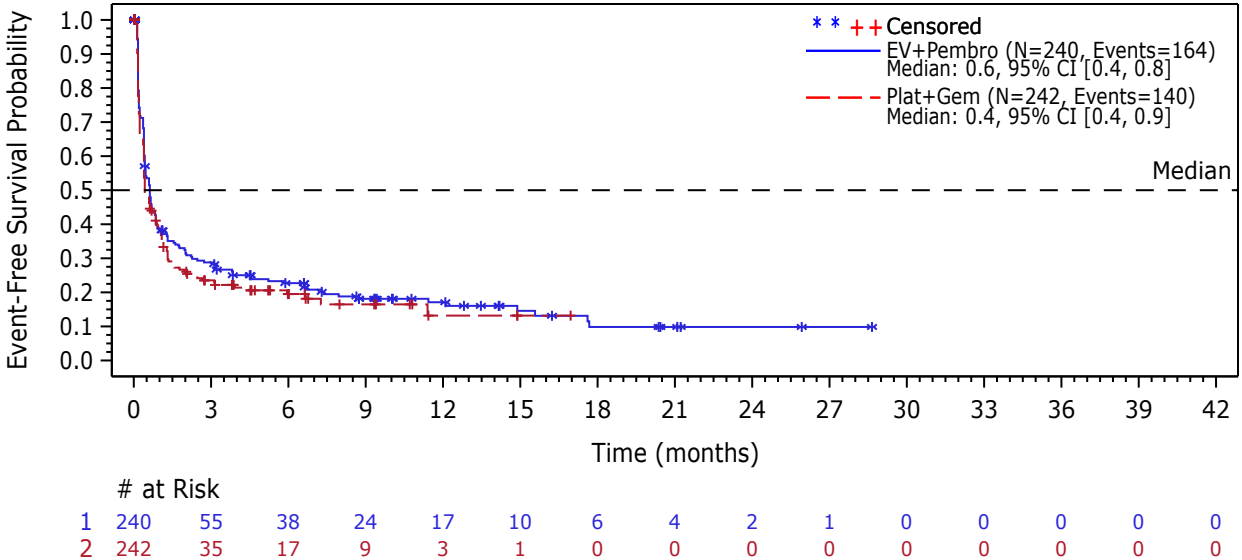
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.11.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Role Functioning (MID=10) - Analysis Set mITT 1



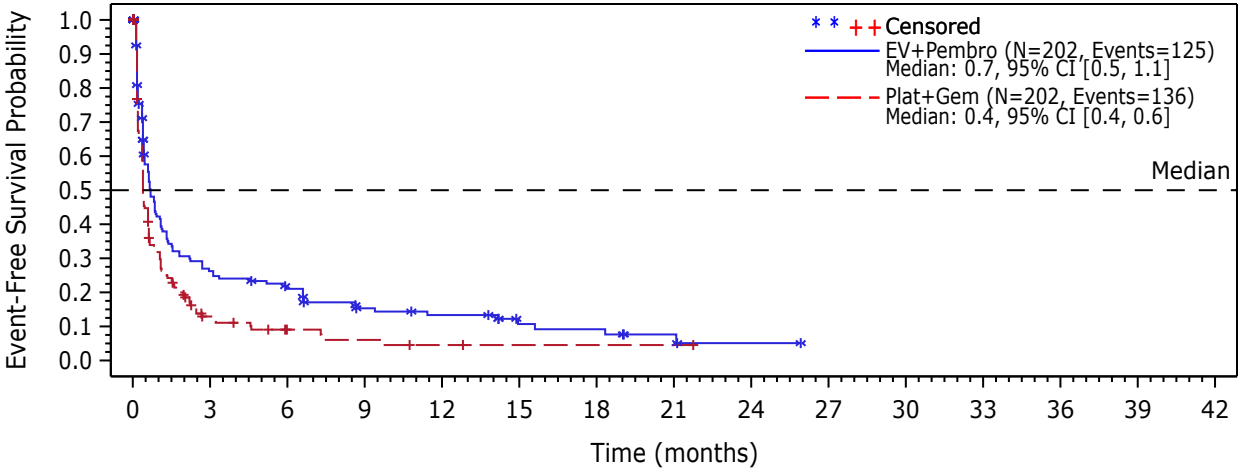
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.11.2: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Role Functioning (MID=10) - Analysis Set mITT 2



at Risk

1	202	36	27	16	13	7	6	3	1	0	0	0	0	0	0
2	202	14	6	4	2	1	1	1	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

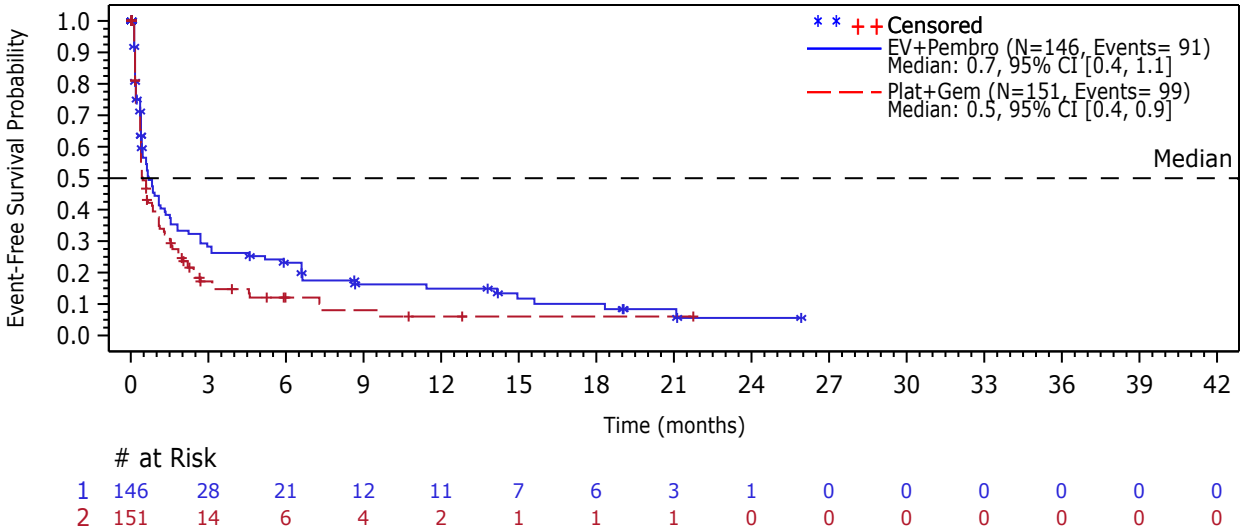
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.11.2.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Role Functioning (MID=10) by Sex - Analysis Set mITT 2

Sex: Male



at Risk

1	146	28	21	12	11	7	6	3	1	0	0	0	0	0	0
2	151	14	6	4	2	1	1	1	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

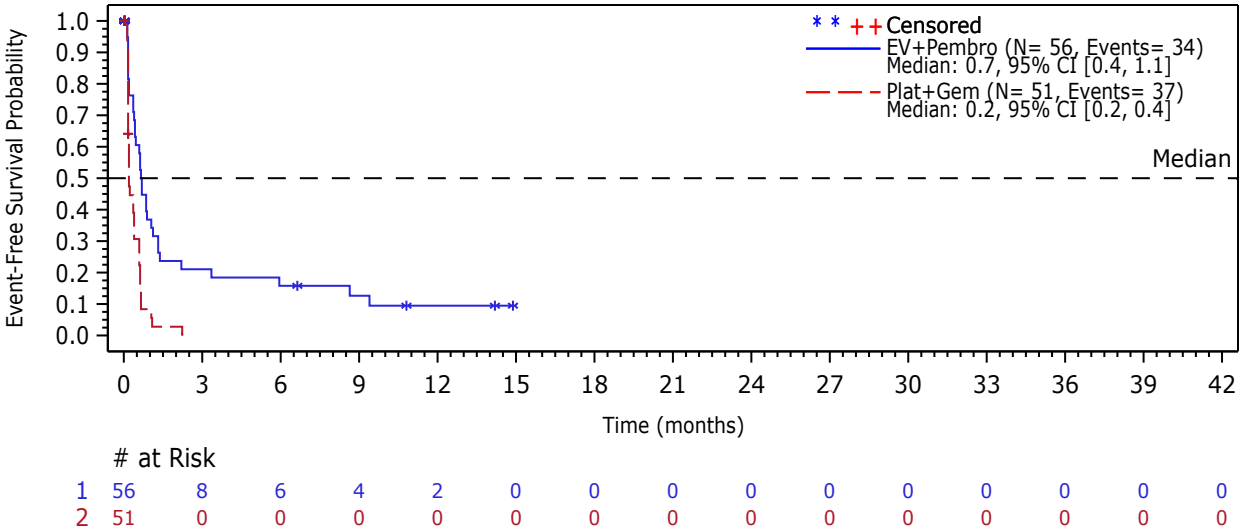
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.11.2.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Role Functioning (MID=10) by Sex - Analysis Set mITT 2

Sex: Female



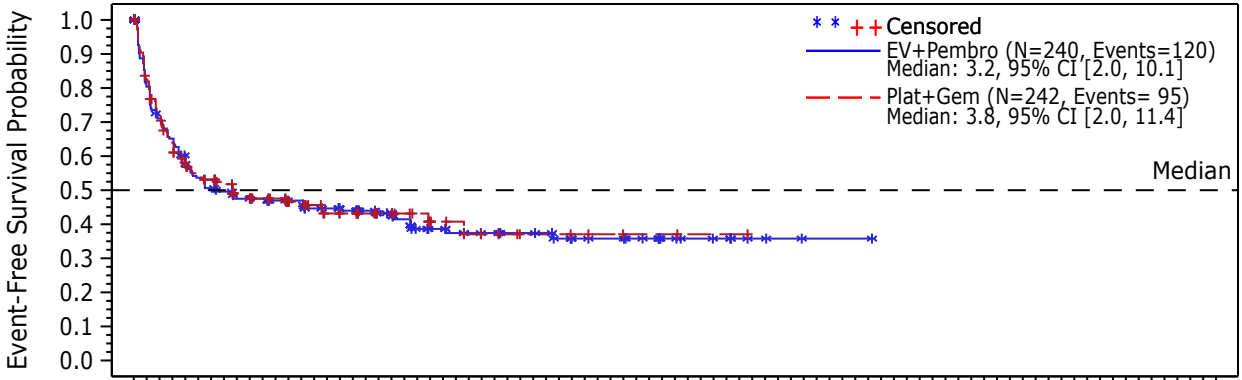
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.12.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Emotional Functioning (MID=10) - Analysis Set mITT 1



at Risk

1	240	100	82	59	34	25	17	10	3	1	0	0	0	0	0
2	242	83	48	25	12	5	3	2	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

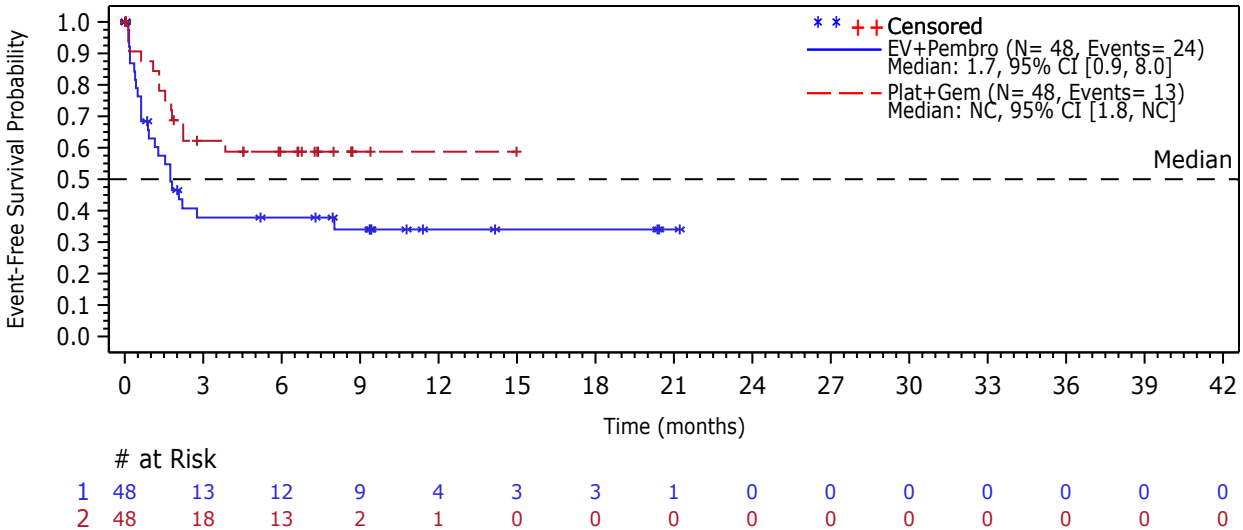
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.12.1.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Emotional Functioning (MID=10) by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Present



at Risk

1	48	13	12	9	4	3	3	1	0	0	0	0	0	0	0
2	48	18	13	2	1	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

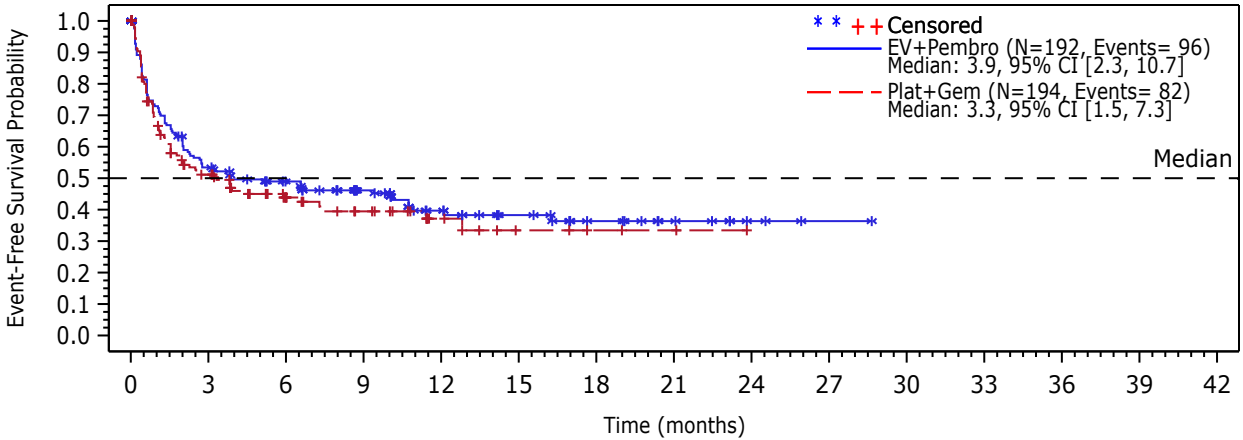
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.12.1.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Emotional Functioning (MID=10) by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Absent



at Risk

1	192	87	70	50	30	22	14	9	3	1	0	0	0	0	0
2	194	65	35	23	11	5	3	2	0	0	0	0	0	0	0

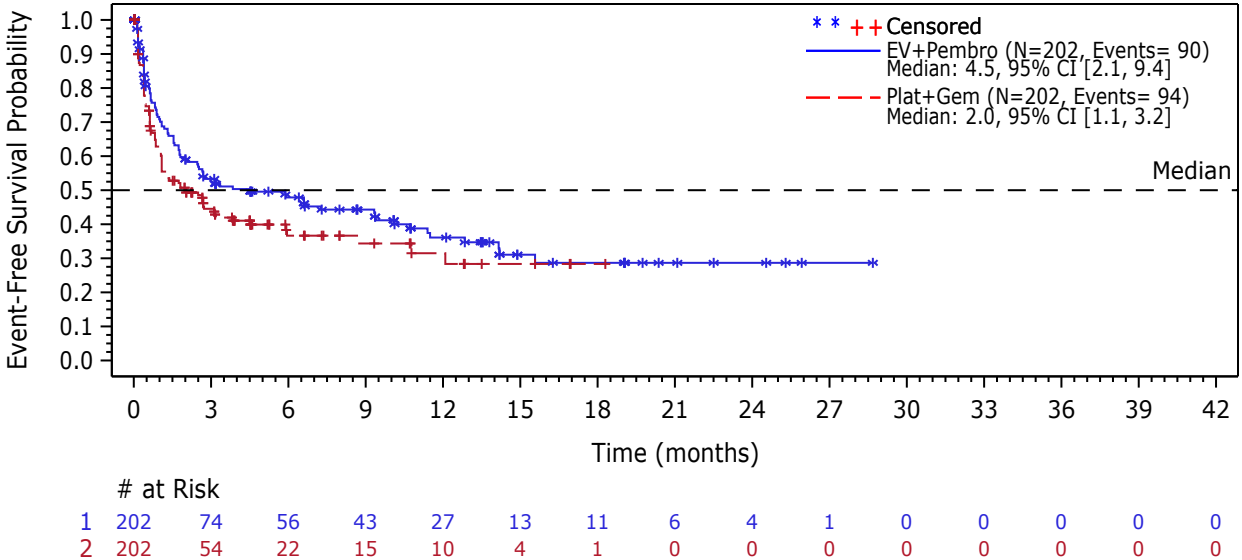
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.12.2: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Emotional Functioning (MID=10) - Analysis Set mITT 2



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

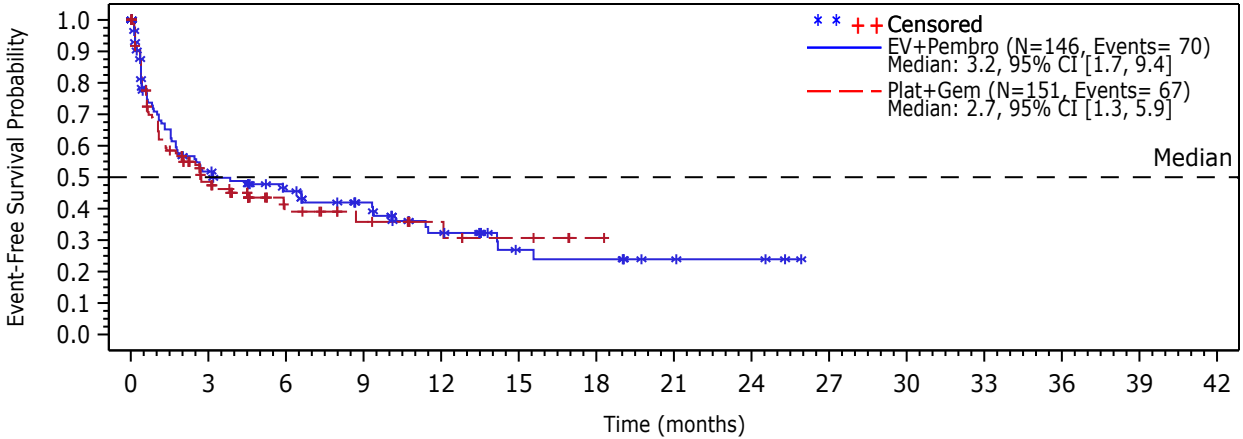
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.12.2.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Emotional Functioning (MID=10) by Sex - Analysis Set mITT 2

Sex: Male



at Risk

1	146	53	40	30	17	9	8	4	3	0	0	0	0	0	0
2	151	44	17	11	7	4	1	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

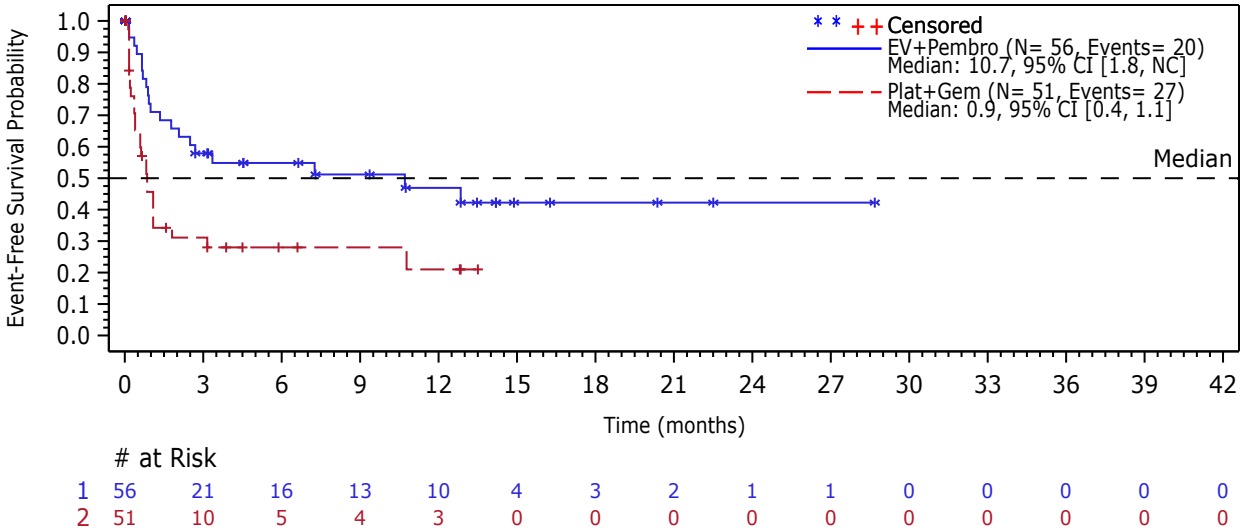
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.12.2.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Emotional Functioning (MID=10) by Sex - Analysis Set mITT 2

Sex: Female



at Risk

1	56	21	16	13	10	4	3	2	1	1	0	0	0	0	0
2	51	10	5	4	3	0	0	0	0	0	0	0	0	0	0

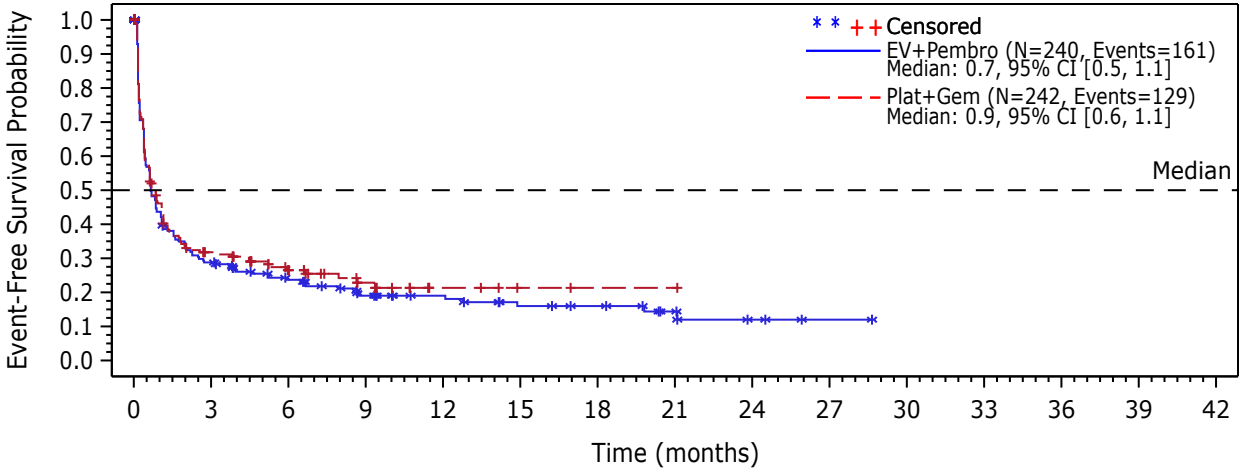
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.13.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Social Functioning (MID=10) - Analysis Set mITT 1



at Risk

1	240	56	39	26	20	14	12	7	3	1	0	0	0	0	0
2	242	49	29	15	5	2	1	1	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

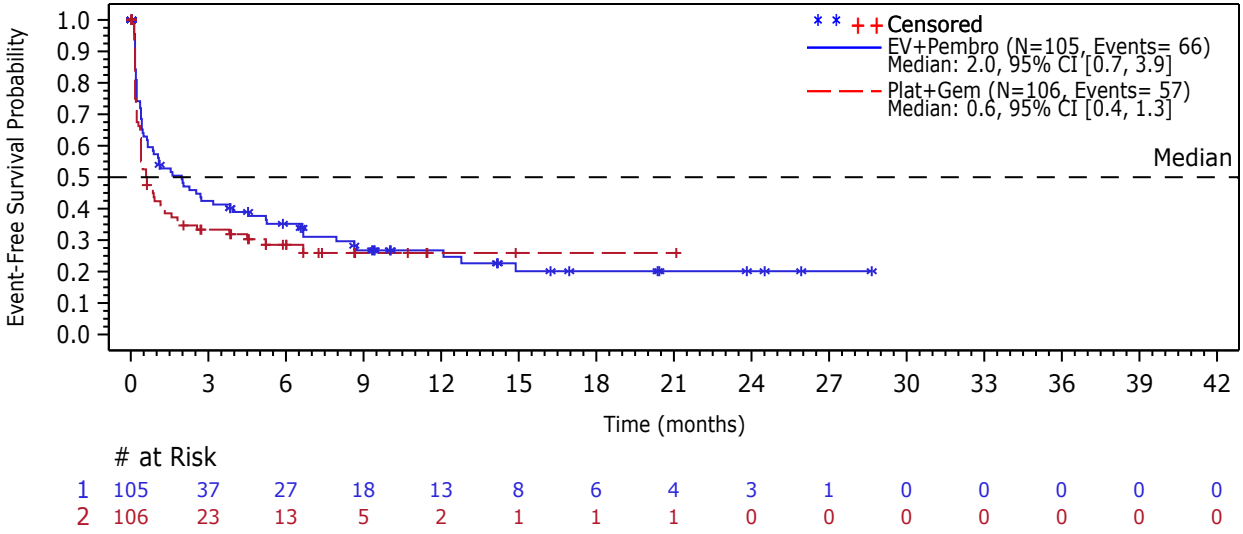
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.13.1.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Social Functioning (MID=10) by Age - Analysis Set mITT 1

Age: < 65 years



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

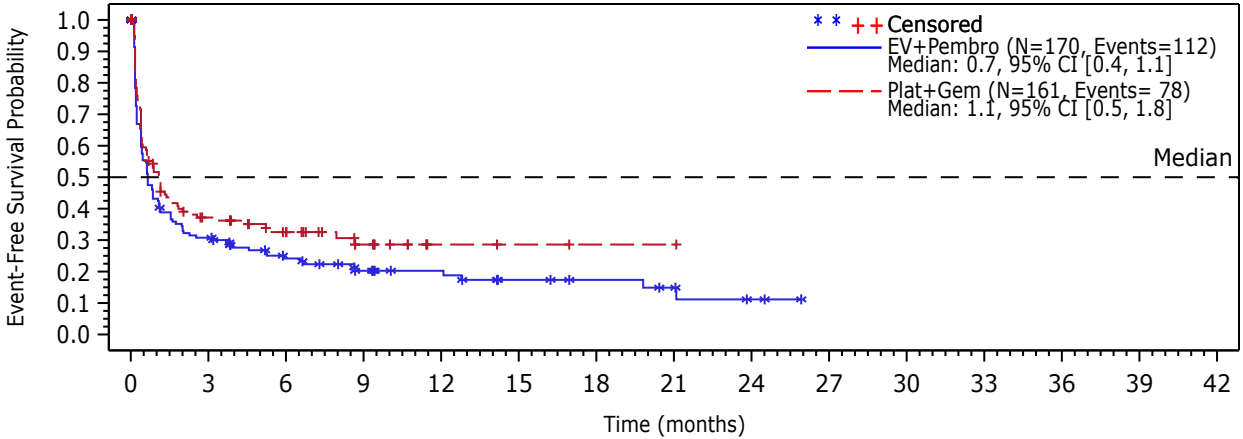
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.13.1.2: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Social Functioning (MID=10) by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Visceral metastases



at Risk

1	170	42	27	18	14	9	7	5	2	0	0	0	0	0	0
2	161	38	24	12	3	2	1	1	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

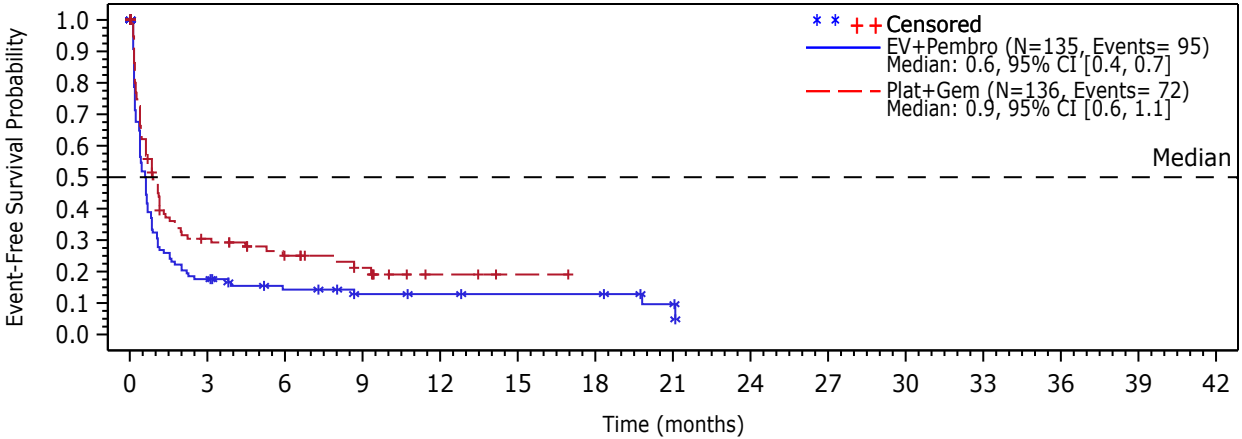
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.13.1.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Social Functioning (MID=10) by Age - Analysis Set mITT 1

Age: >= 65 years



at Risk

1	135	19	12	8	7	6	6	3	0	0	0	0	0	0	0
2	136	26	16	10	3	1	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

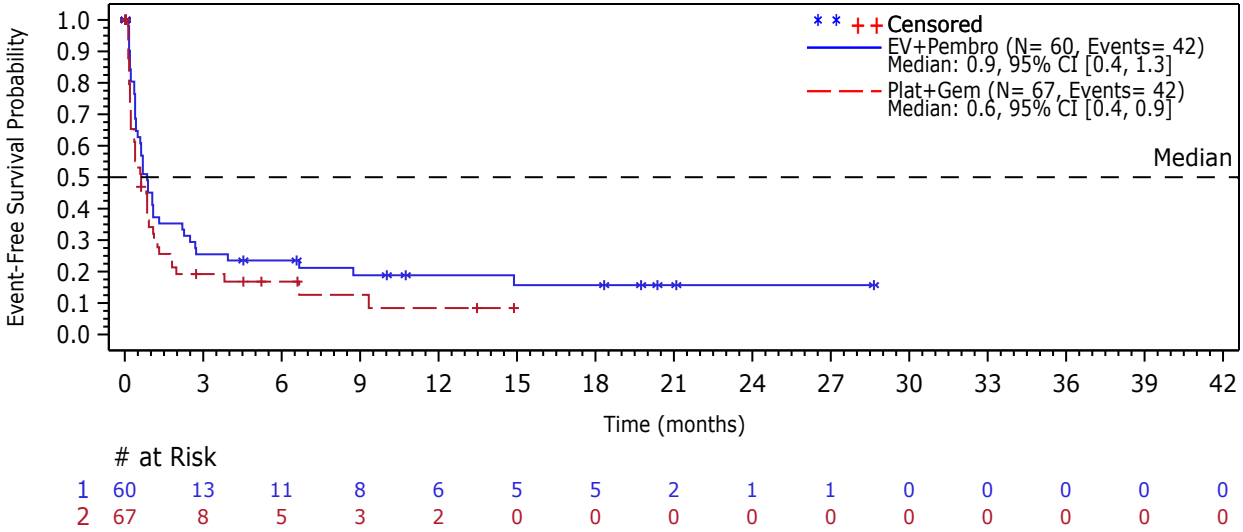
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.13.1.2: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Social Functioning (MID=10) by Metastases at Baseline - Analysis Set mITT 1

Metastases at Baseline: Lymph node only



at Risk

1	60	13	11	8	6	5	5	2	1	1	0	0	0	0	0
2	67	8	5	3	2	0	0	0	0	0	0	0	0	0	0

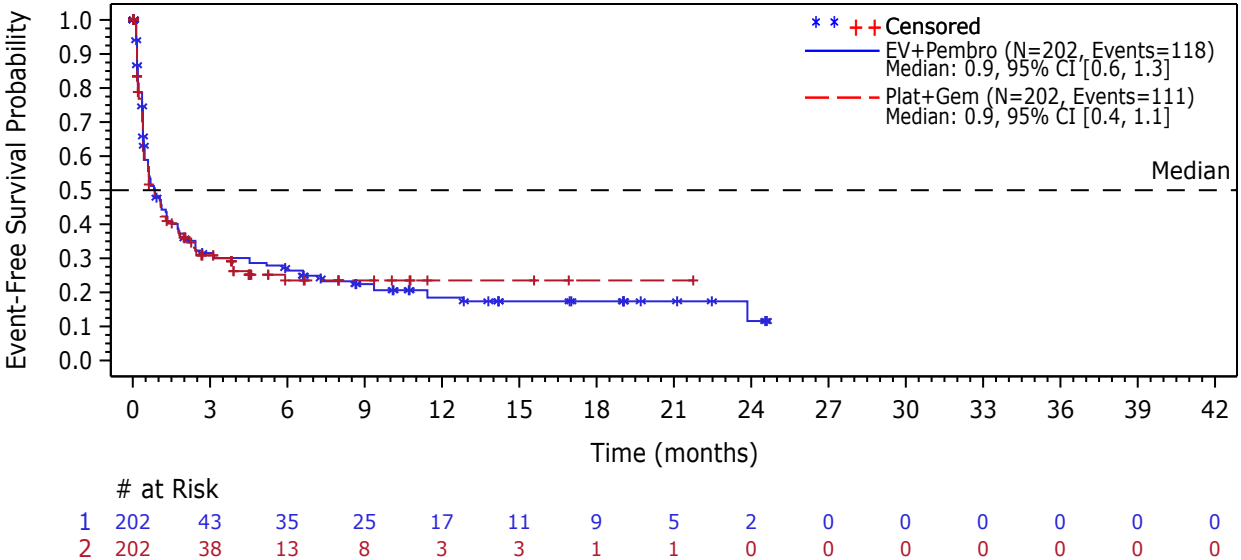
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.13.2: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Social Functioning (MID=10) - Analysis Set mITT 2



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

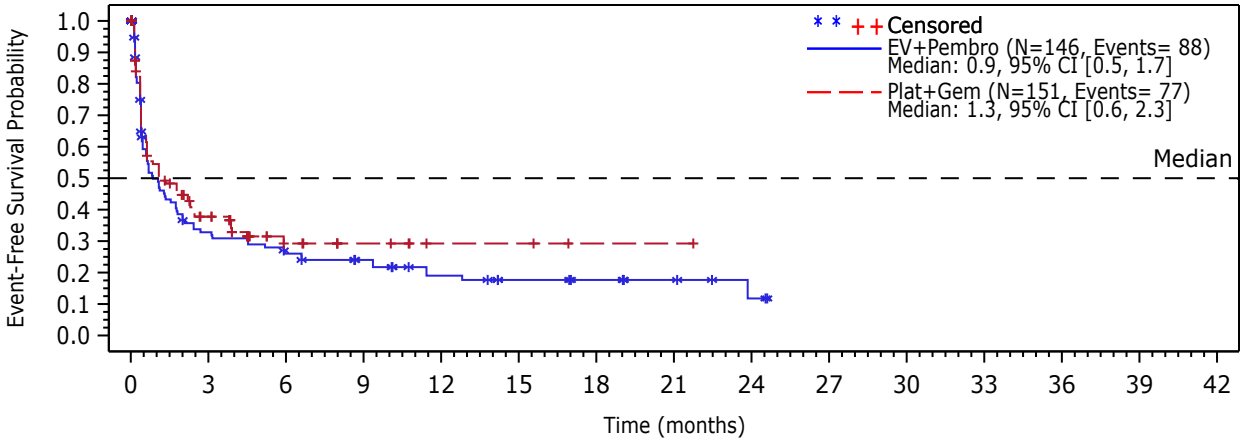
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.13.2.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Social Functioning (MID=10) by Sex - Analysis Set mITT 2

Sex: Male



at Risk

1	146	34	26	21	14	10	8	5	2	0	0	0	0	0	0
2	151	36	12	7	3	3	1	1	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

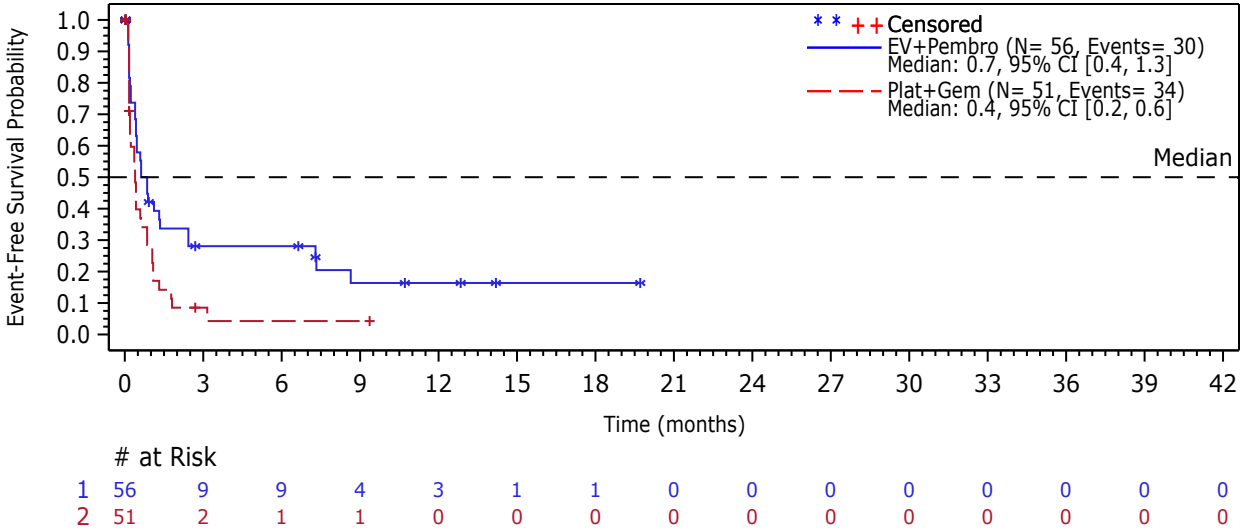
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.13.2.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Social Functioning (MID=10) by Sex - Analysis Set mITT 2

Sex: Female



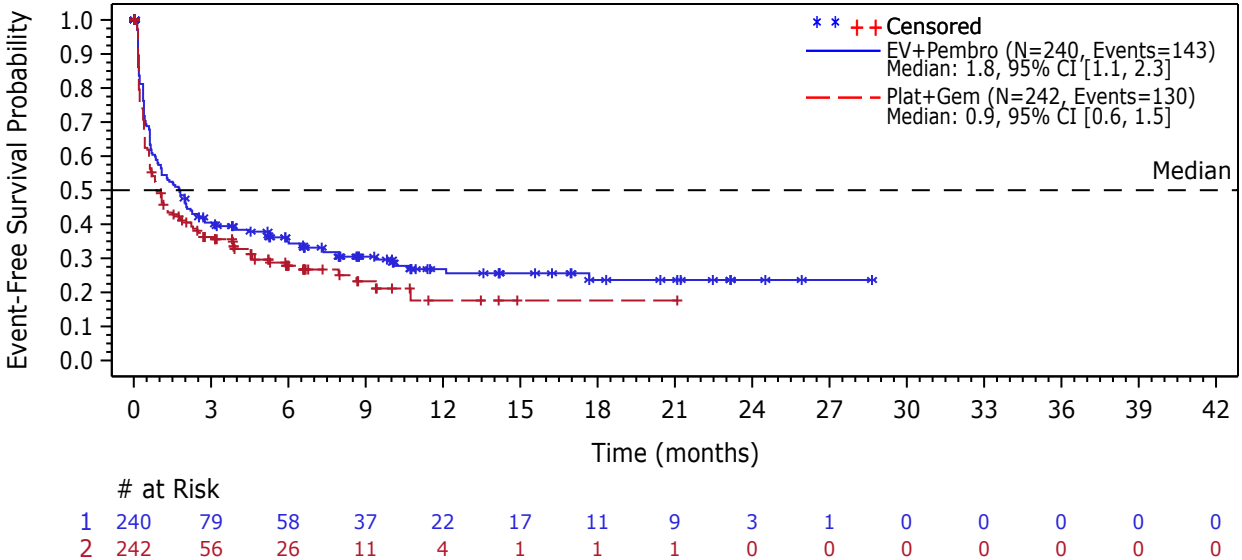
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.14.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Cognitive Functioning (MID=10) - Analysis Set mITT 1



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

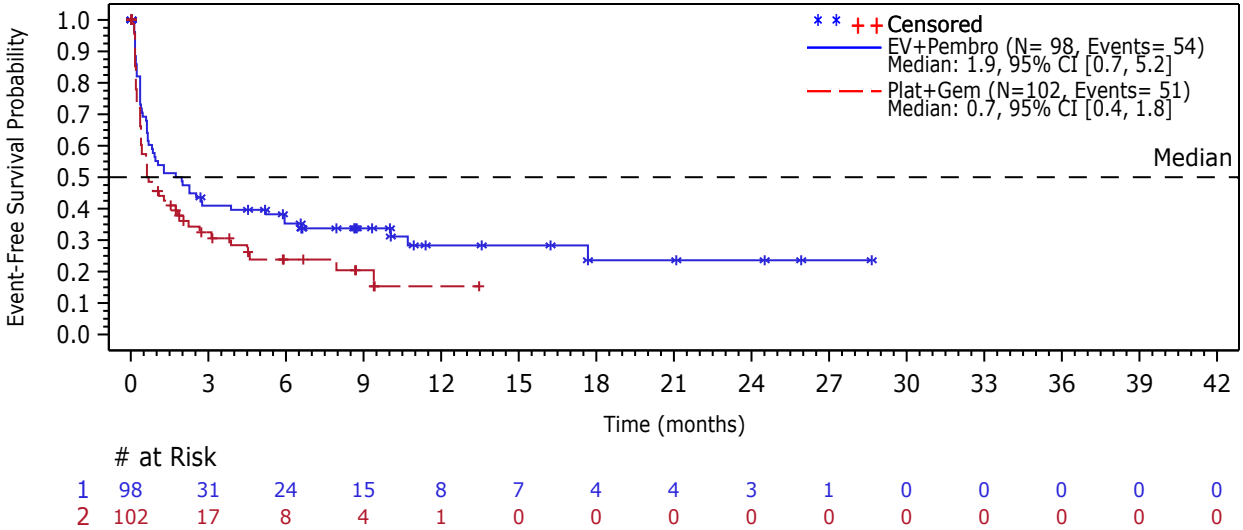
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.14.1.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Cognitive Functioning (MID=10) by Region - Analysis Set mITT 1

Region: Europe



at Risk

1	98	31	24	15	8	7	4	4	3	1	0	0	0	0	0
2	102	17	8	4	1	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

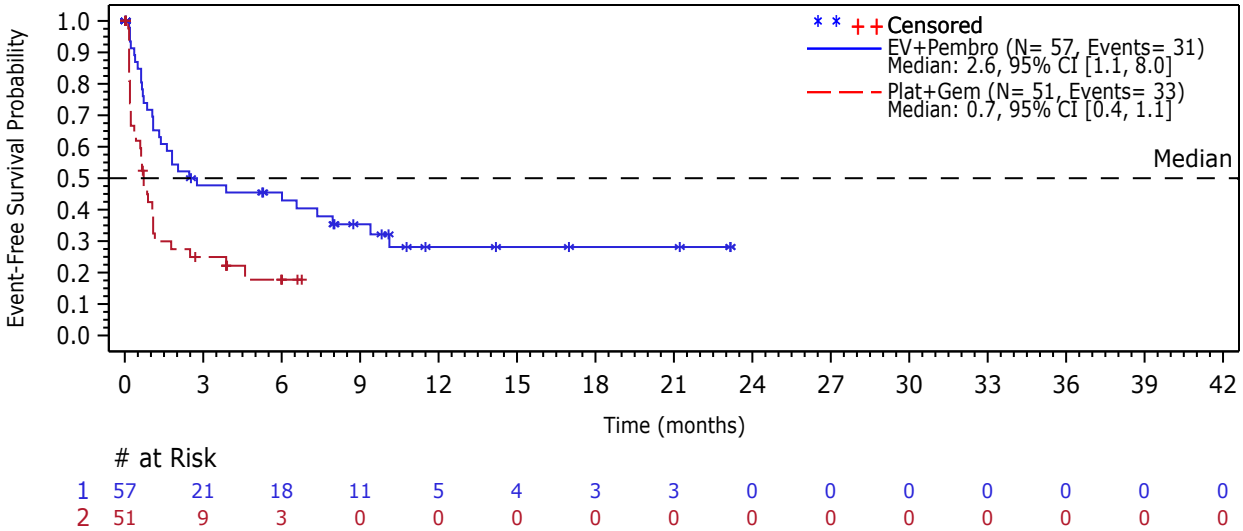
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.14.1.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Cognitive Functioning (MID=10) by Region - Analysis Set mITT 1

Region: North America



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

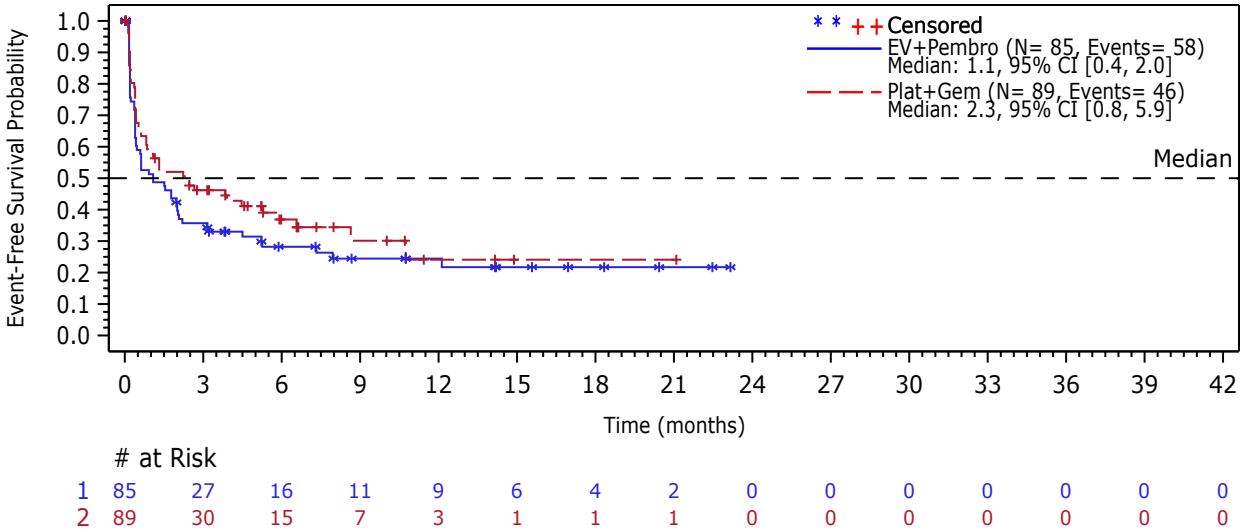
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.14.1.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Cognitive Functioning (MID=10) by Region - Analysis Set mITT 1

Region: Rest of World



at Risk

1	85	27	16	11	9	6	4	2	0	0	0	0	0	0	0
2	89	30	15	7	3	1	1	1	0	0	0	0	0	0	0

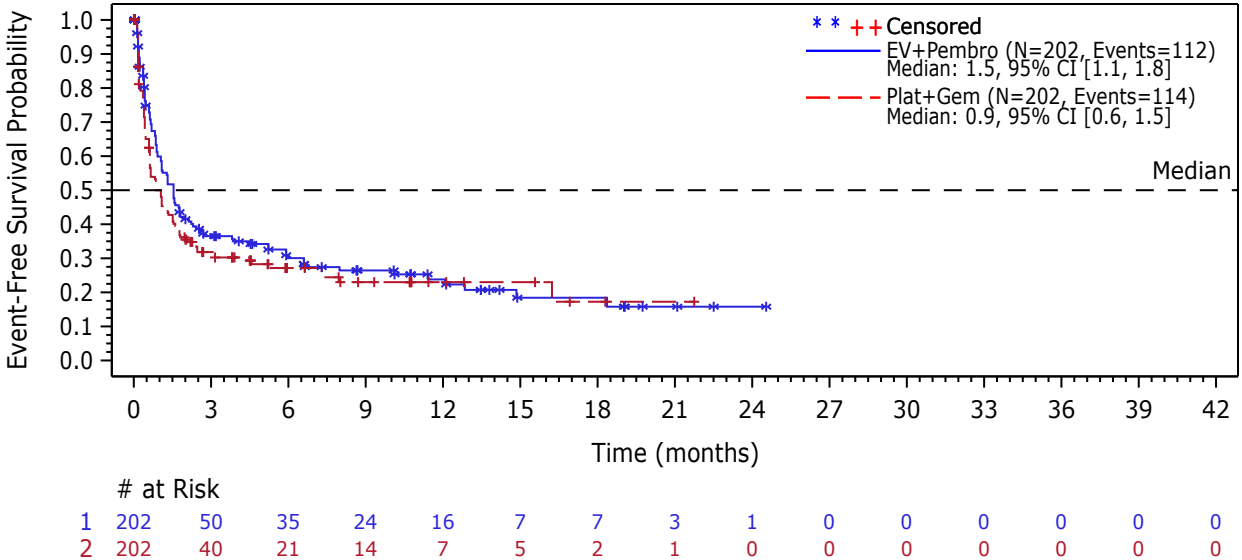
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.14.2: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Cognitive Functioning (MID=10) - Analysis Set mITT 2



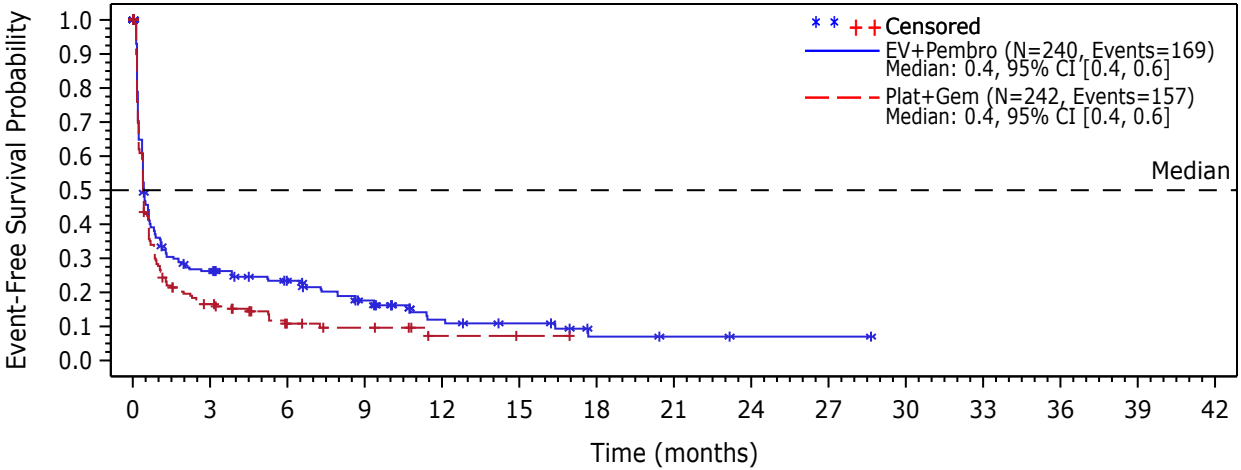
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.15.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Fatigue (MID=10) - Analysis Set mITT 1



at Risk

1	240	50	38	25	11	8	3	2	1	1	0	0	0	0	0
2	242	26	10	7	2	1	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

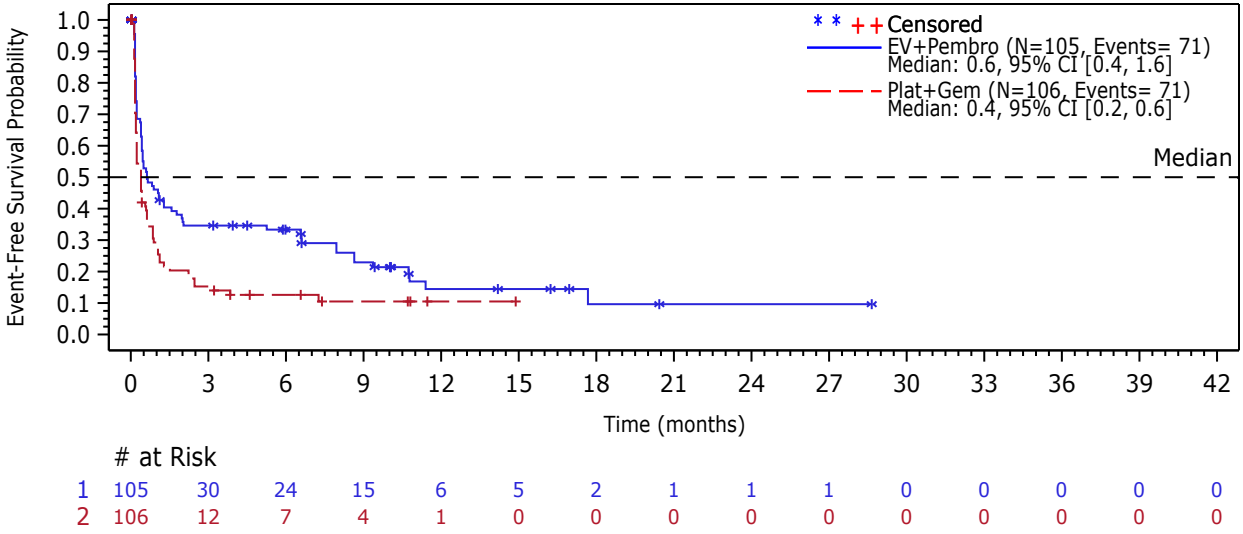
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.15.1.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Fatigue (MID=10) by Age - Analysis Set mITT 1

Age: < 65 years



at Risk

1	105	30	24	15	6	5	2	1	1	1	0	0	0	0	0
2	106	12	7	4	1	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

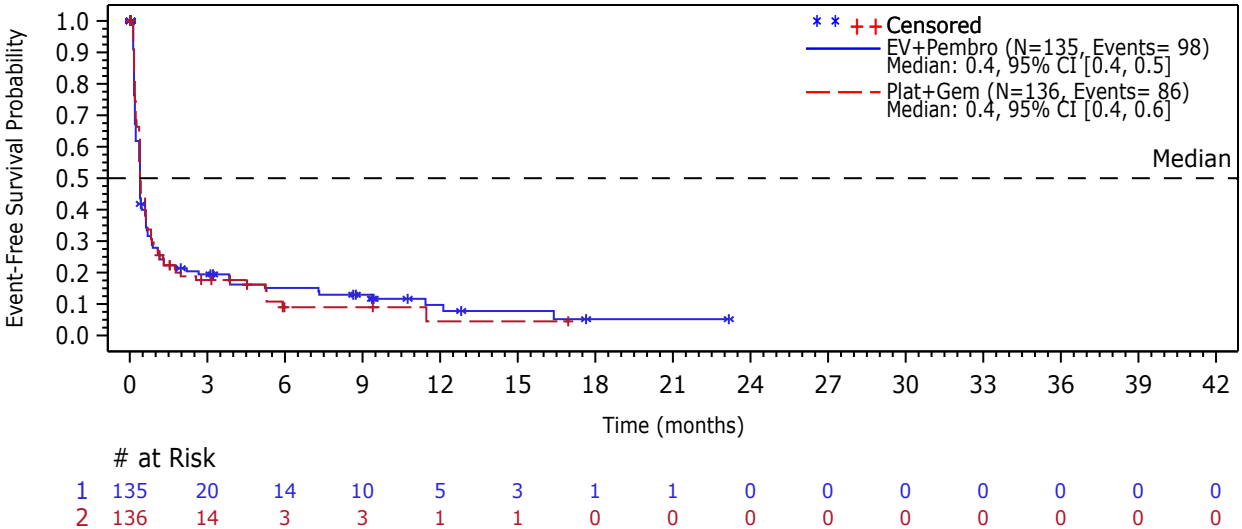
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.15.1.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Fatigue (MID=10) by Age - Analysis Set mITT 1

Age: >= 65 years



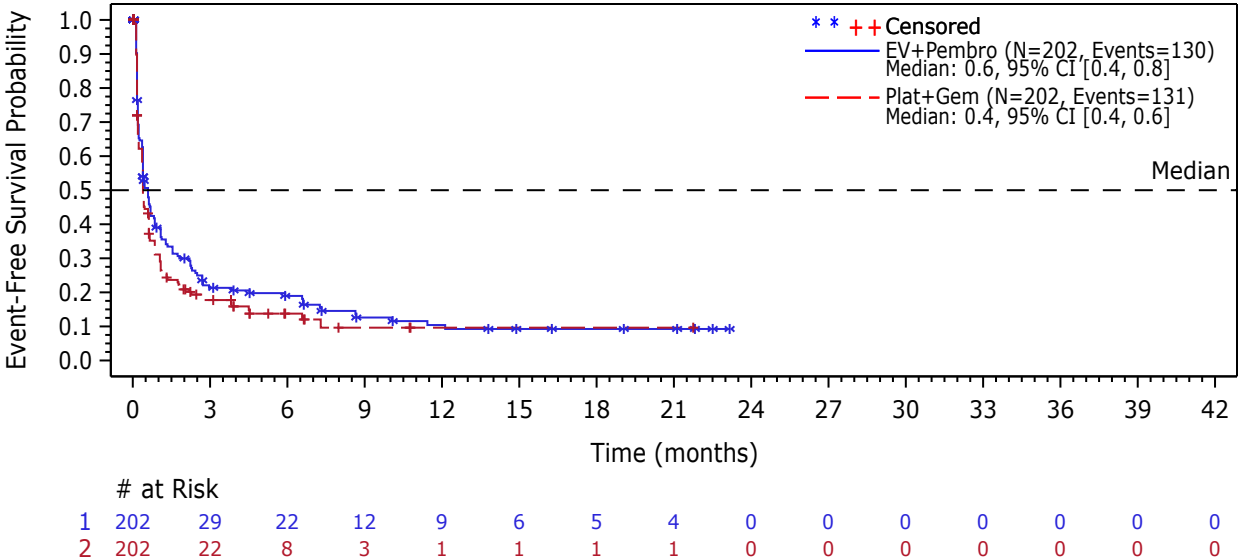
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.15.2: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Fatigue (MID=10) - Analysis Set mITT 2



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

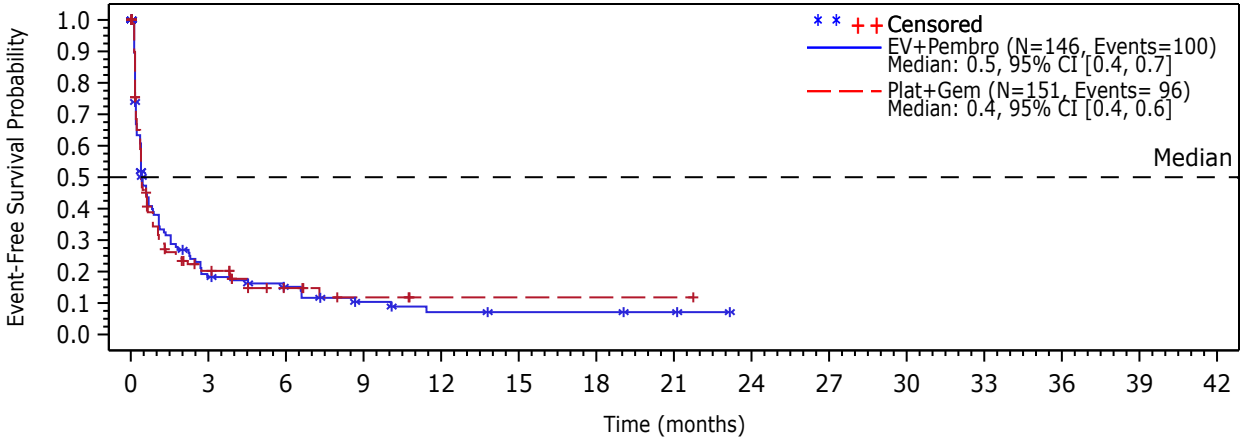
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.15.2.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Fatigue (MID=10) by Sex - Analysis Set mITT 2

Sex: Male



at Risk

1	146	19	13	7	4	3	3	2	0	0	0	0	0	0	0
2	151	19	7	3	1	1	1	1	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

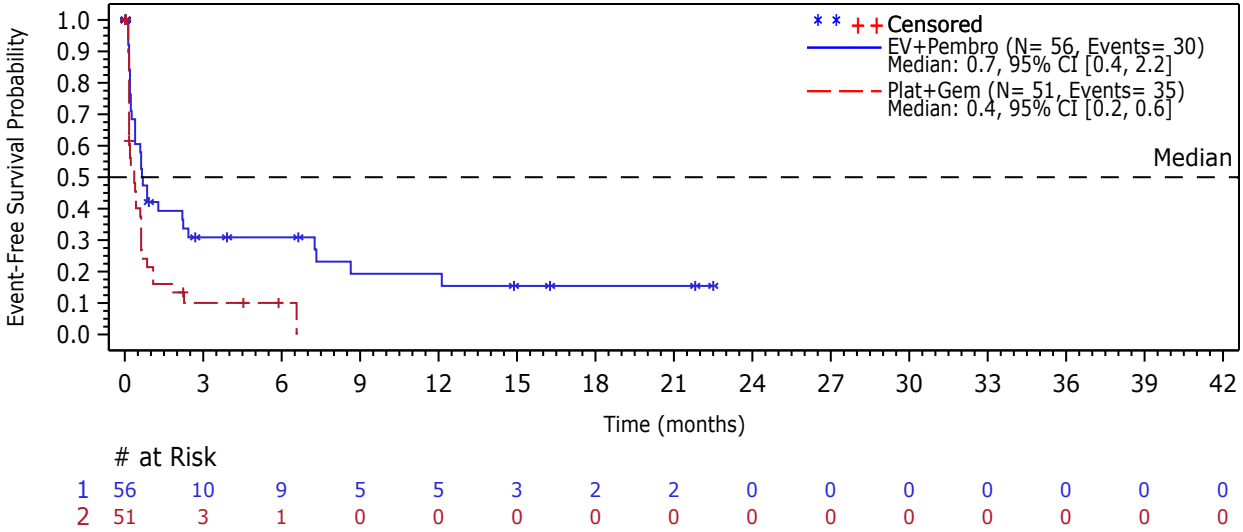
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.15.2.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Fatigue (MID=10) by Sex - Analysis Set mITT 2

Sex: Female



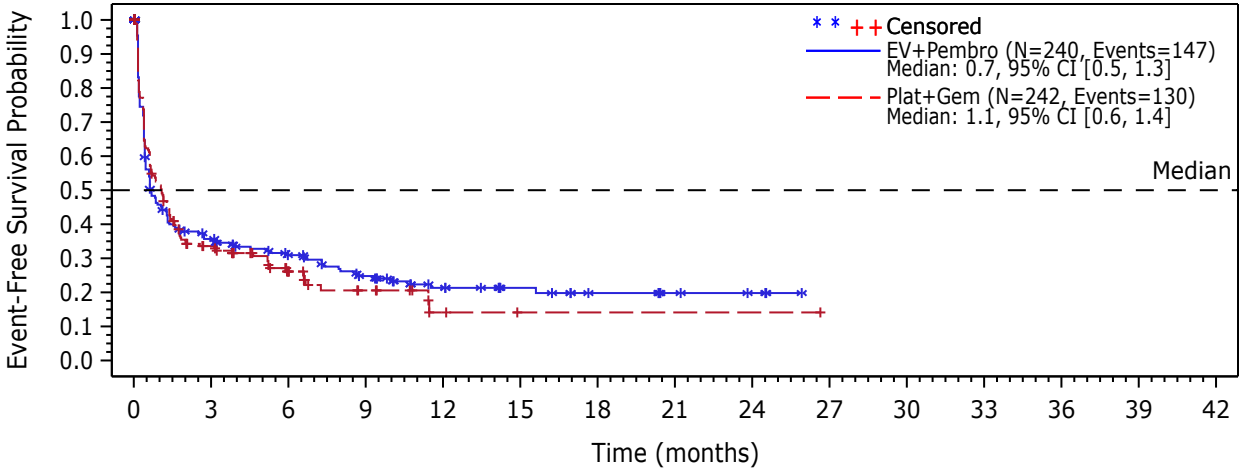
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.16.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Pain (MID=10) - Analysis Set mITT 1



at Risk

1	240	65	48	34	21	14	9	5	3	0	0	0	0	0	0
2	242	50	24	11	3	1	1	1	1	0	0	0	0	0	0

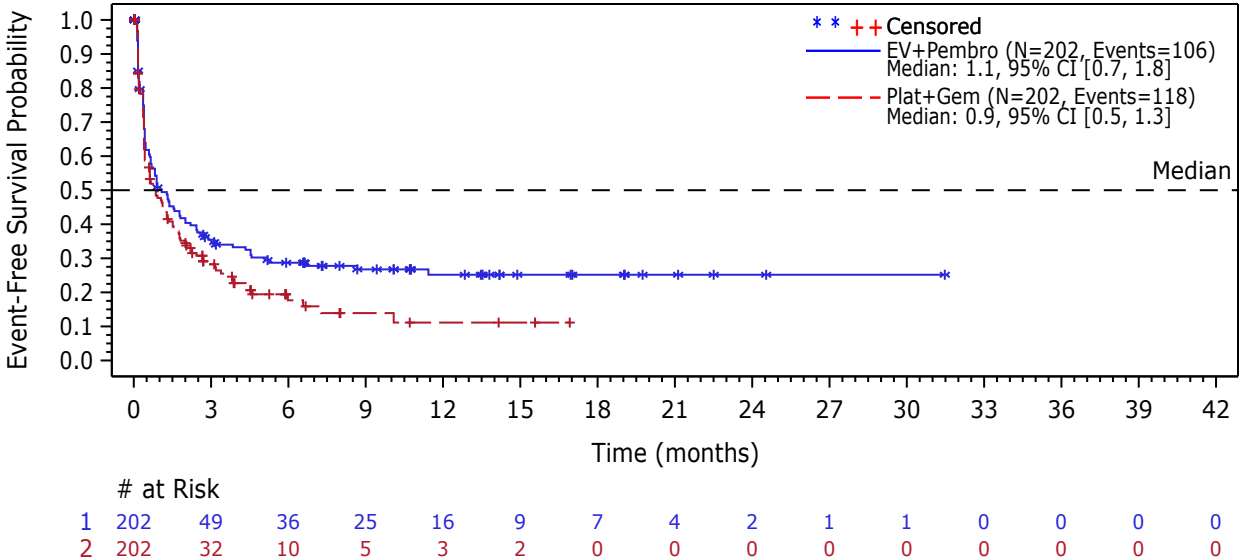
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.16.2: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Pain (MID=10) - Analysis Set mITT 2



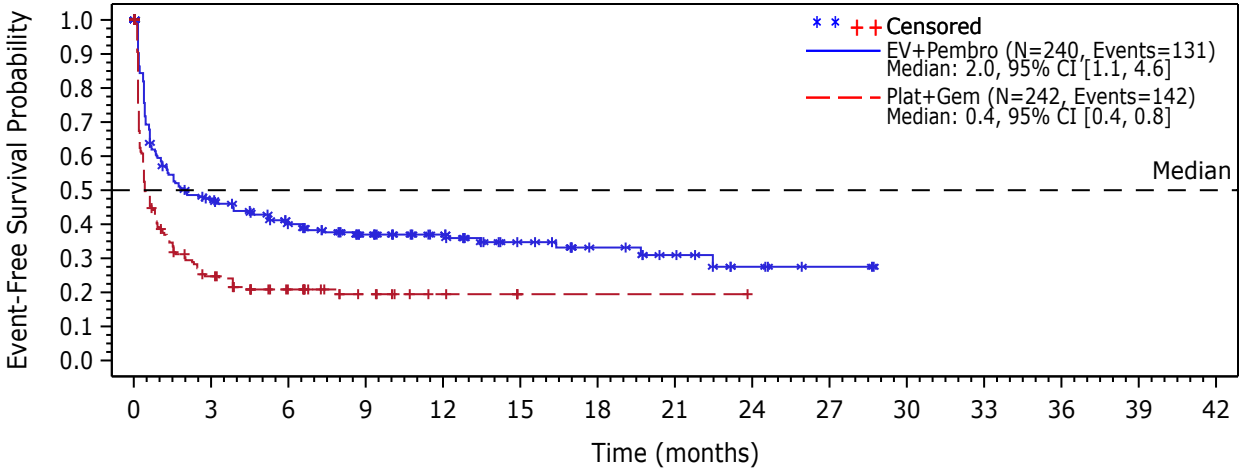
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.17.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Nausea and Vomiting (MID=10) - Analysis Set mITT 1



at Risk

1	240	93	69	50	38	24	16	11	5	2	0	0	0	0	0
2	242	41	22	11	5	1	1	1	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

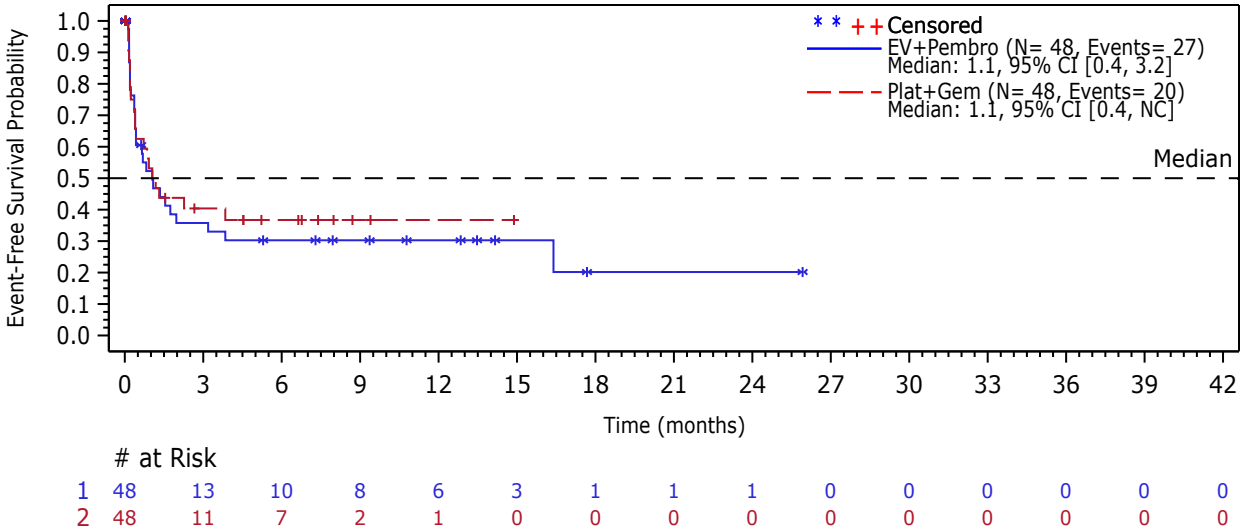
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.17.1.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Nausea and Vomiting (MID=10) by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Present



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

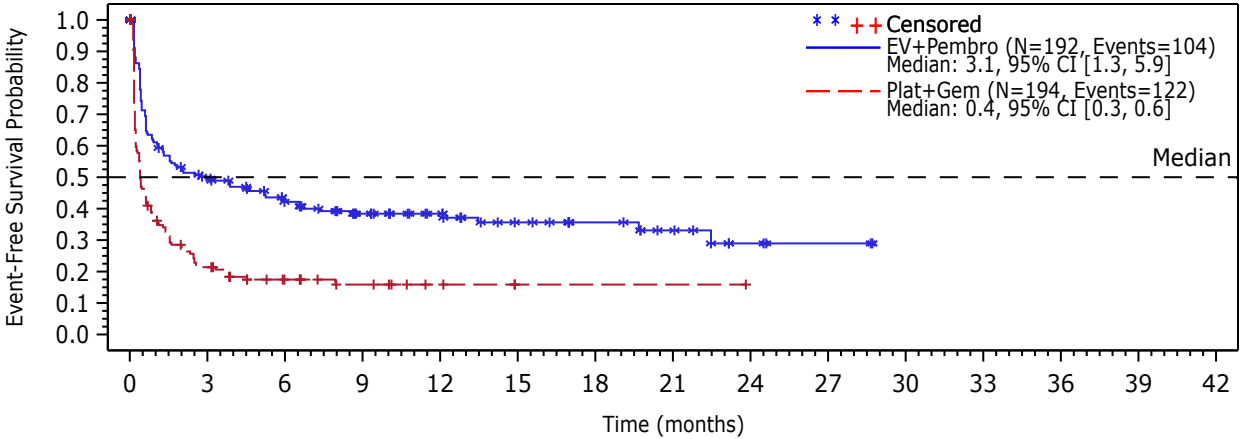
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.17.1.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Nausea and Vomiting (MID=10) by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Absent



at Risk

1	192	80	59	42	32	21	15	10	4	2	0	0	0	0	0
2	194	30	15	9	4	1	1	1	0	0	0	0	0	0	0

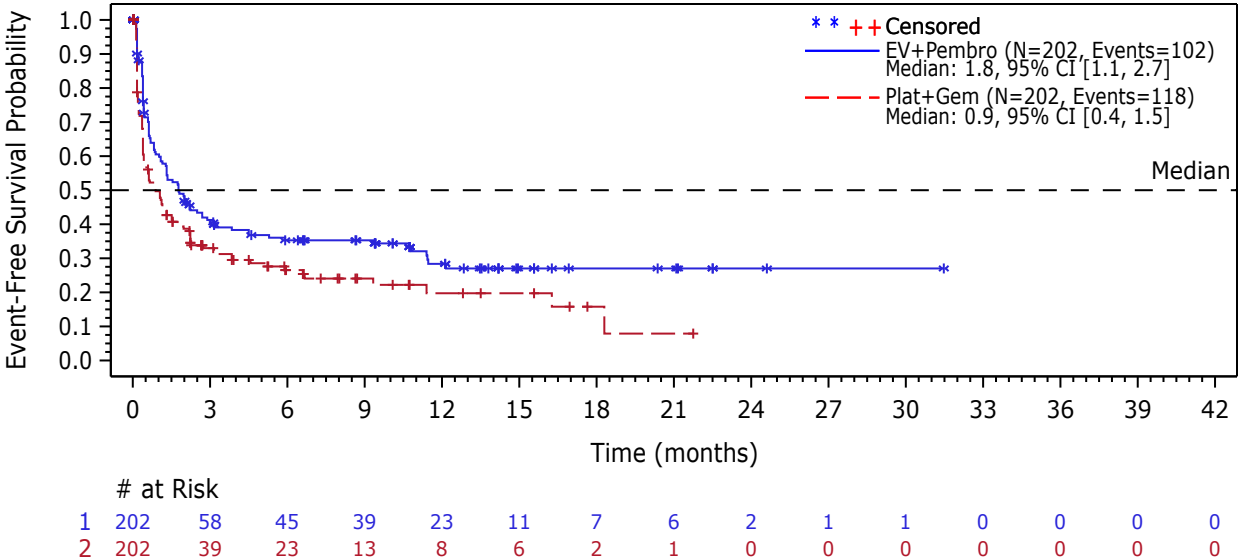
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.17.2: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Nausea and Vomiting (MID=10) - Analysis Set mITT 2



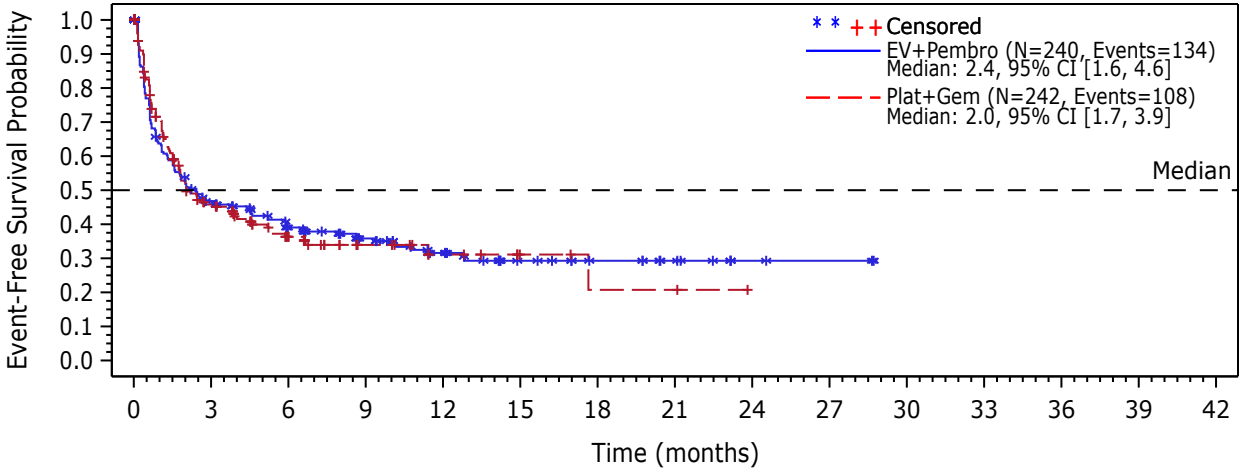
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.18.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Shortness of Breath (MID=10) - Analysis Set mITT 1



at Risk

1	240	91	66	47	32	18	13	9	3	2	0	0	0	0	0
2	242	69	35	16	9	4	2	2	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

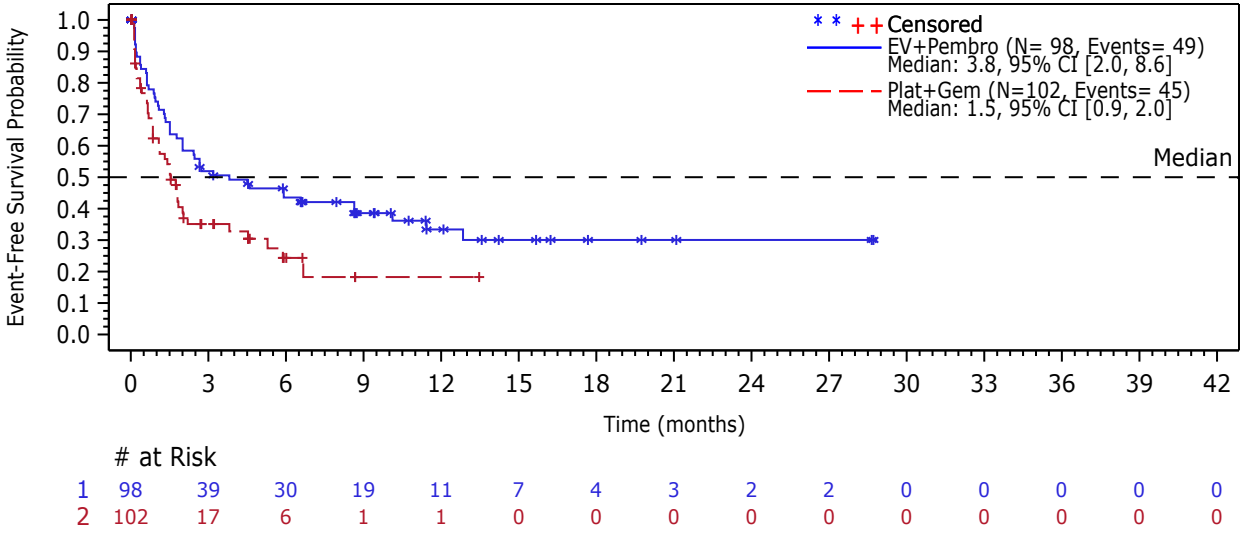
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.18.1.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Shortness of Breath (MID=10) by Region - Analysis Set mITT 1

Region: Europe



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

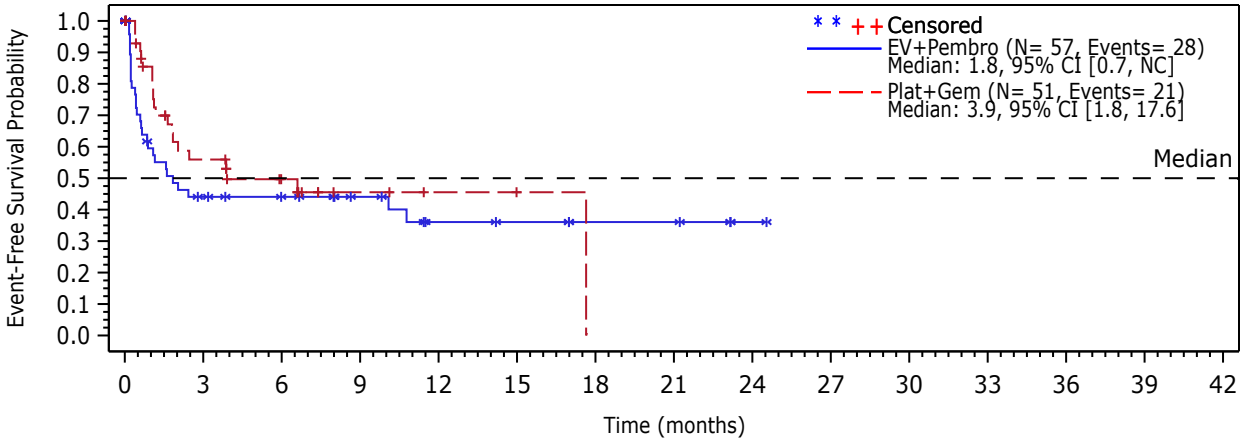
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.18.1.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Shortness of Breath (MID=10) by Region - Analysis Set mITT 1

Region: North America



at Risk

1	57	19	16	12	7	6	4	4	1	0	0	0	0	0	0
2	51	20	12	4	2	1	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

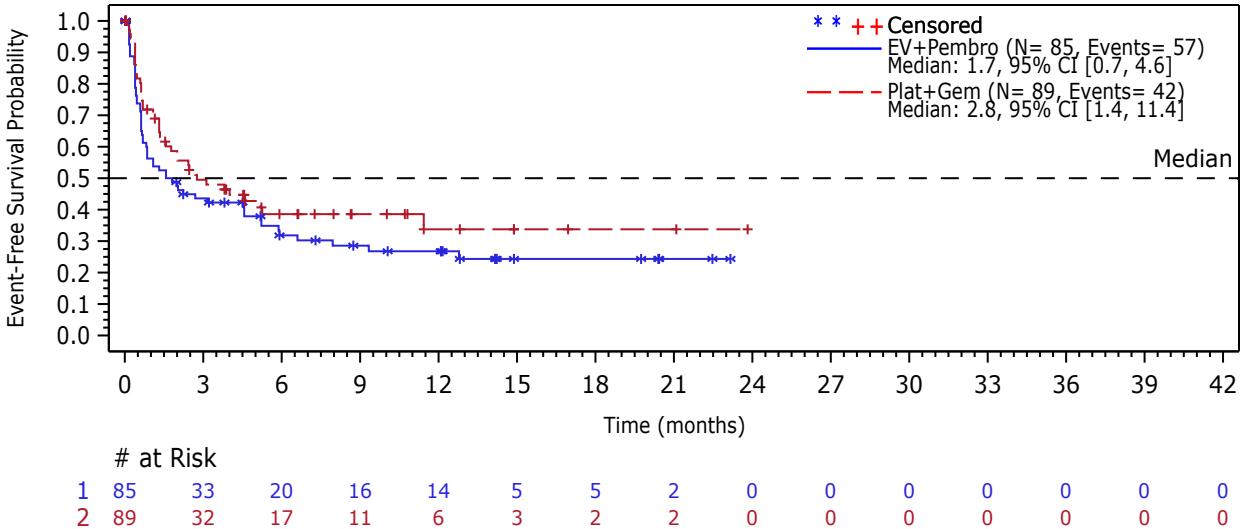
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.18.1.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Shortness of Breath (MID=10) by Region - Analysis Set mITT 1

Region: Rest of World



at Risk

1	85	33	20	16	14	5	5	2	0	0	0	0	0	0	0
2	89	32	17	11	6	3	2	2	0	0	0	0	0	0	0

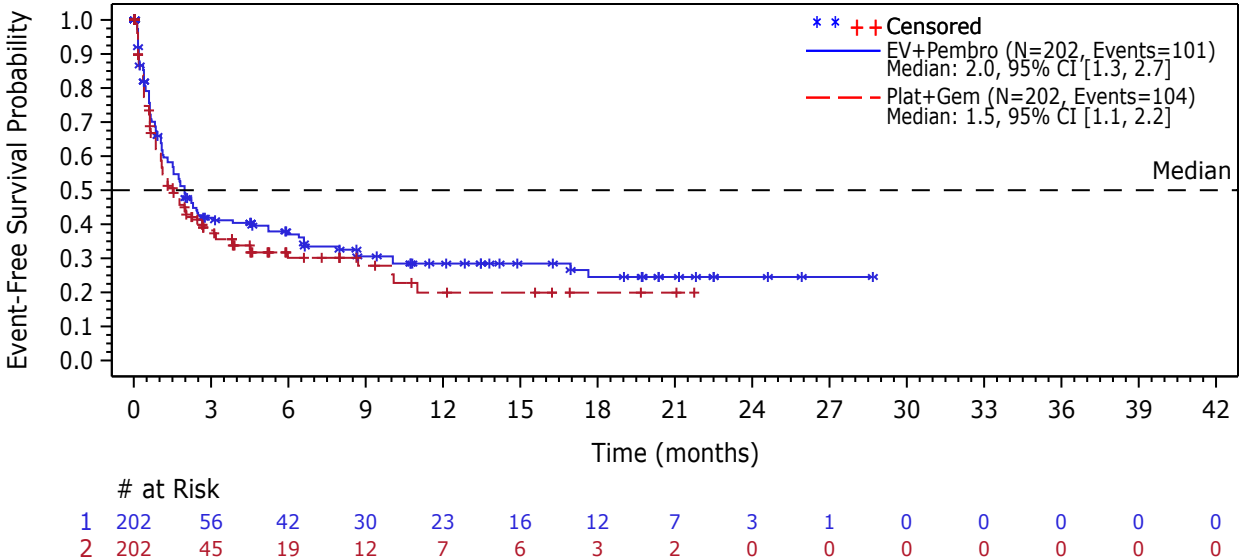
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.18.2: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Shortness of Breath (MID=10) - Analysis Set mITT 2



at Risk

1	202	56	42	30	23	16	12	7	3	1	0	0	0	0	0
2	202	45	19	12	7	6	3	2	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

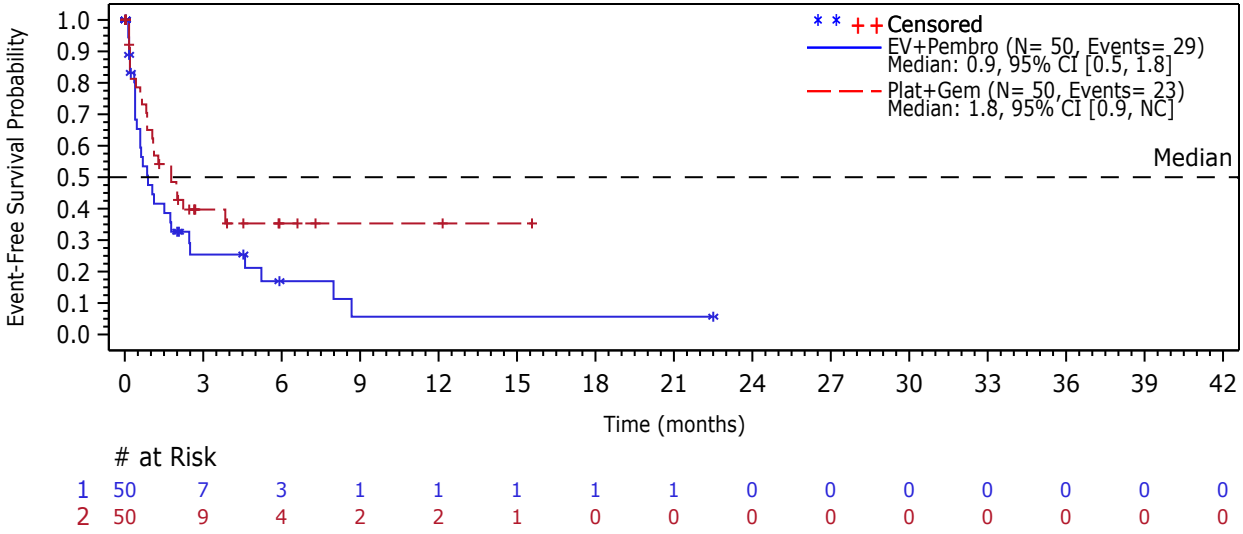
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.18.2.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Shortness of Breath (MID=10) by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Present



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

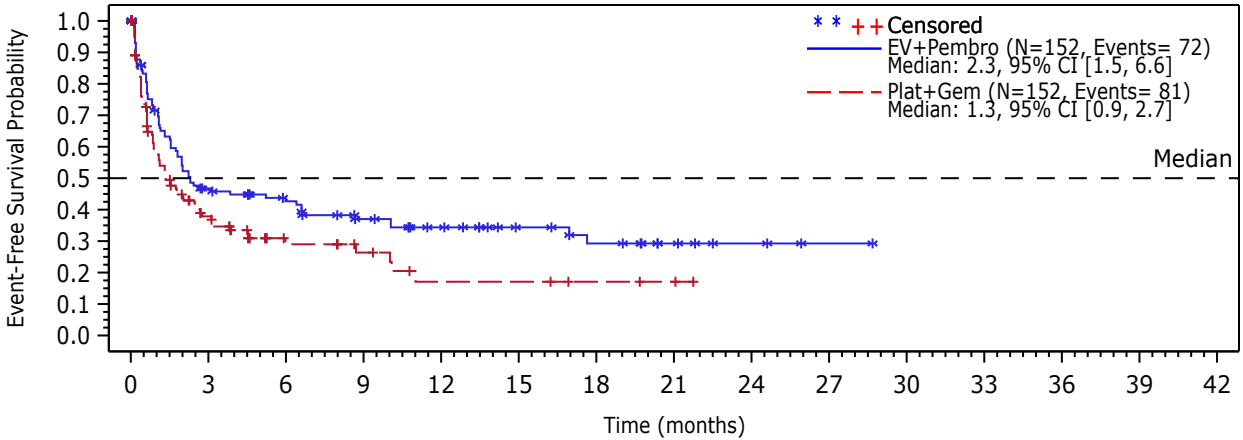
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.18.2.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Shortness of Breath (MID=10) by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Absent



# at Risk															
1	152	49	39	29	22	15	11	6	3	1	0	0	0	0	0
2	152	36	15	10	5	5	3	2	0	0	0	0	0	0	0

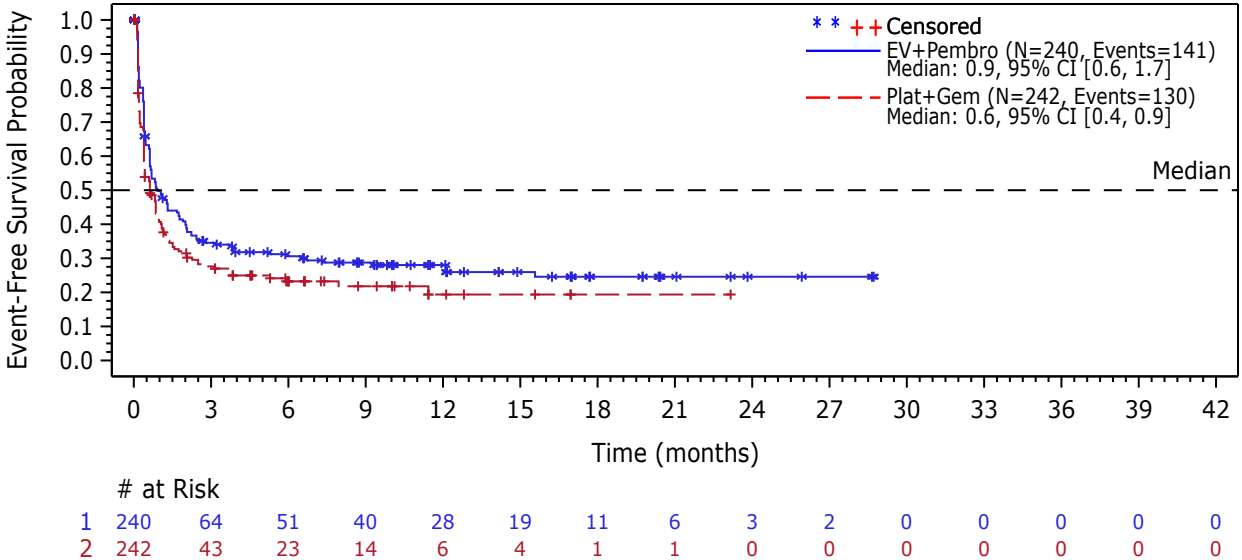
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.19.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Loss of Appetite (MID=10) - Analysis Set mITT 1



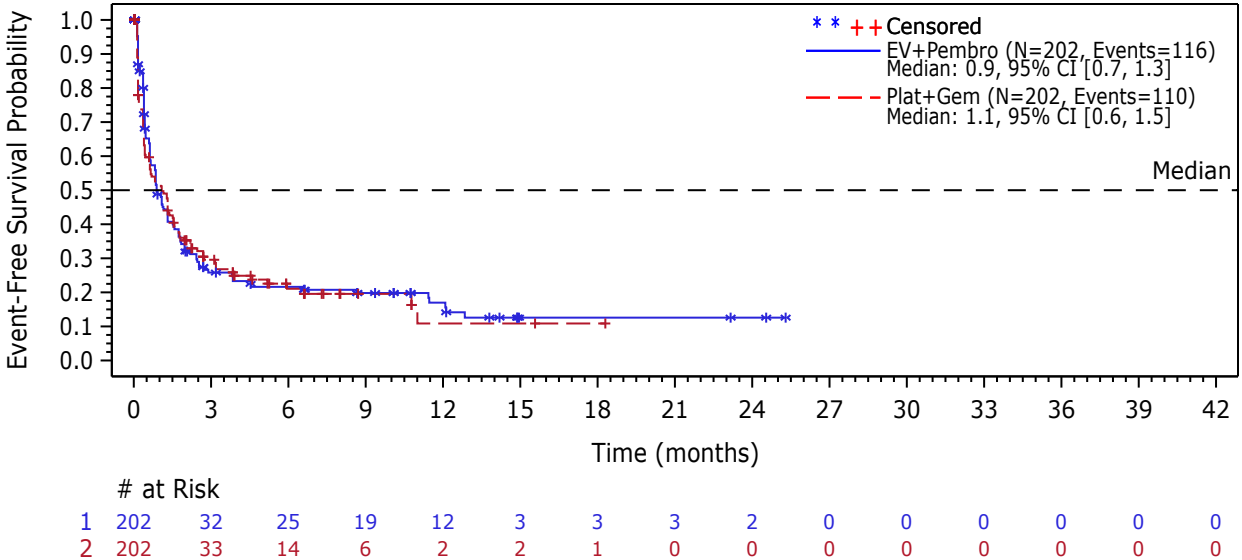
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.19.2: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Loss of Appetite (MID=10) - Analysis Set mITT 2



at Risk

1	202	32	25	19	12	3	3	3	2	0	0	0	0	0	0
2	202	33	14	6	2	2	1	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

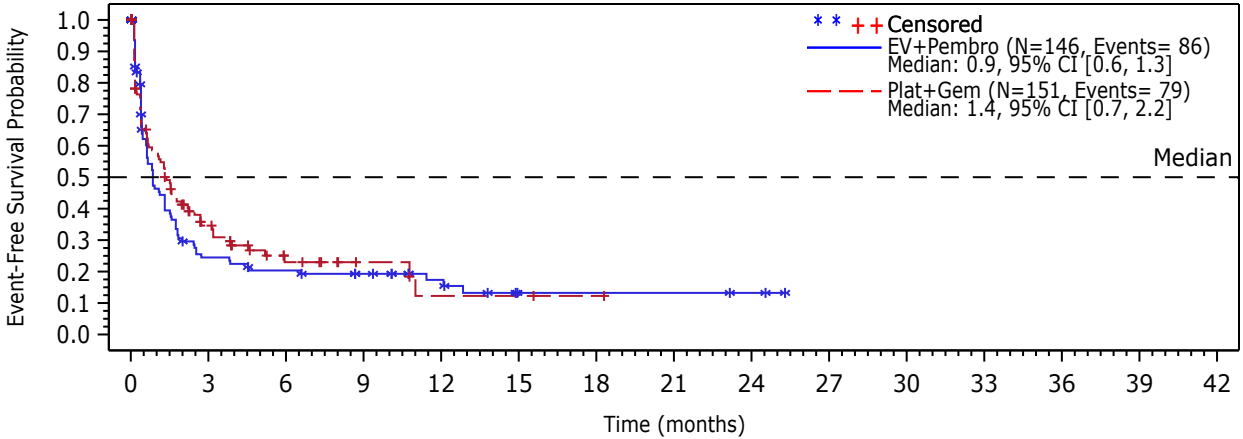
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.19.2.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Loss of Appetite (MID=10) by Sex - Analysis Set mITT 2

Sex: Male



at Risk

1	146	24	19	15	9	3	3	3	2	0	0	0	0	0	0
2	151	29	11	5	2	2	1	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

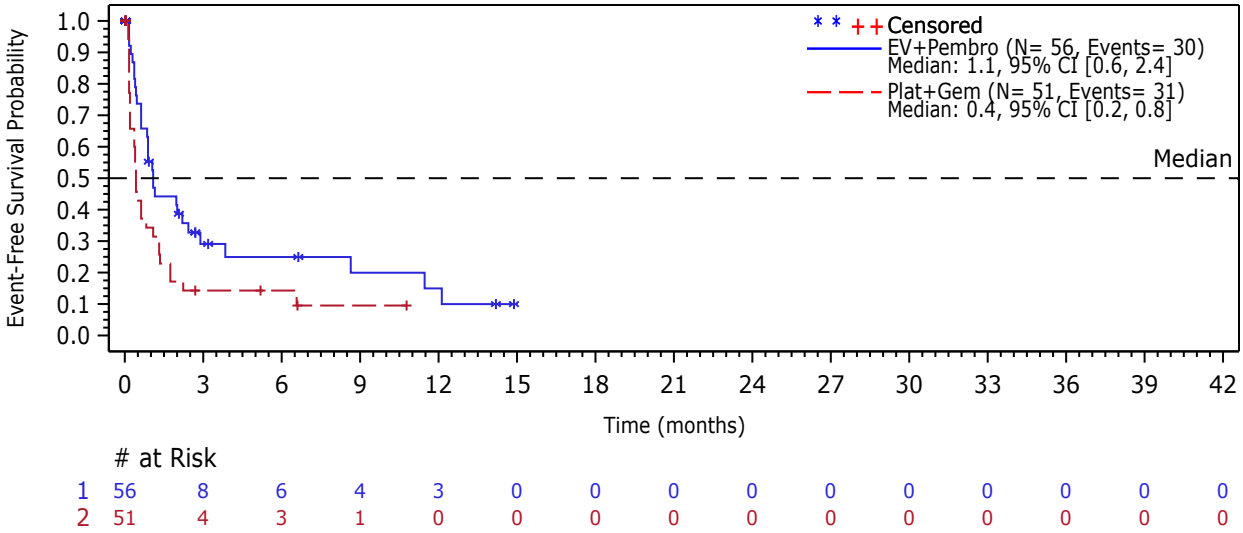
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.19.2.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Loss of Appetite (MID=10) by Sex - Analysis Set mITT 2

Sex: Female



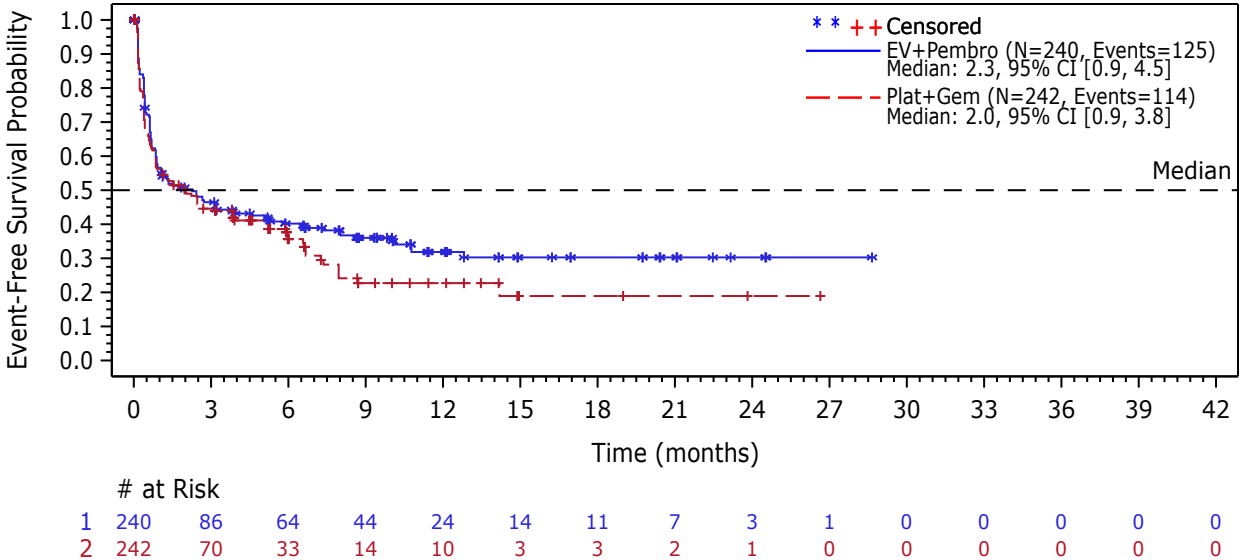
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.20.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Sleep Disturbance (MID=10) - Analysis Set mITT 1



at Risk

1	240	86	64	44	24	14	11	7	3	1	0	0	0	0	0
2	242	70	33	14	10	3	3	2	1	0	0	0	0	0	0

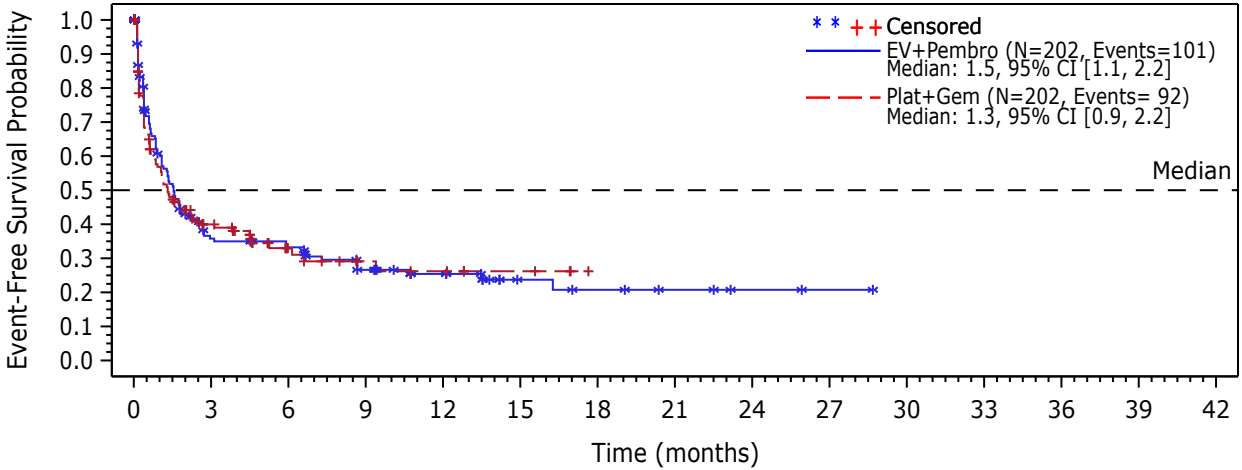
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.20.2: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Sleep Disturbance (MID=10) - Analysis Set mITT 2



at Risk

1	202	44	38	26	18	8	6	4	2	1	0	0	0	0	0
2	202	43	17	10	8	4	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

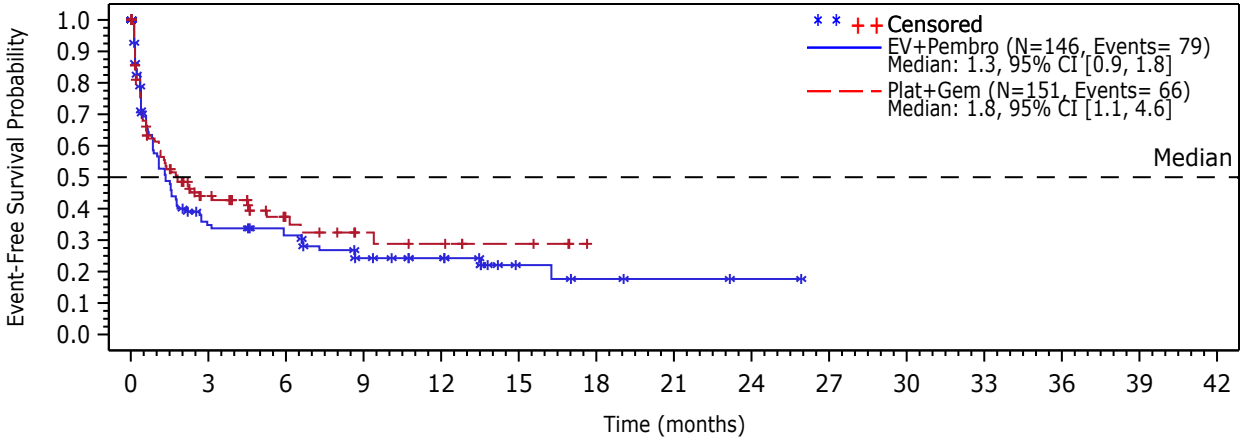
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.20.2.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Sleep Disturbance (MID=10) by Sex - Analysis Set mITT 2

Sex: Male



at Risk

1	146	33	28	18	14	5	3	2	1	0	0	0	0	0	0
2	151	35	15	9	7	4	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

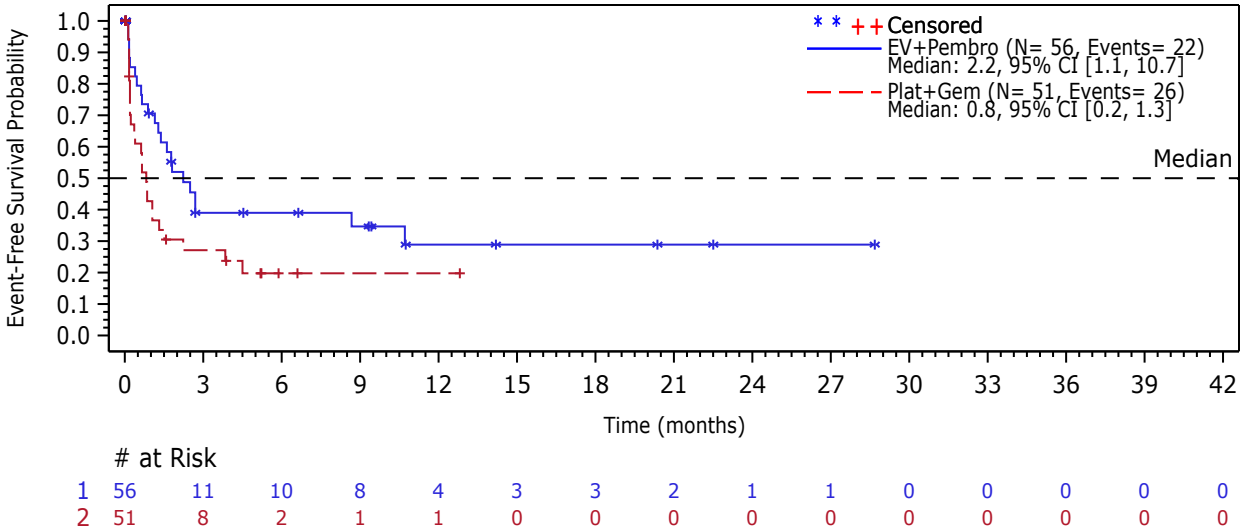
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.20.2.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Sleep Disturbance (MID=10) by Sex - Analysis Set mITT 2

Sex: Female



at Risk

1	56	11	10	8	4	3	3	2	1	1	0	0	0	0	0
2	51	8	2	1	1	0	0	0	0	0	0	0	0	0	0

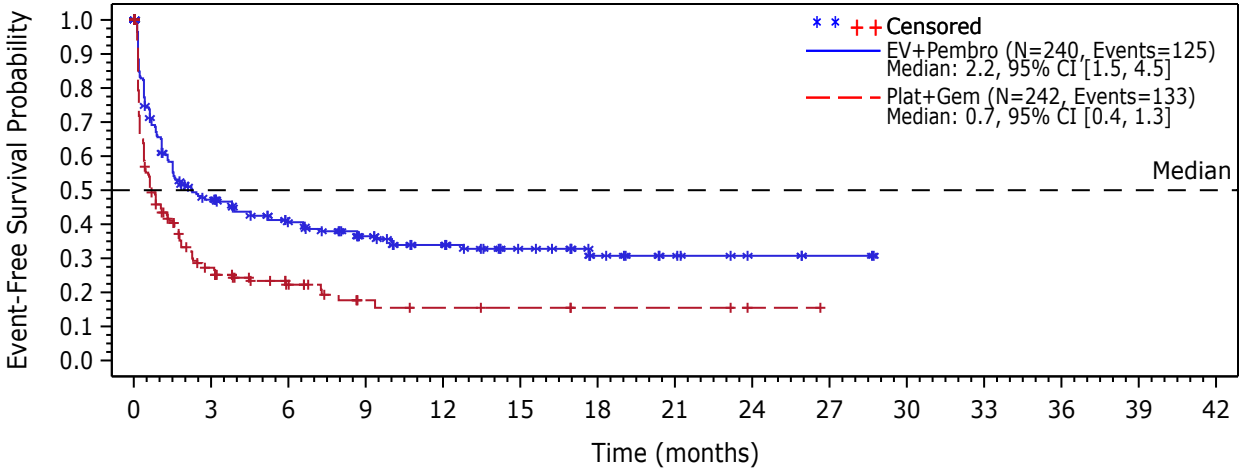
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.21.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Constipation (MID=10) - Analysis Set mITT 1



at Risk

1	240	86	62	46	34	22	13	8	4	2	0	0	0	0	0
2	242	39	19	8	6	5	3	3	1	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

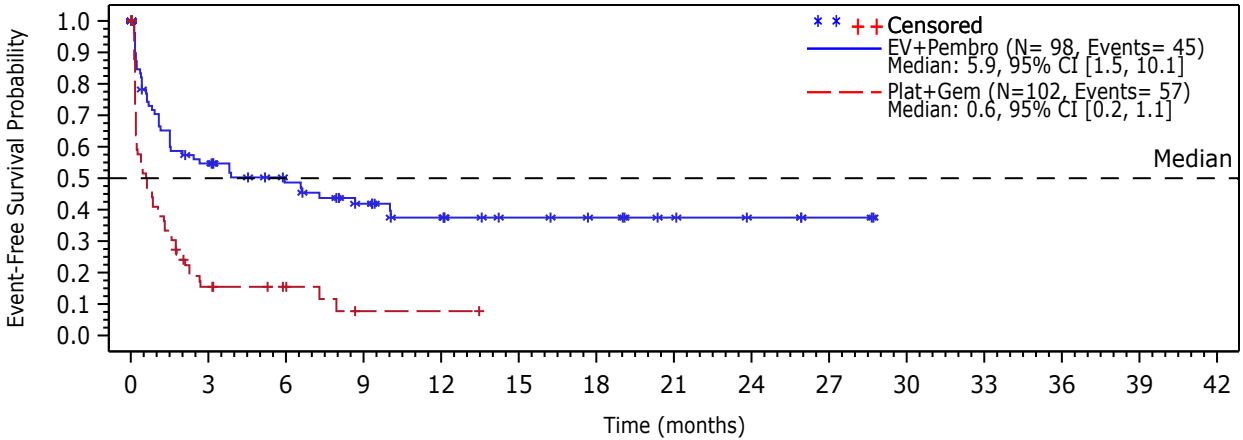
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.21.1.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Constipation (MID=10) by Region - Analysis Set mITT 1

Region: Europe



at Risk

1	98	41	30	22	16	11	9	6	4	2	0	0	0	0	0
2	102	9	5	1	1	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

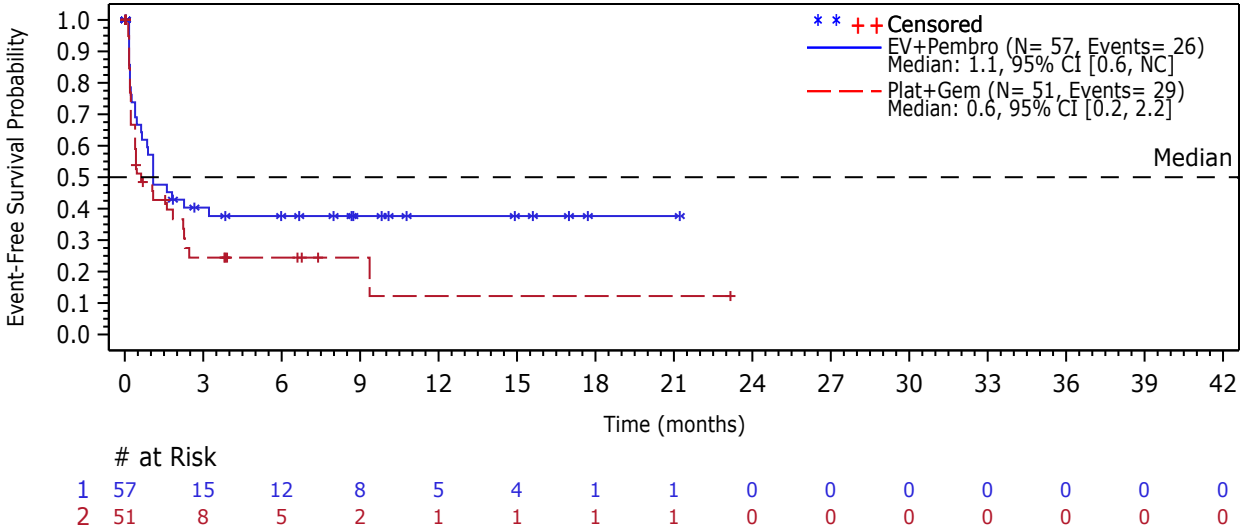
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.21.1.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Constipation (MID=10) by Region - Analysis Set mITT 1

Region: North America



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

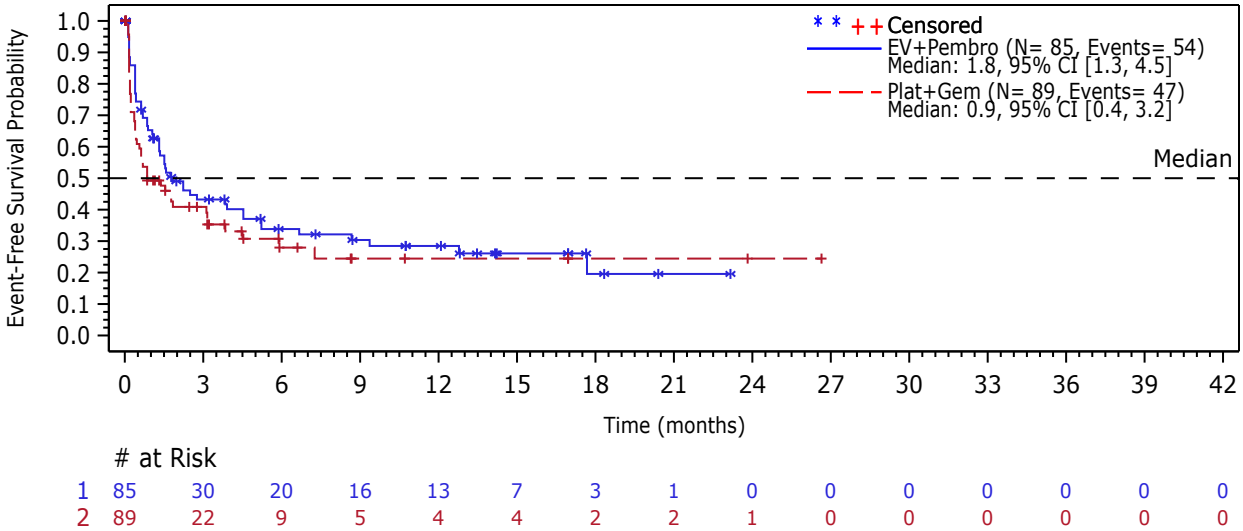
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.21.1.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Constipation (MID=10) by Region - Analysis Set mITT 1

Region: Rest of World



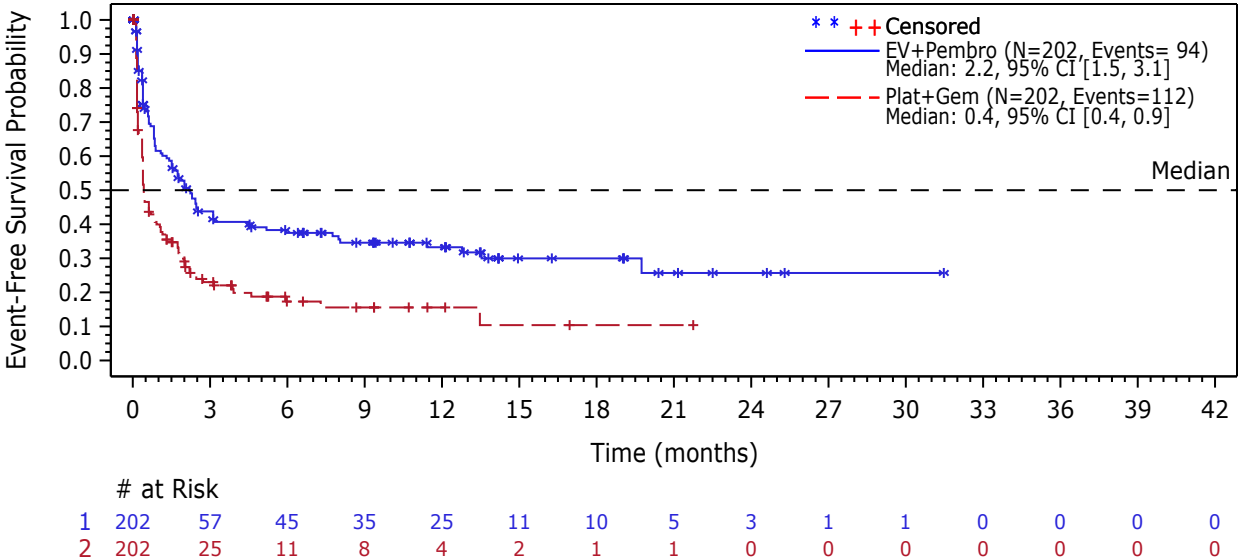
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.21.2: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Constipation (MID=10) - Analysis Set mITT 2



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

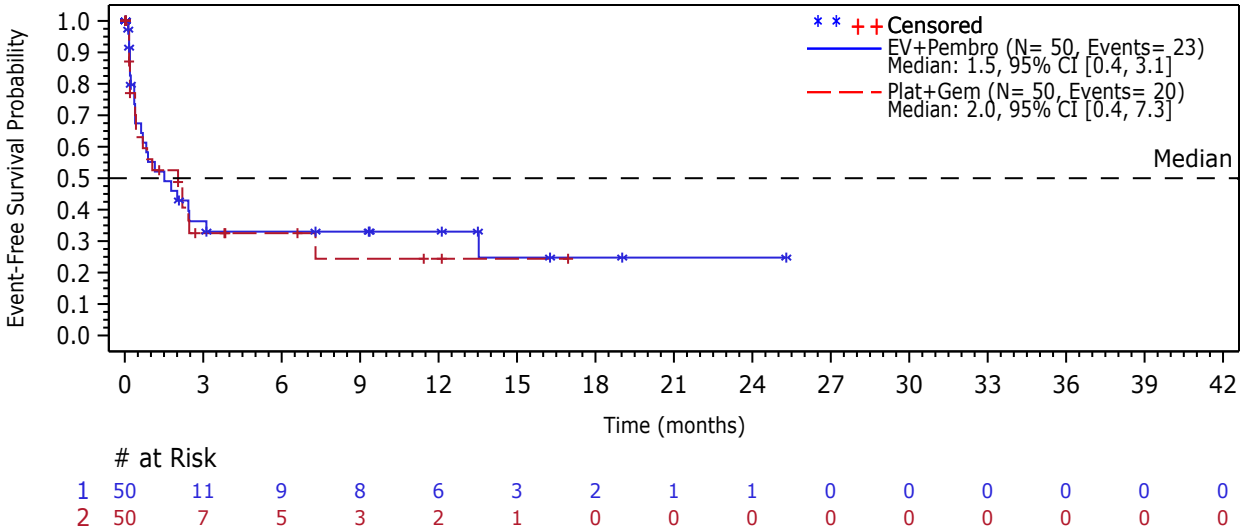
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.21.2.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Constipation (MID=10) by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Present



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

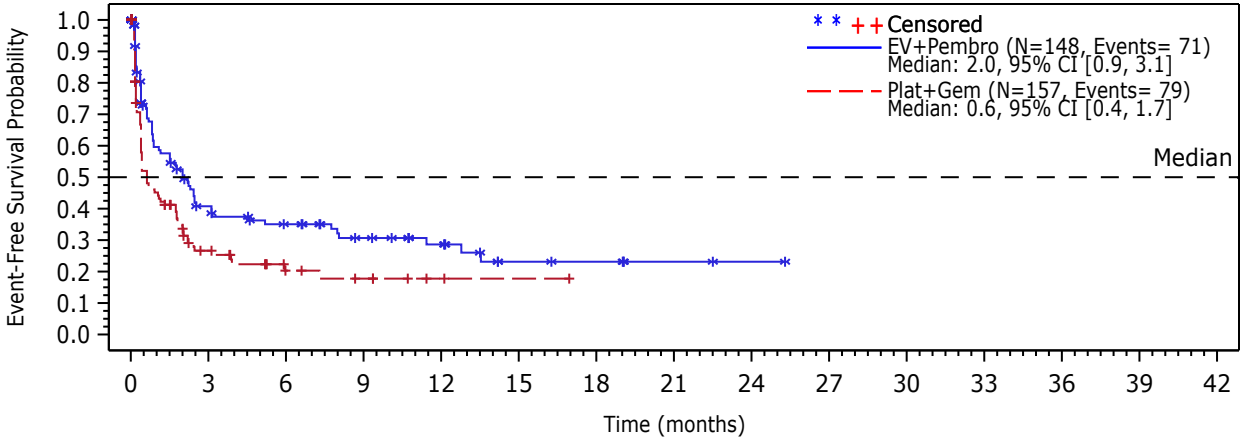
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.21.2.2: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Constipation (MID=10) by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Visceral metastases



at Risk

1	148	37	28	20	14	6	5	2	1	0	0	0	0	0	0
2	157	21	9	6	2	1	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

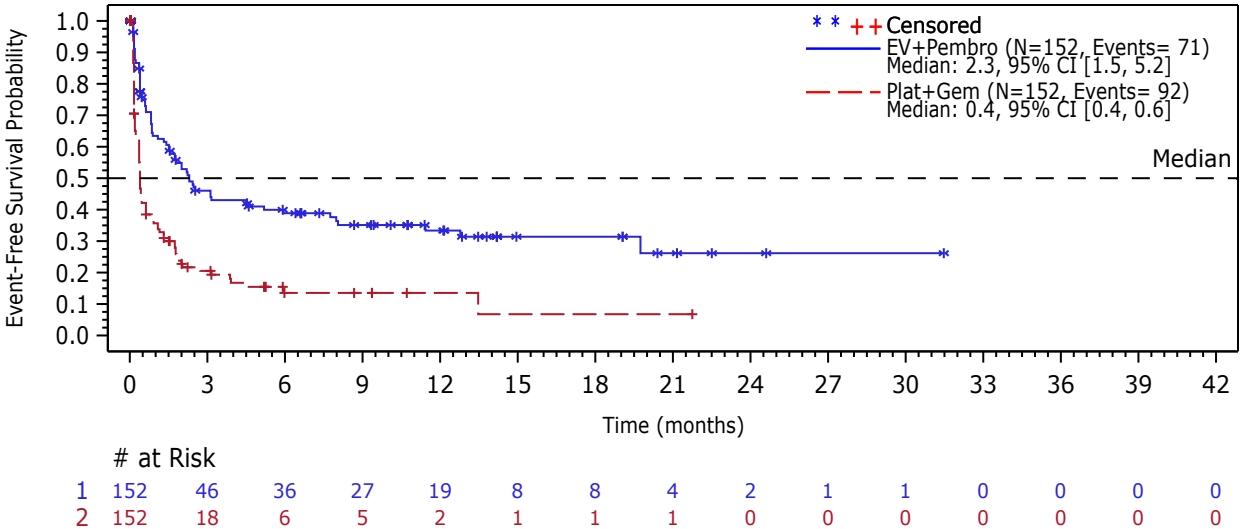
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.21.2.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Constipation (MID=10) by Liver Metastases - Analysis Set mITT 2

Liver Metastases: Absent



at Risk

1	152	46	36	27	19	8	8	4	2	1	1	0	0	0	0
2	152	18	6	5	2	1	1	1	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

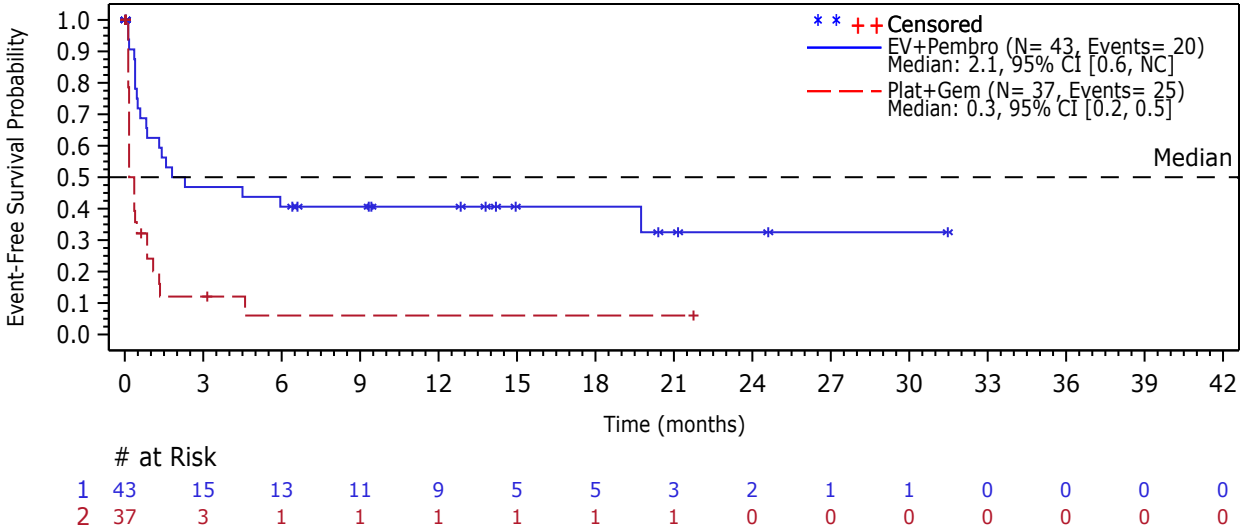
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.21.2.2: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Constipation (MID=10) by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Lymph node only



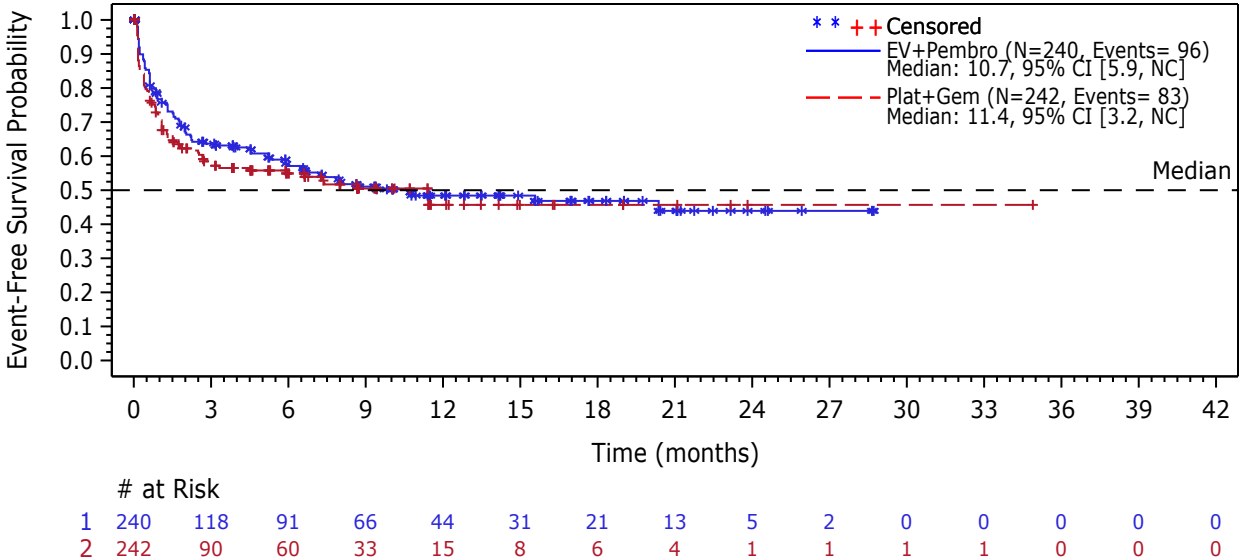
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.22.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Financial Impact (MID=10) - Analysis Set mITT 1



at Risk

1	240	118	91	66	44	31	21	13	5	2	0	0	0	0	0
2	242	90	60	33	15	8	6	4	1	1	1	1	0	0	0

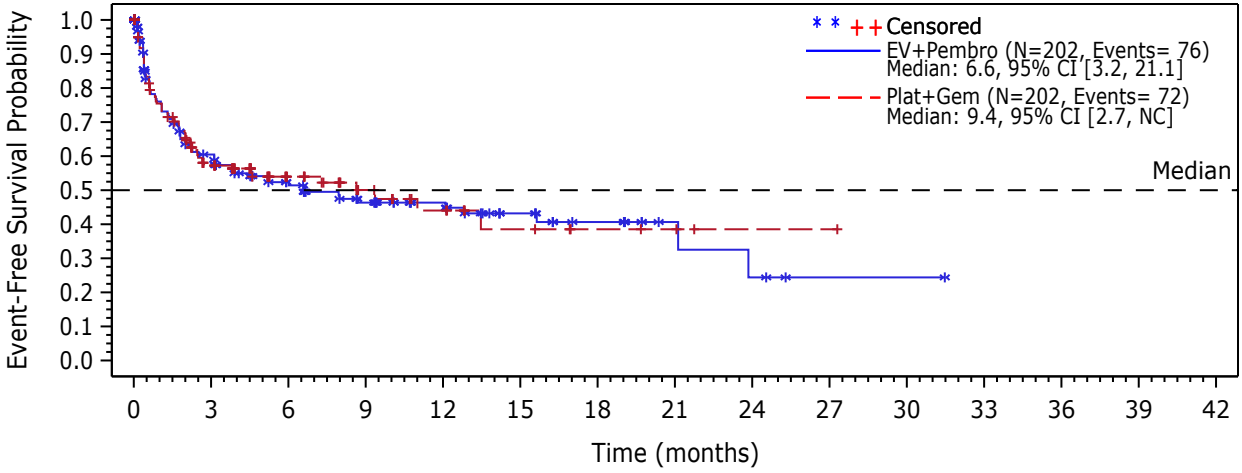
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.22.2: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Financial Impact (MID=10) - Analysis Set mITT 2



at Risk

1	202	79	56	42	31	19	12	5	3	1	1	0	0	0	0
2	202	71	34	20	13	7	4	3	1	1	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

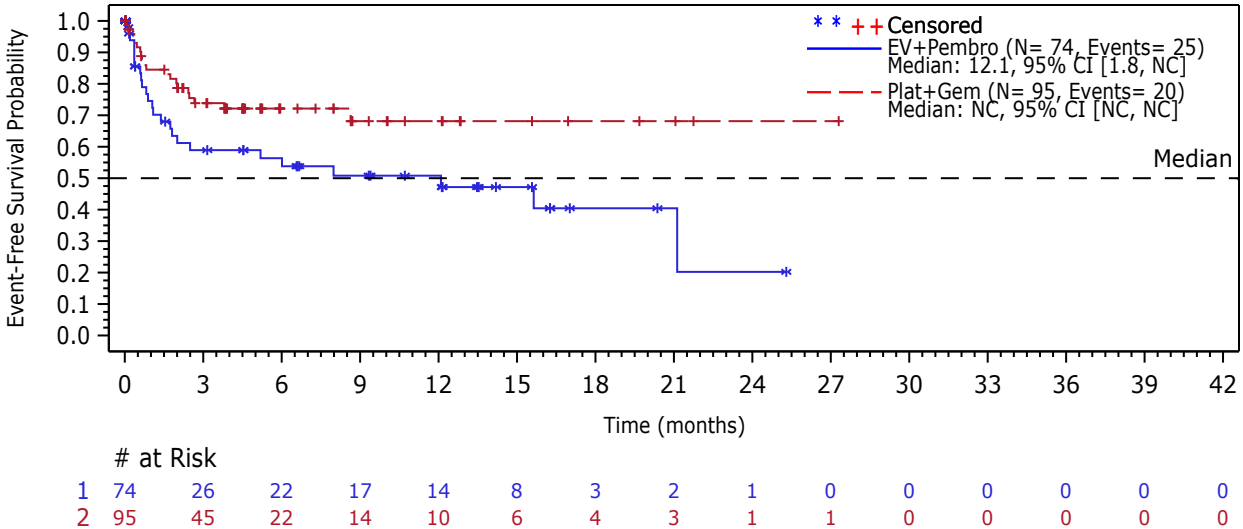
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.22.2.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Financial Impact (MID=10) by Region - Analysis Set mITT 2

Region: Europe



at Risk

1	74	26	22	17	14	8	3	2	1	0	0	0	0	0	0
2	95	45	22	14	10	6	4	3	1	1	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

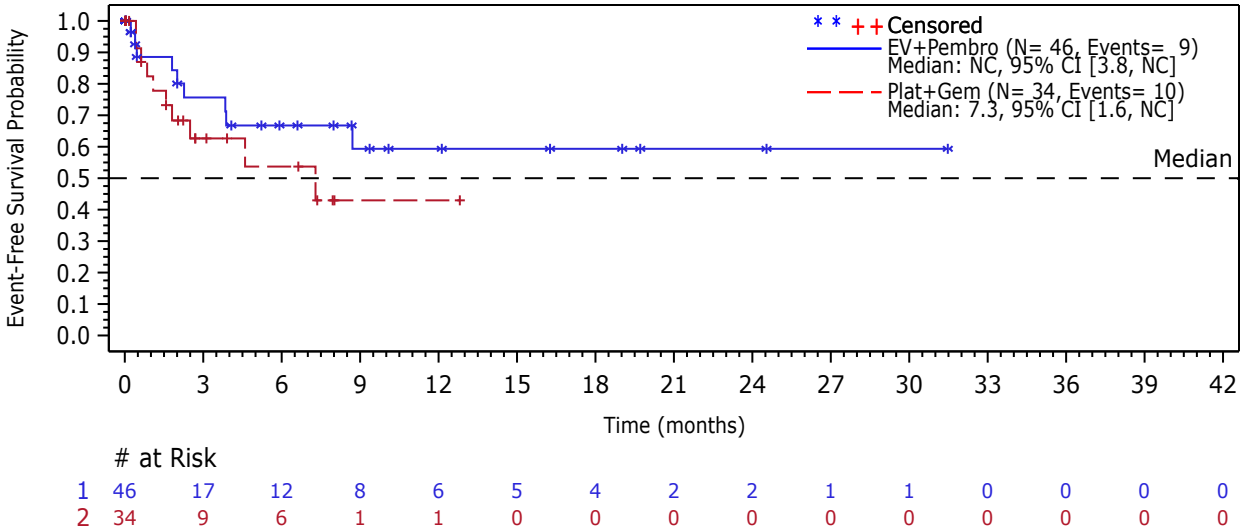
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.22.2.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Financial Impact (MID=10) by Region - Analysis Set mITT 2

Region: North America



at Risk

1	46	17	12	8	6	5	4	2	2	1	1	0	0	0	0
2	34	9	6	1	1	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

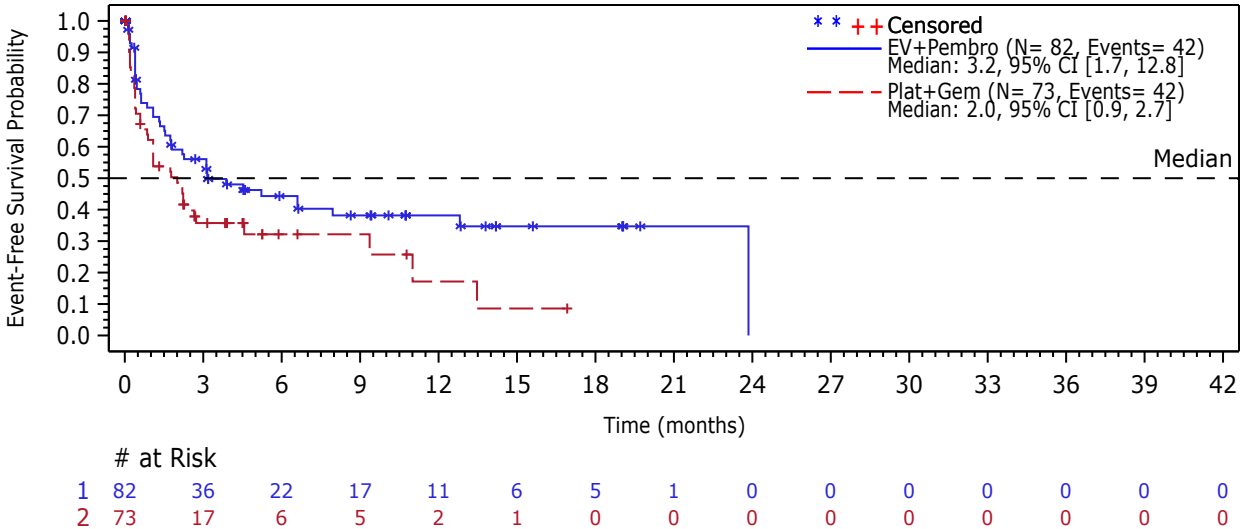
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.22.2.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Financial Impact (MID=10) by Region - Analysis Set mITT 2

Region: Rest of World



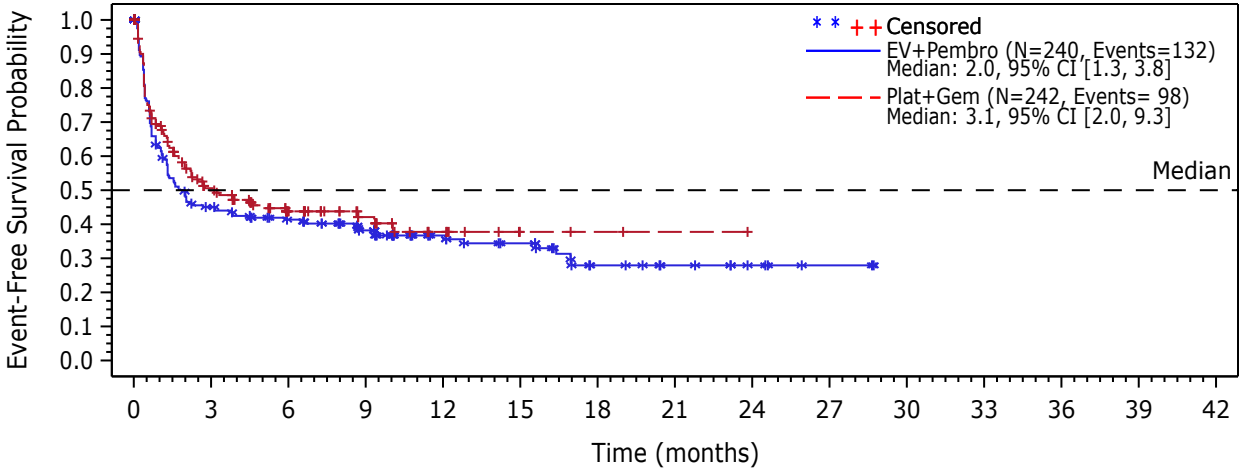
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.23.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Diarrhea (MID=10) - Analysis Set mITT 1



at Risk

1	240	88	73	54	33	26	13	9	5	2	0	0	0	0	0
2	242	76	41	23	10	3	2	1	0	0	0	0	0	0	0

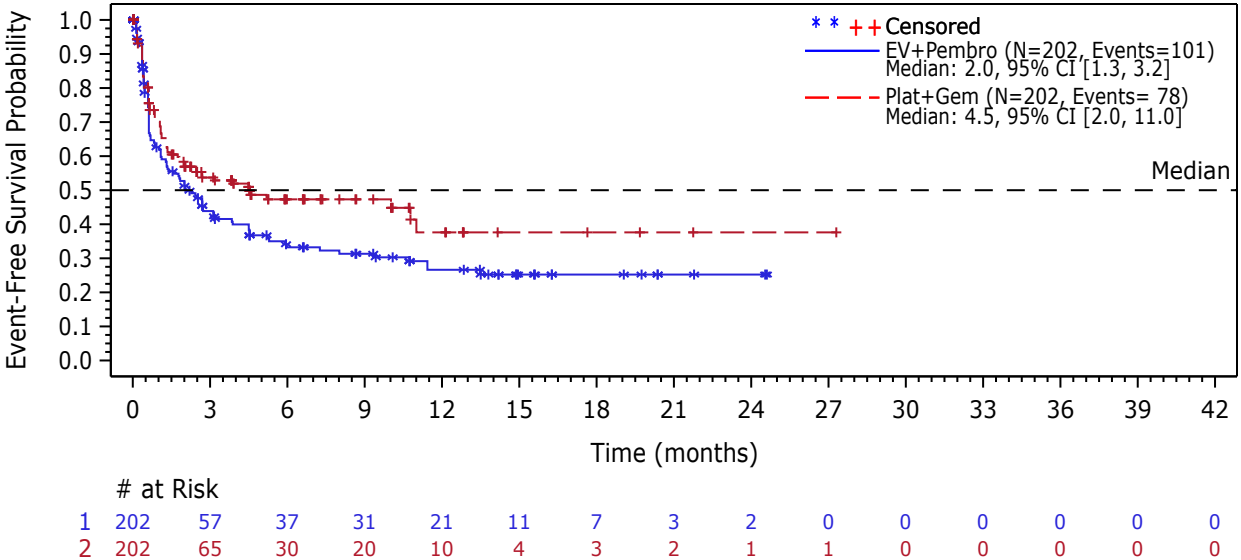
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.23.2: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Diarrhea (MID=10) - Analysis Set mITT 2



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

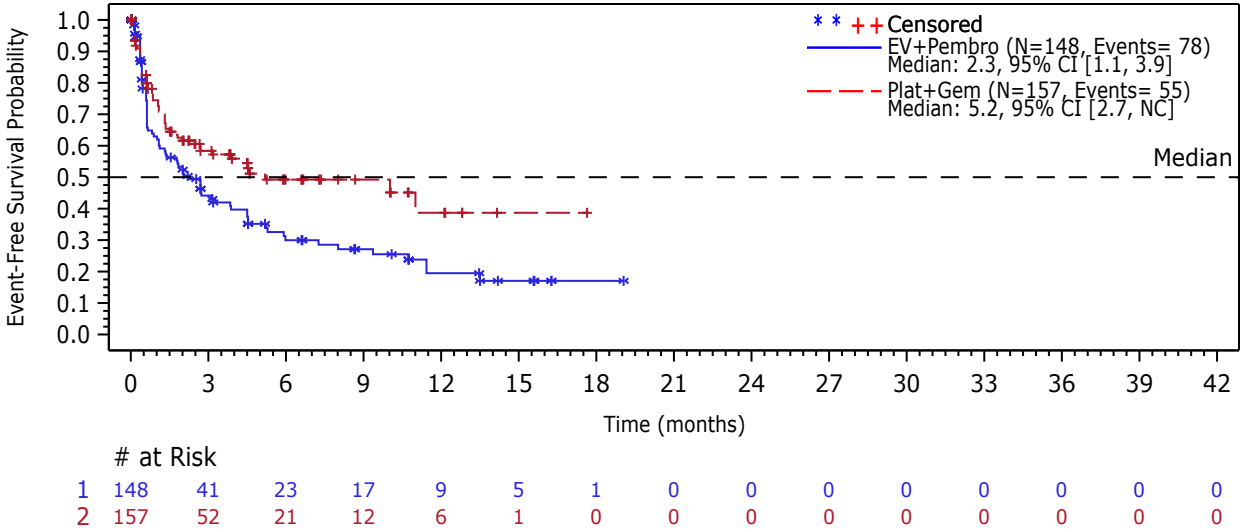
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.23.2.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Diarrhea (MID=10) by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Visceral metastases



at Risk

1	148	41	23	17	9	5	1	0	0	0	0	0	0	0	0
2	157	52	21	12	6	1	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

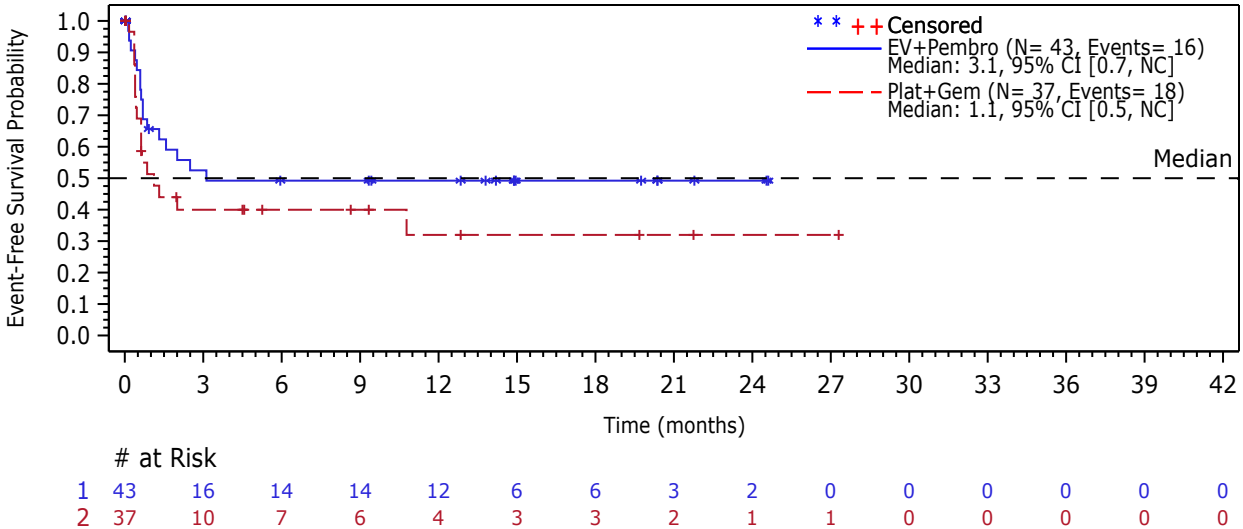
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.23.2.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to first Deterioration of Diarrhea (MID=10) by Metastases at Baseline - Analysis Set mITT 2

Metastases at Baseline: Lymph node only



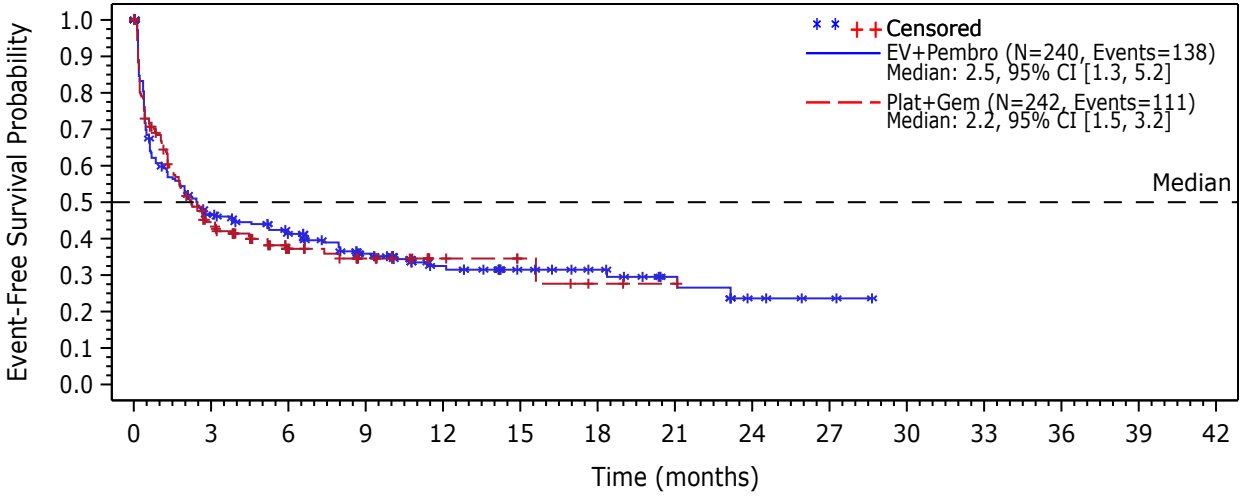
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=10 point increase before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.24.1: EQ-5D-5L - Kaplan-Meier Plot of Time to first Deterioration of VAS (MID=15) - Analysis Set mITT 1



at Risk

1	240	93	75	52	32	21	17	10	4	2	0	0	0	0	0
2	242	72	33	20	8	5	2	1	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; VAS=visual analogue scale.

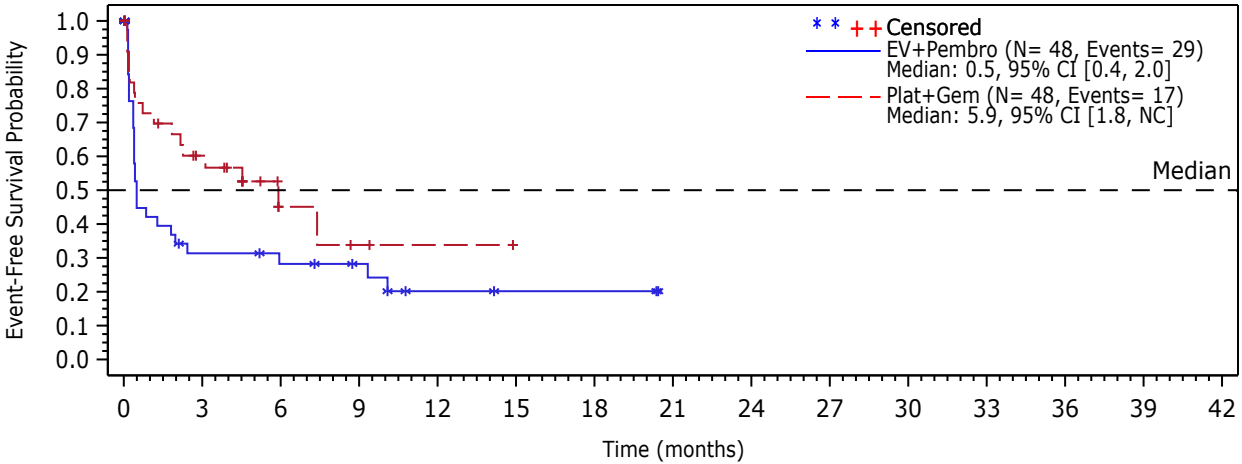
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=15 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.24.1.1: EQ-5D-5L - Kaplan-Meier Plot of Time to first Deterioration of VAS (MID=15) by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Present



at Risk

1	48	11	9	7	3	2	2	0	0	0	0	0	0	0	0
2	48	17	4	2	1	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; VAS=visual analogue scale.

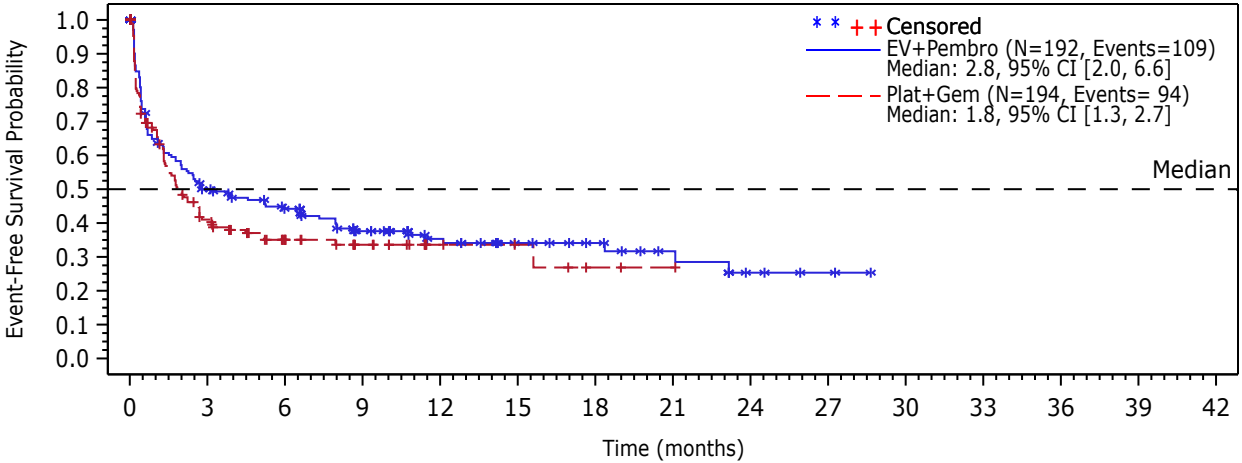
Note: Time to first deterioration is defined as time from randomization to the first observation with a >=15 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.24.1.1: EQ-5D-5L - Kaplan-Meier Plot of Time to first Deterioration of VAS (MID=15) by Liver Metastases - Analysis Set mITT 1

Liver Metastases: Absent



at Risk

1	192	82	66	45	29	19	15	10	4	2	0	0	0	0	0
2	194	55	29	18	7	5	2	1	0	0	0	0	0	0	0

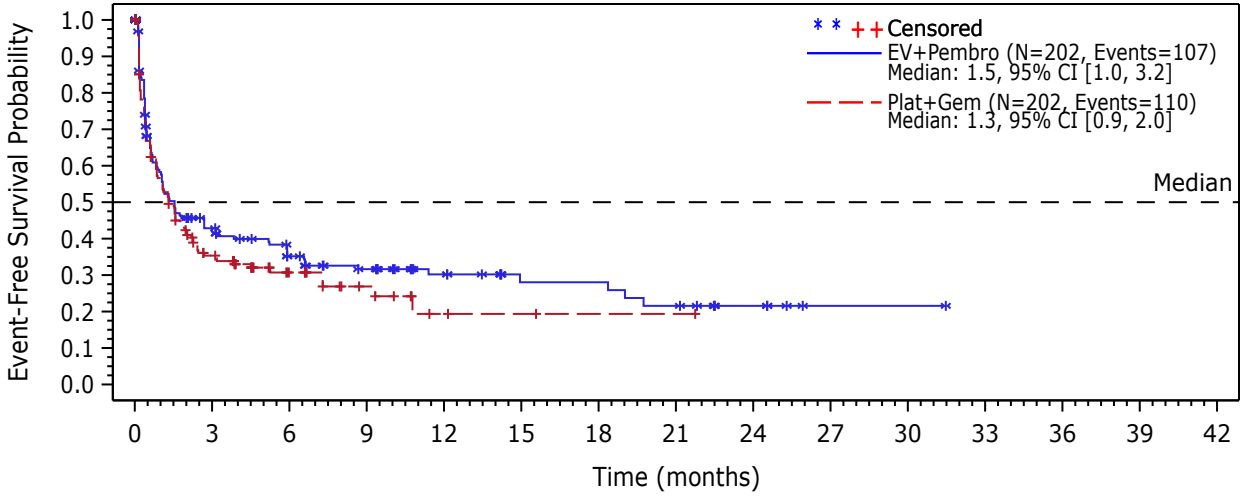
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; VAS=visual analogue scale.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=15 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.3003.24.2: EQ-5D-5L - Kaplan-Meier Plot of Time to first Deterioration of VAS (MID=15) - Analysis Set mITT 2



at Risk

1	202	61	42	32	21	13	13	10	5	1	1	0	0	0	0
2	202	48	20	10	3	2	1	1	0	0	0	0	0	0	0

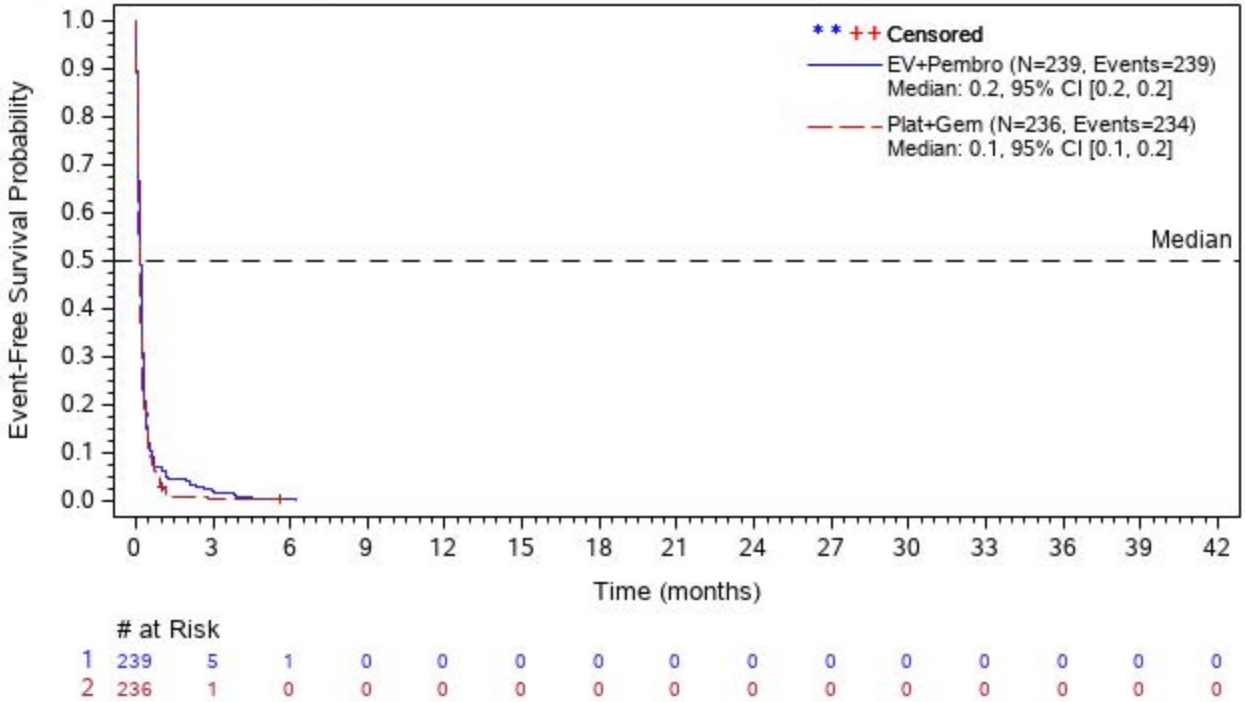
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EQ-5D-5L=European Quality of Life 5 dimensions 5 level; EV=enfortumab vedotin; Gem=gemcitabine; MID=minimal important difference; mITT=modified intent-to-treat; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; VAS=visual analogue scale.

Note: Time to first deterioration is defined as time from randomization to the first observation with a >=15 point decrease before subsequent anticancer treatment. Otherwise, censoring date is the date of the last available assessment of the parameter before subsequent anticancer treatment (if any).

Patients with no baseline and/or no post-baseline assessments as well as patients whose baseline scores do not allow for further deterioration are censored at the date of randomization.

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.1.1.1: Kaplan-Meier Plot of Time to first TEAE - Analysis Set mSAF 1

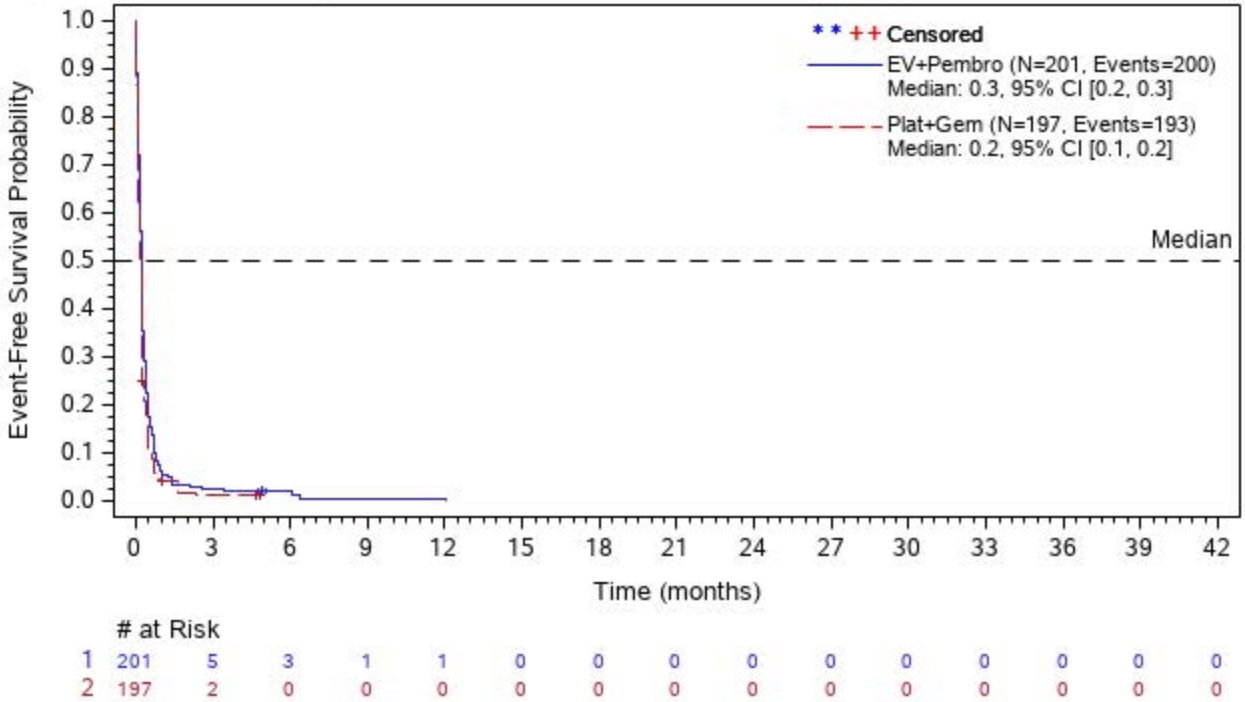


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.1.2.1: Kaplan-Meier Plot of Time to first TEAE - Analysis Set mSAF 2



at Risk

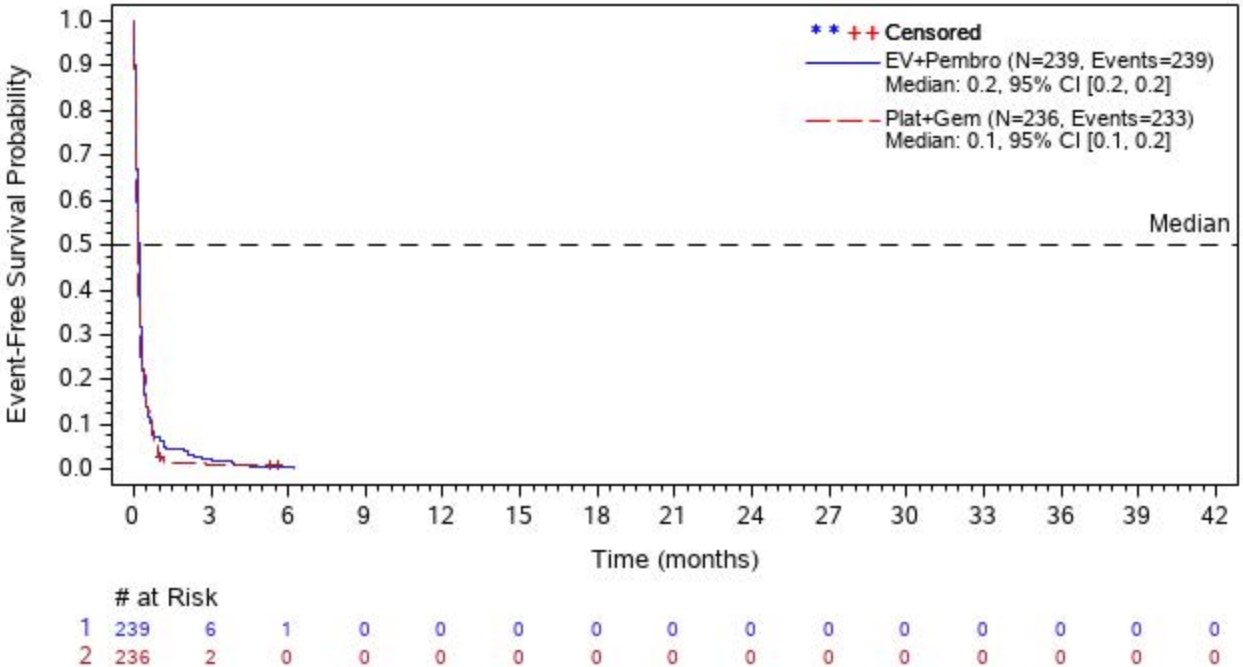
1	201	5	3	1	1	0	0	0	0	0	0	0	0	0	0
2	197	2	0	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.2.1.1: Kaplan-Meier Plot of Time to first Non-Severe TEAEs (CTCAE Grade < 3) - Analysis Set mSAF 1

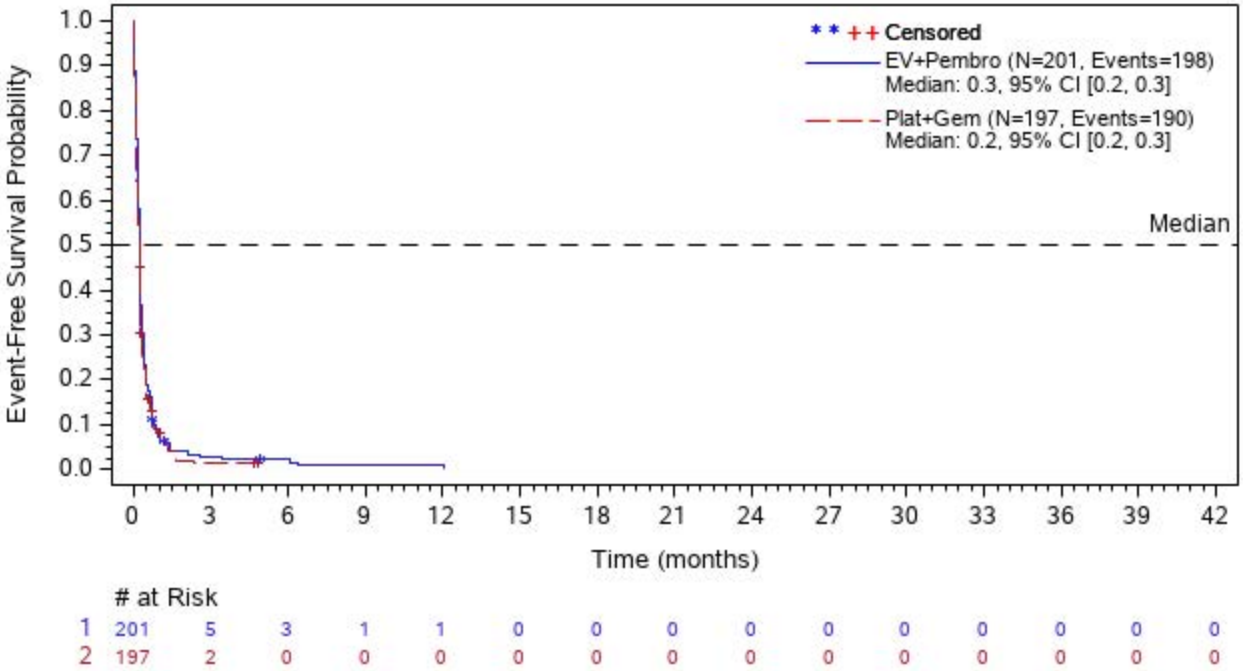


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.2.2.1: Kaplan-Meier Plot of Time to first Non-Severe TEAEs (CTCAE Grade < 3) - Analysis Set mSAF 2

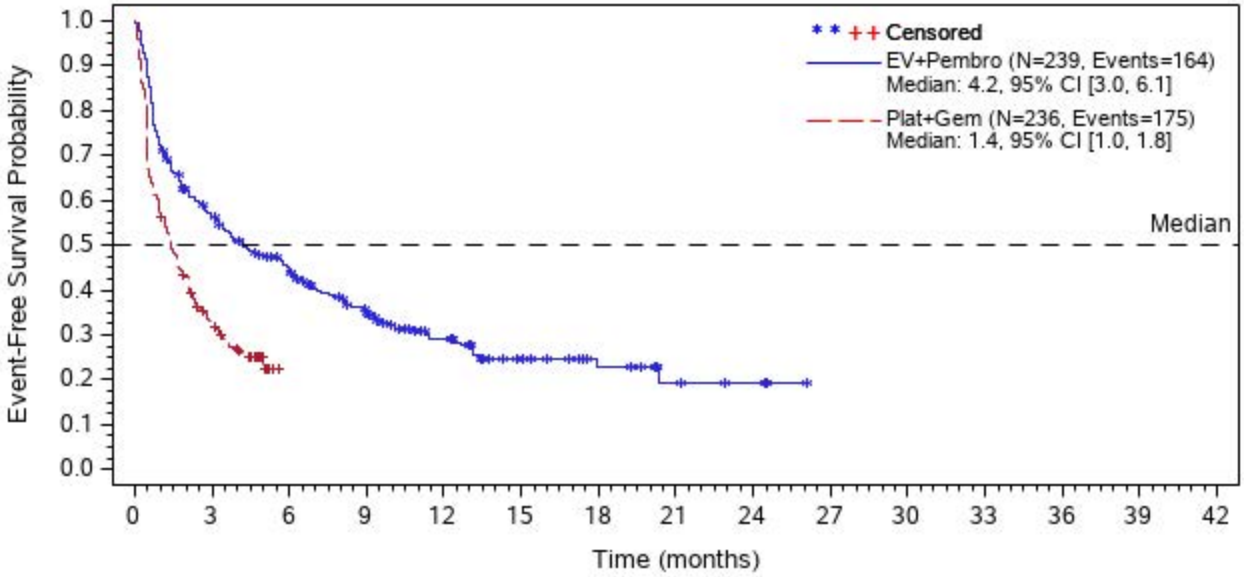


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.3.1.1: Kaplan-Meier Plot of Time to first Severe TEAEs (CTCAE Grade >= 3) - Analysis Set mSAF 1



at Risk

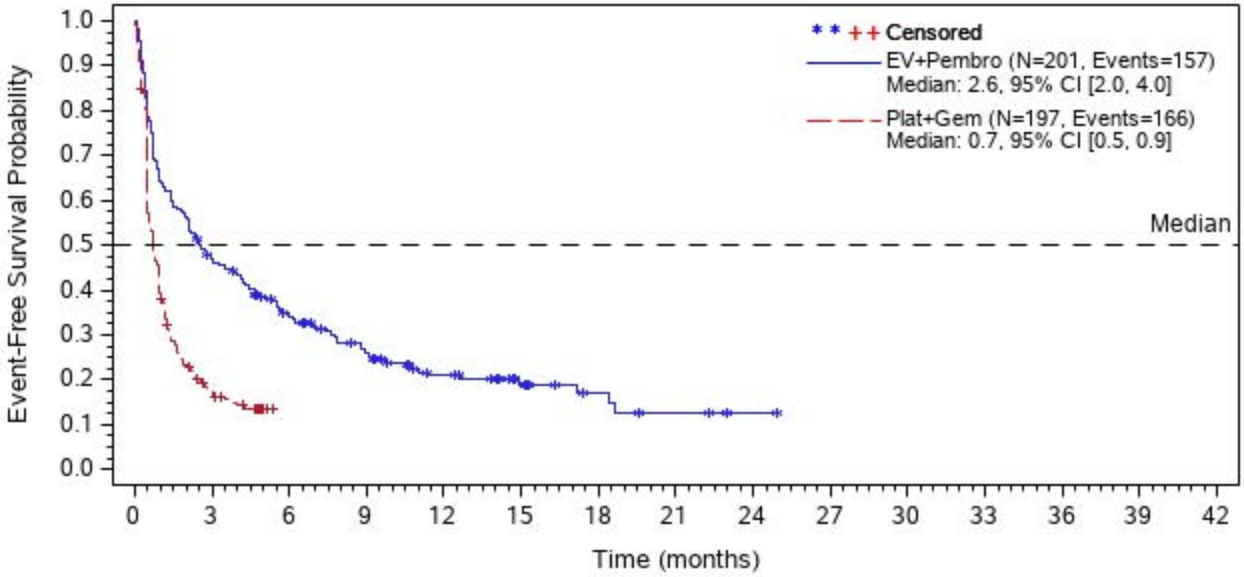
1	239	129	94	64	38	22	13	5	3	0	0	0	0	0	0
2	236	71	0	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.3.2.1: Kaplan-Meier Plot of Time to first Severe TEAEs (CTCAE Grade >= 3) - Analysis Set mSAF 2



at Risk

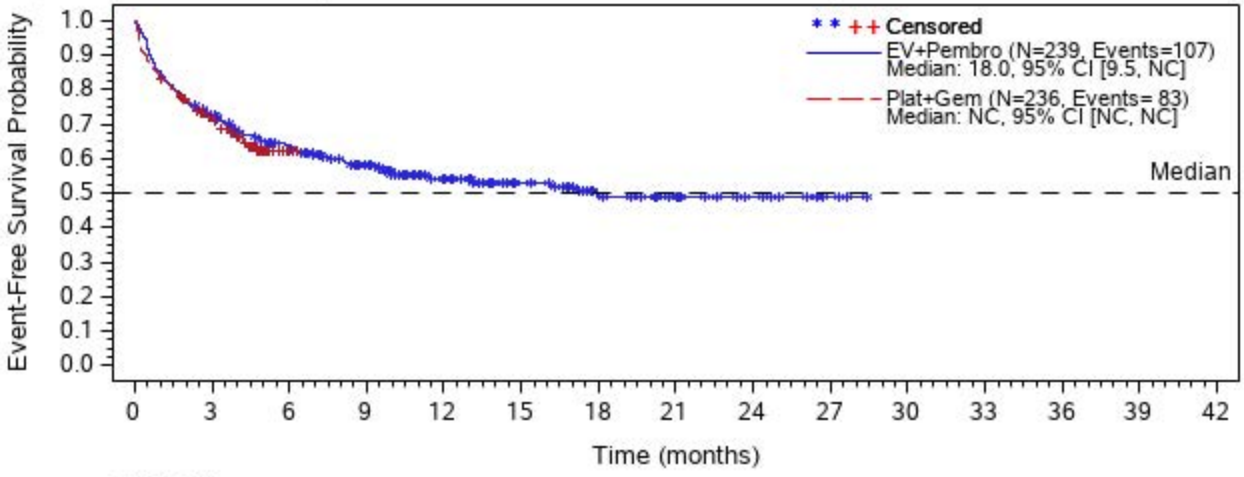
1	201	92	62	42	26	16	8	4	1	0	0	0	0	0	0
2	197	30	0	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.4.1.1: Kaplan-Meier Plot of Time to first TESAE - Analysis Set mSAF 1



at Risk

1	239	171	133	104	70	48	28	18	10	3	0	0	0	0	0
2	236	154	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAE=treatment-emergent serious adverse event.

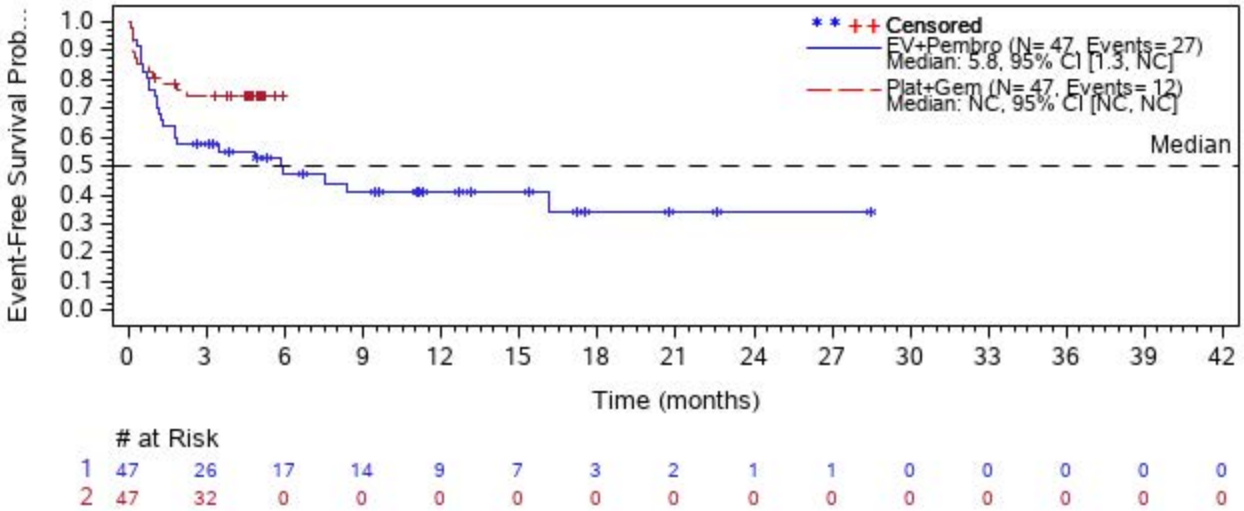
Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.4.1.2.1: Kaplan-Meier Plot of Time to first TESAE by Liver Metastases - Analysis Set mSAF 1

Liver Metastases: Present



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAE=treatment-emergent serious adverse event.

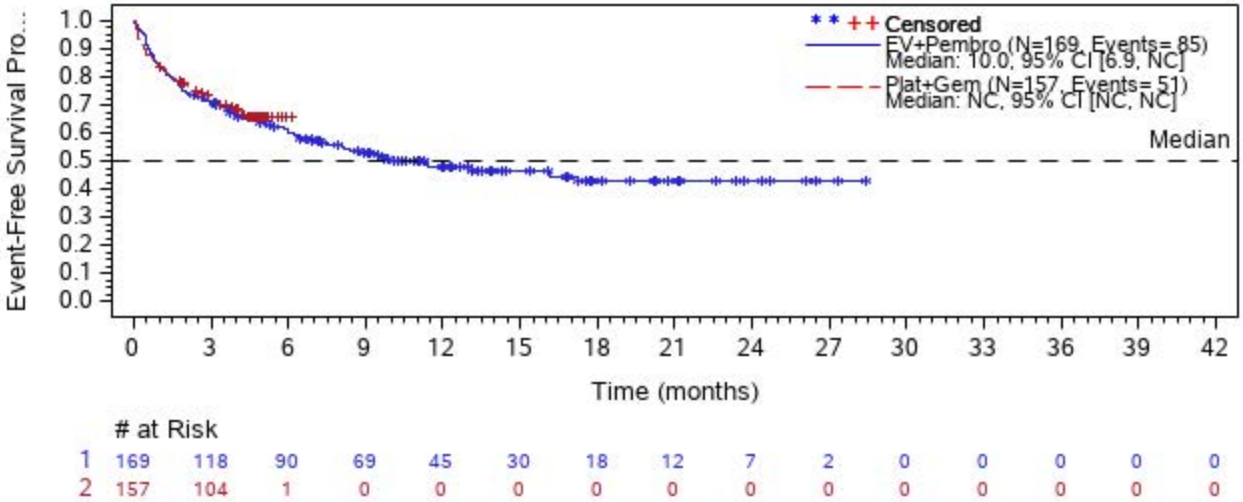
Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.4.1.2.5: Kaplan-Meier Plot of Time to first TESAE by Metastases at Baseline - Analysis Set mSAF 1

Metastases at Baseline: Visceral metastases



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAE=treatment-emergent serious adverse event.

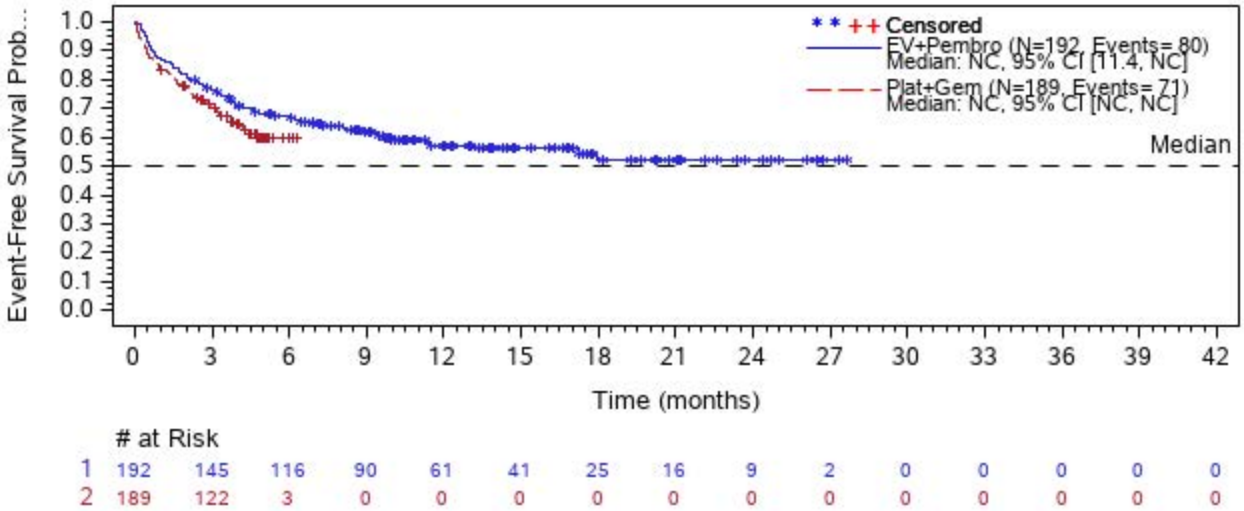
Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.4.1.2.1: Kaplan-Meier Plot of Time to first TESAE by Liver Metastases - Analysis Set mSAF 1

Liver Metastases: Absent



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAE=treatment-emergent serious adverse event.

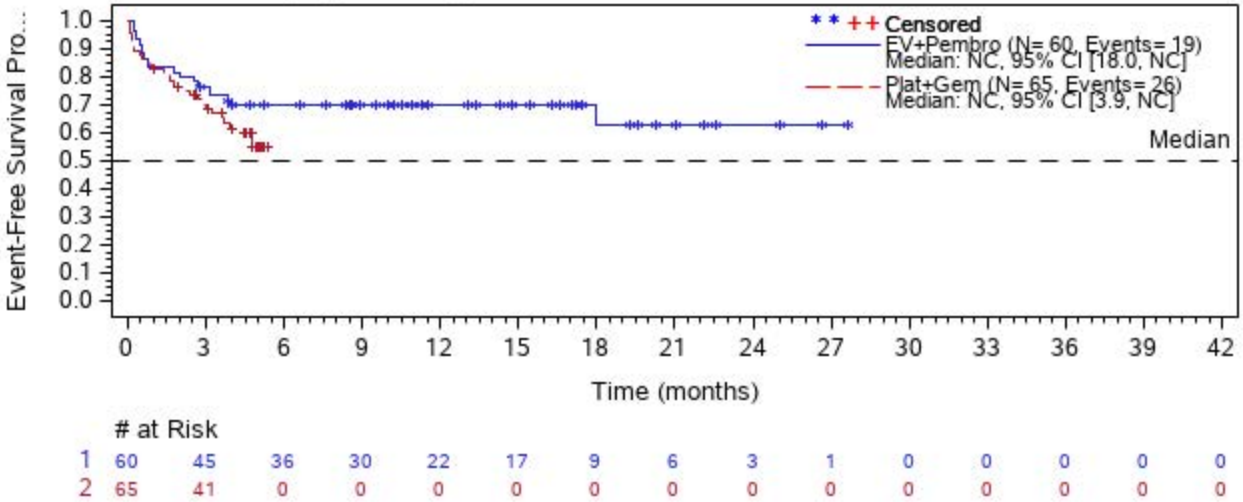
Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.4.1.2.5: Kaplan-Meier Plot of Time to first TESAE by Metastases at Baseline - Analysis Set mSAF 1

Metastases at Baseline: Lymph node only



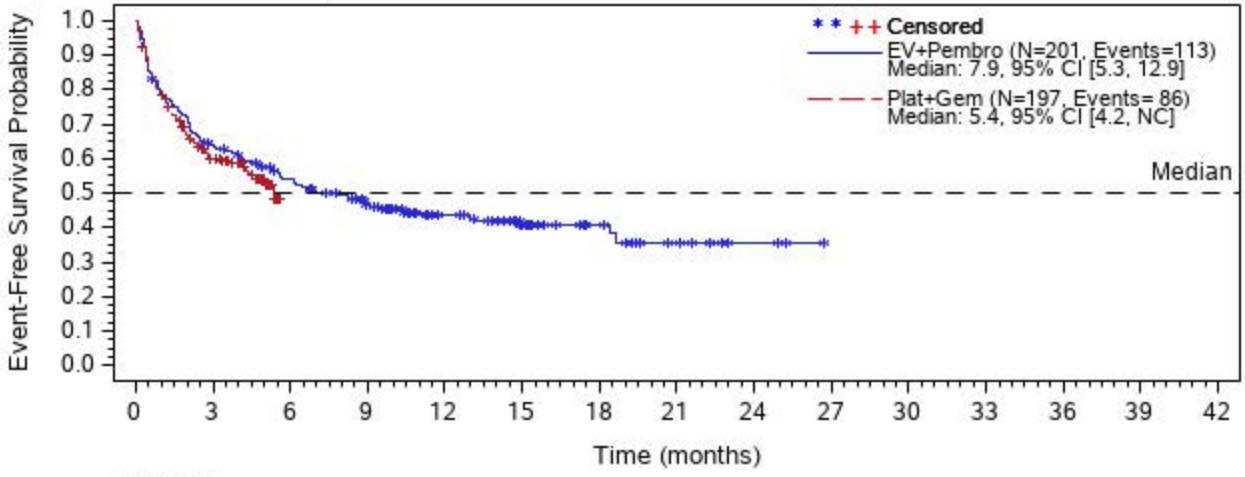
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAE=treatment-emergent serious adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.4.2.1: Kaplan-Meier Plot of Time to first TESAE - Analysis Set mSAF 2



at Risk

1	201	125	98	74	48	32	18	9	3	0	0	0	0	0	0
2	197	100	0	0	0	0	0	0	0	0	0	0	0	0	0

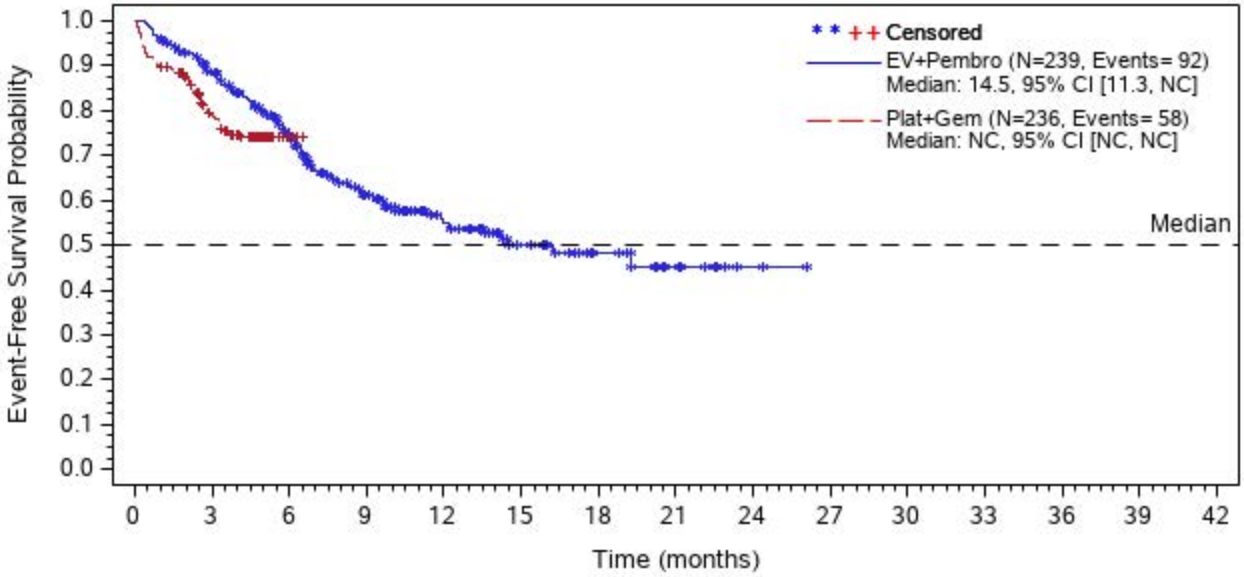
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAE=treatment-emergent serious adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.5.1.1: Kaplan-Meier Plot of Time to first Treatment Discontinuation of Any Study Drugs due to TEAEs - Analysis Set mSAF 1



at Risk

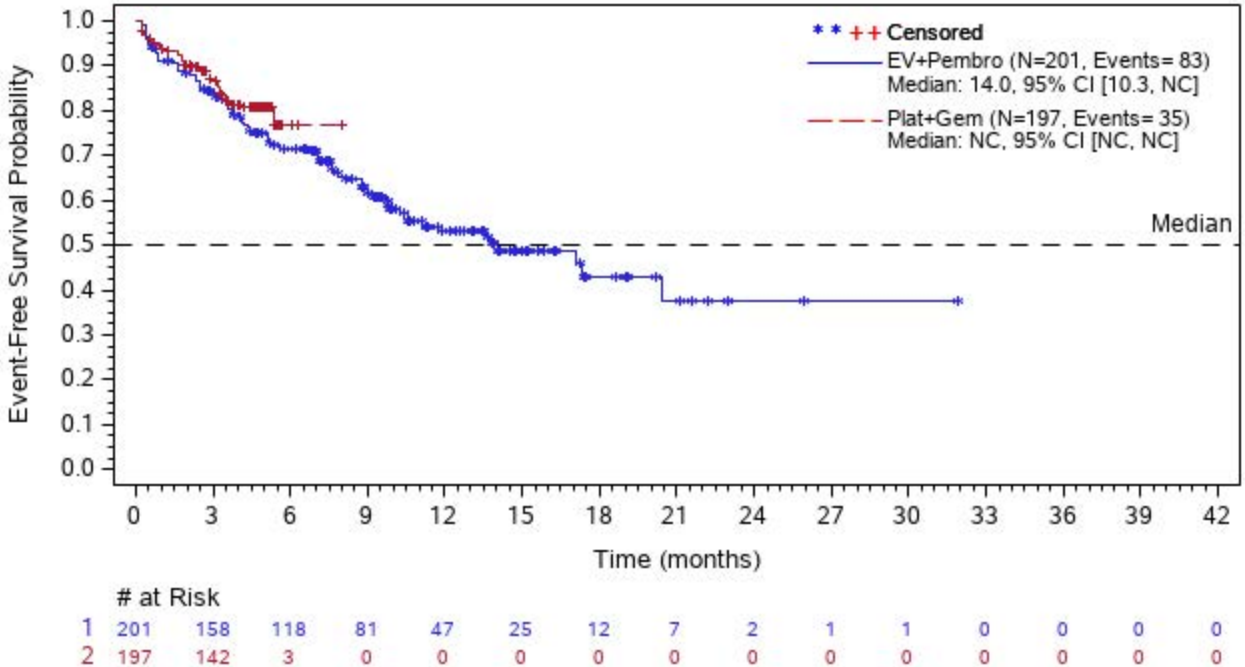
1	239	194	141	92	57	34	19	9	2	0	0	0	0	0	0
2	236	164	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.5.2.1: Kaplan-Meier Plot of Time to first Treatment Discontinuation of Any Study Drugs due to TEAEs - Analysis Set mSAF 2

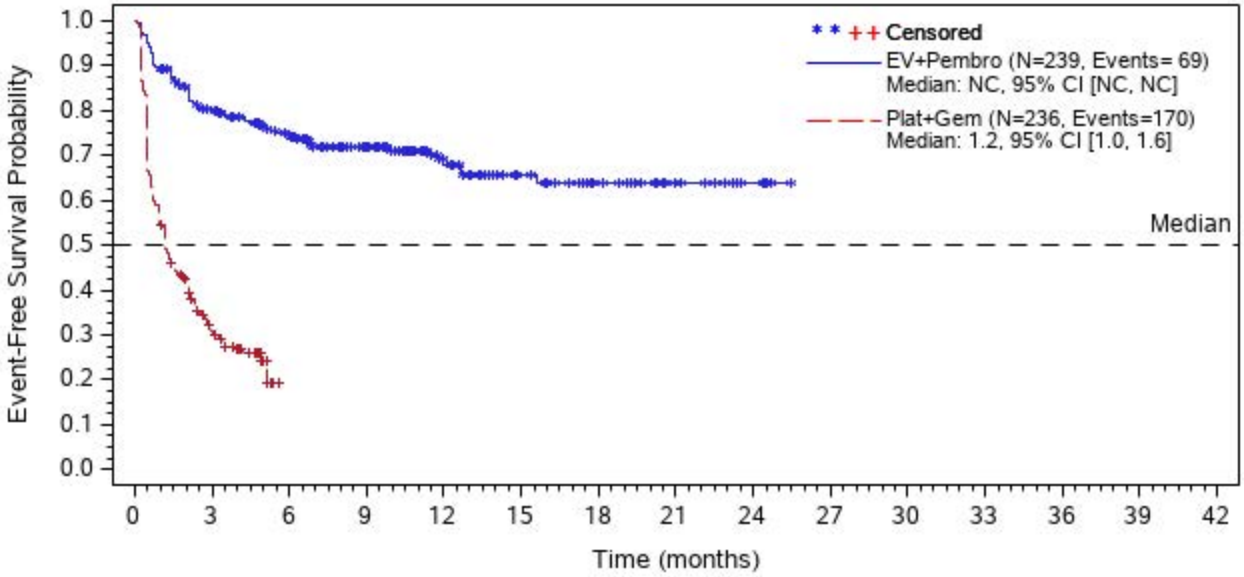


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.6.1.1: Kaplan-Meier Plot of Time to first TEAE - Blood and lymphatic system disorders (SOC) - Analysis Set mSAF 1



at Risk

1	239	174	137	101	62	39	25	13	6	0	0	0	0	0	0
2	236	62	0	0	0	0	0	0	0	0	0	0	0	0	0

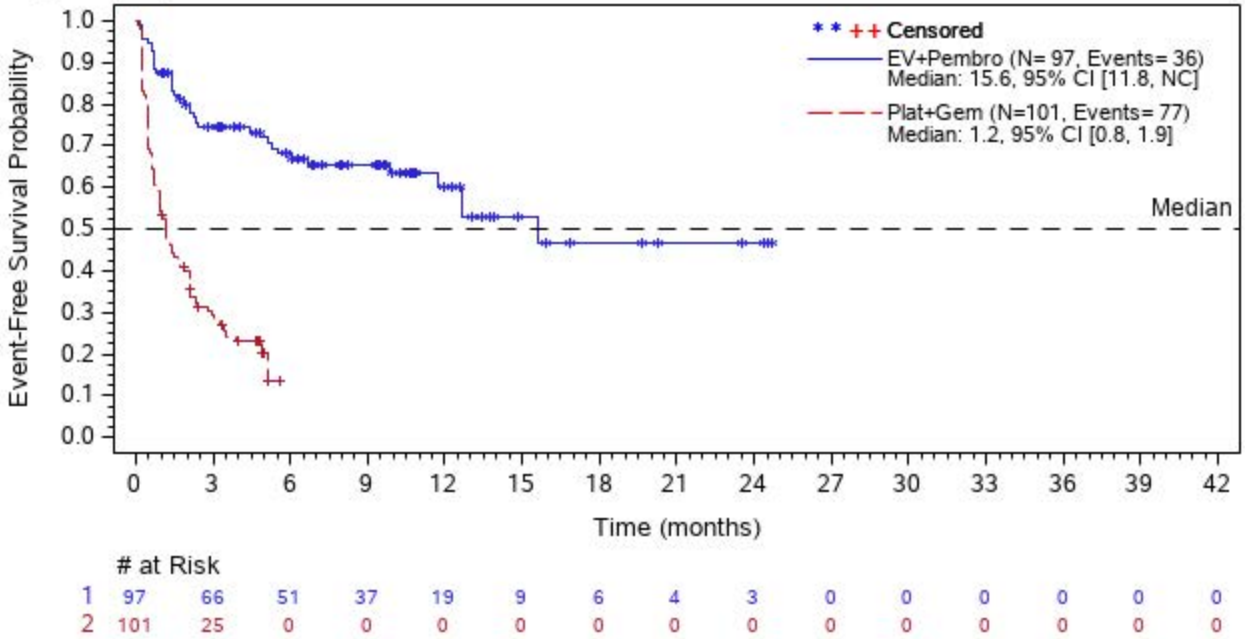
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.6.1.2.3: Kaplan-Meier Plot of Time to first TEAE - Blood and lymphatic system disorders (SOC) - Analysis Set mSAF 1

Region: Europe



at Risk

1	97	66	51	37	19	9	6	4	3	0	0	0	0	0	0
2	101	25	0	0	0	0	0	0	0	0	0	0	0	0	0

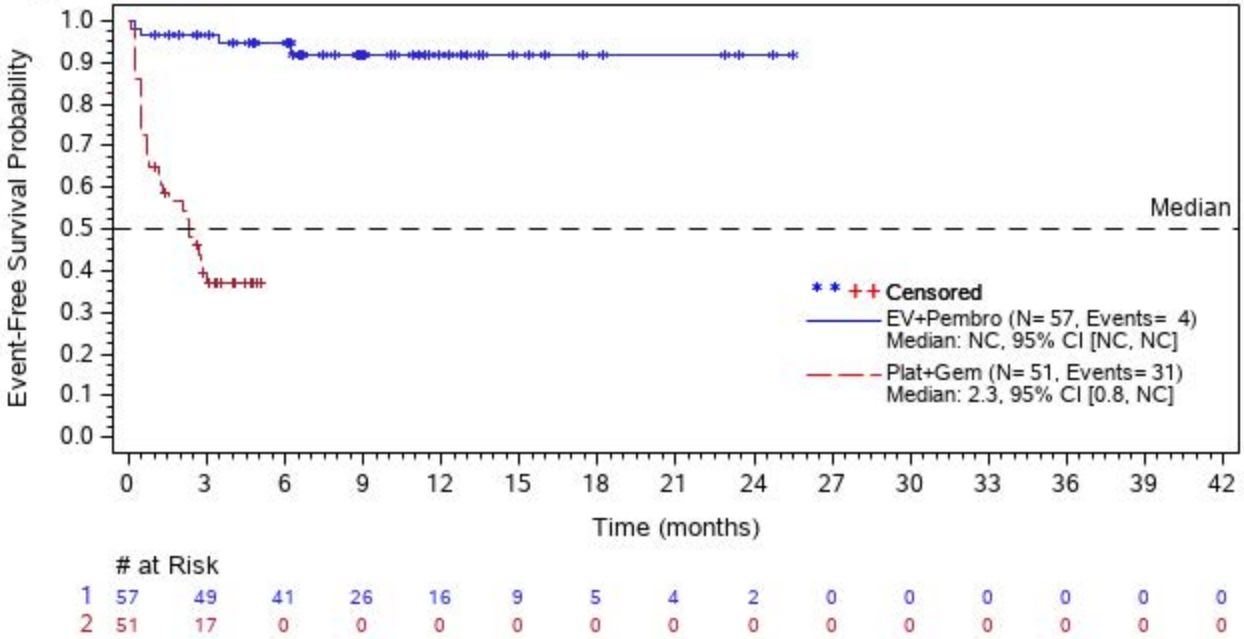
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.6.1.2.3: Kaplan-Meier Plot of Time to first TEAE - Blood and lymphatic system disorders (SOC) - Analysis Set mSAF 1

Region: North America



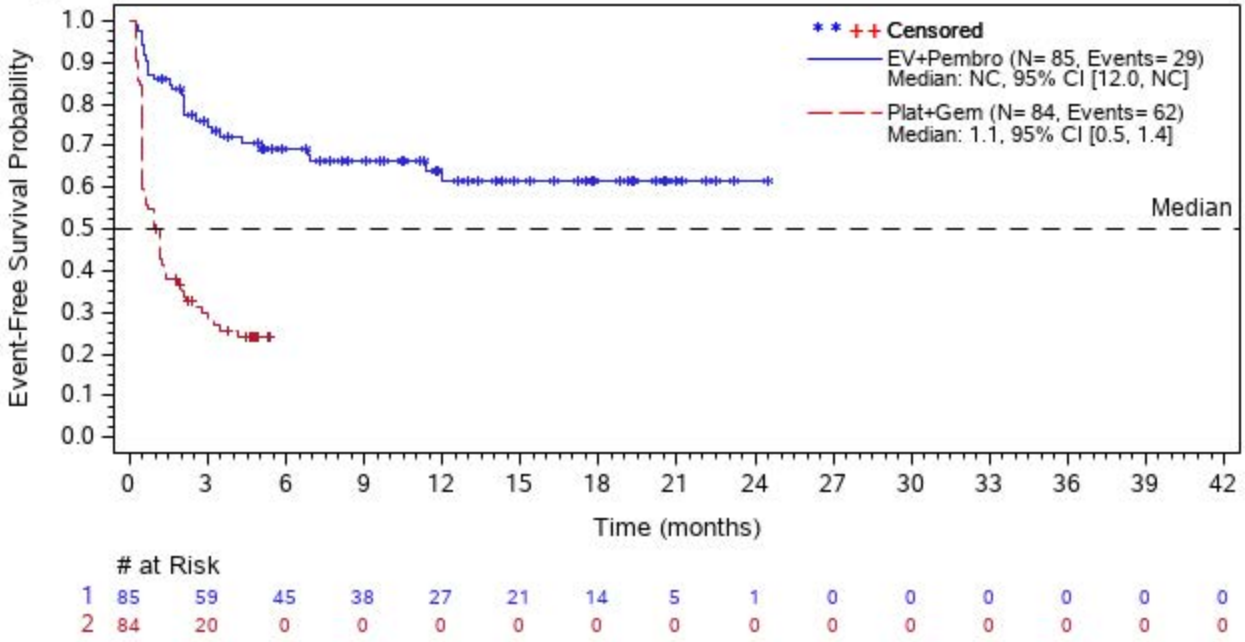
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.6.1.2.3: Kaplan-Meier Plot of Time to first TEAE - Blood and lymphatic system disorders (SOC) - Analysis Set mSAF 1

Region: Rest of World



at Risk

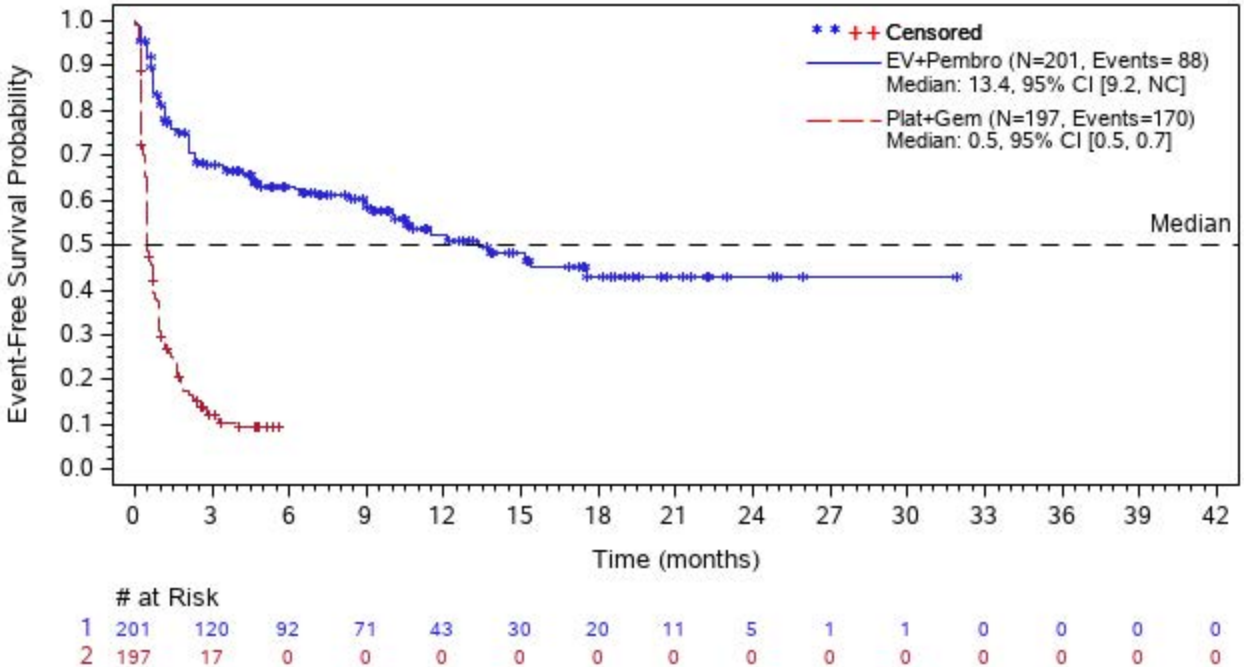
1	85	59	45	38	27	21	14	5	1	0	0	0	0	0	0
2	84	20	0	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.6.2.1: Kaplan-Meier Plot of Time to first TEAE - Blood and lymphatic system disorders (SOC) - Analysis Set mSAF 2



at Risk

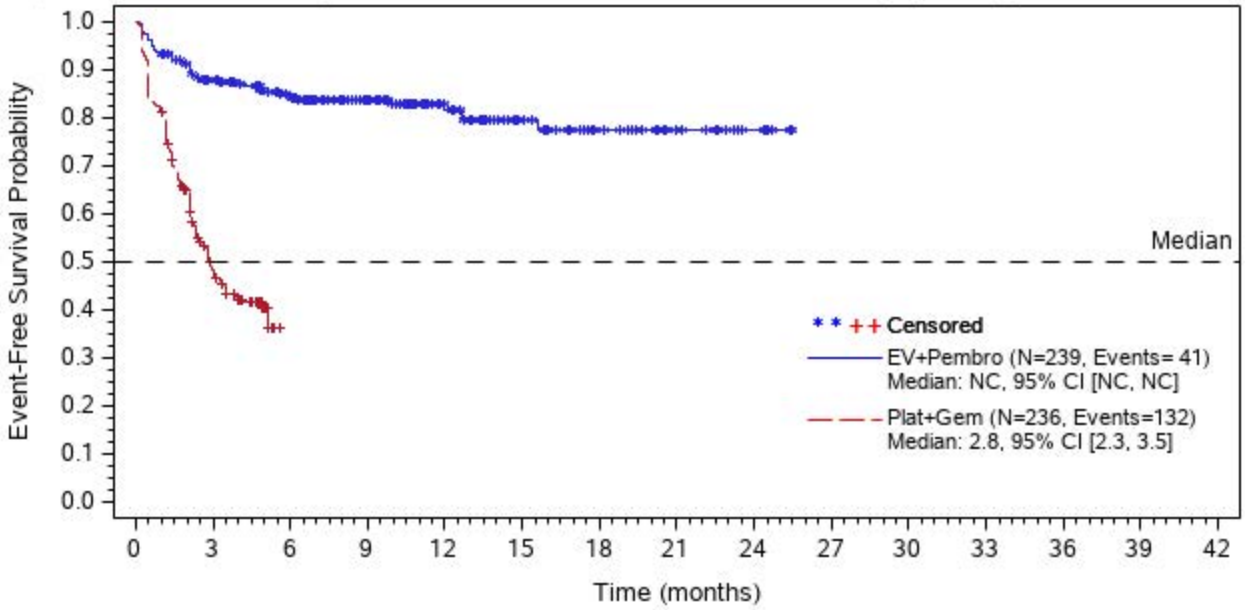
1	201	120	92	71	43	30	20	11	5	1	1	0	0	0	0
2	197	17	0	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.7.1.1: Kaplan-Meier Plot of Time to first TEAE - Anaemia (PT) - Analysis Set mSAF 1



at Risk

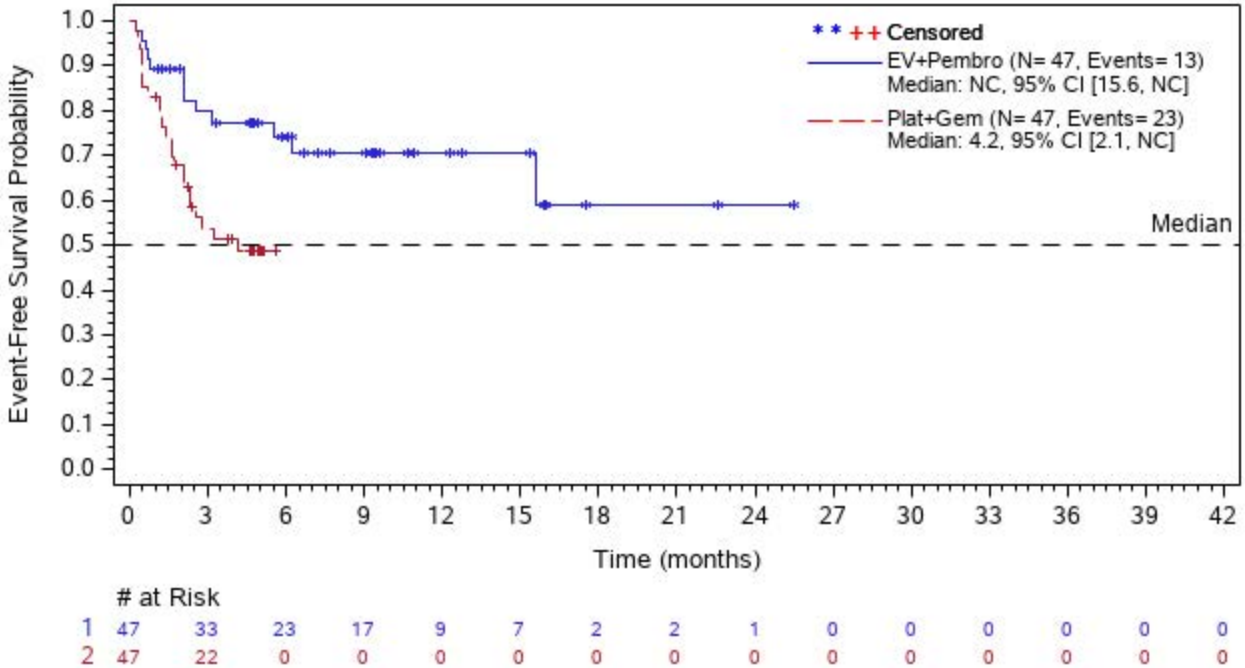
1	239	189	152	113	74	46	29	16	7	0	0	0	0	0	0
2	236	100	0	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.7.1.2.1: Kaplan-Meier Plot of Time to first TEAE - Anaemia (PT) - Analysis Set mSAF 1 Liver Metastases: Present

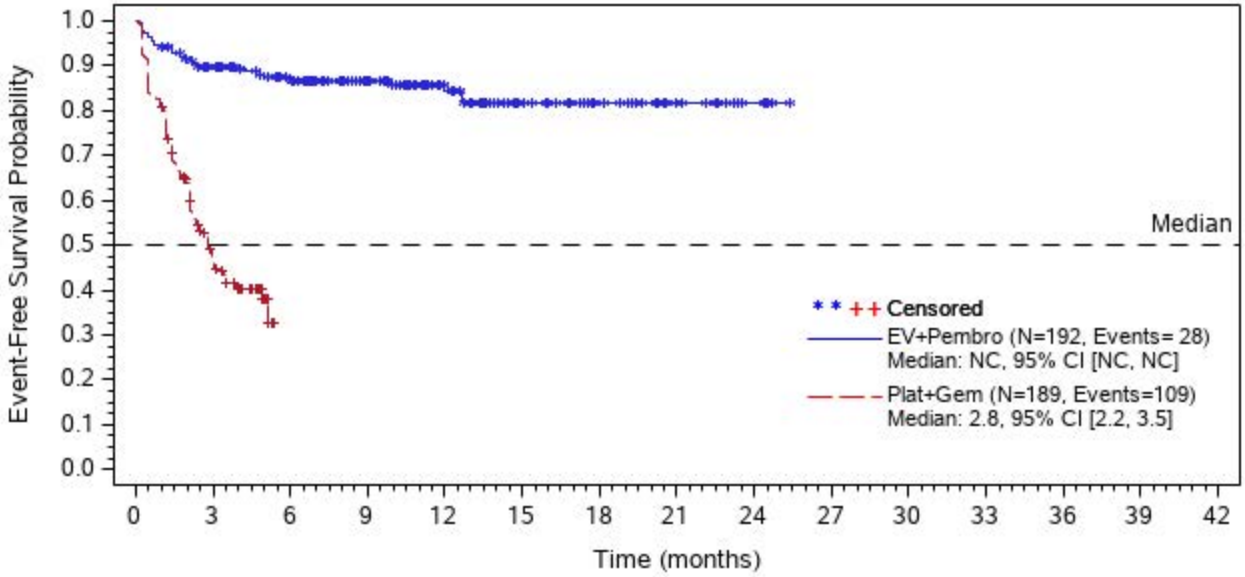


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.7.1.2.1: Kaplan-Meier Plot of Time to first TEAE - Anaemia (PT) - Analysis Set mSAF 1 Liver Metastases: Absent



at Risk

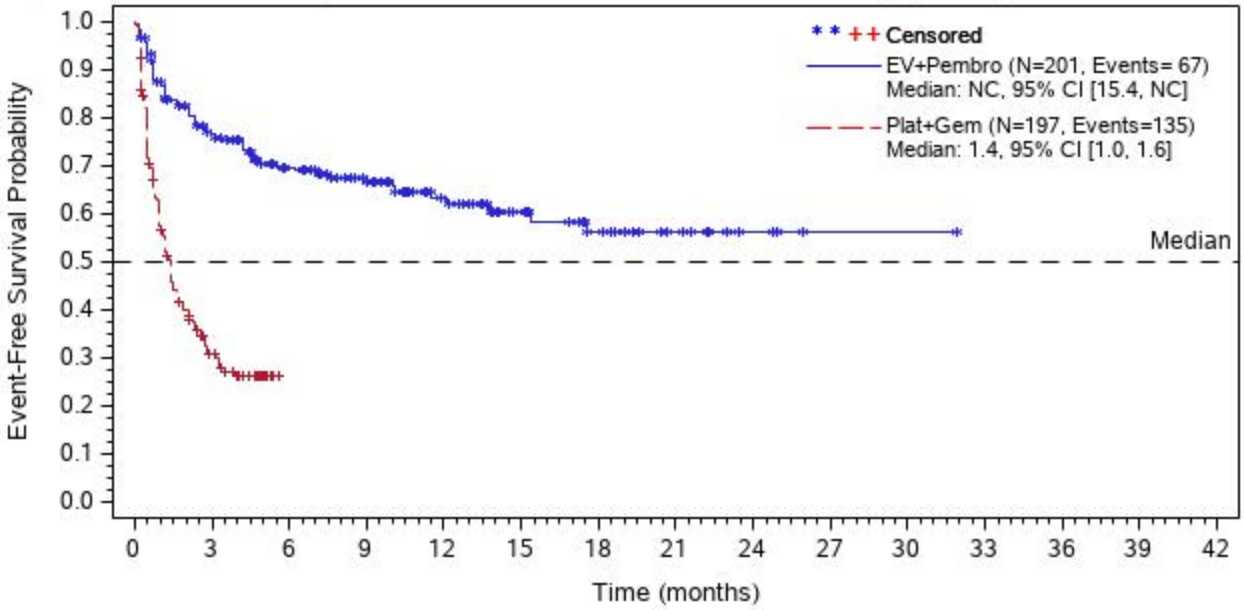
1	192	156	129	96	65	39	27	14	6	0	0	0	0	0	0
2	189	78	0	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.7.2.1: Kaplan-Meier Plot of Time to first TEAE - Anaemia (PT) - Analysis Set mSAF 2



at Risk

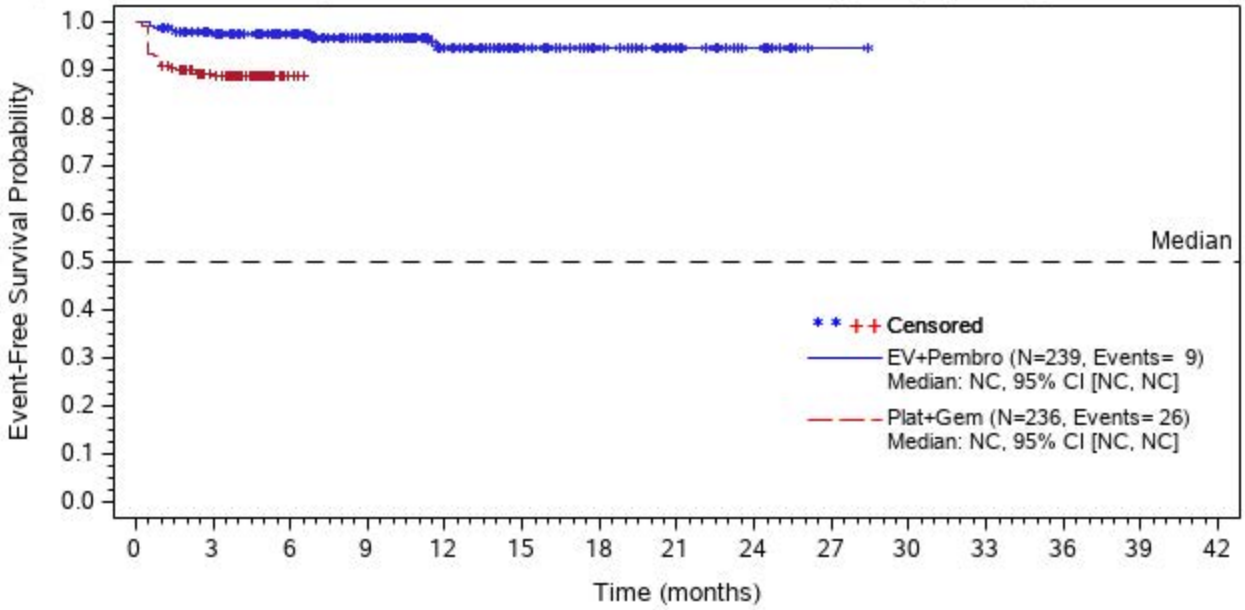
1	201	134	102	79	50	33	22	12	5	1	1	0	0	0	0
2	197	47	0	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.8.1.1: Kaplan-Meier Plot of Time to first TEAE - Leukopenia (PT) - Analysis Set mSAF 1



at Risk

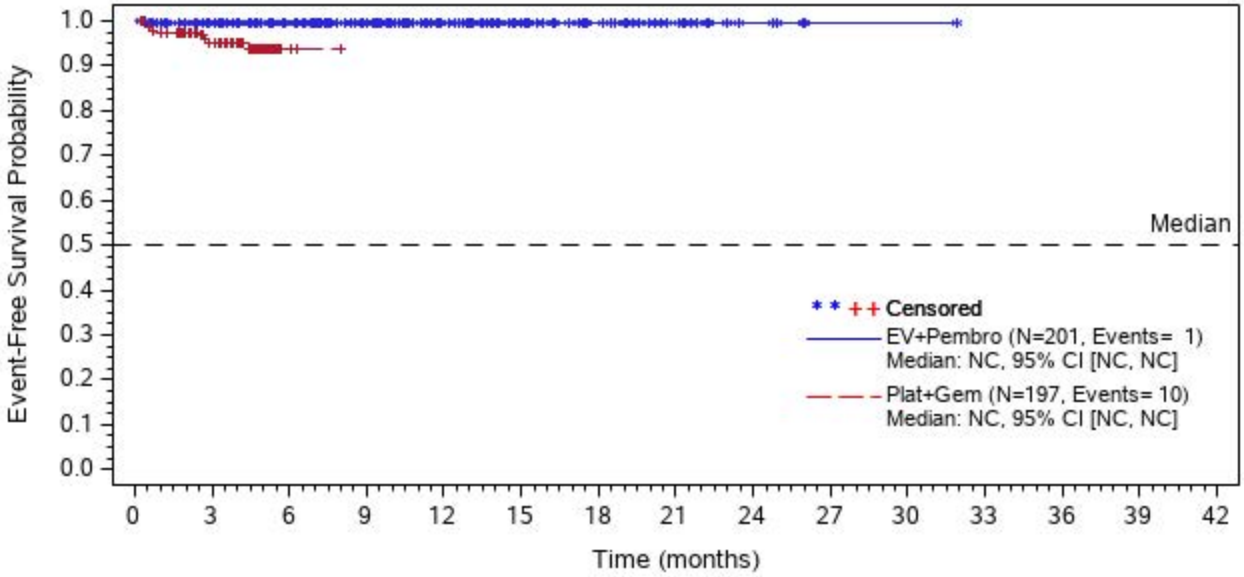
1	239	205	164	125	83	55	38	22	12	1	0	0	0	0	0
2	236	177	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.8.2.1: Kaplan-Meier Plot of Time to first TEAE - Febrile neutropenia (PT) - Analysis Set mSAF 2



at Risk

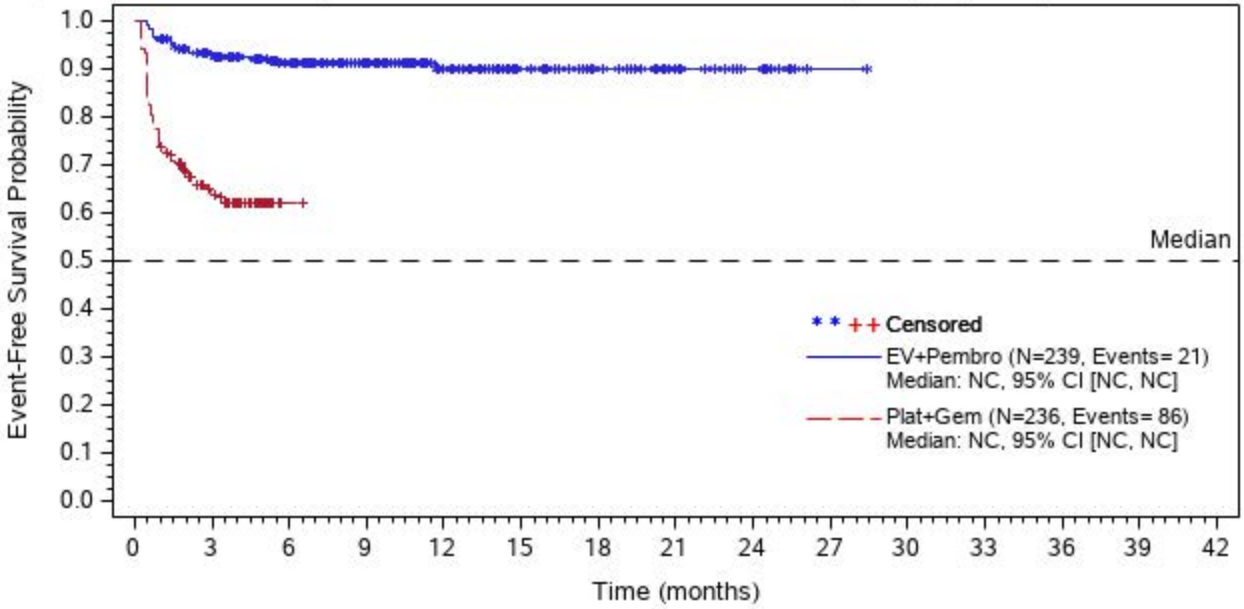
1	201	171	140	109	73	51	31	18	6	1	1	0	0	0	0
2	197	145	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.9.1.1: Kaplan-Meier Plot of Time to first TEAE - Neutropenia (PT) - Analysis Set mSAF 1



at Risk

1	239	198	155	120	77	51	35	20	12	1	0	0	0	0	0
2	236	122	1	0	0	0	0	0	0	0	0	0	0	0	0

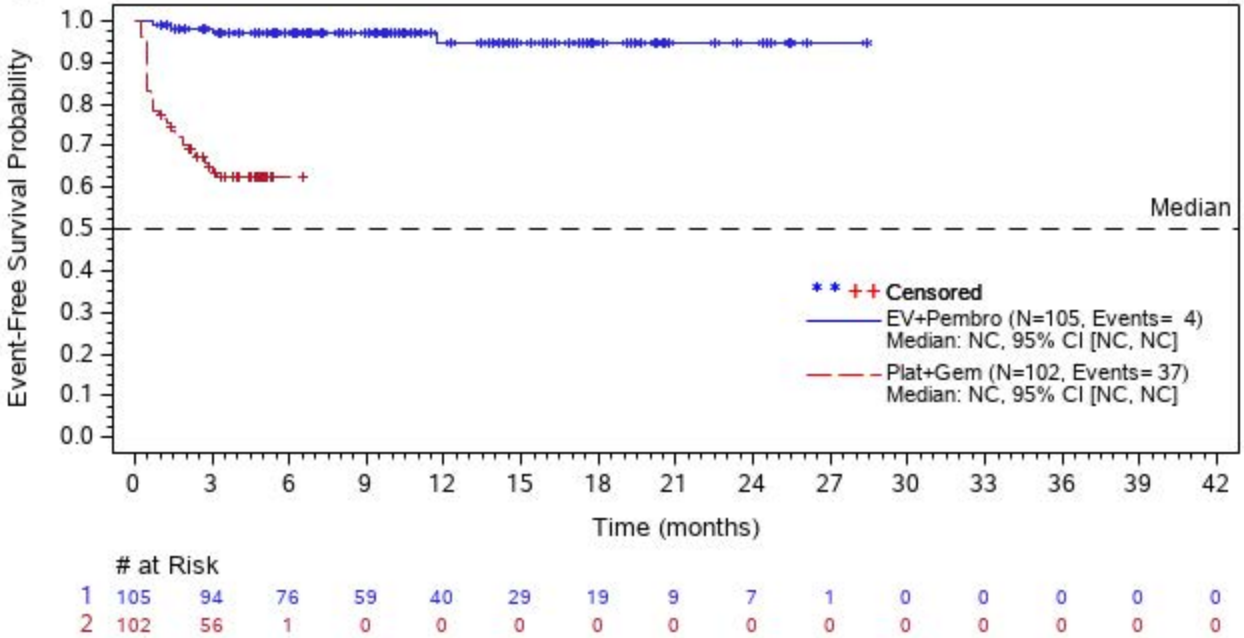
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.9.1.2.2: Kaplan-Meier Plot of Time to first TEAE - Neutropenia (PT) - Analysis Set mSAF 1

Age: < 65 years



at Risk

1	105	94	76	59	40	29	19	9	7	1	0	0	0	0	0
2	102	56	1	0	0	0	0	0	0	0	0	0	0	0	0

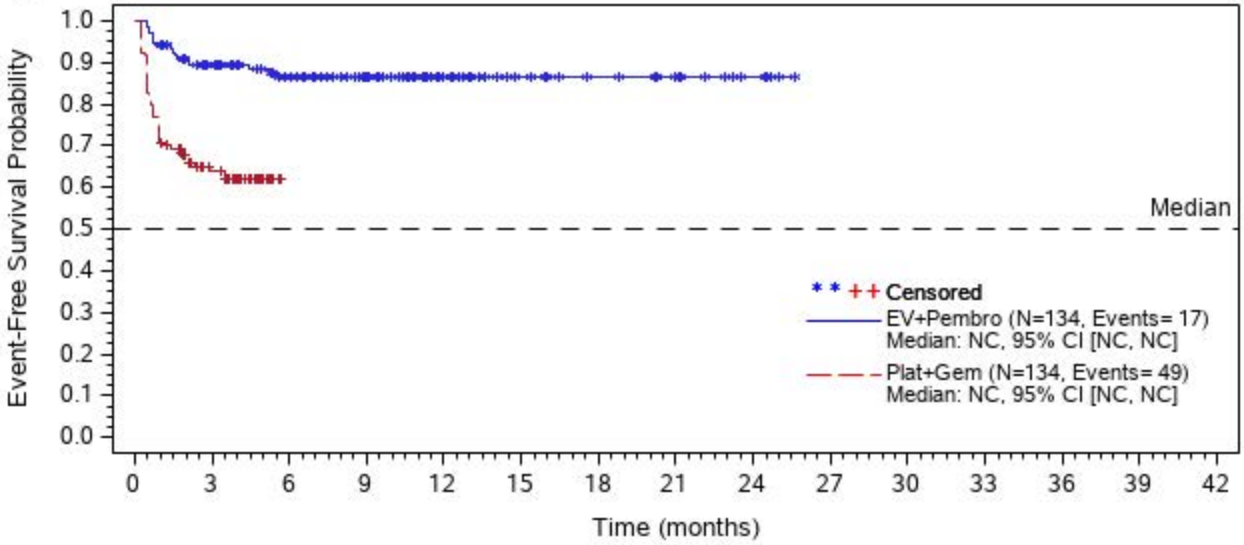
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.9.1.2.2: Kaplan-Meier Plot of Time to first TEAE - Neutropenia (PT) - Analysis Set mSAF 1

Age: >= 65 years



at Risk

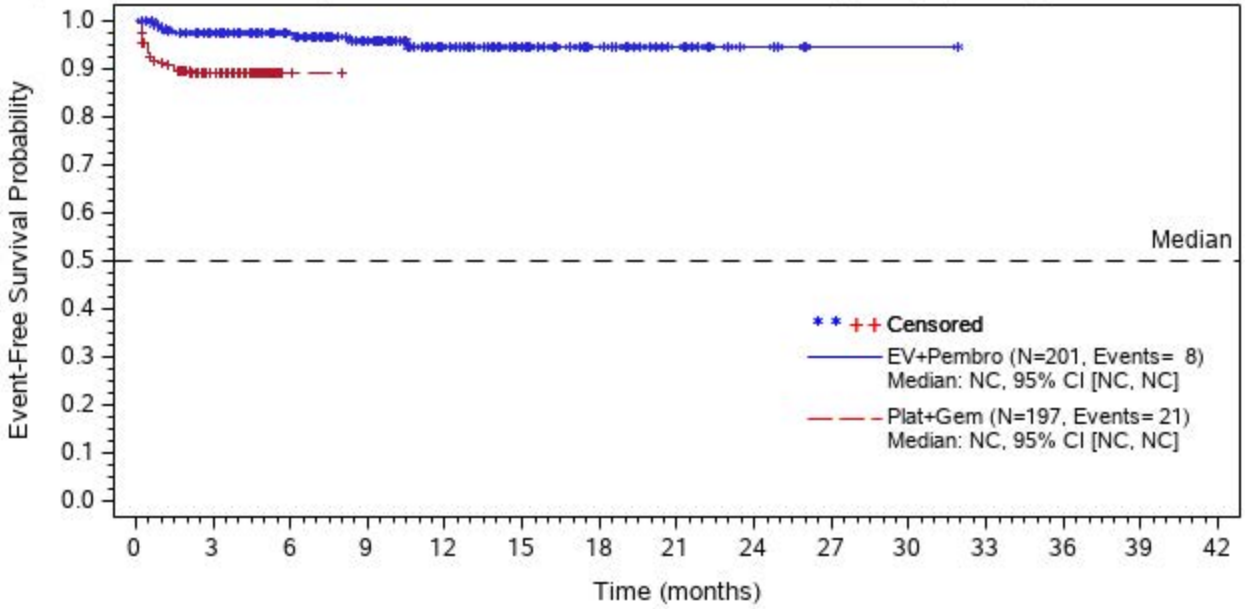
1	134	104	79	61	37	22	16	11	5	0	0	0	0	0	0
2	134	66	0	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.9.2.1: Kaplan-Meier Plot of Time to first TEAE - Leukopenia (PT) - Analysis Set mSAF 2



at Risk

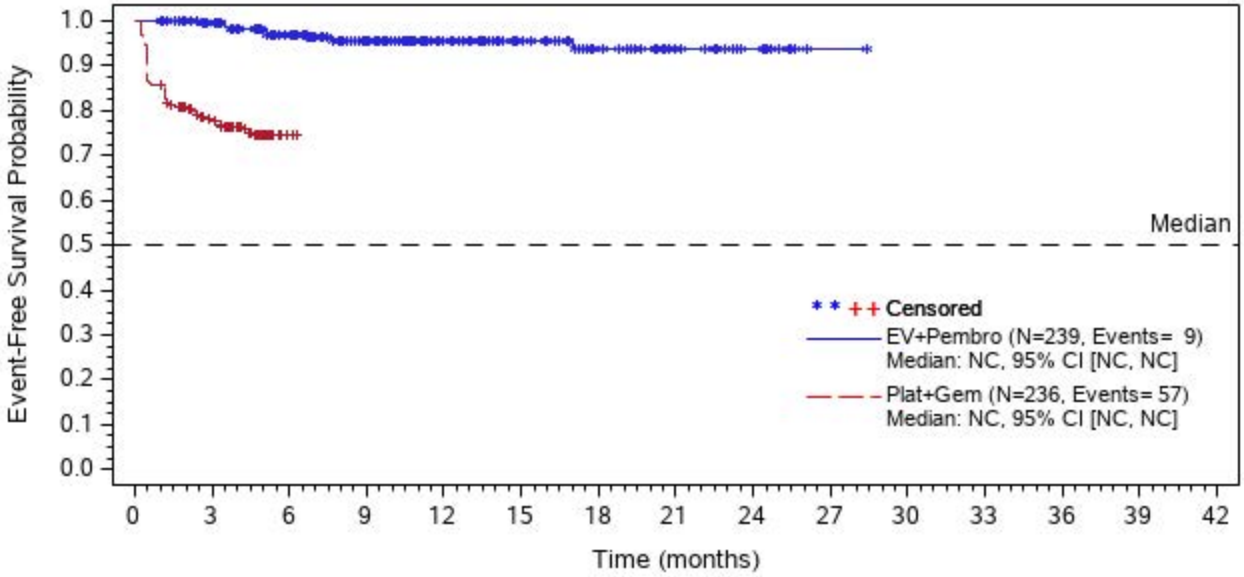
1	201	166	135	104	69	49	30	17	6	1	1	0	0	0	0
2	197	132	2	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.10.1.1: Kaplan-Meier Plot of Time to first TEAE - Thrombocytopenia (PT) - Analysis Set mSAF 1



at Risk

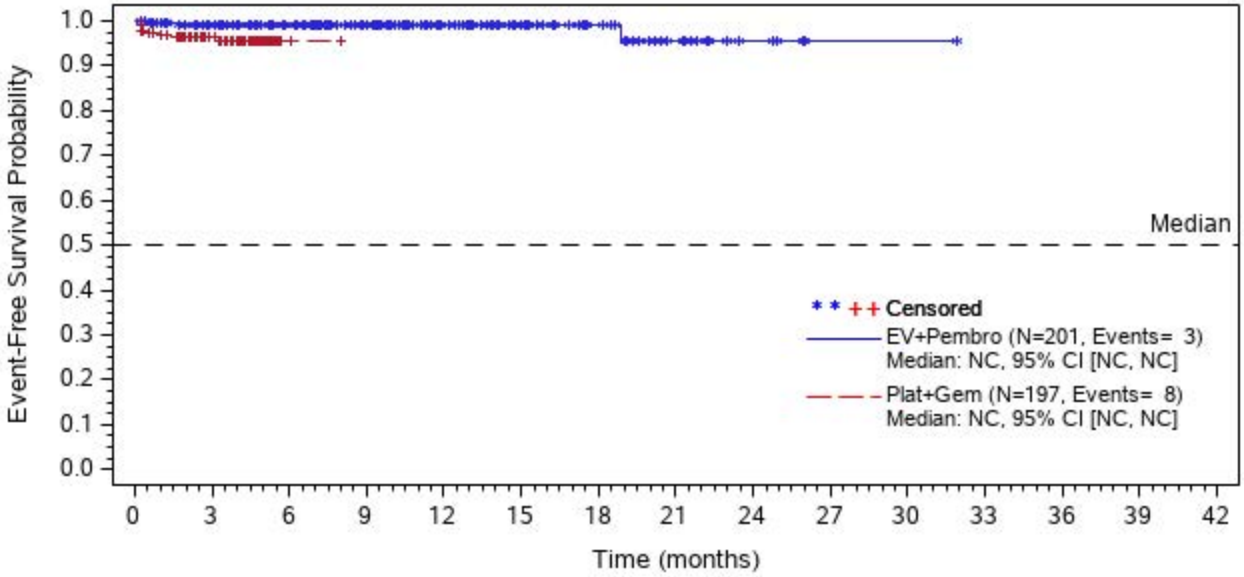
1	239	210	167	127	83	56	37	21	12	1	0	0	0	0	0
2	236	158	2	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.10.2.1: Kaplan-Meier Plot of Time to first TEAE - Lymphopenia (PT) - Analysis Set mSAF 2



at Risk

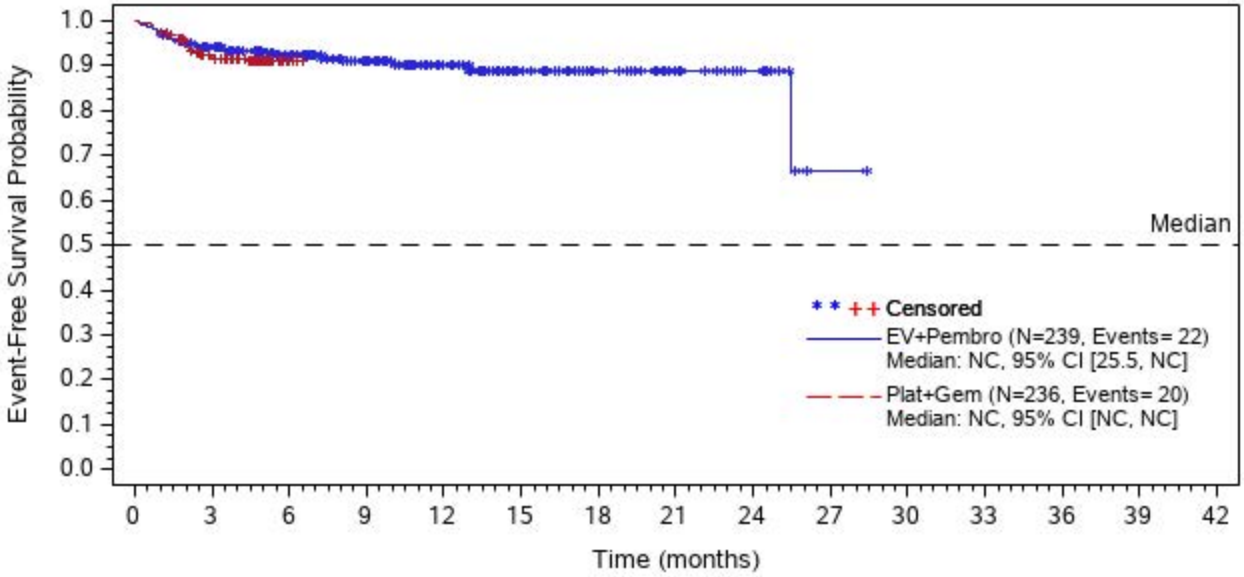
1	201	170	139	108	72	51	31	17	6	1	1	0	0	0	0
2	197	144	2	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.11.1.1: Kaplan-Meier Plot of Time to first TEAE - Cardiac disorders (SOC) - Analysis Set mSAF 1



at Risk

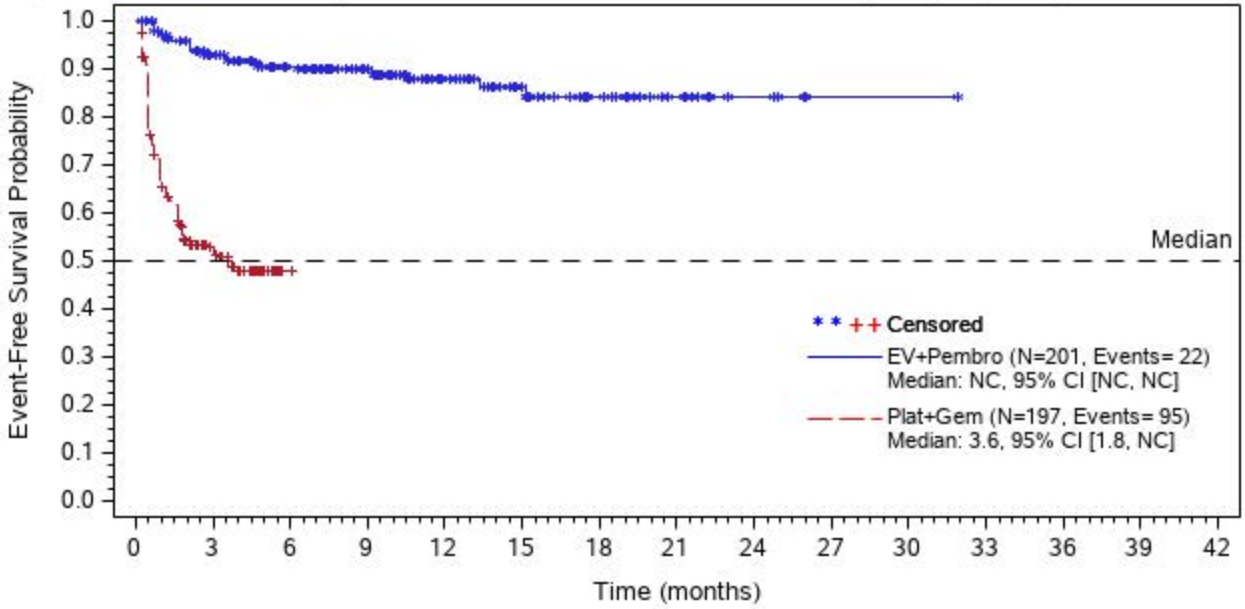
1	239	199	156	121	83	54	37	20	11	1	0	0	0	0	0
2	236	189	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.11.2.1: Kaplan-Meier Plot of Time to first TEAE - Neutropenia (PT) - Analysis Set mSAF 2



at Risk

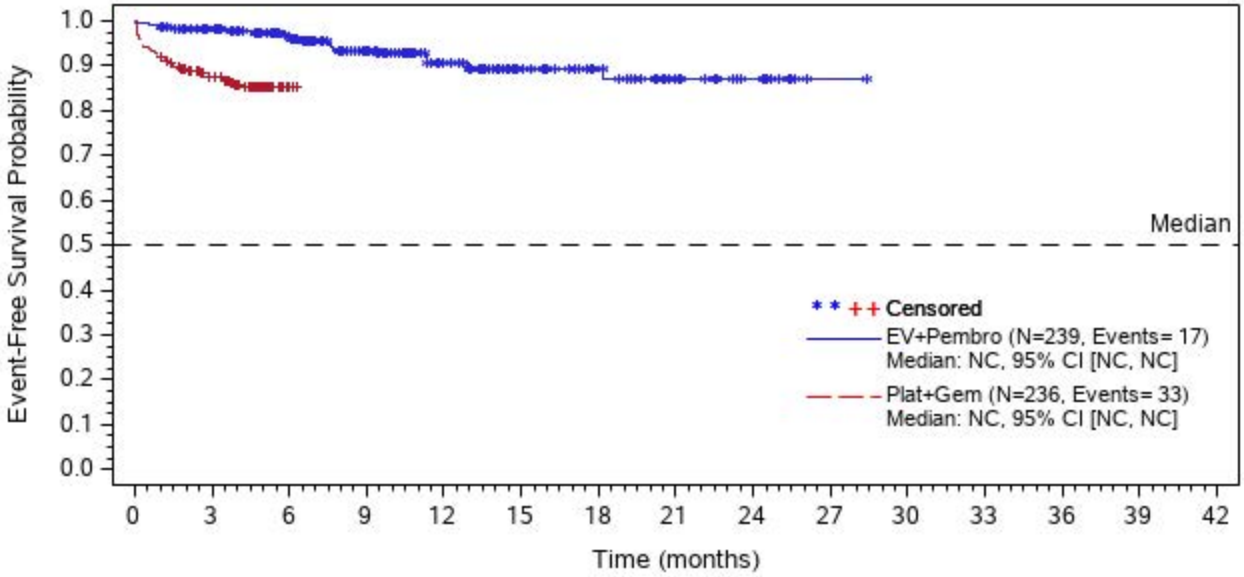
1	201	160	127	100	63	45	28	16	6	1	1	0	0	0	0
2	197	75	1	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.12.1.1: Kaplan-Meier Plot of Time to first TEAE - Ear and labyrinth disorders (SOC) - Analysis Set mSAF 1



at Risk

1	239	207	163	123	80	54	38	20	11	1	0	0	0	0	0
2	236	173	3	0	0	0	0	0	0	0	0	0	0	0	0

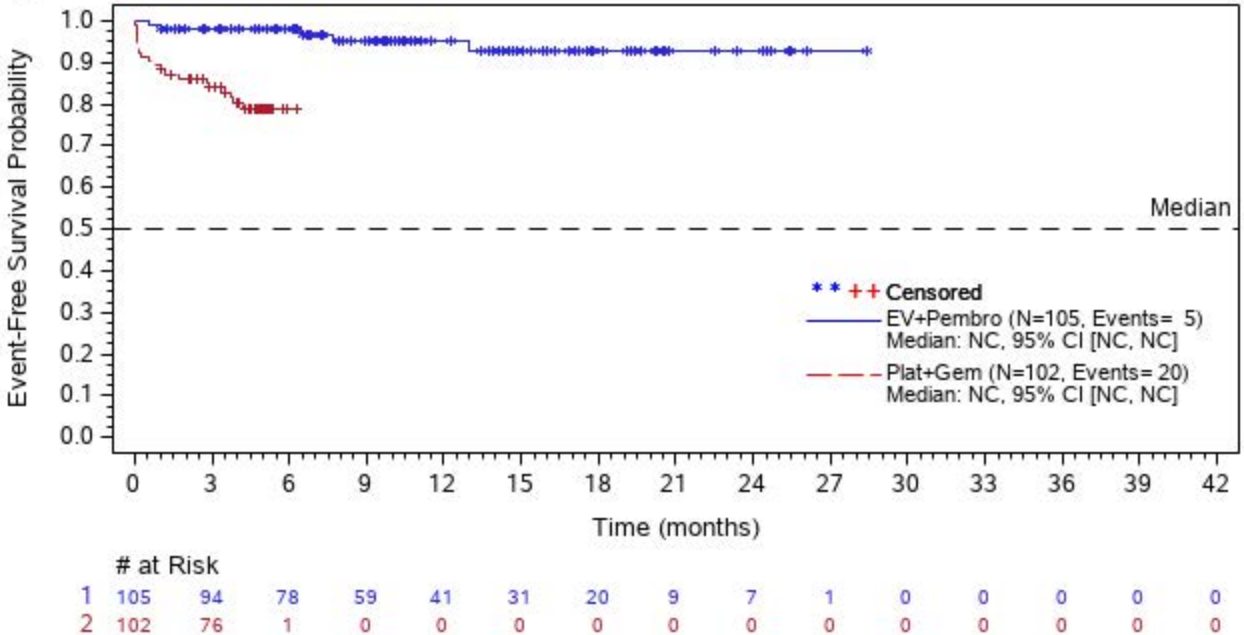
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.12.1.2.2: Kaplan-Meier Plot of Time to first TEAE - Ear and labyrinth disorders (SOC) - Analysis Set mSAF 1

Age: < 65 years



at Risk

1	105	94	78	59	41	31	20	9	7	1	0	0	0	0	0
2	102	76	1	0	0	0	0	0	0	0	0	0	0	0	0

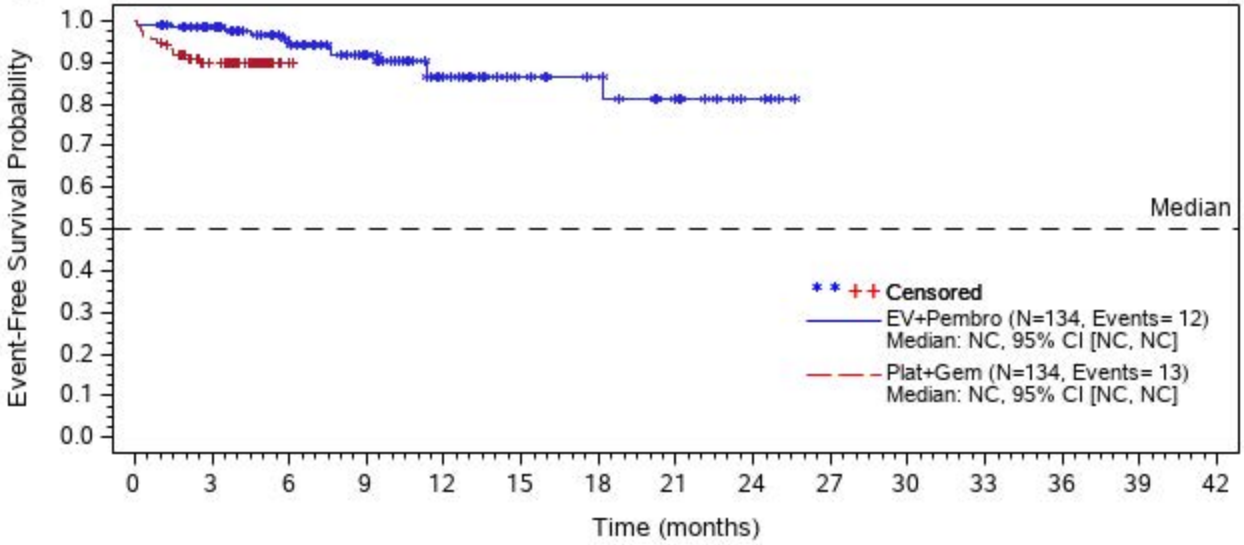
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.12.1.2.2: Kaplan-Meier Plot of Time to first TEAE - Ear and labyrinth disorders (SOC) - Analysis Set mSAF 1

Age: >= 65 years



at Risk

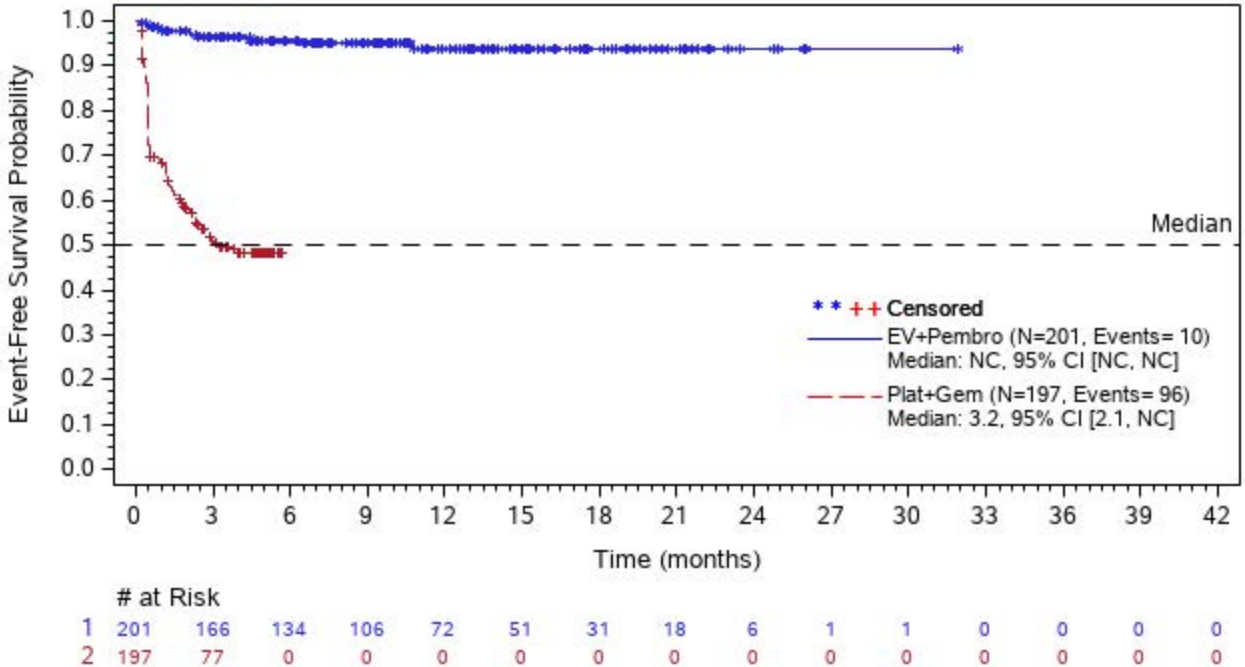
1	134	113	85	64	39	23	18	11	4	0	0	0	0	0	0
2	134	97	2	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.12.2.1: Kaplan-Meier Plot of Time to first TEAE - Thrombocytopenia (PT) - Analysis Set mSAF 2

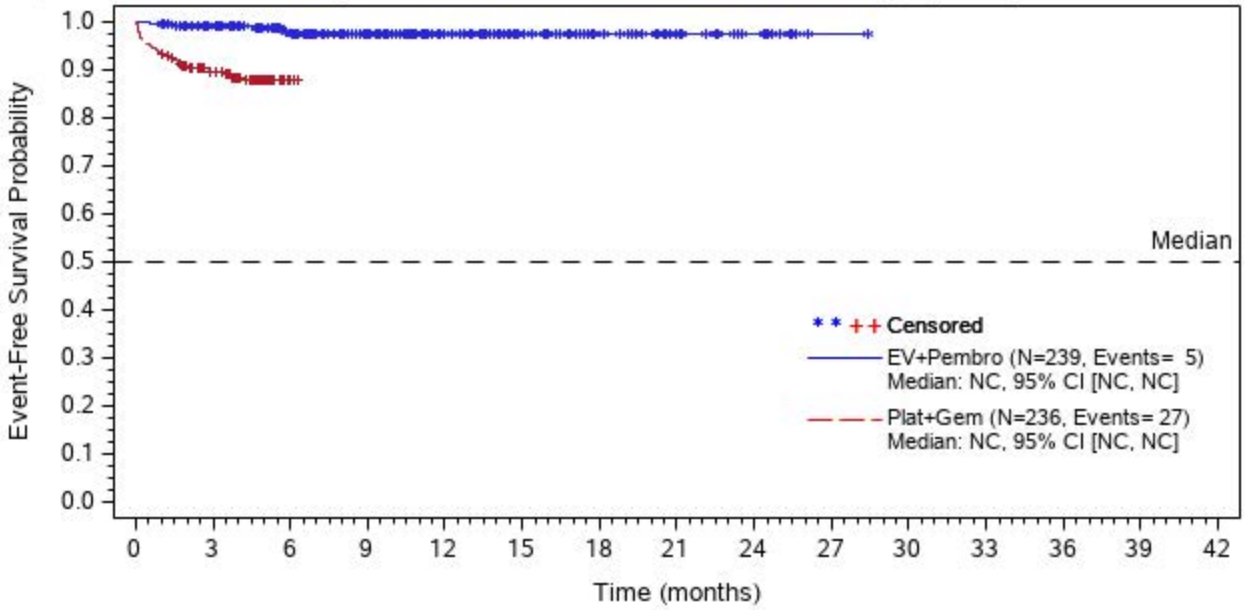


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.13.1.1: Kaplan-Meier Plot of Time to first TEAE - Tinnitus (PT) - Analysis Set mSAF 1



at Risk

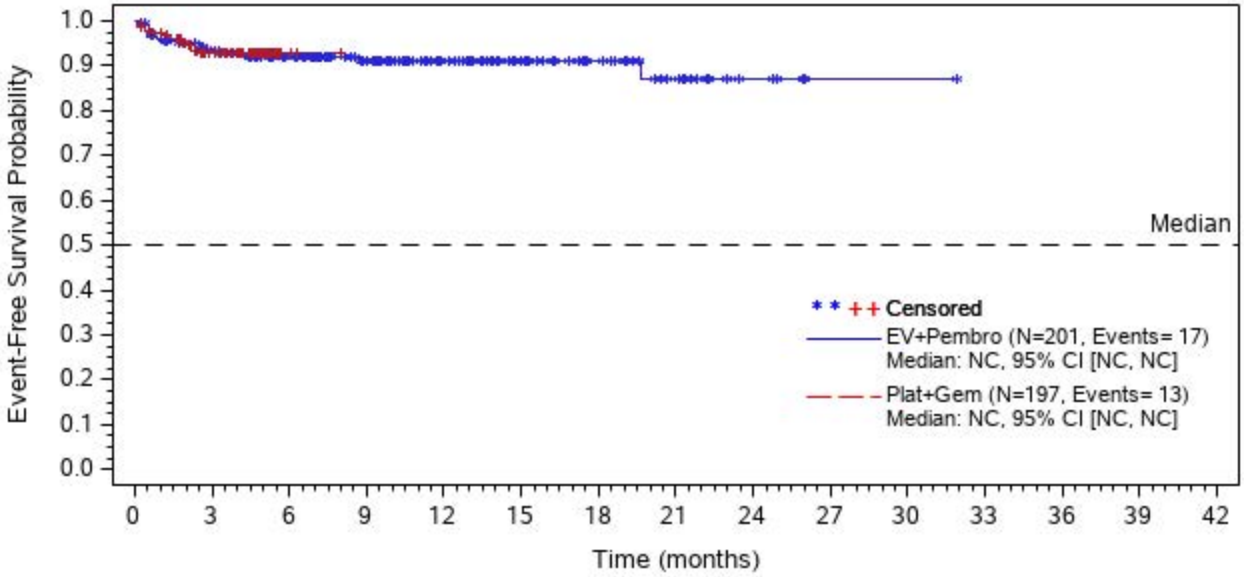
1	239	209	165	128	85	57	38	21	12	1	0	0	0	0	0
2	236	177	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.13.2.1: Kaplan-Meier Plot of Time to first TEAE - Cardiac disorders (SOC) - Analysis Set mSAF 2



at Risk

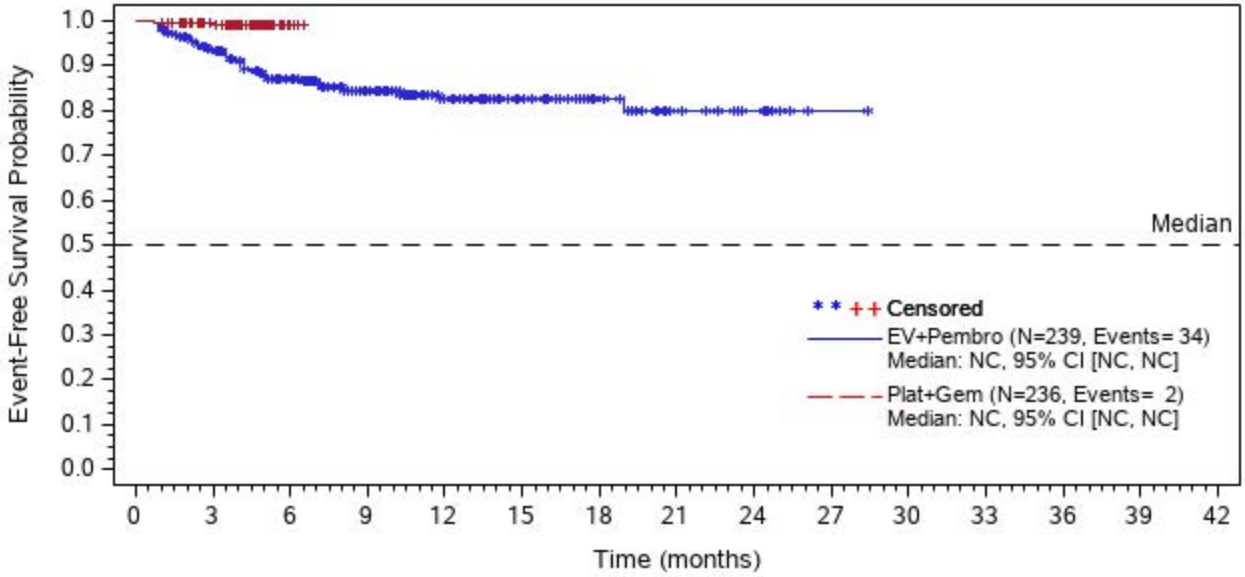
1	201	167	136	107	71	50	31	18	6	1	1	0	0	0	0
2	197	141	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.14.1.1: Kaplan-Meier Plot of Time to first TEAE - Endocrine disorders (SOC) - Analysis Set mSAF 1



at Risk

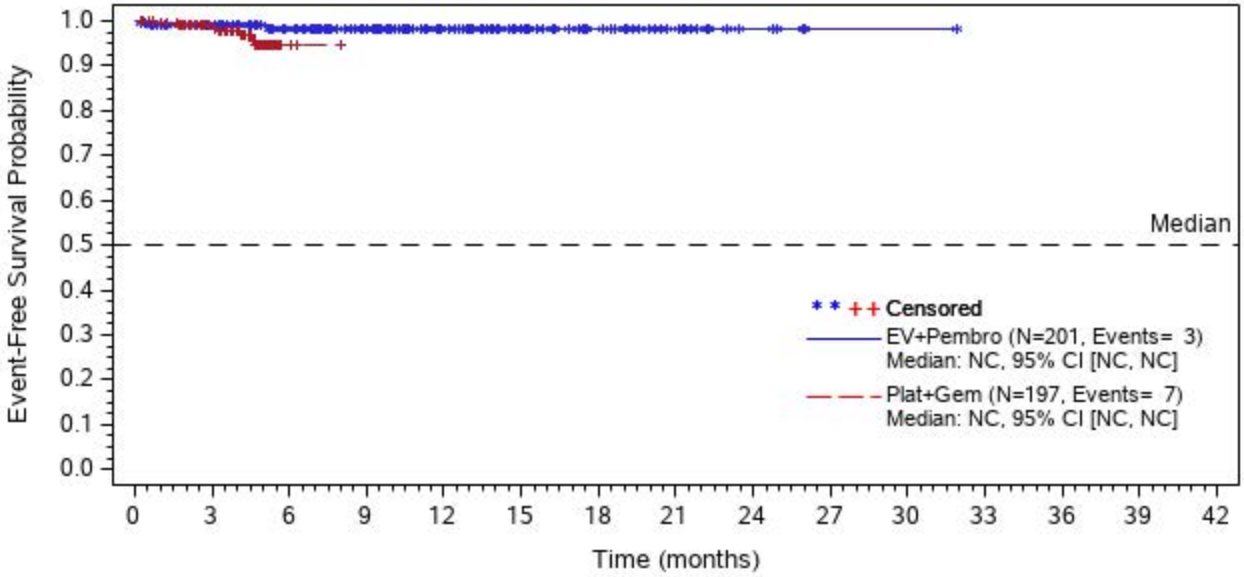
1	239	196	148	110	73	50	33	17	10	1	0	0	0	0	0
2	236	199	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.14.2.1: Kaplan-Meier Plot of Time to first TEAE - Ear and labyrinth disorders (SOC) - Analysis Set mSAF 2



at Risk

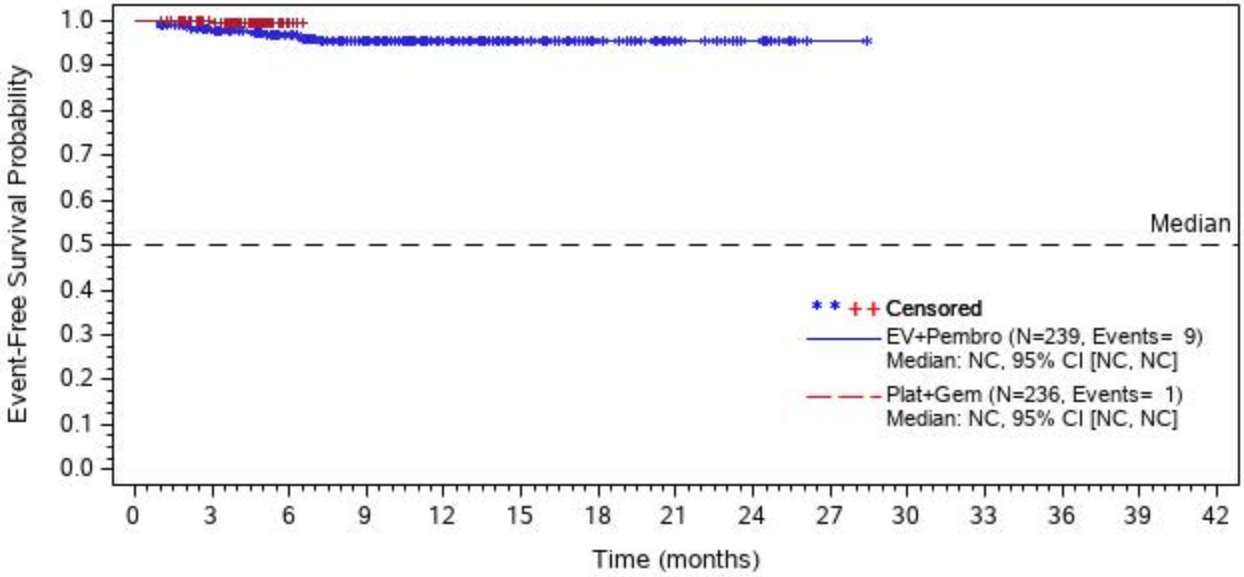
1	201	169	137	106	72	51	31	18	6	1	1	0	0	0	0
2	197	148	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.15.1.1: Kaplan-Meier Plot of Time to first TEAE - Hyperthyroidism (PT) - Analysis Set mSAF 1



at Risk

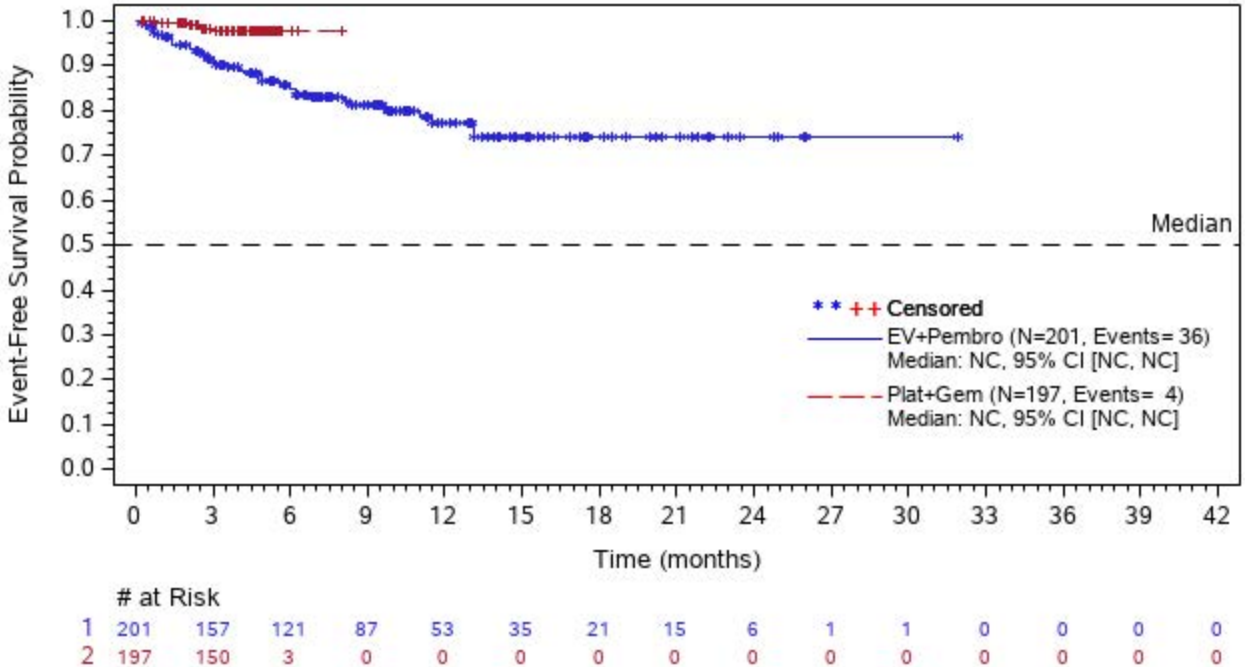
1	239	206	164	125	83	56	37	20	12	1	0	0	0	0	0
2	236	200	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.15.2.1: Kaplan-Meier Plot of Time to first TEAE - Endocrine disorders (SOC) - Analysis Set mSAF 2



at Risk

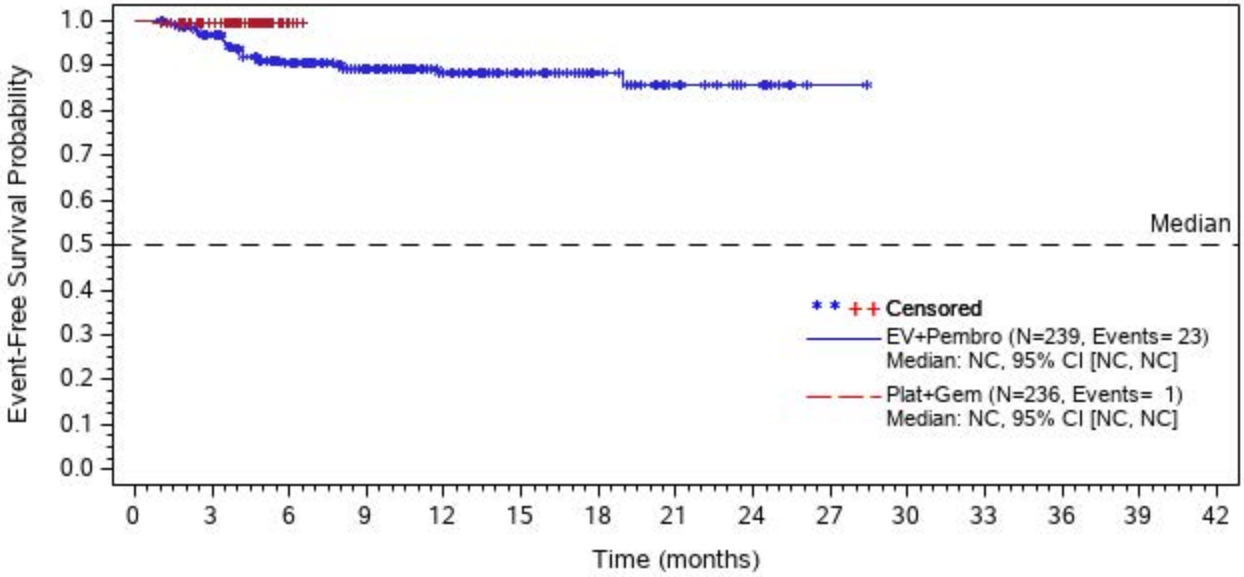
1	201	157	121	87	53	35	21	15	6	1	1	0	0	0	0
2	197	150	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.16.1.1: Kaplan-Meier Plot of Time to first TEAE - Hypothyroidism (PT) - Analysis Set mSAF 1



at Risk

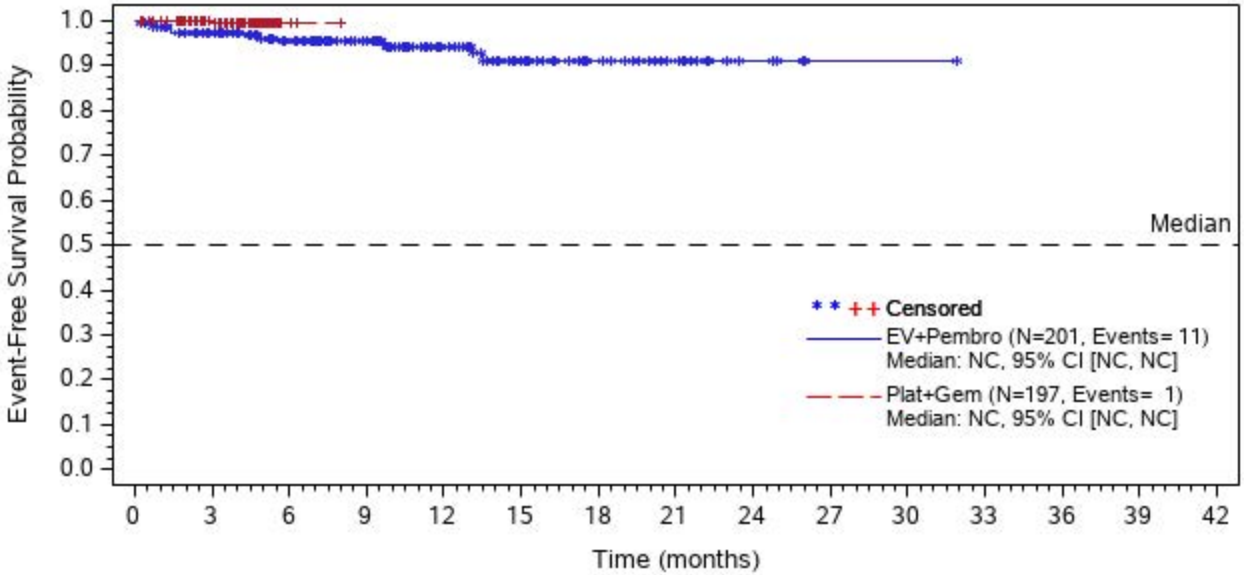
1	239	204	154	116	77	53	36	19	11	1	0	0	0	0	0
2	236	199	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.16.2.1: Kaplan-Meier Plot of Time to first TEAE - Hyperthyroidism (PT) - Analysis Set mSAF 2



at Risk

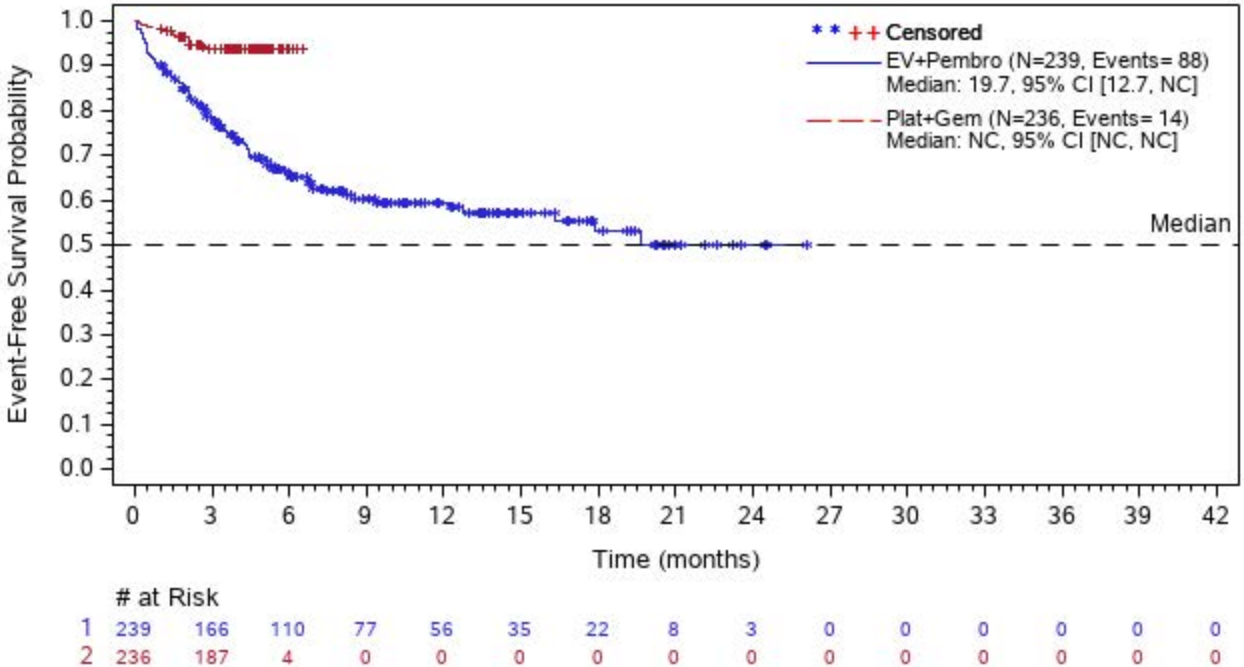
1	201	167	133	103	67	45	27	18	6	1	1	0	0	0	0
2	197	151	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.17.1.1: Kaplan-Meier Plot of Time to first TEAE - Eye disorders (SOC) - Analysis Set mSAF 1

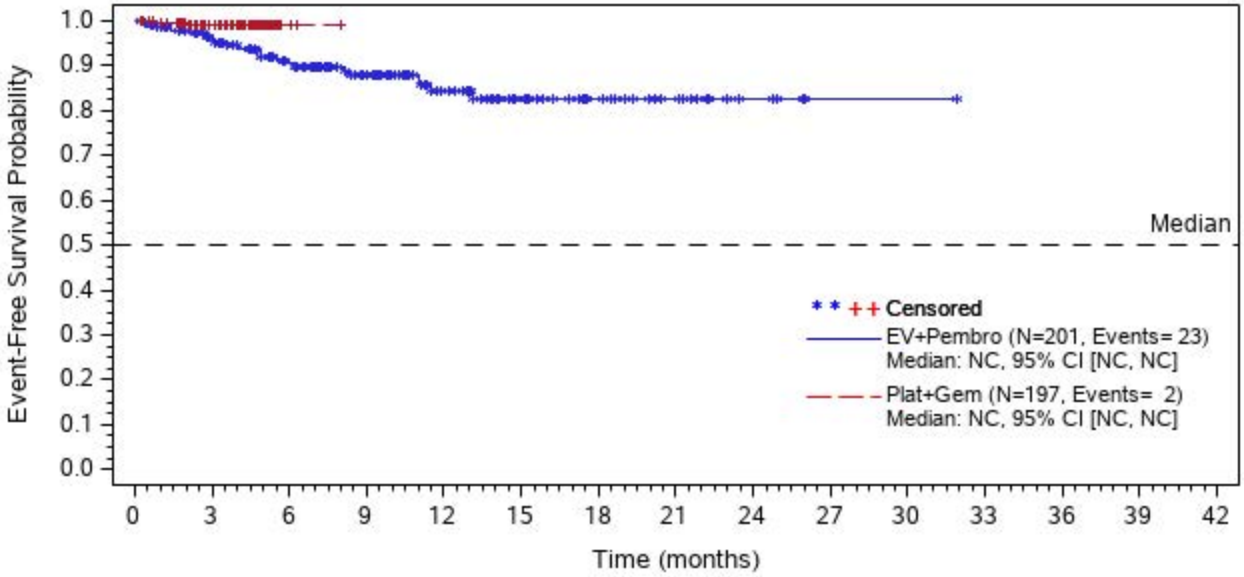


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.17.2.1: Kaplan-Meier Plot of Time to first TEAE - Hypothyroidism (PT) - Analysis Set mSAF 2



at Risk

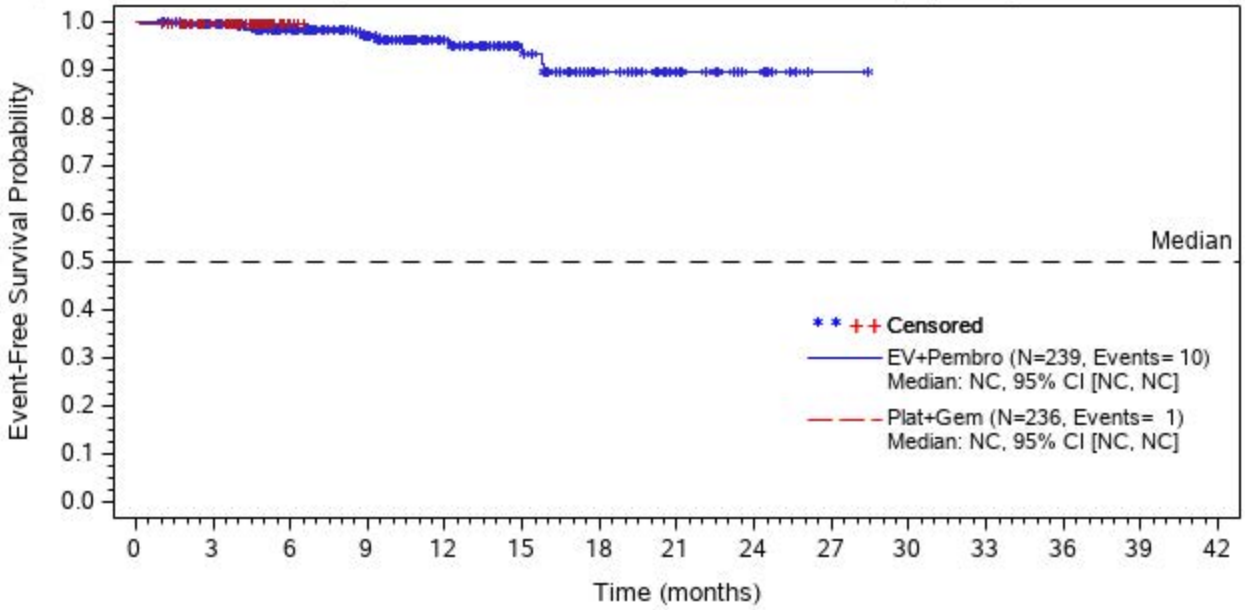
1	201	165	129	95	59	40	24	16	6	1	1	0	0	0	0
2	197	150	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.18.1.1: Kaplan-Meier Plot of Time to first TEAE - Cataract (PT) - Analysis Set mSAF 1



at Risk

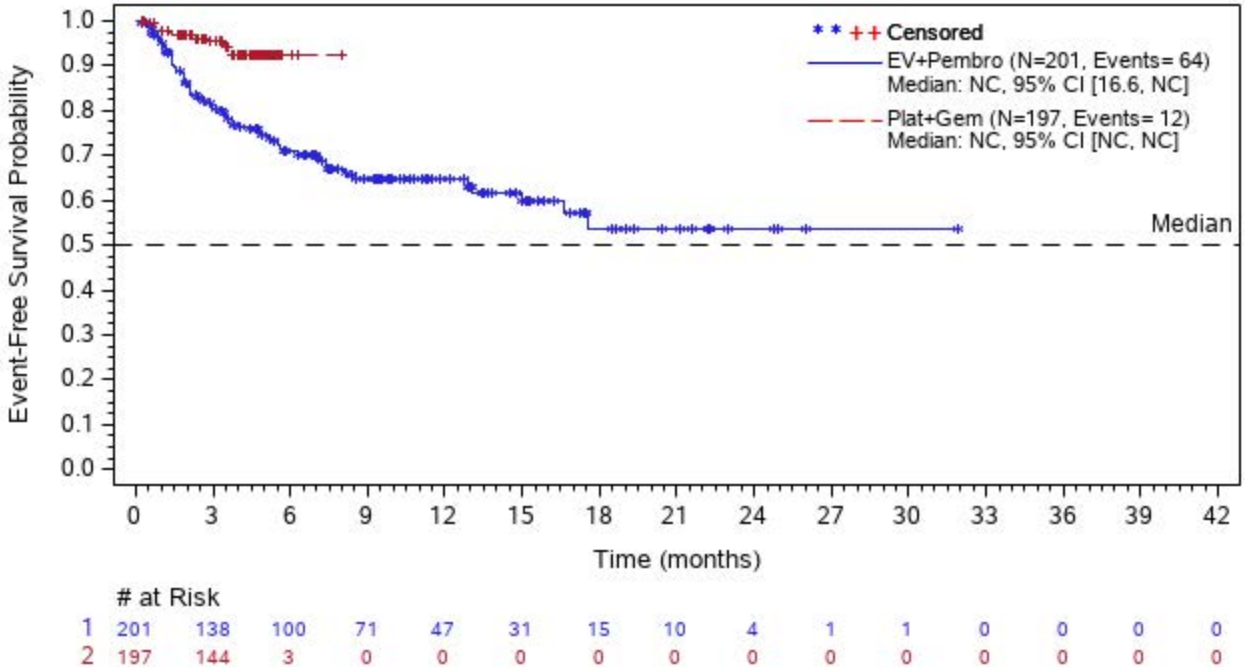
1	239	210	166	127	83	52	34	17	8	1	0	0	0	0	0
2	236	199	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.18.2.1: Kaplan-Meier Plot of Time to first TEAE - Eye disorders (SOC) - Analysis Set mSAF 2

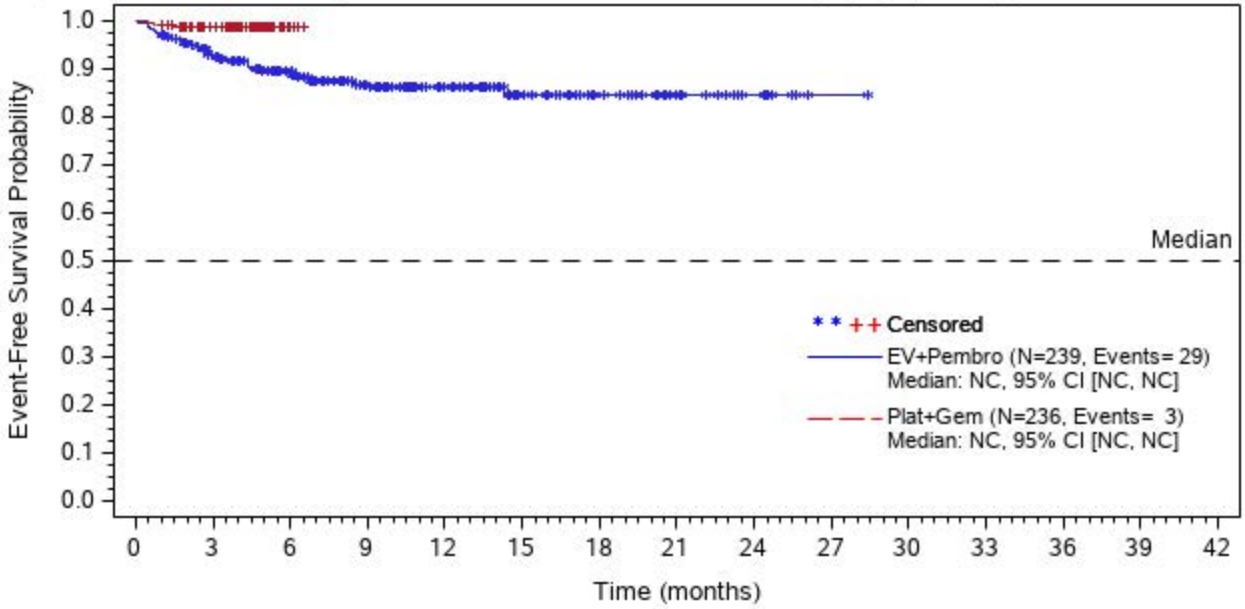


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.19.1.1: Kaplan-Meier Plot of Time to first TEAE - Dry eye (PT) - Analysis Set mSAF 1



at Risk

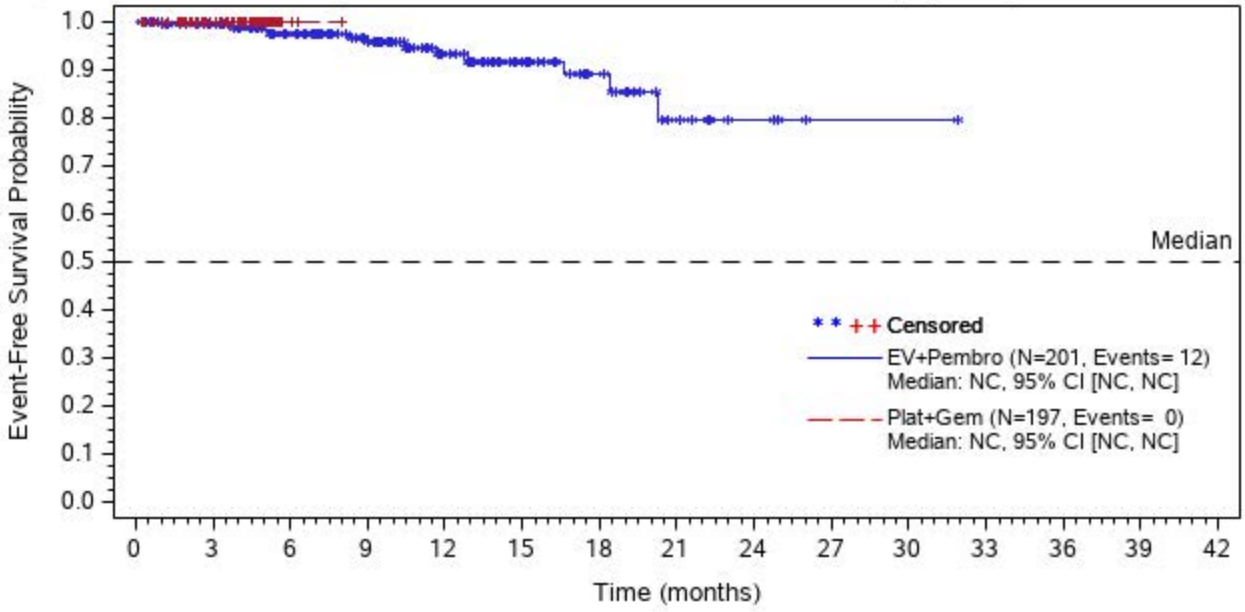
1	239	196	150	112	79	50	35	19	10	1	0	0	0	0	0
2	236	198	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.19.2.1: Kaplan-Meier Plot of Time to first TEAE - Cataract (PT) - Analysis Set mSAF 2



at Risk

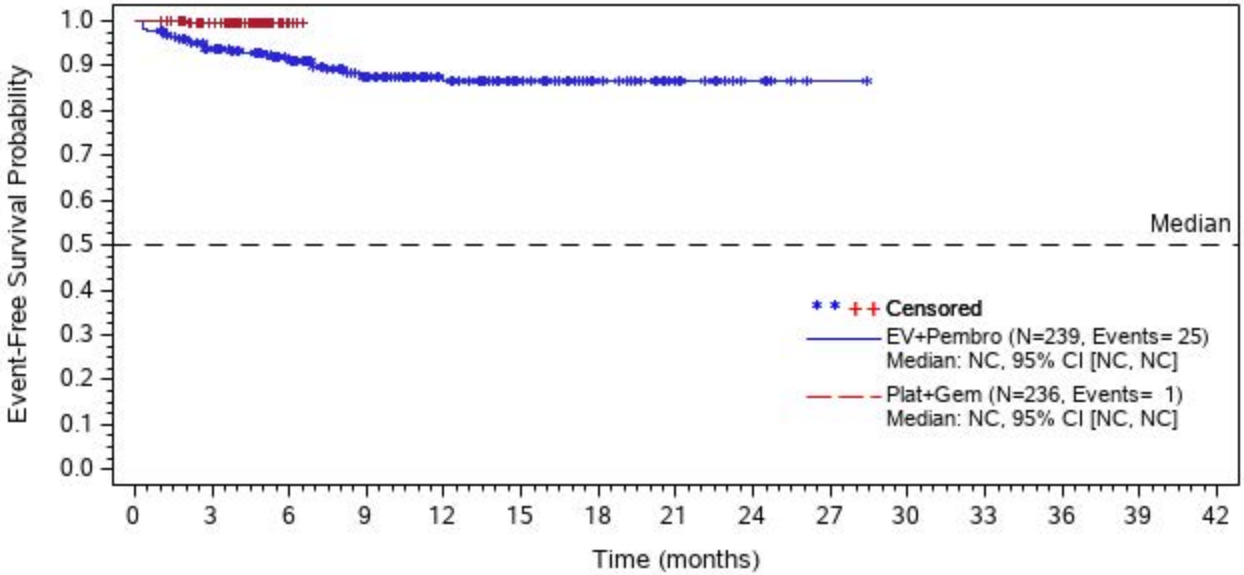
1	201	170	136	106	68	46	25	12	5	1	1	0	0	0	0
2	197	151	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.20.1.1: Kaplan-Meier Plot of Time to first TEAE - Lacrimation increased (PT) - Analysis Set mSAF 1



at Risk

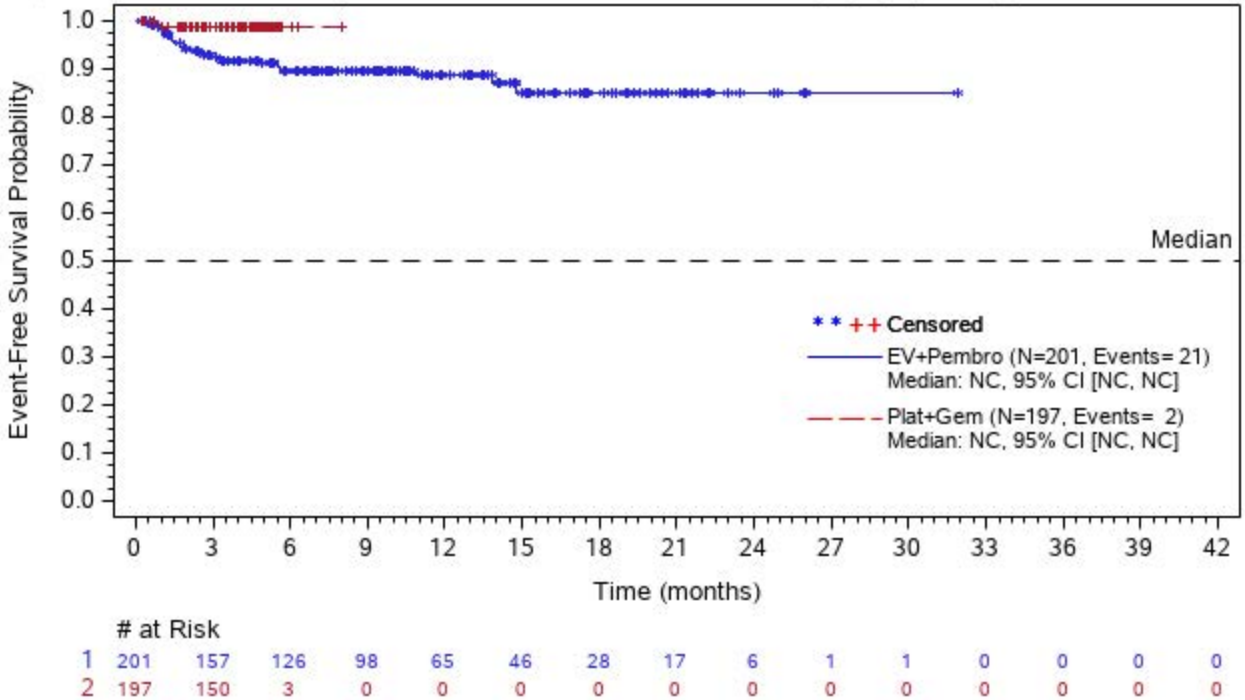
1	239	198	154	113	75	53	34	17	8	1	0	0	0	0	0
2	236	199	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.20.2.1: Kaplan-Meier Plot of Time to first TEAE - Dry eye (PT) - Analysis Set mSAF 2



at Risk

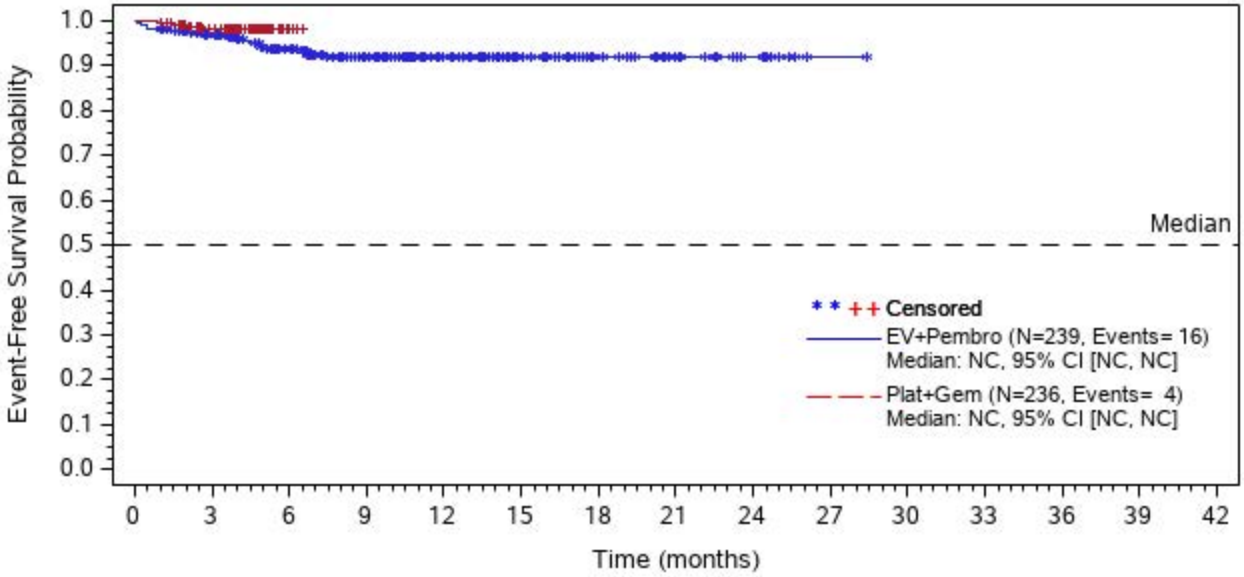
1	201	157	126	98	65	46	28	17	6	1	1	0	0	0	0
2	197	150	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.21.1.1: Kaplan-Meier Plot of Time to first TEAE - Vision blurred (PT) - Analysis Set mSAF 1



at Risk

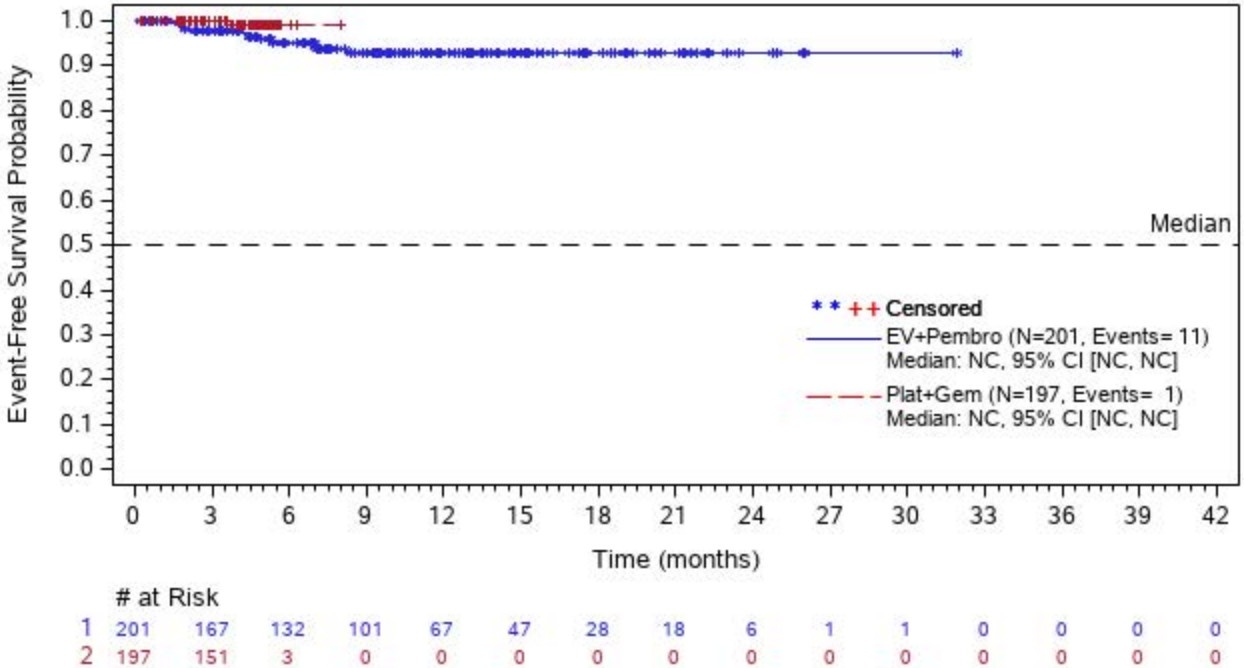
1	239	204	159	121	83	55	36	20	11	1	0	0	0	0	0
2	236	196	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.21.2.1: Kaplan-Meier Plot of Time to first TEAE - Lacrimation increased (PT) - Analysis Set mSAF 2



at Risk

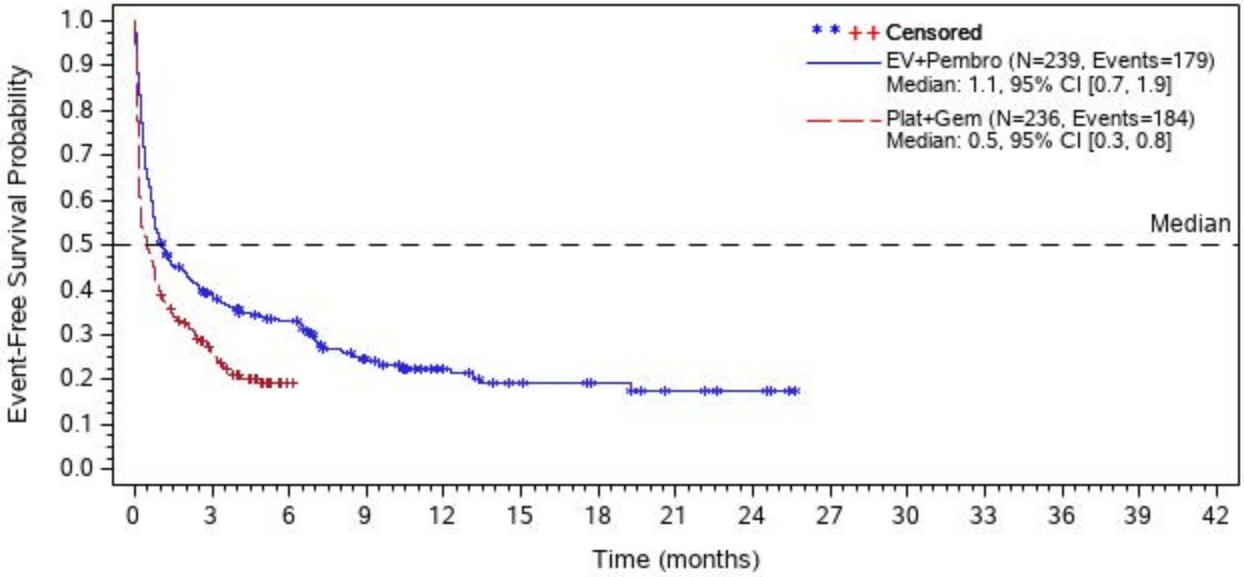
1	201	167	132	101	67	47	28	18	6	1	1	0	0	0	0
2	197	151	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.22.1.1: Kaplan-Meier Plot of Time to first TEAE - Gastrointestinal disorders (SOC) - Analysis Set mSAF 1



at Risk

1	239	85	64	38	21	14	11	7	4	0	0	0	0	0	0
2	236	51	1	0	0	0	0	0	0	0	0	0	0	0	0

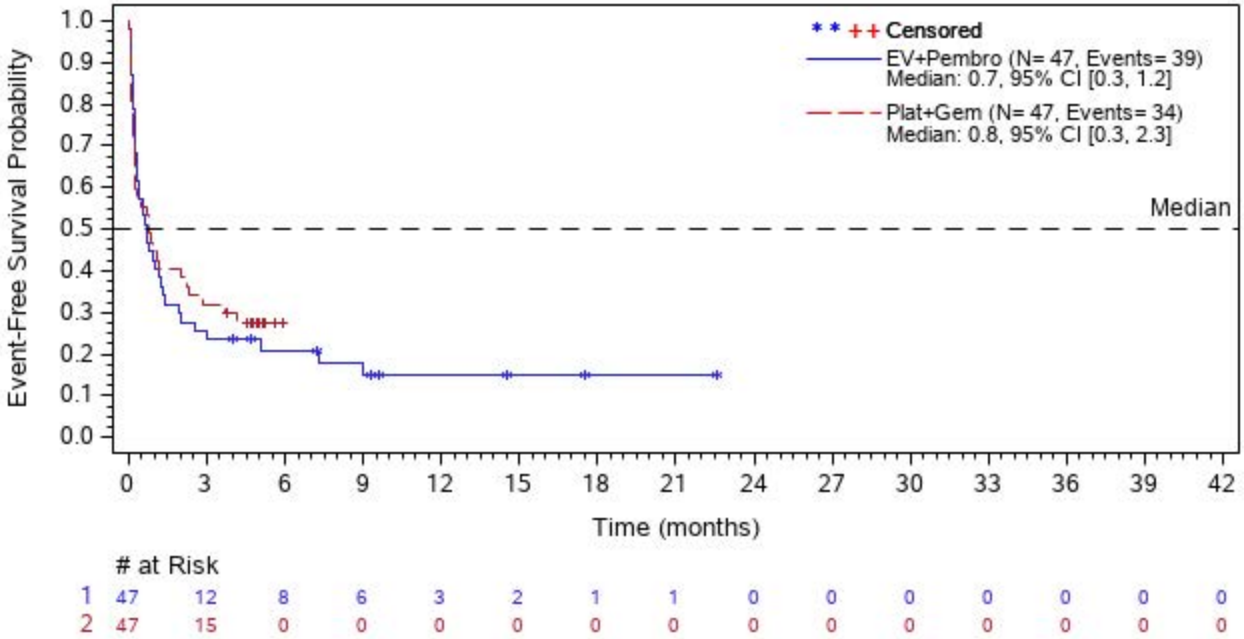
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.22.1.2.1: Kaplan-Meier Plot of Time to first TEAE - Gastrointestinal disorders (SOC) - Analysis Set mSAF 1

Liver Metastases: Present



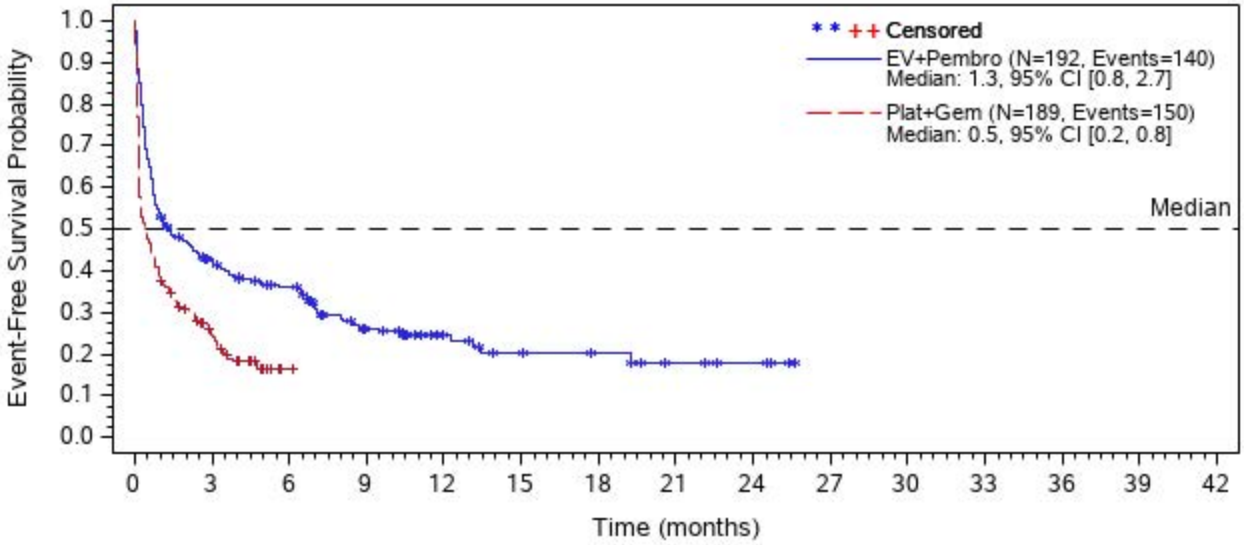
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.22.1.2.1: Kaplan-Meier Plot of Time to first TEAE - Gastrointestinal disorders (SOC) - Analysis Set mSAF 1

Liver Metastases: Absent



at Risk

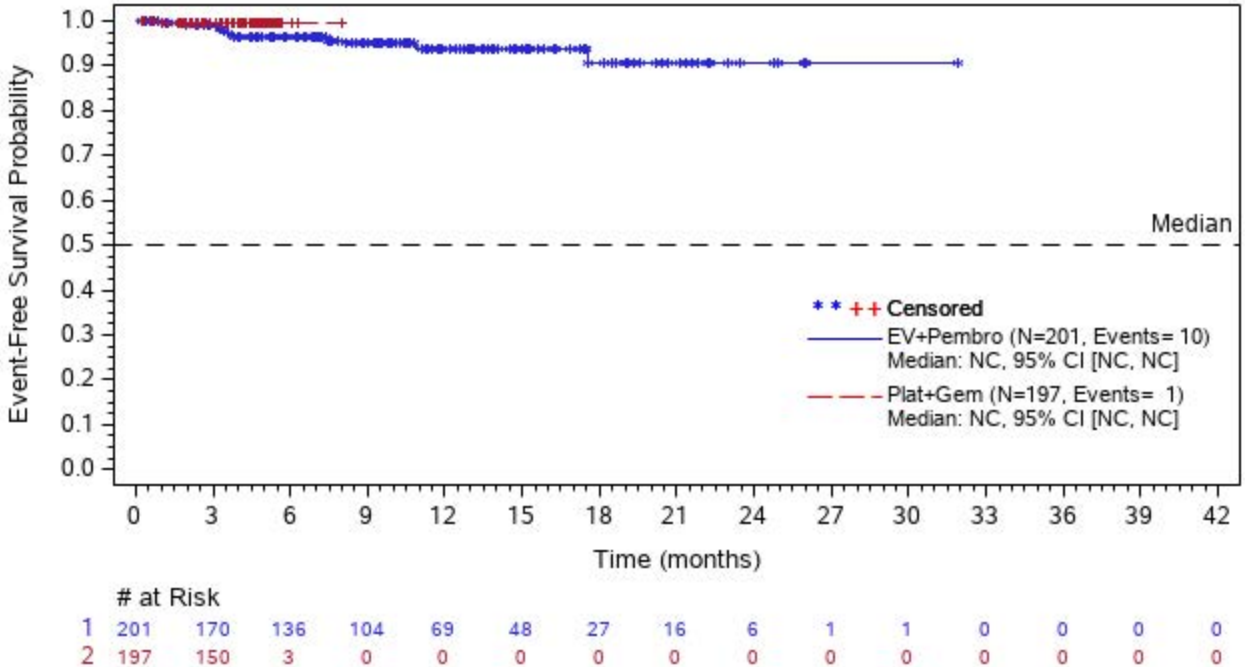
1	192	73	56	32	18	12	10	6	4	0	0	0	0	0	0
2	189	36	1	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.22.2.1: Kaplan-Meier Plot of Time to first TEAE - Vision blurred (PT) - Analysis Set mSAF 2



at Risk

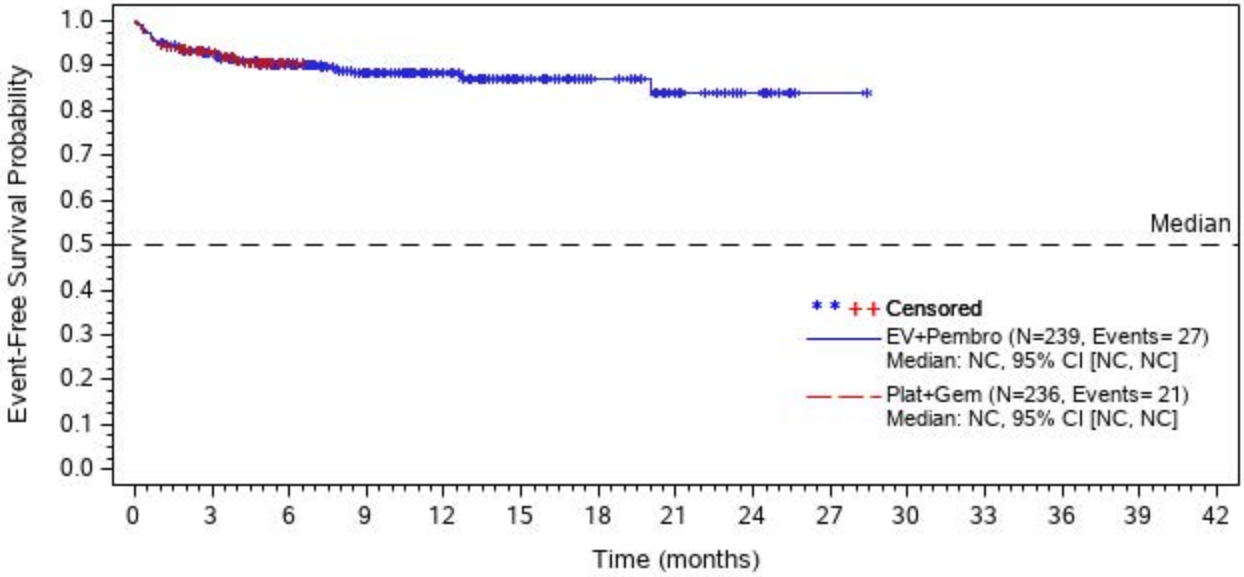
1	201	170	136	104	69	48	27	16	6	1	1	0	0	0	0
2	197	150	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.23.1.1: Kaplan-Meier Plot of Time to first TEAE - Abdominal pain (PT) - Analysis Set mSAF 1



at Risk

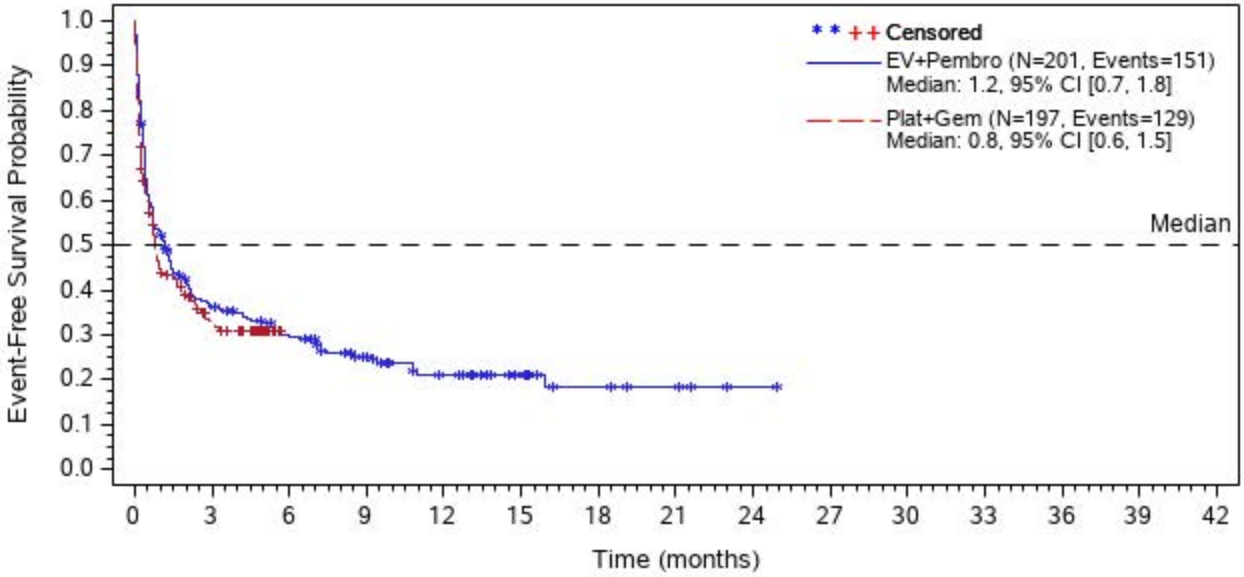
1	239	197	154	118	79	51	34	20	11	1	0	0	0	0	0
2	236	187	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.23.2.1: Kaplan-Meier Plot of Time to first TEAE - Gastrointestinal disorders (SOC) - Analysis Set mSAF 2



at Risk

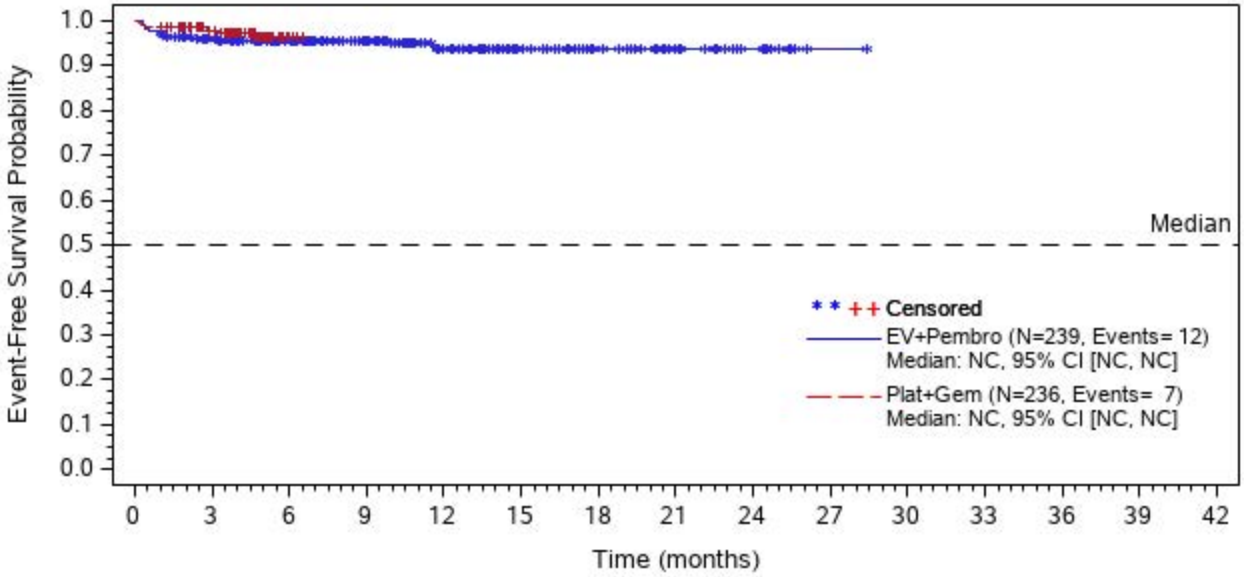
1	201	68	51	35	23	13	6	4	1	0	0	0	0	0	0
2	197	47	0	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.24.1.1: Kaplan-Meier Plot of Time to first TEAE - Abdominal pain upper (PT) - Analysis Set mSAF 1



at Risk

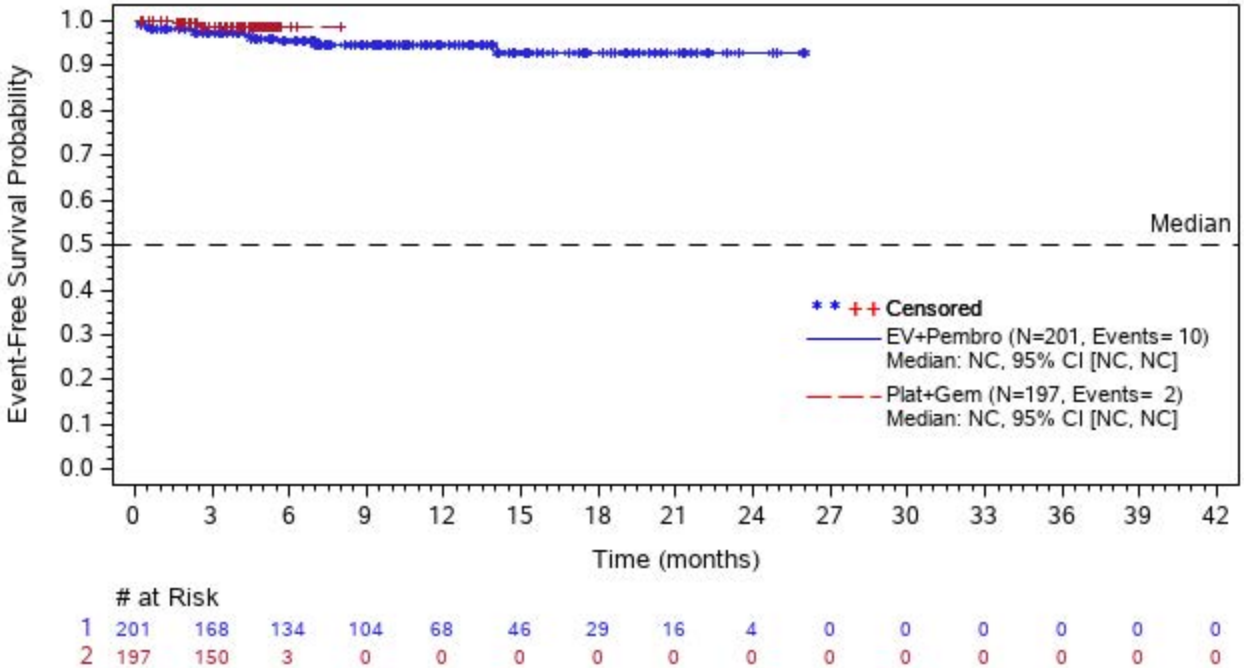
1	239	202	162	127	84	56	39	22	12	1	0	0	0	0	0
2	236	196	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.24.2.1: Kaplan-Meier Plot of Time to first TEAE - Abdominal distension (PT) - Analysis Set mSAF 2



at Risk

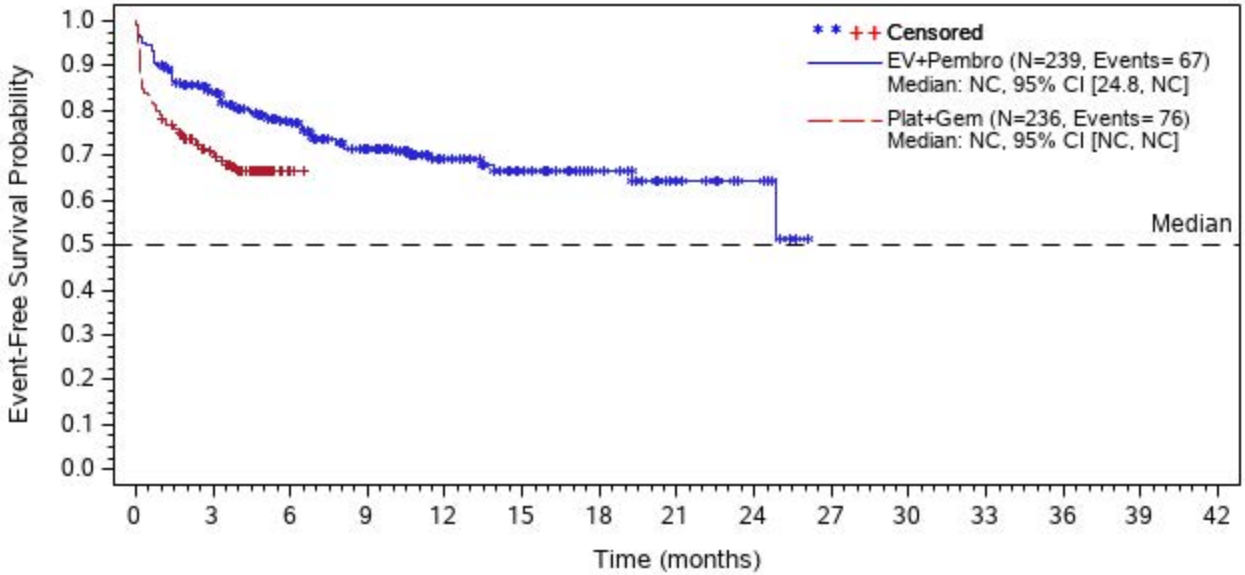
1	201	168	134	104	68	46	29	16	4	0	0	0	0	0	0
2	197	150	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.25.1.1: Kaplan-Meier Plot of Time to first TEAE - Constipation (PT) - Analysis Set mSAF 1



at Risk

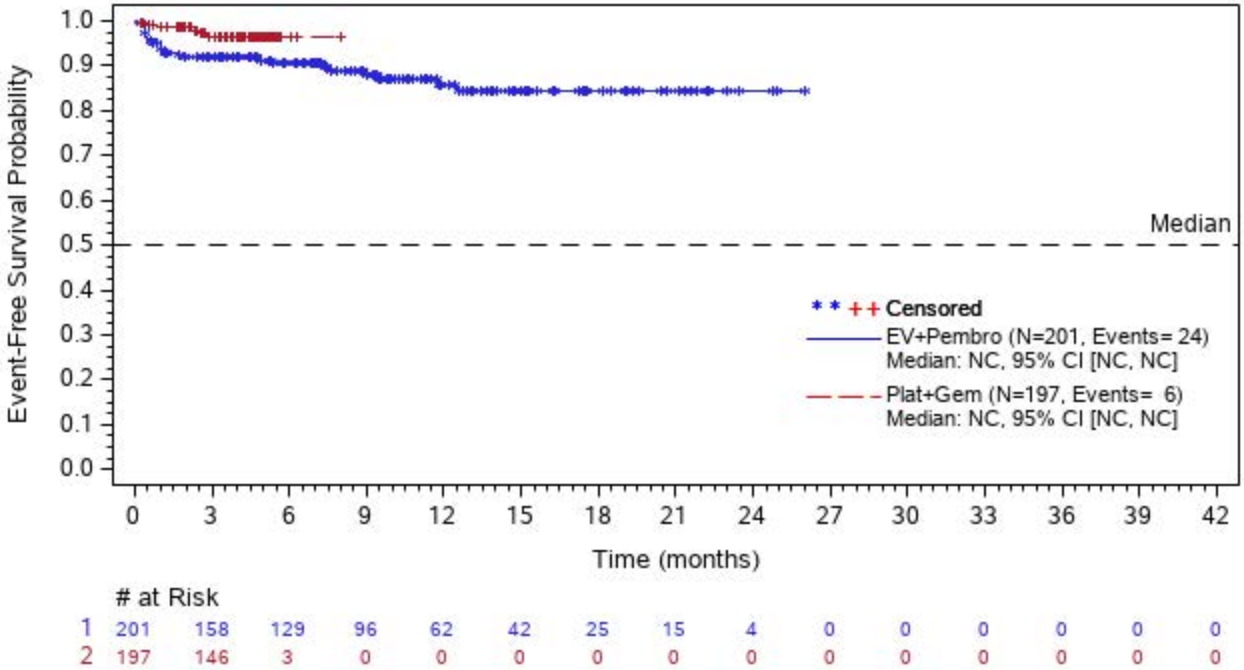
1	239	179	137	102	67	47	31	16	9	0	0	0	0	0	0
2	236	140	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.25.2.1: Kaplan-Meier Plot of Time to first TEAE - Abdominal pain (PT) - Analysis Set mSAF 2



at Risk

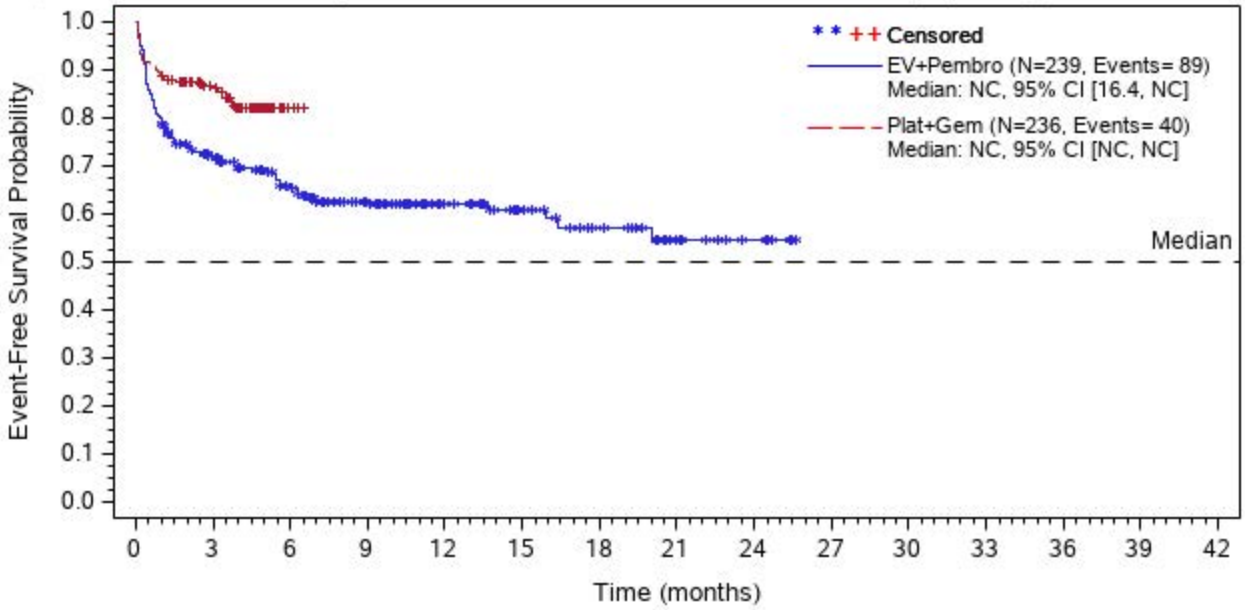
1	201	158	129	96	62	42	25	15	4	0	0	0	0	0	0
2	197	146	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.26.1.1: Kaplan-Meier Plot of Time to first TEAE - Diarrhoea (PT) - Analysis Set mSAF 1



at Risk

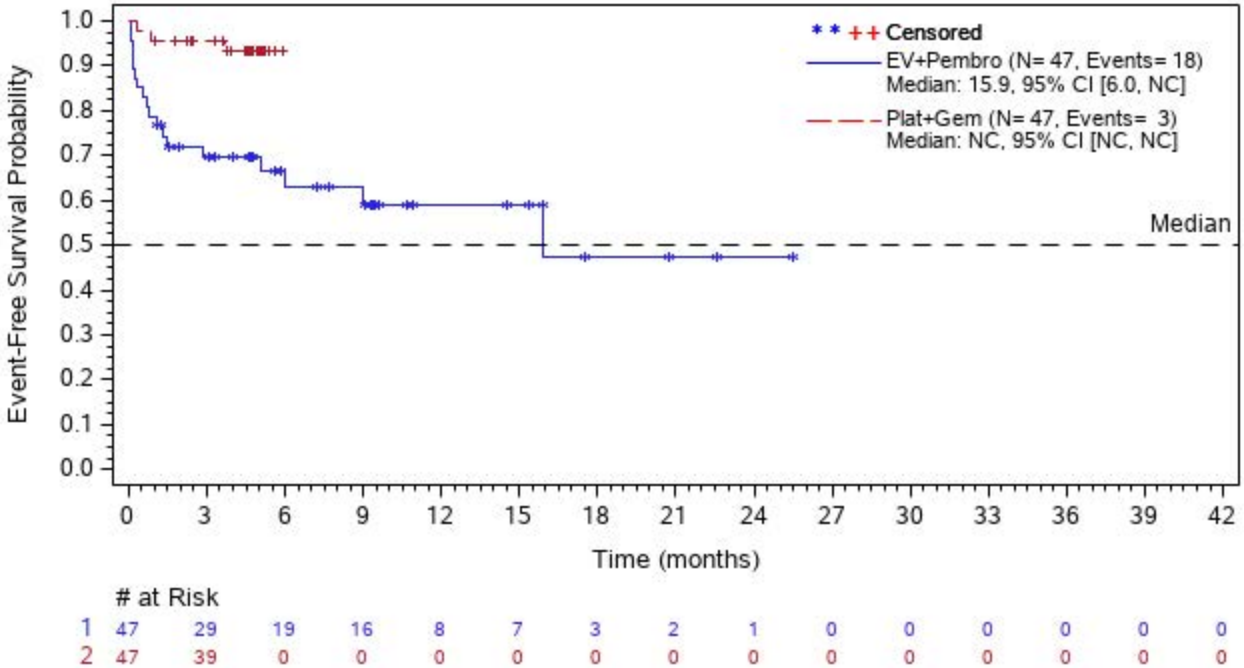
1	239	155	121	92	57	40	29	14	7	0	0	0	0	0	0
2	236	174	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.26.1.2.1: Kaplan-Meier Plot of Time to first TEAE - Diarrhoea (PT) - Analysis Set mSAF 1 Liver Metastases: Present

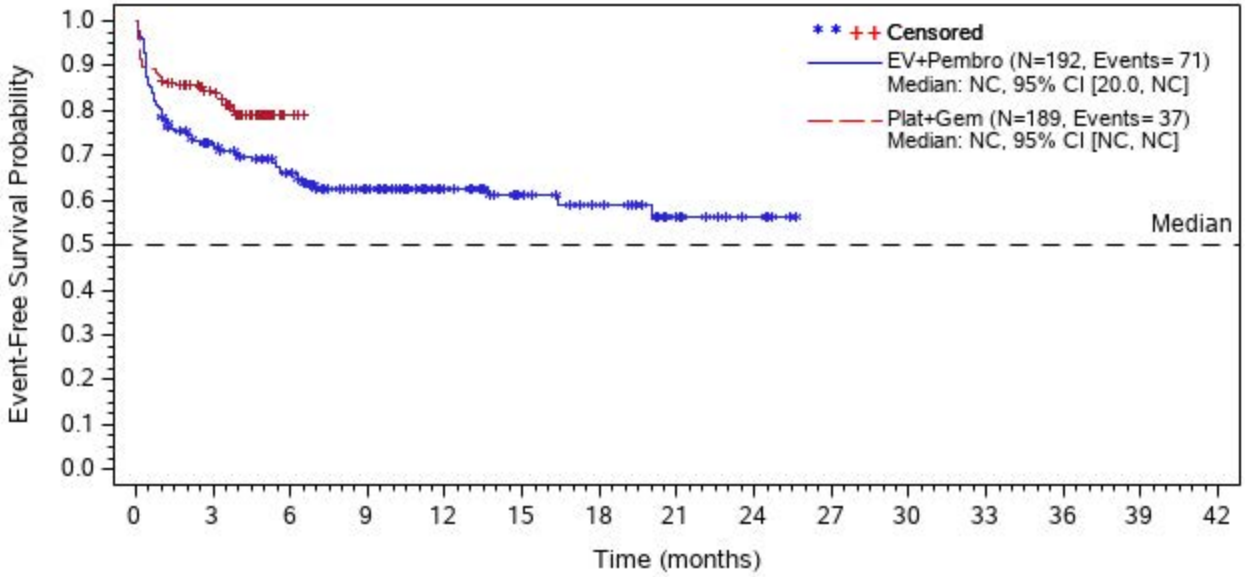


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.26.1.2.1: Kaplan-Meier Plot of Time to first TEAE - Diarrhoea (PT) - Analysis Set mSAF 1 Liver Metastases: Absent



at Risk

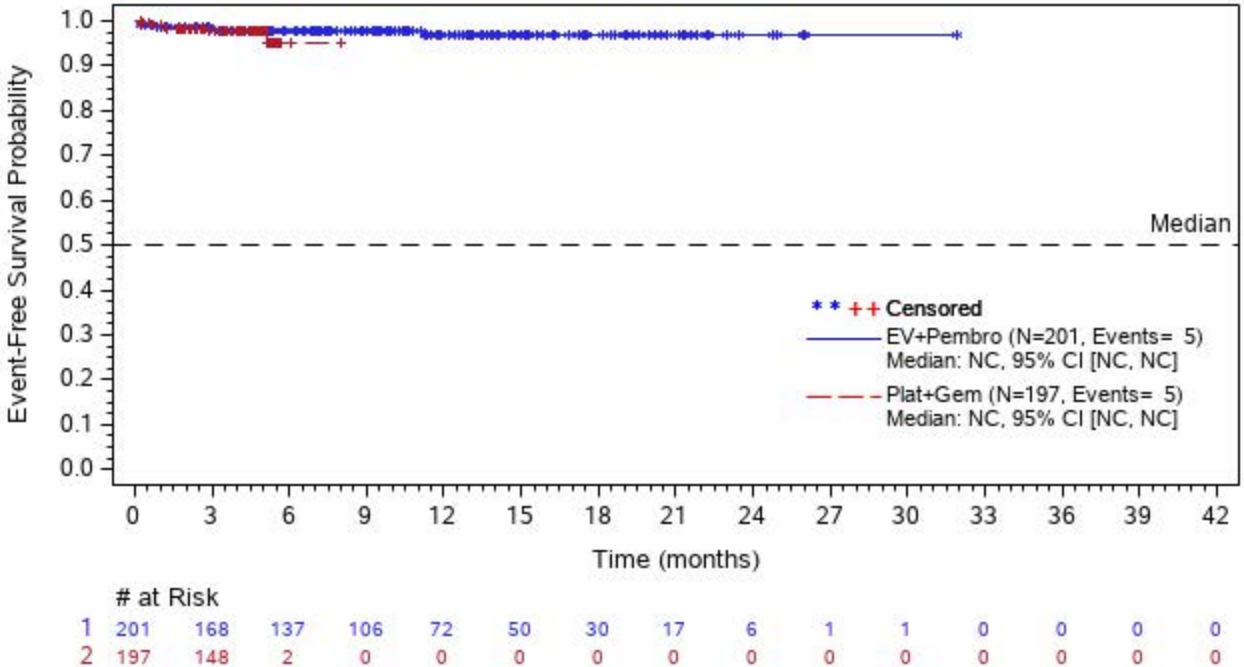
1	192	126	102	76	49	33	26	12	6	0	0	0	0	0	0
2	189	135	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.26.2.1: Kaplan-Meier Plot of Time to first TEAE - Abdominal pain upper (PT) - Analysis Set mSAF 2



at Risk

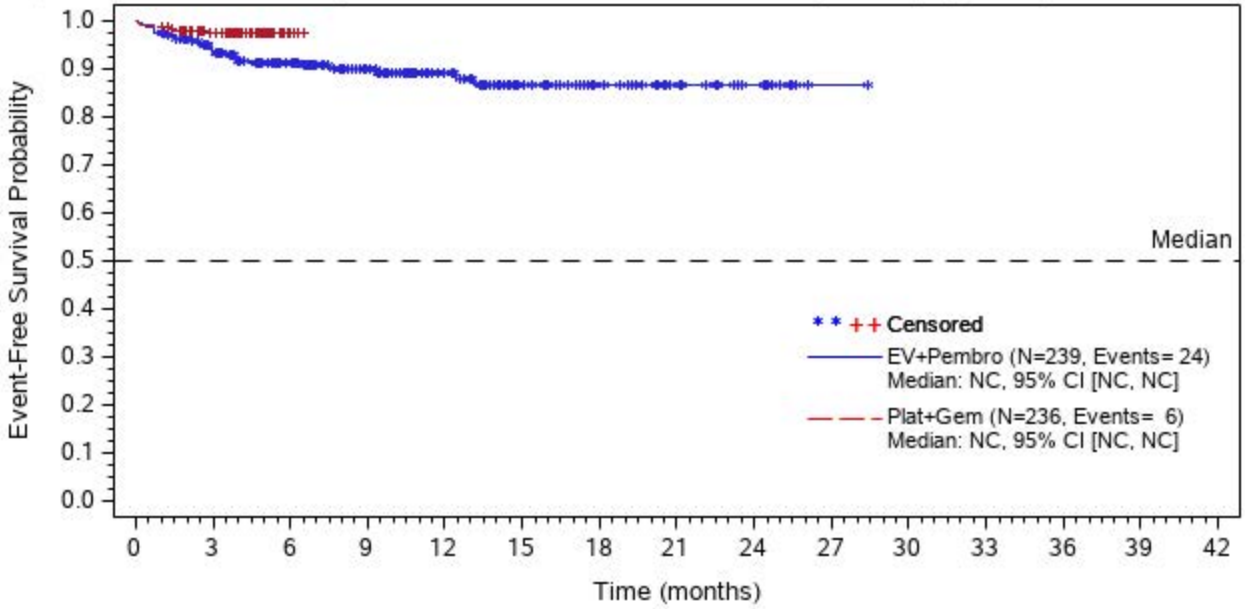
1	201	168	137	106	72	50	30	17	6	1	1	0	0	0	0
2	197	148	2	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.27.1.1: Kaplan-Meier Plot of Time to first TEAE - Dry mouth (PT) - Analysis Set mSAF 1



at Risk

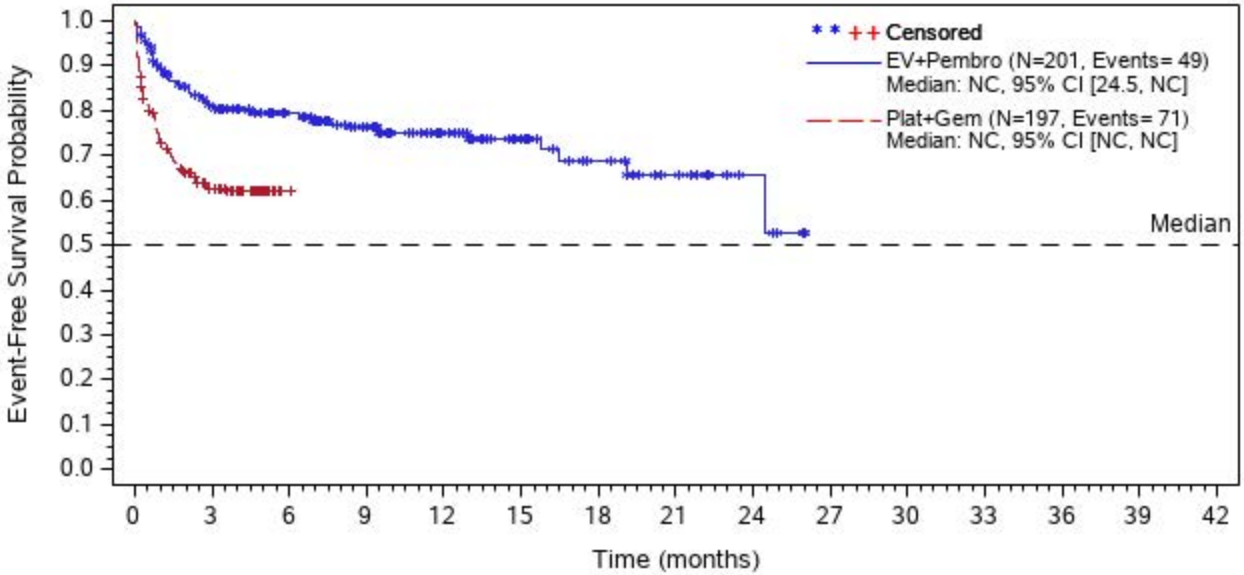
1	239	197	152	117	80	54	36	21	12	1	0	0	0	0	0
2	236	194	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.27.2.1: Kaplan-Meier Plot of Time to first TEAE - Constipation (PT) - Analysis Set mSAF 2



at Risk

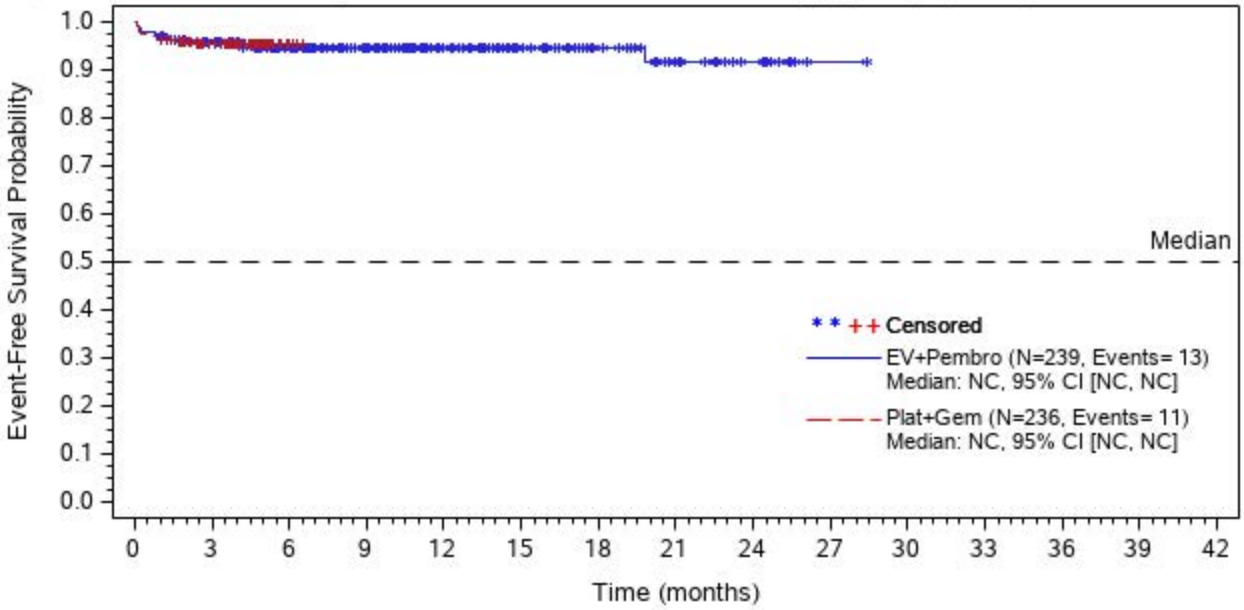
1	201	141	113	83	60	40	24	15	5	0	0	0	0	0	0
2	197	94	1	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.28.1.1: Kaplan-Meier Plot of Time to first TEAE - Dyspepsia (PT) - Analysis Set mSAF 1



at Risk

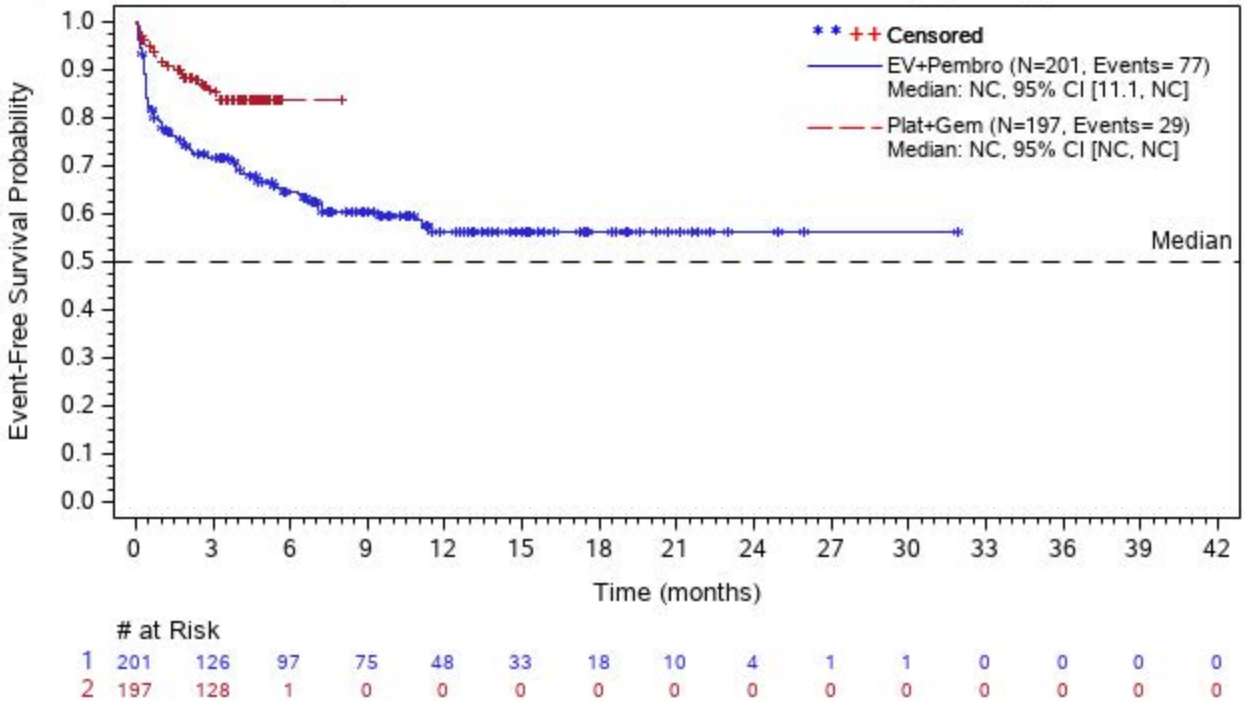
1	239	202	163	127	84	56	37	21	12	1	0	0	0	0	0
2	236	190	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.28.2.1: Kaplan-Meier Plot of Time to first TEAE - Diarrhoea (PT) - Analysis Set mSAF 2



at Risk

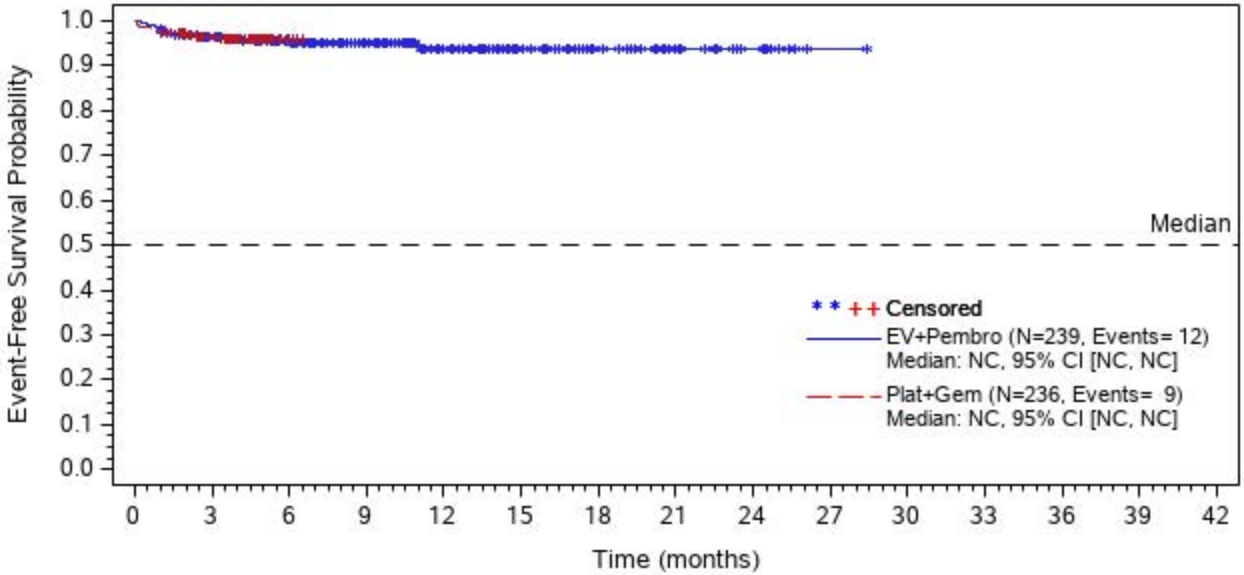
1	201	126	97	75	48	33	18	10	4	1	1	0	0	0	0
2	197	128	1	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.29.1.1: Kaplan-Meier Plot of Time to first TEAE - Gastrooesophageal reflux disease (PT) - Analysis Set mSAF 1



at Risk

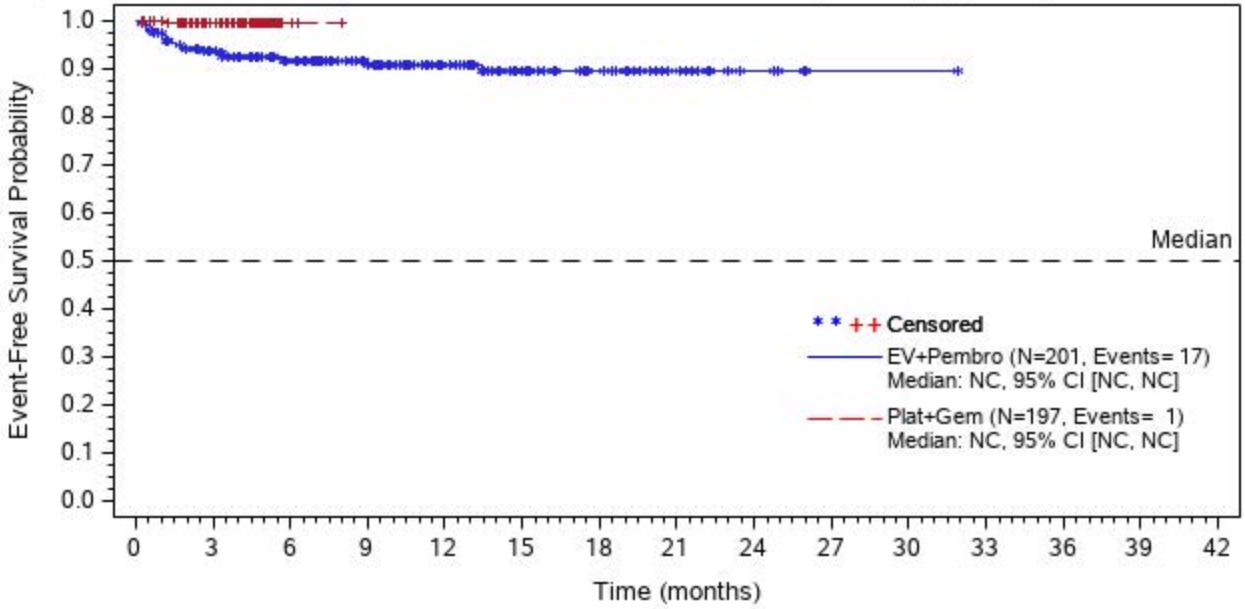
1	239	203	158	124	83	56	37	20	11	1	0	0	0	0	0
2	236	193	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.29.2.1: Kaplan-Meier Plot of Time to first TEAE - Dry mouth (PT) - Analysis Set mSAF 2



at Risk

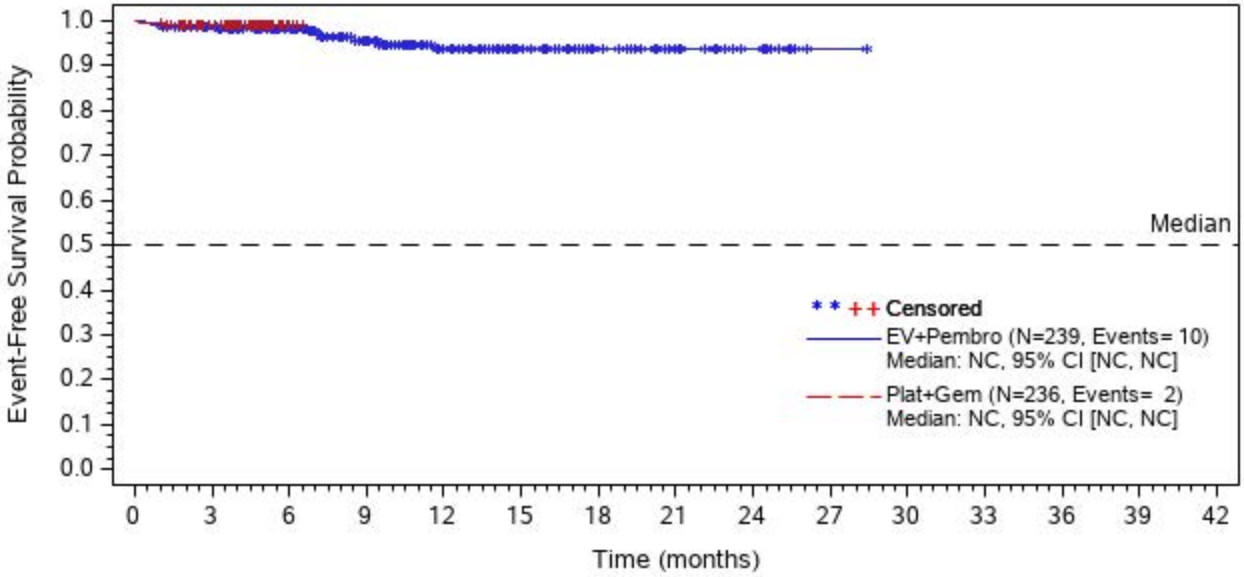
1	201	162	131	102	68	47	30	17	6	1	1	0	0	0	0
2	197	150	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.30.1.1: Kaplan-Meier Plot of Time to first TEAE - Haemorrhoids (PT) - Analysis Set mSAF 1



at Risk

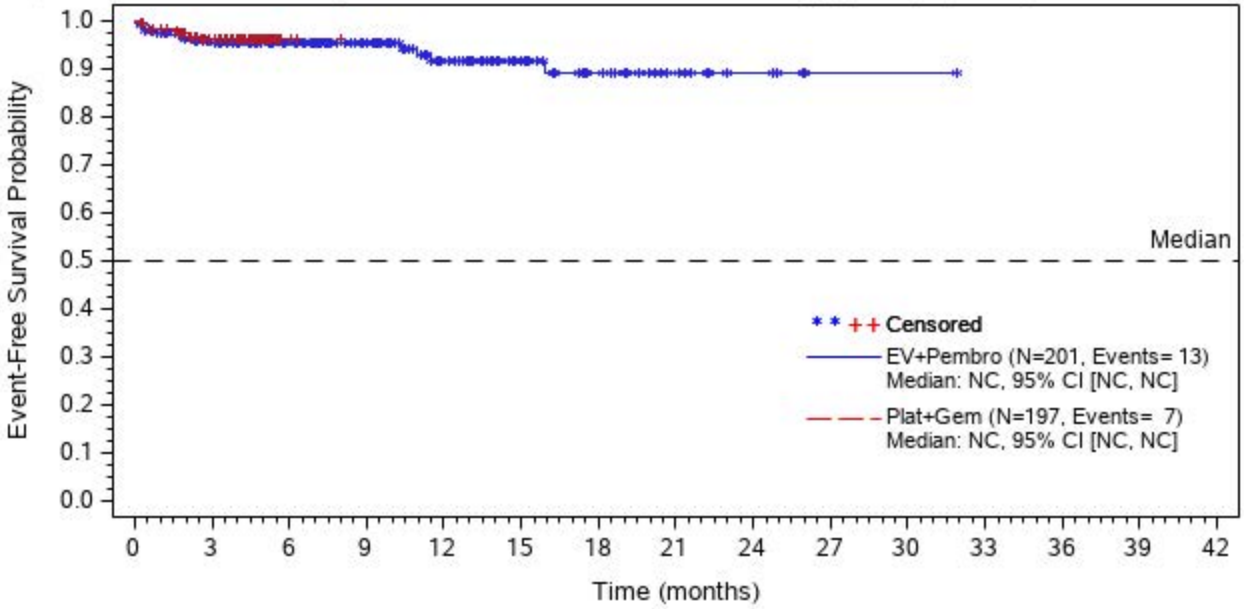
1	239	208	166	124	79	52	34	20	11	1	0	0	0	0	0
2	236	198	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.30.2.1: Kaplan-Meier Plot of Time to first TEAE - Dyspepsia (PT) - Analysis Set mSAF 2



at Risk

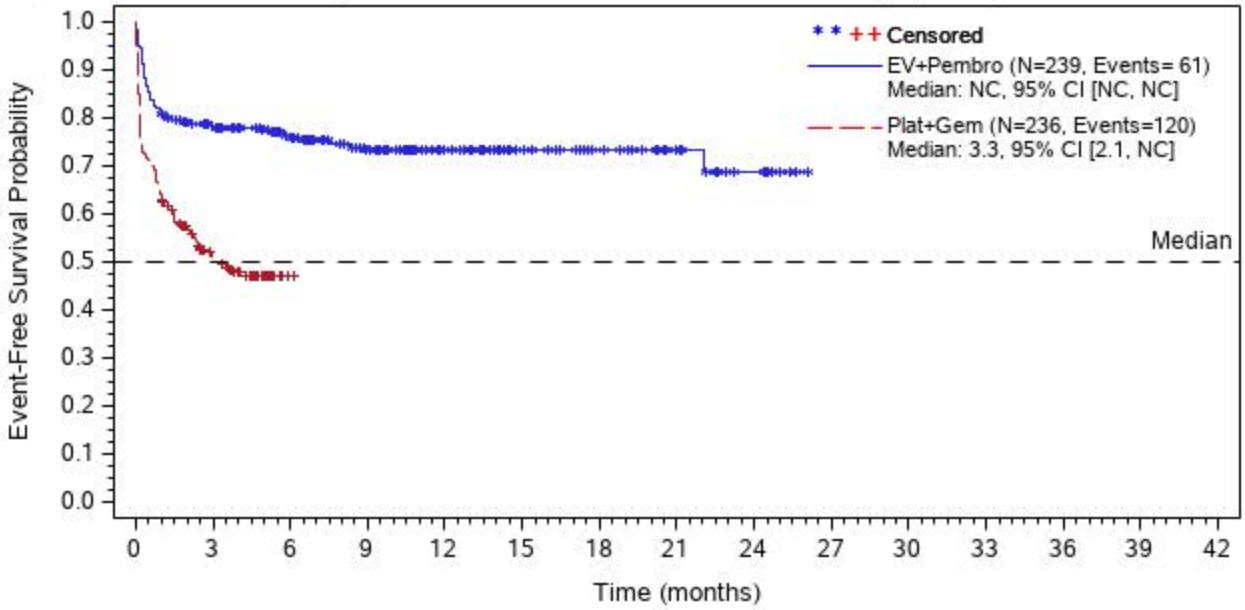
1	201	162	134	103	67	47	27	15	6	1	1	0	0	0	0
2	197	144	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.31.1.1: Kaplan-Meier Plot of Time to first TEAE - Nausea (PT) - Analysis Set mSAF 1



at Risk

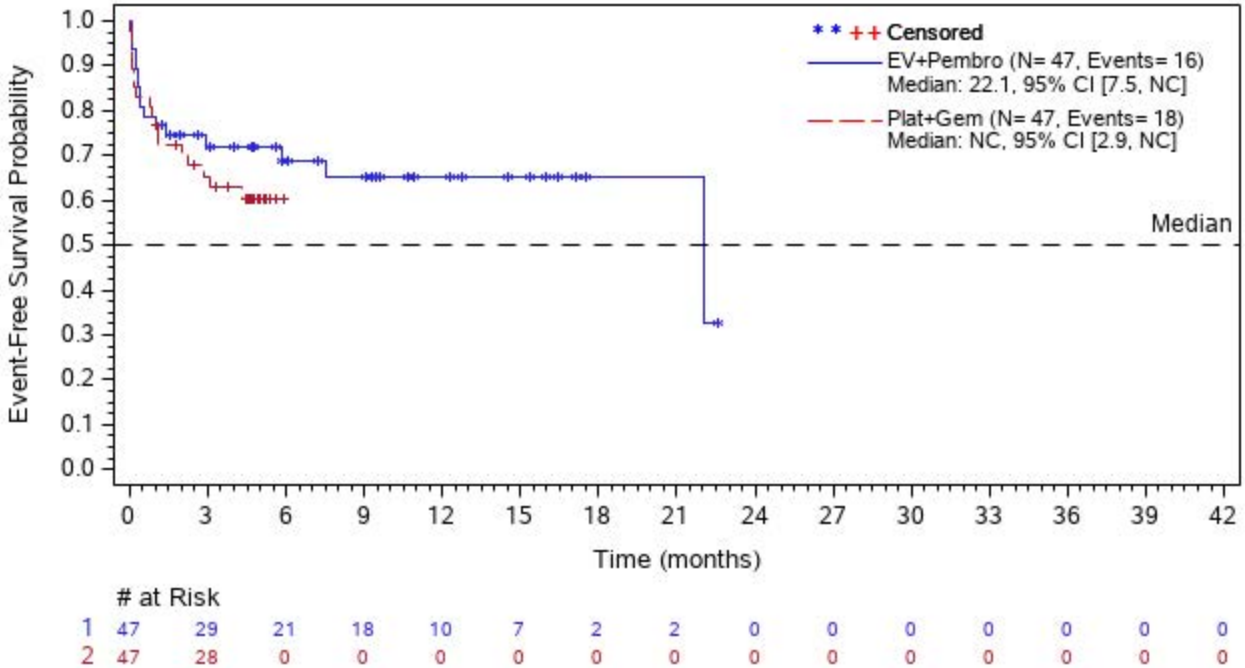
1	239	165	132	101	67	46	32	19	10	0	0	0	0	0	0
2	236	100	1	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.31.1.2.1: Kaplan-Meier Plot of Time to first TEAE - Nausea (PT) - Analysis Set mSAF 1 Liver Metastases: Present

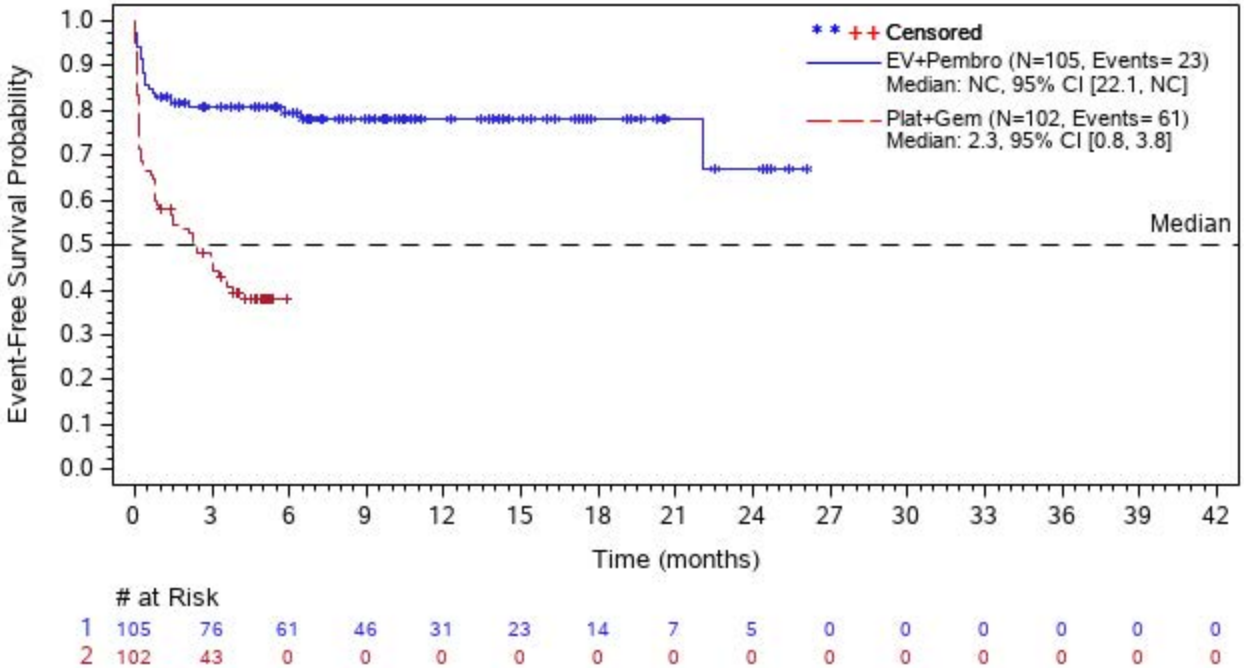


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.31.1.2.2: Kaplan-Meier Plot of Time to first TEAE - Nausea (PT) - Analysis Set mSAF 1
Age: < 65 years



at Risk

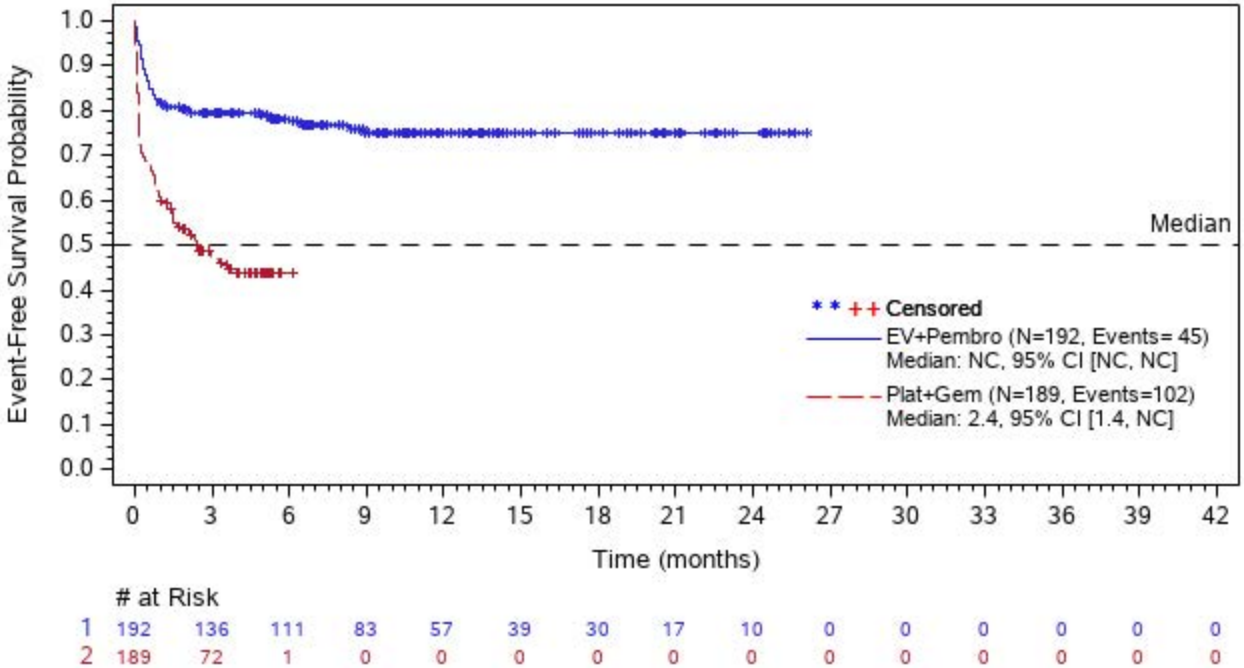
1	105	76	61	46	31	23	14	7	5	0	0	0	0	0	0
2	102	43	0	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.31.1.2.1: Kaplan-Meier Plot of Time to first TEAE - Nausea (PT) - Analysis Set mSAF 1 Liver Metastases: Absent



at Risk

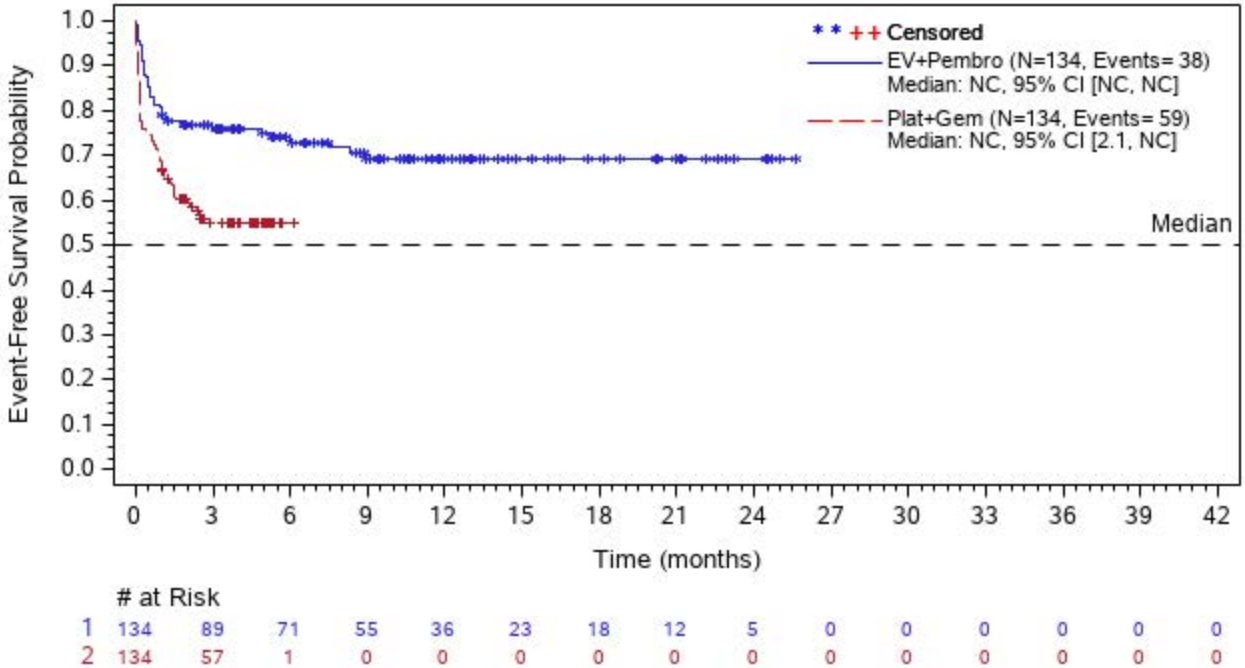
1	192	136	111	83	57	39	30	17	10	0	0	0	0	0	0
2	189	72	1	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.31.1.2.2: Kaplan-Meier Plot of Time to first TEAE - Nausea (PT) - Analysis Set mSAF 1
Age: >= 65 years



at Risk

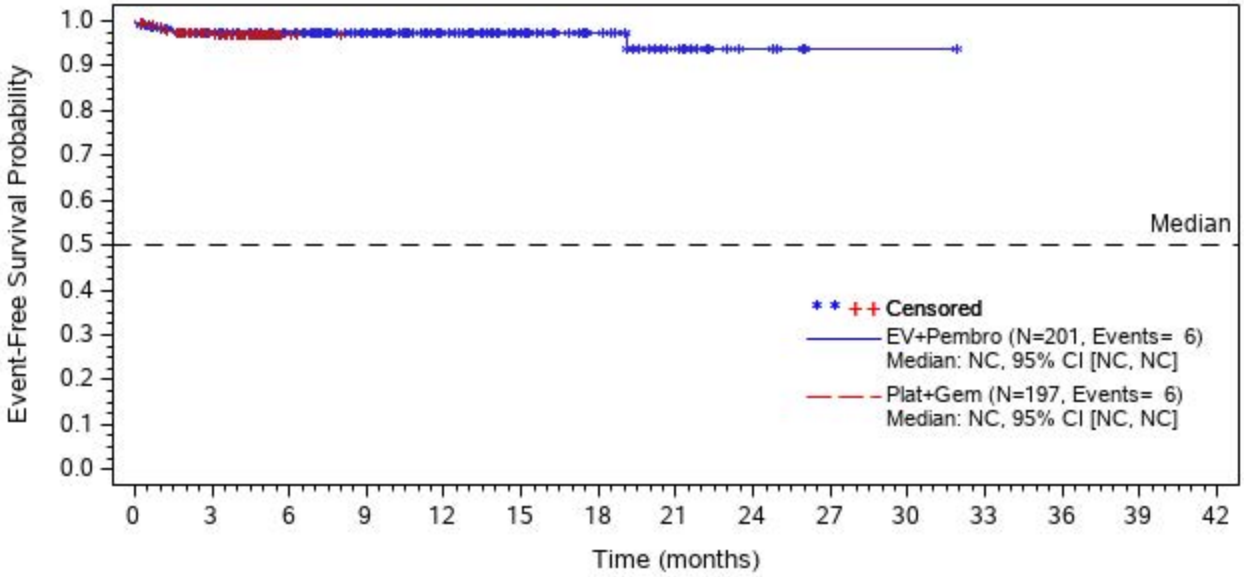
1	134	89	71	55	36	23	18	12	5	0	0	0	0	0	0
2	134	57	1	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.31.2.1: Kaplan-Meier Plot of Time to first TEAE - Gastrooesophageal reflux disease (PT) - Analysis Set mSAF 2



at Risk

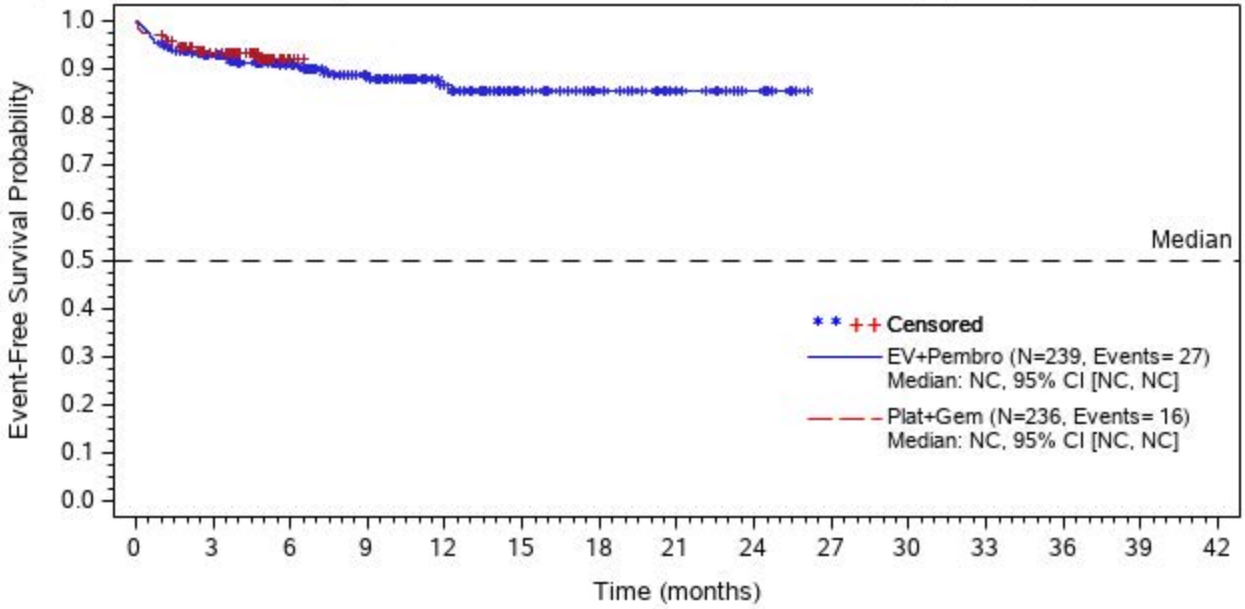
1	201	166	135	106	72	51	31	17	6	1	1	0	0	0	0
2	197	148	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.32.1.1: Kaplan-Meier Plot of Time to first TEAE - Stomatitis (PT) - Analysis Set mSAF 1



at Risk

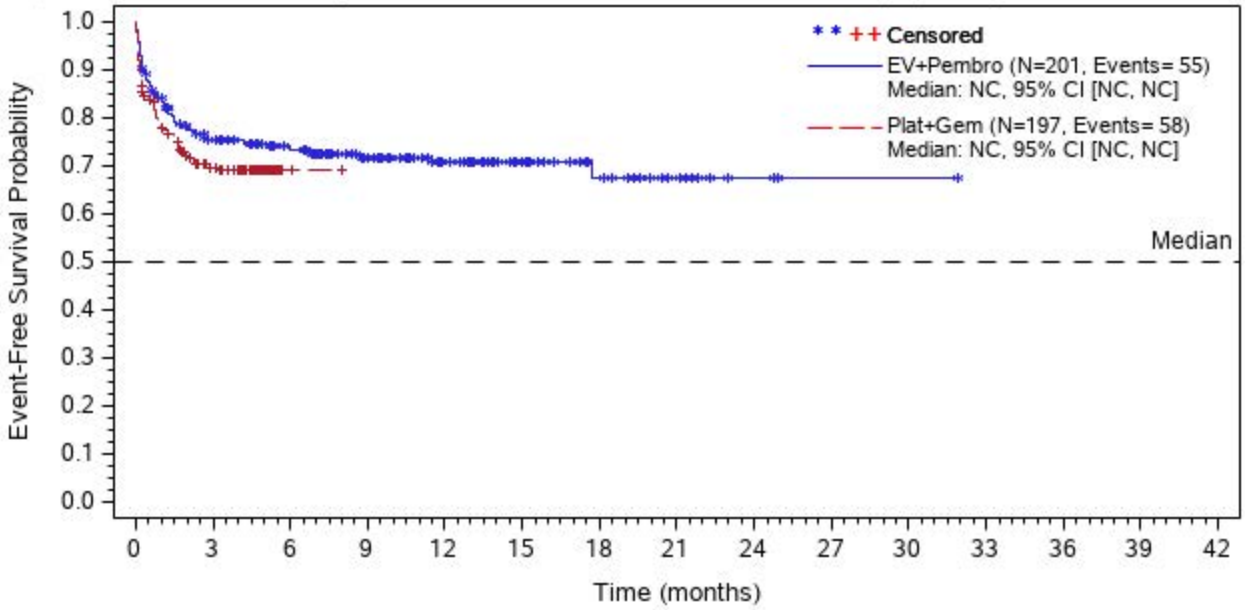
1	239	194	152	114	73	47	33	19	10	0	0	0	0	0	0
2	236	185	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.32.2.1: Kaplan-Meier Plot of Time to first TEAE - Nausea (PT) - Analysis Set mSAF 2



at Risk

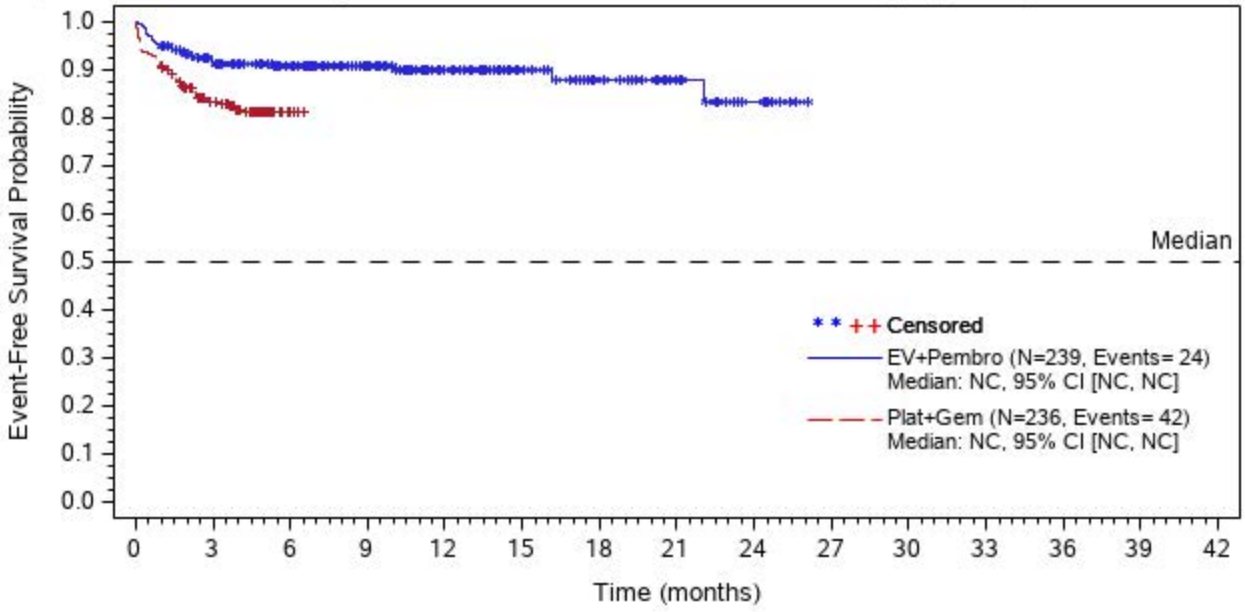
1	201	131	109	82	58	38	20	11	4	1	1	0	0	0	0
2	197	105	2	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.33.1.1: Kaplan-Meier Plot of Time to first TEAE - Vomiting (PT) - Analysis Set mSAF 1



at Risk

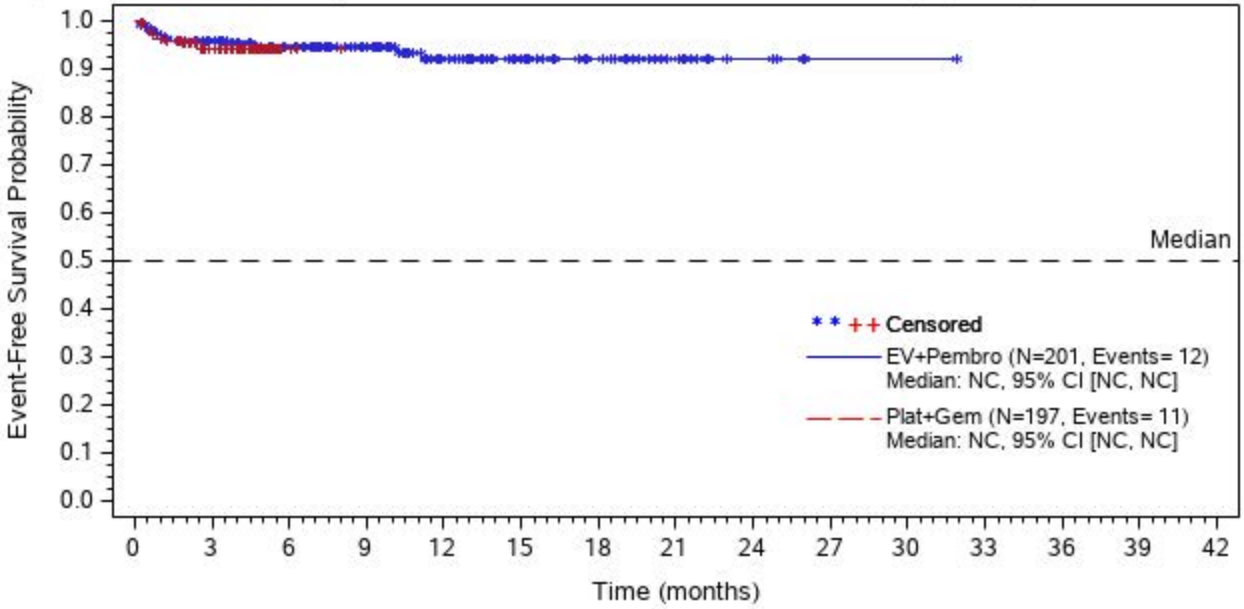
1	239	196	157	122	81	55	38	21	10	0	0	0	0	0	0
2	236	168	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.33.2.1: Kaplan-Meier Plot of Time to first TEAE - Stomatitis (PT) - Analysis Set mSAF 2



at Risk

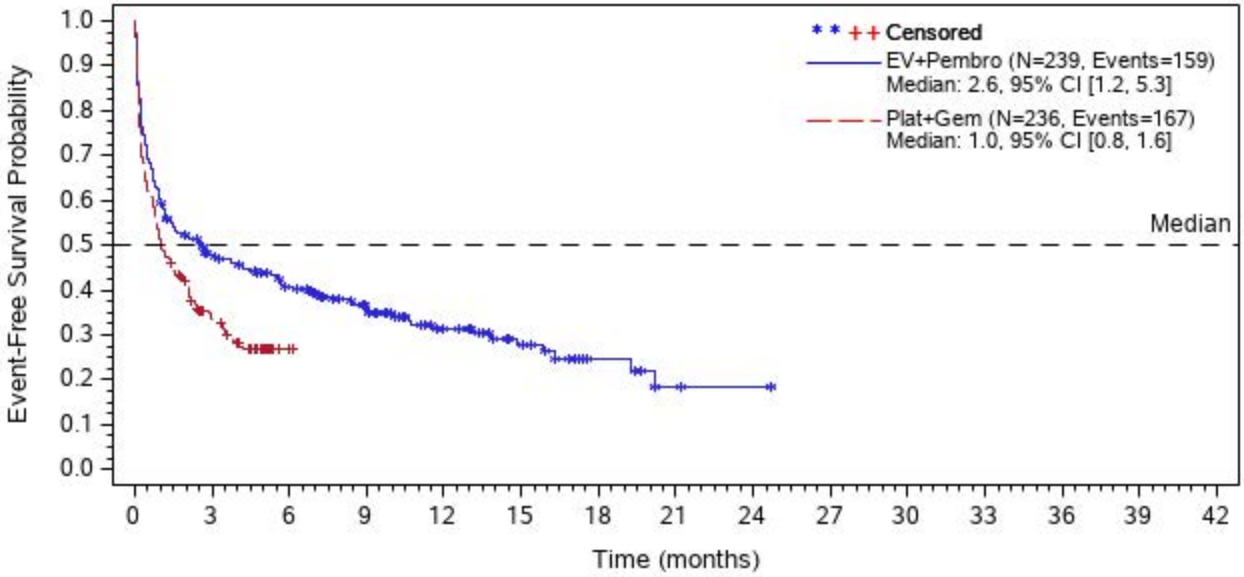
1	201	163	133	103	65	45	29	16	6	1	1	0	0	0	0
2	197	140	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.34.1.1: Kaplan-Meier Plot of Time to first TEAE - General disorders and administration site conditions (SOC) - Analysis Set mSAF 1



at Risk

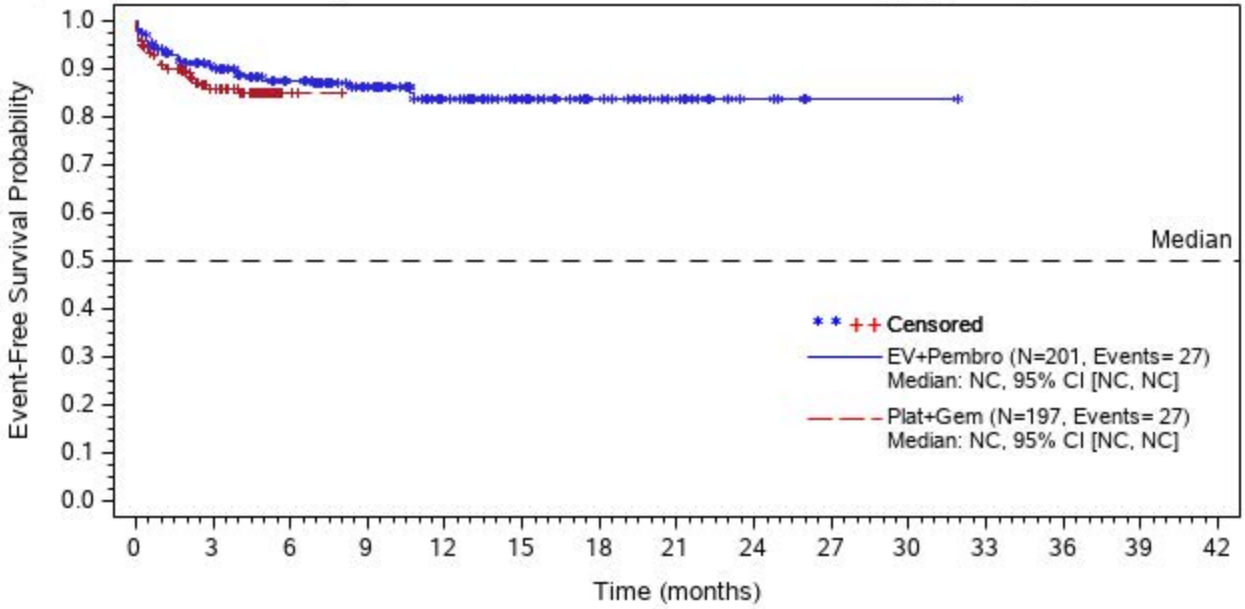
1	239	103	79	56	33	20	9	3	2	0	0	0	0	0	0
2	236	69	2	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.34.2.1: Kaplan-Meier Plot of Time to first TEAE - Vomiting (PT) - Analysis Set mSAF 2



at Risk

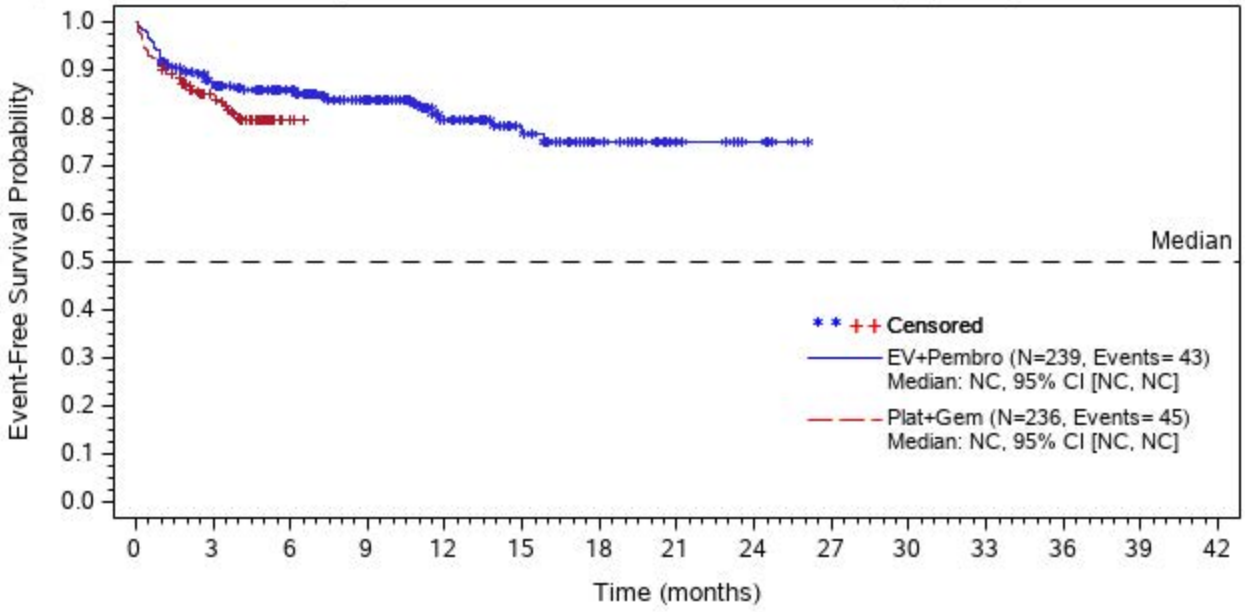
1	201	157	127	98	66	47	27	18	6	1	1	0	0	0	0
2	197	130	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.35.1.1: Kaplan-Meier Plot of Time to first TEAE - Asthenia (PT) - Analysis Set mSAF 1



at Risk

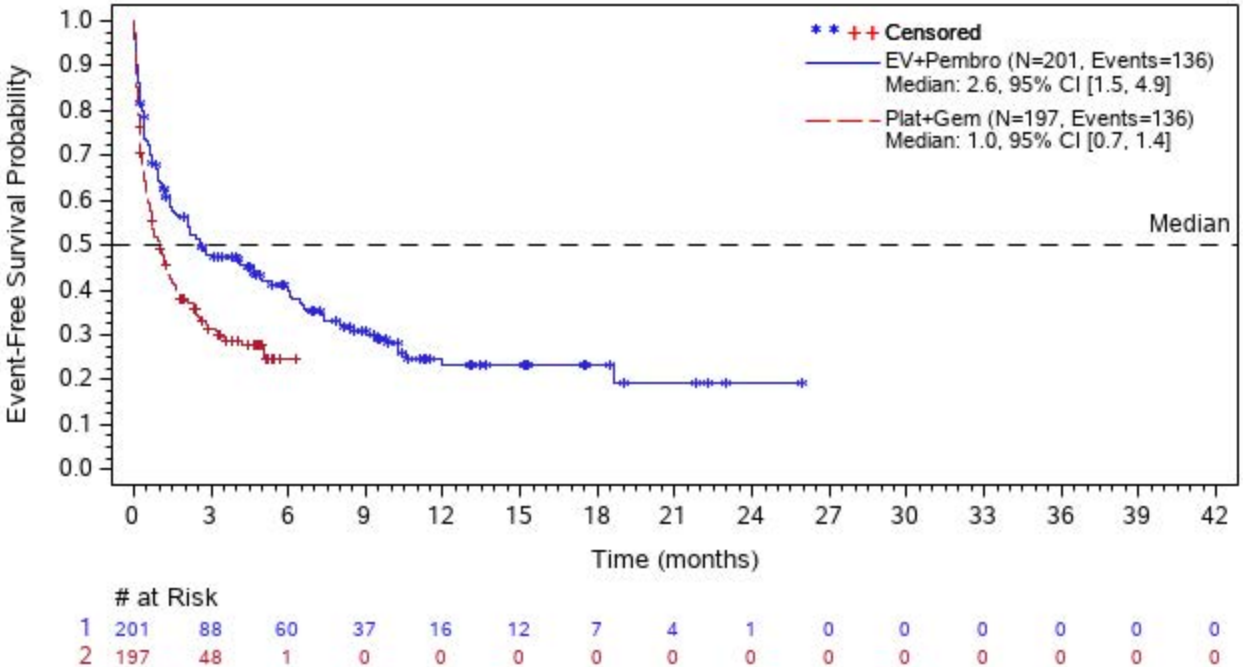
1	239	187	150	114	72	47	27	11	6	0	0	0	0	0	0
2	236	173	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.35.2.1: Kaplan-Meier Plot of Time to first TEAE - General disorders and administration site conditions (SOC) - Analysis Set mSAF 2



at Risk

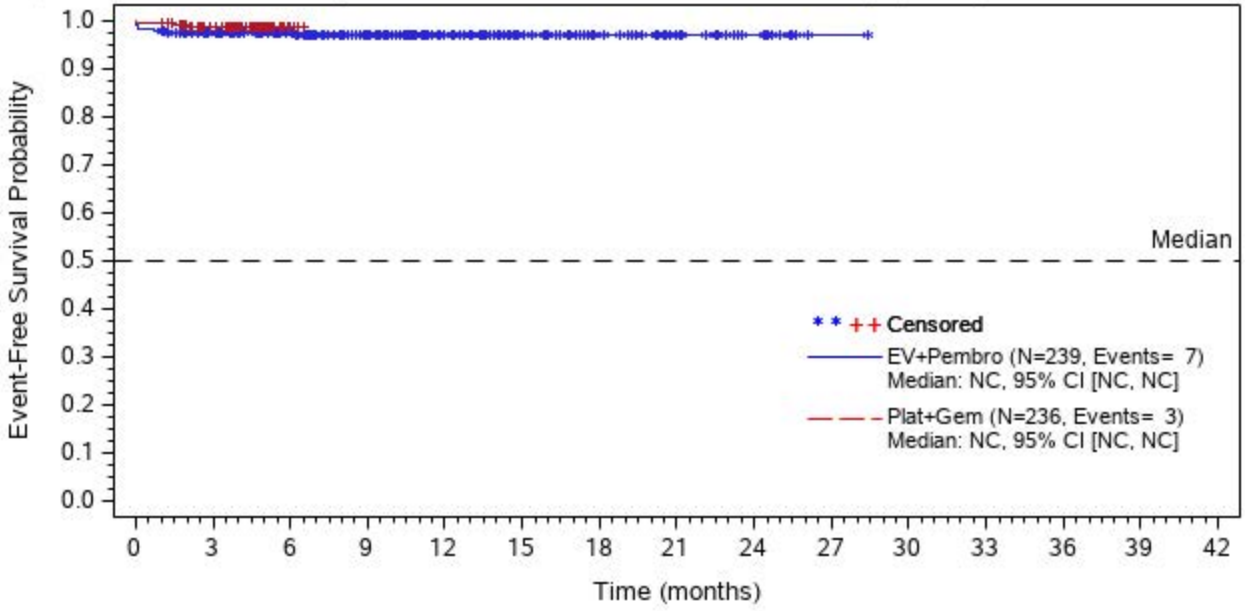
1	201	88	60	37	16	12	7	4	1	0	0	0	0	0	0
2	197	48	1	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.36.1.1: Kaplan-Meier Plot of Time to first TEAE - Chills (PT) - Analysis Set mSAF 1



at Risk

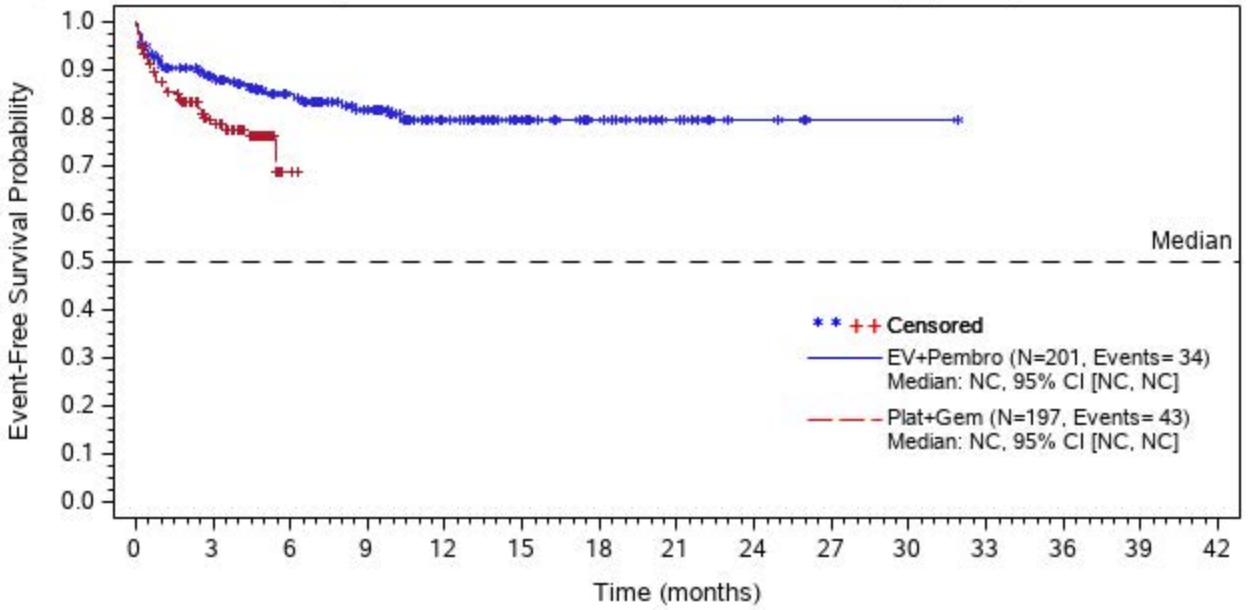
1	239	205	167	129	85	57	38	22	12	1	0	0	0	0	0
2	236	199	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.36.2.1: Kaplan-Meier Plot of Time to first TEAE - Asthenia (PT) - Analysis Set mSAF 2



at Risk

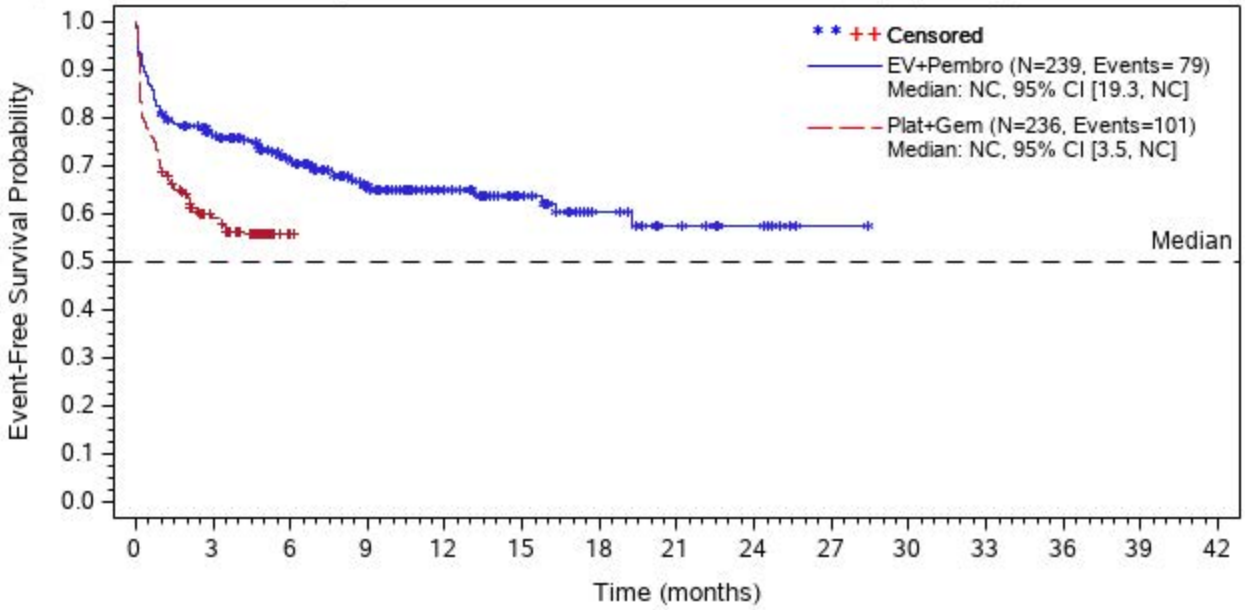
1	201	151	119	90	58	41	24	14	4	1	1	0	0	0	0
2	197	120	2	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.37.1.1: Kaplan-Meier Plot of Time to first TEAE - Fatigue (PT) - Analysis Set mSAF 1



at Risk

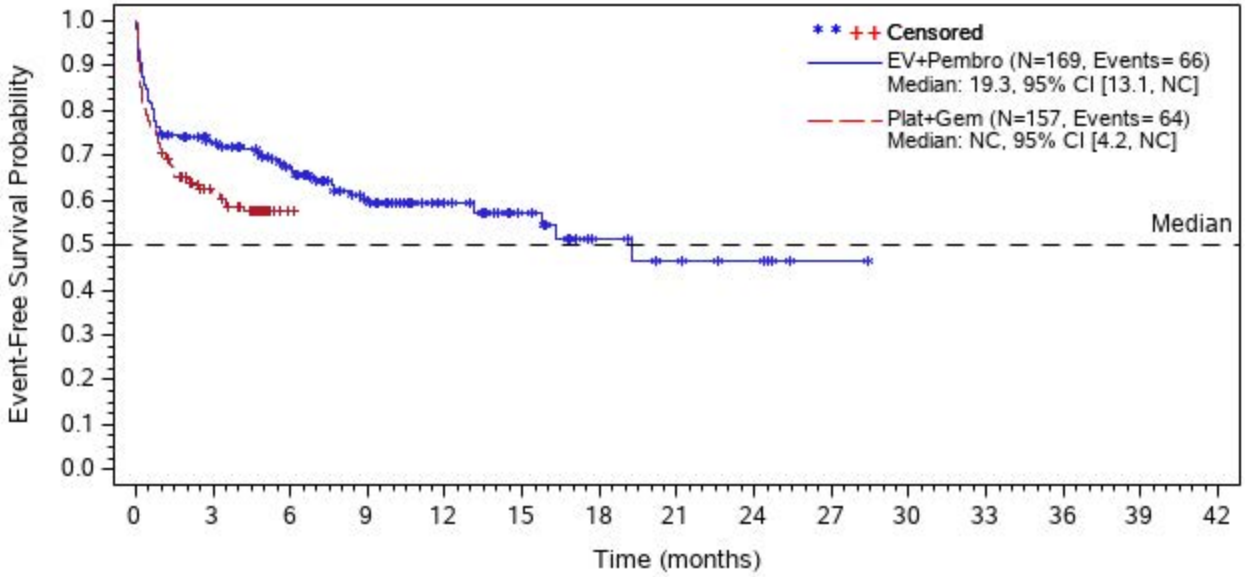
1	239	164	125	90	59	40	23	14	9	1	0	0	0	0	0
2	236	116	2	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.37.1.2.5: Kaplan-Meier Plot of Time to first TEAE - Fatigue (PT) - Analysis Set mSAF 1 Metastases at Baseline: Visceral metastases



at Risk

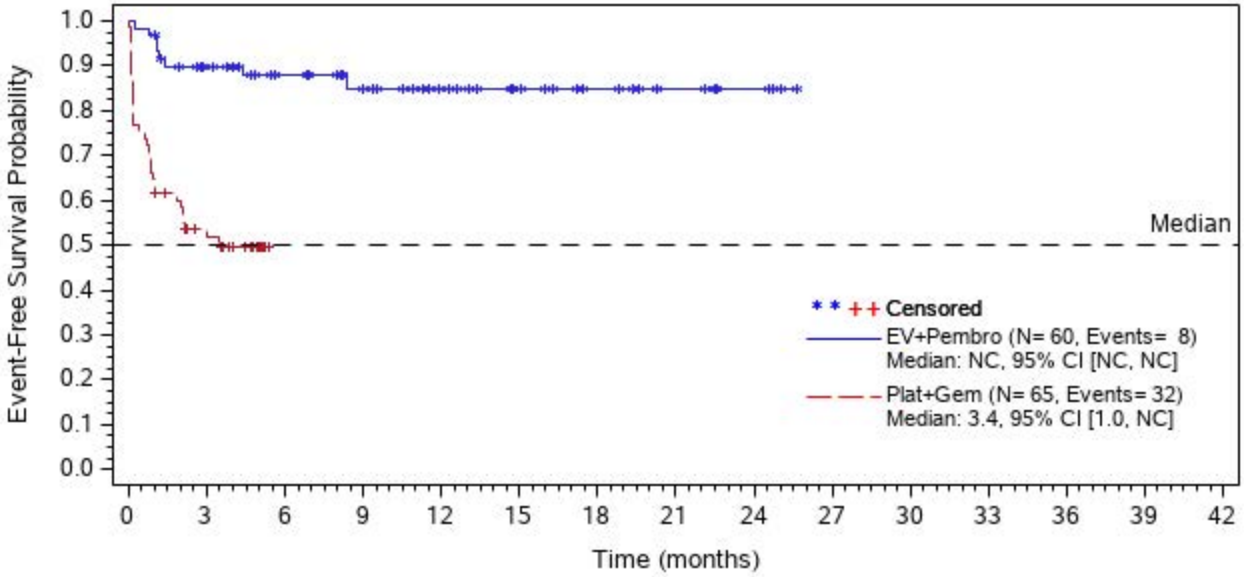
1	169	110	84	57	35	23	11	7	5	1	0	0	0	0	0
2	157	80	1	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.37.1.2.5: Kaplan-Meier Plot of Time to first TEAE - Fatigue (PT) - Analysis Set mSAF 1 Metastases at Baseline: Lymph node only



at Risk

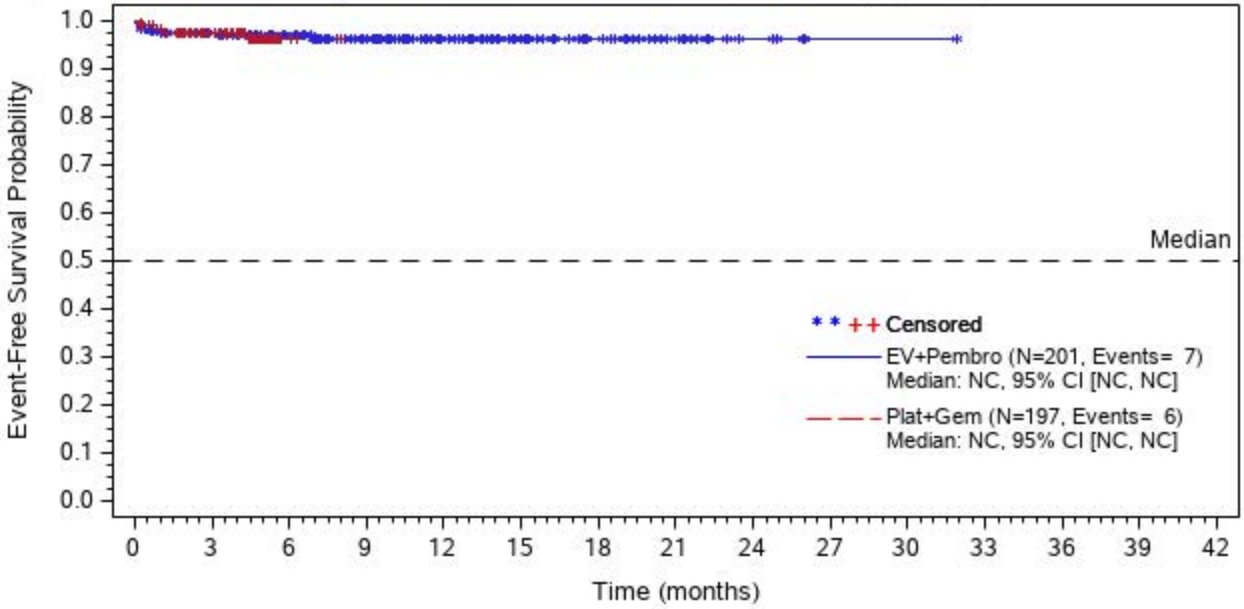
1	60	48	37	31	23	17	12	7	4	0	0	0	0	0	0
2	65	28	0	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.37.2.1: Kaplan-Meier Plot of Time to first TEAE - Chills (PT) - Analysis Set mSAF 2



at Risk

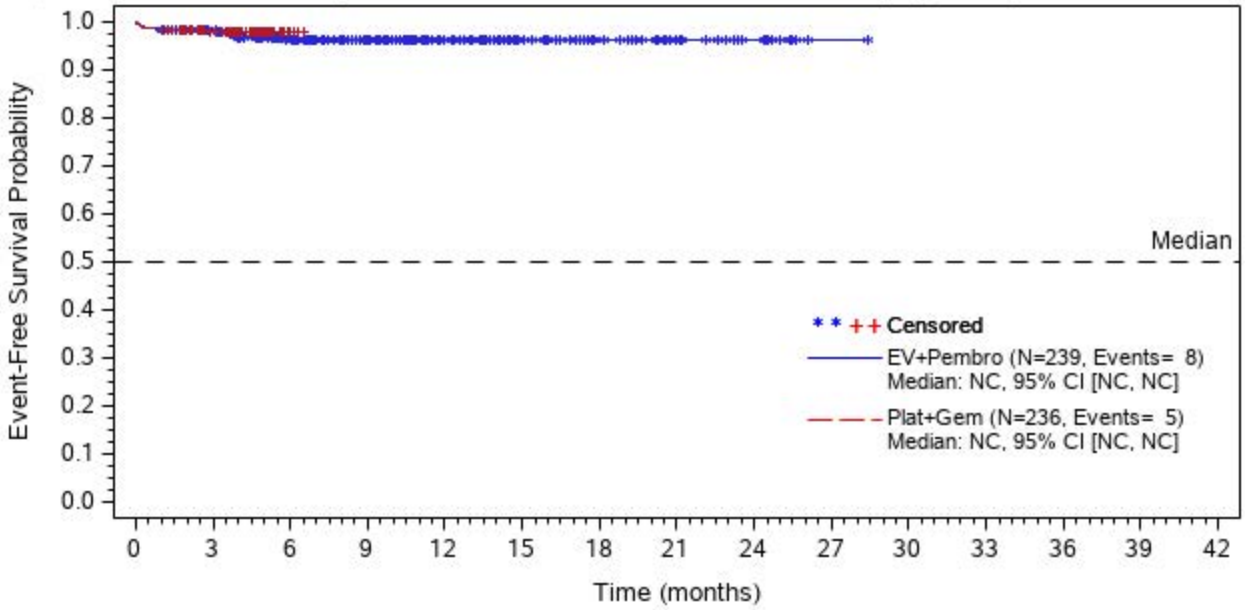
1	201	169	137	106	72	51	31	18	6	1	1	0	0	0	0
2	197	148	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.38.1.1: Kaplan-Meier Plot of Time to first TEAE - Malaise (PT) - Analysis Set mSAF 1



at Risk

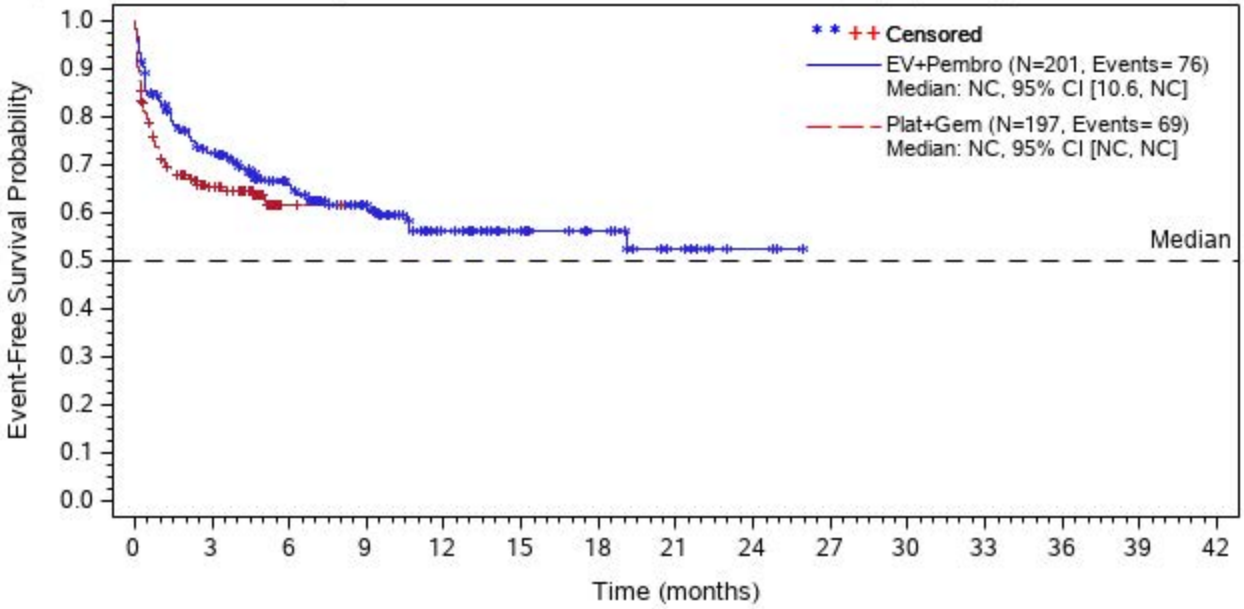
1	239	208	163	127	83	55	38	21	12	1	0	0	0	0	0
2	236	195	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.38.2.1: Kaplan-Meier Plot of Time to first TEAE - Fatigue (PT) - Analysis Set mSAF 2



at Risk

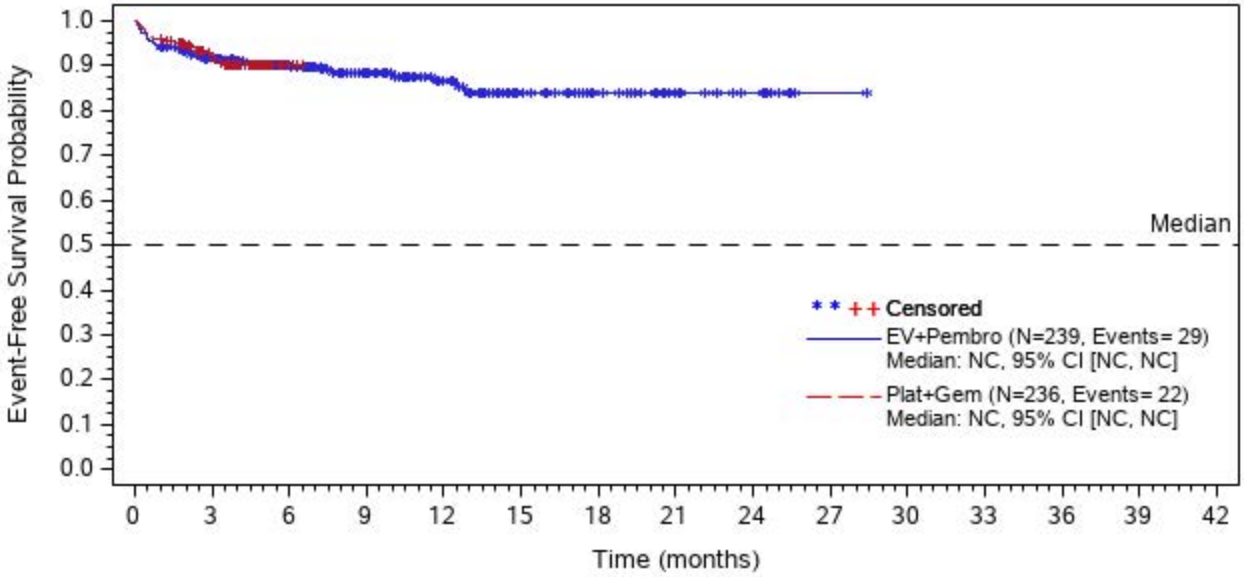
1	201	129	94	69	39	27	18	10	3	0	0	0	0	0	0
2	197	99	2	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.39.1.1: Kaplan-Meier Plot of Time to first TEAE - Oedema peripheral (PT) - Analysis Set mSAF 1



at Risk

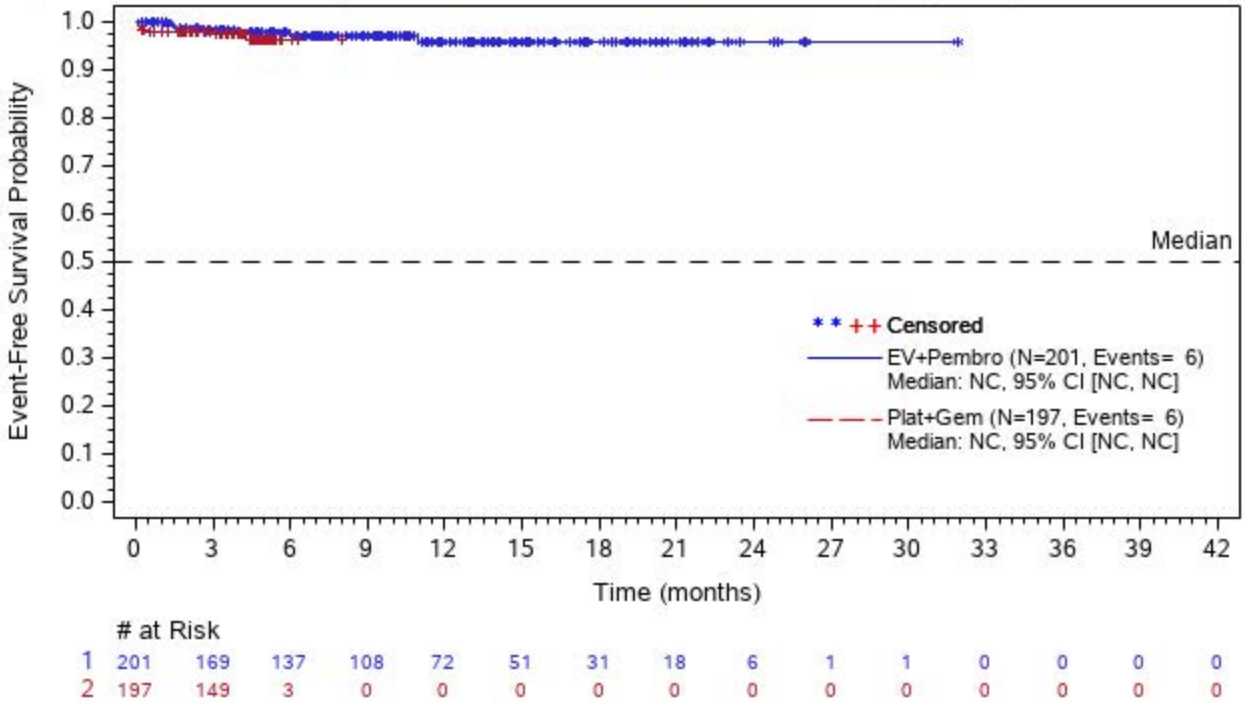
1	239	191	151	114	77	50	34	18	11	1	0	0	0	0	0
2	236	187	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.39.2.1: Kaplan-Meier Plot of Time to first TEAE - Malaise (PT) - Analysis Set mSAF 2



at Risk

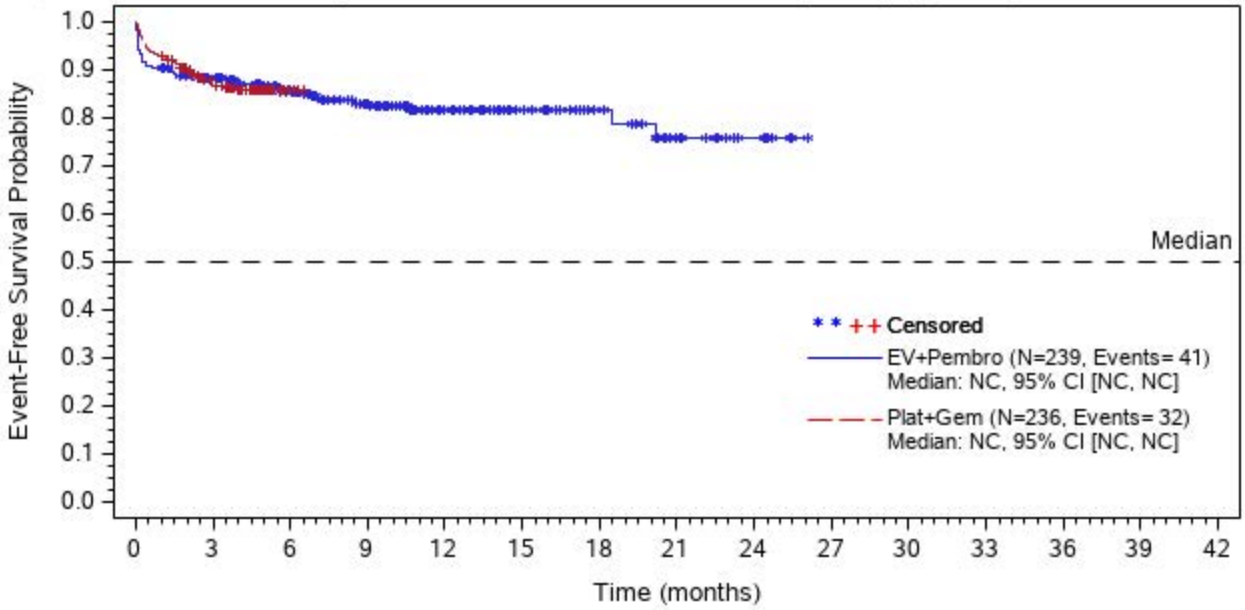
1	201	169	137	108	72	51	31	18	6	1	1	0	0	0	0
2	197	149	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.40.1.1: Kaplan-Meier Plot of Time to first TEAE - Pyrexia (PT) - Analysis Set mSAF 1



at Risk

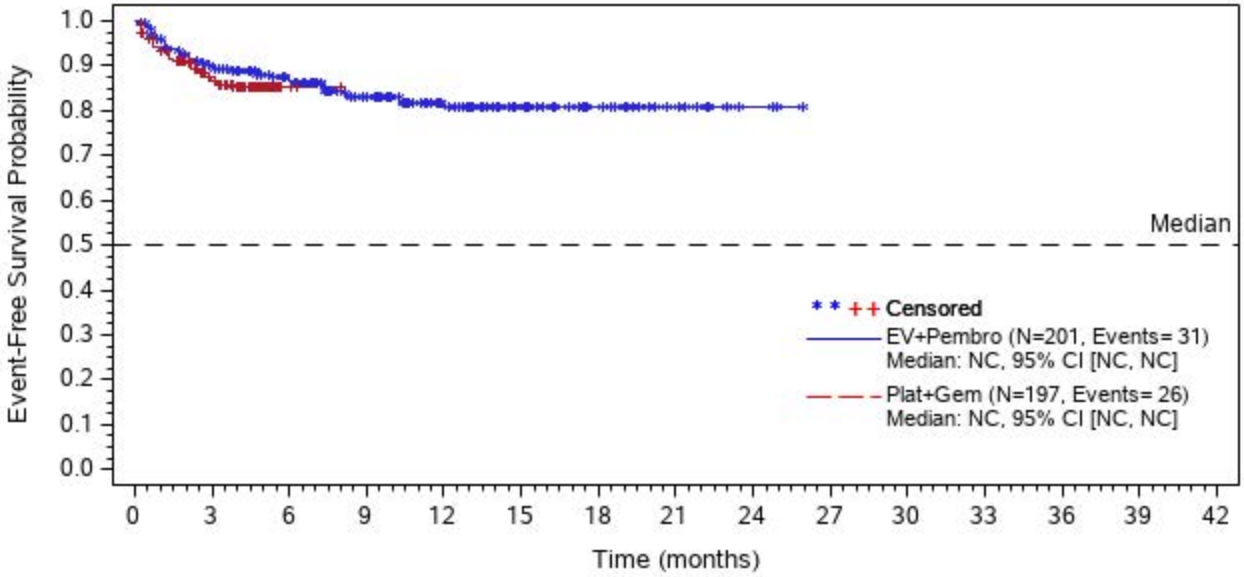
1	239	189	153	116	74	49	34	17	8	0	0	0	0	0	0
2	236	175	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.40.2.1: Kaplan-Meier Plot of Time to first TEAE - Oedema peripheral (PT) - Analysis Set mSAF 2



at Risk

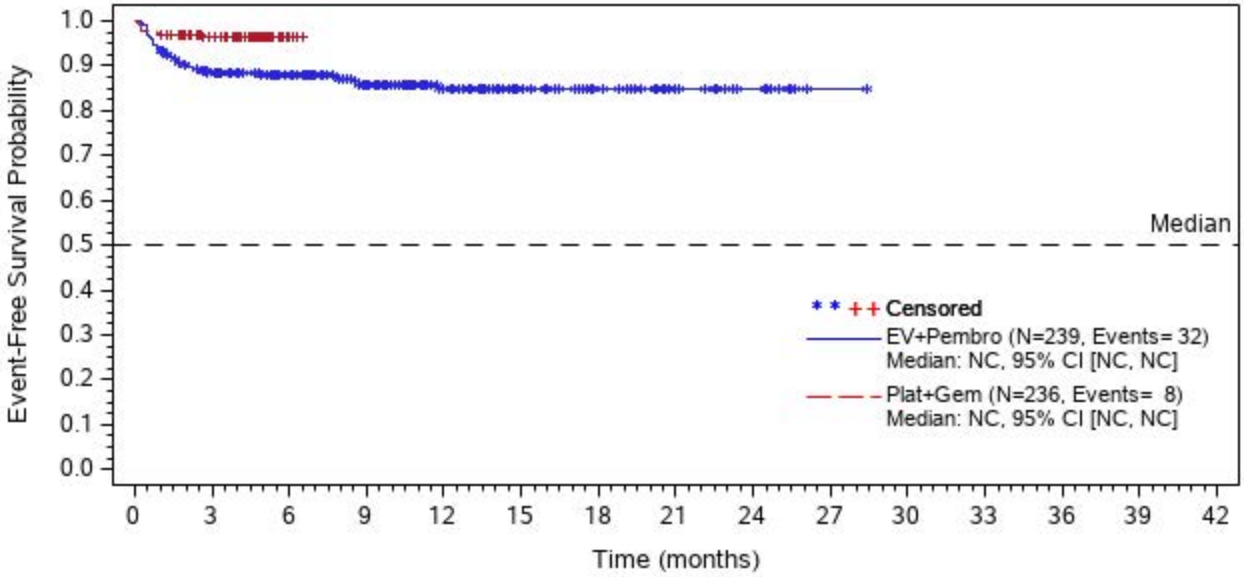
1	201	156	127	94	63	43	25	13	4	0	0	0	0	0	0
2	197	129	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.41.1.1: Kaplan-Meier Plot of Time to first TEAE - Hepatobiliary disorders (SOC) - Analysis Set mSAF 1



at Risk

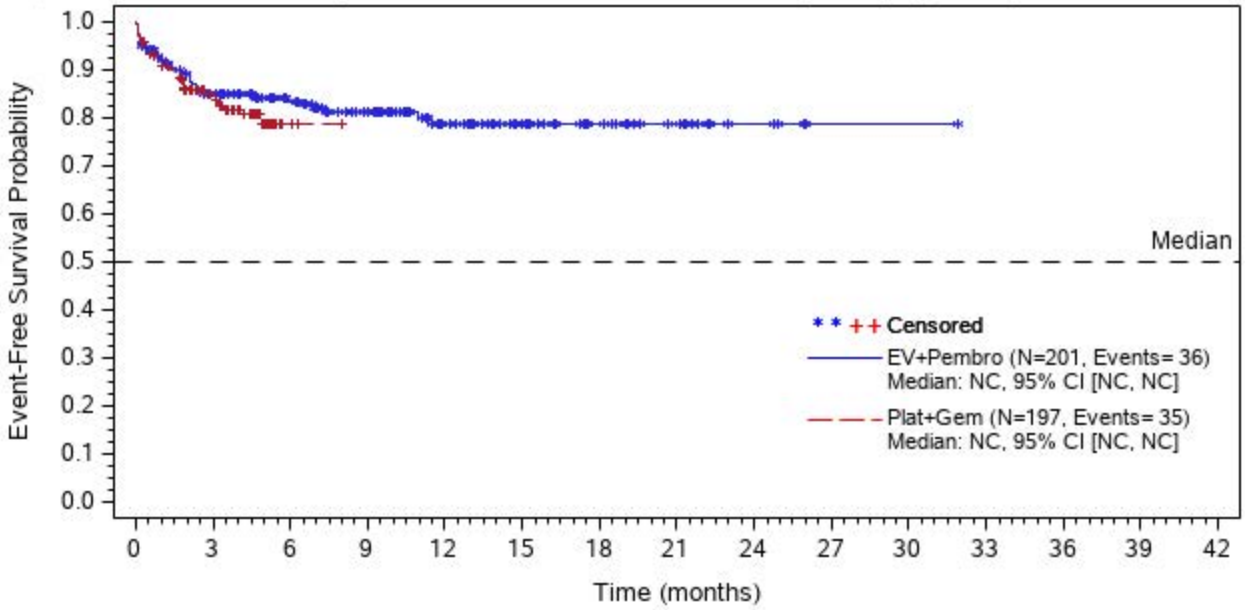
1	239	190	153	115	73	48	32	17	10	1	0	0	0	0	0
2	236	193	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.41.2.1: Kaplan-Meier Plot of Time to first TEAE - Pyrexia (PT) - Analysis Set mSAF 2



at Risk

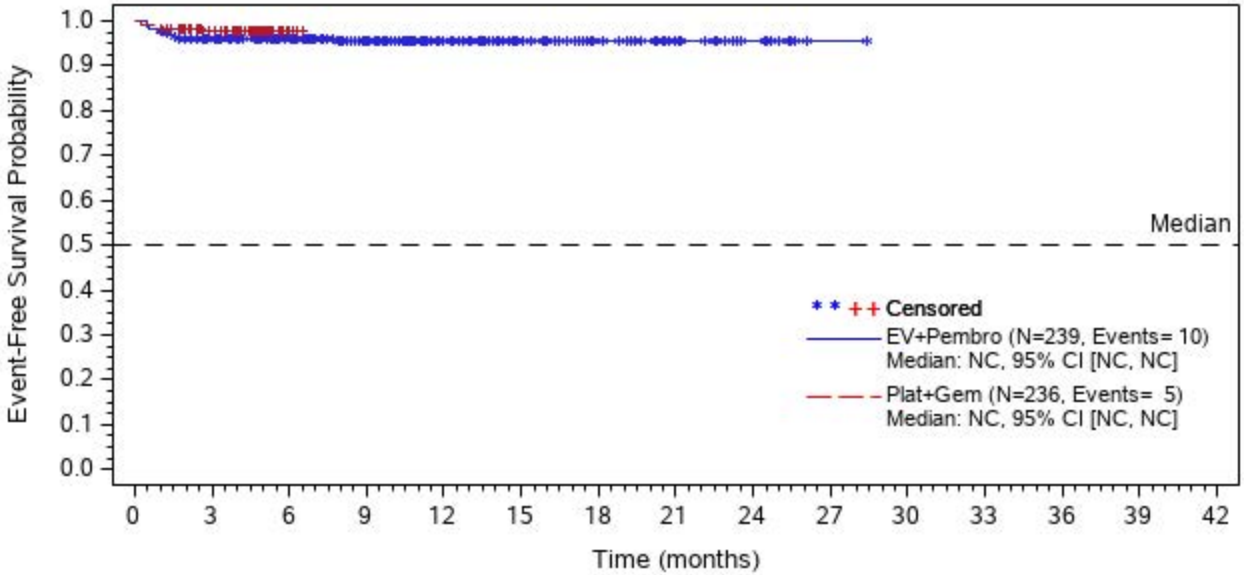
1	201	148	119	92	58	42	26	16	6	1	1	0	0	0	0
2	197	129	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.42.1.1: Kaplan-Meier Plot of Time to first TEAE - Hypertransaminasaemia (PT) - Analysis Set mSAF 1



at Risk

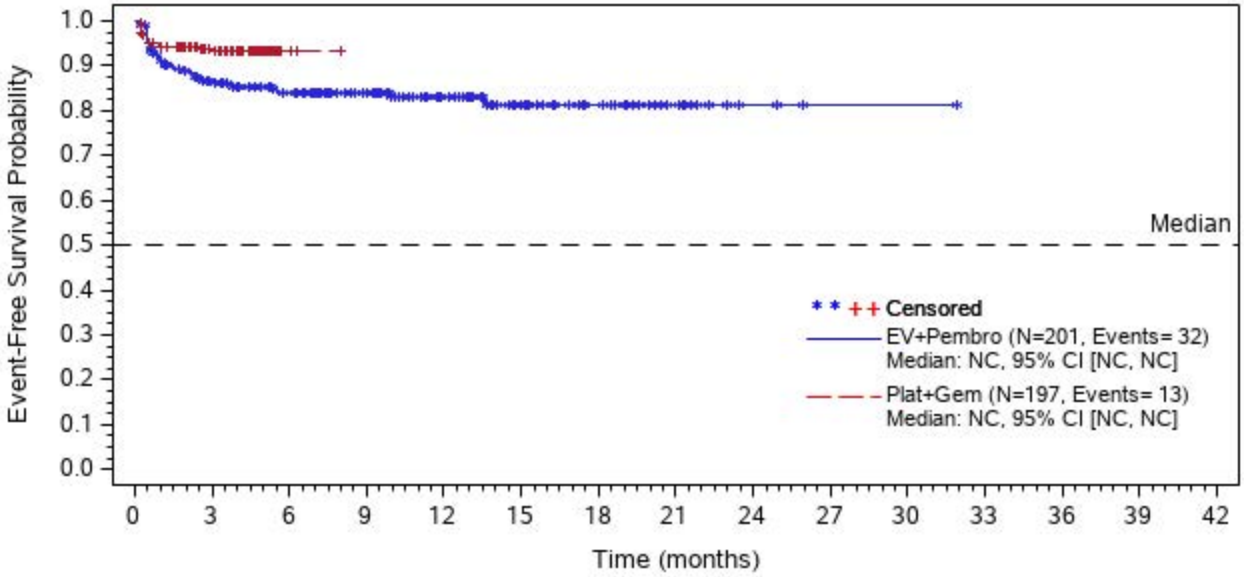
1	239	204	163	125	82	54	36	20	11	1	0	0	0	0	0
2	236	195	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.42.2.1: Kaplan-Meier Plot of Time to first TEAE - Hepatobiliary disorders (SOC) - Analysis Set mSAF 2



at Risk

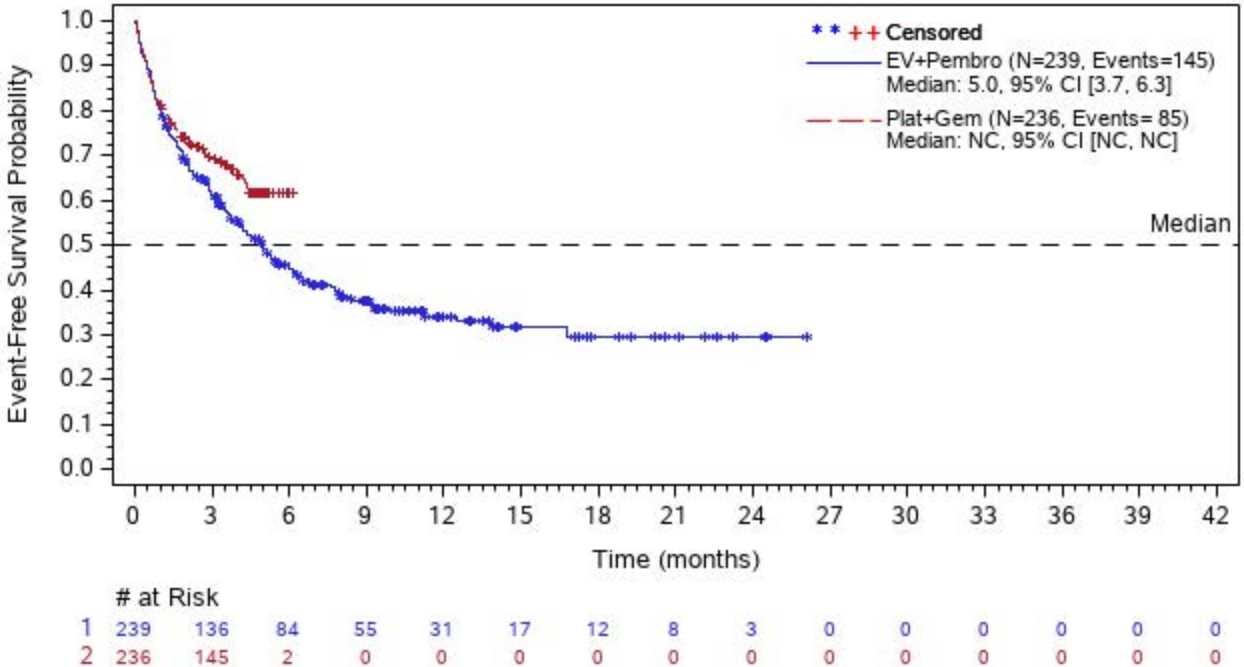
1	201	150	122	95	65	44	26	14	4	1	1	0	0	0	0
2	197	142	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.43.1.1: Kaplan-Meier Plot of Time to first TEAE - Infections and infestations (SOC) - Analysis Set mSAF 1

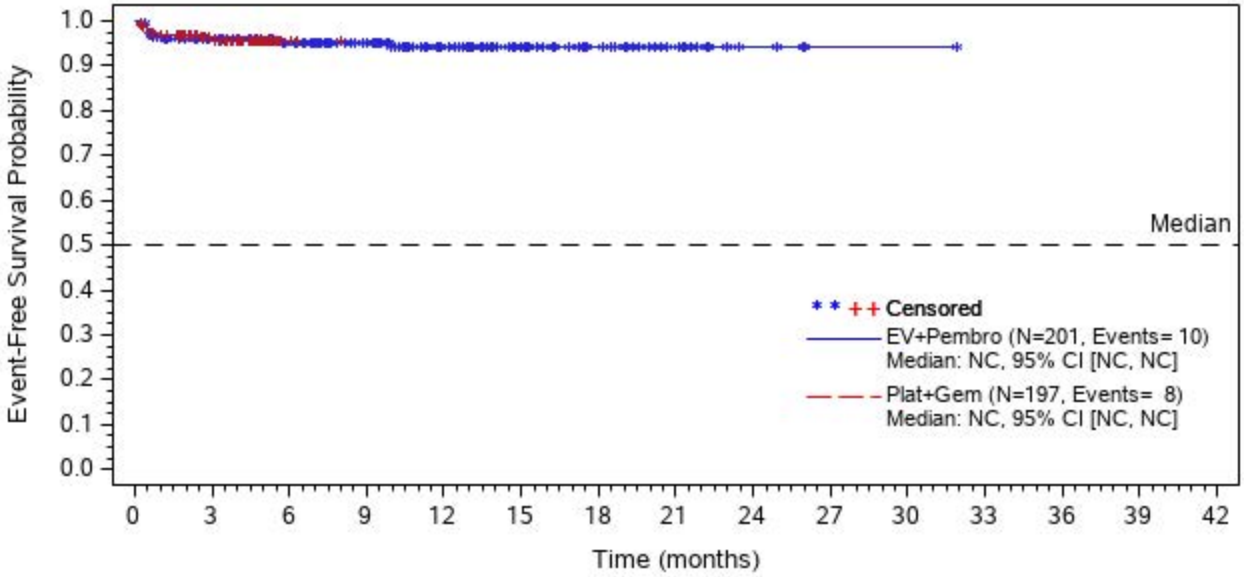


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.43.2.1: Kaplan-Meier Plot of Time to first TEAE - Hypertransaminasaemia (PT) - Analysis Set mSAF 2



at Risk

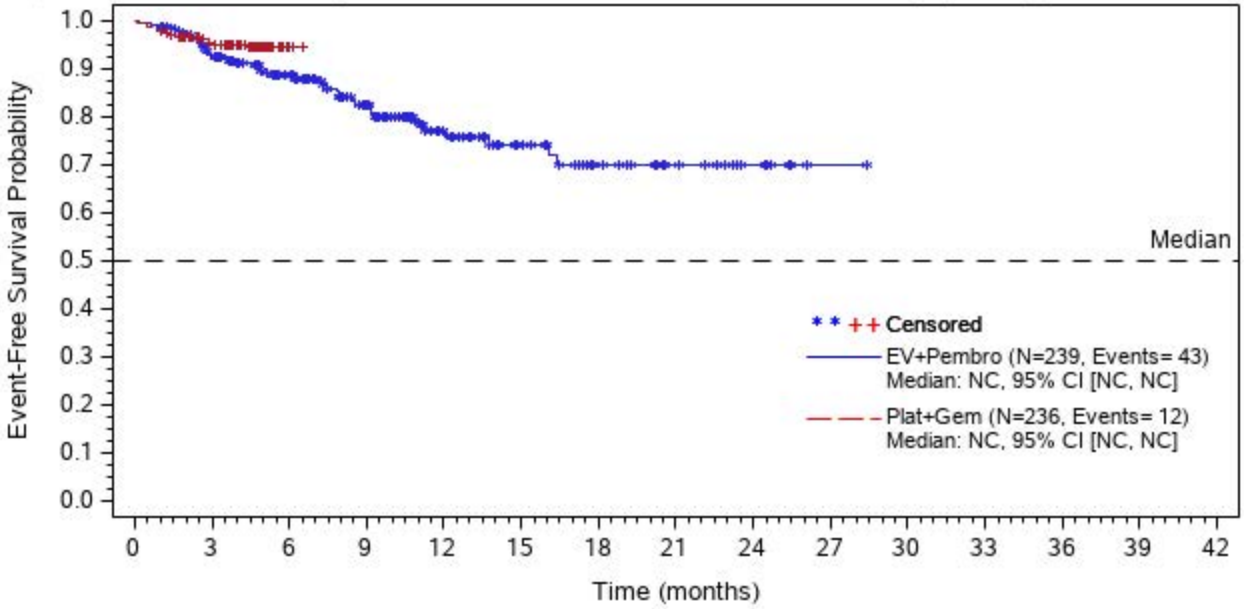
1	201	165	133	105	70	49	30	17	5	1	1	0	0	0	0
2	197	146	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.44.1.1: Kaplan-Meier Plot of Time to first TEAE - COVID-19 (PT) - Analysis Set mSAF 1



at Risk

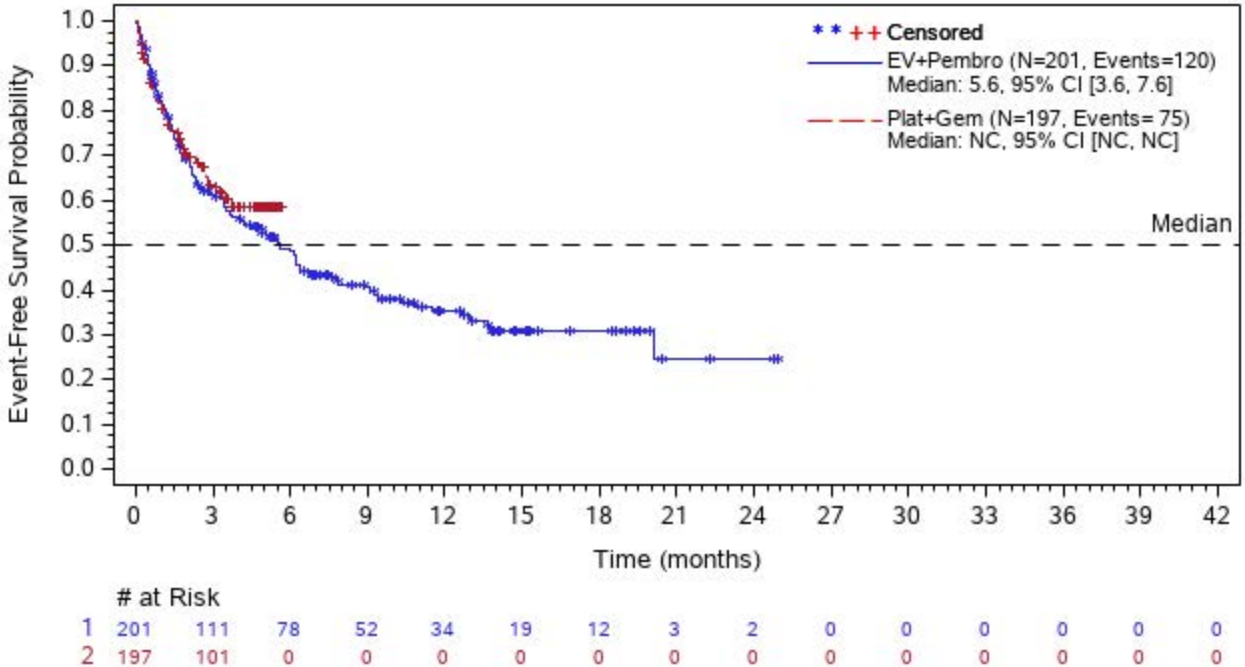
1	239	195	151	109	65	41	26	16	8	1	0	0	0	0	0
2	236	192	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.44.2.1: Kaplan-Meier Plot of Time to first TEAE - Infections and infestations (SOC) - Analysis Set mSAF 2

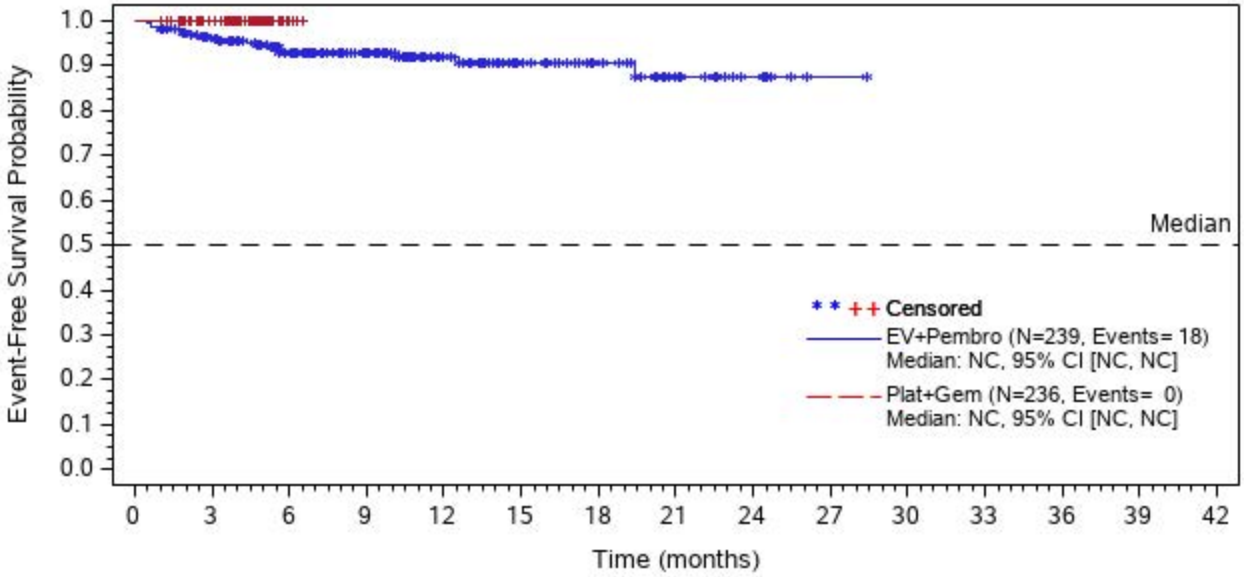


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.45.1.1: Kaplan-Meier Plot of Time to first TEAE - Conjunctivitis (PT) - Analysis Set mSAF 1



at Risk

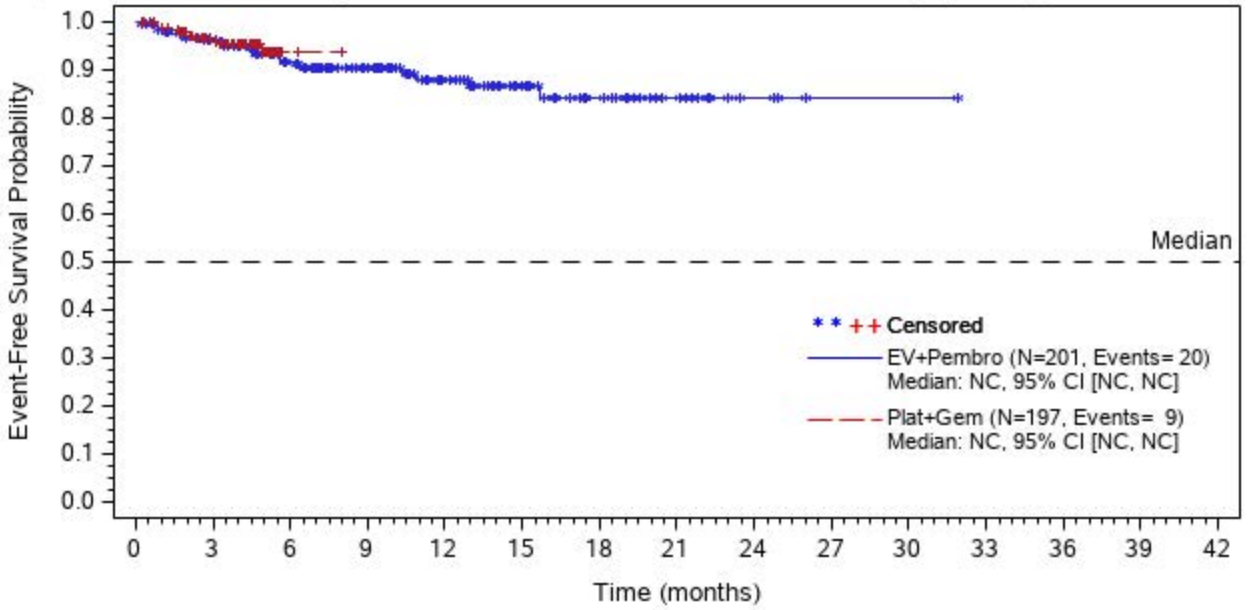
1	239	203	157	121	78	51	36	18	9	1	0	0	0	0	0
2	236	200	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.45.2.1: Kaplan-Meier Plot of Time to first TEAE - COVID-19 (PT) - Analysis Set mSAF 2



at Risk

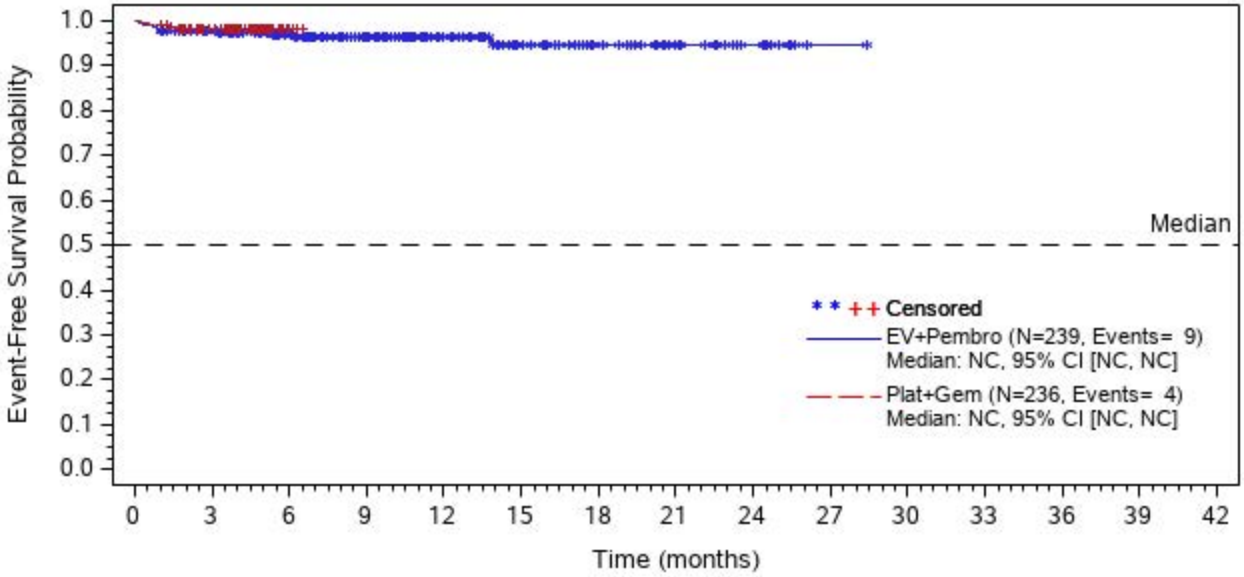
1	201	165	129	97	65	44	26	14	5	1	1	0	0	0	0
2	197	146	2	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.46.1.1: Kaplan-Meier Plot of Time to first TEAE - Oral candidiasis (PT) - Analysis Set mSAF 1



at Risk

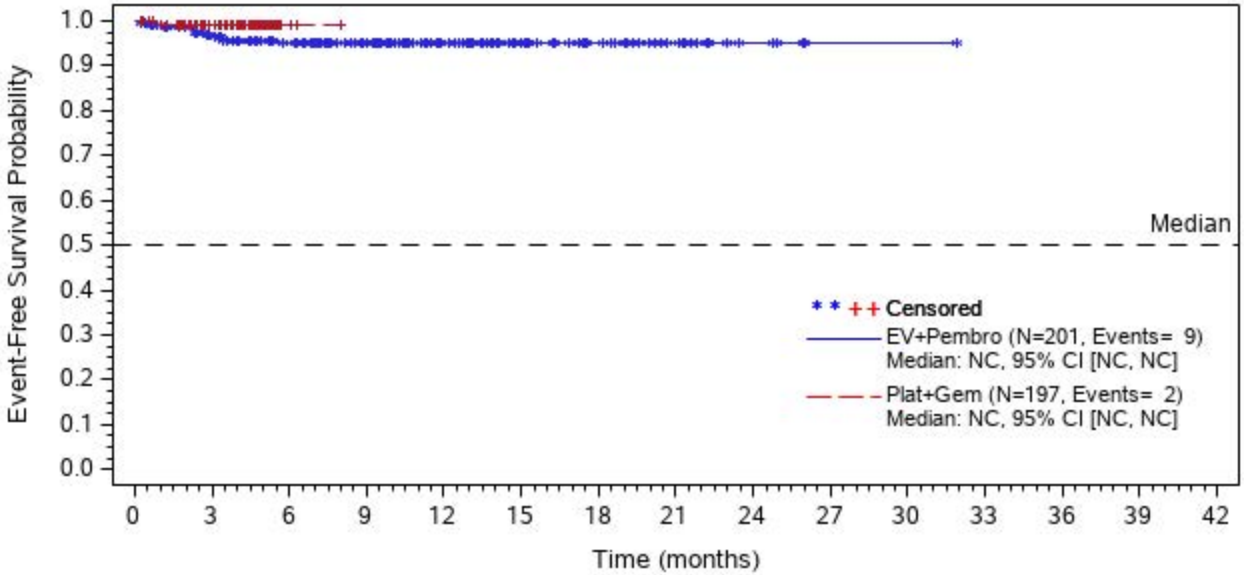
1	239	207	164	127	84	56	38	22	12	1	0	0	0	0	0
2	236	197	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.46.2.1: Kaplan-Meier Plot of Time to first TEAE - Oral candidiasis (PT) - Analysis Set mSAF 2



at Risk

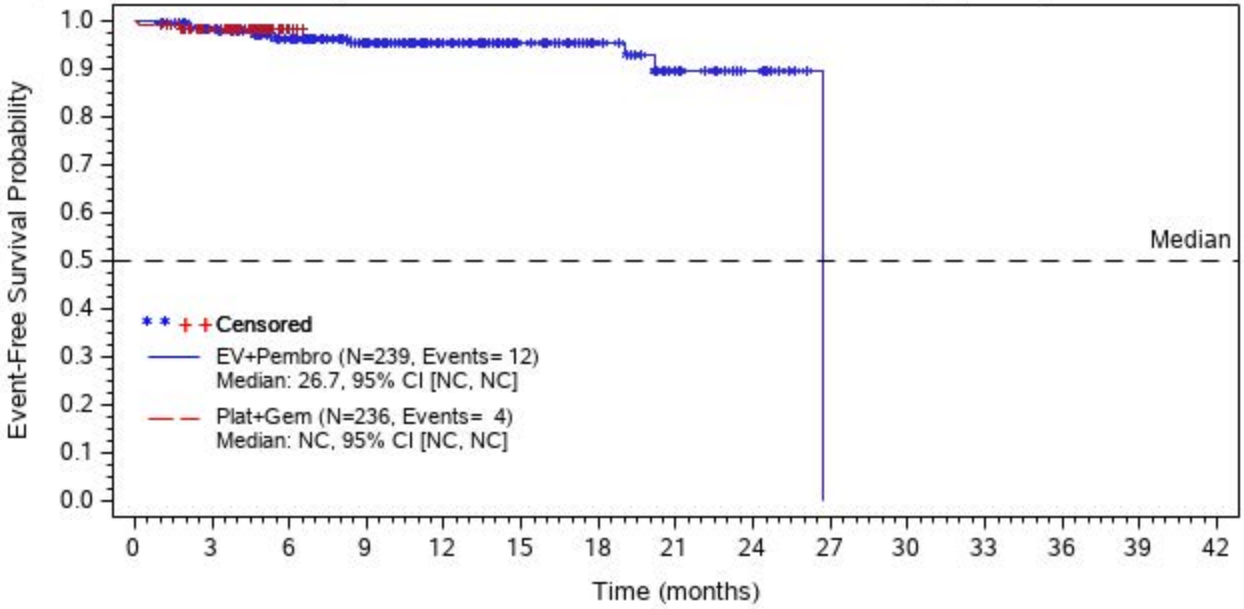
1	201	166	136	107	72	50	31	18	6	1	1	0	0	0	0
2	197	150	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.47.1.1: Kaplan-Meier Plot of Time to first TEAE - Pneumonia (PT) - Analysis Set mSAF 1



at Risk

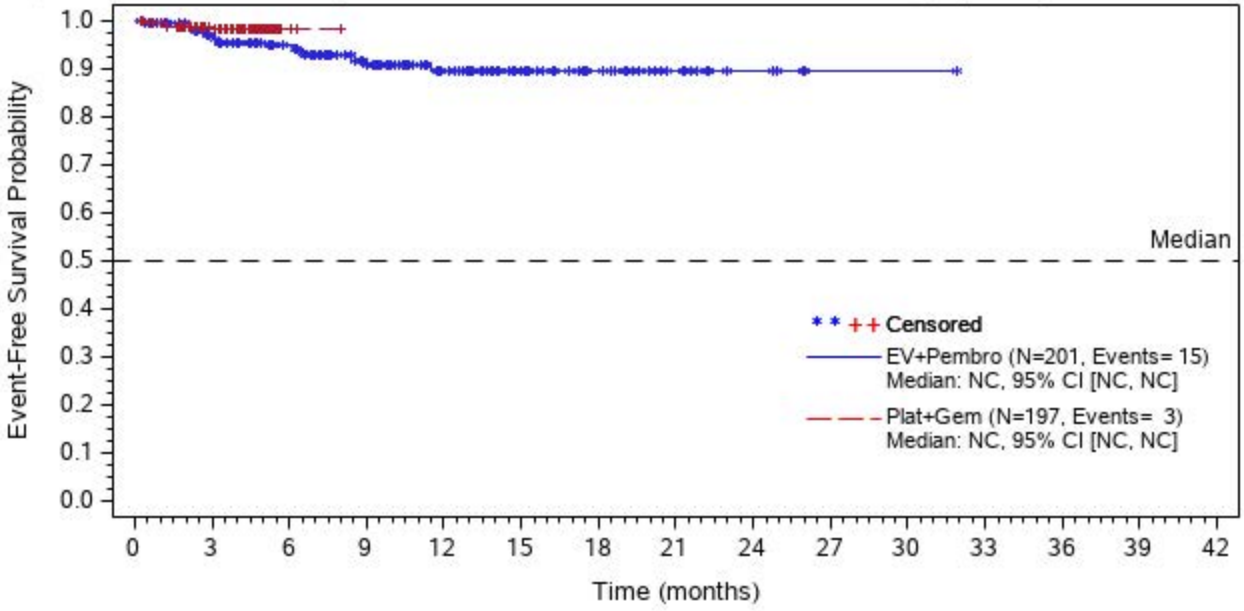
1	239	207	164	125	85	57	39	20	10	0	0	0	0	0	0
2	236	197	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.47.2.1: Kaplan-Meier Plot of Time to first TEAE - Pneumonia (PT) - Analysis Set mSAF 2



at Risk

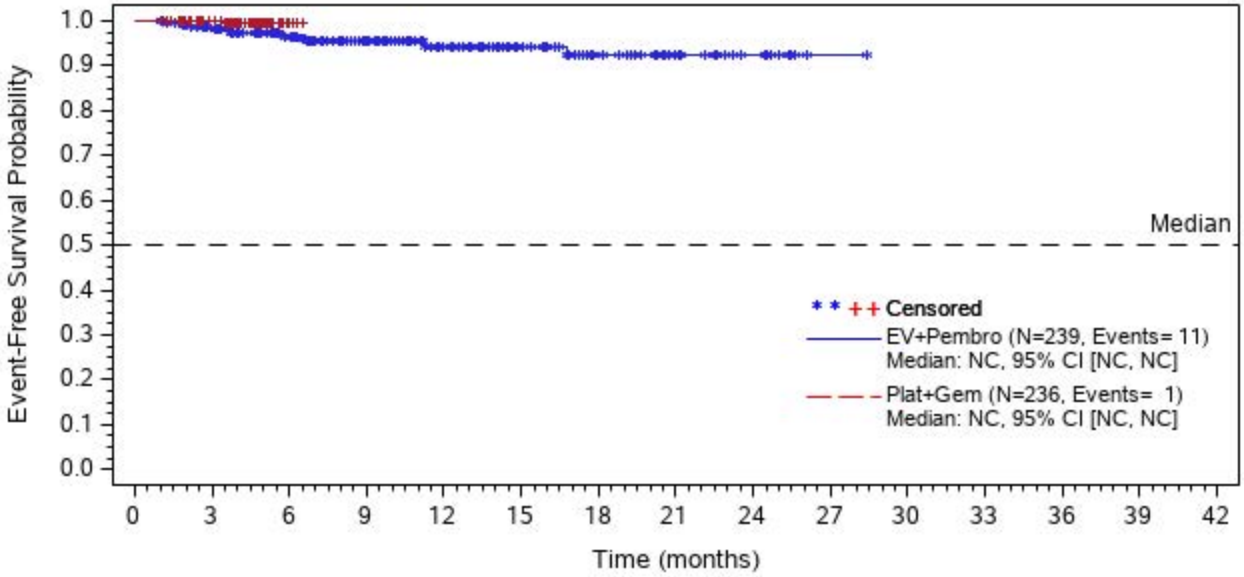
1	201	167	136	103	70	48	29	16	6	1	1	0	0	0	0
2	197	149	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.48.1.1: Kaplan-Meier Plot of Time to first TEAE - Upper respiratory tract infection (PT) - Analysis Set mSAF 1



at Risk

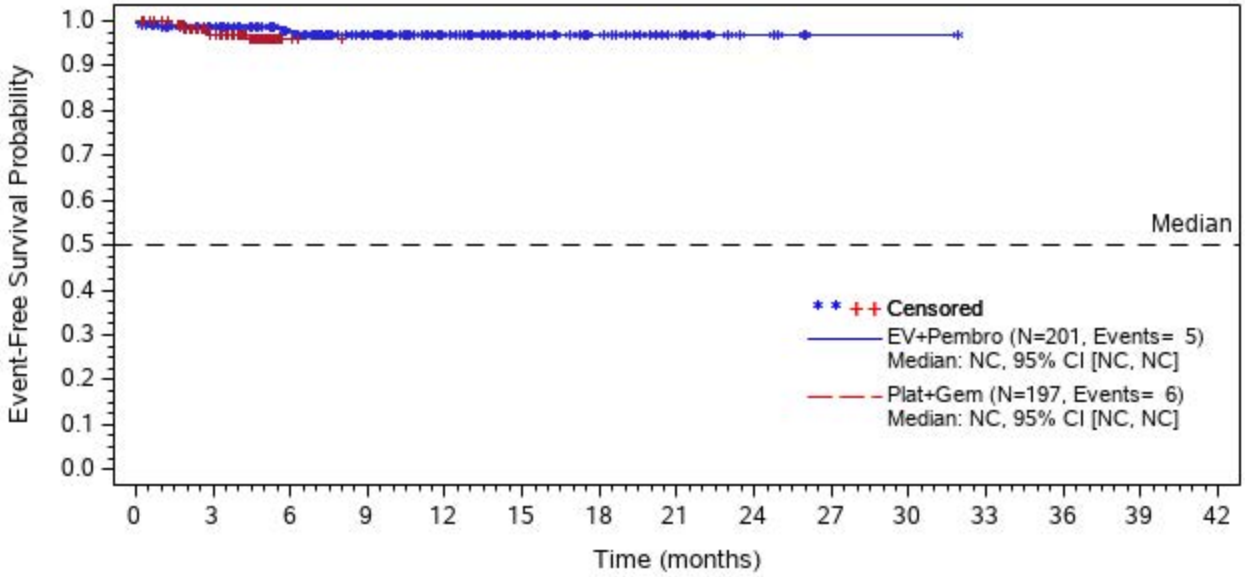
1	239	207	162	123	81	54	36	19	10	1	0	0	0	0	0
2	236	200	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.48.2.1: Kaplan-Meier Plot of Time to first TEAE - Pyelonephritis (PT) - Analysis Set mSAF 2



at Risk

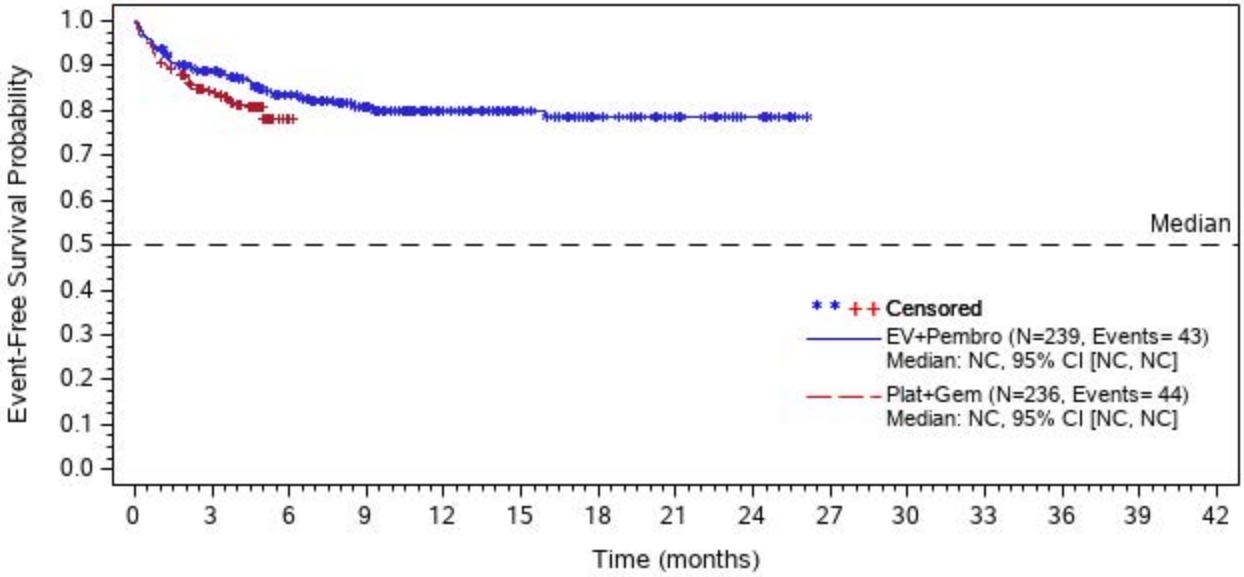
1	201	168	136	104	69	50	30	18	6	1	1	0	0	0	0
2	197	147	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.49.1.1: Kaplan-Meier Plot of Time to first TEAE - Urinary tract infection (PT) - Analysis Set mSAF 1



at Risk

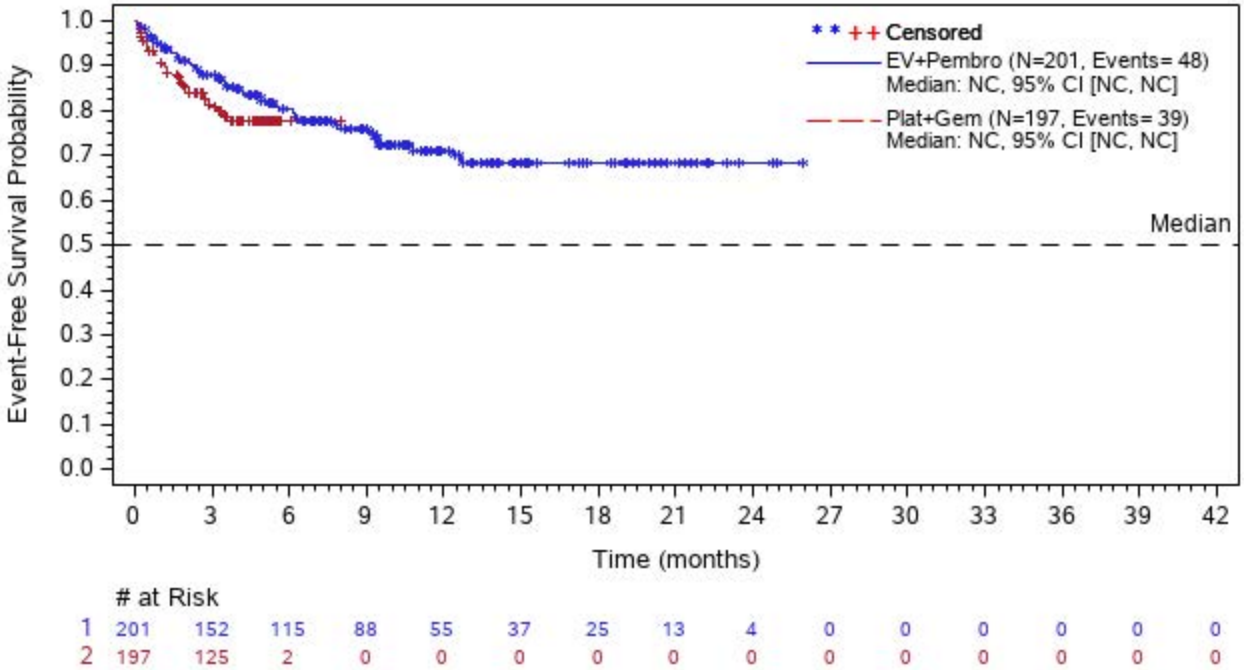
1	239	190	149	115	76	51	34	21	11	0	0	0	0	0	0
2	236	171	2	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.49.2.1: Kaplan-Meier Plot of Time to first TEAE - Urinary tract infection (PT) - Analysis Set mSAF 2



at Risk

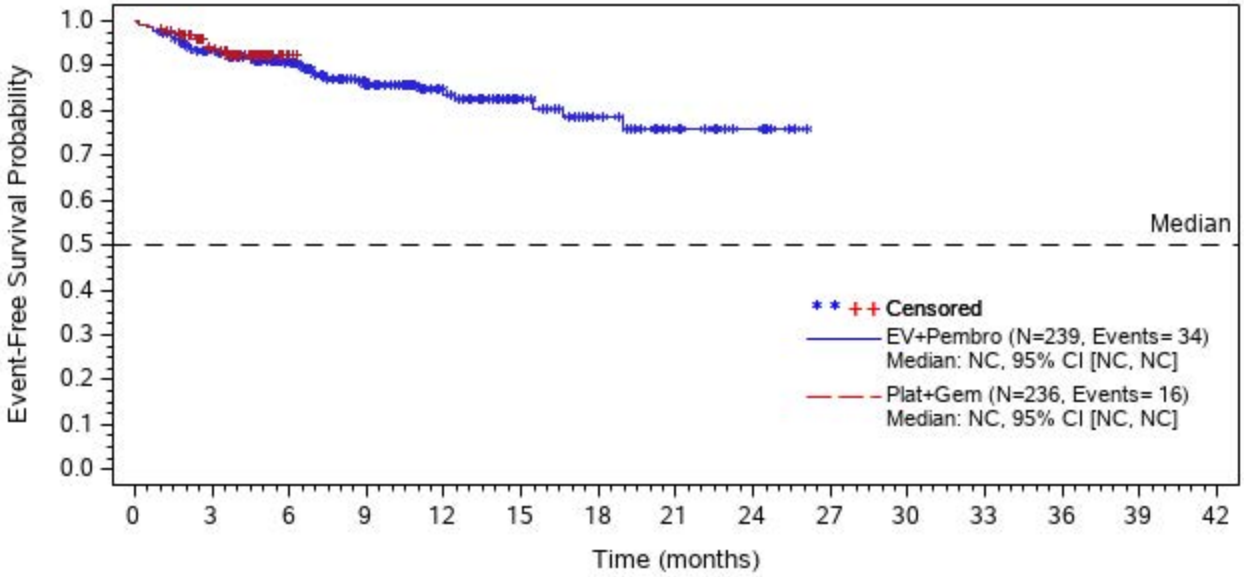
1	201	152	115	88	55	37	25	13	4	0	0	0	0	0	0
2	197	125	2	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.50.1.1: Kaplan-Meier Plot of Time to first TEAE - Injury, poisoning and procedural complications (SOC) - Analysis Set mSAF 1



at Risk

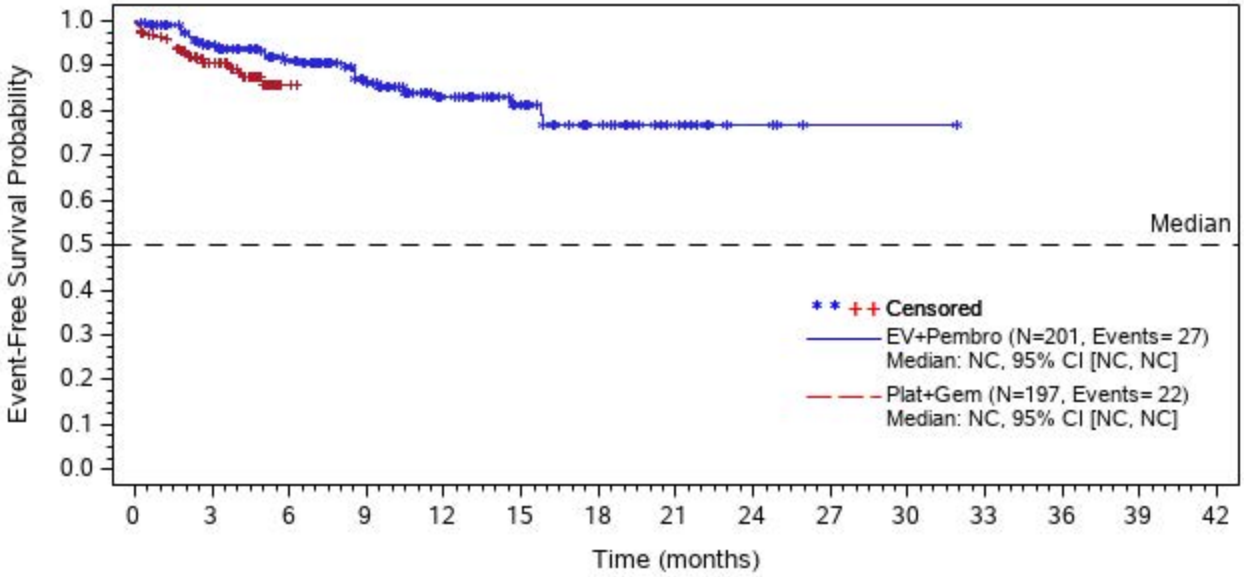
1	239	200	155	111	73	48	32	17	9	0	0	0	0	0	0
2	236	188	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.50.2.1: Kaplan-Meier Plot of Time to first TEAE - Injury, poisoning and procedural complications (SOC) - Analysis Set mSAF 2



at Risk

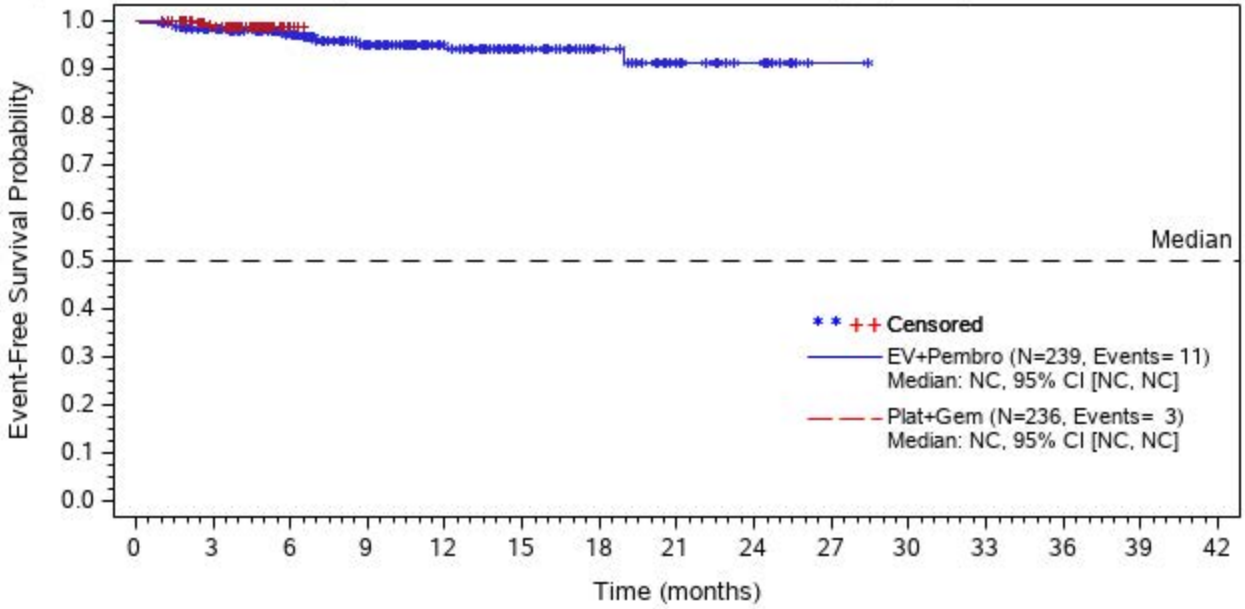
1	201	163	129	95	63	45	26	15	5	1	1	0	0	0	0
2	197	139	2	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.51.1.1: Kaplan-Meier Plot of Time to first TEAE - Fall (PT) - Analysis Set mSAF 1



at Risk

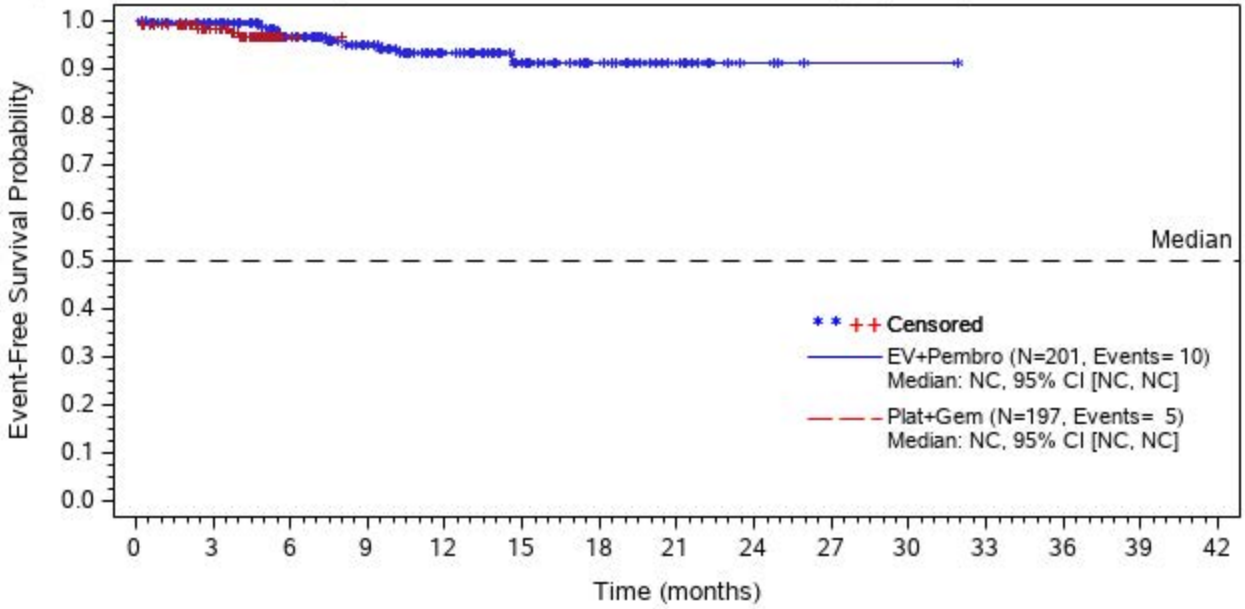
1	239	208	165	124	81	56	37	20	12	1	0	0	0	0	0
2	236	197	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.51.2.1: Kaplan-Meier Plot of Time to first TEAE - Fall (PT) - Analysis Set mSAF 2



at Risk

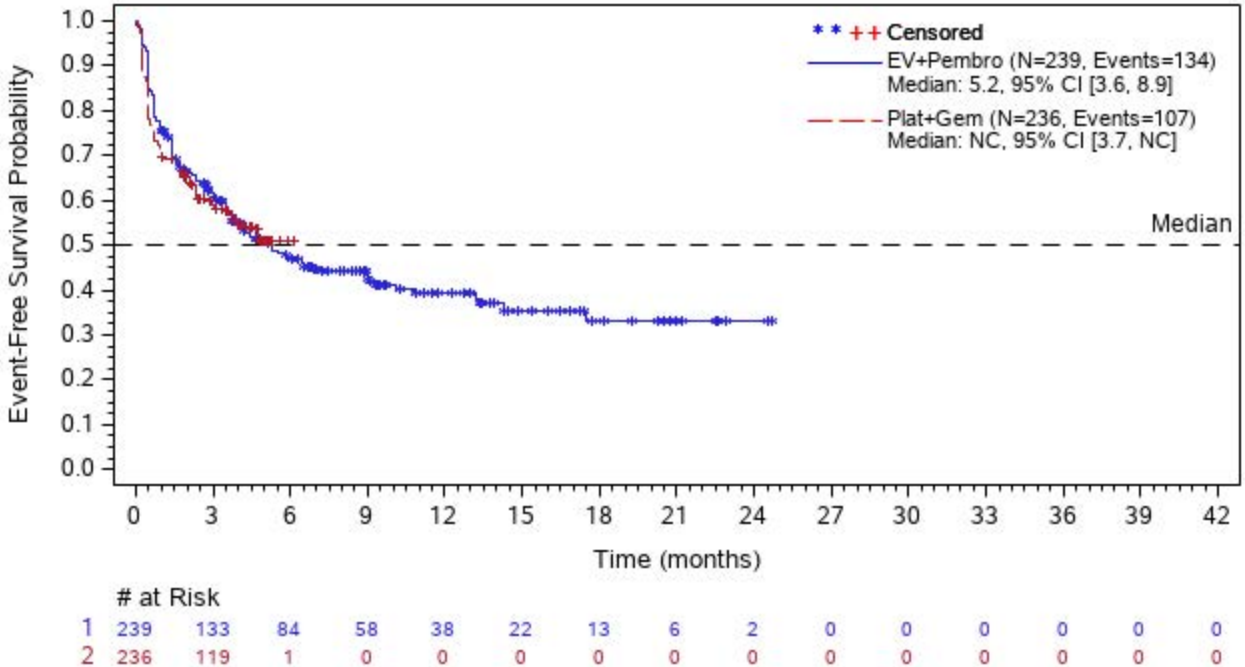
1	201	171	137	106	70	49	30	17	5	1	1	0	0	0	0
2	197	149	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.52.1.1: Kaplan-Meier Plot of Time to first TEAE - Investigations (SOC) - Analysis Set mSAF 1



at Risk

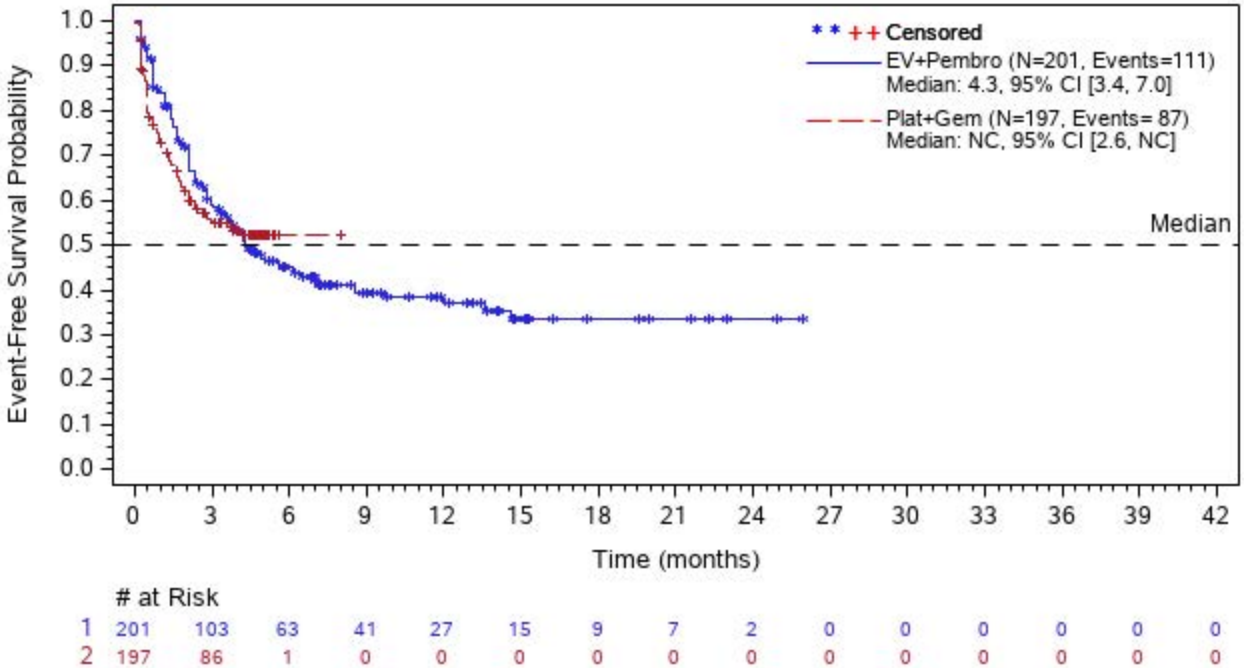
1	239	133	84	58	38	22	13	6	2	0	0	0	0	0	0
2	236	119	1	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.52.2.1: Kaplan-Meier Plot of Time to first TEAE - Investigations (SOC) - Analysis Set mSAF 2



at Risk

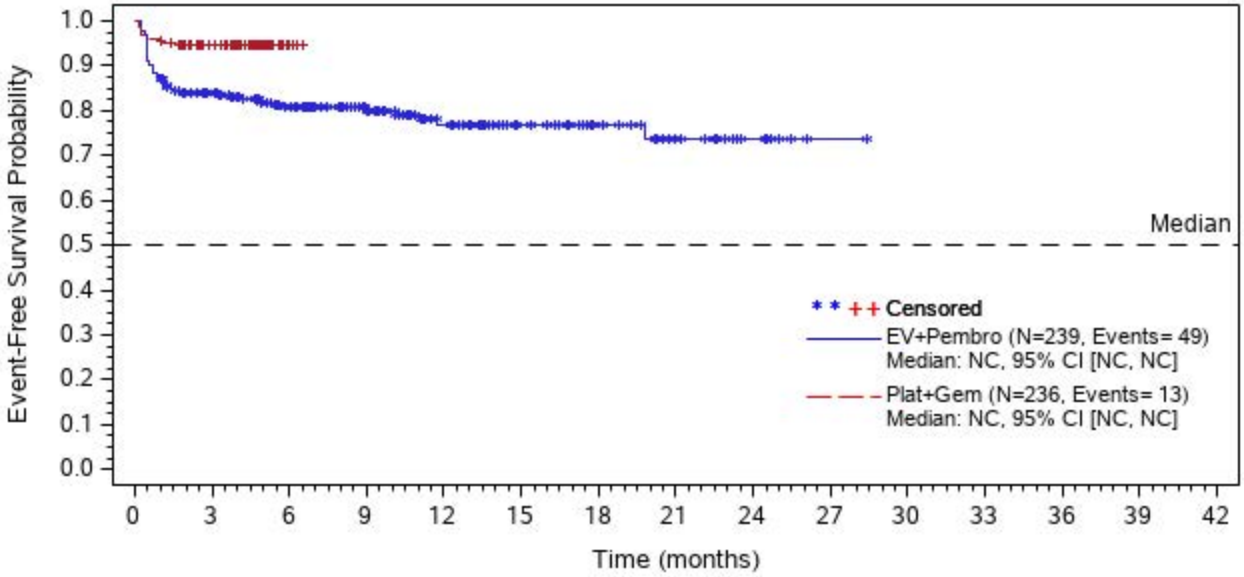
1	201	103	63	41	27	15	9	7	2	0	0	0	0	0	0
2	197	86	1	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.53.1.1: Kaplan-Meier Plot of Time to first TEAE - Alanine aminotransferase increased (PT) - Analysis Set mSAF 1



at Risk

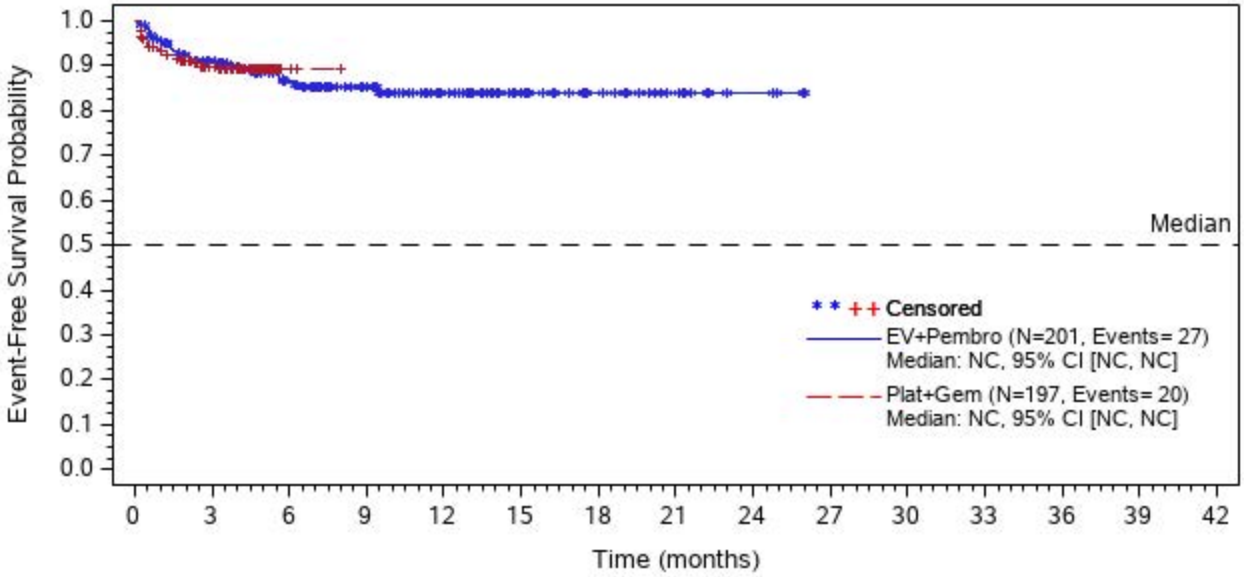
1	239	176	134	99	67	44	30	17	8	1	0	0	0	0	0
2	236	190	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.53.2.1: Kaplan-Meier Plot of Time to first TEAE - Alanine aminotransferase increased (PT) - Analysis Set mSAF 2



at Risk

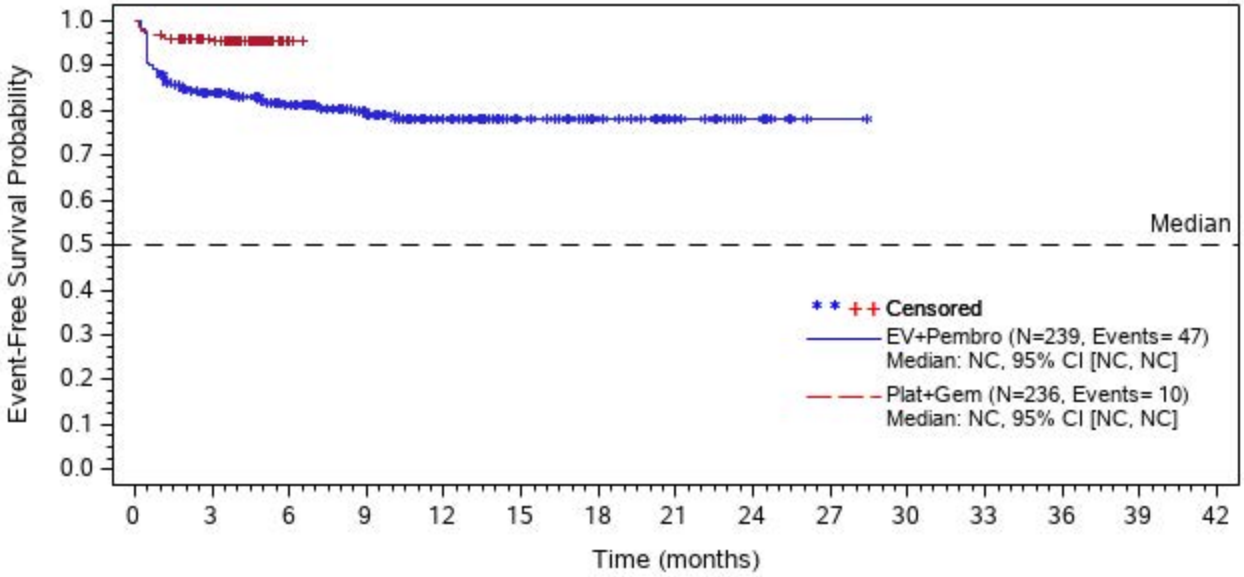
1	201	156	121	91	61	42	25	14	5	0	0	0	0	0	0
2	197	134	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.54.1.1: Kaplan-Meier Plot of Time to first TEAE - Aspartate aminotransferase increased (PT) - Analysis Set mSAF 1



at Risk

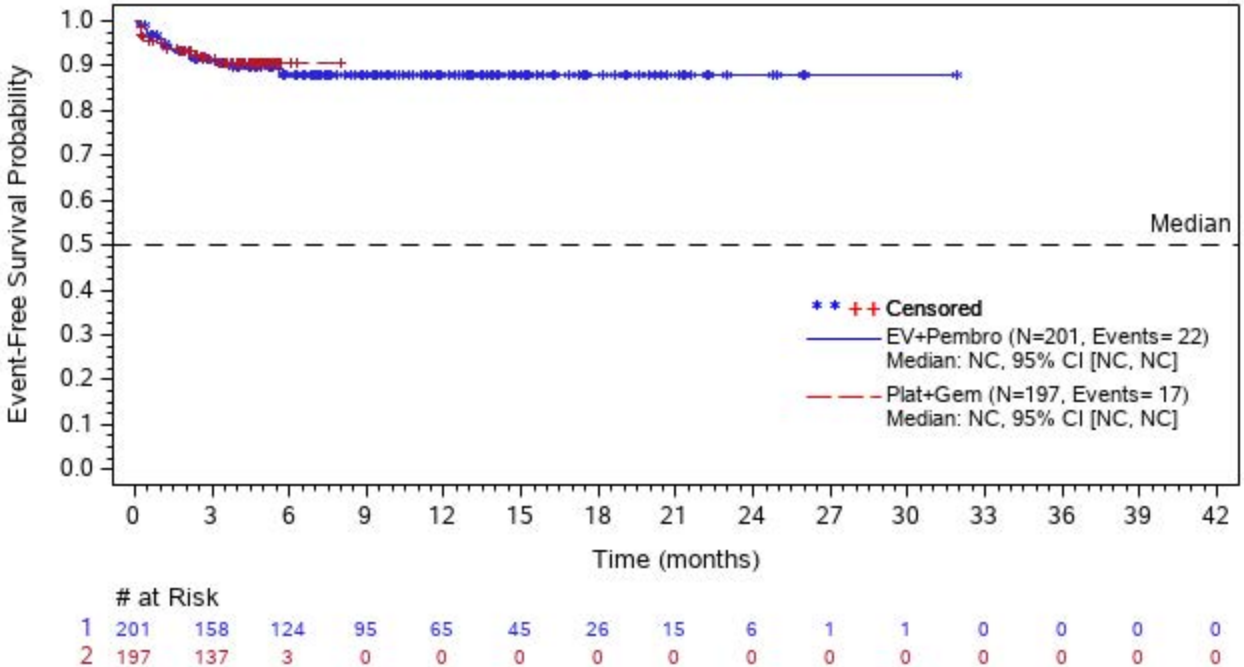
1	239	177	136	99	68	45	32	18	9	1	0	0	0	0	0
2	236	192	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.54.2.1: Kaplan-Meier Plot of Time to first TEAE - Aspartate aminotransferase increased (PT) - Analysis Set mSAF 2



at Risk

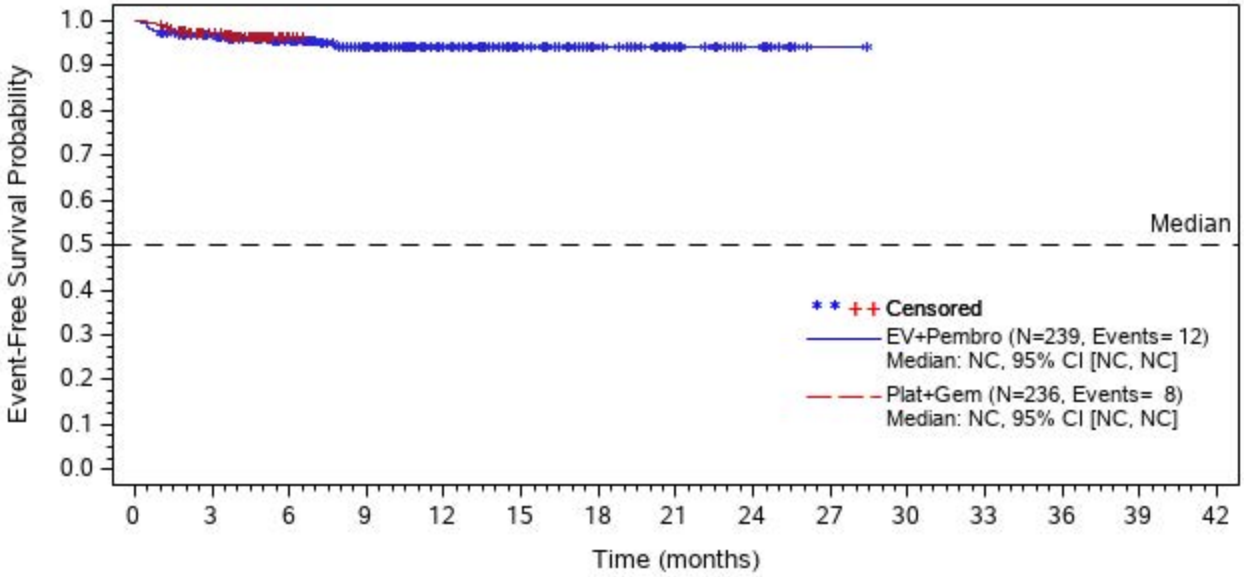
1	201	158	124	95	65	45	26	15	6	1	1	0	0	0	0
2	197	137	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.55.1.1: Kaplan-Meier Plot of Time to first TEAE - Blood alkaline phosphatase increased (PT) - Analysis Set mSAF 1



at Risk

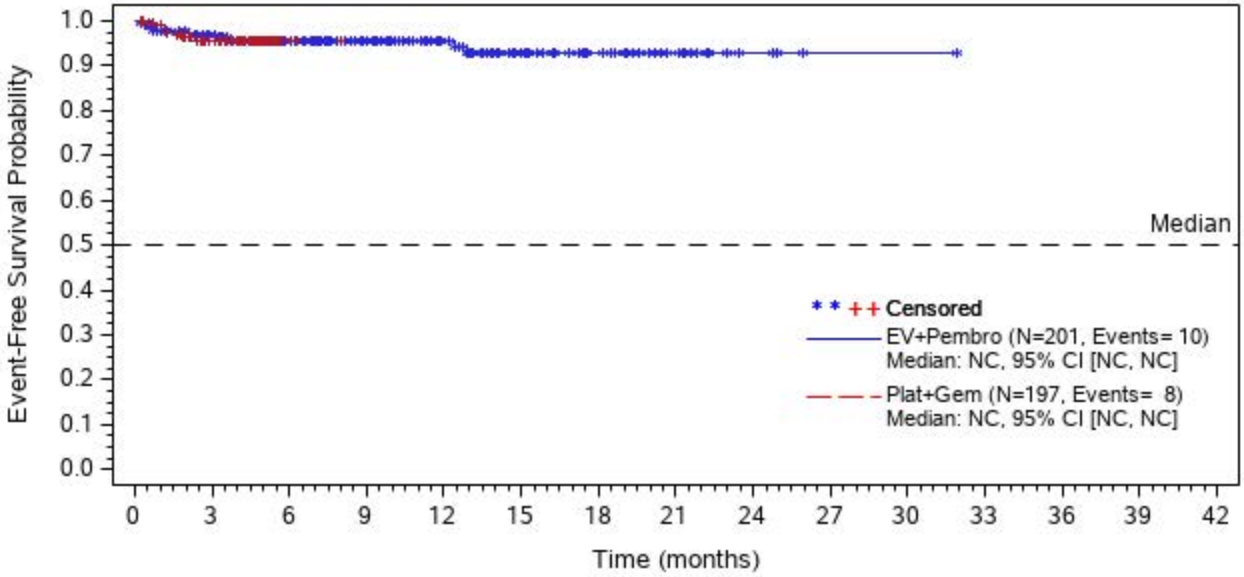
1	239	205	162	123	83	57	39	22	12	1	0	0	0	0	0
2	236	194	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.55.2.1: Kaplan-Meier Plot of Time to first TEAE - Blood alkaline phosphatase increased (PT) - Analysis Set mSAF 2



at Risk

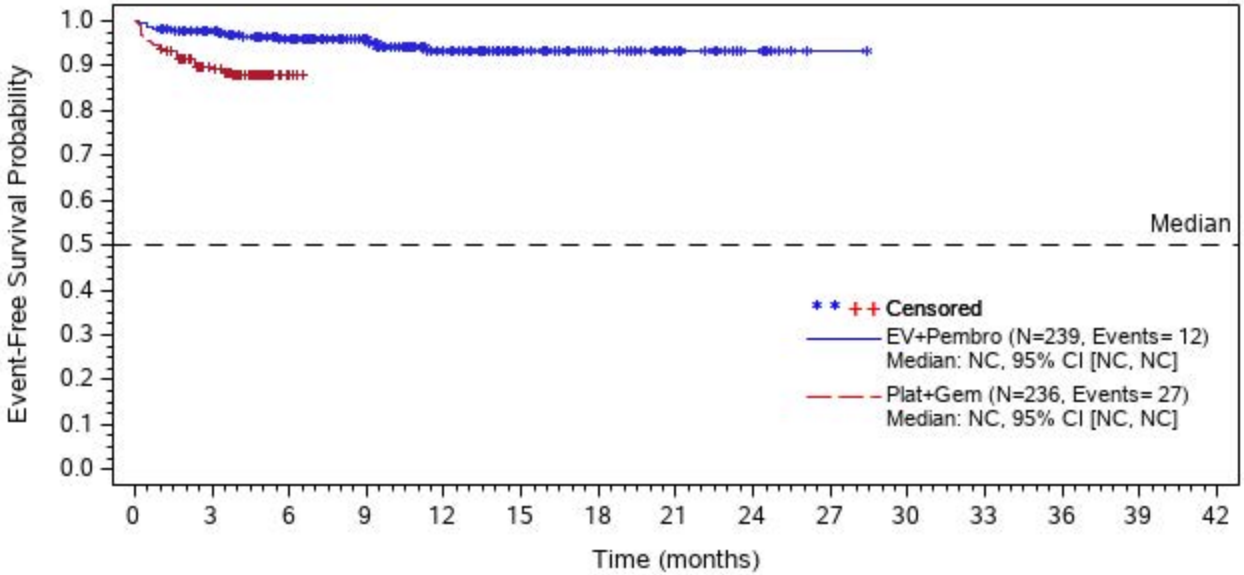
1	201	165	132	103	71	48	30	17	5	1	1	0	0	0	0
2	197	146	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.56.1.1: Kaplan-Meier Plot of Time to first TEAE - Blood creatinine increased (PT) - Analysis Set mSAF 1



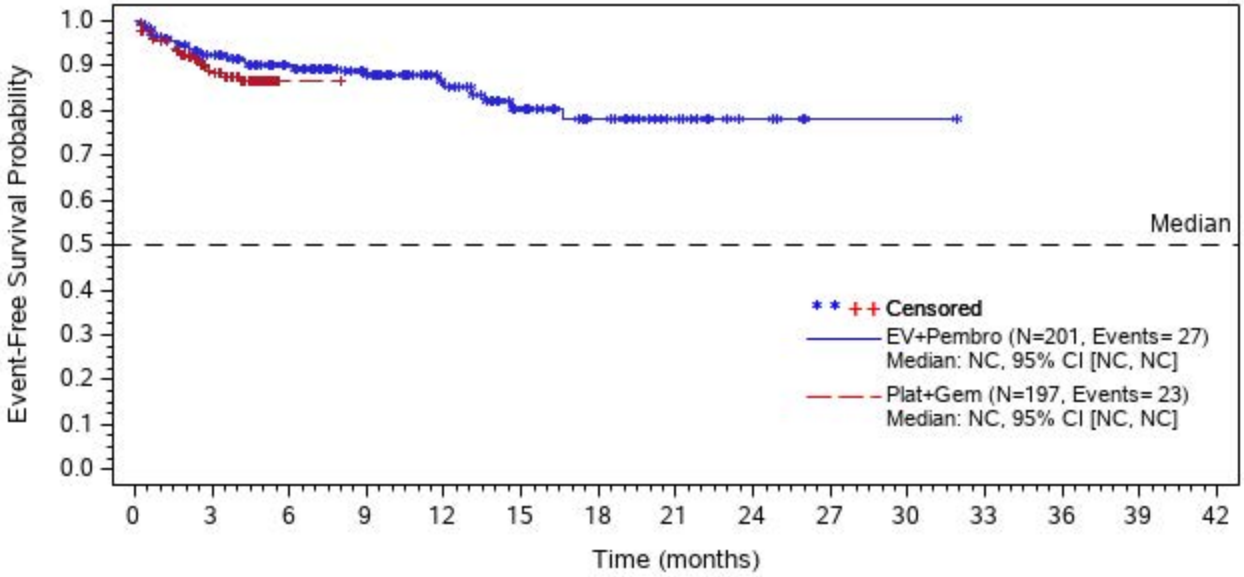
# at Risk															
1	239	207	164	127	82	54	37	20	10	1	0	0	0	0	0
2	236	180	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.56.2.1: Kaplan-Meier Plot of Time to first TEAE - Blood creatinine increased (PT) - Analysis Set mSAF 2



at Risk

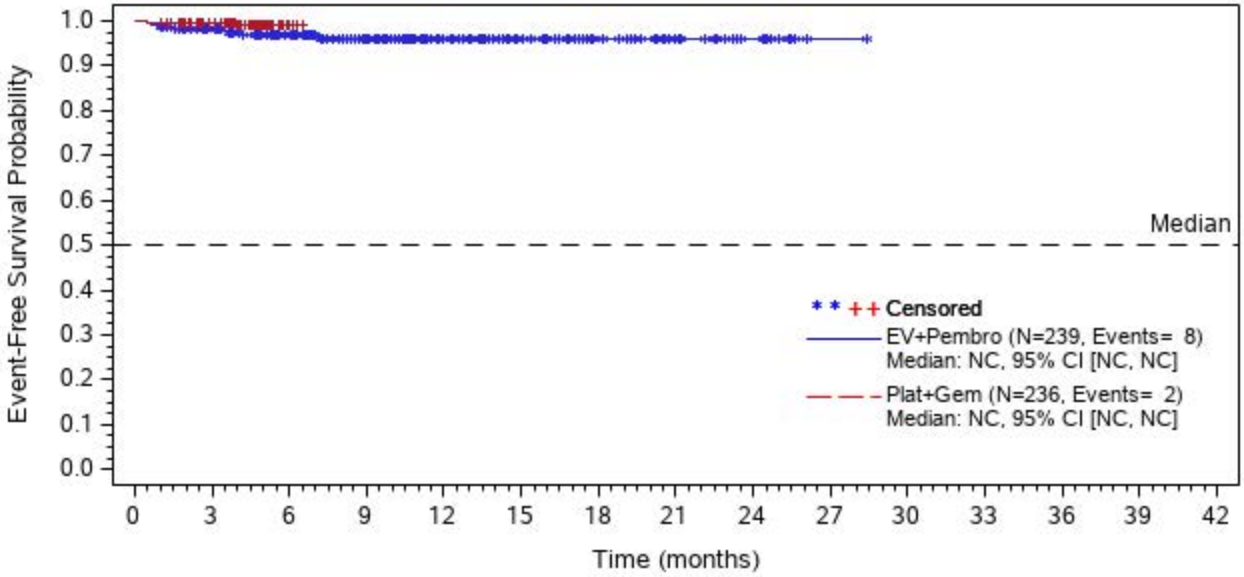
1	201	159	129	99	64	43	28	17	6	1	1	0	0	0	0
2	197	134	1	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.57.1.1: Kaplan-Meier Plot of Time to first TEAE - Gamma-glutamyltransferase increased (PT) - Analysis Set mSAF 1



at Risk

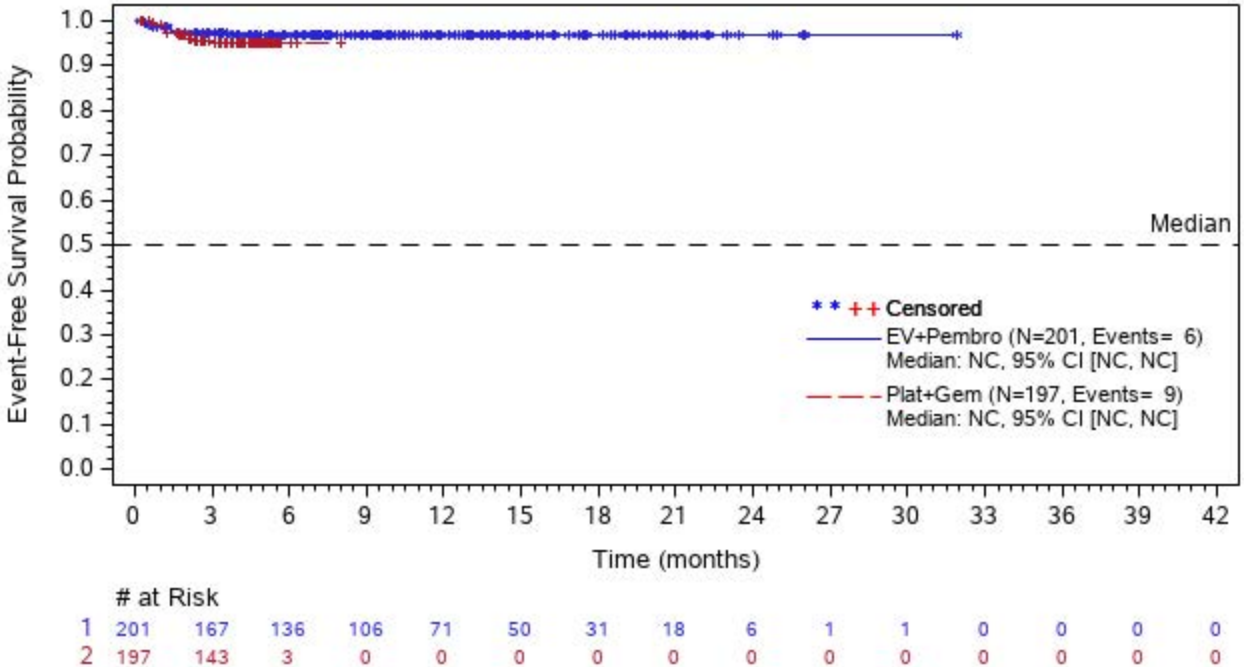
1	239	209	165	127	84	58	39	22	12	1	0	0	0	0	0
2	236	199	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.57.2.1: Kaplan-Meier Plot of Time to first TEAE - Blood lactate dehydrogenase increased (PT) - Analysis Set mSAF 2



at Risk

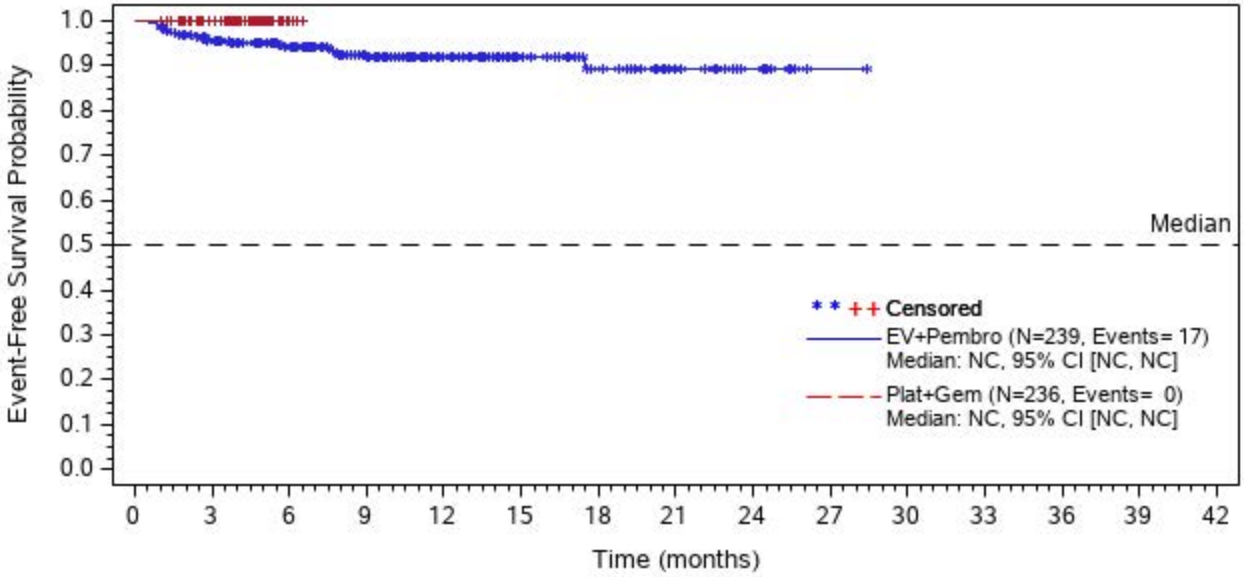
1	201	167	136	106	71	50	31	18	6	1	1	0	0	0	0
2	197	143	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.58.1.1: Kaplan-Meier Plot of Time to first TEAE - Lipase increased (PT) - Analysis Set mSAF 1



at Risk

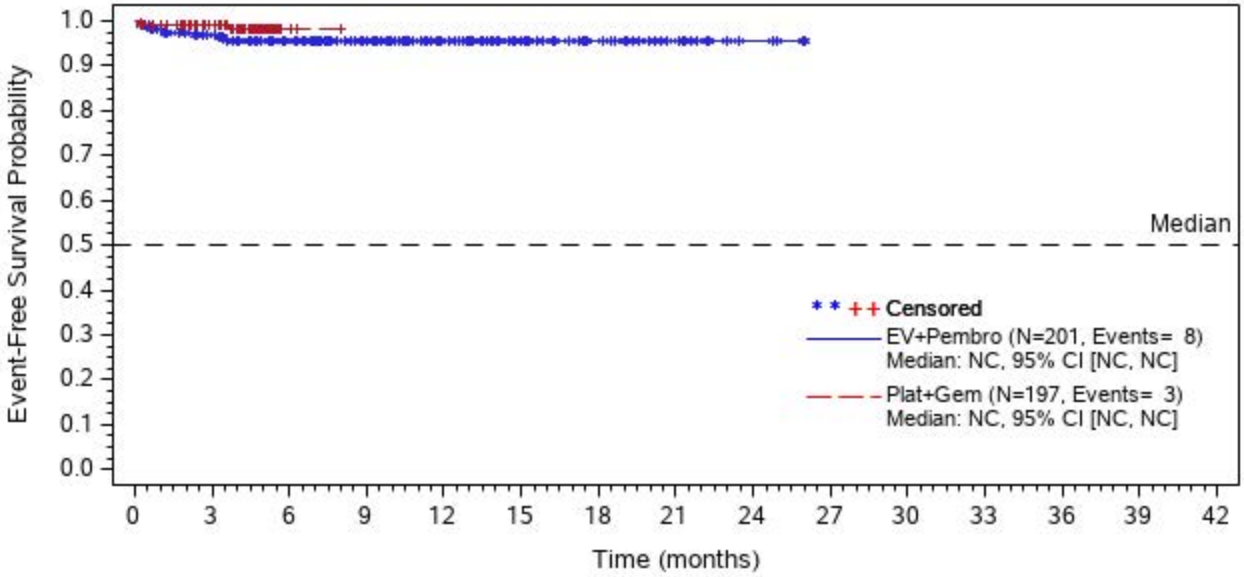
1	239	203	160	121	79	51	35	20	11	1	0	0	0	0	0
2	236	200	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.58.2.1: Kaplan-Meier Plot of Time to first TEAE - Lymphocyte count decreased (PT) - Analysis Set mSAF 2



at Risk

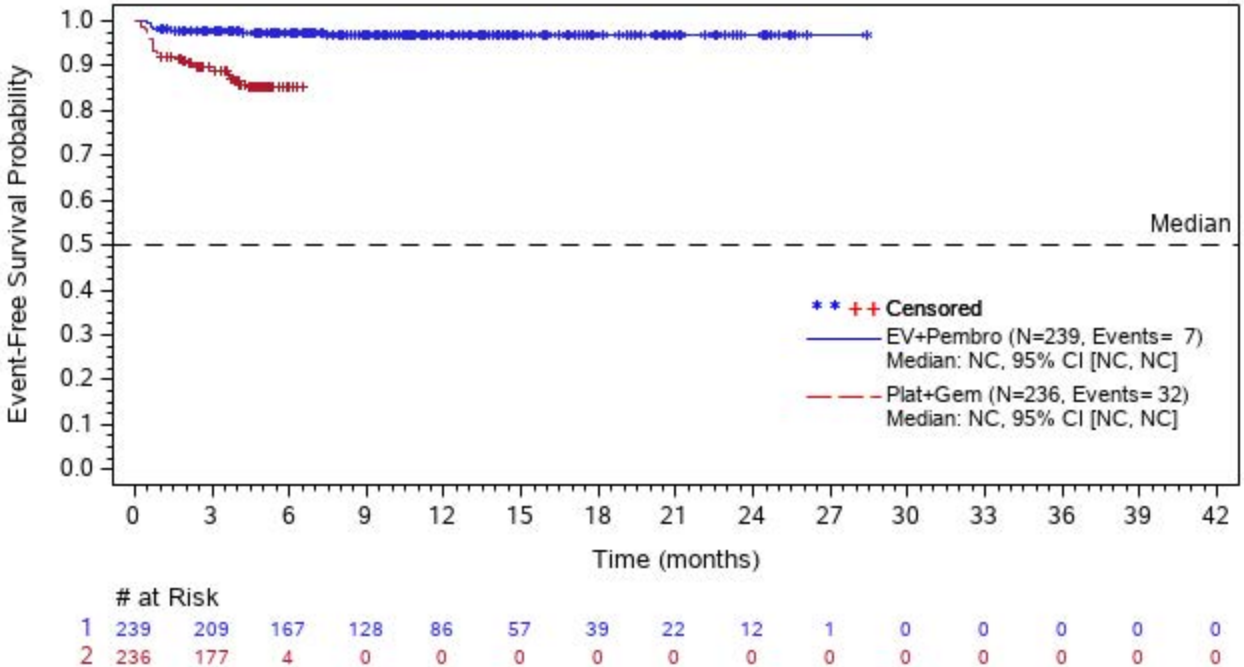
1	201	166	133	103	70	49	30	17	5	0	0	0	0	0	0
2	197	151	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.59.1.1: Kaplan-Meier Plot of Time to first TEAE - Neutrophil count decreased (PT) - Analysis Set mSAF 1



at Risk

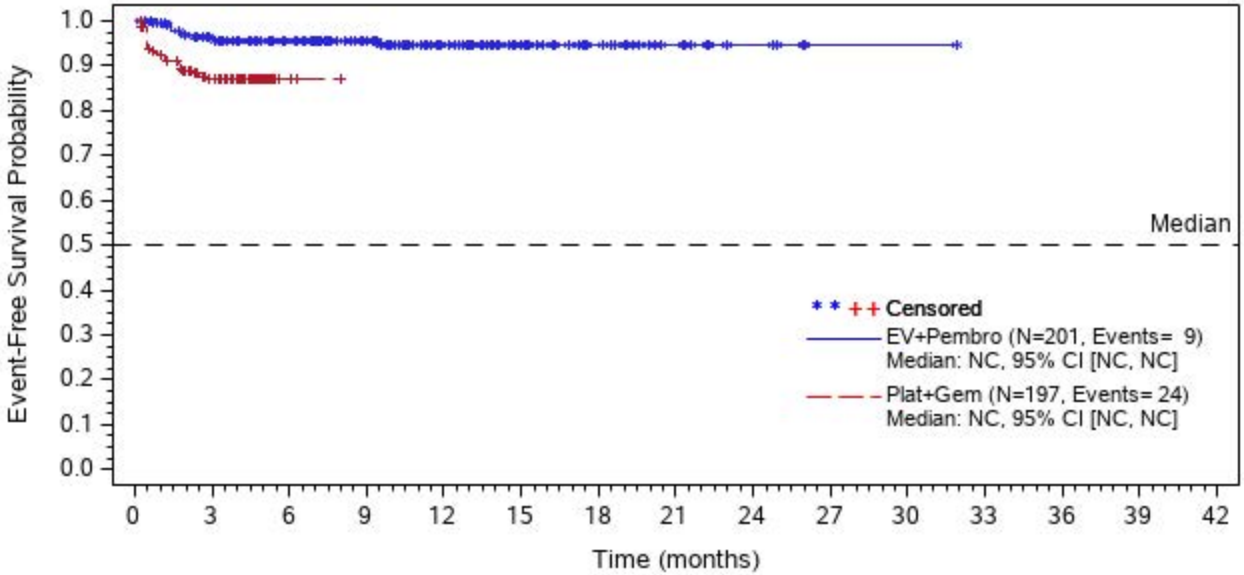
1	239	209	167	128	86	57	39	22	12	1	0	0	0	0	0
2	236	177	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.59.2.1: Kaplan-Meier Plot of Time to first TEAE - Neutrophil count decreased (PT) - Analysis Set mSAF 2



at Risk

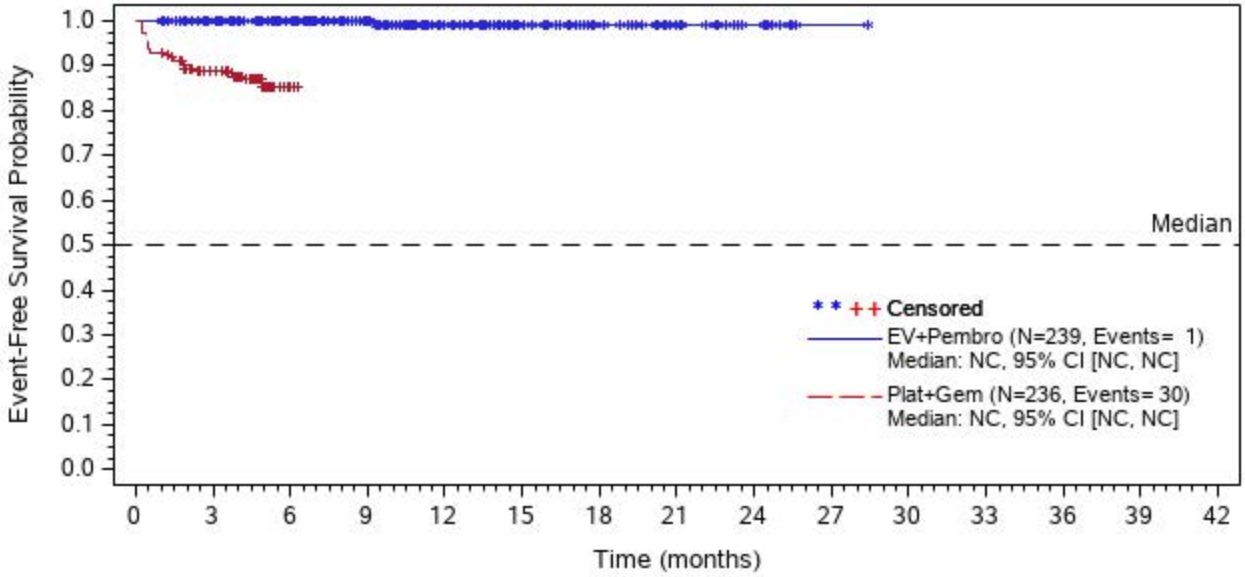
1	201	165	134	104	69	47	27	15	6	1	1	0	0	0	0
2	197	132	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.60.1.1: Kaplan-Meier Plot of Time to first TEAE - Platelet count decreased (PT) - Analysis Set mSAF 1



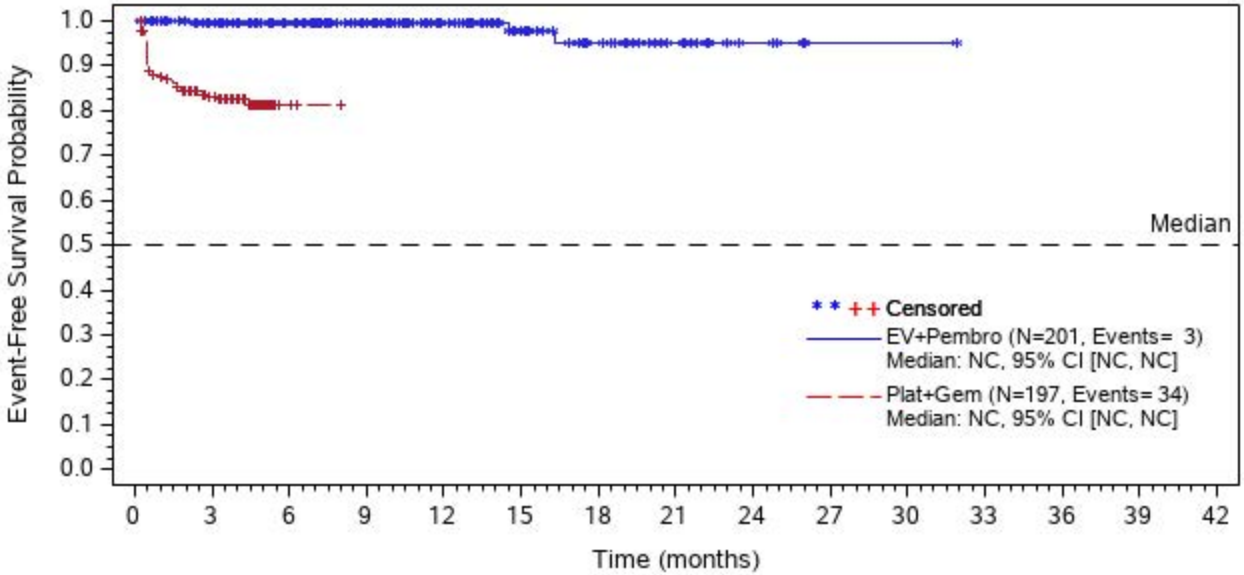
# at Risk															
1	239	211	169	131	86	57	38	21	11	1	0	0	0	0	0
2	236	176	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.60.2.1: Kaplan-Meier Plot of Time to first TEAE - Platelet count decreased (PT) - Analysis Set mSAF 2



at Risk

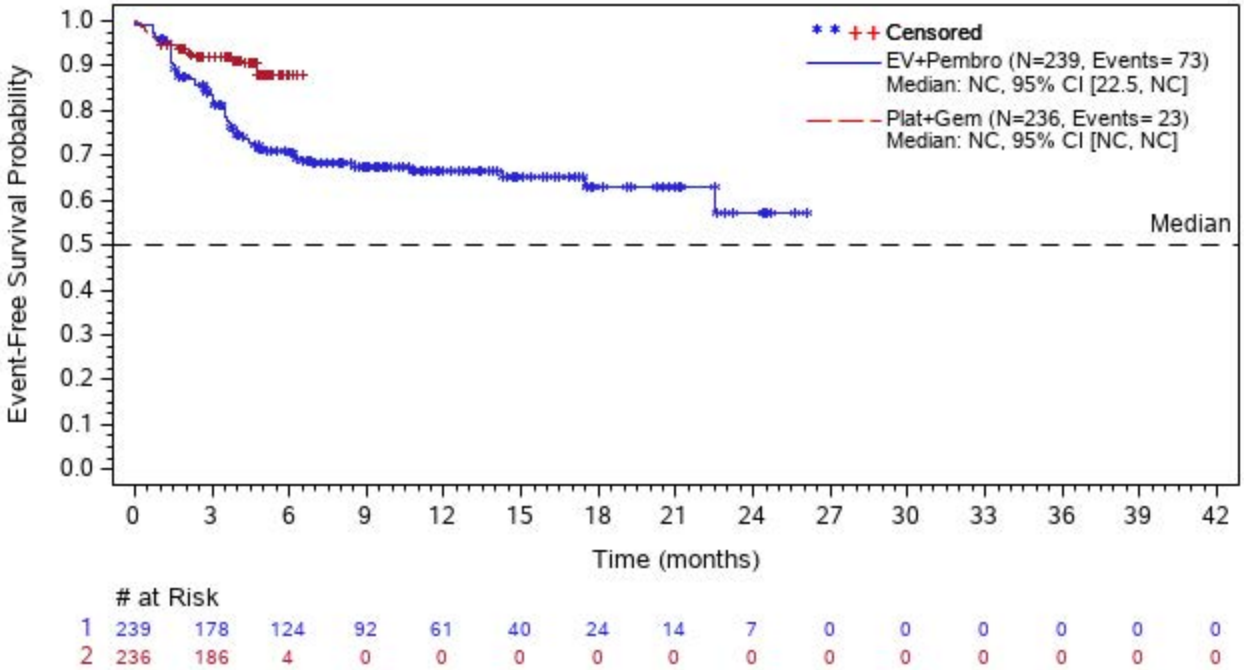
1	201	170	139	108	73	50	30	17	6	1	1	0	0	0	0
2	197	128	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.61.1.1: Kaplan-Meier Plot of Time to first TEAE - Weight decreased (PT) - Analysis Set mSAF 1



at Risk

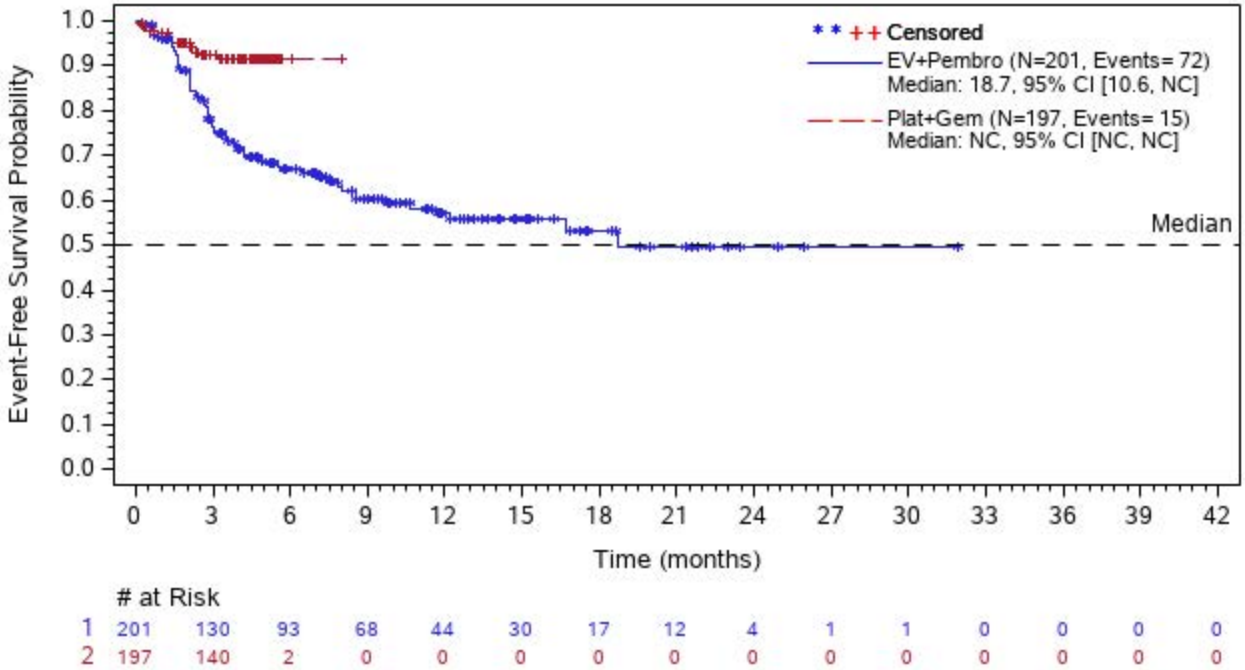
1	239	178	124	92	61	40	24	14	7	0	0	0	0	0	0
2	236	186	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.61.2.1: Kaplan-Meier Plot of Time to first TEAE - Weight decreased (PT) - Analysis Set mSAF 2



at Risk

1	201	130	93	68	44	30	17	12	4	1	1	0	0	0	0
2	197	140	2	0	0	0	0	0	0	0	0	0	0	0	0

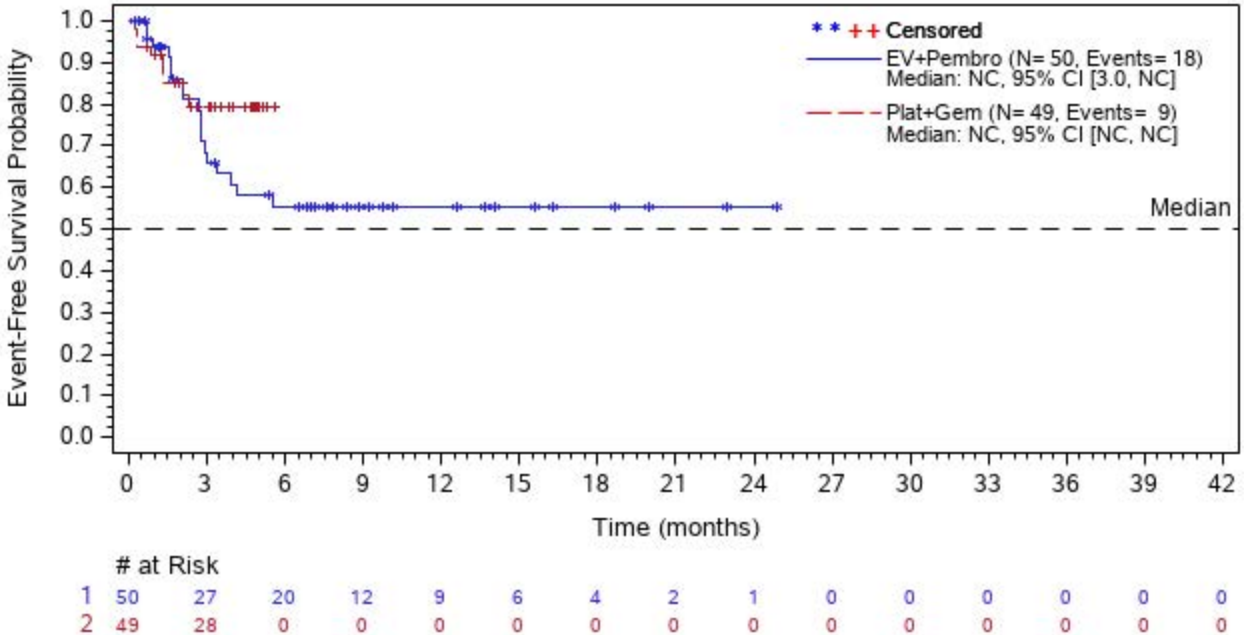
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.61.2.2.1: Kaplan-Meier Plot of Time to first TEAE - Weight decreased (PT) - Analysis Set mSAF 2

Liver Metastases: Present



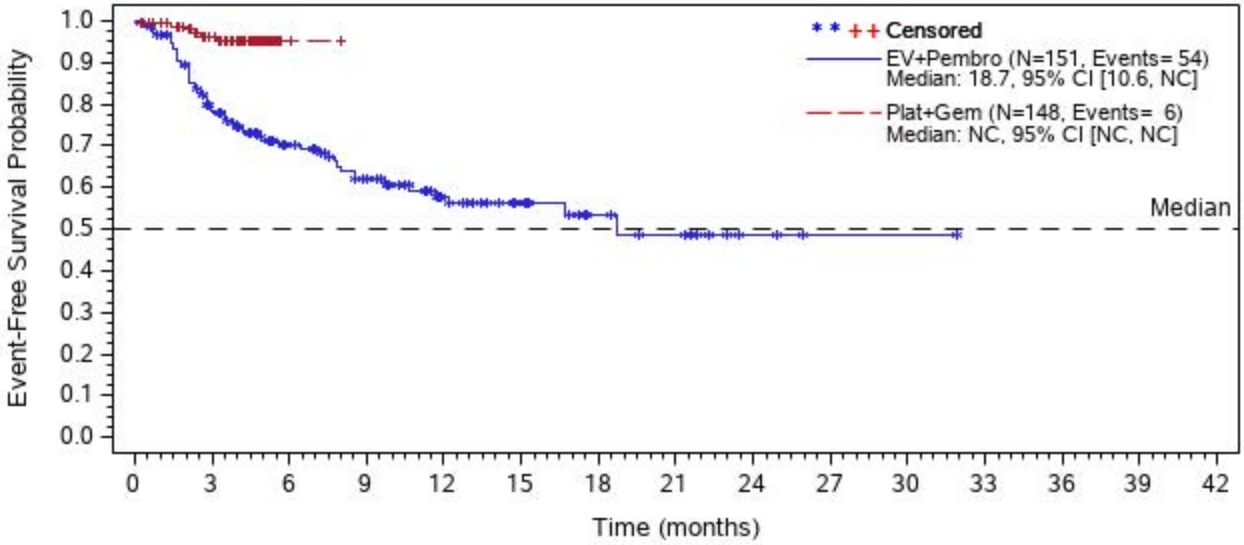
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.61.2.2.1: Kaplan-Meier Plot of Time to first TEAE - Weight decreased (PT) - Analysis Set mSAF 2

Liver Metastases: Absent



at Risk

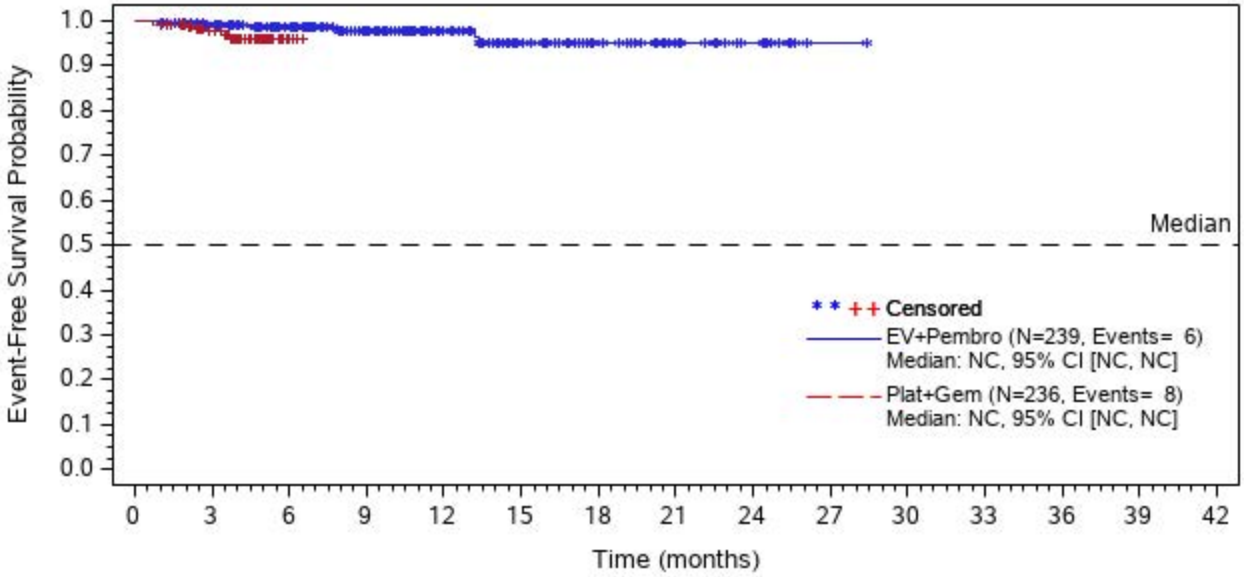
1	151	103	73	56	35	24	13	10	3	1	1	0	0	0	0
2	148	112	2	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.62.1.1: Kaplan-Meier Plot of Time to first TEAE - Weight increased (PT) - Analysis Set mSAF 1



at Risk

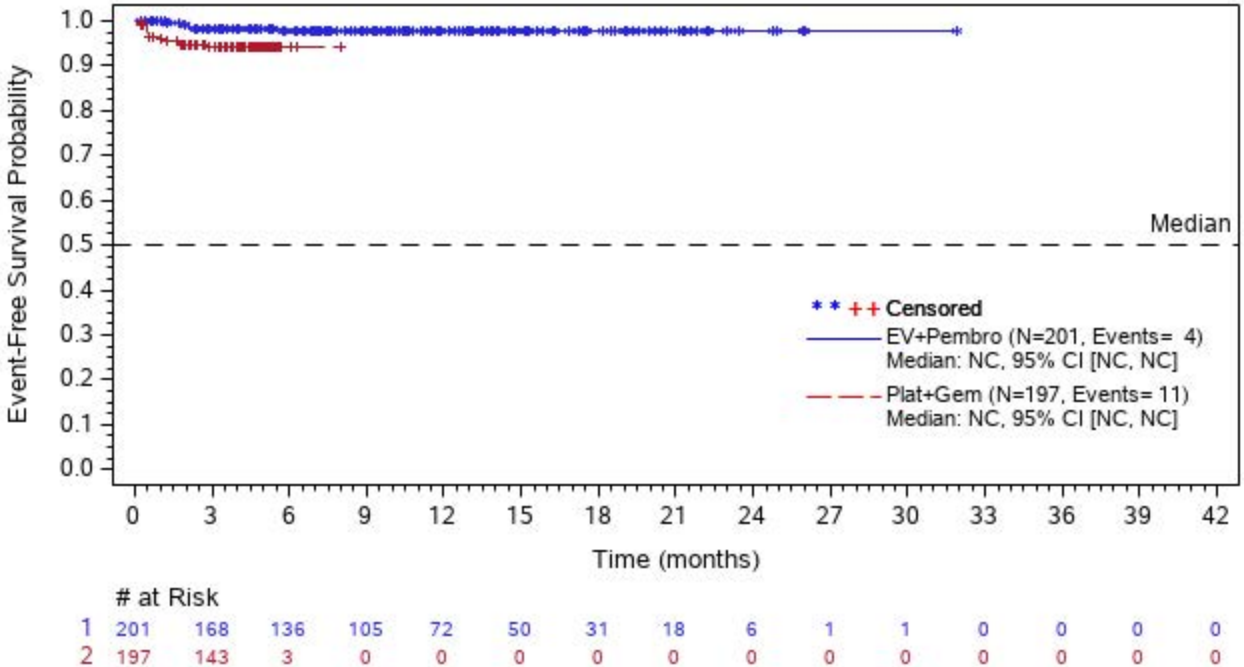
1	239	209	166	127	86	56	38	21	12	1	0	0	0	0	0
2	236	196	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.62.2.1: Kaplan-Meier Plot of Time to first TEAE - White blood cell count decreased (PT) - Analysis Set mSAF 2



at Risk

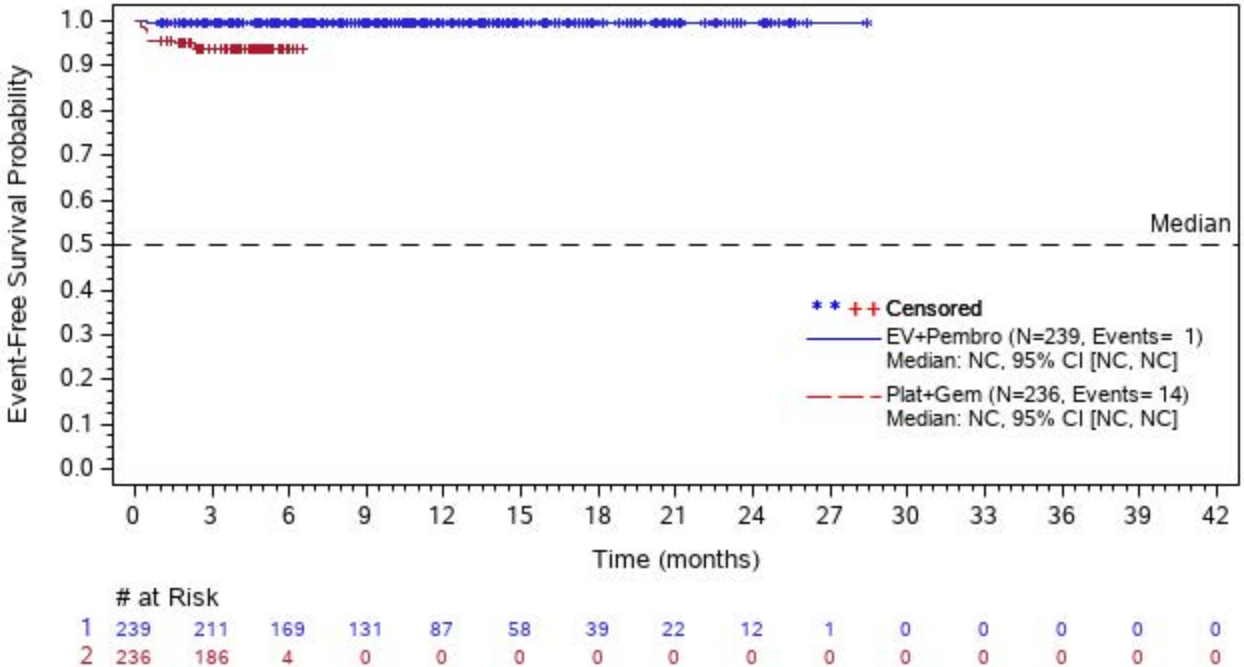
1	201	168	136	105	72	50	31	18	6	1	1	0	0	0	0
2	197	143	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.63.1.1: Kaplan-Meier Plot of Time to first TEAE - White blood cell count decreased (PT) - Analysis Set mSAF 1



at Risk

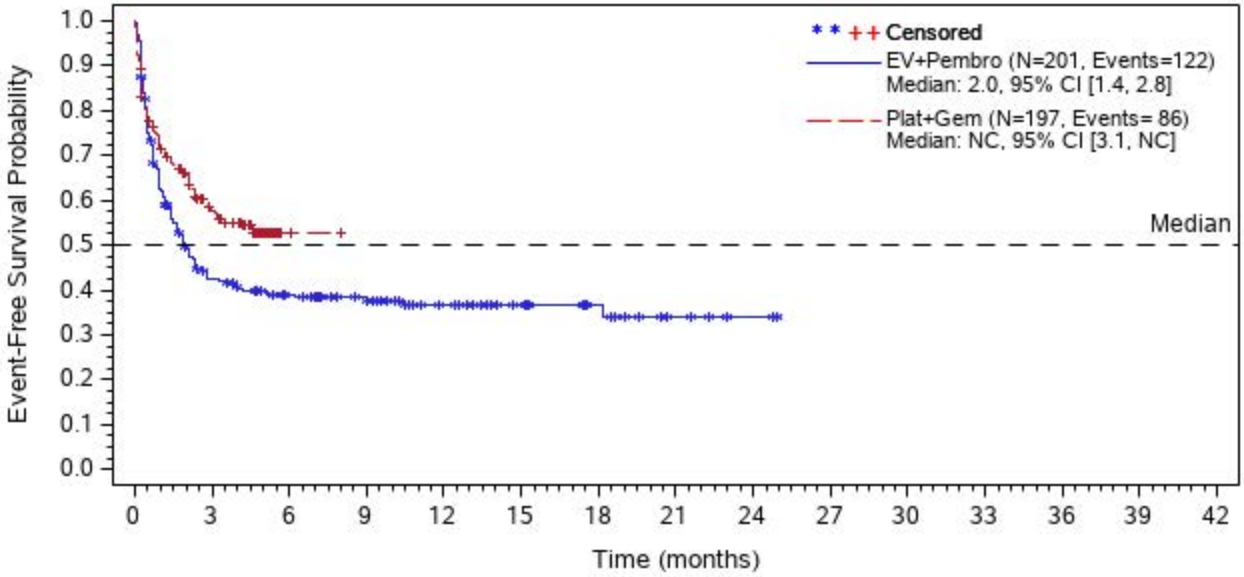
1	239	211	169	131	87	58	39	22	12	1	0	0	0	0	0
2	236	186	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.63.2.1: Kaplan-Meier Plot of Time to first TEAE - Metabolism and nutrition disorders (SOC) - Analysis Set mSAF 2



at Risk

1	201	77	61	50	32	23	14	7	3	0	0	0	0	0	0
2	197	89	2	0	0	0	0	0	0	0	0	0	0	0	0

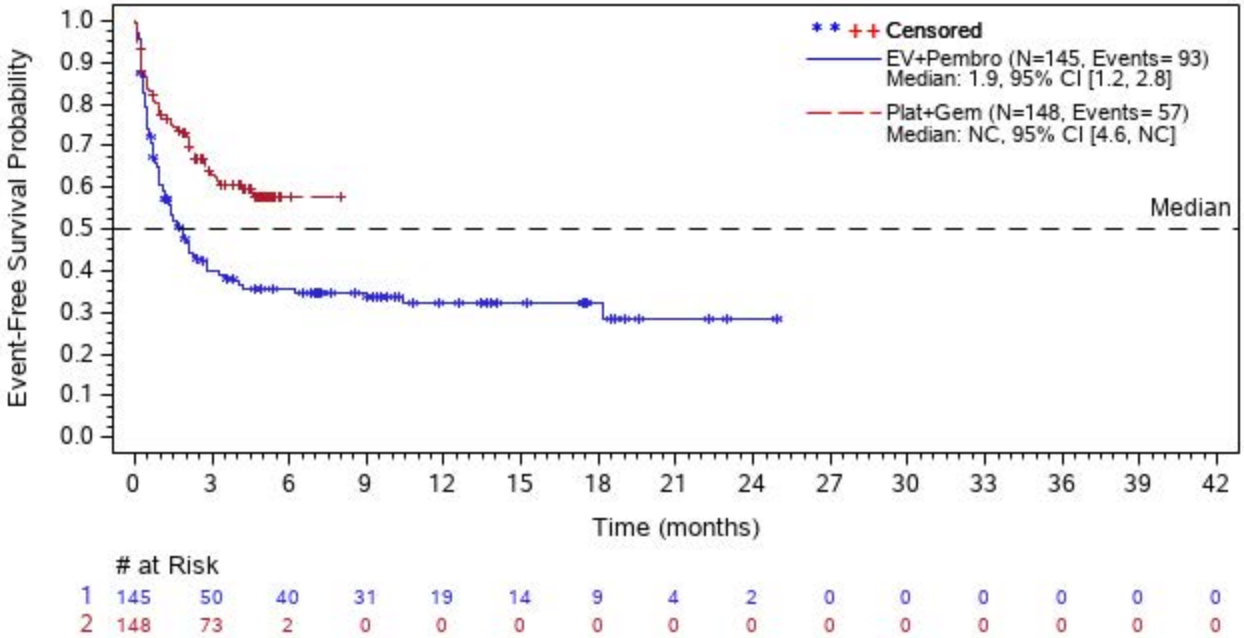
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.63.2.2.4: Kaplan-Meier Plot of Time to first TEAE - Metabolism and nutrition disorders (SOC) - Analysis Set mSAF 2

Sex: Male



at Risk

1	145	50	40	31	19	14	9	4	2	0	0	0	0	0	0
2	148	73	2	0	0	0	0	0	0	0	0	0	0	0	0

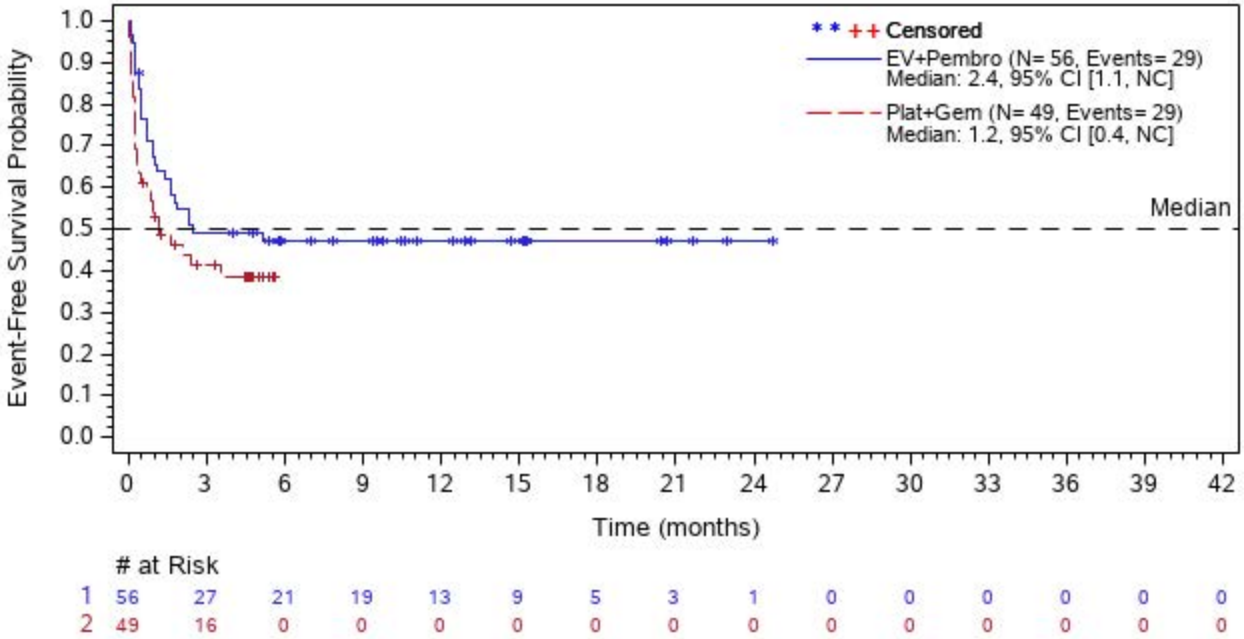
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.63.2.2.4: Kaplan-Meier Plot of Time to first TEAE - Metabolism and nutrition disorders (SOC) - Analysis Set mSAF 2

Sex: Female

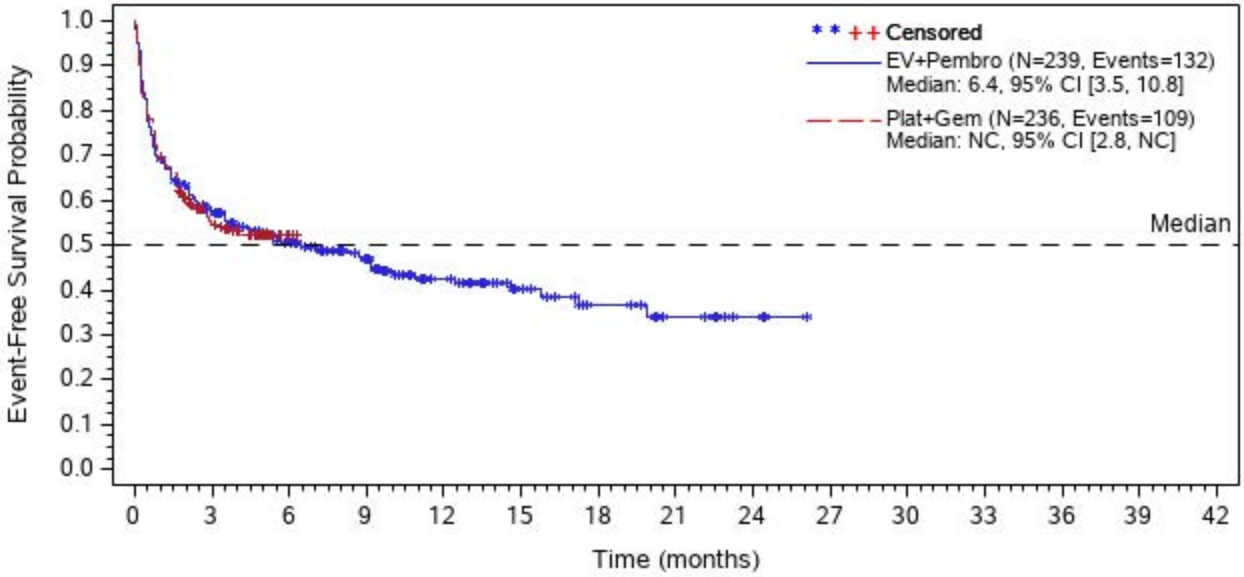


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.64.1.1: Kaplan-Meier Plot of Time to first TEAE - Metabolism and nutrition disorders (SOC) - Analysis Set mSAF 1



at Risk

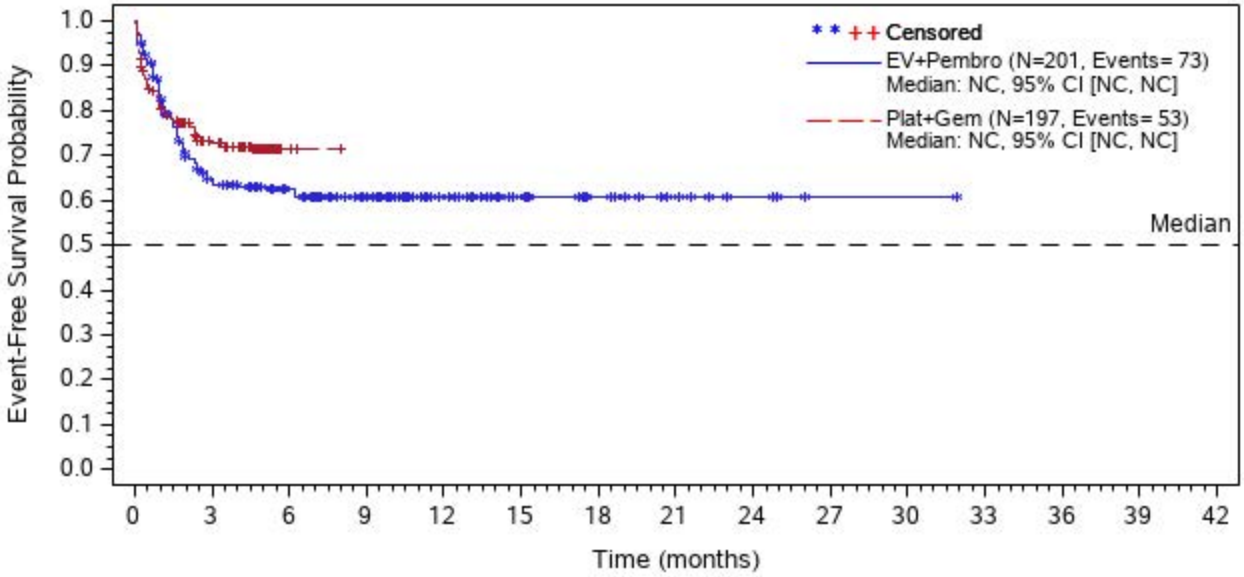
1	239	128	93	71	45	26	16	9	3	0	0	0	0	0	0
2	236	113	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.64.2.1: Kaplan-Meier Plot of Time to first TEAE - Decreased appetite (PT) - Analysis Set mSAF 2



at Risk

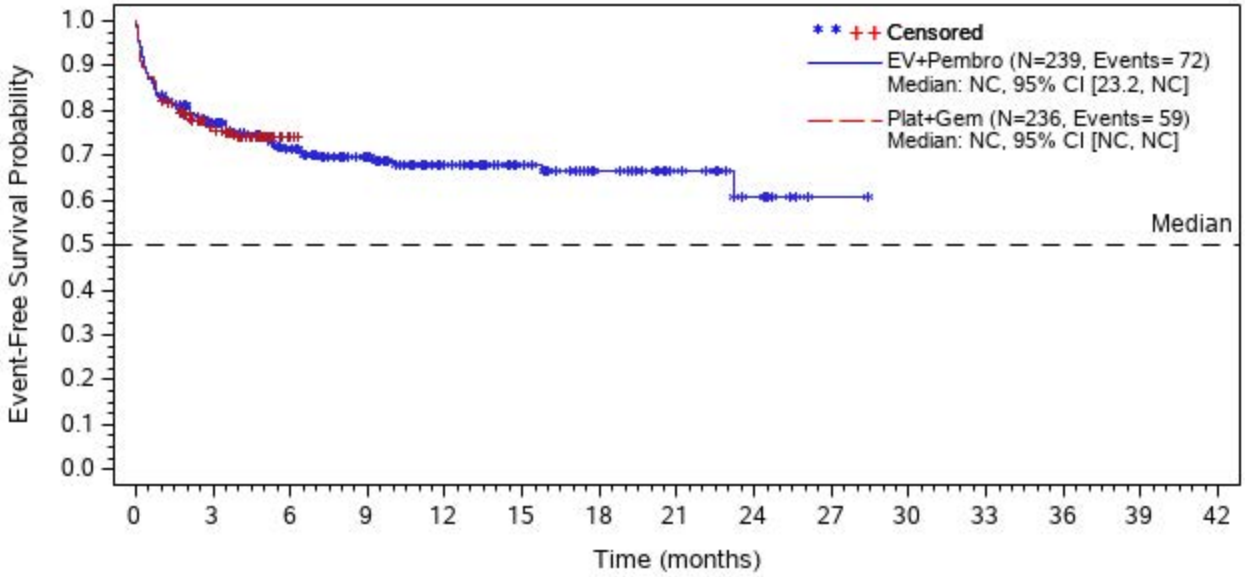
1	201	112	90	69	45	31	19	11	5	1	1	0	0	0	0
2	197	109	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.65.1.1: Kaplan-Meier Plot of Time to first TEAE - Decreased appetite (PT) - Analysis Set mSAF 1



at Risk

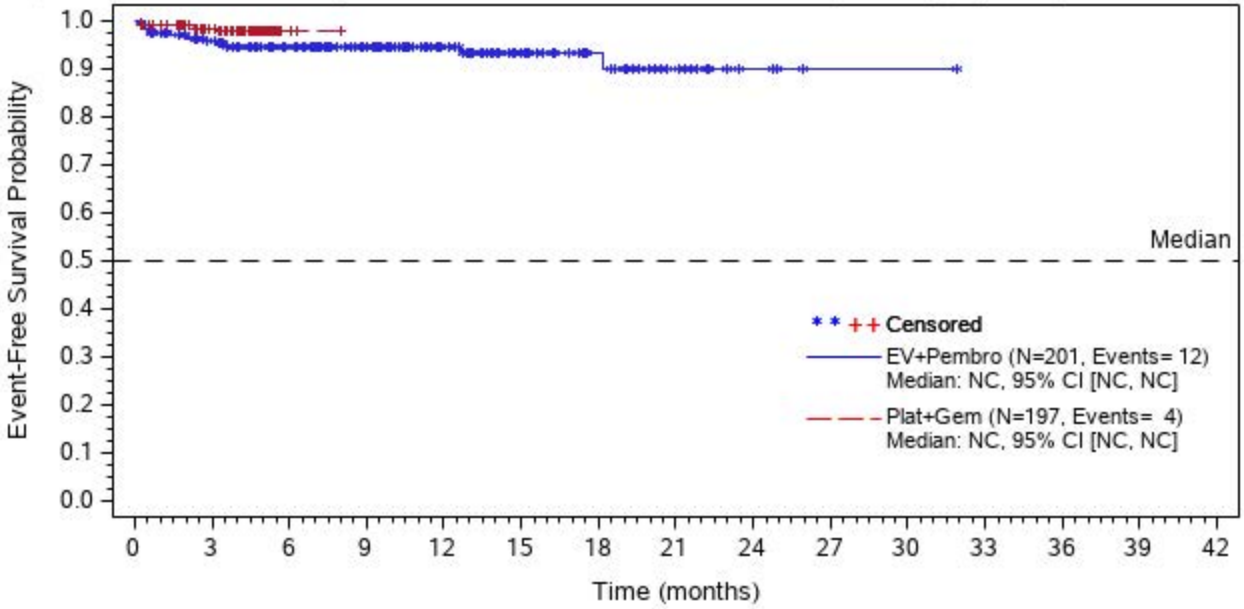
1	239	167	122	97	66	47	32	18	9	1	0	0	0	0	0
2	236	150	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.65.2.1: Kaplan-Meier Plot of Time to first TEAE - Dehydration (PT) - Analysis Set mSAF 2



at Risk

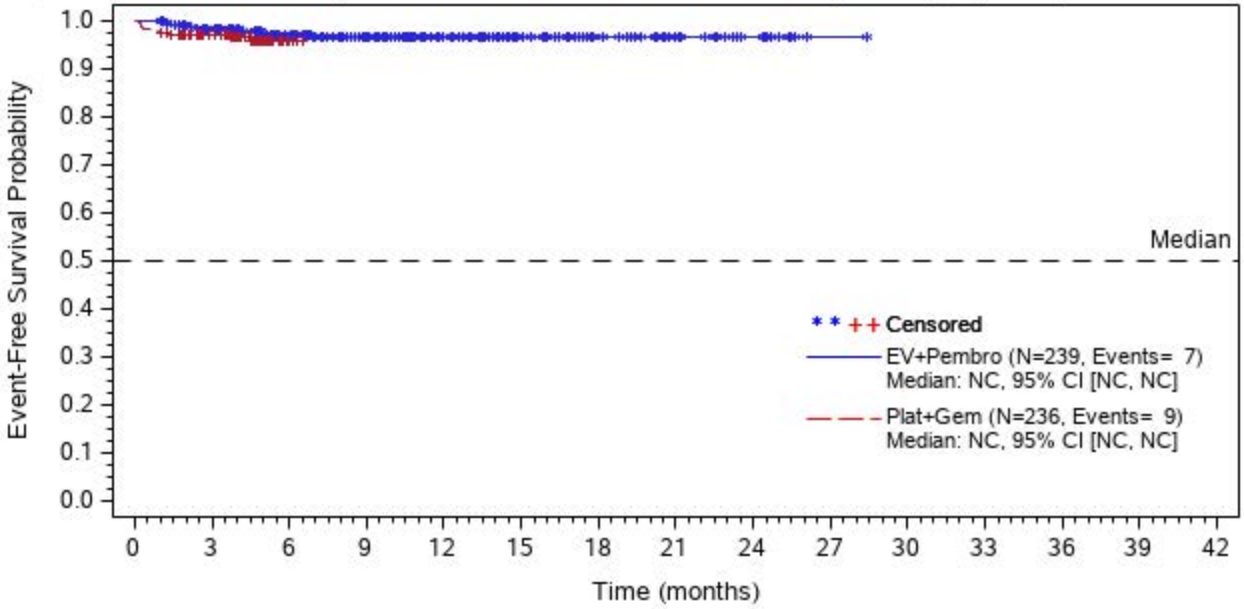
1	201	166	136	105	70	47	28	16	5	1	1	0	0	0	0
2	197	149	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.66.1.1: Kaplan-Meier Plot of Time to first TEAE - Dehydration (PT) - Analysis Set mSAF 1



at Risk

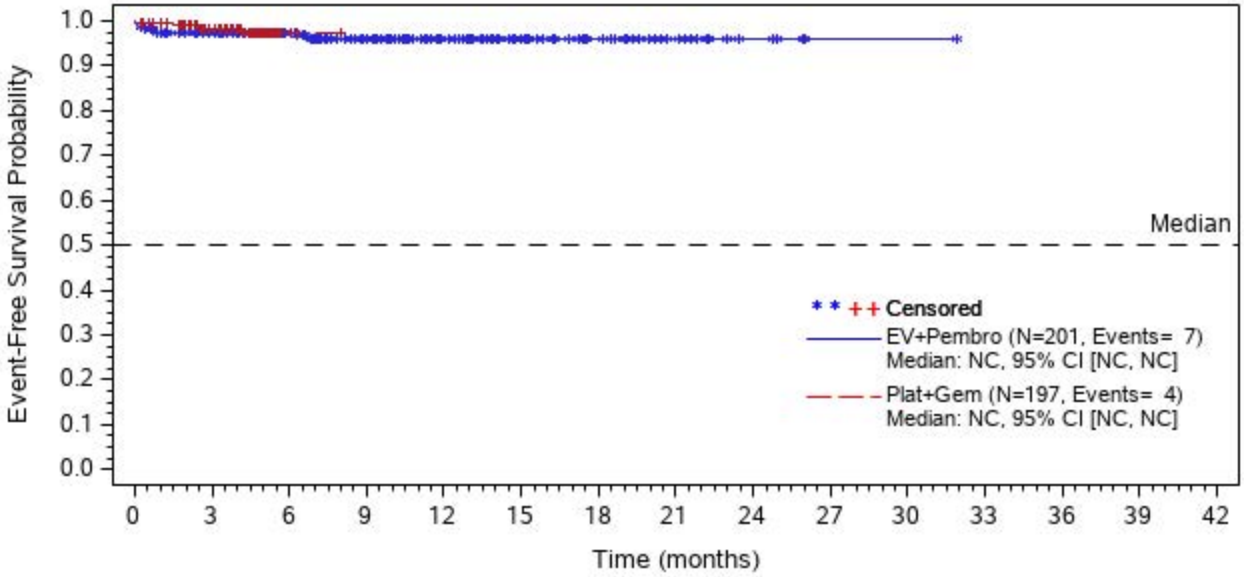
1	239	209	165	127	87	58	39	22	12	1	0	0	0	0	0
2	236	197	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.66.2.1: Kaplan-Meier Plot of Time to first TEAE - Hypercalcaemia (PT) - Analysis Set mSAF 2



at Risk

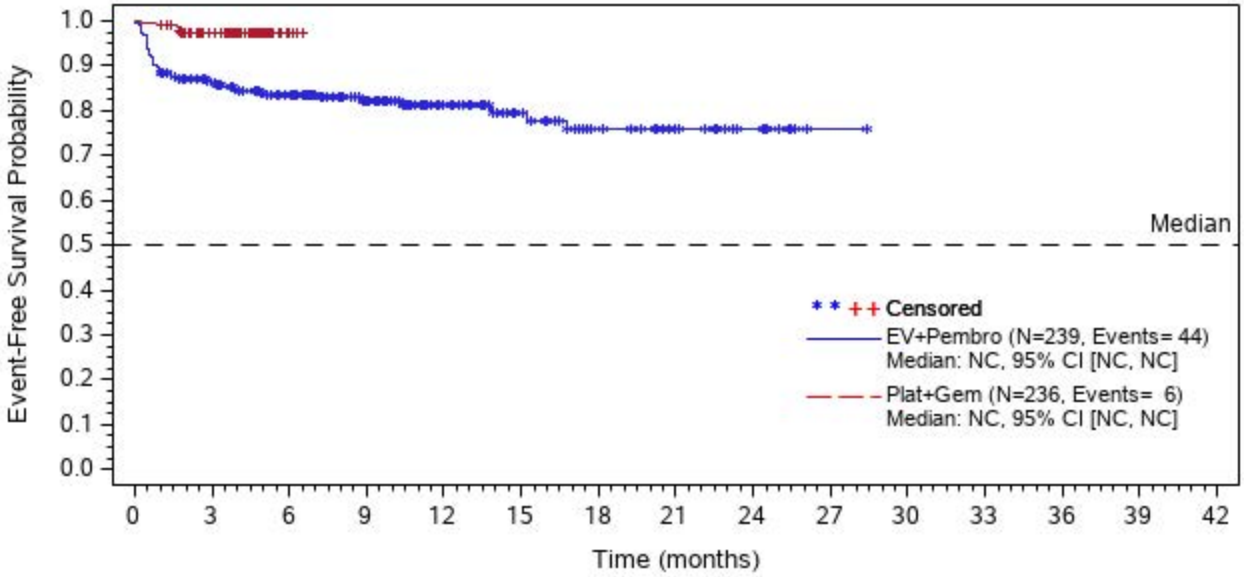
1	201	169	138	107	72	50	30	17	6	1	1	0	0	0	0
2	197	150	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.67.1.1: Kaplan-Meier Plot of Time to first TEAE - Hyperglycaemia (PT) - Analysis Set mSAF 1



at Risk

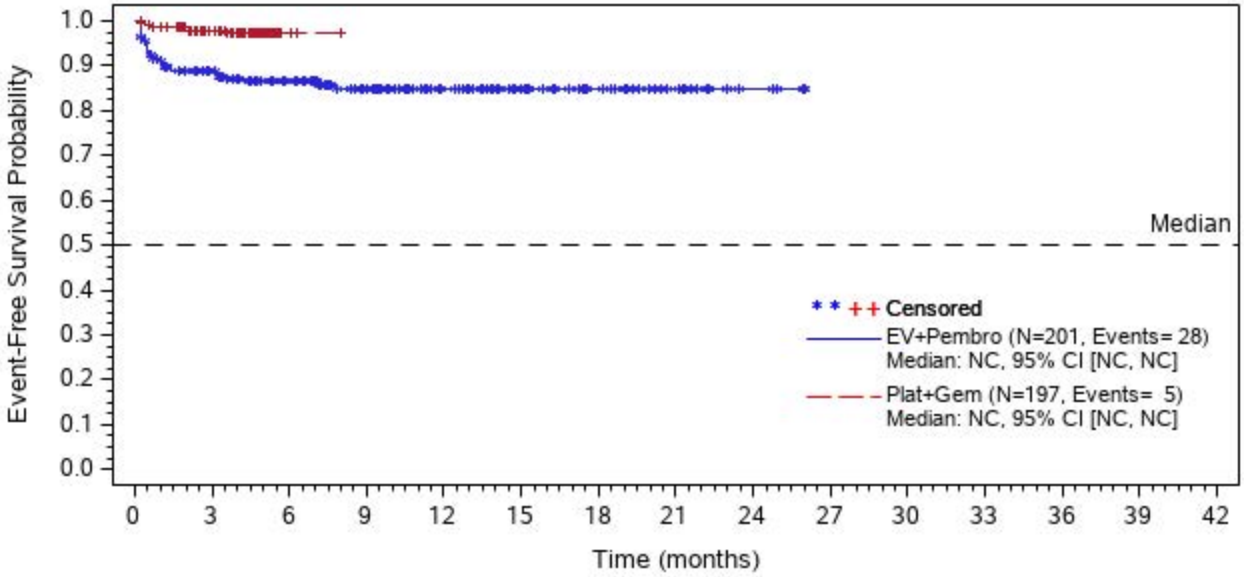
1	239	181	146	111	68	45	29	18	10	1	0	0	0	0	0
2	236	194	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.67.2.1: Kaplan-Meier Plot of Time to first TEAE - Hyperglycaemia (PT) - Analysis Set mSAF 2



at Risk

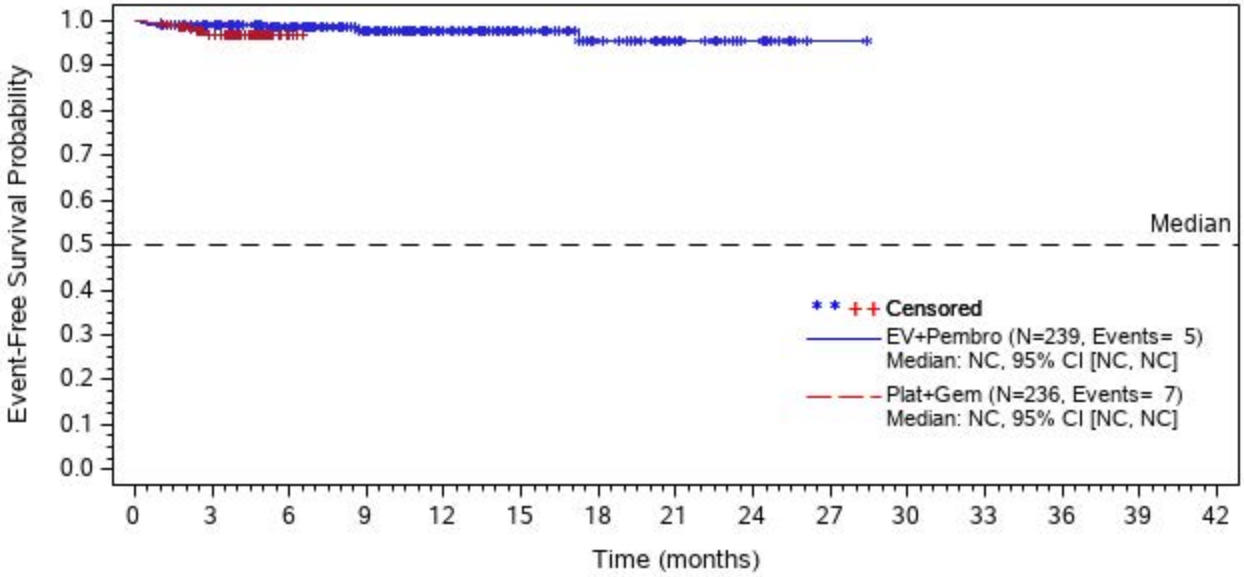
1	201	154	121	93	63	45	28	16	5	0	0	0	0	0	0
2	197	148	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.68.1.1: Kaplan-Meier Plot of Time to first TEAE - Hyperkalaemia (PT) - Analysis Set mSAF 1



at Risk

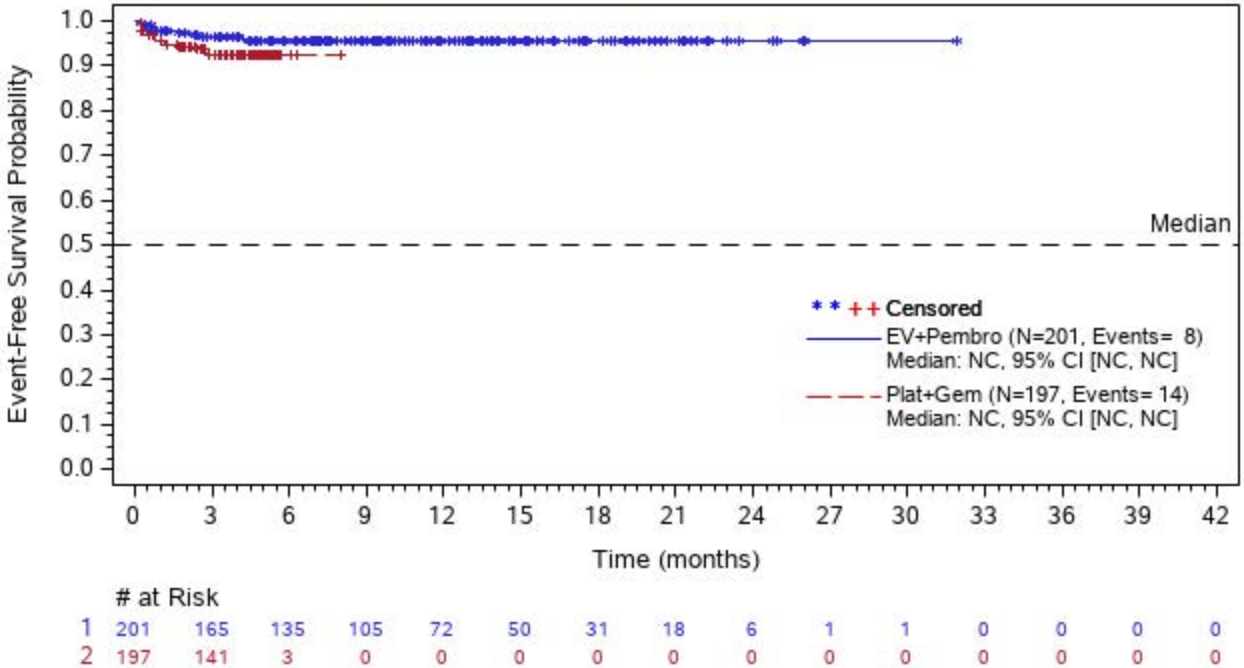
1	239	210	168	129	85	57	37	22	12	1	0	0	0	0	0
2	236	193	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.68.2.1: Kaplan-Meier Plot of Time to first TEAE - Hyperkalaemia (PT) - Analysis Set mSAF 2



at Risk

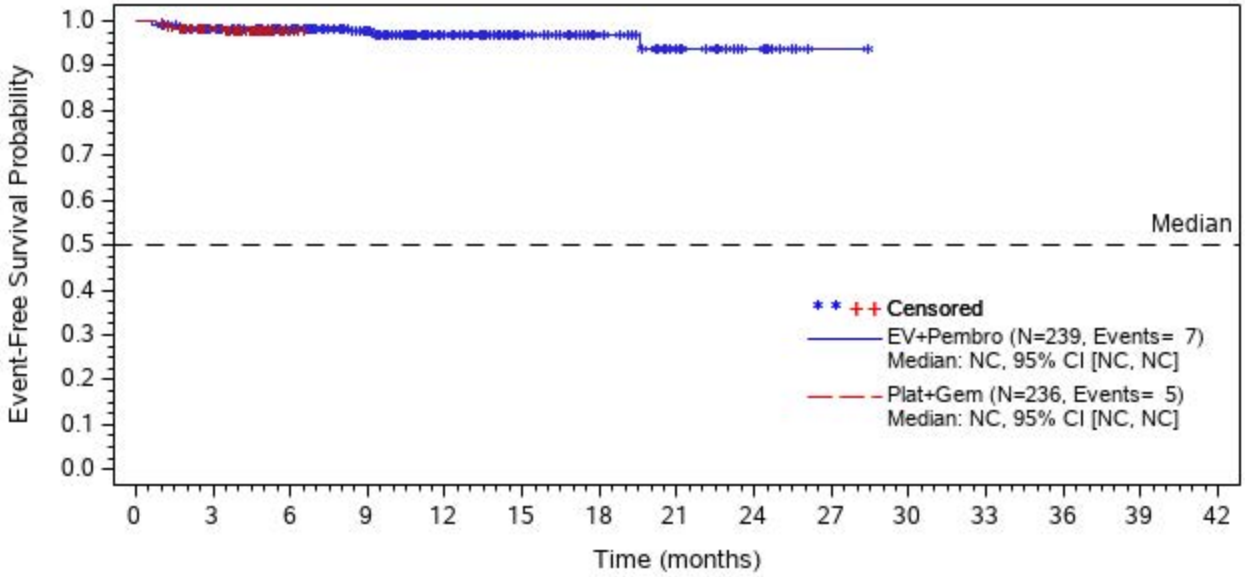
1	201	165	135	105	72	50	31	18	6	1	1	0	0	0	0
2	197	141	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.69.1.1: Kaplan-Meier Plot of Time to first TEAE - Hypocalcaemia (PT) - Analysis Set mSAF 1



at Risk

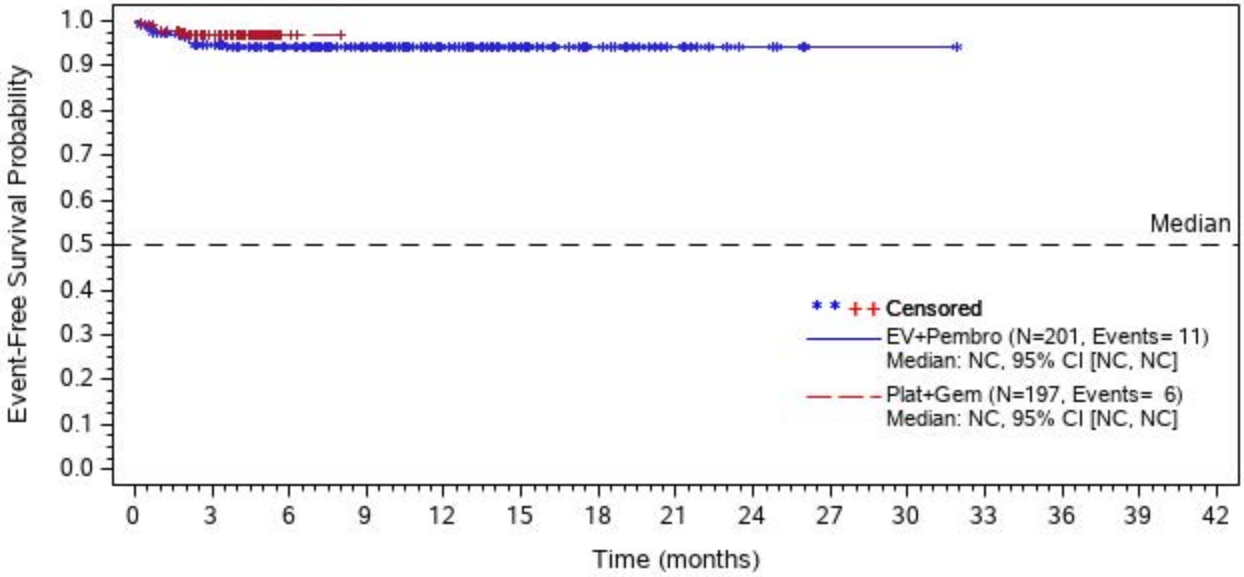
1	239	209	168	129	85	56	38	20	10	1	0	0	0	0	0
2	236	196	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.69.2.1: Kaplan-Meier Plot of Time to first TEAE - Hypoalbuminaemia (PT) - Analysis Set mSAF 2



at Risk

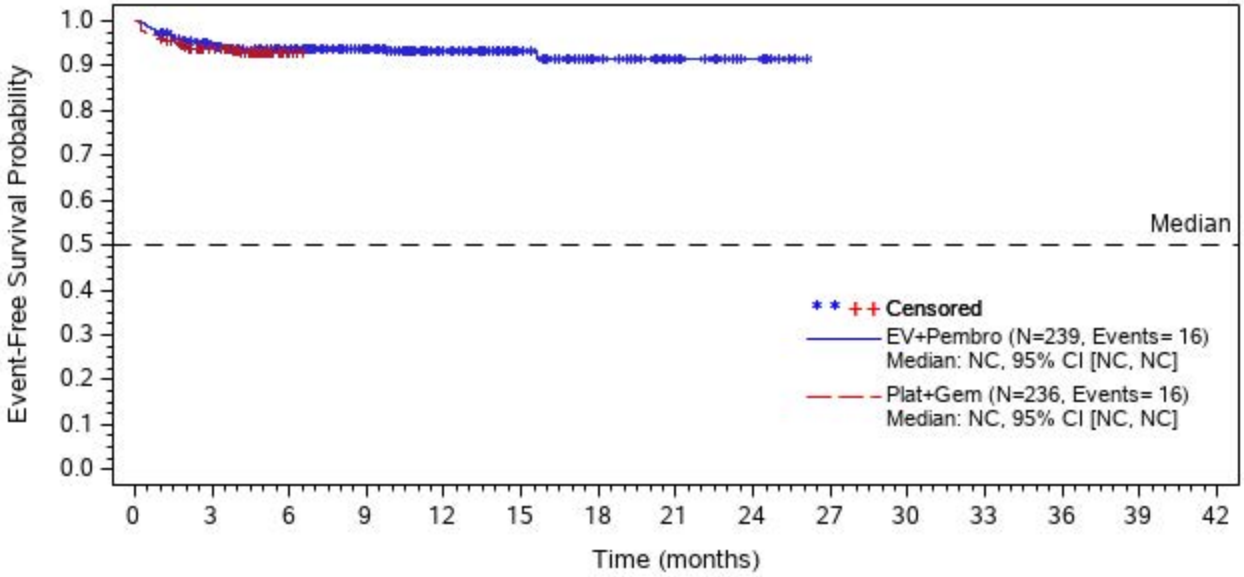
1	201	165	135	104	69	48	29	16	6	1	1	0	0	0	0
2	197	147	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.70.1.1: Kaplan-Meier Plot of Time to first TEAE - Hypokalaemia (PT) - Analysis Set mSAF 1



at Risk

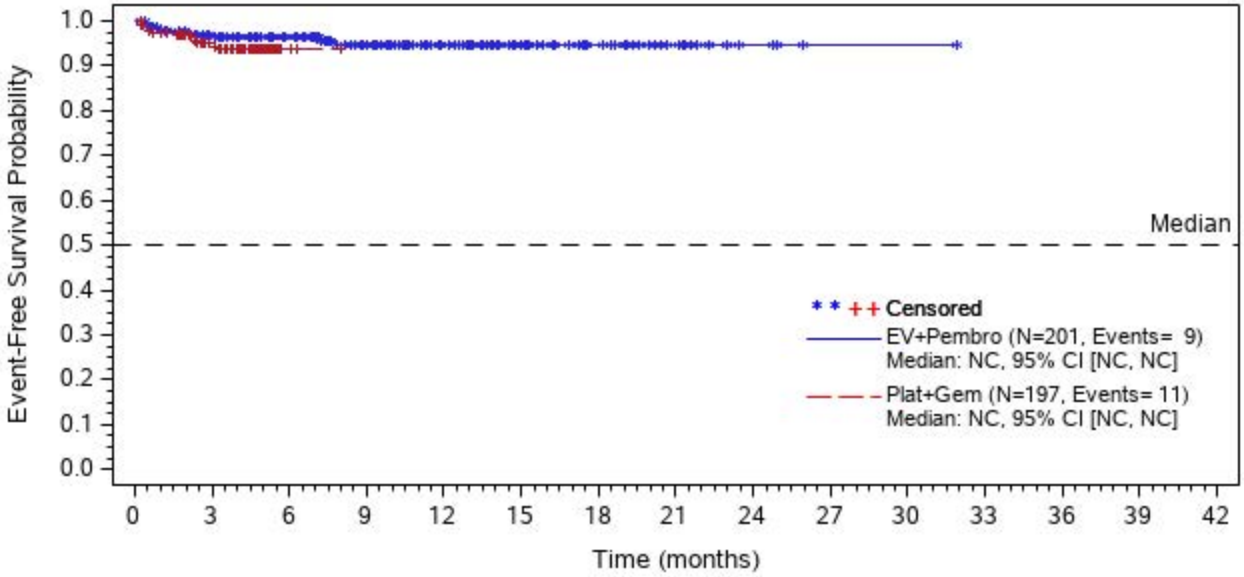
1	239	203	163	130	86	57	37	20	10	0	0	0	0	0	0
2	236	189	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.70.2.1: Kaplan-Meier Plot of Time to first TEAE - Hypocalcaemia (PT) - Analysis Set mSAF 2



at Risk

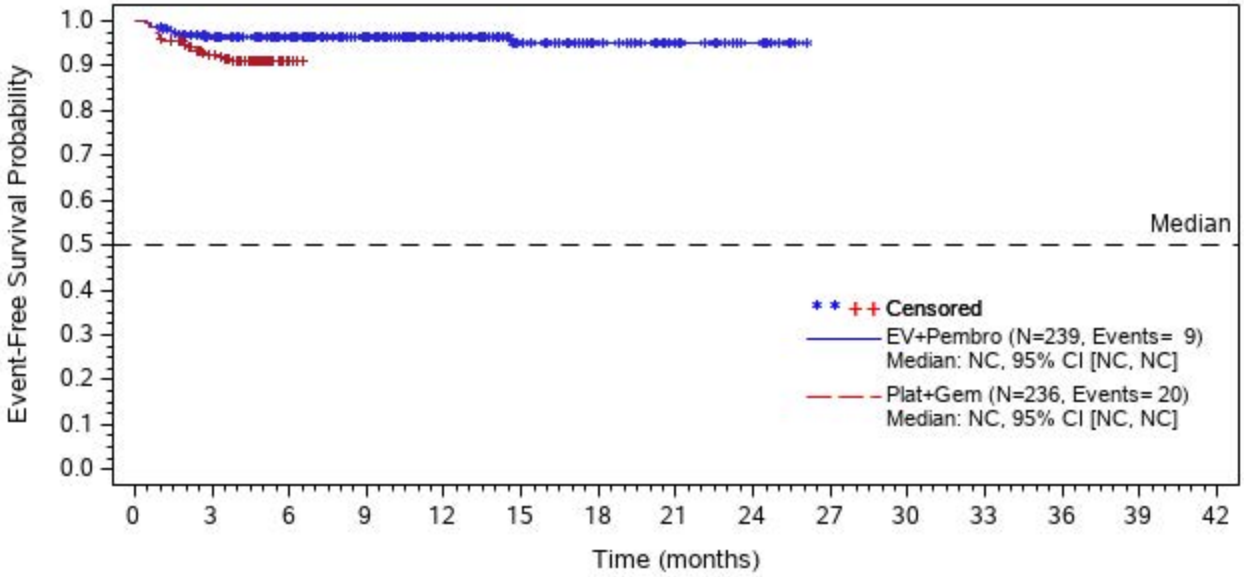
1	201	167	136	103	70	49	29	16	5	1	1	0	0	0	0
2	197	142	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.71.1.1: Kaplan-Meier Plot of Time to first TEAE - Hypomagnesaemia (PT) - Analysis Set mSAF 1



at Risk

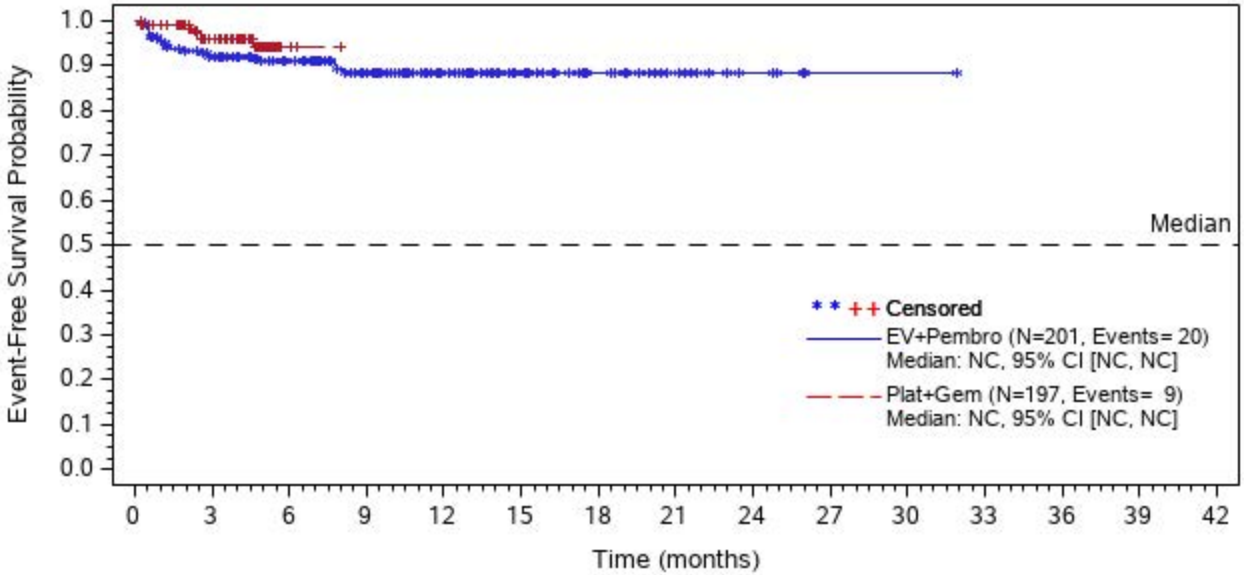
1	239	206	166	129	86	56	38	21	11	0	0	0	0	0	0
2	236	187	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.71.2.1: Kaplan-Meier Plot of Time to first TEAE - Hypokalaemia (PT) - Analysis Set mSAF 2



at Risk

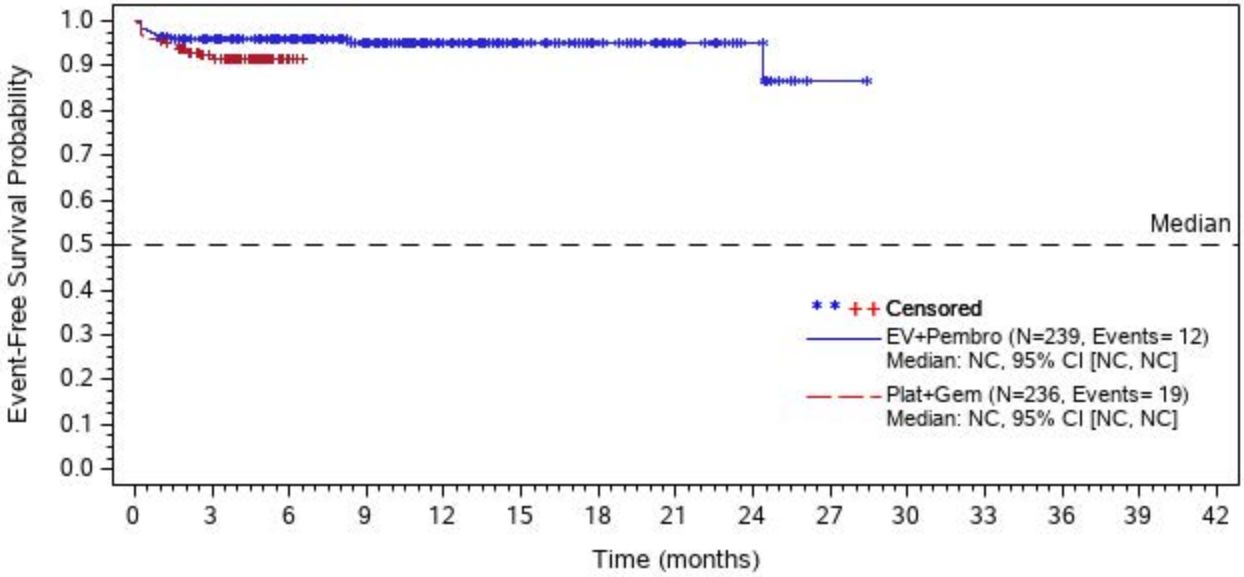
1	201	160	129	99	67	46	27	16	6	1	1	0	0	0	0
2	197	147	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.72.1.1: Kaplan-Meier Plot of Time to first TEAE - Hyponatraemia (PT) - Analysis Set mSAF 1



at Risk

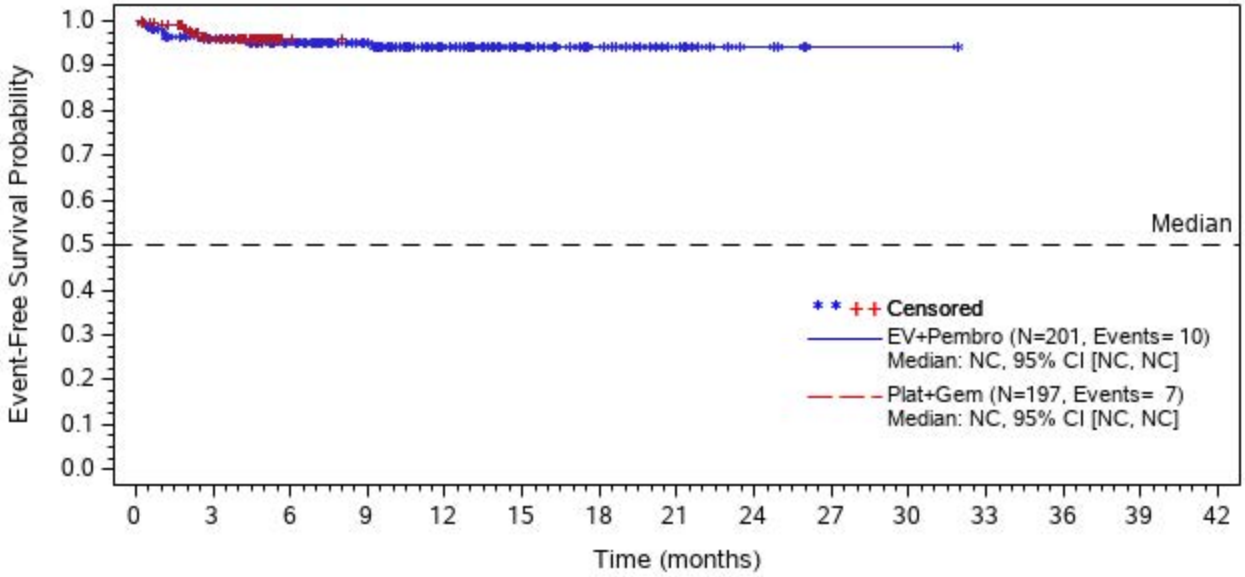
1	239	202	164	126	83	55	39	22	12	1	0	0	0	0	0
2	236	189	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.72.2.1: Kaplan-Meier Plot of Time to first TEAE - Hypomagnesaemia (PT) - Analysis Set mSAF 2



at Risk

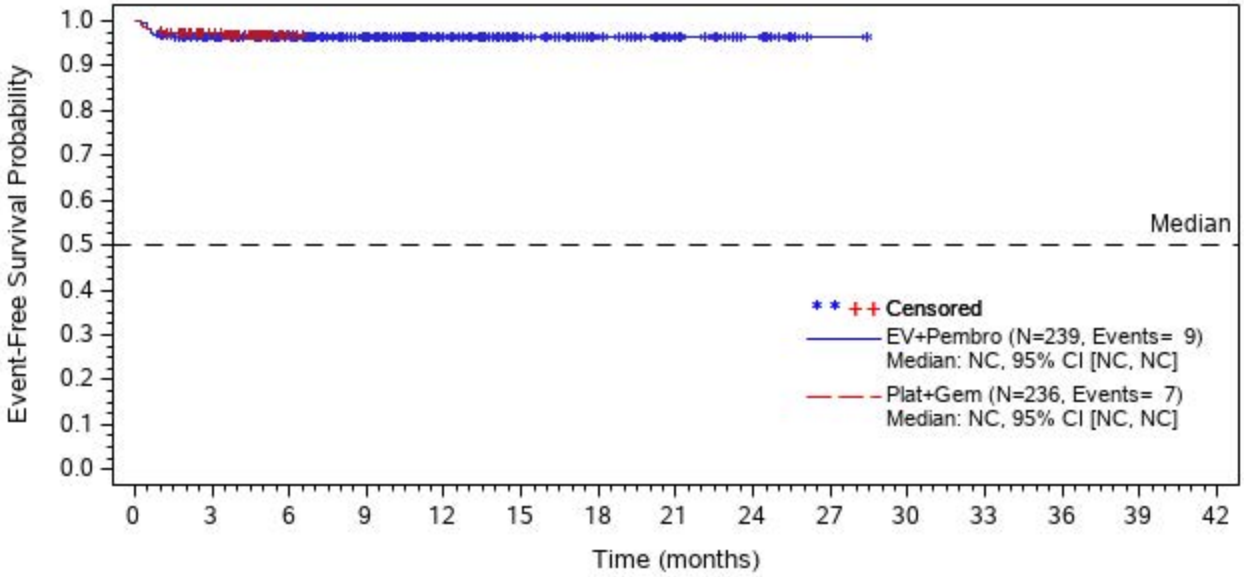
1	201	165	136	106	69	47	28	16	6	1	1	0	0	0	0
2	197	144	2	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.73.1.1: Kaplan-Meier Plot of Time to first TEAE - Hypophosphataemia (PT) - Analysis Set mSAF 1



at Risk

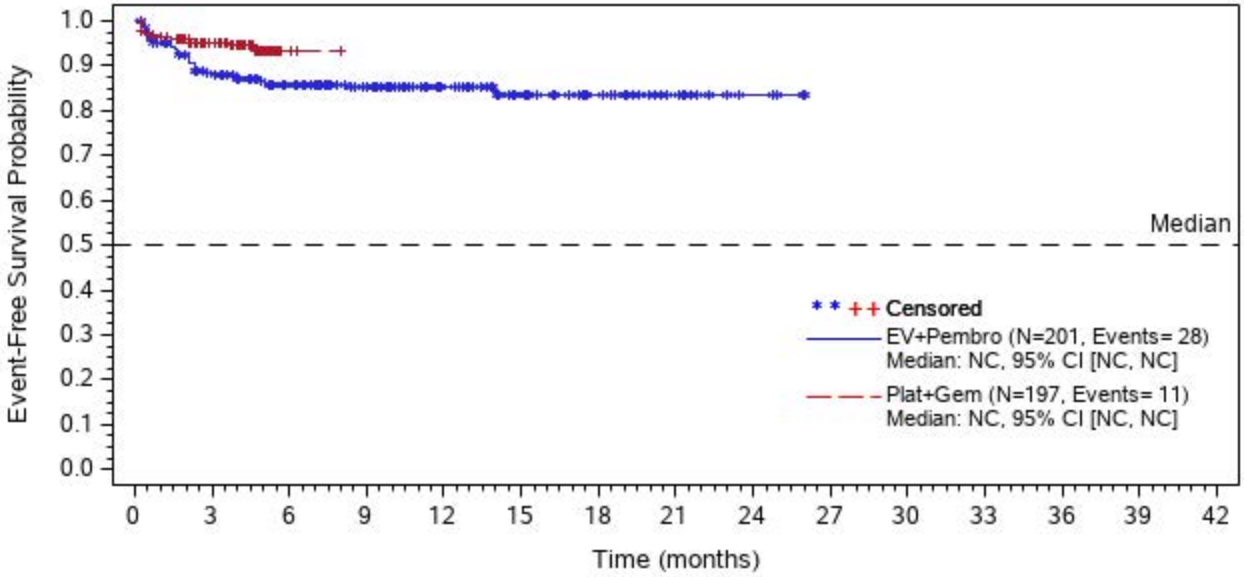
1	239	203	164	127	85	56	39	22	12	1	0	0	0	0	0
2	236	196	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.73.2.1: Kaplan-Meier Plot of Time to first TEAE - Hyponatraemia (PT) - Analysis Set mSAF 2



at Risk

1	201	155	125	97	65	46	29	16	5	0	0	0	0	0	0
2	197	146	3	0	0	0	0	0	0	0	0	0	0	0	0

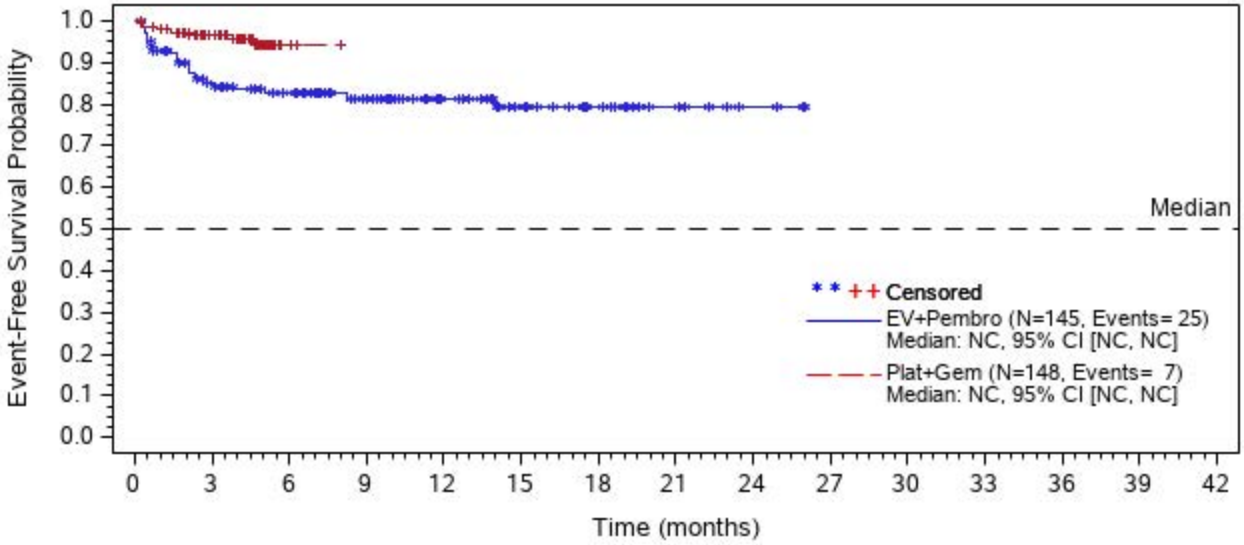
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.73.2.2.4: Kaplan-Meier Plot of Time to first TEAE - Hyponatraemia (PT) - Analysis Set mSAF 2

Sex: Male



at Risk

1	145	105	88	66	44	30	20	10	4	0	0	0	0	0	0
2	148	112	3	0	0	0	0	0	0	0	0	0	0	0	0

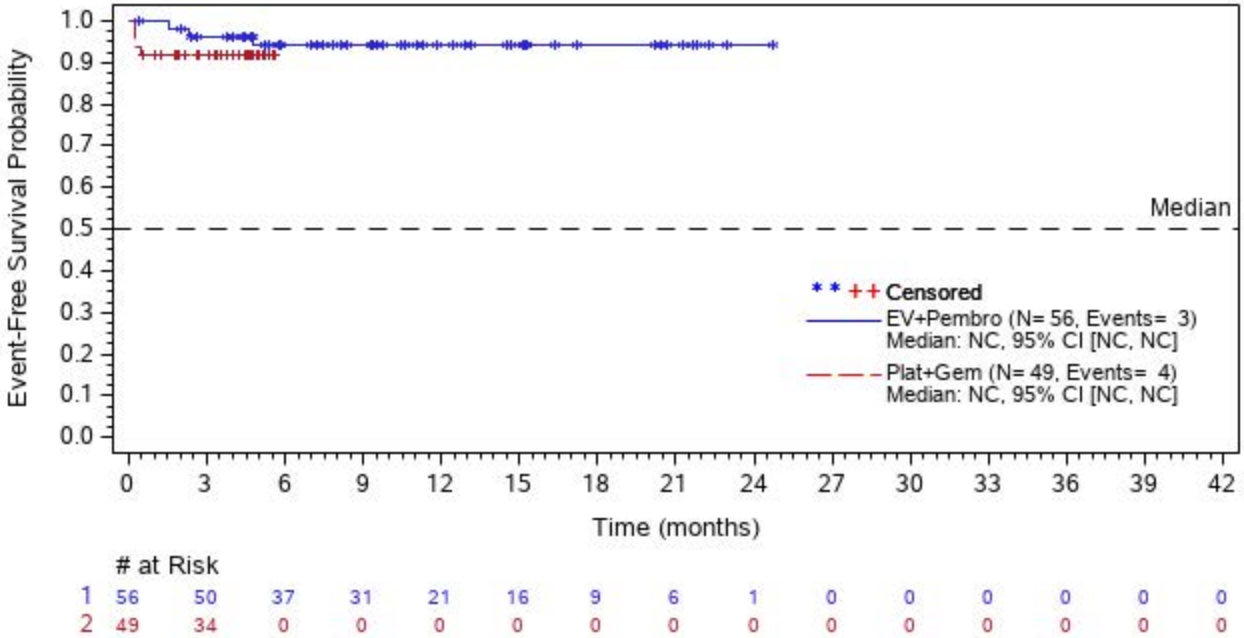
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.73.2.2.4: Kaplan-Meier Plot of Time to first TEAE - Hyponatraemia (PT) - Analysis Set mSAF 2

Sex: Female



at Risk

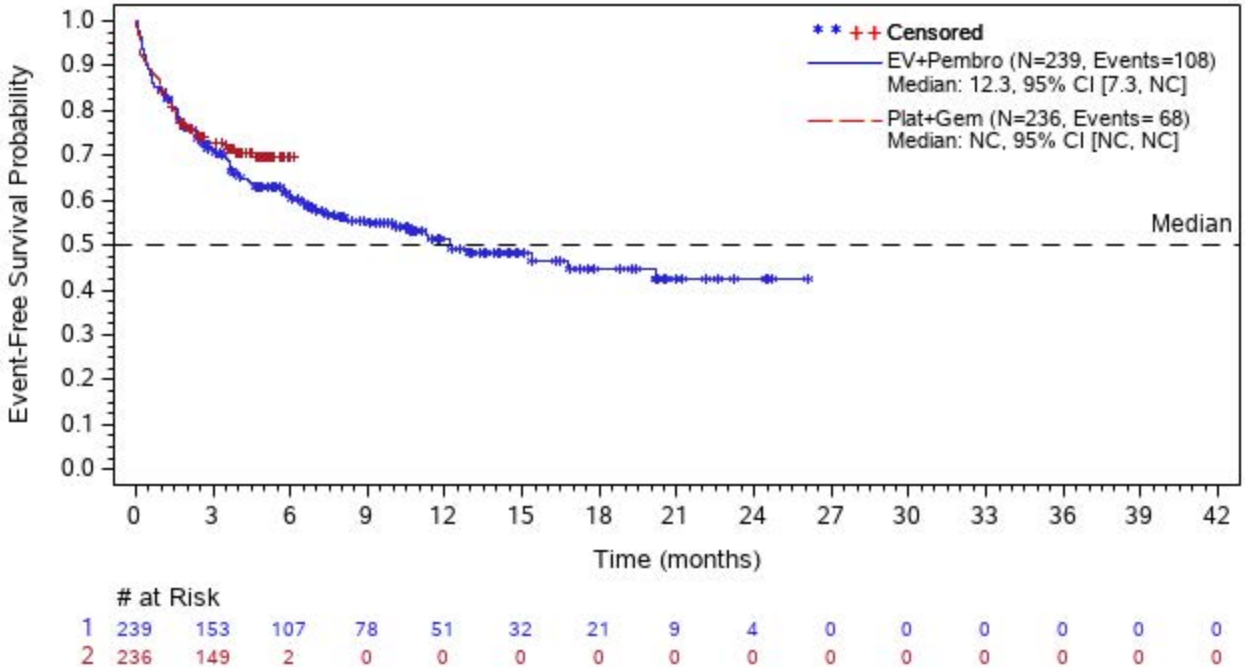
1	56	50	37	31	21	16	9	6	1	0	0	0	0	0	0
2	49	34	0	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.74.1.1: Kaplan-Meier Plot of Time to first TEAE - Musculoskeletal and connective tissue disorders (SOC) - Analysis Set mSAF 1



at Risk

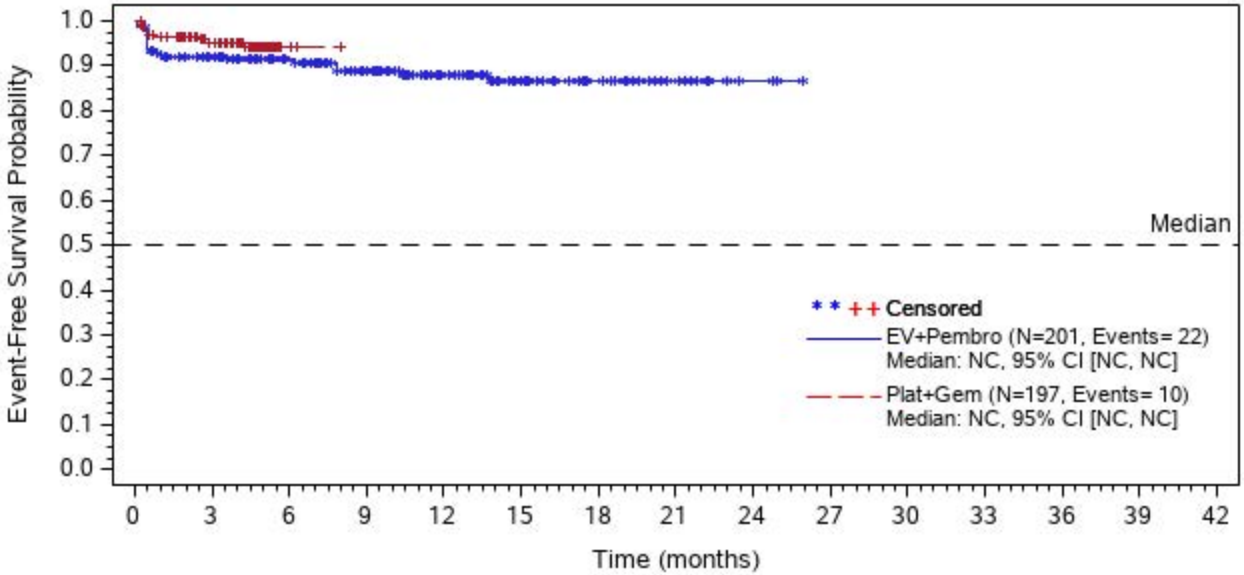
1	239	153	107	78	51	32	21	9	4	0	0	0	0	0	0
2	236	149	2	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.74.2.1: Kaplan-Meier Plot of Time to first TEAE - Hypophosphataemia (PT) - Analysis Set mSAF 2



at Risk

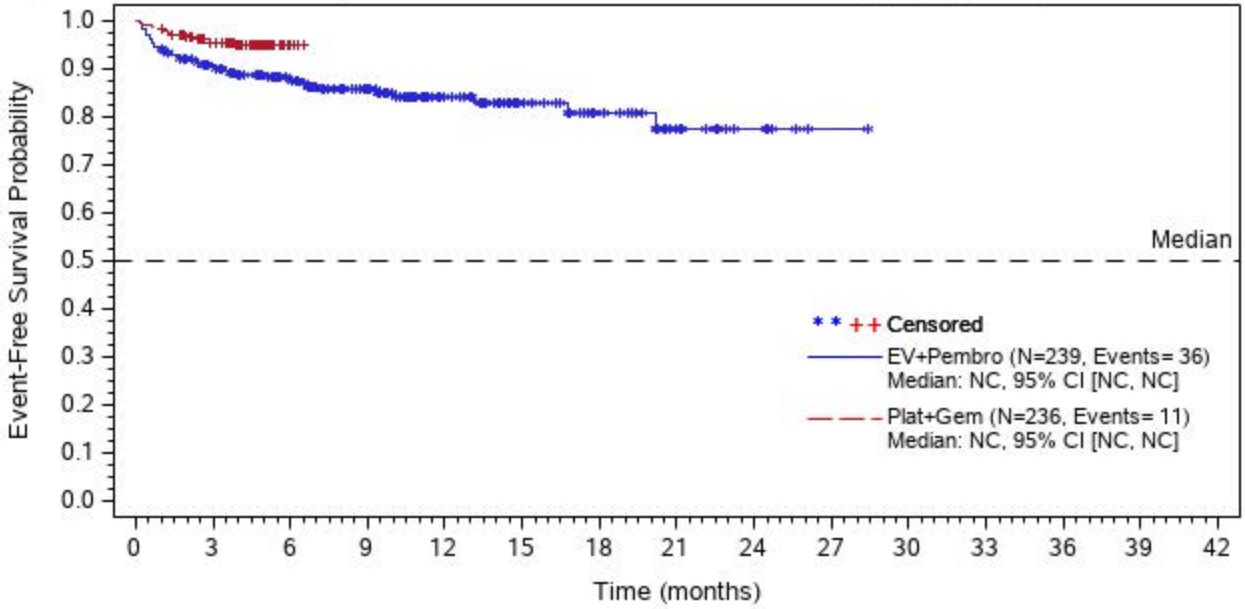
1	201	161	132	101	68	47	27	14	4	0	0	0	0	0	0
2	197	145	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.75.1.1: Kaplan-Meier Plot of Time to first TEAE - Arthralgia (PT) - Analysis Set mSAF 1



at Risk

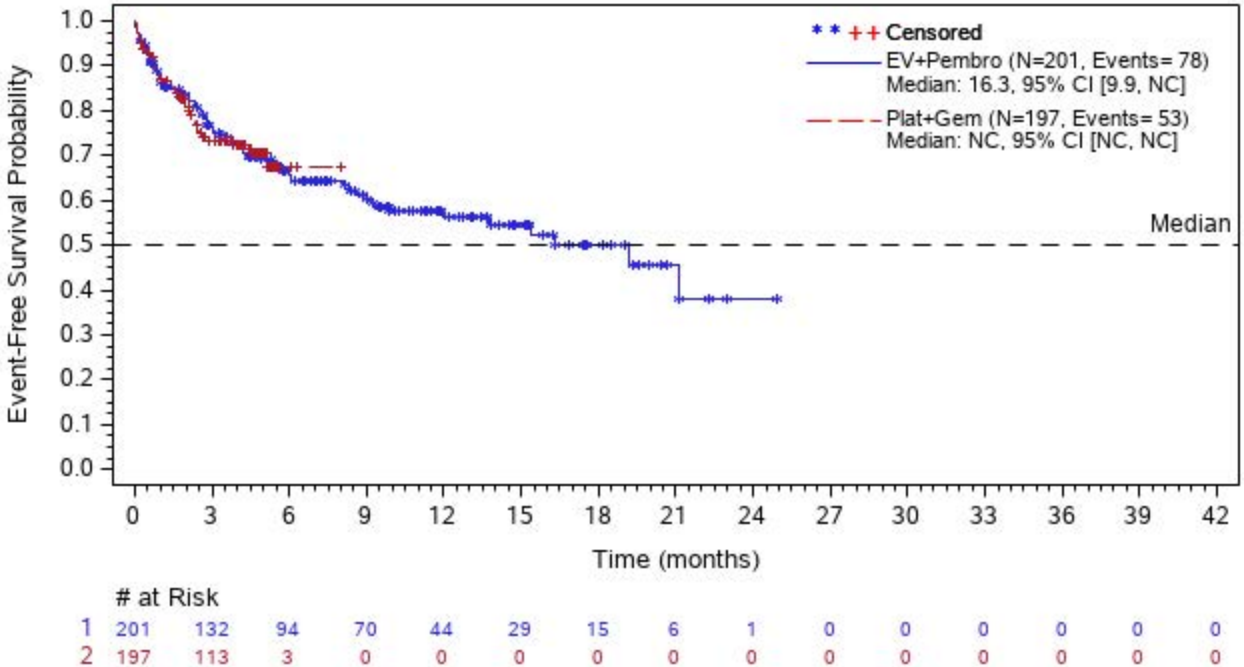
1	239	193	150	113	72	49	33	15	7	1	0	0	0	0	0
2	236	192	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.75.2.1: Kaplan-Meier Plot of Time to first TEAE - Musculoskeletal and connective tissue disorders (SOC) - Analysis Set mSAF 2



at Risk

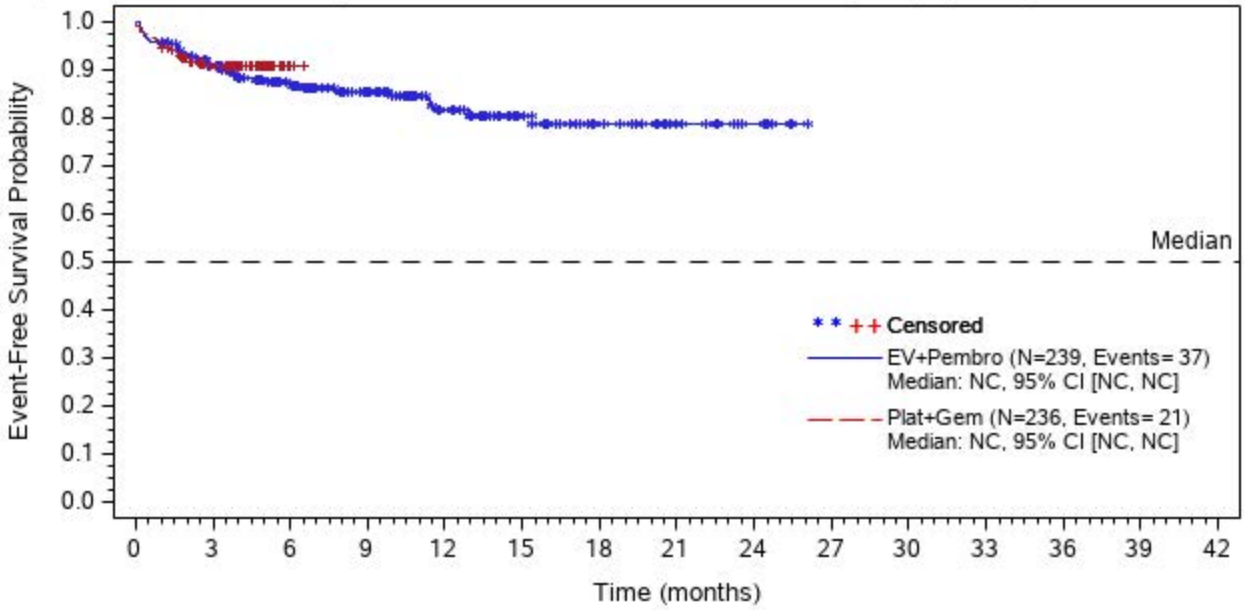
1	201	132	94	70	44	29	15	6	1	0	0	0	0	0	0
2	197	113	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.76.1.1: Kaplan-Meier Plot of Time to first TEAE - Back pain (PT) - Analysis Set mSAF 1



at Risk

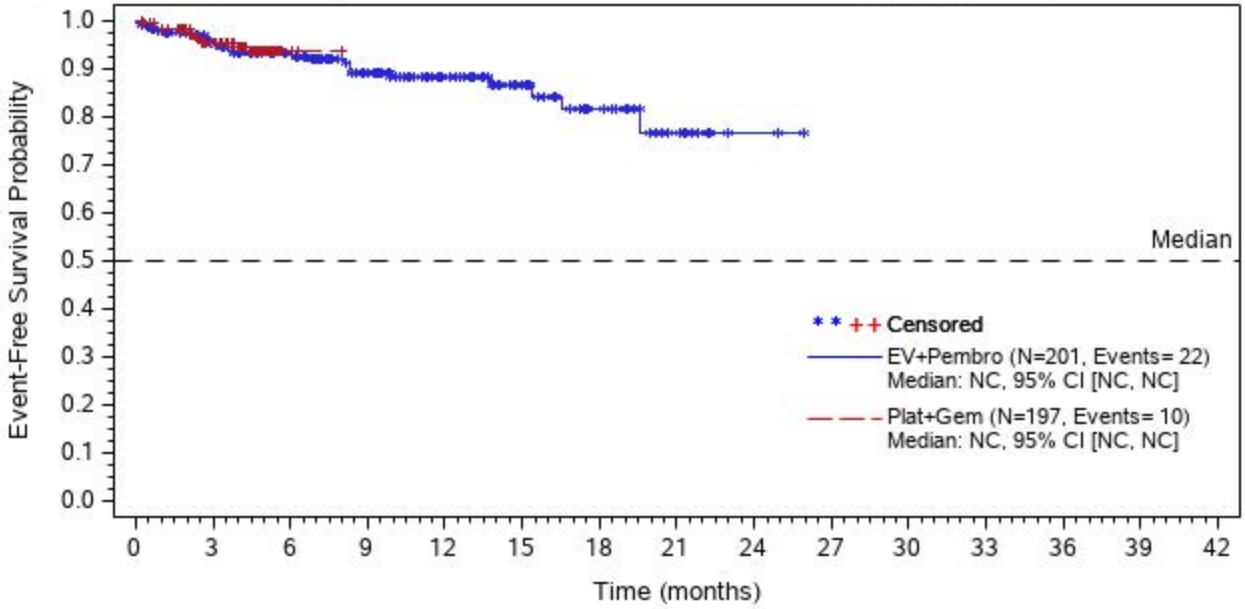
1	239	194	149	117	75	49	32	17	9	0	0	0	0	0	0
2	236	183	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.76.2.1: Kaplan-Meier Plot of Time to first TEAE - Arthralgia (PT) - Analysis Set mSAF 2



at Risk

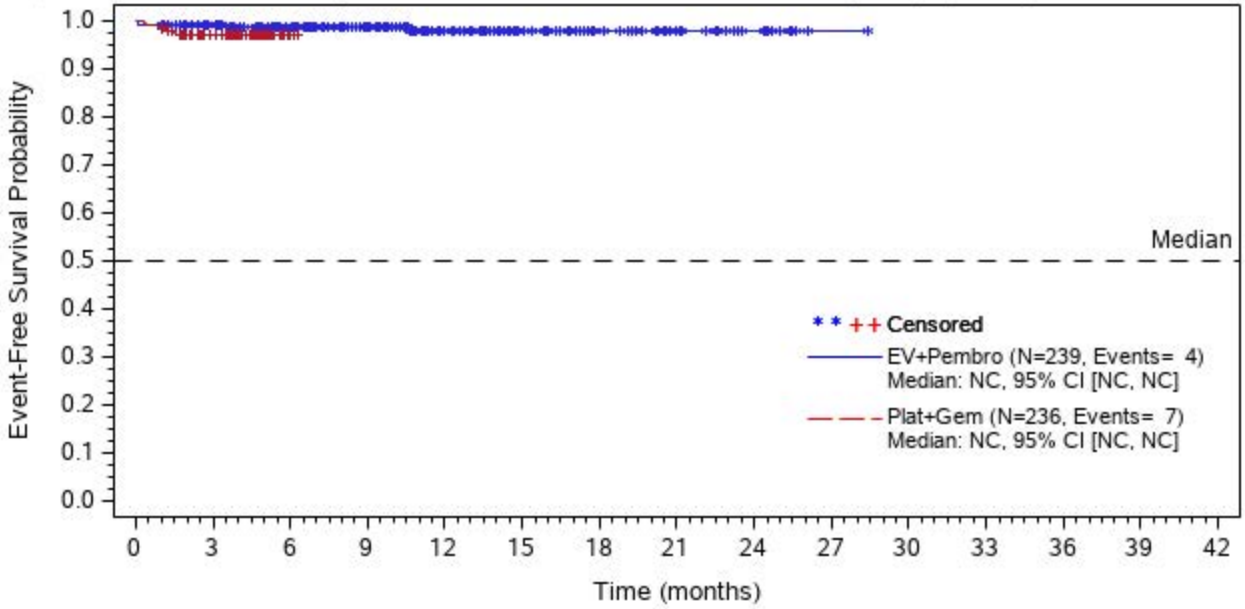
1	201	165	130	96	64	43	24	11	2	0	0	0	0	0	0
2	197	143	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.77.1.1: Kaplan-Meier Plot of Time to first TEAE - Bone pain (PT) - Analysis Set mSAF 1



at Risk

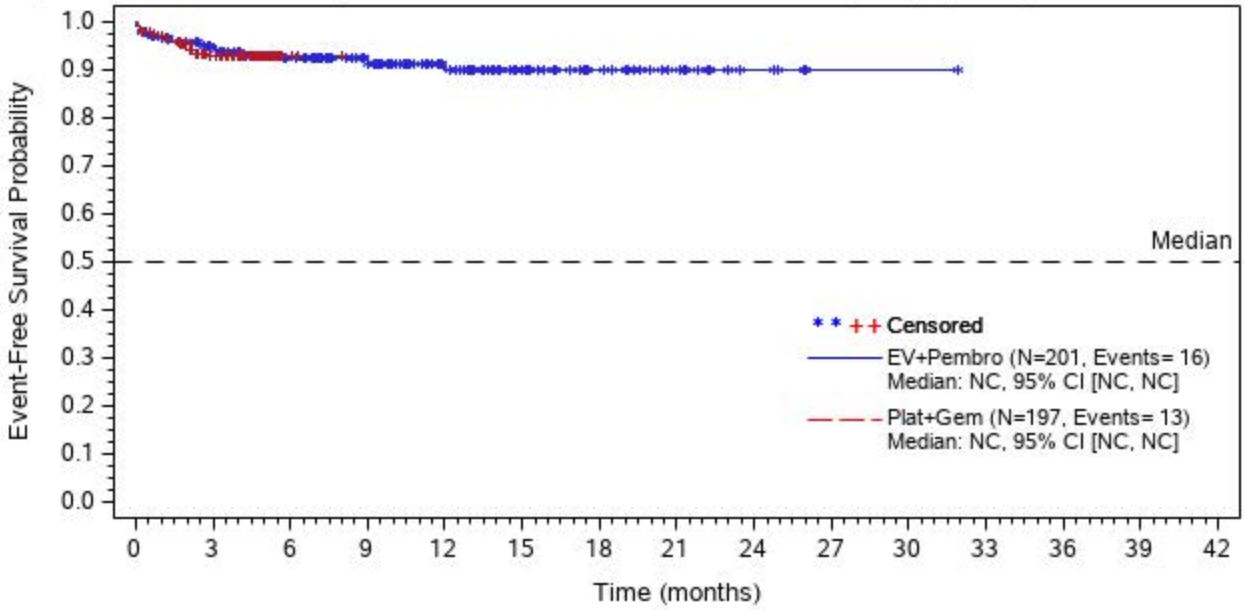
1	239	209	167	130	86	58	39	22	12	1	0	0	0	0	0
2	236	194	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.77.2.1: Kaplan-Meier Plot of Time to first TEAE - Back pain (PT) - Analysis Set mSAF 2



at Risk

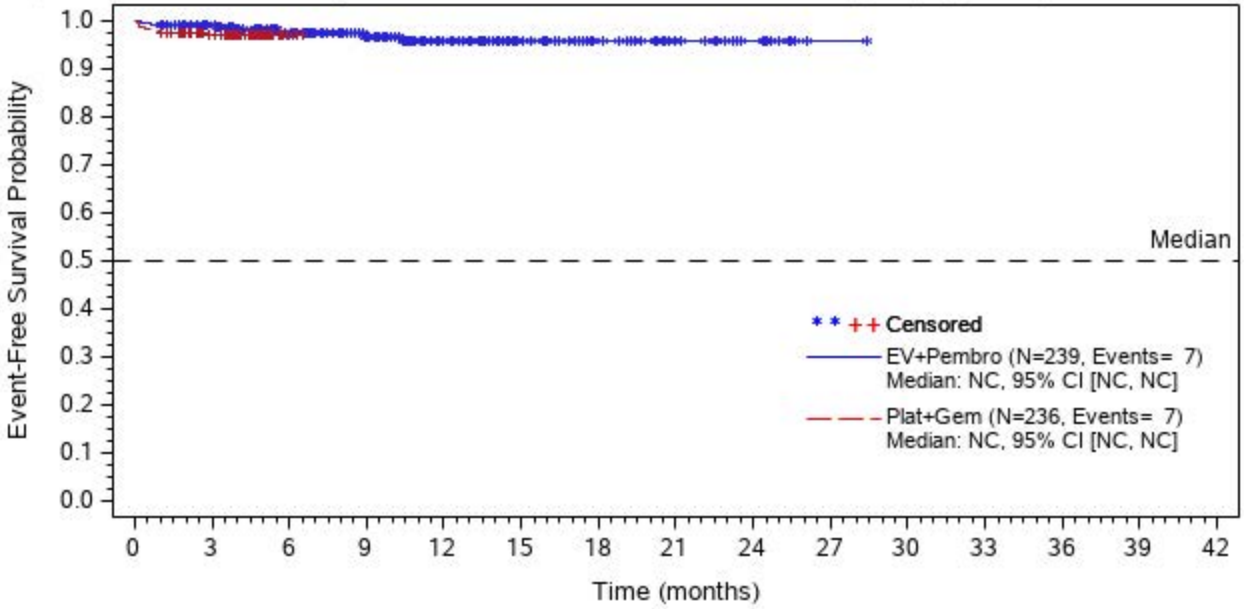
1	201	163	130	102	67	45	27	16	5	1	1	0	0	0	0
2	197	142	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.78.1.1: Kaplan-Meier Plot of Time to first TEAE - Flank pain (PT) - Analysis Set mSAF 1



at Risk

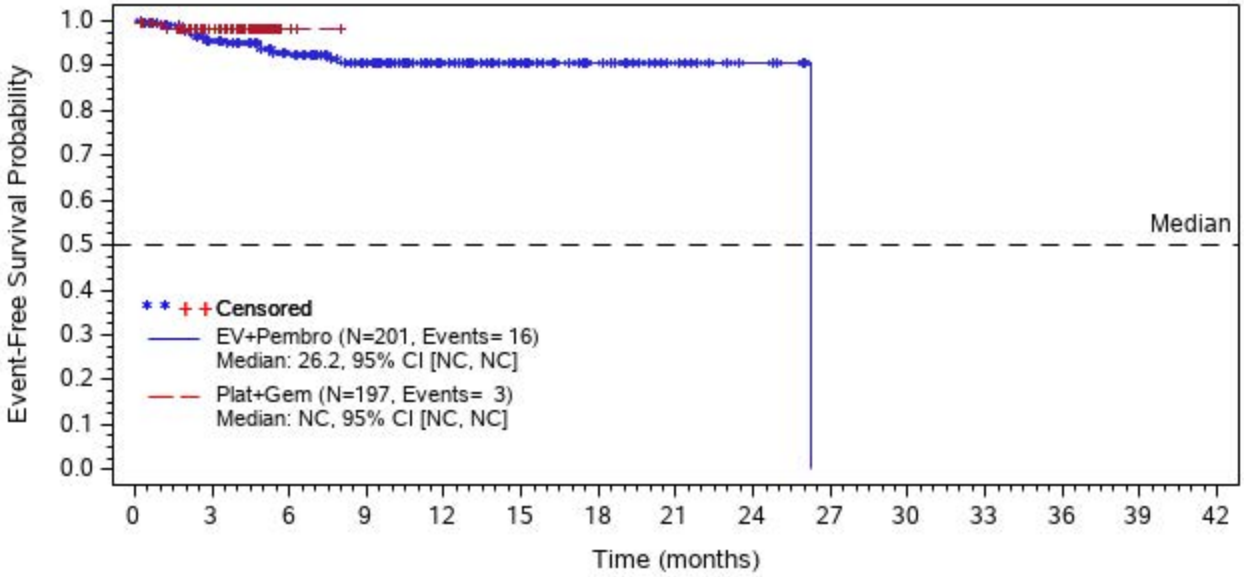
1	239	209	166	127	84	55	37	21	12	1	0	0	0	0	0
2	236	193	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.78.2.1: Kaplan-Meier Plot of Time to first TEAE - Muscular weakness (PT) - Analysis Set mSAF 2



at Risk

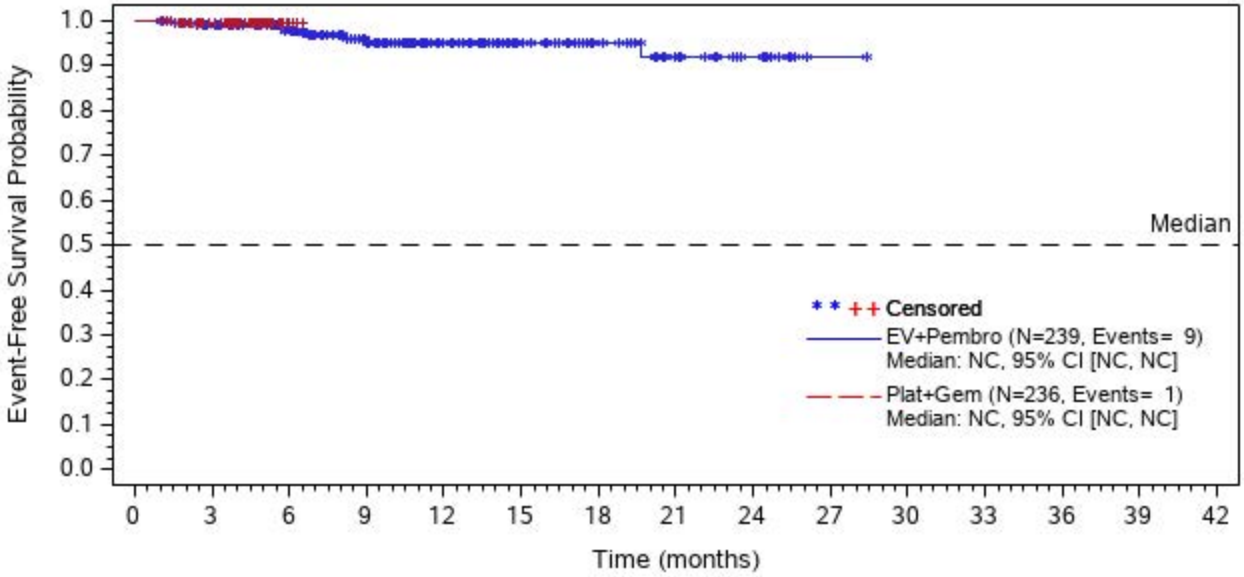
1	201	164	132	102	68	49	29	16	6	0	0	0	0	0	0
2	197	149	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.79.1.1: Kaplan-Meier Plot of Time to first TEAE - Muscle spasms (PT) - Analysis Set mSAF 1



at Risk

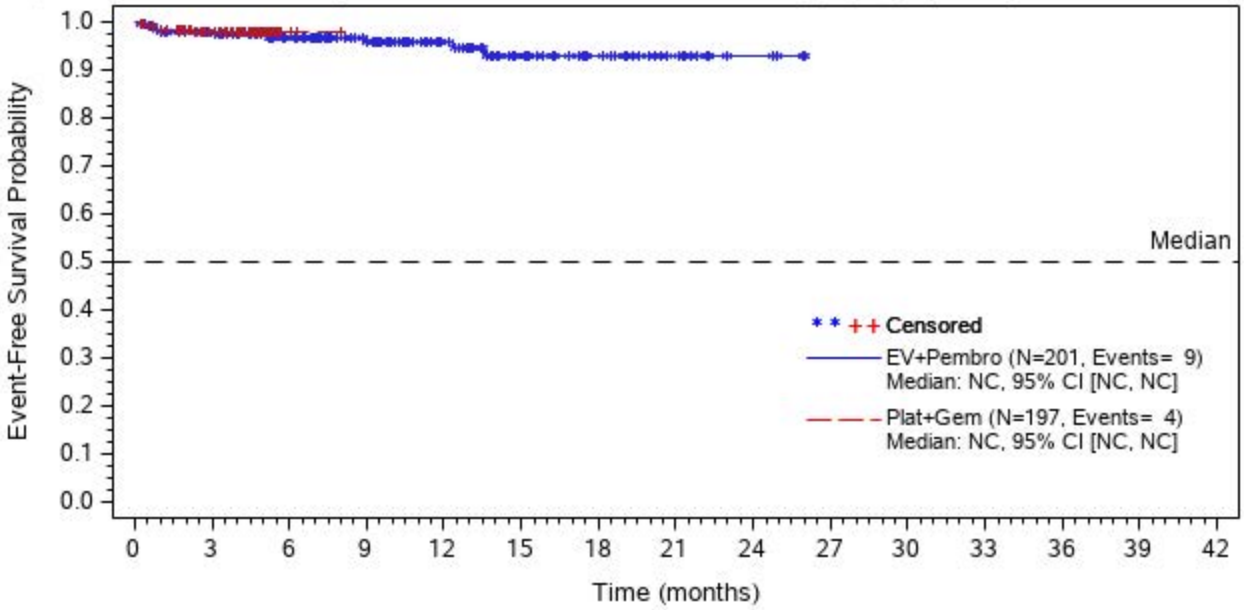
1	239	209	166	127	84	55	37	21	12	1	0	0	0	0	0
2	236	199	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.79.2.1: Kaplan-Meier Plot of Time to first TEAE - Myalgia (PT) - Analysis Set mSAF 2



at Risk

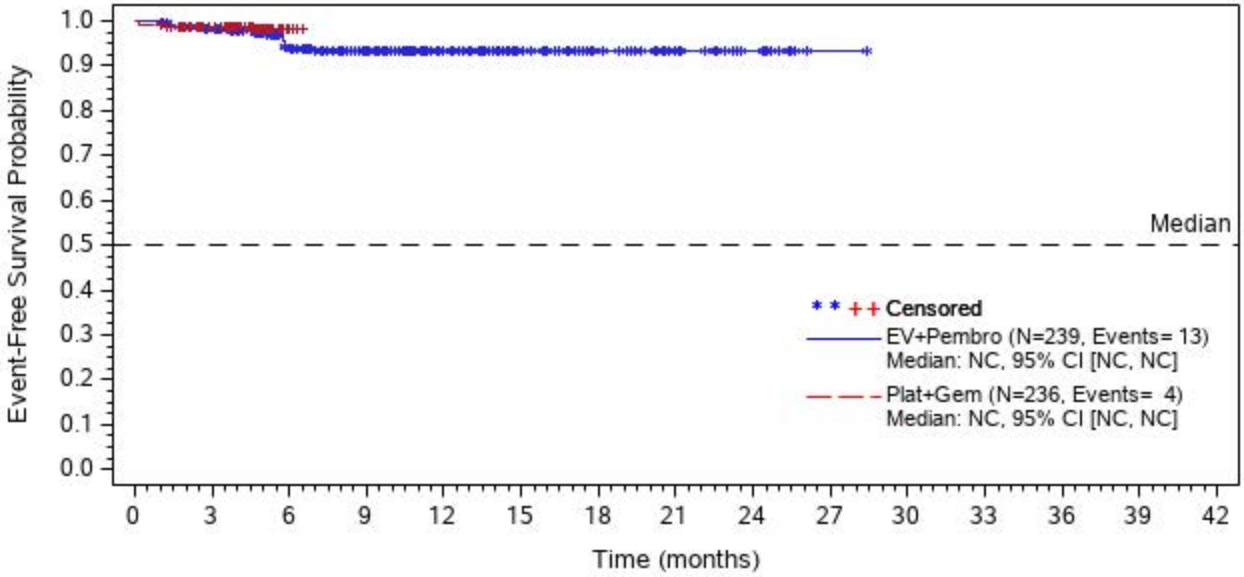
1	201	167	135	105	69	45	28	16	5	0	0	0	0	0	0
2	197	148	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.80.1.1: Kaplan-Meier Plot of Time to first TEAE - Muscular weakness (PT) - Analysis Set mSAF 1



at Risk

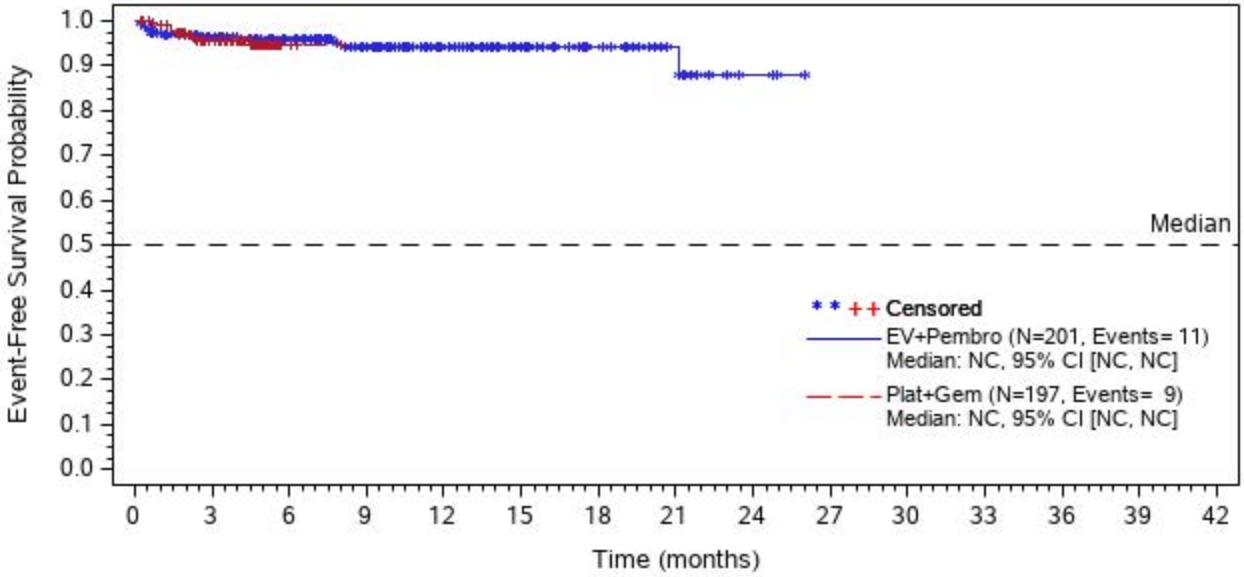
1	239	208	159	124	83	56	38	21	11	1	0	0	0	0	0
2	236	199	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.80.2.1: Kaplan-Meier Plot of Time to first TEAE - Pain in extremity (PT) - Analysis Set mSAF 2



at Risk

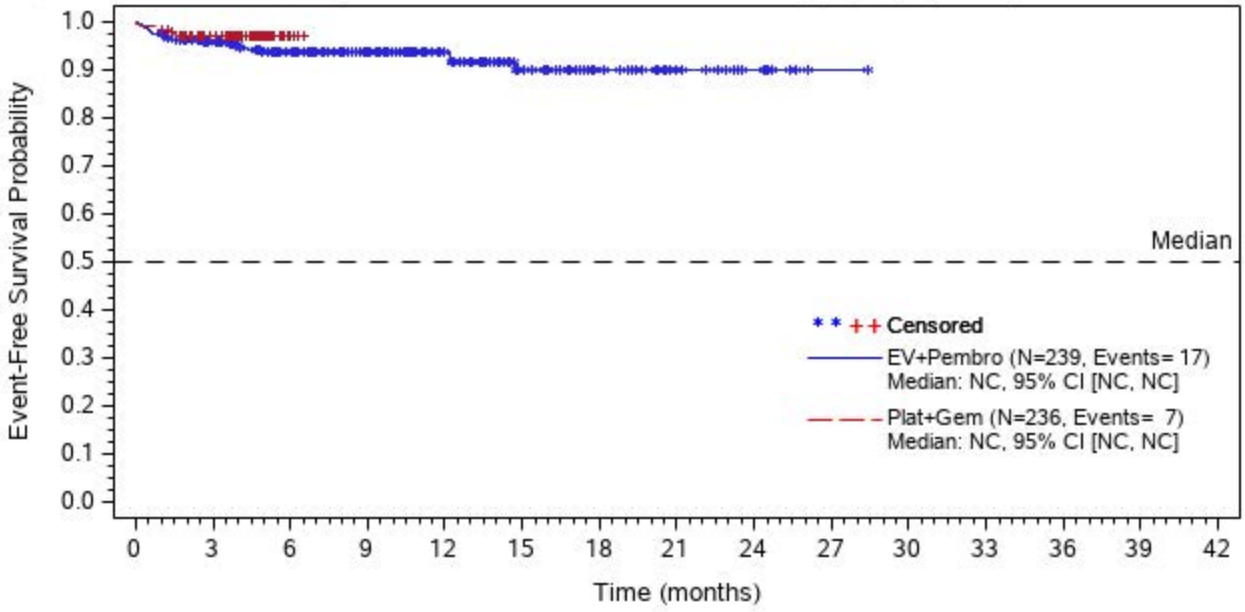
1	201	165	135	104	68	47	27	15	3	0	0	0	0	0	0
2	197	144	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.81.1.1: Kaplan-Meier Plot of Time to first TEAE - Myalgia (PT) - Analysis Set mSAF 1



at Risk

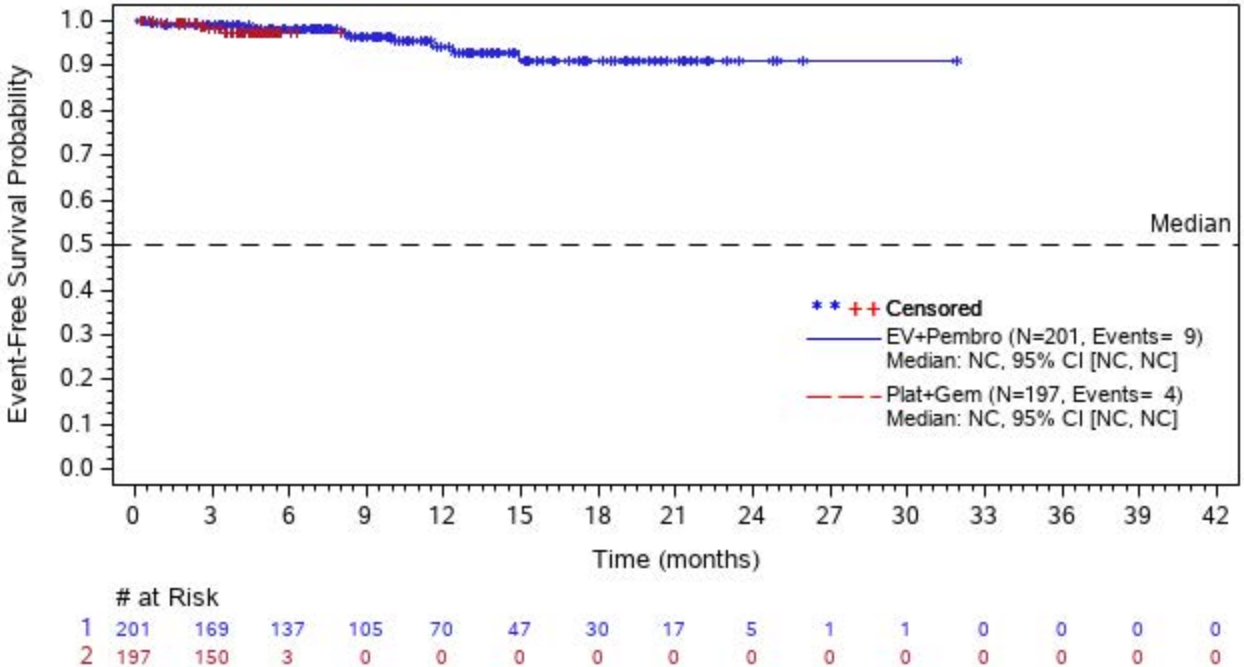
1	239	202	161	125	84	53	35	18	10	1	0	0	0	0	0
2	236	195	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.81.2.1: Kaplan-Meier Plot of Time to first TEAE - Neoplasms benign, malignant and unspecified (incl cysts and polyps) (SOC) - Analysis Set mSAF 2



at Risk

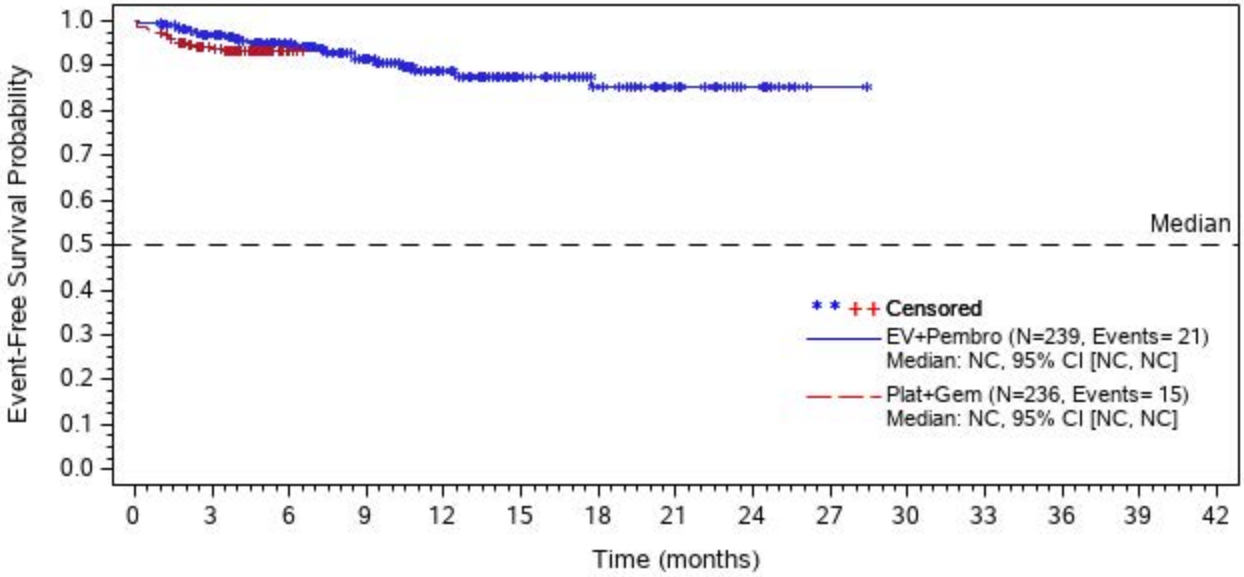
1	201	169	137	105	70	47	30	17	5	1	1	0	0	0	0
2	197	150	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.82.1.1: Kaplan-Meier Plot of Time to first TEAE - Pain in extremity (PT) - Analysis Set mSAF 1



at Risk

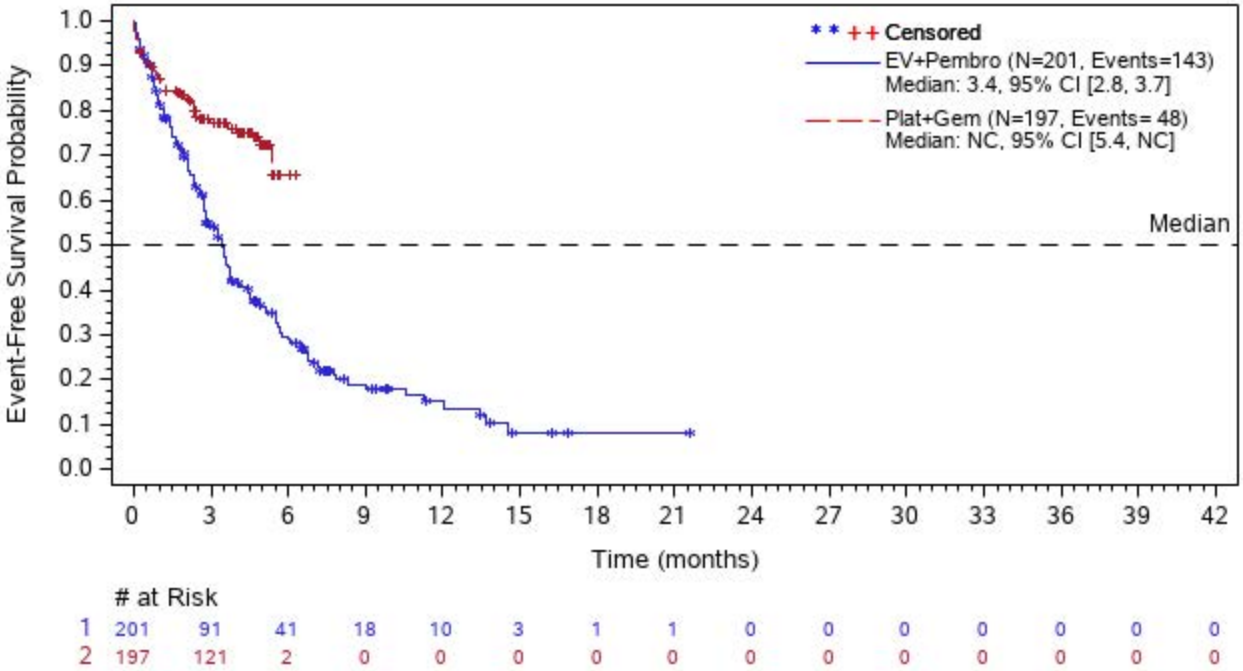
1	239	204	161	120	80	51	36	21	11	1	0	0	0	0	0
2	236	188	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.82.2.1: Kaplan-Meier Plot of Time to first TEAE - Nervous system disorders (SOC) - Analysis Set mSAF 2

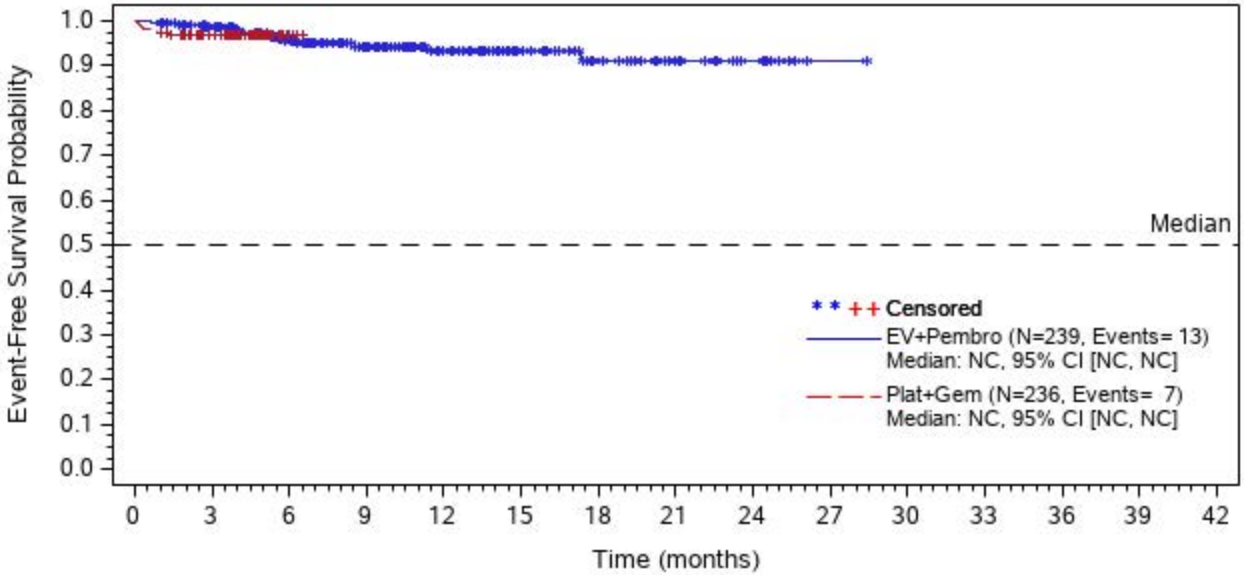


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.83.1.1: Kaplan-Meier Plot of Time to first TEAE - Neoplasms benign, malignant and unspecified (incl cysts and polyps) (SOC) - Analysis Set mSAF 1



at Risk

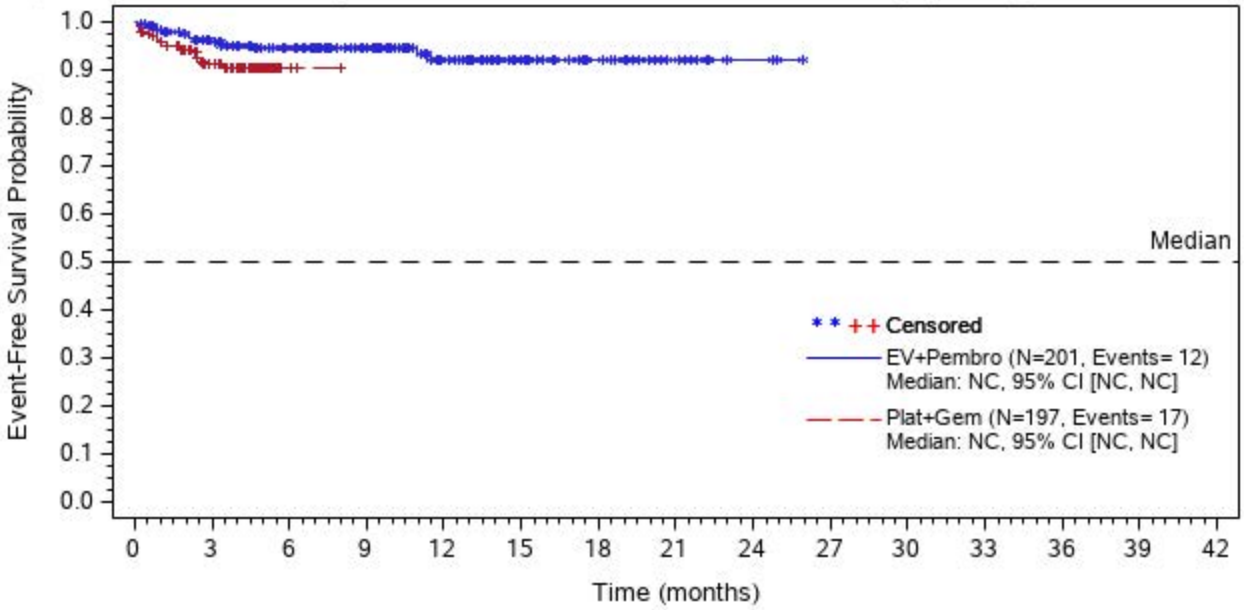
1	239	209	164	126	83	55	36	20	11	1	0	0	0	0	0
2	236	196	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.83.2.1: Kaplan-Meier Plot of Time to first TEAE - Dizziness (PT) - Analysis Set mSAF 2



at Risk

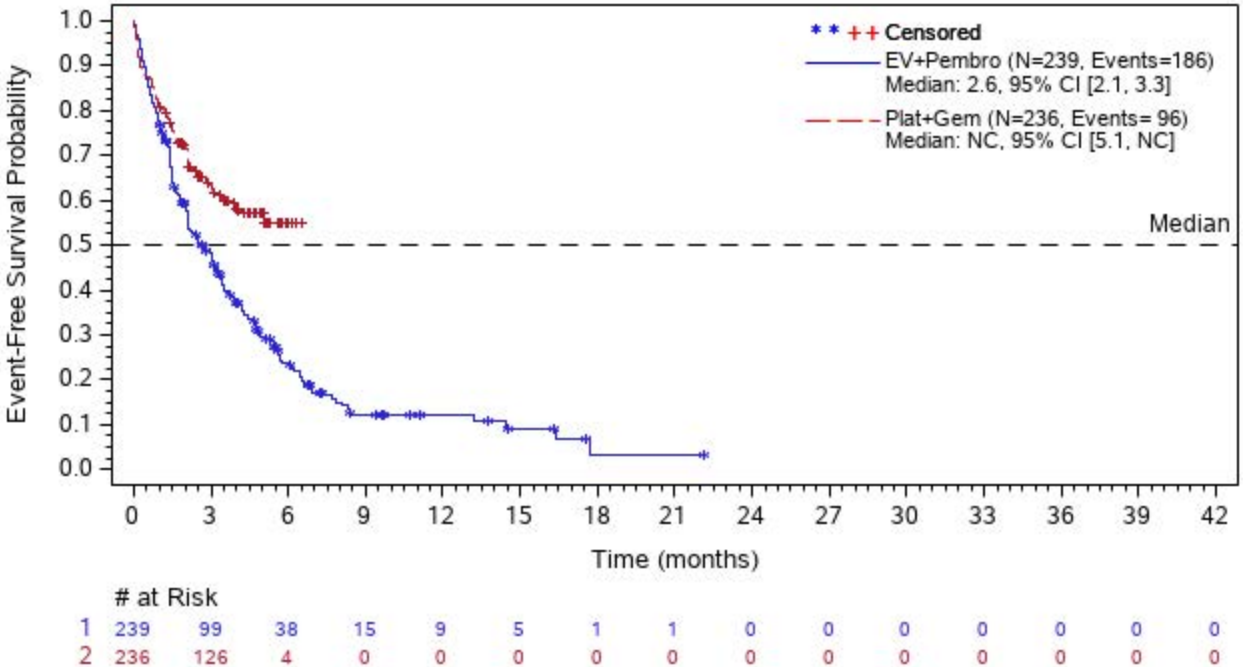
1	201	164	135	106	68	47	27	14	4	0	0	0	0	0	0
2	197	139	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.84.1.1: Kaplan-Meier Plot of Time to first TEAE - Nervous system disorders (SOC) - Analysis Set mSAF 1



at Risk

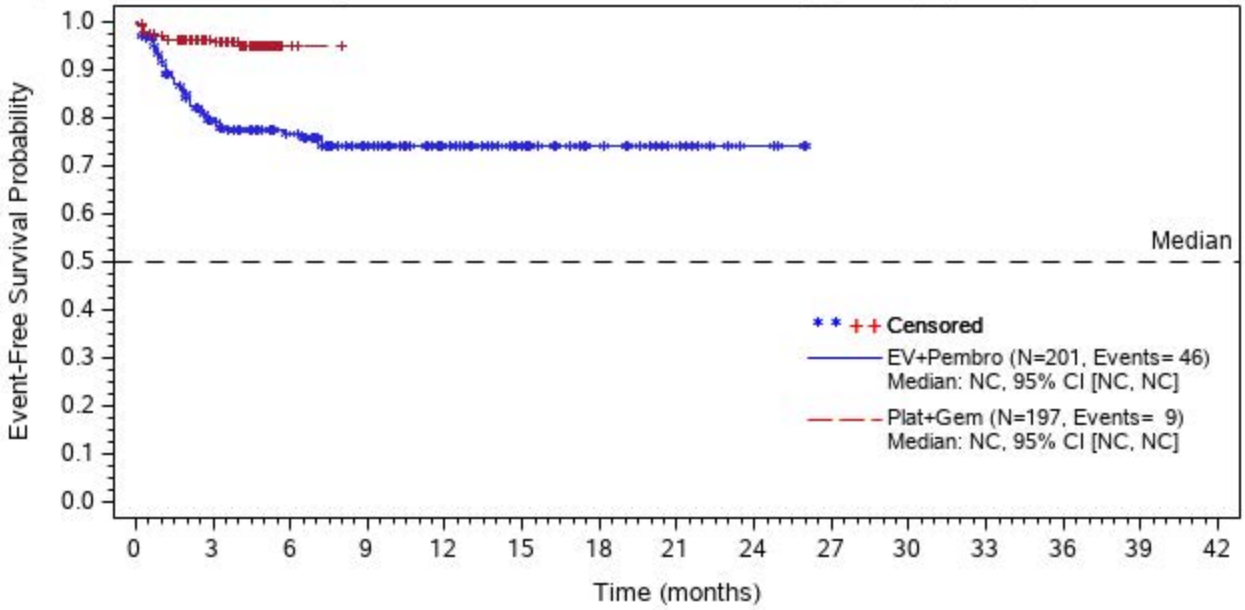
1	239	99	38	15	9	5	1	1	0	0	0	0	0	0	0
2	236	126	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.84.2.1: Kaplan-Meier Plot of Time to first TEAE - Dysgeusia (PT) - Analysis Set mSAF 2



at Risk

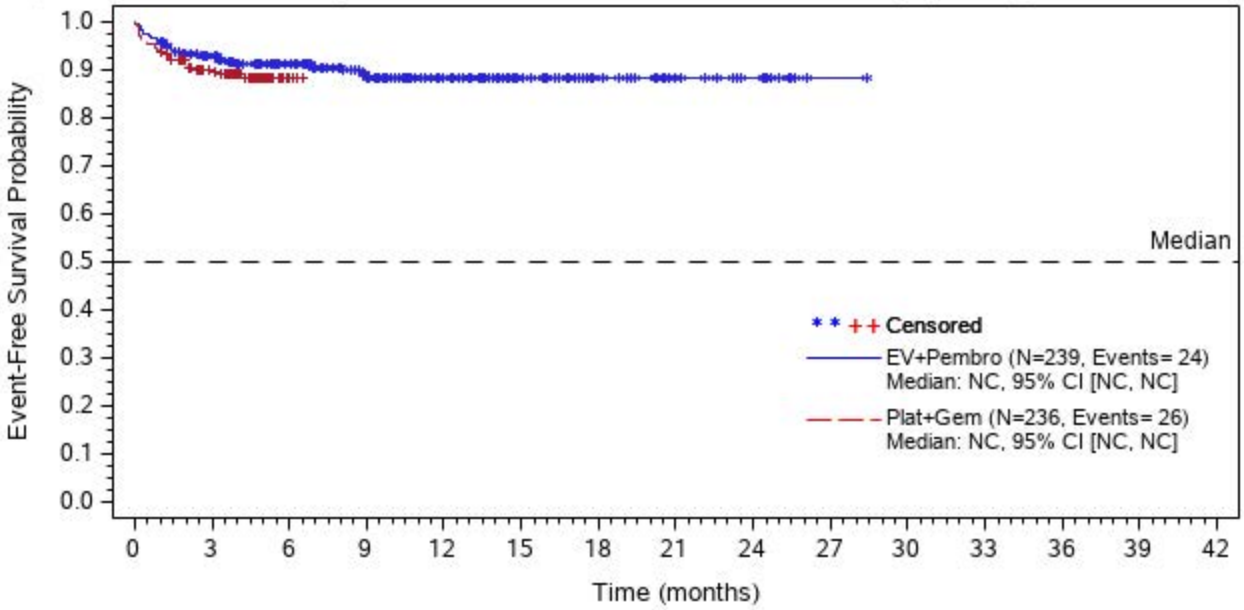
1	201	135	106	78	56	40	23	15	5	0	0	0	0	0	0
2	197	145	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.85.1.1: Kaplan-Meier Plot of Time to first TEAE - Dizziness (PT) - Analysis Set mSAF 1



at Risk

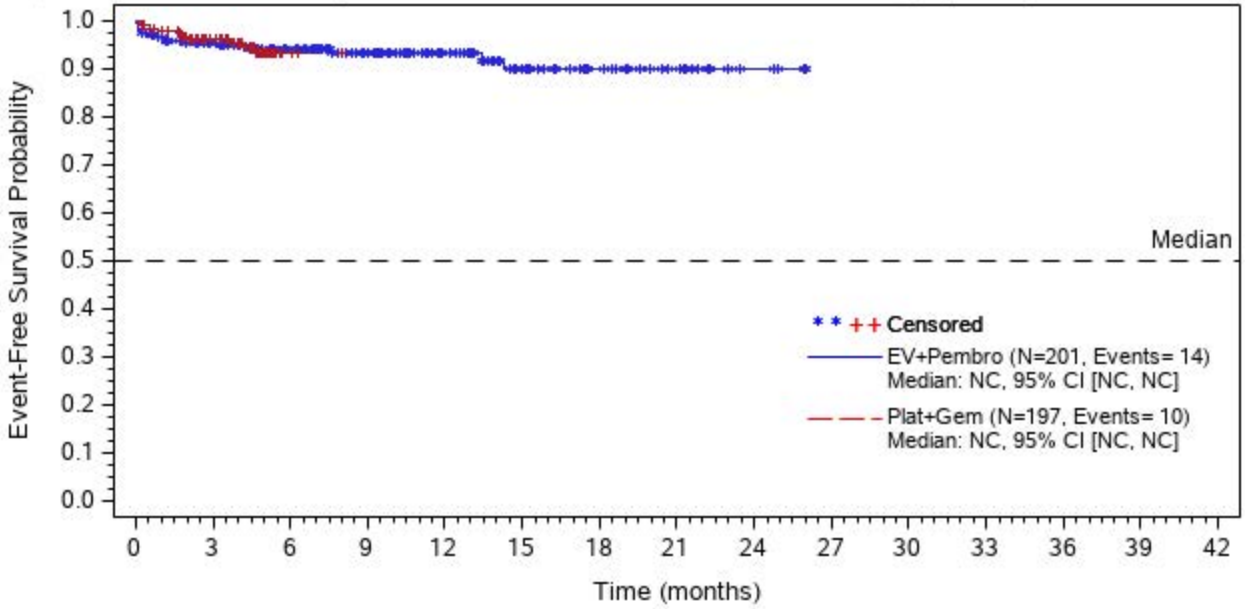
1	239	194	151	116	79	53	35	19	12	1	0	0	0	0	0
2	236	180	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.85.2.1: Kaplan-Meier Plot of Time to first TEAE - Headache (PT) - Analysis Set mSAF 2



at Risk

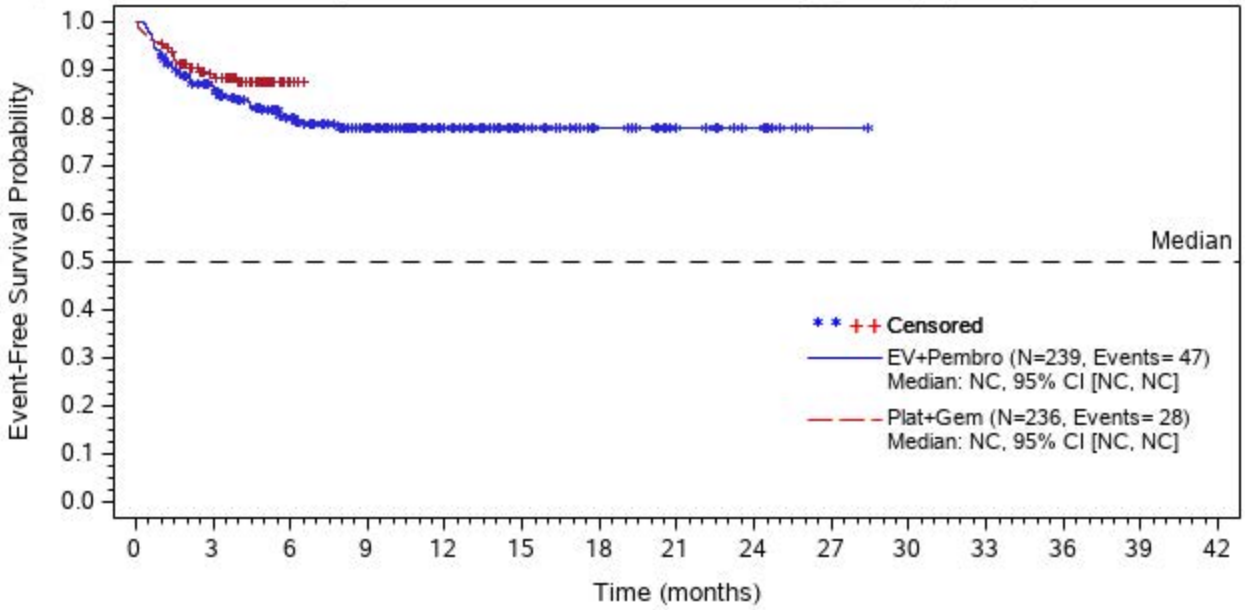
1	201	162	131	102	67	44	26	15	4	0	0	0	0	0	0
2	197	144	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.86.1.1: Kaplan-Meier Plot of Time to first TEAE - Dysgeusia (PT) - Analysis Set mSAF 1



at Risk

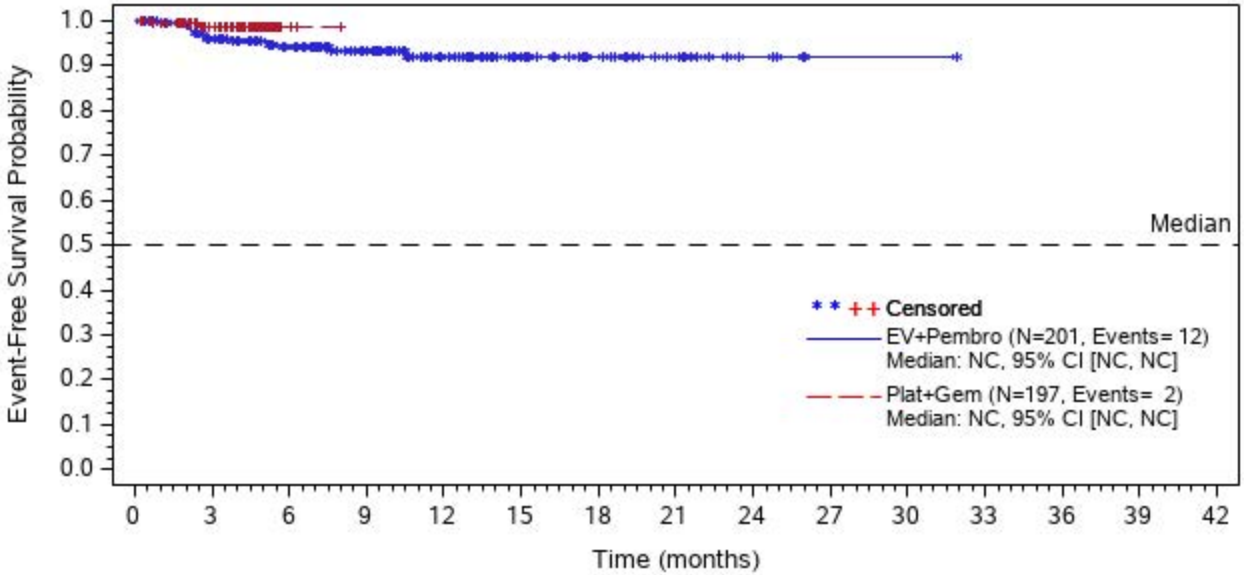
1	239	181	133	102	65	42	28	16	10	1	0	0	0	0	0
2	236	176	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.86.2.1: Kaplan-Meier Plot of Time to first TEAE - Paraesthesia (PT) - Analysis Set mSAF 2



at Risk

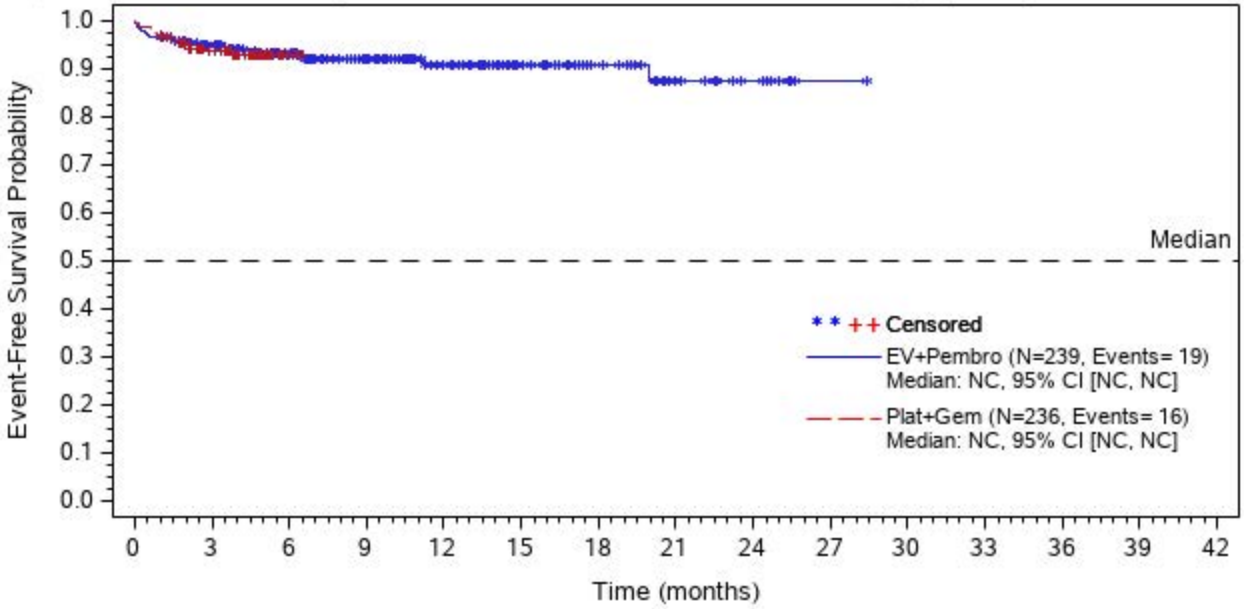
1	201	164	131	99	65	44	27	16	6	1	1	0	0	0	0
2	197	149	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.87.1.1: Kaplan-Meier Plot of Time to first TEAE - Headache (PT) - Analysis Set mSAF 1



at Risk

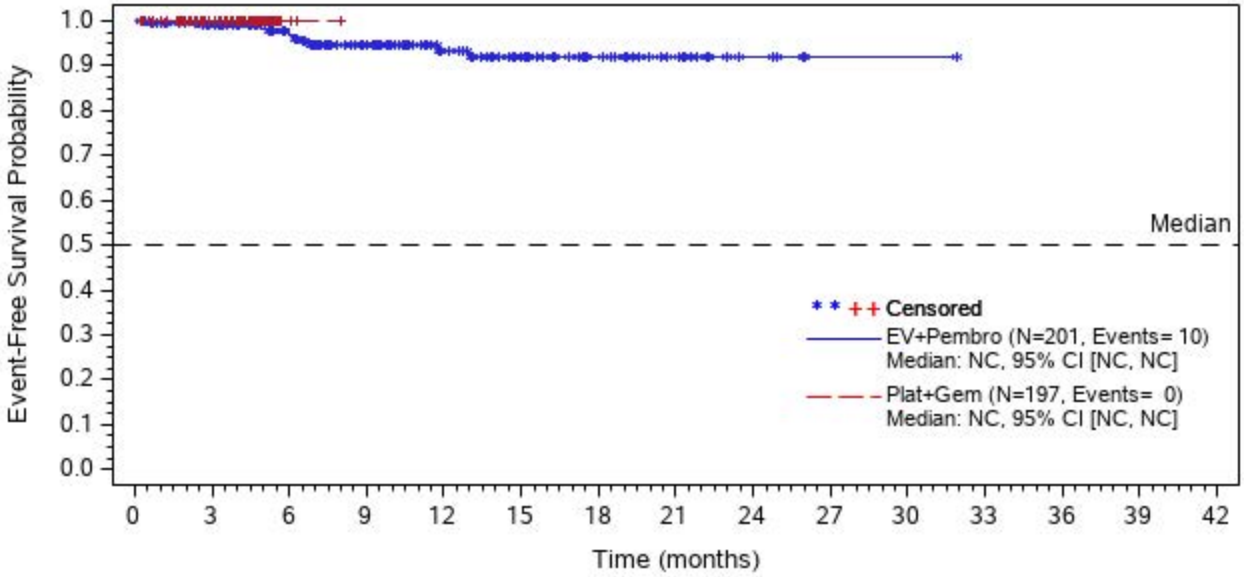
1	239	199	155	118	79	51	33	17	10	1	0	0	0	0	0
2	236	189	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.87.2.1: Kaplan-Meier Plot of Time to first TEAE - Peripheral motor neuropathy (PT) - Analysis Set mSAF 2



at Risk

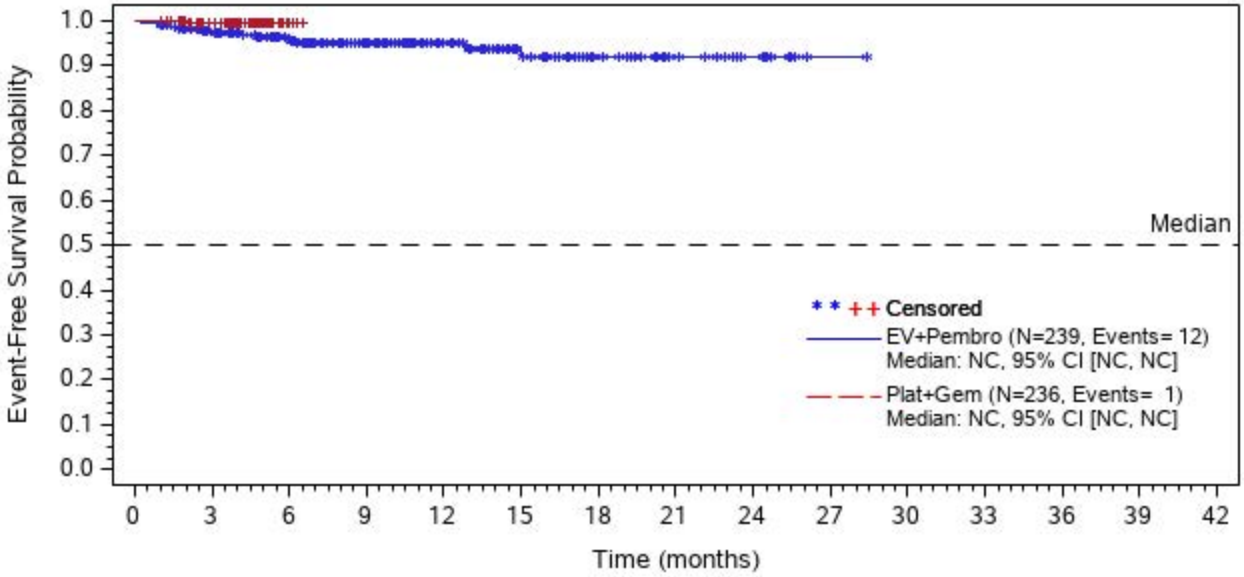
1	201	169	137	104	68	50	30	18	6	1	1	0	0	0	0
2	197	151	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.88.1.1: Kaplan-Meier Plot of Time to first TEAE - Hypoaesthesia (PT) - Analysis Set mSAF 1



at Risk

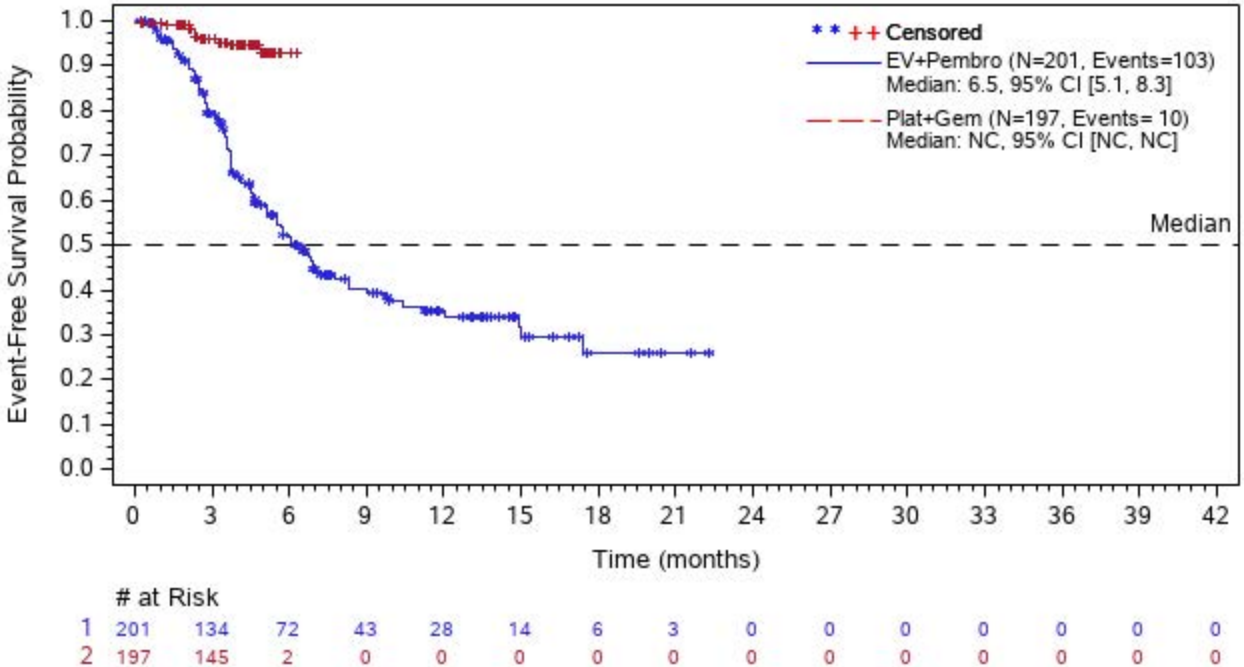
1	239	206	163	123	82	52	34	19	11	1	0	0	0	0	0
2	236	199	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.88.2.1: Kaplan-Meier Plot of Time to first TEAE - Peripheral sensory neuropathy (PT) - Analysis Set mSAF 2



at Risk

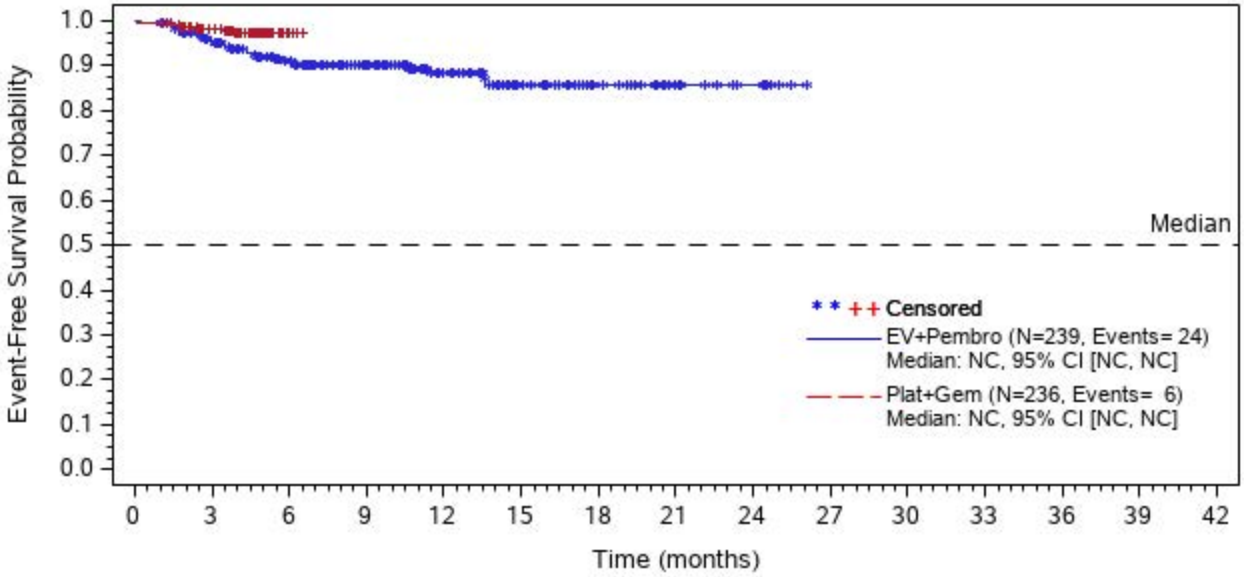
1	201	134	72	43	28	14	6	3	0	0	0	0	0	0	0
2	197	145	2	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.89.1.1: Kaplan-Meier Plot of Time to first TEAE - Paraesthesia (PT) - Analysis Set mSAF 1



at Risk

1	239	201	155	119	80	50	32	16	9	0	0	0	0	0	0
2	236	197	4	0	0	0	0	0	0	0	0	0	0	0	0

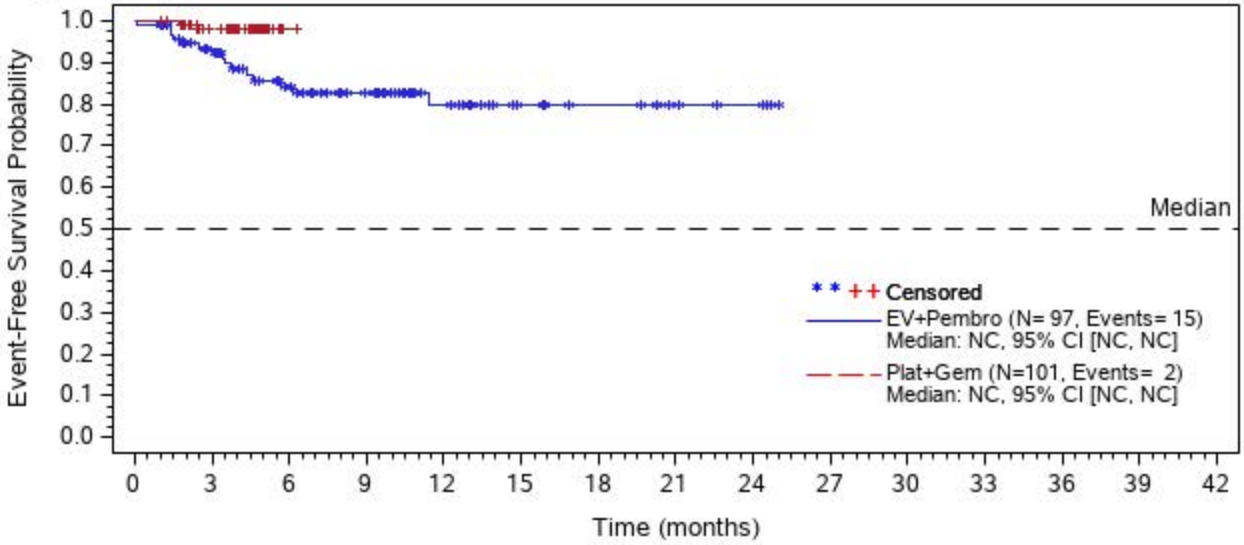
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.89.1.2.3: Kaplan-Meier Plot of Time to first TEAE - Paraesthesia (PT) - Analysis Set mSAF 1

Region: Europe



at Risk

1	97	78	59	43	26	14	11	6	4	0	0	0	0	0	0
2	101	82	1	0	0	0	0	0	0	0	0	0	0	0	0

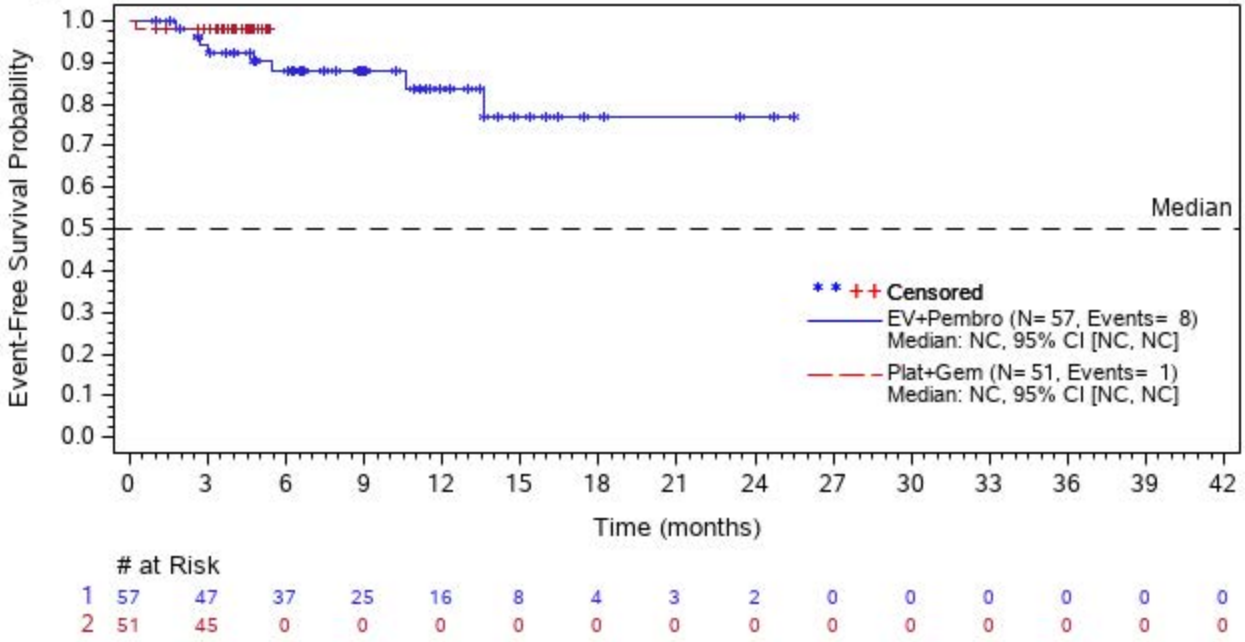
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.89.1.2.3: Kaplan-Meier Plot of Time to first TEAE - Paraesthesia (PT) - Analysis Set mSAF 1

Region: North America



at Risk

1	57	47	37	25	16	8	4	3	2	0	0	0	0	0	0
2	51	45	0	0	0	0	0	0	0	0	0	0	0	0	0

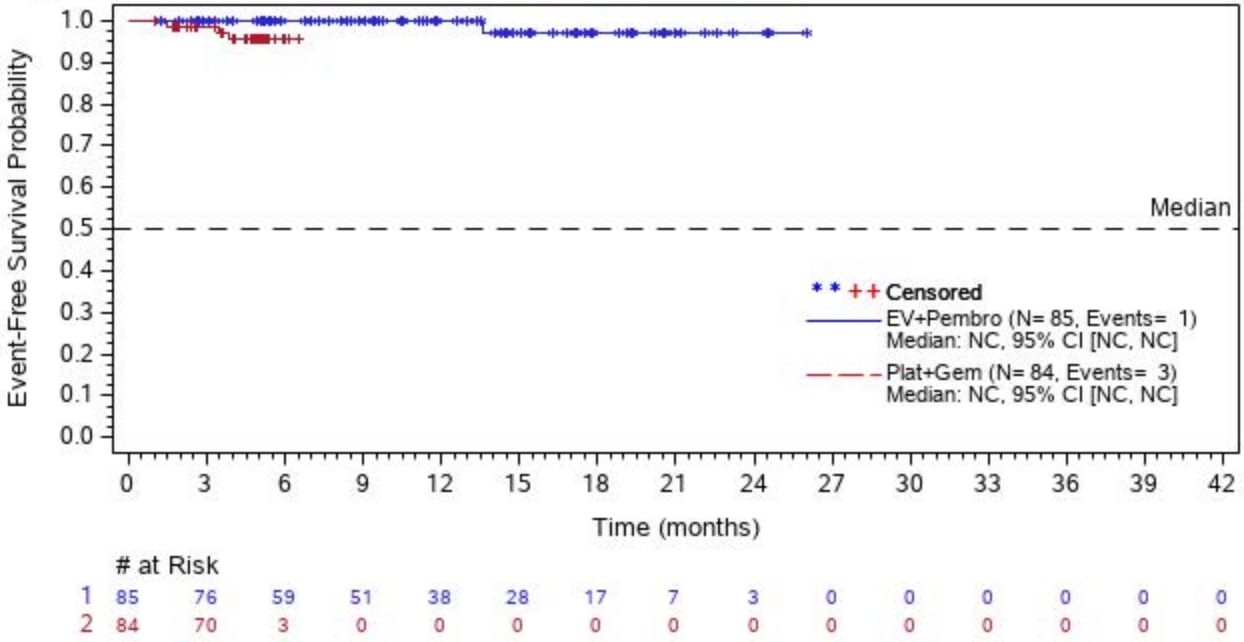
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.89.1.2.3: Kaplan-Meier Plot of Time to first TEAE - Paraesthesia (PT) - Analysis Set mSAF 1

Region: Rest of World



at Risk

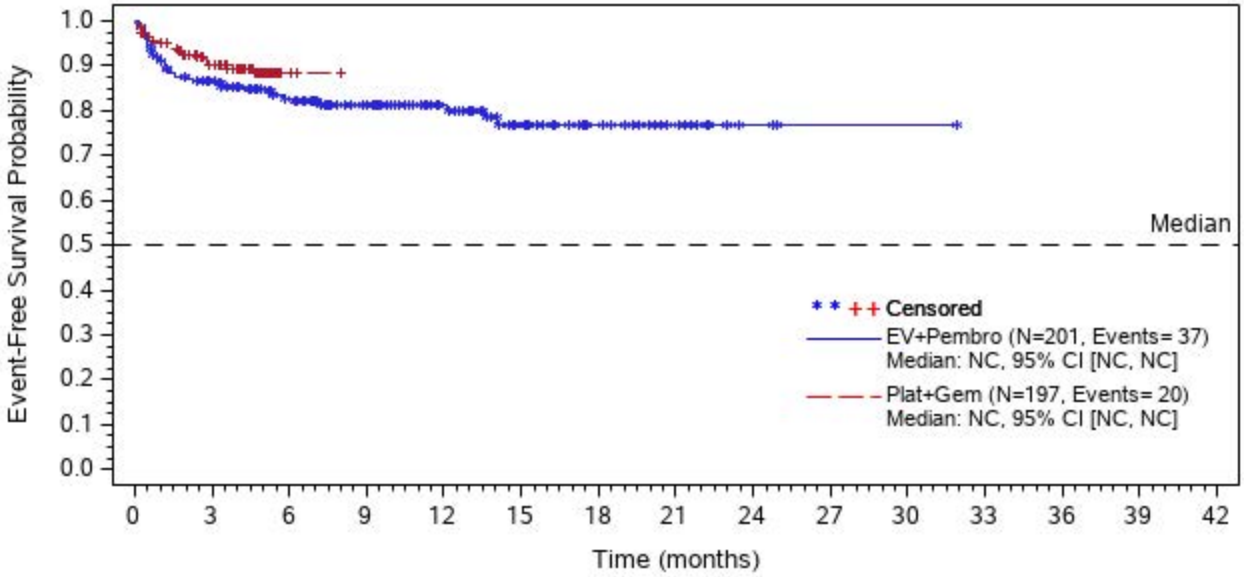
1	85	76	59	51	38	28	17	7	3	0	0	0	0	0	0
2	84	70	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.89.2.1: Kaplan-Meier Plot of Time to first TEAE - Psychiatric disorders (SOC) - Analysis Set mSAF 2



at Risk

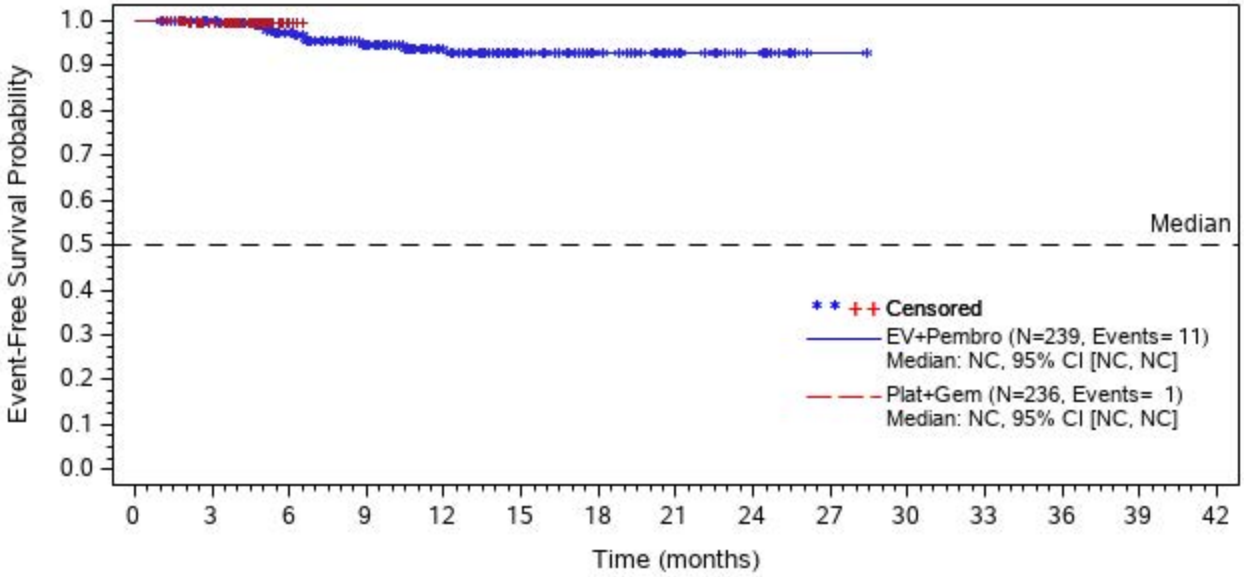
1	201	152	119	91	63	41	25	14	4	1	1	0	0	0	0
2	197	137	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.90.1.1: Kaplan-Meier Plot of Time to first TEAE - Peripheral motor neuropathy (PT) - Analysis Set mSAF 1



at Risk

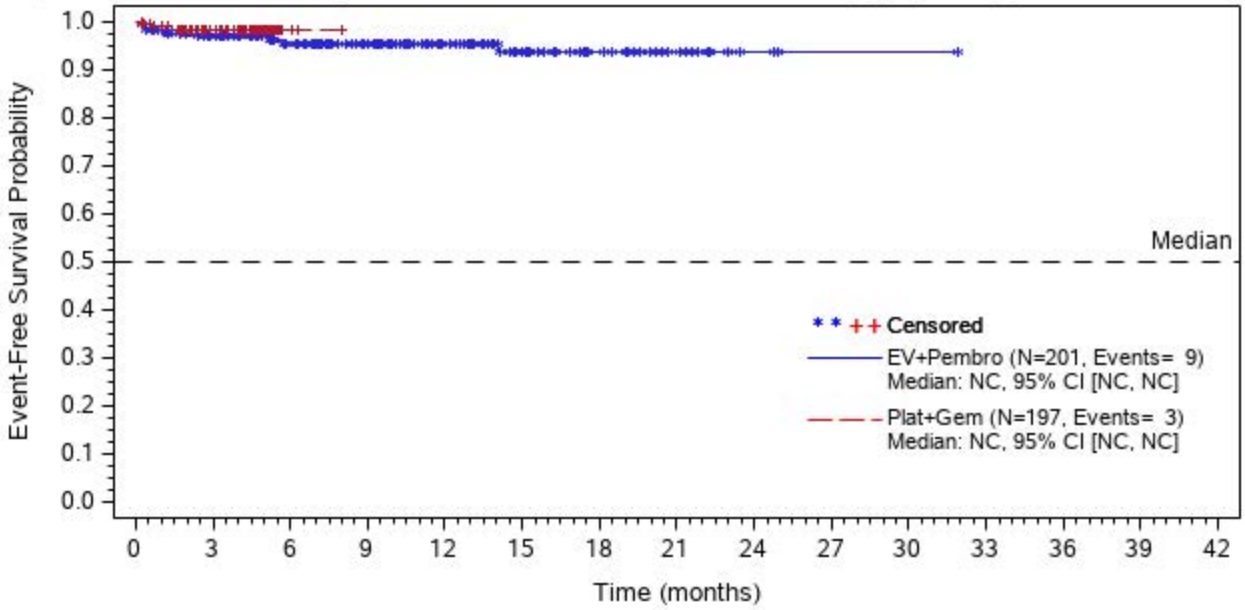
1	239	211	164	123	81	54	37	20	11	1	0	0	0	0	0
2	236	199	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.90.2.1: Kaplan-Meier Plot of Time to first TEAE - Anxiety (PT) - Analysis Set mSAF 2



at Risk

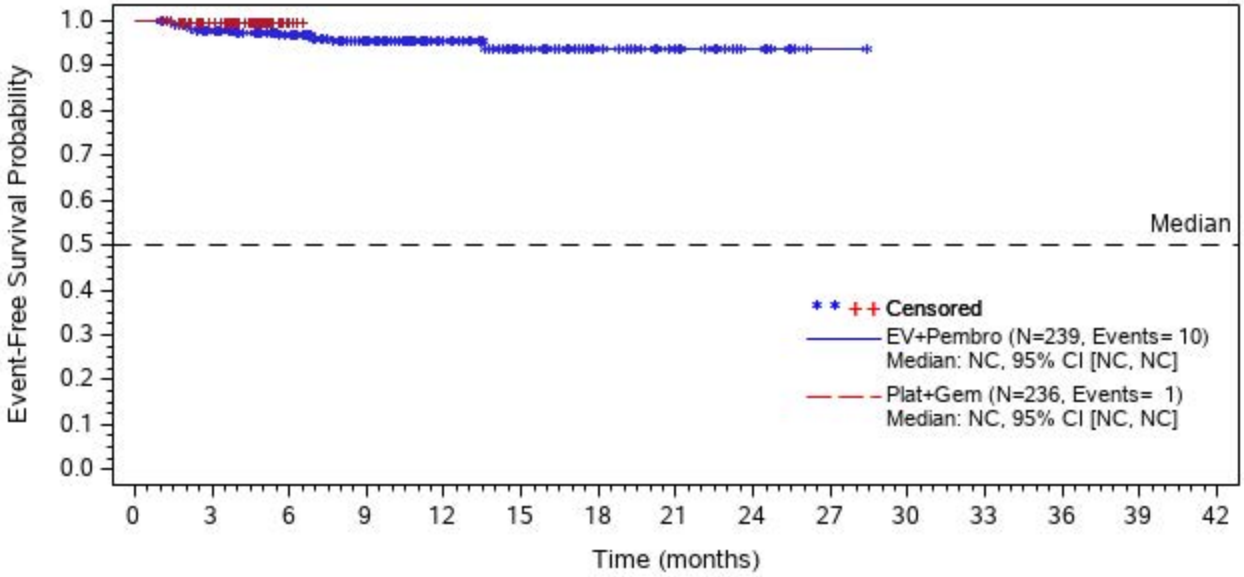
1	201	167	135	105	69	46	27	15	4	1	1	0	0	0	0
2	197	148	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.91.1.1: Kaplan-Meier Plot of Time to first TEAE - Peripheral sensorimotor neuropathy (PT) - Analysis Set mSAF 1



at Risk

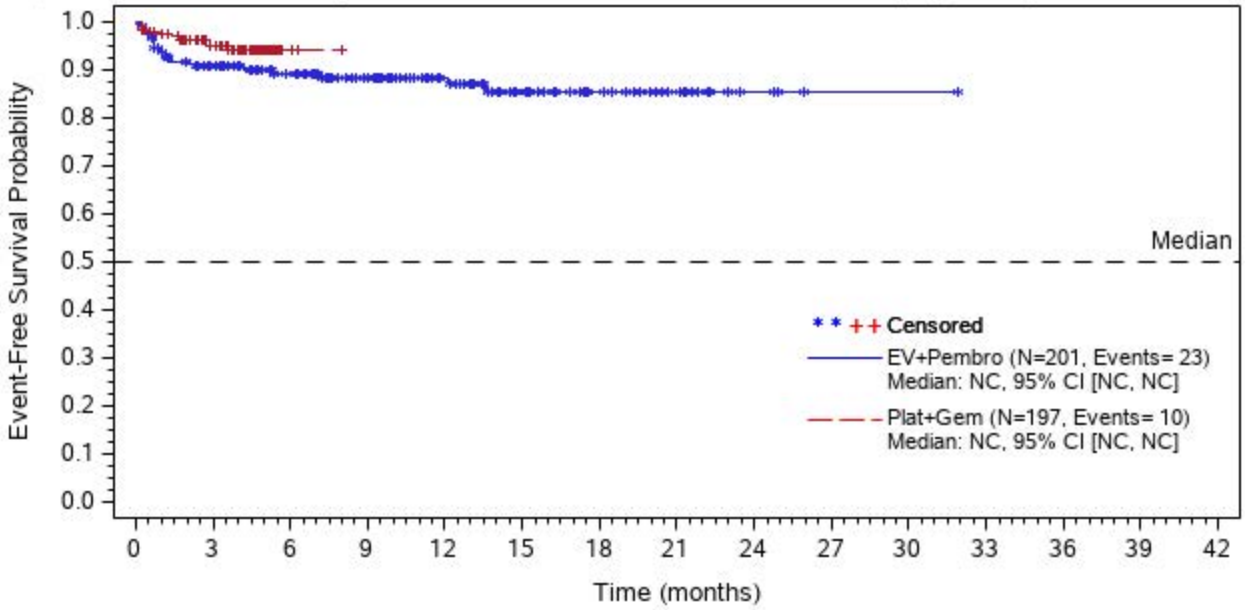
1	239	206	163	124	82	53	34	20	10	1	0	0	0	0	0
2	236	199	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.91.2.1: Kaplan-Meier Plot of Time to first TEAE - Insomnia (PT) - Analysis Set mSAF 2



at Risk

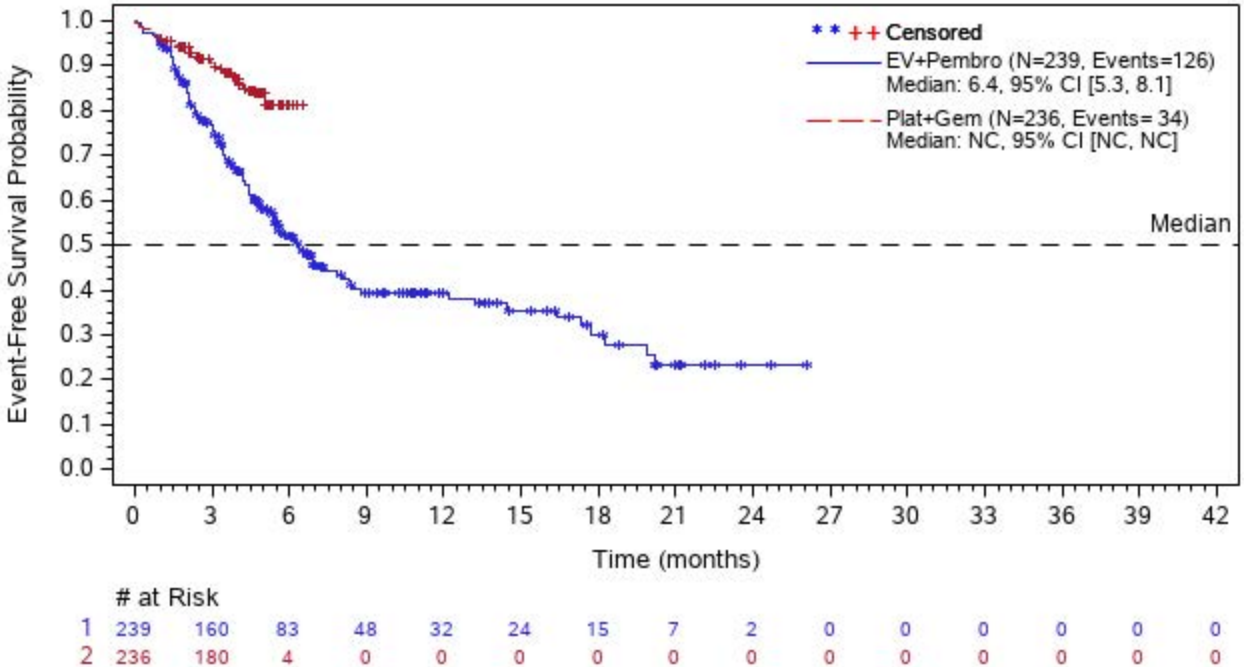
1	201	155	124	94	65	44	27	16	5	1	1	0	0	0	0
2	197	143	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.92.1.1: Kaplan-Meier Plot of Time to first TEAE - Peripheral sensory neuropathy (PT) - Analysis Set mSAF 1



at Risk

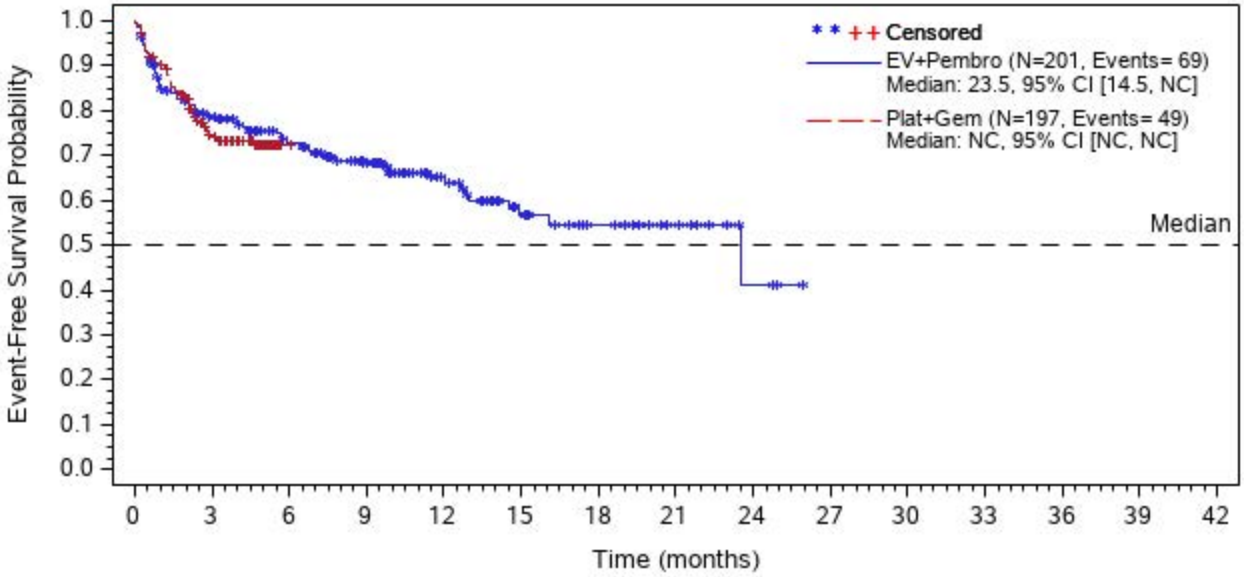
1	239	160	83	48	32	24	15	7	2	0	0	0	0	0	0
2	236	180	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.92.2.1: Kaplan-Meier Plot of Time to first TEAE - Renal and urinary disorders (SOC) - Analysis Set mSAF 2



at Risk

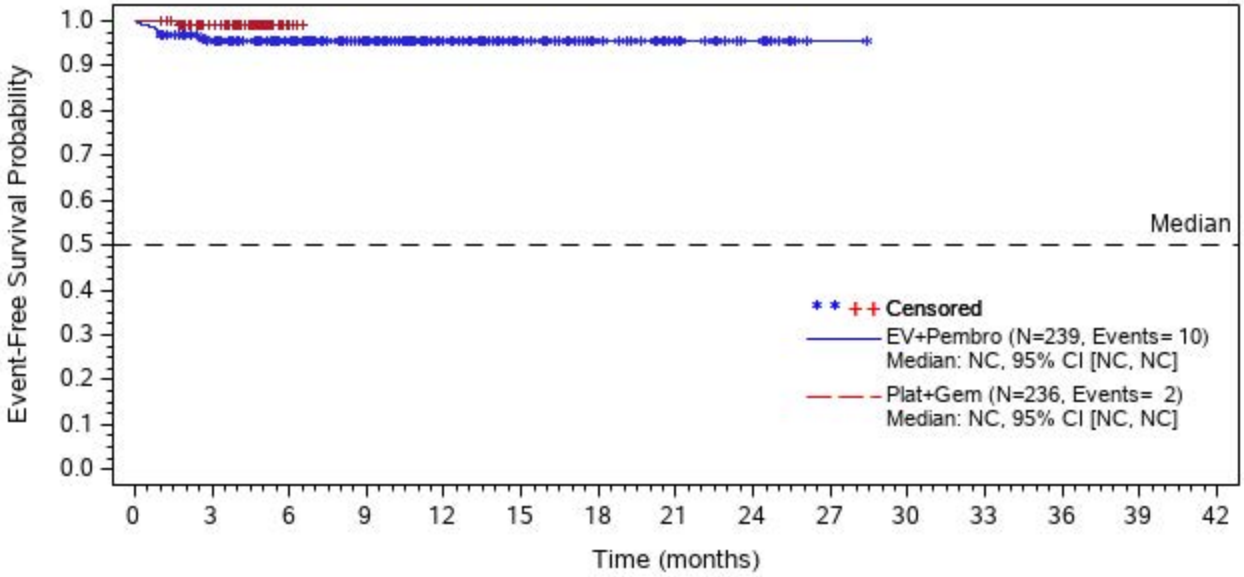
1	201	142	111	86	54	33	21	12	3	0	0	0	0	0	0
2	197	114	1	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.93.1.1: Kaplan-Meier Plot of Time to first TEAE - Taste disorder (PT) - Analysis Set mSAF 1



at Risk

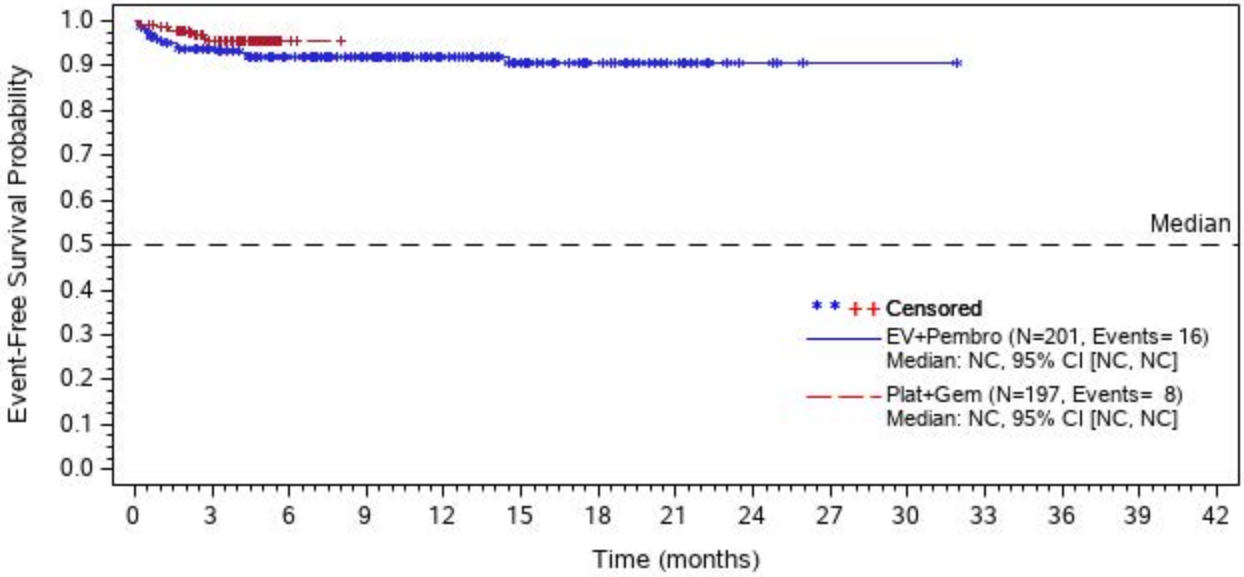
1	239	201	161	124	81	55	37	21	12	1	0	0	0	0	0
2	236	198	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.93.2.1: Kaplan-Meier Plot of Time to first TEAE - Acute kidney injury (PT) - Analysis Set mSAF 2



at Risk

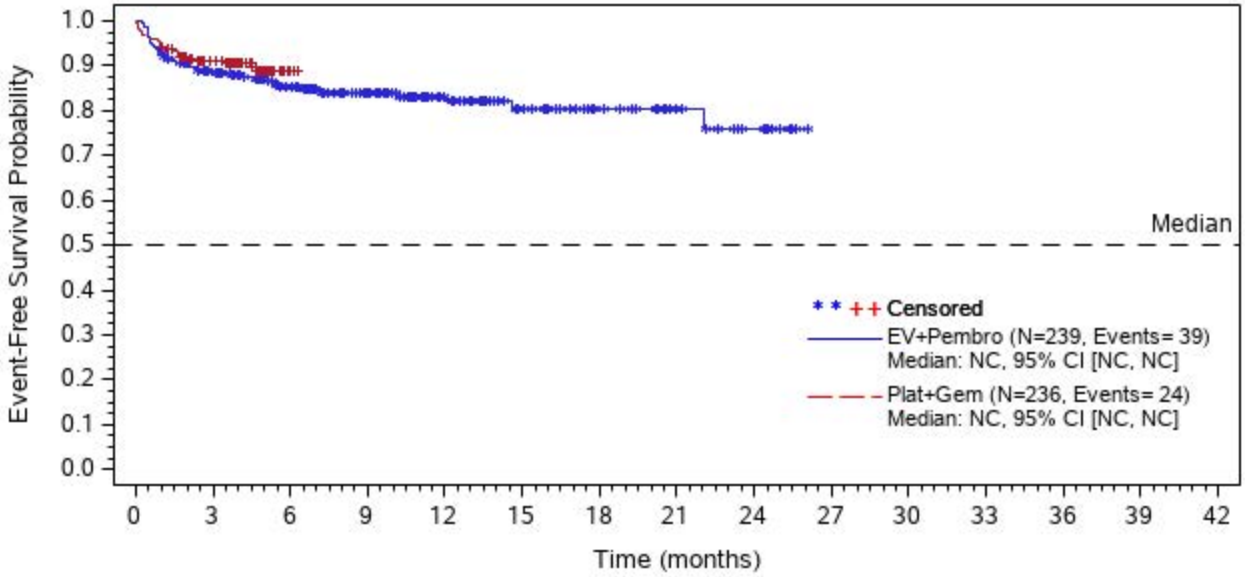
1	201	165	135	107	71	49	29	16	5	1	1	0	0	0	0
2	197	145	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.94.1.1: Kaplan-Meier Plot of Time to first TEAE - Psychiatric disorders (SOC) - Analysis Set mSAF 1



at Risk

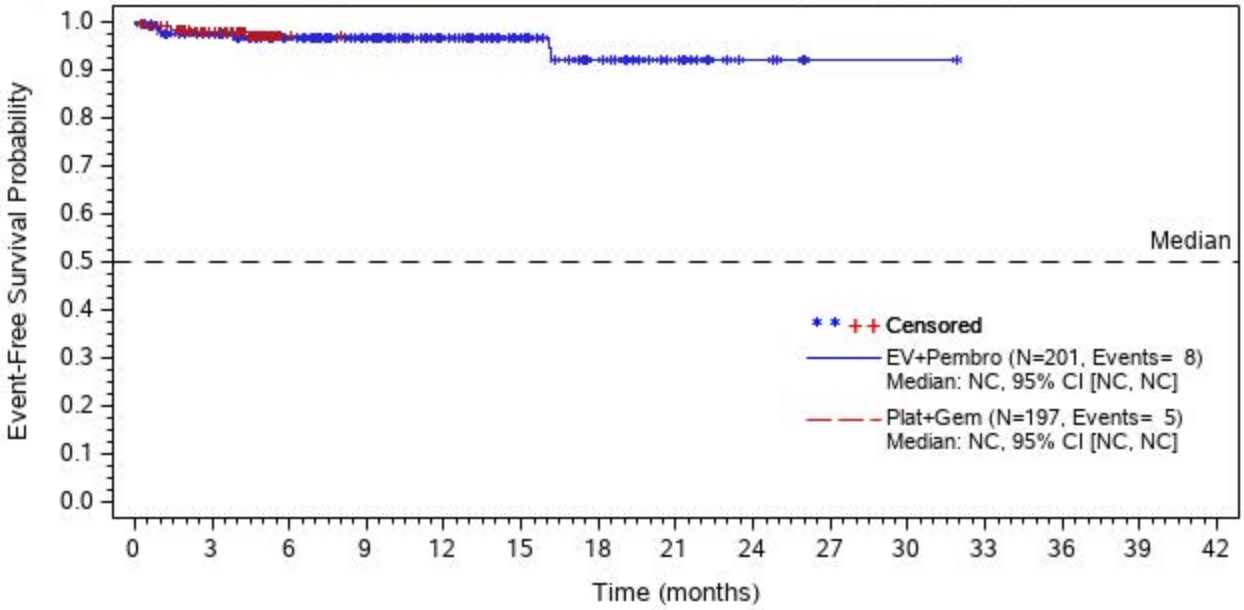
1	239	189	145	111	72	49	33	19	11	0	0	0	0	0	0
2	236	183	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.94.2.1: Kaplan-Meier Plot of Time to first TEAE - Dysuria (PT) - Analysis Set mSAF 2



at Risk

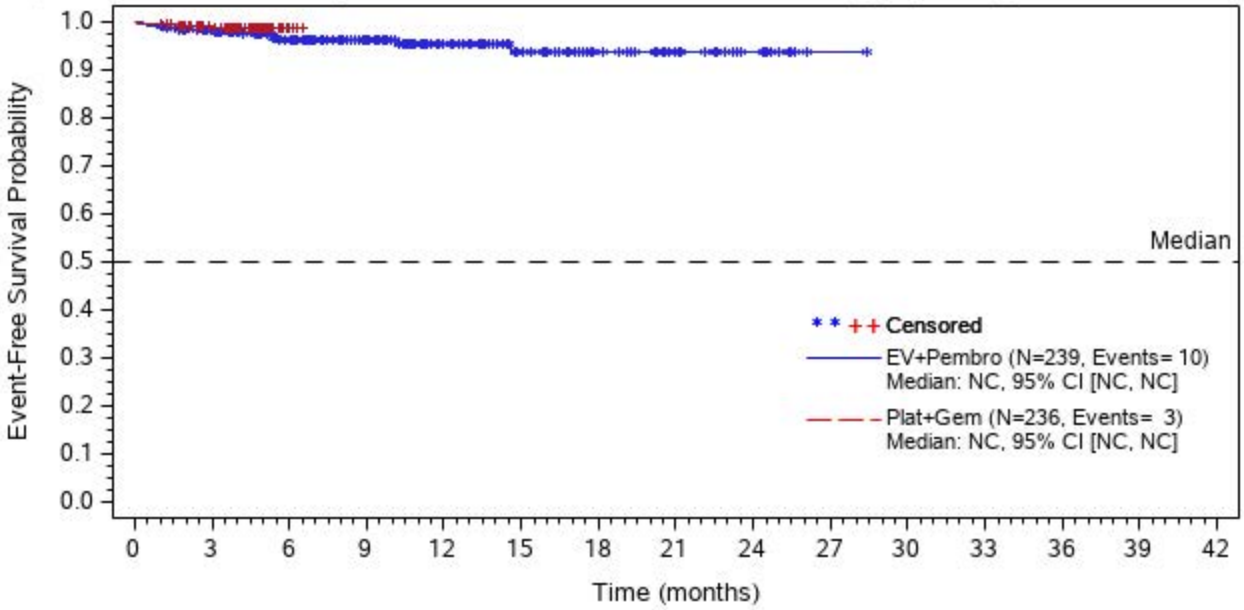
1	201	168	138	108	72	50	30	18	6	1	1	0	0	0	0
2	197	148	2	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.95.1.1: Kaplan-Meier Plot of Time to first TEAE - Anxiety (PT) - Analysis Set mSAF 1



at Risk

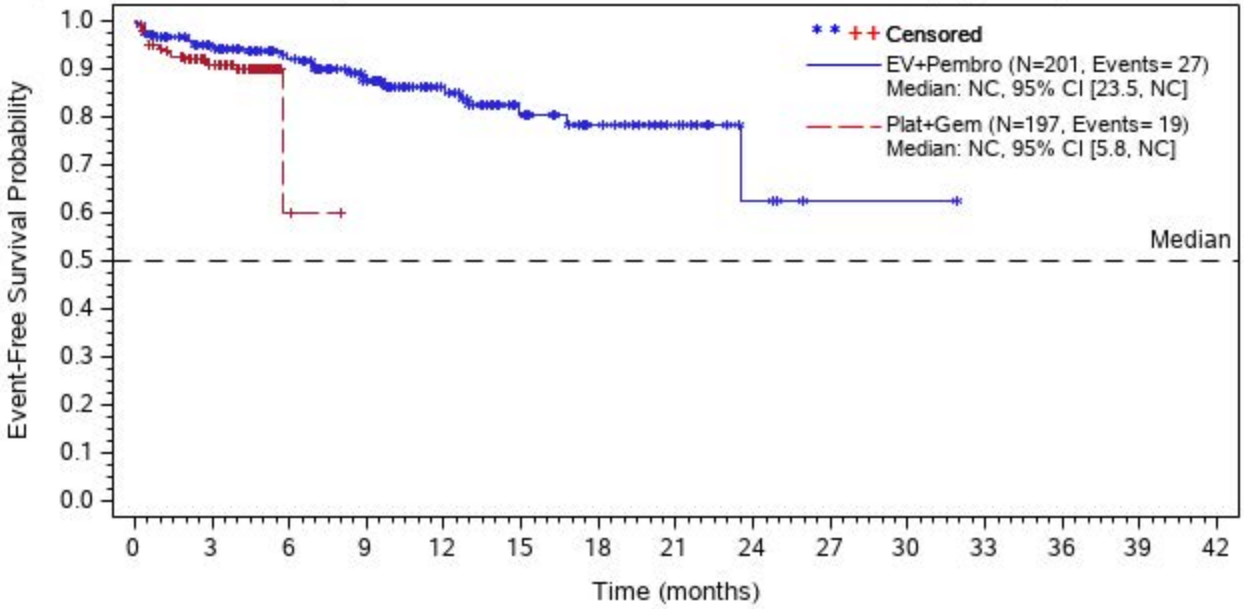
1	239	207	165	128	84	56	37	22	12	1	0	0	0	0	0
2	236	198	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.95.2.1: Kaplan-Meier Plot of Time to first TEAE - Haematuria (PT) - Analysis Set mSAF 2



at Risk

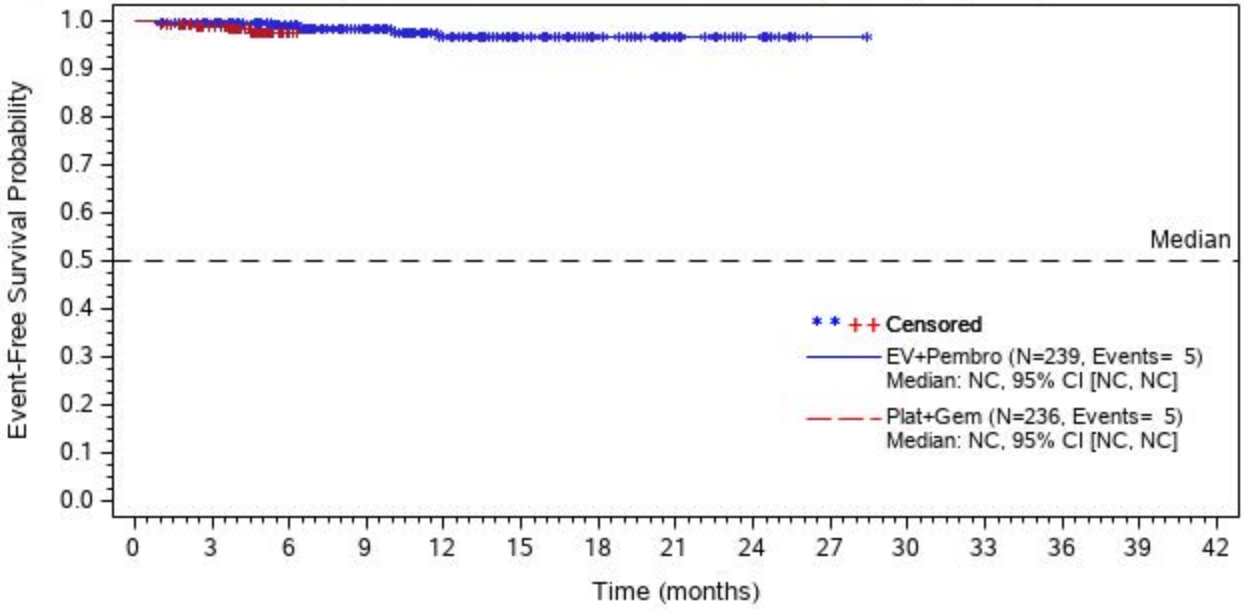
1	201	163	130	99	68	44	27	16	4	1	1	0	0	0	0
2	197	137	2	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.96.1.1: Kaplan-Meier Plot of Time to first TEAE - Depression (PT) - Analysis Set mSAF 1



at Risk

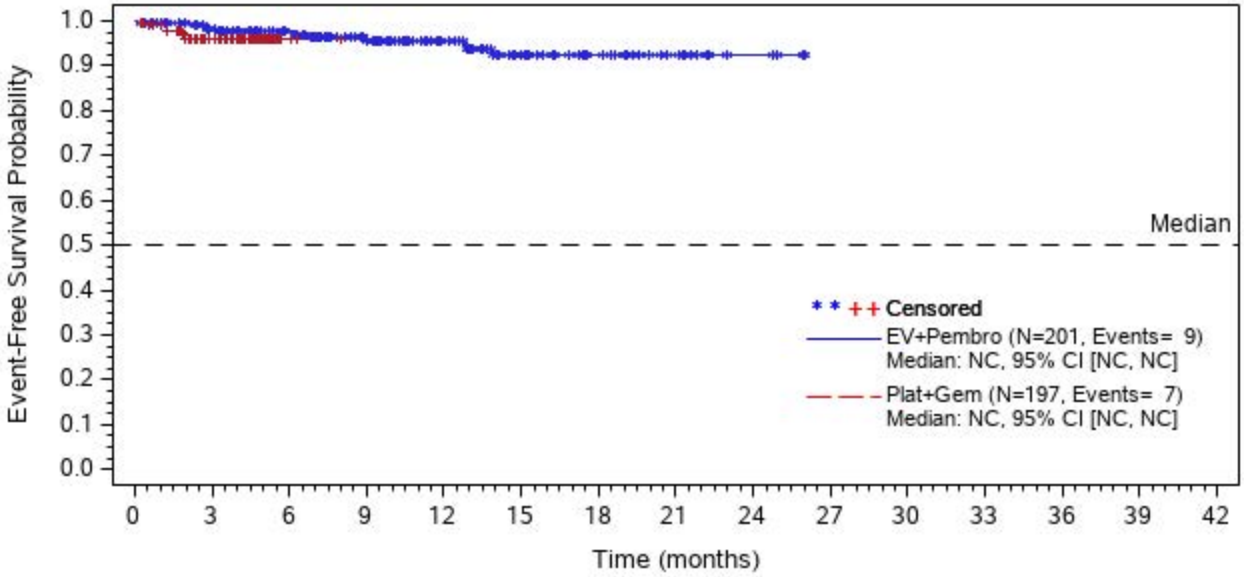
1	239	210	167	130	85	58	39	22	12	1	0	0	0	0	0
2	236	197	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.96.2.1: Kaplan-Meier Plot of Time to first TEAE - Reproductive system and breast disorders (SOC) - Analysis Set mSAF 2



at Risk

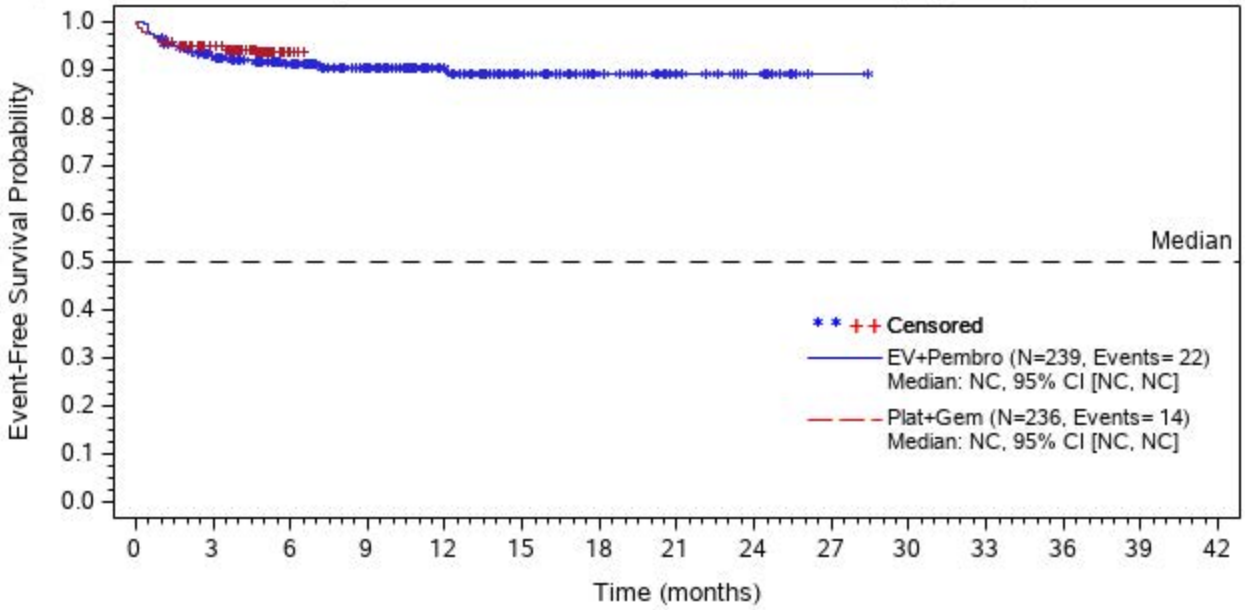
1	201	168	137	104	70	47	28	16	5	0	0	0	0	0	0
2	197	144	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.97.1.1: Kaplan-Meier Plot of Time to first TEAE - Insomnia (PT) - Analysis Set mSAF 1



at Risk

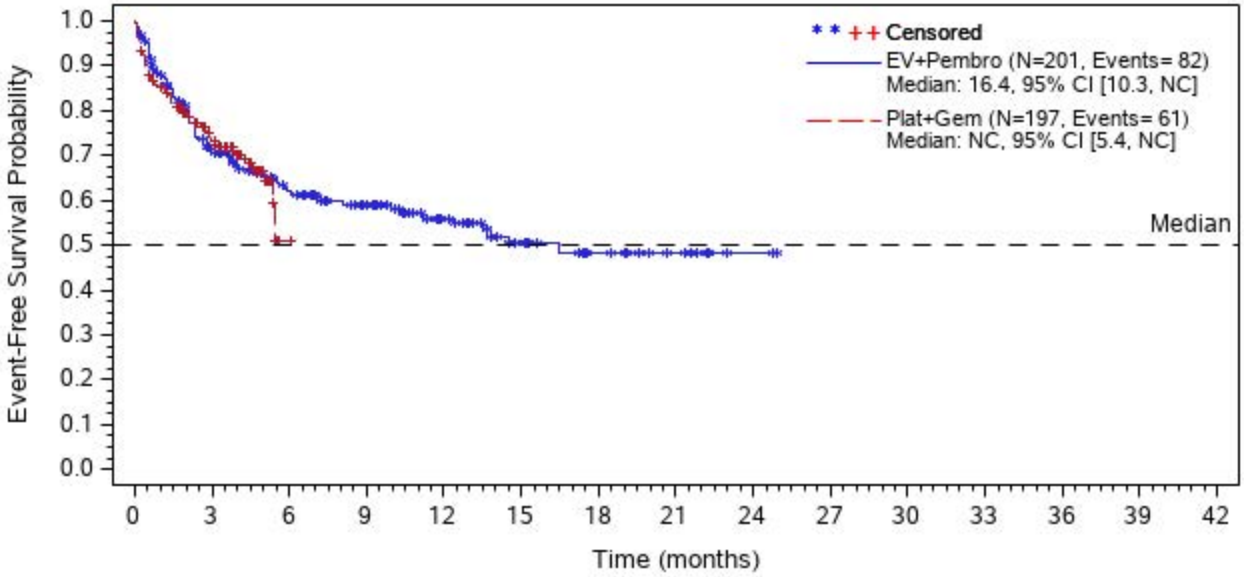
1	239	196	153	119	76	51	34	19	12	1	0	0	0	0	0
2	236	190	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.97.2.1: Kaplan-Meier Plot of Time to first TEAE - Respiratory, thoracic and mediastinal disorders (SOC) - Analysis Set mSAF 2



at Risk

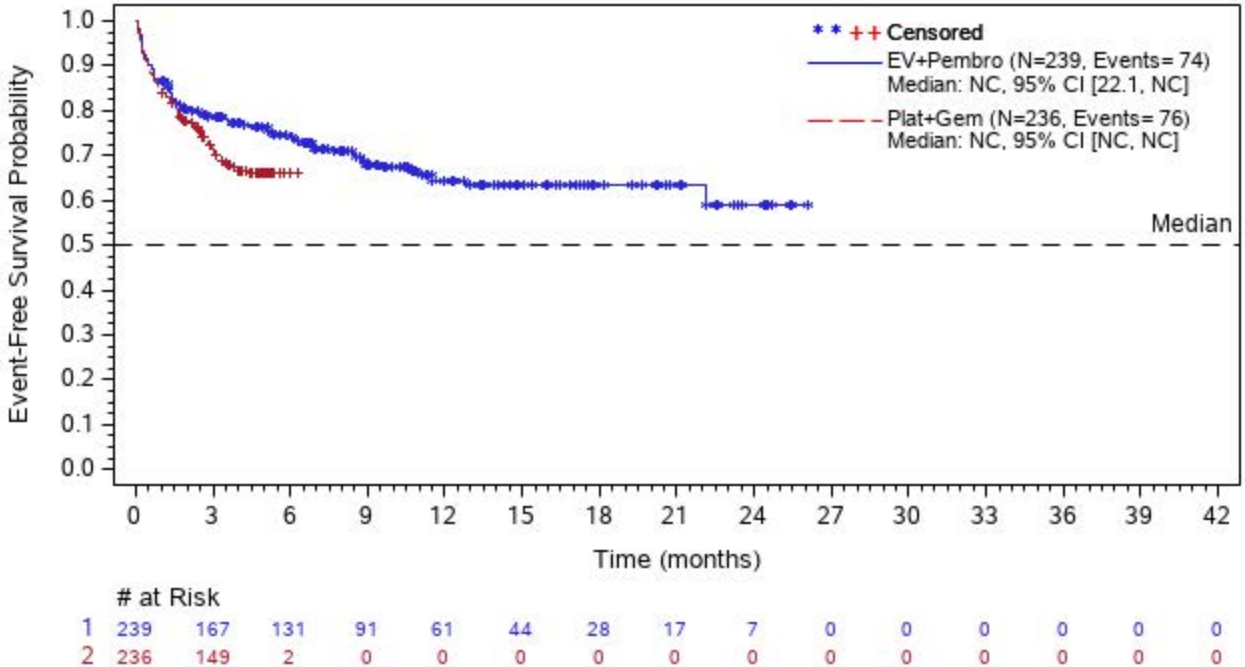
1	201	127	92	71	47	28	16	9	2	0	0	0	0	0	0
2	197	115	1	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.98.1.1: Kaplan-Meier Plot of Time to first TEAE - Renal and urinary disorders (SOC) - Analysis Set mSAF 1



at Risk

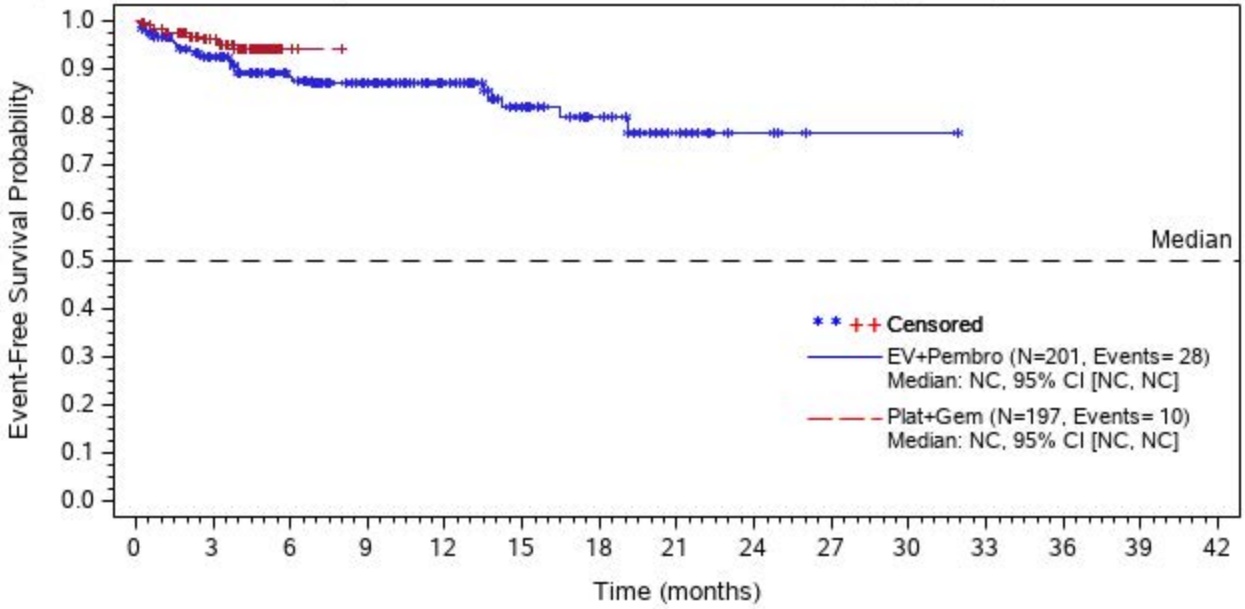
1	239	167	131	91	61	44	28	17	7	0	0	0	0	0	0
2	236	149	2	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.98.2.1: Kaplan-Meier Plot of Time to first TEAE - Cough (PT) - Analysis Set mSAF 2



at Risk

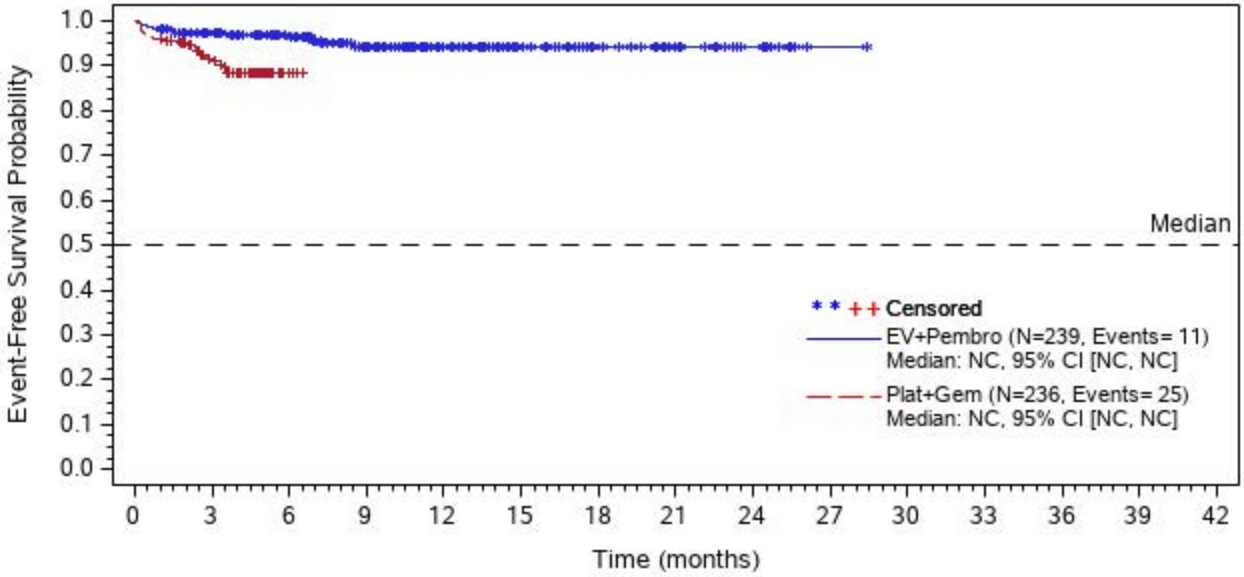
1	201	161	124	94	67	45	27	15	5	1	1	0	0	0	0
2	197	146	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.99.1.1: Kaplan-Meier Plot of Time to first TEAE - Acute kidney injury (PT) - Analysis Set mSAF 1



at Risk

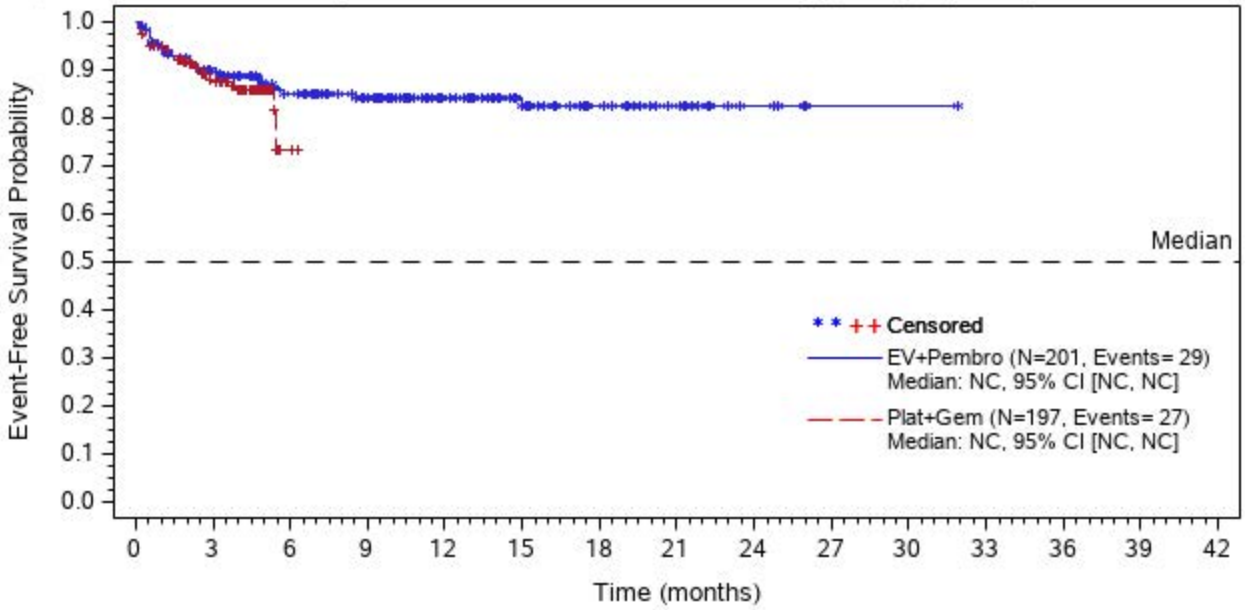
1	239	205	165	126	84	55	37	22	12	1	0	0	0	0	0
2	236	187	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.99.2.1: Kaplan-Meier Plot of Time to first TEAE - Dyspnoea (PT) - Analysis Set mSAF 2



at Risk

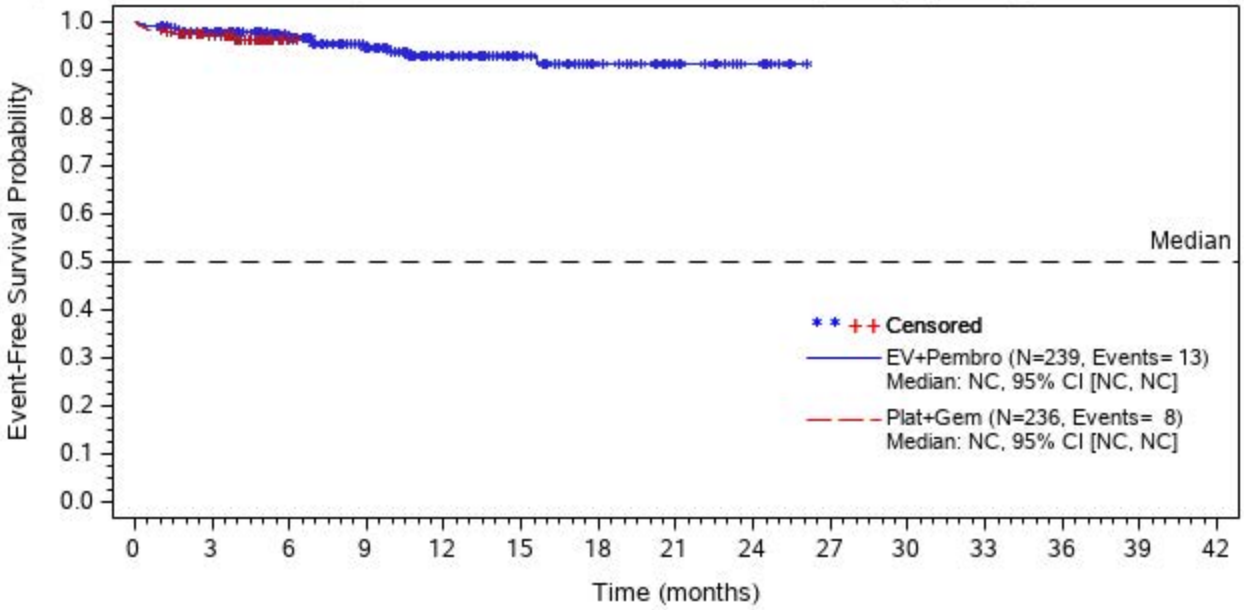
1	201	156	124	100	67	47	28	17	6	1	1	0	0	0	0
2	197	138	2	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.100.1.1: Kaplan-Meier Plot of Time to first TEAE - Dysuria (PT) - Analysis Set mSAF 1



at Risk

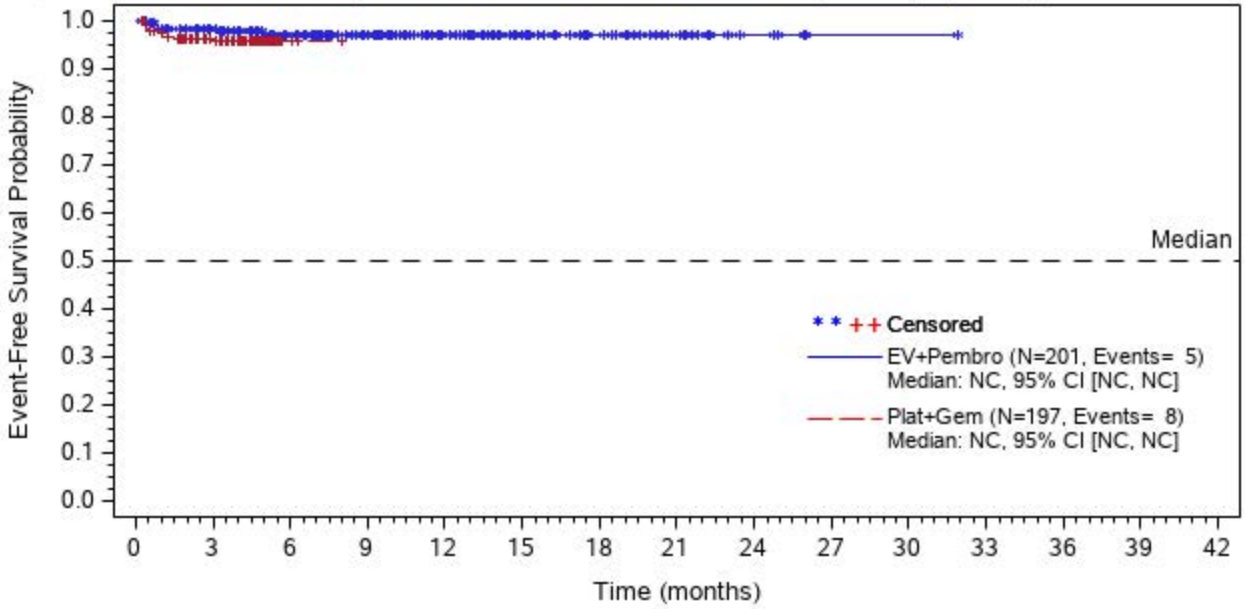
1	239	207	165	125	81	54	34	19	9	0	0	0	0	0	0
2	236	195	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.100.2.1: Kaplan-Meier Plot of Time to first TEAE - Epistaxis (PT) - Analysis Set mSAF 2



at Risk

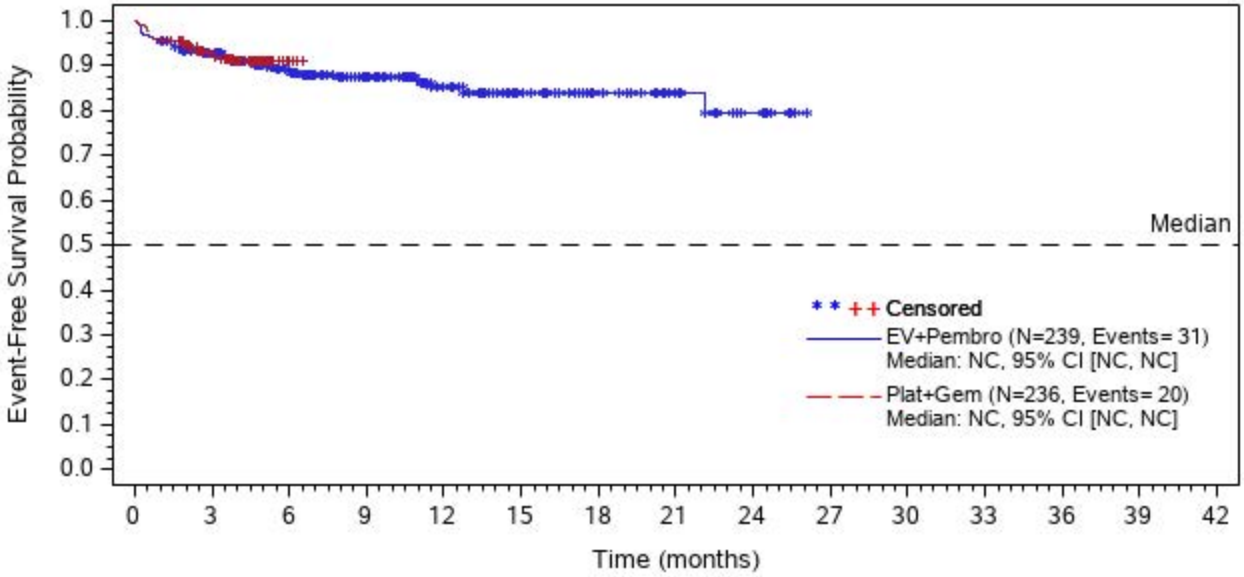
1	201	170	137	106	72	50	31	18	6	1	1	0	0	0	0
2	197	145	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.101.1.1: Kaplan-Meier Plot of Time to first TEAE - Haematuria (PT) - Analysis Set mSAF 1



at Risk

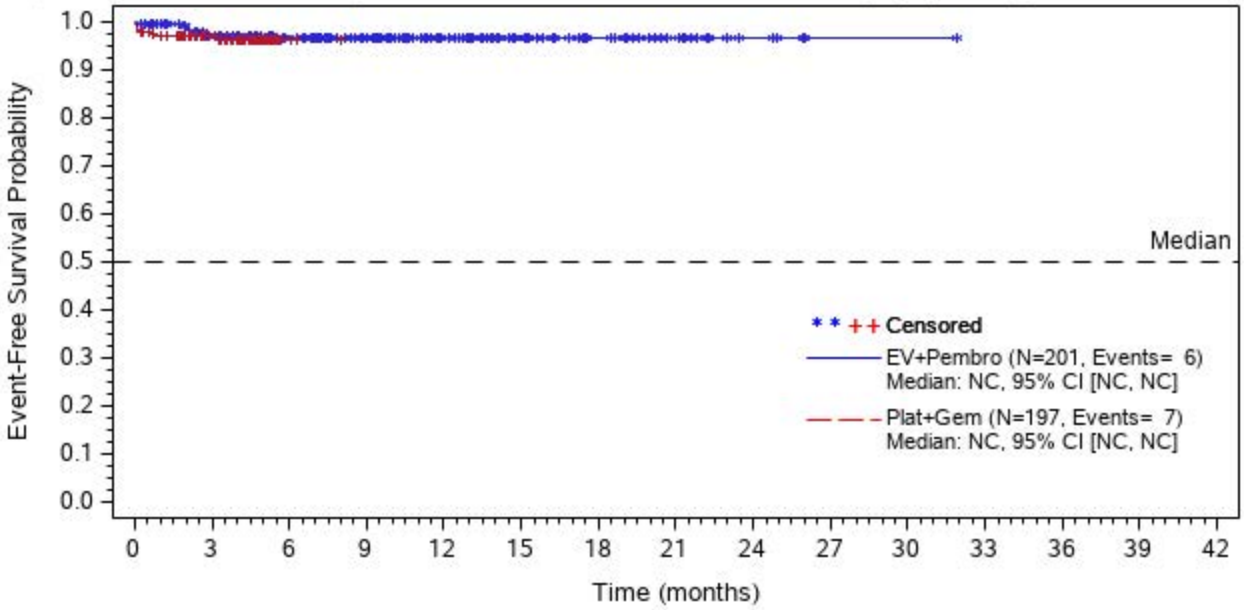
1	239	197	154	116	79	53	36	20	10	0	0	0	0	0	0
2	236	186	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.101.2.1: Kaplan-Meier Plot of Time to first TEAE - Hiccups (PT) - Analysis Set mSAF 2



at Risk

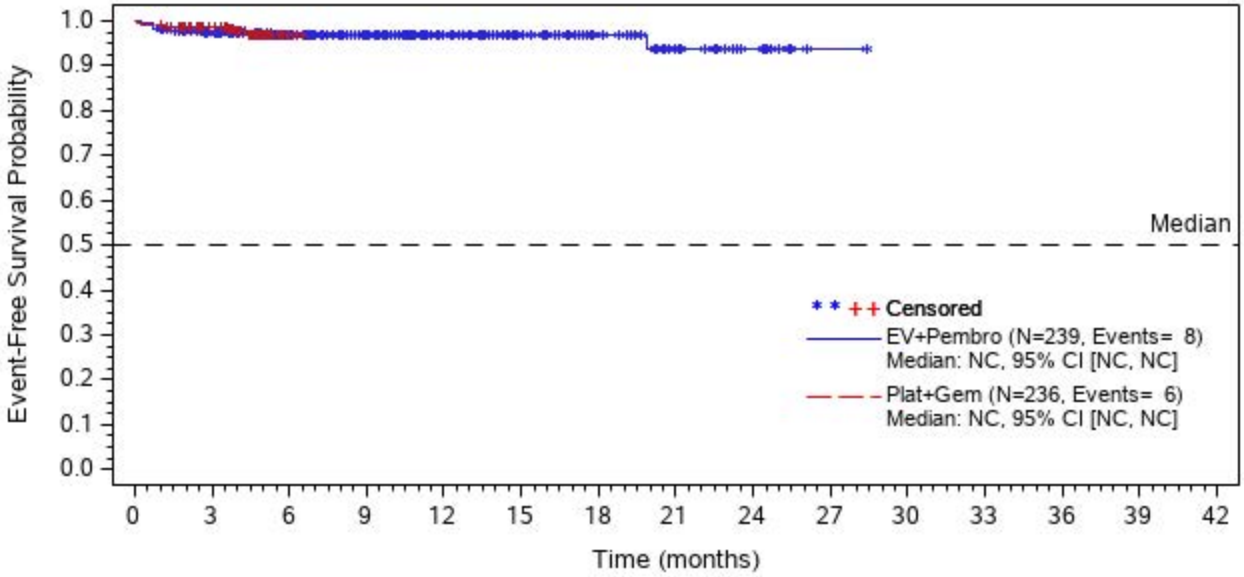
1	201	166	135	107	71	49	30	18	6	1	1	0	0	0	0
2	197	146	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.102.1.1: Kaplan-Meier Plot of Time to first TEAE - Pollakiuria (PT) - Analysis Set mSAF 1



at Risk

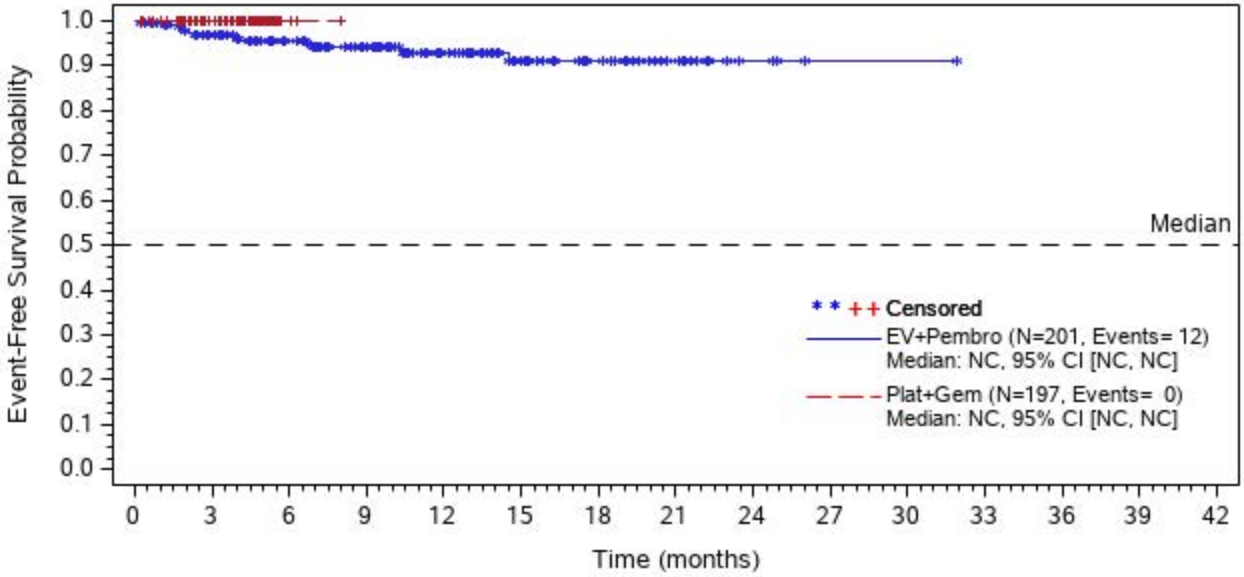
1	239	205	162	126	85	58	39	21	11	1	0	0	0	0	0
2	236	198	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.102.2.1: Kaplan-Meier Plot of Time to first TEAE - Pneumonitis (PT) - Analysis Set mSAF 2



at Risk

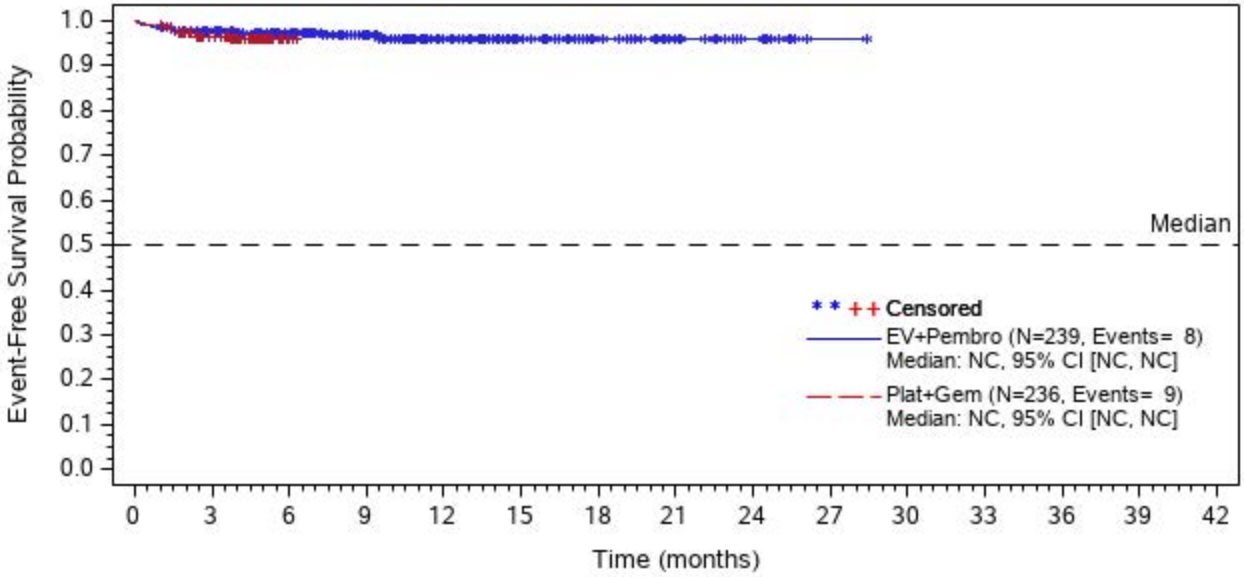
1	201	166	135	105	70	47	30	17	5	1	1	0	0	0	0
2	197	151	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.103.1.1: Kaplan-Meier Plot of Time to first TEAE - Urinary retention (PT) - Analysis Set mSAF 1



at Risk

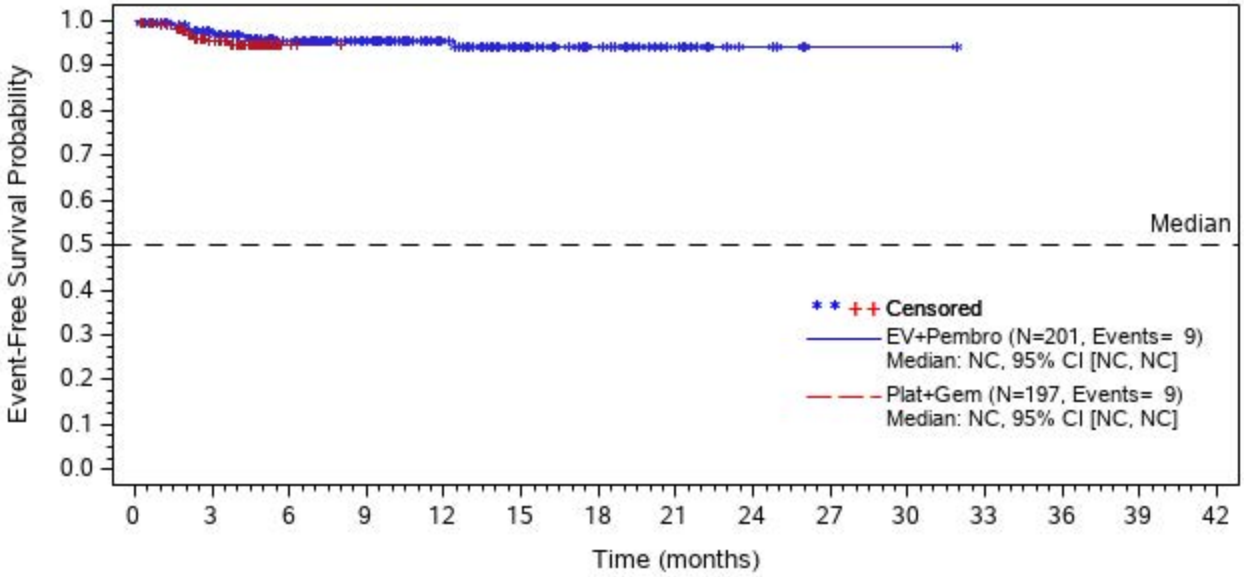
1	239	207	167	128	86	57	39	22	12	1	0	0	0	0	0
2	236	195	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.103.2.1: Kaplan-Meier Plot of Time to first TEAE - Pulmonary embolism (PT) - Analysis Set mSAF 2



at Risk

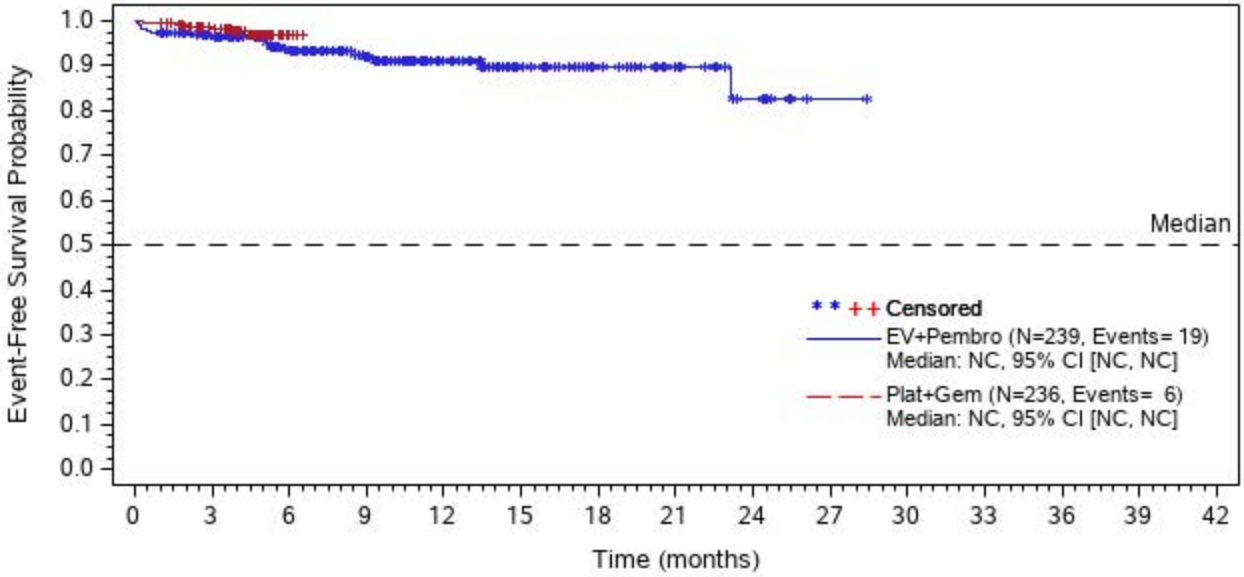
1	201	169	137	107	73	51	31	18	6	1	1	0	0	0	0
2	197	143	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.104.1.1: Kaplan-Meier Plot of Time to first TEAE - Reproductive system and breast disorders (SOC) - Analysis Set mSAF 1



at Risk

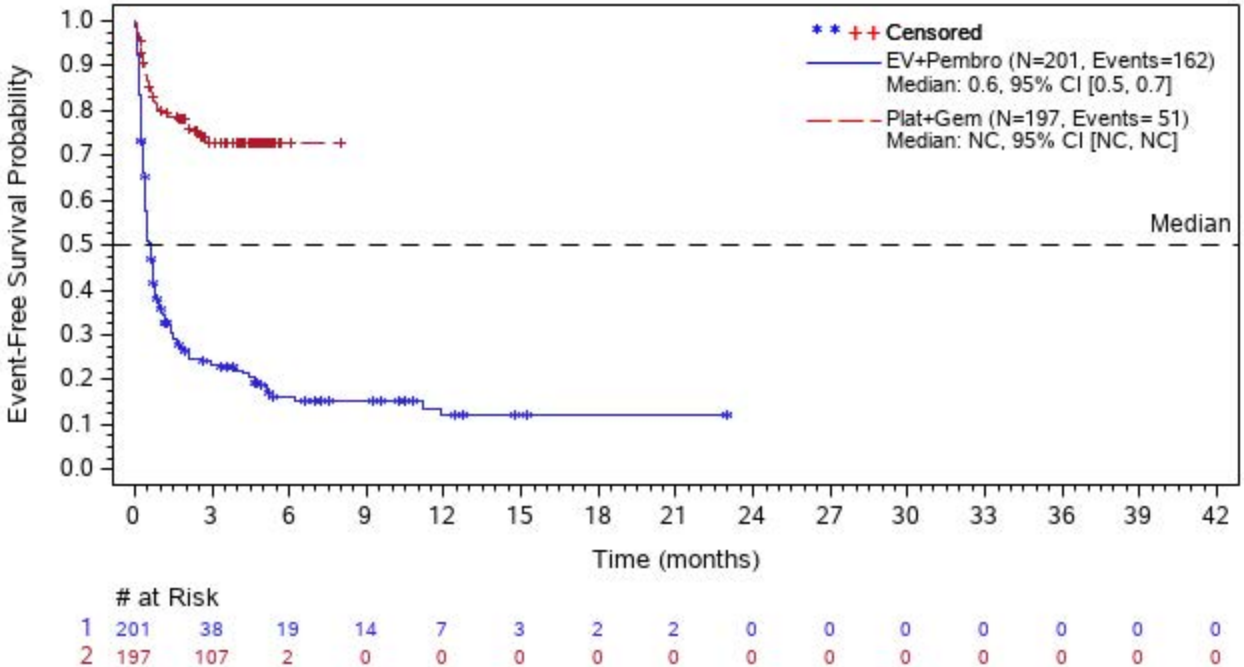
1	239	205	161	124	82	53	35	20	10	1	0	0	0	0	0
2	236	198	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.104.2.1: Kaplan-Meier Plot of Time to first TEAE - Skin and subcutaneous tissue disorders (SOC) - Analysis Set mSAF 2



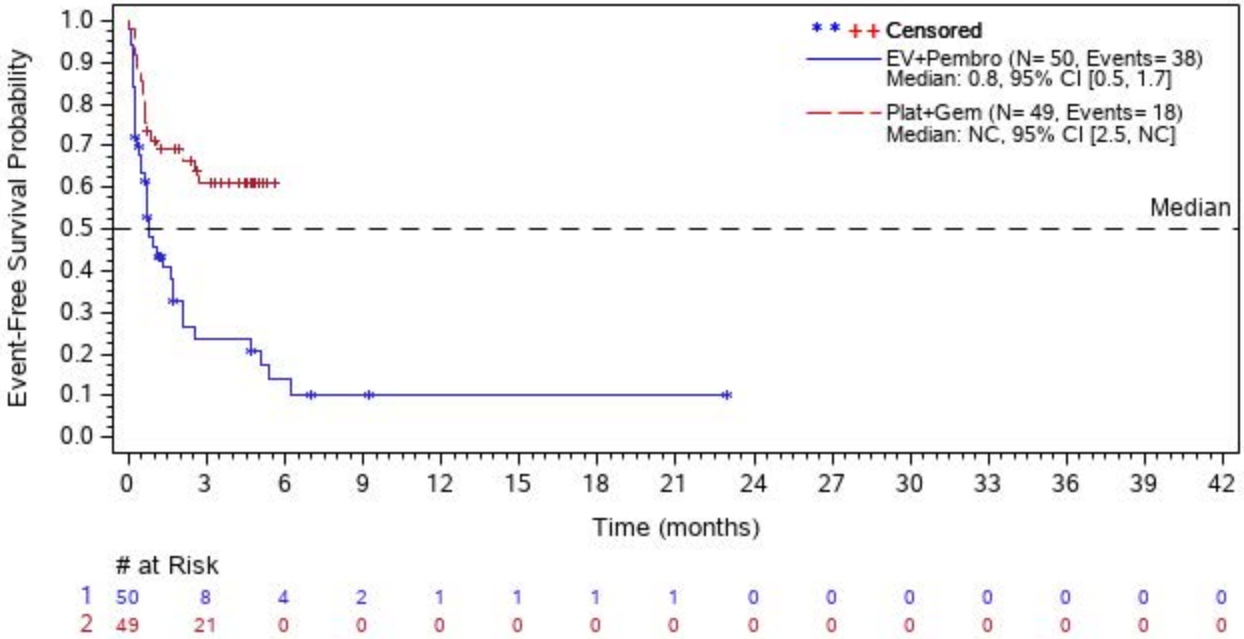
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.104.2.2.1: Kaplan-Meier Plot of Time to first TEAE - Skin and subcutaneous tissue disorders (SOC) - Analysis Set mSAF 2

Liver Metastases: Present



at Risk

1	50	8	4	2	1	1	1	1	0	0	0	0	0	0	0
2	49	21	0	0	0	0	0	0	0	0	0	0	0	0	0

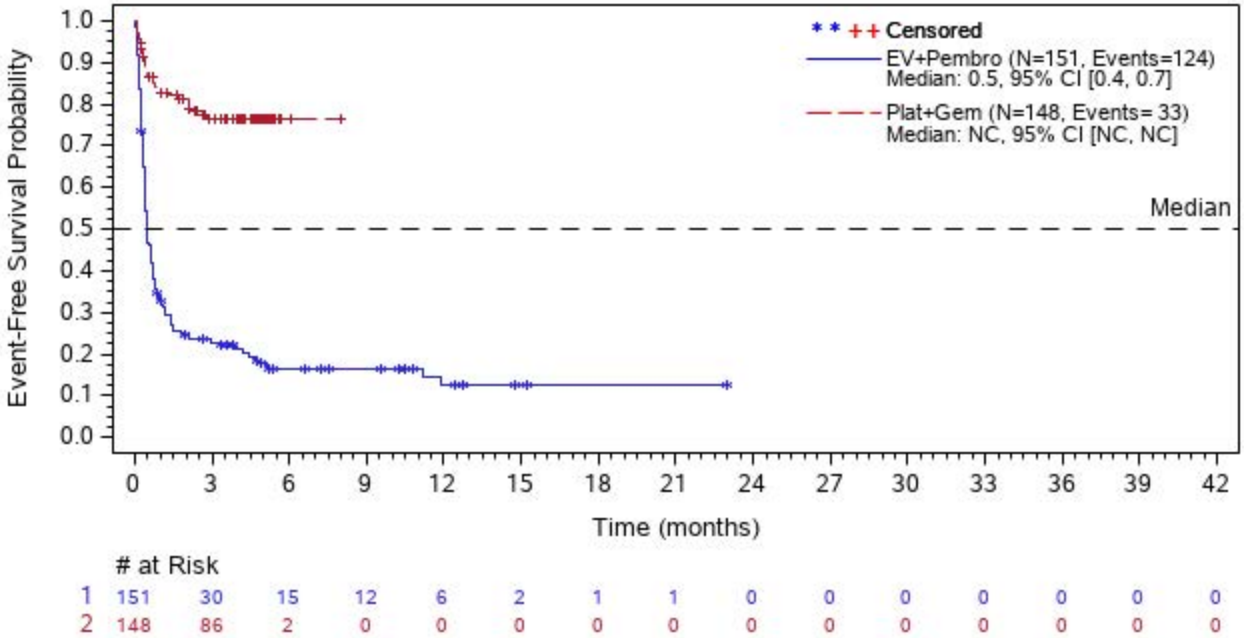
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.104.2.2.1: Kaplan-Meier Plot of Time to first TEAE - Skin and subcutaneous tissue disorders (SOC) - Analysis Set mSAF 2

Liver Metastases: Absent

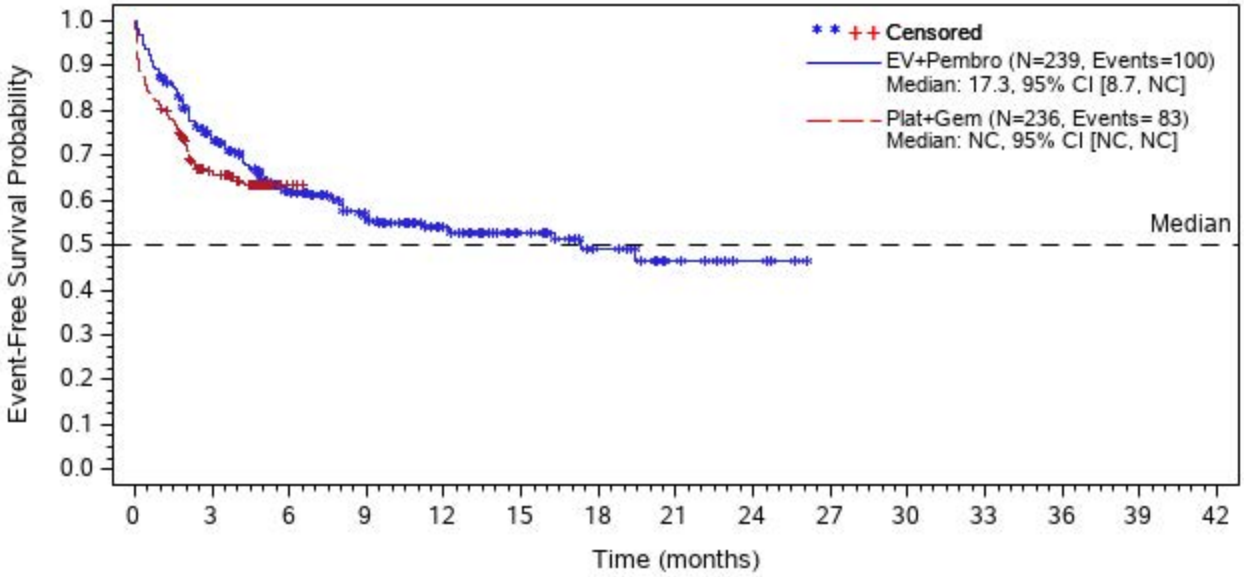


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.105.1.1: Kaplan-Meier Plot of Time to first TEAE - Respiratory, thoracic and mediastinal disorders (SOC) - Analysis Set mSAF 1



at Risk

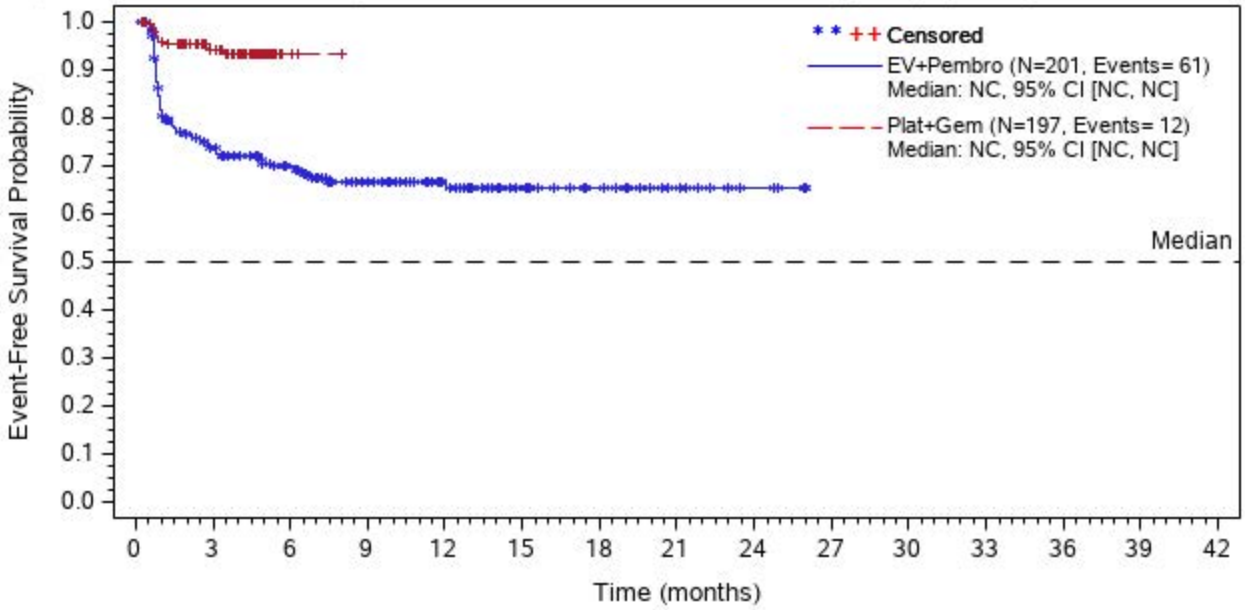
1	239	161	109	78	54	35	22	11	5	0	0	0	0	0	0
2	236	136	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.105.2.1: Kaplan-Meier Plot of Time to first TEAE - Alopecia (PT) - Analysis Set mSAF 2



at Risk

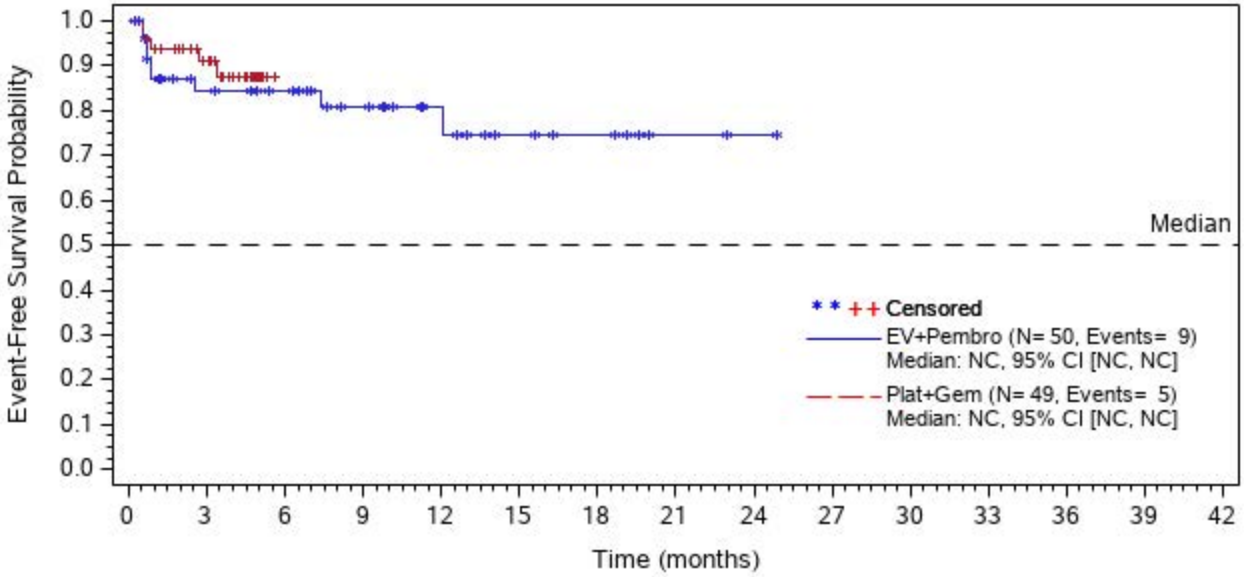
1	201	124	97	73	49	30	20	11	4	0	0	0	0	0	0
2	197	142	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.105.2.2.1: Kaplan-Meier Plot of Time to first TEAE - Alopecia (PT) - Analysis Set mSAF 2 Liver Metastases: Present



at Risk

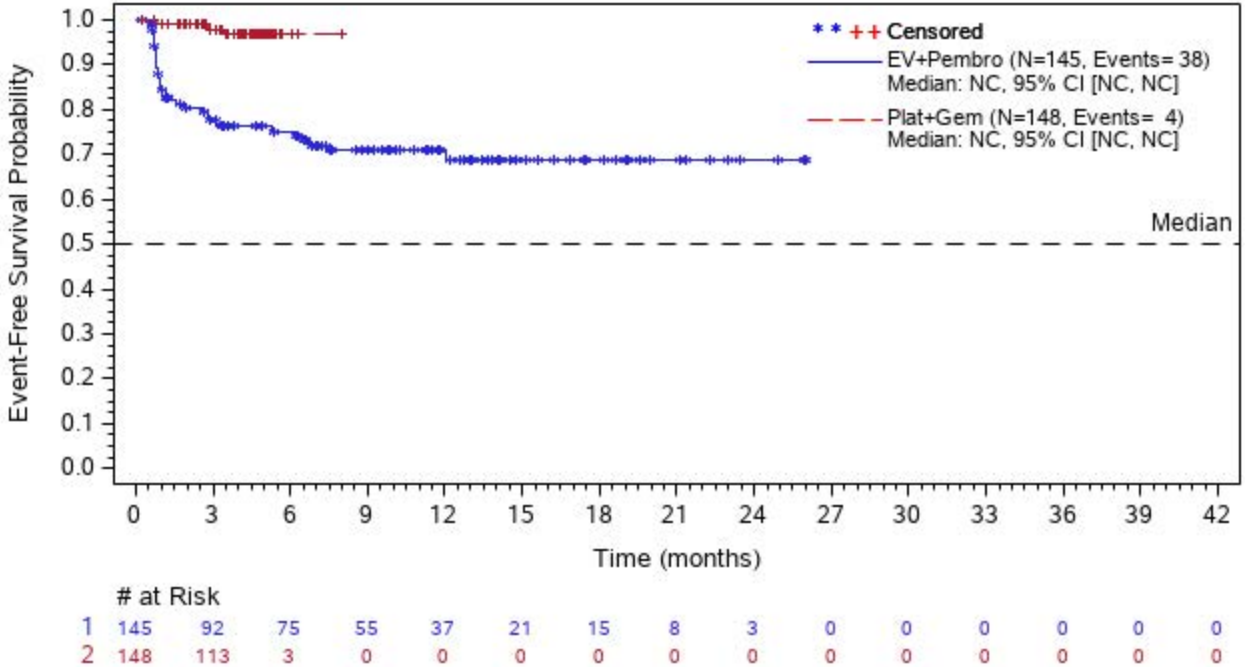
1	50	32	27	19	13	8	6	2	1	0	0	0	0	0	0
2	49	31	0	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.105.2.2.4: Kaplan-Meier Plot of Time to first TEAE - Alopecia (PT) - Analysis Set mSAF 2
Sex: Male



at Risk

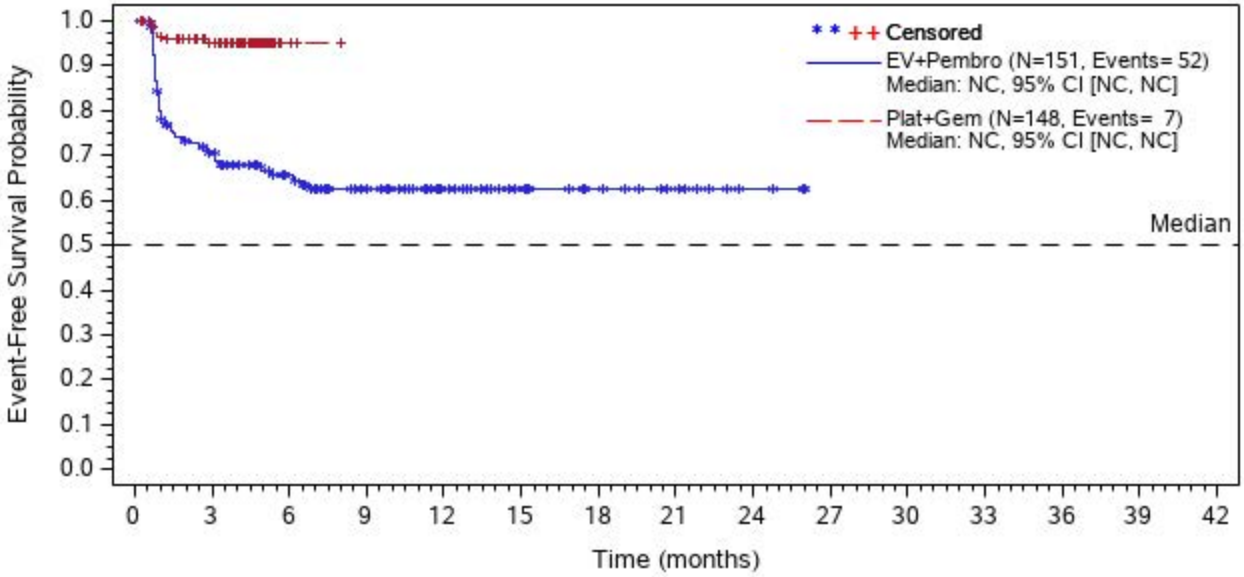
1	145	92	75	55	37	21	15	8	3	0	0	0	0	0	0
2	148	113	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.105.2.2.1: Kaplan-Meier Plot of Time to first TEAE - Alopecia (PT) - Analysis Set mSAF 2 Liver Metastases: Absent



at Risk

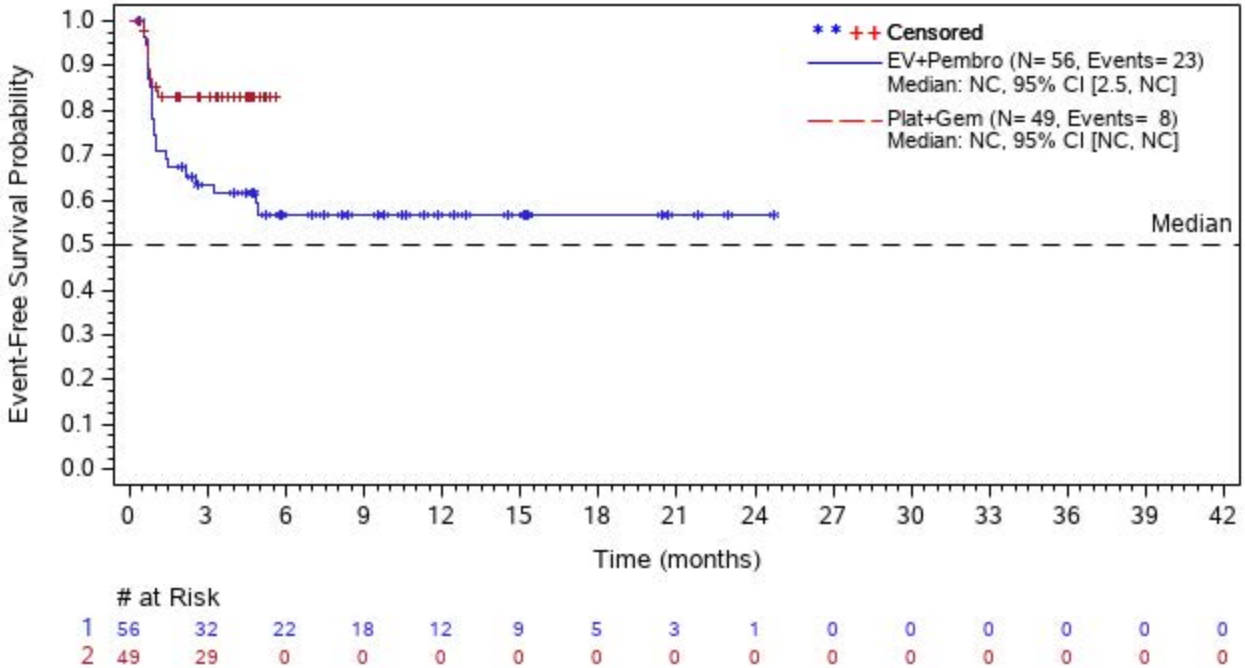
1	151	92	70	54	36	22	14	9	3	0	0	0	0	0	0
2	148	111	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.105.2.2.4: Kaplan-Meier Plot of Time to first TEAE - Alopecia (PT) - Analysis Set mSAF 2
Sex: Female



at Risk

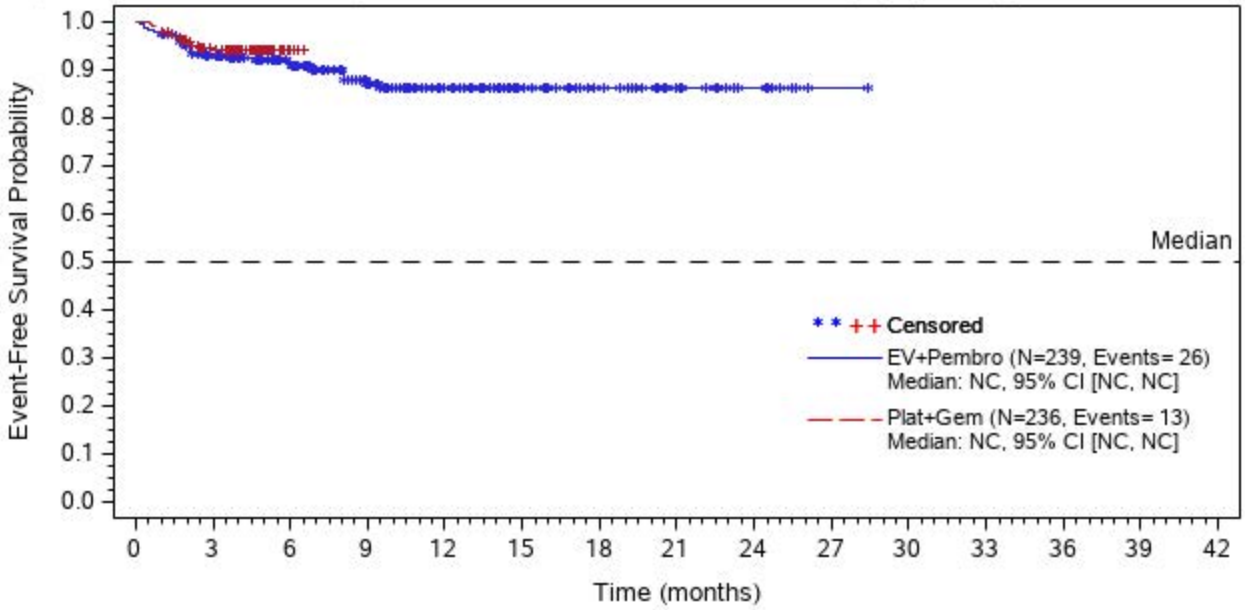
1	56	32	22	18	12	9	5	3	1	0	0	0	0	0	0
2	49	29	0	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.106.1.1: Kaplan-Meier Plot of Time to first TEAE - Cough (PT) - Analysis Set mSAF 1



at Risk

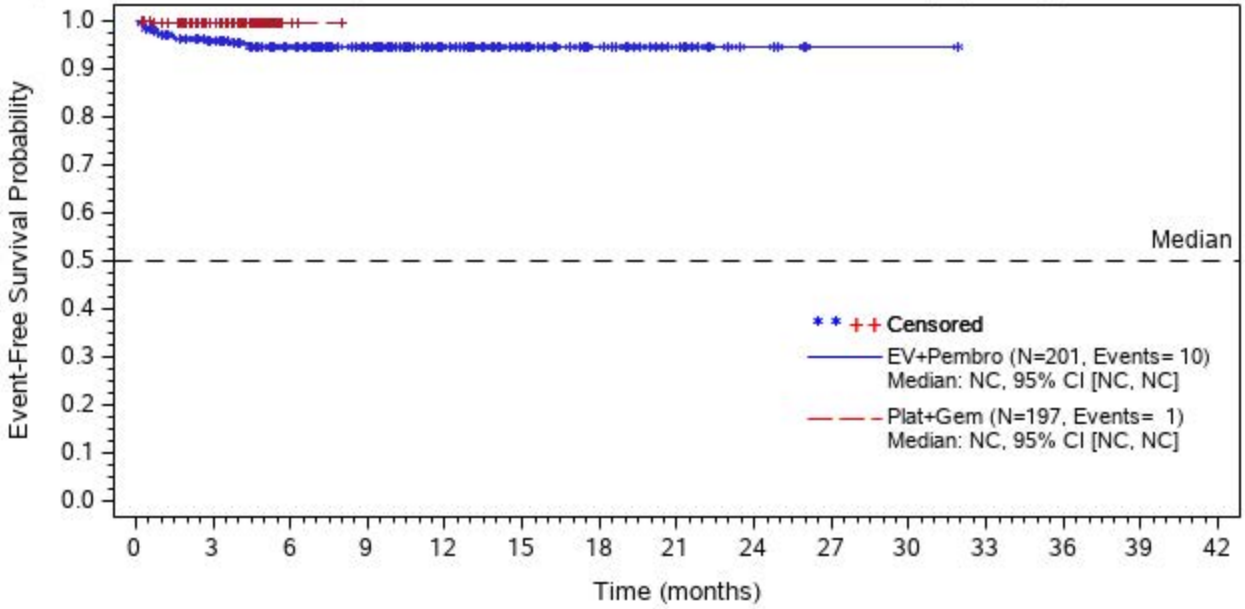
1	239	197	153	110	75	49	33	19	10	1	0	0	0	0	0
2	236	191	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.106.2.1: Kaplan-Meier Plot of Time to first TEAE - Dermatitis (PT) - Analysis Set mSAF 2



at Risk

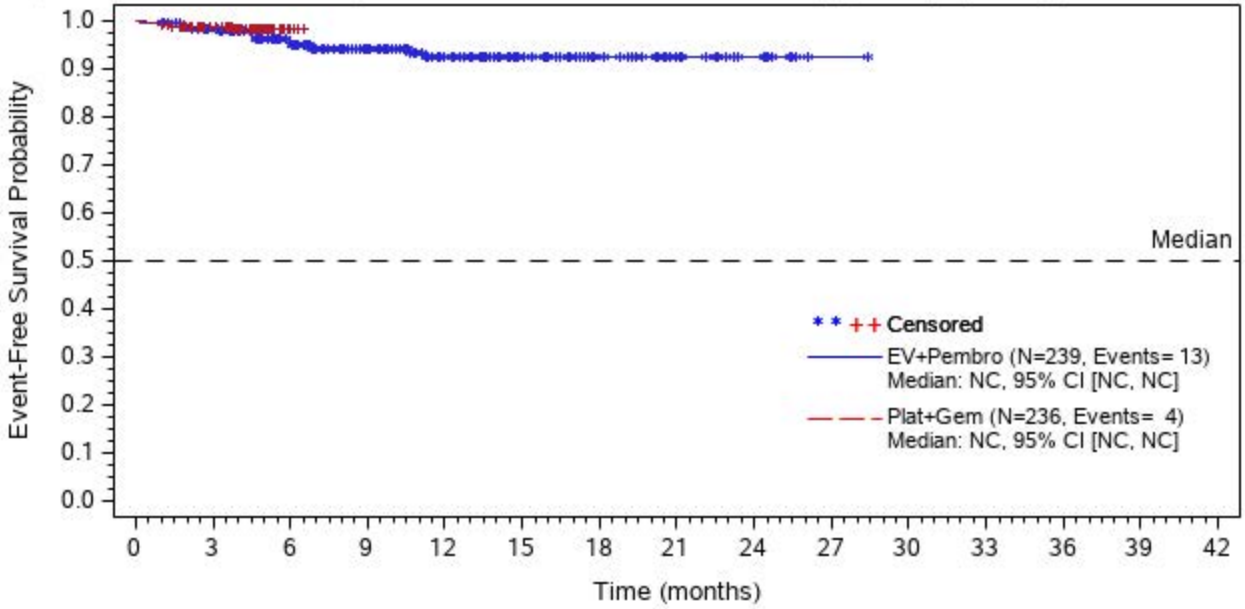
1	201	163	132	102	67	49	31	18	6	1	1	0	0	0	0
2	197	150	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.107.1.1: Kaplan-Meier Plot of Time to first TEAE - Dysphonia (PT) - Analysis Set mSAF 1



at Risk

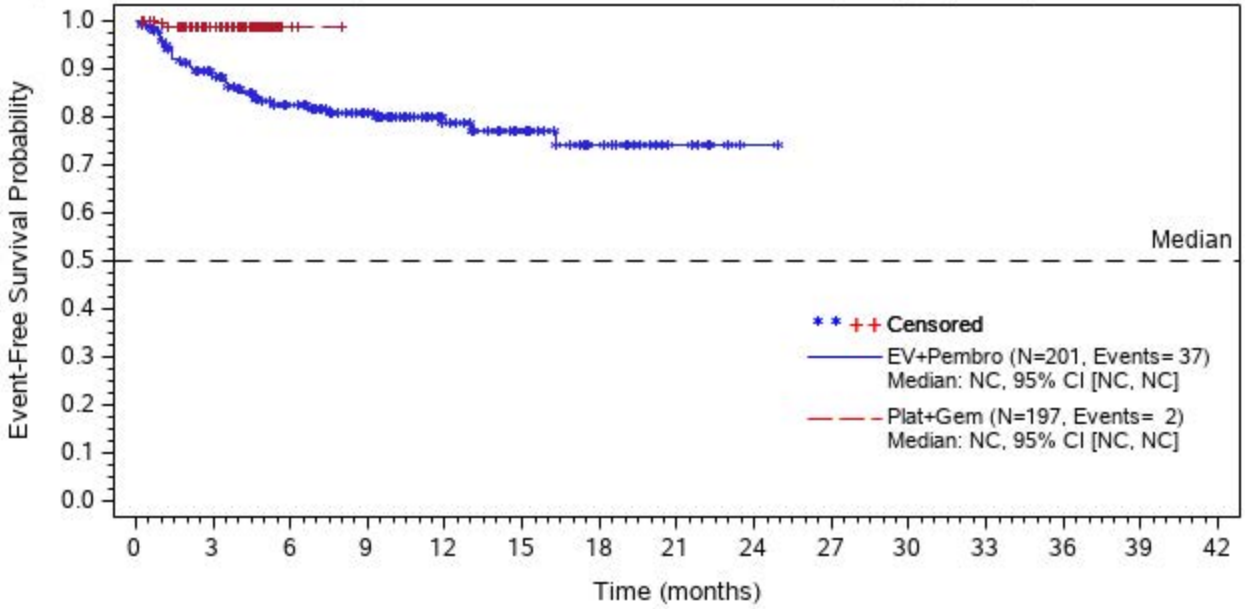
1	239	207	160	123	81	55	37	20	11	1	0	0	0	0	0
2	236	197	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.107.2.1: Kaplan-Meier Plot of Time to first TEAE - Dry skin (PT) - Analysis Set mSAF 2



at Risk

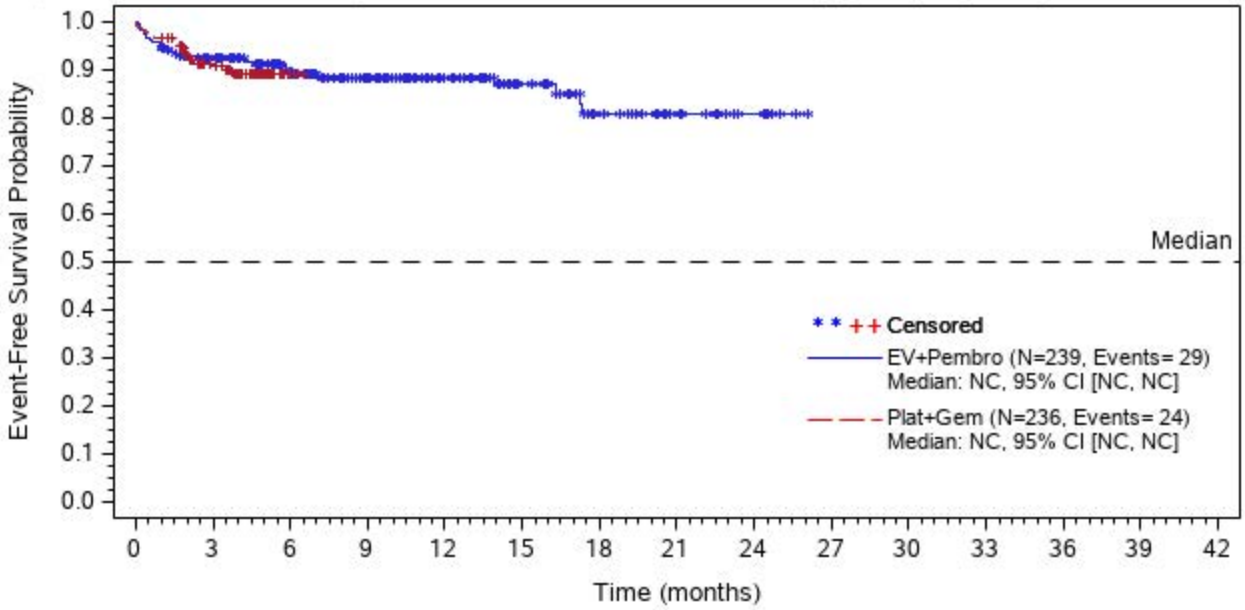
1	201	151	114	89	54	38	20	8	1	0	0	0	0	0	0
2	197	149	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.108.1.1: Kaplan-Meier Plot of Time to first TEAE - Dyspnoea (PT) - Analysis Set mSAF 1



at Risk

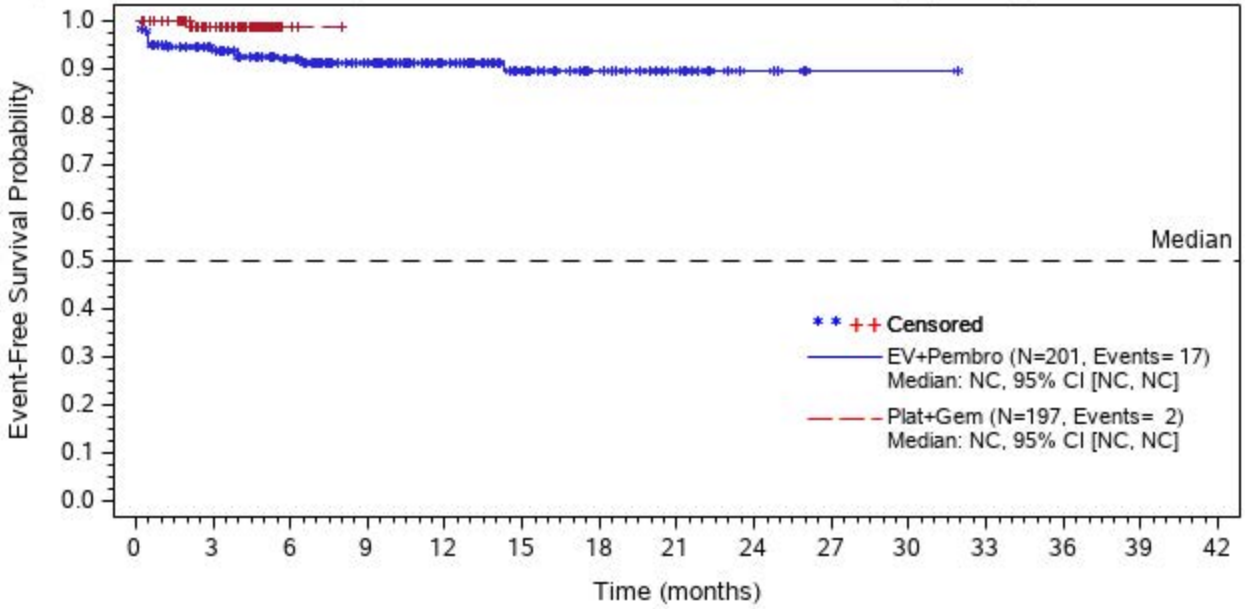
1	239	197	153	117	82	54	33	18	9	0	0	0	0	0	0
2	236	185	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.108.2.1: Kaplan-Meier Plot of Time to first TEAE - Eczema (PT) - Analysis Set mSAF 2



at Risk

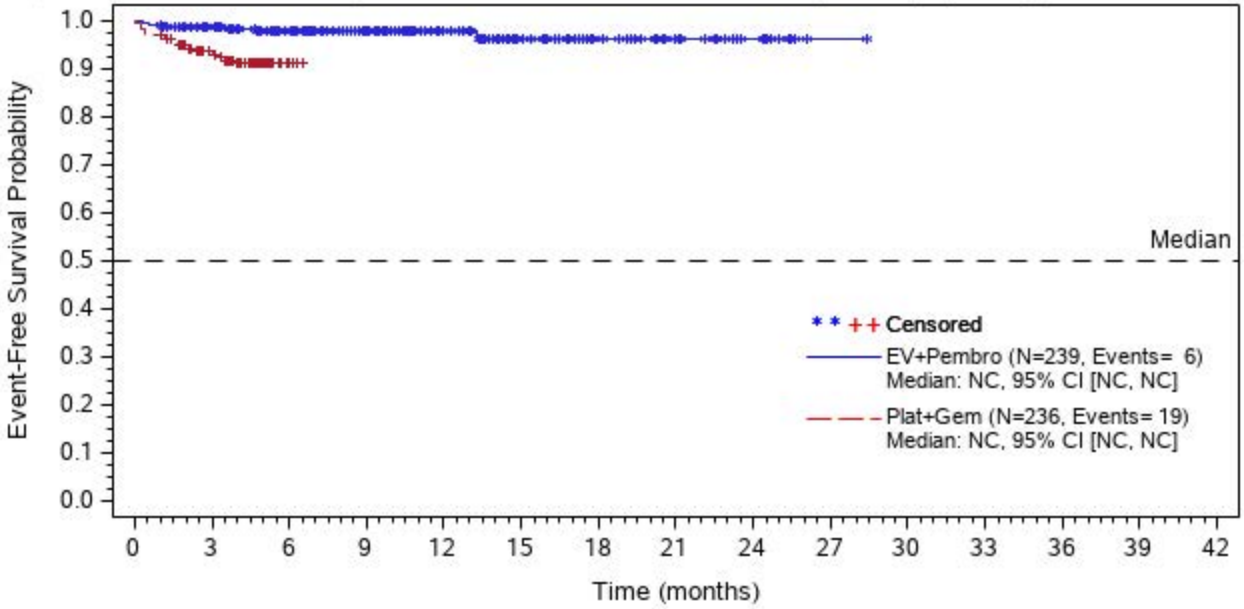
1	201	160	129	99	68	45	27	16	5	1	1	0	0	0	0
2	197	149	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.109.1.1: Kaplan-Meier Plot of Time to first TEAE - Epistaxis (PT) - Analysis Set mSAF 1



at Risk

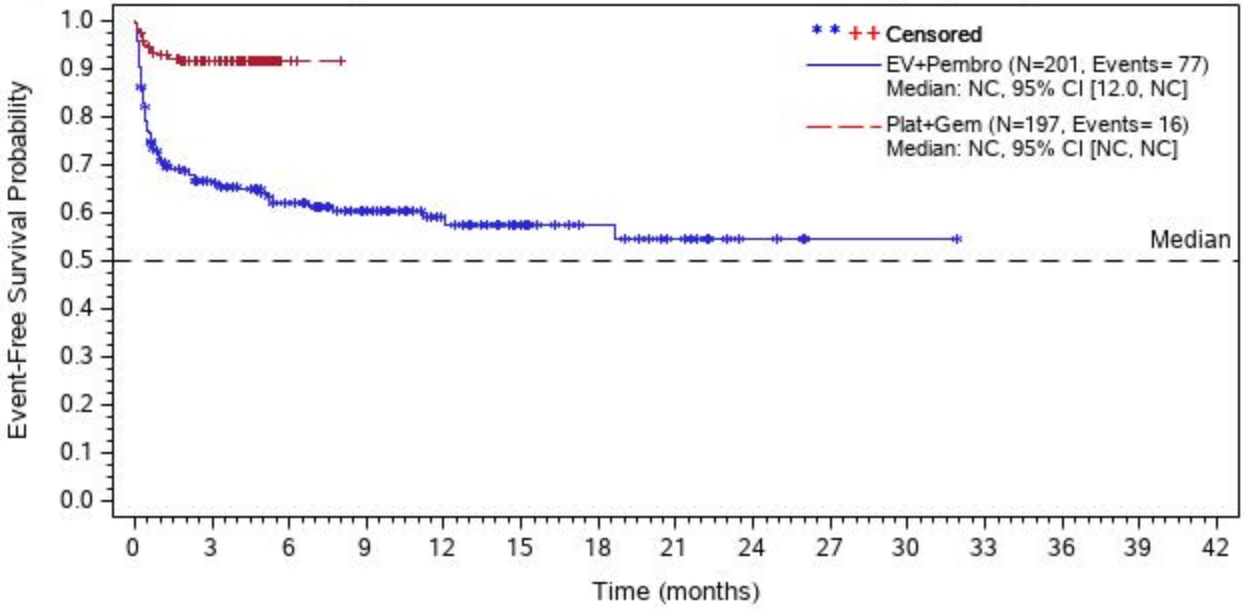
1	239	208	165	128	86	57	38	22	12	1	0	0	0	0	0
2	236	188	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.109.2.1: Kaplan-Meier Plot of Time to first TEAE - Pruritus (PT) - Analysis Set mSAF 2



at Risk

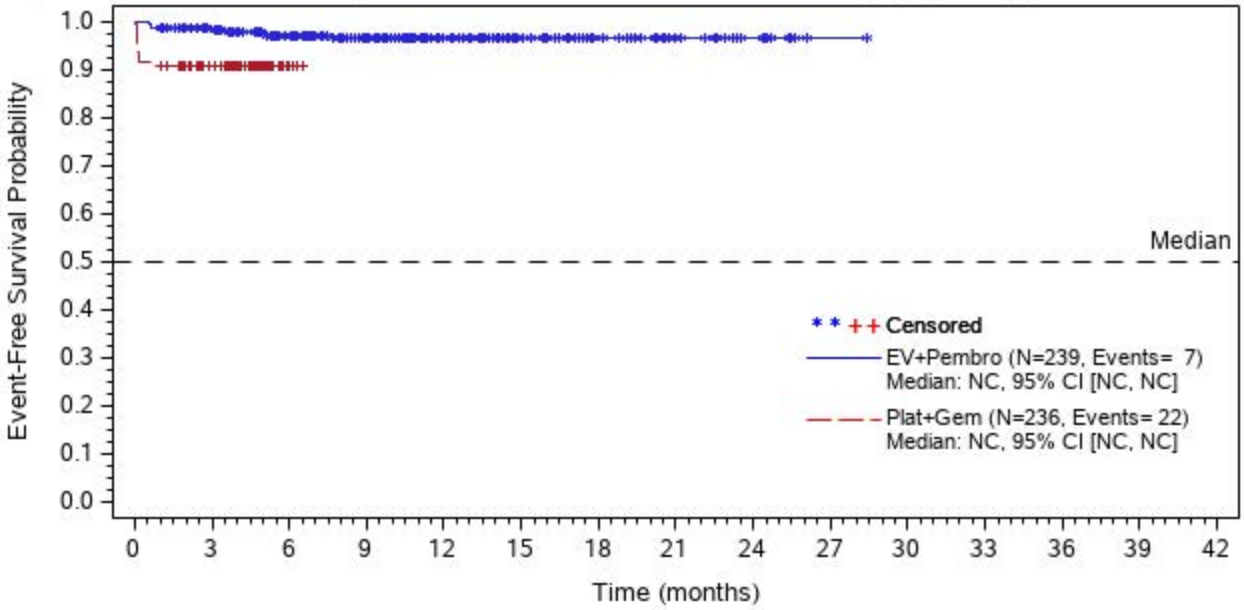
1	201	109	81	62	43	29	18	12	4	1	1	0	0	0	0
2	197	138	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.110.1.1: Kaplan-Meier Plot of Time to first TEAE - Hiccups (PT) - Analysis Set mSAF 1



at Risk

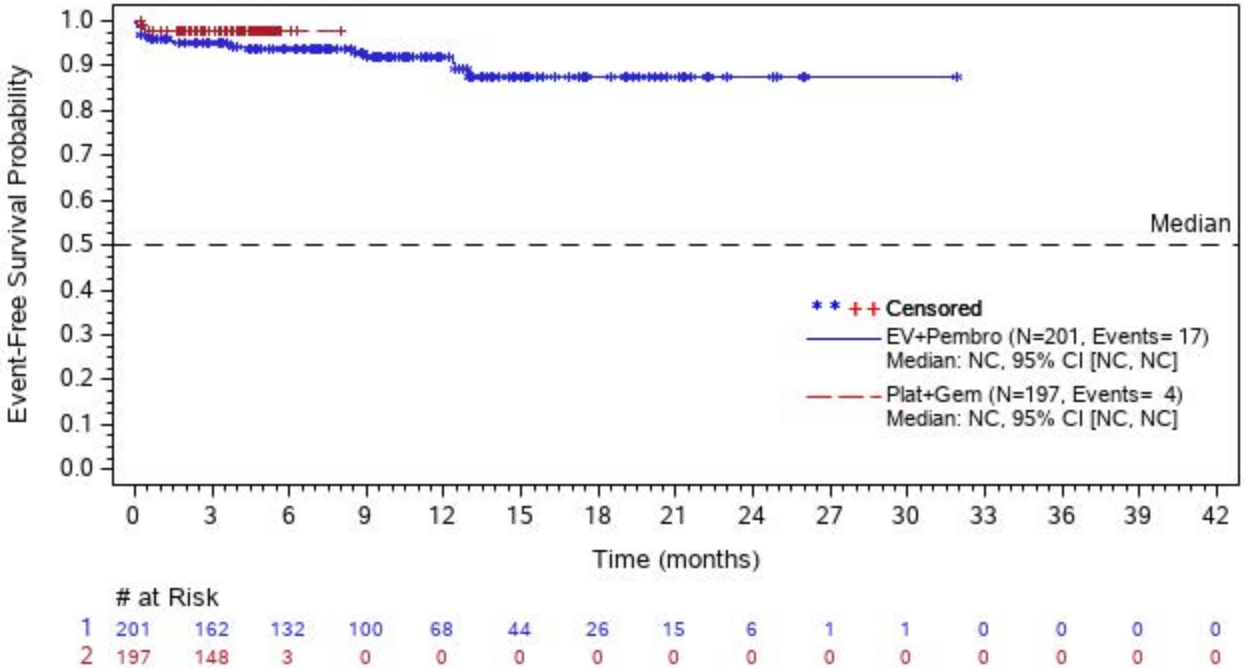
1	239	208	167	129	85	56	37	20	11	1	0	0	0	0	0
2	236	180	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.110.2.1: Kaplan-Meier Plot of Time to first TEAE - Rash macular (PT) - Analysis Set mSAF 2



at Risk

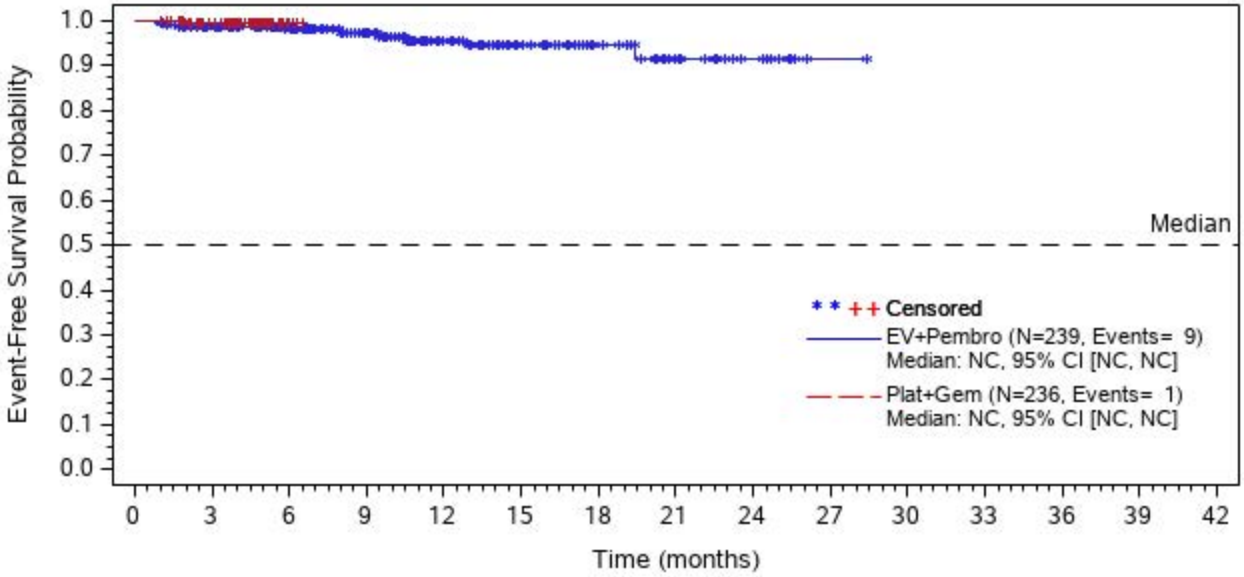
1	201	162	132	100	68	44	26	15	6	1	1	0	0	0	0
2	197	148	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.111.1.1: Kaplan-Meier Plot of Time to first TEAE - Nasal congestion (PT) - Analysis Set mSAF 1



at Risk

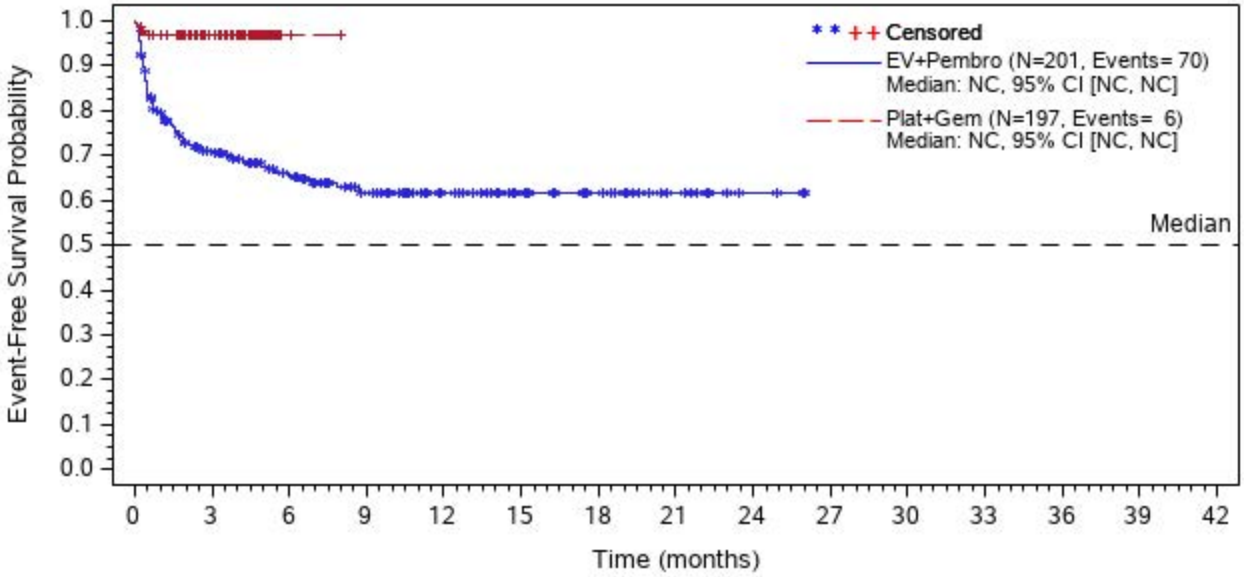
1	239	209	167	128	83	56	37	20	11	1	0	0	0	0	0
2	236	199	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.111.2.1: Kaplan-Meier Plot of Time to first TEAE - Rash maculo-papular (PT) - Analysis Set mSAF 2



at Risk

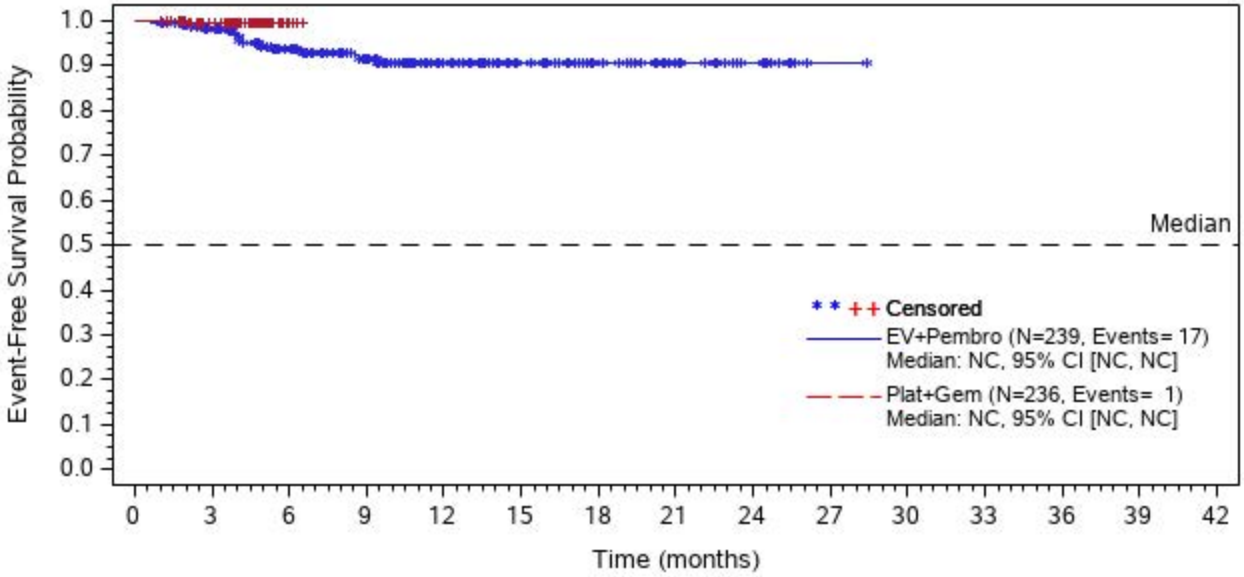
1	201	122	94	71	49	33	23	13	3	0	0	0	0	0	0
2	197	146	2	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.112.1.1: Kaplan-Meier Plot of Time to first TEAE - Pneumonitis (PT) - Analysis Set mSAF 1



at Risk

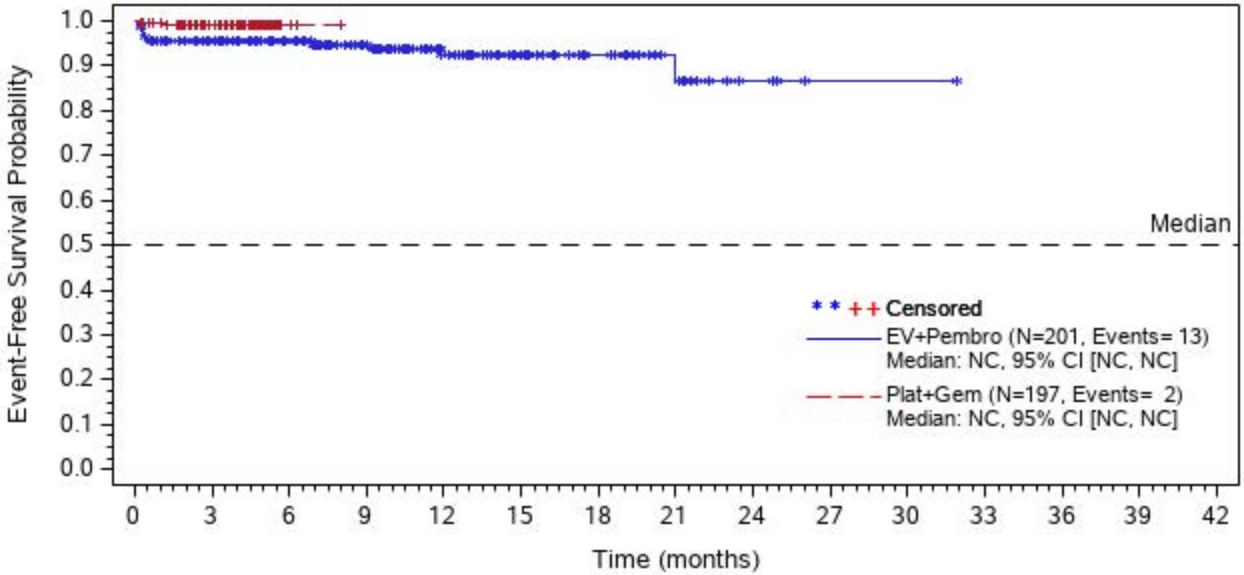
1	239	208	161	124	84	57	39	22	12	1	0	0	0	0	0
2	236	199	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.112.2.1: Kaplan-Meier Plot of Time to first TEAE - Rash papular (PT) - Analysis Set mSAF 2



at Risk

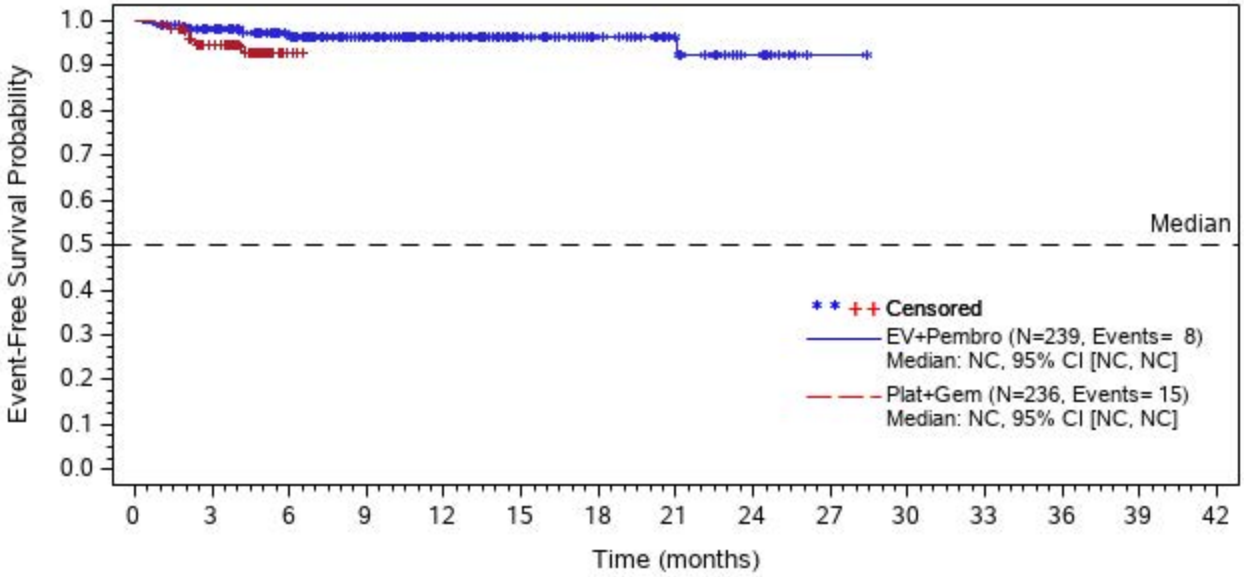
1	201	163	132	100	64	44	27	15	5	1	1	0	0	0	0
2	197	149	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.113.1.1: Kaplan-Meier Plot of Time to first TEAE - Pulmonary embolism (PT) - Analysis Set mSAF 1



at Risk

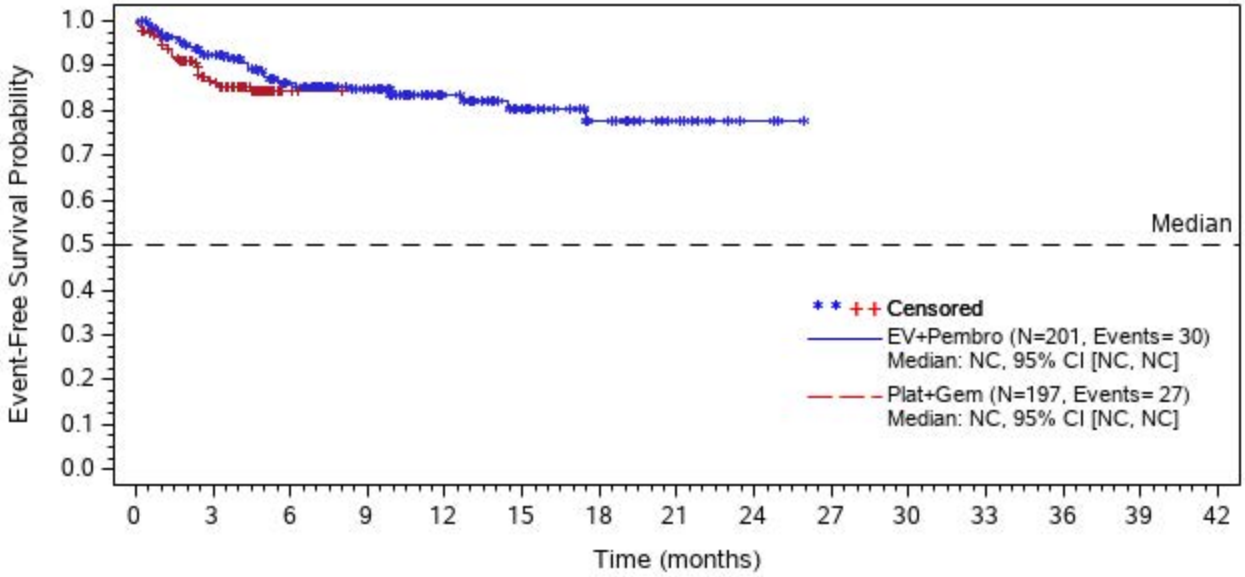
1	239	207	163	125	84	56	38	22	11	1	0	0	0	0	0
2	236	190	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.113.2.1: Kaplan-Meier Plot of Time to first TEAE - Vascular disorders (SOC) - Analysis Set mSAF 2



at Risk

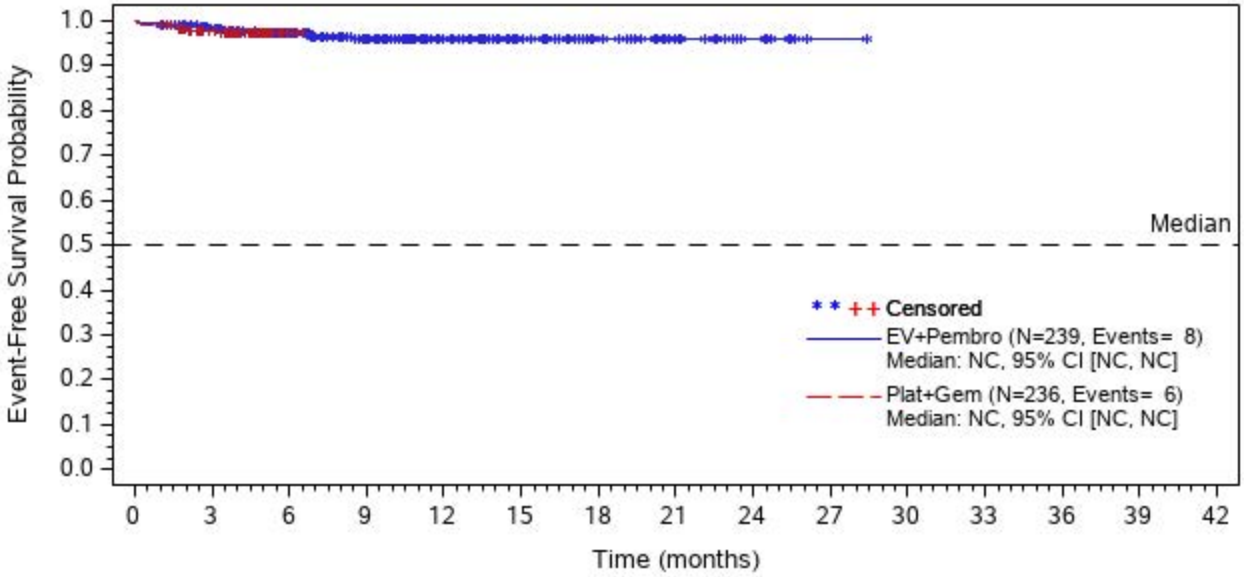
1	201	160	123	95	61	42	24	14	4	0	0	0	0	0	0
2	197	132	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.114.1.1: Kaplan-Meier Plot of Time to first TEAE - Rhinorrhoea (PT) - Analysis Set mSAF 1



at Risk

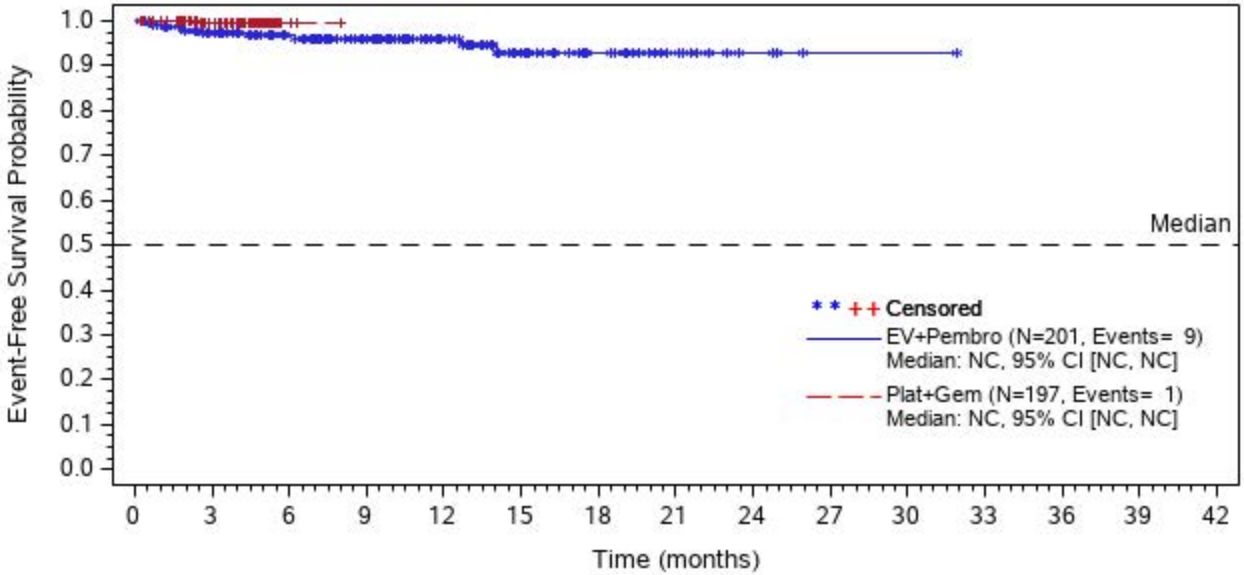
1	239	208	163	124	81	55	37	20	10	1	0	0	0	0	0
2	236	195	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.114.2.1: Kaplan-Meier Plot of Time to first TEAE - Hypotension (PT) - Analysis Set mSAF 2



at Risk

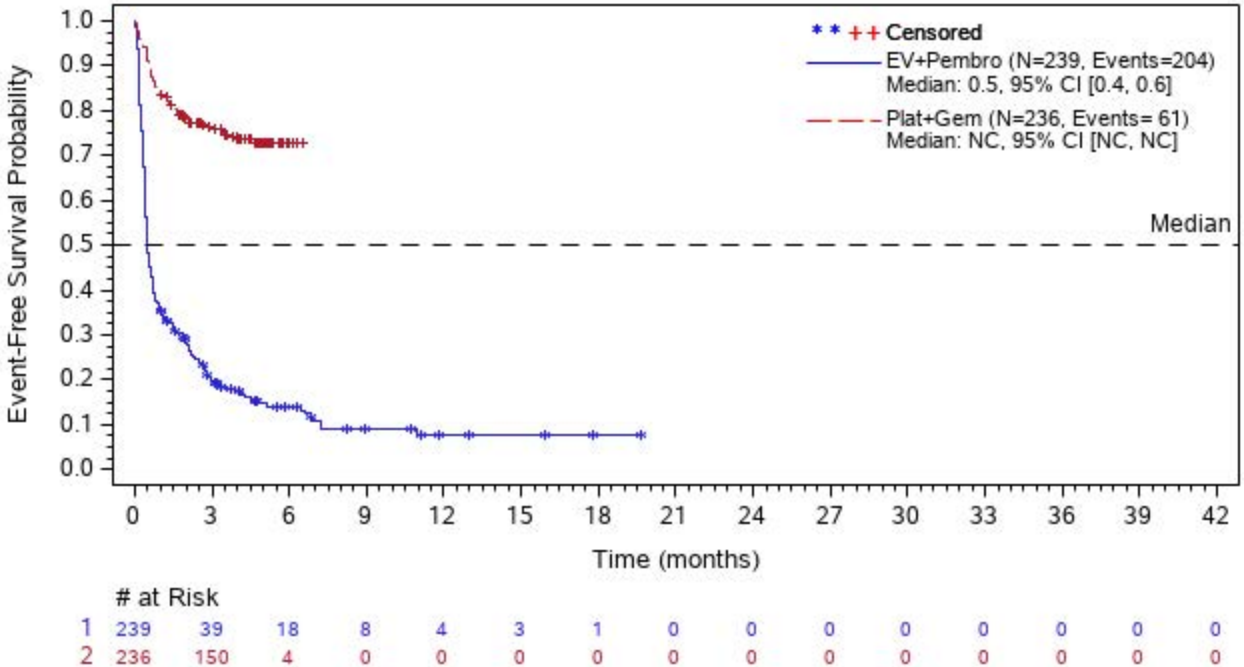
1	201	167	136	107	71	47	27	15	5	1	1	0	0	0	0
2	197	150	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.115.1.1: Kaplan-Meier Plot of Time to first TEAE - Skin and subcutaneous tissue disorders (SOC) - Analysis Set mSAF 1



at Risk

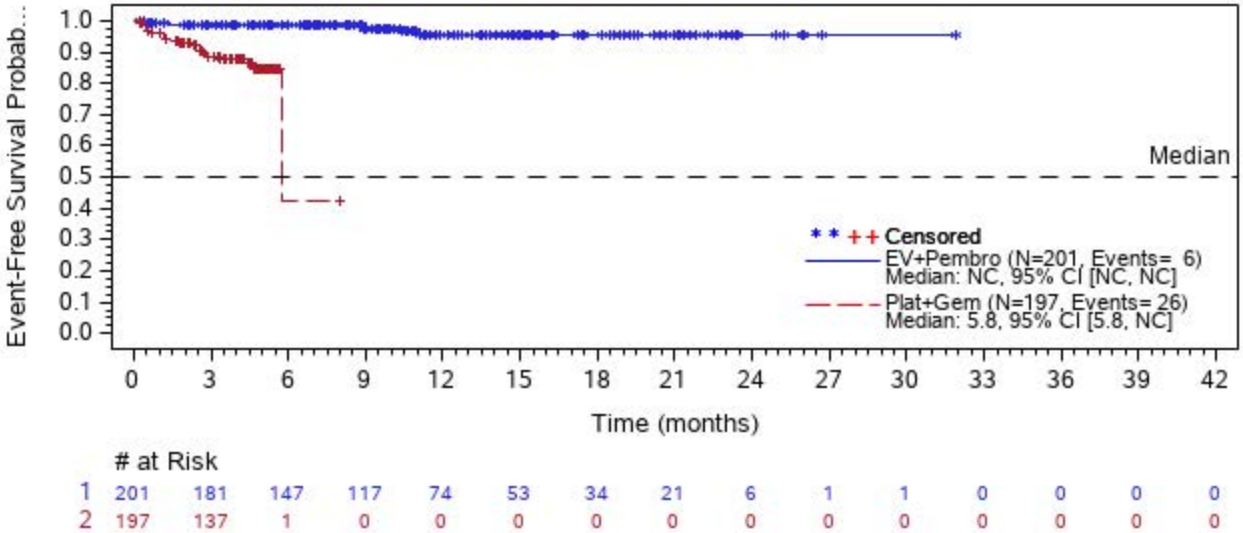
1	239	39	18	8	4	3	1	0	0	0	0	0	0	0	0
2	236	150	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.115.2.1: Kaplan-Meier Plot of Time to first TESAE - Blood and lymphatic system disorders (SOC) - Analysis Set mSAF 2



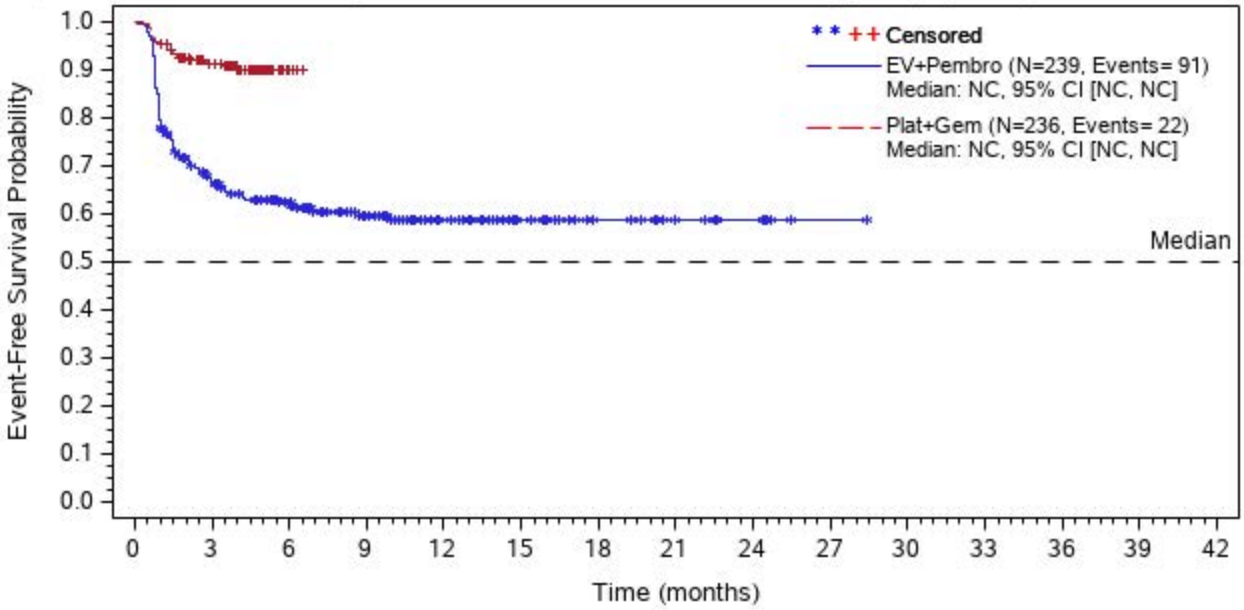
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.116.1.1: Kaplan-Meier Plot of Time to first TEAE - Alopecia (PT) - Analysis Set mSAF 1



at Risk

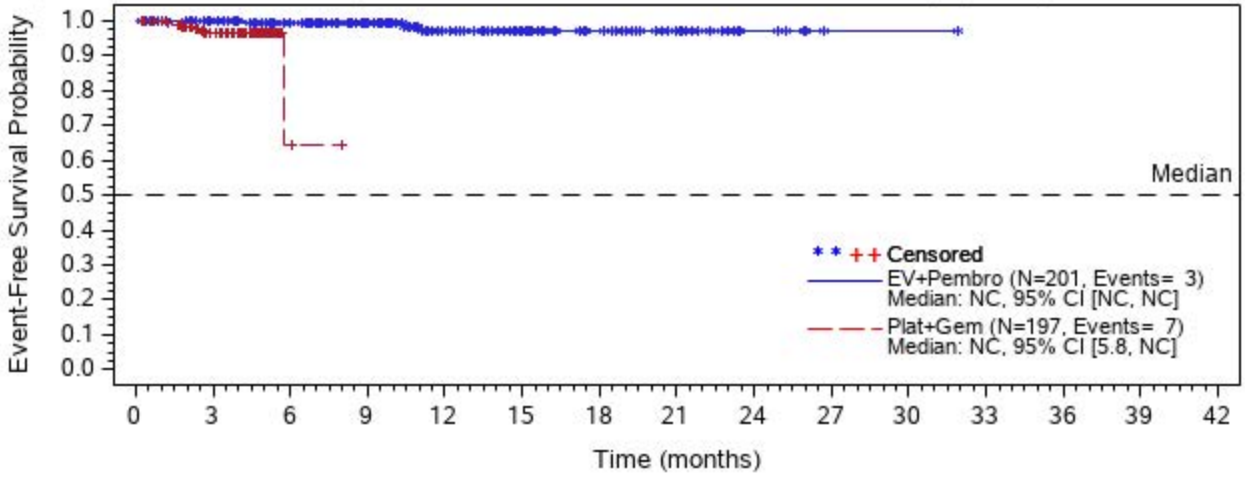
1	239	139	105	75	49	31	19	11	7	1	0	0	0	0	0
2	236	180	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.116.2.1: Kaplan-Meier Plot of Time to first TESAE - Anaemia (PT) - Analysis Set mSAF 2



at Risk

1	201	183	148	119	75	53	34	21	6	1	1	0	0	0	0
2	197	146	2	0	0	0	0	0	0	0	0	0	0	0	0

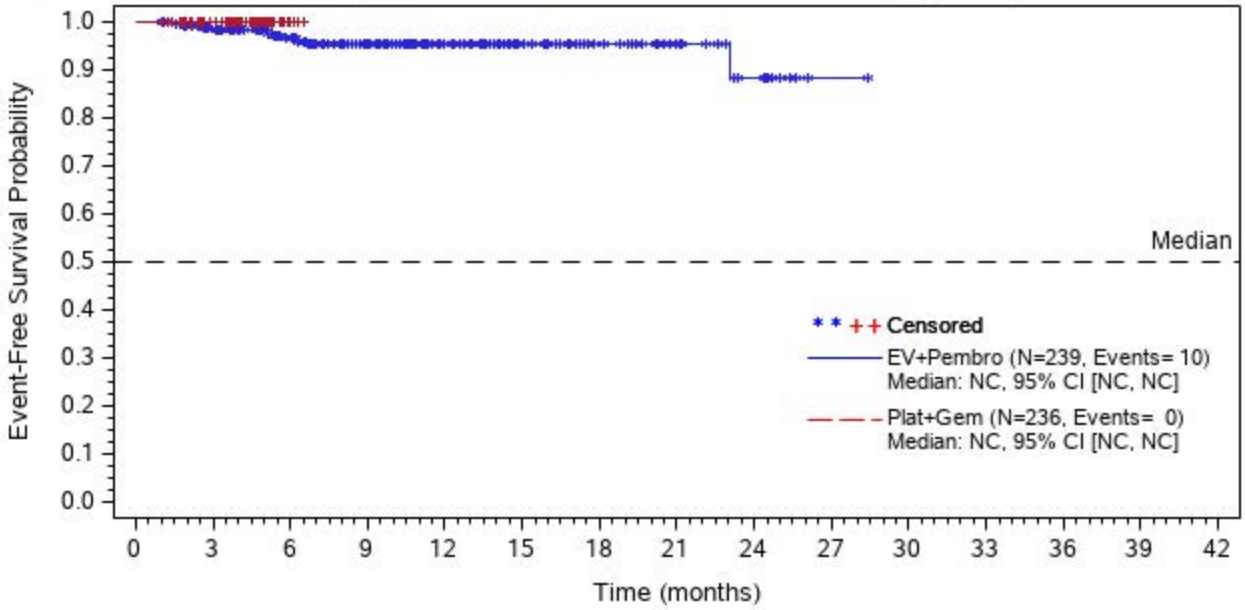
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TESAE=treatment-emergent serious adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.117.1.1: Kaplan-Meier Plot of Time to first TEAE - Blister (PT) - Analysis Set mSAF 1



at Risk

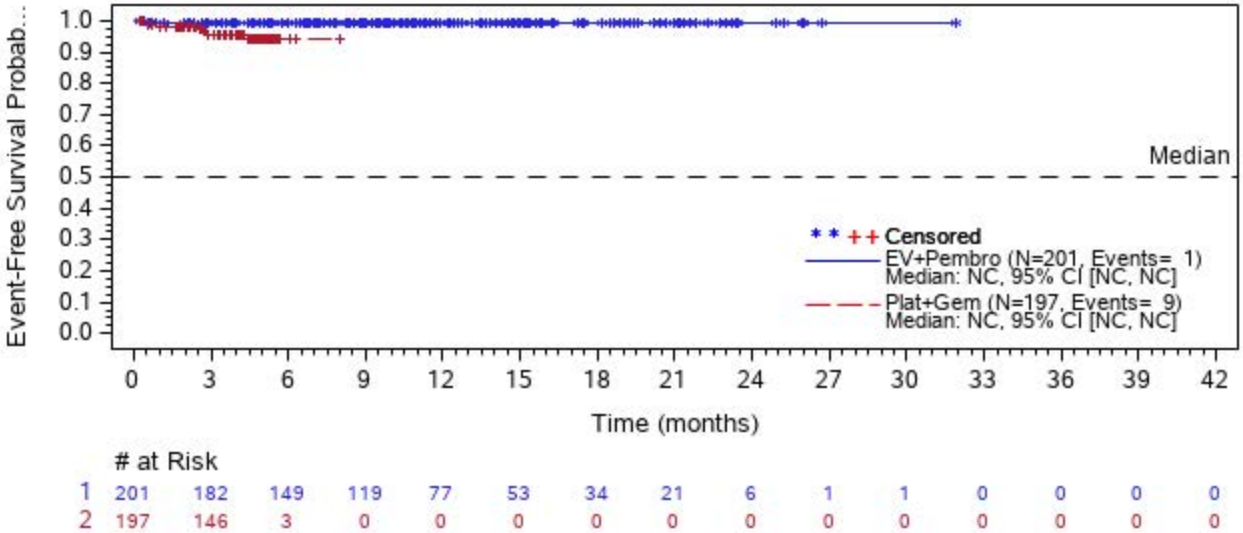
1	239	207	164	125	83	54	36	20	11	1	0	0	0	0	0
2	236	200	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.117.2.1: Kaplan-Meier Plot of Time to first TESAE - Febrile neutropenia (PT) - Analysis Set mSAF 2



at Risk

1	201	182	149	119	77	53	34	21	6	1	1	0	0	0	0
2	197	146	3	0	0	0	0	0	0	0	0	0	0	0	0

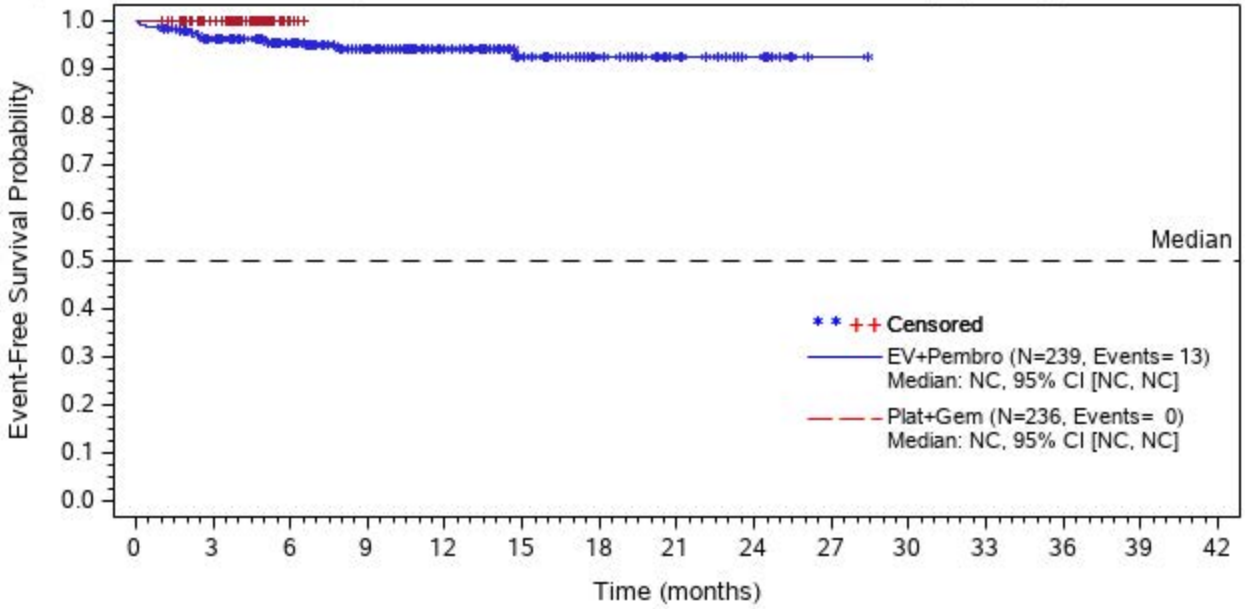
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TESAE=treatment-emergent serious adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.118.1.1: Kaplan-Meier Plot of Time to first TEAE - Dermatitis (PT) - Analysis Set mSAF 1



at Risk

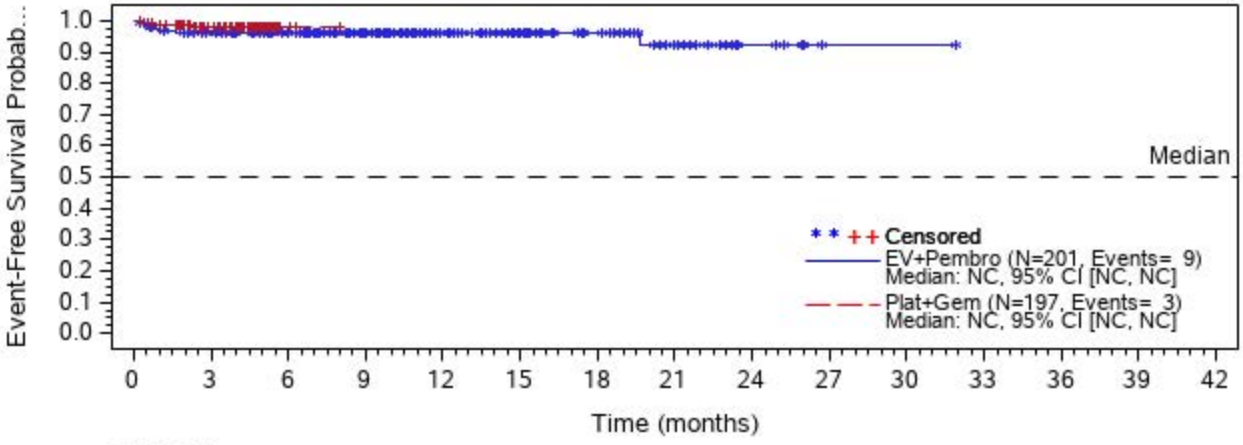
1	239	203	160	122	82	53	35	20	11	1	0	0	0	0	0
2	236	200	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.118.2.1: Kaplan-Meier Plot of Time to first TESAE - Cardiac disorders (SOC) - Analysis Set mSAF 2



at Risk

1	201	179	149	119	77	53	34	20	6	1	1	0	0	0	0
2	197	149	3	0	0	0	0	0	0	0	0	0	0	0	0

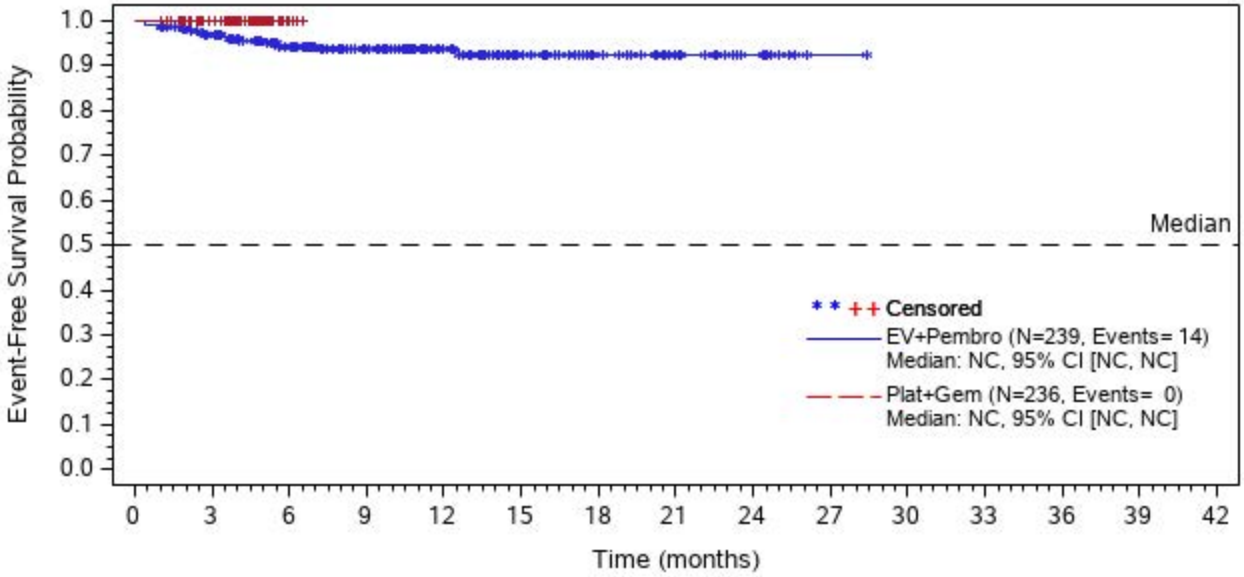
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.119.1.1: Kaplan-Meier Plot of Time to first TEAE - Dermatitis bullous (PT) - Analysis Set mSAF 1



at Risk

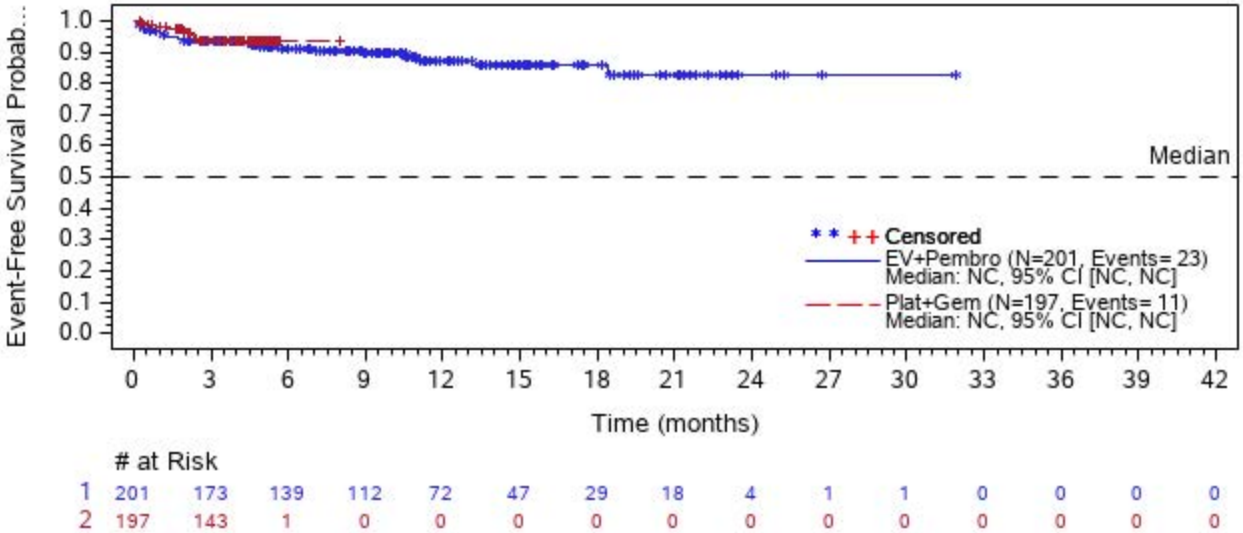
1	239	204	159	122	82	52	34	21	11	1	0	0	0	0	0
2	236	200	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.119.2.1: Kaplan-Meier Plot of Time to first TESAE - Gastrointestinal disorders (SOC) - Analysis Set mSAF 2



at Risk

1	201	173	139	112	72	47	29	18	4	1	1	0	0	0	0
2	197	143	1	0	0	0	0	0	0	0	0	0	0	0	0

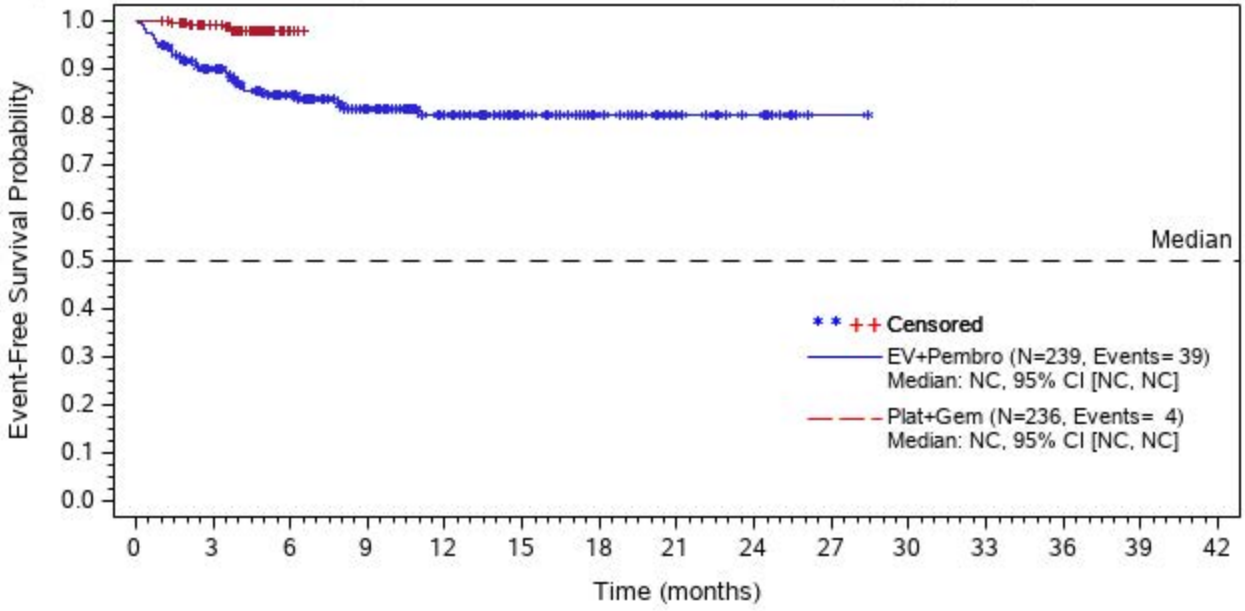
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.120.1.1: Kaplan-Meier Plot of Time to first TEAE - Dry skin (PT) - Analysis Set mSAF 1



at Risk

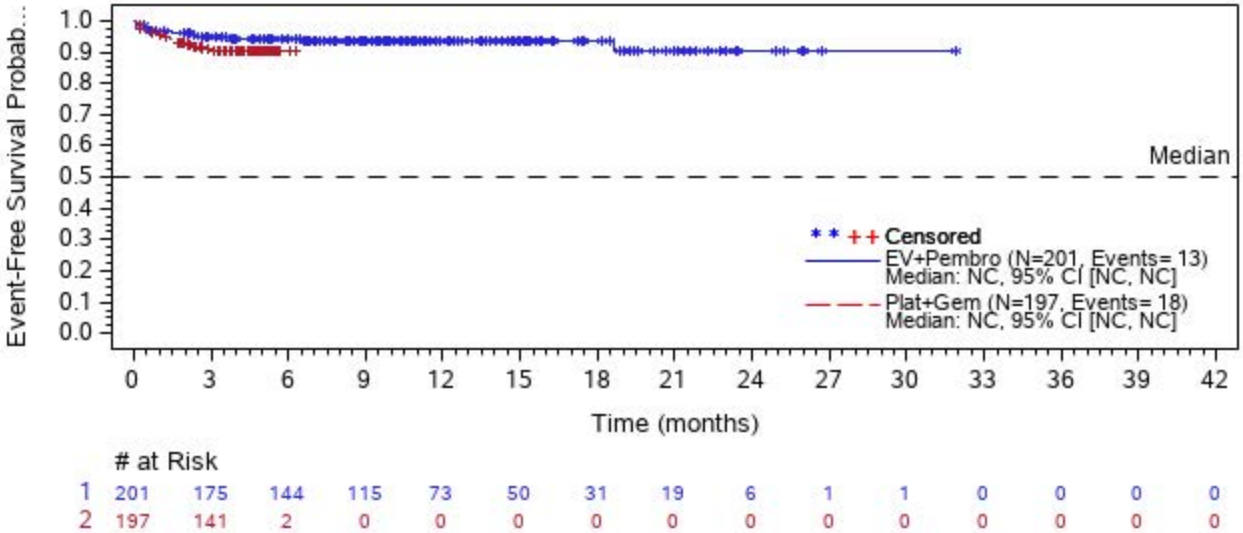
1	239	189	139	103	70	48	32	17	11	1	0	0	0	0	0
2	236	198	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.120.2.1: Kaplan-Meier Plot of Time to first TESAE - General disorders and administration site conditions (SOC) - Analysis Set mSAF 2



at Risk

1	201	175	144	115	73	50	31	19	6	1	1	0	0	0	0
2	197	141	2	0	0	0	0	0	0	0	0	0	0	0	0

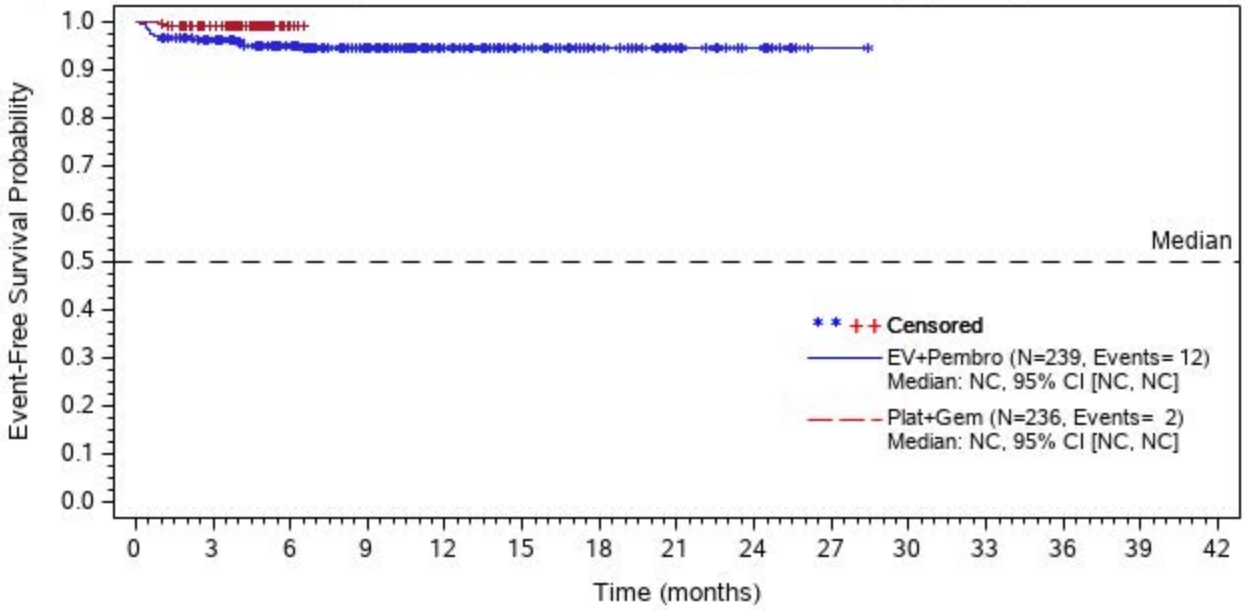
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.121.1.1: Kaplan-Meier Plot of Time to first TEAE - Eczema (PT) - Analysis Set mSAF 1



at Risk

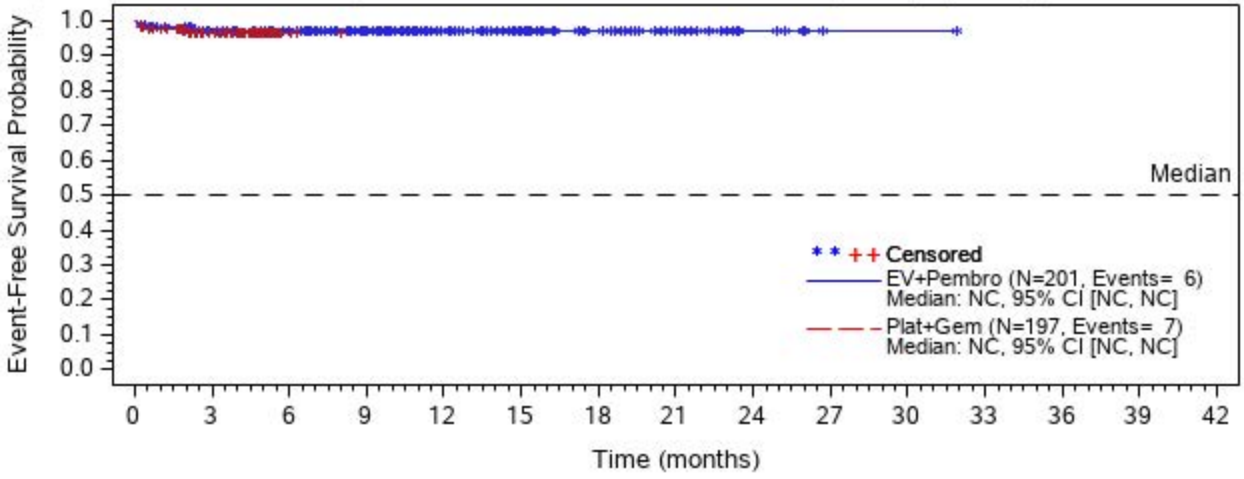
1	239	202	161	123	82	56	38	21	12	1	0	0	0	0	0
2	236	199	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.121.2.1: Kaplan-Meier Plot of Time to first TESAE - Pyrexia (PT) - Analysis Set mSAF 2



at Risk

1	201	177	145	117	75	52	33	20	6	1	1	0	0	0	0
2	197	145	3	0	0	0	0	0	0	0	0	0	0	0	0

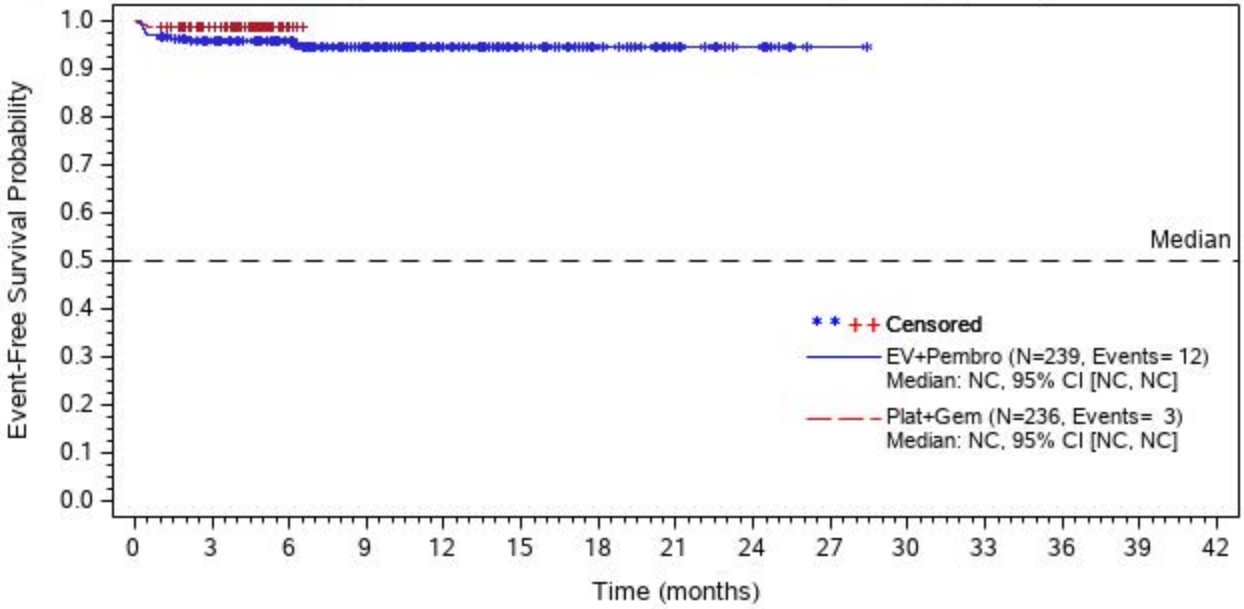
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TESAE=treatment-emergent serious adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.122.1.1: Kaplan-Meier Plot of Time to first TEAE - Erythema (PT) - Analysis Set mSAF 1



at Risk

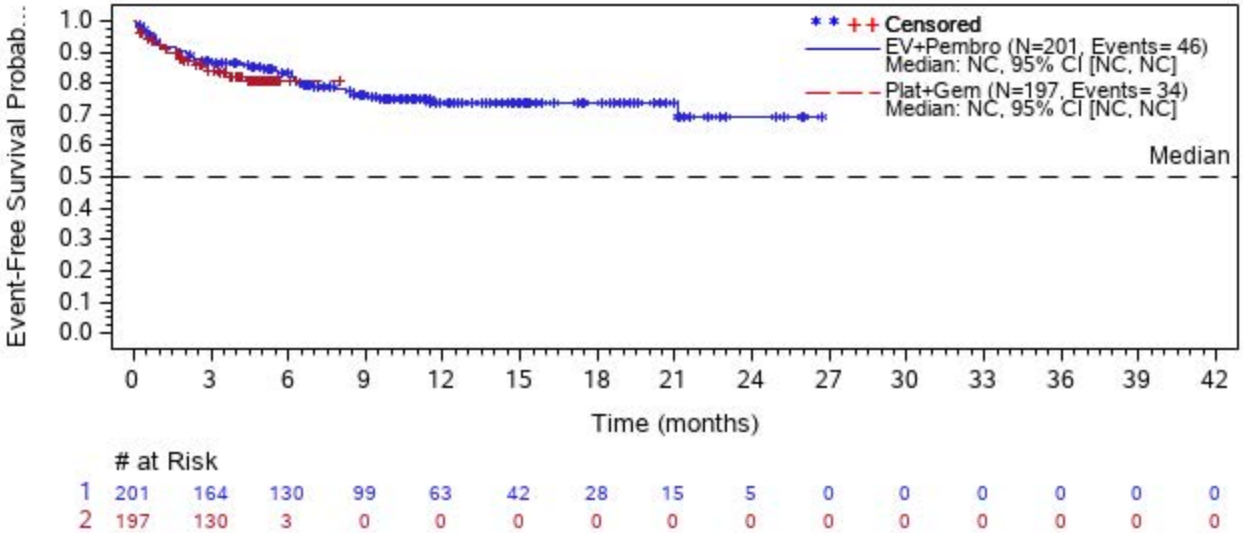
1	239	201	160	121	79	54	36	19	11	1	0	0	0	0	0
2	236	198	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.122.2.1: Kaplan-Meier Plot of Time to first TESAE - Infections and infestations (SOC) - Analysis Set mSAF 2



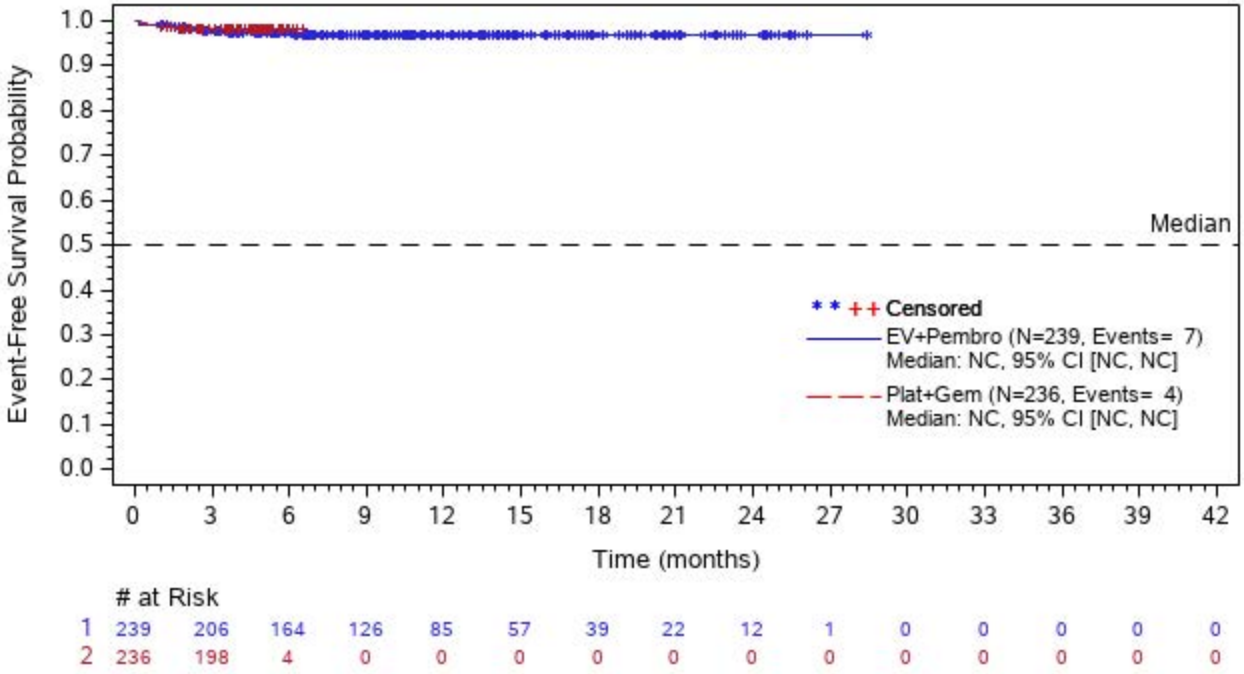
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.123.1.1: Kaplan-Meier Plot of Time to first TEAE - Hyperhidrosis (PT) - Analysis Set mSAF 1



at Risk

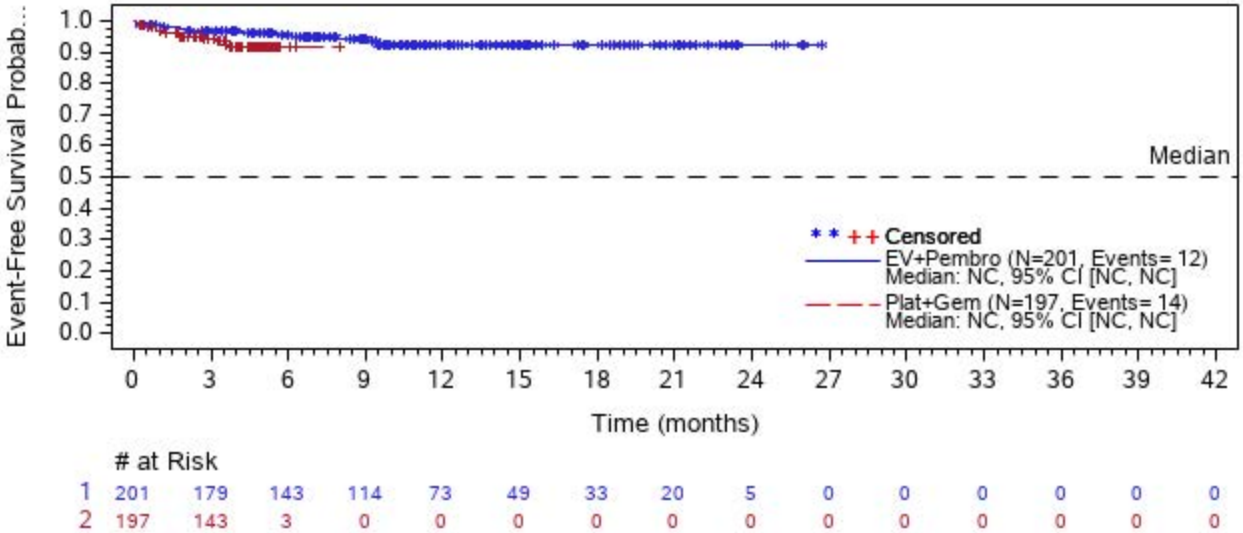
1	239	206	164	126	85	57	39	22	12	1	0	0	0	0	0
2	236	198	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.123.2.1: Kaplan-Meier Plot of Time to first TESAE - Urinary tract infection (PT) - Analysis Set mSAF 2



at Risk

1	201	179	143	114	73	49	33	20	5	0	0	0	0	0	0
2	197	143	3	0	0	0	0	0	0	0	0	0	0	0	0

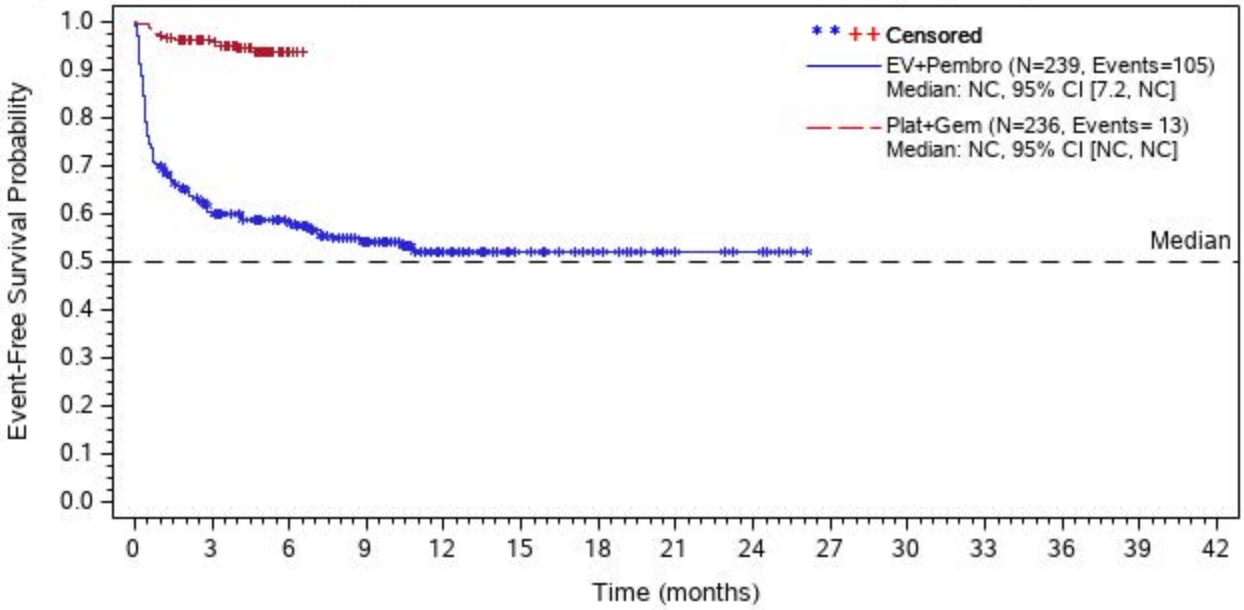
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TESAE=treatment-emergent serious adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.124.1.1: Kaplan-Meier Plot of Time to first TEAE - Pruritus (PT) - Analysis Set mSAF 1



at Risk

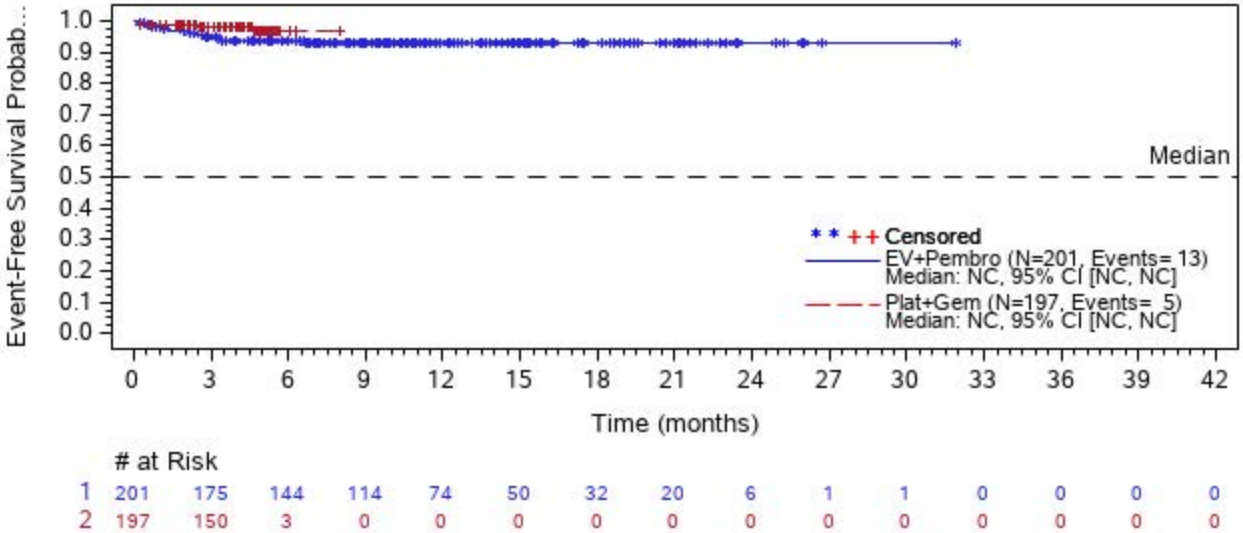
1	239	124	98	70	41	23	16	7	5	0	0	0	0	0	0
2	236	191	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.124.2.1: Kaplan-Meier Plot of Time to first TESAE - Metabolism and nutrition disorders (SOC) - Analysis Set mSAF 2



at Risk

1	201	175	144	114	74	50	32	20	6	1	1	0	0	0	0
2	197	150	3	0	0	0	0	0	0	0	0	0	0	0	0

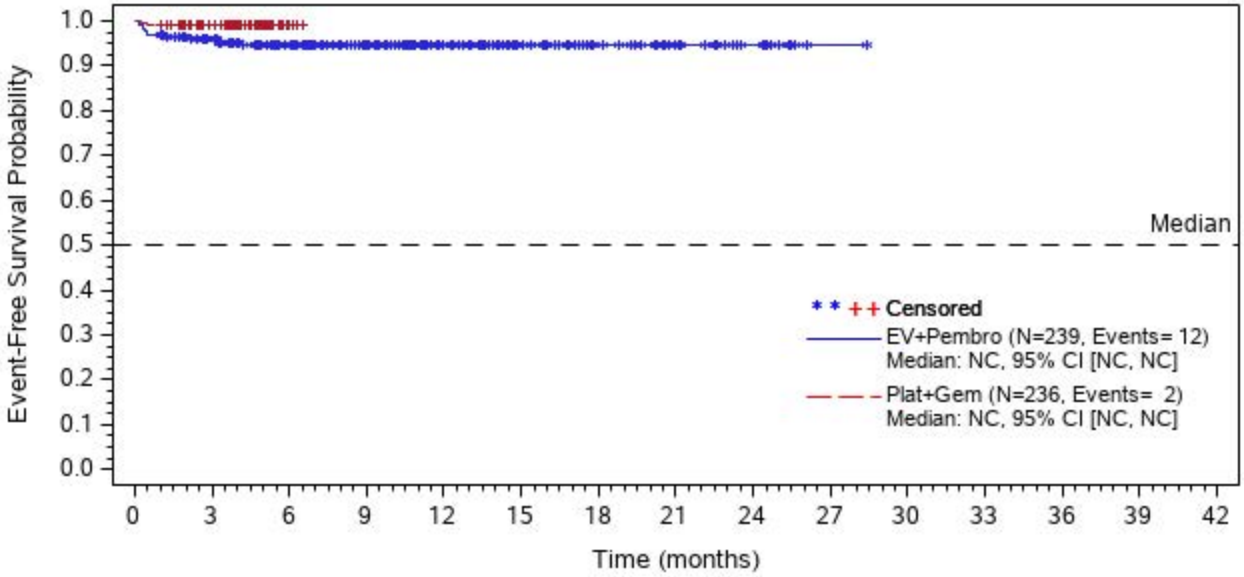
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.125.1.1: Kaplan-Meier Plot of Time to first TEAE - Rash erythematous (PT) - Analysis Set mSAF 1



at Risk

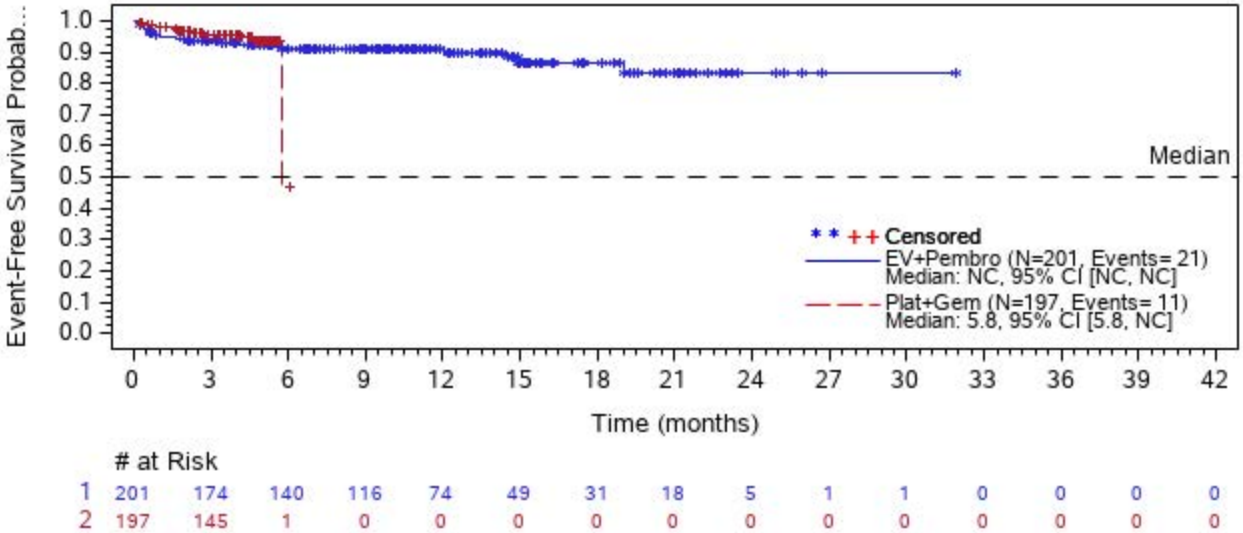
1	239	202	158	123	84	55	36	21	11	1	0	0	0	0	0
2	236	198	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.125.2.1: Kaplan-Meier Plot of Time to first TESAE - Renal and urinary disorders (SOC) - Analysis Set mSAF 2



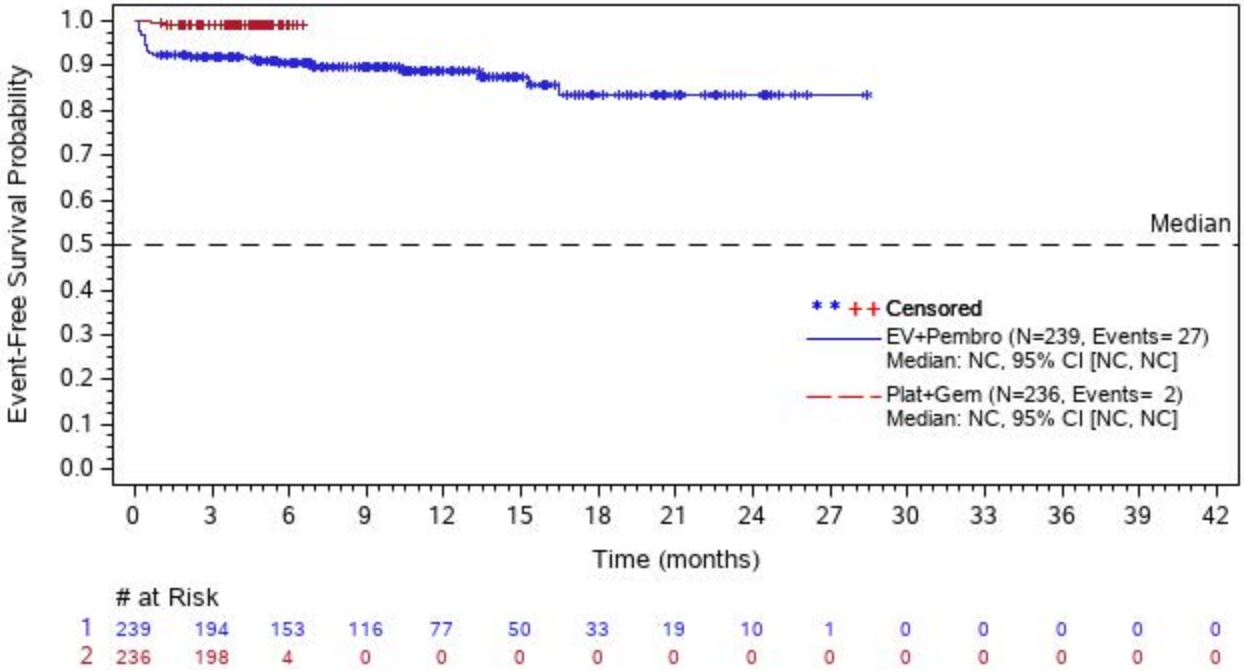
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.126.1.1: Kaplan-Meier Plot of Time to first TEAE - Rash macular (PT) - Analysis Set mSAF 1



at Risk

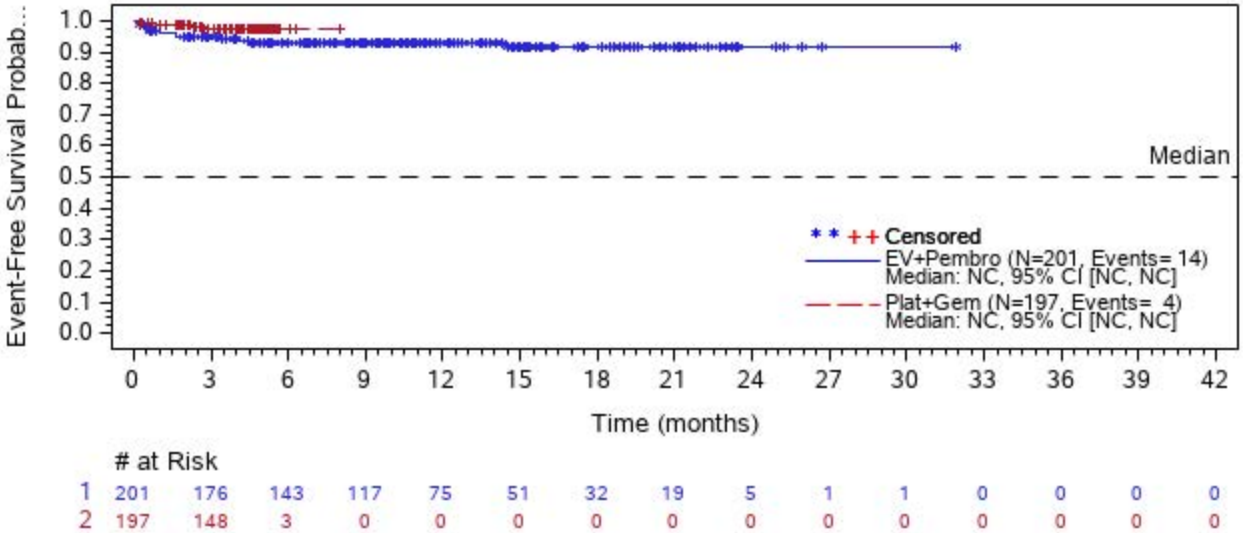
1	239	194	153	116	77	50	33	19	10	1	0	0	0	0	0
2	236	198	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.126.2.1: Kaplan-Meier Plot of Time to first TESAE - Acute kidney injury (PT) - Analysis Set mSAF 2



at Risk

1	201	176	143	117	75	51	32	19	5	1	1	0	0	0	0
2	197	148	3	0	0	0	0	0	0	0	0	0	0	0	0

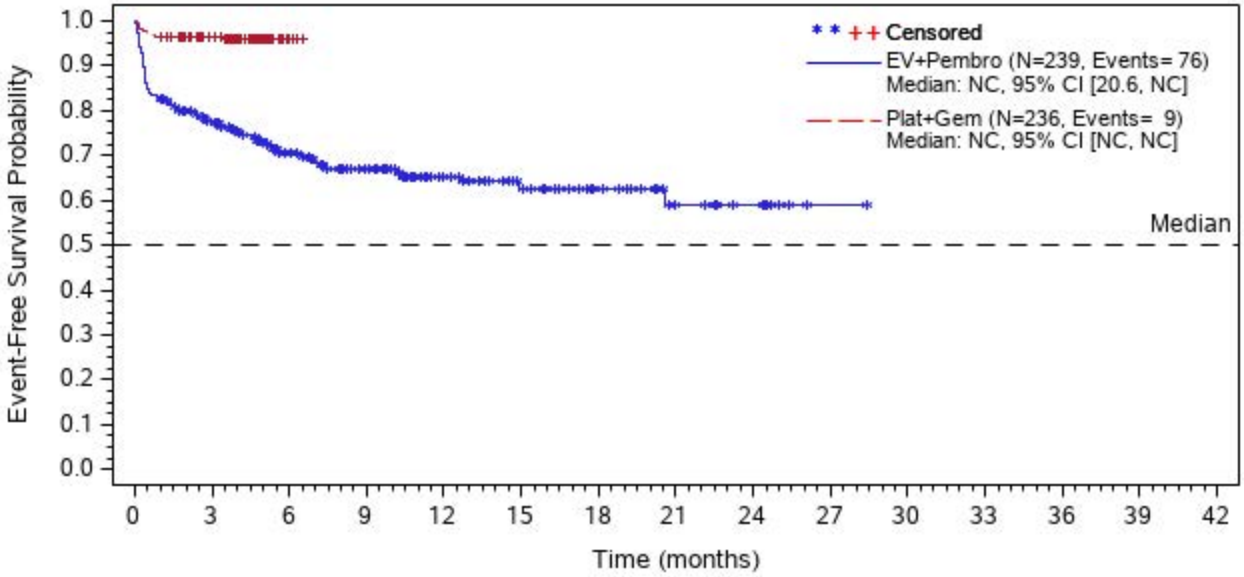
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TESAE=treatment-emergent serious adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.127.1.1: Kaplan-Meier Plot of Time to first TEAE - Rash maculo-papular (PT) - Analysis Set mSAF 1



at Risk

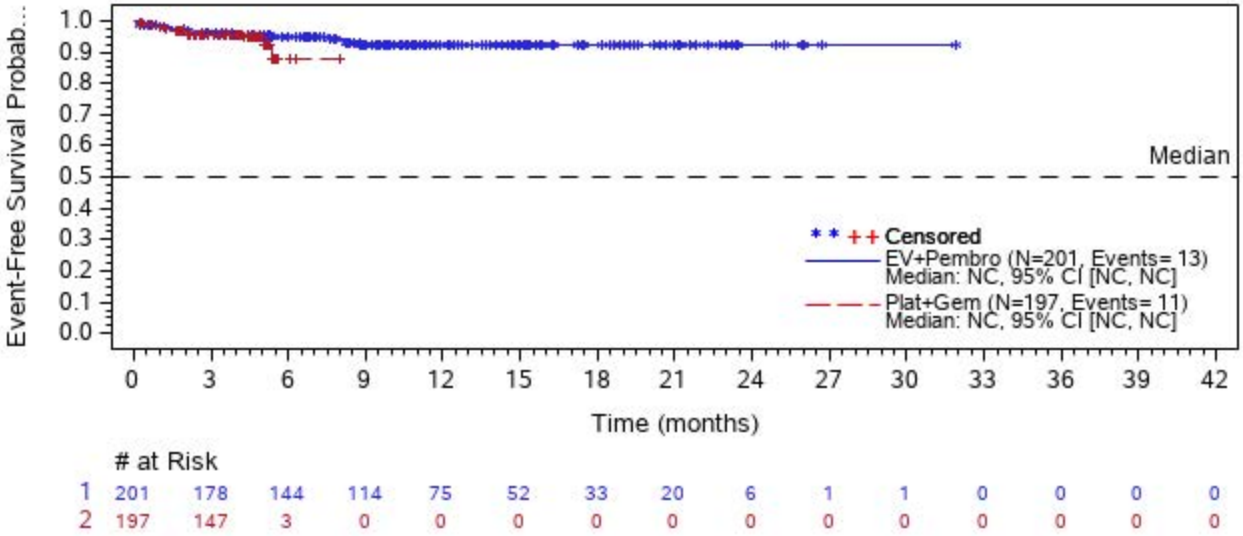
1	239	162	113	87	55	39	28	15	10	1	0	0	0	0	0
2	236	192	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.127.2.1: Kaplan-Meier Plot of Time to first TESAE - Respiratory, thoracic and mediastinal disorders (SOC) - Analysis Set mSAF 2



at Risk

1	201	178	144	114	75	52	33	20	6	1	1	0	0	0	0
2	197	147	3	0	0	0	0	0	0	0	0	0	0	0	0

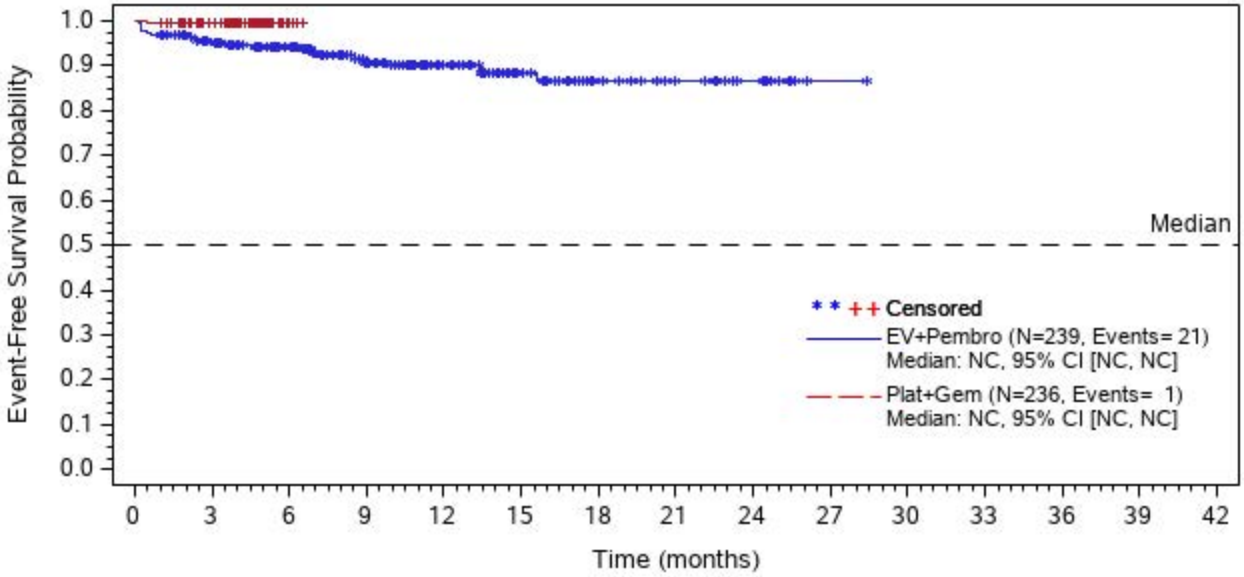
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.128.1.1: Kaplan-Meier Plot of Time to first TEAE - Rash papular (PT) - Analysis Set mSAF 1



at Risk

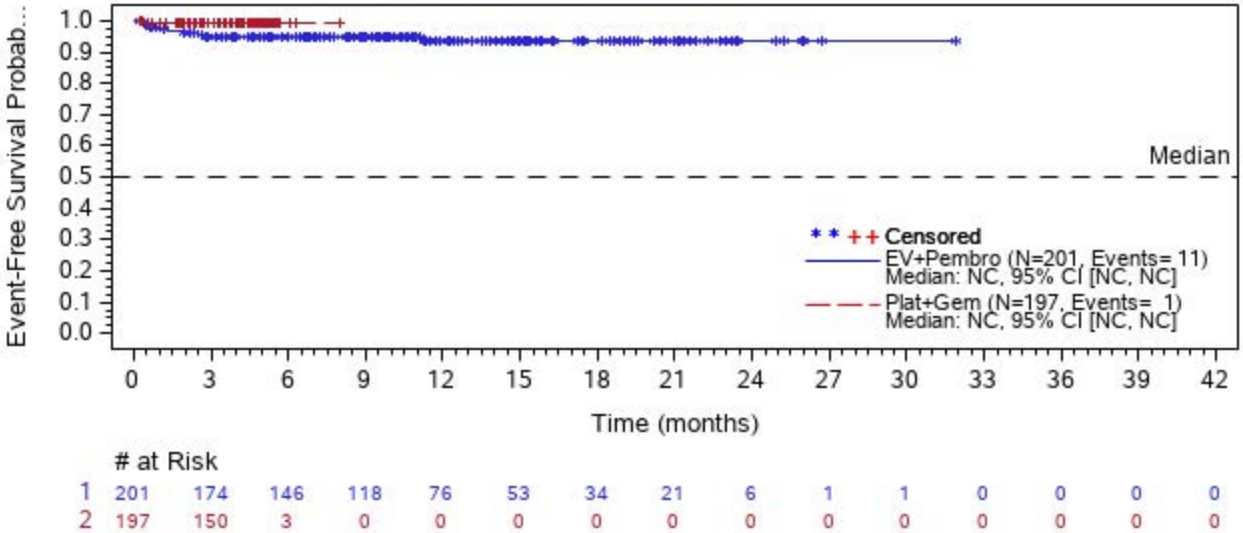
1	239	200	159	117	78	49	30	19	12	1	0	0	0	0	0
2	236	199	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.128.2.1: Kaplan-Meier Plot of Time to first TESAE - Skin and subcutaneous tissue disorders (SOC) - Analysis Set mSAF 2



at Risk

1	201	174	146	118	76	53	34	21	6	1	1	0	0	0	0
2	197	150	3	0	0	0	0	0	0	0	0	0	0	0	0

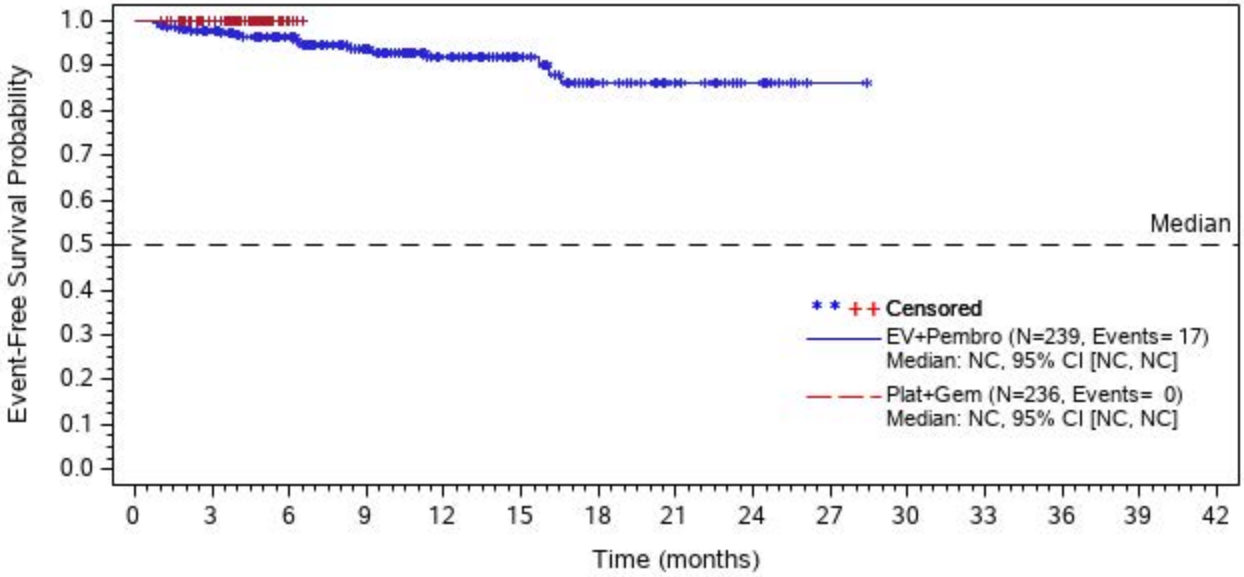
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.129.1.1: Kaplan-Meier Plot of Time to first TEAE - Skin hyperpigmentation (PT) - Analysis Set mSAF 1



at Risk

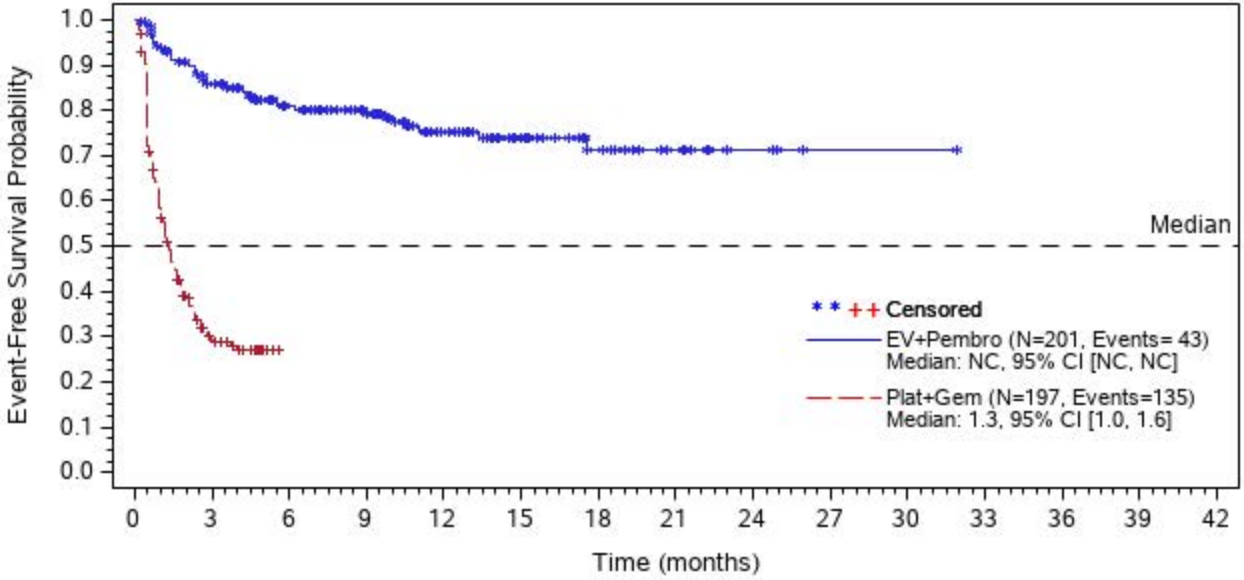
1	239	206	163	123	80	54	33	20	11	1	0	0	0	0	0
2	236	200	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.129.2.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Blood and lymphatic system disorders (SOC) - Analysis Set mSAF 2



at Risk

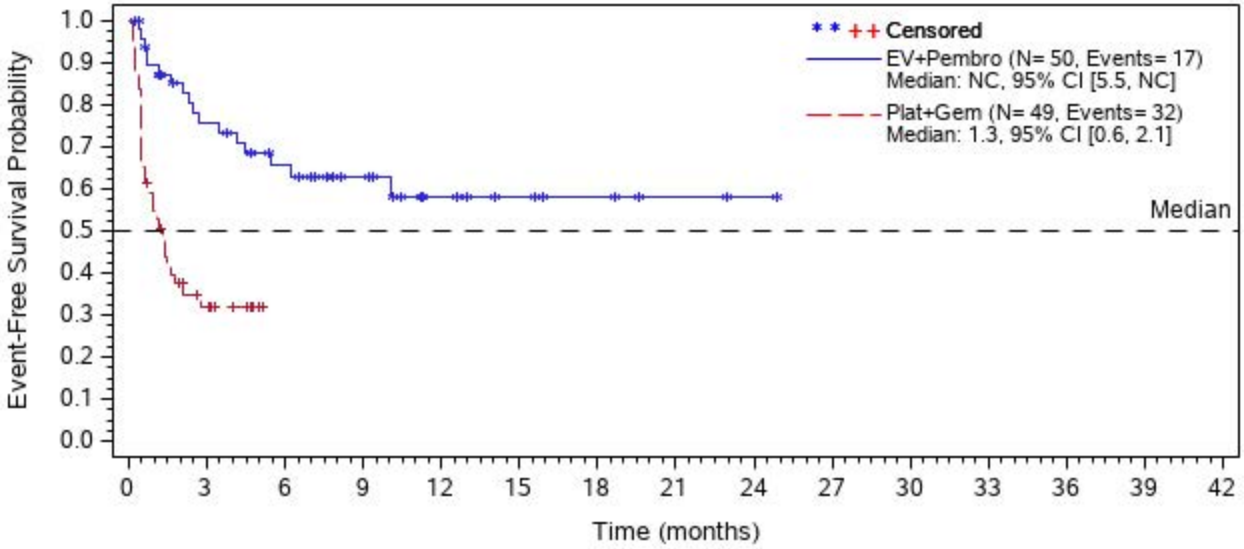
1	201	152	118	96	63	44	24	14	5	1	1	0	0	0	0
2	197	44	0	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.129.2.2.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Blood and lymphatic system disorders (SOC) - Analysis Set mSAF 2
Liver Metastases: Present



at Risk

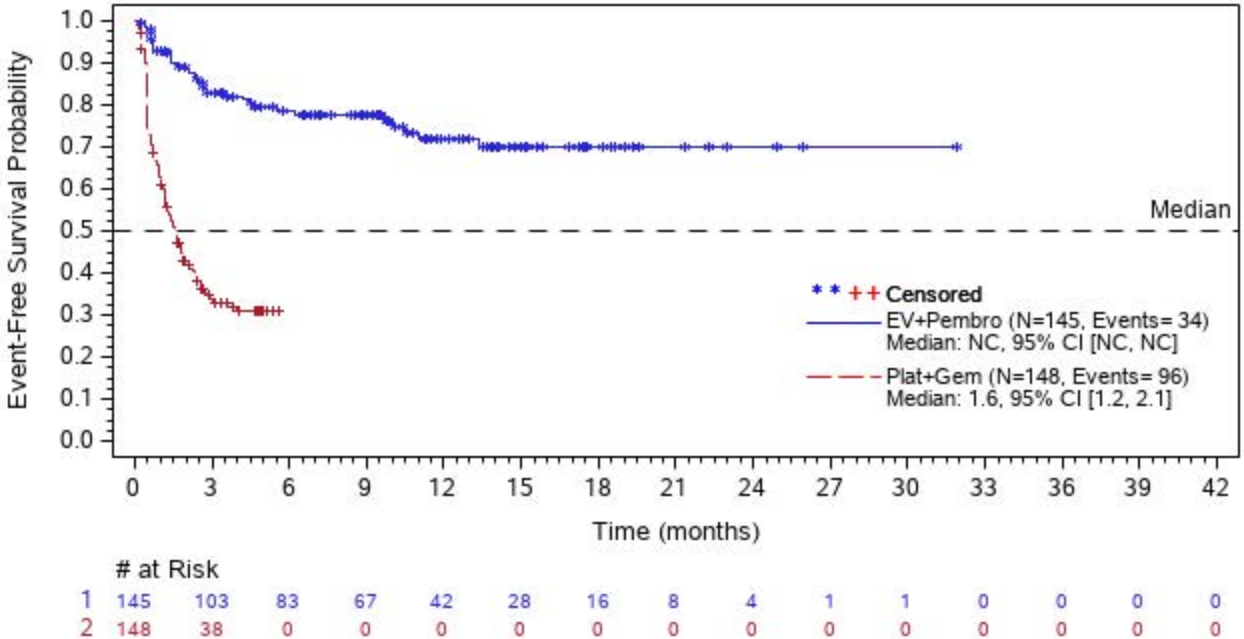
1	50	32	23	16	9	6	4	2	1	0	0	0	0	0	0
2	49	11	0	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.129.2.2.4: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Blood and lymphatic system disorders (SOC) - Analysis Set mSAF 2
Sex: Male



at Risk

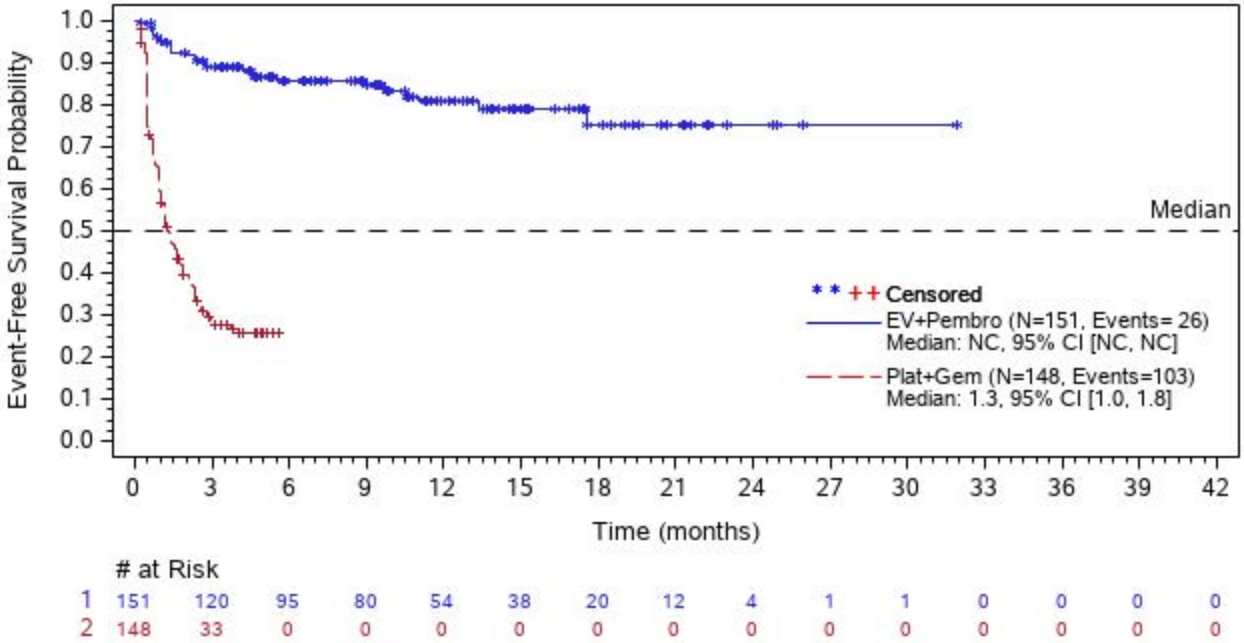
1	145	103	83	67	42	28	16	8	4	1	1	0	0	0	0
2	148	38	0	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.129.2.2.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Blood and lymphatic system disorders (SOC) - Analysis Set mSAF 2
Liver Metastases: Absent



at Risk

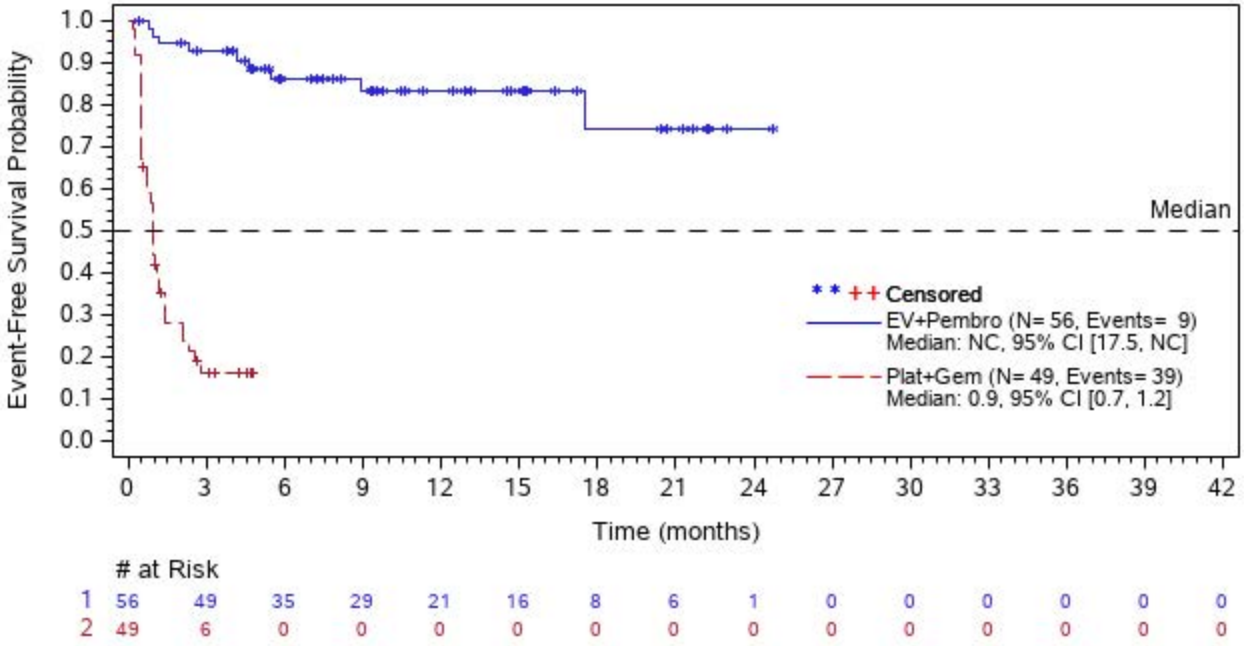
1	151	120	95	80	54	38	20	12	4	1	1	0	0	0	0
2	148	33	0	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.129.2.2.4: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Blood and lymphatic system disorders (SOC) - Analysis Set mSAF 2
Sex: Female



at Risk

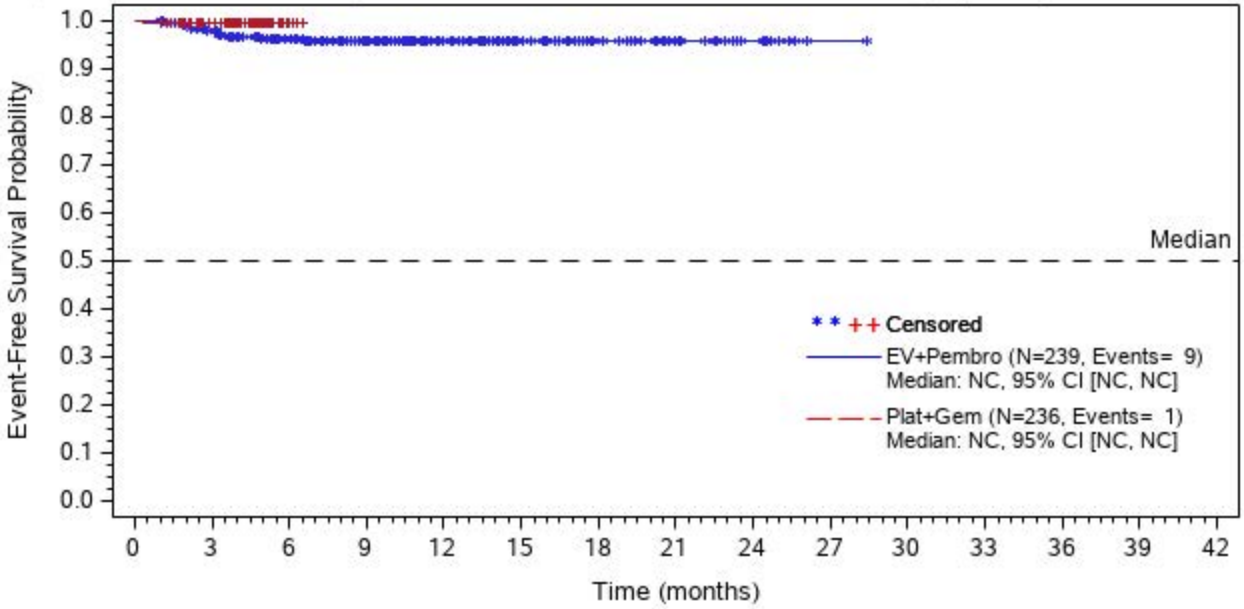
1	56	49	35	29	21	16	8	6	1	0	0	0	0	0	0
2	49	6	0	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.130.1.1: Kaplan-Meier Plot of Time to first TEAE - Skin ulcer (PT) - Analysis Set mSAF 1



at Risk

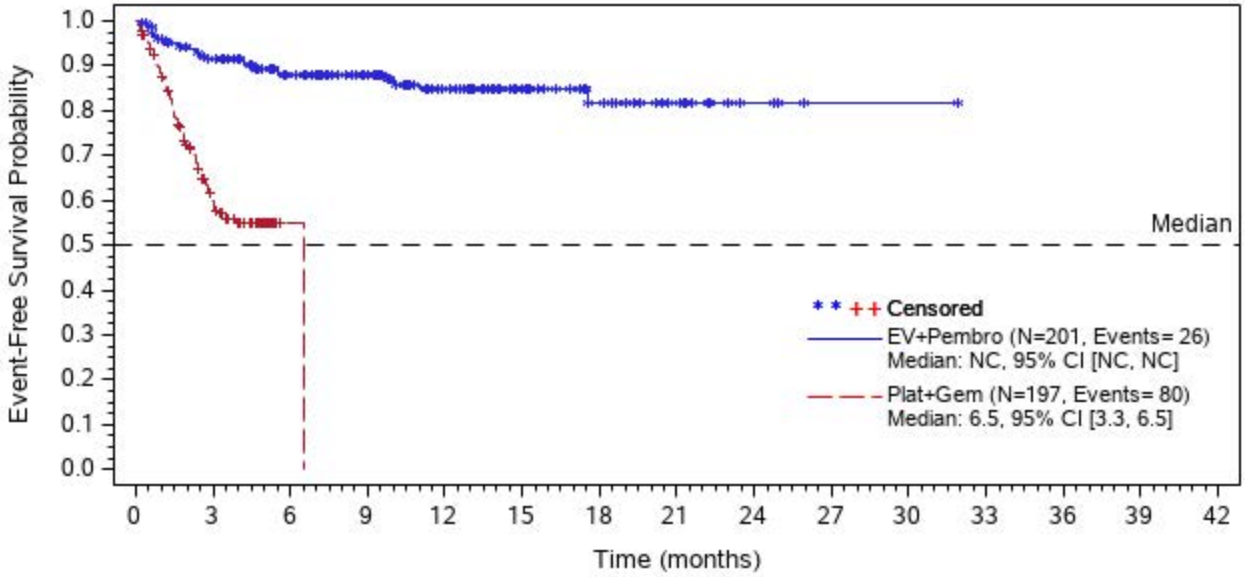
1	239	207	164	127	84	56	38	21	11	1	0	0	0	0	0
2	236	199	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.130.2.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Anaemia (PT) - Analysis Set mSAF 2



at Risk

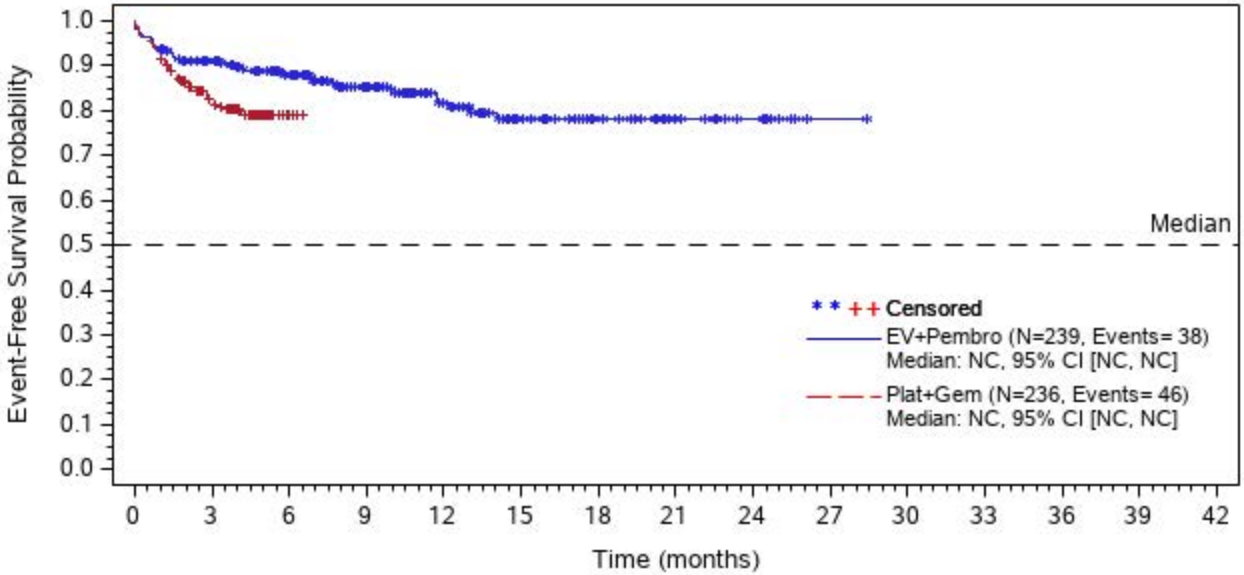
1	201	161	128	102	69	47	27	16	5	1	1	0	0	0	0
2	197	93	1	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.131.1.1: Kaplan-Meier Plot of Time to first TEAE - Vascular disorders (SOC) - Analysis Set mSAF 1



at Risk

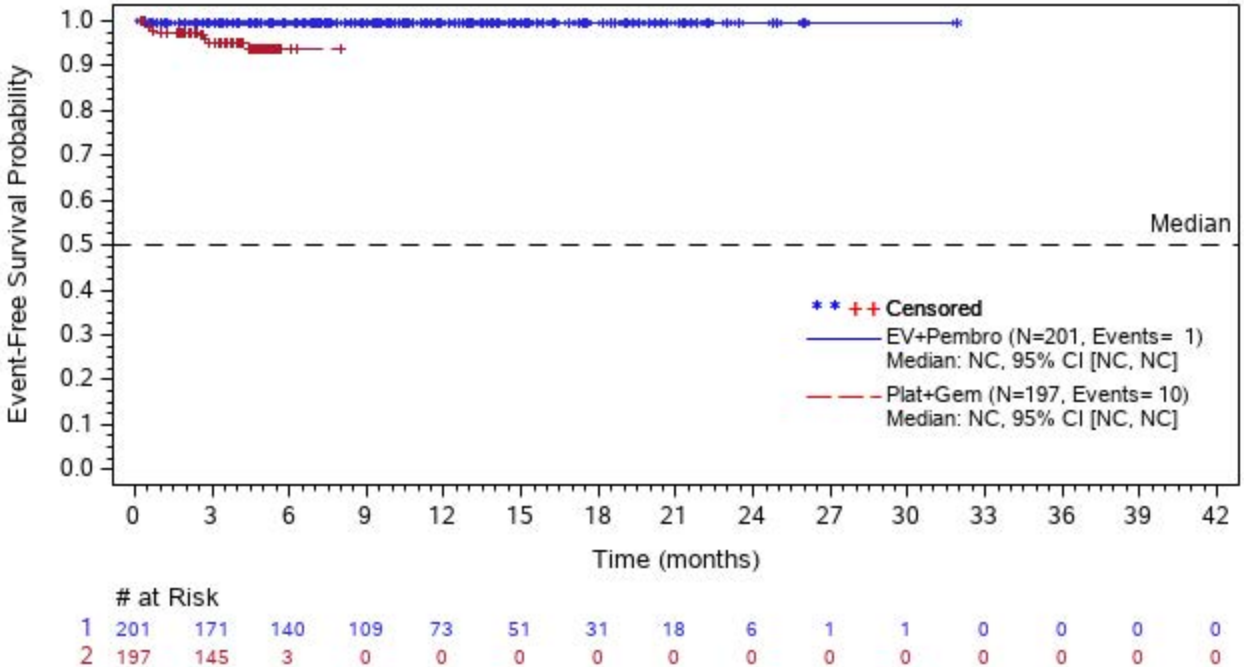
1	239	192	153	113	76	48	33	17	10	1	0	0	0	0	0
2	236	166	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.131.2.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Febrile neutropenia (PT) - Analysis Set mSAF 2



at Risk

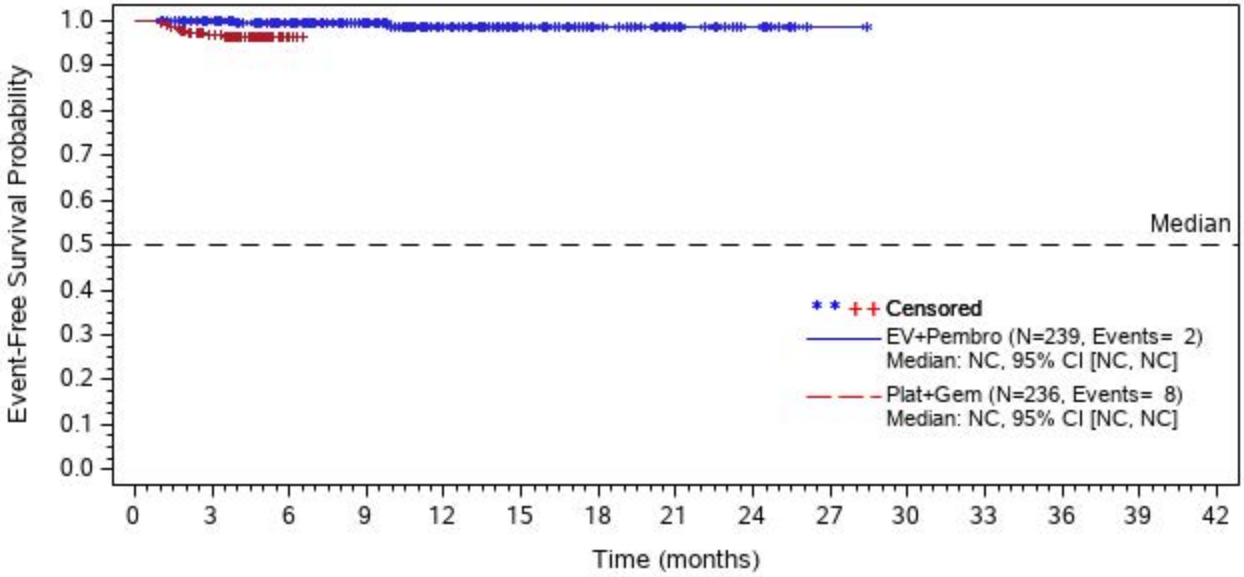
1	201	171	140	109	73	51	31	18	6	1	1	0	0	0	0
2	197	145	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.132.1.1: Kaplan-Meier Plot of Time to first TEAE - Deep vein thrombosis (PT) - Analysis Set mSAF 1



at Risk

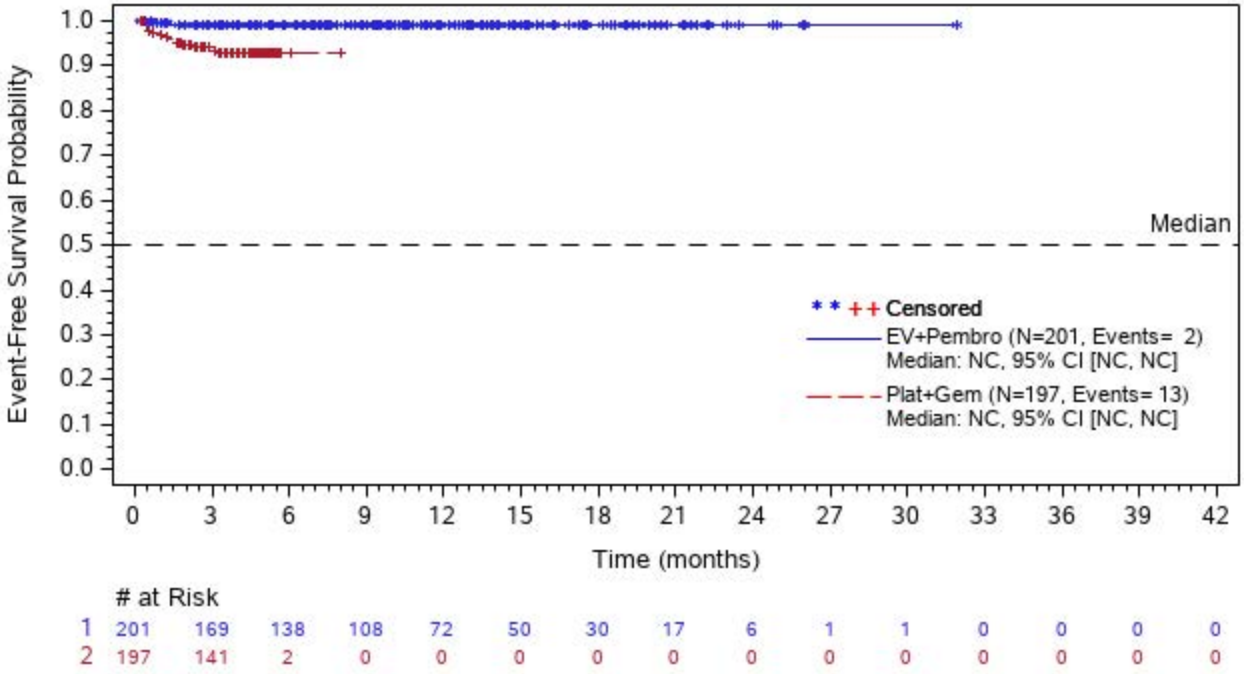
1	239	211	169	131	87	58	39	22	12	1	0	0	0	0	0
2	236	194	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.132.2.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Leukopenia (PT) - Analysis Set mSAF 2



at Risk

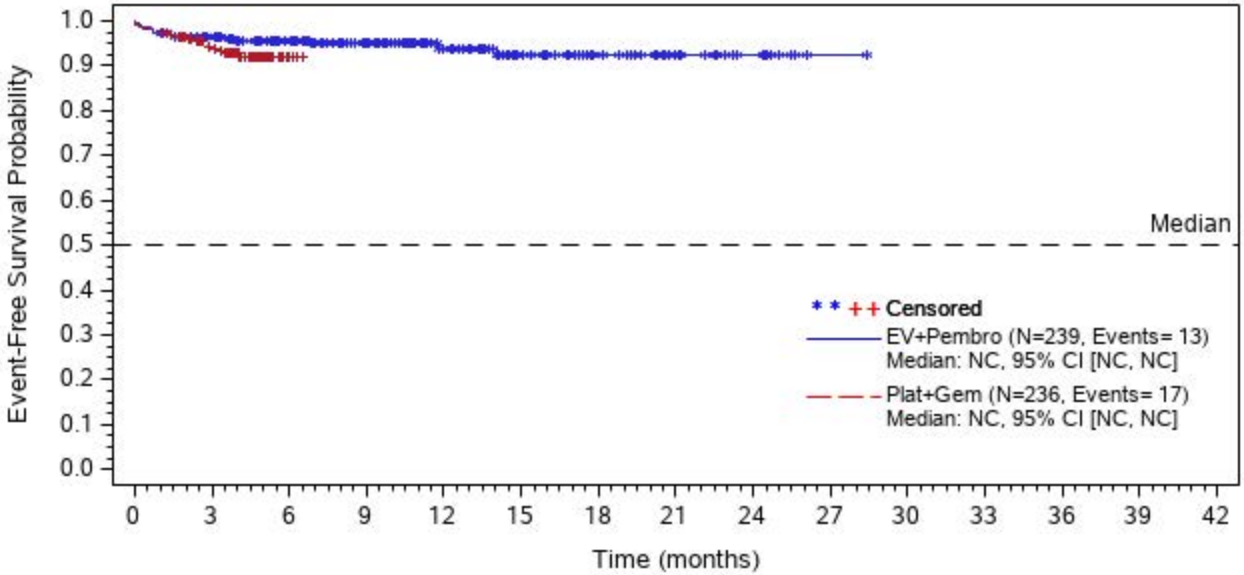
1	201	169	138	108	72	50	30	17	6	1	1	0	0	0	0
2	197	141	2	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.133.1.1: Kaplan-Meier Plot of Time to first TEAE - Hypertension (PT) - Analysis Set mSAF 1



at Risk

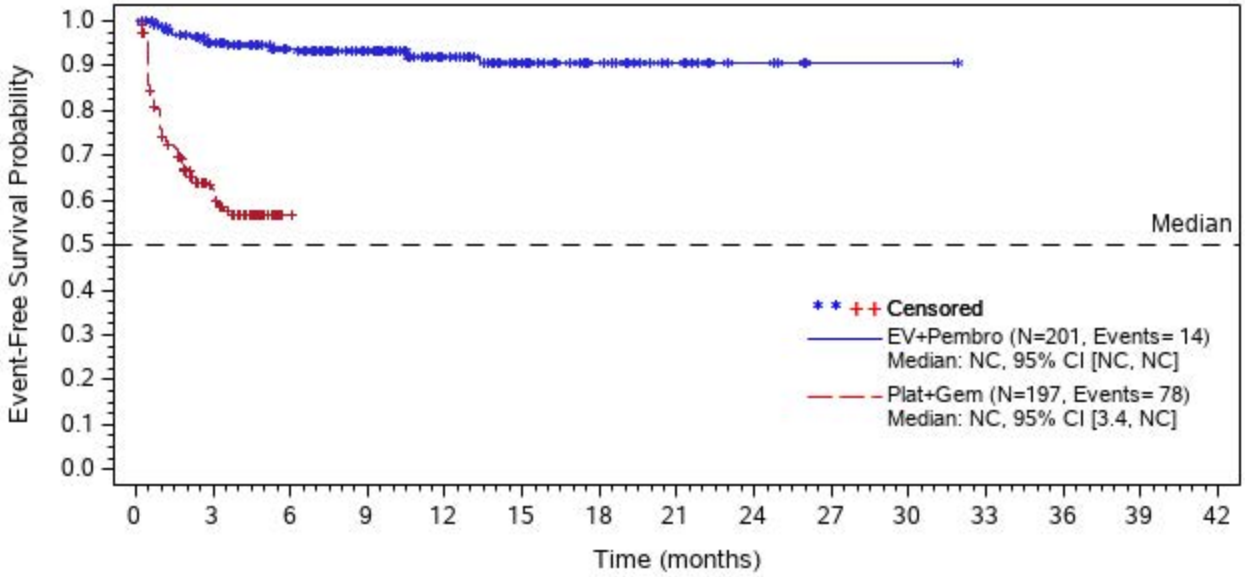
1	239	203	162	124	83	54	37	20	11	1	0	0	0	0	0
2	236	189	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.133.2.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Neutropenia (PT) - Analysis Set mSAF 2



at Risk

1	201	164	132	104	67	48	28	16	6	1	1	0	0	0	0
2	197	91	1	0	0	0	0	0	0	0	0	0	0	0	0

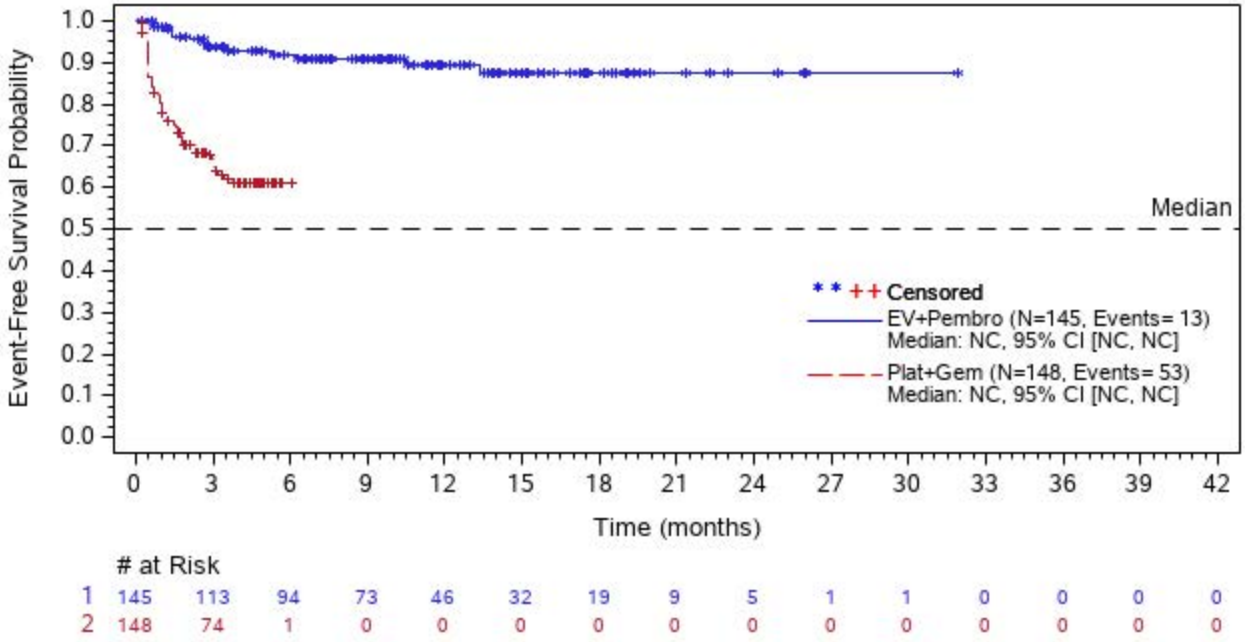
Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.133.2.2.4: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Neutropenia (PT) - Analysis Set mSAF 2

Sex: Male



at Risk

1	145	113	94	73	46	32	19	9	5	1	1	0	0	0	0
2	148	74	1	0	0	0	0	0	0	0	0	0	0	0	0

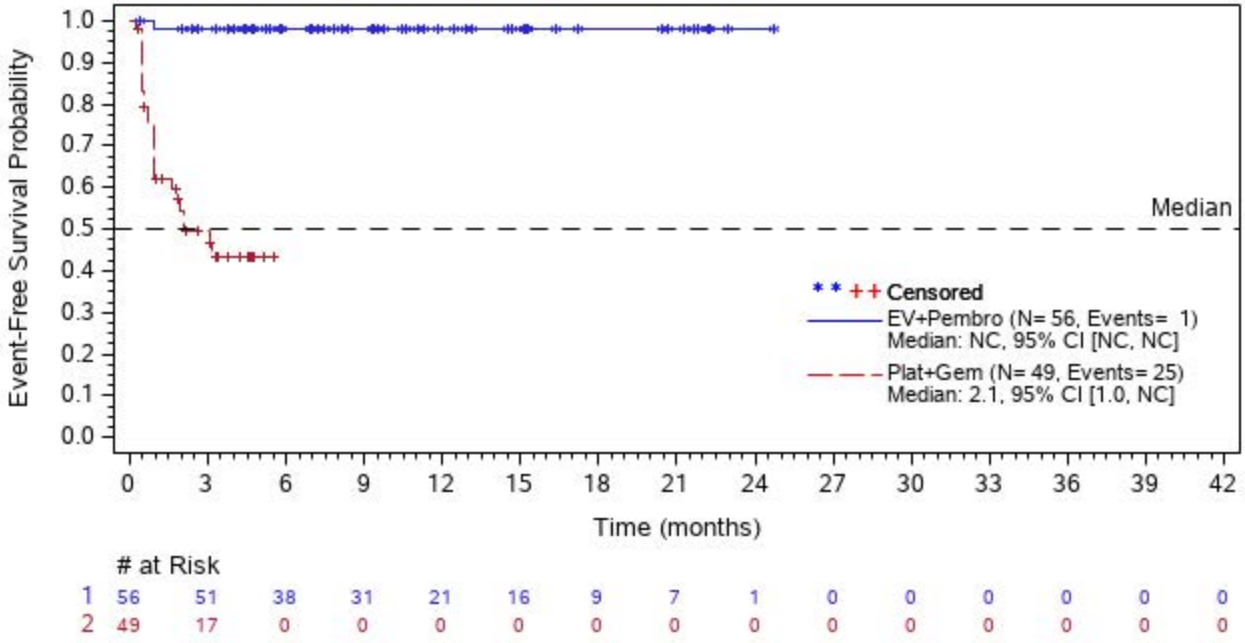
Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.133.2.2.4: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Neutropenia (PT) - Analysis Set mSAF 2

Sex: Female



at Risk

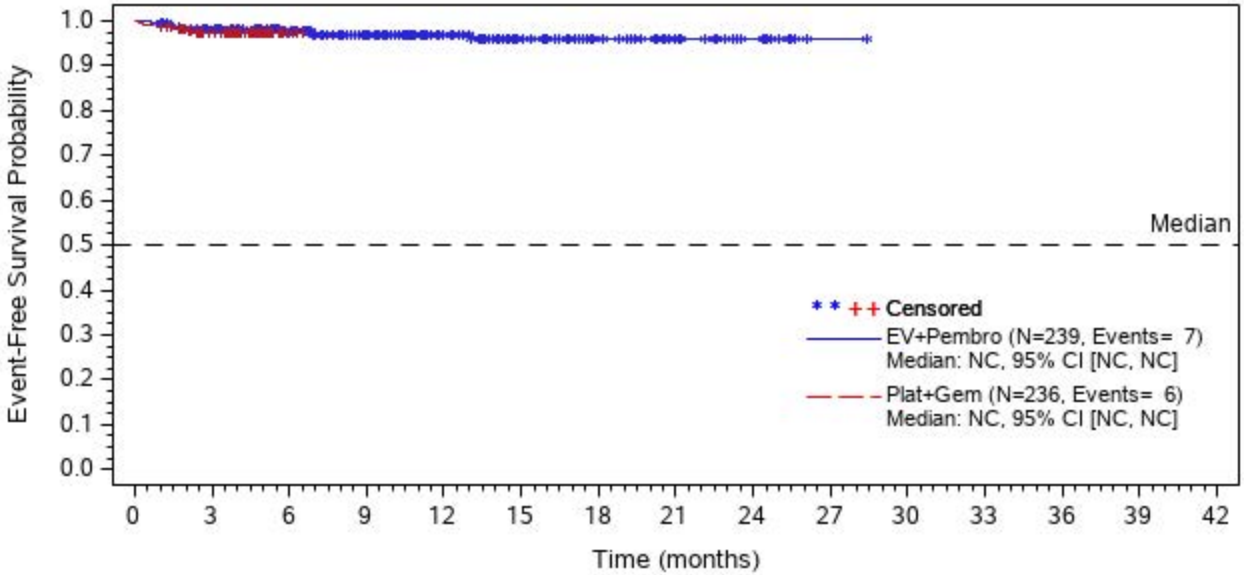
1	56	51	38	31	21	16	9	7	1	0	0	0	0	0	0
2	49	17	0	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.134.1.1: Kaplan-Meier Plot of Time to first TEAE - Hypotension (PT) - Analysis Set mSAF 1



at Risk

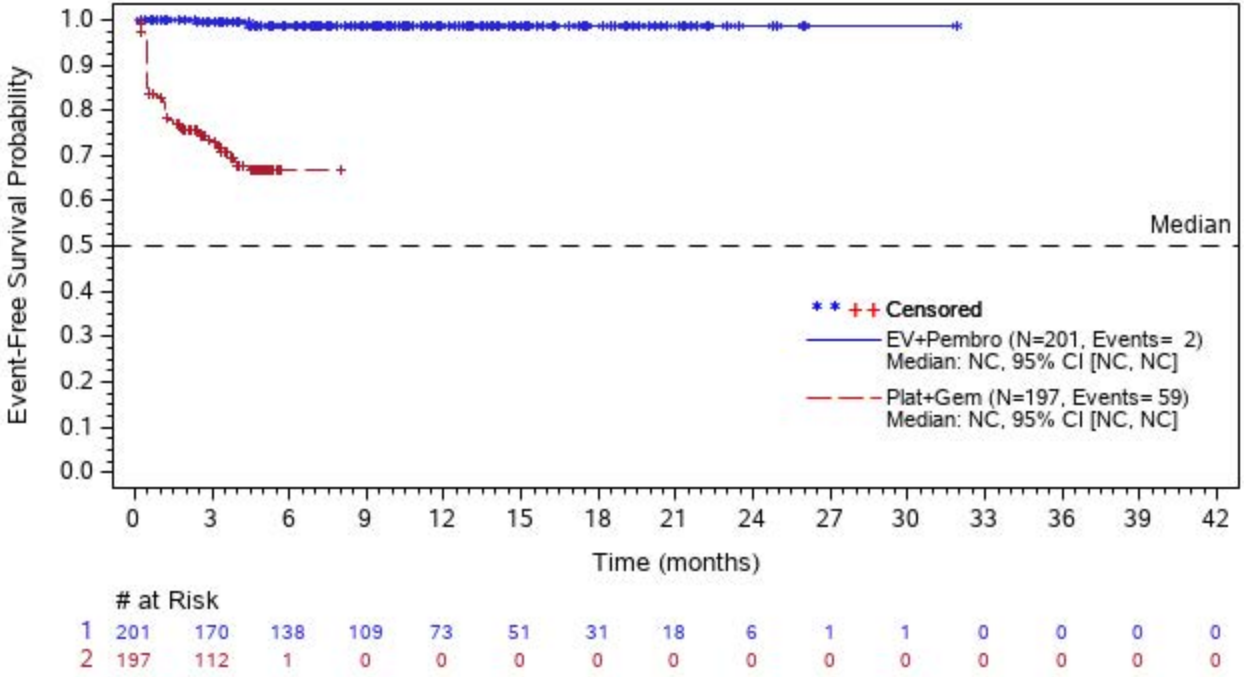
1	239	209	168	130	87	57	39	22	12	1	0	0	0	0	0
2	236	195	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.134.2.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Thrombocytopenia (PT) - Analysis Set mSAF 2



at Risk

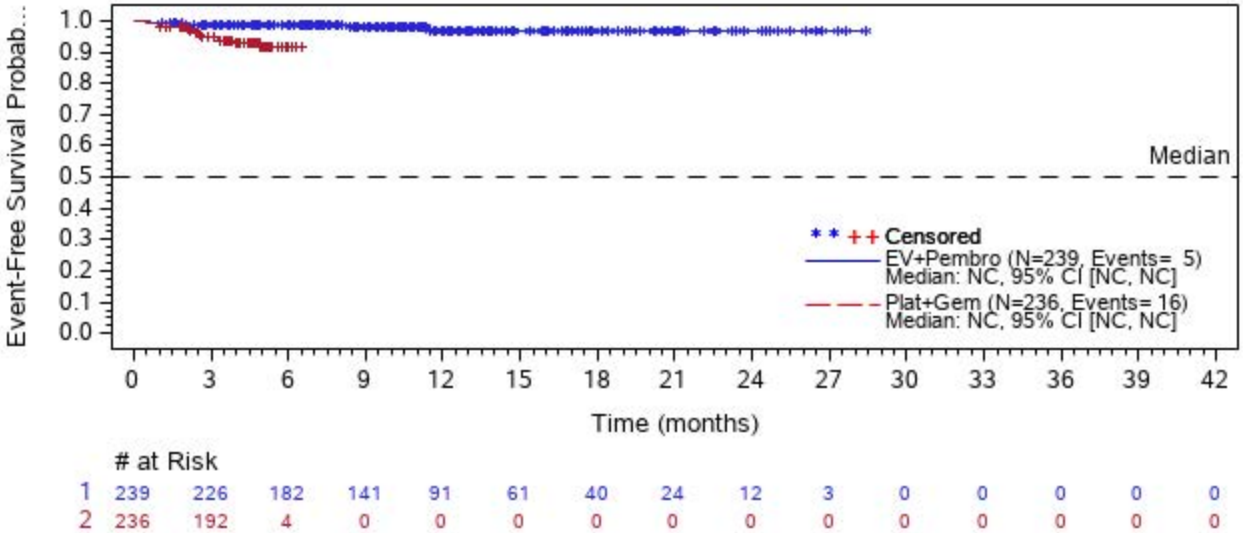
1	201	170	138	109	73	51	31	18	6	1	1	0	0	0	0
2	197	112	1	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.135.1.1: Kaplan-Meier Plot of Time to first TESAE - Blood and lymphatic system disorders (SOC) - Analysis Set mSAF 1



at Risk

1	239	226	182	141	91	61	40	24	12	3	0	0	0	0	0
2	236	192	4	0	0	0	0	0	0	0	0	0	0	0	0

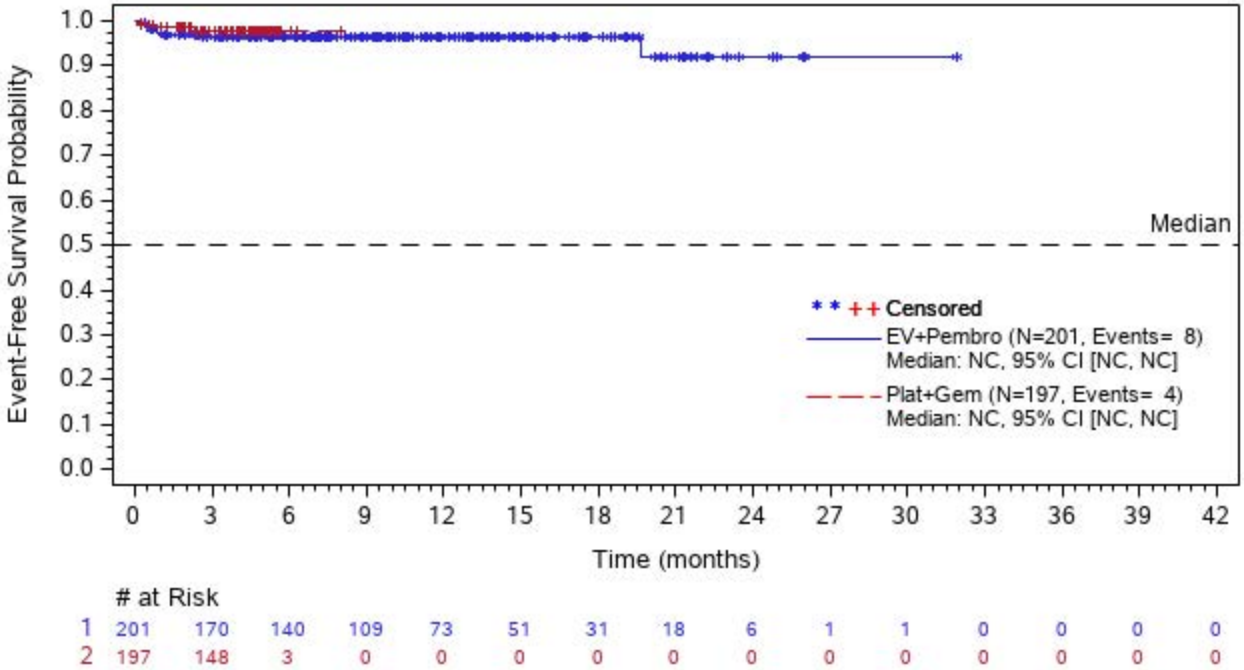
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.135.2.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Cardiac disorders (SOC) - Analysis Set mSAF 2



at Risk

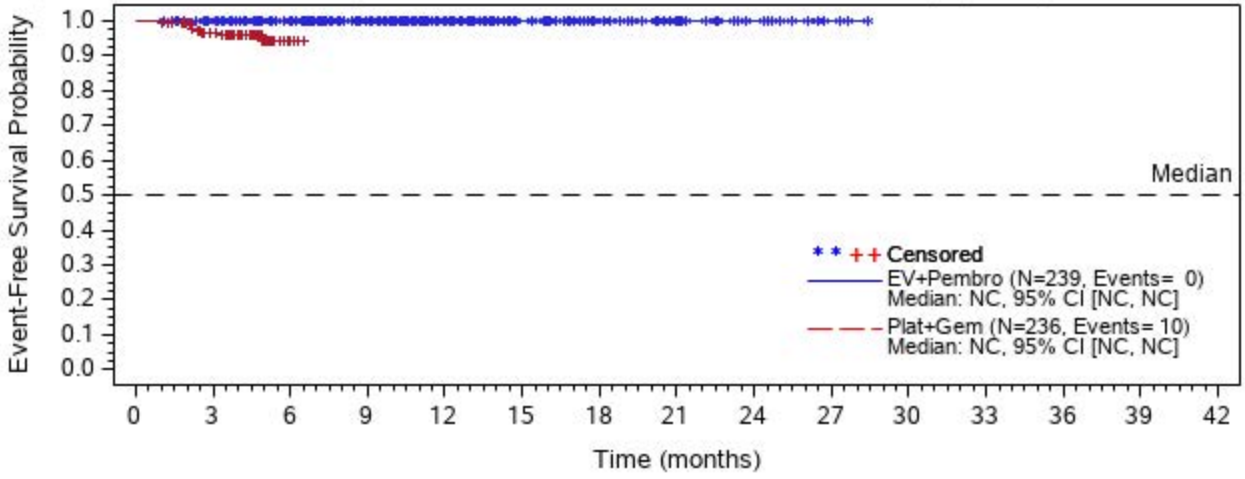
1	201	170	140	109	73	51	31	18	6	1	1	0	0	0	0
2	197	148	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.136.1.1: Kaplan-Meier Plot of Time to first TESAE - Anaemia (PT) - Analysis Set mSAF 1



at Risk

1	239	229	183	143	93	62	40	24	12	3	0	0	0	0	0
2	236	195	4	0	0	0	0	0	0	0	0	0	0	0	0

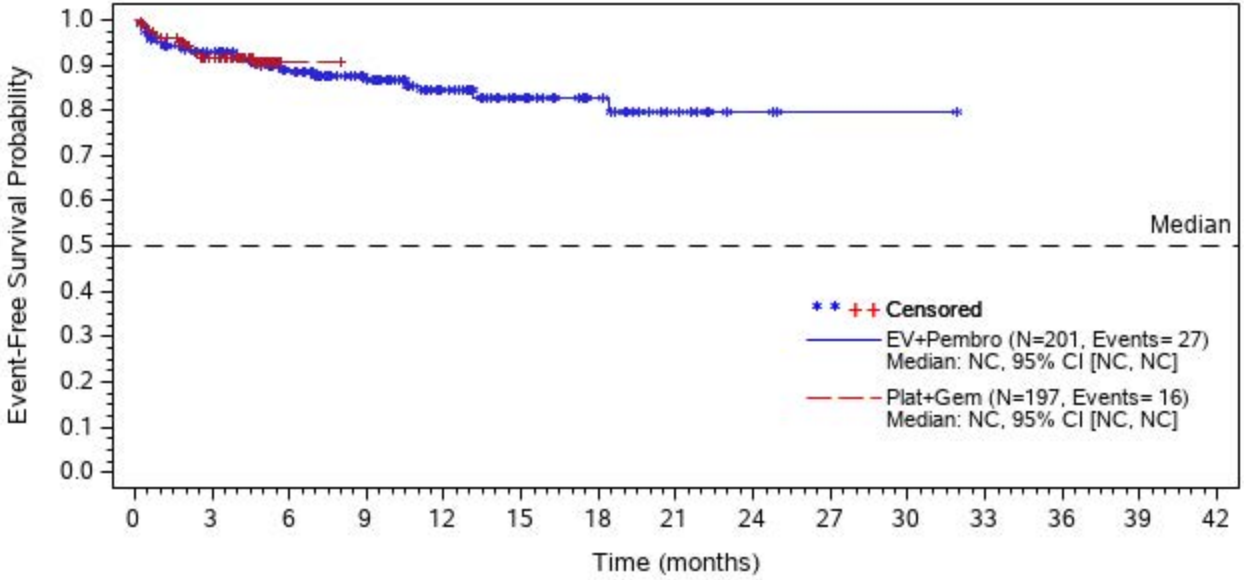
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TESAE=treatment-emergent serious adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.136.2.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Gastrointestinal disorders (SOC) - Analysis Set mSAF 2



at Risk

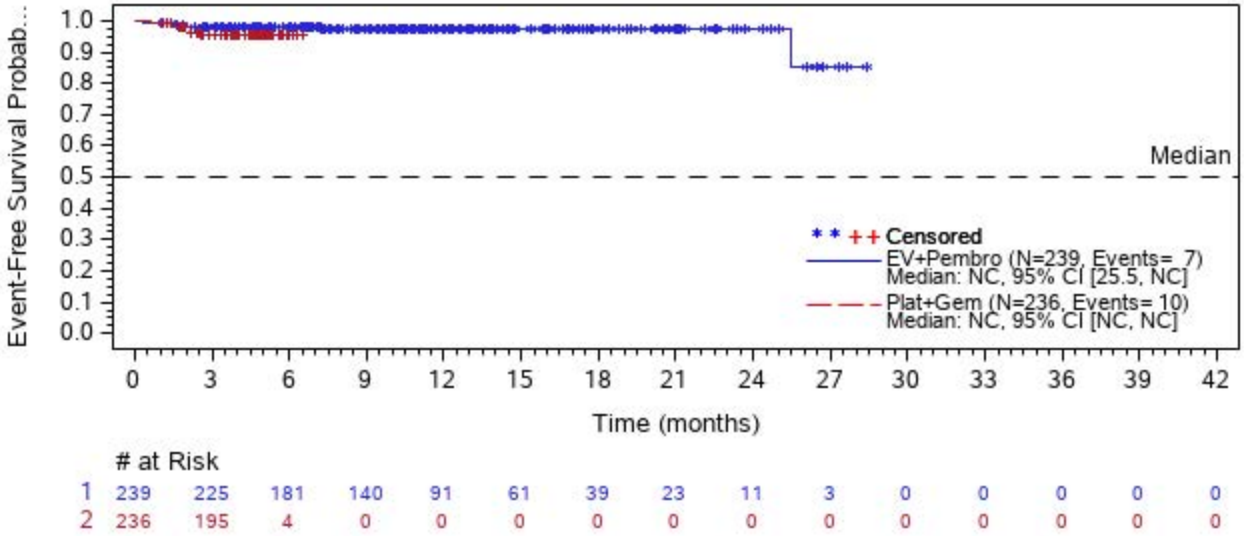
1	201	162	129	97	64	43	25	13	4	1	1	0	0	0	0
2	197	139	1	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.137.1.1: Kaplan-Meier Plot of Time to first TESAE - Cardiac disorders (SOC) - Analysis Set mSAF 1



at Risk

1	239	225	181	140	91	61	39	23	11	3	0	0	0	0	0
2	236	195	4	0	0	0	0	0	0	0	0	0	0	0	0

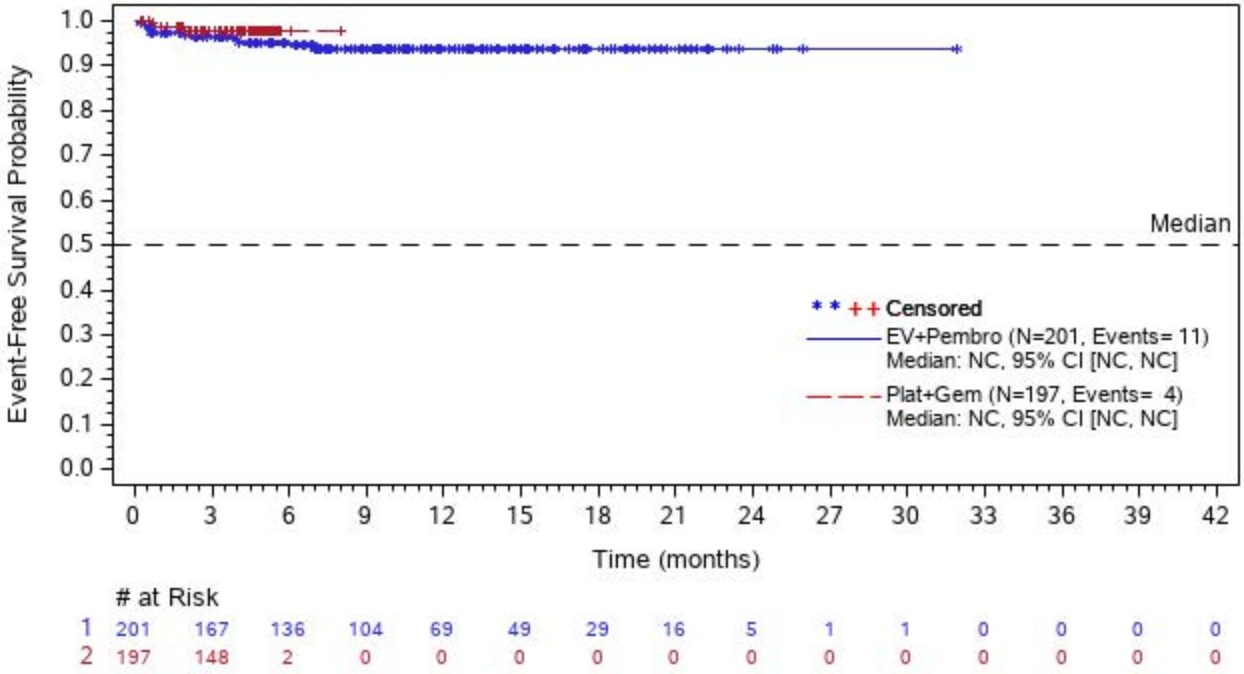
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.137.2.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Diarrhoea (PT) - Analysis Set mSAF 2



at Risk

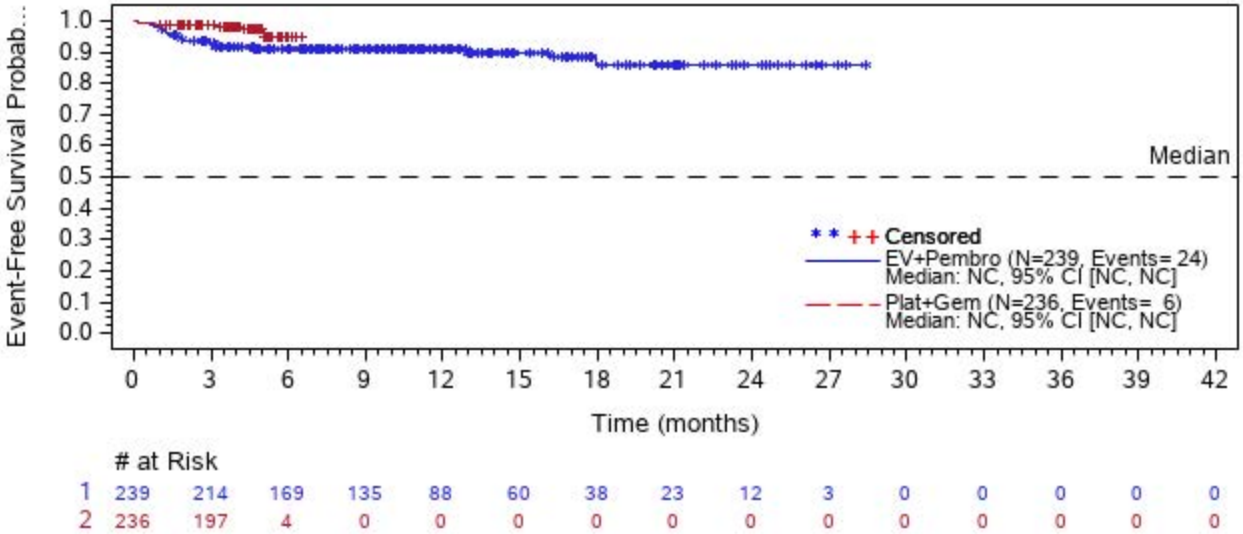
1	201	167	136	104	69	49	29	16	5	1	1	0	0	0	0
2	197	148	2	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.138.1.1: Kaplan-Meier Plot of Time to first TESAE - Gastrointestinal disorders (SOC) - Analysis Set mSAF 1



at Risk

1	239	214	169	135	88	60	38	23	12	3	0	0	0	0	0
2	236	197	4	0	0	0	0	0	0	0	0	0	0	0	0

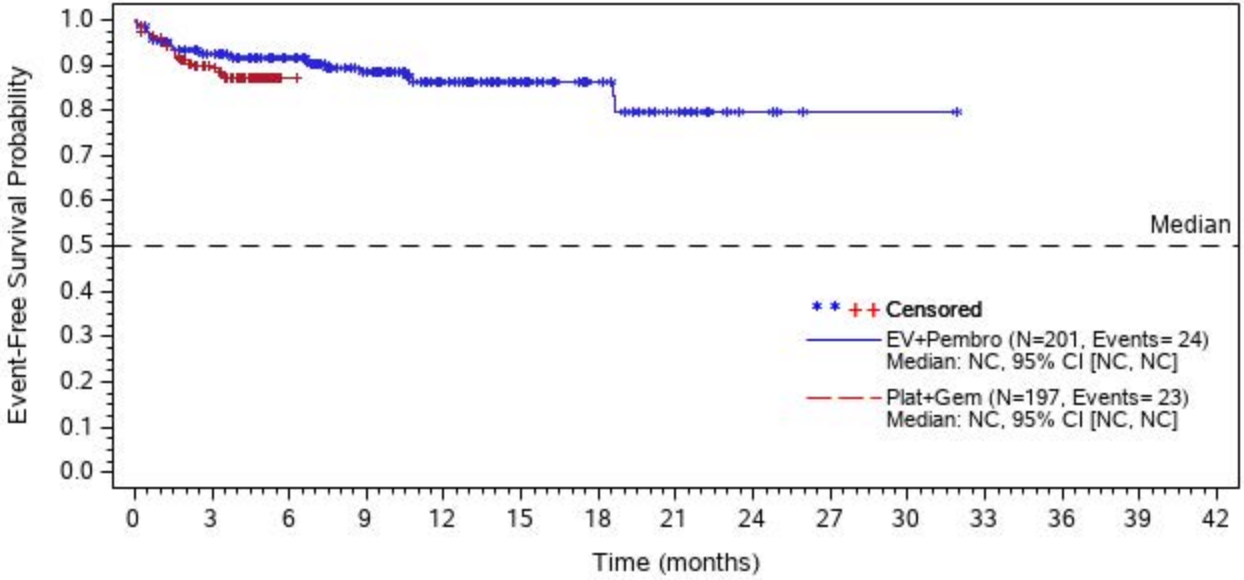
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.138.2.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - General disorders and administration site conditions (SOC) - Analysis Set mSAF 2



at Risk

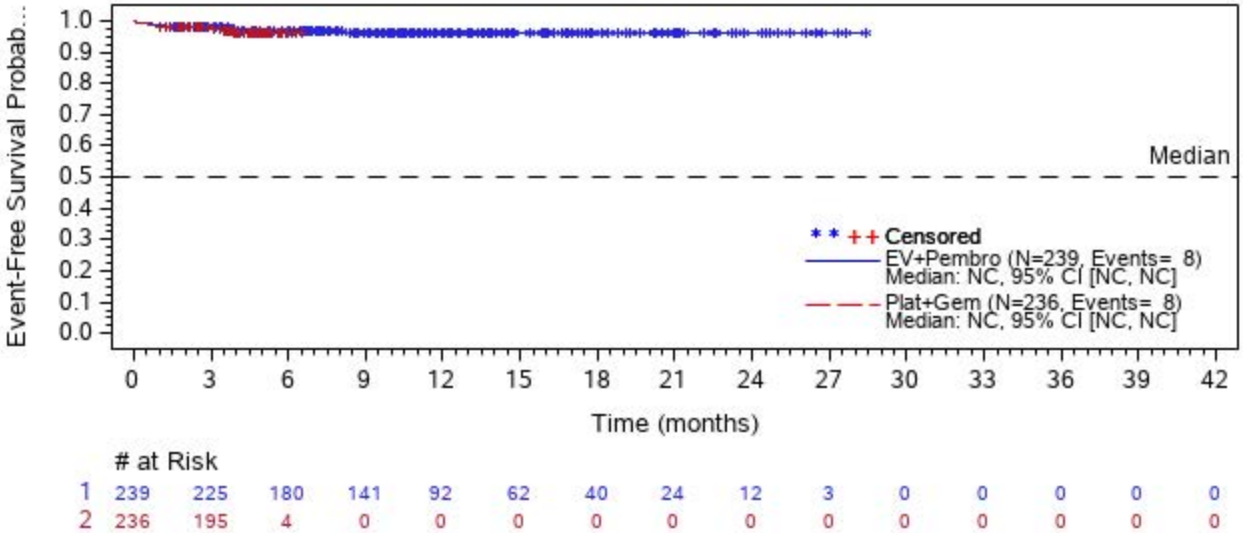
1	201	162	133	101	64	45	28	16	5	1	1	0	0	0	0
2	197	140	1	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.139.1.1: Kaplan-Meier Plot of Time to first TESAE - General disorders and administration site conditions (SOC) - Analysis Set mSAF 1



at Risk

1	239	225	180	141	92	62	40	24	12	3	0	0	0	0	0
2	236	195	4	0	0	0	0	0	0	0	0	0	0	0	0

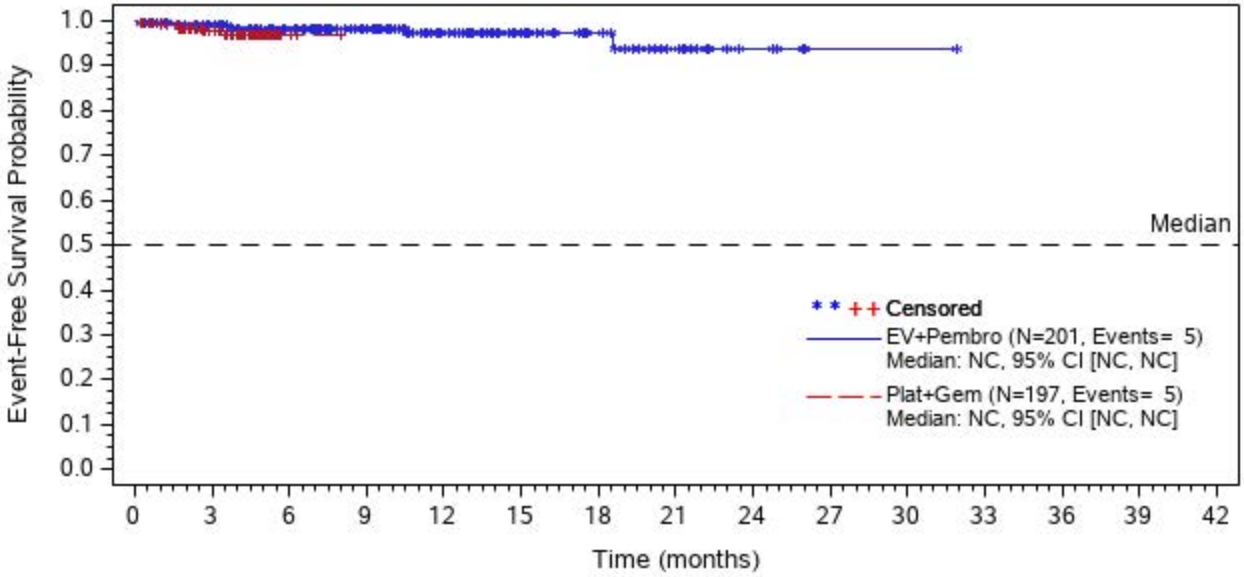
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.139.2.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Asthenia (PT) - Analysis Set mSAF 2



at Risk

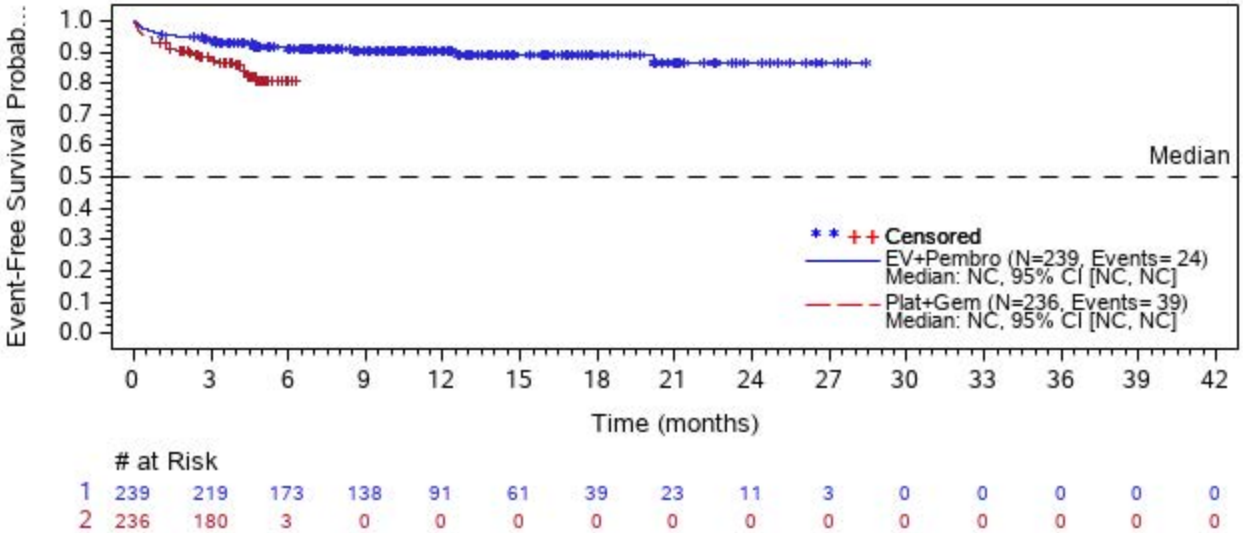
1	201	170	139	108	72	50	31	18	6	1	1	0	0	0	0
2	197	148	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.140.1.1: Kaplan-Meier Plot of Time to first TESAE - Infections and infestations (SOC) - Analysis Set mSAF 1



at Risk

1	239	219	173	138	91	61	39	23	11	3	0	0	0	0	0
2	236	180	3	0	0	0	0	0	0	0	0	0	0	0	0

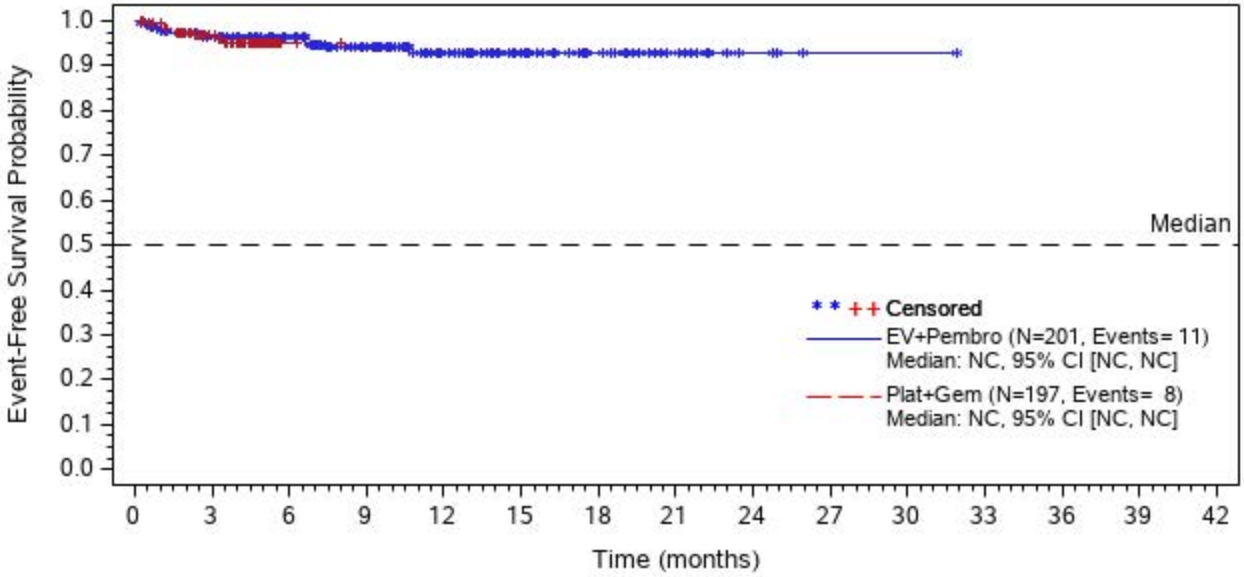
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.140.2.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Fatigue (PT) - Analysis Set mSAF 2



at Risk

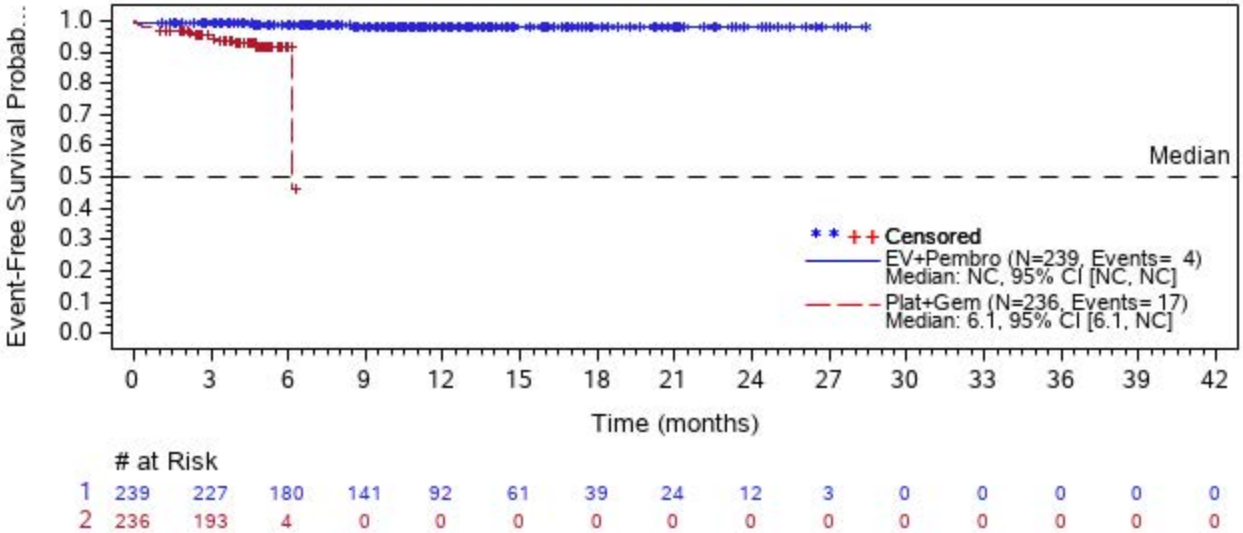
1	201	166	137	104	67	47	29	16	5	1	1	0	0	0	0
2	197	147	2	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.141.1.1: Kaplan-Meier Plot of Time to first TESAE - Urinary tract infection (PT) - Analysis Set mSAF 1



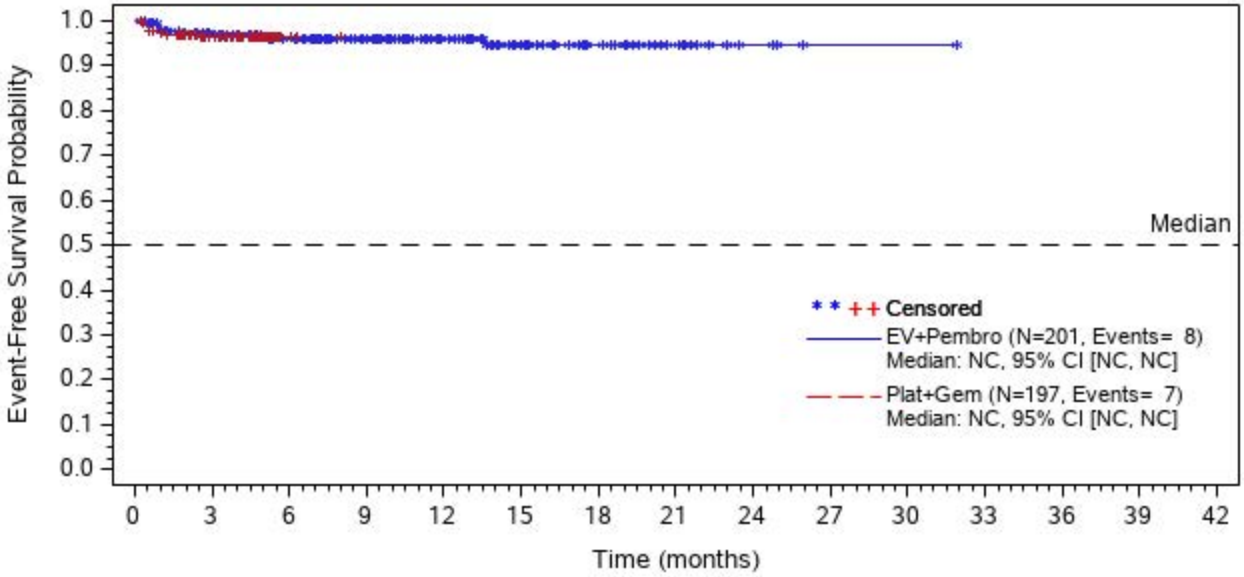
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TESAE=treatment-emergent serious adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.141.2.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Hepatobiliary disorders (SOC) - Analysis Set mSAF 2



at Risk

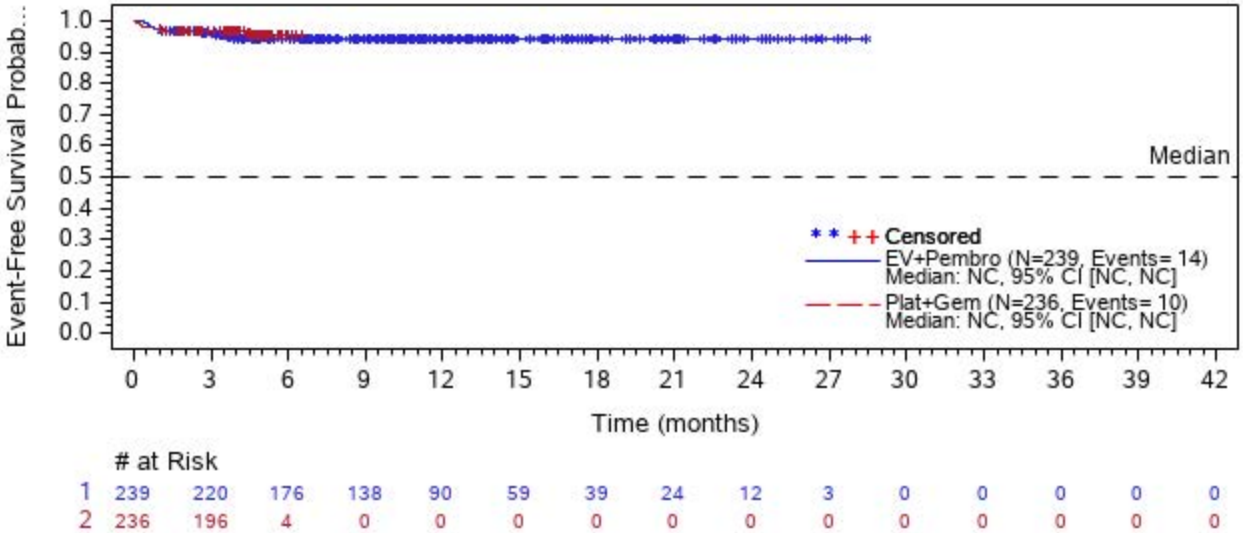
1	201	166	136	106	72	49	29	16	5	1	1	0	0	0	0
2	197	146	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.142.1.1: Kaplan-Meier Plot of Time to first TESAE - Metabolism and nutrition disorders (SOC) - Analysis Set mSAF 1



at Risk

1	239	220	176	138	90	59	39	24	12	3	0	0	0	0	0
2	236	196	4	0	0	0	0	0	0	0	0	0	0	0	0

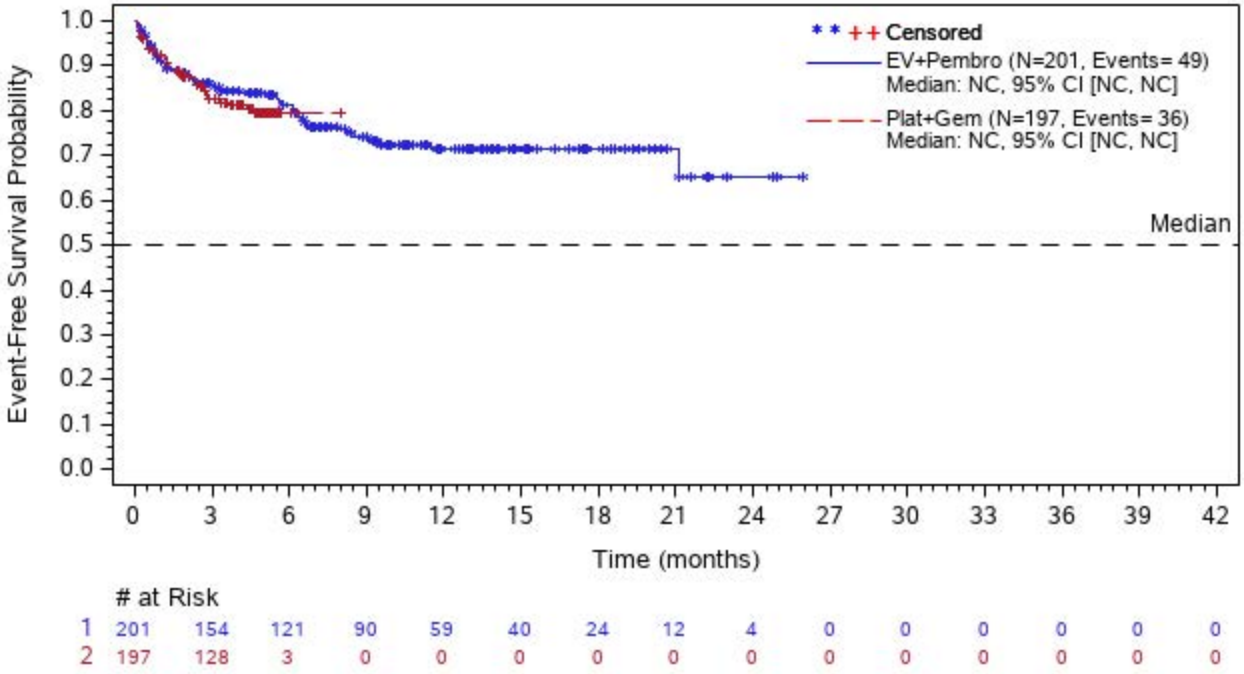
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.142.2.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Infections and infestations (SOC) - Analysis Set mSAF 2



at Risk

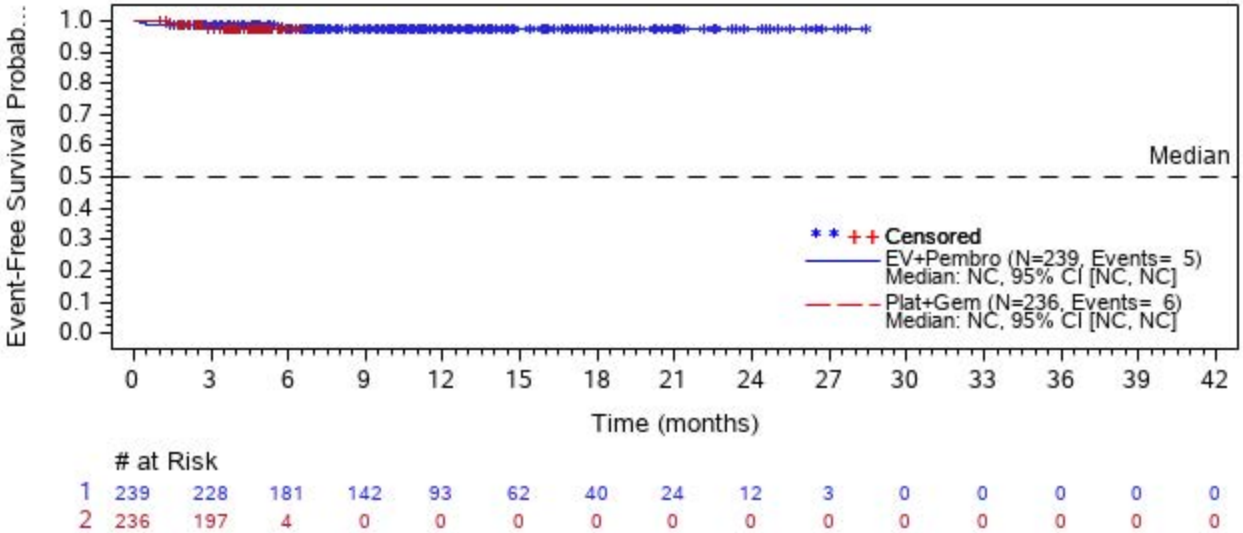
1	201	154	121	90	59	40	24	12	4	0	0	0	0	0	0
2	197	128	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.143.1.1: Kaplan-Meier Plot of Time to first TESAE - Musculoskeletal and connective tissue disorders (SOC) - Analysis Set mSAF 1



at Risk

1	239	228	181	142	93	62	40	24	12	3	0	0	0	0	0
2	236	197	4	0	0	0	0	0	0	0	0	0	0	0	0

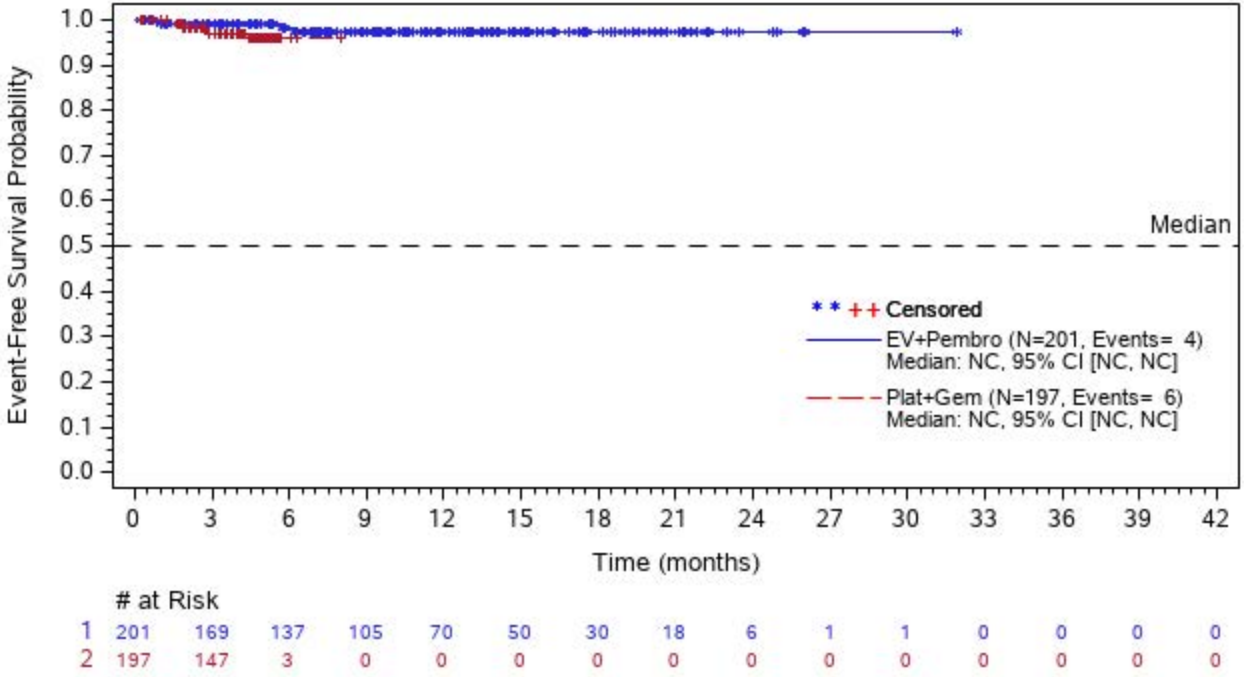
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.143.2.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Pyelonephritis (PT) - Analysis Set mSAF 2



at Risk

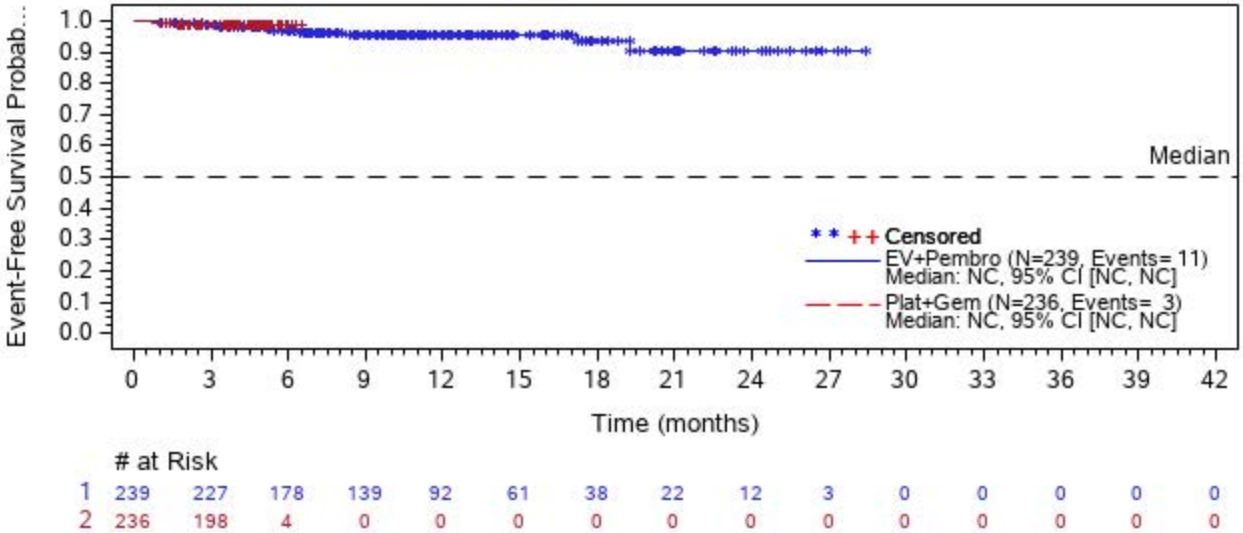
1	201	169	137	105	70	50	30	18	6	1	1	0	0	0	0
2	197	147	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.144.1.1: Kaplan-Meier Plot of Time to first TESAE - Nervous system disorders (SOC) - Analysis Set mSAF 1



at Risk

1	239	227	178	139	92	61	38	22	12	3	0	0	0	0	0
2	236	198	4	0	0	0	0	0	0	0	0	0	0	0	0

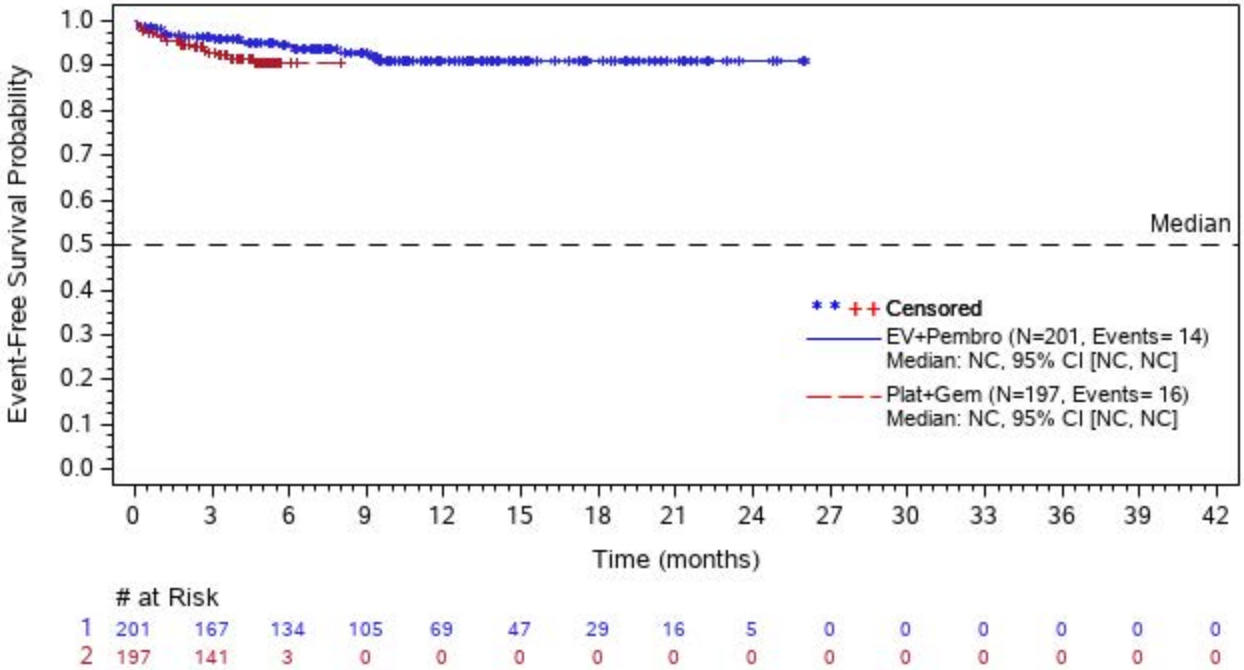
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.144.2.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Urinary tract infection (PT) - Analysis Set mSAF 2



at Risk

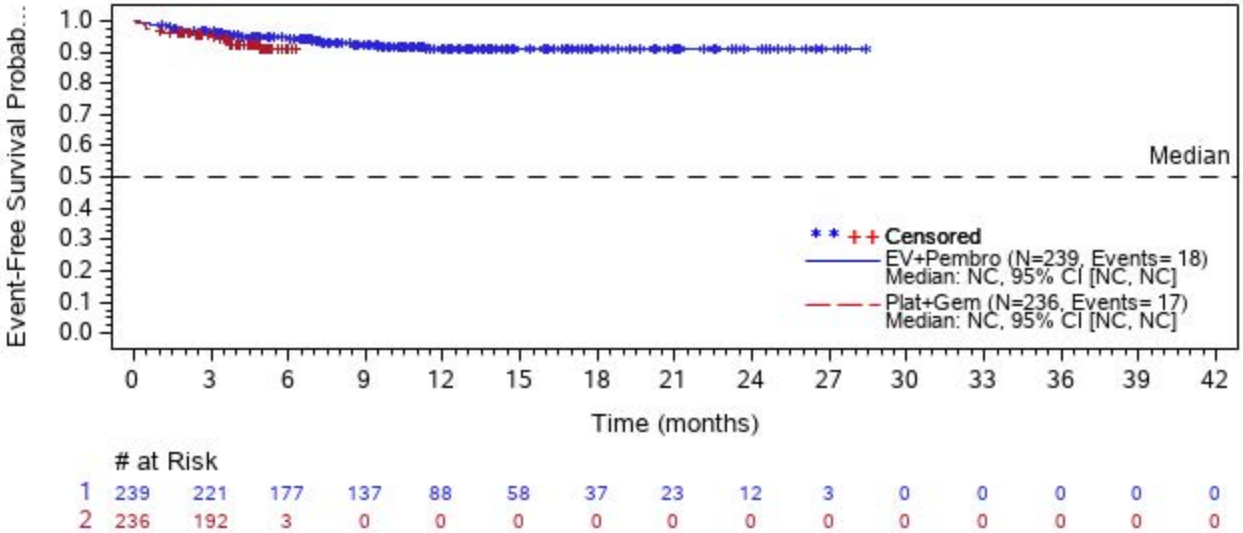
1	201	167	134	105	69	47	29	16	5	0	0	0	0	0	0
2	197	141	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.145.1.1: Kaplan-Meier Plot of Time to first TESAE - Renal and urinary disorders (SOC) - Analysis Set mSAF 1



at Risk

1	239	221	177	137	88	58	37	23	12	3	0	0	0	0	0
2	236	192	3	0	0	0	0	0	0	0	0	0	0	0	0

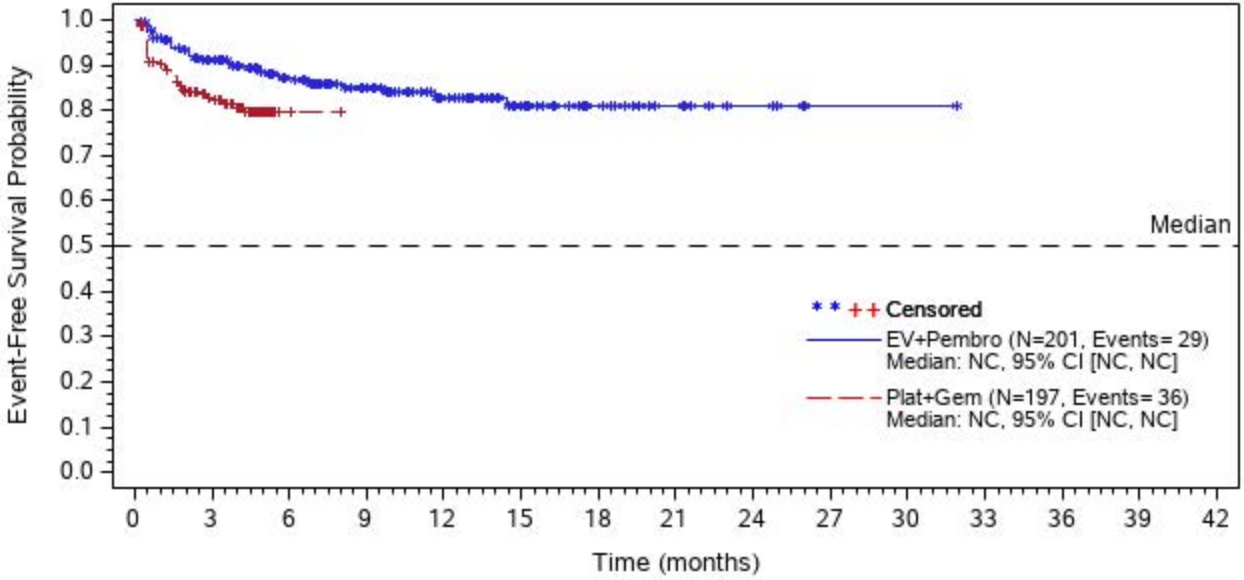
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.145.2.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Investigations (SOC) - Analysis Set mSAF 2



at Risk

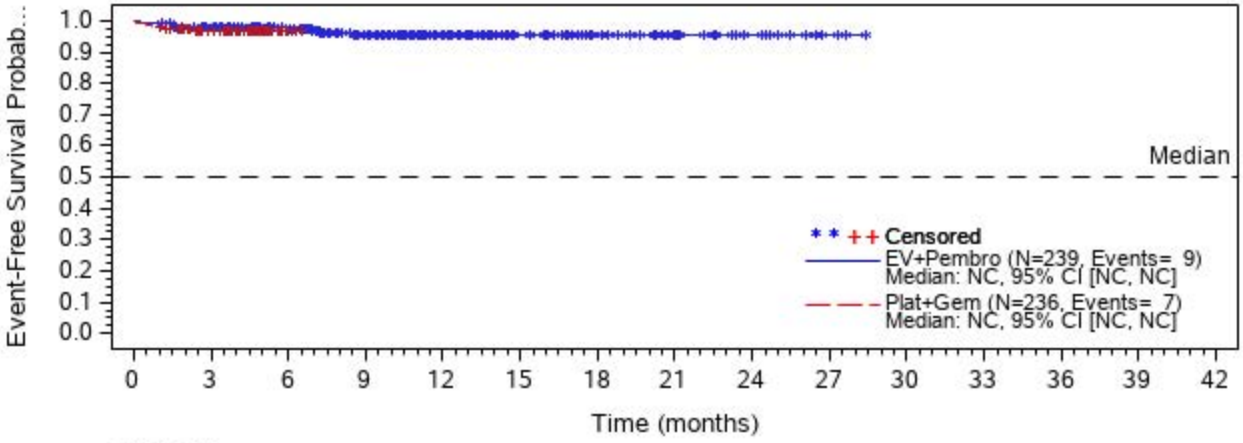
1	201	159	123	93	63	41	23	14	6	1	1	0	0	0	0
2	197	126	2	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.146.1.1: Kaplan-Meier Plot of Time to first TESAE - Acute kidney injury (PT) - Analysis Set mSAF 1



at Risk

1	239	225	179	139	90	59	38	23	12	3	0	0	0	0	0
2	236	196	4	0	0	0	0	0	0	0	0	0	0	0	0

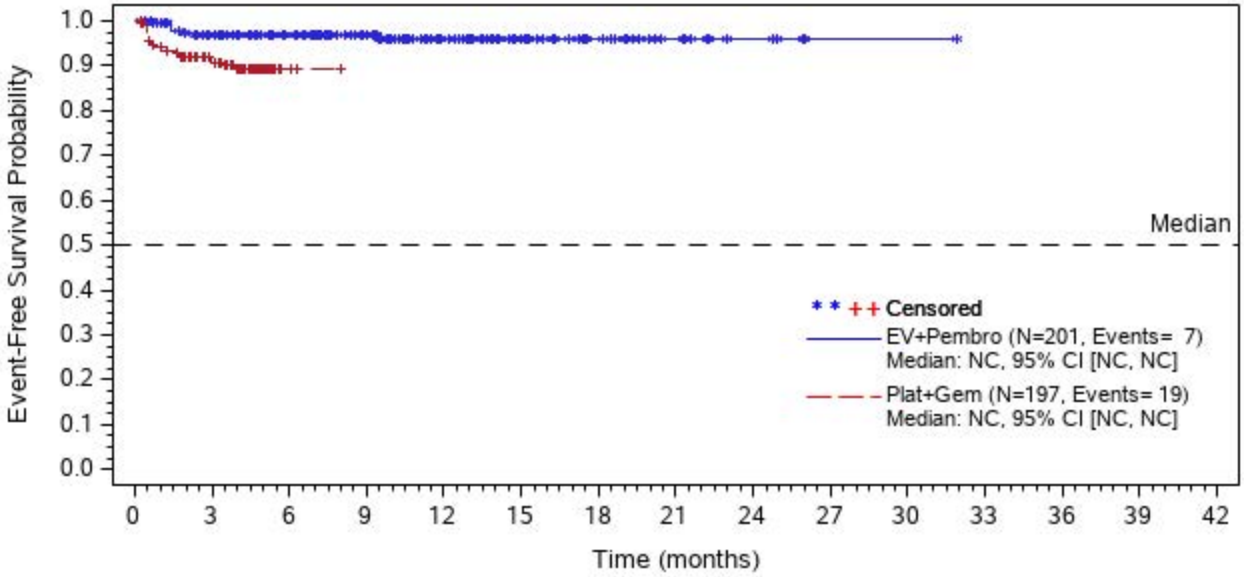
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TESAE=treatment-emergent serious adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.146.2.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Neutrophil count decreased (PT) - Analysis Set mSAF 2



at Risk

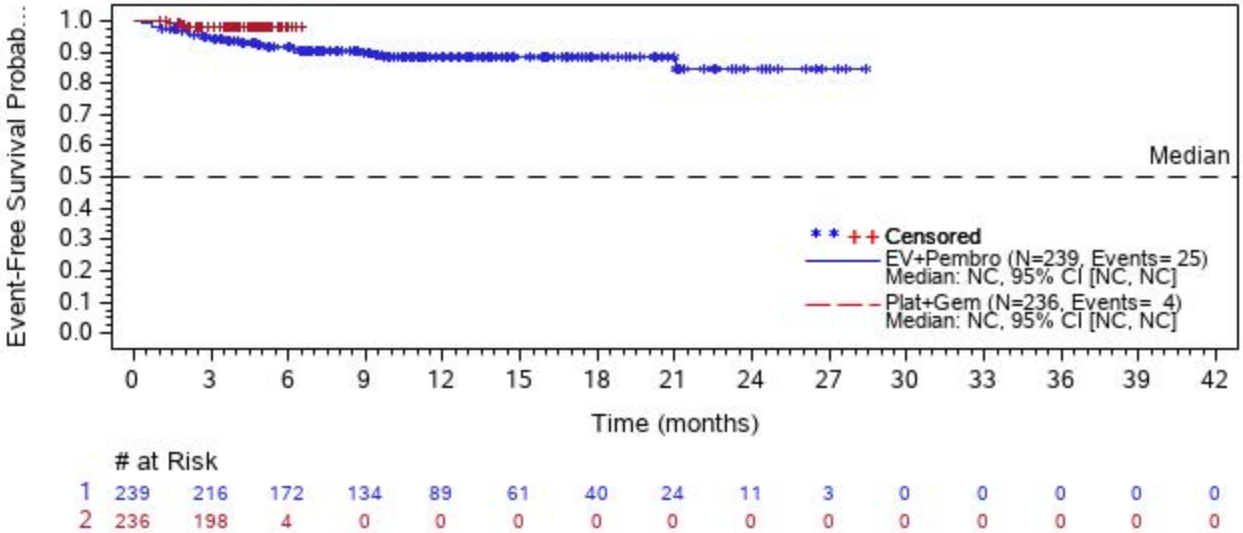
1	201	166	136	106	69	47	27	15	6	1	1	0	0	0	0
2	197	139	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.147.1.1: Kaplan-Meier Plot of Time to first TESAE - Respiratory, thoracic and mediastinal disorders (SOC) - Analysis Set mSAF 1



at Risk

1	239	216	172	134	89	61	40	24	11	3	0	0	0	0	0
2	236	198	4	0	0	0	0	0	0	0	0	0	0	0	0

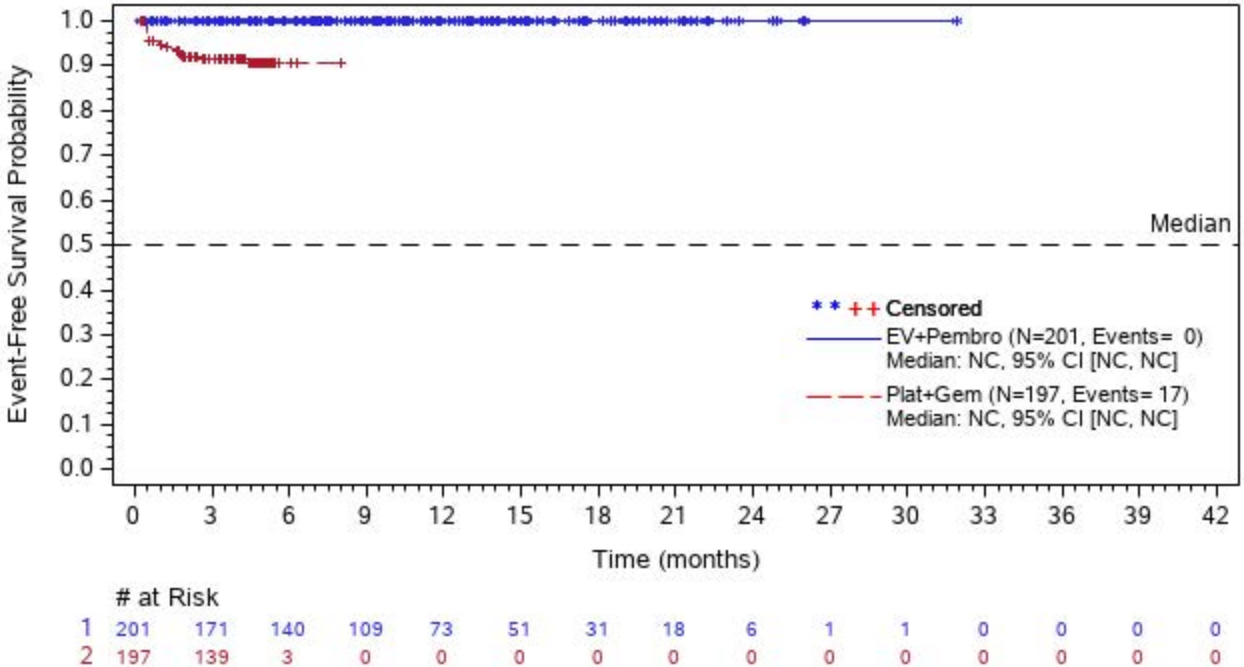
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.147.2.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Platelet count decreased (PT) - Analysis Set mSAF 2



at Risk

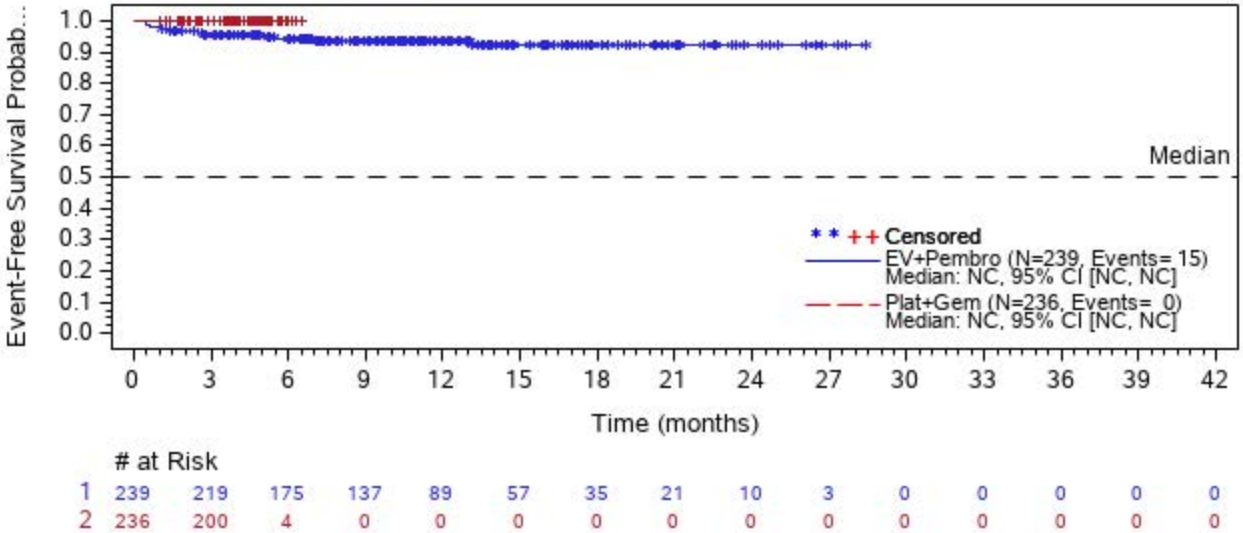
1	201	171	140	109	73	51	31	18	6	1	1	0	0	0	0
2	197	139	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.148.1.1: Kaplan-Meier Plot of Time to first TESAE - Skin and subcutaneous tissue disorders (SOC) - Analysis Set mSAF 1



at Risk

1	239	219	175	137	89	57	35	21	10	3	0	0	0	0	0
2	236	200	4	0	0	0	0	0	0	0	0	0	0	0	0

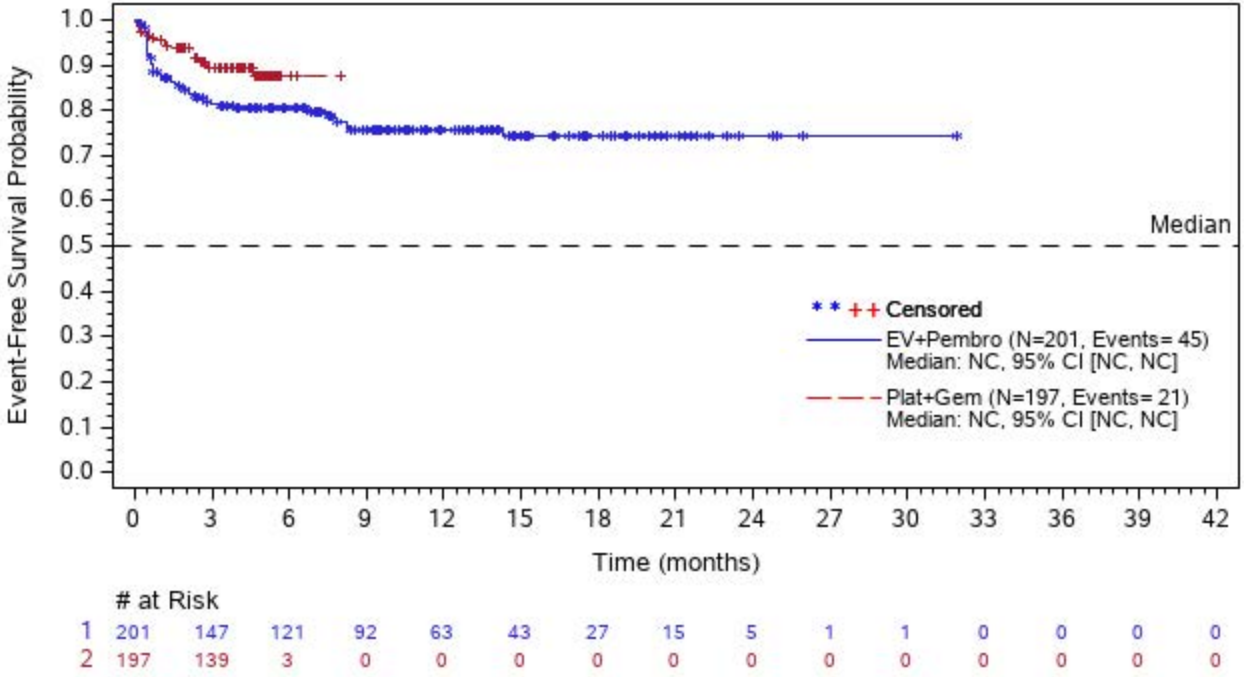
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TESAE=treatment-emergent serious adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.148.2.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Metabolism and nutrition disorders (SOC) - Analysis Set mSAF 2



at Risk

1	201	147	121	92	63	43	27	15	5	1	1	0	0	0	0
2	197	139	3	0	0	0	0	0	0	0	0	0	0	0	0

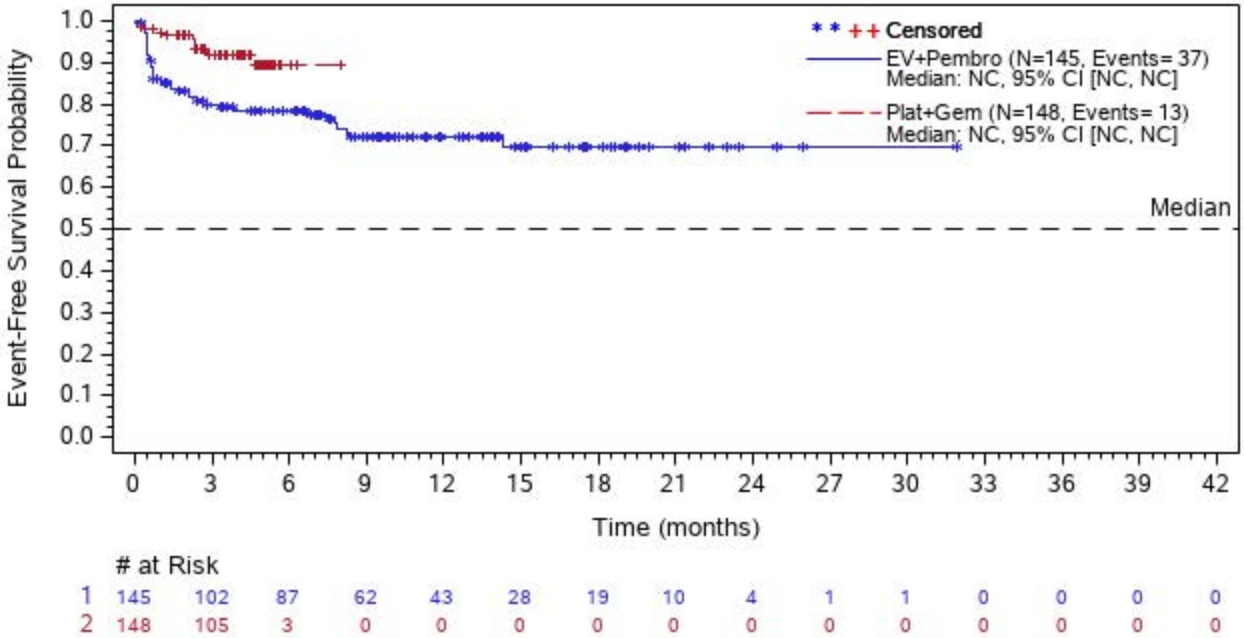
Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.148.2.2.4: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Metabolism and nutrition disorders (SOC) - Analysis Set mSAF 2

Sex: Male



at Risk

1	145	102	87	62	43	28	19	10	4	1	1	0	0	0	0
2	148	105	3	0	0	0	0	0	0	0	0	0	0	0	0

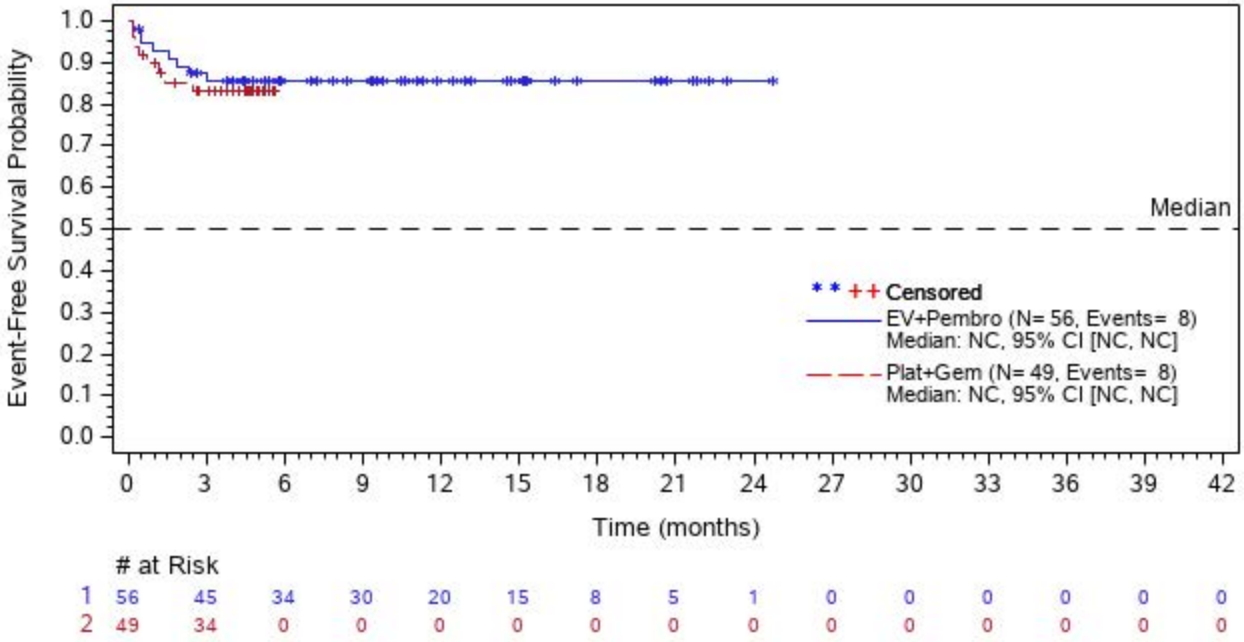
Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.148.2.2.4: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Metabolism and nutrition disorders (SOC) - Analysis Set mSAF 2

Sex: Female



at Risk

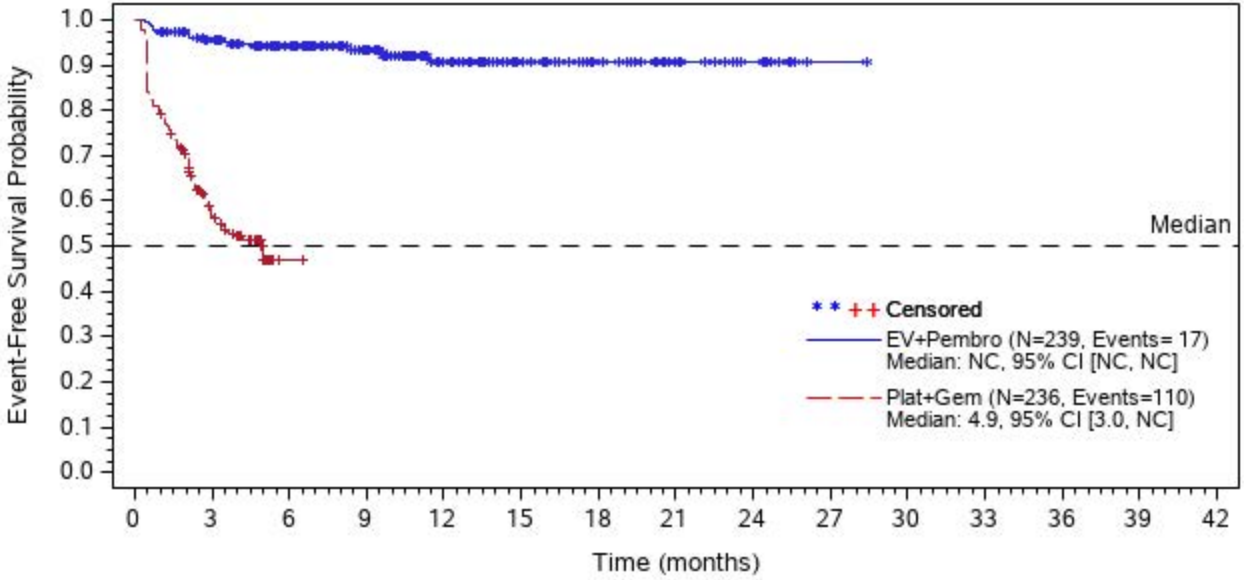
1	56	45	34	30	20	15	8	5	1	0	0	0	0	0	0
2	49	34	0	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.149.1.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Blood and lymphatic system disorders (SOC) - Analysis Set mSAF 1



at Risk

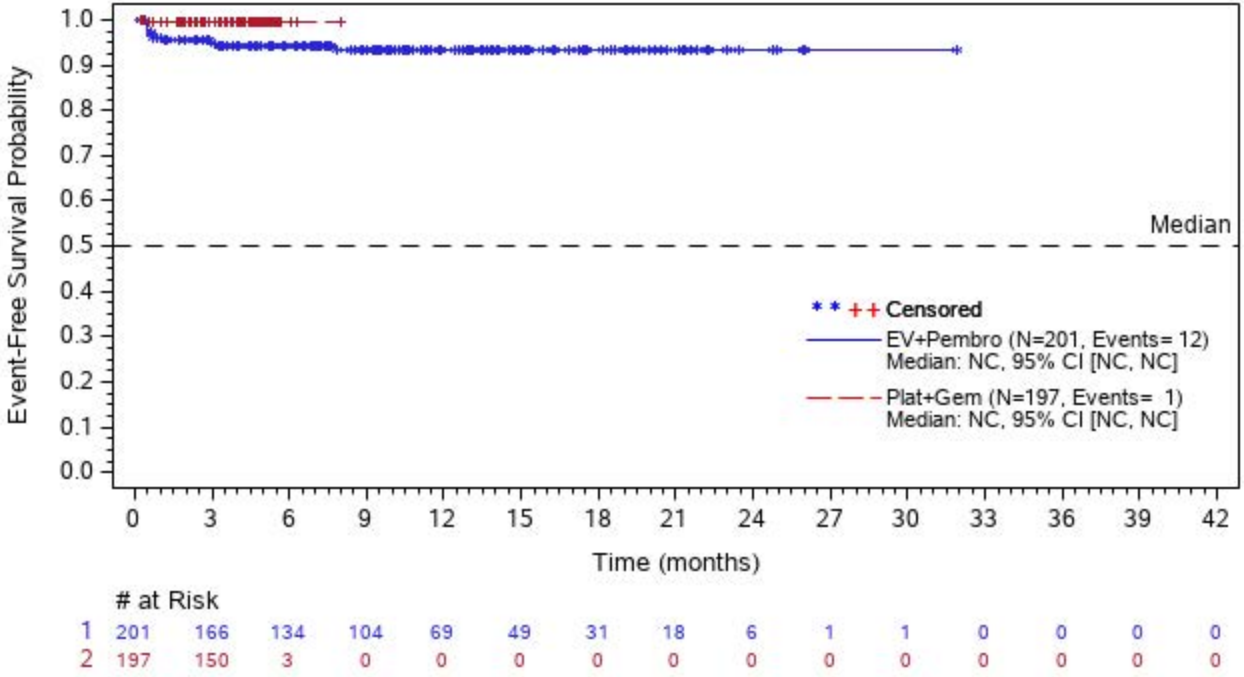
1	239	206	163	125	80	54	37	20	12	1	0	0	0	0	0
2	236	115	1	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.149.2.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Hyperglycaemia (PT) - Analysis Set mSAF 2



at Risk

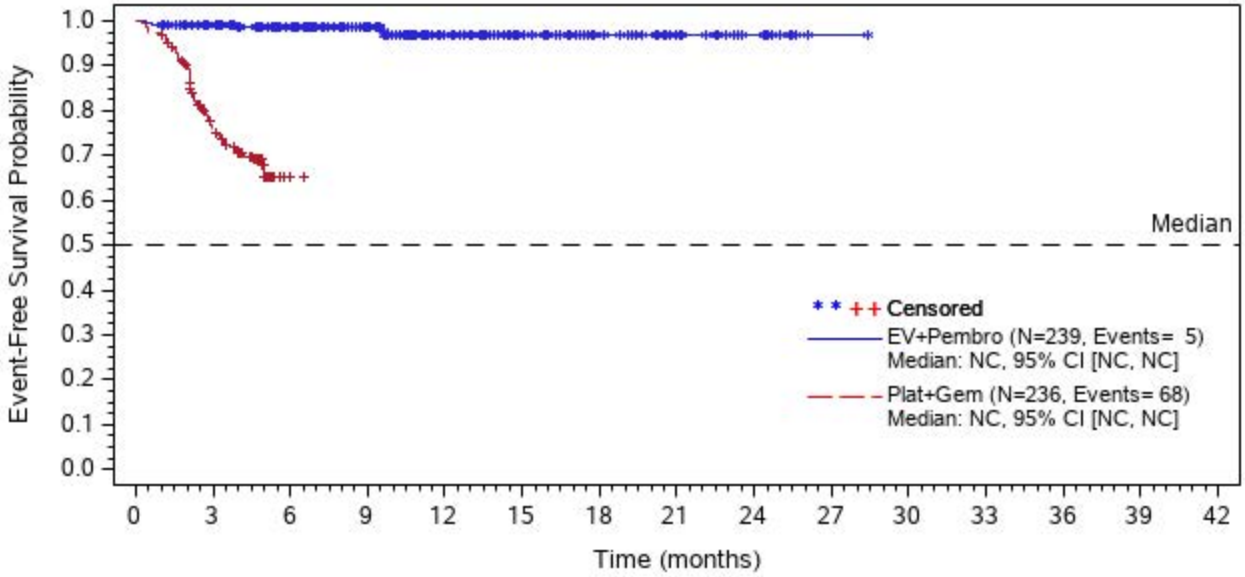
1	201	166	134	104	69	49	31	18	6	1	1	0	0	0	0
2	197	150	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.150.1.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Anaemia (PT) - Analysis Set mSAF 1



at Risk

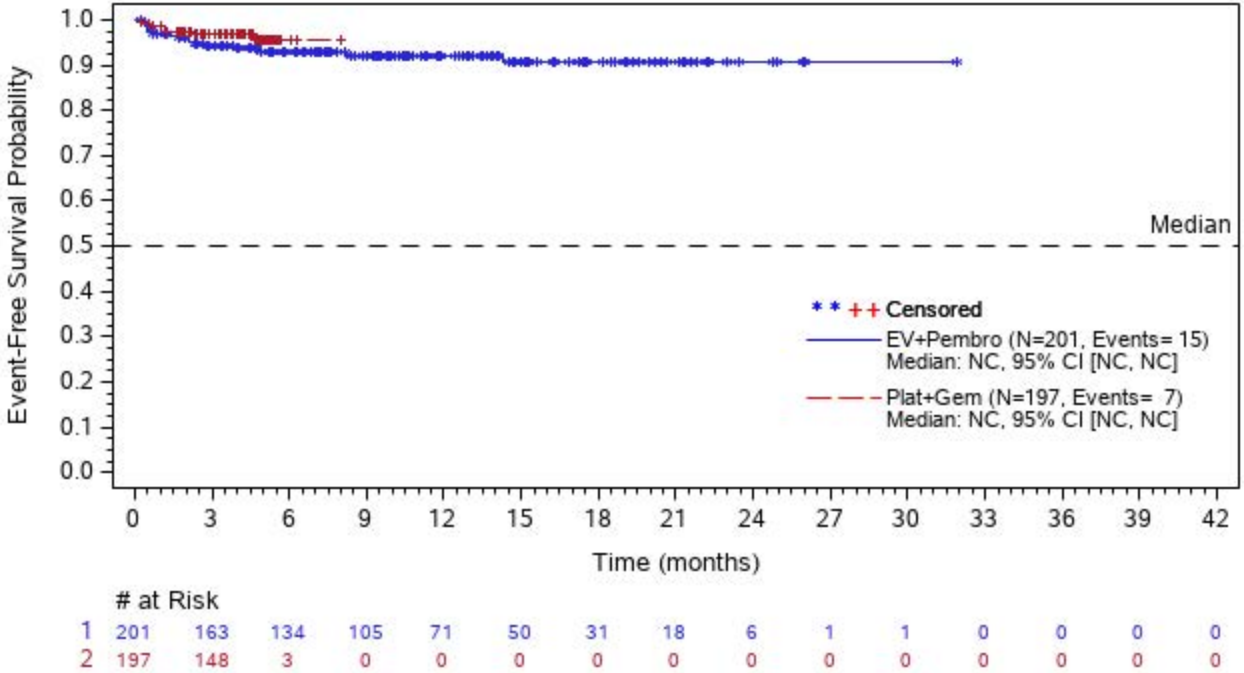
1	239	211	169	131	86	58	39	22	12	1	0	0	0	0	0
2	236	155	2	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.150.2.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Hyponatraemia (PT) - Analysis Set mSAF 2



at Risk

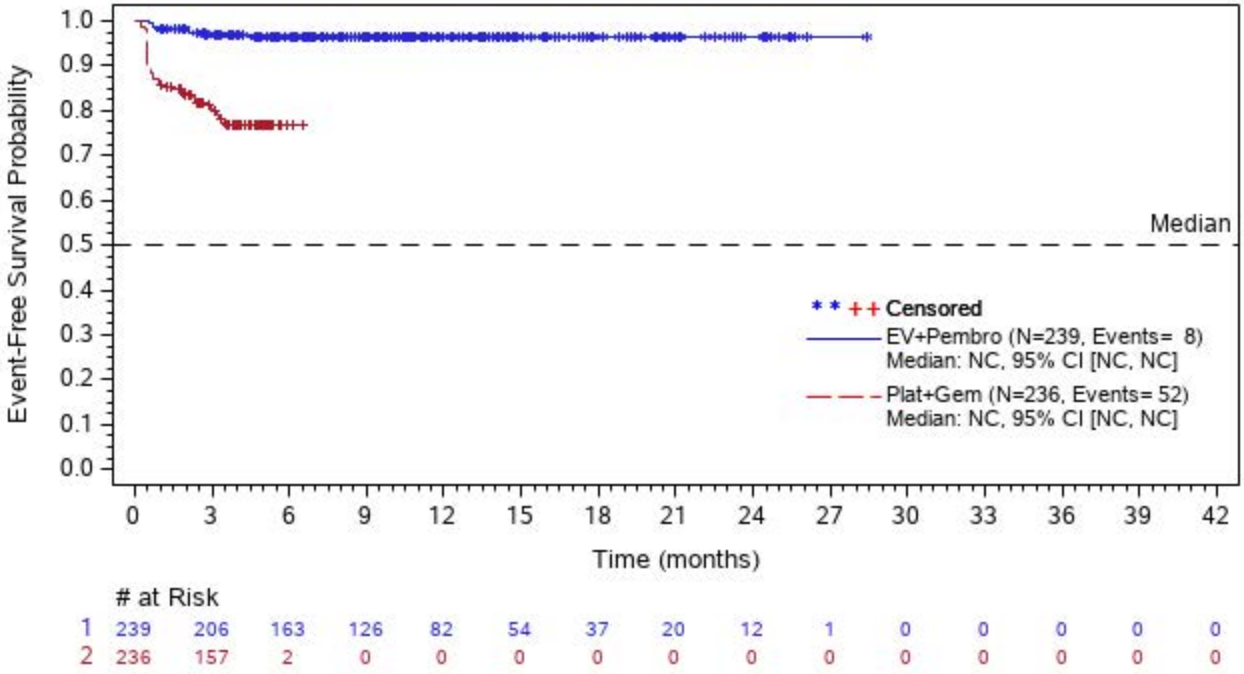
1	201	163	134	105	71	50	31	18	6	1	1	0	0	0	0
2	197	148	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.151.1.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Neutropenia (PT) - Analysis Set mSAF 1



at Risk

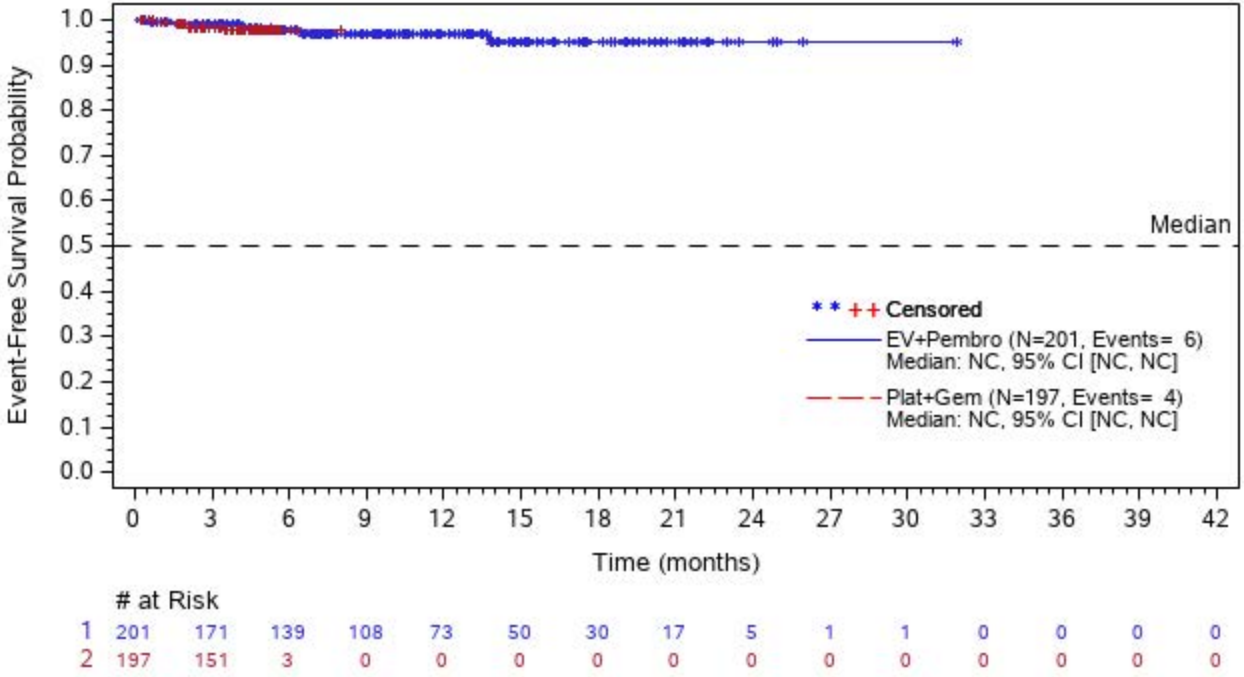
1	239	206	163	126	82	54	37	20	12	1	0	0	0	0	0
2	236	157	2	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.151.2.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Musculoskeletal and connective tissue disorders (SOC) - Analysis Set mSAF 2



at Risk

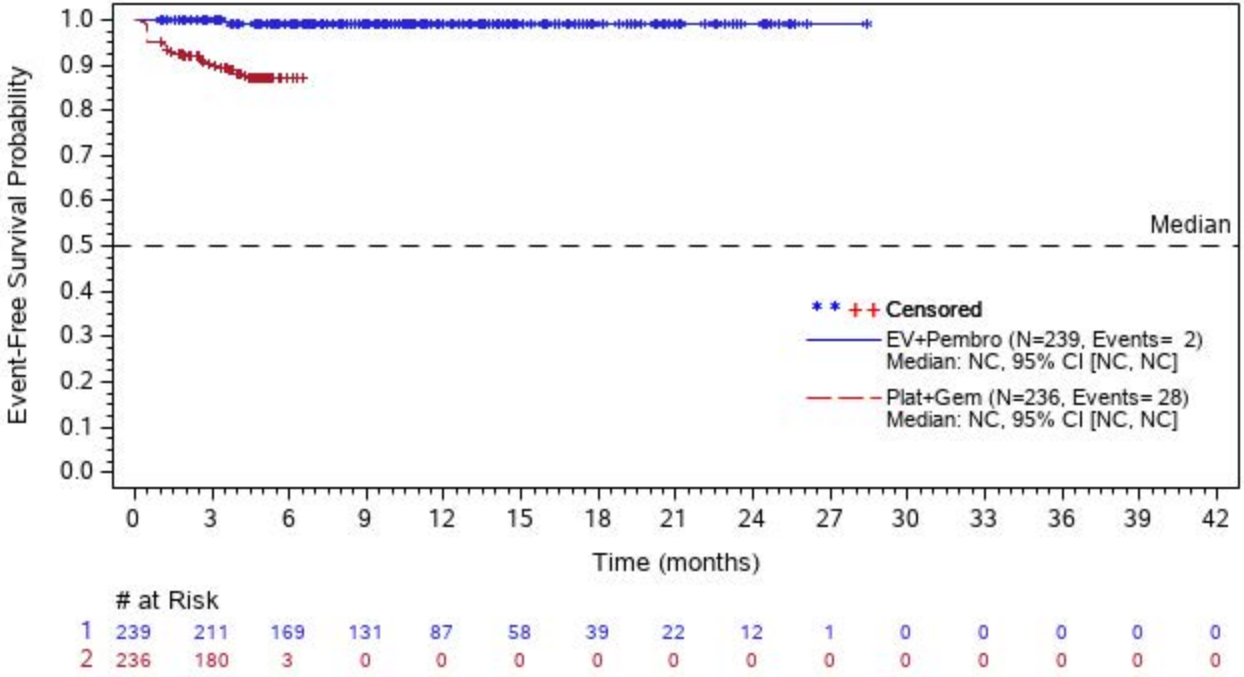
1	201	171	139	108	73	50	30	17	5	1	1	0	0	0	0
2	197	151	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.152.1.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Thrombocytopenia (PT) - Analysis Set mSAF 1



at Risk

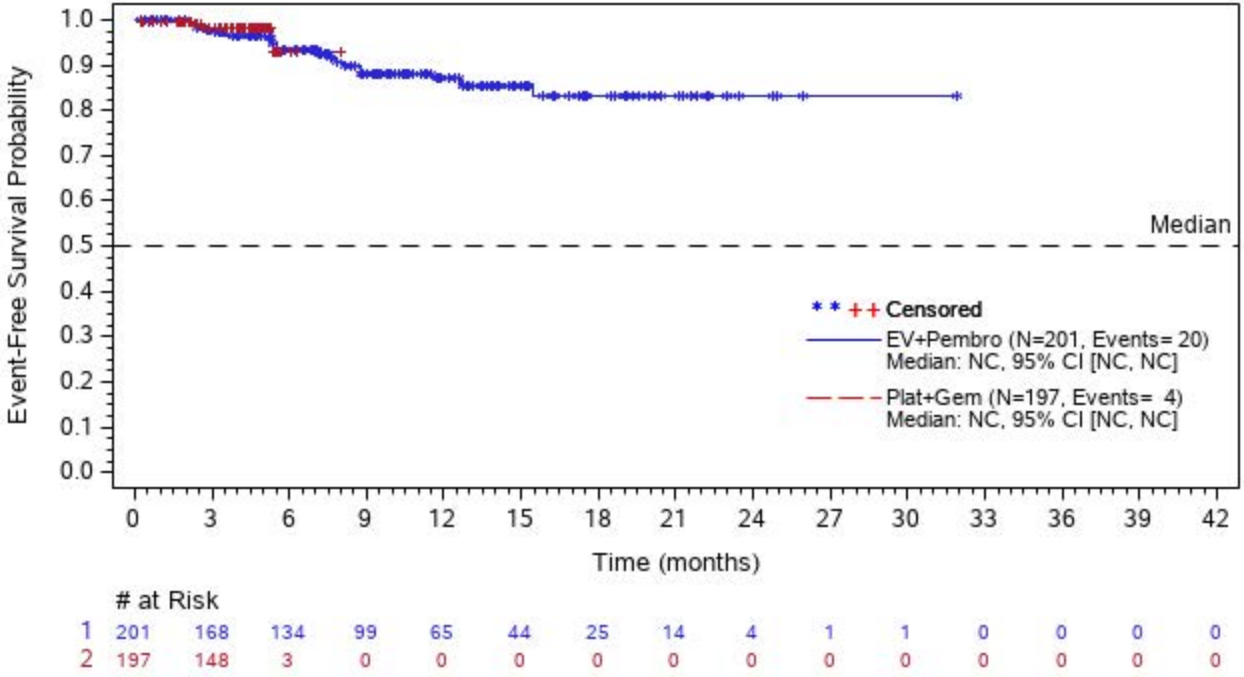
1	239	211	169	131	87	58	39	22	12	1	0	0	0	0	0
2	236	180	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.152.2.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Nervous system disorders (SOC) - Analysis Set mSAF 2



at Risk

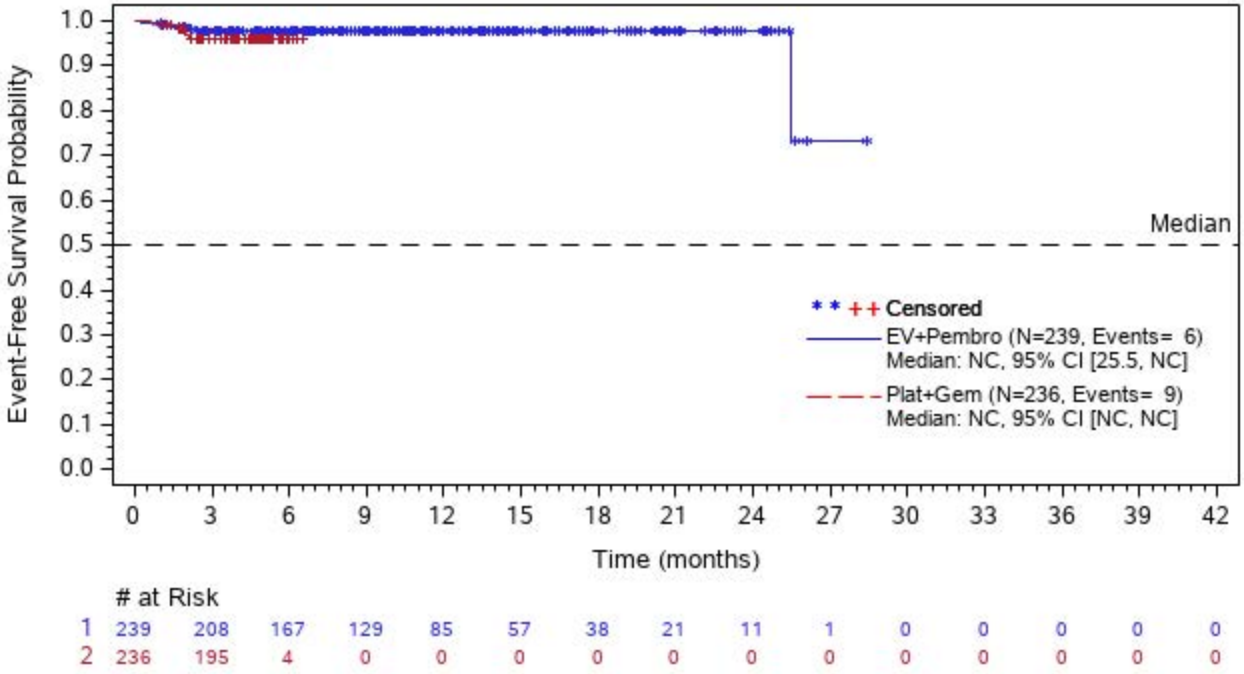
1	201	168	134	99	65	44	25	14	4	1	1	0	0	0	0
2	197	148	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.153.1.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Cardiac disorders (SOC) - Analysis Set mSAF 1



at Risk

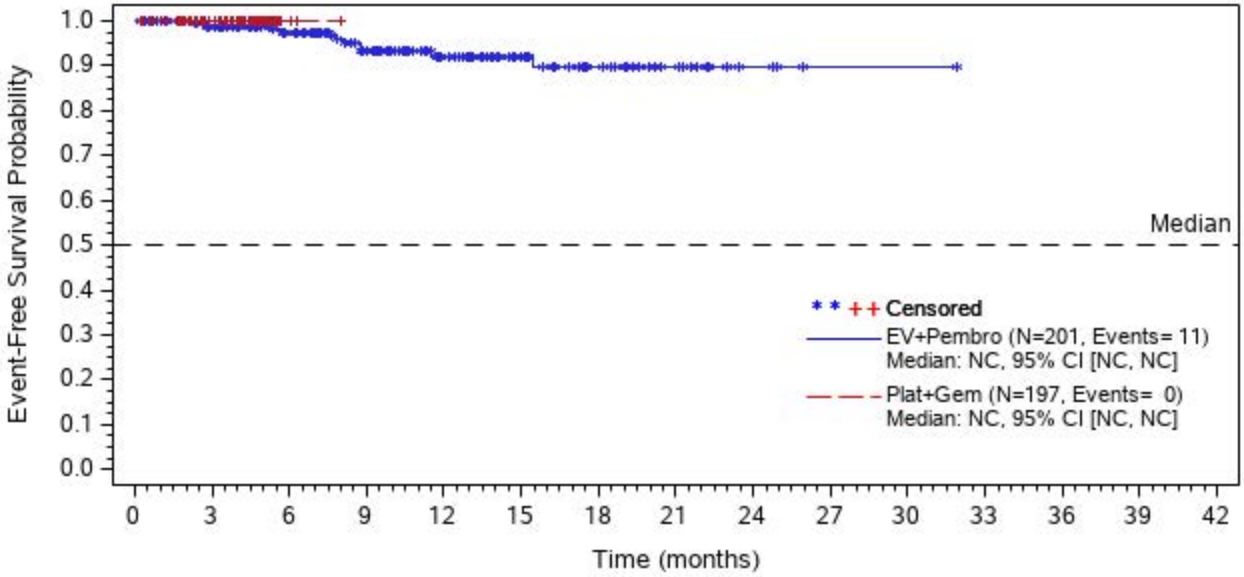
1	239	208	167	129	85	57	38	21	11	1	0	0	0	0	0
2	236	195	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.153.2.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Peripheral sensory neuropathy (PT) - Analysis Set mSAF 2



at Risk

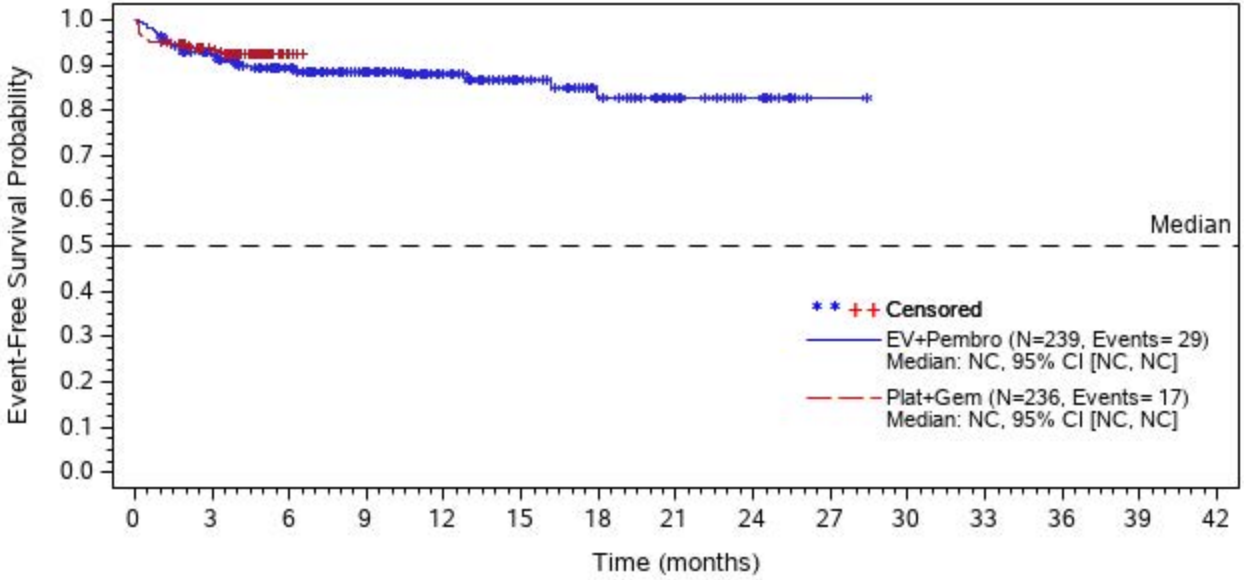
1	201	169	137	102	67	46	27	15	4	1	1	0	0	0	0
2	197	151	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.154.1.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Gastrointestinal disorders (SOC) - Analysis Set mSAF 1



at Risk

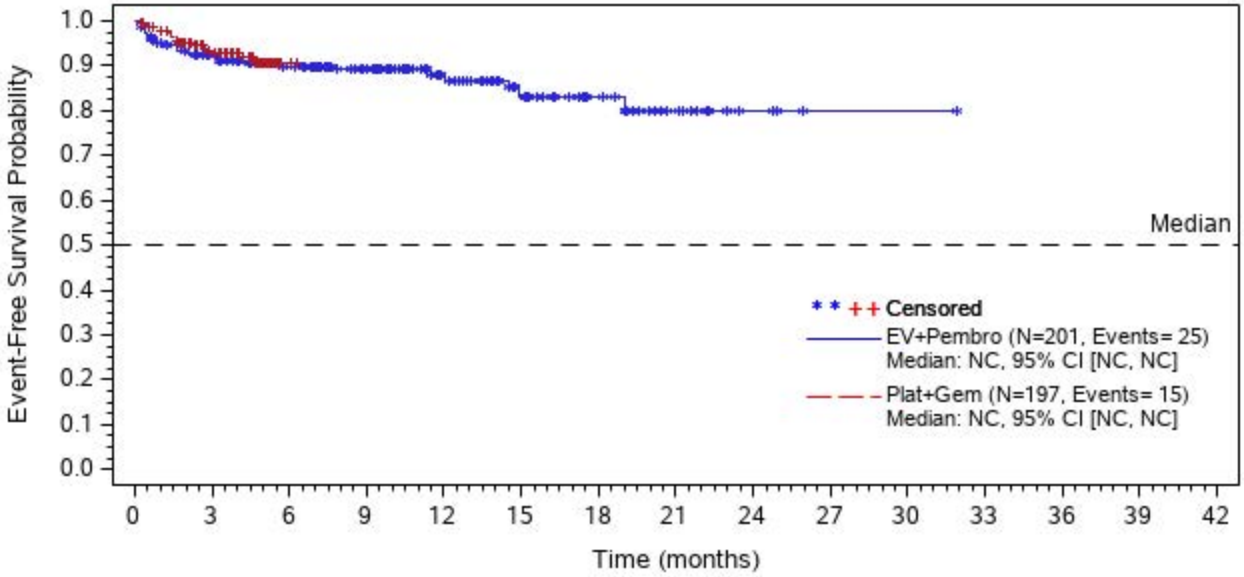
1	239	196	154	120	80	56	38	21	12	1	0	0	0	0	0
2	236	188	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.154.2.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Renal and urinary disorders (SOC) - Analysis Set mSAF 2



at Risk

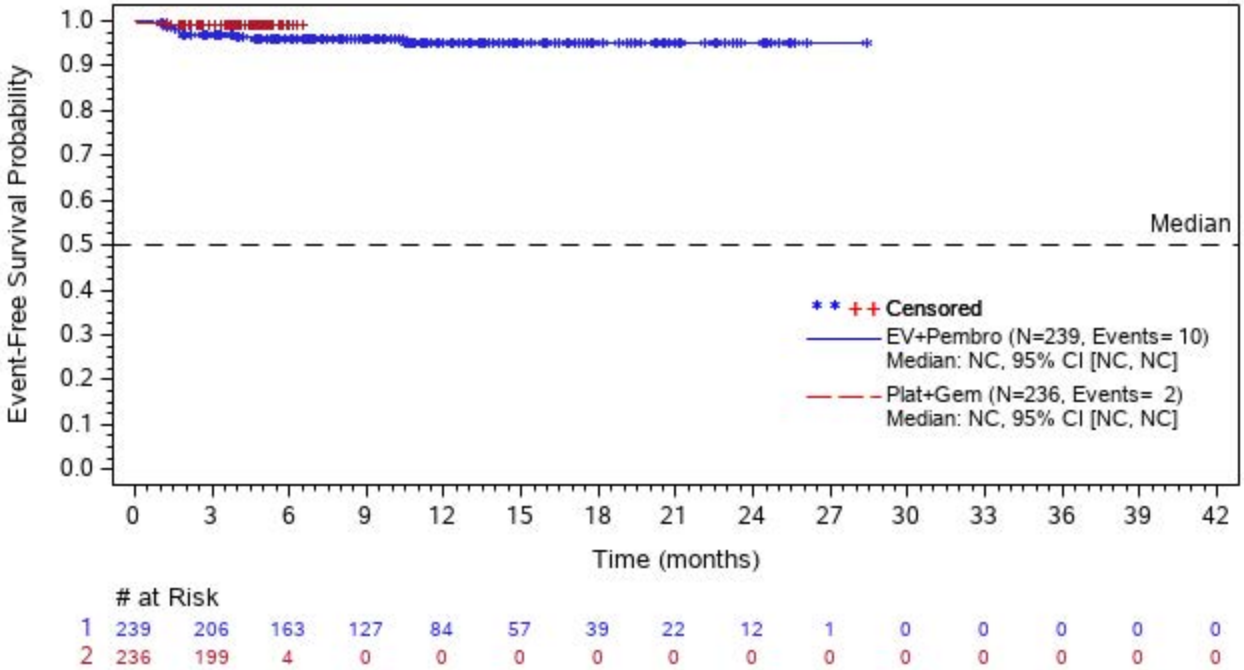
1	201	164	133	105	69	46	28	15	5	1	1	0	0	0	0
2	197	143	2	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.155.1.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Diarrhoea (PT) - Analysis Set mSAF 1



at Risk

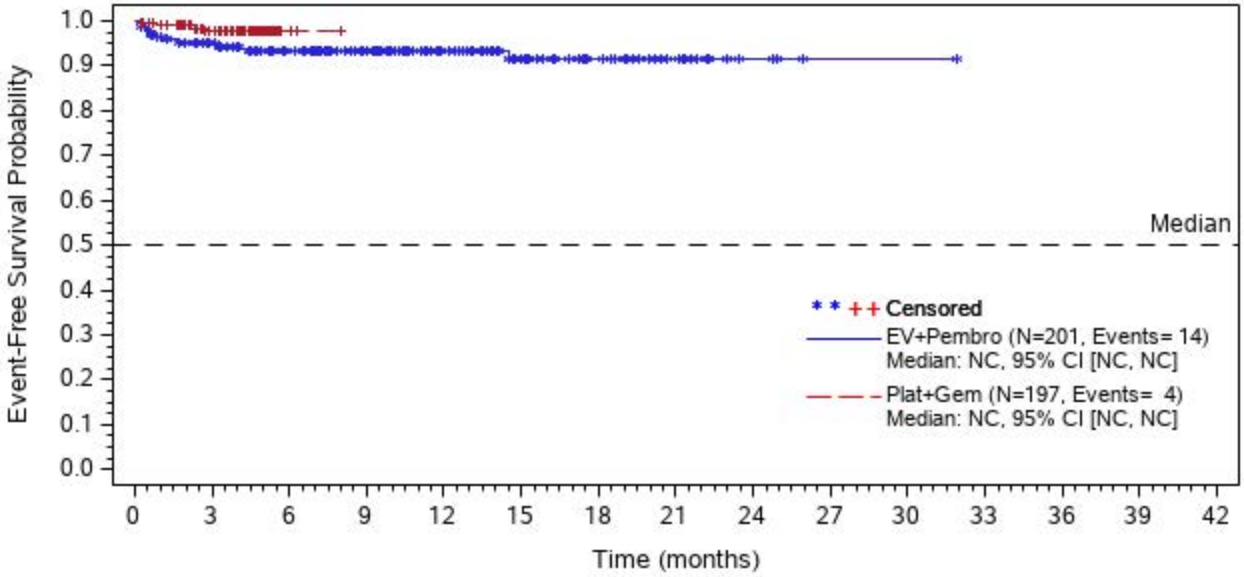
1	239	206	163	127	84	57	39	22	12	1	0	0	0	0	0
2	236	199	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.155.2.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Acute kidney injury (PT) - Analysis Set mSAF 2



at Risk

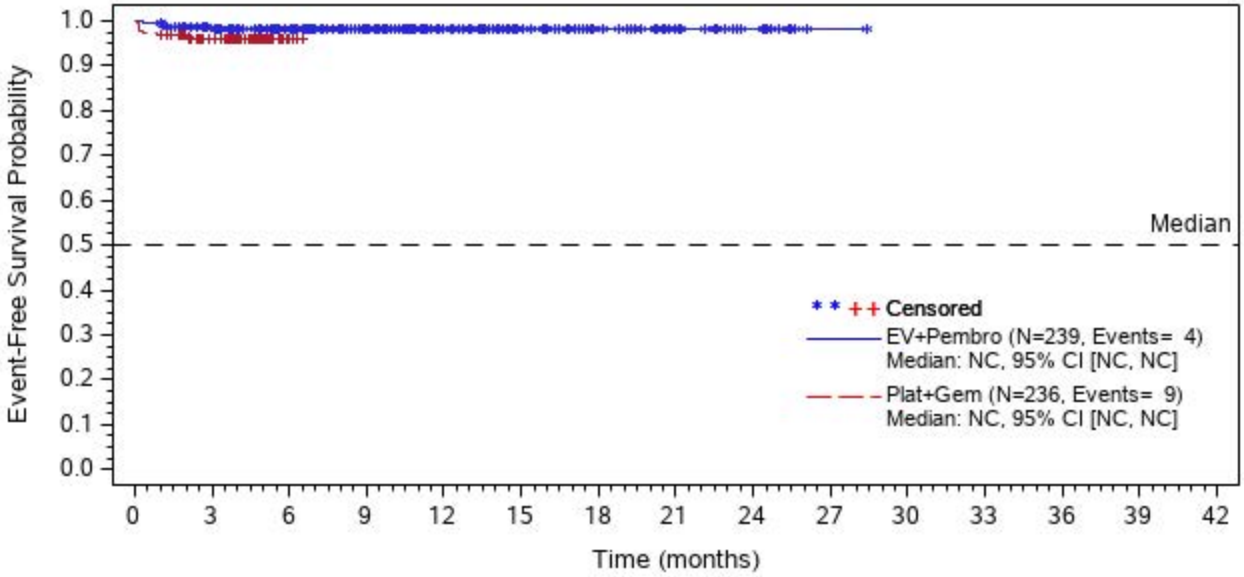
1	201	167	136	107	71	49	29	16	5	1	1	0	0	0	0
2	197	148	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.156.1.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Nausea (PT) - Analysis Set mSAF 1



at Risk

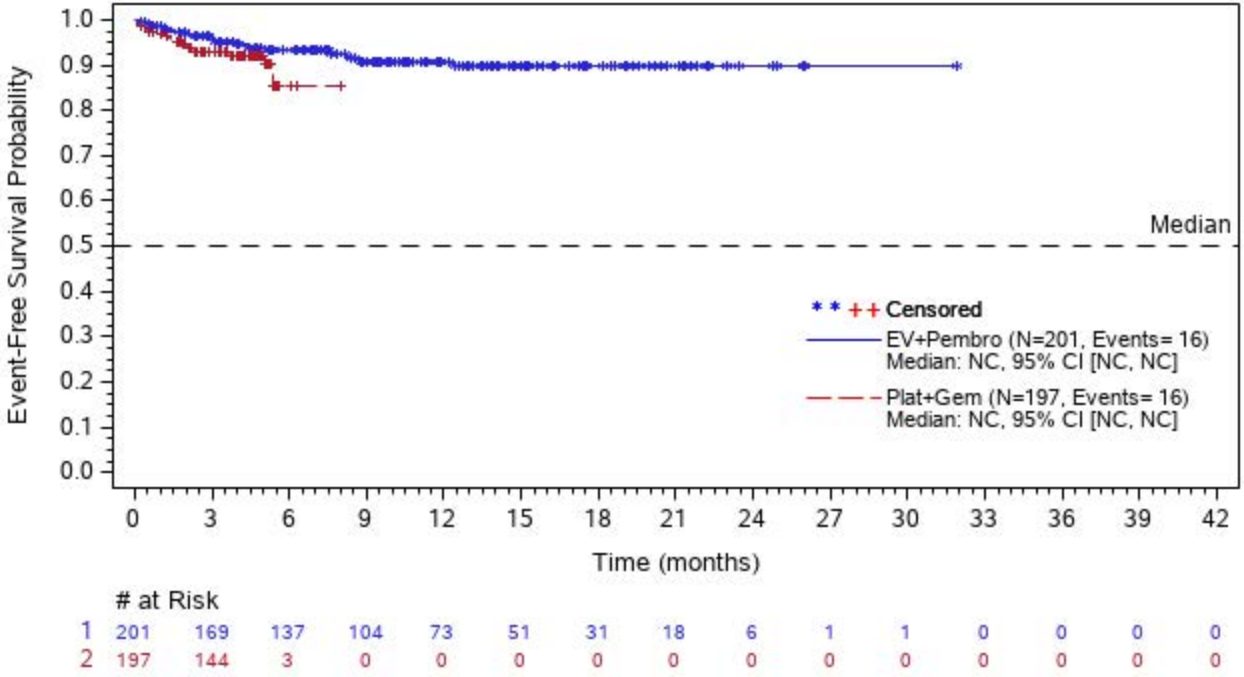
1	239	208	168	130	86	58	39	22	12	1	0	0	0	0	0
2	236	192	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.156.2.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Respiratory, thoracic and mediastinal disorders (SOC) - Analysis Set mSAF 2



at Risk

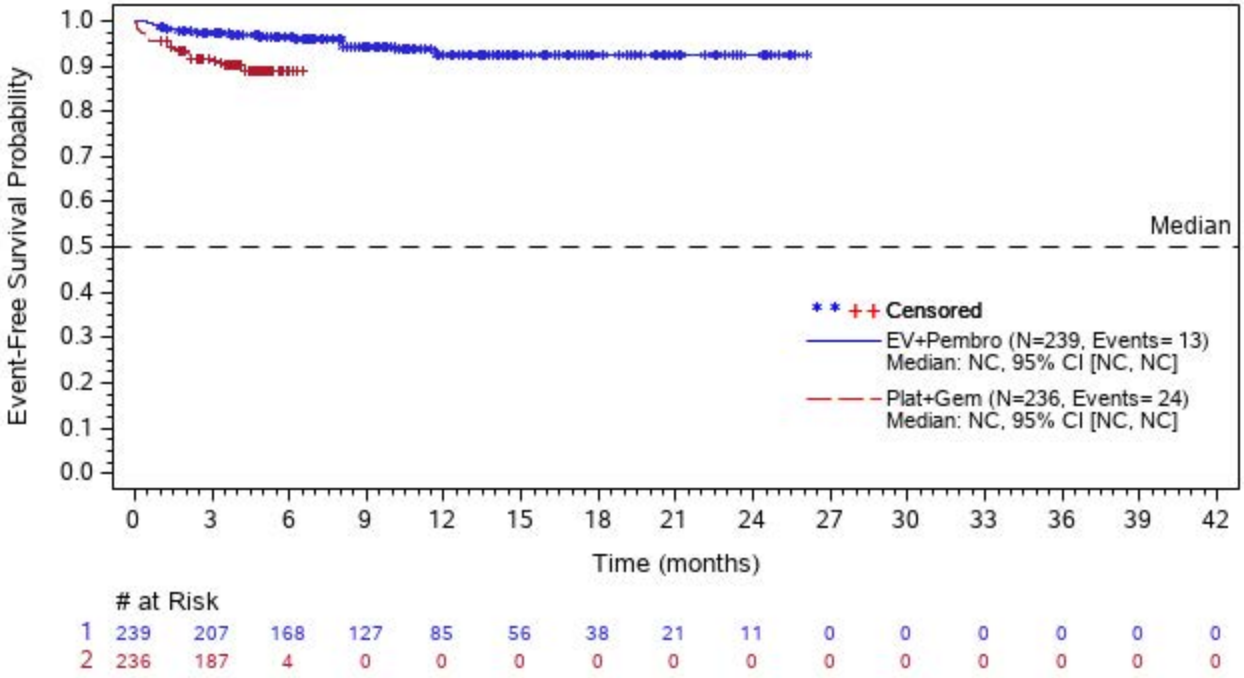
1	201	169	137	104	73	51	31	18	6	1	1	0	0	0	0
2	197	144	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.157.1.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - General disorders and administration site conditions (SOC) - Analysis Set mSAF 1



at Risk

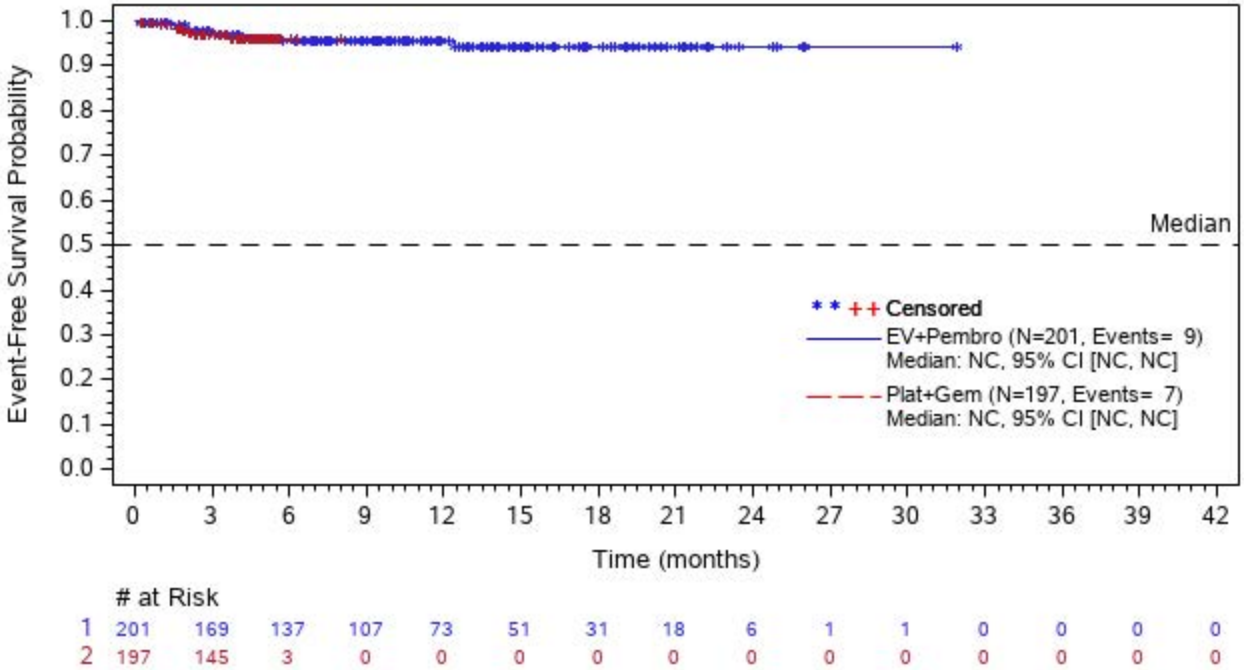
1	239	207	168	127	85	56	38	21	11	0	0	0	0	0	0
2	236	187	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.157.2.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Pulmonary embolism (PT) - Analysis Set mSAF 2



at Risk

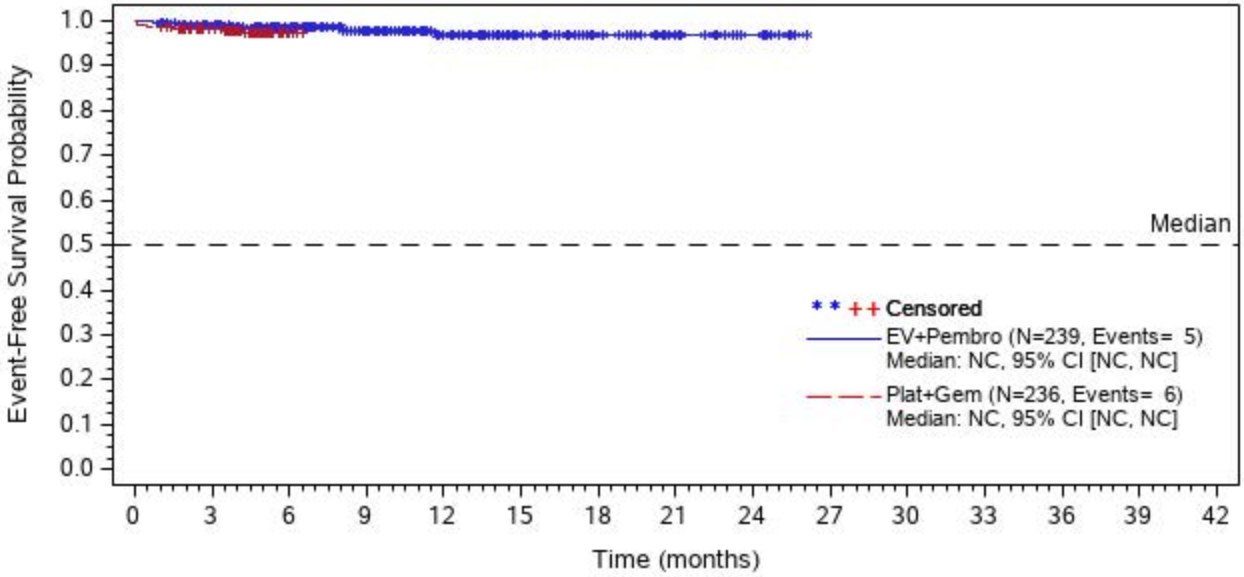
1	201	169	137	107	73	51	31	18	6	1	1	0	0	0	0
2	197	145	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.158.1.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Asthenia (PT) - Analysis Set mSAF 1



at Risk

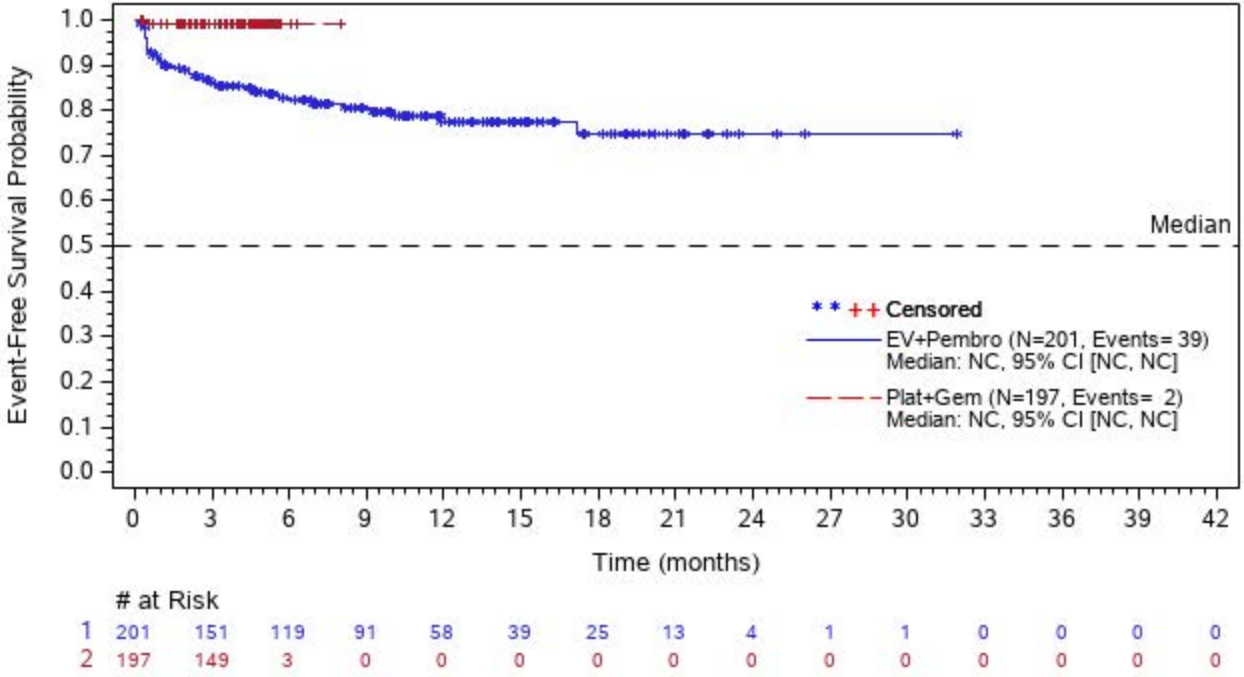
1	239	210	169	130	86	57	38	21	11	0	0	0	0	0	0
2	236	197	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.158.2.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Skin and subcutaneous tissue disorders (SOC) - Analysis Set mSAF 2



at Risk

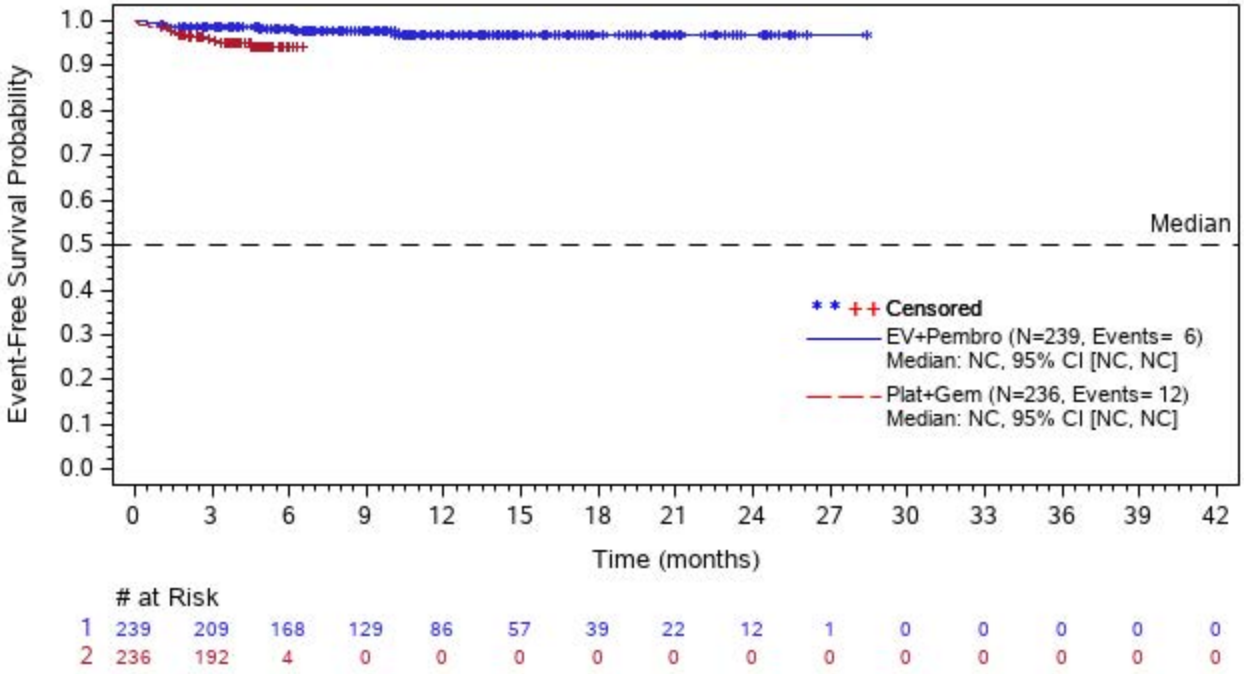
1	201	151	119	91	58	39	25	13	4	1	1	0	0	0	0
2	197	149	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.159.1.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Fatigue (PT) - Analysis Set mSAF 1



at Risk

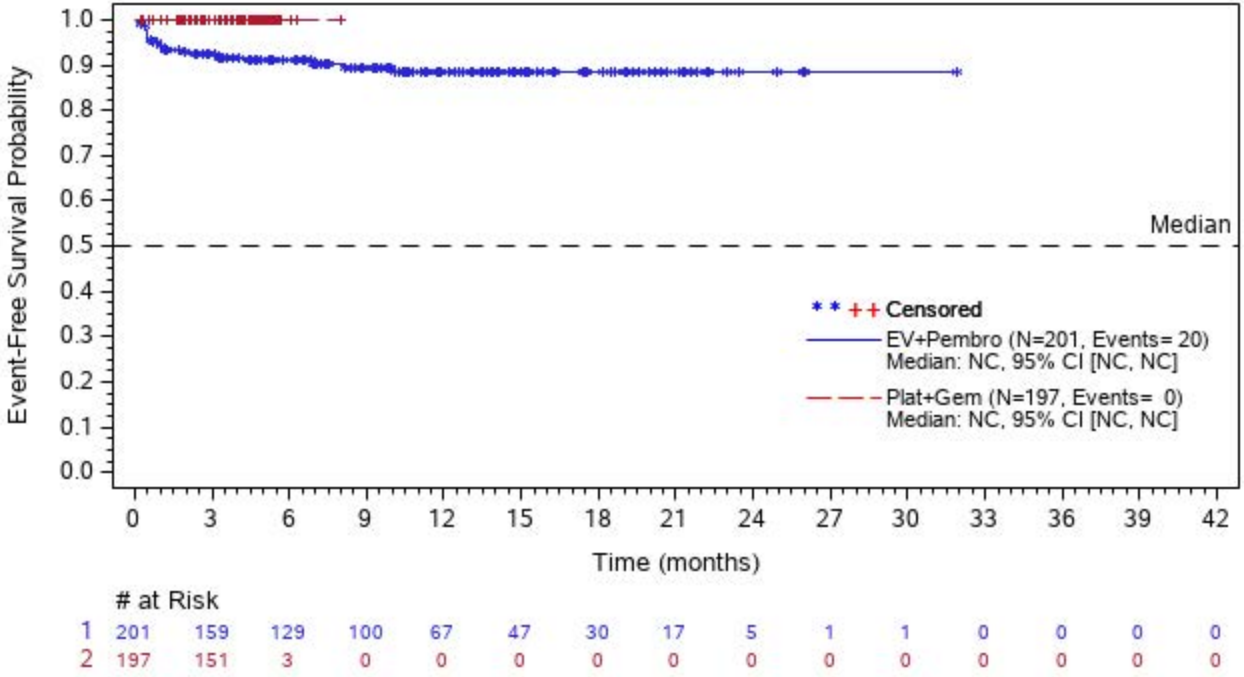
1	239	209	168	129	86	57	39	22	12	1	0	0	0	0	0
2	236	192	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.159.2.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Rash maculo-papular (PT) - Analysis Set mSAF 2



at Risk

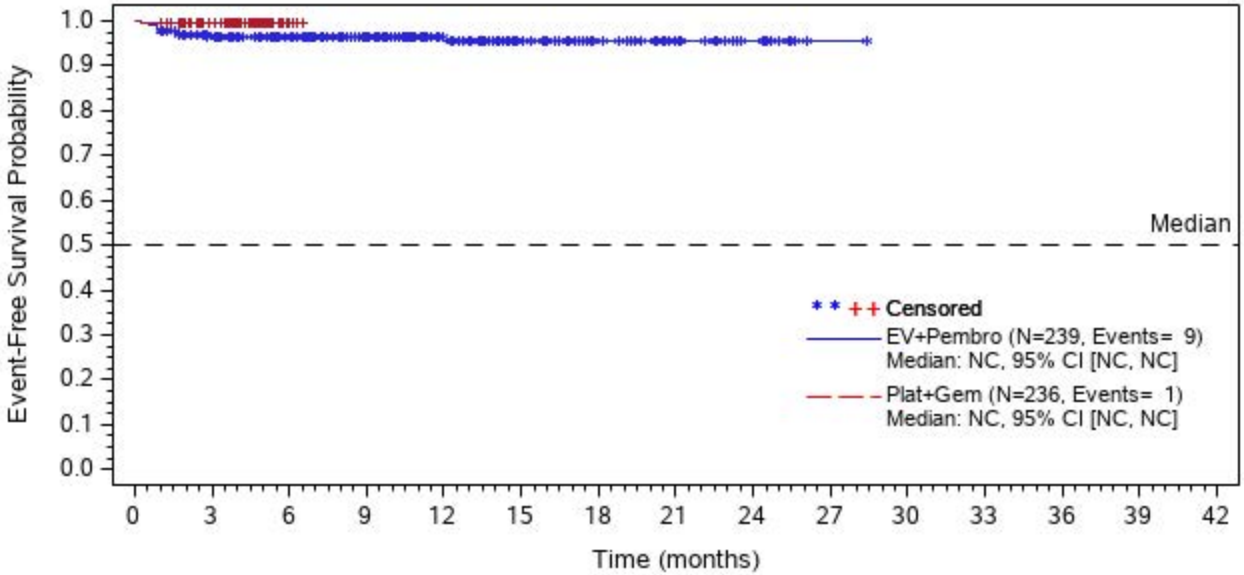
1	201	159	129	100	67	47	30	17	5	1	1	0	0	0	0
2	197	151	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.160.1.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Hepatobiliary disorders (SOC) - Analysis Set mSAF 1



at Risk

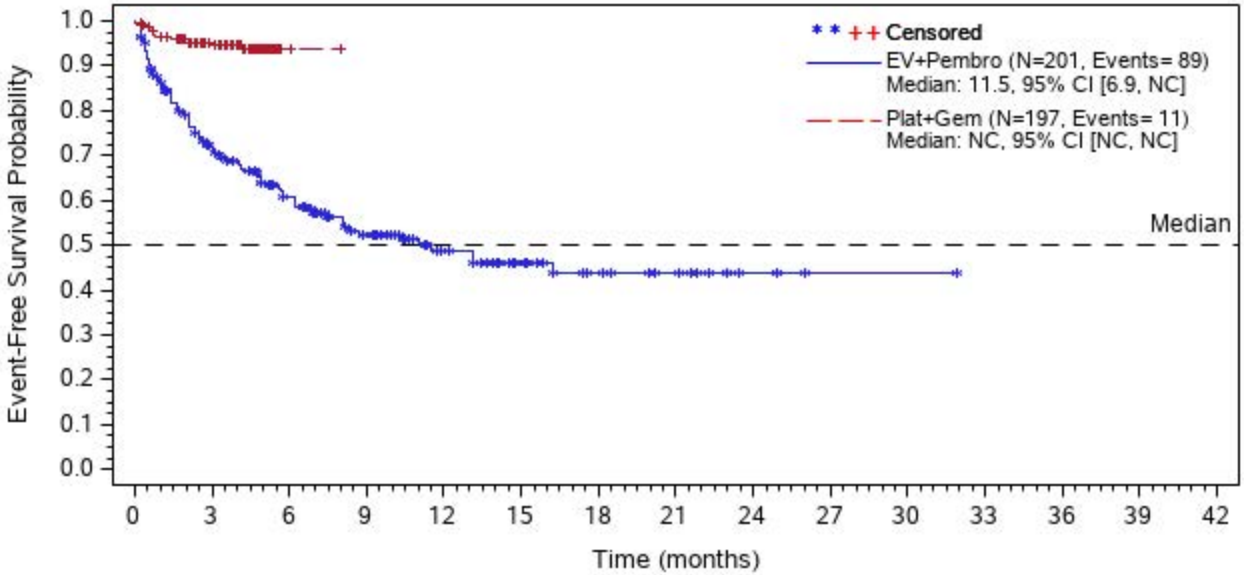
1	239	206	166	129	85	57	38	22	12	1	0	0	0	0	0
2	236	200	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.160.2.1: Kaplan-Meier Plot of Time to first TEAESI - Immune related and infusion reactions - Analysis Set mSAF 2



at Risk

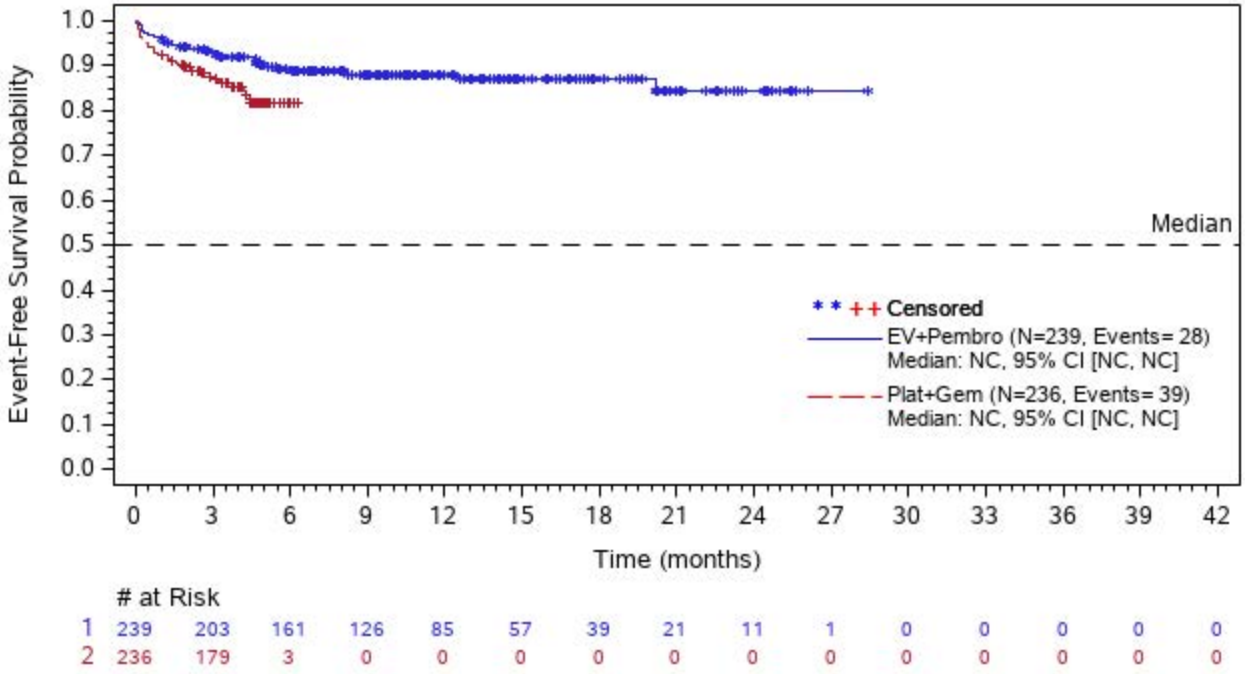
1	201	127	90	60	37	24	15	11	4	1	1	0	0	0	0
2	197	144	2	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.161.1.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Infections and infestations (SOC) - Analysis Set mSAF 1



at Risk

1	239	203	161	126	85	57	39	21	11	1	0	0	0	0	0
2	236	179	3	0	0	0	0	0	0	0	0	0	0	0	0

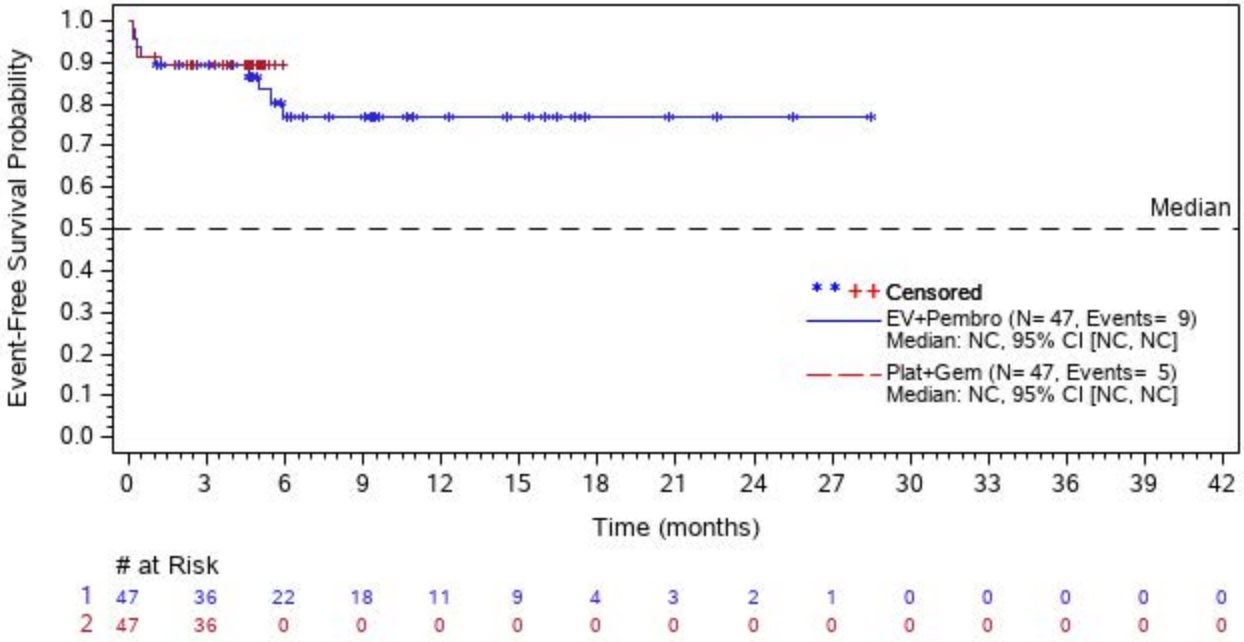
Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.161.1.2.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Infections and infestations (SOC) - Analysis Set mSAF 1

Liver Metastases: Present



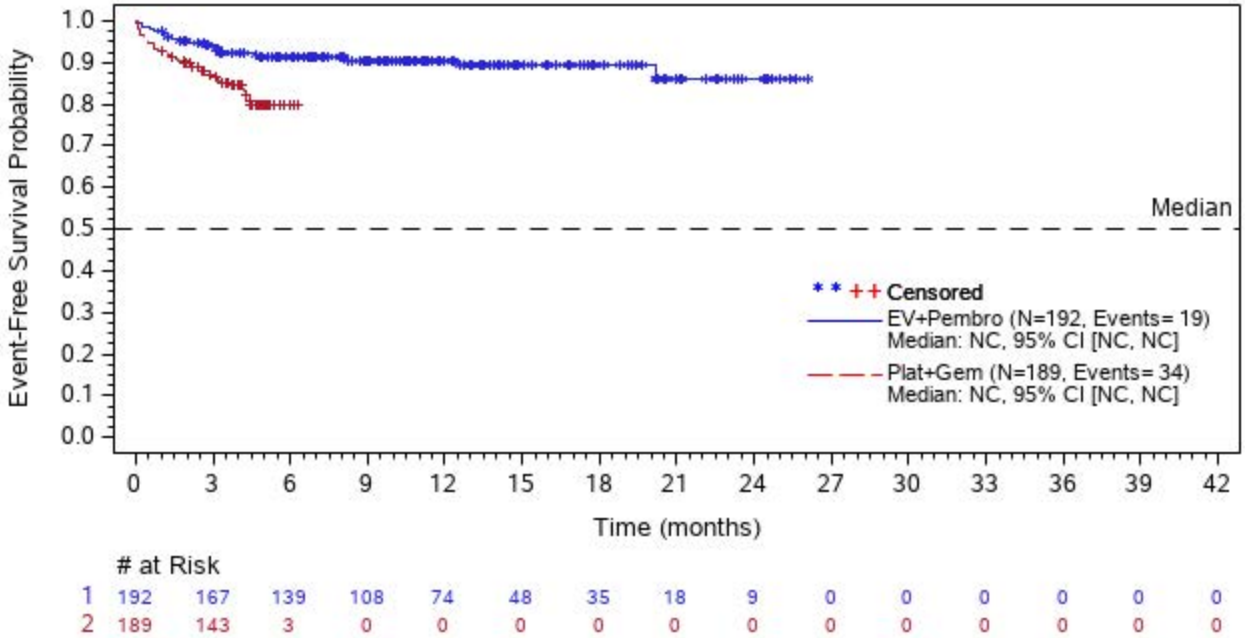
Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.161.1.2.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Infections and infestations (SOC) - Analysis Set mSAF 1

Liver Metastases: Absent



at Risk

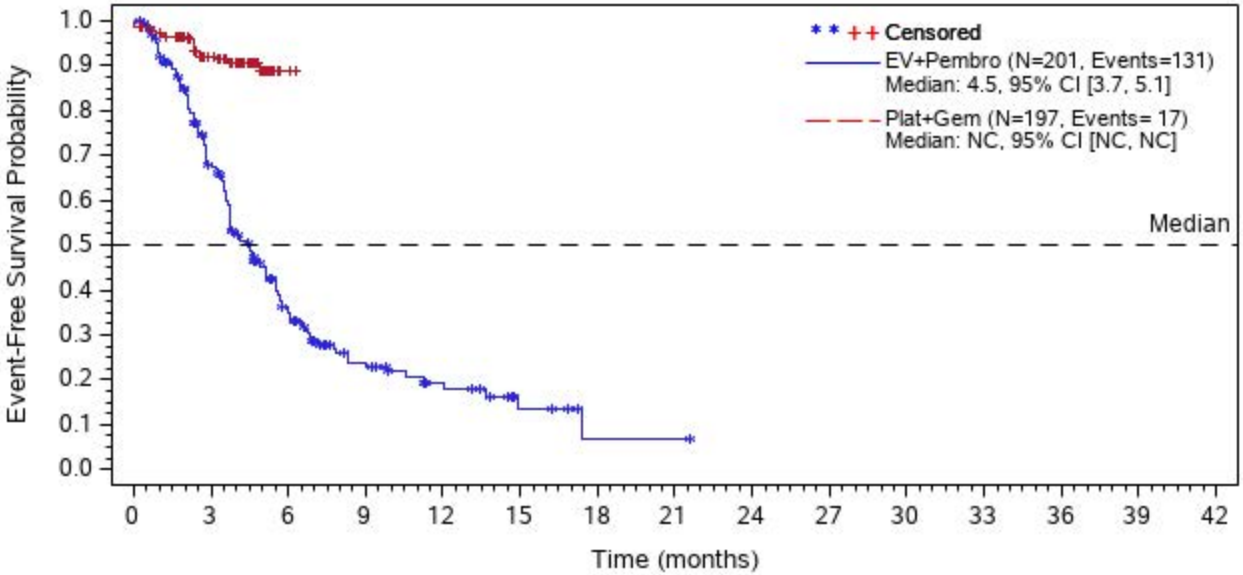
1	192	167	139	108	74	48	35	18	9	0	0	0	0	0	0
2	189	143	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.161.2.1: Kaplan-Meier Plot of Time to first TEAESI - Peripheral neuropathy - Analysis Set mSAF 2



at Risk

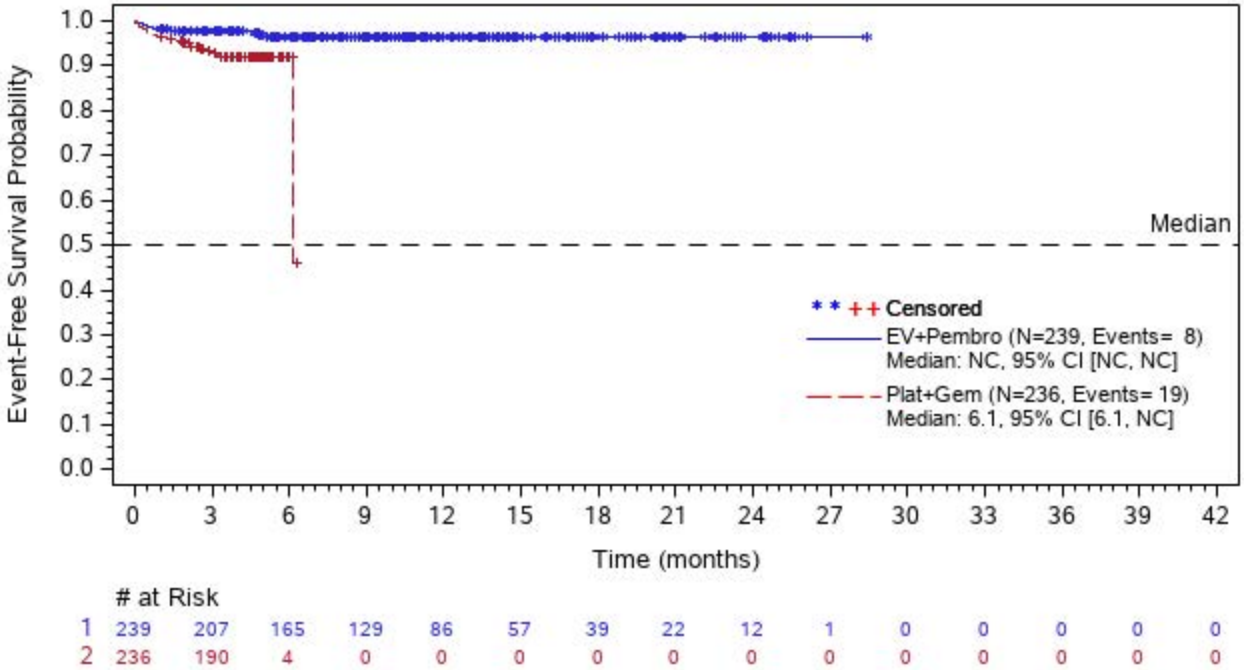
1	201	115	49	24	14	5	1	1	0	0	0	0	0	0	0
2	197	140	2	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.162.1.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Urinary tract infection (PT) - Analysis Set mSAF 1



at Risk

1	239	207	165	129	86	57	39	22	12	1	0	0	0	0	0
2	236	190	4	0	0	0	0	0	0	0	0	0	0	0	0

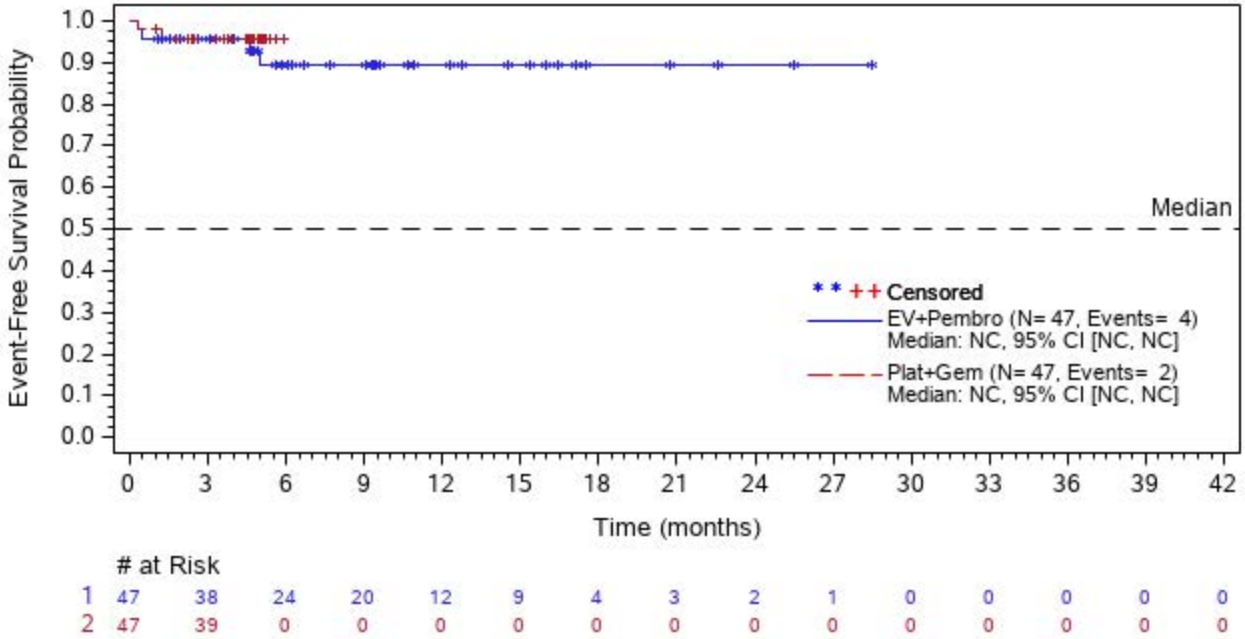
Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.162.1.2.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Urinary tract infection (PT) - Analysis Set mSAF 1

Liver Metastases: Present



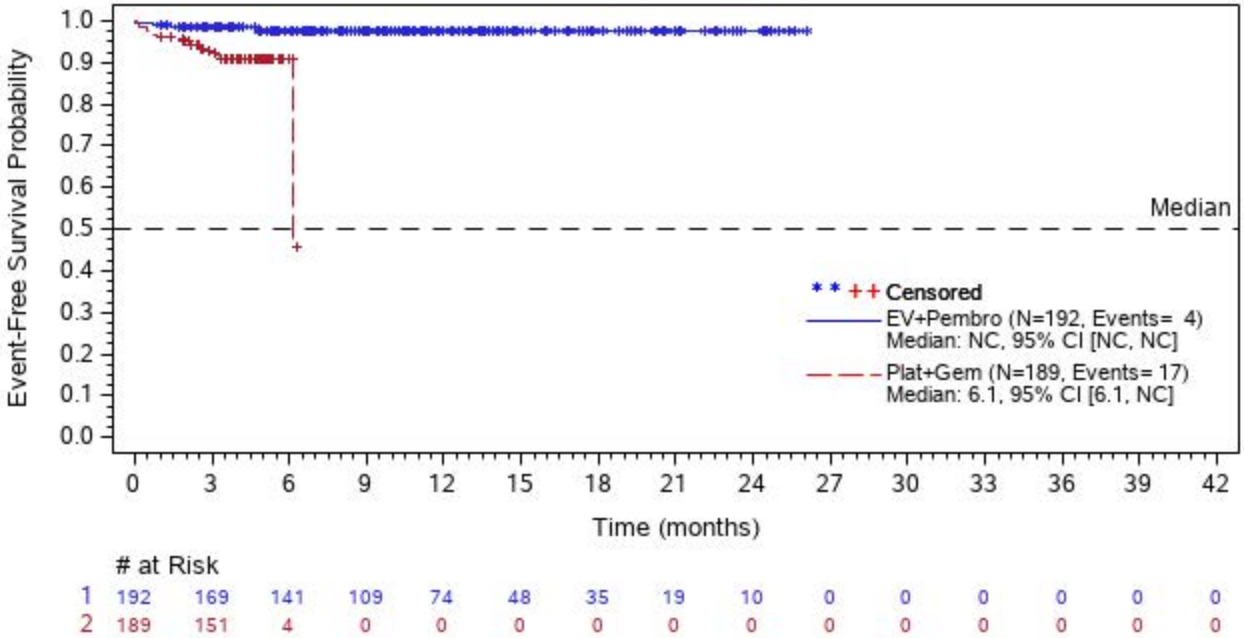
Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.162.1.2.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Urinary tract infection (PT) - Analysis Set mSAF 1

Liver Metastases: Absent

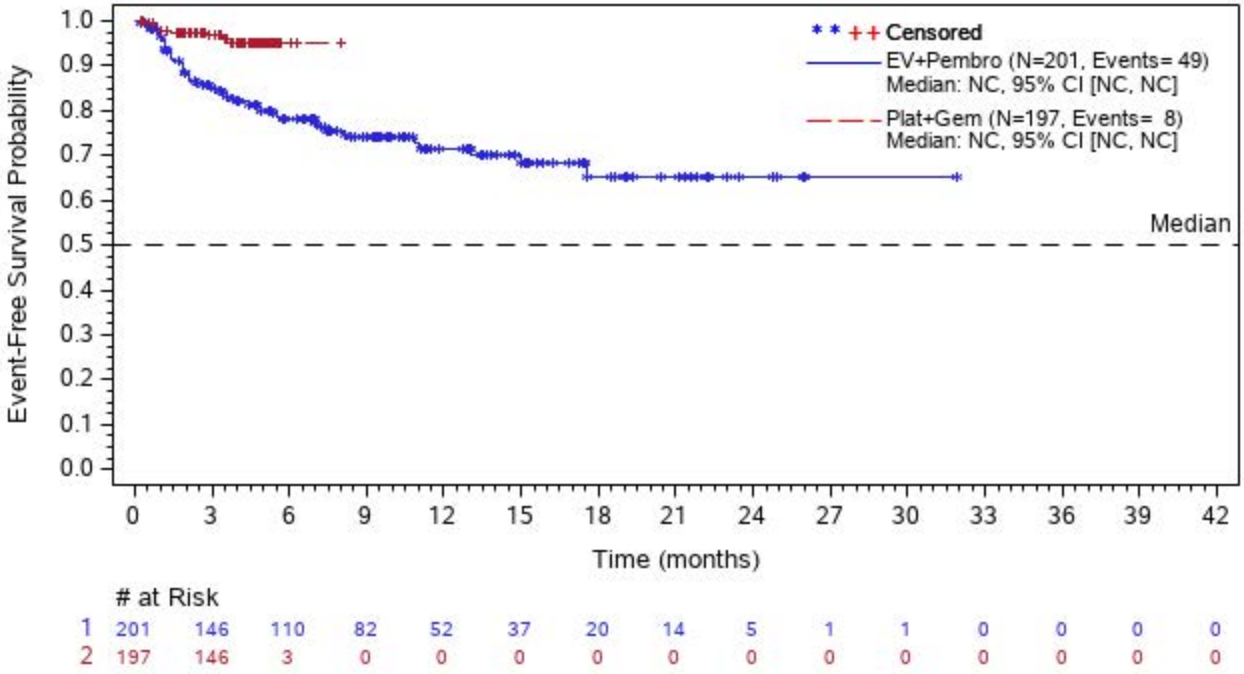


Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.162.2.1: Kaplan-Meier Plot of Time to first TEAESI - Ocular disorders - Analysis Set mSAF 2

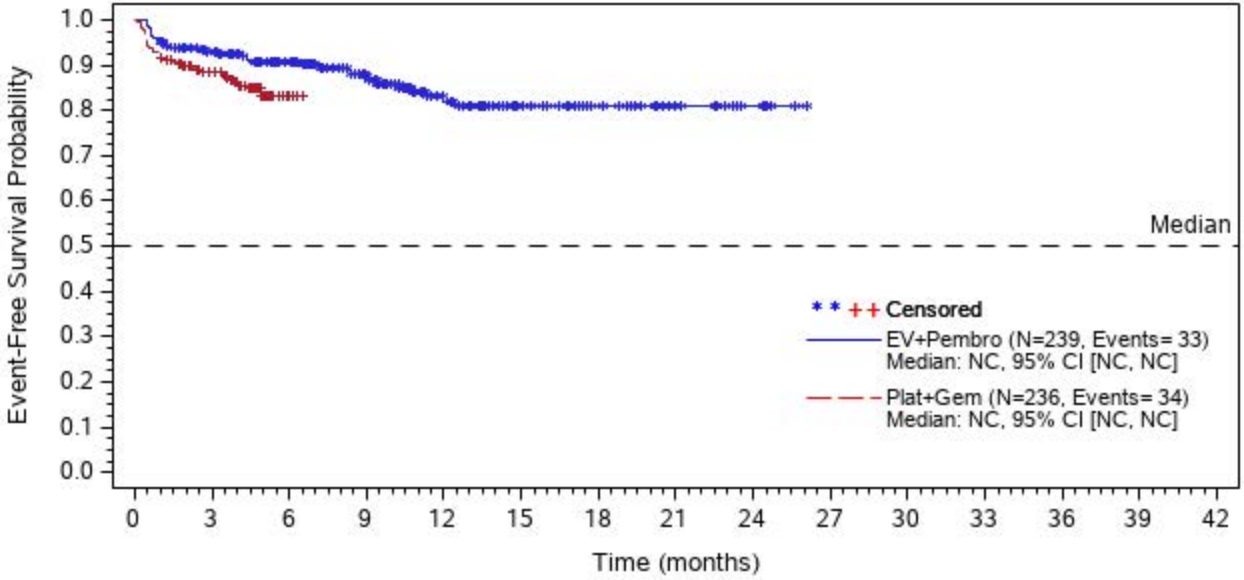


Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.163.1.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Investigations (SOC) - Analysis Set mSAF 1



at Risk

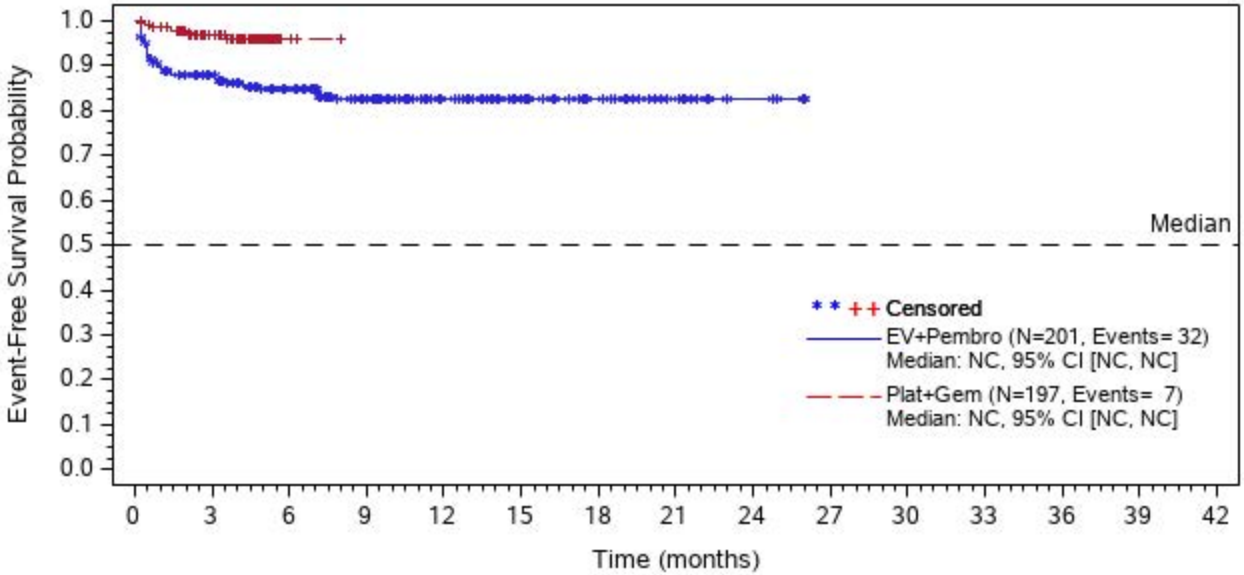
1	239	201	160	120	73	46	32	16	8	0	0	0	0	0	0
2	236	177	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.163.2.1: Kaplan-Meier Plot of Time to first TEAESI - Hyperglycemia - Analysis Set mSAF 2



at Risk

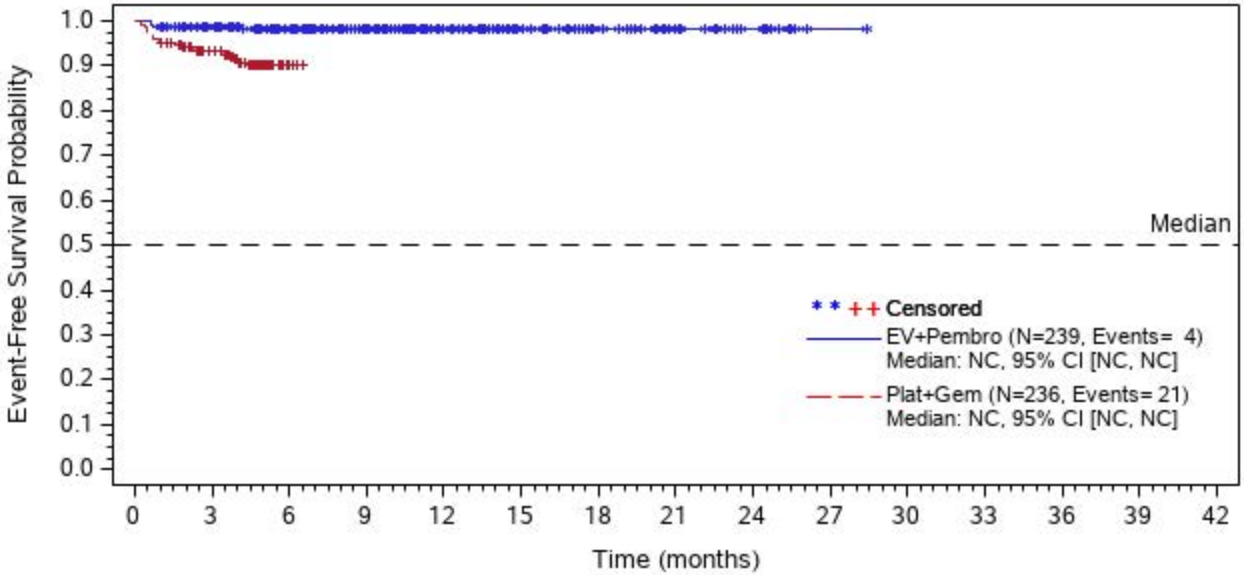
1	201	154	120	91	62	44	27	15	5	0	0	0	0	0	0
2	197	146	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.164.1.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Neutrophil count decreased (PT) - Analysis Set mSAF 1



at Risk

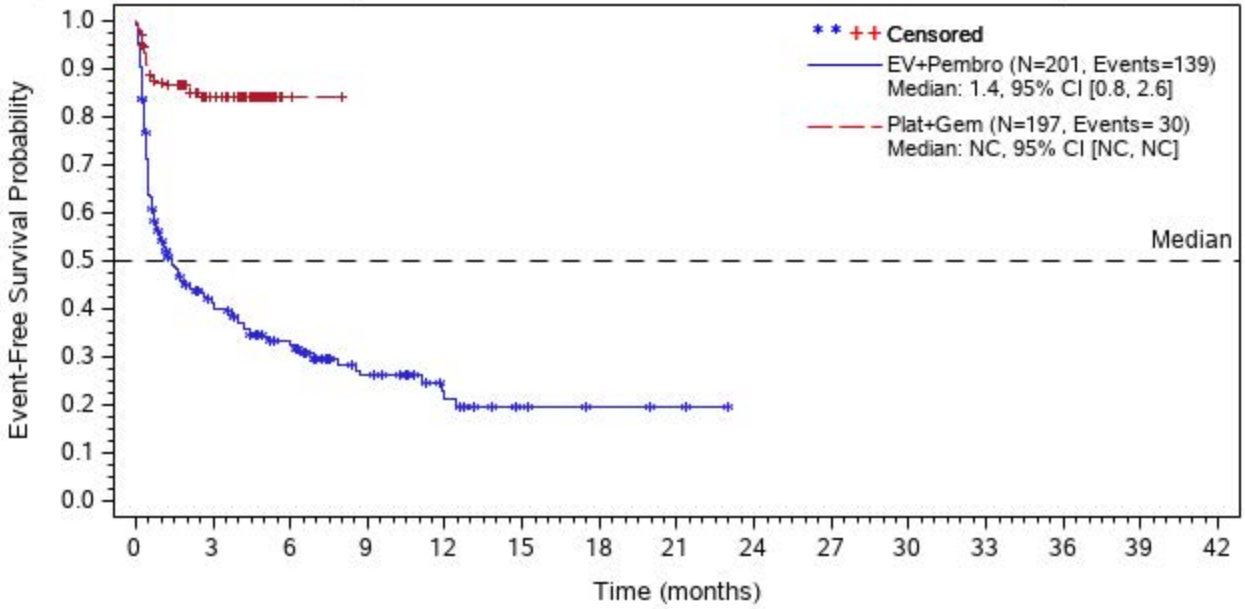
1	239	210	168	130	86	57	39	22	12	1	0	0	0	0	0
2	236	185	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.164.2.1: Kaplan-Meier Plot of Time to first TEAESI - Skin reactions - Analysis Set mSAF 2



at Risk

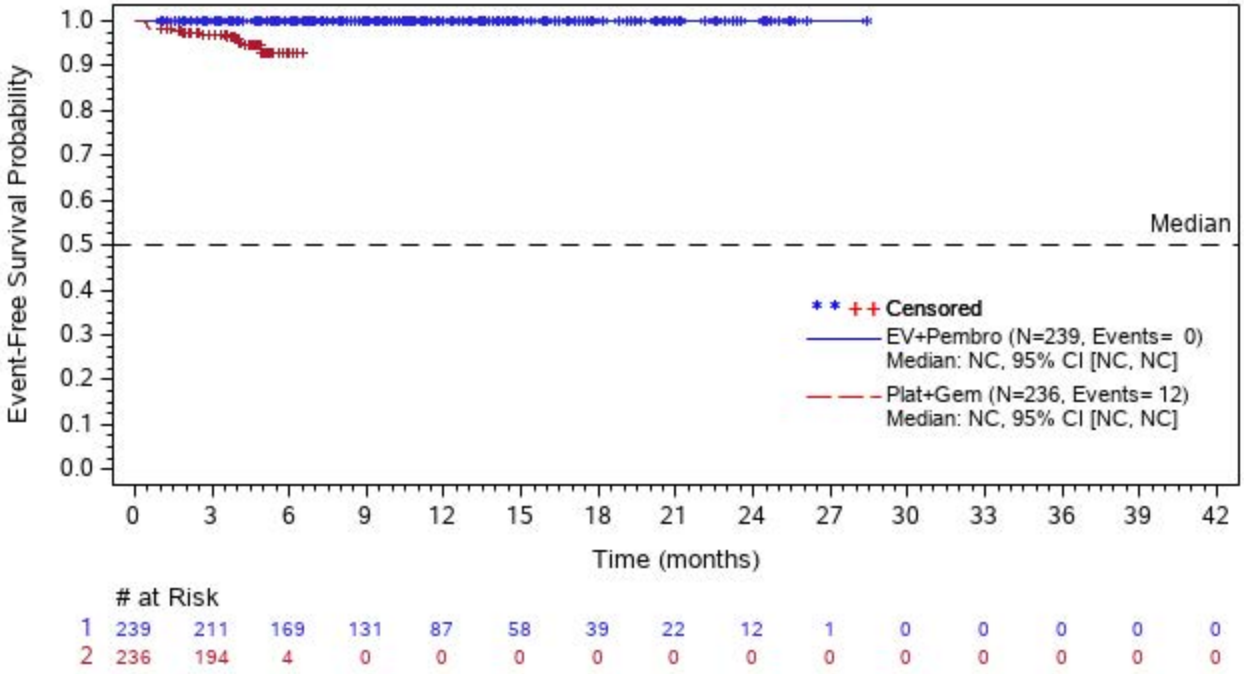
1	201	70	45	24	13	5	3	2	0	0	0	0	0	0	0
2	197	124	2	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.165.1.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Platelet count decreased (PT) - Analysis Set mSAF 1



at Risk

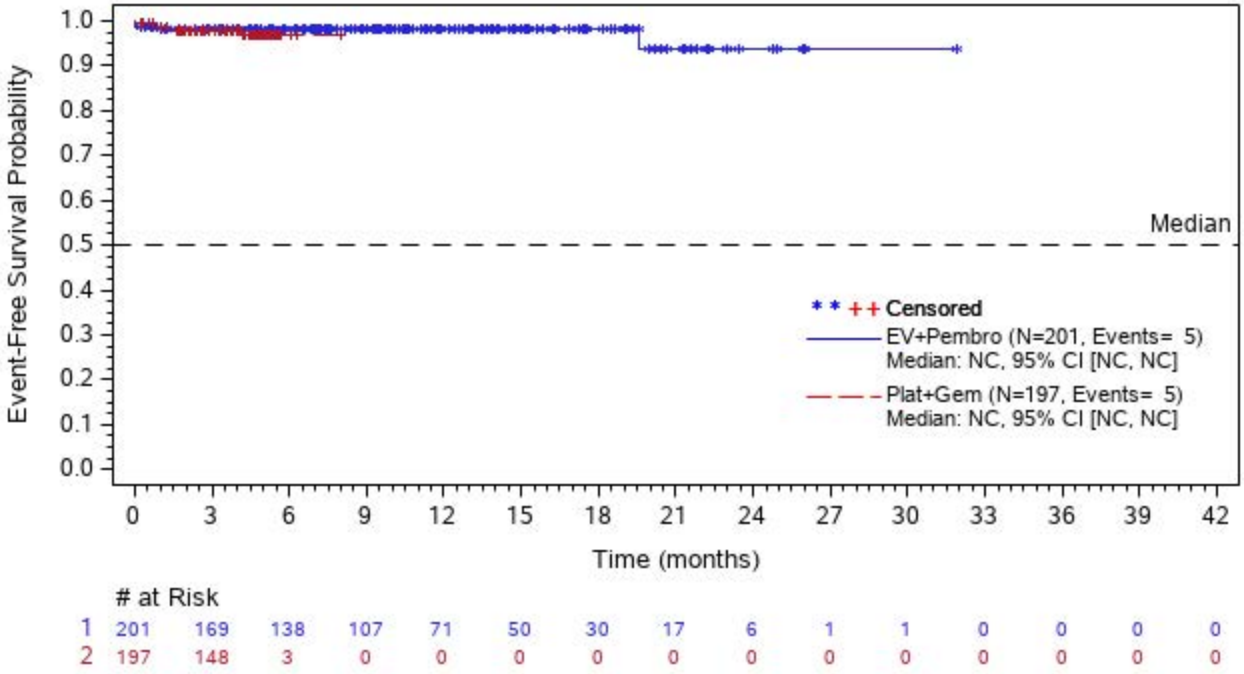
1	239	211	169	131	87	58	39	22	12	1	0	0	0	0	0
2	236	194	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.165.2.1: Kaplan-Meier Plot of Time to first TEAESI - Infusion related reactions (IRR) - Analysis Set mSAF 2



at Risk

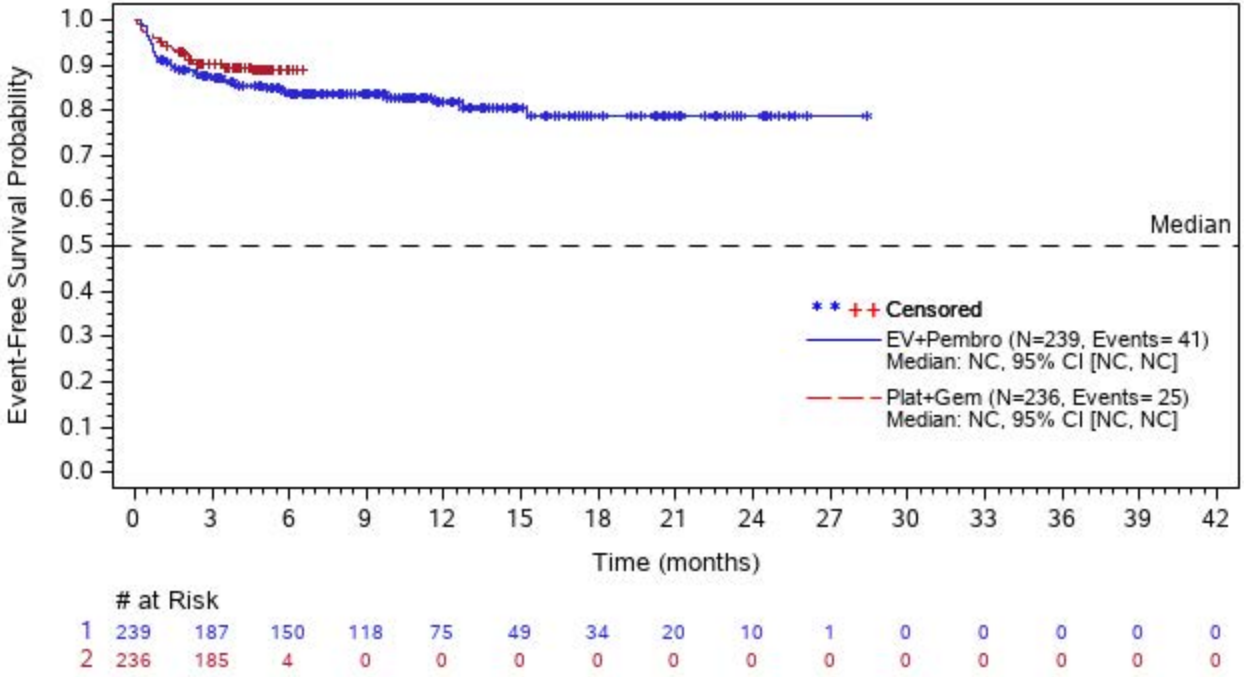
1	201	169	138	107	71	50	30	17	6	1	1	0	0	0	0
2	197	148	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.166.1.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Metabolism and nutrition disorders (SOC) - Analysis Set mSAF 1



at Risk

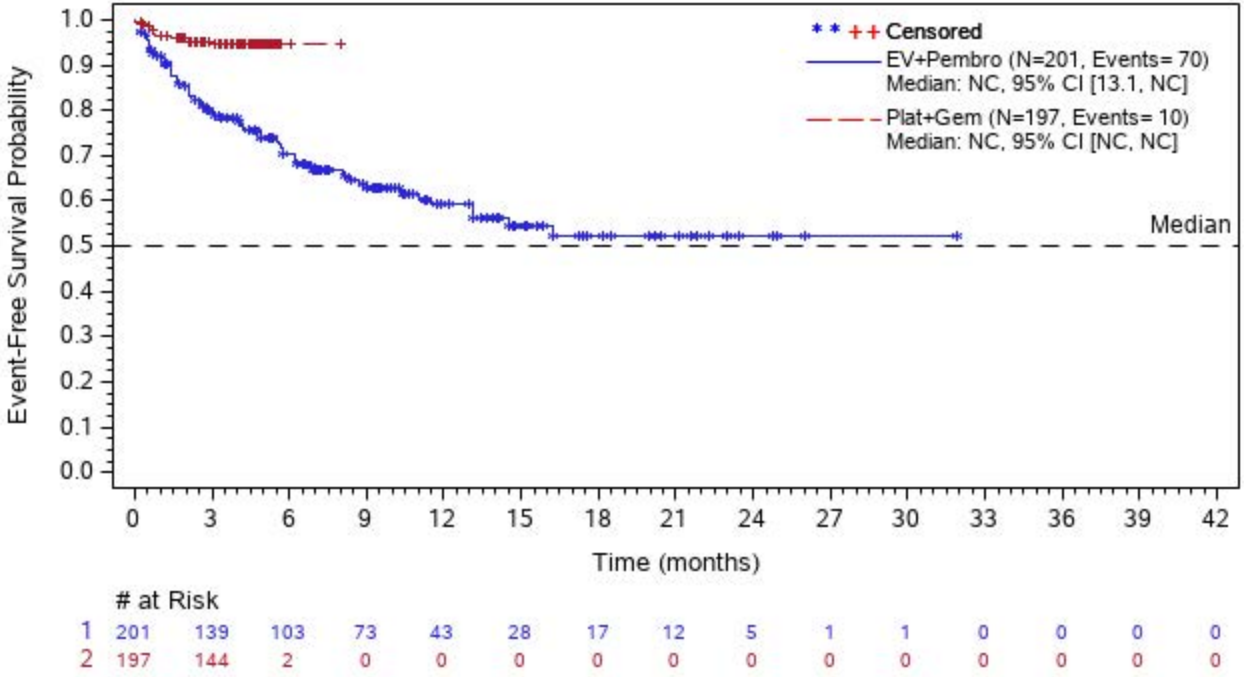
1	239	187	150	118	75	49	34	20	10	1	0	0	0	0	0
2	236	185	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.166.2.1: Kaplan-Meier Plot of Time to first Non-Severe TEAESI (CTCAE Grade < 3) - Immune related and infusion reactions - Analysis Set mSAF 2

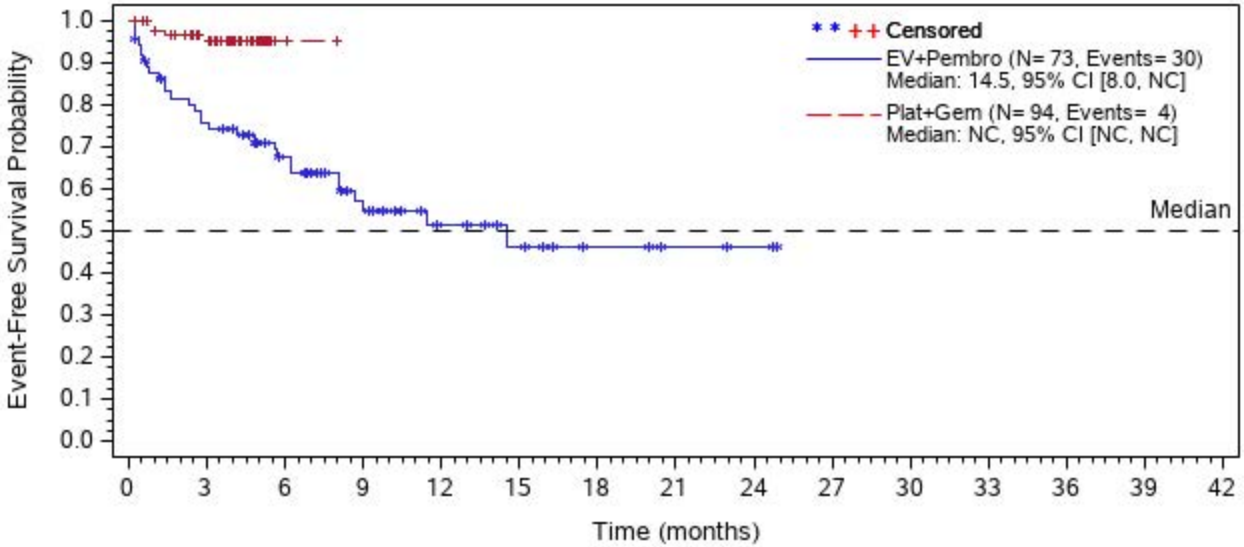


Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.166.2.2.3: Kaplan-Meier Plot of Time to first Non-Severe TEAESI (CTCAE Grade < 3) - Immune related and infusion reactions - Analysis Set mSAF 2
Region: Europe



at Risk

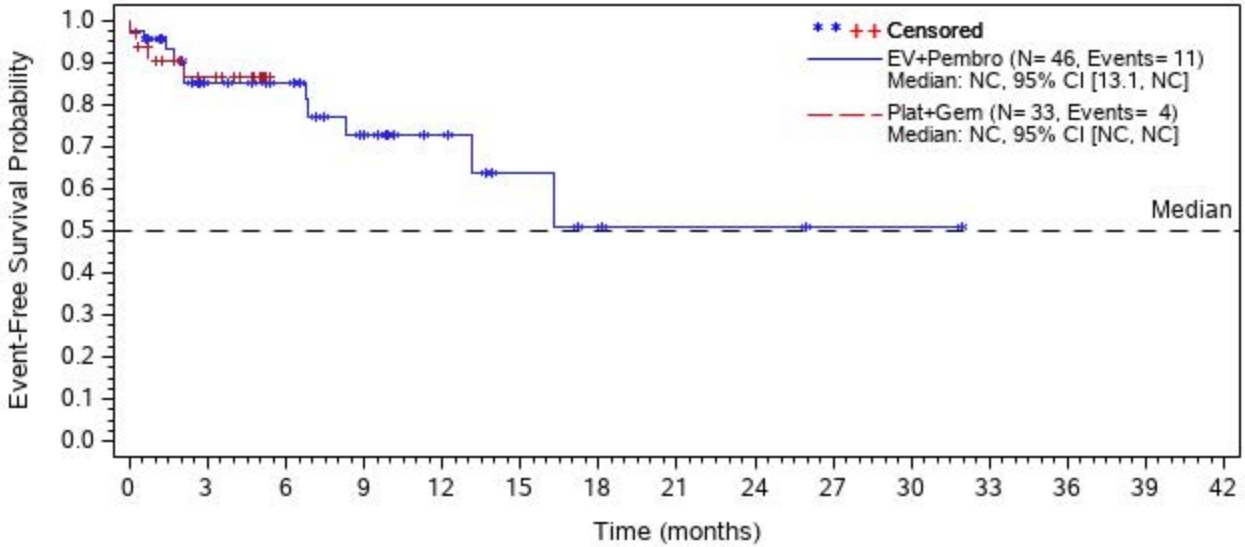
1	73	51	38	24	13	9	5	3	2	0	0	0	0	0	0
2	94	73	2	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.166.2.2.3: Kaplan-Meier Plot of Time to first Non-Severe TEAESI (CTCAE Grade < 3) - Immune related and infusion reactions - Analysis Set mSAF 2
Region: North America



at Risk

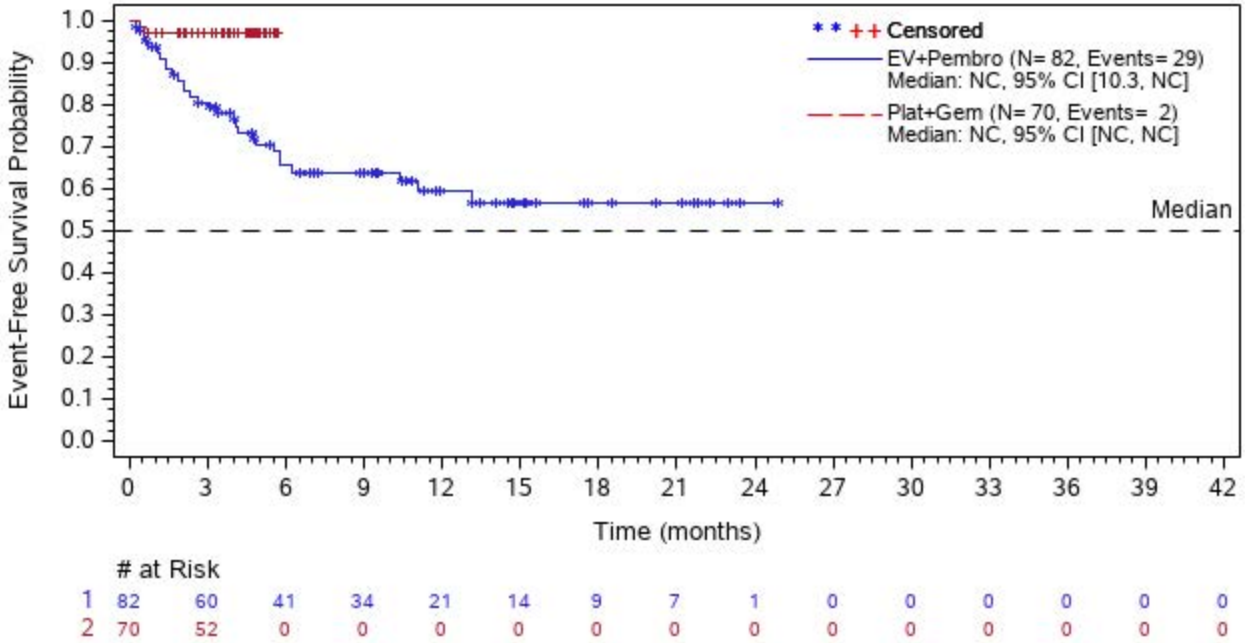
1	46	28	24	15	9	5	3	2	2	1	1	0	0	0	0
2	33	19	0	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.166.2.2.3: Kaplan-Meier Plot of Time to first Non-Severe TEAESI (CTCAE Grade < 3) - Immune related and infusion reactions - Analysis Set mSAF 2
Region: Rest of World



at Risk

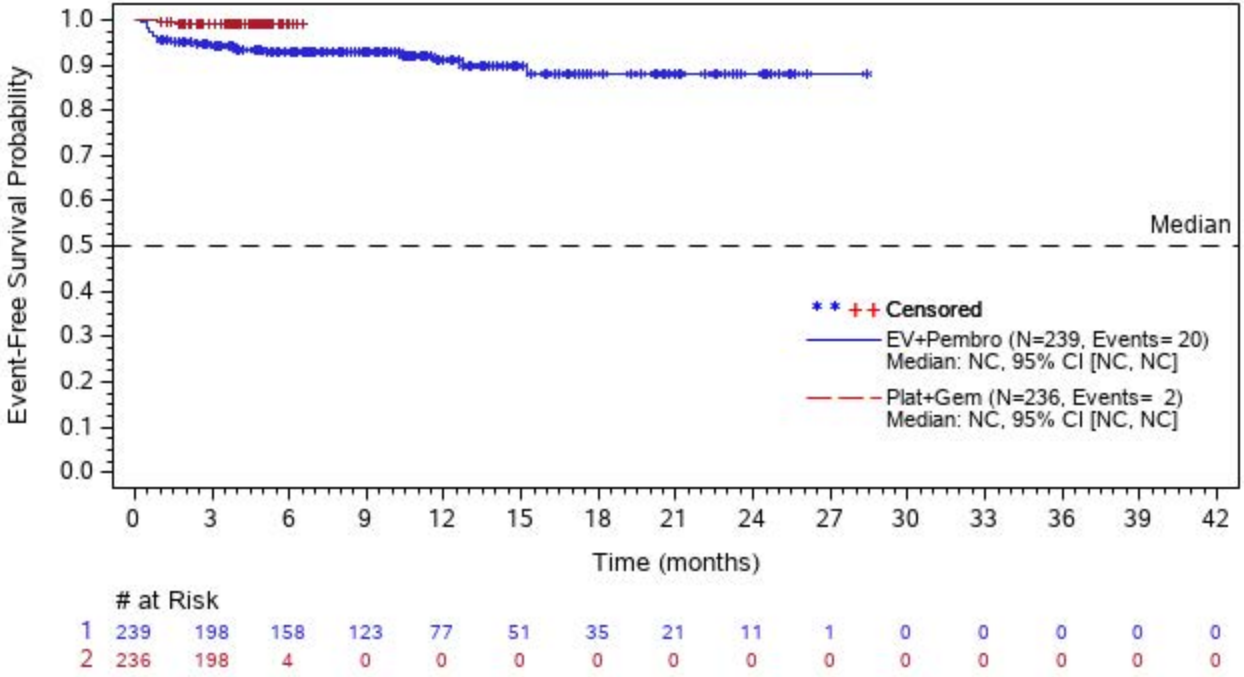
1	82	60	41	34	21	14	9	7	1	0	0	0	0	0	0
2	70	52	0	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.167.1.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Hyperglycaemia (PT) - Analysis Set mSAF 1



at Risk

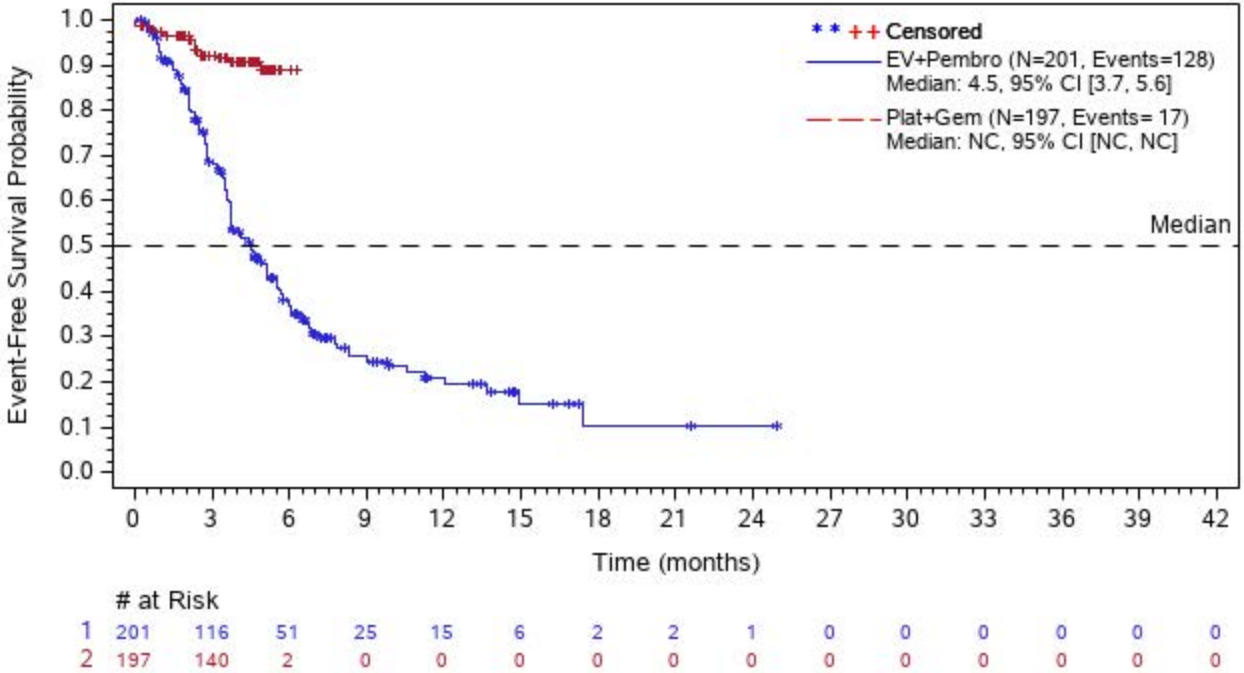
1	239	198	158	123	77	51	35	21	11	1	0	0	0	0	0
2	236	198	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.167.2.1: Kaplan-Meier Plot of Time to first Non-Severe TEAESI (CTCAE Grade < 3) - Peripheral neuropathy - Analysis Set mSAF 2



at Risk

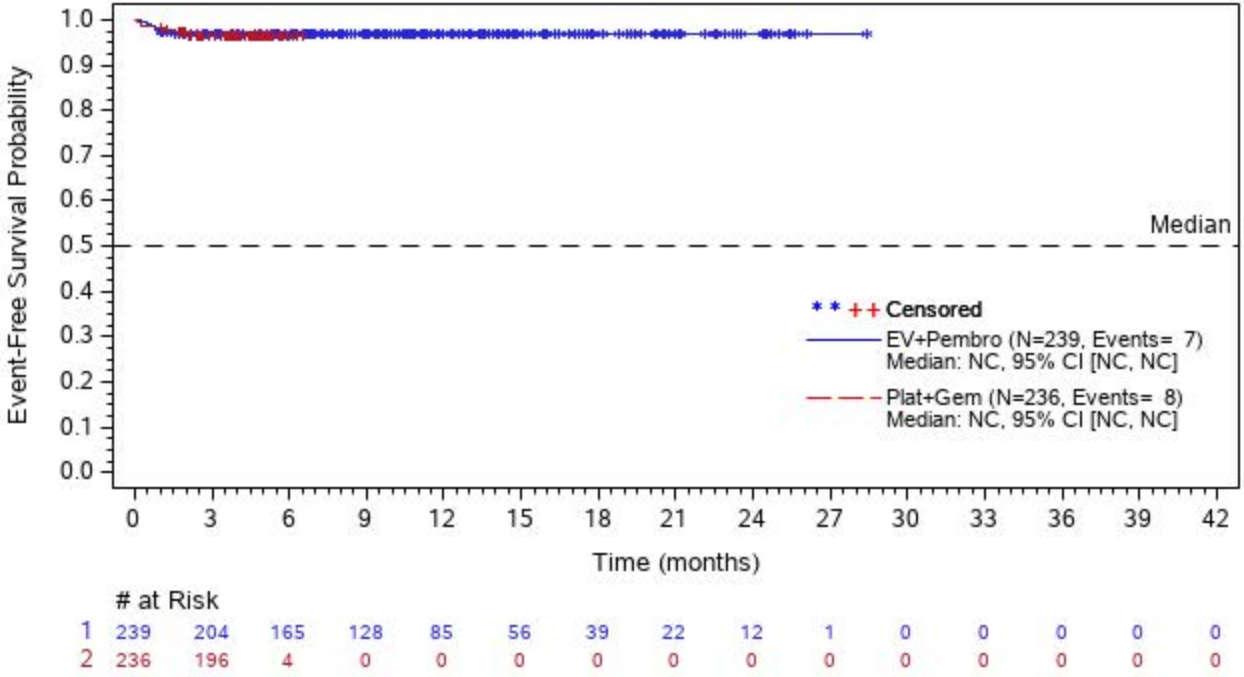
1	201	116	51	25	15	6	2	2	1	0	0	0	0	0	0
2	197	140	2	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.168.1.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Hyponatraemia (PT) - Analysis Set mSAF 1



at Risk

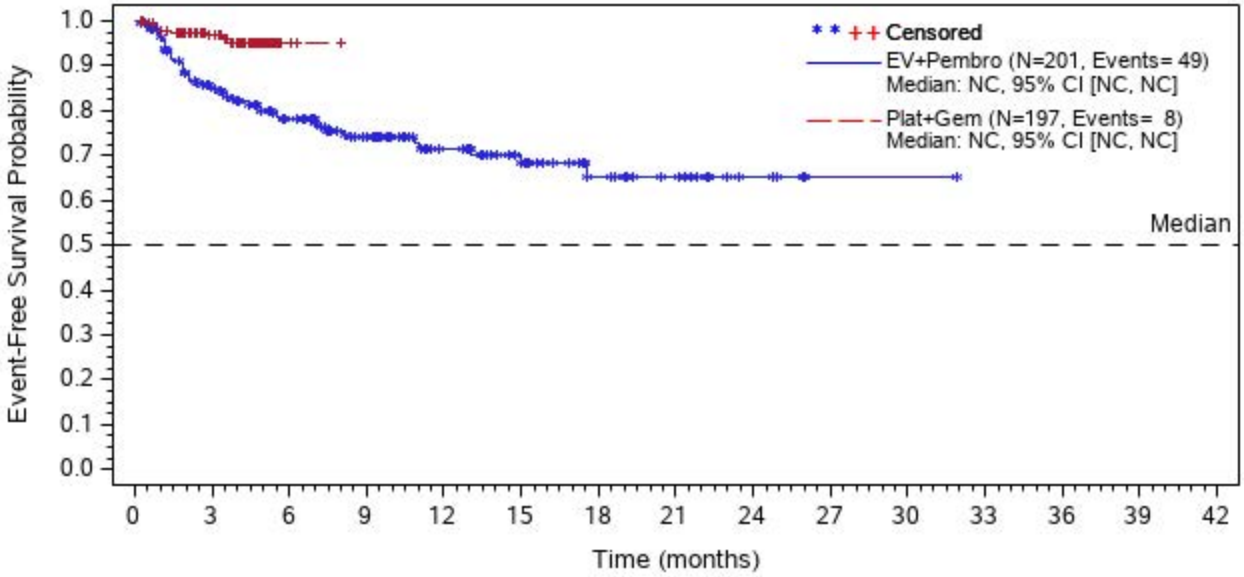
1	239	204	165	128	85	56	39	22	12	1	0	0	0	0	0
2	236	196	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.168.2.1: Kaplan-Meier Plot of Time to first Non-Severe TEAESI (CTCAE Grade < 3) - Ocular disorders - Analysis Set mSAF 2



at Risk

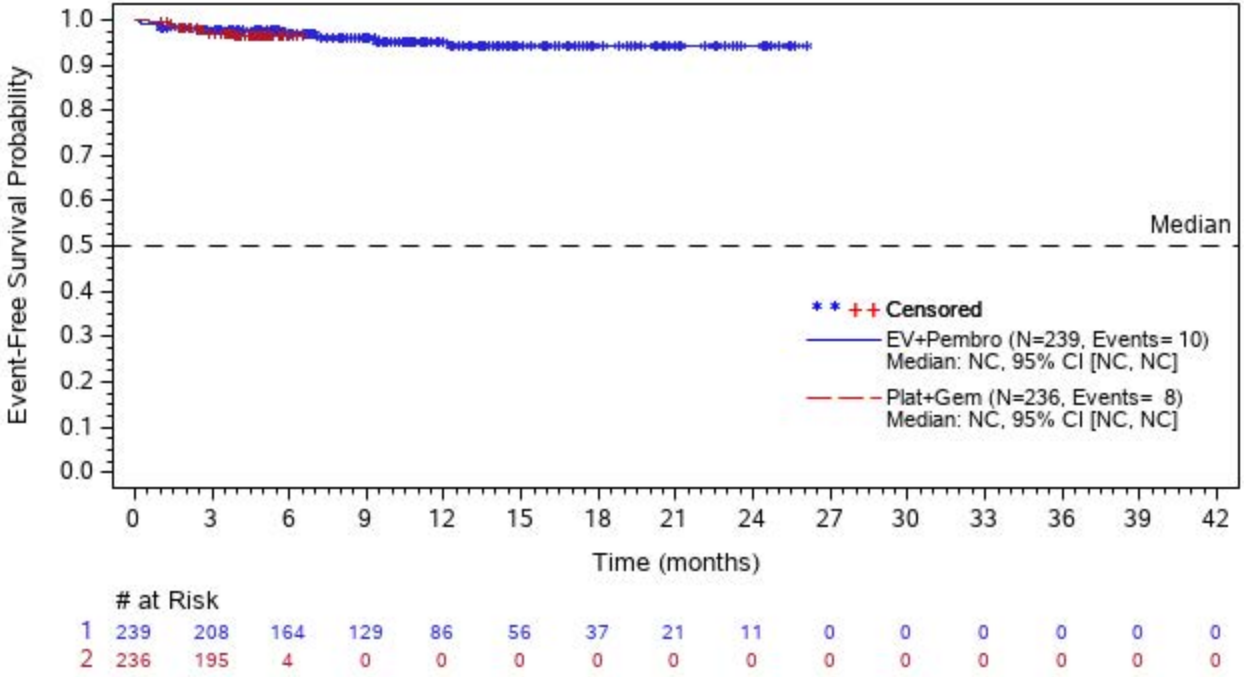
1	201	146	110	82	52	37	20	14	5	1	1	0	0	0	0
2	197	146	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.169.1.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Musculoskeletal and connective tissue disorders (SOC) - Analysis Set mSAF 1



at Risk

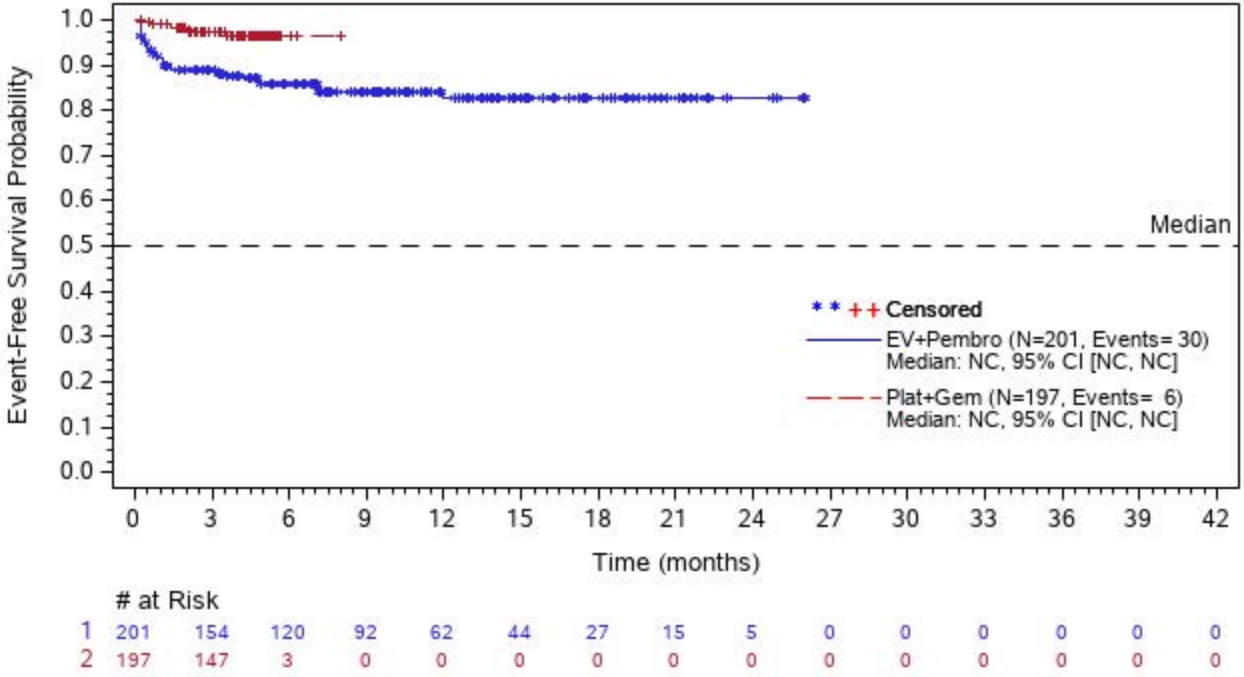
1	239	208	164	129	86	56	37	21	11	0	0	0	0	0	0
2	236	195	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.169.2.1: Kaplan-Meier Plot of Time to first Non-Severe TEAESI (CTCAE Grade < 3) - Hyperglycemia - Analysis Set mSAF 2



at Risk

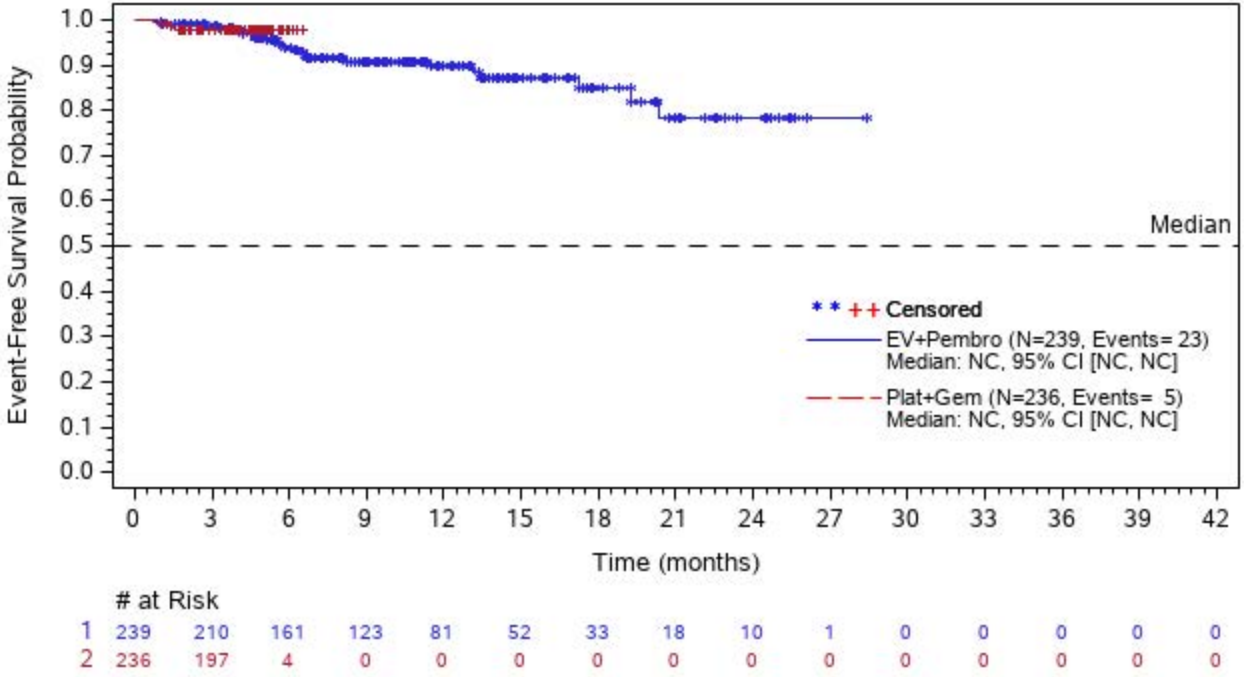
1	201	154	120	92	62	44	27	15	5	0	0	0	0	0	0
2	197	147	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.170.1.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Nervous system disorders (SOC) - Analysis Set mSAF 1



at Risk

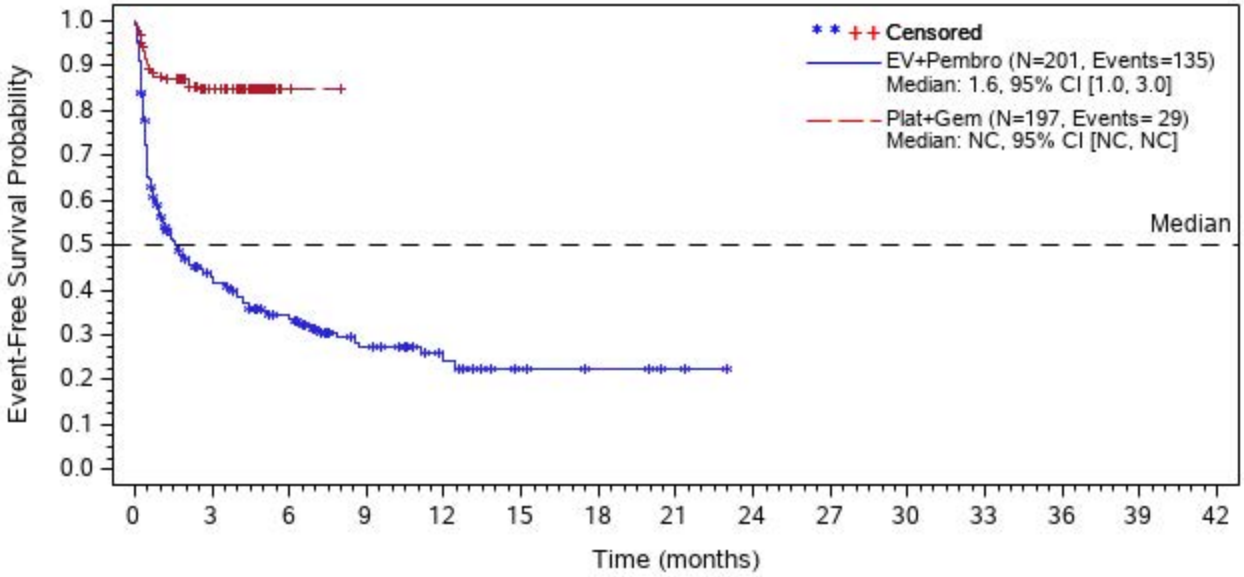
1	239	210	161	123	81	52	33	18	10	1	0	0	0	0	0
2	236	197	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.170.2.1: Kaplan-Meier Plot of Time to first Non-Severe TEAESI (CTCAE Grade < 3) - Skin reactions - Analysis Set mSAF 2



at Risk

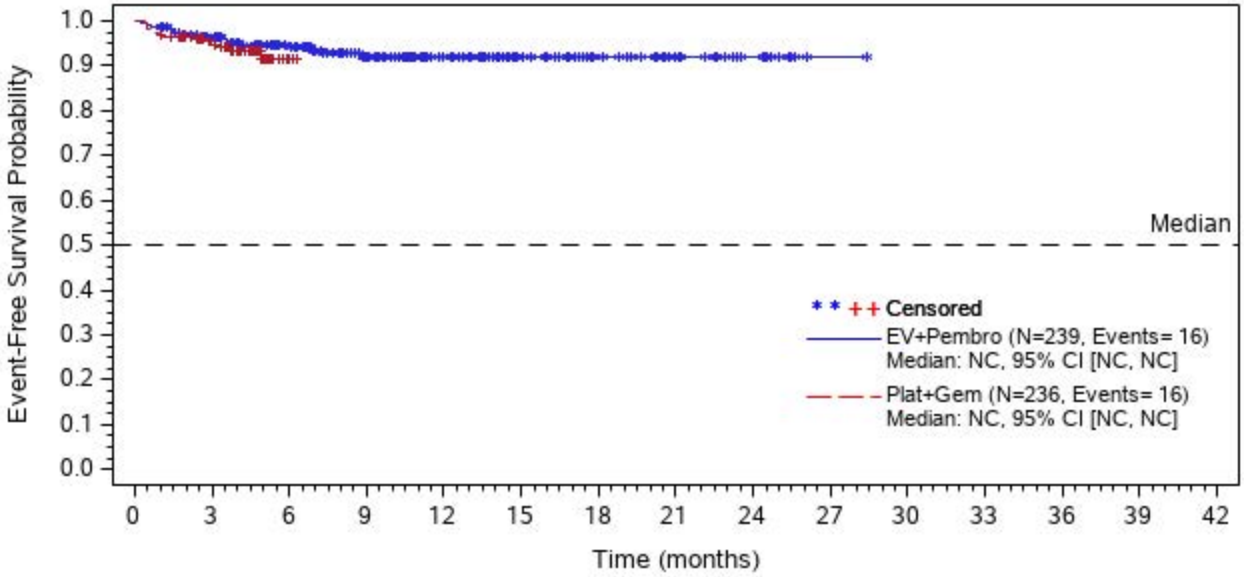
1	201	71	46	25	15	6	4	2	0	0	0	0	0	0	0
2	197	125	2	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.171.1.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Renal and urinary disorders (SOC) - Analysis Set mSAF 1



at Risk

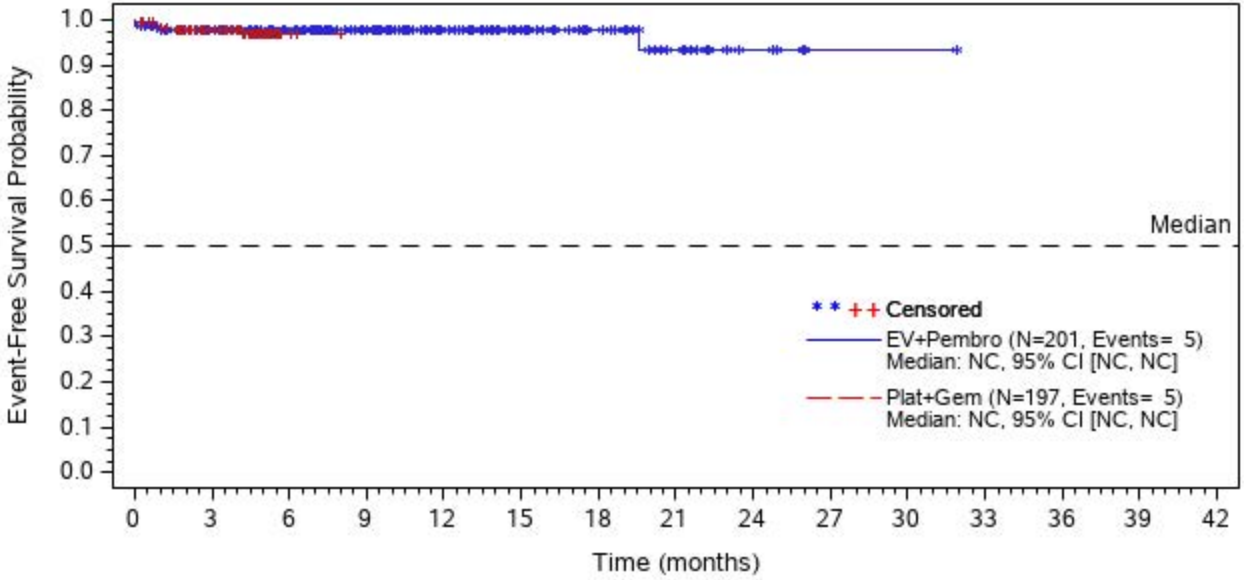
1	239	206	163	125	84	56	38	22	12	1	0	0	0	0	0
2	236	193	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.171.2.1: Kaplan-Meier Plot of Time to first Non-Severe TEAESI (CTCAE Grade < 3) - Infusion related reactions (IRR) - Analysis Set mSAF 2



at Risk

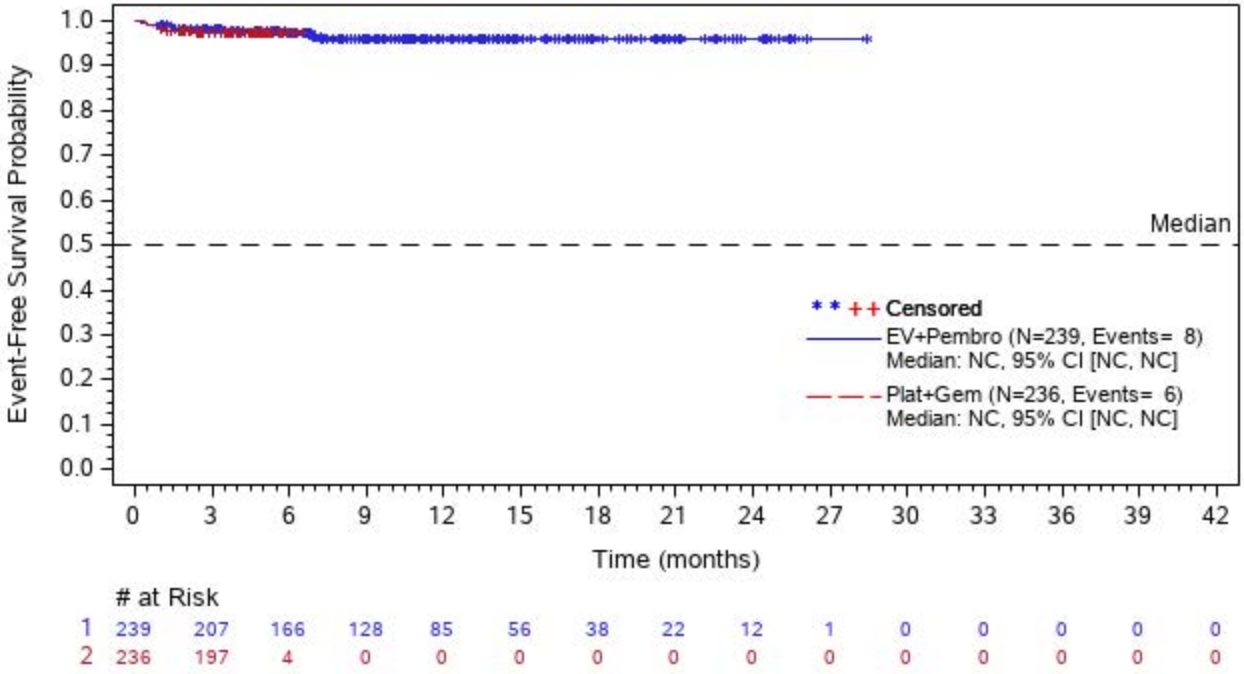
1	201	169	138	107	71	50	30	17	6	1	1	0	0	0	0
2	197	148	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.172.1.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Acute kidney injury (PT) - Analysis Set mSAF 1



at Risk

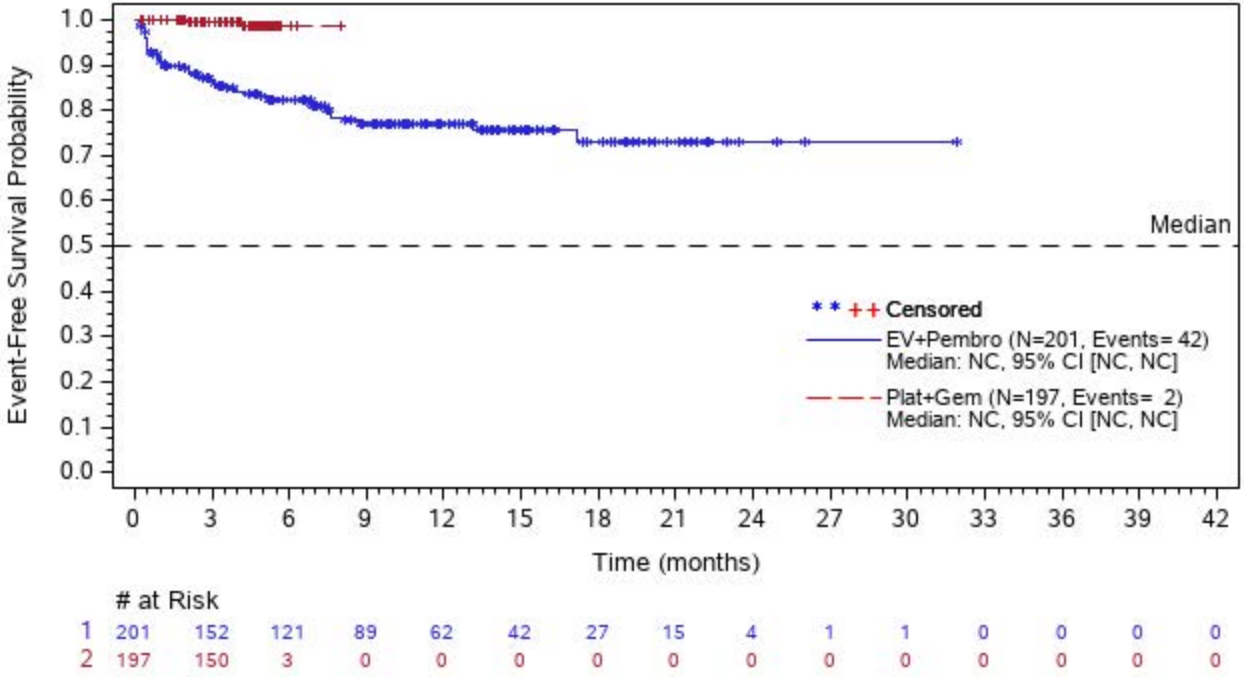
1	239	207	166	128	85	56	38	22	12	1	0	0	0	0	0
2	236	197	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.172.2.1: Kaplan-Meier Plot of Time to first Severe TEAESI (CTCAE Grade >= 3) - Immune related and infusion reactions - Analysis Set mSAF 2



at Risk

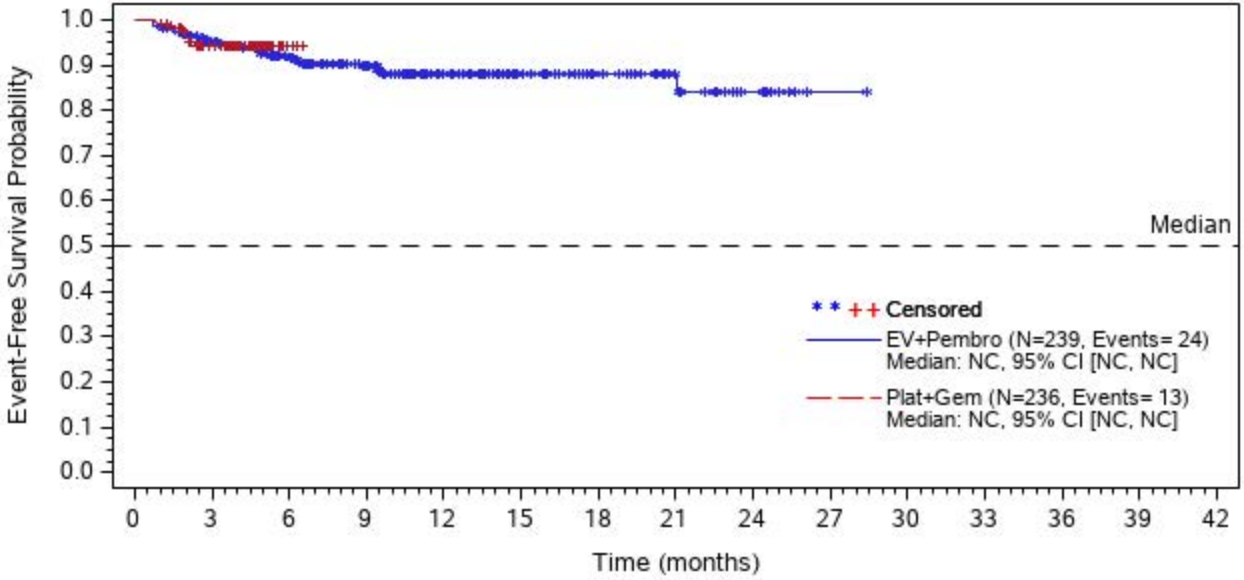
1	201	152	121	89	62	42	27	15	4	1	1	0	0	0	0
2	197	150	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.173.1.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Respiratory, thoracic and mediastinal disorders (SOC) - Analysis Set mSAF 1



at Risk

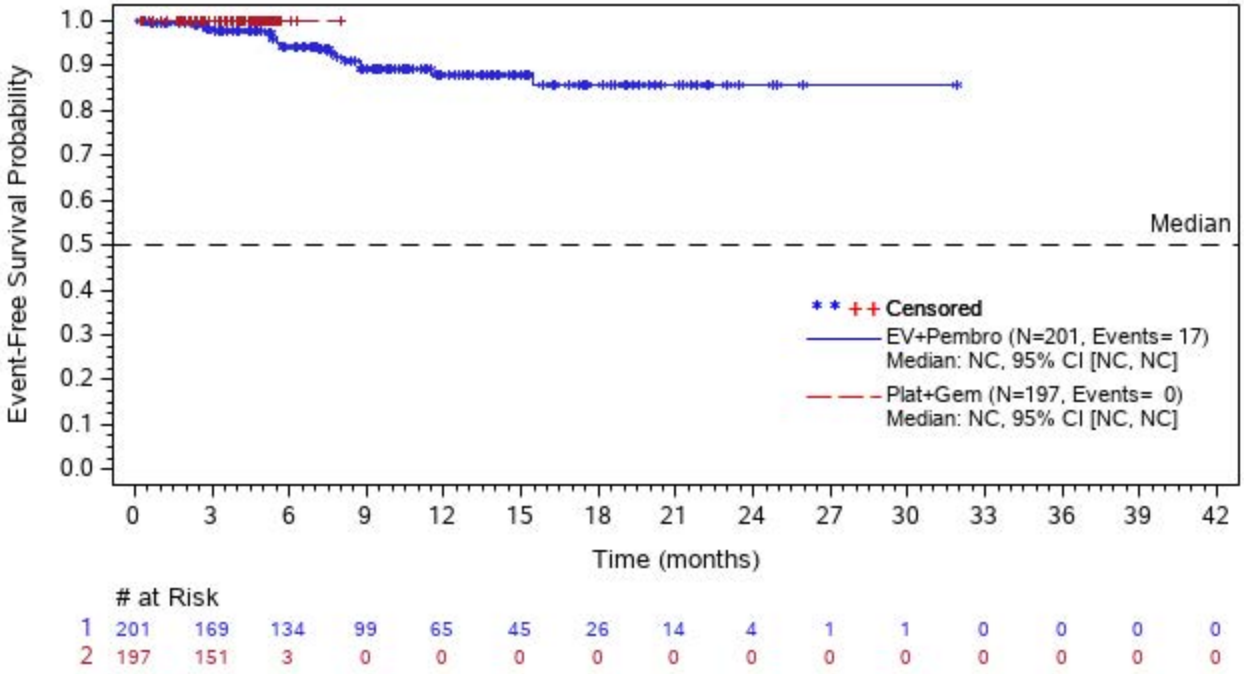
1	239	204	163	124	85	57	39	22	11	1	0	0	0	0	0
2	236	190	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.173.2.1: Kaplan-Meier Plot of Time to first Severe TEAESI (CTCAE Grade >= 3) - Peripheral neuropathy - Analysis Set mSAF 2



at Risk

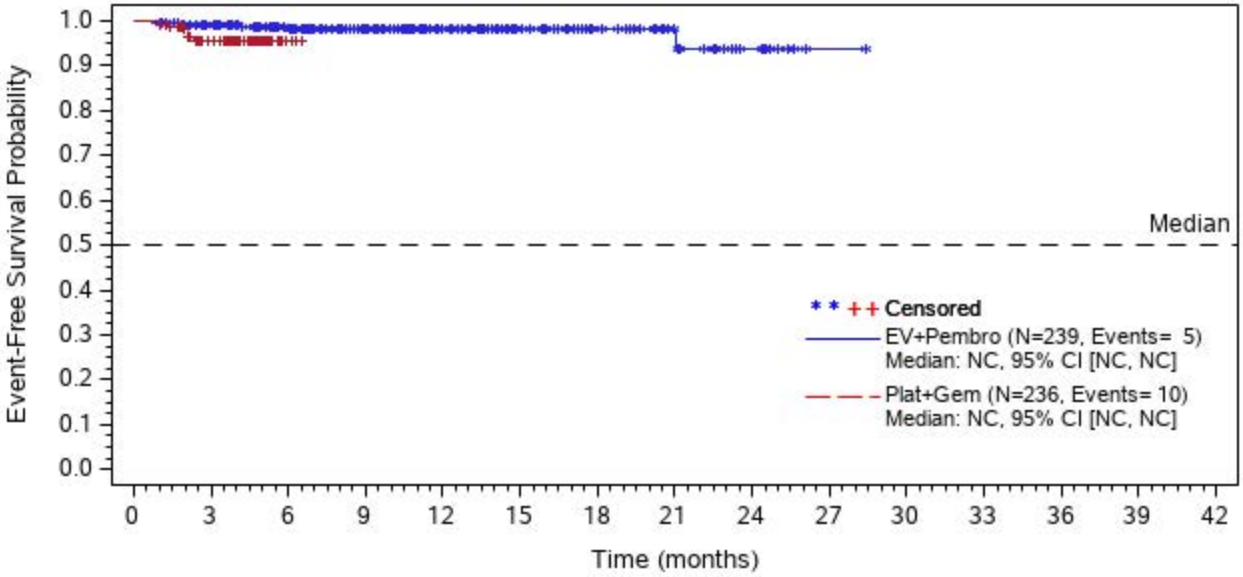
1	201	169	134	99	65	45	26	14	4	1	1	0	0	0	0
2	197	151	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.174.1.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Pulmonary embolism (PT) - Analysis Set mSAF 1



at Risk

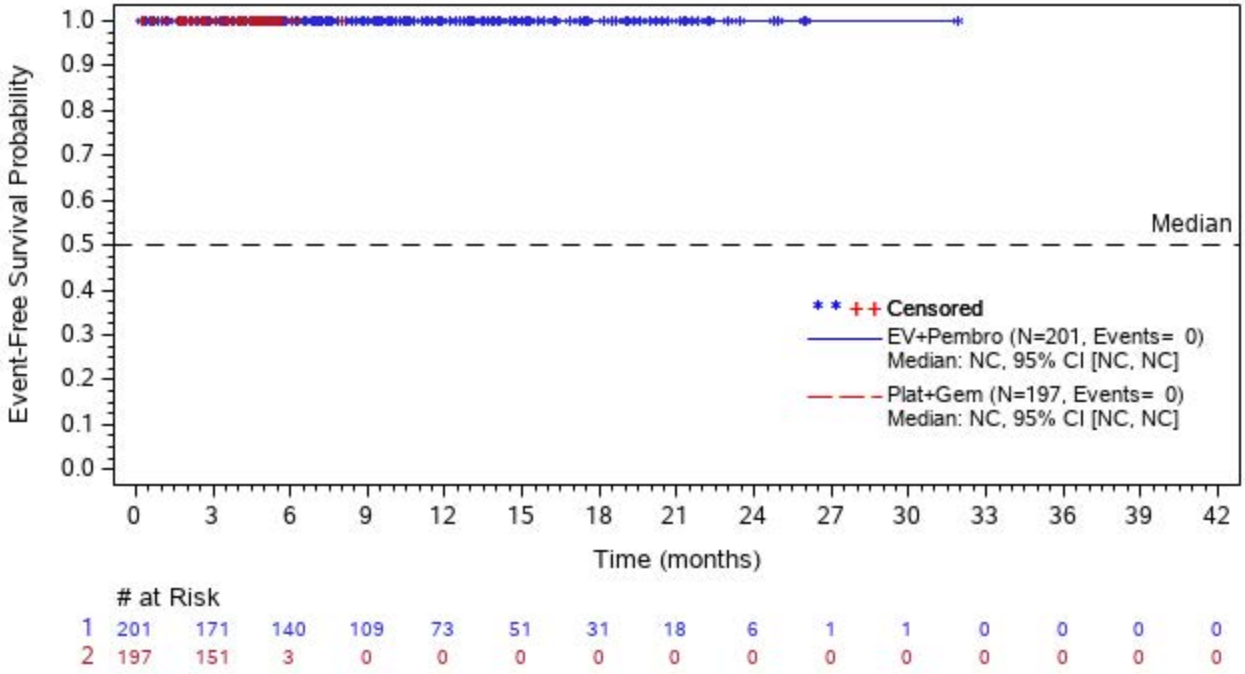
1	239	209	166	128	86	58	39	22	11	1	0	0	0	0	0
2	236	192	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.174.2.1: Kaplan-Meier Plot of Time to first Severe TEAESI (CTCAE Grade >= 3) - Ocular disorders - Analysis Set mSAF 2



at Risk

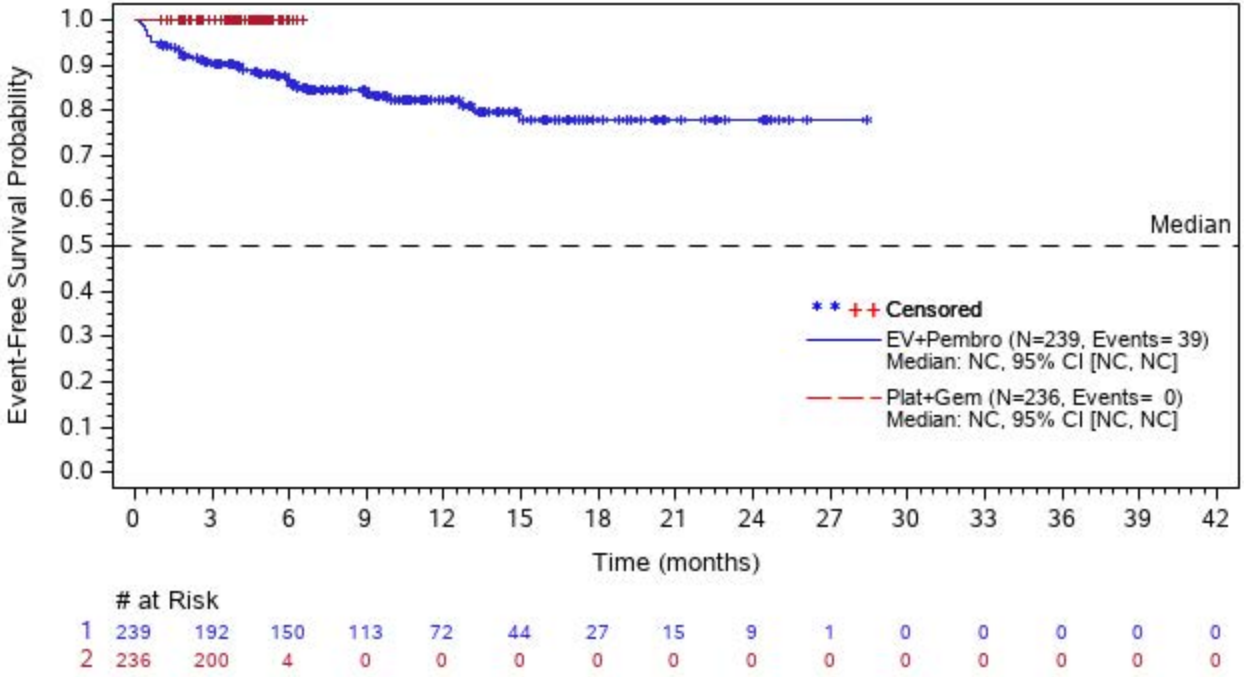
1	201	171	140	109	73	51	31	18	6	1	1	0	0	0	0
2	197	151	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.175.1.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Skin and subcutaneous tissue disorders (SOC) - Analysis Set mSAF 1



at Risk

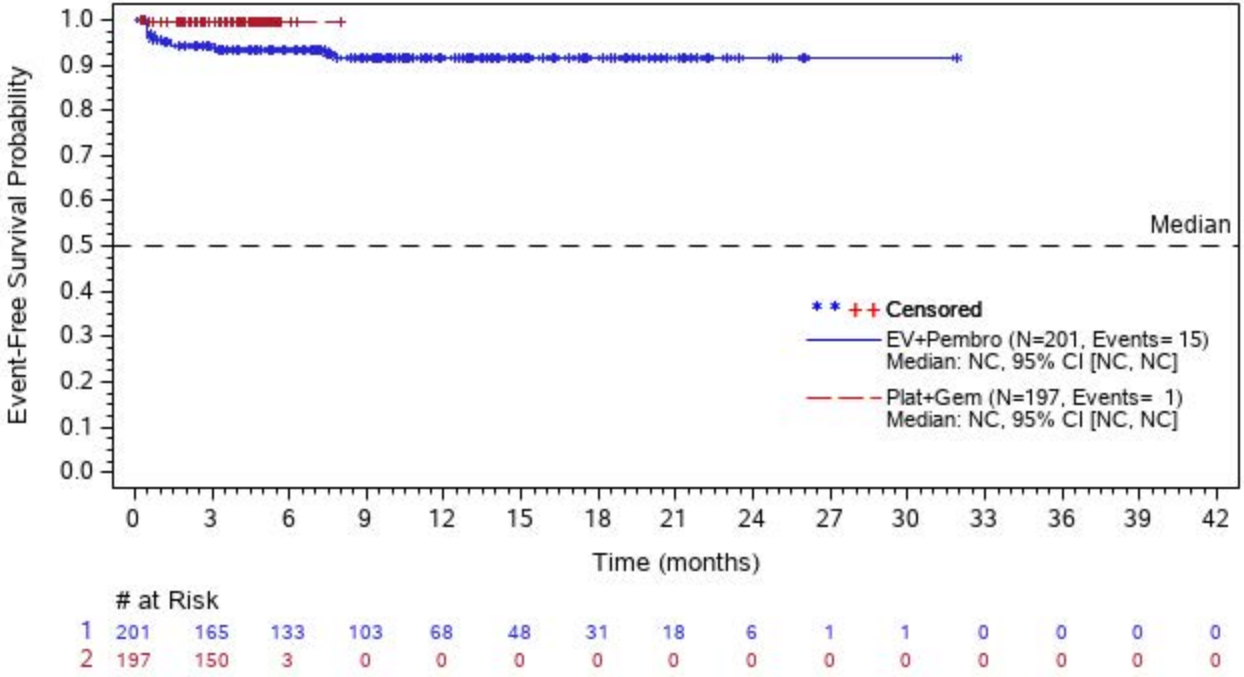
1	239	192	150	113	72	44	27	15	9	1	0	0	0	0	0
2	236	200	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.175.2.1: Kaplan-Meier Plot of Time to first Severe TEAESI (CTCAE Grade >= 3) - Hyperglycemia - Analysis Set mSAF 2



at Risk

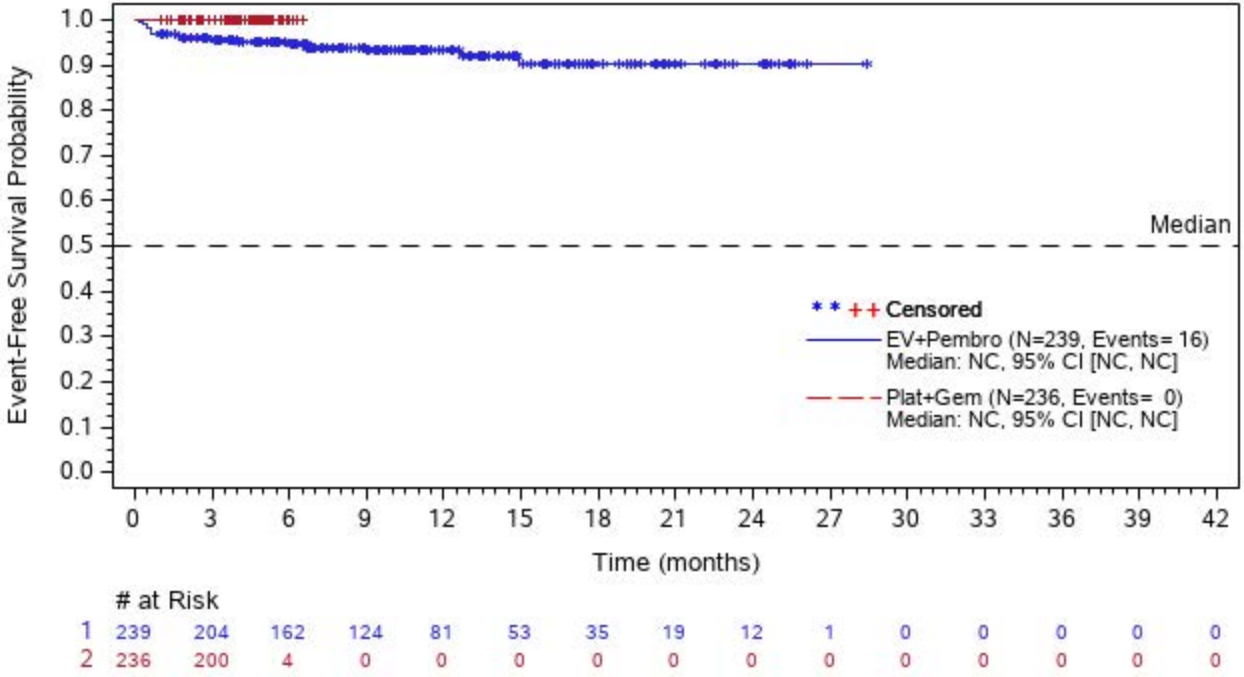
1	201	165	133	103	68	48	31	18	6	1	1	0	0	0	0
2	197	150	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.176.1.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Rash maculo-papular (PT) - Analysis Set mSAF 1

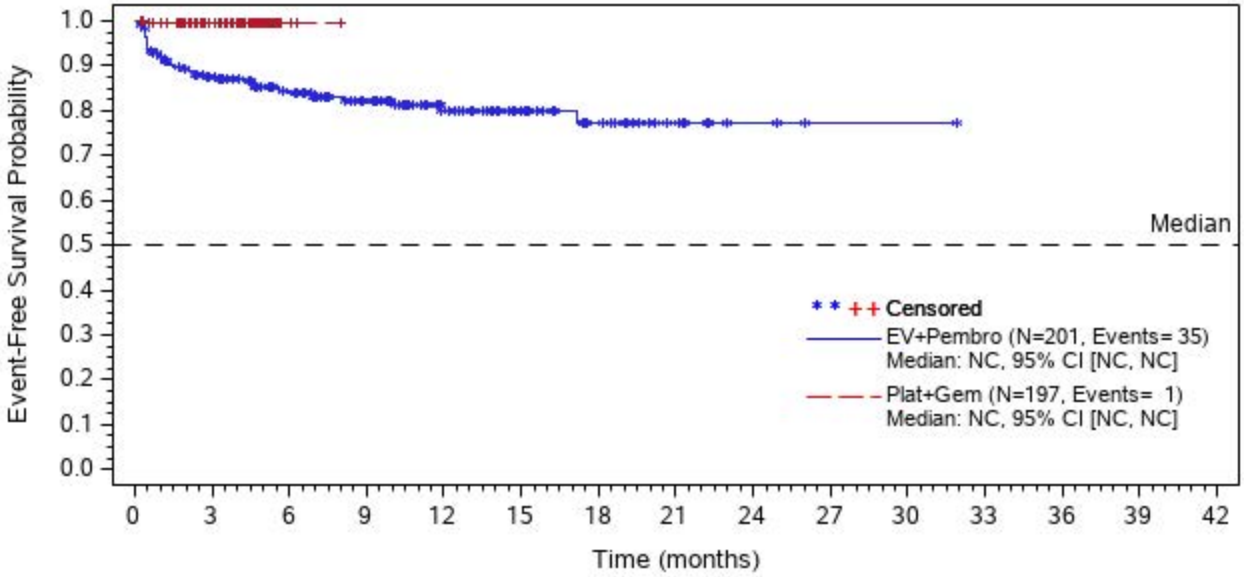


Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.176.2.1: Kaplan-Meier Plot of Time to first Severe TEAESI (CTCAE Grade >= 3) - Skin reactions - Analysis Set mSAF 2



at Risk

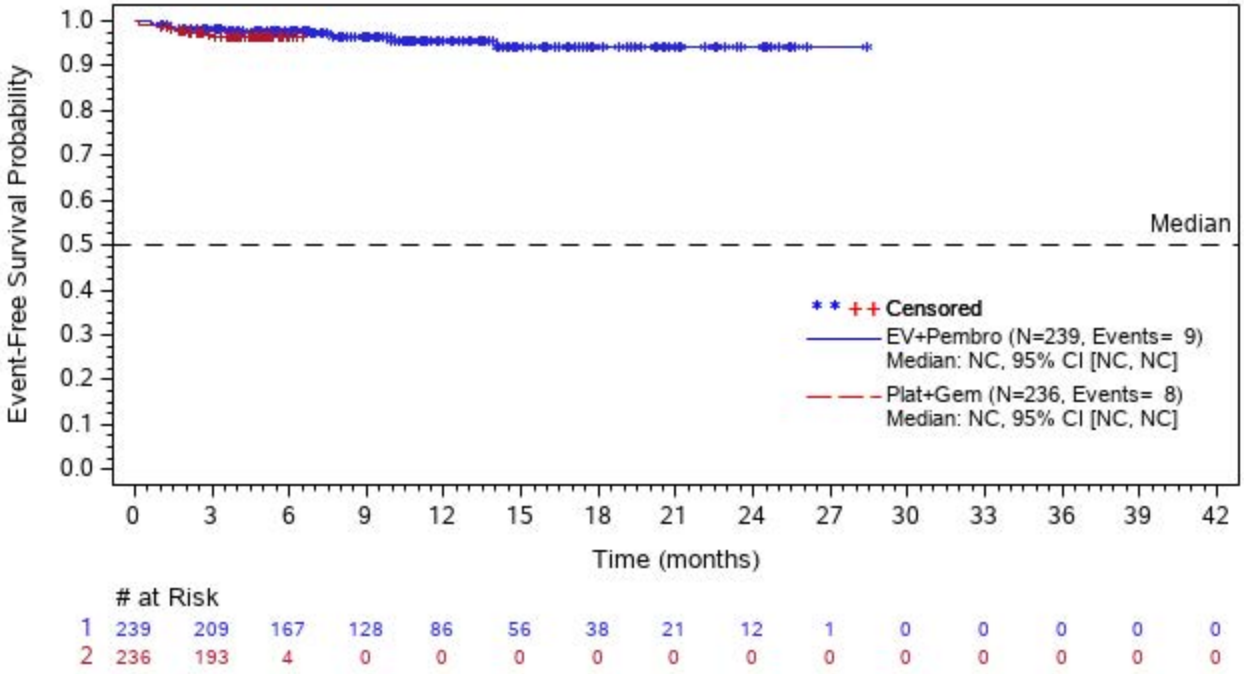
1	201	154	122	92	59	40	24	12	4	1	1	0	0	0	0
2	197	150	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.177.1.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Vascular disorders (SOC) - Analysis Set mSAF 1



at Risk

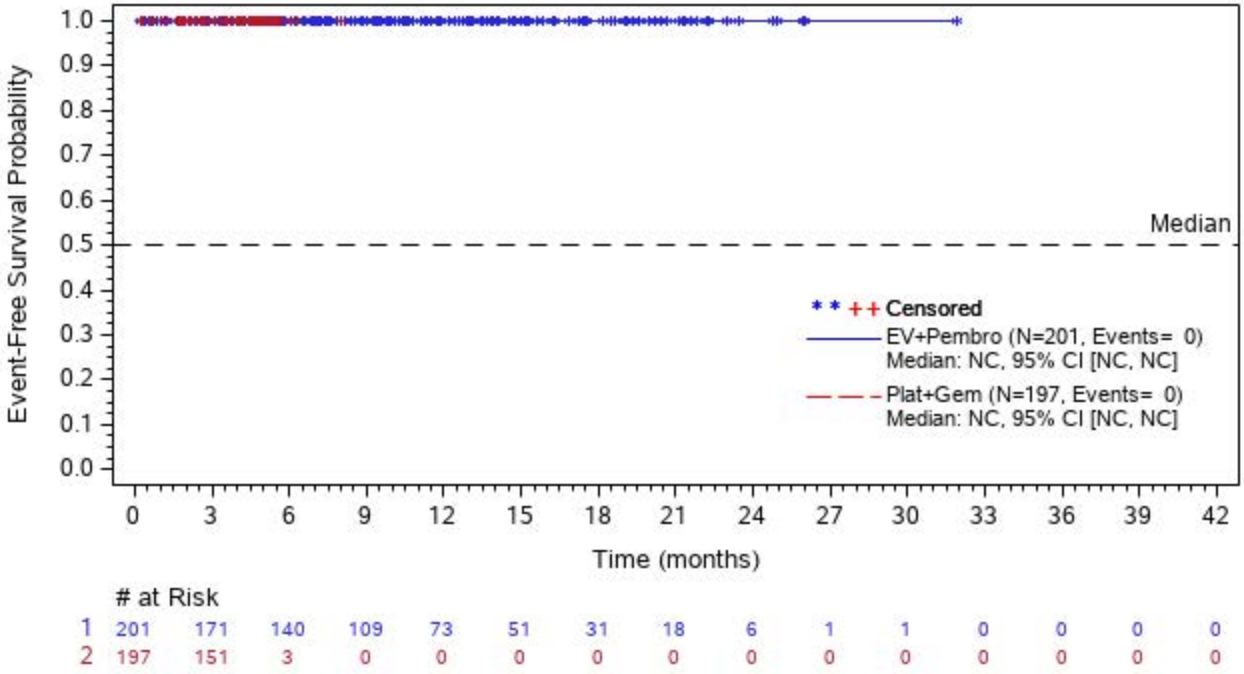
1	239	209	167	128	86	56	38	21	12	1	0	0	0	0	0
2	236	193	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; mSAF=modified safety analysis set; N=number of patients; NC=not calculated; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; SOC=system organ classes; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.177.2.1: Kaplan-Meier Plot of Time to first Severe TEAESI (CTCAE Grade >= 3) - Infusion related reactions (IRR) - Analysis Set mSAF 2



at Risk

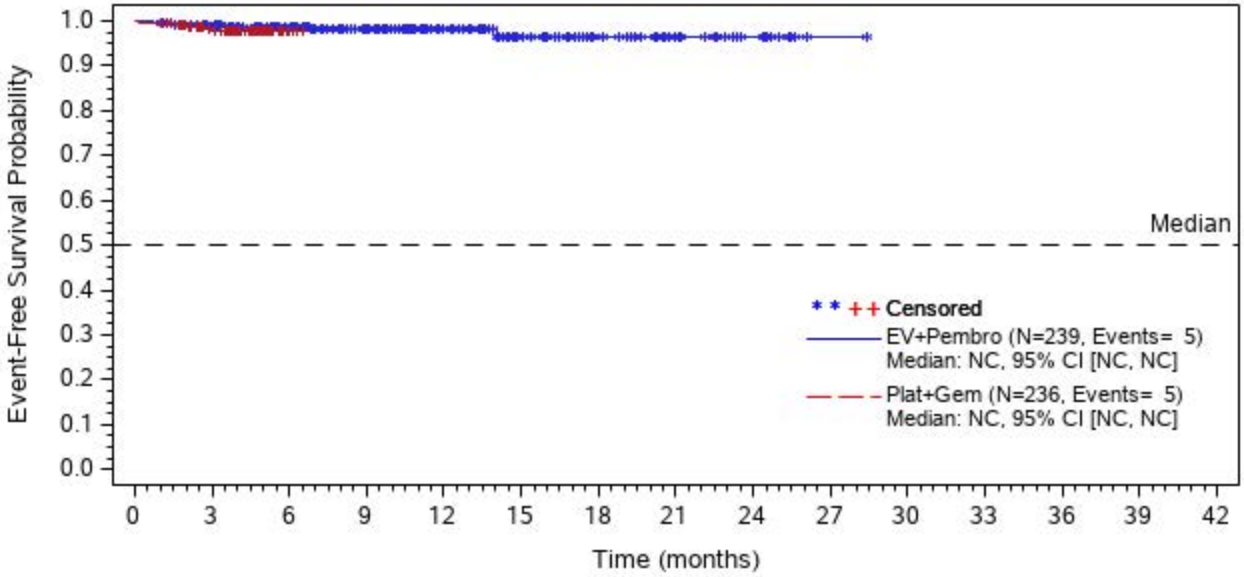
1	201	171	140	109	73	51	31	18	6	1	1	0	0	0	0
2	197	151	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.178.1.1: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Hypertension (PT) - Analysis Set mSAF 1



at Risk

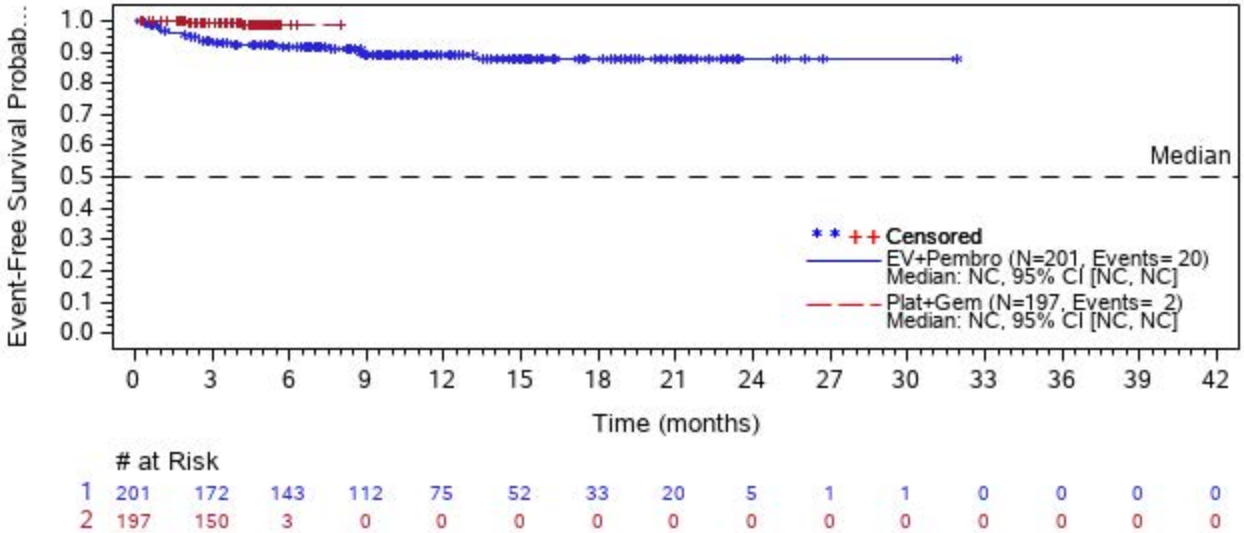
1	239	209	167	129	87	57	39	22	12	1	0	0	0	0	0
2	236	196	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; PT=preferred term; TEAE=treatment-emergent adverse event.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.178.2.1: Kaplan-Meier Plot of Time to first TESAESI - Immune related and infusion reactions - Analysis Set mSAF 2



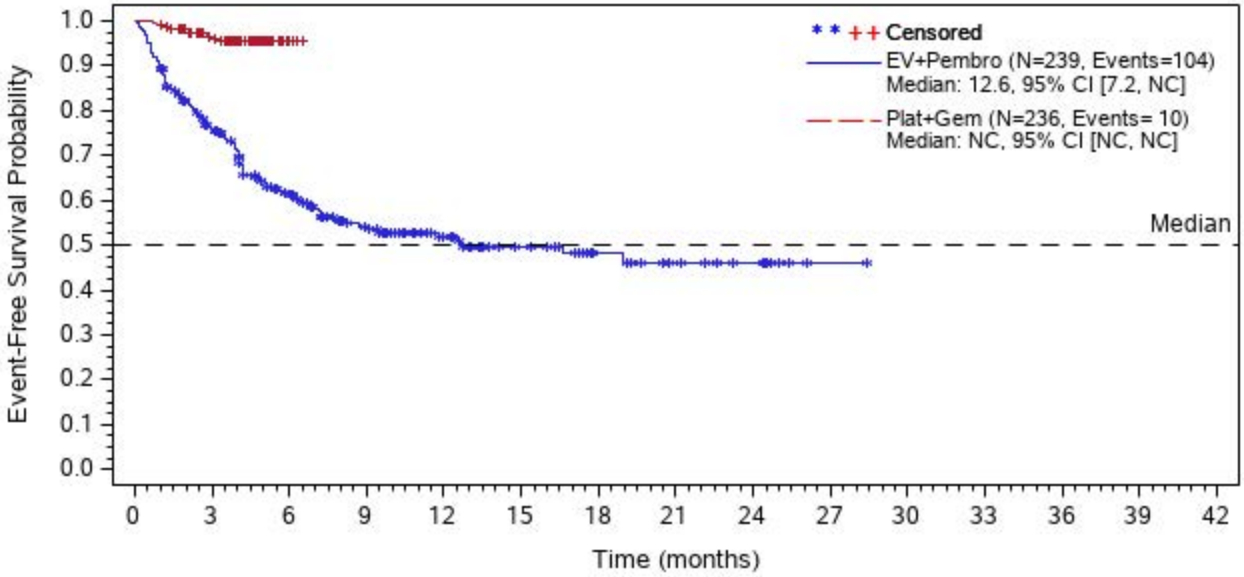
Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAESI=treatment-emergent serious adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.179.1.1: Kaplan-Meier Plot of Time to first TEAESI - Immune related and infusion reactions - Analysis Set mSAF 1



at Risk

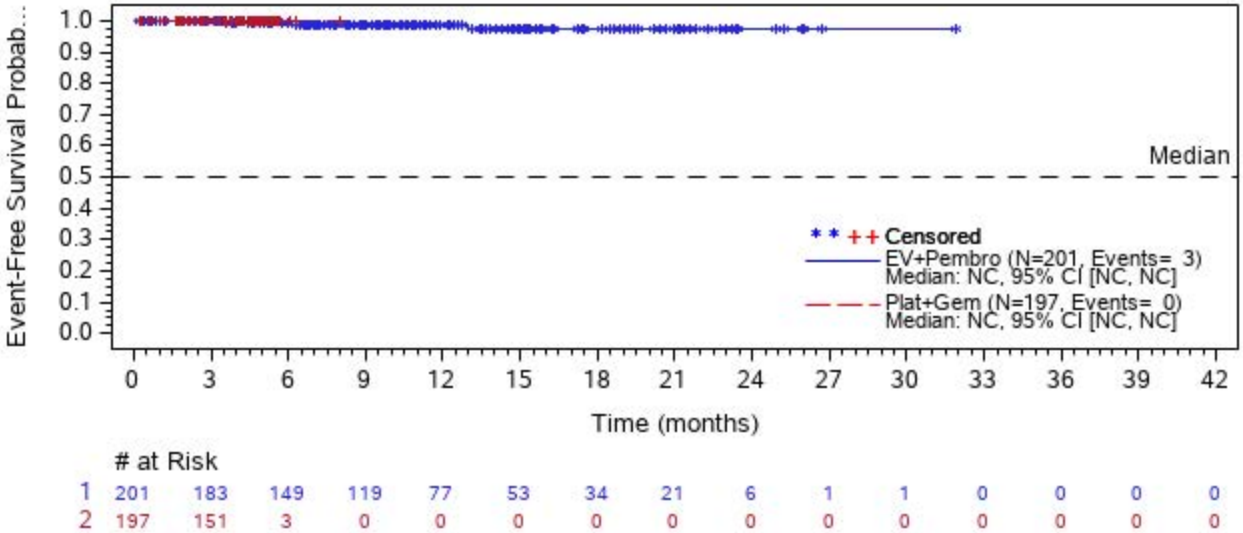
1	239	165	110	77	54	35	22	15	10	1	0	0	0	0	0
2	236	194	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.179.2.1: Kaplan-Meier Plot of Time to first TESAESI - Peripheral neuropathy - Analysis Set mSAF 2



at Risk

1	201	183	149	119	77	53	34	21	6	1	1	0	0	0	0
2	197	151	3	0	0	0	0	0	0	0	0	0	0	0	0

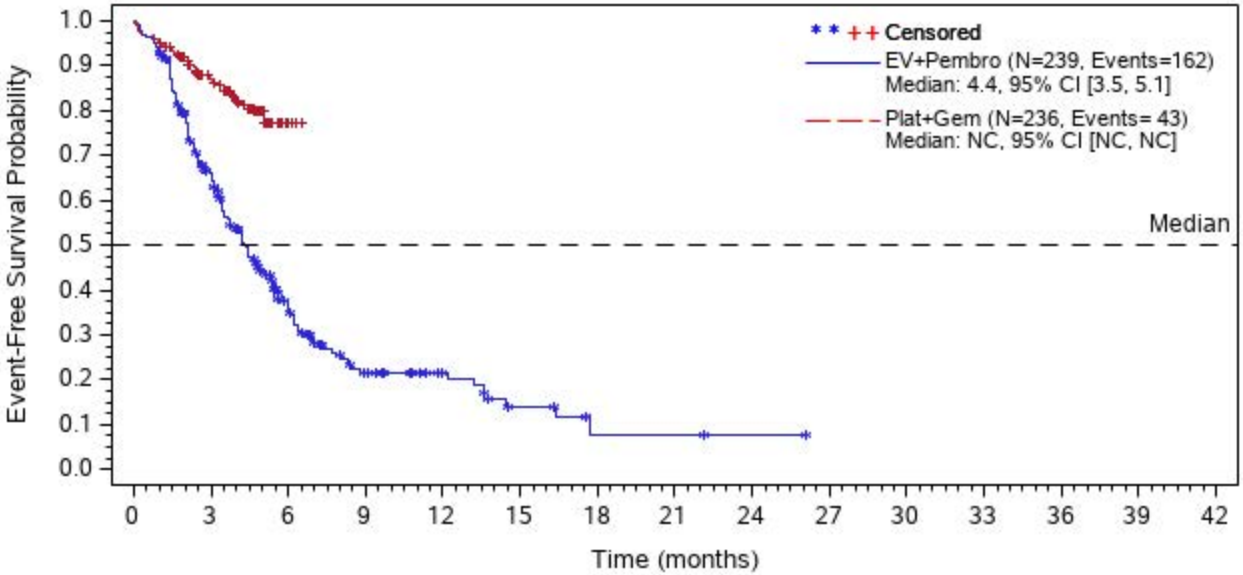
Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAESI=treatment-emergent serious adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.180.1.1: Kaplan-Meier Plot of Time to first TEAESI - Peripheral neuropathy - Analysis Set mSAF 1



at Risk

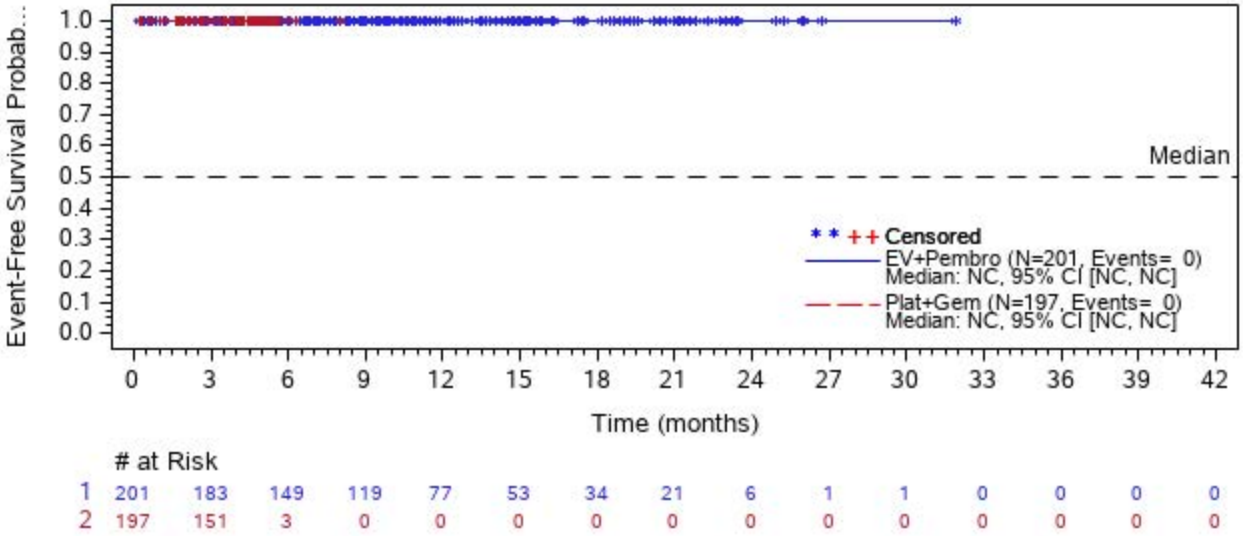
1	239	137	58	26	15	7	2	2	1	0	0	0	0	0	0
2	236	174	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.180.2.1: Kaplan-Meier Plot of Time to first TESAESI - Ocular disorders - Analysis Set mSAF 2



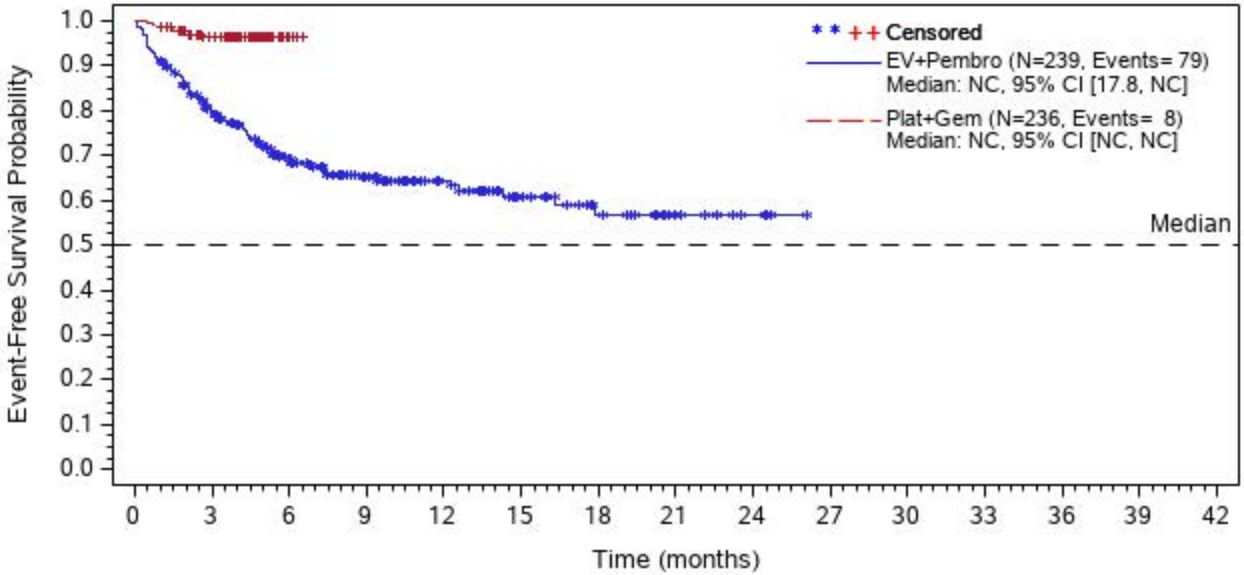
Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAESI=treatment-emergent serious adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.181.1.1: Kaplan-Meier Plot of Time to first TEAESI - Ocular disorders - Analysis Set mSAF 1



at Risk

1	239	169	117	84	60	39	26	12	6	0	0	0	0	0	0
2	236	193	4	0	0	0	0	0	0	0	0	0	0	0	0

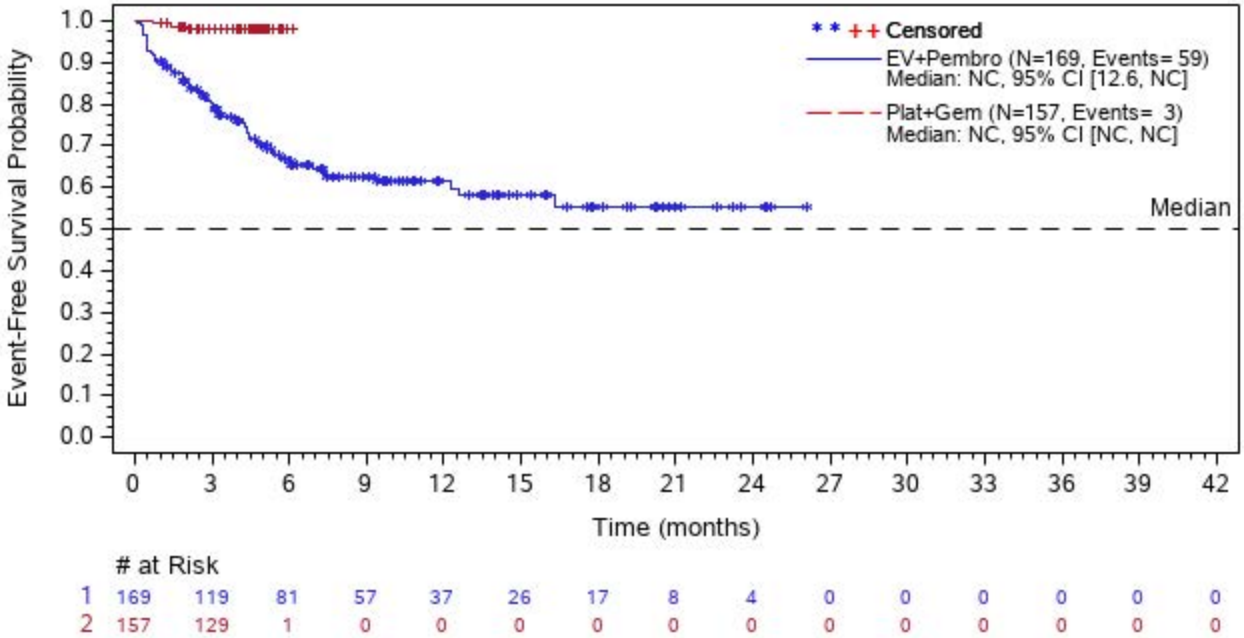
Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.181.1.2.5: Kaplan-Meier Plot of Time to first TEAESI - Ocular disorders - Analysis Set mSAF 1

Metastases at Baseline: Visceral metastases



at Risk

1	169	119	81	57	37	26	17	8	4	0	0	0	0	0	0
2	157	129	1	0	0	0	0	0	0	0	0	0	0	0	0

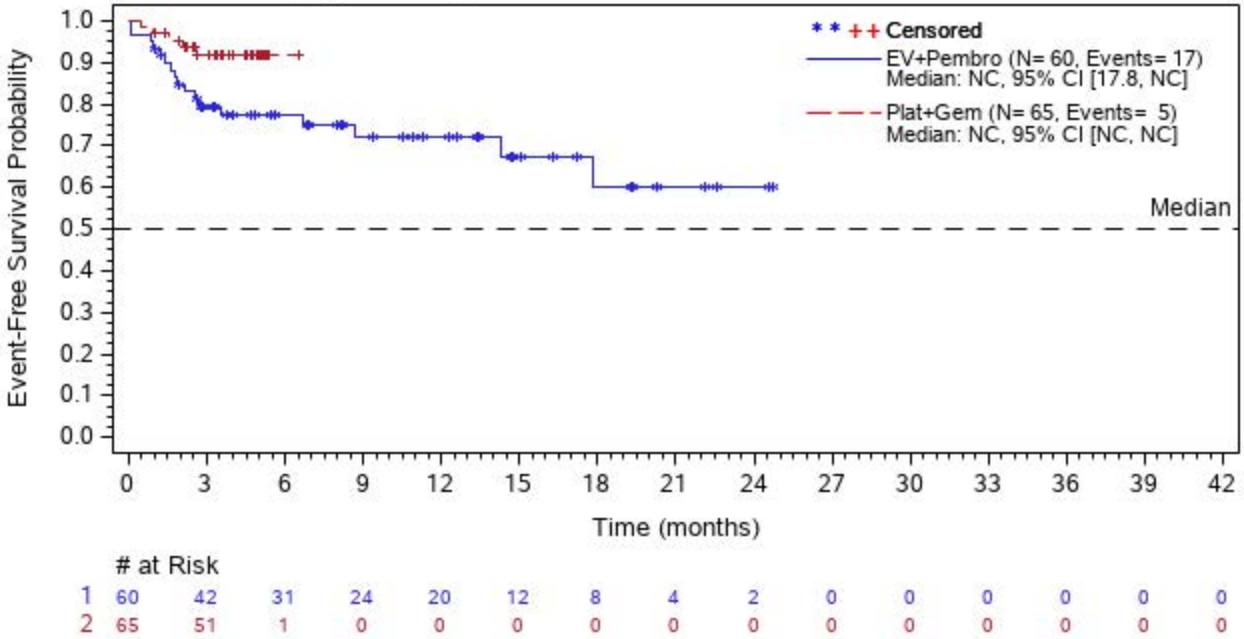
Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.181.1.2.5: Kaplan-Meier Plot of Time to first TEAESI - Ocular disorders - Analysis Set mSAF 1

Metastases at Baseline: Lymph node only

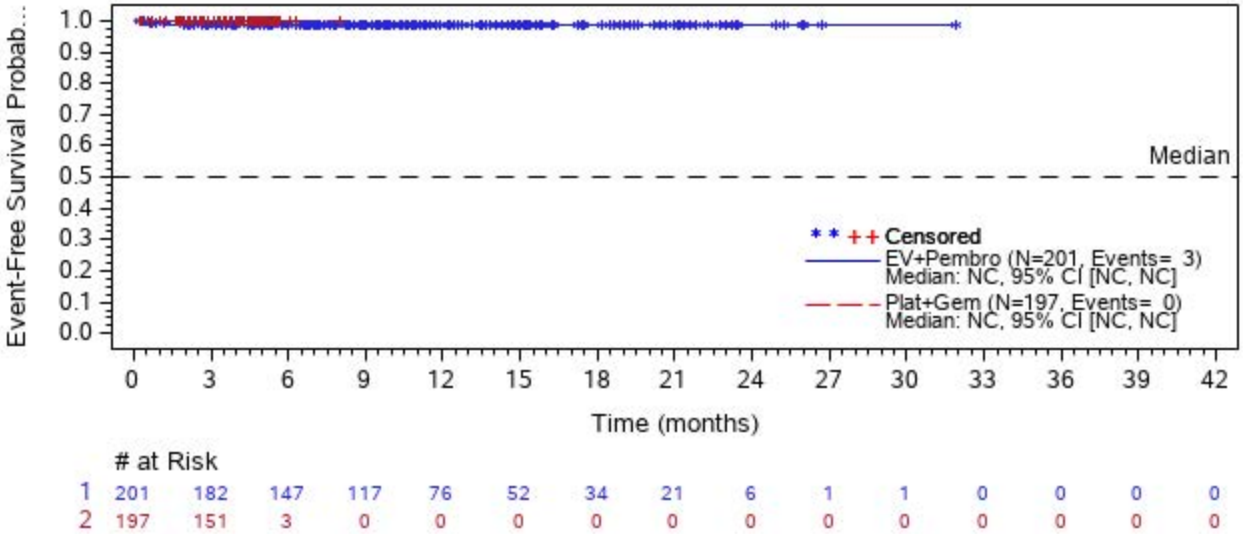


Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.181.2.1: Kaplan-Meier Plot of Time to first TESAESI - Hyperglycemia - Analysis Set mSAF 2



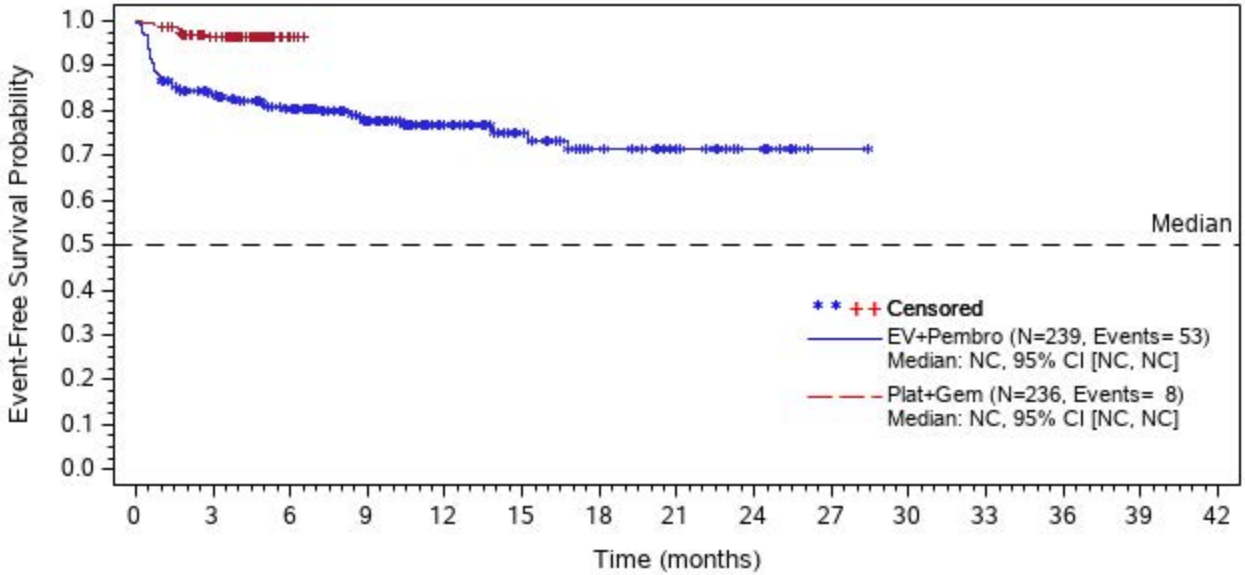
Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAESI=treatment-emergent serious adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.182.1.1: Kaplan-Meier Plot of Time to first TEAESI - Hyperglycemia - Analysis Set mSAF 1



at Risk

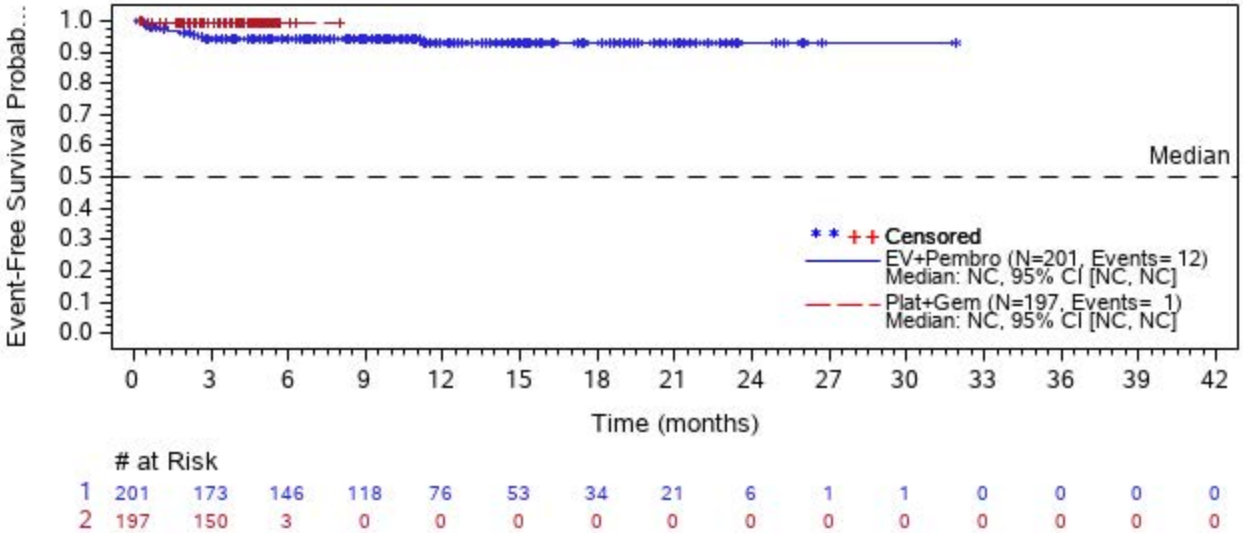
1	239	176	142	106	66	43	28	17	9	1	0	0	0	0	0
2	236	192	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.182.2.1: Kaplan-Meier Plot of Time to first TESAESI - Skin reactions - Analysis Set mSAF 2



at Risk

1	201	173	146	118	76	53	34	21	6	1	1	0	0	0	0
2	197	150	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAESI=treatment-emergent serious adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

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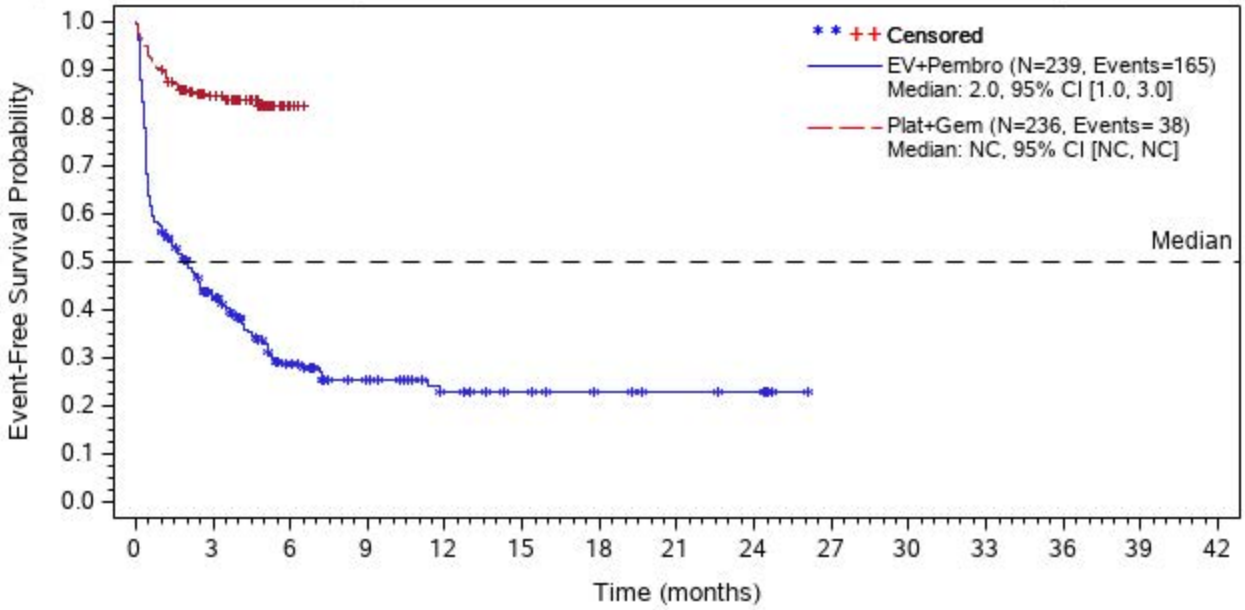
ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.183.1.1: Kaplan-Meier Plot of Time to first TEAESI - Skin reactions - Analysis Set mSAF 1



at Risk

1	239	86	42	27	16	12	9	7	6	0	0	0	0	0	0
2	236	166	4	0	0	0	0	0	0	0	0	0	0	0	0

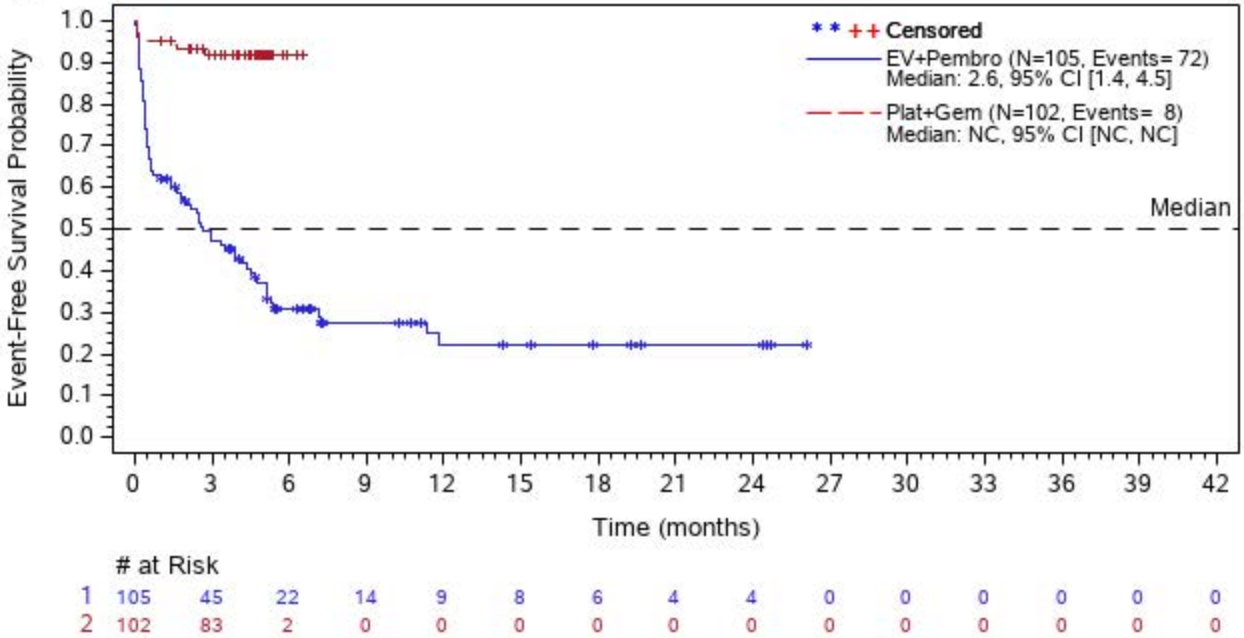
Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.183.1.2.2: Kaplan-Meier Plot of Time to first TEAESI - Skin reactions - Analysis Set mSAF 1

Age: < 65 years



at Risk

1	105	45	22	14	9	8	6	4	4	0	0	0	0	0	0
2	102	83	2	0	0	0	0	0	0	0	0	0	0	0	0

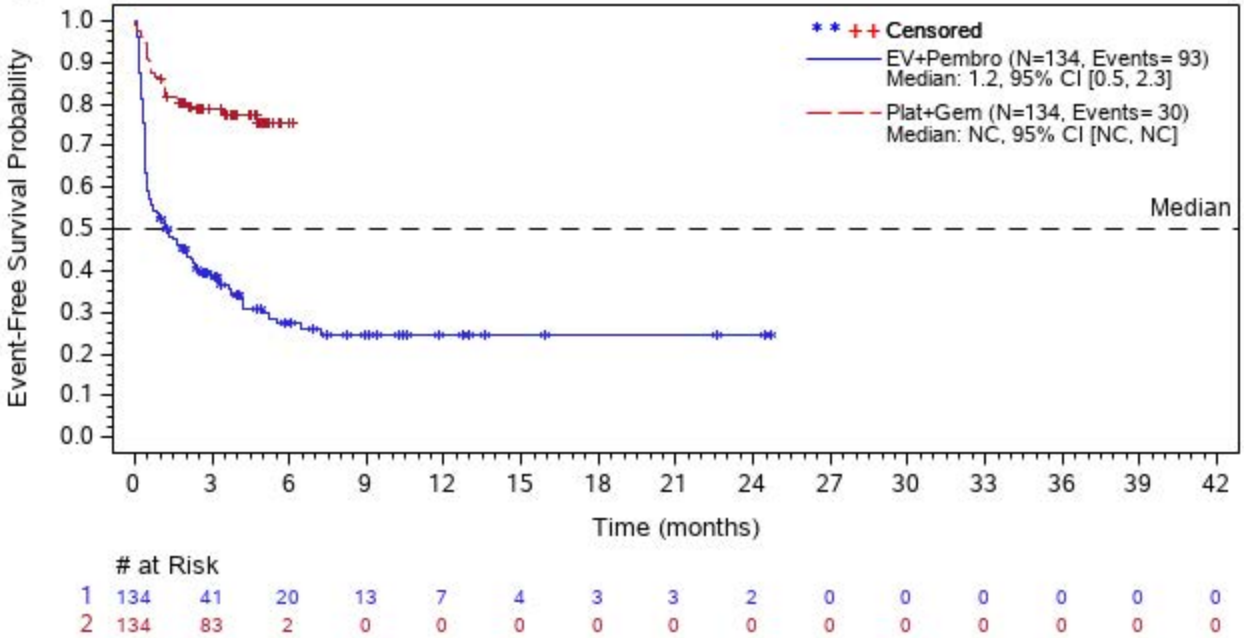
Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.183.1.2.2: Kaplan-Meier Plot of Time to first TEAESI - Skin reactions - Analysis Set mSAF 1

Age: >= 65 years



at Risk

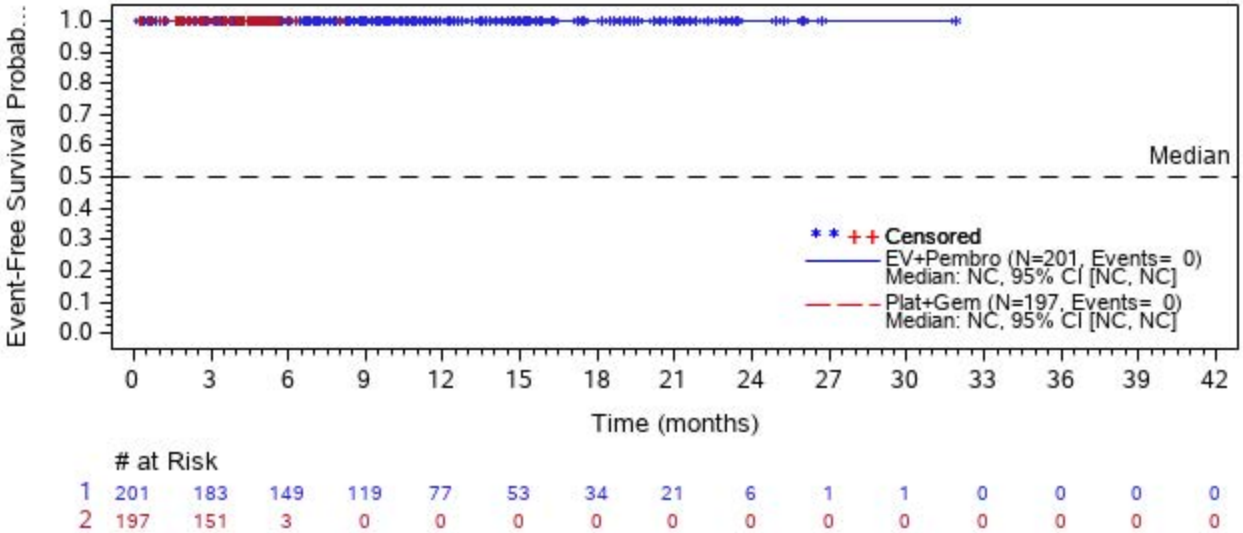
1	134	41	20	13	7	4	3	3	2	0	0	0	0	0	0
2	134	83	2	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.183.2.1: Kaplan-Meier Plot of Time to first TESAESI - Infusion related reactions (IRR) - Analysis Set mSAF 2



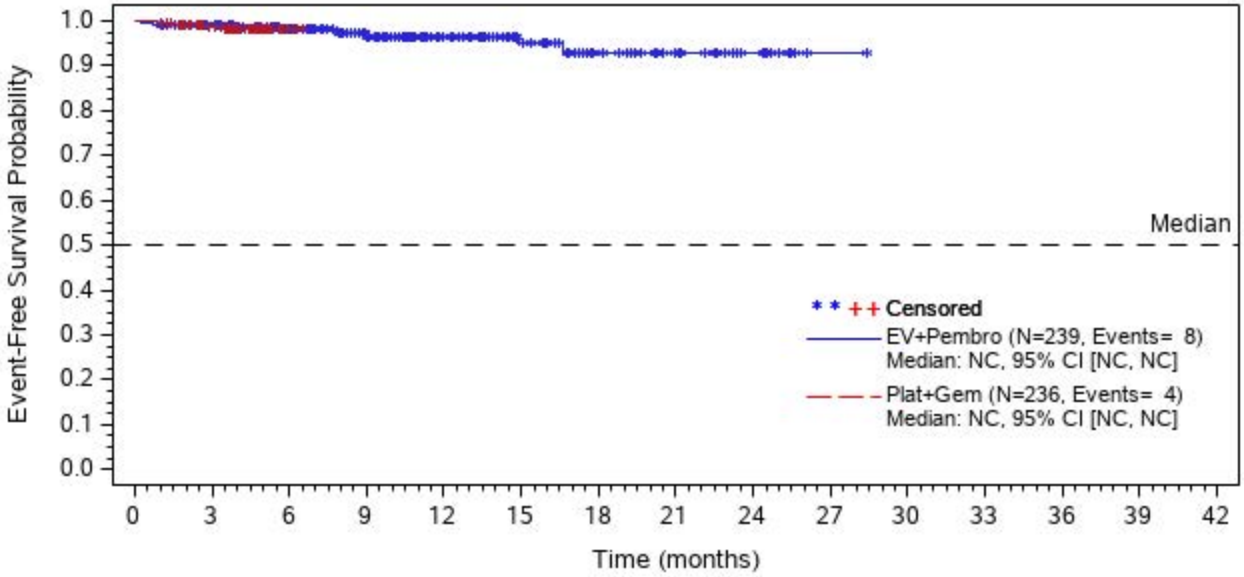
Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAESI=treatment-emergent serious adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.184.1.1: Kaplan-Meier Plot of Time to first TEAESI - Infusion related reactions (IRR) - Analysis Set mSAF 1



at Risk

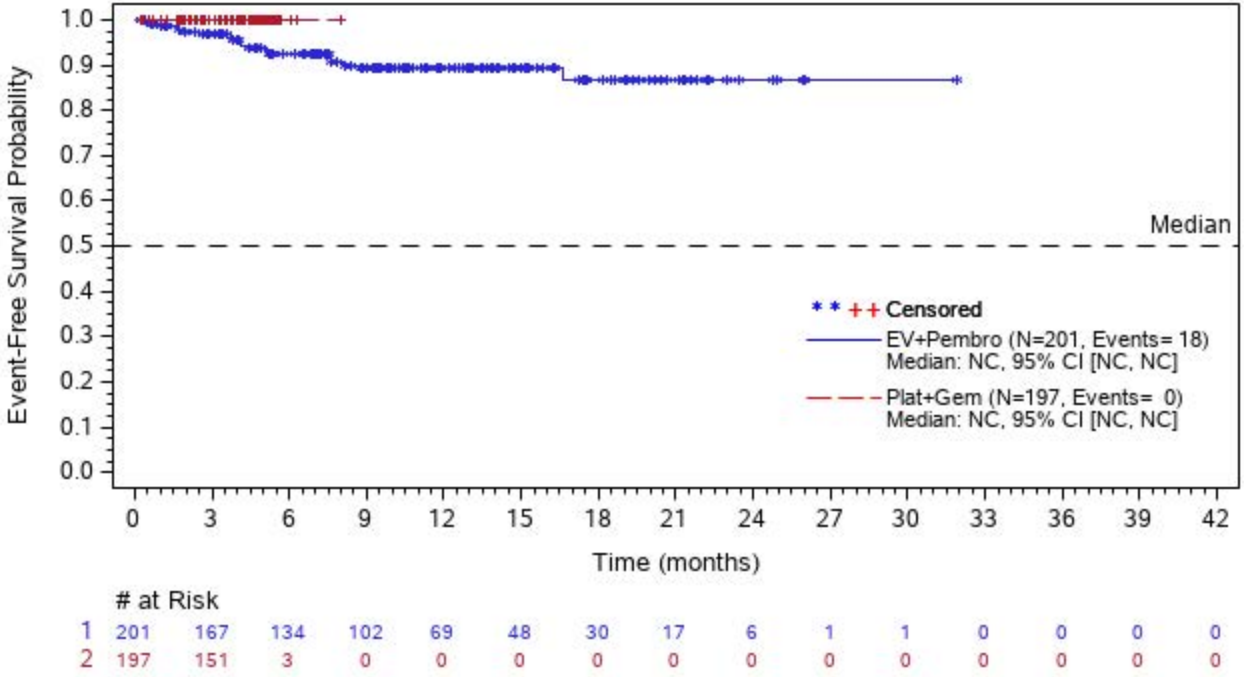
1	239	209	166	128	86	57	37	22	12	1	0	0	0	0	0
2	236	197	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.184.2.1: Kaplan-Meier Plot of Time to first TEAESI leading to discontinuation from study medication - Immune related and infusion reactions - Analysis Set mSAF 2



at Risk

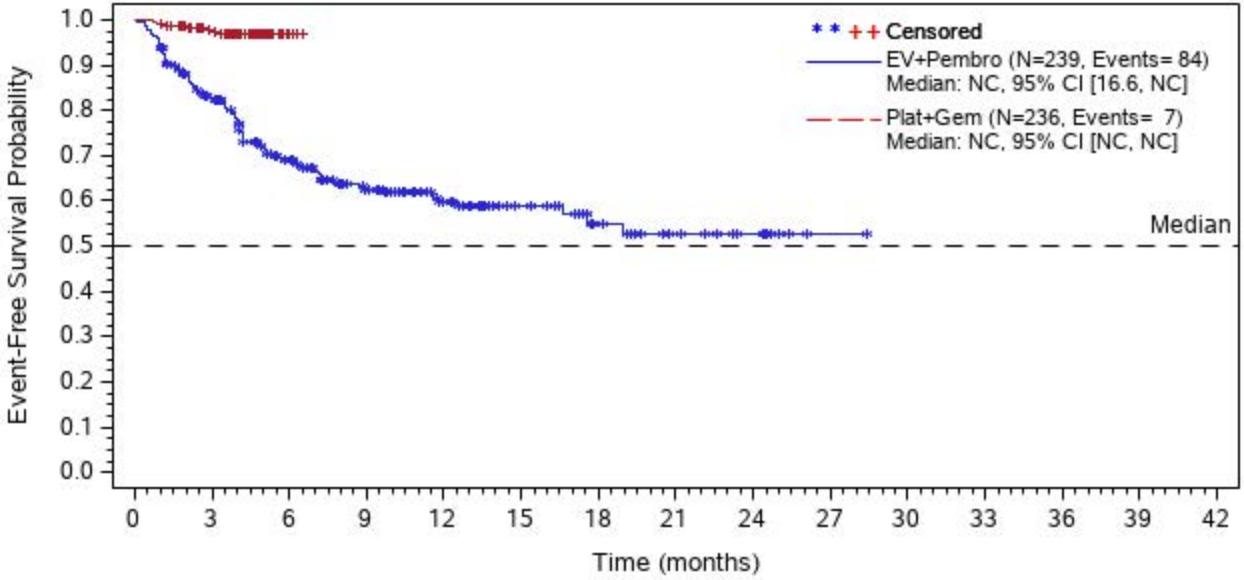
1	201	167	134	102	69	48	30	17	6	1	1	0	0	0	0
2	197	151	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.185.1.1: Kaplan-Meier Plot of Time to first Non-Severe TEAESI (CTCAE Grade < 3) - Immune related and infusion reactions - Analysis Set mSAF 1



at Risk

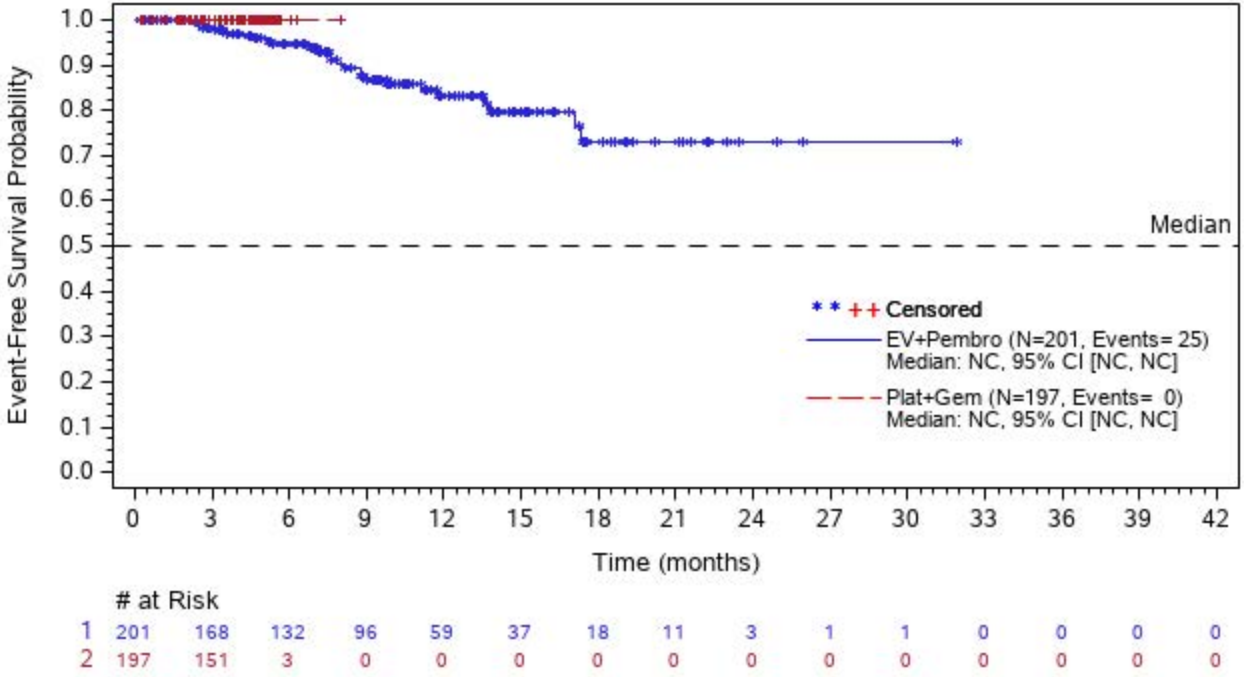
1	239	176	120	85	61	39	25	16	10	1	0	0	0	0	0
2	236	196	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.185.2.1: Kaplan-Meier Plot of Time to first TEAESI leading to discontinuation from study medication - Peripheral neuropathy - Analysis Set mSAF 2



at Risk

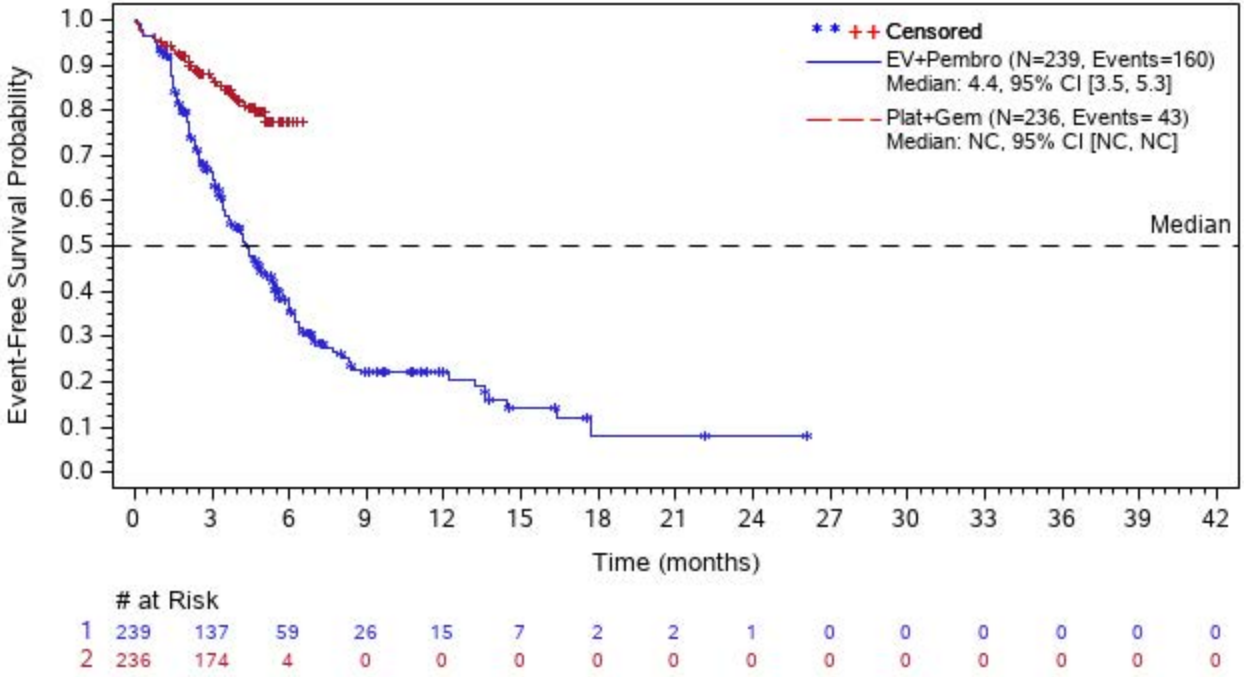
1	201	168	132	96	59	37	18	11	3	1	1	0	0	0	0
2	197	151	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.186.1.1: Kaplan-Meier Plot of Time to first Non-Severe TEAESI (CTCAE Grade < 3) - Peripheral neuropathy - Analysis Set mSAF 1

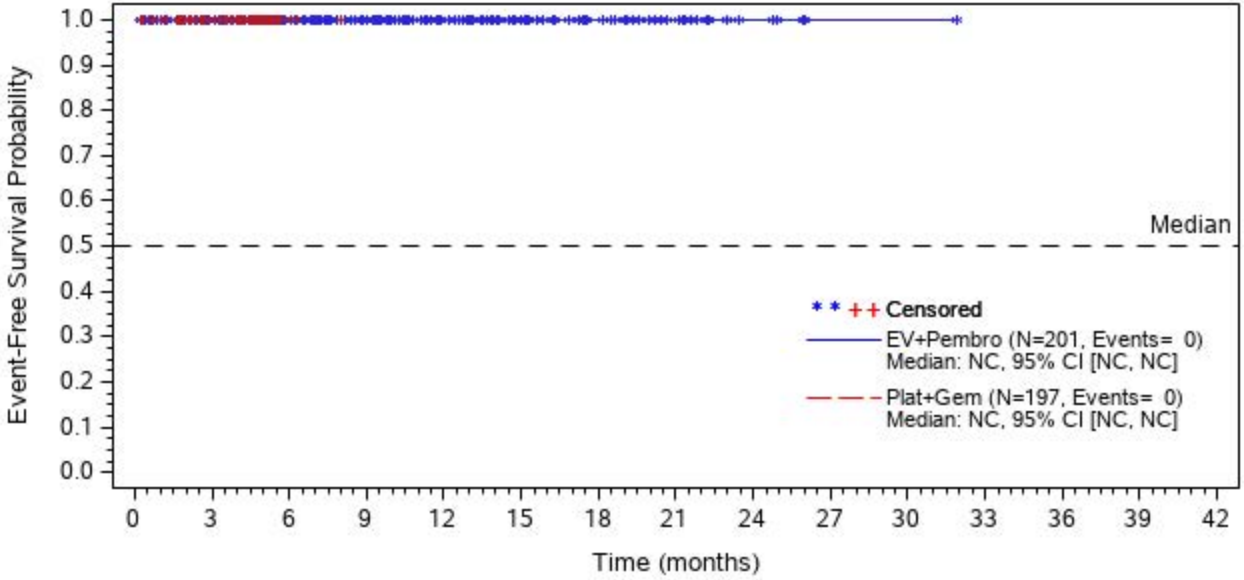


Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.186.2.1: Kaplan-Meier Plot of Time to first TEAESI leading to discontinuation from study medication - Ocular disorders - Analysis Set mSAF 2



at Risk

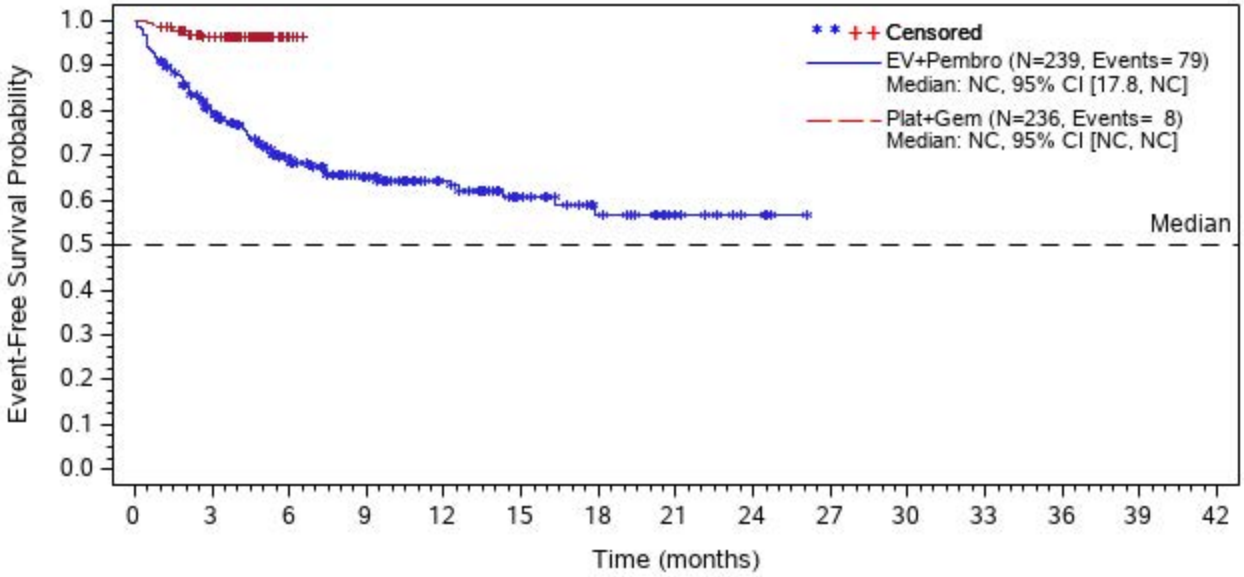
1	201	171	140	109	73	51	31	18	6	1	1	0	0	0	0
2	197	151	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.187.1.1: Kaplan-Meier Plot of Time to first Non-Severe TEAESI (CTCAE Grade < 3) - Ocular disorders - Analysis Set mSAF 1



at Risk

1	239	169	117	84	60	39	26	12	6	0	0	0	0	0	0
2	236	193	4	0	0	0	0	0	0	0	0	0	0	0	0

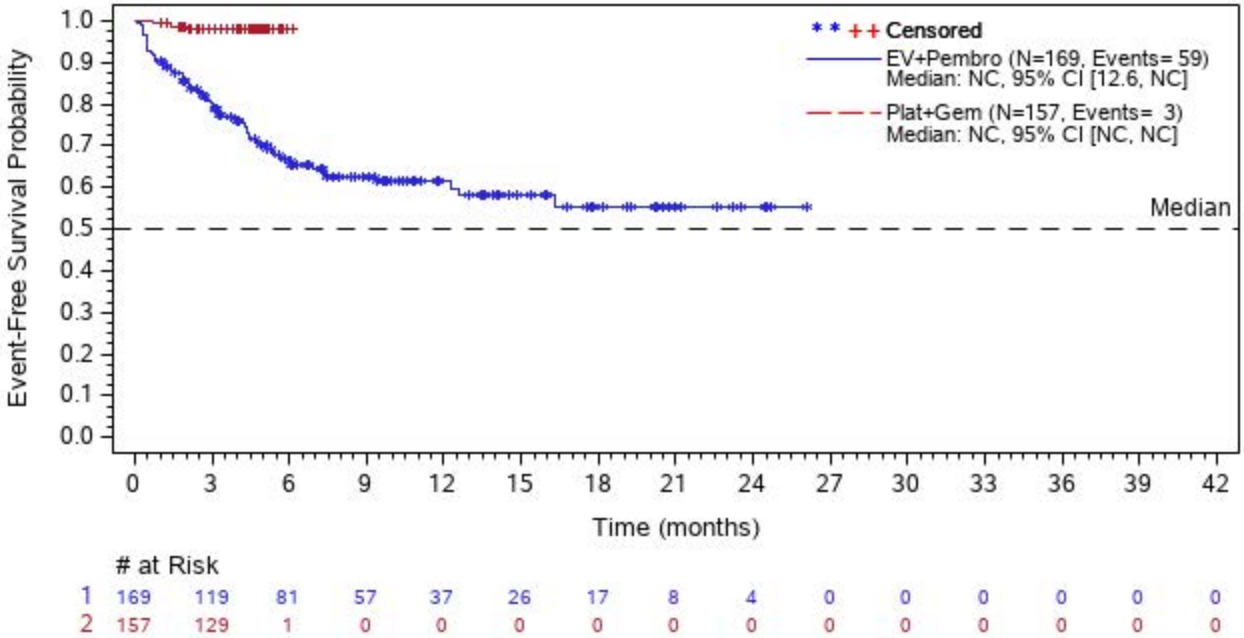
Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.187.1.2.5: Kaplan-Meier Plot of Time to first Non-Severe TEAESI (CTCAE Grade < 3) - Ocular disorders - Analysis Set mSAF 1

Metastases at Baseline: Visceral metastases



at Risk

1	169	119	81	57	37	26	17	8	4	0	0	0	0	0	0
2	157	129	1	0	0	0	0	0	0	0	0	0	0	0	0

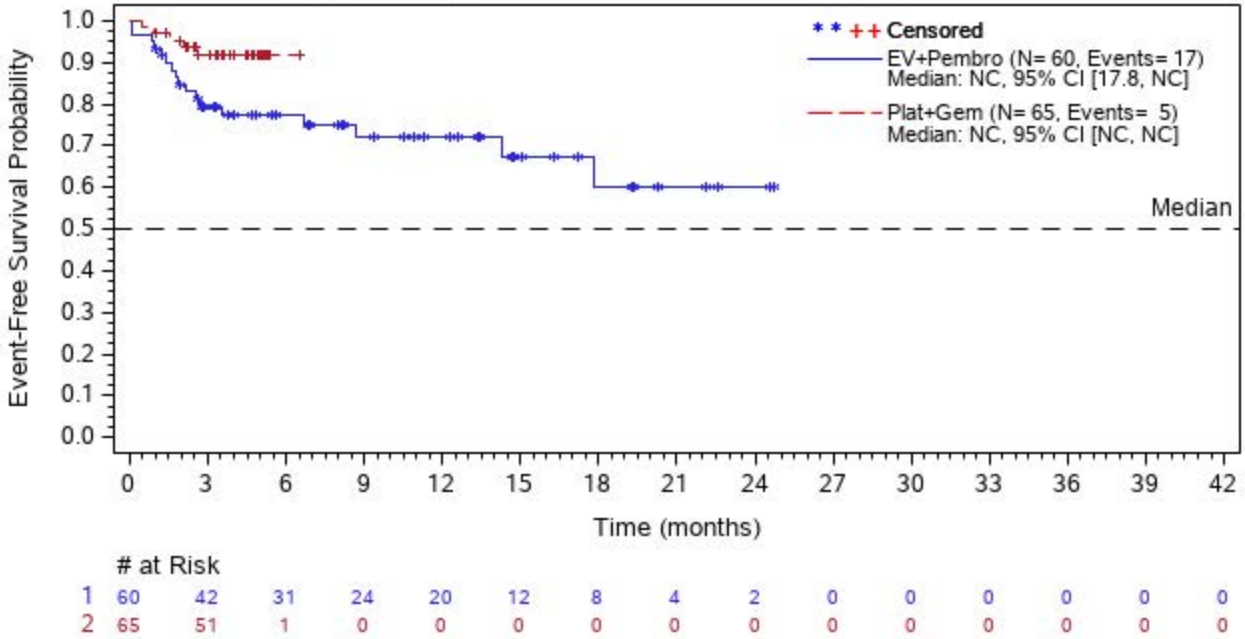
Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.187.1.2.5: Kaplan-Meier Plot of Time to first Non-Severe TEAESI (CTCAE Grade < 3) - Ocular disorders - Analysis Set mSAF 1

Metastases at Baseline: Lymph node only

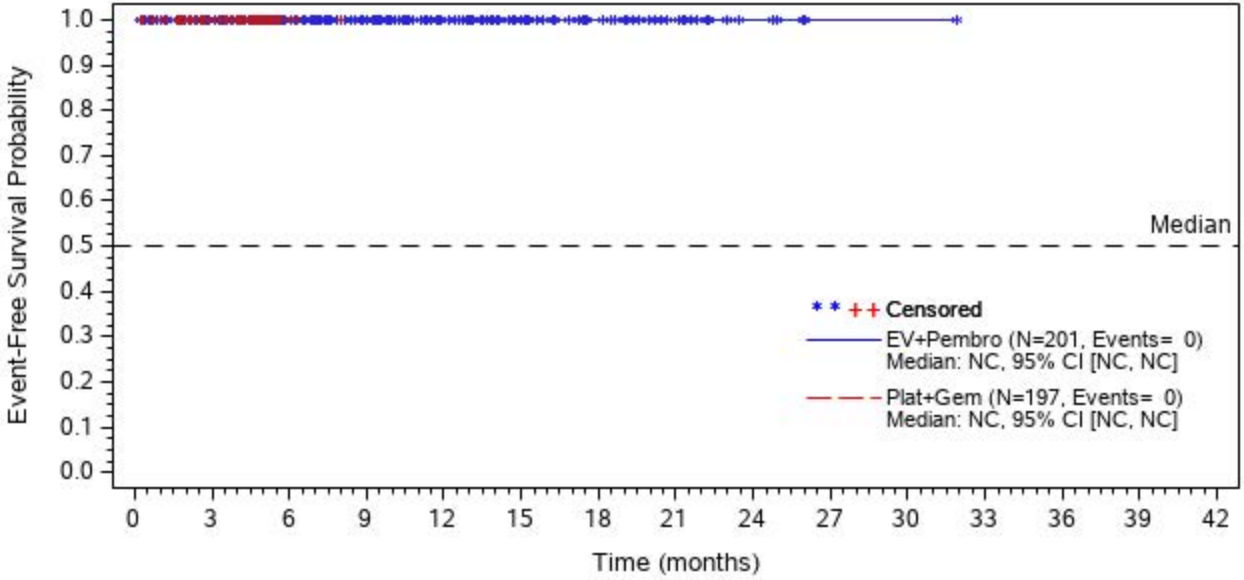


Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.187.2.1: Kaplan-Meier Plot of Time to first TEAESI leading to discontinuation from study medication - Hyperglycemia - Analysis Set mSAF 2



at Risk

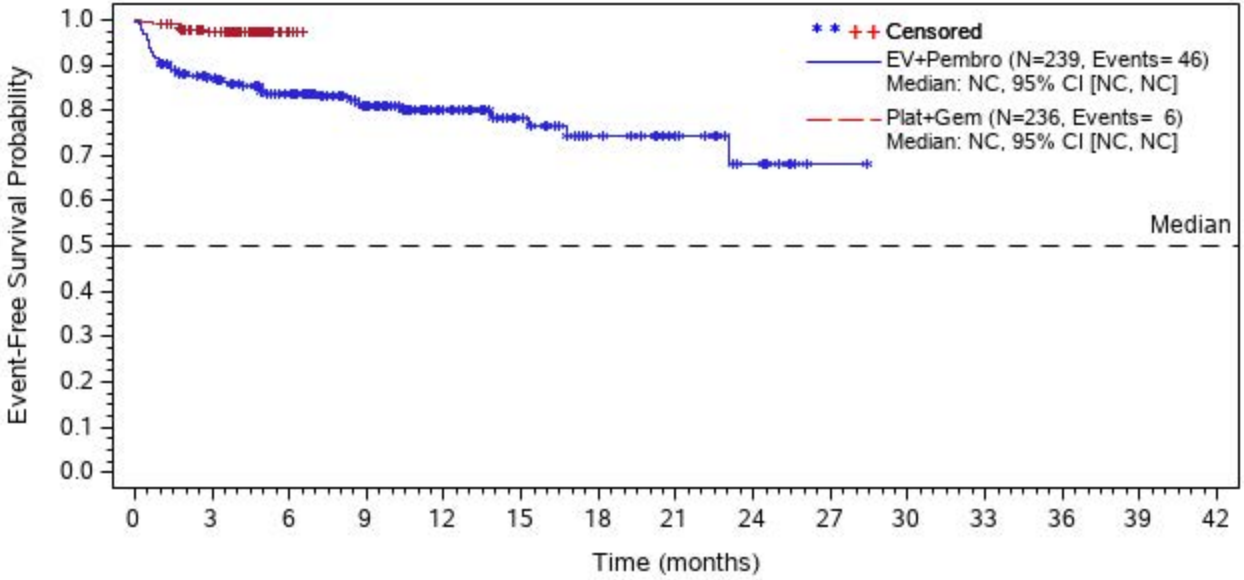
1	201	171	140	109	73	51	31	18	6	1	1	0	0	0	0
2	197	151	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.188.1.1: Kaplan-Meier Plot of Time to first Non-Severe TEAESI (CTCAE Grade < 3) - Hyperglycemia - Analysis Set mSAF 1



at Risk

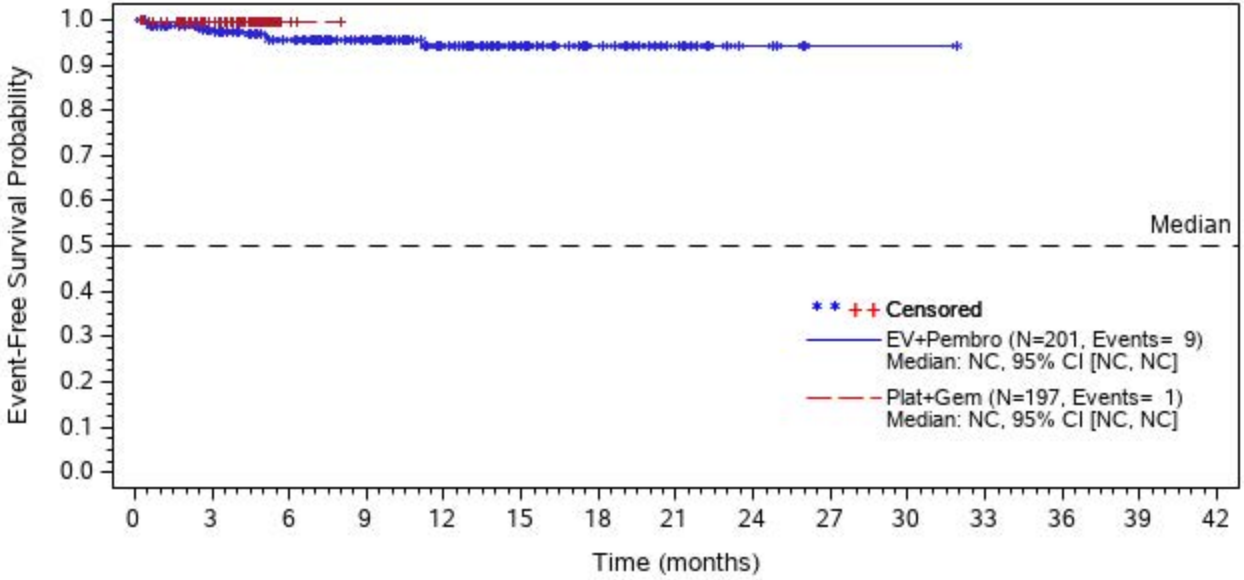
1	239	184	147	108	68	44	29	18	9	1	0	0	0	0	0
2	236	194	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.188.2.1: Kaplan-Meier Plot of Time to first TEAESI leading to discontinuation from study medication - Skin reactions - Analysis Set mSAF 2



at Risk

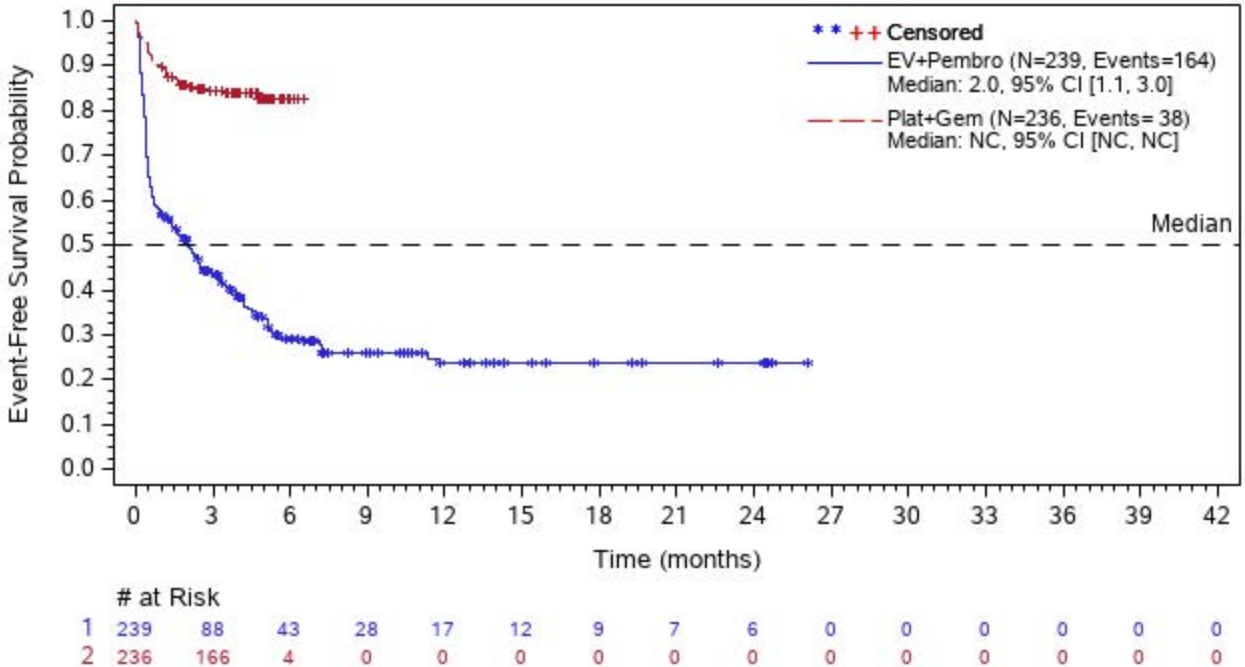
1	201	169	137	106	71	49	30	18	6	1	1	0	0	0	0
2	197	150	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.189.1.1: Kaplan-Meier Plot of Time to first Non-Severe TEAESI (CTCAE Grade < 3) - Skin reactions - Analysis Set mSAF 1



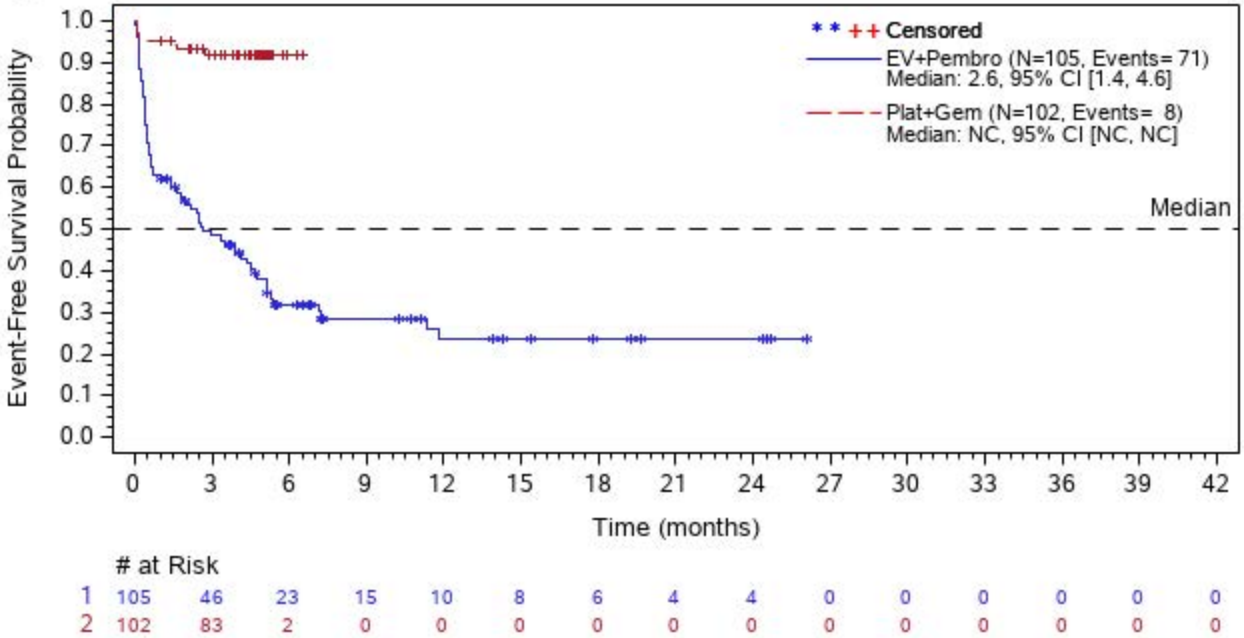
Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.189.1.2.2: Kaplan-Meier Plot of Time to first Non-Severe TEAESI (CTCAE Grade < 3) - Skin reactions - Analysis Set mSAF 1

Age: < 65 years



at Risk

1	105	46	23	15	10	8	6	4	4	0	0	0	0	0	0
2	102	83	2	0	0	0	0	0	0	0	0	0	0	0	0

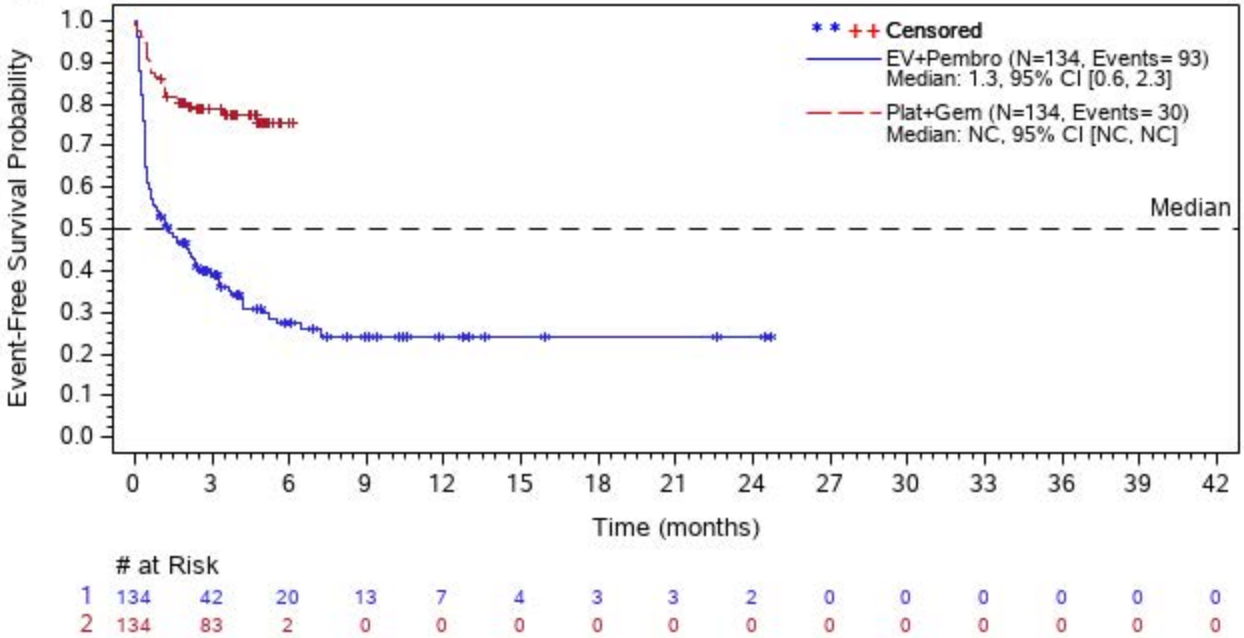
Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.189.1.2.2: Kaplan-Meier Plot of Time to first Non-Severe TEAESI (CTCAE Grade < 3) - Skin reactions - Analysis Set mSAF 1

Age: >= 65 years



at Risk

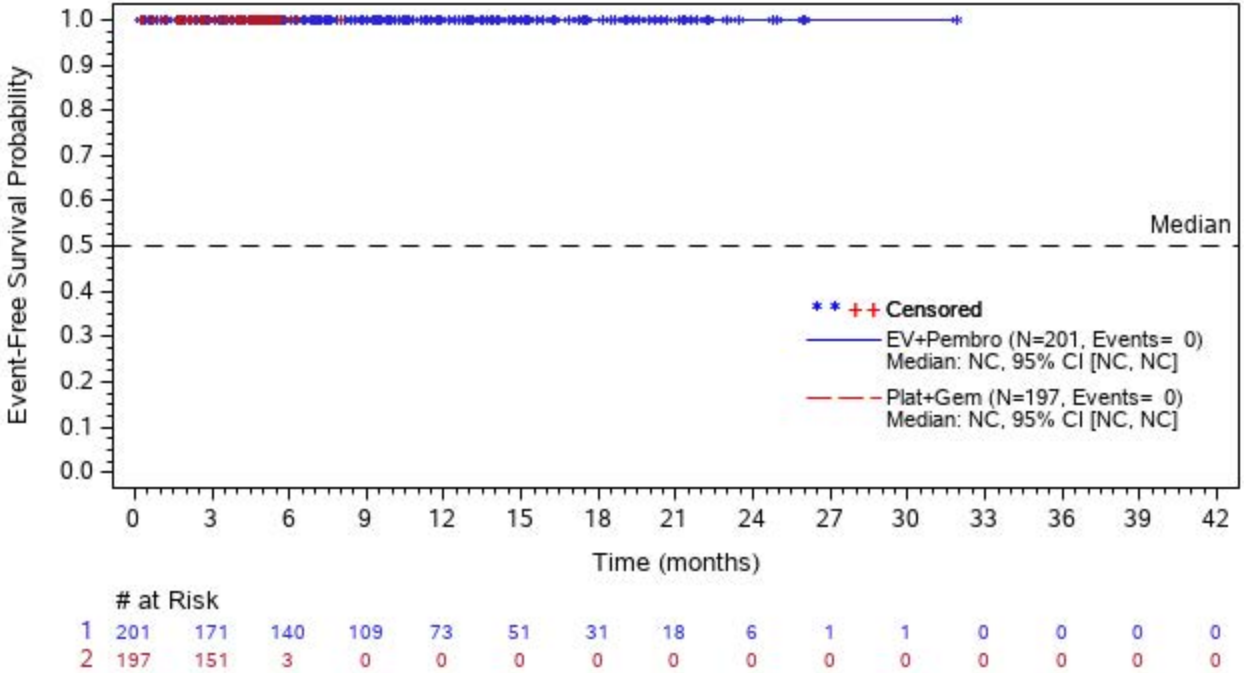
1	134	42	20	13	7	4	3	3	2	0	0	0	0	0	0
2	134	83	2	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.189.2.1: Kaplan-Meier Plot of Time to first TEAESI leading to discontinuation from study medication - Infusion related reactions (IRR) - Analysis Set mSAF 2



at Risk

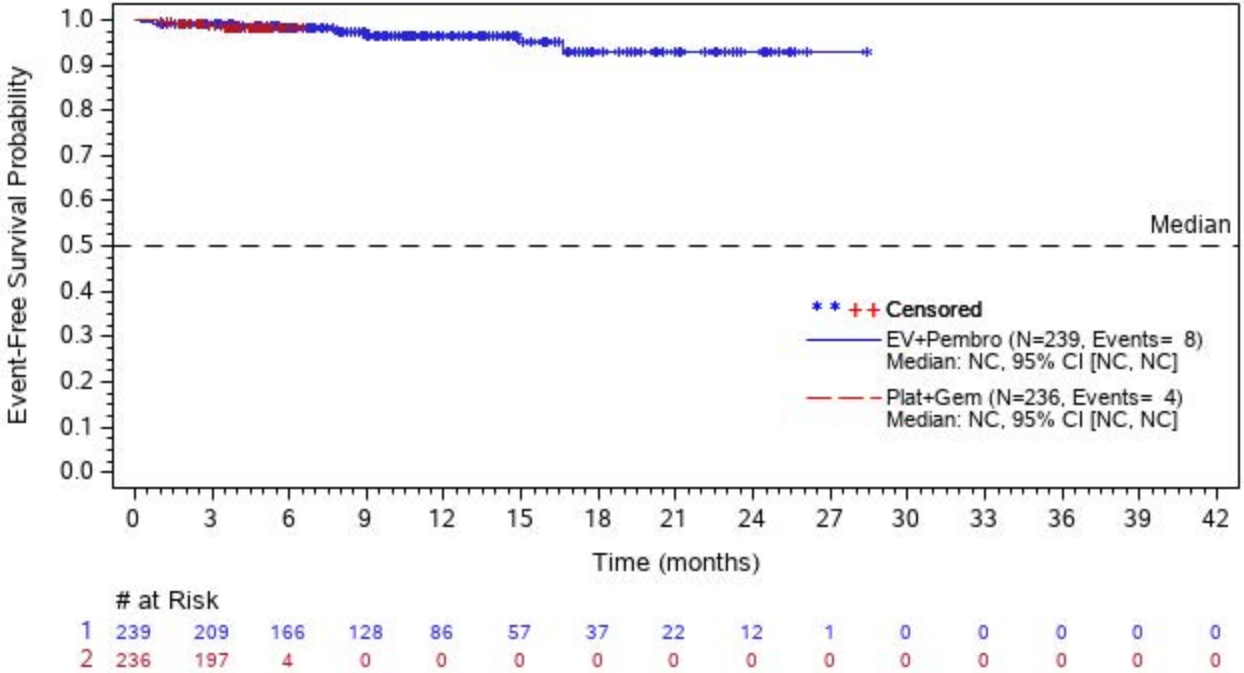
1	201	171	140	109	73	51	31	18	6	1	1	0	0	0	0
2	197	151	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.190.1.1: Kaplan-Meier Plot of Time to first Non-Severe TEAESI (CTCAE Grade < 3) - Infusion related reactions (IRR) - Analysis Set mSAF 1



at Risk

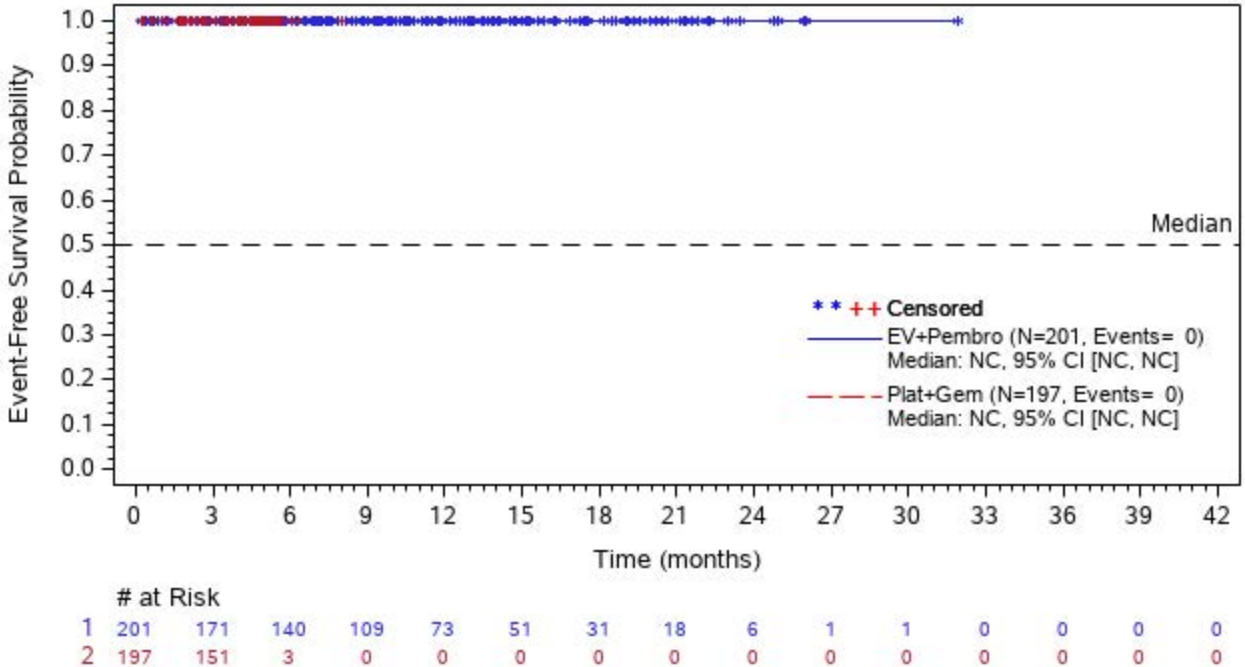
1	239	209	166	128	86	57	37	22	12	1	0	0	0	0	0
2	236	197	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.190.2.1: Kaplan-Meier Plot of Time to first TEAESI leading to death - Immune related and infusion reactions - Analysis Set mSAF 2

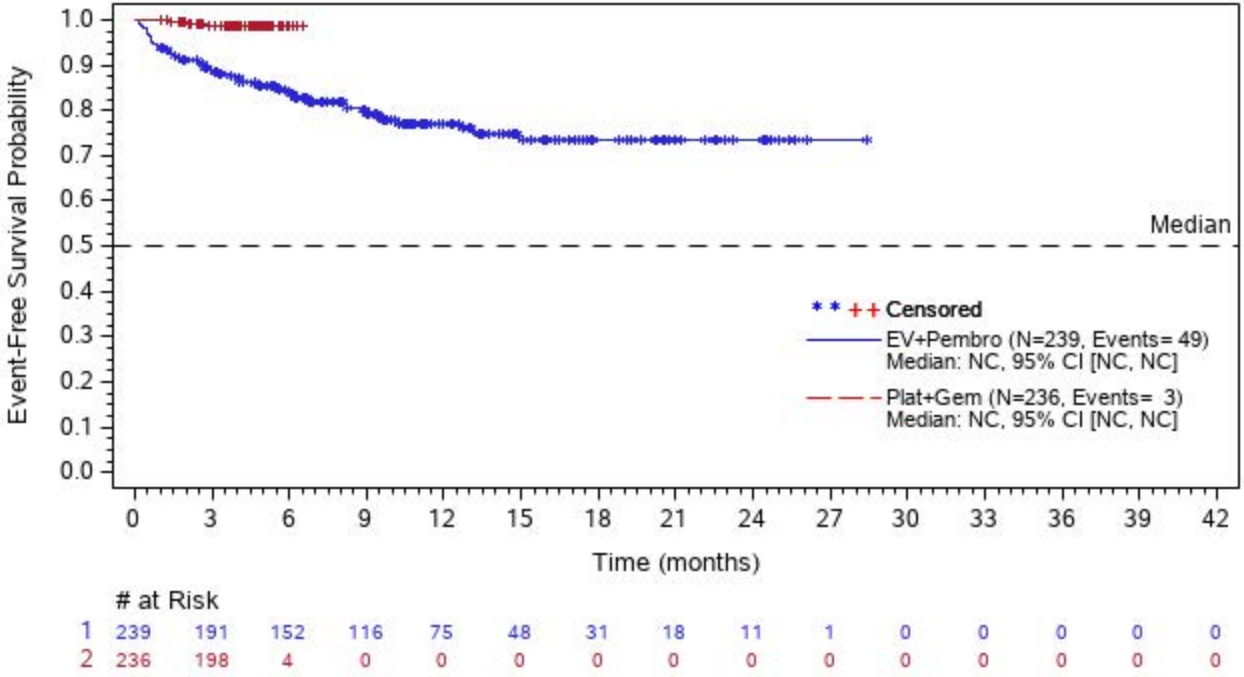


Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.191.1.1: Kaplan-Meier Plot of Time to first Severe TEAESI (CTCAE Grade >= 3) - Immune related and infusion reactions - Analysis Set mSAF 1



at Risk

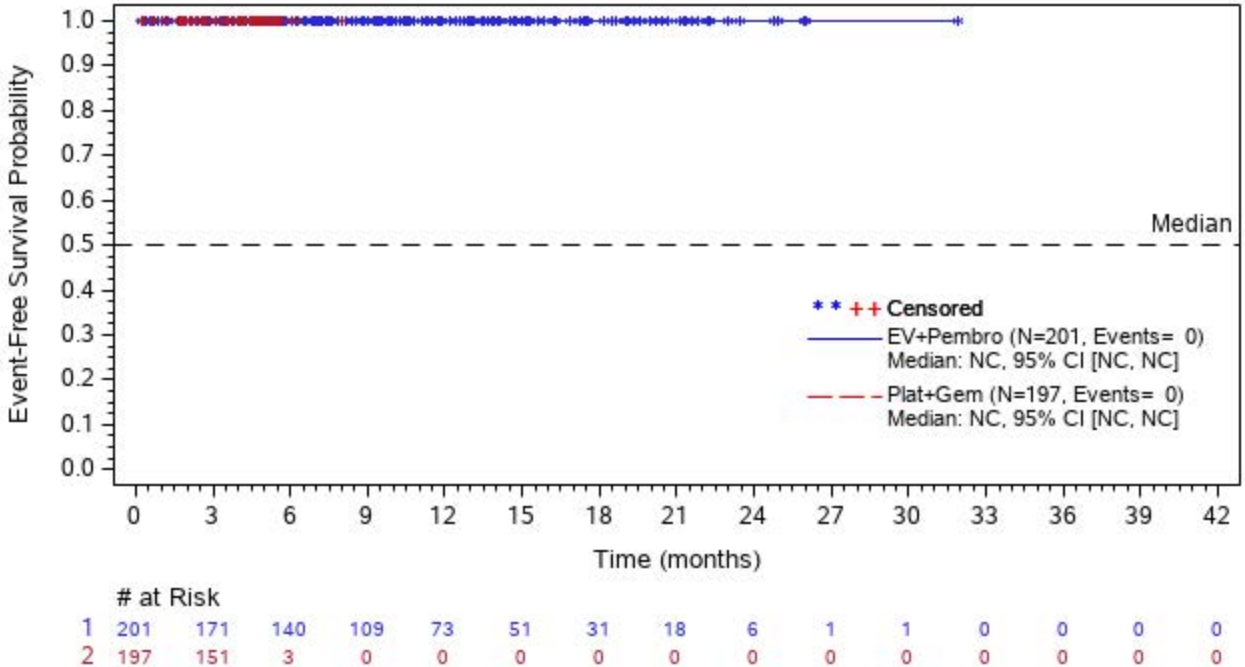
1	239	191	152	116	75	48	31	18	11	1	0	0	0	0	0
2	236	198	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.191.2.1: Kaplan-Meier Plot of Time to first TEAESI leading to death - Peripheral neuropathy - Analysis Set mSAF 2

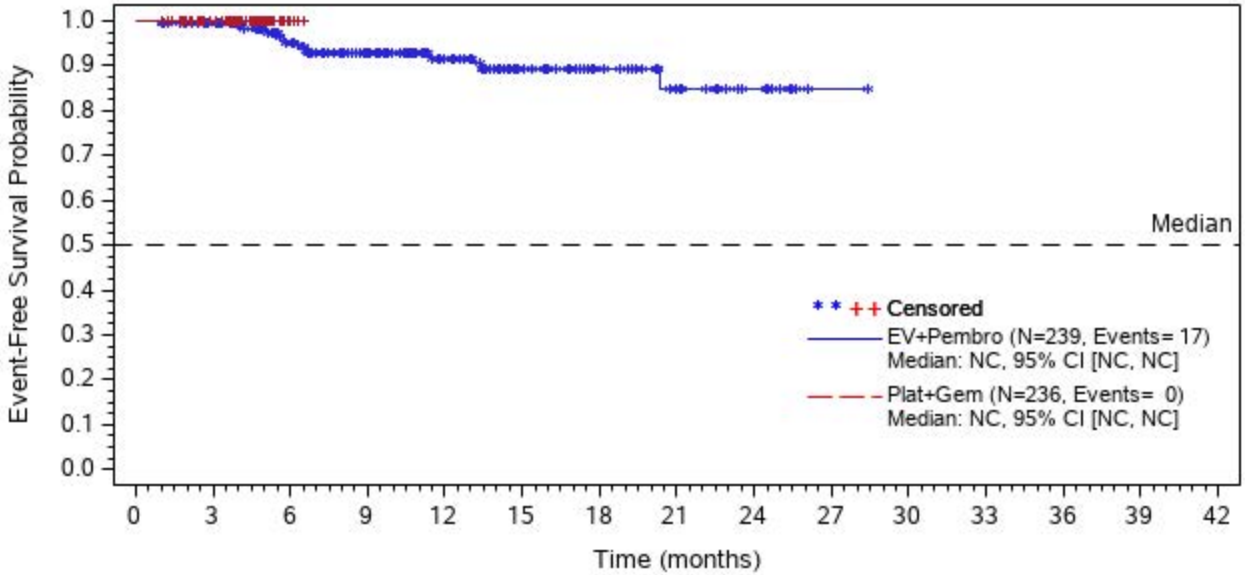


Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.192.1.1: Kaplan-Meier Plot of Time to first Severe TEAESI (CTCAE Grade >= 3) - Peripheral neuropathy - Analysis Set mSAF 1



at Risk

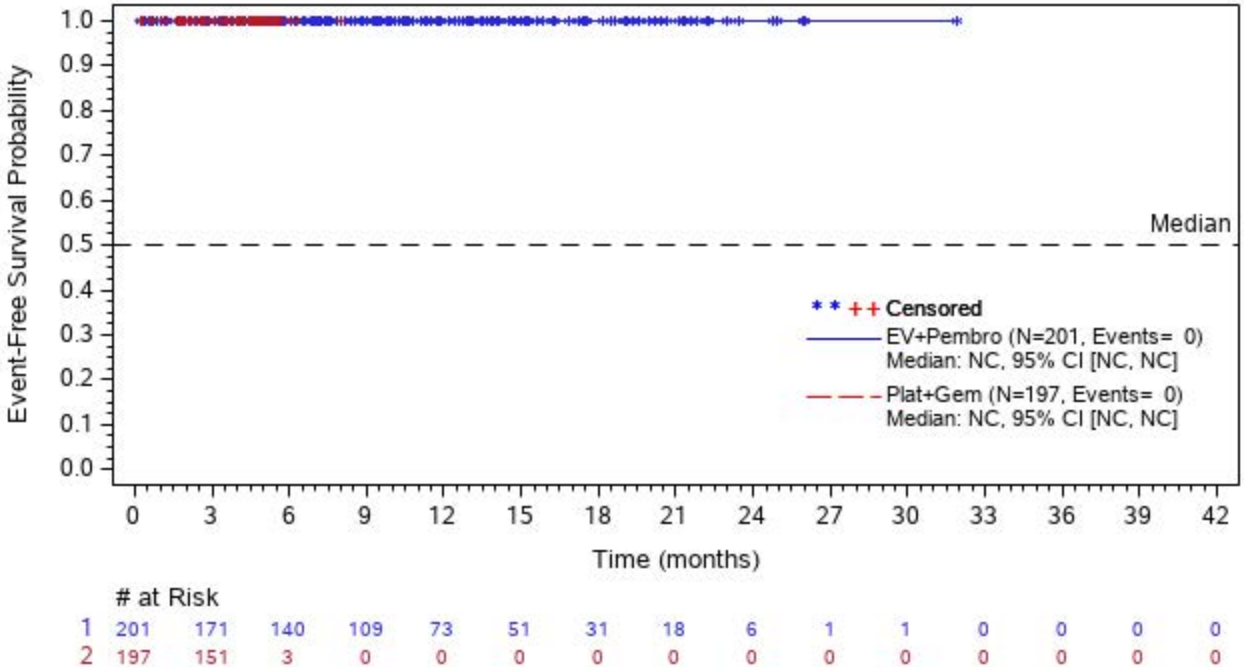
1	239	211	163	125	83	53	35	19	10	1	0	0	0	0	0
2	236	200	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.192.2.1: Kaplan-Meier Plot of Time to first TEAESI leading to death - Ocular disorders - Analysis Set mSAF 2



at Risk

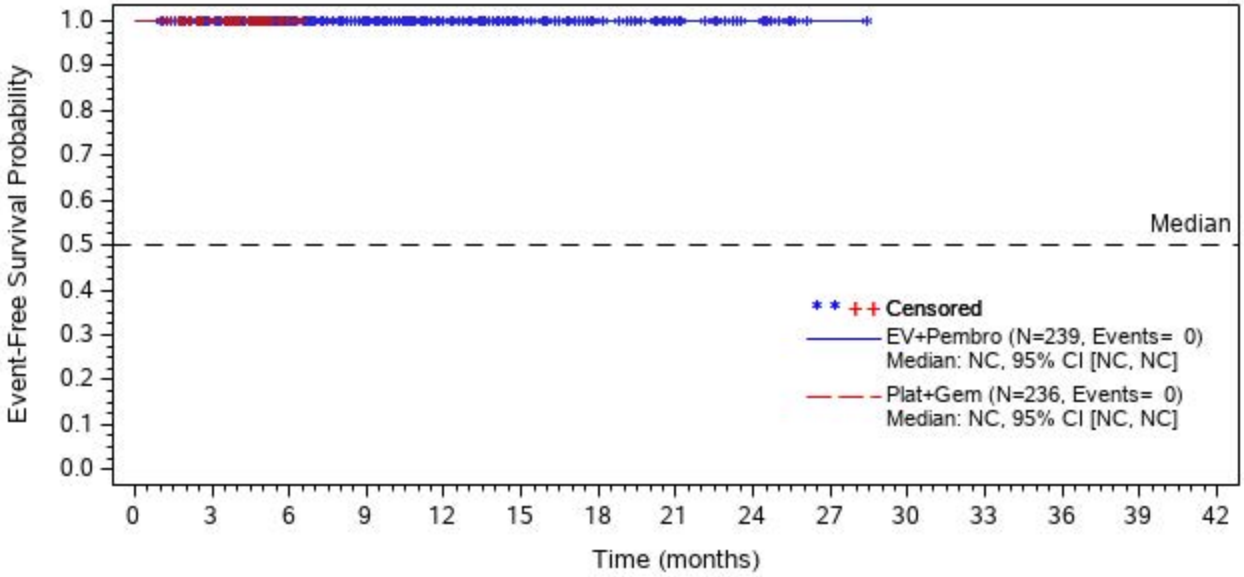
1	201	171	140	109	73	51	31	18	6	1	1	0	0	0	0
2	197	151	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.193.1.1: Kaplan-Meier Plot of Time to first Severe TEAESI (CTCAE Grade >= 3) - Ocular disorders - Analysis Set mSAF 1



at Risk

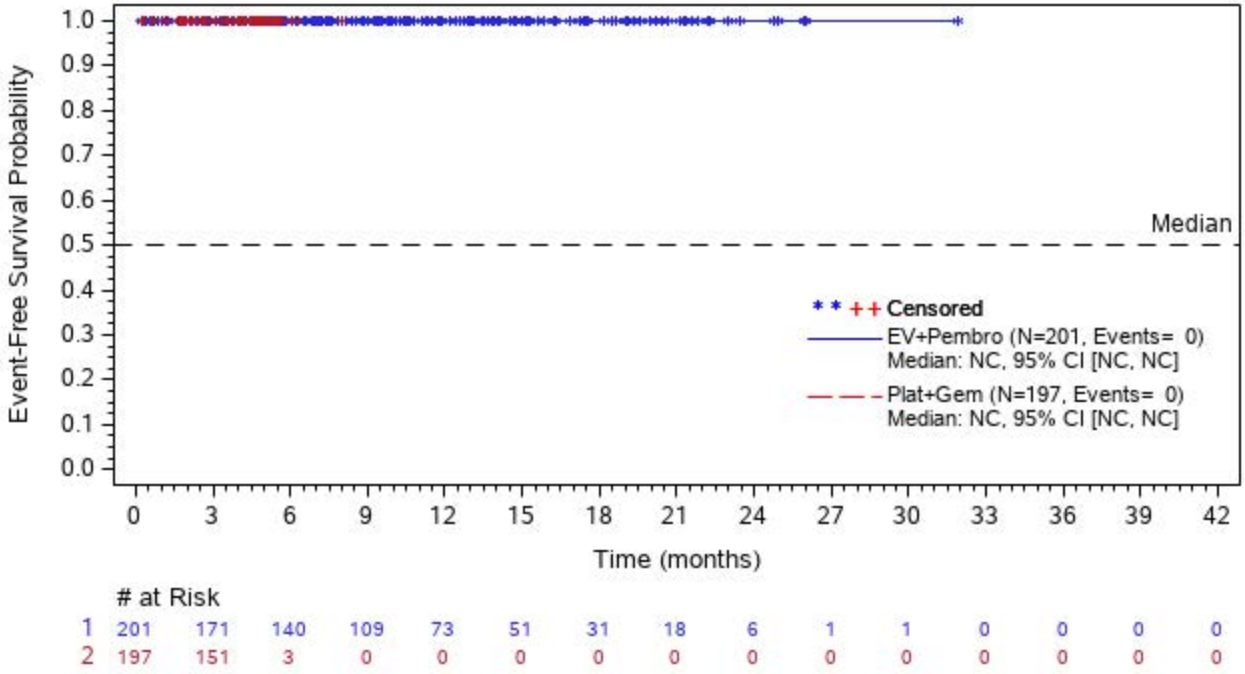
1	239	211	169	131	87	58	39	22	12	1	0	0	0	0	0
2	236	200	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.193.2.1: Kaplan-Meier Plot of Time to first TEAESI leading to death - Hyperglycemia - Analysis Set mSAF 2



at Risk

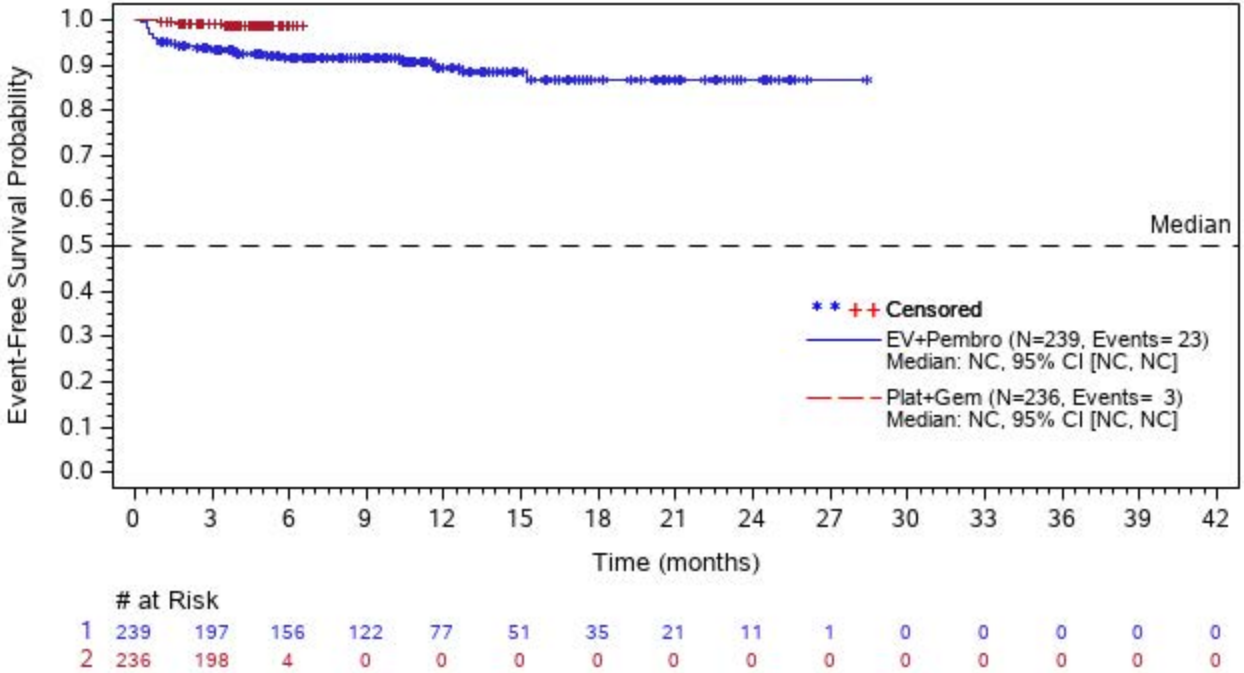
1	201	171	140	109	73	51	31	18	6	1	1	0	0	0	0
2	197	151	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.194.1.1: Kaplan-Meier Plot of Time to first Severe TEAESI (CTCAE Grade >= 3) - Hyperglycemia - Analysis Set mSAF 1



at Risk

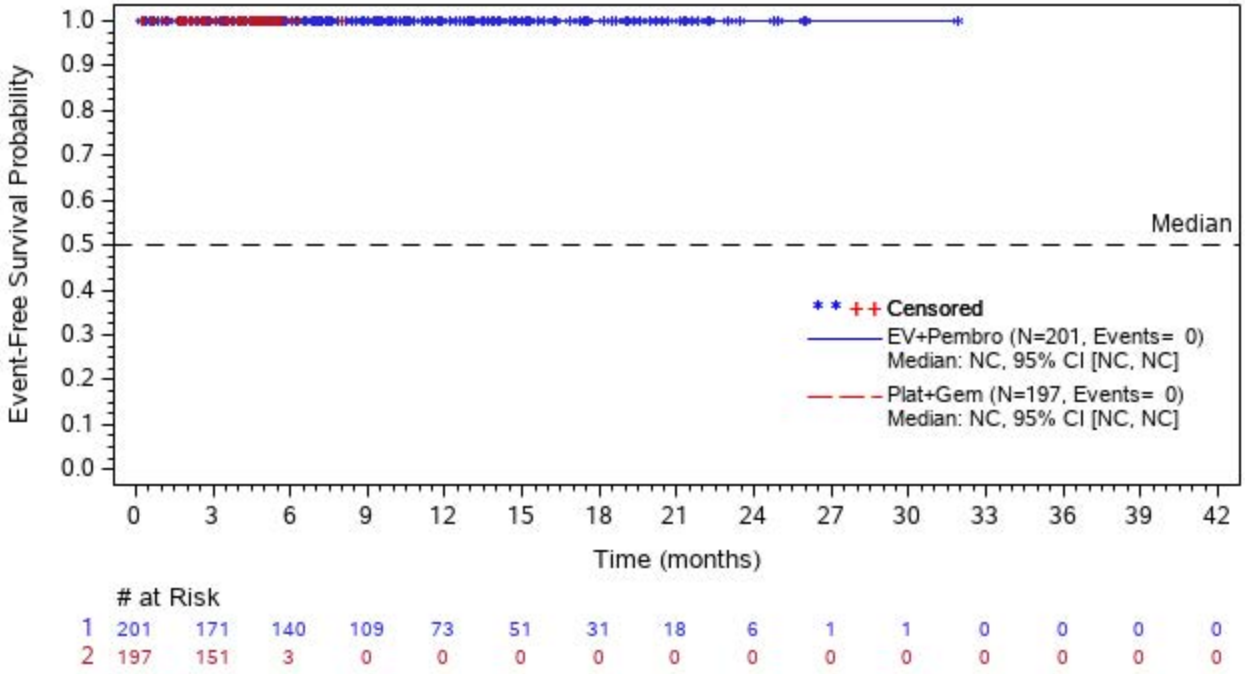
1	239	197	156	122	77	51	35	21	11	1	0	0	0	0	0
2	236	198	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.194.2.1: Kaplan-Meier Plot of Time to first TEAESI leading to death - Skin reactions - Analysis Set mSAF 2



at Risk

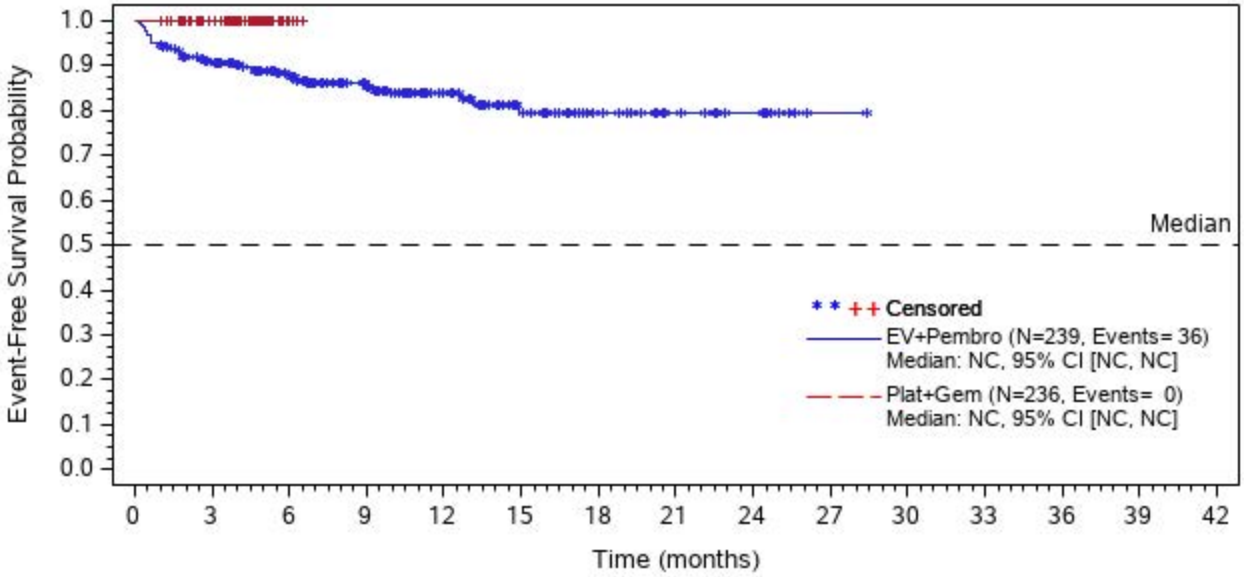
1	201	171	140	109	73	51	31	18	6	1	1	0	0	0	0
2	197	151	3	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.195.1.1: Kaplan-Meier Plot of Time to first Severe TEAESI (CTCAE Grade >= 3) - Skin reactions - Analysis Set mSAF 1



at Risk

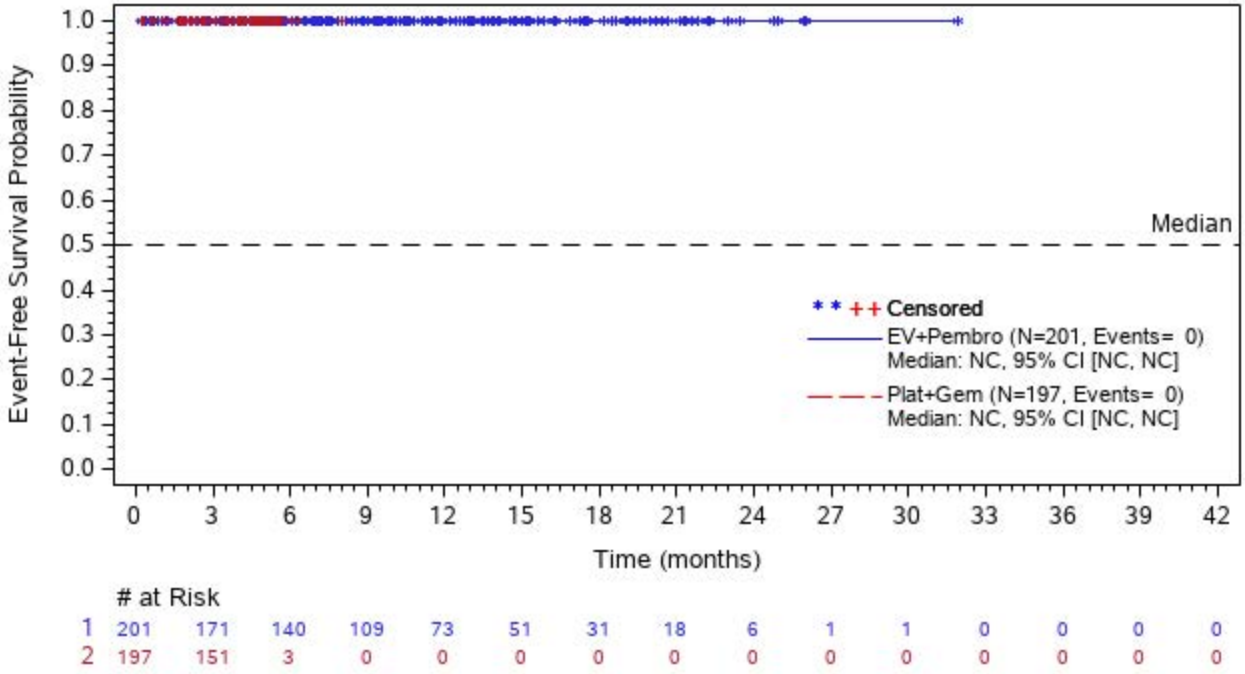
1	239	193	151	115	74	45	28	16	10	1	0	0	0	0	0
2	236	200	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.195.2.1: Kaplan-Meier Plot of Time to first TEAESI leading to death - Infusion related reactions (IRR) - Analysis Set mSAF 2

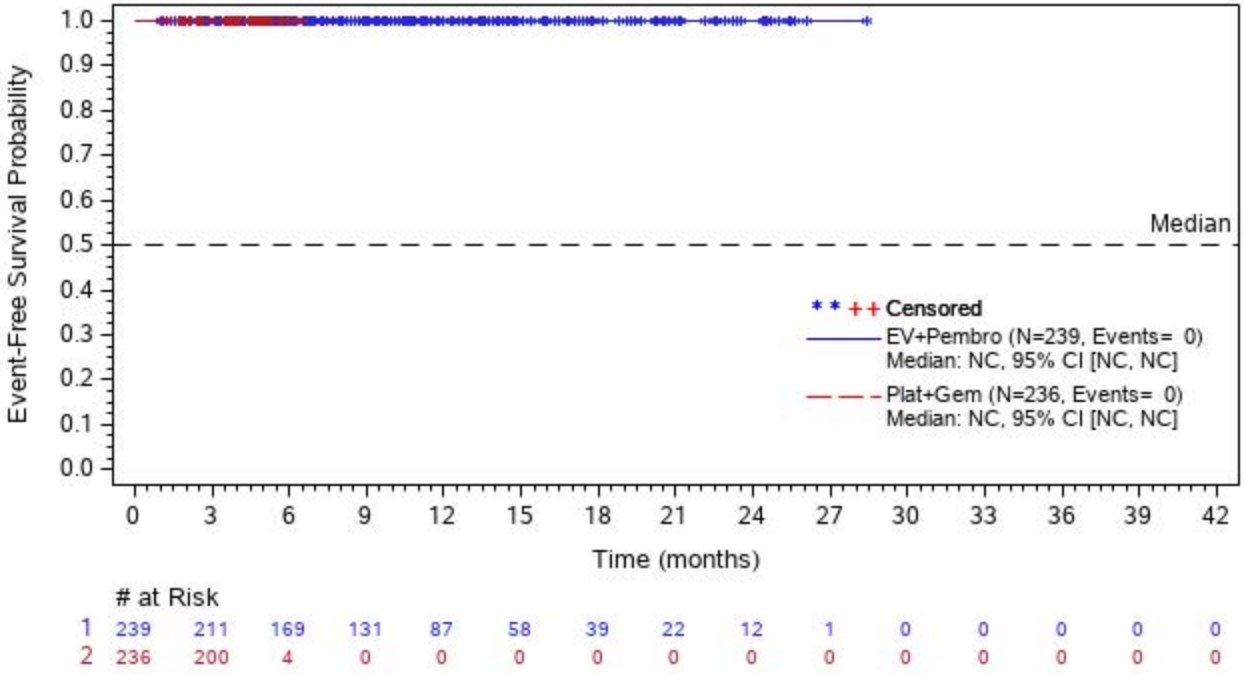


Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.196.1.1: Kaplan-Meier Plot of Time to first Severe TEAESI (CTCAE Grade >= 3) - Infusion related reactions (IRR) - Analysis Set mSAF 1



at Risk

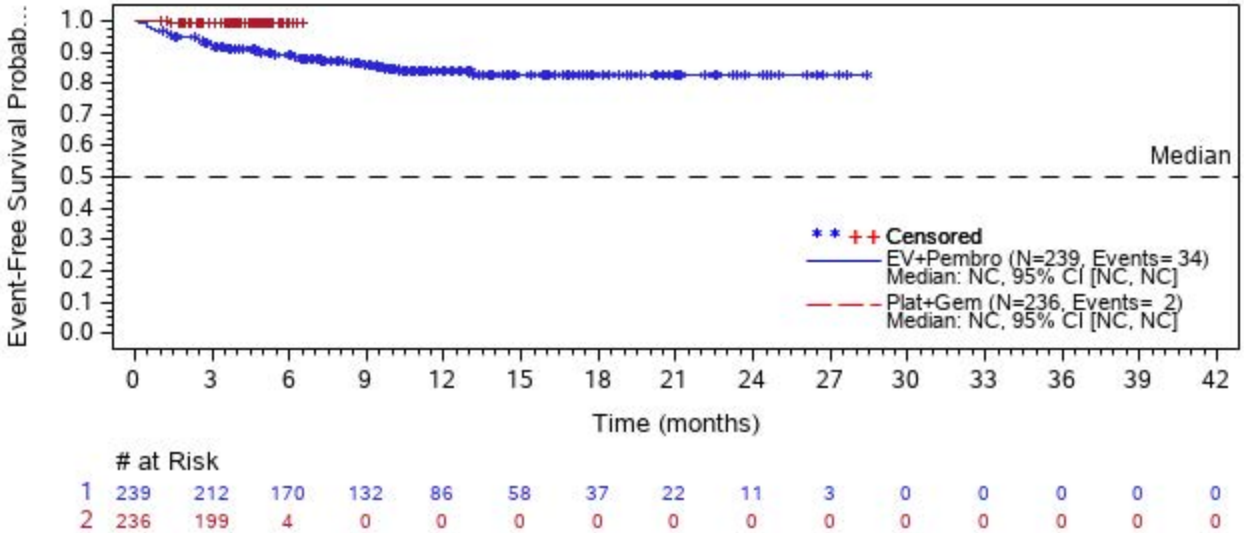
1	239	211	169	131	87	58	39	22	12	1	0	0	0	0	0
2	236	200	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.197.1.1: Kaplan-Meier Plot of Time to first TESAESI - Immune related and infusion reactions - Analysis Set mSAF 1



at Risk

1	239	212	170	132	86	58	37	22	11	3	0	0	0	0	0
2	236	199	4	0	0	0	0	0	0	0	0	0	0	0	0

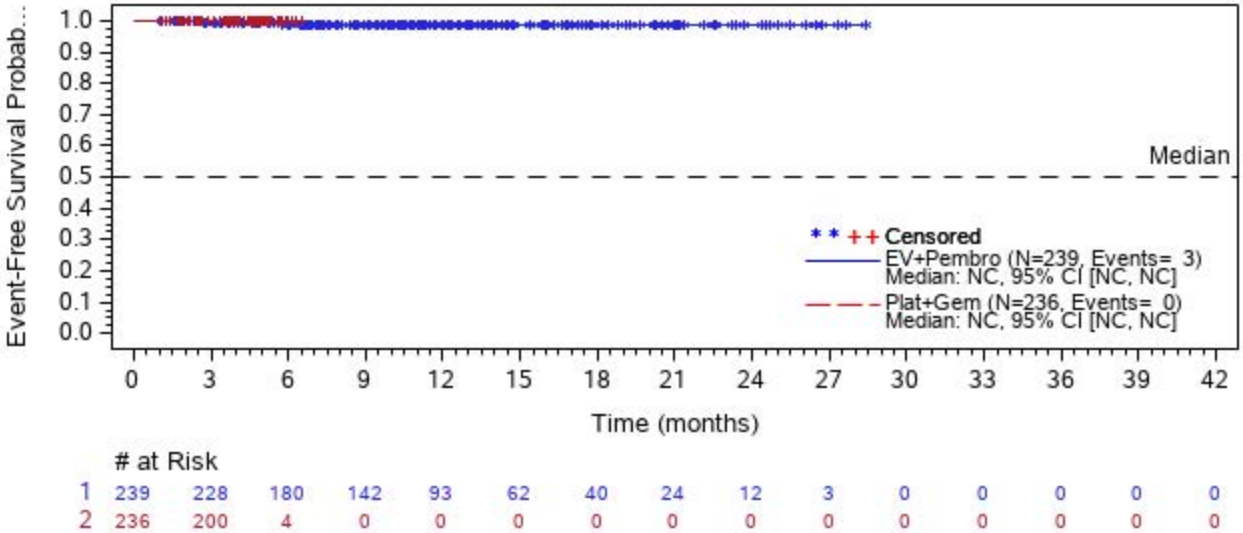
Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAESI=treatment-emergent serious adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.198.1.1: Kaplan-Meier Plot of Time to first TESAESI - Peripheral neuropathy - Analysis Set mSAF 1



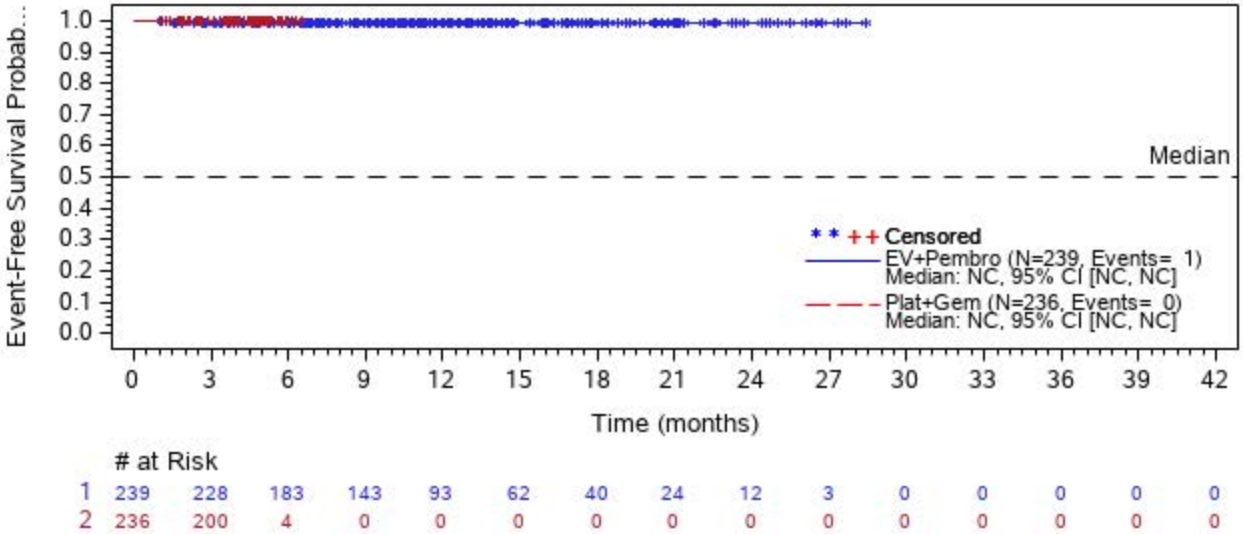
Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAESI=treatment-emergent serious adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.199.1.1: Kaplan-Meier Plot of Time to first TESAESI - Ocular disorders - Analysis Set mSAF 1



at Risk

1	239	228	183	143	93	62	40	24	12	3	0	0	0	0	0
2	236	200	4	0	0	0	0	0	0	0	0	0	0	0	0

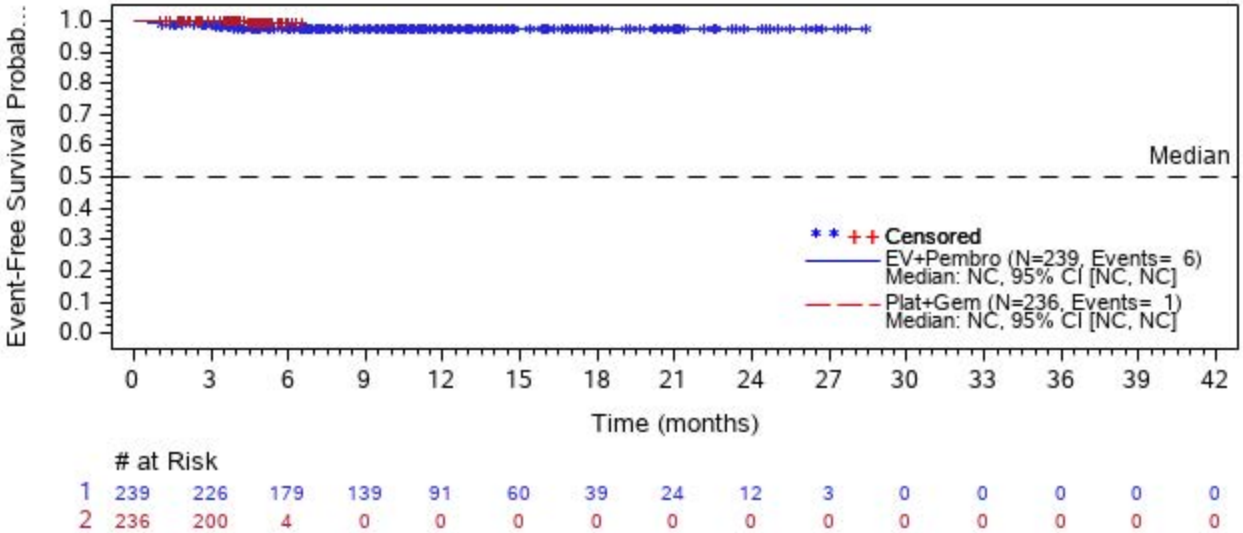
Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAESI=treatment-emergent serious adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.200.1.1: Kaplan-Meier Plot of Time to first TESAESI - Hyperglycemia - Analysis Set mSAF 1



at Risk

1	239	226	179	139	91	60	39	24	12	3	0	0	0	0	0
2	236	200	4	0	0	0	0	0	0	0	0	0	0	0	0

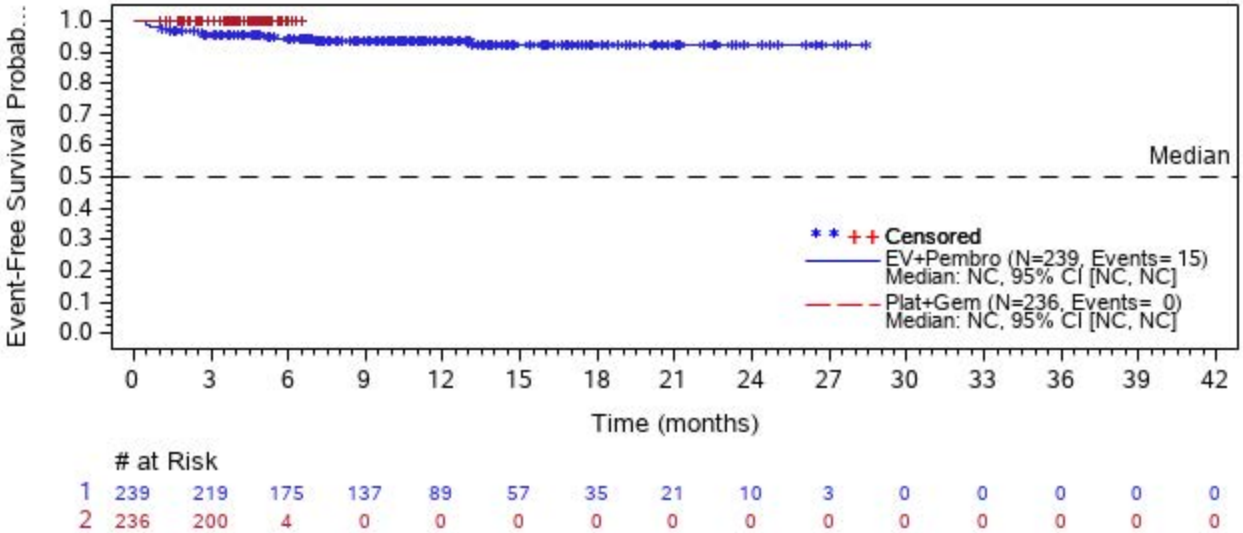
Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAESI=treatment-emergent serious adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.201.1.1: Kaplan-Meier Plot of Time to first TESAESI - Skin reactions - Analysis Set mSAF 1



at Risk

1	239	219	175	137	89	57	35	21	10	3	0	0	0	0	0
2	236	200	4	0	0	0	0	0	0	0	0	0	0	0	0

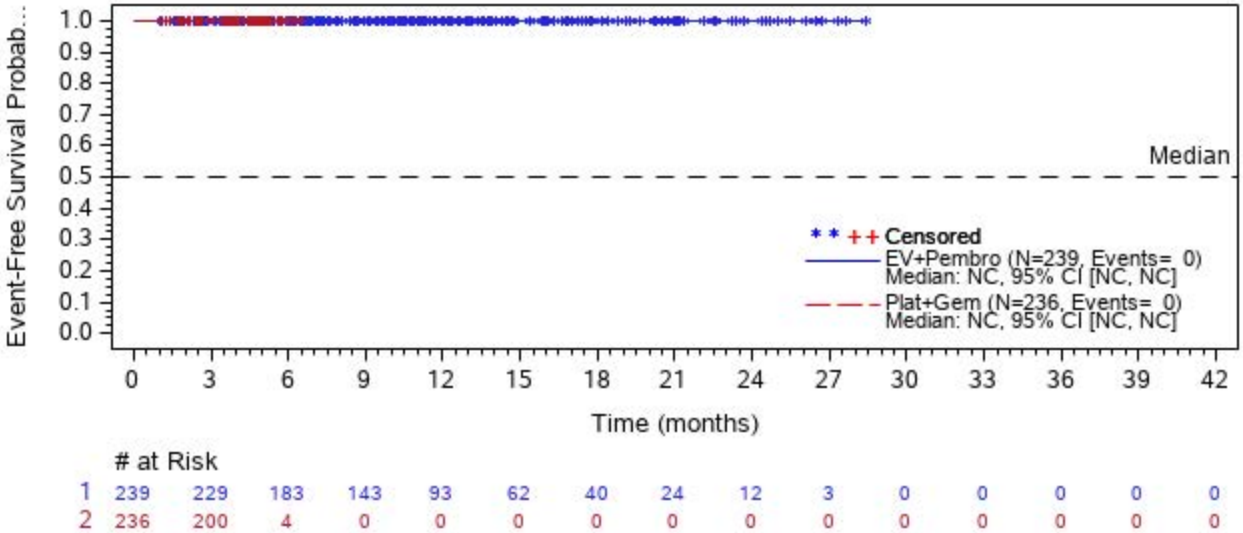
Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAESI=treatment-emergent serious adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.202.1.1: Kaplan-Meier Plot of Time to first TESAESI - Infusion related reactions (IRR) - Analysis Set mSAF 1



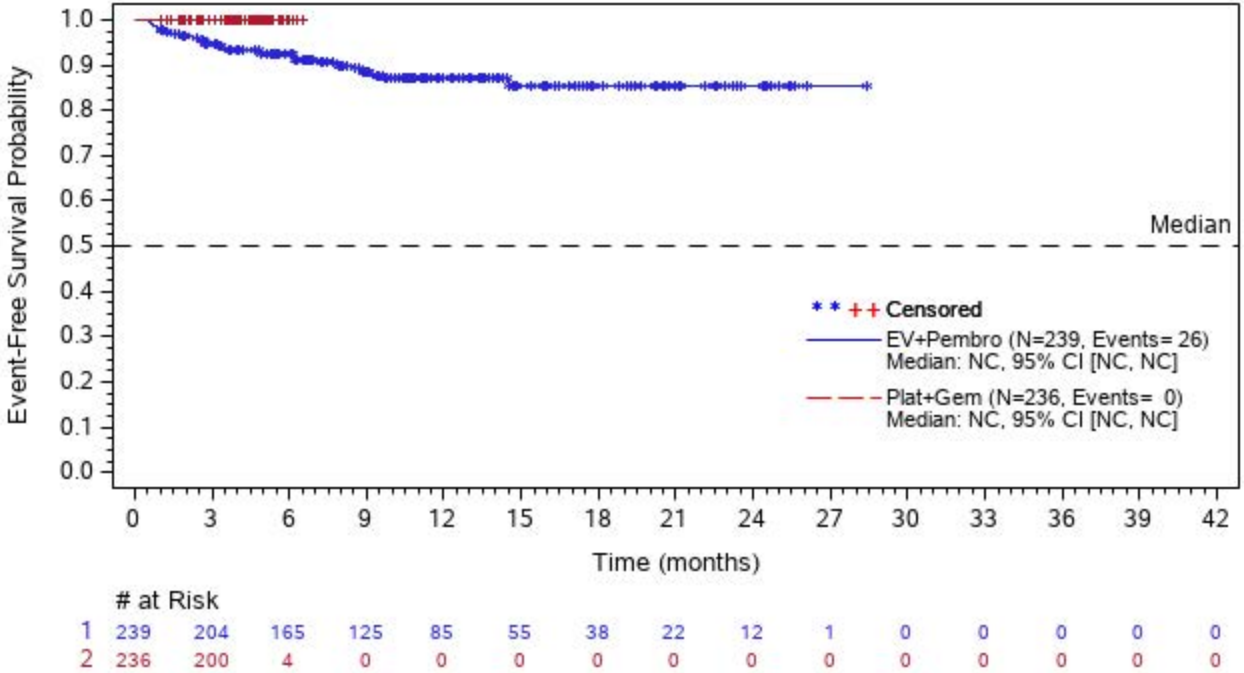
Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TESAESI=treatment-emergent serious adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date) for Plat+Gem and min(data cutoff date, date of last dose of study treatment + 90 days, death date) for EV+Pembro (if no anticancer therapy started).

In case a new anticancer therapy was initiated between 1 and 30 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date). In case a new anticancer therapy was initiated between 31 and 90 days after last dose of treatment medication, censoring date was defined as min(data cutoff date, date of new anticancer treatment, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.203.1.1: Kaplan-Meier Plot of Time to first TEAESI leading to discontinuation from study medication - Immune related and infusion reactions - Analysis Set mSAF 1



at Risk

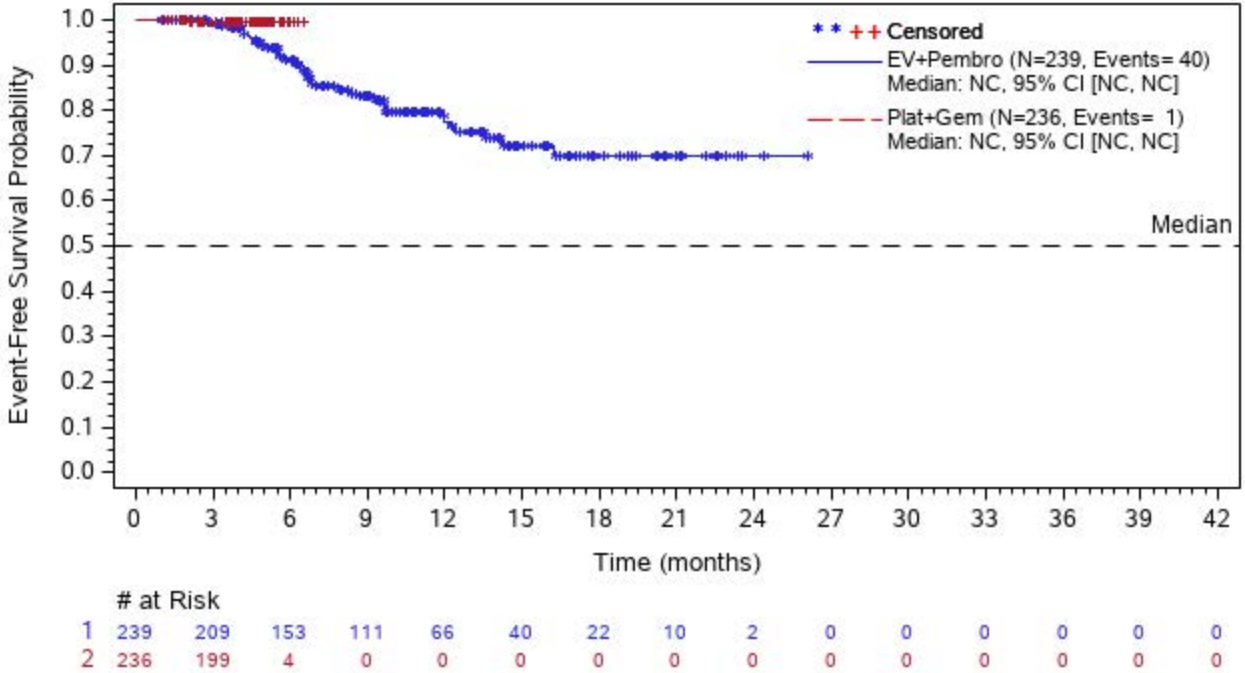
1	239	204	165	125	85	55	38	22	12	1	0	0	0	0	0
2	236	200	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.204.1.1: Kaplan-Meier Plot of Time to first TEAESI leading to discontinuation from study medication - Peripheral neuropathy - Analysis Set mSAF 1



at Risk

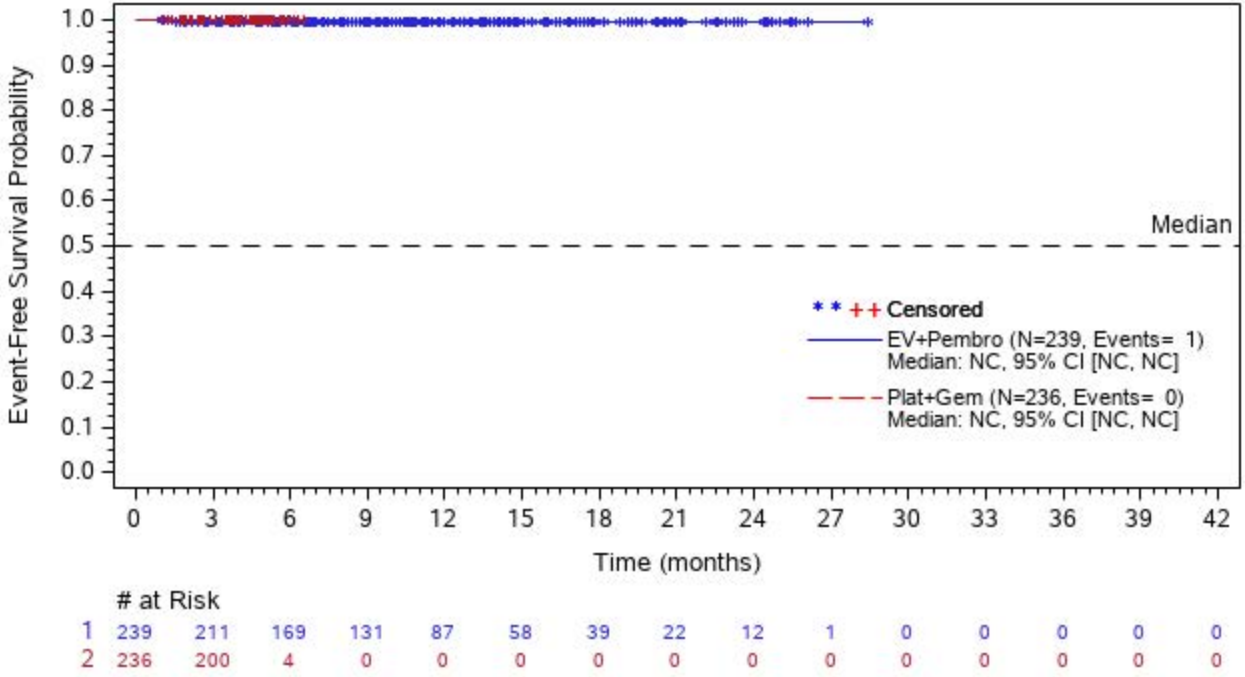
1	239	209	153	111	66	40	22	10	2	0	0	0	0	0	0
2	236	199	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.205.1.1: Kaplan-Meier Plot of Time to first TEAESI leading to discontinuation from study medication - Ocular disorders - Analysis Set mSAF 1



at Risk

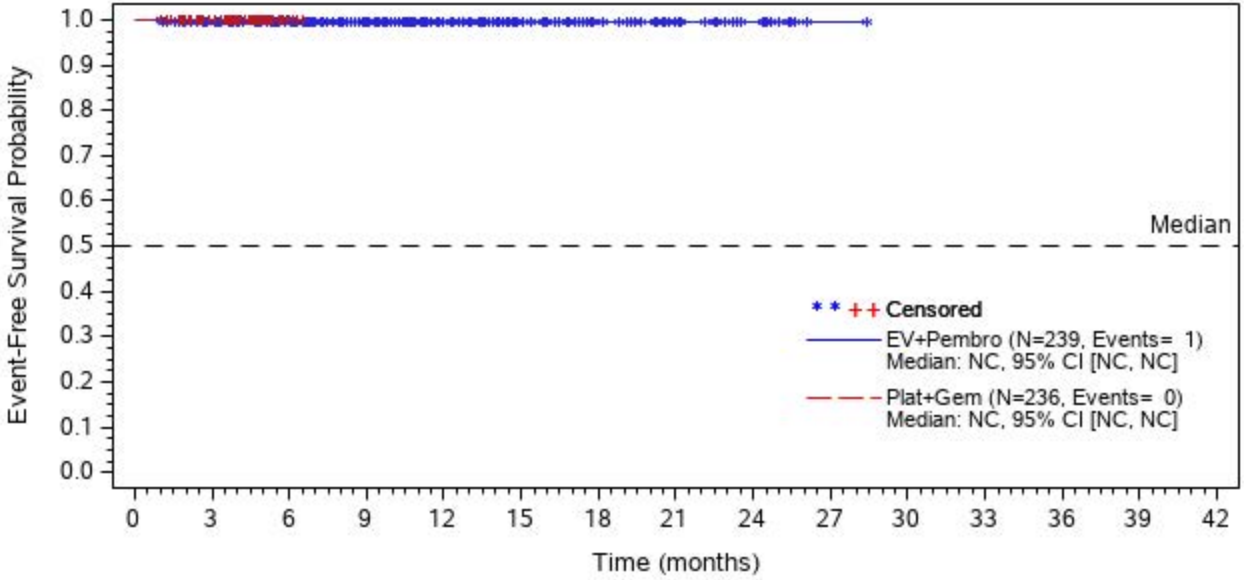
1	239	211	169	131	87	58	39	22	12	1	0	0	0	0	0
2	236	200	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.206.1.1: Kaplan-Meier Plot of Time to first TEAESI leading to discontinuation from study medication - Hyperglycemia - Analysis Set mSAF 1



at Risk

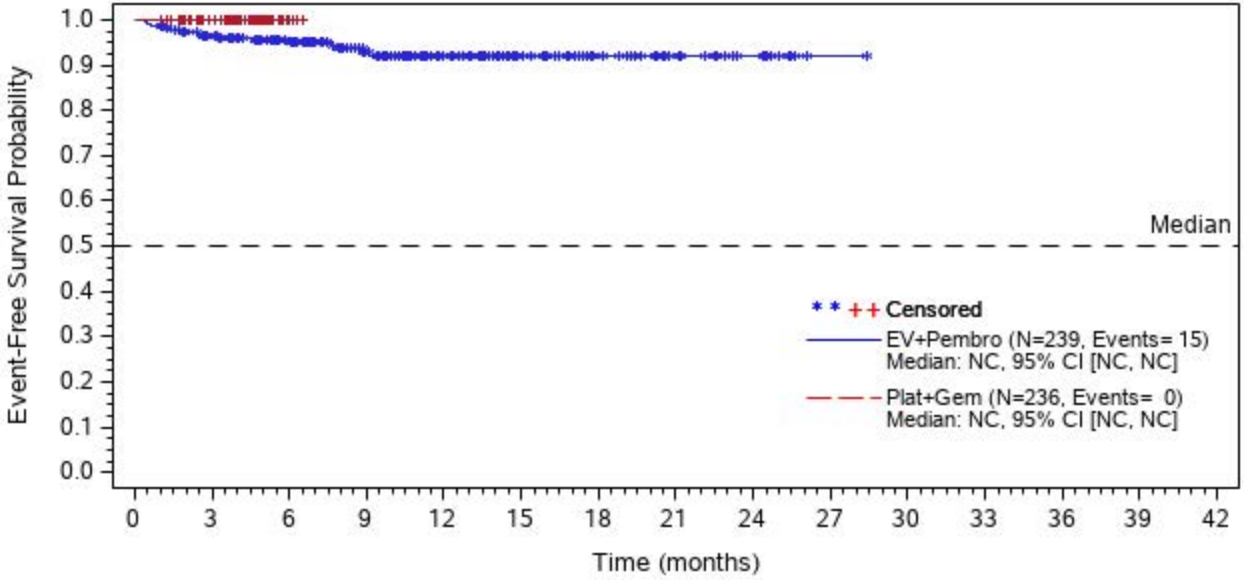
1	239	211	169	131	87	58	39	22	12	1	0	0	0	0	0
2	236	200	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.207.1.1: Kaplan-Meier Plot of Time to first TEAESI leading to discontinuation from study medication - Skin reactions - Analysis Set mSAF 1



at Risk

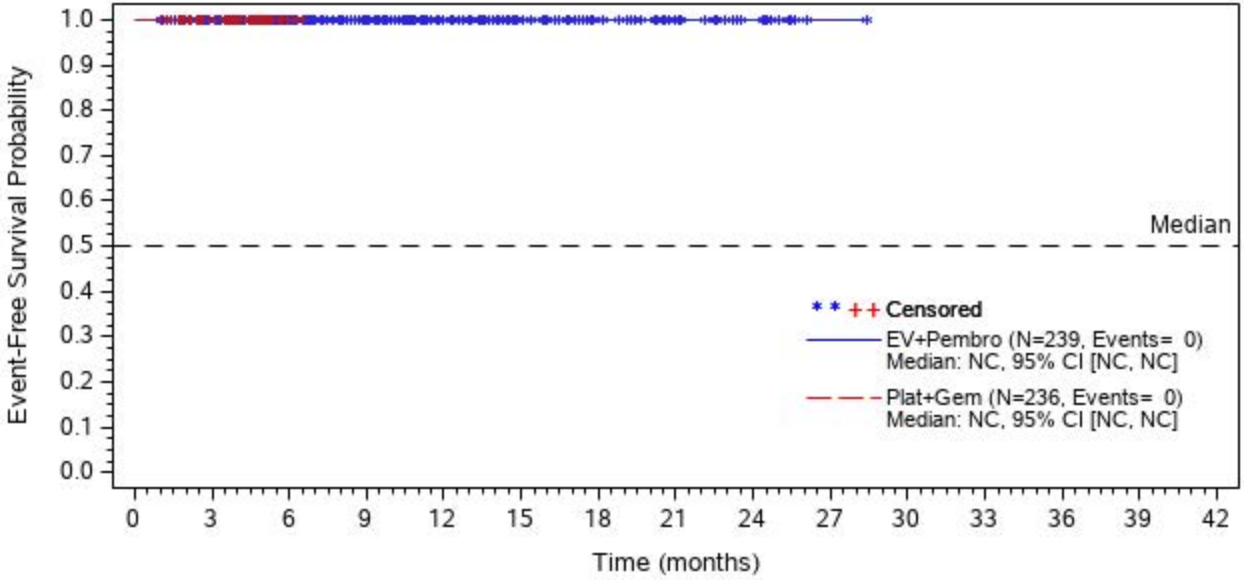
1	239	207	166	124	84	56	37	21	12	1	0	0	0	0	0
2	236	200	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.208.1.1: Kaplan-Meier Plot of Time to first TEAESI leading to discontinuation from study medication - Infusion related reactions (IRR) - Analysis Set mSAF 1



at Risk

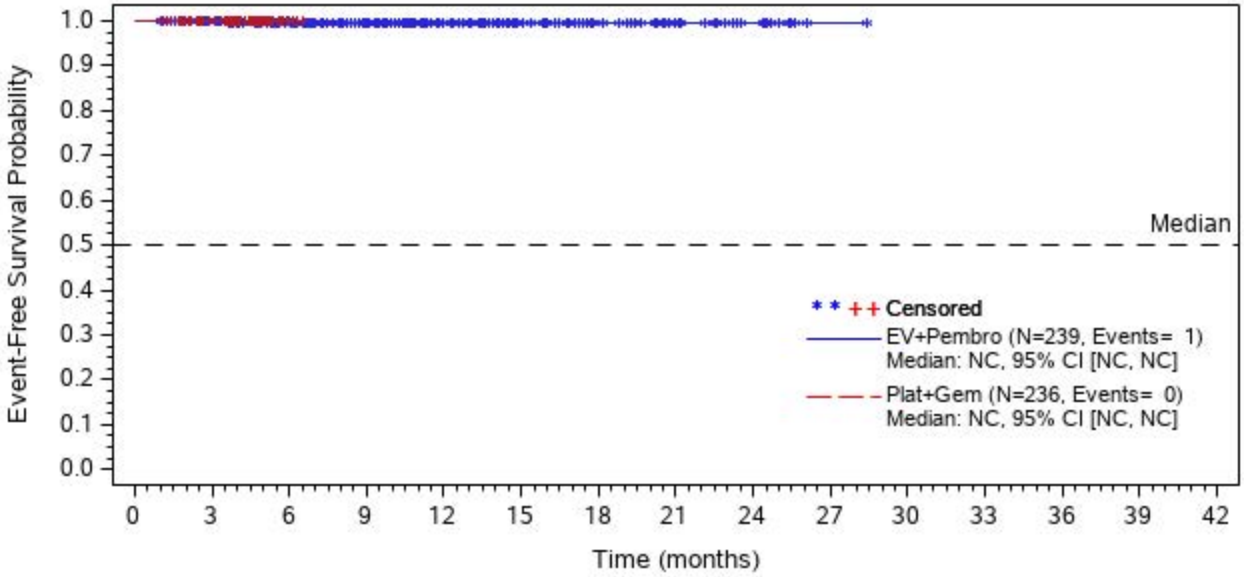
1	239	211	169	131	87	58	39	22	12	1	0	0	0	0	0
2	236	200	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.209.1.1: Kaplan-Meier Plot of Time to first TEAESI leading to death - Immune related and infusion reactions - Analysis Set mSAF 1



at Risk

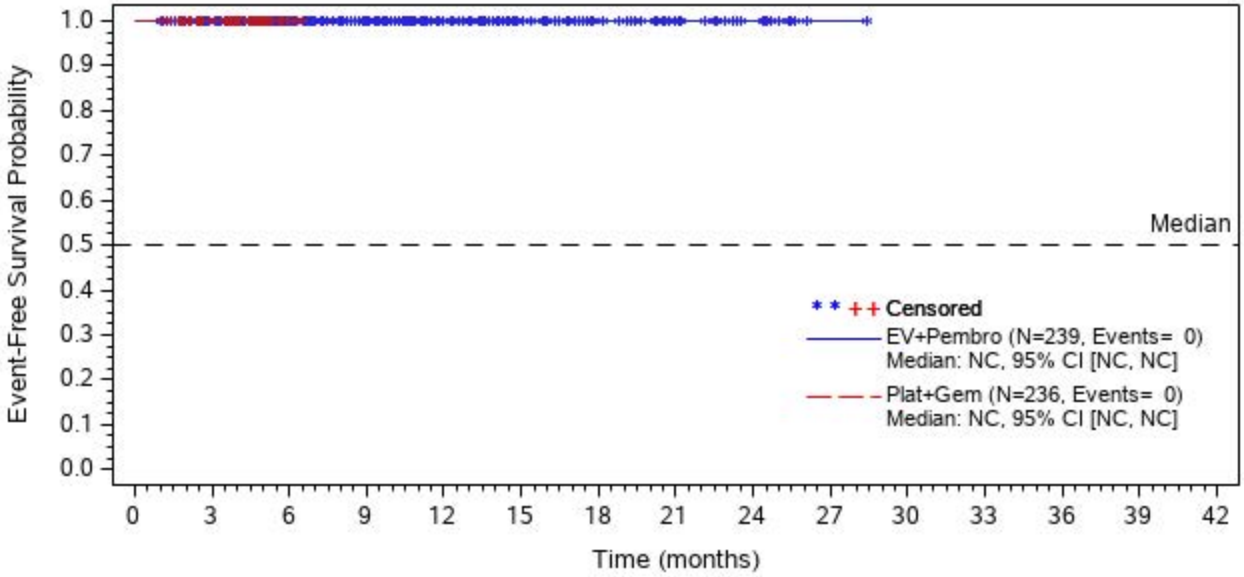
1	239	211	169	131	87	58	39	22	12	1	0	0	0	0	0
2	236	200	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.210.1.1: Kaplan-Meier Plot of Time to first TEAESI leading to death - Peripheral neuropathy - Analysis Set mSAF 1



at Risk

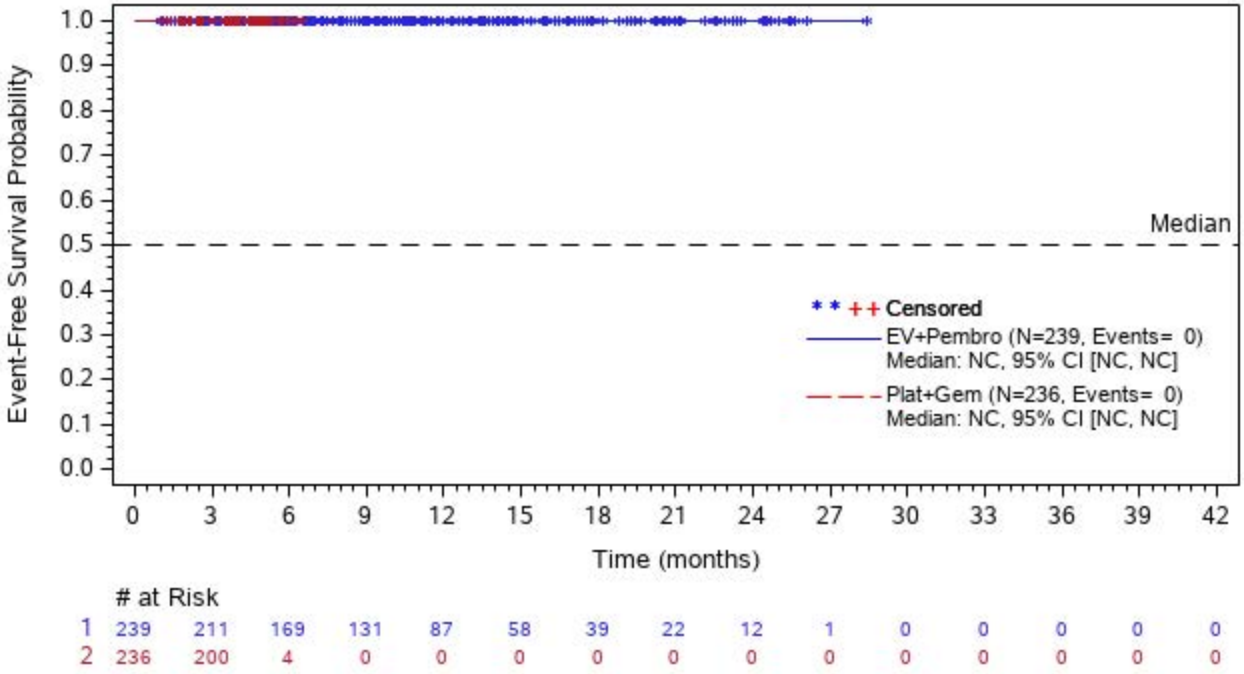
1	239	211	169	131	87	58	39	22	12	1	0	0	0	0	0
2	236	200	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.211.1.1: Kaplan-Meier Plot of Time to first TEAESI leading to death - Ocular disorders - Analysis Set mSAF 1



at Risk

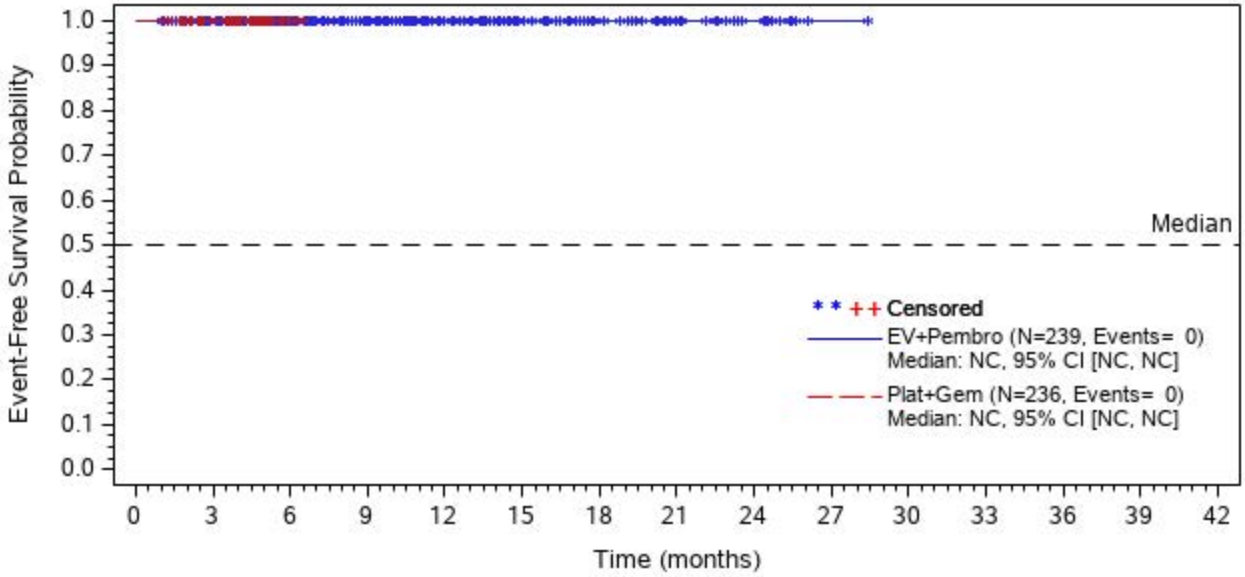
1	239	211	169	131	87	58	39	22	12	1	0	0	0	0	0
2	236	200	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.212.1.1: Kaplan-Meier Plot of Time to first TEAESI leading to death - Hyperglycemia - Analysis Set mSAF 1



at Risk

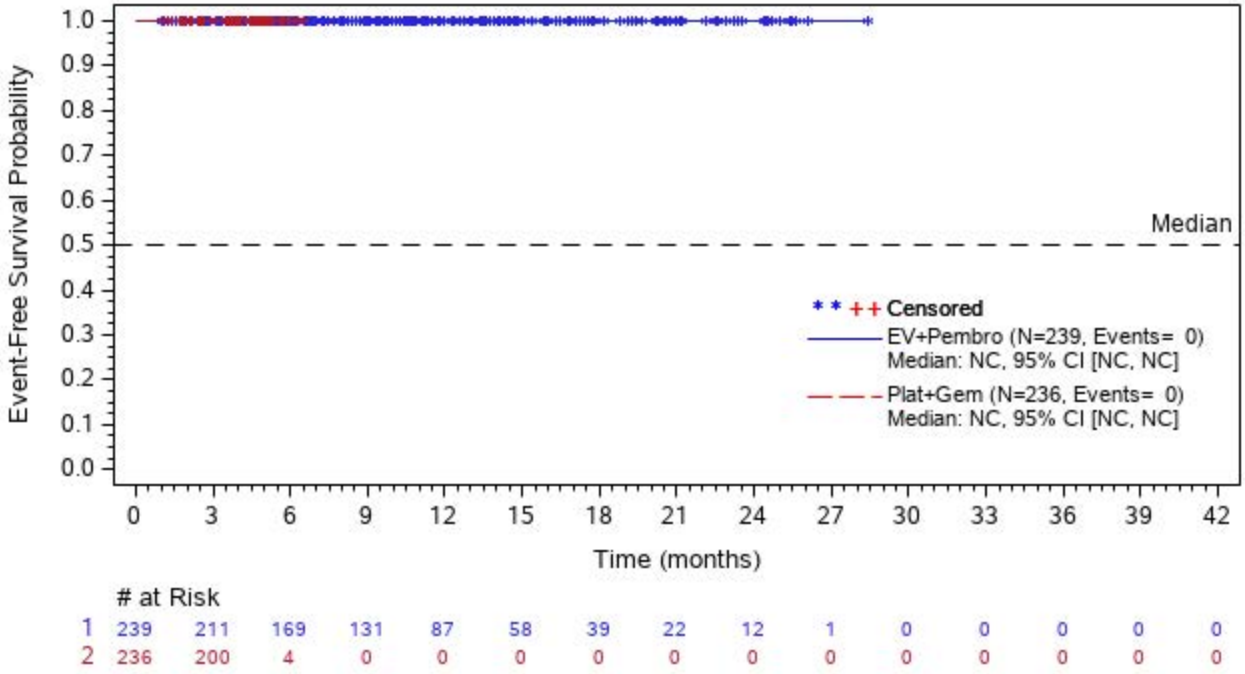
1	239	211	169	131	87	58	39	22	12	1	0	0	0	0	0
2	236	200	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.213.1.1: Kaplan-Meier Plot of Time to first TEAESI leading to death - Skin reactions - Analysis Set mSAF 1



at Risk

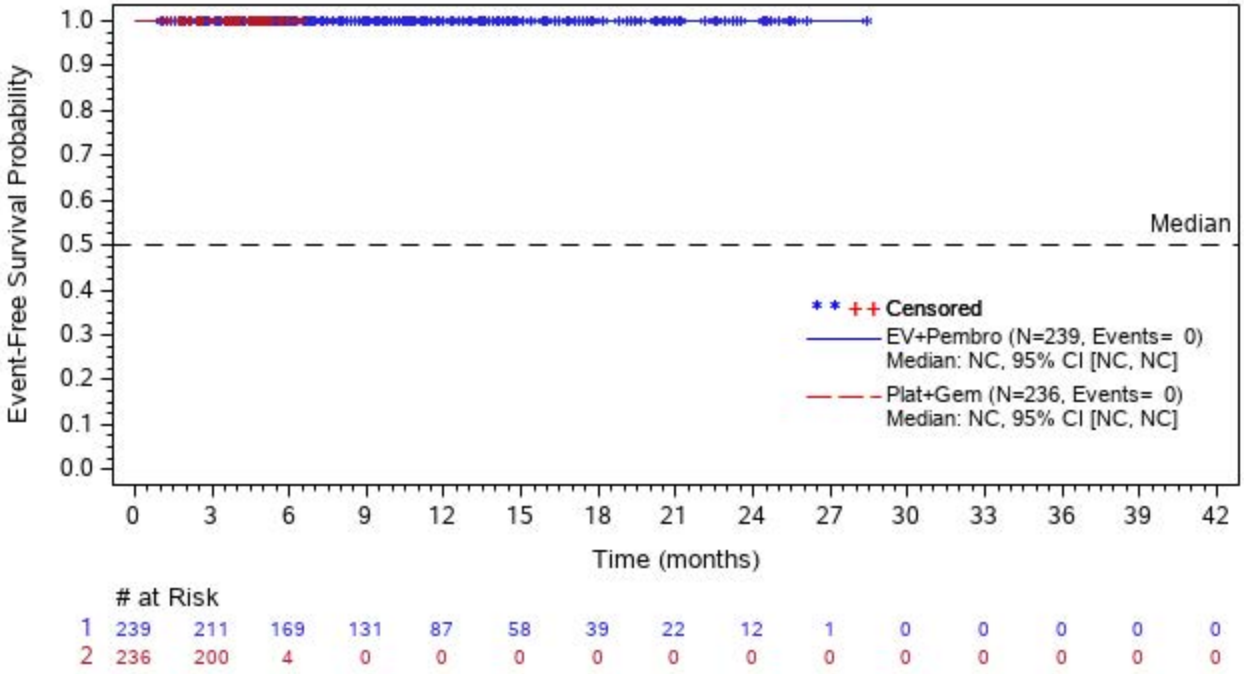
1	239	211	169	131	87	58	39	22	12	1	0	0	0	0	0
2	236	200	4	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023

Figure 302.1.2002.214.1.1: Kaplan-Meier Plot of Time to first TEAESI leading to death - Infusion related reactions (IRR) - Analysis Set mSAF 1



Abbreviations: CI=confidence interval; EV=enfortumab vedotin; Gem=gemcitabine; HR=hazard ratio; mSAF=modified safety analysis set; N=number of patients; Pembro=pembrolizumab; Plat=cisplatin or carboplatin; TEAESI=treatment-emergent adverse event of special interest.

Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(data cutoff date, date of last dose of study treatment + 30 days, death date).

ASTELLAS Data Cutoff Date: 08AUG2023